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ATTORNEYS FOR DEFENDANT IMPERATIVE CARE, INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

INARI MEDICAL, INC.,

Plaintiff,

v.

IMPERATIVE CARE, INC.,

Defendants.

Civil Action No. 5:24-cv-03117-EKL

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT PURSUANT TO PATENT LOCAL RULE 4-3

Hon. Eumi K. Lee

Hearing Date and Time:
July 16, 2025, at 10:00am

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Pursuant to Patent Local Rule 4-3 and the Court's Case Management and Scheduling Order (D.I. 54), Plaintiff Inari Medical, Inc. ("Inari") and Defendant Imperative Care, Inc. ("Imperative Care"), by and through their respective undersigned counsel, submit with Exhibit A the following Joint Claim Construction and Prehearing Statement ("Joint Statement") for U.S. Patent Nos. 11,974,910, 11,969,333, 11,554,005, 11,744,691, 11,844,921, 11,697,012, 11,865,291, 12,016,580, 12,109,384, and 12,156,669 (collectively, "the Asserted Patents").[1] In accordance with the Court's Standing Order for Patent Cases, the Patents are attached as Exhibits B-K.

I. CLAIM TERMS ON WHICH THE PARTIES AGREE (PATENT L.R. 4.3(A))

The parties do not currently agree on the construction of any proposed terms of the Asserted Patents.

II. DISPUTED TERMS AND SUPPORTING EVIDENCE (PATENT LOCAL RULE 4-3(B))

Pursuant to Patent Local Rule 4-3(b), the chart attached as Exhibit A to this statement sets forth (a) the claim terms from the Patents for which the parties have not agreed on a construction, (b) each party's proposed constructions for those terms, (c) references from the specification or prosecution history of the Patents that each party contends support its proposed construction, and (d) extrinsic evidence known to each party on which it intends to rely either to support its proposed construction or to oppose the other party's proposed construction.

The parties will continue to discuss their disputed constructions in an attempt to narrow, if not eliminate, at least some of these disputes. Each party also expressly reserves the right to rely on the evidence identified by the other party, to propose additional or responsive claim constructions, and to supplement its proposed claim constructions and supporting evidence as claim construction discovery progresses and the parties fully brief the issues.

III. MOST SIGNIFICANT AND DISPOSITIVE TERMS (PATENT L.R. 4.3(C))

The parties together proposed more than ten terms for construction. The parties met and conferred to select the most significant contested terms for construction, and agreed three

[1] Currently pending is Inari's Motion to Amend seeking to add claims of U.S. Patent No. 12,239,333. (D.I. 88.)

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

terms are most significant, and, in accordance with Patent Local Rule 4-3(c), each party identified an equal number of additional most significant terms, three additional terms each. Exhibit A thus identifies all the terms that are proposed for construction, beginning with the nine terms identified as most significant to the resolution of the case, which are also listed below:

1. "filament";
2. "aspiration pump";
3. "wherein the first pressure source is the same as the second pressure source";
4. "tubular member defining a lumen configured to slidably receive the second catheter";
5. "interventional device";
6. "support"
7. "shaped to be intravascularly advanced"
8. "clot canister"/"clot cannister"
9. "wherein" clause of the '691 Patent beginning "wherein upon user actuation".

The parties understand that one or both parties contend that the constructions of some of these terms may be claim dispositive, depending on how the terms are construed. The parties have provided impact statements for the contested claim construction terms in the chart attached as Exhibit A to this Joint Statement.

IV. LENGTH OF TIME FOR CLAIM CONSTRUCTION HEARING (PATENT L.R. 4.3(D))

The claim construction hearing is currently scheduled for July 24, 2025. *See* D.I. 54. The parties estimate that three hours should be scheduled for the claim construction hearing. *See* Patent Standing Order at V.C. That time should be divided equally between the parties.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

V. WITNESSES TO BE CALLED AT CLAIM CONSTRUCTION HEARING (PATENT L.R. 4.3(E))

As reflected in Exhibit A, the parties have identified expert witnesses in connection with claim construction issues and will exchange declarations setting forth these witnesses' testimony and opinions related to claim construction on or before April 28, 2025, with depositions and claim construction discovery to be completed by May 28, 2025. *See* D.I. No. 54 at 3. However, the parties do not currently expect to call any witnesses to present live testimony at the hearing.

VI. IDENTIFICATION OF ANY FACTUAL FINDINGS REQUESTED FROM THE COURT RELATED TO CLAIM CONSTRUCTION (PATENT L.R. 4.3(F))

The parties seek factual findings only to the extent that the experts may disagree how a person of ordinary skill in the art, as of the filing dates of the Patents, would have interpreted the claim terms identified in Exhibit A.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Respectfully Submitted,

Dated: April 28, 2025

PERKINS COIE LLP

By: */s/ Daniel T. Keese*

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IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Dated: April 28, 2025

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IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

FILER'S ATTESTATION

Pursuant to Civil L.R. 5-1(i)(3), regarding signatures, I, Daniel T. Keese, attest that concurrence in the filing of this document has been obtained.

Dated: April 28, 2025 By: */s/ Daniel T. Keese*

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

EXHIBIT A

EXHIBIT A

I. Terms Identified as Most Significant by the Parties

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
1. "filament"[1] '910 Patent, Claim 7; 11-'333 Patent, Claims 11, 12, 30, 31; '005 Patent, Claims 1, 3, 9, 10, 12, 13; '580 Patent, Claims 15-17; '669 Patent, Claims 12, 26, 27; '012 Patent, Claims 1, 2, 9;	Plain and ordinary meaning; a thin, flexible length of material formed by one or more strands of material **Intrinsic Evidence** '910 Patent[2] at Fig. 1, Figs. 9A-9C, Fig. 11, Fig. 20C, Fig. 24 5:36-6:5 '012 Patent[3] at Abstract, Figs. 1-7, Fig. 10, Fig. 12, 1:64-2:14, 2:23-28, 2:34-36, 2:51-64, 3:1-18, 3:61-4:4, 4:10-13, 4:25-40, 4:50-5:8, 5:38-45, 5:55-6:25, 8:5-16, 8:27-37, 9:7-62,	The term "filament" means "one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes" **Intrinsic Evidence** '012 patent[5] - 2:1-5, 2:55-58, 3:1-18, 4:10-14, 4:51-5:8, 5:38-45, 8:5-16, 8:31-37, 9:7-43, 12:44-14:35, 15:22-39, 17:47-49, 18:12-31, 19:20-32, 19:42-46, 20:22-57, Figs. 6-9. '005 patent[6] - 5:30-65.

[1] The term "filament" also appears in at least claims 18, 22, 24, and 25 of the '12-333 Patent.

[2] Inari has cited to the specification of the '910 Patent, which has substantially the same disclosure as the related '691, 11-'333, and '005 Patents.

[3] Inari has cited to the specification of the '012 Patent, which has substantially the same disclosure as the related '921, '291, and '384 Patents.

[5] Imperative Care has cited to the '012 patent in this chart, which has substantially the same specification as the '921, '291 and '384 patents. Imperative Care incorporates within its citations the similar portions of the '921, '291 and '384 patents.

[6] Imperative Care has cited to the '005 patent in this chart, which has substantially the same specification as the '691, '333, and '910 patents. Imperative Care incorporates within its citations the similar portions of the '691, '333, and '910 patents.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
'921 Patent, Claims 1, 3, 9, 10; '291 Patent, Claims 1, 3, 4, 15; '384 Patent, Claims 1, 3, 4, 6, 9, 15, 17, 18, 19, 23, 25, 26, 27	12:44-14:40, 14:60-67, 15:22-16:6, 17:47-49, 17:64-18:31, 19:20-32, 19:42-46, 20:22-51 '580 Patent[4] at Figs. 11-13B, 17:46-18:48 Claims of the '910, 11-'333, '005, '580, '669, 12-'333, '012, '921, '291, and/or '384 Patents U.S. Pat. App. 16/117,519 at paragraphs [0004]-[0010], [0014]-[0019], [0026]-[0029], [0033]-[0035], [0043]-[0045], [0047]-[0050], [0055]-[0056], [0061]-[0062], [0064]-[0075], [0074], [0081], Figs. 1-10, Fig. 12. U.S. Prov. Pat. App. 62/554,931 at Paragraphs [0003]-[0009], [0013]-[0018], [0025]-[0028], [0032]-[0034], [0042]-[0044], [0046]-[0049], [0054]-[0055], [0060]-[0061], [0063]-[0074], Figs. 1-10, Fig. 12. Prosecution histories of the asserted patents. '011 FH at December 14, 2022 NOA	U.S. Pat. App. 16/117,519 – [0006], [0008]-[0010], [0014]-[0015], [0018]-[0019], [0026]-[0029], [0043]-[0044], [0047]-[0050], [0056], [0062], [0064]-[0070], [0074], [0081], Figs. 1, 6-9. '580 patent[7] - 17:46-18:48, Figs. 13A-13B. U.S. Prov. Pat. App. 62/554,931 – [0005], [0007]-[0008], [0013]-[0014], [0017]-[0018], [0025]-[0028], [0042]-[0043], [0046]-[0049], [0055], [0061], [0063]-[0069], [0073], Figs. 1, 6-9. '011 Patent Prosecution History, Office Action dated August 19, 2022, at 3-6. Prosecution histories of the asserted patents. *Imperative Care, Inc. v. Inari Medical, Inc.*, IPR2024-01157: • Paper 1 • Paper 5 • Paper 7

[4] Inari has cited to the specification of the '580 Patent, which has substantially the same disclosure as the related '669 and 12-'333 Patents.

[7] Imperative Care has cited to the '580 patent in this chart, which has substantially the same specification as the '669 patent. Imperative Care incorporates within its citations the similar portions of the '669 patent.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	'012 FH at Nov. 23, 2022 NOA 11,969,331 FH at Feb. 1, 2023 Nonfinal Rejection at 8-10 and May 8, 2023 Final Rejection at 9-10 11,000,682 FH at July 24, 2020 Nonfinal Rejection at 11, Nov. 16, 2020 Response to Nonfinal Rejection at 1-11, and January 27, 2021 NOA at 5 Arguments made in IPR proceedings for the Asserted Patents. **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the '910, 11-'333, '005, '580, '669, 12-'333, '012, '921, '291, and/or '384 Patents. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care. Merriam-webster.com: "filament" is "a single thread or a thin flexible threadlike object,	• Ex. 1003 *and similar arguments from the related IPRs.* U.S. Pat. No. 12,109,384 at Claim 1. **Extrinsic Evidence** Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	process, or appendage" (https://web.archive.org/web/20170818203220/https://www.merriam-webster.com/dictionary/filament) Dictionary.com: "filament" is a "very fine thread or threadlike structure; a fiber or fibril" (https://web.archive.org/web/20170717183619/https:/www.dictionary.com/browse/filament) American Heritage College Dictionary (Fourth Edition, 2004): "A fine or thinly spun thread, fiber, or wire"	
Impact Statement	The construction of this term is important to the parties' validity and invalidity positions. Not claim dispositive.	
2. "aspiration pump" '691 Patent, Claim 14	Plain and ordinary meaning; pump that generates or generates and stores vacuum pressure for aspiration **Intrinsic Evidence** '910 Patent at Abstract, Fig. 1, Fig. 8, Figs. 11-12, 1:23-28, 4:23-50, 6:41-47, 6:57-7:23, 7:25-38, 14:61-66, 15:57-16:15, 16:53-56, 19:27-31, 19:51-61, 21:50-61, 23:5-52, 24:2-10, 26:38-41, 27:29-33, 28:16-33, 29:30-35 Claims of the '691 Patent	The term "aspiration pump" is a device that is operated to generate negative pressure to aspirate. **Intrinsic Evidence** '691 patent – 4:23-50, 6:55-16:28, 23:65-24:6, Figs. 1-9, 11, 12, 15, 17, 19-21, 24. Prosecution history of the '691 patent. **Extrinsic Evidence**

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	Prosecution history of the '691 Patent. '691 FH at June 21, 2023 Nonfinal Rejection at 3-4 and 7-18-2023 Notice of Allowance at 3 Arguments made in IPR proceedings for the '691 Patent and/or related patents. 11,642,209 FH at Sept. 23, 2022 Nonfinal Rejection at 6-7, 9, 11 and Feb. 10, 2023 Final Rejection at 5, 7 **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the '691 Patent. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care.	Definition of "pump" from Merriam-Webster.com (attached hereto) Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.
Impact Statement	The construction of this term may be relevant to the parties' infringement and non-infringement positions. Not claim dispositive.	

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
3. "wherein the first pressure source is the same as the second pressure source" '910 Patent, Claims 4, 13	The first pressure source and the second pressure source are the same structure **Intrinsic Evidence** '910 Patent at Fig. 1, Fig. 11, 7:28-41, 15:65-16:5, 16:53-56, 21:50-61, 27:18-33, 28:48-50 Claims of the '910 Patent Prosecution history of the '910 Patent. Arguments made in IPR proceedings for related patents. **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the '910 Patent. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care.	The "wherein" clause needs no construction. Claims 4 and 13 are invalid under 35 U.S.C. §112(d) because the claims do not "specify a further limitation of the subject matter claimed" in the claims from which they depend. **Intrinsic Evidence** '910 patent – 6:6-13, 10:46-11:26, 13:6-43, 20:58-28:10, 29:49-53, 33:24-30, 34:52-63, Fig. 1, 4A, 11-12, 15, 18E, 21A-21B, 23, claims 1, 11. Prosecution history of the '910 patent. **Extrinsic Evidence** Definition of "source" from Merriam-Webster.com (attached hereto) Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
Impact Statement	The construction of this term is dispositive of claims 4 and 13 of the '910 patent, if the term is construed as rendering the claims invalid for violating Section 112(d). Inari believes that resolution of this dispute will not resolve claims 1-3, 5-8, 11-15, and 18-20 of the '910 Patent.	The construction of this term is dispositive of claims 4 and 13 of the '910 patent, if the term is construed as rendering the claims invalid for violating Section 112(d).
4. "tubular member defining a lumen configured to slidably receive the second catheter" '910 Patent, Claim 7	Plain and ordinary meaning; tubular member allowing a second catheter to be inserted through the lumen of the tubular member **Intrinsic Evidence** '910 Patent at Abstract, Fig. 1, Fig. 3D, Figs. 9A-9C, Figs. 11-12, Fig. 15, 19:64-20:2, 20:58-28:10 Claims of the '910 Patent Prosecution history of the '910 Patent. Arguments made in IPR proceedings for related patents. 11,559,382 FH at Sept. 1, 2021 Nonfinal Rejection at 14-16 and April 11, 2022 Final Rejection at 14-15	The term "tubular member defining a lumen configured to slidably receive the second catheter" needs no construction. **Intrinsic Evidence** '910 patent - '910 patent –20:58-28:10, Fig. 11-12, 15. Prosecution history of the '910 patent. **Extrinsic Evidence** Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	'331 FH at February 1, 2023 Nonfinal Rejection at 8-9, May 8, 2023 Final Rejection at 9, Aug. 8, 2023 Amendment After Final Rejection at 9, Sept. 15, 2023 NOA at 3, Oct. 23, 2023 NOA at 2-3, Jan. 10, 2024 NOA at 3-4, March 13, 2024 NOA at 3-4 **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the '910 Patent. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care. Merriam-webster.com: "slidable" is "capable of sliding or being slid" (https://web.archive.org/web/20201005210238/https://www.merriam-webster.com/dictionary/slidable)	
Impact Statement	The construction of this term may be relevant to the parties' infringement and non-infringement positions. Not claim dispositive.	

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
5. "interventional device" '580 Patent, Claims 1, 16, 30, 33; '669 Patent, Claims 1, 5, 12, 15, 19, 26, 27	Device advanced to clot to physically engage with clot to capture, loosen, and/or break up clot **Intrinsic Evidence** '580 Patent at Abstract, Figs. 2A-2G, Fig. 10, Fig. 14, 3:46-60, 4:62-5:63, 6:26-36, 7:25-39, 7:59-8:55, 9:51-56, 11:62-12:3, 13:5-14:56, 15:25-29, 16:12-14, 16:21-42, 18:60-67, 19:11-20:3029, 20:41-49, 21:15-19, 22:16-24:30 '910 Patent at 4:30-33, 5:61-67, 20:31-52, 24:11-21, 28:20-33, 28:51-30:41 Prosecution history of the '580 and '669 Patents. Claims of the '580, and/or '669 Patents '314 FH at Oct. 16, 2020 Nonfinal Rejection at 3-6, 10, 12-15, 17 **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning	The term "interventional device" means a device that extends beyond the distal end of the catheter or elongated shaft to engage clots in the blood vessel. **Intrinsic Evidence** '580 patent – abstract, 1:21-27, 3:46-63, 5:16-6:36, 7:25-8:55, 13:5-16:32, 19:1-21:52, 22:16-34, 22:48-56, 23:8-32, 23:42-49, 23:63-24:30, Figs. 2A-2G, 10, 14, Prosecution history of the '580 and '669 patents. **Extrinsic Evidence** Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	and scope of the term in the context of the patent claims of the '580 and/or '669 Patents. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care.	
Impact Statement	The construction of this term may be relevant to the parties' infringement and non-infringement positions, but is not dispositive of any of the claims of the '580 and '668 Patents listed above, much less all of them.	The construction of this term is claim dispositive of the asserted claims in the '580 and '669 patents if the Court adopts Imperative Care's construction.
6. "support" '005 patent – claim 10-11; '291 patent – claim 1-2, 15	Plain and ordinary meaning (not indefinite) **Intrinsic Evidence** '910 Patent at Fig. 1, Figs. 9A-9C, Fig. 11, Fig. 20C, 5:36-6:5 '012 Patent at Abstract, Figs. 1-5, Fig. 12, 2:51-66, 3:19-28, 6:26-7:31, 8:17-56, 9:24-43, 9:54-10:36, 12:46-60, 13:5-16, 16:32-17:29 Claims of the '005 and/or '291 Patents Prosecution history of the '005 and '291 Patents. '291 FH August 9, 2023 Notice of Allowance at 2-3	The term "support" is indefinite for failing to particularly point out and distinctly claim the subject matter which the application regards as the invention. **Intrinsic Evidence** '005 patent – 5:23-60, 14:60-15:55, 17:28-62, 20:66-21:49, 28:34-50, Figs. 1, 11, 17, 24. '291 patent – abstract, 2:15-32, 3:19-44, 6:48-7:15, 8:17-37, 9:54-10:56, 16:32-17:29, 18:38-43, Figs. 1-3, 12 '005 Patent Prosecution History, Office Action dated Oct. 5, 2022 at 2-7 (and references cited therein).

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	U.S. Pat. App. 16/117,519 at Abstract, Claim 18, [0006]-[0008], [0011], [0014]-[0018], [0026]-[0029], [0033]-[0039], [0043]-[0044], [0048]-[0052], [0058], [0064]-[0066], [0078]-[0079], Figs. 1-5, Fig. 12. U.S. Prov. Pat. App. 62/554,931 at Abstract, Claim 18, Paragraphs [0005]-[0007], [0010], [0013]-[0017], [0025]-[0028], [0032]-[0038], [0042]-[0043], [0047]-[0051], [0057], [0063]-[0065], [0077]-[0078], Figs. 1-5, Fig. 12. Arguments made in IPR proceedings for the '005 Patent and/or related patents to the '005 Patent and/or '291 Patent **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the '005 and/or '291 Patents. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care.	'291 Patent Prosecution History, Notice of Allowance dated Aug. 9, 2023 at 2-4 (and referenced cited therein). U.S. Pat. App. 16/117,519. '682 Patent Prosecution History, Office Action dated July 24, 2020, at 4-6. '682 Patent Prosecution History, Office Action Response dated November 16, 2020, at 7. **Extrinsic Evidence** Definition of "support" from Merriam-Webster.com (attached hereto) Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.

IMPERATIVE Ex. 1034
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Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
Impact Statement	The construction of this term is dispositive of asserted claims 10-15 of the '005 patent and the asserted claims of the '291 patent, if Imperative Care's indefiniteness argument is adopted.	
7. "shaped to be intravascularly advanced" '910 patent – claim 1, 11	A catheter structure sized and made of materials so that it can be moved through the vasculature of a patient to the location of a pulmonary embolism (not indefinite) **Intrinsic Evidence** '910 Patent at Abstract, Fig. 1, Fig. 3D, Figs. 9A-16E, 4:17-25, 20:58-23:4, 26:25-47, 27:4-17, 29:9-21 Claims of the '910 Patent '910 Patent prosecution history. Arguments made in IPR proceedings for related patents. **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the '910 Patent. In addition,	The term "shaped to be intravascularly advanced" is indefinite for failing to particularly point out and distinctly claim the subject matter which the application regards as the invention. **Intrinsic Evidence** '910 patent – 4:17-33, 22:11-53, 26:25-47, 29:9-21, Fig. 12. '910 patent prosecution history. **Extrinsic Evidence** Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care.	
Impact Statement	The construction of this term is dispositive of the asserted claims of the '910 patent, if Imperative Care's indefiniteness argument is adopted.	
8. "clot canister"/"clot cannister" 11-'333 Patent, Claims 1, 6-8, 16, 18, 20, 25-26, 35, 37; '005 Patent, Claims 1, 10	Structure that captures and at least temporarily holds aspirated clot material **Intrinsic Evidence** '910 Patent at Figs. 4A-4C, Figs. 19-20E, 10:46-11:26, 31:9-50, 32:61-33:21 Claims of the 11-'333 and/or '005 Patents Arguments made in IPR proceedings for the '005 Patent and/or related patents. 11-'333 and '005 Patent prosecution histories. '209 FH at Feb. 10, 2023 Final Rejection at 9-10 '331 FH at May 8, 2023 Final Rejection at 5 **Extrinsic Evidence**	The term "clot canister/clot cannister" means a container that temporarily captures clot material. **Intrinsic Evidence** '005 patent – 12:39-45, 31:9-50, 33:2-6, Fig. 19. '580 patent – 7:1-24, 1:40-58, 8:57-9:60, 13:20-43, 15:66-16:20, 21:20-40, Figs. 1A-1B, 3A-3C. 11-'333 and '005 patent prosecution histories. **Extrinsic Evidence** Definition of "canister" from Merriam-Webster.com (attached hereto) Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the 11-'333 and/or '005 Patents. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care.	view of the specification at the time of the alleged invention.
Impact Statement	The construction of this term may be relevant to the parties' infringement and non-infringement positions. Not claim dispositive.	
9. "wherein" clause '691 patent – claim 14	Plain and ordinary meaning (not indefinite) (Inari objects that this is multiple terms that cannot be counted as a single term for construction) **Intrinsic Evidence** '910 Patent at Abstract, Fig. 1, Fig. 3D, Figs. 8-9C, Figs. 11-12, Fig. 15, 4:17-50, 6:34-7:23, 7:25-38, 13:46-47, 14:61-66, 18:11-20:2, 20:58-28:33, 28:48-50 Claims of the '691 Patent '691Patent prosecution history.	The "wherein" clause beginning "wherein upon user actuation" renders the claim indefinite for improperly combining method steps with an apparatus claim. '691 patent and patent prosecution history. **Extrinsic Evidence** Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	'691 FH at June 21, 2023 Nonfinal Rejection at 5-9 and 7-18-2023 Notice of Allowance at 2-3 Arguments made in IPR proceedings for the '691 Patent and/or related patents. '382 FH at Sept. 1, 2021 Nonfinal Rejection at 5, 7-8, 11 and April 11, 2022 Final Rejection at 3-4, 9-10 '209 FH at Sept. 23, 2022 Nonfinal Rejection at 7-10, Dec. 22, 2022 Nonfinal Rejection at 7-8, and Feb. 10, 2023 Final Rejection at 5-8 **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the '691 Patent. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care.	
Impact Statement	The construction of this term is dispositive for the asserted claims of the '691 patent, if Imperative Care's indefiniteness argument is adopted.	

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

II. Disputed Terms Not Identified as Most Significant by the Parties

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
10. "proximal"[8] 11-'333 Patent, Claims 1, 20; '012 Patent, Claim 1; '580 Patent, Claim 1; '669 Patent, Claim 1, 10, 15, 14;	Positioned closer along the fluid path to the operator and/or the pressure/ aspiration source; opposite of distal **Intrinsic Evidence** '910 Patent at Abstract, Fig. 1, Fig. 8, Fig. 9A-10B, Fig. 11, Fig. 12, Fig. 13A-14C, Fig. 16A-16E, Fig. 17, 3:19-26, 3:41-44, 3:48-50, 4:19-23, 4:40-47, 5:8-12, 5:30-40, 5:50-67, 6:42-47, 7:8-23, 10:16-18, 10:38-45, 14:61-66, 15:7-20, 15:33-37,15:49-52, 16:37-48, 16:56-17:9, 17:23-25, 17:29-52, 18:48-55, 19:43-50, 21:13-20, 21:28-36, 21:44-49, 21:62-22:10, 22:16-23:4, 23:37-40, 23:48-52, 24:2-7, 24:22-25:17, 25:28-41, 26:15-19, 26:44-55, 27:4-17, 27:34-41, 27:51-67, 28:34-55, 29:12-30:2, 30:14-20 '580 Patent at Figs. 1A-1B, Figs 2B-2C, Figs. 5-8, Abstract, 4:21-33, 4:39-42, 5:4-7, 5:49-63, 6:5-13, 8:24-29, 10:7-12, 10:43-12:47, 13:8-31, 14:4-9, 14:27-40, 14:59-63, 15:5-8, 15:51-61, 17:7-12 17:56-60, 19:14-26, 20:3-6, 21:5-15, 22:16-34, 23:8-32, 23:63-24:30	The term "proximal" means closer to the operator than the distal portion **Intrinsic Evidence** '333 patent – 3:19-22, 5:8-12, 5: 30-50, 15:7-56, 16:33-17:5, 17:40-63, 21:13-27, 22:16-29, 22:54-58, 25:1-17, 27:62-67, 28:39-55, 29:12-30:24, Figs. 1, 9A-9C, 10A-10B, 11, 13A, 14C, 16E, 17, 18A-18H. '012 patent – 6:24-47, 6:56-7:63, 9:63-10:36, 11:13-63, 16:32-17:10, Fig. 1, 3, 12. '580 patent – 4:21-26, 4:39-42, 5:64-6:48, 7:25-8:29, 10:7-12, 10:42-12:53, 13:5-33, 13:65-15:16, 17:7-12, 17:56-18:4, 19:11-19:39, 20:3-22, 22:16-33, 23:63-24:13, Figs. 1A-1B, 2A-2G, 5-8. Prosecution histories of the 11-'333, '012, '580, and '669 patents. **Extrinsic Evidence** Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in

[8] The term "proximal" also appears in at least claim 17 of the '12-333 Patent.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	'012 Patent at Fig. 1, Fig. 3, Fig. 12, 6:30-37, 6:56-7:45, 7:60-63, 9:63-10:67, 11:13-21, 11:29-42, 11:52-63, 16:34-67 Claims of the 11-'333,'580, '669, 12-'333, and/or '012 Patents Prosecution histories of the 11-'333, '012, '580, and '669 Patents. '382 FH at Sept. 1, 2022 Nonfinal Rejection at 4-5 and April 11, 2022 Final Rejection at 6 '331 FH at Feb. 1, 2023 Nonfinal Rejection at 5, April 3, 2023 Amendment After Nonfinal Rejection at 6-7, May 8, 2023 Final Rejection at 3, 7-8, Aug. 8, 2023 Amendment After Final Rejection at 8-9, Sept. 15, 2023 NOA at 2-3, Oct. 23, 2023 NOA at 2-3, Jan. 10, 2024 NOA at 3-4, and March 13, 2024 NOA at 3-4 11,154,314 FH at Oct. 16, 2020 Nonfinal Rejection at 3-4, 8-9, 11, 15 **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having	view of the specification at the time of the alleged invention.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent claims of the 11-'333, '012, '580, '669, and/or 12-'333 Patents. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care. Oxford English Reference Dictionary (Revised Second Edition, 2002): "situated nearer to the center of the body or point of attachment (opp. DISTAL)" American Heritage College Dictionary (Fourth Edition, 2004): "Anatomy Nearer to a point of reference such as an origin, a point of attachment, or the midline of the body." Merriam-webster.com: "next to or nearest the point of attachment or origin, a central point, or the point of view; especially : located toward the center of the body — compare DISTAL" (https://web.archive.org/web/20170817171854/https://www.merriam-webster.com/dictionary/proximal)	
Impact Statement	The construction of this term may relate to the parties' infringement, noninfringement, validity and invalidity positions, and provides explanation. Not claim dispositive.	This construction has no impact on any issue.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
11. "distal"[9] '910 Patent, Claims 1, 11; 11-'333 Patent, Claims 1, 4, 20, 23; '691 Patent, Claim 20; '012 Patent, Claim 1; '580 Patent, Claims 1, 9 16; '669 Patent, Claims 11, 25;	Positioned farther away along the fluid path from the operator and/or the pressure/aspiration source; opposite of proximal **Intrinsic Evidence** '910 Patent at Abstract, Fig. 1, Fig. 8, Fig. 9A-10B, Fig. 11, Fig. 12, Fig. 13A-14C, Fig. 16A-16E, Fig. 17, 3:19-26, 3:40-44, 3:48-50, 4:19-23, 4:40-47, 5:8-12, 5:30-41, 5:50-67, 6:42-47, 7:8-23, 10:16-18, 10:38-45, 14:61-66, 15:7-20, 15:33-37, 15:49-52, 16:37-48, 16:56-17:9, 17:23-25, 17:29-52, 18:48-55, 19:43-50, 21:13-20, 21:28-36, 21:44-49, , 21:62-22:10, 22:16-23:4, 23:37-40, 23:48-52, 24:2-7, 24:22-25:17, 25:28-41, , 26:15-19, 26:44-55, 27:4-17, 27:34-41, 27:51-67, 28:34-55, 29:12-30:2, 30:14-20 '580 Patent at Figs. 1A-1B, Figs 2B-2C, Figs. 5-8, Abstract, 4:21-33, 4:39-42, 5:4-7, 5:49-63, 6:5-13, 8:24-29, 10:7-12, 10:43-12:47, 13:8-31, 14:4-9, 14:27-40, 14:59-63, 15:5-8, 15:51-61, 17:7-12, 17:56-60, 19:14-26, 20:3-6, 21:5-15, 22:16-34, 23:8-32, 23:63-24:30 '012 Patent at Fig. 1, Fig. 3, Fig. 12, 6:30-37, 6:56-7:45, 7:60-63, 9:63-10:67, 11:13-21, 11:29-42, 11:52-63, 16:34-67	The term "distal" means further from the operator than the proximal portion **Intrinsic Evidence** '333 patent – abstract, 3:19-50, 4:16-50, 5:8-12, 5:30-54, 6:41-47, 7:8-23, 10:13-45, 14:61-66, 15:7-56, 16:33-17:9, 17:29-63, 18:42-55, 19:43-50, 21:13-23:4, 23:30-25:17, 26:10-24, 26:48-56, 27:4-16, 27:34-67, 28:39-55, 29:12-30:24, Figs. 1, 8, 9A-9C, 10A-10B, 11-14C, 15, 16E, 17, 18A-18H. '012 patent – 6:24-47, 6:56-7:63, 9:63-10:67, 11:13-63, 16:32-17:29, Fig. 1, 3, 12. '580 patent – 3:1-4, 4:21-26, 4:39-42, 4:62-6:48, 7:25-8:29, 10:7-12, 10:42-12:53, 13:5-33, 13:65-15:16, 15:51-15:65, 17:7-12, 17:56-18:4, 19:11-19:39, 19:60-66, 20:3-22, 22:16-33, 23:8-32, 23:63-24:13, 24:19-30, Figs. 1A-1B, 2A-2G, 5-8. '910, 11-'333, '691, '012, '580, and '669 patent prosecution histories. **Extrinsic Evidence**

[9] The term "distal" also appears in at least claim 17 of the '12-333 Patent.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	Claims of the '910, 11-'333, '691, '580, '669, 12-'333, and/or '012 Patents '910, 11-'333, '691, '012, '580, and '669 Patent prosecution histories '382 FH at Sept. 01, 2021 Nonfinal Rejection at 4-5, 7-8, 10-11, 13-17 and April 11, 2022 Final Rejection at 3, 5-6, 9, 11, 13-14 '331 FH at April 3, 2023 Amendment After Nonfinal Rejection at 6-7, May 8, 2023 Final Rejection at 3-4, Aug. 8, 2023 Amendment After Final Rejection at 8, Sept. 15, 2023 NOA at 2-3, Oct. 23, 2023 NOA at 2-4, Jan. 10, 2024 NOA at 3-4, March 13, 2024 NOA at 3-4 11,986,382 FH at May 25, 2023 Nonfinal Rejection at 11 '314 FH at Oct. 16, 2020 Nonfinal Rejection at 3-4, 10, 15, 18 **Extrinsic Evidence** Brian Brown and/or Paul Zalesky may provide testimony regarding how one of ordinary skill in the art at the time of the invention, having reviewed the relevant intrinsic and extrinsic evidence, would have understood the meaning and scope of the term in the context of the patent	Definition of "pump" from Merriam-Webster.com (attached hereto) Expert Testimony of Troy Thornton regarding how a POSITA would understand the term in view of the specification at the time of the alleged invention.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

Claim Term	Inari's Proposed Construction and Support	Imperative Care's Proposed Construction and Support
	claims of the '910, 11-'333, '691, '012, '580, '669, and/or 12-'333 Patents. In addition, Inari may also call Brian Brown and/or Paul Zalesky to address any expert testimony offered by Imperative Care. Oxford English Reference Dictionary (Revised Second Edition, 2002): "situated away from the center of the body or point of attachment (opp. PROXIMAL)" American Heritage College Dictionary (Fourth Edition, 2004): "anatomically located far from a point of reference" Merriam-webster.com: "situated away from the point of attachment or origin or a central point especially of the body compare PROXIMAL" (https://web.archive.org/web/20171205013855/https://www.merriam-webster.com/dictionary/distal)	
Impact Statement	The construction of this term may relate to the parties' infringement, noninfringement, validity and invalidity positions, and provides explanation. Not claim dispositive.	This construction has no impact on any issue.

IMPERATIVE Ex. 1034
IPR Petititon - US 11,554,005

EXHIBIT B

US011974910B2

(12) **United States Patent**
Merritt et al.

(10) **Patent No.: US 11,974,910 B2**
(45) **Date of Patent: May 7, 2024**

(54) **SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS**

(71) Applicant: **Inari Medical, Inc.**, Irvine, CA (US)

(72) Inventors: **Ben Merritt**, San Clemente, CA (US); **Jacqueline Macias**, Fullerton, CA (US); **Brian Michael Strauss**, San Clemente, CA (US); **Thomas Tu**, Louisville, KY (US); **John Coleman Thress**, Capistrano Beach, CA (US); **Paul Lubock**, Monarch Beach, CA (US)

(73) Assignee: **Inari Medical, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/342,553**

(22) Filed: **Jun. 27, 2023**

(65) **Prior Publication Data**

US 2023/0338131 A1 Oct. 26, 2023

Related U.S. Application Data

(63) Continuation of application No. 18/167,757, filed on Feb. 10, 2023, which is a continuation of application
(Continued)

(51) **Int. Cl.**
A61F 2/01 (2006.01)
A61B 17/12 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/01*** (2013.01); ***A61B 17/12109*** (2013.01); ***A61M 1/815*** (2021.05);
(Continued)

(58) **Field of Classification Search**
CPC ... A61F 2/01; A61B 17/12109; A61B 17/221; A61B 2017/22034; A61B 2017/22079;
(Continued)

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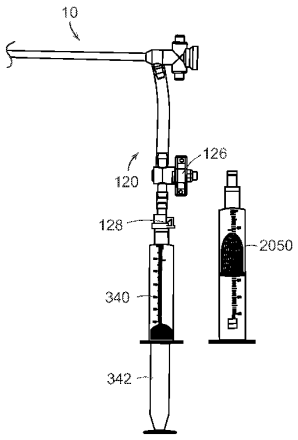
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(Continued)

Primary Examiner — Susan S Su
Assistant Examiner — Eric Rassavong
(74) *Attorney, Agent, or Firm* — Perkins Coie LLP

(57) **ABSTRACT**

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.

20 Claims, 38 Drawing Sheets



Related U.S. Application Data

No. 17/976,711, filed on Oct. 28, 2022, which is a continuation of application No. 17/865,315, filed on Jul. 14, 2022, now Pat. No. 11,642,209, which is a continuation of application No. 16/536,185, filed on Aug. 8, 2019, now Pat. No. 11,559,382.

(60) Provisional application No. 62/718,248, filed on Aug. 13, 2018, provisional application No. 62/718,269, filed on Aug. 13, 2018.

(51) **Int. Cl.**

A61B 17/22	(2006.01)
A61B 17/221	(2006.01)
A61M 1/00	(2006.01)
A61M 25/10	(2013.01)

(52) **U.S. Cl.**

CPC ***A61M 1/84*** (2021.05); *A61B 2017/22034* (2013.01); *A61B 2017/22079* (2013.01); *A61B 17/221* (2013.01); *A61B 2217/005* (2013.01); *A61M 1/79* (2021.05); *A61M 25/10* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/005; A61M 1/815; A61M 1/84; A61M 1/79; A61M 25/10

See application file for complete search history.

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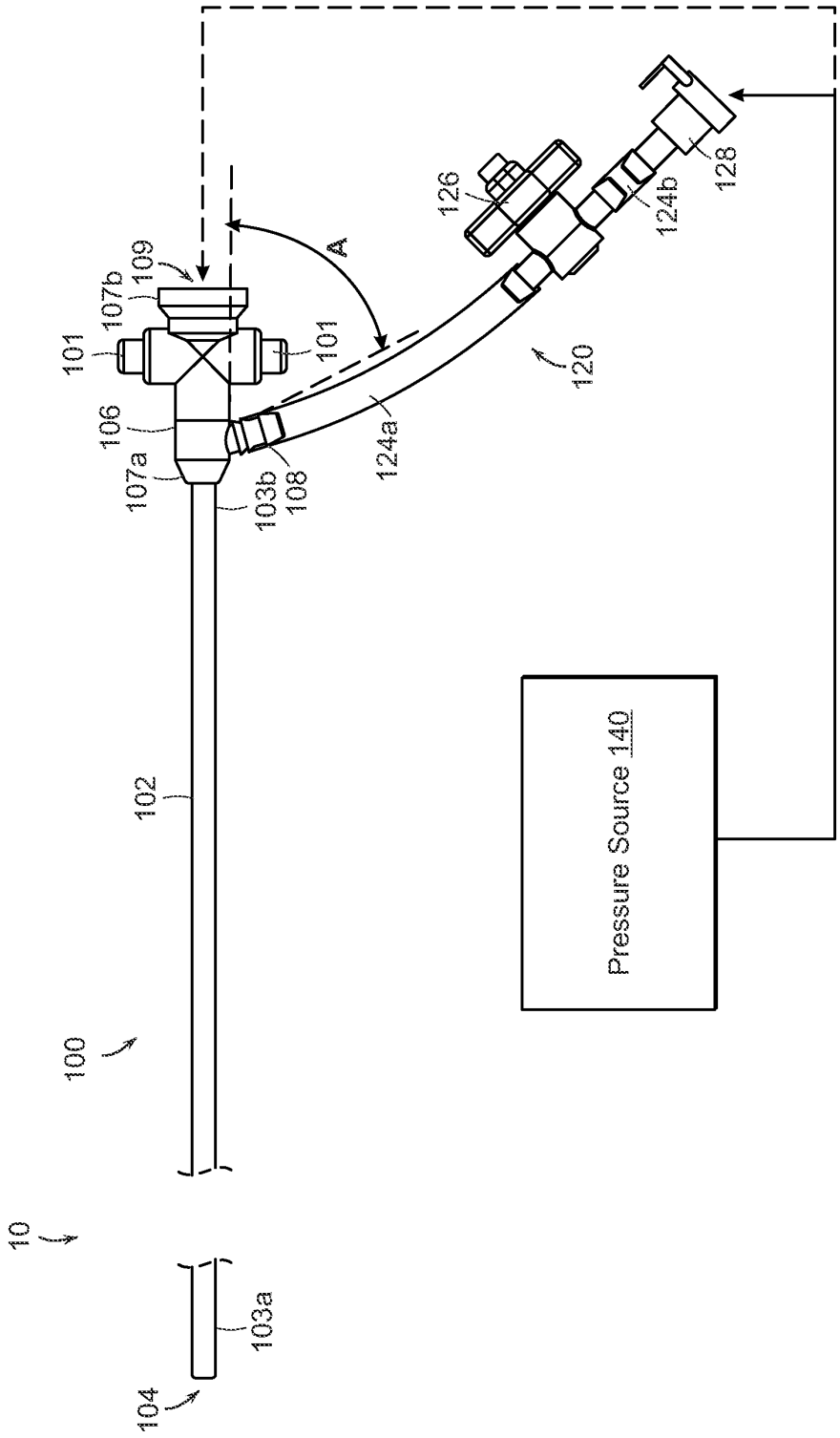

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107b
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Pressure Source 140

FIG. 1

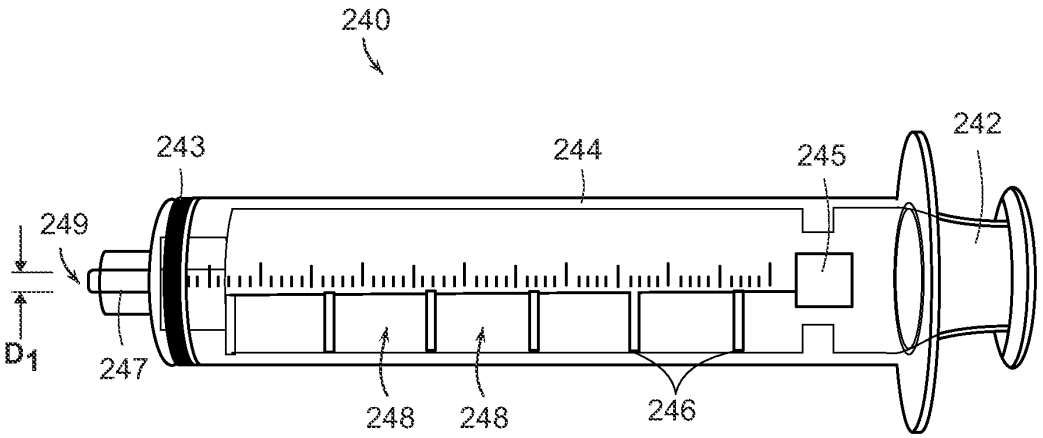

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FIG. 2

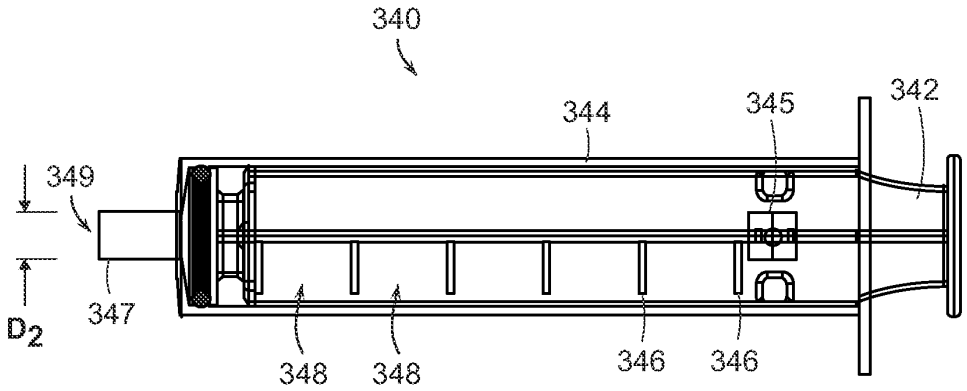

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FIG. 3A

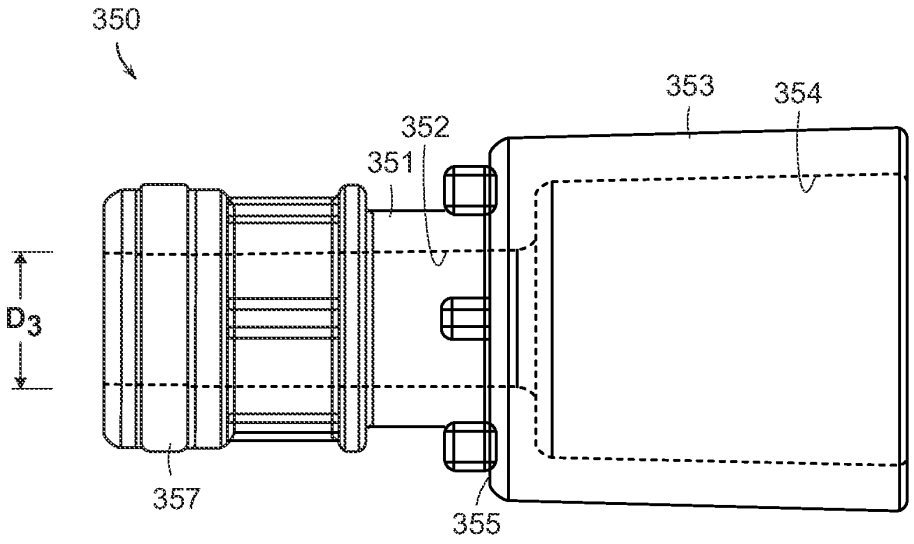


FIG. 3B

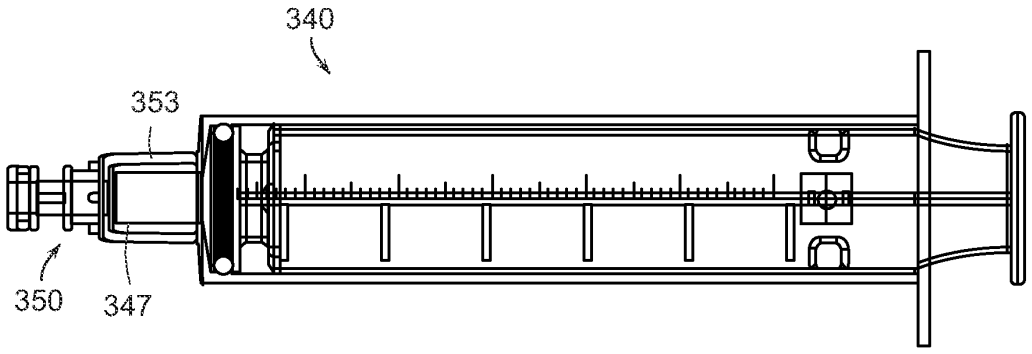


FIG. 3C

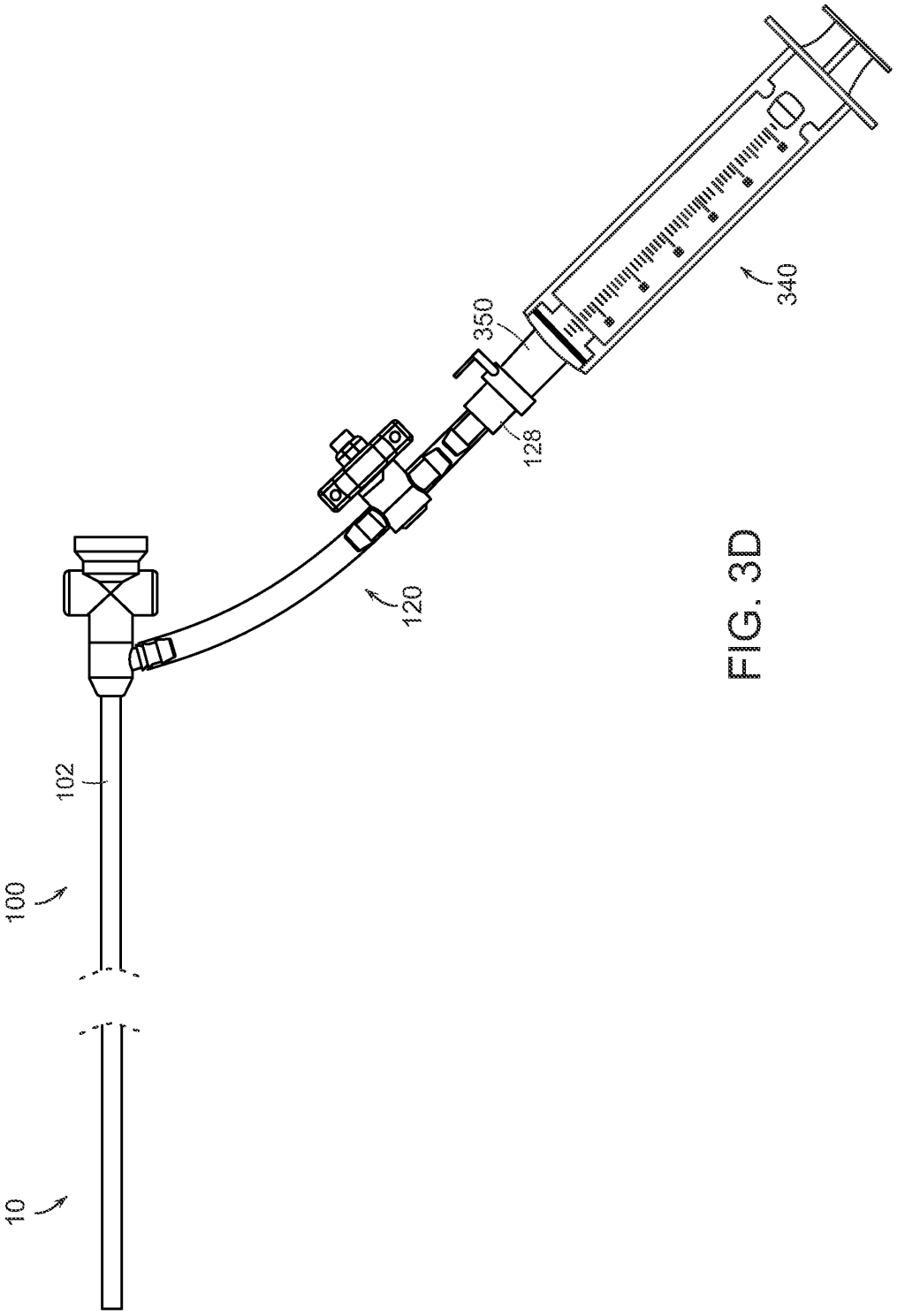
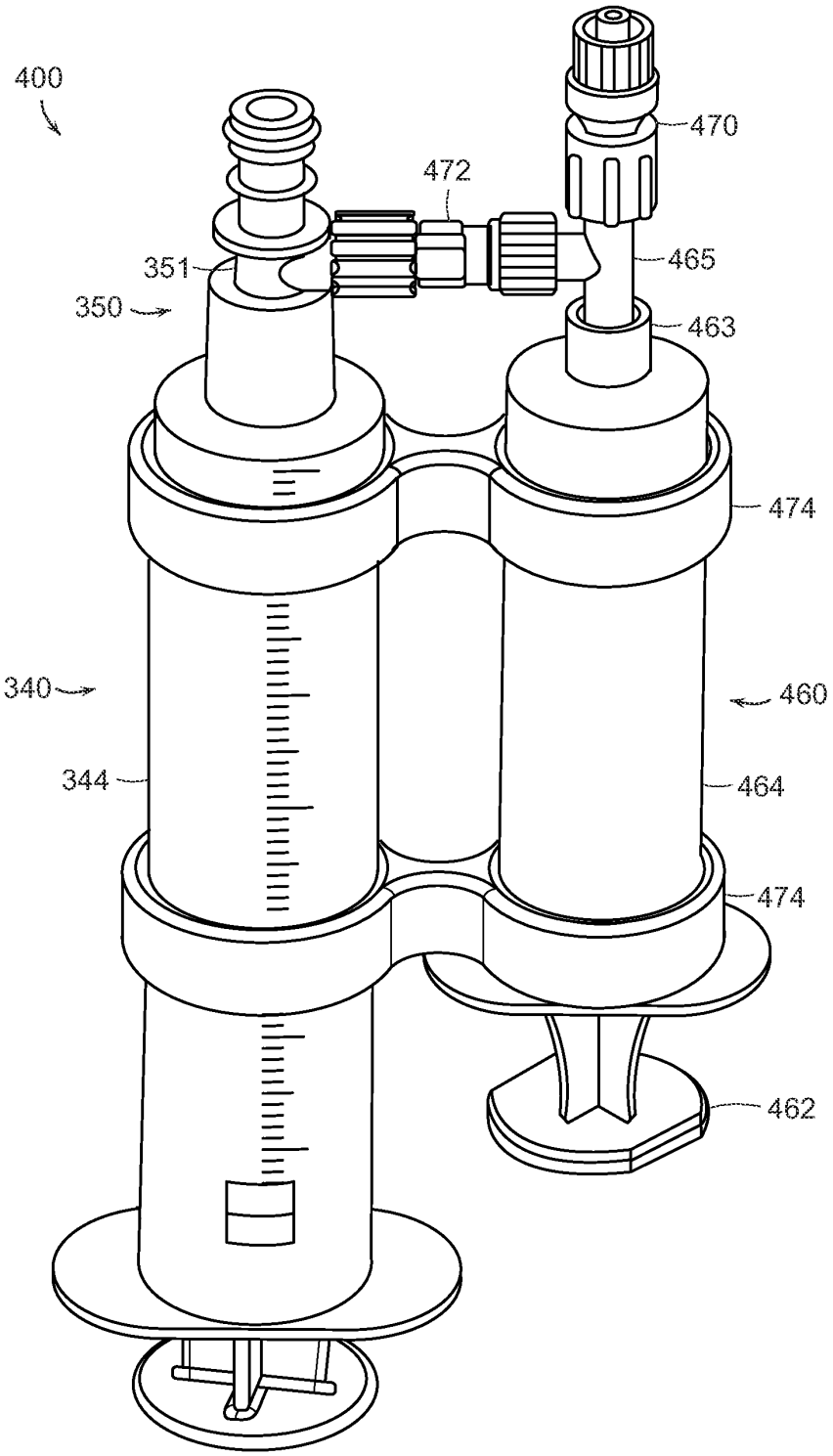


FIG. 3D

FIG. 4A



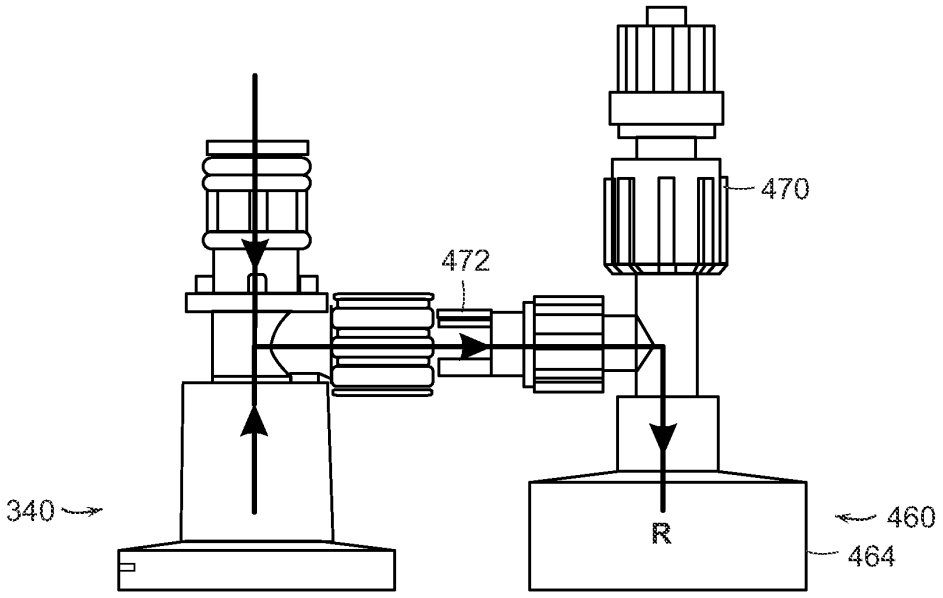


FIG. 4B

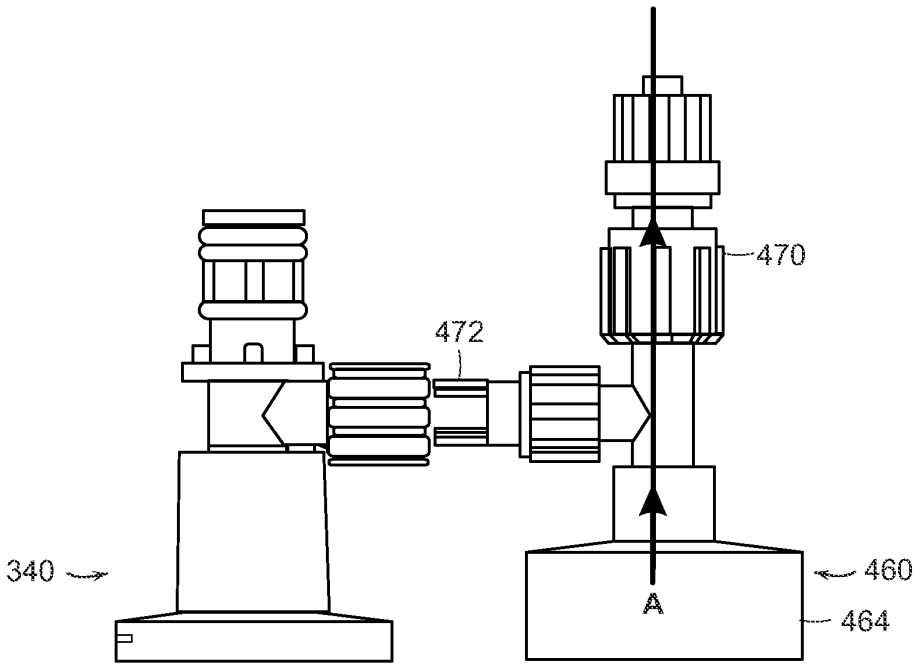


FIG. 4C

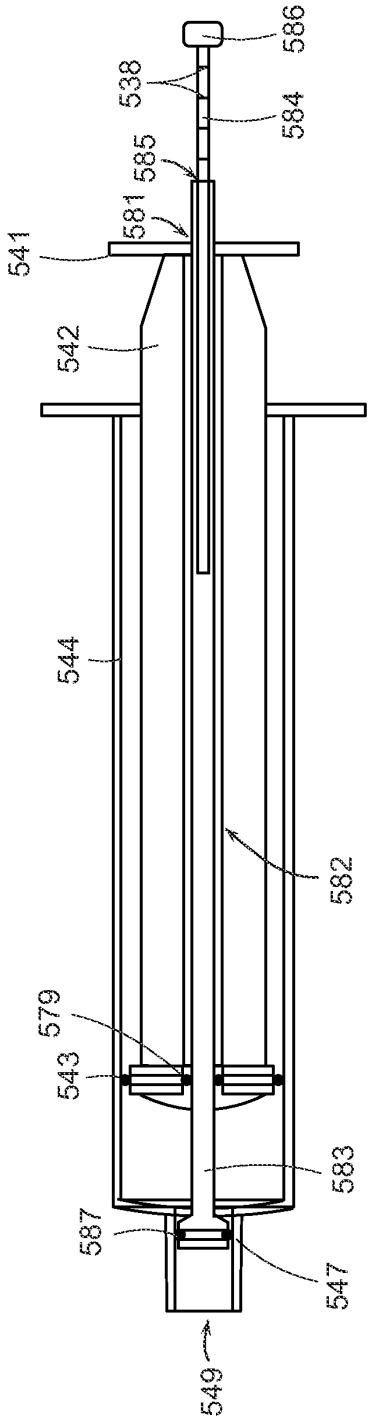


FIG. 5

FIG. 6

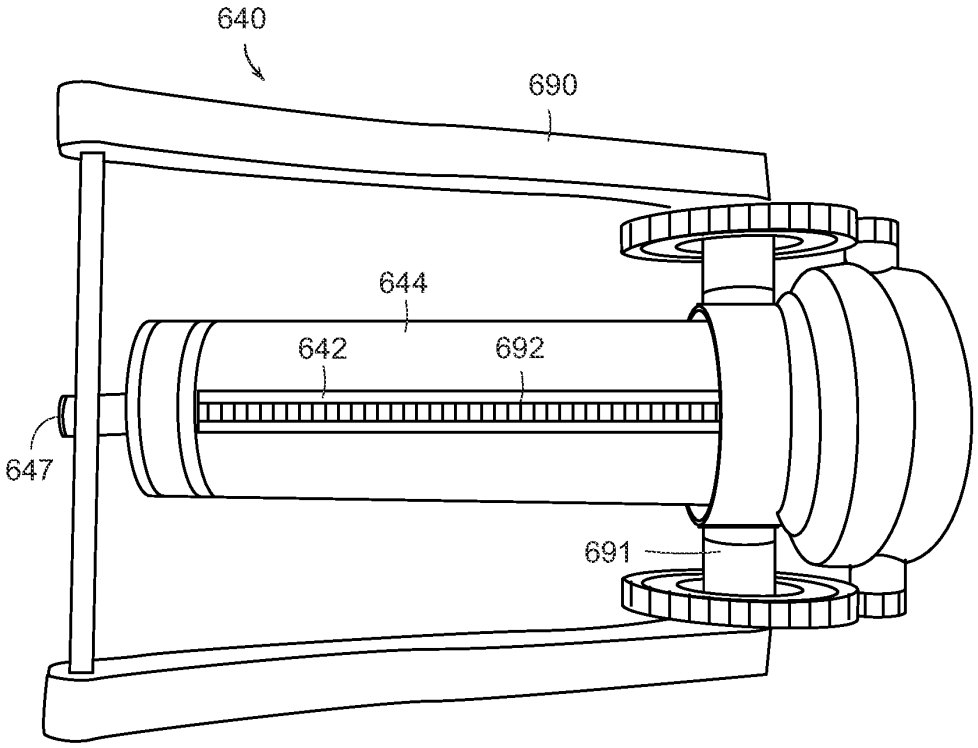
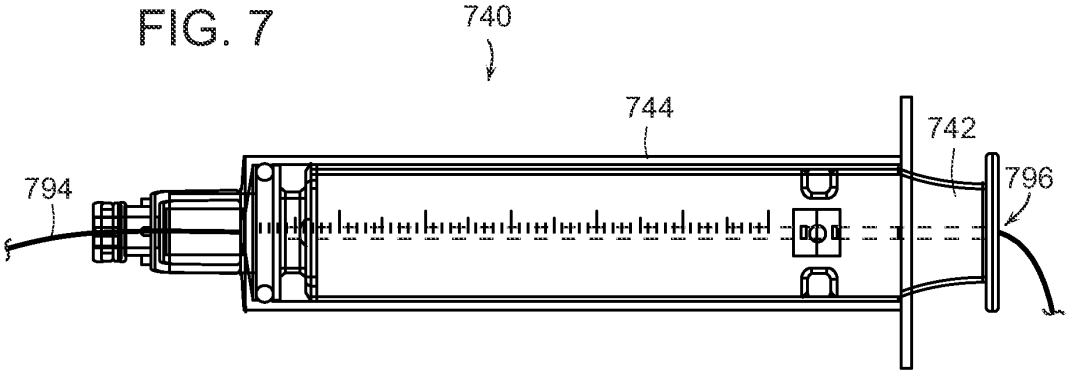


FIG. 7



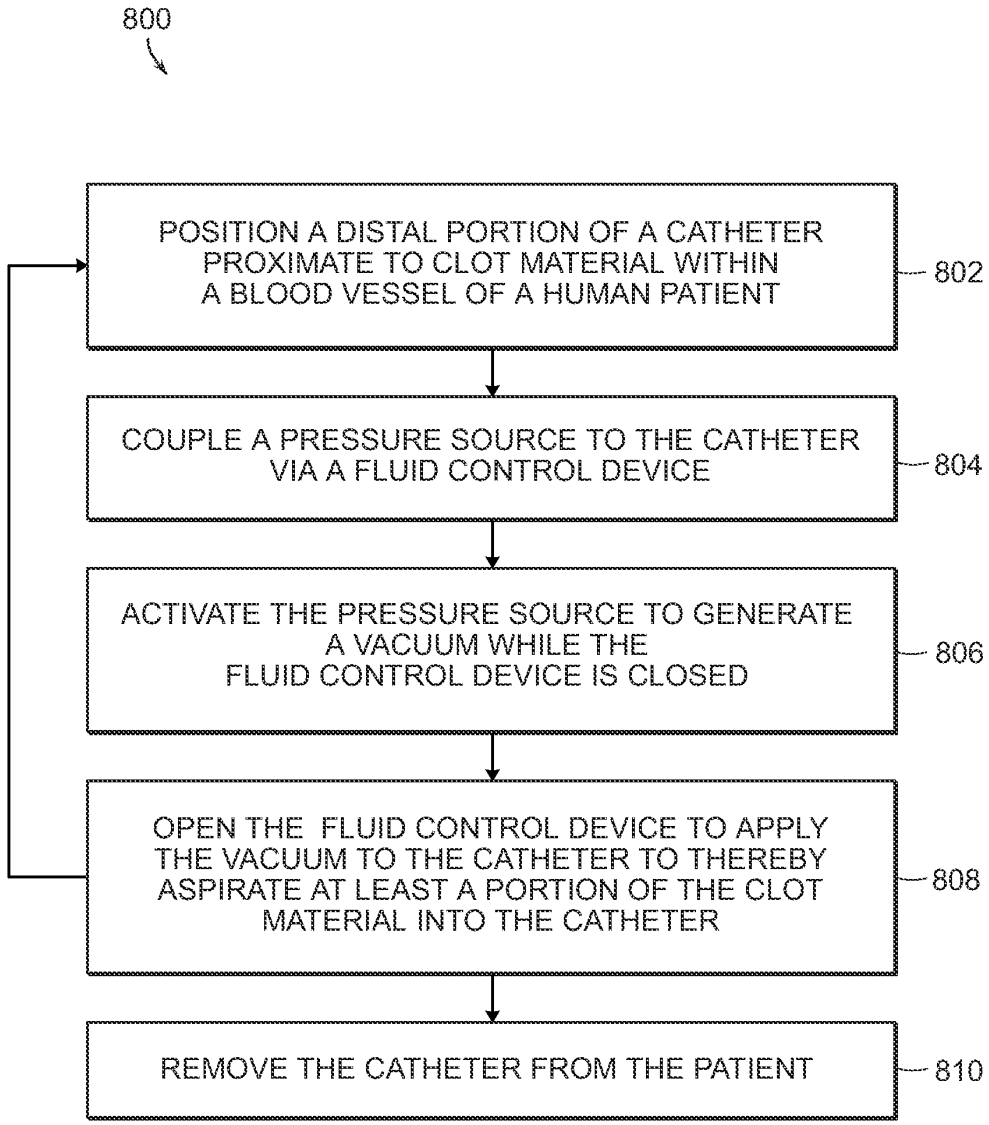

800
POSITION A DISTAL PORTION OF A CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF A HUMAN PATIENT
802
COUPLE A PRESSURE SOURCE TO THE CATHETER VIA A FLUID CONTROL DEVICE
804
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
806
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE CATHETER
808
REMOVE THE CATHETER FROM THE PATIENT
810

FIG. 8

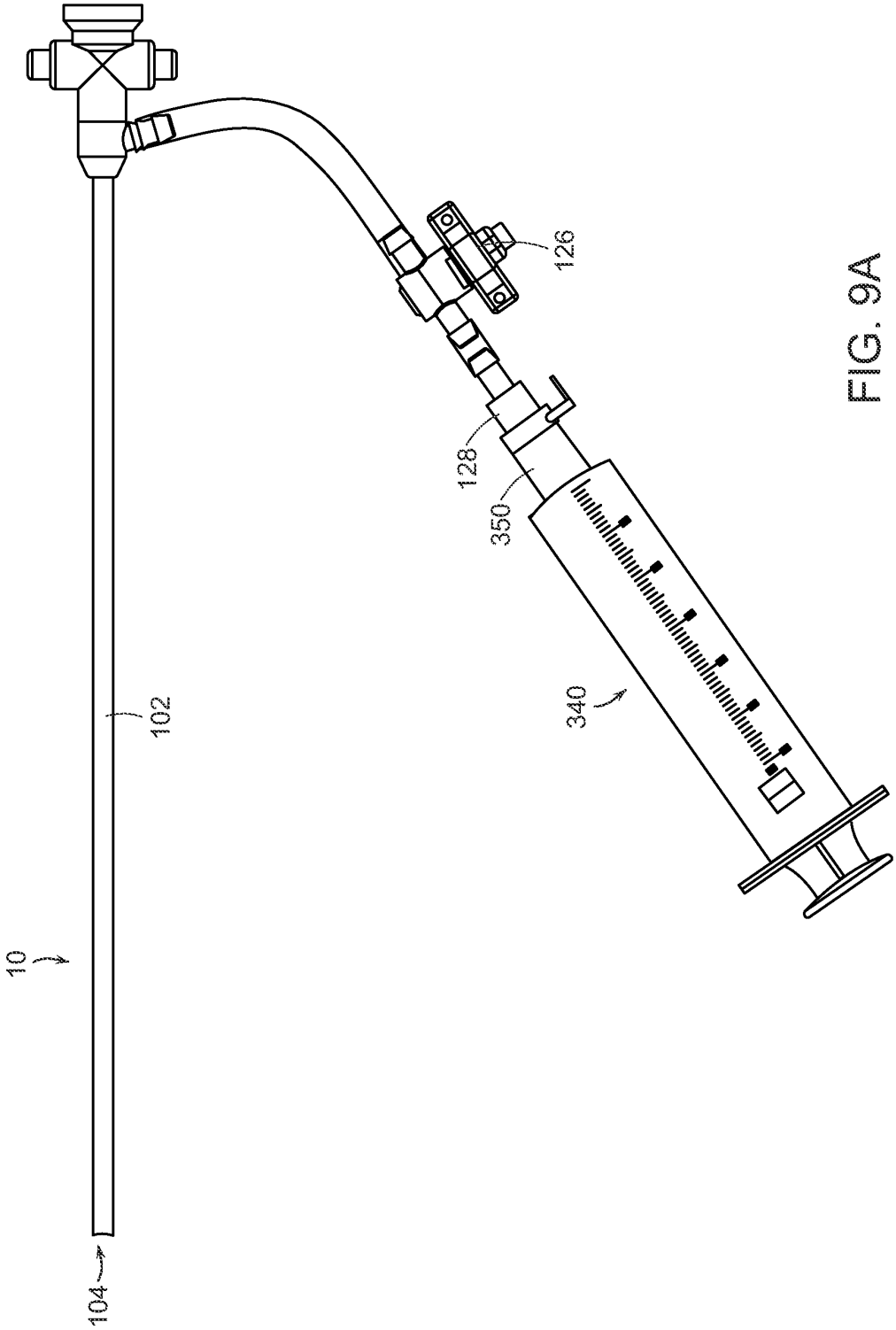


FIG. 9A

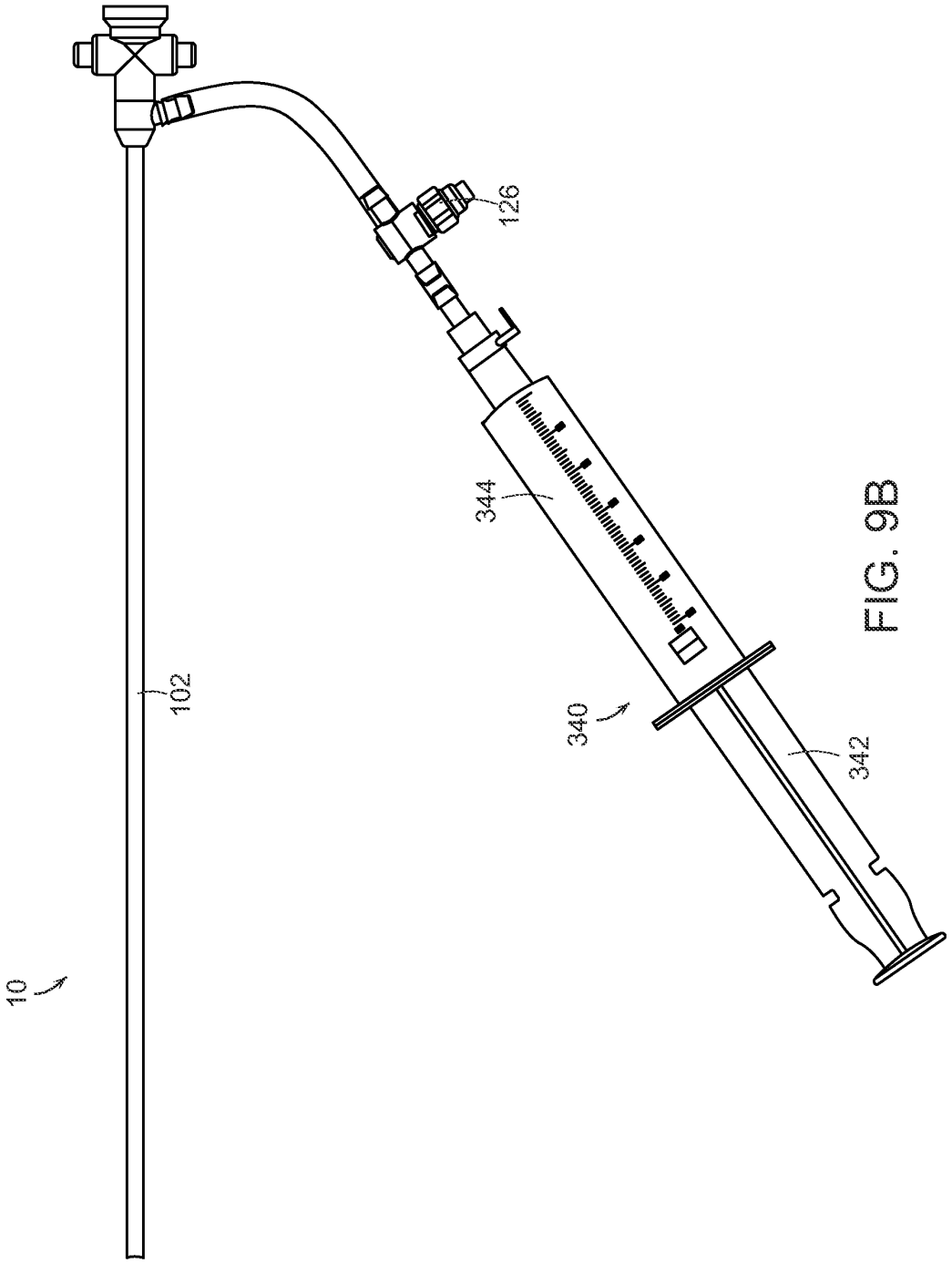


FIG. 9B

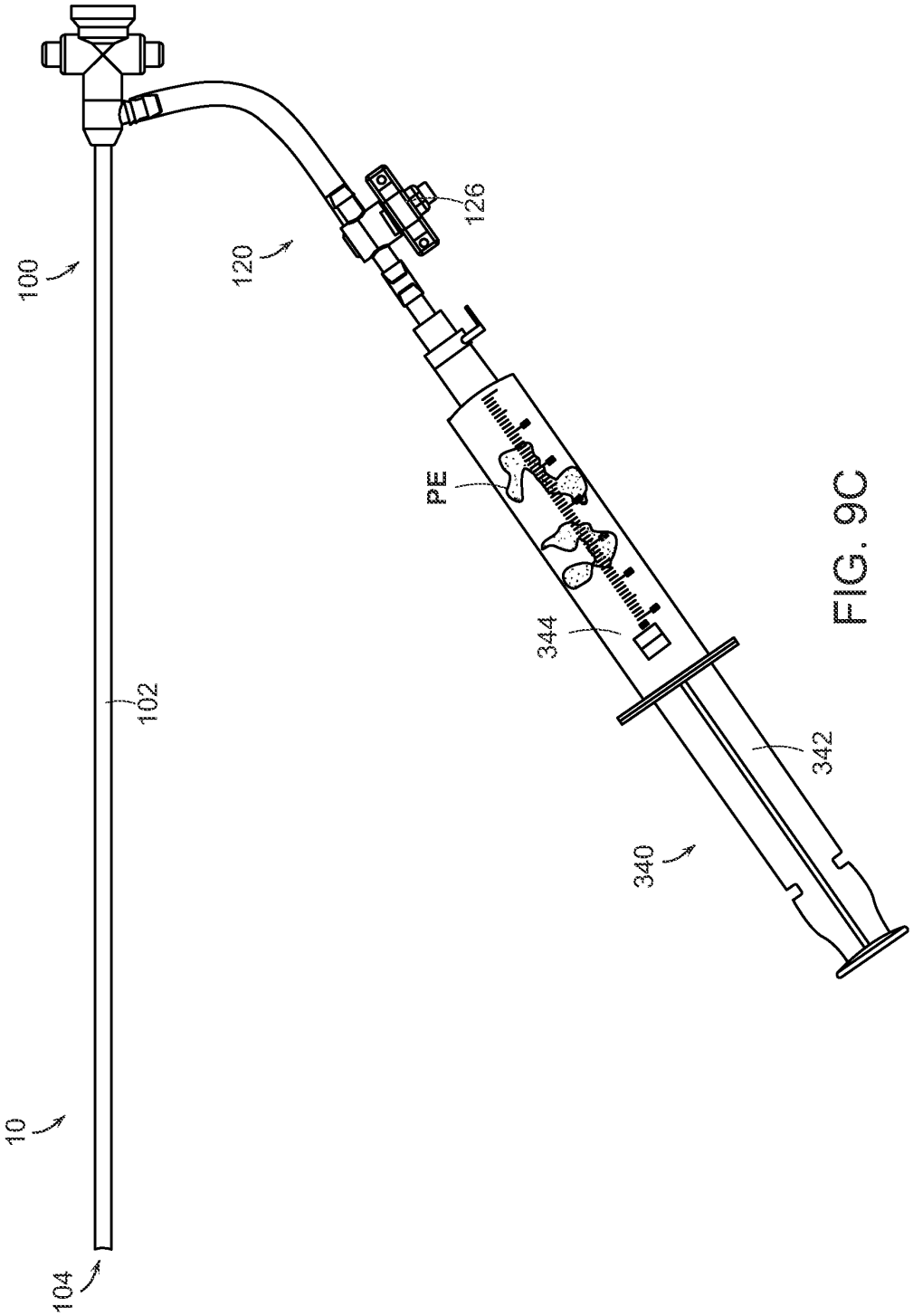


FIG. 9C

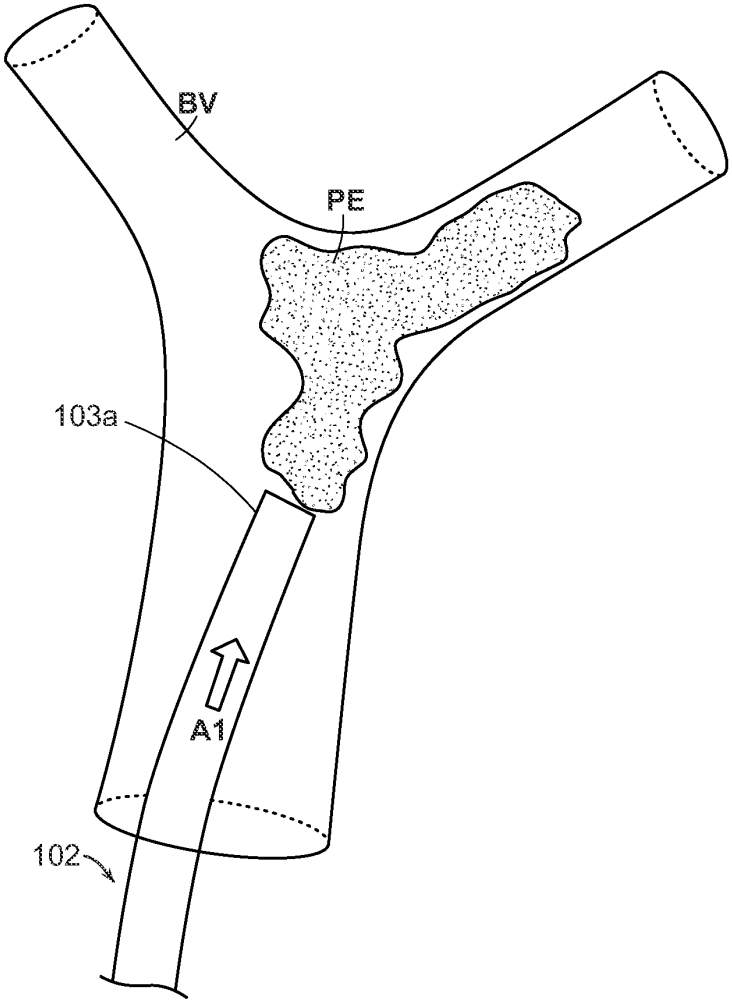


FIG. 10A

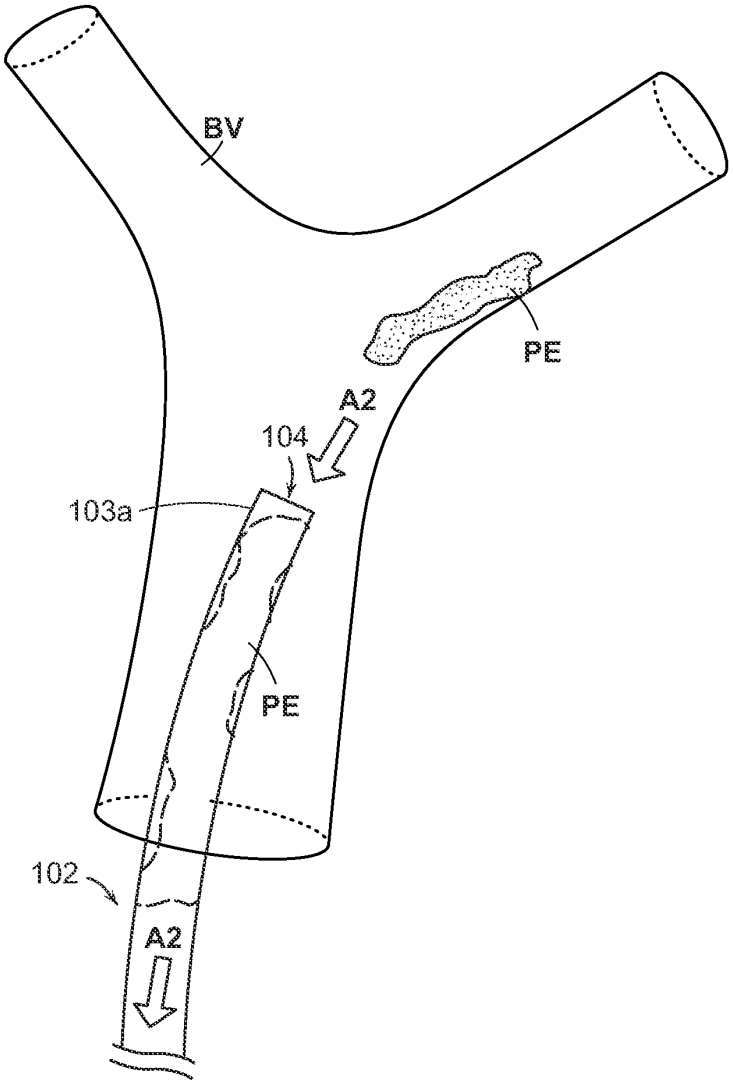


FIG. 10B

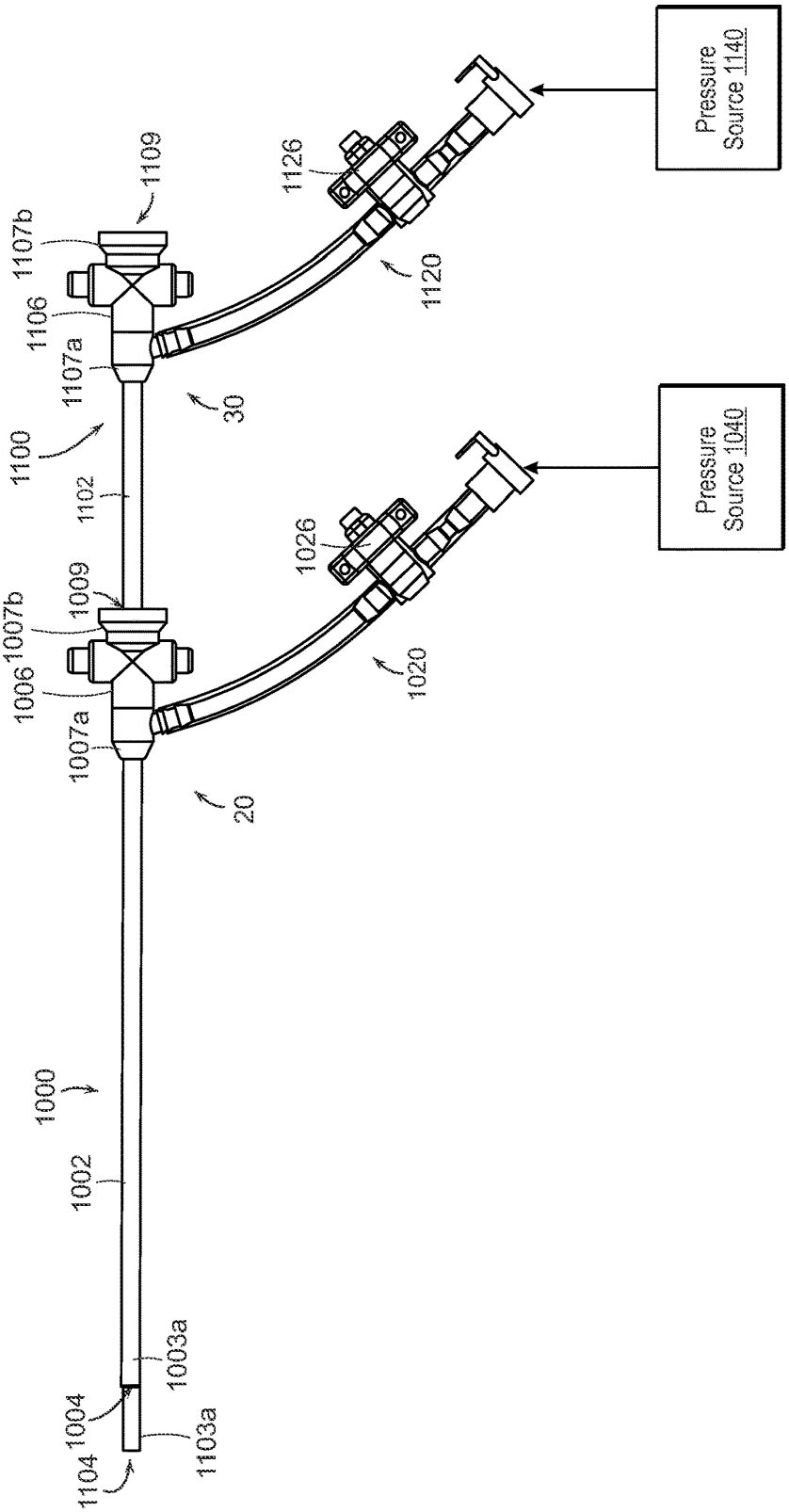

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FIG. 11

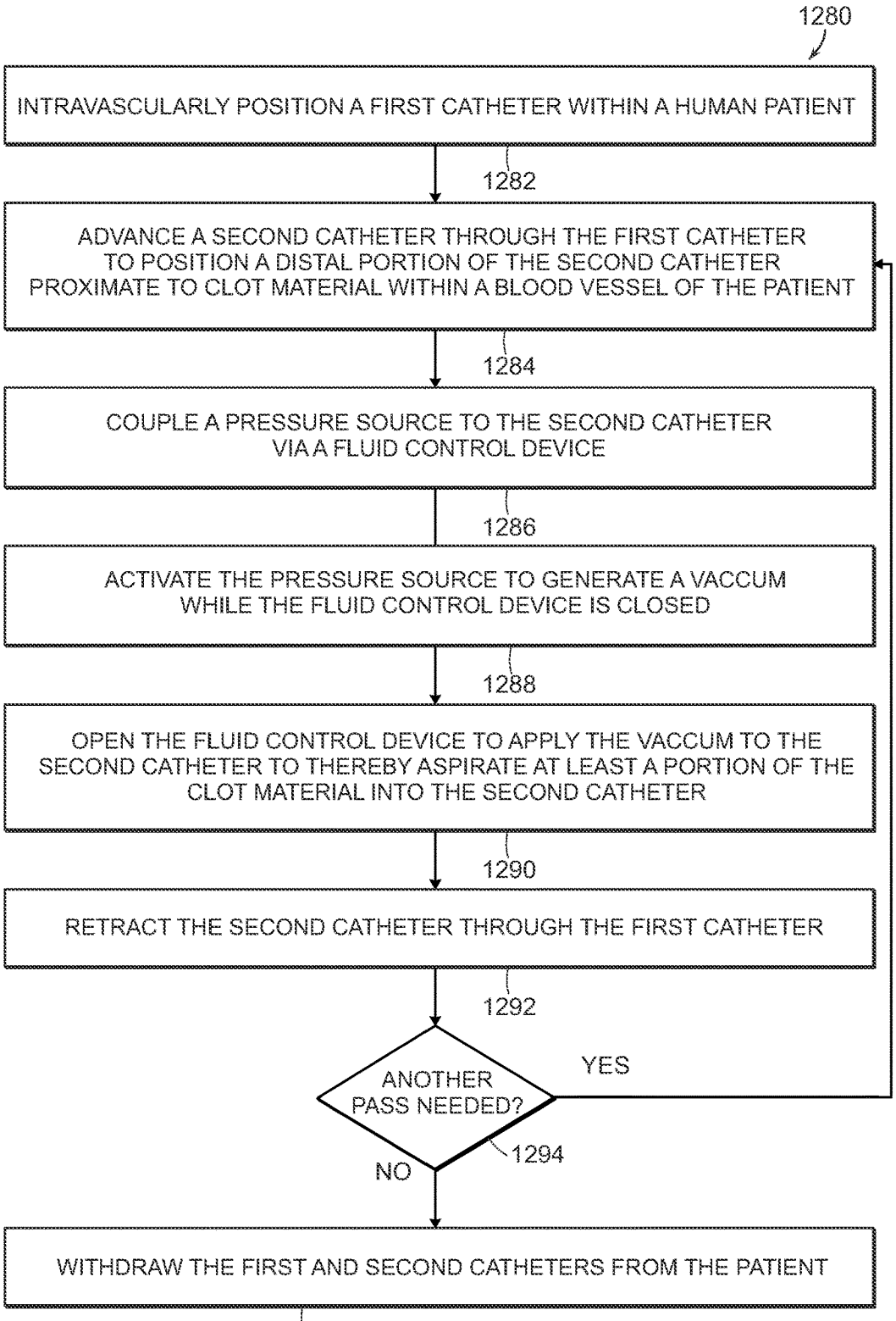

1280
INTRAVASCULARLY POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT
1282
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF THE PATIENT
1284
COUPLE A PRESSURE SOURCE TO THE SECOND CATHETER VIA A FLUID CONTROL DEVICE
1286
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACCUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
1288
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACCUM TO THE SECOND CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE SECOND CATHETER
1290
RETRACT THE SECOND CATHETER THROUGH THE FIRST CATHETER
1292
ANOTHER PASS NEEDED?
YES
1294
NO
WITHDRAW THE FIRST AND SECOND CATHETERS FROM THE PATIENT
1296

FIG. 12

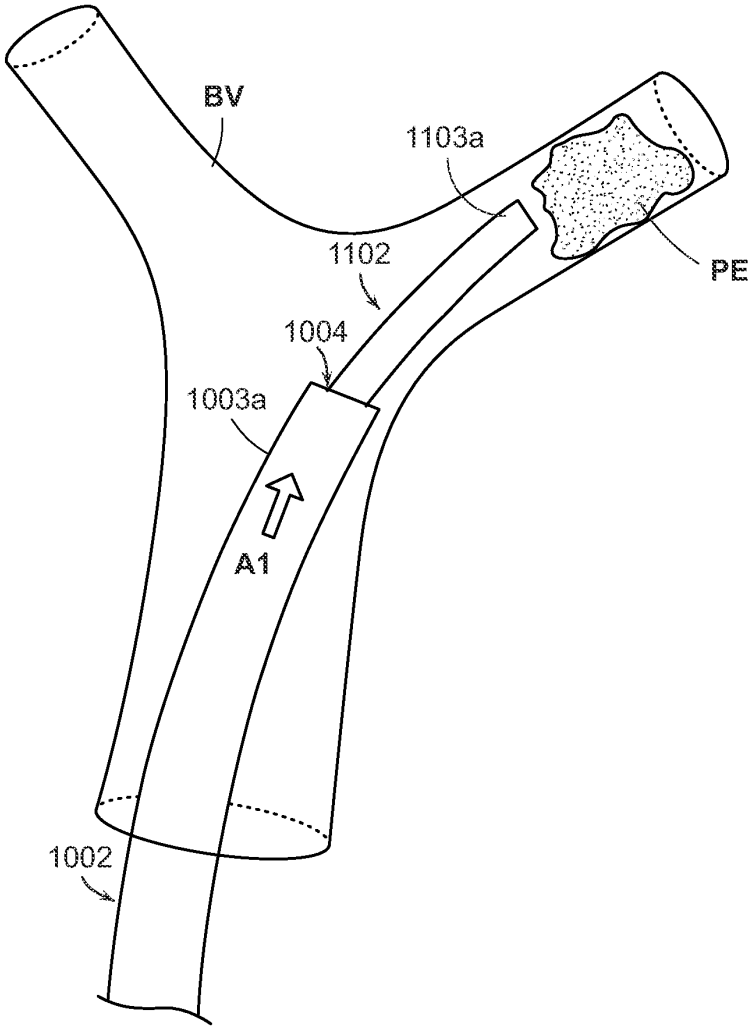


FIG. 13A

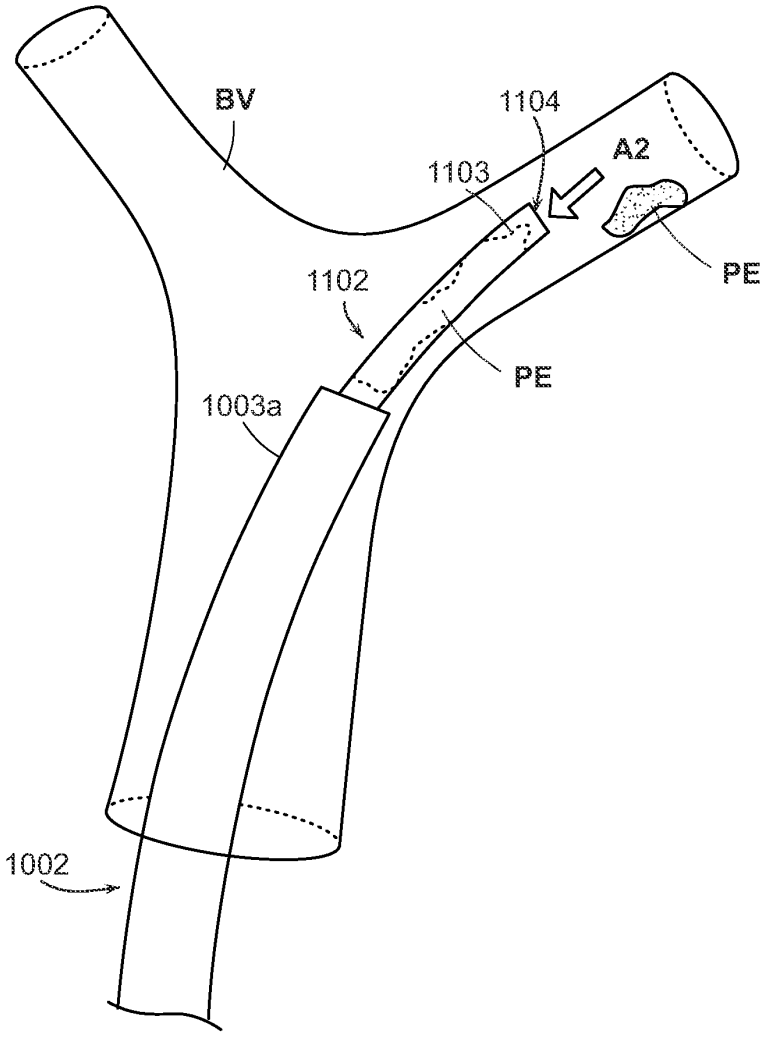


FIG. 13B

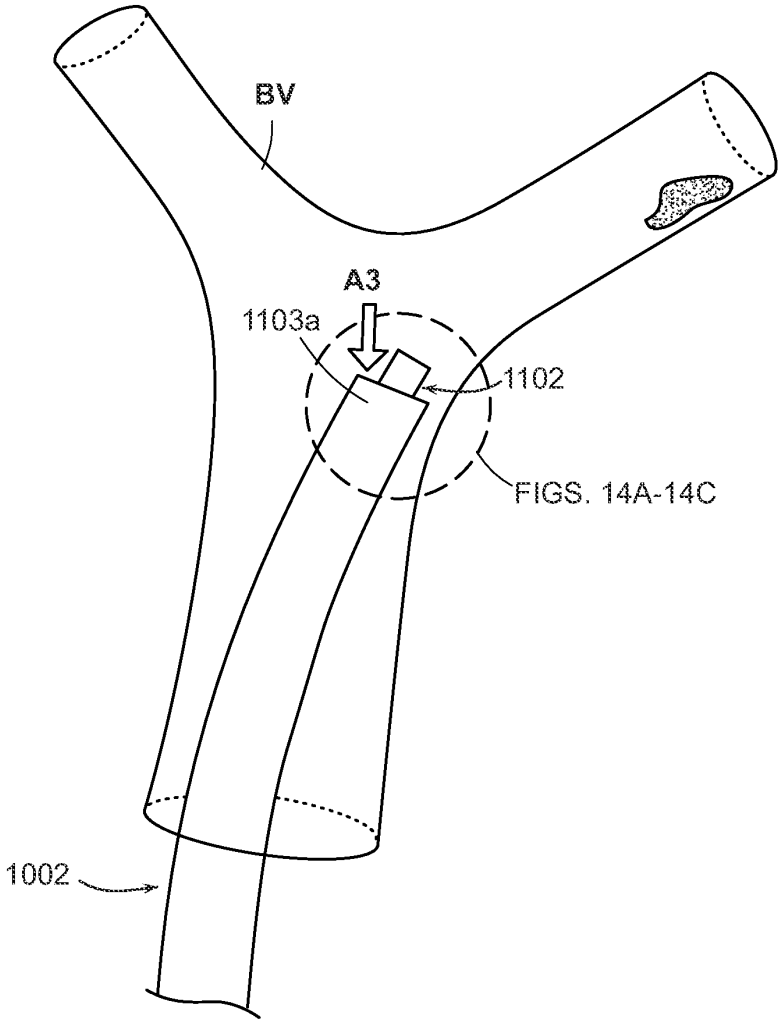


FIG. 13C

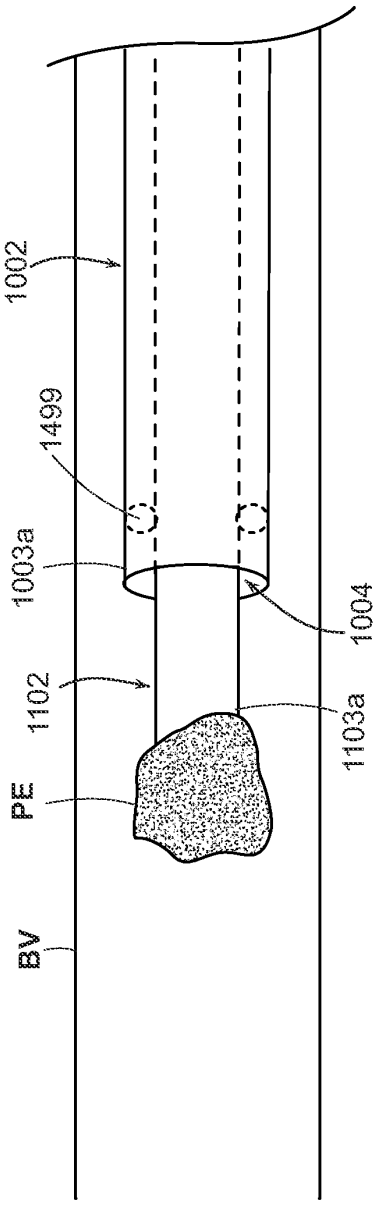


FIG. 14A

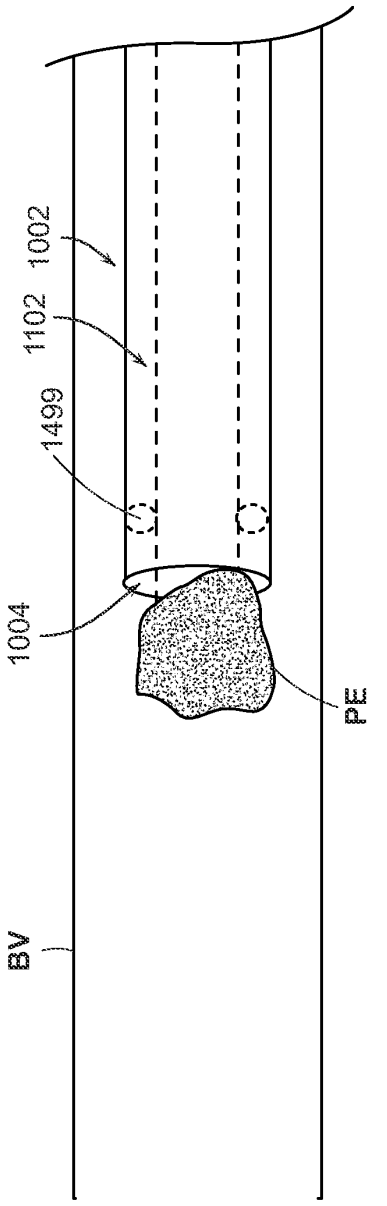


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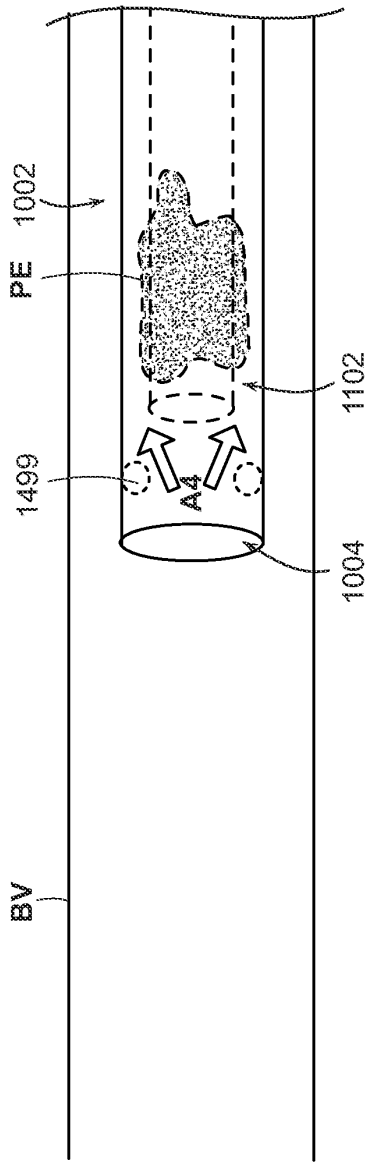


FIG. 14C

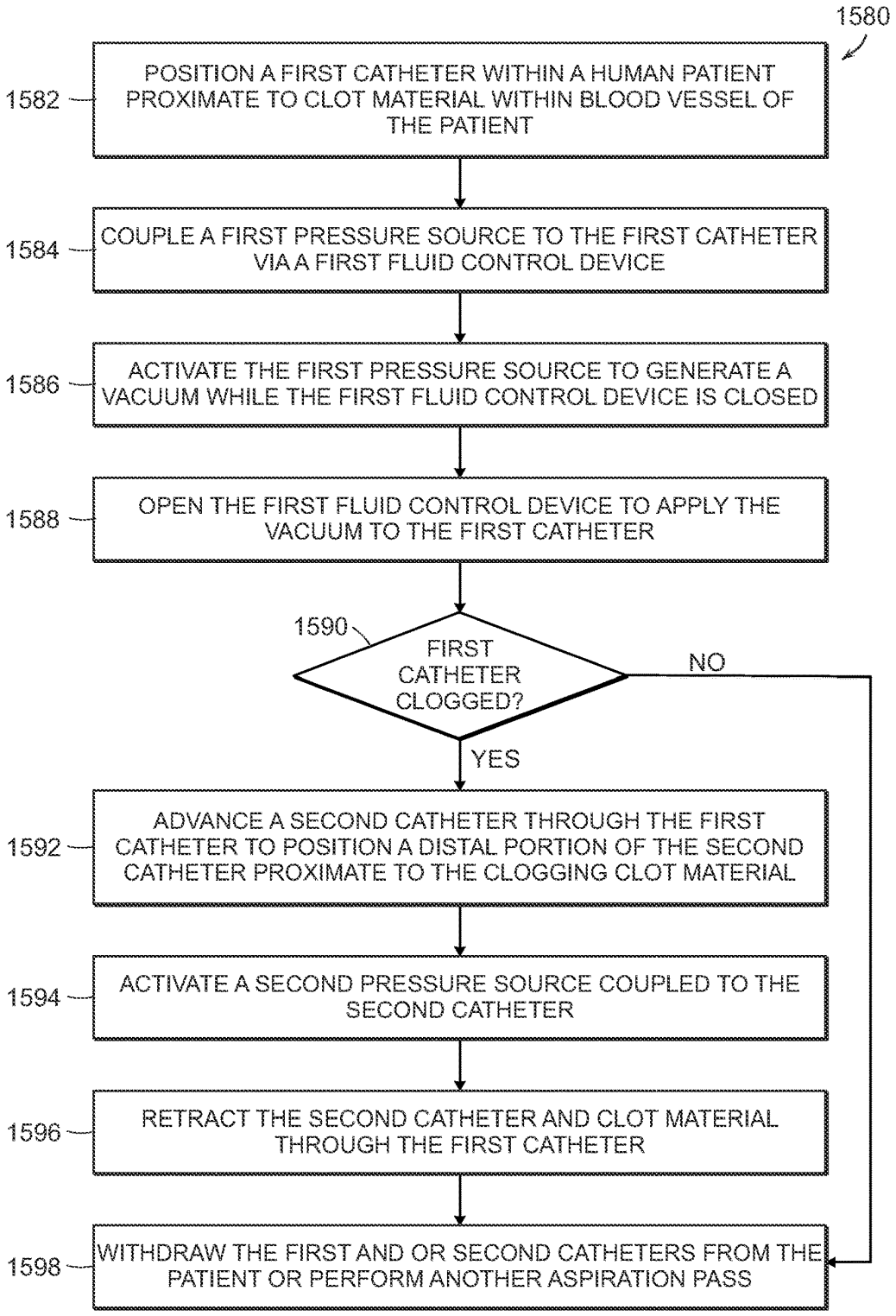

1580
1582
POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT PROXIMATE TO CLOT MATERIAL WITHIN BLOOD VESSEL OF THE PATIENT
1584
COUPLE A FIRST PRESSURE SOURCE TO THE FIRST CATHETER VIA A FIRST FLUID CONTROL DEVICE
1586
ACTIVATE THE FIRST PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FIRST FLUID CONTROL DEVICE IS CLOSED
1588
OPEN THE FIRST FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE FIRST CATHETER
1590
FIRST CATHETER CLOGGED?
NO
YES
1592
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO THE CLOGGING CLOT MATERIAL
1594
ACTIVATE A SECOND PRESSURE SOURCE COUPLED TO THE SECOND CATHETER
1596
RETRACT THE SECOND CATHETER AND CLOT MATERIAL THROUGH THE FIRST CATHETER
1598
WITHDRAW THE FIRST AND OR SECOND CATHETERS FROM THE PATIENT OR PERFORM ANOTHER ASPIRATION PASS

FIG. 15

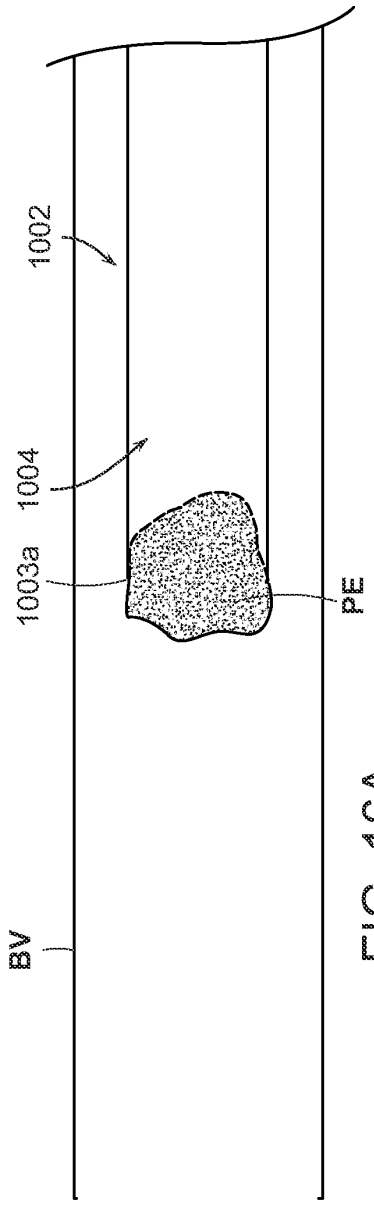


FIG. 16A

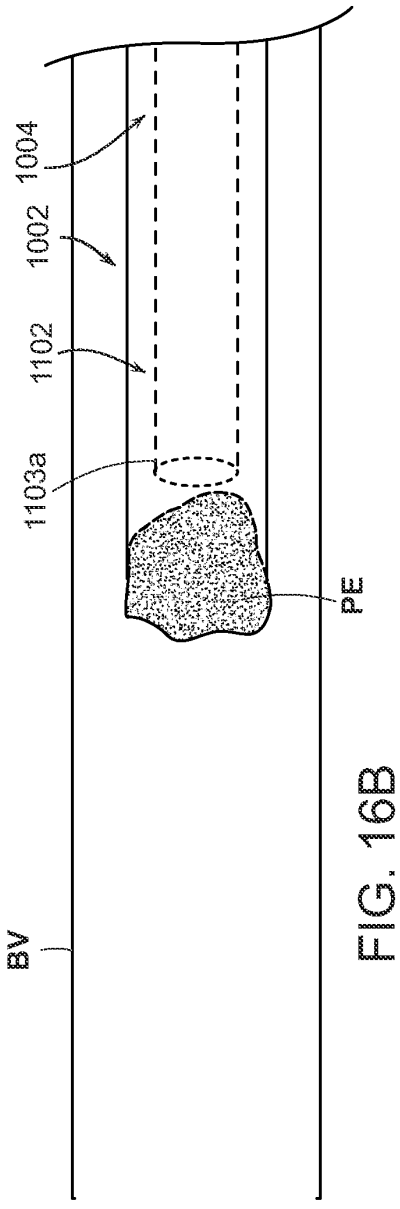


FIG. 16B

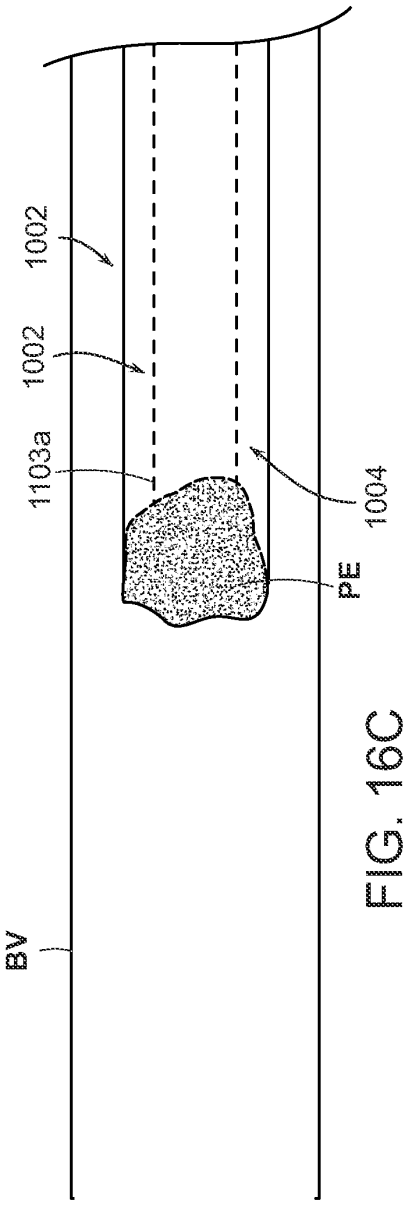


FIG. 16C

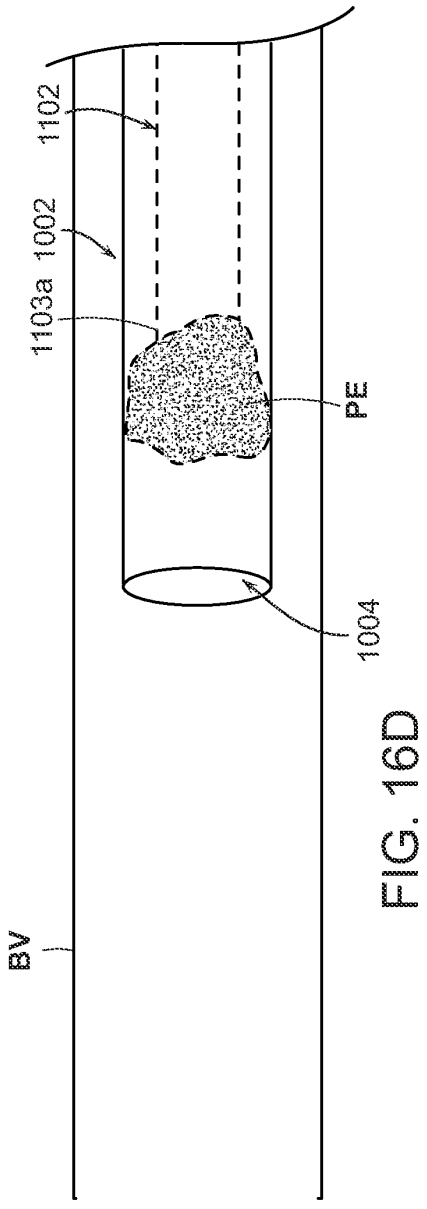


FIG. 16D

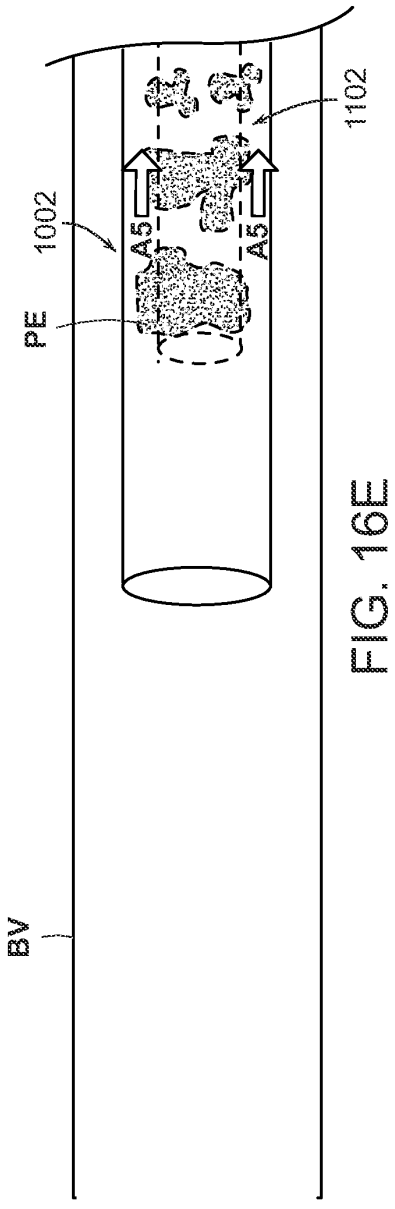


FIG. 16E

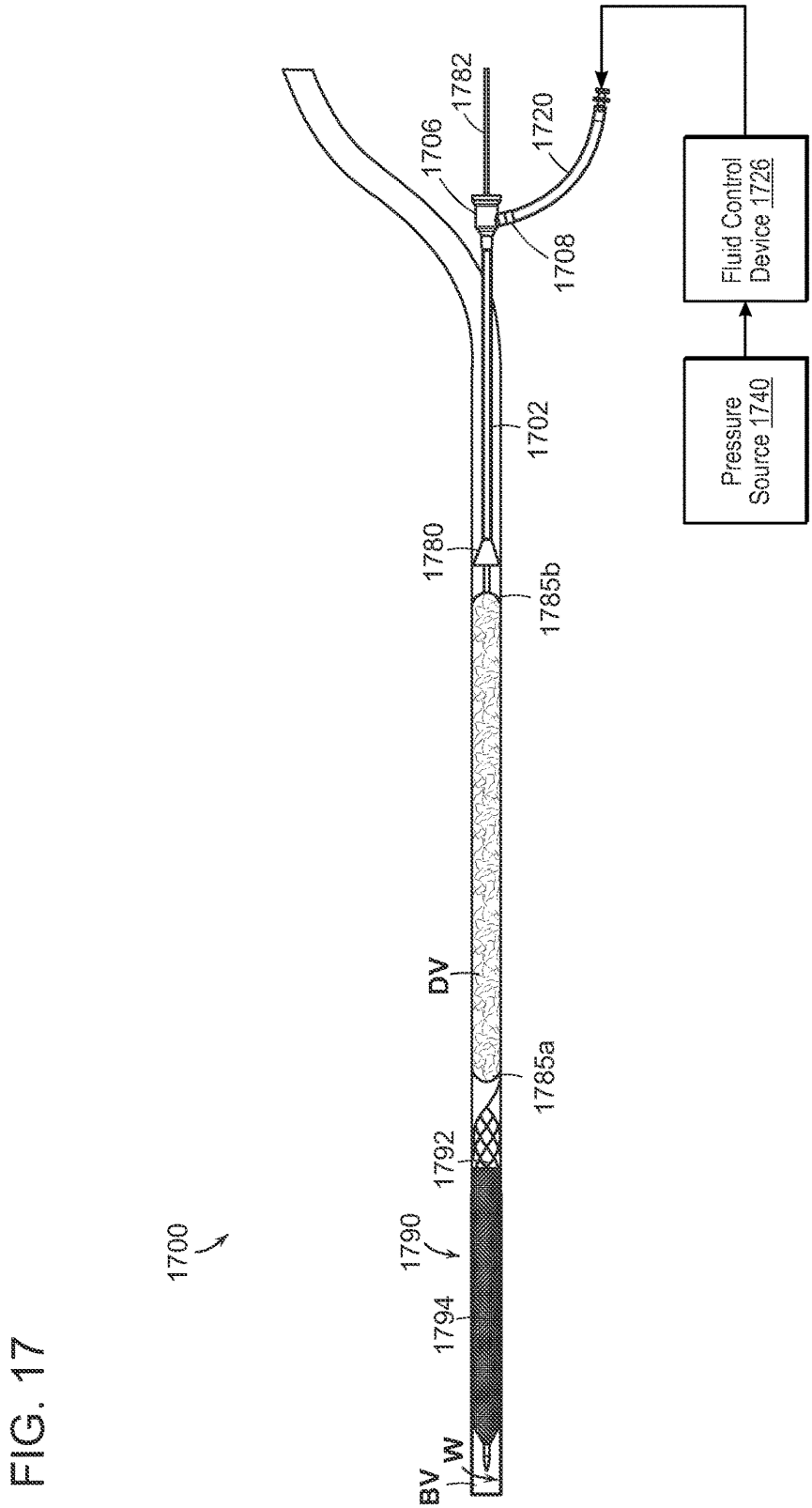

1782
1706
1720
1708
Fluid Control Device 1726
Pressure Source 1740
1702
1780
1785b
DV
1785a
1792
1790
1794
BV
W
1700

FIG. 17

FIG. 18A

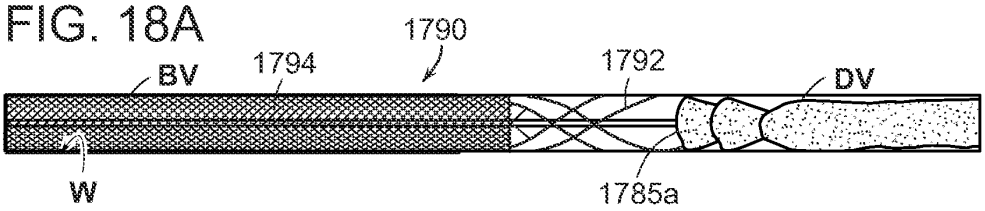


FIG. 18B

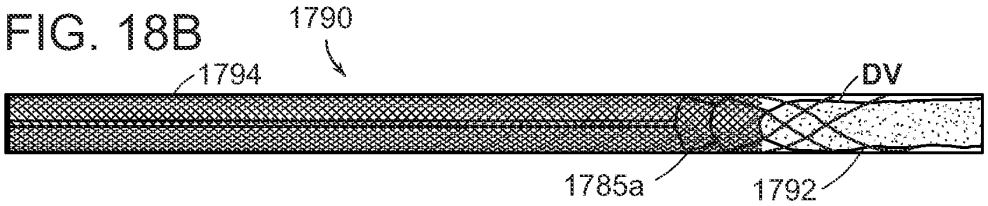


FIG. 18C

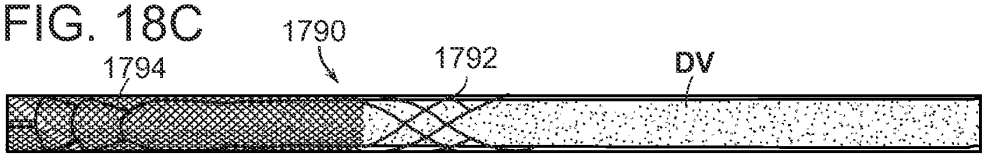


FIG. 18D

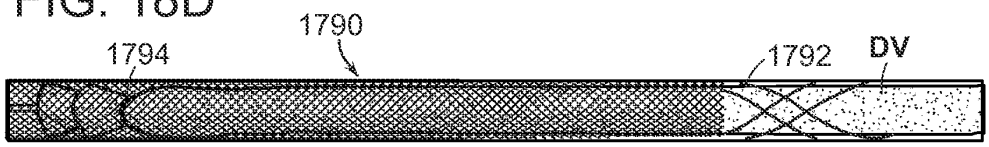


FIG. 18E

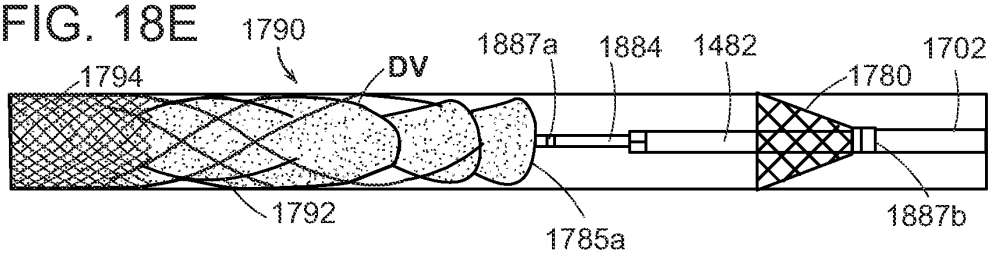


FIG. 18F

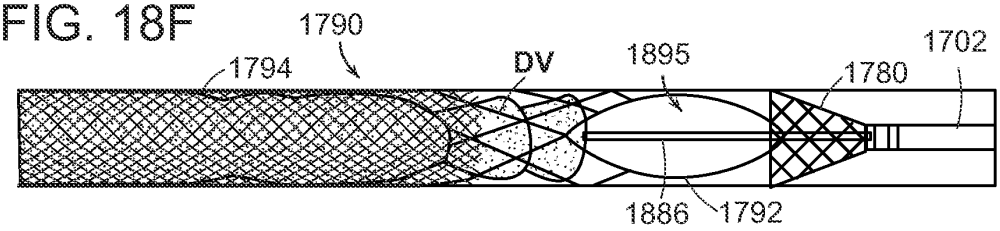


FIG. 18G

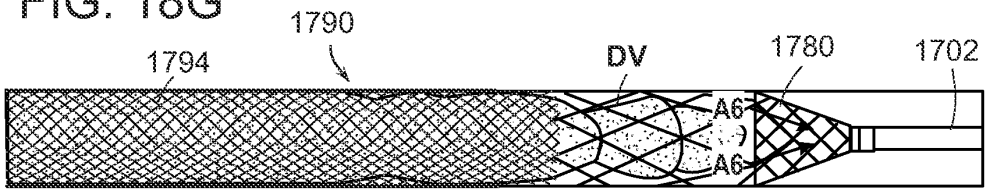
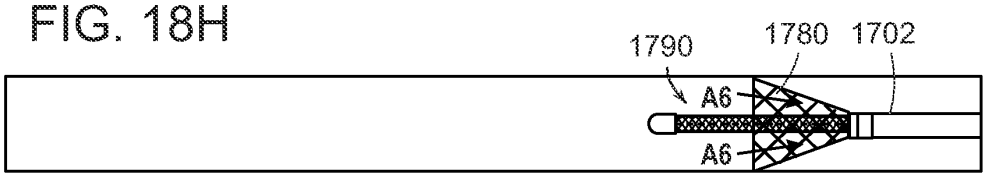


FIG. 18H



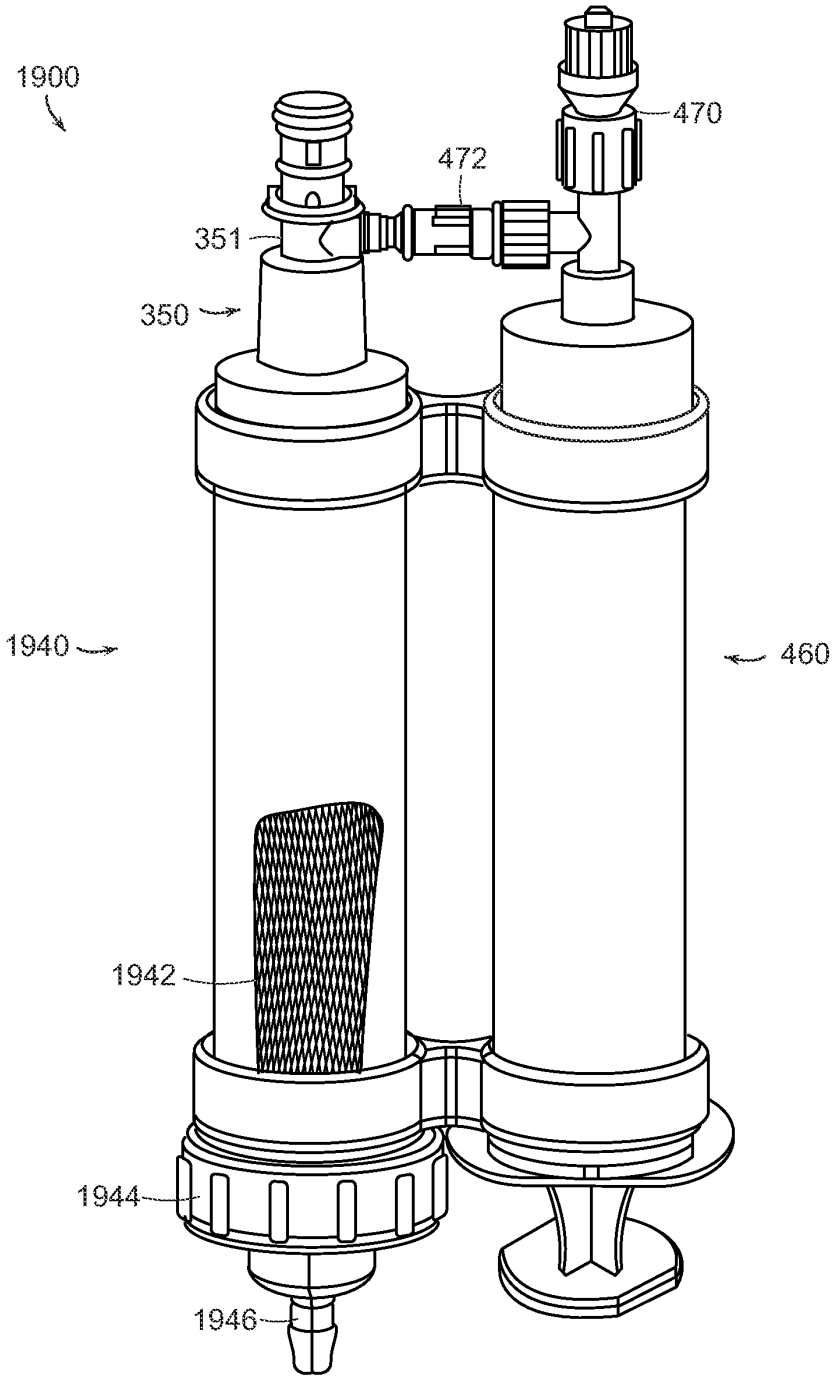


FIG. 19

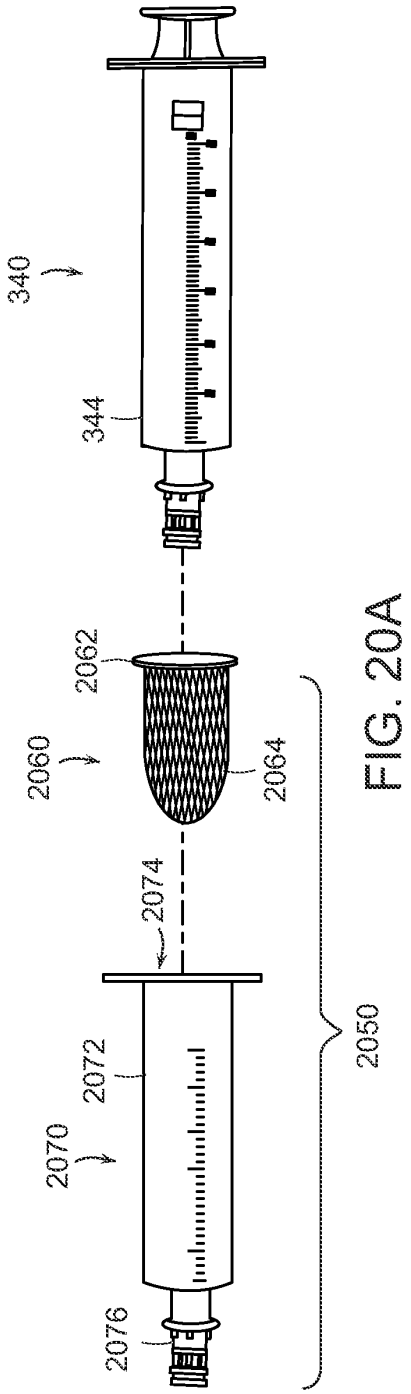


FIG. 20A

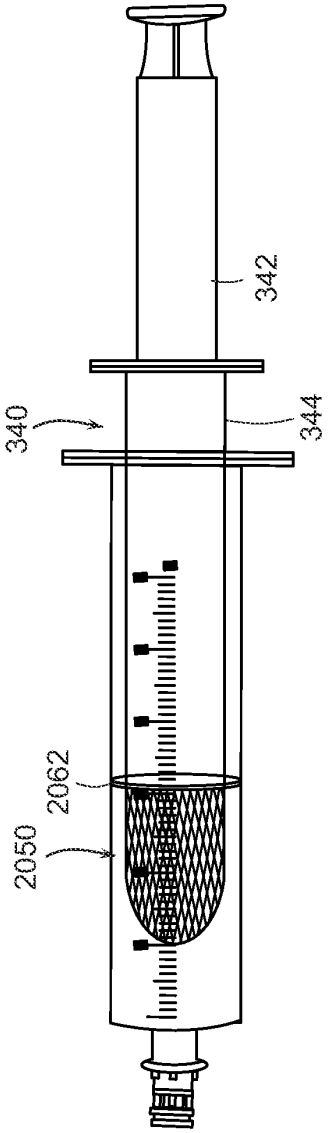


FIG. 20B

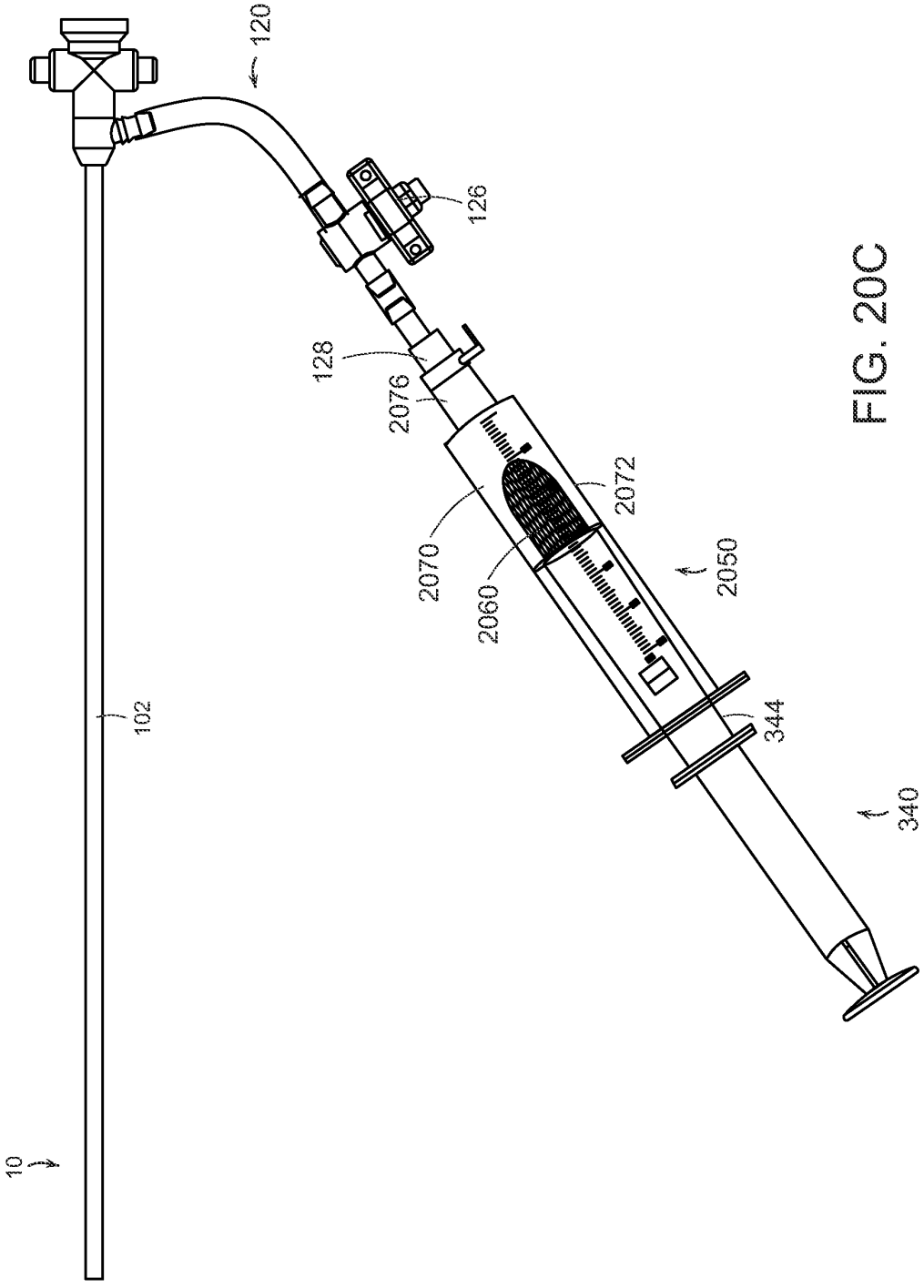


FIG. 20C

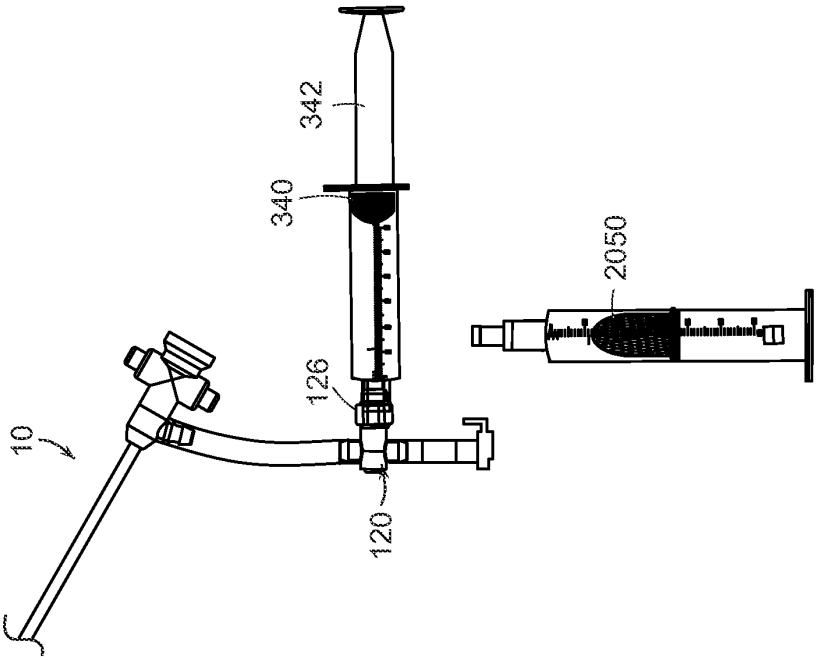


FIG. 20E

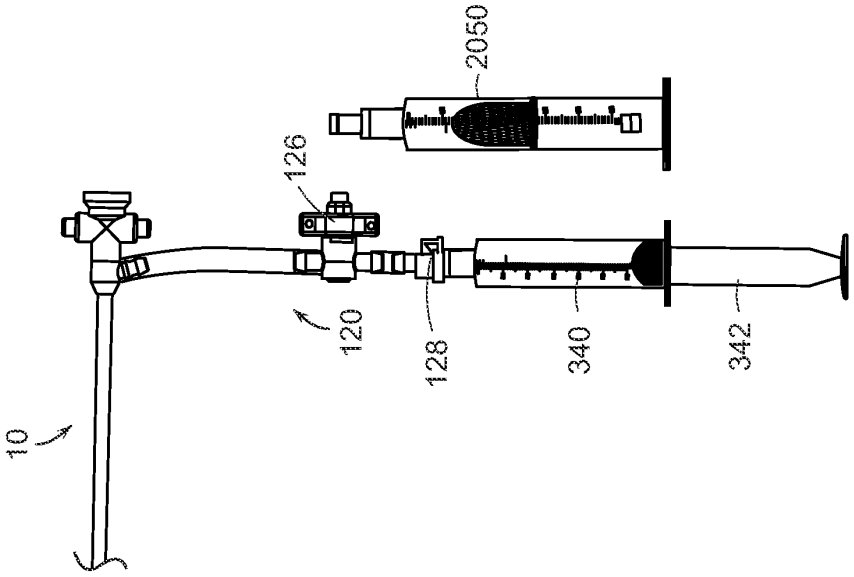


FIG. 20D

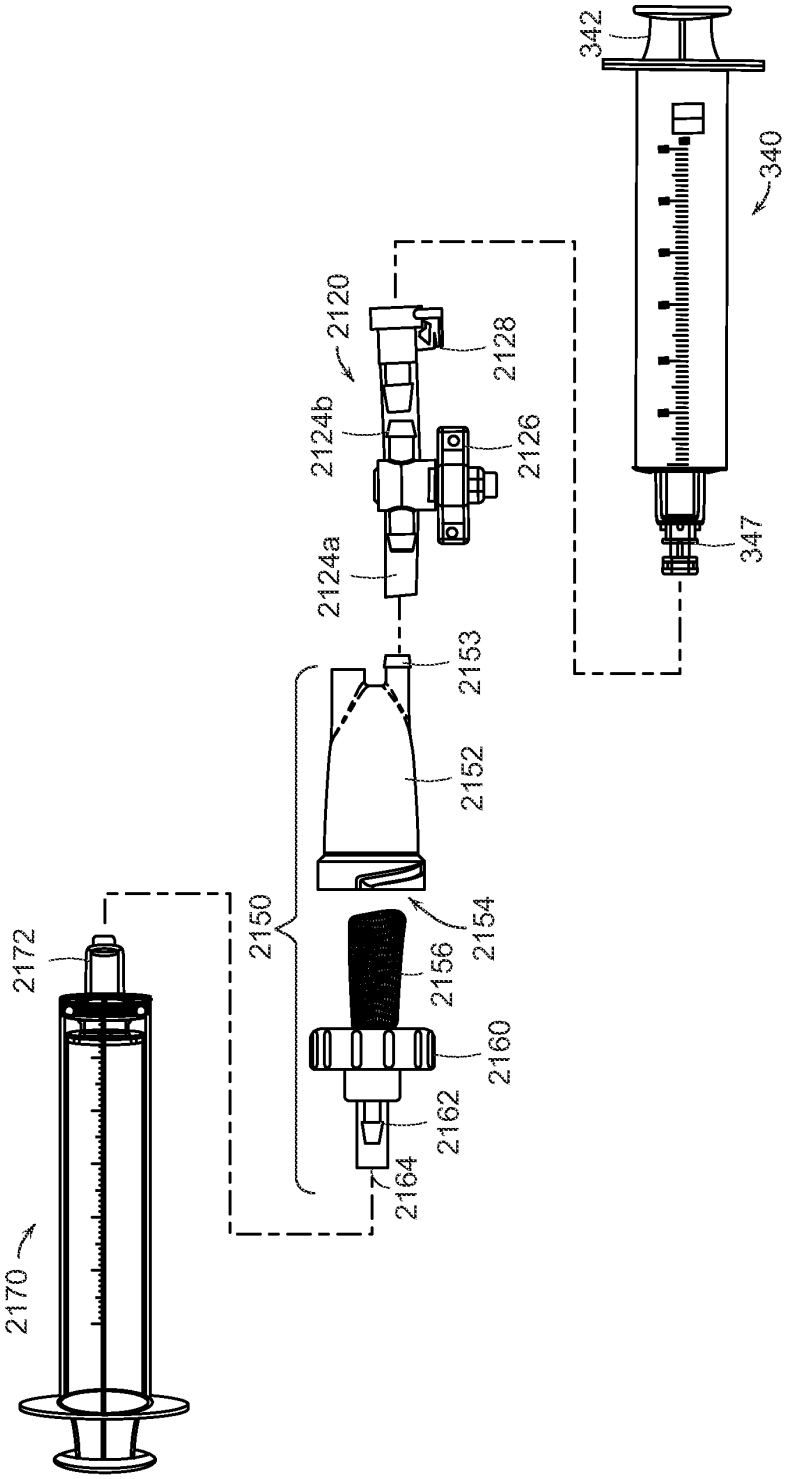

342
340
2120
2128
2124b
2126
347
2124a
2153
2152
2150
2154
2156
2172
2160
2162
2164
2170

FIG. 21A

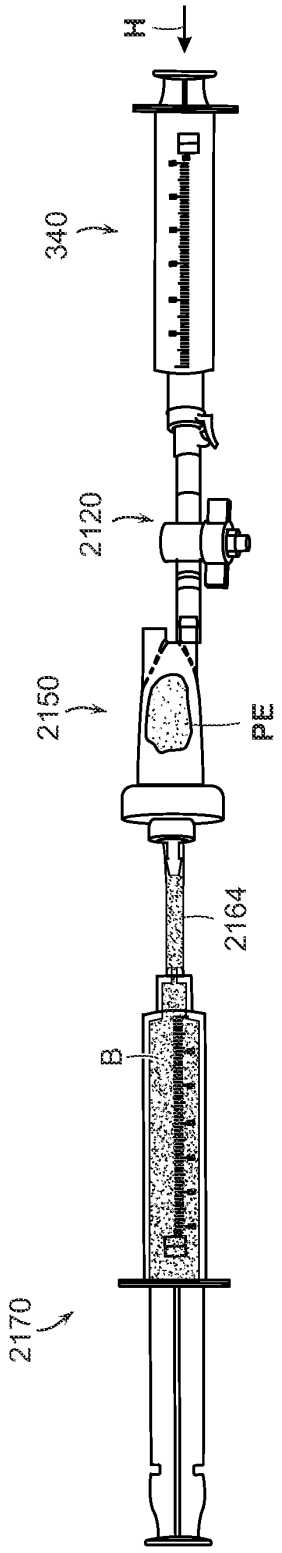


FIG. 21B

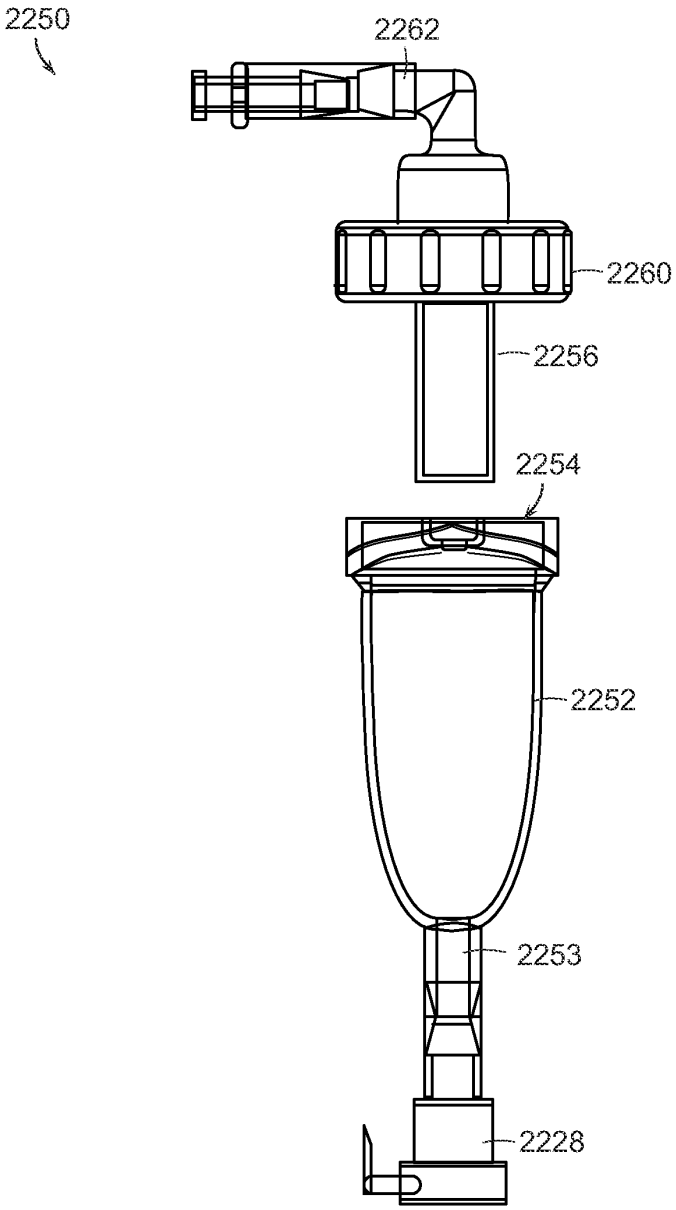


FIG. 22

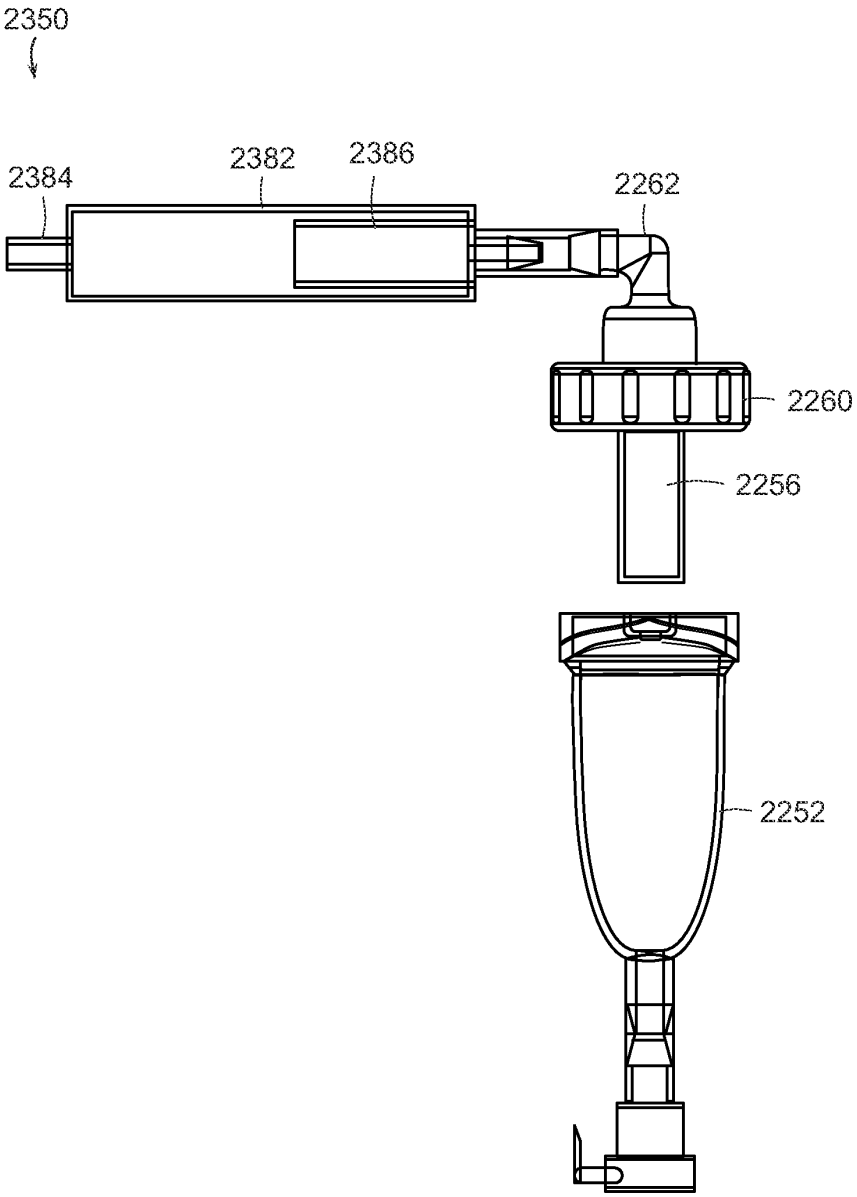


FIG. 23

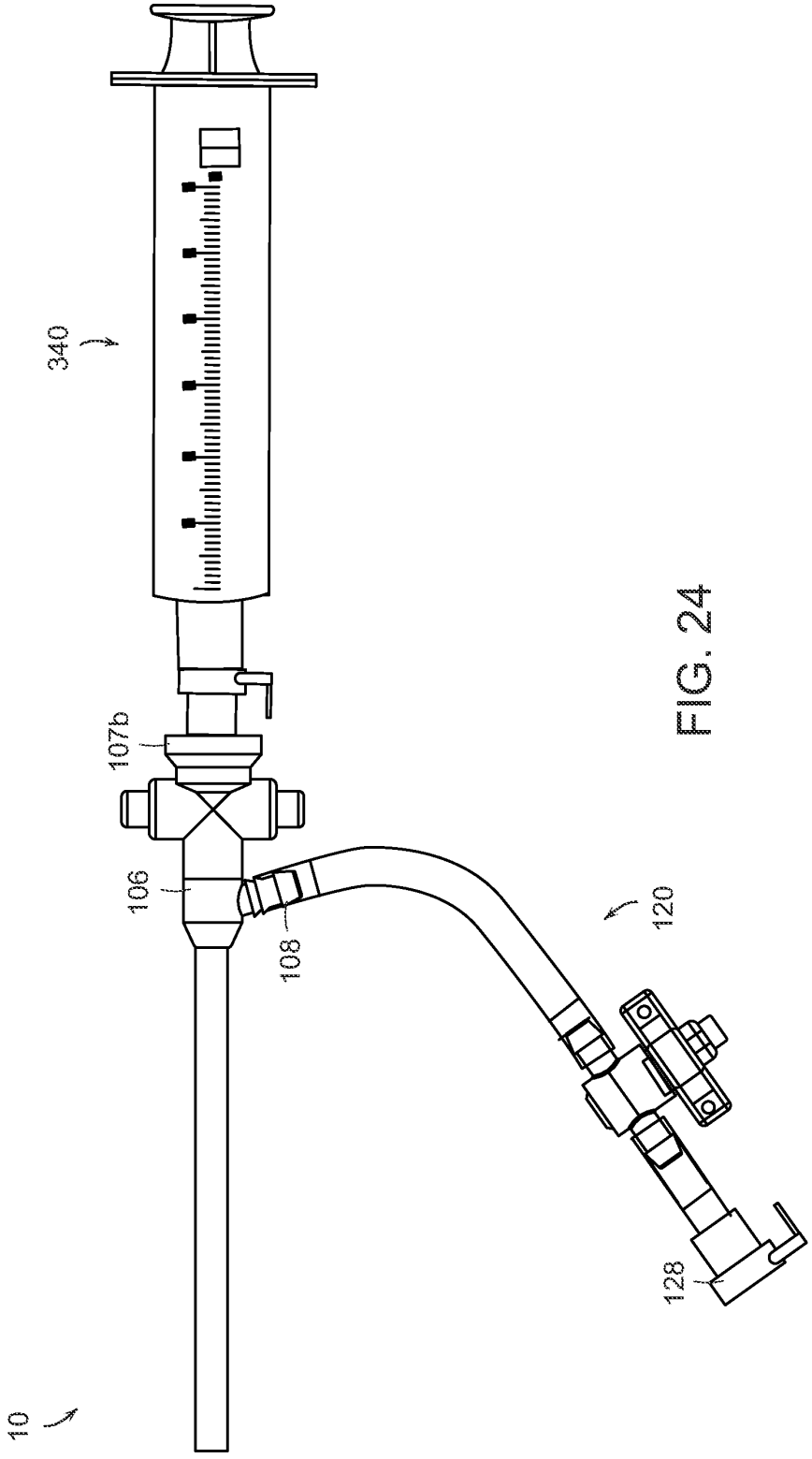


FIG. 24

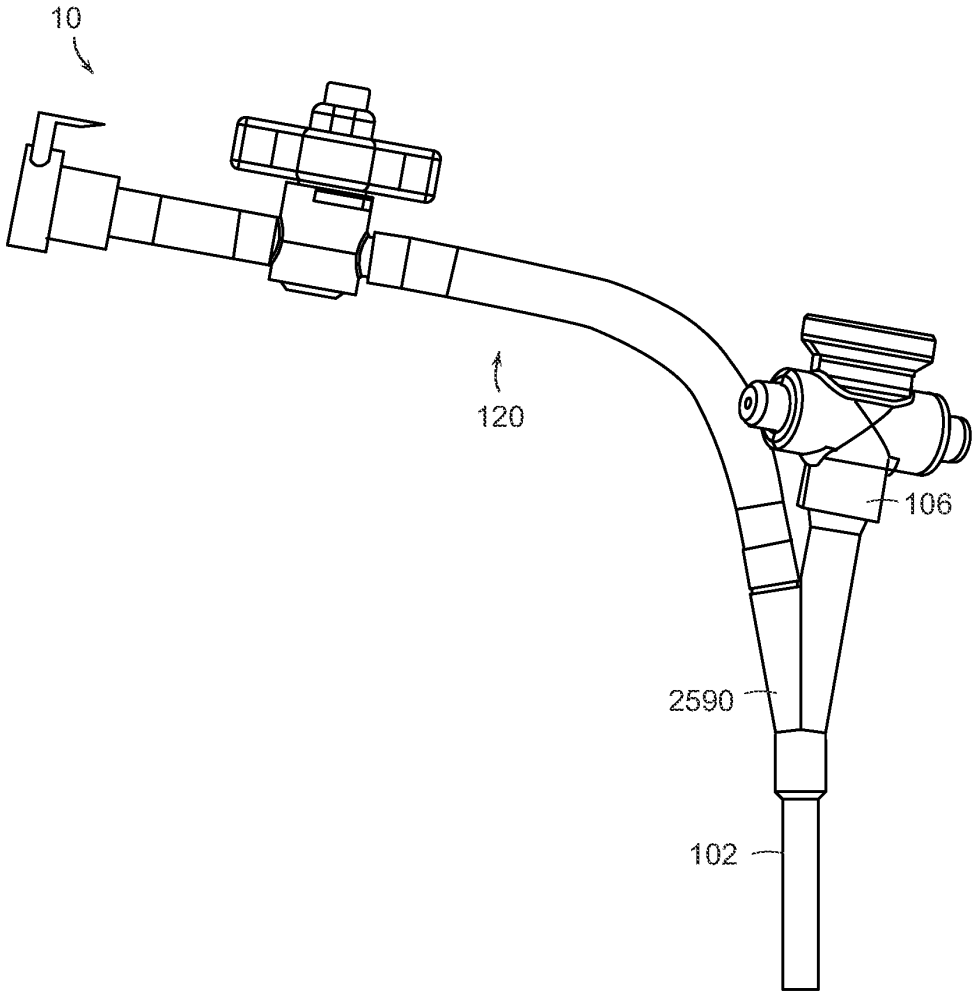


FIG. 25

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/167,757, filed Feb. 10, 2023, which is a continuation of U.S. patent application Ser. No. 17/976,711, filed Oct. 28, 2022, which is a continuation of U.S. patent application Ser. No. 17/865,315, filed Jul. 14, 2022, which is a continuation of U.S. patent application Ser. No. 16/536,185, filed Aug. 8, 2019, and issued as U.S. Pat. No. 11,559,382, which claims the benefit of U.S. Provisional Patent Application No. 62/718,269, filed on Aug. 13, 2018, and U.S. Provisional Patent Application No. 62/718,248, filed on Aug. 13, 2018, each of which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

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

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.

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.

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.

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.

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.

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.

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.

Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

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.

FIG. **1** is a partially schematic side view of a clot removal system configured in accordance with the present technology.

FIG. **2** is a side view of a locking syringe configured in accordance with the present technology.

FIG. **3**A is a side view of a locking syringe configured in accordance with the present technology.

FIG. **3**B is a side view of an adaptor for connecting the locking syringe of FIG. **3**A to the clot removal system of FIG. **1** configured in accordance with the present technology.

FIG. **3**C is a side view of the adaptor of FIG. **3**B coupled to the locking syringe of FIG. **3**A.

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FIG. **3**D is a side view of the locking syringe of FIG. **3**A coupled to the clot removal system of FIG. **1** via the adaptor of FIG. **3**B.

FIG. **4**A is a perspective side view of another pressure source configured in accordance with the present technology, and FIGS. **4**B and **4**C are enlarged schematic side views of the pressure source of FIG. **4**A during operation.

FIG. **5** is a cross-sectional side view of an automatic release syringe configured in accordance with the present technology.

FIG. **6** is a perspective top view of a syringe configured in accordance with the present technology.

FIG. **7** is a side view of an over-wire locking syringe configured in accordance with the present technology.

FIG. **8** is a flow diagram of a process or method for operating a clot removal system in accordance with the present technology.

FIGS. **9**A-**9**C are side views of a proximal portion of the clot removal system of FIG. **1** during a clot removal procedure using the locking syringe of FIG. **3** in accordance with the present technology.

FIGS. **10**A and **10**B are schematic illustrations of a distal portion of the clot removal system of FIG. **1** during a clot removal procedure in accordance with the present technology.

FIG. **11** is a partially schematic side view of another clot removal system configured in accordance with the present technology.

FIG. **12** is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

FIGS. **13**A-**14**C are schematic illustrations of a distal portion of the clot removal system of FIG. **11** during a clot removal procedure in accordance with the present technology.

FIG. **15** is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

FIGS. **16**A-**16**E are schematic illustrations of a distal portion of the clot removal system of FIG. **11** during a clot removal procedure in accordance with the present technology.

FIG. **17** is a partially schematic side view of another clot removal system configured in accordance with the present technology.

FIGS. **18**A-**18**H are side views of a distal portion of the clot removal system shown of FIG. **17** during a clot removal procedure in accordance with the present technology.

FIG. **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.

FIG. **20**A is a partially-exploded side view of a filter device and pressure source configured in accordance with the present technology.

FIG. **20**B is a perspective side view of the syringe of FIG. **20**A coupled to the filter device of the FIG. **20**A.

FIG. **20**C is a side view of the filter device and syringe of FIG. **20**B coupled to the clot removal system of FIG. **1**.

FIGS. **20**D and **20**E are side views of the syringe of FIG. **20**A coupled to the clot removal system of FIG. **1** for reintroducing blood to a patient.

FIG. **21**A is a partially-exploded side view of a filter device, a pressure source, and a reinfusion syringe configured in accordance with the present technology.

FIG. **21**B is a perspective side view of the filter device of FIG. **21**A coupled to the pressure source and the reinfusion syringe of FIG. **21**A.

FIG. **22** is a partially-exploded side view of a filter device configured in accordance with the present technology.

FIG. **23** is a partially-exploded side view of a filter device configured in accordance with the present technology.

FIG. **24** is an enlarged isometric view of the clot removal system of FIG. **1** configured in accordance with the present technology.

FIG. **25** is an enlarged isometric view of the clot removal system of FIG. **1** configured in accordance with the present technology.

DETAILED DESCRIPTION

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.

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.

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 FIGS. **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 FIGS. **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 FIGS. **1-25**.

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.

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

FIG. **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 **103***a* and a proximal portion **103***b*. The catheter subsystem **100** further includes a valve **106** that can be integral with or coupled to the proximal portion **103***b* of the catheter **102**.

In the illustrated embodiment, the valve **106** includes a distal portion **107***a*, a proximal portion **107***b*, and a lumen **109** extending therethrough from the distal portion **107***a* to the proximal portion **107***b*. The valve **106** further includes a flow controller (obscured in FIG. **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 FIGS. **11-16**E), 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 Ser. No. 16/117,519, filed Aug. 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 **107***b* 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. Pat. No. 9,526,864, filed Jun. 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.

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 **124***a* and a second tubing section **124***b*), 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 **124***a* and (ii) the connector **128** via the second tubing section **124***b*. 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 **124***a*, and/or a diameter of the second tubing section **124***b*.

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 **124***a* and/or the tubing section **124***b*. 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 FIG. **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 **103***a* of the catheter **102**.

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.

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 FIGS. **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 **103***a* 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 **103***a* 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

As described in detail above with reference to FIG. **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.

FIG. **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 FIG. **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**.

Referring to both FIGS. **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.

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.

FIG. **3**A 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 FIG. **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 FIG. **3**A (and FIG. **3**C) 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.

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 FIGS. **2** and **3**A 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.

FIG. **3**B 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. FIG. **3**C is a side view of the adaptor **350** coupled to the syringe **340**, and FIG. **3**D 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 FIG. **3**C for the sake of illustration. Referring to FIG. **3**B, the, 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.

Referring to FIGS. **3**A-**3**D 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 snuggly 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**.

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**.

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** (FIG. **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

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
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

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
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

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 **103***a* 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).

Moreover, as shown in FIG. **3**D, 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 **103***a* 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 **103***a* 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).

FIG. **4**A is a side perspective view a pressure source **400** including the syringe **340** ("primary syringe **340**") shown in FIGS. **3**A-**3**D 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.

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**.

FIGS. **4**B and **4**C are enlarged schematic side views of the pressure source **400** during operation. More specifically, FIGS. **4**B and **4**C 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 FIGS. **4**A and **4**B 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** (FIG. **1**), and/or the tubing subsystem **120** (FIG. **1**) into the secondary syringe **460**. This flow path is indicated by the arrows R in FIG. **4**B. Referring to FIGS. **4**A and **4**C 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 FIG. **4**C.

Referring to FIGS. **1** and **3**A-**4**C 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 FIG. **3**D). When the pressure source is coupled to the tubing subsystem **120**, retraction of the plunger **462** of the secondary syringe **460** evacuates an evacuatable 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.

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.

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**.

In some embodiments, (e.g., as described in greater detail below with reference to FIG. **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 FIGS. **4**B and **4**C. 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 FIGS. **4**B and **4**C.

FIG. **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 FIG. **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 FIGS. **2** and **3**A-**3**D. 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 FIGS. **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.

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**.

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.

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**.

FIG. **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 FIGS. **2**-**3**D 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 FIG. **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**.

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**.

Referring again to FIG. **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 **103***a* 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 **107***b* 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, FIG. **24** is an enlarged isometric view of the assembly **10** showing the pressure source **340** coupled directly to the proximal portion **107***b* 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 FIG. **24**, any of the pressure sources described in detail above with reference to FIGS. **2-6** can be configured to be coupled to the proximal portion **107***b* 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, FIG. **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**.

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 **107***b* 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, FIG. **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 FIG. **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 FIG. **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 **107***b* 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**.

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** (FIGS. **4A-4C**) can be coupled via one or more one-way valves to the syringes **240**, **540**, **640** or **740** (FIGS. **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** (FIG. **2**) and the syringe **340** (FIG. **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

FIG. **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. FIGS. **9A-9C** are side views of a proximal portion of the assembly **10**, and FIGS. **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, FIGS. **9A-9C** are side views of the assembly **10** including the syringe **340** and adaptor **350** (FIGS. **3A-3D**), and FIGS. **10A** and **10B** are side views of the catheter **102** with the distal portion **103***a* 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 FIGS. **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 FIGS. **2-7**.

At block **802**, the method **800** includes positioning the distal portion **103***a* 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 FIG. **10A**, a distal terminus of the distal portion **103***a* 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.

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 A**1**) to a position proximate to the clot material PE as illustrated in FIG. **10**A.

In some embodiments, to confirm the position of the distal portion **103***a* 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 **103***a* 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 **103***a* 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 **103***a* of the catheter is not fully engaged with the clot material PE. Accordingly, to locate the distal portion **103***a* of the catheter **102** just proximal of the clot material PE, the operator can (i) first determine that distal portion **103***a* 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 **103***a* 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 **103***a* 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.

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.

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 FIG. **9**A, the tip **347** (shown in FIGS. **3**A and **3**C but obscured in FIG. **9**A) 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 FIG. **9**A.

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 FIG. **9**B, 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** (FIGS. **4**A-**4**C) 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.

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 FIG. **9**C, 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 FIG. **10**B, application of the vacuum causes suction at the distal tip **103***a* of the catheter **102** (e.g., as indicated by arrow A**2**) 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 **103***a* 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. FIG. 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.

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).

Sometimes, as shown in FIG. 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.

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.

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 (FIGS. 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 FIGS. 15-16E, a second clot removal assembly can be telescoped through the first assembly 10 to facilitate removal of the clogged clot material PE.

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. Pat. No. 9,526,864, filed Jun. 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Pat. No. 8,784,434, filed Mar. 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 (FIG. 10B) after a first aspiration pass.

IV. Selected Embodiments of Telescoping Clot Removal Systems and Associated Methods of Clot Removal

FIG. 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 FIGS. 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**.

The first and second catheters **1002**, **1102** each comprise an elongated shaft defining a lumen **1004**, **1104** and having a distal portion **1003***a*, **1103***a*, respectively. The first and second valves **1006**, **1106** each include (i) a distal portion **1007***a*, **1107***a*, (ii) a proximal portion **1007***b*, **1107***b*, (iii) a lumen **1009**, **1109** extending therethrough, and (iv) a flow controller (obscured in FIG. **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**.

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 **1103***a* 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 FIGS. **14**A-**14**C), 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.

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 FIGS. **1**-**10**B. 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 pressures sources **1040**, **1140** can be omitted, or the pressure sources **1040**, **1140** can be fluidly coupled and/or integrally formed.

FIG. **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. FIGS. **13**A-**13**C are schematic illustrations of a distal portion of the assemblies **20**, **30** during a clot removal procedure in accordance with the present technology. FIGS. **14**A-**14**C 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 FIGS. **11** and **13**A-**14**C 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.

At block **1282**, the method **1280** includes intravascularly positioning the first catheter **1002** within a human patient. FIG. **13**A, for example, illustrates the first catheter **1002** after it has been advanced (e.g., as indicated by arrow A**1**) 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 **1003***a* 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 **1003***a* 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 FIG. **8**.

At block **1284**, the method **1280** includes advancing the second catheter **1102** through the first catheter **1002** until the distal portion **1103***a* 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 **1103***a* of the second catheter **1102** through the first valve **1006** before advancing the second catheter **1102** (e.g., as indicated by the arrow A**1**) 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 **1103***a* 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.

FIG. **13**A 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 FIG. **13**A, 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.

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 FIGS. **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**).

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**.

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 FIG. **13**B, application of the vacuum causes suction (e.g., as indicated by arrow A**2**) 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 **1103***a* 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 **1103***a* of the second catheter **1102** compared to simply activating the second pressure source **1140** while it is fluidly connected to the second catheter **1102**.

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 **1003***a* 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 **1003***a* 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.

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 Ser. No. 16/258,344, filed Jan. 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.

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 FIG. **13**C, 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 A**3**) at the distal portion **1003***a* 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.

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 **1103***a* of the second catheter **1102**. FIG. **14**A, for example, is an enlarged view of the distal portion of the assemblies **20**, **30** shown in FIG. **13**C and illustrating a portion of the clot material PE stuck to or dangling from the distal portion **1103***a* 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**).

FIGS. **14**B and **14**C 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 FIG. **14**C, 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 A**4**). 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**.

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.

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 **1103***a* 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**).

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.

FIG. **15** is a flow diagram of another process or method **1580** for operating a clot removal system including the assemblies **20**, **30** (FIG. **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. FIG. **16**A is an enlarged side view of a distal portion of the first assembly **20**, and FIGS. **16**B-**16**E 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 FIGS. **11** and **16**A-**16**E 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.

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 FIGS. **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 FIGS. **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 **1003***a* of the first catheter **1002**.

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**). FIG. **16**A, 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 **1003***a* 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 FIG. **8**).

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 **1103***a* of the second catheter **1102** is positioned in or proximate to the clogging clot material PE. For example, FIG. **16**B 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 **1103***a* of the second catheter **1102** through the first valve **1006** (FIG. **11**) before advancing the second catheter **1102** through the lumen **1004** of the first catheter **1002**.

At block **1594**, the method **1580** includes activating the second pressure source **1140** (FIG. **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 FIGS. **2-7**) can be coupled to the second catheter **1102** via the second fluid control device **1126** (FIG. **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.

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**. FIG. **16**C, for example, illustrates a portion of the clot material PE stuck to or extending from the distal portion **1103***a* of the second catheter **1102** after aspirating the second catheter **1102**. In the embodiment illustrated in FIG. **16**C, 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**.

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, FIG. **16**D 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**. FIG. **16**E, 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 A**5**).

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**.

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

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.

FIG. **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 FIG. **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.

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 FIG. **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 FIGS. **18**E and **18**F, 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 Apr. 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

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, FIG. **17** shows the system **1700** after (i) advancing the sheath **1702** to a position proximate to a proximal portion **1785***b* 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 **1785***a* of the clot material DV), and (iv) expanding the interventional device **1790** from the compressed delivery state to the deployed state.

FIGS. **18**A-**18**H are enlarged views of a distal portion of the system **1700** during a clot removal procedure in accordance with the present technology. In general, FIGS. **18**A-**18**H 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**.

Referring first to FIG. **18**A, proximal retraction of the interventional device **1790** causes the coring element **1792** to separate and/or core the distal end portion **1785***a* of the clot material DV from the walls W of the blood vessel BV. As shown in FIG. **18**B, continued proximal retraction of the interventional device **1790** through the clot material DV causes the cylindrical element **1794** to capture the distal end portion **1785***a* of the clot material therein. FIGS. **18**C-**18**E 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 FIG. **18**E, the proximal end portion **1785***b* 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 FIG. **18**E, a first radiopaque marker **1887***a* can be positioned on a distal end portion of the inner shaft **1884** and a second radiopaque marker **1887***b* can be positioned on a distal end portion of the sheath **1702**.

In some embodiments, as shown in FIG. **18**F, 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** (FIG. **18**E). 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 **1885***a*) relative to the distal end portion of the sheath **1702** (e.g., the second radiopaque marker **1885***b*). 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**.

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 FIG. **18**G. As shown in FIG. **18**H, 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** (FIG. **17**), and from the patient's body.

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 FIG. **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 FIGS. **18**G and **18**H, application of the vacuum can generate instantaneous or nearly instantaneous suction (e.g., as indicated by arrows A**6**) 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

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. FIGS. **19**-**20**E 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.

For example, FIG. **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 FIGS. **4**A-**4**C. 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** (FIGS. **4**A-**4**C). 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** (FIG. **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**).

In the illustrated embodiment, the canister **1940** further includes a filter **1942**. The canister **1940** is shown as transparent in FIG. **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**.

FIGS. **20**A-**20**E 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 FIGS. **2**-**7**. For example, FIG. **20**A is a partially-exploded side view of the filter device **2050** and the pressure source **340** (FIGS. **3**A-**3**D). 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 FIG. **20**C). 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.

FIG. **20**B 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 FIG. **20**B (and FIGS. **20**C-**20**E) 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.

FIG. **20**C 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 FIG. **20**C, 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.

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, FIGS. **20**D and **20**E 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 FIG. **20**D, 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 FIG. **20**E, 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 FIGS. **20**A-**20**E 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**).

FIGS. **21**A and **21**B 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 FIGS. **2**-**7**. For example, FIG. **21**A is a partially-exploded side view of the filter device **2150** and the pressure source **340** (FIGS. **3**A-**3**D). 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.

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 **2124***a* and a second tubing section **2124***b*), 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**.

In operation, during a clot removal procedure, the pressure source **340** can be decoupled from the connector **128** (FIG. **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, FIG. **21**B 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 FIGS. **21**A and **21**B 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** (FIG. **1**), an IV line (not shown), or another suitable connection point for reintroducing blood to the patient,

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 FIG. **21**B, 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.

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** (FIG. **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.

FIG. **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 FIGS. **2**-**7**. In general, the filter device **2250** is generally similar to the filter device **2150** described in detail with reference to FIGS. **21**A and **21**B. 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 FIGS. **3**A-**3**D). 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 FIG. **22**. In one aspect of the present technology, this arrangement makes the filter device more ergonomic during use.

FIG. **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 FIGS. **2**-**7**. The filter device **2350** is generally identical to the filter device **2250** described in detail with reference to FIG. **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.

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 FIGS. **2** and **4-7**). In some embodiments, the filter devices can be formed as a component of the tubing subsystem **120** (FIG. **1**). Moreover, the filter devices can include any number of filters and/or housings to provide any number of filtration stages.

CONCLUSION

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.

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.

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.

We claim:

1. A clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient, comprising:

a first clot aspiration assembly, including:

a first catheter;

a first pressure source; and

a first fluid control device between the first catheter and the first pressure source, wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter,

wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the first position, and

wherein, upon movement of the first fluid control device from the first position to the second position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter; and

a second clot aspiration assembly, including:

a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism;

a second pressure source; and

a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter,

wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and

wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

2. The clot system of claim **1** wherein the first catheter has a first length, and wherein the second catheter has a second length longer than the first length.

3. The clot treatment system of claim **1** wherein the first catheter has a size of 24 French, and wherein the size of the the second catheter has is 16 French.

4. The clot treatment system of claim **1** wherein the first pressure source is the same as the second pressure source.

5. The clot treatment system of claim **1** wherein the first pressure source and the second pressure source comprise an electric pump.

6. The clot treatment system of claim **1** wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.

7. The clot treatment system of claim **6** wherein the hemostasis valve comprises:

a tubular member defining a lumen configured to slidably receive the second catheter; and

a filament extending at least partially around the tubular member, wherein the filament is moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal around the second catheter and (b) a second position wherein the filament is moved to at least partially open the lumen.

8. The clot treatment system of claim **1** wherein the first fluid control device is user actuatable to move between the first position and the second positions of the first fluid control device, and wherein the second fluid control device is user actuatable to move between the first positoin and the second position of the second fluid control device.

9. The clot treatment system of claim **1** wherein the first pressure source is a first syringe, and wherein the second pressure source is a second syringe.

10. The clot treatment system of claim 1 wherein the first pressure source is a first vacuum-pressure locking syringe, and wherein the second pressure source is a second vacuum-pressure locking syringe.

11. A clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient, comprising:

a first clot aspiration assembly, including:

a first catheter; and

a first pressure source configured to be fluidly coupled to the first catheter and to generate suction at a distal portion of the first catheter; and

a second clot aspiration assembly, including:

a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism;

a second pressure source; and

a fluid control device between the second catheter and the second pressure source, wherein the fluid control device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter,

wherein the second pressure source is configured to generate vacuum pressure while the fluid control device is in the first position, and

wherein, upon movement of the fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

12. The clot treatment system of claim 11 wherein the first catheter has a size of 24 French, and wherein the size of the the second catheter is 16 French.

13. The clot treatment system of claim 11 wherein the first pressure source is the same as the second pressure source.

14. The clot treatment system of claim 11 wherein the first pressure source and the second pressure source comprise an electric pump.

15. The clot treatment system of claim 11 wherein the first clot aspiration assembly further includes a hemostasis valve configured to receive the second catheter.

16. The clot treatment system of claim 15 wherein the hemostasis valve is fluidly coupled to a proximal end portion of the first catheter, and wherein the first pressure source is fluidly coupled to the first catheter via a tube branching from the first catheter distal to the proximal end portion of the first catheter.

17. The clot treatment system of claim 16 wherein the hemostasis valve is a first hemostasis valve, wherein the tube is a first tube, and wherein the second clot aspiration assembly further includes a second hemostasis valve fluidly coupled to a proximal end portion of the second catheter, and wherein the second pressure source is fluidly coupled to the second catheter via a second tube branching from the second catheter distal to the proximal end portion of the second catheter.

18. The clot treatment system of claim 11 wherein the first catheter has a size of 24 French, wherein the size of the second catheter is 16 French, and wherein the first pressure source and the second pressure source comprise an electric pump.

19. The clot treatment systme of claim 15 wherein the first pressure source is the same as the second pressure source.

20. The clot treatment systme of claim 7 wherein the first pressure source is the same as the second pressure source.

* * * * *

EXHIBIT C

US011969333B2

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Merritt et al.

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(54) **SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS**

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(58) **Field of Classification Search**
CPC ... A61F 2/01; A61B 17/12109; A61B 17/221; A61B 2017/22034; A61B 2017/22079;
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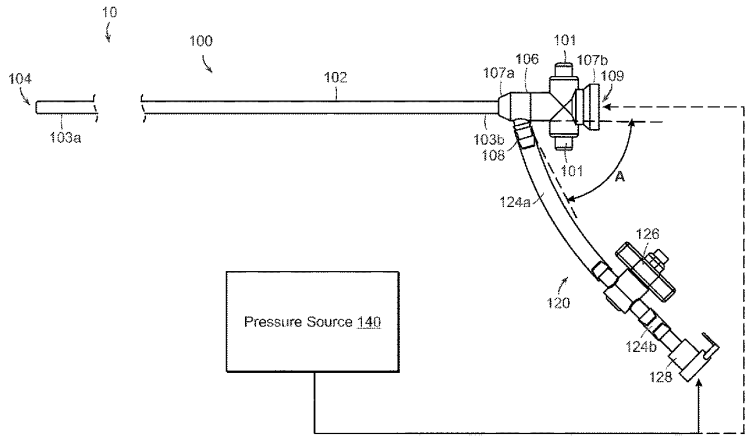
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(57) **ABSTRACT**

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.

38 Claims, 38 Drawing Sheets



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Related U.S. Application Data

No. 17/976,711, filed on Oct. 28, 2022, which is a continuation of application No. 17/865,315, filed on Jul. 14, 2022, now Pat. No. 11,642,209, which is a continuation of application No. 16/536,185, filed on Aug. 8, 2019, now Pat. No. 11,559,382.

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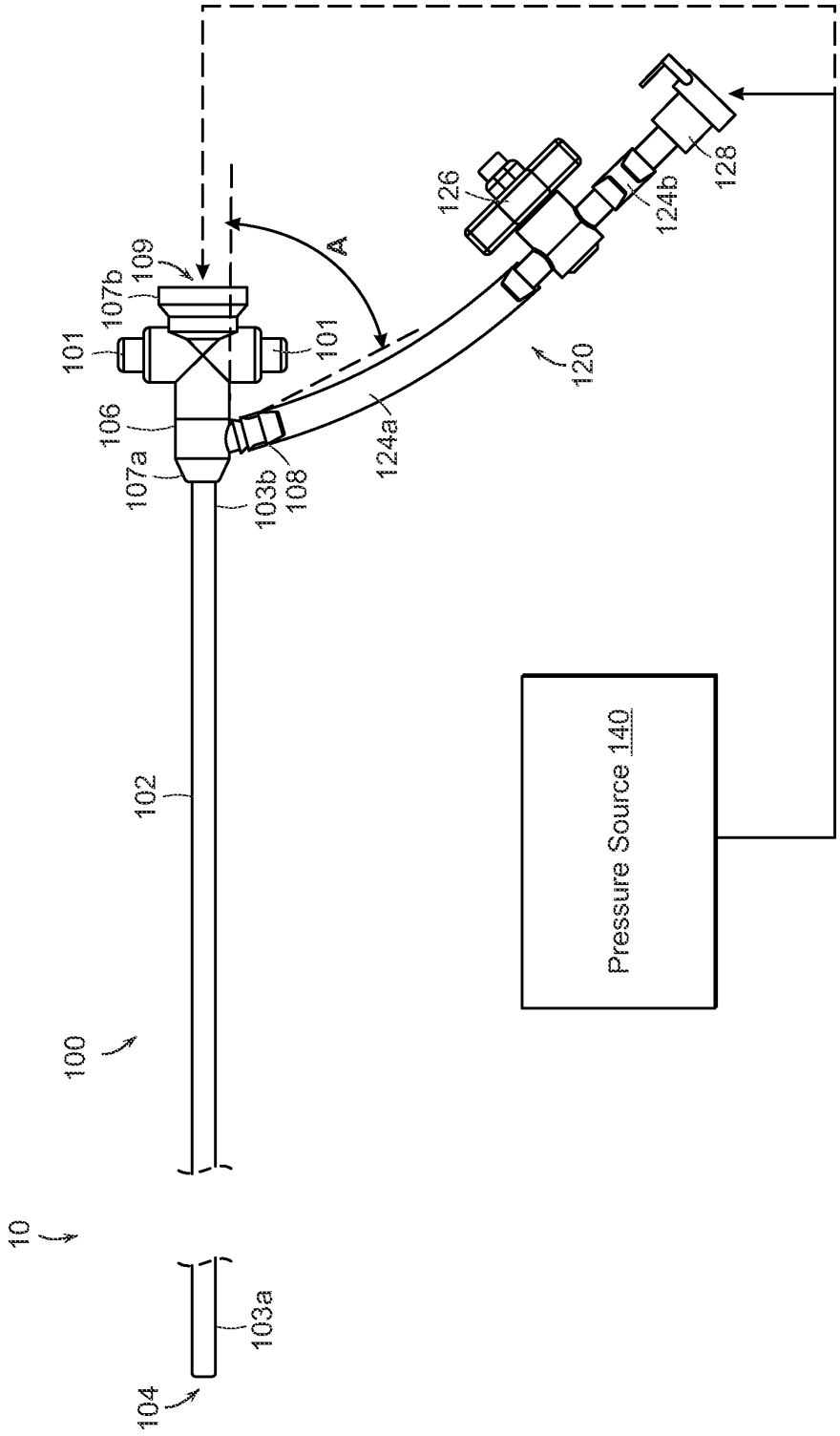

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124b
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103a
104

FIG. 1

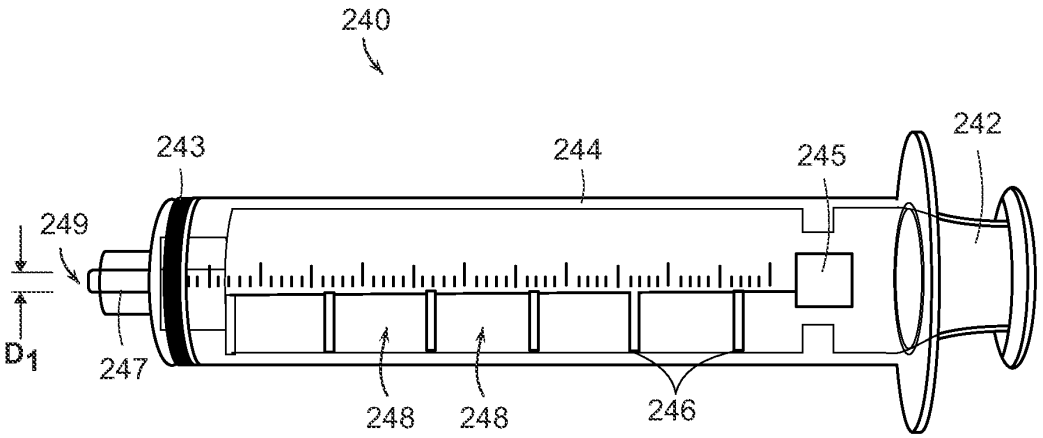

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FIG. 2

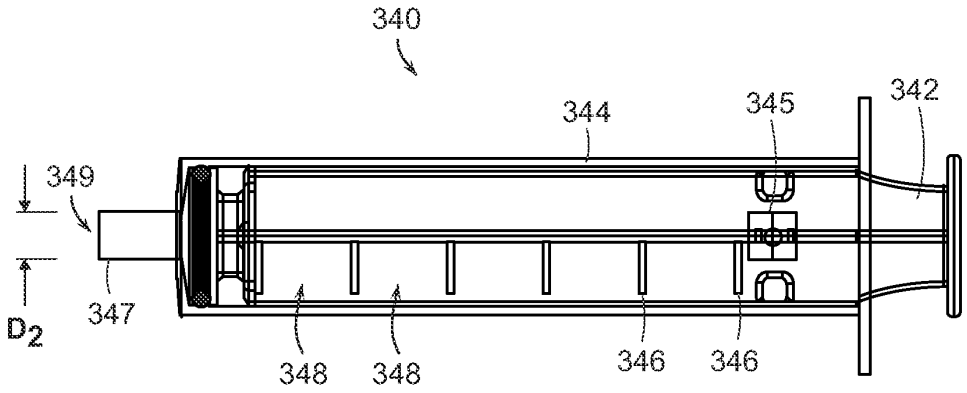

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FIG. 3A

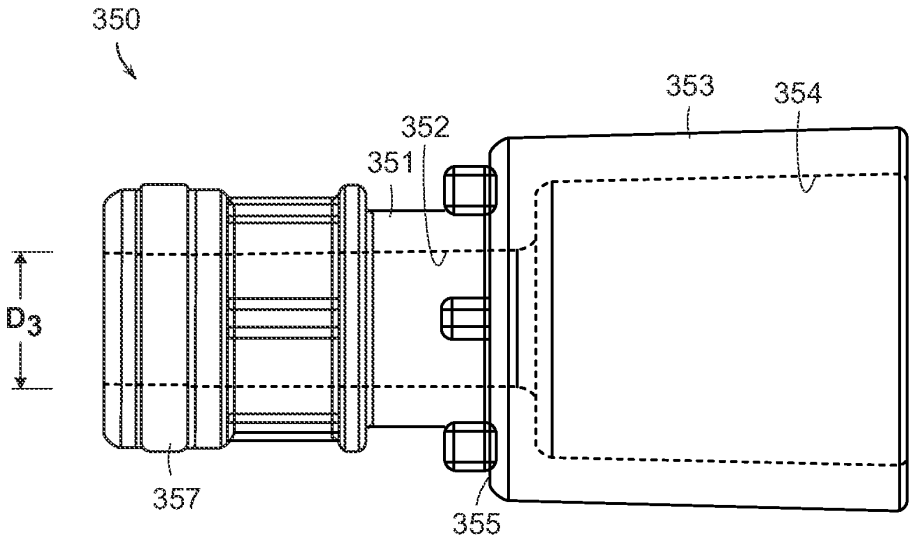


FIG. 3B

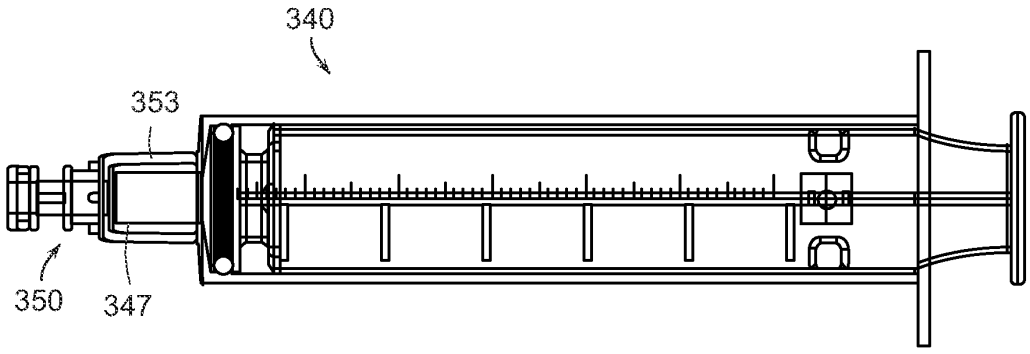


FIG. 3C

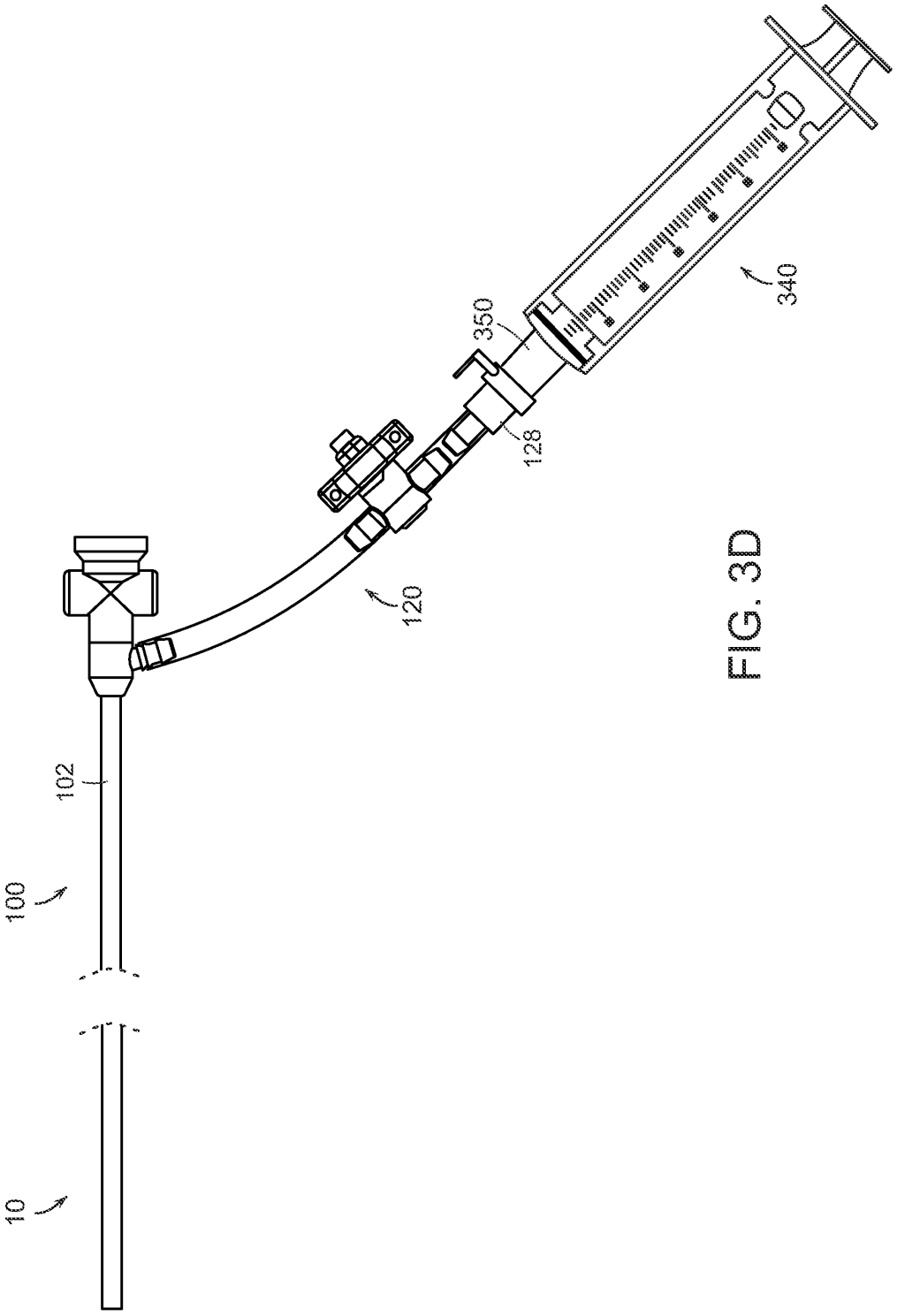
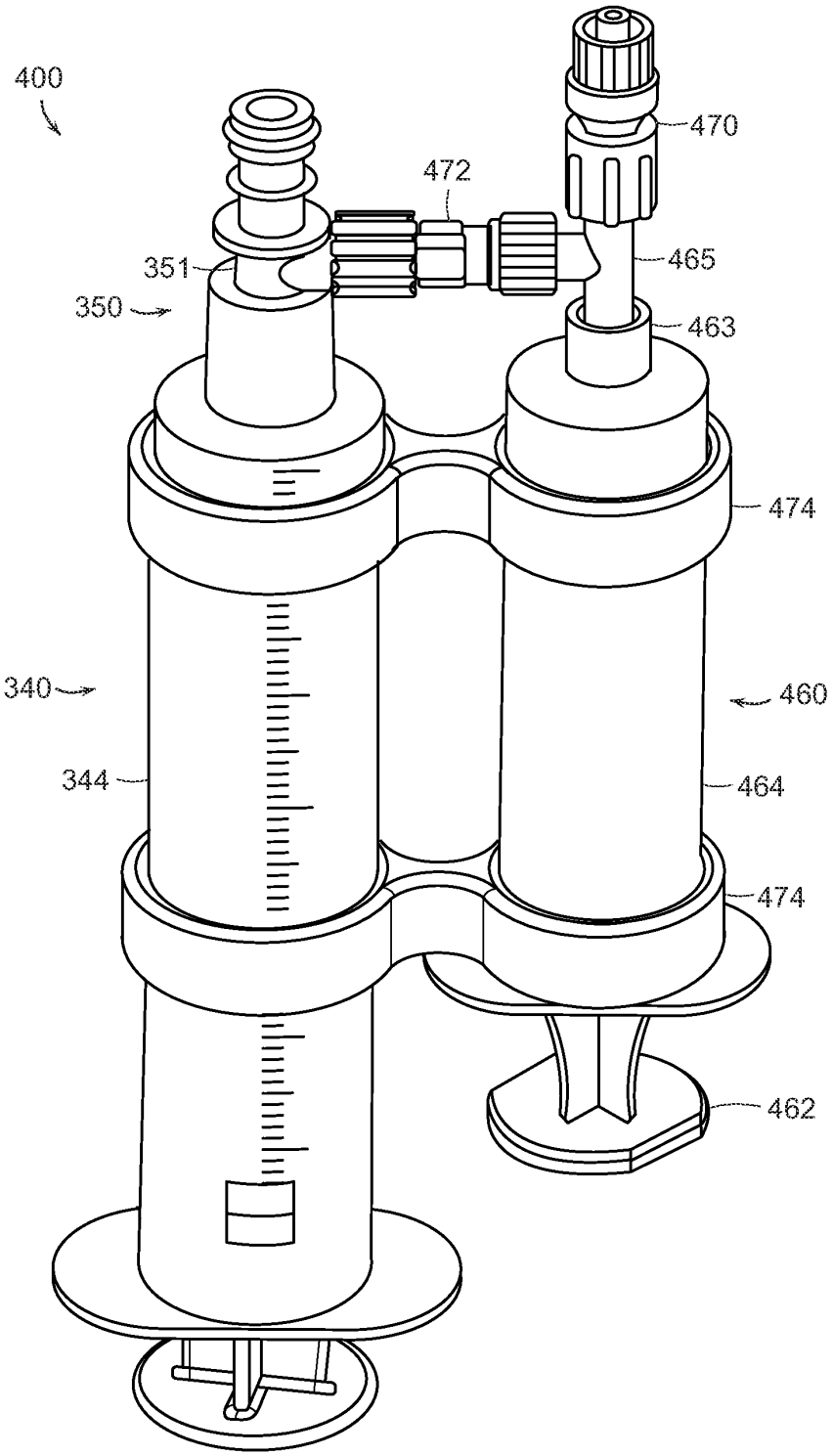


FIG. 3D

FIG. 4A



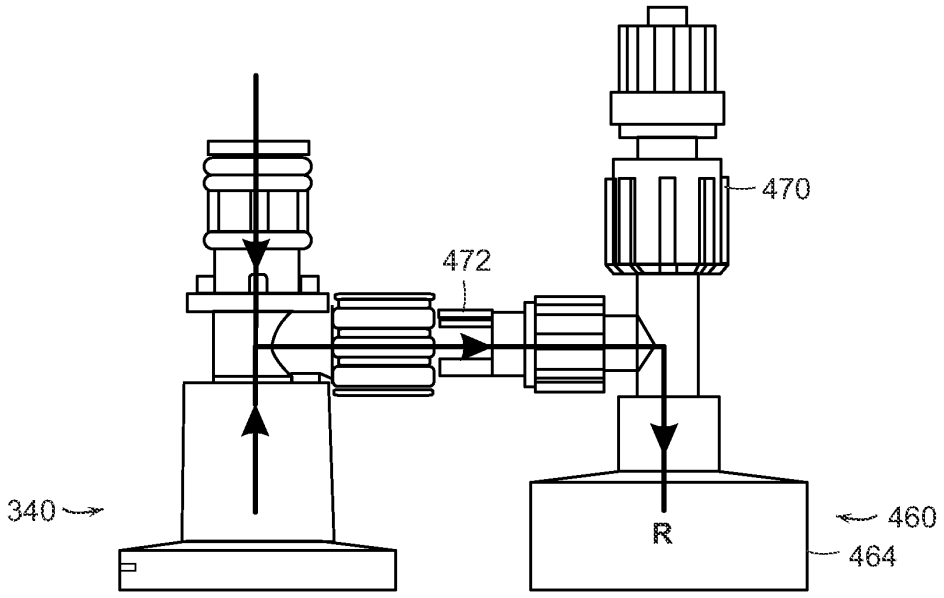


FIG. 4B

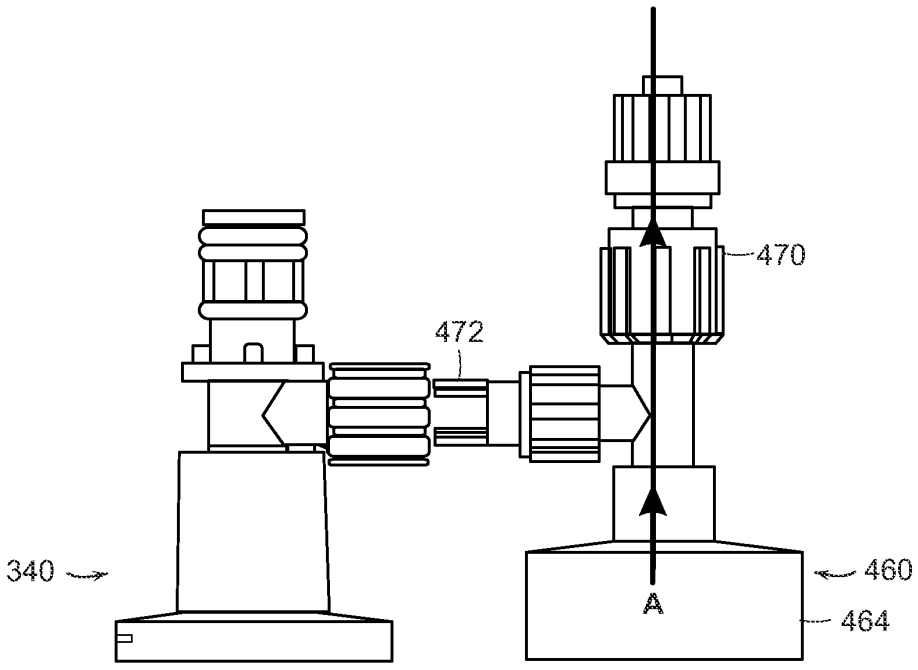


FIG. 4C

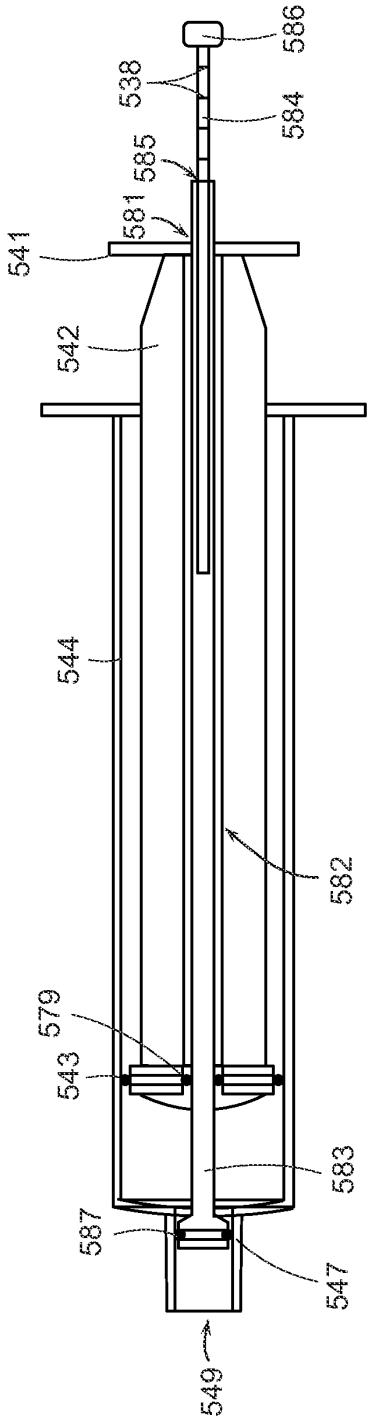


FIG. 5

FIG. 6

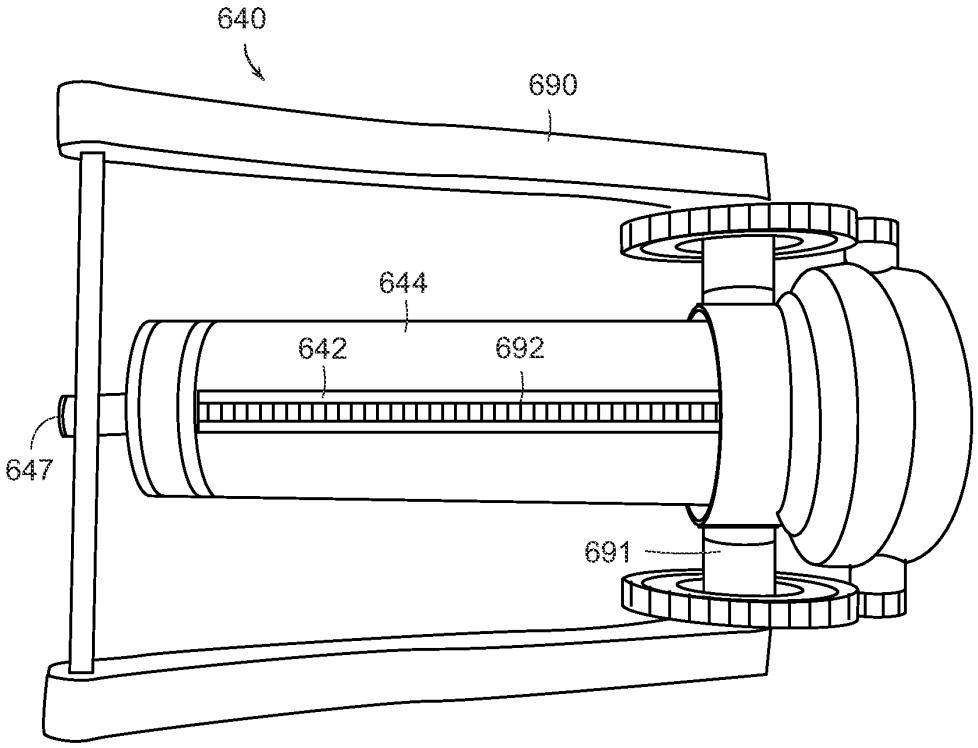
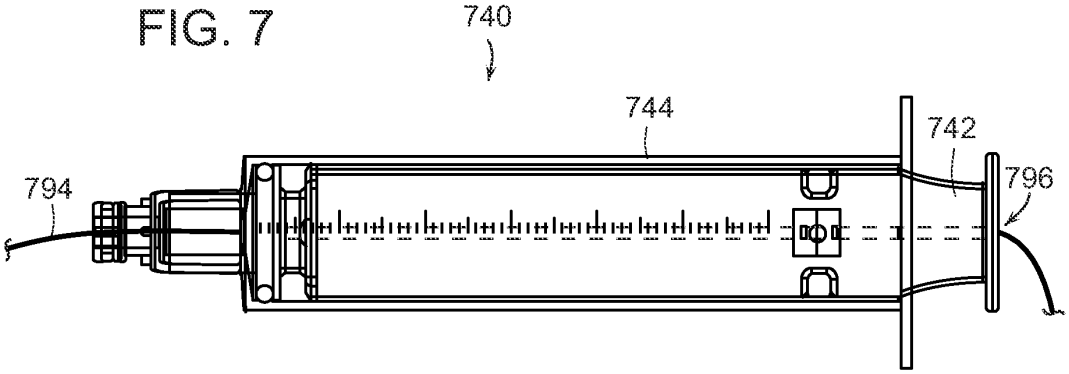


FIG. 7



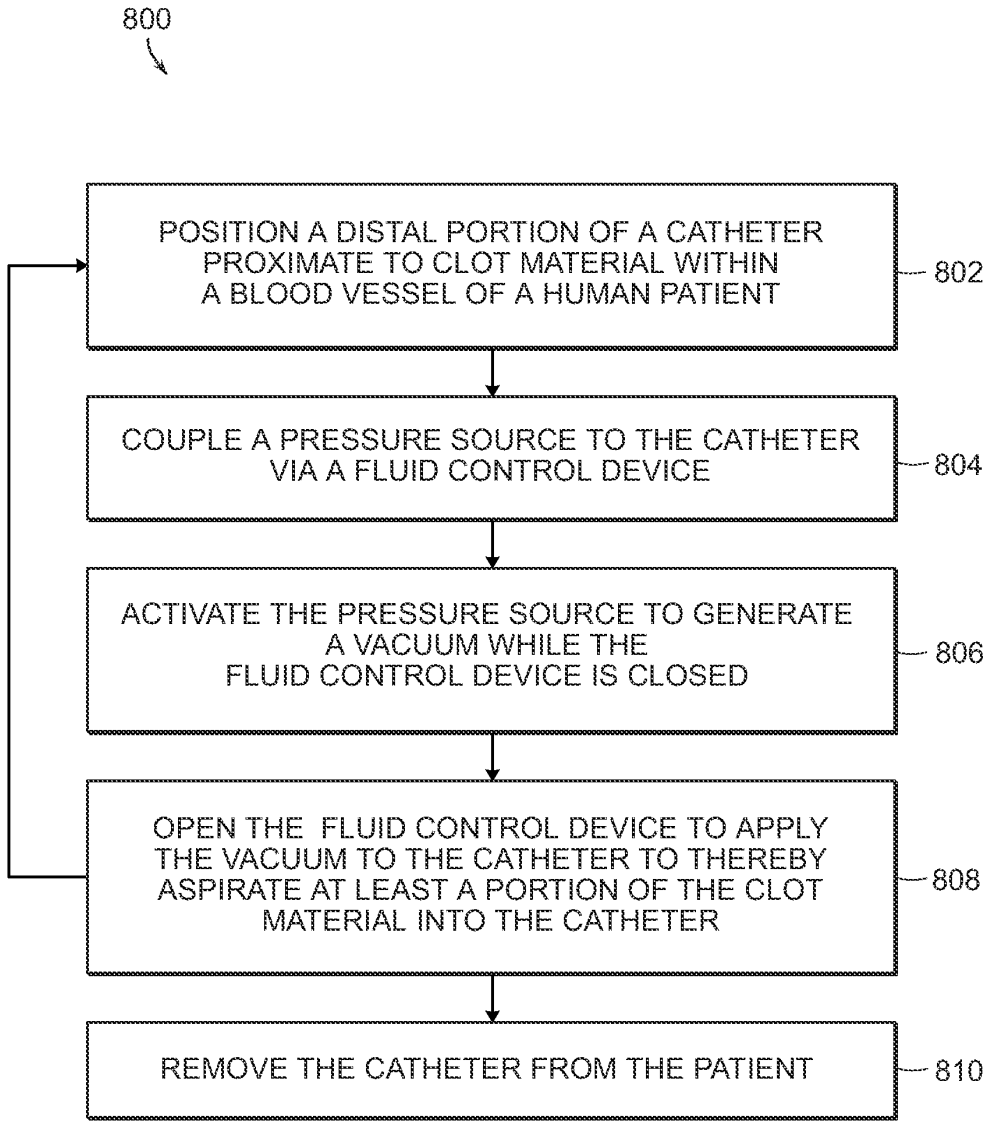

800
POSITION A DISTAL PORTION OF A CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF A HUMAN PATIENT
802
COUPLE A PRESSURE SOURCE TO THE CATHETER VIA A FLUID CONTROL DEVICE
804
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
806
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE CATHETER
808
REMOVE THE CATHETER FROM THE PATIENT
810

FIG. 8

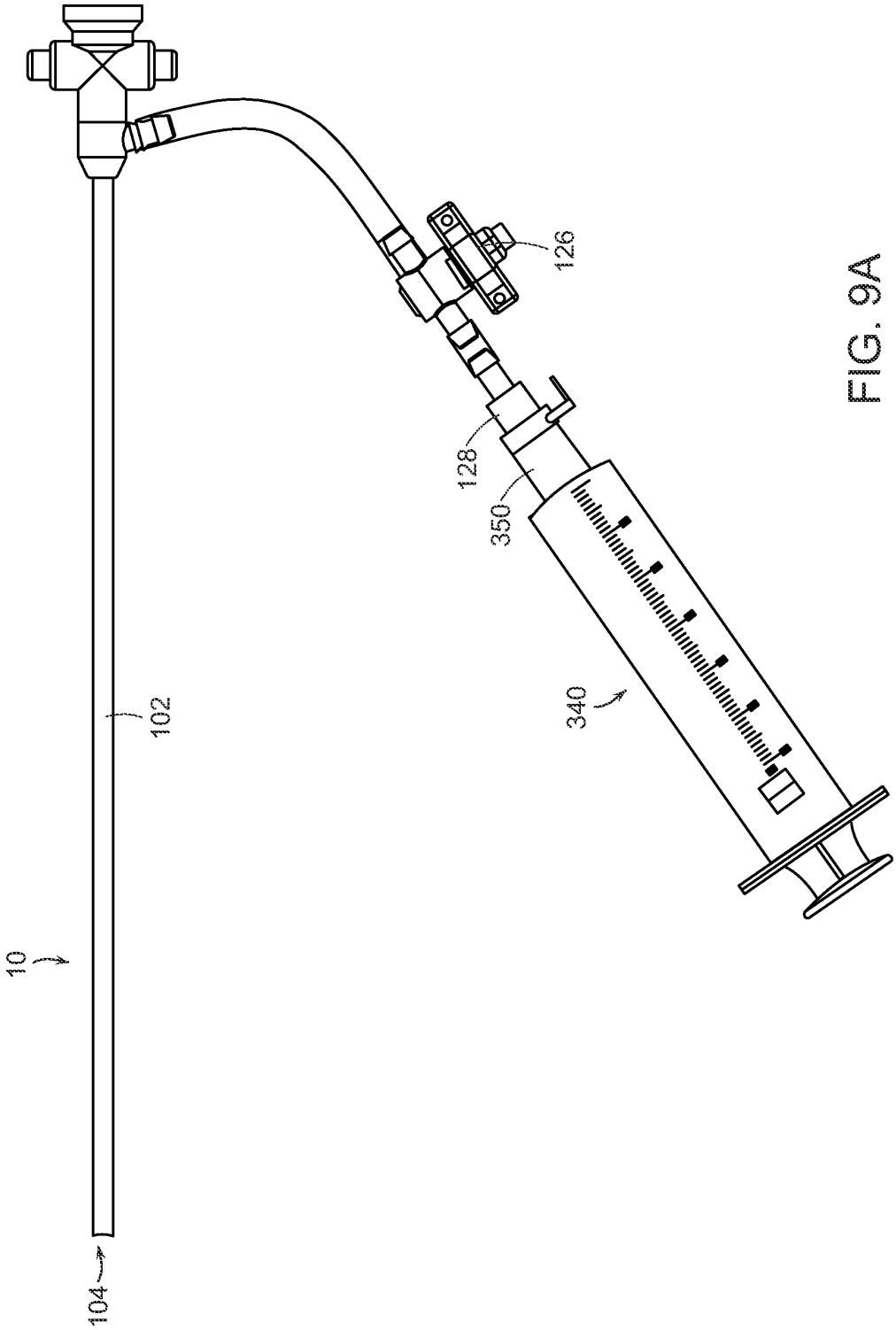


FIG. 9A

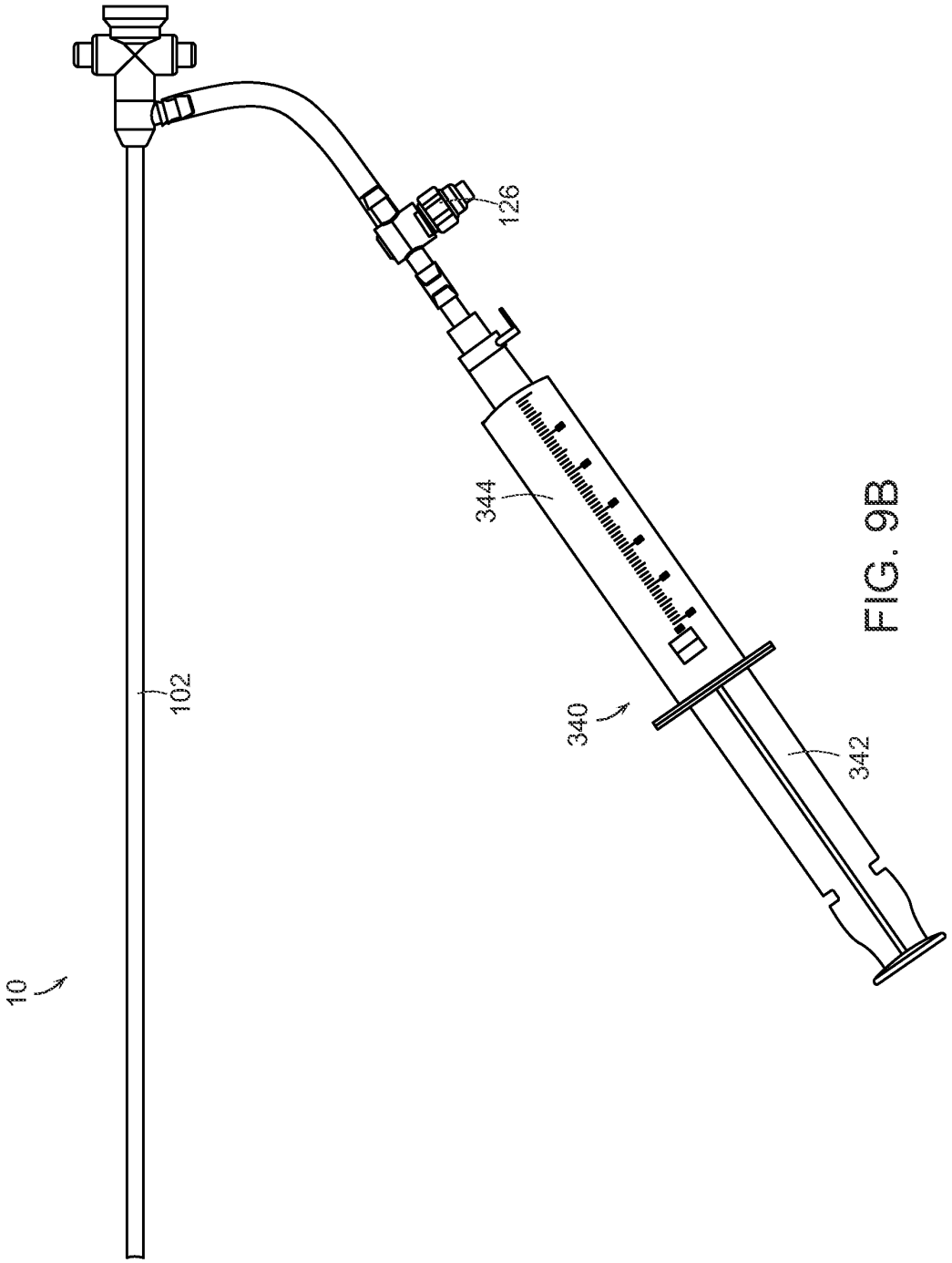


FIG. 9B

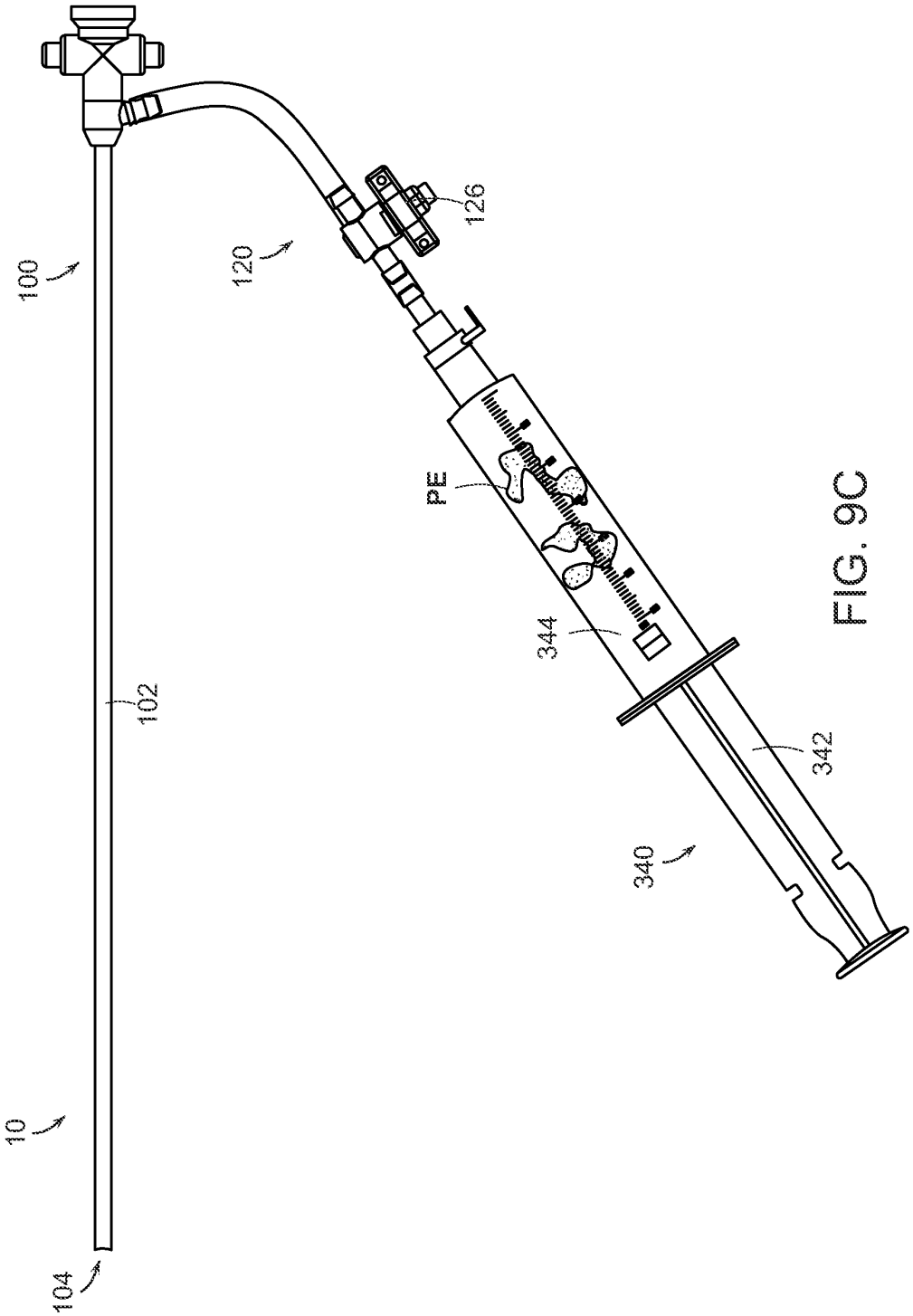


FIG. 9C

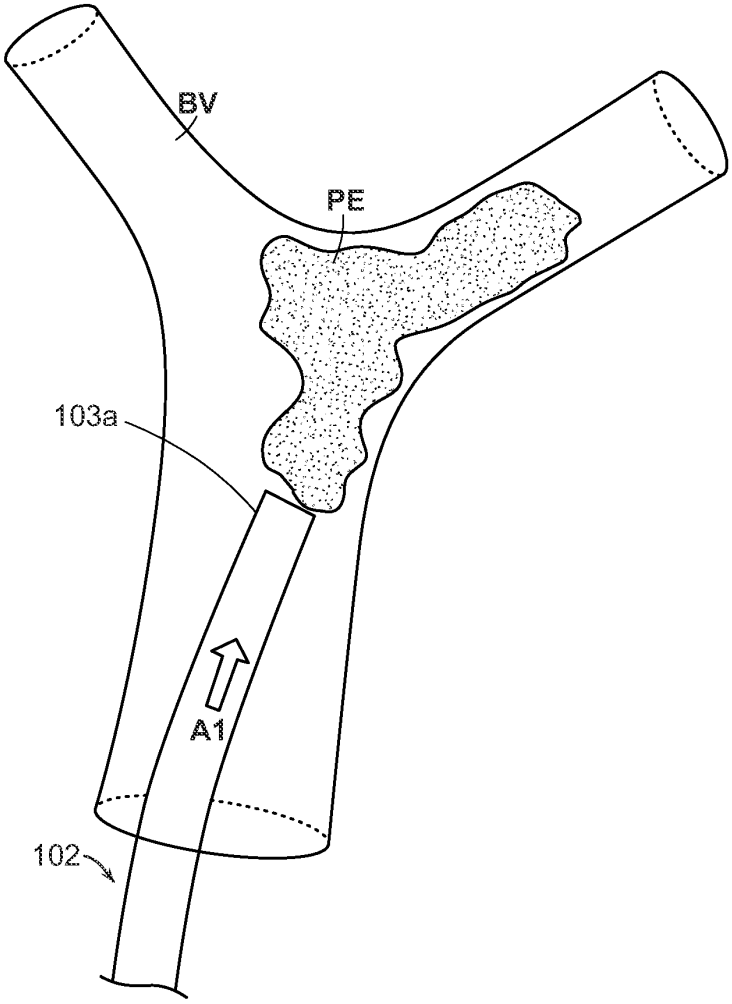


FIG. 10A

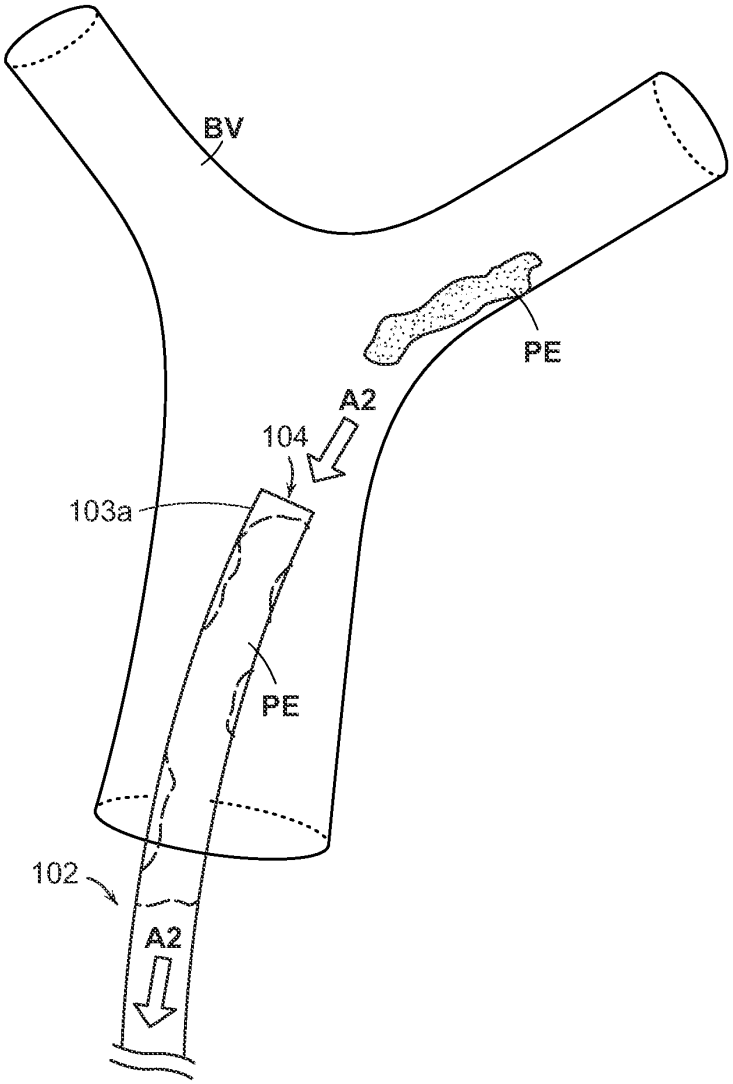


FIG. 10B

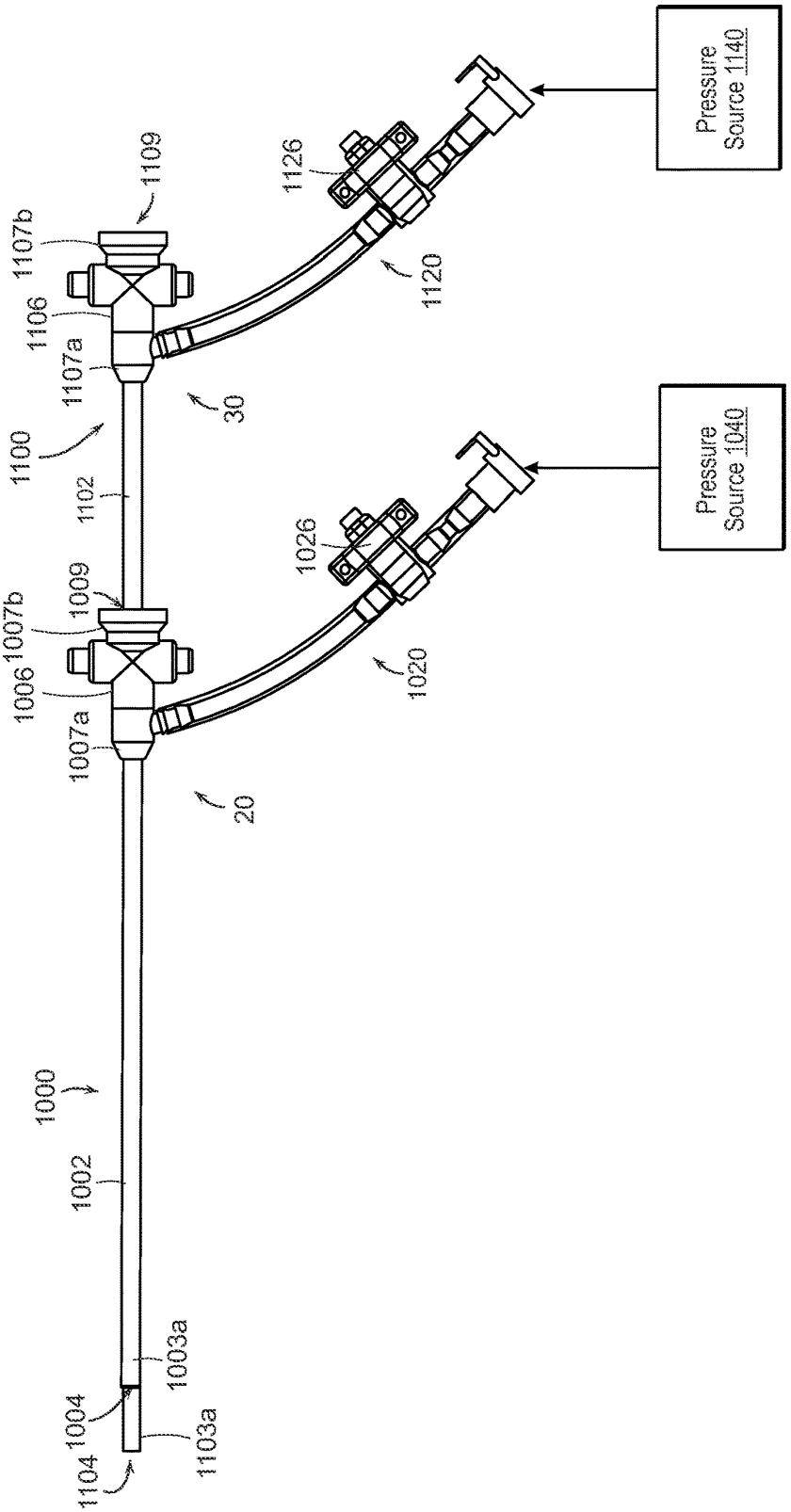

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FIG. 11

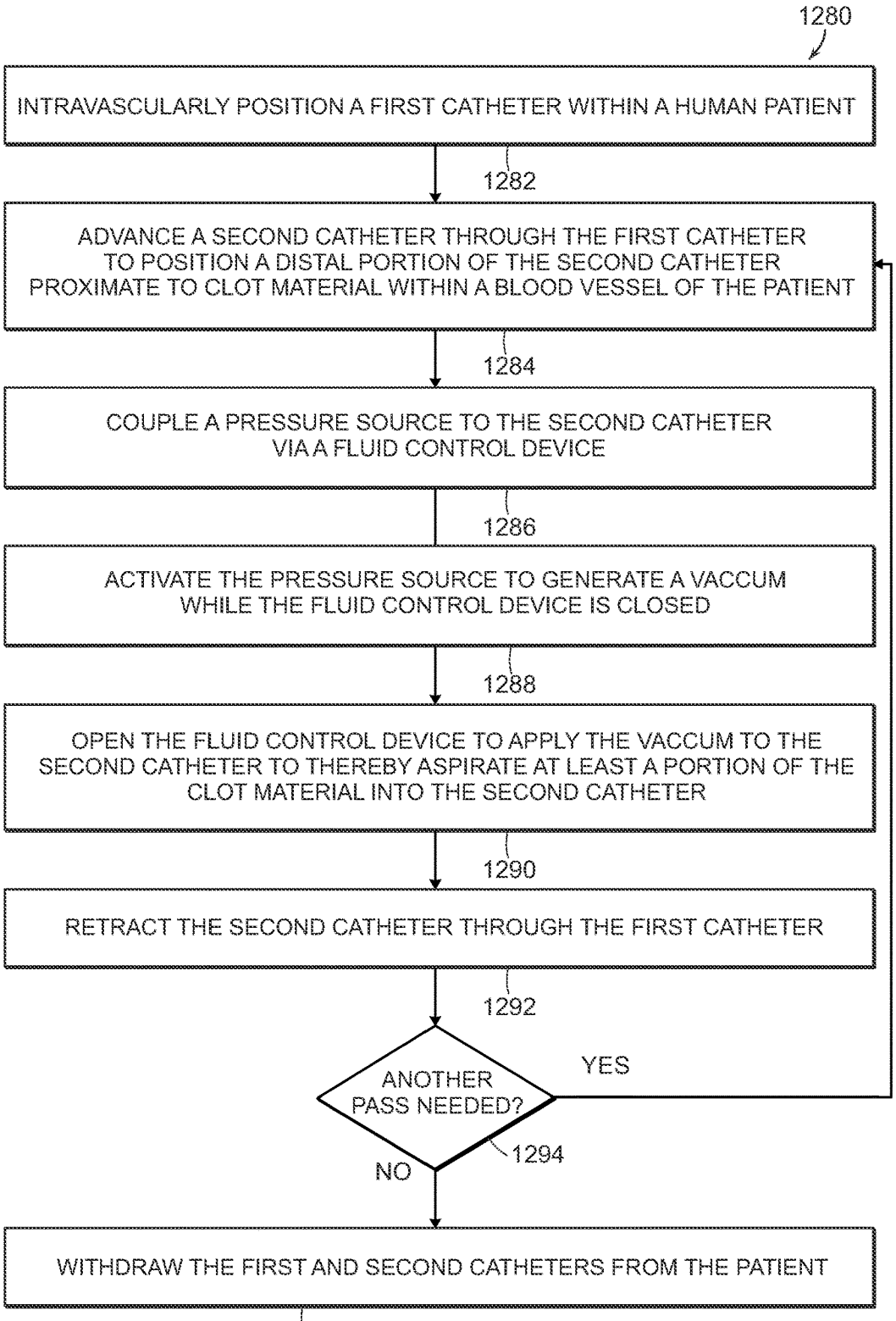

1280
INTRAVASCULARLY POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT
1282
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF THE PATIENT
1284
COUPLE A PRESSURE SOURCE TO THE SECOND CATHETER VIA A FLUID CONTROL DEVICE
1286
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACCUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
1288
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACCUM TO THE SECOND CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE SECOND CATHETER
1290
RETRACT THE SECOND CATHETER THROUGH THE FIRST CATHETER
1292
ANOTHER PASS NEEDED?
YES
1294
NO
WITHDRAW THE FIRST AND SECOND CATHETERS FROM THE PATIENT
1296

FIG. 12

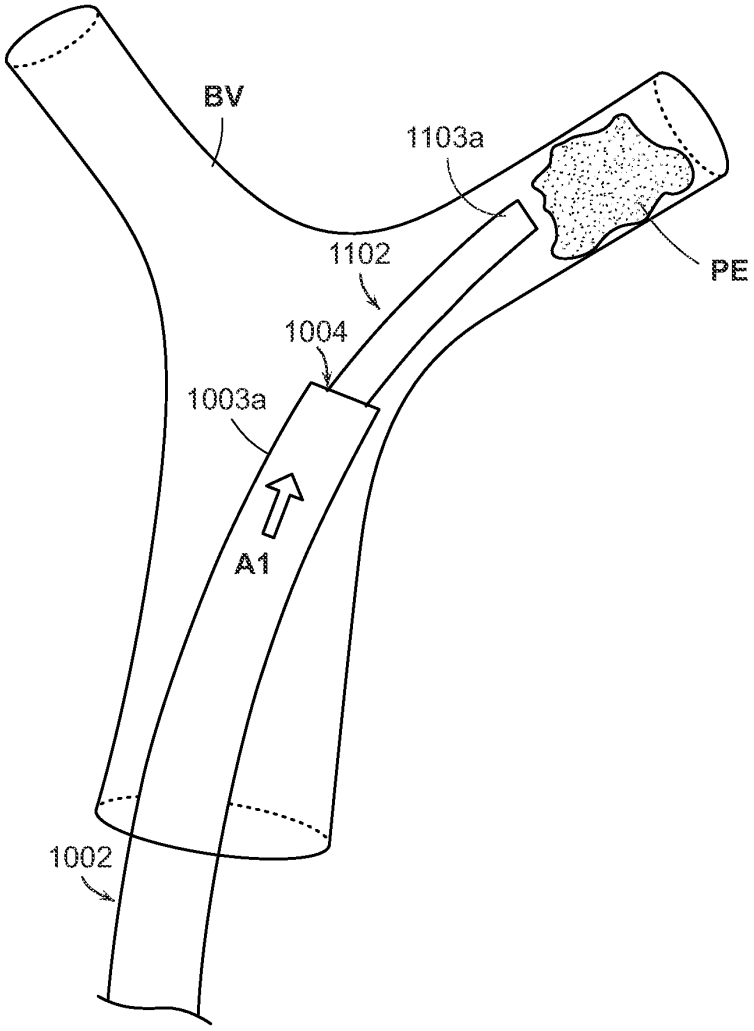


FIG. 13A

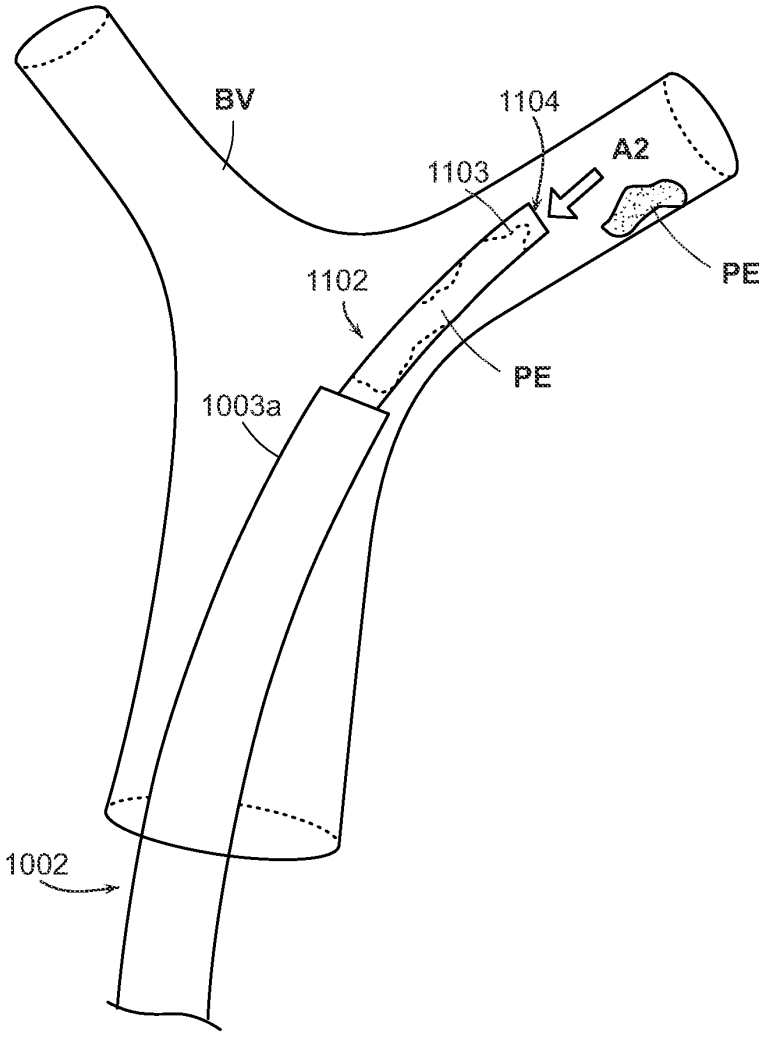


FIG. 13B

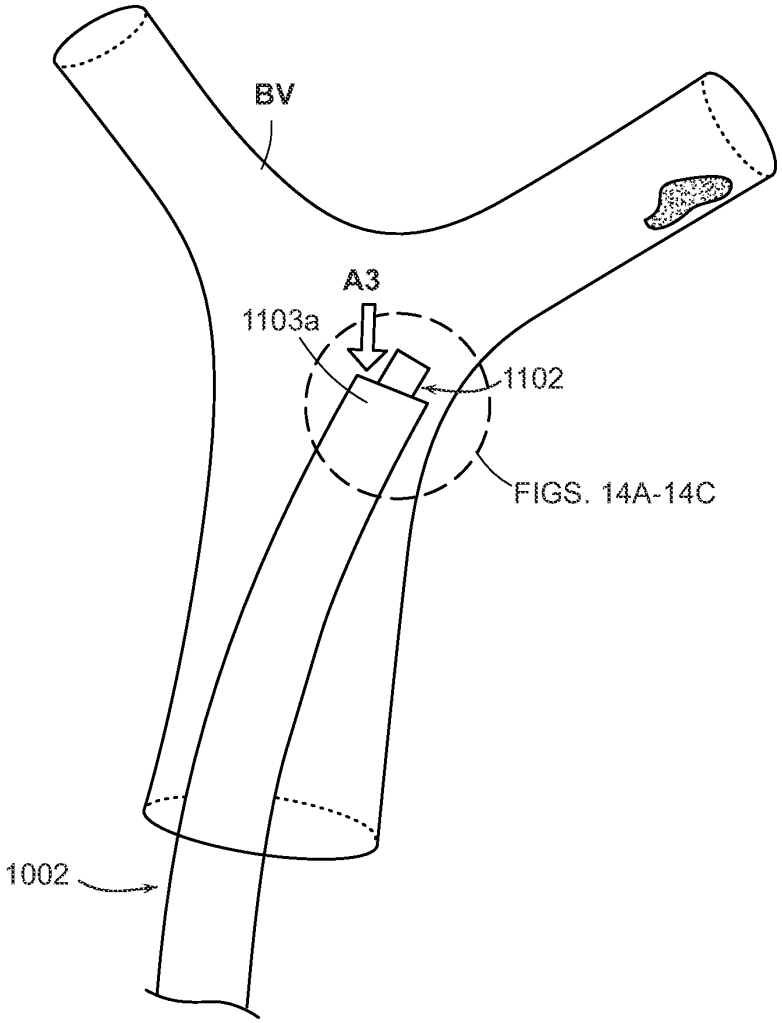


FIG. 13C

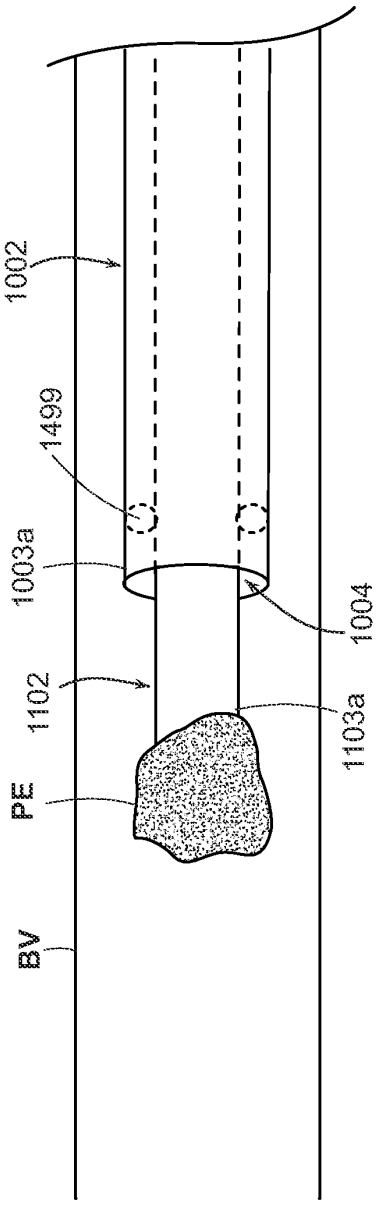


FIG. 14A

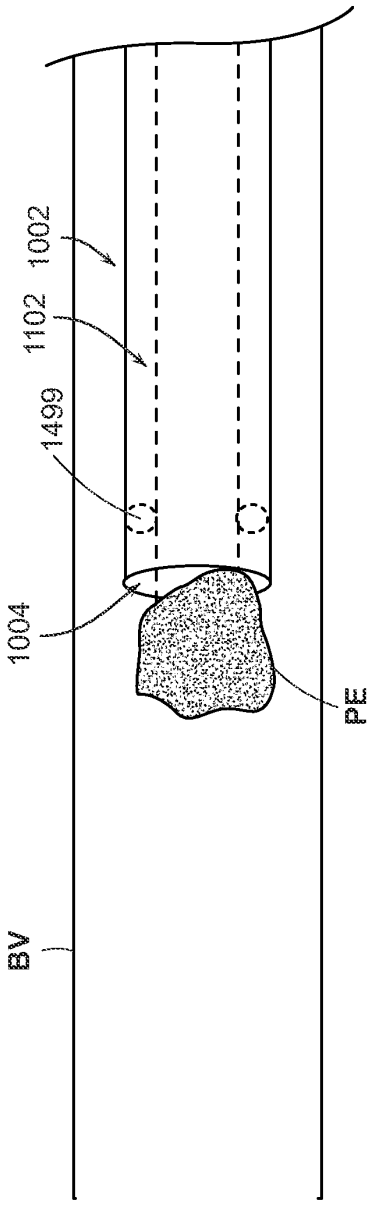


FIG. 14B

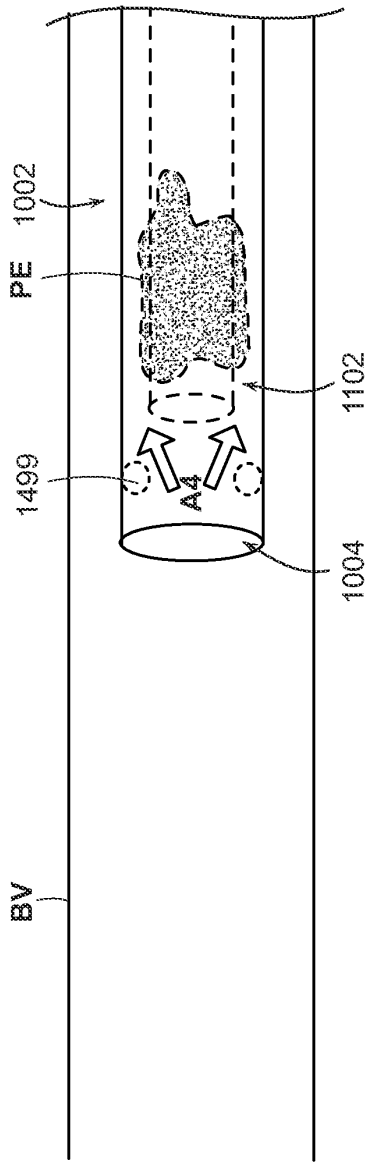


FIG. 14C

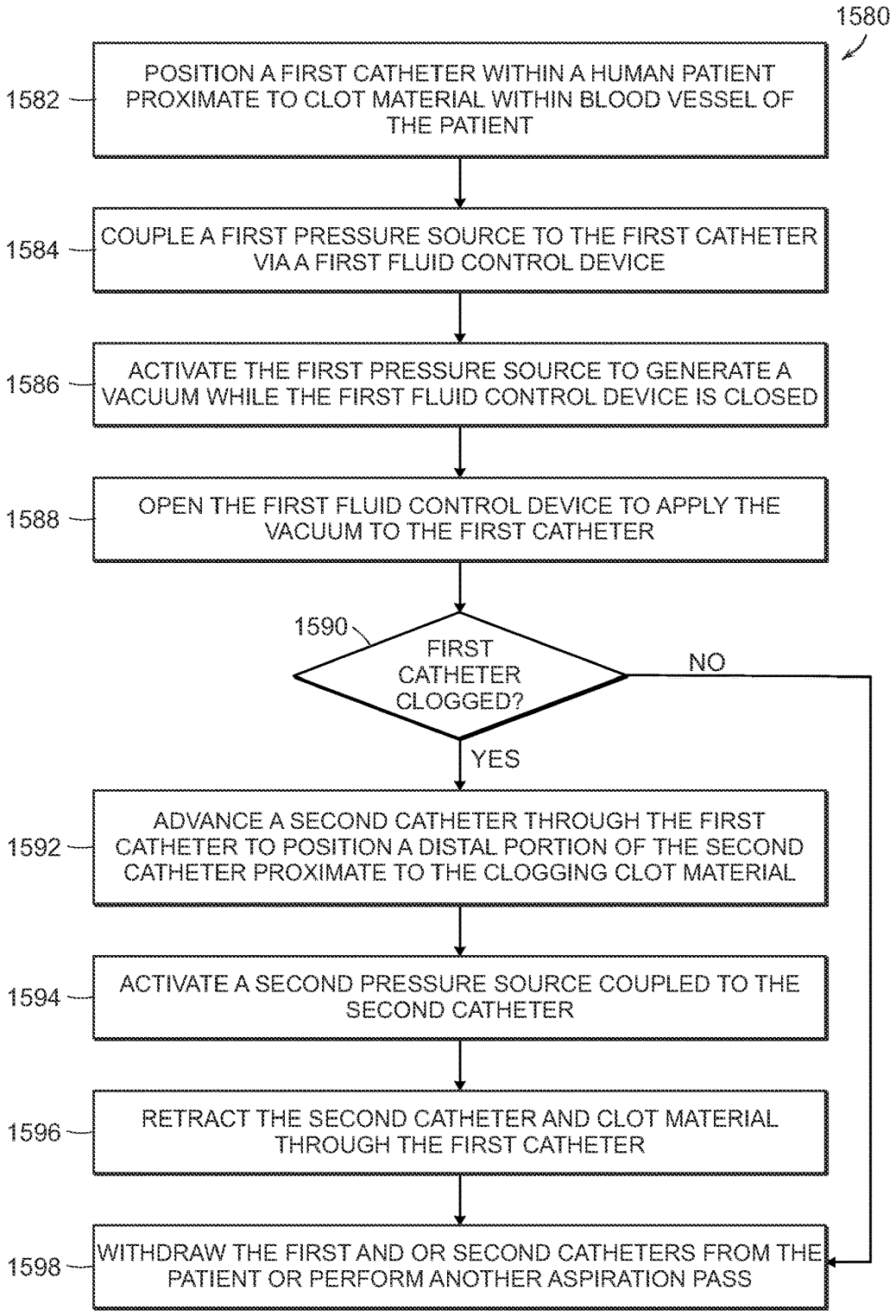

1580
1582
POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT PROXIMATE TO CLOT MATERIAL WITHIN BLOOD VESSEL OF THE PATIENT
1584
COUPLE A FIRST PRESSURE SOURCE TO THE FIRST CATHETER VIA A FIRST FLUID CONTROL DEVICE
1586
ACTIVATE THE FIRST PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FIRST FLUID CONTROL DEVICE IS CLOSED
1588
OPEN THE FIRST FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE FIRST CATHETER
1590
FIRST CATHETER CLOGGED?
NO
YES
1592
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO THE CLOGGING CLOT MATERIAL
1594
ACTIVATE A SECOND PRESSURE SOURCE COUPLED TO THE SECOND CATHETER
1596
RETRACT THE SECOND CATHETER AND CLOT MATERIAL THROUGH THE FIRST CATHETER
1598
WITHDRAW THE FIRST AND OR SECOND CATHETERS FROM THE PATIENT OR PERFORM ANOTHER ASPIRATION PASS

FIG. 15

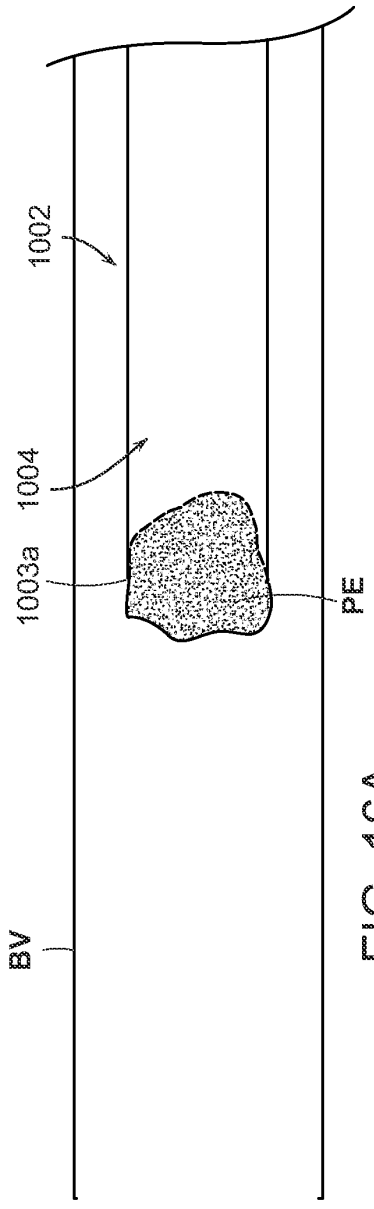


FIG. 16A

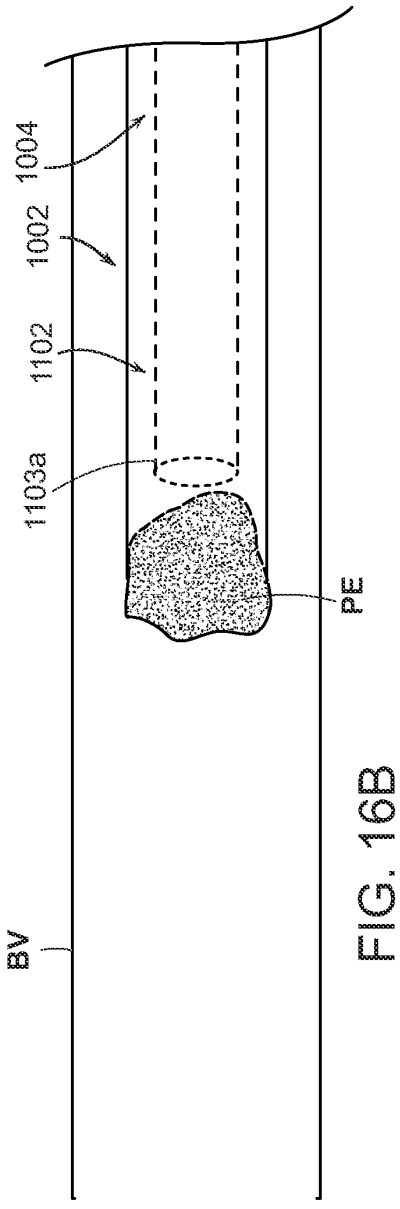


FIG. 16B

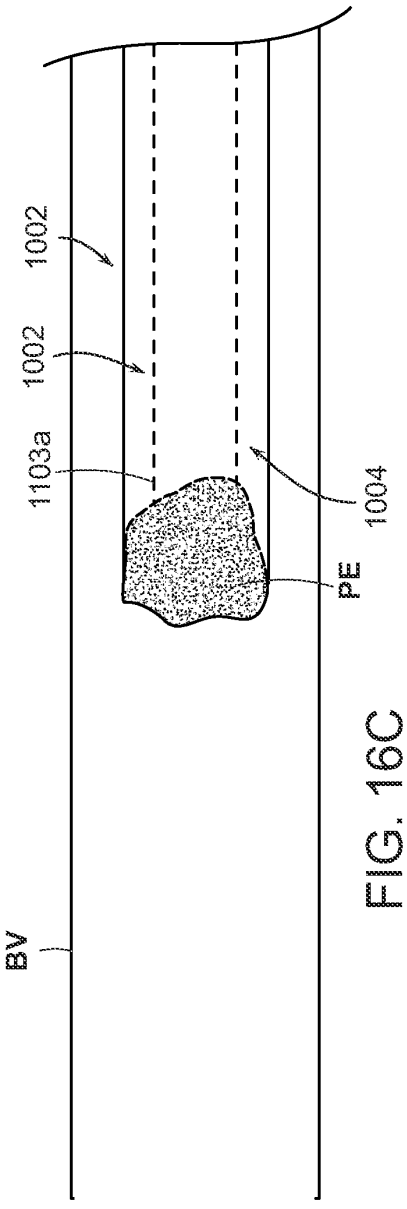


FIG. 16C

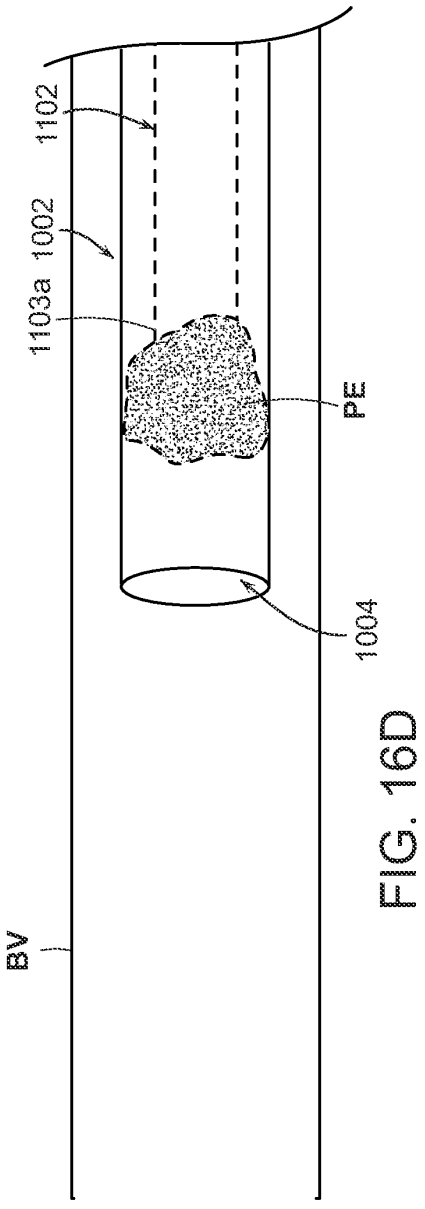


FIG. 16D

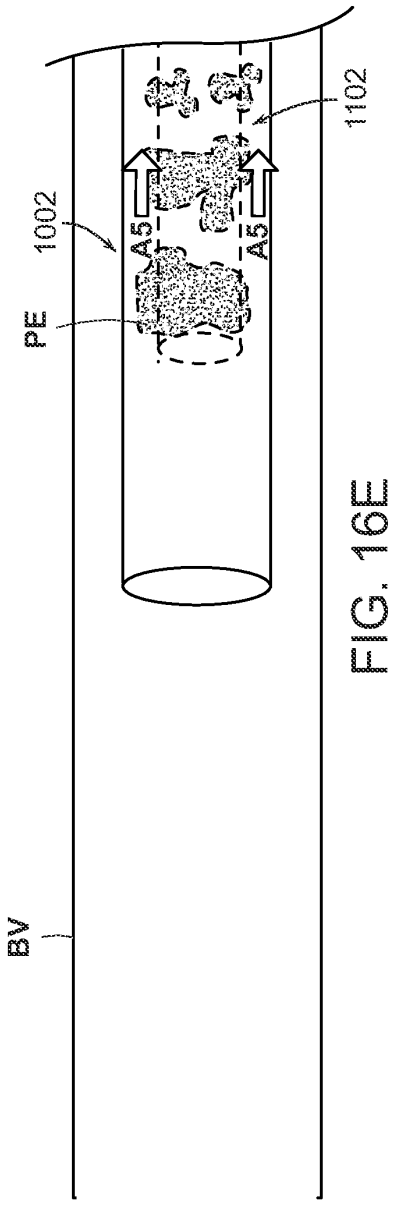


FIG. 16E

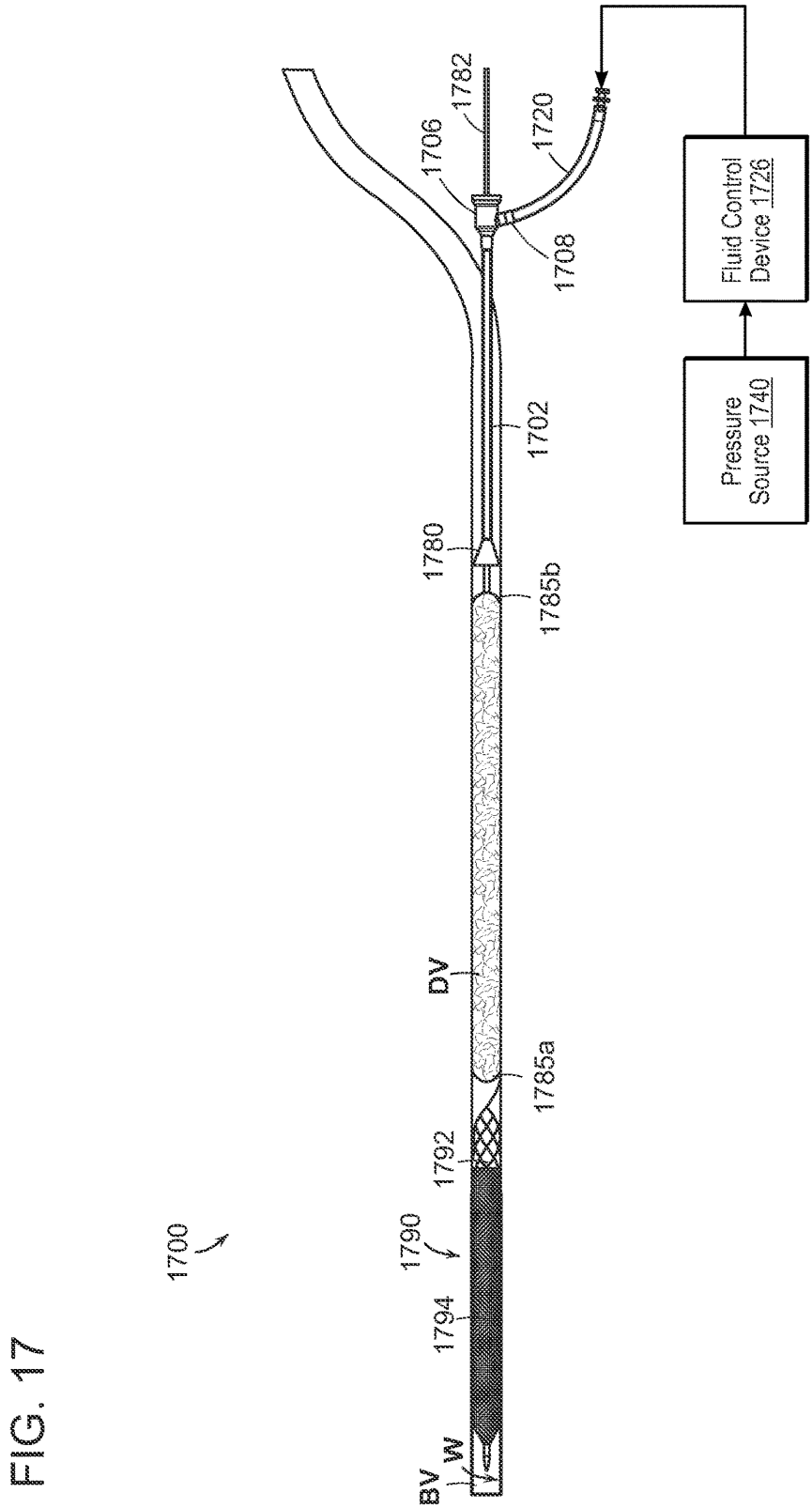

1782
1706
1720
1708
Fluid Control Device 1726
Pressure Source 1740
1702
1780
1785b
DV
1785a
1792
1790
1794
BV
W
1700

FIG. 17

FIG. 18A

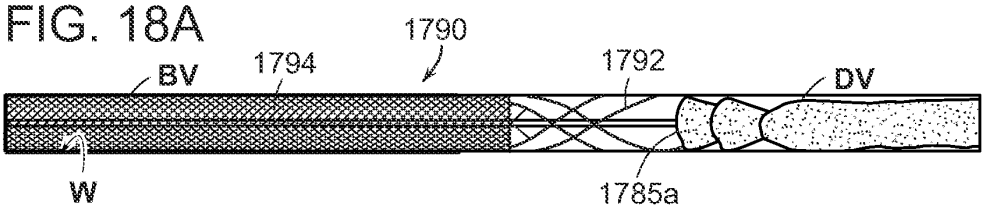


FIG. 18B

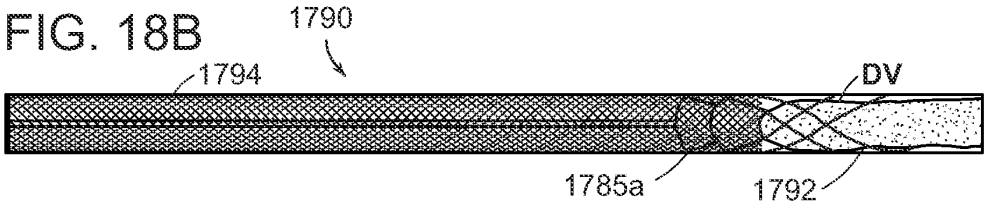


FIG. 18C

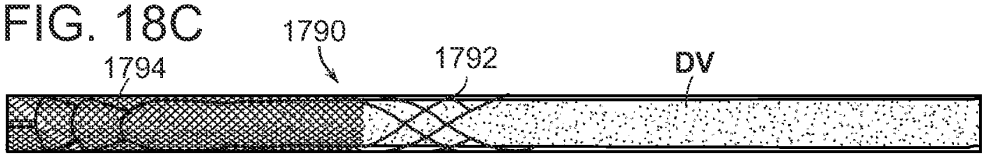


FIG. 18D

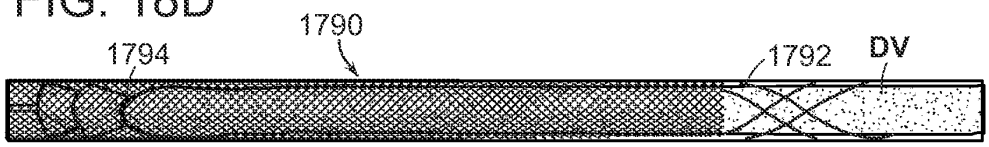


FIG. 18E

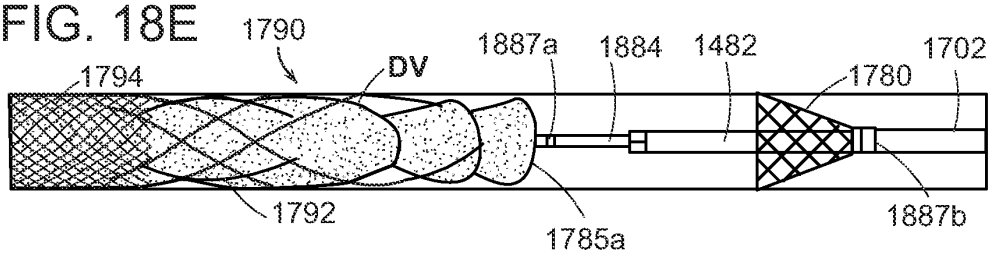


FIG. 18F

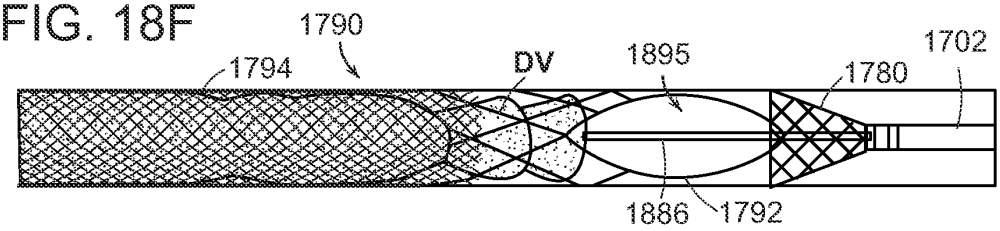


FIG. 18G

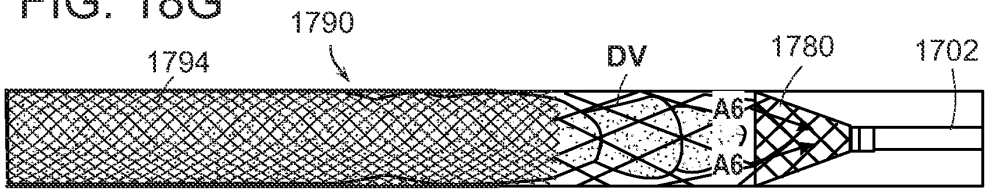
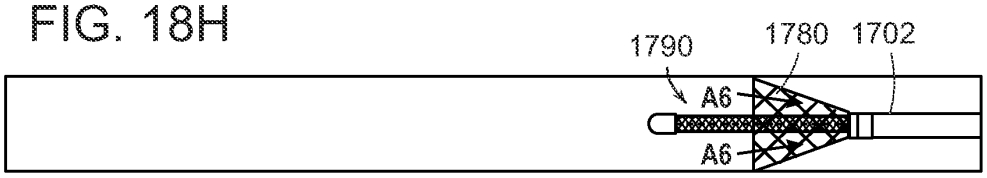


FIG. 18H



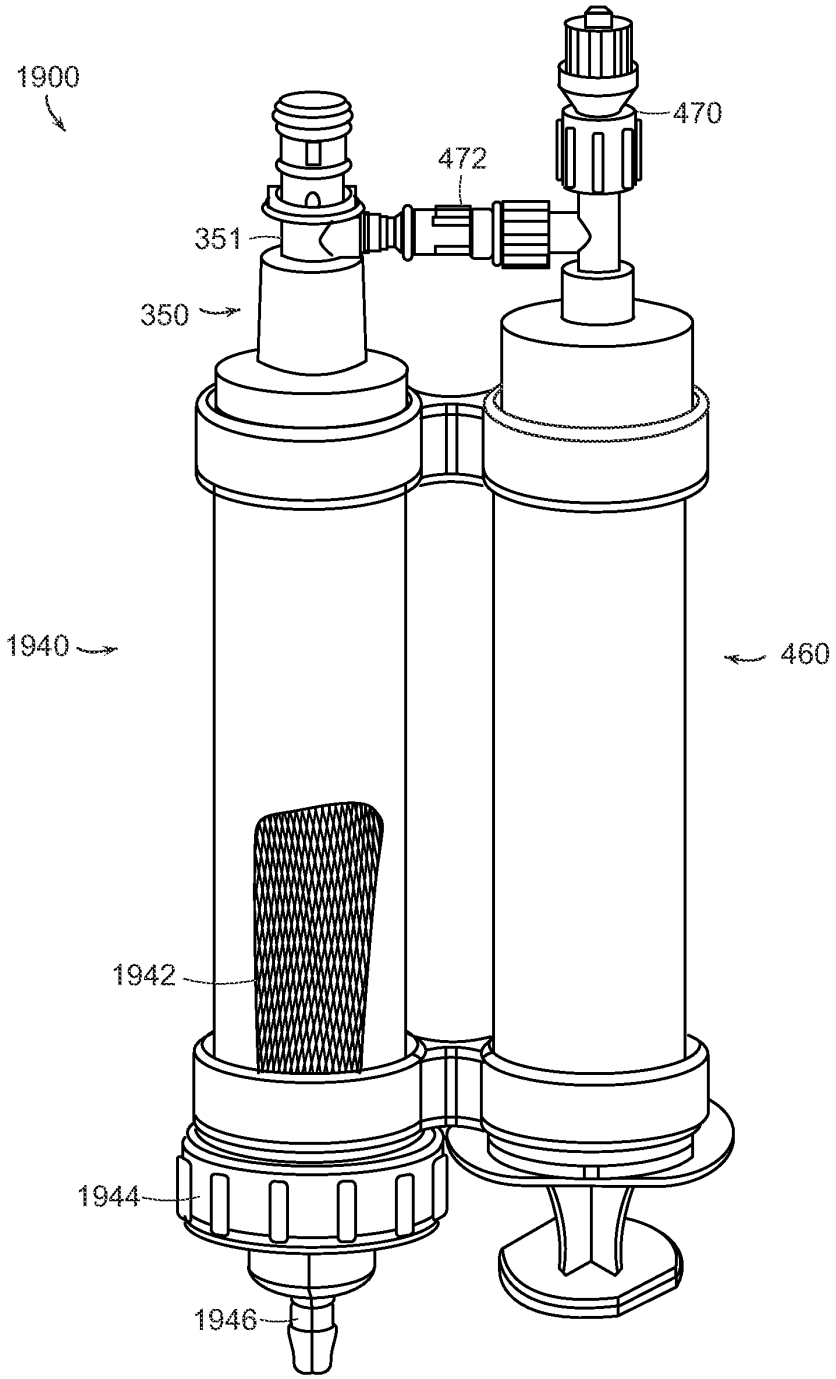


FIG. 19

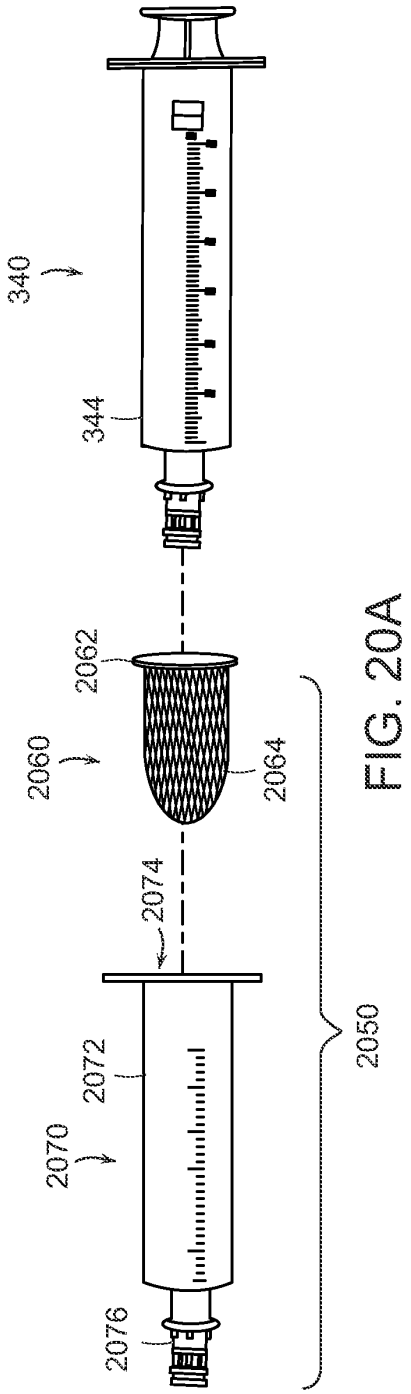


FIG. 20A

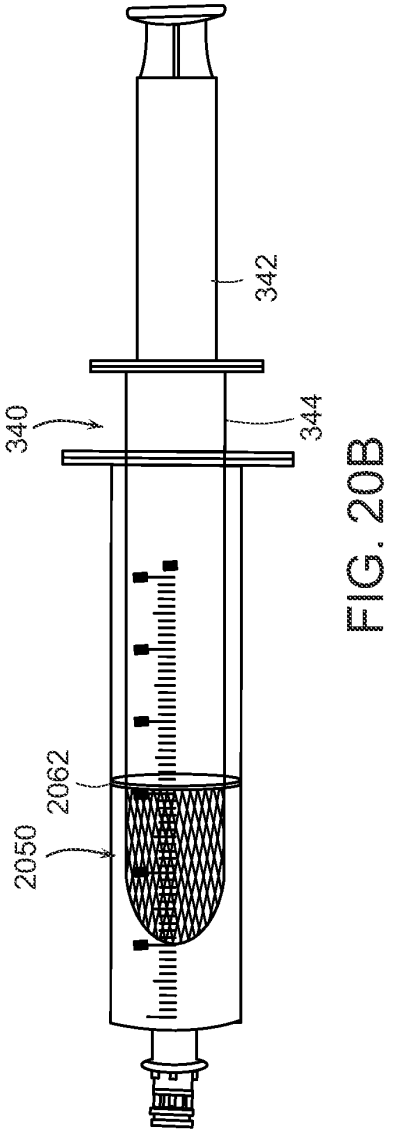


FIG. 20B

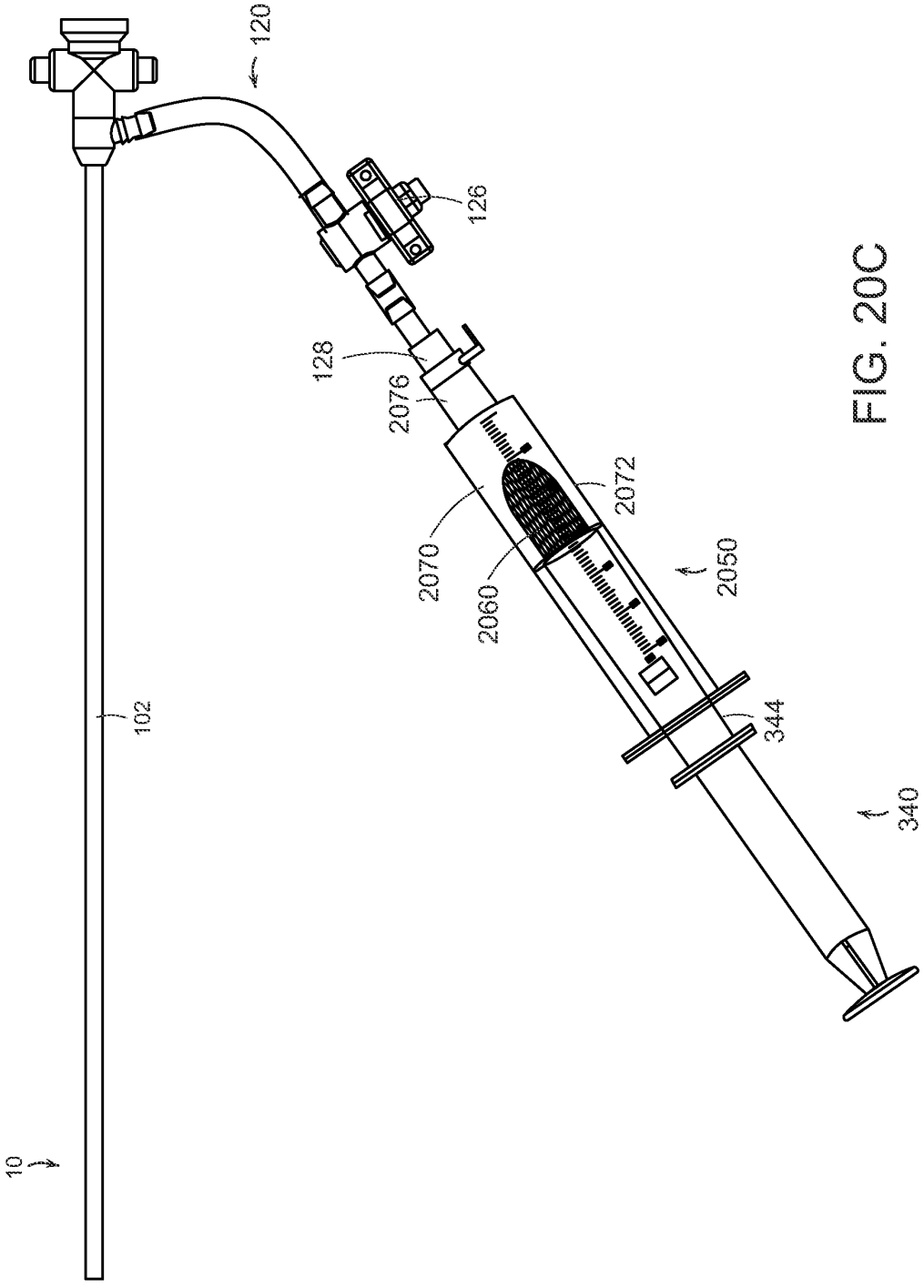


FIG. 20C

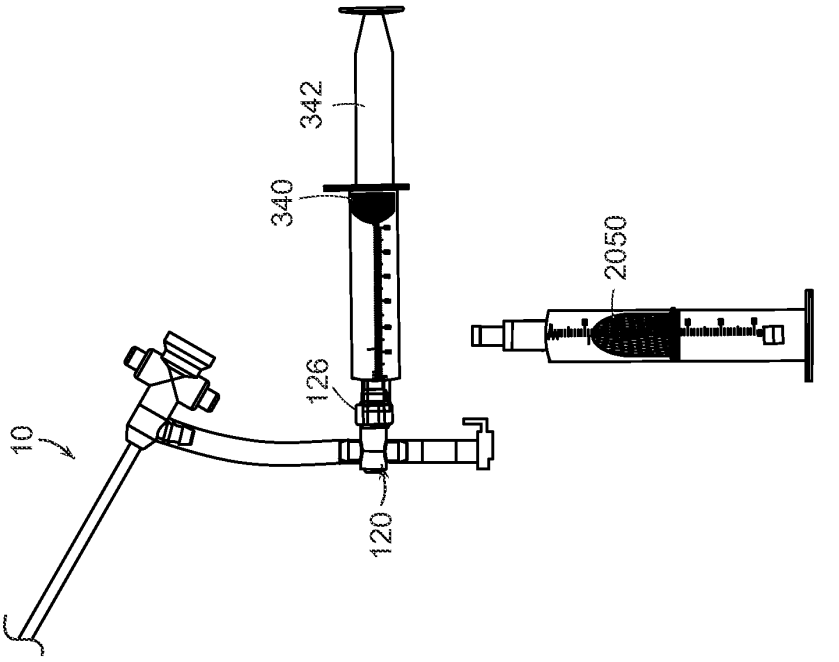


FIG. 20E

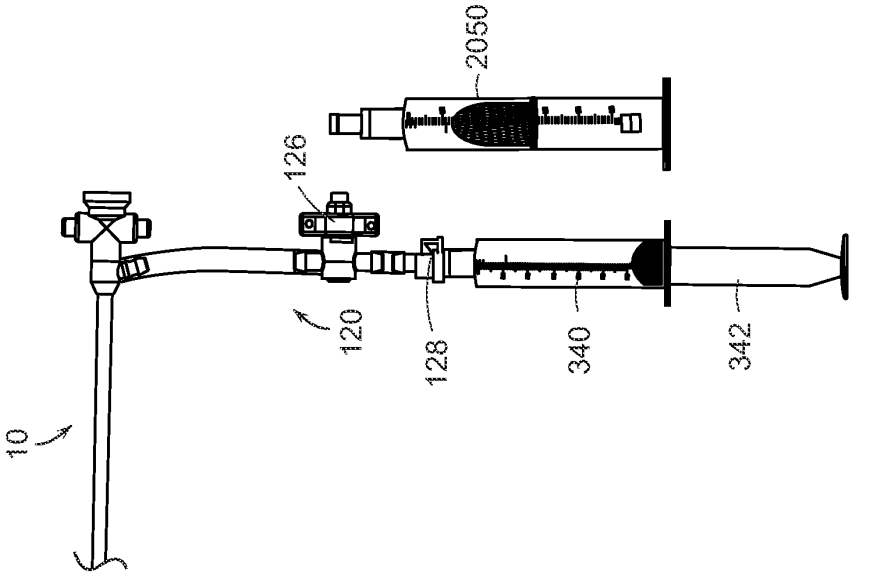


FIG. 20D

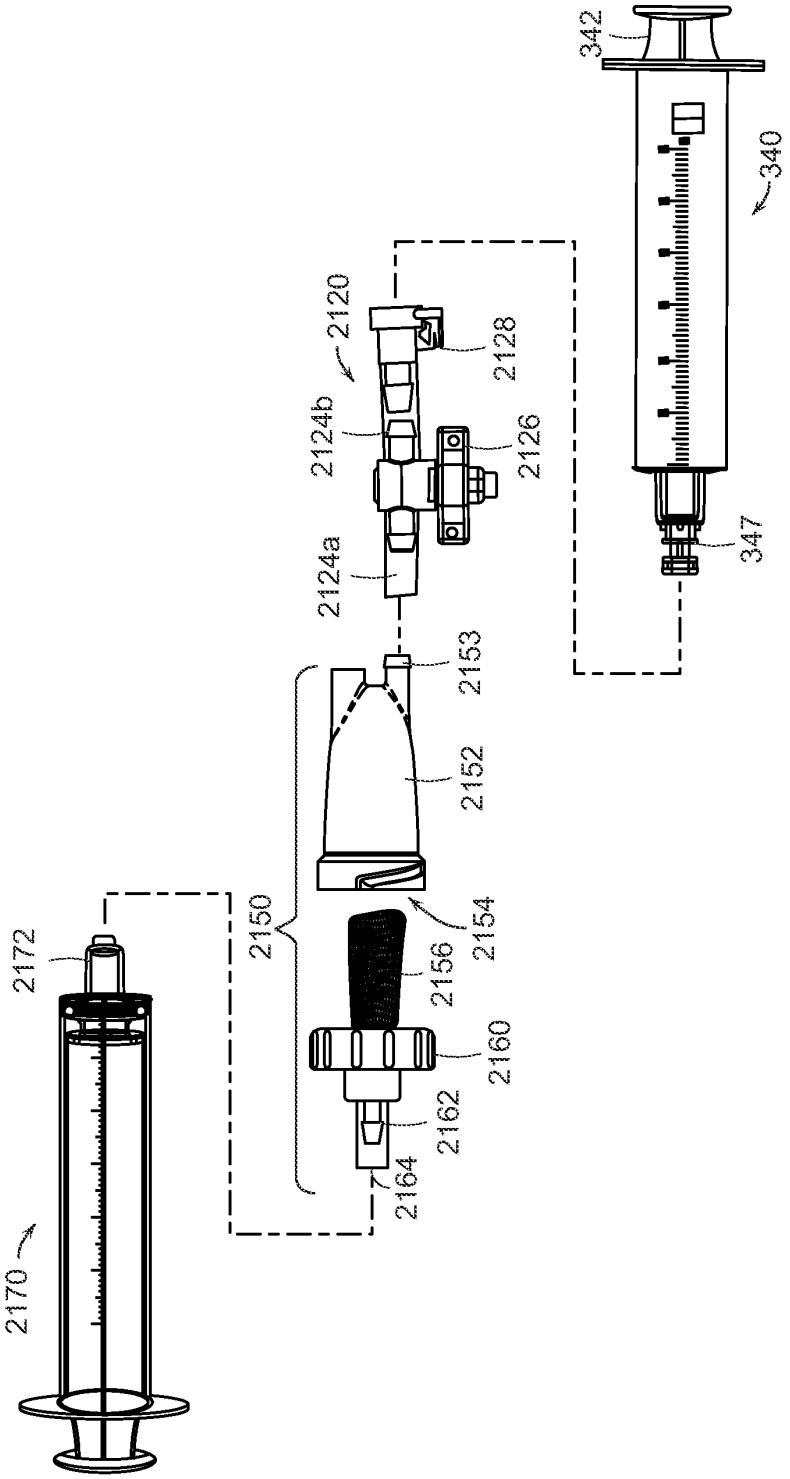

342
340
2120
2128
2124b
2126
347
2124a
2153
2152
2150
2154
2156
2172
2160
2162
2164
2170

FIG. 21A

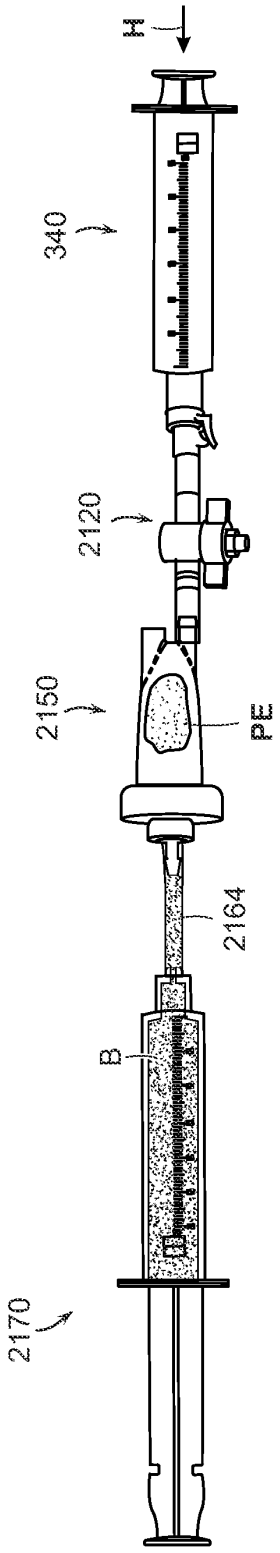


FIG. 21B

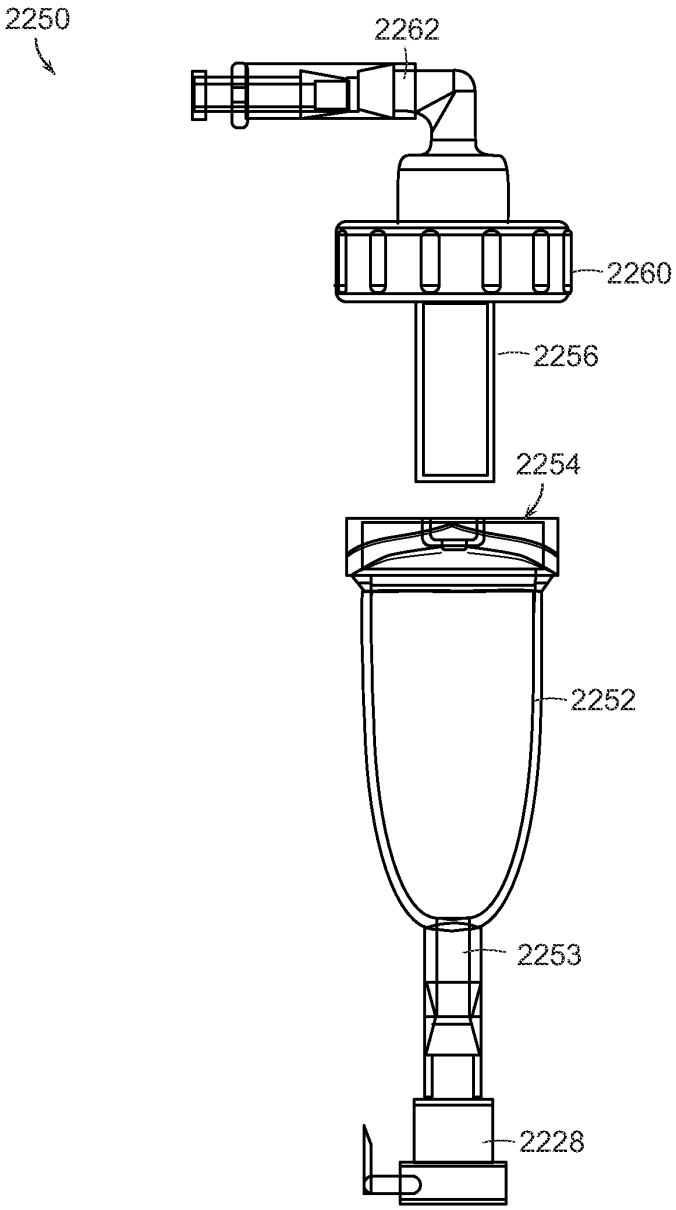


FIG. 22

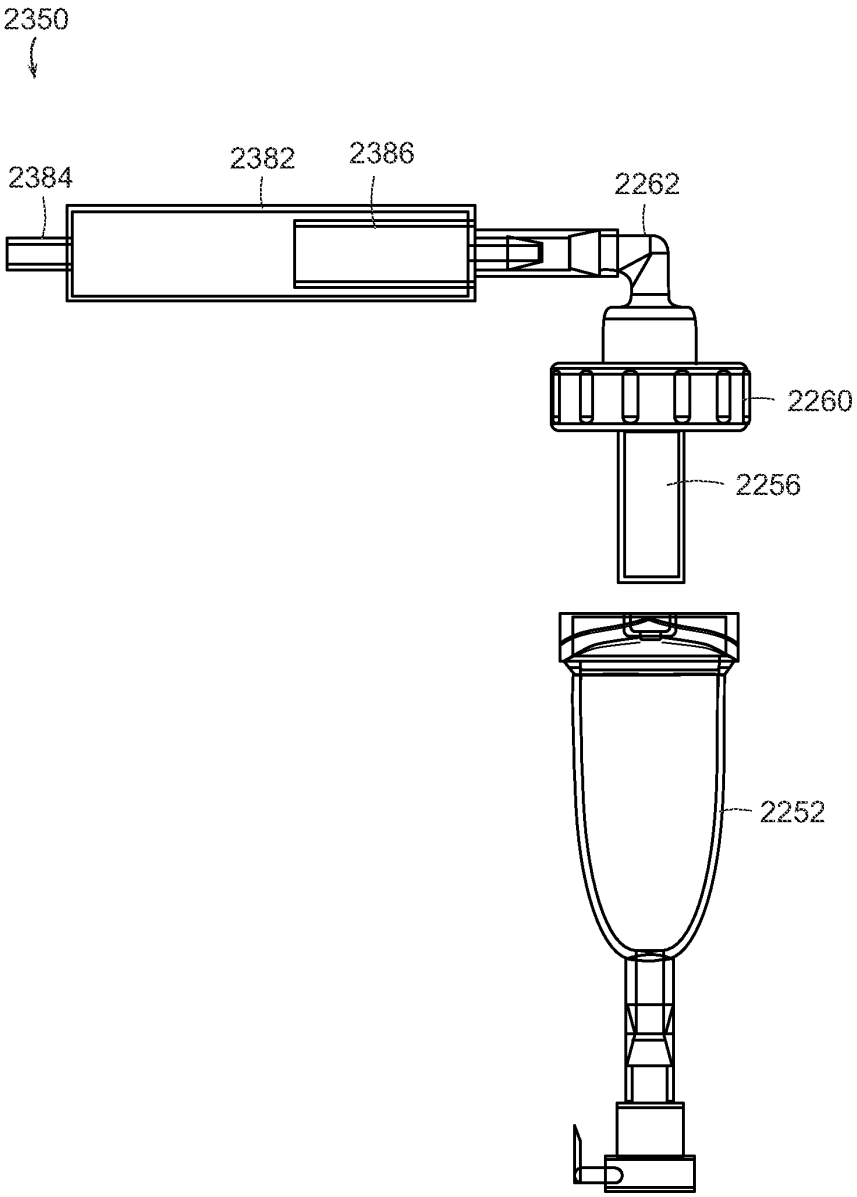


FIG. 23

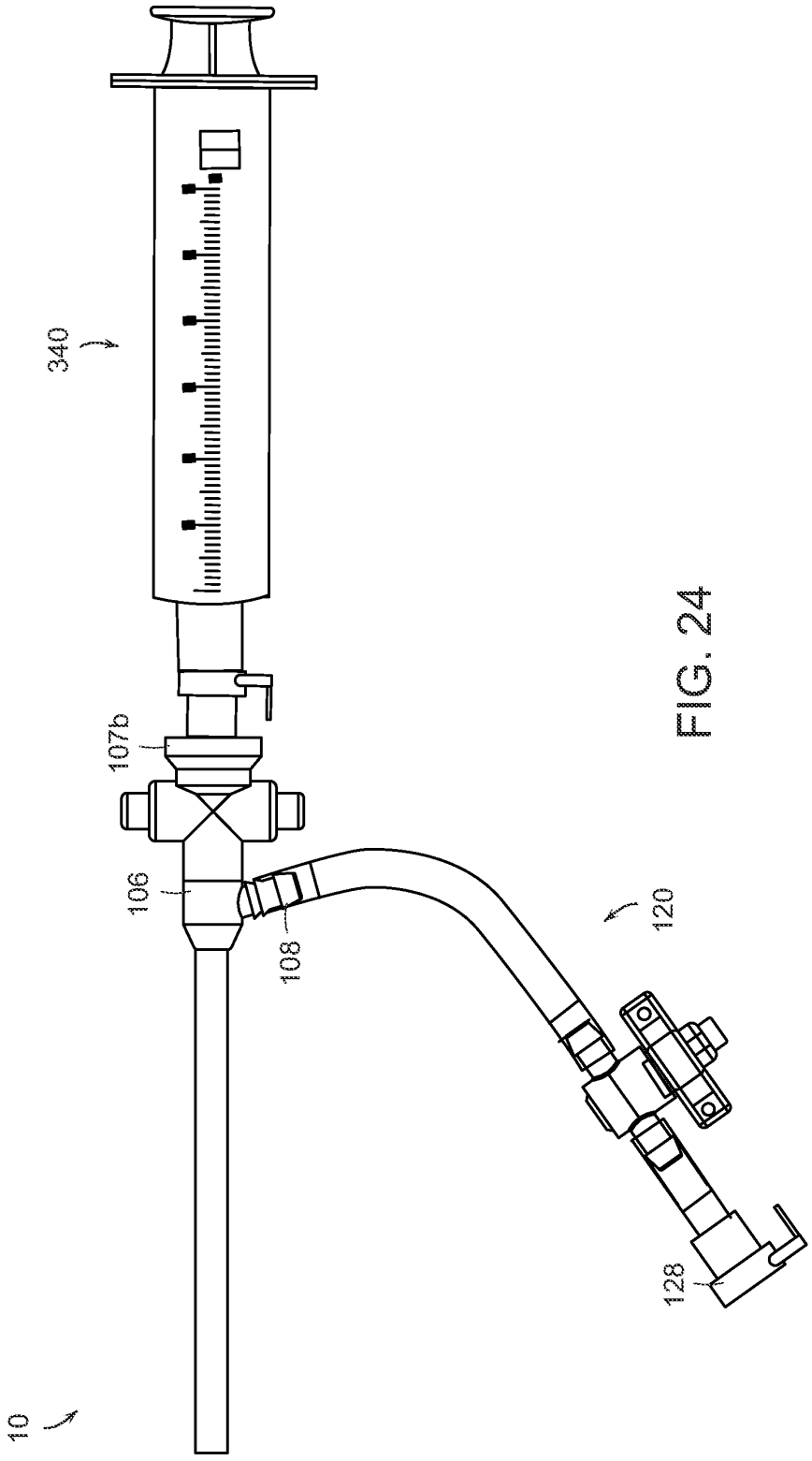


FIG. 24

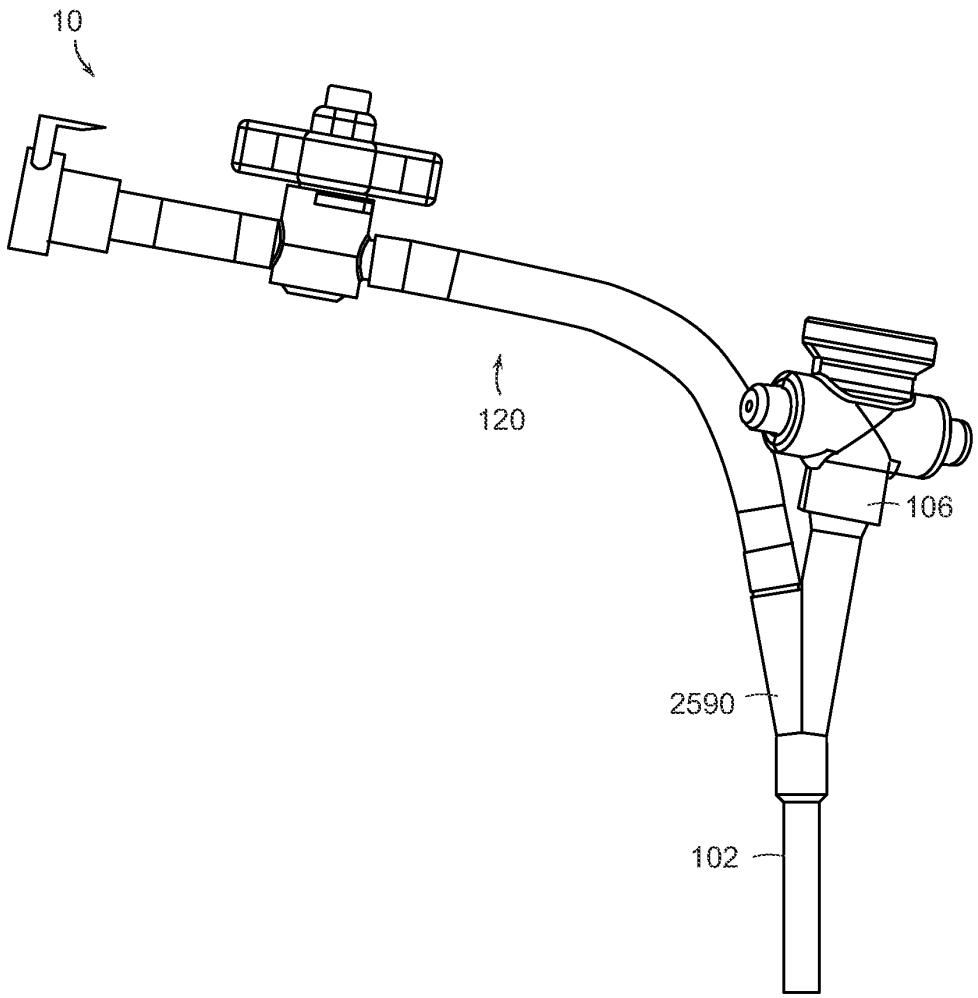


FIG. 25

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/167,757, filed Feb. 10, 2023, which is a continuation of U.S. patent application Ser. No. 17/976,711, filed Oct. 28, 2022, which is a continuation of U.S. patent application Ser. No. 17/865,315, filed Jul. 14, 2022, which is a continuation of U.S. patent application Ser. No. 16/536,185, filed Aug. 8, 2019, and issued as U.S. Pat. No. 11,559,382, which claims the benefit of U.S. Provisional Patent Application No. 62/718,269, filed on Aug. 13, 2018, and U.S. Provisional Patent Application No. 62/718,248, filed on Aug. 13, 2018, each of which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

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

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.

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.

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.

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.

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.

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.

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.

Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

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.

FIG. **1** is a partially schematic side view of a clot removal system configured in accordance with the present technology.

FIG. **2** is a side view of a locking syringe configured in accordance with the present technology.

FIG. **3**A is a side view of a locking syringe configured in accordance with the present technology.

FIG. **3**B is a side view of an adaptor for connecting the locking syringe of FIG. **3**A to the clot removal system of FIG. **1** configured in accordance with the present technology.

FIG. **3**C is a side view of the adaptor of FIG. **3**B coupled to the locking syringe of FIG. **3**A.

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FIG. **3**D is a side view of the locking syringe of FIG. **3**A coupled to the clot removal system of FIG. **1** via the adaptor of FIG. **3**B.

FIG. **4**A is a perspective side view of another pressure source configured in accordance with the present technology, and FIGS. **4**B and **4**C are enlarged schematic side views of the pressure source of FIG. **4**A during operation.

FIG. **5** is a cross-sectional side view of an automatic release syringe configured in accordance with the present technology.

FIG. **6** is a perspective top view of a syringe configured in accordance with the present technology.

FIG. **7** is a side view of an over-wire locking syringe configured in accordance with the present technology.

FIG. **8** is a flow diagram of a process or method for operating a clot removal system in accordance with the present technology.

FIGS. **9**A-**9**C are side views of a proximal portion of the clot removal system of FIG. **1** during a clot removal procedure using the locking syringe of FIG. **3** in accordance with the present technology.

FIGS. **10**A and **10**B are schematic illustrations of a distal portion of the clot removal system of FIG. **1** during a clot removal procedure in accordance with the present technology.

FIG. **11** is a partially schematic side view of another clot removal system configured in accordance with the present technology.

FIG. **12** is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

FIGS. **13**A-**14**C are schematic illustrations of a distal portion of the clot removal system of FIG. **11** during a clot removal procedure in accordance with the present technology.

FIG. **15** is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

FIGS. **16**A-**16**E are schematic illustrations of a distal portion of the clot removal system of FIG. **11** during a clot removal procedure in accordance with the present technology.

FIG. **17** is a partially schematic side view of another clot removal system configured in accordance with the present technology.

FIGS. **18**A-**18**H are side views of a distal portion of the clot removal system shown of FIG. **17** during a clot removal procedure in accordance with the present technology.

FIG. **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.

FIG. **20**A is a partially-exploded side view of a filter device and pressure source configured in accordance with the present technology.

FIG. **20**B is a perspective side view of the syringe of FIG. **20**A coupled to the filter device of the FIG. **20**A.

FIG. **20**C is a side view of the filter device and syringe of FIG. **20**B coupled to the clot removal system of FIG. **1**.

FIGS. **20**D and **20**E are side views of the syringe of FIG. **20**A coupled to the clot removal system of FIG. **1** for reintroducing blood to a patient.

FIG. **21**A is a partially-exploded side view of a filter device, a pressure source, and a reinfusion syringe configured in accordance with the present technology.

FIG. **21**B is a perspective side view of the filter device of FIG. **21**A coupled to the pressure source and the reinfusion syringe of FIG. **21**A.

FIG. **22** is a partially-exploded side view of a filter device configured in accordance with the present technology.

FIG. **23** is a partially-exploded side view of a filter device configured in accordance with the present technology.

FIG. **24** is an enlarged isometric view of the clot removal system of FIG. **1** configured in accordance with the present technology.

FIG. **25** is an enlarged isometric view of the clot removal system of FIG. **1** configured in accordance with the present technology.

DETAILED DESCRIPTION

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.

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.

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 FIGS. **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 FIGS. **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 FIGS. **1-25**.

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.

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

FIG. **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 **103***a* and a proximal portion **103***b*. The catheter subsystem **100** further includes a valve **106** that can be integral with or coupled to the proximal portion **103***b* of the catheter **102**.

In the illustrated embodiment, the valve **106** includes a distal portion **107***a*, a proximal portion **107***b*, and a lumen **109** extending therethrough from the distal portion **107***a* to the proximal portion **107***b*. The valve **106** further includes a flow controller (obscured in FIG. **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 FIGS. **11-16**E), 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 Ser. No. 16/117,519, filed Aug. 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 **107***b* 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. Pat. No. 9,526,864, filed Jun. 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.

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 **124***a* and a second tubing section **124***b*), 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 **124***a* and (ii) the connector **128** via the second tubing section **124***b*. 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 **124***a*, and/or a diameter of the second tubing section **124***b*.

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 **124***a* and/or the tubing section **124***b*. 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 FIG. **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 **103***a* of the catheter **102**.

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.

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 FIGS. **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 **103***a* 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 **103***a* 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

As described in detail above with reference to FIG. **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.

FIG. **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 FIG. **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**.

Referring to both FIGS. **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.

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.

FIG. **3**A 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 FIG. **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 FIG. **3**A (and FIG. **3**C) 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.

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 FIGS. **2** and **3**A 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.

FIG. **3**B 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. FIG. **3**C is a side view of the adaptor **350** coupled to the syringe **340**, and FIG. **3**D 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 FIG. **3**C for the sake of illustration. Referring to FIG. **3**B, the, 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.

Referring to FIGS. **3**A-**3**D 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 snuggly 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**.

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**.

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** (FIG. **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

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
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

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
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

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 **103***a* 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).

Moreover, as shown in FIG. **3**D, 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 **103***a* 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 **103***a* 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).

FIG. **4**A is a side perspective view a pressure source **400** including the syringe **340** ("primary syringe **340**") shown in FIGS. **3**A-**3**D 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.

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**.

FIGS. **4**B and **4**C are enlarged schematic side views of the pressure source **400** during operation. More specifically, FIGS. **4**B and **4**C 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 FIGS. **4**A and **4**B 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** (FIG. **1**), and/or the tubing subsystem **120** (FIG. **1**) into the secondary syringe **460**. This flow path is indicated by the arrows R in FIG. **4**B. Referring to FIGS. **4**A and **4**C 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 FIG. **4**C.

Referring to FIGS. **1** and **3**A-**4**C 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 FIG. **3**D). When the pressure source is coupled to the tubing subsystem **120**, retraction of the plunger **462** of the secondary syringe **460** evacuates an evacuatable 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.

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.

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**.

In some embodiments, (e.g., as described in greater detail below with reference to FIG. **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 FIGS. **4**B and **4**C. 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 FIGS. **4**B and **4**C.

FIG. **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 FIG. **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 FIGS. **2** and **3**A-**3**D. 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 FIGS. **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.

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**.

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.

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**.

FIG. **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 FIGS. **2**-**3**D 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 FIG. **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**.

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**.

Referring again to FIG. **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 **103***a* 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 **107***b* 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, FIG. **24** is an enlarged isometric view of the assembly **10** showing the pressure source **340** coupled directly to the proximal portion **107***b* 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 FIG. **24**, any of the pressure sources described in detail above with reference to FIGS. **2-6** can be configured to be coupled to the proximal portion **107***b* 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, FIG. **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**.

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 **107***b* 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, FIG. **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 FIG. **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 FIG. **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 **107***b* 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**.

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** (FIGS. **4A-4C**) can be coupled via one or more one-way valves to the syringes **240**, **540**, **640** or **740** (FIGS. **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** (FIG. **2**) and the syringe **340** (FIG. **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

FIG. **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. FIGS. **9A-9C** are side views of a proximal portion of the assembly **10**, and FIGS. **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, FIGS. **9A-9C** are side views of the assembly **10** including the syringe **340** and adaptor **350** (FIGS. **3A-3D**), and FIGS. **10A** and **10B** are side views of the catheter **102** with the distal portion **103***a* 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 FIGS. **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 FIGS. **2-7**.

At block **802**, the method **800** includes positioning the distal portion **103***a* 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 FIG. **10A**, a distal terminus of the distal portion **103***a* 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.

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 A**1**) to a position proximate to the clot material PE as illustrated in FIG. **10**A.

In some embodiments, to confirm the position of the distal portion **103***a* 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 **103***a* 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 **103***a* 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 **103***a* of the catheter is not fully engaged with the clot material PE. Accordingly, to locate the distal portion **103***a* of the catheter **102** just proximal of the clot material PE, the operator can (i) first determine that distal portion **103***a* 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 **103***a* 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 **103***a* 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.

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.

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 FIG. **9**A, the tip **347** (shown in FIGS. **3**A and **3**C but obscured in FIG. **9**A) 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 FIG. **9**A.

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 FIG. **9**B, 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** (FIGS. **4**A-**4**C) 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.

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 FIG. **9**C, 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 FIG. **10**B, application of the vacuum causes suction at the distal tip **103***a* of the catheter **102** (e.g., as indicated by arrow A**2**) 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 **103***a* 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. FIG. 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.

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).

Sometimes, as shown in FIG. 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.

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.

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 (FIGS. 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 FIGS. 15-16E, a second clot removal assembly can be telescoped through the first assembly 10 to facilitate removal of the clogged clot material PE.

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. Pat. No. 9,526,864, filed Jun. 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Pat. No. 8,784,434, filed Mar. 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 (FIG. 10B) after a first aspiration pass.

IV. Selected Embodiments of Telescoping Clot Removal Systems and Associated Methods of Clot Removal

FIG. 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 FIGS. 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**.

The first and second catheters **1002**, **1102** each comprise an elongated shaft defining a lumen **1004**, **1104** and having a distal portion **1003***a*, **1103***a*, respectively. The first and second valves **1006**, **1106** each include (i) a distal portion **1007***a*, **1107***a*, (ii) a proximal portion **1007***b*, **1107***b*, (iii) a lumen **1009**, **1109** extending therethrough, and (iv) a flow controller (obscured in FIG. **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**.

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 **1103***a* 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 FIGS. **14**A-**14**C), 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.

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 FIGS. **1**-**10**B. 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 pressures sources **1040**, **1140** can be omitted, or the pressure sources **1040**, **1140** can be fluidly coupled and/or integrally formed.

FIG. **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. FIGS. **13**A-**13**C are schematic illustrations of a distal portion of the assemblies **20**, **30** during a clot removal procedure in accordance with the present technology. FIGS. **14**A-**14**C 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 FIGS. **11** and **13**A-**14**C 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.

At block **1282**, the method **1280** includes intravascularly positioning the first catheter **1002** within a human patient. FIG. **13**A, for example, illustrates the first catheter **1002** after it has been advanced (e.g., as indicated by arrow A**1**) 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 **1003***a* 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 **1003***a* 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 FIG. **8**.

At block **1284**, the method **1280** includes advancing the second catheter **1102** through the first catheter **1002** until the distal portion **1103***a* 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 **1103***a* of the second catheter **1102** through the first valve **1006** before advancing the second catheter **1102** (e.g., as indicated by the arrow A**1**) 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 **1103***a* 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.

FIG. **13**A 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 FIG. **13**A, 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.

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 FIGS. **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**).

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**.

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 FIG. **13**B, application of the vacuum causes suction (e.g., as indicated by arrow A**2**) 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 **1103***a* 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 **1103***a* of the second catheter **1102** compared to simply activating the second pressure source **1140** while it is fluidly connected to the second catheter **1102**.

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 **1003***a* 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 **1003***a* 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.

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 Ser. No. 16/258,344, filed Jan. 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.

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 FIG. **13**C, 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 A**3**) at the distal portion **1003***a* 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.

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 **1103***a* of the second catheter **1102**. FIG. **14**A, for example, is an enlarged view of the distal portion of the assemblies **20**, **30** shown in FIG. **13**C and illustrating a portion of the clot material PE stuck to or dangling from the distal portion **1103***a* 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**).

FIGS. **14**B and **14**C 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 FIG. **14**C, 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 A**4**). 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**.

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.

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 **1103***a* 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**).

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.

FIG. **15** is a flow diagram of another process or method **1580** for operating a clot removal system including the assemblies **20**, **30** (FIG. **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. FIG. **16**A is an enlarged side view of a distal portion of the first assembly **20**, and FIGS. **16**B-**16**E 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 FIGS. **11** and **16**A-**16**E 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.

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 FIGS. **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 FIGS. **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 **1003***a* of the first catheter **1002**.

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**). FIG. **16**A, 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 **1003***a* 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 FIG. **8**).

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 **1103***a* of the second catheter **1102** is positioned in or proximate to the clogging clot material PE. For example, FIG. **16**B 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 **1103***a* of the second catheter **1102** through the first valve **1006** (FIG. **11**) before advancing the second catheter **1102** through the lumen **1004** of the first catheter **1002**.

At block **1594**, the method **1580** includes activating the second pressure source **1140** (FIG. **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 FIGS. **2-7**) can be coupled to the second catheter **1102** via the second fluid control device **1126** (FIG. **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.

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**. FIG. **16**C, for example, illustrates a portion of the clot material PE stuck to or extending from the distal portion **1103***a* of the second catheter **1102** after aspirating the second catheter **1102**. In the embodiment illustrated in FIG. **16**C, 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**.

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, FIG. **16**D 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**. FIG. **16**E, 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 A**5**).

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**.

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

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.

FIG. **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 FIG. **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.

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 FIG. **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 FIGS. **18**E and **18**F, 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 Apr. 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

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, FIG. **17** shows the system **1700** after (i) advancing the sheath **1702** to a position proximate to a proximal portion **1785***b* 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 **1785***a* of the clot material DV), and (iv) expanding the interventional device **1790** from the compressed delivery state to the deployed state.

FIGS. **18**A-**18**H are enlarged views of a distal portion of the system **1700** during a clot removal procedure in accordance with the present technology. In general, FIGS. **18**A-**18**H 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**.

Referring first to FIG. **18**A, proximal retraction of the interventional device **1790** causes the coring element **1792** to separate and/or core the distal end portion **1785***a* of the clot material DV from the walls W of the blood vessel BV. As shown in FIG. **18**B, continued proximal retraction of the interventional device **1790** through the clot material DV causes the cylindrical element **1794** to capture the distal end portion **1785***a* of the clot material therein. FIGS. **18**C-**18**E 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 FIG. **18**E, the proximal end portion **1785***b* 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 FIG. **18**E, a first radiopaque marker **1887***a* can be positioned on a distal end portion of the inner shaft **1884** and a second radiopaque marker **1887***b* can be positioned on a distal end portion of the sheath **1702**.

In some embodiments, as shown in FIG. **18**F, 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** (FIG. **18**E). 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 **1885***a*) relative to the distal end portion of the sheath **1702** (e.g., the second radiopaque marker **1885***b*). 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**.

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 FIG. **18**G. As shown in FIG. **18**H, 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** (FIG. **17**), and from the patient's body.

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 FIG. **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 FIGS. **18**G and **18**H, application of the vacuum can generate instantaneous or nearly instantaneous suction (e.g., as indicated by arrows A**6**) 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

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. FIGS. **19**-**20**E 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.

For example, FIG. **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 FIGS. **4**A-**4**C. 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** (FIGS. **4**A-**4**C). 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** (FIG. **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**).

In the illustrated embodiment, the canister **1940** further includes a filter **1942**. The canister **1940** is shown as transparent in FIG. **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**.

FIGS. **20**A-**20**E 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 FIGS. **2**-**7**. For example, FIG. **20**A is a partially-exploded side view of the filter device **2050** and the pressure source **340** (FIGS. **3**A-**3**D). 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 FIG. **20**C). 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.

FIG. **20**B 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 FIG. **20**B (and FIGS. **20**C-**20**E) 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.

FIG. **20**C 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 FIG. **20**C, 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.

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, FIGS. **20**D and **20**E 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 FIG. **20**D, 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 FIG. **20**E, 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 FIGS. **20**A-**20**E 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**).

FIGS. **21**A and **21**B 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 FIGS. **2**-**7**. For example, FIG. **21**A is a partially-exploded side view of the filter device **2150** and the pressure source **340** (FIGS. **3**A-**3**D). 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.

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 **2124***a* and a second tubing section **2124***b*), 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**.

In operation, during a clot removal procedure, the pressure source **340** can be decoupled from the connector **128** (FIG. **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, FIG. **21**B 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 FIGS. **21**A and **21**B 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** (FIG. **1**), an IV line (not shown), or another suitable connection point for reintroducing blood to the patient,

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 FIG. **21**B, 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.

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** (FIG. **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.

FIG. **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 FIGS. **2**-**7**. In general, the filter device **2250** is generally similar to the filter device **2150** described in detail with reference to FIGS. **21**A and **21**B. 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 FIGS. **3**A-**3**D). 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 FIG. **22**. In one aspect of the present technology, this arrangement makes the filter device more ergonomic during use.

FIG. **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 FIGS. **2**-**7**. The filter device **2350** is generally identical to the filter device **2250** described in detail with reference to FIG. **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.

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 FIGS. 2 and 4-7). In some embodiments, the filter devices can be formed as a component of the tubing subsystem 120 (FIG. 1). Moreover, the filter devices can include any number of filters and/or housings to provide any number of filtration stages.

CONCLUSION

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.

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.

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.

We claim:

1. A method of treating a pulmonary embolism within a vasculature of a patient, the method comprising:

advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism, wherein a lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister;

generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister; and

moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the pulmonary embolism and blood are aspirated into the clot canister, wherein in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister, and wherein the clot canister includes a filter configured to filter the blood from the portion of the pulmonary embolism.

2. The method of claim 1 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 16 French or greater through the vasculature.

3. The method of claim 1 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature.

4. The method of claim 1 wherein advancing the aspiration catheter includes advancing the aspiration catheter such that a distal end portion of the aspiration catheter is positioned proximate to the pulmonary embolism within a pulmonary artery of the patient.

5. The method of claim 1 wherein the method further comprises:

receiving the filtered blood through a fluid outlet of the clot canister; and

reintroducing the filtered blood into the vasculature of the patient.

6. The method of claim 1 wherein the method further comprises removing the filter from within the clot canister.

7. The method of claim 1 wherein the method further comprises removing the portion of the pulmonary embolism from within the clot canister.

8. The method of claim 7 wherein the method further comprises:

after removing the portion of the pulmonary embolism from within the clot canister, positioning the filter within the clot canister;

repeating generating vacuum pressure within the clot canister via the aspiration source while the valve is in the first position; and

repeating moving the valve from the first position to the second position thereby applying the vacuum pressure to the lumen of the aspiration catheter to aspirate at least another portion of the pulmonary embolism and additional blood into the clot canister.

9. The method of claim 1 wherein the valve comprises a lever, and wherein moving the valve from the first position to the second position includes rotating the lever.

10. The method of claim 1 wherein the method further comprises selectively providing fluid access to the lumen of the aspiration catheter via a hemostasis valve fluidly coupled to the aspiration catheter.

11. The method of claim 10 wherein selectively providing fluid access to the lumen of the aspiration catheter includes decreasing a tension on a filament of the hemostasis valve thereby providing fluid access to the lumen of the aspiration catheter and increasing the tension on the filament to inhibit fluid access to the lumen of the aspiration catheter.

12. The method of claim 11 wherein decreasing the tension on the filament includes depressing a button coupled to the hemostasis valve.

13. The method of claim 10 wherein the hemostasis valve is fluidly coupled to a proximal end portion of the aspiration catheter, and wherein the clot canister is fluidly coupled to the lumen of the aspiration catheter via a tube branching from the aspiration catheter distal to the proximal end portion of the aspiration catheter.

14. The method of claim 1 wherein the method further comprises:

positioning a clot treatment device within the lumen of the aspiration catheter; and

engaging a portion of the pulmonary embolism with the clot treatment device thereby disrupting the pulmonary embolism.

15. The method of claim **1** wherein the aspiration source is an electric pump.

16. The method of claim **1** wherein the clot canister has a first volume, and wherein the aspiration source has a second volume greater than the first volume.

17. The method of claim **1** wherein the filter has a generally tubular shape.

18. The method of claim **1** wherein advancing the aspiration catheter comprises inserting through the vasculature an aspiration catheter having a size of 16 French or greater and an inner diameter, and wherein the fluid path from the aspiration catheter through the valve to the clot canister has a diameter that is the same as or greater than the inner diameter.

19. The method of claim **1** wherein the aspiration source has a volume of 60 cubic centimeters or greater.

20. A method of treating a deep vein thrombosis within a vasculature of a patient, the method comprising:

advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the deep vein thrombosis, wherein a lumen of the aspiration catheter is fluidly coupled along a fluid path to a clot canister and an aspiration source proximal to the clot canister;

generating vacuum pressure within the clot canister via the aspiration source while a valve positioned along the fluid path between the aspiration catheter and the clot canister is in a first position that inhibits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister; and

moving the valve from the first position to a second position thereby applying the vacuum pressure to the lumen of the aspiration catheter such that at least a portion of the deep vein thrombosis and blood are aspirated into the clot canister, wherein in the second position the valve permits fluid flow along the fluid path from the lumen of the aspiration catheter to the clot canister, and wherein the clot canister includes a filter configured to filter the blood from the portion of the deep vein thrombosis.

21. The method of claim **20** wherein advancing the aspiration catheter comprises inserting a catheter having a size of 16 French or greater through the vasculature.

22. The method of claim **20** wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature.

23. The method of claim **20** wherein advancing the aspiration catheter includes advancing the aspiration catheter such that a distal end portion of the aspiration catheter is positioned proximate to the deep vein thrombosis within a peripheral vasculature of the patient.

24. The method of claim **20** wherein the method further comprises:

receiving the filtered blood through a fluid outlet of the clot canister; and

reintroducing the filtered blood into the vasculature of the patient.

25. The method of claim **20** wherein the method further comprises removing the filter from within the clot canister.

26. The method of claim **20** wherein the method further comprises removing the portion of the deep vein thrombosis from within the clot canister.

27. The method of claim **26** wherein the method further comprises:

after removing the portion of the deep vein thrombosis from within the clot canister, positioning the filter within the clot canister;

repeating generating vacuum pressure within the clot canister via the aspiration source while the valve is in the first position; and

repeating moving the valve from the first position to the second position thereby applying the vacuum pressure to the lumen of the aspiration catheter to aspirate at least another portion of the deep vein thrombosis and additional blood into the clot canister.

28. The method of claim **20** wherein the valve comprises a lever, and wherein moving the valve from the first position to the second position includes rotating the lever.

29. The method of claim **20** wherein the method further comprises selectively providing fluid access to the lumen of the aspiration catheter via a hemostasis valve fluidly coupled to the aspiration catheter.

30. The method of claim **20** wherein selectively providing fluid access to the lumen of the aspiration catheter includes decreasing a tension on a filament of the hemostasis valve thereby providing fluid access to the lumen of the aspiration catheter and increasing the tension on the filament to inhibit fluid access to the lumen of the aspiration catheter.

31. The method of claim **30** wherein decreasing the tension on the filament includes depressing a button coupled to the hemostasis valve.

32. The method of claim **30** wherein the hemostasis valve is fluidly coupled to a proximal end portion of the aspiration catheter, and wherein the clot canister is fluidly coupled to the lumen of the aspiration catheter via a tube branching from the aspiration catheter distal to the proximal end portion of the aspiration catheter.

33. The method of claim **20** wherein the method further comprises:

positioning a clot treatment device within the lumen of the aspiration catheter; and

engaging a portion of the deep vein thrombosis with the clot treatment device thereby disrupting the deep vein thrombosis.

34. The method of claim **20** wherein the aspiration source is an electric pump.

35. The method of claim **20** wherein the clot canister has a first volume, and wherein the aspiration source has a second volume greater than the first volume.

36. The method of claim **20** wherein the filter has a generally tubular shape.

37. The method of claim **20** wherein advancing the aspiration catheter comprises inserting through the vasculature an aspiration catheter having a size of 16 French or greater and an inner diameter, and wherein the fluid path from the aspiration catheter through the valve to the clot canister has a diameter that is the same as or greater than the inner diameter.

38. The method of claim **20** wherein the aspiration source has a volume of 60 cubic centimeters or greater.

* * * * *

EXHIBIT D

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Merritt et al.

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(54) **SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS**

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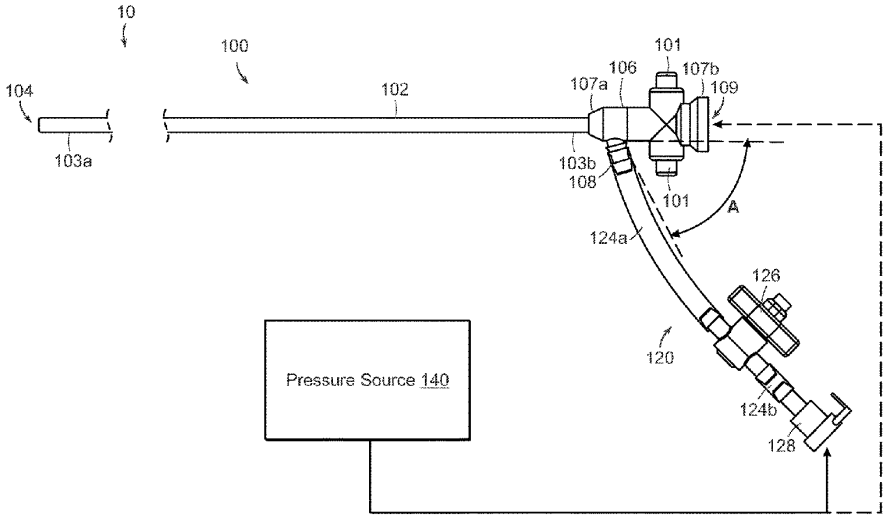
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(57) **ABSTRACT**

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.

15 Claims, 38 Drawing Sheets



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See application file for complete search history.

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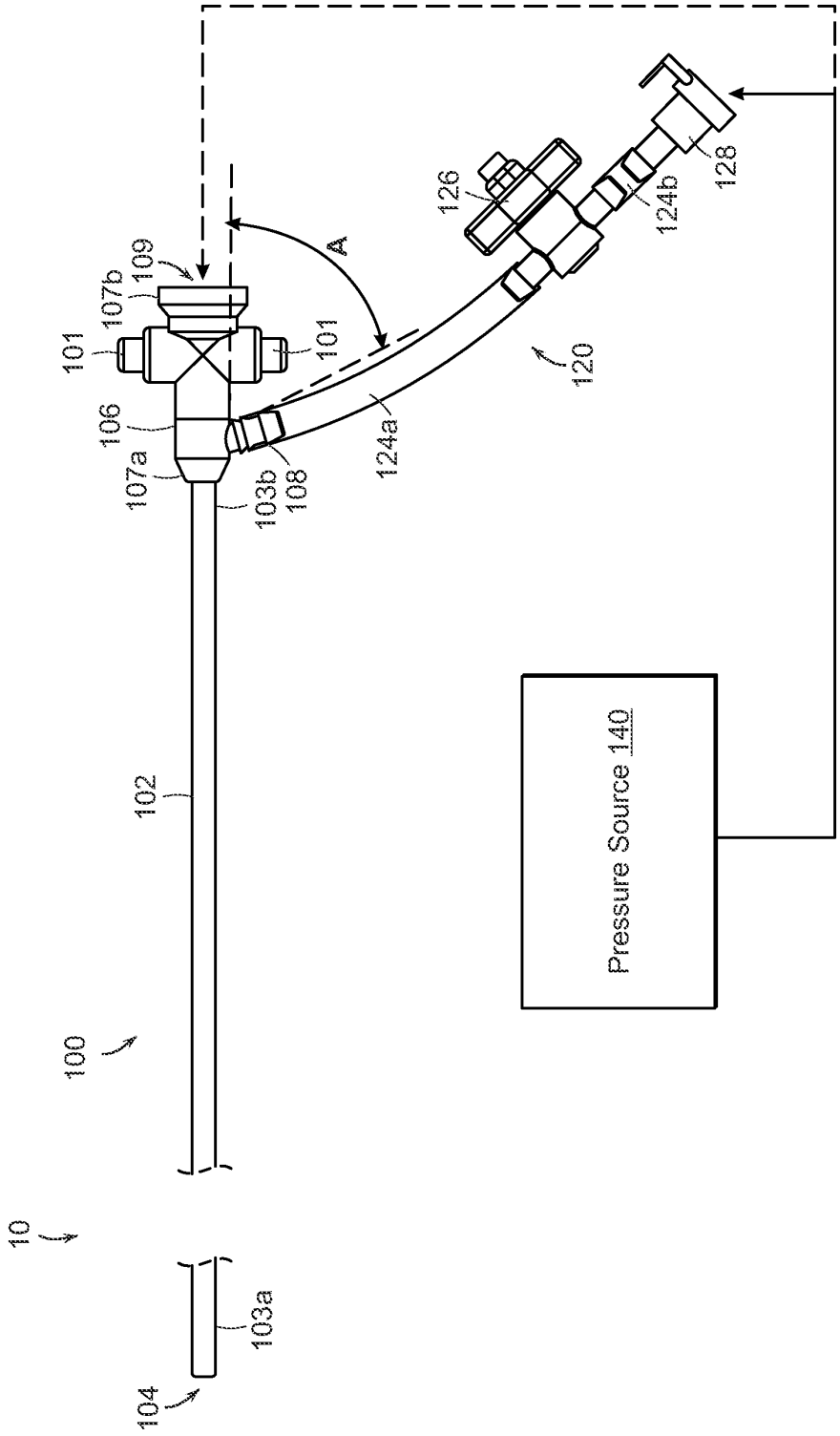

A
126
124b
128
109
107b
101
101
120
106
124a
107a
103b
108
102
100
10
103a
104
Pressure Source 140

FIG. 1

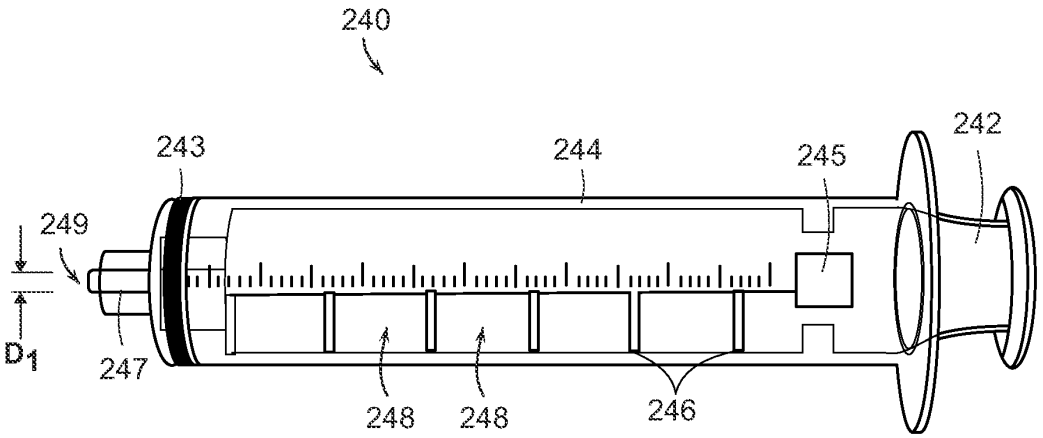

240
243
244
245
242
249
D_1
247
248
248
246

FIG. 2

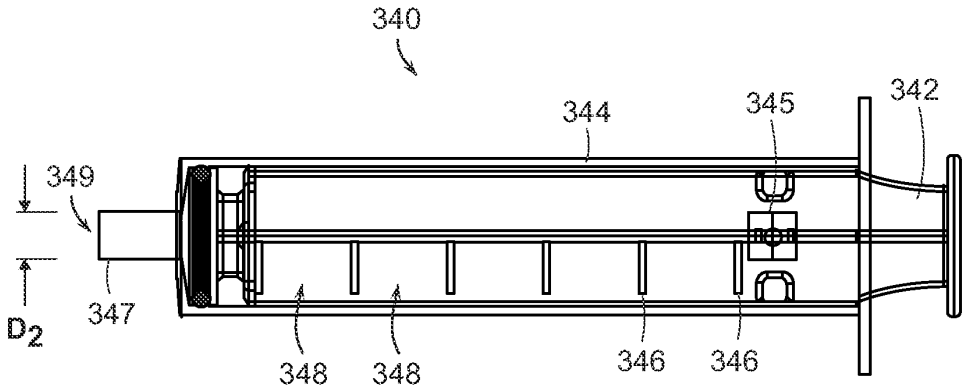

340
344
345
342
349
D_2
347
348
348
346
346

FIG. 3A

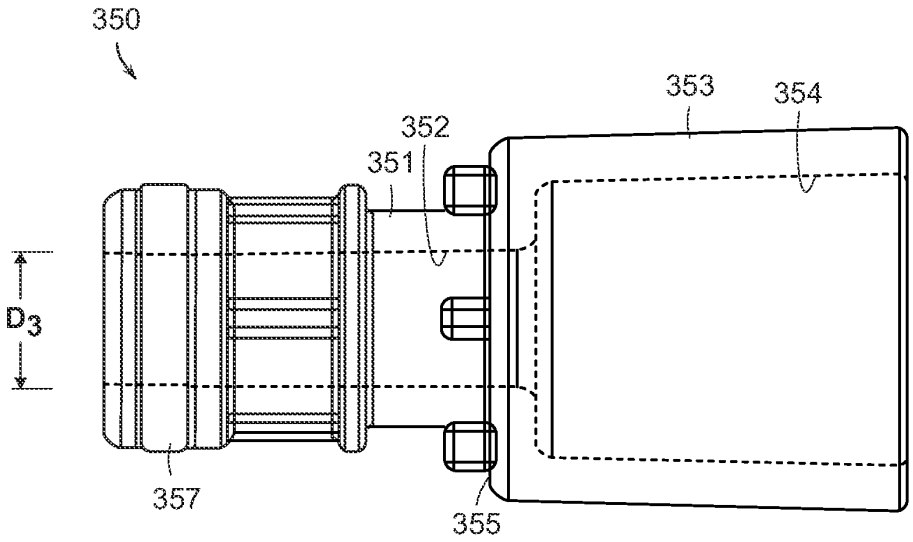


FIG. 3B

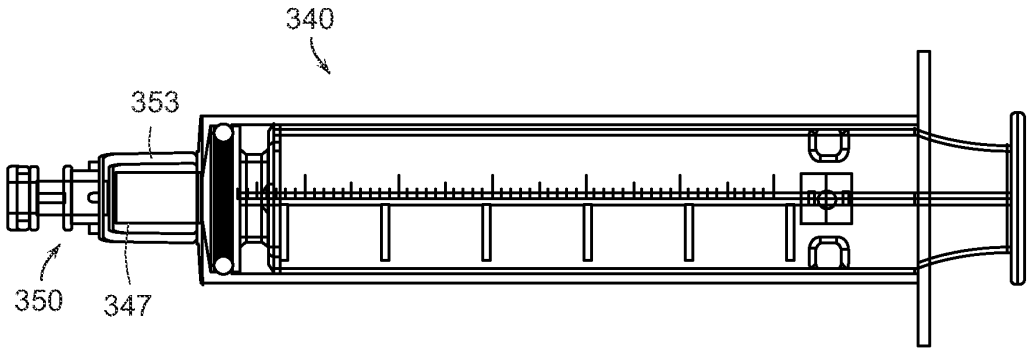


FIG. 3C

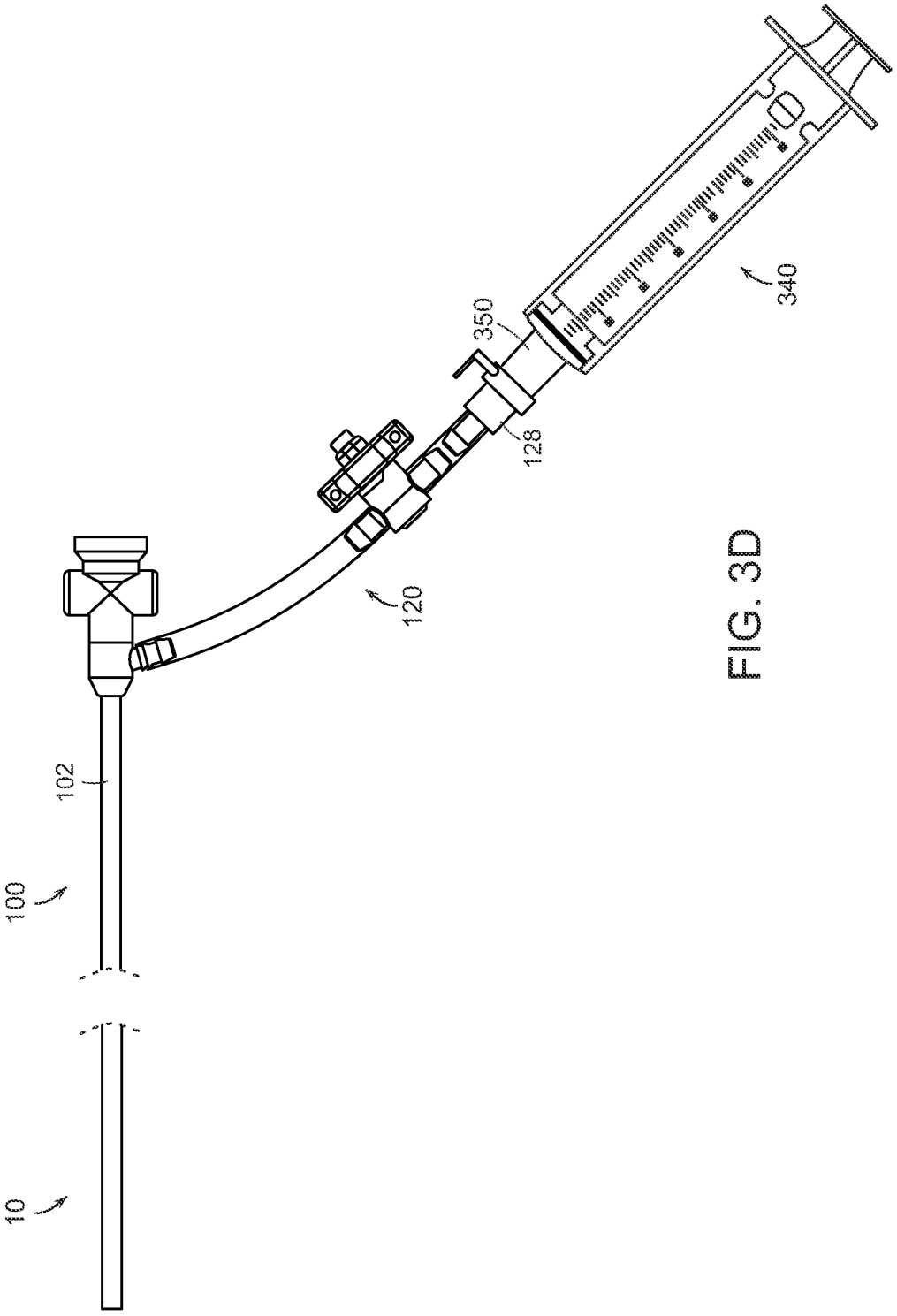
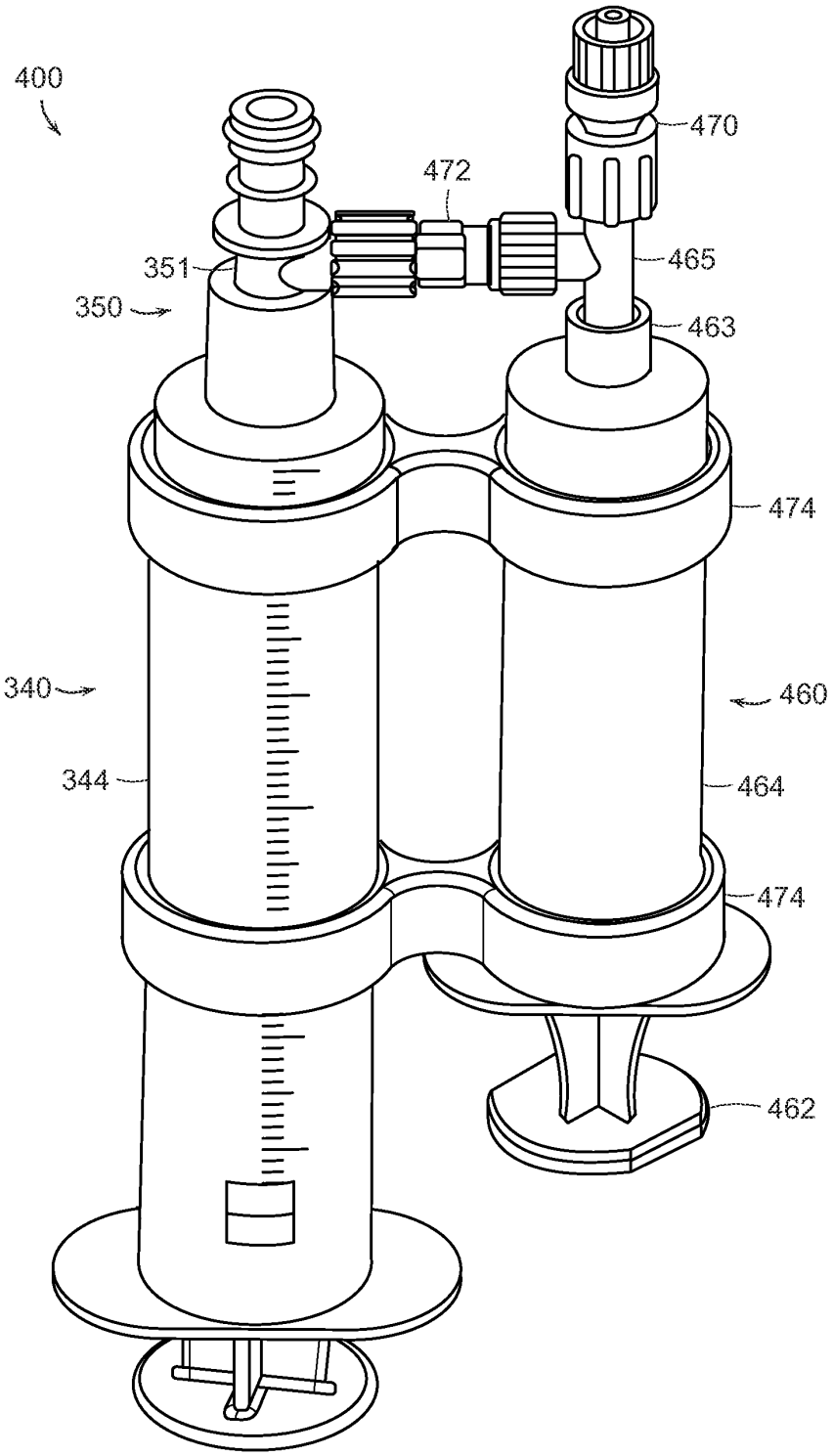


FIG. 3D

FIG. 4A



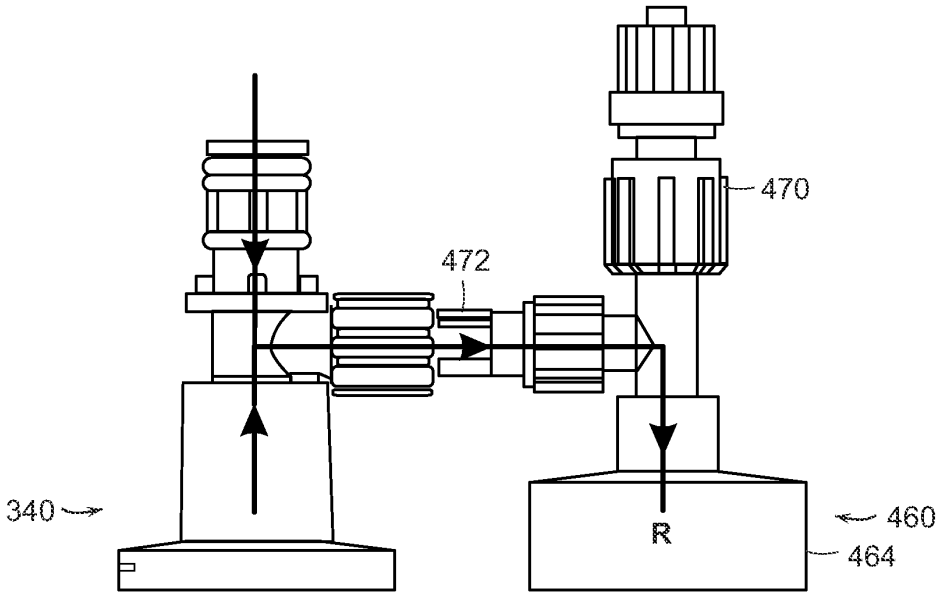


FIG. 4B

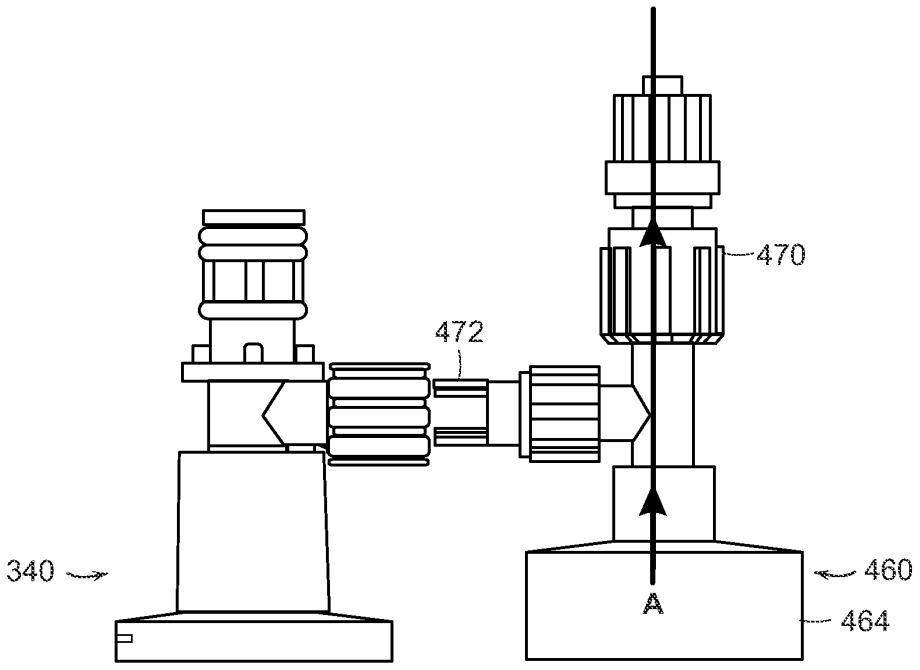


FIG. 4C

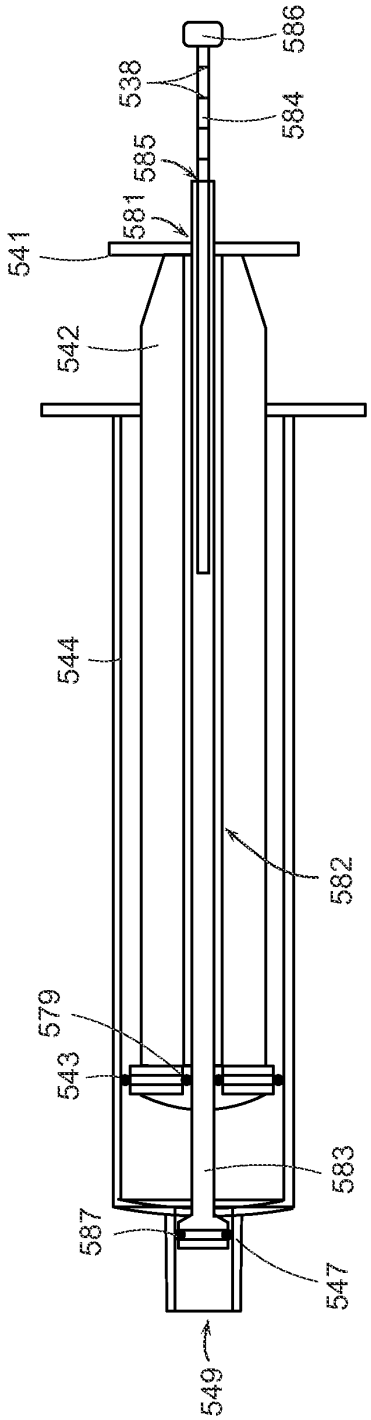


FIG. 5

FIG. 6

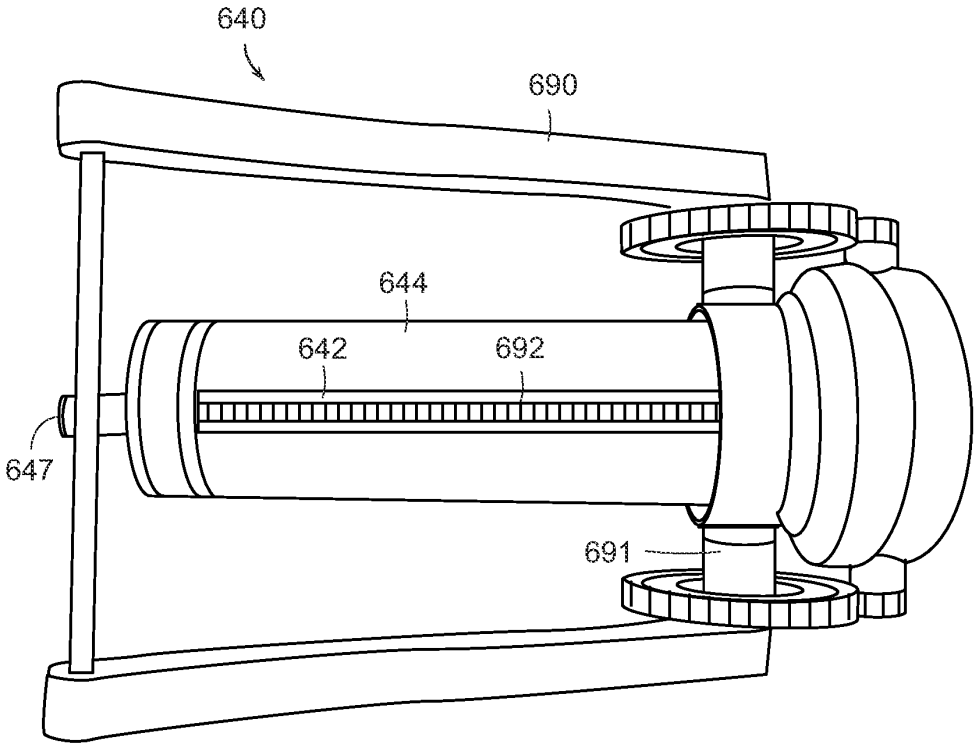
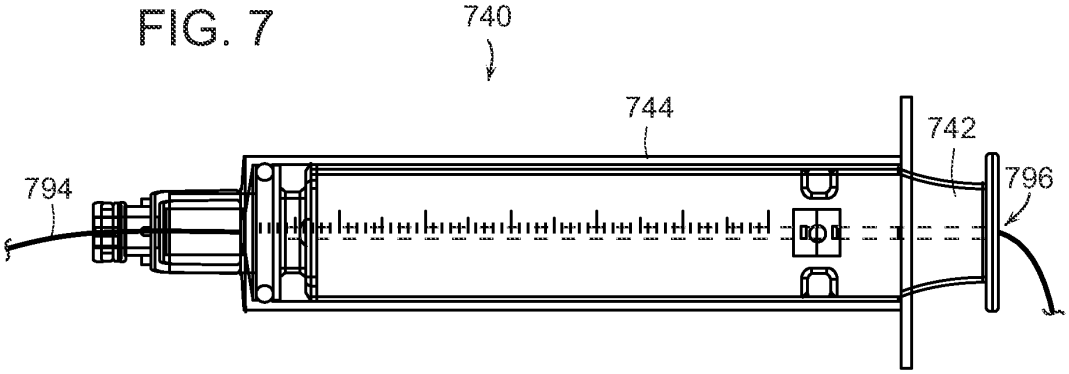


FIG. 7



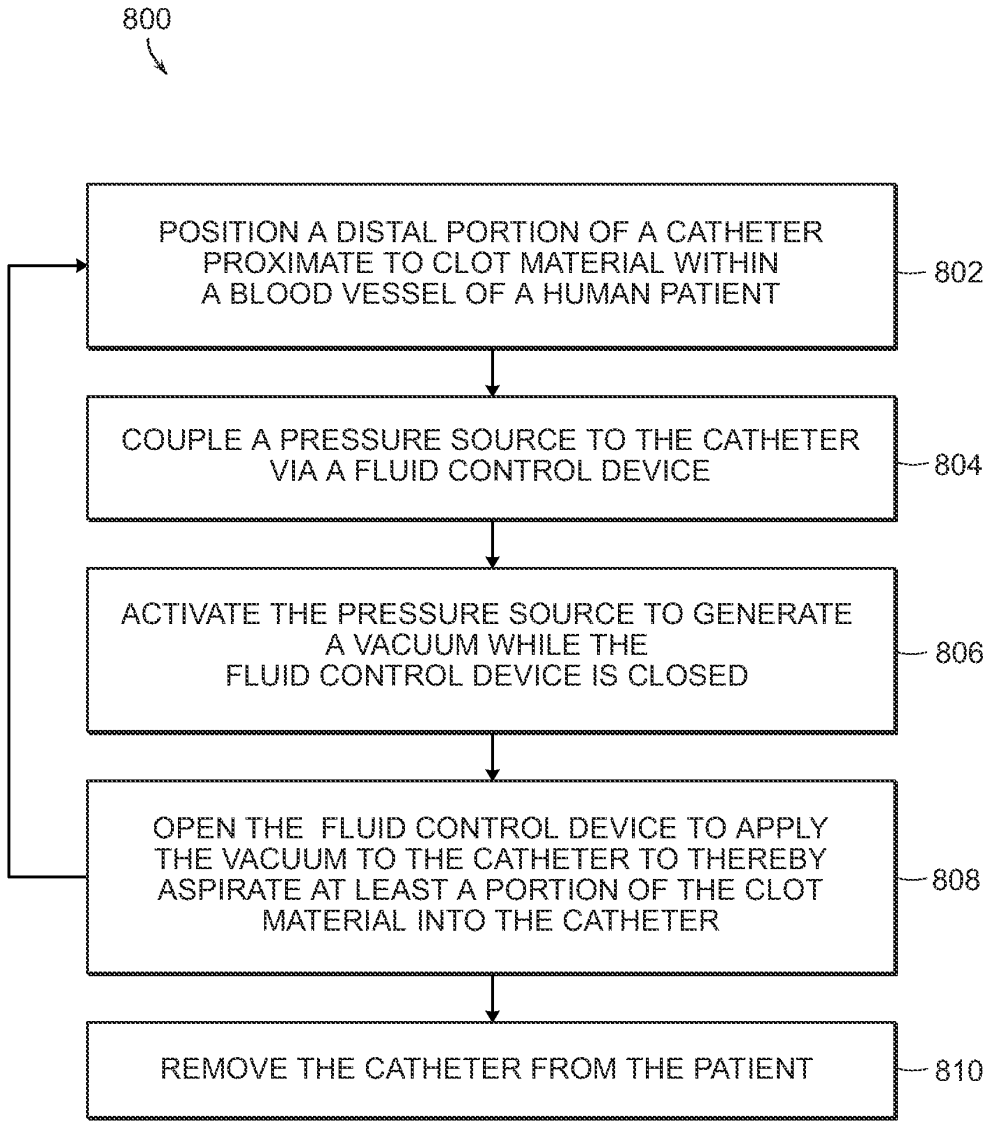

800
POSITION A DISTAL PORTION OF A CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF A HUMAN PATIENT
802
COUPLE A PRESSURE SOURCE TO THE CATHETER VIA A FLUID CONTROL DEVICE
804
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
806
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE CATHETER
808
REMOVE THE CATHETER FROM THE PATIENT
810

FIG. 8

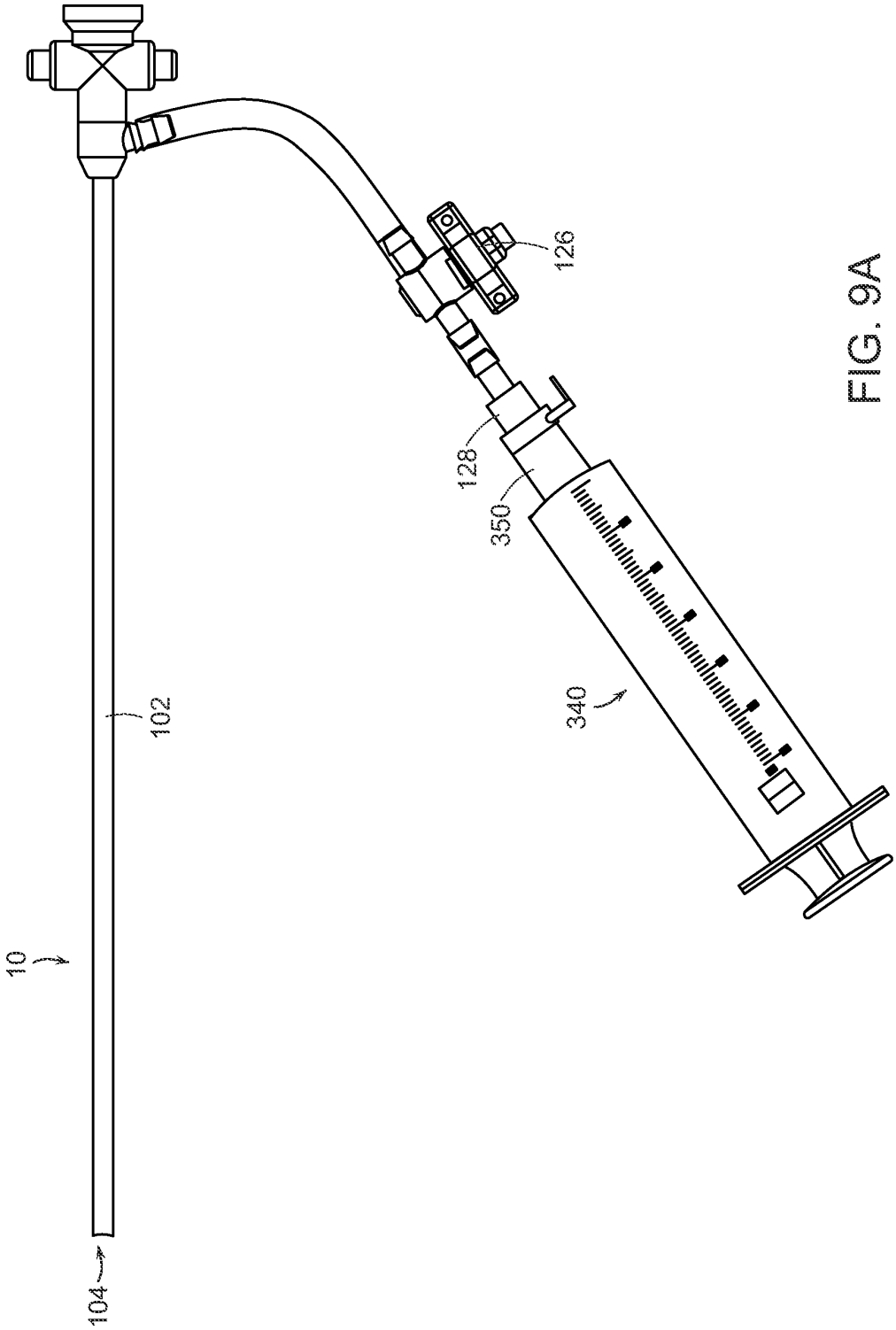


FIG. 9A

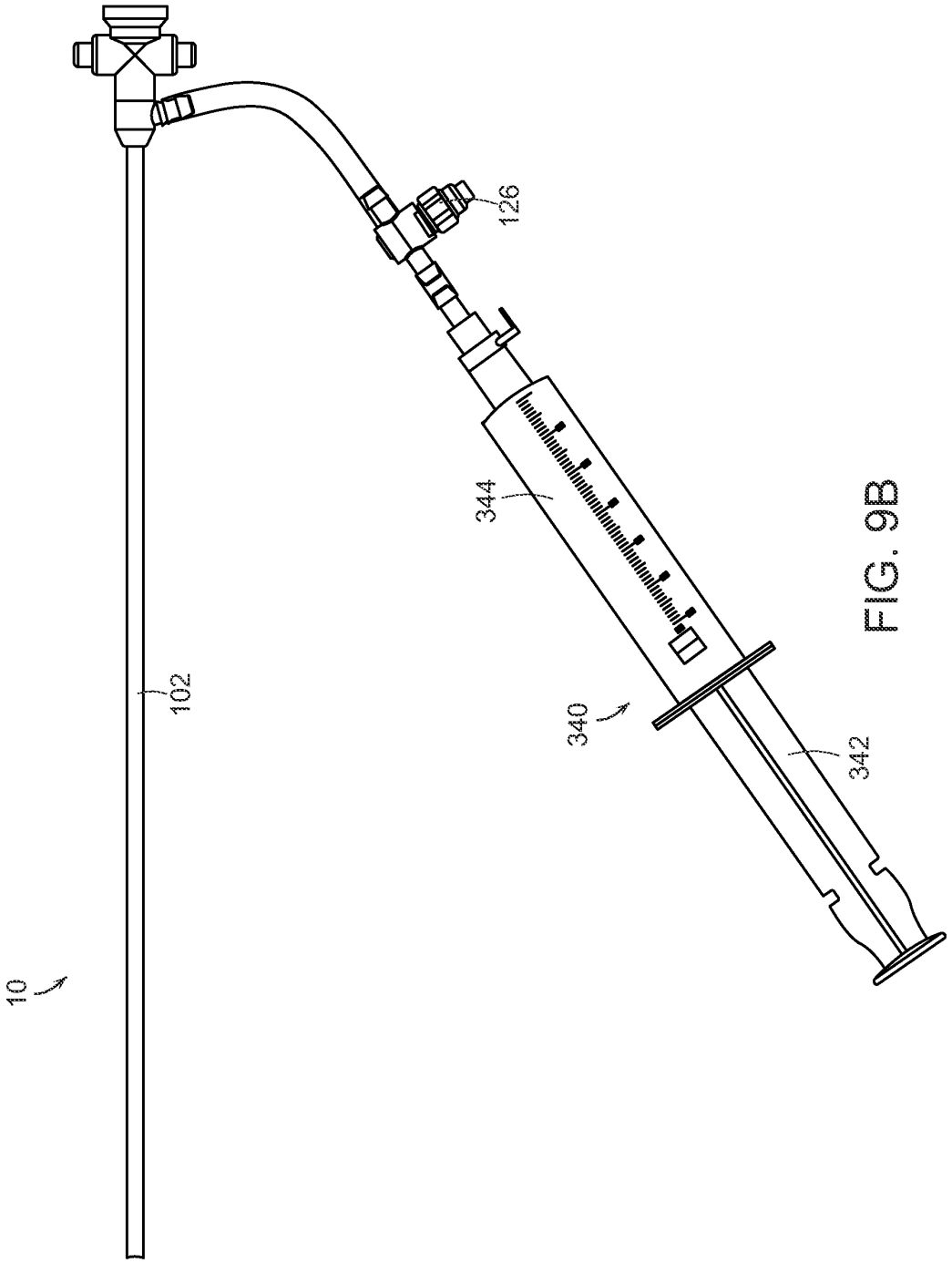


FIG. 9B

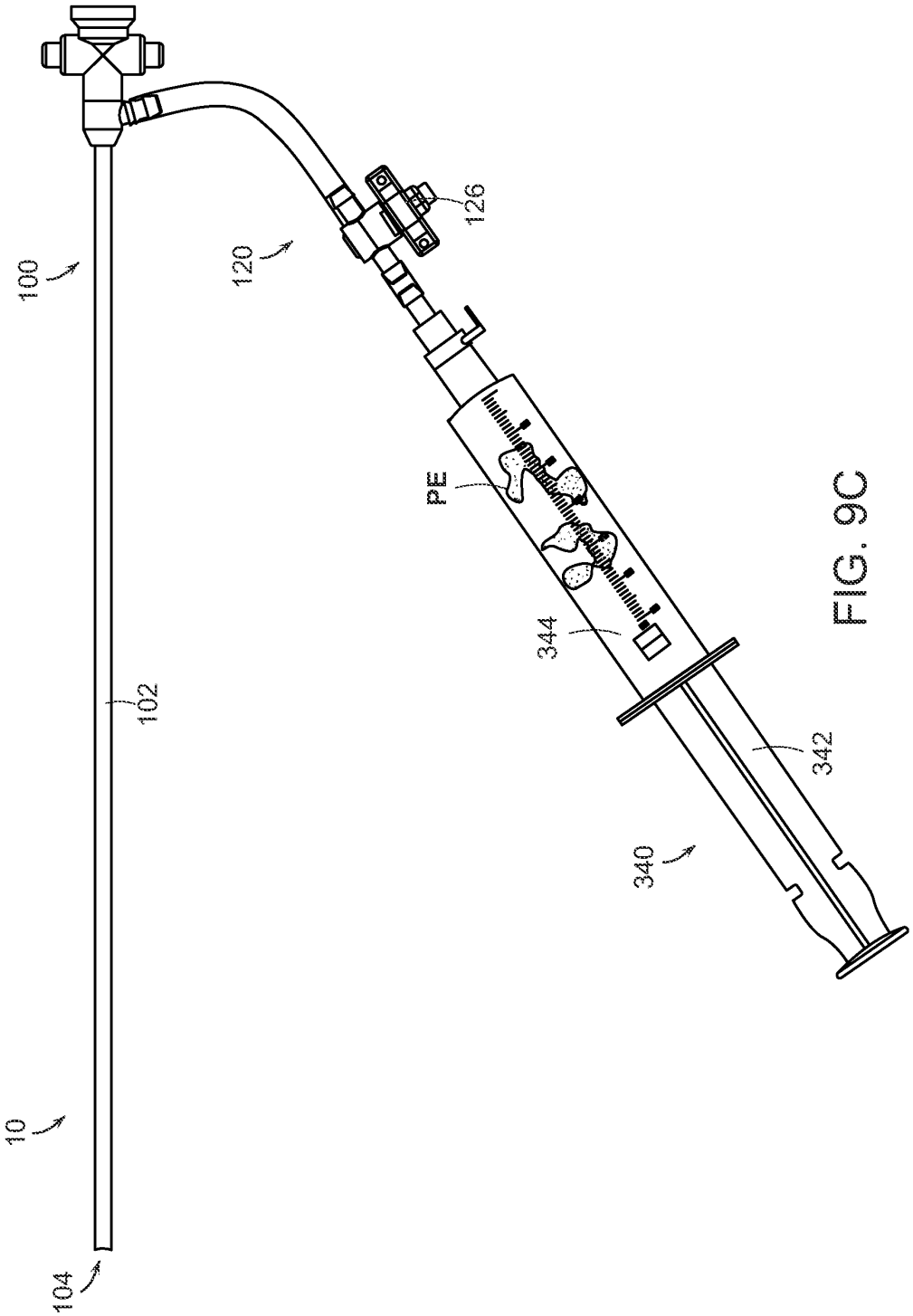


FIG. 9C

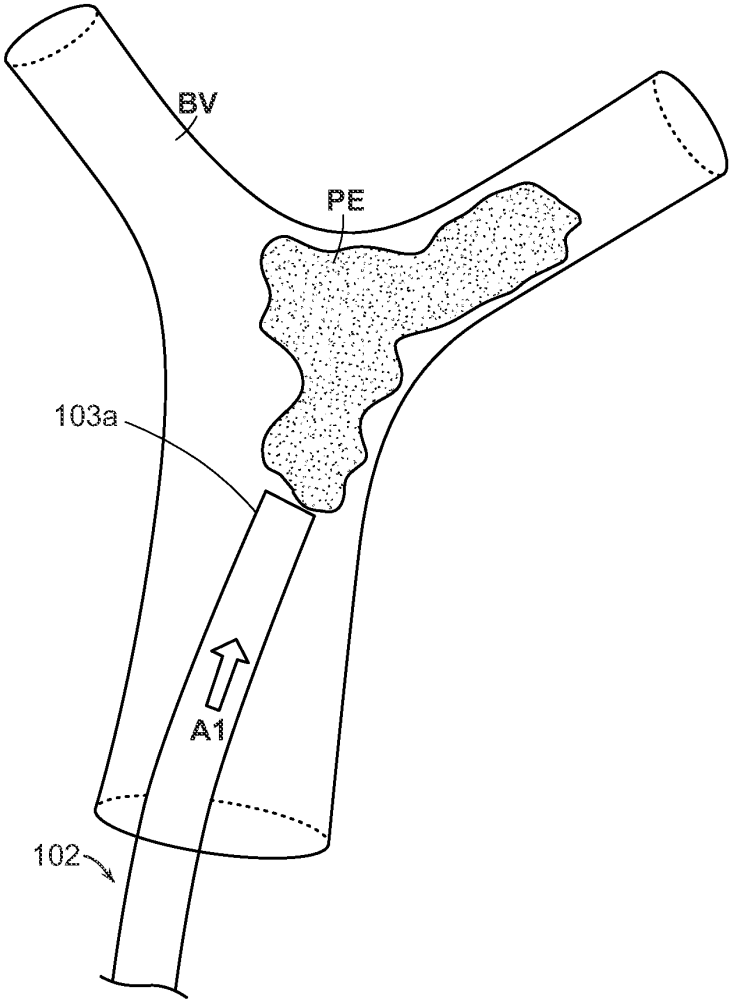


FIG. 10A

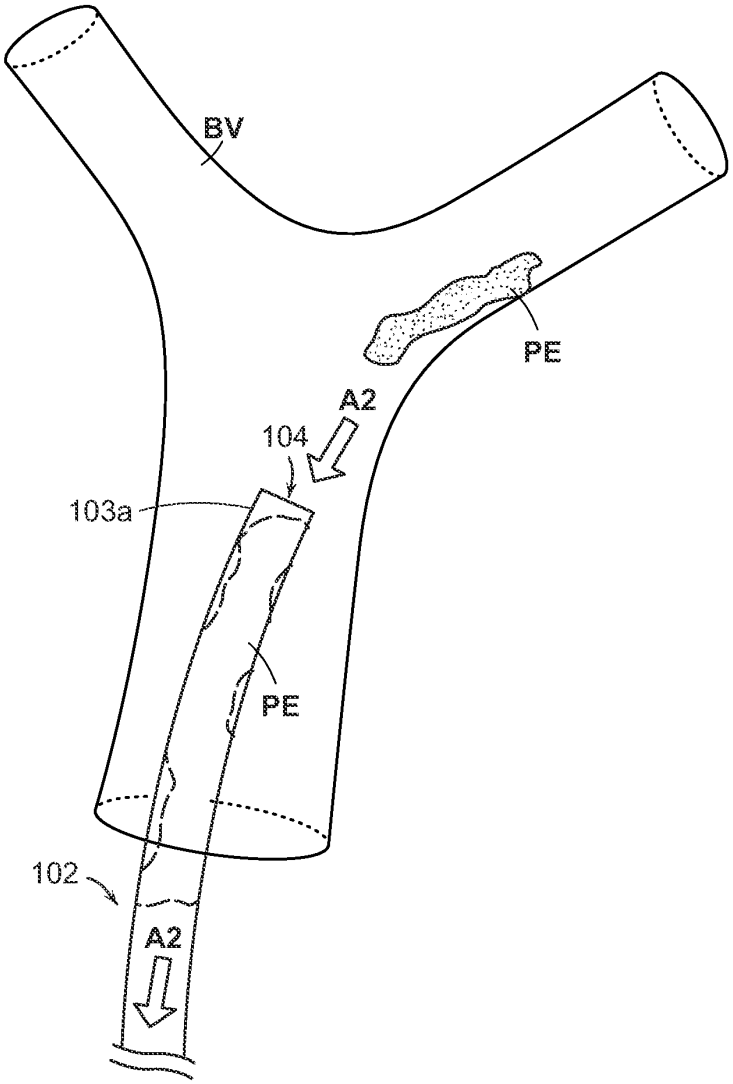


FIG. 10B

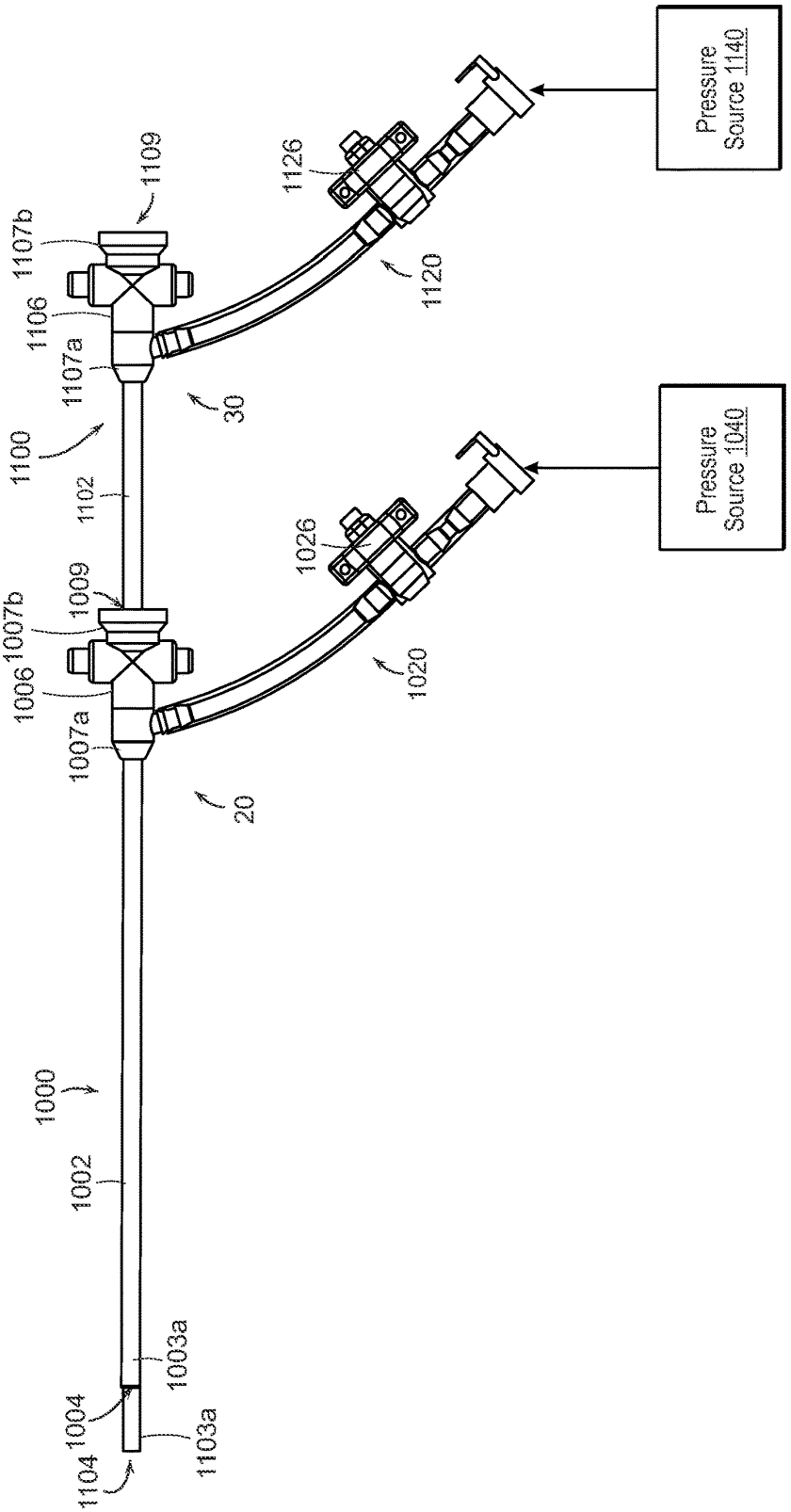

Pressure Source 1140
Pressure Source 1040
1109
1126
1107b
1120
1106
1107a
30
1100
1102
1026
1009
1007b
1020
1006
1007a
20
1000
1002
1003a
1004
1103a
1104

FIG. 11

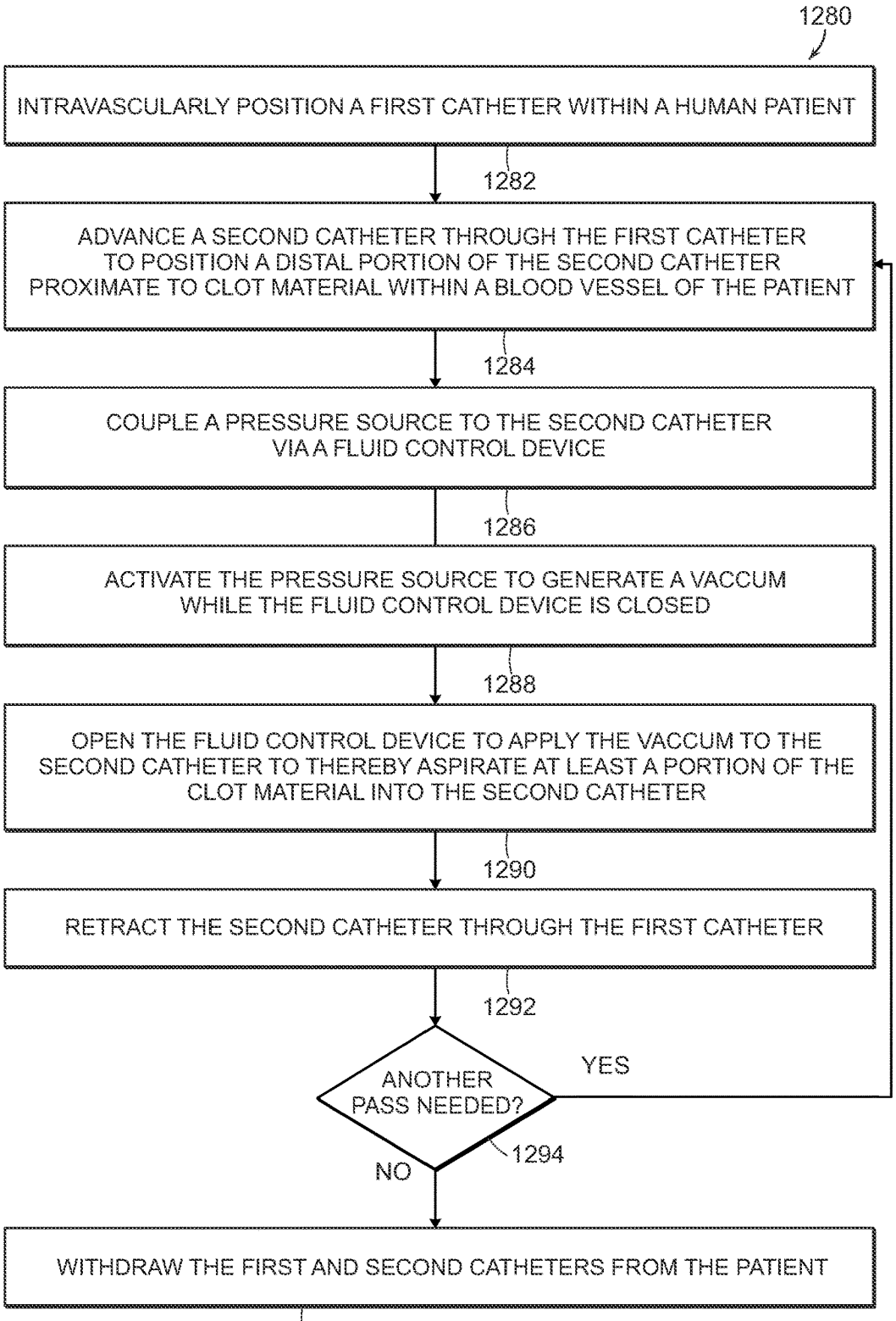

1280
INTRAVASCULARLY POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT
1282
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF THE PATIENT
1284
COUPLE A PRESSURE SOURCE TO THE SECOND CATHETER VIA A FLUID CONTROL DEVICE
1286
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACCUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
1288
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACCUM TO THE SECOND CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE SECOND CATHETER
1290
RETRACT THE SECOND CATHETER THROUGH THE FIRST CATHETER
1292
ANOTHER PASS NEEDED?
YES
1294
NO
WITHDRAW THE FIRST AND SECOND CATHETERS FROM THE PATIENT
1296

FIG. 12

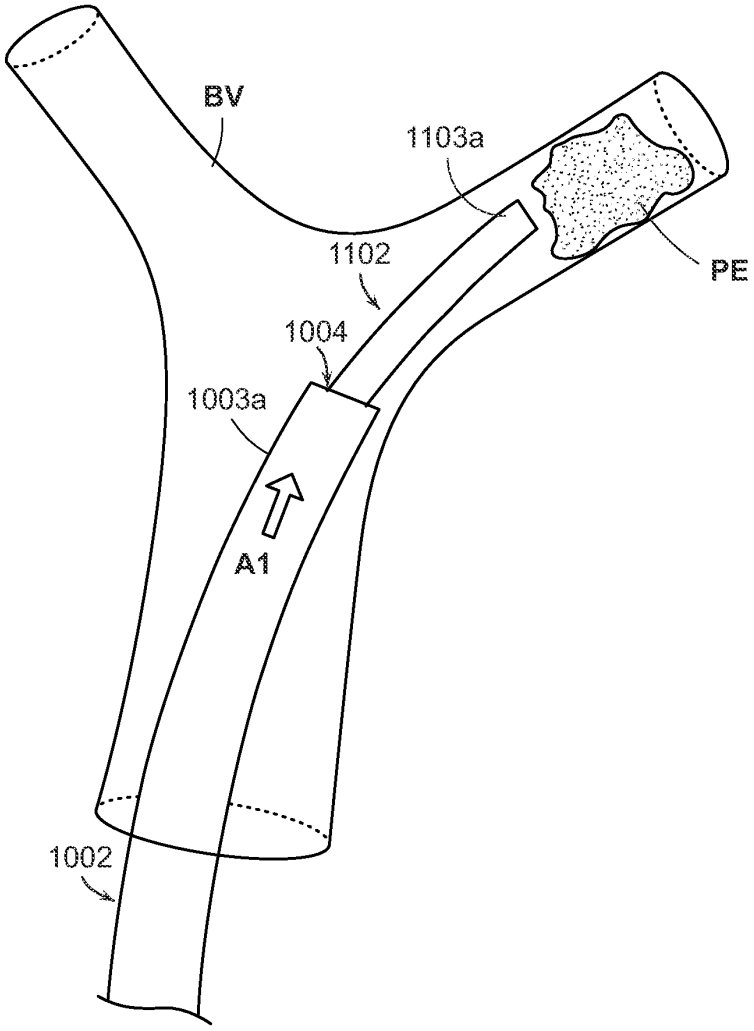


FIG. 13A

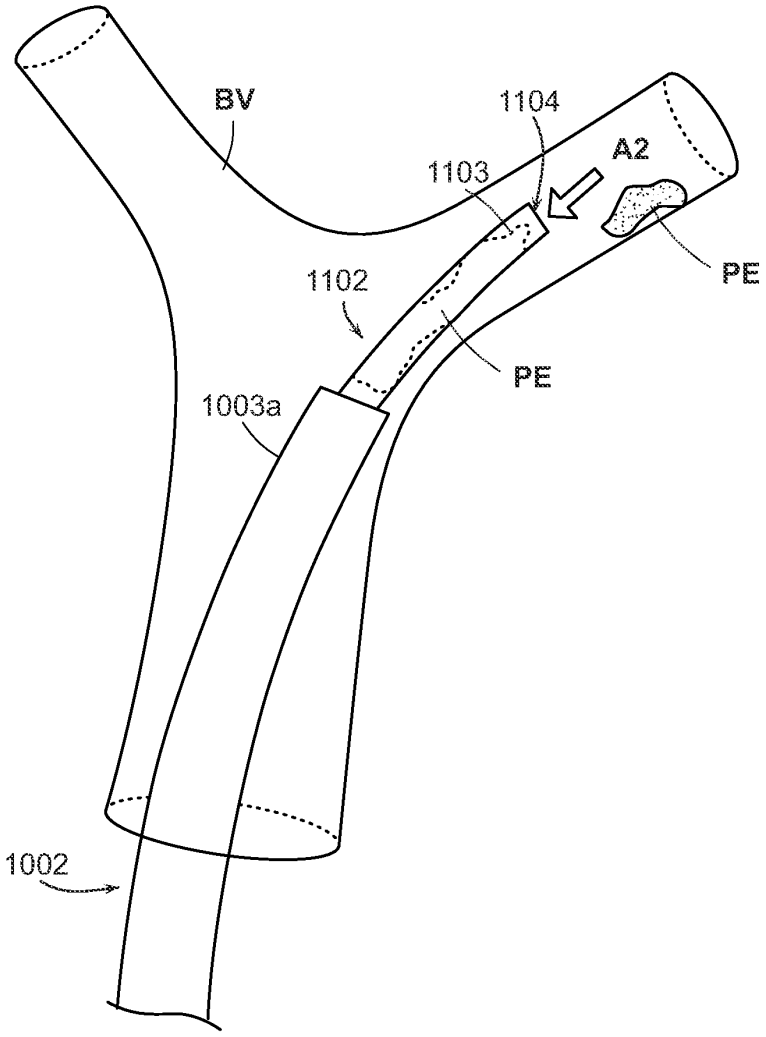


FIG. 13B

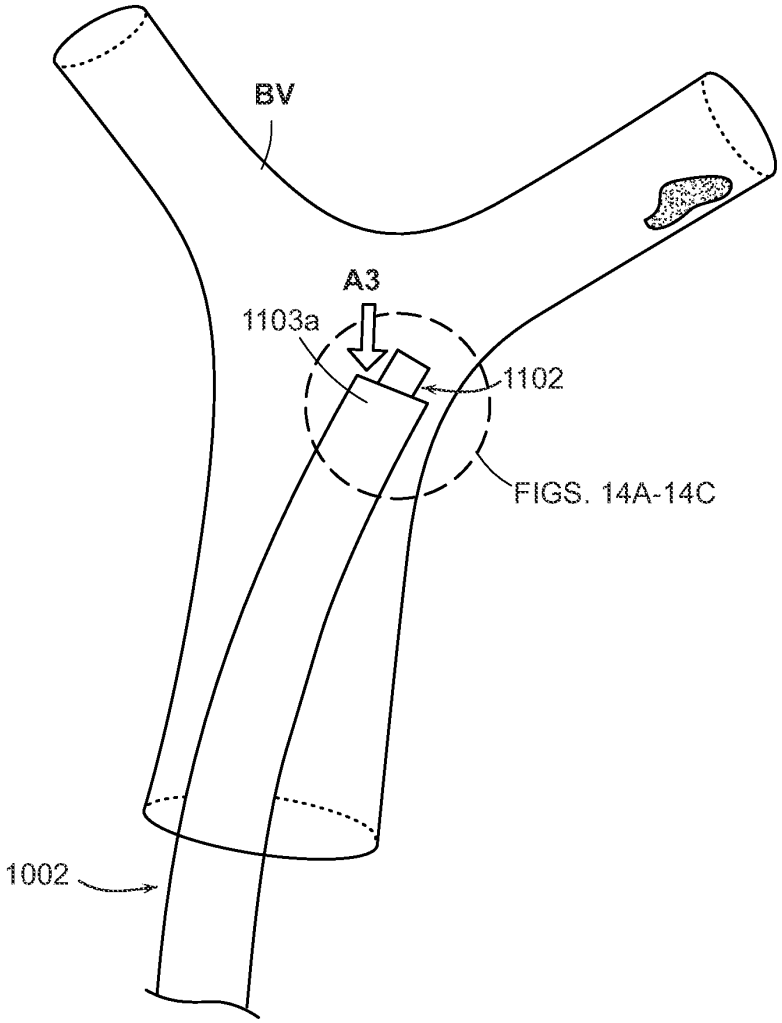


FIG. 13C

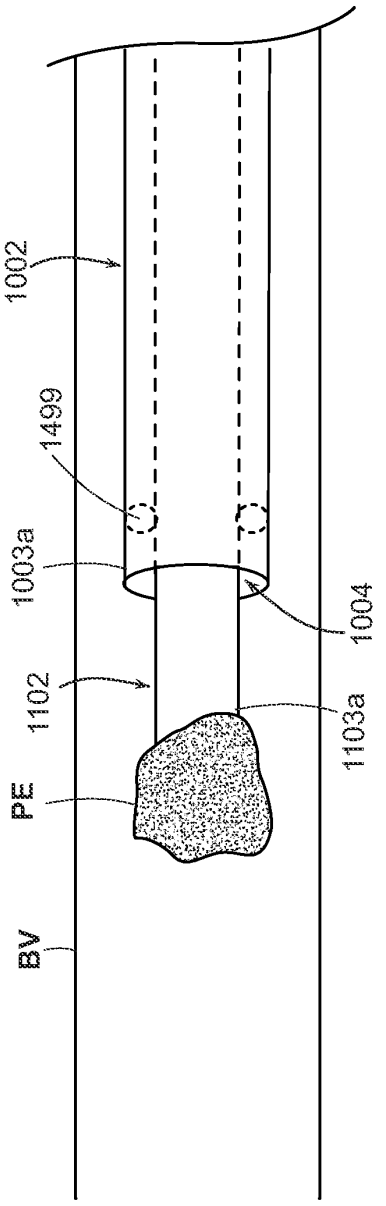


FIG. 14A

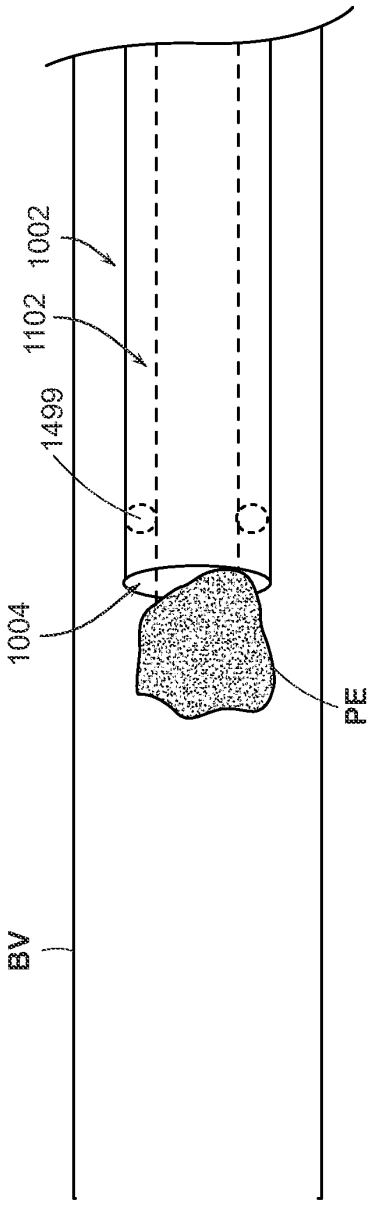


FIG. 14B

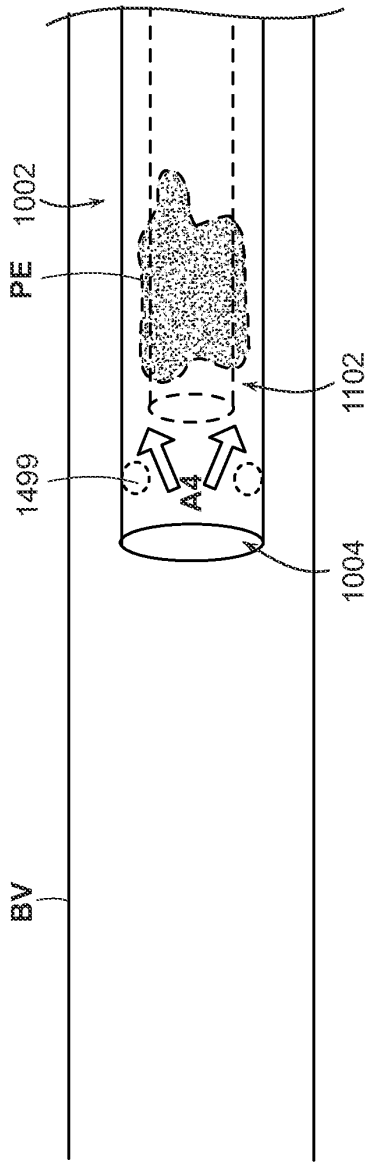


FIG. 14C

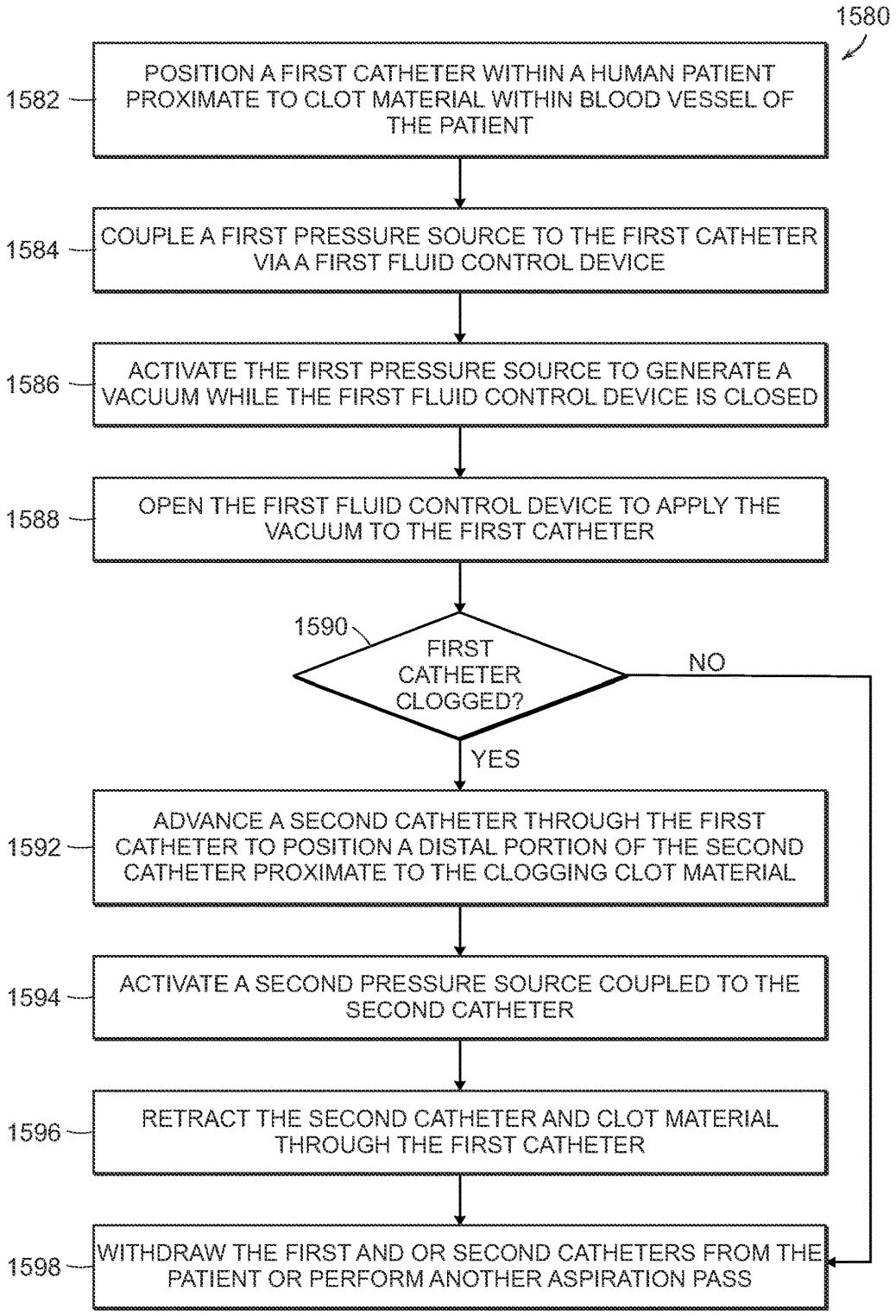

1580
1582
POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT PROXIMATE TO CLOT MATERIAL WITHIN BLOOD VESSEL OF THE PATIENT
1584
COUPLE A FIRST PRESSURE SOURCE TO THE FIRST CATHETER VIA A FIRST FLUID CONTROL DEVICE
1586
ACTIVATE THE FIRST PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FIRST FLUID CONTROL DEVICE IS CLOSED
1588
OPEN THE FIRST FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE FIRST CATHETER
1590
FIRST CATHETER CLOGGED?
NO
YES
1592
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO THE CLOGGING CLOT MATERIAL
1594
ACTIVATE A SECOND PRESSURE SOURCE COUPLED TO THE SECOND CATHETER
1596
RETRACT THE SECOND CATHETER AND CLOT MATERIAL THROUGH THE FIRST CATHETER
1598
WITHDRAW THE FIRST AND OR SECOND CATHETERS FROM THE PATIENT OR PERFORM ANOTHER ASPIRATION PASS

FIG. 15

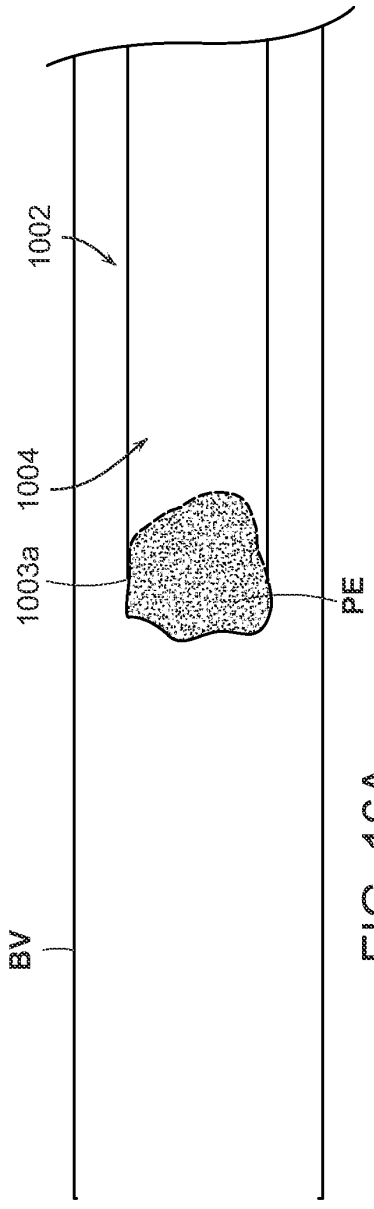


FIG. 16A

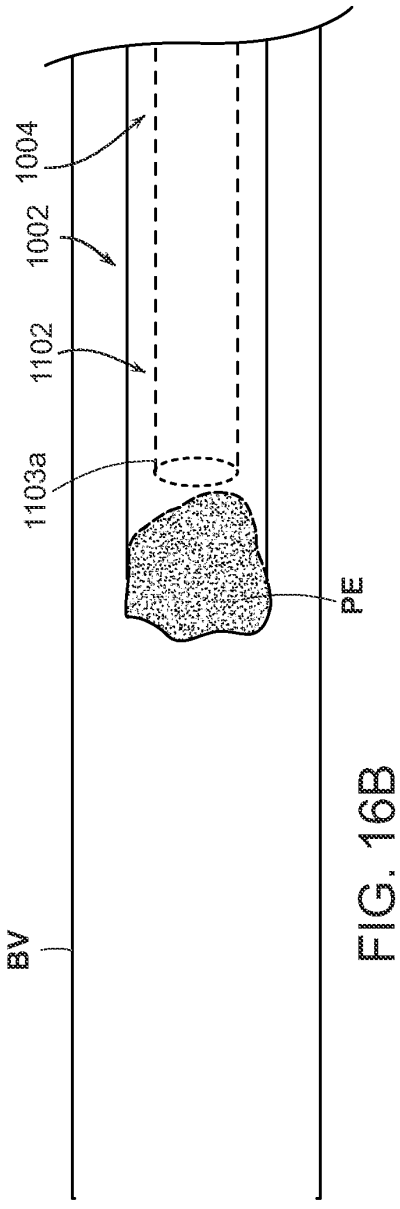


FIG. 16B

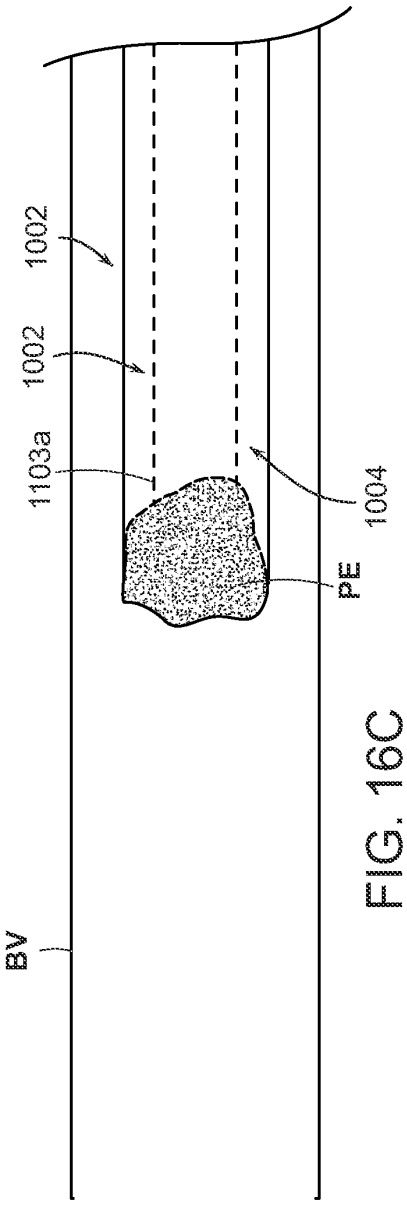


FIG. 16C

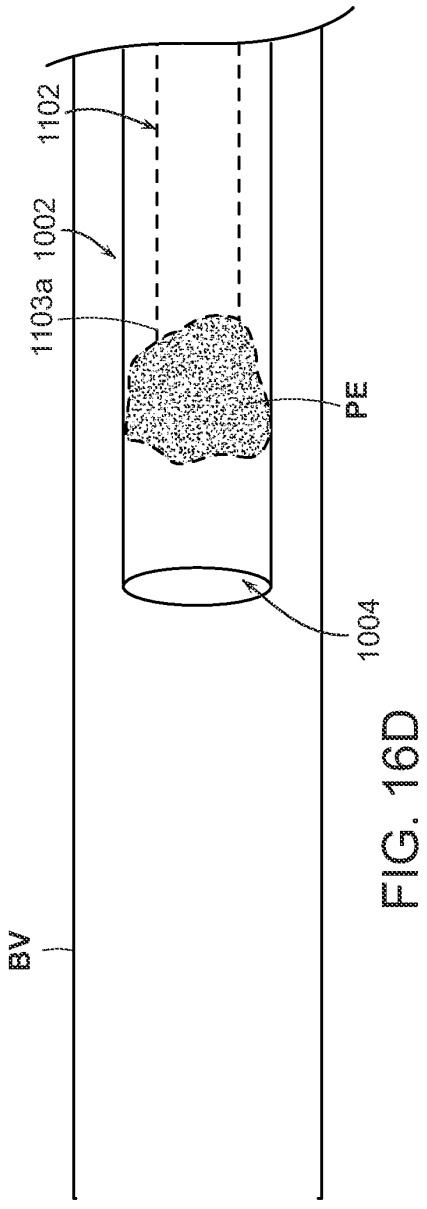


FIG. 16D

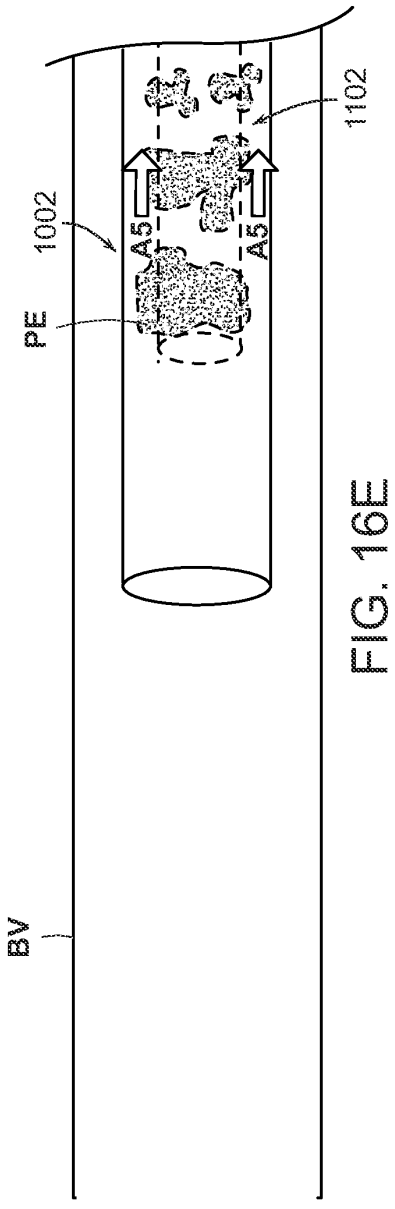


FIG. 16E

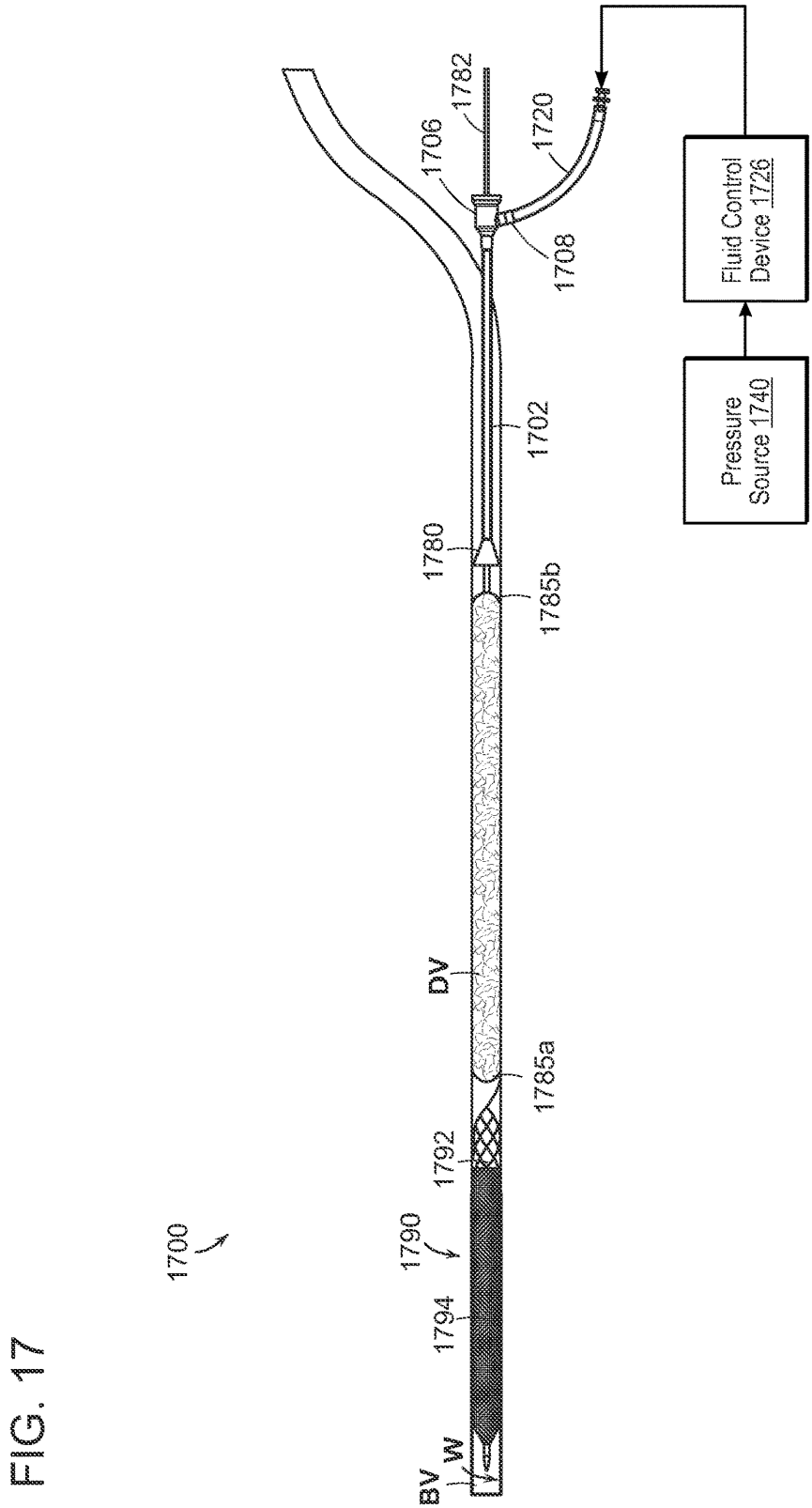

1782
1706
1720
1708
Fluid Control Device 1726
Pressure Source 1740
1702
1780
1785b
DV
1785a
1792
1790
1794
BV
W
1700

FIG. 17

FIG. 18A

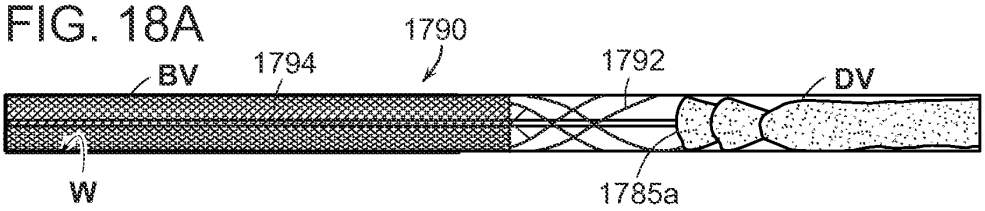


FIG. 18B

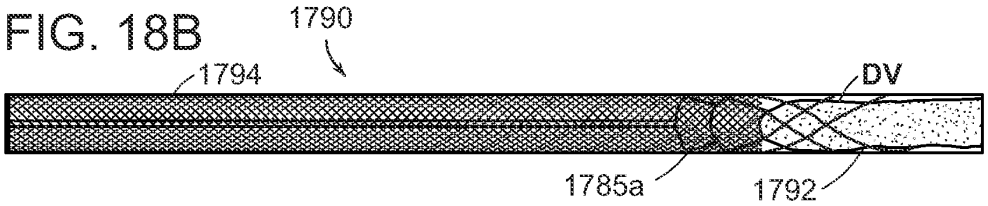


FIG. 18C

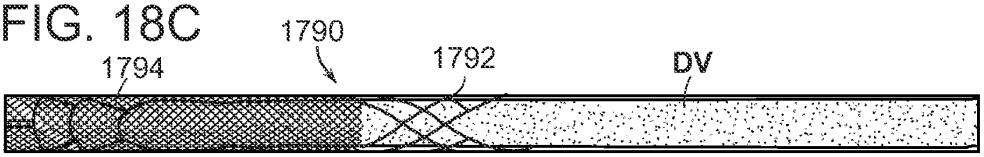


FIG. 18D

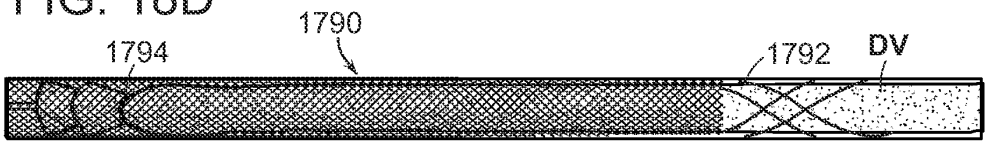


FIG. 18E

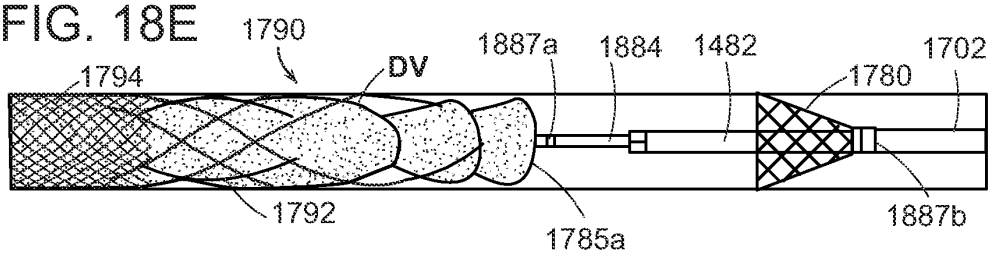


FIG. 18F

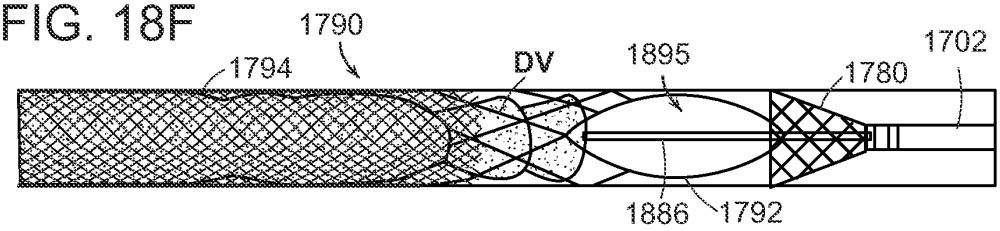


FIG. 18G

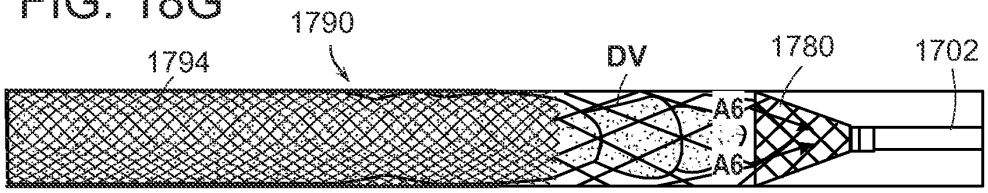
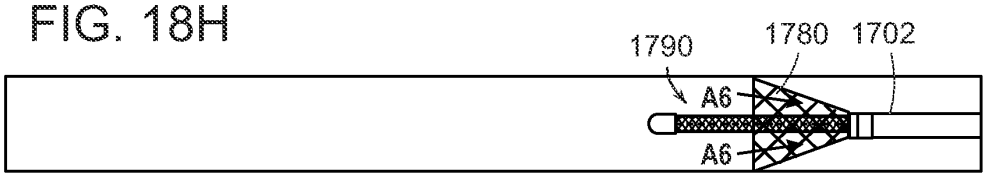


FIG. 18H



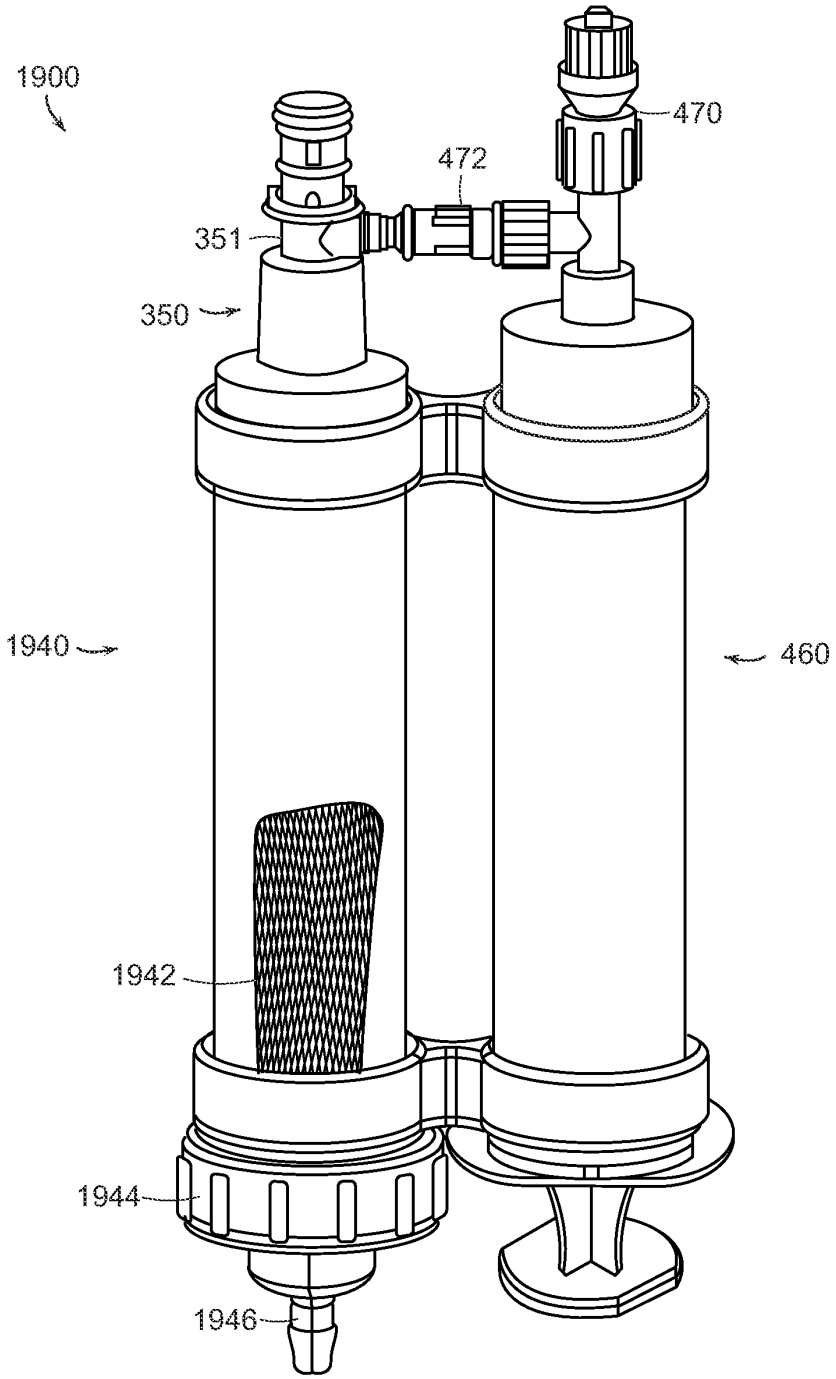


FIG. 19

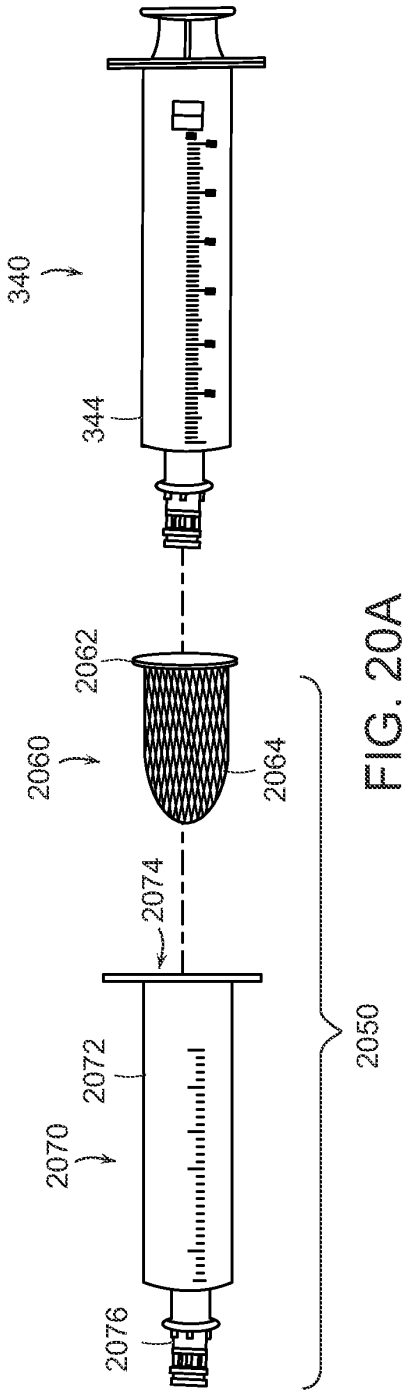


FIG. 20A

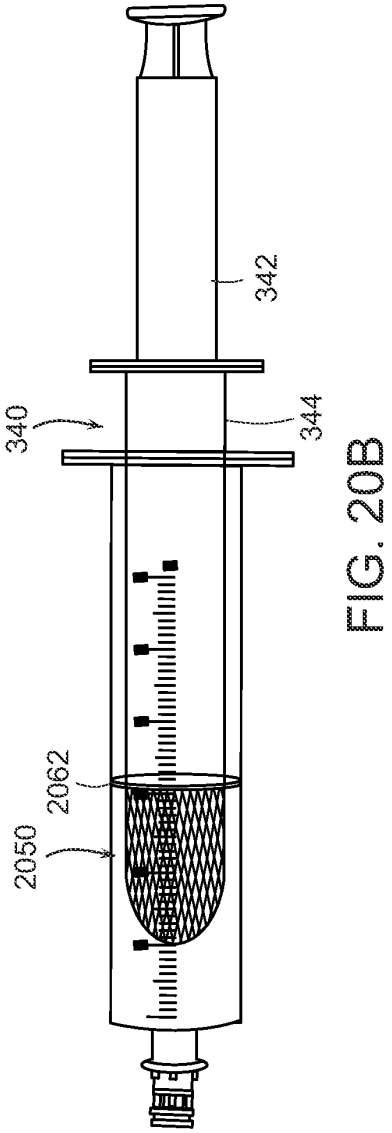


FIG. 20B

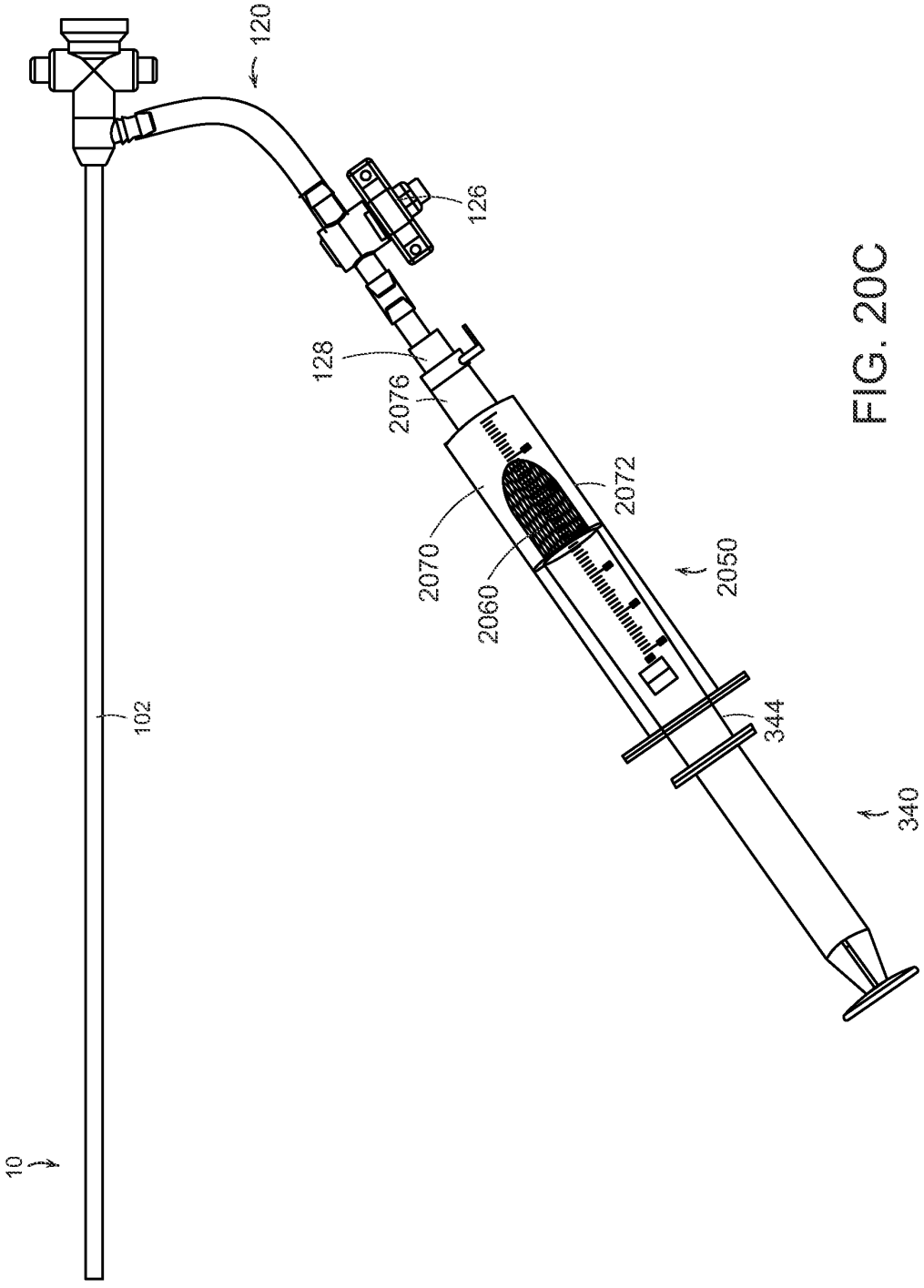


FIG. 20C

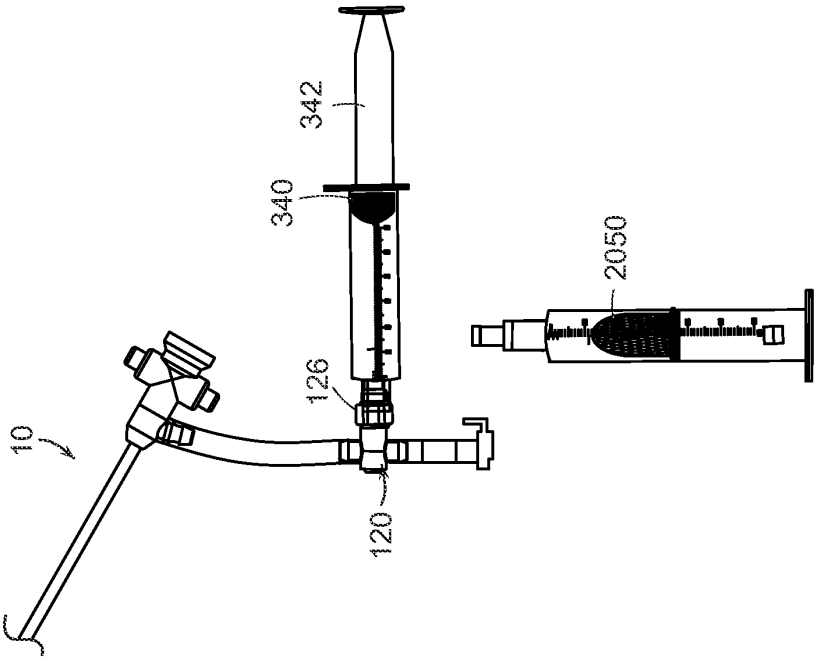


FIG. 20E

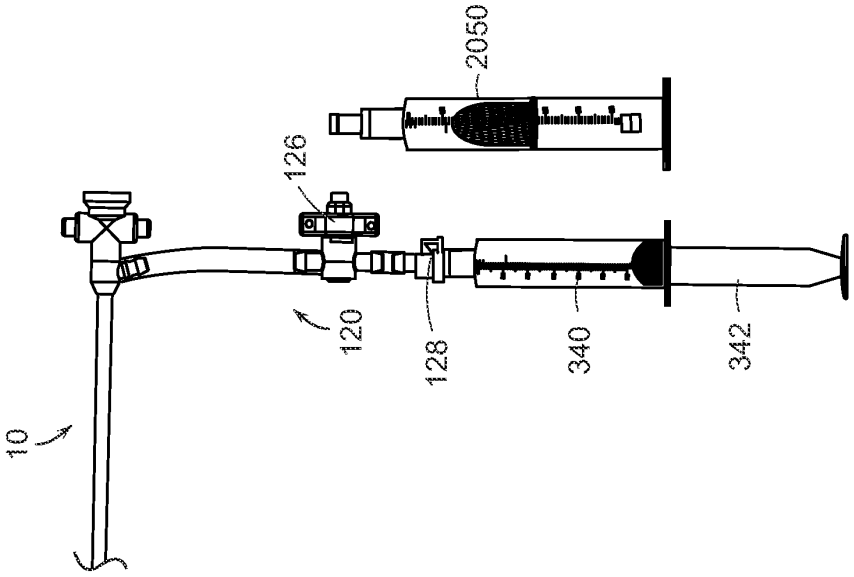


FIG. 20D

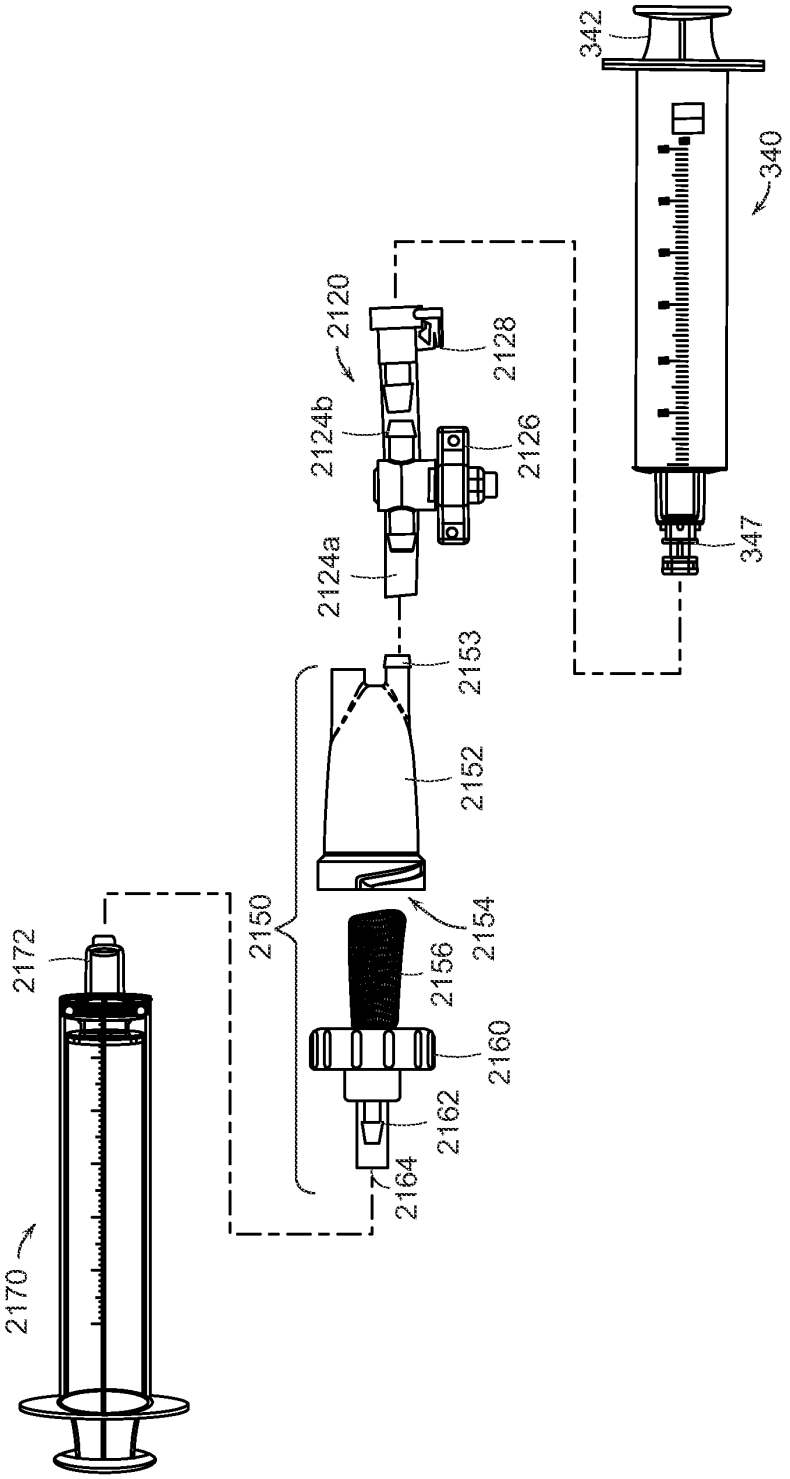

342
340
2120
2128
2124b
2126
347
2124a
2153
2152
2150
2154
2156
2172
2160
2162
2164
2170

FIG. 21A

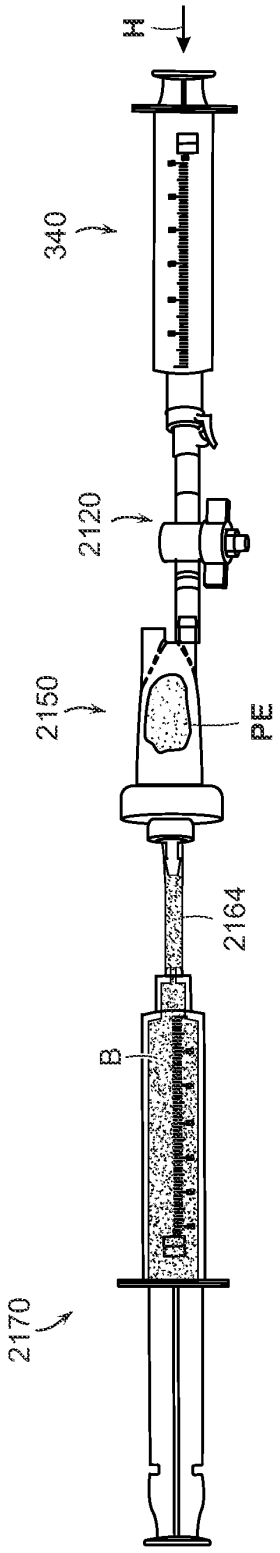


FIG. 21B

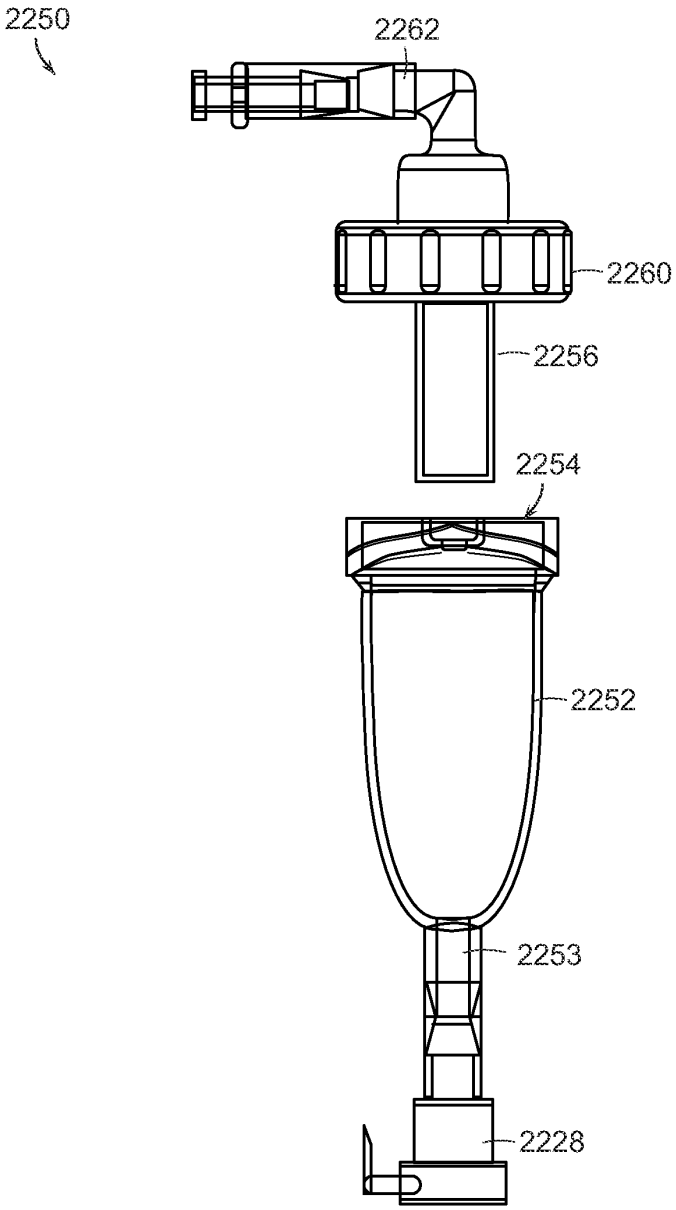


FIG. 22

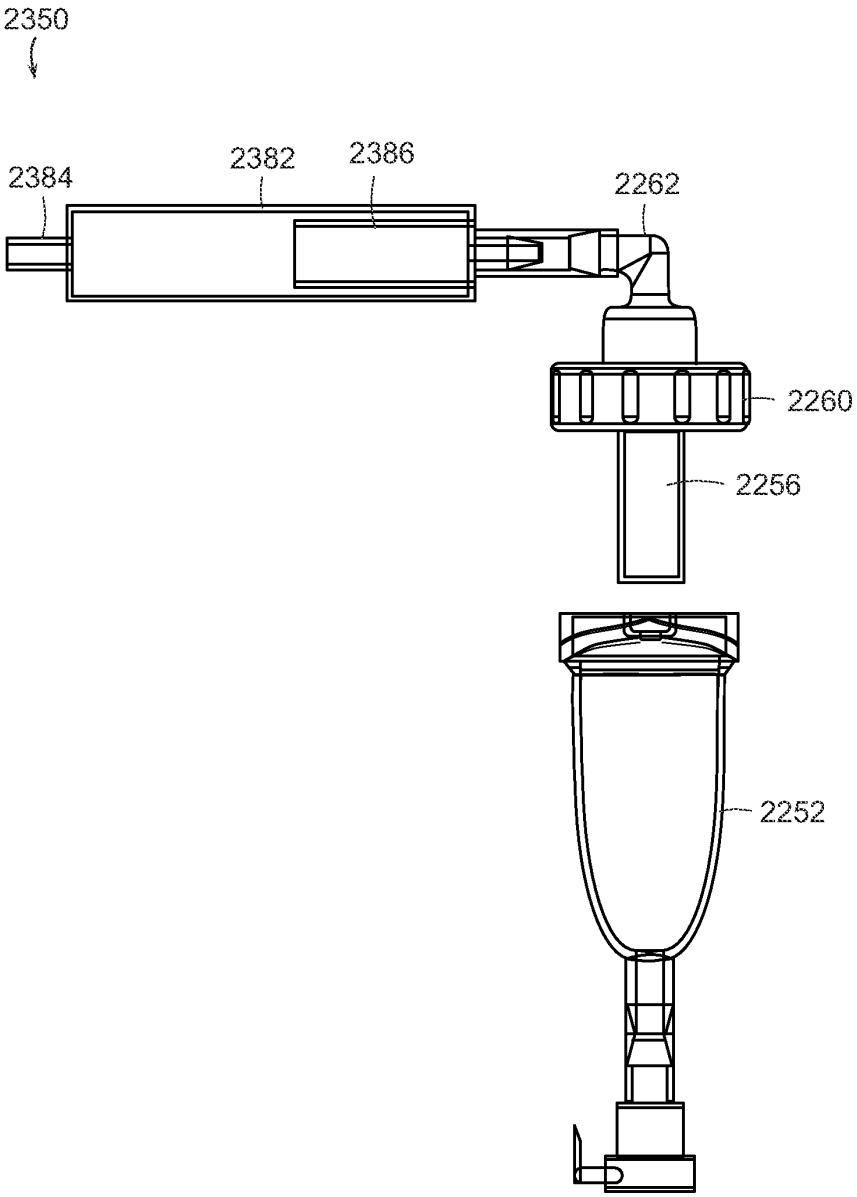


FIG. 23

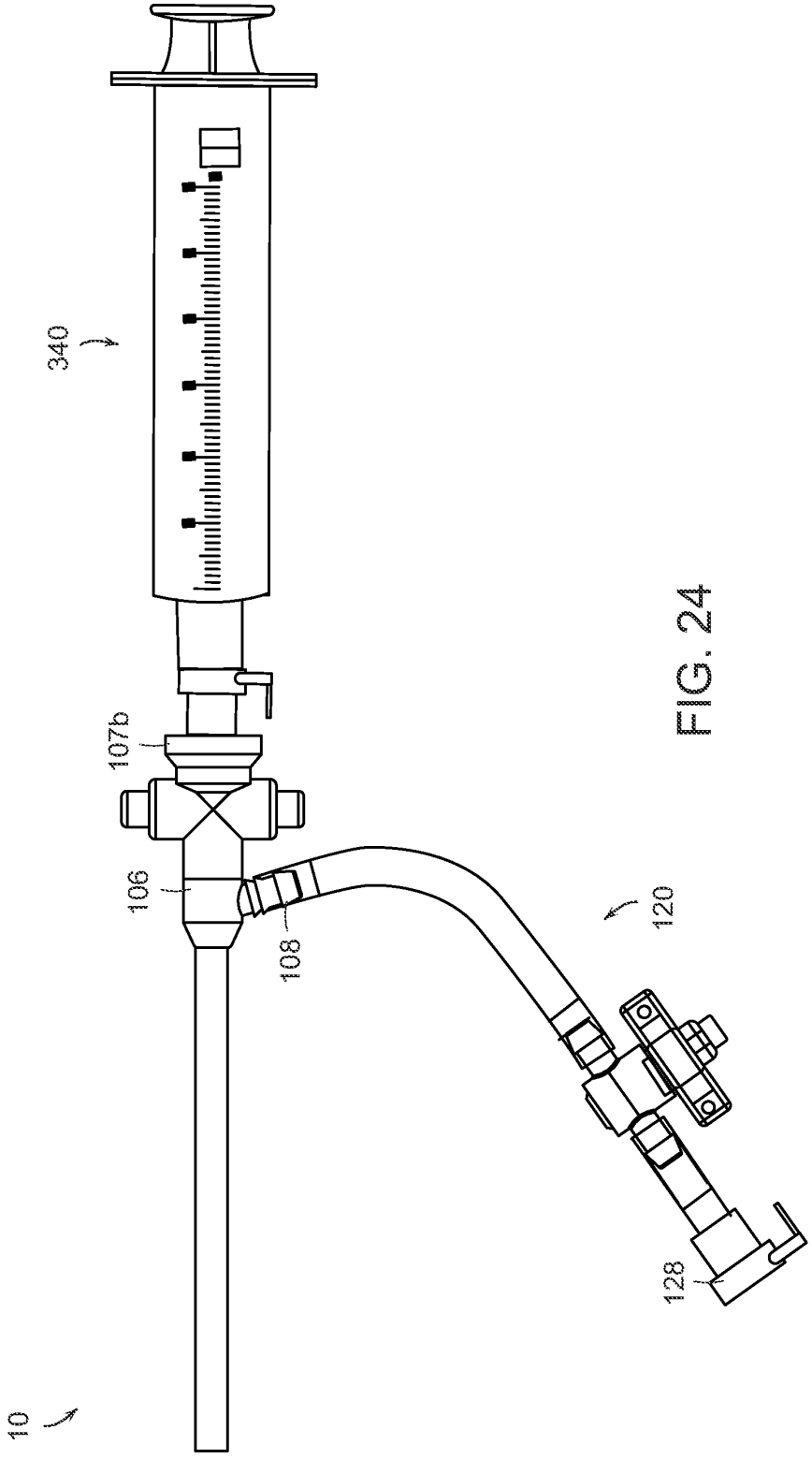


FIG. 24

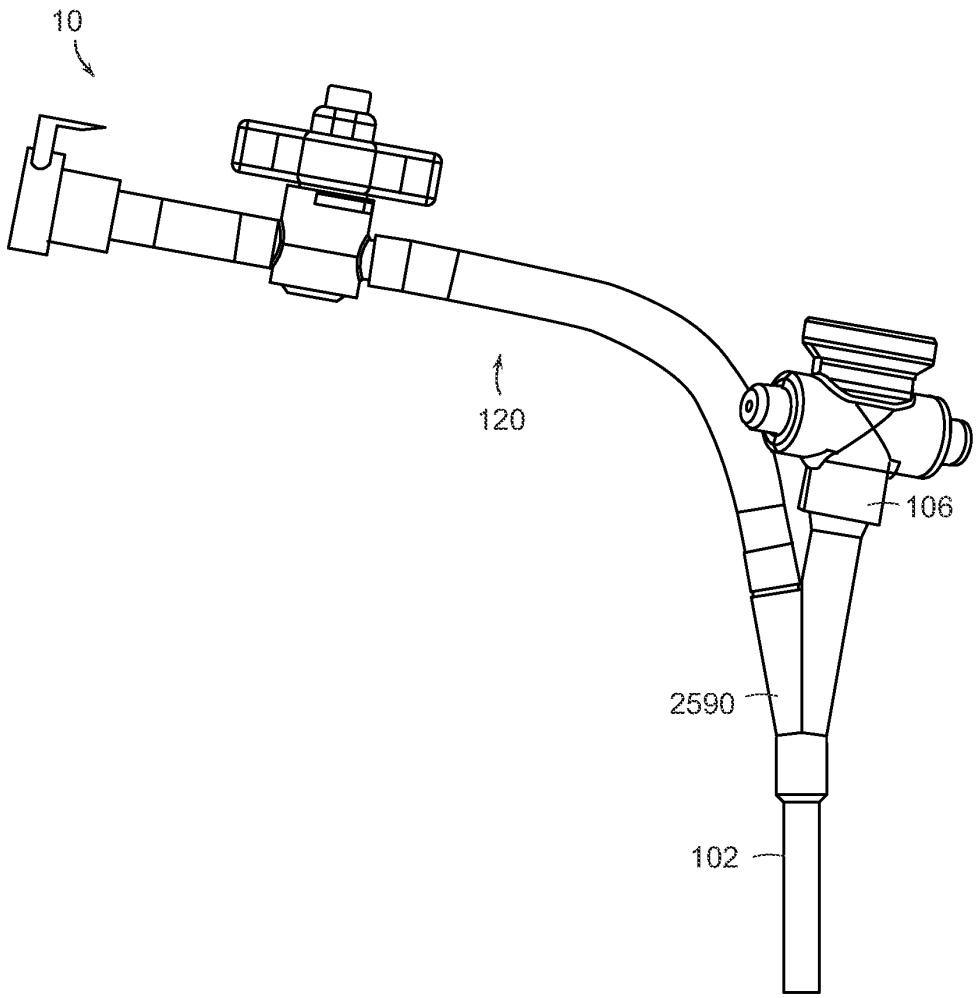


FIG. 25

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/536,185, filed Aug. 8, 2019, which claims the benefit of U.S. Provisional Patent Application No. 62/718,269, filed on Aug. 13, 2018, and U.S. Provisional Patent Application No. 62/718,248, filed on Aug. 13, 2018, each of which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

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

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.

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.

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.

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.

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.

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.

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.

Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

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.

FIG. **1** is a partially schematic side view of a clot removal system configured in accordance with the present technology.

FIG. **2** is a side view of a locking syringe configured in accordance with the present technology.

FIG. **3**A is a side view of a locking syringe configured in accordance with the present technology.

FIG. **3**B is a side view of an adaptor for connecting the locking syringe of FIG. **3**A to the clot removal system of FIG. **1** configured in accordance with the present technology.

FIG. **3**C is a side view of the adaptor of FIG. **3**B coupled to the locking syringe of FIG. **3**A.

FIG. **3**D is a side view of the locking syringe of FIG. **3**A coupled to the clot removal system of FIG. **1** via the adaptor of FIG. **3**B.

FIG. **4**A is a perspective side view of another pressure source configured in accordance with the present technology, and FIGS. **4**B and **4**C are enlarged schematic side views of the pressure source of FIG. **4**A during operation.

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FIG. **5** is a cross-sectional side view of an automatic release syringe configured in accordance with the present technology.

FIG. **6** is a perspective top view of a syringe configured in accordance with the present technology.

FIG. **7** is a side view of an over-wire locking syringe configured in accordance with the present technology.

FIG. **8** is a flow diagram of a process or method for operating a clot removal system in accordance with the present technology.

FIGS. **9**A-**9**C are side views of a proximal portion of the clot removal system of FIG. **1** during a clot removal procedure using the locking syringe of FIG. **3** in accordance with the present technology.

FIGS. **10**A and **10**B are schematic illustrations of a distal portion of the clot removal system of FIG. **1** during a clot removal procedure in accordance with the present technology.

FIG. **11** is a partially schematic side view of another clot removal system configured in accordance with the present technology.

FIG. **12** is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

FIGS. **13**A-**14**C are schematic illustrations of a distal portion of the clot removal system of FIG. **11** during a clot removal procedure in accordance with the present technology.

FIG. **15** is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

FIGS. **16**A-**16**E are schematic illustrations of a distal portion of the clot removal system of FIG. **11** during a clot removal procedure in accordance with the present technology.

FIG. **17** is a partially schematic side view of another clot removal system configured in accordance with the present technology.

FIGS. **18**A-**18**H are side views of a distal portion of the clot removal system shown of FIG. **17** during a clot removal procedure in accordance with the present technology.

FIG. **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.

FIG. **20**A is a partially-exploded side view of a filter device and pressure source configured in accordance with the present technology.

FIG. **20**B is a perspective side view of the syringe of FIG. **20**A coupled to the filter device of the FIG. **20**A.

FIG. **20**C is a side view of the filter device and syringe of FIG. **20**B coupled to the clot removal system of FIG. **1**.

FIGS. **20**D and **20**E are side views of the syringe of FIG. **20**A coupled to the clot removal system of FIG. **1** for reintroducing blood to a patient.

FIG. **21**A is a partially-exploded side view of a filter device, a pressure source, and a reinfusion syringe configured in accordance with the present technology.

FIG. **21**B is a perspective side view of the filter device of FIG. **21**A coupled to the pressure source and the reinfusion syringe of FIG. **21**A.

FIG. **22** is a partially-exploded side view of a filter device configured in accordance with the present technology.

FIG. **23** is a partially-exploded side view of a filter device configured in accordance with the present technology.

FIG. **24** is an enlarged isometric view of the clot removal system of FIG. **1** configured in accordance with the present technology.

FIG. **25** is an enlarged isometric view of the clot removal system of FIG. **1** configured in accordance with the present technology.

DETAILED DESCRIPTION

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.

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.

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 FIGS. **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 FIGS. **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 FIGS. **1-25**.

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.

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

FIG. **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 **103***a* and a proximal portion **103***b*. The catheter subsystem **100** further includes a valve **106** that can be integral with or coupled to the proximal portion **103***b* of the catheter **102**.

In the illustrated embodiment, the valve **106** includes a distal portion **107***a*, a proximal portion **107***b*, and a lumen **109** extending therethrough from the distal portion **107***a* to the proximal portion **107***b*. The valve **106** further includes a flow controller (obscured in FIG. **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 FIGS. **11-16**E), 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 Ser. No. 16/117,519, filed Aug. 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 **107***b* 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. Pat. No. 9,526,864, filed Jun. 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.

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 **124***a* and a second tubing section **124***b*), 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 **124***a* and (ii) the connector **128** via the second tubing section **124***b*. 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 **124***a*, and/or a diameter of the second tubing section **124***b*.

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 **124***a* and/or the tubing section **124***b*. 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 FIG. **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 **103***a* of the catheter **102**.

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.

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 FIGS. **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 103*a* 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 103*a* 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

As described in detail above with reference to FIG. 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.

FIG. 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 FIG. 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.

Referring to both FIGS. 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.

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.

FIG. 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 FIG. 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 FIG. 3A (and FIG. 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.

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 FIGS. 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.

FIG. 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. FIG. 3C is a side view of the adaptor 350 coupled to the syringe 340, and FIG. 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 FIG. 3C for the sake of illustration. Referring to FIG. 3B, the, 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.

Referring to FIGS. 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 snuggly 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.

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.

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 (FIG. 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

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
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

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
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

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 103*a* 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).

Moreover, as shown in FIG. 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 103*a* 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 103*a* 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).

FIG. 4A is a side perspective view a pressure source 400 including the syringe 340 ("primary syringe 340") shown in FIGS. 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.

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**.

FIGS. **4**B and **4**C are enlarged schematic side views of the pressure source **400** during operation. More specifically, FIGS. **4**B and **4**C 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 FIGS. **4**A and **4**B 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** (FIG. **1**), and/or the tubing subsystem **120** (FIG. **1**) into the secondary syringe **460**. This flow path is indicated by the arrows R in FIG. **4**B. Referring to FIGS. **4**A and **4**C 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 FIG. **4**C.

Referring to FIGS. **1** and **3**A-**4**C 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 FIG. **3**D). When the pressure source is coupled to the tubing subsystem **120**, retraction of the plunger **462** of the secondary syringe **460** evacuates an evacuatable 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.

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.

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**.

In some embodiments, (e.g., as described in greater detail below with reference to FIG. **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 FIGS. **4**B and **4**C. 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 FIGS. **4**B and **4**C.

FIG. **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 inter-

vening fluid control device, such as the fluid control device **126** shown in FIG. **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 FIGS. **2** and **3**A-**3**D. 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 FIGS. **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.

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**.

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.

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**.

FIG. **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 FIGS. **2**-**3**D 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 FIG. **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**.

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**.

Referring again to FIG. **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 **103***a* 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 **107***b* 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, FIG. **24** is an enlarged isometric view of the assembly **10** showing the pressure source **340** coupled directly to the proximal portion **107***b* 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 FIG. **24**, any of the pressure sources described in detail above with reference to FIGS. **2-6** can be configured to be coupled to the proximal portion **107***b* 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, FIG. **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**.

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 **107***b* 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, FIG. **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 FIG. **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 FIG. **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 **107***b* 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**.

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** (FIGS. **4A-4C**) can be coupled via one or more one-way valves to the syringes **240**, **540**, **640** or **740** (FIGS. **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** (FIG. **2**) and the syringe **340** (FIG. **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

FIG. **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. FIGS. **9A-9C** are side views of a proximal portion of the assembly **10**, and FIGS. **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, FIGS. **9A-9C** are side views of the assembly **10** including the syringe **340** and adaptor **350** (FIGS. **3A-3D**), and FIGS. **10A** and **10B** are side views of the catheter **102** with the distal portion **103***a* 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 FIGS. **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 FIGS. **2-7**.

At block **802**, the method **800** includes positioning the distal portion **103***a* 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 FIG. **10A**, a distal terminus of the distal portion **103***a* 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.

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 A**1**) to a position proximate to the clot material PE as illustrated in FIG. **10**A.

In some embodiments, to confirm the position of the distal portion **103***a* 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 **103***a* 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 **103***a* 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 **103***a* of the catheter is not fully engaged with the clot material PE. Accordingly, to locate the distal portion **103***a* of the catheter **102** just proximal of the clot material PE, the operator can (i) first determine that distal portion **103***a* 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 **103***a* 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 **103***a* 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.

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.

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 FIG. **9**A, the tip **347** (shown in FIGS. **3**A and **3**C but obscured in FIG. **9**A) 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 FIG. **9**A.

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 FIG. **9**B, 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** (FIGS. **4**A-**4**C) 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.

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 FIG. **9**C, 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 FIG. **10**B, application of the vacuum causes suction at the distal tip **103***a* of the catheter **102** (e.g., as indicated by arrow A**2**) 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 **103***a* 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**. FIG. **9**C, 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**.

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**).

Sometimes, as shown in FIG. **10**B, 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.

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.

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** (FIGS. **4**A-**4**C) 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 FIGS. **15-16**E, a second clot removal assembly can be telescoped through the first assembly **10** to facilitate removal of the clogged clot material PE.

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. Pat. No. 9,526,864, filed Jun. 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Pat. No. 8,784,434, filed Mar. 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 (FIG. **10**B) after a first aspiration pass.

IV. Selected Embodiments of Telescoping Clot Removal Systems and Associated Methods of Clot Removal

FIG. **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 FIGS. **1-10**B. 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**.

The first and second catheters **1002**, **1102** each comprise an elongated shaft defining a lumen **1004**, **1104** and having a distal portion **1003***a*, **1103***a*, respectively. The first and second valves **1006**, **1106** each include (i) a distal portion **1007***a*, **1107***a*, (ii) a proximal portion **1007***b*, **1107***b*, (iii) a lumen **1009**, **1109** extending therethrough, and (iv) a flow controller (obscured in FIG. **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**.

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 **1103***a* 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 FIGS. **14**A-**14**C), 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.

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 FIGS. **1**-**10**B. 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 pressures sources **1040**, **1140** can be omitted, or the pressure sources **1040**, **1140** can be fluidly coupled and/or integrally formed.

FIG. **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. FIGS. **13**A-**13**C are schematic illustrations of a distal portion of the assemblies **20**, **30** during a clot removal procedure in accordance with the present technology. FIGS. **14**A-**14**C 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 FIGS. **11** and **13**A-**14**C 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.

At block **1282**, the method **1280** includes intravascularly positioning the first catheter **1002** within a human patient. FIG. **13**A, for example, illustrates the first catheter **1002** after it has been advanced (e.g., as indicated by arrow A**1**) 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 **1003***a* 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 **1003***a* 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 FIG. **8**.

At block **1284**, the method **1280** includes advancing the second catheter **1102** through the first catheter **1002** until the distal portion **1103***a* 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 **1103***a* of the second catheter **1102** through the first valve **1006** before advancing the second catheter **1102** (e.g., as indicated by the arrow A**1**) 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 **1103***a* 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.

FIG. **13**A 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 FIG. **13**A, 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.

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 FIGS. **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**).

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**.

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 FIG. **13**B, application of the vacuum causes suction (e.g., as indicated by arrow A**2**) 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 **1103***a* 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 **1103***a* of the second catheter **1102** compared to simply activating the second pressure source **1140** while it is fluidly connected to the second catheter **1102**.

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 **1003***a* 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 **1003***a* 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.

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 Ser. No. 16/258,344, filed Jan. 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.

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 FIG. **13**C, 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 A**3**) at the distal portion **1003***a* 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.

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 **1103***a* of the second catheter **1102**. FIG. **14**A, for example, is an enlarged view of the distal portion of the assemblies **20**, **30** shown in FIG. **13**C and illustrating a portion of the clot material PE stuck to or dangling from the distal portion **1103***a* 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**).

FIGS. **14**B and **14**C 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 FIG. **14**C, 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 A**4**). 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**.

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.

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 **1103***a* 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**).

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.

FIG. **15** is a flow diagram of another process or method **1580** for operating a clot removal system including the assemblies **20**, **30** (FIG. **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. FIG. **16**A is an enlarged side view of a distal portion of the first assembly **20**, and FIGS. **16**B-**16**E 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 FIGS. **11** and **16**A-**16**E 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.

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 FIGS. **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 FIGS. **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 **1003***a* of the first catheter **1002**.

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**). FIG. **16**A, 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 **1003***a* 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 FIG. **8**).

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 **1103***a* of the second catheter **1102** is positioned in or proximate to the clogging clot material PE. For example, FIG. **16**B 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 **1103***a* of the second catheter **1102** through the first valve **1006** (FIG. **11**) before advancing the second catheter **1102** through the lumen **1004** of the first catheter **1002**.

At block **1594**, the method **1580** includes activating the second pressure source **1140** (FIG. **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 FIGS. **2-7**) can be coupled to the second catheter **1102** via the second fluid control device **1126** (FIG. **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.

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**. FIG. **16**C, for example, illustrates a portion of the clot material PE stuck to or extending from the distal portion **1103***a* of the second catheter **1102** after aspirating the second catheter **1102**. In the embodiment illustrated in FIG. **16**C, 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**.

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, FIG. **16**D 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**. FIG. **16**E, 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 A**5**).

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**.

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

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.

FIG. **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 FIG. **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.

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 FIG. **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 FIGS. **18**E and **18**F, 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 Apr. 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

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, FIG. **17** shows the system **1700** after (i) advancing the sheath **1702** to a position proximate to a proximal portion **1785***b* 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 **1785***a* of the clot material DV), and (iv) expanding the interventional device **1790** from the compressed delivery state to the deployed state.

FIGS. **18**A-**18**H are enlarged views of a distal portion of the system **1700** during a clot removal procedure in accordance with the present technology. In general, FIGS. **18**A-**18**H 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**.

Referring first to FIG. **18**A, proximal retraction of the interventional device **1790** causes the coring element **1792** to separate and/or core the distal end portion **1785***a* of the clot material DV from the walls W of the blood vessel BV. As shown in FIG. **18**B, continued proximal retraction of the interventional device **1790** through the clot material DV causes the cylindrical element **1794** to capture the distal end portion **1785***a* of the clot material therein. FIGS. **18**C-**18**E 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 FIG. **18**E, the proximal end portion **1785***b* 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 FIG. **18**E, a first radiopaque marker **1887***a* can be positioned on a distal end portion of the inner shaft **1884** and a second radiopaque marker **1887***b* can be positioned on a distal end portion of the sheath **1702**.

In some embodiments, as shown in FIG. **18**F, 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** (FIG. **18**E). 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 **1885***a*) relative to the distal end portion of the sheath **1702** (e.g., the second radiopaque marker **1885***b*). 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**.

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 FIG. **18**G. As shown in FIG. **18**H, 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** (FIG. **17**), and from the patient's body.

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 FIG. **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 FIGS. **18**G and **18**H, application of the vacuum can generate instantaneous or nearly instantaneous suction (e.g., as indicated by arrows A**6**) 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

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. FIGS. **19**-**20**E 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.

For example, FIG. **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 FIGS. **4**A-**4**C. 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** (FIGS. **4**A-**4**C). 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** (FIG. **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**).

In the illustrated embodiment, the canister **1940** further includes a filter **1942**. The canister **1940** is shown as transparent in FIG. **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**.

FIGS. **20**A-**20**E 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 FIGS. **2**-**7**. For example, FIG. **20**A is a partially-exploded side view of the filter device **2050** and the pressure source **340** (FIGS. **3**A-**3**D). 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 FIG. **20**C). 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.

FIG. **20**B 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 FIG. **20**B (and FIGS. **20**C-**20**E) 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.

FIG. **20**C 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 FIG. **20**C, 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.

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, FIGS. **20**D and **20**E 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 FIG. **20**D, 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 FIG. **20**E, 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 FIGS. **20**A-**20**E 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**).

FIGS. **21**A and **21**B 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 FIGS. **2-7**. For example, FIG. **21**A is a partially-exploded side view of the filter device **2150** and the pressure source **340** (FIGS. **3**A-**3**D). 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.

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 **2124***a* and a second tubing section **2124***b*), 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**.

In operation, during a clot removal procedure, the pressure source **340** can be decoupled from the connector **128** (FIG. **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, FIG. **21**B 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 FIGS. **21**A and **21**B 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** (FIG. **1**), an IV line (not shown), or another suitable connection point for reintroducing blood to the patient.

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 FIG. **21**B, 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.

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** (FIG. **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.

FIG. **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 FIGS. **2-7**. In general, the filter device **2250** is generally similar to the filter device **2150** described in detail with reference to FIGS. **21**A and **21**B. 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 FIGS. **3**A-**3**D). 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 FIG. **22**. In one aspect of the present technology, this arrangement makes the filter device more ergonomic during use.

FIG. **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 FIGS. **2-7**. The filter device **2350** is generally identical to the filter device **2250** described in detail with reference to FIG. **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.

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 FIGS. **2** and **4-7**). In some embodiments, the filter devices can be formed as a component of the tubing subsystem **120** (FIG. **1**). Moreover, the filter devices can include any number of filters and/or housings to provide any number of filtration stages.

Conclusion

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.

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.

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.

We claim:

1. A vacuum aspiration system, comprising:

a housing;

a flow path extending through the housing;

an on-off control in the flow path;

a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;

a clot cannister fluidly coupled to the flow path; and

a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises:

a tubular member defining a lumen configured to slidably receive the second catheter;

a constricting mechanism including a filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member couped to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and

a biasing system configured to bias the first member and the second member to the first position.

2. The vacuum aspiration system of claim **1** wherein the tubular member is pliable.

3. The vacuum aspiration system of claim **1** wherein the first portion of the filament extends in a loop completely around the tubular member.

4. The vacuum aspiration system of claim **1** wherein the first member of the actuator comprises a first button and the second member of the actuator comprises a second button, wherein the first button and the second button are undepressed in the first position, and wherein the first button and the second button are depressed in the second position.

5. The vacuum aspiration system of claim **1** wherein, when the first member and the second member of the actuator are in the first position, the lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the lumen and adjacent to a first end of the tubular member and (b) a second volume outside the central lumen and adjacent to a second end of the tubular member.

6. The vacuum aspiration system of claim **1** wherein, when the first member and the second member of the actuator are in the first position, the lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent to either a first end or a second end of the tubular member.

7. The vacuum aspiration system of claim **1** wherein the lumen of the tubular member extends a long a first longitudinal axis, wherein the first member and the second member of the actuator are movable between the first and second positions along a second longitudinal axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis.

8. The vacuum aspiration system of claim **1** wherein the biasing system comprises a first compression spring coupled to the first member and a second compression spring coupled to the second member.

9. The vacuum aspiration system of claim **1** wherein, in the first position, the first member and the second member of the actuator pull the filament to circumferentially constrict the tubular member such that the lumen is constricted and sealed.

10. A vacuum aspiration system, comprising:

a housing;

a flow path extending through the housing;

an on-off control in the flow path;

a first catheter in fluid communication with the flow path and a connector configured to place a source of aspiration in communication with the flow path;

a clot cannister fluidly coupled to the flow path; and

a hemostasis valve in the housing configured to receive a second catheter and direct the second catheter through the first catheter, wherein the hemostasis valve comprises

(a) a support;

(b) an actuator having a least a first member movably coupled to the support;

(c) a collapsible tubular sidewall defining a lumen carried by the support;

(d) a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and

(e) a first spring configured to move the first member in a direction that pulls the first end portion such that a diameter of the lumen decreases in response to reducing a diameter of the loop.

11. The vacuum aspiration system of claim **10**, further comprising a second member movably coupled to the support.

12. The vacuum aspiration system of claim **11** wherein the filament further comprises a second end portion extending away from the loop to the second member.

13. The vacuum aspiration system of claim **12** first end portion, the loop, and the second end portion are one continuous filament.

14. The vacuum aspiration system of claim **12** wherein first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to reduce the diameter of the lumen and provide a seal around a device extending through the lumen.

15. The vacuum aspiration system of claim **12** wherein the first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to close the lumen.

* * * * *

EXHIBIT E

US011744691B2

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Merritt et al.

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(45) **Date of Patent: Sep. 5, 2023**

(54) **SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS**

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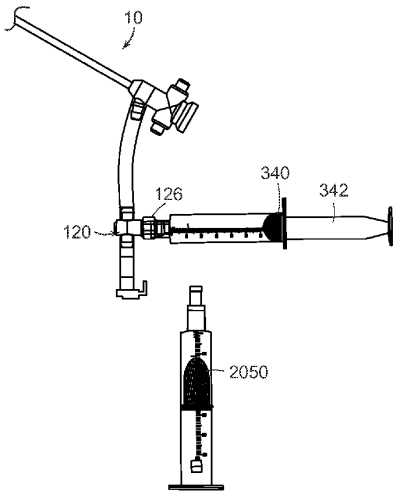
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(57) **ABSTRACT**

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.

31 Claims, 38 Drawing Sheets



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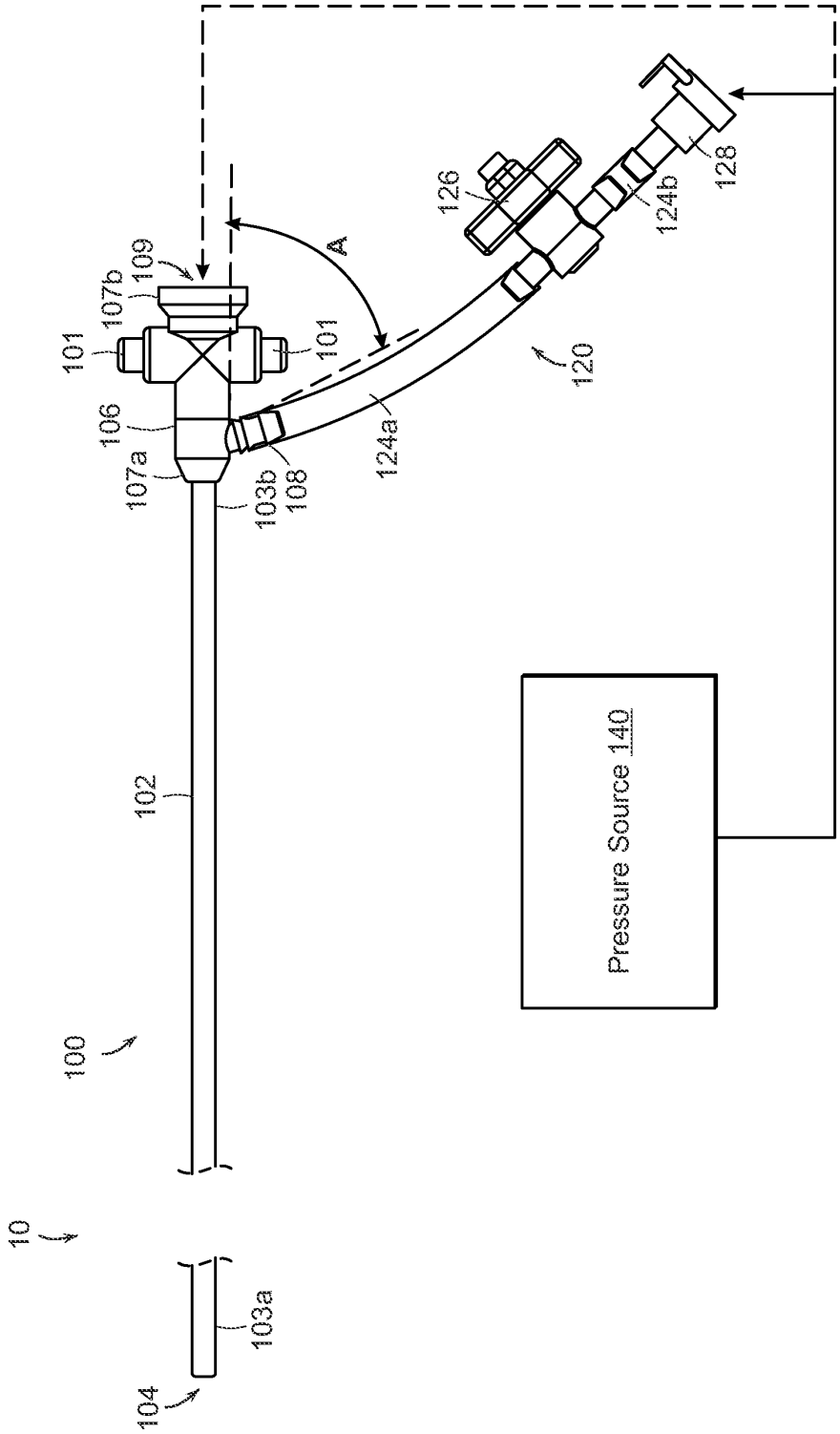

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128
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107b
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124a
107a
103b
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102
Pressure Source 140
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103a
104

FIG. 1

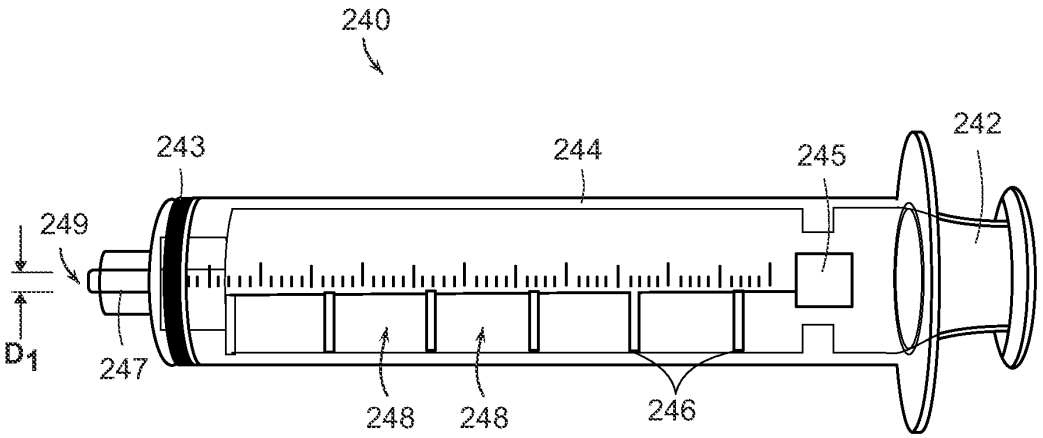

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FIG. 2

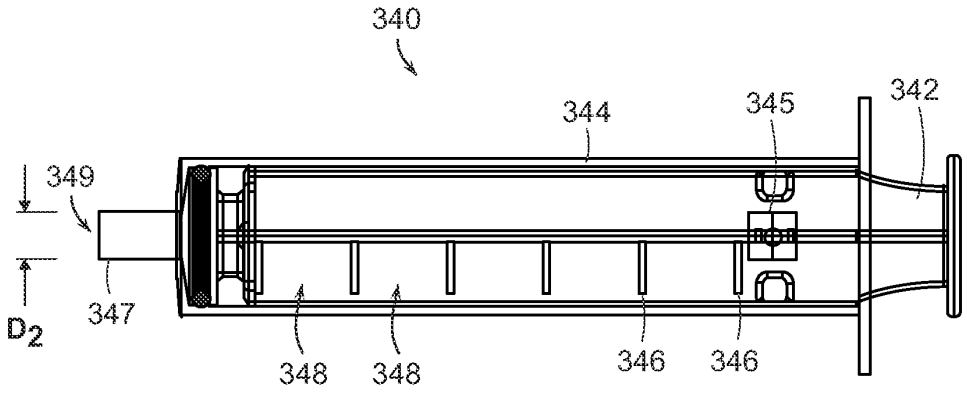

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FIG. 3A

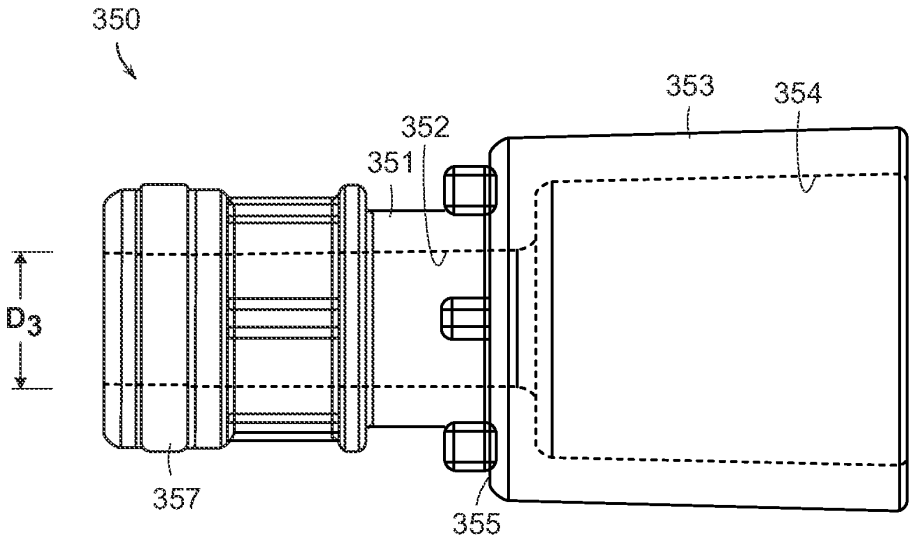


FIG. 3B

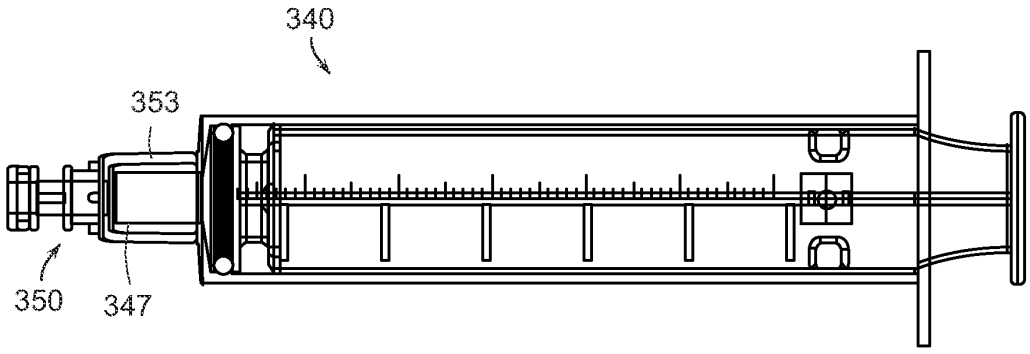


FIG. 3C

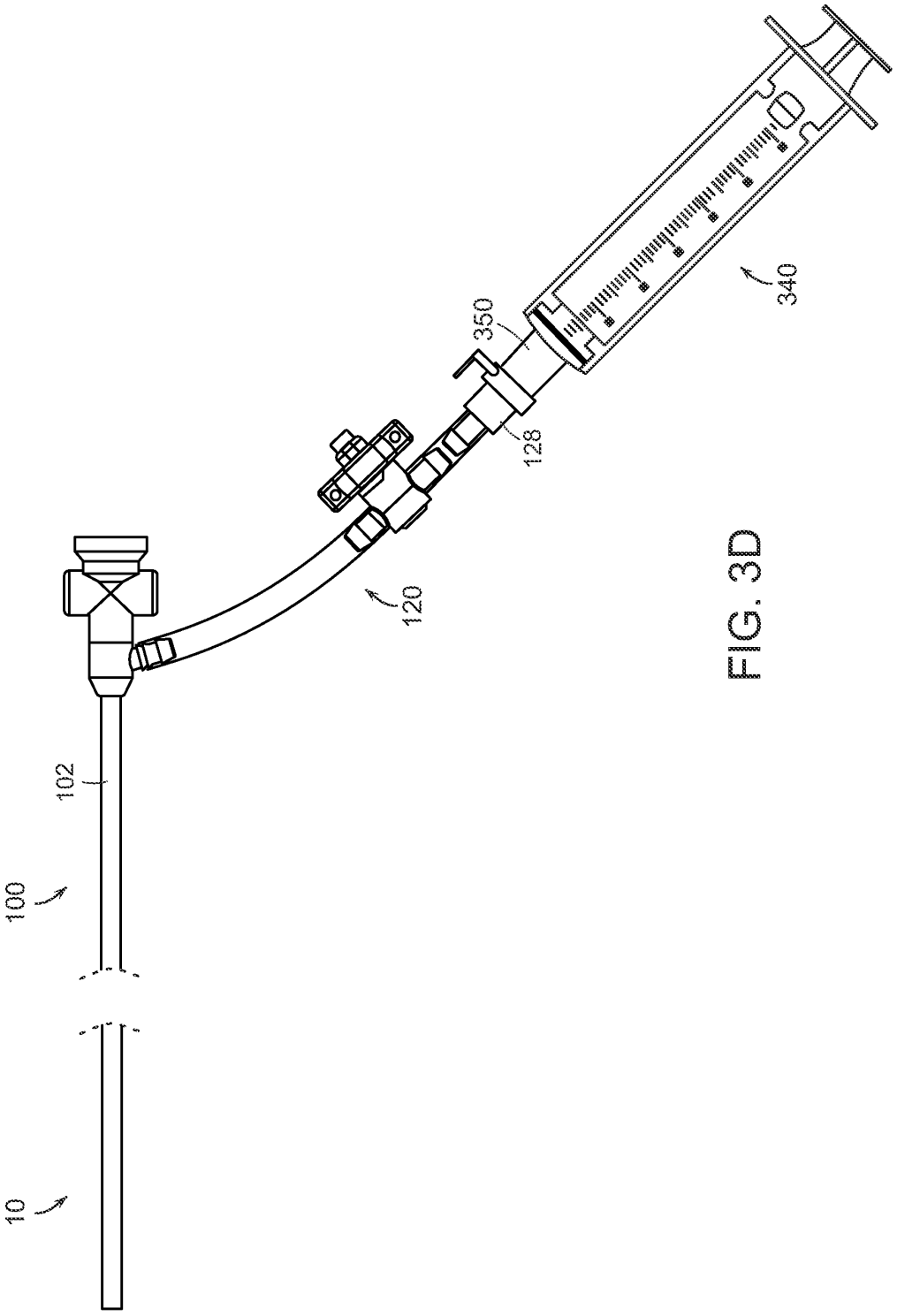
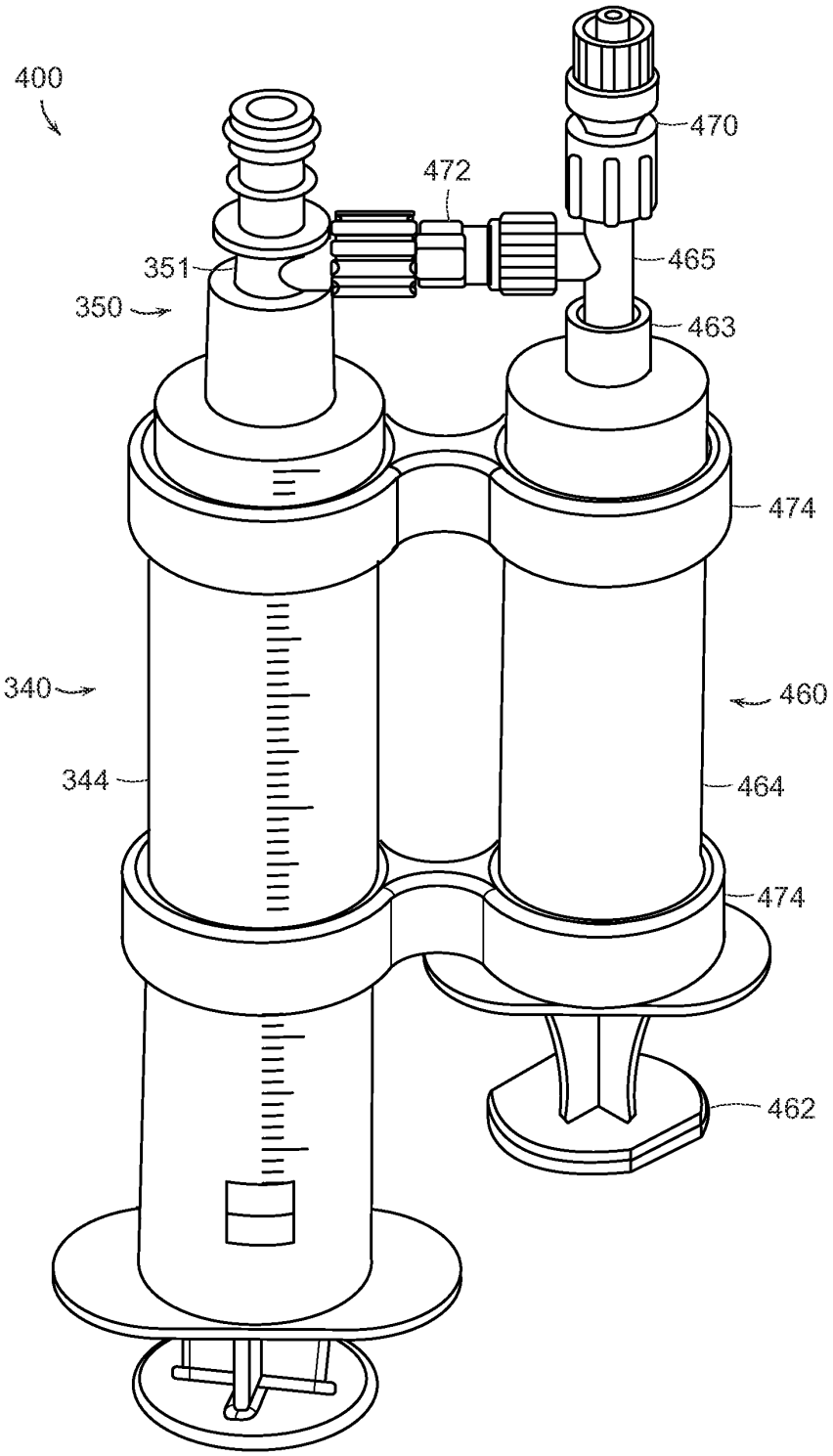


FIG. 3D

FIG. 4A



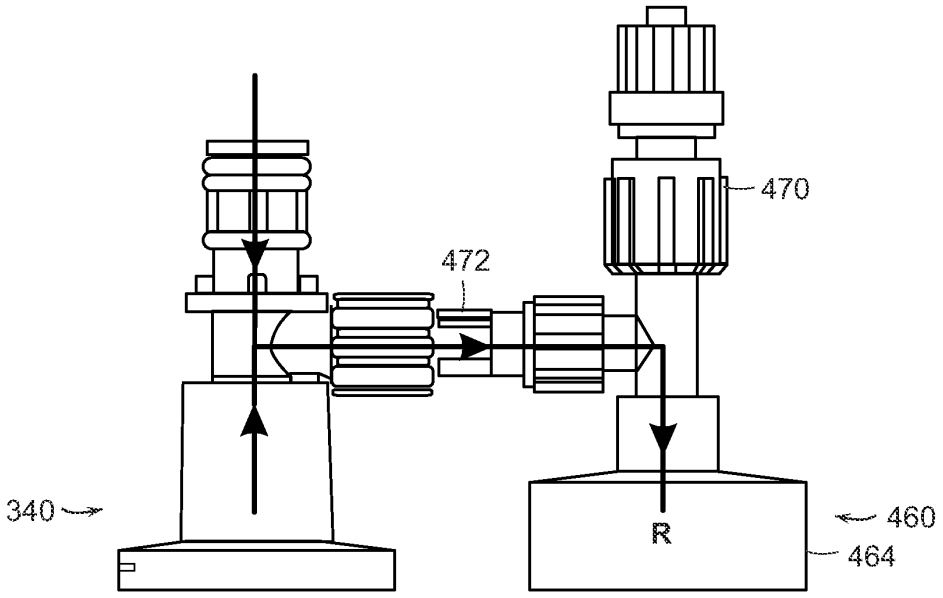


FIG. 4B

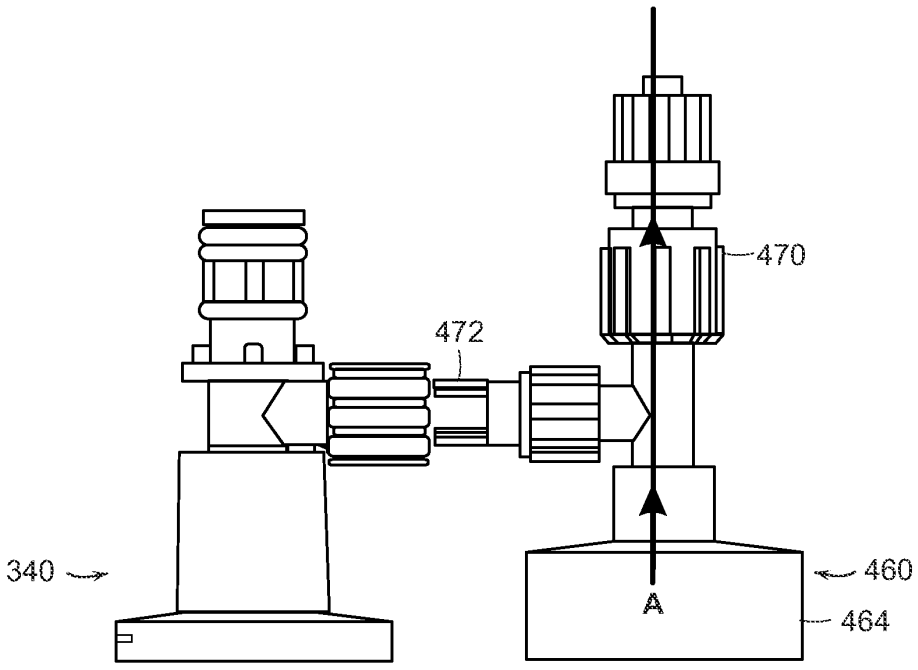


FIG. 4C

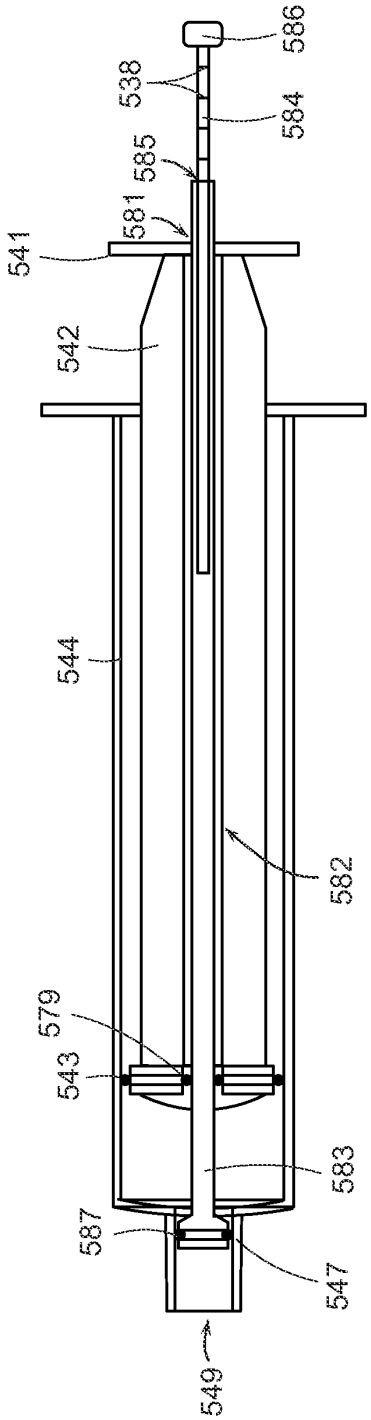


FIG. 5

FIG. 6

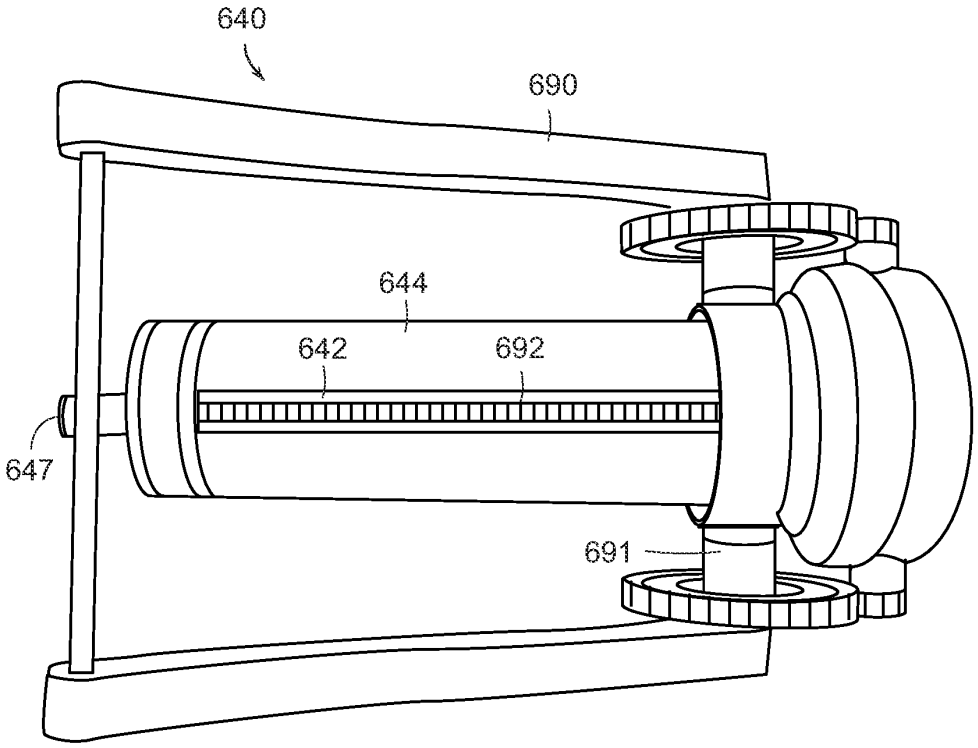
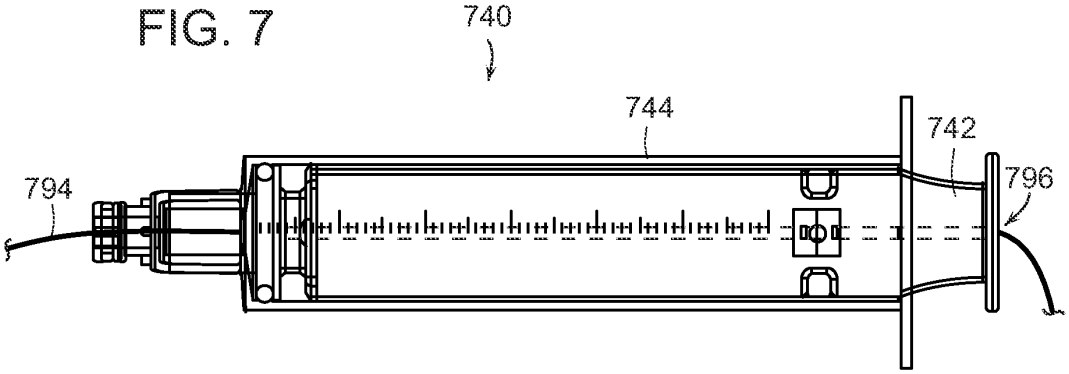


FIG. 7



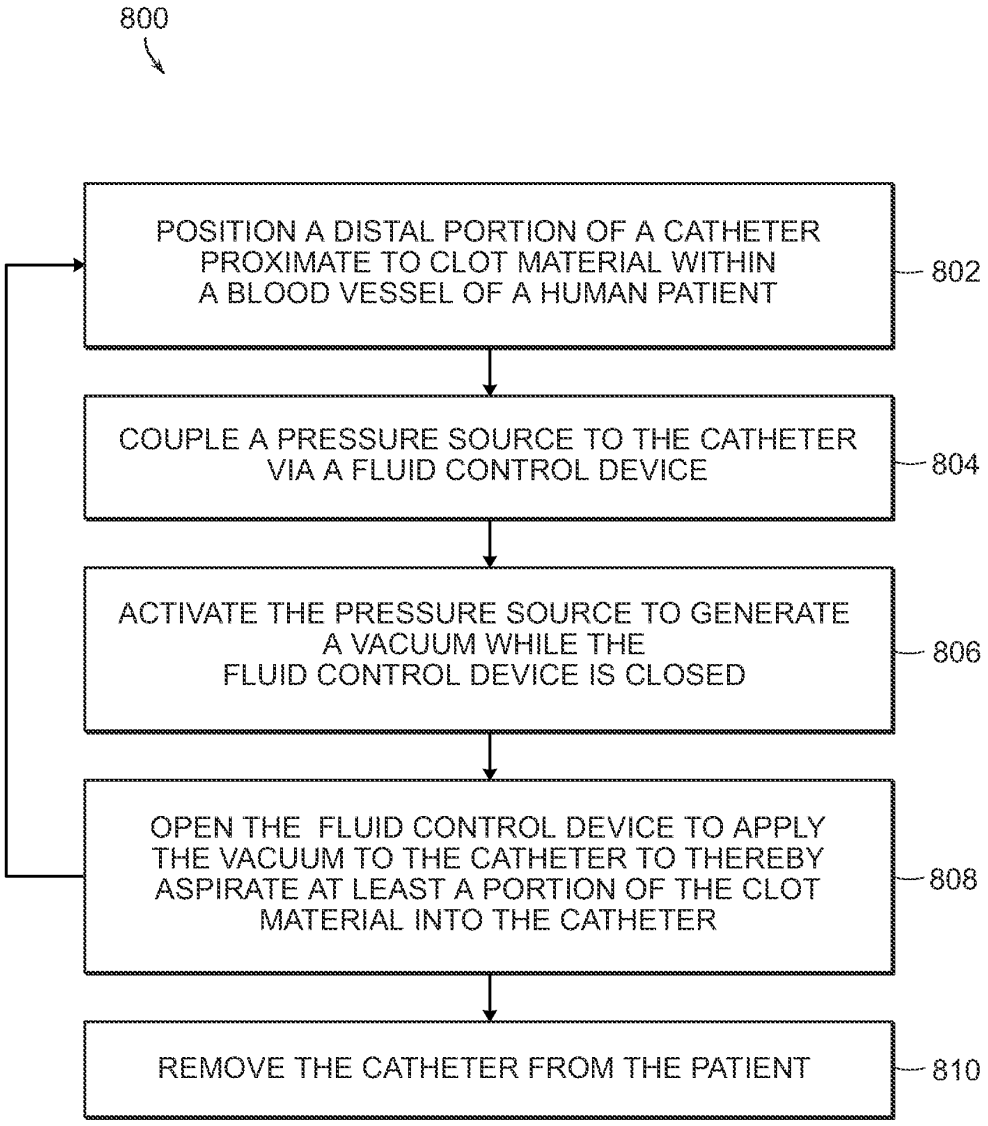

800
POSITION A DISTAL PORTION OF A CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF A HUMAN PATIENT
802
COUPLE A PRESSURE SOURCE TO THE CATHETER VIA A FLUID CONTROL DEVICE
804
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
806
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE CATHETER
808
REMOVE THE CATHETER FROM THE PATIENT
810

FIG. 8

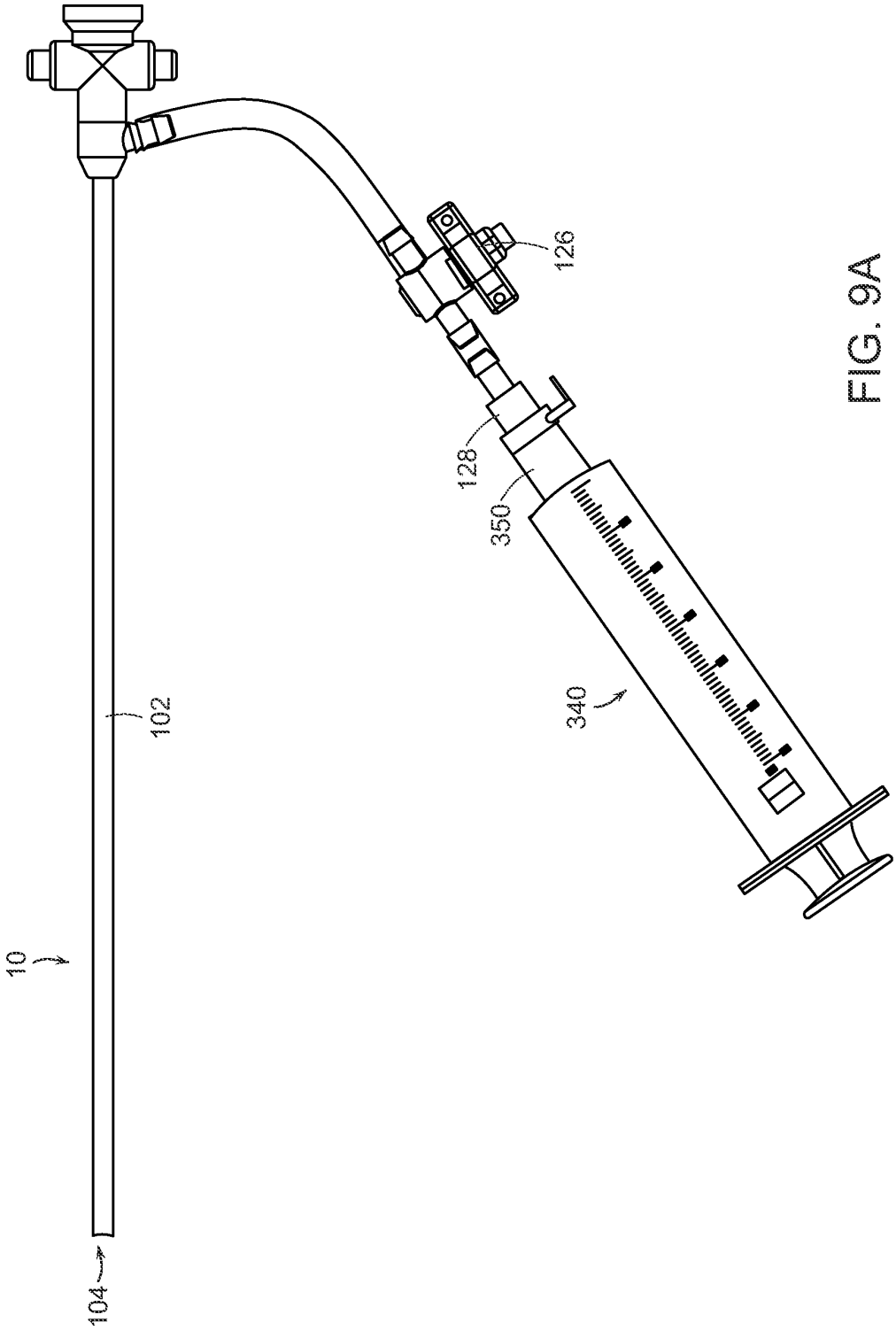


FIG. 9A

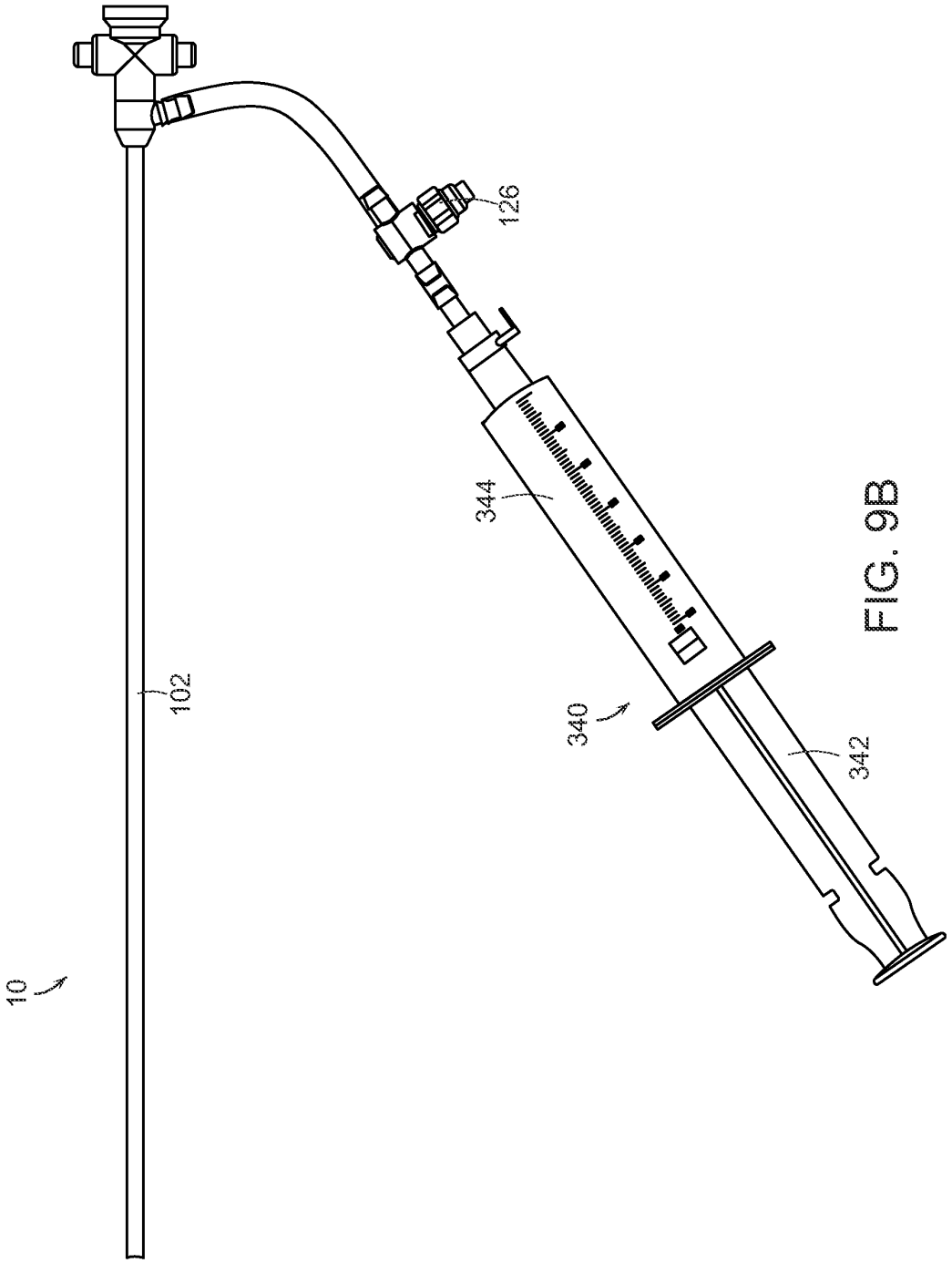


FIG. 9B

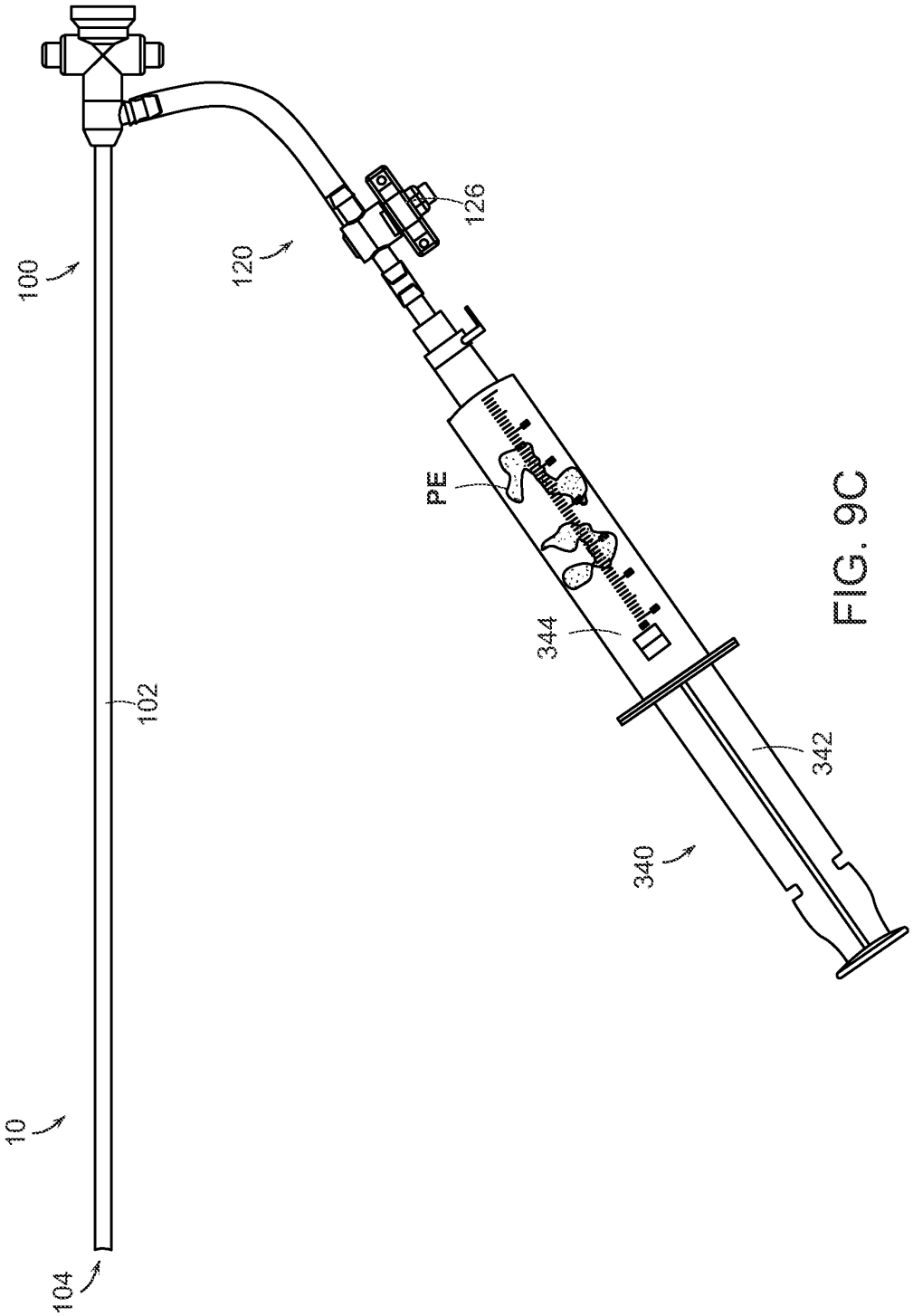


FIG. 9C

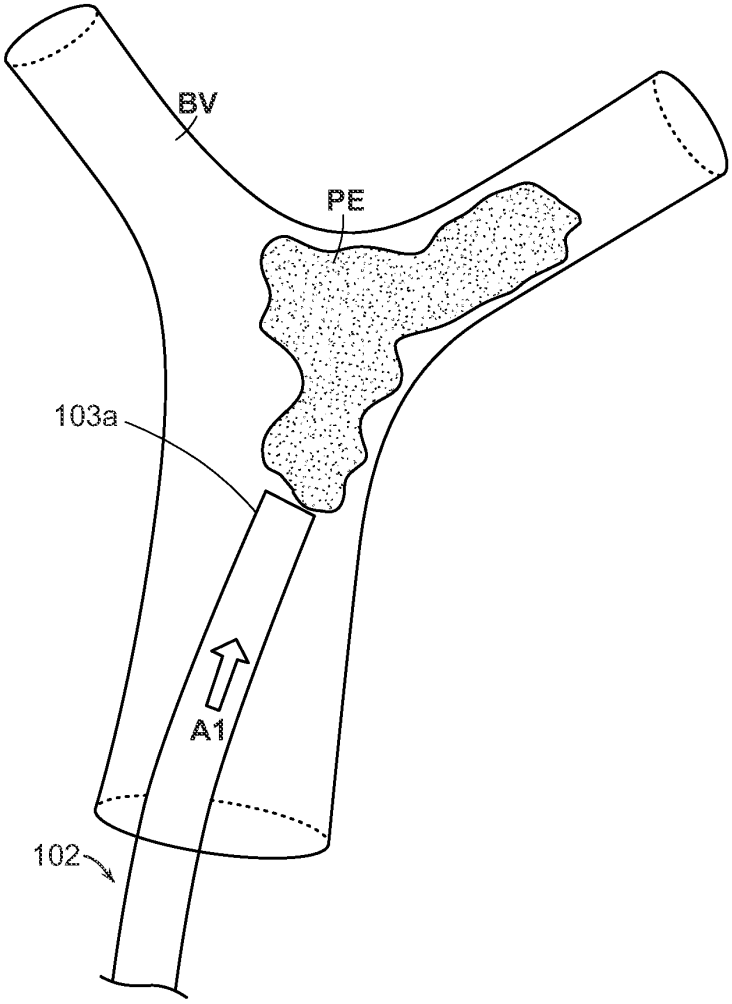


FIG. 10A

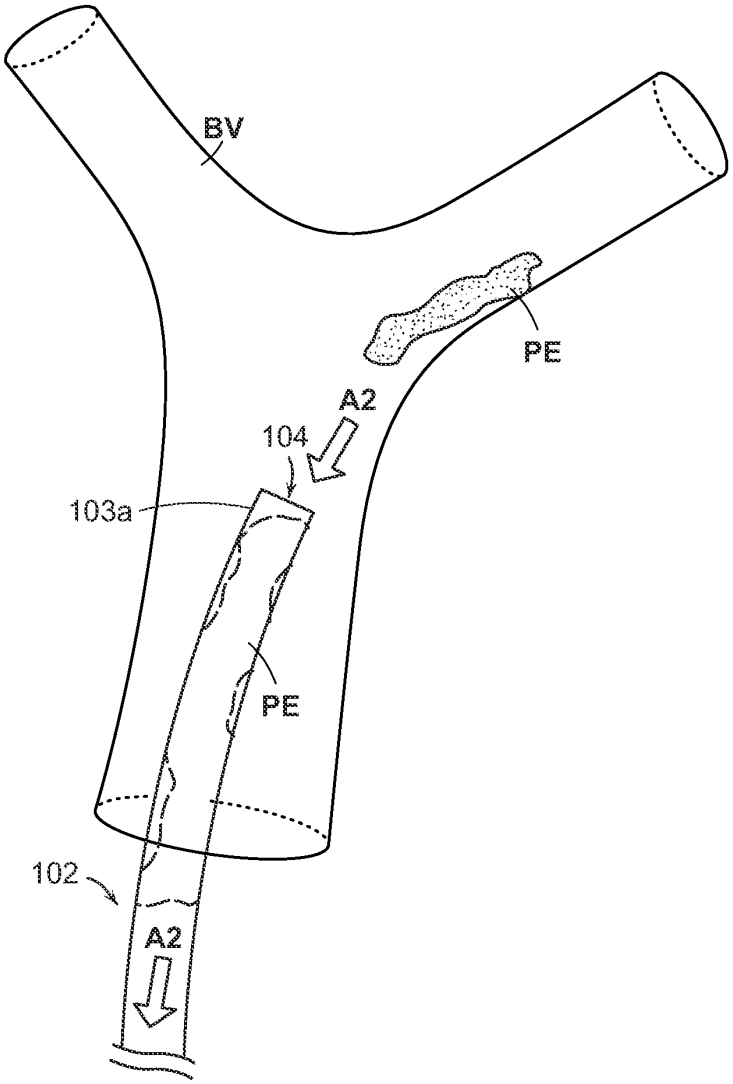


FIG. 10B

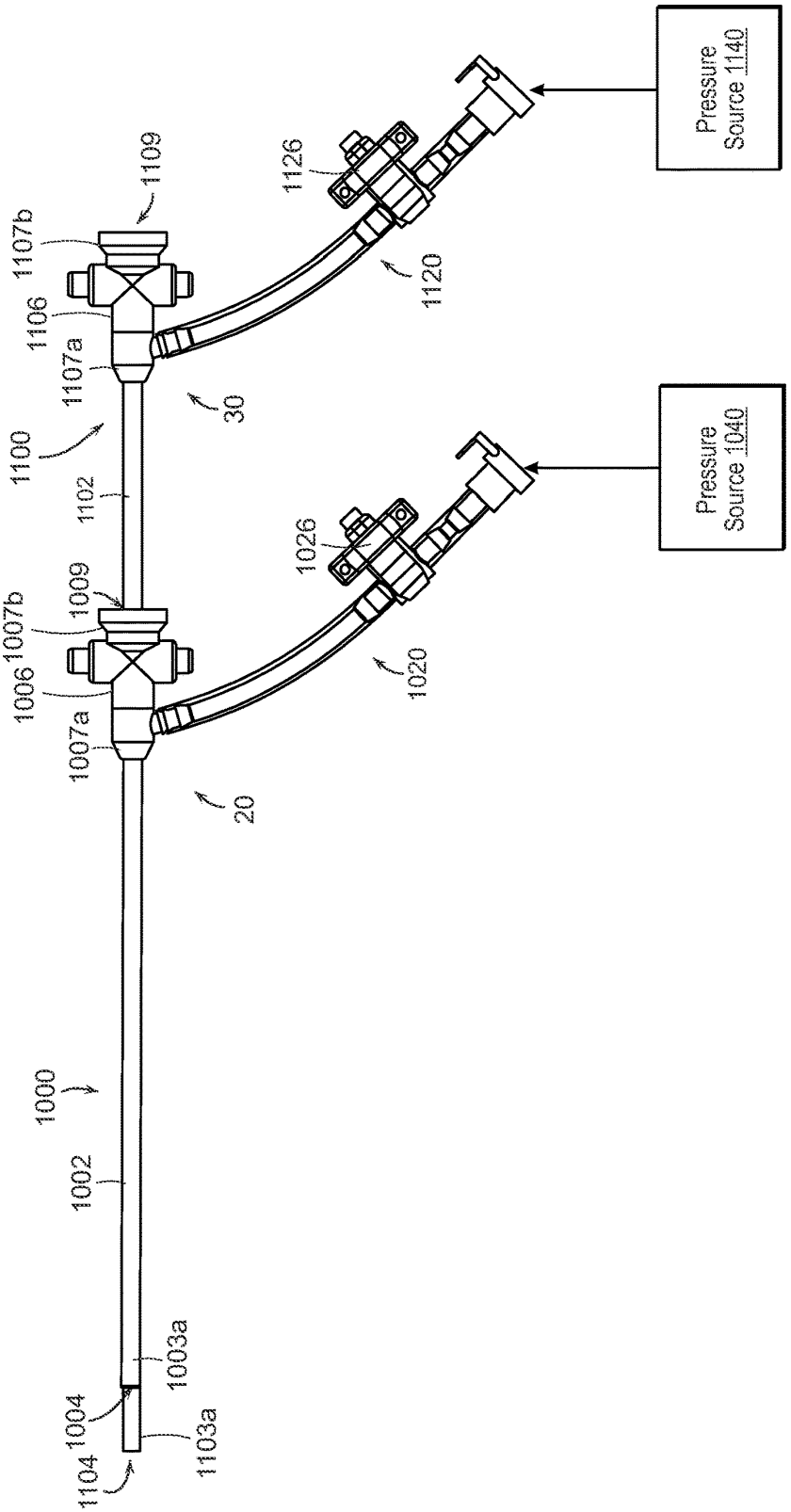

Pressure Source 1140
Pressure Source 1040
1109
1126
1107b
1120
1106
1107a
30
1100
1102
1026
1009
1007b
1020
1006
1007a
20
1000
1002
1003a
1004
1103a
1104

FIG. 11

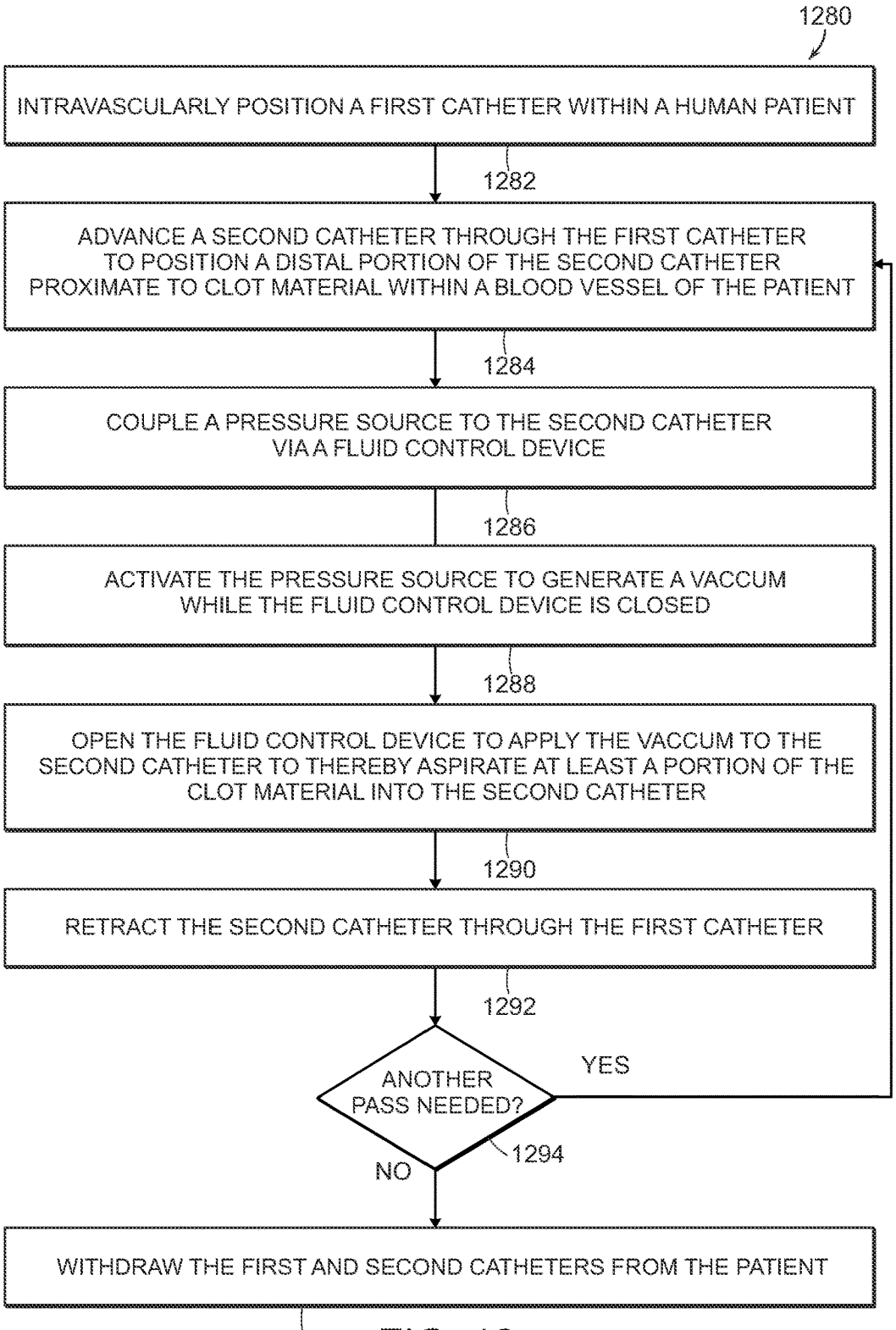

1280
INTRAVASCULARLY POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT
1282
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF THE PATIENT
1284
COUPLE A PRESSURE SOURCE TO THE SECOND CATHETER VIA A FLUID CONTROL DEVICE
1286
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACCUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
1288
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACCUM TO THE SECOND CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE SECOND CATHETER
1290
RETRACT THE SECOND CATHETER THROUGH THE FIRST CATHETER
1292
ANOTHER PASS NEEDED?
YES
1294
NO
WITHDRAW THE FIRST AND SECOND CATHETERS FROM THE PATIENT
1296

FIG. 12

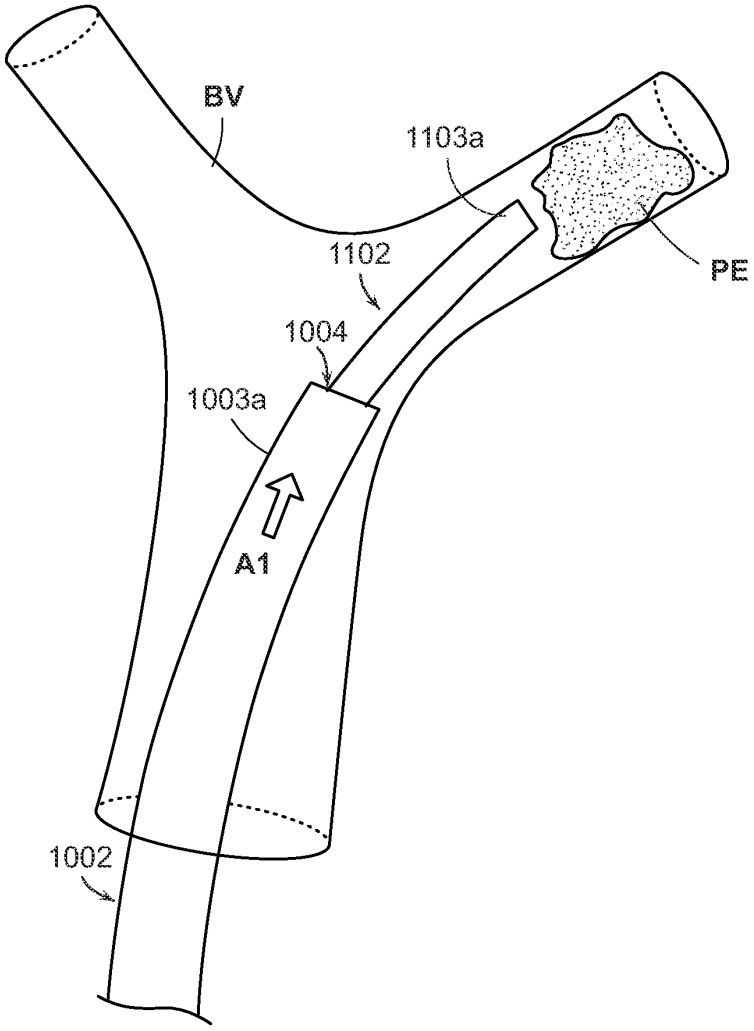


FIG. 13A

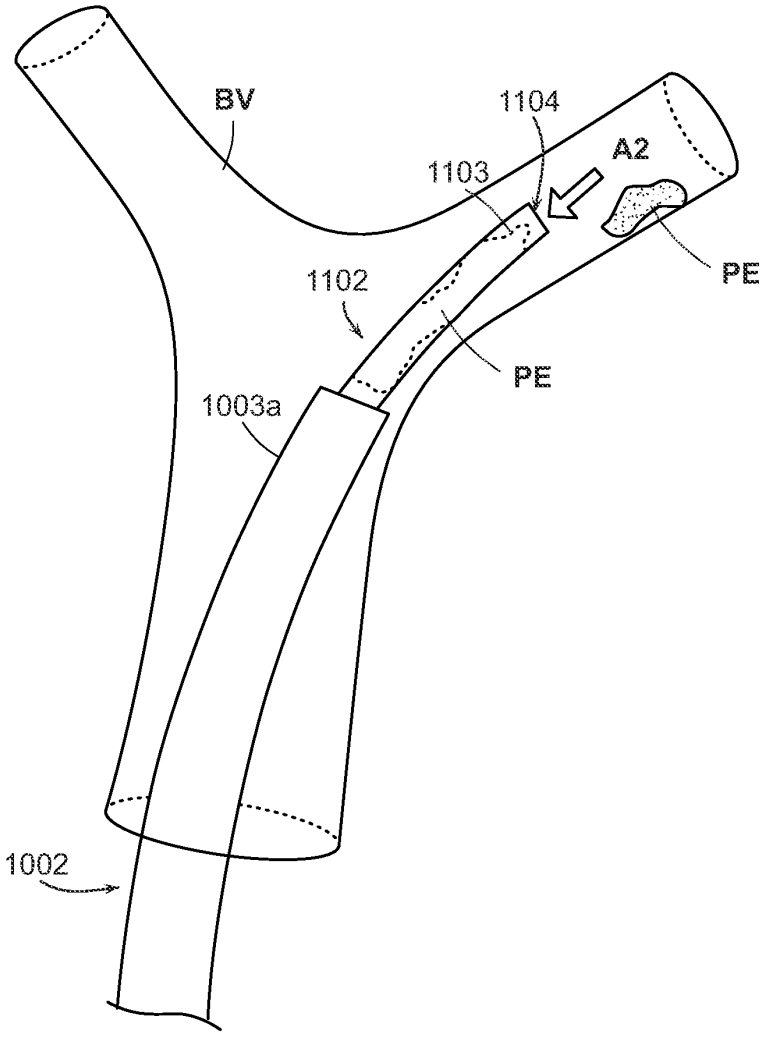


FIG. 13B

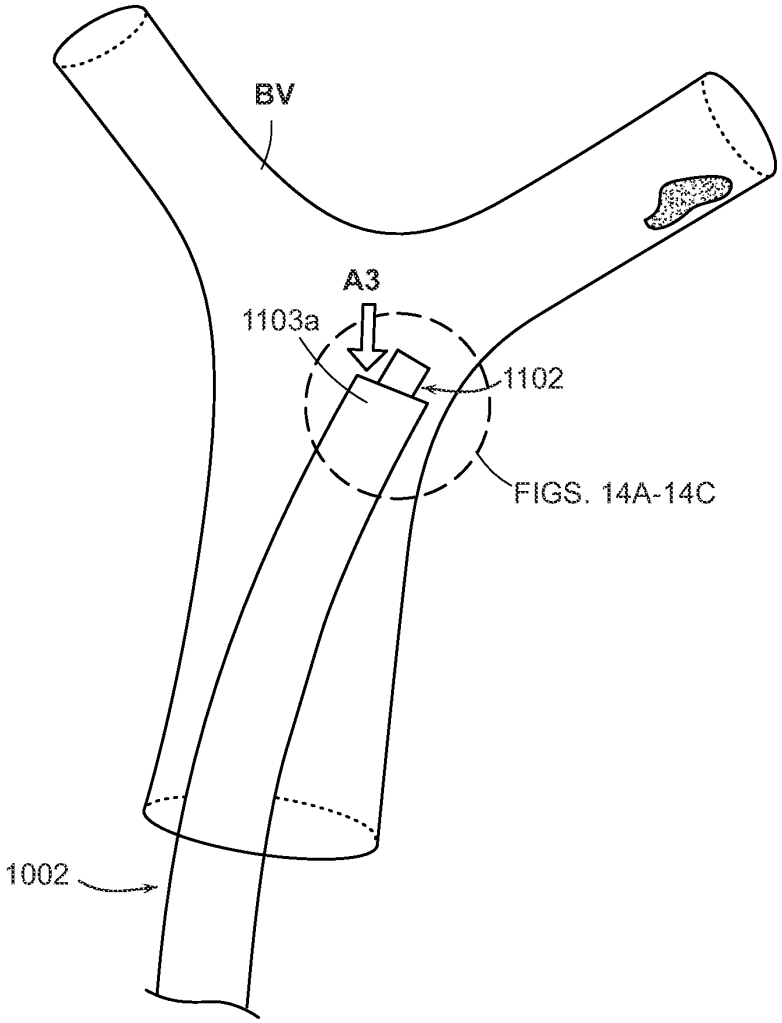


FIG. 13C

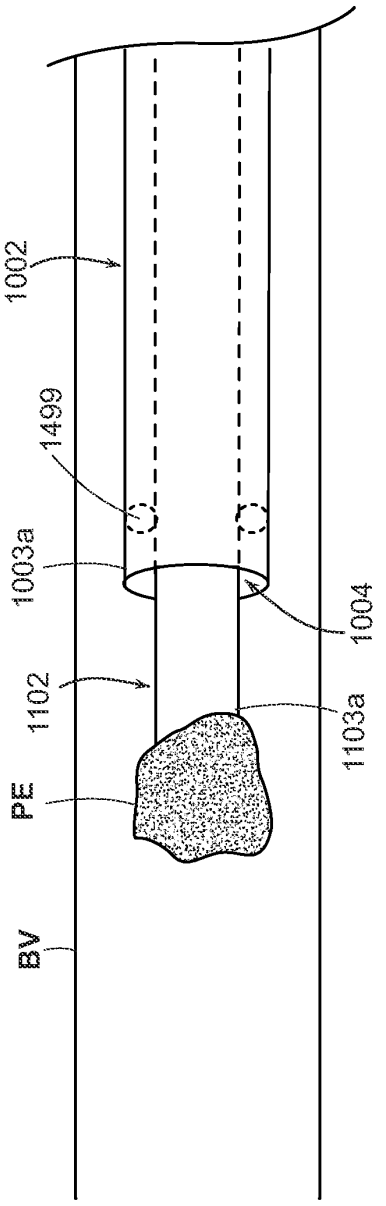


FIG. 14A

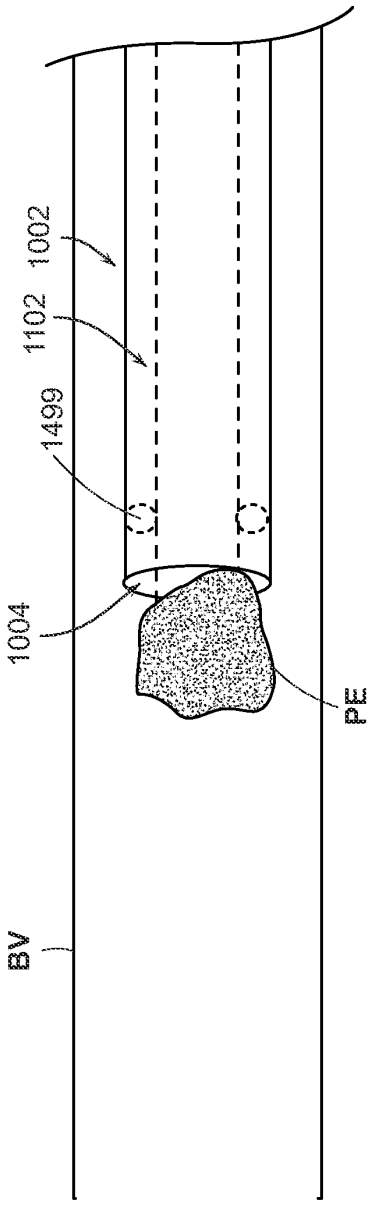


FIG. 14B

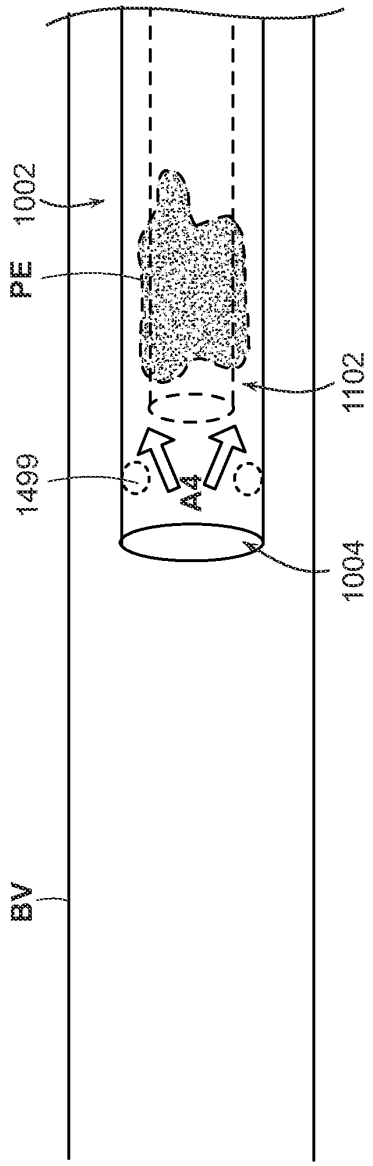


FIG. 14C

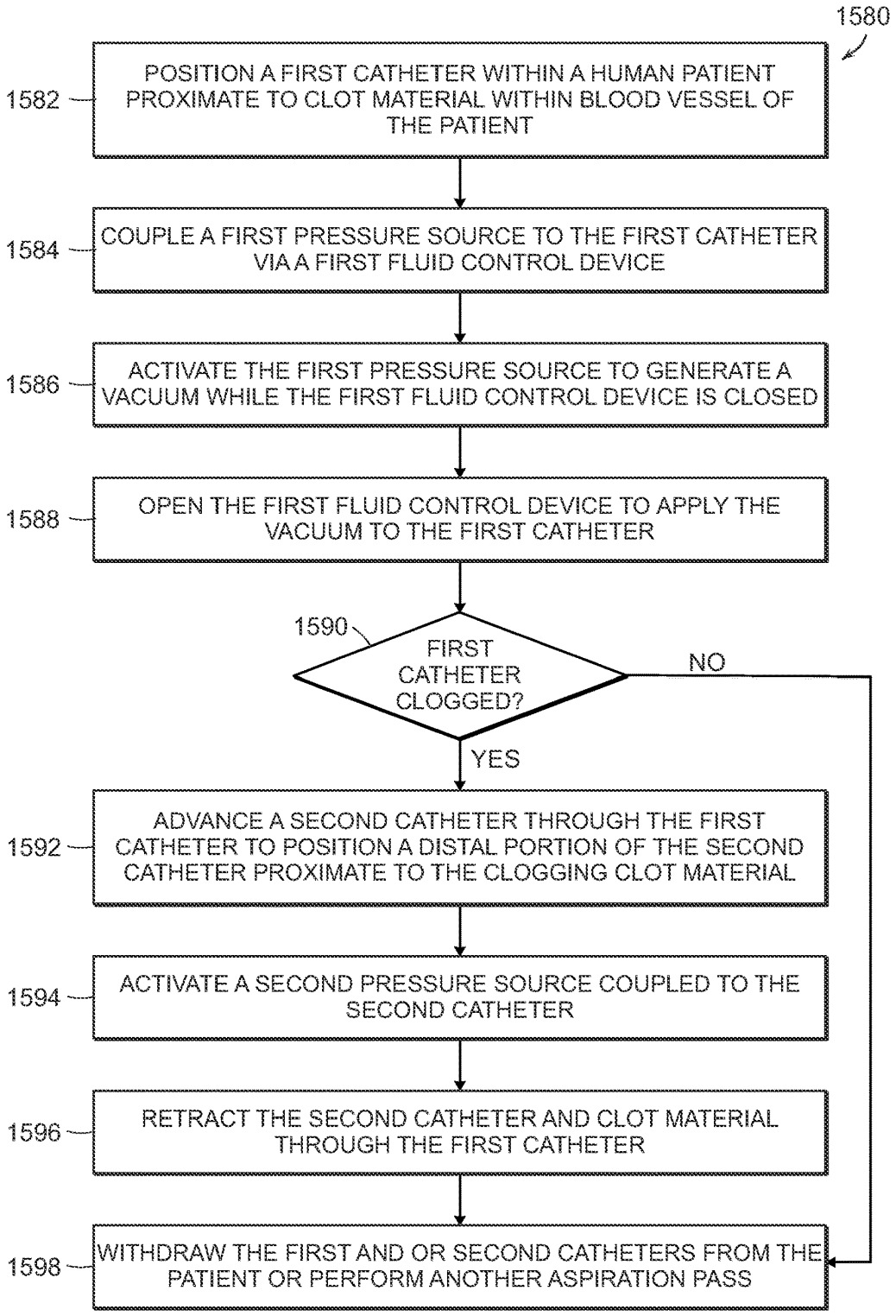

1580
1582
POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT PROXIMATE TO CLOT MATERIAL WITHIN BLOOD VESSEL OF THE PATIENT
1584
COUPLE A FIRST PRESSURE SOURCE TO THE FIRST CATHETER VIA A FIRST FLUID CONTROL DEVICE
1586
ACTIVATE THE FIRST PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FIRST FLUID CONTROL DEVICE IS CLOSED
1588
OPEN THE FIRST FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE FIRST CATHETER
1590
FIRST CATHETER CLOGGED?
NO
YES
1592
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO THE CLOGGING CLOT MATERIAL
1594
ACTIVATE A SECOND PRESSURE SOURCE COUPLED TO THE SECOND CATHETER
1596
RETRACT THE SECOND CATHETER AND CLOT MATERIAL THROUGH THE FIRST CATHETER
1598
WITHDRAW THE FIRST AND OR SECOND CATHETERS FROM THE PATIENT OR PERFORM ANOTHER ASPIRATION PASS

FIG. 15

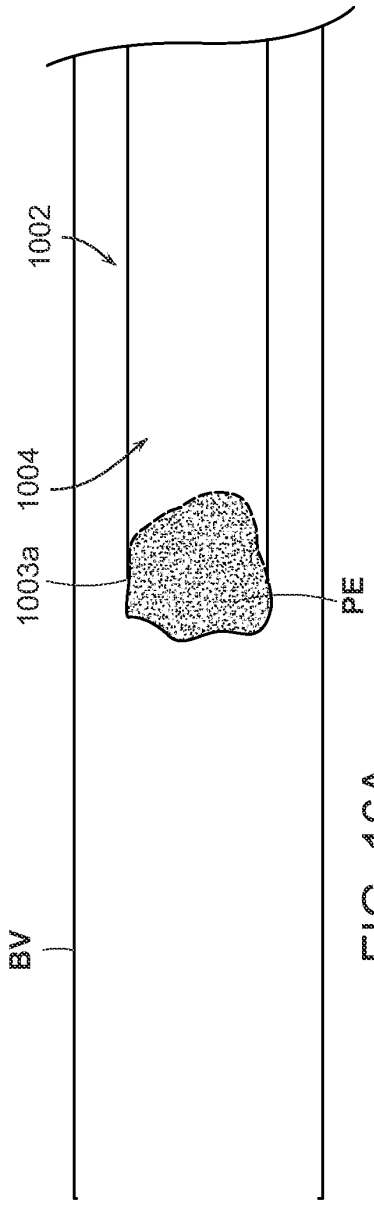


FIG. 16A

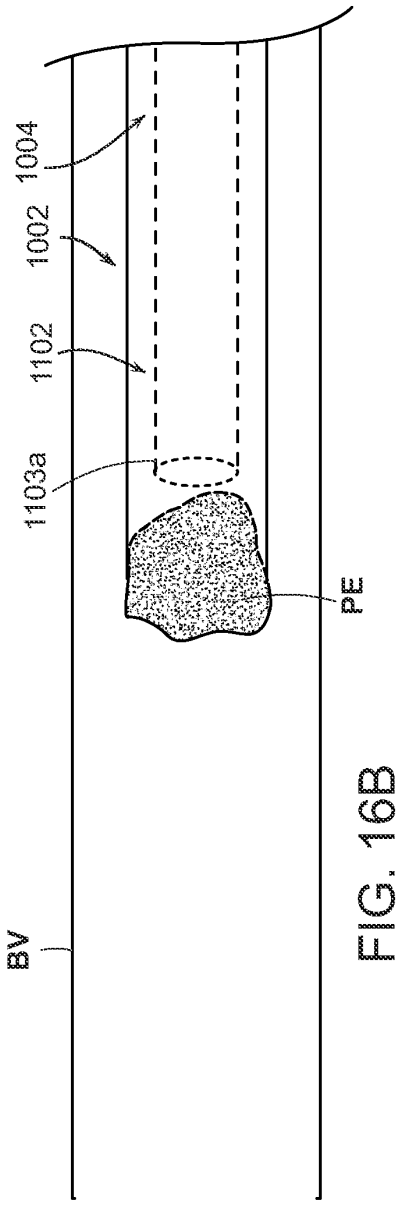


FIG. 16B

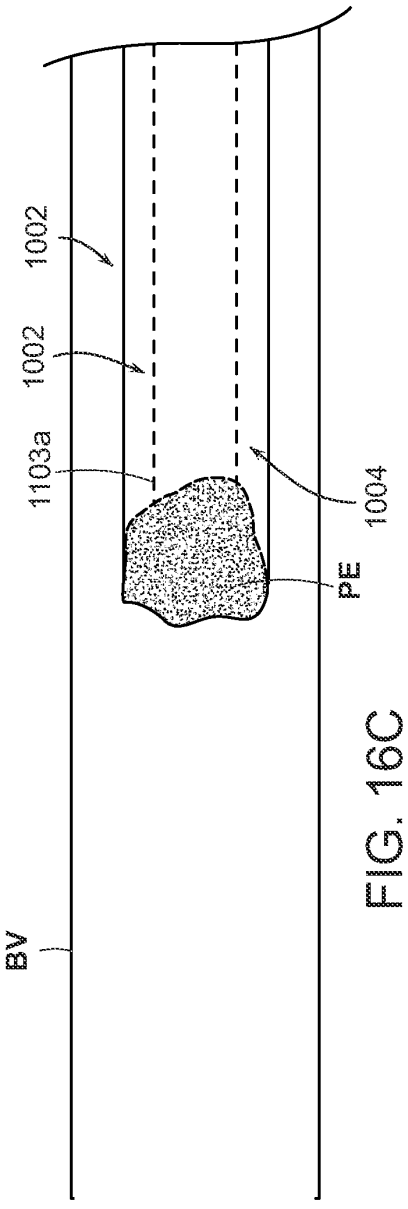


FIG. 16C

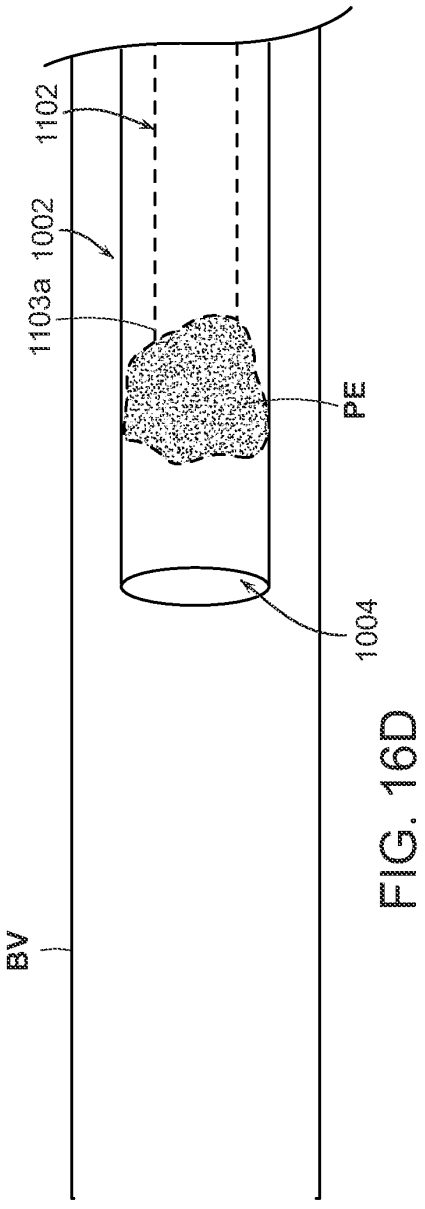


FIG. 16D

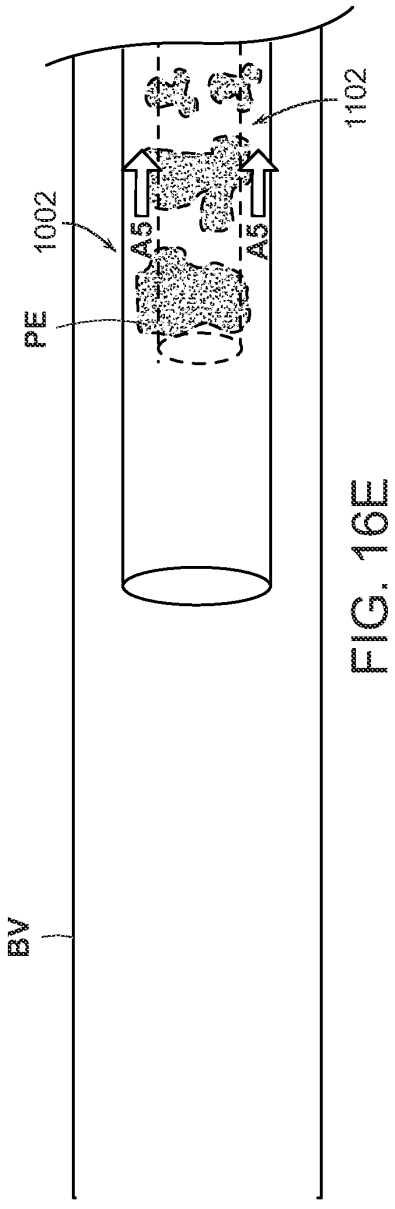


FIG. 16E

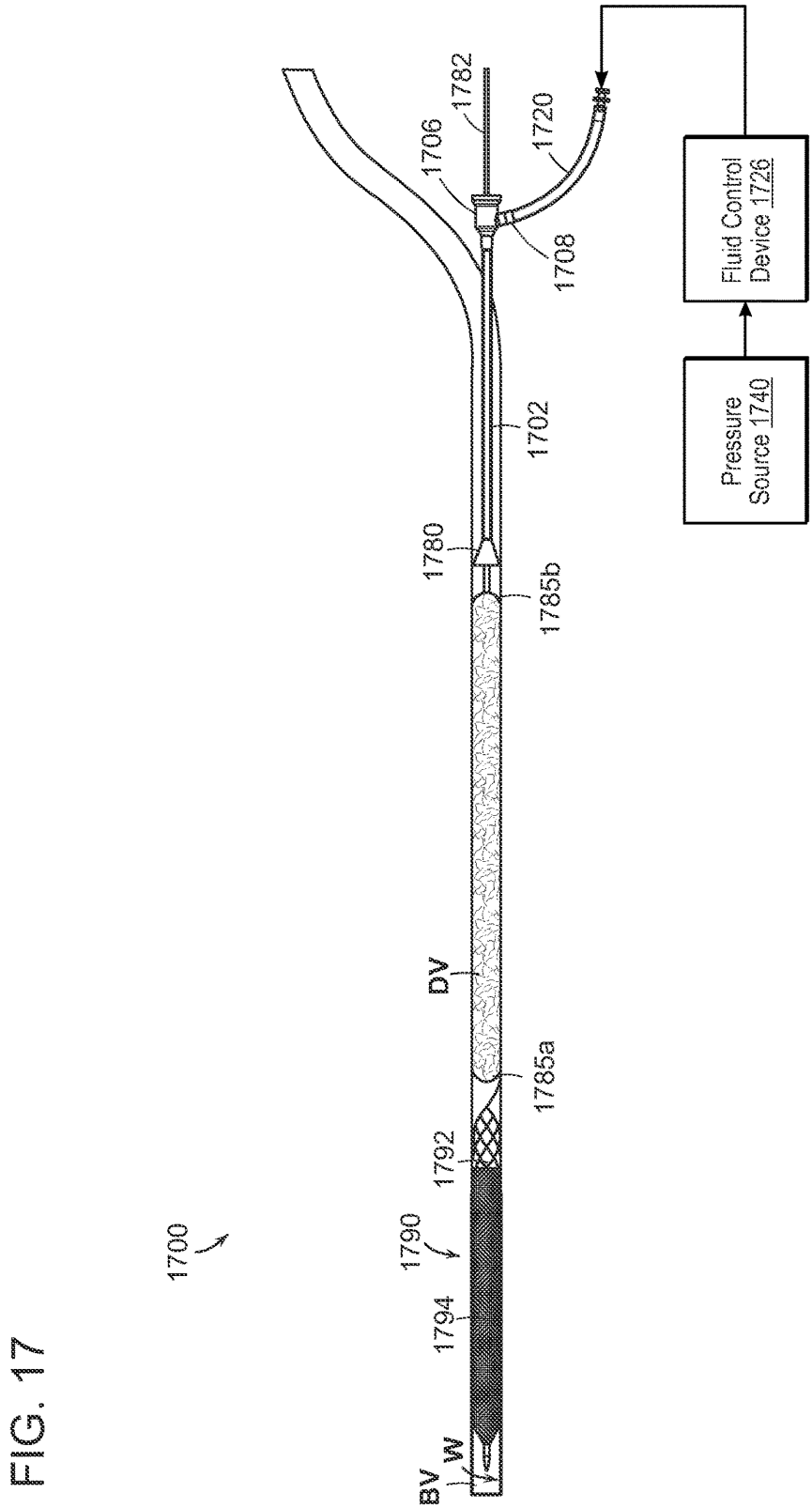

1782
1706
1720
1708
Fluid Control Device 1726
Pressure Source 1740
1702
1780
1785b
DV
1785a
1792
1790
1794
BV
W
1700

FIG. 17

FIG. 18A

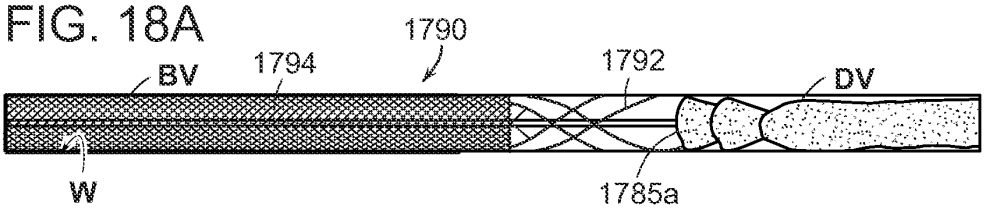


FIG. 18B

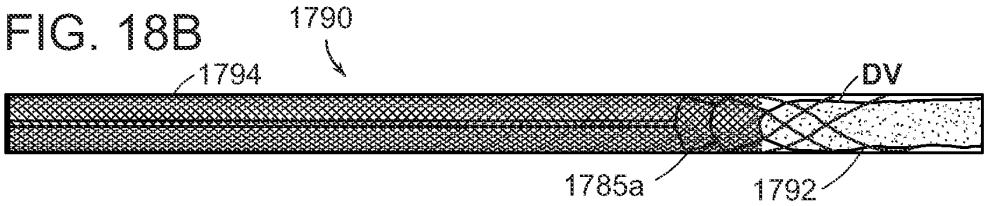


FIG. 18C

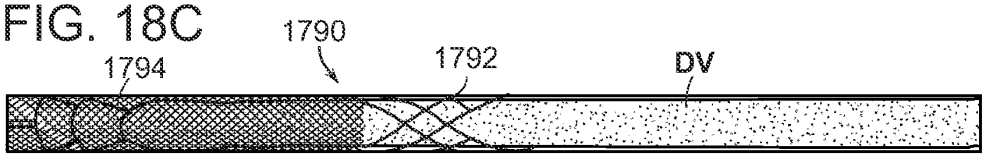


FIG. 18D

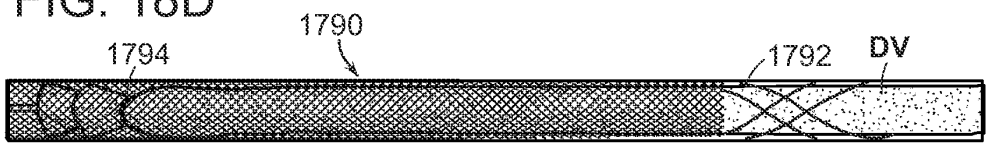


FIG. 18E

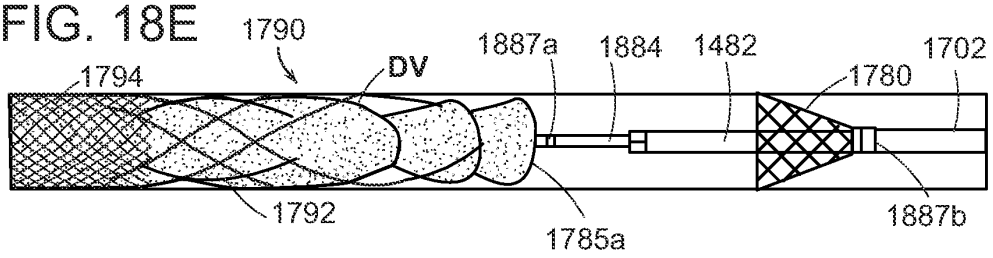


FIG. 18F

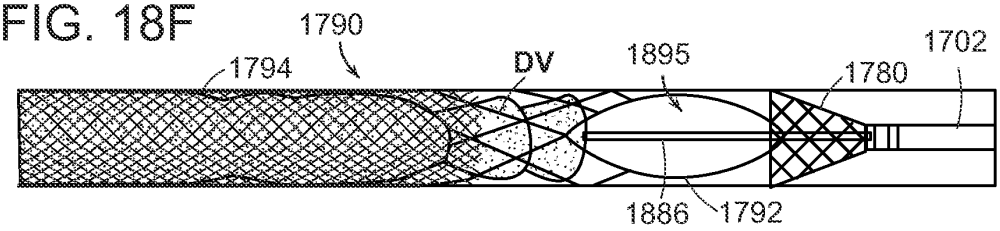


FIG. 18G

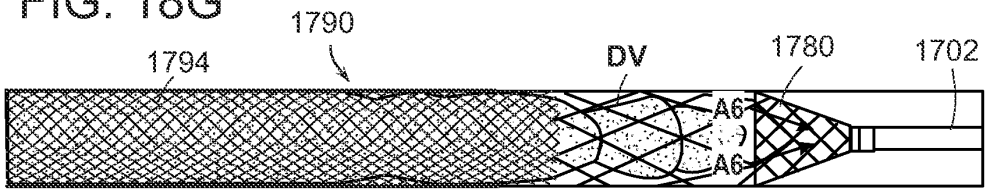
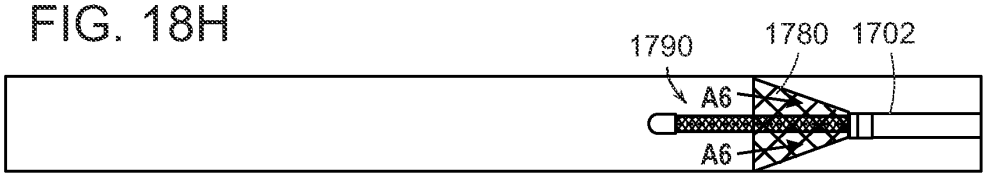


FIG. 18H



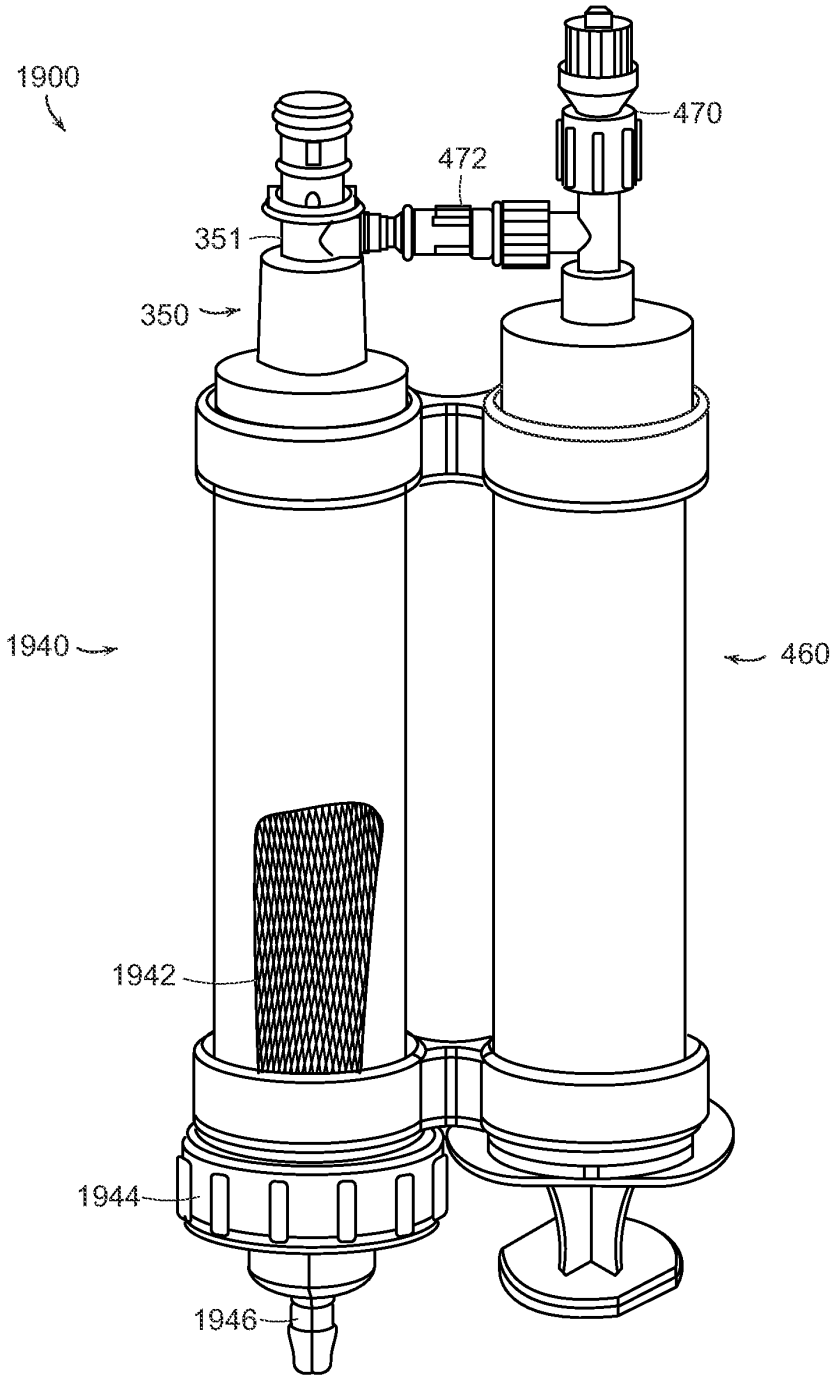


FIG. 19

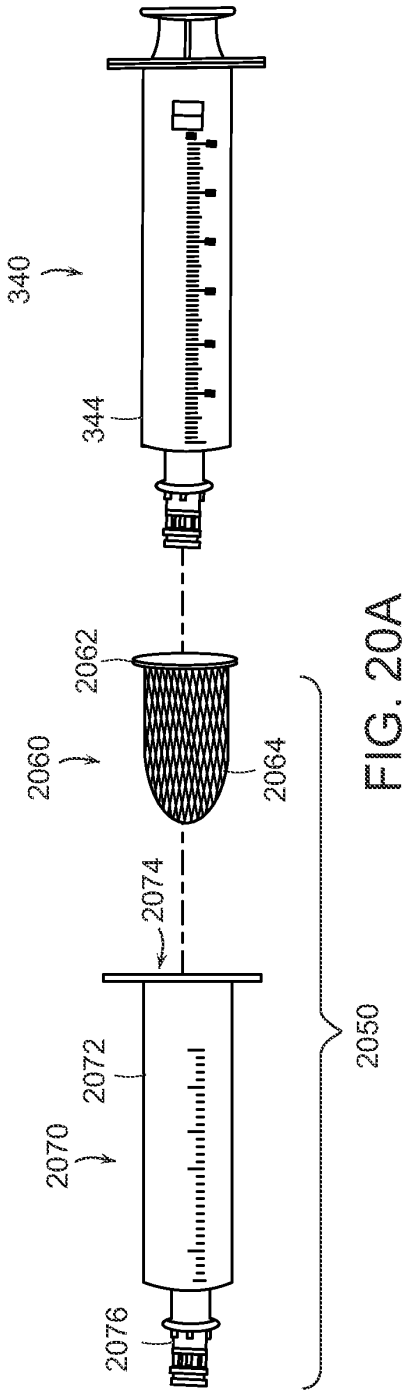


FIG. 20A

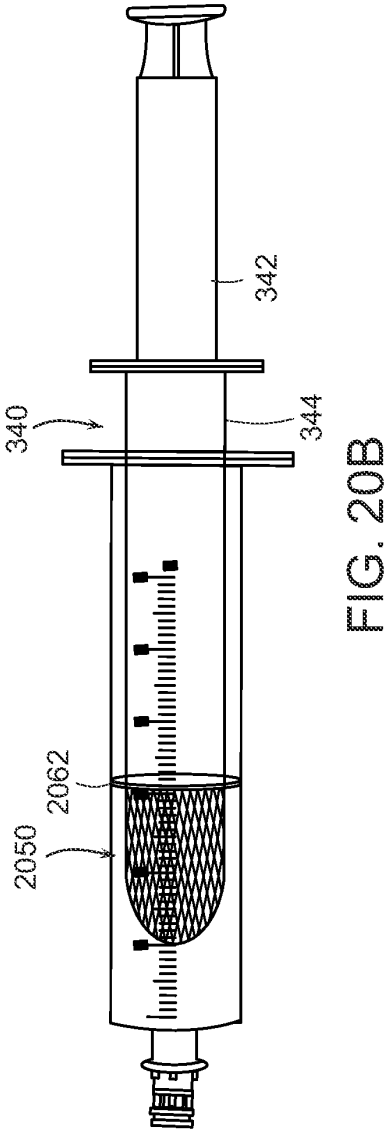


FIG. 20B

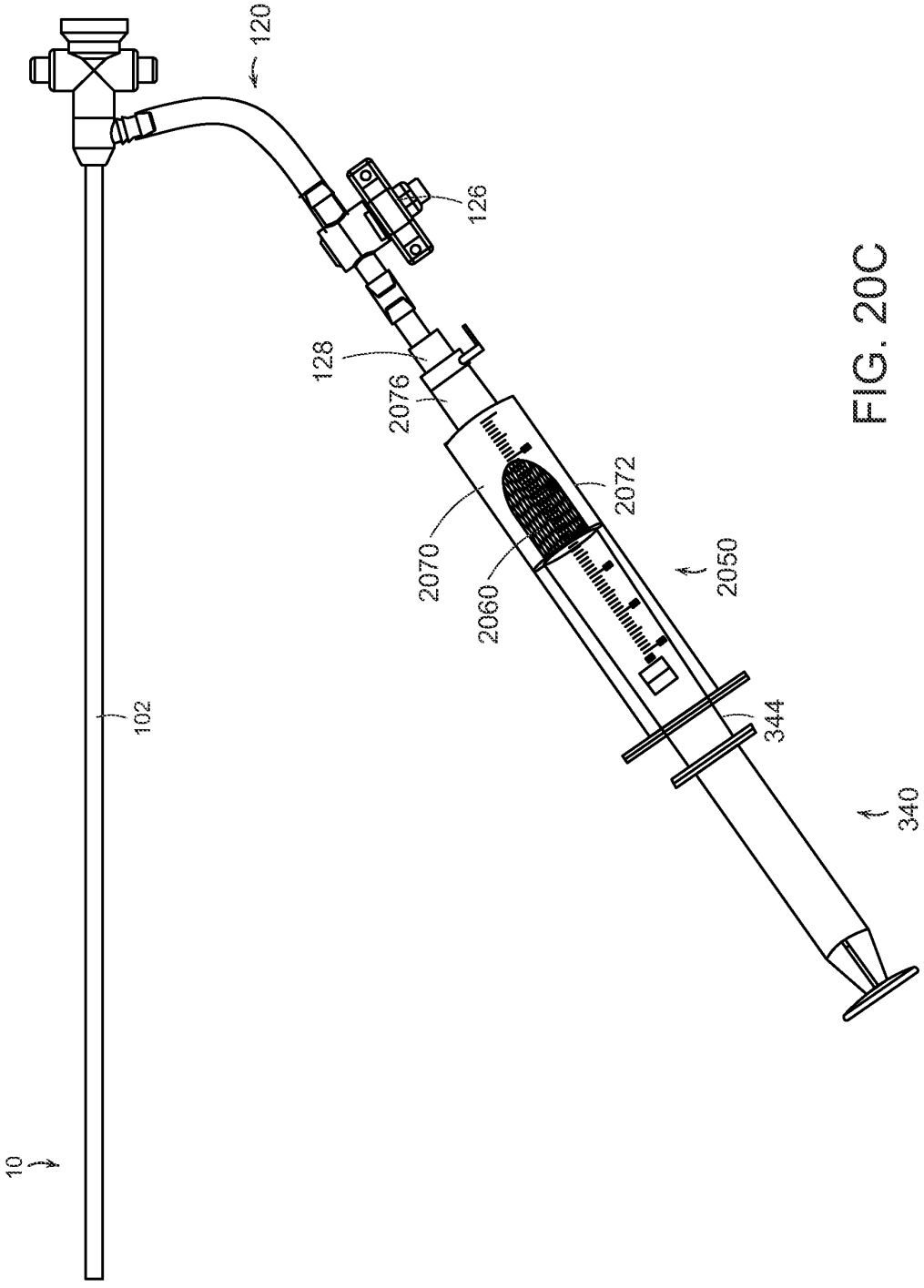


FIG. 20C

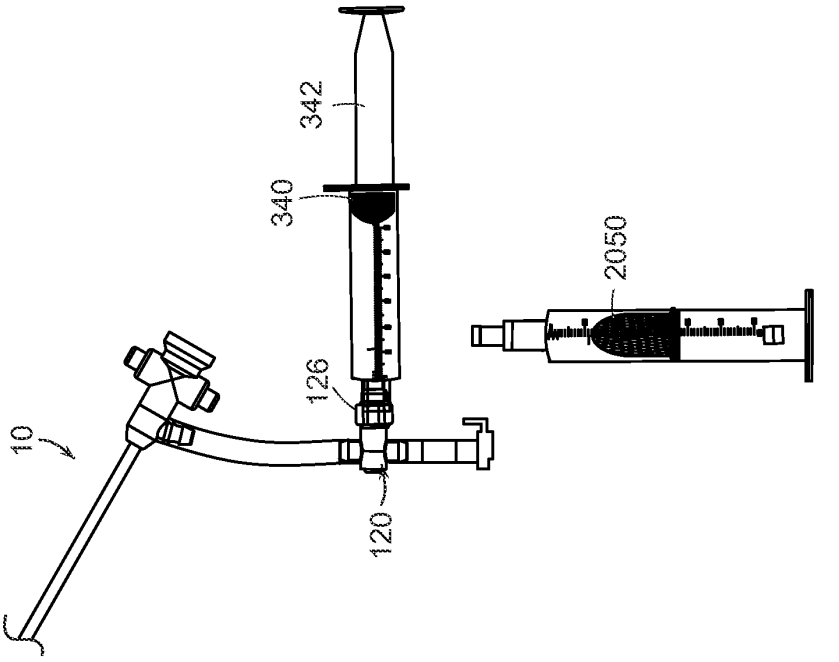


FIG. 20E

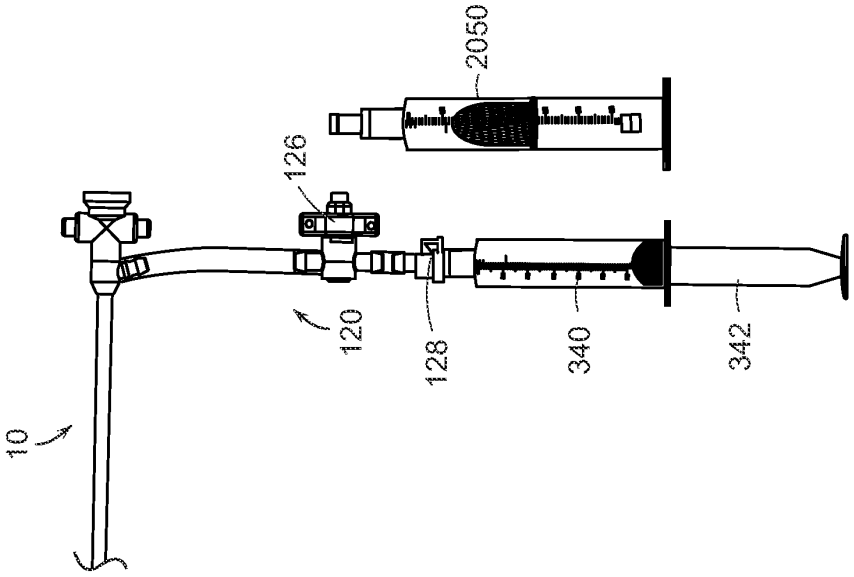


FIG. 20D

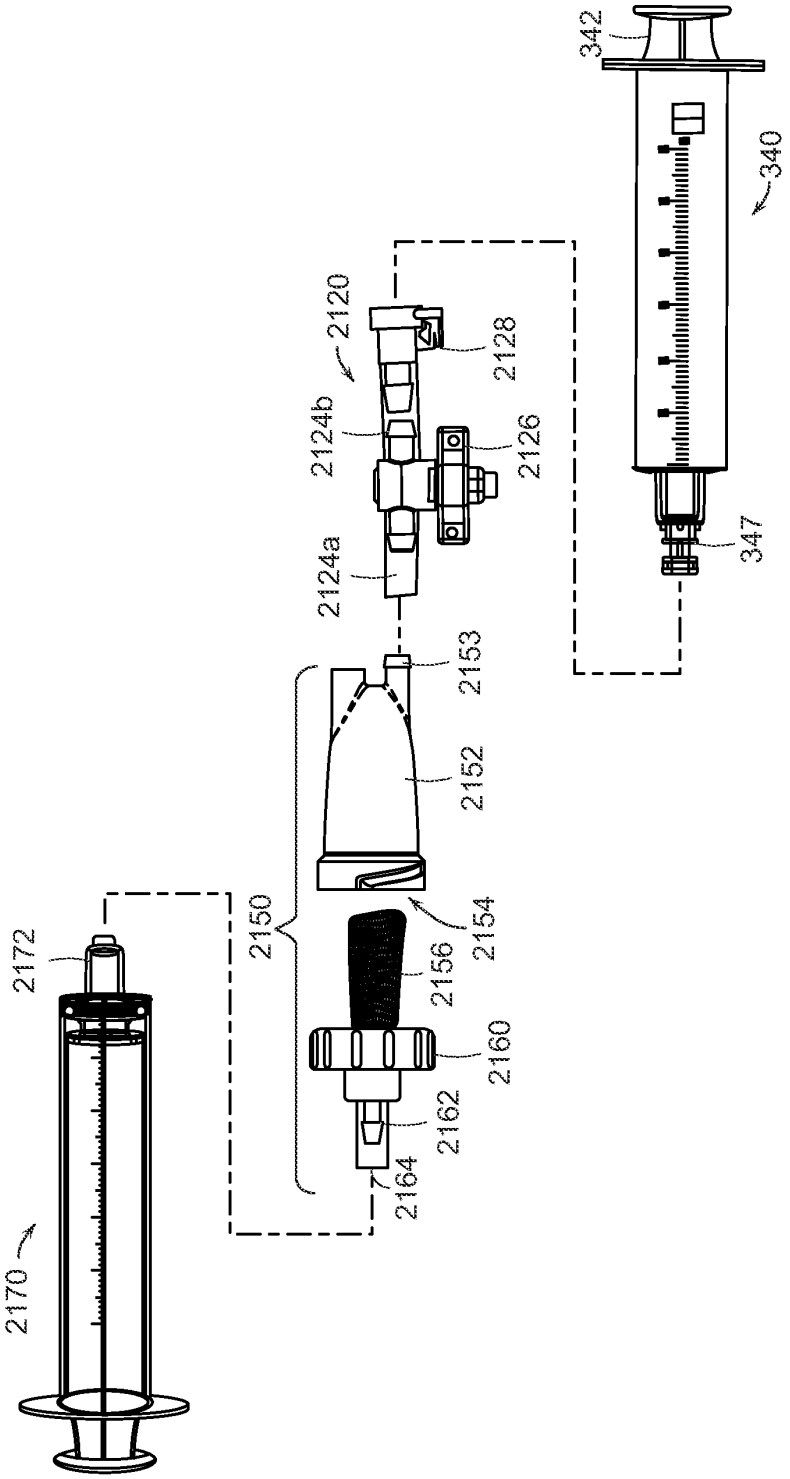

342
340
2120
2128
2124b
2126
347
2124a
2153
2152
2150
2154
2156
2172
2160
2162
2164
2170

FIG. 21A

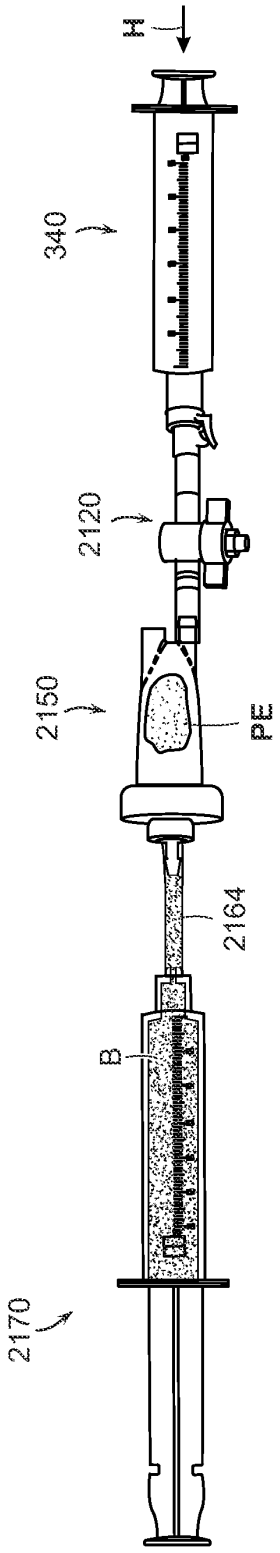


FIG. 21B

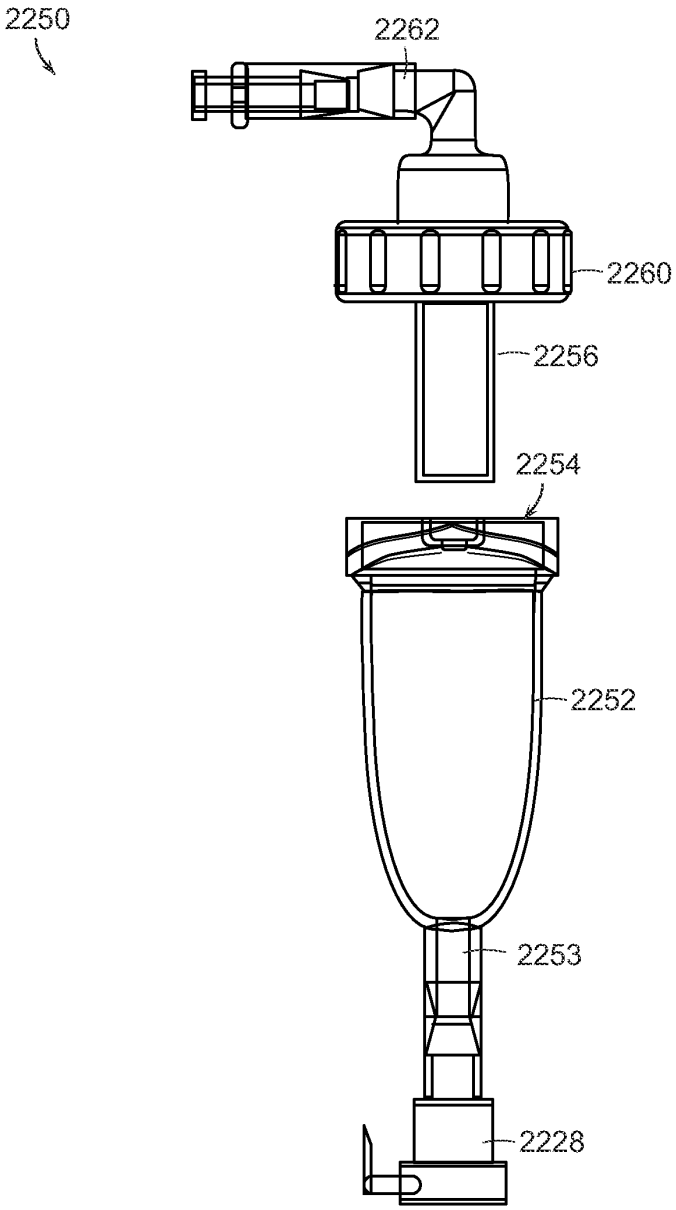


FIG. 22

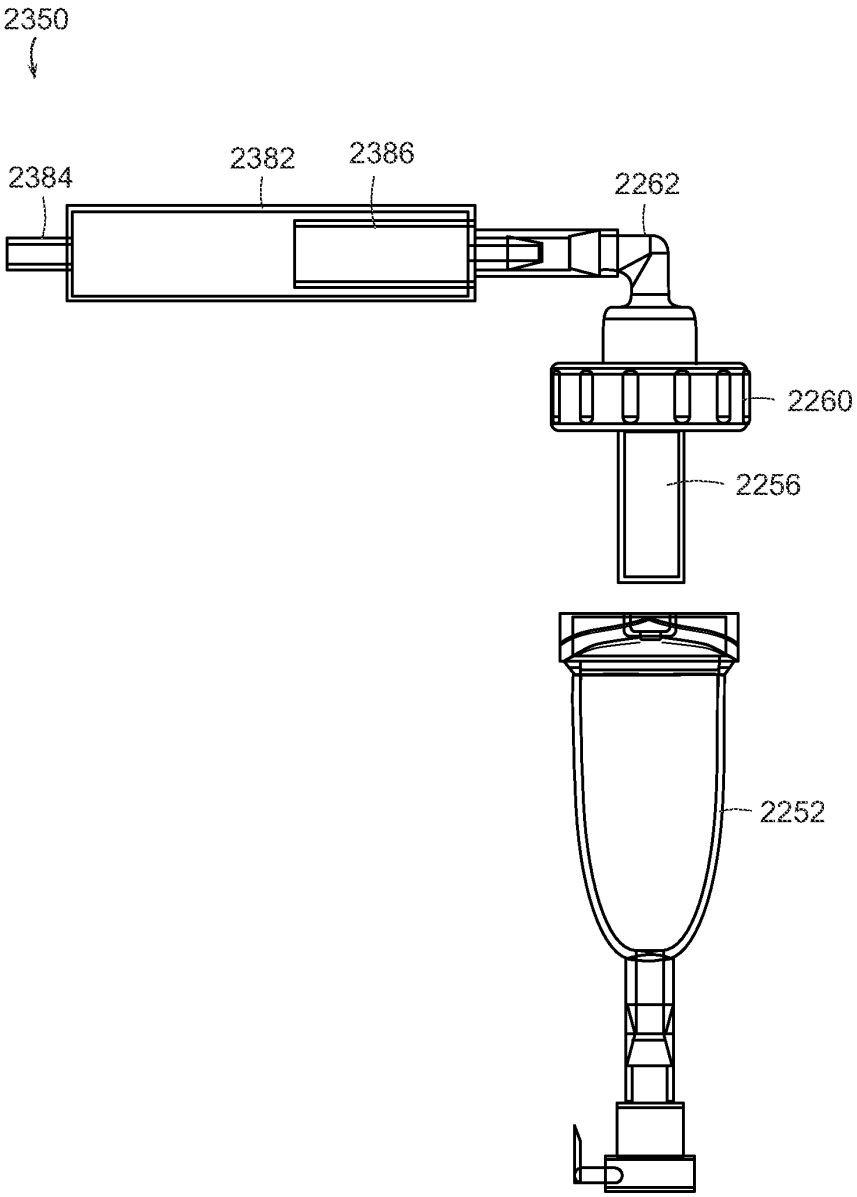


FIG. 23

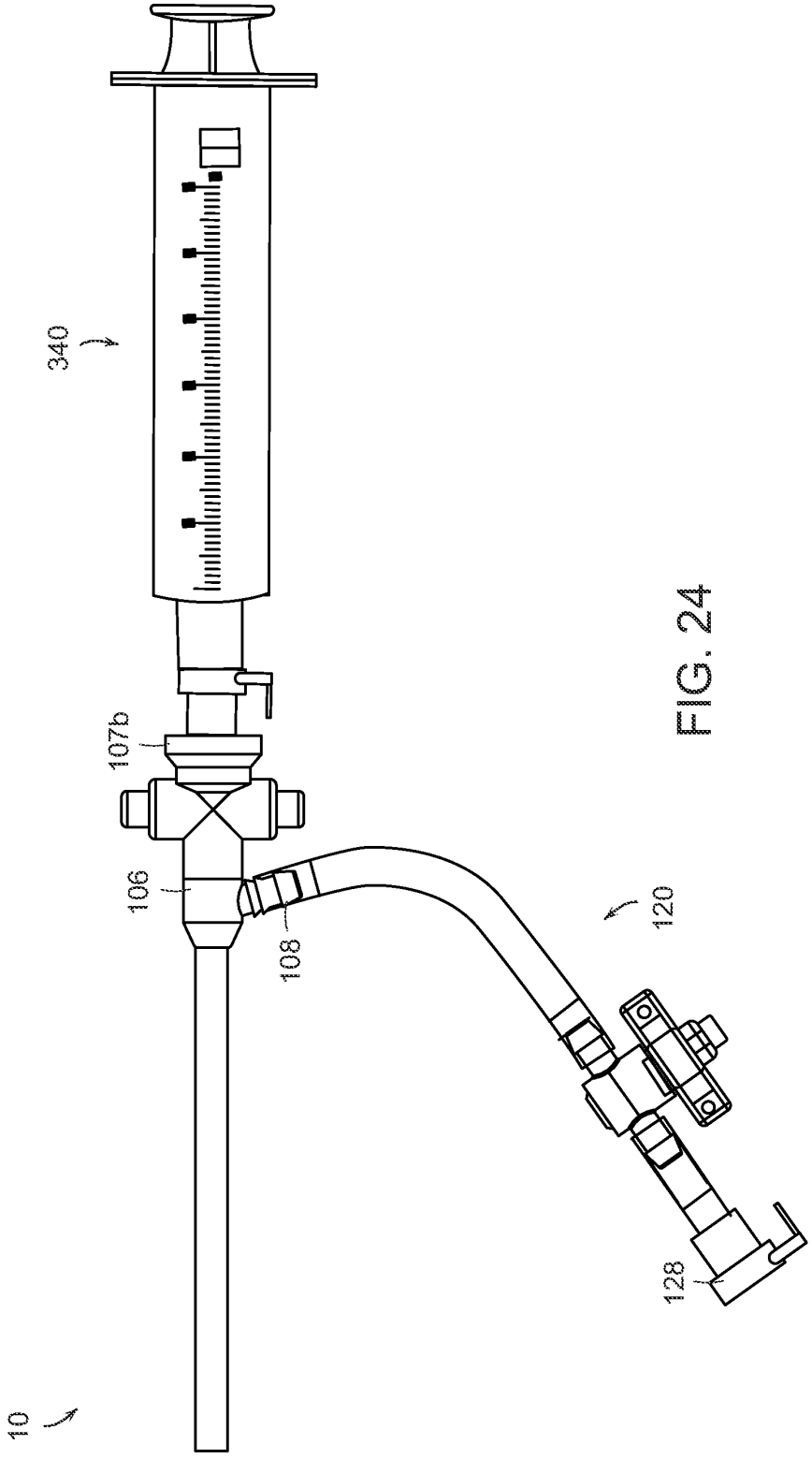


FIG. 24

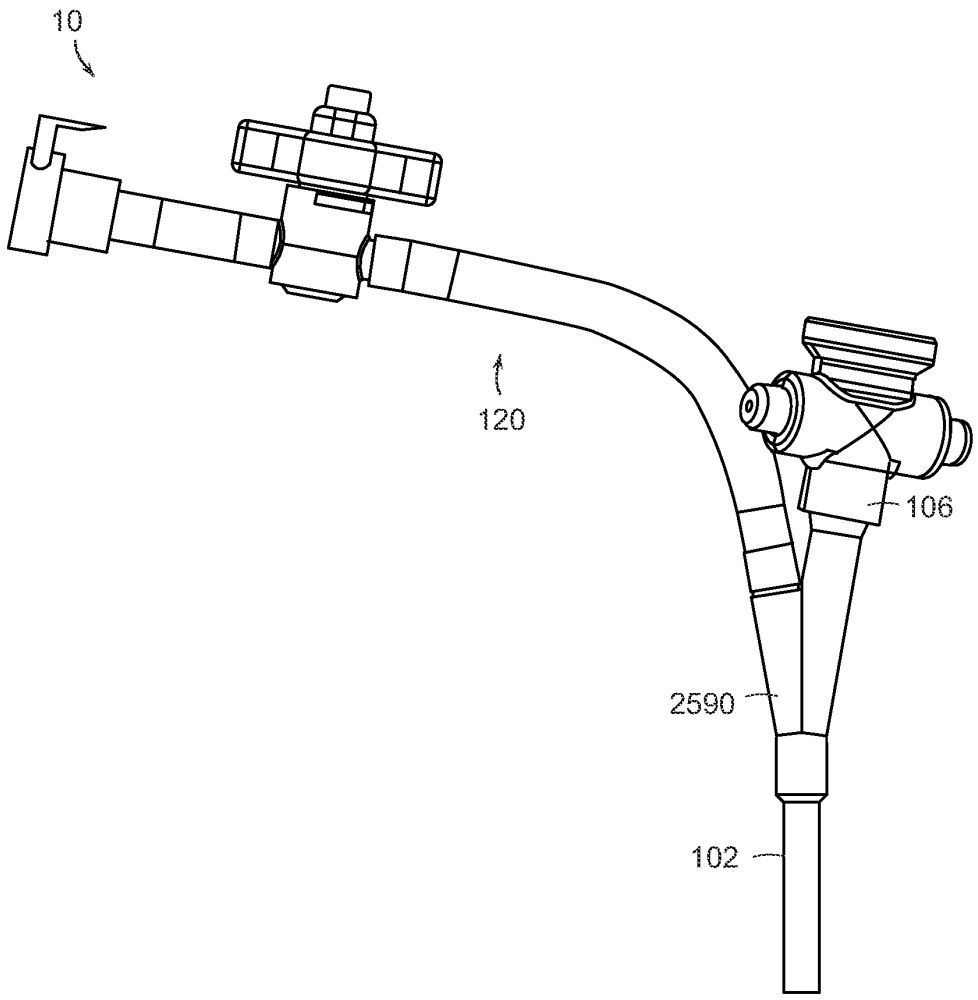


FIG. 25

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/167,757, filed Feb. 10, 2023, which is a continuation of U.S. patent application Ser. No. 17/976,711, filed Oct. 28, 2022, which is a continuation of U.S. patent application Ser. No. 17/865,315, filed Jul. 14, 2022, which is a continuation of U.S. patent application Ser. No. 16/536,185, filed Aug. 8, 2019, and issued as U.S. Pat. No. 11,559,382, which claims the benefit of U.S. Provisional Patent Application No. 62/718,269, filed on Aug. 13, 2018, and U.S. Provisional Patent Application No. 62/718,248, filed on Aug. 13, 2018, each of which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

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

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.

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.

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.

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.

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.

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.

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.

Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

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.

FIG. **1** is a partially schematic side view of a clot removal system configured in accordance with the present technology.

FIG. **2** is a side view of a locking syringe configured in accordance with the present technology.

FIG. **3**A is a side view of a locking syringe configured in accordance with the present technology.

FIG. **3**B is a side view of an adaptor for connecting the locking syringe of FIG. **3**A to the clot removal system of FIG. **1** configured in accordance with the present technology.

FIG. **3**C is a side view of the adaptor of FIG. **3**B coupled to the locking syringe of FIG. **3**A.

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FIG. **3**D is a side view of the locking syringe of FIG. **3**A coupled to the clot removal system of FIG. **1** via the adaptor of FIG. **3**B.

FIG. **4**A is a perspective side view of another pressure source configured in accordance with the present technology, and FIGS. **4**B and **4**C are enlarged schematic side views of the pressure source of FIG. **4**A during operation.

FIG. **5** is a cross-sectional side view of an automatic release syringe configured in accordance with the present technology.

FIG. **6** is a perspective top view of a syringe configured in accordance with the present technology.

FIG. **7** is a side view of an over-wire locking syringe configured in accordance with the present technology.

FIG. **8** is a flow diagram of a process or method for operating a clot removal system in accordance with the present technology.

FIGS. **9**A-**9**C are side views of a proximal portion of the clot removal system of FIG. **1** during a clot removal procedure using the locking syringe of FIG. **3** in accordance with the present technology.

FIGS. **10**A and **10**B are schematic illustrations of a distal portion of the clot removal system of FIG. **1** during a clot removal procedure in accordance with the present technology.

FIG. **11** is a partially schematic side view of another clot removal system configured in accordance with the present technology.

FIG. **12** is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

FIGS. **13**A-**14**C are schematic illustrations of a distal portion of the clot removal system of FIG. **11** during a clot removal procedure in accordance with the present technology.

FIG. **15** is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

FIGS. **16**A-**16**E are schematic illustrations of a distal portion of the clot removal system of FIG. **11** during a clot removal procedure in accordance with the present technology.

FIG. **17** is a partially schematic side view of another clot removal system configured in accordance with the present technology.

FIGS. **18**A-**18**H are side views of a distal portion of the clot removal system shown of FIG. **17** during a clot removal procedure in accordance with the present technology.

FIG. **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.

FIG. **20**A is a partially-exploded side view of a filter device and pressure source configured in accordance with the present technology.

FIG. **20**B is a perspective side view of the syringe of FIG. **20**A coupled to the filter device of the FIG. **20**A.

FIG. **20**C is a side view of the filter device and syringe of FIG. **20**B coupled to the clot removal system of FIG. **1**.

FIGS. **20**D and **20**E are side views of the syringe of FIG. **20**A coupled to the clot removal system of FIG. **1** for reintroducing blood to a patient.

FIG. **21**A is a partially-exploded side view of a filter device, a pressure source, and a reinfusion syringe configured in accordance with the present technology.

FIG. **21**B is a perspective side view of the filter device of FIG. **21**A coupled to the pressure source and the reinfusion syringe of FIG. **21**A.

FIG. **22** is a partially-exploded side view of a filter device configured in accordance with the present technology.

FIG. **23** is a partially-exploded side view of a filter device configured in accordance with the present technology.

FIG. **24** is an enlarged isometric view of the clot removal system of FIG. **1** configured in accordance with the present technology.

FIG. **25** is an enlarged isometric view of the clot removal system of FIG. **1** configured in accordance with the present technology.

DETAILED DESCRIPTION

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.

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.

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 FIGS. **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 FIGS. **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 FIGS. **1-25**.

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.

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

FIG. **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 **103***a* and a proximal portion **103***b*. The catheter subsystem **100** further includes a valve **106** that can be integral with or coupled to the proximal portion **103***b* of the catheter **102**.

In the illustrated embodiment, the valve **106** includes a distal portion **107***a*, a proximal portion **107***b*, and a lumen **109** extending therethrough from the distal portion **107***a* to the proximal portion **107***b*. The valve **106** further includes a flow controller (obscured in FIG. **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 FIGS. **11-16**E), 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 Ser. No. 16/117,519, filed Aug. 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 **107***b* 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. Pat. No. 9,526,864, filed Jun. 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.

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 **124***a* and a second tubing section **124***b*), 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 **124***a* and (ii) the connector **128** via the second tubing section **124***b*. 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 **124***a*, and/or a diameter of the second tubing section **124***b*.

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 **124***a* and/or the tubing section **124***b*. 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 FIG. **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 **103***a* of the catheter **102**.

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.

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 FIGS. **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 **103***a* 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 **103***a* 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

As described in detail above with reference to FIG. **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.

FIG. **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 FIG. **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**.

Referring to both FIGS. **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.

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.

FIG. **3**A 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 FIG. **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 FIG. **3**A (and FIG. **3**C) 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.

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 FIGS. **2** and **3**A 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.

FIG. **3**B 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. FIG. **3**C is a side view of the adaptor **350** coupled to the syringe **340**, and FIG. **3**D 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 FIG. **3**C for the sake of illustration. Referring to FIG. **3**B, the, 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.

Referring to FIGS. **3**A-**3**D 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 snuggly 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**.

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**.

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** (FIG. **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

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
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

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
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

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 **103***a* 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).

Moreover, as shown in FIG. **3**D, 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 **103***a* 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 **103***a* 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).

FIG. **4**A is a side perspective view a pressure source **400** including the syringe **340** ("primary syringe **340**") shown in FIGS. **3**A-**3**D 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.

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**.

FIGS. **4**B and **4**C are enlarged schematic side views of the pressure source **400** during operation. More specifically, FIGS. **4**B and **4**C 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 FIGS. **4**A and **4**B 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** (FIG. **1**), and/or the tubing subsystem **120** (FIG. **1**) into the secondary syringe **460**. This flow path is indicated by the arrows R in FIG. **4**B. Referring to FIGS. **4**A and **4**C 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 FIG. **4**C.

Referring to FIGS. **1** and **3**A-**4**C 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 FIG. **3**D). When the pressure source is coupled to the tubing subsystem **120**, retraction of the plunger **462** of the secondary syringe **460** evacuates an evacuatable 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.

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.

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**.

In some embodiments, (e.g., as described in greater detail below with reference to FIG. **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 FIGS. **4**B and **4**C. 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 FIGS. **4**B and **4**C.

FIG. **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 FIG. **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 FIGS. **2** and **3**A-**3**D. 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 FIGS. **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.

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**.

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.

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**.

FIG. **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 FIGS. **2**-**3**D 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 FIG. **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**.

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**.

Referring again to FIG. **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 **103***a* 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 150 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 **107***b* 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, FIG. **24** is an enlarged isometric view of the assembly **10** showing the pressure source **340** coupled directly to the proximal portion **107***b* 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 FIG. **24**, any of the pressure sources described in detail above with reference to FIGS. **2-6** can be configured to be coupled to the proximal portion **107***b* 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, FIG. **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**.

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 **107***b* 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, FIG. **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 FIG. **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 FIG. **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 **107***b* 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**.

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** (FIGS. **4A-4C**) can be coupled via one or more one-way valves to the syringes **240**, **540**, **640** or **740** (FIGS. **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** (FIG. **2**) and the syringe **340** (FIG. **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

FIG. **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. FIGS. **9A-9C** are side views of a proximal portion of the assembly **10**, and FIGS. **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, FIGS. **9A-9C** are side views of the assembly **10** including the syringe **340** and adaptor **350** (FIGS. **3A-3D**), and FIGS. **10A** and **10B** are side views of the catheter **102** with the distal portion **103***a* 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 FIGS. **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 FIGS. **2-7**.

At block **802**, the method **800** includes positioning the distal portion **103***a* 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 FIG. **10A**, a distal terminus of the distal portion **103***a* 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.

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 A**1**) to a position proximate to the clot material PE as illustrated in FIG. **10**A.

In some embodiments, to confirm the position of the distal portion **103***a* 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 **103***a* 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 **103***a* 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 **103***a* of the catheter is not fully engaged with the clot material PE. Accordingly, to locate the distal portion **103***a* of the catheter **102** just proximal of the clot material PE, the operator can (i) first determine that distal portion **103***a* 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 **103***a* 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 **103***a* 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.

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.

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 FIG. **9**A, the tip **347** (shown in FIGS. **3**A and **3**C but obscured in FIG. **9**A) 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 FIG. **9**A.

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 FIG. **9**B, 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** (FIGS. **4**A-**4**C) 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.

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 FIG. **9**C, 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 FIG. **10**B, application of the vacuum causes suction at the distal tip **103***a* of the catheter **102** (e.g., as indicated by arrow A**2**) 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 **103***a* 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**. FIG. **9**C, 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**.

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**).

Sometimes, as shown in FIG. **10**B, 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.

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.

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** (FIGS. **4**A-**4**C) 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 FIGS. **15-16**E, a second clot removal assembly can be telescoped through the first assembly **10** to facilitate removal of the clogged clot material PE.

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. Pat. No. 9,526,864, filed Jun. 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Pat. No. 8,784,434, filed Mar. 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 (FIG. **10**B) after a first aspiration pass.

IV. Selected Embodiments of Telescoping Clot Removal Systems and Associated Methods of Clot Removal

FIG. **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 FIGS. **1-10**B. 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**.

The first and second catheters **1002**, **1102** each comprise an elongated shaft defining a lumen **1004**, **1104** and having a distal portion **1003***a*, **1103***a*, respectively. The first and second valves **1006**, **1106** each include (i) a distal portion **1007***a*, **1107***a*, (ii) a proximal portion **1007***b*, **1107***b*, (iii) a lumen **1009**, **1109** extending therethrough, and (iv) a flow controller (obscured in FIG. **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**.

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 **1103***a* 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 FIGS. **14**A-**14**C), 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.

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 FIGS. **1**-**10**B. 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 pressures sources **1040**, **1140** can be omitted, or the pressure sources **1040**, **1140** can be fluidly coupled and/or integrally formed.

FIG. **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. FIGS. **13**A-**13**C are schematic illustrations of a distal portion of the assemblies **20**, **30** during a clot removal procedure in accordance with the present technology. FIGS. **14**A-**14**C 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 FIGS. **11** and **13**A-**14**C 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.

At block **1282**, the method **1280** includes intravascularly positioning the first catheter **1002** within a human patient. FIG. **13**A, for example, illustrates the first catheter **1002** after it has been advanced (e.g., as indicated by arrow A**1**) 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 **1003***a* 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 **1003***a* 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 FIG. **8**.

At block **1284**, the method **1280** includes advancing the second catheter **1102** through the first catheter **1002** until the distal portion **1103***a* 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 **1103***a* of the second catheter **1102** through the first valve **1006** before advancing the second catheter **1102** (e.g., as indicated by the arrow A**1**) 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 **1103***a* 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.

FIG. **13**A 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 FIG. **13**A, 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.

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 FIGS. **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**).

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**.

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 FIG. **13**B, application of the vacuum causes suction (e.g., as indicated by arrow A**2**) 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 **1103***a* 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 **1103***a* of the second catheter **1102** compared to simply activating the second pressure source **1140** while it is fluidly connected to the second catheter **1102**.

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 **1003***a* 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 **1003***a* 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.

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 Ser. No. 16/258,344, filed Jan. 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.

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 FIG. **13**C, 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 A**3**) at the distal portion **1003***a* 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.

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 **1103***a* of the second catheter **1102**. FIG. **14**A, for example, is an enlarged view of the distal portion of the assemblies **20**, **30** shown in FIG. **13**C and illustrating a portion of the clot material PE stuck to or dangling from the distal portion **1103***a* 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**).

FIGS. **14**B and **14**C 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 FIG. **14**C, 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**.

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.

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 **1103***a* 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**).

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.

FIG. **15** is a flow diagram of another process or method **1580** for operating a clot removal system including the assemblies **20**, **30** (FIG. **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. FIG. **16**A is an enlarged side view of a distal portion of the first assembly **20**, and FIGS. **16**B-**16**E 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 FIGS. **11** and **16**A-**16**E 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.

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 FIGS. **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 FIGS. **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 **1003***a* of the first catheter **1002**.

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**). FIG. **16**A, 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 **1003***a* 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 FIG. **8**).

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 **1103***a* of the second catheter **1102** is positioned in or proximate to the clogging clot material PE. For example, FIG. **16**B 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 **1103***a* of the second catheter **1102** through the first valve **1006** (FIG. **11**) before advancing the second catheter **1102** through the lumen **1004** of the first catheter **1002**.

At block **1594**, the method **1580** includes activating the second pressure source **1140** (FIG. **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 FIGS. **2-7**) can be coupled to the second catheter **1102** via the second fluid control device **1126** (FIG. **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.

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**. FIG. **16**C, for example, illustrates a portion of the clot material PE stuck to or extending from the distal portion **1103***a* of the second catheter **1102** after aspirating the second catheter **1102**. In the embodiment illustrated in FIG. **16**C, 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**.

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, FIG. **16**D 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**. FIG. **16**E, 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 A**5**).

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**.

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

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.

FIG. **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 FIG. **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.

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 FIG. **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 FIGS. **18**E and **18**F, 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 Apr. 26, 2017, and titled "DEVICES AND

METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

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, FIG. **17** shows the system **1700** after (i) advancing the sheath **1702** to a position proximate to a proximal portion **1785***b* 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 **1785***a* of the clot material DV), and (iv) expanding the interventional device **1790** from the compressed delivery state to the deployed state.

FIGS. **18**A-**18**H are enlarged views of a distal portion of the system **1700** during a clot removal procedure in accordance with the present technology. In general, FIGS. **18**A-**18**H 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**.

Referring first to FIG. **18**A, proximal retraction of the interventional device **1790** causes the coring element **1792** to separate and/or core the distal end portion **1785***a* of the clot material DV from the walls W of the blood vessel BV. As shown in FIG. **18**B, continued proximal retraction of the interventional device **1790** through the clot material DV causes the cylindrical element **1794** to capture the distal end portion **1785***a* of the clot material therein. FIGS. **18**C-**18**E 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 FIG. **18**E, the proximal end portion **1785***b* 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 FIG. **18**E, a first radiopaque marker **1887***a* can be positioned on a distal end portion of the inner shaft **1884** and a second radiopaque marker **1887***b* can be positioned on a distal end portion of the sheath **1702**.

In some embodiments, as shown in FIG. **18**F, 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** (FIG. **18**E). 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 **1885***a*) relative to the distal end portion of the sheath **1702** (e.g., the second radiopaque marker **1885***b*). 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**.

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 FIG. **18**G. As shown in FIG. **18**H, 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** (FIG. **17**), and from the patient's body.

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 FIG. **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 FIGS. **18**G and **18**H, application of the vacuum can generate instantaneous or nearly instantaneous suction (e.g., as indicated by arrows A**6**) 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

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. FIGS. **19**-**20**E 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.

For example, FIG. **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 FIGS. **4**A-**4**C. 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** (FIGS. **4**A-**4**C). 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** (FIG. **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**).

In the illustrated embodiment, the canister **1940** further includes a filter **1942**. The canister **1940** is shown as transparent in FIG. **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**.

FIGS. **20**A-**20**E 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 FIGS. **2**-**7**. For example, FIG. **20**A is a partially-exploded side view of the filter device **2050** and the pressure source **340** (FIGS. **3**A-**3**D). 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 FIG. **20**C). 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.

FIG. **20**B 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 FIG. **20**B (and FIGS. **20**C-**20**E) 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.

FIG. **20**C 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 FIG. **20**C, 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.

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, FIGS. **20**D and **20**E 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 FIG. **20**D, 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 FIG. **20**E, 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 FIGS. **20**A-**20**E 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**).

FIGS. **21**A and **21**B 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 FIGS. **2-7**. For example, FIG. **21**A is a partially-exploded side view of the filter device **2150** and the pressure source **340** (FIGS. **3**A-**3**D). 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.

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 **2124***a* and a second tubing section **2124***b*), 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**.

In operation, during a clot removal procedure, the pressure source **340** can be decoupled from the connector **128** (FIG. **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, FIG. **21**B 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 FIGS. **21**A and **21**B 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** (FIG. **1**), an IV line (not shown), or another suitable connection point for reintroducing blood to the patient,

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 FIG. **21**B, 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.

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** (FIG. **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.

FIG. **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 FIGS. **2-7**. In general, the filter device **2250** is generally similar to the filter device **2150** described in detail with reference to FIGS. **21**A and **21**B. 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 FIGS. **3**A-**3**D). 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 FIG. **22**. In one aspect of the present technology, this arrangement makes the filter device more ergonomic during use.

FIG. **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 FIGS. **2-7**. The filter device **2350** is generally identical to the filter device **2250** described in detail with reference to FIG. **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.

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 FIGS. **2** and **4-7**). In some embodiments, the filter devices can be formed as a component of the tubing subsystem **120** (FIG. **1**). Moreover, the filter devices can include any number of filters and/or housings to provide any number of filtration stages.

Conclusion

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.

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.

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.

We claim:

1. An aspiration system with accelerated response, comprising:

an aspiration pump in communication with a first chamber;

a coupled assembly including:

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; 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 hemostasis valve is configured to receive a second catheter and direct the second catheter through the aspiration catheter.

3. The aspiration system of claim **2** 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.

4. The aspiration system of claim **1** wherein the second chamber is removably carried by the assembly.

5. The aspiration system of claim **1** wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.

6. The aspiration system of claim **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.

7. The aspiration system of claim **6** wherein the clot material comprises a pulmonary embolism.

8. The aspiration system **6** wherein the clot material comprises a deep vein thrombus.

9. The aspiration system of claim **1** wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.

10. The aspiration system of claim **1**, further comprising a filter in the second chamber.

11. The aspiration system of claim **10** wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

12. The aspiration system of claim **10** wherein the filter is removable from within the second chamber.

13. The aspiration system of claim **1** wherein the first chamber is fluidically coupled in serial to the second chamber.

14. 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 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.

15. The aspiration system of claim **14**, further comprising a filter in the second chamber.

16. The aspiration system of claim **15** wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

17. The aspiration system of claim **15** wherein the filter is removable from within the second chamber.

18. The aspiration system of claim 14 wherein the first chamber is fluidically coupled in serial to the second chamber.

19. The aspiration system of claim 14 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.

20. The aspiration system of claim 19 wherein the aspiration catheter has a distal end portion configured to be positioned proximate to clot material within the blood vessel of the patient.

21. The aspiration system of claim 20 wherein the clot material comprises a pulmonary embolism.

22. The aspiration system of claim 20 wherein the clot material comprises a deep vein thrombus.

23. An aspiration system with accelerated response, comprising:

an aspiration pump in communication with a first chamber;

a coupled assembly including:

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.

24. The aspiration system of claim 23 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.

25. The aspiration system of claim 23 wherein the second chamber is removably coupled between the aspiration pump and the aspiration catheter.

26. The aspiration system of claim 23 further comprising a filter in the second chamber, wherein the filter is removable from within the second chamber.

27. The aspiration system of claim 23 wherein the first chamber is fluidically coupled in serial to the second chamber.

28. 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 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.

29. The aspiration system of claim 28, further comprising a filter in the second chamber, wherein the filter is removable from within the second chamber.

30. The aspiration system of claim 28 wherein the first chamber is fluidically coupled in serial to the second chamber.

31. The aspiration system of claim 28 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.

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EXHIBIT F

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(12) **United States Patent**
Merritt et al.

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(54) **HEMOSTASIS VALVES AND METHODS OF USE**

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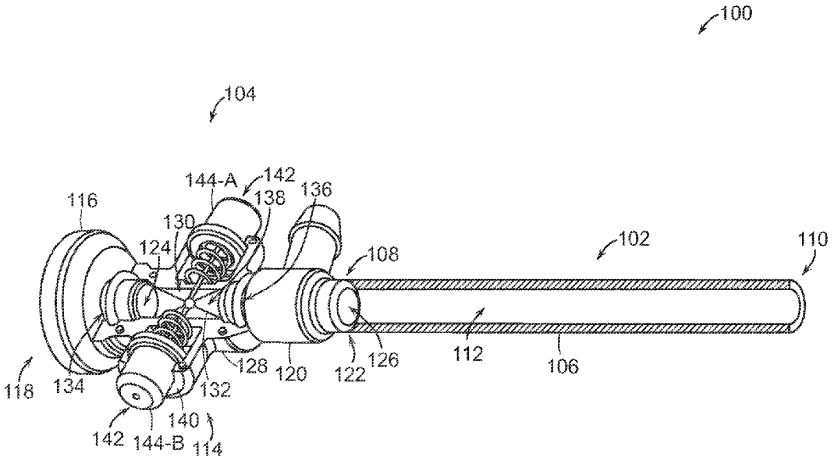
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(57) **ABSTRACT**

Devices, systems, and methods for sealing medical devices, particularly during intravascular access, are disclosed herein. Some aspects relate to a hemostatic valve for sealing a wide range of medical devices, such as catheters, wires, embolectomy systems. The valve can include an elongate member having a first end, a second end, and a central lumen extending therebetween. A reinforcement structure extends along at least a portion of the elongate member and is coupled to the elongate member. A shell defining a first aperture and a second aperture may be included, which first and second apertures can be fluidly coupled by the elongate member. A tensioning mechanism is coupled to the shell and to the elongate member, the tensioning mechanism can be moveable between a first configuration wherein the tensioning mechanism is collapsed and the central lumen is sealed and a second configuration wherein the central lumen is open.

26 Claims, 10 Drawing Sheets



IMPERATIVE Ex. 1034
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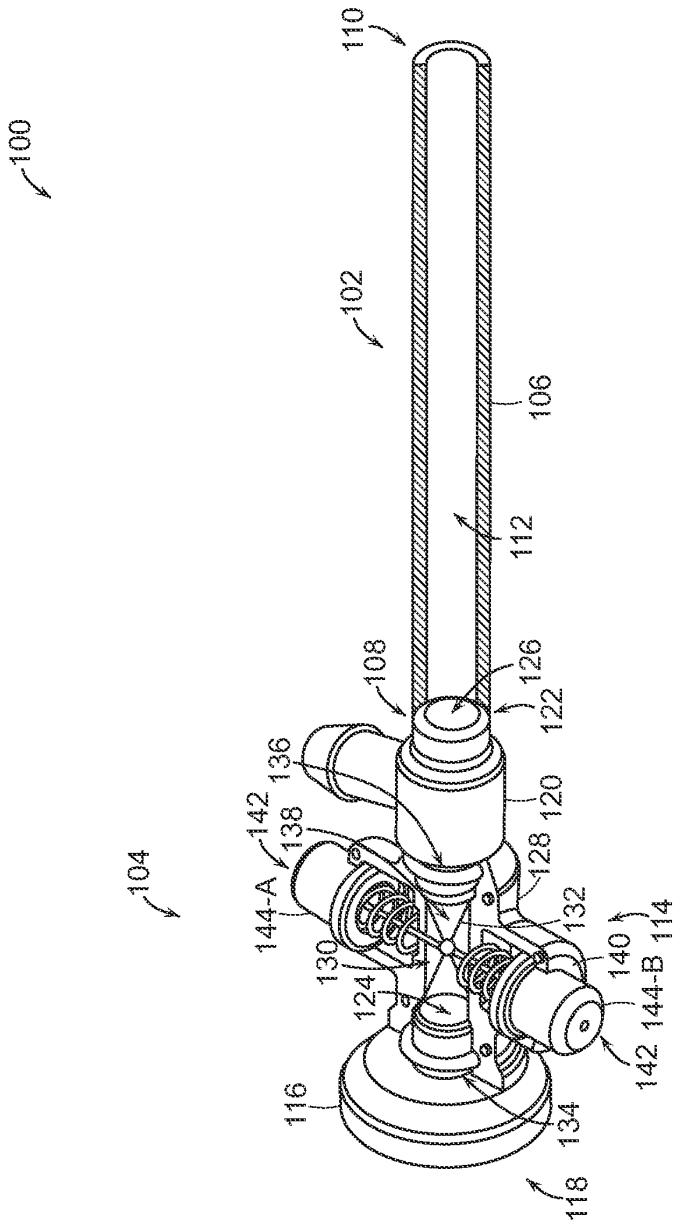

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FIG. 1

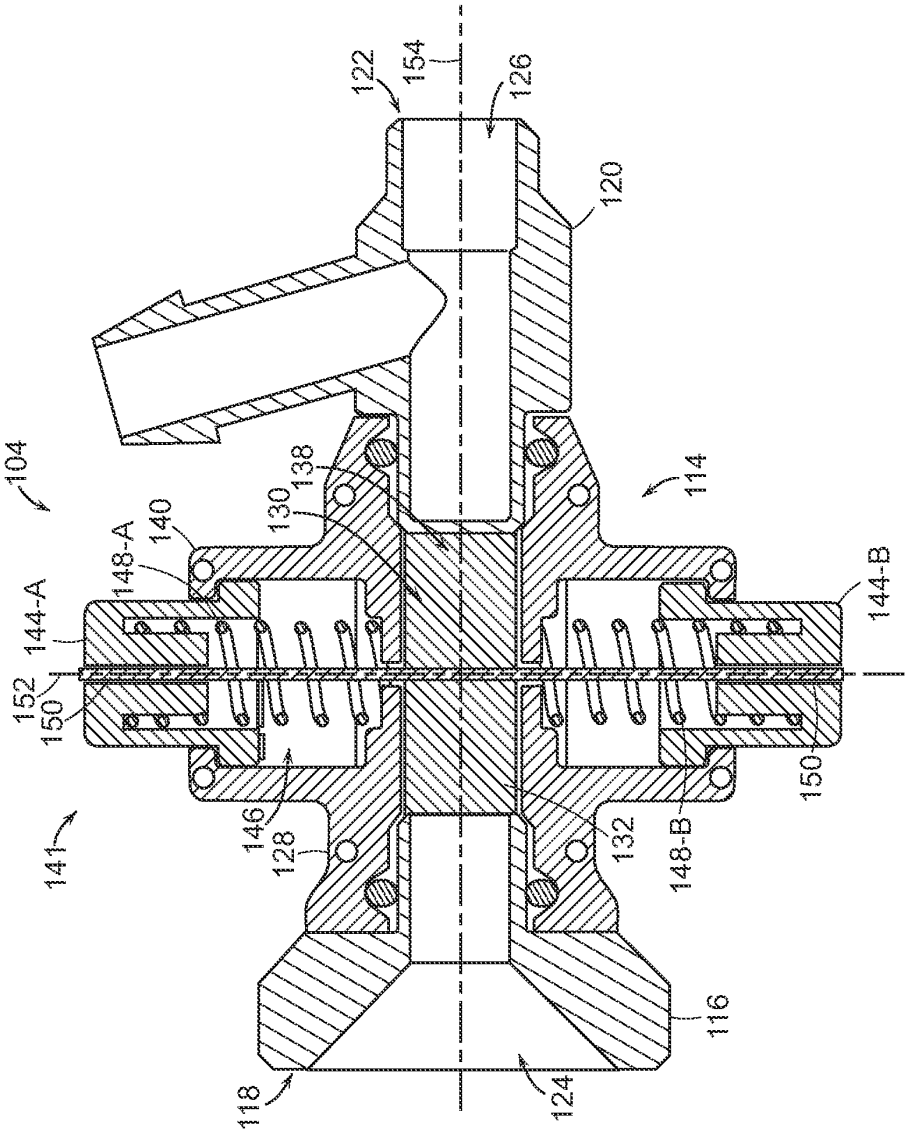

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FIG. 2

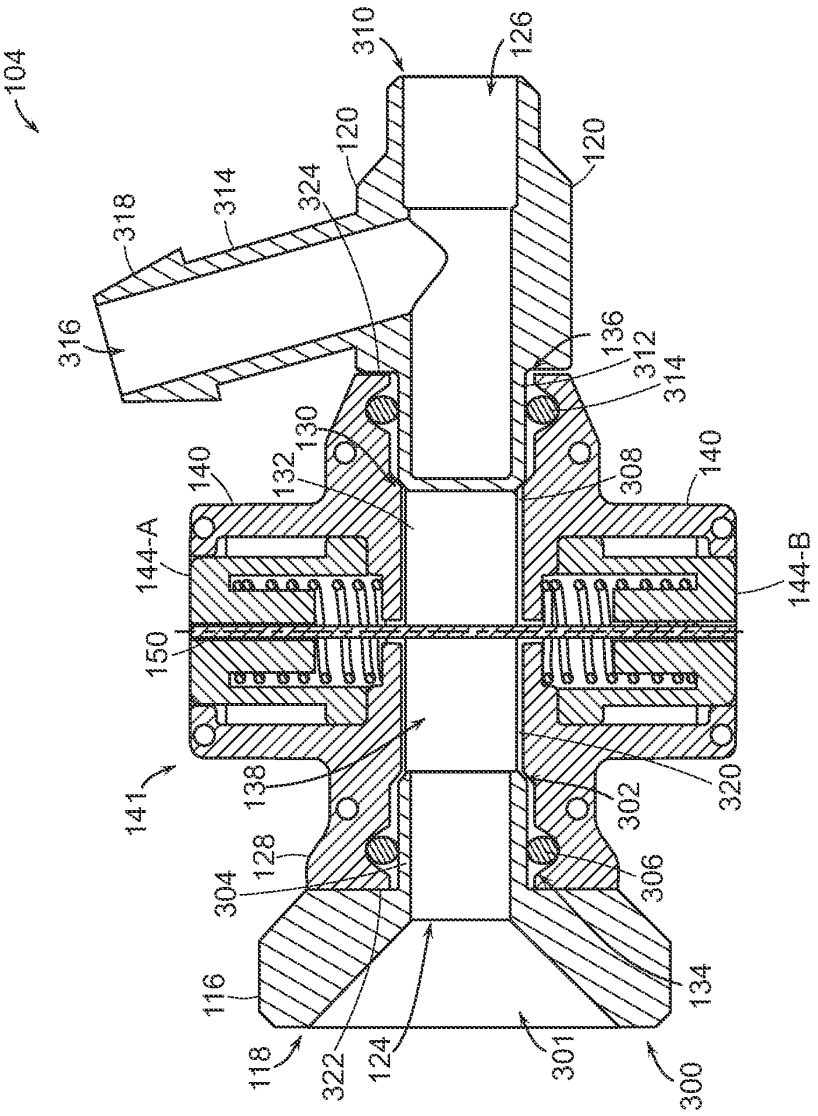

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FIG. 3

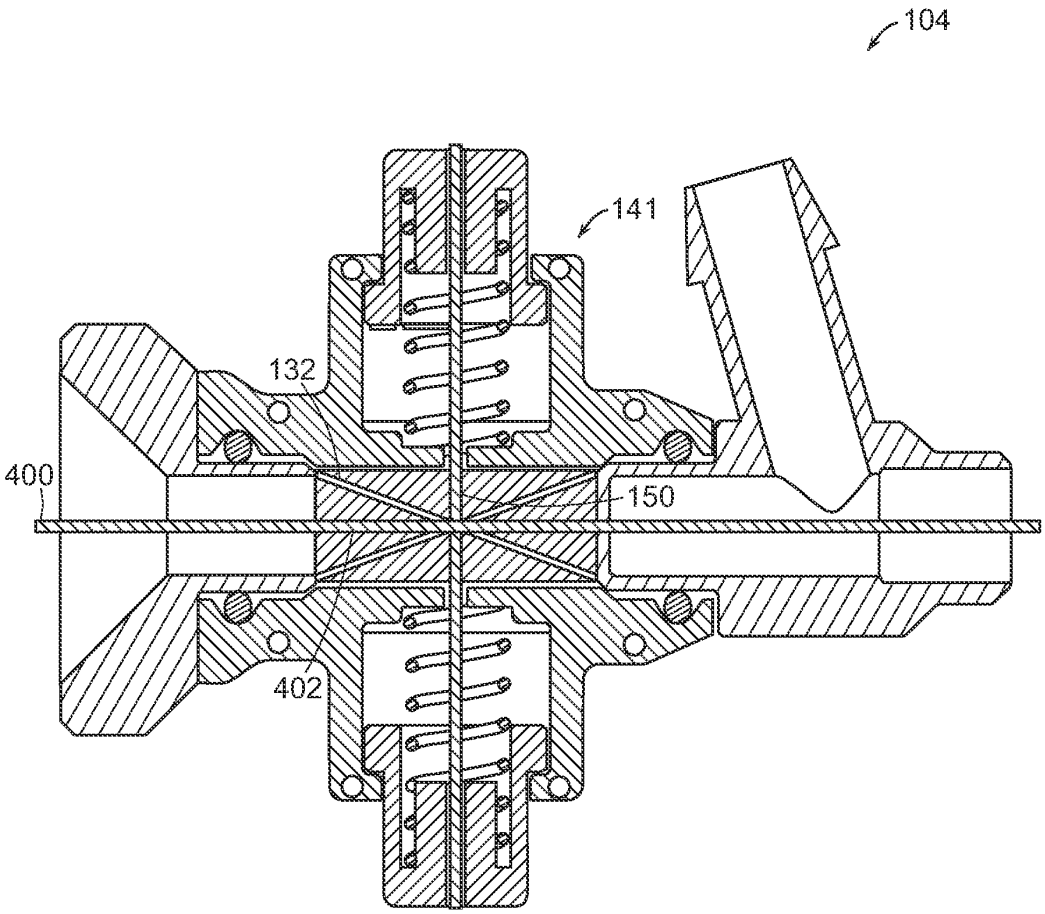


FIG. 4

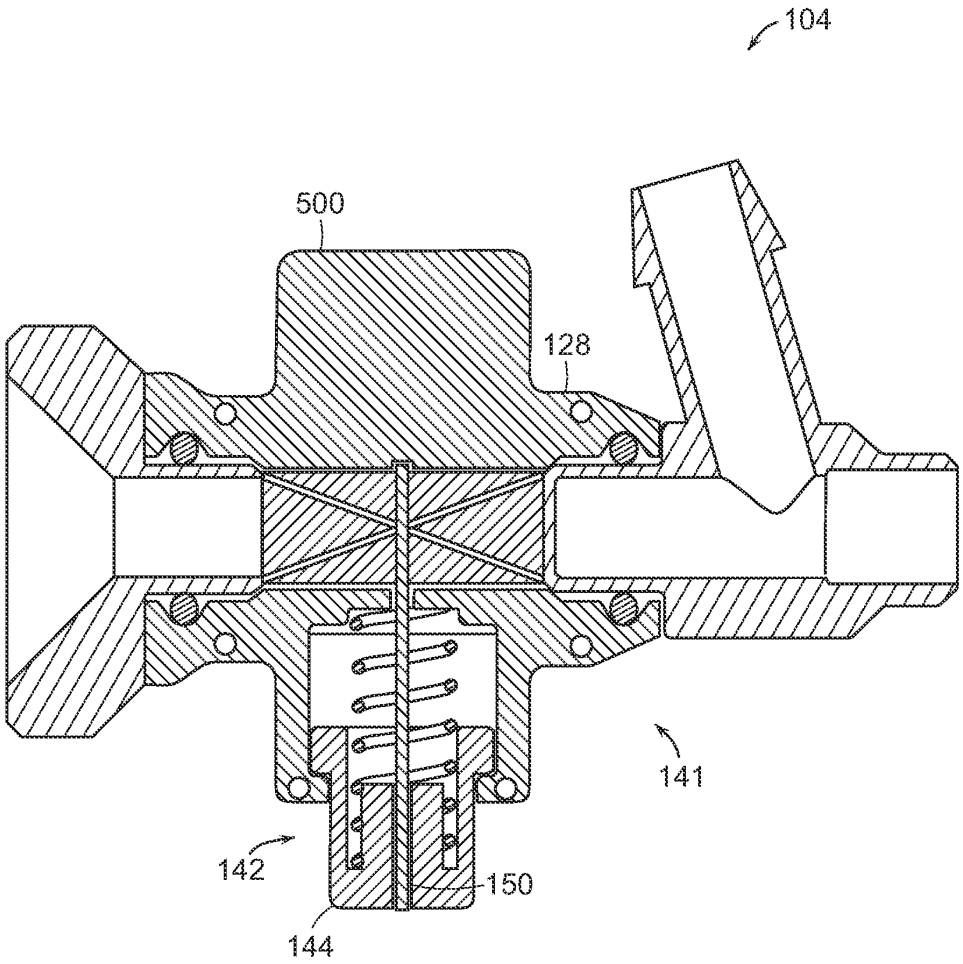


FIG. 5

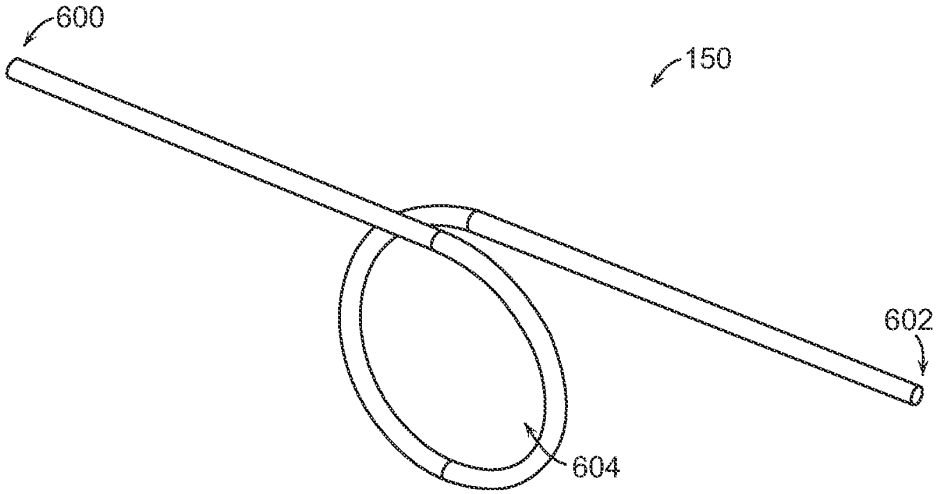


FIG. 6

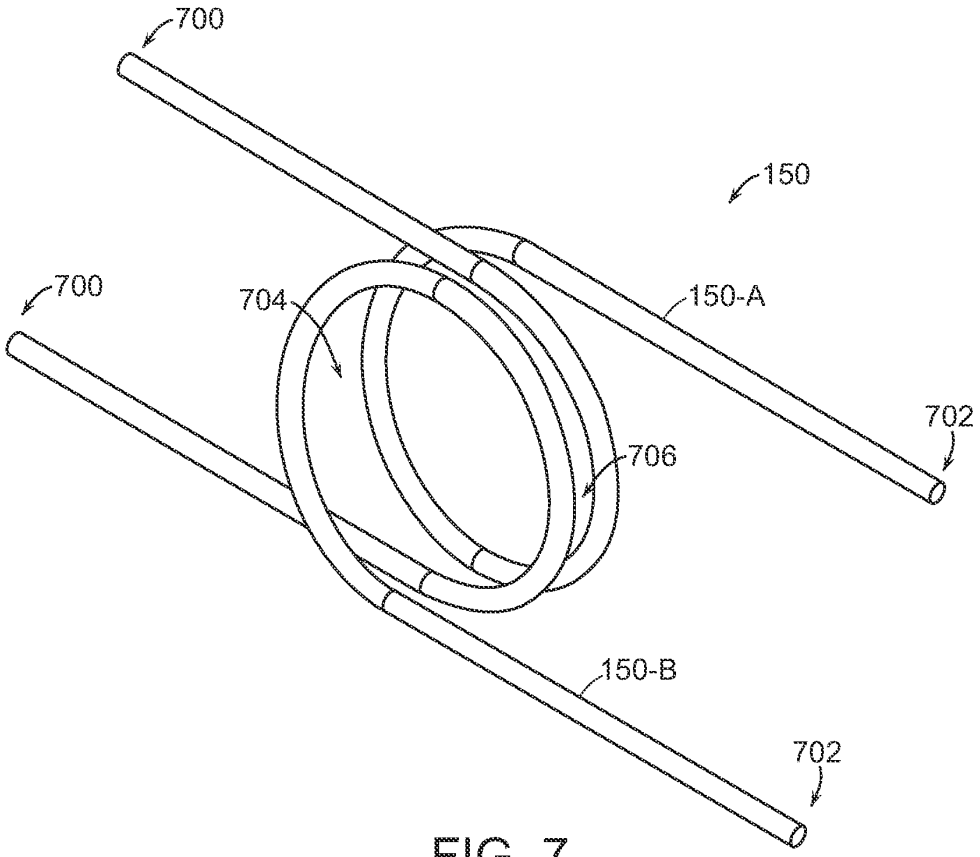


FIG. 7

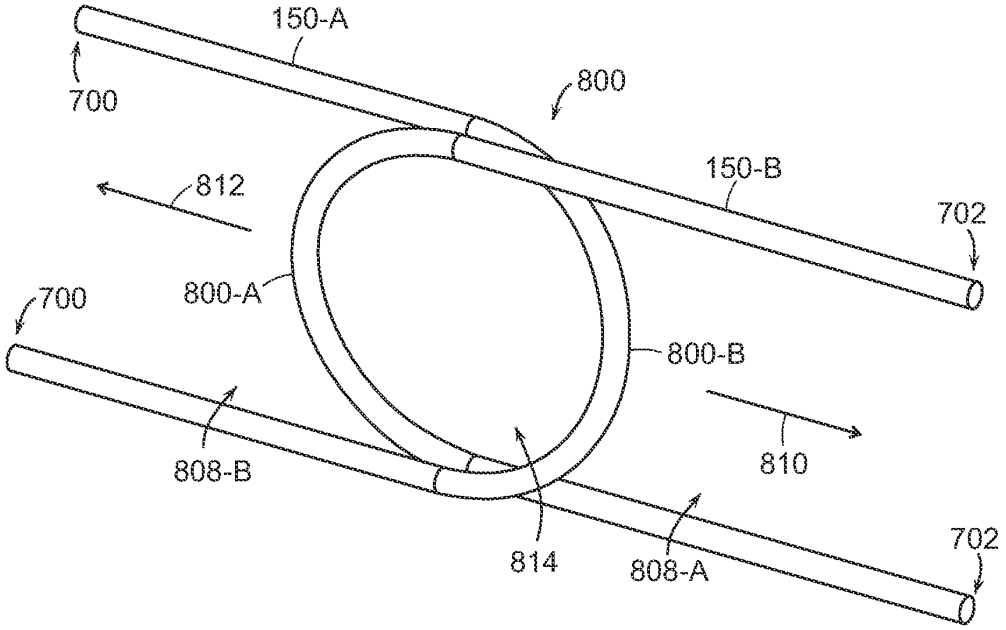

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FIG. 8

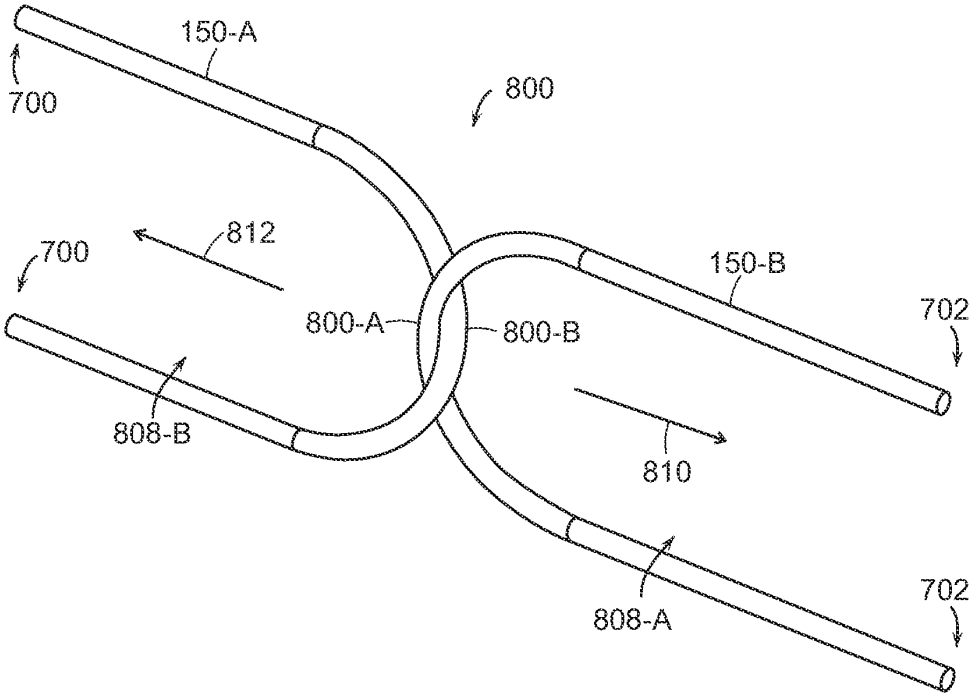

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FIG. 9

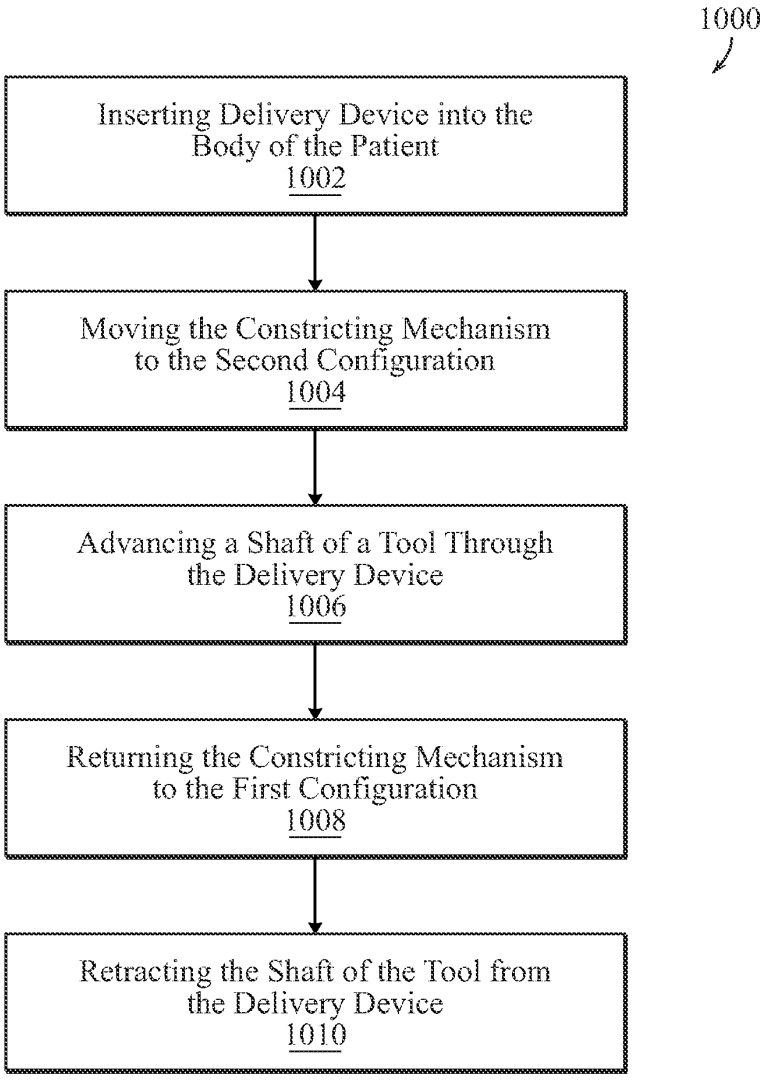

1000
Inserting Delivery Device into the Body of the Patient
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Moving the Constricting Mechanism to the Second Configuration
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Advancing a Shaft of a Tool Through the Delivery Device
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Returning the Constricting Mechanism to the First Configuration
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Retracting the Shaft of the Tool from the Delivery Device
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FIG. 10

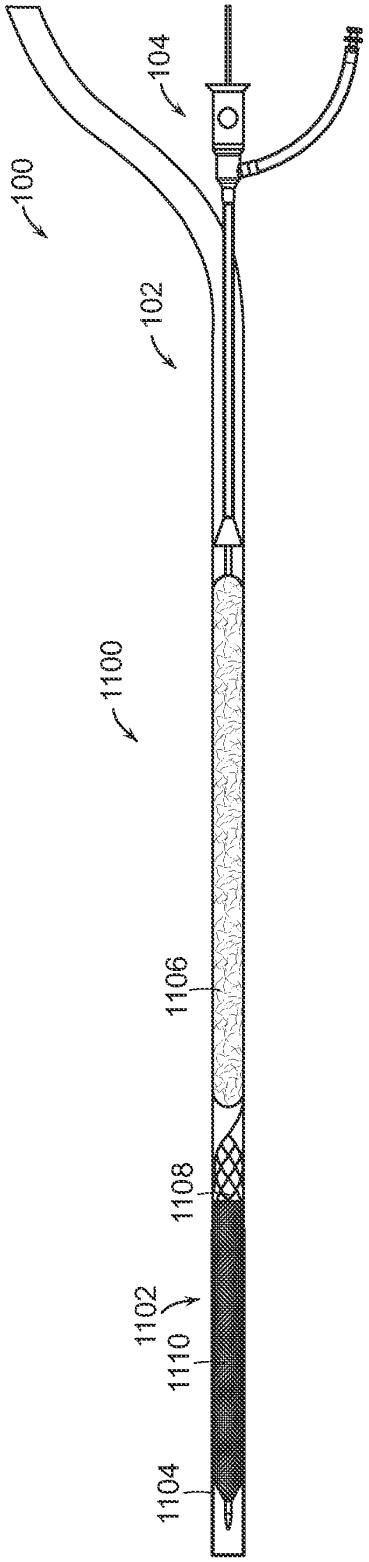


FIG. 11

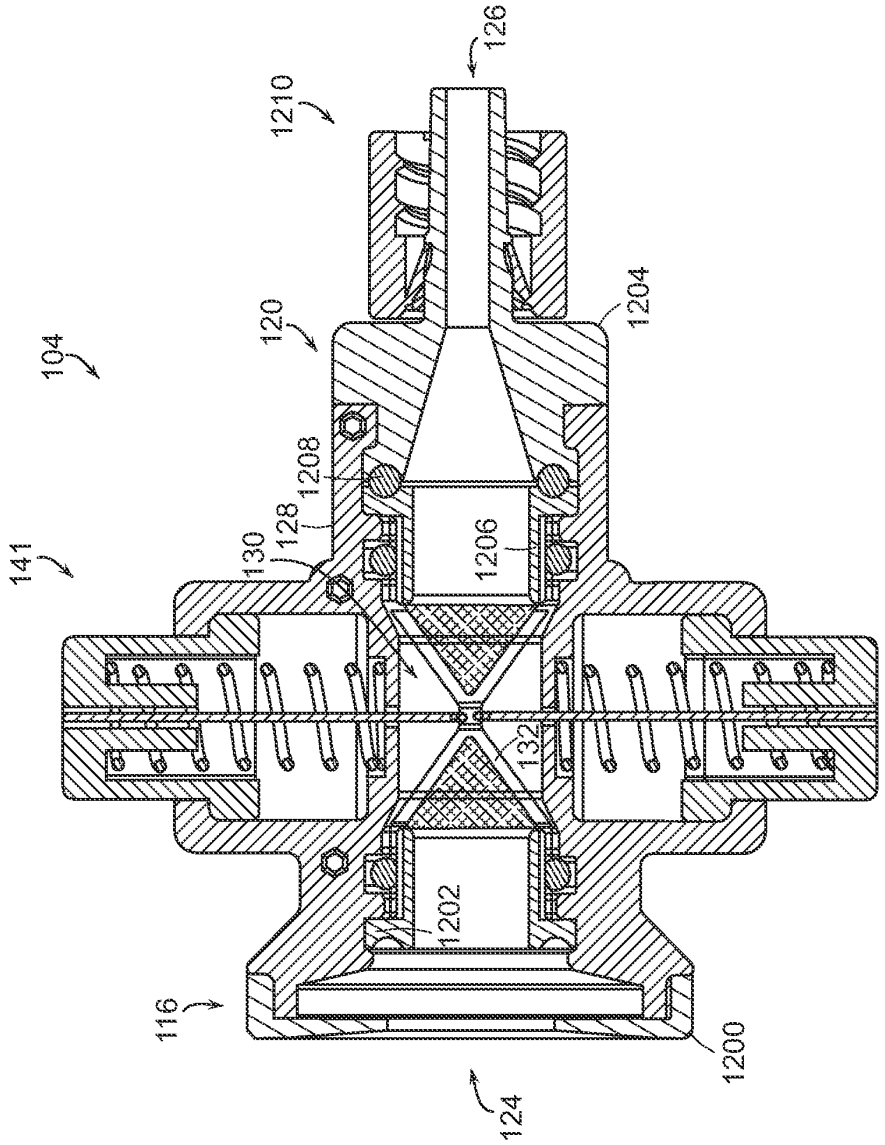

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FIG. 12

HEMOSTASIS VALVES AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/117,519, filed on Aug. 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which claims the benefit of U.S. Provisional Patent Application No. 62/554,931, filed on Sep. 6, 2017, and titled "HEMOSTASIS VALVES AND METHODS OF USE," each of which is herein incorporated by reference in its entirety.

BACKGROUND

During a surgical procedure, a portion of a patient's body (e.g., vasculature) is accessed to allow for performance of a desired intervention or treatment. During such surgical procedures, it is desired to minimize patient blood loss, prevent delivery of air into the vasculature, and to maintain the sterility of the accessed portions or sites of the patient's body so as to prevent issues such as infection. Further, the desire for improved patient outcomes has led to the development of hemostasis valves that facilitate minimally invasive surgery.

In minimally invasive surgery, small incisions are created through a blood vessel which one or several catheters are inserted. Each of these one or several catheters can define a lumen extending longitudinally through that catheter. These catheters are moved to a position proximate to tissue, nerves, or other body structures targeted by the surgery, and then tools for performing the procedure are inserted through the lumens of some or all of these catheters.

To minimize blood loss, prevent delivery of air into the vasculature, and to facilitate maintenance of sterility within the patient's body (e.g., blood vessel), these catheters are equipped with hemostasis valves. These valves seal or selectably seal the lumens of the catheters. In many instances, these valves can seal the lumen of the catheter when a tool extends through the catheter, and specifically through the valve. Additionally the valves can seal the lumen when a tool is removed or does not extend through the catheter.

While such traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use. The drawbacks of such valve designs may in turn increase the complexity of any surgery performed therewith and/or reduce patient safety (e.g., bleeding, infection, and/or other detrimental complications). Accordingly, new and improved hemostasis valves and methods of use are desired.

SUMMARY

The following relates to valves, medical systems incorporating valves, and methods of using the same. The valve can include a tubular member that can be constricted, collapsed, and/or sealed by one or several tensioning mechanisms. The tensioning mechanism can include at least one filament that extends around at least a portion of the tubular member. The filament can interact with the tubular member to constrict, collapse, and/or seal the tubular member via manipulation of the tensioning mechanism(s). A tool can be inserted through the valve to gain access to a patient's body and specifically to gain access to a blood vessel. Through the use of the tensioning mechanism and filament to constrict, collapse, and/or seal the tubular member, the valve can seal around a wide range of tool sizes and shapes, as well as multiple tools of differing sizes simultaneously. Additionally, such a valve creates a robust seal that maintains its seal when a vacuum is applied such as occurs during aspiration.

Aspects of the present disclosure relate to a hemostatic valve for sealing a medical device. The hemostatic valve includes an elongate member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the elongate member is pliable. The hemostatic valve can include a reinforcement structure extending along at least a portion of the elongate member, such that the reinforcement structure is coupled to the elongate member. The hemostatic valve includes an active tensioning mechanism coupled to the elongate member. In some embodiments, the tensioning mechanism is moveable between a first configuration in which the central lumen is constricted and sealed and a second configuration in which the central lumen is open. Optionally, the valve may be manually adjusted by the user to intermediate positions between fully open and fully closed. Additionally, an instrument (e.g. catheter) may provide an intermediate position where the valve creates hemostasis without user adjustment.

In some embodiments, the elongate member can be a compliant polymer tube. In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the elongate member. In some embodiments, the reinforcement structure is positioned between the at least one filament and the elongate member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member. In some embodiments, the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member. In some embodiments, the central portion of the compliant polymer tube that is constrained or collapsed by the tensioning mechanism, and at least one filament, is not coupled to the reinforcement structure.

In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments there are two tensioning mechanisms coupled to the at least one filament that operate in opposite directions. In some embodiments the two tensioning mechanisms are attached to the same filament. In some embodiments the two tensioning mechanisms are attached to opposing filaments. In some embodiments, the actuator can be moveable to control movement of the at least one filament from a first position in which the central lumen is constricted and sealed to a second position in which the central lumen is open. In some embodiments, the at least one filament is in the first position when the tensioning mechanism is in the first configuration. In some embodiments, the actuator is biased towards the first position. In some embodiments, the actuator is biased toward the second position. In some embodiments, the actuator can be a manual actuator.

In some embodiments, the at least one filament forms a loop around the elongate member. In some embodiments, the at least one filament forms a bight around a portion of the elongate member. In some embodiments, the at least one filament can include a first filament and a second filament. In some embodiments, each of the first filament and the second filament are coupled to the same actuator. In some

embodiments, each of the first filament and the second filament are coupled to different actuators. In some embodiments, the first filament and the second filament are moveable from the first position to the second position. In some embodiments, each of the first filament and the second filament form a loop around the elongate member. In some embodiments, the first filament forms a first bight around a first portion of the elongate member, and the second filament forms a second bight around a second portion of the elongate member. In some embodiments, the first bight extends through the second bight.

In some embodiments, the hemostatic valve can include a shell defining a first aperture and a second aperture. In some embodiments, the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture. In some embodiments, the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve. In some embodiments, the central lumen can comprise a single lumen, and in some embodiments, the central lumen can comprise a plurality of lumens.

One aspect of the present disclosure relates to a delivery system for intravascular access of a blood vessel within a patient's body. The delivery system includes a catheter having a first end, a second end, and a catheter lumen extending therebetween and a hemostatic valve coupled to the first end of the catheter. The hemostatic valve includes a tubular member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the central lumen of the tubular member is fluidly coupled with the catheter lumen. The hemostatic valve includes an active tensioning mechanism coupled to the tubular member, the tensioning mechanism can be moveable between a first configuration in which the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration in which the central lumen is open.

In some embodiments, the hemostatic valve further includes a reinforcement structure extending along at least a portion of the tubular member. In some embodiments, the reinforcement structure is located between the tensioning mechanism and the tubular member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member. In some embodiments, the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member. In some embodiments, the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments, moving the tensioning mechanism from the first configuration to the second configuration can include moving the actuator and the thereto coupled at least one filament from a first position to a second position. In some embodiments, the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

In some embodiments, the actuator can be a manual actuator. In some embodiments, the actuator can include a pair of opposing and depressable buttons, which buttons can be biased towards an undepressed position. In some embodiments, the central lumen is sealed when the buttons are in the undepressed position. In some embodiments, the filament can be a monofilament. In some embodiments, the filament can be at least one of: a polymer filament; or a metallic filament. In some embodiments, the catheter can include a thrombus extraction device.

One aspect of the present disclosure relates to a method of sealing a delivery device accessing a blood vessel of a patient. The method includes inserting the delivery device including a catheter and a hemostatic valve into the blood vessel of the patient. In some embodiments, the catheter can have a first end, a second end, and a catheter lumen extending therethrough. In some embodiments, the hemostatic valve can be coupled to the first end and can have a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member. In some embodiments, the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel. The method can include moving the tensioning mechanism of the hemostatic valve to a second configuration. In some embodiments, the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration. The method can include advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member. The method can include returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

In some embodiments, the method includes retracting the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the hemostatic valve can include a reinforcement structure located between the at least one filament and the tubular member.

In some embodiments, the at least one filament forms a loop around the elongate member, and moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop. In some embodiments, the filament forms at least one bight around a portion of the elongate member. In some embodiments, the filament can include a first filament and a second filament. In some embodiments, the at least one bight can include a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament. In some embodiments, the first and

second bights overlap to encircle a portion of the tubular member within a constricting area.

In some embodiments, moving the tensioning mechanism from the second configuration to the first configuration can include moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member. In some embodiments, the tensioning mechanism can include an actuator. In some embodiments, moving the tensioning mechanism to the second configuration can include manipulating the actuator. In some embodiments, the method includes applying a vacuum to the delivery device and/or delivery system to aspirate material through the catheter. In some embodiments, the central lumen remains sealed during the aspiration. In some embodiments, the tool can include a thrombus extraction device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of one embodiment of a delivery device.

FIG. **2** is a side-section view of one embodiment of a hemostasis valve in a first configuration.

FIG. **3** is a side-section view of one embodiment of the valve in a second configuration.

FIG. **4** is a side-section view of one embodiment of the valve in the first configuration and with a tool extending through the valve.

FIG. **5** is a side-section view of one embodiment of a single-button hemostasis valve in a first configuration.

FIG. **6** is a perspective view of a filament of a valve forming a loop.

FIG. **7** is a perspective view of two filaments of a valve, each of the filaments forming a loop.

FIG. **8** is a perspective view of two overlapping and interlocked bights in an open configuration.

FIG. **9** is a perspective view of two overlapping and interlocked bights in a closed configuration.

FIG. **10** is a flowchart illustrating one embodiment of a method for sealing a valve and/or catheter.

FIG. **11** is a side view of one embodiment of a thrombectomy system including the delivery device.

FIG. **12** is a side-section view of another embodiment of a hemostasis valve having two-piece caps.

DETAILED DESCRIPTION

The present disclosure relates to a valve that can be used a hemostasis valve. This valve, also referred to herein as a garrote valve can seal with or without a tool extending through the valve. The garrote valve provides convenient, single-handed operation for a wide range of medical devices including catheters, wires, embolectomy systems, or the like. This single-handed operation of the garrote valve allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure. Combined with single-handed operation, the garrote valve provides robust sealing either with or without a tool extending through the valve. This robust sealing minimizes leakage in applications with a pressure differential on different sides of the valve. This pressure differential can arise, for example, during the application of vacuum aspiration in a procedure. Even under such conditions, as well as under other conditions, the garrote valve maintains seal integrity and prevents leakage in one or both directions.

The garrote valve includes a tubular member. The tubular member is a flexible member that defines a central lumen, which can, in some embodiments, define a single lumen, and in some embodiments, defines a plurality of lumens. In some embodiments, each of the plurality of lumens can comprise the same size and shape, and in some embodiments, some or all of the plurality of lumens can comprise different sizes and shapes. In some embodiments, for example, the plurality of lumens can comprise a lumen sized and/or shaped to receive a guide wire and a lumen sized and/or shaped to receive a tool. The tubular member extends at least partially through a constricting mechanism. The constricting mechanism can be moved from a first configuration to a second configuration, and the constricting mechanism can collapse and/or seal the central lumen of the tubular member when the constricting mechanism is in the first configuration. The constricting mechanism creates the above-discussed robust seal of the tubular member and thus of the valve.

With reference now to FIG. **1**, a perspective view of one embodiment of a delivery system **100**, also referred to herein as a delivery device **100**, is shown. The delivery system **100** can include a catheter **102** and a garrote valve **104**, also referred to herein as valve **104**. The catheter **102** can comprise a shaft **106**, also referred to herein as an elongate sheath **106**, having a proximal end **108**, also referred to herein as a first end **108**, that can connect to the valve **104** and a distal end **110**, also referred to herein as a second end **110**. The shaft **106** can define a catheter lumen **112** extending from the proximal end **108** of the shaft **106** to the distal end **110** of the shaft **106**. The catheter **102** and specifically the shaft **106** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the catheter **102** can be flexible and/or can be made from a biocompatible material. The elongate sheath **106** can have an outer diameter of at least 4 French, at least 6 French, at least 8 French, at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 4 French and 30 French, between 8 French and 24 French, between 12 French and 20 French, and/or any other or intermediate size.

The valve **104** can include an outer shell **114**. The outer shell **114** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the outer shell **114** can be made from one or several polymers or composites. The outer shell **114** can include features that allow interaction with and/or control of the valve **104** to move the valve **104** between the first configuration and the second configuration.

The outer shell **114** can include a proximal cap **116** located at a proximal end **118** of the outer shell **114** and a distal cap **120** located at a distal end **122** of the shell **114**. The proximal cap **116** can include and/or house a proximal aperture **124**, also referred to herein as a proximal channel **124**, a first channel **124**, or a first aperture **124**, that extends through the proximal cap **116**, and the distal cap **120** can include and/or house a distal aperture **126**, also referred to herein as a distal channel **126**, a second channel **126**, or second aperture **126**, that extends through the distal cap **120**. As seen in FIG. **1**, the distal cap **120** connects to the shaft **106** of the catheter **102** at the distal end **122** of the valve **104**.

The proximal cap **116** and the distal cap **120** are connected via a housing **128**. The housing **128** can be a one-piece housing **128** or a multi-piece housing **128**. In the embodiment depicted in FIG. **1**, the housing comprises a two-piece housing **128**. The housing **128** can be configured to receive and couple with each of the proximal cap **116** and the distal cap **120**, and as seen in FIG. **1**, the housing **128** is coupled

with each of the proximal cap **116** and the distal cap **120** to secure the relative position of the proximal cap **116** and the distal cap **120** with respect to each other.

The housing **128** can define an interior channel **130** through which an elongate member **132**, also referred to herein as a tubular member **132**, a septum **132**, or a tubular septum **132**, can extend and connect the proximal cap **116** and the distal cap **120**. The elongate member **132** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the elongate member **132** can comprise a compliant tubular structure that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the elongate member **132** can facilitate the collapse, and specifically the uniform collapse of the elongate member **132** and the sealing of the elongate member **132**. In some embodiments, the elongate member **132** is an elastic, resilient material that may comprise a polymer including either a natural or synthetic polymer. In some embodiments, the elongate member can comprise an elastic, resilient material that may comprise silicone, urethane, ethylene-vinyl acetate, natural or synthetic rubber or other elastomers known in the art. In some embodiments, the elongate member **132** can comprise a silicone tube.

The elongate member **132** can comprise a proximal end **134**, also referred to herein as a first end **134**, that can couple to the proximal cap **116**, and a distal end **136**, also referred to herein as a second end **136**, that can couple to the distal cap **120**. The elongate member **132** can define a central lumen **138** that can extend from the first end **134** to the second end **136** of the elongate member **132**. The elongate member **132** can be coupled to the proximal cap **116** such that the central lumen **138** is fluidly coupled with the proximal aperture **124** of the proximal cap **116**, and the elongate member **132** can be coupled to the distal cap **120** such that the central lumen **138**, as seen in FIG. **2** and in FIG. **3**, is fluidly coupled with the distal aperture **126** of the distal cap **120**.

The central lumen **138** of the elongate member **132** can be defined by a wall of the elongate member **132** that can have a thickness that is uniform along the length of the elongate member **132** between the first end **134** and the second end **136**, or that is non-uniform along the length of the elongate member **132** between the first end **134** and the second end **136**. In some embodiments, the wall can have a thickness that is approximately between 0.005 inches and 0.05 inches, and/or approximately between 0.010 inches and 0.030 inches. As used anywhere herein, "approximately" refers to a range of +/−10% of the value and/or range of values for which "approximately" is used.

In some embodiments, the elongate member **132** can be cylindrically shaped, and specifically can be circular-cylindrically shaped. In some embodiments, the elongate member **132** can be dog-bone shaped to facilitate, for example, connection to each of the proximal cap **116** and the distal cap **120**. In some embodiments, the elongate member **132** can include one or several outward-extending protuberances that engage with all or portions of a constricting mechanism **141**, also referred to herein as a tensioning mechanism **141**, of the valve **104** to secure a position of all or portions of the constricting mechanism **141** with respect to the elongate member **132**. In some embodiments, the constricting mechanism **141** can be self-adjusting to seal around tools of different sizes extending through the valve **104**.

The constricting mechanism **141** can, in some embodiments, collapse and seal the elongate member **132** via compression and/or constriction, and specifically via constriction with at least one filament **150**. The constricting mechanism **141** can comprise: an actuator **142** which can be a manual actuator such as one or several buttons **144**; and the at least one filament **150** that can extend at least partially around the elongate member **132**. In some embodiments, the use of the constricting mechanism **141** can facilitate sealing of the valve around tools or instruments of a wide range of sizes and/or diameters, and particularly around tools or instruments that fit through the elongate member **132**.

The housing **128** can further include one or several retention features **140**. The one or several retention features **140** of the housing can engage with and retain all or portions of the constricting mechanism **141** of the valve **104**. In some embodiments, the one or several retention features **140** of the housing **128** can retain the actuator **142** and/or can couple the actuator **142** to the housing **128**. The actuator **142** can comprise any desired type of actuator including, for example, a manual actuator and/or an automated actuator such as, for example, an electromechanical actuator including a solenoid-based actuator. In some embodiments, the actuator can comprise one or several buttons **144**, and specifically, as depicted in FIG. **1**, the actuator **142** can comprise a first button **144**-A and a second button **144**-B. Alternatively, and as depicted in FIG. **5**, the actuator **142** can comprise a single button **144**. In such an embodiment, the filament **150** can be coupled to the single button **144** and to a portion of the housing **128** such as, for example, to grip portion **500** of the housing **128** such that the movement of the single button **144** causes the sealing and/or opening of the elongate member **132** and of the valve **104**.

The actuator **142** can be biased towards a configuration such as, for example, biased towards the first configuration or biased towards the second configuration. As depicted in FIG. **2**, which shows the constricting mechanism **141** in the first configuration, the actuator **142** can be biased towards the first configuration wherein the elongate member **132** is collapsed and/or sealed by a bias feature **146**. In this first configuration, the buttons **144** can be in a first position, also referred to herein as an undepressed position. This bias feature **146** can, as shown in FIG. **2**, include a first spring **148**-A configured to bias the first button **144**-A towards the first position corresponding to the first configuration of the constricting mechanism **141**, and a second spring **148**-B configured to bias the second button **144**-B towards a first position corresponding to the first configuration of the constricting mechanism **141**. One or both of the first spring **148**-A and the second spring **148**-B can comprise a tension spring, compression spring, a torsion spring, a coil spring, or any other desired type of spring.

In some embodiments, one or both of the first spring **148**-A and the second spring **148**-B can generate sufficient force so as to allow actuation of the actuator **142** with a single hand and so as to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. In some embodiments, one or both of the first spring **148**-A and the second spring **148**-B can generate a force of: at least 0.1 pounds, at least 0.2 pounds, at least 0.3 pounds, at least 0.4 pounds, at least 0.5 pounds, at least 0.6 pounds, at least 0.7 pounds, at least 0.8 pounds, at least 0.9 pounds, at least 1 pound, at least 1.5 pounds, at least 2 pounds, at least 3 pounds, at least 5 pounds, and/or at least 10 pounds and in some embodiments one or both of the first spring **148**-A and the second spring **148**-B can generate a force approximately between: 0.1 and 10 pounds, 0.1 and 5 pounds, 0.1 and 1.5 pounds, 0.2 and 1 pounds, and/or 0.4 and 0.8 pounds.

The constricting mechanism **141** can include at least one filament **150** that extends at least partially around the elongate member **132**. In some embodiments, the at least one filament **150** can circumferentially constrict the elongate member **132** to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. The filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal. In some embodiments, the filament **150** can be nylon, stainless steel, nitinol, silicone, or the like. In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament. In some embodiments, the filament **150** can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

The filament **150** can be coupled to the actuator **142** such that the filament **150** selectively constricts, collapses, and/or seals the elongate member **132**, and specifically the central lumen **138** of the elongate member **132** based on the movement and/or position of the actuator **142**. In some embodiments, the filament **150** can be connected to one or both of the buttons **144**-A, **144**-B such that the filament **150** collapses, constricts, and/or seals the elongate member **132** and specifically the central lumen **138** of the elongate member **132** when the buttons **144**-A, **144**-B are in the first position, and the filament **150** can be connected to one or both of the buttons **144**-A, **144**-B such that the elongate member **132** and specifically the central lumen **138** of the elongate member **132** is open and uncollapsed when the buttons **144**-A, **144**-B are in the second position. In some embodiments in which the actuator **142** comprises a single button **144**, as depicted in FIG. **5**, the filament **150** can be connected to the button **144** and to the housing **128** such that the filament **150** is tightened when the button **144** moves to the first position.

In some embodiments, the at least one filament **150** can extend along an axis **152** that can be perpendicular to a central axis **154** of the elongate member **132** and/or of the apertures **124**, **126**. In some embodiments, the axis **152** of the at least one filament **150** can intersect and be perpendicular to the central axis **154** of the elongate member **132** and/or of the apertures **124**, **126**. In some embodiments, the actuator **142**, and specifically the buttons **144**-A, **144**-B can move along this axis **152** when moved from the first position to the second position.

In FIG. **3**, an embodiment of the valve **104** with the constricting mechanism **141** in the second configuration is shown. As specifically shown, both of the first and second buttons **144**-A, **144**-B are in the second position, depressed into the retention features **140** of the housing **128**. In this second position, the filament **150** is loosened, thereby allowing the expansion of the elongate member **132** and the unsealing of the central lumen **138** of the elongate member **132**.

As further seen in FIG. **3**, the proximal cap **116** has a proximal end **300** and a distal end **302**. The proximal cap **116** can include a funnel portion **301** of the proximal aperture **124**, which funnel portion **301** can facilitate insertion of a tool into the proximal aperture **124**. The distal end **302** of the proximal cap **116** can partially extend into the interior channel **130** of the housing **128**. The proximal cap **116** can include a mating feature **304** that can mate with the proximal end **134** of the elongate member **132**. In some embodiments, the proximal end **134** of the elongate member **132** can fit over the mating feature **304** of the proximal cap **116**. The proximal end **134** of the elongate member **132** can be compressed between the mating feature **304** of the elongate member **132** and a portion of the interior channel **130** of the housing **128** into which the mating feature **304** is inserted to thereby secure the proximal end **134** of the elongate member **132** on the mating feature **304**. In some embodiments, the proximal end **134** of the elongate member **132** can be further secured on the mating feature **304** by a proximal O-ring **306** that can be compressed between the housing **128** and the mating feature **304** of the proximal cap **116** to sealingly couple the elongate member **132** to the proximal cap **116**.

The distal cap **120** has a proximal end **308** and a distal end **310**. The distal cap can include a mating feature **312** located on the proximal end **308** of the distal cap **120**, which mating feature **312** can mate with the distal end **136** of the elongate member **132**. In some embodiments, the distal end **136** of the elongate member **132** can fit over the mating feature **312** of the distal cap **123**. The distal end **136** of the elongate member **132** can be compressed between the mating feature **312** of the elongate member **132** and a portion of the interior channel **130** of the housing **128** into which the mating feature **312** is inserted to thereby secure the distal end **136** of the elongate member **132** on the mating feature **312**. In some embodiments, the distal end **136** of the elongate member **132** can be further secured on the mating feature **312** by a distal O-ring **314** that can be compressed between the housing **128** and the mating feature **312** of the proximal cap **116** to sealingly couple the elongate member **132** to the distal cap **120**.

The distal cap **120** can, in some embodiments, further include a side port barb **314** that can extend laterally away from the distal cap **120** and specifically away from the distal aperture **126** of the distal cap **120**. The side port barb **314** can define a side port channel **316** that can extend through the side port barb **314** and fluidly connect to the distal aperture **126**. In some embodiments, the side port barb **314** can include a securement feature **318** such as a barb that can secure coupling of a hose or tube to the side port barb **314**.

In some embodiments, the side barb **314** can be used to apply a vacuum to the portions of the delivery device **100**, and particularly to portions of the delivery device **100** that are distal of the axis **152** along which the elongate member **132** seals. This vacuum can be applied to aspirate a material through the delivery device **100**, and specifically through the catheter **102** of the delivery device. This aspirated material can be a biological material including, for example, bodily fluids, multi-phase bodily materials that can include, for example, a fluidic portion and at least one solid portion, or the like.

In some embodiments, due to the narrowing shape of the elongate member **132** when the constricting mechanism **141** is in the first configuration, a vacuum applied to the portions of the delivery device **100** distal to the axis **152** draws the elongate member **132** towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve **104**. This attribute of the valve **104** can provide benefits over other valve designs in which a vacuum can compromise the seal of the valve, and thus the ability to draw a vacuum and aspirate can be limited.

In some embodiments, the valve **104** can further include a reinforcement structure **320** that can extend along all or portions of the elongate member **132**. The reinforcement structure **320** can facilitate the uniform collapse of the elongate member **132**, can prevent the at least one filament **150** from cutting through and/or tearing the elongate member **132**, and can assist in guiding one or several tools

through the elongate member **132**. The reinforcement structure **320** can be tubular, can extend along and around the elongate member **132**, and can be positioned so as to be between the elongate member **132** and the at least one filament **150**.

The reinforcement structure **320** can include a proximal end **322** and a distal end **324**. In some embodiments, the reinforcement structure **320** extends along and around the elongate member **132**, and is positioned such that the proximal end **322** of the reinforcement structure **320** is proximate to the first end **134** of the elongate member **132** and the distal end **324** of the reinforcement structure **320** is proximate to the second end **136** of the elongate member **132**.

The reinforcement structure **320** can be coupled to the elongate member **132**. In some embodiments, the reinforcement structure **320** is coupled to the elongate member **132** along the length of the reinforcement structure **320**, and in some embodiments, the reinforcement structure **320** is coupled to the elongate member **132** and distinct positions along the length of the elongate member **132** and/or the reinforcement structure **320**. In one embodiment, for example, the reinforcement structure **320** can be coupled to the elongate member **132** at one or both of the proximal end **322** of the reinforcement structure **320** and the distal end **324** of the reinforcement structure **320** and/or at one or both of the first end **134** and the second end **136** of the elongate member **132**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via one or several other components of the valve **104**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via the compression of the reinforcement structure **320** and the elongate member **132** between the housing **128** and one or both of the proximal **116** and the distal **120**.

In some embodiments, the reinforcement structure **320** can be adhered to the elongate member **132** via, for example, an adhesive such as silicone adhesive. In some embodiments, the adhesive can be circumferentially applied to the reinforcement structure **320** and/or the elongate member **132** in an adhesive ring that can, for example, a have a length approximately between: 0.010 inches and 0.5 inches; 0.02 and 0.4 inches; 0.050 inches and 0.0250 inches, or any other or intermediate range.

In one embodiment, each of the proximal end **322** and the distal end **324** of the reinforcement structure **320** can be adhered via an adhesive to the elongate member **132**. In such an embodiment, the reinforcement structure **320** may be uncoupled to the elongate member **132** at positions other than the coupling at one or both of the proximal end **322** and the distal end **324** of the reinforcement structure **320**, and thus the reinforcement structure **320** is uncoupled to the elongate member **132** at a position between the first end **134** and the second end **136** of the elongate member **134** and/or between the proximal end **322** and the distal end **324** of the reinforcement structure **320**.

The lack of coupling of the reinforcement structure **320** to the elongate member **132** can facilitate and improve the collapse of the elongate member **132** around a tool **400**, also referred to herein as instrument **400** or device **400**, inserted through the valve **104** as shown in FIG. **4**. The tool **400** can be any device inserted through the valve **104** including, for example, one or several additional catheters, lines, wires, grippers, punches, cutters, or the like. As seen in FIG. **4**, the tool **400** is inserted through the valve **104** and specifically through the elongate member **132** of the valve. As shown, the constricting mechanism **141** is in the first configuration and the elongate member **132** and the central lumen **138** of the elongate member **132** is collapsed around the tool **400**, and specifically around a shaft **402** of the tool **400** to thereby seal the valve **104** around the tool **400** and specifically around the shaft **402** of the tool **400**. The constricting mechanism **141** can seal around tools **400** that fit through the elongate member **132**, regardless of the size of the tool **400**. Thus, the valve can be used with a wide variety of tools.

The reinforcement structure **320** can comprise a variety of designs, shapes, sizes, and materials. In some embodiments, the reinforcement structure **320** can be sized and shaped so as to receive elongate member **132** and to be positioned between the elongate member **132** and the at least one filament **150**. In some embodiments, the reinforcement structure **320** can be made from a material sufficiently strong to prevent the cutting of the at least one filament **150** through the elongate member **132**.

In some embodiments, the reinforcement structure can comprise a coil or a mesh sheath. The mesh sheath can, in some embodiments, comprise a braided mesh. The braided mesh can be made from any desired number of wires in any desired configuration. In some embodiments, the braided mesh can comprise a 4 wire braided mesh, an 8 wire braided mesh, a 12 wire braided mesh, a 16 wire braided mesh, a 20 wire braided mesh, a 24 wire braided mesh, a 32 wire braided mesh, a 48 wire braided mesh, a 64 wire braided mesh, a 72 wire braided mesh, an 80 wire braided mesh, a 96 wire braided mesh, or any other or intermediate braided mesh. In some embodiments, the braided mesh can comprise: a 1×1 configuration. In some embodiments, the wire in the braided mesh can be any desired material including, for example, a metal wire such as a nitinol wire or a stainless steel wire, a polymer wire, or a natural wire. In one embodiment, the braided mesh can comprise a 48 wire mesh in a 1×1 configuration made with a nitinol wire having a diameter of 0.003 inches.

With reference now to FIGS. **6** through **9**, different embodiments and/or configurations of the filament **150** are shown. The filament **150** can comprise a single filament **150** having a first end **600** and a second end **602** as shown in FIG. **6**. The filament **150**, and specifically which first and second ends **600**, **602** can be coupled to the actuator **142** to move the filament **150** between the first and second configurations or positions and/or from the first configuration or position to the second configuration or position. In some embodiments, both of the first end **600** and the second end **602** can be coupled to a single button **144**, in some embodiments, each of the first end **600** and the second end **602** can be coupled to different buttons **144**, and in some embodiments, one of the first end **600** and the second end **602** can be coupled to a button **144** and the other of the first end **600** and the second end **602** can be coupled to the housing **128** or other portion of the valve **104**.

In some embodiments, the filament **150** can comprise multiple filaments, and specifically, as shown in FIGS. **7** through **9**, the filament **150** can comprise a first filament **150**-A and a second filament **150**-B. In embodiments in which the filament **150** comprises multiple filaments, each of the multiple filaments can have a first end **700** and a second end **702**. The first and second filaments **150**-A, **150**-B can be coupled to the actuator **142**. In such embodiments, the first and second ends **700**, **702** can be coupled to the actuator **142** to move the filaments **150**-A, **150**-B between the first and second configurations and/or from the first configuration to the second configuration. In some embodiments, both of the first end **700** and the second end **702** of one or more of the multiple filaments **150** can be

coupled to a single button **144**, in some embodiments, each of the first end **700** and the second end **702** of one or more of the multiple filaments **150** can be coupled to different buttons **144**, and in some embodiments, one of the first end **700** and the second end **702** of one or more of the multiple filaments **150** can be coupled to one button **144** and the other of the first end **700** and the second end **702** of those one or more filaments **150** can be coupled to the housing **128** or other portion of the valve **104**.

The filament **150** can be arranged in a variety of configurations. In some embodiments, the filament **150** can be configured to form a single loop **604** that can extend around the elongate member **132** and/or through which the elongate member **132** can be received as shown in FIG. **6**, and in some embodiments, the filament **150** can be configured to form multiple loops, and specifically a first loop **704** and a second loop **706** as shown in FIG. **7**. The first and second loops **704**, **706** can each receive the elongate member **132**. In some embodiments, a diameter or size of the loop **604**, or of the loops **704**, **706** can decrease when the constricting mechanism **141** is moved from the second configuration to the first configuration.

In some embodiments, the filament **150** can be configured to form a bight **800**, which bight **800** can be a single bight or multiple bights. As used herein, a "bight" refers to a U-shaped section between the two ends of the filament **150**. As depicted in FIGS. **8** and **9**, the bight **800** can comprise multiple bights, and specifically a first bight **800**-A and a second bight **800**-B. In some embodiments, the first bight **800**-A can extend through the second bight **800**-B such that the first and second bights **800**-A, **800**-B interlock, whereas in other embodiments, the first and second bights **800**-A, **800**-B can be non-interlocking. Similarly, in embodiments containing the filament **150** having multiple loops, one or several of the multiple loops can be interlocking.

In some embodiments, the bight **800**, and specifically one or both of the first bight **800**-A and the second bight **800**-B can be formed around a portion of the elongate member **132** and/or can extend around a portion of the elongate member **132**. Each bight **800** can define a partially enclosed receiving area **808** wherein the elongate member **132** can be received. Thus, the first bight **800**-A can define a first receiving area **808**-A and the second bight **800**-B can define a second receiving area **808**-B.

As seen in FIGS. **8** and **9**, multiple bights, and specifically the first and the second bights **800**-A, **800**-B can be positioned and oriented such that the first bight **800**-A has a first orientation or first direction as indicated by arrow **810**, and the second bight has a second orientation or second direction as indicated by the arrow **812**. In some embodiments, the first orientation is different from the second orientation such that the first and second receiving areas **808**-A, **808**-B overlap and define an encircled area **814**, also referred to herein as a constricting area **814**. The elongate member **132** can be received within the encircled area **814**. In embodiments in which bights **800**-A, **800**-B overlap to define the encircled area **814**, the movement of the constricting mechanism **141** to the first configuration can result in and/or include the first bight **800**-A moving in the direction indicated by the arrow **810** and/or the second bight **800**-B moving in the direction indicated by the arrow **812**, which movement of the bights **800**-A, **800**-B decreases the size of the encircled area **814** and constricts, collapses, and/or seals the elongate member **132** extending through the encircled area **814**.

The filament(s) **150** forming the bights **800** can each apply an arcuate line or narrow longitudinal zone of pressure to the elongate member **132**. If the filament(s) are circular in cross-section, the zone of pressure can be very small, and can, in some embodiments, be less than the diameter or thickness of the filament. In some embodiments, the filaments have a diameter or width less than about 2.5 mm, less than about 2 mm, less than about 1.5 mm, less than about 1.25 mm, less than about 1 mm, less than about 0.75 mm, less than about 0.5 mm, and/or less than about 0.25 mm. In some embodiments, the filaments can have a diameter or width of between about 0.01 mm and 2.5 mm, between about 0.05 mm and 2 mm, between about 0.1 mm and 1 mm, and/or between about and 0.70 mm. In some embodiments, the arcuate line or zone of pressure may form two opposing arcs and in other embodiments, the arcuate line of pressure may be a singular substantially circular line or zone that encircles the elongate member at least once. The longitudinal length of the of the line or zone of pressure may be very short compared to other valves known in the art. In some embodiments, the longitudinal length of the zone of pressure applied to the elongate member **132** by the filament(s) **150** may be less than about 2.0 mm and in some embodiments less than about 0.5 mm. In some embodiments, the filament(s) **150** can have any desired cross-sectional shape including, for example, a circular cross-section, a rectangular cross-section, an oval cross-section, a square cross-section, a polygonal cross-section, a triangular cross-section, or any other desired shape of cross-section.

With reference now to FIG. **10**, a flowchart illustrating one embodiment of a process **1000** for sealing a valve **104** and/or catheter **102** accessing a body of a patient is shown. The process **1000** can be performed using the valve **104** and/or the delivery system **100**. The process **1000** begins at block **1002**, wherein the delivery device **100**, and specifically the catheter **102** of the delivery device **100** is inserted into the body of the patient. In some embodiments, this can include inserting the catheter **102** into a portion of the circulator system of the patient such as, for example, a blood vessel including an artery or a venous vessel. In some embodiments, the delivery device **100** can be inserted into the body of the patient directly through an aperture or incision in the patient, and in some embodiments, the delivery device **100** can be inserted into the body of the patient via another catheter or device. In some embodiments, the constricting mechanism **141** can be in the first configuration while the delivery device **100** and/or the catheter **102** is inserted into the patient's body.

After the delivery device **100** is inserted into the body of the patient, the process **1000** proceeds to block **1004**, wherein the constricting mechanism **141** is moved from the first configuration to the second configuration. As described above, the central lumen **138** of the elongate member **132** is unsealed when the constricting mechanism **141** is in the second configuration. In some embodiments, the moving of the constricting mechanism **141** from the first configuration to the second configuration can include the manipulation of the actuator **142** and/or the control of the actuator **142**, and specifically the depressing of the one or several buttons **144** to move the filament **150** from the first position to the second position to allow the expansion and opening of the central lumen **138** of the elongate member **132**.

After the constricting mechanism **141** is moved from the first configuration to the second configuration, the process **1000** proceeds to block **1006**, wherein the tool **400**, and specifically the shaft **402** of the tool **400** is advanced through the delivery device **100** and specifically through the valve **104** until a first end of the tool reaches a desired position within the body of the patient. In some embodiments, a

portion of the shaft **402** can be positioned within the central lumen **138** of the elongate member **132** after the advancing of the tool **400** through the delivery device **100**. In some embodiments, after the tool **400** is advanced through the delivery device **100**, the desired procedure can be performed with the tool.

After the tool **400** is advanced through the delivery device **100**, or while the tool **400** is being advanced through the delivery device **100**, the process **1000** proceeds to block **1008**, wherein the constricting mechanism **141** is returned to the first configuration. In some embodiments, the returning of the constricting mechanism **141** to the first configuration can include the release of the one or several buttons **144** and/or the control of the actuator **142** to reconfigure the constricting mechanism **141** to the first configuration. In some embodiments, the return of the constricting mechanism **141** to the first configuration can result in the collapse and/or sealing of the elongate member **132** and specifically the central lumen **138** of the elongate member **132** around the tool **400** and specifically around the shaft **402** of the tool **400**. The return of the constricting mechanism **141** to the first configuration, or the movement of the constricting mechanism **141** to the first configuration can include the decreasing of the size and/or diameter of one or several loops formed by the filament **150** and/or the movement of one or several bights **800** such as, for example, the movement of the first bight **800**-A in the first direction indicated by arrow **810** and the movement of the second bight **800**-B in the second direction indicated by arrow **812** to reduce the size of the constricting area **814**. In some embodiments, after the constricting mechanism is returned to the first configuration, the desired procedure can be performed with the tool.

After the constricting mechanism is returned to the first configuration, the process **1000** proceeds to block **1010**, wherein the tool **400**, and specifically the shaft **402** of the tool **400** is retracted from the delivery device **100**, and more specifically from the valve **104**. In some embodiments, the valve **104** can remain sealed during the retracing of the tool **400** and/or the shaft **402** of the tool. In some embodiments, the valve **104** remains sealed during the retracting of the tool **400** and/or the retracting of the shaft **402** of the tool **400** as the constricting mechanism **141** can remain in the first configuration during the retracing of the tool **400** and/or the shaft **402** of the tool **400**.

In some embodiments, the constricting mechanism **141** can be moved to the second configuration to allow the retraction of the tool **400** and/or the shaft **402** of the tool **400** from the valve **104**, and the constricting mechanism **141** can be returned to the first configuration when the tool **400** and/or the shaft **402** of the tool **400** is removed from the valve **104**. In some embodiments, the retraction of the tool **400** and/or shaft **402** of the tool **400** from the valve **104** can be performed with the constricting mechanism **141** left in the first configuration. In some embodiments, the constricting mechanism **141** can be moved to the second configuration, and then returned to the first configuration via the manipulation and/or control of the actuator **142**, which manipulation and/or control of the actuator **142** can include the depressing of the one or several buttons **144** to move the constricting mechanism **141** to the second configuration, and the release of the one or several buttons **144** to return the constricting mechanism **141** to the first configuration. In some embodiments, if the procedure is complete, the delivery device **100** can then be removed from the body of the patient, and any incision created for the procedure can be closed.

With reference now to FIG. **11**, a side view of one embodiment of a thrombectomy system **1100** including the delivery device **100** and a thrombus extraction device **1102** is shown. In some embodiments, the thrombectomy system **1100** can be used to access a blood vessel **1104** to treat and/or extract a thrombus **1106** from the blood vessel **1104**. The thrombus extraction device **1102** can include a self-expanding coring element **206** and expandable cylindrical portion **208**. In some embodiments, and as shown in FIG. **11**, the thrombus extraction device **1102** can be the tool **400** that can extend through the valve **104**, and in some embodiments, the valve **104** can be a part of the thrombus extraction device **1102**. Further details of thrombectomy systems, thrombus extraction devices, and methods of using the same are disclosed in: U.S. application Ser. No. 15/268,296, filed Sep. 16, 2016, and entitled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS"; U.S. application Ser. No. 15/498,320, filed Apr. 26, 2017, and entitled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION"; and U.S. application Ser. No. 15/466,740, filed on Mar. 22, 2017, and entitled "DEVICE AND METHOD FOR TREATING VASCULAR OCCLUSION", the entirety of each of which is hereby incorporated by reference herein.

With reference now to FIG. **12**, a side-section view of another embodiment of the hemostasis valve **104** having two piece caps **116**, **120** is shown. The valve **104** can include a housing **128** defining an interior channel **130** through which the tubular member **132** can extend. The valve **104** can include the proximal cap **116** and the distal cap **120**. In some embodiments, the proximal cap **116** can comprise a two piece cap and can include a proximal exterior member **1200** and a proximal channel member **1202**. In some embodiments, the distal cap **120** can comprise a two-piece cap and can include a distal exterior member **1204** and a distal channel member **1206**. In some embodiments, this coupling between the proximal exterior member **1200** and the proximal channel member **1202** and/or the coupling between the distal exterior member **1204** and the distal channel member **1206** can be a sealed coupling so as to prevent the leakage of material including fluid or gas between the respective ones of the proximal exterior member **1200** and the proximal channel member **1202** and/or the distal exterior member **1204** and the distal channel member **1206**. In some embodiments, this sealing coupling can be achieved and/or maintained via a seal such as an **1208** that can be positioned between the proximal exterior member **1200** and the proximal channel member **1202** and/or between the distal exterior member **1204** and the distal channel member **1206**.

In some embodiments, the proximal exterior member **1200** can be coupled, and in some embodiments, rotatingly coupled to the proximal channel member **1202** in a manner to allow the rotation of the proximal exterior member **1200** without rotating the proximal channel member **1202**. Similarly, in some embodiments, the distal exterior member **1204** can be rotatingly coupled to the distal channel member **1206** in a manner to allow the rotation of the distal exterior member **1204** without the rotating of the distal channel member **1206**. In some such embodiments, the channel members **1202**, **1206** can be non-rotatable with respect to the housing **128** and/or the tubular member **132**, and one or both of the exterior members **1200**, **1204** can be rotatable with respect to the housing **128** and/or the tubular member **132**. In such an embodiment, the maintaining of the rotational position of the channel members **1202**, **1206** with respect to the housing **128** and/or the tubular member **132** can prevent

the twisting of the tubular member **132** which can result in the sealing of the tubular member **132** regardless of the configuration of the constructing mechanism **141**.

The exterior members **1200**, **1204** can comprise a variety of shapes and sizes and can include a variety of features. In some embodiments, one or both of the exterior members **1200**, **1204** can be coupled to, for example, a shaft similar to the shaft **106** shown in FIG. **1**. In some embodiments, for example, the distal exterior member **1204** can be coupled to a shaft **106**, including, for example, can be non-detachably coupled to the shaft **106**. In some embodiments, one or both of the exterior members can include one or several features configured to facilitate coupling with the valve **104**. These one or several features can include, for example, one or several male or female: connectors; couplers; attachment mechanisms; or the like. In some embodiments, these one or several features can facilitate use of the valve with other existing components, instruments, tools, or the like. In some embodiments, for example, one or both of the exterior members **1200**, **1204** can comprise either a male or female luer fitting, and specifically as shown in FIG. **12**, the distal exterior member **1204** can comprise a male luer fitting **1210**.

Several aspects of the present technology are set forth in the following examples.

1. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:
   an elongate member having a first end, a second end, and a central lumen extending therebetween, wherein the elongate member is pliable;
   a reinforcement structure extending along at least a portion of the elongate member, wherein the reinforcement structure is coupled to the elongate member; and
   an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.
2. The hemostatic valve of example 1, wherein the elongate member comprises a compliant polymer tube.
3. The hemostatic valve of example 1 or 2, wherein the tensioning mechanism comprises at least one filament extending at least partially around the elongate member.
4. The hemostatic valve of example 3, wherein the reinforcement structure is positioned between the at least one filament and the elongate member.

The hemostatic valve of example 4, wherein the reinforcement structure comprises a braided mesh.

6. The hemostatic valve of example 4 or 5, wherein the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member.
7. The hemostatic valve of example 6, wherein the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member.
8. The hemostatic valve of any one of examples 3-7, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein the actuator is moveable to control movement of the at least one filament from a first position wherein the central lumen is constricted and sealed to a second position wherein the central lumen is open, wherein the at least one filament is in the first position when the tensioning mechanism is in the first configuration.
9. The hemostatic valve of example 8, wherein the actuator is biased towards the first position.
10. The hemostatic valve of example 8 or 9, wherein the actuator is biased toward the second position.
11. The hemostatic valve of any one of examples 8-10, wherein the actuator comprises a manual actuator.
12. The hemostatic valve of any one of examples 8-11, wherein the at least one filament forms a loop around the elongate member.
13. The hemostatic valve of any one of examples 8-12, wherein the at least one filament forms a bight around a portion of the elongate member.
14. The hemostatic valve of any one of examples 8-13, wherein the at least one filament comprises a first filament and a second filament, wherein each of the first filament and the second filament are coupled to the actuator, and wherein the first filament and the second filament are moveable from the first position to the second position.
15. The hemostatic valve of example 14, wherein each of the first filament and the second filament form a loop around the elongate member.
16. The hemostatic valve of example 14 or 15, wherein the first filament forms a first bight around a first portion of the elongate member, and wherein the second filament forms a second bight around a second portion of the elongate member.
17. The hemostatic valve of example 16, wherein the first bight extends through the second bight.
18. The hemostatic valve of any one of examples 1-17, further comprising a shell defining a first aperture and a second aperture, wherein the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture.
19. The hemostatic valve of any one of examples 1-18, wherein the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve.
20. The hemostatic valve of any one of examples 1-19, wherein the central lumen comprises a single lumen.
21. The hemostatic valve of any one of examples 1-20, wherein the central lumen comprises a plurality of lumens.
22. A delivery system for intravascular access of a blood vessel within a patient's body, the delivery system comprising:
   a catheter having a first end, a second end, and a catheter lumen extending therebetween;
   a hemostatic valve coupled to the first end of the catheter, the hemostatic valve comprising:
      a tubular member having a first end, a second end, and a central lumen extending therebetween, wherein the central lumen of the tubular member is fluidly coupled with the catheter lumen; and
      an active tensioning mechanism coupled to the tubular member, the tensioning mechanism moveable between a first configuration wherein the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration wherein the central lumen is open.
23. The delivery system of example 22, wherein the hemostatic valve further comprises a reinforcement structure extending along at least a portion of the tubular member.

24. The delivery system of example 22 or 23, wherein the reinforcement structure is located between the tensioning mechanism and the tubular member.

25. The delivery system of example 24, wherein the reinforcement structure comprises a braided mesh.

26. The delivery system of example 24 or 25, wherein the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member.

27. The delivery system of example 26, wherein the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member.

28. The delivery system of example 27, wherein the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

29. The delivery system of any one of examples 22-28, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member.

30. The delivery system of example 29, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein moving the tensioning mechanism from the first configuration to the second configuration comprises moving the actuator and the thereto coupled at least one filament from a first position to a second position, wherein the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

31. The delivery system of example 30, wherein the actuator comprises a manual actuator.

32. The delivery system of example 31, wherein the actuator comprises a pair of opposing and depressable buttons, wherein the buttons are biased towards an undepressed position.

33. The delivery system of example 31 or 32, wherein the central lumen is sealed when the buttons are in the undepressed position.

34. The delivery system of any one of examples 30-33, wherein the filament comprises a monofilament.

35. The delivery system of any one of examples 30-34, wherein the filament comprises at least one of: a polymer filament; or a metallic filament.

36. The delivery system of any one of examples 22-35, wherein the catheter comprises a thrombus extraction device.

37. A method of sealing a delivery device accessing a blood vessel of a patient, the method comprising:

inserting the delivery device comprising a catheter and a hemostatic valve into the blood vessel of the patient, the catheter having a first end, a second end, and a catheter lumen extending therethrough, and the hemostatic valve coupled to the first end and having a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member, wherein the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel;

moving the tensioning mechanism of the hemostatic valve to a second configuration, wherein the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration;

advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member; and

returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

38. The method of example 37, further comprising retracting the shaft of the tool from the delivery device.

39. The method of example 38, wherein the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device.

40. The method of example 38 or 39, wherein the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and wherein the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

41. The method of any one of examples 37-40, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member, wherein the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration.

42. The method of example 41, wherein the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration.

43. The method of example 41 or 42, wherein the hemostatic valve comprises a reinforcement structure located between the at least one filament and the tubular member.

44. The method of any one of examples 41-43, wherein the at least one filament forms a loop around the elongate member, and wherein moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop.

45. The method of any one of examples 41-44, wherein the filament forms at least one bight around a portion of the elongate member.

46. The method of example 45, wherein the filament comprises a first filament and a second filament, and wherein the at least one bight comprises a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament, wherein the first and second bights overlap to encircle a portion of the tubular member within an constricting area.

47. The method of example 46, wherein moving the tensioning mechanism from the second configuration to the first configuration comprises moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member.

48. The method of any one of examples 37-47, wherein the tensioning mechanism comprises an actuator, and wherein moving the tensioning mechanism to the second configuration comprises manipulating the actuator.

49. The method of any one of examples 37-48, further comprising applying a vacuum to the delivery device to aspirate material through the catheter, wherein the central lumen remains sealed during the aspiration.

50. The method of any one of examples 37-49, wherein the tool comprises a thrombus extraction device.

51. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:

an elongate member having a first end, a second end, and a central lumen comprising a plurality of lumens extending therebetween, wherein the elongate member is pliable; and

an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.

Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

In the previous description, various embodiments of the present invention are described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

The use of the terms "a" and "an" and "the" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. The term "connected" is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

What is claimed is:

1. A valve, comprising:

an elongate member defining a lumen;

an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and

a biasing member configured to bias the actuator to the first position.

2. The valve of claim **1** wherein the elongate member is pliable.

3. The valve of claim **1** wherein the filament extends in a loop around the elongate member.

4. The valve of claim **1** wherein the actuator is a button, wherein the button is undepressed in the first position, and wherein the button is depressed in the second position.

5. The valve of claim **1** wherein, when the actuator is in the first position, the lumen is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the lumen and adjacent to a first end of the elongate member and (b) a second volume outside the lumen and adjacent to a second end of the elongate member.

6. The valve of claim **1** wherein, when the actuator is in the first position, the lumen is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the lumen and adjacent to either a first end or a second end of the elongate member.

7. The valve of claim **1** wherein the lumen extends a long a first longitudinal axis, wherein the actuator is movable between the first and second positions along a second longitudinal axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis.

8. The valve of claim **1** wherein the biasing member is a compression spring.

9. The valve of claim **1** wherein, in the first position, the actuator pulls the filament to circumferentially constrict the elongate member such that the lumen is constricted and sealed.

10. The valve of claim **1** wherein the actuator is a first actuator, wherein the filament is a first filament, wherein the biasing member is a first biasing member, and wherein the active tensioning mechanism further comprises:

a second actuator coupled to the elongate member via a second filament extending at least partially around the elongate member, wherein the second actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and

a second biasing member configured to bias the second actuator to the first position.

11. The valve of claim **10** wherein the first filament has a first end portion coupled to the first actuator and a second end portion coupled to the first actuator, and wherein the

second filament has a first end portion coupled to the second actuator and a second end portion coupled to the second actuator.

12. The valve of claim **11** wherein the first filament and the second filament at least partially overlap to define a constricting region about the elongate member.

13. The valve of claim **12** wherein, when the second actuator is moved to the second position and/or the second actuator is moved to the second position, a size of the constricting region increases.

14. The valve of claim **10** wherein the first filament extends in a loop around the elongate member, and wherein the second filament extends through the loop of the first filament around the elongate member.

15. A valve, comprising:

an elongate member defining a lumen;

a filament coupled to the elongate member;

an actuator coupled to the filament, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second position wherein the lumen is at least partially open; and

a biasing member configured to bias the actuator to the first position.

16. The valve of claim **15** wherein the filament extends at least partially around the elongate member.

17. The valve of claim **16** wherein, in the first position, the actuator pulls the filament to circumferentially constrict the elongate member such that the lumen is constricted and sealed.

18. The valve of claim **15** wherein the elongate member is pliable.

19. The valve of claim **15** wherein the filament is mono-filament.

20. The valve of claim **15** wherein the actuator is a button that is undepressed in the first position and depressed in the second position, wherein the button is movable between the first and second positions along a first longitudinal axis, wherein the lumen extends a long a second longitudinal axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis.

21. A valve, comprising:

an elongate member defining a lumen;

a filament coupled to the elongate member; and

an actuator coupled to the elongate member, wherein the actuator is moveable between

(a) a first position in which the actuator pulls the filament to collapse the elongate member such that the lumen is constricted and sealed and

(b) a second position wherein the lumen is at least partially open;

a biasing member configured to bias the actuator to the first position.

22. The valve of claim **21** wherein the elongate member is pliable, and wherein the filament extends at least partially around the elongate member.

23. The valve of claim **21** wherein the elongate member is pliable, and wherein the filament is looped around the elongate member.

24. The valve of claim **21** wherein the actuator does not substantially pull the filament in the second position such that the elongate member can expand.

25. A valve, comprising:

an elongate member defining a lumen; and

an active tensioning mechanism including a first actuator coupled to the elongate member via a first filament and a second actuator coupled to the elongate member via a second filament,

wherein the first filament and the second filament at least partially overlap to define a constricting region,

wherein the elongate member extends through the constricting region, and

wherein the first actuator and/or the second actuator is moveable between (a) a first position in which the constricting region has a decreased size such that the lumen is constricted and sealed and (b) a second position in which the constricting region has an increased size such that the lumen is at least partially open.

26. The valve of claim **25**, further comprising at least one biasing member configured to bias the first actuator and/or the second actuator to the first position.

* * * * *

EXHIBIT G

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Merritt et al.

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(45) **Date of Patent: Jul. 11, 2023**

(54) **HEMOSTASIS VALVES AND METHODS OF USE**

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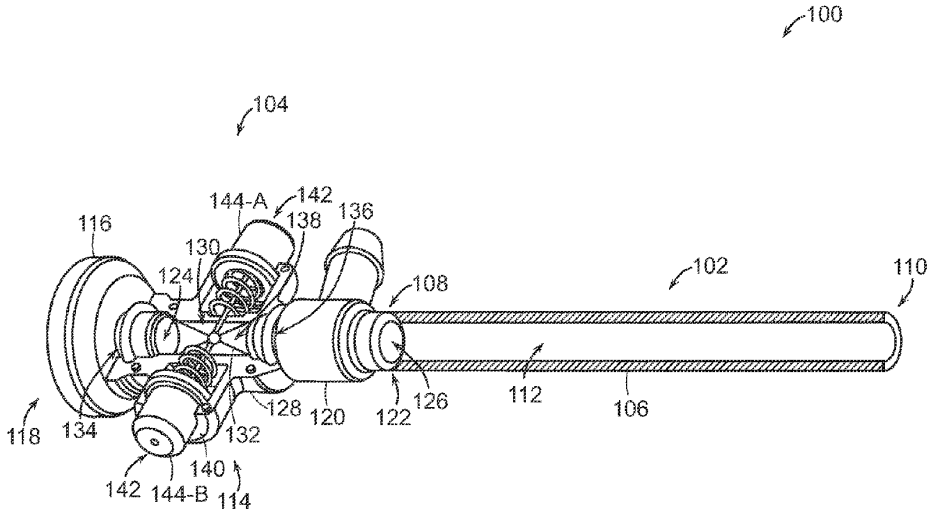
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(57) **ABSTRACT**

Devices, systems, and methods for sealing medical devices, particularly during intravascular access, are disclosed herein. Some aspects relate to a hemostatic valve for sealing a wide range of medical devices, such as catheters, wires, embolectomy systems. The valve can include an elongate member having a first end, a second end, and a central lumen extending therebetween. A reinforcement structure extends along at least a portion of the elongate member and is coupled to the elongate member. A shell defining a first aperture and a second aperture may be included, which first and second apertures can be fluidly coupled by the elongate member. A tensioning mechanism is coupled to the shell and to the elongate member, the tensioning mechanism can be moveable between a first configuration wherein the tensioning mechanism is collapsed and the central lumen is sealed and a second configuration wherein the central lumen is open.

9 Claims, 10 Drawing Sheets



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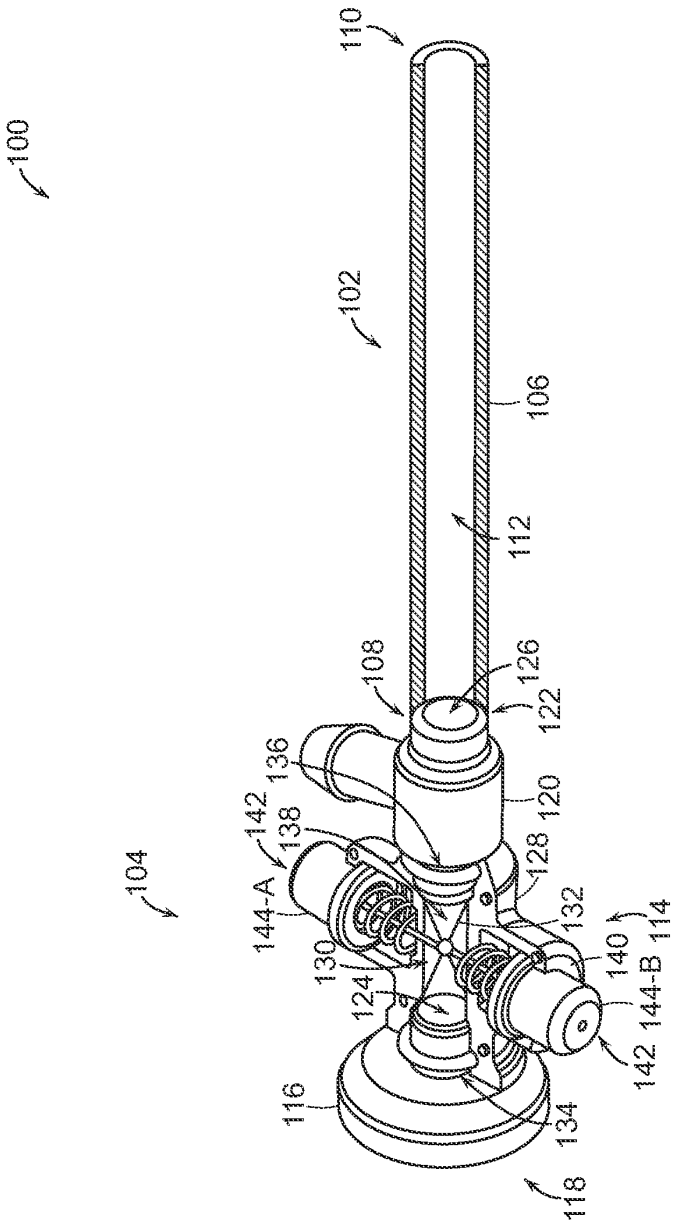

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FIG. 1

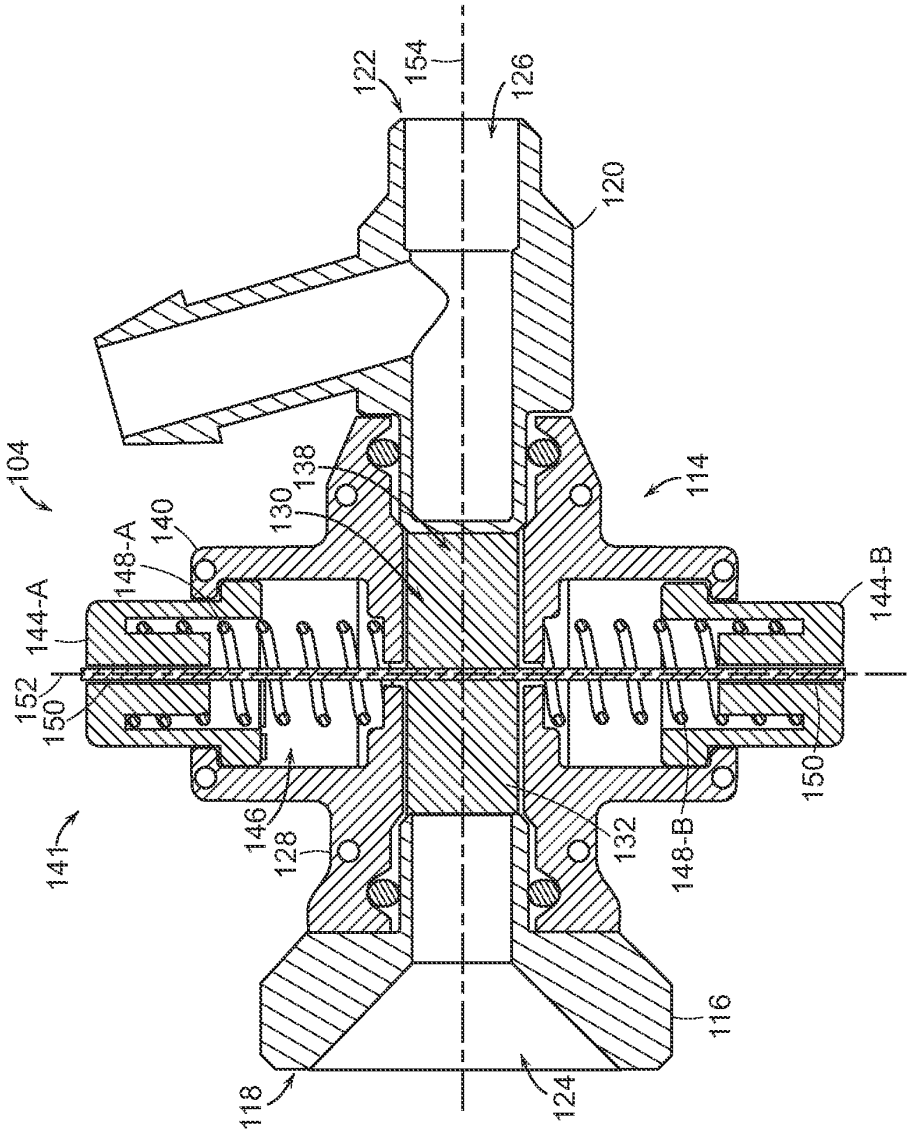

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FIG. 2

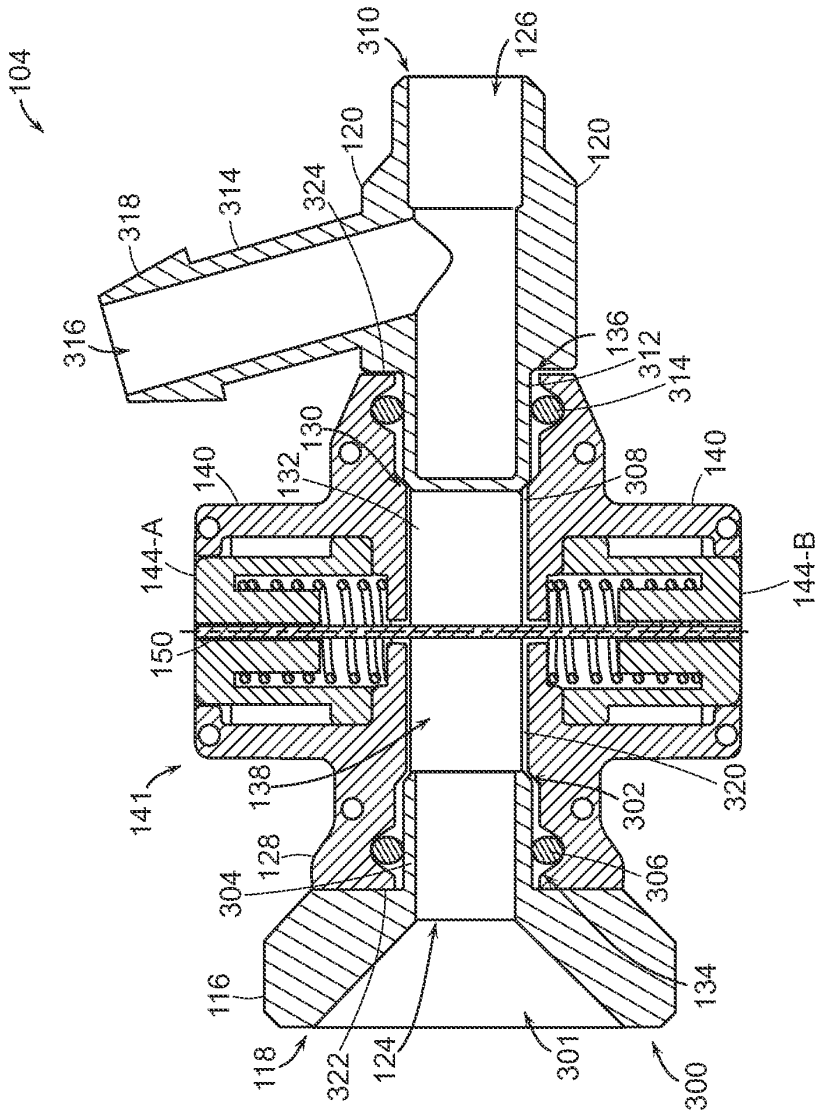

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FIG. 3

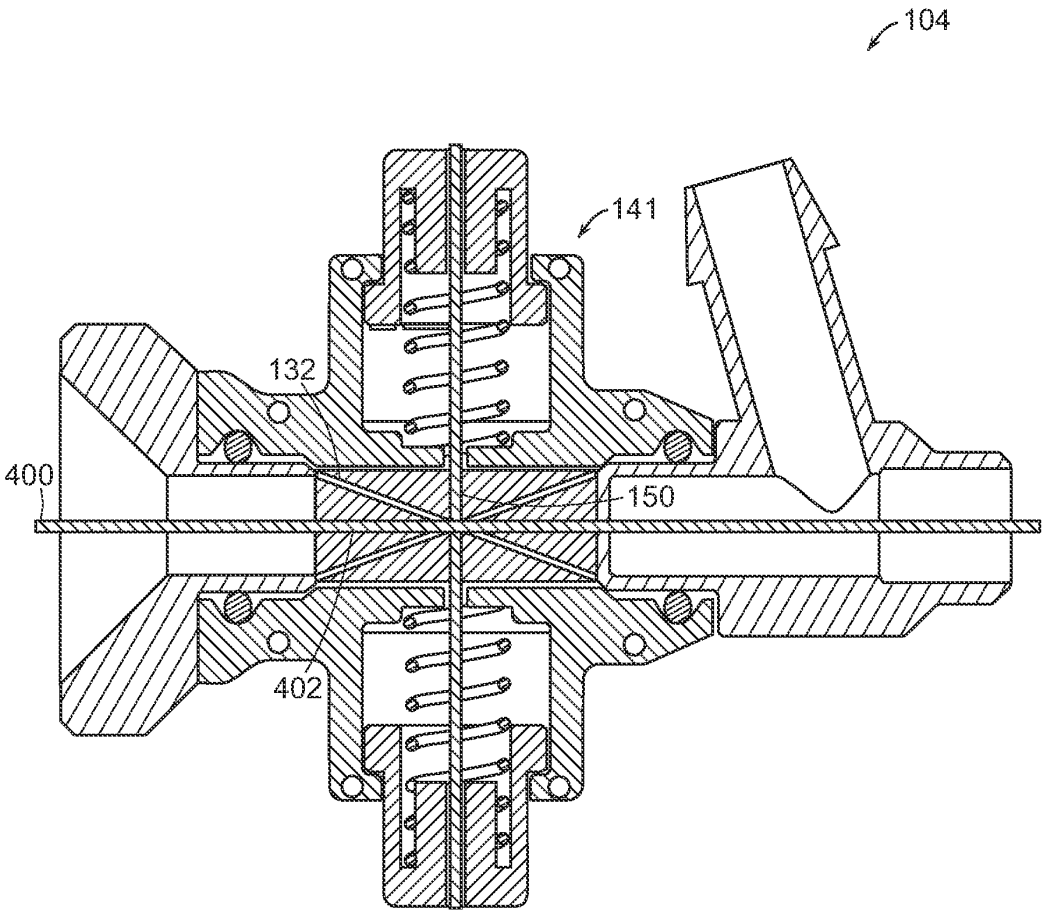


FIG. 4

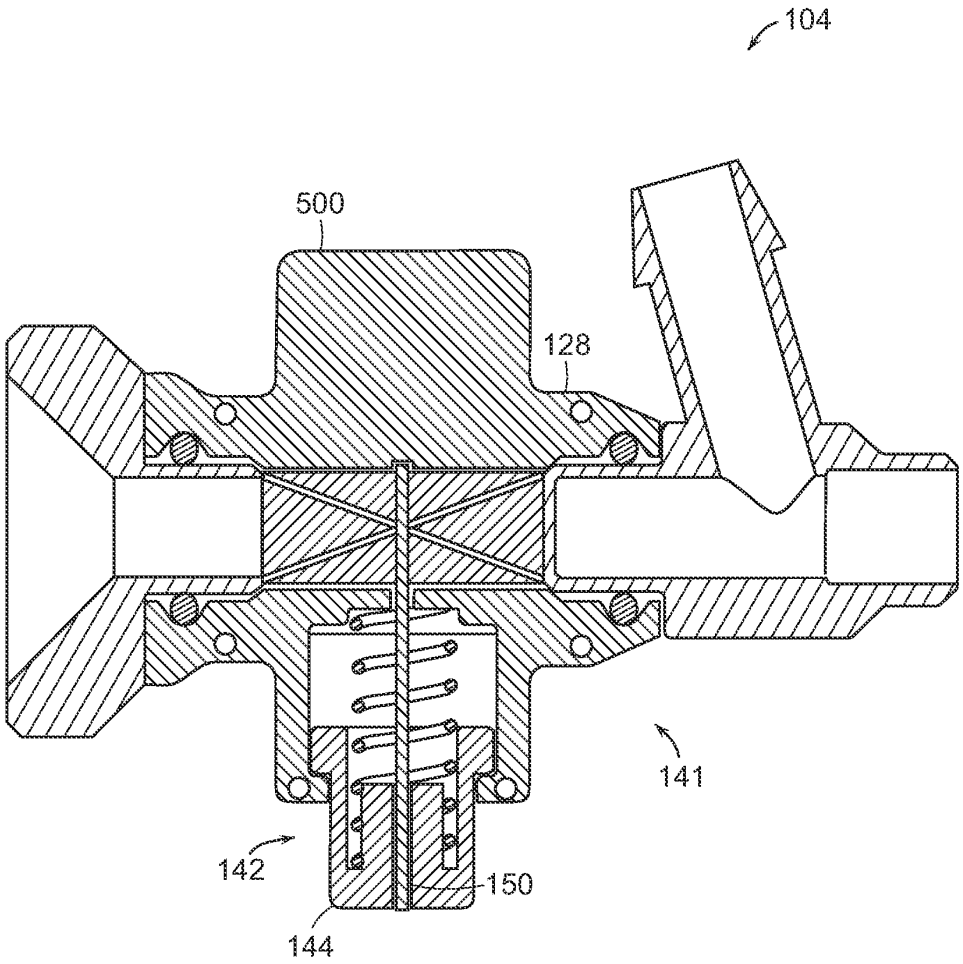


FIG. 5

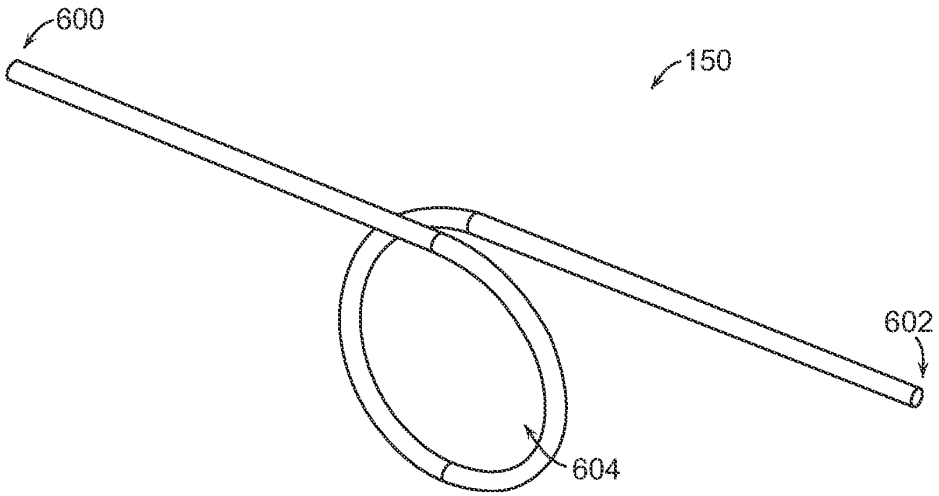


FIG. 6

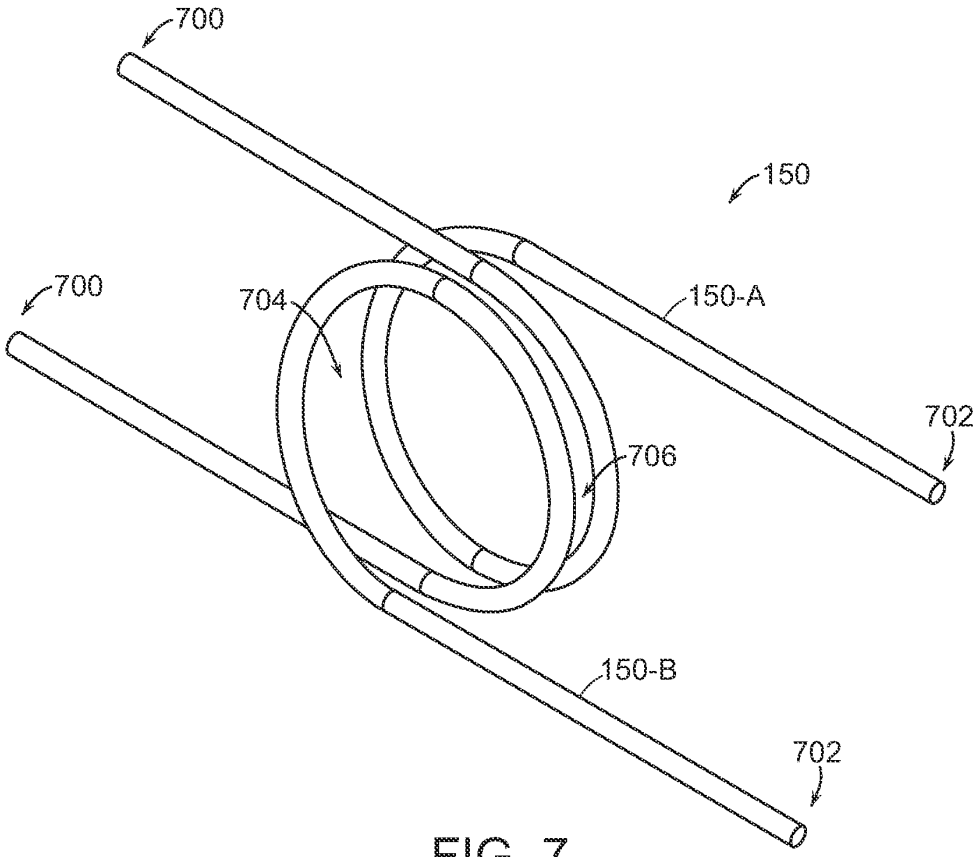


FIG. 7

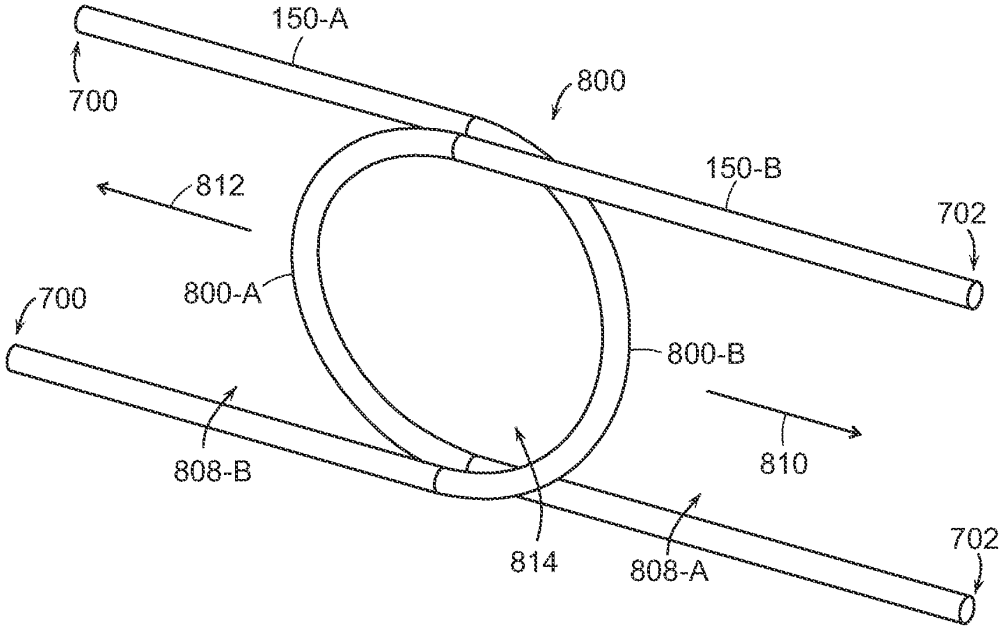

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FIG. 8

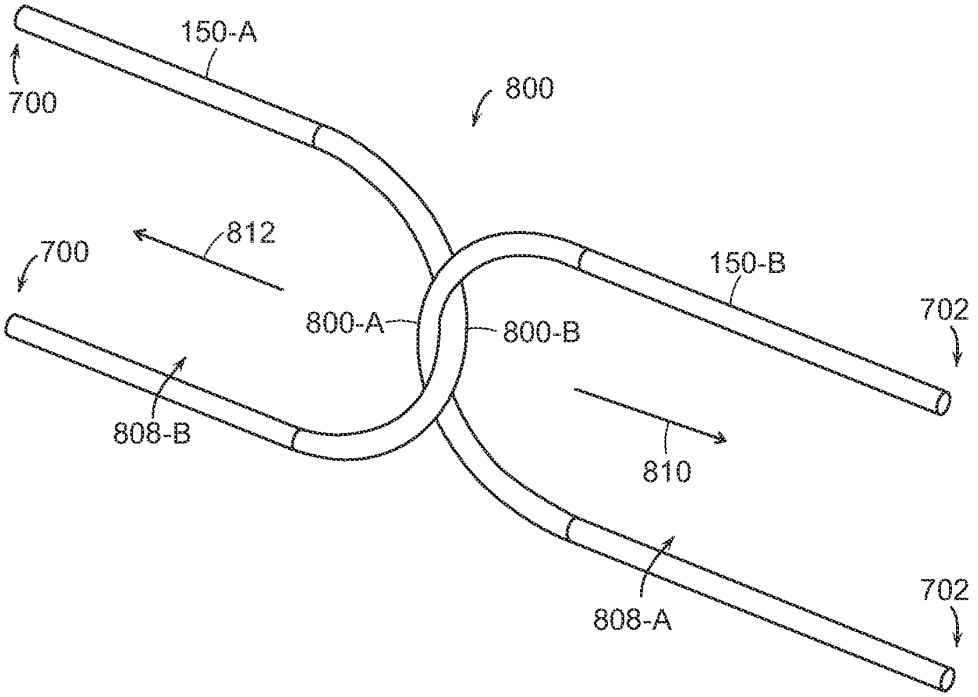

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FIG. 9

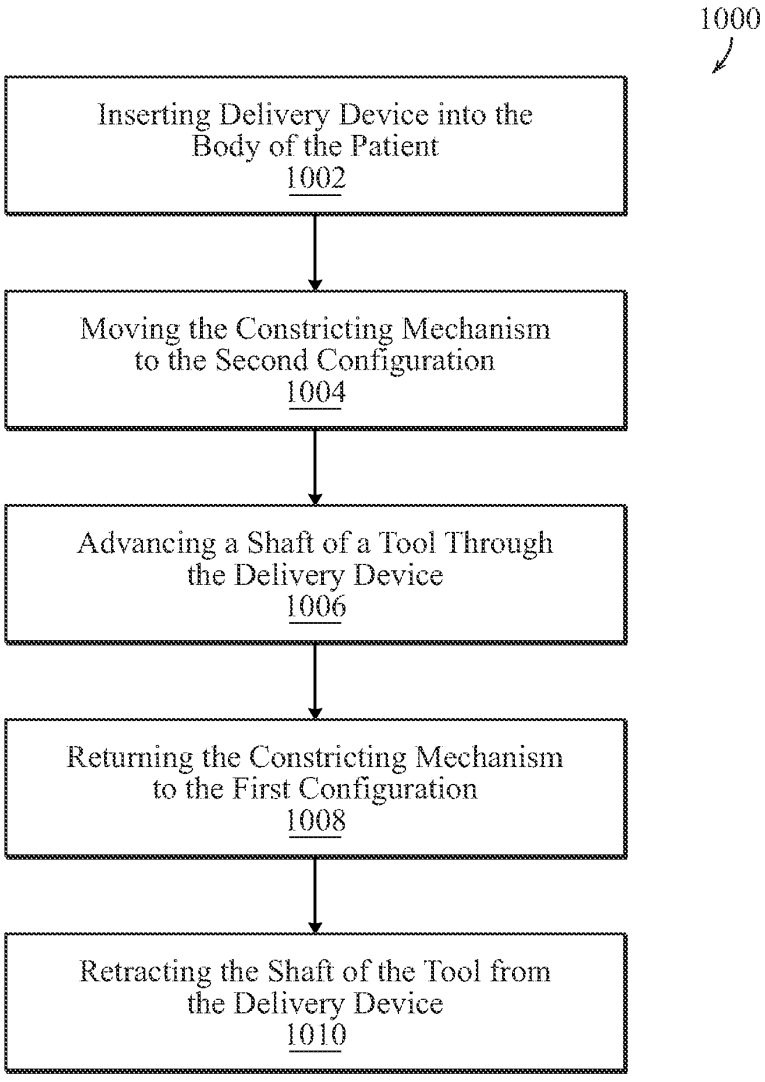

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Inserting Delivery Device into the Body of the Patient
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Moving the Constricting Mechanism to the Second Configuration
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Advancing a Shaft of a Tool Through the Delivery Device
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Returning the Constricting Mechanism to the First Configuration
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Retracting the Shaft of the Tool from the Delivery Device
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FIG. 10

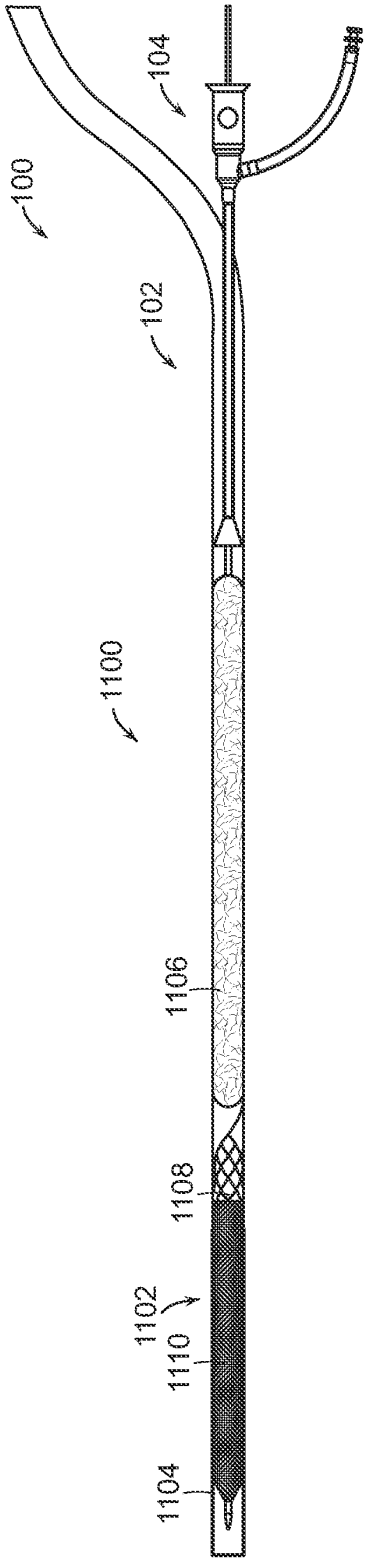


FIG. 11

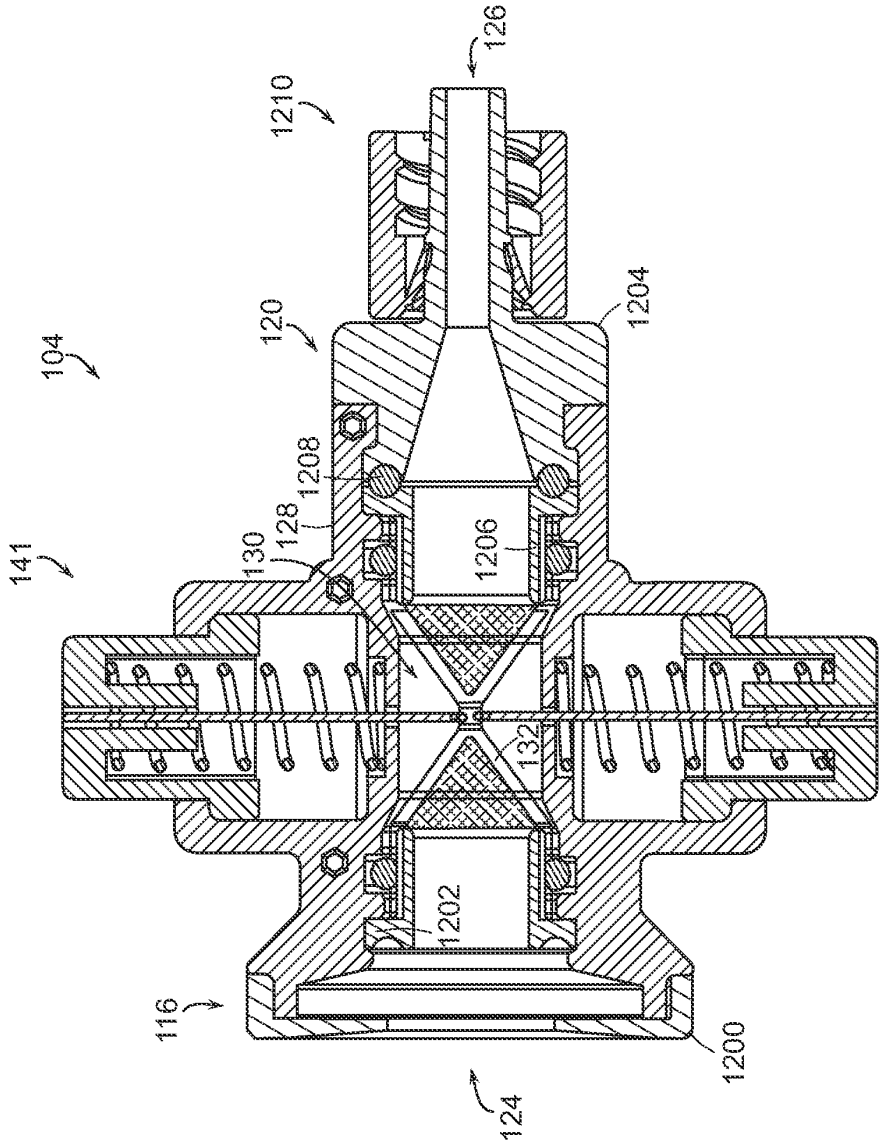

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FIG. 12

HEMOSTASIS VALVES AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 17/705,189, filed on Mar. 25, 2022, entitled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. patent application Ser. No. 17/226,318, filed on Apr. 9, 2021, entitled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. patent application Ser. No. 16/117,519, filed on Aug. 30, 2018, now issued as U.S. Pat. No. 11,000,682, and entitled "HEMOSTASIS VALVES AND METHODS OF USE," which claims the benefit of U.S. Provisional Patent Application No. 62/554,931, filed on Sep. 6, 2017, and entitled "HEMOSTASIS VALVES AND METHODS OF USE," each of which is herein incorporated by reference in its entirety.

BACKGROUND

During a surgical procedure, a portion of a patient's body (e.g., vasculature) is accessed to allow for performance of a desired intervention or treatment. During such surgical procedures, it is desired to minimize patient blood loss, prevent delivery of air into the vasculature, and to maintain the sterility of the accessed portions or sites of the patient's body so as to prevent issues such as infection. Further, the desire for improved patient outcomes has led to the development of hemostasis valves that facilitate minimally invasive surgery.

In minimally invasive surgery, small incisions are created through a blood vessel which one or several catheters are inserted. Each of these one or several catheters can define a lumen extending longitudinally through that catheter. These catheters are moved to a position proximate to tissue, nerves, or other body structures targeted by the surgery, and then tools for performing the procedure are inserted through the lumens of some or all of these catheters.

To minimize blood loss, prevent delivery of air into the vasculature, and to facilitate maintenance of sterility within the patient's body (e.g., blood vessel), these catheters are equipped with hemostasis valves. These valves seal or selectably seal the lumens of the catheters. In many instances, these valves can seal the lumen of the catheter when a tool extends through the catheter, and specifically through the valve. Additionally the valves can seal the lumen when a tool is removed or does not extend through the catheter.

While such traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use. The drawbacks of such valve designs may in turn increase the complexity of any surgery performed therewith and/or reduce patient safety (e.g., bleeding, infection, and/or other detrimental complications). Accordingly, new and improved hemostasis valves and methods of use are desired.

SUMMARY

The following relates to valves, medical systems incorporating valves, and methods of using the same. The valve can include a tubular member that can be constricted, collapsed, and/or sealed by one or several tensioning mechanisms. The tensioning mechanism can include at least one filament that extends around at least a portion of the tubular member. The filament can interact with the tubular member to constrict, collapse, and/or seal the tubular member via manipulation of the tensioning mechanism(s). A tool can be inserted through the valve to gain access to a patient's body and specifically to gain access to a blood vessel. Through the use of the tensioning mechanism and filament to constrict, collapse, and/or seal the tubular member, the valve can seal around a wide range of tool sizes and shapes, as well as multiple tools of differing sizes simultaneously. Additionally, such a valve creates a robust seal that maintains its seal when a vacuum is applied such as occurs during aspiration.

Aspects of the present disclosure relate to a hemostatic valve for sealing a medical device. The hemostatic valve includes an elongate member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the elongate member is pliable. The hemostatic valve can include a reinforcement structure extending along at least a portion of the elongate member, such that the reinforcement structure is coupled to the elongate member. The hemostatic valve includes an active tensioning mechanism coupled to the elongate member. In some embodiments, the tensioning mechanism is moveable between a first configuration in which the central lumen is constricted and sealed and a second configuration in which the central lumen is open. Optionally, the valve may be manually adjusted by the user to intermediate positions between fully open and fully closed. Additionally, an instrument (e.g. catheter) may provide an intermediate position where the valve creates hemostasis without user adjustment.

In some embodiments, the elongate member can be a compliant polymer tube. In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the elongate member. In some embodiments, the reinforcement structure is positioned between the at least one filament and the elongate member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member. In some embodiments, the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member. In some embodiments, the central portion of the compliant polymer tube that is constrained or collapsed by the tensioning mechanism, and at least one filament, is not coupled to the reinforcement structure.

In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments there are two tensioning mechanisms coupled to the at least one filament that operate in opposite directions. In some embodiments the two tensioning mechanisms are attached to the same filament. In some embodiments the two tensioning mechanisms are attached to opposing filaments. In some embodiments, the actuator can be moveable to control movement of the at least one filament from a first position in which the central lumen is constricted and sealed to a second position in which the central lumen is open. In some embodiments, the at least one filament is in the first position when the tensioning mechanism is in the first configuration. In some embodiments, the actuator is biased towards the first position. In some embodiments, the actuator is biased toward the second position. In some embodiments, the actuator can be a manual actuator.

In some embodiments, the at least one filament forms a loop around the elongate member. In some embodiments, the at least one filament forms a bight around a portion of the elongate member. In some embodiments, the at least one filament can include a first filament and a second filament. In some embodiments, each of the first filament and the second filament are coupled to the same actuator. In some embodiments, each of the first filament and the second filament are coupled to different actuators. In some embodiments, the first filament and the second filament are moveable from the first position to the second position. In some embodiments, each of the first filament and the second filament form a loop around the elongate member. In some embodiments, the first filament forms a first bight around a first portion of the elongate member, and the second filament forms a second bight around a second portion of the elongate member. In some embodiments, the first bight extends through the second bight.

In some embodiments, the hemostatic valve can include a shell defining a first aperture and a second aperture. In some embodiments, the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture. In some embodiments, the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve. In some embodiments, the central lumen can comprise a single lumen, and in some embodiments, the central lumen can comprise a plurality of lumens.

One aspect of the present disclosure relates to a delivery system for intravascular access of a blood vessel within a patient's body. The delivery system includes a catheter having a first end, a second end, and a catheter lumen extending therebetween and a hemostatic valve coupled to the first end of the catheter. The hemostatic valve includes a tubular member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the central lumen of the tubular member is fluidly coupled with the catheter lumen. The hemostatic valve includes an active tensioning mechanism coupled to the tubular member, the tensioning mechanism can be moveable between a first configuration in which the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration in which the central lumen is open.

In some embodiments, the hemostatic valve further includes a reinforcement structure extending along at least a portion of the tubular member. In some embodiments, the reinforcement structure is located between the tensioning mechanism and the tubular member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member. In some embodiments, the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member. In some embodiments, the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments, moving the tensioning mechanism from the first configuration to the second configuration can include moving the actuator and the thereto coupled at least one filament from a first position to a second position. In some embodiments, the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

In some embodiments, the actuator can be a manual actuator. In some embodiments, the actuator can include a pair of opposing and depressable buttons, which buttons can be biased towards an undepressed position. In some embodiments, the central lumen is sealed when the buttons are in the undepressed position. In some embodiments, the filament can be a monofilament. In some embodiments, the filament can be at least one of: a polymer filament; or a metallic filament. In some embodiments, the catheter can include a thrombus extraction device.

One aspect of the present disclosure relates to a method of sealing a delivery device accessing a blood vessel of a patient. The method includes inserting the delivery device including a catheter and a hemostatic valve into the blood vessel of the patient. In some embodiments, the catheter can have a first end, a second end, and a catheter lumen extending therethrough. In some embodiments, the hemostatic valve can be coupled to the first end and can have a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member. In some embodiments, the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel. The method can include moving the tensioning mechanism of the hemostatic valve to a second configuration. In some embodiments, the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration. The method can include advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member. The method can include returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

In some embodiments, the method includes retracting the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the hemostatic valve can include a reinforcement structure located between the at least one filament and the tubular member.

In some embodiments, the at least one filament forms a loop around the elongate member, and moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop. In some embodiments, the filament forms at least one bight around a portion of the

elongate member. In some embodiments, the filament can include a first filament and a second filament. In some embodiments, the at least one bight can include a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament. In some embodiments, the first and second bights overlap to encircle a portion of the tubular member within a constricting area.

In some embodiments, moving the tensioning mechanism from the second configuration to the first configuration can include moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member. In some embodiments, the tensioning mechanism can include an actuator. In some embodiments, moving the tensioning mechanism to the second configuration can include manipulating the actuator. In some embodiments, the method includes applying a vacuum to the delivery device and/or delivery system to aspirate material through the catheter. In some embodiments, the central lumen remains sealed during the aspiration. In some embodiments, the tool can include a thrombus extraction device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of one embodiment of a delivery device.

FIG. **2** is a side-section view of one embodiment of a hemostasis valve in a first configuration.

FIG. **3** is a side-section view of one embodiment of the valve in a second configuration.

FIG. **4** is a side-section view of one embodiment of the valve in the first configuration and with a tool extending through the valve.

FIG. **5** is a side-section view of one embodiment of a single-button hemostasis valve in a first configuration.

FIG. **6** is a perspective view of a filament of a valve forming a loop.

FIG. **7** is a perspective view of two filaments of a valve, each of the filaments forming a loop.

FIG. **8** is a perspective view of two overlapping and interlocked bights in an open configuration.

FIG. **9** is a perspective view of two overlapping and interlocked bights in a closed configuration.

FIG. **10** is a flowchart illustrating one embodiment of a method for sealing a valve and/or catheter.

FIG. **11** is a side view of one embodiment of a thrombectomy system including the delivery device.

FIG. **12** is a side-section view of another embodiment of a hemostasis valve having two-piece caps.

DETAILED DESCRIPTION

The present disclosure relates to a valve that can be used a hemostasis valve. This valve, also referred to herein as a garrote valve can seal with or without a tool extending through the valve. The garrote valve provides convenient, single-handed operation for a wide range of medical devices including catheters, wires, embolectomy systems, or the like. This single-handed operation of the garrote valve allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure. Combined with single-handed operation, the garrote valve provides robust sealing either with or without a tool extending through the valve. This robust sealing minimizes leakage in applications with a pressure differential on different sides of the valve. This pressure differential can arise, for example, during the application of vacuum aspiration in a procedure. Even under such conditions, as well as under other conditions, the garrote valve maintains seal integrity and prevents leakage in one or both directions.

The garrote valve includes a tubular member. The tubular member is a flexible member that defines a central lumen, which can, in some embodiments, define a single lumen, and in some embodiments, defines a plurality of lumens. In some embodiments, each of the plurality of lumens can comprise the same size and shape, and in some embodiments, some or all of the plurality of lumens can comprise different sizes and shapes. In some embodiments, for example, the plurality of lumens can comprise a lumen sized and/or shaped to receive a guide wire and a lumen sized and/or shaped to receive a tool. The tubular member extends at least partially through a constricting mechanism. The constricting mechanism can be moved from a first configuration to a second configuration, and the constricting mechanism can collapse and/or seal the central lumen of the tubular member when the constricting mechanism is in the first configuration. The constricting mechanism creates the above-discussed robust seal of the tubular member and thus of the valve.

With reference now to FIG. **1**, a perspective view of one embodiment of a delivery system **100**, also referred to herein as a delivery device **100**, is shown. The delivery system **100** can include a catheter **102** and a garrote valve **104**, also referred to herein as valve **104**. The catheter **102** can comprise a shaft **106**, also referred to herein as an elongate sheath **106**, having a proximal end **108**, also referred to herein as a first end **108**, that can connect to the valve **104** and a distal end **110**, also referred to herein as a second end **110**. The shaft **106** can define a catheter lumen **112** extending from the proximal end **108** of the shaft **106** to the distal end **110** of the shaft **106**. The catheter **102** and specifically the shaft **106** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the catheter **102** can be flexible and/or can be made from a biocompatible material. The elongate sheath **106** can have an outer diameter of at least 4 French, at least 6 French, at least 8 French, at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 4 French and 30 French, between 8 French and 24 French, between 12 French and 20 French, and/or any other or intermediate size.

The valve **104** can include an outer shell **114**. The outer shell **114** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the outer shell **114** can be made from one or several polymers or composites. The outer shell **114** can include features that allow interaction with and/or control of the valve **104** to move the valve **104** between the first configuration and the second configuration.

The outer shell **114** can include a proximal cap **116** located at a proximal end **118** of the outer shell **114** and a distal cap **120** located at a distal end **122** of the shell **114**. The proximal cap **116** can include and/or house a proximal aperture **124**, also referred to herein as a proximal channel **124**, a first channel **124**, or a first aperture **124**, that extends through the proximal cap **116**, and the distal cap **120** can include and/or house a distal aperture **126**, also referred to herein as a distal channel **126**, a second channel **126**, or second aperture **126**, that extends through the distal cap **120**. As seen in FIG. **1**, the distal cap **120** connects to the shaft **106** of the catheter **102** at the distal end **122** of the valve **104**.

The proximal cap **116** and the distal cap **120** are connected via a housing **128**. The housing **128** can be a one-piece housing **128** or a multi-piece housing **128**. In the embodiment depicted in FIG. **1**, the housing comprises a two-piece housing **128**. The housing **128** can be configured to receive and couple with each of the proximal cap **116** and the distal cap **120**, and as seen in FIG. **1**, the housing **128** is coupled with each of the proximal cap **116** and the distal cap **120** to secure the relative position of the proximal cap **116** and the distal cap **120** with respect to each other.

The housing **128** can define an interior channel **130** through which an elongate member **132**, also referred to herein as a tubular member **132**, a septum **132**, or a tubular septum **132**, can extend and connect the proximal cap **116** and the distal cap **120**. The elongate member **132** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the elongate member **132** can comprise a compliant tubular structure that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the elongate member **132** can facilitate the collapse, and specifically the uniform collapse of the elongate member **132** and the sealing of the elongate member **132**. In some embodiments, the elongate member **132** is an elastic, resilient material that may comprise a polymer including either a natural or synthetic polymer. In some embodiments, the elongate member can comprise an elastic, resilient material that may comprise silicone, urethane, ethylene-vinyl acetate, natural or synthetic rubber or other elastomers known in the art. In some embodiments, the elongate member **132** can comprise a silicone tube.

The elongate member **132** can comprise a proximal end **134**, also referred to herein as a first end **134**, that can couple to the proximal cap **116**, and a distal end **136**, also referred to herein as a second end **136**, that can couple to the distal cap **120**. The elongate member **132** can define a central lumen **138** that can extend from the first end **134** to the second end **136** of the elongate member **132**. The elongate member **132** can be coupled to the proximal cap **116** such that the central lumen **138** is fluidly coupled with the proximal aperture **124** of the proximal cap **116**, and the elongate member **132** can be coupled to the distal cap **120** such that the central lumen **138**, as seen in FIG. **2** and in FIG. **3**, is fluidly coupled with the distal aperture **126** of the distal cap **120**.

The central lumen **138** of the elongate member **132** can be defined by a wall of the elongate member **132** that can have a thickness that is uniform along the length of the elongate member **132** between the first end **134** and the second end **136**, or that is non-uniform along the length of the elongate member **132** between the first end **134** and the second end **136**. In some embodiments, the wall can have a thickness that is approximately between 0.005 inches and 0.05 inches, and/or approximately between 0.010 inches and 0.030 inches. As used anywhere herein, "approximately" refers to a range of +/−10% of the value and/or range of values for which "approximately" is used.

In some embodiments, the elongate member **132** can be cylindrically shaped, and specifically can be circular-cylindrically shaped. In some embodiments, the elongate member **132** can be dog-bone shaped to facilitate, for example, connection to each of the proximal cap **116** and the distal cap **120**. In some embodiments, the elongate member **132** can include one or several outward-extending protuberances that engage with all or portions of a constricting mechanism **141**, also referred to herein as a tensioning mechanism **141**, of the valve **104** to secure a position of all or portions of the constricting mechanism **141** with respect to the elongate member **132**. In some embodiments, the constricting mechanism **141** can be self-adjusting to seal around tools of different sizes extending through the valve **104**.

The constricting mechanism **141** can, in some embodiments, collapse and seal the elongate member **132** via compression and/or constriction, and specifically via constriction with at least one filament **150**. The constricting mechanism **141** can comprise: an actuator **142** which can be a manual actuator such as one or several buttons **144**; and the at least one filament **150** that can extend at least partially around the elongate member **132**. In some embodiments, the use of the constricting mechanism **141** can facilitate sealing of the valve around tools or instruments of a wide range of sizes and/or diameters, and particularly around tools or instruments that fit through the elongate member **132**.

The housing **128** can further include one or several retention features **140**. The one or several retention features **140** of the housing can engage with and retain all or portions of the constricting mechanism **141** of the valve **104**. In some embodiments, the one or several retention features **140** of the housing **128** can retain the actuator **142** and/or can couple the actuator **142** to the housing **128**. The actuator **142** can comprise any desired type of actuator including, for example, a manual actuator and/or an automated actuator such as, for example, an electromechanical actuator including a solenoid-based actuator. In some embodiments, the actuator can comprise one or several buttons **144**, and specifically, as depicted in FIG. **1**, the actuator **142** can comprise a first button **144**-A and a second button **144**-B. Alternatively, and as depicted in FIG. **5**, the actuator **142** can comprise a single button **144**. In such an embodiment, the filament **150** can be coupled to the single button **144** and to a portion of the housing **128** such as, for example, to grip portion **500** of the housing **128** such that the movement of the single button **144** causes the sealing and/or opening of the elongate member **132** and of the valve **104**.

The actuator **142** can be biased towards a configuration such as, for example, biased towards the first configuration or biased towards the second configuration. As depicted in FIG. **2**, which shows the constricting mechanism **141** in the first configuration, the actuator **142** can be biased towards the first configuration wherein the elongate member **132** is collapsed and/or sealed by a bias feature **146**. In this first configuration, the buttons **144** can be in a first position, also referred to herein as an undepressed position. This bias feature **146** can, as shown in FIG. **2**, include a first spring **148**-A configured to bias the first button **144**-A towards the first position corresponding to the first configuration of the constricting mechanism **141**, and a second spring **148**-B configured to bias the second button **144**-B towards a first position corresponding to the first configuration of the constricting mechanism **141**. One or both of the first spring **148**-A and the second spring **148**-B can comprise a tension spring, compression spring, a torsion spring, a coil spring, or any other desired type of spring.

In some embodiments, one or both of the first spring **148**-A and the second spring **148**-B can generate sufficient force so as to allow actuation of the actuator **142** with a single hand and so as to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. In some embodiments, one or both of the first spring **148**-A and the second spring **148**-B can generate a force of: at least 0.1 pounds, at least 0.2 pounds, at least 0.3 pounds, at least 0.4 pounds, at least 0.5 pounds, at least 0.6 pounds, at least 0.7 pounds, at least 0.8 pounds, at least 0.9 pounds, at least 1 pound, at least 1.5 pounds, at least 2

pounds, at least 3 pounds, at least 5 pounds, and/or at least 10 pounds and in some embodiments one or both of the first spring **148**-A and the second spring **148**-B can generate a force approximately between: 0.1 and 10 pounds, 0.1 and 5 pounds, 0.1 and 1.5 pounds, 0.2 and 1 pounds, and/or 0.4 and 0.8 pounds.

The constricting mechanism **141** can include at least one filament **150** that extends at least partially around the elongate member **132**. In some embodiments, the at least one filament **150** can circumferentially constrict the elongate member **132** to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. The filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal. In some embodiments, the filament **150** can be nylon, stainless steel, nitinol, silicone, or the like. In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament. In some embodiments, the filament **150** can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

The filament **150** can be coupled to the actuator **142** such that the filament **150** selectively constricts, collapses, and/or seals the elongate member **132**, and specifically the central lumen **138** of the elongate member **132** based on the movement and/or position of the actuator **142**. In some embodiments, the filament **150** can be connected to one or both of the buttons **144**-A, **144**-B such that the filament **150** collapses, constricts, and/or seals the elongate member **132** and specifically the central lumen **138** of the elongate member **132** when the buttons **144**-A, **144**-B are in the first position, and the filament **150** can be connected to one or both of the buttons **144**-A, **144**-B such that the elongate member **132** and specifically the central lumen **138** of the elongate member **132** is open and uncollapsed when the buttons **144**-A, **144**-B are in the second position. In some embodiments in which the actuator **142** comprises a single button **144**, as depicted in FIG. **5**, the filament **150** can be connected to the button **144** and to the housing **128** such that the filament **150** is tightened when the button **144** moves to the first position.

In some embodiments, the at least one filament **150** can extend along an axis **152** that can be perpendicular to a central axis **154** of the elongate member **132** and/or of the apertures **124**, **126**. In some embodiments, the axis **152** of the at least one filament **150** can intersect and be perpendicular to the central axis **154** of the elongate member **132** and/or of the apertures **124**, **126**. In some embodiments, the actuator **142**, and specifically the buttons **144**-A, **144**-B can move along this axis **152** when moved from the first position to the second position.

In FIG. **3**, an embodiment of the valve **104** with the constricting mechanism **141** in the second configuration is shown. As specifically shown, both of the first and second buttons **144**-A, **144**-B are in the second position, depressed into the retention features **140** of the housing **128**. In this second position, the filament **150** is loosened, thereby allowing the expansion of the elongate member **132** and the unsealing of the central lumen **138** of the elongate member **132**.

As further seen in FIG. **3**, the proximal cap **116** has a proximal end **300** and a distal end **302**. The proximal cap **116** can include a funnel portion **301** of the proximal aperture **124**, which funnel portion **301** can facilitate insertion of a tool into the proximal aperture **124**. The distal end **302** of the proximal cap **116** can partially extend into the interior channel **130** of the housing **128**. The proximal cap **116** can include a mating feature **304** that can mate with the proximal end **134** of the elongate member **132**. In some embodiments, the proximal end **134** of the elongate member **132** can fit over the mating feature **304** of the proximal cap **116**. The proximal end **134** of the elongate member **132** can be compressed between the mating feature **304** of the elongate member **132** and a portion of the interior channel **130** of the housing **128** into which the mating feature **304** is inserted to thereby secure the proximal end **134** of the elongate member **132** on the mating feature **304**. In some embodiments, the proximal end **134** of the elongate member **132** can be further secured on the mating feature **304** by a proximal O-ring **306** that can be compressed between the housing **128** and the mating feature **304** of the proximal cap **116** to sealingly couple the elongate member **132** to the proximal cap **116**.

The distal cap **120** has a proximal end **308** and a distal end **310**. The distal cap can include a mating feature **312** located on the proximal end **308** of the distal cap **120**, which mating feature **312** can mate with the distal end **136** of the elongate member **132**. In some embodiments, the distal end **136** of the elongate member **132** can fit over the mating feature **312** of the distal cap **123**. The distal end **136** of the elongate member **132** can be compressed between the mating feature **312** of the elongate member **132** and a portion of the interior channel **130** of the housing **128** into which the mating feature **312** is inserted to thereby secure the distal end **136** of the elongate member **132** on the mating feature **312**. In some embodiments, the distal end **136** of the elongate member **132** can be further secured on the mating feature **312** by a distal O-ring **314** that can be compressed between the housing **128** and the mating feature **312** of the proximal cap **116** to sealingly couple the elongate member **132** to the distal cap **120**.

The distal cap **120** can, in some embodiments, further include a side port barb **314** that can extend laterally away from the distal cap **120** and specifically away from the distal aperture **126** of the distal cap **120**. The side port barb **314** can define a side port channel **316** that can extend through the side port barb **314** and fluidly connect to the distal aperture **126**. In some embodiments, the side port barb **314** can include a securement feature **318** such as a barb that can secure coupling of a hose or tube to the side port barb **314**.

In some embodiments, the side barb **314** can be used to apply a vacuum to the portions of the delivery device **100**, and particularly to portions of the delivery device **100** that are distal of the axis **152** along which the elongate member **132** seals. This vacuum can be applied to aspirate a material through the delivery device **100**, and specifically through the catheter **102** of the delivery device. This aspirated material can be a biological material including, for example, bodily fluids, multi-phase bodily materials that can include, for example, a fluidic portion and at least one solid portion, or the like.

In some embodiments, due to the narrowing shape of the elongate member **132** when the constricting mechanism **141** is in the first configuration, a vacuum applied to the portions of the delivery device **100** distal to the axis **152** draws the elongate member **132** towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve **104**. This attribute of the valve **104** can provide benefits over other valve designs in which a vacuum can compromise the seal of the valve, and thus the ability to draw a vacuum and aspirate can be limited.

In some embodiments, the valve **104** can further include a reinforcement structure **320** that can extend along all or portions of the elongate member **132**. The reinforcement structure **320** can facilitate the uniform collapse of the elongate member **132**, can prevent the at least one filament **150** from cutting through and/or tearing the elongate member **132**, and can assist in guiding one or several tools through the elongate member **132**. The reinforcement structure **320** can be tubular, can extend along and around the elongate member **132**, and can be positioned so as to be between the elongate member **132** and the at least one filament **150**.

The reinforcement structure **320** can include a proximal end **322** and a distal end **324**. In some embodiments, the reinforcement structure **320** extends along and around the elongate member **132**, and is positioned such that the proximal end **322** of the reinforcement structure **320** is proximate to the first end **134** of the elongate member **132** and the distal end **324** of the reinforcement structure **320** is proximate to the second end **136** of the elongate member **132**.

The reinforcement structure **320** can be coupled to the elongate member **132**. In some embodiments, the reinforcement structure **320** is coupled to the elongate member **132** along the length of the reinforcement structure **320**, and in some embodiments, the reinforcement structure **320** is coupled to the elongate member **132** and distinct positions along the length of the elongate member **132** and/or the reinforcement structure **320**. In one embodiment, for example, the reinforcement structure **320** can be coupled to the elongate member **132** at one or both of the proximal end **322** of the reinforcement structure **320** and the distal end **324** of the reinforcement structure **320** and/or at one or both of the first end **134** and the second end **136** of the elongate member **132**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via one or several other components of the valve **104**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via the compression of the reinforcement structure **320** and the elongate member **132** between the housing **128** and one or both of the proximal **116** and the distal **120**.

In some embodiments, the reinforcement structure **320** can be adhered to the elongate member **132** via, for example, an adhesive such as silicone adhesive. In some embodiments, the adhesive can be circumferentially applied to the reinforcement structure **320** and/or the elongate member **132** in an adhesive ring that can, for example, a have a length approximately between: 0.010 inches and 0.5 inches; 0.02 and 0.4 inches; 0.050 inches and 0.0250 inches, or any other or intermediate range.

In one embodiment, each of the proximal end **322** and the distal end **324** of the reinforcement structure **320** can be adhered via an adhesive to the elongate member **132**. In such an embodiment, the reinforcement structure **320** may be uncoupled to the elongate member **132** at positions other than the coupling at one or both of the proximal end **322** and the distal end **324** of the reinforcement structure **320**, and thus the reinforcement structure **320** is uncoupled to the elongate member **132** at a position between the first end **134** and the second end **136** of the elongate member **134** and/or between the proximal end **322** and the distal end **324** of the reinforcement structure **320**.

The lack of coupling of the reinforcement structure **320** to the elongate member **132** can facilitate and improve the collapse of the elongate member **132** around a tool **400**, also referred to herein as instrument **400** or device **400**, inserted through the valve **104** as shown in FIG. **4**. The tool **400** can be any device inserted through the valve **104** including, for example, one or several additional catheters, lines, wires, grippers, punches, cutters, or the like. As seen in FIG. **4**, the tool **400** is inserted through the valve **104** and specifically through the elongate member **132** of the valve. As shown, the constricting mechanism **141** is in the first configuration and the elongate member **132** and the central lumen **138** of the elongate member **132** is collapsed around the tool **400**, and specifically around a shaft **402** of the tool **400** to thereby seal the valve **104** around the tool **400** and specifically around the shaft **402** of the tool **400**. The constricting mechanism **141** can seal around tools **400** that fit through the elongate member **132**, regardless of the size of the tool **400**. Thus, the valve can be used with a wide variety of tools.

The reinforcement structure **320** can comprise a variety of designs, shapes, sizes, and materials. In some embodiments, the reinforcement structure **320** can be sized and shaped so as to receive elongate member **132** and to be positioned between the elongate member **132** and the at least one filament **150**. In some embodiments, the reinforcement structure **320** can be made from a material sufficiently strong to prevent the cutting of the at least one filament **150** through the elongate member **132**.

In some embodiments, the reinforcement structure can comprise a coil or a mesh sheath. The mesh sheath can, in some embodiments, comprise a braided mesh. The braided mesh can be made from any desired number of wires in any desired configuration. In some embodiments, the braided mesh can comprise a 4 wire braided mesh, an 8 wire braided mesh, a 12 wire braided mesh, a 16 wire braided mesh, a 20 wire braided mesh, a 24 wire braided mesh, a 32 wire braided mesh, a 48 wire braided mesh, a 64 wire braided mesh, a 72 wire braided mesh, an 80 wire braided mesh, a 96 wire braided mesh, or any other or intermediate braided mesh. In some embodiments, the braided mesh can comprise: a 1×1 configuration. In some embodiments, the wire in the braided mesh can be any desired material including, for example, a metal wire such as a nitinol wire or a stainless steel wire, a polymer wire, or a natural wire. In one embodiment, the braided mesh can comprise a 48 wire mesh in a 1×1 configuration made with a nitinol wire having a diameter of 0.003 inches.

With reference now to FIGS. **6** through **9**, different embodiments and/or configurations of the filament **150** are shown. The filament **150** can comprise a single filament **150** having a first end **600** and a second end **602** as shown in FIG. **6**. The filament **150**, and specifically which first and second ends **600**, **602** can be coupled to the actuator **142** to move the filament **150** between the first and second configurations or positions and/or from the first configuration or position to the second configuration or position. In some embodiments, both of the first end **600** and the second end **602** can be coupled to a single button **144**, in some embodiments, each of the first end **600** and the second end **602** can be coupled to different buttons **144**, and in some embodiments, one of the first end **600** and the second end **602** can be coupled to a button **144** and the other of the first end **600** and the second end **602** can be coupled to the housing **128** or other portion of the valve **104**.

In some embodiments, the filament **150** can comprise multiple filaments, and specifically, as shown in FIGS. **7** through **9**, the filament **150** can comprise a first filament **150**-A and a second filament **150**-B. In embodiments in which the filament **150** comprises multiple filaments, each of the multiple filaments can have a first end **700** and a second end **702**. The first and second filaments **150**-A,

150-B can be coupled to the actuator 142. In such embodiments, the first and second ends 700, 702 can be coupled to the actuator 142 to move the filaments 150-A, 150-B between the first and second configurations and/or from the first configuration to the second configuration. In some embodiments, both of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to a single button 144, in some embodiments, each of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to different buttons 144, and in some embodiments, one of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to one button 144 and the other of the first end 700 and the second end 702 of those one or more filaments 150 can be coupled to the housing 128 or other portion of the valve 104.

The filament 150 can be arranged in a variety of configurations. In some embodiments, the filament 150 can be configured to form a single loop 604 that can extend around the elongate member 132 and/or through which the elongate member 132 can be received as shown in FIG. 6, and in some embodiments, the filament 150 can be configured to form multiple loops, and specifically a first loop 704 and a second loop 706 as shown in FIG. 7. The first and second loops 704, 706 can each receive the elongate member 132. In some embodiments, a diameter or size of the loop 604, or of the loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.

In some embodiments, the filament 150 can be configured to form a bight 800, which bight 800 can be a single bight or multiple bights. As used herein, a "bight" refers to a U-shaped section between the two ends of the filament 150. As depicted in FIGS. 8 and 9, the bight 800 can comprise multiple bights, and specifically a first bight 800-A and a second bight 800-B. In some embodiments, the first bight 800-A can extend through the second bight 800-B such that the first and second bights 800-A, 800-B interlock, whereas in other embodiments, the first and second bights 800-A, 800-B can be non-interlocking. Similarly, in embodiments containing the filament 150 having multiple loops, one or several of the multiple loops can be interlocking.

In some embodiments, the bight 800, and specifically one or both of the first bight 800-A and the second bight 800-B can be formed around a portion of the elongate member 132 and/or can extend around a portion of the elongate member 132. Each bight 800 can define a partially enclosed receiving area 808 wherein the elongate member 132 can be received. Thus, the first bight 800-A can define a first receiving area 808-A and the second bight 800-B can define a second receiving area 808-B.

As seen in FIGS. 8 and 9, multiple bights, and specifically the first and the second bights 800-A, 800-B can be positioned and oriented such that the first bight 800-A has a first orientation or first direction as indicated by arrow 810, and the second bight has a second orientation or second direction as indicated by the arrow 812. In some embodiments, the first orientation is different from the second orientation such that the first and second receiving areas 808-A, 808-B overlap and define an encircled area 814, also referred to herein as a constricting area 814. The elongate member 132 can be received within the encircled area 814. In embodiments in which bights 800-A, 800-B overlap to define the encircled area 814, the movement of the constricting mechanism 141 to the first configuration can result in and/or include the first bight 800-A moving in the direction indicated by the arrow 810 and/or the second bight 800-B moving in the direction indicated by the arrow 812, which movement of the bights 800-A, 800-B decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area 814.

The filament(s) 150 forming the bights 800 can each apply an arcuate line or narrow longitudinal zone of pressure to the elongate member 132. If the filament(s) are circular in cross-section, the zone of pressure can be very small, and can, in some embodiments, be less than the diameter or thickness of the filament. In some embodiments, the filaments have a diameter or width less than about 2.5 mm, less than about 2 mm, less than about 1.5 mm, less than about 1.25 mm, less than about 1 mm, less than about 0.75 mm, less than about 0.5 mm, and/or less than about 0.25 mm. In some embodiments, the filaments can have a diameter or width of between about 0.01 mm and 2.5 mm, between about 0.05 mm and 2 mm, between about 0.1 mm and 1 mm, and/or between about 0.125 mm and 0.70 mm. In some embodiments, the arcuate line or zone of pressure may form two opposing arcs and in other embodiments, the arcuate line of pressure may be a singular substantially circular line or zone that encircles the elongate member at least once. The longitudinal length of the of the line or zone of pressure may be very short compared to other valves known in the art. In some embodiments, the longitudinal length of the zone of pressure applied to the elongate member 132 by the filament (s) 150 may be less than about 2.0 mm and in some embodiments less than about 0.5 mm. In some embodiments, the filament(s) 150 can have any desired cross-sectional shape including, for example, a circular cross-section, a rectangular cross-section, an oval cross-section, a square cross-section, a polygonal cross-section, a triangular cross-section, or any other desired shape of cross-section.

With reference now to FIG. 10, a flowchart illustrating one embodiment of a process 1000 for sealing a valve 104 and/or catheter 102 accessing a body of a patient is shown. The process 1000 can be performed using the valve 104 and/or the delivery system 100. The process 1000 begins at block 1002, wherein the delivery device 100, and specifically the catheter 102 of the delivery device 100 is inserted into the body of the patient. In some embodiments, this can include inserting the catheter 102 into a portion of the circulator system of the patient such as, for example, a blood vessel including an artery or a venous vessel. In some embodiments, the delivery device 100 can be inserted into the body of the patient directly through an aperture or incision in the patient, and in some embodiments, the delivery device 100 can be inserted into the body of the patient via another catheter or device. In some embodiments, the constricting mechanism 141 can be in the first configuration while the delivery device 100 and/or the catheter 102 is inserted into the patient's body.

After the delivery device 100 is inserted into the body of the patient, the process 1000 proceeds to block 1004, wherein the constricting mechanism 141 is moved from the first configuration to the second configuration. As described above, the central lumen 138 of the elongate member 132 is unsealed when the constricting mechanism 141 is in the second configuration. In some embodiments, the moving of the constricting mechanism 141 from the first configuration to the second configuration can include the manipulation of the actuator 142 and/or the control of the actuator 142, and specifically the depressing of the one or several buttons 144 to move the filament 150 from the first position to the second position to allow the expansion and opening of the central lumen 138 of the elongate member 132.

After the constricting mechanism **141** is moved from the first configuration to the second configuration, the process **1000** proceeds to block **1006**, wherein the tool **400**, and specifically the shaft **402** of the tool **400** is advanced through the delivery device **100** and specifically through the valve **104** until a first end of the tool reaches a desired position within the body of the patient. In some embodiments, a portion of the shaft **402** can be positioned within the central lumen **138** of the elongate member **132** after the advancing of the tool **400** through the delivery device **100**. In some embodiments, after the tool **400** is advanced through the delivery device **100**, the desired procedure can be performed with the tool.

After the tool **400** is advanced through the delivery device **100**, or while the tool **400** is being advanced through the delivery device **100**, the process **1000** proceeds to block **1008**, wherein the constricting mechanism **141** is returned to the first configuration. In some embodiments, the returning of the constricting mechanism **141** to the first configuration can include the release of the one or several buttons **144** and/or the control of the actuator **142** to reconfigure the constricting mechanism **141** to the first configuration. In some embodiments, the return of the constricting mechanism **141** to the first configuration can result in the collapse and/or sealing of the elongate member **132** and specifically the central lumen **138** of the elongate member **132** around the tool **400** and specifically around the shaft **402** of the tool **400**. The return of the constricting mechanism **141** to the first configuration, or the movement of the constricting mechanism **141** to the first configuration can include the decreasing of the size and/or diameter of one or several loops formed by the filament **150** and/or the movement of one or several bights **800** such as, for example, the movement of the first bight **800**-A in the first direction indicated by arrow **810** and the movement of the second bight **800**-B in the second direction indicated by arrow **812** to reduce the size of the constricting area **814**. In some embodiments, after the constricting mechanism is returned to the first configuration, the desired procedure can be performed with the tool.

After the constricting mechanism is returned to the first configuration, the process **1000** proceeds to block **1010**, wherein the tool **400**, and specifically the shaft **402** of the tool **400** is retracted from the delivery device **100**, and more specifically from the valve **104**. In some embodiments, the valve **104** can remain sealed during the retracing of the tool **400** and/or the shaft **402** of the tool. In some embodiments, the valve **104** remains sealed during the retracting of the tool **400** and/or the retracting of the shaft **402** of the tool **400** as the constricting mechanism **141** can remain in the first configuration during the retracing of the tool **400** and/or the shaft **402** of the tool **400**.

In some embodiments, the constricting mechanism **141** can be moved to the second configuration to allow the retraction of the tool **400** and/or the shaft **402** of the tool **400** from the valve **104**, and the constricting mechanism **141** can be returned to the first configuration when the tool **400** and/or the shaft **402** of the tool **400** is removed from the valve **104**. In some embodiments, the retraction of the tool **400** and/or shaft **402** of the tool **400** from the valve **104** can be performed with the constricting mechanism **141** left in the first configuration. In some embodiments, the constricting mechanism **141** can be moved to the second configuration, and then returned to the first configuration via the manipulation and/or control of the actuator **142**, which manipulation and/or control of the actuator **142** can include the depressing of the one or several buttons **144** to move the constricting mechanism **141** to the second configuration, and the release of the one or several buttons **144** to return the constricting mechanism **141** to the first configuration. In some embodiments, if the procedure is complete, the delivery device **100** can then be removed from the body of the patient, and any incision created for the procedure can be closed.

With reference now to FIG. **11**, a side view of one embodiment of a thrombectomy system **1100** including the delivery device **100** and a thrombus extraction device **1102** is shown. In some embodiments, the thrombectomy system **1100** can be used to access a blood vessel **1104** to treat and/or extract a thrombus **1106** from the blood vessel **1104**. The thrombus extraction device **1102** can include a self-expanding coring element **206** and expandable cylindrical portion **208**. In some embodiments, and as shown in FIG. **11**, the thrombus extraction device **1102** can be the tool **400** that can extend through the valve **104**, and in some embodiments, the valve **104** can be a part of the thrombus extraction device **1102**. Further details of thrombectomy systems, thrombus extraction devices, and methods of using the same are disclosed in: U.S. application Ser. No. 15/268,296, filed Sep. 16, 2016, and entitled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS"; U.S. application Ser. No. 15/498,320, filed Apr. 26, 2017, and entitled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION"; and U.S. application Ser. No. 15/466,740, filed on Mar. 22, 2017, and entitled "DEVICE AND METHOD FOR TREATING VASCULAR OCCLUSION", the entirety of each of which is hereby incorporated by reference herein.

With reference now to FIG. **12**, a side-section view of another embodiment of the hemostasis valve **104** having two piece caps **116**, **120** is shown. The valve **104** can include a housing **128** defining an interior channel **130** through which the tubular member **132** can extend. The valve **104** can include the proximal cap **116** and the distal cap **120**. In some embodiments, the proximal cap **116** can comprise a two piece cap and can include a proximal exterior member **1200** and a proximal channel member **1202**. In some embodiments, the distal cap **120** can comprise a two-piece cap and can include a distal exterior member **1204** and a distal channel member **1206**. In some embodiments, this coupling between the proximal exterior member **1200** and the proximal channel member **1202** and/or the coupling between the distal exterior member **1204** and the distal channel member **1206** can be a sealed coupling so as to prevent the leakage of material including fluid or gas between the respective ones of the proximal exterior member **1200** and the proximal channel member **1202** and/or the distal exterior member **1204** and the distal channel member **1206**. In some embodiments, this sealing coupling can be achieved and/or maintained via a seal such as an O-ring **1208** that can be positioned between the proximal exterior member **1200** and the proximal channel member **1202** and/or between the distal exterior member **1204** and the distal channel member **1206**.

In some embodiments, the proximal exterior member **1200** can be coupled, and in some embodiments, rotatingly coupled to the proximal channel member **1202** in a manner to allow the rotation of the proximal exterior member **1200** without rotating the proximal channel member **1202**. Similarly, in some embodiments, the distal exterior member **1204** can be rotatingly coupled to the distal channel member **1206** in a manner to allow the rotation of the distal exterior member **1204** without the rotating of the distal channel member **1206**. In some such embodiments, the channel

members **1202**, **1206** can be non-rotatable with respect to the housing **128** and/or the tubular member **132**, and one or both of the exterior members **1200**, **1204** can be rotatable with respect to the housing **128** and/or the tubular member **132**. In such an embodiment, the maintaining of the rotational position of the channel members **1202**, **1206** with respect to the housing **128** and/or the tubular member **132** can prevent the twisting of the tubular member **132** which can result in the sealing of the tubular member **132** regardless of the configuration of the constructing mechanism **141**.

The exterior members **1200**, **1204** can comprise a variety of shapes and sizes and can include a variety of features. In some embodiments, one or both of the exterior members **1200**, **1204** can be coupled to, for example, a shaft similar to the shaft **106** shown in FIG. **1**. In some embodiments, for example, the distal exterior member **1204** can be coupled to a shaft **106**, including, for example, can be non-detachably coupled to the shaft **106**. In some embodiments, one or both of the exterior members can include one or several features configured to facilitate coupling with the valve **104**. These one or several features can include, for example, one or several male or female: connectors; couplers; attachment mechanisms; or the like. In some embodiments, these one or several features can facilitate use of the valve with other existing components, instruments, tools, or the like. In some embodiments, for example, one or both of the exterior members **1200**, **1204** can comprise either a male or female luer fitting, and specifically as shown in FIG. **12**, the distal exterior member **1204** can comprise a male luer fitting **1210**.

Several aspects of the present technology are set forth in the following examples.

1. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:
   - an elongate member having a first end, a second end, and a central lumen extending therebetween, wherein the elongate member is pliable;
   - a reinforcement structure extending along at least a portion of the elongate member, wherein the reinforcement structure is coupled to the elongate member; and
   - an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.

2. The hemostatic valve of example 1, wherein the elongate member comprises a compliant polymer tube.

3. The hemostatic valve of example 1 or 2, wherein the tensioning mechanism comprises at least one filament extending at least partially around the elongate member.

4. The hemostatic valve of example 3, wherein the reinforcement structure is positioned between the at least one filament and the elongate member.

5. The hemostatic valve of example 4, wherein the reinforcement structure comprises a braided mesh.

6. The hemostatic valve of example 4 or 5, wherein the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member.

7. The hemostatic valve of example 6, wherein the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member.

8. The hemostatic valve of any one of examples 3-7, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein the actuator is moveable to control movement of the at least one filament from a first position wherein the central lumen is constricted and sealed to a second position wherein the central lumen is open, wherein the at least one filament is in the first position when the tensioning mechanism is in the first configuration.

9. The hemostatic valve of example 8, wherein the actuator is biased towards the first position.

10. The hemostatic valve of example 8 or 9, wherein the actuator is biased toward the second position.

11. The hemostatic valve of any one of examples 8-10, wherein the actuator comprises a manual actuator.

12. The hemostatic valve of any one of examples 8-11, wherein the at least one filament forms a loop around the elongate member.

13. The hemostatic valve of any one of examples 8-12, wherein the at least one filament forms a bight around a portion of the elongate member.

14. The hemostatic valve of any one of examples 8-13, wherein the at least one filament comprises a first filament and a second filament, wherein each of the first filament and the second filament are coupled to the actuator, and wherein the first filament and the second filament are moveable from the first position to the second position.

15. The hemostatic valve of example 14, wherein each of the first filament and the second filament form a loop around the elongate member.

16. The hemostatic valve of example 14 or 15, wherein the first filament forms a first bight around a first portion of the elongate member, and wherein the second filament forms a second bight around a second portion of the elongate member.

17. The hemostatic valve of example 16, wherein the first bight extends through the second bight.

18. The hemostatic valve of any one of examples 1-17, further comprising a shell defining a first aperture and a second aperture, wherein the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture.

19. The hemostatic valve of any one of examples 1-18, wherein the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve.

20. The hemostatic valve of any one of examples 1-19, wherein the central lumen comprises a single lumen.

21. The hemostatic valve of any one of examples 1-20, wherein the central lumen comprises a plurality of lumens.

22. A delivery system for intravascular access of a blood vessel within a patient's body, the delivery system comprising:

a catheter having a first end, a second end, and a catheter lumen extending therebetween;

a hemostatic valve coupled to the first end of the catheter, the hemostatic valve comprising:
   - a tubular member having a first end, a second end, and a central lumen extending therebetween, wherein the central lumen of the tubular member is fluidly coupled with the catheter lumen; and
   - an active tensioning mechanism coupled to the tubular member, the tensioning mechanism moveable between a first configuration wherein the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration wherein the central lumen is open.

23. The delivery system of example 22, wherein the hemostatic valve further comprises a reinforcement structure extending along at least a portion of the tubular member.

24. The delivery system of example 22 or 23, wherein the reinforcement structure is located between the tensioning mechanism and the tubular member.

25. The delivery system of example 24, wherein the reinforcement structure comprises a braided mesh.

26. The delivery system of example 24 or 25, wherein the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member.

27. The delivery system of example 26, wherein the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member.

28. The delivery system of example 27, wherein the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

29. The delivery system of any one of examples 22-28, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member.

30. The delivery system of example 29, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein moving the tensioning mechanism from the first configuration to the second configuration comprises moving the actuator and the thereto coupled at least one filament from a first position to a second position, wherein the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

31. The delivery system of example 30, wherein the actuator comprises a manual actuator.

32. The delivery system of example 31, wherein the actuator comprises a pair of opposing and depressable buttons, wherein the buttons are biased towards an undepressed position.

33. The delivery system of example 31 or 32, wherein the central lumen is sealed when the buttons are in the undepressed position.

34. The delivery system of any one of examples 30-33, wherein the filament comprises a monofilament.

35. The delivery system of any one of examples 30-34, wherein the filament comprises at least one of: a polymer filament; or a metallic filament.

36. The delivery system of any one of examples 22-35, wherein the catheter comprises a thrombus extraction device.

37. A method of sealing a delivery device accessing a blood vessel of a patient, the method comprising:

inserting the delivery device comprising a catheter and a hemostatic valve into the blood vessel of the patient, the catheter having a first end, a second end, and a catheter lumen extending therethrough, and the hemostatic valve coupled to the first end and having a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member, wherein the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel;

moving the tensioning mechanism of the hemostatic valve to a second configuration, wherein the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration;

advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member; and

returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

38. The method of example 37, further comprising retracting the shaft of the tool from the delivery device.

39. The method of example 38, wherein the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device.

40. The method of example 38 or 39, wherein the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and wherein the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

41. The method of any one of examples 37-40, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member, wherein the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration.

42. The method of example 41, wherein the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration.

43. The method of example 41 or 42, wherein the hemostatic valve comprises a reinforcement structure located between the at least one filament and the tubular member.

44. The method of any one of examples 41-43, wherein the at least one filament forms a loop around the elongate member, and wherein moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop.

45. The method of any one of examples 41-44, wherein the filament forms at least one bight around a portion of the elongate member.

46. The method of example 45, wherein the filament comprises a first filament and a second filament, and wherein the at least one bight comprises a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament, wherein the first and second bights overlap to encircle a portion of the tubular member within an constricting area.

47. The method of example 46, wherein moving the tensioning mechanism from the second configuration to the first configuration comprises moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member.

48. The method of any one of examples 37-47, wherein the tensioning mechanism comprises an actuator, and wherein moving the tensioning mechanism to the second configuration comprises manipulating the actuator.

49. The method of any one of examples 37-48, further comprising applying a vacuum to the delivery device to aspirate material through the catheter, wherein the central lumen remains sealed during the aspiration.

50. The method of any one of examples 37-49, wherein the tool comprises a thrombus extraction device.

51. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:

an elongate member having a first end, a second end, and a central lumen comprising a plurality of lumens extending therebetween, wherein the elongate member is pliable; and

an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.

Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

In the previous description, various embodiments of the present invention are described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

The use of the terms "a" and "an" and "the" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. The term "connected" is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

The invention claimed is:

1. An aspiration catheter, comprising:

an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;

a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising

(a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and

(b) a constricting mechanism having at least a first actuator, a first filament formed into a loop around the collapsible tubular sidewall, the filament having at least a first end portion extending away from the loop and connected to the first actuator, and a first spring configured to move the first actuator in a direction that pulls the first end portion such that a diameter of the valve lumen decreases in response to reducing a diameter of the loop.

2. The aspiration catheter of claim **1** wherein:

the collapsible tubular sidewall comprises a tubular member defining the valve lumen configured to slidably receive the elongate, flexible tubular body;

the constricting mechanism further comprises a second actuator and a second spring coupled to the second actuator; and

the filament further comprises a second end portion extending away from the loop in a different direction than the first end portion and connected to the second actuator, and wherein the first actuator and the second actuator are moveable between (a) a first position wherein the filament circumferentially constricts the valve lumen to create a seal about the elongate, flexible tubular body and (b) a second position wherein the filament is moved to open the valve lumen at least partially.

3. The aspiration catheter of claim **2** wherein the tubular member is pliable.

4. The aspiration catheter of claim **2** wherein the first actuator comprises a first button and the second actuator comprises a second button, wherein the first button and the second button are undepressed in the first position, and wherein the first button and the second button are depressed in the second position.

5. The aspiration catheter of claim **2** wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when a pressure differential exists between (a) a first volume outside the valve lumen and adjacent to a first end of the tubular member and (b) a second volume outside the central lumen and adjacent to a second end of the tubular member.

6. The aspiration catheter of claim **2** wherein, when the first actuator and the second actuator are in the first position, the valve lumen of the tubular member is configured to remain constricted and sealed when vacuum pressure is applied to a volume outside the valve lumen and adjacent to either a first end or a second end of the tubular member.

7. The aspiration catheter of claim **2** wherein the valve lumen of the tubular member extends a long a first longitudinal axis, wherein the first actuator and the second

actuator are movable between the first and second positions along a second longitudinal axis, and wherein the first longitudinal axis is orthogonal to the second longitudinal axis.

8. The aspiration catheter of claim **2** wherein the first spring comprises a first compression spring coupled to the first member and the second spring comprises a second compression spring coupled to the second member.

9. The aspiration catheter of claim **2** wherein, in the first position, the first actuator and the second actuator pull the filament to circumferentially constrict the collapsible tubular member such that the valve lumen is constricted and sealed.

* * * * *

EXHIBIT H

US011865291B2

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Merritt et al.

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(45) **Date of Patent: Jan. 9, 2024**

(54) **HEMOSTASIS VALVES AND METHODS OF USE**

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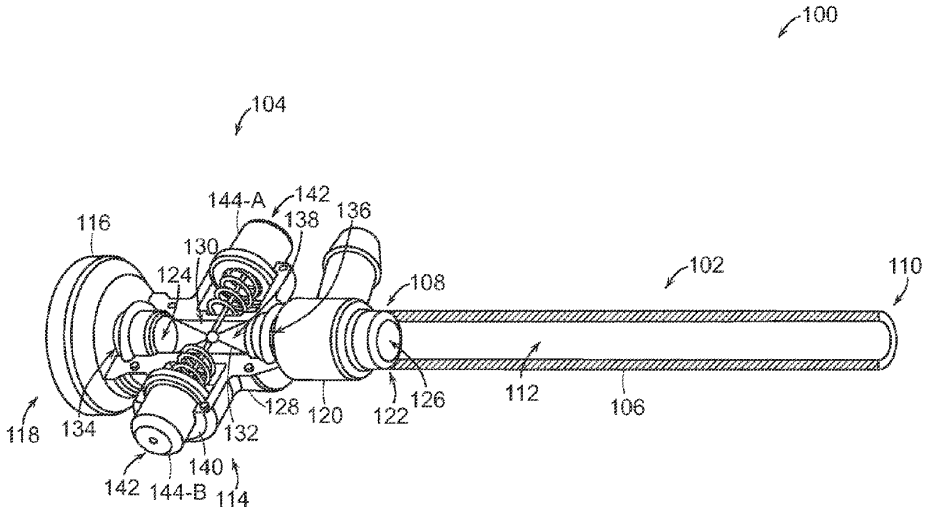
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(57) **ABSTRACT**

Devices, systems, and methods for sealing medical devices, particularly during intravascular access, are disclosed herein. Some aspects relate to a hemostatic valve for sealing a wide range of medical devices, such as catheters, wires, embolectomy systems. The valve can include an elongate member having a first end, a second end, and a central lumen extending therebetween. A reinforcement structure extends along at least a portion of the elongate member and is coupled to the elongate member. A shell defining a first aperture and a second aperture may be included, which first and second apertures can be fluidly coupled by the elongate member. A tensioning mechanism is coupled to the shell and to the elongate member, the tensioning mechanism can be moveable between a first configuration wherein the tensioning mechanism is collapsed and the central lumen is sealed and a second configuration wherein the central lumen is open.

20 Claims, 10 Drawing Sheets



IMPERATIVE Ex. 1034
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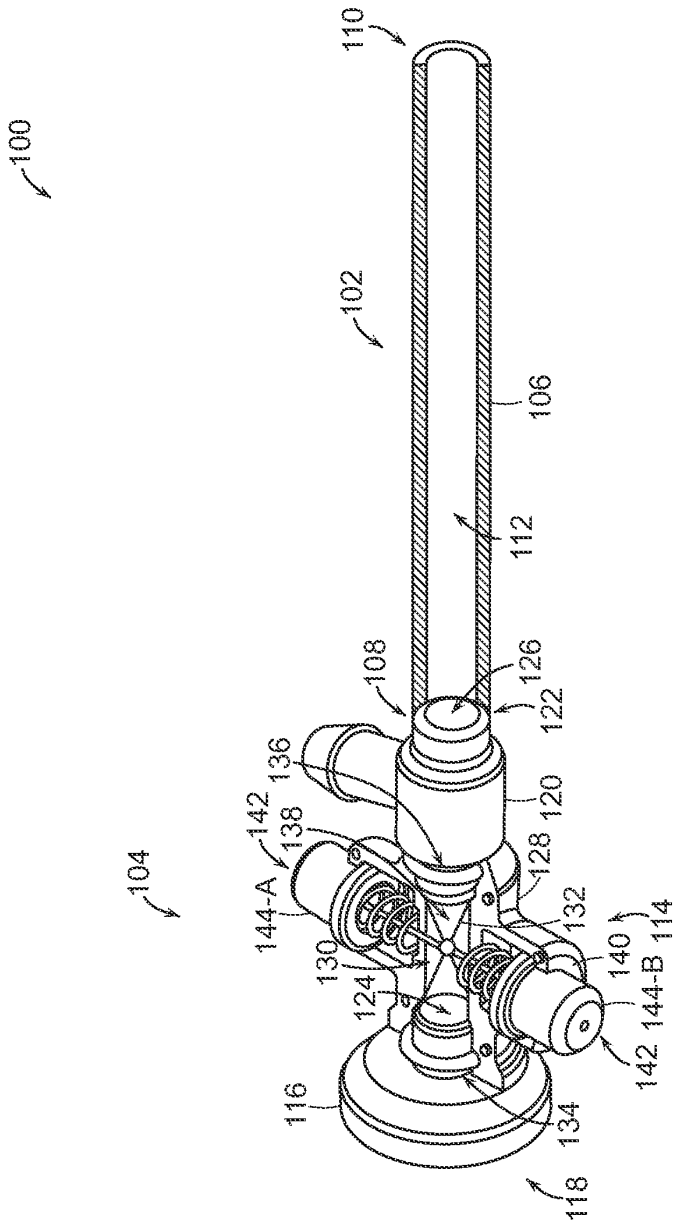

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FIG. 1

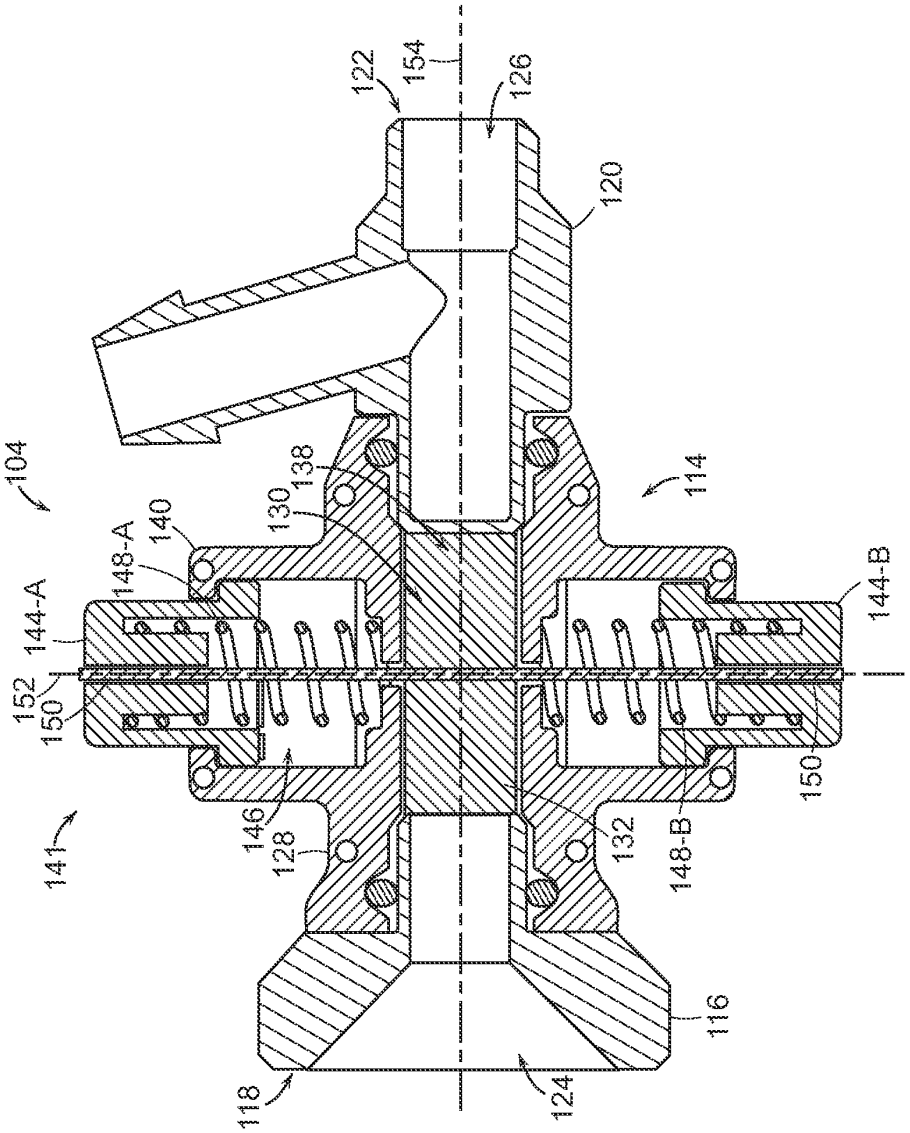

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FIG. 2

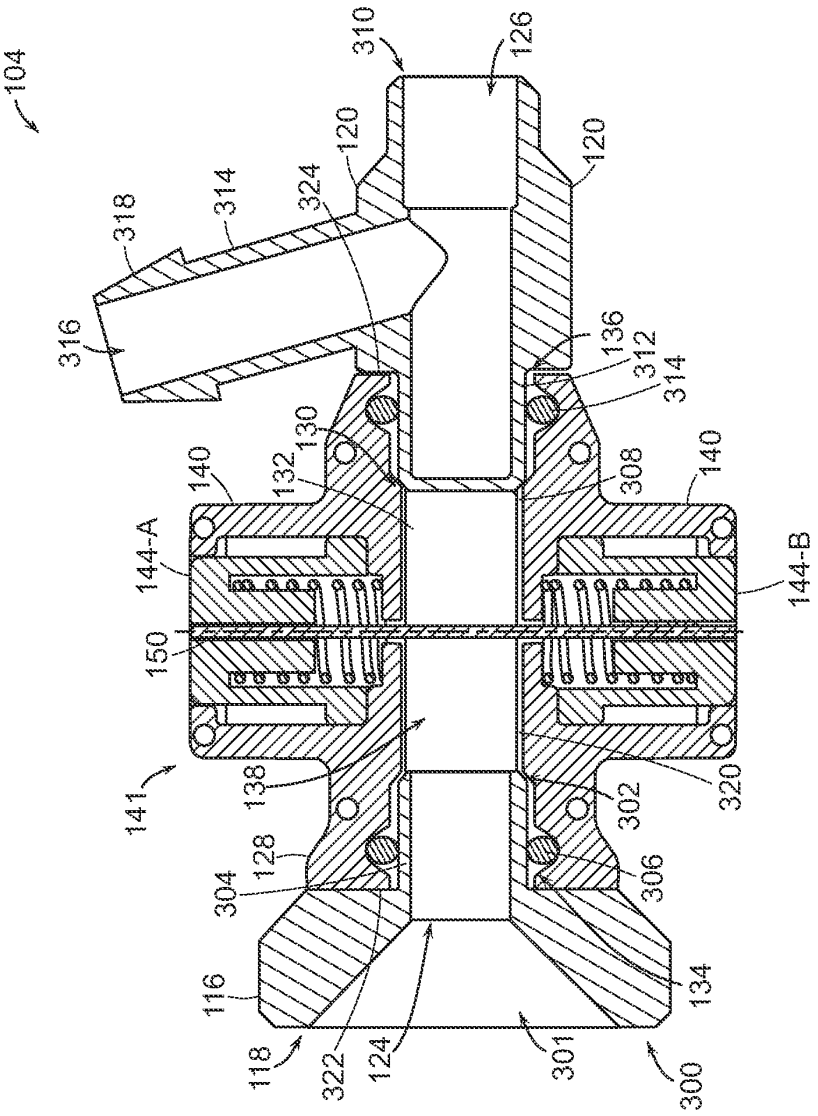

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FIG. 3

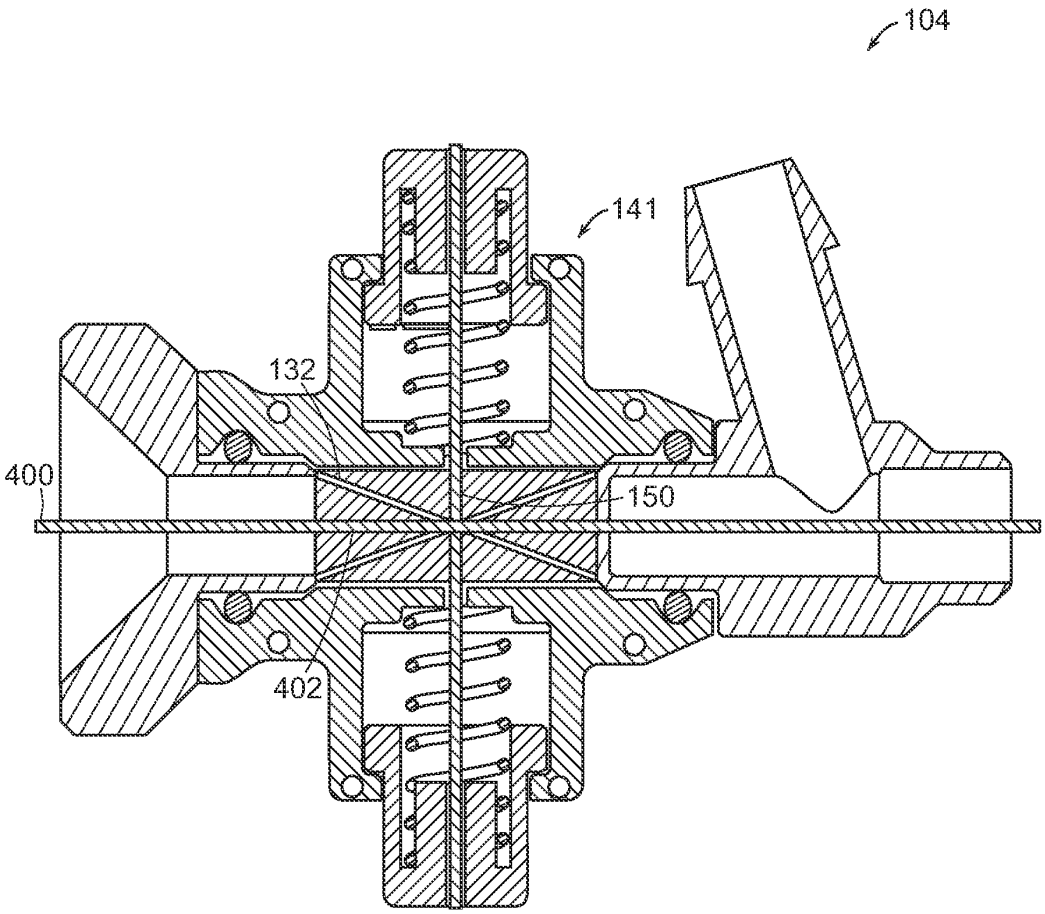


FIG. 4

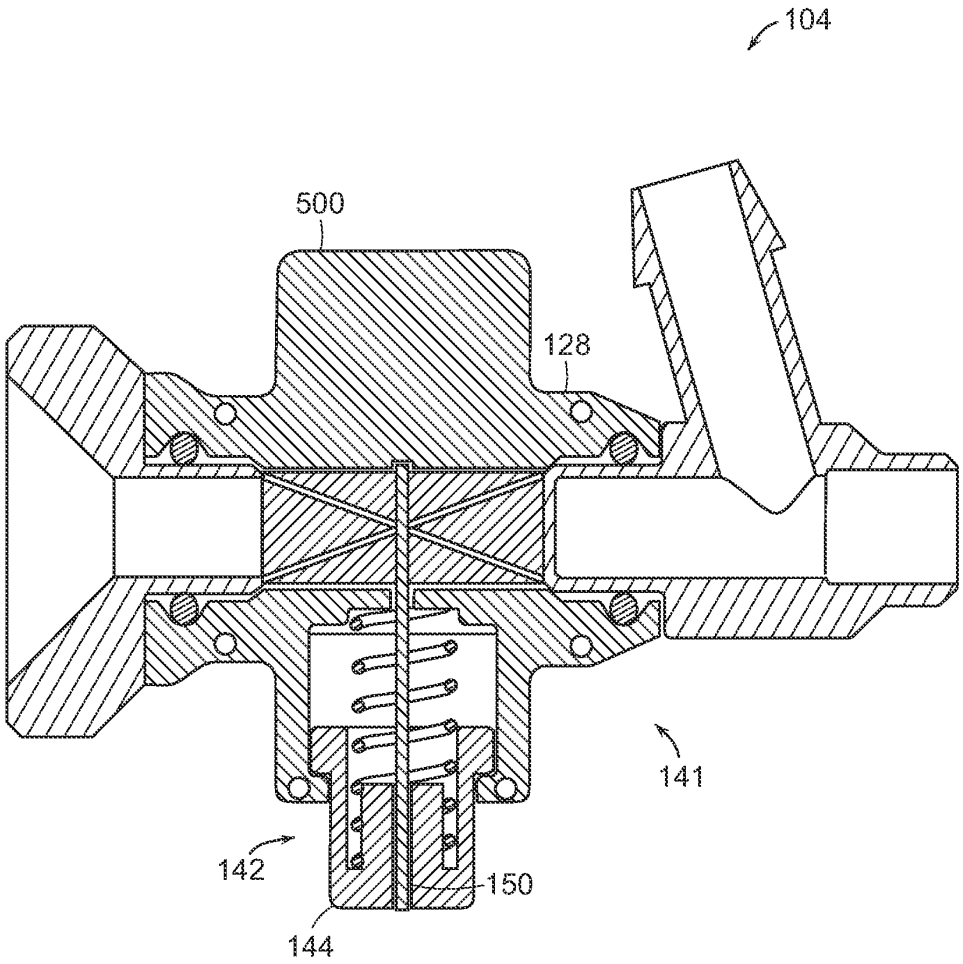


FIG. 5

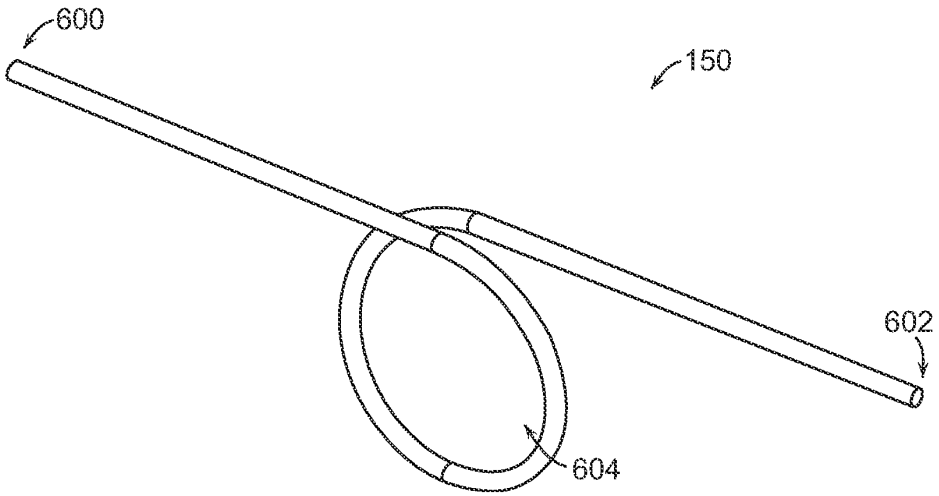


FIG. 6

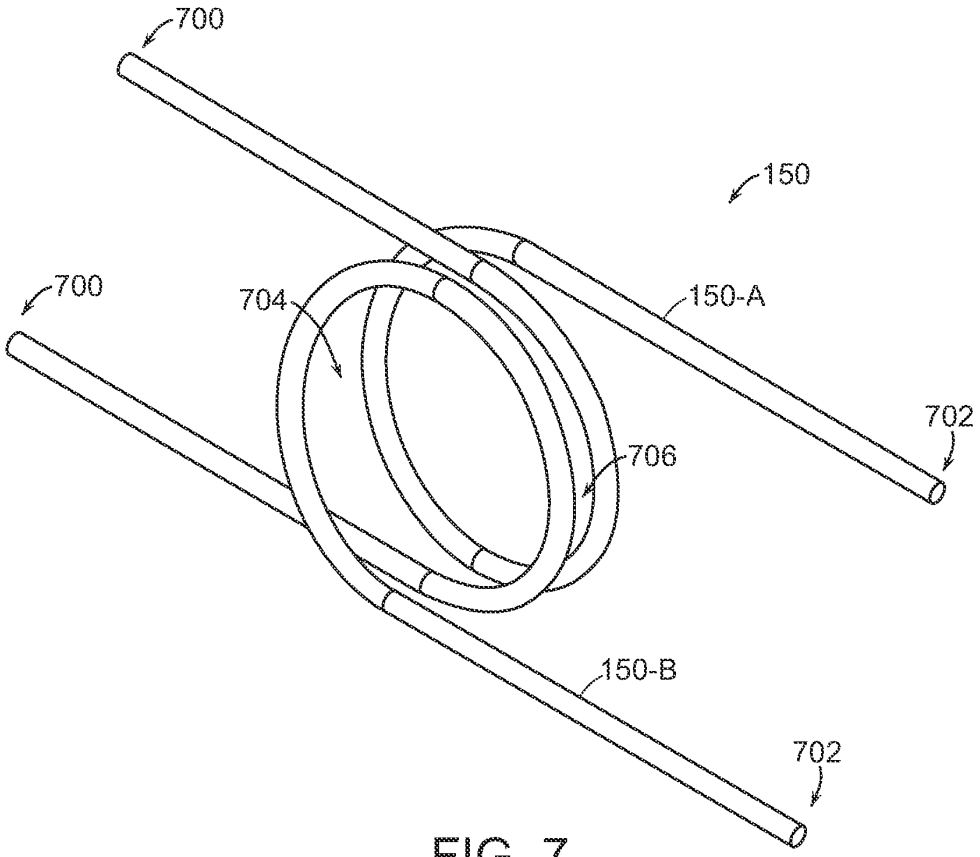


FIG. 7

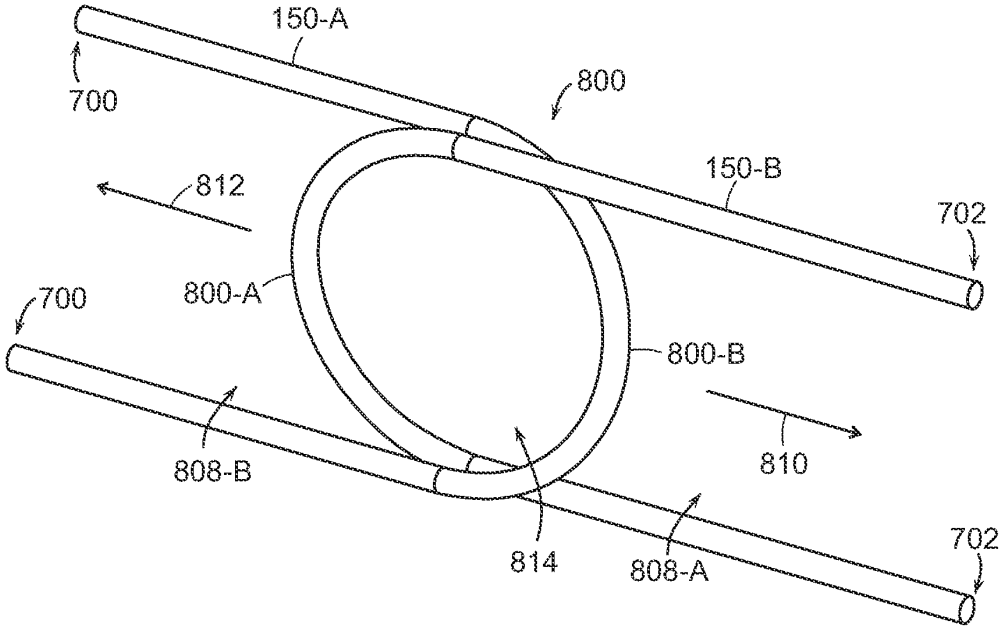

150-A
700
800
150-B
812
702
700
800-A
800-B
808-B
810
814
808-A
702

FIG. 8

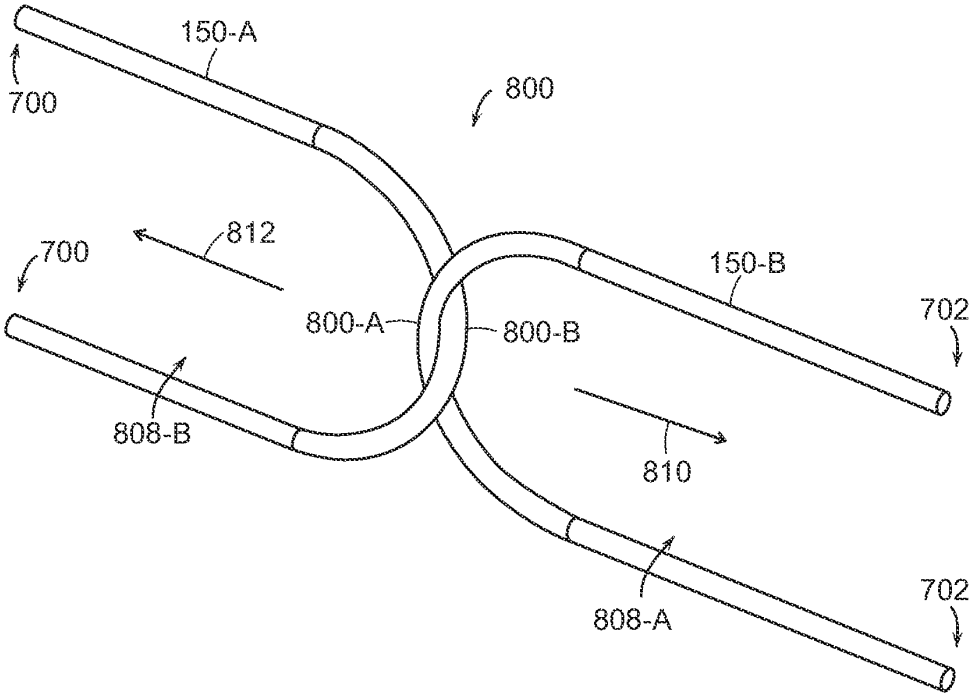

150-A
700
800
700
812
150-B
800-A
800-B
702
808-B
810
808-A
702

FIG. 9

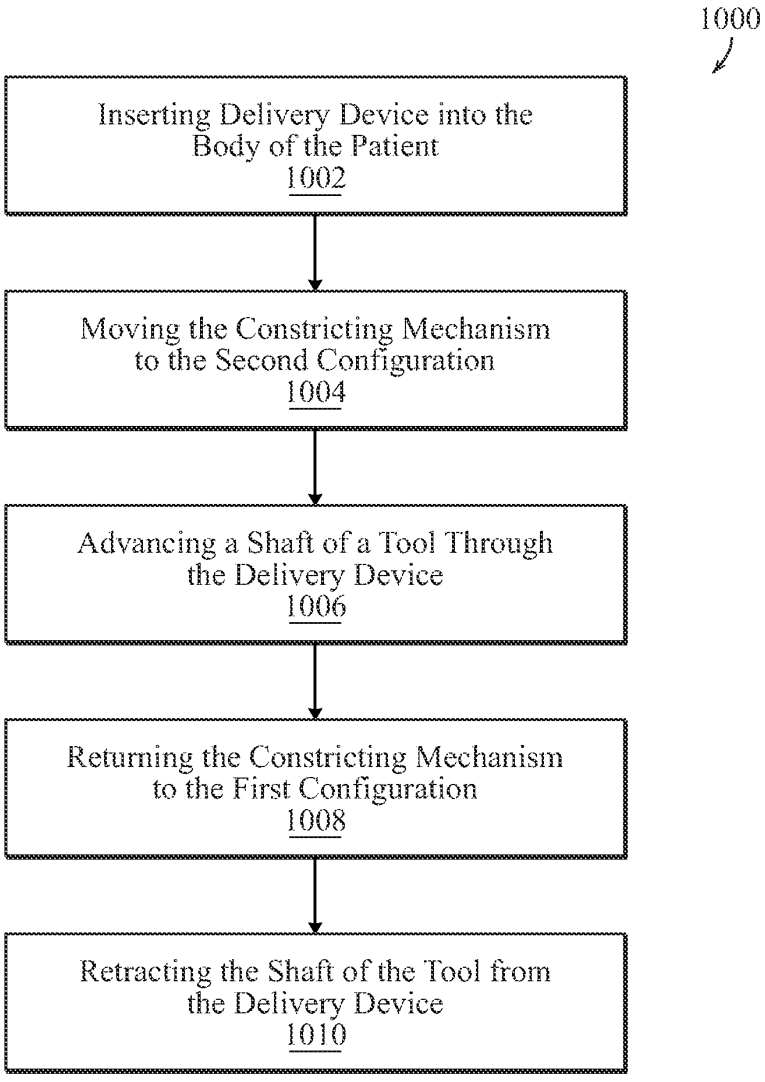

1000
Inserting Delivery Device into the Body of the Patient
1002
Moving the Constricting Mechanism to the Second Configuration
1004
Advancing a Shaft of a Tool Through the Delivery Device
1006
Returning the Constricting Mechanism to the First Configuration
1008
Retracting the Shaft of the Tool from the Delivery Device
1010

FIG. 10

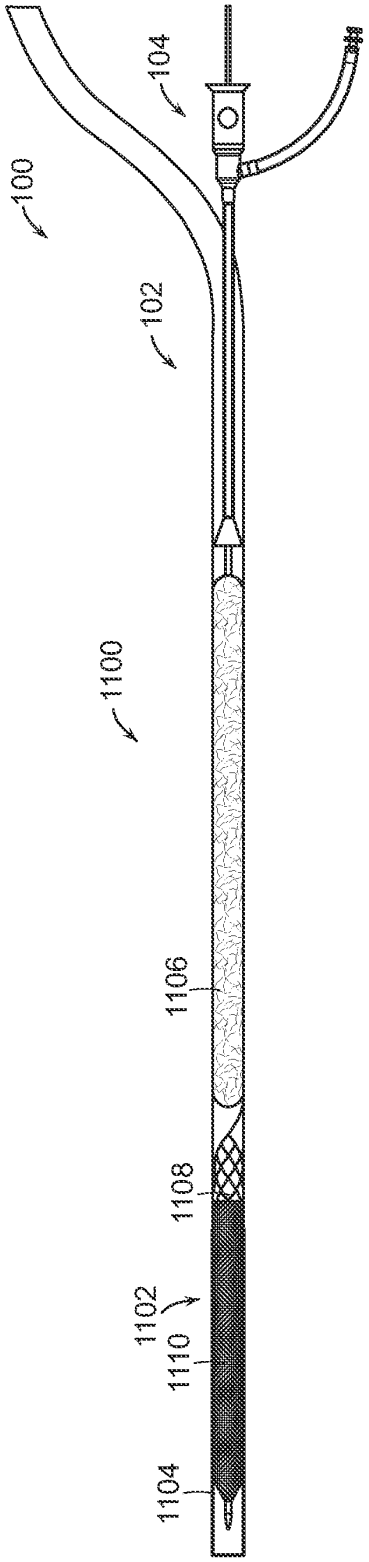


FIG. 11

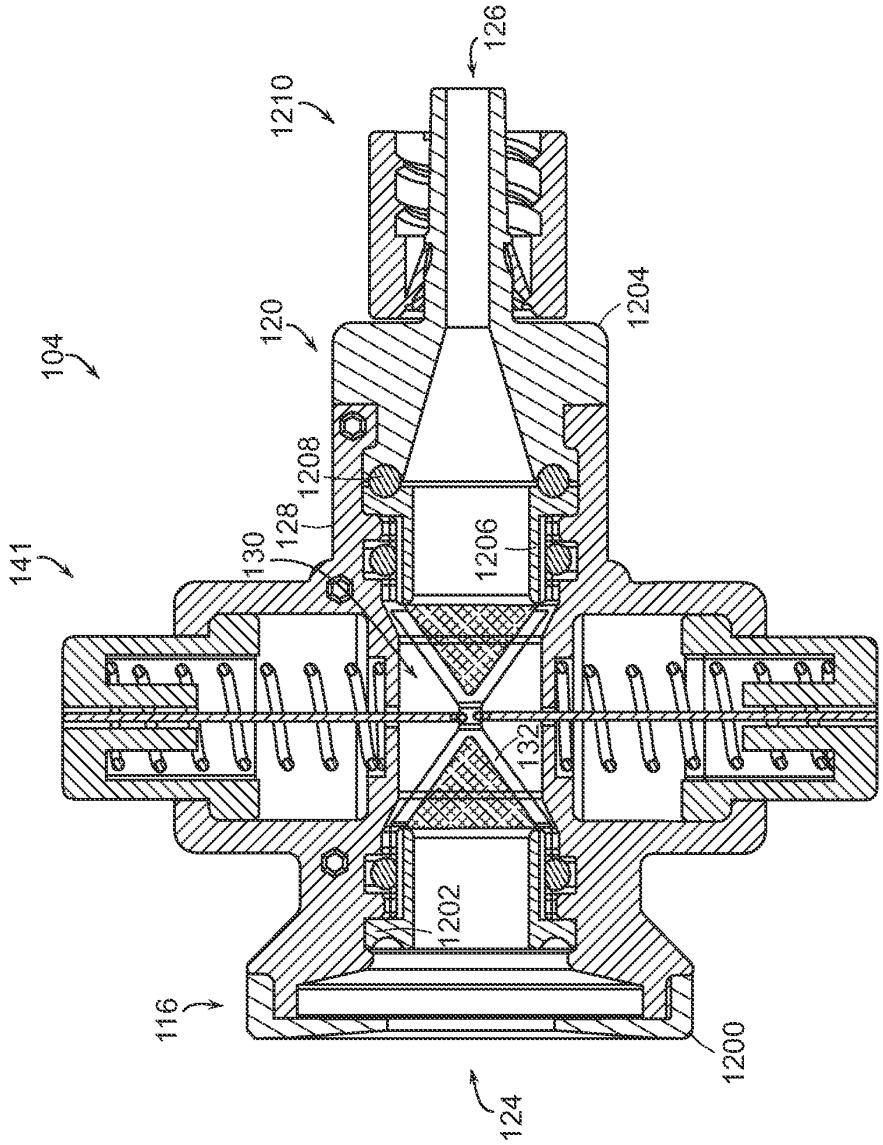

126
1210
120
104
1204
1208
128
130
141
1206
132
1202
116
1200
124

FIG. 12

HEMOSTASIS VALVES AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 17/705,189, filed on Mar. 25, 2022, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. patent application Ser. No. 17/226,318, filed on Apr. 9, 2021, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. patent application Ser. No. 16/117,519, filed on Aug. 30, 2018, now issued as U.S. Pat. No. 11,000,682, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which claims the benefit of U.S. Provisional Patent Application No. 62/554,931, filed on Sep. 6, 2017, and titled "HEMOSTASIS VALVES AND METHODS OF USE," each of which is herein incorporated by reference herein in its entirety.

BACKGROUND

During a surgical procedure, a portion of a patient's body (e.g., vasculature) is accessed to allow for performance of a desired intervention or treatment. During such surgical procedures, it is desired to minimize patient blood loss, prevent delivery of air into the vasculature, and to maintain the sterility of the accessed portions or sites of the patient's body so as to prevent issues such as infection. Further, the desire for improved patient outcomes has led to the development of hemostasis valves that facilitate minimally invasive surgery.

In minimally invasive surgery, small incisions are created through a blood vessel which one or several catheters are inserted. Each of these one or several catheters can define a lumen extending longitudinally through that catheter. These catheters are moved to a position proximate to tissue, nerves, or other body structures targeted by the surgery, and then tools for performing the procedure are inserted through the lumens of some or all of these catheters.

To minimize blood loss, prevent delivery of air into the vasculature, and to facilitate maintenance of sterility within the patient's body (e.g., blood vessel), these catheters are equipped with hemostasis valves. These valves seal or selectably seal the lumens of the catheters. In many instances, these valves can seal the lumen of the catheter when a tool extends through the catheter, and specifically through the valve. Additionally the valves can seal the lumen when a tool is removed or does not extend through the catheter.

While such traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use. The drawbacks of such valve designs may in turn increase the complexity of any surgery performed therewith and/or reduce patient safety (e.g., bleeding, infection, and/or other detrimental complications). Accordingly, new and improved hemostasis valves and methods of use are desired.

SUMMARY

The following relates to valves, medical systems incorporating valves, and methods of using the same. The valve can include a tubular member that can be constricted, collapsed, and/or sealed by one or several tensioning mechanisms. The tensioning mechanism can include at least one filament that extends around at least a portion of the tubular member. The filament can interact with the tubular member to constrict, collapse, and/or seal the tubular member via manipulation of the tensioning mechanism(s). A tool can be inserted through the valve to gain access to a patient's body and specifically to gain access to a blood vessel. Through the use of the tensioning mechanism and filament to constrict, collapse, and/or seal the tubular member, the valve can seal around a wide range of tool sizes and shapes, as well as multiple tools of differing sizes simultaneously. Additionally, such a valve creates a robust seal that maintains its seal when a vacuum is applied such as occurs during aspiration.

Aspects of the present disclosure relate to a hemostatic valve for sealing a medical device. The hemostatic valve includes an elongate member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the elongate member is pliable. The hemostatic valve can include a reinforcement structure extending along at least a portion of the elongate member, such that the reinforcement structure is coupled to the elongate member. The hemostatic valve includes an active tensioning mechanism coupled to the elongate member. In some embodiments, the tensioning mechanism is moveable between a first configuration in which the central lumen is constricted and sealed and a second configuration in which the central lumen is open. Optionally, the valve may be manually adjusted by the user to intermediate positions between fully open and fully closed. Additionally, an instrument (e.g. catheter) may provide an intermediate position where the valve creates hemostasis without user adjustment.

In some embodiments, the elongate member can be a compliant polymer tube. In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the elongate member. In some embodiments, the reinforcement structure is positioned between the at least one filament and the elongate member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member. In some embodiments, the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member. In some embodiments, the central portion of the compliant polymer tube that is constrained or collapsed by the tensioning mechanism, and at least one filament, is not coupled to the reinforcement structure.

In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments there are two tensioning mechanisms coupled to the at least one filament that operate in opposite directions. In some embodiments the two tensioning mechanisms are attached to the same filament. In some embodiments the two tensioning mechanisms are attached to opposing filaments. In some embodiments, the actuator can be moveable to control movement of the at least one filament from a first position in which the central lumen is constricted and sealed to a second position in which the central lumen is open. In some embodiments, the at least one filament is in the first position when the tensioning mechanism is in the first configuration. In some embodiments, the actuator is biased towards the first position. In some embodiments, the actuator is biased toward the second position. In some embodiments, the actuator can be a manual actuator.

In some embodiments, the at least one filament forms a loop around the elongate member. In some embodiments, the at least one filament forms a bight around a portion of the elongate member. In some embodiments, the at least one filament can include a first filament and a second filament. In some embodiments, each of the first filament and the second filament are coupled to the same actuator. In some embodiments, each of the first filament and the second filament are coupled to different actuators. In some embodiments, the first filament and the second filament are moveable from the first position to the second position. In some embodiments, each of the first filament and the second filament form a loop around the elongate member. In some embodiments, the first filament forms a first bight around a first portion of the elongate member, and the second filament forms a second bight around a second portion of the elongate member. In some embodiments, the first bight extends through the second bight.

In some embodiments, the hemostatic valve can include a shell defining a first aperture and a second aperture. In some embodiments, the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture. In some embodiments, the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve. In some embodiments, the central lumen can comprise a single lumen, and in some embodiments, the central lumen can comprise a plurality of lumens.

One aspect of the present disclosure relates to a delivery system for intravascular access of a blood vessel within a patient's body. The delivery system includes a catheter having a first end, a second end, and a catheter lumen extending therebetween and a hemostatic valve coupled to the first end of the catheter. The hemostatic valve includes a tubular member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the central lumen of the tubular member is fluidly coupled with the catheter lumen. The hemostatic valve includes an active tensioning mechanism coupled to the tubular member, the tensioning mechanism can be moveable between a first configuration in which the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration in which the central lumen is open.

In some embodiments, the hemostatic valve further includes a reinforcement structure extending along at least a portion of the tubular member. In some embodiments, the reinforcement structure is located between the tensioning mechanism and the tubular member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member. In some embodiments, the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member. In some embodiments, the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments, moving the tensioning mechanism from the first configuration to the second configuration can include moving the actuator and the thereto coupled at least one filament from a first position to a second position. In some embodiments, the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

In some embodiments, the actuator can be a manual actuator. In some embodiments, the actuator can include a pair of opposing and depressable buttons, which buttons can be biased towards an undepressed position. In some embodiments, the central lumen is sealed when the buttons are in the undepressed position. In some embodiments, the filament can be a monofilament. In some embodiments, the filament can be at least one of: a polymer filament; or a metallic filament. In some embodiments, the catheter can include a thrombus extraction device.

One aspect of the present disclosure relates to a method of sealing a delivery device accessing a blood vessel of a patient. The method includes inserting the delivery device including a catheter and a hemostatic valve into the blood vessel of the patient. In some embodiments, the catheter can have a first end, a second end, and a catheter lumen extending therethrough. In some embodiments, the hemostatic valve can be coupled to the first end and can have a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member. In some embodiments, the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel. The method can include moving the tensioning mechanism of the hemostatic valve to a second configuration. In some embodiments, the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration. The method can include advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member. The method can include returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

In some embodiments, the method includes retracting the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the hemostatic valve can include a reinforcement structure located between the at least one filament and the tubular member.

In some embodiments, the at least one filament forms a loop around the elongate member, and moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop. In some embodiments, the filament forms at least one bight around a portion of the

elongate member. In some embodiments, the filament can include a first filament and a second filament. In some embodiments, the at least one bight can include a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament. In some embodiments, the first and second bights overlap to encircle a portion of the tubular member within a constricting area.

In some embodiments, moving the tensioning mechanism from the second configuration to the first configuration can include moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member. In some embodiments, the tensioning mechanism can include an actuator. In some embodiments, moving the tensioning mechanism to the second configuration can include manipulating the actuator. In some embodiments, the method includes applying a vacuum to the delivery device and/or delivery system to aspirate material through the catheter. In some embodiments, the central lumen remains sealed during the aspiration. In some embodiments, the tool can include a thrombus extraction device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of one embodiment of a delivery device.

FIG. **2** is a side-section view of one embodiment of a hemostasis valve in a first configuration.

FIG. **3** is a side-section view of one embodiment of the valve in a second configuration.

FIG. **4** is a side-section view of one embodiment of the valve in the first configuration and with a tool extending through the valve.

FIG. **5** is a side-section view of one embodiment of a single-button hemostasis valve in a first configuration.

FIG. **6** is a perspective view of a filament of a valve forming a loop.

FIG. **7** is a perspective view of two filaments of a valve, each of the filaments forming a loop.

FIG. **8** is a perspective view of two overlapping and interlocked bights in an open configuration.

FIG. **9** is a perspective view of two overlapping and interlocked bights in a closed configuration.

FIG. **10** is a flowchart illustrating one embodiment of a method for sealing a valve and/or catheter.

FIG. **11** is a side view of one embodiment of a thrombectomy system including the delivery device.

FIG. **12** is a side-section view of another embodiment of a hemostasis valve having two-piece caps.

DETAILED DESCRIPTION

The present disclosure relates to a valve that can be used a hemostasis valve. This valve, also referred to herein as a garrote valve can seal with or without a tool extending through the valve. The garrote valve provides convenient, single-handed operation for a wide range of medical devices including catheters, wires, embolectomy systems, or the like. This single-handed operation of the garrote valve allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure. Combined with single-handed operation, the garrote valve provides robust sealing either with or without a tool extending through the valve. This robust sealing minimizes leakage in applications with a pressure differential on different sides of the valve. This pressure differential can arise, for example, during the application of vacuum aspiration in a procedure. Even under such conditions, as well as under other conditions, the garrote valve maintains seal integrity and prevents leakage in one or both directions.

The garrote valve includes a tubular member. The tubular member is a flexible member that defines a central lumen, which can, in some embodiments, define a single lumen, and in some embodiments, defines a plurality of lumens. In some embodiments, each of the plurality of lumens can comprise the same size and shape, and in some embodiments, some or all of the plurality of lumens can comprise different sizes and shapes. In some embodiments, for example, the plurality of lumens can comprise a lumen sized and/or shaped to receive a guide wire and a lumen sized and/or shaped to receive a tool. The tubular member extends at least partially through a constricting mechanism. The constricting mechanism can be moved from a first configuration to a second configuration, and the constricting mechanism can collapse and/or seal the central lumen of the tubular member when the constricting mechanism is in the first configuration. The constricting mechanism creates the above-discussed robust seal of the tubular member and thus of the valve.

With reference now to FIG. **1**, a perspective view of one embodiment of a delivery system **100**, also referred to herein as a delivery device **100**, is shown. The delivery system **100** can include a catheter **102** and a garrote valve **104**, also referred to herein as valve **104**. The catheter **102** can comprise a shaft **106**, also referred to herein as an elongate sheath **106**, having a proximal end **108**, also referred to herein as a first end **108**, that can connect to the valve **104** and a distal end **110**, also referred to herein as a second end **110**. The shaft **106** can define a catheter lumen **112** extending from the proximal end **108** of the shaft **106** to the distal end **110** of the shaft **106**. The catheter **102** and specifically the shaft **106** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the catheter **102** can be flexible and/or can be made from a biocompatible material. The elongate sheath **106** can have an outer diameter of at least 4 French, at least 6 French, at least 8 French, at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 4 French and 30 French, between 8 French and 24 French, between 12 French and 20 French, and/or any other or intermediate size.

The valve **104** can include an outer shell **114**. The outer shell **114** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the outer shell **114** can be made from one or several polymers or composites. The outer shell **114** can include features that allow interaction with and/or control of the valve **104** to move the valve **104** between the first configuration and the second configuration.

The outer shell **114** can include a proximal cap **116** located at a proximal end **118** of the outer shell **114** and a distal cap **120** located at a distal end **122** of the shell **114**. The proximal cap **116** can include and/or house a proximal aperture **124**, also referred to herein as a proximal channel **124**, a first channel **124**, or a first aperture **124**, that extends through the proximal cap **116**, and the distal cap **120** can include and/or house a distal aperture **126**, also referred to herein as a distal channel **126**, a second channel **126**, or second aperture **126**, that extends through the distal cap **120**. As seen in FIG. **1**, the distal cap **120** connects to the shaft **106** of the catheter **102** at the distal end **122** of the valve **104**.

The proximal cap **116** and the distal cap **120** are connected via a housing **128**. The housing **128** can be a one-piece housing **128** or a multi-piece housing **128**. In the embodiment depicted in FIG. **1**, the housing comprises a two-piece housing **128**. The housing **128** can be configured to receive and couple with each of the proximal cap **116** and the distal cap **120**, and as seen in FIG. **1**, the housing **128** is coupled with each of the proximal cap **116** and the distal cap **120** to secure the relative position of the proximal cap **116** and the distal cap **120** with respect to each other.

The housing **128** can define an interior channel **130** through which an elongate member **132**, also referred to herein as a tubular member **132**, a septum **132**, or a tubular septum **132**, can extend and connect the proximal cap **116** and the distal cap **120**. The elongate member **132** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the elongate member **132** can comprise a compliant tubular structure that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the elongate member **132** can facilitate the collapse, and specifically the uniform collapse of the elongate member **132** and the sealing of the elongate member **132**. In some embodiments, the elongate member **132** is an elastic, resilient material that may comprise a polymer including either a natural or synthetic polymer. In some embodiments, the elongate member can comprise an elastic, resilient material that may comprise silicone, urethane, ethylene-vinyl acetate, natural or synthetic rubber or other elastomers known in the art. In some embodiments, the elongate member **132** can comprise a silicone tube.

The elongate member **132** can comprise a proximal end **134**, also referred to herein as a first end **134**, that can couple to the proximal cap **116**, and a distal end **136**, also referred to herein as a second end **136**, that can couple to the distal cap **120**. The elongate member **132** can define a central lumen **138** that can extend from the first end **134** to the second end **136** of the elongate member **132**. The elongate member **132** can be coupled to the proximal cap **116** such that the central lumen **138** is fluidly coupled with the proximal aperture **124** of the proximal cap **116**, and the elongate member **132** can be coupled to the distal cap **120** such that the central lumen **138**, as seen in FIG. **2** and in FIG. **3**, is fluidly coupled with the distal aperture **126** of the distal cap **120**.

The central lumen **138** of the elongate member **132** can be defined by a wall of the elongate member **132** that can have a thickness that is uniform along the length of the elongate member **132** between the first end **134** and the second end **136**, or that is non-uniform along the length of the elongate member **132** between the first end **134** and the second end **136**. In some embodiments, the wall can have a thickness that is approximately between 0.005 inches and 0.05 inches, and/or approximately between 0.010 inches and 0.030 inches. As used anywhere herein, "approximately" refers to a range of +/−10% of the value and/or range of values for which "approximately" is used.

In some embodiments, the elongate member **132** can be cylindrically shaped, and specifically can be circular-cylindrically shaped. In some embodiments, the elongate member **132** can be dog-bone shaped to facilitate, for example, connection to each of the proximal cap **116** and the distal cap **120**. In some embodiments, the elongate member **132** can include one or several outward-extending protuberances that engage with all or portions of a constricting mechanism **141**, also referred to herein as a tensioning mechanism **141**, of the valve **104** to secure a position of all or portions of the constricting mechanism **141** with respect to the elongate member **132**. In some embodiments, the constricting mechanism **141** can be self-adjusting to seal around tools of different sizes extending through the valve **104**.

The constricting mechanism **141** can, in some embodiments, collapse and seal the elongate member **132** via compression and/or constriction, and specifically via constriction with at least one filament **150**. The constricting mechanism **141** can comprise: an actuator **142** which can be a manual actuator such as one or several buttons **144**; and the at least one filament **150** that can extend at least partially around the elongate member **132**. In some embodiments, the use of the constricting mechanism **141** can facilitate sealing of the valve around tools or instruments of a wide range of sizes and/or diameters, and particularly around tools or instruments that fit through the elongate member **132**.

The housing **128** can further include one or several retention features **140**. The one or several retention features **140** of the housing can engage with and retain all or portions of the constricting mechanism **141** of the valve **104**. In some embodiments, the one or several retention features **140** of the housing **128** can retain the actuator **142** and/or can couple the actuator **142** to the housing **128**. The actuator **142** can comprise any desired type of actuator including, for example, a manual actuator and/or an automated actuator such as, for example, an electromechanical actuator including a solenoid-based actuator. In some embodiments, the actuator can comprise one or several buttons **144**, and specifically, as depicted in FIG. **1**, the actuator **142** can comprise a first button **144**-A and a second button **144**-B. Alternatively, and as depicted in FIG. **5**, the actuator **142** can comprise a single button **144**. In such an embodiment, the filament **150** can be coupled to the single button **144** and to a portion of the housing **128** such as, for example, to grip portion **500** of the housing **128** such that the movement of the single button **144** causes the sealing and/or opening of the elongate member **132** and of the valve **104**.

The actuator **142** can be biased towards a configuration such as, for example, biased towards the first configuration or biased towards the second configuration. As depicted in FIG. **2**, which shows the constricting mechanism **141** in the first configuration, the actuator **142** can be biased towards the first configuration wherein the elongate member **132** is collapsed and/or sealed by a bias feature **146**. In this first configuration, the buttons **144** can be in a first position, also referred to herein as an undepressed position. This bias feature **146** can, as shown in FIG. **2**, include a first spring **148**-A configured to bias the first button **144**-A towards the first position corresponding to the first configuration of the constricting mechanism **141**, and a second spring **148**-B configured to bias the second button **144**-B towards a first position corresponding to the first configuration of the constricting mechanism **141**. One or both of the first spring **148**-A and the second spring **148**-B can comprise a tension spring, compression spring, a torsion spring, a coil spring, or any other desired type of spring.

In some embodiments, one or both of the first spring **148**-A and the second spring **148**-B can generate sufficient force so as to allow actuation of the actuator **142** with a single hand and so as to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. In some embodiments, one or both of the first spring **148**-A and the second spring **148**-B can generate a force of: at least 0.1 pounds, at least 0.2 pounds, at least 0.3 pounds, at least 0.4 pounds, at least 0.5 pounds, at least 0.6 pounds, at least 0.7 pounds, at least 0.8 pounds, at least 0.9 pounds, at least 1 pound, at least 1.5 pounds, at least 2

pounds, at least 3 pounds, at least 5 pounds, and/or at least 10 pounds and in some embodiments one or both of the first spring **148**-A and the second spring **148**-B can generate a force approximately between: 0.1 and 10 pounds, 0.1 and 5 pounds, 0.1 and 1.5 pounds, 0.2 and 1 pounds, and/or 0.4 and 0.8 pounds.

The constricting mechanism **141** can include at least one filament **150** that extends at least partially around the elongate member **132**. In some embodiments, the at least one filament **150** can circumferentially constrict the elongate member **132** to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. The filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal. In some embodiments, the filament **150** can be nylon, stainless steel, nitinol, silicone, or the like. In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament. In some embodiments, the filament **150** can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

The filament **150** can be coupled to the actuator **142** such that the filament **150** selectively constricts, collapses, and/or seals the elongate member **132**, and specifically the central lumen **138** of the elongate member **132** based on the movement and/or position of the actuator **142**. In some embodiments, the filament **150** can be connected to one or both of the buttons **144**-A, **144**-B such that the filament **150** collapses, constricts, and/or seals the elongate member **132** and specifically the central lumen **138** of the elongate member **132** when the buttons **144**-A, **144**-B are in the first position, and the filament **150** can be connected to one or both of the buttons **144**-A, **144**-B such that the elongate member **132** and specifically the central lumen **138** of the elongate member **132** is open and uncollapsed when the buttons **144**-A, **144**-B are in the second position. In some embodiments in which the actuator **142** comprises a single button **144**, as depicted in FIG. **5**, the filament **150** can be connected to the button **144** and to the housing **128** such that the filament **150** is tightened when the button **144** moves to the first position.

In some embodiments, the at least one filament **150** can extend along an axis **152** that can be perpendicular to a central axis **154** of the elongate member **132** and/or of the apertures **124**, **126**. In some embodiments, the axis **152** of the at least one filament **150** can intersect and be perpendicular to the central axis **154** of the elongate member **132** and/or of the apertures **124**, **126**. In some embodiments, the actuator **142**, and specifically the buttons **144**-A, **144**-B can move along this axis **152** when moved from the first position to the second position.

In FIG. **3**, an embodiment of the valve **104** with the constricting mechanism **141** in the second configuration is shown. As specifically shown, both of the first and second buttons **144**-A, **144**-B are in the second position, depressed into the retention features **140** of the housing **128**. In this second position, the filament **150** is loosened, thereby allowing the expansion of the elongate member **132** and the unsealing of the central lumen **138** of the elongate member **132**.

As further seen in FIG. **3**, the proximal cap **116** has a proximal end **300** and a distal end **302**. The proximal cap **116** can include a funnel portion **301** of the proximal aperture **124**, which funnel portion **301** can facilitate insertion of a tool into the proximal aperture **124**. The distal end **302** of the proximal cap **116** can partially extend into the interior channel **130** of the housing **128**. The proximal cap **116** can include a mating feature **304** that can mate with the proximal end **134** of the elongate member **132**. In some embodiments, the proximal end **134** of the elongate member **132** can fit over the mating feature **304** of the proximal cap **116**. The proximal end **134** of the elongate member **132** can be compressed between the mating feature **304** of the elongate member **132** and a portion of the interior channel **130** of the housing **128** into which the mating feature **304** is inserted to thereby secure the proximal end **134** of the elongate member **132** on the mating feature **304**. In some embodiments, the proximal end **134** of the elongate member **132** can be further secured on the mating feature **304** by a proximal O-ring **306** that can be compressed between the housing **128** and the mating feature **304** of the proximal cap **116** to sealingly couple the elongate member **132** to the proximal cap **116**.

The distal cap **120** has a proximal end **308** and a distal end **310**. The distal cap can include a mating feature **312** located on the proximal end **308** of the distal cap **120**, which mating feature **312** can mate with the distal end **136** of the elongate member **132**. In some embodiments, the distal end **136** of the elongate member **132** can fit over the mating feature **312** of the distal cap **123**. The distal end **136** of the elongate member **132** can be compressed between the mating feature **312** of the elongate member **132** and a portion of the interior channel **130** of the housing **128** into which the mating feature **312** is inserted to thereby secure the distal end **136** of the elongate member **132** on the mating feature **312**. In some embodiments, the distal end **136** of the elongate member **132** can be further secured on the mating feature **312** by a distal O-ring **314** that can be compressed between the housing **128** and the mating feature **312** of the proximal cap **116** to sealingly couple the elongate member **132** to the distal cap **120**.

The distal cap **120** can, in some embodiments, further include a side port barb **314** that can extend laterally away from the distal cap **120** and specifically away from the distal aperture **126** of the distal cap **120**. The side port barb **314** can define a side port channel **316** that can extend through the side port barb **314** and fluidly connect to the distal aperture **126**. In some embodiments, the side port barb **314** can include a securement feature **318** such as a barb that can secure coupling of a hose or tube to the side port barb **314**.

In some embodiments, the side barb **314** can be used to apply a vacuum to the portions of the delivery device **100**, and particularly to portions of the delivery device **100** that are distal of the axis **152** along which the elongate member **132** seals. This vacuum can be applied to aspirate a material through the delivery device **100**, and specifically through the catheter **102** of the delivery device. This aspirated material can be a biological material including, for example, bodily fluids, multi-phase bodily materials that can include, for example, a fluidic portion and at least one solid portion, or the like.

In some embodiments, due to the narrowing shape of the elongate member **132** when the constricting mechanism **141** is in the first configuration, a vacuum applied to the portions of the delivery device **100** distal to the axis **152** draws the elongate member **132** towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve **104**. This attribute of the valve **104** can provide benefits over other valve designs in which a vacuum can compromise the seal of the valve, and thus the ability to draw a vacuum and aspirate can be limited.

In some embodiments, the valve **104** can further include a reinforcement structure **320** that can extend along all or portions of the elongate member **132**. The reinforcement structure **320** can facilitate the uniform collapse of the elongate member **132**, can prevent the at least one filament **150** from cutting through and/or tearing the elongate member **132**, and can assist in guiding one or several tools through the elongate member **132**. The reinforcement structure **320** can be tubular, can extend along and around the elongate member **132**, and can be positioned so as to be between the elongate member **132** and the at least one filament **150**.

The reinforcement structure **320** can include a proximal end **322** and a distal end **324**. In some embodiments, the reinforcement structure **320** extends along and around the elongate member **132**, and is positioned such that the proximal end **322** of the reinforcement structure **320** is proximate to the first end **134** of the elongate member **132** and the distal end **324** of the reinforcement structure **320** is proximate to the second end **136** of the elongate member **132**.

The reinforcement structure **320** can be coupled to the elongate member **132**. In some embodiments, the reinforcement structure **320** is coupled to the elongate member **132** along the length of the reinforcement structure **320**, and in some embodiments, the reinforcement structure **320** is coupled to the elongate member **132** and distinct positions along the length of the elongate member **132** and/or the reinforcement structure **320**. In one embodiment, for example, the reinforcement structure **320** can be coupled to the elongate member **132** at one or both of the proximal end **322** of the reinforcement structure **320** and the distal end **324** of the reinforcement structure **320** and/or at one or both of the first end **134** and the second end **136** of the elongate member **132**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via one or several other components of the valve **104**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via the compression of the reinforcement structure **320** and the elongate member **132** between the housing **128** and one or both of the proximal **116** and the distal **120**.

In some embodiments, the reinforcement structure **320** can be adhered to the elongate member **132** via, for example, an adhesive such as silicone adhesive. In some embodiments, the adhesive can be circumferentially applied to the reinforcement structure **320** and/or the elongate member **132** in an adhesive ring that can, for example, a have a length approximately between: 0.010 inches and 0.5 inches; 0.02 and 0.4 inches; 0.050 inches and 0.0250 inches, or any other or intermediate range.

In one embodiment, each of the proximal end **322** and the distal end **324** of the reinforcement structure **320** can be adhered via an adhesive to the elongate member **132**. In such an embodiment, the reinforcement structure **320** may be uncoupled to the elongate member **132** at positions other than the coupling at one or both of the proximal end **322** and the distal end **324** of the reinforcement structure **320**, and thus the reinforcement structure **320** is uncoupled to the elongate member **132** at a position between the first end **134** and the second end **136** of the elongate member **134** and/or between the proximal end **322** and the distal end **324** of the reinforcement structure **320**.

The lack of coupling of the reinforcement structure **320** to the elongate member **132** can facilitate and improve the collapse of the elongate member **132** around a tool **400**, also referred to herein as instrument **400** or device **400**, inserted through the valve **104** as shown in FIG. **4**. The tool **400** can be any device inserted through the valve **104** including, for example, one or several additional catheters, lines, wires, grippers, punches, cutters, or the like. As seen in FIG. **4**, the tool **400** is inserted through the valve **104** and specifically through the elongate member **132** of the valve. As shown, the constricting mechanism **141** is in the first configuration and the elongate member **132** and the central lumen **138** of the elongate member **132** is collapsed around the tool **400**, and specifically around a shaft **402** of the tool **400** to thereby seal the valve **104** around the tool **400** and specifically around the shaft **402** of the tool **400**. The constricting mechanism **141** can seal around tools **400** that fit through the elongate member **132**, regardless of the size of the tool **400**. Thus, the valve can be used with a wide variety of tools.

The reinforcement structure **320** can comprise a variety of designs, shapes, sizes, and materials. In some embodiments, the reinforcement structure **320** can be sized and shaped so as to receive elongate member **132** and to be positioned between the elongate member **132** and the at least one filament **150**. In some embodiments, the reinforcement structure **320** can be made from a material sufficiently strong to prevent the cutting of the at least one filament **150** through the elongate member **132**.

In some embodiments, the reinforcement structure can comprise a coil or a mesh sheath. The mesh sheath can, in some embodiments, comprise a braided mesh. The braided mesh can be made from any desired number of wires in any desired configuration. In some embodiments, the braided mesh can comprise a 4 wire braided mesh, an 8 wire braided mesh, a 12 wire braided mesh, a 16 wire braided mesh, a 20 wire braided mesh, a 24 wire braided mesh, a 32 wire braided mesh, a 48 wire braided mesh, a 64 wire braided mesh, a 72 wire braided mesh, an 80 wire braided mesh, a 96 wire braided mesh, or any other or intermediate braided mesh. In some embodiments, the braided mesh can comprise: a 1×1 configuration. In some embodiments, the wire in the braided mesh can be any desired material including, for example, a metal wire such as a nitinol wire or a stainless steel wire, a polymer wire, or a natural wire. In one embodiment, the braided mesh can comprise a 48 wire mesh in a 1×1 configuration made with a nitinol wire having a diameter of 0.003 inches.

With reference now to FIGS. **6** through **9**, different embodiments and/or configurations of the filament **150** are shown. The filament **150** can comprise a single filament **150** having a first end **600** and a second end **602** as shown in FIG. **6**. The filament **150**, and specifically which first and second ends **600**, **602** can be coupled to the actuator **142** to move the filament **150** between the first and second configurations or positions and/or from the first configuration or position to the second configuration or position. In some embodiments, both of the first end **600** and the second end **602** can be coupled to a single button **144**, in some embodiments, each of the first end **600** and the second end **602** can be coupled to different buttons **144**, and in some embodiments, one of the first end **600** and the second end **602** can be coupled to a button **144** and the other of the first end **600** and the second end **602** can be coupled to the housing **128** or other portion of the valve **104**.

In some embodiments, the filament **150** can comprise multiple filaments, and specifically, as shown in FIGS. **7** through **9**, the filament **150** can comprise a first filament **150**-A and a second filament **150**-B. In embodiments in which the filament **150** comprises multiple filaments, each of the multiple filaments can have a first end **700** and a second end **702**. The first and second filaments **150**-A,

150-B can be coupled to the actuator 142. In such embodiments, the first and second ends 700, 702 can be coupled to the actuator 142 to move the filaments 150-A, 150-B between the first and second configurations and/or from the first configuration to the second configuration. In some embodiments, both of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to a single button 144, in some embodiments, each of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to different buttons 144, and in some embodiments, one of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to one button 144 and the other of the first end 700 and the second end 702 of those one or more filaments 150 can be coupled to the housing 128 or other portion of the valve 104.

The filament 150 can be arranged in a variety of configurations. In some embodiments, the filament 150 can be configured to form a single loop 604 that can extend around the elongate member 132 and/or through which the elongate member 132 can be received as shown in FIG. 6, and in some embodiments, the filament 150 can be configured to form multiple loops, and specifically a first loop 704 and a second loop 706 as shown in FIG. 7. The first and second loops 704, 706 can each receive the elongate member 132. In some embodiments, a diameter or size of the loop 604, or of the loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.

In some embodiments, the filament 150 can be configured to form a bight 800, which bight 800 can be a single bight or multiple bights. As used herein, a "bight" refers to a U-shaped section between the two ends of the filament 150. As depicted in FIGS. 8 and 9, the bight 800 can comprise multiple bights, and specifically a first bight 800-A and a second bight 800-B. In some embodiments, the first bight 800-A can extend through the second bight 800-B such that the first and second bights 800-A, 800-B interlock, whereas in other embodiments, the first and second bights 800-A, 800-B can be non-interlocking. Similarly, in embodiments containing the filament 150 having multiple loops, one or several of the multiple loops can be interlocking.

In some embodiments, the bight 800, and specifically one or both of the first bight 800-A and the second bight 800-B can be formed around a portion of the elongate member 132 and/or can extend around a portion of the elongate member 132. Each bight 800 can define a partially enclosed receiving area 808 wherein the elongate member 132 can be received. Thus, the first bight 800-A can define a first receiving area 808-A and the second bight 800-B can define a second receiving area 808-B.

As seen in FIGS. 8 and 9, multiple bights, and specifically the first and the second bights 800-A, 800-B can be positioned and oriented such that the first bight 800-A has a first orientation or first direction as indicated by arrow 810, and the second bight has a second orientation or second direction as indicated by the arrow 812. In some embodiments, the first orientation is different from the second orientation such that the first and second receiving areas 808-A, 808-B overlap and define an encircled area 814, also referred to herein as a constricting area 814. The elongate member 132 can be received within the encircled area 814. In embodiments in which bights 800-A, 800-B overlap to define the encircled area 814, the movement of the constricting mechanism 141 to the first configuration can result in and/or include the first bight 800-A moving in the direction indicated by the arrow 810 and/or the second bight 800-B moving in the direction indicated by the arrow 812, which movement of the bights 800-A, 800-B decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area 814.

The filament(s) 150 forming the bights 800 can each apply an arcuate line or narrow longitudinal zone of pressure to the elongate member 132. If the filament(s) are circular in cross-section, the zone of pressure can be very small, and can, in some embodiments, be less than the diameter or thickness of the filament. In some embodiments, the filaments have a diameter or width less than about 2.5 mm, less than about 2 mm, less than about 1.5 mm, less than about 1.25 mm, less than about 1 mm, less than about 0.75 mm, less than about 0.5 mm, and/or less than about 0.25 mm. In some embodiments, the filaments can have a diameter or width of between about 0.01 mm and 2.5 mm, between about 0.05 mm and 2 mm, between about 0.1 mm and 1 mm, and/or between about 0.125 mm and 0.70 mm. In some embodiments, the arcuate line or zone of pressure may form two opposing arcs and in other embodiments, the arcuate line of pressure may be a singular substantially circular line or zone that encircles the elongate member at least once. The longitudinal length of the of the line or zone of pressure may be very short compared to other valves known in the art. In some embodiments, the longitudinal length of the zone of pressure applied to the elongate member 132 by the filament(s) 150 may be less than about 2.0 mm and in some embodiments less than about 0.5 mm. In some embodiments, the filament(s) 150 can have any desired cross-sectional shape including, for example, a circular cross-section, a rectangular cross-section, an oval cross-section, a square cross-section, a polygonal cross-section, a triangular cross-section, or any other desired shape of cross-section.

With reference now to FIG. 10, a flowchart illustrating one embodiment of a process 1000 for sealing a valve 104 and/or catheter 102 accessing a body of a patient is shown. The process 1000 can be performed using the valve 104 and/or the delivery system 100. The process 1000 begins at block 1002, wherein the delivery device 100, and specifically the catheter 102 of the delivery device 100 is inserted into the body of the patient. In some embodiments, this can include inserting the catheter 102 into a portion of the circulator system of the patient such as, for example, a blood vessel including an artery or a venous vessel. In some embodiments, the delivery device 100 can be inserted into the body of the patient directly through an aperture or incision in the patient, and in some embodiments, the delivery device 100 can be inserted into the body of the patient via another catheter or device. In some embodiments, the constricting mechanism 141 can be in the first configuration while the delivery device 100 and/or the catheter 102 is inserted into the patient's body.

After the delivery device 100 is inserted into the body of the patient, the process 1000 proceeds to block 1004, wherein the constricting mechanism 141 is moved from the first configuration to the second configuration. As described above, the central lumen 138 of the elongate member 132 is unsealed when the constricting mechanism 141 is in the second configuration. In some embodiments, the moving of the constricting mechanism 141 from the first configuration to the second configuration can include the manipulation of the actuator 142 and/or the control of the actuator 142, and specifically the depressing of the one or several buttons 144 to move the filament 150 from the first position to the second position to allow the expansion and opening of the central lumen 138 of the elongate member 132.

After the constricting mechanism **141** is moved from the first configuration to the second configuration, the process **1000** proceeds to block **1006**, wherein the tool **400**, and specifically the shaft **402** of the tool **400** is advanced through the delivery device **100** and specifically through the valve **104** until a first end of the tool reaches a desired position within the body of the patient. In some embodiments, a portion of the shaft **402** can be positioned within the central lumen **138** of the elongate member **132** after the advancing of the tool **400** through the delivery device **100**. In some embodiments, after the tool **400** is advanced through the delivery device **100**, the desired procedure can be performed with the tool.

After the tool **400** is advanced through the delivery device **100**, or while the tool **400** is being advanced through the delivery device **100**, the process **1000** proceeds to block **1008**, wherein the constricting mechanism **141** is returned to the first configuration. In some embodiments, the returning of the constricting mechanism **141** to the first configuration can include the release of the one or several buttons **144** and/or the control of the actuator **142** to reconfigure the constricting mechanism **141** to the first configuration. In some embodiments, the return of the constricting mechanism **141** to the first configuration can result in the collapse and/or sealing of the elongate member **132** and specifically the central lumen **138** of the elongate member **132** around the tool **400** and specifically around the shaft **402** of the tool **400**. The return of the constricting mechanism **141** to the first configuration, or the movement of the constricting mechanism **141** to the first configuration can include the decreasing of the size and/or diameter of one or several loops formed by the filament **150** and/or the movement of one or several bights **800** such as, for example, the movement of the first bight **800**-A in the first direction indicated by arrow **810** and the movement of the second bight **800**-B in the second direction indicated by arrow **812** to reduce the size of the constricting area **814**. In some embodiments, after the constricting mechanism is returned to the first configuration, the desired procedure can be performed with the tool.

After the constricting mechanism is returned to the first configuration, the process **1000** proceeds to block **1010**, wherein the tool **400**, and specifically the shaft **402** of the tool **400** is retracted from the delivery device **100**, and more specifically from the valve **104**. In some embodiments, the valve **104** can remain sealed during the retracing of the tool **400** and/or the shaft **402** of the tool. In some embodiments, the valve **104** remains sealed during the retracting of the tool **400** and/or the retracting of the shaft **402** of the tool **400** as the constricting mechanism **141** can remain in the first configuration during the retracing of the tool **400** and/or the shaft **402** of the tool **400**.

In some embodiments, the constricting mechanism **141** can be moved to the second configuration to allow the retraction of the tool **400** and/or the shaft **402** of the tool **400** from the valve **104**, and the constricting mechanism **141** can be returned to the first configuration when the tool **400** and/or the shaft **402** of the tool **400** is removed from the valve **104**. In some embodiments, the retraction of the tool **400** and/or shaft **402** of the tool **400** from the valve **104** can be performed with the constricting mechanism **141** left in the first configuration. In some embodiments, the constricting mechanism **141** can be moved to the second configuration, and then returned to the first configuration via the manipulation and/or control of the actuator **142**, which manipulation and/or control of the actuator **142** can include the depressing of the one or several buttons **144** to move the constricting mechanism **141** to the second configuration, and the release of the one or several buttons **144** to return the constricting mechanism **141** to the first configuration. In some embodiments, if the procedure is complete, the delivery device **100** can then be removed from the body of the patient, and any incision created for the procedure can be closed.

With reference now to FIG. **11**, a side view of one embodiment of a thrombectomy system **1100** including the delivery device **100** and a thrombus extraction device **1102** is shown. In some embodiments, the thrombectomy system **1100** can be used to access a blood vessel **1104** to treat and/or extract a thrombus **1106** from the blood vessel **1104**. The thrombus extraction device **1102** can include a self-expanding coring element **206** and expandable cylindrical portion **208**. In some embodiments, and as shown in FIG. **11**, the thrombus extraction device **1102** can be the tool **400** that can extend through the valve **104**, and in some embodiments, the valve **104** can be a part of the thrombus extraction device **1102**. Further details of thrombectomy systems, thrombus extraction devices, and methods of using the same are disclosed in: U.S. application Ser. No. 15/268,296, filed Sep. 16, 2016, and entitled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS"; U.S. application Ser. No. 15/498,320, filed Apr. 26, 2017, and entitled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION"; and U.S. application Ser. No. 15/466,740, filed on Mar. 22, 2017, and entitled "DEVICE AND METHOD FOR TREATING VASCULAR OCCLUSION", the entirety of each of which is hereby incorporated by reference herein.

With reference now to FIG. **12**, a side-section view of another embodiment of the hemostasis valve **104** having two piece caps **116**, **120** is shown. The valve **104** can include a housing **128** defining an interior channel **130** through which the tubular member **132** can extend. The valve **104** can include the proximal cap **116** and the distal cap **120**. In some embodiments, the proximal cap **116** can comprise a two piece cap and can include a proximal exterior member **1200** and a proximal channel member **1202**. In some embodiments, the distal cap **120** can comprise a two-piece cap and can include a distal exterior member **1204** and a distal channel member **1206**. In some embodiments, this coupling between the proximal exterior member **1200** and the proximal channel member **1202** and/or the coupling between the distal exterior member **1204** and the distal channel member **1206** can be a sealed coupling so as to prevent the leakage of material including fluid or gas between the respective ones of the proximal exterior member **1200** and the proximal channel member **1202** and/or the distal exterior member **1204** and the distal channel member **1206**. In some embodiments, this sealing coupling can be achieved and/or maintained via a seal such as an O-ring **1208** that can be positioned between the proximal exterior member **1200** and the proximal channel member **1202** and/or between the distal exterior member **1204** and the distal channel member **1206**.

In some embodiments, the proximal exterior member **1200** can be coupled, and in some embodiments, rotatingly coupled to the proximal channel member **1202** in a manner to allow the rotation of the proximal exterior member **1200** without rotating the proximal channel member **1202**. Similarly, in some embodiments, the distal exterior member **1204** can be rotatingly coupled to the distal channel member **1206** in a manner to allow the rotation of the distal exterior member **1204** without the rotating of the distal channel member **1206**. In some such embodiments, the channel

members **1202**, **1206** can be non-rotatable with respect to the housing **128** and/or the tubular member **132**, and one or both of the exterior members **1200**, **1204** can be rotatable with respect to the housing **128** and/or the tubular member **132**. In such an embodiment, the maintaining of the rotational position of the channel members **1202**, **1206** with respect to the housing **128** and/or the tubular member **132** can prevent the twisting of the tubular member **132** which can result in the sealing of the tubular member **132** regardless of the configuration of the constructing mechanism **141**.

The exterior members **1200**, **1204** can comprise a variety of shapes and sizes and can include a variety of features. In some embodiments, one or both of the exterior members **1200**, **1204** can be coupled to, for example, a shaft similar to the shaft **106** shown in FIG. **1**. In some embodiments, for example, the distal exterior member **1204** can be coupled to a shaft **106**, including, for example, can be non-detachably coupled to the shaft **106**. In some embodiments, one or both of the exterior members can include one or several features configured to facilitate coupling with the valve **104**. These one or several features can include, for example, one or several male or female: connectors; couplers; attachment mechanisms; or the like. In some embodiments, these one or several features can facilitate use of the valve with other existing components, instruments, tools, or the like. In some embodiments, for example, one or both of the exterior members **1200**, **1204** can comprise either a male or female luer fitting, and specifically as shown in FIG. **12**, the distal exterior member **1204** can comprise a male luer fitting **1210**.

Several aspects of the present technology are set forth in the following examples.

1. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:
an elongate member having a first end, a second end, and a central lumen extending therebetween, wherein the elongate member is pliable;
a reinforcement structure extending along at least a portion of the elongate member, wherein the reinforcement structure is coupled to the elongate member; and
an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.
2. The hemostatic valve of example 1, wherein the elongate member comprises a compliant polymer tube.
3. The hemostatic valve of example 1 or 2, wherein the tensioning mechanism comprises at least one filament extending at least partially around the elongate member.
4. The hemostatic valve of example 3, wherein the reinforcement structure is positioned between the at least one filament and the elongate member.
5. The hemostatic valve of example 4, wherein the reinforcement structure comprises a braided mesh.
6. The hemostatic valve of example 4 or 5, wherein the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member.
7. The hemostatic valve of example 6, wherein the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member.
8. The hemostatic valve of any one of examples 3-7, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein the actuator is moveable to control movement of the at least one filament from a first position wherein the central lumen is constricted and sealed to a second position wherein the central lumen is open, wherein the at least one filament is in the first position when the tensioning mechanism is in the first configuration.
9. The hemostatic valve of example 8, wherein the actuator is biased towards the first position.
10. The hemostatic valve of example 8 or 9, wherein the actuator is biased toward the second position.
11. The hemostatic valve of any one of examples 8-10, wherein the actuator comprises a manual actuator.
12. The hemostatic valve of any one of examples 8-11, wherein the at least one filament forms a loop around the elongate member.
13. The hemostatic valve of any one of examples 8-12, wherein the at least one filament forms a bight around a portion of the elongate member.
14. The hemostatic valve of any one of examples 8-13, wherein the at least one filament comprises a first filament and a second filament, wherein each of the first filament and the second filament are coupled to the actuator, and wherein the first filament and the second filament are moveable from the first position to the second position.
15. The hemostatic valve of example 14, wherein each of the first filament and the second filament form a loop around the elongate member.
16. The hemostatic valve of example 14 or 15, wherein the first filament forms a first bight around a first portion of the elongate member, and wherein the second filament forms a second bight around a second portion of the elongate member.
17. The hemostatic valve of example 16, wherein the first bight extends through the second bight.
18. The hemostatic valve of any one of examples 1-17, further comprising a shell defining a first aperture and a second aperture, wherein the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture.
19. The hemostatic valve of any one of examples 1-18, wherein the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve.
20. The hemostatic valve of any one of examples 1-19, wherein the central lumen comprises a single lumen.
21. The hemostatic valve of any one of examples 1-20, wherein the central lumen comprises a plurality of lumens.
22. A delivery system for intravascular access of a blood vessel within a patient's body, the delivery system comprising:
a catheter having a first end, a second end, and a catheter lumen extending therebetween;
a hemostatic valve coupled to the first end of the catheter, the hemostatic valve comprising:
a tubular member having a first end, a second end, and a central lumen extending therebetween, wherein the central lumen of the tubular member is fluidly coupled with the catheter lumen; and
an active tensioning mechanism coupled to the tubular member, the tensioning mechanism moveable between a first configuration wherein the tensioning mechanism constricts on the central lumen and the

central lumen is sealed and a second configuration wherein the central lumen is open.

23. The delivery system of example 22, wherein the hemostatic valve further comprises a reinforcement structure extending along at least a portion of the tubular member.

24. The delivery system of example 22 or 23, wherein the reinforcement structure is located between the tensioning mechanism and the tubular member.

25. The delivery system of example 24, wherein the reinforcement structure comprises a braided mesh.

26. The delivery system of example 24 or 25, wherein the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member.

27. The delivery system of example 26, wherein the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member.

28. The delivery system of example 27, wherein the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

29. The delivery system of any one of examples 22-28, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member.

30. The delivery system of example 29, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein moving the tensioning mechanism from the first configuration to the second configuration comprises moving the actuator and the thereto coupled at least one filament from a first position to a second position, wherein the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

31. The delivery system of example 30, wherein the actuator comprises a manual actuator.

32. The delivery system of example 31, wherein the actuator comprises a pair of opposing and depressable buttons, wherein the buttons are biased towards an undepressed position.

33. The delivery system of example 31 or 32, wherein the central lumen is sealed when the buttons are in the undepressed position.

34. The delivery system of any one of examples 30-33, wherein the filament comprises a monofilament.

35. The delivery system of any one of examples 30-34, wherein the filament comprises at least one of: a polymer filament; or a metallic filament.

36. The delivery system of any one of examples 22-35, wherein the catheter comprises a thrombus extraction device.

37. A method of sealing a delivery device accessing a blood vessel of a patient, the method comprising:

inserting the delivery device comprising a catheter and a hemostatic valve into the blood vessel of the patient, the catheter having a first end, a second end, and a catheter lumen extending therethrough, and the hemostatic valve coupled to the first end and having a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member, wherein the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel;

moving the tensioning mechanism of the hemostatic valve to a second configuration, wherein the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration;

advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member; and

returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

38. The method of example 37, further comprising retracting the shaft of the tool from the delivery device.

39. The method of example 38, wherein the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device.

40. The method of example 38 or 39, wherein the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and wherein the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

41. The method of any one of examples 37-40, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member, wherein the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration.

42. The method of example 41, wherein the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration.

43. The method of example 41 or 42, wherein the hemostatic valve comprises a reinforcement structure located between the at least one filament and the tubular member.

44. The method of any one of examples 41-43, wherein the at least one filament forms a loop around the elongate member, and wherein moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop.

45. The method of any one of examples 41-44, wherein the filament forms at least one bight around a portion of the elongate member.

46. The method of example 45, wherein the filament comprises a first filament and a second filament, and wherein the at least one bight comprises a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament, wherein the first and second bights overlap to encircle a portion of the tubular member within an constricting area.

47. The method of example 46, wherein moving the tensioning mechanism from the second configuration to the first configuration comprises moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member.

48. The method of any one of examples 37-47, wherein the tensioning mechanism comprises an actuator, and

wherein moving the tensioning mechanism to the second configuration comprises manipulating the actuator.

49. The method of any one of examples 37-48, further comprising applying a vacuum to the delivery device to aspirate material through the catheter, wherein the central lumen remains sealed during the aspiration.

50. The method of any one of examples 37-49, wherein the tool comprises a thrombus extraction device.

51. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:

an elongate member having a first end, a second end, and a central lumen comprising a plurality of lumens extending therebetween, wherein the elongate member is pliable; and

an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.

Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

In the previous description, various embodiments of the present invention are described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

The use of the terms "a" and "an" and "the" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. The term "connected" is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

The invention claimed is:

1. A hemostasis valve, comprising:

a support;

an actuator having at least a first member movably coupled to the support;

a collapsible tubular sidewall defining a lumen carried by the support;

a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and

a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop.

2. The hemostasis valve of claim **1**, further comprising a second member movably coupled to the support.

3. The hemostasis valve of claim **2** wherein the filament further comprises a second end portion extending away from the loop to the second member.

4. The hemostasis valve of claim **3** wherein the first end portion, the loop, and the second end portion are one continuous filament.

5. The hemostasis valve of claim **3** wherein first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to reduce the diameter of the lumen and provide a seal around a device extending through the lumen.

6. The hemostasis valve of claim **3** wherein the first member and the second member are biased in a direction that places the first end portion and the second end portion under sufficient tension to close the lumen.

7. The hemostasis valve of claim **1** wherein the lumen extends along a longitudinal axis, and wherein the direction is a direction away from the longitudinal axis.

8. The hemostasis valve of claim **1** wherein the lumen extends along a longitudinal axis, and wherein the direction is a direction orthogonal to the longitudinal axis.

9. The hemostasis valve of claim **1** wherein the spring is positioned between the first member and the support.

10. The hemostasis valve of claim **1** wherein the first member is a button.

11. The hemostasis valve of claim **10** wherein the direction is a first direction, and wherein the button is depressible in a second direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop.

12. The hemostasis valve of claim **1** wherein the direction is a first direction, and wherein the first member is actuatable in a second direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop.

13. The hemostasis valve of claim **12** wherein the first direction is opposite the second direction.

14. The hemostasis valve of claim **13** wherein the lumen extends along a longitudinal axis, and wherein the first direction and the second direction are orthogonal to the longitudinal axis.

15. The hemostasis valve of claim **1** wherein the actuator further comprises a second member movably coupled to the support, wherein the filament further comprises a second end portion extending away from the loop to the second member, wherein the spring is a first spring, wherein the direction is a first direction, and further comprising a second spring configured to move the second member in a second direction that pulls the second end portion away from the tubular sidewall, reducing the diameter of the lumen in response to reducing the diameter of the loop.

16. The hemostasis valve of claim **15** wherein the first direction is opposite to the second direction.

17. The hemostasis valve of claim **15** wherein the first member is actuatable in the second direction and/or the second member is actuatable in the first direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop.

18. An aspiration catheter system, comprising:

an aspiration catheter defining a lumen and having a proximal end portion; and

a hemostasis valve comprising—

a support;

an actuator having at least a first member movably coupled to the support;

a collapsible tubular sidewall defining a lumen carried by the support, wherein the lumen of the tubular sidewall is selectively fluidly couplable to the lumen of the aspiration catheter;

a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member; and

a spring configured to move the first member in a direction that pulls the first end portion away from the tubular sidewall, reducing a diameter of the lumen in response to reducing a diameter of the loop to fluidly decouple the lumen of the tubular sidewall from the lumen of the aspiration catheter.

19. The aspiration catheter system of claim **1** wherein the direction is a first direction, and wherein the first member is actuatable in a second direction to move the first end portion toward the tubular sidewall to increase the diameter of the lumen in response to increasing the diameter of the loop to fluidly couple the lumen of the tubular sidewall to the lumen of the aspiration catheter.

20. A hemostasis valve, comprising:

a support;

a button movably coupled to the support;

a collapsible tubular sidewall carried by the support and defining a lumen;

a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the button; and

a biasing member positioned between the support and the button, wherein the biasing member is configured to bias the button in a direction that pulls the first end portion away from the tubular sidewall to reduce a diameter of the loop to thereby reduce a diameter of the lumen.

* * * * *

EXHIBIT I

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(12) **United States Patent**
Quick et al.

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(54) **SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS**

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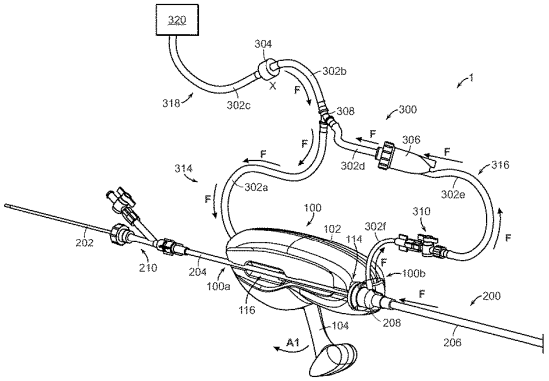
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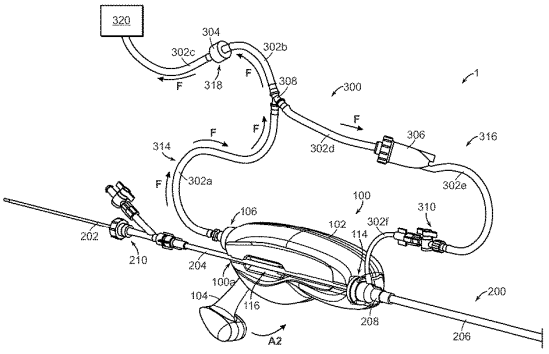
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(57) **ABSTRACT**

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

34 Claims, 20 Drawing Sheets





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See application file for complete search history.

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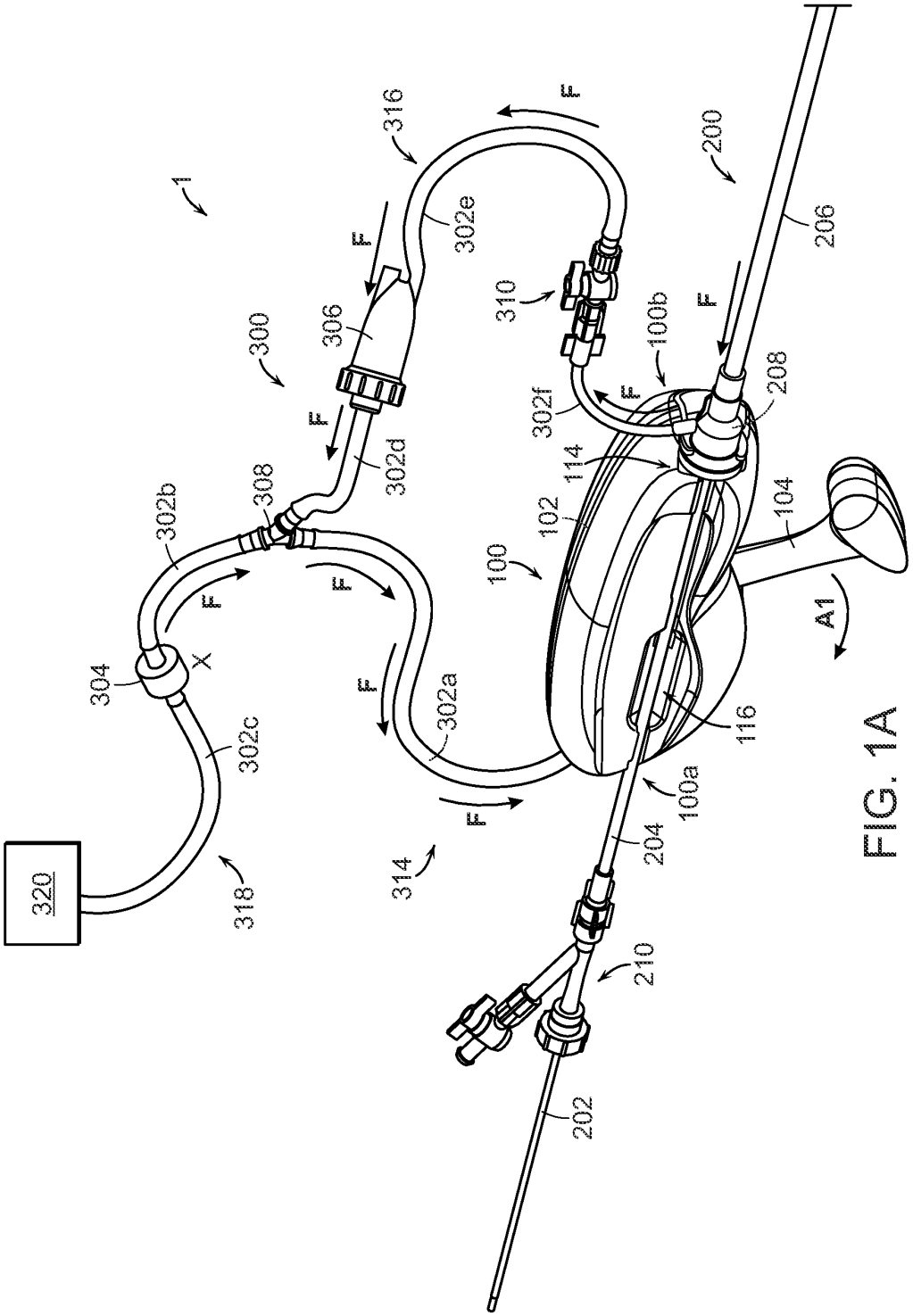

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FIG. 1A

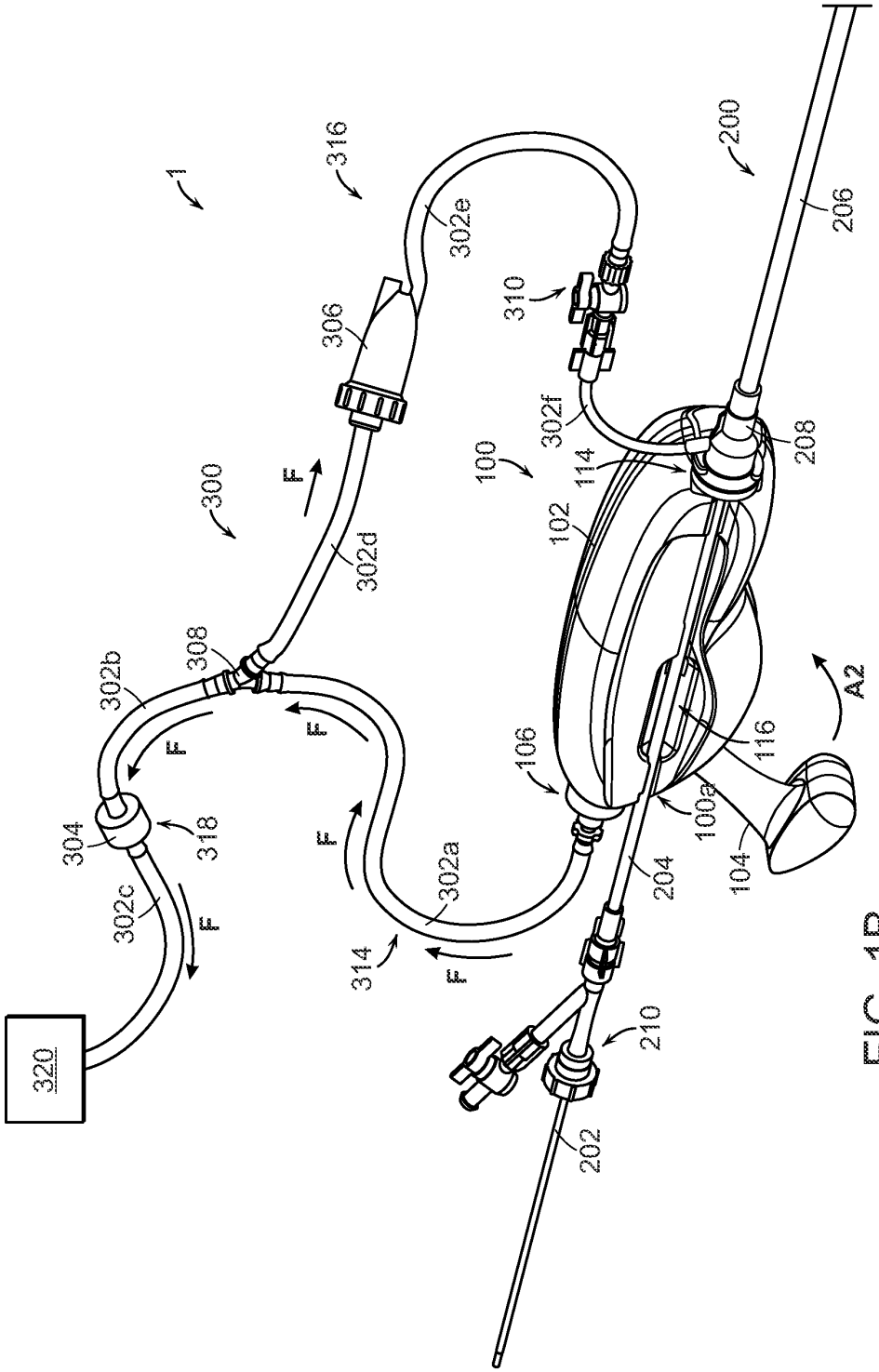

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FIG. 1B

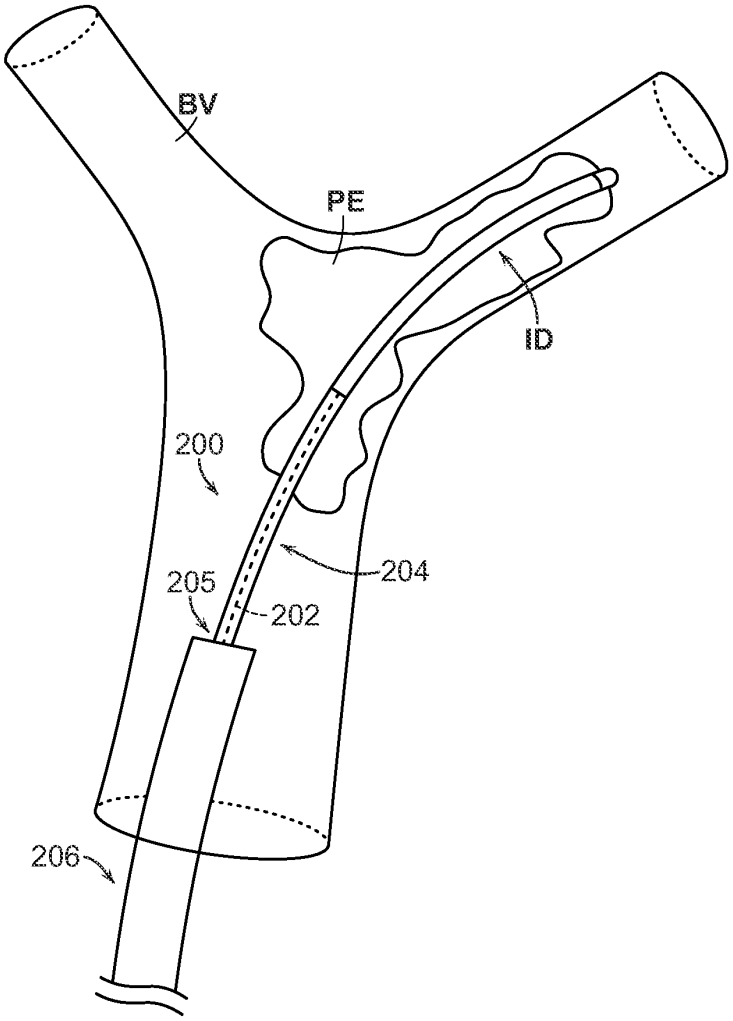


FIG. 2A

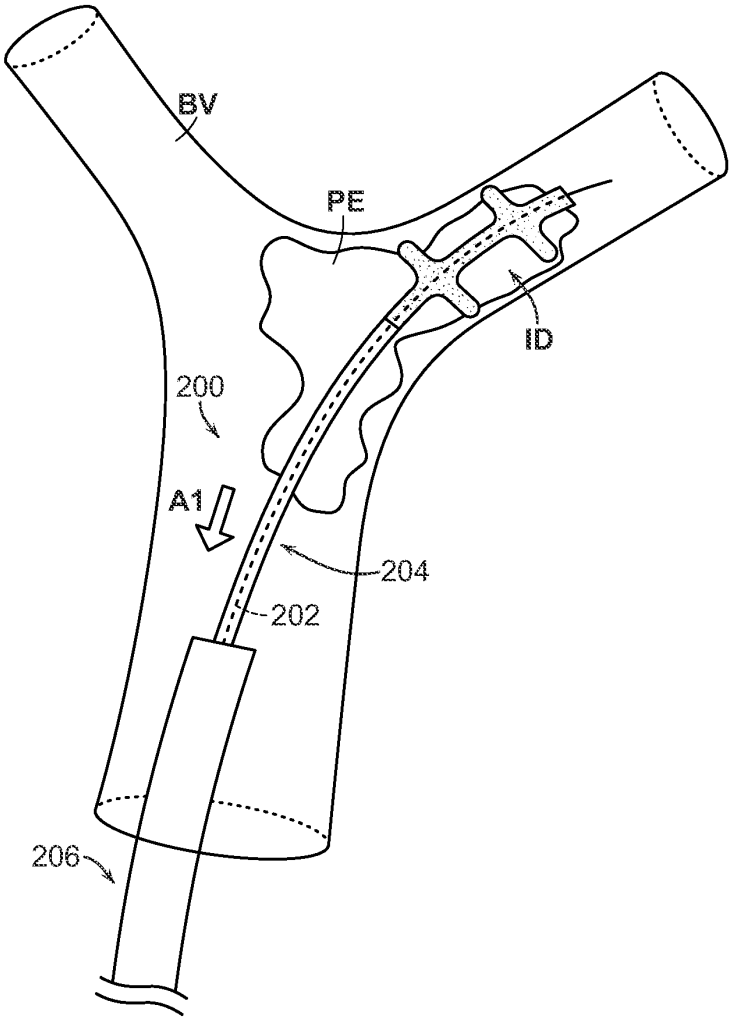


FIG. 2B

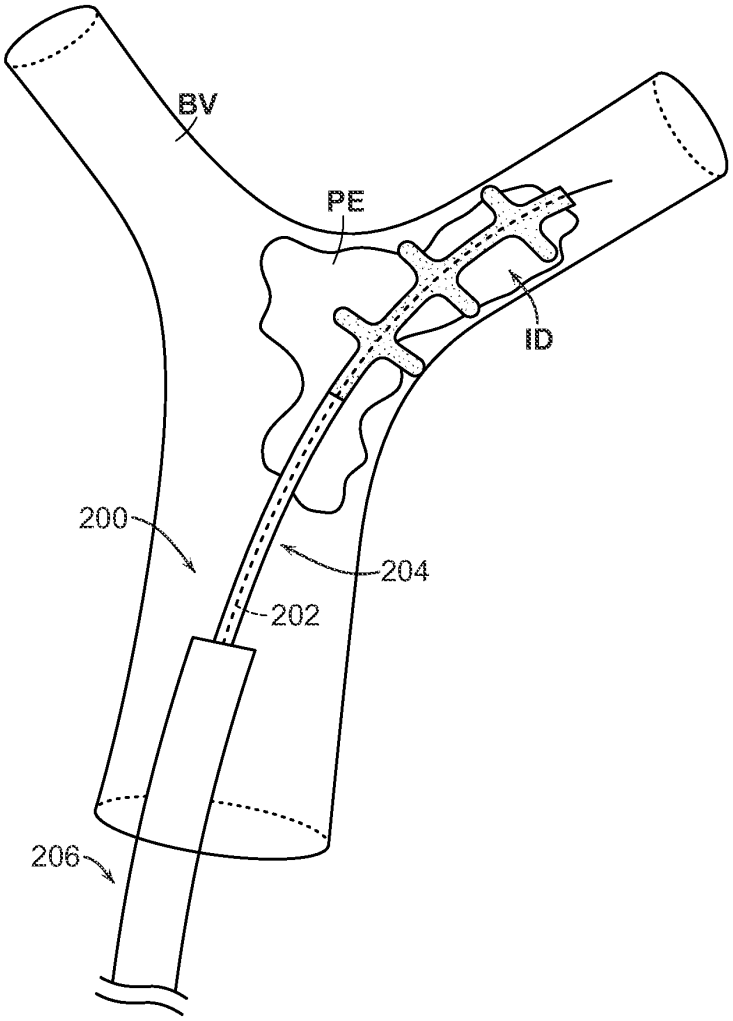


FIG. 2C

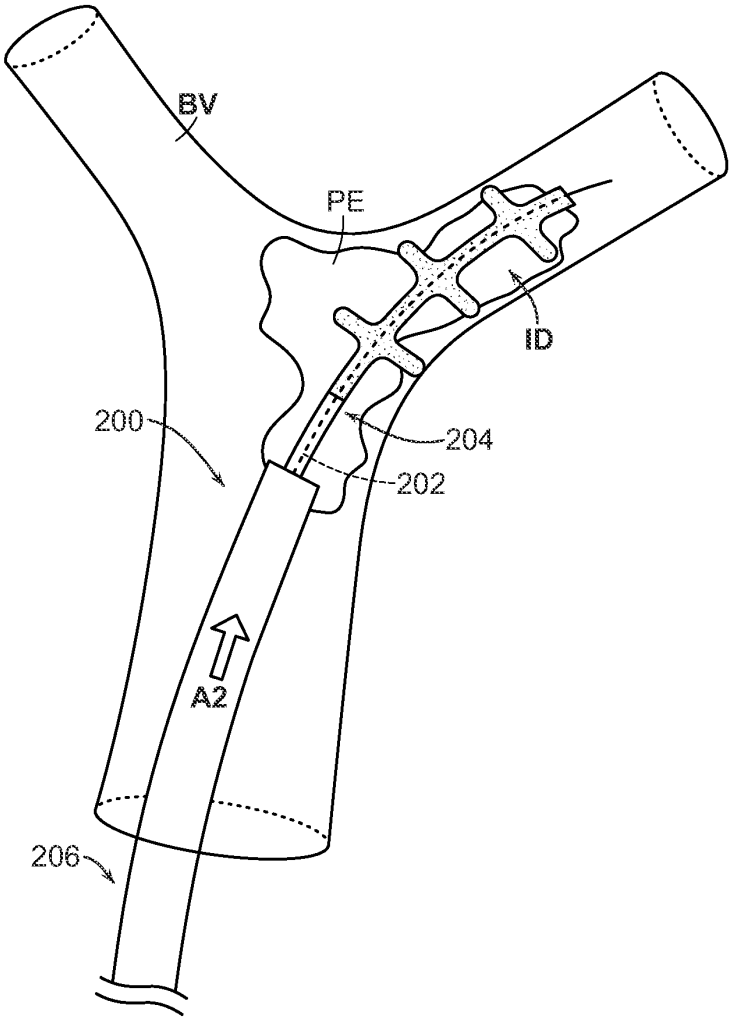


FIG. 2D

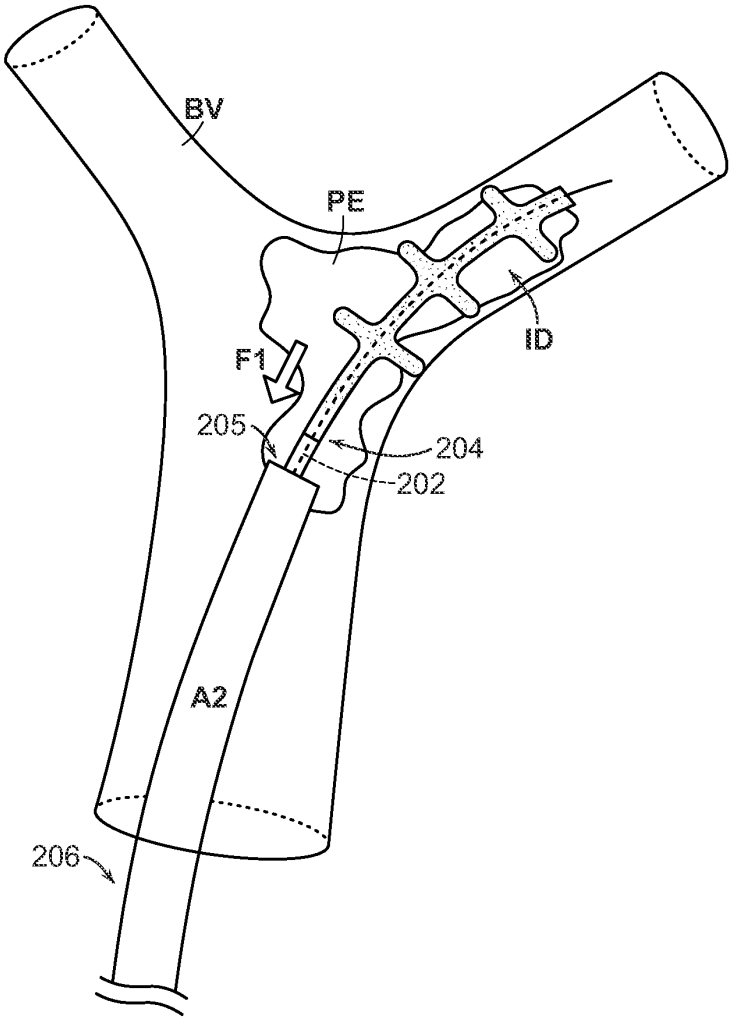


FIG. 2E

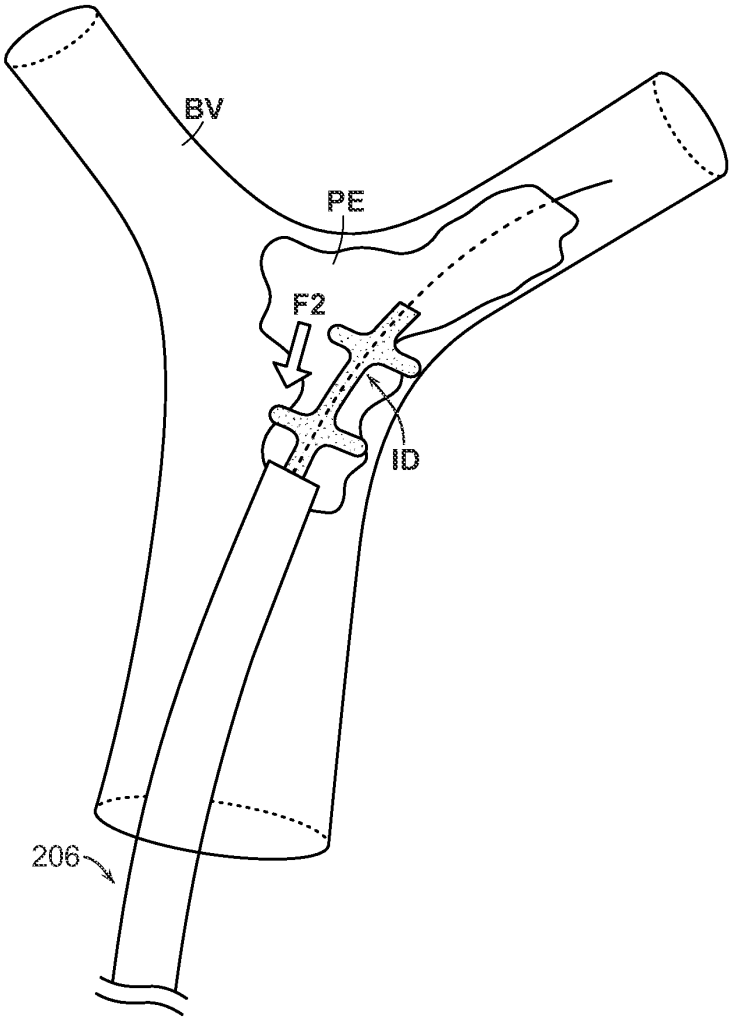


FIG. 2F

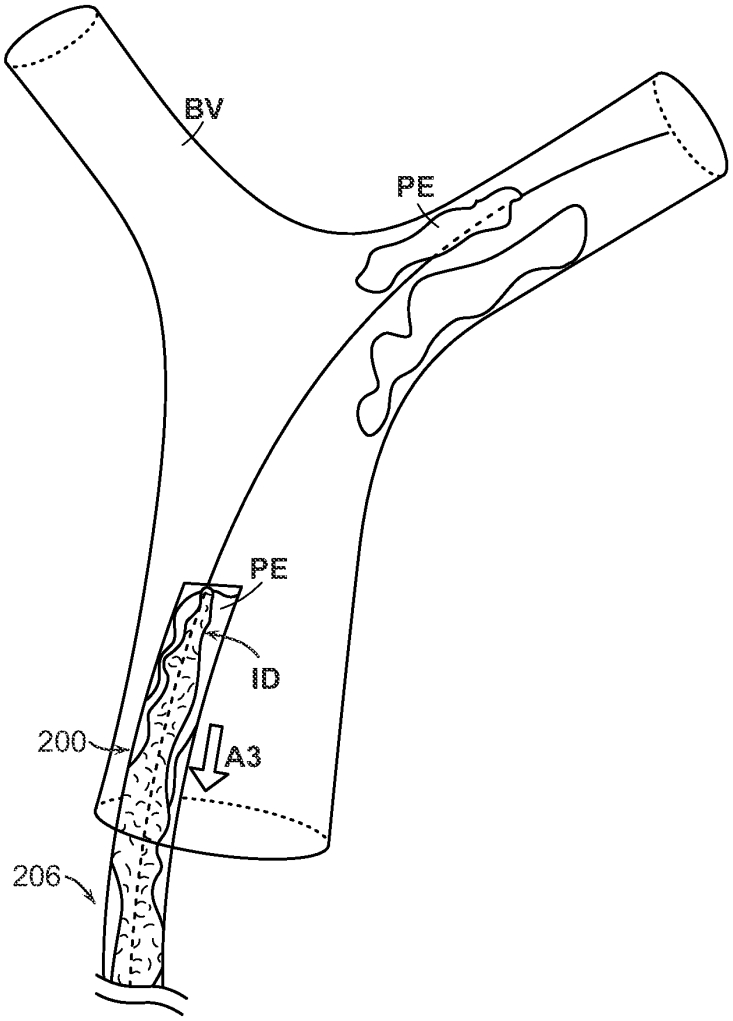


FIG. 2G

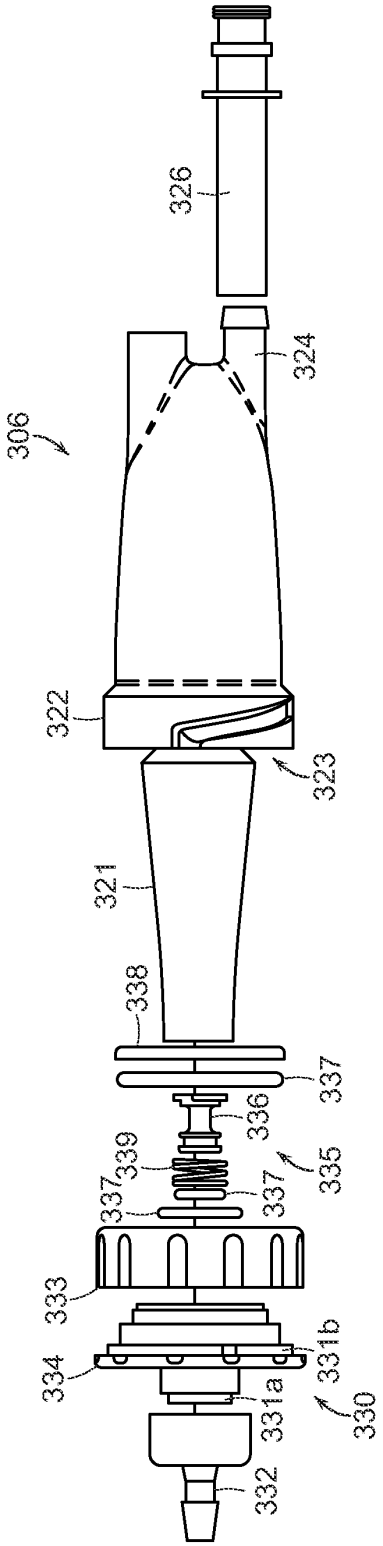

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FIG. 3A

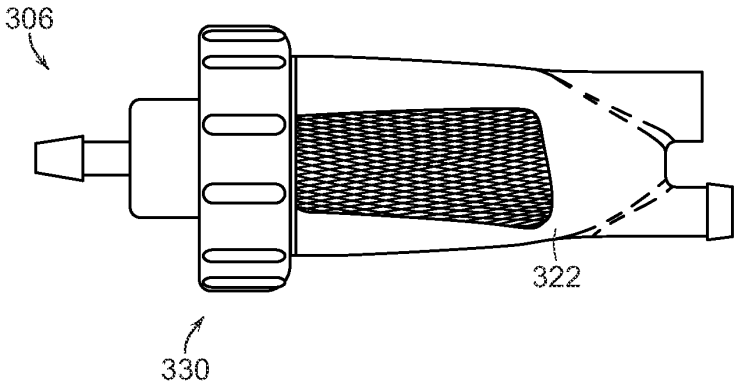


FIG. 3B

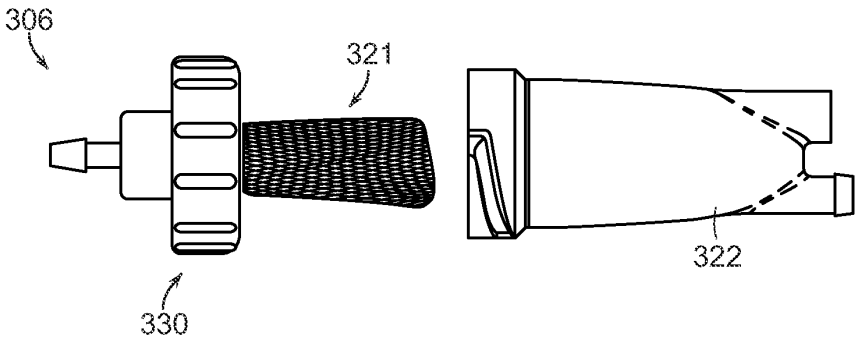


FIG. 3C

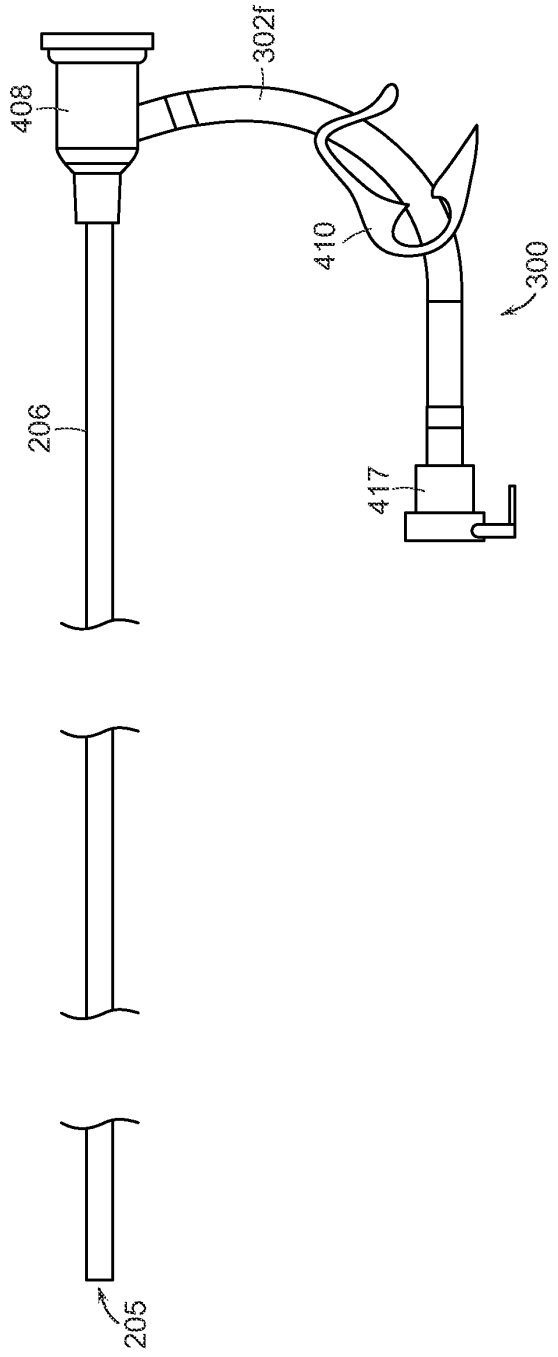


FIG. 4

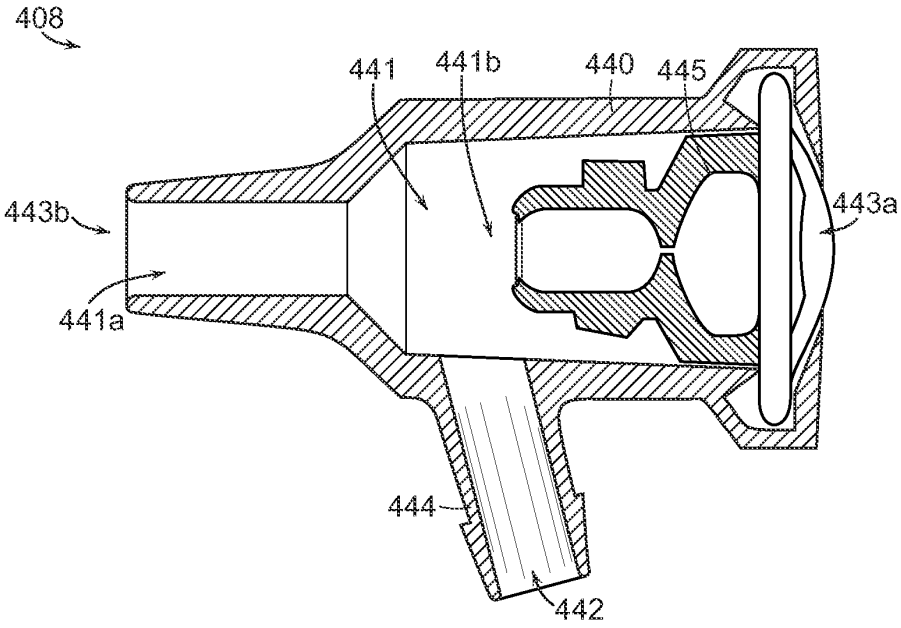

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FIG. 5

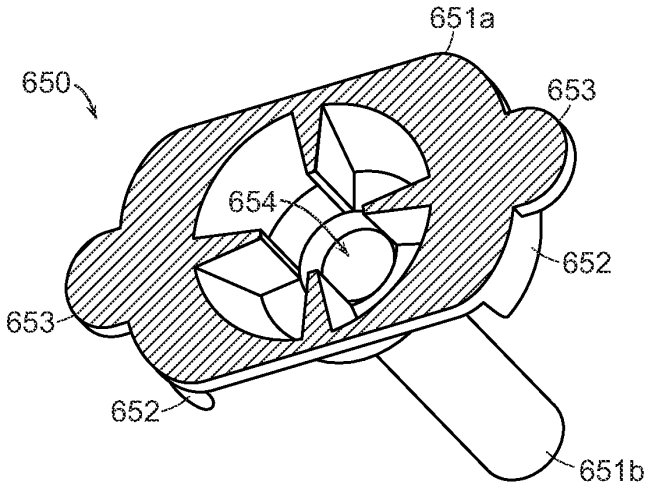

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FIG. 6

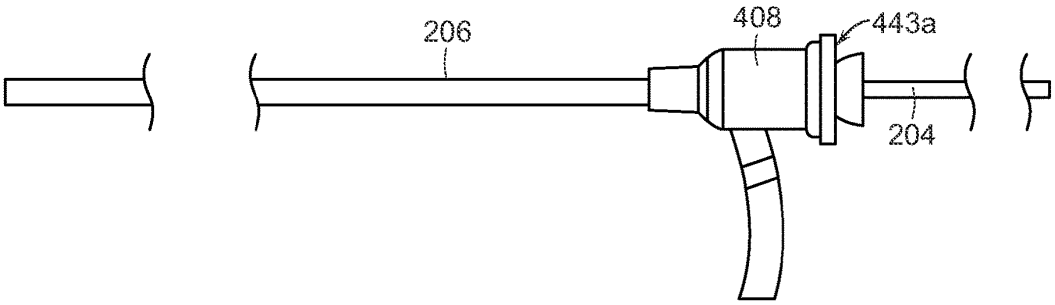

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FIG. 7A

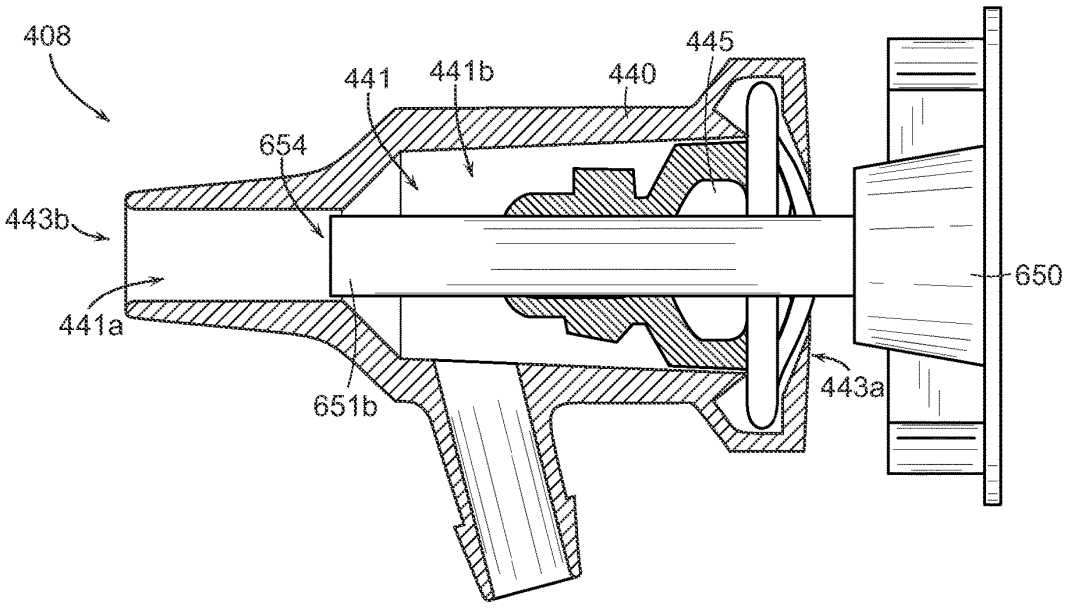

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FIG. 7B

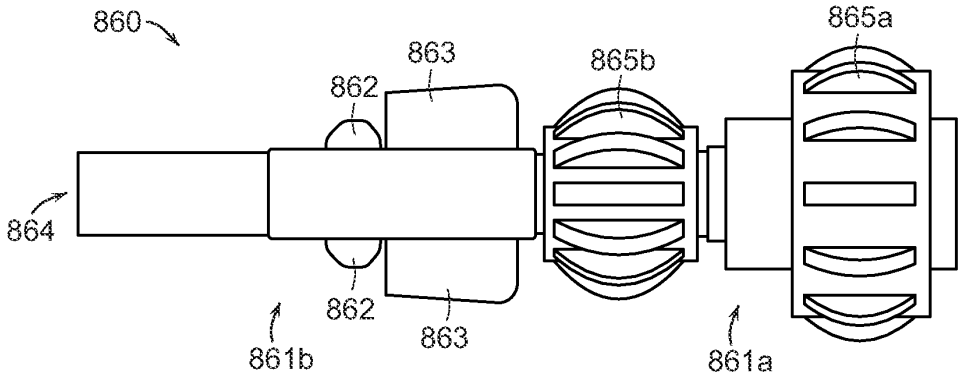


FIG. 8

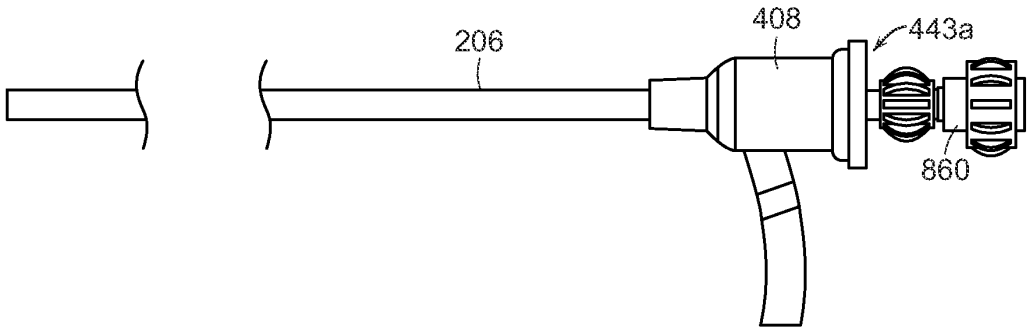


FIG. 9

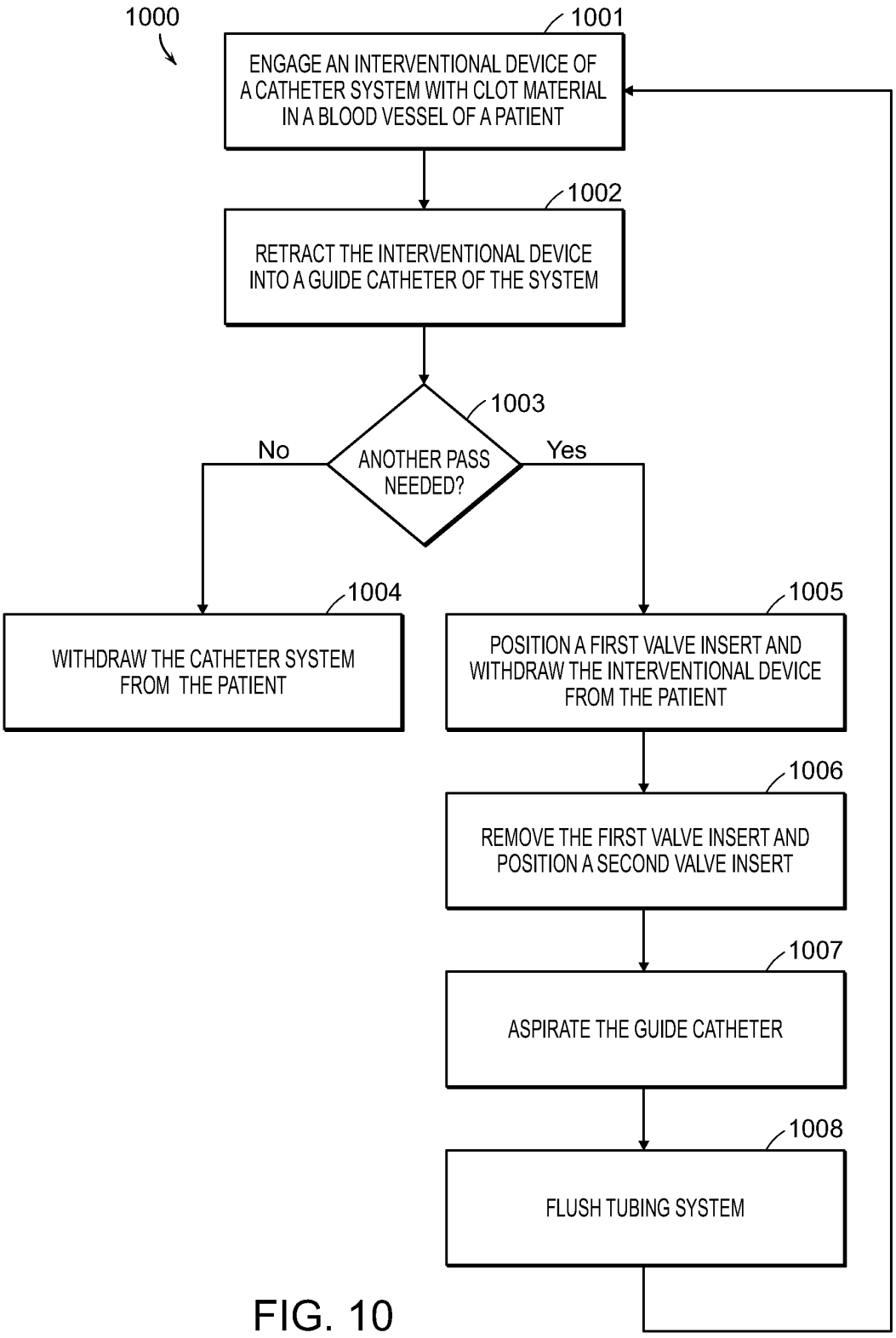

1000
1001
ENGAGE AN INTERVENTIONAL DEVICE OF A CATHETER SYSTEM WITH CLOT MATERIAL IN A BLOOD VESSEL OF A PATIENT
1002
RETRACT THE INTERVENTIONAL DEVICE INTO A GUIDE CATHETER OF THE SYSTEM
1003
ANOTHER PASS NEEDED?
No
Yes
1004
WITHDRAW THE CATHETER SYSTEM FROM THE PATIENT
1005
POSITION A FIRST VALVE INSERT AND WITHDRAW THE INTERVENTIONAL DEVICE FROM THE PATIENT
1006
REMOVE THE FIRST VALVE INSERT AND POSITION A SECOND VALVE INSERT
1007
ASPIRATE THE GUIDE CATHETER
1008
FLUSH TUBING SYSTEM

FIG. 10

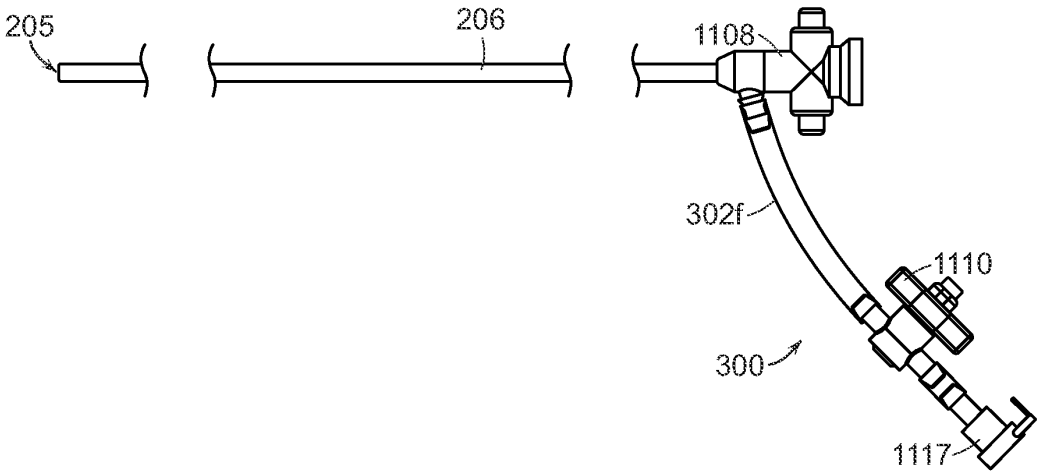


FIG. 11

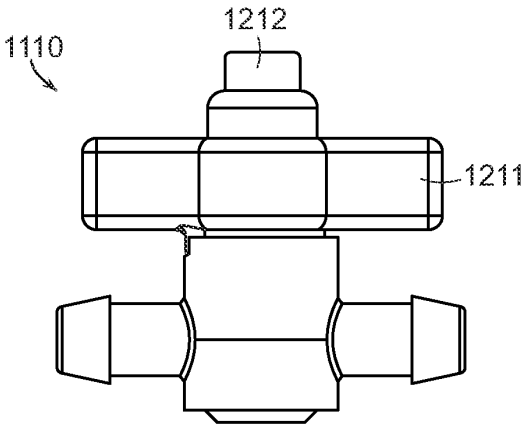


FIG. 12

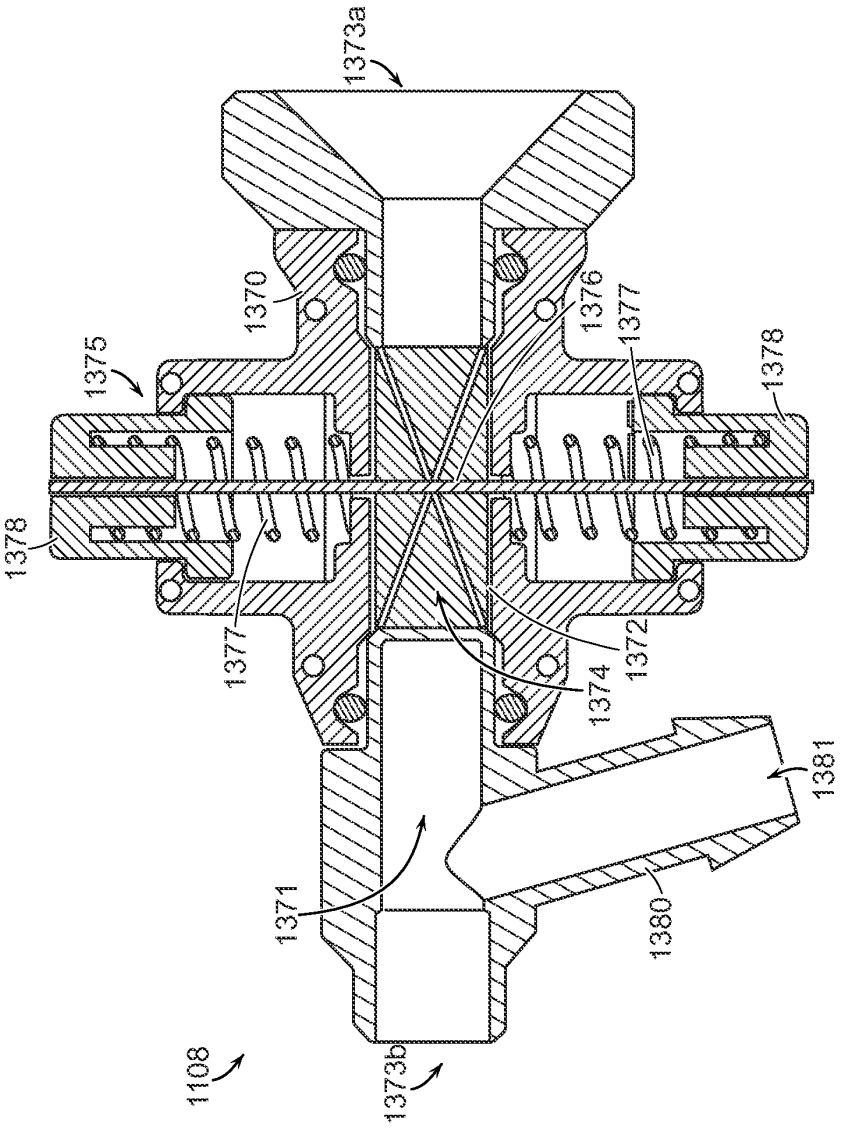

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FIG. 13A

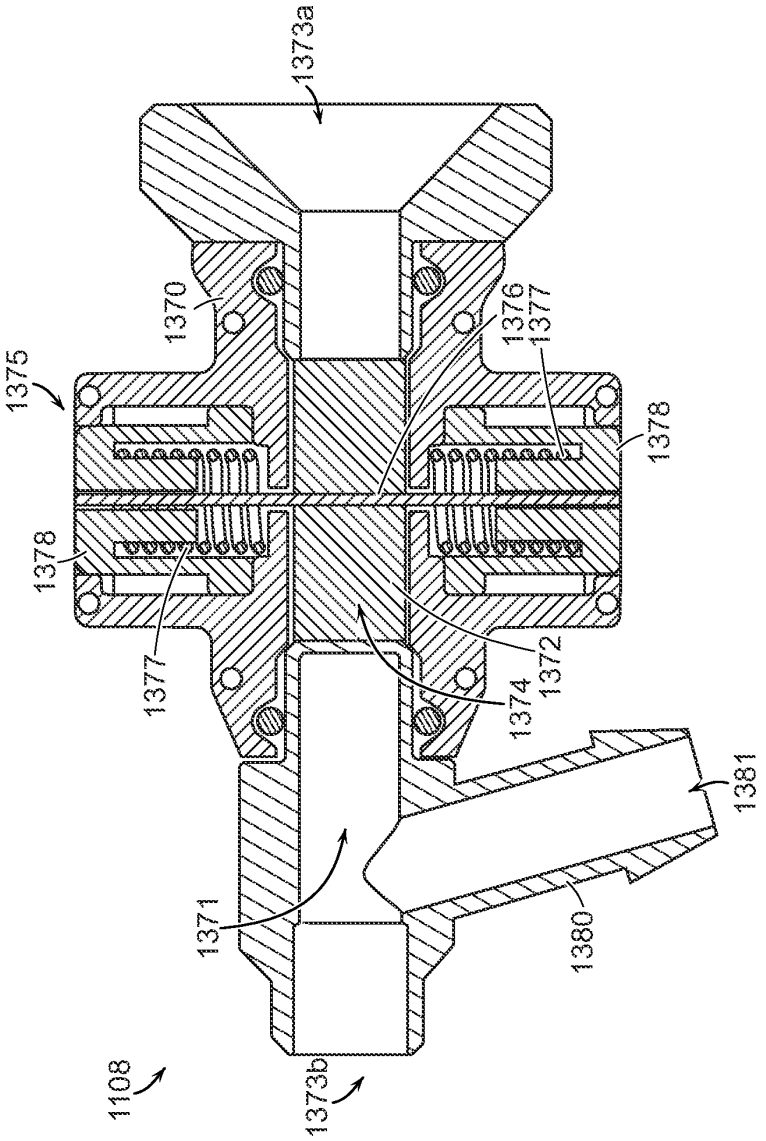

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FIG. 13B

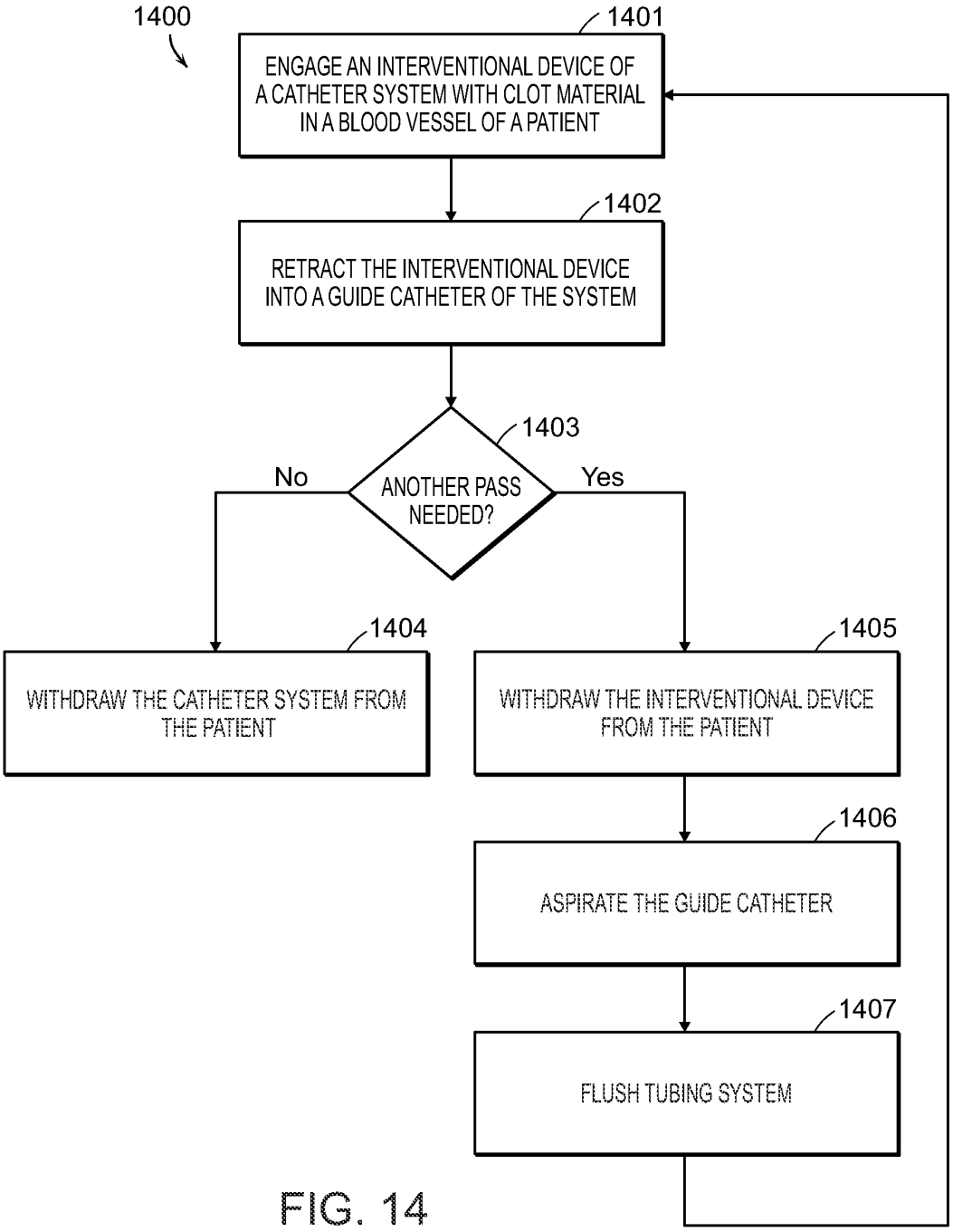

1400
1401
ENGAGE AN INTERVENTIONAL DEVICE OF A CATHETER SYSTEM WITH CLOT MATERIAL IN A BLOOD VESSEL OF A PATIENT
1402
RETRACT THE INTERVENTIONAL DEVICE INTO A GUIDE CATHETER OF THE SYSTEM
1403
ANOTHER PASS NEEDED?
No
Yes
1404
WITHDRAW THE CATHETER SYSTEM FROM THE PATIENT
1405
WITHDRAW THE INTERVENTIONAL DEVICE FROM THE PATIENT
1406
ASPIRATE THE GUIDE CATHETER
1407
FLUSH TUBING SYSTEM

FIG. 14

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

CROSS-REFERENCE TO RELATED APPLICATION

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

TECHNICAL FIELD

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

BACKGROUND

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.

When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenos after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clot material.

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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.

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

FIGS. **2**A-**2**G are schematic illustrations of a distal portion of the retraction and aspiration system during a clot removal procedure in accordance with embodiments of the present technology.

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

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

FIG. **5** is a side cross-sectional view of the attachment member shown in FIG. **4**.

FIG. **6** is an isometric view of a first valve insert in accordance with embodiments of the present technology.

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

FIG. **8** is a side view of a second valve insert in accordance with embodiments of the present technology.

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

FIG. **10** is a flow diagram of a process or method for operating the retraction and aspiration system in accordance with embodiments of the present technology.

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

FIG. **12** is a side view of the fluid control unit shown in FIG. **11** in accordance with embodiments of the present technology.

FIGS. **13**A and **13**B are side cross-sectional views of the attachment member shown in FIG. **11** in a first configuration and a second configuration, respectively, in accordance with embodiments of the present technology.

FIG. **14** is a flow diagram of a process or method for operating the retraction and aspiration system in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

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

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

With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a retraction and aspiration apparatus and/or an associated catheter system with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the retraction and aspiration system of the present technology can be used in any orientation suitable to the user.

I. SELECTED EMBODIMENTS OF RETRACTION/ASPIRATION SYSTEMS AND METHODS OF USE

FIGS. **1**A and **1**B are perspective views of a proximal portion of a clot retrieval system **1** configured in accordance with embodiments of the present technology, shown in a first state and a second state, respectively. Referring to FIGS. **1**A and **1**B together, the clot retrieval system **1** includes a retraction and aspiration device **100** ("RA device **100**"), a catheter system **200**, and a tubing system **300**. In some embodiments, the RA device **100** is coupleable to the catheter system **200** and operable to simultaneously (i) retract a portion of the catheter system **200** and (ii) aspirate through the catheter system **200**. In certain embodiments, the RA device **100** and catheter system **200** can both be fluidly coupled to the tubing system **300** to enable material (e.g., blood and clot material) aspirated from the catheter system **200** to flow into the tubing system **300**. In particular, the RA device **100**, the catheter system **200**, and the tubing system **300** can be the same as or similar to one or more of the retraction and aspiration devices, catheter systems, and tubing systems disclosed in U.S. Pat. No. 9,526,864, filed Jun. 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED METHODS," which is incorporated herein by reference in its entirety.

FIGS. **2**A-**2**G are schematic illustrations of a distal portion of the clot retrieval system **1** during a clot removal procedure in accordance with embodiments of the present technology. In particular, FIGS. **2**A-**2**G illustrate a distal portion of the catheter system **200** that is positioned proximate to an embolism or clot material within a blood vessel

(e.g., a pulmonary blood vessel). Accordingly, operation of the catheter system **200** is described with references to FIGS. **2**A-**2**G.

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

As further shown in FIG. **2**A, the delivery sheath **204** and the interventional device ID can be positioned at least partially within the clot material PE. Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. The catheter system **200** can include an introducer **210** (FIGS. **1**A and **1**B; e.g., a Y-connector with a hemostasis valve) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer **210** and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve and into the main pulmonary artery. Depending on the location of the embolism, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the pulmonary embolism.

As shown in FIGS. **2**B and **2**C, the delivery sheath **204** can be withdrawn proximally (e.g., as indicated by arrow A**1** in FIG. **2**B) to allow the interventional device ID to expand within the clot material PE, thereby grabbing the clot material PE that is nearby. Although FIG. **2**B shows the interventional device ID positioned at the treatment site such that a distal terminus of the interventional device ID is distal of a distal terminus of the clot material PE, in some procedures the interventional device ID may be positioned such that the distal terminus of the interventional device ID is proximal of the distal terminus of the clot material PE. As shown in FIG. **2**D, in some embodiments the guide catheter **206** can optionally be advanced distally (e.g., as indicated by arrow A**2**) until the guide catheter **206** is positioned proximate to a proximal portion of the clot material PE.

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

The housing **102** can further include a channel **116** that extends proximally from the opening **114** along approximately the length of the housing **102**, as shown in FIGS. **1**A and **1**B. The channel **116** can have a height at least as great as the outer diameter of the delivery sheath **204** of the catheter system **200** (and/or another component of the catheter system **200**) such that the delivery sheath **204** can fit sideways through the channel **116**. In some embodiments, the pull member **202** and the interventional device ID (FIGS. **2**A-**2**G) can be pre-loaded into the delivery sheath **204**, and the delivery sheath **204** can be fed distally through the channel **116** (e.g., either via the proximal end of the channel **116** or first pushed sideways through a portion of the channel **116**) and into the guide catheter **206**. In other embodiments, the interventional device ID and the delivery sheath **204** are fed into the guide catheter **206** and the interventional device ID is deployed prior to coupling the guide catheter **206** to the RA device **100**.

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

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

More specifically, the first portion **314** can include the tubing section **302***a*. The drainage portion **318** can include (i) the tubing section **302***b*, (ii) a first fluid control unit (e.g., a valve) **304**, and (iii) the tubing section **302***c*. The second portion **316** can include (i) the tubing section **302***d*, (ii) a clot reservoir **306**, (iii) the tubing section **302***e*, (iv) a second fluid control unit **310**, and (v) the tubing section **302***f*. In some embodiments, the first fluid control unit **304** can be a one-way valve (e.g., a check valve) that only allows fluid flow from the first portion **314** and/or second portion **316** to the drainage portion **318** (and not vice-versa). In certain embodiments, as described in detail with reference to FIGS. **3**A-**3**C, the clot reservoir **306** can also include a one-way valve that only allows fluid flow from the second portion **316** to the drainage portion **318** (and not vice-versa). In some embodiments, the second fluid control unit **310** can be a stopcock or a clamp that is externally operated to regulate the flow of liquid through the second portion **316** of the tubing system **300**. A Y-connector **308** can fluidly couple the first, second, and drainage portions **314**, **316**, **318**. In other embodiments, the first, second, and/or drainage portions **314**, **316**, **318** can have more or fewer tubing sections, connectors, and/or fluid control unit and/or other suitable configurations.

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

As shown in FIG. **1**B, moving the lever **104** from the second position to the first position (indicated by arrow A**2** in FIG. **1**B) creates a positive pressure (e.g., indicated by arrows F in FIG. **1**B) in the first portion **314** and drainage portion **318** of the tubing system **300**. The clot reservoir **306** prevents the positive pressure from affecting the aspiration lumen of the catheter system **200**, thereby preventing backflow of fluid into the blood vessel BV at the treatment site. With respect to the catheter system **200**, when the lever **104** is actuated from the second position to the first position, the RA device **100** does not engage the delivery sheath **204** or the push member **202** to move these components. Thus, the next time the lever **104** is actuated relative to the housing **102**, the RA device **100** engages a new portion of the delivery sheath **204** and push member **202** such that the delivery sheath **204** and push member **202** are incrementally retracted proximally each time the lever **104** is "pumped" (e.g., moved from the first position toward the second position and then back toward the first position).

Depending on the age and size of the clot material PE, local anatomical and/or physiological conditions, and position of the interventional device ID relative to the clot material PE, the lever **104** can be pumped several times to fully extract the clot material PE and/or interventional device ID from the treatment site. For example, FIGS. **2**D and **2**E show the proximal movement of the delivery sheath **204** and pull member **202** after a first pump of the lever **104**. FIGS. **2**E and **2**F show the proximal movement of the delivery sheath **204**, pull member **202**, and interventional device ID after a second pump of the lever **104** (e.g., including a second instance of pressure generation indicated by arrows F**1** and F**2** in FIGS. **2**E and **2**F, respectively). In some embodiments, the interventional device ID and the clot material PE can be fully withdrawn into the guide catheter **206** after a single pump of the lever **104**. In other embodiments, such as those procedures where the interventional device ID is initially positioned such that a distal terminus of the interventional device ID is proximal of a distal terminus of the clot material PE (the clot material PE often originates in a vein of the patient's leg, and thus is cast into an elongated, worm-like shape), it can take several pumps of the lever **104** to fully withdraw the clot material PE into the guide catheter **206**. Thus, in some embodiments, even when the interventional device ID is positioned within the guide catheter **206** such that a distal terminus of the interventional device ID is proximal of the distal terminus of the guide catheter **206**, the lever **104** can be pumped several more times to continue to withdraw the clot material PE into the guide catheter **206** and the tubing system **300** (e.g., into the second portion **316**, the clot reservoir **306**, and/or the drainage portion **318**).

Once the clot material PE is positioned within the guide catheter **206** such that a distal terminus of the clot material PE is proximal from a distal terminus of the guide catheter **206**, the catheter system **200** can be withdrawn proximally (e.g., as indicated by arrow A**3** in FIG. **2**G) from the treatment site, and removed from the patient. However, sometimes, as shown in FIG. **2**G, retracting the interventional device ID and delivery sheath **204** into the guide catheter **206** may not remove all of the clot material PE (or a desired amount of the clot material PE) from the blood vessel BV. That is, a single "pass" (e.g., a deployment of the interventional device ID and subsequent retraction of the interventional device ID into the guide catheter **206**) may not adequately remove the clot material PE from the blood vessel BV. In such instances, the operator of the clot retrieval system **1** may wish to make another pass with the interventional device ID to remove all or a portion of the remaining clot material PE in the blood vessel BV.

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

II. SELECTED EMBODIMENTS OF CLOT RESERVOIRS AND ASSOCIATED METHODS OF USE

FIGS. **3**A-**3**C are a fully-exploded view, an isometric view, and a partially-exploded view of the clot reservoir **306** of the clot retrieval system **1**. With reference to FIG. **3**A, the clot reservoir **306** includes a housing **322** defining a chamber **323**, a filter **321** configured to be positioned within the housing **322**, and a cap assembly **330** configured to be coupled to the housing **322**. The housing **322** can include a

port **324** configured to be removably, fluidly coupled to the catheter system **200**. In some embodiments, a tubing section **326** is coupled to the port **324** during priming of the clot retrieval system **1** and, as described in further detail below with reference to FIGS. **10** and **14**, during flushing of the tubing system **300**. In certain embodiments the tubing section **326** is semi-permanently coupled to the housing **322** and can be used to fluidly couple the housing **322** to the tubing system **300** and/or the catheter system **200**.

In the embodiment illustrated in FIG. **3**A, the cap assembly **330** includes a fluid connector (e.g., a barbed outlet) **332** for connecting to the tubing system **300** (e.g., to the tubing section **302***d* shown in FIGS. **1**A and **1**B), a nut **333** for releasably securing the cap assembly **330** to the housing **322** (e.g., via a threaded coupling), a first cap portion **334**, and a second cap portion **338**. In some embodiments, the fluid connector **332** is secured to the first cap portion **334** via an adhesive **331***a*, and the first cap portion **334** is secured to the nut **333** via a second adhesive **331***b*. In some embodiments, the first and second adhesives **331***a*, **331***b* are the same. The cap assembly **330** can further include a check valve assembly **335** positioned between the first and second cap portions **334**, **338** and comprising a piston **336** and a spring **339** (e.g., a passivated compression spring). The check valve assembly **335** provides for one-way fluid flow through the clot reservoir **306**, for example, from the catheter system **200** to the reservoir **320** (FIGS. **1**A and **1**B). The clot reservoir **306** can further include one or more O-rings **337** for sealing the various components.

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

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

III. SELECTED EMBODIMENTS OF ATTACHMENT/VALVE MEMBERS, AND ASSOCIATED DEVICES AND METHODS OF USE

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

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

FIG. **5** is a side cross-sectional view of the attachment member **408** show in FIG. **4**. As shown in the embodiment of FIG. **5**, the attachment member **408** includes a body or housing **440** having a proximal opening **443***a*, a distal opening **443***b*, and a first lumen **441** extending between the proximal and distal openings **443***a* and **443***b*. The first lumen **441** further comprises a first portion **441***a* having a first diameter (e.g., a constant first diameter) and a second portion **441***b* having a second diameter greater than the first diameter. In some embodiments, the first diameter can be generally the same as the outer diameter of the guide catheter **206**. The housing **443** further includes a branch portion **444** configured to be coupled to the tubing section **302***f* and having a second lumen **442** branching from the first lumen **441**. In some embodiments, the second lumen **442** can have a relatively large diameter (e.g., between about 0.098 inch and 0.210 inch, about 0.210 inch, greater than 0.210 inch, etc.) to help inhibit clogging and/or collecting of clot material within the attachment member **408** during, for example, aspiration of the guide catheter **206**.

As illustrated in the embodiment of FIG. **5**, the attachment member **408** can further include a valve **445** within the second portion **441***b* of the first lumen **441**. The valve **445** can be, for example, a hemostasis valve configured to maintain hemostasis by preventing fluid flow in the proximal direction through the proximal opening **443***a* of the attach-

ment member **408** as the delivery sheath **204**, the pull member **202**, the guidewire, the interventional device ID, and/or other components of the catheter system **200** are inserted through the valve **445** for advancement to the treatment site in the blood vessel BV.

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

Referring to FIG. **6**, the first valve insert **650** includes a proximal portion **651***a*, a distal portion **651***b* extending from the proximal portion **651***a*, and a lumen **654**. As illustrated in the embodiment of FIG. **6**, the proximal portion **651***a* can optionally include one or more first engagement features (e.g., flanges, tabs, etc.) **652** configured to engage with the attachment member **408** of the of the catheter system **200** to securely position (e.g., lock, mate, flush, etc.) the first valve insert **650** within the attachment member **408**. For example, in some embodiments, the first engagement features **652** can be configured to "snap" into (e.g., mate with) corresponding grooves on the attachment member **408**. The proximal portion **651***a* can further include one or more second engagement features **653** (e.g., flanges, tabs, etc.) configured to be gripped by an operator to enable the operator to, for example, easily manipulate and/or position the first valve insert **650** within the attachment member **408**.

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

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

FIG. **8** is a side view of a second valve insert **860** (e.g., an aspiration insert) in accordance with embodiments of the present technology. Similar to the first valve insert **650**, the second valve insert **860** is configured to be inserted at least partially into the first lumen **441** of the attachment member **408** (e.g., through the valve **445**) through the proximal opening **443***a* of the attachment member **408**. Accordingly, FIG. **9** is a side view of the second valve insert **860** inserted into the attachment member **408** in accordance with embodiments of the present technology.

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

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

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

FIG. **10** is a flow diagram of a process or method **1000** for operating the clot retrieval system **1** including the attachment member **408** and the first and second valve inserts **650**, **860** to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with embodiments of the present technology. Although some features of the method **1000** are described in the context of

the embodiments shown in FIGS. **1**A-**9** for sake of illustration, one skilled in the art will readily understand that the method **1000** can be carried out using other suitable systems and/or devices.

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

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

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

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

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

The first valve insert **650** can be advanced over the delivery sheath **204** and/or guidewire of the catheter system **200** until it is positioned (e.g., seated) at least partially within the attachment member **408** (FIGS. **7**A and **7**B). Once the first valve insert **650** is positioned within the attachment member **408**, the interventional device ID and delivery sheath can be fully withdrawn from the patient. For example, in some embodiments, the operator may grip a portion of the delivery sheath **204** that is exposed proximally from the RA device **100** and pull the delivery sheath **204** and interventional device ID proximally through the guide catheter **206**. In some embodiments, the first valve insert **650** is only positioned within the attachment member **408** when the interventional device ID is proximate the attachment member **408**. That is, the operator may partially withdraw the delivery sheath **204** and interventional device ID within the guide catheter **206** before advancing the first valve insert **650** into position. In some embodiments, the delivery sheath **204** includes a marking (e.g., a specific color pattern) configured to indicate to the operator that the distal end of the delivery sheath **204** and/or the interventional device ID is near (e.g., proximally approaching) the attachment member **408**. In certain embodiments, the guidewire of the catheter system **200** is pinned during withdrawal of the interventional device ID and the delivery sheath **204** such that the guidewire does not move relative to the interventional device ID and the delivery sheath **204**. Therefore, in such embodiments, the guidewire does not need to be re-advanced to the treatment site prior to an additional pass.

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

The method **1000** includes removing the first valve insert **650** and positioning the second valve insert **860** (FIG. **9**) (block **1006**). For example, the first valve insert **650** can be withdrawn proximally over the guidewire of the catheter system **200** and the second valve insert **860** can then be advanced distally over the guidewire until it is positioned within the attachment member **408**. In some embodiments, the first valve insert **650** is removed and the second valve insert **860** is inserted into the attachment member **408** immediately after the delivery sheath **204** and interventional device ID are withdrawn from the patient. Prompt removal

of the first valve insert **650** can restore function of the valve **445** and prevent excess blood from leaking through the lumen **654** of the first valve insert **650** once the delivery sheath **204** and interventional device ID are removed.

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

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

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

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

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

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

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

Additional details of the systems, devices, and methods described above with reference to FIGS. **4-9** are provided in Appendix B to this application.

IV. OTHER SELECTED EMBODIMENTS OF ATTACHMENT/VALVE MEMBERS, AND ASSOCIATED DEVICES AND METHODS OF USE

FIG. **11** is a side view of an attachment/valve member **1108** ("attachment member **1108**") of the catheter system

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

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

FIG. 12 is a side view of the stopcock 1110 in accordance with embodiments of the present technology. In the embodiment illustrated in FIG. 12, the stopcock 1110 includes a grip member (e.g., a handle, a knob, etc.) 1211 that can be actuated (e.g., twisted by the hand of an operator) to partially or fully restrict fluid flow through the tubing section 302*f*. In some embodiments, the stopcock 1110 also includes an injection port 1212 (e.g., a needleless injection port) configured to receive a syringe or other fluid delivery member therethrough. In some embodiments, the injection port 1212 permits fluid to be introduced into the attachment member 1108 and the guide catheter 206 without requiring that a connector 1117 be decoupled from the tubing system 300. For example, in some embodiments, an operator can actuate the stopcock 1110 (e.g., twist the grip member 1211) to close the stopcock 1110 and subsequently introduce a syringe at the injection port 1212 to flush the guide catheter 206 with a fluid (e.g., saline) introduced via the syringe.

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

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

As shown, a tubular member (e.g., an elongate member) 1372 can extend at least partially through the first lumen 1371 to define a central lumen 1374 that is generally coaxial with the first lumen 1371. In some embodiments, the tubular member 1372 can comprise a compliant tubular structure (e.g., a silicon tube) that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the tubular member 1372 can facilitate the collapse, and specifically the uniform collapse of the tubular member 1372 and sealing of the tubular member 1372. For example, the attachment member 1108 can further include an actuation mechanism 1375 coupled to the tubular member 1372 and configured to collapse and seal the tubular member 1372 via compression and/or constriction of one or more filaments 1376 coupled to the tubular member 1372.

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

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

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

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

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

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

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

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

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

The delivery sheath **204** and/or another component of the catheter system **200** may then be manually (e.g., by the operator) or automatically pulled proximally to withdraw the interventional device ID from the patient. Before the interventional device ID and associated clot material PE are withdrawn through the attachment member **1108**, the actuation mechanism **1375** of the attachment member **1108** can be actuated (e.g., by depressing the buttons **1378**) to move the tubular member **1372** to the second configuration (e.g., to open the tubular member **1372**) such that the central lumen **1374** of the tubular member **1372** and the first lumen **1371** of the housing **1370** together provide a continuous lumen of generally constant diameter. Accordingly, the interventional device ID can be fully withdrawn (e.g., retracted proximally) through the attachment member **1108** without causing a significant amount of clot material PE associated with the interventional device ID to remain in the attachment member **1108**—thus minimizing the risk of reintroducing clot material to the patient upon an additional pass using the interventional device ID (or another interventional device). Moreover, in certain embodiments, the guidewire of the catheter system **200** is pinned during withdrawal of the interventional device ID and the delivery sheath **204** such that the guidewire does not move relative to the interventional device ID and the delivery sheath **204**. Therefore, in such embodiments, the guidewire does not need to be re-advanced to the treatment site prior to an additional pass.

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

In some embodiments, the guide catheter **206** can be aspirated without use of the RA device **100**. For example, a syringe or other pressure source can be fluidly coupled directly to the connector **1117** and used to aspirate the guide catheter **206**. In such embodiments, opening of the stopcock **1110** fluidly connects the syringe to the lumen **205** of the guide catheter **206** and closing of the stopcock **1110** fluidly disconnects the syringe from the lumen **205** of the guide catheter **206**. In some embodiments, the syringe or other pressure source can be pre-charged with a vacuum—such as by drawing a plunger of the syringe with the stopcock **1110**

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

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

After the tubing system **300** has been flushed, the method **1400** can return to block **1401**. In particular, the same interventional device ID and delivery sheath **204** can be cleaned and subsequently advanced through the guide catheter **206** and to the remaining clot material PE in the blood vessel. In some embodiments, a new interventional device ID and delivery sheath **204** can be used for each pass to reduce the likelihood of contamination (e.g., reintroduction of clot material PE). Once the desired amount of clot material PE has been removed from the patient, the catheter system **200** may be fully withdrawn from the patient (block **1404**).

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

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

Additional details of the systems, devices, and methods described above with reference to FIGS. **11-14** are provided in Appendix C to this application.

V. EXAMPLES

1. A method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:
   - engaging a first interventional device with the clot material at the treatment site in the blood vessel;
   - retracting the first interventional device and a portion of the clot material into a distal portion of an elongated shaft;
   - inserting a first valve insert into an attachment member coupled to a proximal portion of the elongated shaft;
   - withdrawing the first interventional device and the portion of the clot material proximally through (a) the elongated shaft, (b) the attachment member, and (c) the first valve insert;
   - inserting a second valve insert into the attachment member instead of the first valve insert;
   - aspirating the elongated shaft; and
   - advancing a second interventional device distally through the elongated shaft to the treatment site.

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

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

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

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

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

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

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

9. The method of example 8 wherein aspirating the elongated shaft includes—
   - coupling a syringe to the elongated shaft via a fluid control unit, wherein opening of the fluid control unit fluidly connects the syringe to the elongated shaft, and wherein closing of the fluid control device fluidly disconnects the syringe from the elongated shaft;

drawing a plunger of the syringe to generate a vacuum while the fluid control unit is closed; and

opening the fluid control unit to apply the vacuum to the elongated shaft to thereby aspirate the portion of the remaining clot material into the elongated shaft.

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

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

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

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

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

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

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

aspirating the elongated shaft; and

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

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

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

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

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

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

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

coupling a syringe to the elongated shaft via a stopcock, wherein opening of the stopcock fluidly connects the syringe to the elongated shaft, and wherein closing of the stopcock fluidly disconnects the syringe from the elongated shaft;

drawing a plunger of the syringe to generate a vacuum while the stopcock is closed; and

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

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

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

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

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

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

sealing the attachment member;

aspirating the elongated shaft; and

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

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

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

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

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

unsealing the attachment member; and

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

VI. CONCLUSION

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.

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.

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.

We claim:

1. A method for the intravascular treatment of clot material within a blood vessel, the method comprising:

positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel;

pre-charging a vacuum in a pressure source;

fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft;

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

advancing an interventional device distally through the attachment member and the elongated shaft; and

engaging the interventional device with a second portion of the clot material remaining within the blood vessel.

2. The method of claim **1** wherein the method further comprises withdrawing the interventional device and the second portion of the clot material into the elongated shaft.

3. The method of claim **2** wherein the method further comprises withdrawing the interventional device and the second portion of the clot material through the attachment member.

4. The method of claim **3** wherein the method further comprises unsealing the attachment member before withdrawing the interventional device and the second portion of the clot material through the attachment member.

5. The method of claim **1** wherein unsealing the attachment member includes exercising a valve of the attachment member such that a lumen of the attachment member has a diameter that is about equal to an inner diameter of the elongated shaft.

6. The method of claim **1** wherein unsealing the attachment member includes pressing one or more buttons on the attachment member.

7. The method of claim **1** wherein the pressure source is a syringe.

8. The method of claim **7** wherein pre-charging the vacuum includes withdrawing a plunger of the syringe.

9. The method of claim **1** wherein fluidly connecting the pressure source to the elongated shaft to apply the pre-charged vacuum generates suction at the distal portion of the elongated shaft.

10. The method of claim **1** wherein the blood vessel is a pulmonary blood vessel.

11. The method of claim **1** wherein the pressure source is fluidly coupled to the elongated shaft via a fluid control device, and wherein (a) opening of the fluid control device fluidly connects the pressure source to the elongated shaft and (b) closing of the fluid control device fluidly disconnects the pressure source from the elongated shaft.

12. The method of claim **11** wherein pre-charging the vacuum in the pressure source includes activating the pressure source while the fluid control device is closed, and wherein fluidly connecting the pressure source to the elongated shaft includes opening the fluid control device.

13. The method of claim **11** wherein the fluid control device comprises a user-actuatable valve.

14. The method of claim **1** wherein the attachment member comprises a hemostasis valve.

15. The method of claim **14** wherein the hemostasis valve includes a tubular member, a button, and a filament coupled to the button and the tubular member, and wherein unsealing the hemostasis valve includes pressing the button to loosen the filament to allow the tubular member to expand.

16. The method of claim **15** wherein the method further comprises, after at least partially advancing the interventional device distally through the hemostasis valve, releasing the button to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device.

17. The method of claim **16** wherein the hemostasis valve further includes a spring, and wherein releasing the button to tighten the filament includes driving the button with the spring to tighten the filament.

18. The method of claim **1** wherein the method further comprises collecting at least some of the first portion of the clot material within a filter chamber fluidly coupled between the pressure source and the elongated shaft.

19. The method of claim **18** wherein the method further comprises removing a filter from within the filter chamber to provide access to the at least some of the first portion of the clot material.

20. The method of claim **19** wherein the filter includes a plurality of pores sized to inhibit the clot material from flowing therethrough and to permit blood to flow therethrough.

21. The method of claim **18** wherein the filter chamber is fluidly coupled to the elongated shaft via a first fluid path, wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path, and wherein the first fluid path branches from the second fluid path.

22. The method of claim **21** wherein the attachment member is a hemostasis valve.

23. The method of claim **22** wherein unsealing the hemostasis valve includes actuating at least one button of the hemostasis valve.

24. The method of claim **18** wherein the filter chamber is spaced apart from the pressure source and connected to the pressure source via at least one tube.

25. The method of claim **18** wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—

a port configured to be fluidly coupled to the elongated shaft via at least one first tube; and

a fluid connector configured to be coupled to the pressure source via at least one second tube, wherein the filter is in the housing and fluidly coupled between the port and the fluid connector, and wherein the elongated shaft is fluidly coupled to the pressure source via the filter chamber.

26. The method of claim **25** wherein the elongated shaft is fluidly coupled to the pressure source via the filter chamber along a first fluid path.

27. The method of claim **26** wherein the attachment member is fluidly coupled to the elongated shaft along a second fluid path at least partially different than the first fluid path.

28. The method of claim **27** wherein the attachment member comprises a hemostasis valve.

29. The method of claim **28** wherein unsealing the hemostasis valve includes actuating at least one button of the hemostasis valve.

30. The method of claim **1** wherein engaging the interventional device with the second portion of the clot material remaining within the blood vessel includes translating the interventional device relative to the elongated shaft.

31. The method of claim **1** wherein the method further comprises flushing the clot container with a fluid after

aspirating the first portion of the clot material into the elongated shaft and/or after engaging the interventional device with the second portion of the clot material.

32. The method of claim **31** wherein the fluid is saline.

33. The method of claim **1** wherein the pressure source is coupled to the elongated shaft via at least one tube, and wherein the method further comprises flushing the at least one tube with a fluid after aspirating the first portion of the clot material into the elongated shaft and/or after engaging the interventional device with the second portion of the clot material.

34. The method of claim **33** wherein the fluid is saline.

* * * * *

EXHIBIT J

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(12) **United States Patent**
Merritt et al.

(10) **Patent No.: US 12,109,384 B2**
(45) **Date of Patent: Oct. 8, 2024**

(54) **HEMOSTASIS VALVES AND METHODS OF USE**

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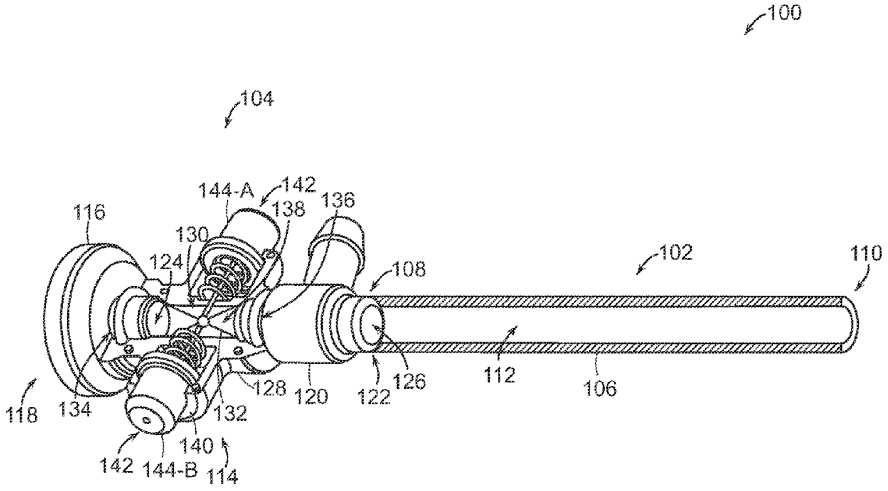
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(57) **ABSTRACT**

Devices, systems, and methods for sealing medical devices, particularly during intravascular access, are disclosed herein. Some aspects relate to a hemostatic valve for sealing a wide range of medical devices, such as catheters, wires, embolectomy systems. The valve can include an elongate member having a first end, a second end, and a central lumen extending therebetween. A reinforcement structure extends along at least a portion of the elongate member and is coupled to the elongate member. A shell defining a first aperture and a second aperture may be included, which first and second apertures can be fluidly coupled by the elongate member. A tensioning mechanism is coupled to the shell and to the elongate member, the tensioning mechanism can be moveable between a first configuration wherein the tensioning mechanism is collapsed and the central lumen is sealed and a second configuration wherein the central lumen is open.

30 Claims, 10 Drawing Sheets



IMPERATIVE Ex. 1034
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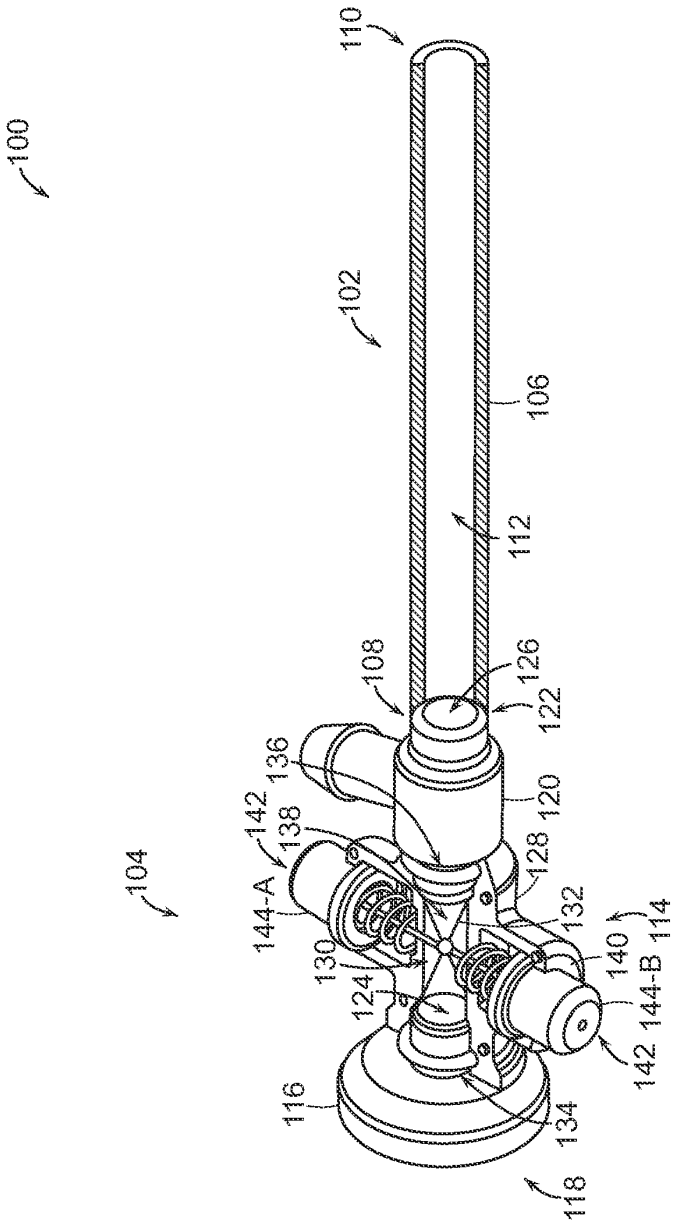

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FIG. 1

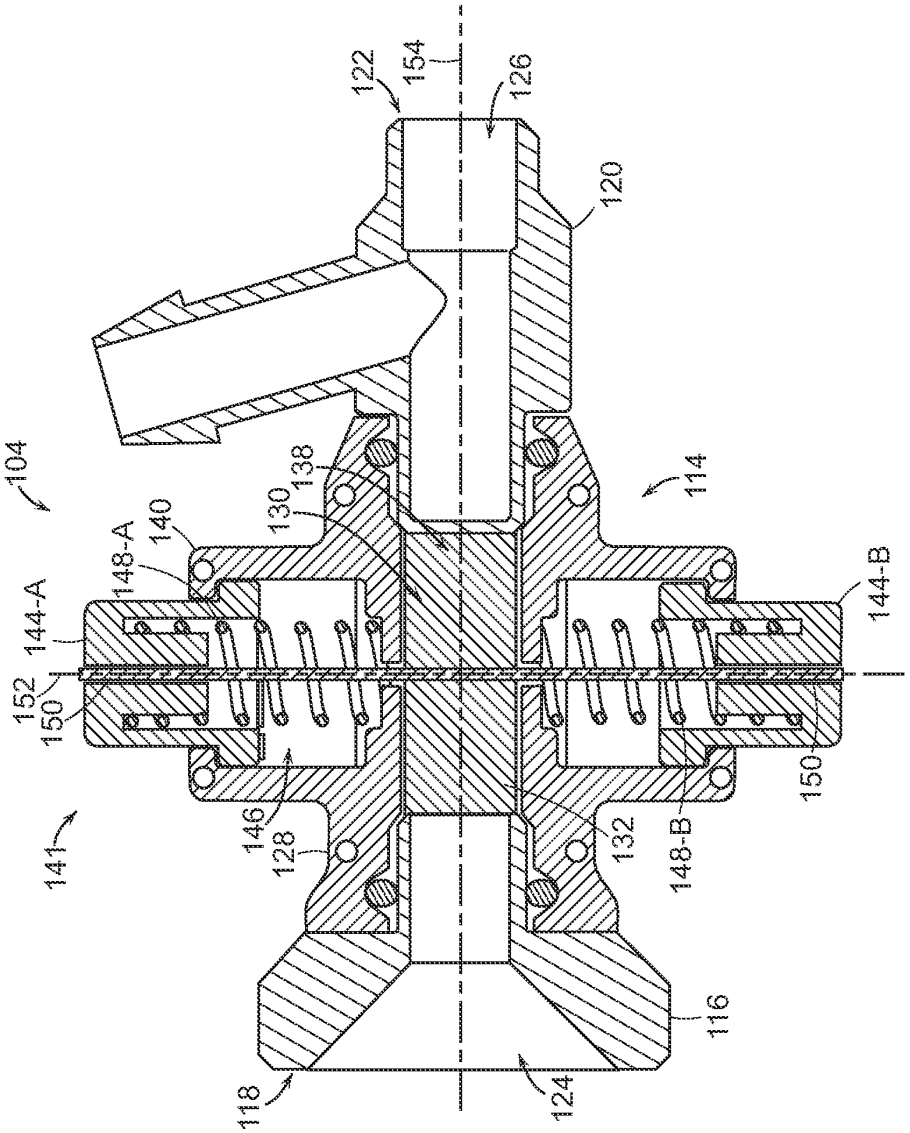

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FIG. 2

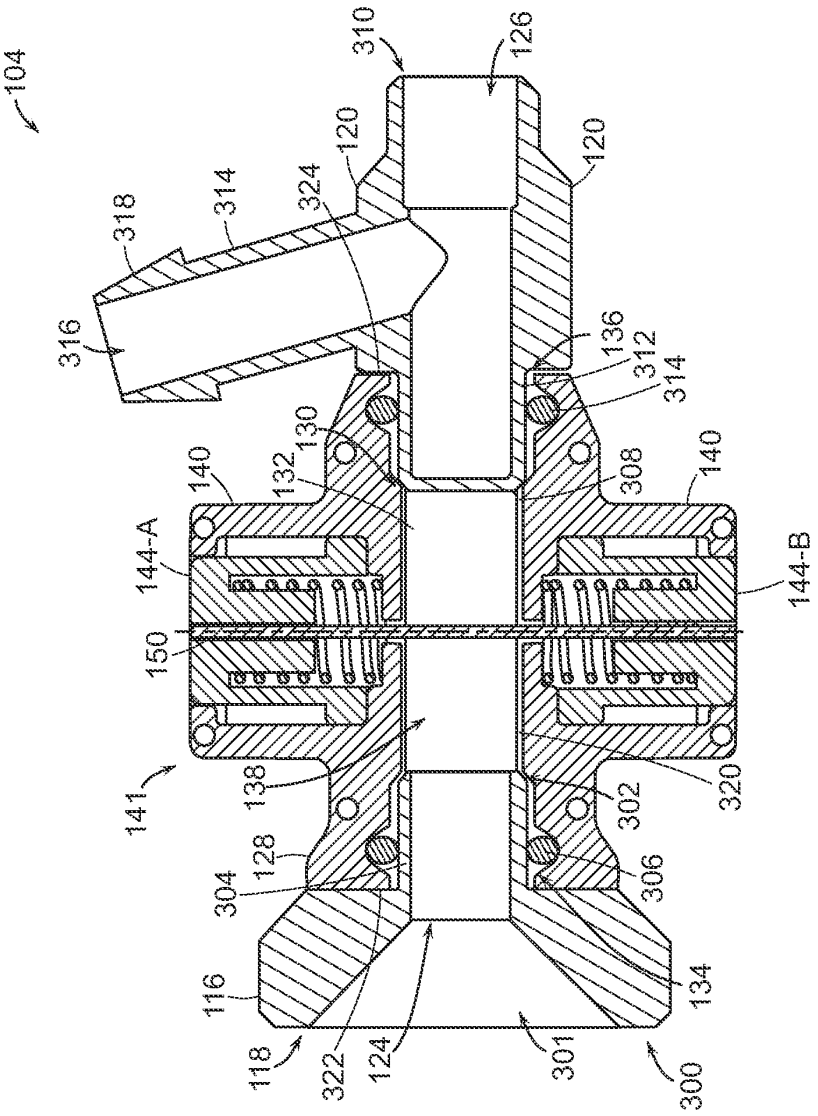

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FIG. 3

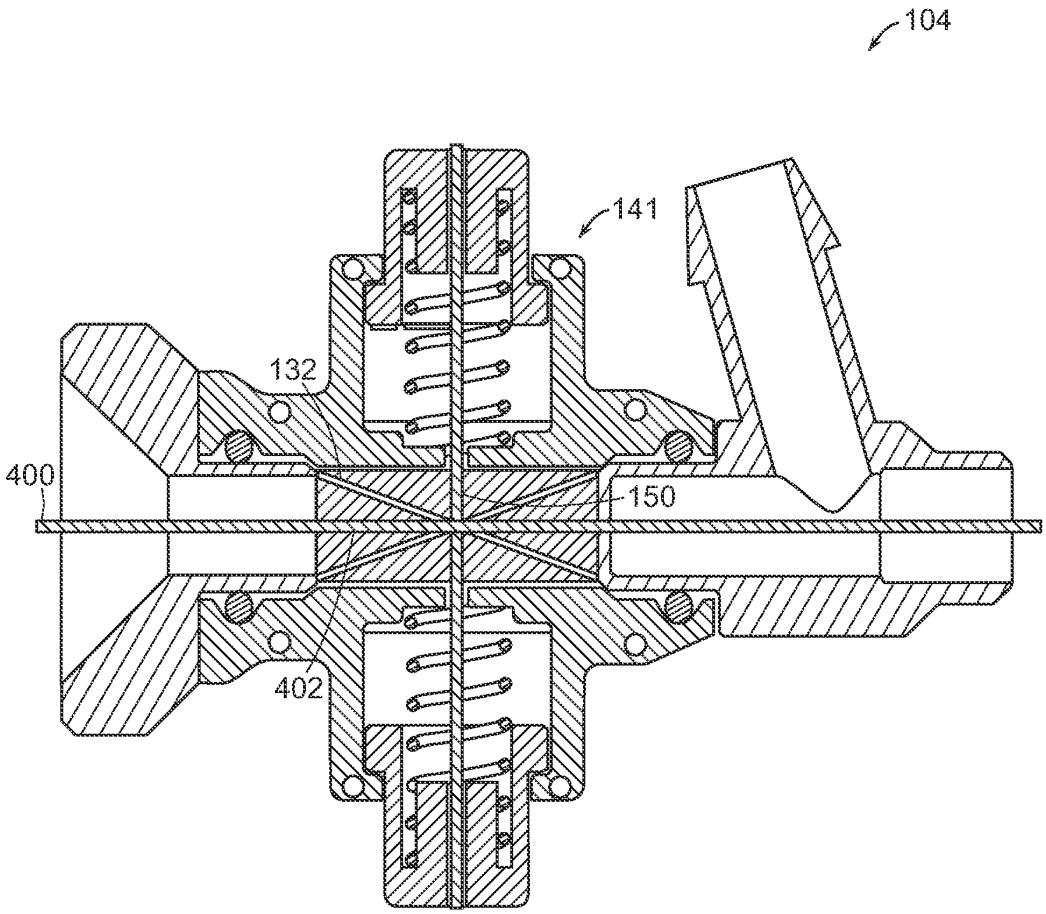


FIG. 4

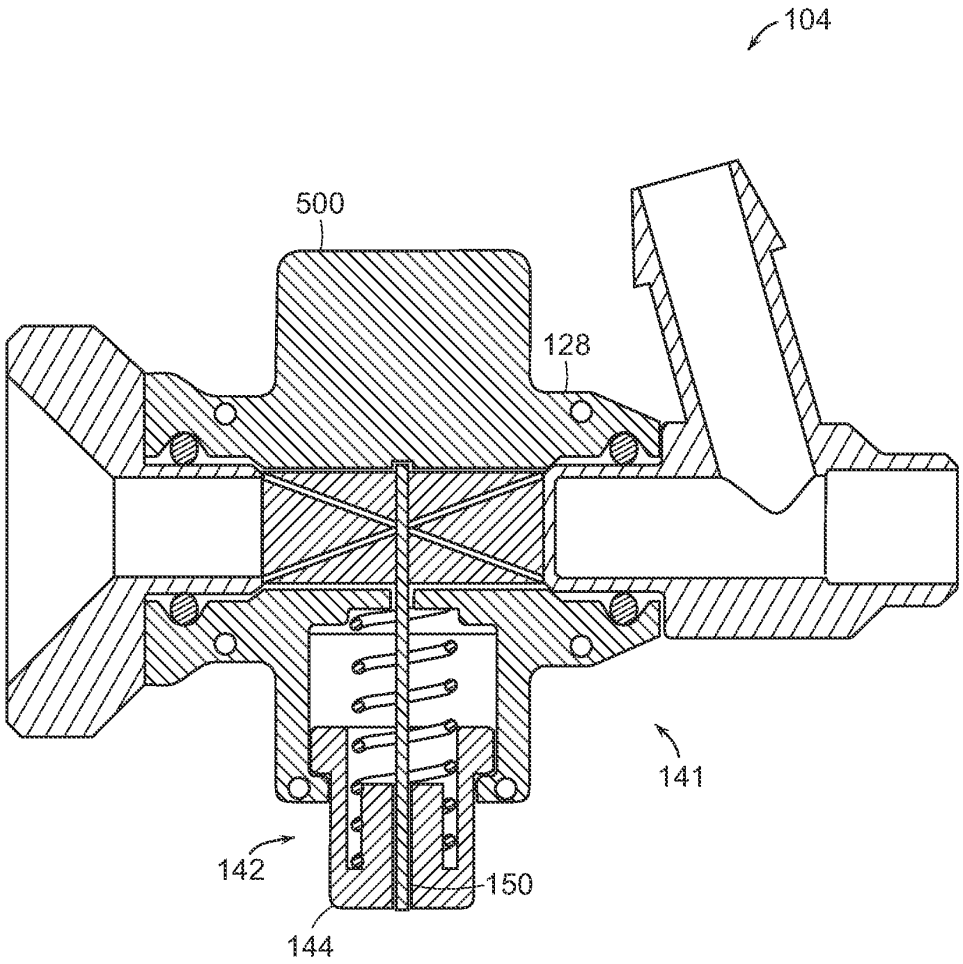


FIG. 5

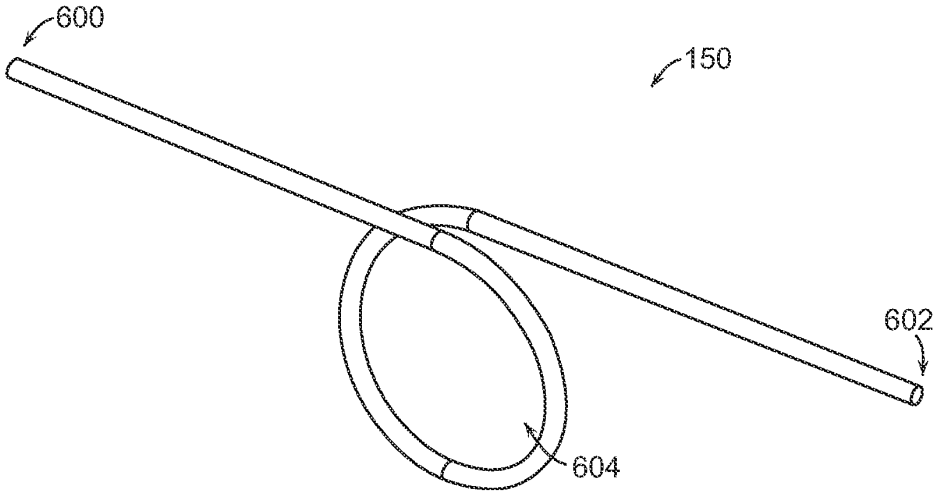


FIG. 6

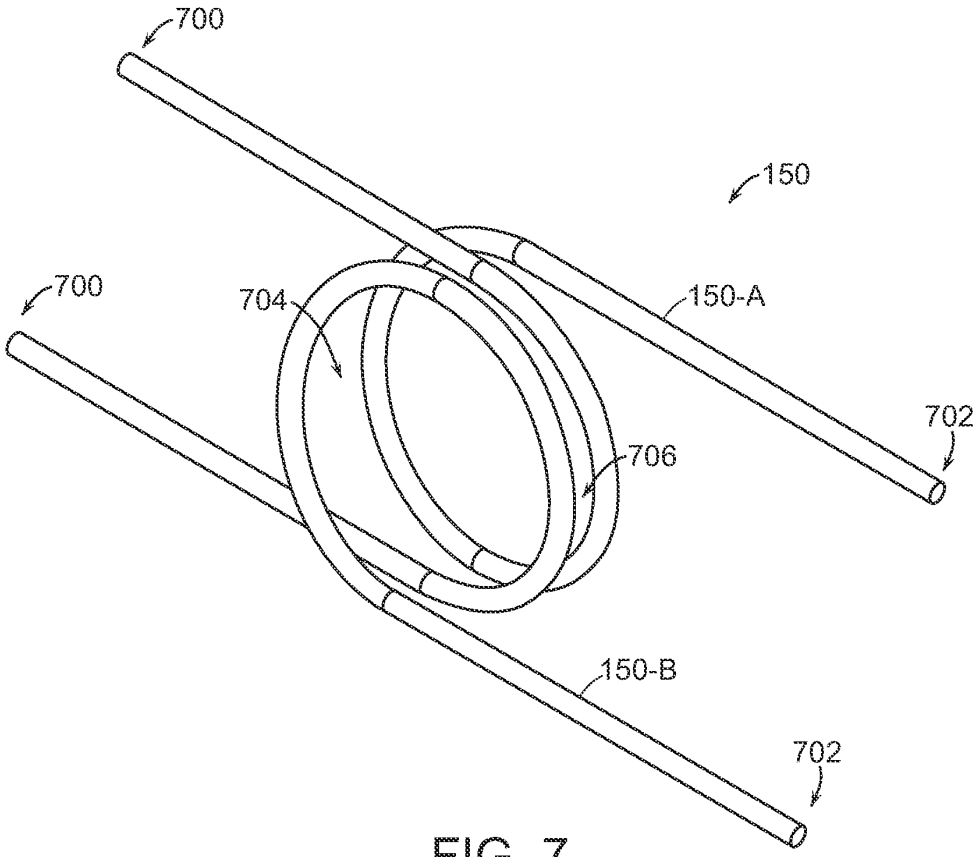


FIG. 7

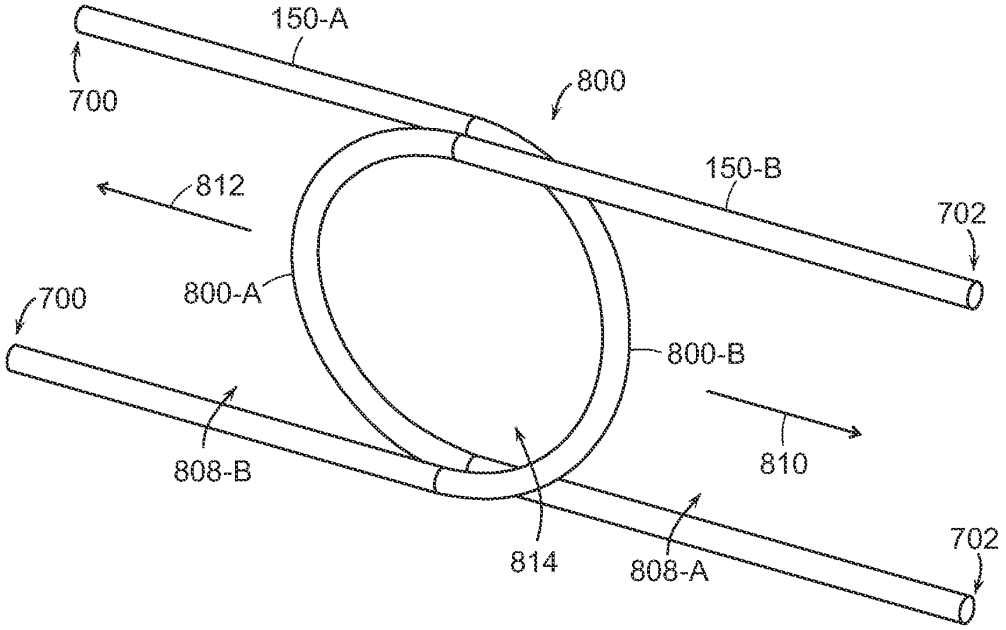

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FIG. 8

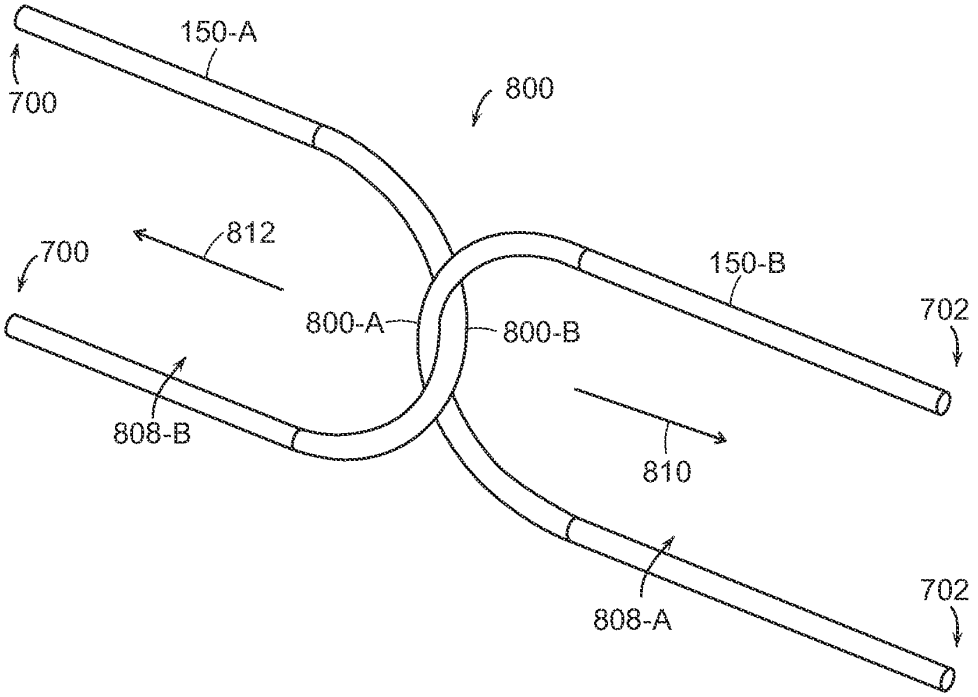

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FIG. 9

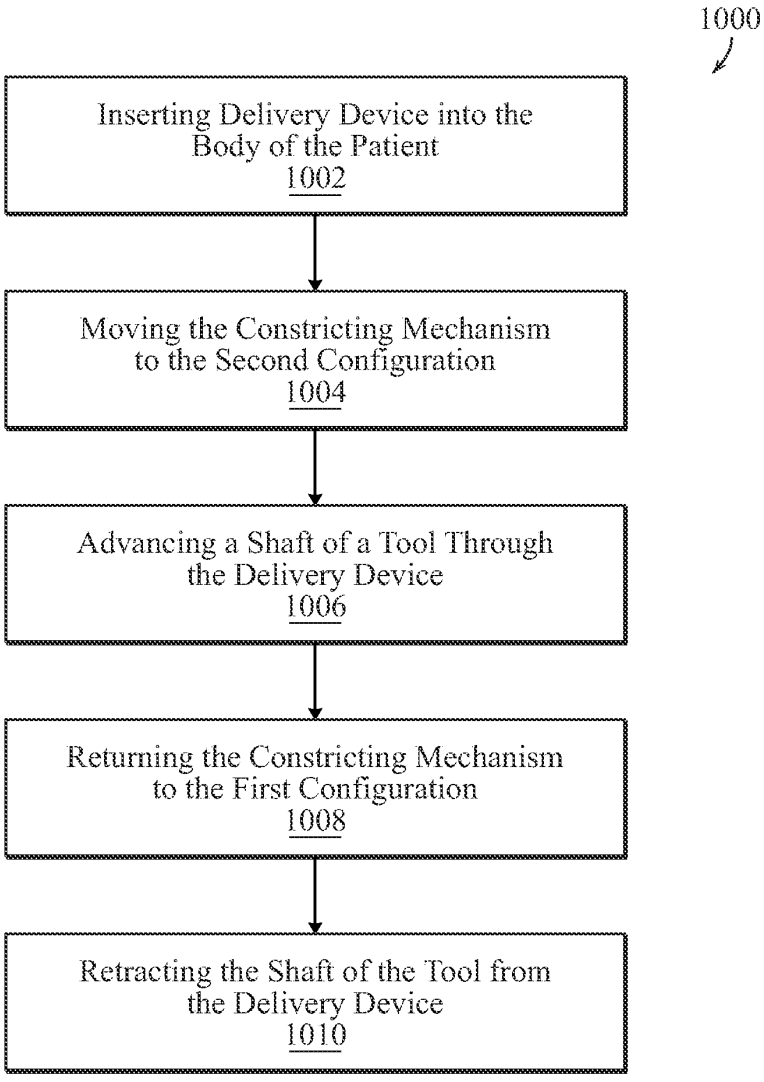

1000
Inserting Delivery Device into the Body of the Patient
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Moving the Constricting Mechanism to the Second Configuration
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Advancing a Shaft of a Tool Through the Delivery Device
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Returning the Constricting Mechanism to the First Configuration
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Retracting the Shaft of the Tool from the Delivery Device
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FIG. 10

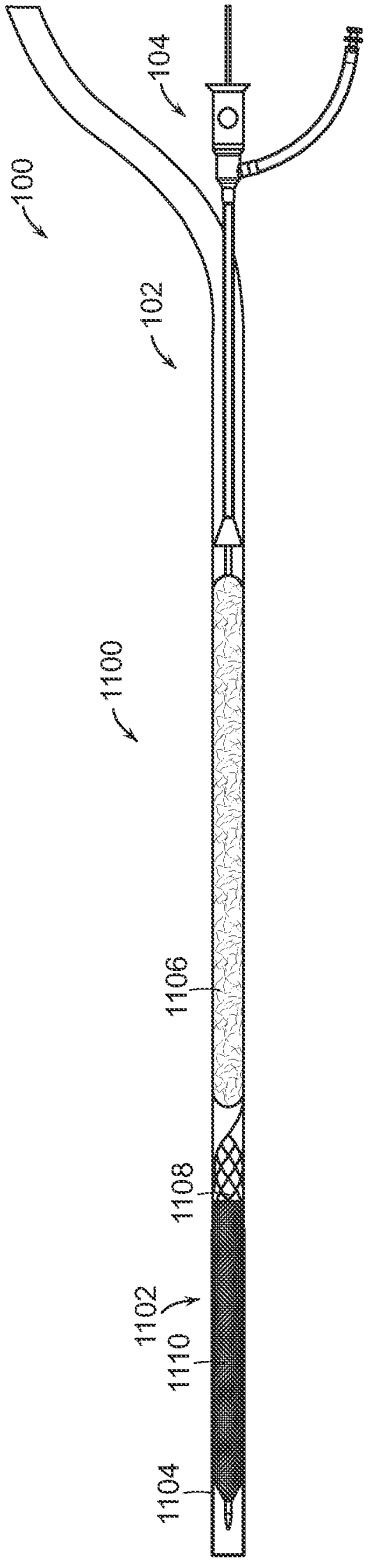


FIG. 11

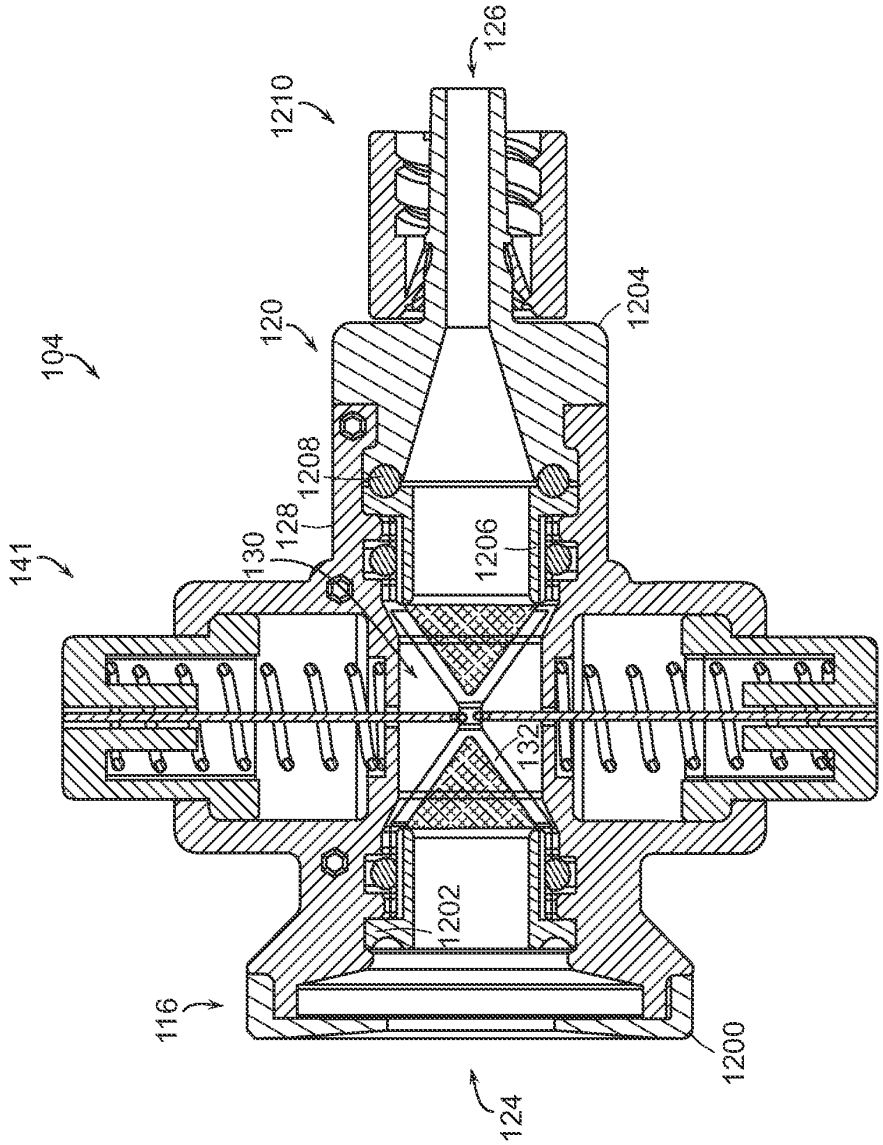

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FIG. 12

HEMOSTASIS VALVES AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/515,079, filed on Nov. 20, 2023, titled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. patent application Ser. No. 17/226,318, filed on Apr. 9, 2021, issued as U.S. Pat. No. 11,844,921, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is a continuation of U.S. patent application Ser. No. 16/117,519, filed on Aug. 30, 2018, now issued as U.S. Pat. No. 11,000,682, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which claims the benefit of U.S. Provisional Patent Application No. 62/554,931, filed on Sep. 6, 2017, and titled "HEMOSTASIS VALVES AND METHODS OF USE," each of which is incorporated by reference herein in its entirety.

BACKGROUND

During a surgical procedure, a portion of a patient's body (e.g., vasculature) is accessed to allow for performance of a desired intervention or treatment. During such surgical procedures, it is desired to minimize patient blood loss, prevent delivery of air into the vasculature, and to maintain the sterility of the accessed portions or sites of the patient's body so as to prevent issues such as infection. Further, the desire for improved patient outcomes has led to the development of hemostasis valves that facilitate minimally invasive surgery.

In minimally invasive surgery, small incisions are created through a blood vessel which one or several catheters are inserted. Each of these one or several catheters can define a lumen extending longitudinally through that catheter. These catheters are moved to a position proximate to tissue, nerves, or other body structures targeted by the surgery, and then tools for performing the procedure are inserted through the lumens of some or all of these catheters.

To minimize blood loss, prevent delivery of air into the vasculature, and to facilitate maintenance of sterility within the patient's body (e.g., blood vessel), these catheters are equipped with hemostasis valves. These valves seal or selectably seal the lumens of the catheters. In many instances, these valves can seal the lumen of the catheter when a tool extends through the catheter, and specifically through the valve. Additionally the valves can seal the lumen when a tool is removed or does not extend through the catheter.

While such traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use. The drawbacks of such valve designs may in turn increase the complexity of any surgery performed therewith and/or reduce patient safety (e.g., bleeding, infection, and/or other detrimental complications). Accordingly, new and improved hemostasis valves and methods of use are desired.

SUMMARY

The following relates to valves, medical systems incorporating valves, and methods of using the same. The valve can include a tubular member that can be constricted, collapsed, and/or sealed by one or several tensioning mechanisms. The tensioning mechanism can include at least one filament that extends around at least a portion of the tubular member. The filament can interact with the tubular member to constrict, collapse, and/or seal the tubular member via manipulation of the tensioning mechanism(s). A tool can be inserted through the valve to gain access to a patient's body and specifically to gain access to a blood vessel. Through the use of the tensioning mechanism and filament to constrict, collapse, and/or seal the tubular member, the valve can seal around a wide range of tool sizes and shapes, as well as multiple tools of differing sizes simultaneously. Additionally, such a valve creates a robust seal that maintains its seal when a vacuum is applied such as occurs during aspiration.

Aspects of the present disclosure relate to a hemostatic valve for sealing a medical device. The hemostatic valve includes an elongate member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the elongate member is pliable. The hemostatic valve can include a reinforcement structure extending along at least a portion of the elongate member, such that the reinforcement structure is coupled to the elongate member. The hemostatic valve includes an active tensioning mechanism coupled to the elongate member. In some embodiments, the tensioning mechanism is moveable between a first configuration in which the central lumen is constricted and sealed and a second configuration in which the central lumen is open. Optionally, the valve may be manually adjusted by the user to intermediate positions between fully open and fully closed. Additionally, an instrument (e.g. catheter) may provide an intermediate position where the valve creates hemostasis without user adjustment.

In some embodiments, the elongate member can be a compliant polymer tube. In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the elongate member. In some embodiments, the reinforcement structure is positioned between the at least one filament and the elongate member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member. In some embodiments, the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member. In some embodiments, the central portion of the compliant polymer tube that is constrained or collapsed by the tensioning mechanism, and at least one filament, is not coupled to the reinforcement structure.

In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments there are two tensioning mechanisms coupled to the at least one filament that operate in opposite directions. In some embodiments the two tensioning mechanisms are attached to the same filament. In some embodiments the two tensioning mechanisms are attached to opposing filaments. In some embodiments, the actuator can be moveable to control movement of the at least one filament from a first position in which the central lumen is constricted and sealed to a second position in which the central lumen is open. In some embodiments, the at least one filament is in the first position when the tensioning mechanism is in the first configuration. In some embodiments, the actuator is biased towards the first position. In some embodiments, the actuator is biased toward the second position. In some embodiments, the actuator can be a manual actuator.

In some embodiments, the at least one filament forms a loop around the elongate member. In some embodiments, the at least one filament forms a bight around a portion of the elongate member. In some embodiments, the at least one filament can include a first filament and a second filament. In some embodiments, each of the first filament and the second filament are coupled to the same actuator. In some embodiments, each of the first filament and the second filament are coupled to different actuators. In some embodiments, the first filament and the second filament are moveable from the first position to the second position. In some embodiments, each of the first filament and the second filament form a loop around the elongate member. In some embodiments, the first filament forms a first bight around a first portion of the elongate member, and the second filament forms a second bight around a second portion of the elongate member. In some embodiments, the first bight extends through the second bight.

In some embodiments, the hemostatic valve can include a shell defining a first aperture and a second aperture. In some embodiments, the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture. In some embodiments, the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve. In some embodiments, the central lumen can comprise a single lumen, and in some embodiments, the central lumen can comprise a plurality of lumens.

One aspect of the present disclosure relates to a delivery system for intravascular access of a blood vessel within a patient's body. The delivery system includes a catheter having a first end, a second end, and a catheter lumen extending therebetween and a hemostatic valve coupled to the first end of the catheter. The hemostatic valve includes a tubular member having a first end, a second end, and a central lumen extending therebetween. In some embodiments, the central lumen of the tubular member is fluidly coupled with the catheter lumen. The hemostatic valve includes an active tensioning mechanism coupled to the tubular member, the tensioning mechanism can be moveable between a first configuration in which the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration in which the central lumen is open.

In some embodiments, the hemostatic valve further includes a reinforcement structure extending along at least a portion of the tubular member. In some embodiments, the reinforcement structure is located between the tensioning mechanism and the tubular member. In some embodiments, the reinforcement structure can be a braided mesh. In some embodiments, the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member. In some embodiments, the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member. In some embodiments, the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the tensioning mechanism can include an actuator coupled to the at least one filament. In some embodiments, moving the tensioning mechanism from the first configuration to the second configuration can include moving the actuator and the thereto coupled at least one filament from a first position to a second position. In some embodiments, the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

In some embodiments, the actuator can be a manual actuator. In some embodiments, the actuator can include a pair of opposing and depressable buttons, which buttons can be biased towards an undepressed position. In some embodiments, the central lumen is sealed when the buttons are in the undepressed position. In some embodiments, the filament can be a monofilament. In some embodiments, the filament can be at least one of: a polymer filament; or a metallic filament. In some embodiments, the catheter can include a thrombus extraction device.

One aspect of the present disclosure relates to a method of sealing a delivery device accessing a blood vessel of a patient. The method includes inserting the delivery device including a catheter and a hemostatic valve into the blood vessel of the patient. In some embodiments, the catheter can have a first end, a second end, and a catheter lumen extending therethrough. In some embodiments, the hemostatic valve can be coupled to the first end and can have a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member. In some embodiments, the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel. The method can include moving the tensioning mechanism of the hemostatic valve to a second configuration. In some embodiments, the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration. The method can include advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member. The method can include returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

In some embodiments, the method includes retracting the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device. In some embodiments, the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

In some embodiments, the tensioning mechanism can include at least one filament extending at least partially around the tubular member. In some embodiments, the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration. In some embodiments, the hemostatic valve can include a reinforcement structure located between the at least one filament and the tubular member.

In some embodiments, the at least one filament forms a loop around the elongate member, and moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop. In some embodiments, the filament forms at least one bight around a portion of the

elongate member. In some embodiments, the filament can include a first filament and a second filament. In some embodiments, the at least one bight can include a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament. In some embodiments, the first and second bights overlap to encircle a portion of the tubular member within a constricting area.

In some embodiments, moving the tensioning mechanism from the second configuration to the first configuration can include moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member. In some embodiments, the tensioning mechanism can include an actuator. In some embodiments, moving the tensioning mechanism to the second configuration can include manipulating the actuator. In some embodiments, the method includes applying a vacuum to the delivery device and/or delivery system to aspirate material through the catheter. In some embodiments, the central lumen remains sealed during the aspiration. In some embodiments, the tool can include a thrombus extraction device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of one embodiment of a delivery device.

FIG. **2** is a side-section view of one embodiment of a hemostasis valve in a first configuration.

FIG. **3** is a side-section view of one embodiment of the valve in a second configuration.

FIG. **4** is a side-section view of one embodiment of the valve in the first configuration and with a tool extending through the valve.

FIG. **5** is a side-section view of one embodiment of a single-button hemostasis valve in a first configuration.

FIG. **6** is a perspective view of a filament of a valve forming a loop.

FIG. **7** is a perspective view of two filaments of a valve, each of the filaments forming a loop.

FIG. **8** is a perspective view of two overlapping and interlocked bights in an open configuration.

FIG. **9** is a perspective view of two overlapping and interlocked bights in a closed configuration.

FIG. **10** is a flowchart illustrating one embodiment of a method for sealing a valve and/or catheter.

FIG. **11** is a side view of one embodiment of a thrombectomy system including the delivery device.

FIG. **12** is a side-section view of another embodiment of a hemostasis valve having two-piece caps.

DETAILED DESCRIPTION

The present disclosure relates to a valve that can be used a hemostasis valve. This valve, also referred to herein as a garrote valve can seal with or without a tool extending through the valve. The garrote valve provides convenient, single-handed operation for a wide range of medical devices including catheters, wires, embolectomy systems, or the like. This single-handed operation of the garrote valve allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure. Combined with single-handed operation, the garrote valve provides robust sealing either with or without a tool extending through the valve. This robust sealing minimizes leakage in applications with a pressure differential on different sides of the valve. This pressure differential can arise, for example, during the application of vacuum aspiration in a procedure. Even under such conditions, as well as under other conditions, the garrote valve maintains seal integrity and prevents leakage in one or both directions.

The garrote valve includes a tubular member. The tubular member is a flexible member that defines a central lumen, which can, in some embodiments, define a single lumen, and in some embodiments, defines a plurality of lumens. In some embodiments, each of the plurality of lumens can comprise the same size and shape, and in some embodiments, some or all of the plurality of lumens can comprise different sizes and shapes. In some embodiments, for example, the plurality of lumens can comprise a lumen sized and/or shaped to receive a guide wire and a lumen sized and/or shaped to receive a tool. The tubular member extends at least partially through a constricting mechanism. The constricting mechanism can be moved from a first configuration to a second configuration, and the constricting mechanism can collapse and/or seal the central lumen of the tubular member when the constricting mechanism is in the first configuration. The constricting mechanism creates the above-discussed robust seal of the tubular member and thus of the valve.

With reference now to FIG. **1**, a perspective view of one embodiment of a delivery system **100**, also referred to herein as a delivery device **100**, is shown. The delivery system **100** can include a catheter **102** and a garrote valve **104**, also referred to herein as valve **104**. The catheter **102** can comprise a shaft **106**, also referred to herein as an elongate sheath **106**, having a proximal end **108**, also referred to herein as a first end **108**, that can connect to the valve **104** and a distal end **110**, also referred to herein as a second end **110**. The shaft **106** can define a catheter lumen **112** extending from the proximal end **108** of the shaft **106** to the distal end **110** of the shaft **106**. The catheter **102** and specifically the shaft **106** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the catheter **102** can be flexible and/or can be made from a biocompatible material. The elongate sheath **106** can have an outer diameter of at least 4 French, at least 6 French, at least 8 French, at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 4 French and 30 French, between 8 French and 24 French, between 12 French and 20 French, and/or any other or intermediate size.

The valve **104** can include an outer shell **114**. The outer shell **114** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the outer shell **114** can be made from one or several polymers or composites. The outer shell **114** can include features that allow interaction with and/or control of the valve **104** to move the valve **104** between the first configuration and the second configuration.

The outer shell **114** can include a proximal cap **116** located at a proximal end **118** of the outer shell **114** and a distal cap **120** located at a distal end **122** of the shell **114**. The proximal cap **116** can include and/or house a proximal aperture **124**, also referred to herein as a proximal channel **124**, a first channel **124**, or a first aperture **124**, that extends through the proximal cap **116**, and the distal cap **120** can include and/or house a distal aperture **126**, also referred to herein as a distal channel **126**, a second channel **126**, or second aperture **126**, that extends through the distal cap **120**. As seen in FIG. **1**, the distal cap **120** connects to the shaft **106** of the catheter **102** at the distal end **122** of the valve **104**.

The proximal cap **116** and the distal cap **120** are connected via a housing **128**. The housing **128** can be a one-piece housing **128** or a multi-piece housing **128**. In the embodiment depicted in FIG. **1**, the housing comprises a two-piece housing **128**. The housing **128** can be configured to receive and couple with each of the proximal cap **116** and the distal cap **120**, and as seen in FIG. **1**, the housing **128** is coupled with each of the proximal cap **116** and the distal cap **120** to secure the relative position of the proximal cap **116** and the distal cap **120** with respect to each other.

The housing **128** can define an interior channel **130** through which an elongate member **132**, also referred to herein as a tubular member **132**, a septum **132**, or a tubular septum **132**, can extend and connect the proximal cap **116** and the distal cap **120**. The elongate member **132** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the elongate member **132** can comprise a compliant tubular structure that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the elongate member **132** can facilitate the collapse, and specifically the uniform collapse of the elongate member **132** and the scaling of the elongate member **132**. In some embodiments, the elongate member **132** is an elastic, resilient material that may comprise a polymer including either a natural or synthetic polymer. In some embodiments, the elongate member can comprise an elastic, resilient material that may comprise silicone, urethane, ethylene-vinyl acetate, natural or synthetic rubber or other elastomers known in the art. In some embodiments, the elongate member **132** can comprise a silicone tube.

The elongate member **132** can comprise a proximal end **134**, also referred to herein as a first end **134**, that can couple to the proximal cap **116**, and a distal end **136**, also referred to herein as a second end **136**, that can couple to the distal cap **120**. The elongate member **132** can define a central lumen **138** that can extend from the first end **134** to the second end **136** of the elongate member **132**. The elongate member **132** can be coupled to the proximal cap **116** such that the central lumen **138** is fluidly coupled with the proximal aperture **124** of the proximal cap **116**, and the elongate member **132** can be coupled to the distal cap **120** such that the central lumen **138**, as seen in FIG. **2** and in FIG. **3**, is fluidly coupled with the distal aperture **126** of the distal cap **120**.

The central lumen **138** of the elongate member **132** can be defined by a wall of the elongate member **132** that can have a thickness that is uniform along the length of the elongate member **132** between the first end **134** and the second end **136**, or that is non-uniform along the length of the elongate member **132** between the first end **134** and the second end **136**. In some embodiments, the wall can have a thickness that is approximately between 0.005 inches and 0.05 inches, and/or approximately between 0.010 inches and 0.030 inches. As used anywhere herein, "approximately" refers to a range of +/−10% of the value and/or range of values for which "approximately" is used.

In some embodiments, the elongate member **132** can be cylindrically shaped, and specifically can be circular-cylindrically shaped. In some embodiments, the elongate member **132** can be dog-bone shaped to facilitate, for example, connection to each of the proximal cap **116** and the distal cap **120**. In some embodiments, the elongate member **132** can include one or several outward-extending protuberances that engage with all or portions of a constricting mechanism **141**, also referred to herein as a tensioning mechanism **141**, of the valve **104** to secure a position of all or portions of the constricting mechanism **141** with respect to the elongate member **132**. In some embodiments, the constricting mechanism **141** can be self-adjusting to seal around tools of different sizes extending through the valve **104**.

The constricting mechanism **141** can, in some embodiments, collapse and seal the elongate member **132** via compression and/or constriction, and specifically via constriction with at least one filament **150**. The constricting mechanism **141** can comprise: an actuator **142** which can be a manual actuator such as one or several buttons **144**; and the at least one filament **150** that can extend at least partially around the elongate member **132**. In some embodiments, the use of the constricting mechanism **141** can facilitate sealing of the valve around tools or instruments of a wide range of sizes and/or diameters, and particularly around tools or instruments that fit through the elongate member **132**.

The housing **128** can further include one or several retention features **140**. The one or several retention features **140** of the housing can engage with and retain all or portions of the constricting mechanism **141** of the valve **104**. In some embodiments, the one or several retention features **140** of the housing **128** can retain the actuator **142** and/or can couple the actuator **142** to the housing **128**. The actuator **142** can comprise any desired type of actuator including, for example, a manual actuator and/or an automated actuator such as, for example, an electromechanical actuator including a solenoid-based actuator. In some embodiments, the actuator can comprise one or several buttons **144**, and specifically, as depicted in FIG. **1**, the actuator **142** can comprise a first button **144**-A and a second button **144**-B. Alternatively, and as depicted in FIG. **5**, the actuator **142** can comprise a single button **144**. In such an embodiment, the filament **150** can be coupled to the single button **144** and to a portion of the housing **128** such as, for example, to grip portion **500** of the housing **128** such that the movement of the single button **144** causes the sealing and/or opening of the elongate member **132** and of the valve **104**.

The actuator **142** can be biased towards a configuration such as, for example, biased towards the first configuration or biased towards the second configuration. As depicted in FIG. **2**, which shows the constricting mechanism **141** in the first configuration, the actuator **142** can be biased towards the first configuration wherein the elongate member **132** is collapsed and/or sealed by a bias feature **146**. In this first configuration, the buttons **144** can be in a first position, also referred to herein as an undepressed position. This bias feature **146** can, as shown in FIG. **2**, include a first spring **148**-A configured to bias the first button **144**-A towards the first position corresponding to the first configuration of the constricting mechanism **141**, and a second spring **148**-B configured to bias the second button **144**-B towards a first position corresponding to the first configuration of the constricting mechanism **141**. One or both of the first spring **148**-A and the second spring **148**-B can comprise a tension spring, compression spring, a torsion spring, a coil spring, or any other desired type of spring.

In some embodiments, one or both of the first spring **148**-A and the second spring **148**-B can generate sufficient force so as to allow actuation of the actuator **142** with a single hand and so as to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. In some embodiments, one or both of the first spring **148**-A and the second spring **148**-B can generate a force of: at least 0.1 pounds, at least 0.2 pounds, at least 0.3 pounds, at least 0.4 pounds, at least 0.5 pounds, at least 0.6 pounds, at least 0.7 pounds, at least 0.8 pounds, at least 0.9 pounds, at least 1 pound, at least 1.5 pounds, at least 2

pounds, at least 3 pounds, at least 5 pounds, and/or at least 10 pounds and in some embodiments one or both of the first spring **148**-A and the second spring **148**-B can generate a force approximately between: 0.1 and 10 pounds, 0.1 and 5 pounds, 0.1 and 1.5 pounds, 0.2 and 1 pounds, and/or 0.4 and 0.8 pounds.

The constricting mechanism **141** can include at least one filament **150** that extends at least partially around the elongate member **132**. In some embodiments, the at least one filament **150** can circumferentially constrict the elongate member **132** to collapse and seal the elongate member **132** when the constricting mechanism **141** is in the first configuration. The filament can be made from a variety of materials including, for example, a polymer, a synthetic, and/or a metal. In some embodiments, the filament **150** can be nylon, stainless steel, nitinol, silicone, or the like. In some embodiments, the filament can comprise a single strand such as, for example, a monofilament, and in some embodiments, the filament can comprise a plurality of strands that can be, for example, twisted, woven, grouped, and/or fused to form the filament. In some embodiments, the filament **150** can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.

The filament **150** can be coupled to the actuator **142** such that the filament **150** selectively constricts, collapses, and/or seals the elongate member **132**, and specifically the central lumen **138** of the elongate member **132** based on the movement and/or position of the actuator **142**. In some embodiments, the filament **150** can be connected to one or both of the buttons **144**-A, **144**-B such that the filament **150** collapses, constricts, and/or seals the elongate member **132** and specifically the central lumen **138** of the elongate member **132** when the buttons **144**-A, **144**-B are in the first position, and the filament **150** can be connected to one or both of the buttons **144**-A, **144**-B such that the elongate member **132** and specifically the central lumen **138** of the elongate member **132** is open and uncollapsed when the buttons **144**-A, **144**-B are in the second position. In some embodiments in which the actuator **142** comprises a single button **144**, as depicted in FIG. **5**, the filament **150** can be connected to the button **144** and to the housing **128** such that the filament **150** is tightened when the button **144** moves to the first position.

In some embodiments, the at least one filament **150** can extend along an axis **152** that can be perpendicular to a central axis **154** of the elongate member **132** and/or of the apertures **124**, **126**. In some embodiments, the axis **152** of the at least one filament **150** can intersect and be perpendicular to the central axis **154** of the elongate member **132** and/or of the apertures **124**, **126**. In some embodiments, the actuator **142**, and specifically the buttons **144**-A, **144**-B can move along this axis **152** when moved from the first position to the second position.

In FIG. **3**, an embodiment of the valve **104** with the constricting mechanism **141** in the second configuration is shown. As specifically shown, both of the first and second buttons **144**-A, **144**-B are in the second position, depressed into the retention features **140** of the housing **128**. In this second position, the filament **150** is loosened, thereby allowing the expansion of the elongate member **132** and the unscaling of the central lumen **138** of the elongate member **132**.

As further seen in FIG. **3**, the proximal cap **116** has a proximal end **300** and a distal end **302**. The proximal cap **116** can include a funnel portion **301** of the proximal aperture **124**, which funnel portion **301** can facilitate insertion of a tool into the proximal aperture **124**. The distal end **302** of the proximal cap **116** can partially extend into the interior channel **130** of the housing **128**. The proximal cap **116** can include a mating feature **304** that can mate with the proximal end **134** of the elongate member **132**. In some embodiments, the proximal end **134** of the elongate member **132** can fit over the mating feature **304** of the proximal cap **116**. The proximal end **134** of the elongate member **132** can be compressed between the mating feature **304** of the elongate member **132** and a portion of the interior channel **130** of the housing **128** into which the mating feature **304** is inserted to thereby secure the proximal end **134** of the elongate member **132** on the mating feature **304**. In some embodiments, the proximal end **134** of the elongate member **132** can be further secured on the mating feature **304** by a proximal O-ring **306** that can be compressed between the housing **128** and the mating feature **304** of the proximal cap **116** to sealingly couple the elongate member **132** to the proximal cap **116**.

The distal cap **120** has a proximal end **308** and a distal end **310**. The distal cap can include a mating feature **312** located on the proximal end **308** of the distal cap **120**, which mating feature **312** can mate with the distal end **136** of the elongate member **132**. In some embodiments, the distal end **136** of the elongate member **132** can fit over the mating feature **312** of the distal cap **123**. The distal end **136** of the elongate member **132** can be compressed between the mating feature **312** of the elongate member **132** and a portion of the interior channel **130** of the housing **128** into which the mating feature **312** is inserted to thereby secure the distal end **136** of the elongate member **132** on the mating feature **312**. In some embodiments, the distal end **136** of the elongate member **132** can be further secured on the mating feature **312** by a distal O-ring **314** that can be compressed between the housing **128** and the mating feature **312** of the proximal cap **116** to sealingly couple the elongate member **132** to the distal cap **120**.

The distal cap **120** can, in some embodiments, further include a side port barb **314** that can extend laterally away from the distal cap **120** and specifically away from the distal aperture **126** of the distal cap **120**. The side port barb **314** can define a side port channel **316** that can extend through the side port barb **314** and fluidly connect to the distal aperture **126**. In some embodiments, the side port barb **314** can include a securement feature **318** such as a barb that can secure coupling of a hose or tube to the side port barb **314**.

In some embodiments, the side barb **314** can be used to apply a vacuum to the portions of the delivery device **100**, and particularly to portions of the delivery device **100** that are distal of the axis **152** along which the elongate member **132** seals. This vacuum can be applied to aspirate a material through the delivery device **100**, and specifically through the catheter **102** of the delivery device. This aspirated material can be a biological material including, for example, bodily fluids, multi-phase bodily materials that can include, for example, a fluidic portion and at least one solid portion, or the like.

In some embodiments, due to the narrowing shape of the elongate member **132** when the constricting mechanism **141** is in the first configuration, a vacuum applied to the portions of the delivery device **100** distal to the axis **152** draws the elongate member **132** towards the first configuration and can, in some embodiments, increase the strength, robustness, and/or strength of the seal of the valve **104**. This attribute of the valve **104** can provide benefits over other valve designs in which a vacuum can compromise the seal of the valve, and thus the ability to draw a vacuum and aspirate can be limited.

In some embodiments, the valve **104** can further include a reinforcement structure **320** that can extend along all or portions of the elongate member **132**. The reinforcement structure **320** can facilitate the uniform collapse of the elongate member **132**, can prevent the at least one filament **150** from cutting through and/or tearing the elongate member **132**, and can assist in guiding one or several tools through the elongate member **132**. The reinforcement structure **320** can be tubular, can extend along and around the elongate member **132**, and can be positioned so as to be between the elongate member **132** and the at least one filament **150**.

The reinforcement structure **320** can include a proximal end **322** and a distal end **324**. In some embodiments, the reinforcement structure **320** extends along and around the elongate member **132**, and is positioned such that the proximal end **322** of the reinforcement structure **320** is proximate to the first end **134** of the elongate member **132** and the distal end **324** of the reinforcement structure **320** is proximate to the second end **136** of the elongate member **132**.

The reinforcement structure **320** can be coupled to the elongate member **132**. In some embodiments, the reinforcement structure **320** is coupled to the elongate member **132** along the length of the reinforcement structure **320**, and in some embodiments, the reinforcement structure **320** is coupled to the elongate member **132** and distinct positions along the length of the elongate member **132** and/or the reinforcement structure **320**. In one embodiment, for example, the reinforcement structure **320** can be coupled to the elongate member **132** at one or both of the proximal end **322** of the reinforcement structure **320** and the distal end **324** of the reinforcement structure **320** and/or at one or both of the first end **134** and the second end **136** of the elongate member **132**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via one or several other components of the valve **104**. In some embodiments, the reinforcement structure **320** can be coupled to the elongate member **132** via the compression of the reinforcement structure **320** and the elongate member **132** between the housing **128** and one or both of the proximal **116** and the distal **120**.

In some embodiments, the reinforcement structure **320** can be adhered to the elongate member **132** via, for example, an adhesive such as silicone adhesive. In some embodiments, the adhesive can be circumferentially applied to the reinforcement structure **320** and/or the elongate member **132** in an adhesive ring that can, for example, a have a length approximately between: 0.010 inches and 0.5 inches; 0.02 and 0.4 inches; 0.050 inches and 0.0250 inches, or any other or intermediate range.

In one embodiment, each of the proximal end **322** and the distal end **324** of the reinforcement structure **320** can be adhered via an adhesive to the elongate member **132**. In such an embodiment, the reinforcement structure **320** may be uncoupled to the elongate member **132** at positions other than the coupling at one or both of the proximal end **322** and the distal end **324** of the reinforcement structure **320**, and thus the reinforcement structure **320** is uncoupled to the elongate member **132** at a position between the first end **134** and the second end **136** of the elongate member **134** and/or between the proximal end **322** and the distal end **324** of the reinforcement structure **320**.

The lack of coupling of the reinforcement structure **320** to the elongate member **132** can facilitate and improve the collapse of the elongate member **132** around a tool **400**, also referred to herein as instrument **400** or device **400**, inserted through the valve **104** as shown in FIG. **4**. The tool **400** can be any device inserted through the valve **104** including, for example, one or several additional catheters, lines, wires, grippers, punches, cutters, or the like. As seen in FIG. **4**, the tool **400** is inserted through the valve **104** and specifically through the elongate member **132** of the valve. As shown, the constricting mechanism **141** is in the first configuration and the elongate member **132** and the central lumen **138** of the elongate member **132** is collapsed around the tool **400**, and specifically around a shaft **402** of the tool **400** to thereby seal the valve **104** around the tool **400** and specifically around the shaft **402** of the tool **400**. The constricting mechanism **141** can seal around tools **400** that fit through the elongate member **132**, regardless of the size of the tool **400**. Thus, the valve can be used with a wide variety of tools.

The reinforcement structure **320** can comprise a variety of designs, shapes, sizes, and materials. In some embodiments, the reinforcement structure **320** can be sized and shaped so as to receive elongate member **132** and to be positioned between the elongate member **132** and the at least one filament **150**. In some embodiments, the reinforcement structure **320** can be made from a material sufficiently strong to prevent the cutting of the at least one filament **150** through the elongate member **132**.

In some embodiments, the reinforcement structure can comprise a coil or a mesh sheath. The mesh sheath can, in some embodiments, comprise a braided mesh. The braided mesh can be made from any desired number of wires in any desired configuration. In some embodiments, the braided mesh can comprise a 4 wire braided mesh, an 8 wire braided mesh, a 12 wire braided mesh, a 16 wire braided mesh, a 20 wire braided mesh, a 24 wire braided mesh, a 32 wire braided mesh, a 48 wire braided mesh, a 64 wire braided mesh, a 72 wire braided mesh, an 80 wire braided mesh, a 96 wire braided mesh, or any other or intermediate braided mesh. In some embodiments, the braided mesh can comprise: a 1×1 configuration. In some embodiments, the wire in the braided mesh can be any desired material including, for example, a metal wire such as a nitinol wire or a stainless steel wire, a polymer wire, or a natural wire. In one embodiment, the braided mesh can comprise a 48 wire mesh in a 1×1 configuration made with a nitinol wire having a diameter of 0.003 inches.

With reference now to FIGS. **6** through **9**, different embodiments and/or configurations of the filament **150** are shown. The filament **150** can comprise a single filament **150** having a first end **600** and a second end **602** as shown in FIG. **6**. The filament **150**, and specifically which first and second ends **600**, **602** can be coupled to the actuator **142** to move the filament **150** between the first and second configurations or positions and/or from the first configuration or position to the second configuration or position. In some embodiments, both of the first end **600** and the second end **602** can be coupled to a single button **144**, in some embodiments, each of the first end **600** and the second end **602** can be coupled to different buttons **144**, and in some embodiments, one of the first end **600** and the second end **602** can be coupled to a button **144** and the other of the first end **600** and the second end **602** can be coupled to the housing **128** or other portion of the valve **104**.

In some embodiments, the filament **150** can comprise multiple filaments, and specifically, as shown in FIGS. **7** through **9**, the filament **150** can comprise a first filament **150**-A and a second filament **150**-B. In embodiments in which the filament **150** comprises multiple filaments, each of the multiple filaments can have a first end **700** and a second end **702**. The first and second filaments **150**-A,

150-B can be coupled to the actuator 142. In such embodiments, the first and second ends 700, 702 can be coupled to the actuator 142 to move the filaments 150-A, 150-B between the first and second configurations and/or from the first configuration to the second configuration. In some embodiments, both of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to a single button 144, in some embodiments, each of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to different buttons 144, and in some embodiments, one of the first end 700 and the second end 702 of one or more of the multiple filaments 150 can be coupled to one button 144 and the other of the first end 700 and the second end 702 of those one or more filaments 150 can be coupled to the housing 128 or other portion of the valve 104.

The filament 150 can be arranged in a variety of configurations. In some embodiments, the filament 150 can be configured to form a single loop 604 that can extend around the elongate member 132 and/or through which the elongate member 132 can be received as shown in FIG. 6, and in some embodiments, the filament 150 can be configured to form multiple loops, and specifically a first loop 704 and a second loop 706 as shown in FIG. 7. The first and second loops 704, 706 can each receive the elongate member 132. In some embodiments, a diameter or size of the loop 604, or of the loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.

In some embodiments, the filament 150 can be configured to form a bight 800, which bight 800 can be a single bight or multiple bights. As used herein, a "bight" refers to a U-shaped section between the two ends of the filament 150. As depicted in FIGS. 8 and 9, the bight 800 can comprise multiple bights, and specifically a first bight 800-A and a second bight 800-B. In some embodiments, the first bight 800-A can extend through the second bight 800-B such that the first and second bights 800-A, 800-B interlock, whereas in other embodiments, the first and second bights 800-A, 800-B can be non-interlocking. Similarly, in embodiments containing the filament 150 having multiple loops, one or several of the multiple loops can be interlocking.

In some embodiments, the bight 800, and specifically one or both of the first bight 800-A and the second bight 800-B can be formed around a portion of the elongate member 132 and/or can extend around a portion of the elongate member 132. Each bight 800 can define a partially enclosed receiving area 808 wherein the elongate member 132 can be received. Thus, the first bight 800-A can define a first receiving area 808-A and the second bight 800-B can define a second receiving area 808-B.

As seen in FIGS. 8 and 9, multiple bights, and specifically the first and the second bights 800-A, 800-B can be positioned and oriented such that the first bight 800-A has a first orientation or first direction as indicated by arrow 810, and the second bight has a second orientation or second direction as indicated by the arrow 812. In some embodiments, the first orientation is different from the second orientation such that the first and second receiving areas 808-A, 808-B overlap and define an encircled area 814, also referred to herein as a constricting area 814. The elongate member 132 can be received within the encircled area 814. In embodiments in which bights 800-A, 800-B overlap to define the encircled area 814, the movement of the constricting mechanism 141 to the first configuration can result in and/or include the first bight 800-A moving in the direction indicated by the arrow 810 and/or the second bight 800-B moving in the direction indicated by the arrow 812, which movement of the bights 800-A, 800-B decreases the size of the encircled area 814 and constricts, collapses, and/or seals the elongate member 132 extending through the encircled area 814.

The filament(s) 150 forming the bights 800 can each apply an arcuate line or narrow longitudinal zone of pressure to the elongate member 132. If the filament(s) are circular in cross-section, the zone of pressure can be very small, and can, in some embodiments, be less than the diameter or thickness of the filament. In some embodiments, the filaments have a diameter or width less than about 2.5 mm, less than about 2 mm, less than about 1.5 mm, less than about 1.25 mm, less than about 1 mm, less than about 0.75 mm, less than about 0.5 mm, and/or less than about 0.25 mm. In some embodiments, the filaments can have a diameter or width of between about 0.01 mm and 2.5 mm, between about 0.05 mm and 2 mm, between about 0.1 mm and 1 mm, and/or between about 0.125 mm and 0.70 mm. In some embodiments, the arcuate line or zone of pressure may form two opposing arcs and in other embodiments, the arcuate line of pressure may be a singular substantially circular line or zone that encircles the elongate member at least once. The longitudinal length of the of the line or zone of pressure may be very short compared to other valves known in the art. In some embodiments, the longitudinal length of the zone of pressure applied to the elongate member 132 by the filament (s) 150 may be less than about 2.0 mm and in some embodiments less than about 0.5 mm. In some embodiments, the filament(s) 150 can have any desired cross-sectional shape including, for example, a circular cross-section, a rectangular cross-section, an oval cross-section, a square cross-section, a polygonal cross-section, a triangular cross-section, or any other desired shape of cross-section.

With reference now to FIG. 10, a flowchart illustrating one embodiment of a process 1000 for sealing a valve 104 and/or catheter 102 accessing a body of a patient is shown. The process 1000 can be performed using the valve 104 and/or the delivery system 100. The process 1000 begins at block 1002, wherein the delivery device 100, and specifically the catheter 102 of the delivery device 100 is inserted into the body of the patient. In some embodiments, this can include inserting the catheter 102 into a portion of the circulator system of the patient such as, for example, a blood vessel including an artery or a venous vessel. In some embodiments, the delivery device 100 can be inserted into the body of the patient directly through an aperture or incision in the patient, and in some embodiments, the delivery device 100 can be inserted into the body of the patient via another catheter or device. In some embodiments, the constricting mechanism 141 can be in the first configuration while the delivery device 100 and/or the catheter 102 is inserted into the patient's body.

After the delivery device 100 is inserted into the body of the patient, the process 1000 proceeds to block 1004, wherein the constricting mechanism 141 is moved from the first configuration to the second configuration. As described above, the central lumen 138 of the elongate member 132 is unsealed when the constricting mechanism 141 is in the second configuration. In some embodiments, the moving of the constricting mechanism 141 from the first configuration to the second configuration can include the manipulation of the actuator 142 and/or the control of the actuator 142, and specifically the depressing of the one or several buttons 144 to move the filament 150 from the first position to the second position to allow the expansion and opening of the central lumen 138 of the elongate member 132.

After the constricting mechanism **141** is moved from the first configuration to the second configuration, the process **1000** proceeds to block **1006**, wherein the tool **400**, and specifically the shaft **402** of the tool **400** is advanced through the delivery device **100** and specifically through the valve **104** until a first end of the tool reaches a desired position within the body of the patient. In some embodiments, a portion of the shaft **402** can be positioned within the central lumen **138** of the elongate member **132** after the advancing of the tool **400** through the delivery device **100**. In some embodiments, after the tool **400** is advanced through the delivery device **100**, the desired procedure can be performed with the tool.

After the tool **400** is advanced through the delivery device **100**, or while the tool **400** is being advanced through the delivery device **100**, the process **1000** proceeds to block **1008**, wherein the constricting mechanism **141** is returned to the first configuration. In some embodiments, the returning of the constricting mechanism **141** to the first configuration can include the release of the one or several buttons **144** and/or the control of the actuator **142** to reconfigure the constricting mechanism **141** to the first configuration. In some embodiments, the return of the constricting mechanism **141** to the first configuration can result in the collapse and/or sealing of the elongate member **132** and specifically the central lumen **138** of the elongate member **132** around the tool **400** and specifically around the shaft **402** of the tool **400**. The return of the constricting mechanism **141** to the first configuration, or the movement of the constricting mechanism **141** to the first configuration can include the decreasing of the size and/or diameter of one or several loops formed by the filament **150** and/or the movement of one or several bights **800** such as, for example, the movement of the first bight **800**-A in the first direction indicated by arrow **810** and the movement of the second bight **800**-B in the second direction indicated by arrow **812** to reduce the size of the constricting area **814**. In some embodiments, after the constricting mechanism is returned to the first configuration, the desired procedure can be performed with the tool.

After the constricting mechanism is returned to the first configuration, the process **1000** proceeds to block **1010**, wherein the tool **400**, and specifically the shaft **402** of the tool **400** is retracted from the delivery device **100**, and more specifically from the valve **104**. In some embodiments, the valve **104** can remain sealed during the retracing of the tool **400** and/or the shaft **402** of the tool. In some embodiments, the valve **104** remains sealed during the retracting of the tool **400** and/or the retracting of the shaft **402** of the tool **400** as the constricting mechanism **141** can remain in the first configuration during the retracing of the tool **400** and/or the shaft **402** of the tool **400**.

In some embodiments, the constricting mechanism **141** can be moved to the second configuration to allow the retraction of the tool **400** and/or the shaft **402** of the tool **400** from the valve **104**, and the constricting mechanism **141** can be returned to the first configuration when the tool **400** and/or the shaft **402** of the tool **400** is removed from the valve **104**. In some embodiments, the retraction of the tool **400** and/or shaft **402** of the tool **400** from the valve **104** can be performed with the constricting mechanism **141** left in the first configuration. In some embodiments, the constricting mechanism **141** can be moved to the second configuration, and then returned to the first configuration via the manipulation and/or control of the actuator **142**, which manipulation and/or control of the actuator **142** can include the depressing of the one or several buttons **144** to move the constricting mechanism **141** to the second configuration, and the release of the one or several buttons **144** to return the constricting mechanism **141** to the first configuration. In some embodiments, if the procedure is complete, the delivery device **100** can then be removed from the body of the patient, and any incision created for the procedure can be closed.

With reference now to FIG. **11**, a side view of one embodiment of a thrombectomy system **1100** including the delivery device **100** and a thrombus extraction device **1102** is shown. In some embodiments, the thrombectomy system **1100** can be used to access a blood vessel **1104** to treat and/or extract a thrombus **1106** from the blood vessel **1104**. The thrombus extraction device **1102** can include a self-expanding coring element **206** and expandable cylindrical portion **208**. In some embodiments, and as shown in FIG. **11**, the thrombus extraction device **1102** can be the tool **400** that can extend through the valve **104**, and in some embodiments, the valve **104** can be a part of the thrombus extraction device **1102**. Further details of thrombectomy systems, thrombus extraction devices, and methods of using the same are disclosed in: U.S. application Ser. No. 15/268,296, filed Sep. 16, 2016, and entitled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS"; U.S. application Ser. No. 15/498,320, filed Apr. 26, 2017, and entitled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION"; and U.S. application Ser. No. 15/466,740, filed on Mar. 22, 2017, and entitled "DEVICE AND METHOD FOR TREATING VASCULAR OCCLUSION", the entirety of each of which is hereby incorporated by reference herein.

With reference now to FIG. **12**, a side-section view of another embodiment of the hemostasis valve **104** having two piece caps **116**, **120** is shown. The valve **104** can include a housing **128** defining an interior channel **130** through which the tubular member **132** can extend. The valve **104** can include the proximal cap **116** and the distal cap **120**. In some embodiments, the proximal cap **116** can comprise a two piece cap and can include a proximal exterior member **1200** and a proximal channel member **1202**. In some embodiments, the distal cap **120** can comprise a two-piece cap and can include a distal exterior member **1204** and a distal channel member **1206**. In some embodiments, this coupling between the proximal exterior member **1200** and the proximal channel member **1202** and/or the coupling between the distal exterior member **1204** and the distal channel member **1206** can be a sealed coupling so as to prevent the leakage of material including fluid or gas between the respective ones of the proximal exterior member **1200** and the proximal channel member **1202** and/or the distal exterior member **1204** and the distal channel member **1206**. In some embodiments, this sealing coupling can be achieved and/or maintained via a seal such as an O-ring **1208** that can be positioned between the proximal exterior member **1200** and the proximal channel member **1202** and/or between the distal exterior member **1204** and the distal channel member **1206**.

In some embodiments, the proximal exterior member **1200** can be coupled, and in some embodiments, rotatingly coupled to the proximal channel member **1202** in a manner to allow the rotation of the proximal exterior member **1200** without rotating the proximal channel member **1202**. Similarly, in some embodiments, the distal exterior member **1204** can be rotatingly coupled to the distal channel member **1206** in a manner to allow the rotation of the distal exterior member **1204** without the rotating of the distal channel member **1206**. In some such embodiments, the channel

members **1202**, **1206** can be non-rotatable with respect to the housing **128** and/or the tubular member **132**, and one or both of the exterior members **1200**, **1204** can be rotatable with respect to the housing **128** and/or the tubular member **132**. In such an embodiment, the maintaining of the rotational position of the channel members **1202**, **1206** with respect to the housing **128** and/or the tubular member **132** can prevent the twisting of the tubular member **132** which can result in the sealing of the tubular member **132** regardless of the configuration of the constructing mechanism **141**.

The exterior members **1200**, **1204** can comprise a variety of shapes and sizes and can include a variety of features. In some embodiments, one or both of the exterior members **1200**, **1204** can be coupled to, for example, a shaft similar to the shaft **106** shown in FIG. **1**. In some embodiments, for example, the distal exterior member **1204** can be coupled to a shaft **106**, including, for example, can be non-detachably coupled to the shaft **106**. In some embodiments, one or both of the exterior members can include one or several features configured to facilitate coupling with the valve **104**. These one or several features can include, for example, one or several male or female: connectors; couplers; attachment mechanisms; or the like. In some embodiments, these one or several features can facilitate use of the valve with other existing components, instruments, tools, or the like. In some embodiments, for example, one or both of the exterior members **1200**, **1204** can comprise either a male or female luer fitting, and specifically as shown in FIG. **12**, the distal exterior member **1204** can comprise a male luer fitting **1210**.

Several aspects of the present technology are set forth in the following examples.

1. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:
   - an elongate member having a first end, a second end, and a central lumen extending therebetween, wherein the elongate member is pliable;
   - a reinforcement structure extending along at least a portion of the elongate member, wherein the reinforcement structure is coupled to the elongate member; and
   - an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.

2. The hemostatic valve of example 1, wherein the elongate member comprises a compliant polymer tube.

3. The hemostatic valve of example 1 or 2, wherein the tensioning mechanism comprises at least one filament extending at least partially around the elongate member.

4. The hemostatic valve of example 3, wherein the reinforcement structure is positioned between the at least one filament and the elongate member.

5. The hemostatic valve of example 4, wherein the reinforcement structure comprises a braided mesh.

6. The hemostatic valve of example 4 or 5, wherein the reinforcement structure is coupled to the elongate member at a position proximate to the first end of the elongate member and at a position proximate to the second end of the elongate member.

7. The hemostatic valve of example 6, wherein the reinforcement structure is not coupled to the elongate member at a position between the first end of the elongate member and the second end of the elongate member.

8. The hemostatic valve of any one of examples 3-7, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein the actuator is moveable to control movement of the at least one filament from a first position wherein the central lumen is constricted and sealed to a second position wherein the central lumen is open, wherein the at least one filament is in the first position when the tensioning mechanism is in the first configuration.

9. The hemostatic valve of example 8, wherein the actuator is biased towards the first position.

10. The hemostatic valve of example 8 or 9, wherein the actuator is biased toward the second position.

11. The hemostatic valve of any one of examples 8-10, wherein the actuator comprises a manual actuator.

12. The hemostatic valve of any one of examples 8-11, wherein the at least one filament forms a loop around the elongate member.

13. The hemostatic valve of any one of examples 8-12, wherein the at least one filament forms a bight around a portion of the elongate member.

14. The hemostatic valve of any one of examples 8-13, wherein the at least one filament comprises a first filament and a second filament, wherein each of the first filament and the second filament are coupled to the actuator, and wherein the first filament and the second filament are moveable from the first position to the second position.

15. The hemostatic valve of example 14, wherein each of the first filament and the second filament form a loop around the elongate member.

16. The hemostatic valve of example 14 or 15, wherein the first filament forms a first bight around a first portion of the elongate member, and wherein the second filament forms a second bight around a second portion of the elongate member.

17. The hemostatic valve of example 16, wherein the first bight extends through the second bight.

18. The hemostatic valve of any one of examples 1-17, further comprising a shell defining a first aperture and a second aperture, wherein the elongate member extends from the first aperture to the second aperture and fluidly couples the first aperture and the second aperture.

19. The hemostatic valve of any one of examples 1-18, wherein the tensioning mechanism is self-adjustable to seal around tools of different sizes extending through the hemostatic valve.

20. The hemostatic valve of any one of examples 1-19, wherein the central lumen comprises a single lumen.

21. The hemostatic valve of any one of examples 1-20, wherein the central lumen comprises a plurality of lumens.

22. A delivery system for intravascular access of a blood vessel within a patient's body, the delivery system comprising:
   - a catheter having a first end, a second end, and a catheter lumen extending therebetween;
   - a hemostatic valve coupled to the first end of the catheter, the hemostatic valve comprising:
     - a tubular member having a first end, a second end, and a central lumen extending therebetween, wherein the central lumen of the tubular member is fluidly coupled with the catheter lumen; and
     - an active tensioning mechanism coupled to the tubular member, the tensioning mechanism moveable between a first configuration wherein the tensioning mechanism constricts on the central lumen and the central lumen is sealed and a second configuration wherein the central lumen is open.

23. The delivery system of example 22, wherein the hemostatic valve further comprises a reinforcement structure extending along at least a portion of the tubular member.

24. The delivery system of example 22 or 23, wherein the reinforcement structure is located between the tensioning mechanism and the tubular member.

25. The delivery system of example 24, wherein the reinforcement structure comprises a braided mesh.

26. The delivery system of example 24 or 25, wherein the reinforcement structure is coupled to the tubular member at a position proximate to the first end of the tubular member and at a position proximate to the second end of the tubular member.

27. The delivery system of example 26, wherein the reinforcement structure is adhered to the tubular member at the first end of the tubular member and at the second end of the tubular member.

28. The delivery system of example 27, wherein the reinforcement structure is uncoupled to the tubular member between the first end of the tubular member and the second end of the tubular member.

29. The delivery system of any one of examples 22-28, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member.

30. The delivery system of example 29, wherein the tensioning mechanism comprises an actuator coupled to the at least one filament, wherein moving the tensioning mechanism from the first configuration to the second configuration comprises moving the actuator and the thereto coupled at least one filament from a first position to a second position, wherein the filament constricts and seals the central lumen of the tubular member when the filament is in the first position.

31. The delivery system of example 30, wherein the actuator comprises a manual actuator.

32. The delivery system of example 31, wherein the actuator comprises a pair of opposing and depressable buttons, wherein the buttons are biased towards an undepressed position.

33. The delivery system of example 31 or 32, wherein the central lumen is sealed when the buttons are in the undepressed position.

34. The delivery system of any one of examples 30-33, wherein the filament comprises a monofilament.

35. The delivery system of any one of examples 30-34, wherein the filament comprises at least one of: a polymer filament; or a metallic filament.

36. The delivery system of any one of examples 22-35, wherein the catheter comprises a thrombus extraction device.

37. A method of sealing a delivery device accessing a blood vessel of a patient, the method comprising:

inserting the delivery device comprising a catheter and a hemostatic valve into the blood vessel of the patient, the catheter having a first end, a second end, and a catheter lumen extending therethrough, and the hemostatic valve coupled to the first end and having a tubular member defining a central lumen fluidly coupled with the catheter lumen and a tensioning mechanism coupled with the tubular member, wherein the tensioning mechanism collapses and seals the central lumen in a first configuration and thereby seals access to the blood vessel;

moving the tensioning mechanism of the hemostatic valve to a second configuration, wherein the central lumen is open and access to the blood vessel is unsealed when the tensioning mechanism is in the second configuration;

advancing a shaft of a tool through the delivery device until a first end of the tool reaches a desired position within the blood vessel of the patient and a portion of the shaft is positioned within the central lumen of the tubular member; and

returning the tensioning mechanism of the hemostatic valve to the first configuration such that the tubular member collapses on the shaft of the tool and seals around the shaft of the tool.

38. The method of example 37, further comprising retracting the shaft of the tool from the delivery device.

39. The method of example 38, wherein the tensioning mechanism is maintained in the first configuration during and after the retracting of the shaft of the tool from the delivery device.

40. The method of example 38 or 39, wherein the tensioning mechanism is moved to the second configuration during the retracting of the shaft of the tool from the delivery device, and wherein the tensioning mechanism is returned to the first configuration after the shaft of the tool is retracted from the delivery device.

41. The method of any one of examples 37-40, wherein the tensioning mechanism comprises at least one filament extending at least partially around the tubular member, wherein the at least one filament collapses the tubular member when the tensioning mechanism is in the first configuration.

42. The method of example 41, wherein the at least one filament circumferentially constricts the tubular member to collapse the tubular member when the tensioning mechanism is in the first configuration.

43. The method of example 41 or 42, wherein the hemostatic valve comprises a reinforcement structure located between the at least one filament and the tubular member.

44. The method of any one of examples 41-43, wherein the at least one filament forms a loop around the elongate member, and wherein moving the tensioning mechanism from the second configuration to the first configuration reduces a size of the loop to thereby constrict the tubular member within the loop.

45. The method of any one of examples 41-44, wherein the filament forms at least one bight around a portion of the elongate member.

46. The method of example 45, wherein the filament comprises a first filament and a second filament, and wherein the at least one bight comprises a first bight oriented in a first direction and formed by the first filament and a second bight oriented in a second direction and formed by the second filament, wherein the first and second bights overlap to encircle a portion of the tubular member within an constricting area.

47. The method of example 46, wherein moving the tensioning mechanism from the second configuration to the first configuration comprises moving the first bight in the first direction and the second bight in the direction to reduce the size of the constricting area and collapse and seal the central lumen of the tubular member.

48. The method of any one of examples 37-47, wherein the tensioning mechanism comprises an actuator, and wherein moving the tensioning mechanism to the second configuration comprises manipulating the actuator.

49. The method of any one of examples 37-48, further comprising applying a vacuum to the delivery device to aspirate material through the catheter, wherein the central lumen remains sealed during the aspiration.

50. The method of any one of examples 37-49, wherein the tool comprises a thrombus extraction device.

51. A hemostatic valve for sealing a medical device, the hemostatic valve comprising:

an elongate member having a first end, a second end, and a central lumen comprising a plurality of lumens extending therebetween, wherein the elongate member is pliable; and

an active tensioning mechanism coupled to the elongate member, wherein the tensioning mechanism is moveable between a first configuration wherein the central lumen is constricted and sealed and a second configuration wherein the central lumen is open.

Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

In the previous description, various embodiments of the present invention are described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

The use of the terms "a" and "an" and "the" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. The term "connected" is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

What is claimed is:

1. A valve assembly, comprising:

a tubular member defining a lumen;

a first filament extending in a first loop around the tubular member, wherein the first filament is flexible;

a second filament extending in a second loop around the tubular member, wherein the second filament is flexible;

a pair of actuators movable from a first position to a second position, wherein—

the first filament includes a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon by a second one of the actuators;

the second filament includes a first portion operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators;

in the first position, the actuators are positioned to tension the first filament and the second filament thereby decreasing a dimension of the first loop and a dimension of the second loop to constrict the lumen of the tubular member;

in the second position, the actuators are positioned to loosen the first filament and the second filament thereby permitting the tubular member to expand against the first loop and the second loop to increase the dimension of the first loop and the dimension of the second loop to at least partially open the lumen of the tubular member; and

the actuators are biased to the first position.

2. The valve assembly of claim **1** wherein the first loop extends completely around the tubular member, and wherein the second loop extends completely around the tubular member.

3. The valve assembly of claim **1** wherein the first portion of the first filament is a first end portion of the first filament, wherein the second portion of the first filament is a second end portion of the first filament, wherein the first portion of the second filament is a first end portion of the second filament, and wherein the second portion of the second filament is a second end portion of the second filament.

4. The valve assembly of claim **3** wherein the first end portion of first filament is directly attached to the first one of the actuators, wherein the second end portion of the first filament is directly attached to the second one of the actuators, wherein the first end portion of the second filament is directly attached to the first one of the actuators, and wherein the second end portion of the second filament is directly attached to the second one of the actuators.

5. The valve assembly of claim **1** wherein the tubular member extends along a longitudinal axis, and wherein the first loop is proximate to the second loop along the longitudinal axis.

6. The valve assembly of claim **1** wherein the first filament and the second filament each comprise a plurality of strands woven together.

7. The valve assembly of claim **1** wherein the tubular member is elastically deformable.

8. The valve assembly of claim 1 wherein the tubular member is configured to resiliently expand.

9. The valve assembly of claim 1, further comprising a rigid housing, wherein the tubular member, the first filament, and the second filament are positioned within the housing, and wherein the actuators are movably coupled to the housing.

10. The valve assembly of claim 1 wherein the actuators are depressed toward one another in the second position, and wherein the actuators are moved away from one another in the first position.

11. The valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 14 French.

12. The valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 16 French.

13. The valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 20 French.

14. The valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 24 French.

15. A valve assembly, comprising:

a tubular member defining a lumen, wherein the tubular member is elastically deformable from a first position in which the lumen is constricted to a second position in which the lumen is at least partially open;

a first actuator;

a second actuator;

a first filament configured in a first loop completely around the tubular member and having a first portion extending from the first loop toward the first actuator and a second portion extending from the first loop toward the second actuator; and

a second filament configured in a second loop completely around the tubular member and having a first portion extending from the second loop toward the first actuator and a second portion extending from the second loop toward the second actuator;

wherein—

the first actuator and the second actuator are biased away from one another to elastically deform the tubular member to the first position by (a) increasing a tension in the first filament to decrease a dimension of the first loop and (b) increasing a tension in the second filament to decrease a dimension of the second loop; and

the first actuator and the second actuator are movable toward one another to permit the tubular member to return to the second position by (a) decreasing the tension in the first filament and (b) decreasing the tension in the second filament.

16. The valve assembly of claim 15 wherein the first actuator and the second actuator each comprise a button.

17. The valve assembly of claim 15 wherein the first filament is flexible, and wherein the second filament is flexible.

18. The valve assembly of claim 15 wherein the first portion of first filament is directly attached to the first actuator, wherein the second portion of the first filament is directly attached to the second actuator, wherein the first portion of the second filament is directly attached to the first actuator, and wherein the second portion of the second filament is directly attached to the second actuator.

19. The valve assembly of claim 15 wherein the tubular member extends along a longitudinal axis, wherein the first portion of the first filament extends toward the first actuator along a first axis extending generally orthogonal to the longitudinal axis proximate the tubular member, wherein the second portion of the first filament extends toward the second actuator along a second axis extending generally orthogonal to the longitudinal axis proximate the tubular member, wherein the first portion of the second filament extends toward the first actuator along a third axis extending generally orthogonal to the longitudinal axis proximate the tubular member, wherein the second portion of the second filament extends toward the second actuator along a fourth axis extending generally orthogonal to the longitudinal axis proximate the tubular member, wherein the second axis is positioned between the first axis and the fourth axis, and wherein the fourth axis is positioned between the second axis and the third axis.

20. The valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 16 French.

21. The valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 20 French.

22. The valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 24 French.

23. A valve assembly, comprising:

a tubular member defining a lumen;

a first filament extending in a first loop around the tubular member;

a second filament extending in a second loop around the tubular member; and

a pair of actuators biased to circumferentially constrict the first loop and the second loop to elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open.

24. The valve assembly of claim 23 wherein the actuators each comprise a button.

25. The valve assembly of claim 23 wherein the first filament includes a first portion operably coupled to a first one of the actuators and a second portion operably coupled to a second one of the actuators, and wherein the second filament includes a first portion operably coupled to the first one of the actuators and a second portion operably coupled to the second one of the actuators.

26. The valve assembly of claim 25 wherein the first portion of first filament is directly attached to the first one of the actuators, wherein the second portion of the first filament is directly attached to the second one of the actuators, wherein the first portion of the second filament is directly attached to the first one of the actuators, and wherein the second portion of the second filament is directly attached to the second one of the actuators.

27. The valve assembly of claim 23 wherein the first filament is flexible, and wherein the second filament is flexible.

28. The valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 16 French.

29. The valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 20 French.

30. The valve assembly of claim **23** wherein, in the second position, the tubular member has a diameter of at least 24 French.

* * * * *

EXHIBIT K

US012156669B2

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Quick et al.

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(45) **Date of Patent: *Dec. 3, 2024**

(54) **SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS**

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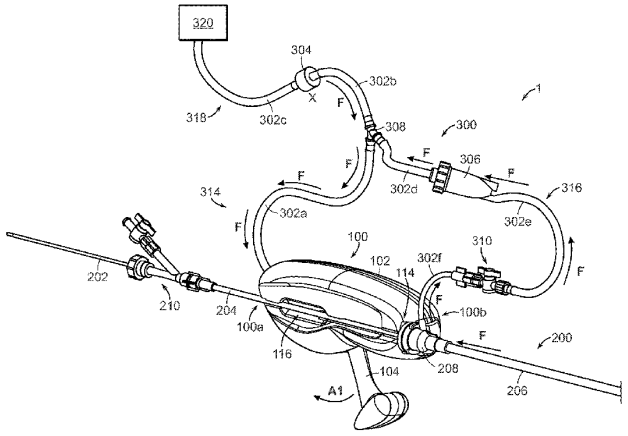
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(57) **ABSTRACT**

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



material within the attachment/valve member. The method can further include resealing and aspirating the guide catheter before advancing another interventional device to the clot material to again engage and remove clot material from the blood vessel.

30 Claims, 20 Drawing Sheets

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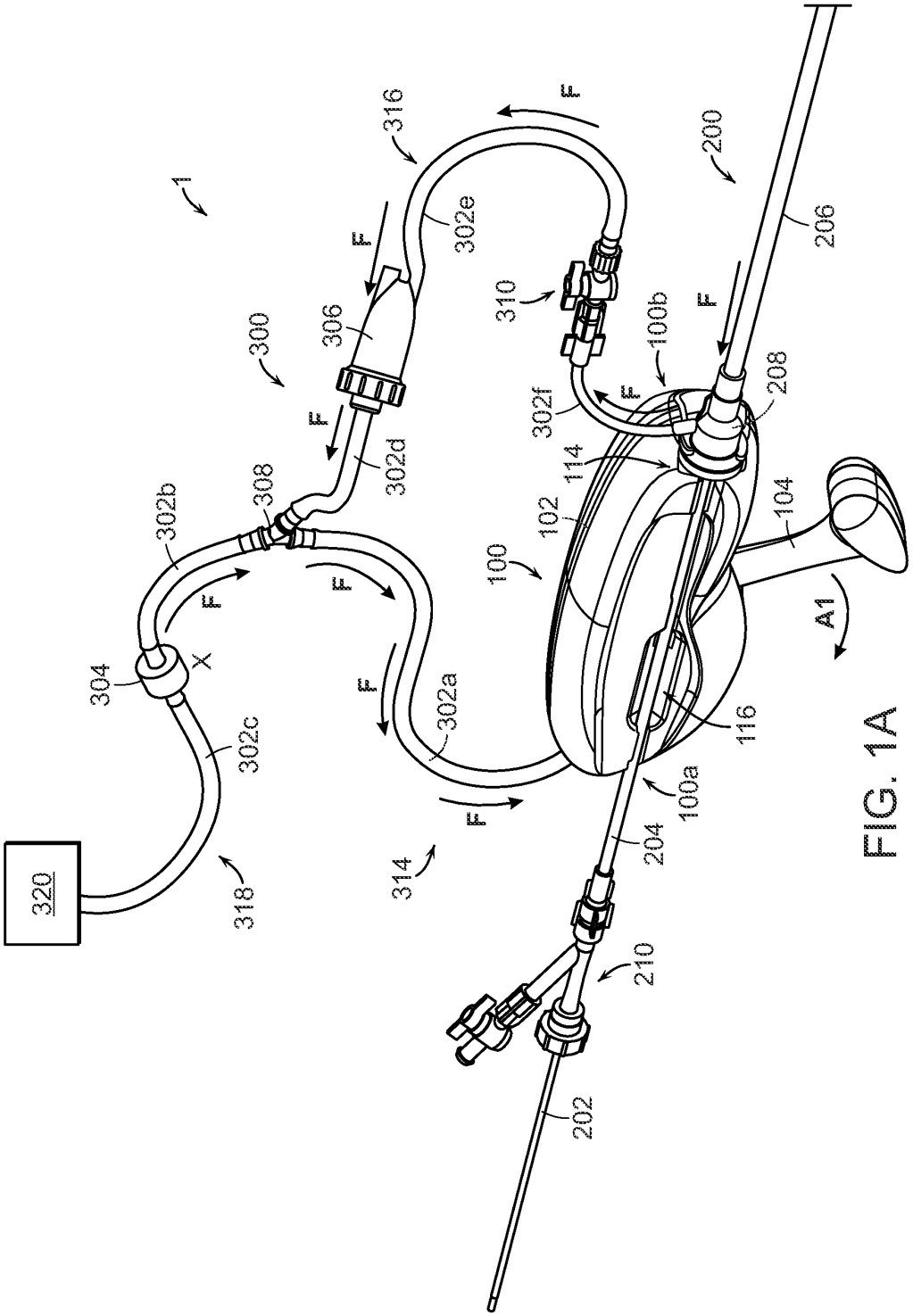

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FIG. 1A

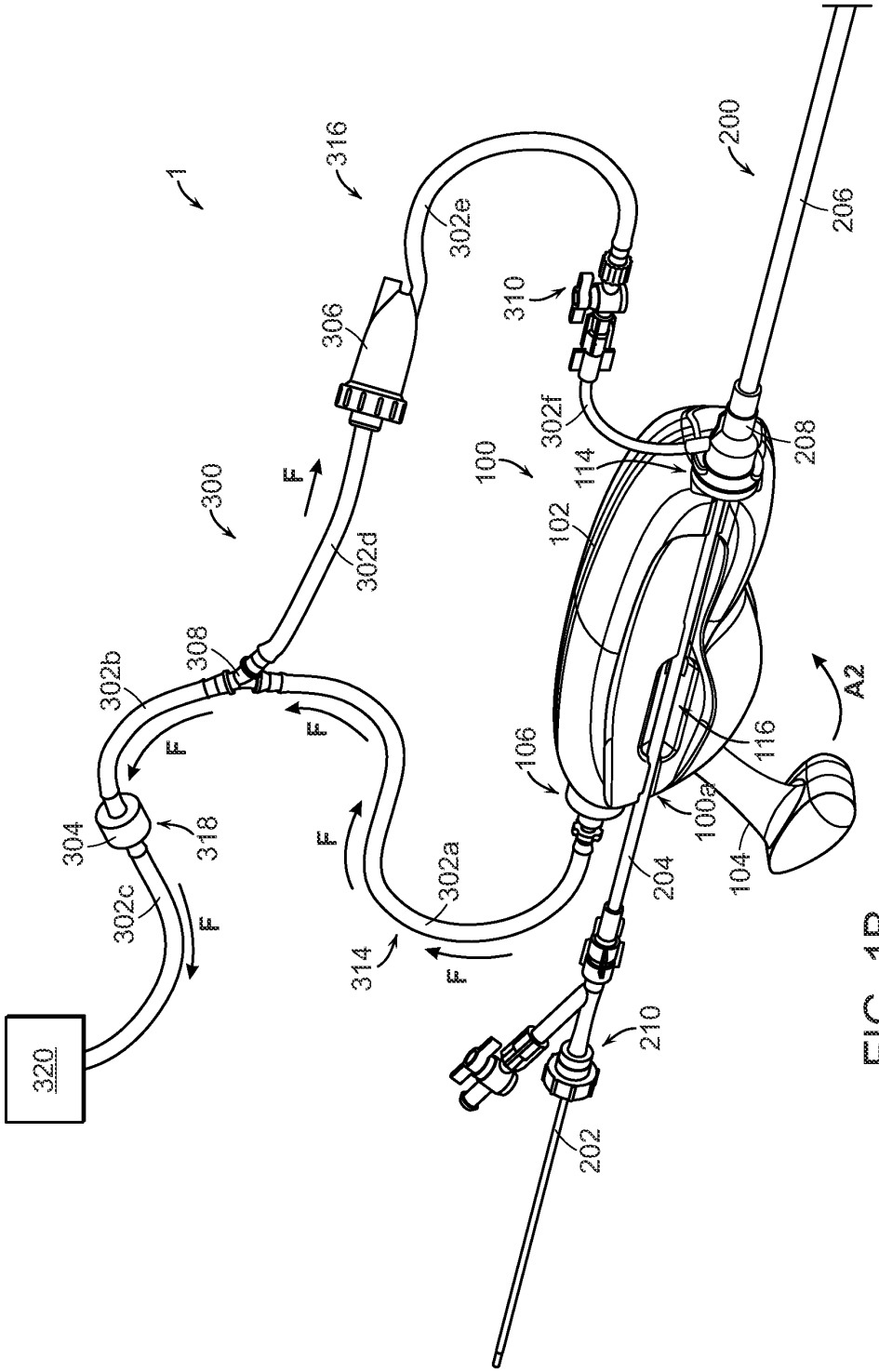

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FIG. 1B

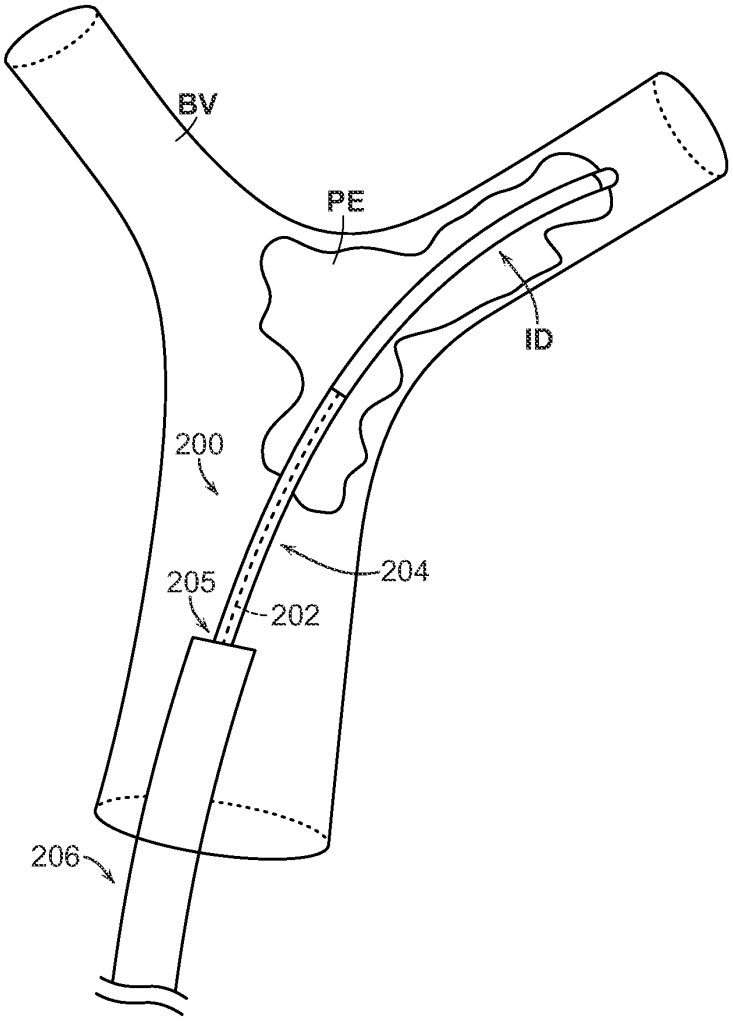


FIG. 2A

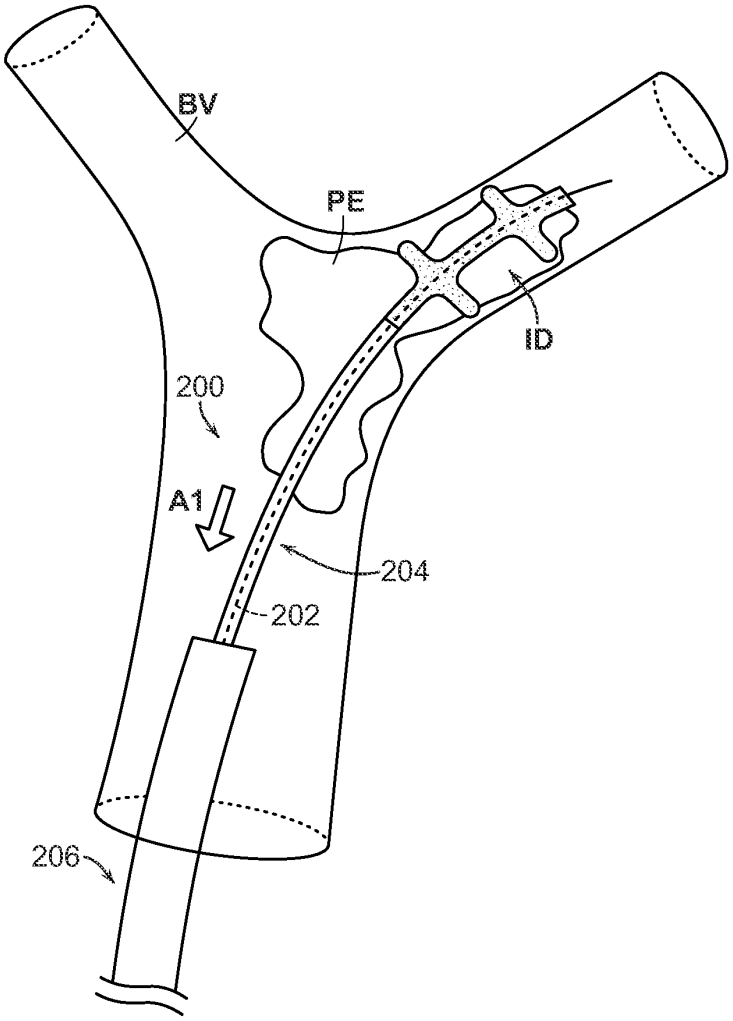


FIG. 2B

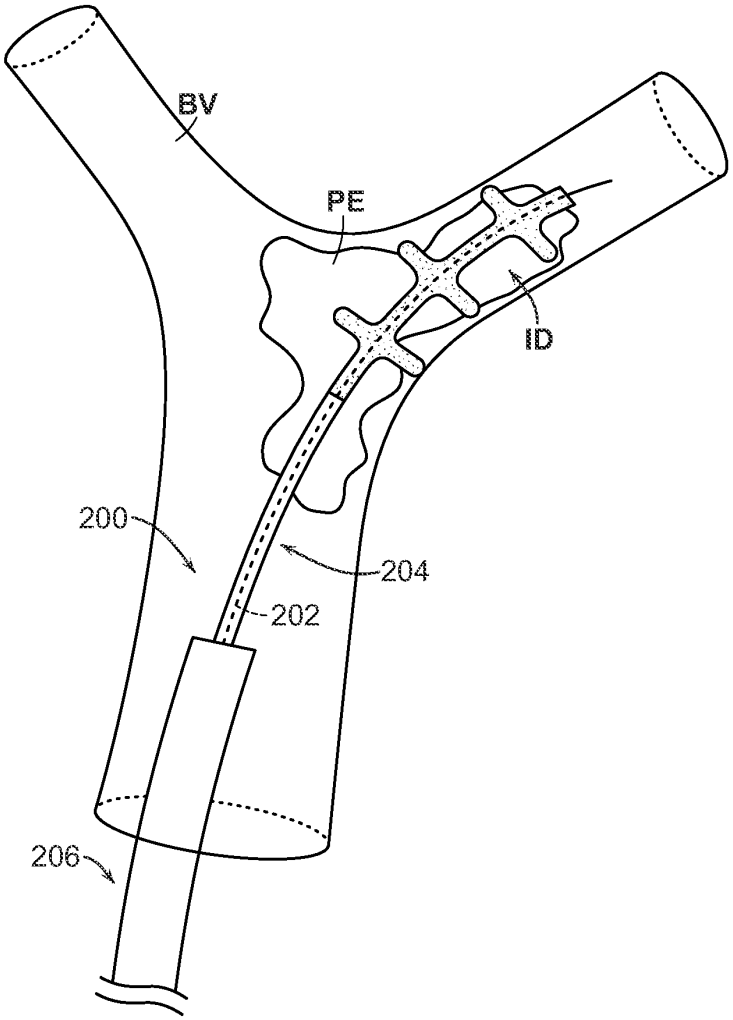


FIG. 2C

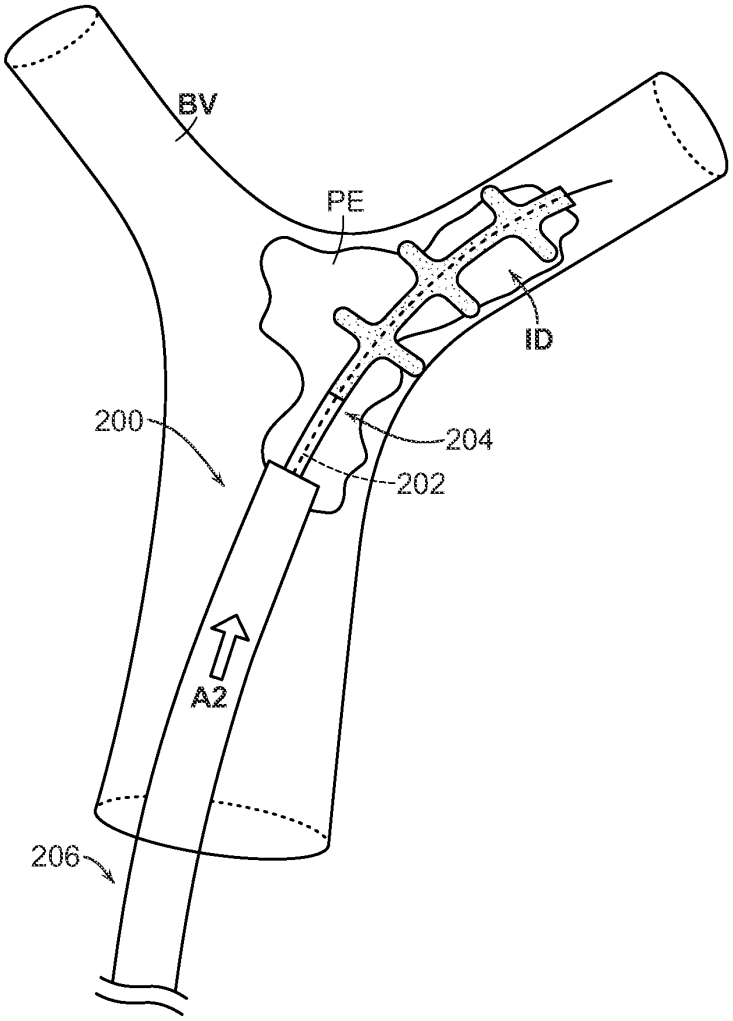


FIG. 2D

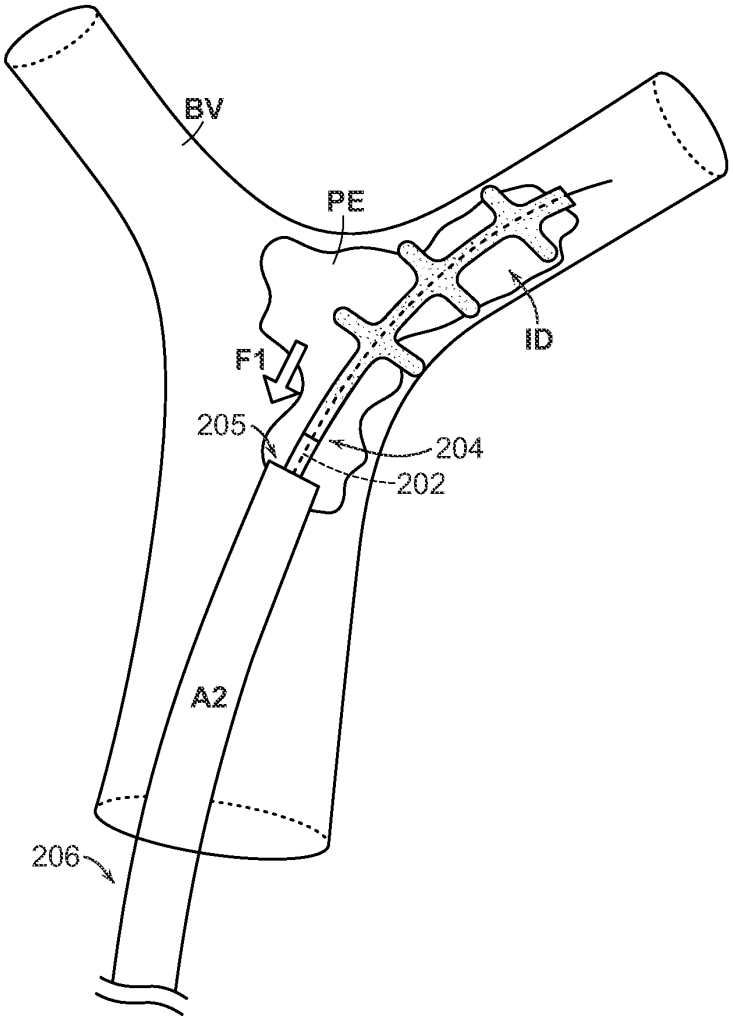


FIG. 2E

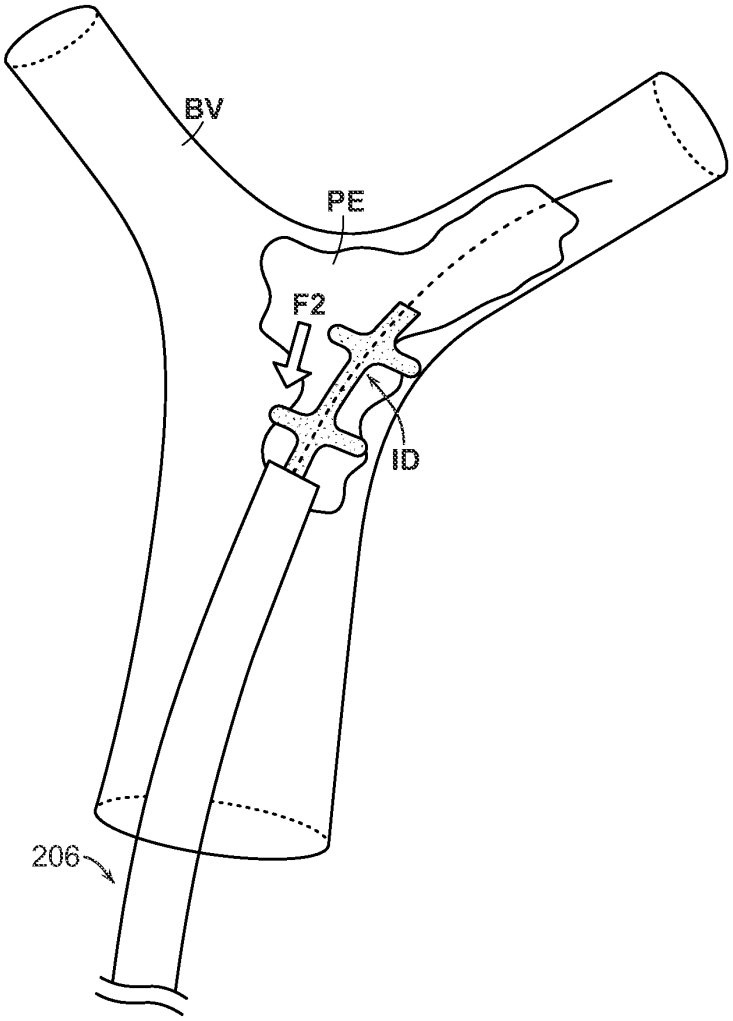


FIG. 2F

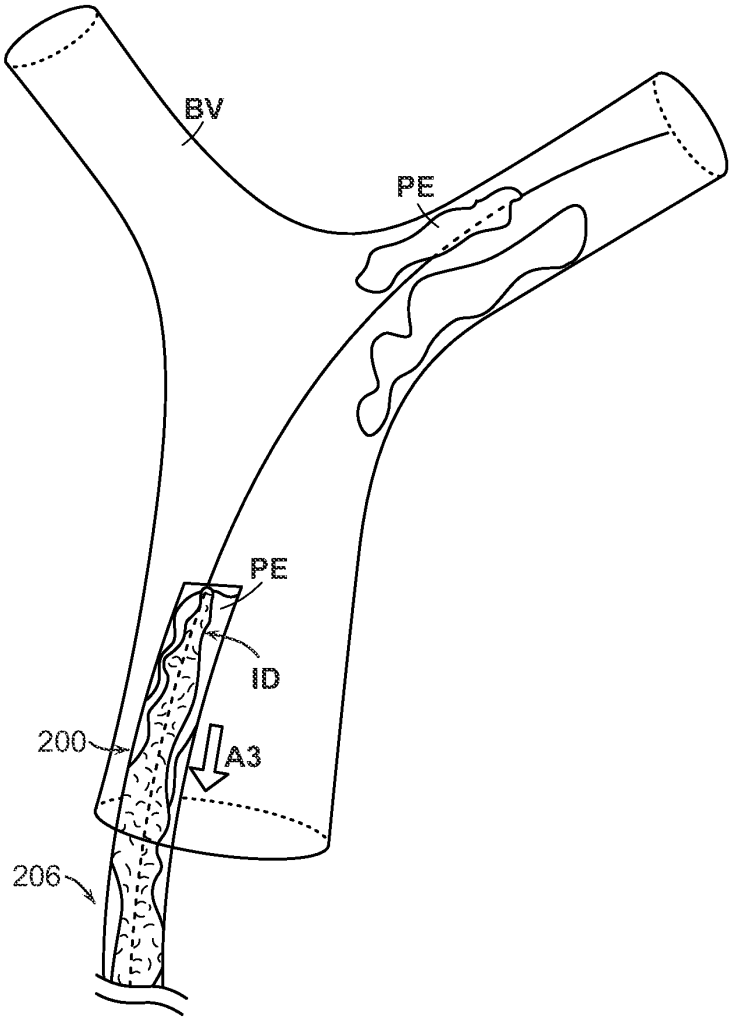


FIG. 2G

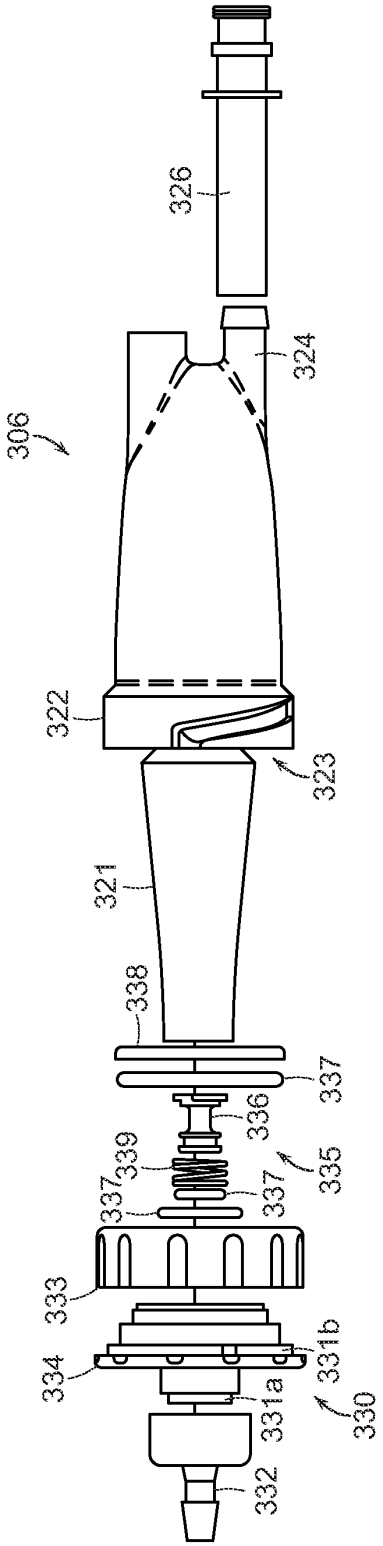

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FIG. 3A

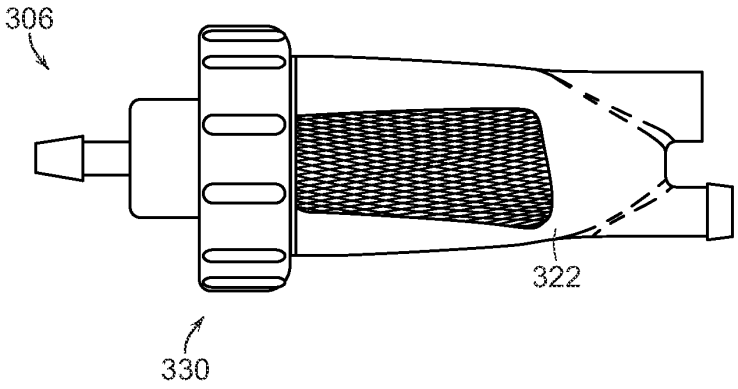


FIG. 3B

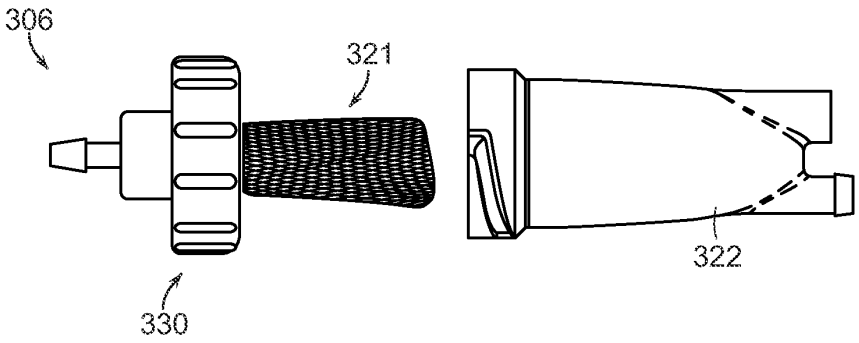


FIG. 3C

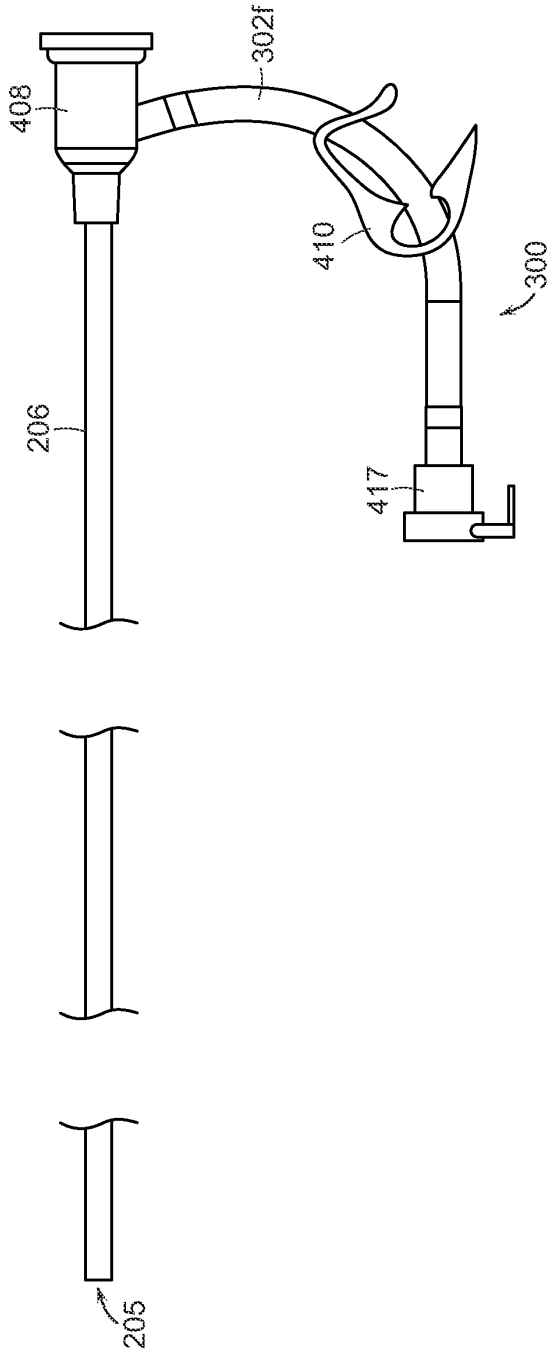


FIG. 4

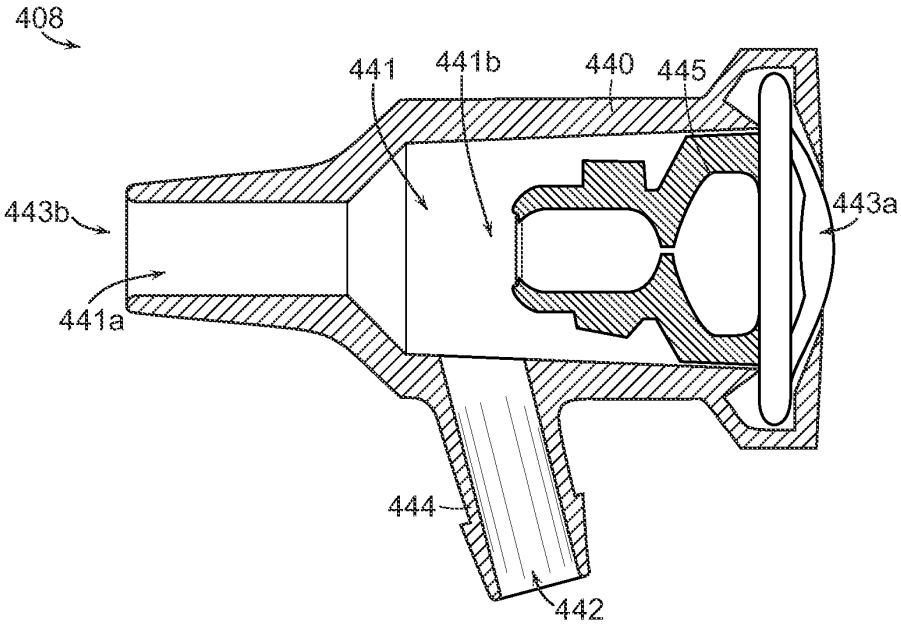

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FIG. 5

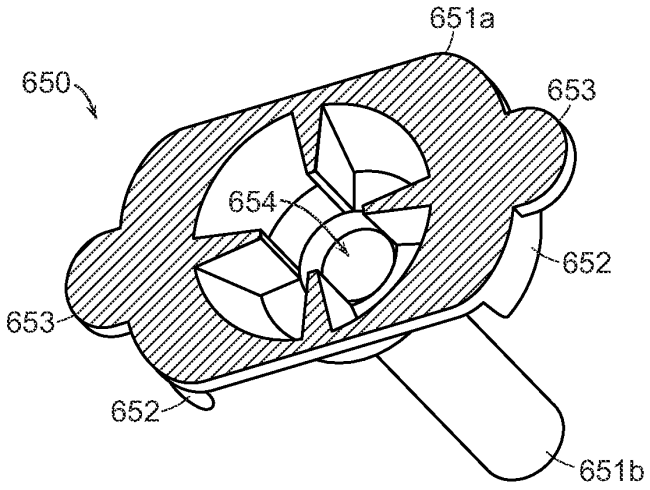

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FIG. 6

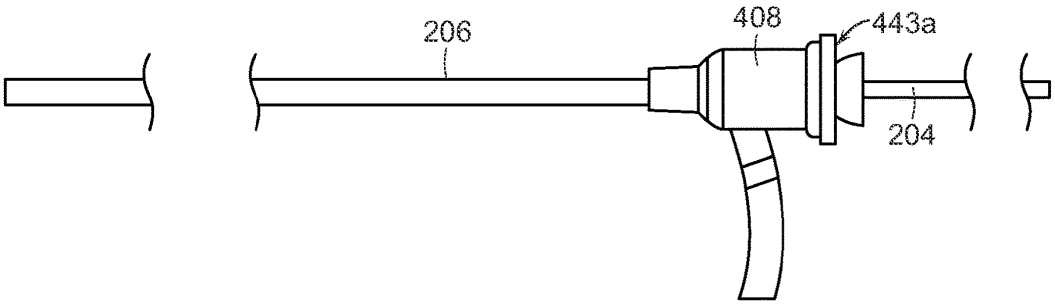

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FIG. 7A

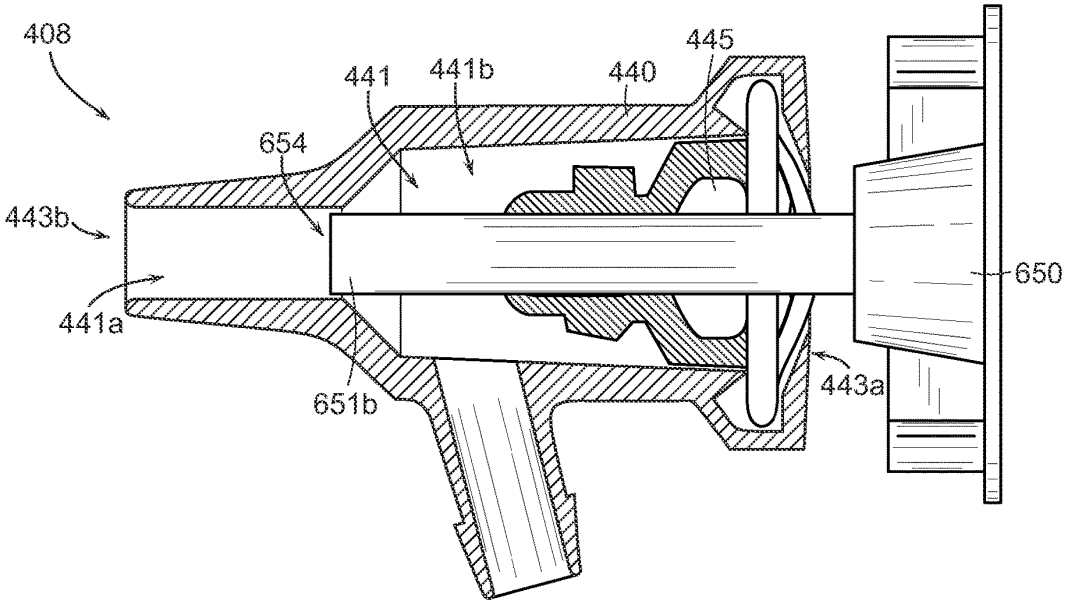

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FIG. 7B

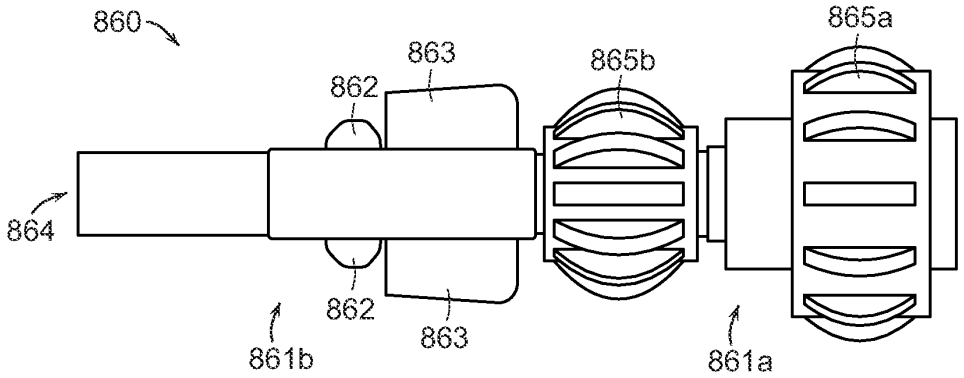


FIG. 8

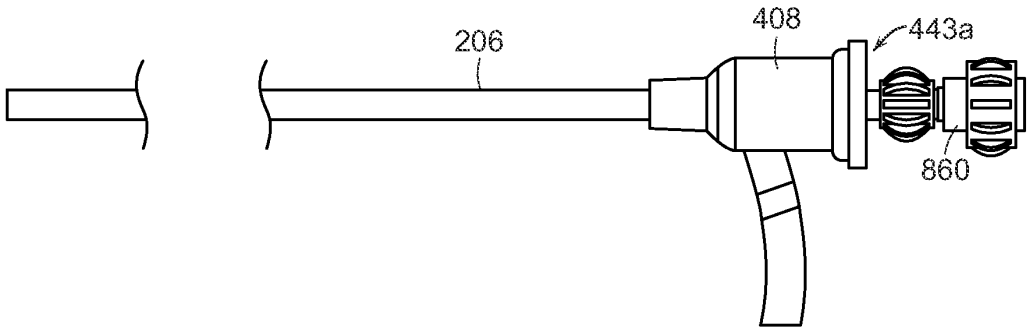


FIG. 9

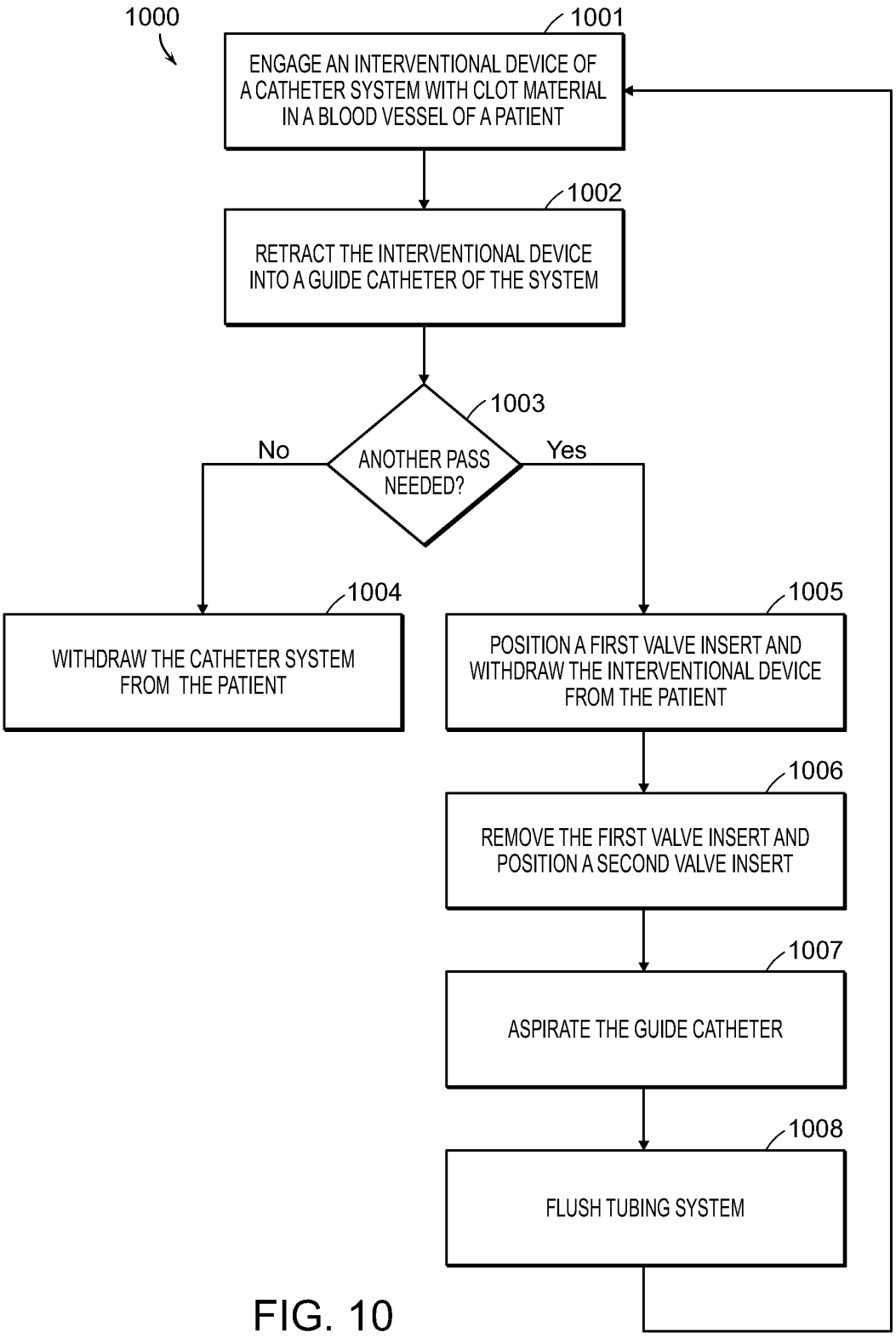

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ENGAGE AN INTERVENTIONAL DEVICE OF A CATHETER SYSTEM WITH CLOT MATERIAL IN A BLOOD VESSEL OF A PATIENT
1002
RETRACT THE INTERVENTIONAL DEVICE INTO A GUIDE CATHETER OF THE SYSTEM
1003
ANOTHER PASS NEEDED?
No
Yes
1004
WITHDRAW THE CATHETER SYSTEM FROM THE PATIENT
1005
POSITION A FIRST VALVE INSERT AND WITHDRAW THE INTERVENTIONAL DEVICE FROM THE PATIENT
1006
REMOVE THE FIRST VALVE INSERT AND POSITION A SECOND VALVE INSERT
1007
ASPIRATE THE GUIDE CATHETER
1008
FLUSH TUBING SYSTEM

FIG. 10

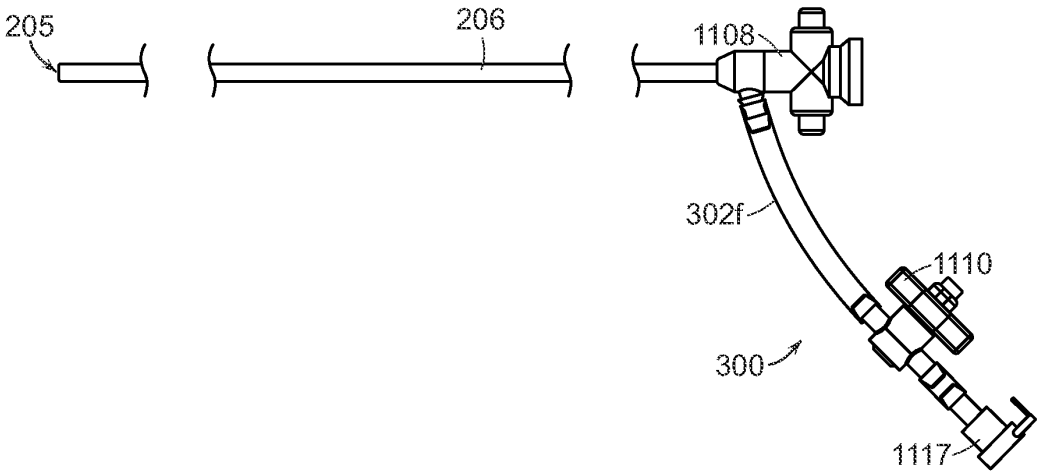


FIG. 11

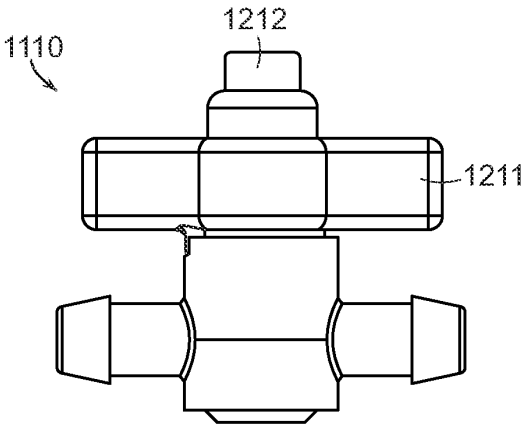


FIG. 12

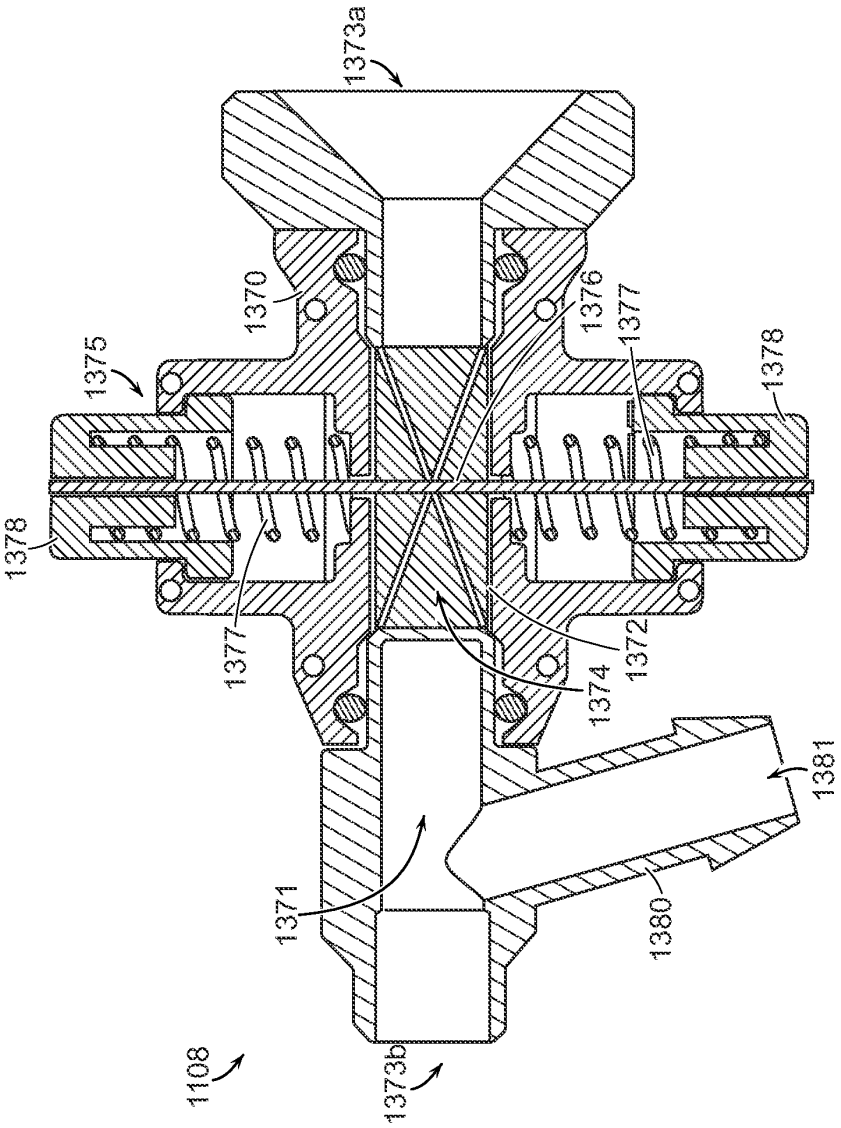

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FIG. 13A

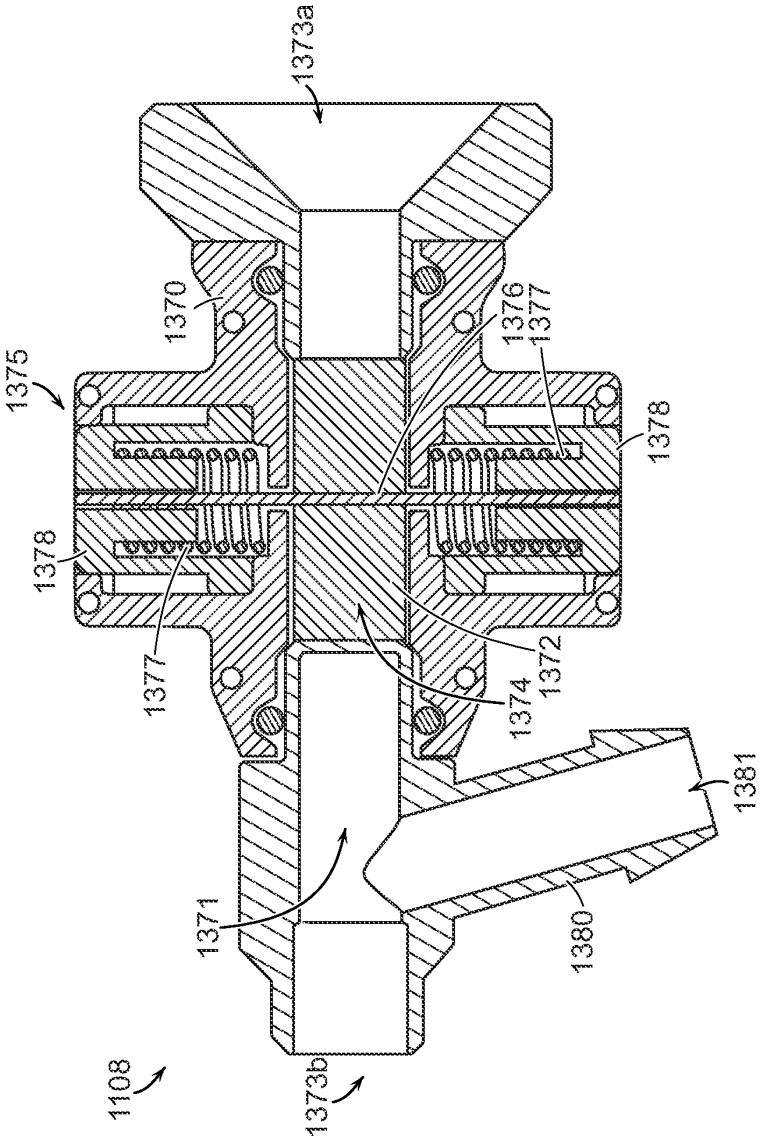

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FIG. 13B

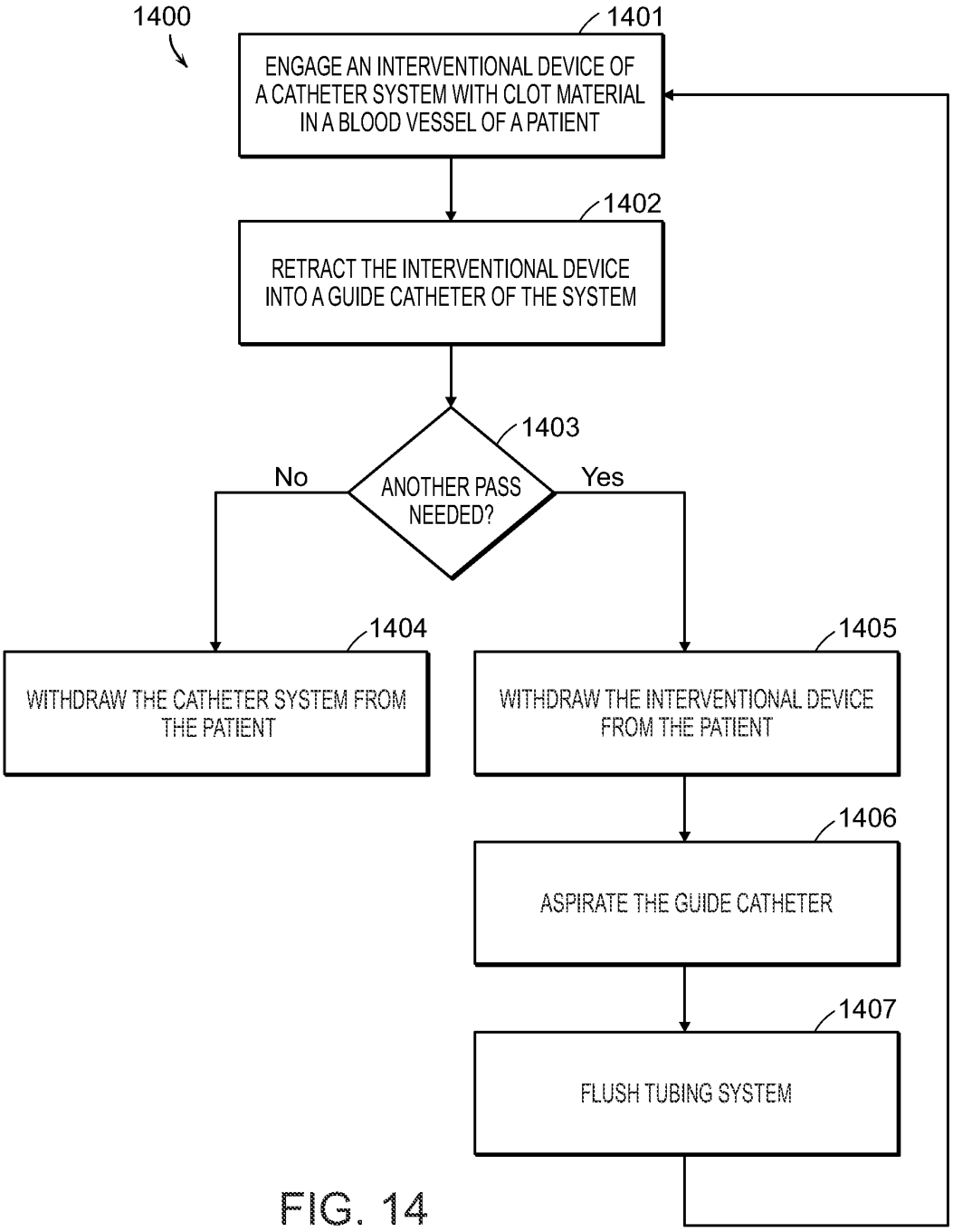

1400
1401
ENGAGE AN INTERVENTIONAL DEVICE OF A CATHETER SYSTEM WITH CLOT MATERIAL IN A BLOOD VESSEL OF A PATIENT
1402
RETRACT THE INTERVENTIONAL DEVICE INTO A GUIDE CATHETER OF THE SYSTEM
1403
ANOTHER PASS NEEDED?
No
Yes
1404
WITHDRAW THE CATHETER SYSTEM FROM THE PATIENT
1405
WITHDRAW THE INTERVENTIONAL DEVICE FROM THE PATIENT
1406
ASPIRATE THE GUIDE CATHETER
1407
FLUSH TUBING SYSTEM

FIG. 14

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

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 17/865,307, filed Jul. 14, 2022, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is a continuation of U.S. patent application Ser. No. 17/498,642, filed on Oct. 11, 2021, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is a continuation of U.S. patent application Ser. No. 16/258,344, filed on Jan. 25, 2019, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is now issued as U.S. Pat. No. 11,154,314, which claims the benefit of U.S. Provisional Patent Application No. 62/622,691, filed on Jan. 26, 2018, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," each of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

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

BACKGROUND

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.

When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenos after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clot material.

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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.

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Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

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

FIGS. **2**A-**2**G are schematic illustrations of a distal portion of the retraction and aspiration system during a clot removal procedure in accordance with embodiments of the present technology.

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

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

FIG. **5** is a side cross-sectional view of the attachment member shown in FIG. **4**.

FIG. **6** is an isometric view of a first valve insert in accordance with embodiments of the present technology.

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

FIG. **8** is a side view of a second valve insert in accordance with embodiments of the present technology.

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

FIG. **10** is a flow diagram of a process or method for operating the retraction and aspiration system in accordance with embodiments of the present technology.

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

FIG. **12** is a side view of the fluid control unit shown in FIG. **11** in accordance with embodiments of the present technology.

FIGS. **13**A and **13**B are side cross-sectional views of the attachment member shown in FIG. **11** in a first configuration and a second configuration, respectively, in accordance with embodiments of the present technology.

FIG. **14** is a flow diagram of a process or method for operating the retraction and aspiration system in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

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

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

With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a retraction and aspiration apparatus and/or an associated catheter system with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the retraction and aspiration system of the present technology can be used in any orientation suitable to the user.

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

FIGS. **1**A and **1**B are perspective views of a proximal portion of a clot retrieval system **1** configured in accordance with embodiments of the present technology, shown in a first state and a second state, respectively. Referring to FIGS. **1**A and **1**B together, the clot retrieval system **1** includes a retraction and aspiration device **100** ("RA device **100**"), a catheter system **200**, and a tubing system **300**. In some embodiments, the RA device **100** is coupleable to the catheter system **200** and operable to simultaneously (i) retract a portion of the catheter system **200** and (ii) aspirate through the catheter system **200**. In certain embodiments, the RA device **100** and catheter system **200** can both be fluidly coupled to the tubing system **300** to enable material (e.g., blood and clot material) aspirated from the catheter system **200** to flow into the tubing system **300**. In particular, the RA device **100**, the catheter system **200**, and the tubing system **300** can be the same as or similar to one or more of the retraction and aspiration devices, catheter systems, and tubing systems disclosed in U.S. Pat. No. 9,526,864, filed Jun. 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED METHODS," which is incorporated herein by reference in its entirety.

FIGS. **2**A-**2**G are schematic illustrations of a distal portion of the clot retrieval system **1** during a clot removal procedure in accordance with embodiments of the present

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technology. In particular, FIGS. **2**A-**2**G illustrate a distal portion of the catheter system **200** that is positioned proximate to an embolism or clot material within a blood vessel (e.g., a pulmonary blood vessel). Accordingly, operation of the catheter system **200** is described with references to FIGS. **2**A-**2**G.

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

As further shown in FIG. **2**A, the delivery sheath **204** and the interventional device ID can be positioned at least partially within the clot material PE. Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. The catheter system **200** can include an introducer **210** (FIGS. **1**A and **1**B; e.g., a Y-connector with a hemostasis valve) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer **210** and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve and into the main pulmonary artery. Depending on the location of the embolism, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the pulmonary embolism.

As shown in FIGS. **2**B and **2**C, the delivery sheath **204** can be withdrawn proximally (e.g., as indicated by arrow A**1** in FIG. **2**B) to allow the interventional device ID to expand within the clot material PE, thereby grabbing the clot material PE that is nearby. Although FIG. **2**B shows the interventional device ID positioned at the treatment site such that a distal terminus of the interventional device ID is distal of a distal terminus of the clot material PE, in some procedures the interventional device ID may be positioned such that the distal terminus of the interventional device ID is proximal of the distal terminus of the clot material PE. As shown in FIG. **2**D, in some embodiments the guide catheter **206** can optionally be advanced distally (e.g., as indicated by arrow A**2**) until the guide catheter **206** is positioned proximate to a proximal portion of the clot material PE.

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

The housing **102** can further include a channel **116** that extends proximally from the opening **114** along approximately the length of the housing **102**, as shown in FIGS. **1**A and **1**B. The channel **116** can have a height at least as great as the outer diameter of the delivery sheath **204** of the catheter system **200** (and/or another component of the catheter system **200**) such that the delivery sheath **204** can fit sideways through the channel **116**. In some embodiments, the pull member **202** and the interventional device ID (FIGS. **2**A-**2**G) can be pre-loaded into the delivery sheath **204**, and the delivery sheath **204** can be fed distally through the channel **116** (e.g., either via the proximal end of the channel **116** or first pushed sideways through a portion of the channel **116**) and into the guide catheter **206**. In other embodiments, the interventional device ID and the delivery sheath **204** are fed into the guide catheter **206** and the interventional device ID is deployed prior to coupling the guide catheter **206** to the RA device **100**.

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

The tubing system **300** of the clot retrieval system **1** fluidly couples the pressure source of the RA device **100** to the aspiration lumen of the catheter system **200**. When the RA device **100** is coupled to the catheter system **200**, movement of the lever **104** functions to simultaneously generate negative pressure in the pressure source and to retract a portion of the catheter system **200**, as described above. The tubing system **300** has a first portion **314** coupled to the pressure source, a second portion **316** coupled to the guide catheter **206**, and a drainage portion **318** coupled to a reservoir **320** (e.g., a vinyl bag). The first portion **314**, second portion **316**, and/or drainage portion **318** can include one or more tubing sections **302** (labeled individually as tubing sections **302***a*-**302***f*) and/or fluid control unit, such as one or more control valves. In certain embodiments, one or

more of the tubing sections **302** can have a relatively large diameter (e.g., greater than about 0.1 inch, greater than about 0.210 inch, etc.) to help inhibit clogging of clot material within the tubing system **300**.

More specifically, the first portion **314** can include the tubing section **302***a*. The drainage portion **318** can include (i) the tubing section **302***b*, (ii) a first fluid control unit (e.g., a valve) **304**, and (iii) the tubing section **302***c*. The second portion **316** can include (i) the tubing section **302***d*, (ii) a clot reservoir **306**, (iii) the tubing section **302***e*, (iv) a second fluid control unit **310**, and (v) the tubing section **302***f*. In some embodiments, the first fluid control unit **304** can be a one-way valve (e.g., a check valve) that only allows fluid flow from the first portion **314** and/or second portion **316** to the drainage portion **318** (and not vice-versa). In certain embodiments, as described in detail with reference to FIGS. **3**A-**3**C, the clot reservoir **306** can also include a one-way valve that only allows fluid flow from the second portion **316** to the drainage portion **318** (and not vice-versa). In some embodiments, the second fluid control unit **310** can be a stopcock or a clamp that is externally operated to regulate the flow of liquid through the second portion **316** of the tubing system **300**. A Y-connector **308** can fluidly couple the first, second, and drainage portions **314**, **316**, **318**. In other embodiments, the first, second, and/or drainage portions **314**, **316**, **318** can have more or fewer tubing sections, connectors, and/or fluid control unit and/or other suitable configurations.

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

As shown in FIG. **1**B, moving the lever **104** from the second position to the first position (indicated by arrow A**2** in FIG. **1**B) creates a positive pressure (e.g., indicated by arrows F in FIG. **1**B) in the first portion **314** and drainage portion **318** of the tubing system **300**. The clot reservoir **306** prevents the positive pressure from affecting the aspiration lumen of the catheter system **200**, thereby preventing backflow of fluid into the blood vessel BV at the treatment site. With respect to the catheter system **200**, when the lever **104** is actuated from the second position to the first position, the RA device **100** does not engage the delivery sheath **204** or the push member **202** to move these components. Thus, the next time the lever **104** is actuated relative to the housing **102**, the RA device **100** engages a new portion of the delivery sheath **204** and push member **202** such that the delivery sheath **204** and push member **202** are incrementally retracted proximally each time the lever **104** is "pumped" (e.g., moved from the first position toward the second position and then back toward the first position).

Depending on the age and size of the clot material PE, local anatomical and/or physiological conditions, and position of the interventional device ID relative to the clot material PE, the lever **104** can be pumped several times to fully extract the clot material PE and/or interventional device ID from the treatment site. For example, FIGS. **2**D and **2**E show the proximal movement of the delivery sheath **204** and pull member **202** after a first pump of the lever **104**. FIGS. **2**E and **2**F show the proximal movement of the delivery sheath **204**, pull member **202**, and interventional device ID after a second pump of the lever **104** (e.g., including a second instance of pressure generation indicated by arrows F**1** and F**2** in FIGS. **2**E and **2**F, respectively). In some embodiments, the interventional device ID and the clot material PE can be fully withdrawn into the guide catheter **206** after a single pump of the lever **104**. In other embodiments, such as those procedures where the interventional device ID is initially positioned such that a distal terminus of the interventional device ID is proximal of a distal terminus of the clot material PE (the clot material PE often originates in a vein of the patient's leg, and thus is cast into an elongated, worm-like shape), it can take several pumps of the lever **104** to fully withdraw the clot material PE into the guide catheter **206**. Thus, in some embodiments, even when the interventional device ID is positioned within the guide catheter **206** such that a distal terminus of the interventional device ID is proximal of the distal terminus of the guide catheter **206**, the lever **104** can be pumped several more times to continue to withdraw the clot material PE into the guide catheter **206** and the tubing system **300** (e.g., into the second portion **316**, the clot reservoir **306**, and/or the drainage portion **318**).

Once the clot material PE is positioned within the guide catheter **206** such that a distal terminus of the clot material PE is proximal from a distal terminus of the guide catheter **206**, the catheter system **200** can be withdrawn proximally (e.g., as indicated by arrow A**3** in FIG. **2**G) from the treatment site, and removed from the patient. However, sometimes, as shown in FIG. **2**G, retracting the interventional device ID and delivery sheath **204** into the guide catheter **206** may not remove all of the clot material PE (or a desired amount of the clot material PE) from the blood vessel BV. That is, a single "pass" (e.g., a deployment of the interventional device ID and subsequent retraction of the interventional device ID into the guide catheter **206**) may not adequately remove the clot material PE from the blood vessel BV. In such instances, the operator of the clot retrieval system **1** may wish to make another pass with the interventional device ID to remove all or a portion of the remaining clot material PE in the blood vessel BV.

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

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

FIGS. **3**A-**3**C are a fully-exploded view, an isometric view, and a partially-exploded view of the clot reservoir **306** of the clot retrieval system **1**. With reference to FIG. **3**A, the clot reservoir **306** includes a housing **322** defining a chamber **323**, a filter **321** configured to be positioned within the housing **322**, and a cap assembly **330** configured to be

coupled to the housing **322**. The housing **322** can include a port **324** configured to be removably, fluidly coupled to the catheter system **200**. In some embodiments, a tubing section **326** is coupled to the port **324** during priming of the clot retrieval system **1** and, as described in further detail below with reference to FIGS. **10** and **14**, during flushing of the tubing system **300**. In certain embodiments the tubing section **326** is semi-permanently coupled to the housing **322** and can be used to fluidly couple the housing **322** to the tubing system **300** and/or the catheter system **200**.

In the embodiment illustrated in FIG. **3**A, the cap assembly **330** includes a fluid connector (e.g., a barbed outlet) **332** for connecting to the tubing system **300** (e.g., to the tubing section **302***d* shown in FIGS. **1**A and **1**B), a nut **333** for releasably securing the cap assembly **330** to the housing **322** (e.g., via a threaded coupling), a first cap portion **334**, and a second cap portion **338**. In some embodiments, the fluid connector **332** is secured to the first cap portion **334** via an adhesive **331***a*, and the first cap portion **334** is secured to the nut **333** via a second adhesive **331***b*. In some embodiments, the first and second adhesives **331***a*, **331***b* are the same. The cap assembly **330** can further include a check valve assembly **335** positioned between the first and second cap portions **334**, **338** and comprising a piston **336** and a spring **339** (e.g., a passivated compression spring). The check valve assembly **335** provides for one-way fluid flow through the clot reservoir **306**, for example, from the catheter system **200** to the reservoir **320** (FIGS. **1**A and **1**B). The clot reservoir **306** can further include one or more O-rings **337** for sealing the various components.

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

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

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

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

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

FIG. **5** is a side cross-sectional view of the attachment member **408** show in FIG. **4**. As shown in the embodiment of FIG. **5**, the attachment member **408** includes a body or housing **440** having a proximal opening **443***a*, a distal opening **443***b*, and a first lumen **441** extending between the proximal and distal openings **443***a* and **443***b*. The first lumen **441** further comprises a first portion **441***a* having a first diameter (e.g., a constant first diameter) and a second portion **441***b* having a second diameter greater than the first diameter. In some embodiments, the first diameter can be generally the same as the outer diameter of the guide catheter **206**. The housing **443** further includes a branch portion **444** configured to be coupled to the tubing section **302***f* and having a second lumen **442** branching from the first lumen **441**. In some embodiments, the second lumen **442** can have a relatively large diameter (e.g., between about 0.098 inch and 0.210 inch, about 0.210 inch, greater than 0.210 inch, etc.) to help inhibit clogging and/or collecting of clot material within the attachment member **408** during, for example, aspiration of the guide catheter **206**.

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

inserted through the valve **445** for advancement to the treatment site in the blood vessel BV.

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

Referring to FIG. **6**, the first valve insert **650** includes a proximal portion **651***a*, a distal portion **651***b* extending from the proximal portion **651***a*, and a lumen **654**. As illustrated in the embodiment of FIG. **6**, the proximal portion **651***a* can optionally include one or more first engagement features (e.g., flanges, tabs, etc.) **652** configured to engage with the attachment member **408** of the of the catheter system **200** to securely position (e.g., lock, mate, flush, etc.) the first valve insert **650** within the attachment member **408**. For example, in some embodiments, the first engagement features **652** can be configured to "snap" into (e.g., mate with) corresponding grooves on the attachment member **408**. The proximal portion **651***a* can further include one or more second engagement features **653** (e.g., flanges, tabs, etc.) configured to be gripped by an operator to enable the operator to, for example, easily manipulate and/or position the first valve insert **650** within the attachment member **408**.

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

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

FIG. **8** is a side view of a second valve insert **860** (e.g., an aspiration insert) in accordance with embodiments of the present technology. Similar to the first valve insert **650**, the second valve insert **860** is configured to be inserted at least partially into the first lumen **441** of the attachment member **408** (e.g., through the valve **445**) through the proximal opening **443***a* of the attachment member **408**. Accordingly, FIG. **9** is a side view of the second valve insert **860** inserted into the attachment member **408** in accordance with embodiments of the present technology.

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

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

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

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

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

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

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

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

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

The first valve insert **650** can be advanced over the delivery sheath **204** and/or guidewire of the catheter system **200** until it is positioned (e.g., seated) at least partially within the attachment member **408** (FIGS. **7**A and **7**B). Once the first valve insert **650** is positioned within the attachment member **408**, the interventional device ID and delivery sheath can be fully withdrawn from the patient. For example, in some embodiments, the operator may grip a portion of the delivery sheath **204** that is exposed proximally from the RA device **100** and pull the delivery sheath **204** and interventional device ID proximally through the guide catheter **206**. In some embodiments, the first valve insert **650** is only positioned within the attachment member **408** when the interventional device ID is proximate the attachment member **408**. That is, the operator may partially withdraw the delivery sheath **204** and interventional device ID within the guide catheter **206** before advancing the first valve insert **650** into position. In some embodiments, the delivery sheath **204** includes a marking (e.g., a specific color pattern) configured to indicate to the operator that the distal end of the delivery sheath **204** and/or the interventional device ID is near (e.g., proximally approaching) the attachment member **408**. In certain embodiments, the guidewire of the catheter system **200** is pinned during withdrawal of the interventional device ID and the delivery sheath **204** such that the guidewire does not move relative to the interventional device ID and the delivery sheath **204**. Therefore, in such embodiments, the guidewire does not need to be re-advanced to the treatment site prior to an additional pass.

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

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

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

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

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

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

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

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

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

Additional details of the systems, devices, and methods described above with reference to FIGS. **4-9** are provided in Appendix B to this application.

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

FIG. **11** is a side view of an attachment/valve member **1108** ("attachment member **1108**") of the catheter system **200** and a second fluid control unit **1110** of the tubing system **300** in accordance with embodiments of the present technology. The attachment member **1108** and the second fluid control unit **1110** can have some features generally similar to the features of the attachment members **208**, **408** and the second fluid control unit **310**, **410**, respectively, described above with reference to FIGS. **1A-10**. For example, the attachment member **1108** can be integral with or coupled to

a proximal portion of the guide catheter **206** and configured to be detachably coupled to the RA device **100** (FIGS. **1**A and **1**B; e.g., via a snap-fit arrangement) to at least partially secure the catheter system **200** to the RA device **100**. When secured to the RA Device **100**, the attachment member **1108** can fluidly connect the lumen **205** (e.g., an aspiration lumen) of the guide catheter **206** to the tubing system **300** of the clot retrieval system **1** via the tubing section **302***f*. Likewise, the second fluid control unit **1110** can be a stopcock ("stopcock **1110**") that is externally operable to regulate the flow of fluid through the tubing section **302***f*.

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

FIG. **12** is a side view of the stopcock **1110** in accordance with embodiments of the present technology. In the embodiment illustrated in FIG. **12**, the stopcock **1110** includes a grip member (e.g., a handle, a knob, etc.) **1211** that can be actuated (e.g., twisted by the hand of an operator) to partially or fully restrict fluid flow through the tubing section **302***f*. In some embodiments, the stopcock **1110** also includes an injection port **1212** (e.g., a needleless injection port) configured to receive a syringe or other fluid delivery member therethrough. In some embodiments, the injection port **1212** permits fluid to be introduced into the attachment member **1108** and the guide catheter **206** without requiring that a connector **1117** be decoupled from the tubing system **300**. For example, in some embodiments, an operator can actuate the stopcock **1110** (e.g., twist the grip member **1211**) to close the stopcock **1110** and subsequently introduce a syringe at the injection port **1212** to flush the guide catheter **206** with a fluid (e.g., saline) introduced via the syringe.

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

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

As shown, a tubular member (e.g., an elongate member) **1372** can extend at least partially through the first lumen **1371** to define a central lumen **1374** that is generally coaxial with the first lumen **1371**. In some embodiments, the tubular member **1372** can comprise a compliant tubular structure (e.g., a silicon tube) that can be, for example, a thin-walled compliant tubular structure. The thin-walled structure of the tubular member **1372** can facilitate the collapse, and specifically the uniform collapse of the tubular member **1372** and sealing of the tubular member **1372**. For example, the attachment member **1108** can further include an actuation mechanism **1375** coupled to the tubular member **1372** and configured to collapse and seal the tubular member **1372** via compression and/or constriction of one or more filaments **1376** coupled to the tubular member **1372**.

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

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

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

FIG. **14** is a flow diagram of a process or method **1400** for operating the clot retrieval system **1** including the attachment member **1108** to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with embodiments of the present technology. Although some features of the method **1400** are described in the context of the embodiments shown in FIGS. **1**A, **1**B, and **11-13** for sake of illustration, one skilled in the

art will readily understand that the method **1400** can be carried out using other suitable systems and/or devices.

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

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

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

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

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

The delivery sheath **204** and/or another component of the catheter system **200** may then be manually (e.g., by the operator) or automatically pulled proximally to withdraw the interventional device ID from the patient. Before the interventional device ID and associated clot material PE are withdrawn through the attachment member **1108**, the actuation mechanism **1375** of the attachment member **1108** can be actuated (e.g., by depressing the buttons **1378**) to move the tubular member **1372** to the second configuration (e.g., to open the tubular member **1372**) such that the central lumen **1374** of the tubular member **1372** and the first lumen **1371** of the housing **1370** together provide a continuous lumen of generally constant diameter. Accordingly, the interventional device ID can be fully withdrawn (e.g., retracted proximally) through the attachment member **1108** without causing a significant amount of clot material PE associated with the interventional device ID to remain in the attachment member **1108**—thus minimizing the risk of reintroducing clot material to the patient upon an additional pass using the interventional device ID (or another interventional device). Moreover, in certain embodiments, the guidewire of the catheter system **200** is pinned during withdrawal of the interventional device ID and the delivery sheath **204** such that the guidewire does not move relative to the interventional device ID and the delivery sheath **204**. Therefore, in such embodiments, the guidewire does not need to be re-advanced to the treatment site prior to an additional pass.

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

In some embodiments, the guide catheter **206** can be aspirated without use of the RA device **100**. For example, a syringe or other pressure source can be fluidly coupled directly to the connector **1117** and used to aspirate the guide catheter **206**. In such embodiments, opening of the stopcock **1110** fluidly connects the syringe to the lumen **205** of the guide catheter **206** and closing of the stopcock **1110** fluidly disconnects the syringe from the lumen **205** of the guide catheter **206**. In some embodiments, the syringe or other pressure source can be pre-charged with a vacuum—such as by drawing a plunger of the syringe with the stopcock **1110** closed. The stopcock **1110** can then be opened to instantaneously or nearly instantaneously (e.g., immediately) apply the stored vacuum pressure to the tubing system **300** and to the lumen **205** of the guide catheter **206**, thereby generating suction throughout the guide catheter **206**. In particular, suction can be generated at a distal portion of the guide catheter **206**. In one aspect of the present technology, pre-charging or storing the vacuum before applying the

vacuum to the lumen **205** of the guide catheter **206** is expected to generate greater suction forces with a faster ramp time (and correspondingly greater fluid flow velocities) at and/or near a distal portion of the guide catheter **206** as compared to, for example, simply activating the pressure source of the RA device **100** by cycling the lever **104** of the RA device **100**. These suction forces generated by application of the stored vacuum can be used to not only aspirate the guide catheter **206**, but also to aspirate or otherwise remove some or all of the clot material PE remaining in the blood vessel BV after retraction of the interventional device ID.

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

After the tubing system **300** has been flushed, the method **1400** can return to block **1401**. In particular, the same interventional device ID and delivery sheath **204** can be cleaned and subsequently advanced through the guide catheter **206** and to the remaining clot material PE in the blood vessel. In some embodiments, a new interventional device ID and delivery sheath **204** can be used for each pass to reduce the likelihood of contamination (e.g., reintroduction of clot material PE). Once the desired amount of clot material PE has been removed from the patient, the catheter system **200** may be fully withdrawn from the patient (block **1404**).

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

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

Additional details of the systems, devices, and methods described above with reference to FIGS. **11-14** are provided in Appendix C to this application.

V. Examples

1. A method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:
   - engaging a first interventional device with the clot material at the treatment site in the blood vessel;
   - retracting the first interventional device and a portion of the clot material into a distal portion of an elongated shaft;
   - inserting a first valve insert into an attachment member coupled to a proximal portion of the elongated shaft;
   - withdrawing the first interventional device and the portion of the clot material proximally through (a) the elongated shaft, (b) the attachment member, and (c) the first valve insert;
   - inserting a second valve insert into the attachment member instead of the first valve insert;
   - aspirating the elongated shaft; and
   - advancing a second interventional device distally through the elongated shaft to the treatment site.
2. The method of example 1 wherein, after inserting the first valve insert into the attachment member, the first valve insert and the attachment member together define a lumen having a generally constant diameter.
3. The method of example 2 wherein the diameter of the lumen is generally the same as the diameter of the elongated shaft.
4. The method of any one of examples 1-3 wherein inserting the first valve insert into the attachment member includes exercising a valve of the attachment member.
5. The method of any one of examples 1-4, further comprising actuating the second valve insert to seal the attachment member.
6. The method of any one of examples 1-5 wherein the first interventional device and the second interventional device are the same interventional device, and wherein the method further comprises cleaning the interventional device to remove the portion of the clot material.
7. The method of any one of examples 1-6, further comprising engaging the second interventional device with remaining clot material at the treatment site in the blood vessel.
8. The method of any one of examples 1-7 wherein aspirating the elongated shaft includes aspirating, into the elongated shaft, at least a portion of clot material remaining at the treatment site in the blood vessel.
9. The method of example 8 wherein aspirating the elongated shaft includes—
   - coupling a syringe to the elongated shaft via a fluid control unit, wherein opening of the fluid control unit fluidly connects the syringe to the elongated shaft, and wherein closing of the fluid control device fluidly disconnects the syringe from the elongated shaft;
   - drawing a plunger of the syringe to generate a vacuum while the fluid control unit is closed; and
   - opening the fluid control unit to apply the vacuum to the elongated shaft to thereby aspirate the portion of the remaining clot material into the elongated shaft.

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

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

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

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

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

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

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

17. The method of one of examples 11-16 wherein aspirating the elongated shaft includes—
coupling a syringe to the elongated shaft via a stopcock, wherein opening of the stopcock fluidly connects the syringe to the elongated shaft, and wherein closing of the stopcock fluidly disconnects the syringe from the elongated shaft;
drawing a plunger of the syringe to generate a vacuum while the stopcock is closed; and
opening the stopcock to apply the vacuum to the elongated shaft to thereby aspirate, into the elongated shaft, at least a portion of clot material remaining at the treatment site in the blood vessel.

18. A method for the intravascular treatment of clot material from a treatment site within a blood vessel of a human patient, the method comprising:
engaging an interventional device with the clot material at the treatment site in the blood vessel;
retracting the interventional device and a portion of the clot material into a distal portion of a lumen of an elongated shaft;
unsealing an attachment member coupled to a proximal portion of the elongated shaft;
withdrawing the interventional device and the portion of the clot material through the lumen of the elongated shaft and through the attachment member;
sealing the attachment member;
aspirating the elongated shaft; and
advancing the same or a different interventional device distally through the lumen of the elongated shaft to the treatment site.

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

20. The method of example 18 or 19, further comprising:
engaging the same or the different interventional device with clot material remaining in the blood vessel; and
retracting the same or the different interventional device interventional device and a portion of the remaining clot material into the distal portion of the lumen of the elongated shaft;
unsealing the attachment member; and
withdrawing the same or the different interventional device and the portion of the remaining clot material through the lumen of the elongated shaft and through the attachment member.

VI. Conclusion

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.

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.

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.

I claim:

1. An aspiration system, comprising:
a vacuum source;
connection tubing fluidically coupled to the vacuum source;
a catheter fluidically coupled to the vacuum source;
a filter chamber fluidically coupled to the connection tubing at a location apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—
a port configured to be fluidically coupled to the catheter; and
a fluid connector configured to be fluidically coupled to the connection tubing; and
wherein the filter is in the housing along a first fluid path, wherein the first fluid path fluidically couples the port and the fluid connector, and wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path;
a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter; and
a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.

2. The aspiration system of claim 1 wherein the flow controller comprises a flow control unit between the filter chamber and the catheter.

3. The aspiration system of claim 2 wherein the flow control unit comprises a user-actuatable valve.

4. The aspiration system of claim 1 wherein the catheter is fluidically connected in serial to the filter chamber along the first fluid path.

5. The aspiration system of claim 1, further comprising the interventional device.

6. The aspiration system of claim 5 wherein the interventional device is configured to be inserted through the hemostasis valve and the catheter past a distal end portion of the catheter.

7. The aspiration system of claim 6 wherein the interventional device comprises:
an elongate shaft having a distal portion; and
a clot engagement member coupled to a distal portion of the elongate shaft, wherein the clot engagement member is shaped and sized to disrupt clot material.

8. The aspiration system of claim 1 wherein the filter is removable from within the housing.

9. The aspiration system of claim 1 wherein the filter chamber is removably coupled to the connection tubing.

10. The aspiration system of claim 1 wherein the filter encloses a region within the housing, wherein the fluid connector is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

11. The aspiration system of claim 1 wherein a distal portion of the first fluid path and a distal portion of the second fluid path overlap.

12. The aspiration system of claim 1 wherein—
the hemostasis valve comprises a tubular member, a button, a spring coupled to the button, and a filament coupled to the button and the tubular member,
the button is configured to be actuated from a first position to a second position to loosen the filament to allow the tubular member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve,
and the spring is configured to bias the button to the first position.

13. The aspiration system of claim 1 wherein the vacuum source is syringe.

14. The aspiration system of claim 1 wherein the vacuum source comprises a vacuum chamber, wherein the connection tubing is fluidically coupled to the vacuum chamber, and wherein the catheter is fluidically coupled to the vacuum chamber via the filter chamber along the first fluid path.

15. An aspiration system, comprising:
a vacuum source;
a catheter fluidically coupled to the vacuum source via a first fluid path;
a filter chamber along the first fluid path and spaced apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—
a first port configured to be fluidically coupled to the catheter; and
a second port configured to be fluidically coupled to the vacuum source; and
wherein the filter is in the housing along the first fluid path between the first port and the second port;
a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter; and
a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.

16. The aspiration system of claim 15 wherein the flow controller comprises a flow control unit between the filter chamber and the catheter.

17. The aspiration system of claim 16 wherein the flow control unit comprises a user-actuatable valve.

18. The aspiration system of claim 15 wherein the catheter is fluidically connected in serial to the filter chamber along the first fluid path.

19. The aspiration system of claim 15, further comprising the interventional device.

20. The aspiration system of claim 19 wherein the interventional device is configured to be inserted through the hemostasis valve and the catheter past a distal end portion of the catheter.

21. The aspiration system of claim 20 wherein the interventional device comprises:
an elongate shaft having a distal portion; and
a clot engagement member coupled to a distal portion of the elongate shaft, wherein the clot engagement member is shaped and sized to disrupt clot material.

22. The aspiration system of claim 15 wherein the filter is removable from within the housing.

23. The aspiration system of claim 15 wherein the filter chamber is removably coupled along the first fluid path.

24. The aspiration system of claim **15** wherein the filter encloses a region within the housing, wherein the second port is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

25. The aspiration system of claim **15** wherein a distal portion of the first fluid path and a distal portion of the second fluid path overlap.

26. The aspiration system of claim **15** wherein the hemostasis valve comprises a tubular member, a button, and a filament coupled to the button and the tubular member, and wherein the button is configured to be actuated from a first position to a second position to loosen the filament to allow the tubular member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve.

27. The aspiration system of claim **26** wherein the button is movable from the second position to the first position to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device.

28. The aspiration system of claim **27** wherein the hemostasis valve further comprises a spring configured to bias the button to the first position.

29. The aspiration system of claim **15** wherein the vacuum source is syringe.

30. The aspiration system of claim **15** wherein the vacuum source comprises a vacuum chamber, and wherein the catheter is fluidically coupled to vacuum chamber via the first fluid path.

* * * * *

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Case Name: Inari Medical, Inc. v. Imperative Care, Inc., et al
Case Number: 5:24-cv-03117-EKL
Filer: Inari Medical, Inc.
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Docket Text:
CLAIM CONSTRUCTION STATEMENT *(Joint) Claim Construction and Prehearing Statement Pursuant to Patent Local Rule 4-3* filed by Inari Medical, Inc.. (Attachments: # (1) Exhibit A, # (2) Exhibit B, # (3) Exhibit C, # (4) Exhibit D, # (5) Exhibit E, # (6) Exhibit F, # (7) Exhibit G, # (8) Exhibit H, # (9) Exhibit I, # (10) Exhibit J, # (11) Exhibit K)(Keese, Daniel) (Filed on 4/28/2025)

5:24-cv-03117-EKL Notice has been electronically mailed to:

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5:24-cv-03117-EKL Please see Local Rule 5-5; Notice has NOT been electronically mailed to:

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:C:\fakepath\2025-04-28 Joint Claim Construction and Prehearing Statement.pdf
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Document description: Exhibit A
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