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ATTORNEYS FOR PLAINTIFF
INARI MEDICAL, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

INARI MEDICAL, INC.,

Plaintiff,

v.

IMPERATIVE CARE, INC. ,

Defendant.

Case No. 4:24-cv-03117-EKL

INARI'S NOTICE OF MOTION AND MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT

Hearing Date: May 29, 2025
Time: 1:30 p.m.
Location: San Jose Federal Courthouse, Courtroom 7, 4th Floor
Judge: Eumi K. Lee

Imperative Care v. Inari Medical
U.S. Patent 11,974,910
Imperative Care Ex. 1043

NOTICE OF MOTION

PLEASE TAKE NOTICE that on May 29, 2025, at 1:30 p.m., or as soon thereafter as this matter may be heard, in Courtroom 7, 4th Floor, located at 280 South First Street, San Jose, CA 95113, Plaintiff Inari Medical, Inc. ("Inari") will and hereby does move for leave to file a Third Amended Complaint, in the above-captioned matter. The Third Amended Complaint seeks to include an additional count of patent infringement for U.S. Patent No. 12,239,333, which the Patent Office just issued on March 4, 2025, the day before Inari filed this motion.

This motion is made pursuant to Federal Rule of Civil Procedure 15(a)(2) and is based upon this Notice of Motion and Motion, the following Memorandum of Points and Authorities in support of this Motion, the exhibits thereto, including the Third Amended Complaint (Decl. of T. Bervik ("Bervik Decl."), ¶ 2, Ex. 1)[1] and a redline copy of the text (not exhibits) of the Third Amended Complaint against the text of the Second Amended Complaint (Ex. 2), the complete files and records in this action, and any further information that may be presented to the Court at or before the hearing on this motion. This motion is made following the conference of counsel pursuant to, and in satisfaction of, Local Rule 7-2, which took place on February 27, 2025. *See* Bervik Decl., ¶ 7.

[1] All cited exhibits are attached to the Bervik Declaration, which authenticates those exhibits. Notably, there are a large volume of the exhibits attached to Inari's Second Amended Complaint, all of which Inari intends to re-submit in full with its Third Amended Complaint (assuming that it is permitted to file its Third Amended Complaint). For the Court's convenience, Inari only includes here the two new exhibits relating to the patent it seeks to add in Exhibit 1. Specifically, Exhibit W to Exhibit 1 (the proposed Third Amended Complaint) is the new '333 Patent, and Exhibit X to Exhibit 1 is the claim chart for the '333 Patent to be attached to the Third Amended Complaint.

I. INTRODUCTION

Plaintiff Inari Medical, Inc. ("Inari" or "Plaintiff") seeks leave pursuant to Rule 15(a)(2) of the Federal Rules of Civil Procedure to file a Third Amended Complaint against Defendant Imperative Care, Inc. ("Truvic" or "Defendant").[2] The proposed amended complaint is identical to the operative complaint but for the addition of a claim of infringement based on one new asserted patent, which issued on March 4, 2025: United States Patent No. 12,239,333 (the "'333 Patent"). (Ex. 1 (including new Exhibits W (the '333 Patent) and X (claim chart for the '333 Patent)); Ex. 2 (redlines).)[3]

Leave to amend is liberally granted, and there is good cause to grant such leave here. Inari could not have brought this motion or acted more quickly to get the new '333 Patent added to the case, since it just issued the day before Inari filed this motion. There is also no unfair prejudice to Truvic due to the timing of this motion: discovery is at an early stage, and the case has not yet come anywhere close to the point where a patent owner would typically be required to narrow the number of asserted patents and claims. Given that the new '333 Patent is related to patents already asserted, it will be efficient to treat it together with this case, rather than forcing Inari to file a separate suit (which would then presumably be related to or consolidated with this case anyway). As such, Inari respectfully asks the Court to grant this motion.

II. BACKGROUND

Inari, the undisputed market leader and innovator for the types of thrombectomy devices at issue in this case, tried to avoid this suit by asking Truvic to cease selling its copycat devices until the parties could resolve the infringement issues. Truvic refused, necessitating this litigation. In a complaint filed on May 22, 2024, Inari asserted eight patents from two families. (ECF No. 1.)

The Patent Office has deemed Inari's many inventions and innovations worthy of more

[2] The company that originally designed the accused products was named "Truvic" and the accused products still bear that name. To avoid confusion between two "I" companies, Inari has referred to the defendant here as "Truvic" throughout the case.

[3] To the extent necessary, Inari also seeks leave under Patent Local Rule 3-6 to supplement its Infringement Contentions to add a new claim chart addressing the '333 Patent.

than fifty patents and continues to issue new patents to Inari, including patents over prior art on which Truvic relies in this case. As new patents issue that cover Truvic's products, Inari filed a first amended complaint that added a ninth patent from a third family (ECF No. 20), and then a second amended complaint that added two more new patents and removed one of the originally asserted patents (ECF No. 68).[4]

The Patent Office just issued this new '333 Patent on March 4, 2025, the day before Inari filed this motion. Inari could not have included the '333 Patent in its Second Amended Complaint, because the '333 Patent had not yet issued when that Second Amended Complaint was due under the Scheduling Order. (ECF No. 54.)

On February 12, 2025, just days after the deadline for amendment of the complaint without leave, the Patent Office sent Inari an Issue Notification for the new '333 Patent, indicating that patent, which has a particular focus on aspects of the clot collection reservoirs used in thrombectomy systems, would issue on March 4, 2025. *See* Ex. 3.

Inari immediately notified Truvic that it intended to add the '333 Patent to this case, also offering to work with Truvic to provide infringement contentions for the new '333 Patent in advance of that new patent's issuance date. *See* Ex. 4 (email dated Feb. 14, 2025). Truvic responded that it opposes the addition of the '333 Patent to the case, arguing that it will be unfairly prejudiced by the addition of another patent to the case. *Id*. (email dated Feb. 21, 2025). Inari is thus forced to file this motion. Truvic did not respond to Inari's offer to provide its supplemental infringement contentions and a claim chart for the '333 Patent.

The Scheduling Order in this case permitted amendments to the complaint without leave through February 7, 2025. That Order also sets a schedule through a claim construction hearing on July 24, 2025. (ECF No. 54.) But the Court has so far not set a date for the completion of fact discovery or any subsequent case activities. (*Id.*)

[4] Related patents typically share a specification and have other common features (*e.g.*, a common priority date), but each patent in a family of related patents will have claims of varying scope that cover different aspects of any invention(s) described in the specification. *See, e.g.*, Annotated Patent Digest (Matthews) § 5:79 (2025). Thus, each patent must be evaluated on its own merits, rather than treating related patents all as one. That said, there are often overlapping issues of claim construction across related patents in a single family.

Truvic has not yet raised, and the Court has not addressed, any process for the narrowing of patents and claims, but such processes typically take place (if at all) further in the case, after the parties have had the opportunity for full discovery.

III. MOTION FOR LEAVE TO AMEND SHOULD BE GRANTED HERE

A. Leave To Amend Is Freely Granted

Under the Federal Rules of Civil Procedure, leave to amend pleadings is to be "freely give[n]." Fed. R. Civ. Proc. 15(a)(2); *Eminence Cap., LLC v. Aspeon Inc.*, 316 F.3d 1048, 1051-52 (9th Cir. 2003) (internal quotation marks omitted) ("Rule 15 advises the court that leave shall be freely given when justice so requires. This policy is to be applied with extreme liberality."). Therefore, unless an opposing party can show that a proposed amendment causes undue prejudice, or that a motion to amend was brought in bad faith or with dilatory motive, such motions are generally granted. *See Foman v. Davis*, 371 U.S. 178, 182 (1962).

B. Supplementation Is In The Interests Of Justice And Should Be Permitted Here

Inari seeks to update the Second Amended Complaint to account for events that occurred since Inari filed it on February 7, 2025—namely, the Patent Office's issuance of the '333 Patent on March 4, 2025.

1. Inari Is Acting Diligently And In Good Faith To Conserve Judicial Resources

There is no credible argument that Inari has delayed bringing this motion—it could not have acted more quickly after issuance of the new '333 Patent to add it to this case. Likewise, Inari's addition of the '333 Patent is not made for any improper purpose, such as delay, or in bad faith, but is instead designed to protect Inari's intellectual property rights and conserve judicial resources by litigating similar patents covering related technologies in a single judicial action.

It is indisputably most efficient to litigate the '333 Patent with the existing patents-in-suit. All of the previously asserted patents in this case involve thrombectomy systems. In addition, already-asserted United States Patent Nos. 12,016,580 and 12,156,669 are part of the same patent family as the '333 Patent. All three of these patents relate to thrombectomy systems employing aspiration catheters, including filtering and collection of clots in the system. These three patents share the same priority application (United States Provisional Patent Application

No. 62/622,691), the same priority date (January 26, 2018), and use many of the same claim terms. As such, the new '333 Patent—although containing a different claim scope than other patents already in the case—will involve many or all of the same witnesses, documents, and accused products as are implicated by the existing claims. In these circumstances, courts consistently grant motions to amend. *See, e.g.*, *Aten Int'l Co. v. Emine Tech. Co.*, No. 8:09-cv-843, 2010 WL 1462110, at *2-*5 (C.D. Cal. Apr. 12, 2010) (granting leave to amend to add three related patents because the patents and accused products were related, discovery had not closed and claim construction hearing had not taken place yet, and Rule 15 encourages adding claims to pleadings for judicial economy). Based on these common issues, judicial economy is best served by litigating the '333 Patent in this action. *See Ziptronix, Inc. v. Omnivision Techs.*, Inc., No. 4:10-cv-5525-SBA, 2012 WL 3155554, at *5 (N.D. Cal. Aug. 2, 2012) (granting motion to amend to add related patents maximizes judicial efficiency "by disposing of related claims in one matter," "ensures that the patents are interpreted in a consistent manner," and "avoids the possibility of inconsistent judgments"); *see also SanDisk Corp. v. STMicroelectronics, Inc.*, No. 5:04-cv-4379-JF-RS, 2009 WL 1404689, at *3 (N.D. Cal. May 19, 2009) (granting motion where new patents had the same specification, inventors, and priority date, shared many of the same claim terms, and would be asserted against essentially the same products). Requiring the '333 Patent to be litigated separately would force the Court and parties to needlessly duplicate the work done in this case. Indeed, Inari assumes that, if it filed a separate (related) suit, that suit would be consolidated into this one for efficiency.

2. The Proposed Amendments Will Not Unfairly Or Unduly Prejudice Truvic

Truvic complains that it will suffer undue prejudice if Inari is allowed to amend. To be clear, Truvic does not argue that Inari's infringement claim is baseless or frivolous. It just does not want to have to defend another infringement claim. But it is hardly "unfair" or "undue" prejudice to require it to defend a meritorious infringement claim, even if it is accused of also infringing other patents.

Truvic ties its prejudice arguments to the number of patents and claims already in dispute. But there is no rule, whether under the Federal Rules or otherwise, that limits the number of

patents that Inari can assert. The number of patents and claims at issue here is a direct result of the scope of Inari's inventions and Truvic's infringement. While some courts require patent owners to eventually narrow the number of claims that will be tried to a jury (usually requiring the defendants to also limit the number of prior art references on which they will rely), this case is nowhere near the stage where that limiting typically happens. *E.g.*, *Apple Inc. v. Samsung Elecs. Co.*, No. 5:12-cv-630-LHK Dkt. 471, p. 2 (N.D. Cal. Apr. 24, 2013) (requiring parties to initially limit number of patents ten days before close of fact discovery and further limit number of patents after expert discovery); *Huawei Techs. Co. v. Samsung Elecs. Co.*, No. 3:16-cv-2787-WHO Dkt. 143, p. 2 (N.D. Cal June 2, 2017) (ordering initial reduction of patents one week after fact discovery cutoff and additional reduction one week after close of expert discovery). Courts are clear that patent owners are entitled to full discovery before having to narrow their cases. *Jawbone Innovations, LLC v. Meta Platforms, Inc.*, No. 6:23-cv-158, 2023 WL 8856049, at *2 (W.D. Tex. Dec. 20, 2023) ("Numerous courts … have noted that limiting claims is not appropriate before the patentee receives discovery and invalidity contentions.") (collecting cases); *Carl Zeiss AG v. Nikon Corp*., No. 2:17-cv-3221, 2018 WL 1858183, at *1-*2 (C.D. Cal. Mar. 1, 2018) (denying motion to limit claims before discovery was complete).

Truvic complains that it will be expensive to litigate another patent, but efficiency, including judicial economy, is the very reason that the '333 Patent should be added to this case. It makes no sense that Inari should be required to file a new lawsuit on this new patent, particularly when the new '333 Patent is related to other patents in the case. Moreover, the expense is a result of Truvic's infringement of the patent, not a justification for preventing Inari—the party being harmed—from seeking judicial relief to address the infringement.

Finally, Truvic suggests that adding another patent to the case is unfair because of the stage of the case. That is simply wrong. Discovery in this case is in at an early stage, with Truvic having just begun producing documents in late February, days before this motion was filed. The Court has not even set a date for the close of fact discovery. *See* Dkt. 54. Accordingly, there is ample time for Truvic to investigate and conduct discovery on Inari's additional claims. *See Ziptronix*, 2012 WL 3155554, at *4 ("Plaintiff has persuasively argued that Defendants will

not suffer undue prejudice if the proposed amendment is allowed because discovery in this case has just begun.").

Initial claim construction deadlines are approaching, with the parties set to exchange terms for construction, but Truvic has had notice regarding Inari's proposed addition of the '333 Patent since February 14, 2025, which gave it ample time to prepare for that deadline, particularly when coupled with Inari's offer to provide its contentions for the '333 Patent before filing this motion. *See* Ex. 4. Truvic never responded to that offer. *Id*. Inari nonetheless is serving supplemental infringement contentions on Truvic that include the new '333 Patent (and a full claim chart for it) simultaneously with service of this motion.

To the extent that the Truvic needs a few extra weeks to prepare to exchange terms for construction, moreover, there would have been room in the schedule to accommodate reasonable extensions had Truvic not decided to prolong the handling of the new '333 Patent by opposing this motion. Truvic notably did not ask for an extension, however: it simply objects to Inari asserting infringement at all. That is not a justification for denying Inari's motion.

3. Amendment Is Not Futile

Inari's claims of infringement are not futile. As set forth in Inari's proposed Third Amended Complaint (*see* Ex. 1), and the associated claim chart (*see* Ex. X to Ex. 1), Truvic's accused Symphony system meets every element of the asserted claims of the '333 Patent.

IV. CONCLUSION

For the foregoing reasons, Inari respectfully requests that the Court grant its leave to amend to add a claim of infringement for the brand-new '333 Patent.

Dated: March 5, 2025

By: */s/ Trevor J. Bervik*

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ATTORNEYS FOR PLAINTIFF INARI MEDICAL, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
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INARI MEDICAL, INC.,

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v.

IMPERATIVE CARE, INC. ,

Defendant.

Case No. 4:24-cv-03117-EKL

DECLARATION OF TREVOR J. BERVIK IN SUPPORT OF PLAINTIFF INARI MEDICAL, INC.'S MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT

Judge: Eumi K. Lee

I, Trevor Bervik, hereby declare as follows:

1. I am an attorney at Perkins Coie LLP and counsel for Plaintiff Inari Medical, Inc. ("Inari") in this case. I am licensed to practice law in the State of Colorado. On February 14, 2025 and on application, this Court authorized me to appear in this case on a *pro hac vice* basis. I am submitting this declaration in support of Inari's Motion for Leave to File Third Amended Complaint. I make this declaration based on my personal knowledge, unless otherwise indicated.

2. Inari seeks leave to file the Third Amended Complaint pursuant to Federal Rule of Civil Procedure 15(a)(2). Pursuant to Judge Eumi K. Lee's Standing Order for Civil Cases, I am attaching a true and correct copy of a "clean" version of the proposed Third Amended Complaint as **Exhibit 1**. For convenience, I have appended new Exhibits W (U.S. Patent No. 12,239,333) and X (Infringement Analysis – Claim 1 of U.S. Patent No. 12,239,333) to **Exhibit 1**. I have not appended previously provided Exhibits A through V, as previously provided as Exhibits to Inari's Second Amended Complaint, as those exhibits remain the same. I am also attaching a true and correct copy of a "redlined" version, compared against the Second Amended Complaint, as **Exhibit 2**. In order to minimize the file size of **Exhibit 2**, I have not appended new Exhibits W and X to **Exhibit 2**.

3. In its Third Amended Complaint, Inari seeks to include an additional count of patent infringement for U.S. Patent No. 12,239,333 (the "'333 Patent"). The '333 Patent issued on March 4, 2025, which occurred after Inari filed its Second Amended Complaint and one day before Inari filed this motion.

4. Inari filed suit against Defendant Imperative Care, Inc. ("Truvic") on May 22, 2024, alleging that Defendant's Symphony Thrombectomy System infringed asserted claims of eight of Inari's patents. On July 9, 2024, Inari filed its first amended complaint asserting an additional patent. On July 29, 2024, Truvic filed an answer to Inari's first amended complaint. On February 7, 2025, Inari filed its second amended complaint, withdrawing a previously asserted patent and asserting two new patents, for a total of ten asserted patents. On February 21, 2025, Truvic filed an answer to Inari's second amended complaint.

5. Five days after filing its second amended complaint, on February 12, 2025, Inari received an Issue Notification from the USPTO, indicating that a pending Inari application would issue as the '333 Patent on March 4, 2025. I am attaching a true and correct copy of the USPTO's Issue Notification for the 12-'333 Patent as **Exhibit 3**.

6. On February 14, 2025, Inari's counsel, Amanda Tessar, sent an email to counsel of record for Truvic to inform Truvic's counsel that the USPTO will issue the 12-'333 Patent on March 4, 2025 and that Inari intends to seek leave from the Court to add the patent to this case through a Third Amended Complaint. In her email, Ms. Tessar asked Truvic's counsel whether Truvic will oppose Inari's upcoming motion. On February 21, 2025, Truvic's counsel, Joshua Stowell, responded to Ms. Tessar and indicated that Truvic will oppose Inari's motion. I am attaching a true and correct copy of this email exchange as **Exhibit 4**.

7. On February 27, 2025, the parties met-and-conferred, via videoconference and in accordance with the requirements of Local Rule 7-2 of the Northern District of California, to discuss Inari's motion and Truvic's opposition. I and Attorney Amanda Tessar attended this meet-and-confer on behalf of Inari. Attorney Joshua Stowell attended on behalf of Truvic. During the meet-and-confer, Mr. Stowell confirmed that Truvic still intends to oppose Inari's motion.

Dated and signed this 5th day of March, 2025, at Denver, Colorado.

Dated: March 5, 2025

By: */s/ Trevor J. Bervik*
Trevor J. Bervik

EXHIBIT 1

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ATTORNEYS FOR PLAINTIFF INARI MEDICAL, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INARI MEDICAL, INC., Plaintiff, v. IMPERATIVE CARE, INC., Defendant.	Case No. 5:24-cv-3117-EKL THIRD AMENDED COMPLAINT FOR PATENT INFRINGEMENT DEMAND FOR JURY TRIAL

1. Plaintiff Inari Medical, Inc. ("Inari") files this Third Amended Complaint for Patent Infringement against Defendant Imperative Care, Inc. ("Imperative Care," "Truvic," or "Defendant")[1] and respectfully shows the Court as follows:

INTRODUCTION AND SUMMARY OF THE CASE

2. Inari is a pioneering healthcare company with a mission of improving outcomes for patients suffering from life-threatening pulmonary embolism ("PE") and deep vein thrombosis ("DVT," blood clots in larger veins, such as in the legs). After years of effort and sustained investment, Inari successfully developed, proved the efficacy of, and received regulatory (FDA) clearance for its transformational (and award-winning) ClotTriever® and FlowTriever® systems.

3. These thrombectomy devices differ significantly from any prior and competing treatments for PE and DVT. For example, Inari offers a host of product features that are separately and collectively innovative, including but not limited to Inari products' use of vacuum pressure for aspiration (the "Whoosh"™ technology), their "hemostasis valve" design, their pressure settings, the size of the catheters involved, and their blood filtering and return systems. In recognition of Inari's contributions, the Patent and Trademark Office has to date awarded Inari dozens of patents.

4. This is not to say that it has been a trivial process to educate and win over, one-by-one, the multitude of cardiologists, vascular surgeons, interventional radiologists, and other doctors charged with the treatment of patients suffering from PE and DVT, who are accustomed to the less-effective, traditional treatments for blood clots recommended by the American Medical Association even today. This has taken an extraordinary effort. Through investment, persistence, and superior products, however, Inari has single-handedly created and supplied a market for its aspiration-based mechanical thrombectomy devices, saving patient lives in the process.

[1] Inari's original complaint named Truvic Medical, Inc. as a defendant. Counsel for Imperative Care has confirmed that Truvic Medical, Inc. was merged out of existence, so this Second Amended Complaint removes Truvic Medical, Inc. as a separately named defendant.

5. Having worked so hard to develop and protect its products through the patenting process, and having worked so hard to win over doctors to create a market for those products, Inari cannot stand idly by as other competitors—wanting to replicate Inari's success—begin to copy Inari's products and use Inari's patented inventions. That is exactly the model that Truvic has followed here, however. Truvic, moreover, refuses to desist in its infringement, despite repeated notices and requests to stop using Inari's intellectual property. Inari therefore is forced to bring this suit, asserting eleven patents: United States 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, 12,156,669, and 12,239,333.

THE PARTIES

6. Plaintiff Inari is a Delaware corporation having its principal place of business and headquarters at 6001 Oak Canyon, Suite 100, Irvine, California.

7. Defendant Imperative Care, Inc. ("Imperative Care") is a Delaware corporation having its principal place of business and headquarters at 1359 Dell Avenue, Campbell, California. Imperative Care acquired Truvic Medical, Inc. in July 2021 and eventually this entity merged into Imperative Care, Inc.

JURISDICTION AND VENUE

8. Inari brings this action for patent infringement. This action arises under the Patent Act, 35 U.S.C. § 1, et seq.

9. This Court has subject matter jurisdiction over this action pursuant to at least 15 U.S.C. § 1121(a) and 28 U.S.C. §§ 1331 and 1338.

10. This Court has personal jurisdiction over Imperative Care because it maintains a principal place of business in Campbell, Santa Clara County, California and has purposefully availed itself of the privilege of conducting business in this District such that it should reasonably and fairly anticipate being brought into court in this District.

11. Venue is proper in this District pursuant to at least 28 U.S.C. §§ 1391(b) and (c) and § 1400(b). Venue is proper in this District under 28 U.S.C. § 1400(b) because Defendant has committed acts of patent infringement in this Judicial District and has an established place

of business in this Judicial District.

FACTUAL ALLEGATIONS UNDERLYING INARI'S CLAIMS

Inari's Innovations And Efforts To Develop Its Thrombectomy Products

12. Venous thromboembolism ("VTE") is a disease caused by blood clot formation in the veins of the body, and is, unfortunately, a leading cause of both death and disease worldwide. Pulmonary embolism ("PE") and deep vein thrombosis ("DVT") are common types of VTE. DVT is a type of blood clot that typically forms in the deep veins of a limb, such as the leg, and can develop into PE if portions of the clot break off and migrate to the pulmonary system. PE is a life-threatening condition that occurs when a clot breaks free and becomes lodged in the arteries of the lungs.

13. Inari is the world's leading developer of catheter-based aspiration and/or mechanical thrombectomy devices that treat PE and DVT through aspiration (*e.g.*, by using suction to remove clot material) and/or mechanical mechanisms of action (*e.g.*, using mechanical objects to disrupt clot material). Inari was and is a pioneer in changing the standard of care for PE and DVT from thrombolytics-based treatments (*i.e.*, treatments with drugs called "lytics" that break down blood clots that have formed in blood vessels) and surgeries—which have been plagued with drawbacks relating to effectiveness and side effects—to treatment with aspiration-based mechanical systems. Inari's lifesaving products, including its FlowTriever and ClotTriever systems, have received widespread acclaim for their efficacy in treating PE and/or DVT.[2] Inari's innovations have also been repeatedly recognized by the United State Patent and Trademark Office, which has issued Inari over fifty United States patents and is in the process of allowing additional claims in multiple pending applications.

14. Inari's first product, its FlowTriever system, represented a major leap in treatment for venous thromboembolism, including PE. During procedures, FlowTriever targets aspiration (adjustable negative vacuum pressure) directly to the thrombus via catheters. FlowTriever may be used to facilitate aspiration and removal of the thrombus through, for example, the Triever24,

[2] *See* https://ir.inarimedical.com/news-events/press-releases.

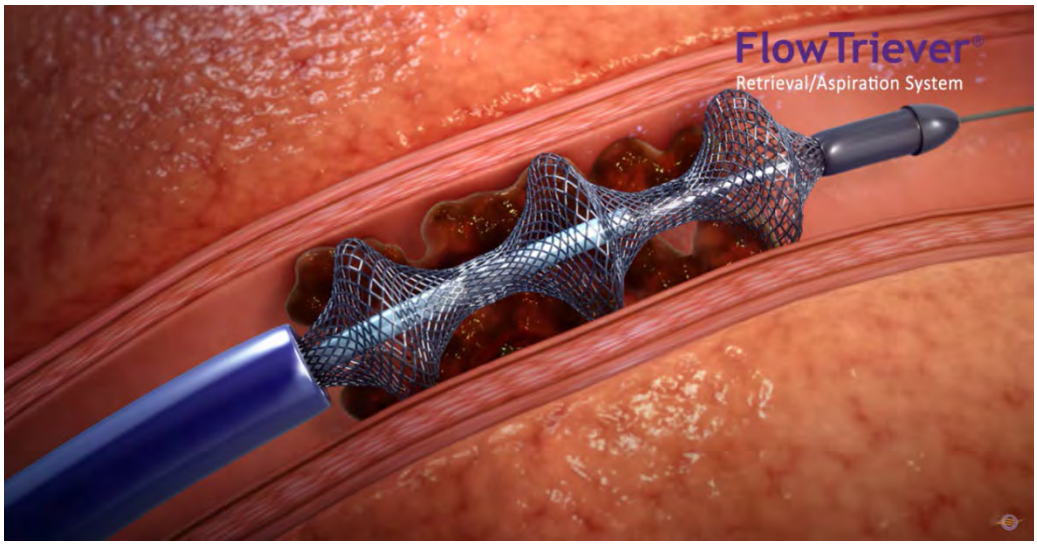
Triever20, and/or Triever16 catheters, aspirating at least a portion of the clot material. The Triever catheters are introduced through a vascular access sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus or emboli. The 16F Triever Catheter and 20F Triever Catheter are capable of telescoping from the 24F Triever Catheter for extended reach to the thrombus.[3] FlowTriever generates vacuum using large-bore locking syringes. FlowTriever's catheter technology further optionally allows for a catheter with expanding mesh disks at the distal end to mechanically engage and disrupt clot materials.

15. Inari received FDA clearance for its FlowTriever system in November 2016. This clearance had indications for use for non-surgical removal of clot material from blood vessels in the peripheral vasculature. This version of FlowTriever included an Aspiration Guide Catheter, a FlowTriever Catheter, and a Retraction Aspirator. The FlowTriever Catheter is inserted through the Aspiration Guide Catheter and advanced to the thrombus (*i.e.*, the blood clot). Self-expanding wireform disks are deployed to engage the thrombus by retracting the outer delivery catheter. The hand-lever operated Retraction Aspirator in this version of FlowTriever simultaneously aspirates fluids and retracts the FlowTriever Catheter with at least a portion of the thrombus into the Aspiration Guide Catheter to capture clot and restore blood flow.

16. The more recent versions of the FlowTriever system allow the removal of the FlowTriever Catheter from the patient and aspiration of clot material through the Aspiration Guide Catheter without the simultaneous removal of the Aspiration Guide Catheter.[4] A capture from a FlowTriever video depicting the distal end of a FlowTriever catheter is below:

[3] The "French" ("F") scale is commonly used to measure the size of catheters. 1 French (1F) equals 1/3 mm.

[4] *See* FDA 510(k) Premarket Notification K162970 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162970.pdf).



(Guide Catheter (purple), FlowTriever Catheter (pale blue), and self-expanding wireform disks (grey).)

17. From April 2016 to November 2017, Inari conducted the FlowTriever Pulmonary Embolectomy Clinical Study ("FLARE") to evaluate the safety and effectiveness of the FlowTriever system for use in the removal of emboli from the pulmonary arteries in the treatment of acute pulmonary embolism. The results were strikingly positive.[5]

18. Inari received expanded FDA clearance to market FlowTriever for treating PE (in addition to the prior clearance for peripheral vasculature generally) in May 2018.[6] This made FlowTriever the first FDA-cleared aspiration-mechanical system for treating PE, and the first FDA-cleared aspiration-mechanical system for treating both PE and peripheral vasculature thrombosis. The PE-specific clearance was based upon the strength of the results from the FLARE Clinical Study.[7]

19. Inari continued to improve the performance of FlowTriever over the years. By December 2018, Inari developed and received FDA clearance for a telescoping version of FlowTriever, for instance, meaning that a smaller diameter catheter can be advanced through

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[5] *See* https://www.clinicaltrials.gov/study/NCT02692586?rank=8&lead=Inari%20Medical.

[6] *See* FDA 510(k) Premarket Notification K180466 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180466.pdf).

[7] *See* https://ir.inarimedical.com/news-releases/news-release-details/flowtriever-system-inari-medical-receives-fda-510k-clearance.

(inside) a larger diameter catheter for extended reach. This version of FlowTriever includes the Triever16 Catheter (16F outer catheter), the Triever20 Catheter (20F outer catheter), the FlowTriever Catheter, and two Large Bore 60cc Syringes, one for Triever16 and one for Triever20, for aspiration purposes. The Triever16 Catheter is capable of extending through and past the distal end from the Triever20 Catheter to reach the thrombus. Each Triever Catheter is connected to a pressure source, such as a Large Bore 60cc Syringe.

20. From December 2018 to February 2019, Inari conducted a limited market release of the telescoping FlowTriever and gathered physician feedback according to a clinical evaluation plan. The positive evaluation results proved the telescoping combination of Triever16 and Triever20 to be excellent for treating large RV (right ventricular)/LV (left ventricular) clots in the left pulmonary arteries, vasculature with challenging anatomy, and the distal segments with occlusive clot. Overall, using the telescoping combination is more efficient than using a single outer catheter.

21. By September 2019, Inari developed and received FDA clearance for Triever24, a 24F outer catheter.[8] This catheter can be used in a telescoping combination with Triever16.

22. Separately from its work on FlowTriever, Inari also received FDA clearance for its ClotTriever system in February 2017. ClotTriever was designed for clot removal, including for acute and chronic clots (i.e., including DVT) using mesh forms to engage and then withdraw clots.[9]

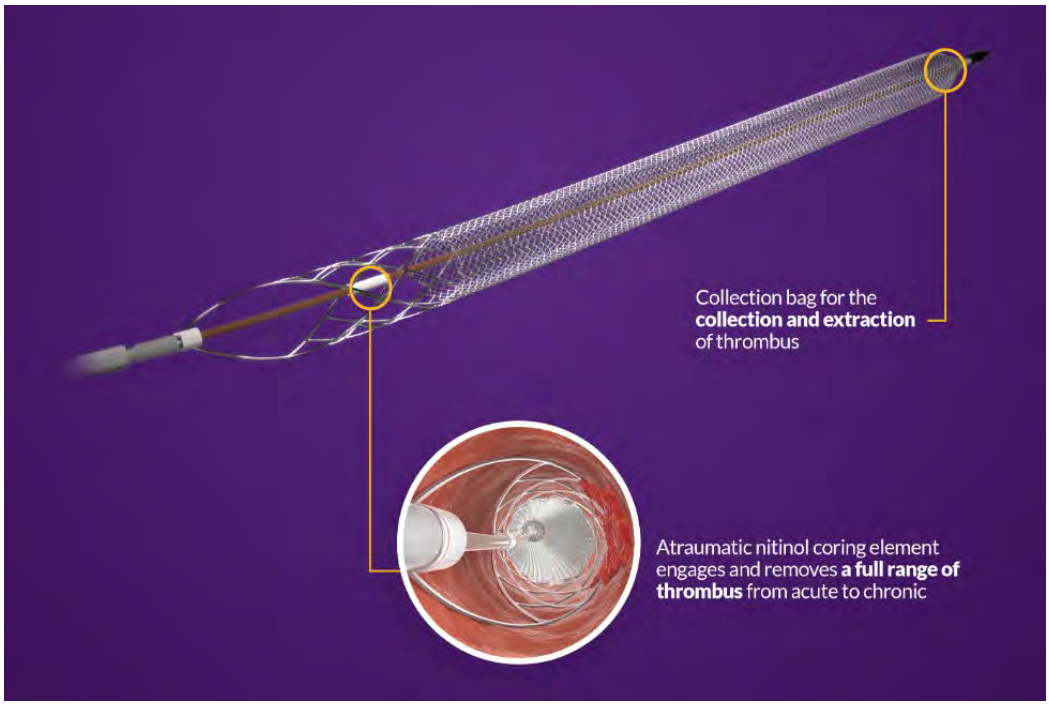
23. The first version of ClotTriever consists of the ClotTriever Sheath and the ClotTriever Catheter. The ClotTriever Sheath consists of a polymeric sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port with tubing clamp, and a proximal hemostatic valve. The ClotTriever Catheter consists of three preassembled polymeric coaxial catheters terminating in an expandable member and tissue collection net. At the proximal end

[8] *See* FDA 510(k) Premarket Notification K191710 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191710.pdf).

[9] *See* FDA 510(k) Premarket Notification K193462 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193462.pdf).

of the catheter is a handle used to enable expansion of the expandable member and net.

24. The expanded structures of the ClotTriever are drawn through the vessel obstruction to capture clot and restore blood flow by "non-surgical removal of soft thrombi and emboli from blood vessels."[10] A figure depicting the ClotTriever system is shown below:



25. As with FlowTriever, Inari continues to improve the performance of ClotTriever over the years. By December 2017, Inari had developed and received FDA clearance for replacing the tissue collection net with a collapsible clot collection bag.[11] In September 2018, Inari started the ClotTriever Outcomes ("CLOUT") Registry Clinical Study to evaluate real-world patient outcomes after treatment of acute, subacute, and chronic proximal lower extremity DVT with the ClotTriever system. Inari announced the interim results of the study on March 12, 2024, with the results showing that ClotTriever significantly reduced rates of "post-thrombotic syndrome" over historical DVT trials.[12] On September 9, 2020, Inari received FDA clearance

[10] *See* FDA 510(k) Premarket Notification K163549 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163549.pdf).

[11] *See* FDA 510(k) Premarket Notification K173470 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173470.pdf).

[12] *See* https://ir.inarimedical.com/node/10506/pdf.

to market ClotTriever specifically for the treatment of DVT.[13]

Truvic's Copycat Devices

26. Founded in 2016, Imperative Care is a medical technology company developing products in a wide array of disparate health-related areas. For instance, its various products include ones directed at stroke solutions, vascular disease treatments, digital health, and robotics.

27. In July 2021, Imperative Care acquired Truvic Medical, Inc.,[14] a thrombectomy device developer that, based on recorded filings, was incorporated in 2020. Truvic Medical, Inc. has two lines of thrombectomy products—the Prodigy Thrombectomy System ("Prodigy") and the Symphony Thrombectomy System ("Symphony" or "Symphony system"). Symphony is the system that most directly competes with Inari's treatment systems, while Prodigy targets clots in much smaller arteries.

28. Like FlowTriever and ClotTriever, Symphony is intended for the non-surgical removal of fresh, soft emboli and thrombi from blood vessels. The Symphony system as a whole is comprised of at least the 24F Symphony Catheter, 16F Symphony Catheter (with a working length of either 82 cm or 117 cm), Truvic Generator, 24F Symphony Dilator, 16F Symphony Dilator, Truvic Canister, 24F Symphony Advance Long Dilator, 16F Symphony ProHelix, Truvic Tubeset, and 24F Symphony ProHelix, although not all parts of the system need to be or are used for every patient procedure, and Truvic may have or be developing additional components for or to be used with the Symphony system. The Symphony system, like Inari's products, is designed to remove thrombus/embolus from veins and large arteries using controlled aspiration. The Symphony Catheter targets aspiration from the Truvic Generator directly to the thrombus. The Symphony ProHelix may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter by mechanically engaging and disrupting the clot material. The Symphony Catheters and Symphony Dilators are introduced through a vascular

[13] *See* FDA 510(k) Premarket Notification K193462 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193462.pdf).

[14] All references to "Truvic" should be understood to include Imperative Care, unless the context dictates otherwise.

access sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the Truvic Generator, connected using the Truvic Tubeset and the Truvic Canister, to aspirate thrombus. The 16F Symphony Catheter is capable of telescoping from the 24F Symphony Catheter for, *inter alia*, extended reach to the thrombus. As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter over a guidewire, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter.[15]

29. In February 2023, Truvic received FDA clearance to market its Symphony system.[16] This FDA clearance is limited to marketing Symphony for DVT treatment. It is common in the industry for doctors to use cleared FDA devices to treat problems beyond those for which they are indicated, however—a phenomenon often referred to as "off-label" usage. For instance, now that Truvic can sell its Symphony systems for DVT, doctors might also use those systems for the treatment of PE. In fact, there have been scattered reports that doctors are already doing exactly that with Truvic's systems at least occasionally, including with procedures where Truvic sales representatives have participated.

30. Truvic began marketing and selling its Symphony system to physicians and hospitals by no later than mid-2023, after it had received its FDA clearance for DVT.

31. In an October 2023 submission to ClinicalTrials.gov, Imperative Care stated that it will conduct a clinical study to evaluate the safety and efficacy of Symphony in the treatment

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[15] Inari has obtained information regarding the design and operation of the Symphony system from multiple sources, including Truvic's product brochure (attached as Exhibit A), it's FDA-cleared "Instructions for Use" ("IFU") (attached as Exhibit B), a video on Symphony's website (available at https://www.truvic.com/symphony-product and at https://vimeo.com/817718796), and its own examinations of a Symphony system.

[16] *See* 510(k) Premarket Notification K223216 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223216.pdf).

of PE from December 2023 to April 2025.[17] Upon completion of this study, the FDA will presumably clear Truvic to market Symphony for the treatment of PE. At that point, Inari expects that Symphony usage for PE will increase from a trickle of off-label uses by particular doctors to a much larger flow of regular PE procedures. Upon information and belief, Truvic began marketing and selling its Symphony system to physicians and hospitals that engaged in procedures for PE in approximately mid-2023, after Truvic had received its FDA clearance for DVT.

32. Truvic designed its Symphony system after Inari had introduced FlowTriever into the market. Truvic's Symphony system significantly overlaps with and mirrors the FlowTriever design. The two products share many similar features and mechanisms, such as telescoping aspiration catheters (including 16F catheters inserted through a 24F catheter), an intervening member used in addition to the catheter, the design of a hemostasis valve between the aspiration catheter and the aspiration source, and the design of the removable clot-filtering canister.

33. There is a long list of other indicia that Truvic has intentionally copied Inari's devices and is doing its best to target the market that Inari has created from scratch. For instance, Truvic has been systematically recruiting and attempting (sometimes successfully) to hire away key Inari personnel, including sales representatives, apparently intent on drawing on their product knowledge and the network of connections they created through Inari's investments. Additionally, Truvic has been systematically targeting the network of doctors who have become top Inari customers for Truvic's own sales, which allows Truvic to save the time and cost of converting doctors from traditional treatments like lytics. Instead, Truvic is simply stealing market share created by Inari's efforts that have begun to shift the VTE treatment paradigm. Truvic sales representatives have also persuaded doctors to allow them to observe procedures performed with Inari devices, which is highly unusual, and—even more unusually—have sometimes convinced doctors to exclude Inari sales representatives from being present when procedures are performed with Inari's own devices.

[17] *See* https://www.clinicaltrials.gov/study/NCT06062329?rank=1&lead=Imperative%20Care,%20Inc.

34. Inari contacted Truvic in September 2023, just months after Truvic had obtained FDA clearance for Symphony, to give notice of Inari's patents. In response, Truvic refused to provide Inari with one of its Symphony systems for analysis, claiming that the Symphony systems—*i.e.*, the same systems already being used by doctors in patient procedures—is "confidential." Truvic's response was irregular and concerning.

35. Upon information and belief, Truvic has been producing, using, promoting, selling, and inducing physicians and hospitals to buy and use the Symphony system. For example, Truvic's sales representatives have successfully convinced and are successfully convincing physicians, such as those at Beaumont Health and Cardiovascular Institute of the South (to name just a few hospitals), to perform thrombectomy procedures with Symphony, displacing sales and/or sales opportunities for Inari products.

36. Based upon the promotional literature that Truvic has distributed and made available online, as well as statements and actions by Truvic's sales representatives and Inari's own examination of a Symphony system that Inari very recently obtained, Truvic directly and indirectly infringes the Inari patents described below through manufacture, sale, offer for sale, and/or use of the Symphony products.

The Patents-In-Suit

37. On May 7, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,974,910 ("the '910 Patent"), entitled "System for Treating Embolism and Associate Devices and Methods." Inari owns all rights, title, and interest in and to the '910 Patent and possesses all rights of recovery under the '910 Patent. A true and correct copy of the '910 Patent is attached as Exhibit C.

38. The '910 Patent is valid and enforceable.

39. On April 30, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,969,333 ("the 11-'333 Patent"), entitled "System for Treating Embolism and Associate Devices and Methods." Inari owns all rights, title, and interest in and to the 11-'333 Patent and possesses all rights of recovery under the 11-'333 Patent. A true and correct copy of the 11-'333 Patent is attached as Exhibit D.

40. The 11-'333 Patent is valid and enforceable.

41. On January 17, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,554,005 ("the '005 Patent"), entitled "System for Treating Embolism and Associated Devices and Methods." Inari owns all rights, title, and interest in and to the '005 Patent and possesses all rights of recovery under the '005 Patent. A true and accurate copy of the '005 Patent is attached as Exhibit E.[18]

42. The '005 Patent is valid and enforceable.

43. On September 5, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,744,691 ("the '691 Patent"), entitled "System for Treating Embolism and Associated Devices and Methods." Inari owns all rights, title, and interest in and to the '691 Patent and possesses all rights of recovery under the '691 Patent. A true and accurate copy of the '691 Patent is attached as Exhibit F.[19]

44. The '691 Patent is valid and enforceable.

45. On December 19, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,844,921 ("the '921 Patent"), entitled "Hemostasis Valves and Methods of Use." Inari owns all rights, title, and interest in and to the '921 Patent and possesses all rights of recovery under the '921 Patent. A true and accurate copy of the '921 Patent is attached as Exhibit G.

46. The '921 Patent is valid and enforceable.

47. On July 11, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,697,012 ("the '012 Patent"), entitled "Hemostasis Valves and Methods of Use." Inari owns all rights, title, and interest in and to the '012 Patent and possesses all rights of recovery under the '012 Patent. A true and accurate copy of the '012 Patent is attached as Exhibit H.

[18] Inari recently filed a revised certificate of correction to add two inadvertently omitted inventors, John Thress and Paul Lubock, to the '005 Patent.

[19] Inari recently filed a revised certificate of correction to add two inadvertently omitted inventors, John Thress and Paul Lubock, to the '691 Patent.

48. The ’012 Patent is valid and enforceable.

49. On January 9, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,865,291 (“the ’291 Patent”), entitled “Hemostasis Valves and Methods of Use.” Inari owns all rights, title, and interest in and to the ’291 Patent and possesses all rights of recovery under the ’291 Patent. A true and accurate copy of the ’291 Patent is attached as Exhibit I.

50. The ’291 Patent is valid and enforceable.

51. On June 25, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 12,016,580 (“the ’580 Patent”), entitled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods.” Inari owns all rights, title, and interest in and to the ’580 Patent and possesses all rights of recovery under the ’580 Patent. A true and accurate copy of the ’580 Patent is attached as Exhibit J.

52. The ’580 Patent is valid and enforceable.

53. On October 8, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 12,109,384 (“the ’384 Patent”), entitled “Hemostasis Valves and Methods of Use.” Inari owns all rights, title, and interest in and to the ’384 Patent and possesses all rights of recovery under the ’384 Patent. A true and accurate copy of the ’384 Patent is attached as Exhibit K.

54. The ’384 Patent is valid and enforceable.

55. On December 3, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 12,156,669 (“the ’669 Patent”), entitled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods.” Inari owns all rights, title, and interest in and to the ’669 Patent and possesses all rights of recovery under the ’669 Patent. A true and accurate copy of the ’669 Patent is attached as Exhibit L.

56. The ’669 Patent is valid and enforceable.

57. On March 4, 2025, the United States Patent and Trademark Office duly and legally issued United States Patent No. 12,239,333 (“the 12-’333 Patent”), entitled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods.” Inari owns all

rights, title, and interest in and to the 12-'333 Patent and possesses all rights of recovery under the 12-'333 Patent. A true and accurate copy of the 12-'333 Patent is attached as Exhibit W.

58. The 12-'333 Patent is valid and enforceable.

Inari Put Truvic On Notice Of Its Infringement, But Truvic Refused To Stop

59. In September 2023, after Truvic had received FDA clearance to market its Symphony system and Inari began to hear reports that Truvic was beginning to do so, Inari wrote to Defendant to inform them of Inari's belief that Defendant was infringing at least United States Patent Nos. 11,559,382 and 11,744,691 and that Defendant would infringe other allowed claims of pending applications in the "System for Treating Embolism and Associate Devices and Methods" family and the pending claims of Published Application No. 17/498,642 (which has since issued as the '580 Patent) once those claims issued. Inari further explained that it believed that the hemostasis valves in the Symphony system might infringe Inari's hemostasis valve patents, including: United States Patent Nos. 11,554,005, 11,697,012, and allowed claims of Application No. 18/142,518 (later issued as United States Patent No. 11,865,291). The letter further attached the ten patents and applications referenced. Inari's letter requested that Truvic provide a sample Symphony product for analysis (*e.g.*, including to confirm its hemostasis valve design) and requested that Defendant cease or delay its launch of its Symphony products until patent issues were resolved. Inari also invited a dialogue and asked Defendant to identify any genuine basis that they had for believing that they were not infringing Inari's patents.

60. On December 1, 2023, Truvic replied by email, refusing to provide a sample Symphony product because "details of the Symphony product are proprietary, and at this time we are not willing to provide a sample to you that would allow you to benefit from the product…."

61. On January 15, 2024, almost four months after Inari's letter, Truvic finally provided a substantive response to Inari's September 2023 letter. For all but one of the patents that Inari had identified, Truvic did not identify a single noninfringement argument. Instead, Truvic argued that the patents were invalid based on identified prior art.

62. On April 24, 2024, Inari sent another letter to Truvic, responding to Truvic's

invalidity allegations and identifying multiple additional Inari patents that Truvic is infringing. For instance, Inari explained that it had received notices of allowance for the patent applications that have now issued as the '910 and 11-'333 Patents (and that are asserted here). Inari explained that the claims in these new patents were issuing over the prior art identified by Truvic and that the Symphony system would practice these patents upon issuance. The letter further explained that Inari had been able to analyze a Symphony system and had now concluded that the hemostasis valves of the Symphony system indeed infringe the '005, '921, '012, and '291 Patents, as had been suggested was likely in Inari's September 2023 letter.

63. On February 14, 2025, Inari sent an e-mail to counsel for Truvic that the 12-'333 Patent would be issuing on March 4, 2025 and that Inari intended to assert infringement and serve supplemental contentions and amend its complaint, adding the 12-'333 Patent.

64. Despite Inari's notice to Defendant by a series of letters and emails, Defendant has continued to market infringing Symphony systems. Inari is therefore forced to file this suit.

COUNT 1: INFRINGEMENT OF THE '910 PATENT

65. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

66. The '910 Patent is titled "System for Treating Embolism and Associated Devices and Methods." The '910 Patent discloses improved clot-removing systems and methods for pulmonary embolisms that solve problems with prior art clot-removal devices. The '910 Patent solves these problems through its inventions that include, for example, an aspiration system configured to allow for aspiration using vacuum, comprising both a first and second aspiration system comprising, respectively: a first and second catheter; a first and second pressure source; and a first and second fluid control device between the respective catheters and pressure sources. (Ex. C at cl. 1.) Each of the fluid control devices can be moved between a first position where the pressure source is disconnected from the catheter (allowing the pressure source to generate vacuum pressure) and a second position where the pressure source is fluidly connected to the catheter (where vacuum from the pressure source generates suction at the distal end of the catheter). (*See id.*) The '910 Patent teaches that the second aspiration catheter of the second

aspiration assembly is advanceable through the first aspiration catheter of the first aspiration assembly and that the second catheter has a size of 16F, while the first catheter has a size of 24F. (*See id.* at cl. 1, cl. 3.)

67. Defendant directly infringes—literally and/or under the doctrine of equivalents—at least claims 1 and 3 of the '910 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

68. The Symphony system practices each limitation of at least claims 1 and 3 of the '910 Patent.

69. For example, claim 1 of the '910 Patent recites:

> [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

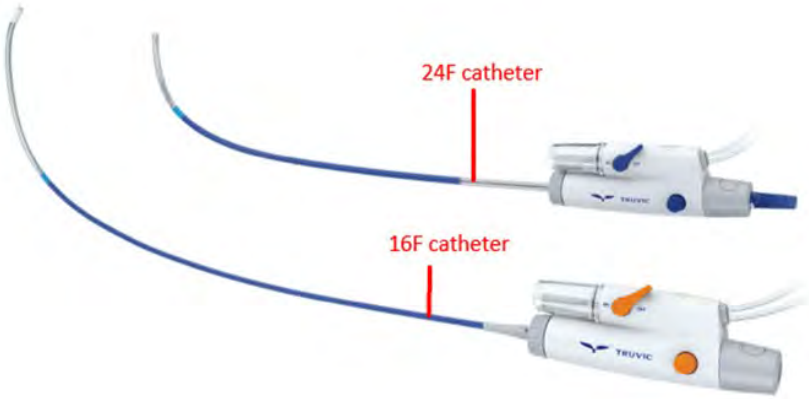
to the second catheter,

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.

70. Claim 3 further recites: "[t]he clot treatment system of claim 1 wherein the first catheter has a size of 24 French, and wherein the size of the [] second catheter [] is 16 French."

71. To the extent the preamble of claim 1 is construed to be limiting, the Truvic Symphony system practices the requirements of the preamble, "[a] clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient," as can be seen in the claim chart in Exhibit M. Specifically, the Symphony system is a clot treatment system for treating clot material from pulmonary embolisms, "[t]he Truvic Symphony Thrombectomy System employs "next generation thrombus removal" with "powerful, focused aspiration" for treating (*e.g.*, removing) clot material from within a blood vessel." (Ex. A at 2-4.) The Symphony system is further a system for treating clot material comprising a pulmonary embolism in the vasculature of the patient, as demonstrated by: doctors' use of the system for exactly that purpose; the Symphony system being used in clinical trials for treatment of pulmonary embolisms; and Defendant seeking clearance for using the Symphony system for treatment of pulmonary embolism (clot material in the pulmonary vasculature). *See* SYMPHONY-PE Study for Treatment of Pulmonary Embolism (available at https://classic.clinicaltrials.gov/ct2/show/NCT06062329).

72. The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a 24F catheter (first catheter), a vacuum pump and a clot canister comprising the first pressure source, and a controller handle for a 24F catheter including a Dual-Action Vacuum Control operated by a lever (a first fluid control device) between the 24F catheter and the first pressure source:

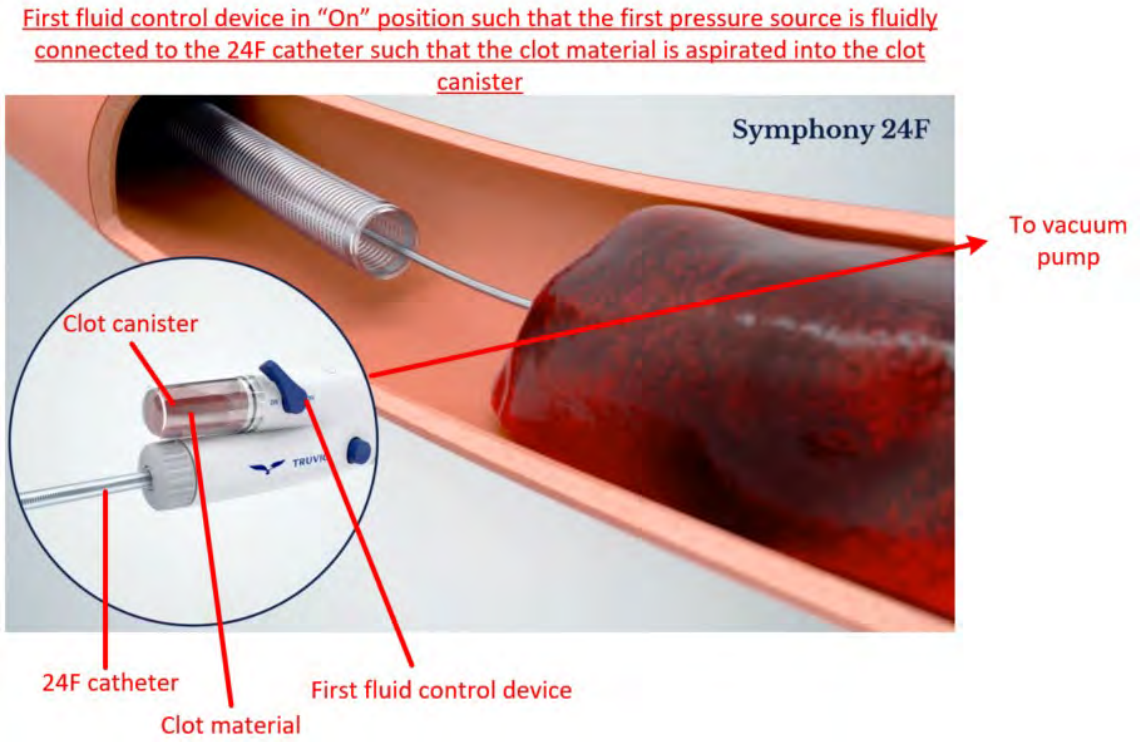


(Ex. A at 2 (annotations added).)

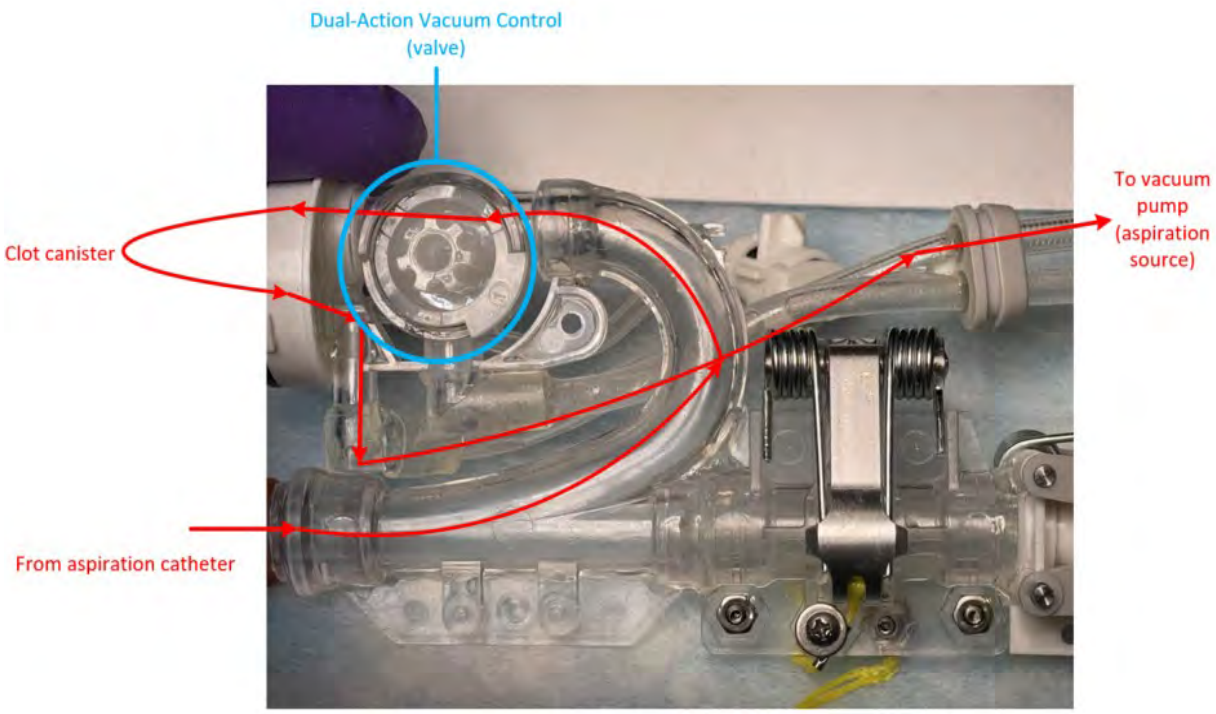
(Annotated diagram of Symphony system handle, including the first catheter, connection to a first pressure source (clot canister and vacuum pump), and a first fluid control device (the Dual-Action Vacuum Control operated by a lever).)

73. The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a Dual-Action Vacuum Control operated by a lever (a first fluid control device) between the 24F catheter and the first pressure source (comprised of the clot canister and the vacuum pump) that in a first position (off) fluidly disconnects the first pressure source from the 24F catheter and that in a second position (on) fluidly connects the first pressure source to the 24F catheter:

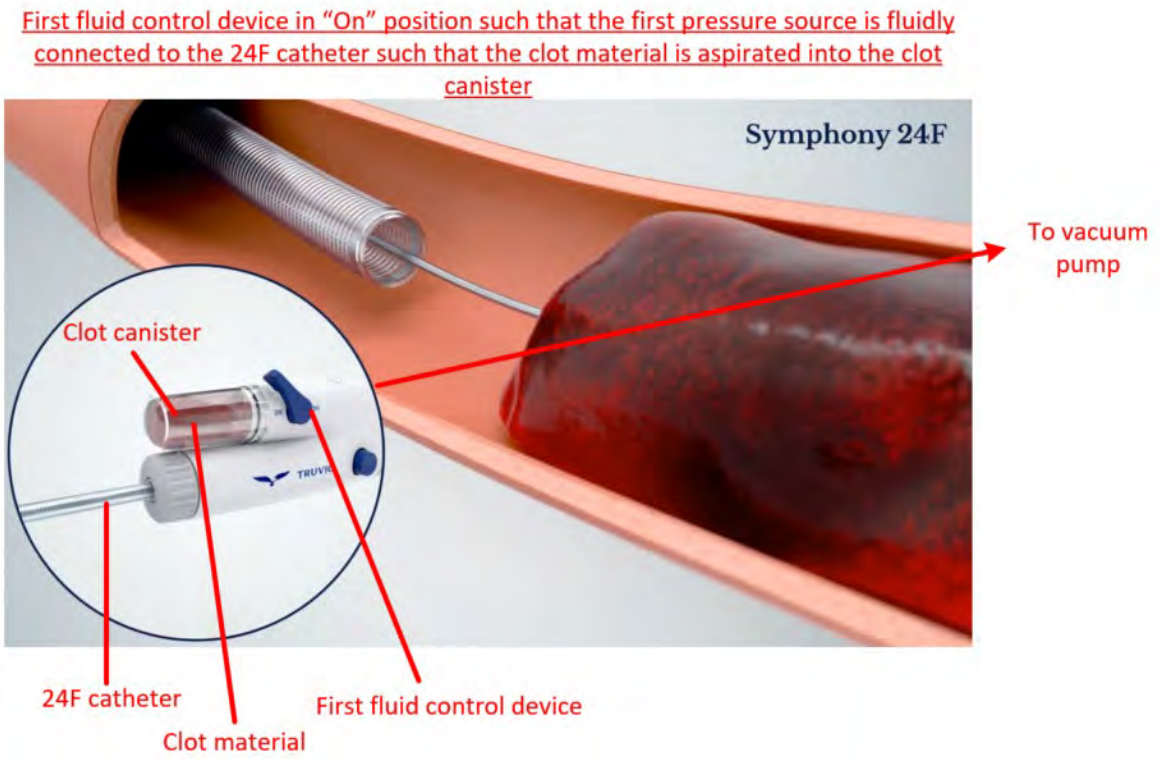


(Annotated screen capture from Symphony product video.)



(Annotated image of internal portion of controller handle housing.)

(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)

(Annotated image of Symphony housing (internal).)

74. The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a controller handle for a 24F catheter including a Dual-Action Vacuum Control operated by a lever (a first fluid control device) between the 24F catheter and the first pressure source (comprised of the clot canister and the vacuum pump) that in a first position (off) fluidly disconnects the first pressure source from the 24F catheter and that in a second position (on) fluidly connects the first pressure source to the 24F catheter. As detailed above, the first pressure source (clot canister and vacuum pump) creates a vacuum in the clot canister while the handle lever is in the first (off) position, and then vacuum pressure is applied to the first (24F) catheter to generate suction at the distal portion of the catheter (positioned near the clot material) when the handle lever is moved from the first position to the second (on) position:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

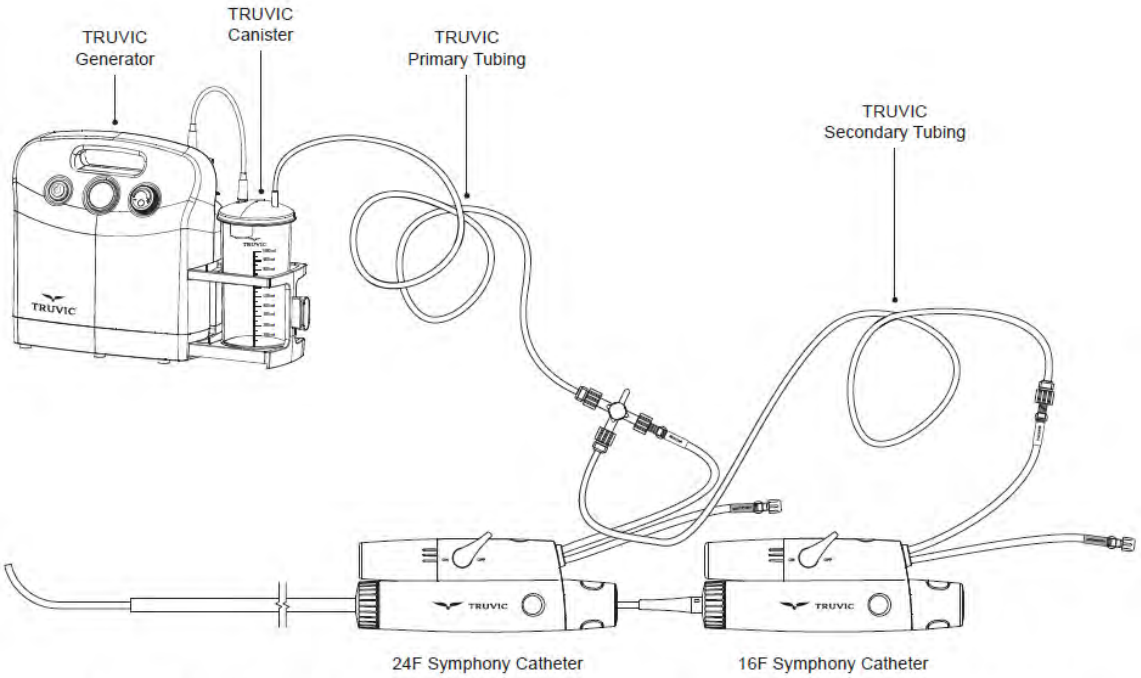


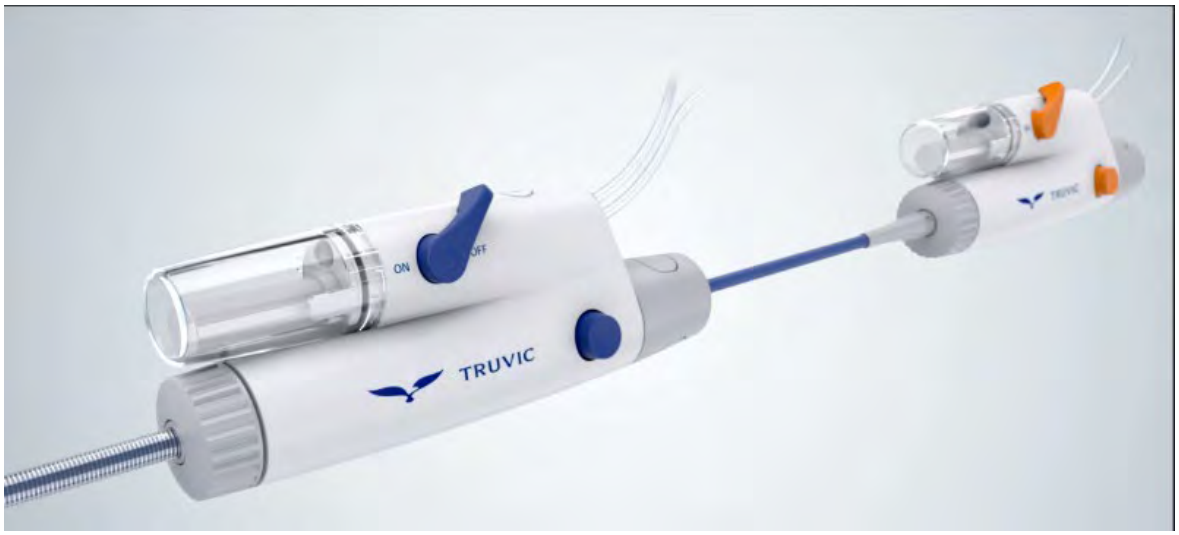
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

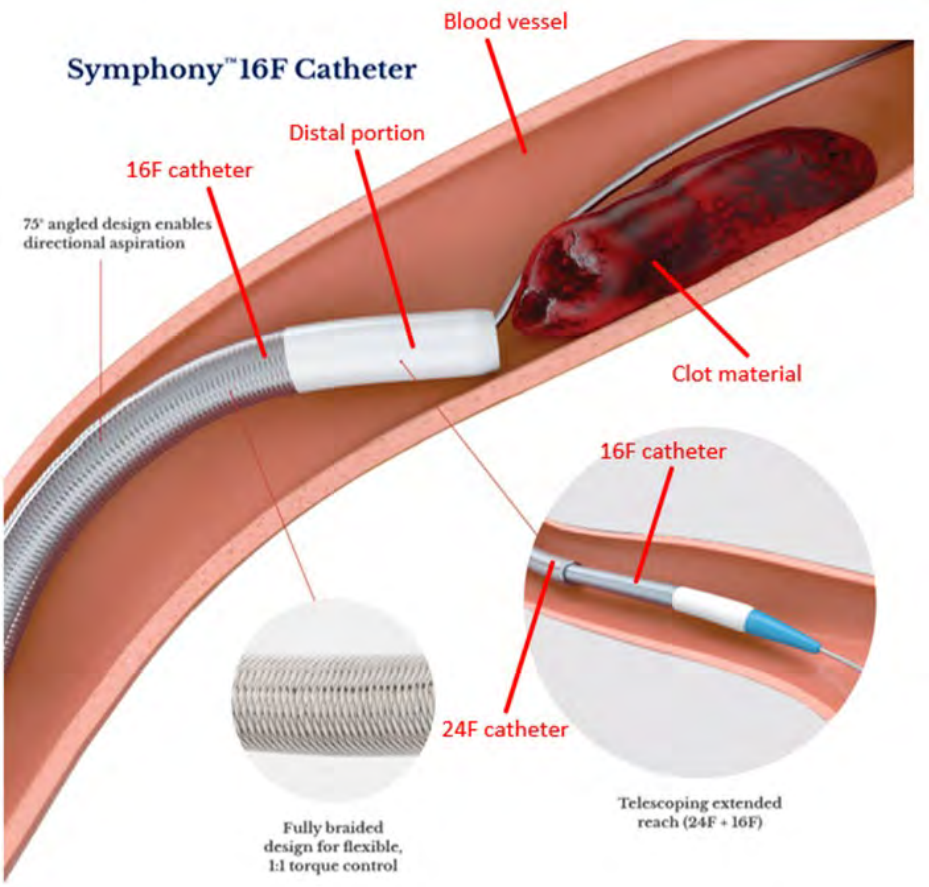
(Ex. B at 8.)

75. The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M.

Specifically, the Symphony system has a second aspiration assembly including a second (16F) catheter that can be advanced through the first (24F) catheter, where the second (16F) catheter is shaped to be telescoped through the 24F catheter and advanced through a patient's vasculature to position the distal end of the second catheter proximate to clot material, *e.g.*, a pulmonary embolism:

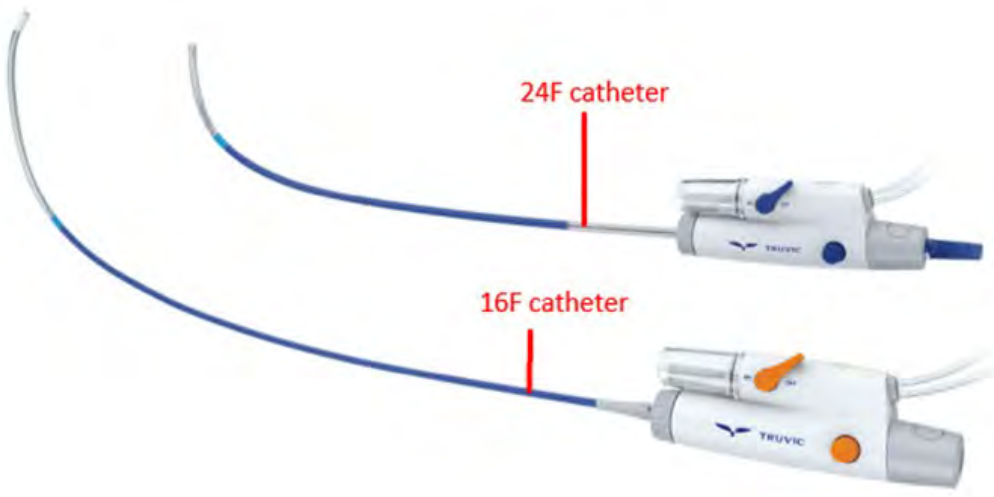


(Screen capture from Symphony product video.)

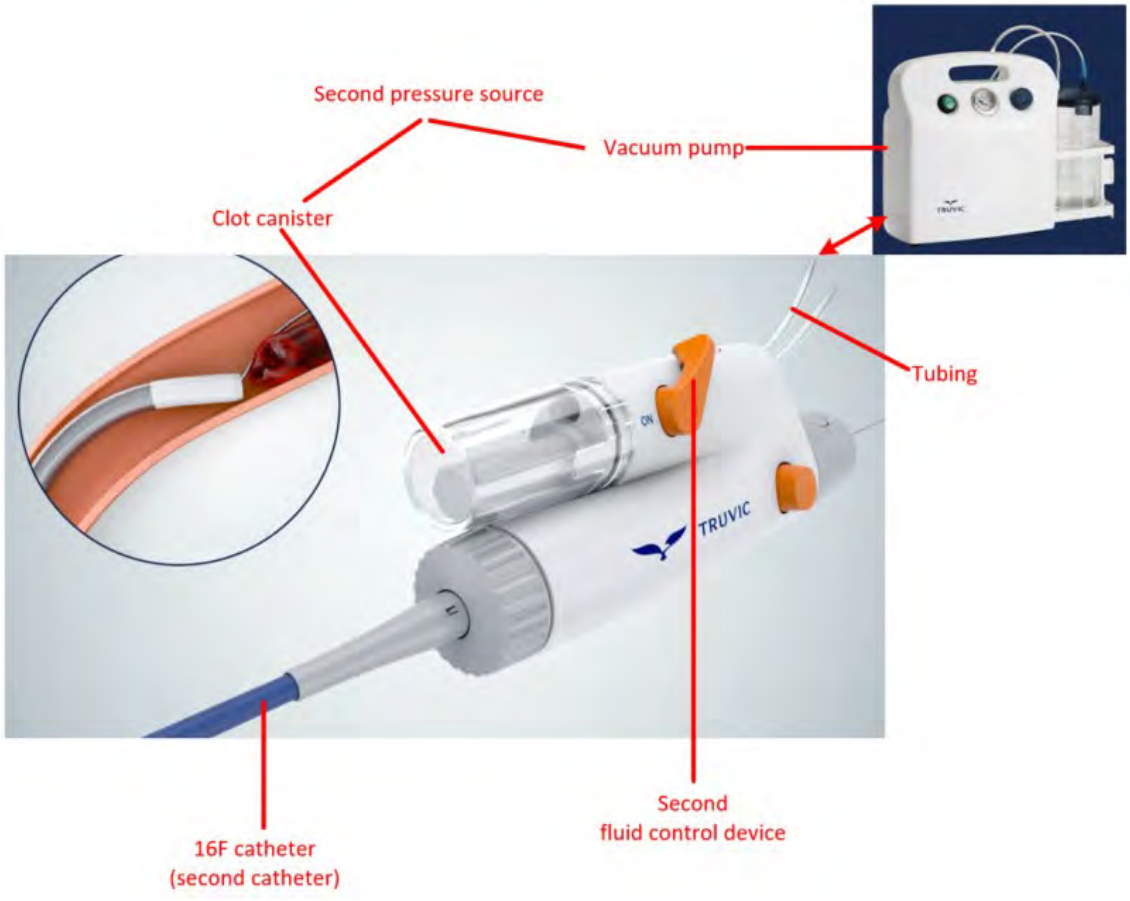


(Ex. A at 4 (annotations added).)

76. The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a 16F catheter (second catheter), a vacuum pump and a clot canister comprising the second pressure source, and a controller handle for a 16F catheter including a Dual-Action Vacuum Control operated by a lever (a second fluid control device) between the 16F catheter and the second pressure source:

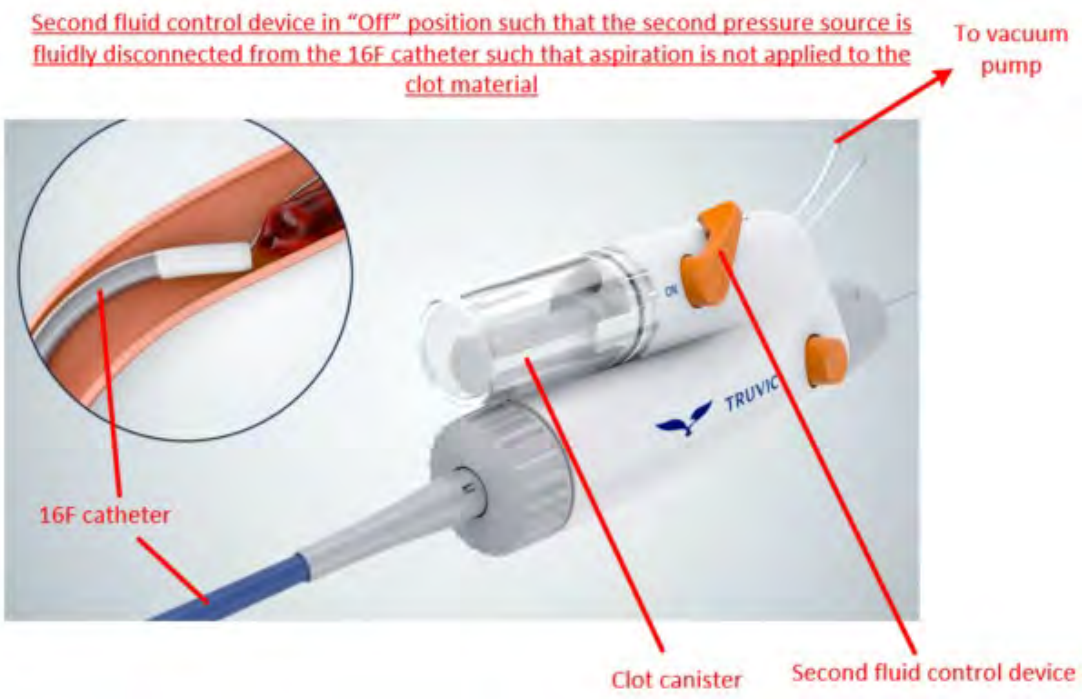


(Ex. A at 2 (annotations added).)

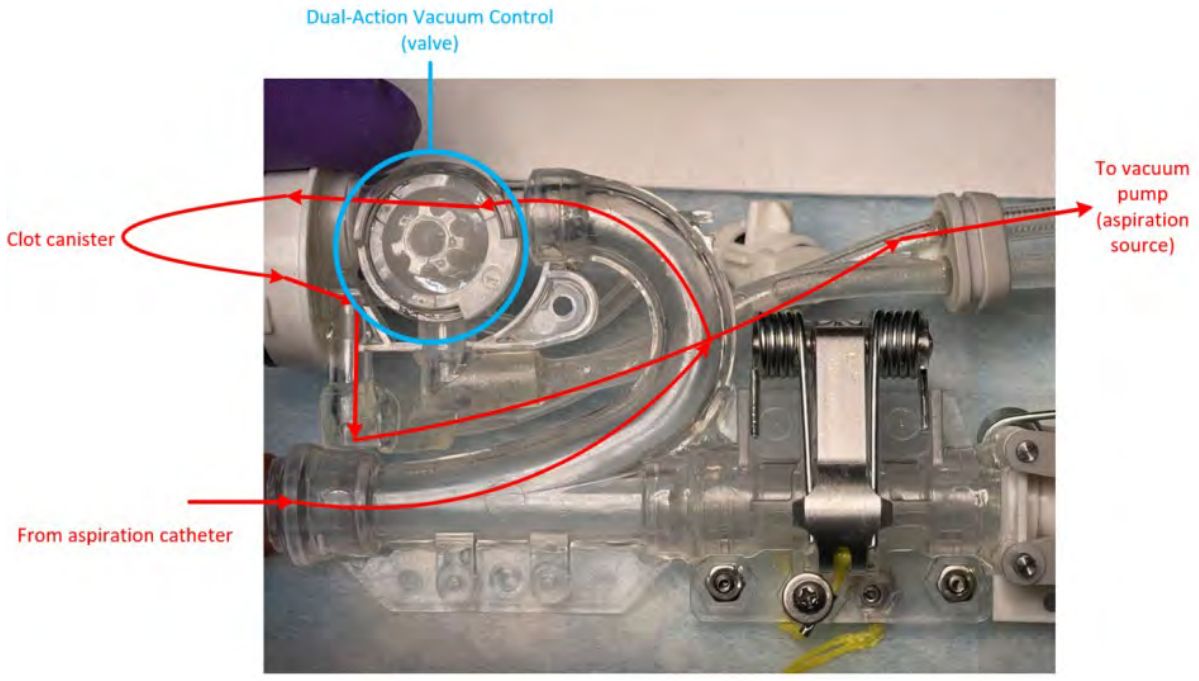


(Annotated diagram of Symphony system handle, including the second catheter, connection to a second pressure source (clot canister and vacuum pump), and a second fluid control device (the Dual-Action Vacuum Control operated by a lever).)

77. The vacuum control lever of the second fluid control device can be moved from the first (off) position where the second catheter is fluidly disconnected from the second pressure source to a second (on) position where the second catheter is fluidly connected to the second pressure source:

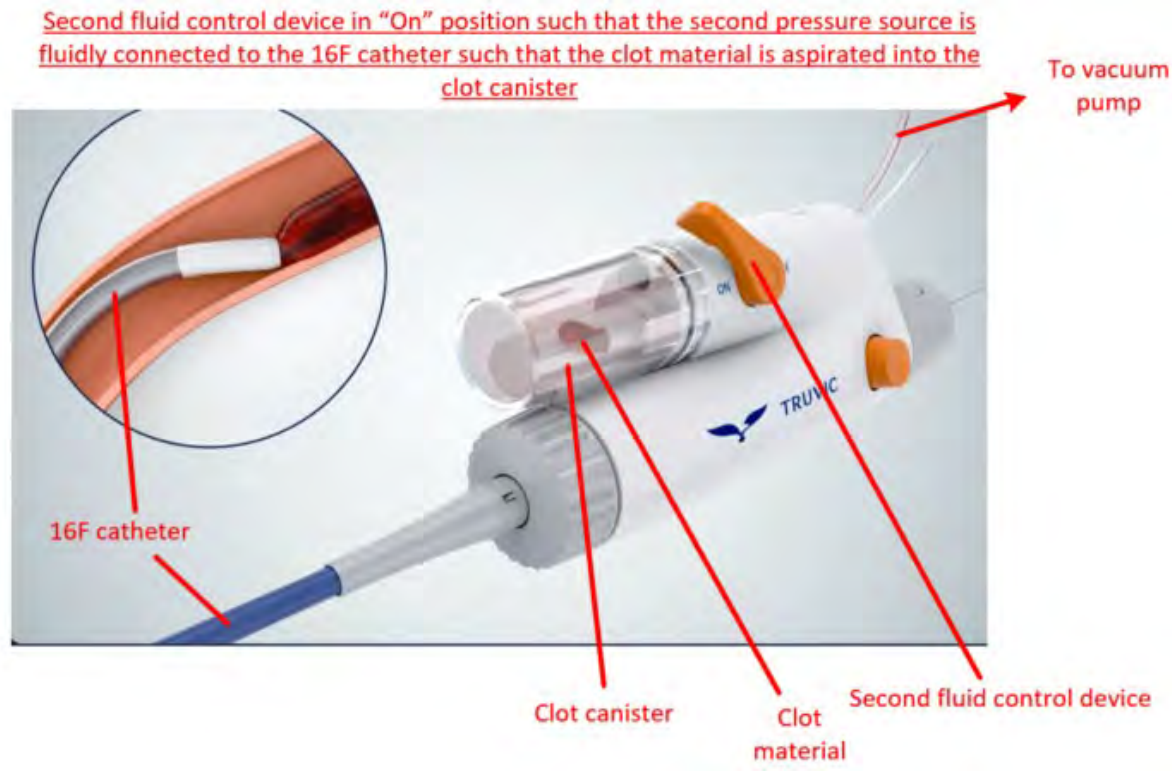


(Annotated screen capture from Symphony product video.)



(Annotated image of internal portion of controller handle housing.)

(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)

(Annotated image of Symphony housing (internal).)

78. The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a controller handle for a 16F catheter including a Dual-Action Vacuum Control operated by a lever (a second fluid control device) between the 16F catheter and the second pressure source (comprised of the clot canister and the vacuum pump) that in a first position (off) fluidly disconnects the second pressure source from the 16F catheter and that in a second position (on) fluidly connects the second pressure source to the 16F catheter. As detailed above, the second pressure source (clot canister and vacuum pump) creates a vacuum in the clot canister while the handle lever is in the first (off) position, and then vacuum pressure is applied to the second (16F) catheter to generate suction at the distal portion of the catheter (positioned near the clot material) when the handle lever is moved from the first position to the second (on) position:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

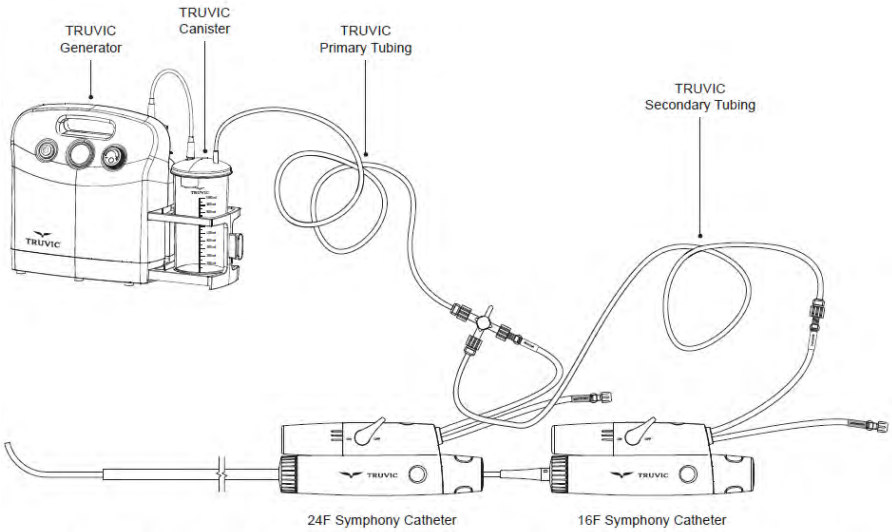


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

79. Additionally, the Symphony system practices claim 3 of the '910 Patent, which recites "[t]he clot treatment system of claim 1 wherein the first catheter has a size of 24 French, and wherein the size of the [] second catheter [] is 16 French," as can be seen in the attached Exhibit M. As can be seen above, the Symphony system includes a 24F catheter that is advanced into a patient's vasculature during thrombectomy procedures, including a 16F catheter telescoped through the 24F catheter.

80. Defendant directly infringes claims of the '910 Patent, including claims 1 and 3, by making, using, selling, offering for sale, and/or importing Symphony system products and their components, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures on pulmonary embolisms) Symphony system products.

81. Defendant induces infringement of claims of the ’910 Patent, including claims 1 and 3, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use Symphony systems that practice claims 1 and 3. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures on patients with pulmonary embolisms.

82. On information and belief, Defendant teaches and/or direct others to perform thrombectomy on pulmonary embolisms using the Symphony system (and components thereof), despite not having received an indication for use for treatment of pulmonary embolisms. Defendant, for example, provides Instructions for Use that state that “Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration.” (Ex. B at 2.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant’s sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating pulmonary embolisms. Defendant additionally is in the process of seeking FDA clearance for the treatment of PE and have an announced intention to formally market its Symphony system to do so.

83. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the ’910 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

84. Defendant’s infringement is with knowledge of the ’910 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated April 24, 2024, that the claims of United States Patent Application No. 18/329,433 (“the ’433 Application”) were scheduled to issue shortly as the ’910 Patent and further provided notice that claims 1 and 3 of the ’433 Application read on the Symphony system and that Defendants would be infringing the

'910 Patent upon its issuance. Inari further attached the notice of allowance for the '433 Application that became the '910 Patent.

85. At a minimum, Defendant has notice of the '910 Patent through the filing of the original Complaint, which was submitted to the Court just a few weeks after the '910 Patent issued.

86. Defendant has continued its infringing activities after the '910 Patent issued, despite knowledge of the allowed claims (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

87. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '910 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

88. To the extent applicable, the requirements of 35 U.S.C. § 154(d) have been met for the allowed claims of the '433 Application from April 24, 2024, to the issuance of the '910 Patent.

89. Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 2: INFRINGEMENT OF THE 11-'333 PATENT

90. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

91. Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claims 20 and 22 of the 11-'333 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

92. The 11-'333 Patent, titled "System for Treating Embolism and Associated Devices and Methods," is part of the same family as the '910 Patent, and shares the same specification. Similar to the '910 Patent, the 11-'333 Patent discloses improved methods of treatment for removing clot material (*e.g.*, thrombi and emboli) from blood vessels of a human patient, particularly from deep veins (DVT or deep vein thromboses) or pulmonary vasculature

(pulmonary embolisms) of human patient. (Ex. D at 4:51-58.) This is accomplished by aspirating the clot material through a catheter fluidly coupled to a pressure source via a valve. (*Id.* at 4:17-25.) The 11-'333 Patent explains that prior art clot-removal devices have been found: to be highly complex and lead to manufacturing and quality control difficulties, as well as delivery issues into patients; to cause trauma to the treatment vessel; to lack the ability to be appropriately fixed against the vessel; and/or to be ineffective at capturing clot material. (*Id.* at 2:33-44.) The 11-'333 Patent solves these problems through its inventions, which include, for example, methods comprising advancing a catheter within a patient's vasculature to treat pulmonary embolism or deep vein thrombosis. (*Id.* at cl. 1, cl. 20.) The aspiration catheter has its distal end placed proximate to the clot material (pulmonary embolism or deep vein thrombosis), while the aspiration catheter lumen is fluidly connected along a path to a clot canister and to an aspiration source proximal to the clot canister. (*Id.*) The methods further comprise steps of generating vacuum pressure in the path between the clot canister and aspiration catheter while a valve is in a first position that inhibits fluid flow from the aspiration catheter to the clot canister, and then moving the valve to a second position that permits fluid flow along the path from the lumen of the aspiration catheter to the clot canister, thereby applying vacuum pressure to the lumen of the aspiration catheter and aspirating at least a portion of clot material into the clot canister. (*Id.*) The 11-'333 Patent further claims aspects of aspiration systems, including a clot canister with a filter-to-filter blood from clot material (*id.*), performing the method with large (16F or 20F or larger diameter catheters (*id.* at cl. 2, cl. 3 cl. 21, cl. 22), and performing the method on clot material in the pulmonary artery (*id.* at cl. 4) or peripheral vasculature of the patient (*id.* at cl. 24).

93. Specifically, claim 20 of the 11-'333 Patent recites:

> [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.

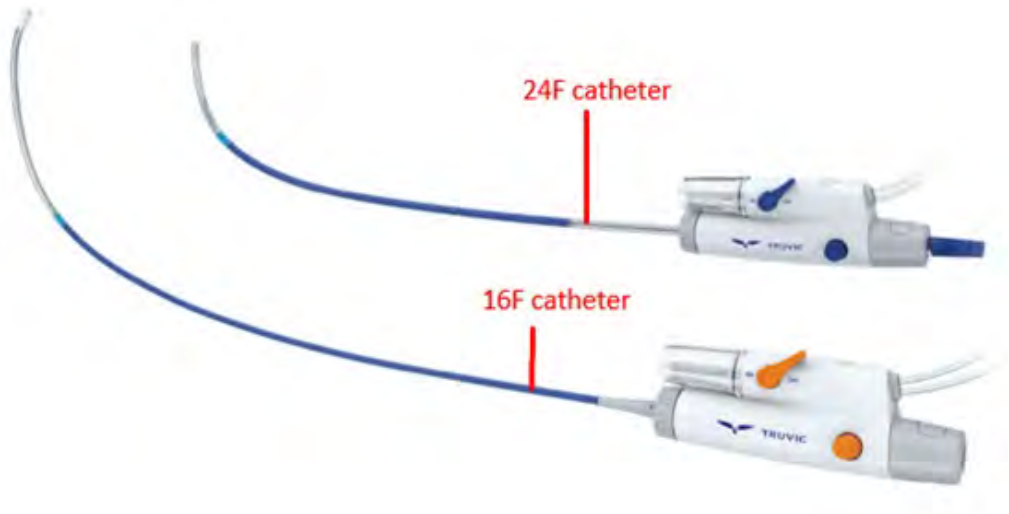
94. Claim 22 of the 11-'333 Patent further recites: "[t]he method of claim 20 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature."

95. Performing thrombectomy on deep vein thrombosis using the Truvic Symphony system practices each limitation of at least claims 20 and 22 of the 11-'333 Patent, as can be seen in the 11-'333 Patent claim chart, attached as Exhibit N.

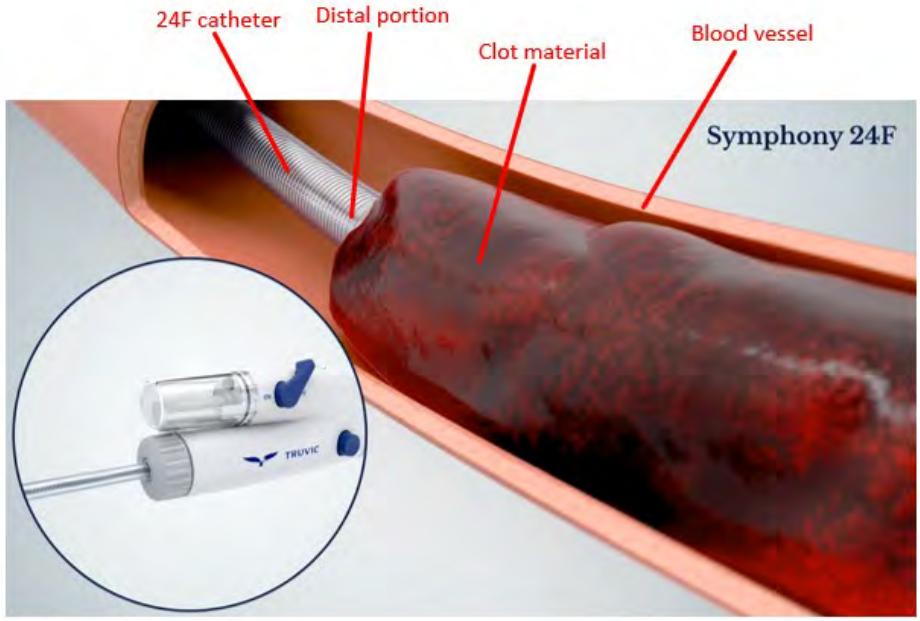
96. To the extent the preamble of claim 20 is construed to be limiting, thrombectomy of deep vein thrombosis with the Symphony system practices the requirements of the preamble, "[a] method of treating a deep vein thrombosis within a vasculature of a patient, the method comprising," as can be seen in Exhibit N. For example, according to Truvic's Symphony Brochure, Symphony employs "next generation thrombus removal" with "powerful, focused aspiration" for treating (*e.g.*, removing) clot material from within a blood vessel. (*See* Ex. A at 2-4.) Symphony's "Instructions for Use" further instruct that the system "is indicated for: [t]he non-surgical removal of fresh, soft emboli and thrombi from blood vessels." (Ex. B at 12.) In addition, Symphony's product website includes a video detailing a method of using Symphony to treat clot material within a blood vessel of a human patient using vacuum aspiration. *See* https://www.truvic.com/symphony-product.

97. Thrombectomy with the Symphony system practices the limitations of claim 20, including "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

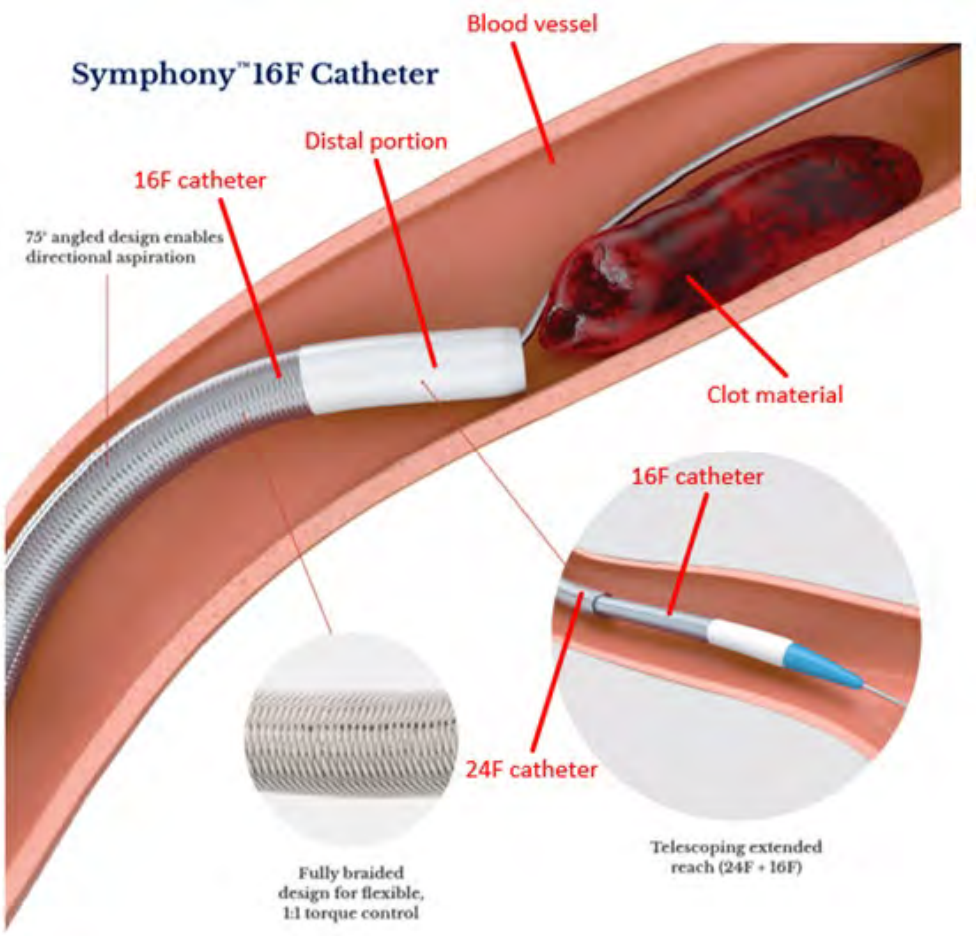
vein thrombosis," as can be seen in Exhibit N. The Symphony system includes a 24F catheter (a "first catheter") and a 16F catheter (a "second catheter"). (*Id.* at 2, 4.) These catheters can be used as aspiration catheters, and the Truvic Symphony system is "intended for use in the peripheral vasculature," such as for deep vein thrombosis.



(Ex. A at 2 (annotations added).)

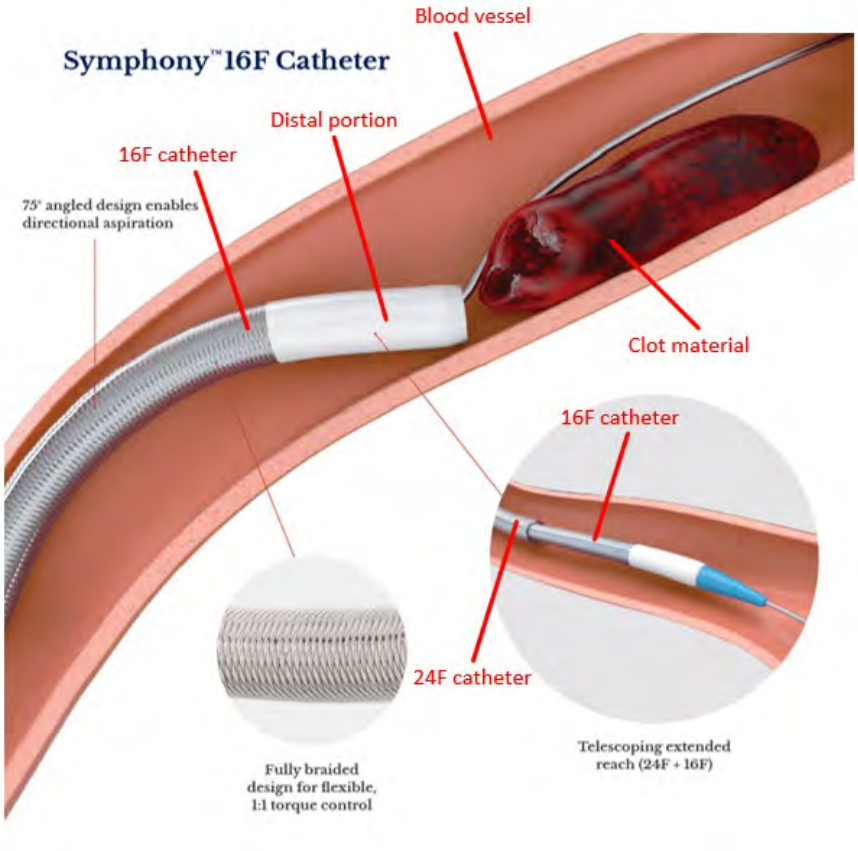


(Annotated screen capture from Symphony product video.)

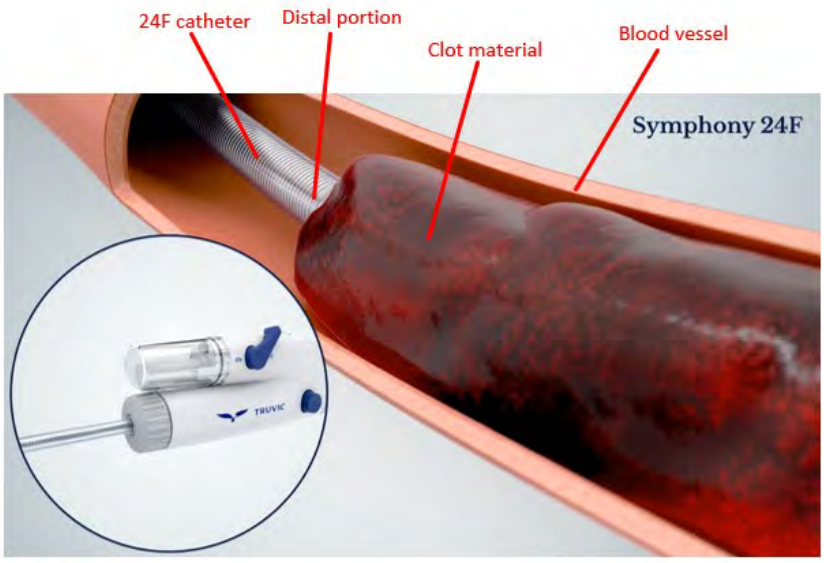


(Ex. A at 4 (annotations added).)

98. In thrombectomy operation, the 16F second catheter can be advanced, including through the 24F first catheter and out of the 24F first catheter, through the vasculature of a patient over a guidewire and/or with a dilator positioned therein (as shown in the image below) until a distal portion of the 16F second catheter is positioned just proximal of clot material within a blood vessel of the vasculature. (*See id.* at 4.) The 24F catheter can also be advanced to a position proximal to the clot material within a blood vessel of the patient's vasculature.



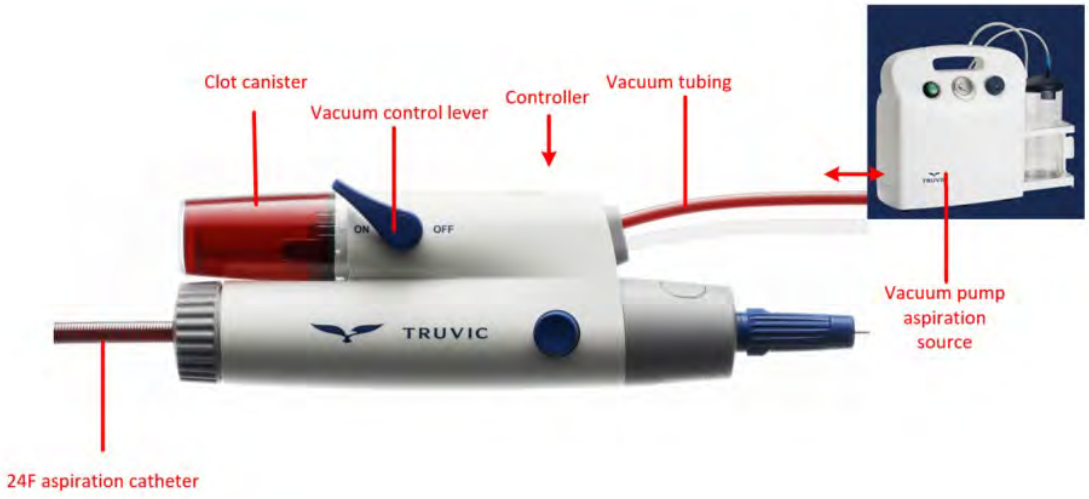
(Ex. A at 4 (annotations added).)



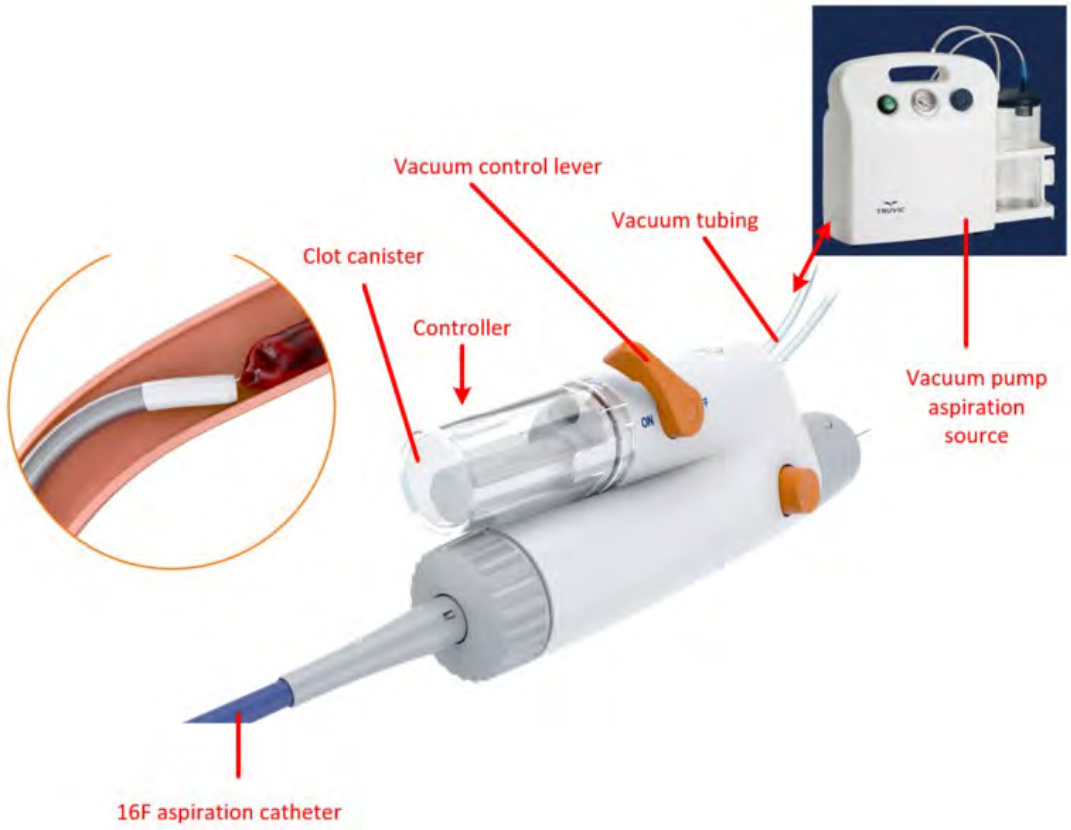
(Annotated screen capture from Symphony product video.)

99. Thrombectomy with the Symphony system practices the limitations of claim 20, including "wherein a lumen of the aspiration catheter is fluidly coupled along a fluid path to a

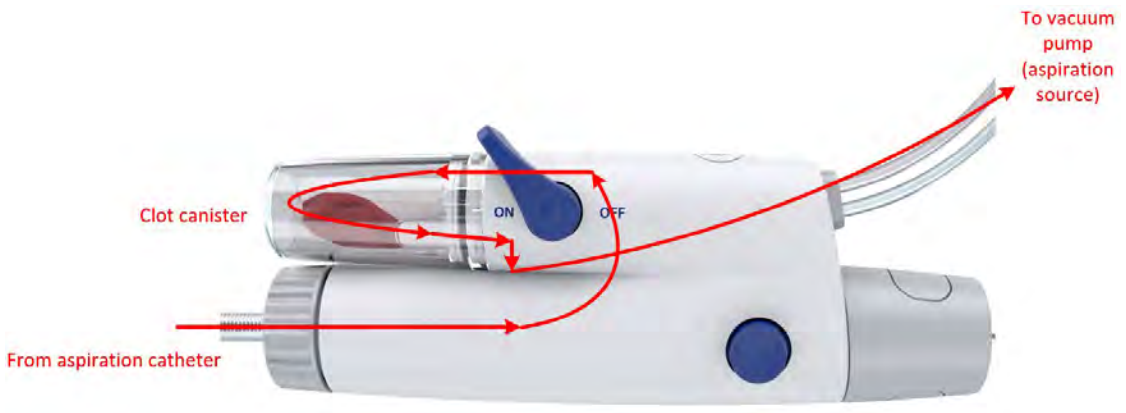
clot canister and an aspiration source proximal to the clot canister," as can be seen in Exhibit N. Specifically, in the Symphony system, the 24F and 16F catheters have lumens that are coupled along a fluid path in the controller handle, and then to an aspiration source that includes a vacuum pump that is located proximal to the clot canister. This can further be seen in the annotated diagrams below:



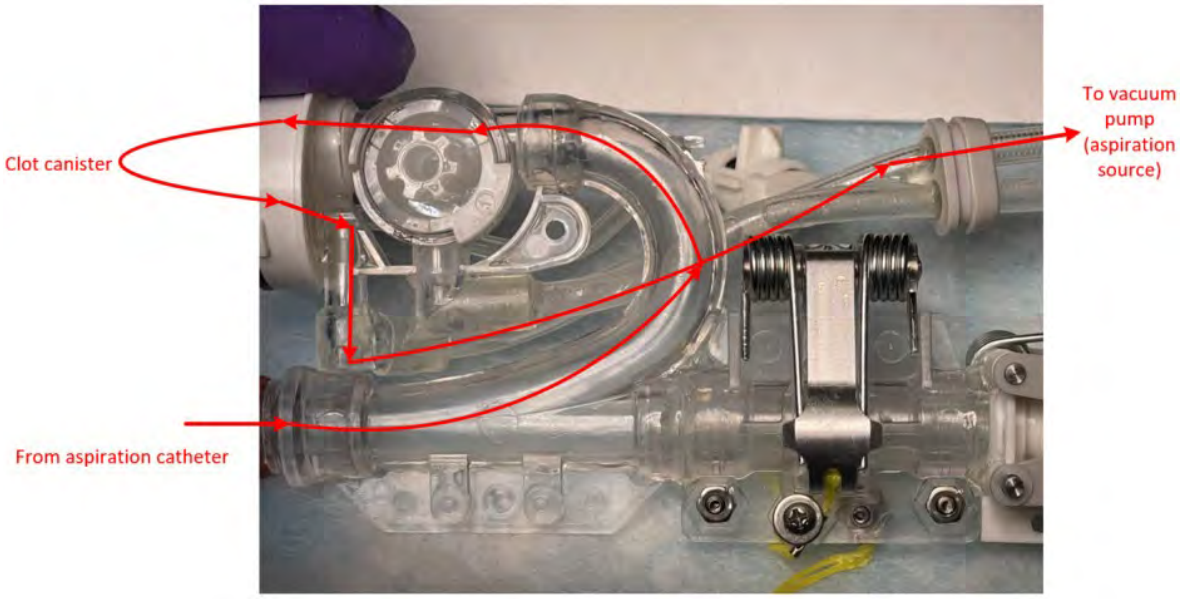
(Annotated diagram of Symphony system.)



(Annotated diagram of the Symphony system.)



(Annotated diagram of Symphony housing with flow path.)



(Annotated image of internal portion of controller handle housing with flow path.)

100. Thrombectomy with the Symphony system practices the limitations of claim 20, including "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," as can be seen in Exhibit N. In the Symphony system, the 24F and 16F

controller handles are coupled to a Truvic Generator and Truvic Canister, or another pressure source, which is a vacuum pressure source:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

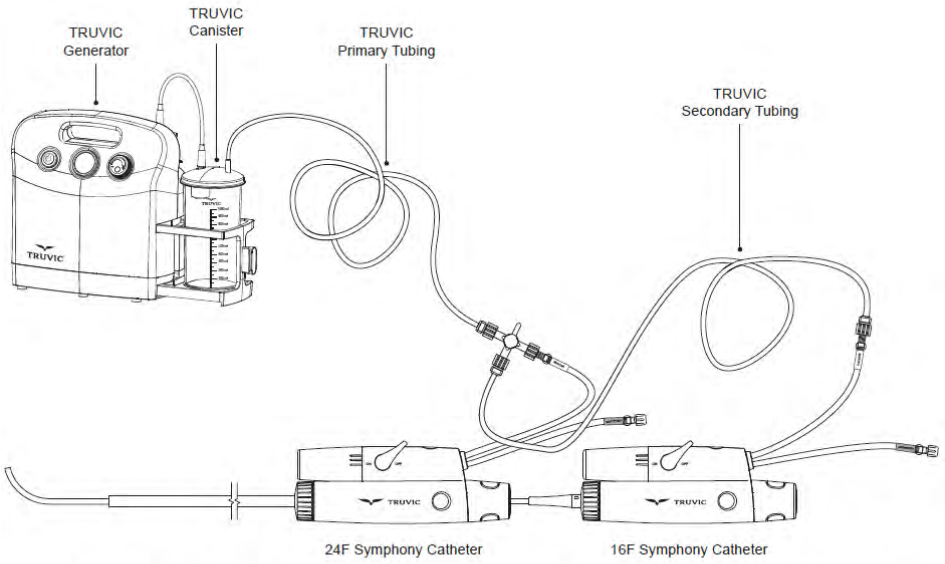
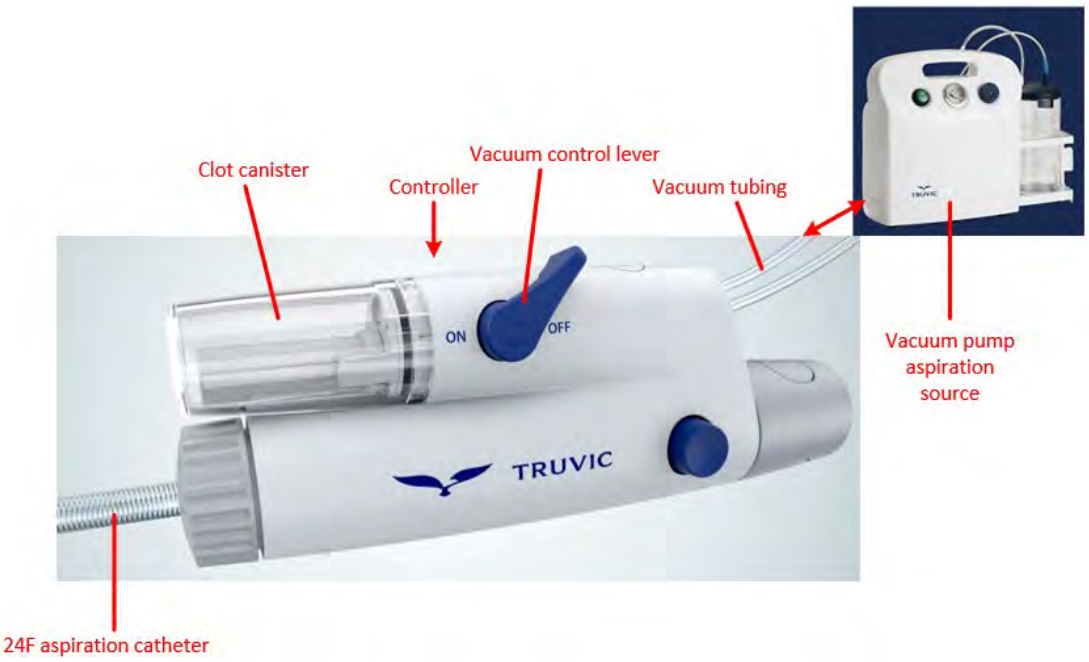


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

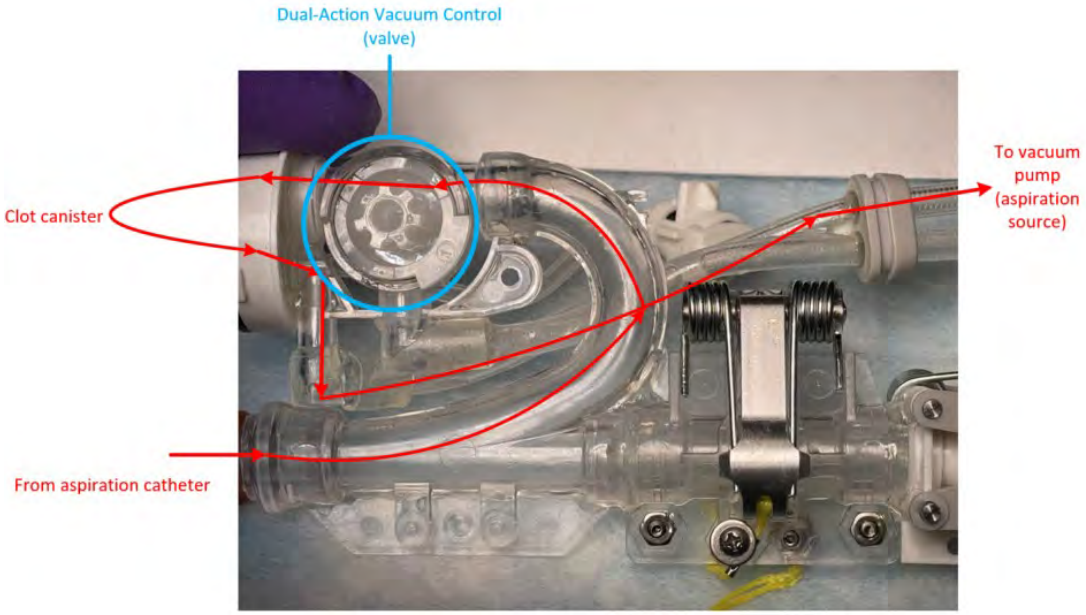
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

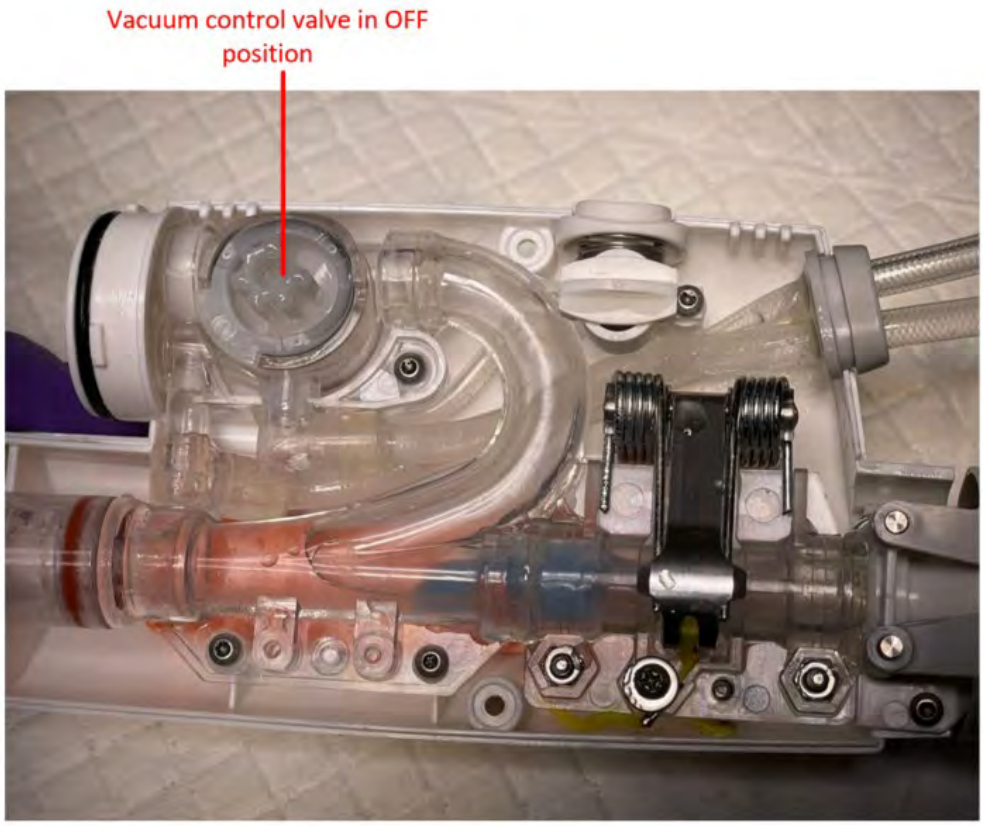
101. During thrombectomy using the Symphony system, the user initially sets the vacuum control lever on the 16F and/or 24F handles to the "OFF" position, which actuates a vacuum valve in the handle, ensuring that vacuum is not applied to the lumen of the 16F and/or 24F aspiration catheters:



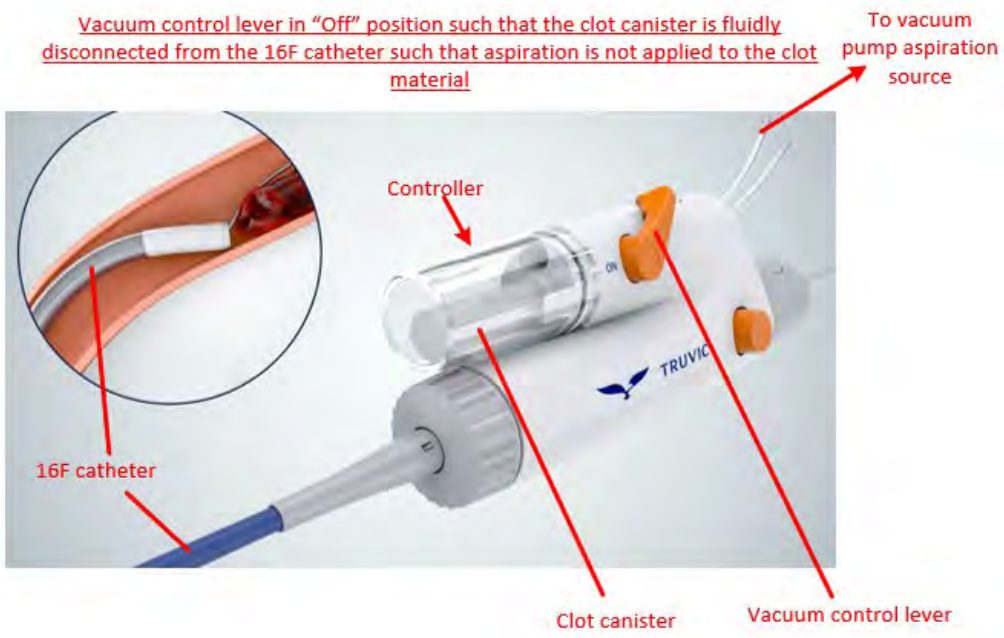
(Annotated diagram of Symphony system.)



(Annotated image of Symphony housing (internal).)



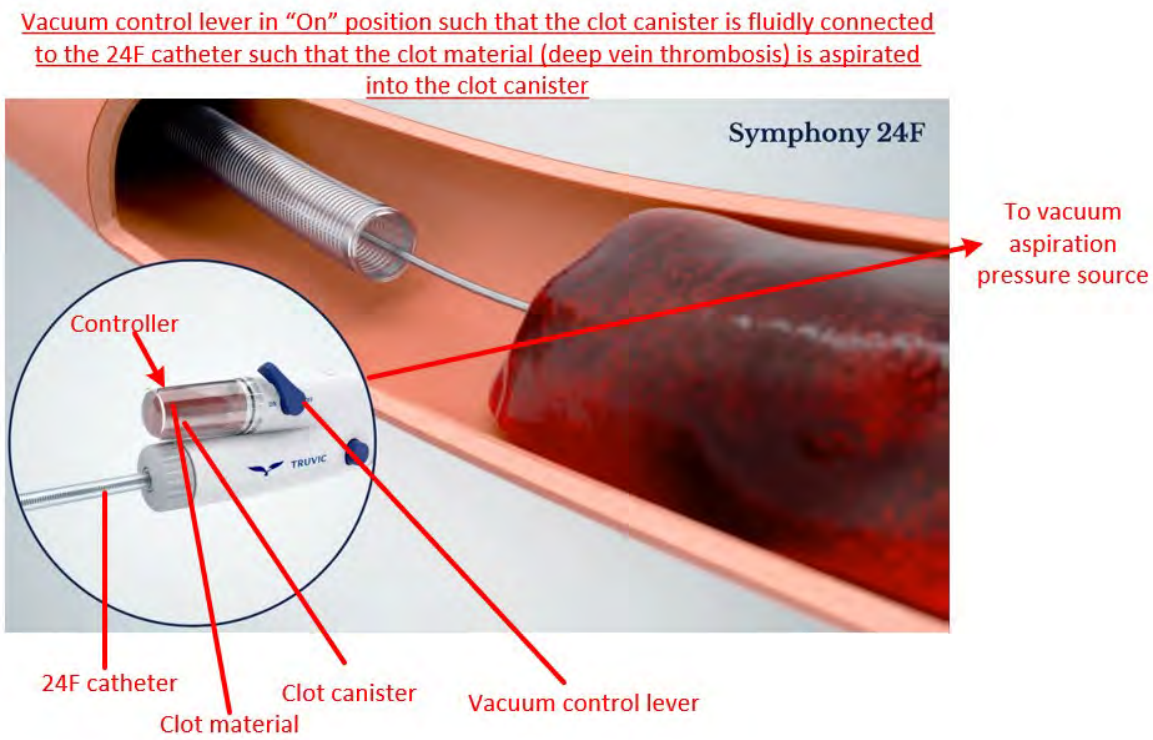
(Annotated image of Symphony housing (internal).)



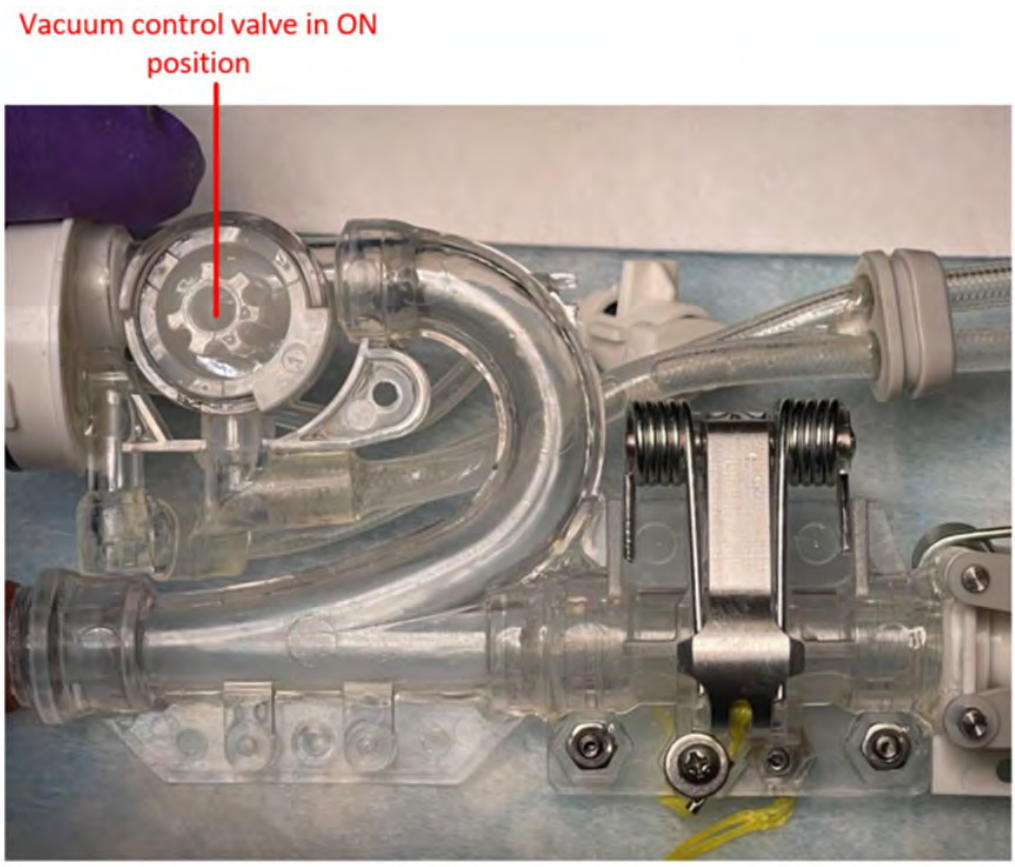
(Annotated screen capture from Symphony product video.)

102. During thrombectomy using the Symphony system, the user moves the vacuum lever on the 16F and/or 24F handles to the "ON" position, which actuates a valve in the handle,

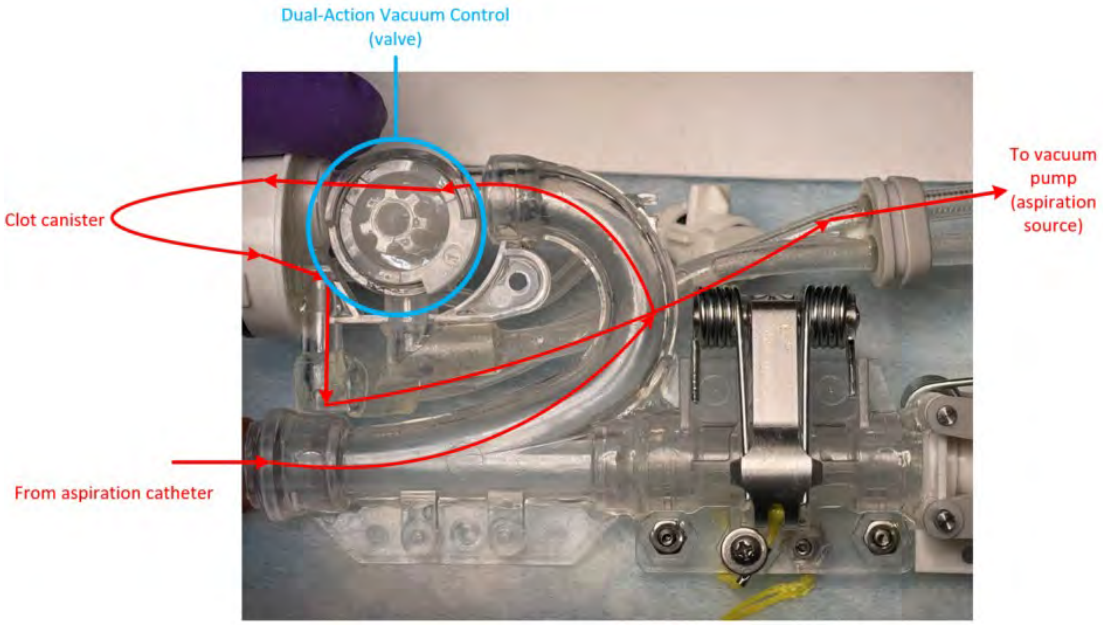
applying vacuum to the lumen of the 16F and/or 24F aspiration catheters:



(Annotated screen capture from Symphony product video.)

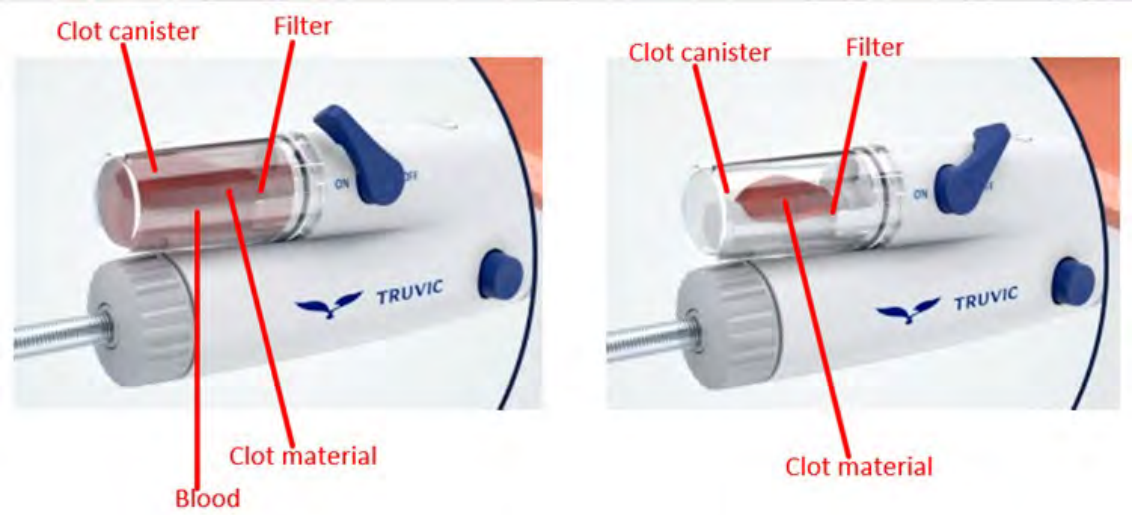


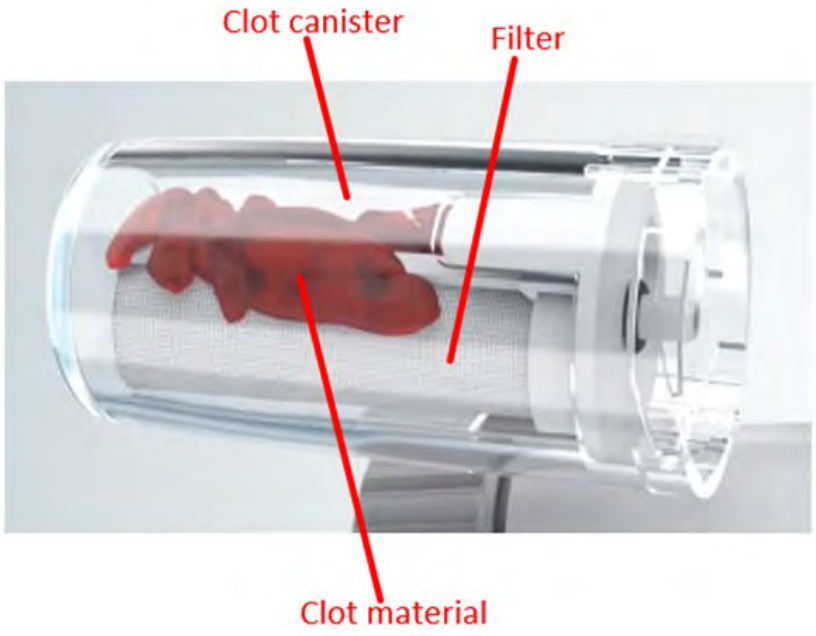
(Annotated image of Symphony housing (internal).)

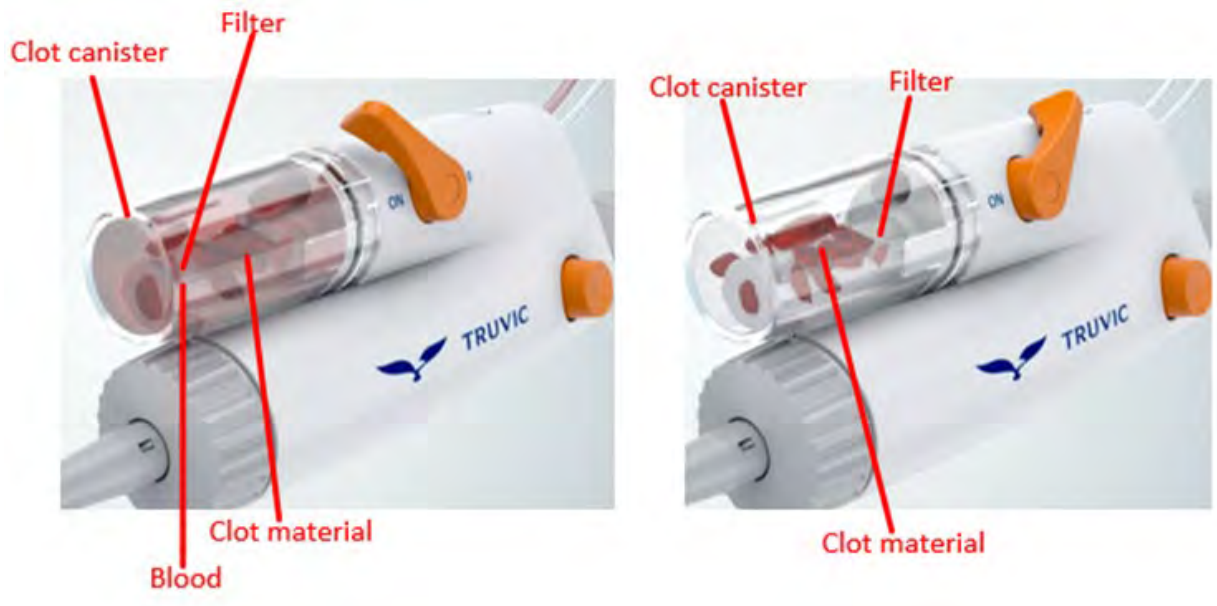


(Annotated image of internal portion of controller handle housing.)

103. Thrombectomy with the Symphony system practices the limitations of claim 20, including "wherein the clot canister includes a filter configured to filter the blood from the portion of the deep vein thrombosis," as can be seen in Exhibit N. Specifically, the clot canisters of the 24F and 16F handles have a filter that filters the blood from the aspirated portion of the clot material, such as a deep vein thrombosis. This allows the blood to pass through the canister, while the clot canister traps the clot material of a deep vein thrombosis.

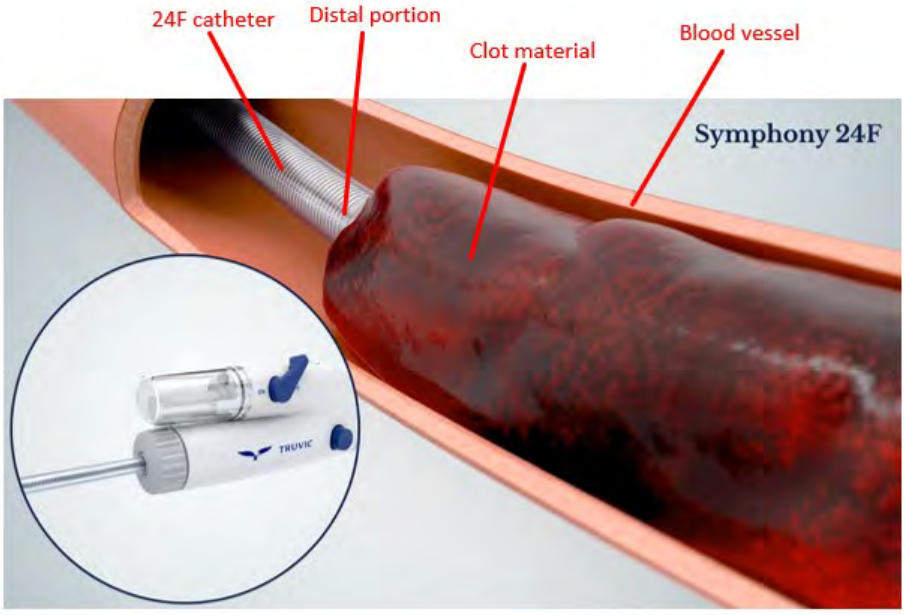






(Annotated screen captures from Symphony product video.)

104. Additionally, thrombectomy with the Symphony system practices claim 22 of the 11-'333 Patent, which recites "[t]he method of claim 20 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature," as can be seen in the attached Exhibit N. The Symphony system includes a 24F catheter that is advanced into a patient's vasculature during thrombectomy procedures, including for deep vein thrombosis, as recited in claim 20 and analyzed above.



(Annotated screen capture from Symphony product video.)

105. Defendant directly infringes claims of the 11-'333 Patent, including claims 20 and 22, when Defendant or persons under its direction and control perform thrombectomy procedures on deep vein thromboses. For example, Defendant directly infringes claims 20 and 22 when testing or using the Symphony system in patients.

106. Defendant induces infringement of claims of the 11-'333 Patent, including claims 20 and 22, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems in a manner that practices the methods of claims 20 and 22. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures on deep vein thromboses with the Truvic Symphony system in a manner that practices the limitations of claims of the 11-'333 Patent, including claims 20 and 22. Defendant instructs and teaches users to perform methods that practice the limitations of claims 20 and 22 with knowledge and/or willful blindness that such acts constitute direct infringement of the 11-'333 Patent.

107. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system in a manner that practices claims of the 11-'333 Patent, including claims 20 and 22. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including methods of treating deep vein thrombosis that practice the 11-'333 Patent.

108. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of

the invention that is especially made or adapted for infringement of the claims of the 11-'333 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

109. Defendant's infringement is with knowledge of the 11-'333 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated April 24, 2024, that the claims of United States Patent Application No. 18/329,450 ("the '450 Application") were scheduled to issue shortly as the 11-'333 Patent and further provided notice that claims 42 and 44 of the '450 Application (renumbered as claims 20 and 22 of the 11-'333 Patent) read on the Symphony system and that Defendant would be infringing the 11-'333 Patent upon its issuance. Inari further attached the notice of allowance and the issue notification for the 11-'333 Patent.

110. At a minimum, Defendant has notice of the 11-'333 Patent through the filing of the original Complaint, which was submitted to the Court just a few weeks after the 11-'333 Patent issued.

111. Defendant has continued its infringing activities after the 11-'333 Patent issued, despite knowledge of the 11-'333 Patent (including knowledge from correspondence with Inari and from the original Complaint), and such infringement has been and continues to be egregious and willful.

112. The requirements of 35 U.S.C. § 287(a) have been met for the 11-'333 Patent. Because the 11-'333 Patent contains only method claims, no marking is required.

113. To the extent applicable, the requirements of 35 U.S.C. § 154(d) have been met for the allowed claims of the '450 Application from April 24, 2024, to the issuance of the 11-'333 Patent.

114. Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 3: INFRINGEMENT OF THE '005 PATENT

115. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

116. The '005 Patent, titled "System for Treating Embolism and Associated Devices

and Methods," is part of the same family as the '910 and 11-'333 Patents, and shares the same specification. Similar to the '910 and 11-'333 Patents, the '005 Patent discloses improved clot-removing systems and methods that solve problems with prior art clot-removal devices. The '005 Patent solves these problems through its inventions that include, for example, a vacuum aspiration system comprising a flow path extending through a housing with an on-off control in the flow path, a catheter, and a clot canister fluidly coupled to the flow path, where the housing further includes an improved hemostasis valve that is configured to receive a second catheter and direct it through the first catheter. (Ex. E at cl. 1.)

117. Defendant directly infringes—literally and/or under the doctrine of equivalents—at least claim 10 of the '005 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

118. The Symphony system practices each limitation of at least claim 10 of the '005 Patent.

119. For example, claim 10 of the '005 Patent recites:

> [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.

120. To the extent the preamble of claim 10 is construed to be limiting, the Truvic Symphony system practices the preamble, a "vacuum aspiration system, comprising," as can be seen in the claim chart in Exhibit O. Specifically, the Symphony system is a vacuum aspiration system for treating clots: "The Symphony Thrombectomy System is designed to remove thrombus/embolus … from the vasculature using controlled aspiration." (Ex. B at 1.)

121. The Symphony system practices the limitations of claim 10, including "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," as can be seen in the claim chart in Exhibit O. The Symphony system includes controller handles (a housing), one for each of a 24F and 16F catheter:

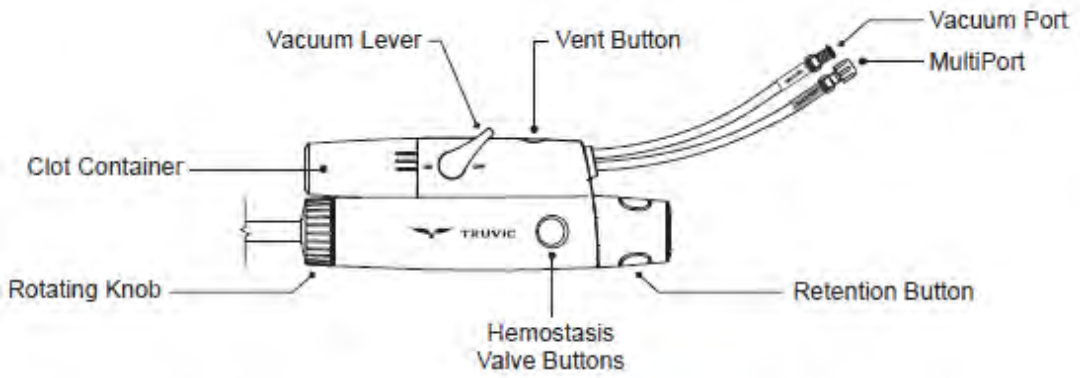
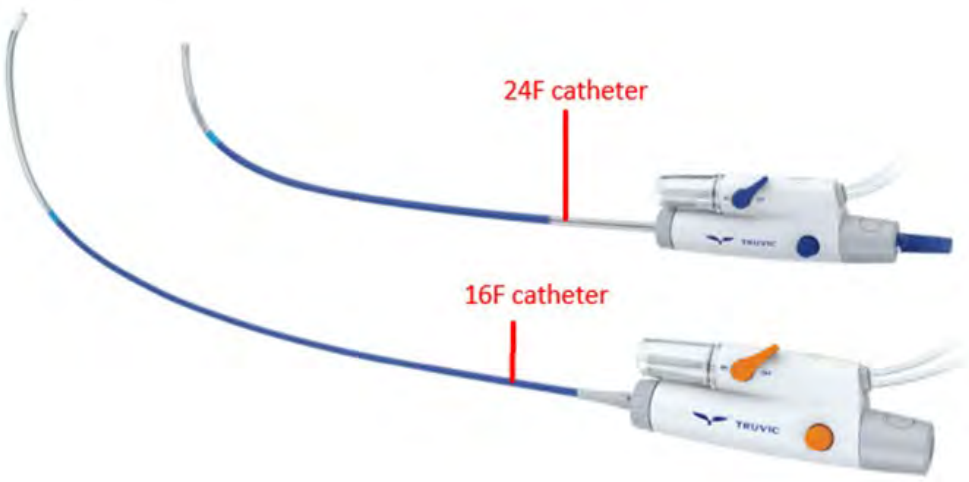


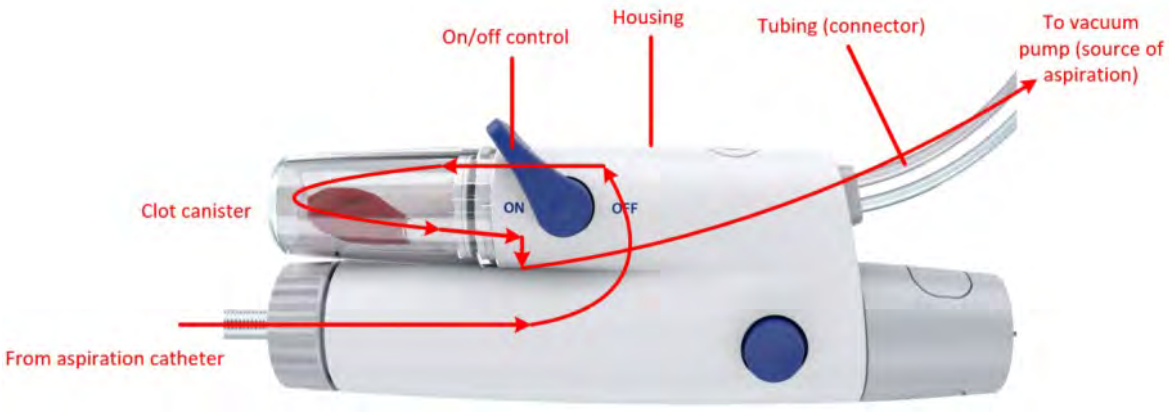
Figure 3: Symphony Catheter Handle, labeled

(Ex. B at 4.)



(Ex. A at 2 (annotations added).)

122. The Symphony handle (housing) includes a flow path through the handle extending from the catheter (in fluid communication with the flow path) through the housing, the on-off control valve, the clot canister, the tubing (connector) to the vacuum pump (source of aspiration) that fluidly connects the lumen of the 24F aspiration catheter (first catheter), the on-off control valve, the clot canister, the tubing (connector), and the vacuum pump (source of aspiration):

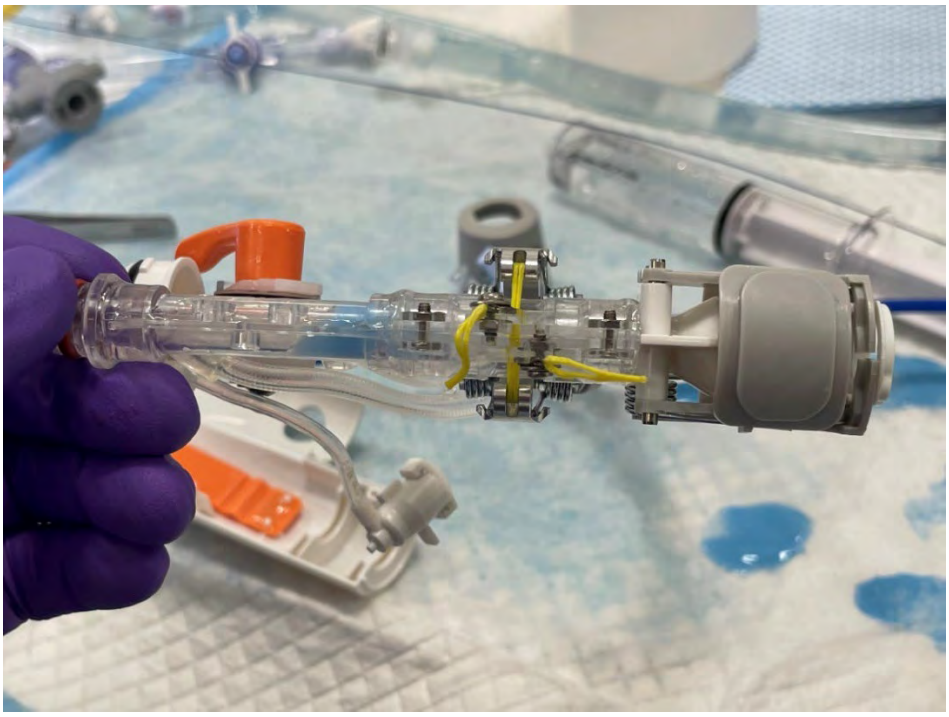


(Annotated diagram of Symphony housing with flow path.)

123. The Symphony system practices the limitations of claim 1, including "a hemostasis valve in the housing configured to receive a second catheter and direct the second

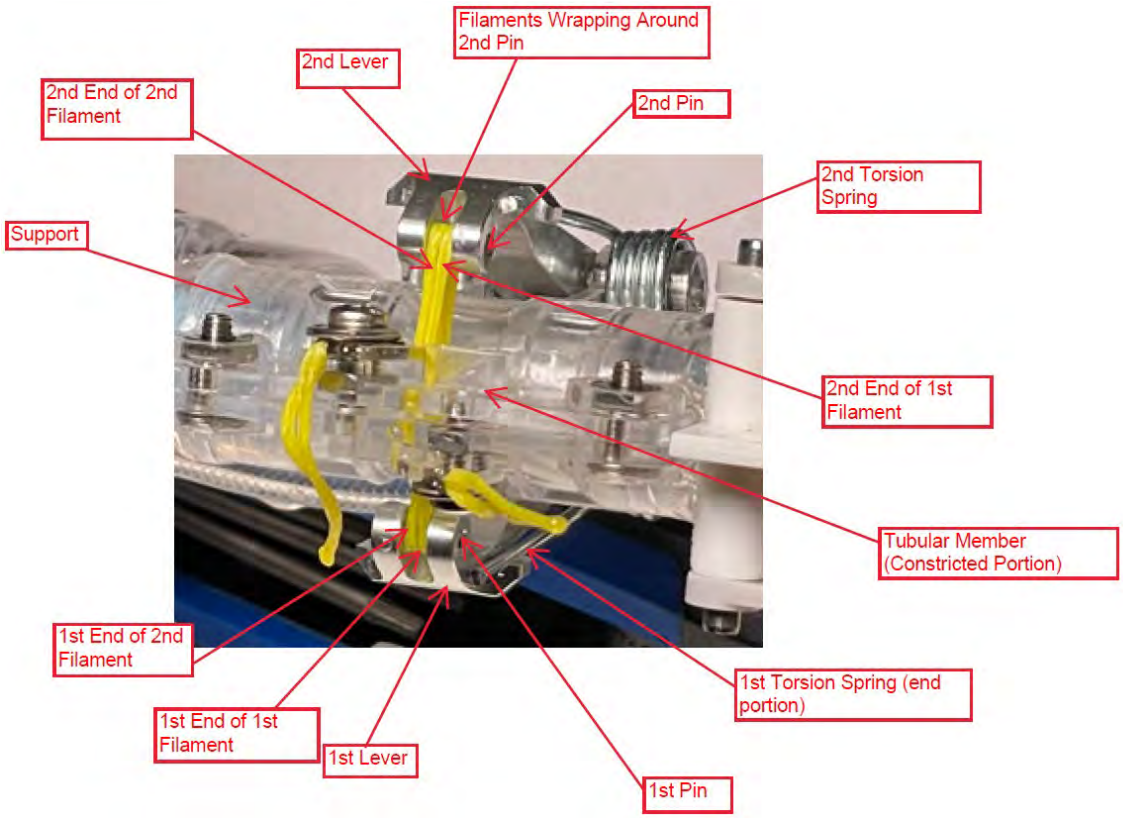
catheter through the first catheter, wherein the hemostasis valve comprises" as can be seen in claim chart in Exhibit O. The Symphony system includes a controller handle with a hemostasis valve in the controller housing:

(Ex. A at 6.)



(Image of internal portion of housing with hemostasis valve.)

124. The Symphony system practices the limitations of claim 1, including "(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; (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," as can be seen in claim chart in Exhibit O. The hemostasis valve in each of the Symphony handles includes a plastic support. It also includes an actuator mechanism having a first member including a first button that pushes against a first lever and second member including a second button that pushes against a second lever, where the lever and buttons are biased outwardly by a first torsion spring(s) and a second torsion spring(s), and the valve has a lumen carried by a plastic support and that can be constricted by first and second filament lines looped around the lumen and wrapped around pins in the first lever and the second lever. This structure can be seen in the annotated picture of the Symphony system below:



(Annotated image of internal portion of Symphony housing, including hemostasis valve.)

125. The torsion springs drive the lever outward such that the pins of the levers tension the filament lines wrapped around the pins of the levers and wrapped in a loop around the tubular member (lumen) of the hemostasis valve to constrict the collapsible sidewall of the lumen by reducing the diameter of the filament loops around it.

126. Defendant directly infringes claims of the ’005 Patent, including claim 10, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant’s direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures) Symphony system products.

127. Defendant induces infringement of claims of the ’005 Patent, including claim 10, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claims 10. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

128. Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof). Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

129. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '005 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

130. Defendant's infringement is with knowledge of the '005 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated September 29, 2023, that the Symphony system might infringe the '005 Patent. Inari further explained, by letter dated April 24, 2024, that a teardown of the hemostasis valves in the Symphony system showed that they infringe Inari's patents.

131. At a minimum, Defendant has notice of the '005 Patent through the filing of the original Complaint.

132. Defendant has continued its infringing activities, despite knowledge of the '005 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

133. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '005 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

134. Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 4: INFRINGEMENT OF THE '691 PATENT

135. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

136. The '691 Patent, titled "System for Treating Embolism and Associated Devices and Methods," is part of the same family as the '910, 11-'333, and '005 Patents, and it shares the same specification. Similar to the '910, 11-'333, and '005 Patents, the '691 Patent discloses improved clot-removing systems and methods that solve problems with prior art clot-removal devices. The '691 Patent solves these problems through its inventions that include, for example, an aspiration system with accelerated response, comprising an aspiration pump coupled with a first chamber, an aspiration catheter in fluid communication in communication with the first chamber via an aspiration tube, further having a second chamber between the aspiration pump and the second chamber that is removable, and where the system has a user-actuatable valve between the second chamber and the aspiration catheter to connect or disconnect negative pressure, allowing pressure to build up in the first and second chambers before connecting negative pressure to the aspiration catheter to aspirate clot material. (*See* Ex. F at cl. 14.) Dependent claims further recite that the system is for treating deep vein thrombosis. (*Id.* at cl. 22.)

137. Defendant directly infringes—literally and/or under the doctrine of equivalents—at least claims 14 and 22 of the '691 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

138. The Symphony system practices each limitation of at least claims 14, 19, 20, and 22 of the '691 Patent.

139. For example, claim 14 of the ’691 Patent recites:

> [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 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.

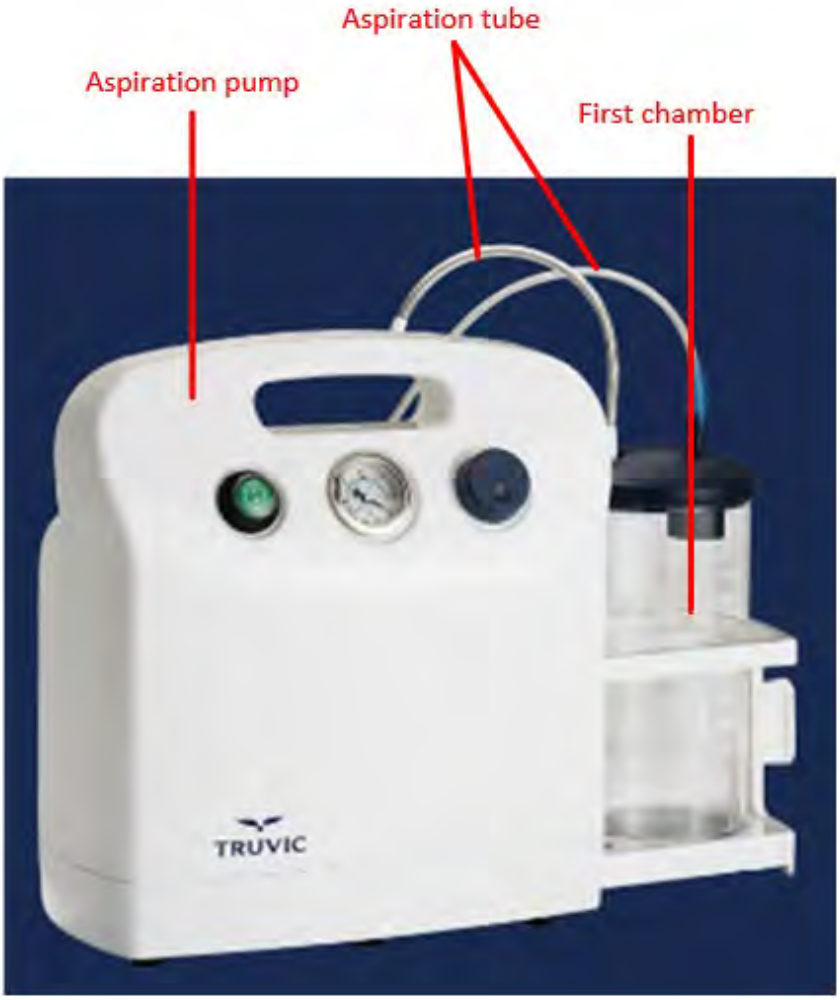
140. Claim 19 of the ’691 Patent depends from claim 14 and further recites “[t]he aspiration system of claim 14 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient.”

141. Claim 20 of the ’691 Patent depends from claim 19 and further recites “[t]he 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.”

142. Claim 22 of the ’691 Patent depends from claim 20 and further recites “[t]he aspiration system of claim 20 wherein the clot material comprises a deep vein thrombus.”

143. To the extent the preamble of claim 14 is construed to be limiting, the Truvic Symphony system practices the requirements of the preamble, “[a]n aspiration system with accelerated response, comprising,” as can be seen in the claim chart in Exhibit P. Specifically, the Symphony system is a vacuum aspiration system with accelerated response used for treating clots: “[t]he Truvic Symphony Thrombectomy System employs “next generation thrombus removal” with “powerful, focused aspiration” for treating (*e.g.*, removing) clot material from within a blood vessel.” (Ex. A at 2-4.).

144. The Symphony system practices the limitations of claim 14, including "an aspiration pump in communication with a first chamber," as can be seen in claim chart in Exhibit P. The Symphony system includes the Truvic Generator comprising a vacuum pump (aspiration pump), an aspiration tube, and a first vacuum chamber (the Truvic Canister):



(Annotated image of Truvic Generator.)

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

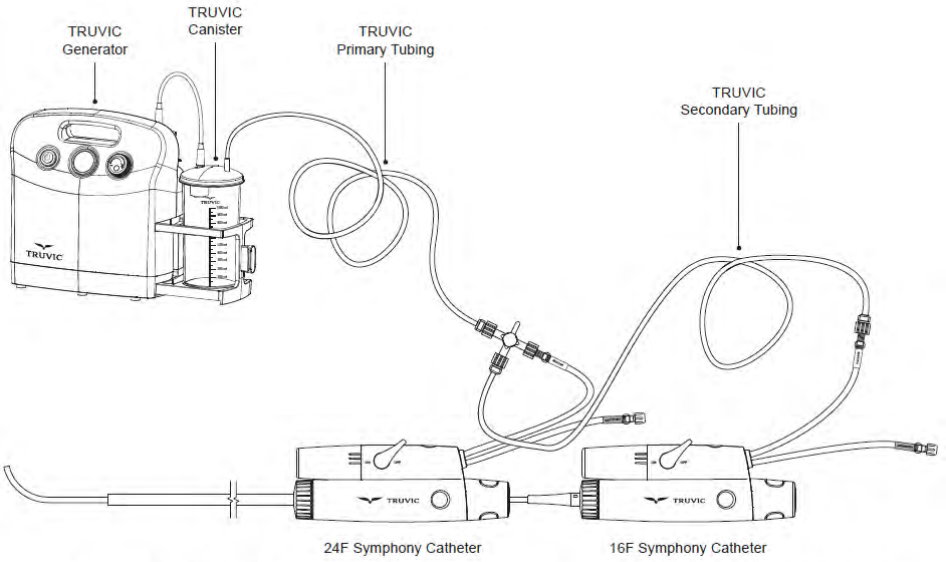
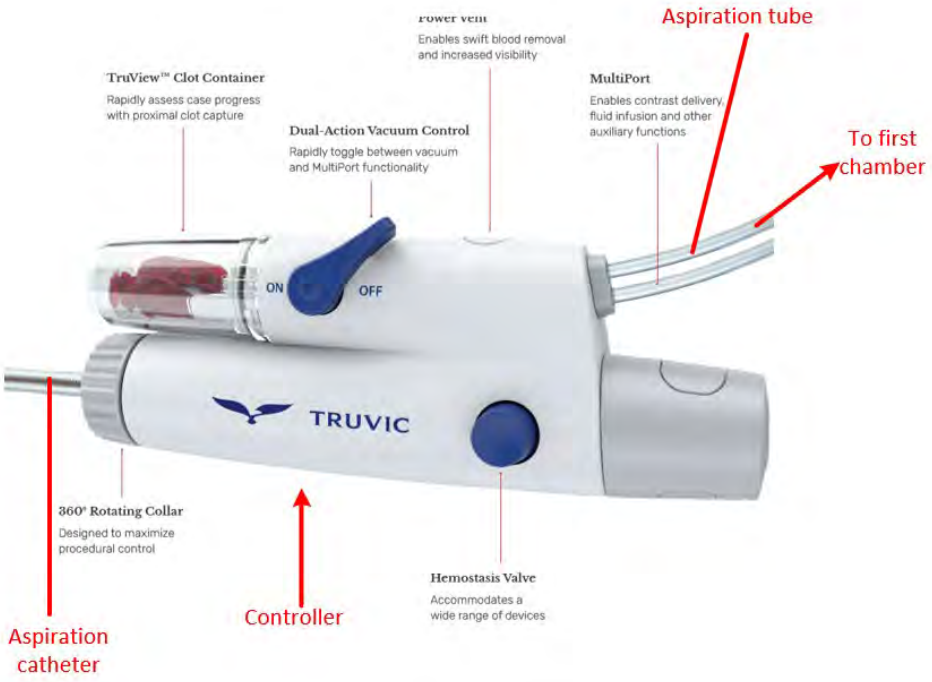


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

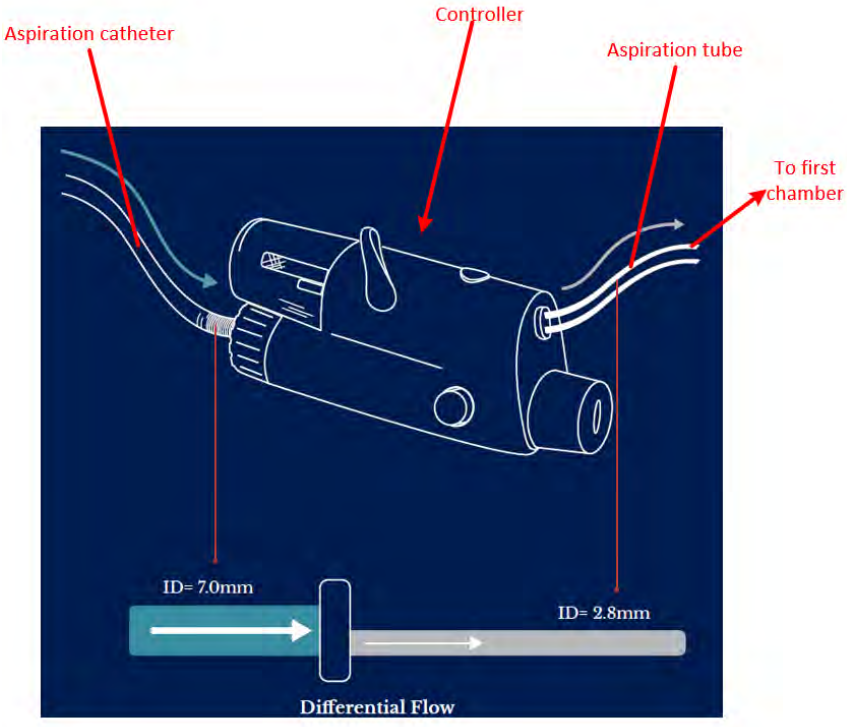
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

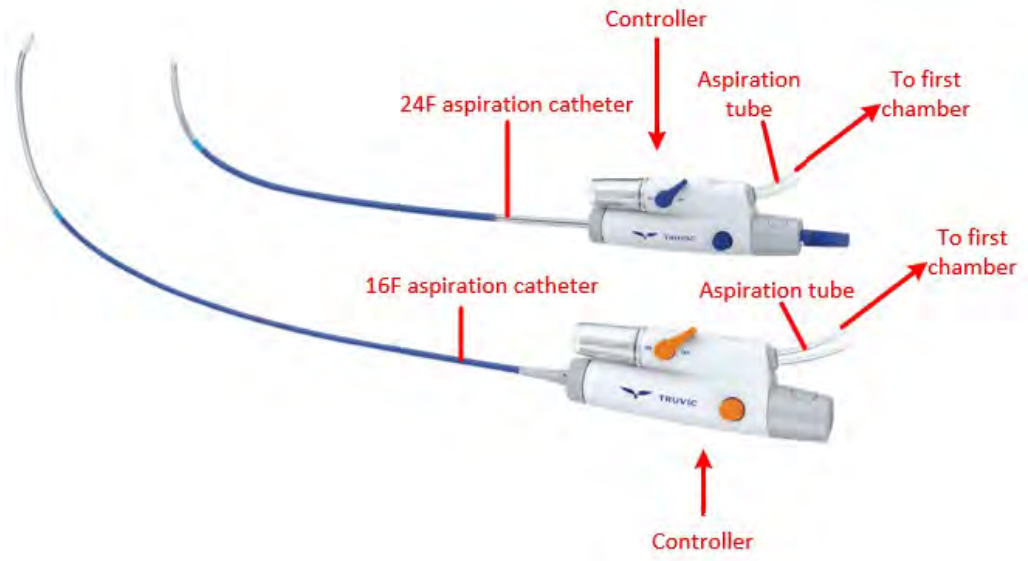
145. The Symphony system practices the limitations of claim 1, including "an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube," as can be seen in claim chart in Exhibit P. The Symphony system includes 24F and 16F catheters in fluid communication with the first chamber of the Truvic Generator through a controller handle by way of an aspiration tube:



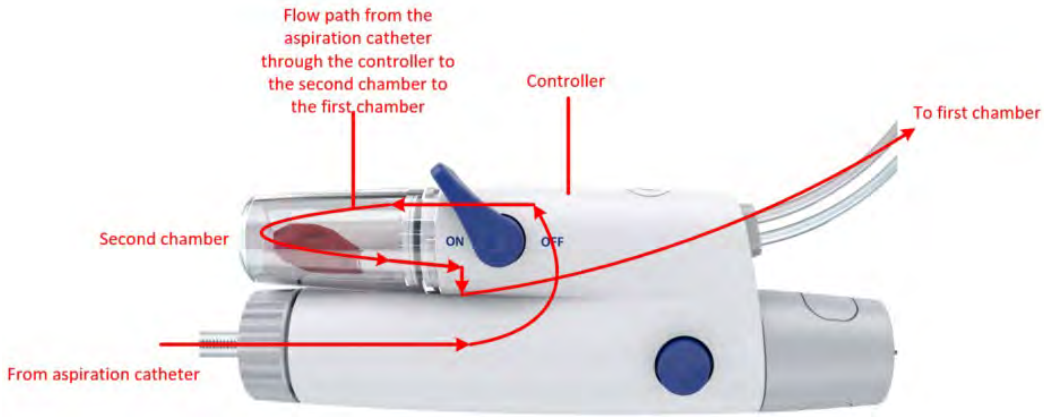
(Ex. A at 6 (annotations added).)



(Ex. A at 7 (annotations added).)

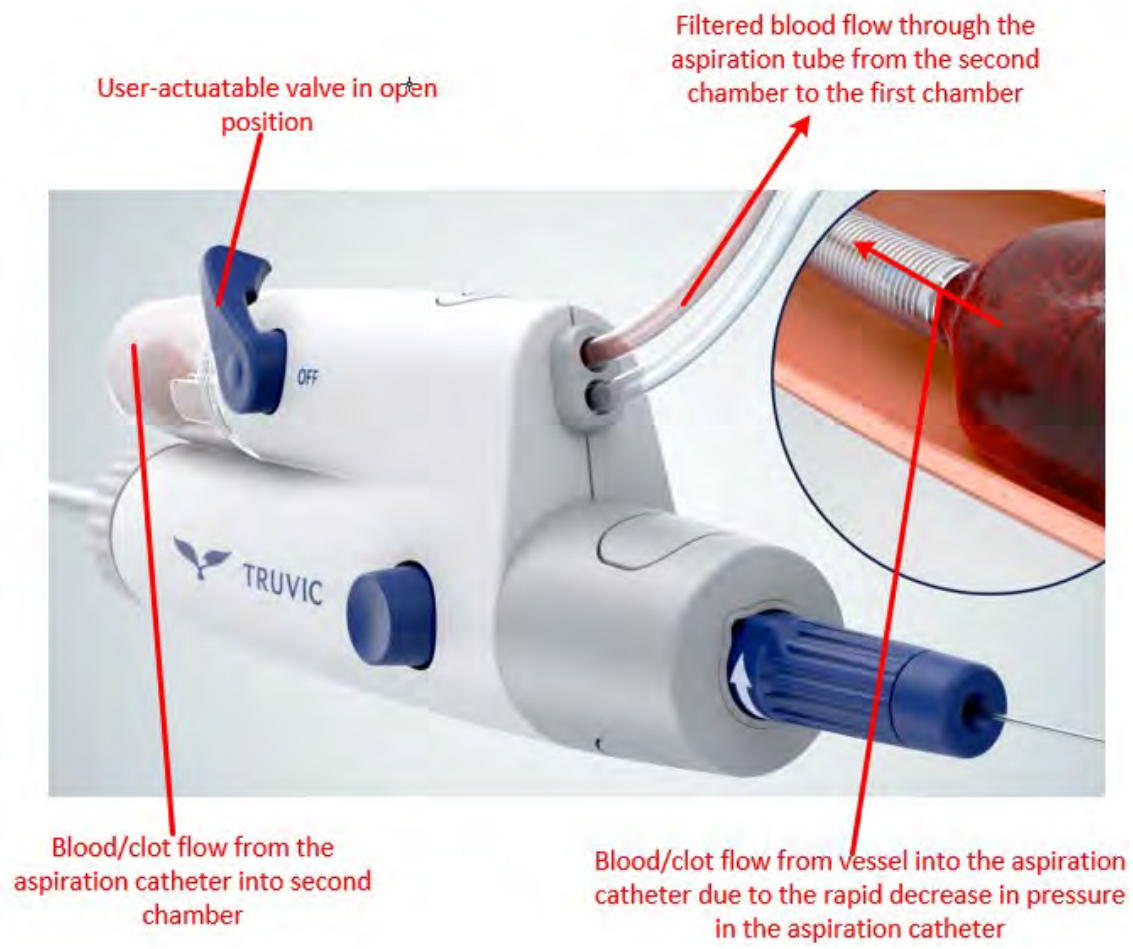


(Ex. A at 2 (annotations added).)

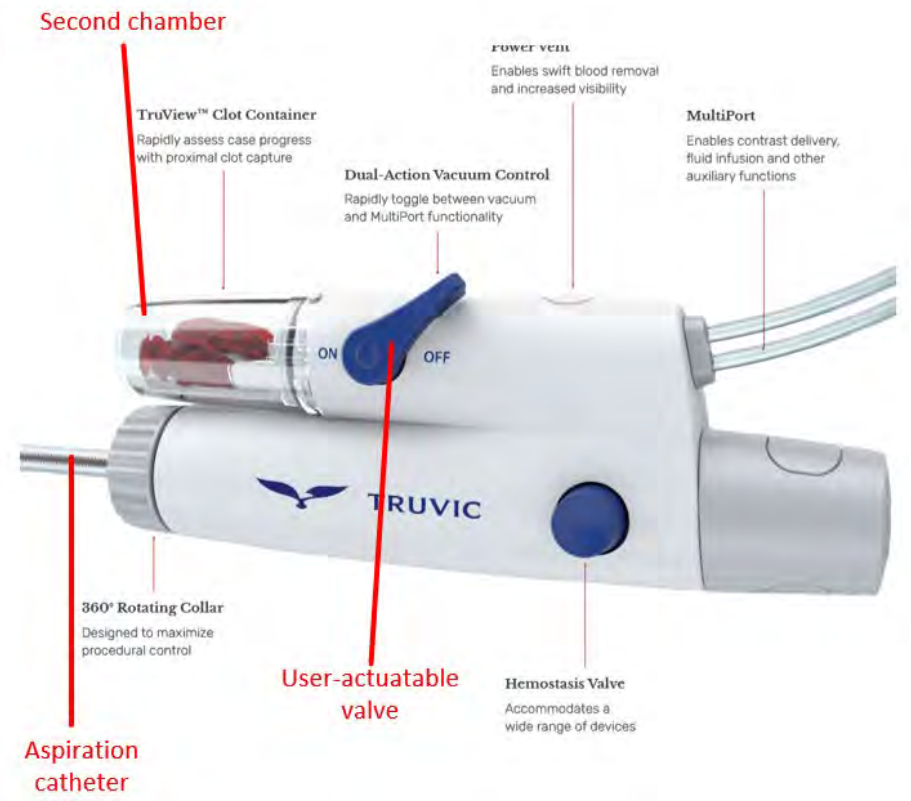


(Annotated diagram of Symphony housing with flow path.)

146. The Symphony system practices the limitations of claim 14, including "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," as can be seen in claim chart in Exhibit P. The Symphony system includes a second chamber on both the 24F and 16F handle controllers, as both have a clot canister that is a second chamber between the aspiration pump (Truvic Generator) and the aspiration catheter, with the clot canister being removable to clean the aspirated clot material filtered from blood:



(Annotated screen capture from Symphony product video.)

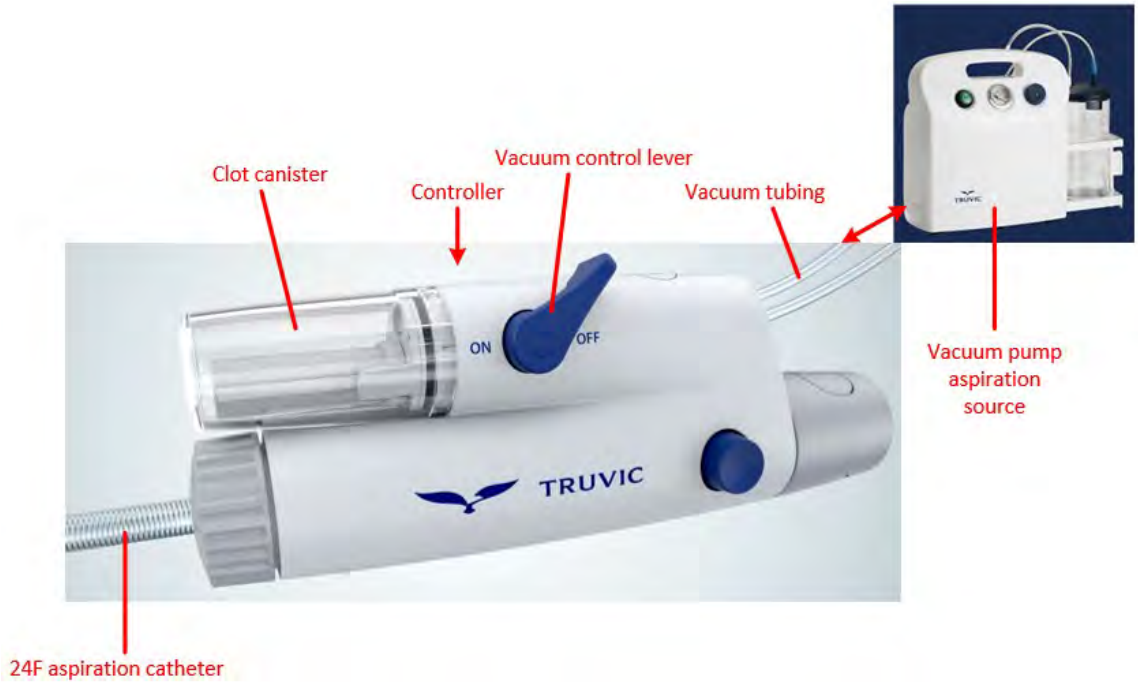


(Ex. A at 6 (annotations added).)

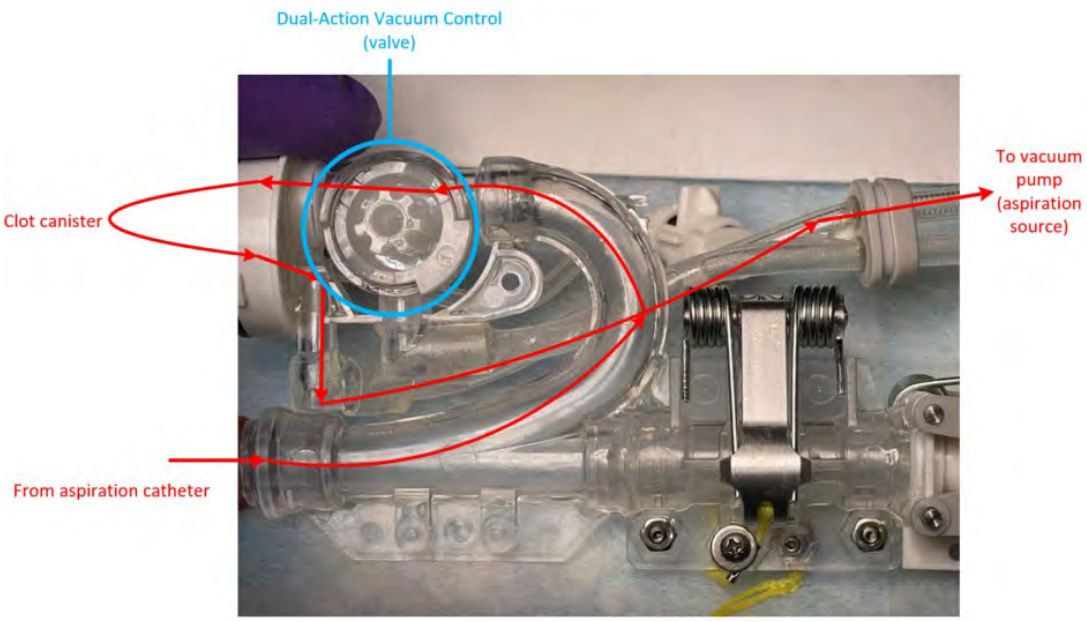
(Annotated screen captures from Symphony product video.)

147. The Symphony system practices the limitations of claim 14, including "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

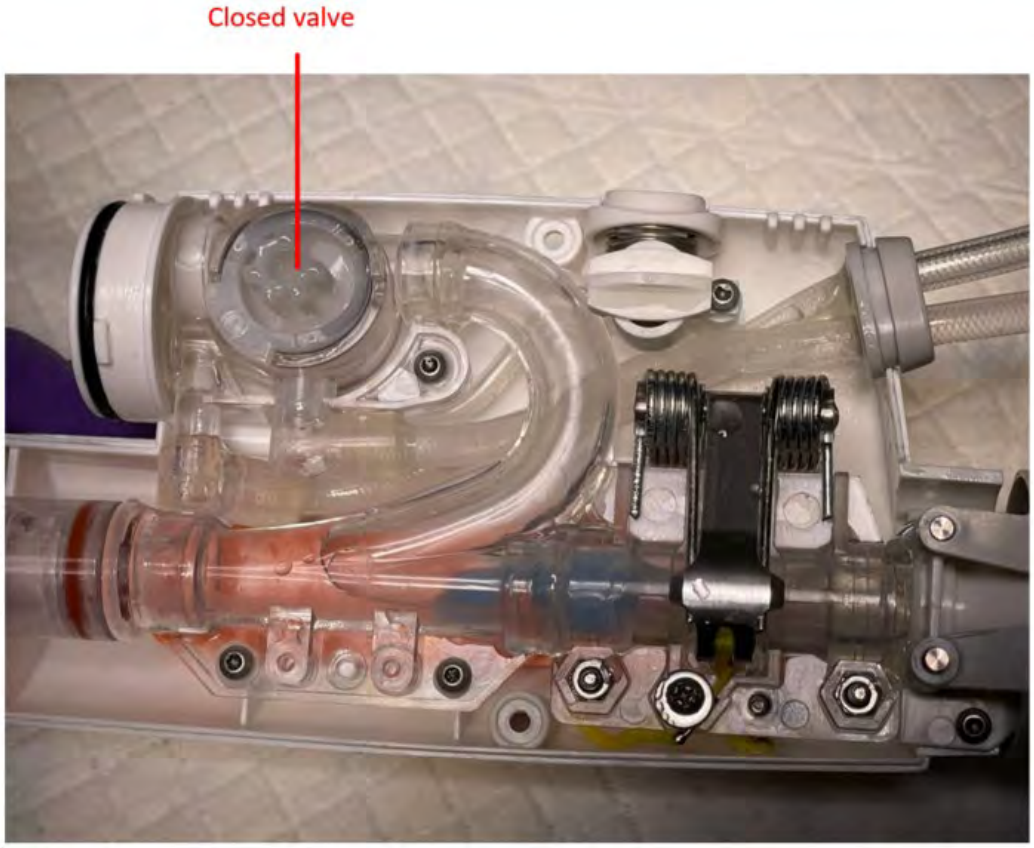
first and second chambers," as can be seen in claim chart in Exhibit P. The Symphony system includes a both the 24F and 16F handle controllers each having a user-actuatable valve in the controller that is controlled by the vacuum control lever on the handles, where negative pressure is generated in the Truvic Canister and the clot container by the Truvic Generator while the vacuum control lever valve is closed ("off"), and negative pressure is applied to the aspiration catheter when the valve is opened ("on"):



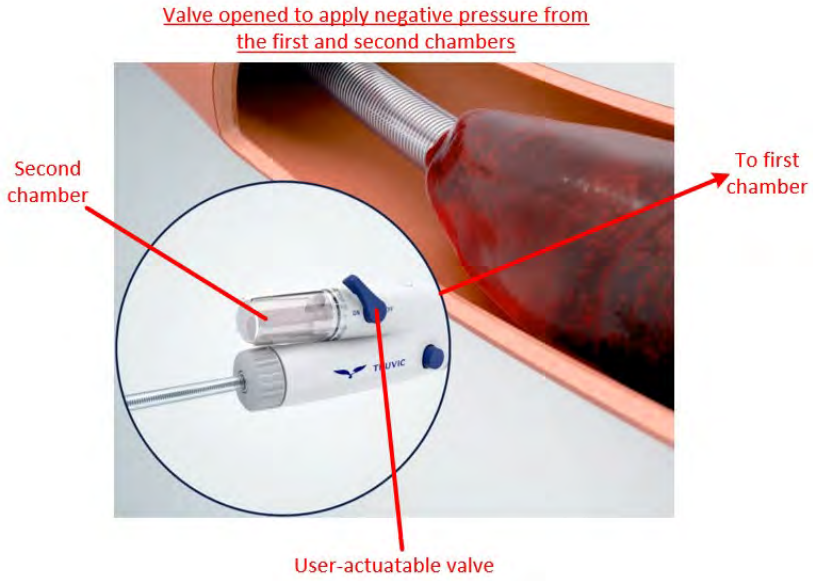
(Annotated diagram of Symphony system.)



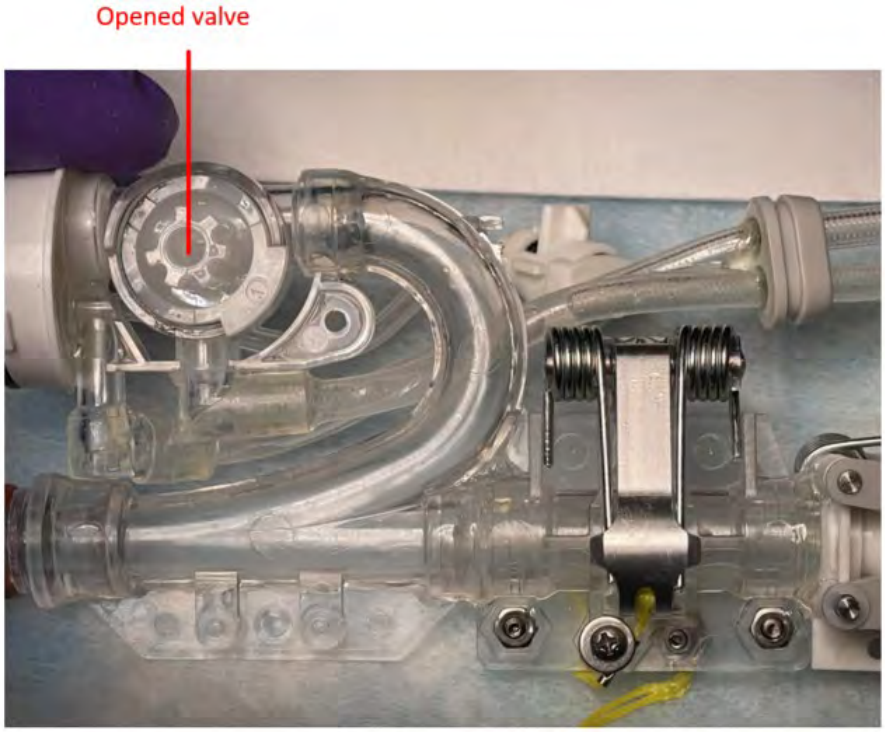
(Annotated image of internal portion of controller handle housing.)



(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)

148. The Truvic Symphony system Instructions For Use further teaches the process of building vacuum of at least -20 inHg using the Truvic Generator when the valve is in the closed (off) position and then moving the control letter to the open (on) position to apply negative pressure to the aspiration catheter:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

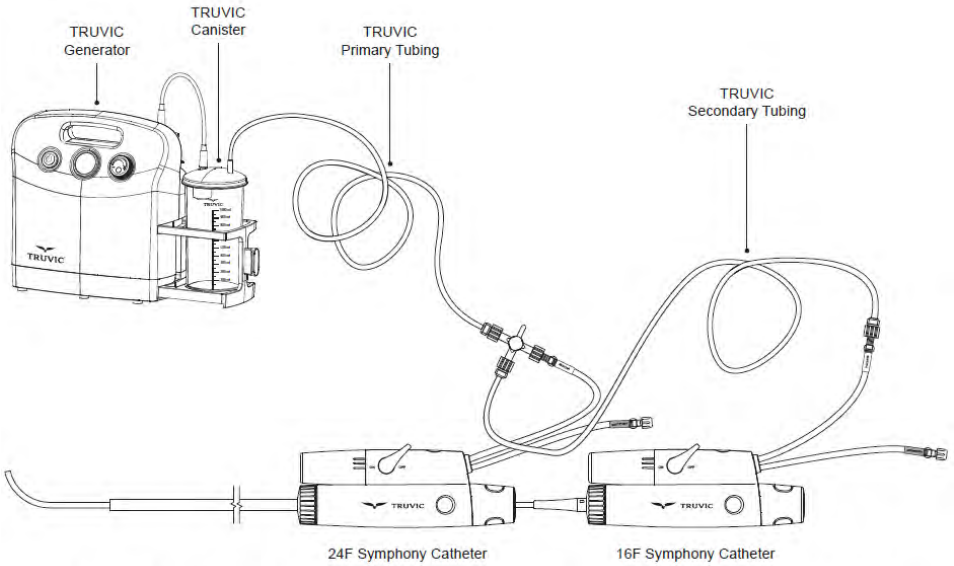


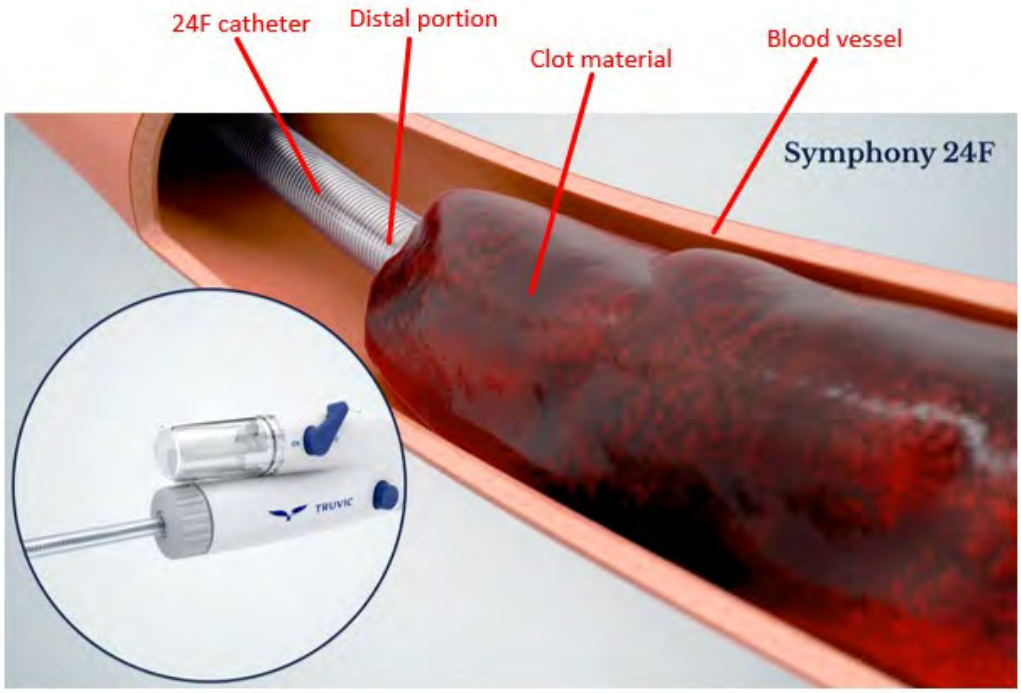
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

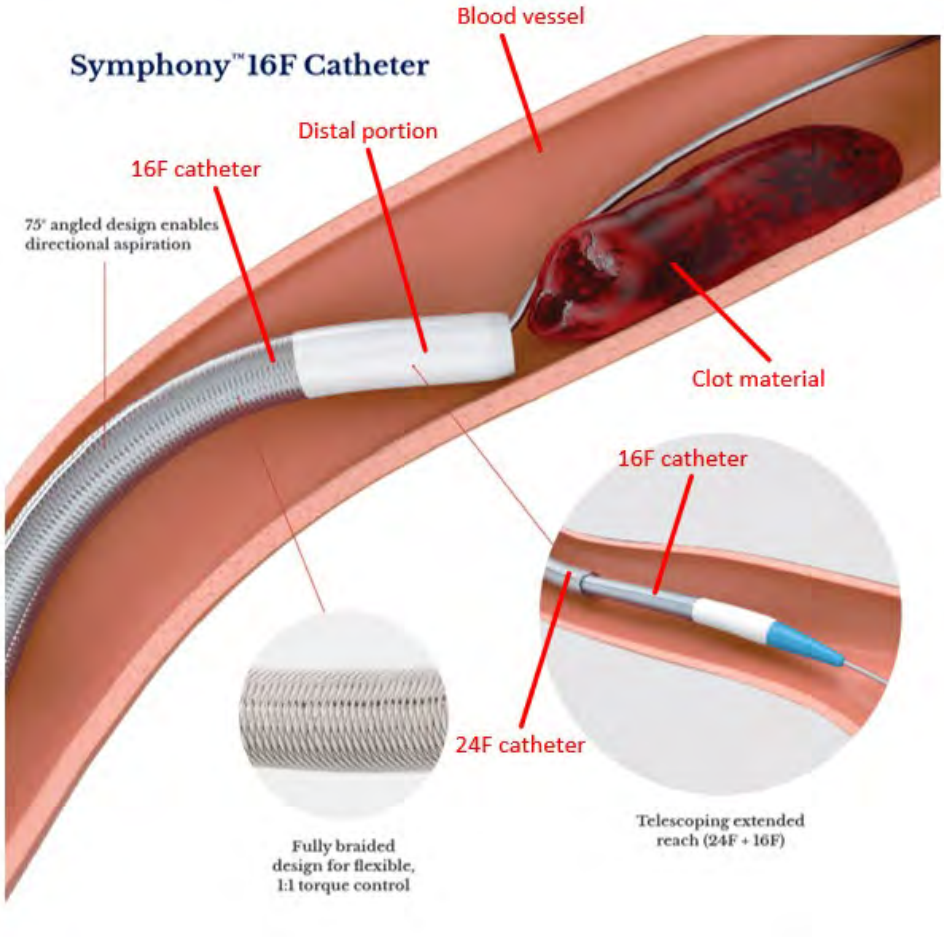
(Ex. B at 8.)

149. The Symphony system practices the limitations of claim 14, including "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," as can be seen in claim chart in Exhibit P. As discussed above, when the user actuates the vacuum control lever on the 24F or 16F handle of the Symphony system, the negative (vacuum) pressure generated in the first and second chambers is applied to the aspiration catheter, the fluid flow from the aspiration catheter to the first and second chambers causes a rapid decrease in the pressure in the aspiration catheter to aspirate clot material.

150. The Symphony system practices the limitations of claim 22, including claims 14, 19, and 20 (from which it depends), including "[t]he aspiration system of claim 14 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient" and "[t]he 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," as can be seen in claim chart in Exhibit P. The Symphony system includes 24F and 16F catheters that are configured to be positioned within a blood vessel with a distal end of the catheter positioned proximate to clot material within the blood vessel:



(Annotated screen capture from Symphony product video.)



(Ex. A at 4 (annotations added).)

151. The Symphony system practices the limitations of claim 22, including claims 14, 19, and 20 (from which it depends), including "[t]he aspiration system of claim 20 wherein the clot material comprises a deep vein thrombus," as can be seen in claim chart in Exhibit P. As discussed above with respect to claim 20 of the '691 Patent, the Symphony system is a treatment system used for fresh soft emboli in the peripheral vasculature of a patient, *e.g.*, for treating DVT.

152. Defendant directly infringes claims of the '691 Patent, including claims 14 and 22, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures) Symphony system products.

153. Defendant induces infringement of claims of the '691 Patent, including claims 14 and 22, by selling Symphony systems (and components thereof) and teaching or directing others,

including physicians, to use the Symphony systems that practice claims 14 and 22. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

154. Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof). Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

155. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '691 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

156. Defendant's infringement is with knowledge of the '691 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated September 29, 2023, that the Symphony system infringes the '691 Patent. Inari further explained to Defendant, by letter dated April 24, 2024, that the Symphony system infringes various claims of the '691 Patent, including claim 22 directed to deep vein thrombosis (DVT) treatment systems.

157. At a minimum, Defendant has notice of the '691 Patent through the filing of the original Complaint, which was submitted to the Court just a few weeks after the '691 Patent

issued.

158. Defendant has continued its infringing activities, despite knowledge of the '691 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

159. Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 5: INFRINGEMENT OF THE '921 PATENT

160. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

161. The '921 Patent, titled "Hemostasis Valves and Methods of Use," discloses improved hemostasis valves and methods of their use. (*See, e.g.*, Ex. G at Abstract, 1:58-62.) Hemostasis valves are used to seal, e.g., to seal around catheters, in order to minimize blood loss, and maintain sterility within the body, such as in a blood vessel. (*Id.* at 1:28-44.) This is critical during surgical procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (*See id.* at 1:18-26.) Improved hemostasis valves are important to maximize patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and practitioners and effective sealing. (*See id.* at 1:45-54, 5:49-67.)

162. The '921 Patent discloses hemostasis valves having an internal elongate member with a lumen (an inner cavity through which something can be inserted), which can be constricted and sealed by a filament wrapped at least partially around, *e.g.*, in a loop around, the tube defining a lumen, where the hemostasis valve further has an actuator (such as a button control mechanism) biased to constrict the elongate member's lumen with the filament and that can be moved between a first position where the lumen is constricted (closing the valve) and to a second position where the lumen is not as constricted (at least partially opening the valve). (*See id.* at cl. 1, Fig. 7, 2:8-25.) Some embodiments disclosed by the '921 Patent have multiple actuators and/or two or more filaments looping at least partially around the elongate member. (*See id.* at cl. 1, cl. 10.)

163. Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claims 1 and 10 of the '921 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

164. The hemostasis valve in the controller handles (housings) of the Symphony system practice each limitation of at least claims 1 and 10 of the '921 Patent.

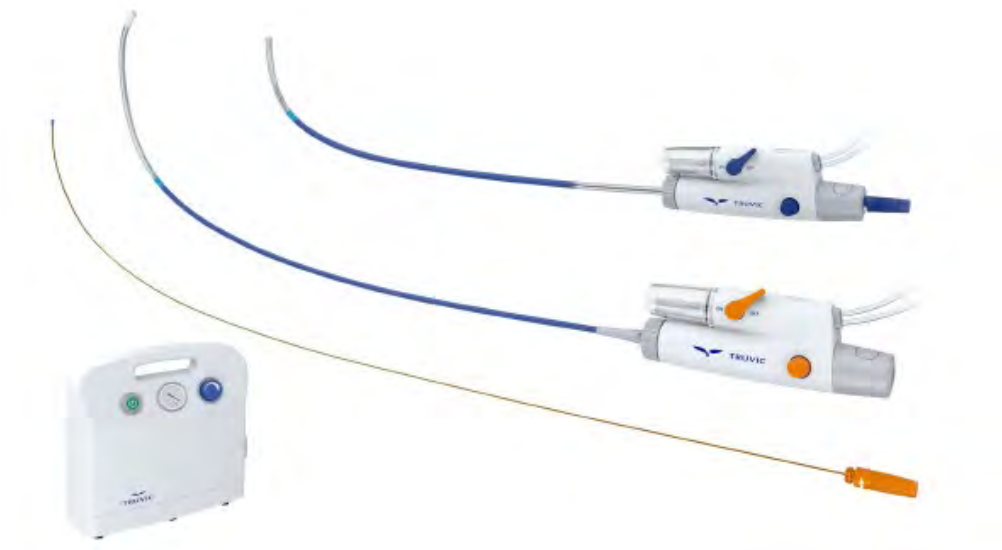
165. For example, claim 1 of the '921 Patent recites:

> [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.

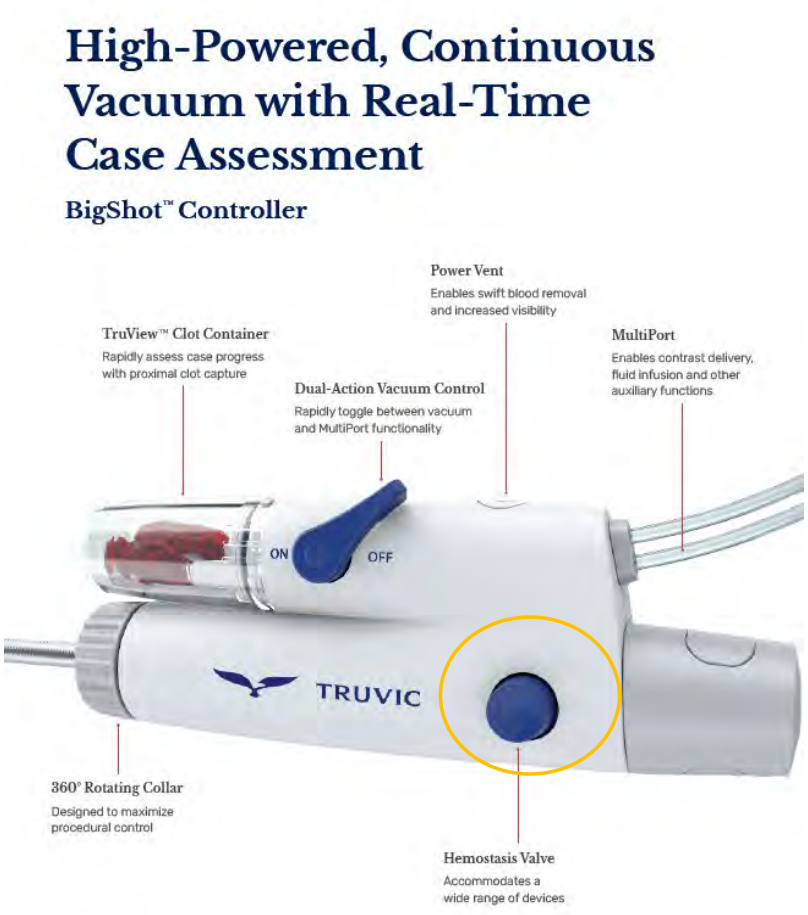
166. Claim 10 of the '921 Patent further recites:

> [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.

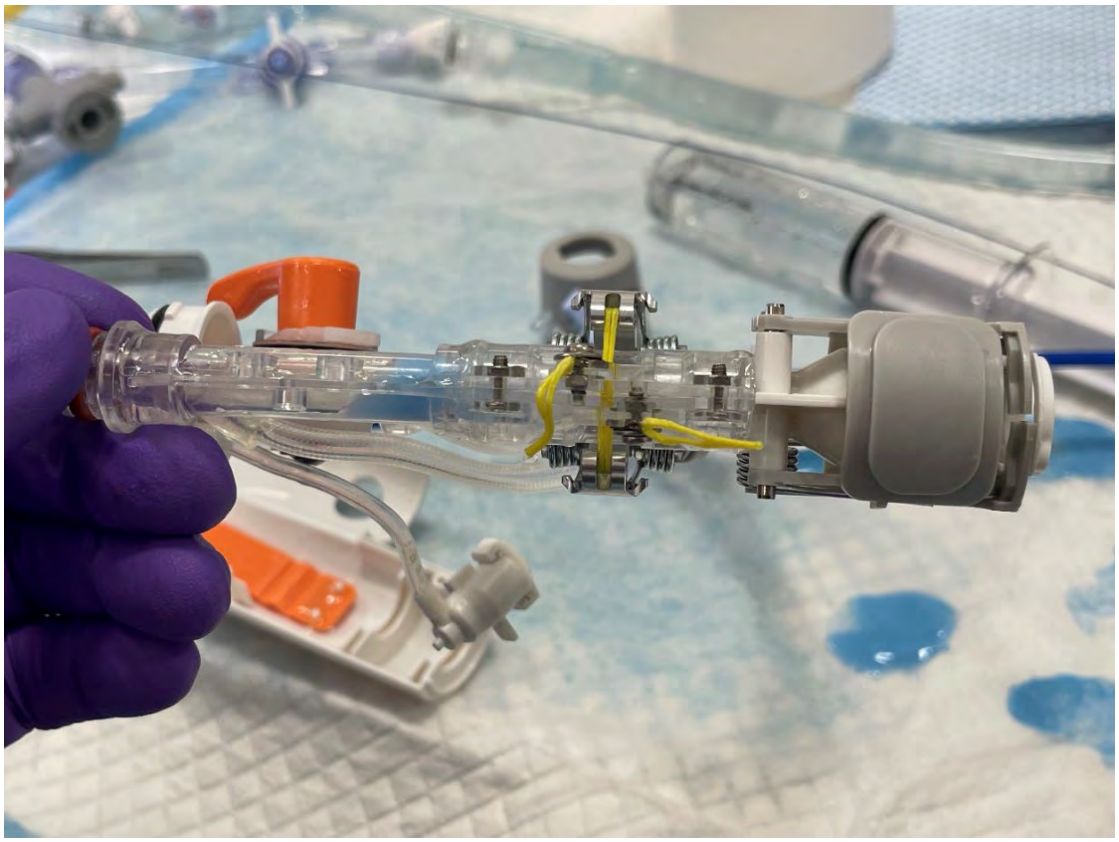
167. The hemostasis valves of the Symphony system practice the requirements of claim 1, including the preamble, "[a] valve, comprising," as can be seen in Exhibit Q. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle). The documentation for the Symphony system makes clear that the controller handles have a hemostasis valve, controlled by the buttons on the handles, as can be seen in the excerpts and the teardown photos below.



(Ex. A at 2.)



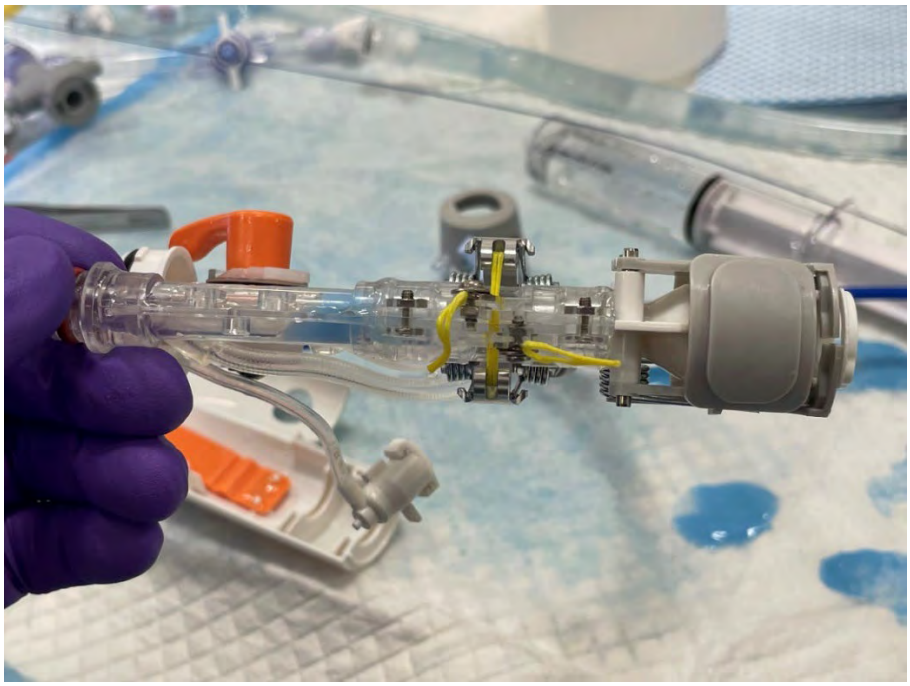
(Annotated Ex. A at 6.)



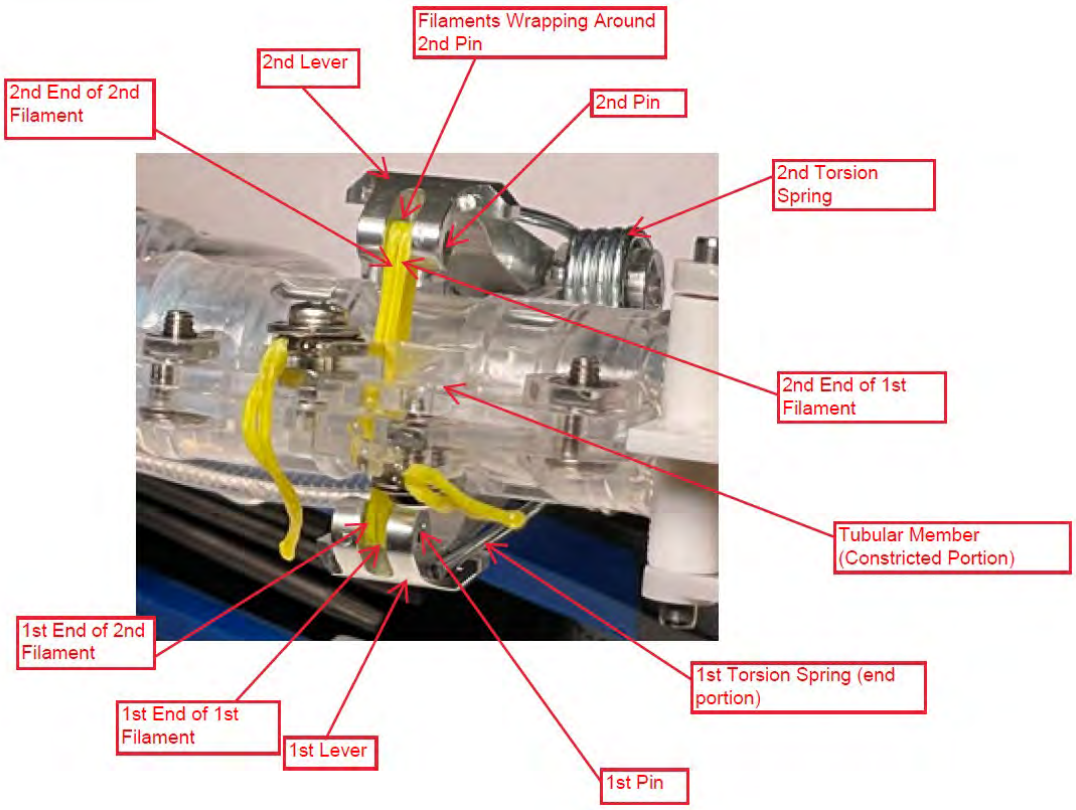
(Image of internal portion of housing with hemostasis valve.)

(Image of internal portion of housing zoomed in on hemostasis valve.)

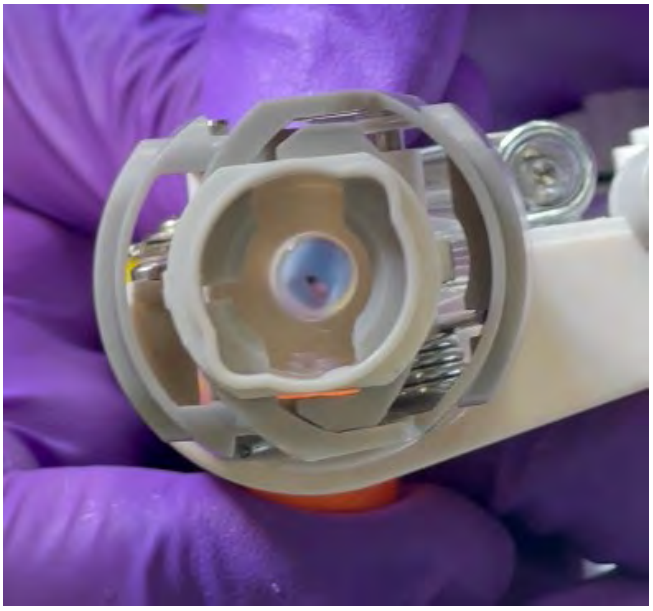
168. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "an elongate member defining a lumen," as can be seen in Exhibit Q. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle) that include an elongate member that defines a lumen.



(Image of internal portion of housing with hemostasis valve.)

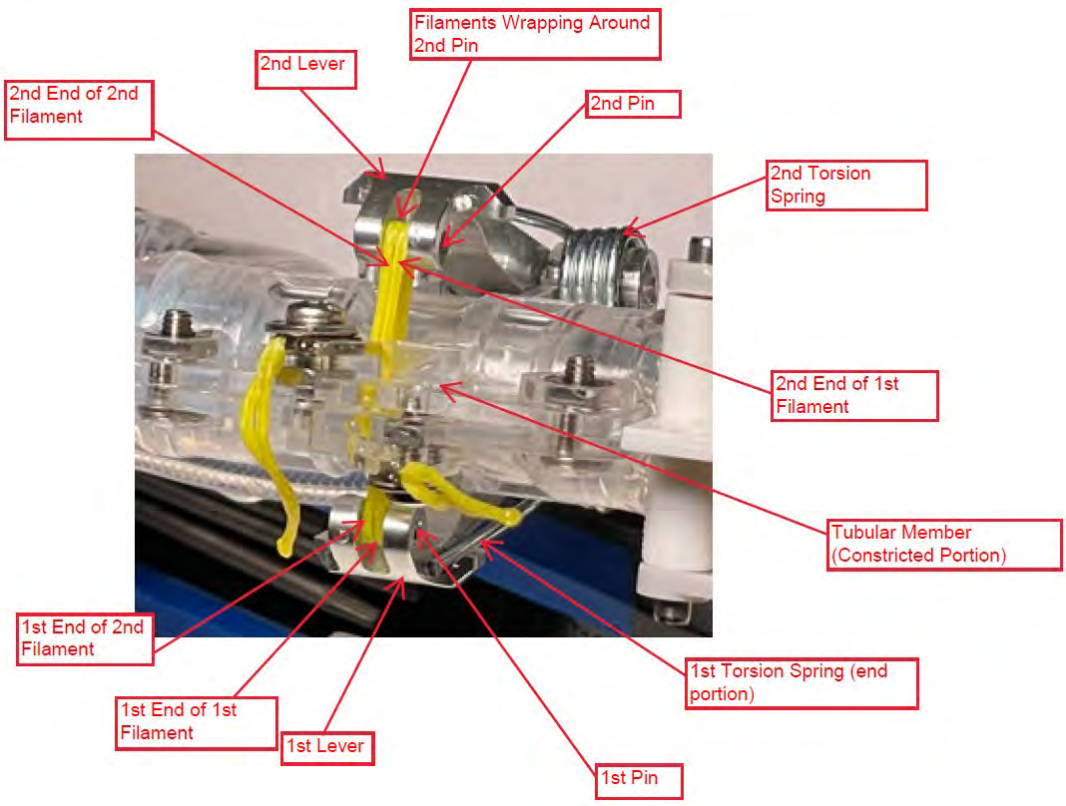


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



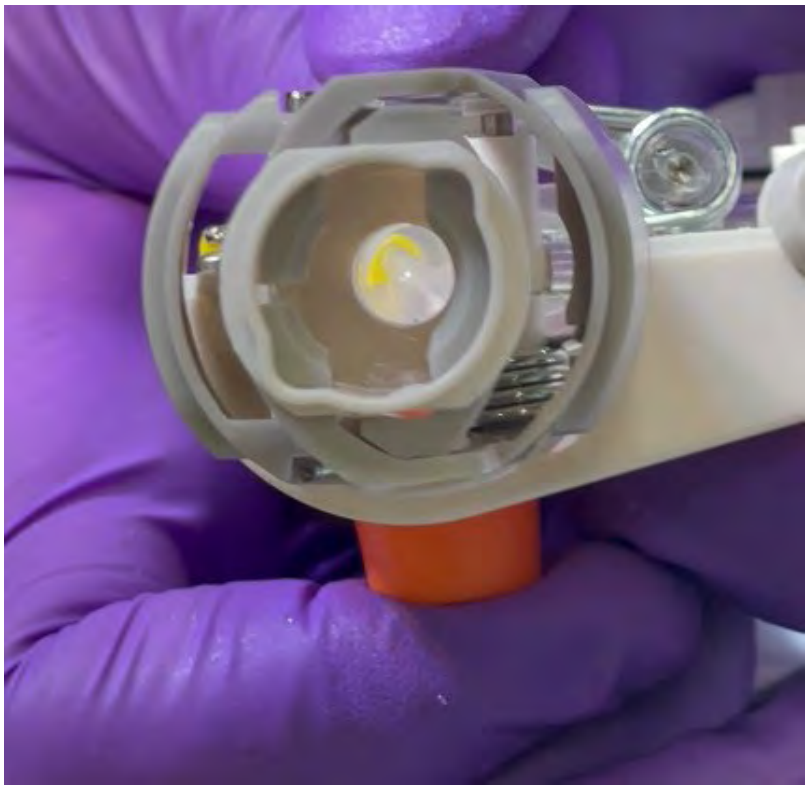
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

169. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "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," as can be seen in Exhibit Q. Specifically, the controller handles of the Symphony system include a hemostasis valve with an active tensioning mechanism where a first and second button control first and second levers and first and second pins coupled to lines (filaments) that loop around the valve's elongate tubular member defining a lumen. The first button/lever/pin to which the first end of the filament line is coupled moves between a first (undepressed button) position where the lumen of the valve is constricted to a second (depressed button) position wherein the lumen is less constricted and at least partially open.

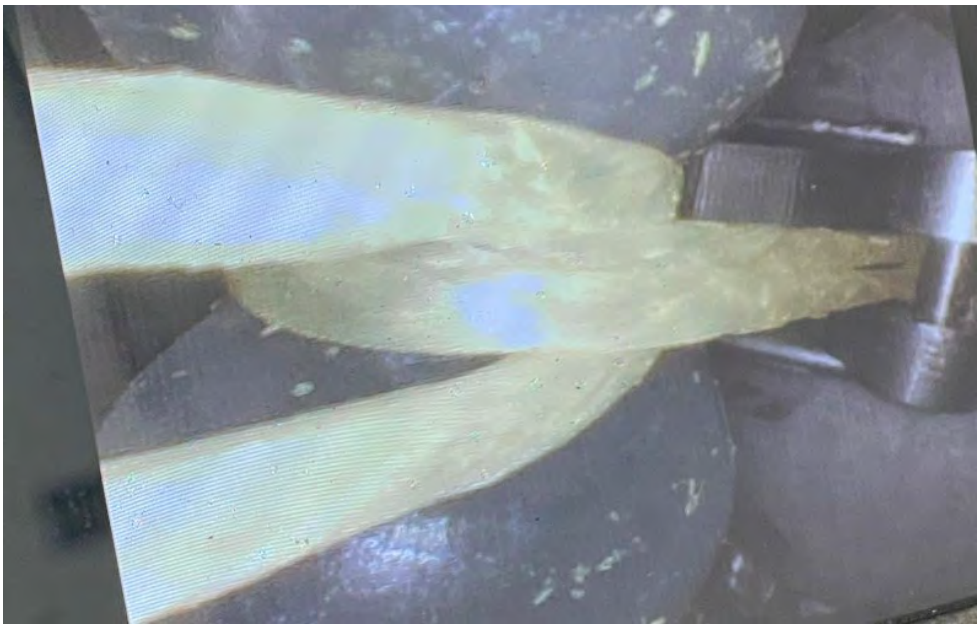


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

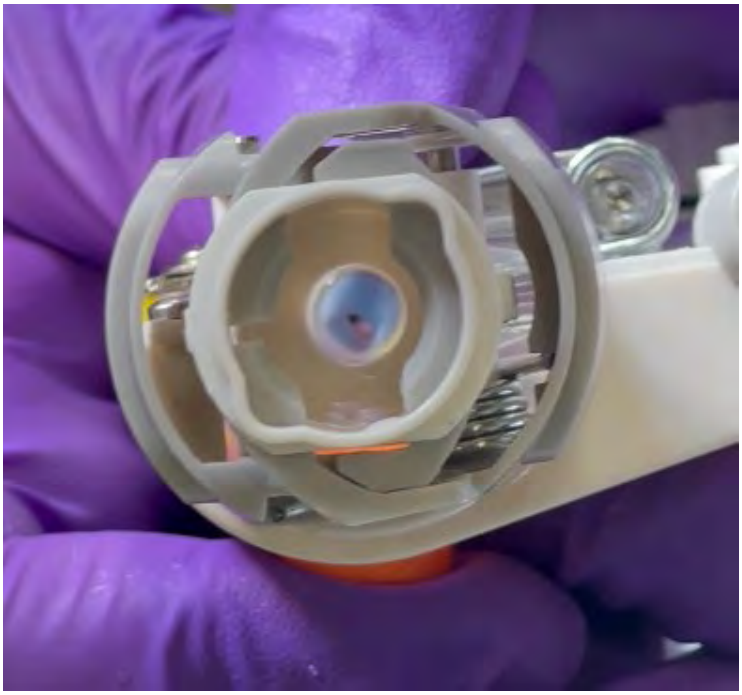
170. In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring(s), releasing tension on the filaments wrapped around the lever pin(s), which decreases the constriction on the lumen of the hemostasis valve. This allows the valve to at least partially open, permitting the introduction of a catheter or other tool through the hemostasis valve. Releasing the button(s), causes the torsion spring(s) to drive the lever outward, increasing tension on the filament lines, sealing the hemostasis valve.



(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



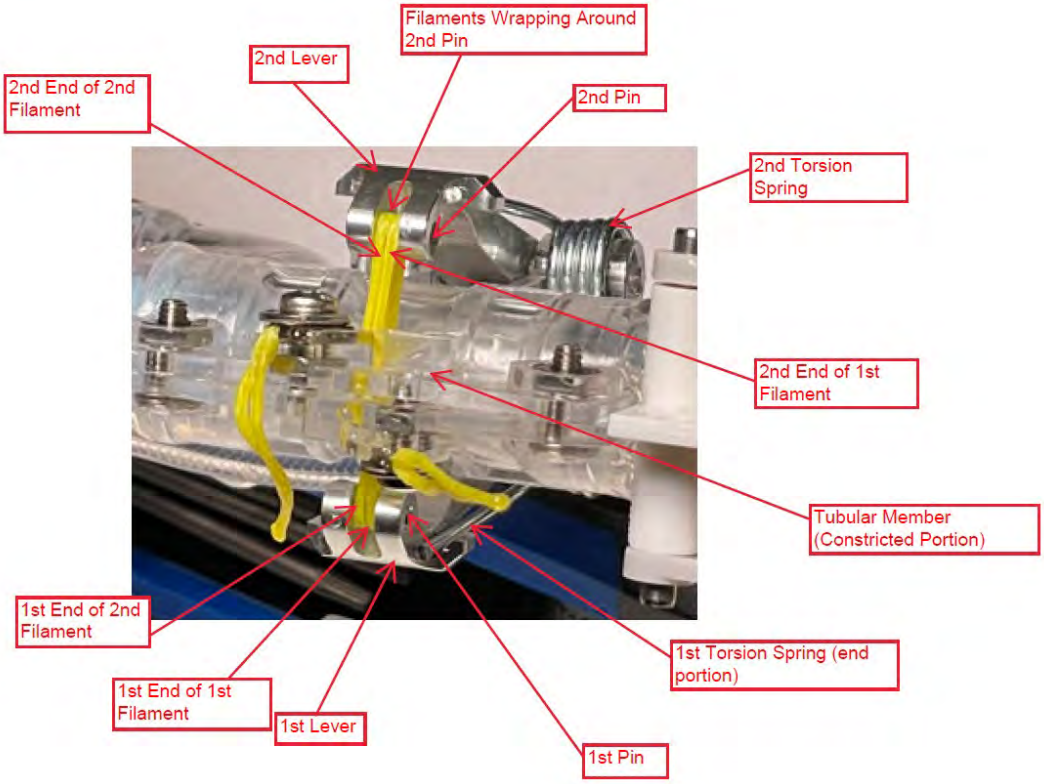
(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)



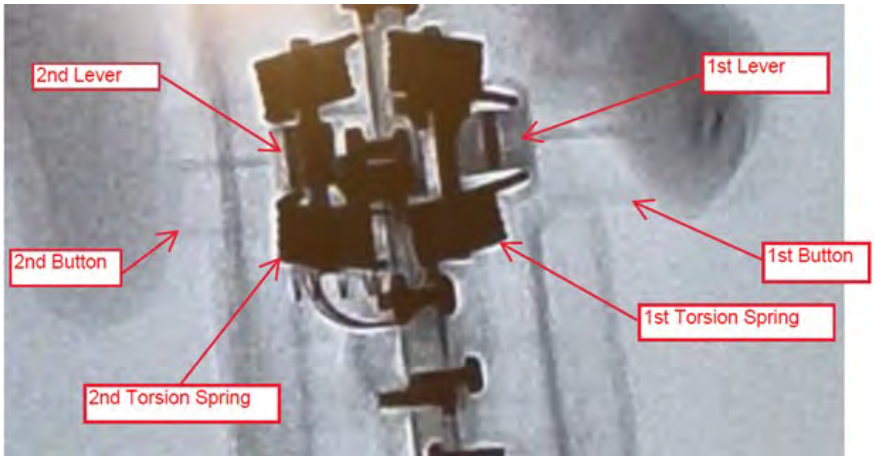
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

171. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a biasing member configured to bias the actuator to the first position." as can be

seen in Exhibit Q. The hemostasis valves of the Symphony handles include a first torsion spring(s) that pushes against the first lever, biasing the actuator to a first position (closed/constricted with an undepressed first button). There are two torsion springs for each of the first lever and the second lever.



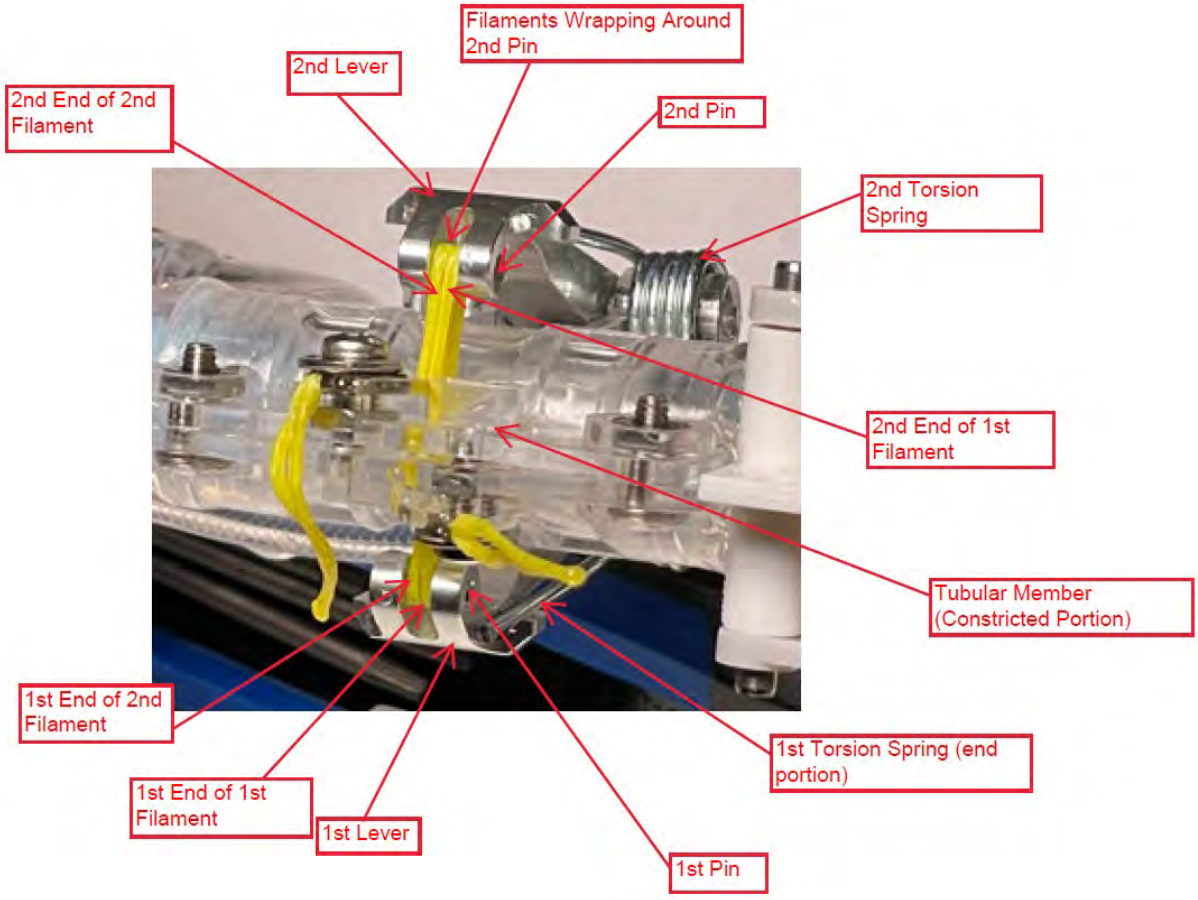
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



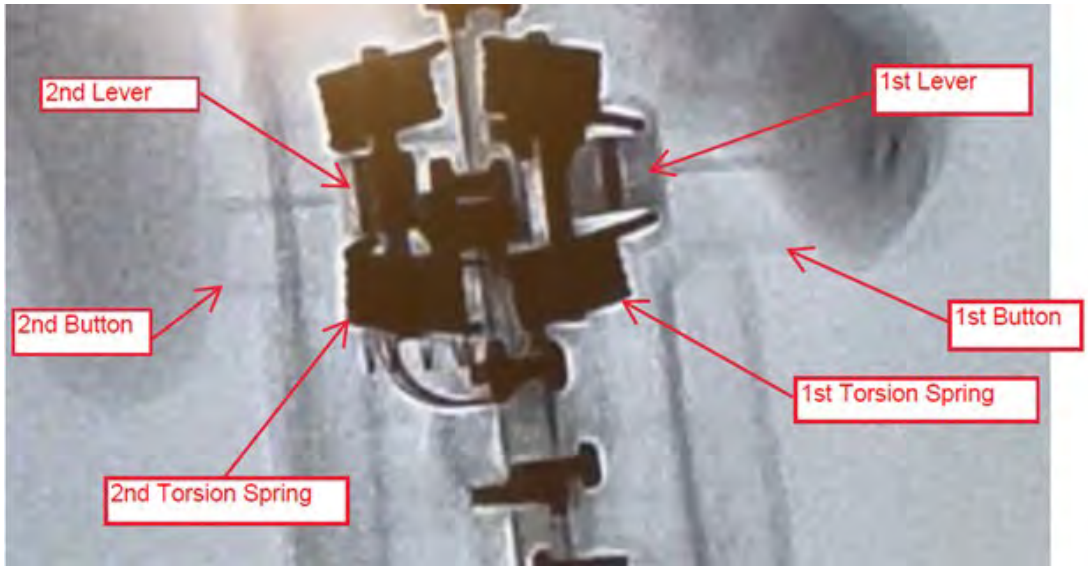
(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs.)

172. The hemostasis valves of the Symphony system practice the requirements of claim 10, including "[t]he 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:" as can be seen in Exhibit Q. The hemostasis valves of the Symphony system comprise a first actuator, as alleged above for claim 1.

173. The hemostasis valves of the Symphony system practice the requirements of claim 10, including "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," as can be seen in Exhibit Q. In addition to the first actuator, the controller handles of the Symphony system include a second actuator where a second button that controls a second lever coupled to lines (filaments) that loop around the valve's elongate tubular member defining a lumen. The second button/lever/pin to which the second end of the second filament line is coupled moves between a first (undepressed button) position where the lumen of the lumen is constricted to a second (depressed button) position wherein the lumen is less constricted and at least partially open.



(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Annoatated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs.)

174. The hemostasis valves of the Symphony system practice the requirements of claim 10, including "a second biasing member configured to bias the second actuator to the first position," as can be seen in Exhibit Q. As with the first actuator, the Symphony system's hemostasis valve also includes a second torsion spring(s) that pushes against the second lever, biasing the actuator to a first position (closed/constricted with an undepressed first button), as can be seen above. There are two springs for each lever.

175. Defendant directly infringes claims of the '921 Patent, including claims 1 and 10, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures utilizing the hemostasis valves) Symphony system products.

176. Defendant induces infringement of claims of the '921 Patent, including claims 1 and 10, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claims 1 and 10. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

177. Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system,

including on information and belief, methods of treating thrombi and emboli.

178. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof) of the invention that is especially made or adapted for infringement of the claims of the ’921 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

179. Defendant has knowledge of the ’921 Patent and its claims. Specifically, Inari notified Defendant that the Symphony system infringes the ’921 Patent, including claims 1 and 10, by letter dated April 24, 2024. Even more specifically, Inari explained that a teardown of the hemostasis valves in the Symphony system showed that they infringe Inari’s patents, including claims 1 and 10 of the ’921 Patent.

180. At a minimum, Defendant has notice of the ’921 Patent through the filing of the original Complaint.

181. Defendant has continued its infringing activities, despite knowledge of the ’921 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

182. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the ’921 Patent, including through the use of Inari’s virtual marking website: https://www.inarimedical.com/inari-patents.

183. Defendant’s infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 6: INFRINGEMENT OF THE ’012 PATENT

184. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

185. The ’012 Patent, titled “Hemostasis Valves and Methods of Use,” is part of the same family as the ’921 Patent, and it shares the same specification. The ’012 Patent discloses improved hemostasis valves and methods of their use. (*See, e.g.*, Ex. H at Abstract, 1:64-2:5.) Hemostasis valves are used to seal, e.g., to seal around catheters, in order to minimize blood loss, and maintain sterility within the body, such as in a blood vessel. (*Id.* at 1:35-51.) This is critical

during surgical procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (*See id.* at 1:24-32.) Improved hemostasis valves are important to maximize patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and practitioners and effective sealing. (*See id.* at 1:51-60, 5:55-6:6.)

186. The '012 Patent discloses hemostasis valves as part of aspiration catheter systems, the catheters having an elongate flexible tube with a central lumen (an inner cavity through which something can be inserted) with a hemostasis valve on the proximal end of the catheter that includes a collapsible sidewall defining a valve lumen coupled to the central lumen of the catheter, and where the hemostasis valve has a constricting mechanism that includes an first actuator coupled to a first filament that is looped around the tubular sidewall of the valve lumen and further includes a spring that moves the actuator in a direction to pull the end portion of the filament to tighten the filament loop and constrict the lumen. (*See id.* at cl. 1, Fig. 7, 2:15-32.) Some embodiments disclosed by the '012 Patent have multiple actuators, *i.e.*, a first actuator comprising a first button and a second actuator comprising a second button. (*See id.* at cl. 1, cl. 2, cl. 4.)

187. Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claim 1 of the '012 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

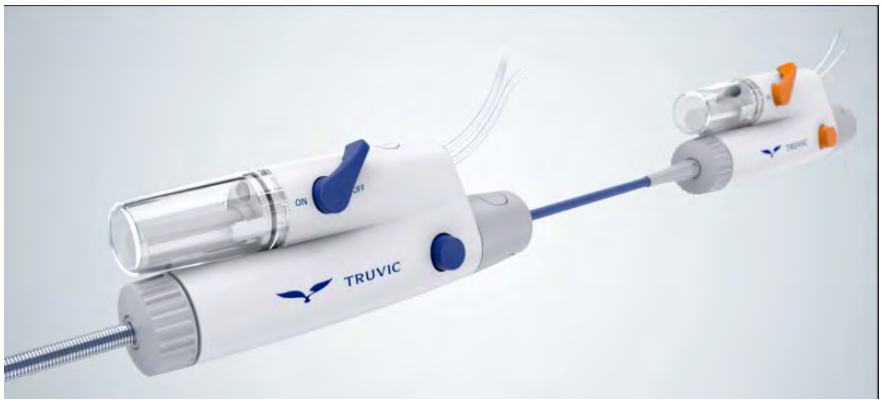
188. The Symphony system practices each limitation of at least claim 1 of the '012 Patent.

189. For example, claim 1 of the '012 Patent recites:

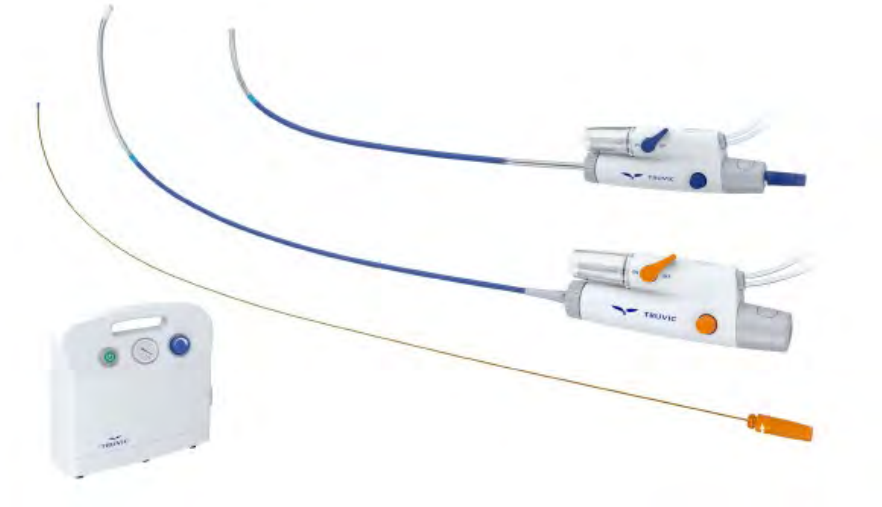
> [1] An aspiration catheter, comprising:
>
> an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;
>
> (a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and
>
> (b) a constricting mechanism having at least a first 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.

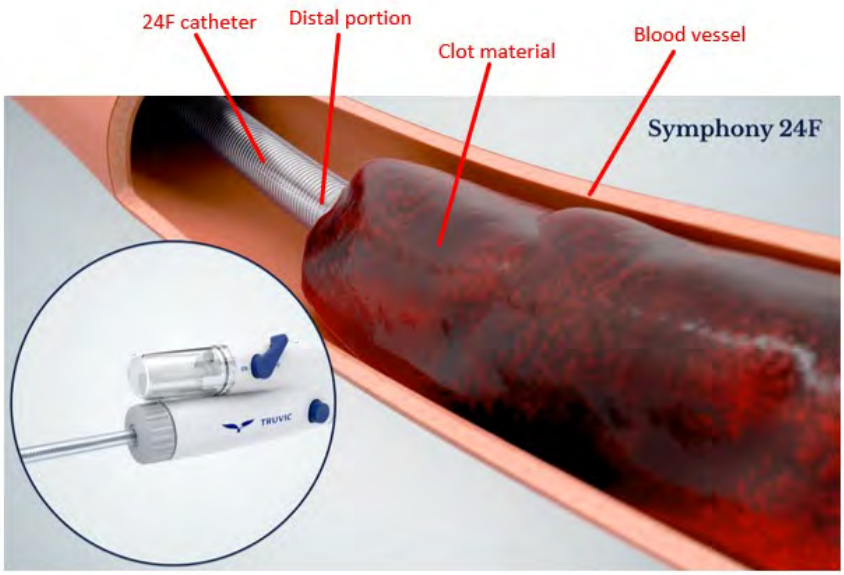
190. The Symphony system including the hemostasis valves practices the requirements of claim 1, including the preamble, "[a]n aspiration catheter, comprising," as can be seen in Exhibit R. The Truvic Symphony system includes aspiration catheter systems for 24F and 16F catheters:



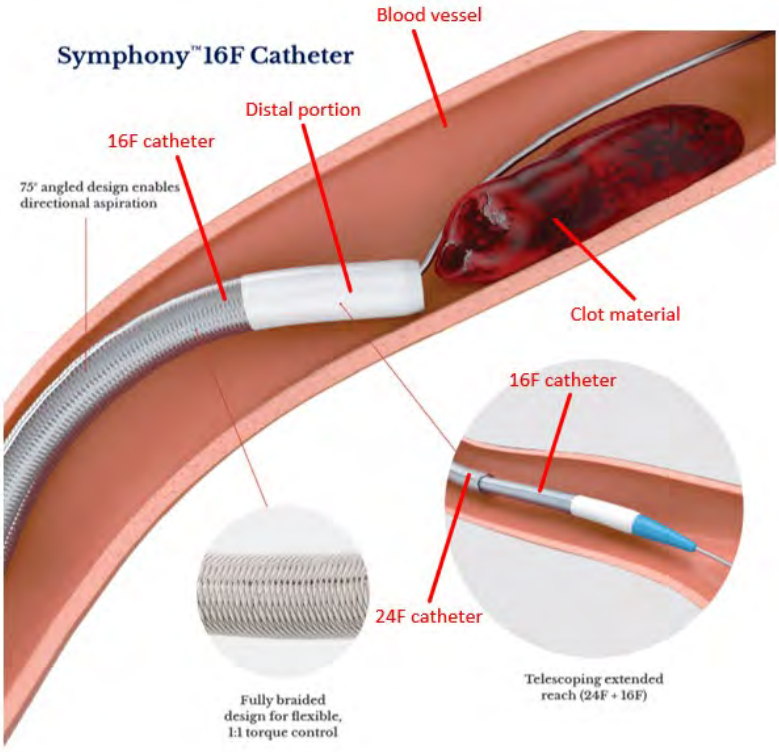
(Screen capture from Symphony product video.)



(Ex. A at 2.)



(Annotated screen capture from Symphony product video.)

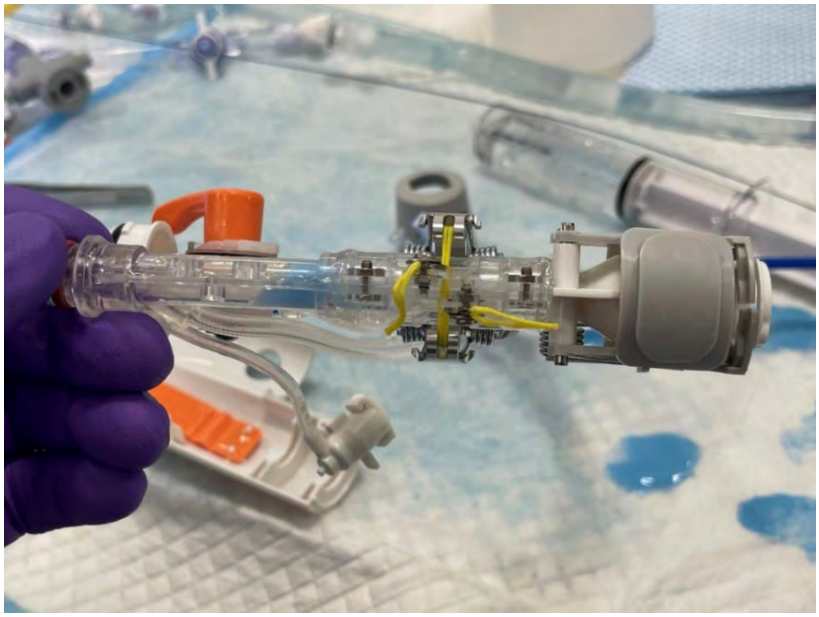


(Ex. A at 4 (annotations added) (showing a telescoping 16F and 24F catheter).)

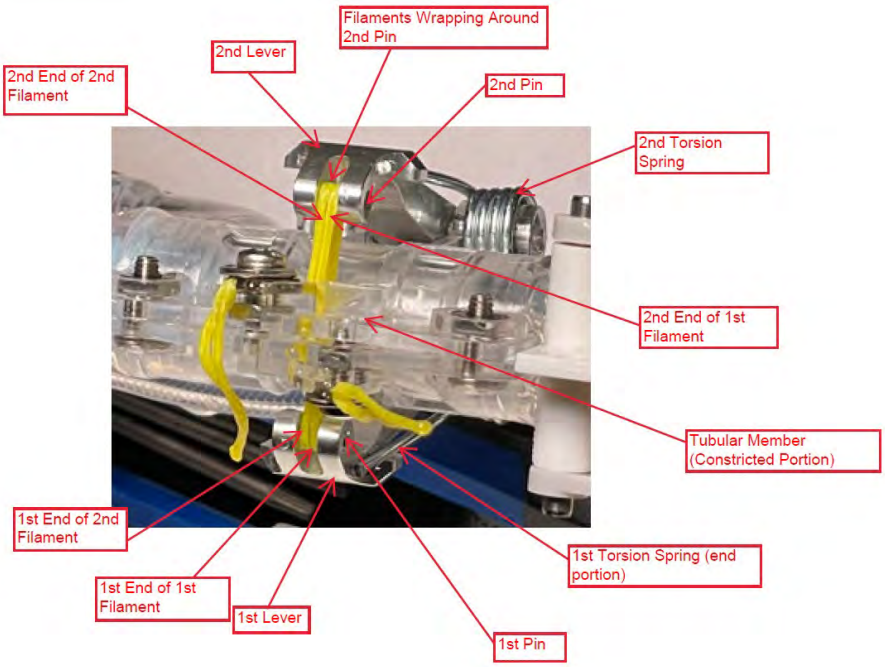
191. The aspiration catheters of the Symphony system practice the requirements of claim 1, including "an elongate, flexible tubular body, having a proximal end, a distal end and a

central lumen," as can be seen in Exhibit R. As discussed above, the 16F and 24F catheters of the Symphony system are flexible tubular bodies with a proximal end (coupled to the housing of the Symphony controller handles) and a distal end that can be advanced into the patient's vasculature, with a central lumen.

192. The Symphony system including the hemostasis valves practices the requirements of claim 1, including "a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising," as can be seen in Exhibit R. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle) that include an elongate member (tubular member) that defines a lumen. The valve's lumen is configured to receive a catheter and/or ProHelix device.



(Image of internal portion of housing with hemostasis valve.)



(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

193. The Symphony Instructions For Use further teaches that the hemostasis valves of the Symphony systems are configured to slidably receive a catheter, *i.e.*, a 24F or 16F catheter, advanced using a dilator and/or a guide wire:

The TRUVIC™ Symphony™ Thrombectomy System is comprised of several devices:

- 24F Symphony Catheter
- 24F Symphony Dilator
- 24F Symphony Advance™ Long Dilator
- 24F Symphony ProHelix™
- 16F Symphony Catheter
- 16F Symphony Dilator
- 16F Symphony ProHelix
- TRUVIC Generator
- TRUVIC Canister
- TRUVIC Tubeset

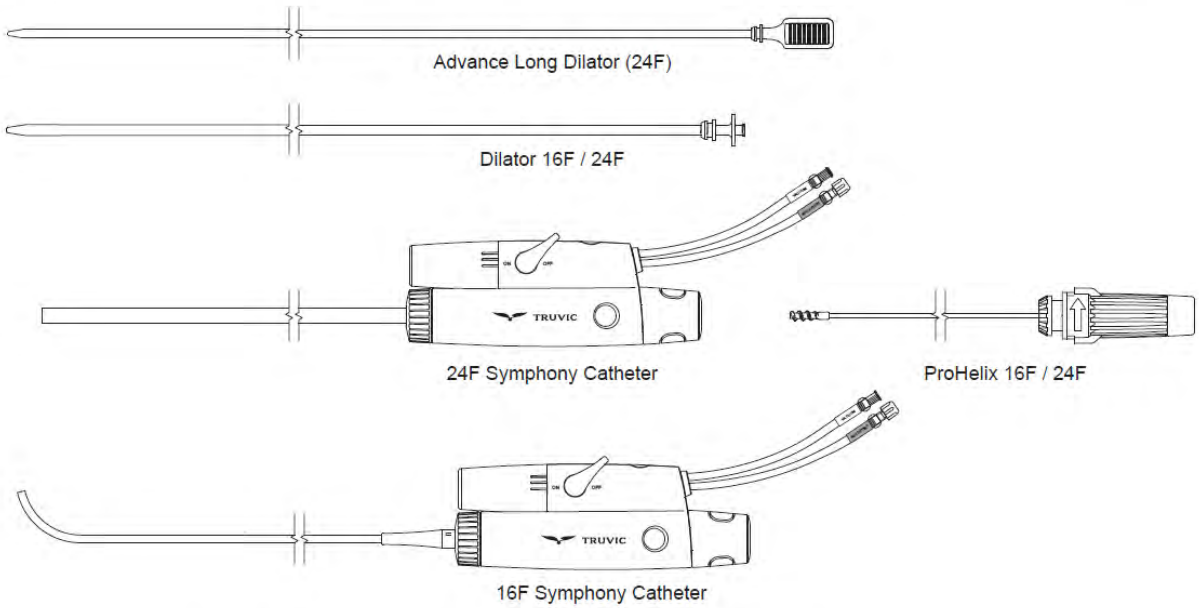


Figure 1: Symphony Thrombectomy System components

(Ex. B at 1.)

PROCEDURE AND PREPARATION

1. Refer to **Warnings, Precautions, and Potential Adverse Events** prior to use.
2. Prepare and place an introducer sheath according to the manufacturer's Instructions for Use.
3. Prior to introducing the Symphony System, ensure an appropriate 0.035" guidewire is placed into the target vessel. When using the 24F Catheter with the 24F Dilator, a guidewire of at least 260cm length should be used. When using the 24F Advance Long Dilator or the Symphony 16F Catheter, a guidewire of at least 300cm length should be used.

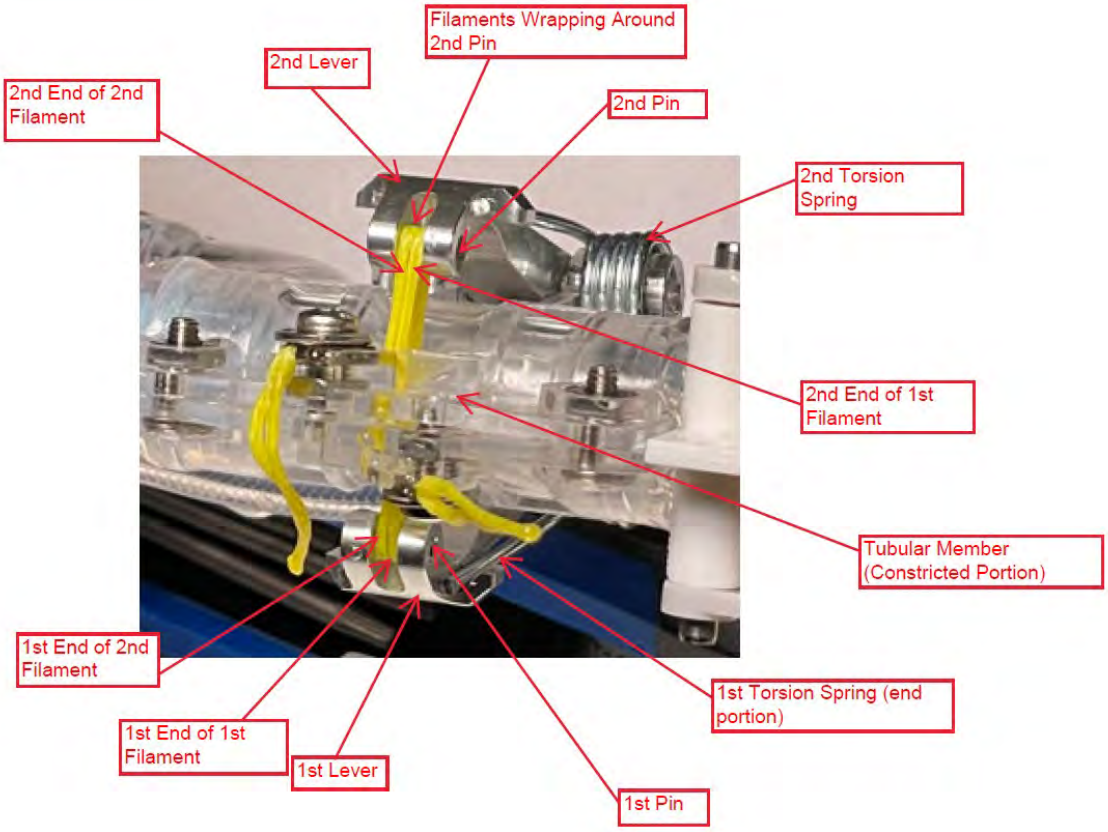
- Press the Hemostasis buttons to open the hemostasis valve and insert the Dilator through the open Hemostasis Valve of the Handle. Advance the Dilator through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
- If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
- Insert the Dilator and Catheter over the previously placed 0.035" guidewire into the introducer sheath.
- Advance the Symphony System until the tip of the Dilator is in the desired position in the selected vessel.
- Connect the Primary Tubing to the Handle tubing labelled "Vacuum".
- Attach the other end of the Primary Tubing to the TRUVIC Canister and ensure the stopcock on the Tubing is closed to the Generator.
- Release the Dilator by pressing the Retention Clip buttons on the Handle.
- When using a 24F Symphony System:
  - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

ii. With the Advance Long Dilator, hold the dilator and guide wire in position and advance the catheter approximately 1 cm. Then press the Hemostasis Valve buttons on the Handle to reduce friction and advance the Catheter over the Dilator to the desired location. While pressing the Hemostasis Valve buttons, completely withdraw the Dilator and maintain the Catheter and guidewire position.

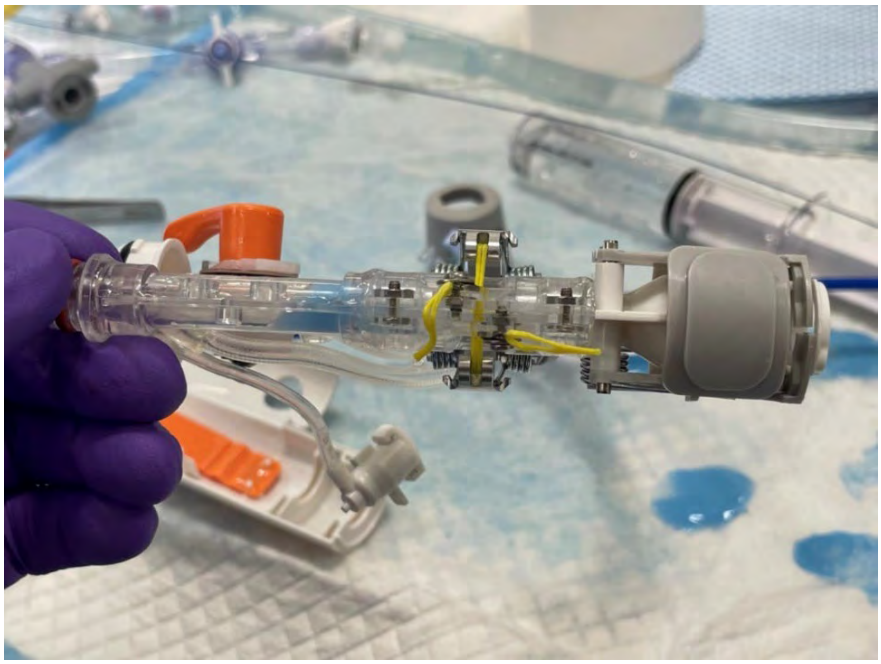
b. When using a 16F Symphony System, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the dilator while maintaining the Catheter and guidewire position.

(Ex. B at 3-5.)

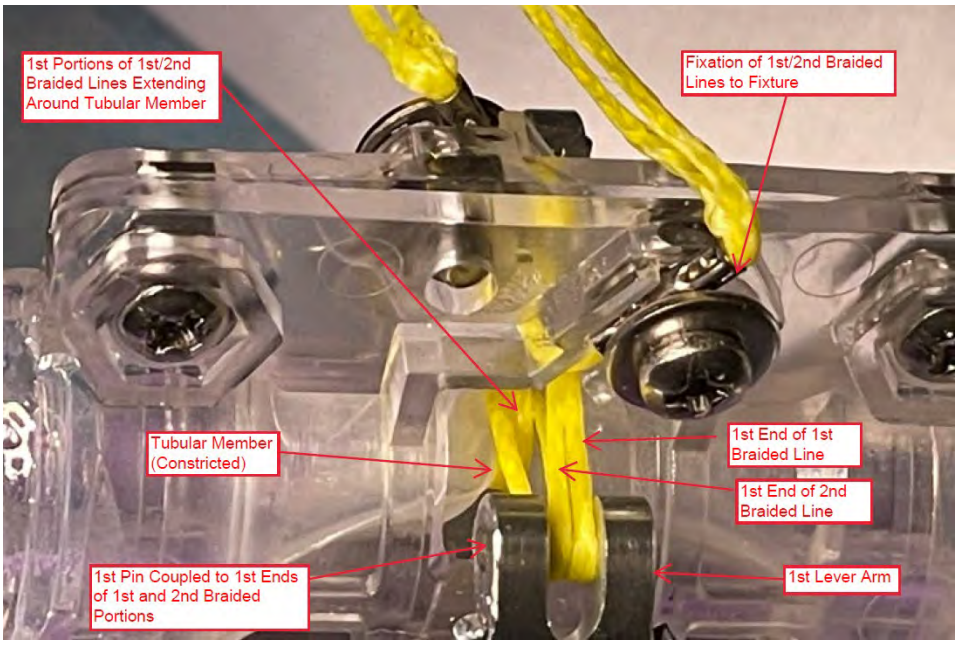
194. The Symphony system including the hemostasis valves practices the requirements of claim 1, including "a collapsible tubular sidewall defining a valve lumen in communication with the central lumen," as can be seen in Exhibit R. The hemostasis valve in each of the 24F and the 16F handles of the Symphony system has a tubular member with a collapsible tubular sidewall defining a lumen that is collapsible and can be constricted to seal the valve lumen (labeled as a tubular member) around a catheter and/or tool.



(Annotated image of internal portion of Symphony housing, including hemostasis valve with tubular member.)



(Image of internal portion of housing with hemostasis valve.)

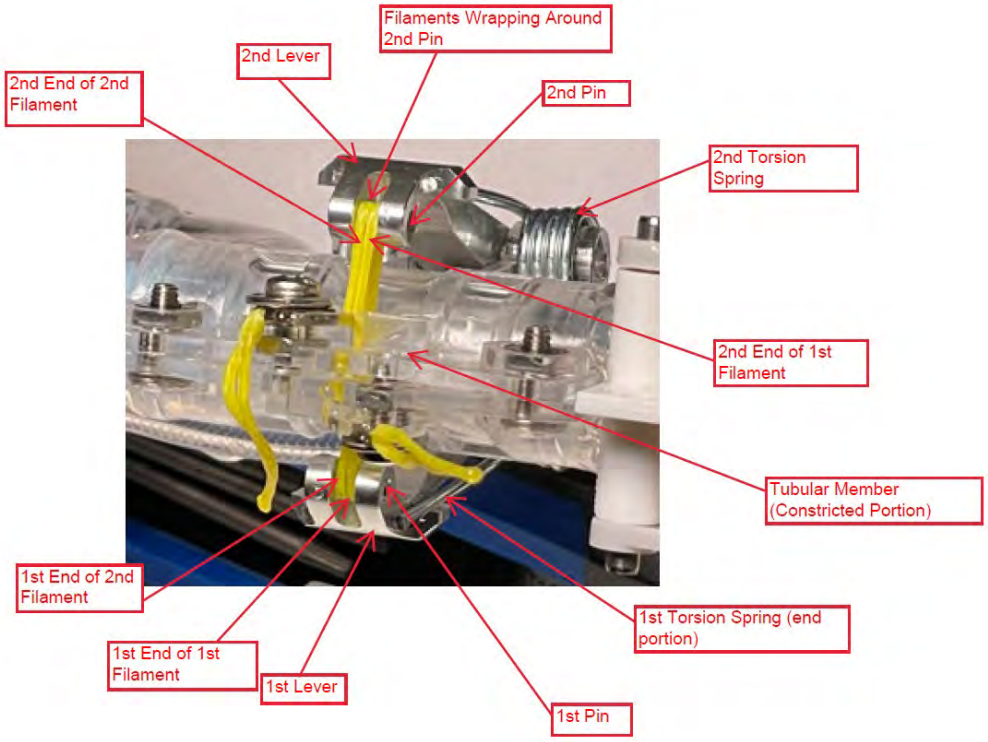


(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)

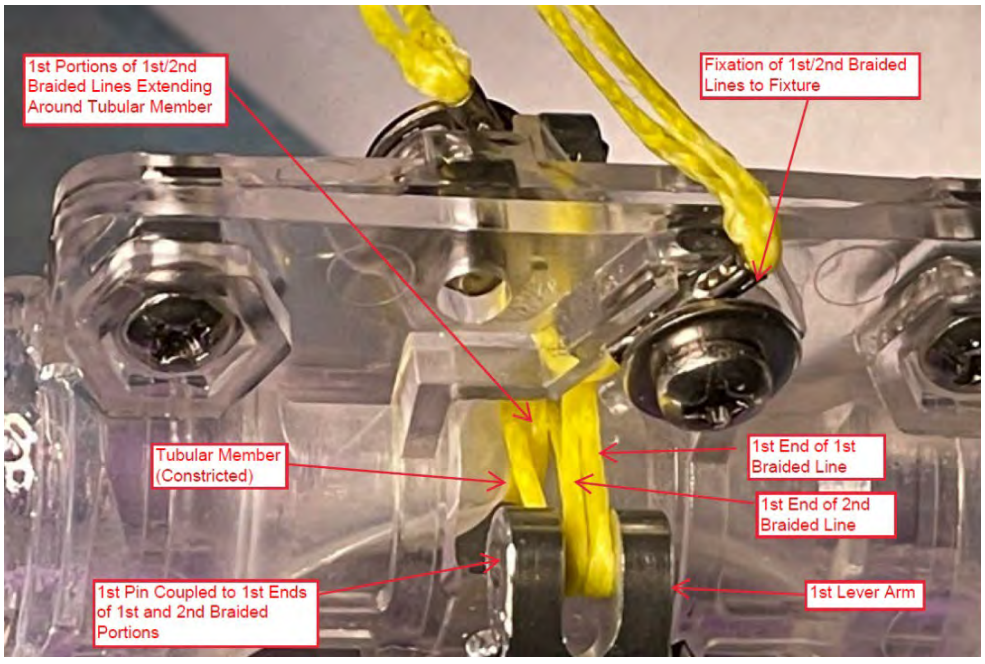
195. The hemostasis valve is in communication with the aspiration catheter, as can be seen above in the Symphony Instructions For Use directing users to advance 24F and/or 16F catheters through a hemostasis valve in the handle.

196. The Symphony system including the hemostasis valves practices the requirements of claim 1, including "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," as can be seen in Exhibit R. The controller handles of the Symphony system each include a hemostasis valve with a constricting mechanism that constricts the valve lumen via a first actuator (a first button that controls a first lever and pin coupled to the end of lines (filaments) that loop around the valve's elongate tubular member with a collapsible tubular sidewall defining a lumen). The first actuator comprising a first button/lever/pin to which the first end of the filament line is coupled, is movable between a first (undepressed button) position where the lumen of the lumen

is constricted to a second (depressed button) position wherein the lumen is less constricted and at least partially open.

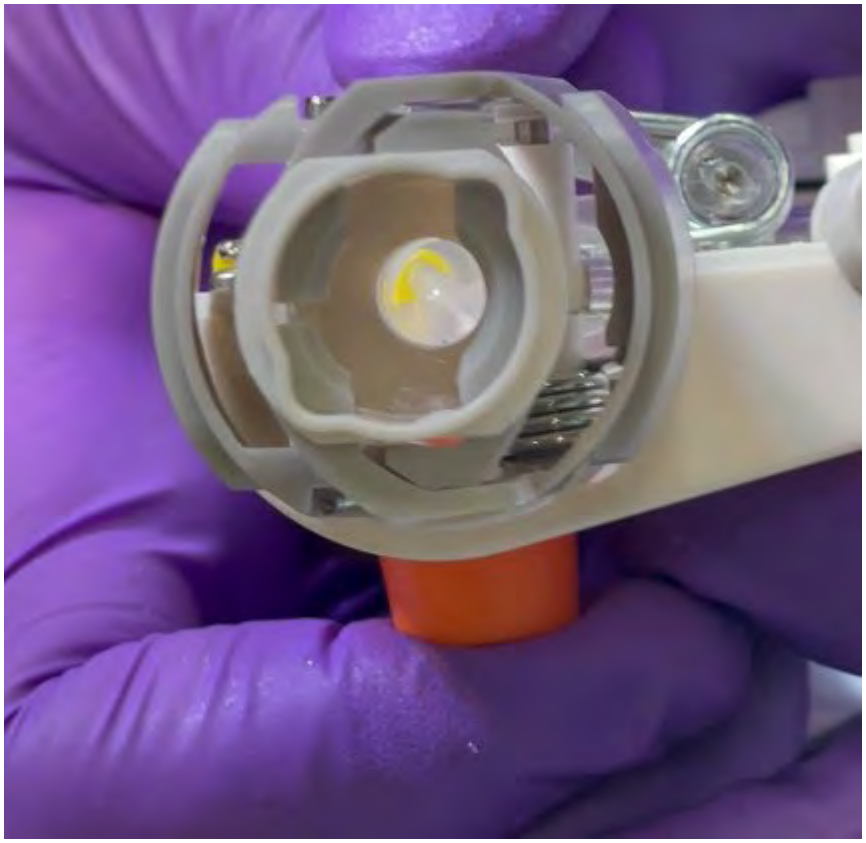


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

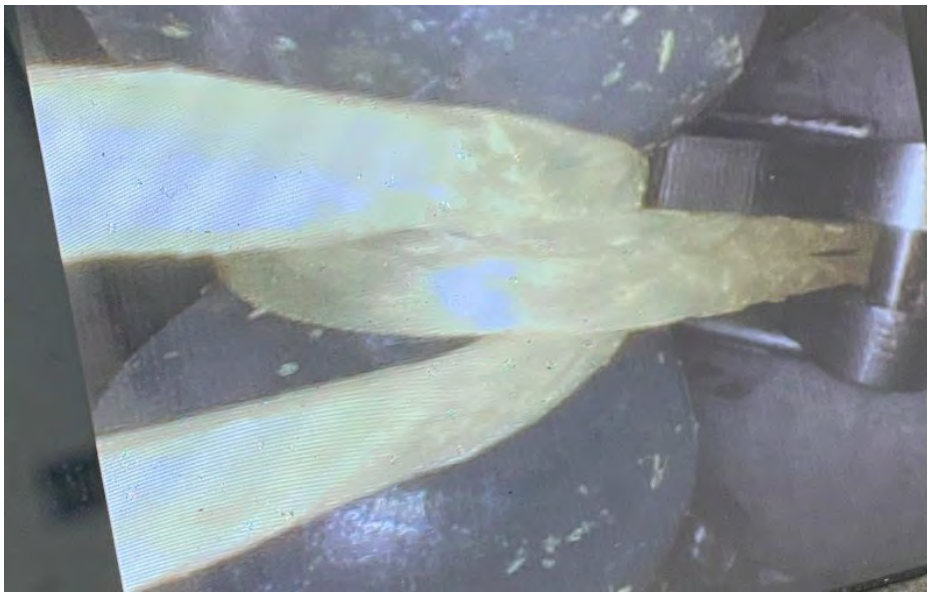


(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)

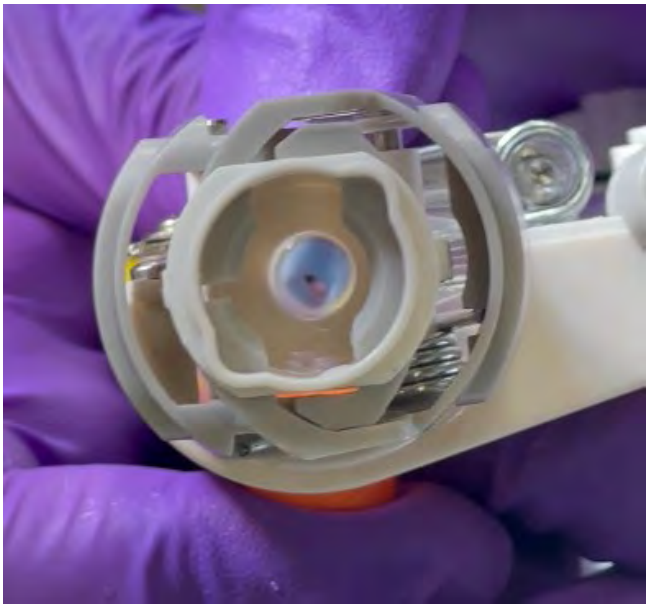
197. The Symphony system's hemostasis valves further include torsion spring(s) configured to move the first actuator's lever and pin outward, thus pulling the first end portion of the filament line, increasing the tension in the loop of the filament line around the valve lumen, thus decreasing the diameter of the valve lumen by constricting the loop to decrease the diameter of the loop. In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring, releasing tension on the filaments wrapped around the lever pin(s), which decreases the constriction on the lumen of the hemostasis valve. This allows the valve to at least partially open, permitting the introduction of a catheter or other tool through the hemostasis valve. Releasing the button(s), causes the torsion spring(s) to drive the lever outward, increasing tension on the filament lines, sealing the hemostasis valve.



(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)



(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

198. Defendant directly infringes claims of the ’012 Patent, including claim 1, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant’s direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures using the hemostasis valves) Symphony system products.

199. Defendant induces infringement of claims of the ’012 Patent, including claim 1 by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claim 1. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

200. Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions For Use that state that the “Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature.” (Ex. B at 2.) The IFU further states that the “Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration.” (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant’s sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

201. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the ’012 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

202. Defendant’s infringement is with knowledge of the ’012 Patent and its claims. Specifically, as described above, Inari notified Defendant that the Symphony system might infringe the ’012 Patent by letter dated September 29, 2023. Inari further explained, in its letter dated April 24, 2024, that a teardown of the hemostasis valves of the Symphony system demonstrated infringement, including infringement of claim 1 of the ’012 Patent.

203. At a minimum, Defendant has notice of the ’012 Patent through the filing of the original Complaint.

204. Defendant has continued its infringing activities, despite knowledge of the ’012 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

205. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the ’012 Patent, including through the use of Inari’s virtual marking website: https://www.inarimedical.com/inari-patents.

206. Defendant’s infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 7: INFRINGEMENT OF THE ’291 PATENT

207. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

208. The ’291 Patent, titled “Hemostasis Valves and Methods of Use,” is part of the same family as the ’921, and ’012 Patents, and it shares the same specification. The ’291 Patent discloses improved hemostasis valves and methods of their use. (*See, e.g.*, Ex. I at Abstract, 1:64-2:3.) Hemostasis valves are used to seal, e.g., to seal around catheters, in order to minimize blood loss, and maintain sterility within the body, such as in a blood vessel. (*Id.* at 1:35-50.) This is critical during surgical procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (*See id.* at 1:24-32.) Improved hemostasis valves are important to maximize patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and practitioners and effective sealing. (*See id.* at 1:51-60, 5:55-6:6.)

209. The ’291 Patent discloses hemostasis valves having a support, an actuator mechanism that is moveable, an elongate tubular member with a collapsible tubular sidewall defining a lumen, where the hemostasis valve further has a constricting mechanism that includes an actuator with a first member (coupled to a first end of a filament) and a second member (coupled to a second end of the filament), where the actuator is biased by a spring to a first

position to constrict the elongate tubular member with the collapsible tubular sidewall defining a valve lumen. (*See id.* at cl. 1, Fig. 7, 2:15-32.) Some embodiments disclosed by the '291 Patent have multiple members for the hemostasis valves, *i.e.*, a first actuator member and a second actuator member used to move the hemostasis valve from a first (constricted) position to a second (un-constricted) position. (*See id.* at cl. 1, cl. 2.)

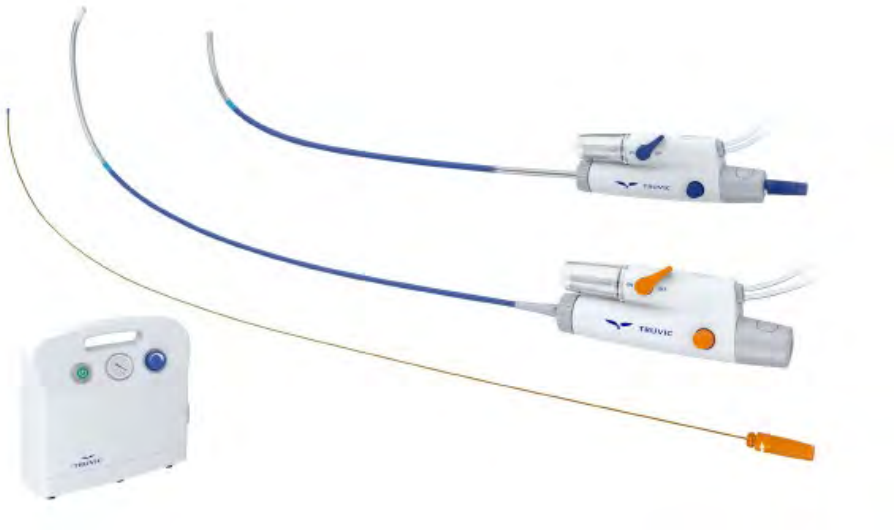
210. Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claim 1 of the '291 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

211. The Symphony system practices each limitation of at least claim 1 of the '291 Patent.

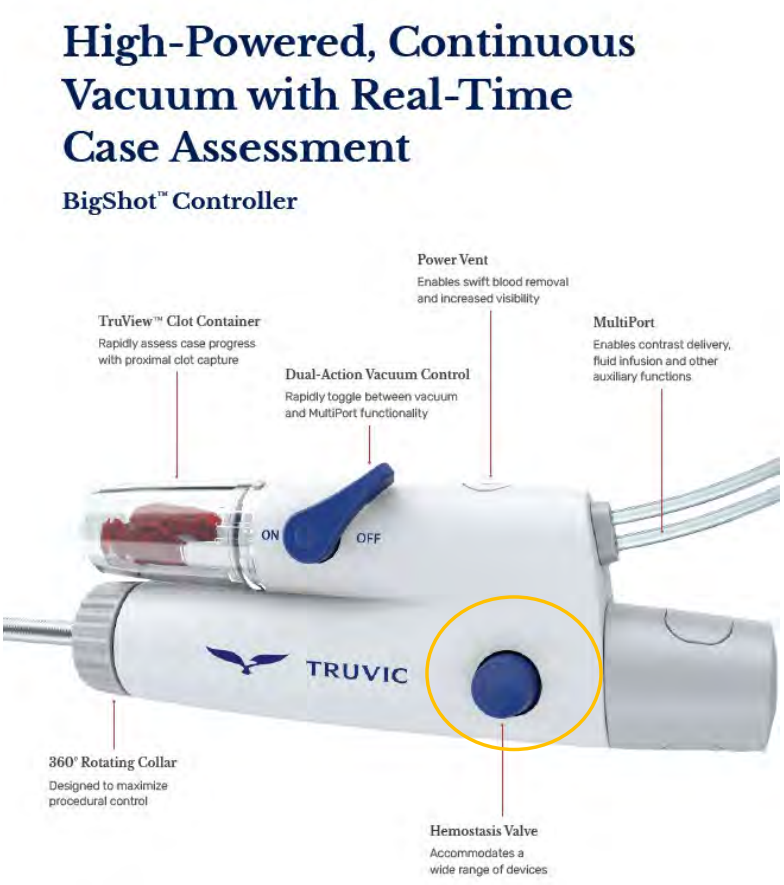
212. For example, claim 1 of the '291 Patent recites:

> [1] A 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.

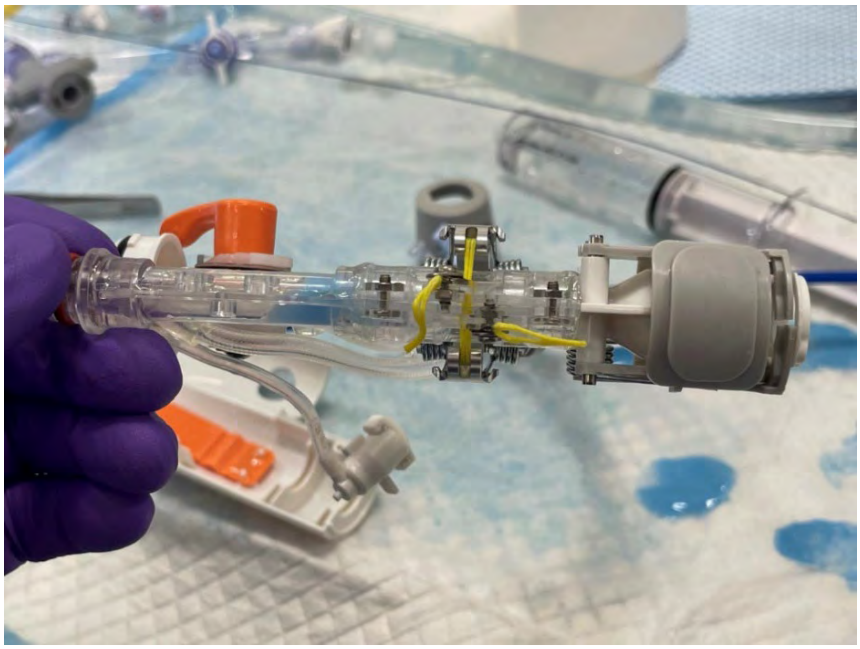
213. The hemostasis valves of the Symphony system practice the requirements of claim 1, including the preamble, "[a] valve, comprising," as can be seen in Exhibit S. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle). Documentation for the Symphony system makes clear that the controller handles have a hemostasis valve, controlled by the buttons on the handles, as can be seen in the excerpts and the teardown photos below.



(Ex. A at 2.)



(Annotated Ex. A at 6.)

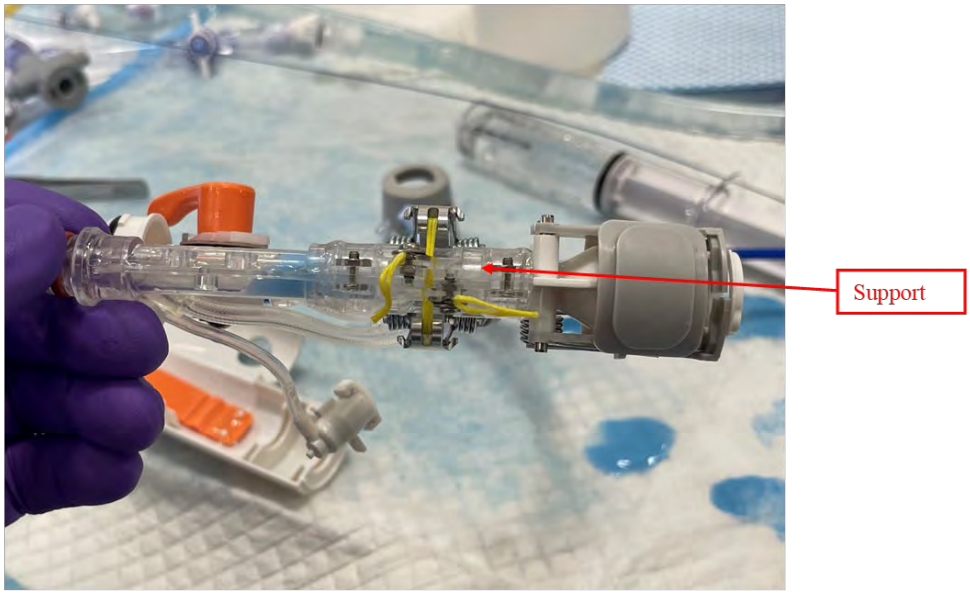


(Image of internal portion of handle housing with hemostasis valve.)

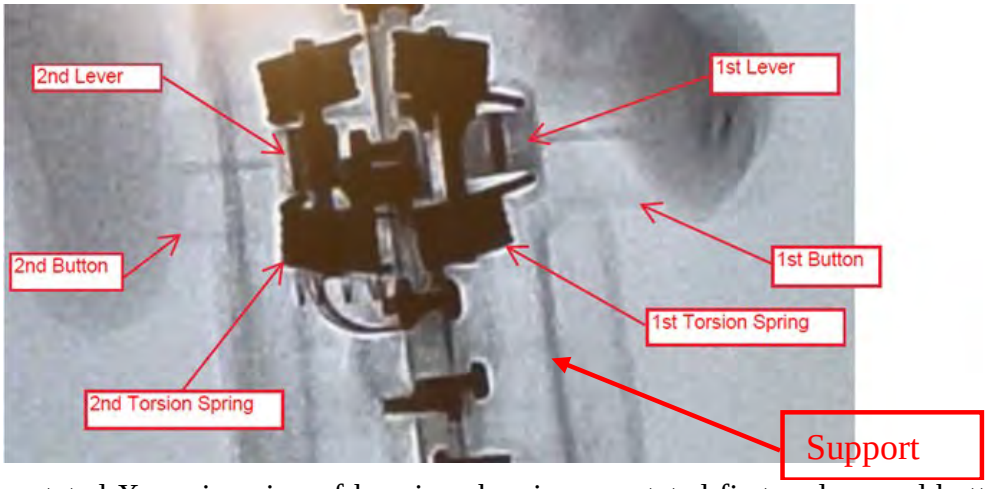
(Image of internal portion of housing zoomed in on hemostasis valve.)

214. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "an actuator having at least a first member movably coupled to the support," as can be seen in Exhibit S. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F

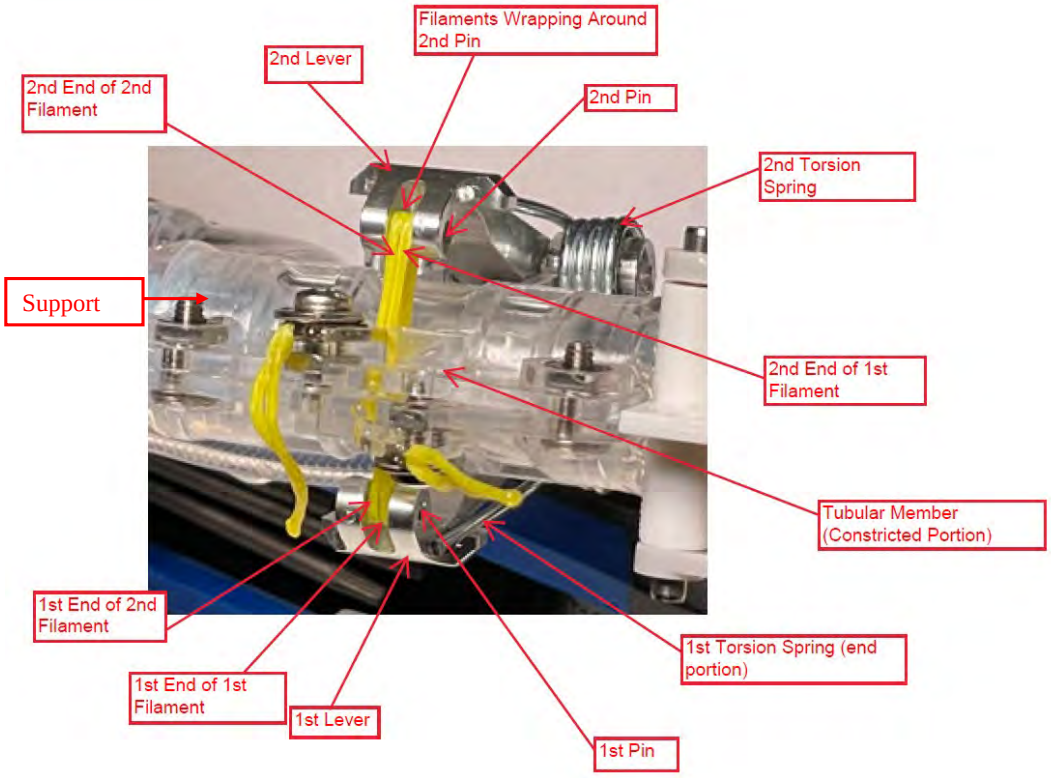
handle) that include a clear plastic support that carries a tubular member and further has an actuator with a first and second member coupled to the support.



(Image of internal portion of housing with hemostasis valve.)

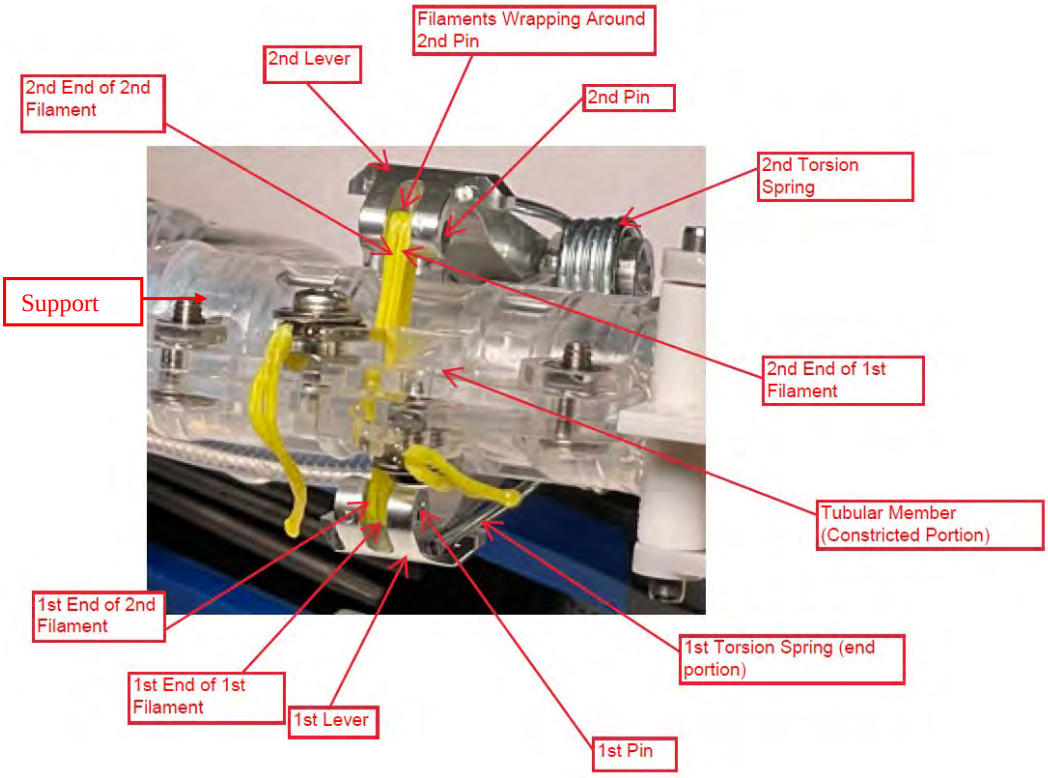


(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of hemostasis valve in Symphony housing.)

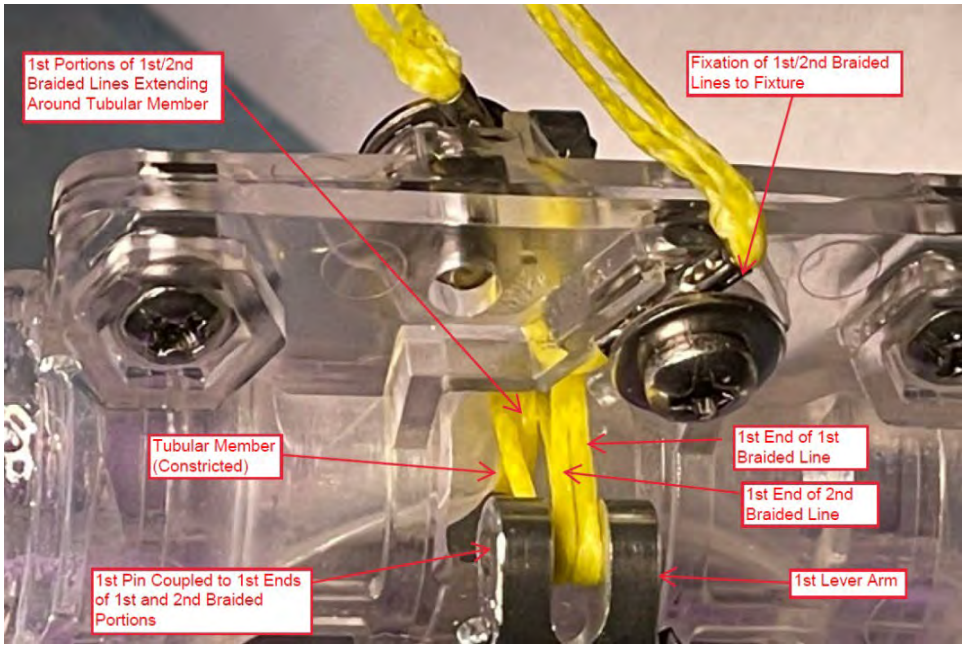


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member and support.)

215. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "an actuator having at least a first member movably coupled to the support," as can be seen in Exhibit S. Specifically, the controller handles of the Symphony system include a hemostasis valve having an actuator mechanism including a first member and a second member (a first that controls the first lever and a second button that controls the second lever coupled to the ends of lines (filaments) that loop around the valve's elongate tubular member defining a lumen). The first member of the actuator is movably coupled to the clear plastic support, specifically the first lever and pin move inward if a first button is depressed, and are driven outward by a spring when the first button is not depressed. The first and second levers are fixed to the centerline of the support with an internal mount within the housing of the controller handle.

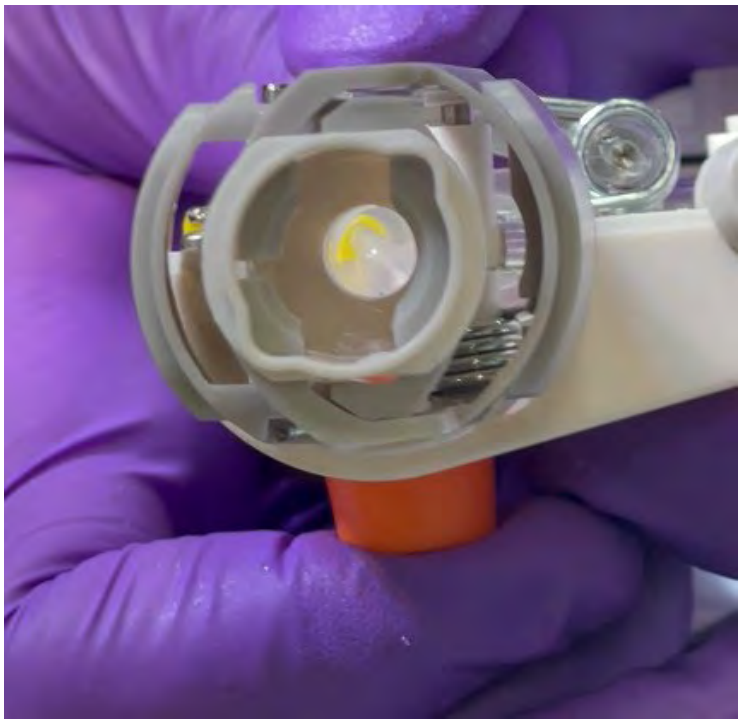


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

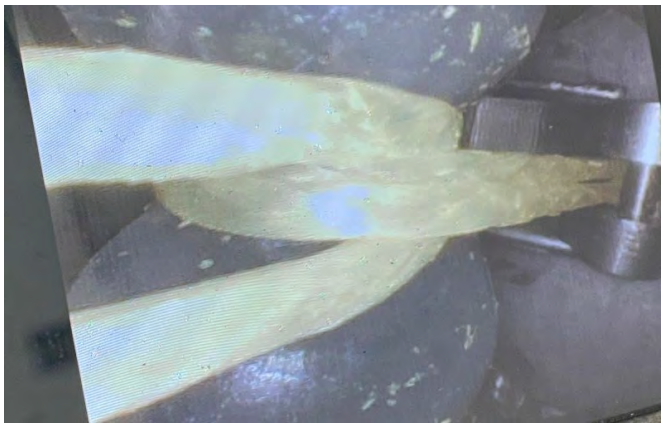


(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)

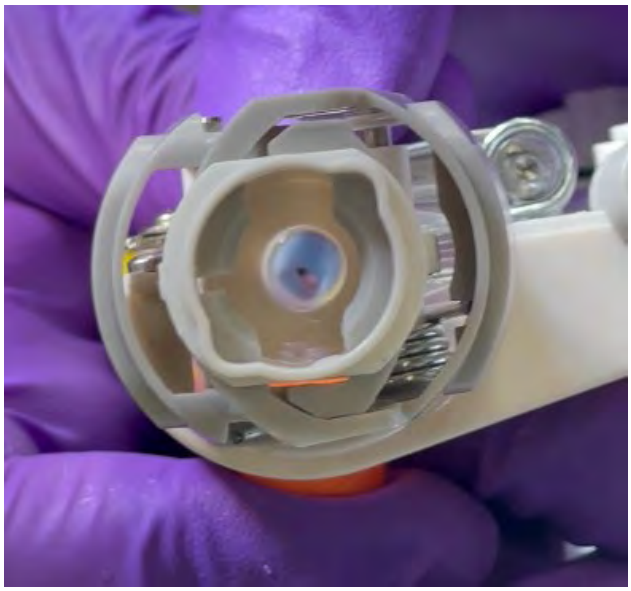
216. In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring(s), releasing tension on the filaments wrapped around the lever pin(s), which decreases the constriction on the lumen of the hemostasis valve. This allows the valve to at least partially open, permitting the introduction of a catheter or other tool through the hemostasis valve. Releasing the button(s), causes the torsion spring(s) to drive the lever outward, increasing tension on the filament lines, sealing the hemostasis valve.



(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve constricted.)

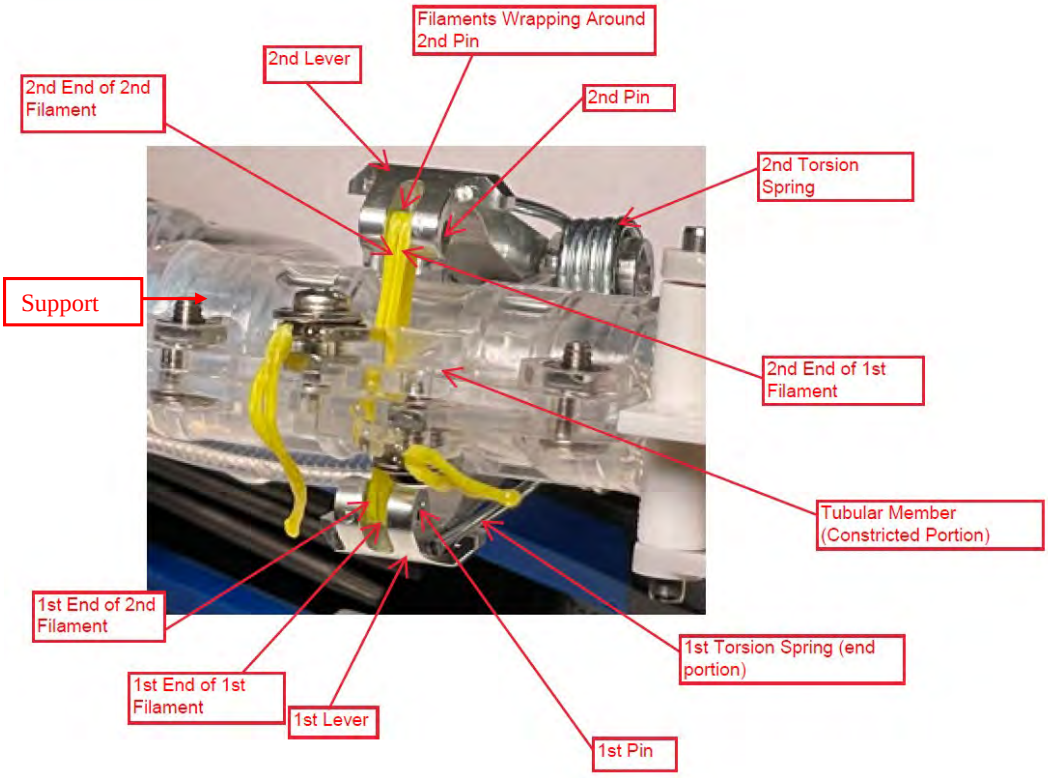


(Internal image of hemostasis valve with filaments encircling and constricting tubular member.)

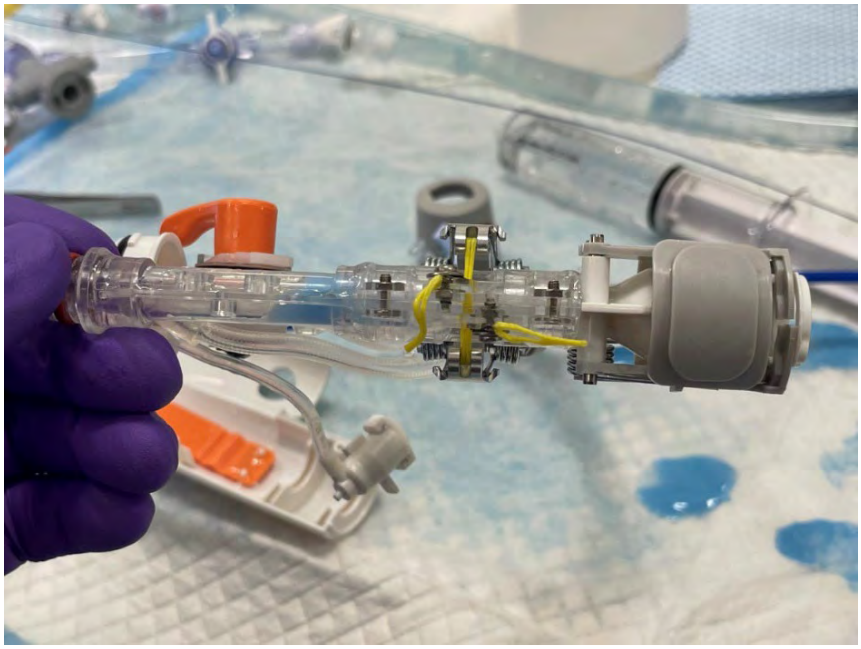


(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve open.)

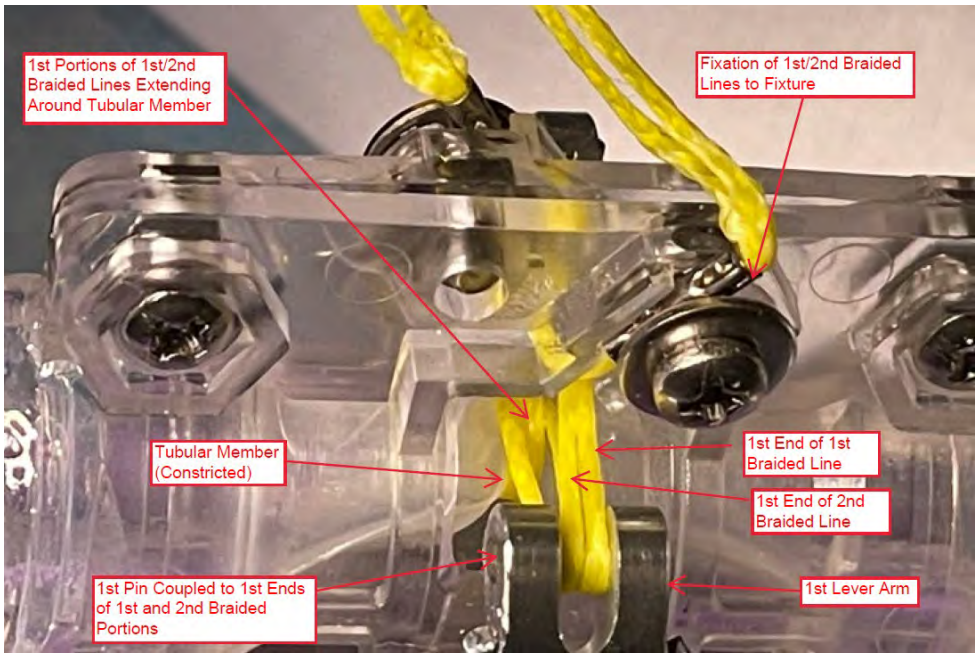
217. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a collapsible tubular sidewall defining a lumen carried by the support," as can be seen in Exhibit S. The hemostasis valve in each of the 24F and the 16F handles of the Symphony system has a central tubular member defining a lumen that is collapsible and can be constricted to seal the valve (labeled as a tubular member).



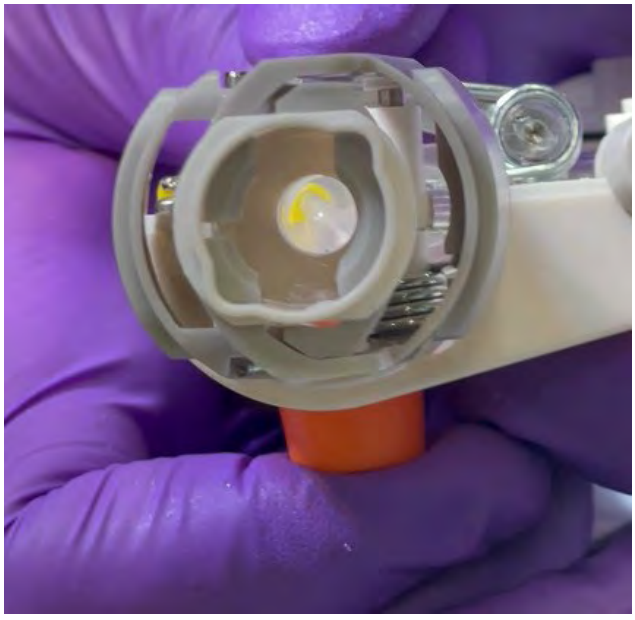
(Annotated image of internal portion of Symphony housing, including hemostasis valve with tubular member.)



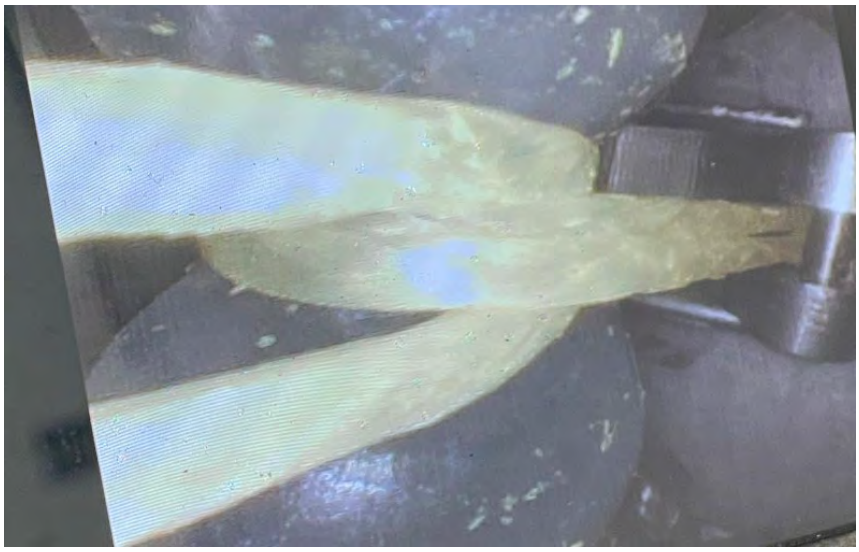
(Image of internal portion of housing with hemostasis valve.)



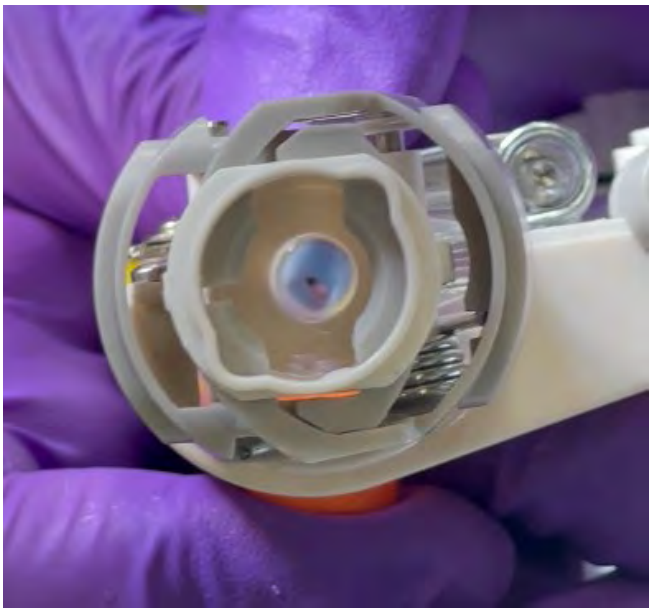
(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)



(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve constricted.)



(Internal image of hemostasis valve with filaments encircling and constricting tubular member.)

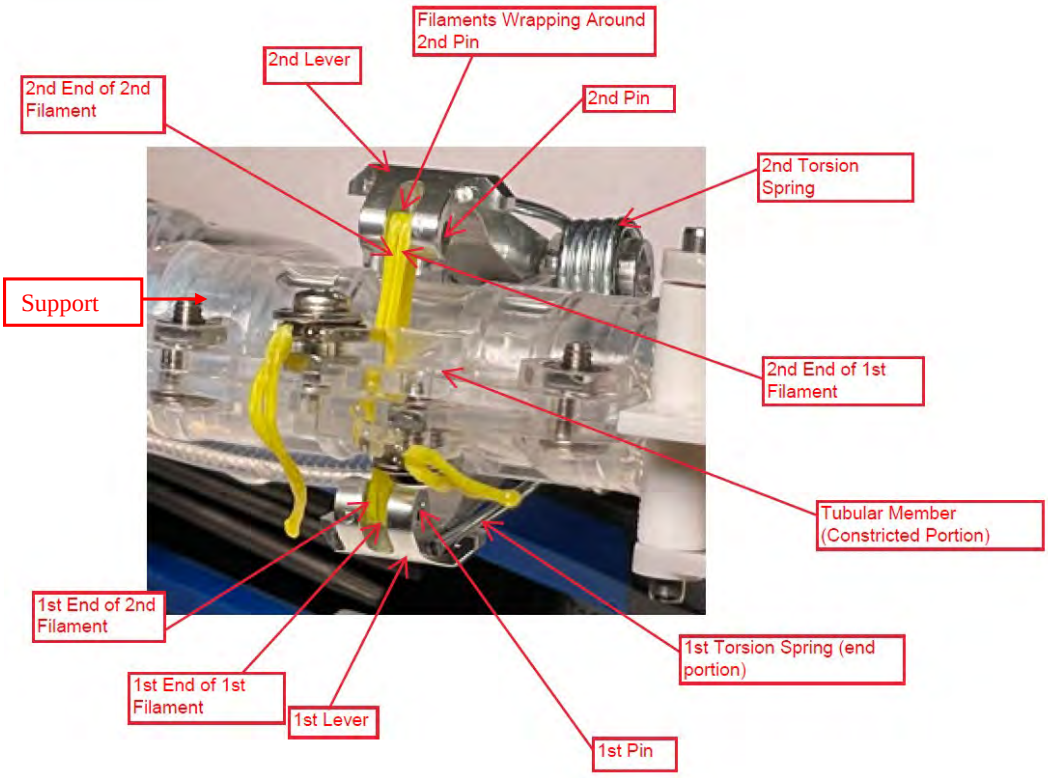


(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve open.)

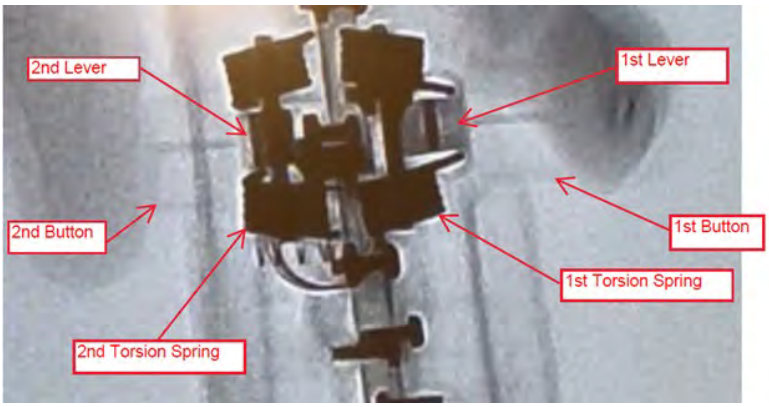
218. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member," as can be seen in Exhibit S. As can be seen in the preceding paragraph, the hemostasis valves include a first filament and a second filament that are looped around the tubular sidewall of the tubular member of the

hemostasis valve, and the filament lines both have a first end portion that extends from the loop to couple to the first pin of the first lever of the first actuator member.

219. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "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," as can be seen in Exhibit S. The hemostasis valve of the Symphony handles includes a first torsion spring that pushes against the first lever, biasing the first member to a first position (closed/constricted with an undepressed first button) and a second torsion spring that pushes against the second lever biasing the second member to the first position. There are two torsion springs for each lever.



(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs.)

220. Defendant directly infringes claims of the '291 Patent, including claim 1, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures using the hemostasis valves) Symphony system products.

221. Defendant induces infringement of claims of the '291 Patent, including claim 1 by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claim 1. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

222. Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-

product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

223. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '291 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

224. Defendant's infringement is with knowledge of the '291 Patent and its claims. Specifically, as described above, Inari notified Defendant that the Symphony system might infringe the allowed claims of United States Patent Application 18/142,518, which has since issued as the '291 Patent, by letter dated September 29, 2023. Inari further explained, in its letter dated April 24, 2024, that a teardown of the hemostasis valves in the Symphony system showed that they infringe Inari's patents, including claim 1 of the '291 Patent.

225. At a minimum, Defendant has notice of the '291 Patent through the filing of the original Complaint.

226. Defendant has continued its infringing activities, despite knowledge of the '291 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

227. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '291 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

228. The requirements of 35 U.S.C. § 154(d) have been met for the allowed claims of the '518 Application from September 29, 2023, to the issuance of the '291 Patent.

229. Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 8: INFRINGEMENT OF THE '580 PATENT

230. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

231. The '580 Patent is titled "Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods." The '580 Patent discloses improved clot-removing methods for intravascular treatment of clot materials that solve problems with prior art clot-removal devices and methods. The '580 Patent solves these problems through its inventions and combination of inventions that include, for example, pre-charging a vacuum in a pressure source, connecting the pressure source to an elongated shaft, e.g., a catheter, to aspirate a first portion of a clot, opening an attachment member at the proximal end, and advancing an interventional device to engage a second portion of the clot remaining after the aspiration pass. (Ex. J at cl. 1.) The interventional device is a mechanical structure that can engage the clot material, and retain it, as the interventional device is withdrawn through the catheter. (*See id.*) The '580 Patent teaches that the using a guide aspiration catheter to advance the interventional device allows for multiple passes (repeated deployments and withdrawals) with the interventional device to remove more clot material. (*See id.* at Fig. 10, 3:45-62.)

232. The '580 Patent further solves problems in the art through a clot reservoir container with a removable filter. (*E.g.*, *id.* at Fig. 3B, Fig. 3C, cls. 18-20.) The '580 Patent teaches that the clot reservoir and filter capture clot material within a housing, while filtered blood is allowed to flow through. (*Id.* at Figs. 3A-3C, 8:60-9:58.) This allows the treating physician to see the captured clot material to help determine whether additional passes are necessary and to remove clot that has been collected by removing and emptying the filter housing. (*Id.*)

233. Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claims 18 and 19 of the '580 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

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234. Specifically, claim 1 of the '580 Patent recites:

> [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.

235. Dependent claim 18 of the '580 Patent recites:

> [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.

236. Dependent claim 19 of the '580 Patent recites:

> [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.

237. Performing thrombectomy using the Truvic Symphony system including its ProHelix device practices each limitation of at least claims 1 (from which claims 18 and 19 depend), 18, and 19 of the '580 Patent, as can be seen in the '580 Patent claim chart, attached as Exhibit T.

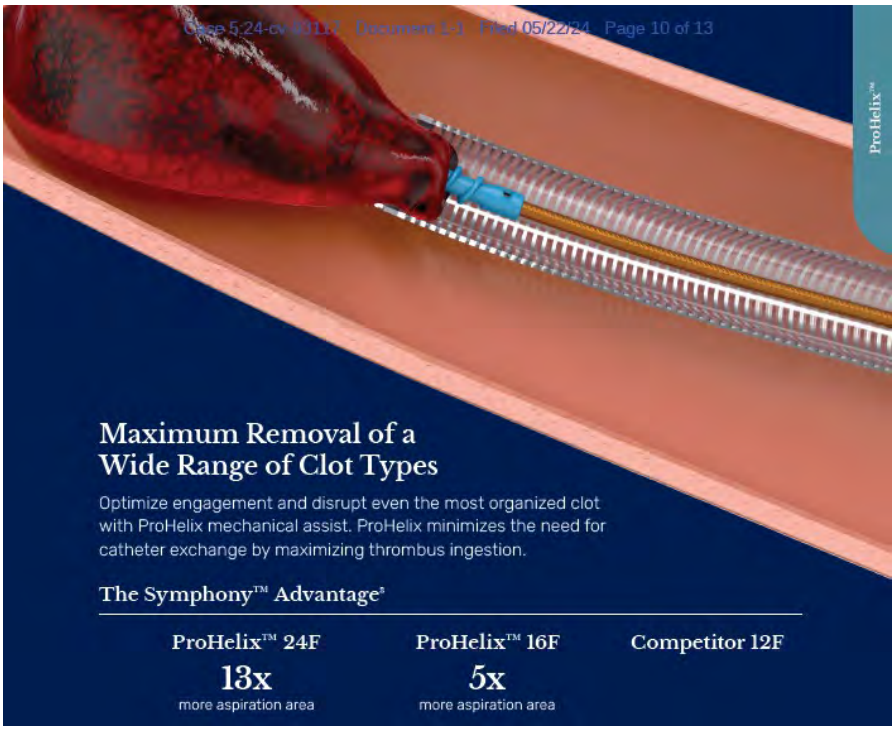
238. To the extent the preamble of claim 1 is construed to be limiting, thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the requirements of the preamble, "[a] method for the intravascular treatment of clot material within a blood vessel, the method comprising," as can be seen in Exhibit T. For example, according to Truvic's Symphony Brochure, Symphony employs "next generation thrombus removal" with

"powerful, focused aspiration" for treating (*e.g.*, removing) clot material from within a blood vessel. (*See* Ex. A at 2-4.) The Symphony Instructions for Use further instruct that the system "is indicated for: [t]he non-surgical removal of fresh, soft emboli and thrombi from blood vessels." (Ex. B at 12.) In addition, Symphony's product website includes a video detailing a method of using the Symphony system to treat clot material within a blood vessel of a human patient using vacuum aspiration. (*See* https://www.truvic.com/symphony-product.)

239. Symphony's Instructions for Use further teach users to advance a 16F or 24F ProHelix device within a catheter to engage the clot:

> As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter.

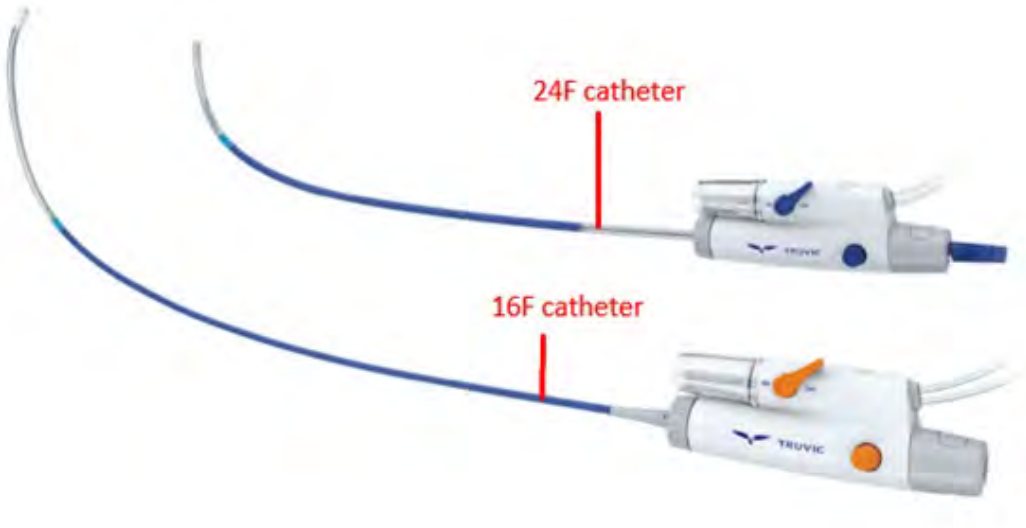
(Ex. B at 1.) Truvic's Symphony Brochure shows this as well:



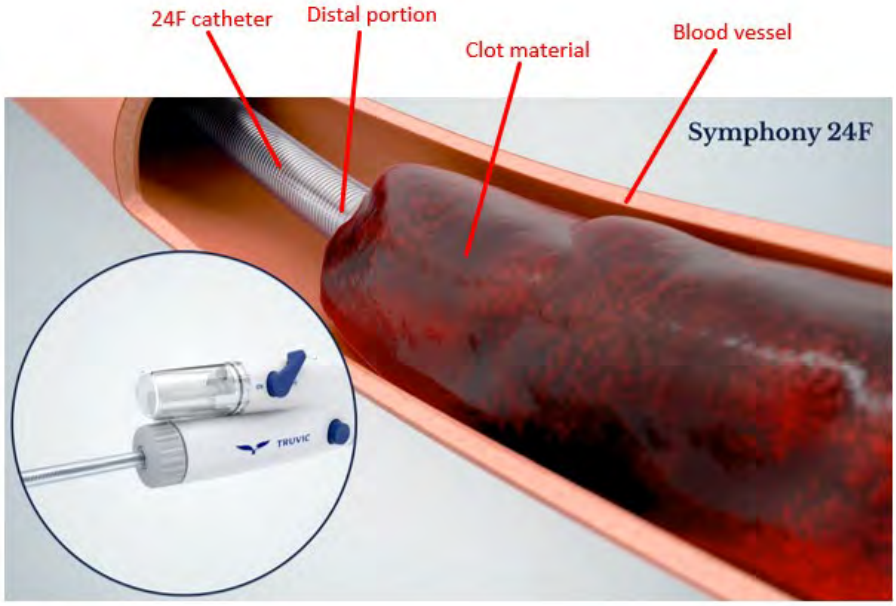
(Ex. A at 10.)

240. Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 1, including "a positioning a distal portion of

an elongated shaft proximate to the clot material within the blood vessel," as can be seen in Exhibit T. The Symphony system includes a 24F catheter (a "first catheter") and a 16F catheter (a "second catheter"). (*Id.* at 2, 4.) These catheters can be used as aspiration catheters, and the Truvic Symphony system is "intended for use in the peripheral vasculature," such as for deep vein thrombosis.



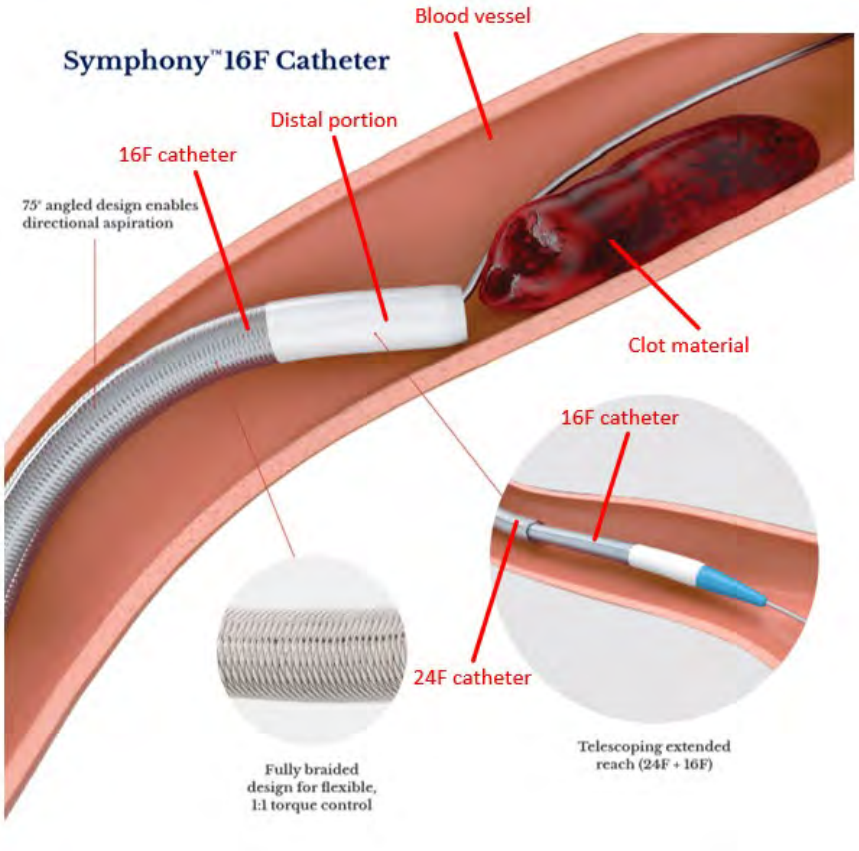
(Ex. A at 2 (annotations added).)



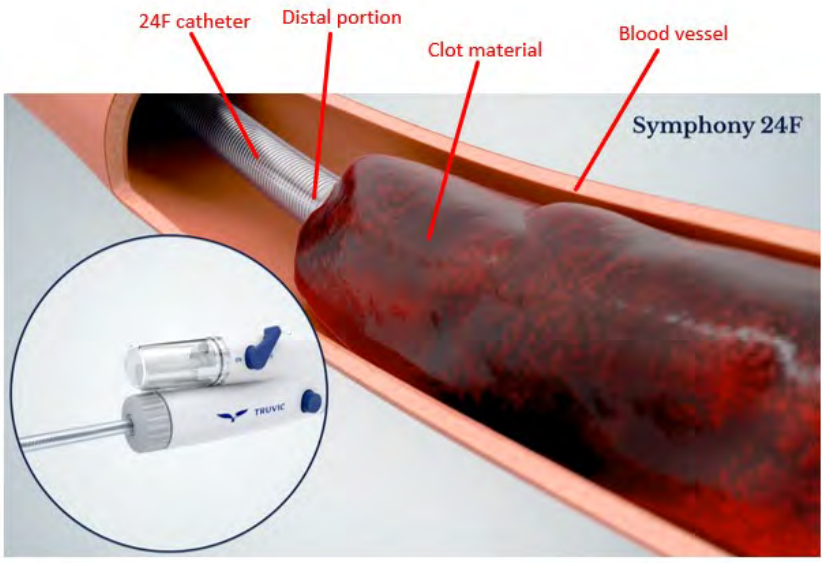
(Annotated screen capture from Symphony product video.)

(Ex. A at 4 (annotations added).)

241. In thrombectomy operations, the 16F second catheter can be advanced, including through the 24F first catheter and out of the 24F first catheter, through the vasculature of a patient over a guidewire and/or with a dilator positioned therein (as shown in the image below) until a distal portion of the 16F second catheter is positioned just proximal of clot material within a blood vessel of the vasculature. (*See id.* at 4.) The 24F catheter can also be advanced to a position proximal to the clot material within a blood vessel of the patient's vasculature. Upon information and belief, practitioners using the Symphony system are intended to and regularly do use this feature.



(Ex. A at 4 (annotations added).)



(Annotated screen capture from Symphony product video.)

242. Thrombectomy with the Symphony system, including thrombectomy with a ProHelix device, practices the limitations of claim 1, including "pre-charging a vacuum in a

pressure source," as can be seen in Exhibit T. In the Symphony system, the 24F and 16F controller handles are coupled to a Truvic Generator and Truvic Canister, or another pressure source, which is a vacuum pressure source:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

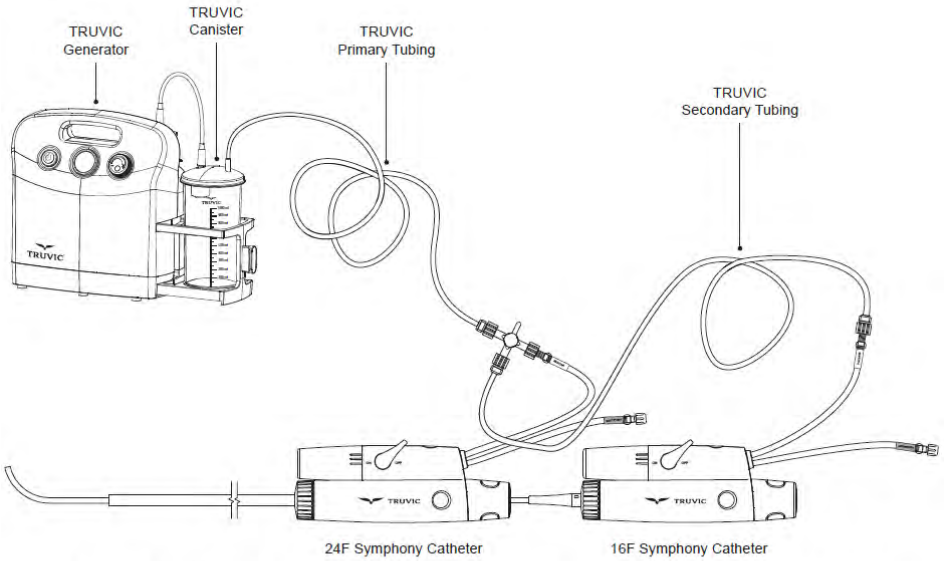
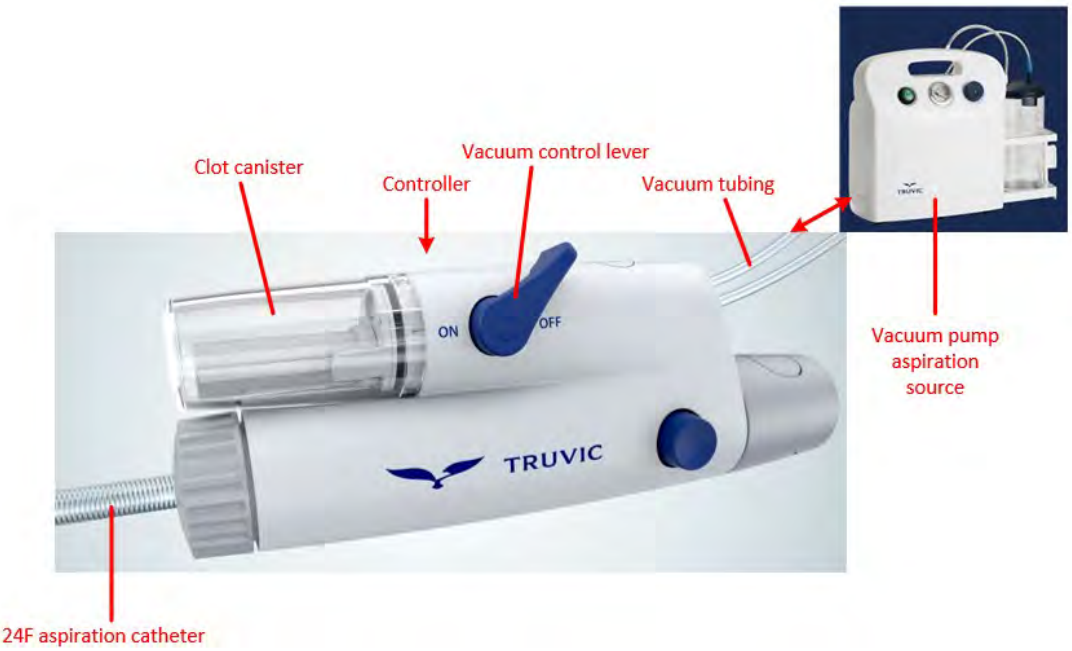


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

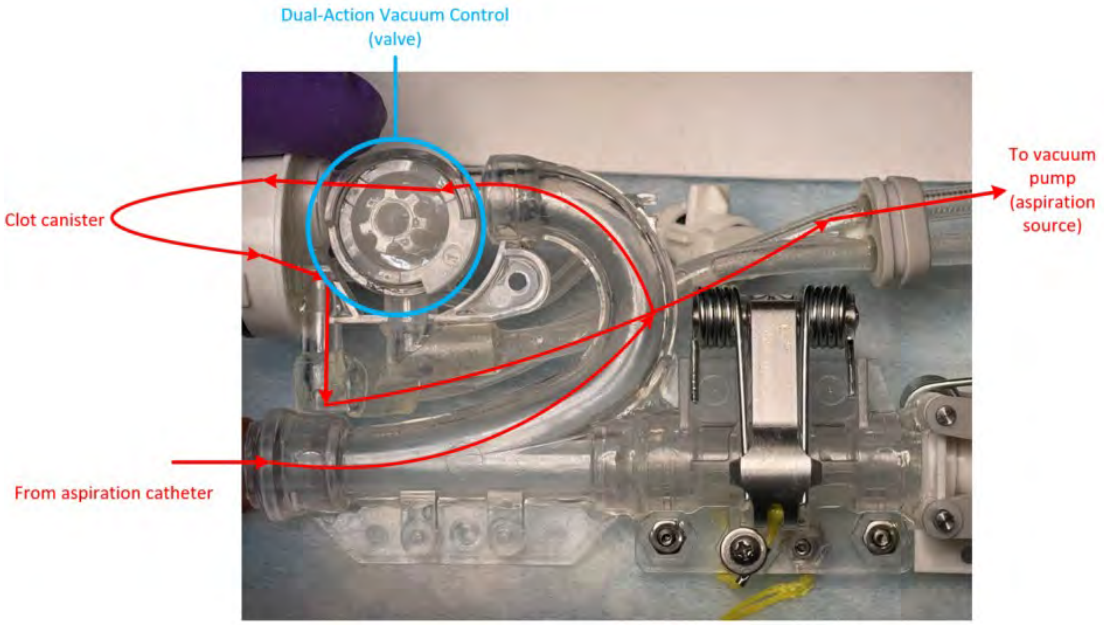
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

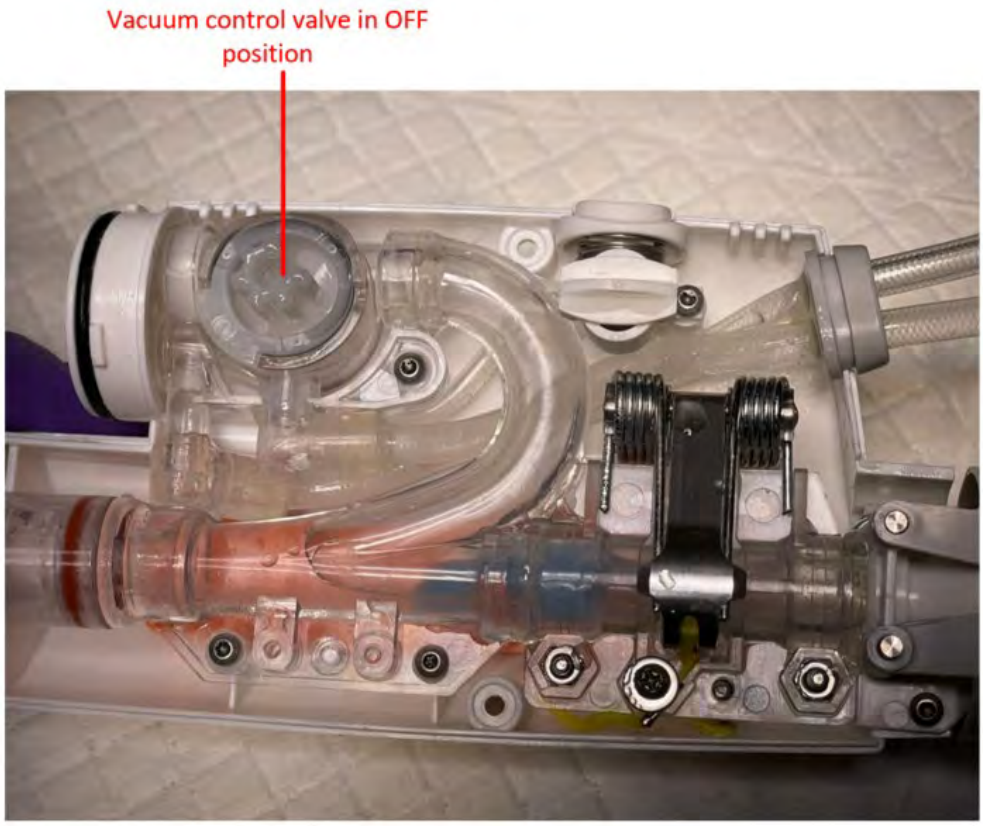
243. During thrombectomy using the Symphony system, the user initially sets the vacuum control lever on the 16F and/or 24F handles to the "OFF" position, which actuates a vacuum valve in the handle, ensuring that vacuum is not applied to the lumen of the 16F and/or 24F aspiration catheters:



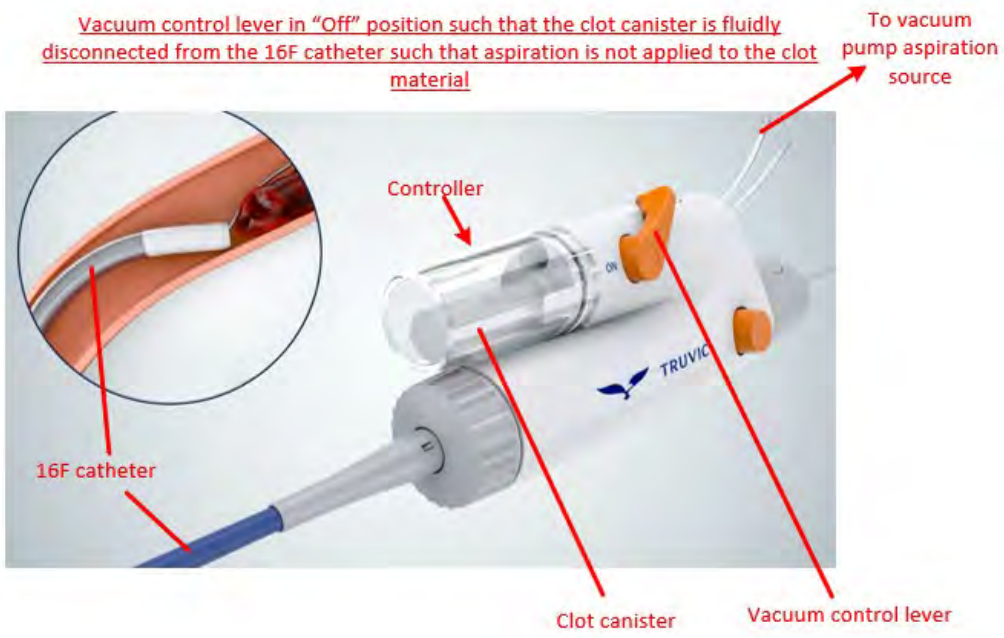
(Annotated diagram of Symphony system.)



(Annotated image of Symphony housing (internal).)



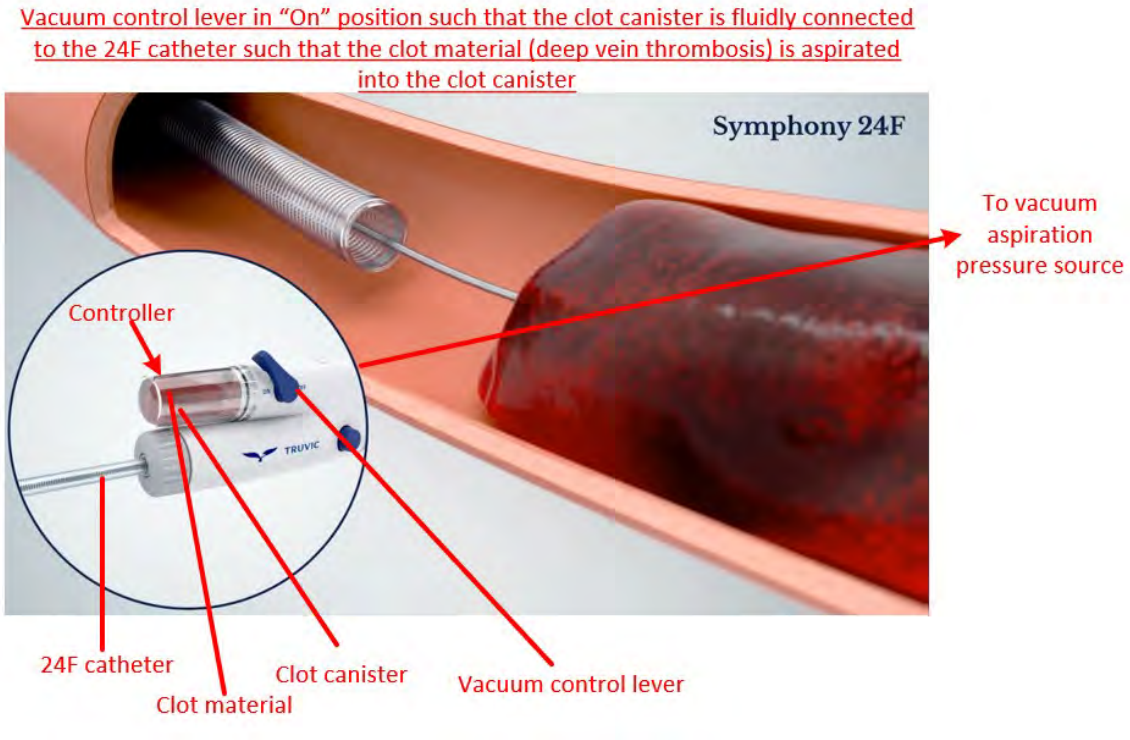
(Annotated image of Symphony housing (internal).)



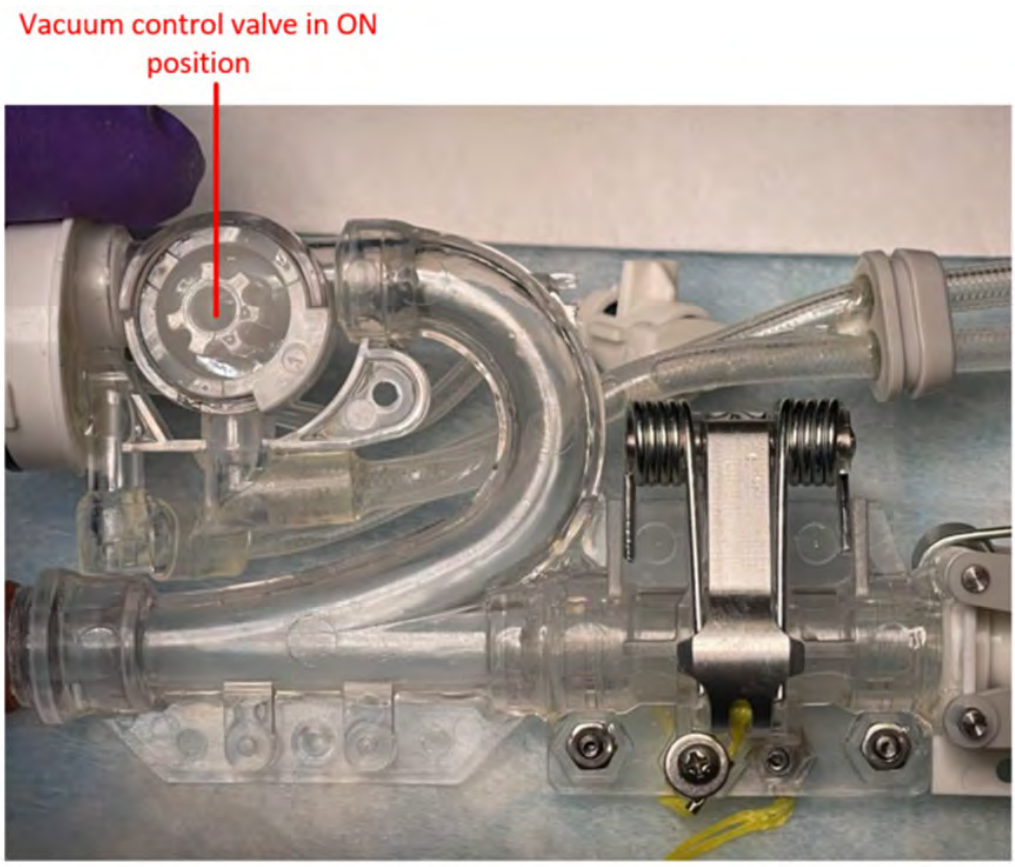
(Annotated screen capture from Symphony product video.)

244. Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 1, including "fluidly connecting the pressure

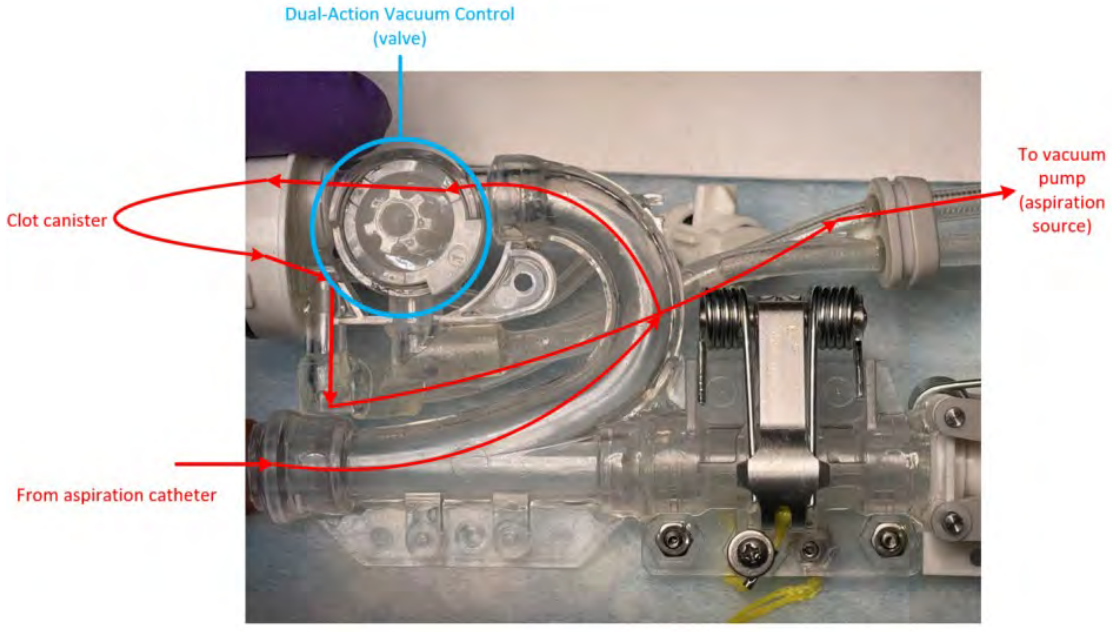
source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft," as can be seen in Exhibit T. Specifically, during thrombectomy using the Symphony system, the user moves the vacuum lever on the 16F and/or 24F handles to the "ON" position, which actuates a valve in the handle, applying vacuum from the vacuum pump aspiration source (*e.g.*, the Truvic Generator and Truvic Canister) to the lumen of the 16F and/or 24F aspiration catheters to aspirate clot:



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)



(Annotated image of internal portion of controller handle housing.)

245. The Symphony IFU further teaches to fluidly connect the catheter to the stored vacuum by turning the vacuum lever to "on" to aspirate a portion of the clot.

12. Confirm the Handle vacuum lever is in the "OFF" position and open the stopcock on the Tubing.
13. Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
14. Confirm tip of the Symphony Catheter is in the desired location.
15. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.
16. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the "OFF" position.
17. If aspiration in another location is desired, reposition the tip of the Catheter using the Dilator, as necessary.
18. Confirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle.

(Ex. B at 5-6, 8-9.)

246. Thrombectomy with the Symphony system using a ProHelix device practices the limitations of claim 1, including "unsealing an attachment member coupled to a proximal portion of the elongated shaft," and "advancing an interventional device distally through the attachment member and the elongated shaft," as can be seen in Exhibit T. Specifically, when using the ProHelix device, Truvic teaches to push the buttons on the 24F or 16F Symphony Handle to release the hemostasis valve and then to advance the ProHelix device over the guidewire to the clot. (Ex. B at 2 ("Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device."), 5 ("Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle."), 6 ("During ProHelix movement, press the Hemostasis Valve buttons on the Handle to reduce friction.").)

247. Thrombectomy with the Symphony system using a ProHelix device practices the limitations of claim 1, including "engaging the interventional device with a second portion of the clot material remaining within the blood vessel," as can be seen in Exhibit T. Specifically,

the IFU teaches users to employ a ProHelix device during procedures to engage a lot and clear clot obstructing the catheter tip, "[t]o resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix."

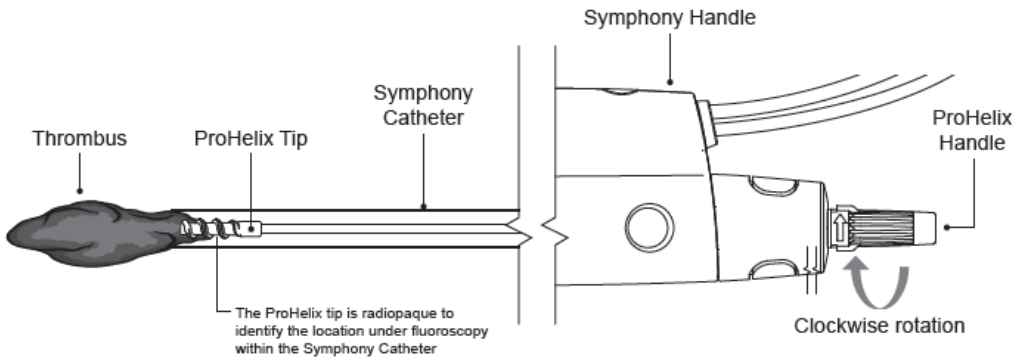
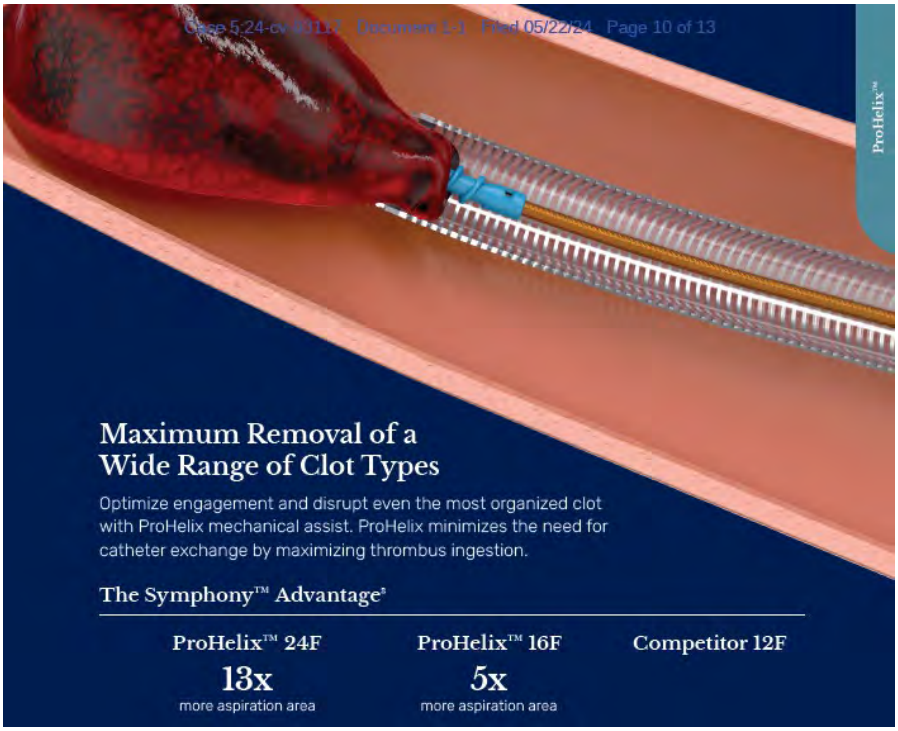


Figure 4: ProHelix engaged with thrombus

(Ex. B at 5.) Truvic's Symphony Brochure shows this as well, as does the Symphony video.



(Ex. A at 10; *see also* https://vimeo.com/817718796.)

248. Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 18, including "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." Specifically, as can be seen in the images from page 4 of the IFU below, the Symphony system handle has a clot container with a filter chamber coupled between the Truvic Generator vacuum pump and the aspiration catheter that captures and filters clot material from blood during thrombectomy:

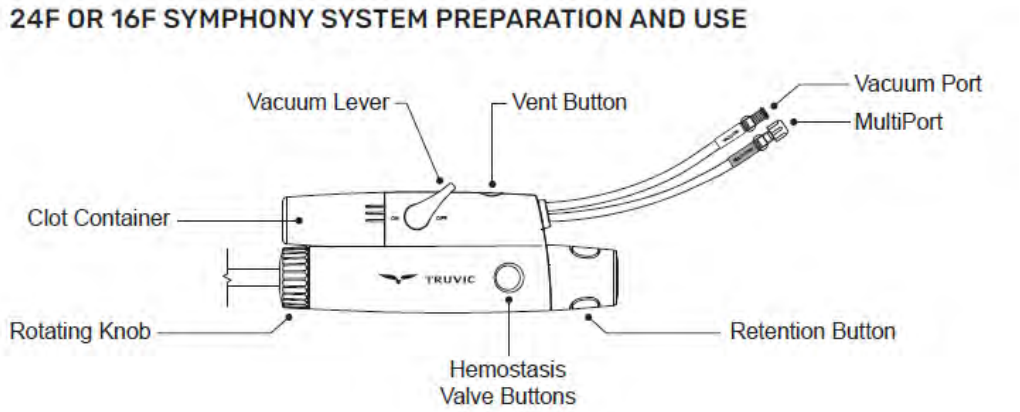
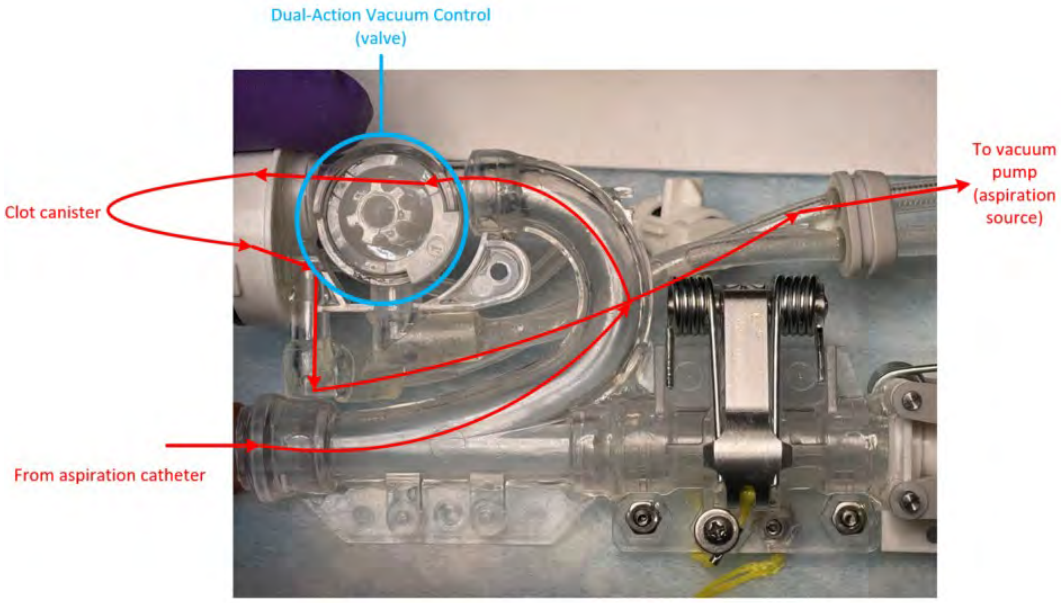
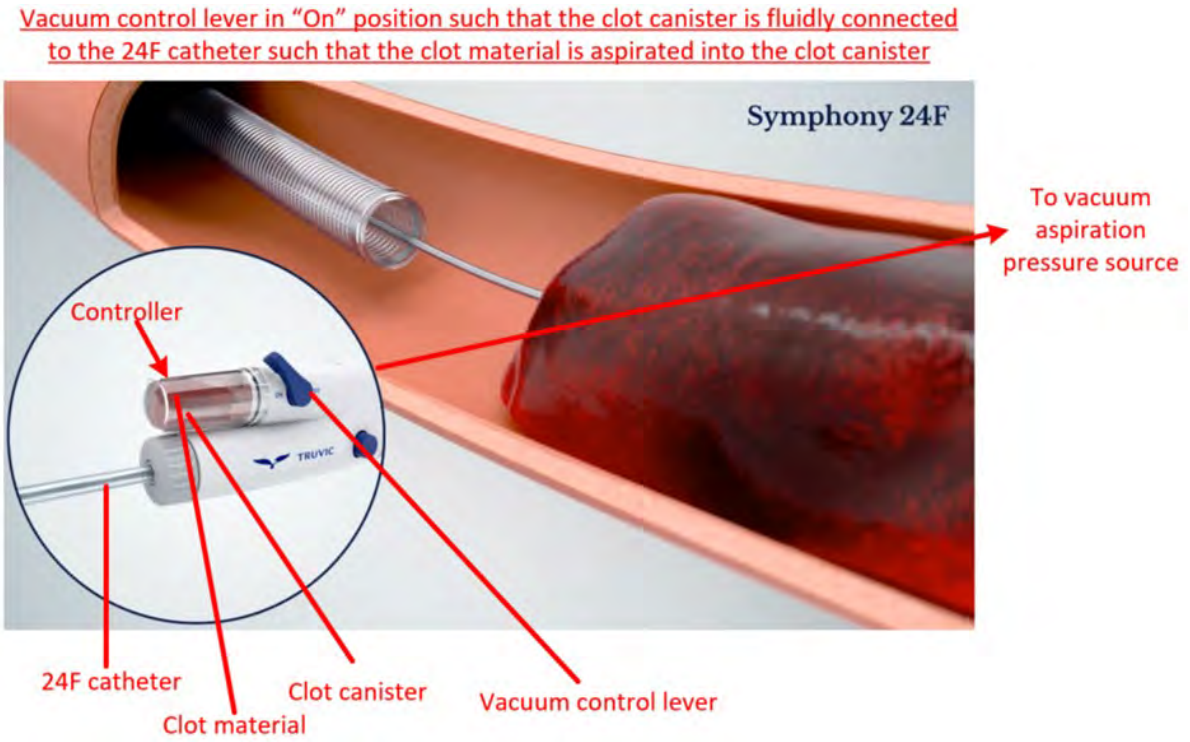


Figure 3: Symphony Catheter Handle, labeled

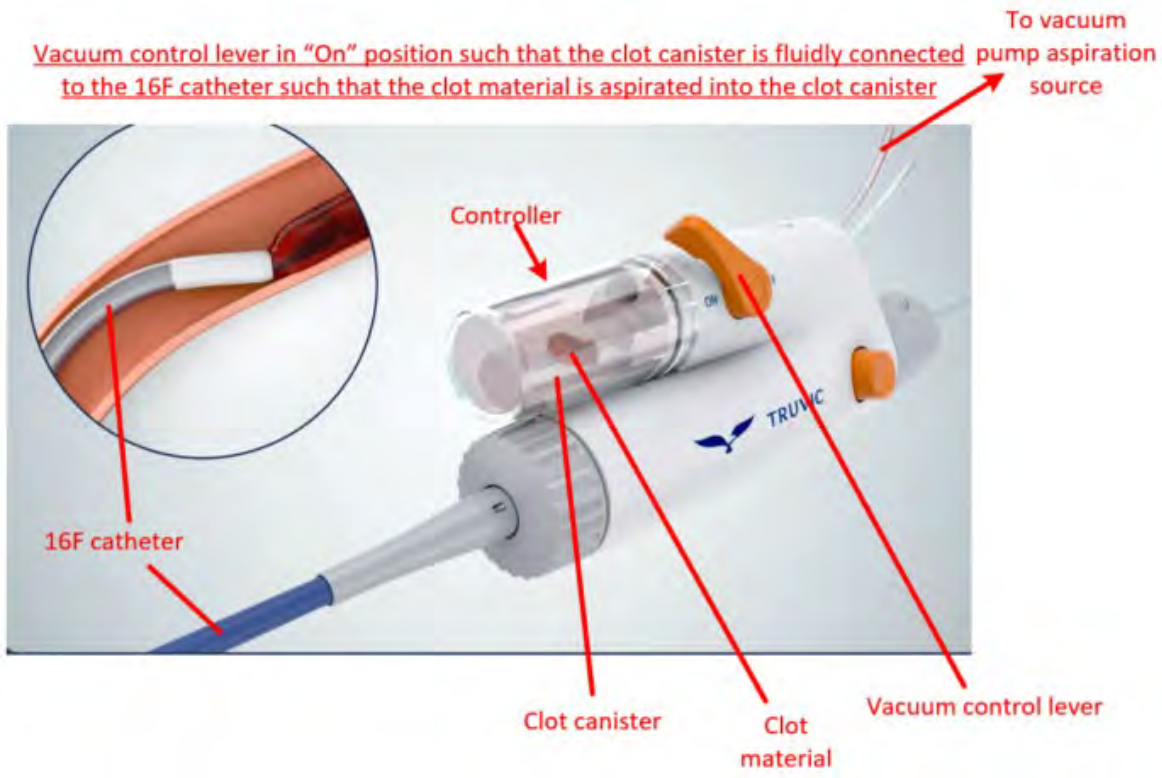
(Ex. B at 4.) The fluid path from the aspiration catheter, through the clot canister to the vacuum pump is labeled in the annotated teardown image below:



(Annotated image of internal portion of controller handle housing.) The clot container includes a removable filter chamber including a housing and removable filter, as can be seen in the annotated images captured from of the Symphony video below:



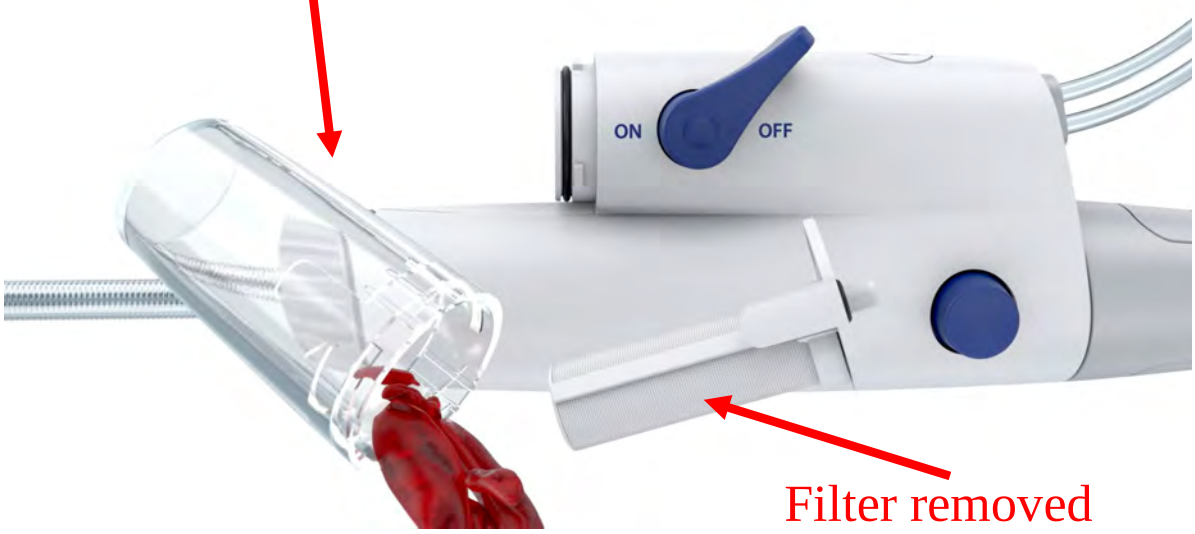
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:45 (https://www.truvic.com/symphony-product).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:55 (https://www.truvic.com/symphony-product).)

249. Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 19, including "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." Specifically, as can be seen in the annotated images from the Symphony video below, Symphony system's clot canister includes a removable filter chamber and a removable filter. To empty the collected clot from the clot canister, the operator removes the clot canister containing the clot and filter, and then removes the filter and the clot from the clot canister housing:

(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:18 (https://www.truvic.com/symphony-product).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

(Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

250. The clear clot container also allows visual access to the captured clot.

251. Defendant directly infringes claims of the ’580 Patent, including claims 18 and 19 when Defendant or persons under its direction and control perform thrombectomy procedures using Symphony system with a ProHelix device. For example, Defendant directly infringes claims 18 and 19 when testing or using the Symphony system in patients.

252. Defendant induces infringement of claims of the ’580 Patent, including claims 18 and 19 by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems in a manner that practices the methods of claims 18 and 19. Defendant actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures with the Truvic Symphony system using a ProHelix device in a manner that practices the limitations of claims of the ’580 Patent, including claims 18 and 19. Defendant instructs and teaches users to perform methods that practice the limitations of claims 18 and 19 with knowledge and/or willful blindness that such acts constitute direct infringement of the ’580 Patent.

253. Defendant, for example, provides Instructions For Use that state that the “Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature.” (Ex. B at 2.) The IFU further states that the “Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration.” (*Id.* at 1.) The IFU further teaches users to employ a ProHelix device during procedures to engage a clot and clear clot material obstructing the catheter tip, “[t]o resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.”

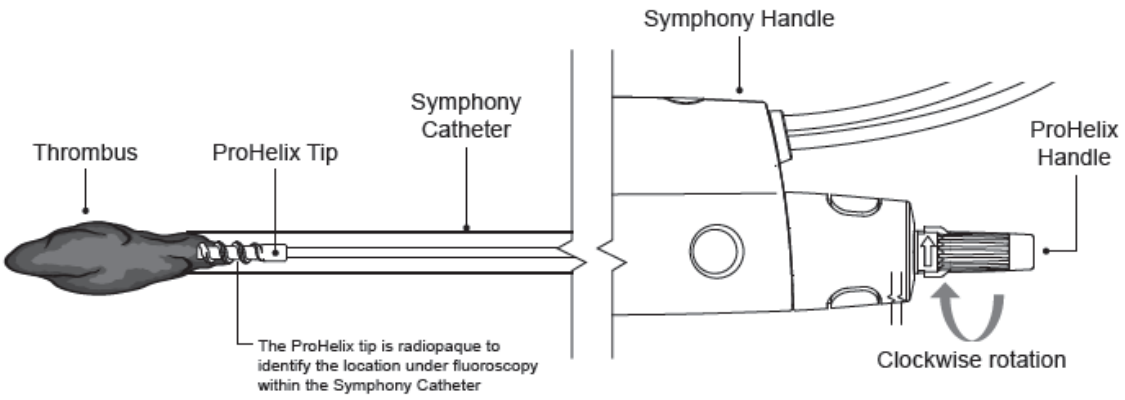


Figure 4: ProHelix engaged with thrombus

(Ex. B at 5.)

254. Defendant further provides brochures and other materials, including animation videos, that detail how to use the Truvic Symphony system in a manner that practices claims of the '580 Patent, including claims 18 and 19. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including methods of treating clots use a ProHelix device that practice the claims of the '580 Patent.

255. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '580 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

256. Defendant's infringement is with knowledge of the '580 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated September 29, 2023, that its products would infringe claims of United States Patent Application No. 17/498,642 ("the '642 Application"), when issued. Inari further attached the published version of this application (United States Published Application No. 2022/0240959) with claim 21, which later issued as claim 1 in identical or substantially identical form.

257. At a minimum, Defendant has notice of the ’580 Patent through the filing of the First Amended Complaint, which was submitted to the Court just a few weeks after the ’580 Patent issued.

258. Defendant has continued its infringing activities after the ’580 Patent issued, despite knowledge of the ’580 Patent (including knowledge from correspondence with Inari and from the First Amended Complaint), and such infringement has been and continues to be egregious and willful.

259. The requirements of 35 U.S.C. § 287(a) have been met for the ’580 Patent. Because the ’580 Patent contains only method claims, no marking is required.

260. The requirements of 35 U.S.C. § 154(d) have been met for the published claims of Publication No. 2022/0240959 from September 29, 2023, to the issuance of the ’580 Patent.

261. Defendant’s infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 9: INFRINGEMENT OF THE ’384 PATENT

262. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

263. The ’384 Patent, titled “Hemostasis Valves and Methods of Use,” is part of the same family as the ’921, ’012, and ’291 Patents, and shares the same specification. The ’384 Patent discloses improved hemostasis valves and methods of their use. (*See, e.g.*, Ex. K at Abstract, 1:65-2:4.) Hemostasis valves are used to seal, *e.g.*, to seal around catheters, in order to minimize blood loss, and maintain sterility within the body, such as in a blood vessel. (*Id.* at 1:36-51.) This is critical during surgical procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (*See id.* at 1:25-33.) Improved hemostasis valves are important to maximize patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and practitioners and effective sealing. (*See id.* at 1:52-61, 5:55-6:6.)

264. The ’384 Patent discloses hemostasis valves having an elongate tubular member defining a lumen, where the hemostasis valve further has a constricting mechanism that includes

a first filament extending in a first loop, a second filament extending in a second loop, and a pair of actuators that are movable between a first position to tension the first and second filament and constrict the lumen of the tubular member and a second position to loosen the first and second filament and partially open the lumen of the tubular member. (*See id.* at cl. 1, Fig. 8, 3:1-18.) The '384 Patent further is directed to embodiments where one of the actuators acts on a first end portion of the first filament and the other actuator acts on a second end portion of the first filament, and the second filament similarly has one end portion acted on by the first actuator and a second end portion acted on by a second actuator. (*See id.* at cl. 1, cl. 3.)

265. Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claims 1 and 3 of the '384 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

266. Specifically, claim 1 recites:

> [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 the 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

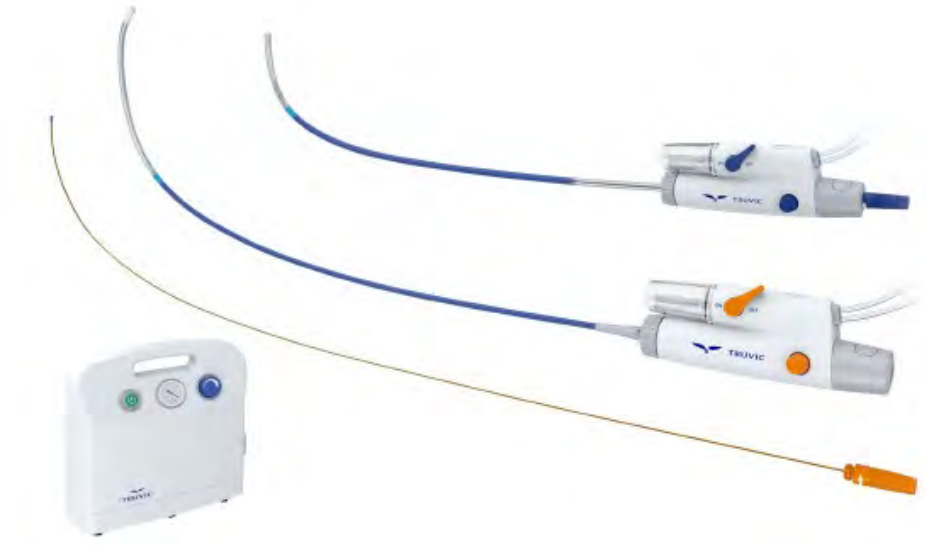
member; and

the actuators are biased to the first position.

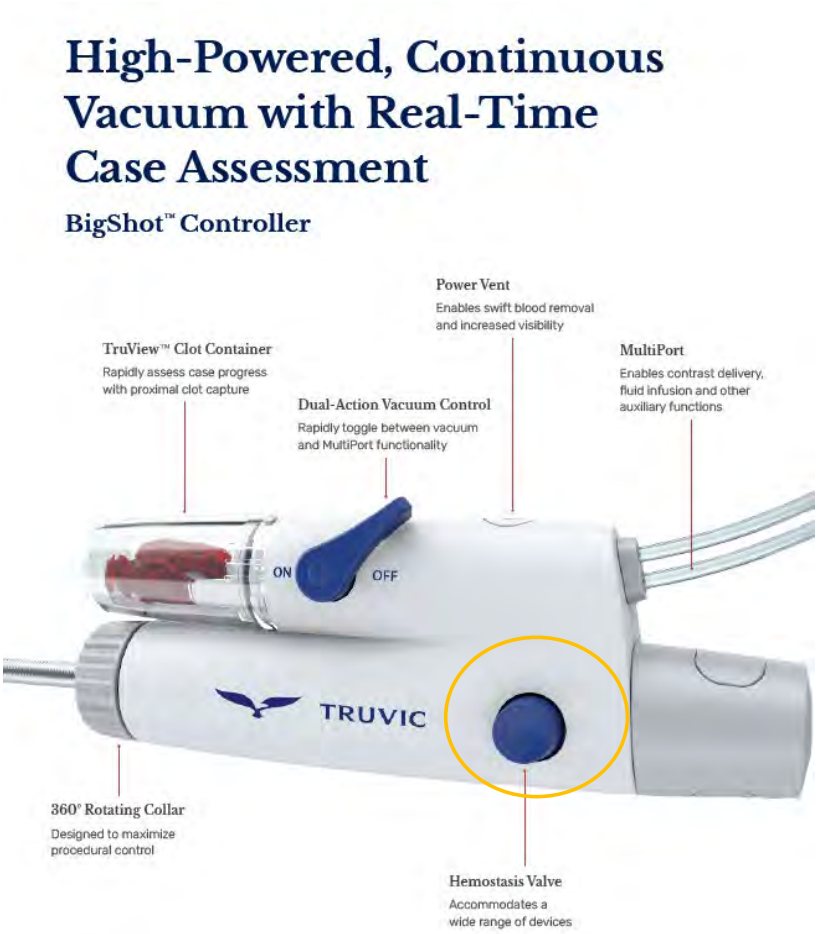
267. Dependent claim 3 recites:

> [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.

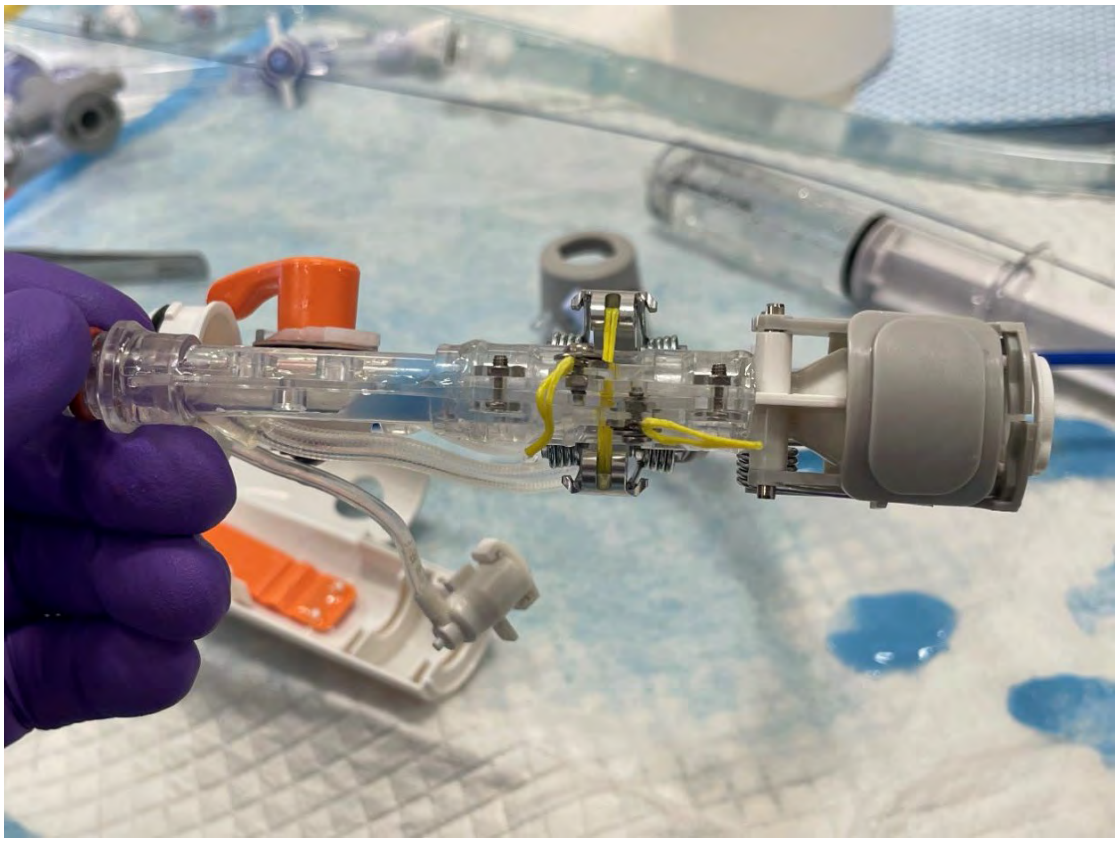
268. The hemostasis valves of the Symphony system practice the elements of claim 1, including the preamble, "[a] valve assembly comprising," as can be seen in Exhibit U. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle). Documentation for the Symphony system makes clear that the controller handles have a hemostasis valve, controlled by the buttons on the handles, as can be seen in the excerpts and the teardown photos below.



(Ex. A at 2.)



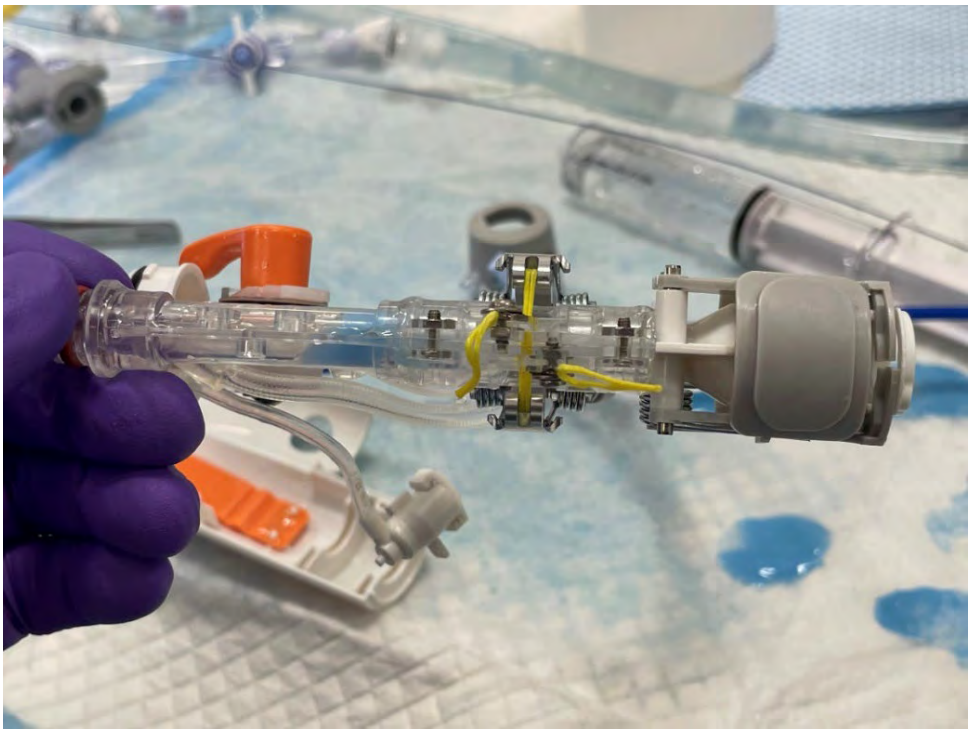
(Annotated Ex. A at 6.)



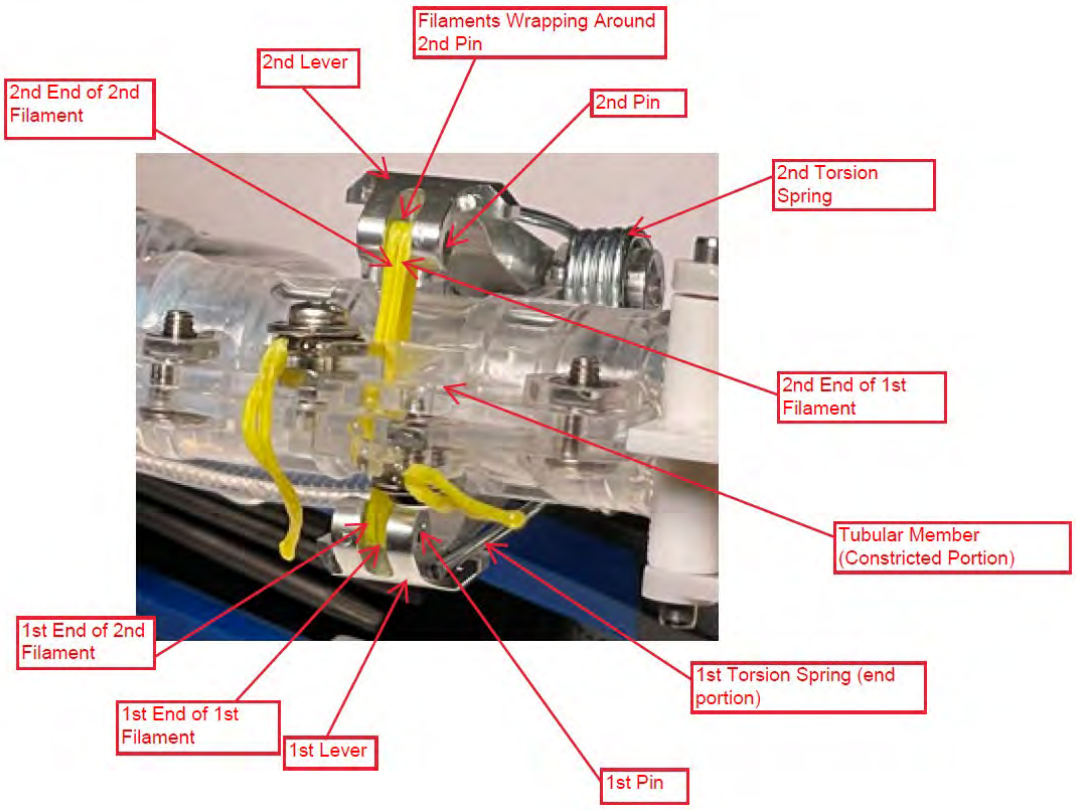
(Image of internal portion of housing with hemostasis valve.)

(Image of internal portion of housing zoomed in on hemostasis valve.)

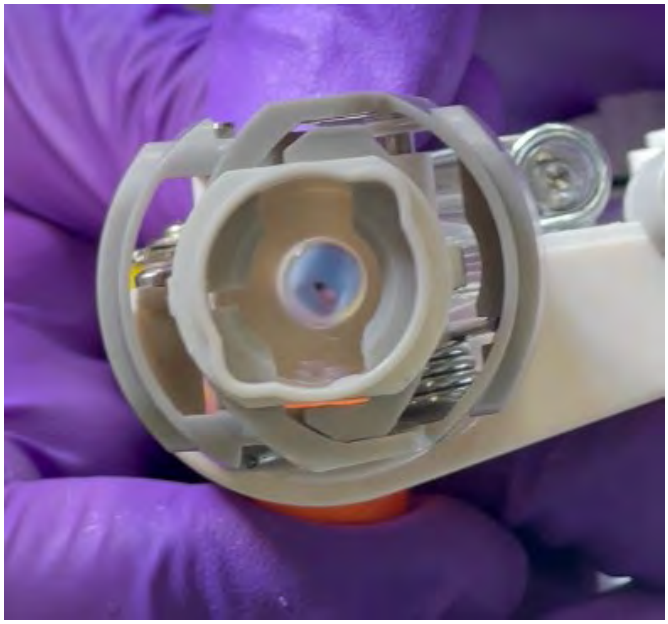
269. The Symphony system practices the limitations of claim 1, including "a tubular member defining a lumen," as can be seen in Exhibit U. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle) that include an elongate tubular member that defines a lumen, as can be seen in the teardown images below.



(Image of internal portion of housing with hemostasis valve.)

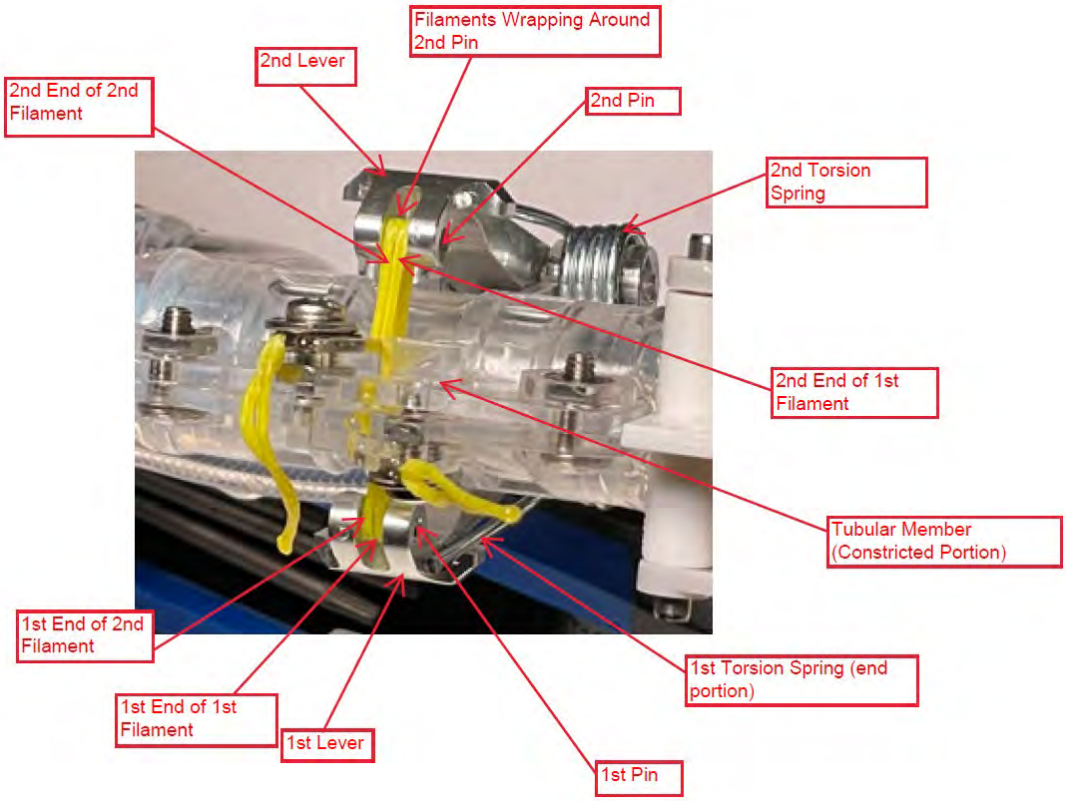


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

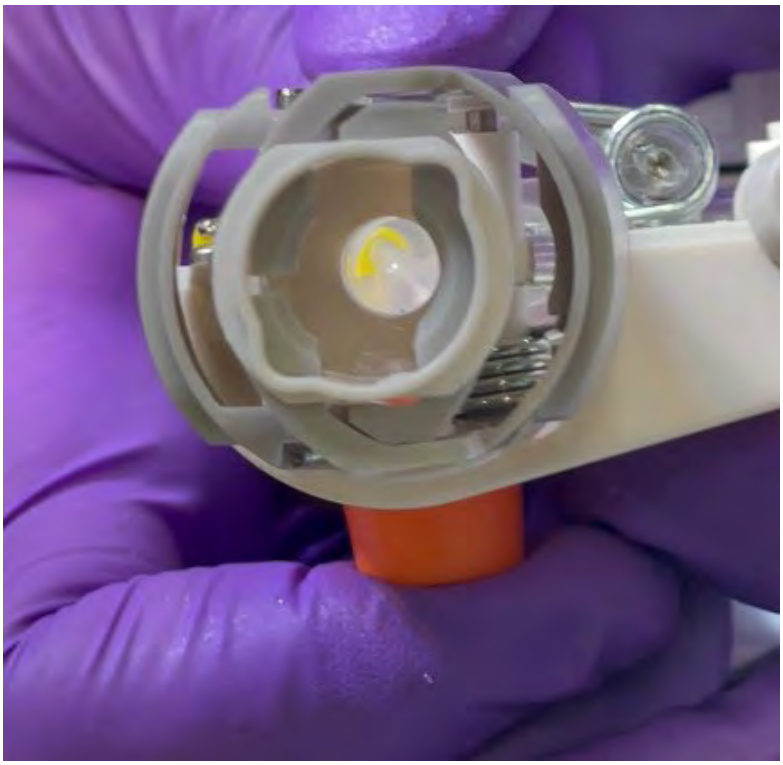


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

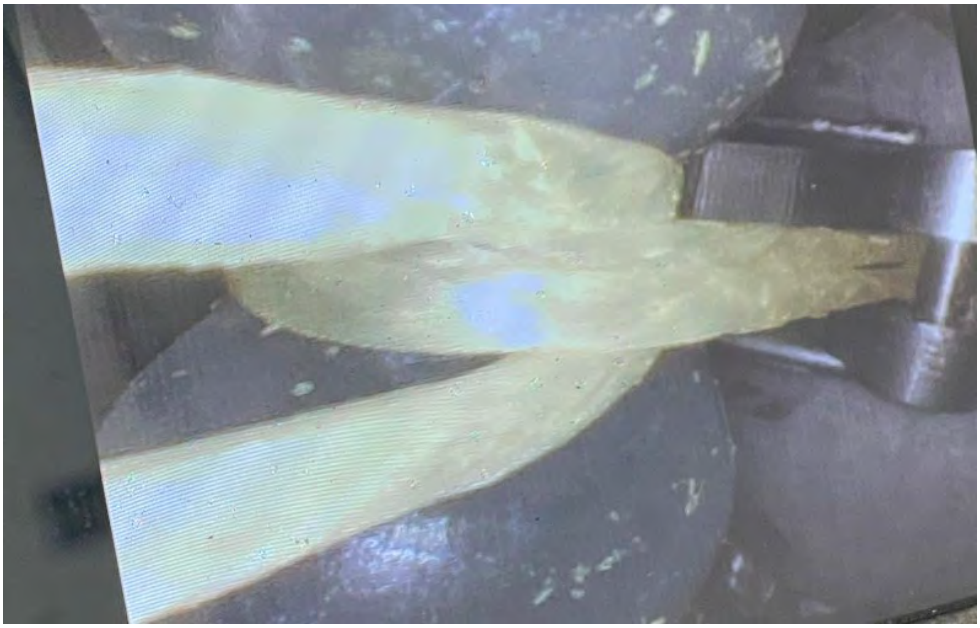
270. Thrombectomy with the Symphony system practices the limitations of claim 1, including "a first filament extending in a first loop around the tubular member, wherein the first filament is flexible," as can be seen in Exhibit U. Specifically, the controller handles of the Symphony system include a hemostasis valve with an active tensioning mechanism where a first and second button control first and second levers and first and second pins coupled to first and second lines (filaments) that loop around the valve's elongate tubular member defining a lumen, and the first and second filaments forming loops are flexible, as can be seen in the teardown images below. The first and second filaments are braided filament lines, which are flexible.



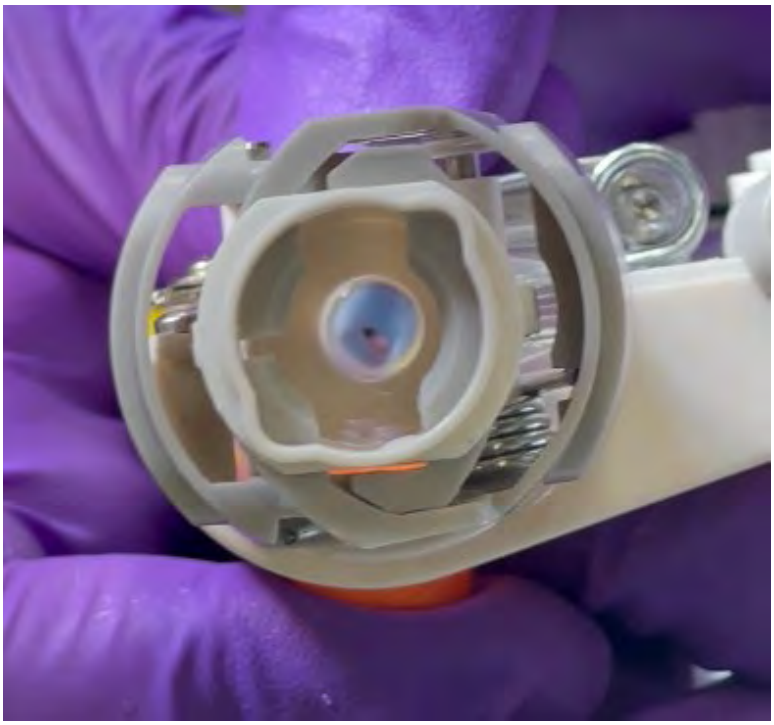
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

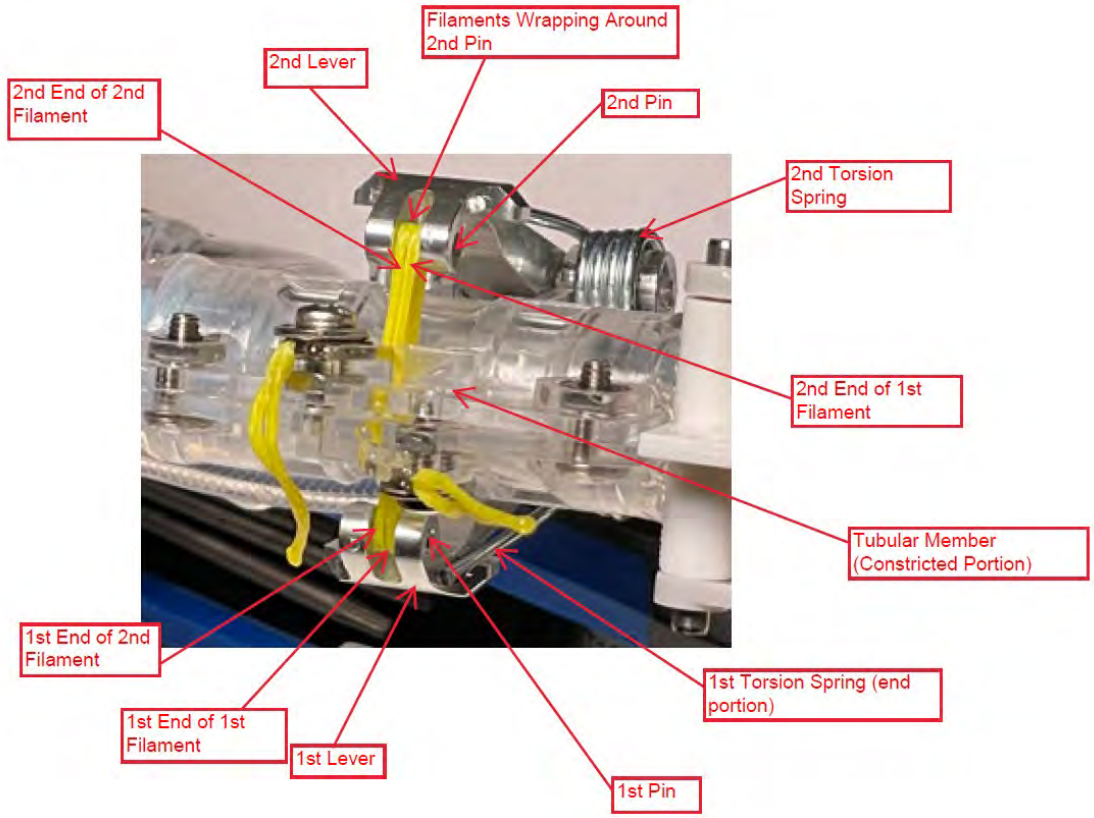


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

271. Thrombectomy with the Symphony system practices the limitations of claim 1, including "a second filament extending in a second loop around the tubular member, wherein the second filament is flexible," as can be seen in Exhibit U, and in the preceding limitation. The first and second filaments are braided filament lines, which are flexible.

272. The Symphony system practices the limitations of claim 1, including "a pair of actuators movable from a first position to a second position," as can be seen in Exhibit U. Specifically, the controller handles of the Symphony system include a hemostasis valve with an active tensioning mechanism with two actuators where a first and second button control first and second levers and first and second pins coupled to lines (filaments) that loop around the valve's elongate tubular member defining a lumen. The first actuator includes the first button/lever/pin to which the first ends of each of the first and the second filaments (lines) are wrapped around and the second actuator includes the second button/lever/pin to which the second ends of each of the first and the second filaments (lines) are wrapped around. The first and second actuators move between a first (undepressed button) position where the lumen of the valve is constricted

to a second (depressed button) position wherein the lumen is less constricted and at least partially open, as can be seen in the teardown images below.



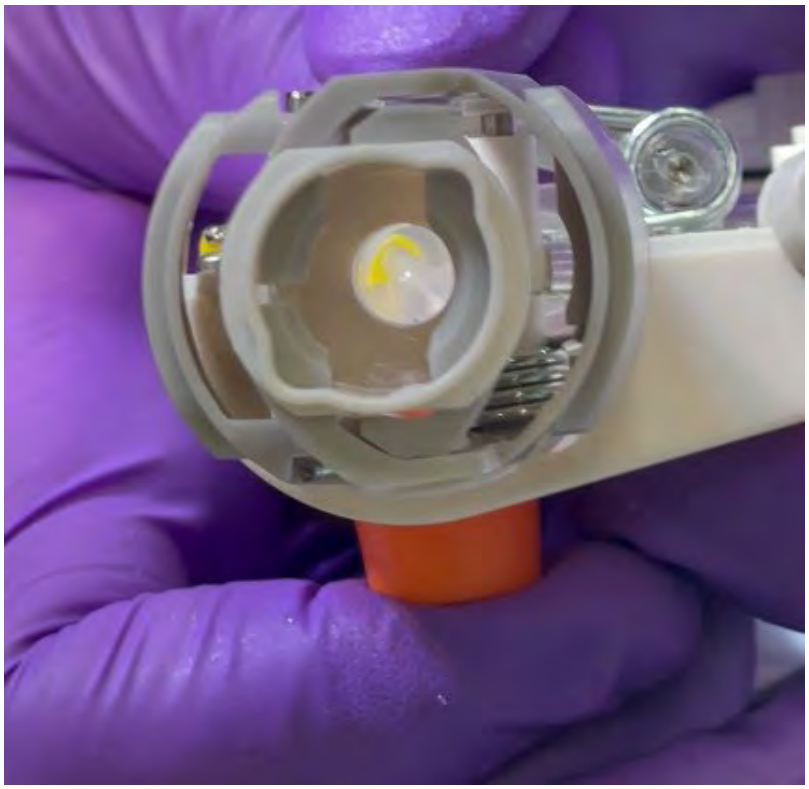
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

273. The Symphony system practices the limitations of claim 1, including "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," as can be seen in Exhibit U. Specifically, as can be seen in the teardown image above, the first end portion of the first filament is coupled to and acted upon by the first actuator (button/lever/pin), and the second end portion of the first filament is coupled to and acted upon by the second actuator (button/lever/pin).

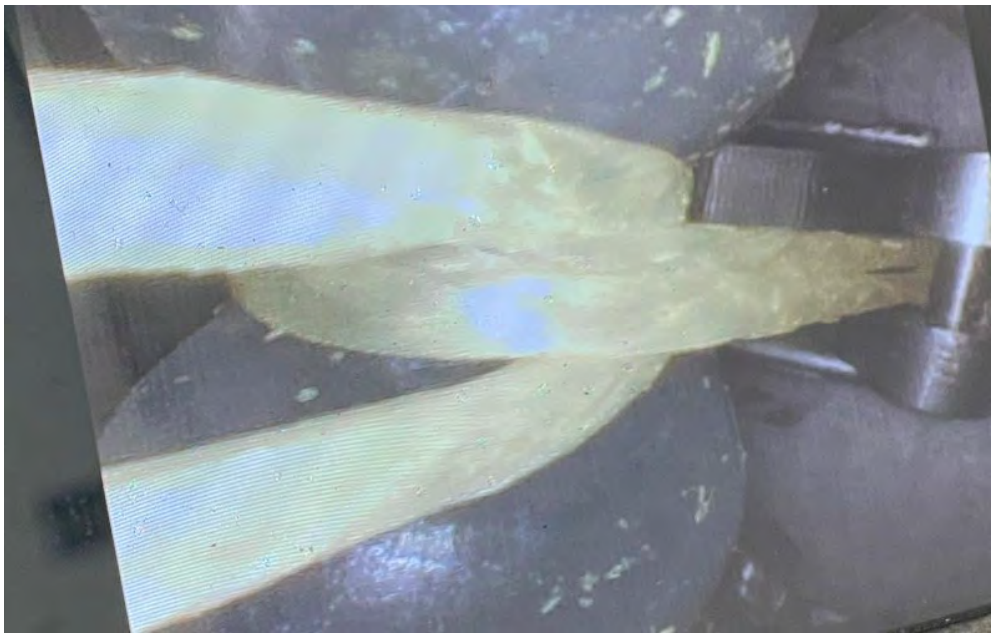
274. The Symphony system practices the limitations of claim 1, including "a second filament includes a first portion operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators," as can be seen in Exhibit U. Specifically, as can be seen in the teardown image above, the first end portion of the second filament is coupled to and acted upon by the first actuator (button/lever/pin), and the second end

portion of the second filament is coupled to and acted upon by the second actuator (button/lever/pin).

275. The Symphony system practices the limitations of claim 1, including "in the first position, the actuators are positioned to tension the first filament and the second filament thereby decreasing the dimension of the first loop and a dimension of the second loop to constrict the lumen of the tubular member," as can be seen in Exhibit U. Specifically, when the actuators are in the first (undepressed buttons) position, the actuators tension the first filament and the second filament, decreasing the dimension of the first loop in the first filament and the second loop in the second filament to constrict the tubular member, as can be seen in the teardown images below.

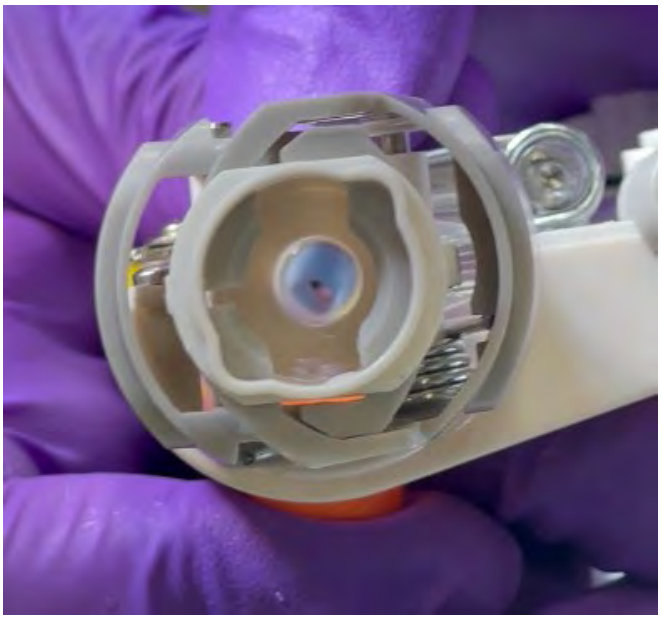


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



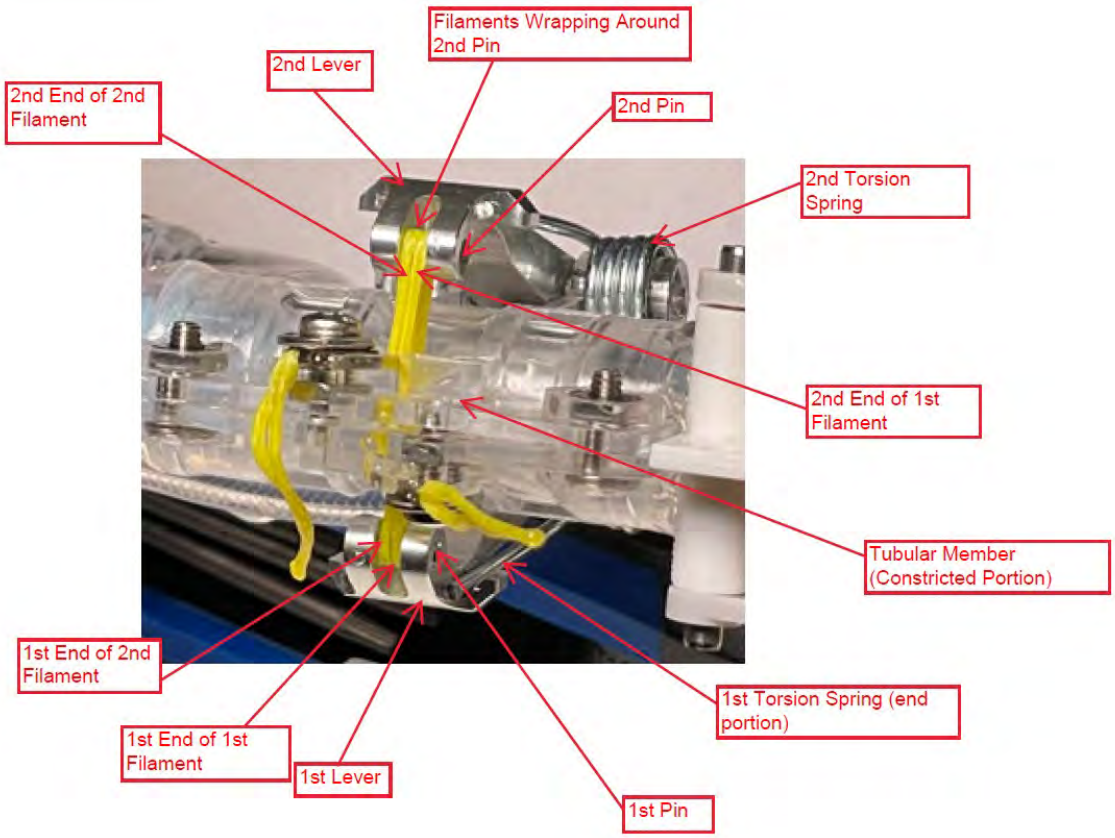
(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

276. The Symphony system practices the limitations of claim 1, including "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," as can be seen in Exhibit U. Specifically, when the actuators are in the second (depressed buttons) position, the actuators push and loosen tension on the first filament and the second filament, allowing the dimension of the first loop in the first filament and the second loop in the second filament to increase and at least partially open the tubular member, as can be seen in the teardown images below.

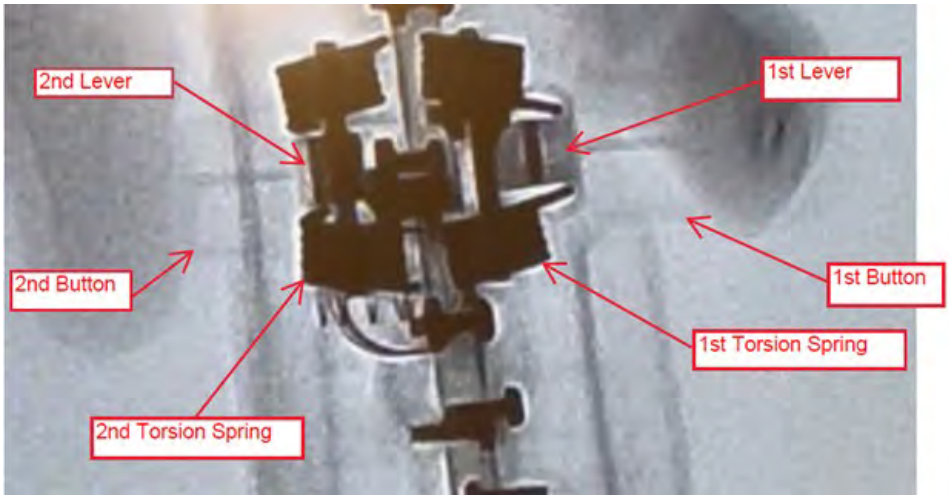


(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve open.)

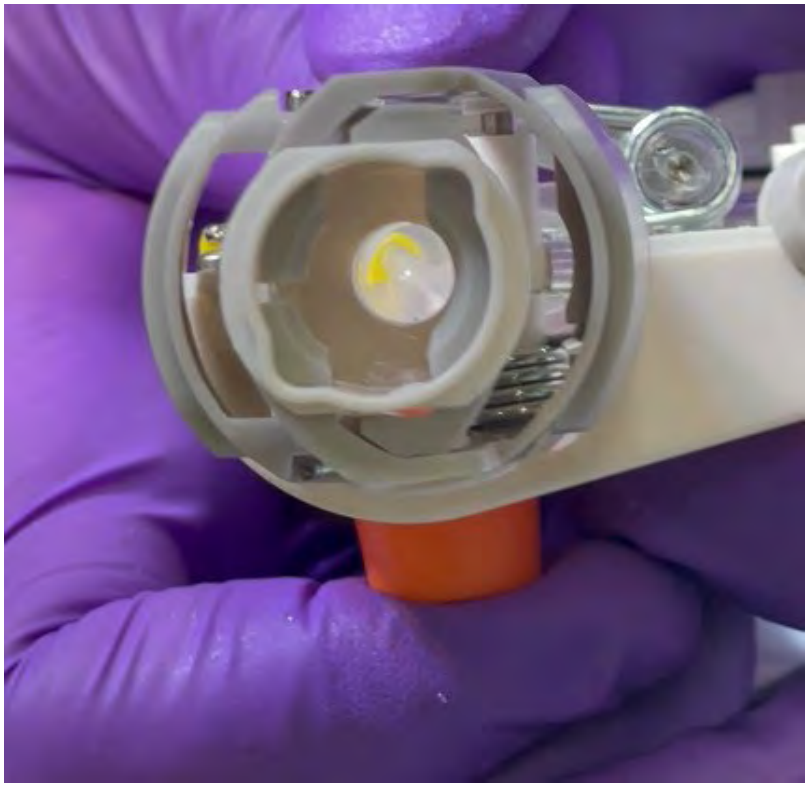
277. The Symphony system practices the limitations of claim 1, including "the actuators are biased to the first position," as can be seen in Exhibit U. Specifically, the first and the second actuators are driven outward/biased to the first (constricted, undepressed button) position by first and second sets of torsion springs that drive the first lever and the second lever outward, as can be seen in the teardown images below.



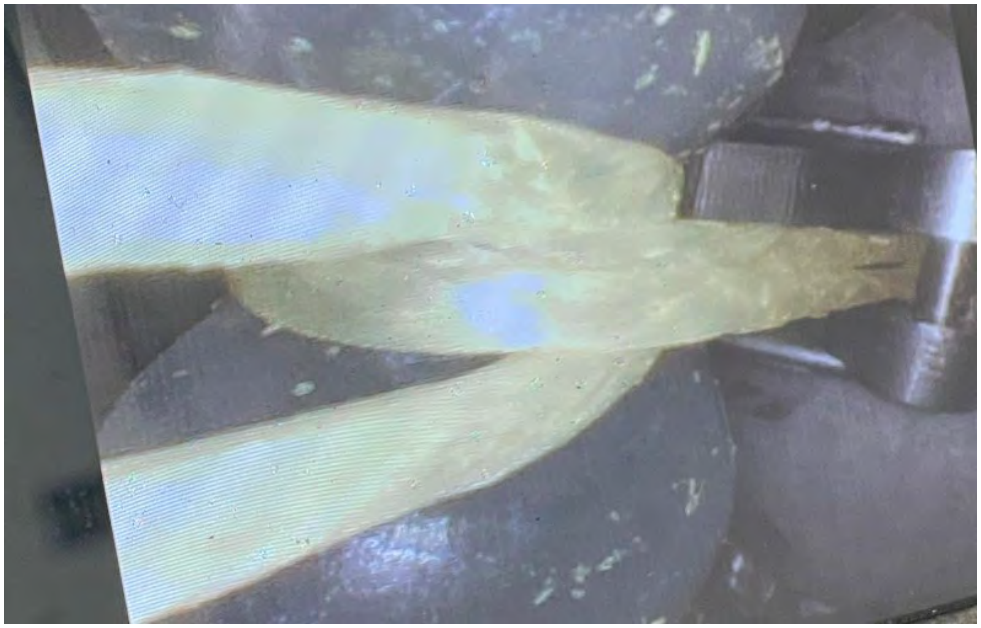
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs.)

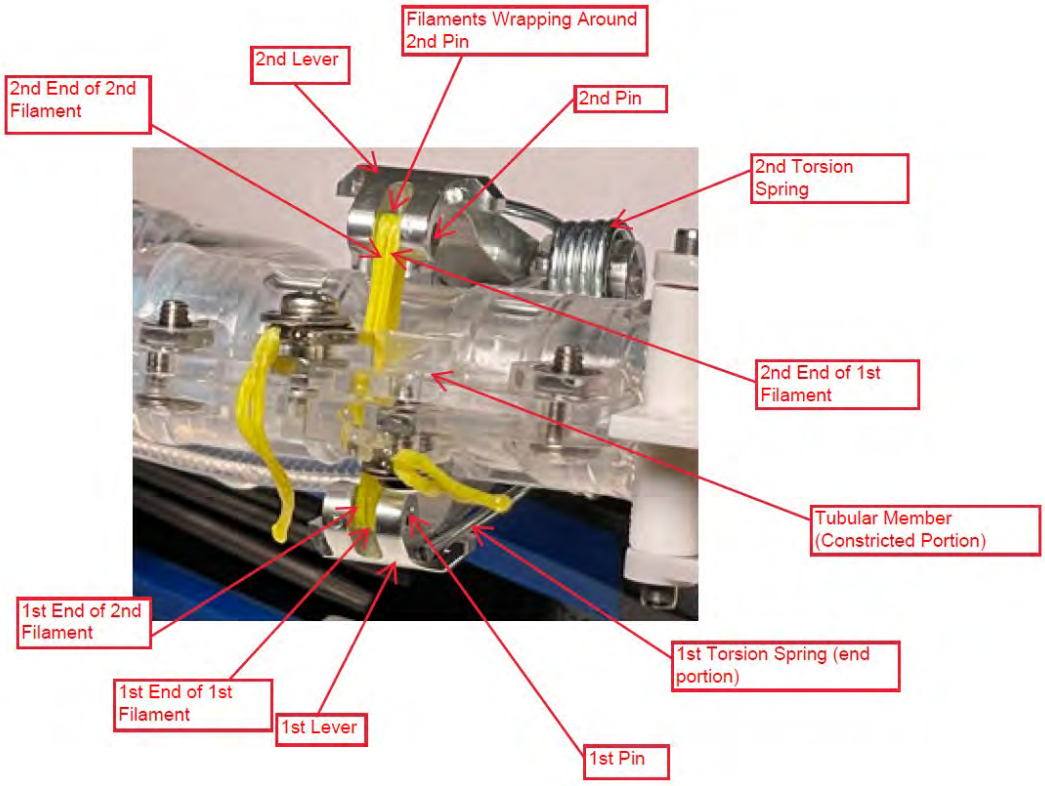


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

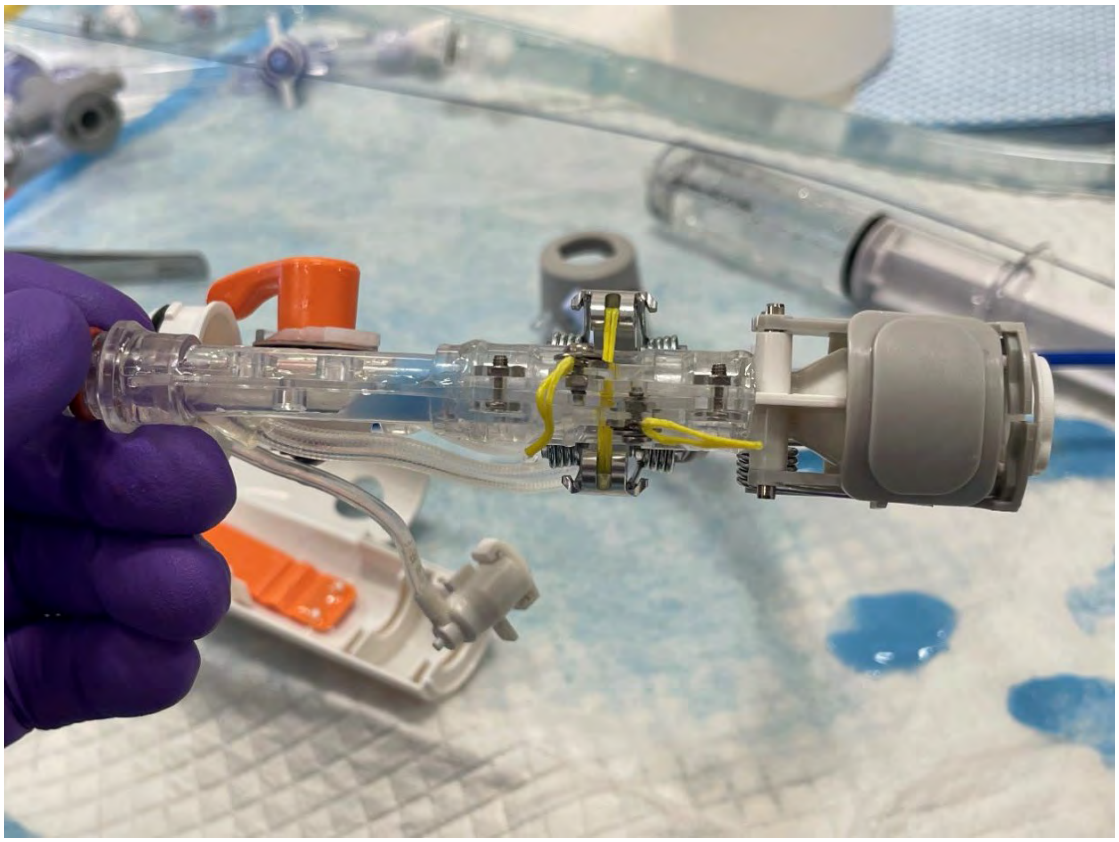


(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

278. Thrombectomy with the Symphony system practices the limitations of claim 3, including "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," as can be seen in Exhibit U. Specifically, the first end portions of the first and second filaments are wrapped around and acted upon by the first actuator, as can be seen in the teardown images below.



(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Image of internal portion of housing with hemostasis valve.)

(Image of internal portion of housing zoomed in on hemostasis valve.)

279. Thrombectomy with the Symphony system practices the limitations of claim 3, including 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," as can be seen in Exhibit U. Specifically, the second end portions of the first and second filaments are wrapped around and acted upon by the second actuator, as can be seen in the teardown images above.

280. Defendant directly infringes claims of the '384 Patent, including claims 1 and 3, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures using the hemostasis valves) Symphony system products.

281. Defendant induces infringement of claims of the '384 Patent, including claims 1 and 3, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony products that practice claims 1 and 3. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

282. Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels…. The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding method of using the Truvic Symphony system,

including on information and belief, methods of treating thrombi and emboli.

283. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the ’384 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

284. At a minimum, Defendant has notice of the ’384 Patent through the filing of the Second Amended Complaint. On information and belief, Defendant has had knowledge of the ’384 Patent via monitoring and investigation of Inari’s patent portfolio, including in response to the notice letters provided by Inari regarding many other patents, including family members of the ’384 Patent.

285. Defendant has continued its infringing activities after the ’384 Patent issued, despite knowledge of the ’384 Patent (including from the Second Amended Complaint), and such infringement has been and continues to be egregious and willful.

286. Defendant’s infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 10: INFRINGEMENT OF THE ’669 PATENT

287. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

288. The ’669 Patent, titled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods,” is part of the same family as the ’580 Patent and shares the same specification. The ’669 Patent discloses improved clot-removing devices for intravascular treatment of clot materials that solve problems with prior art clot-removal devices and methods. The ’669 Patent solves these problems through its inventions and combination of inventions that include, for example, a vacuum source that is coupled to both an elongated shaft, *e.g.*, a catheter, and a filter chamber via a flow controller and a first fluid path. (Ex. L at cl. 15.) The filter chamber includes a housing and filter, where the housing further includes a first port coupled to the catheter and a second port coupled to the vacuum source, and the filter is in the

housing along a first fluid path that includes a flow controller to couple the filter chamber and catheter. (*Id.*) A hemostasis valve is coupled to the catheter along a second fluid path that is at least partially different than the first, where the hemostasis valve inhibits flow along the second path when an interventional device is inserted. (*See id.*, Fig. 10, 3:53-4:3.)

289. The ’669 Patent further solves problems in the art through a filter chamber, or clot reservoir container, having a removable filter. (*E.g.*, *id.* at Fig. 3B, Fig. 3C, cl. 22.) The ’669 Patent teaches that the filter chamber/clot reservoir and filter capture clot material within a housing, while filtered blood is allowed to flow through. (*Id.* at Fig. 3A, Fig. 3B, Fig. 3C, 8:60-9:60.) A filter that is removable from within the housing allows the treating physician to visualize the captured clot material to help determine whether additional passes are necessary and to remove clot that has been collected by removing and emptying the filter housing. (*Id.*) As disclosed in other Inari patents, filtered blood can also be reintroduced to the patient’s vasculature.

290. Defendant directly infringes and indirectly infringes—literally and/or under the doctrine of equivalents—at least claim 15 of the ’669 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

291. Specifically, claim 15 of the ’669 Patent recites:

> [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.

292. The Truvic Symphony system practices each limitation of at least claim 15 of the '669 Patent, as can be seen in the '669 Patent claim chart, attached as Exhibit V.

293. To the extent the preamble of claim 15 is construed to be limiting, the Symphony system practices the requirements of the preamble, "[a]n aspiration system, comprising," as can be seen in Exhibit V. For example, according to Truvic's Symphony Brochure, the Symphony system allows for "[p]owerful, focused Aspiration" that "[m]aximize[s] thrombus removal with high-powered, on-demand, continuous aspiration and in-hand TruView™ clot capture." (Ex. A at 2.) The Symphony Instructions for Use further states that "[t]he Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. The Symphony ProHelix may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter." (Ex. B at 1.) In addition, Symphony's product website includes a video detailing a method of using the Symphony system to treat clot material within a blood vessel of a human patient using vacuum aspiration. (*See* https://www.truvic.com/symphony-product.)

294. The Symphony system practices the limitations of claim 15, including "a vacuum source," as can be seen in Exhibit V. In the Symphony system, the 24F and/or 16F controller handles (shown in an optional telescoping configuration below) are coupled to a Truvic Generator and Truvic Canister, or another pressure source, which is a vacuum source.

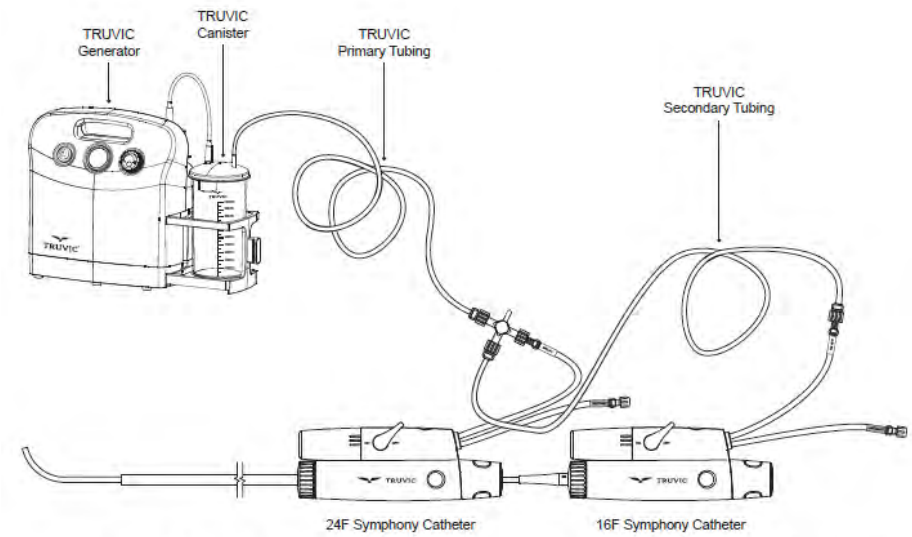


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

295. Symphony's product website includes a video detailing a method of using the Symphony system to treat clot material within a blood vessel of a human patient using the Truvic Generator and Truvic Canister as a vacuum source. (*See* https://www.truvic.com/symphony-product.)

296. The Symphony system practices the limitations of claim 15, including "a catheter fluidically coupled to the vacuum source via a first fluid path," as can be seen in Exhibit V. Specifically, as can be seen in the images from page 8 of the IFU below, the Symphony system includes a catheter coupled to the Truvic Generator and Truvic Canister via the first fluid path through the Symphony system 16F and/or 24F handles (the BigShot Controller Handles).

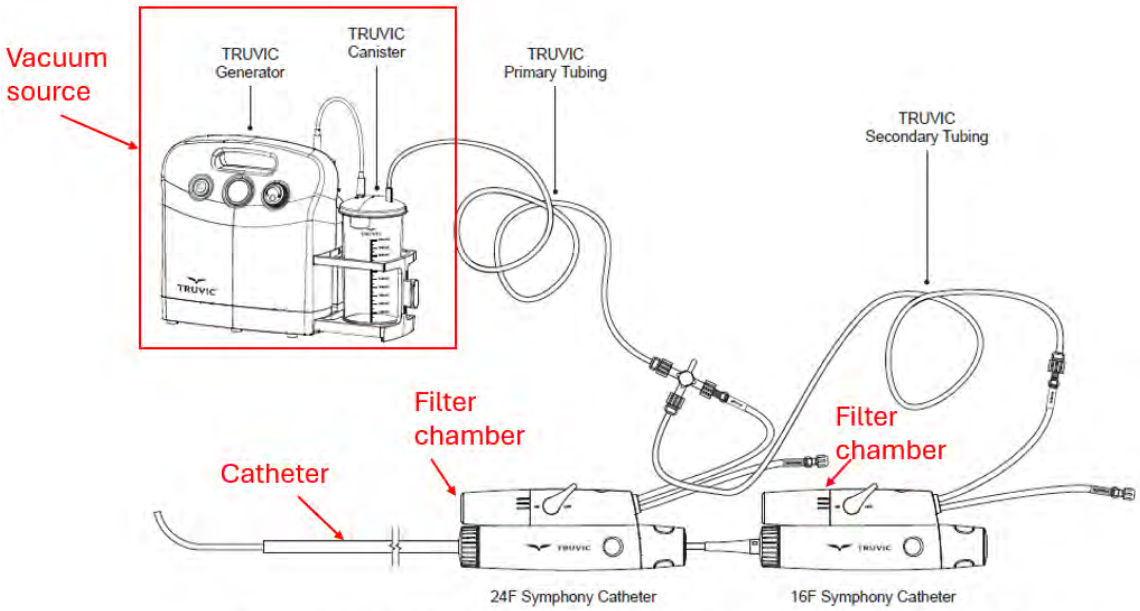
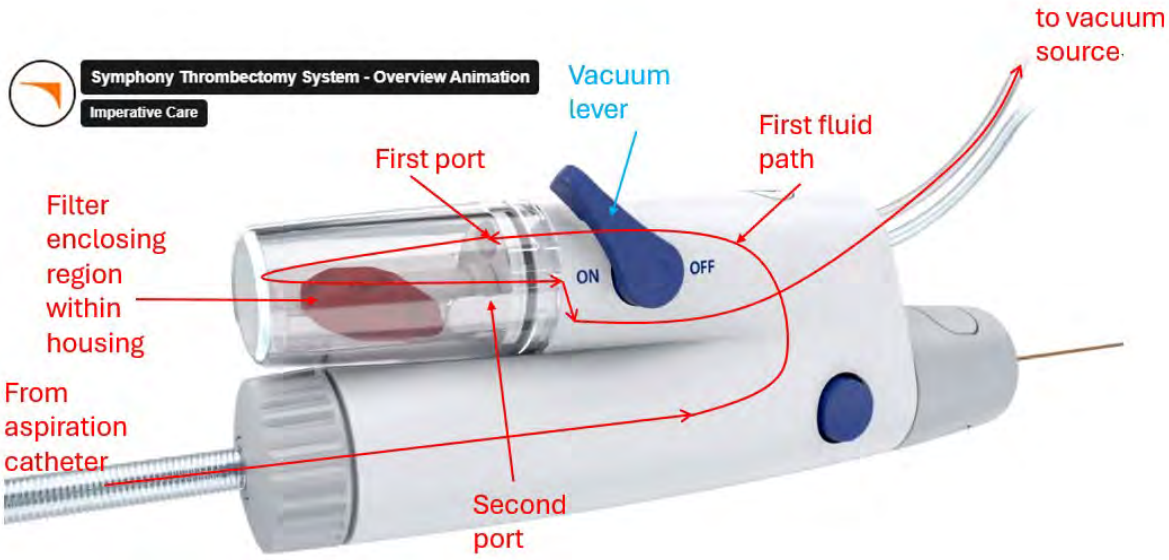
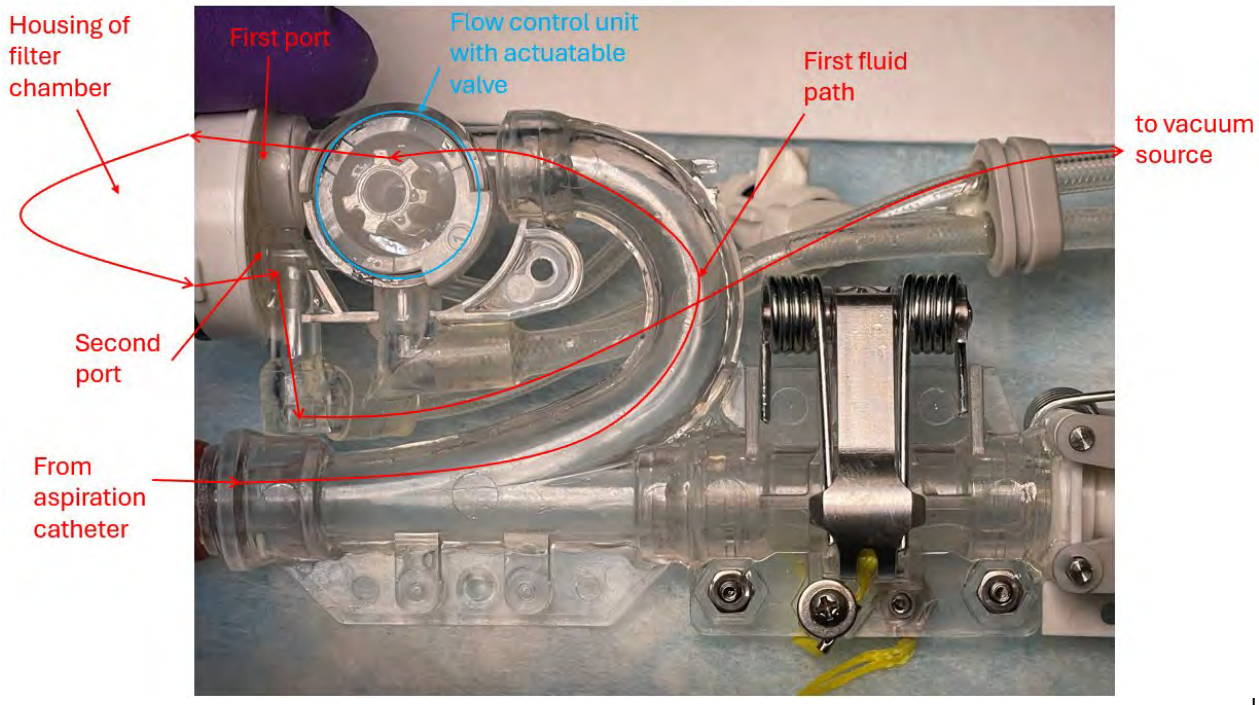


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Ex. B at 8 (annotated) (showing a telescoping configuration).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57 (https://www.truvic.com/symphony-product).)



(Annotated image of internal portion of controller handle housing with flow path.)

297. The Symphony system practices the limitations of claim 15, including "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," as can be seen in Exhibit V. Specifically, as can be seen from the images above and from page 4 of the IFU below, the Symphony system handle has a clot container with a filter chamber coupled to the Truvic Generator and Truvic Canister and the aspiration catheter that captures and filters clot material from blood during thrombectomy.

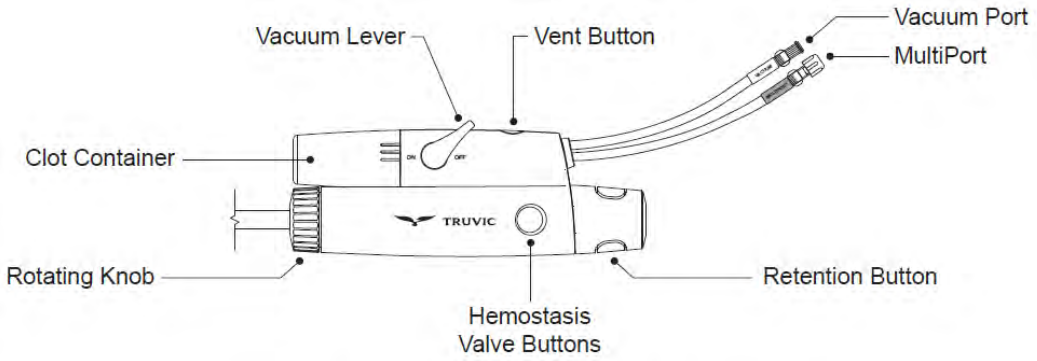


Figure 3: Symphony Catheter Handle, labeled

(Ex. B at 4.)

298. As can be seen from the images from page 8 of the IFU below, the Symphony system includes a filter chamber along the first fluid path that is spaced apart from the Truvic Generator and Truvic Canister (*e.g.*, vacuum source).

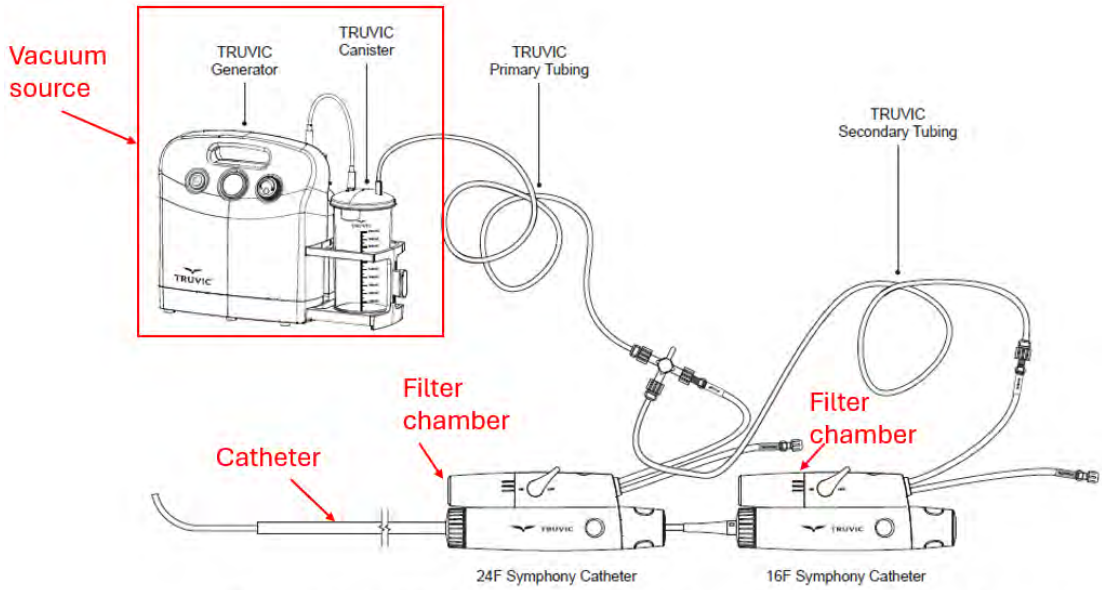
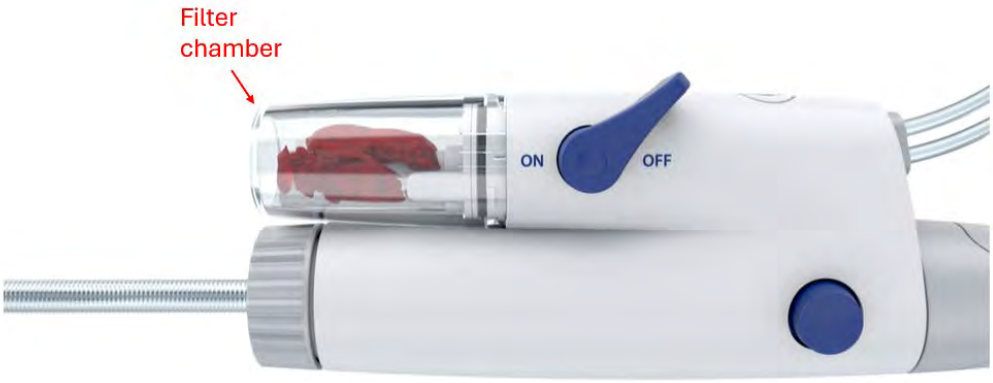


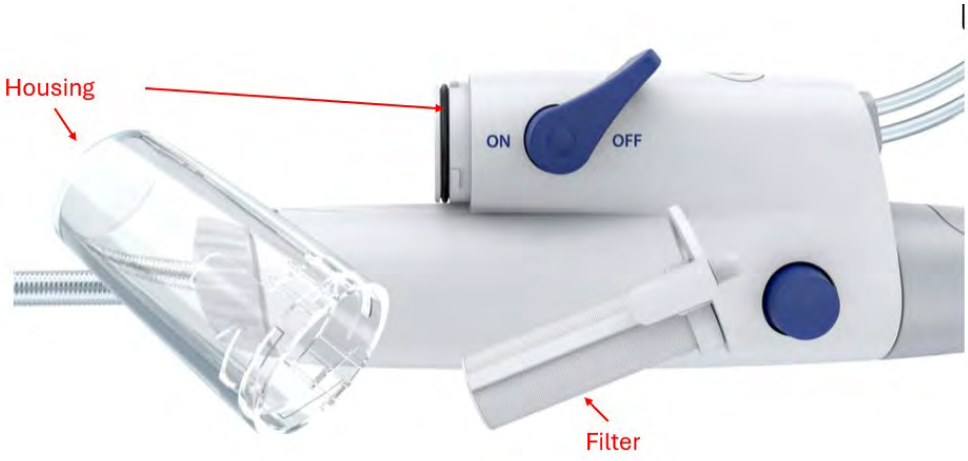
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Ex. B at 8 (annotated).)

299. As can be further seen from the annotated images from the Symphony video below, the Symphony system includes a filter chamber that has a housing and a filter within it.

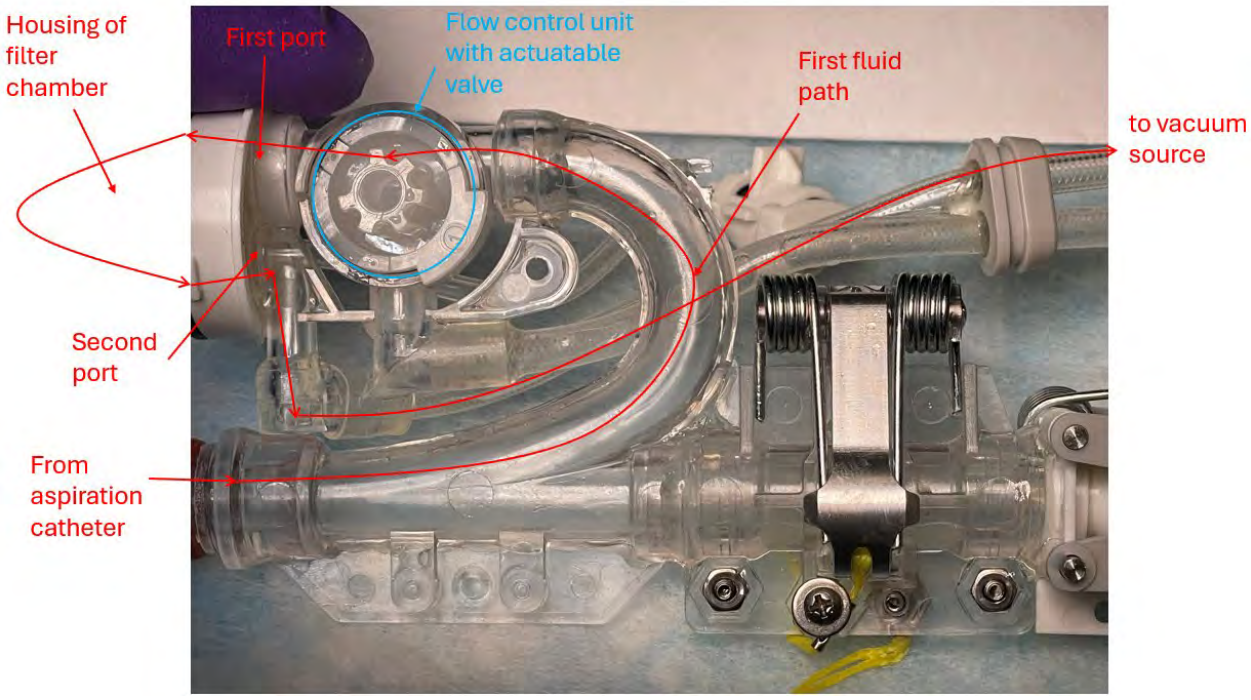


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:15 (https://www.truvic.com/symphony-product).)



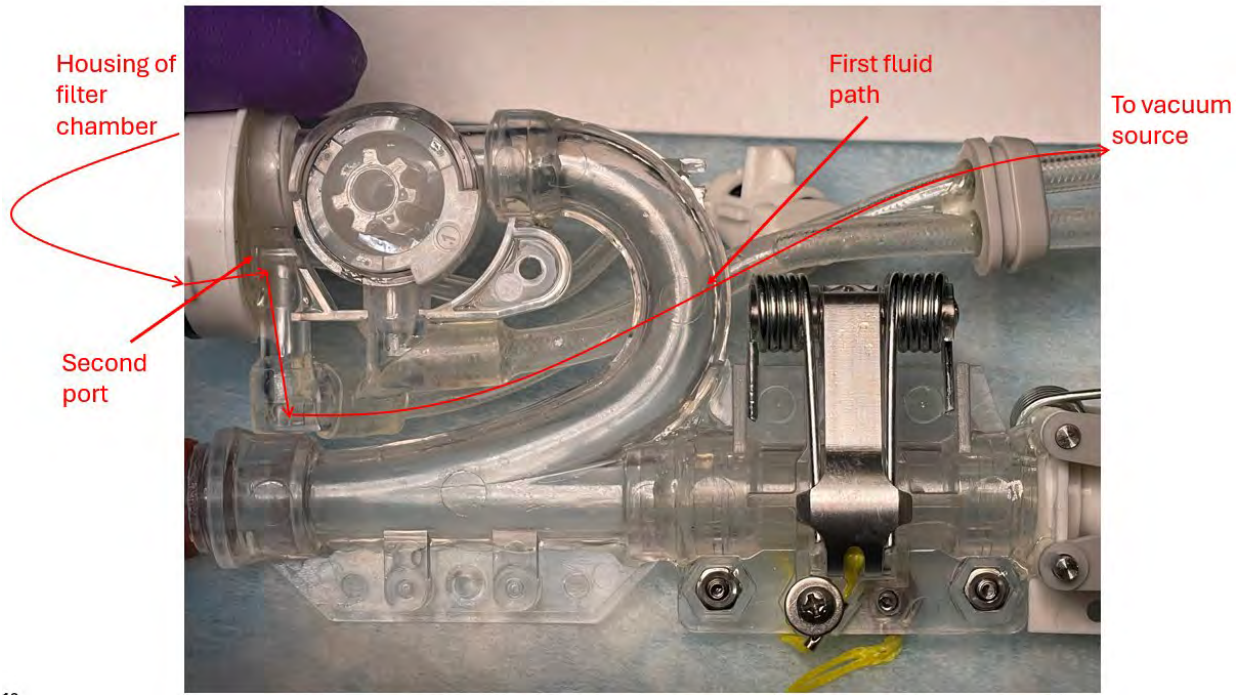
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

300. The Symphony system practices the limitations of claim 15, including "wherein the housing includes—a first port configured to be fluidically coupled to the catheter," as can be seen in Exhibit V. Specifically, the clot canister of the Symphony system includes a first port that is fluidly connected to the aspiration catheter, as shown in the teardown image below.



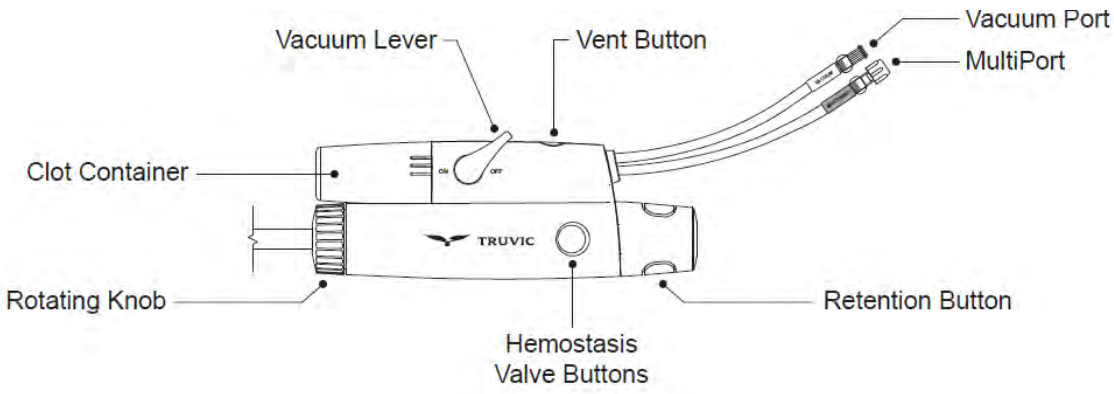
(Annotated image of internal portion of controller handle housing).

301. The Symphony system practices the limitations of claim 15, including "wherein the housing includes—…a second port configured to be fluidically coupled to the vacuum source," as can be seen in Exhibit V. Specifically, the clot canister of the Symphony system includes a second port that is fluidly connected to the Truvic Generator and Truvic Canister (*e.g.*, vacuum source), as shown in the teardown image below.



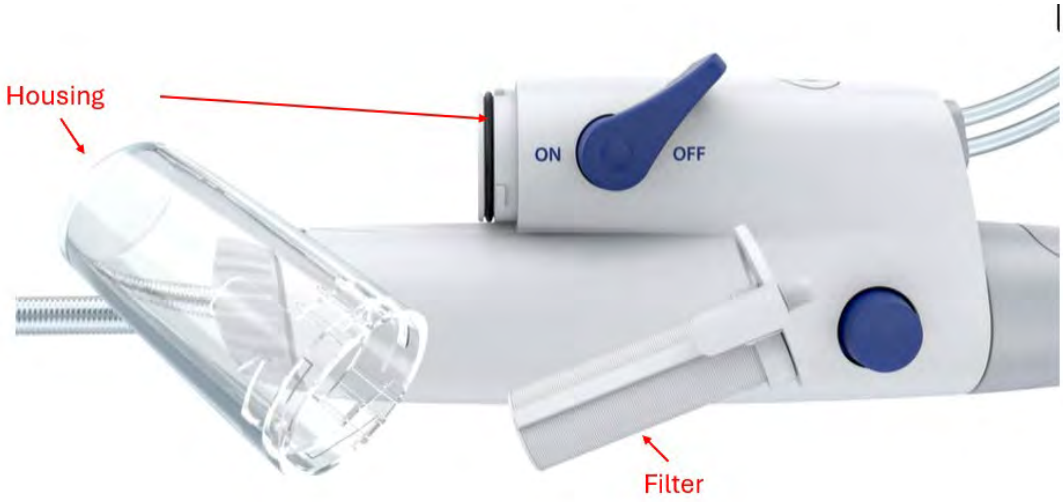
(Annotated image of internal portion of controller handle housing).

302. As can be seen from the images from page 4 of the IFU below, the Symphony system includes a vacuum port that fluidly connects the housing and vacuum source.



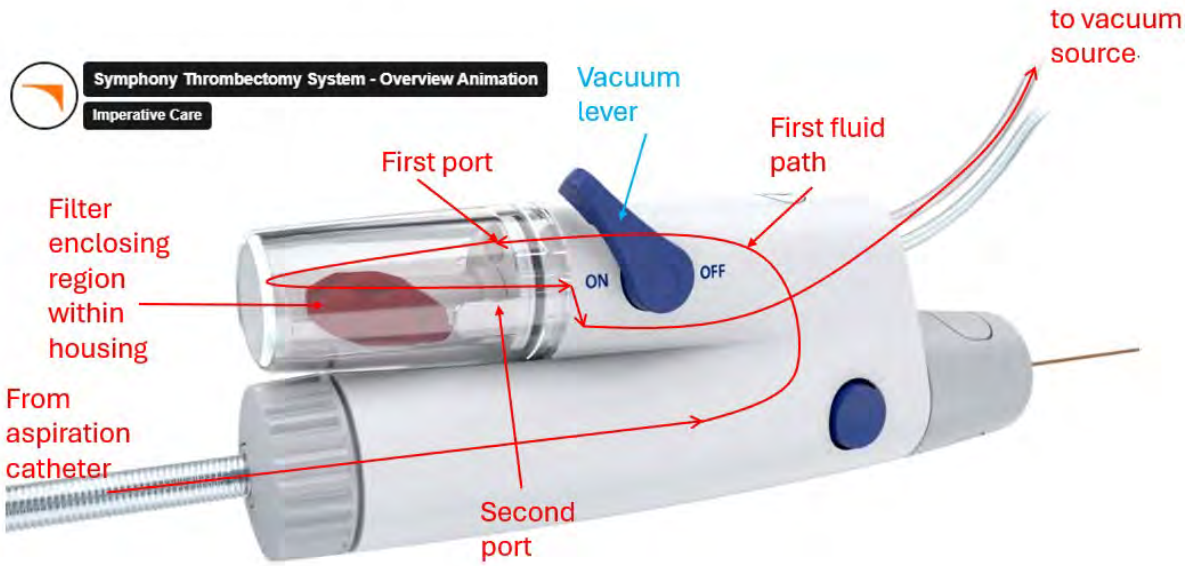
(Ex. B at 4.)

303. Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 15, including "wherein the filter is in the housing along the first fluid path between the first port and the second port," as can be seen in Exhibit V. Specifically, the clot canister of the Symphony system includes a removable filter that is along the first fluid path between the first port that fluidly couples the catheter and the second port that fluidly couples the vacuum source, as shown in the annotated images from the Symphony video below. The housing of the Symphony product receives the clot and blood from the human patient via the first port fluidly coupled to aspiration catheter, where the blood is filtered out of the housing via the second port that is fluidly coupled to the vacuum source.



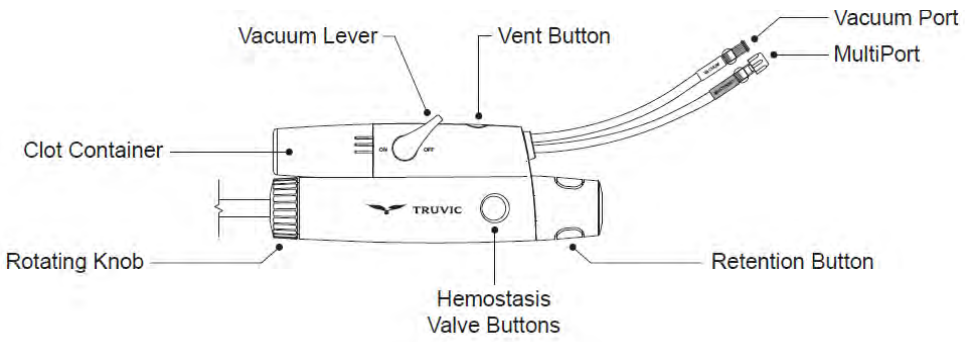
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57 (https://www.truvic.com/symphony-product).)

304. The filter contained within the housing is along the first fluid path.

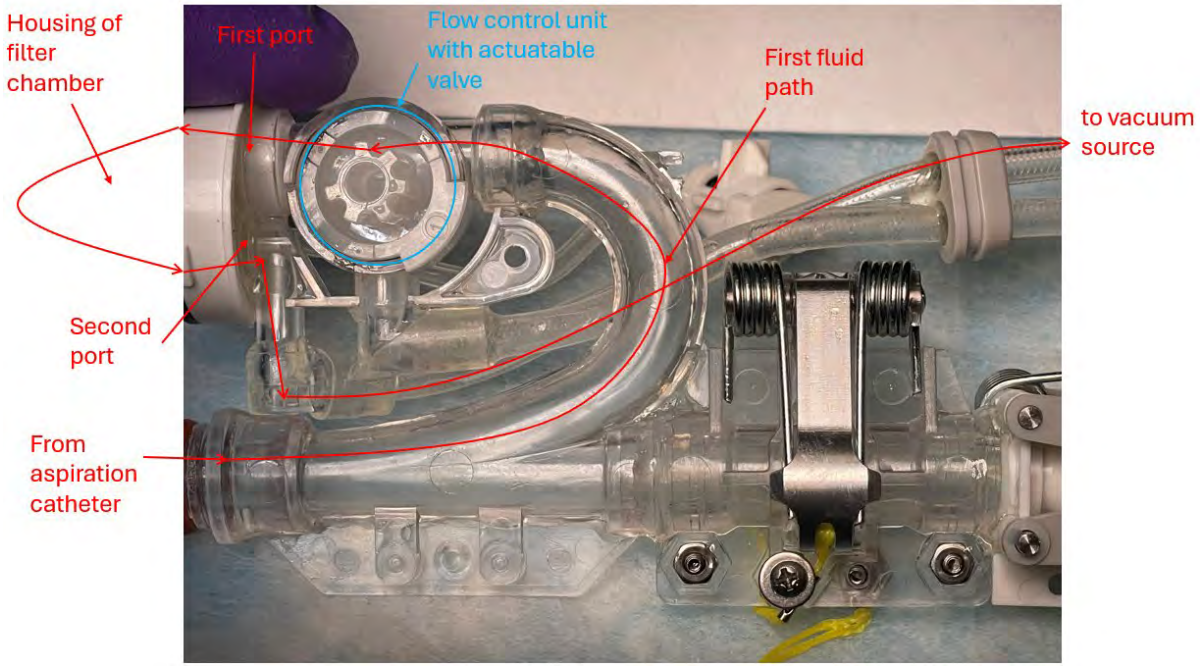


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https:www.truvic.com/symphony-product).)

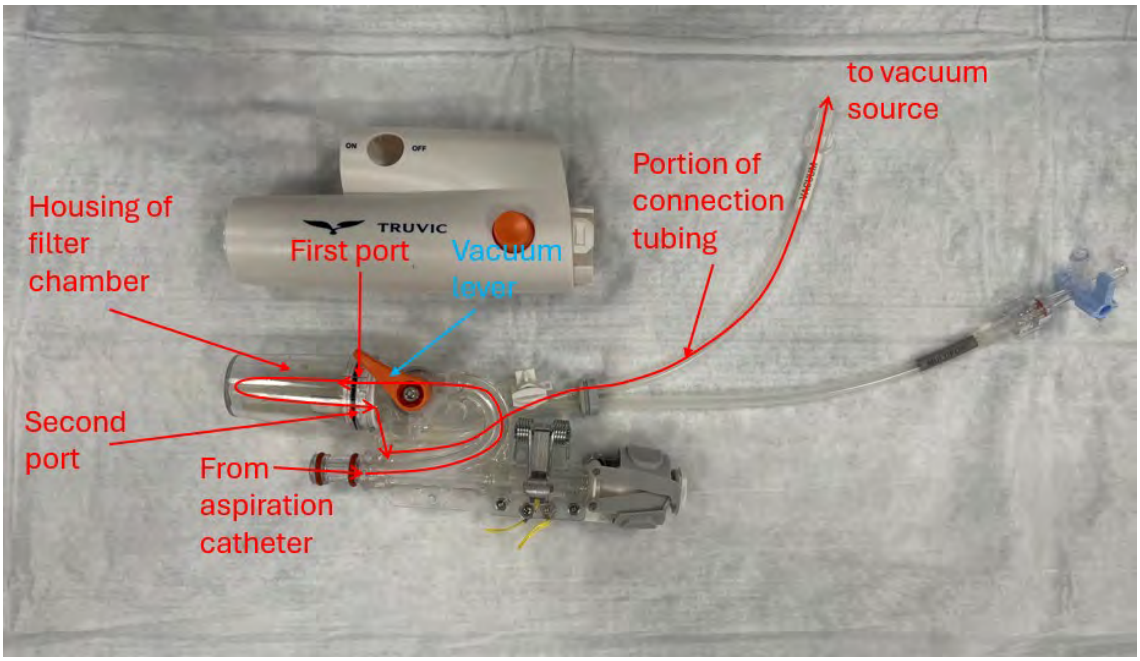
305. The Symphony system practices the limitations of claim 15, including "a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter," as can be seen in Exhibit V. Specifically, as can be seen from the images from page 4 of the IFU below the Symphony system handle includes a vacuum control valve and vacuum lever (*e.g.*, flow controller).



(Ex. B at 3.) As can be seen from the teardown image below, the flow controller is along the first fluid path and couples the filter chamber to the aspiration catheter.



(Annotated image of internal portion of controller handle housing.)

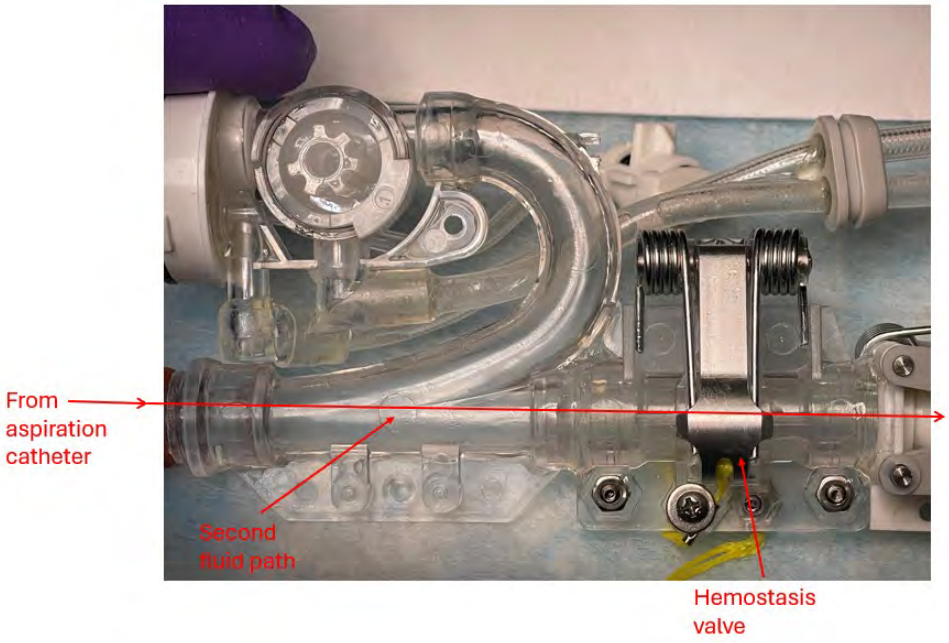


(Annotated image of internal portion of the controller housing with vacuum lever.)

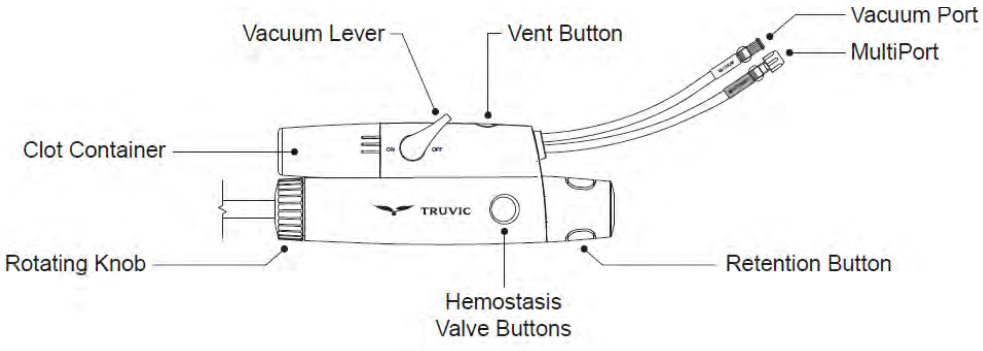
306. As shown in the Symphony system animation video, when the vacuum lever is moved to an "On" position, the clot flows from the human patient, through the aspiration catheter along the first flow path to the housing of the filter chamber.

(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:55 (https:www.truvic.com/symphony-product).)

307. The Symphony system practices the limitations of claim 15, including "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," as can be seen in Exhibit V. Specifically, as can be seen from the IFU and the teardown image below, the hemostasis valve of the Symphony system is fluidically coupled to the aspiration catheter along a second fluid path, that is at least partially different than the first fluid path (e.g., the portion of the second fluid path running from the hemostasis valve toward the aspiration catheter).



(Annotated image of internal portion of controller handle housing.)



(Ex. B. at 4)

308. The IFU teaches that the ProHelix device (the interventional device) can be inserted through the hemostasis valve and the catheter to reach the clot, demonstrating that the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second path (through the hemostasis valve) when an interventional device, such as a ProHelix is inserted through the valve and to the catheter.

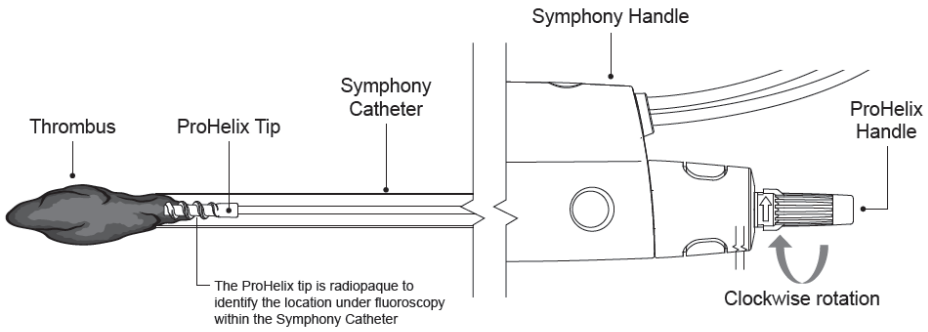


Figure 4: ProHelix engaged with thrombus

(Ex. B at 5.) Moreover, the buttons for the hemostasis valve on the 24F or 16F Symphony handle are configured to be pushed to release the hemostasis valve and then to advance a device, for example a ProHelix device (the interventional device), over the guidewire to the clot. (Ex. B at 5 ("Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle."), 6 ("During ProHelix movement, press the Hemostasis Valve buttons on the Handle to reduce friction.").) The buttons are configured to be released to seal the valve around the inserted device, such as a ProHelix, so that the Symphony hemostasis valve inhibits fluid flow along the second fluid path by clamping down on the inserted ProHelix device.

309. Defendant directly infringes claims of the '669 Patent, including claim 15, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures) Symphony system products, such as with a ProHelix device.

310. Defendant induces infringement of claims of the '669 Patent, including claim 15, by selling Symphony systems and teaching or directing others, including physicians, to use the

Symphony products that practice claim 15. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

311. Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels…. The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding method of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

312. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system, knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '669 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

313. At a minimum, Defendant has notice of the '669 Patent through the filing of the Second Amended Complaint. On information and belief, Defendant has had knowledge of the '669 Patent via monitoring and investigation of Inari's patent portfolio, including in response to the notice letters provided by Inari regarding many other patents, including family members of the '669 Patent.

314. Defendant has continued its infringing activities after the '669 Patent issued, despite knowledge of the '669 Patent (including from the Second Amended Complaint), and such infringement has been and continues to be egregious and willful.

315. Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 11: INFRINGEMENT OF THE 12-'333 PATENT

316. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

317. The 12-'333 Patent, titled "Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods," is part of the same family as the '580 Patent and '669 Patent and shares the same specification. The 12-'333 Patent discloses improved clot-removing devices for intravascular treatment of clot materials that solve problems with prior art clot-removal devices and methods. The 12-'333 Patent solves these problems through its inventions and combination of inventions that include, for example, a clot collection reservoir with a partially transparent housing that defines a chamber, a first port connected to a catheter, and a second port connected to an aspiration source that generates negative pressure in the chamber, where the chamber includes a filter. Ex. W at cl. 1. The filter is substantially cylindrical and prevents clot material and not the blood (drawn in through the catheter) from passing through the filter body and out through the second port. *Id.* The 12-'333 Patent teaches that a transparent housing allows the doctor to see the clot material so they can at least partially determine whether additional passes with an interventional device are needed to remove more clot material. *Id.* at 9:57-64.

318. The 12-'333 Patent further solves problems in the art through a clot reservoir container with a removable filter. *E.g.*, *id.* at Fig. 3B, Fig. 3C, cl. 1. The 12-'333 Patent teaches that the filter chamber/clot reservoir and filter capture clot material within a housing, while filtered blood is allowed to flow through. *Id.* at Fig. 3A, Fig. 3B, Fig. 3C, 9:40-64. This also allows the treating physician to visualize the captured clot material to help determine whether additional passes are necessary and to remove clot material that has been collected by removing and emptying the filter housing. *Id.* As disclosed in other Inari patents, the filtered blood can also be reintroduced to the patient's vasculature to further mitigate blood loss during procedures.

319. Defendant directly and indirectly infringes—literally and/or under the doctrine of

equivalents—at least claim 1 of the 12-'333 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

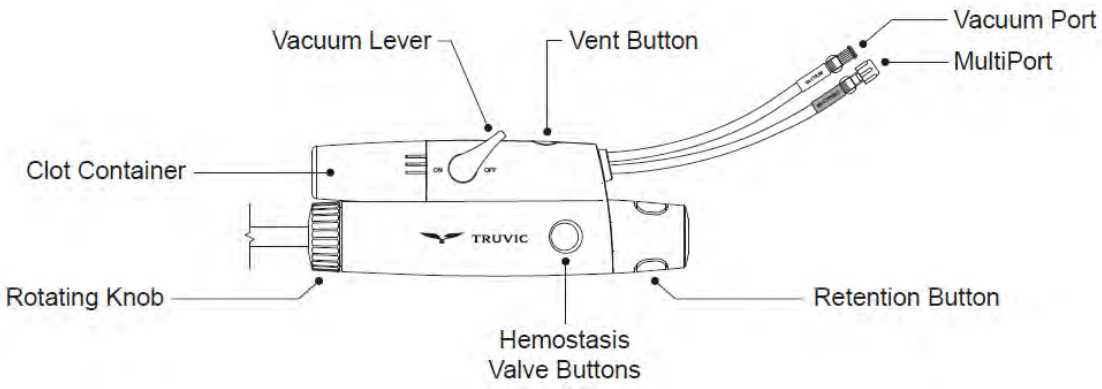
320. Specifically, claim 1 of the 12-'333 Patent recites:

> [1] A clot collection reservoir, comprising:
>
> a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;
>
> a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;
>
> a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber; and
>
> a filter removably positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter body encloses an interior region around the second port;
>
> wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;
>
> wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and
>
> wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.

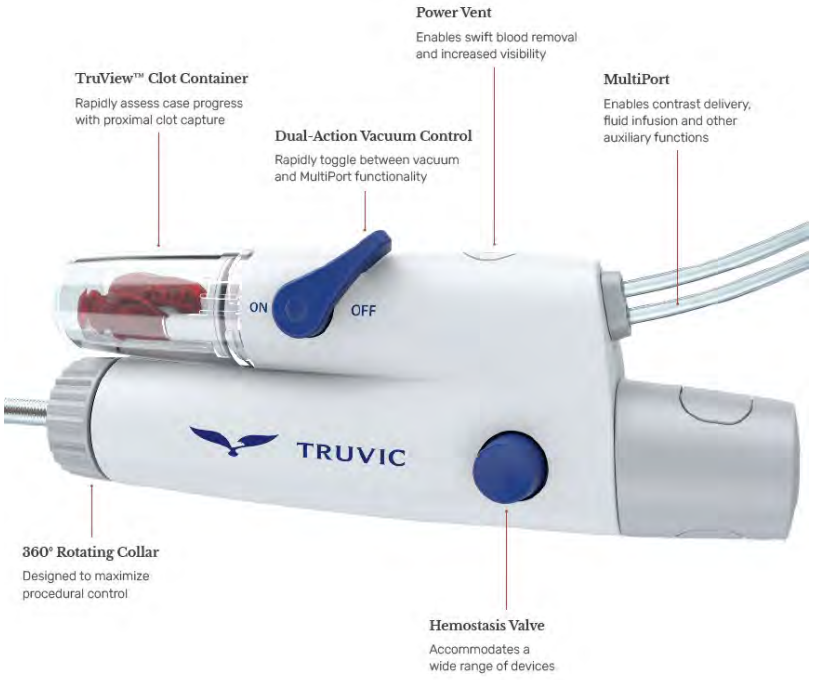
321. The Truvic Symphony system practices each limitation of at least claim 1 of the 12-'333 Patent, as can be seen in the 12-'333 Patent claim chart, attached as Exhibit X.

322. To the extent the preamble of claim 1 is construed to be limiting, the Symphony system practices the requirements of the preamble, "[a] clot collection reservoir, comprising," as can be seen in Exhibit X. In the Symphony system, the 24F and 16F controller handles include a clot collection reservoir. For example, according to the Symphony Instructions for Use the Symphony system includes a clot collection reservoir where a user can "[c]onfirm clot removal

by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle." Ex. B at 5. The IFU depicts the clot collection reservoir of the Symphony system, as shown below.



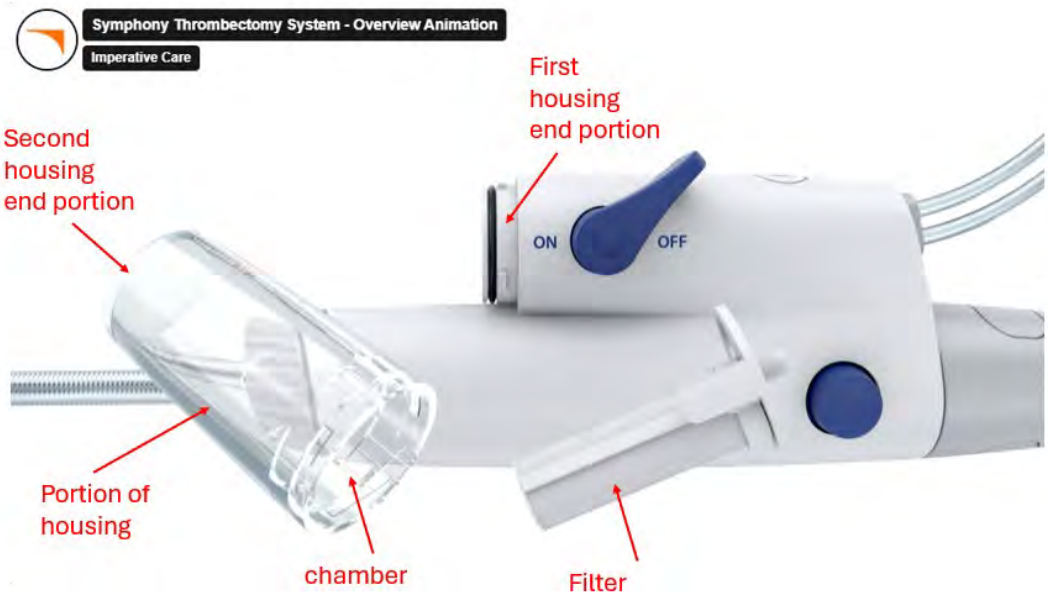
(*Id.* at 4.) Truvic's Symphony Brochure shows the clot collection reservoir as well.



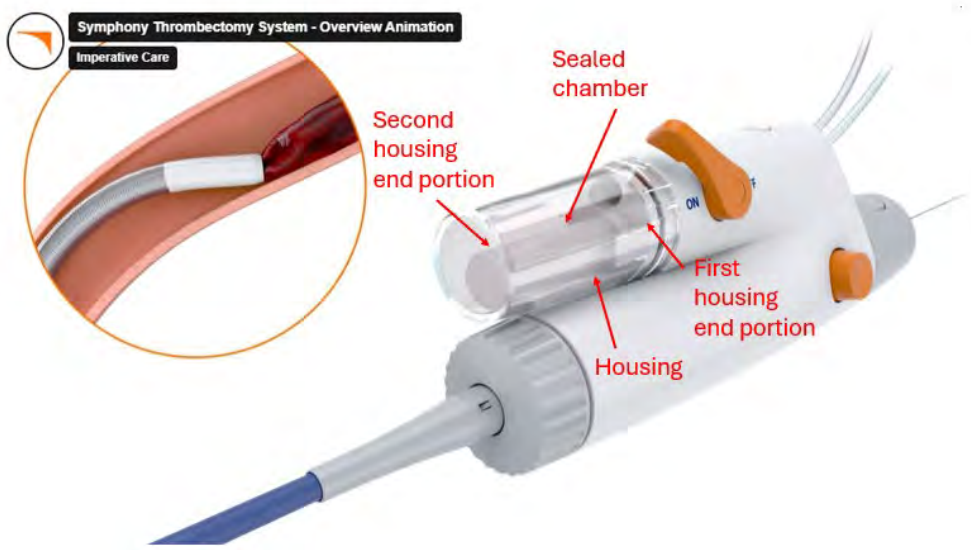
(Ex. A at 6.)

323. The Symphony system practices the limitations of claim 1, including "a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion," as can be seen in Exhibit X. The clot collection reservoir of the Symphony system includes a housing that defines a sealed chamber (*e.g.*, the interior of the housing) with a first housing end portion and a second housing end portion

opposite the first, as can be seen in the annotated images of the Symphony overview animation video below.



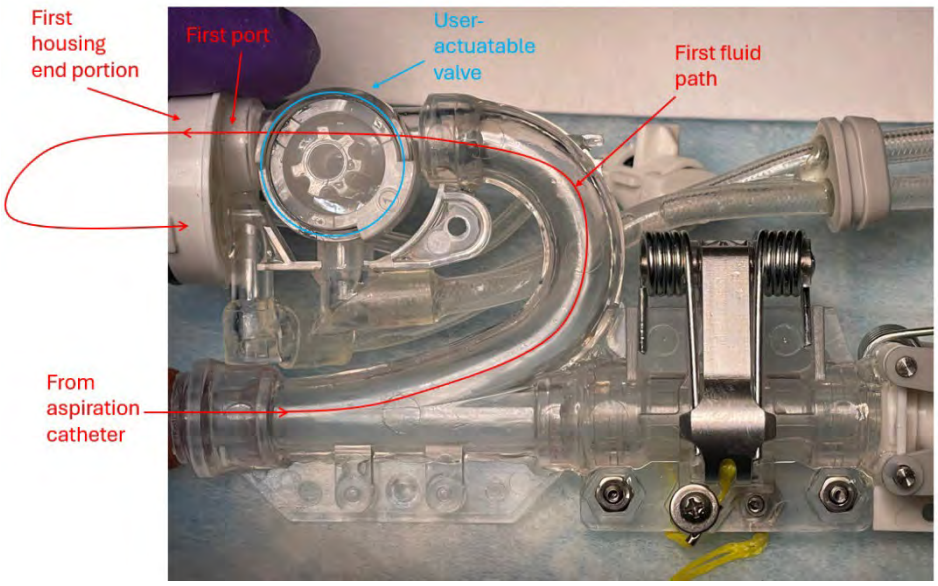
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:57 (https://www.truvic.com/symphony-product).)

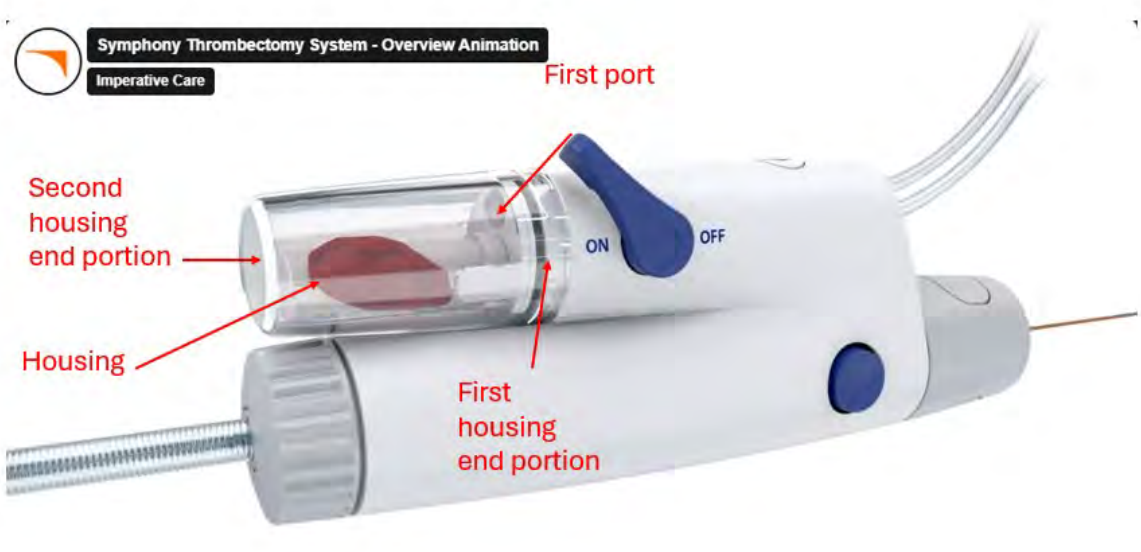
324. The Symphony system practices the limitations of claim 1, including "a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber," as can

be seen in Exhibit X. Specifically, the Symphony 24F and 16F controller handles include a clot collection reservoir with a first port fluidly coupled to an aspiration catheter, providing a fluid flow path to the chamber, as shown in the annotated teardown image below.



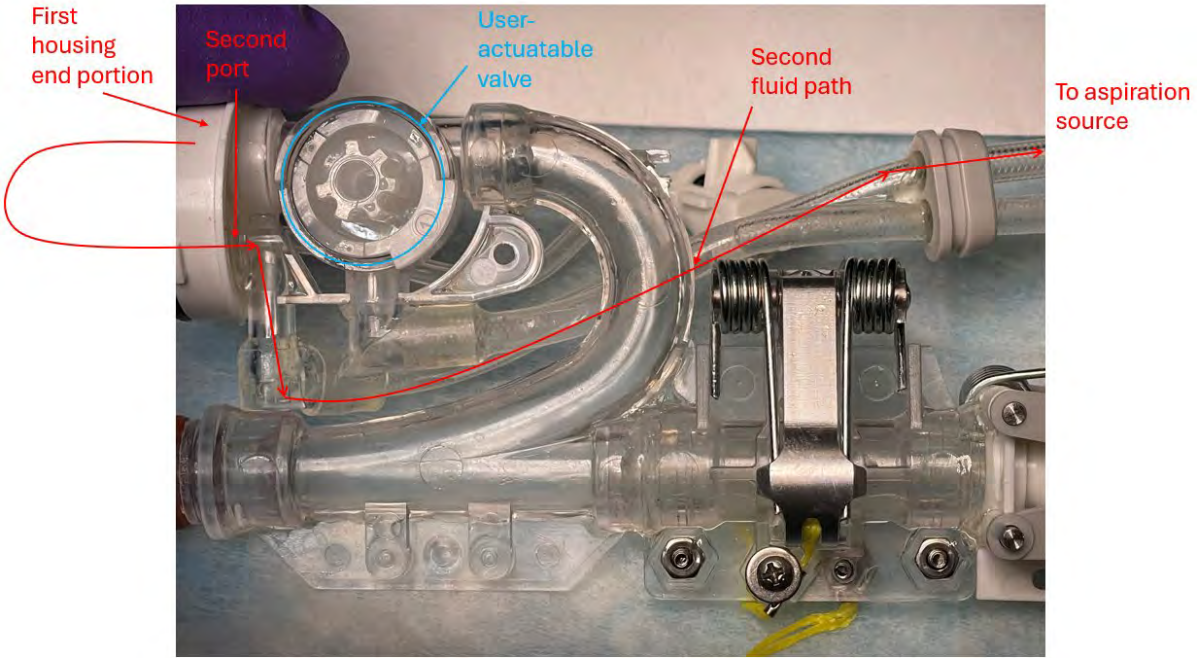
(Annotated image of internal portion of controller handle housing)

325. The first port of the clot collection reservoir is positioned proximate to the first housing end portion such that fluid flows through the first port to the chamber, as shown in the annotated images of the Symphony overview animation video below.



(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57 (https://www.truvic.com/symphony-product).)

326. The Symphony system practices the limitations of claim 1, including "a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber," as can be seen in Exhibit X. Specifically, the Symphony system 24F and 16F handles (BigShot Controller handles) include a clot collection reservoir with a second port fluidly coupled to an aspiration source (the Truvic Generator and Truvic Canister (*e.g.*, an aspiration source)) via a path through the handle, a tubeset, and ultimately to the Truvic Canister, as shown in the annotated teardown image below. The second port provides a second fluid path from the chamber, back through the handle, the tubeset, and ultimately to the aspiration source.



(Annotated image of internal portion of controller handle housing)

327. The Symphony IFU for the Symphony system confirms that the Truvic Generator and Truvic Canister are configured to be fluidly connected to the second port of the clot collection reservoir.

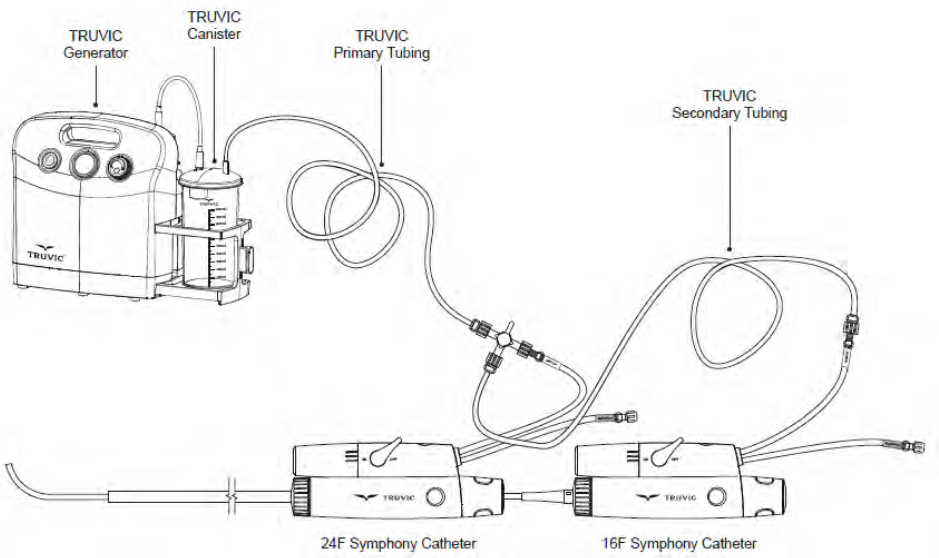
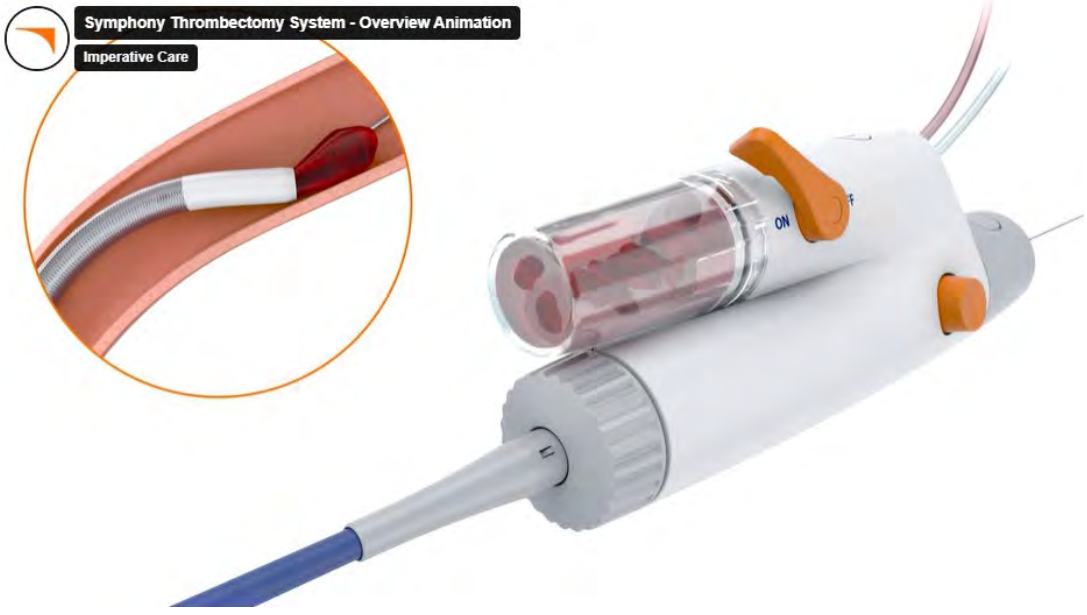


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

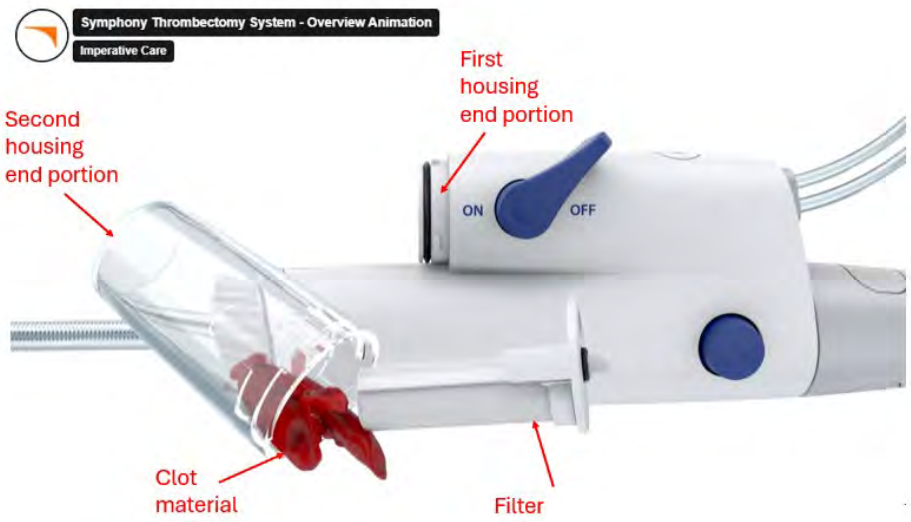
(Ex. B at 8.) And as shown in the Symphony overview video, the second port provides a second fluid path from the chamber for blood to be removed.



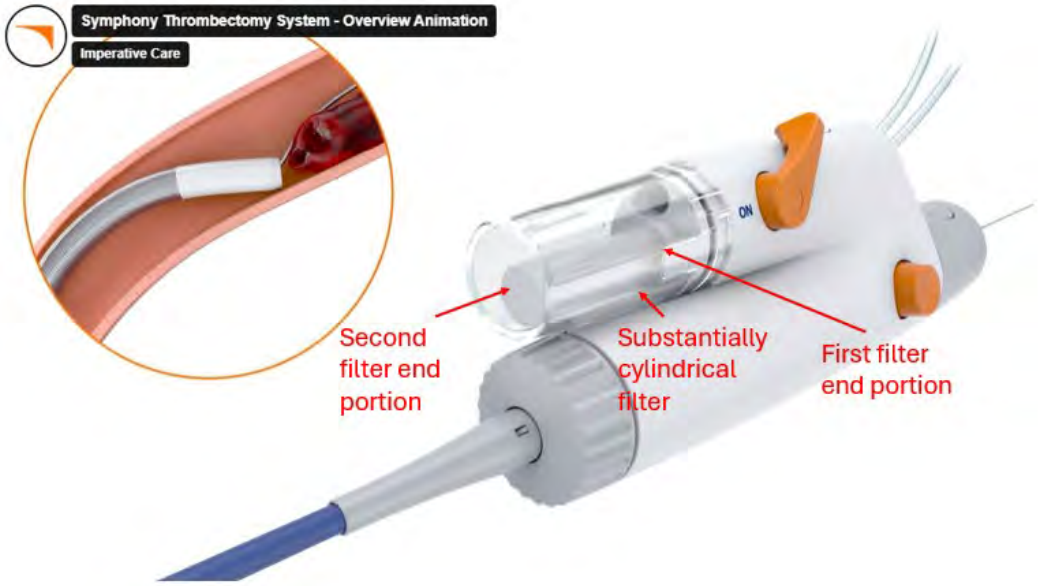
(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:03 (https://www.truvic.com/symphony-product).)

328. The Symphony IFU further confirms that the second port provides a second fluid path that allows blood to evacuate from the chamber. Ex. B at 5.

329. The Symphony system practices the limitations of claim 1, including "a filter removably positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter body extends continuously about the first filter end portion such that the filter encloses an interior region around the second port," as can be seen in Exhibit X. Specifically, the Symphony 24F and 16F controller handles include a clot collection reservoir that has a filter positioned within the chamber of the housing, where the filter body is substantially cylindrical in shape and removable, as shown in the annotated images of the Symphony overview animation video below.



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

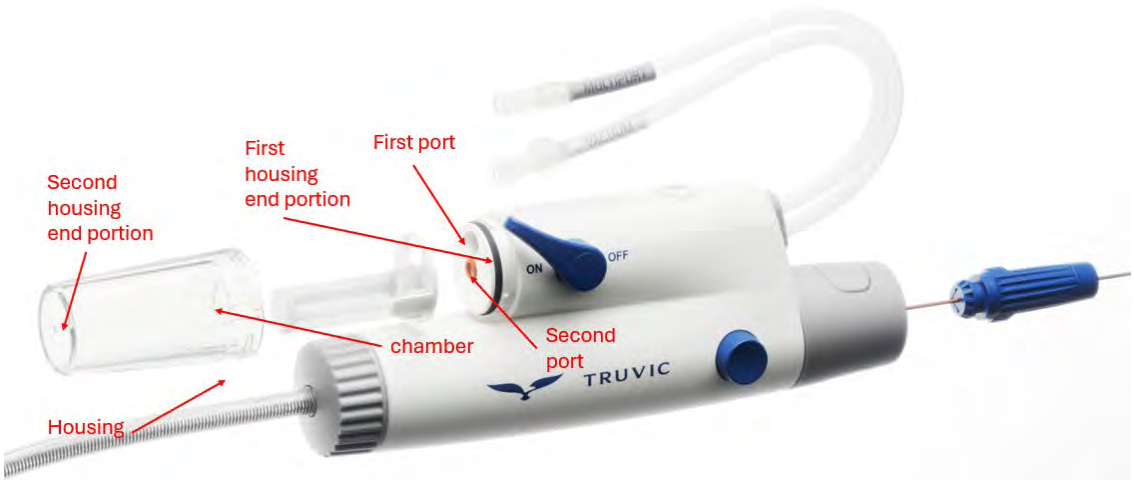


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:47 (https://www.truvic.com/symphony-product).)

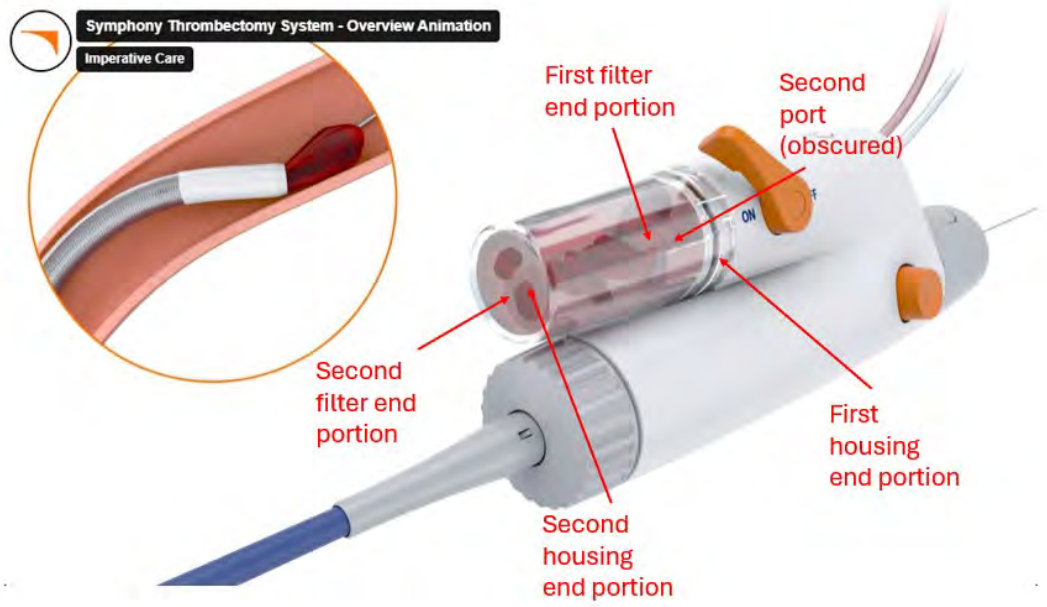
330. The Symphony overview animation video (as can be seen in the annotated images below) confirms that the substantially cylindrical shape of the Symphony's filter extends from a first filter end portion to a second filter end portion, such that the substantially cylindrical filter body extends about the first filter end portion.

(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

331. The Symphony IFU confirms that the filter encloses an interior region around the second port, where it teaches that blood can be evacuated through the second port, but the clot material remains due to the filter inhibiting the clot to pass through the second port. Ex. B at 5 ("Confirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle."). This is also shown in the image from Whipsaw and Symphony Thrombectomy System Overview Animation Video below:

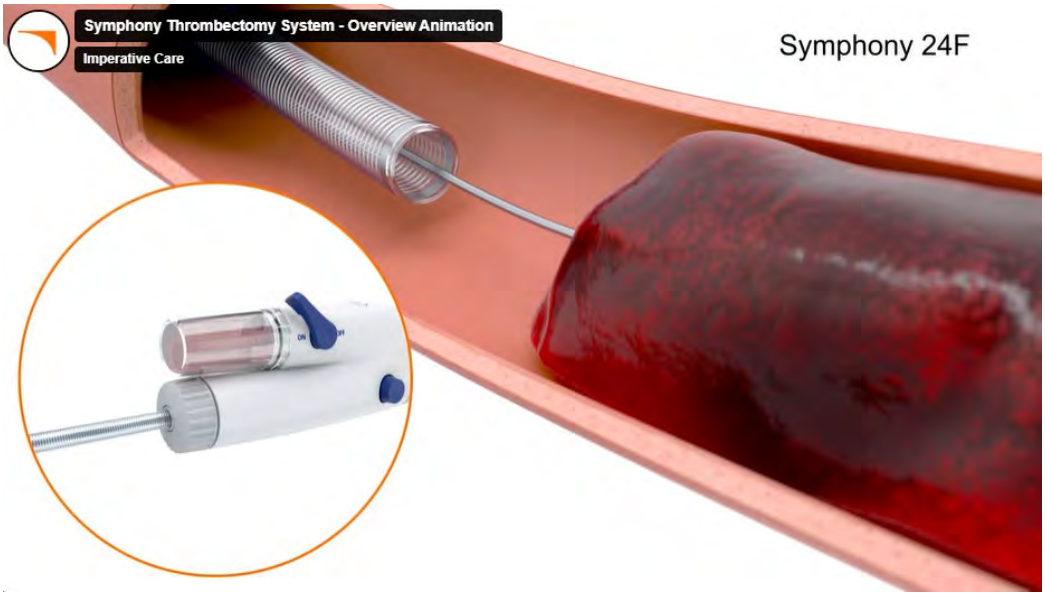


(Annotated image of handle including clot container from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)



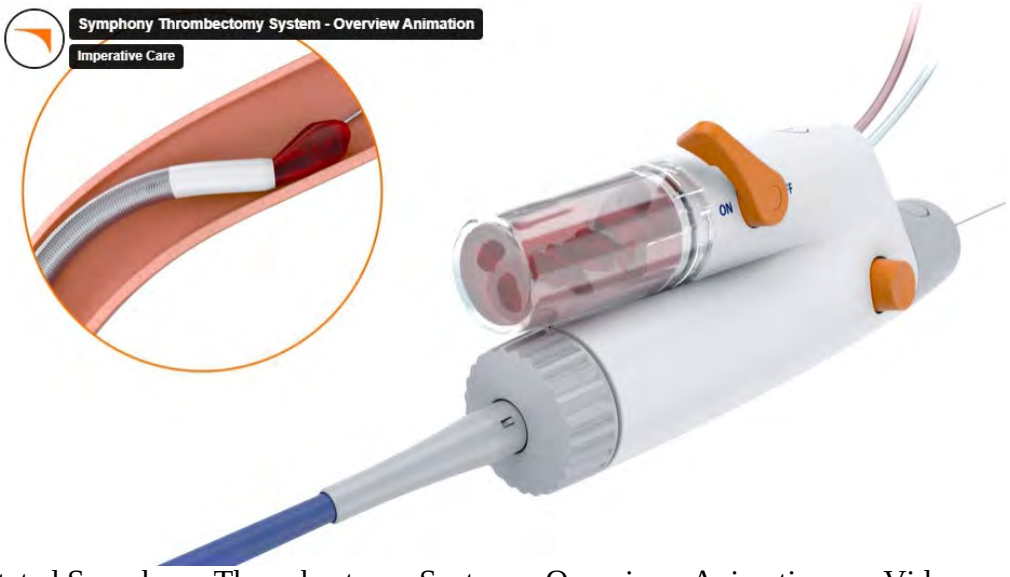
(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:03 (https://www.truvic.com/symphony-product).)

332. The Symphony system practices the limitations of claim 1, including "wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the interior region and through the second port," as can be seen in Exhibit X. Specifically, the Symphony IFU confirms that the Truvic Generator and Truvic Canister (*e.g.*, aspiration source) is configured to generate a negative pressure to begin aspiration of clot material and blood via the first port. Ex. B at 5 ("Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU). Confirm tip of the Symphony Catheter is in the desired location. To begin aspiration, move the vacuum lever on the Handle to the "ON" position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the "OFF" position."). The Symphony overview animation video further shows that clot material and blood are drawn through the first port into the chamber, as can be seen below.



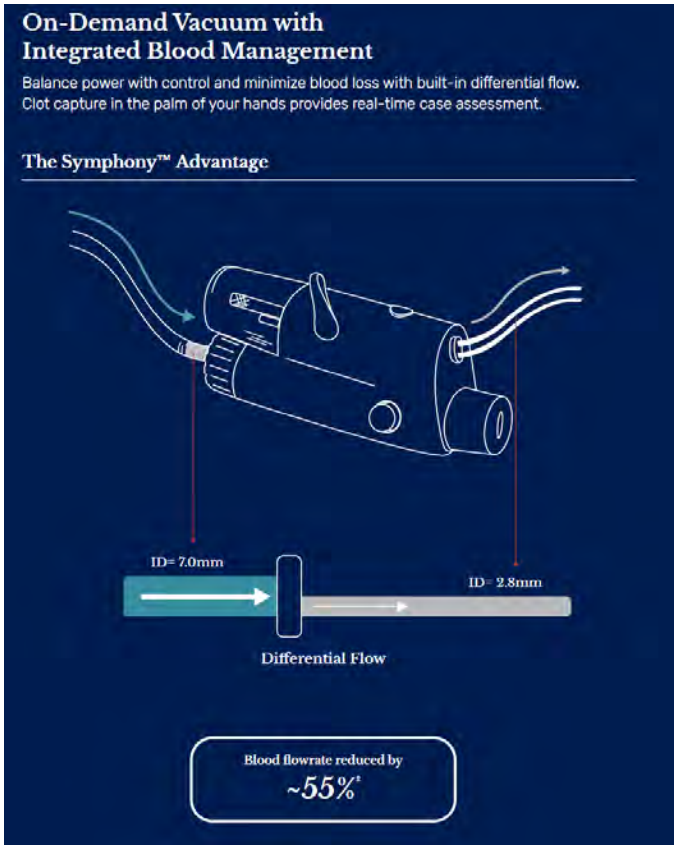
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:47 (https://www.truvic.com/symphony-product).)

333. The IFU also confirms that blood is drawn through the filter into the interior region of the filter and through the second port. Ex. B at 5. The Symphony overview animation video further shows that the blood is drawn through the interior of the filter and through the second port, which leaves the clot material remaining in the sealed chamber.



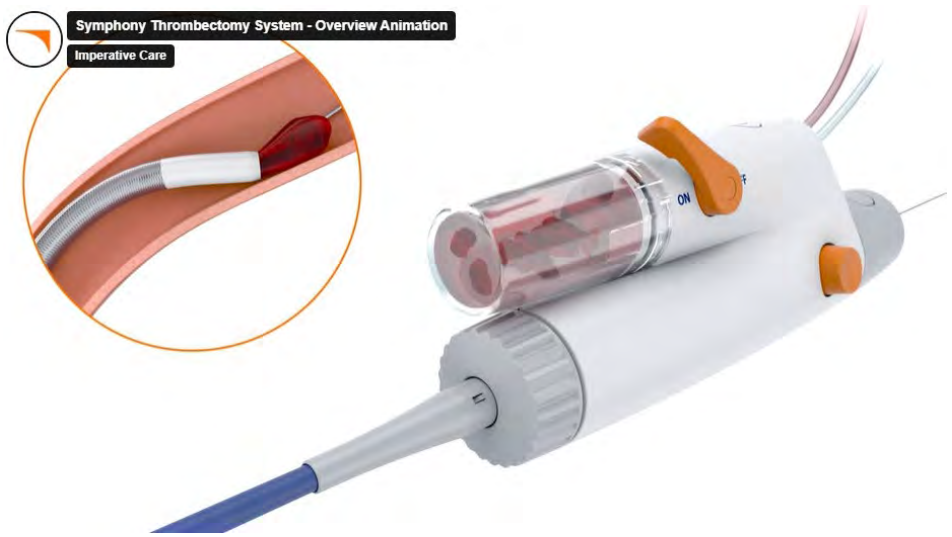
(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:03 (https://www.truvic.com/symphony-product).)

334. Truvic's Symphony Brochure confirms the flow of clot material and blood into the chamber and blood out of the chamber, capturing the clot in the clot container.

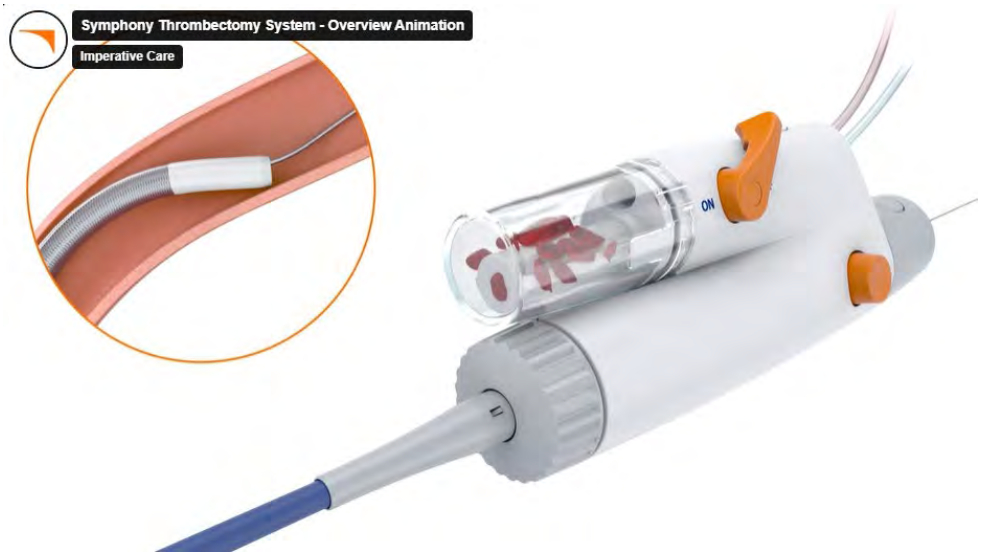


(Ex. A at 7.)

335. The Symphony system practices the limitations of claim 1, including "wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port," as can be seen in Exhibit X. Specifically, the Symphony overview animation video shows that the filter inhibits clot material from passing through its interior region and through the second port. Instead, as can be seen below, the clot material remains in the chamber.



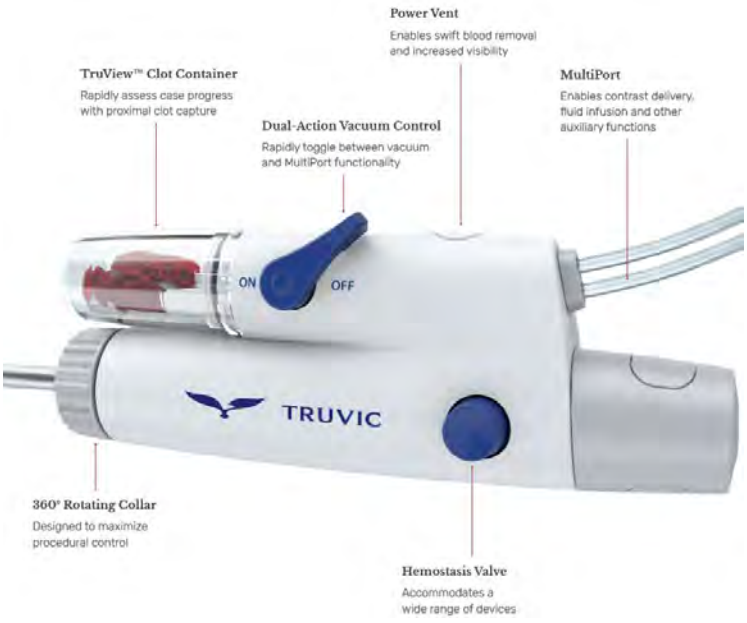
(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:03 (https://www.truvic.com/symphony-product).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:05 (https://www.truvic.com/symphony-product).)

336. The Symphony IFU further confirms that the filter inhibits clot material from passing through its interior region and through the second port. Ex. B at 5.

337. The Symphony system practices the limitations of claim 1, including "wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region," as can be seen in Exhibit X. Specifically, the Symphony IFU confirms that a user of the Symphony system can visualize the clot material in the chamber due to the partial transparency of the outer plastic portion of the clot collection reservoir. Ex. B at 5. Truvic's Symphony Brochure further confirms that the "TruView™ Clot Container" includes an at least partially transparent housing to permit visualization of the clot, as can be seen below.



(Ex. A at 6.)

338. Defendant directly infringes claims of the 12-'333 Patent, including claim 1, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures using the hemostasis valves) Symphony system products.

339. Defendant induces infringement of claims of the 12-'333 Patent, including claim 1, by selling Symphony systems and teaching or directing others, including physicians, to use the Symphony products that practice claim 1. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

340. Defendant teaches and/or directs others to perform thrombectomy on, for example,

deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels…. The Symphony Thrombectomy System is intended for use in the peripheral vasculature." Ex. B at 2. The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vascular using controlled aspiration." *Id.* at 1. Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. *See, e.g.*, https://www.truvic.com/symphony-product. Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding method of using the Truvic Symphony system including on information and belief, methods of treating thrombi and emboli.

341. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system, knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the 12-'333 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

342. Defendant's infringement is with knowledge of the 12-'333 Patent and its claims. Specifically, as described above, Inari notified Defendant, by e-mail dated February 14, 2025, that its products would infringe claims of the 12-'333 Patent, when issued. Inari further notified Defendant that it intended to seek leave to add the 12-'333 Patent to the Complaint and would serve supplemental contentions for the 12-'333 Patent.

343. At a minimum, Defendant has notice of the 12-'333 Patent through the filing of this Complaint. On information and belief, Defendant has had knowledge of the application that would issue as the 12-'333 Patent via monitoring and investigation of Inari's patent portfolio, including in response to the notice letters provided by Inari regarding many other patents, including family members of the 12-'333 Patent.

344. Defendant has continued its infringing activities, despite knowledge of the 12-'333

Patent, and such infringement has been and continues to be egregious and willful.

345. Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Inari requests the following relief:

A. A judgment that the Defendant has infringed one or more claims of each of the '910, 11-'333, '005, '691, '921, '012, '291, '580, '384,'669, and 12-'333 Patents and that such infringement is willful;

B. A preliminary and permanent injunction enjoining Defendant and Defendant's officers, agents, servants, employees, attorneys and any other persons who are in active concert or participation with such persons, from making, selling, using, offering for sale or importing the Symphony Thrombectomy System and components thereof;

C. For an award of damages, including lost profits, no less than a reasonable royalty under 35 U.S.C. § 284, arising from such infringement;

D. For an award of reasonably royalties pursuant to 35 U.S.C. § 154(d) for provisional rights between the publication of a patent application and issuance of substantially identical claims;

E. For increased damages pursuant to 35 U.S.C. § 285 or as otherwise permitted by law;

F. For an award of attorneys' fees and costs pursuant to 35 U.S.C. § 285 or as otherwise permitted by law; and

G. For such other relief as the Court deems just and proper.

Dated: March 5, 2025

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ATTORNEYS FOR PLAINTIFF INARI MEDICAL, INC.

EXHIBIT W

US012239333B2

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

(10) **Patent No.: US 12,239,333 B2**
(45) **Date of Patent: Mar. 4, 2025**

(54) **SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS**

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

(72) Inventors: **Richard Quick**, Mission Viejo, CA (US); **Benjamin Edward Merritt**, San Clemente, CA (US); **John Coleman Thress**, Capistrano Beach, CA (US); **Paul Lubock**, Monarch Beach, CA (US); **Thomas M. Tu**, Louisville, KY (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.: **18/497,249**

(22) Filed: **Oct. 30, 2023**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 17/865,307, filed on Jul. 14, 2022, now Pat. No. 11,849,963, which is a (Continued)

(51) **Int. Cl.**
A61B 17/22 (2006.01)
A61B 17/221 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/22031*** (2013.01); ***A61B 17/22*** (2013.01); ***A61B 17/221*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 1/60; A61M 1/0001; A61M 1/0003; A61M 1/0281; A61M 39/0613;
(Continued)

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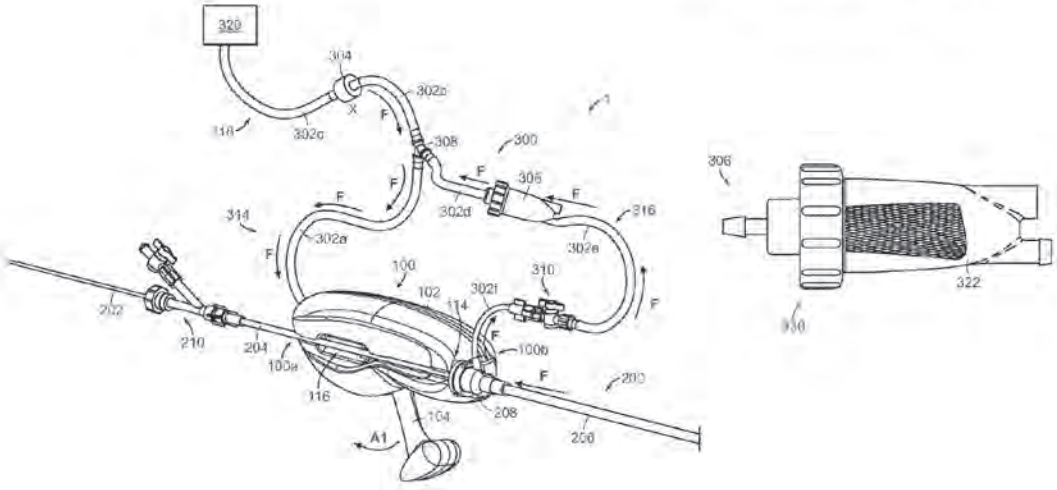
Primary Examiner — Tuan V Nguyen
(74) *Attorney, Agent, or Firm* — Perkins Coie LLP

(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, 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.

28 Claims, 20 Drawing Sheets



Related U.S. Application Data

continuation of application No. 17/498,642, filed on Oct. 11, 2021, now Pat. No. 12,016,580, which is a continuation of application No. 16/258,344, filed on Jan. 25, 2019, now Pat. No. 11,154,314.

(60) Provisional application No. 62/622,691, filed on Jan. 26, 2018.

(51) **Int. Cl.**

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

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(58) **Field of Classification Search**

CPC A61M 2039/027; A61M 2039/062; A61M 25/0122; A61B 17/22031; A61B 2017/22035; A61B 17/22; A61B 17/221; A61B 17/220758; A61B 17/320725; A61B 17/22034; A61B 17/22042; A61B 17/22079; A61B 17/22094

See application file for complete search history.

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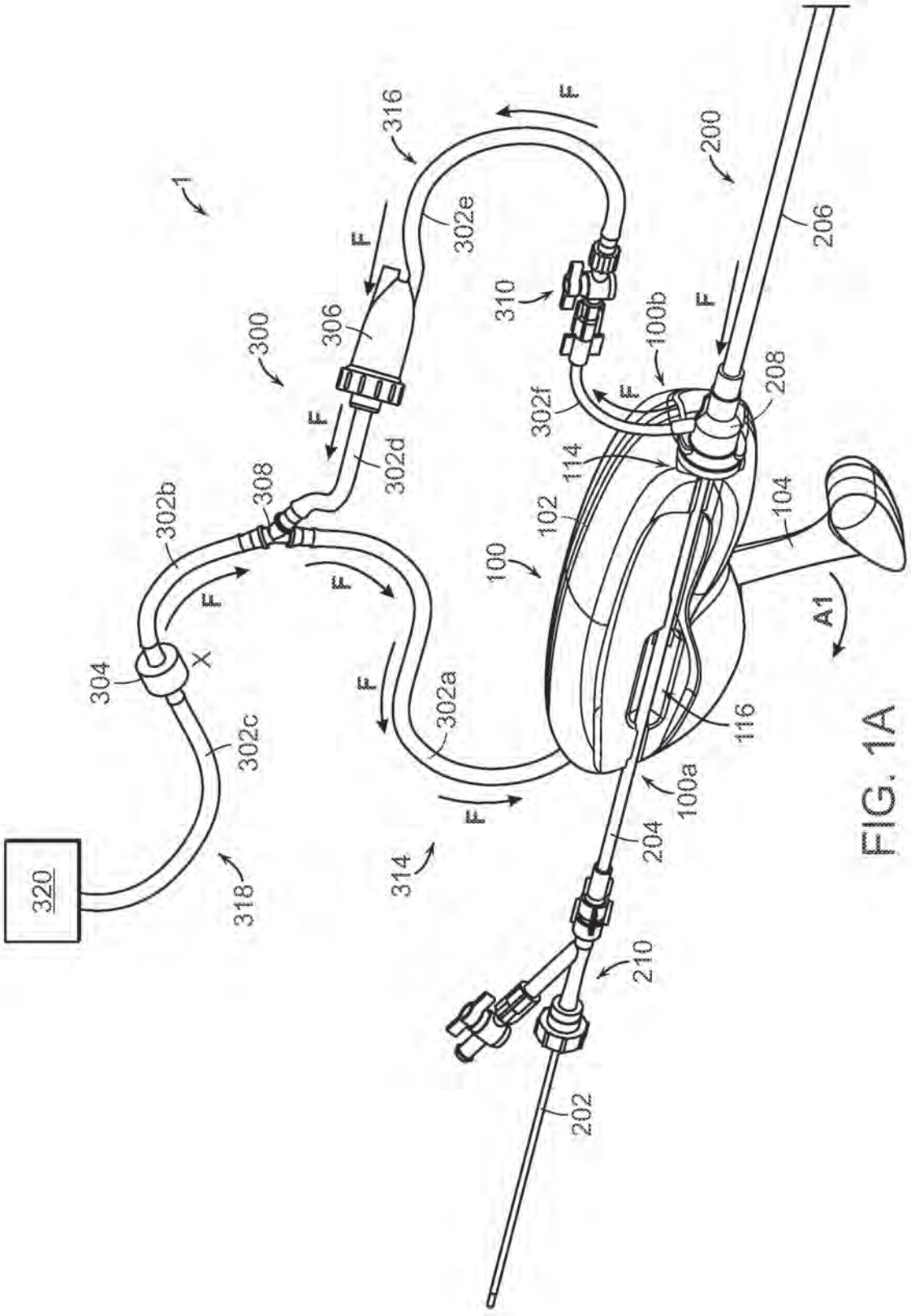
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FIG. 1A

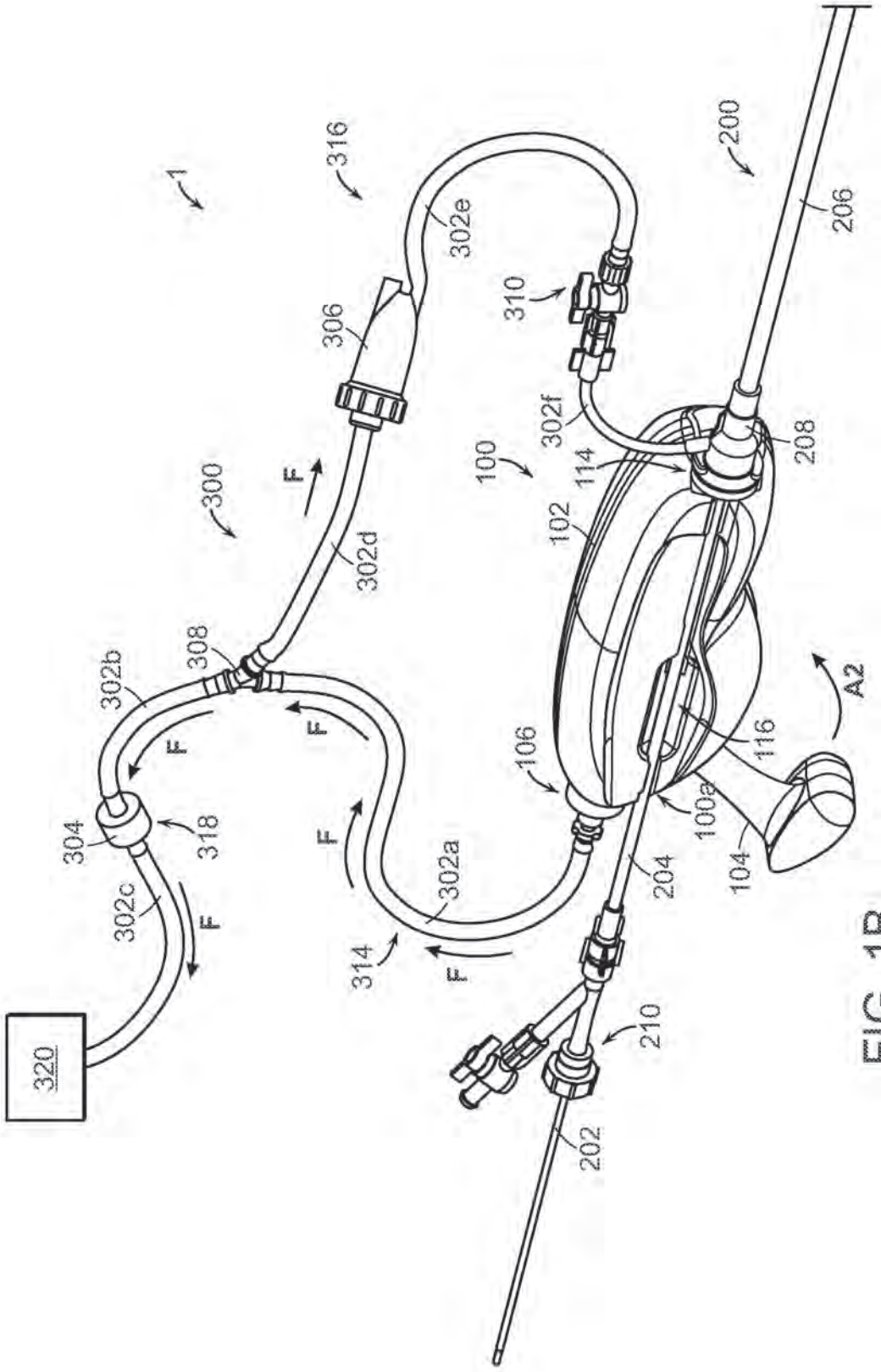
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FIG. 1B

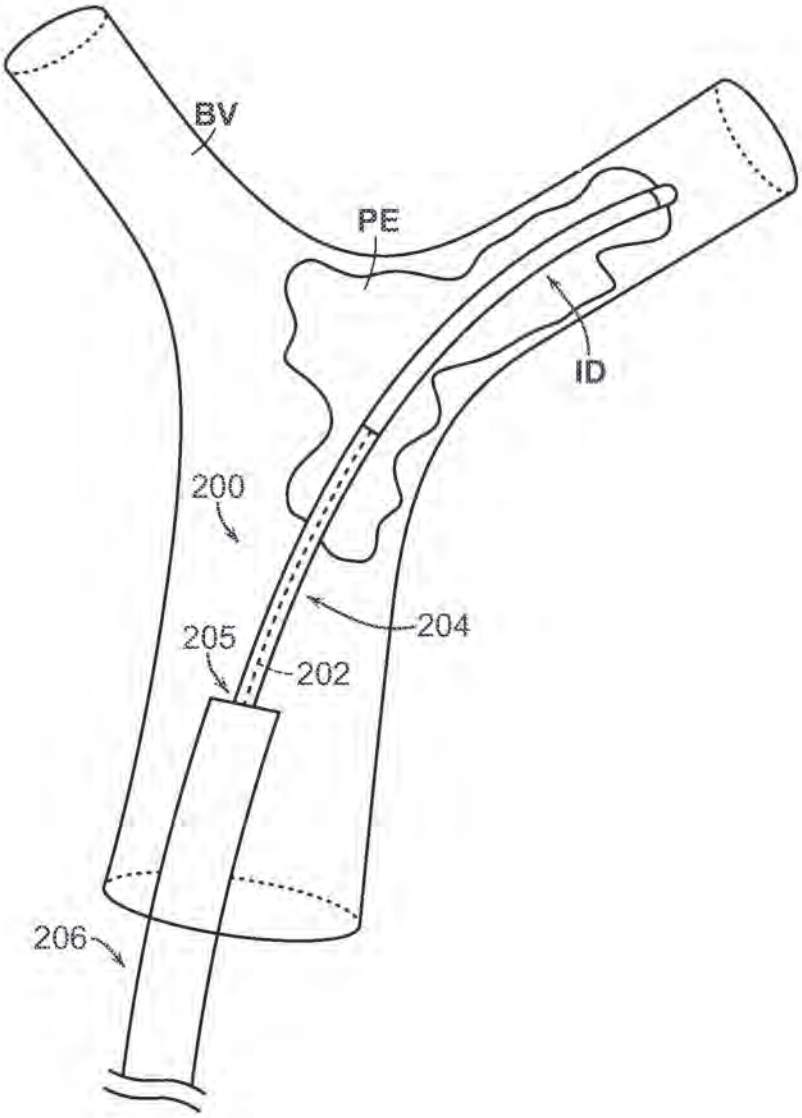


FIG. 2A

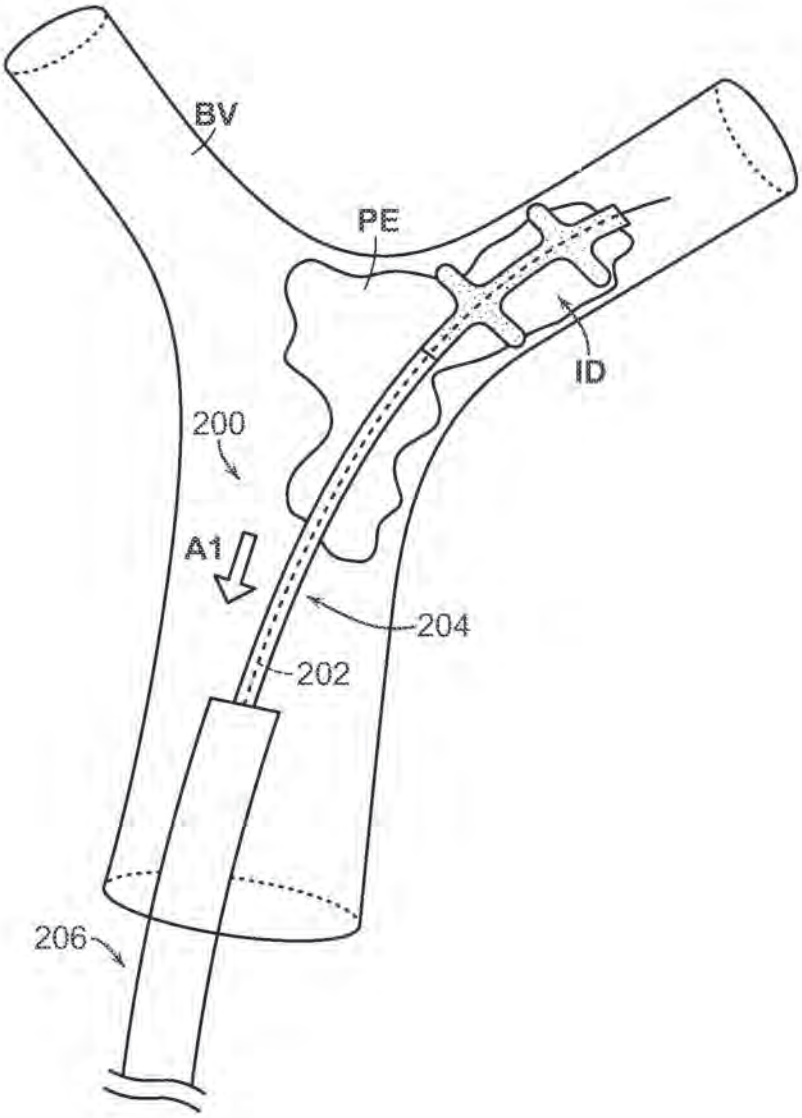


FIG. 2B

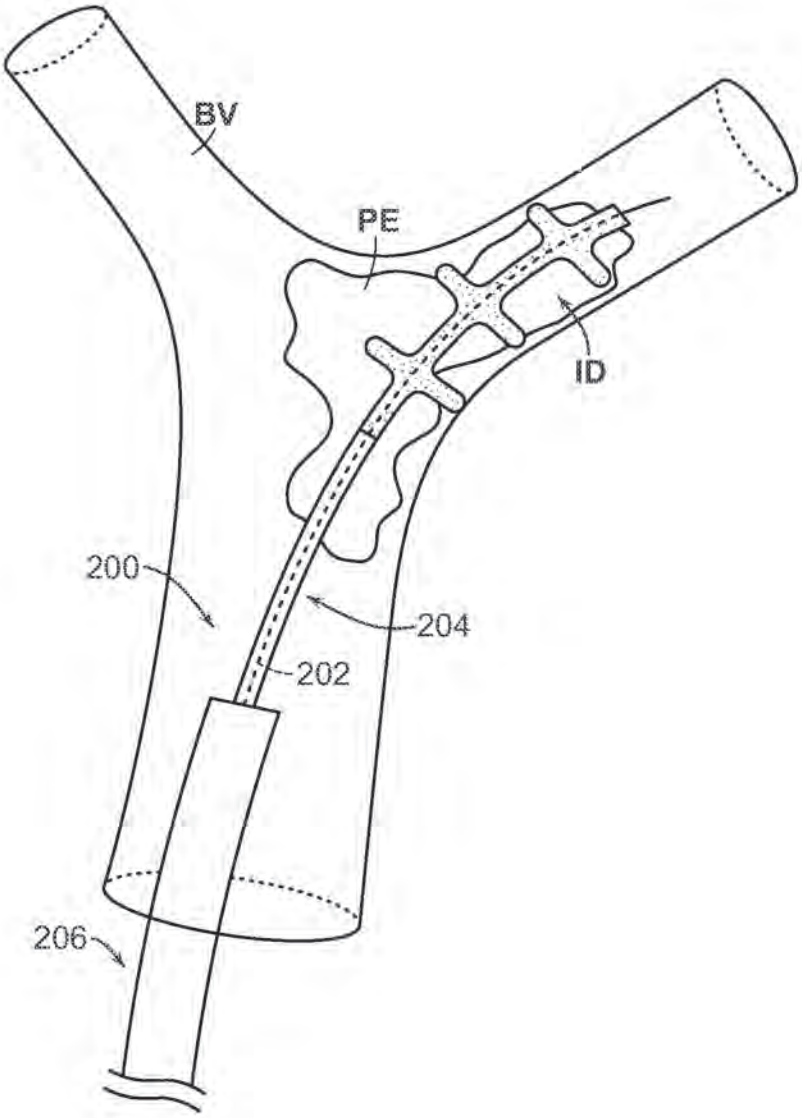


FIG. 2C

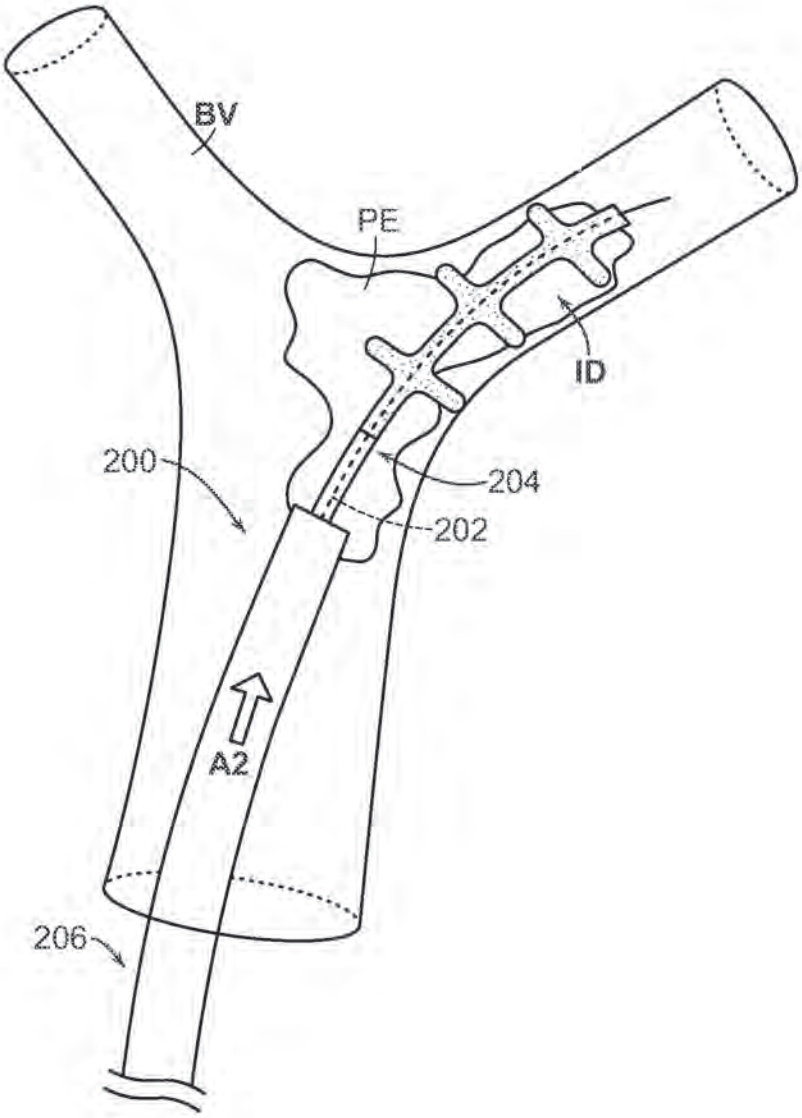


FIG. 2D

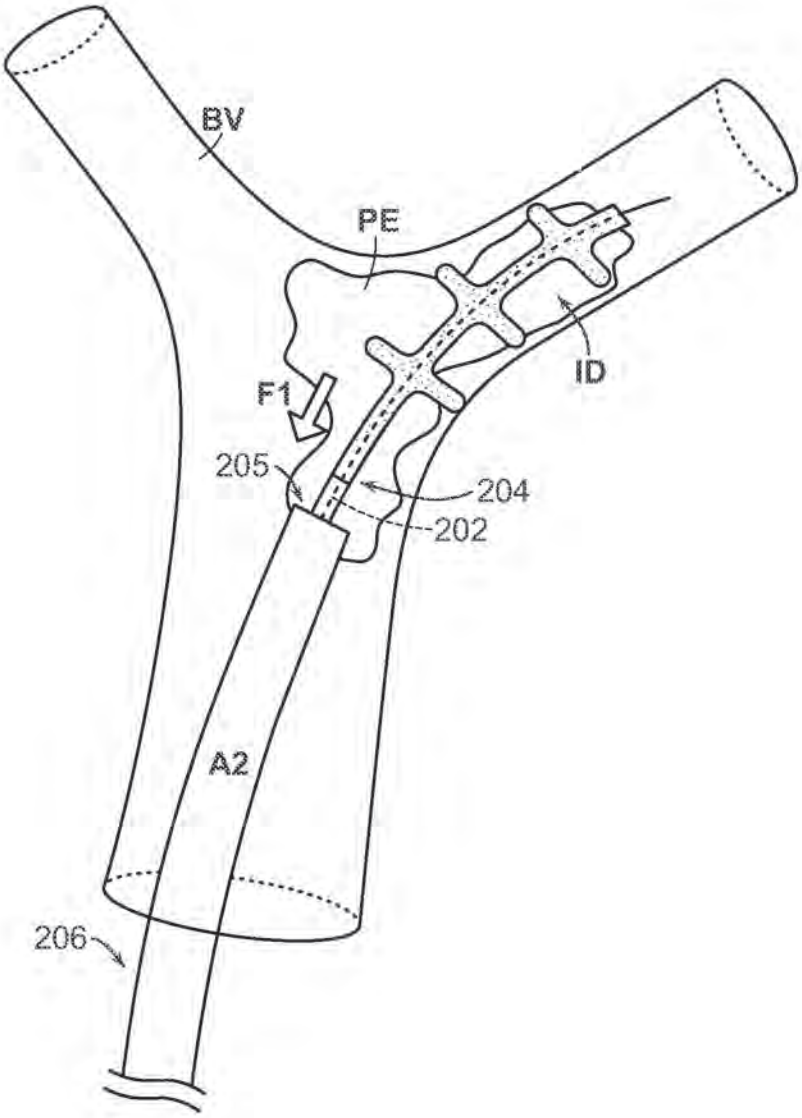


FIG. 2E

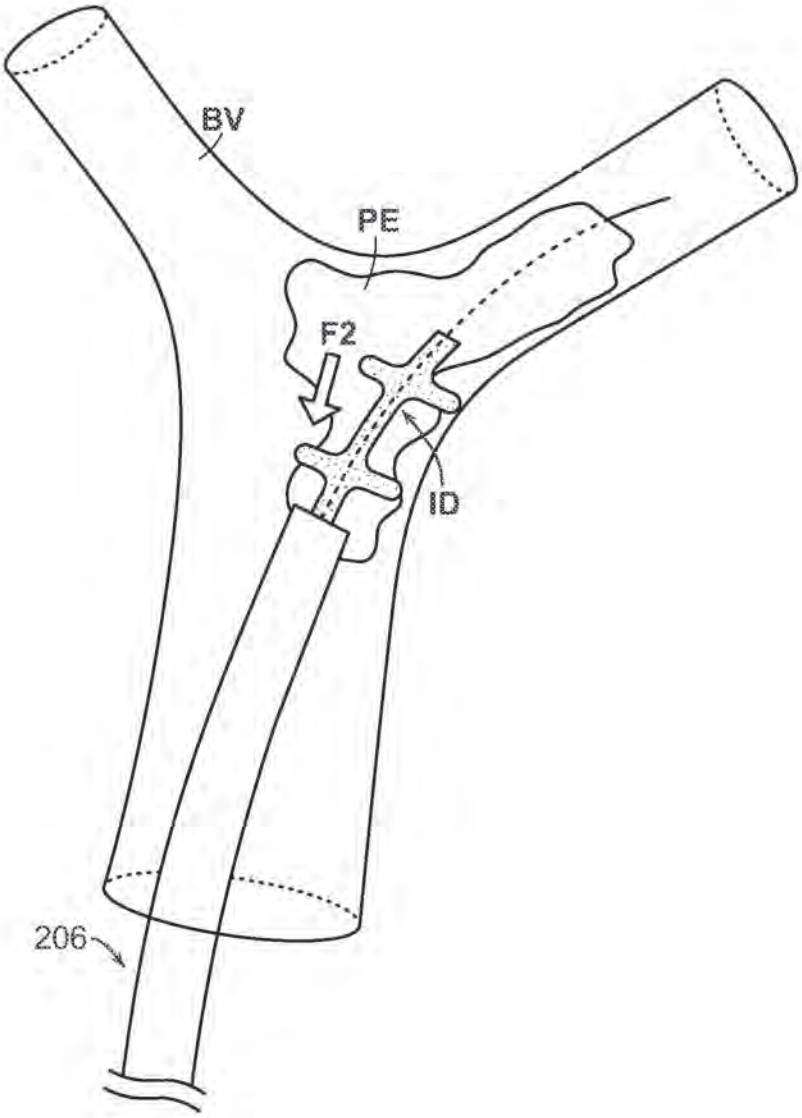
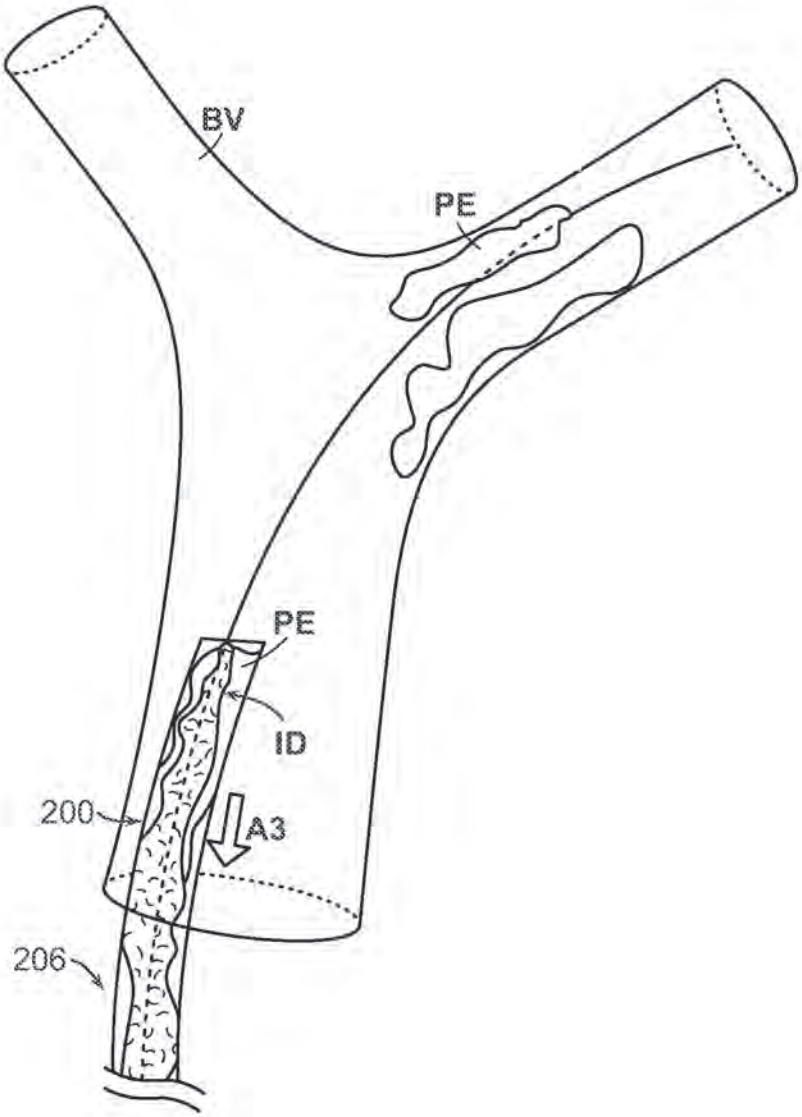


FIG. 2F



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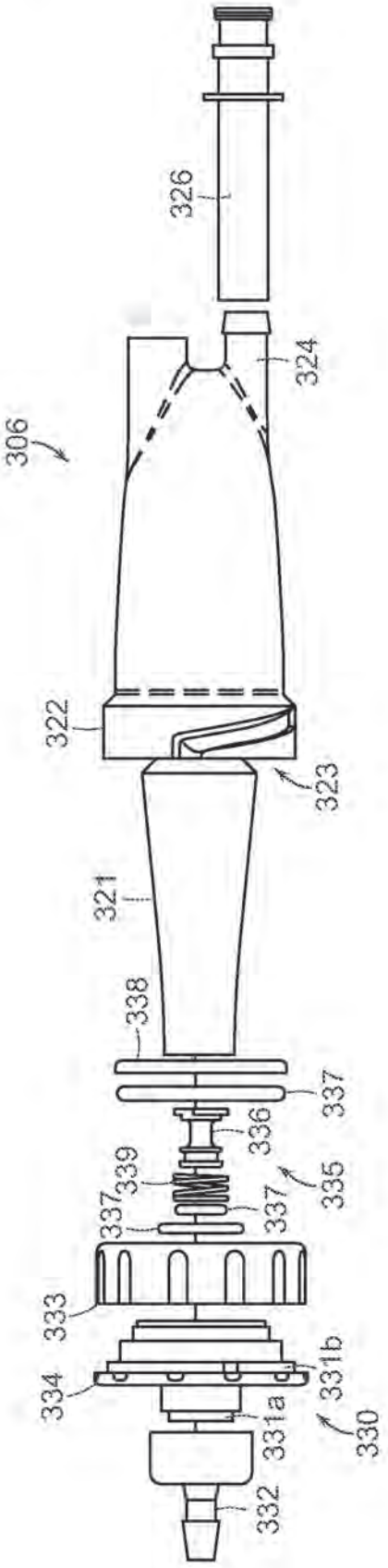
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FIG. 3A

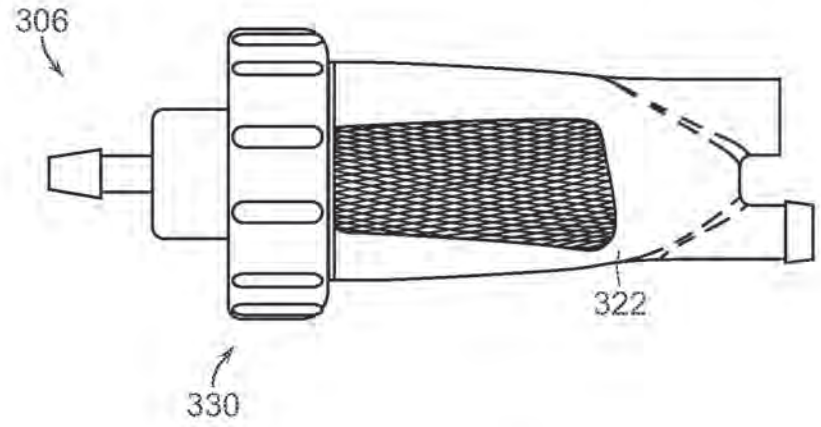


FIG. 3B

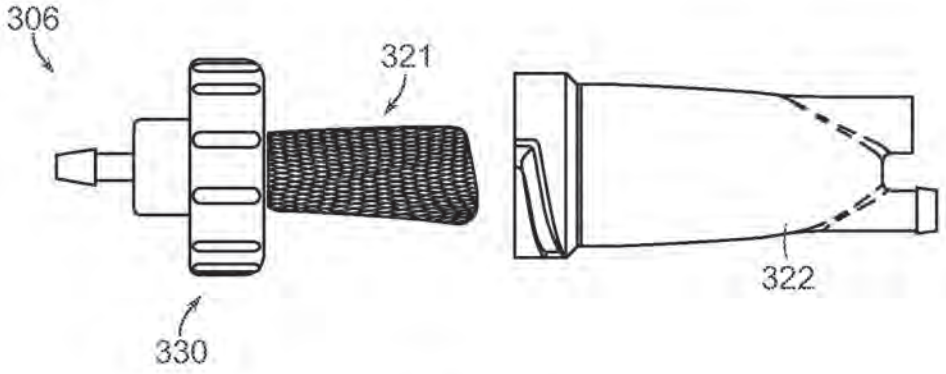
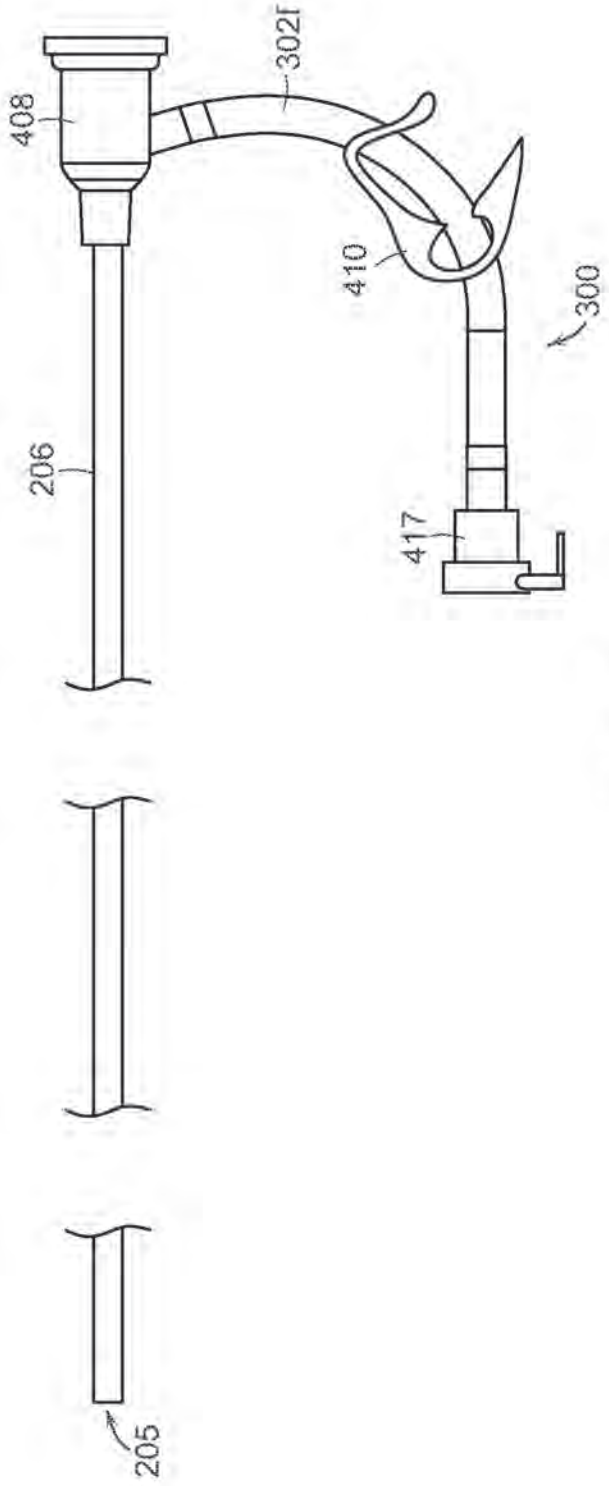


FIG. 3C



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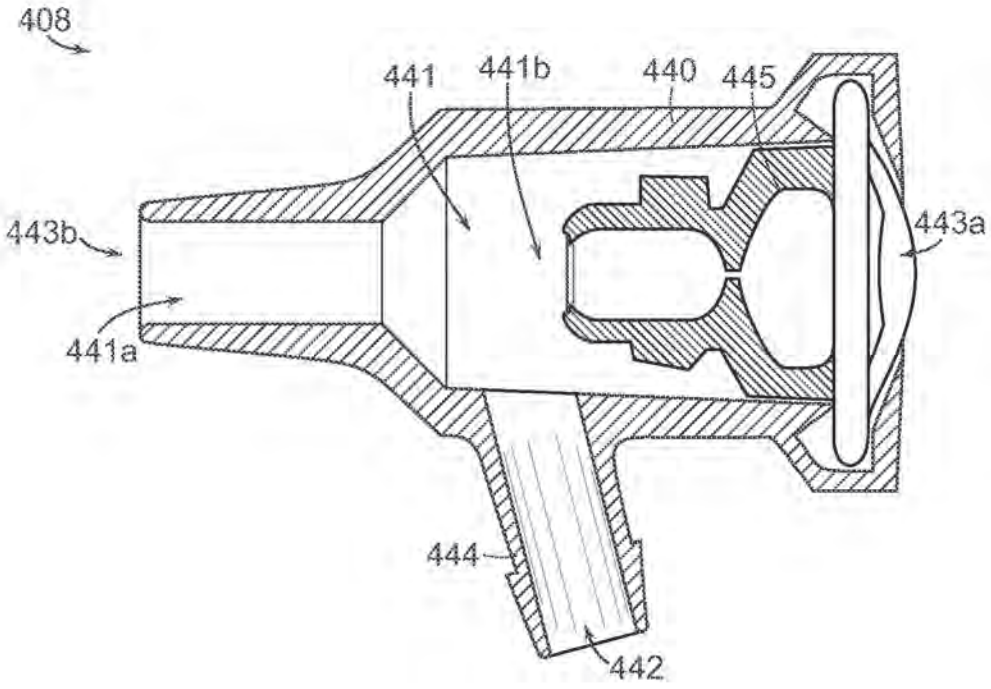
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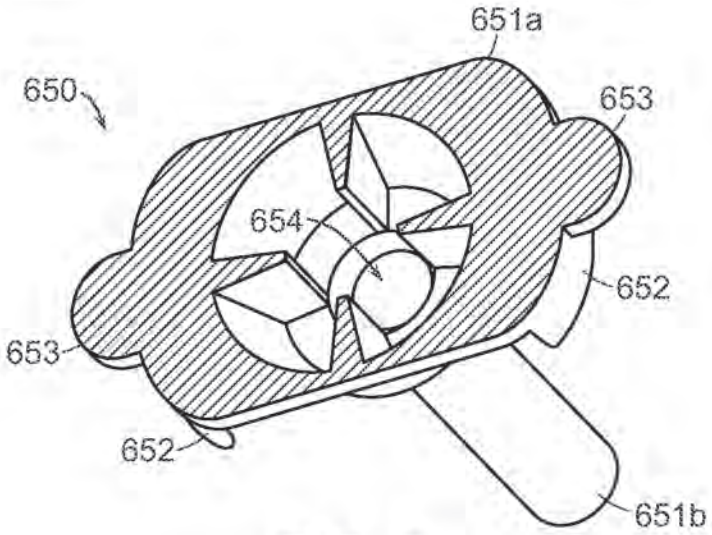
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FIG. 6

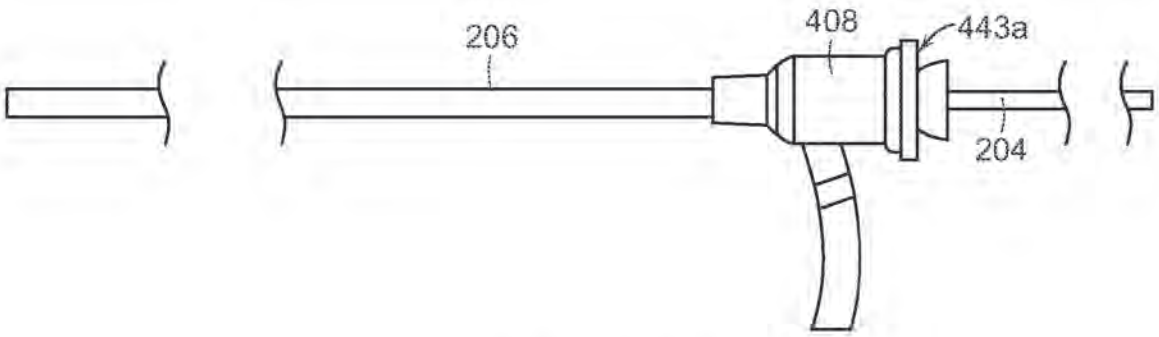
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FIG. 7A

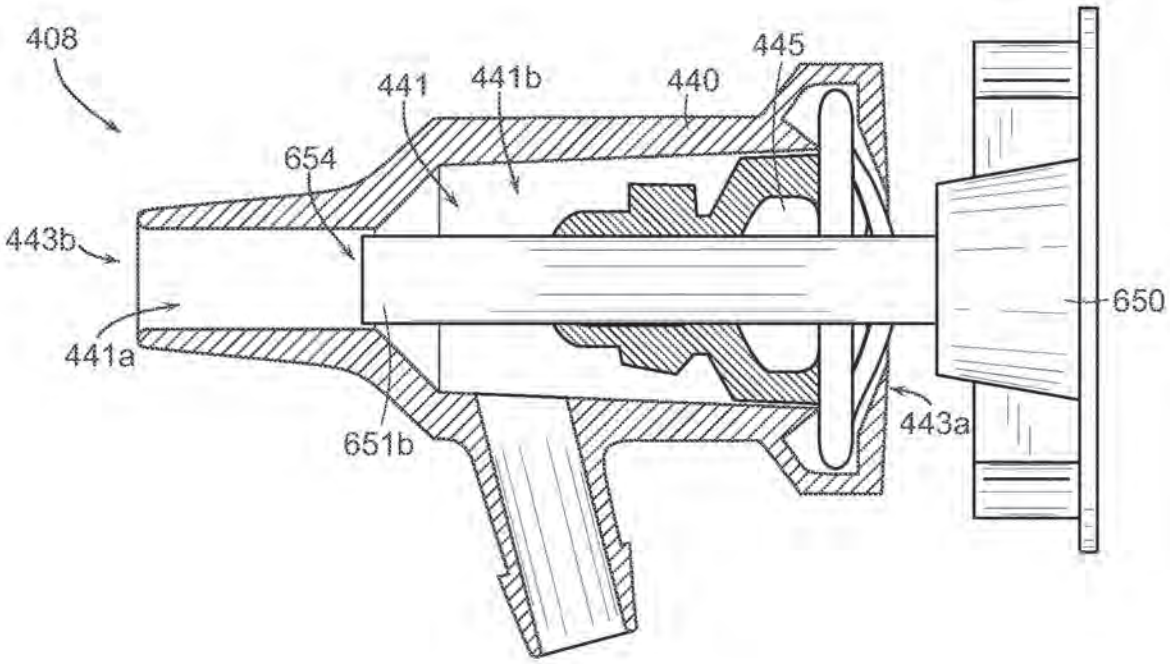
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FIG. 7B

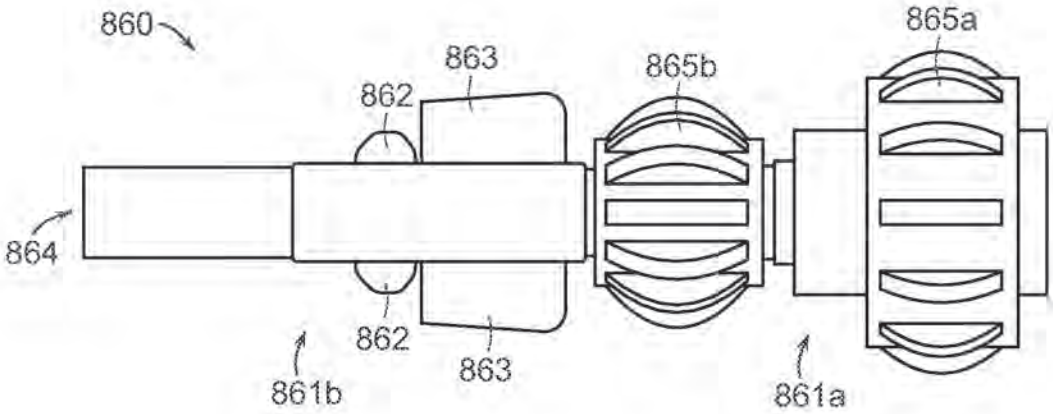


FIG. 8

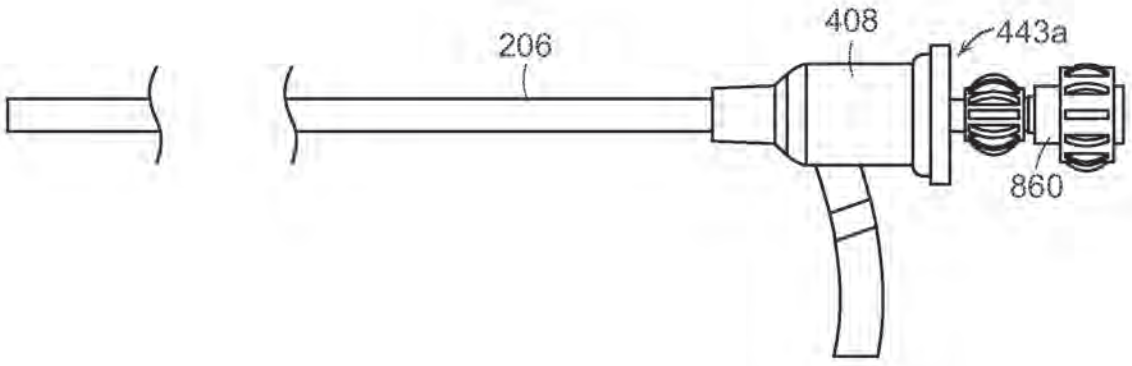


FIG. 9

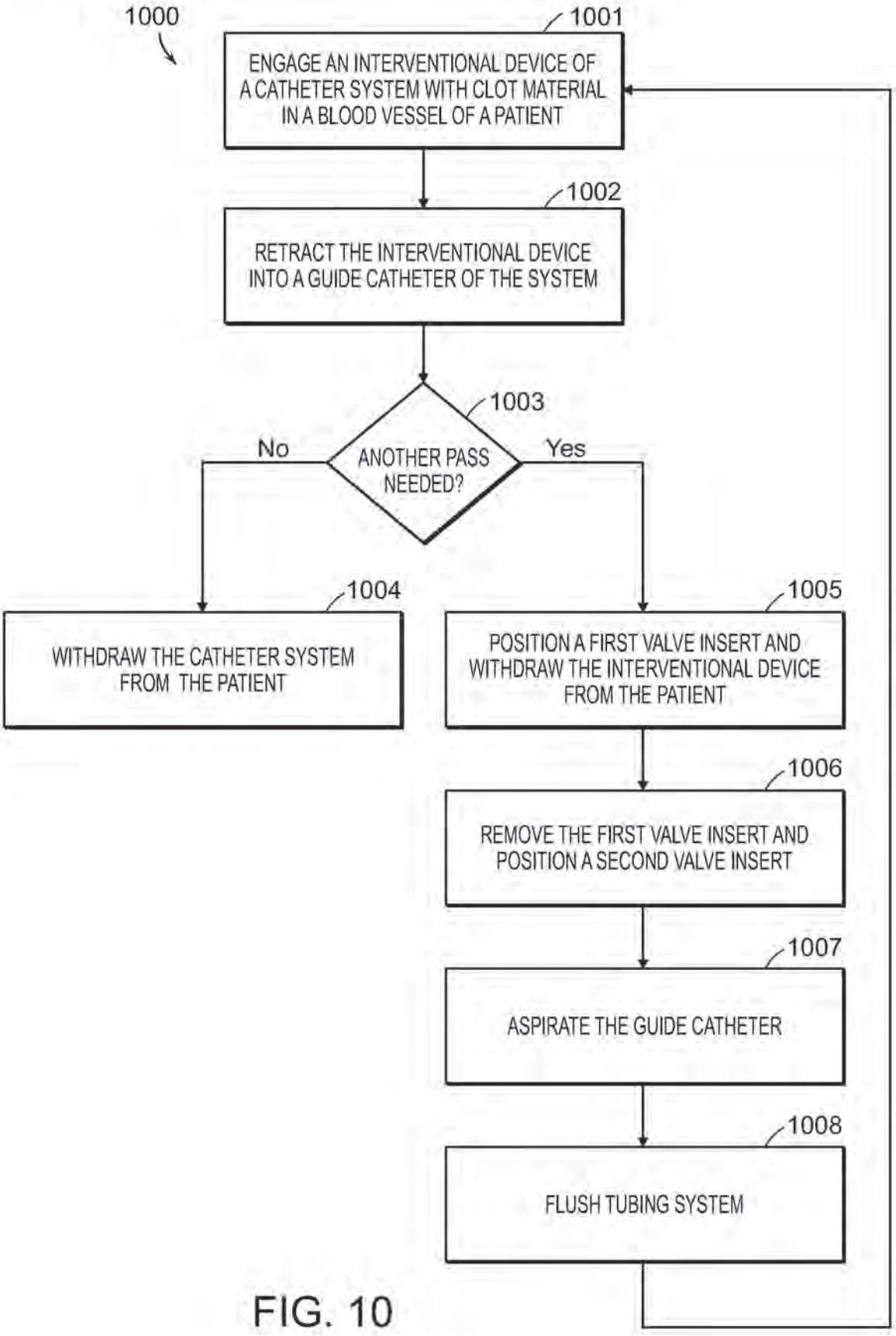

1000
1001
ENGAGE AN INTERVENTIONAL DEVICE OF A CATHETER SYSTEM WITH CLOT MATERIAL IN A BLOOD VESSEL OF A PATIENT
1002
RETRACT THE INTERVENTIONAL DEVICE INTO A GUIDE CATHETER OF THE SYSTEM
1003
ANOTHER PASS NEEDED?
No
Yes
1004
WITHDRAW THE CATHETER SYSTEM FROM THE PATIENT
1005
POSITION A FIRST VALVE INSERT 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

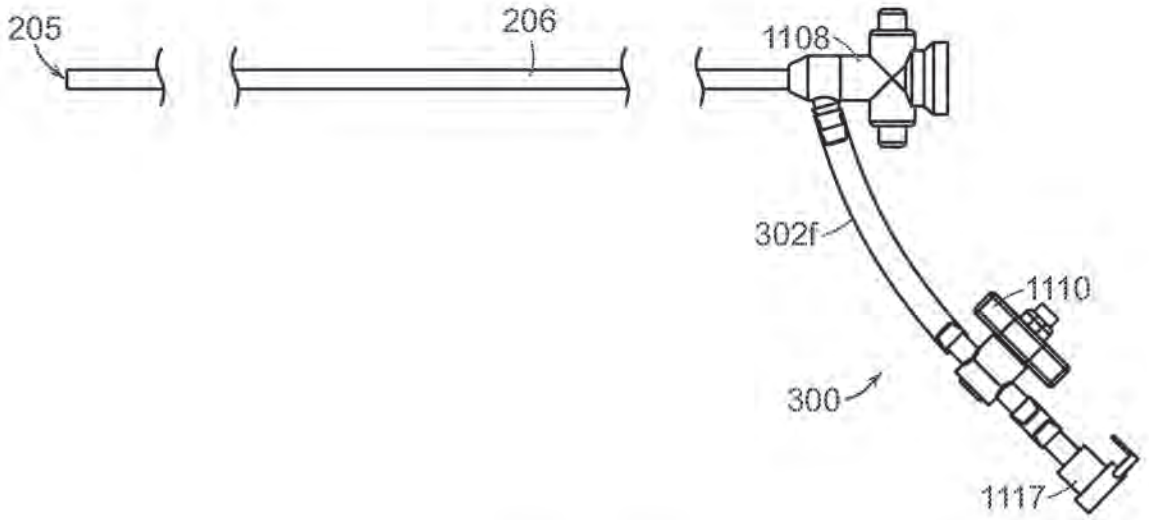


FIG. 11

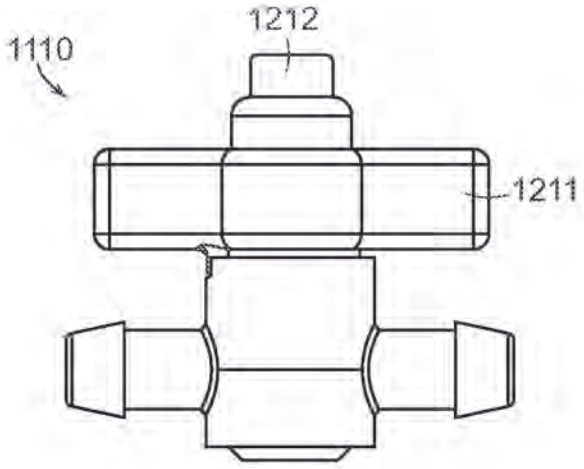


FIG. 12

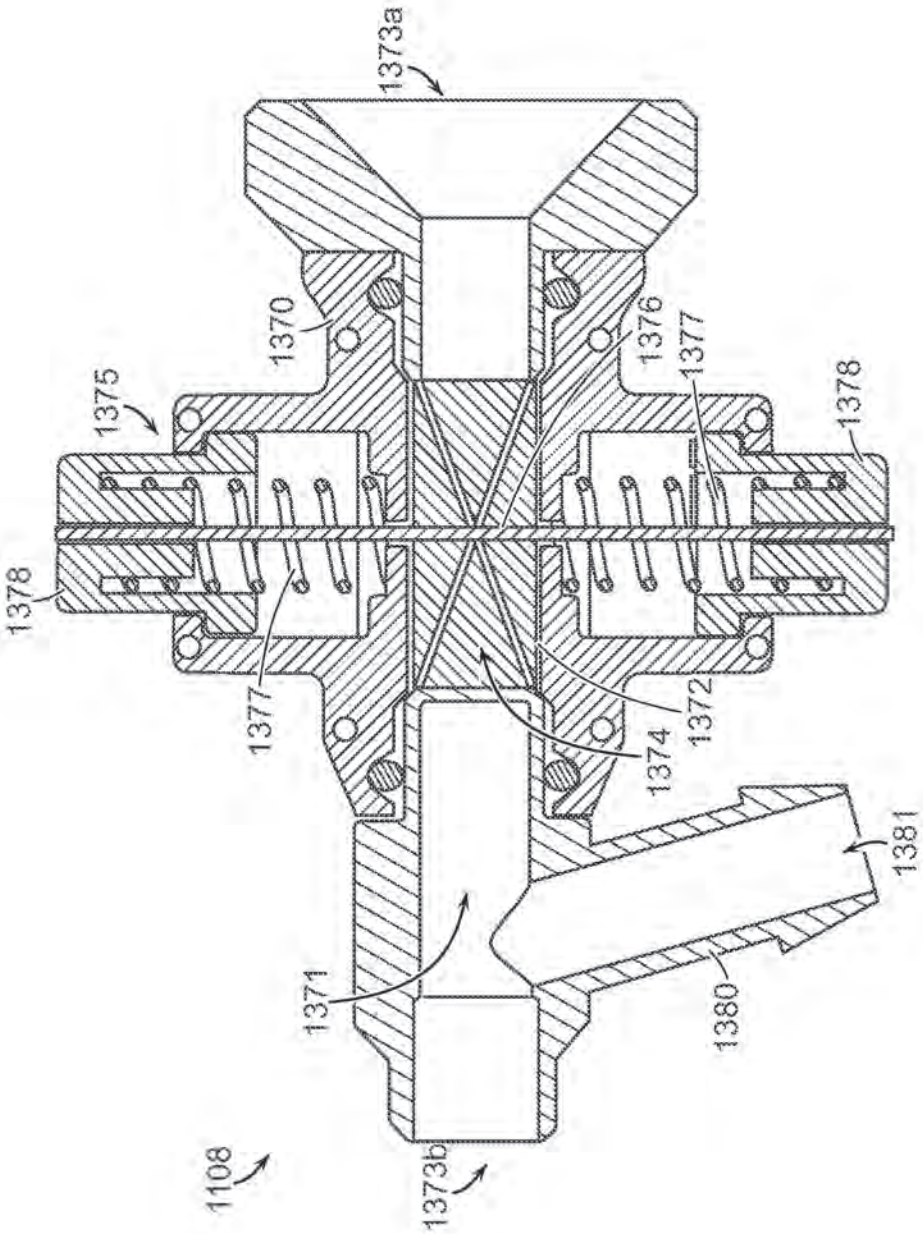

1373a
1370
1376
1377
1375
1378
1378
1377
1372
1374
1381
1371
1380
1108
1373b

FIG. 13A

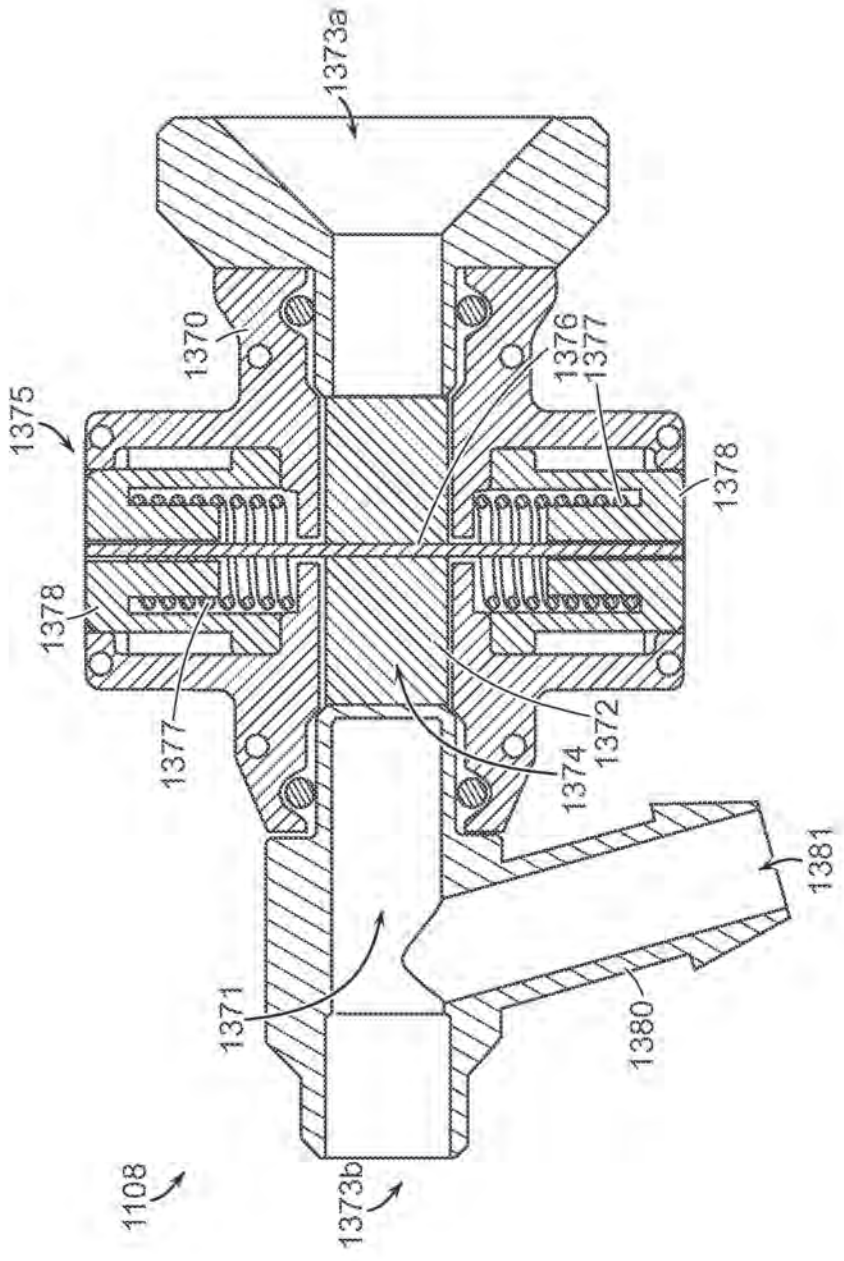

1373a
1370
1376
1377
1375
1378
1378
1377
1372
1374
1381
1371
1380
1108
1373b

FIG. 13B

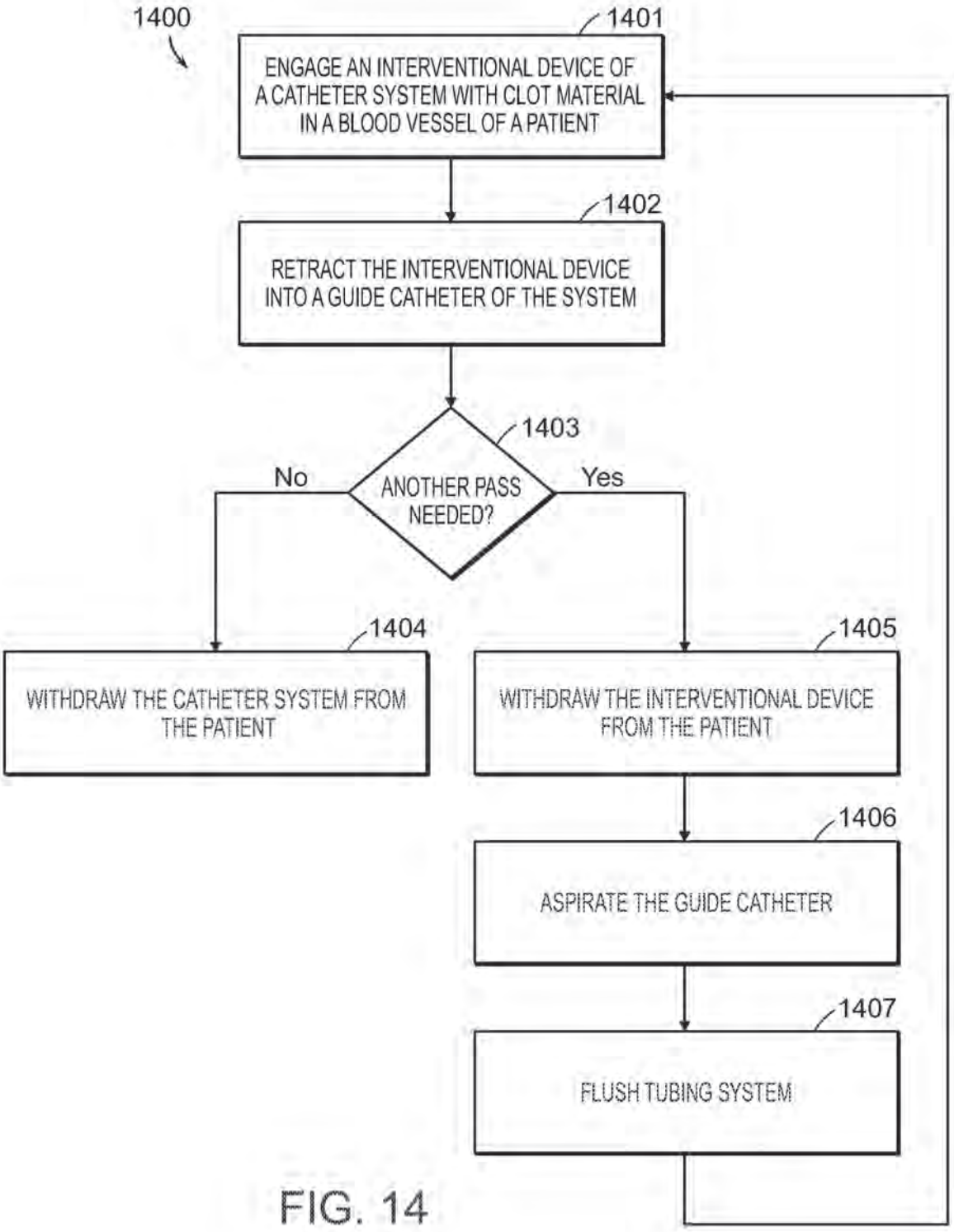

1400
1401
ENGAGE AN INTERVENTIONAL DEVICE OF A CATHETER SYSTEM WITH CLOT MATERIAL IN A BLOOD VESSEL OF A PATIENT
1402
RETRACT THE INTERVENTIONAL DEVICE INTO A GUIDE CATHETER OF THE SYSTEM
1403
ANOTHER PASS NEEDED?
No
Yes
1404
WITHDRAW THE CATHETER SYSTEM FROM THE PATIENT
1405
WITHDRAW THE INTERVENTIONAL 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 on 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," which are incorporated herein by reference in their entireties.

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

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

As further shown in FIG. **2A**, the delivery sheath **204** and the interventional device ID can be positioned at least partially within the clot material PE. Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. The catheter system **200** can include an introducer **210** (FIGS. **1A** and **1B**; e.g., a Y-connector with a hemostasis valve) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer **210** and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve and into the main pulmonary artery. Depending on the location of the embolism, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the pulmonary embolism.

As shown in FIGS. **2B** and **2C**, the delivery sheath **204** can be withdrawn proximally (e.g., as indicated by arrow **A1** in FIG. **2B**) to allow the interventional device ID to expand within the clot material PE, thereby grabbing the clot material PE that is nearby. Although FIG. **2B** shows the interventional device ID positioned at the treatment site such that a distal terminus of the interventional device ID is distal of a distal terminus of the clot material PE, in some procedures the interventional device ID may be positioned such that the distal terminus of the interventional device ID is proximal of the distal terminus of the clot material PE. As shown in FIG. **2D**, in some embodiments the guide catheter **206** can optionally be advanced distally (e.g., as indicated by arrow **A2**) until the guide catheter **206** is positioned proximate to a proximal portion of the clot material PE.

Referring again to FIGS. **1A** and **1B**, the RA device **100** includes (i) a housing **102**, (ii) an actuation mechanism that includes a lever **104** coupled to and extending from the housing **102**, and (iii) a pressure source (obscured in FIGS. **1A** and **1B**; e.g., a syringe) positioned within the housing **102**, coupled to the actuation mechanism, and configured to generate negative and/or positive pressure. The lever **104** is shown in a first position and second position in FIGS. **1A** and **1B**, 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. **1A** and **1B**. The channel **116** can have a height at least as great as the outer diameter of the delivery sheath **204** of the catheter system **200** (and/or another component of the catheter system **200**) such that the delivery sheath **204** can fit sideways through the channel **116**. In some embodiments, the pull member **202** and the interventional device ID (FIGS. **2A-2G**) can be pre-loaded into the delivery sheath **204**, and the delivery sheath **204** can be fed distally through the channel **116** (e.g., either via the proximal end of the channel **116** or first pushed sideways through a portion of the channel **116**) and into the guide catheter **206**. In other embodiments, the interventional device ID and the delivery sheath **204** are fed into the guide catheter **206** and the interventional device ID is deployed prior to coupling the guide catheter **206** to the RA device **100**.

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. **1A-9** for sake of illustration, one skilled in the art will readily understand that the method **1000** can be carried out using other suitable systems and/or devices.

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. **2A-2D** (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. **2E-2G** (block **1002**). In particular, the RA device **100** can be pumped or cycled one or more times (e.g., one time, three times, five times, etc.) to retract the interventional device ID and/or delivery sheath **204** into the guide catheter **206** while simultaneously aspirating the lumen **205** of the guide catheter **206** to remove clot material PE and blood, which are drawn through the attachment member **408** and into the tubing system **300** (e.g., through the clot reservoir **306** to the reservoir **320**).

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. **7A** and **7B**). Once the first valve insert **650** is positioned within the attachment member **408**, the interventional device ID and delivery sheath can be fully withdrawn from the patient. For example, in some embodiments, the operator may grip a portion of the delivery sheath **204** that is exposed proximally from the RA device **100** and pull the delivery sheath **204** and interventional device ID proximally through the guide catheter **206**. In some embodiments, the first valve insert **650** is only positioned within the attachment member **408** when the interventional device ID is proximate the attachment member **408**. That is, the operator may partially withdraw the delivery sheath **204** and interventional device ID within the guide catheter **206** before advancing the first valve insert **650** into position. In some embodiments, the delivery sheath **204** includes a marking (e.g., a specific color pattern) configured to indicate to the operator that the distal end of the delivery sheath **204** and/or the interventional device ID is near (e.g., proximally approaching) the attachment member **408**. In certain embodiments, the guidewire of the catheter system **200** is pinned during withdrawal of the interventional device ID and the delivery sheath **204** such that the guidewire does not move relative to the interventional device ID and the delivery sheath **204**. Therefore, in such embodiments, the guidewire does not need to be re-advanced to the treatment site prior to an additional pass.

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 clot collection reservoir, comprising:

a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;

a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;

a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber; and

a filter removably positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port;

wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;

wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and

wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.

2. The clot collection reservoir of claim 1 wherein the second port is positioned proximate to the second housing end portion.

3. The clot collection reservoir of claim 1, further comprising a cap configured to be releasably coupled to the second housing end portion, wherein the cap is removable from the housing to provide access to the filter.

4. The clot collection reservoir of claim 1 wherein the first filter end portion is curved.

5. The clot collection reservoir of claim 1 wherein the source of aspiration is configured to generate the negative pressure in the chamber via the second port to draw the clot material against the first filter end portion.

6. The clot collection reservoir of claim 1 wherein the housing is entirely transparent, and wherein the first port is integrally formed with the housing.

7. The clot collection reservoir of claim 1 wherein the first filter end portion is positioned closer to the first housing end portion than the second filter end portion, and wherein the second filter end portion is positioned closer to the second housing end portion than the first filter end portion.

8. A clot collection reservoir, comprising:

a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;

a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;

a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber;

a cap configured to be releasably coupled to the second housing end portion; and

a filter coupled to the cap and configured to be positioned when the chamber when the cap is releasably coupled to the second housing end portion, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port;

wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;

wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port;

wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region; and

wherein the cap is removable from the housing to provide access to the filter.

9. A clot collection reservoir, comprising:

a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;

a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;

a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber;

a cap configured to be releasably coupled to the second housing end portion; and

a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port;

wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;

wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port;

wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region; and

wherein the cap and the filter are removable from the housing to provide access to the clot material within the chamber.

10. A clot treatment system, comprising:
an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient;
an aspiration source; and
a clot collection reservoir, comprising—
a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;
a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;
a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber; and
a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port;
wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;
wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and
wherein the filter is removably positioned within the chamber to provide access to the clot material within the chamber.

11. The clot treatment system of claim 10 wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.

12. The clot treatment system of claim 10 wherein the second port is positioned proximate to the second housing end portion.

13. The clot treatment system of claim 10 wherein the clot collection reservoir is spaced apart from the aspiration source, and further comprising at least one tube fluidly coupling the second port to the aspiration source.

14. A clot treatment system, comprising:
an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient;
an aspiration source; and
a clot collection reservoir, comprising—
a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;
a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;
a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber;
a cap configured to be releasably coupled to the second housing end portion; and
a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port;
wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;
wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and
wherein the cap and the filter are removable from the housing to provide access to the clot material within the chamber.

15. A clot treatment system, comprising:
an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient;
an aspiration source;
a clot collection reservoir, comprising—
a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;
a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;
a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber; and
a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port; and
a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user-actuatable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter;
wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port; and
wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.

16. The clot treatment system of claim 15 wherein the aspiration source is configured to generate the negative pressure in the chamber with the valve in the closed position, and wherein the valve is configured to be moved to the open position to apply the negative pressure to the aspiration catheter.

17. A clot treatment system, comprising:
an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient;
a hemostasis valve coupled to a proximal portion of the aspiration catheter;
at least one tube fluidly coupling the first port to a portion of the aspiration catheter distal of the hemostasis valve;

an aspiration source; and

a clot collection reservoir, comprising—

a housing defining a chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;

a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion;

a second port configured to be fluidly coupled to the aspiration source; and

a filter positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port;

wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port; and

wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.

18. The clot treatment system of claim **17** wherein the hemostasis valve comprises:

a tubular member;

a button; and

a filament coupled to the button and the tubular member, wherein the button is actuatable to loosen the filament to unseal the hemostasis valve.

19. The clot treatment system of claim **17** wherein the aspiration source is fluidly couplable to the at least one tube.

20. The clot treatment system of claim **17** wherein the hemostasis valve is configured to receive an instrument therethrough.

21. The clot treatment system of claim **17** wherein the hemostasis valve and the aspiration catheter are configured to receive and route an instrument therethrough.

22. The clot treatment system of claim **17** wherein the hemostasis valve comprises:

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.

23. The clot treatment system of claim **22** wherein the actuators each comprise a button.

24. The clot treatment system of claim **22** 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.

25. The clot treatment system of claim **22** wherein the first filament is flexible, and wherein the second filament is flexible.

26. The clot treatment system of claim **17** wherein the aspiration catheter has a size of at least 16 French.

27. The clot treatment system of claim **17** wherein the aspiration catheter has a size of at least 20 French.

28. The clot treatment system of claim **17** wherein the aspiration catheter has a size of at least 22 French.

* * * * *

EXHIBIT X

INFRINGEMENT ANALYSIS – CLAIM 1 OF UNITED STATES PATENT NO. 12,239,333
TRUVIC SYMPHONY THROMBECTOMY SYSTEM

CLAIM ELEMENT	CORRESPONDING STRUCTURE
[1] A clot collection reservoir, comprising:	The Symphony System includes a clot collection reservoir (including a "clot container" connected to the Symphony Bigshot Controller handle). Specifically, the 24F and 16F Symphony Catheter handles of the Symphony System includes a clot collection reservoir where a user can "[c]onfirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle." (Symphony Thrombectomy System Instructions For Use at 5; Symphony Thrombectomy System Instructions For Use at 6 (same); Symphony Thrombectomy System Instructions For Use at 8 (same).) The clot container of the 24F and 16F Symphony Catheter handles is shown in the Symphony System IFU below.

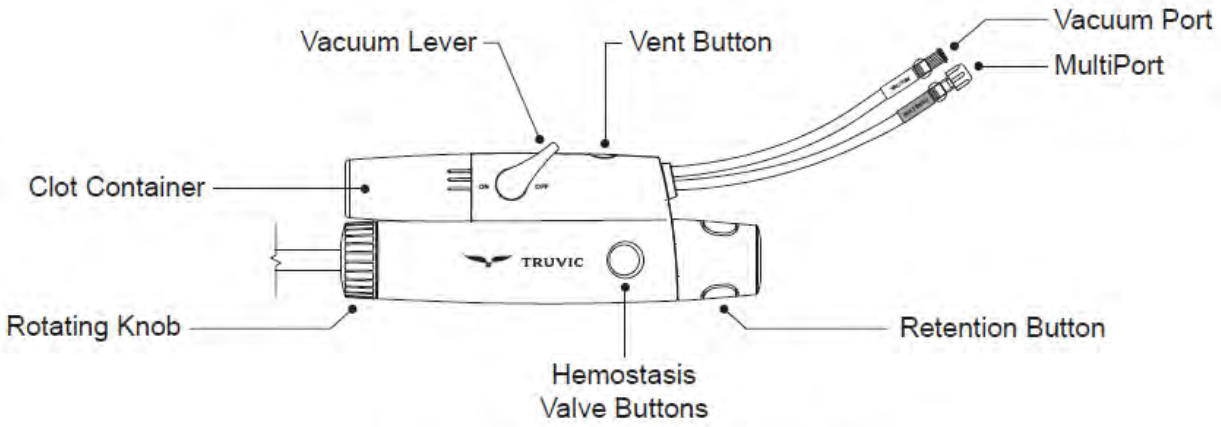
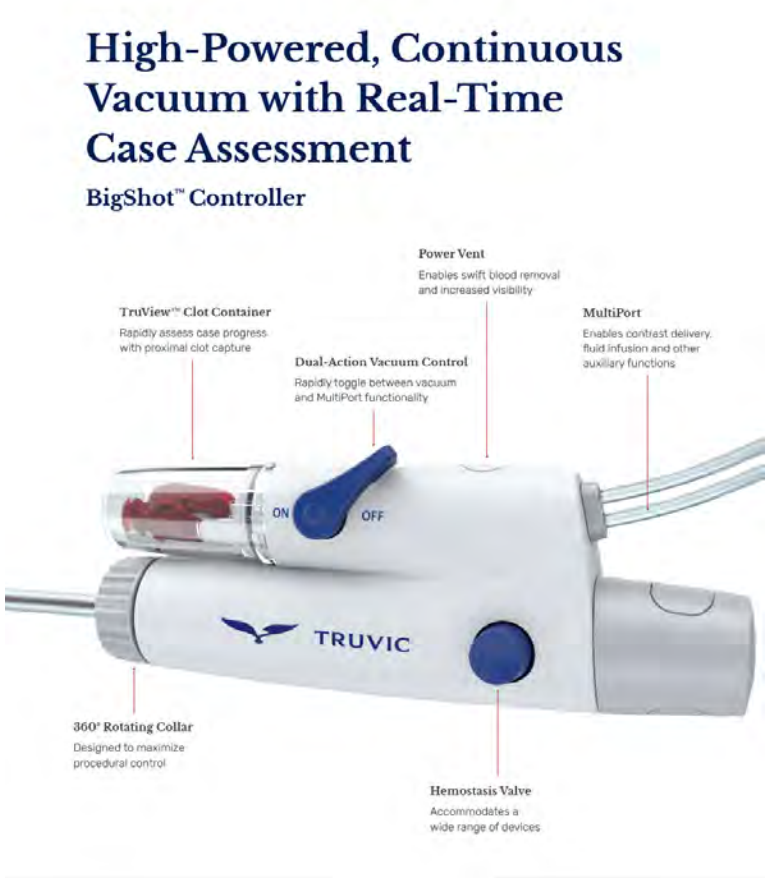
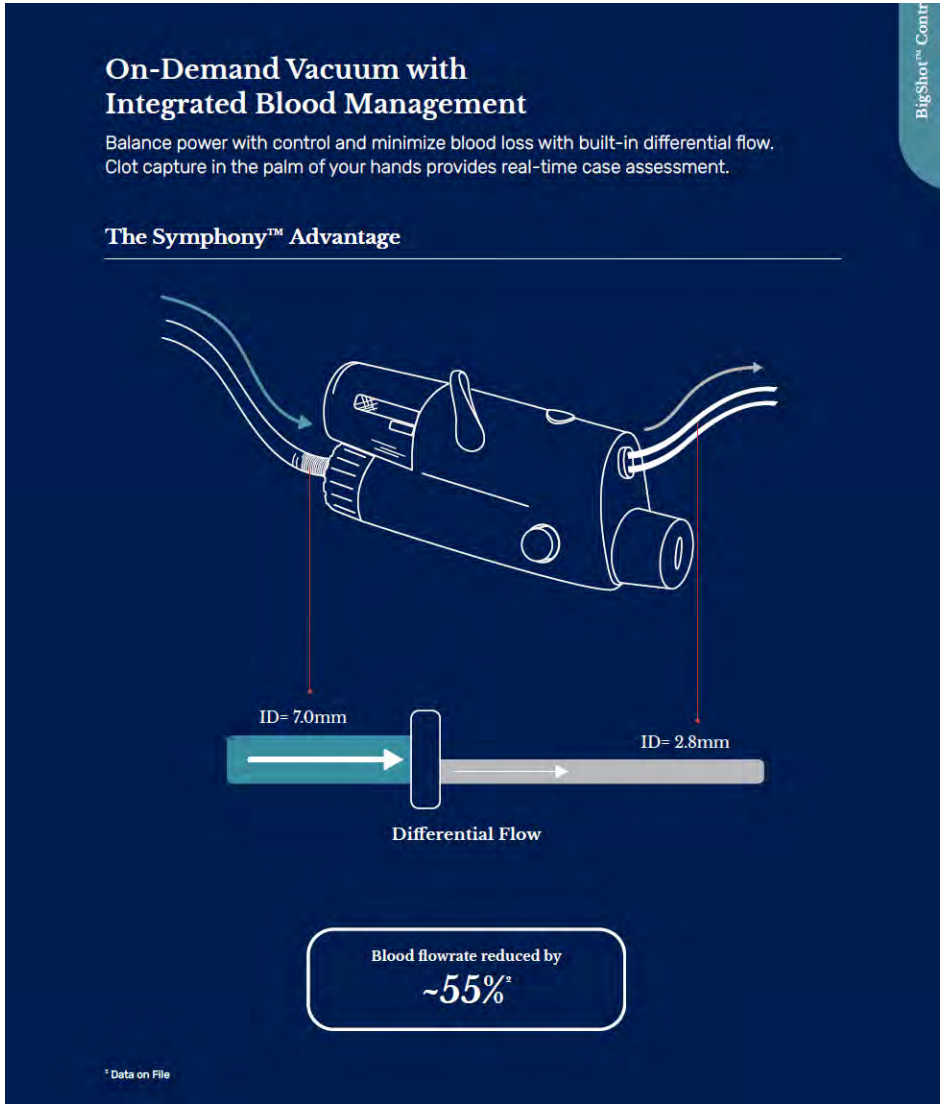


Figure 3: Symphony Catheter Handle, labeled

(Symphony Thrombectomy System Instructions For Use at 4). The Symphony Thrombectomy System Brochure also depicts the clot container of the Symphony Catheter handle, which allows a user to "[r]apidly assess case progress with proximal clot capture" as shown below. (Symphony Thrombectomy System Brochure at 6.)



(Symphony Thrombectomy System Brochure at 6.)

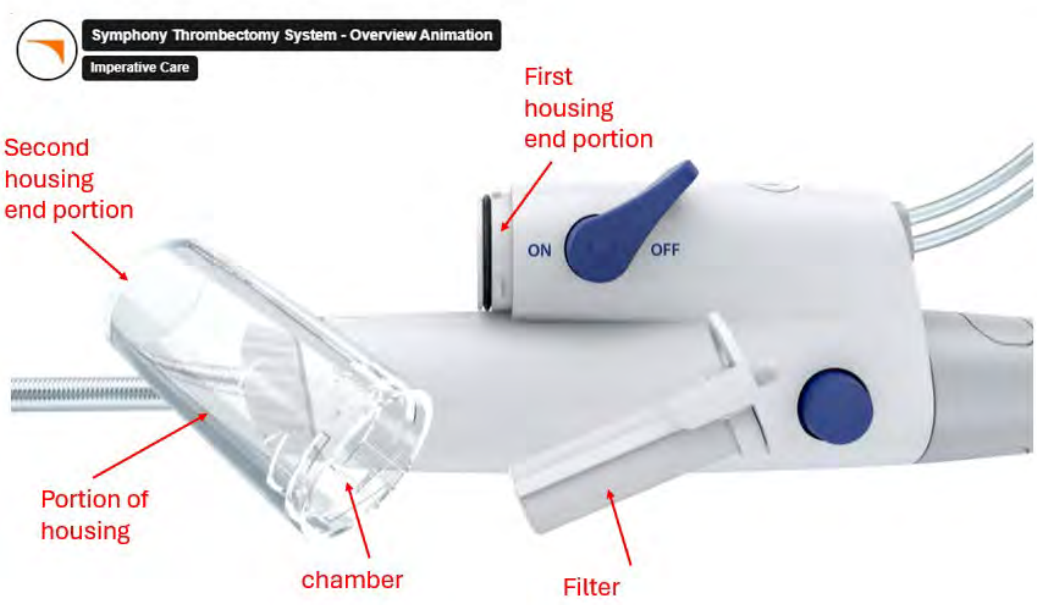


(Symphony Thrombectomy System Brochure at 7.)

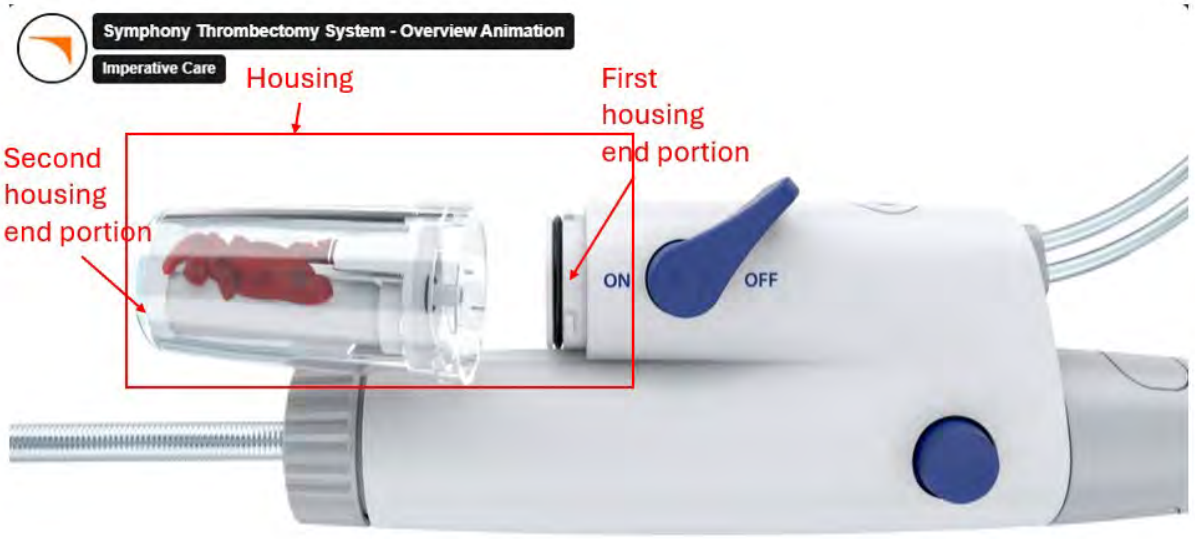
	The clot collection reservoir of the Symphony Catheter handle is also shown on the Whipsaw website.  (Image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)

	 (Image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)

	 (Image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)
a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;	The clot collection reservoir of the Symphony System includes a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion. The clot collection reservoir and the 24F and 16F Catheter Handles includes a housing, which defines a sealed chamber and has a first housing end portion and a second housing end portion opposite the first, as shown in the annotated image below. The removable portion of the clot collection reservoir housing removably attaches to the portion of the housing connected to the 24F and 16F Catheter Handles.

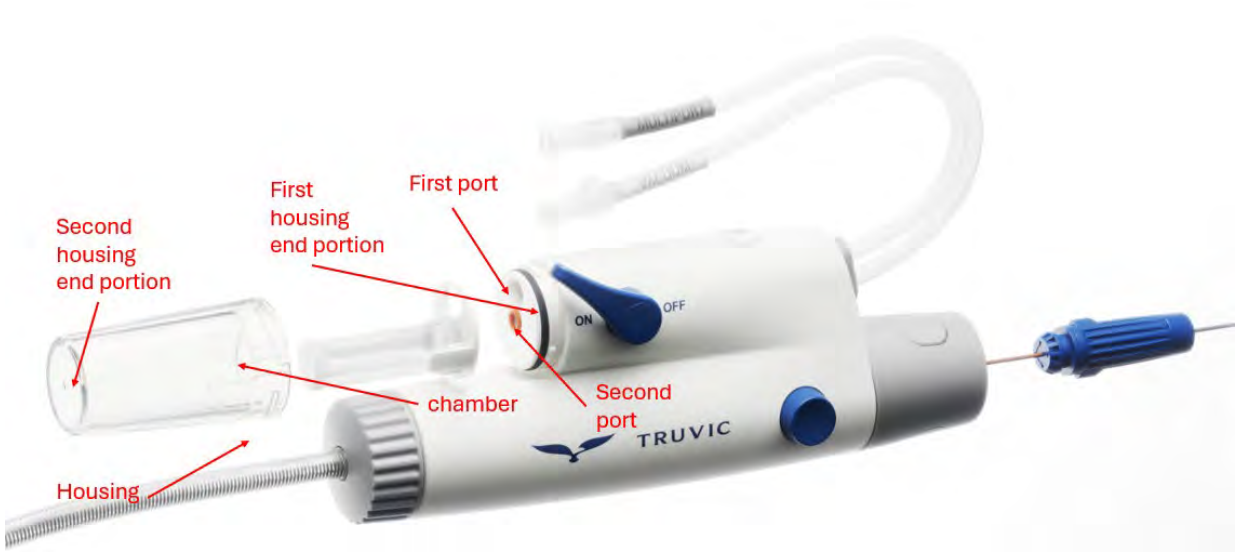


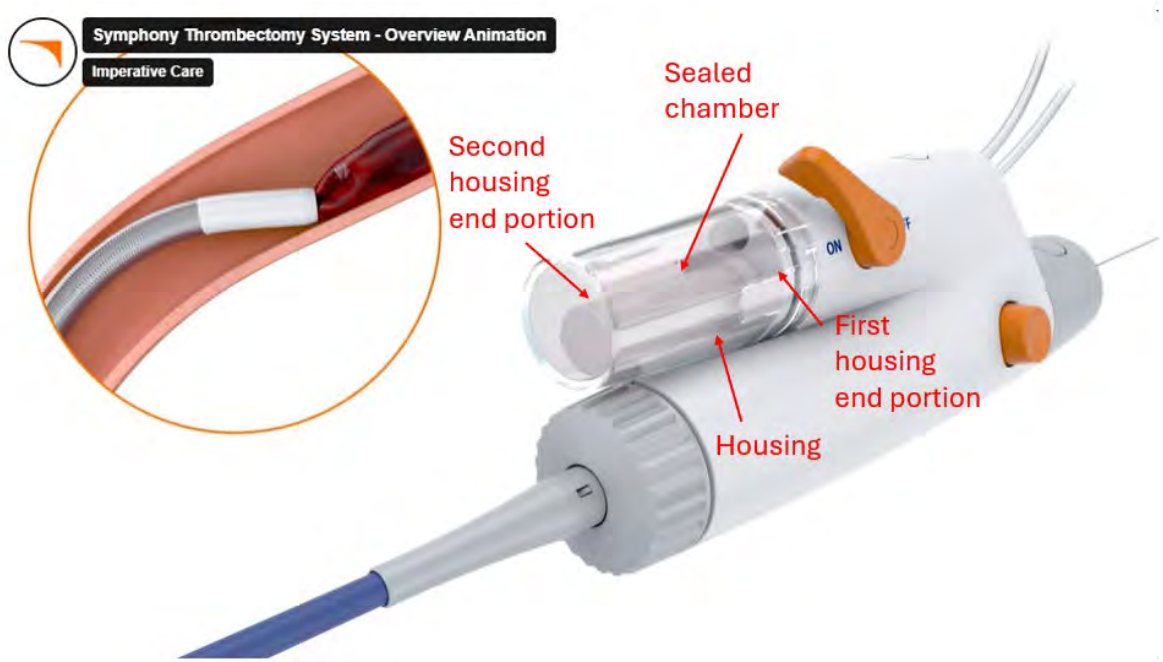
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

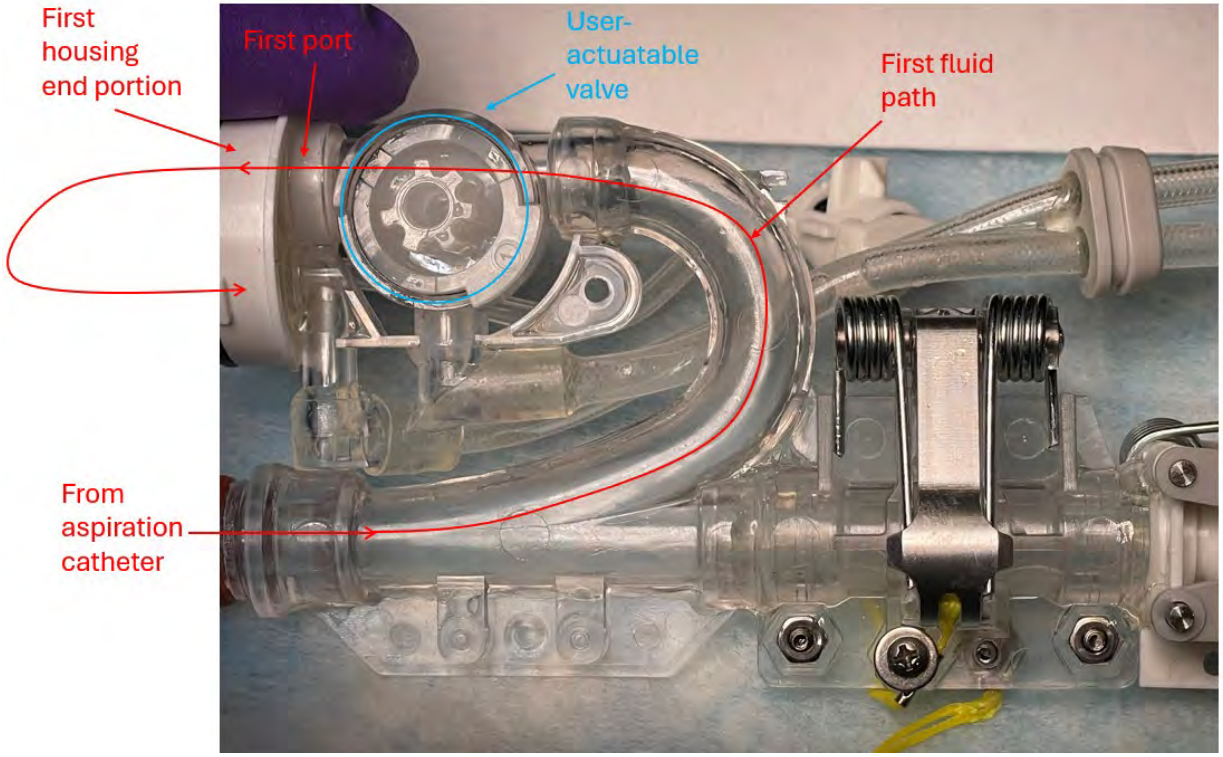


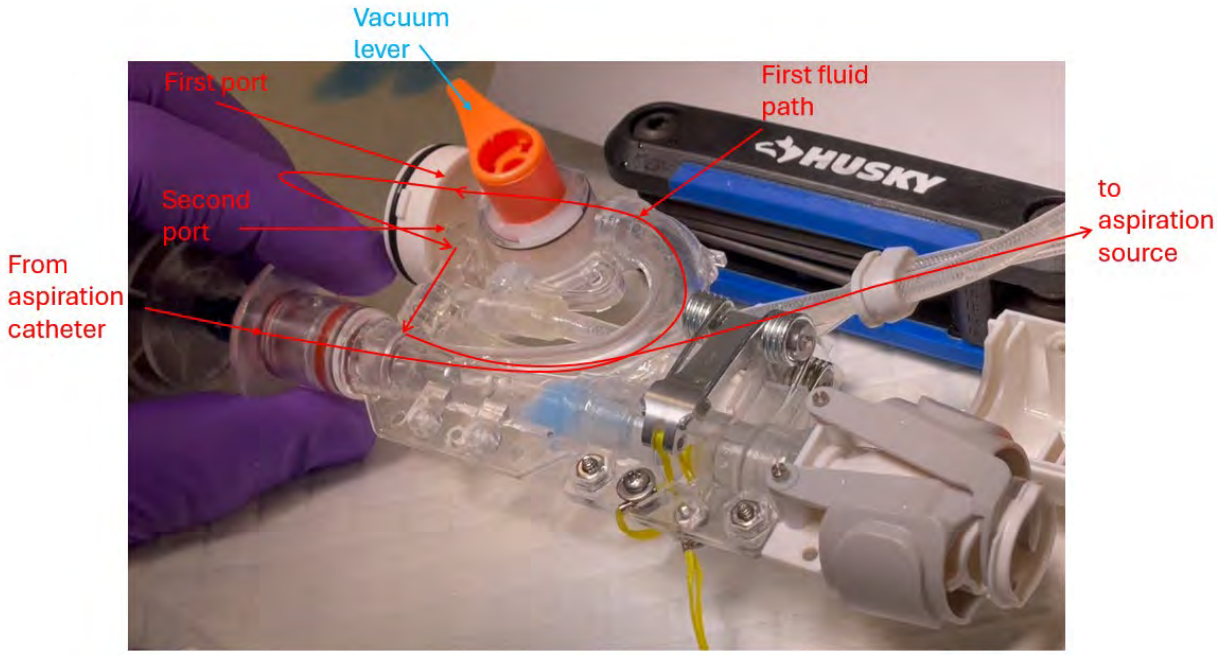
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:19.)

The annotated image from Whipsaw's website below also shows a black rubber ring that helps ensure the chamber of the clot container is sealed so that blood and clot material does not leak out of the clot container during use.

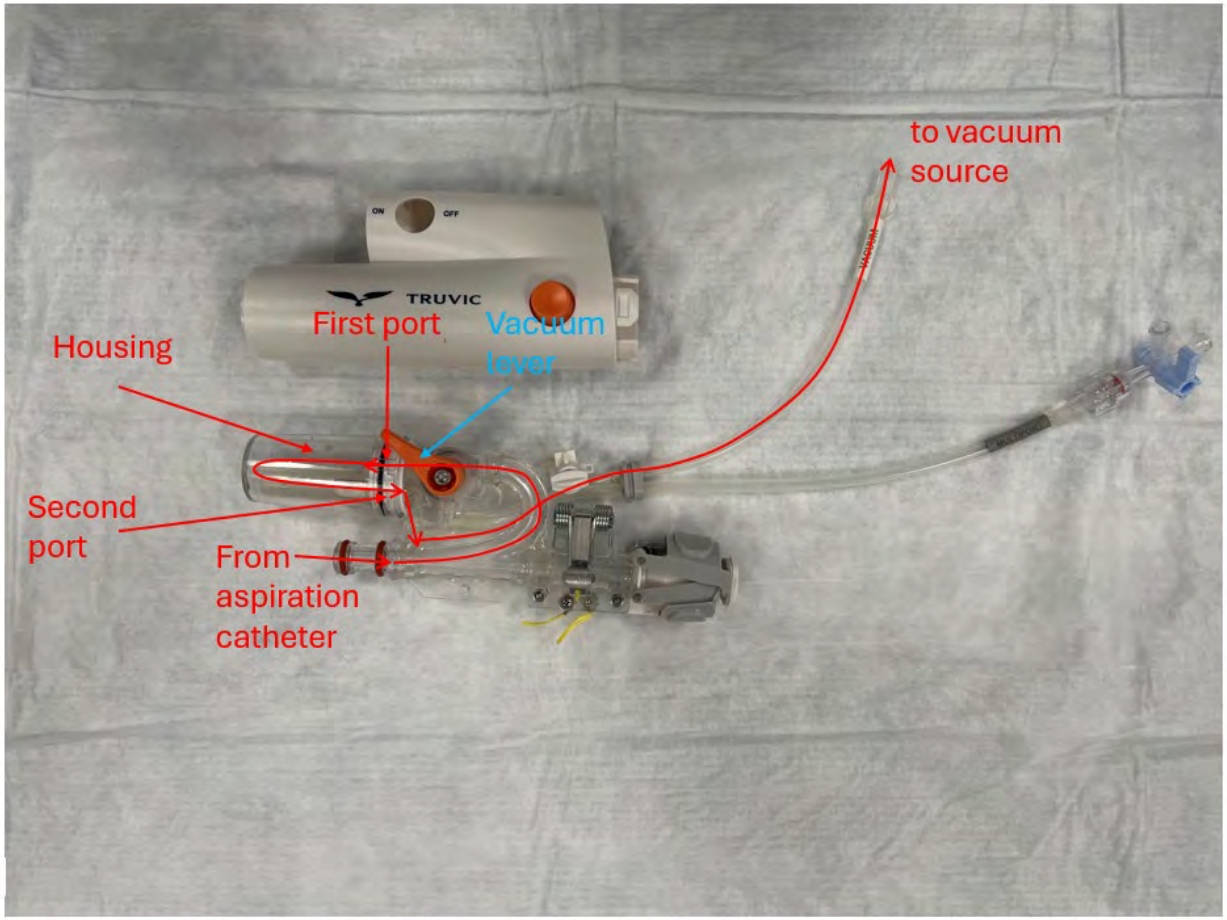
	 (Annotated image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)

	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 1:57.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid	The clot collection reservoir of the Symphony System includes a first port configured to be fluidly coupled to an aspiration catheter, where the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber.

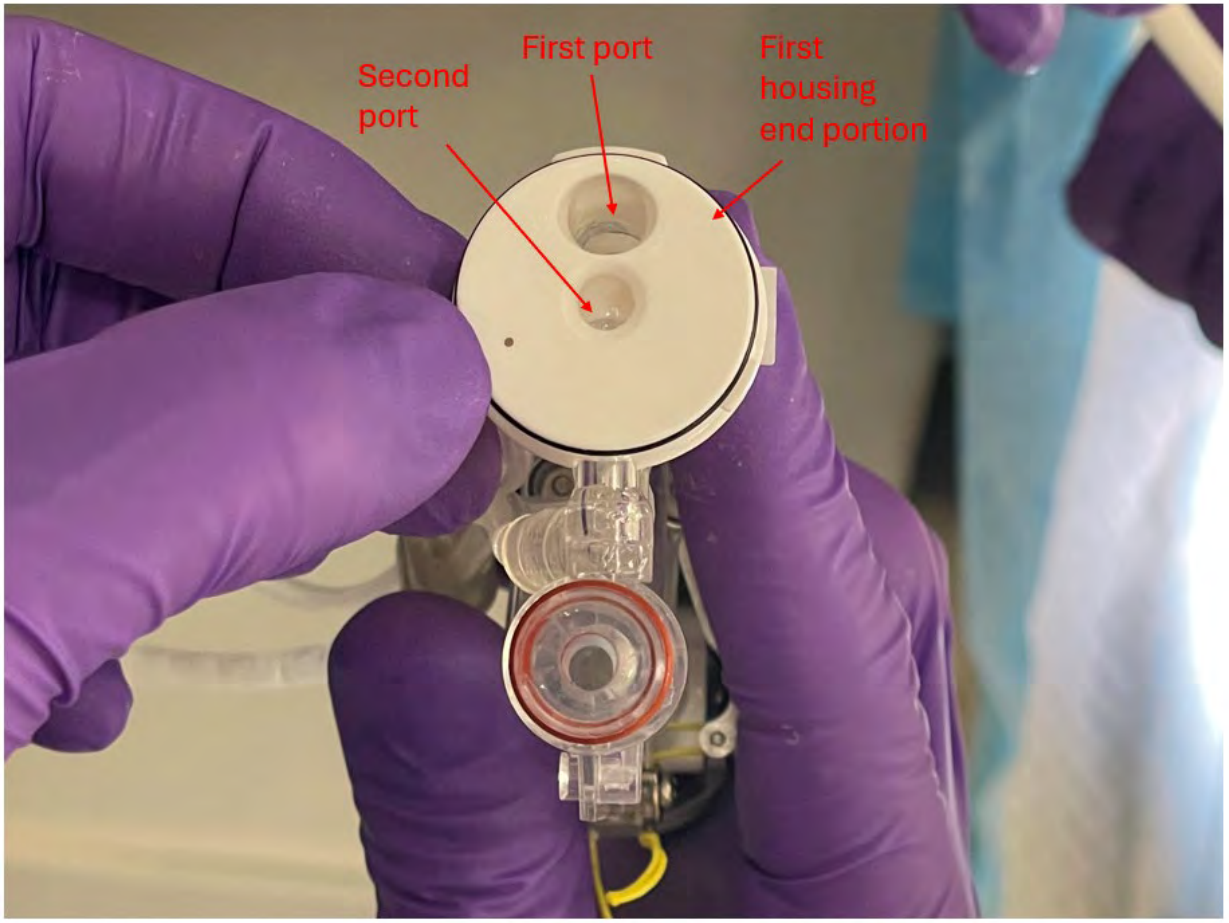
path to the chamber;	Specifically, the clot collection reservoir of the 24F and 16F Symphony Catheter handles includes a first port proximate to the first housing end portion that is coupled to an aspiration catheter when the valve is in the ON position, as shown in the annotated teardown images below.  (Annotated image of internal portion of the controller housing.)



(Annotated image of internal portion of controller housing.)

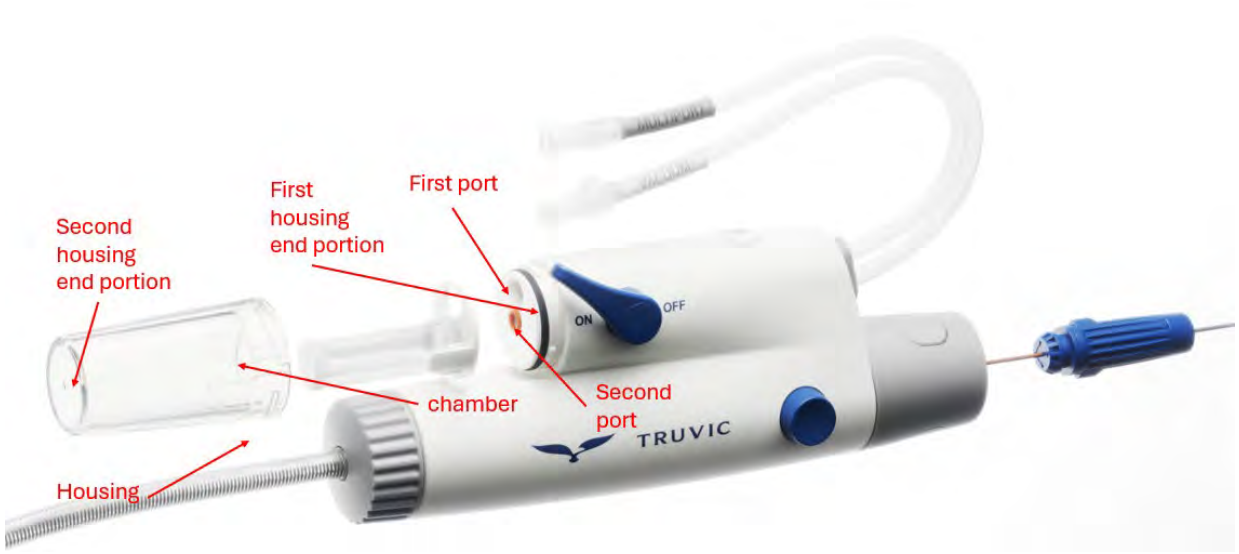


(Annotated image of internal portion of controller housing.)



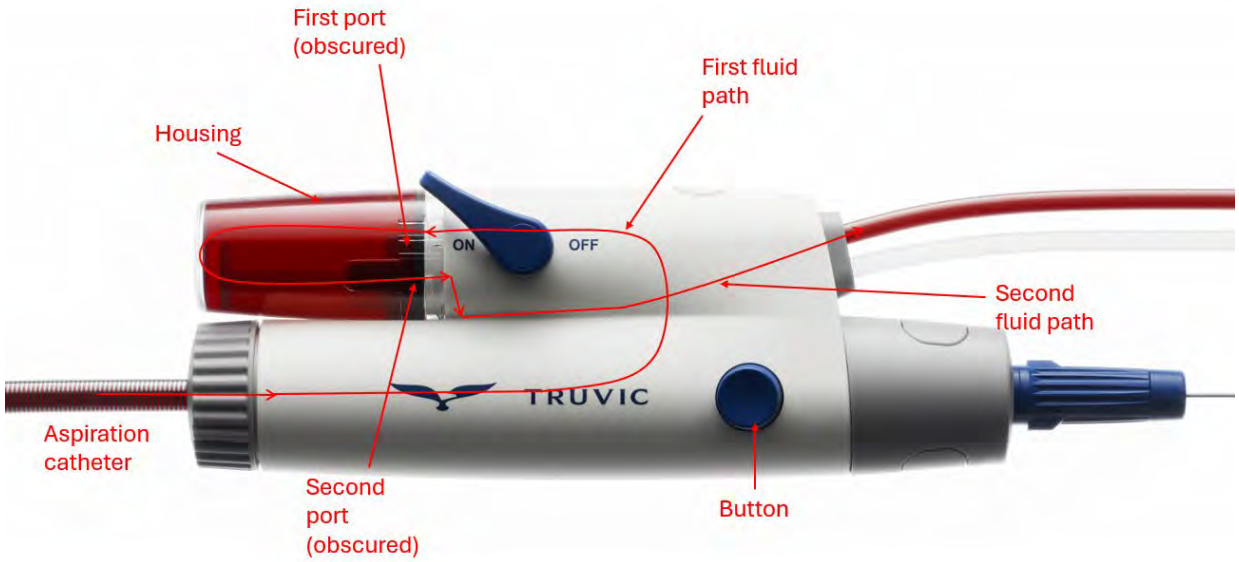
(Annotated image of controller housing showing first and second ports.)

The first port can also be seen in the exploded image from the Whipsaw website of a 24F Symphony Catheter handle with a disassembled clot collection reservoir, which is annotated and reproduced below. The first port is proximate (*e.g.*, near) the first housing end portion of the Symphony Catheter handle.



(Annotated image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)

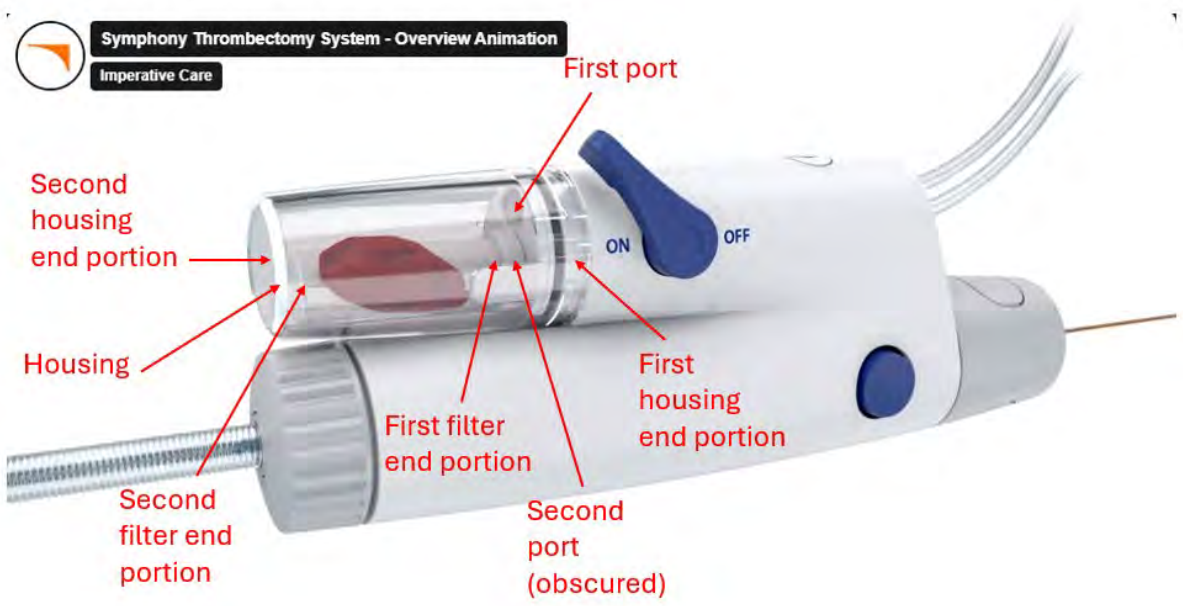
The first port provides a first fluid path from the aspiration catheter to the clot container of the 24F and 16F Symphony Catheter handles, as shown in the annotated image from Whipsaw's website below. Specifically, blood and clot material enters the aspiration catheter and travels along the first fluid path through the first port and into the chamber of the clot container.

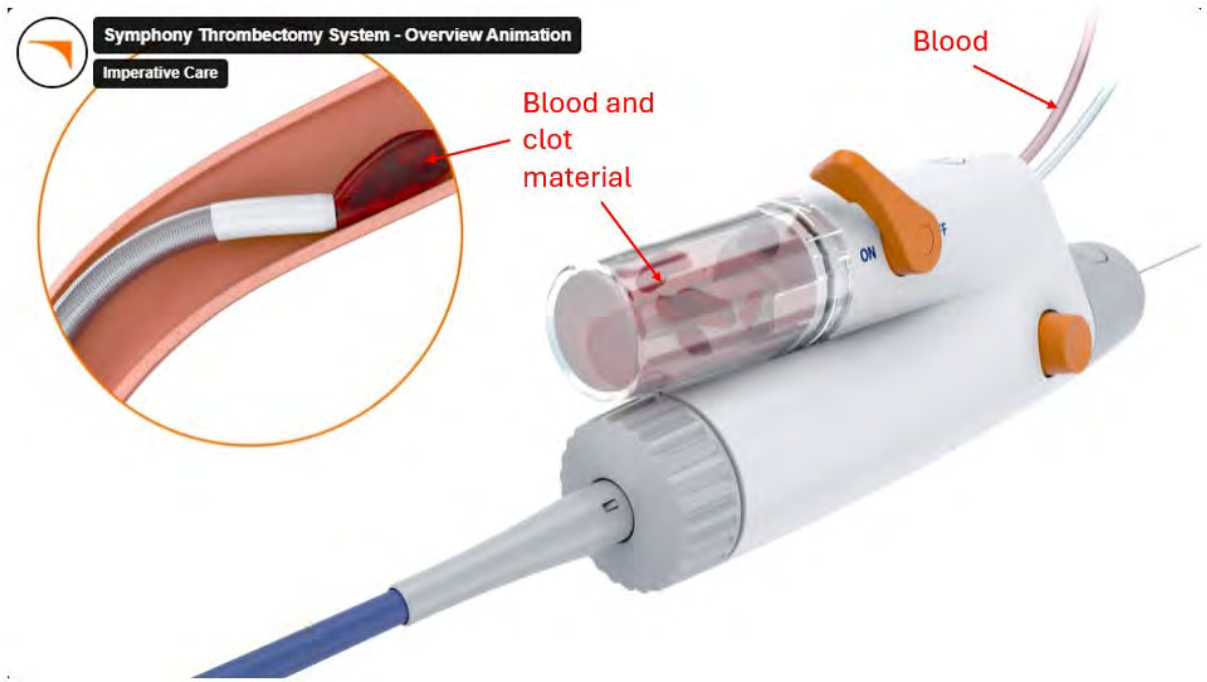


(Annotated image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)

The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration cathethers, travels through the first fluid path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot collection reservoir.

(Symphony Thrombectomy System – Overview Animation Video at 0:45.)

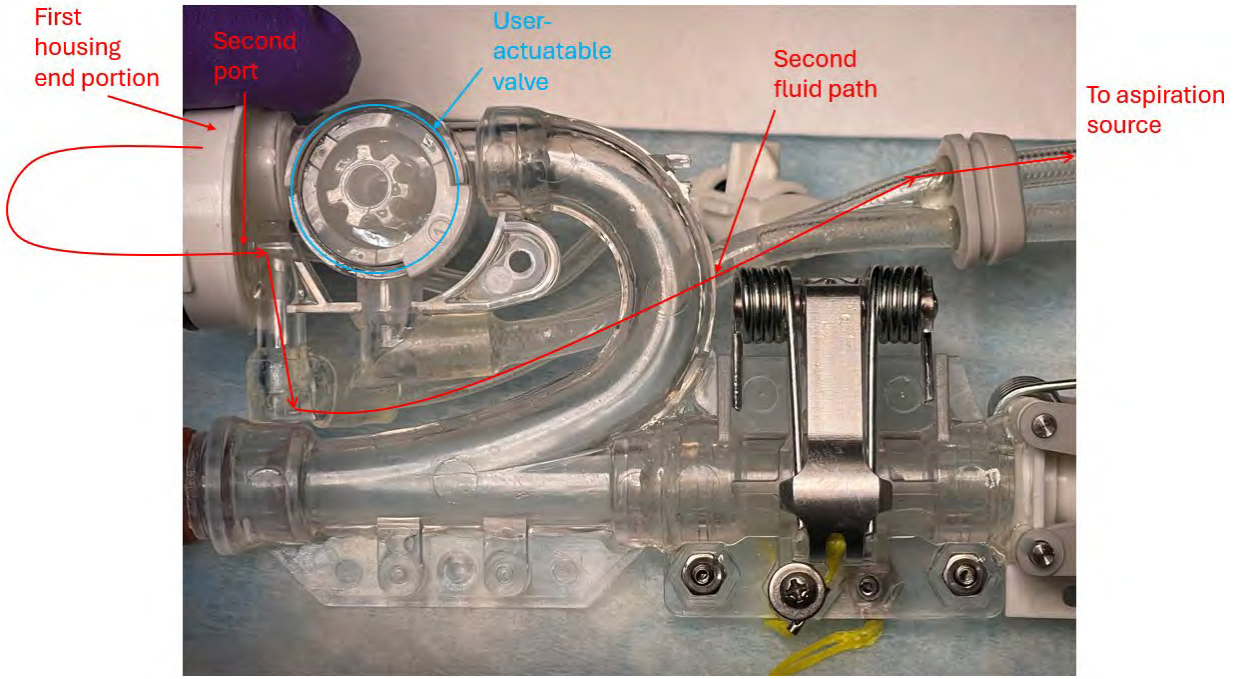
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)



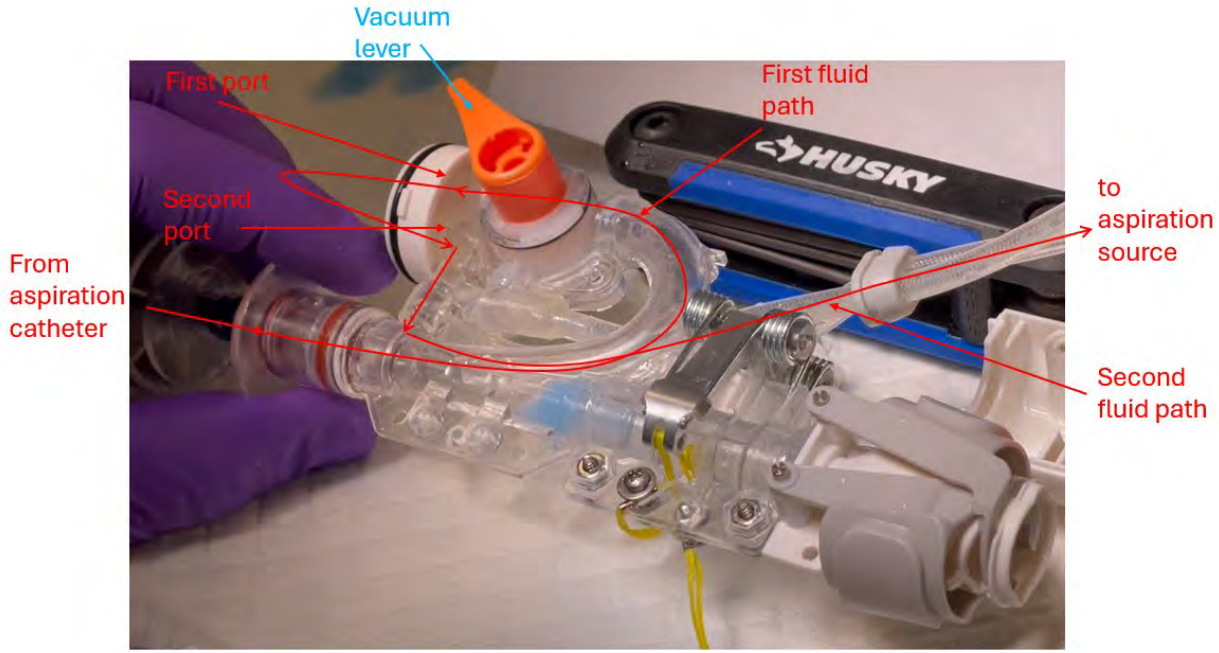
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

Similarly, the Symphony System IFU describes that, during aspiration, blood and clot material moves from the aspiration catheter to the clot container. (Symphony Thrombectomy System Instructions For Use at 5 ("To begin aspiration, move the vacuum lever on the Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the 'OFF' position.").) As shown in the images above, blood and clot material flow through along the first fluid path and through the first port to enter the chamber of the clot container.

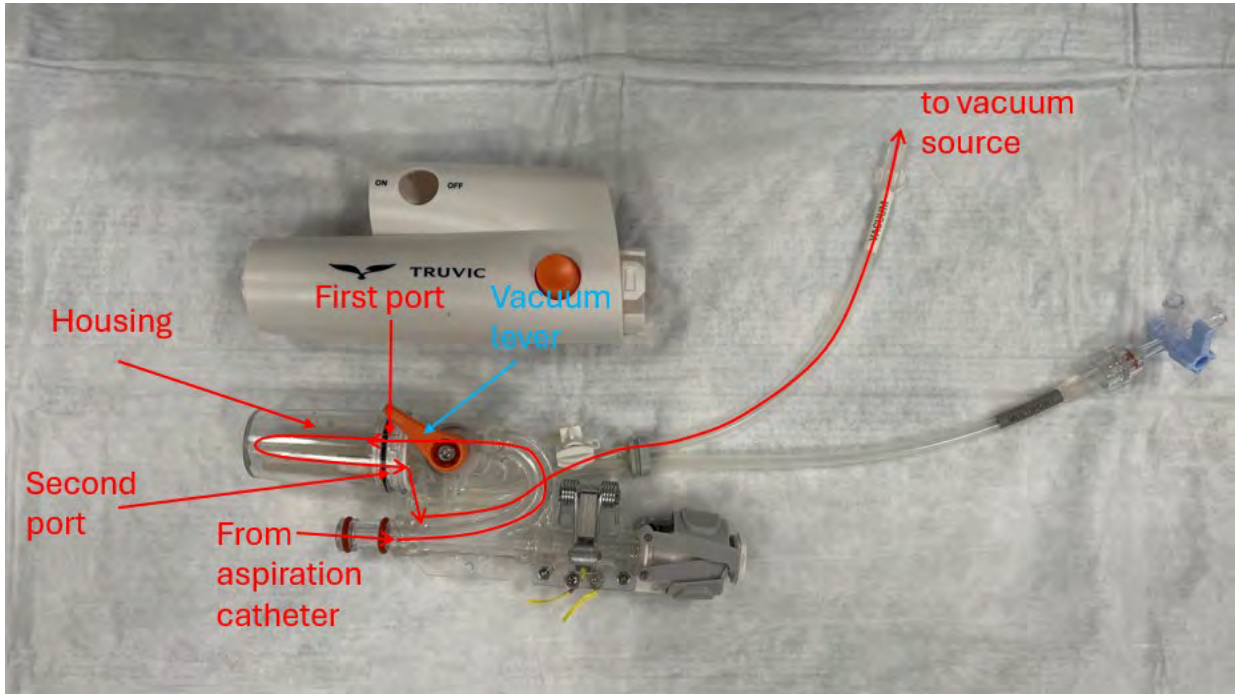
	To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber; and	The clot collection reservoir of the Symphony System includes a second port configured to be fluidly coupled to an aspiration source, where the second port provides a second fluid path from the chamber. Specifically, the clot collection reservoir of the 24F and 16F Symphony Catheter handles includes a second port that is configured to be fluidly coupled to an aspiration source (*e.g.* the Truvic Generator and Truvic Canister) and provides a second fluid path from the chamber of the clot collection reservoir to the aspiration source (*e.g.* the Truvic Canister, which is part of the aspiration source), as shown in the annotated teardown images below.



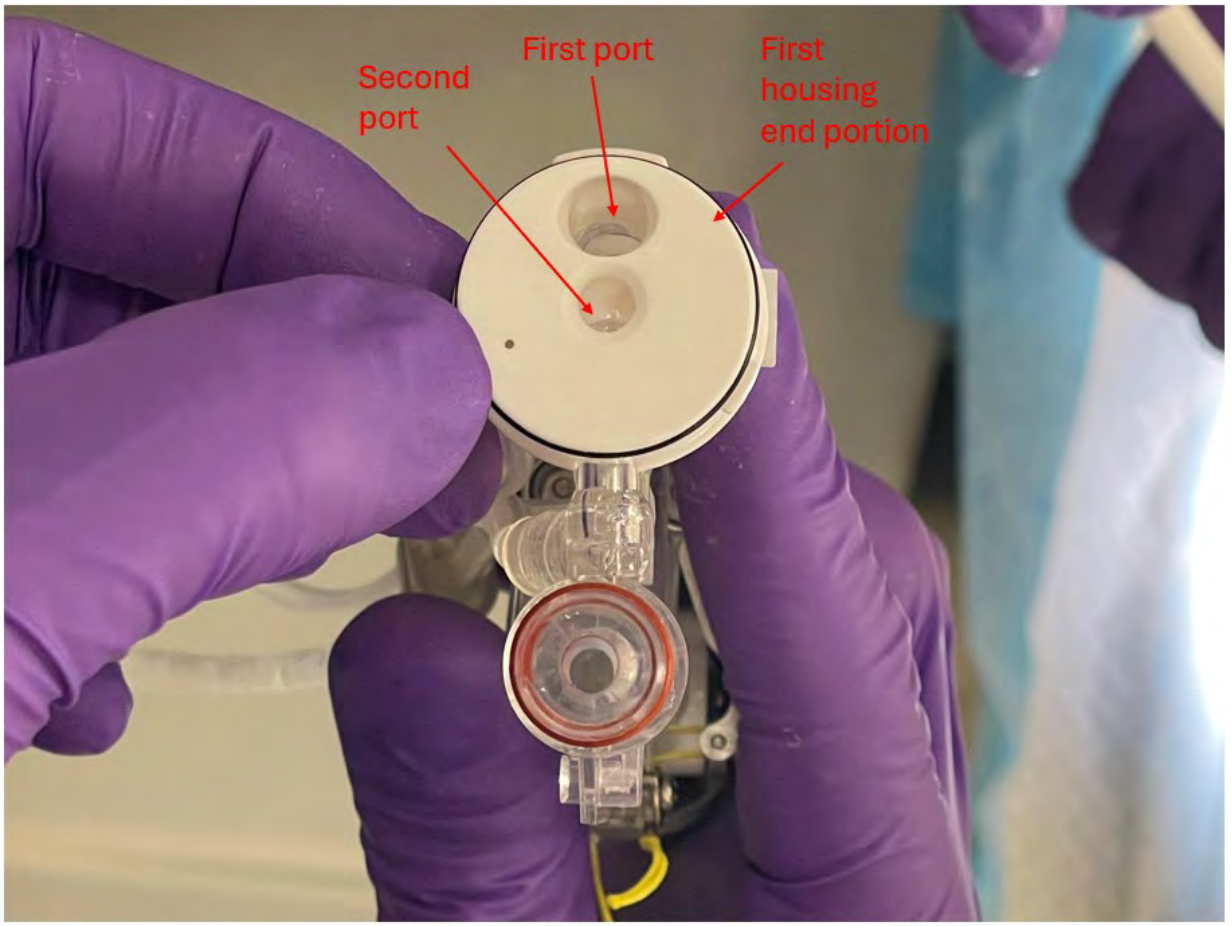
(Annotated image of internal portion of the controller housing.)



(Annotated image of internal portion of the controller housing.)

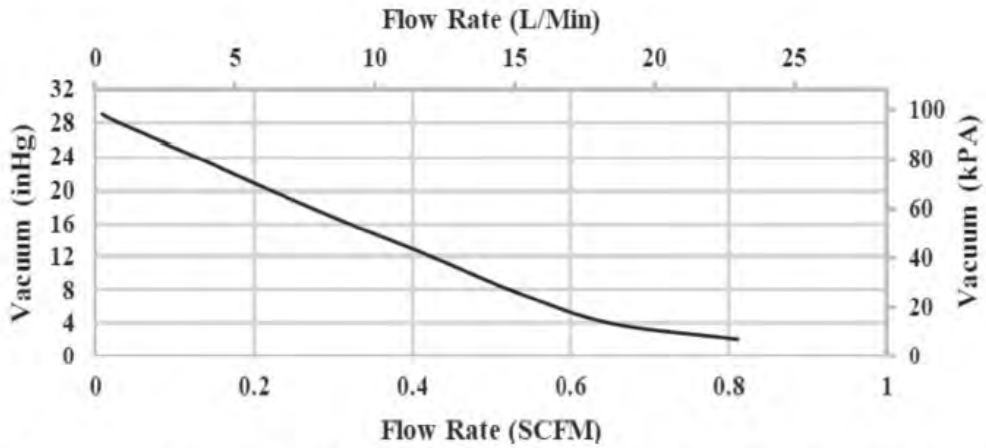


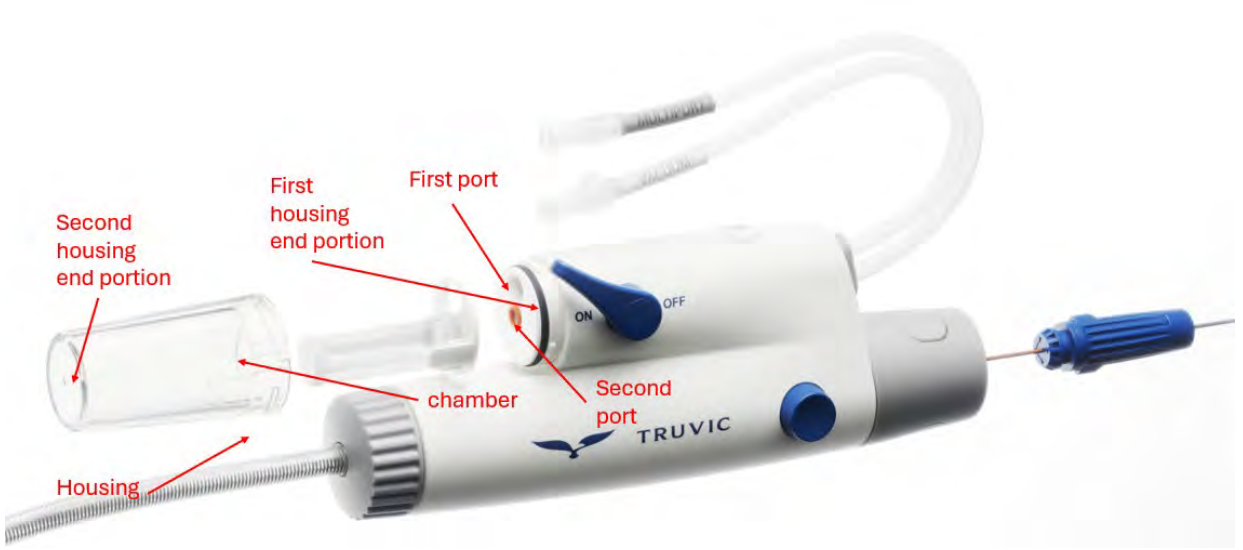
(Annotated image of internal portion of the controller housing.)

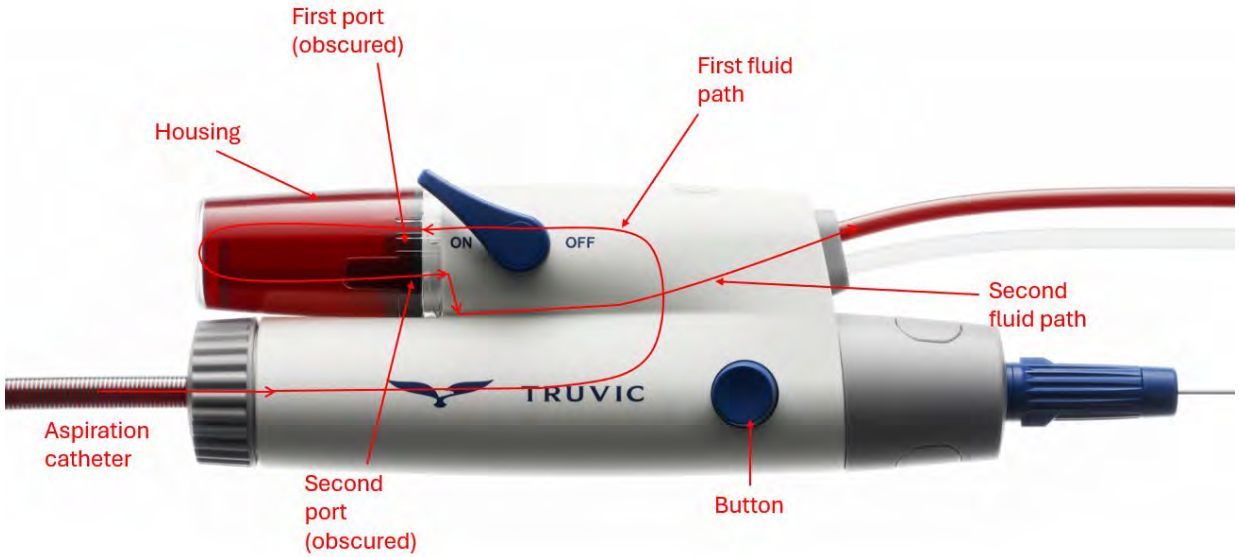


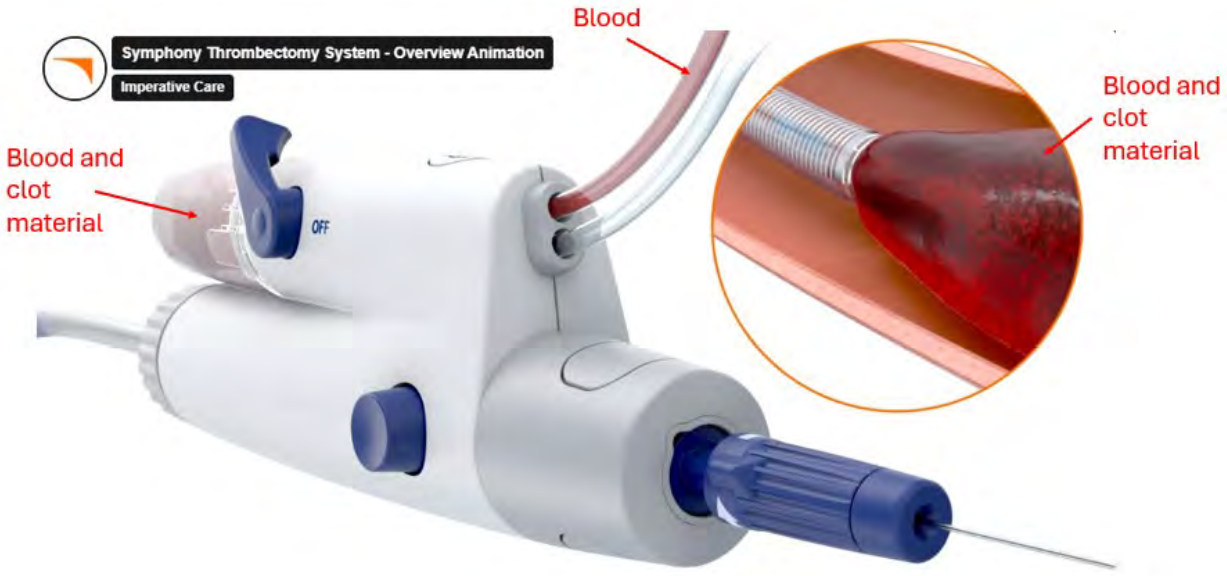
(Annotated image of controller housing showing first and second ports.)

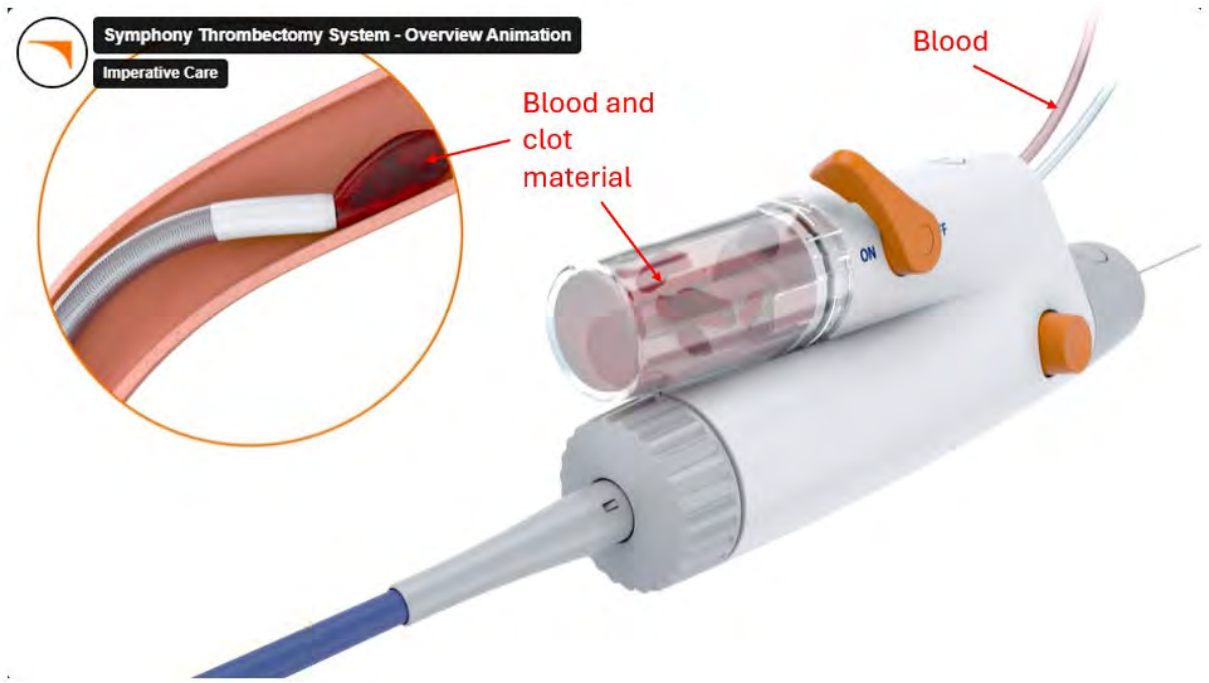
The Symphony System IFU describes how the 24F and 16F Symphony Catheter handles are designed to be used with the Truvic Generator and Truvic Canister for aspiration. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Thrombectomy System is designed to remove thrombus/embolus

	(hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration. The Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus."); Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus."); Symphony Thrombectomy System Instructions For Use at 2 ("The TRUVIC Symphony Thrombectomy Catheters have been verified for use with the TRUVIC Tubeset and TRUVIC Generator. The TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 2.").)  Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator (Symphony Thrombectomy System Instructions For Use at 2 (showing vacuum pressure and flow rate for aspiration source).)

	The second port can also be seen in the exploded image from the Whipsaw website of a 24F Symphony Catheter handle with a disassembled clot collection reservoir, which is annotated and reproduced below.  (Annotated image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) The second port provides a second fluid path from the clot container of the 24F and 16F Symphony Catheter handles, as shown in the annotated image from Whipsaw's website below. Specifically, blood and clot material enters the aspiration catheter and travels along the first fluid path through the first port and into the chamber of the clot container. Blood then passes through the filter, through the second port and along the second fluid path where blood flows through internal tubing within

	the handle toward the Truvic Generator and Truvic Canister (*e.g.*, aspiration source, not shown).  (Annotated image of handle including clot container from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration cathethers, travels through the first fluid path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot container. Blood then flows through the filter, through the second port that provides a second fluid path from

	the chamber of the clot container towards the tubest and then toward the aspiration source.  (Symphony Thrombectomy System – Overview Animation Video at 1:09.)

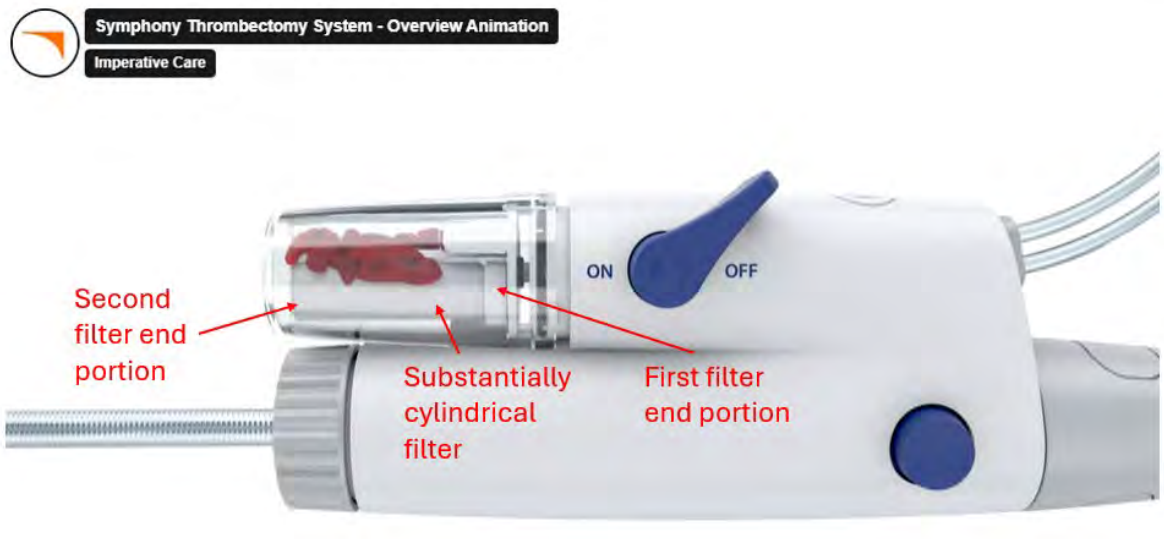


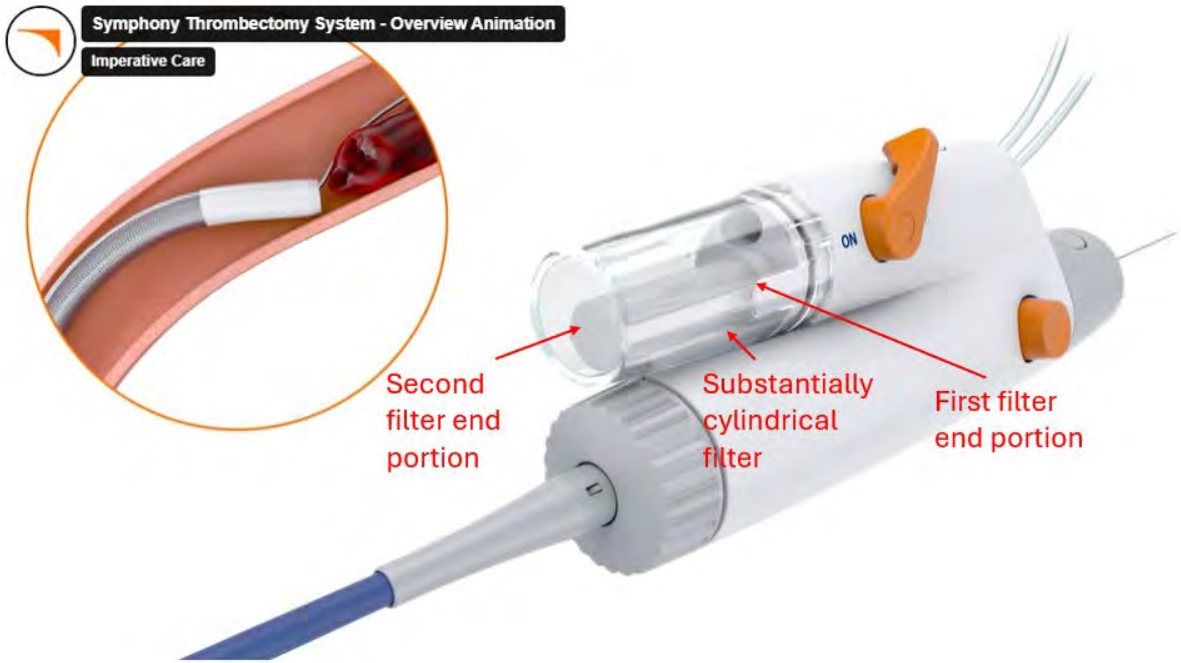
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

Similarly, the Symphony System IFU describes that during aspiration, blood can move from the clot container through the second port and toward the Truvic Canister (*e.g.*, part of the aspiration source). (Symphony Thrombectomy System Instructions For Use at 5 ("To begin aspiration, move the vacuum lever on the Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the 'OFF' position.").) As shown in the images above, blood and clot material flow through along the first fluid path and through the first port to enter the chamber of the clot container.

	To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a filter removably positioned within the chamber, wherein the filter has a substantially cylindrically shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port;	The clot collection reservoir of the Symphony System includes a filter removably positioned within the chamber, where the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and where the filter extends continuously about the first filter end portion such that the filter encloses an interior region around the second port. Specifically, the clot collection reservoir of the 24F and 16F Symphony Catheter handles includes a substantially cylindrical removable filter that is positioned within the chamber, where the filter is continuously about and encloses a region around the second port, as shown in the annotated images of the 24F and 16F Symphony Catheter handles.

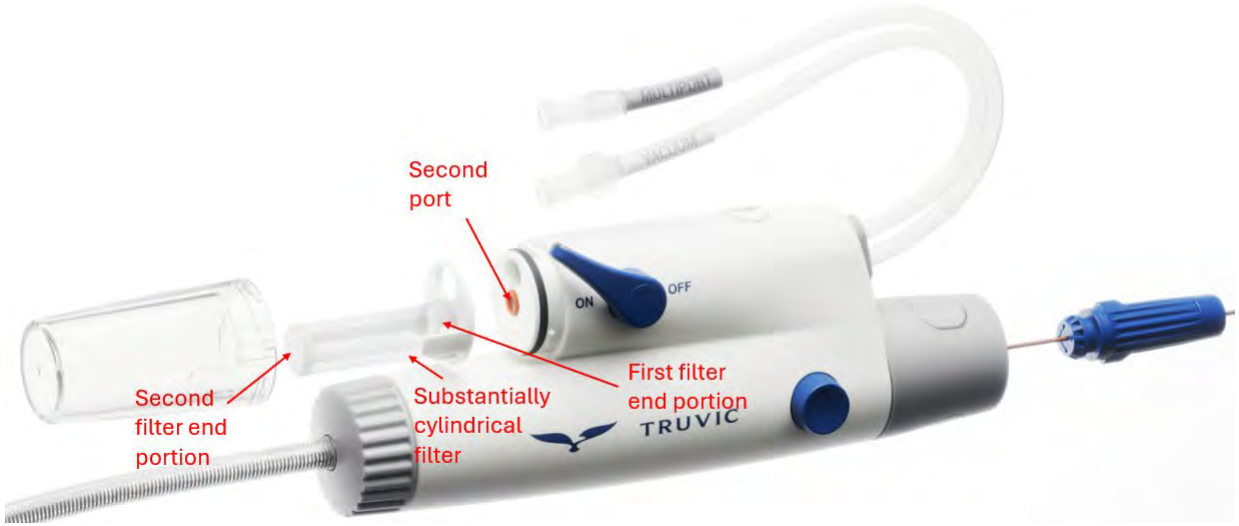
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:18.)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:47.)

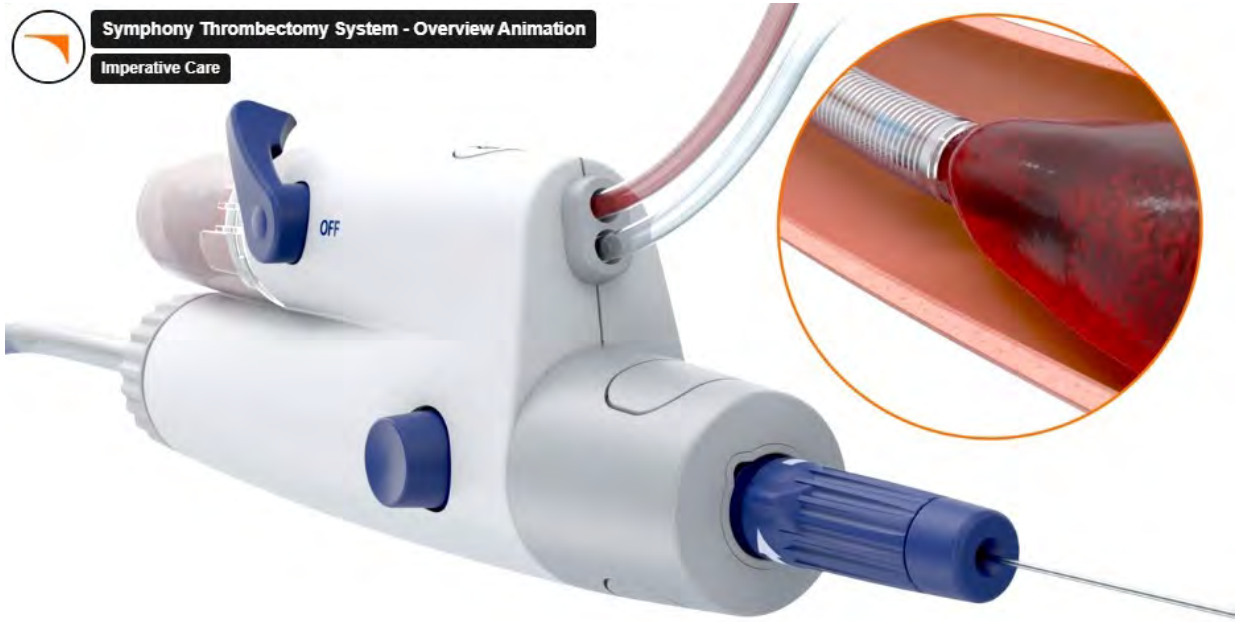
As further shown in the annotated images above, the filter of the 24F and 16F Symphony Catheter handles is substantially cylindrical and extends continuously from a first filter end portion to the second filter end portion. And, as shown in the exploded image from the Whipsaw website of the 24F Symphony Catheter handle, the substantially cylindrical shape of the filter extends from the first filter end portion to the second filter end portion, and also encloses an interior region around the second port, such that it allows blood to pass through the filter and through the second port, while trapping clot material in the clot container.

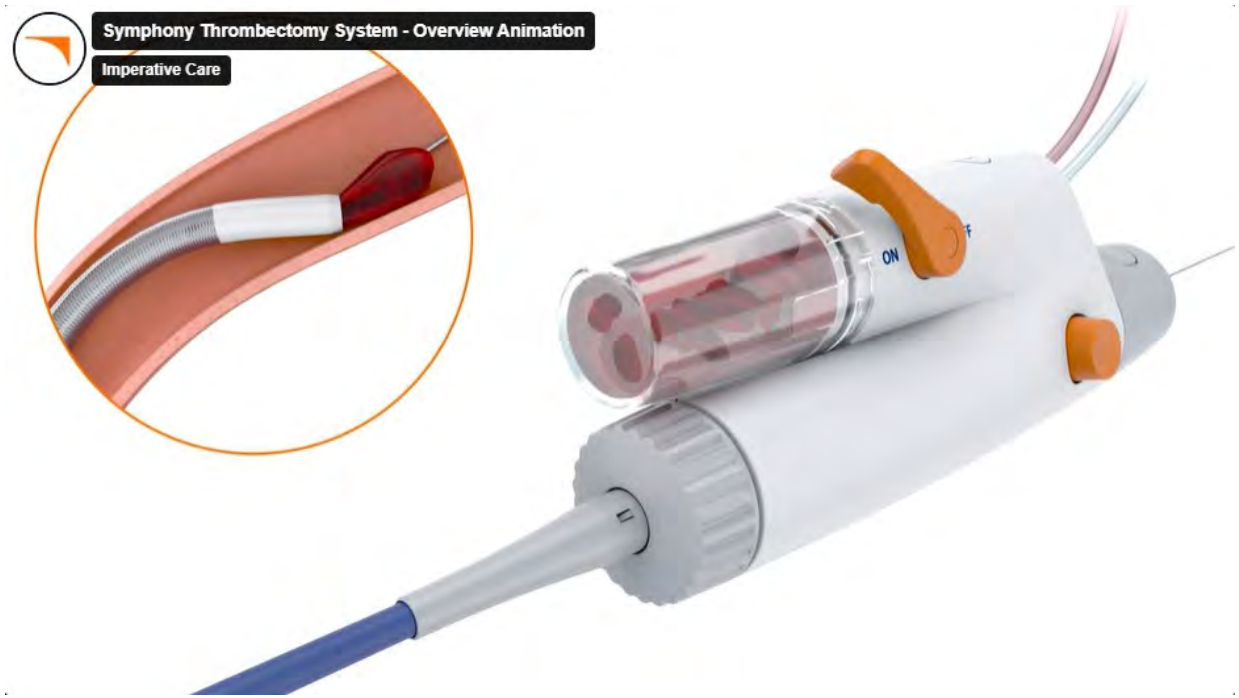


(Annotated image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)

The substantially cylindrical filter encloses an interior region around the second port, such that it prevents clot material from entering the second port. Instead, the filter permits blood to flow through the second port and toward the aspiration source via the second fluid path, as shown in the images below.

	 (Image of handle from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:08.)

	 (Symphony Thrombectomy System – Overview Animation Video at 2:03.)

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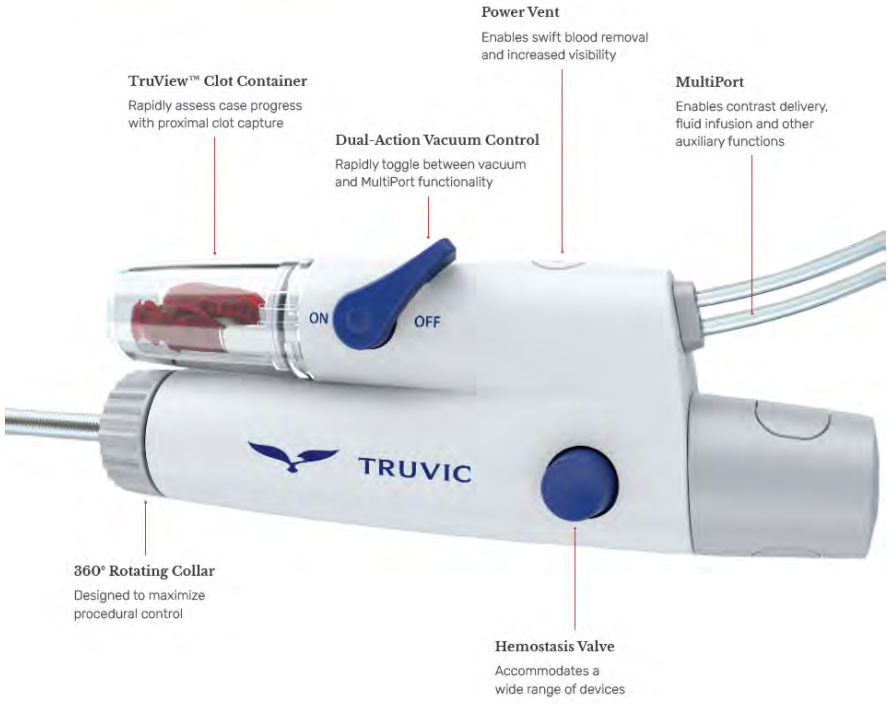


(Symphony Thrombectomy System Brochure at 6.)

	The Symphony System IFU confirms that the filter extends continuously about the first filter end portion and encloses an interior region around the second port, where it describes that blood is allowed to pass through the filter, through the second port, along the second fluid path, and eventually into the Truvic Canister (which is part of the aspiration source). (Symphony Thrombectomy System Instructions For Use at 5 ("When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the handle to the 'OFF' position."); Symphony Thrombectomy System Instructions For Use at 8 (same).) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;	The Symphony System includes an aspiration source that is configured to generate negative pressure in the chamber via the second port to draw blood and clot material from the aspiration catheter through the first port into the chamber and draw blood through the filter into the interior region and through the second port. Specifically, the Truvic Generator and Truvic Canister (*e.g.*, aspiration source) is configured to generate a negative pressure in the chamber of the clot collection reservoir of the 24F and 16F Symphony Catheter handles, as described in the Symphony System IFU. (Symphony Thrombectomy System Instructions For Use at 2 ("The TRUVIC Symphony Thrombectomy Catheters have been verified for use with the TRUVIC Tubeset and TRUVIC Generator. The TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 2.").)

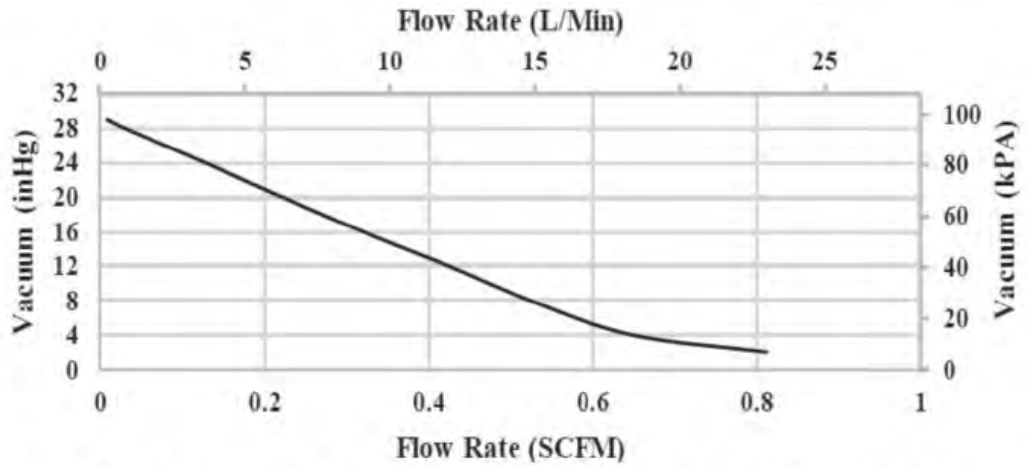
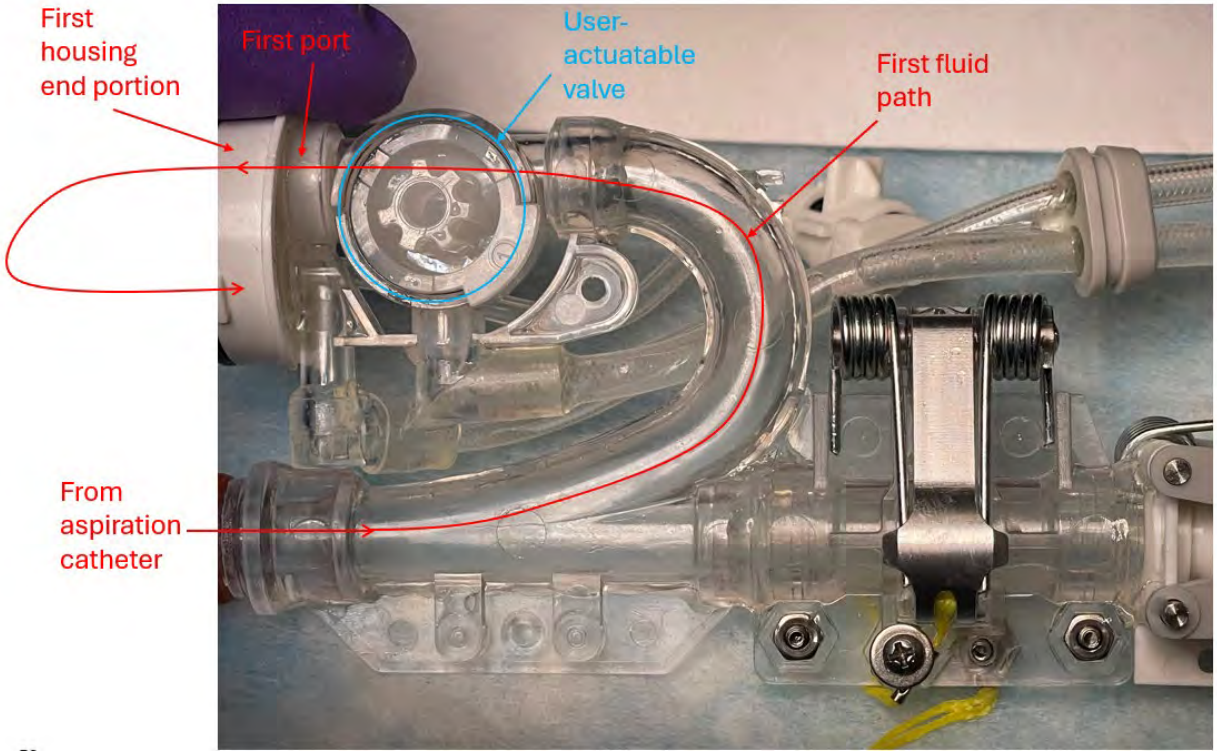


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

(Symphony Thrombectomy System Instructions For Use at 2 (showing vacuum pressure and flow rate for aspiration source).)

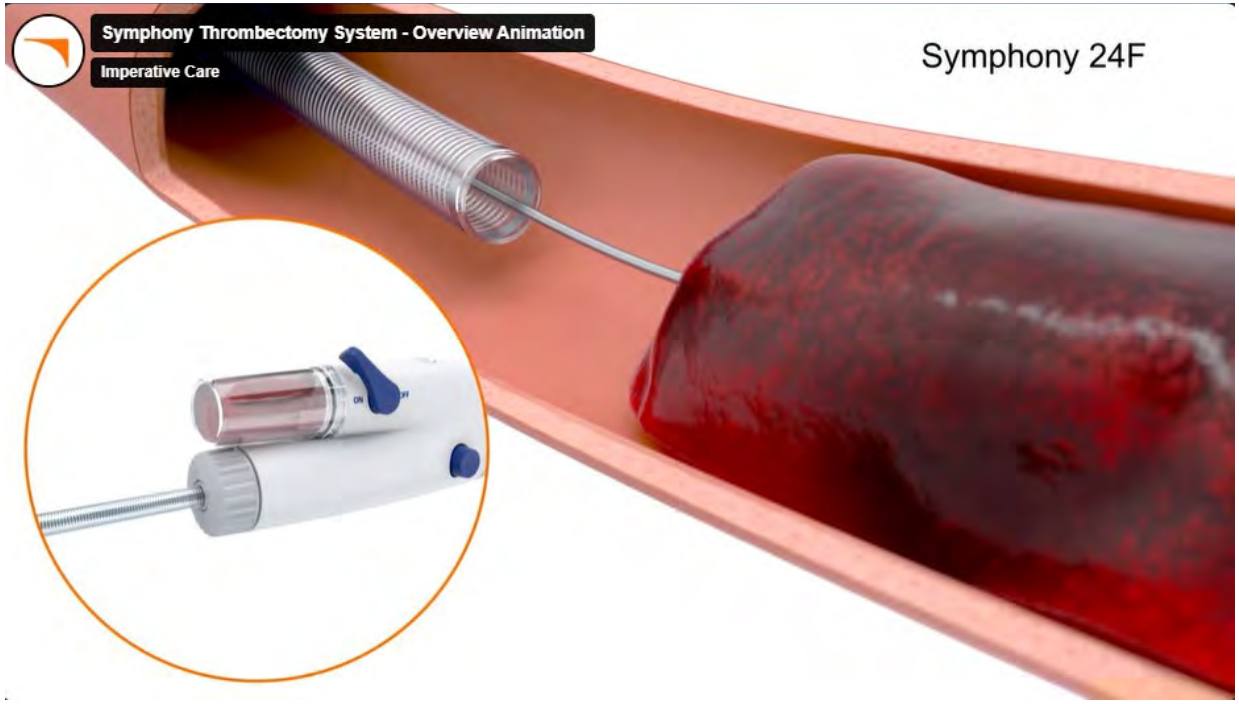
When negative pressure is generated in the chamber of the clot container by the aspiration source (*e.g.* the Truvic Generator and Truvic Canister) and then the vacuum lever is turned to on to connect the aspiration catheter, it causes blood and clot material to be drawn from the human patient, through the aspiration catheter, through the first port (along the first fluid path), and into the chamber of the clot container. In the chamber, blood is filtered from the clot material through the filter. The filtered blood is drawn through the interior region of the filter in the chamber and to the second port, where it flows toward the Truvic Canister along the second fluid path. (Symphony Thrombectomy System Instructions For Use at 5 ("Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to Truvic Generator IFU). Confirm tip of the Symphony Catheter is in the desired location. To begin aspiration, move the vacuum lever on the Handle to the

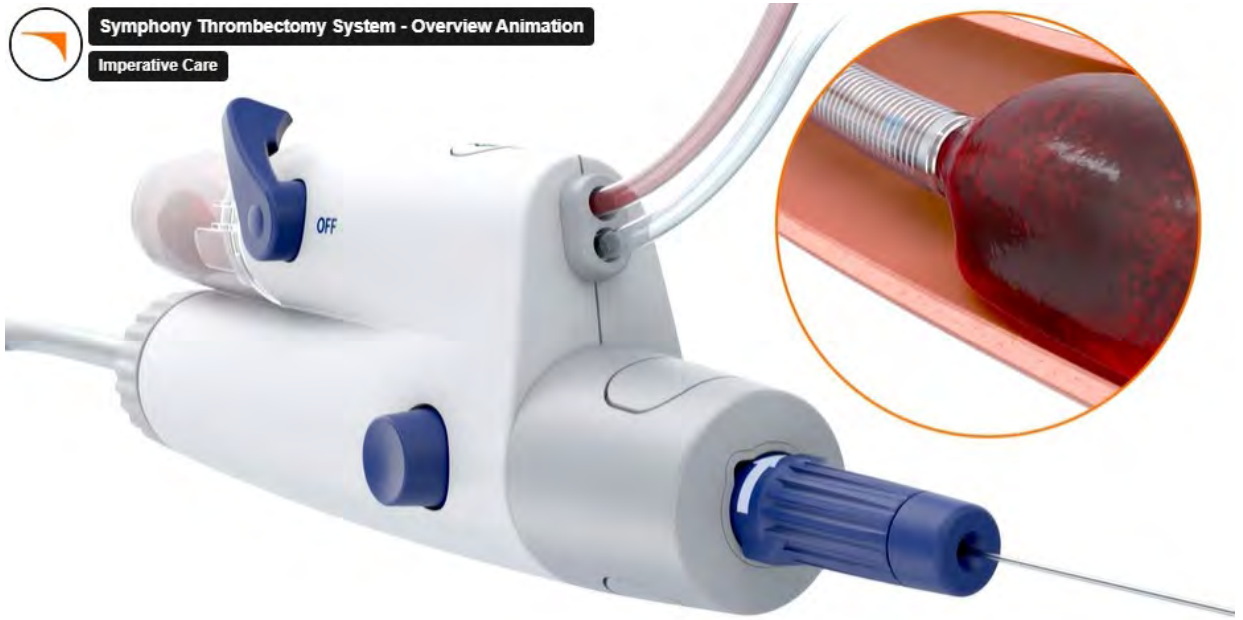
	'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the 'OFF' position."); Symphony Thrombectomy System Instructions For Use at 8 ("Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU). Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy. To begin aspiration, move the vacuum lever on the 16F Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the 16F Handle to the 'OFF' position.").) The flow path of the blood and clot material (*i.e.*, from the aspiration catheter through the first port into the chamber) is shown in the annotated teardown image below.

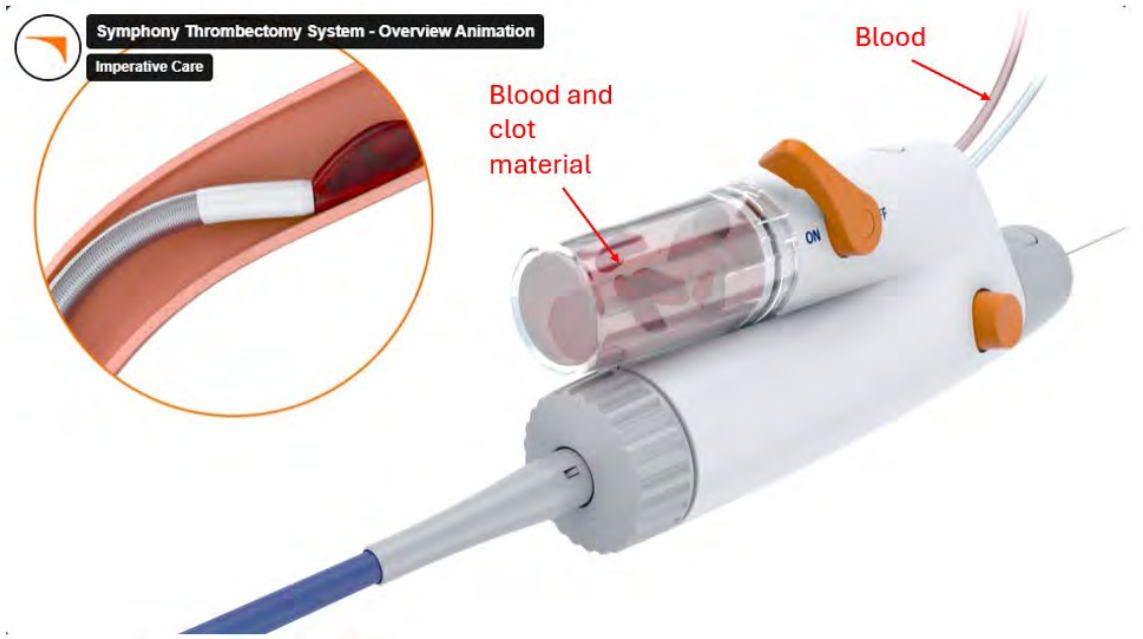


(Annotated image of internal portion of the controller housing.)

The Symphony Thrombectomy System Overview Animation Video also depicts blood and clot material flowing from the aspiration catheter, through the first port, and into the chamber of the clot container.

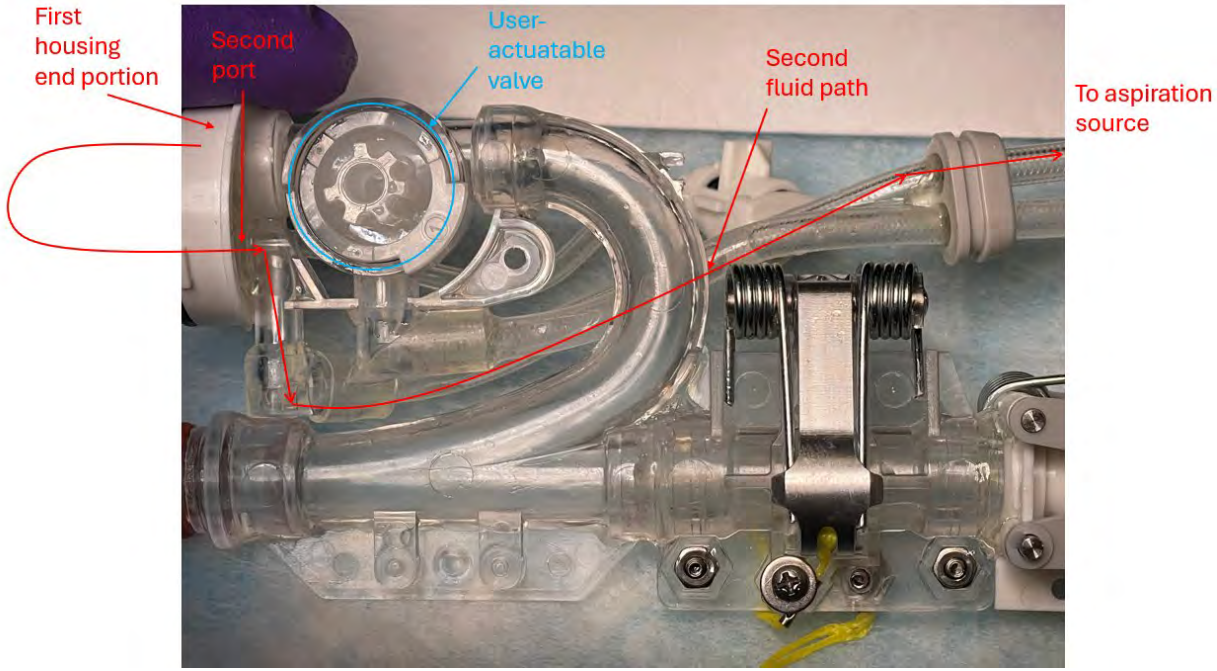
	 (Symphony Thrombectomy System – Overview Animation Video at 0:47.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:05.)



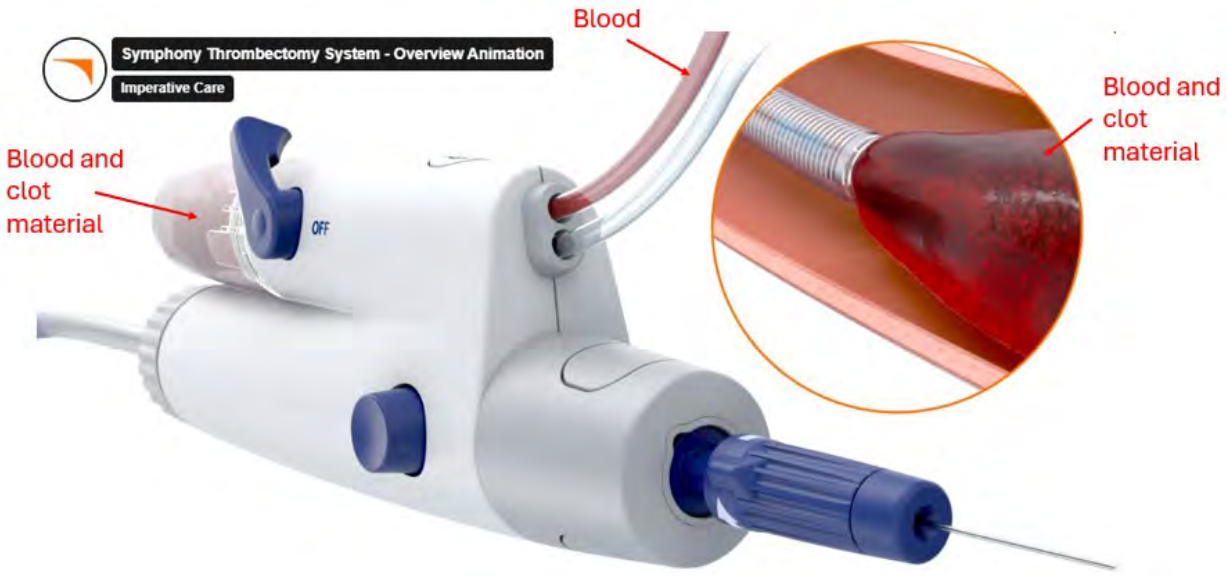
(Symphony Thrombectomy System – Overview Animation Video at 2:01.)

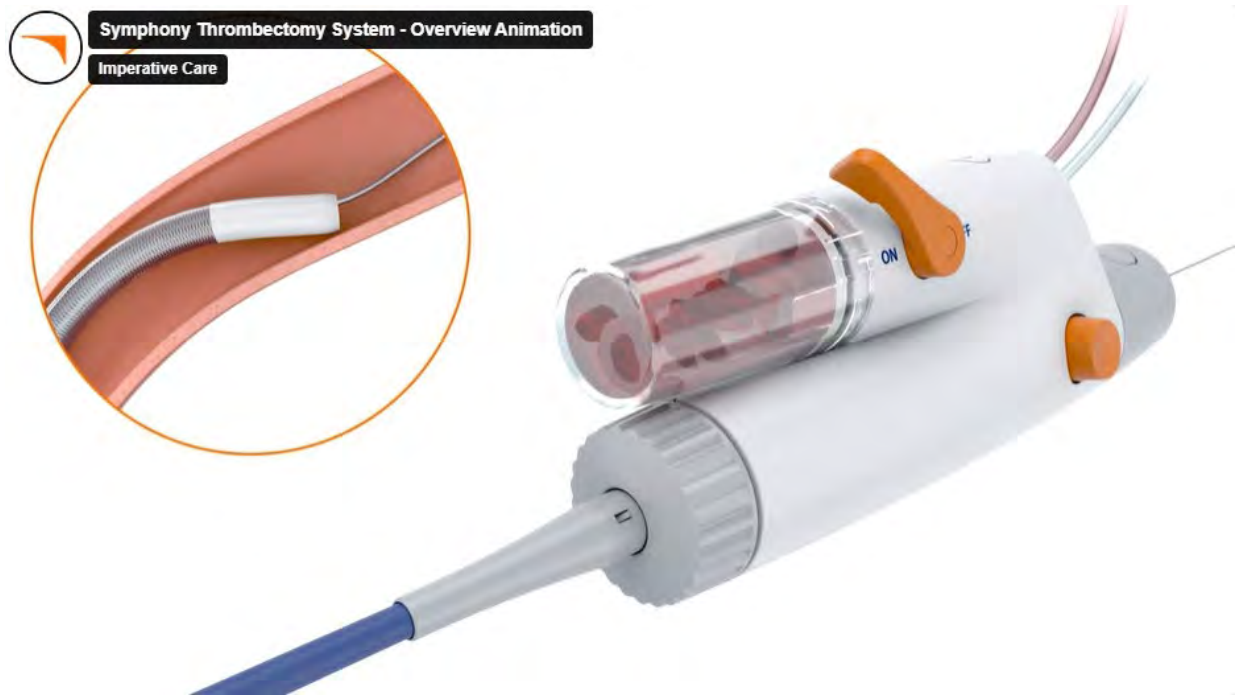
The flow path of the blood (*i.e.*, from the chamber, through the interior region of the filter and through the second port) is shown in the annotated teardown image below.

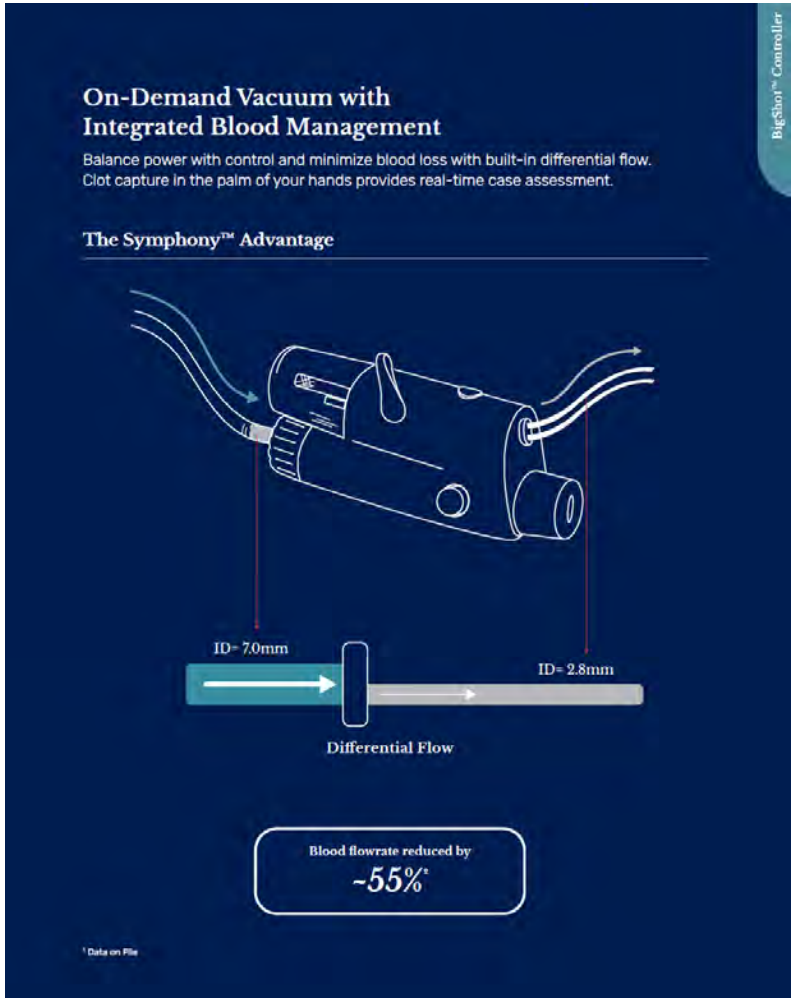


(Annotated image of internal portion of the controller housing.)

The Symphony Thrombectomy System Overview Animation Video also depicts blood flowing from the chamber of the clot container, through the interior of the filter, and through the second port toward the aspiration source.

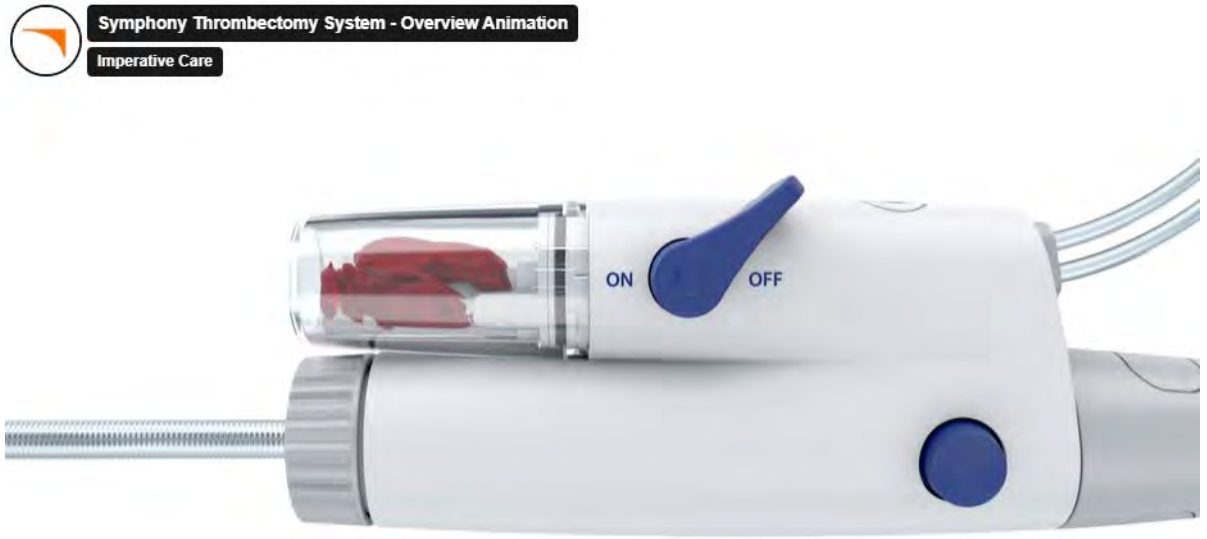
	 (Symphony Thrombectomy System – Overview Animation Video at 1:09.)

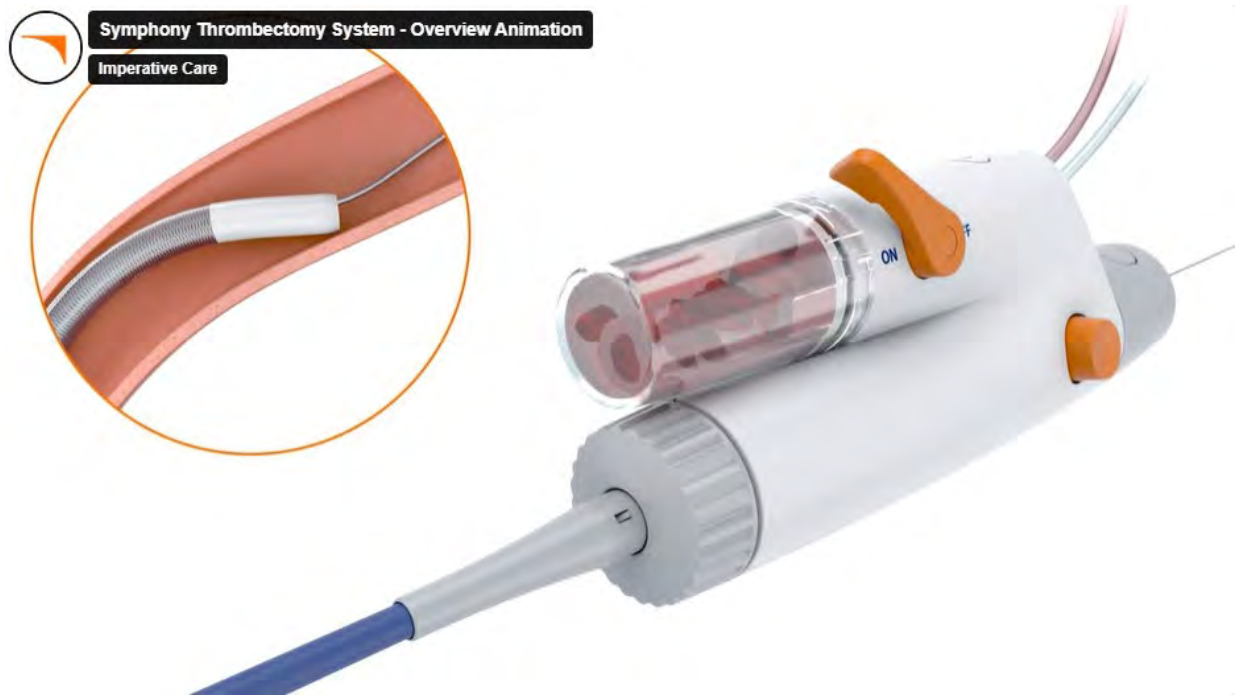
	 (Symphony Thrombectomy System – Overview Animation Video at 2:03.) The Symphony Thrombectomy System Brochure also shows the flow of clot and blood into the chamber and shows blood flowing out of the chamber.

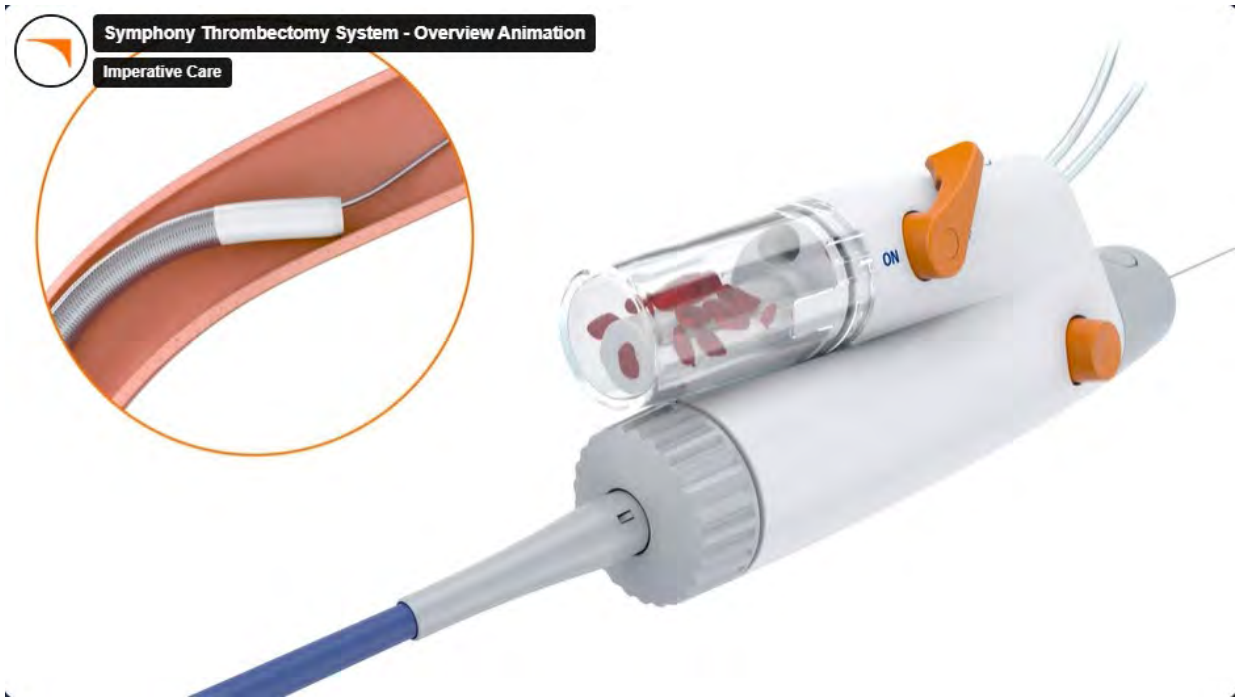


(Symphony Thrombectomy System Brochure at 7.)

To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and	The clot collection reservoir of the Symphony System includes a filter that is configured to inhibit the clot material from passing through the filter into the interior region and through the second port. Specifically, as shown in the images from the Symphony Thrombectomy System Overview Animation Video, the filter of the clot container of the 24F and 16F Symphony Catheter handles is configured to and does inhibit clot material from passing through the filter, into its interior region, and through the second port, thus trapping clot material in the chamber of the clot container.  (Symphony Thrombectomy System – Overview Animation Video at 1:16.)

	 (Symphony Thrombectomy System – Overview Animation Video at 2:03.)



(Symphony Thrombectomy System – Overview Animation Video at 2:05.)

The Symphony System IFU confirms that the filter inhibits clot material from flowing into its interior, and instead allows for blood to flow through its interior and through the second port. (Symphony Thrombectomy System Instructions For Use at 5, 8.) Physical inspection of the Symphony System's filter evidences that the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.

	The Symphony Thrombectomy System Brochure also depicts clot material remaining in the chamber of the clot container so that the physician or user can view the clot and assess progress.  (Symphony Thrombectomy System Brochure at 6.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.	The clot collection reservoir of the Symphony System includes a housing that is at least partially transparent to permit visualization of clot material in the chamber outside of the interior region. Specifically, the housing includes the outer plastic portion of the clot collection reservoir of the 24F and 16F Symphony Catheter handles that is clear (*e.g.*, at least partially transparent), which allows a user of the Symphony System to visualize the clot material in the chamber, outside the interior region of the filter as shown in the Symphony Thrombectomy System Brochure below. (*See also* https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system ("The clot can also be … withdrawn down through the catheter via vacuum where it is then trapped in a clear filter container, allowing the clot to be seen and analyzed by the physician.").

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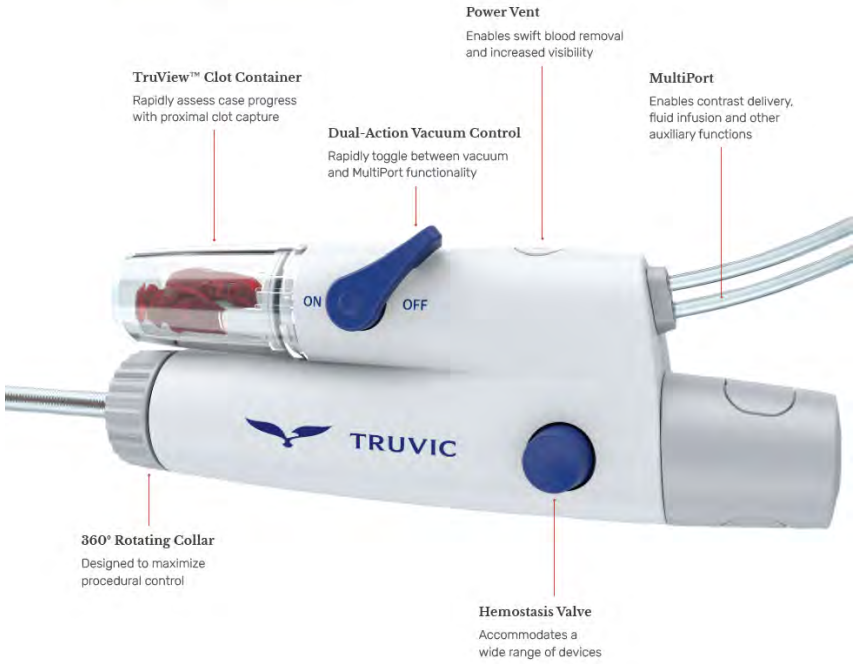
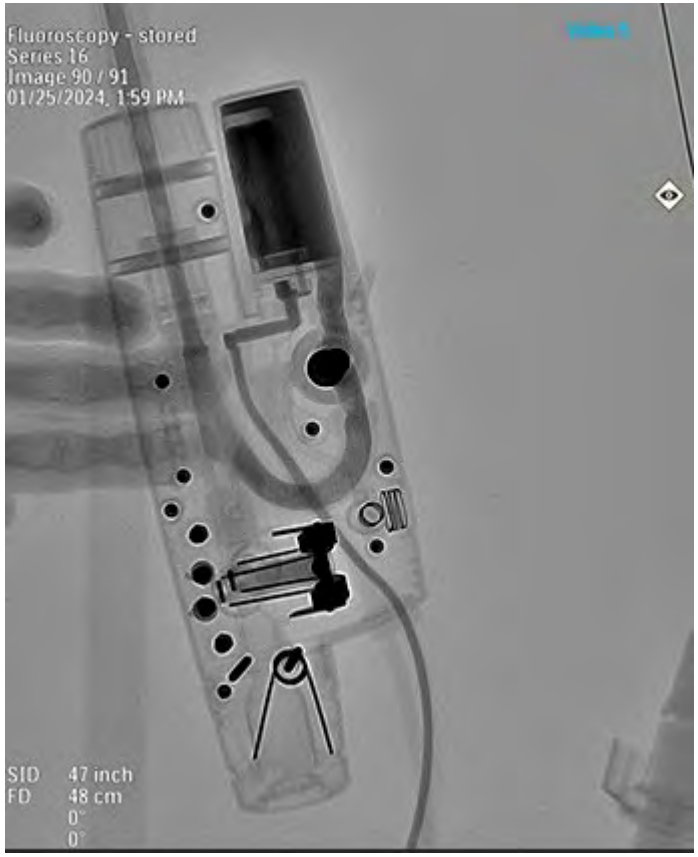
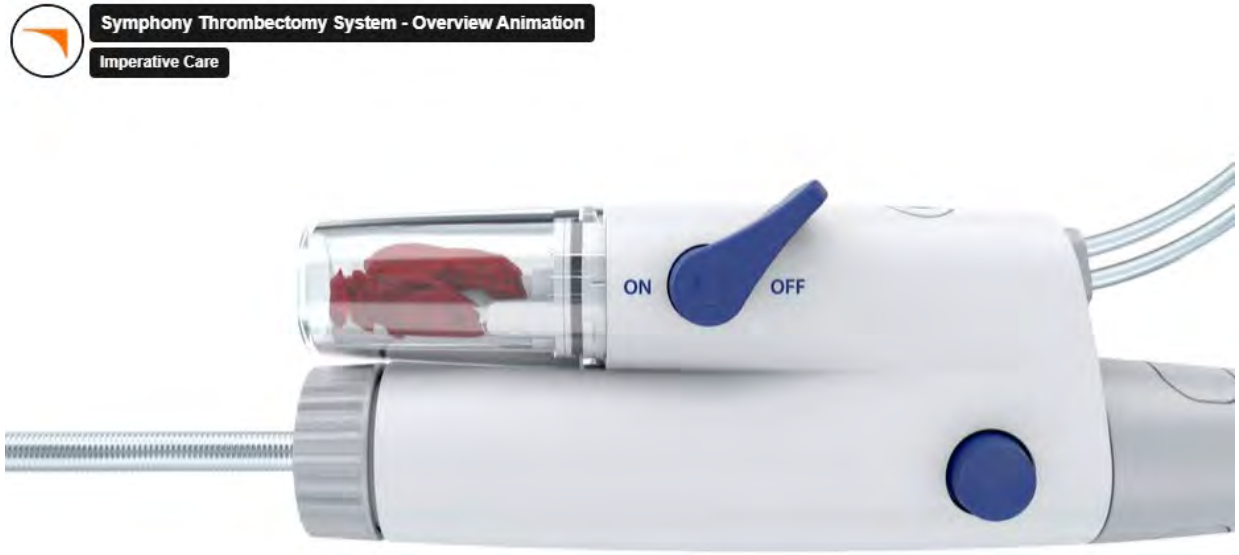


(Symphony Thrombectomy System Brochure at 6.)



(X-ray image showing material in outer plastic portion of the clot collection reservoir.)

Specifically, the Symphony Thrombectomy System Brochure touts the Symphony System's "TruView™" clot capture. (Symphony Thrombectomy System Brochure at 2.)

	The Symphony System IFU confirms that a user is able to visualize the clot material in the chamber of the clot container after blood is evacuated. The images below from the Symphony Thrombectomy System Overview Animation Video further confirms that the housing of the clot container for both the 24F and 16F Symphony Catheter handles includes an outer plastic portion that is partially transparent to allow for a user to visualize the clot material.  (Symphony Thrombectomy System – Overview Animation Video at 1:16 (showing a clear portion of the housing that allows a user to visualize the clot).)

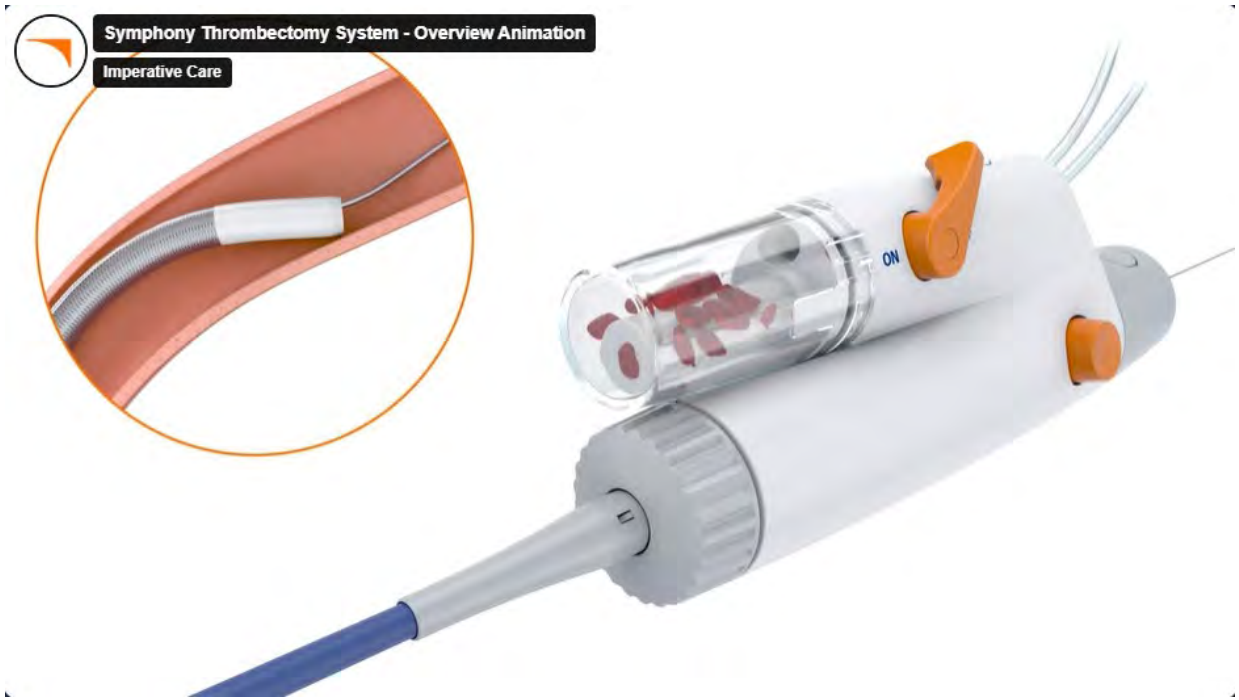
	 (Symphony Thrombectomy System – Overview Animation Video at 2:05 (showing a clear portion of the housing that allows a user to visualize the clot).) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

EXHIBIT 2

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(Additional counsel listed on signature page)

ATTORNEYS FOR PLAINTIFF
INARI MEDICAL, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INARI MEDICAL, INC., Plaintiff, v. IMPERATIVE CARE, INC., Defendant.	Case No. 5:24-cv-3117-EKL ~~SECOND~~THIRD AMENDED COMPLAINT FOR PATENT INFRINGEMENT DEMAND FOR JURY TRIAL

1. Plaintiff Inari Medical, Inc. ("Inari") files this ~~Second~~Third Amended Complaint for Patent Infringement against Defendant Imperative Care, Inc. ("Imperative Care," "Truvic," or "Defendant")[1] and respectfully shows the Court as follows:

INTRODUCTION AND SUMMARY OF THE CASE

2. Inari is a pioneering healthcare company with a mission of improving outcomes for patients suffering from life-threatening pulmonary embolism ("PE") and deep vein thrombosis ("DVT," blood clots in larger veins, such as in the legs). After years of effort and sustained investment, Inari successfully developed, proved the efficacy of, and received regulatory (FDA) clearance for its transformational (and award-winning) ClotTriever® and FlowTriever® systems.

3. These thrombectomy devices differ significantly from any prior and competing treatments for PE and DVT. For example, Inari offers a host of product features that are separately and collectively innovative, including but not limited to Inari products' use of vacuum pressure for aspiration (the "Whoosh"™ technology), their "hemostasis valve" design, their pressure settings, the size of the catheters involved, and their blood filtering and return systems. In recognition of Inari's contributions, the Patent and Trademark Office has to date awarded Inari dozens of patents.

4. This is not to say that it has been a trivial process to educate and win over, one-by-one, the multitude of cardiologists, vascular surgeons, interventional radiologists, and other doctors charged with the treatment of patients suffering from PE and DVT, who are accustomed to the less-effective, traditional treatments for blood clots recommended by the American Medical Association even today. This has taken an extraordinary effort. Through investment, persistence, and superior products, however, Inari has single-handedly created and supplied a market for its aspiration-based mechanical thrombectomy devices, saving patient lives in the process.

[1] Inari's original complaint named Truvic Medical, Inc. as a defendant. Counsel for Imperative Care has confirmed that Truvic Medical, Inc. was merged out of existence, so this Second Amended Complaint removes Truvic Medical, Inc. as a separately named defendant.

5. Having worked so hard to develop and protect its products through the patenting process, and having worked so hard to win over doctors to create a market for those products, Inari cannot stand idly by as other competitors—wanting to replicate Inari's success—begin to copy Inari's products and use Inari's patented inventions. That is exactly the model that Truvic has followed here, however. Truvic, moreover, refuses to desist in its infringement, despite repeated notices and requests to stop using Inari's intellectual property. Inari therefore is forced to bring this suit, asserting ~~ten~~eleven patents: United States 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, and 12,239,333.

THE PARTIES

6. Plaintiff Inari is a Delaware corporation having its principal place of business and headquarters at 6001 Oak Canyon, Suite 100, Irvine, California.

7. Defendant Imperative Care, Inc. ("Imperative Care") is a Delaware corporation having its principal place of business and headquarters at 1359 Dell Avenue, Campbell, California. Imperative Care acquired Truvic Medical, Inc. in July 2021 and eventually this entity merged into Imperative Care, Inc.

JURISDICTION AND VENUE

8. Inari brings this action for patent infringement. This action arises under the Patent Act, 35 U.S.C. § 1, et seq.

9. This Court has subject matter jurisdiction over this action pursuant to at least 15 U.S.C. § 1121(a) and 28 U.S.C. §§ 1331 and 1338.

10. This Court has personal jurisdiction over Imperative Care because it maintains a principal place of business in Campbell, Santa Clara County, California and has purposefully availed itself of the privilege of conducting business in this District such that it should reasonably and fairly anticipate being brought into court in this District.

11. Venue is proper in this District pursuant to at least 28 U.S.C. §§ 1391(b) and (c) and § 1400(b). Venue is proper in this District under 28 U.S.C. § 1400(b) because Defendant has committed acts of patent infringement in this Judicial District and has an established place

of business in this Judicial District.

FACTUAL ALLEGATIONS UNDERLYING INARI'S CLAIMS

Inari's Innovations And Efforts To Develop Its Thrombectomy Products

12. Venous thromboembolism ("VTE") is a disease caused by blood clot formation in the veins of the body, and is, unfortunately, a leading cause of both death and disease worldwide. Pulmonary embolism ("PE") and deep vein thrombosis ("DVT") are common types of VTE. DVT is a type of blood clot that typically forms in the deep veins of a limb, such as the leg, and can develop into PE if portions of the clot break off and migrate to the pulmonary system. PE is a life-threatening condition that occurs when a clot breaks free and becomes lodged in the arteries of the lungs.

13. Inari is the world's leading developer of catheter-based aspiration and/or mechanical thrombectomy devices that treat PE and DVT through aspiration (*e.g.*, by using suction to remove clot material) and/or mechanical mechanisms of action (*e.g.*, using mechanical objects to disrupt clot material). Inari was and is a pioneer in changing the standard of care for PE and DVT from thrombolytics-based treatments (*i.e.*, treatments with drugs called "lytics" that break down blood clots that have formed in blood vessels) and surgeries—which have been plagued with drawbacks relating to effectiveness and side effects—to treatment with aspiration-based mechanical systems. Inari's lifesaving products, including its FlowTriever and ClotTriever systems, have received widespread acclaim for their efficacy in treating PE and/or DVT.[2] Inari's innovations have also been repeatedly recognized by the United State Patent and Trademark Office, which has issued Inari over fifty United States patents and is in the process of allowing additional claims in multiple pending applications.

14. Inari's first product, its FlowTriever system, represented a major leap in treatment for venous thromboembolism, including PE. During procedures, FlowTriever targets aspiration (adjustable negative vacuum pressure) directly to the thrombus via catheters. FlowTriever may be used to facilitate aspiration and removal of the thrombus through, for example, the Triever24,

[2] *See* https://ir.inarimedical.com/news-events/press-releases.

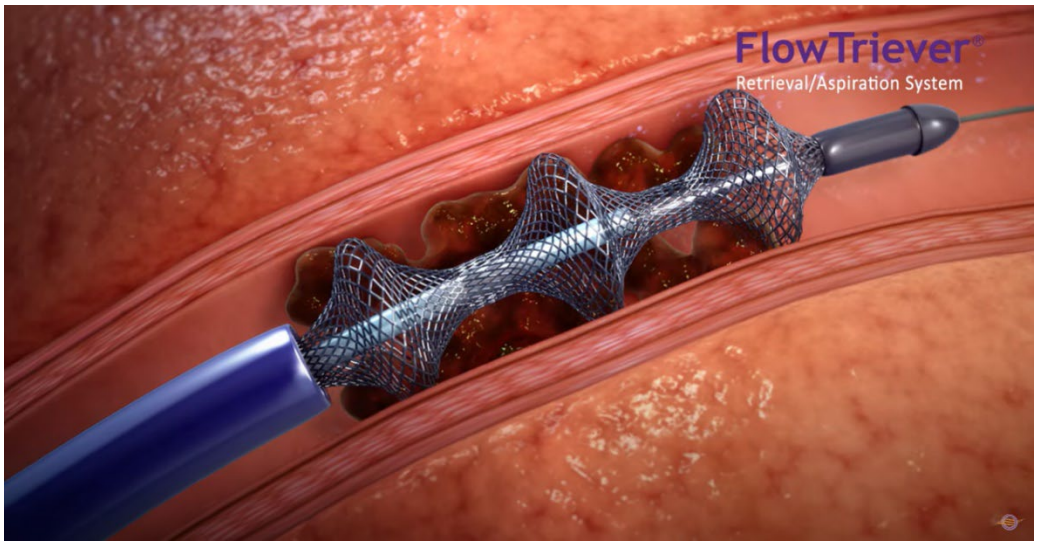
Triever20, and/or Triever16 catheters, aspirating at least a portion of the clot material. The Triever catheters are introduced through a vascular access sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus or emboli. The 16F Triever Catheter and 20F Triever Catheter are capable of telescoping from the 24F Triever Catheter for extended reach to the thrombus.[3] FlowTriever generates vacuum using large-bore locking syringes. FlowTriever's catheter technology further optionally allows for a catheter with expanding mesh disks at the distal end to mechanically engage and disrupt clot materials.

15. Inari received FDA clearance for its FlowTriever system in November 2016. This clearance had indications for use for non-surgical removal of clot material from blood vessels in the peripheral vasculature. This version of FlowTriever included an Aspiration Guide Catheter, a FlowTriever Catheter, and a Retraction Aspirator. The FlowTriever Catheter is inserted through the Aspiration Guide Catheter and advanced to the thrombus (*i.e.*, the blood clot). Self-expanding wireform disks are deployed to engage the thrombus by retracting the outer delivery catheter. The hand-lever operated Retraction Aspirator in this version of FlowTriever simultaneously aspirates fluids and retracts the FlowTriever Catheter with at least a portion of the thrombus into the Aspiration Guide Catheter to capture clot and restore blood flow.

16. The more recent versions of the FlowTriever system allow the removal of the FlowTriever Catheter from the patient and aspiration of clot material through the Aspiration Guide Catheter without the simultaneous removal of the Aspiration Guide Catheter.[4] A capture from a FlowTriever video depicting the distal end of a FlowTriever catheter is below:

[3] The "French" ("F") scale is commonly used to measure the size of catheters. 1 French (1F) equals 1/3 mm.

[4] *See* FDA 510(k) Premarket Notification K162970 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162970.pdf).



(Guide Catheter (purple), FlowTriever Catheter (pale blue), and self-expanding wireform disks (grey).)

17. From April 2016 to November 2017, Inari conducted the FlowTriever Pulmonary Embolectomy Clinical Study ("FLARE") to evaluate the safety and effectiveness of the FlowTriever system for use in the removal of emboli from the pulmonary arteries in the treatment of acute pulmonary embolism. The results were strikingly positive.[5]

18. Inari received expanded FDA clearance to market FlowTriever for treating PE (in addition to the prior clearance for peripheral vasculature generally) in May 2018.[6] This made FlowTriever the first FDA-cleared aspiration-mechanical system for treating PE, and the first FDA-cleared aspiration-mechanical system for treating both PE and peripheral vasculature thrombosis. The PE-specific clearance was based upon the strength of the results from the FLARE Clinical Study.[7]

19. Inari continued to improve the performance of FlowTriever over the years. By December 2018, Inari developed and received FDA clearance for a telescoping version of FlowTriever, for instance, meaning that a smaller diameter catheter can be advanced through

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[5] *See* https://www.clinicaltrials.gov/study/NCT02692586?rank=8&lead=Inari%20Medical.

[6] *See* FDA 510(k) Premarket Notification K180466 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180466.pdf).

[7] *See* https://ir.inarimedical.com/news-releases/news-release-details/flowtriever-system-inari-medical-receives-fda-510k-clearance.

(inside) a larger diameter catheter for extended reach. This version of FlowTriever includes the Triever16 Catheter (16F outer catheter), the Triever20 Catheter (20F outer catheter), the FlowTriever Catheter, and two Large Bore 60cc Syringes, one for Triever16 and one for Triever20, for aspiration purposes. The Triever16 Catheter is capable of extending through and past the distal end from the Triever20 Catheter to reach the thrombus. Each Triever Catheter is connected to a pressure source, such as a Large Bore 60cc Syringe.

20. From December 2018 to February 2019, Inari conducted a limited market release of the telescoping FlowTriever and gathered physician feedback according to a clinical evaluation plan. The positive evaluation results proved the telescoping combination of Triever16 and Triever20 to be excellent for treating large RV (right ventricular)/LV (left ventricular) clots in the left pulmonary arteries, vasculature with challenging anatomy, and the distal segments with occlusive clot. Overall, using the telescoping combination is more efficient than using a single outer catheter.

21. By September 2019, Inari developed and received FDA clearance for Triever24, a 24F outer catheter.[8] This catheter can be used in a telescoping combination with Triever16.

22. Separately from its work on FlowTriever, Inari also received FDA clearance for its ClotTriever system in February 2017. ClotTriever was designed for clot removal, including for acute and chronic clots (i.e., including DVT) using mesh forms to engage and then withdraw clots.[9]

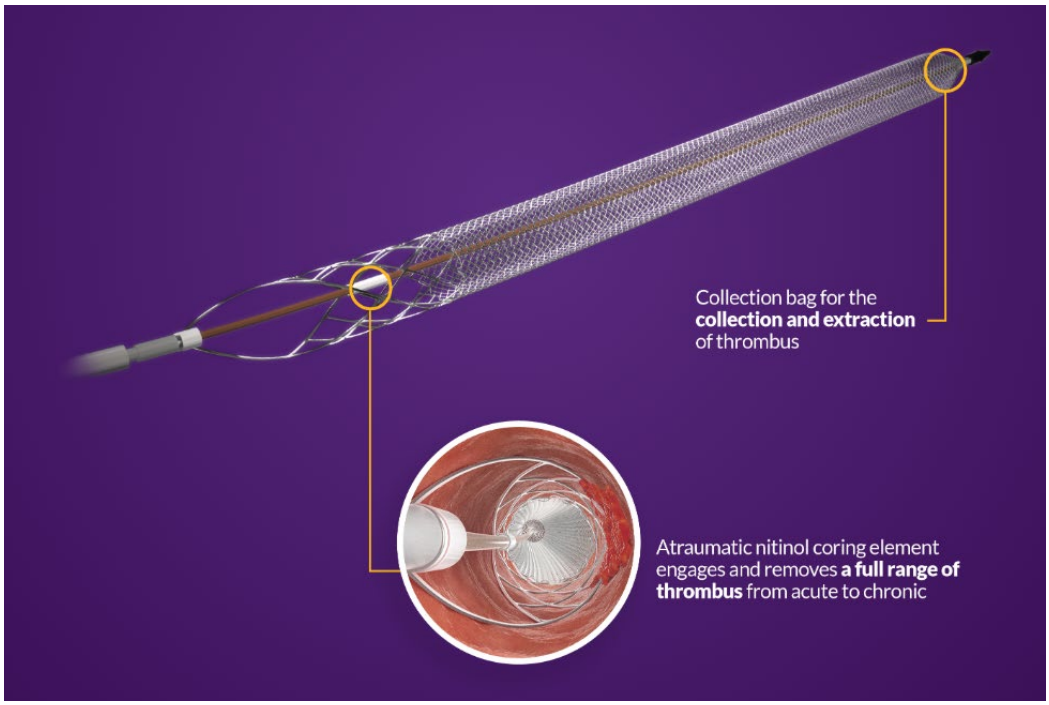
23. The first version of ClotTriever consists of the ClotTriever Sheath and the ClotTriever Catheter. The ClotTriever Sheath consists of a polymeric sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port with tubing clamp, and a proximal hemostatic valve. The ClotTriever Catheter consists of three preassembled polymeric coaxial catheters terminating in an expandable member and tissue collection net. At the proximal end

[8] *See* FDA 510(k) Premarket Notification K191710 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191710.pdf).

[9] *See* FDA 510(k) Premarket Notification K193462 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193462.pdf).

of the catheter is a handle used to enable expansion of the expandable member and net.

24. The expanded structures of the ClotTriever are drawn through the vessel obstruction to capture clot and restore blood flow by "non-surgical removal of soft thrombi and emboli from blood vessels."[10] A figure depicting the ClotTriever system is shown below:



25. As with FlowTriever, Inari continues to improve the performance of ClotTriever over the years. By December 2017, Inari had developed and received FDA clearance for replacing the tissue collection net with a collapsible clot collection bag.[11] In September 2018, Inari started the ClotTriever Outcomes ("CLOUT") Registry Clinical Study to evaluate real-world patient outcomes after treatment of acute, subacute, and chronic proximal lower extremity DVT with the ClotTriever system. Inari announced the interim results of the study on March 12, 2024, with the results showing that ClotTriever significantly reduced rates of "post-thrombotic syndrome" over historical DVT trials.[12] On September 9, 2020, Inari received FDA clearance

[10] *See* FDA 510(k) Premarket Notification K163549 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163549.pdf).

[11] *See* FDA 510(k) Premarket Notification K173470 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173470.pdf).

[12] *See* https://ir.inarimedical.com/node/10506/pdf.

to market ClotTriever specifically for the treatment of DVT.[13]

Truvic's Copycat Devices

26. Founded in 2016, Imperative Care is a medical technology company developing products in a wide array of disparate health-related areas. For instance, its various products include ones directed at stroke solutions, vascular disease treatments, digital health, and robotics.

27. In July 2021, Imperative Care acquired Truvic Medical, Inc.,[14] a thrombectomy device developer that, based on recorded filings, was incorporated in 2020. Truvic Medical, Inc. has two lines of thrombectomy products—the Prodigy Thrombectomy System ("Prodigy") and the Symphony Thrombectomy System ("Symphony" or "Symphony system"). Symphony is the system that most directly competes with Inari's treatment systems, while Prodigy targets clots in much smaller arteries.

28. Like FlowTriever and ClotTriever, Symphony is intended for the non-surgical removal of fresh, soft emboli and thrombi from blood vessels. The Symphony system as a whole is comprised of at least the 24F Symphony Catheter, 16F Symphony Catheter (with a working length of either 82 cm or 117 cm), Truvic Generator, 24F Symphony Dilator, 16F Symphony Dilator, Truvic Canister, 24F Symphony Advance Long Dilator, 16F Symphony ProHelix, Truvic Tubeset, and 24F Symphony ProHelix, although not all parts of the system need to be or are used for every patient procedure, and Truvic may have or be developing additional components for or to be used with the Symphony system. The Symphony system, like Inari's products, is designed to remove thrombus/embolus from veins and large arteries using controlled aspiration. The Symphony Catheter targets aspiration from the Truvic Generator directly to the thrombus. The Symphony ProHelix may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter by mechanically engaging and disrupting the clot material. The Symphony Catheters and Symphony Dilators are introduced through a vascular

[13] *See* FDA 510(k) Premarket Notification K193462 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193462.pdf).

[14] All references to "Truvic" should be understood to include Imperative Care, unless the context dictates otherwise.

access sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the Truvic Generator, connected using the Truvic Tubeset and the Truvic Canister, to aspirate thrombus. The 16F Symphony Catheter is capable of telescoping from the 24F Symphony Catheter for, *inter alia*, extended reach to the thrombus. As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter over a guidewire, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter.[15]

29. In February 2023, Truvic received FDA clearance to market its Symphony system.[16] This FDA clearance is limited to marketing Symphony for DVT treatment. It is common in the industry for doctors to use cleared FDA devices to treat problems beyond those for which they are indicated, however—a phenomenon often referred to as "off-label" usage. For instance, now that Truvic can sell its Symphony systems for DVT, doctors might also use those systems for the treatment of PE. In fact, there have been scattered reports that doctors are already doing exactly that with Truvic's systems at least occasionally, including with procedures where Truvic sales representatives have participated.

30. Truvic began marketing and selling its Symphony system to physicians and hospitals by no later than mid-2023, after it had received its FDA clearance for DVT.

31. In an October 2023 submission to ClinicalTrials.gov, Imperative Care stated that it will conduct a clinical study to evaluate the safety and efficacy of Symphony in the treatment

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[15] Inari has obtained information regarding the design and operation of the Symphony system from multiple sources, including Truvic's product brochure (attached as Exhibit A), it's FDA-cleared "Instructions for Use" ("IFU") (attached as Exhibit B), a video on Symphony's website (available at https://www.truvic.com/symphony-product and at https://vimeo.com/817718796), and its own examinations of a Symphony system.

[16] *See* 510(k) Premarket Notification K223216 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223216.pdf).

of PE from December 2023 to April 2025.[17] Upon completion of this study, the FDA will presumably clear Truvic to market Symphony for the treatment of PE. At that point, Inari expects that Symphony usage for PE will increase from a trickle of off-label uses by particular doctors to a much larger flow of regular PE procedures. Upon information and belief, Truvic began marketing and selling its Symphony system to physicians and hospitals that engaged in procedures for PE in approximately mid-2023, after Truvic had received its FDA clearance for DVT.

32. Truvic designed its Symphony system after Inari had introduced FlowTriever into the market. Truvic's Symphony system significantly overlaps with and mirrors the FlowTriever design. The two products share many similar features and mechanisms, such as telescoping aspiration catheters (including 16F catheters inserted through a 24F catheter), an intervening member used in addition to the catheter, the design of a hemostasis valve between the aspiration catheter and the aspiration source, and the design of the removable clot-filtering canister.

33. There is a long list of other indicia that Truvic has intentionally copied Inari's devices and is doing its best to target the market that Inari has created from scratch. For instance, Truvic has been systematically recruiting and attempting (sometimes successfully) to hire away key Inari personnel, including sales representatives, apparently intent on drawing on their product knowledge and the network of connections they created through Inari's investments. Additionally, Truvic has been systematically targeting the network of doctors who have become top Inari customers for Truvic's own sales, which allows Truvic to save the time and cost of converting doctors from traditional treatments like lytics. Instead, Truvic is simply stealing market share created by Inari's efforts that have begun to shift the VTE treatment paradigm. Truvic sales representatives have also persuaded doctors to allow them to observe procedures performed with Inari devices, which is highly unusual, and—even more unusually—have sometimes convinced doctors to exclude Inari sales representatives from being present when procedures are performed with Inari's own devices.

[17] *See* https://www.clinicaltrials.gov/study/NCT06062329?rank=1&lead=Imperative%20Care,%20Inc.

34. Inari contacted Truvic in September 2023, just months after Truvic had obtained FDA clearance for Symphony, to give notice of Inari's patents. In response, Truvic refused to provide Inari with one of its Symphony systems for analysis, claiming that the Symphony systems—*i.e.*, the same systems already being used by doctors in patient procedures—is "confidential." Truvic's response was irregular and concerning.

35. Upon information and belief, Truvic has been producing, using, promoting, selling, and inducing physicians and hospitals to buy and use the Symphony system. For example, Truvic's sales representatives have successfully convinced and are successfully convincing physicians, such as those at Beaumont Health and Cardiovascular Institute of the South (to name just a few hospitals), to perform thrombectomy procedures with Symphony, displacing sales and/or sales opportunities for Inari products.

36. Based upon the promotional literature that Truvic has distributed and made available online, as well as statements and actions by Truvic's sales representatives and Inari's own examination of a Symphony system that Inari very recently obtained, Truvic directly and indirectly infringes the Inari patents described below through manufacture, sale, offer for sale, and/or use of the Symphony products.

The Patents-In-Suit

37. On May 7, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,974,910 ("the '910 Patent"), entitled "System for Treating Embolism and Associate Devices and Methods." Inari owns all rights, title, and interest in and to the '910 Patent and possesses all rights of recovery under the '910 Patent. A true and correct copy of the '910 Patent is attached as Exhibit C.

38. The '910 Patent is valid and enforceable.

39. On April 30, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,969,333 ("the 11-'333 Patent"), entitled "System for Treating Embolism and Associate Devices and Methods." Inari owns all rights, title, and interest in and to the 11-'333 Patent and possesses all rights of recovery under the 11-'333 Patent. A true and correct copy of the 11-'333 Patent is attached as Exhibit D.

40. The 11-'333 Patent is valid and enforceable.

41. On January 17, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,554,005 ("the '005 Patent"), entitled "System for Treating Embolism and Associated Devices and Methods." Inari owns all rights, title, and interest in and to the '005 Patent and possesses all rights of recovery under the '005 Patent. A true and accurate copy of the '005 Patent is attached as Exhibit E.[18]

42. The '005 Patent is valid and enforceable.

43. On September 5, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,744,691 ("the '691 Patent"), entitled "System for Treating Embolism and Associated Devices and Methods." Inari owns all rights, title, and interest in and to the '691 Patent and possesses all rights of recovery under the '691 Patent. A true and accurate copy of the '691 Patent is attached as Exhibit F.[19]

44. The '691 Patent is valid and enforceable.

45. On December 19, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,844,921 ("the '921 Patent"), entitled "Hemostasis Valves and Methods of Use." Inari owns all rights, title, and interest in and to the '921 Patent and possesses all rights of recovery under the '921 Patent. A true and accurate copy of the '921 Patent is attached as Exhibit G.

46. The '921 Patent is valid and enforceable.

47. On July 11, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,697,012 ("the '012 Patent"), entitled "Hemostasis Valves and Methods of Use." Inari owns all rights, title, and interest in and to the '012 Patent and possesses all rights of recovery under the '012 Patent. A true and accurate copy of the '012 Patent is attached as Exhibit H.

[18] Inari recently filed a revised certificate of correction to add two inadvertently omitted inventors, John Thress and Paul Lubock, to the '005 Patent.

[19] Inari recently filed a revised certificate of correction to add two inadvertently omitted inventors, John Thress and Paul Lubock, to the '691 Patent.

48. The ’012 Patent is valid and enforceable.

49. On January 9, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,865,291 (“the ’291 Patent”), entitled “Hemostasis Valves and Methods of Use.” Inari owns all rights, title, and interest in and to the ’291 Patent and possesses all rights of recovery under the ’291 Patent. A true and accurate copy of the ’291 Patent is attached as Exhibit I.

50. The ’291 Patent is valid and enforceable.

51. On June 25, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 12,016,580 (“the ’580 Patent”), entitled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods.” Inari owns all rights, title, and interest in and to the ’580 Patent and possesses all rights of recovery under the ’580 Patent. A true and accurate copy of the ’580 Patent is attached as Exhibit J.

52. The ’580 Patent is valid and enforceable.

53. On October 8, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 12,109,384 (“the ’384 Patent”), entitled “Hemostasis Valves and Methods of Use.” Inari owns all rights, title, and interest in and to the ’384 Patent and possesses all rights of recovery under the ’384 Patent. A true and accurate copy of the ’384 Patent is attached as Exhibit K.

54. The ’384 Patent is valid and enforceable.

55. On December 3, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 12,156,669 (“the ’669 Patent”), entitled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods.” Inari owns all rights, title, and interest in and to the ’669 Patent and possesses all rights of recovery under the ’669 Patent. A true and accurate copy of the ’669 Patent is attached as Exhibit L.

56. The ’669 Patent is valid and enforceable.

57. On March 4, 2025, the United States Patent and Trademark Office duly and legally issued United States Patent No. 12,239,333 (“the 12-’333 Patent”), entitled “Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods.” Inari owns all

rights, title, and interest in and to the 12-'333 Patent and possesses all rights of recovery under the 12-'333 Patent. A true and accurate copy of the 12-'333 Patent is attached as Exhibit W.

58. The 12-'333 Patent is valid and enforceable.

Inari Put Truvic On Notice Of Its Infringement, But Truvic Refused To Stop

59. ~~57.~~ In September 2023, after Truvic had received FDA clearance to market its Symphony system and Inari began to hear reports that Truvic was beginning to do so, Inari wrote to Defendant to inform them of Inari's belief that Defendant was infringing at least United States Patent Nos. 11,559,382 and 11,744,691 and that Defendant would infringe other allowed claims of pending applications in the "System for Treating Embolism and Associate Devices and Methods" family and the pending claims of Published Application No. 17/498,642 (which has since issued as the '580 Patent) once those claims issued. Inari further explained that it believed that the hemostasis valves in the Symphony system might infringe Inari's hemostasis valve patents, including: United States Patent Nos. 11,554,005, 11,697,012, and allowed claims of Application No. 18/142,518 (later issued as United States Patent No. 11,865,291). The letter further attached the ten patents and applications referenced. Inari's letter requested that Truvic provide a sample Symphony product for analysis (*e.g.*, including to confirm its hemostasis valve design) and requested that Defendant cease or delay its launch of its Symphony products until patent issues were resolved. Inari also invited a dialogue and asked Defendant to identify any genuine basis that they had for believing that they were not infringing Inari's patents.

60. ~~58.~~ On December 1, 2023, Truvic replied by email, refusing to provide a sample Symphony product because "details of the Symphony product are proprietary, and at this time we are not willing to provide a sample to you that would allow you to benefit from the product…."

61. ~~59.~~ On January 15, 2024, almost four months after Inari's letter, Truvic finally provided a substantive response to Inari's September 2023 letter. For all but one of the patents that Inari had identified, Truvic did not identify a single noninfringement argument. Instead, Truvic argued that the patents were invalid based on identified prior art.

62. ~~60.~~ On April 24, 2024, Inari sent another letter to Truvic, responding to Truvic's

invalidity allegations and identifying multiple additional Inari patents that Truvic is infringing. For instance, Inari explained that it had received notices of allowance for the patent applications that have now issued as the '910 and 11-'333 Patents (and that are asserted here). Inari explained that the claims in these new patents were issuing over the prior art identified by Truvic and that the Symphony system would practice these patents upon issuance. The letter further explained that Inari had been able to analyze a Symphony system and had now concluded that the hemostasis valves of the Symphony system indeed infringe the '005, '921, '012, and '291 Patents, as had been suggested was likely in Inari's September 2023 letter.

63. On February 14, 2025, Inari sent an e-mail to counsel for Truvic that the 12-'333 Patent would be issuing on March 4, 2025 and that Inari intended to assert infringement and serve supplemental contentions and amend its complaint, adding the 12-'333 Patent.

64. ~~61.~~ Despite Inari's notice to Defendant by a series of letters and emails, Defendant has continued to market infringing Symphony systems. Inari is therefore forced to file this suit.

COUNT 1: INFRINGEMENT OF THE '910 PATENT

65. ~~62.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

66. ~~63.~~ The '910 Patent is titled "System for Treating Embolism and Associated Devices and Methods." The '910 Patent discloses improved clot-removing systems and methods for pulmonary embolisms that solve problems with prior art clot-removal devices. The '910 Patent solves these problems through its inventions that include, for example, an aspiration system configured to allow for aspiration using vacuum, comprising both a first and second aspiration system comprising, respectively: a first and second catheter; a first and second pressure source; and a first and second fluid control device between the respective catheters and pressure sources. (Ex. C at cl. 1.) Each of the fluid control devices can be moved between a first position where the pressure source is disconnected from the catheter (allowing the pressure source to generate vacuum pressure) and a second position where the pressure source is fluidly connected to the catheter (where vacuum from the pressure source generates suction at the distal end of the catheter). (*See id.*) The '910 Patent teaches that the second aspiration catheter of the

second aspiration assembly is advanceable through the first aspiration catheter of the first aspiration assembly and that the second catheter has a size of 16F, while the first catheter has a size of 24F. (*See id.* at cl. 1, cl. 3.)

67. ~~64.~~ Defendant directly infringes—literally and/or under the doctrine of equivalents—at least claims 1 and 3 of the '910 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

68. ~~65.~~ The Symphony system practices each limitation of at least claims 1 and 3 of the '910 Patent.

69. ~~66.~~ For example, claim 1 of the '910 Patent recites:

> [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,

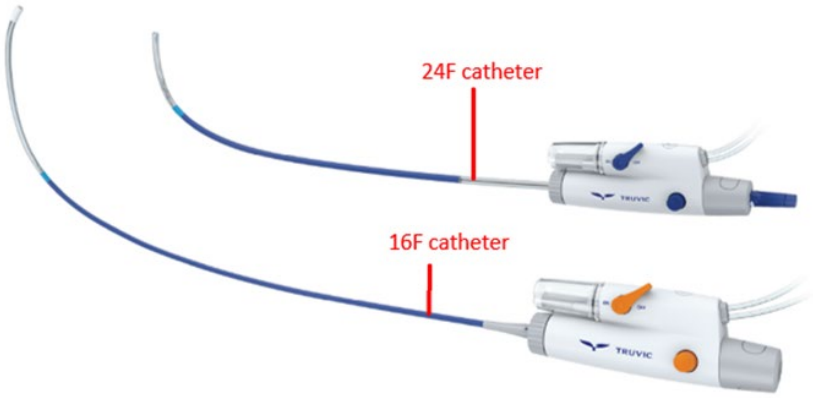
wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter 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.

70. ~~67.~~ Claim 3 further recites: "[t]he clot treatment system of claim 1 wherein the first catheter has a size of 24 French, and wherein the size of the [] second catheter [] is 16 French."

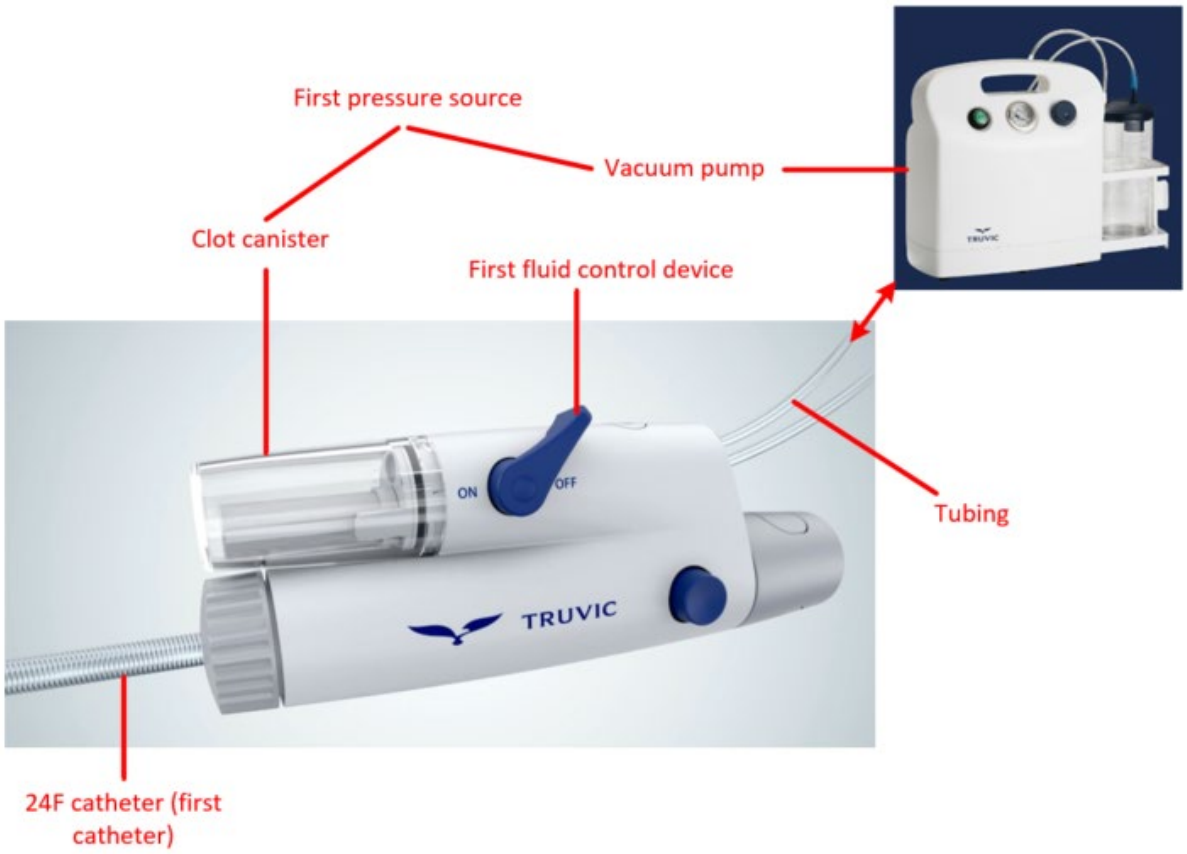
71. ~~68.~~ To the extent the preamble of claim 1 is construed to be limiting, the Truvic Symphony system practices the requirements of the preamble, "[a] clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient," as can be seen in the claim chart in Exhibit M. Specifically, the Symphony system is a clot treatment system for treating clot material from pulmonary embolisms, "[t]he Truvic Symphony Thrombectomy System employs "next generation thrombus removal" with "powerful, focused aspiration" for treating (*e.g.*, removing) clot material from within a blood vessel." (Ex. A at 2-4.) The Symphony system is further a system for treating clot material comprising a pulmonary embolism in the vasculature of the patient, as demonstrated by: doctors' use of the system for exactly that purpose; the Symphony system being used in clinical trials for treatment of pulmonary embolisms; and Defendant seeking clearance for using the Symphony system for treatment of pulmonary embolism (clot material in the pulmonary vasculature). *See* SYMPHONY-PE Study for Treatment of Pulmonary Embolism (available at https://classic.clinicaltrials.gov/ct2/show/NCT06062329).

72. ~~69.~~ The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a 24F catheter (first catheter), a vacuum pump and a clot canister comprising the first pressure source, and a controller handle for a 24F catheter including a Dual-Action Vacuum Control operated by a lever (a first fluid control

device) between the 24F catheter and the first pressure source:



(Ex. A at 2 (annotations added).)

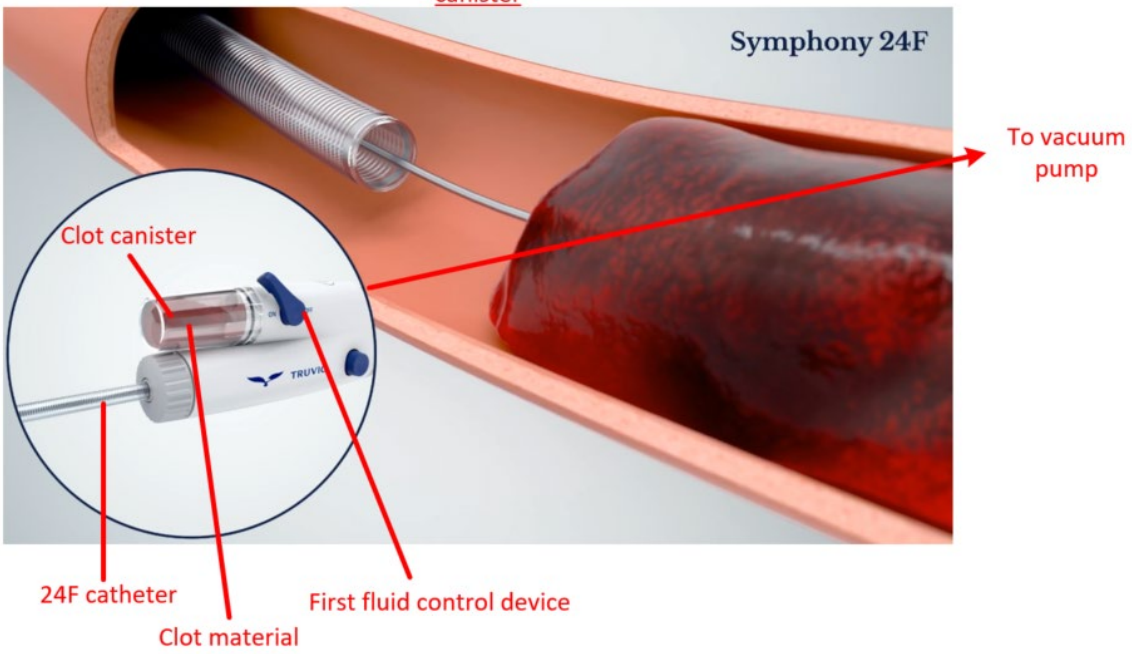


(Annotated diagram of Symphony system handle, including the first catheter, connection to a first pressure source (clot canister and vacuum pump), and a first fluid control device (the Dual-Action Vacuum Control operated by a lever).)

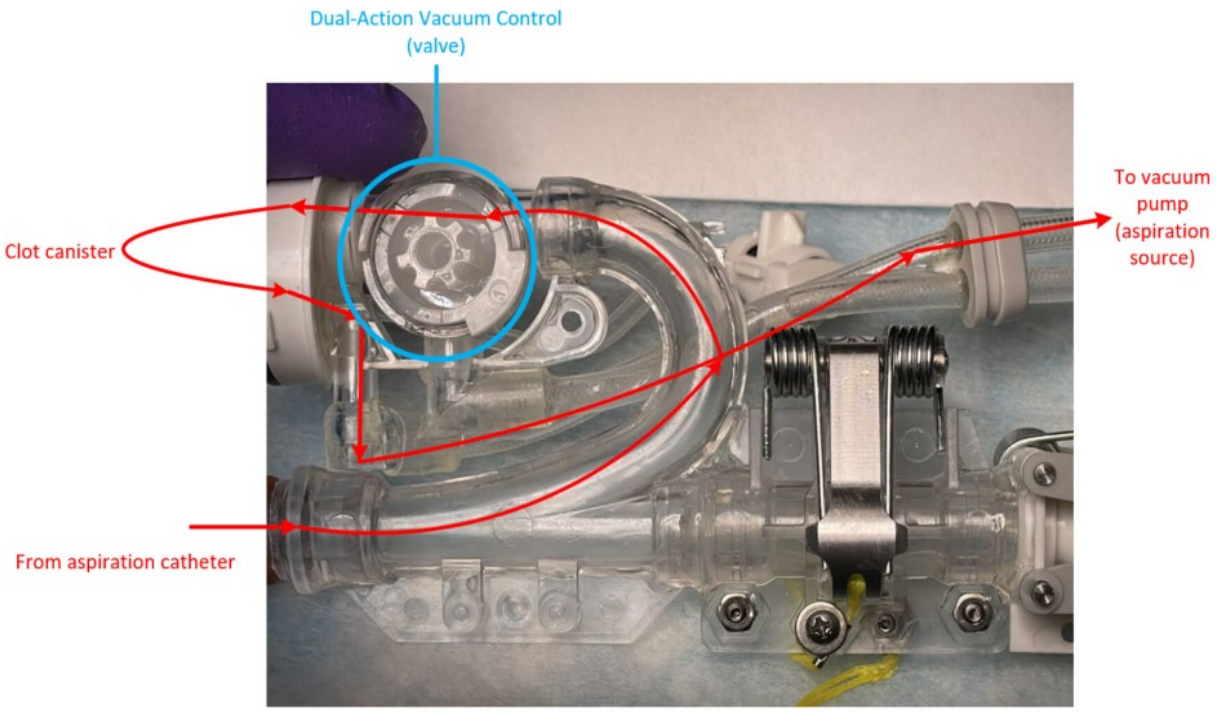
73. ~~70.~~ The Symphony system practices the limitations of claim 1, including "wherein the first fluid control device is movable between (a) a first position in which the first pressure

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," as can be seen in claim chart in Exhibit M. The Symphony system includes a Dual-Action Vacuum Control operated by a lever (a first fluid control device) between the 24F catheter and the first pressure source (comprised of the clot canister and the vacuum pump) that in a first position (off) fluidly disconnects the first pressure source from the 24F catheter and that in a second position (on) fluidly connects the first pressure source to the 24F catheter:

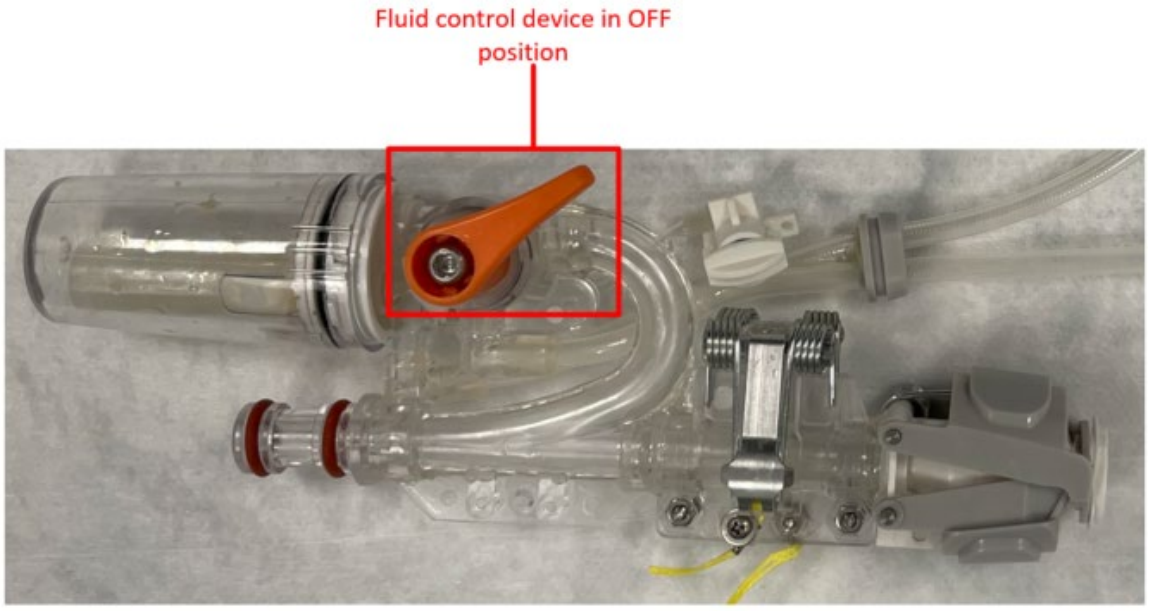
First fluid control device in "On" position such that the first pressure source is fluidly connected to the 24F catheter such that the clot material is aspirated into the clot canister



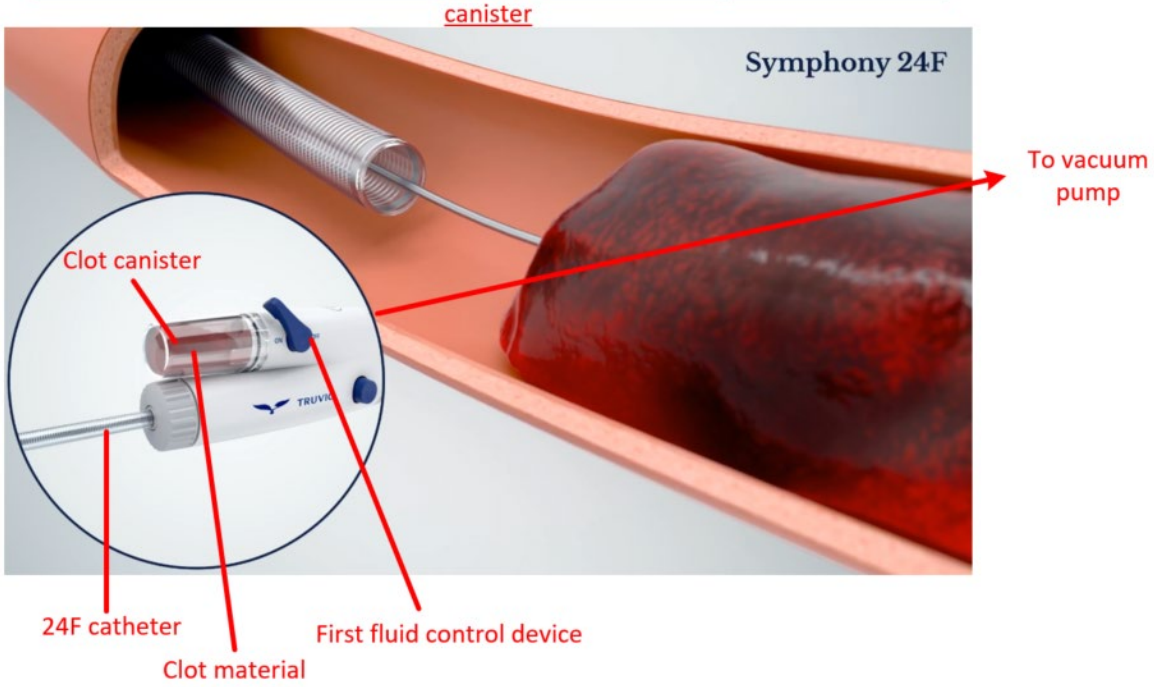
(Annotated screen capture from Symphony product video.)



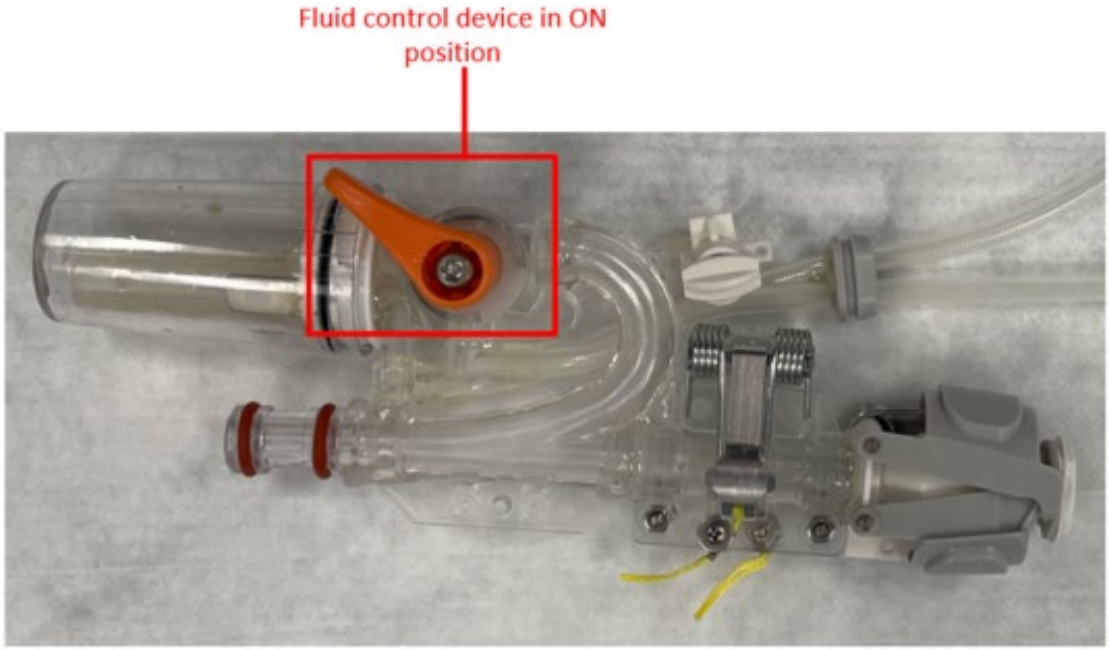
(Annotated image of internal portion of controller handle housing.)



(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)

74. ~~71.~~ The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a controller handle for a 24F catheter including a Dual-Action Vacuum Control operated by a lever (a first fluid control device) between the 24F catheter and the first pressure source (comprised of the clot canister and the vacuum pump) that in a first position (off) fluidly disconnects the first pressure source from the 24F catheter and that in a second position (on) fluidly connects the first pressure source to the 24F catheter. As detailed above, the first pressure source (clot canister and vacuum pump) creates a vacuum in the clot canister while the handle lever is in the first (off) position, and then vacuum pressure is applied to the first (24F) catheter to generate suction at the distal portion of the catheter (positioned near the clot material) when the handle lever is moved from the first position to the second (on) position:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

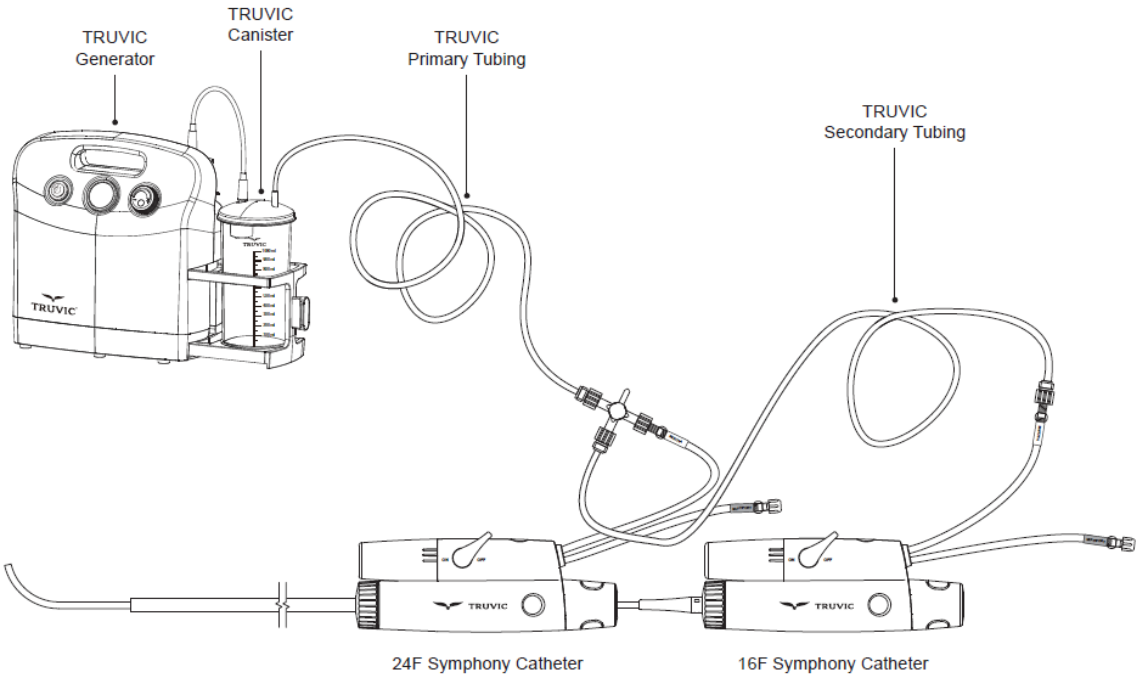


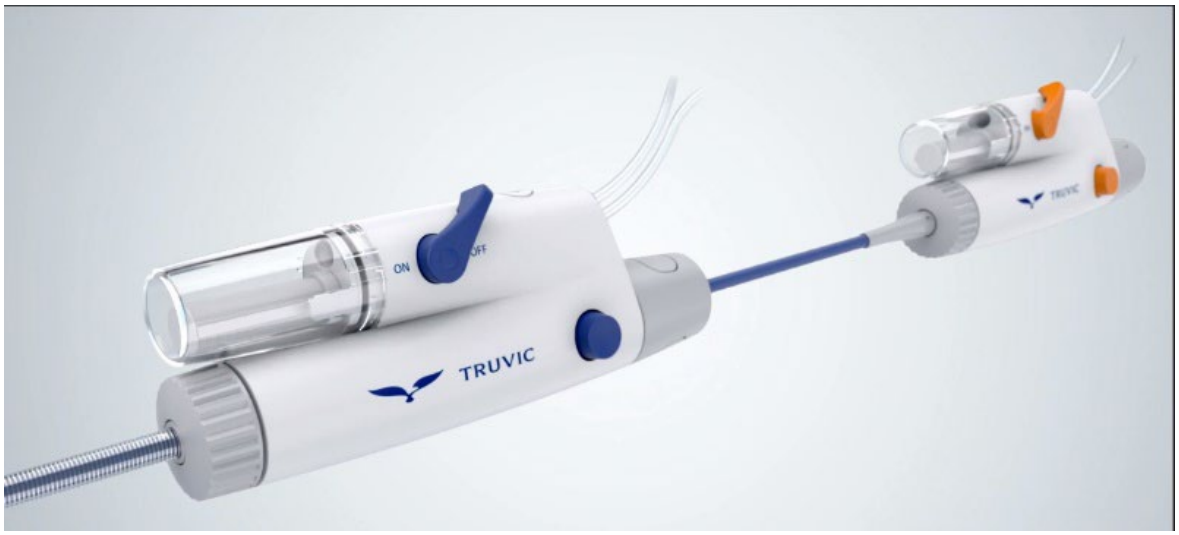
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

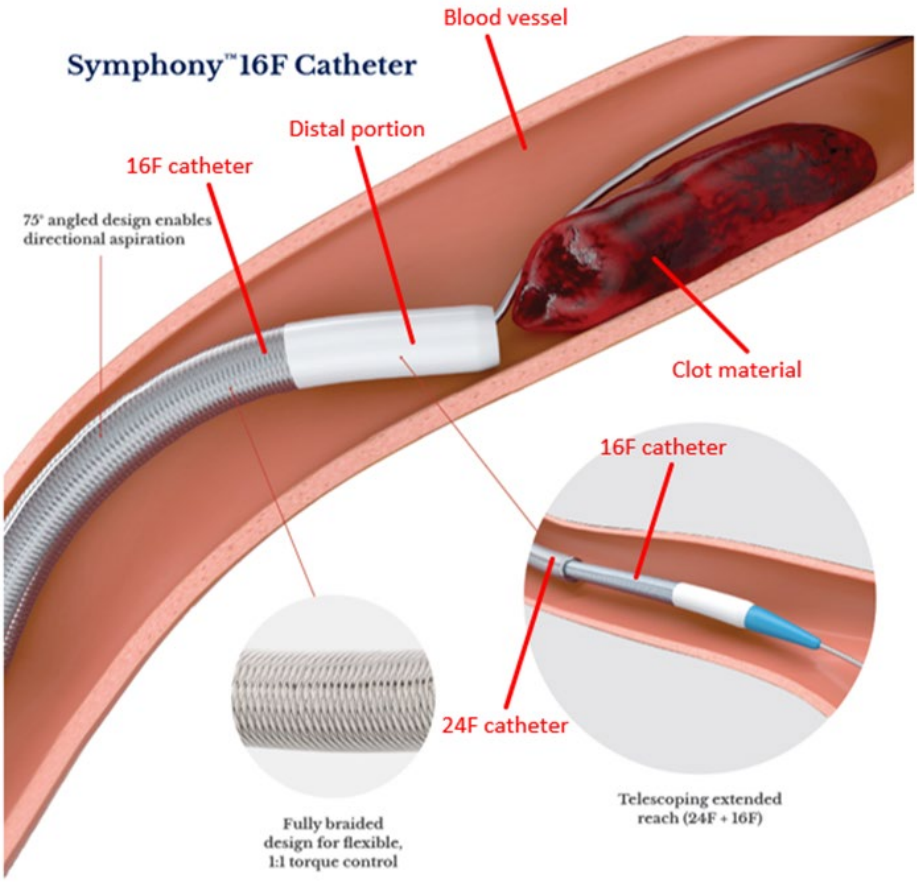
(Ex. B at 8.)

75. ~~72.~~ The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M.

Specifically, the Symphony system has a second aspiration assembly including a second (16F) catheter that can be advanced through the first (24F) catheter, where the second (16F) catheter is shaped to be telescoped through the 24F catheter and advanced through a patient's vasculature to position the distal end of the second catheter proximate to clot material, *e.g.*, a pulmonary embolism:

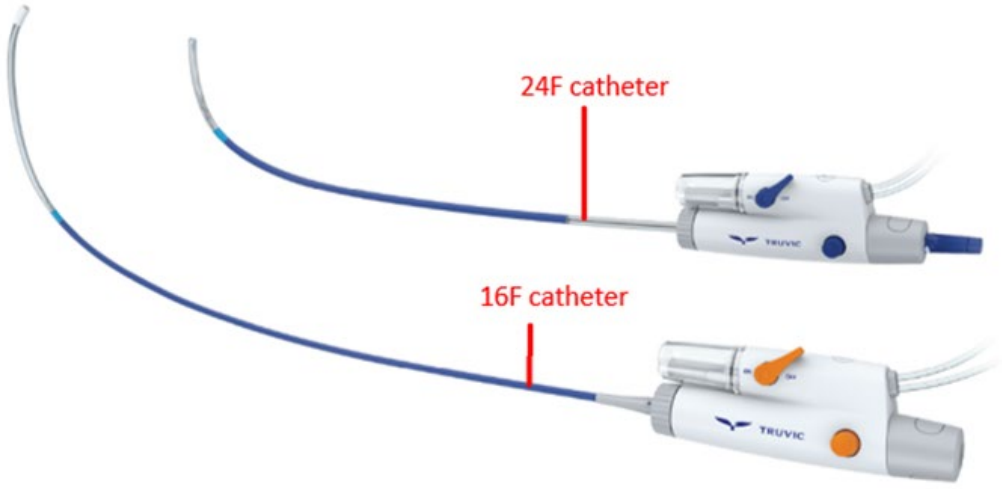


(Screen capture from Symphony product video.)

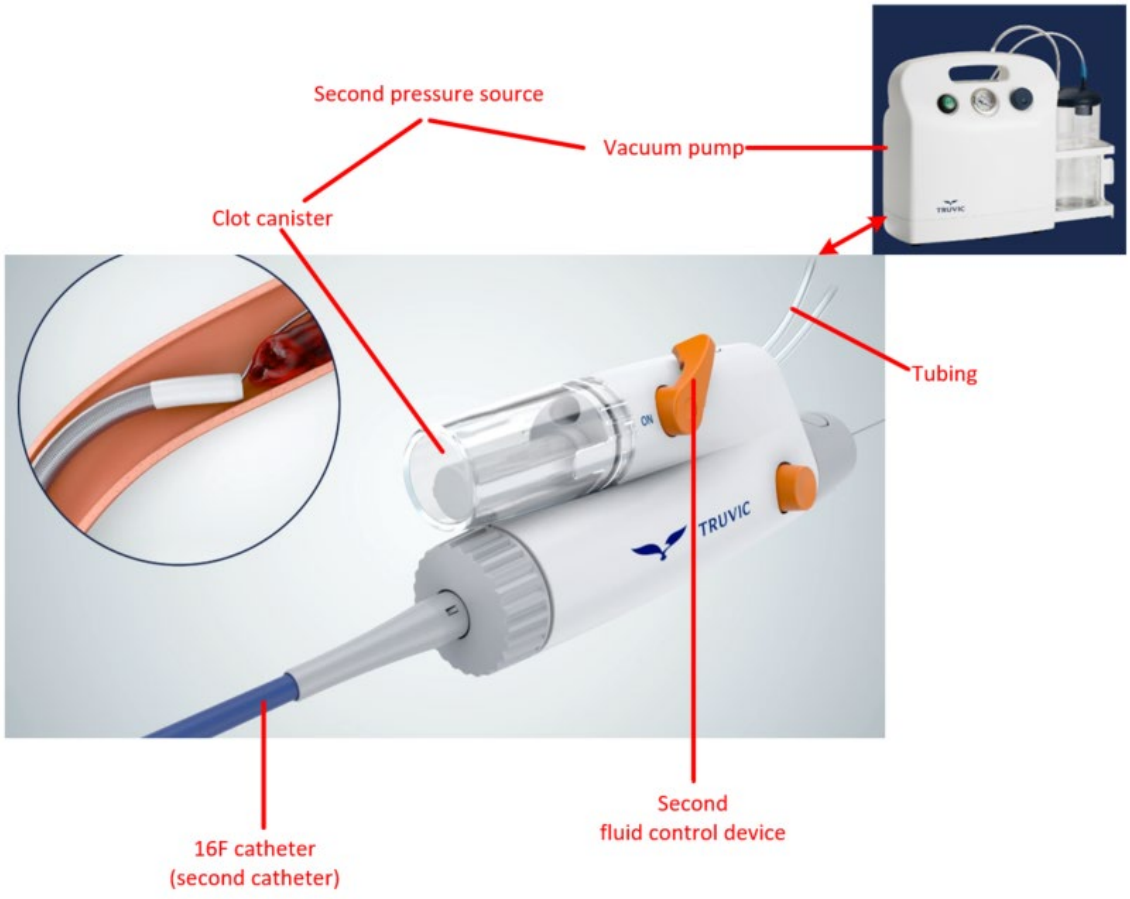


(Ex. A at 4 (annotations added).)

76. ~~73.~~ The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a 16F catheter (second catheter), a vacuum pump and a clot canister comprising the second pressure source, and a controller handle for a 16F catheter including a Dual-Action Vacuum Control operated by a lever (a second fluid control device) between the 16F catheter and the second pressure source:

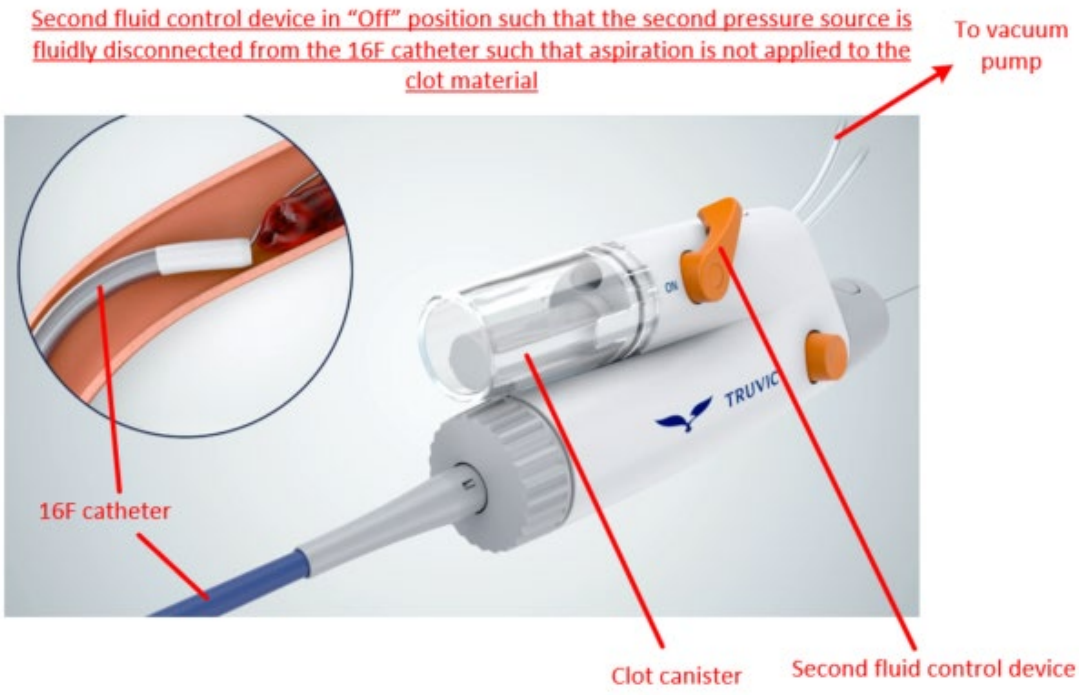


(Ex. A at 2 (annotations added).)

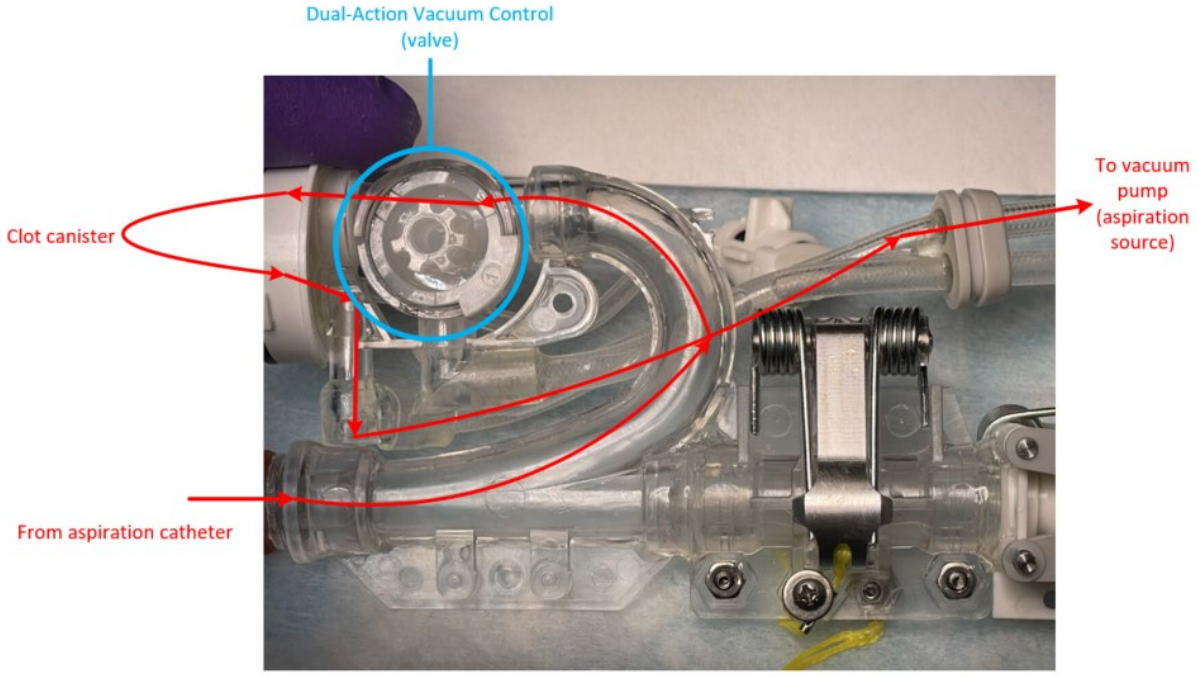


(Annotated diagram of Symphony system handle, including the second catheter, connection to a second pressure source (clot canister and vacuum pump), and a second fluid control device (the Dual-Action Vacuum Control operated by a lever).)

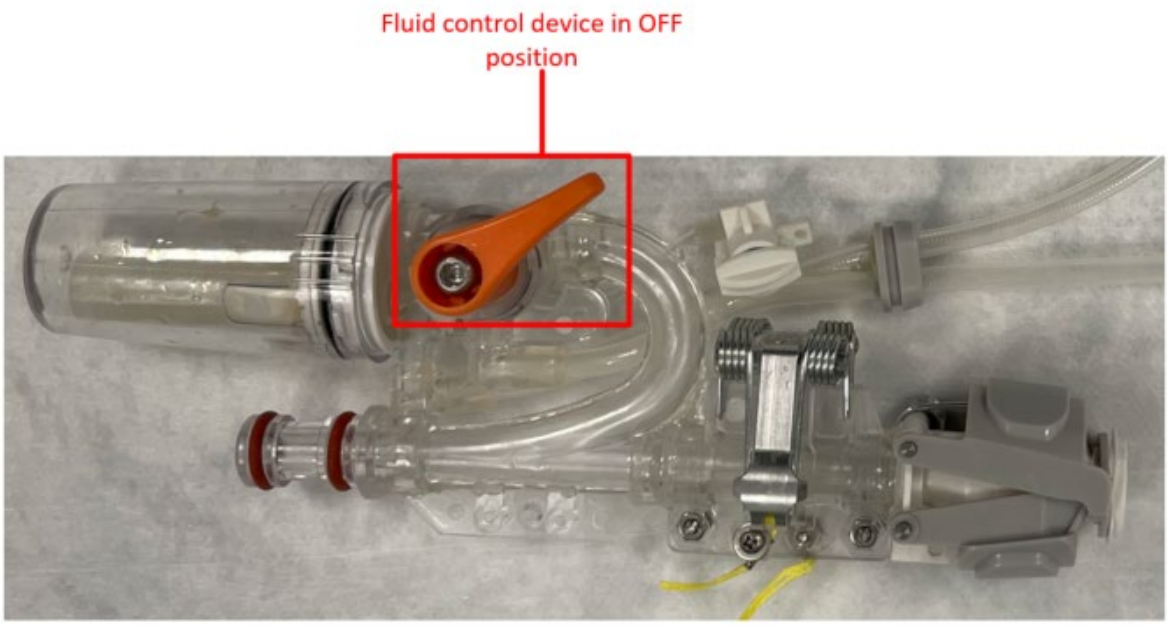
77. ~~74.~~ The vacuum control lever of the second fluid control device can be moved from the first (off) position where the second catheter is fluidly disconnected from the second pressure source to a second (on) position where the second catheter is fluidly connected to the second pressure source:



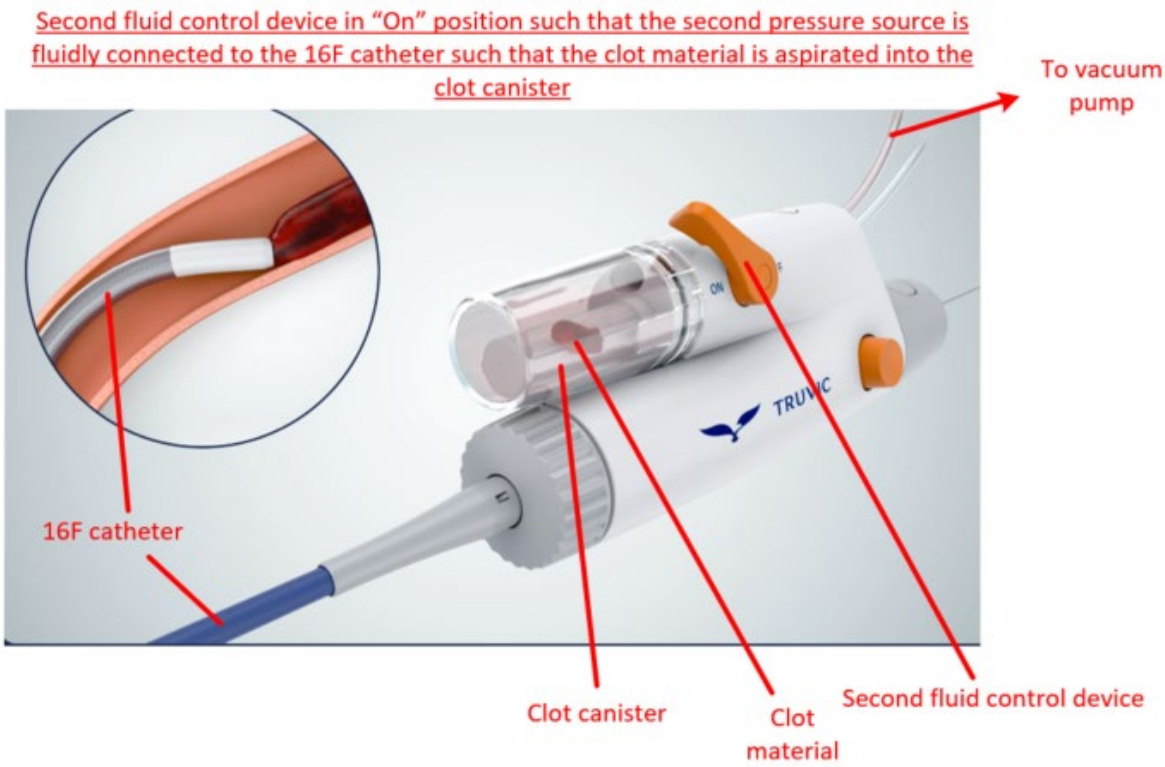
(Annotated screen capture from Symphony product video.)



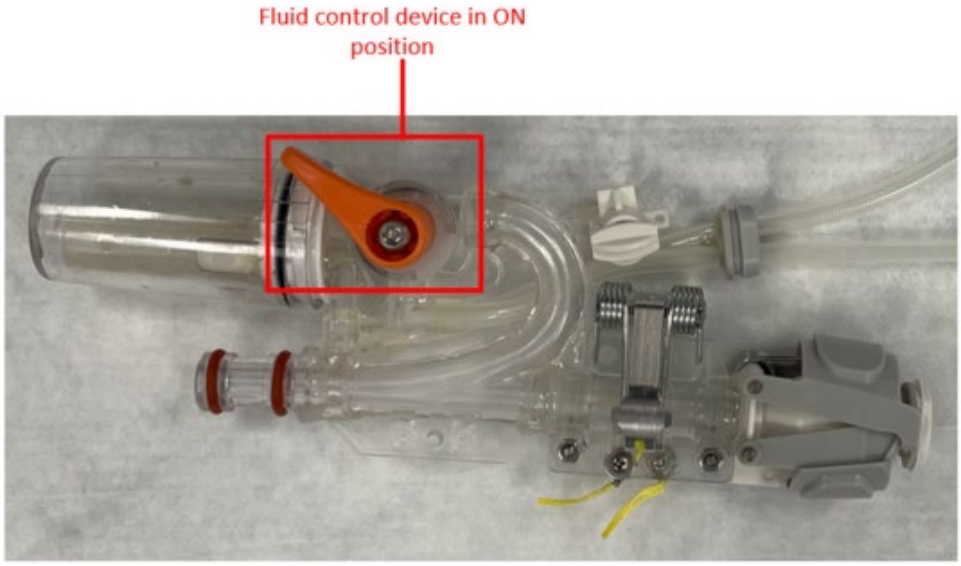
(Annotated image of internal portion of controller handle housing.)



(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)

78. ~~75.~~ The Symphony system practices the limitations of claim 1, including "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," as can be seen in claim chart in Exhibit M. The Symphony system includes a controller handle for a 16F catheter including a Dual-Action Vacuum Control operated by a lever (a second fluid control device) between the 16F catheter and the second pressure source (comprised of the clot canister and the vacuum pump) that in a first position (off) fluidly disconnects the second pressure source from the 16F catheter and that in a second position (on) fluidly connects the second pressure source to the 16F catheter. As detailed above, the second pressure source (clot canister and vacuum pump) creates a vacuum in the clot canister while the handle lever is in the first (off) position, and then vacuum pressure is applied to the second (16F) catheter to generate suction at the distal portion of the catheter (positioned near the clot material) when the handle lever is moved from the first position to the second (on) position:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

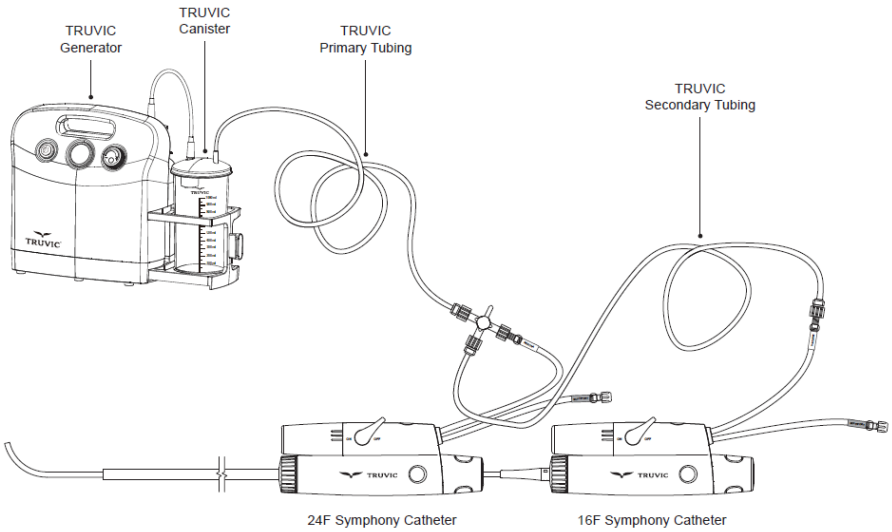


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

79. ~~76.~~ Additionally, the Symphony system practices claim 3 of the '910 Patent, which recites "[t]he clot treatment system of claim 1 wherein the first catheter has a size of 24 French, and wherein the size of the [] second catheter [] is 16 French," as can be seen in the attached Exhibit M. As can be seen above, the Symphony system includes a 24F catheter that is advanced into a patient's vasculature during thrombectomy procedures, including a 16F catheter telescoped through the 24F catheter.

80. ~~77.~~ Defendant directly infringes claims of the '910 Patent, including claims 1 and 3, by making, using, selling, offering for sale, and/or importing Symphony system products and their components, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures on pulmonary embolisms) Symphony system products.

81. ~~78.~~ Defendant induces infringement of claims of the '910 Patent, including claims 1 and 3, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use Symphony systems that practice claims 1 and 3. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures on patients with pulmonary embolisms.

82. ~~79.~~ On information and belief, Defendant teaches and/or direct others to perform thrombectomy on pulmonary embolisms using the Symphony system (and components thereof), despite not having received an indication for use for treatment of pulmonary embolisms. Defendant, for example, provides Instructions for Use that state that "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (Ex. B at 2.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating pulmonary embolisms. Defendant additionally is in the process of seeking FDA clearance for the treatment of PE and have an announced intention to formally market its Symphony system to do so.

83. ~~80.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '910 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

84. ~~81.~~ Defendant's infringement is with knowledge of the '910 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated April 24, 2024, that the claims of United States Patent Application No. 18/329,433 ("the '433 Application") were scheduled to issue shortly as the '910 Patent and further provided notice that claims 1 and 3 of the '433 Application read on the Symphony system and that Defendants would be infringing the

'910 Patent upon its issuance. Inari further attached the notice of allowance for the '433 Application that became the '910 Patent.

85. ~~82.~~ At a minimum, Defendant has notice of the '910 Patent through the filing of the original Complaint, which was submitted to the Court just a few weeks after the '910 Patent issued.

86. ~~83.~~ Defendant has continued its infringing activities after the '910 Patent issued, despite knowledge of the allowed claims (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

87. ~~84.~~ To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '910 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

88. ~~85.~~ To the extent applicable, the requirements of 35 U.S.C. § 154(d) have been met for the allowed claims of the '433 Application from April 24, 2024, to the issuance of the '910 Patent.

89. ~~86.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 2: INFRINGEMENT OF THE 11-'333 PATENT

90. ~~87.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

91. ~~88.~~ Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claims 20 and 22 of the 11-'333 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

92. ~~89.~~ The 11-'333 Patent, titled "System for Treating Embolism and Associated Devices and Methods," is part of the same family as the '910 Patent, and shares the same specification. Similar to the '910 Patent, the 11-'333 Patent discloses improved methods of treatment for removing clot material (*e.g.*, thrombi and emboli) from blood vessels of a human

patient, particularly from deep veins (DVT or deep vein thromboses) or pulmonary vasculature (pulmonary embolisms) of human patient. (Ex. D at 4:51-58.) This is accomplished by aspirating the clot material through a catheter fluidly coupled to a pressure source via a valve. (*Id.* at 4:17-25.) The 11-'333 Patent explains that prior art clot-removal devices have been found: to be highly complex and lead to manufacturing and quality control difficulties, as well as delivery issues into patients; to cause trauma to the treatment vessel; to lack the ability to be appropriately fixed against the vessel; and/or to be ineffective at capturing clot material. (*Id.* at 2:33-44.) The 11-'333 Patent solves these problems through its inventions, which include, for example, methods comprising advancing a catheter within a patient's vasculature to treat pulmonary embolism or deep vein thrombosis. (*Id.* at cl. 1, cl. 20.) The aspiration catheter has its distal end placed proximate to the clot material (pulmonary embolism or deep vein thrombosis), while the aspiration catheter lumen is fluidly connected along a path to a clot canister and to an aspiration source proximal to the clot canister. (*Id.*) The methods further comprise steps of generating vacuum pressure in the path between the clot canister and aspiration catheter while a valve is in a first position that inhibits fluid flow from the aspiration catheter to the clot canister, and then moving the valve to a second position that permits fluid flow along the path from the lumen of the aspiration catheter to the clot canister, thereby applying vacuum pressure to the lumen of the aspiration catheter and aspirating at least a portion of clot material into the clot canister. (*Id.*) The 11-'333 Patent further claims aspects of aspiration systems, including a clot canister with a filter-to-filter blood from clot material (*id.*), performing the method with large (16F or 20F or larger diameter catheters (*id.* at cl. 2, cl. 3 cl. 21, cl. 22), and performing the method on clot material in the pulmonary artery (*id.* at cl. 4) or peripheral vasculature of the patient (*id.* at cl. 24).

93. ~~90.~~ Specifically, claim 20 of the 11-'333 Patent recites:

> [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.

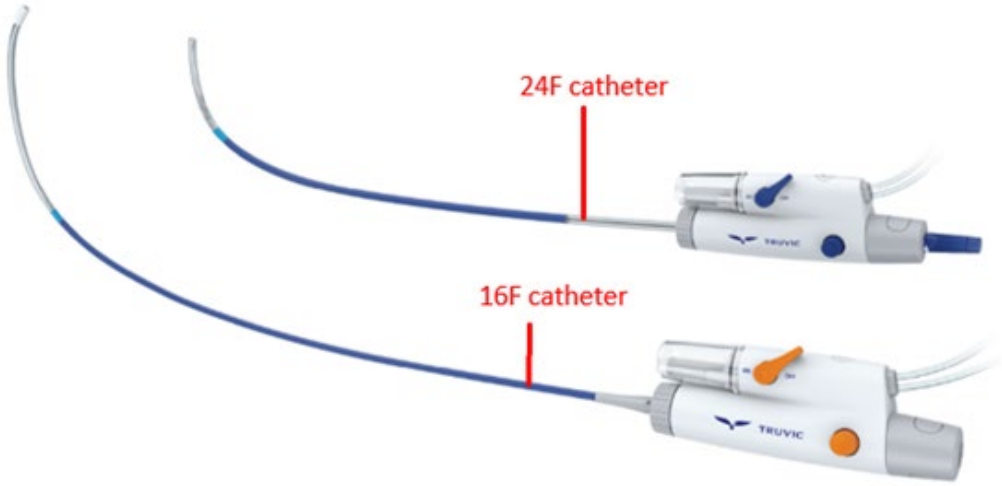
94. ~~91.~~ Claim 22 of the 11-'333 Patent further recites: "[t]he method of claim 20 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature."

95. ~~92.~~ Performing thrombectomy on deep vein thrombosis using the Truvic Symphony system practices each limitation of at least claims 20 and 22 of the 11-'333 Patent, as can be seen in the 11-'333 Patent claim chart, attached as Exhibit N.

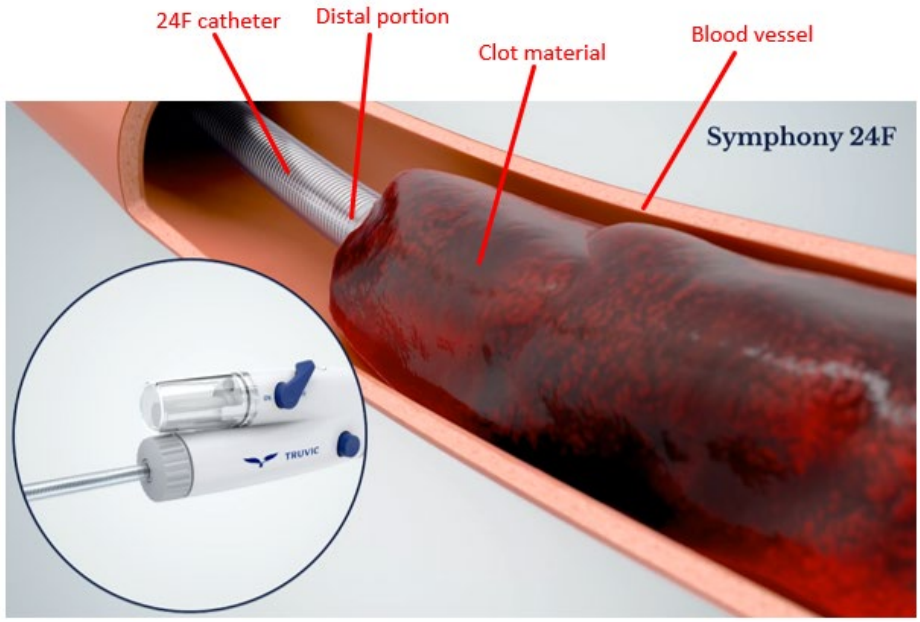
96. ~~93.~~ To the extent the preamble of claim 20 is construed to be limiting, thrombectomy of deep vein thrombosis with the Symphony system practices the requirements of the preamble, "[a] method of treating a deep vein thrombosis within a vasculature of a patient, the method comprising," as can be seen in Exhibit N. For example, according to Truvic's Symphony Brochure, Symphony employs "next generation thrombus removal" with "powerful, focused aspiration" for treating (*e.g.*, removing) clot material from within a blood vessel. (*See* Ex. A at 2-4.) Symphony's "Instructions for Use" further instruct that the system "is indicated for: [t]he non-surgical removal of fresh, soft emboli and thrombi from blood vessels." (Ex. B at 12.) In addition, Symphony's product website includes a video detailing a method of using Symphony to treat clot material within a blood vessel of a human patient using vacuum aspiration. *See* https://www.truvic.com/symphony-product.

97. ~~94.~~ Thrombectomy with the Symphony system practices the limitations of claim 20, including "advancing an aspiration catheter at least partially through the vasculature of the

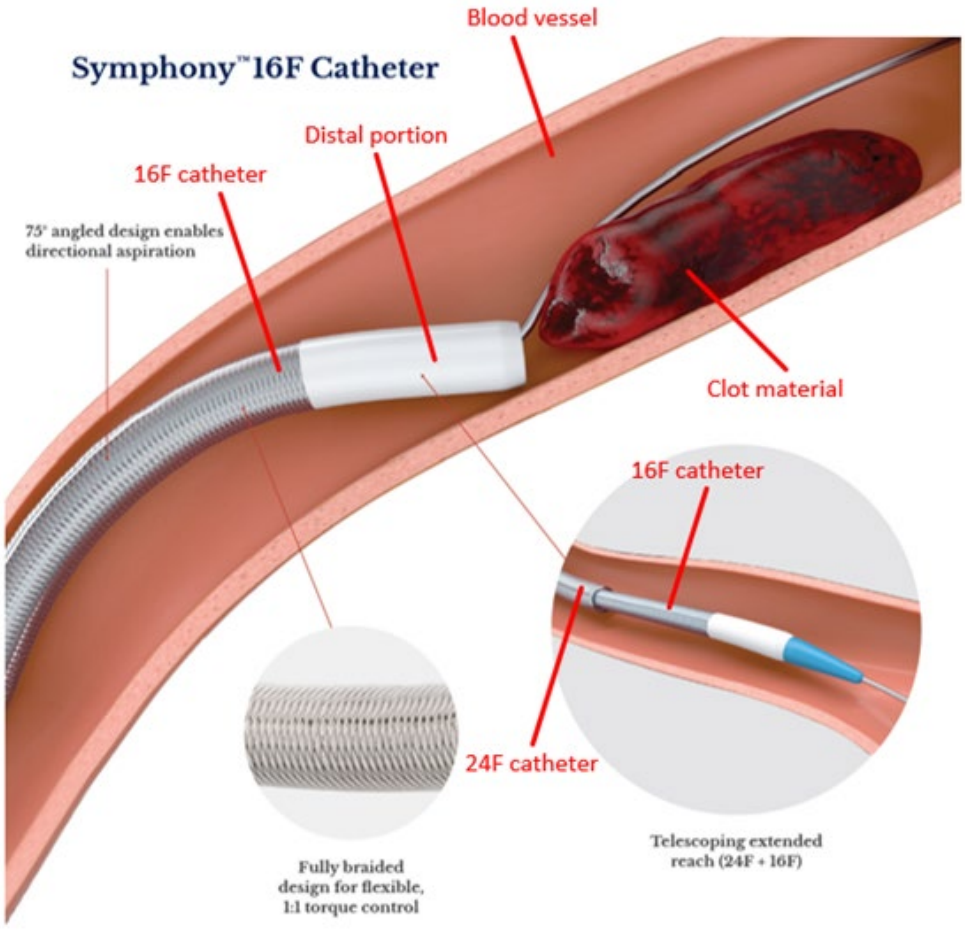
patient such that a distal end portion of the aspiration catheter is positioned proximate to the deep vein thrombosis," as can be seen in Exhibit N. The Symphony system includes a 24F catheter (a "first catheter") and a 16F catheter (a "second catheter"). (*Id.* at 2, 4.) These catheters can be used as aspiration catheters, and the Truvic Symphony system is "intended for use in the peripheral vasculature," such as for deep vein thrombosis.



(Ex. A at 2 (annotations added).)

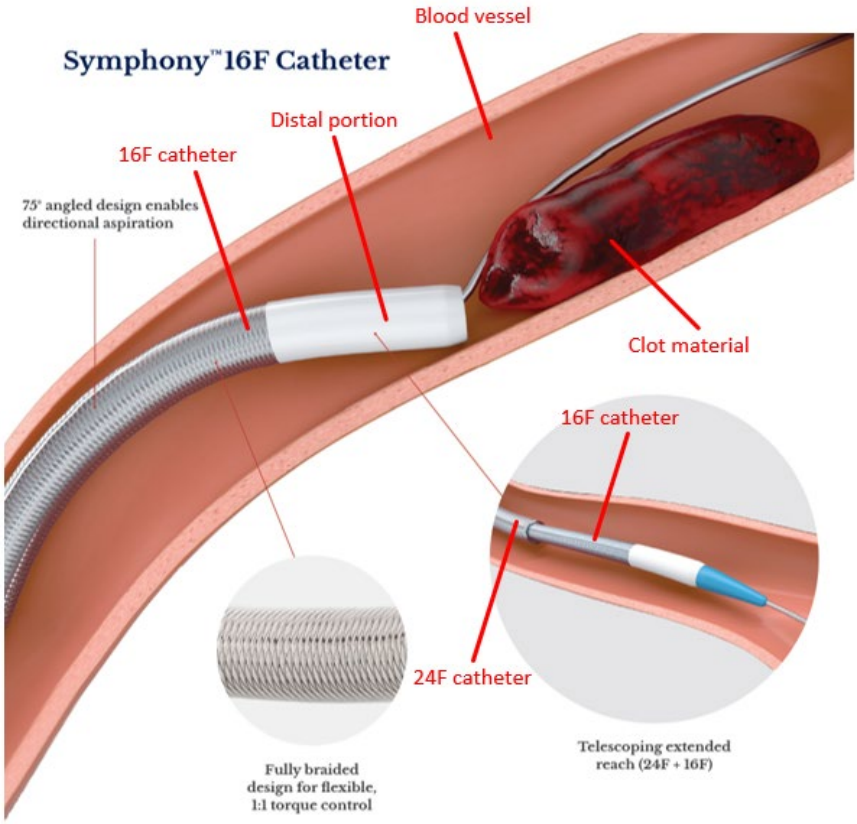


(Annotated screen capture from Symphony product video.)

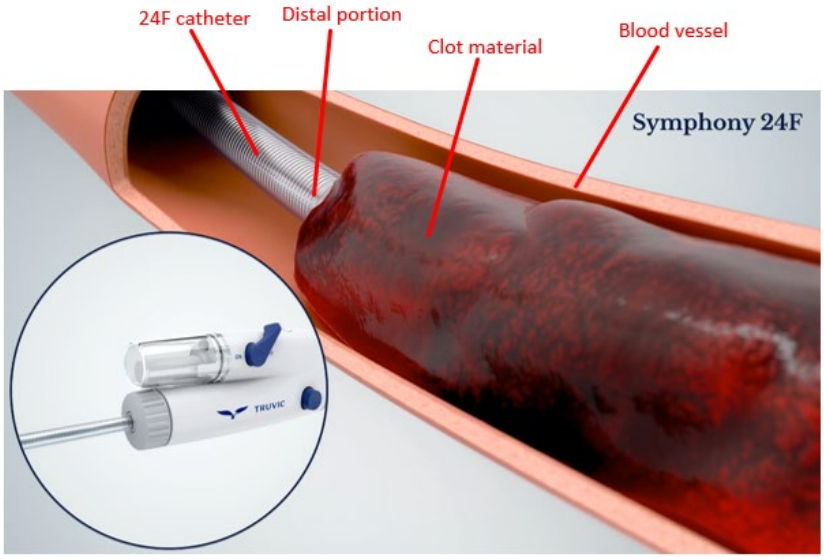


(Ex. A at 4 (annotations added).)

98. ~~95.~~ In thrombectomy operation, the 16F second catheter can be advanced, including through the 24F first catheter and out of the 24F first catheter, through the vasculature of a patient over a guidewire and/or with a dilator positioned therein (as shown in the image below) until a distal portion of the 16F second catheter is positioned just proximal of clot material within a blood vessel of the vasculature. (*See id.* at 4.) The 24F catheter can also be advanced to a position proximal to the clot material within a blood vessel of the patient's vasculature.



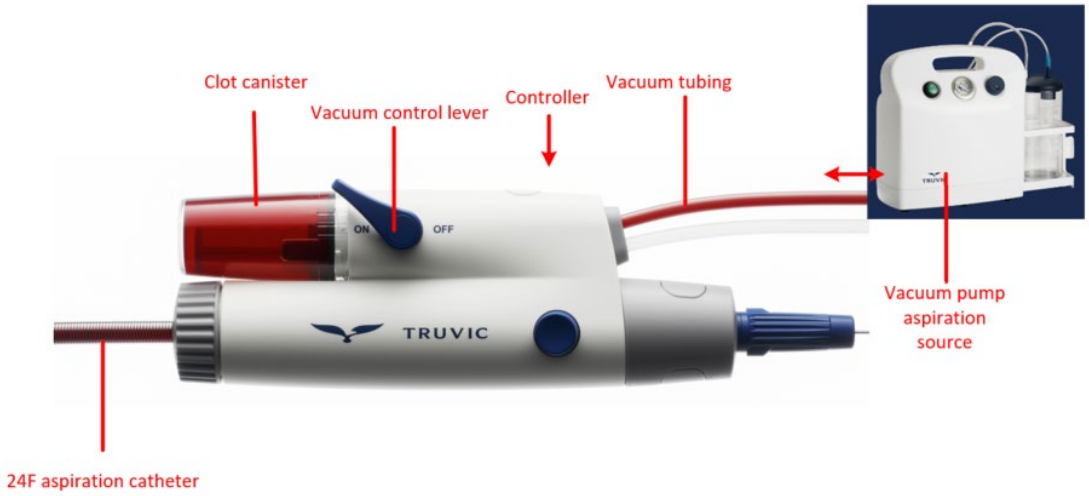
(Ex. A at 4 (annotations added).)



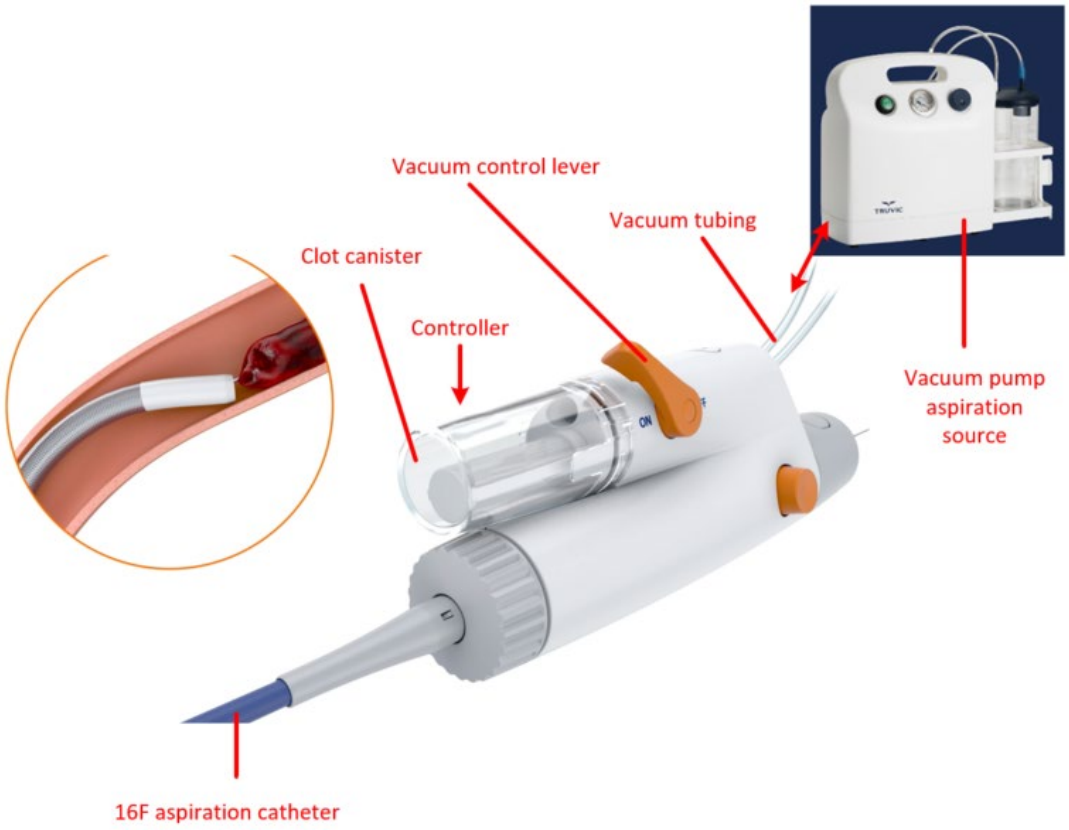
(Annotated screen capture from Symphony product video.)

99. ~~96.~~ Thrombectomy with the Symphony system practices the limitations of claim 20, including "wherein a lumen of the aspiration catheter is fluidly coupled along a fluid path to

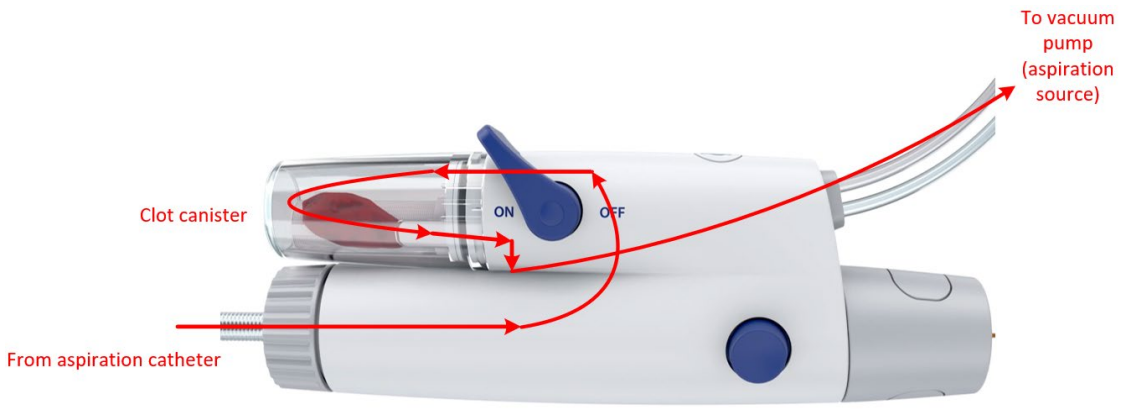
a clot canister and an aspiration source proximal to the clot canister," as can be seen in Exhibit N. Specifically, in the Symphony system, the 24F and 16F catheters have lumens that are coupled along a fluid path in the controller handle, and then to an aspiration source that includes a vacuum pump that is located proximal to the clot canister. This can further be seen in the annotated diagrams below:



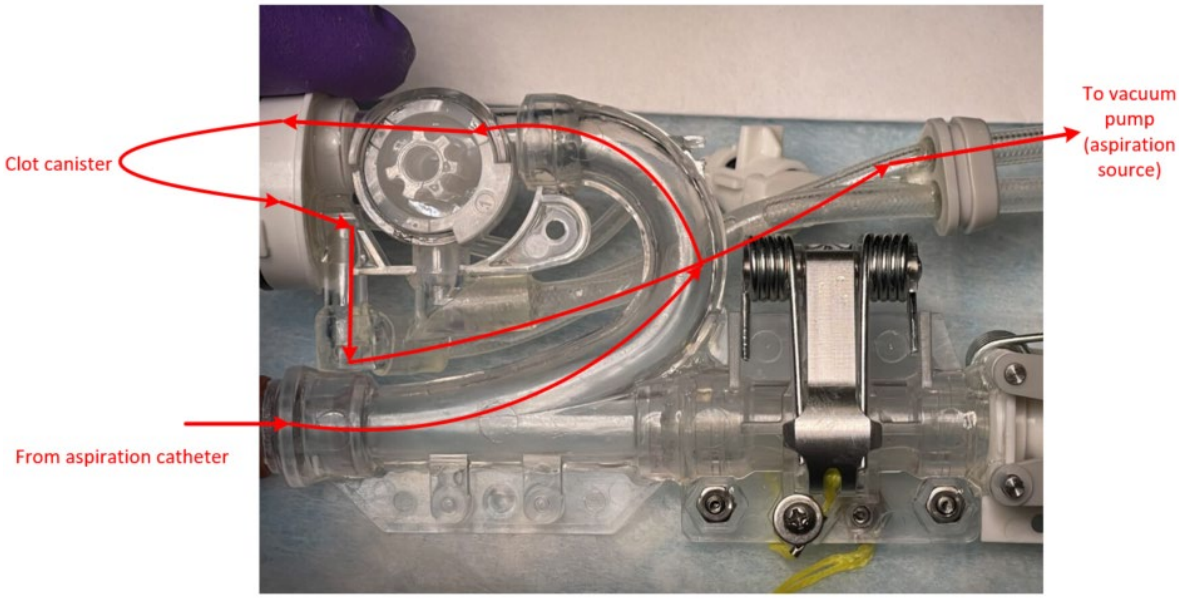
(Annotated diagram of Symphony system.)



(Annotated diagram of the Symphony system.)



(Annotated diagram of Symphony housing with flow path.)



(Annotated image of internal portion of controller handle housing with flow path.)

100. ~~97.~~ Thrombectomy with the Symphony system practices the limitations of claim 20, including "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," as can be seen in Exhibit N. In the Symphony system, the 24F and

16F controller handles are coupled to a Truvic Generator and Truvic Canister, or another pressure source, which is a vacuum pressure source:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

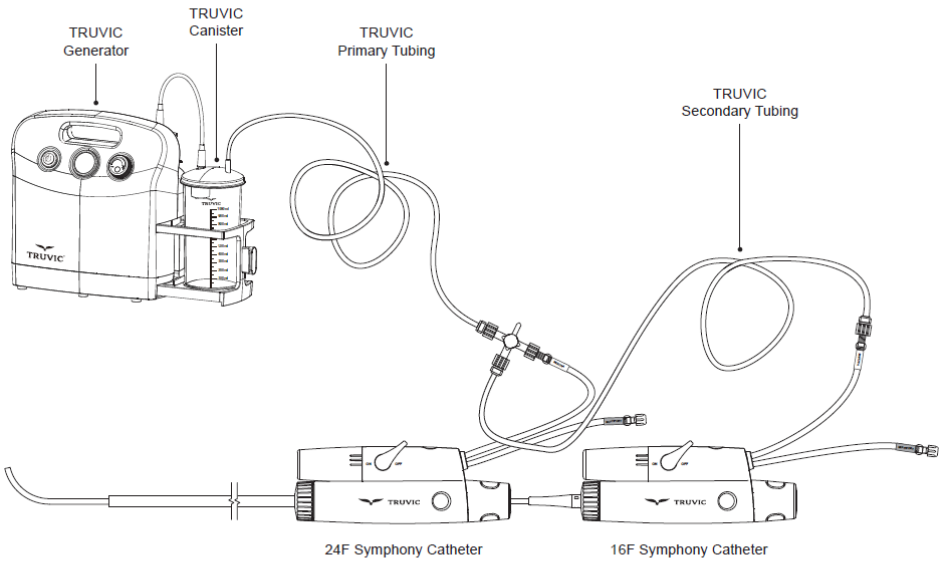
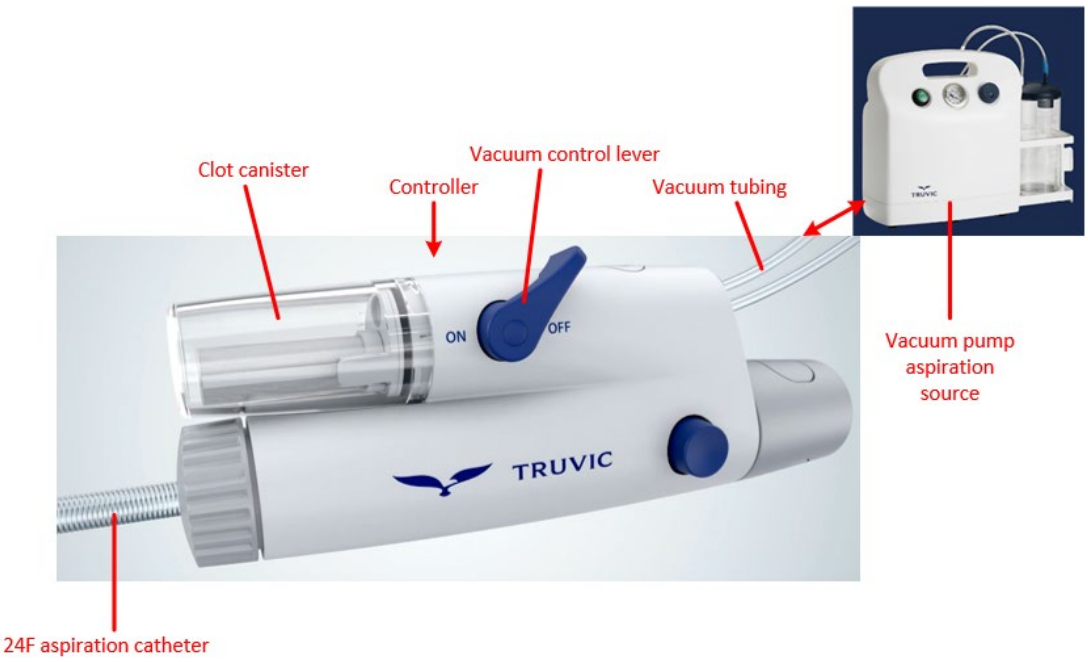


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

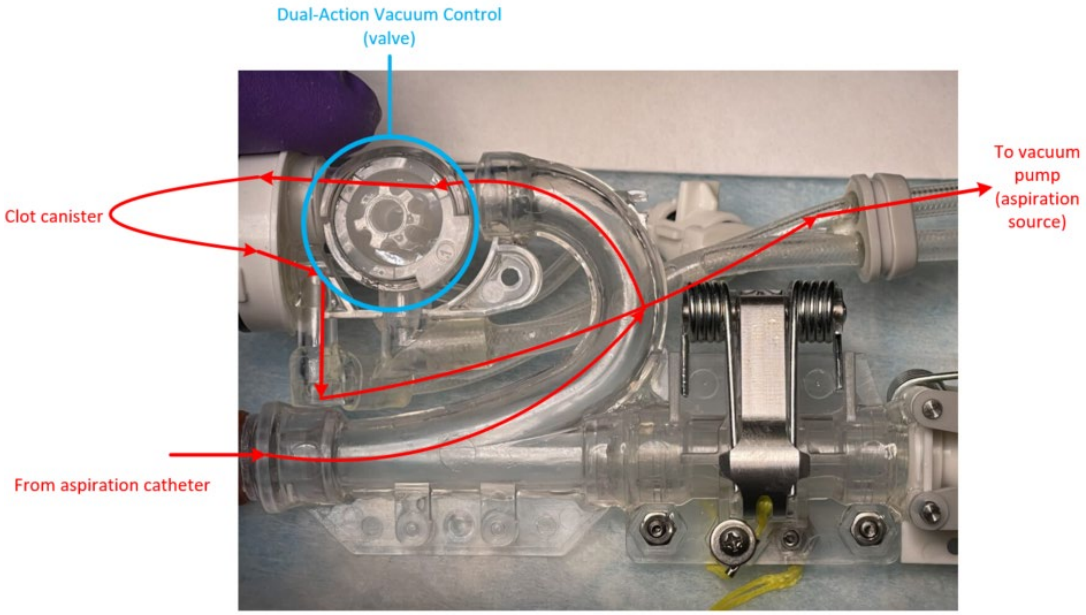
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

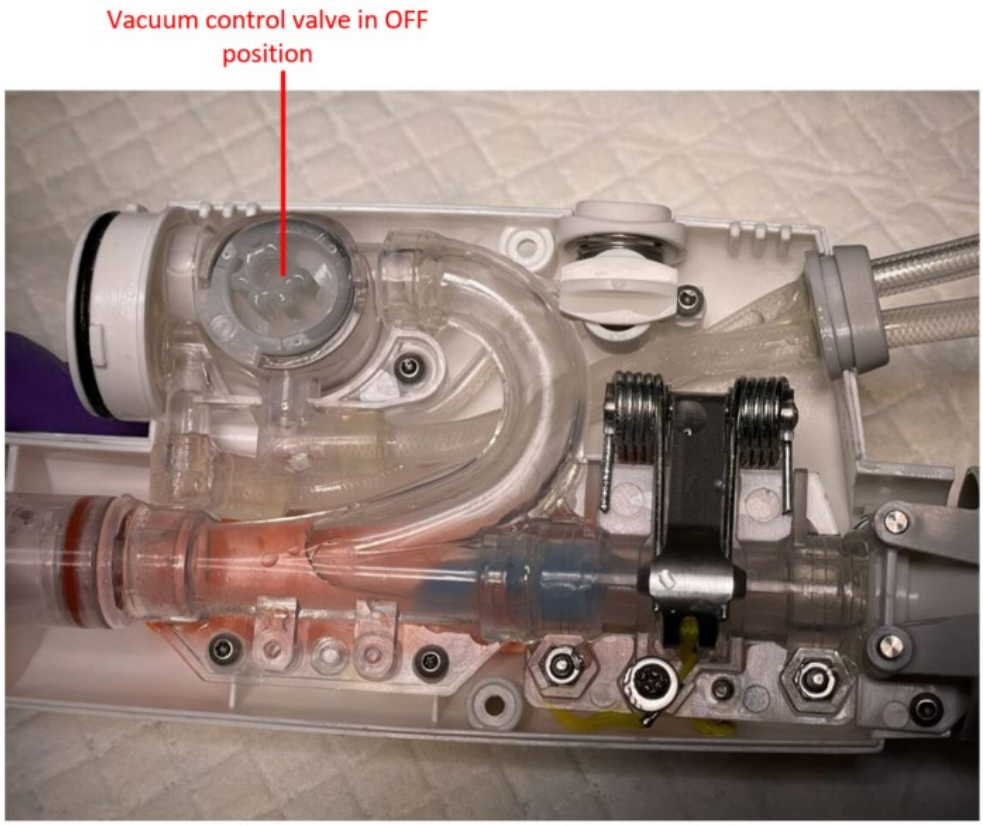
101. ~~98.~~ During thrombectomy using the Symphony system, the user initially sets the vacuum control lever on the 16F and/or 24F handles to the "OFF" position, which actuates a vacuum valve in the handle, ensuring that vacuum is not applied to the lumen of the 16F and/or 24F aspiration catheters:



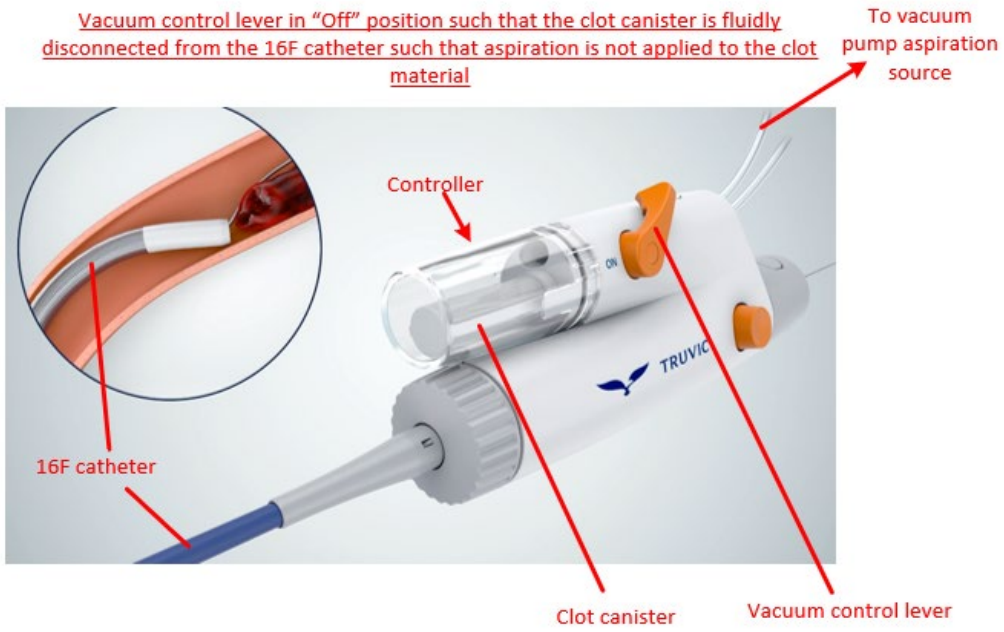
(Annotated diagram of Symphony system.)



(Annotated image of Symphony housing (internal).)



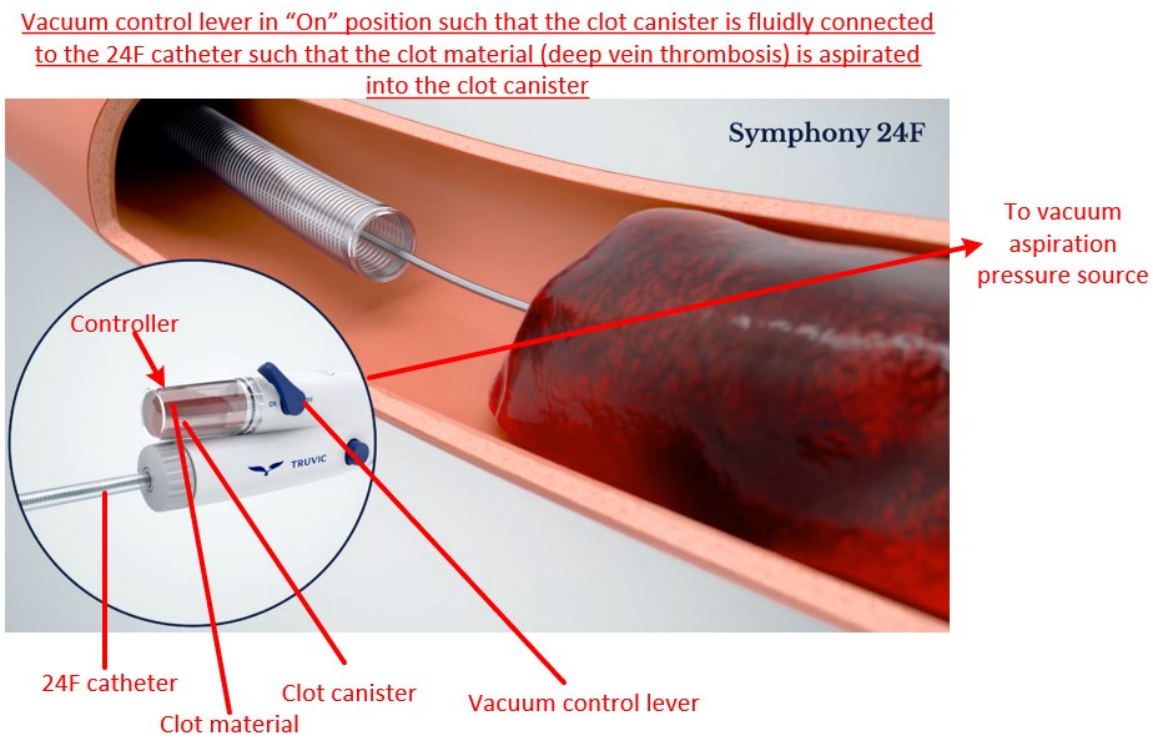
(Annotated image of Symphony housing (internal).)



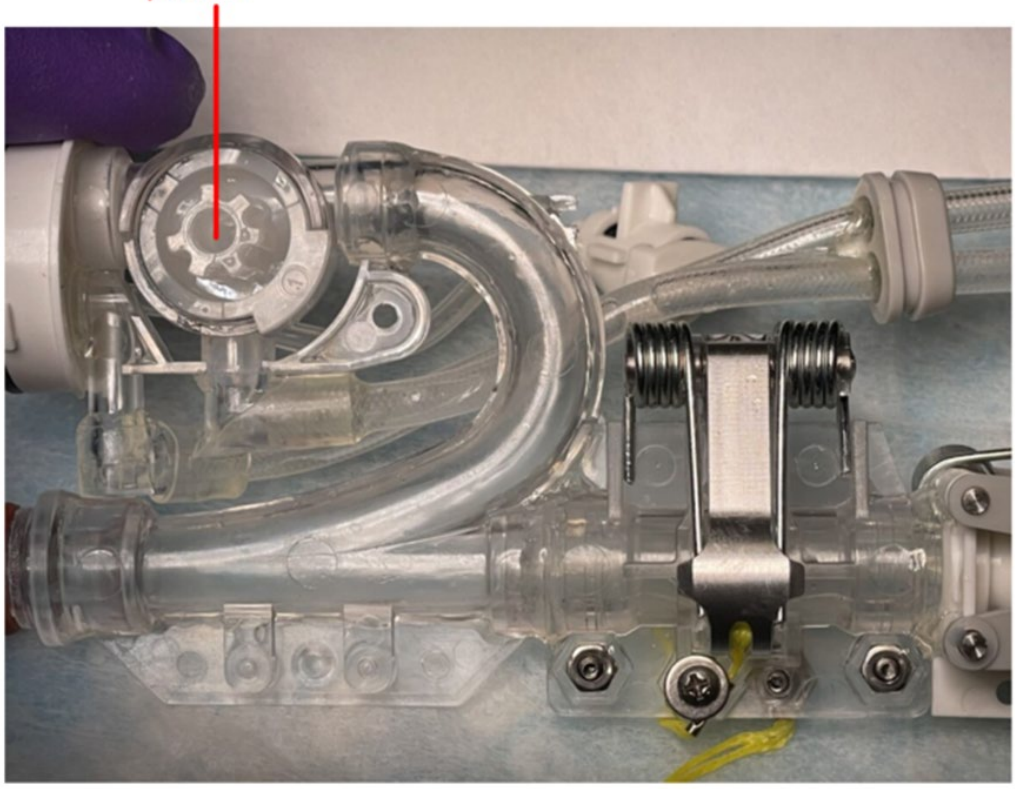
(Annotated screen capture from Symphony product video.)

102. ~~99.~~ During thrombectomy using the Symphony system, the user moves the vacuum lever on the 16F and/or 24F handles to the "ON" position, which actuates a valve in the handle,

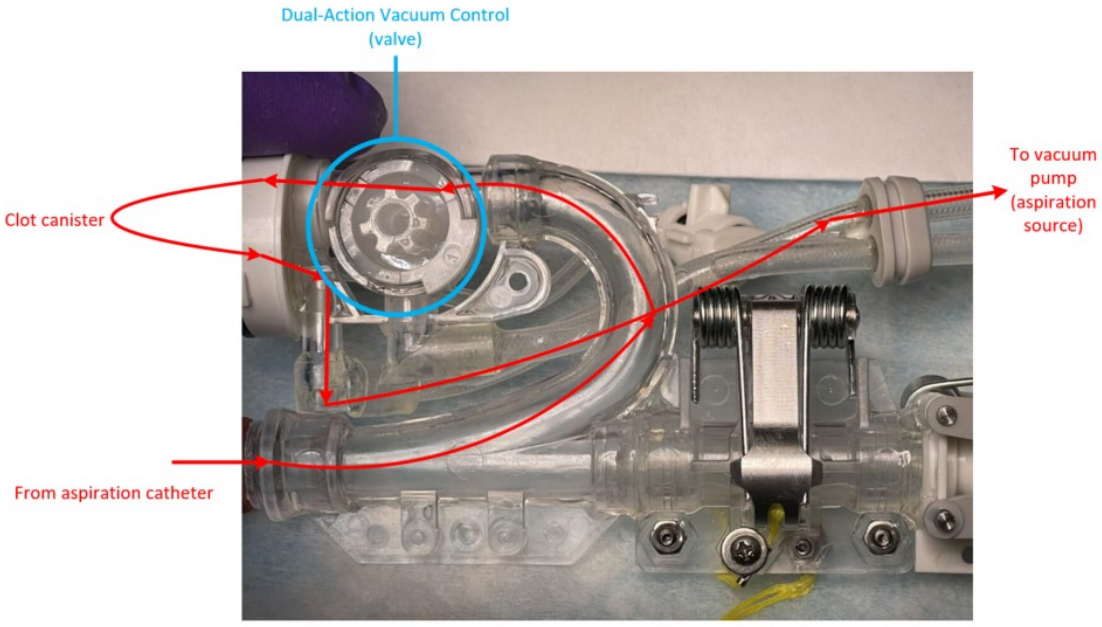
applying vacuum to the lumen of the 16F and/or 24F aspiration catheters:



(Annotated screen capture from Symphony product video.)

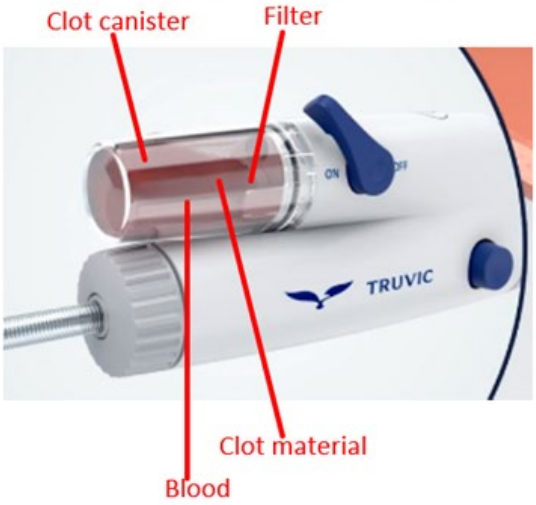


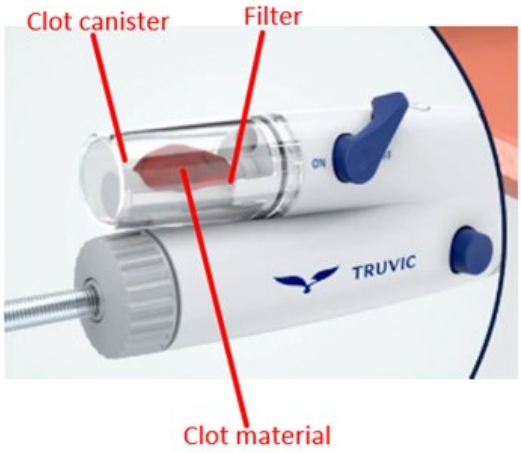
(Annotated image of Symphony housing (internal).)

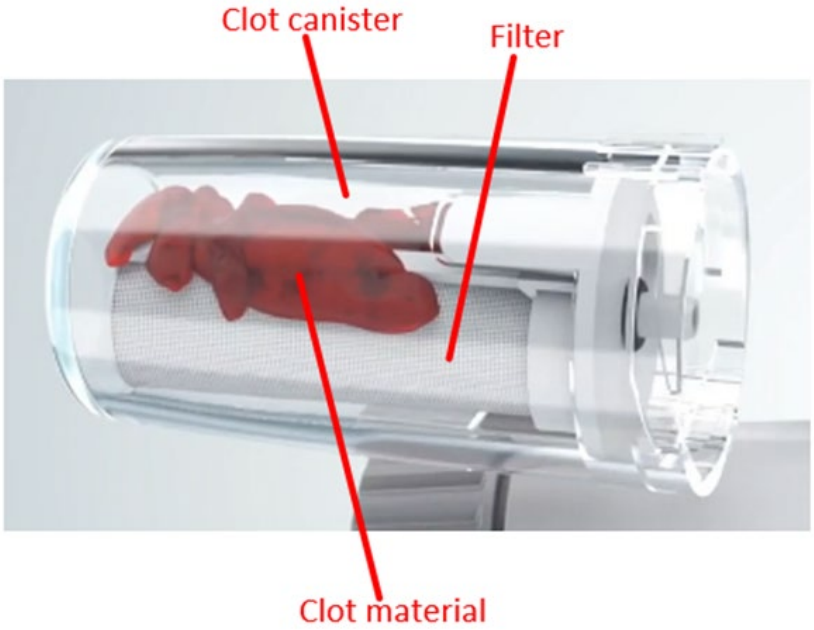


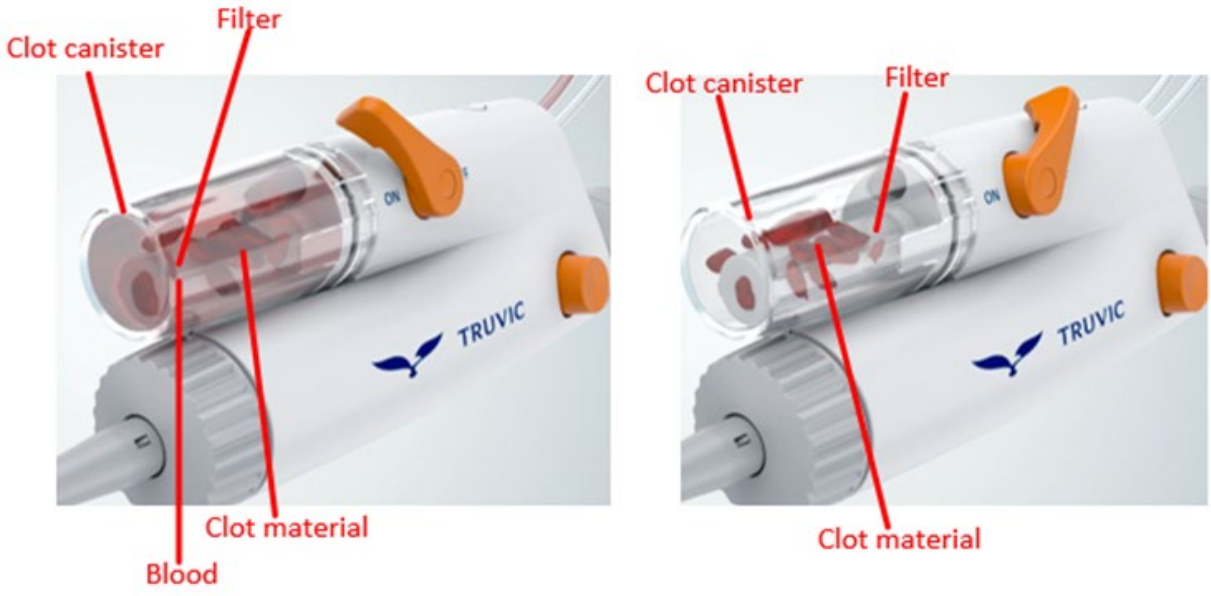
(Annotated image of internal portion of controller handle housing.)

103. ~~100.~~ Thrombectomy with the Symphony system practices the limitations of claim 20, including "wherein the clot canister includes a filter configured to filter the blood from the portion of the deep vein thrombosis," as can be seen in Exhibit N. Specifically, the clot canisters of the 24F and 16F handles have a filter that filters the blood from the aspirated portion of the clot material, such as a deep vein thrombosis. This allows the blood to pass through the canister, while the clot canister traps the clot material of a deep vein thrombosis.



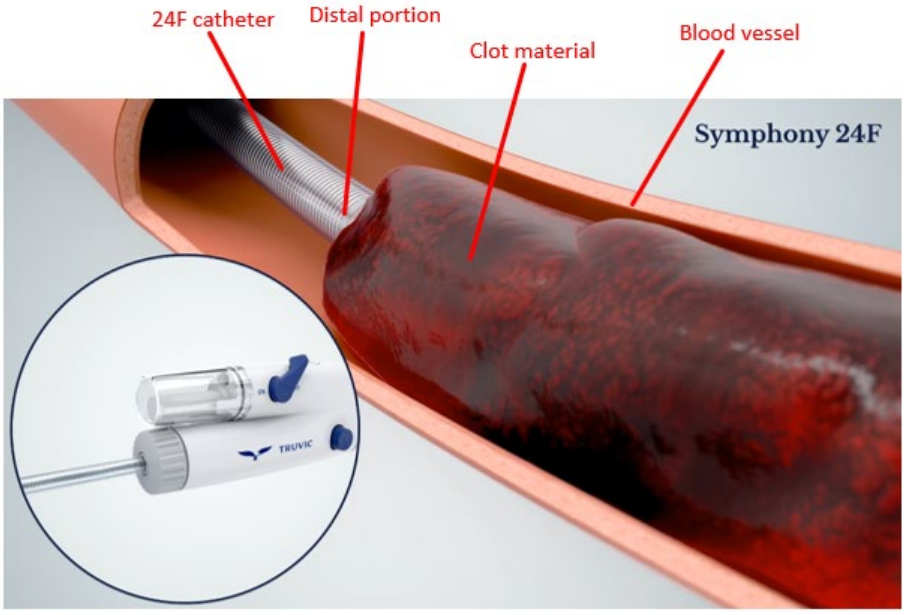






(Annotated screen captures from Symphony product video.)

104. ~~101.~~ Additionally, thrombectomy with the Symphony system practices claim 22 of the 11-'333 Patent, which recites "[t]he method of claim 20 wherein advancing the aspiration catheter comprises inserting a catheter having a size of 20 French or greater through the vasculature," as can be seen in the attached Exhibit N. The Symphony system includes a 24F catheter that is advanced into a patient's vasculature during thrombectomy procedures, including for deep vein thrombosis, as recited in claim 20 and analyzed above.



(Annotated screen capture from Symphony product video.)

105. ~~102.~~ Defendant directly infringes claims of the 11-'333 Patent, including claims 20 and 22, when Defendant or persons under its direction and control perform thrombectomy procedures on deep vein thromboses. For example, Defendant directly infringes claims 20 and 22 when testing or using the Symphony system in patients.

106. ~~103.~~ Defendant induces infringement of claims of the 11-'333 Patent, including claims 20 and 22, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems in a manner that practices the methods of claims 20 and 22. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures on deep vein thromboses with the Truvic Symphony system in a manner that practices the limitations of claims of the 11-'333 Patent, including claims 20 and 22. Defendant instructs and teaches users to perform methods that practice the limitations of claims 20 and 22 with knowledge and/or willful blindness that such acts constitute direct infringement of the 11-'333 Patent.

107. ~~104.~~ Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system in a manner that practices claims of the 11-'333 Patent, including claims 20 and 22. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including methods of treating deep vein thrombosis that practice the 11-'333 Patent.

108. ~~105.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of

the invention that is especially made or adapted for infringement of the claims of the 11-'333 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

109. ~~106.~~ Defendant's infringement is with knowledge of the 11-'333 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated April 24, 2024, that the claims of United States Patent Application No. 18/329,450 ("the '450 Application") were scheduled to issue shortly as the 11-'333 Patent and further provided notice that claims 42 and 44 of the '450 Application (renumbered as claims 20 and 22 of the 11-'333 Patent) read on the Symphony system and that Defendant would be infringing the 11-'333 Patent upon its issuance. Inari further attached the notice of allowance and the issue notification for the 11-'333 Patent.

110. ~~107.~~ At a minimum, Defendant has notice of the 11-'333 Patent through the filing of the original Complaint, which was submitted to the Court just a few weeks after the 11-'333 Patent issued.

111. ~~108.~~ Defendant has continued its infringing activities after the 11-'333 Patent issued, despite knowledge of the 11-'333 Patent (including knowledge from correspondence with Inari and from the original Complaint), and such infringement has been and continues to be egregious and willful.

112. ~~109.~~ The requirements of 35 U.S.C. § 287(a) have been met for the 11-'333 Patent. Because the 11-'333 Patent contains only method claims, no marking is required.

113. ~~110.~~ To the extent applicable, the requirements of 35 U.S.C. § 154(d) have been met for the allowed claims of the '450 Application from April 24, 2024, to the issuance of the 11-'333 Patent.

114. ~~111.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 3: INFRINGEMENT OF THE '005 PATENT

115. ~~112.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

116. ~~113.~~ The '005 Patent, titled "System for Treating Embolism and Associated

Devices and Methods," is part of the same family as the '910 and 11-'333 Patents, and shares the same specification. Similar to the '910 and 11-'333 Patents, the '005 Patent discloses improved clot-removing systems and methods that solve problems with prior art clot-removal devices. The '005 Patent solves these problems through its inventions that include, for example, a vacuum aspiration system comprising a flow path extending through a housing with an on-off control in the flow path, a catheter, and a clot canister fluidly coupled to the flow path, where the housing further includes an improved hemostasis valve that is configured to receive a second catheter and direct it through the first catheter. (Ex. E at cl. 1.)

117. ~~114.~~ Defendant directly infringes—literally and/or under the doctrine of equivalents—at least claim 10 of the '005 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

118. ~~115.~~ The Symphony system practices each limitation of at least claim 10 of the '005 Patent.

119. ~~116.~~ For example, claim 10 of the '005 Patent recites:

> [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.

120. ~~117.~~ To the extent the preamble of claim 10 is construed to be limiting, the Truvic Symphony system practices the preamble, a "vacuum aspiration system, comprising," as can be seen in the claim chart in Exhibit O. Specifically, the Symphony system is a vacuum aspiration system for treating clots: "The Symphony Thrombectomy System is designed to remove thrombus/embolus … from the vasculature using controlled aspiration." (Ex. B at 1.)

121. ~~118.~~ The Symphony system practices the limitations of claim 10, including "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," as can be seen in the claim chart in Exhibit O. The Symphony system includes controller handles (a housing), one for each of a 24F and 16F catheter:

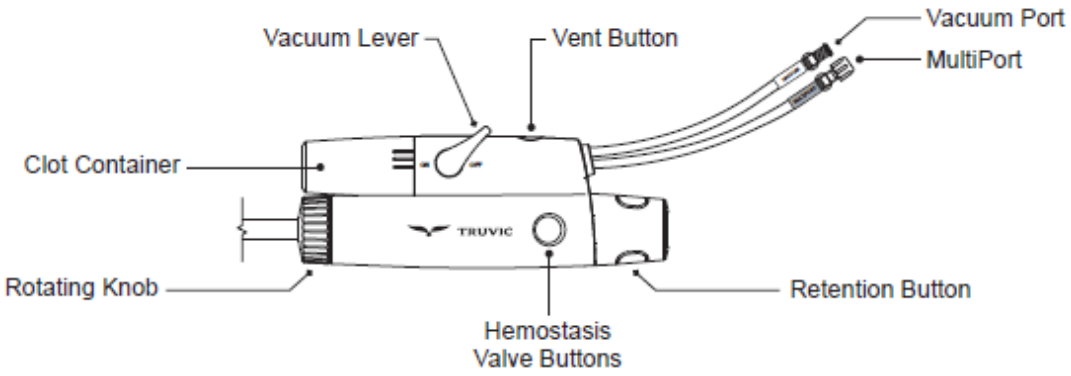
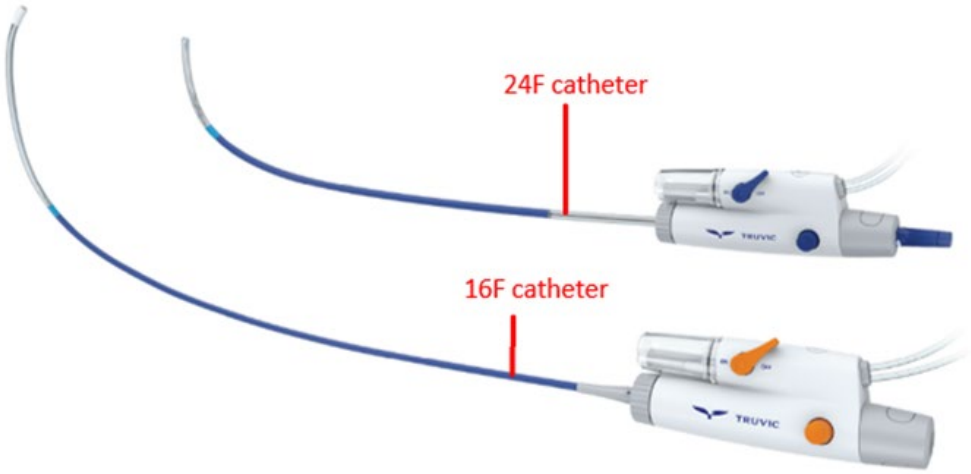


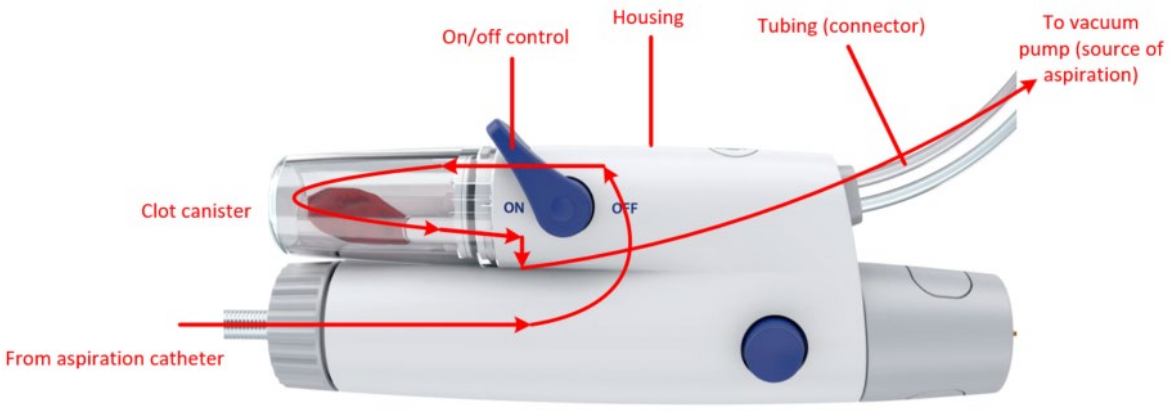
Figure 3: Symphony Catheter Handle, labeled

(Ex. B at 4.)



(Ex. A at 2 (annotations added).)

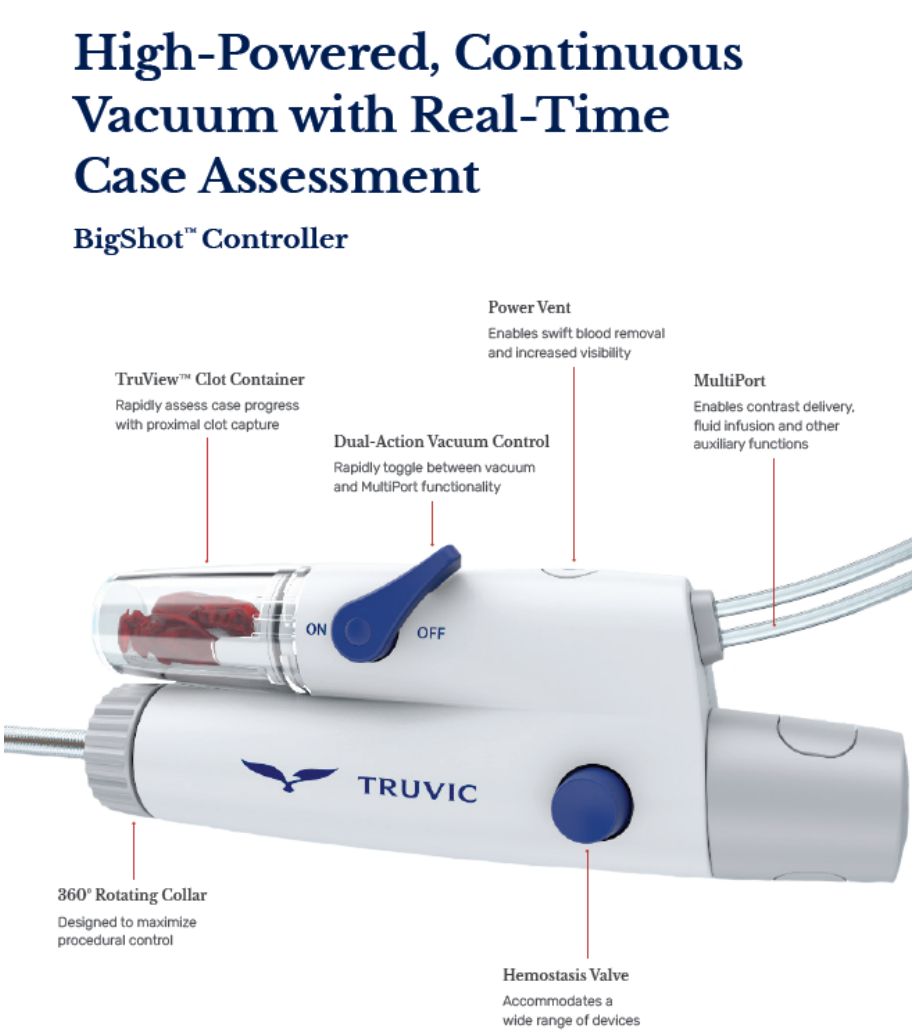
122. ~~119.~~ The Symphony handle (housing) includes a flow path through the handle extending from the catheter (in fluid communication with the flow path) through the housing, the on-off control valve, the clot canister, the tubing (connector) to the vacuum pump (source of aspiration) that fluidly connects the lumen of the 24F aspiration catheter (first catheter), the on-off control valve, the clot canister, the tubing (connector), and the vacuum pump (source of aspiration):



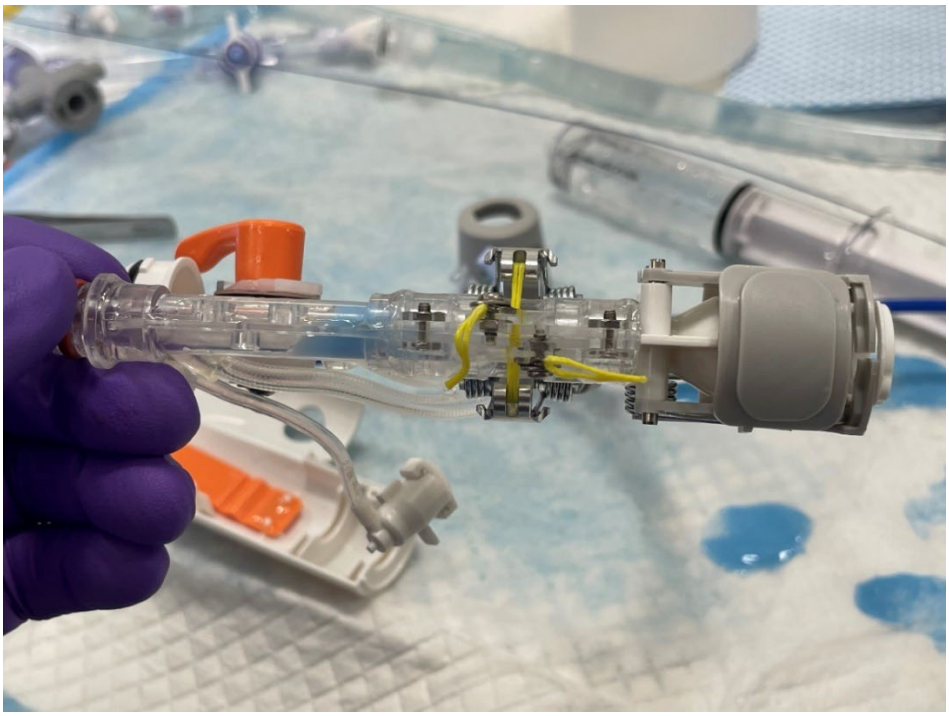
(Annotated diagram of Symphony housing with flow path.)

123. ~~120.~~ The Symphony system practices the limitations of claim 1, including "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" as can be seen in claim chart in Exhibit O. The Symphony system includes a controller handle with a hemostasis valve in the controller housing:

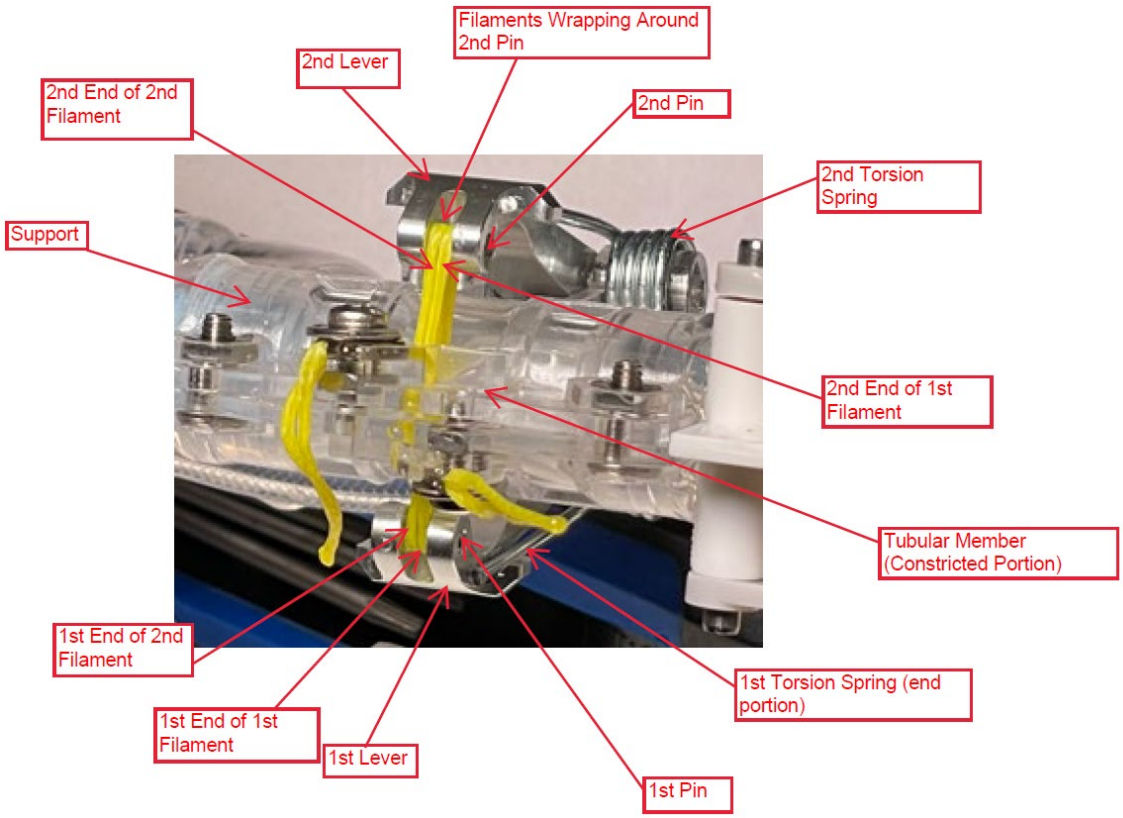


(Ex. A at 6.)



(Image of internal portion of housing with hemostasis valve.)

124. ~~121.~~ The Symphony system practices the limitations of claim 1, including "(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; (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," as can be seen in claim chart in Exhibit O. The hemostasis valve in each of the Symphony handles includes a plastic support. It also includes an actuator mechanism having a first member including a first button that pushes against a first lever and second member including a second button that pushes against a second lever, where the lever and buttons are biased outwardly by a first torsion spring(s) and a second torsion spring(s), and the valve has a lumen carried by a plastic support and that can be constricted by first and second filament lines looped around the lumen and wrapped around pins in the first lever and the second lever. This structure can be seen in the annotated picture of the Symphony system below:



(Annotated image of internal portion of Symphony housing, including hemostasis valve.)

125. ~~122.~~ The torsion springs drive the lever outward such that the pins of the levers tension the filament lines wrapped around the pins of the levers and wrapped in a loop around the tubular member (lumen) of the hemostasis valve to constrict the collapsible sidewall of the lumen by reducing the diameter of the filament loops around it.

126. ~~123.~~ Defendant directly infringes claims of the '005 Patent, including claim 10, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures) Symphony system products.

127. ~~124.~~ Defendant induces infringement of claims of the '005 Patent, including claim 10, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claims 10. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

128. ~~125.~~ Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof). Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

129. ~~126.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '005 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

130. ~~127.~~ Defendant's infringement is with knowledge of the '005 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated September 29, 2023, that the Symphony system might infringe the '005 Patent. Inari further explained, by letter dated April 24, 2024, that a teardown of the hemostasis valves in the Symphony system showed that they infringe Inari's patents.

131. ~~128.~~ At a minimum, Defendant has notice of the '005 Patent through the filing of the original Complaint.

132. ~~129.~~ Defendant has continued its infringing activities, despite knowledge of the '005 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

133. ~~130.~~ To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '005 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

134. ~~131.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 4: INFRINGEMENT OF THE '691 PATENT

135. ~~132.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

136. ~~133.~~ The '691 Patent, titled "System for Treating Embolism and Associated Devices and Methods," is part of the same family as the '910, 11-'333, and '005 Patents, and it shares the same specification. Similar to the '910, 11-'333, and '005 Patents, the '691 Patent discloses improved clot-removing systems and methods that solve problems with prior art clot-removal devices. The '691 Patent solves these problems through its inventions that include, for example, an aspiration system with accelerated response, comprising an aspiration pump coupled with a first chamber, an aspiration catheter in fluid communication in communication with the first chamber via an aspiration tube, further having a second chamber between the aspiration pump and the second chamber that is removable, and where the system has a user-actuatable valve between the second chamber and the aspiration catheter to connect or disconnect negative pressure, allowing pressure to build up in the first and second chambers before connecting negative pressure to the aspiration catheter to aspirate clot material. (*See* Ex. F at cl. 14.) Dependent claims further recite that the system is for treating deep vein thrombosis. (*Id.* at cl. 22.)

137. ~~134.~~ Defendant directly infringes—literally and/or under the doctrine of equivalents—at least claims 14 and 22 of the '691 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

138. ~~135.~~ The Symphony system practices each limitation of at least claims 14, 19, 20, and 22 of the '691 Patent.

139. ~~136.~~ For example, claim 14 of the '691 Patent recites:

> [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 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.

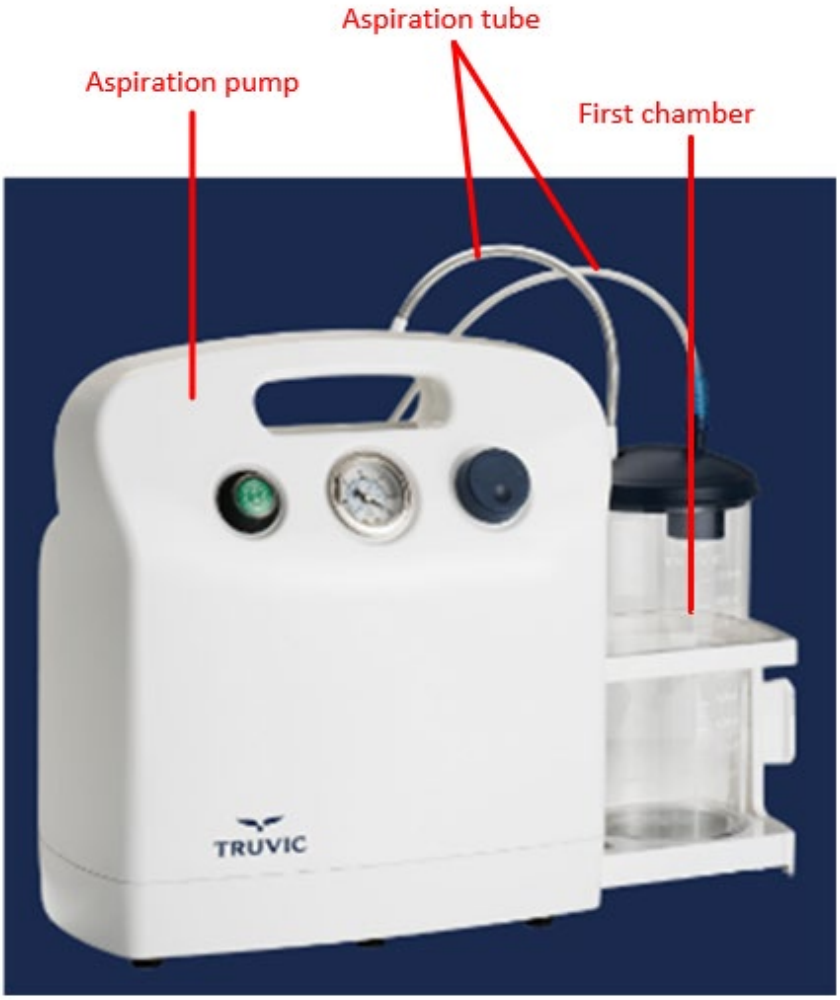
140. ~~137.~~ Claim 19 of the '691 Patent depends from claim 14 and further recites "[t]he aspiration system of claim 14 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient."

141. ~~138.~~ Claim 20 of the '691 Patent depends from claim 19 and further recites "[t]he 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."

142. ~~139.~~ Claim 22 of the '691 Patent depends from claim 20 and further recites "[t]he aspiration system of claim 20 wherein the clot material comprises a deep vein thrombus."

143. ~~140.~~ To the extent the preamble of claim 14 is construed to be limiting, the Truvic Symphony system practices the requirements of the preamble, "[a]n aspiration system with accelerated response, comprising," as can be seen in the claim chart in Exhibit P. Specifically, the Symphony system is a vacuum aspiration system with accelerated response used for treating clots: "[t]he Truvic Symphony Thrombectomy System employs "next generation thrombus removal" with "powerful, focused aspiration" for treating (*e.g.*, removing) clot material from within a blood vessel." (Ex. A at 2-4.).

144. ~~141.~~ The Symphony system practices the limitations of claim 14, including "an aspiration pump in communication with a first chamber," as can be seen in claim chart in Exhibit P. The Symphony system includes the Truvic Generator comprising a vacuum pump (aspiration pump), an aspiration tube, and a first vacuum chamber (the Truvic Canister):



(Annotated image of Truvic Generator.)

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

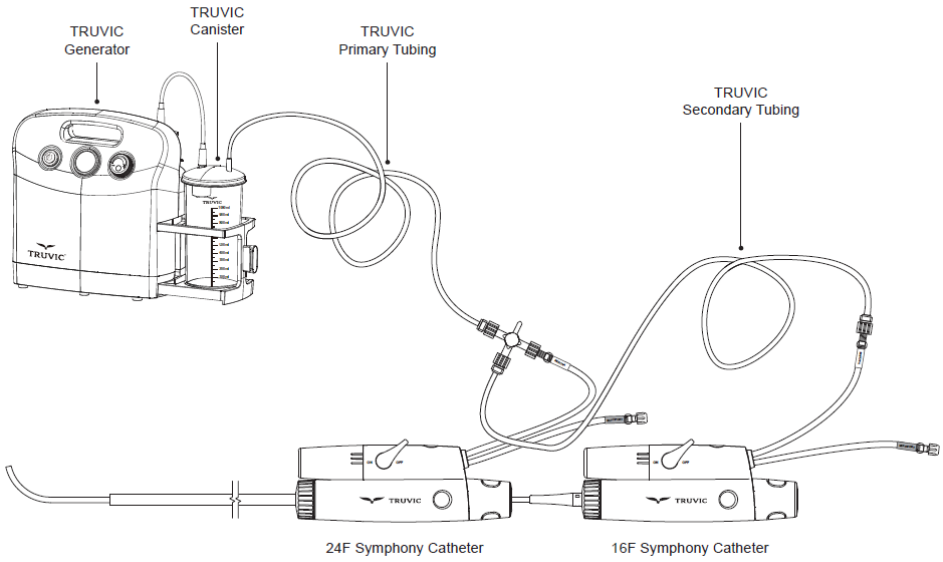
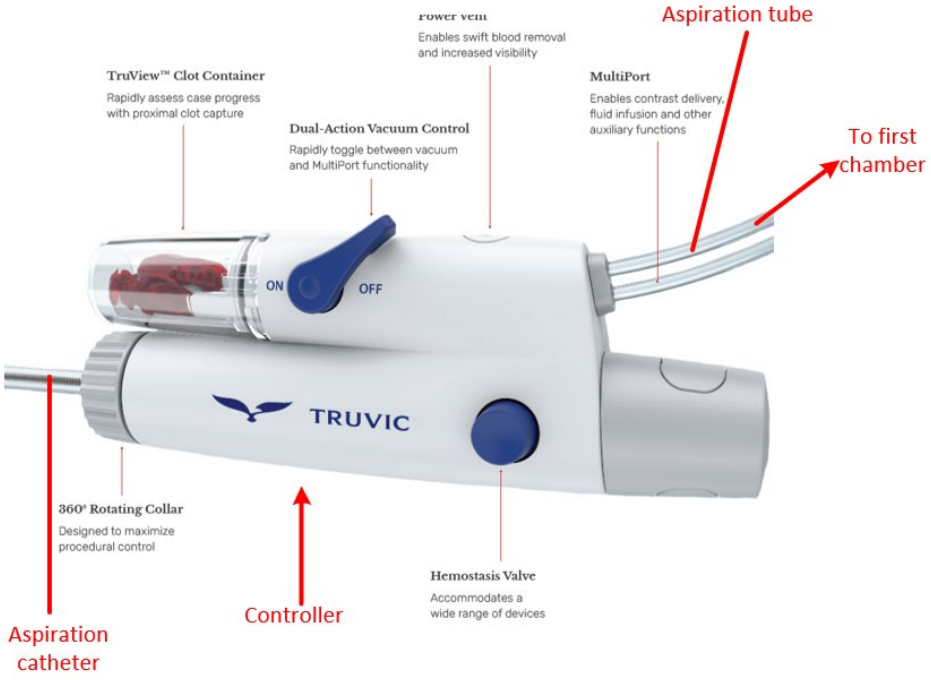


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

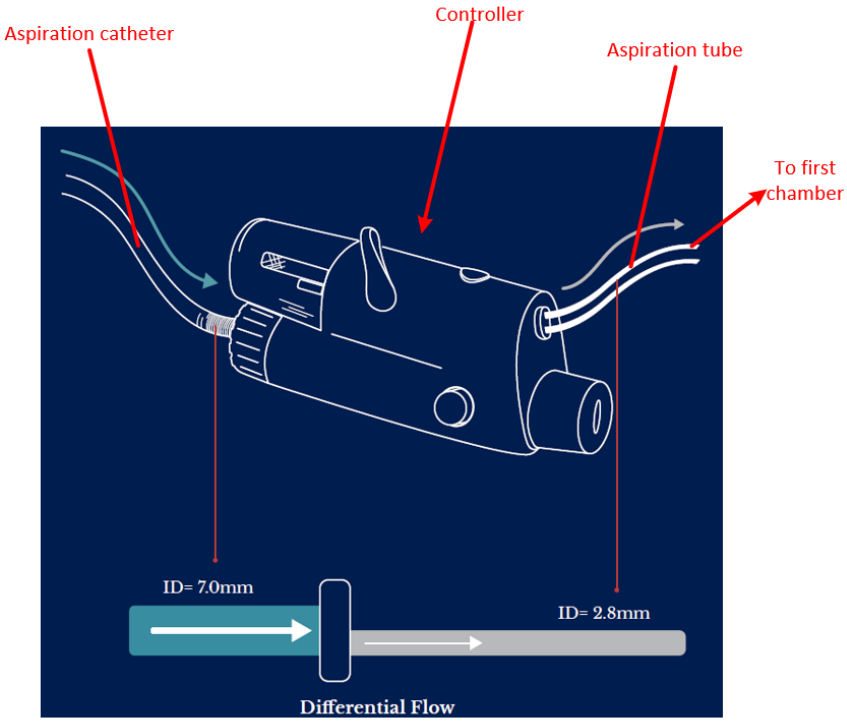
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

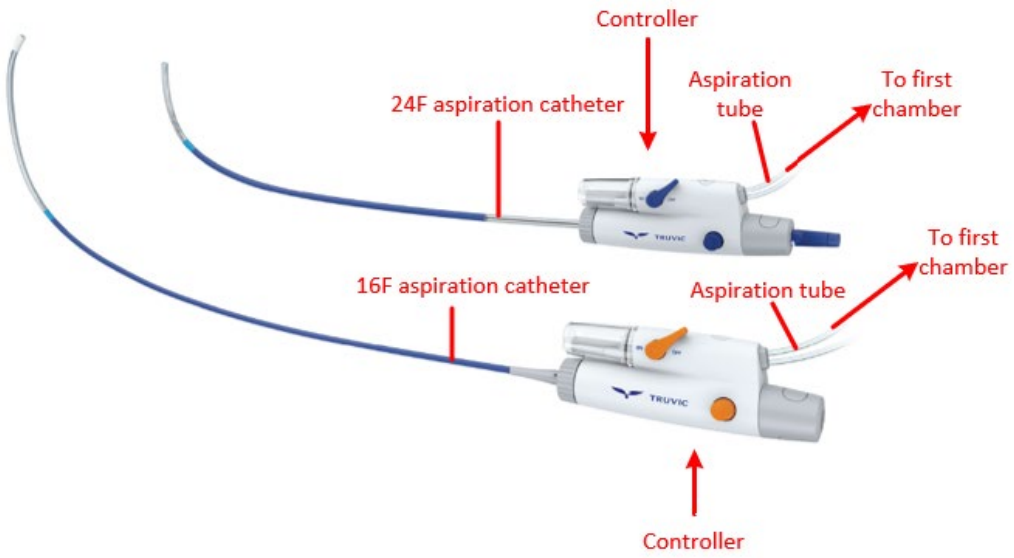
145. ~~142.~~ The Symphony system practices the limitations of claim 1, including "an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube," as can be seen in claim chart in Exhibit P. The Symphony system includes 24F and 16F catheters in fluid communication with the first chamber of the Truvic Generator through a controller handle by way of an aspiration tube:



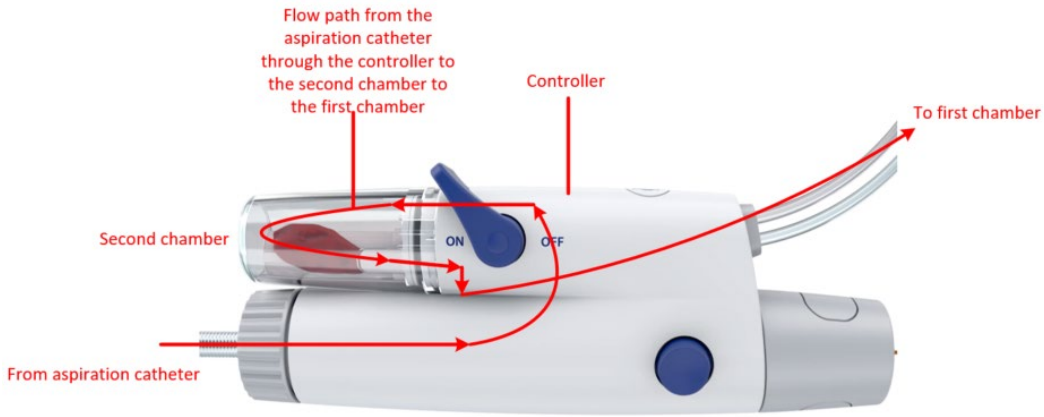
(Ex. A at 6 (annotations added).)



(Ex. A at 7 (annotations added).)

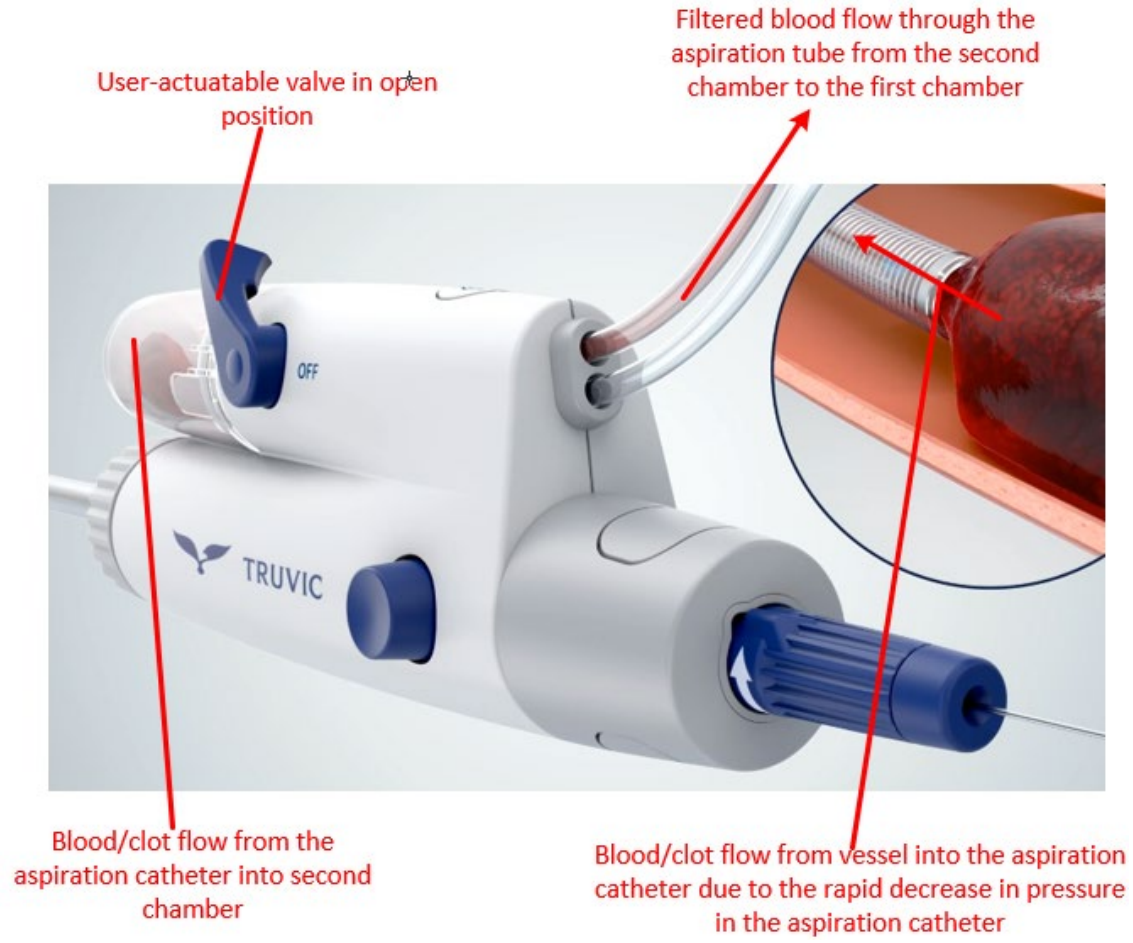


(Ex. A at 2 (annotations added).)

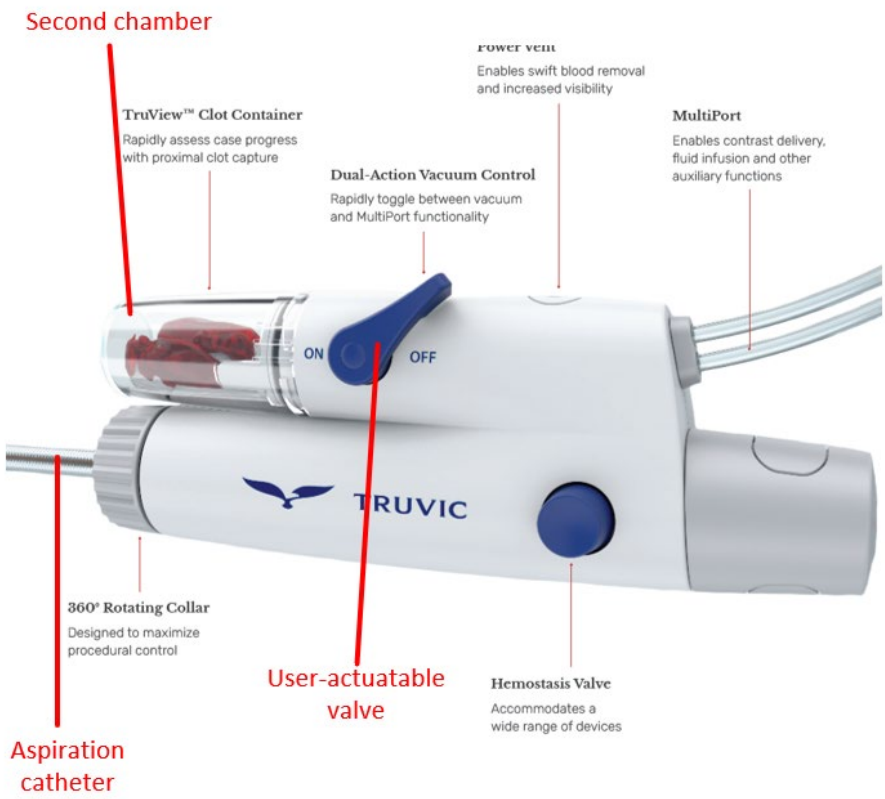


(Annotated diagram of Symphony housing with flow path.)

146. ~~143.~~ The Symphony system practices the limitations of claim 14, including "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," as can be seen in claim chart in Exhibit P. The Symphony system includes a second chamber on both the 24F and 16F handle controllers, as both have a clot canister that is a second chamber between the aspiration pump (Truvic Generator) and the aspiration catheter, with the clot canister being removable to clean the aspirated clot material filtered from blood:



(Annotated screen capture from Symphony product video.)

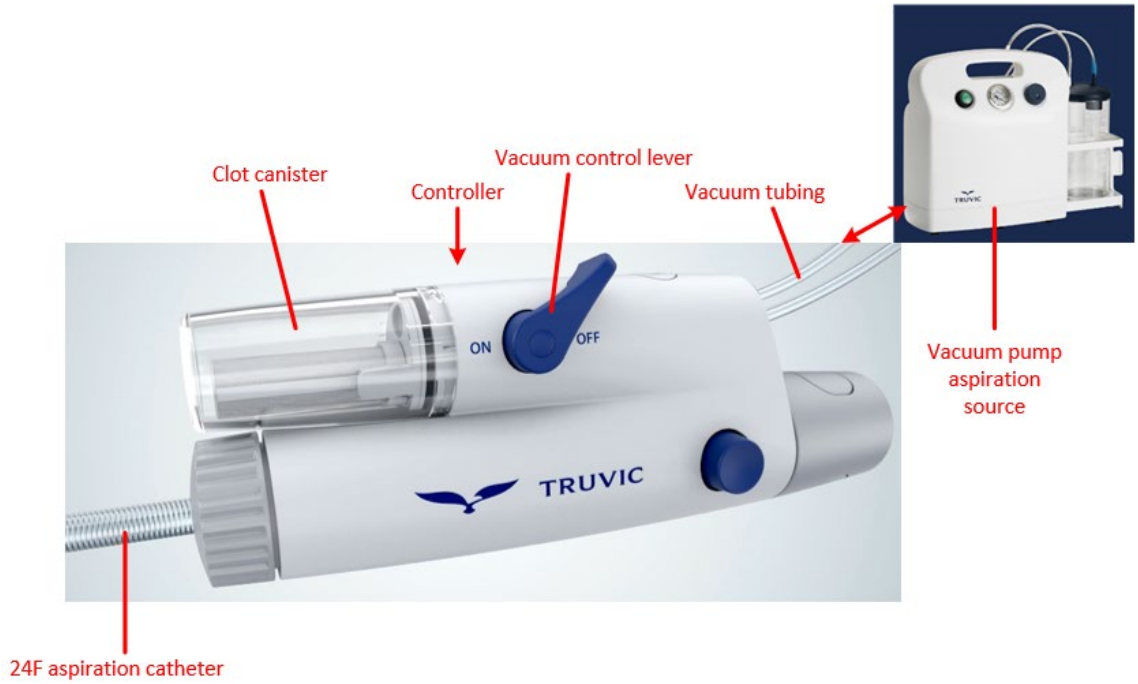


(Ex. A at 6 (annotations added).)

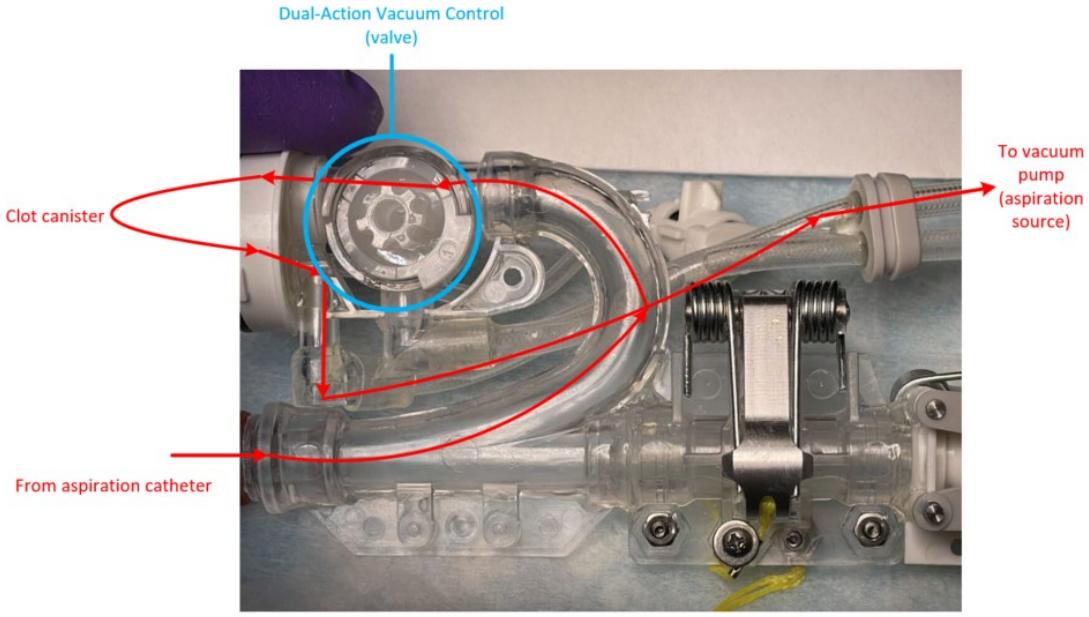
(Annotated screen captures from Symphony product video.)

147. ~~144.~~ The Symphony system practices the limitations of claim 14, including "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

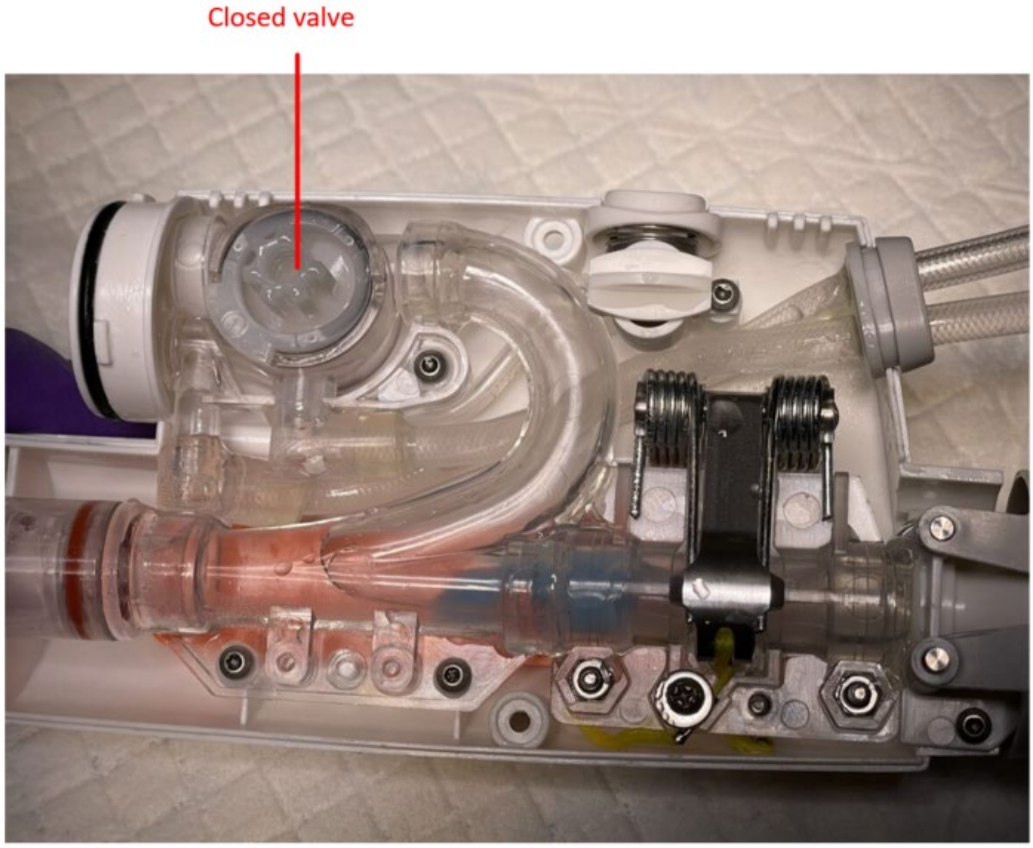
first and second chambers," as can be seen in claim chart in Exhibit P. The Symphony system includes a both the 24F and 16F handle controllers each having a user-actuatable valve in the controller that is controlled by the vacuum control lever on the handles, where negative pressure is generated in the Truvic Canister and the clot container by the Truvic Generator while the vacuum control lever valve is closed ("off"), and negative pressure is applied to the aspiration catheter when the valve is opened ("on"):



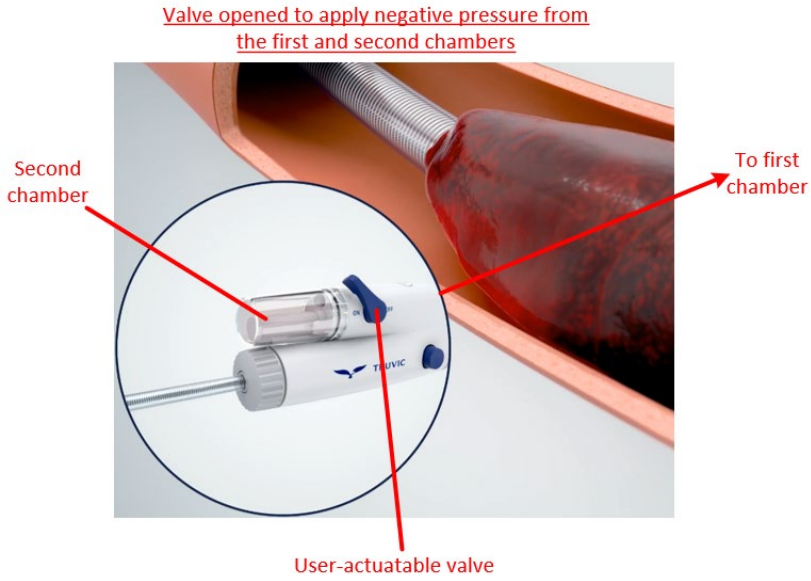
(Annotated diagram of Symphony system.)



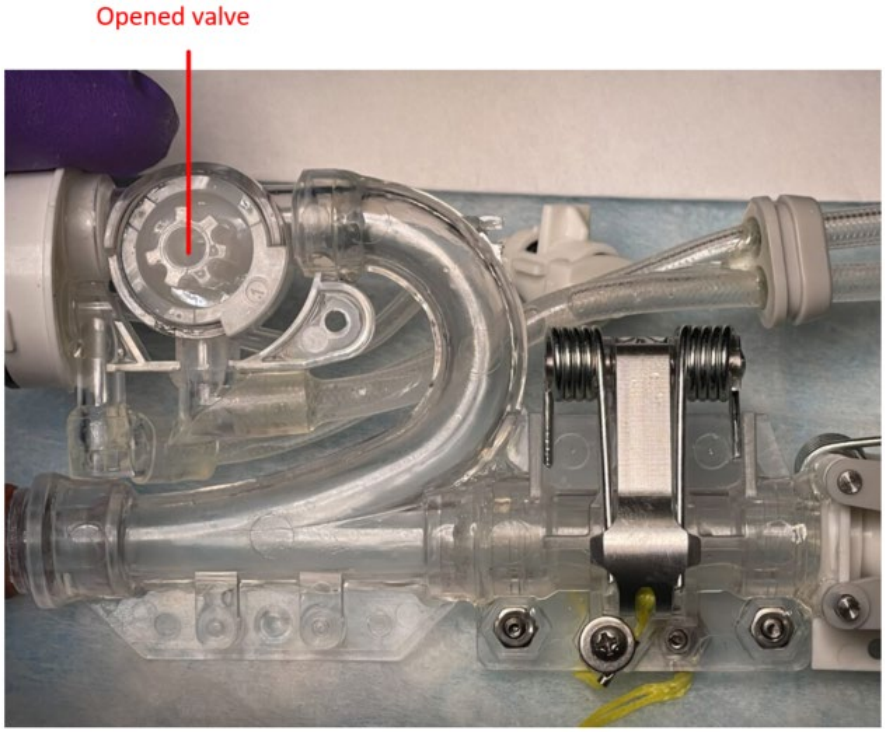
(Annotated image of internal portion of controller handle housing.)



(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)

148. ~~145.~~ The Truvic Symphony system Instructions For Use further teaches the process of building vacuum of at least -20 inHg using the Truvic Generator when the valve is in the closed (off) position and then moving the control letter to the open (on) position to apply negative pressure to the aspiration catheter:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

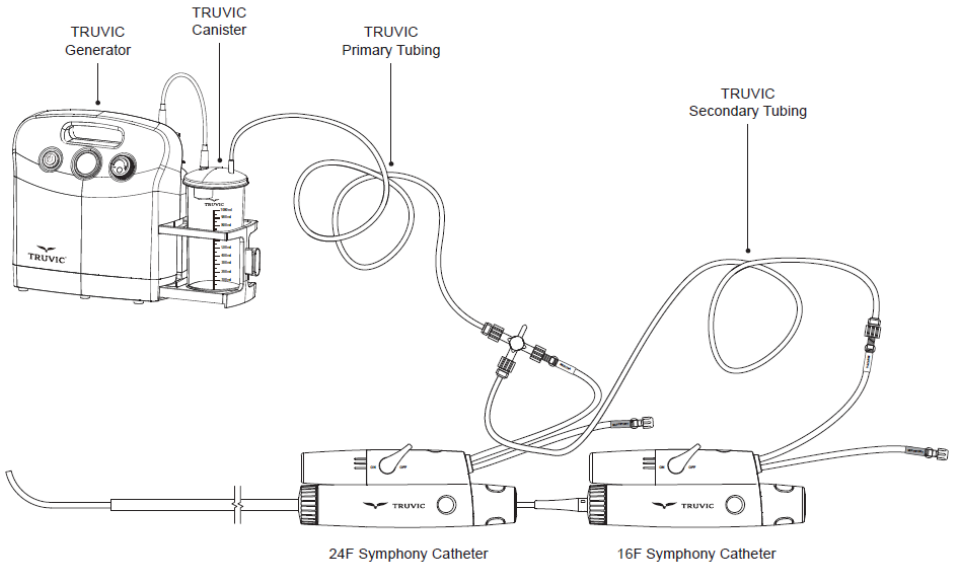


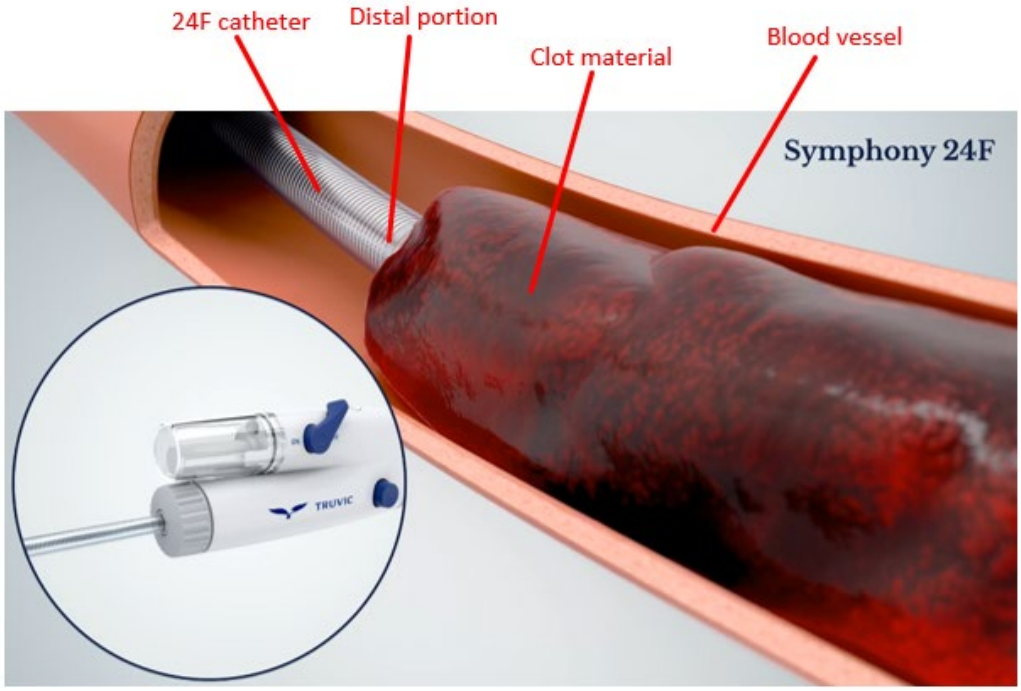
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

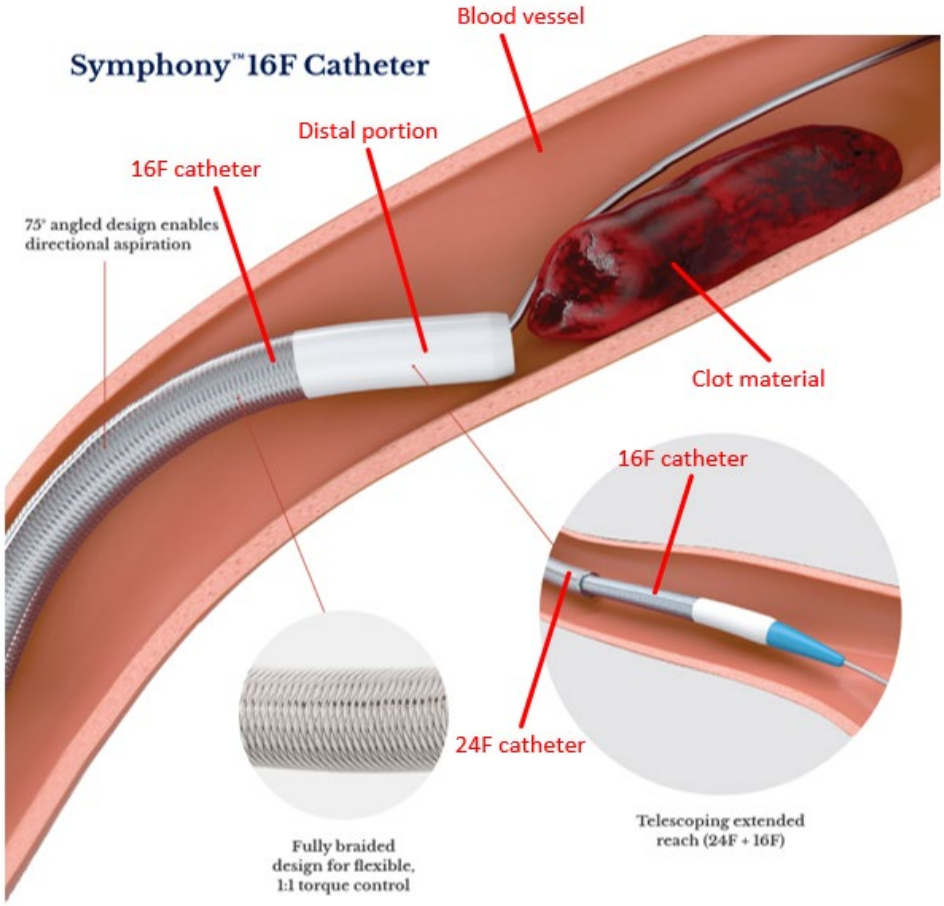
(Ex. B at 8.)

149. ~~146.~~ The Symphony system practices the limitations of claim 14, including "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," as can be seen in claim chart in Exhibit P. As discussed above, when the user actuates the vacuum control lever on the 24F or 16F handle of the Symphony system, the negative (vacuum) pressure generated in the first and second chambers is applied to the aspiration catheter, the fluid flow from the aspiration catheter to the first and second chambers causes a rapid decrease in the pressure in the aspiration catheter to aspirate clot material.

150. ~~147.~~ The Symphony system practices the limitations of claim 22, including claims 14, 19, and 20 (from which it depends), including "[t]he aspiration system of claim 14 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient" and "[t]he 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," as can be seen in claim chart in Exhibit P. The Symphony system includes 24F and 16F catheters that are configured to be positioned within a blood vessel with a distal end of the catheter positioned proximate to clot material within the blood vessel:



(Annotated screen capture from Symphony product video.)



(Ex. A at 4 (annotations added).)

151. ~~148.~~ The Symphony system practices the limitations of claim 22, including claims 14, 19, and 20 (from which it depends), including "[t]he aspiration system of claim 20 wherein the clot material comprises a deep vein thrombus," as can be seen in claim chart in Exhibit P. As discussed above with respect to claim 20 of the '691 Patent, the Symphony system is a treatment system used for fresh soft emboli in the peripheral vasculature of a patient, *e.g.*, for treating DVT.

152. ~~149.~~ Defendant directly infringes claims of the '691 Patent, including claims 14 and 22, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures) Symphony system products.

153. ~~150.~~ Defendant induces infringement of claims of the '691 Patent, including

claims 14 and 22, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claims 14 and 22. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

154. ~~151.~~ Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof). Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

155. ~~152.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '691 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

156. ~~153.~~ Defendant's infringement is with knowledge of the '691 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated September 29, 2023, that the Symphony system infringes the '691 Patent. Inari further explained to Defendant, by letter dated April 24, 2024, that the Symphony system infringes various claims of the '691 Patent, including claim 22 directed to deep vein thrombosis (DVT) treatment systems.

157. ~~154.~~ At a minimum, Defendant has notice of the '691 Patent through the filing of

the original Complaint, which was submitted to the Court just a few weeks after the '691 Patent issued.

158. ~~155.~~ Defendant has continued its infringing activities, despite knowledge of the '691 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

159. ~~156.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 5: INFRINGEMENT OF THE '921 PATENT

160. ~~157.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

161. ~~158.~~ The '921 Patent, titled "Hemostasis Valves and Methods of Use," discloses improved hemostasis valves and methods of their use. (*See, e.g.*, Ex. G at Abstract, 1:58-62.) Hemostasis valves are used to seal, e.g., to seal around catheters, in order to minimize blood loss, and maintain sterility within the body, such as in a blood vessel. (*Id.* at 1:28-44.) This is critical during surgical procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (*See id.* at 1:18-26.) Improved hemostasis valves are important to maximize patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and practitioners and effective sealing. (*See id.* at 1:45-54, 5:49-67.)

162. ~~159.~~ The '921 Patent discloses hemostasis valves having an internal elongate member with a lumen (an inner cavity through which something can be inserted), which can be constricted and sealed by a filament wrapped at least partially around, *e.g.*, in a loop around, the tube defining a lumen, where the hemostasis valve further has an actuator (such as a button control mechanism) biased to constrict the elongate member's lumen with the filament and that can be moved between a first position where the lumen is constricted (closing the valve) and to a second position where the lumen is not as constricted (at least partially opening the valve). (*See id.* at cl. 1, Fig. 7, 2:8-25.) Some embodiments disclosed by the '921 Patent have multiple actuators and/or two or more filaments looping at least partially around the elongate member.

(*See id.* at cl. 1, cl. 10.)

163. ~~160.~~ Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claims 1 and 10 of the '921 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

164. ~~161.~~ The hemostasis valve in the controller handles (housings) of the Symphony system practice each limitation of at least claims 1 and 10 of the '921 Patent.

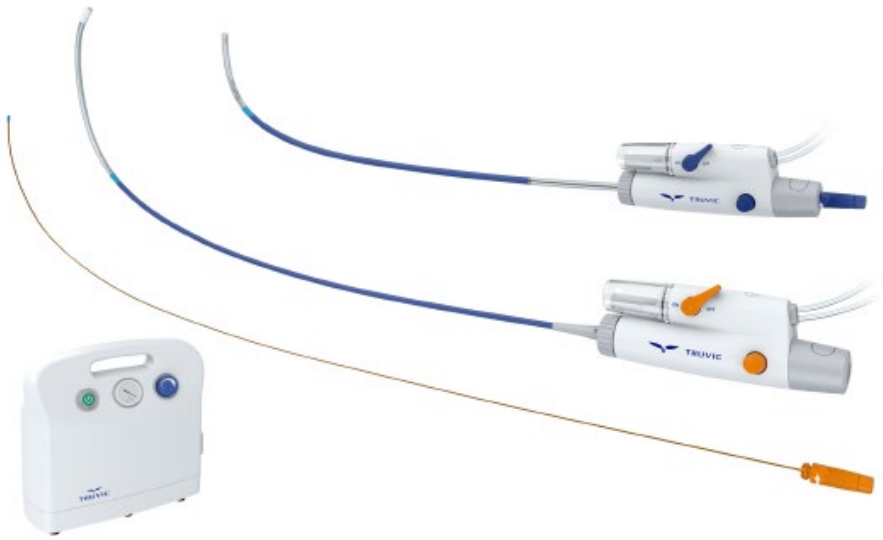
165. ~~162.~~ For example, claim 1 of the '921 Patent recites:

> [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.

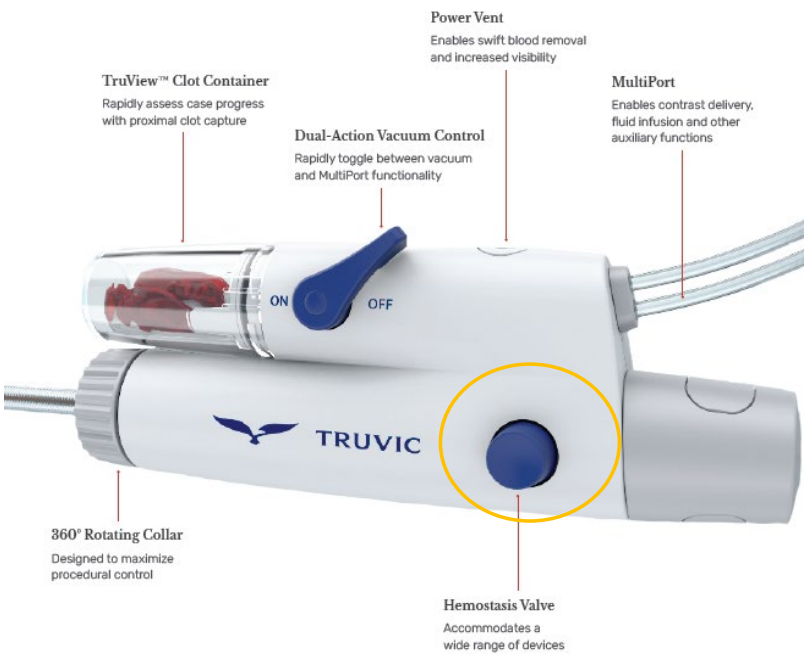
166. ~~163.~~ Claim 10 of the '921 Patent further recites:

> [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.

167. ~~164.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including the preamble, "[a] valve, comprising," as can be seen in Exhibit Q. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle). The documentation for the Symphony system makes clear that the controller handles have a hemostasis valve, controlled by the buttons on the handles, as can be seen in the excerpts and the teardown photos below.



(Ex. A at 2.)

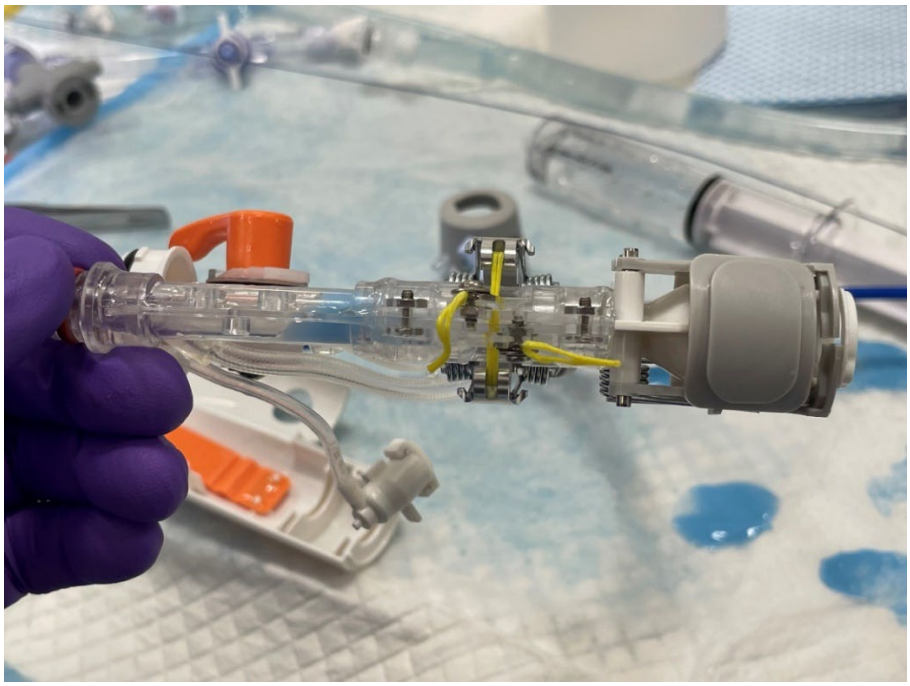


(Annotated Ex. A at 6.)

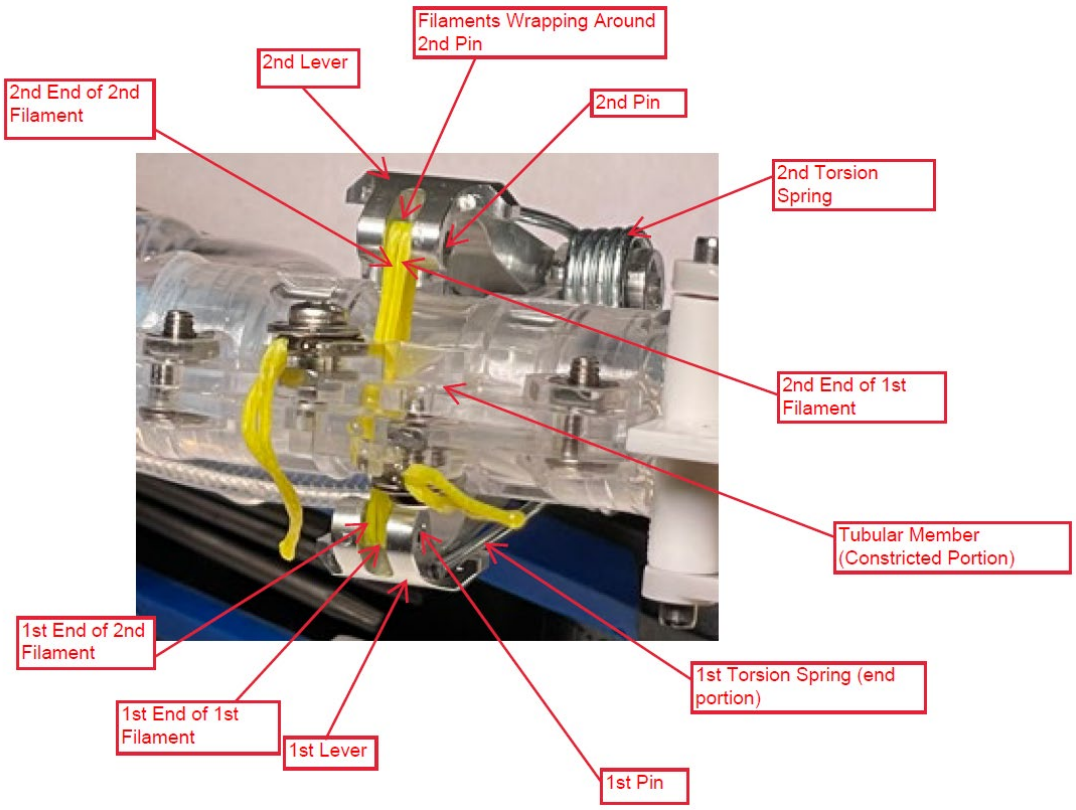
(Image of internal portion of housing with hemostasis valve.)

(Image of internal portion of housing zoomed in on hemostasis valve.)

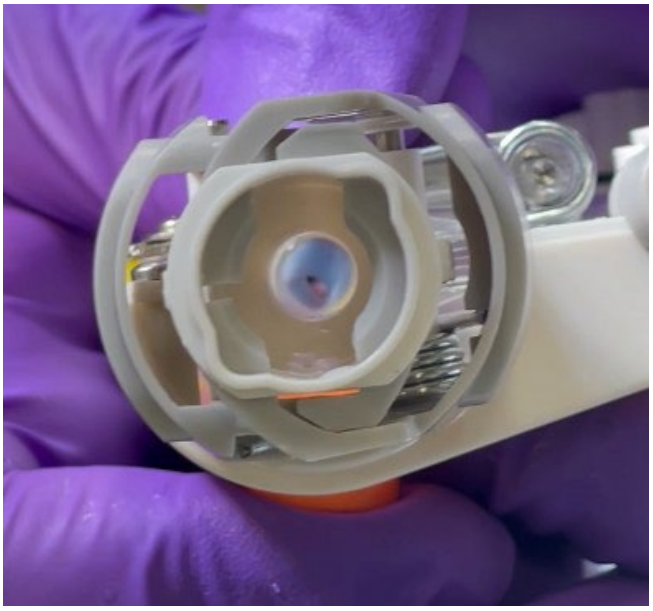
168. ~~165.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including "an elongate member defining a lumen," as can be seen in Exhibit Q. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle) that include an elongate member that defines a lumen.



(Image of internal portion of housing with hemostasis valve.)

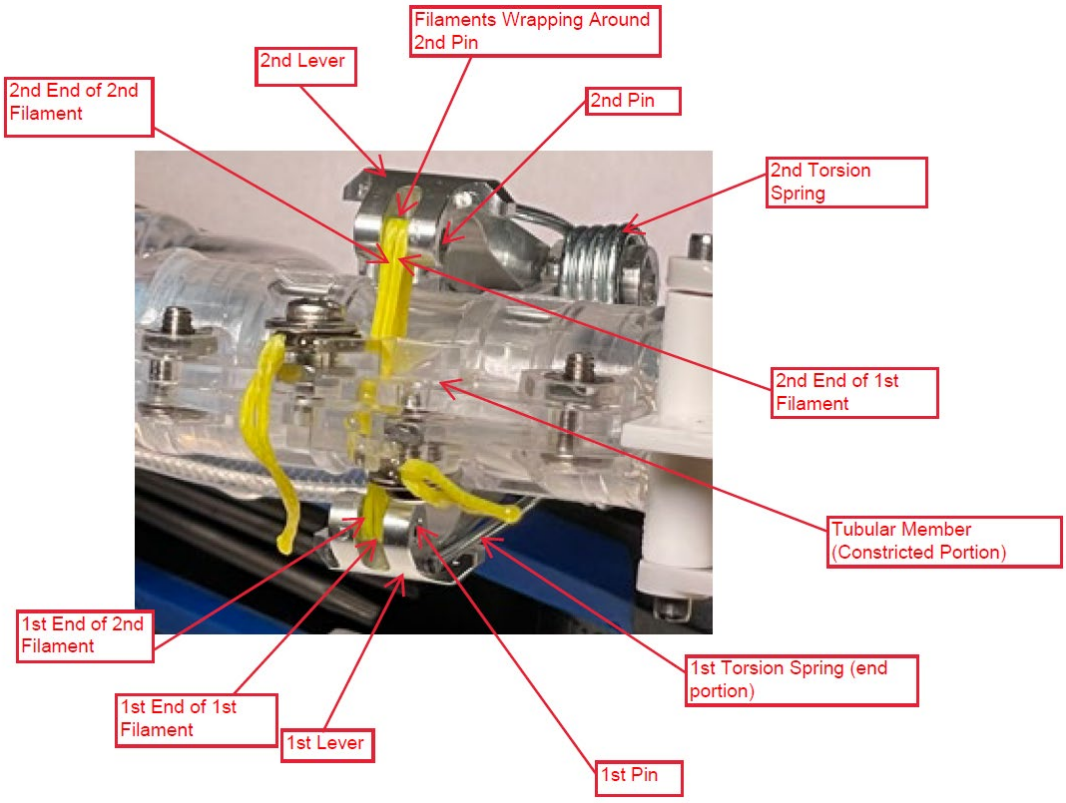


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



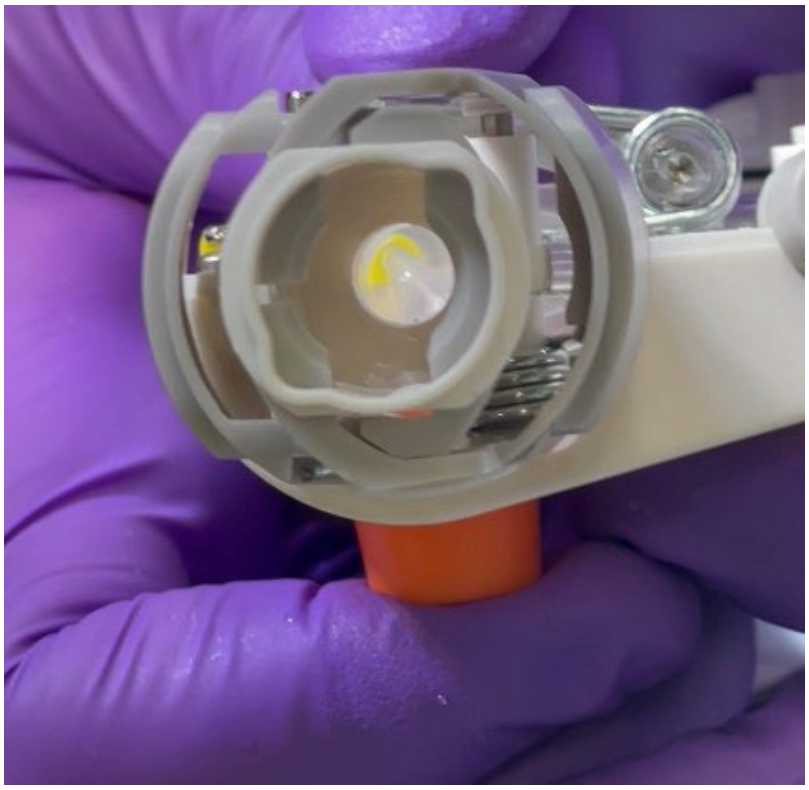
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

169. ~~166.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including "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," as can be seen in Exhibit Q. Specifically, the controller handles of the Symphony system include a hemostasis valve with an active tensioning mechanism where a first and second button control first and second levers and first and second pins coupled to lines (filaments) that loop around the valve's elongate tubular member defining a lumen. The first button/lever/pin to which the first end of the filament line is coupled moves between a first (undepressed button) position where the lumen of the valve is constricted to a second (depressed button) position wherein the lumen is less constricted and at least partially open.

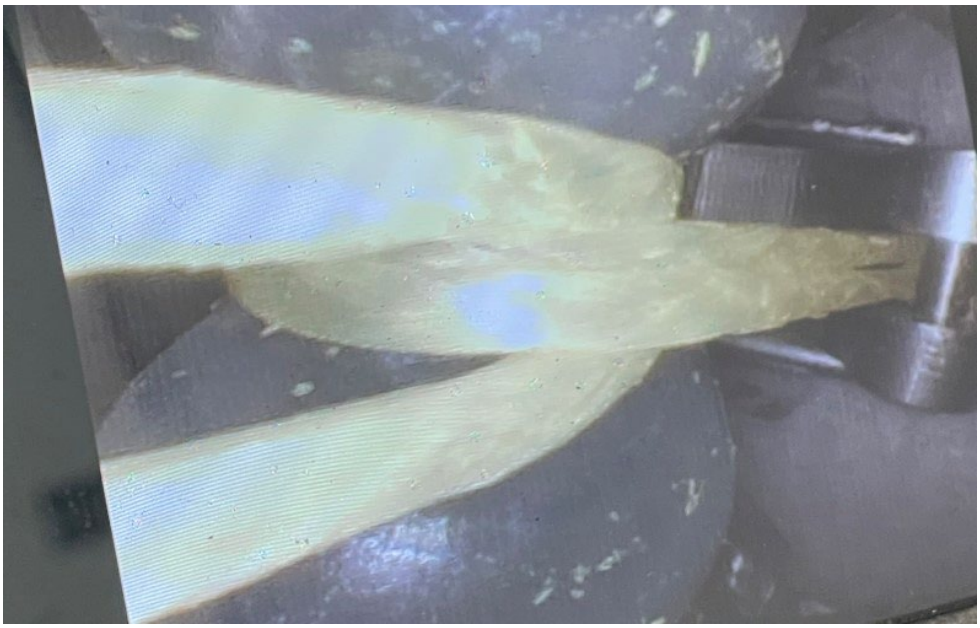


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

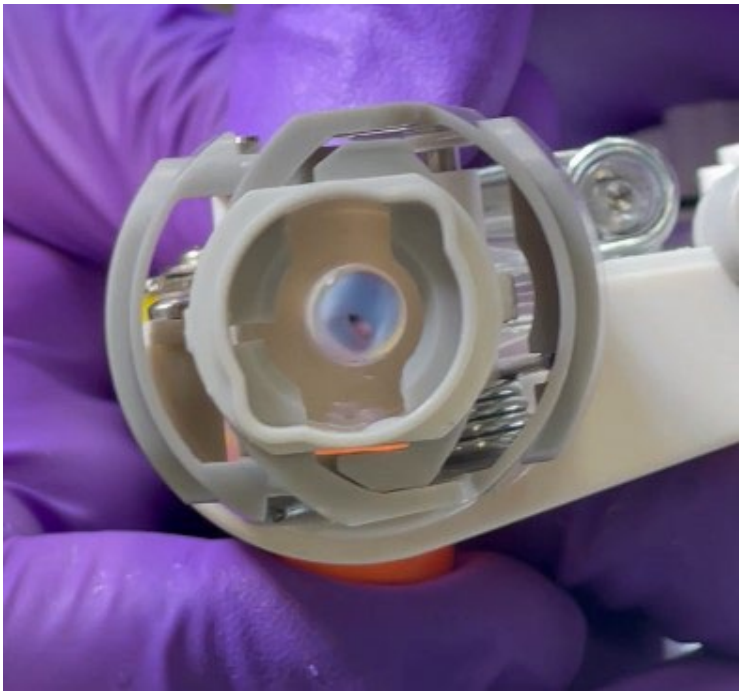
170. ~~167.~~ In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring(s), releasing tension on the filaments wrapped around the lever pin(s), which decreases the constriction on the lumen of the hemostasis valve. This allows the valve to at least partially open, permitting the introduction of a catheter or other tool through the hemostasis valve. Releasing the button(s), causes the torsion spring(s) to drive the lever outward, increasing tension on the filament lines, sealing the hemostasis valve.



(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



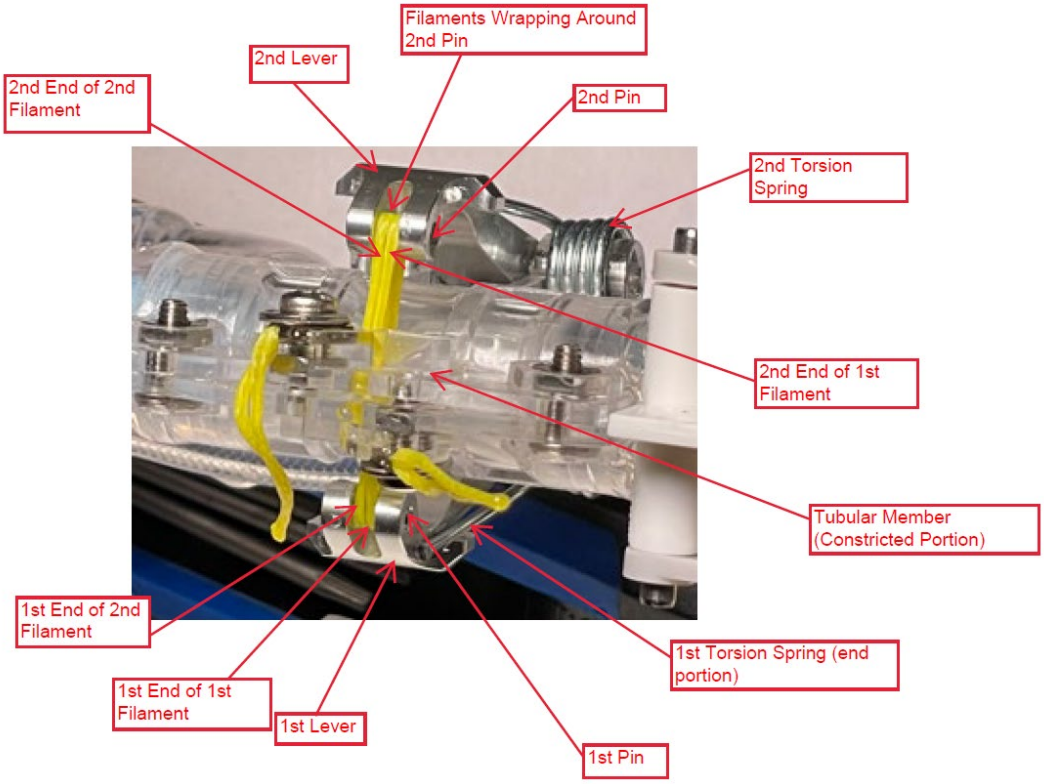
(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)



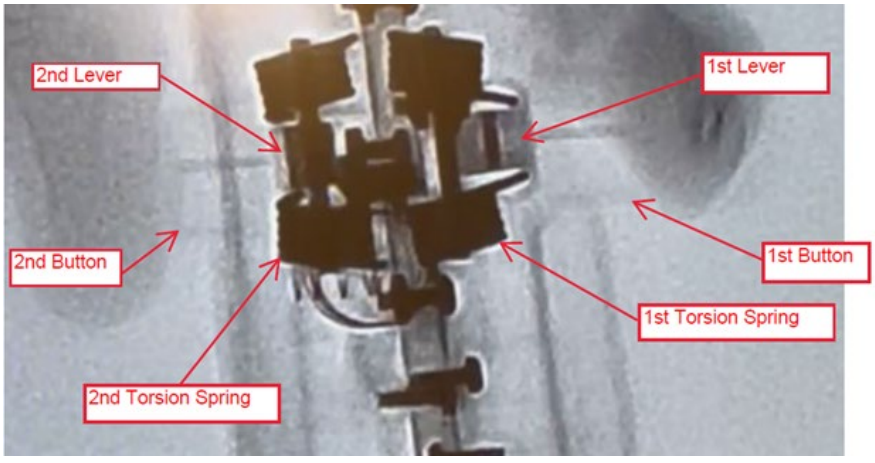
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

171. ~~168.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a biasing member configured to bias the actuator to the first position." as can

be seen in Exhibit Q. The hemostasis valves of the Symphony handles include a first torsion spring(s) that pushes against the first lever, biasing the actuator to a first position (closed/constricted with an undepressed first button). There are two torsion springs for each of the first lever and the second lever.



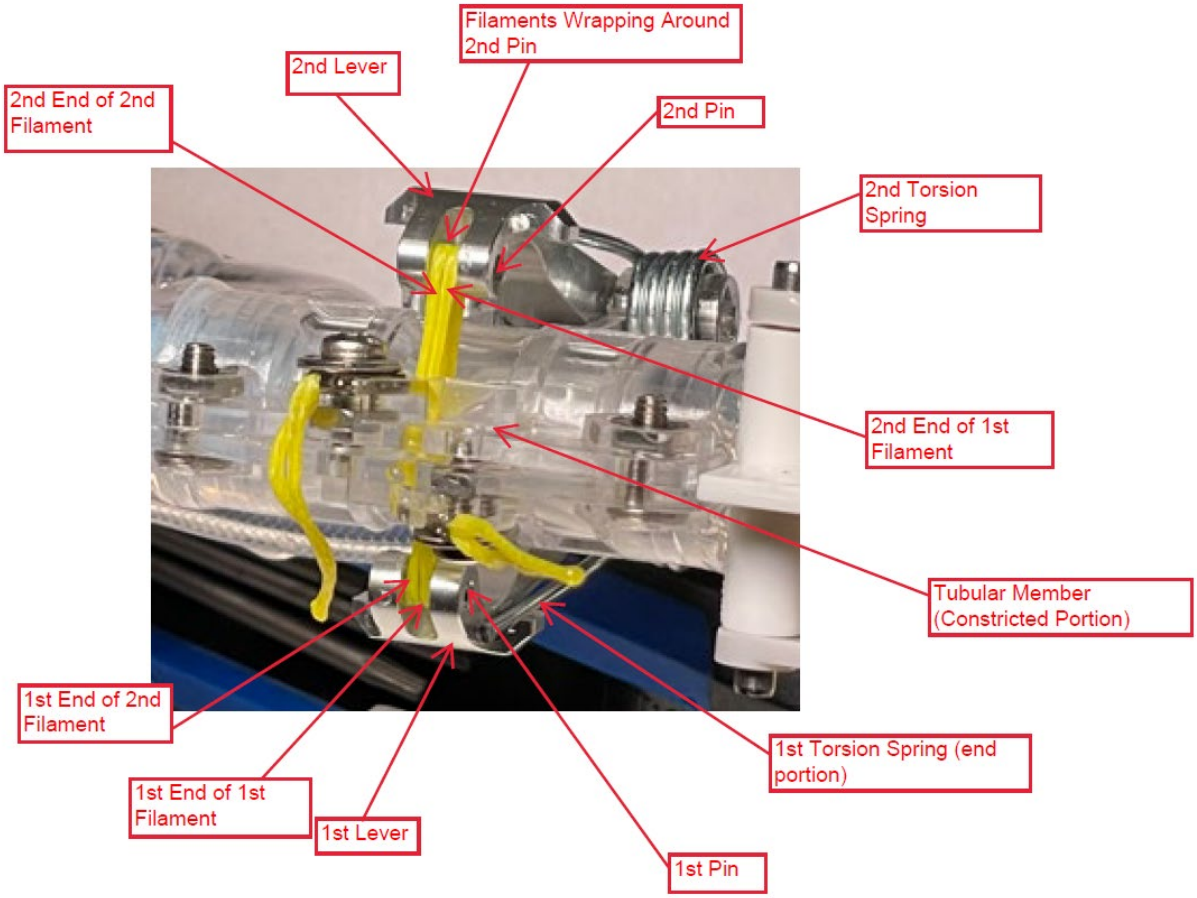
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



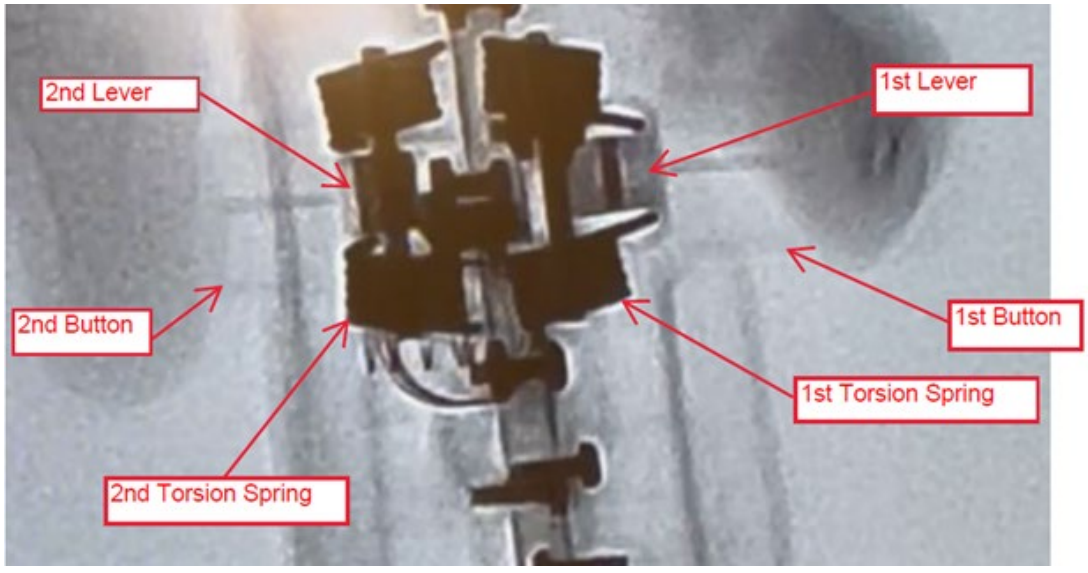
(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs.)

172. ~~169.~~ The hemostasis valves of the Symphony system practice the requirements of claim 10, including "[t]he 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:" as can be seen in Exhibit Q. The hemostasis valves of the Symphony system comprise a first actuator, as alleged above for claim 1.

173. ~~170.~~ The hemostasis valves of the Symphony system practice the requirements of claim 10, including "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," as can be seen in Exhibit Q. In addition to the first actuator, the controller handles of the Symphony system include a second actuator where a second button that controls a second lever coupled to lines (filaments) that loop around the valve's elongate tubular member defining a lumen. The second button/lever/pin to which the second end of the second filament line is coupled moves between a first (undepressed button) position where the lumen of the lumen is constricted to a second (depressed button) position wherein the lumen is less constricted and at least partially open.



(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Annoatated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs.)

174. ~~171.~~ The hemostasis valves of the Symphony system practice the requirements of claim 10, including "a second biasing member configured to bias the second actuator to the first position," as can be seen in Exhibit Q. As with the first actuator, the Symphony system's hemostasis valve also includes a second torsion spring(s) that pushes against the second lever, biasing the actuator to a first position (closed/constricted with an undepressed first button), as can be seen above. There are two springs for each lever.

175. ~~172.~~ Defendant directly infringes claims of the '921 Patent, including claims 1 and 10, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures utilizing the hemostasis valves) Symphony system products.

176. ~~173.~~ Defendant induces infringement of claims of the '921 Patent, including claims 1 and 10, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claims 1 and 10. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

177. ~~174.~~ Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system,

including on information and belief, methods of treating thrombi and emboli.

178. ~~175.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof) of the invention that is especially made or adapted for infringement of the claims of the '921 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

179. ~~176.~~ Defendant has knowledge of the '921 Patent and its claims. Specifically, Inari notified Defendant that the Symphony system infringes the '921 Patent, including claims 1 and 10, by letter dated April 24, 2024. Even more specifically, Inari explained that a teardown of the hemostasis valves in the Symphony system showed that they infringe Inari's patents, including claims 1 and 10 of the '921 Patent.

180. ~~177.~~ At a minimum, Defendant has notice of the '921 Patent through the filing of the original Complaint.

181. ~~178.~~ Defendant has continued its infringing activities, despite knowledge of the '921 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

182. ~~179.~~ To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '921 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

183. ~~180.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 6: INFRINGEMENT OF THE '012 PATENT

184. ~~181.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

185. ~~182.~~ The '012 Patent, titled "Hemostasis Valves and Methods of Use," is part of the same family as the '921 Patent, and it shares the same specification. The '012 Patent discloses improved hemostasis valves and methods of their use. (*See, e.g.*, Ex. H at Abstract, 1:64-2:5.) Hemostasis valves are used to seal, e.g., to seal around catheters, in order to minimize

blood loss, and maintain sterility within the body, such as in a blood vessel. (*Id.* at 1:35-51.) This is critical during surgical procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (*See id.* at 1:24-32.) Improved hemostasis valves are important to maximize patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and practitioners and effective sealing. (*See id.* at 1:51-60, 5:55-6:6.)

186. ~~183.~~ The '012 Patent discloses hemostasis valves as part of aspiration catheter systems, the catheters having an elongate flexible tube with a central lumen (an inner cavity through which something can be inserted) with a hemostasis valve on the proximal end of the catheter that includes a collapsible sidewall defining a valve lumen coupled to the central lumen of the catheter, and where the hemostasis valve has a constricting mechanism that includes an first actuator coupled to a first filament that is looped around the tubular sidewall of the valve lumen and further includes a spring that moves the actuator in a direction to pull the end portion of the filament to tighten the filament loop and constrict the lumen. (*See id.* at cl. 1, Fig. 7, 2:15-32.) Some embodiments disclosed by the '012 Patent have multiple actuators, *i.e.*, a first actuator comprising a first button and a second actuator comprising a second button. (*See id.* at cl. 1, cl. 2, cl. 4.)

187. ~~184.~~ Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claim 1 of the '012 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

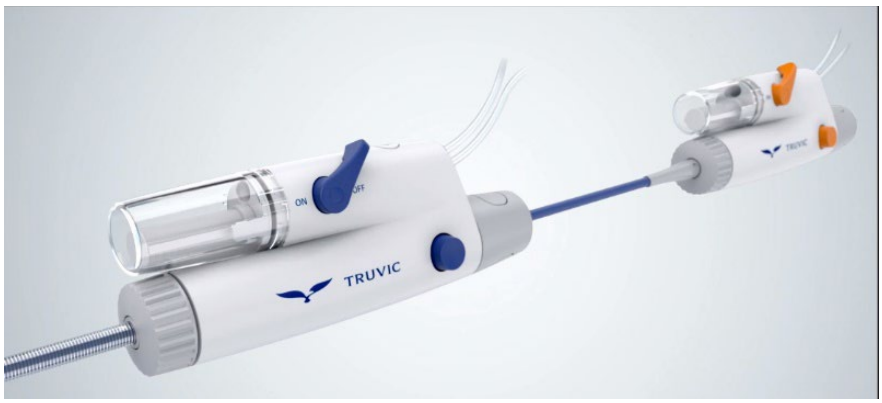
188. ~~185.~~ The Symphony system practices each limitation of at least claim 1 of the '012 Patent.

189. ~~186.~~ For example, claim 1 of the '012 Patent recites:

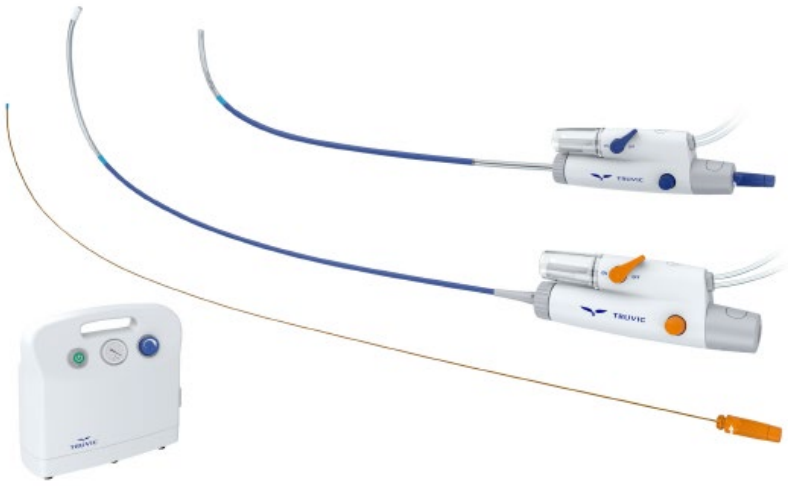
> [1] An aspiration catheter, comprising:
>
> an elongate, flexible tubular body, having a proximal end, a distal end and a central lumen;
>
> (a) a collapsible tubular sidewall defining a valve lumen in communication with the central lumen; and
>
> (b) a constricting mechanism having at least a first 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.

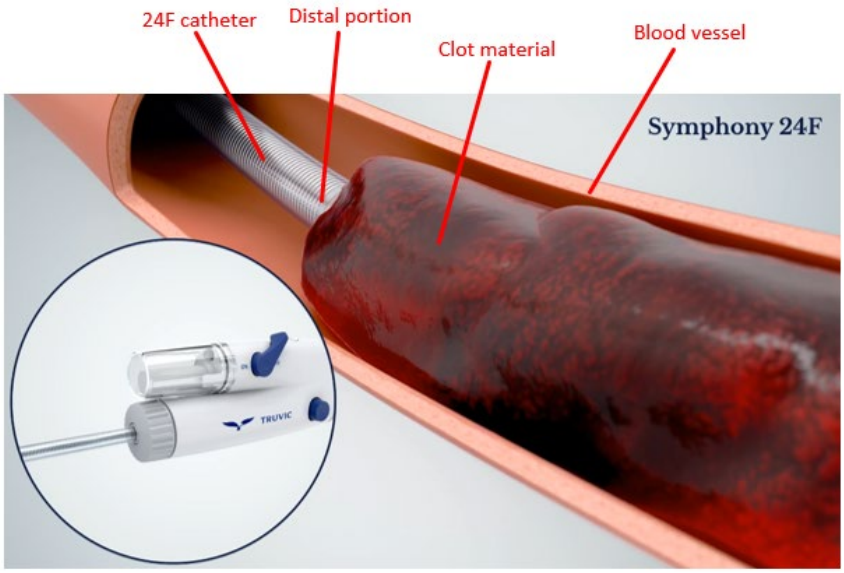
190. ~~187.~~ The Symphony system including the hemostasis valves practices the requirements of claim 1, including the preamble, "[a]n aspiration catheter, comprising," as can be seen in Exhibit R. The Truvic Symphony system includes aspiration catheter systems for 24F and 16F catheters:



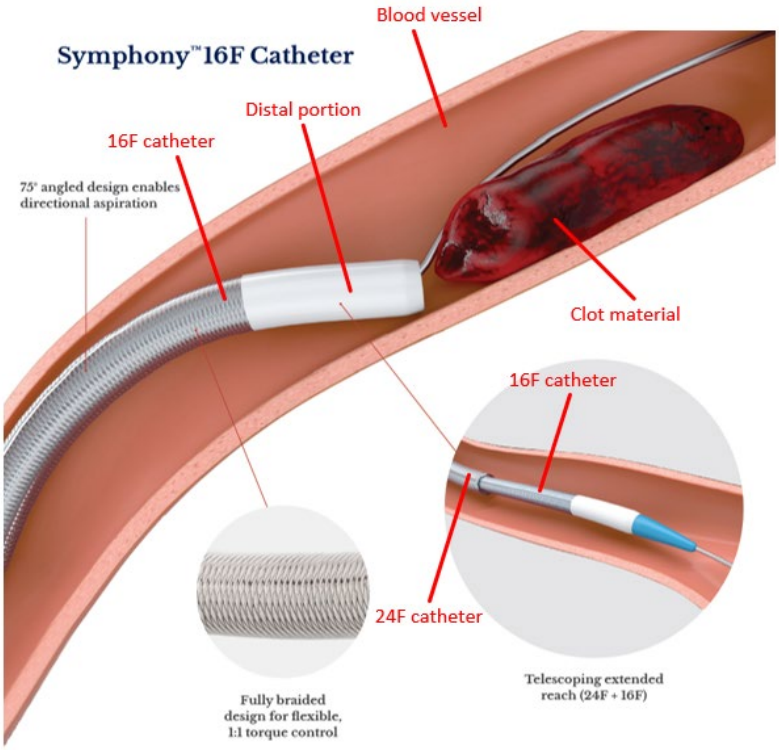
(Screen capture from Symphony product video.)



(Ex. A at 2.)



(Annotated screen capture from Symphony product video.)

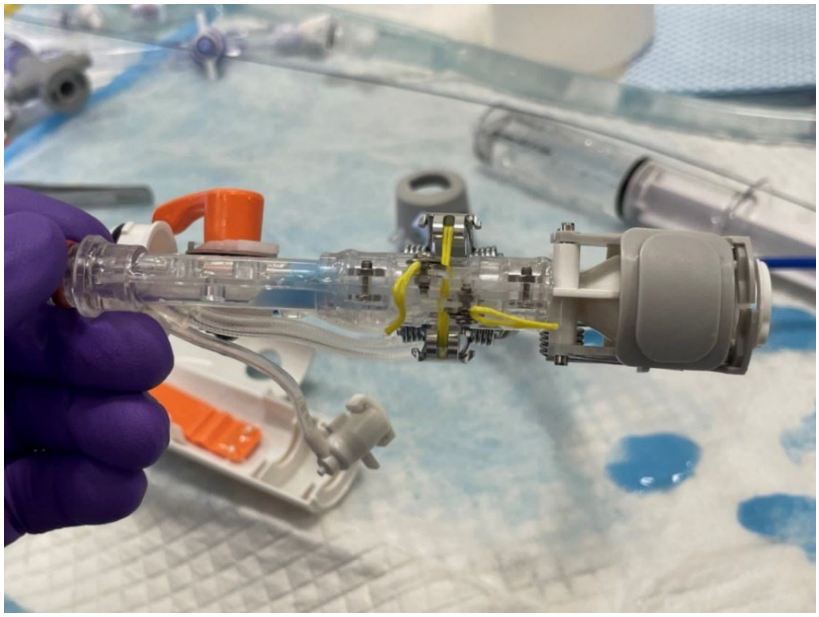


(Ex. A at 4 (annotations added) (showing a telescoping 16F and 24F catheter).)

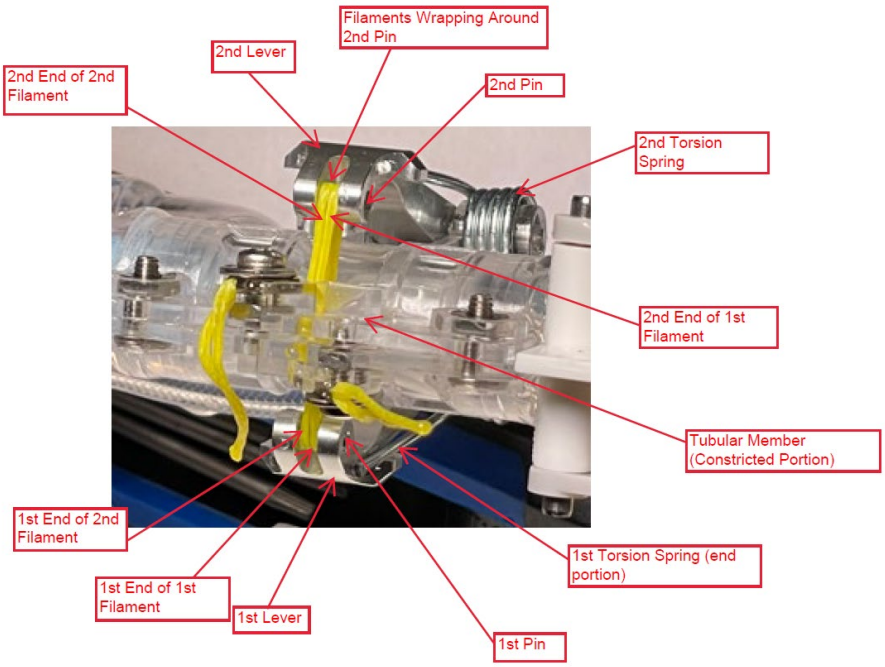
191. ~~188.~~ The aspiration catheters of the Symphony system practice the requirements of claim 1, including "an elongate, flexible tubular body, having a proximal end, a distal end and

a central lumen," as can be seen in Exhibit R. As discussed above, the 16F and 24F catheters of the Symphony system are flexible tubular bodies with a proximal end (coupled to the housing of the Symphony controller handles) and a distal end that can be advanced into the patient's vasculature, with a central lumen.

192. ~~189.~~ The Symphony system including the hemostasis valves practices the requirements of claim 1, including "a hemostasis valve on the proximal end of the catheter, the hemostasis valve comprising," as can be seen in Exhibit R. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle) that include an elongate member (tubular member) that defines a lumen. The valve's lumen is configured to receive a catheter and/or ProHelix device.



(Image of internal portion of housing with hemostasis valve.)



(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

193. ~~190.~~ The Symphony Instructions For Use further teaches that the hemostasis valves of the Symphony systems are configured to slidably receive a catheter, *i.e.*, a 24F or 16F catheter, advanced using a dilator and/or a guide wire:

The TRUVIC™ Symphony™ Thrombectomy System is comprised of several devices:

- 24F Symphony Catheter
- 24F Symphony Dilator
- 24F Symphony Advance™ Long Dilator
- 24F Symphony ProHelix™
- 16F Symphony Catheter
- 16F Symphony Dilator
- 16F Symphony ProHelix
- TRUVIC Generator
- TRUVIC Canister
- TRUVIC Tubeset

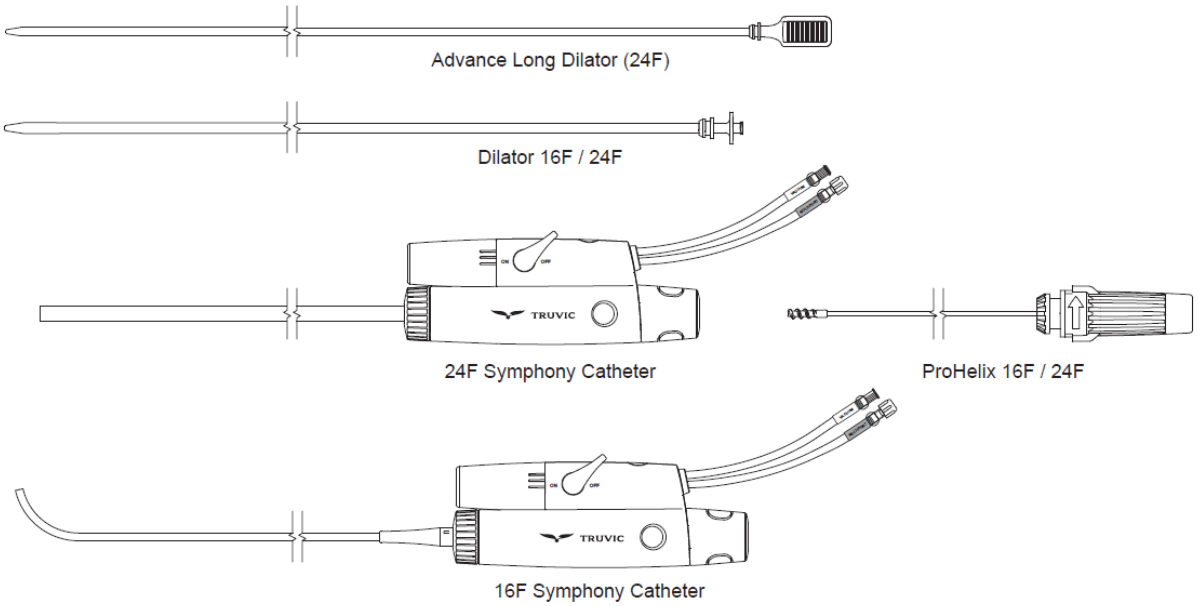


Figure 1: Symphony Thrombectomy System components

(Ex. B at 1.)

PROCEDURE AND PREPARATION

1. Refer to **Warnings, Precautions, and Potential Adverse Events** prior to use.
2. Prepare and place an introducer sheath according to the manufacturer's Instructions for Use.
3. Prior to introducing the Symphony System, ensure an appropriate 0.035" guidewire is placed into the target vessel. When using the 24F Catheter with the 24F Dilator, a guidewire of at least 260cm length should be used. When using the 24F Advance Long Dilator or the Symphony 16F Catheter, a guidewire of at least 300cm length should be used.

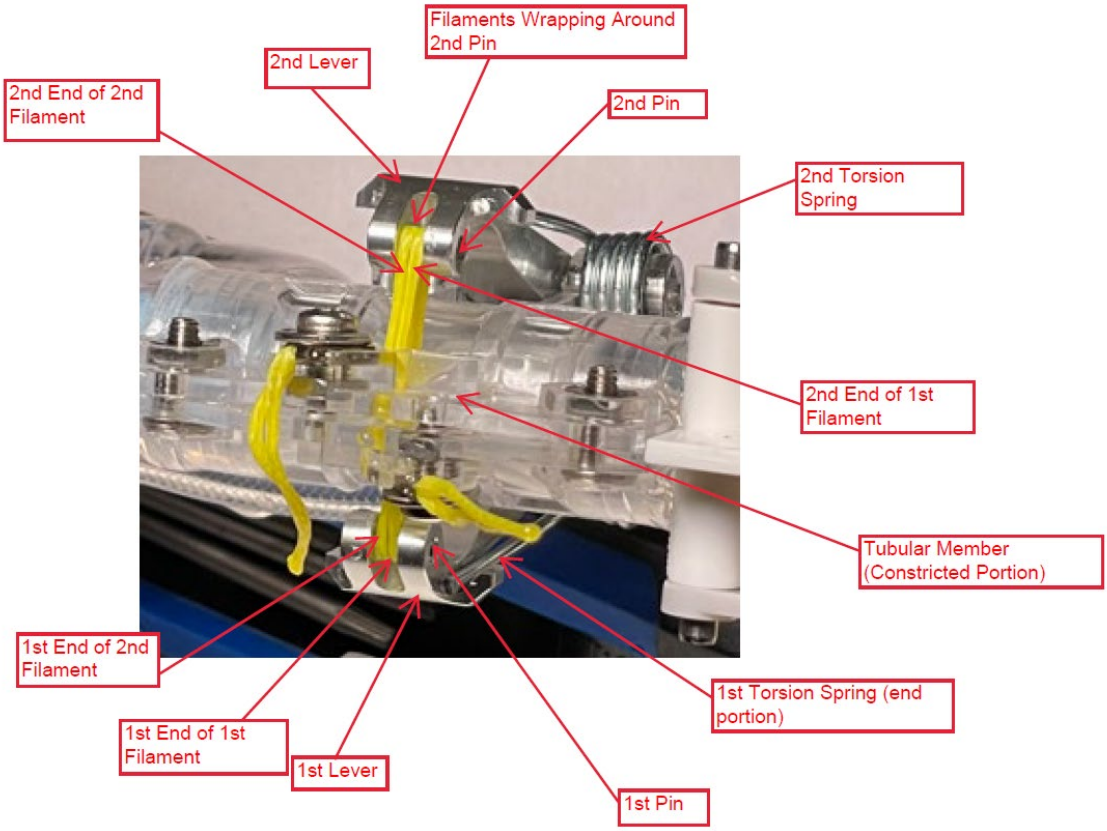
- Press the Hemostasis buttons to open the hemostasis valve and insert the Dilator through the open Hemostasis Valve of the Handle. Advance the Dilator through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
- If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
- Insert the Dilator and Catheter over the previously placed 0.035" guidewire into the introducer sheath.
- Advance the Symphony System until the tip of the Dilator is in the desired position in the selected vessel.
- Connect the Primary Tubing to the Handle tubing labelled "Vacuum".
- Attach the other end of the Primary Tubing to the TRUVIC Canister and ensure the stopcock on the Tubing is closed to the Generator.
- Release the Dilator by pressing the Retention Clip buttons on the Handle.
- When using a 24F Symphony System:
  - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

ii. With the Advance Long Dilator, hold the dilator and guide wire in position and advance the catheter approximately 1 cm. Then press the Hemostasis Valve buttons on the Handle to reduce friction and advance the Catheter over the Dilator to the desired location. While pressing the Hemostasis Valve buttons, completely withdraw the Dilator and maintain the Catheter and guidewire position.

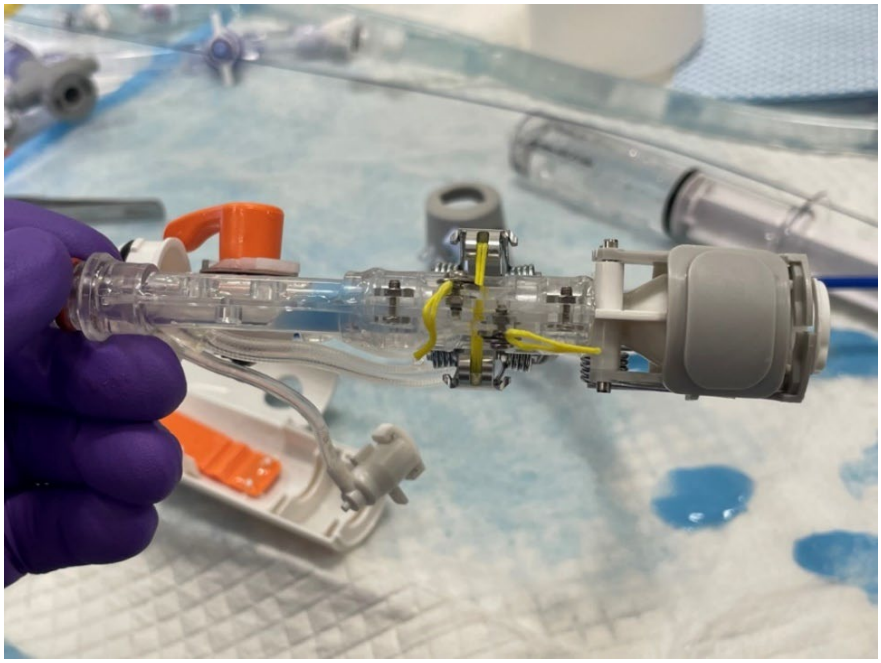
b. When using a 16F Symphony System, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the dilator while maintaining the Catheter and guidewire position.

(Ex. B at 3-5.)

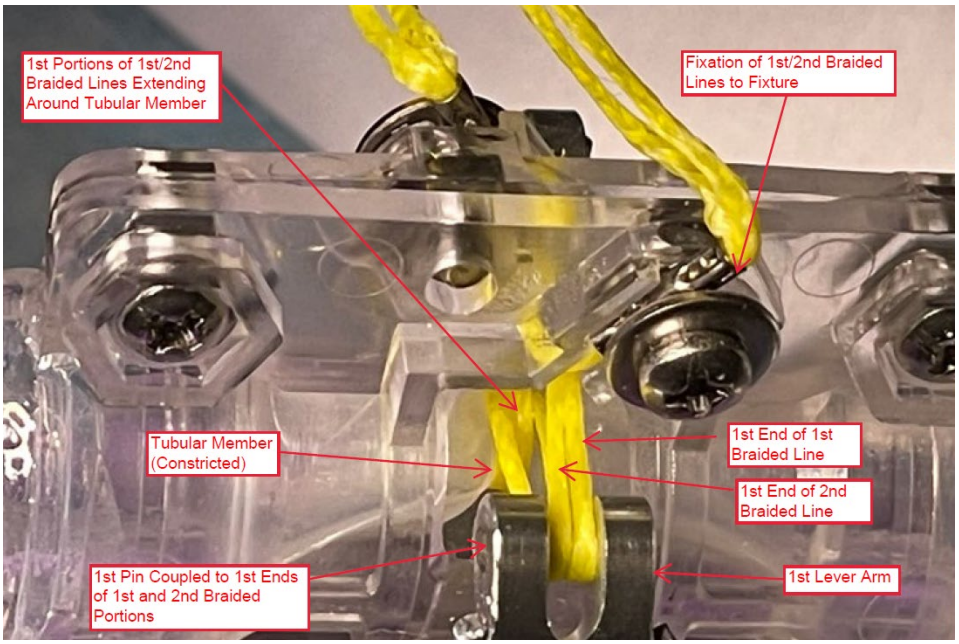
194. ~~191.~~ The Symphony system including the hemostasis valves practices the requirements of claim 1, including "a collapsible tubular sidewall defining a valve lumen in communication with the central lumen," as can be seen in Exhibit R. The hemostasis valve in each of the 24F and the 16F handles of the Symphony system has a tubular member with a collapsible tubular sidewall defining a lumen that is collapsible and can be constricted to seal the valve lumen (labeled as a tubular member) around a catheter and/or tool.



(Annotated image of internal portion of Symphony housing, including hemostasis valve with tubular member.)



(Image of internal portion of housing with hemostasis valve.)

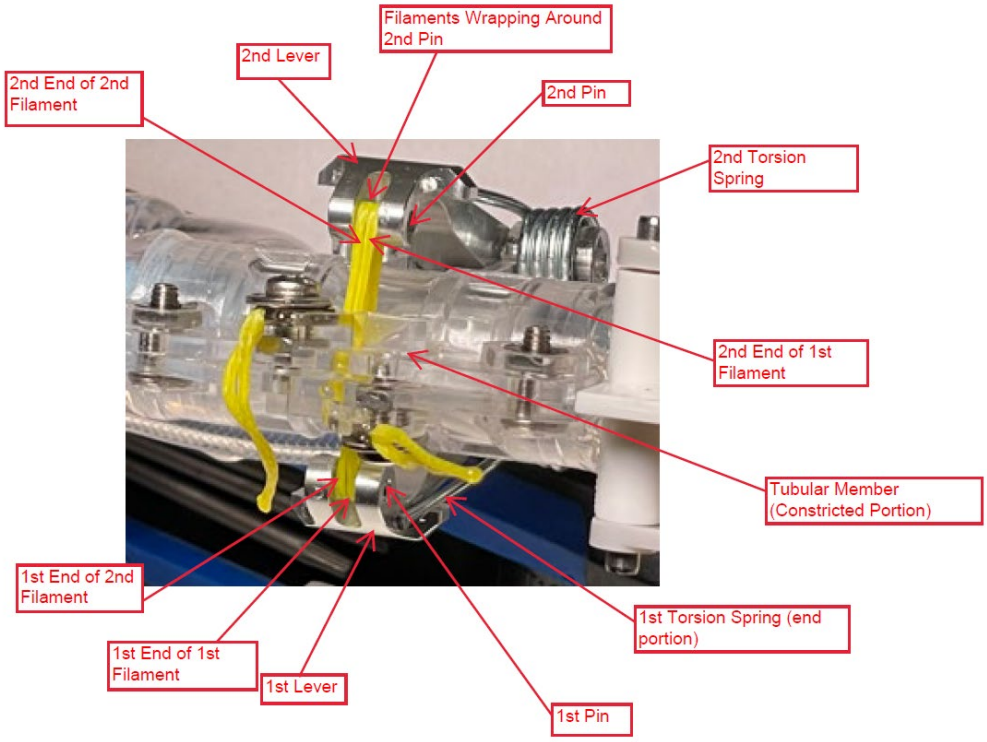


(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)

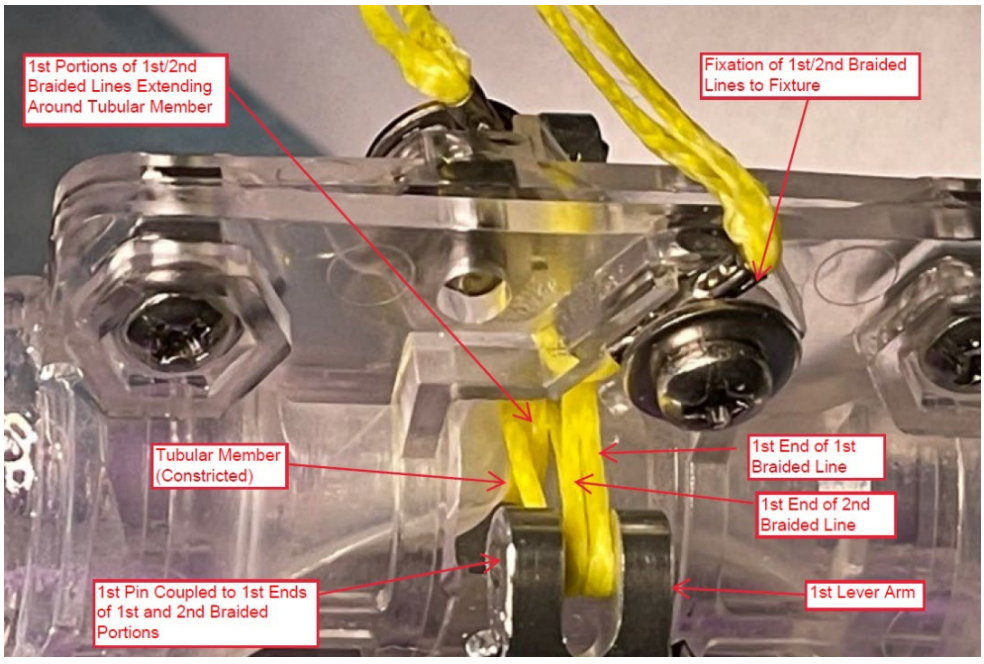
195. ~~192.~~ The hemostasis valve is in communication with the aspiration catheter, as can be seen above in the Symphony Instructions For Use directing users to advance 24F and/or 16F catheters through a hemostasis valve in the handle.

196. ~~193.~~ The Symphony system including the hemostasis valves practices the requirements of claim 1, including "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," as can be seen in Exhibit R. The controller handles of the Symphony system each include a hemostasis valve with a constricting mechanism that constricts the valve lumen via a first actuator (a first button that controls a first lever and pin coupled to the end of lines (filaments) that loop around the valve's elongate tubular member with a collapsible tubular sidewall defining a lumen). The first actuator comprising a first button/lever/pin to which the first end of the filament line is coupled, is movable between a first (undepressed button) position where the

lumen of the lumen is constricted to a second (depressed button) position wherein the lumen is less constricted and at least partially open.

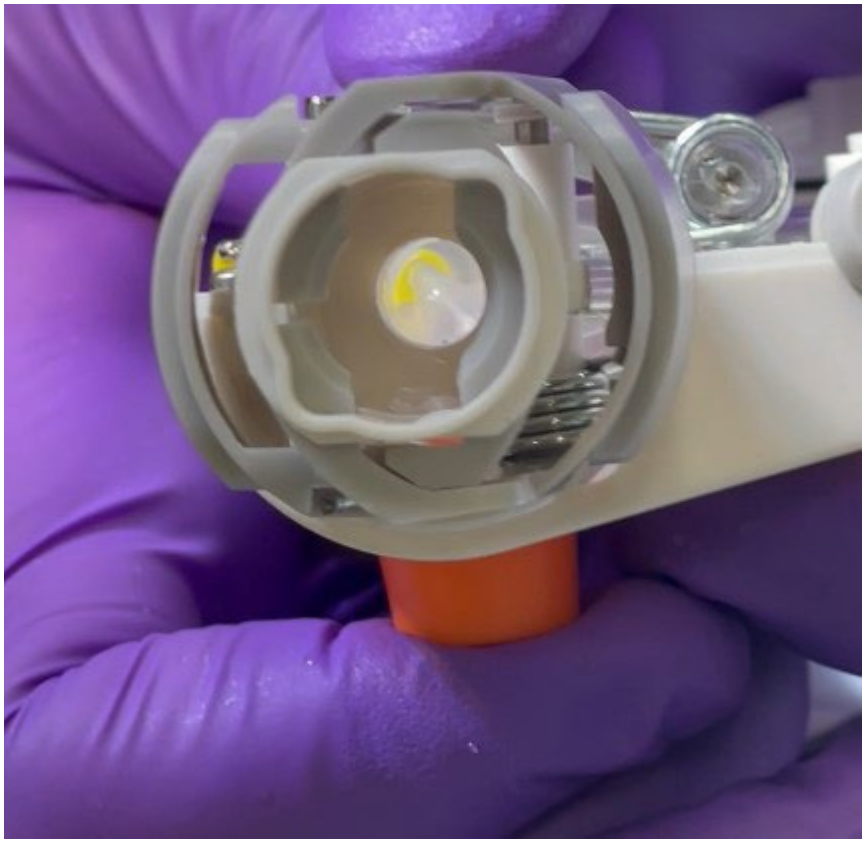


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

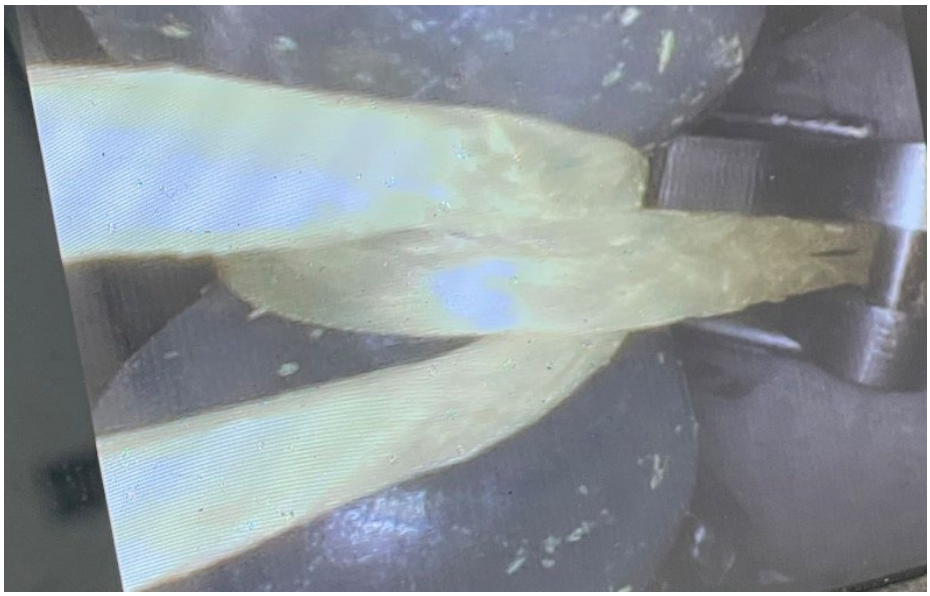


(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)

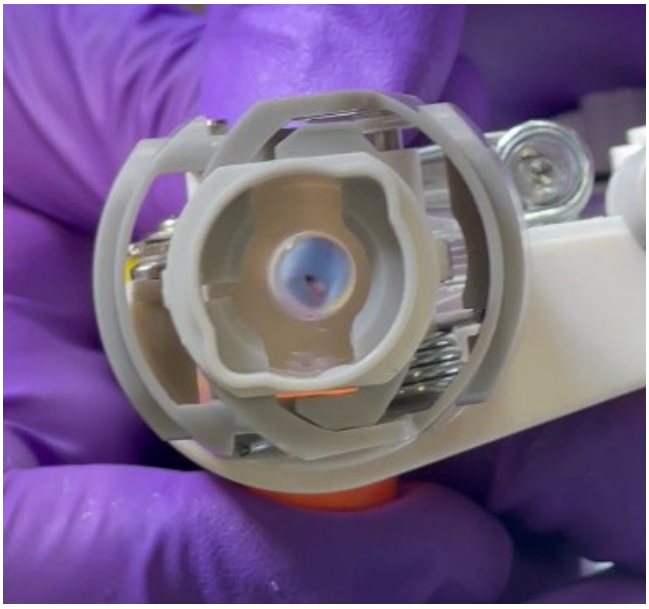
197. ~~194.~~ The Symphony system's hemostasis valves further include torsion spring(s) configured to move the first actuator's lever and pin outward, thus pulling the first end portion of the filament line, increasing the tension in the loop of the filament line around the valve lumen, thus decreasing the diameter of the valve lumen by constricting the loop to decrease the diameter of the loop. In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring, releasing tension on the filaments wrapped around the lever pin(s), which decreases the constriction on the lumen of the hemostasis valve. This allows the valve to at least partially open, permitting the introduction of a catheter or other tool through the hemostasis valve. Releasing the button(s), causes the torsion spring(s) to drive the lever outward, increasing tension on the filament lines, sealing the hemostasis valve.



(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)



(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

198. ~~195.~~ Defendant directly infringes claims of the '012 Patent, including claim 1, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures using the hemostasis valves) Symphony system products.

199. ~~196.~~ Defendant induces infringement of claims of the '012 Patent, including claim 1 by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claim 1. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

200. ~~197.~~ Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions For Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

201. ~~198.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '012 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

202. ~~199.~~ Defendant's infringement is with knowledge of the '012 Patent and its claims. Specifically, as described above, Inari notified Defendant that the Symphony system might infringe the '012 Patent by letter dated September 29, 2023. Inari further explained, in its letter dated April 24, 2024, that a teardown of the hemostasis valves of the Symphony system demonstrated infringement, including infringement of claim 1 of the '012 Patent.

203. ~~200.~~ At a minimum, Defendant has notice of the '012 Patent through the filing of the original Complaint.

204. ~~201.~~ Defendant has continued its infringing activities, despite knowledge of the '012 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

205. ~~202.~~ To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '012 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

206. ~~203.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 7: INFRINGEMENT OF THE '291 PATENT

207. ~~204.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

208. ~~205.~~ The '291 Patent, titled "Hemostasis Valves and Methods of Use," is part of the same family as the '921, and '012 Patents, and it shares the same specification. The '291 Patent discloses improved hemostasis valves and methods of their use. (*See, e.g.*, Ex. I at Abstract, 1:64-2:3.) Hemostasis valves are used to seal, e.g., to seal around catheters, in order to minimize blood loss, and maintain sterility within the body, such as in a blood vessel. (*Id.* at 1:35-50.) This is critical during surgical procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (*See id.* at 1:24-32.) Improved hemostasis valves are important to maximize patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and practitioners and effective sealing. (*See id.* at 1:51-60, 5:55-6:6.)

209. ~~206.~~ The '291 Patent discloses hemostasis valves having a support, an actuator mechanism that is moveable, an elongate tubular member with a collapsible tubular sidewall defining a lumen, where the hemostasis valve further has a constricting mechanism that includes an actuator with a first member (coupled to a first end of a filament) and a second member (coupled to a second end of the filament), where the actuator is biased by a spring to a first

position to constrict the elongate tubular member with the collapsible tubular sidewall defining a valve lumen. (*See id.* at cl. 1, Fig. 7, 2:15-32.) Some embodiments disclosed by the '291 Patent have multiple members for the hemostasis valves, *i.e.*, a first actuator member and a second actuator member used to move the hemostasis valve from a first (constricted) position to a second (un-constricted) position. (*See id.* at cl. 1, cl. 2.)

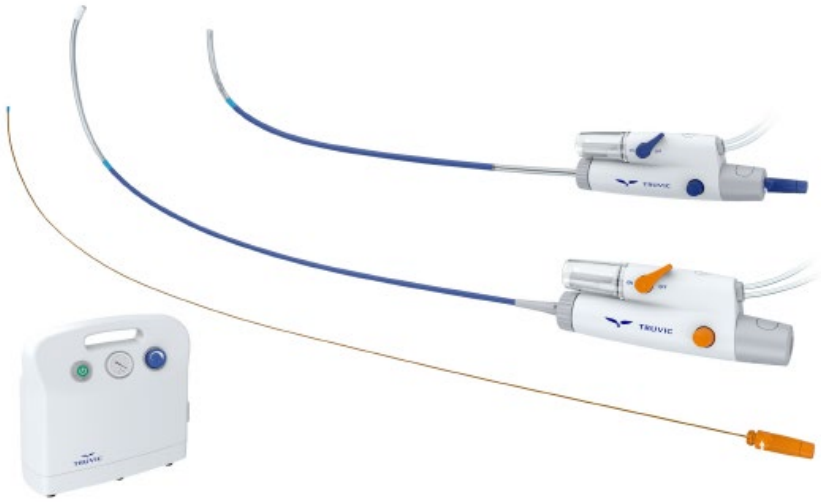
210. ~~207.~~ Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claim 1 of the '291 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

211. ~~208.~~ The Symphony system practices each limitation of at least claim 1 of the '291 Patent.

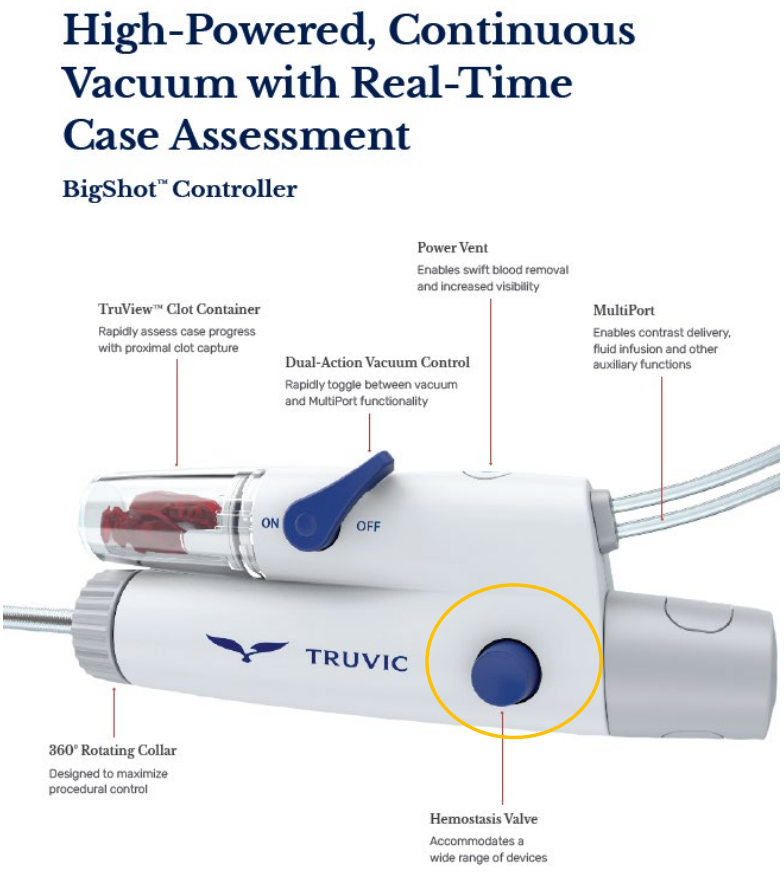
212. ~~209.~~ For example, claim 1 of the '291 Patent recites:

> [1] A 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.

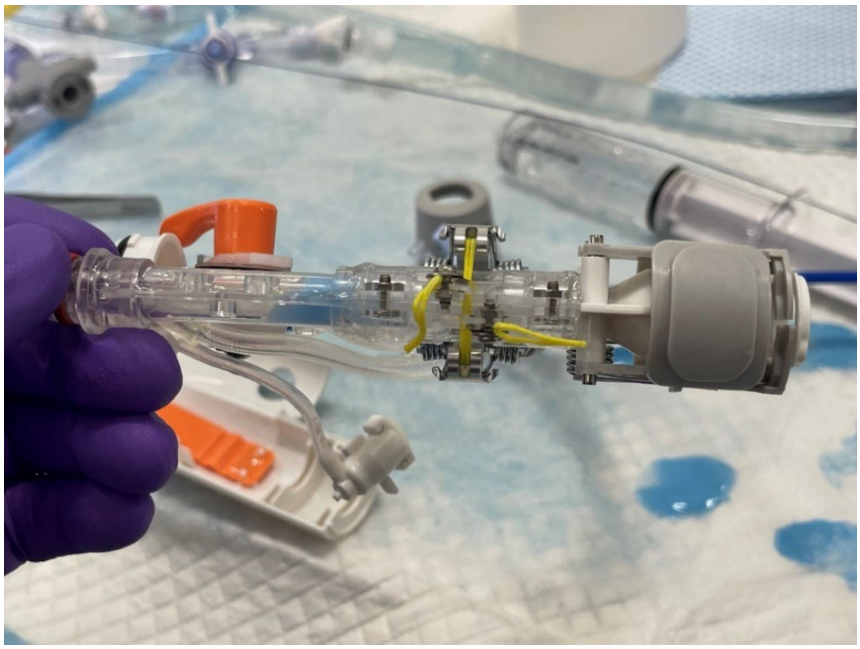
213. ~~210.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including the preamble, "[a] valve, comprising," as can be seen in Exhibit S. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle). Documentation for the Symphony system makes clear that the controller handles have a hemostasis valve, controlled by the buttons on the handles, as can be seen in the excerpts and the teardown photos below.



(Ex. A at 2.)



(Annotated Ex. A at 6.)

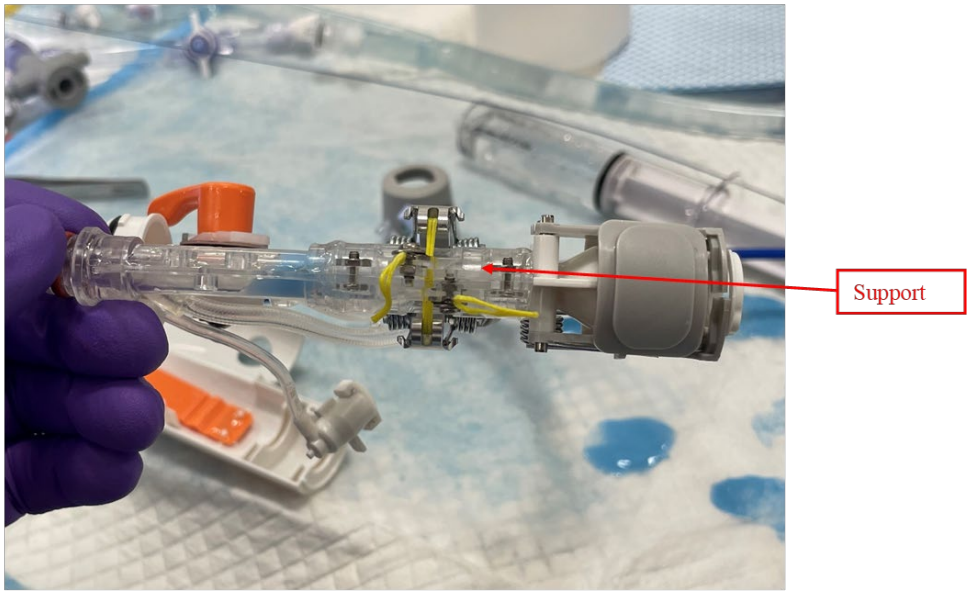


(Image of internal portion of handle housing with hemostasis valve.)

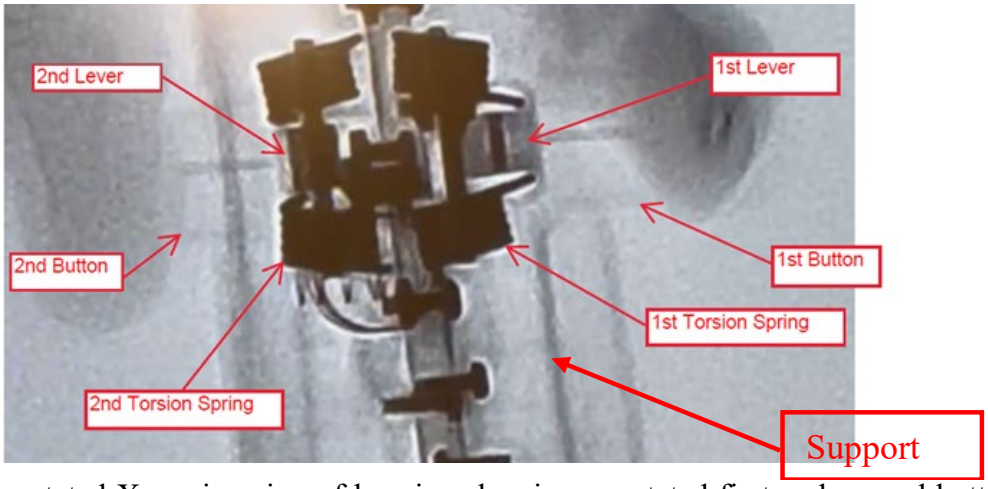
(Image of internal portion of housing zoomed in on hemostasis valve.)

214. ~~211.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including "an actuator having at least a first member movably coupled to the support," as can be seen in Exhibit S. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F

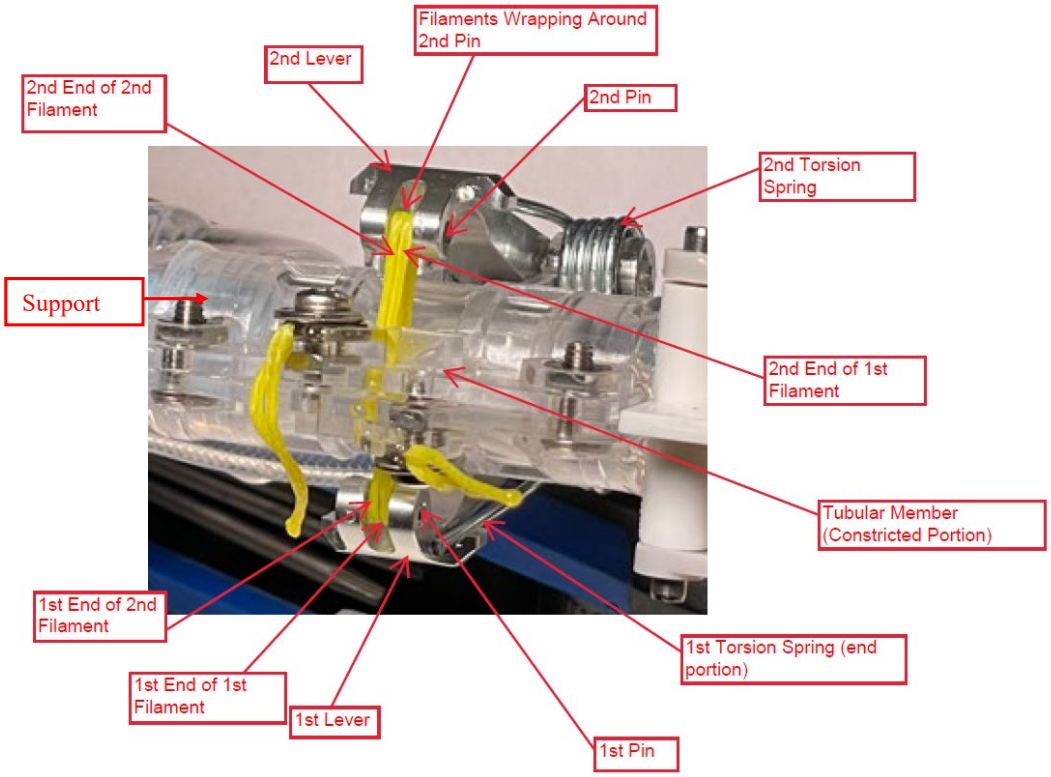
handle) that include a clear plastic support that carries a tubular member and further has an actuator with a first and second member coupled to the support.



(Image of internal portion of housing with hemostasis valve.)

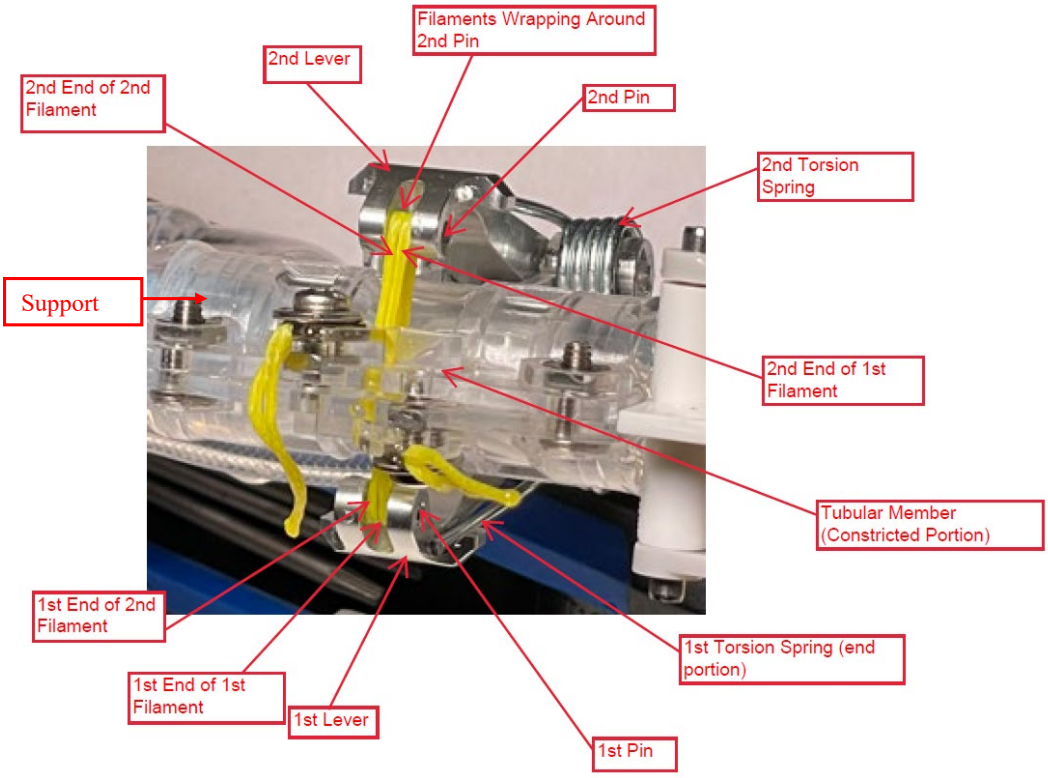


(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of hemostasis valve in Symphony housing.)

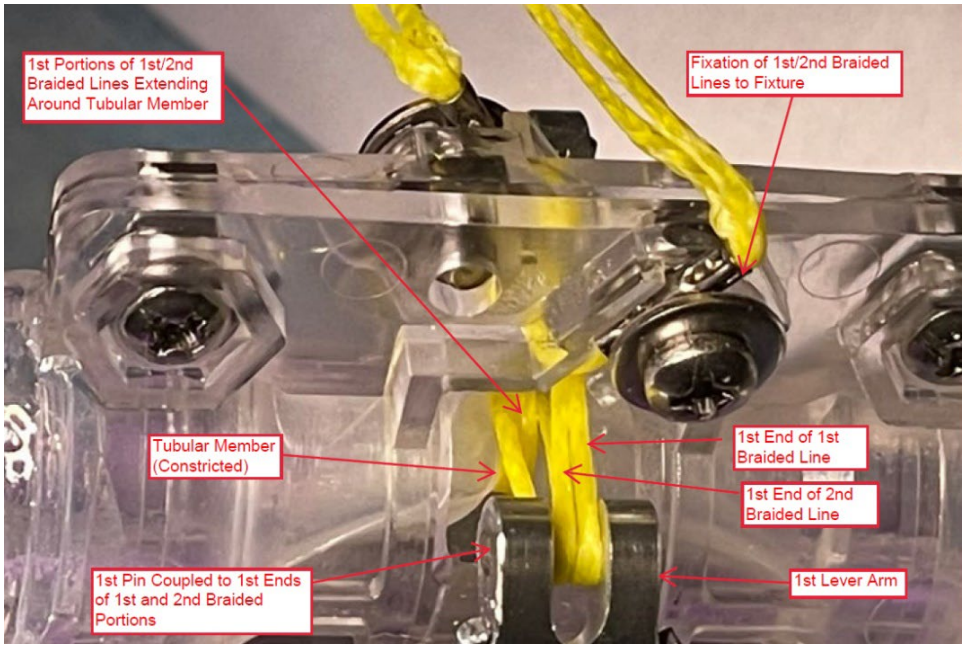


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member and support.)

215. ~~212.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including "an actuator having at least a first member movably coupled to the support," as can be seen in Exhibit S. Specifically, the controller handles of the Symphony system include a hemostasis valve having an actuator mechanism including a first member and a second member (a first that controls the first lever and a second button that controls the second lever coupled to the ends of lines (filaments) that loop around the valve's elongate tubular member defining a lumen). The first member of the actuator is movably coupled to the clear plastic support, specifically the first lever and pin move inward if a first button is depressed, and are driven outward by a spring when the first button is not depressed. The first and second levers are fixed to the centerline of the support with an internal mount within the housing of the controller handle.

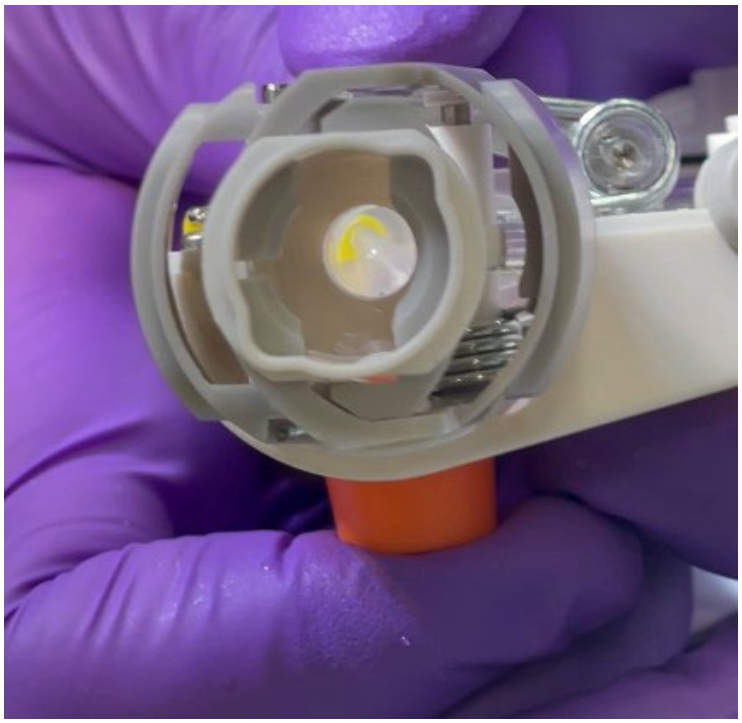


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

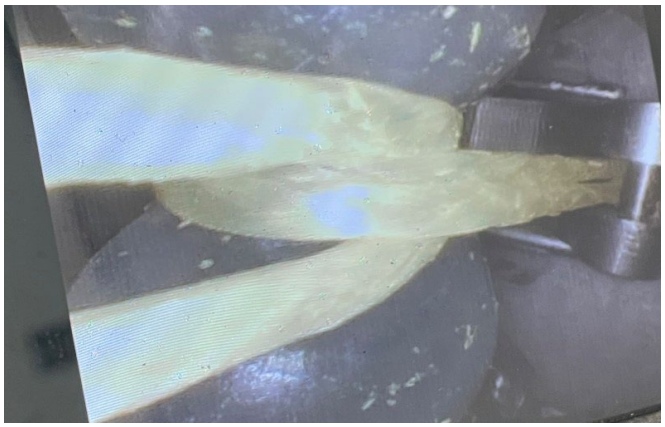


(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)

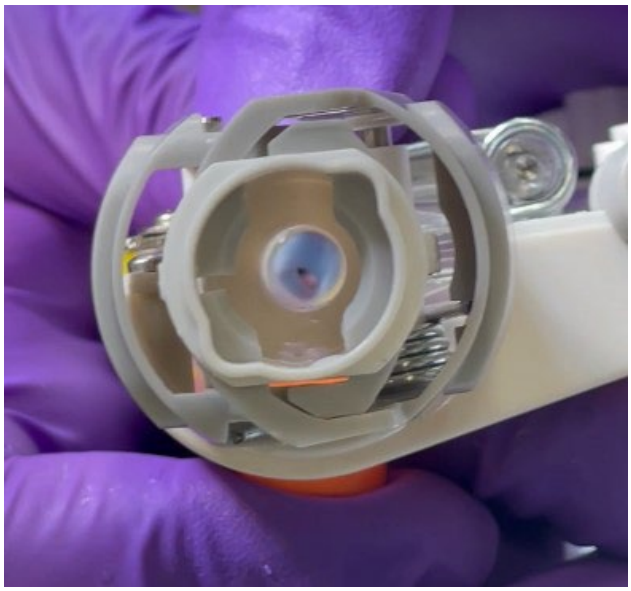
216. ~~213.~~ In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring(s), releasing tension on the filaments wrapped around the lever pin(s), which decreases the constriction on the lumen of the hemostasis valve. This allows the valve to at least partially open, permitting the introduction of a catheter or other tool through the hemostasis valve. Releasing the button(s), causes the torsion spring(s) to drive the lever outward, increasing tension on the filament lines, sealing the hemostasis valve.



(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve constricted.)

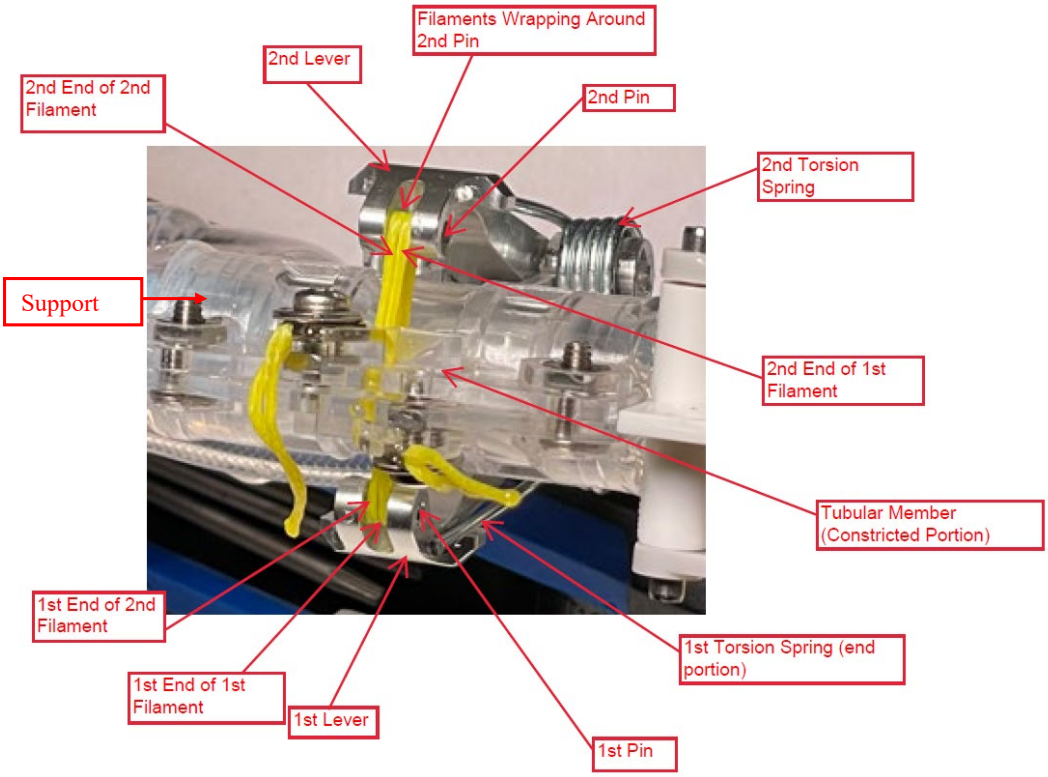


(Internal image of hemostasis valve with filaments encircling and constricting tubular member.)

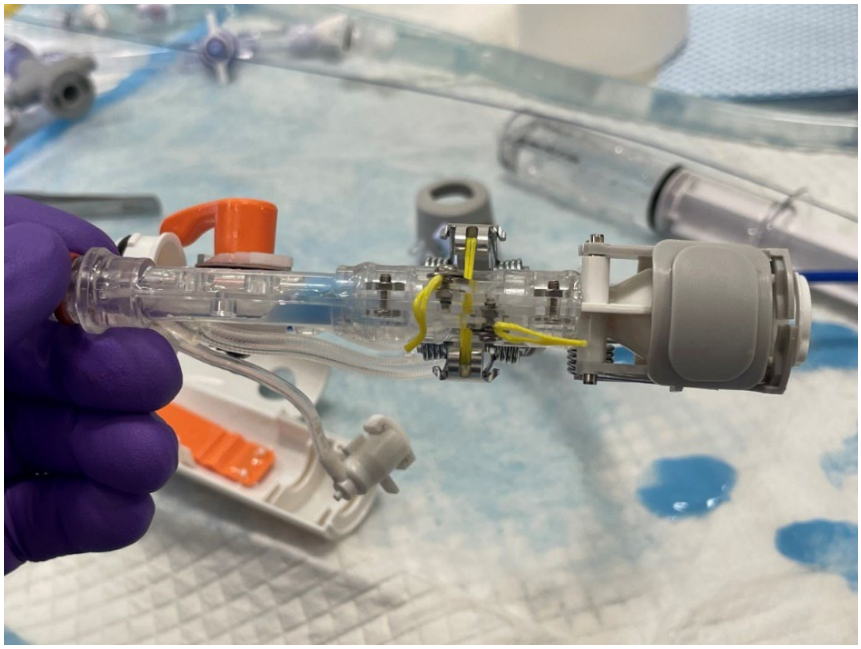


(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve open.)

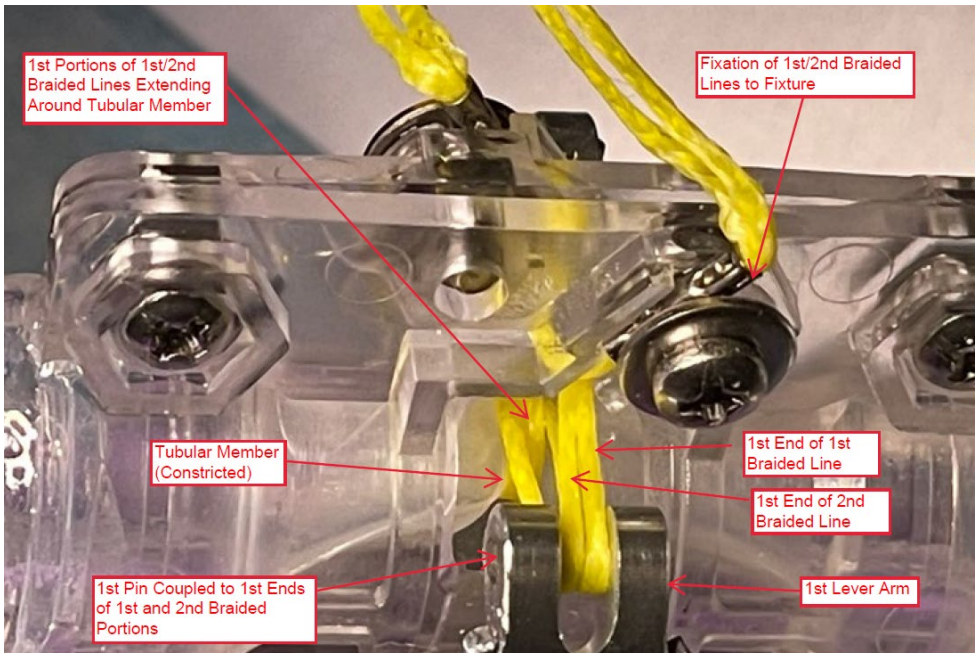
217. ~~214.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a collapsible tubular sidewall defining a lumen carried by the support," as can be seen in Exhibit S. The hemostasis valve in each of the 24F and the 16F handles of the Symphony system has a central tubular member defining a lumen that is collapsible and can be constricted to seal the valve (labeled as a tubular member).



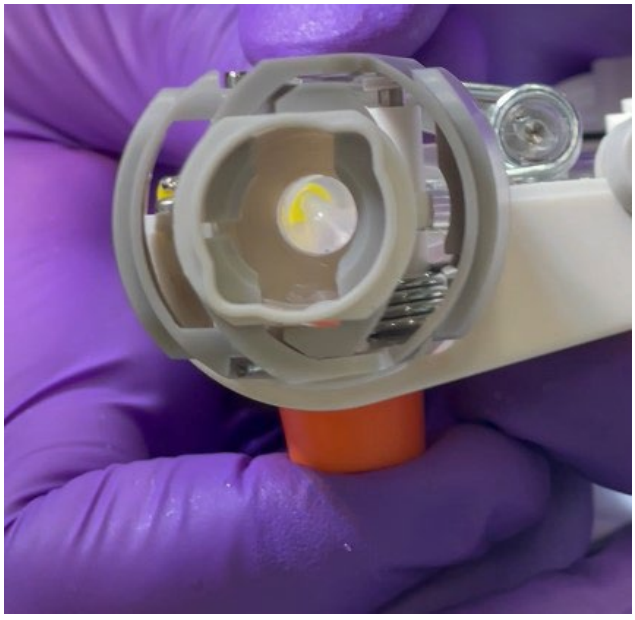
(Annotated image of internal portion of Symphony housing, including hemostasis valve with tubular member.)



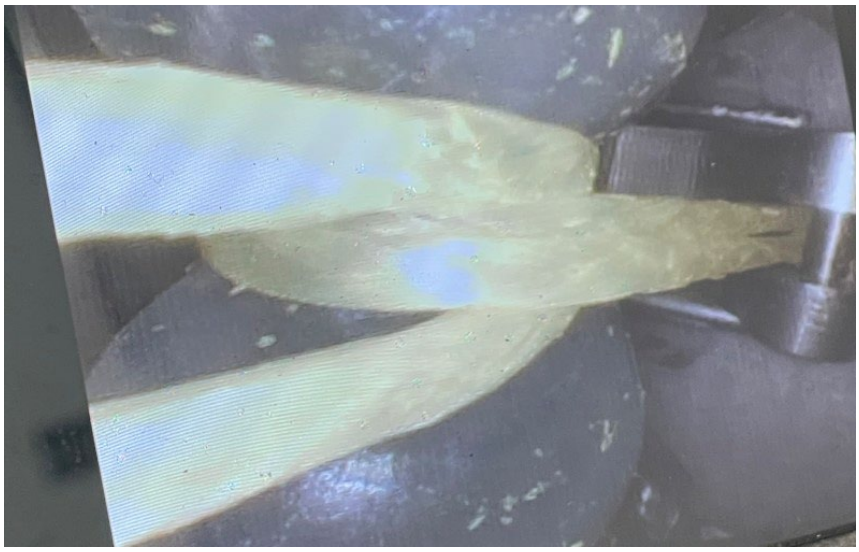
(Image of internal portion of housing with hemostasis valve.)



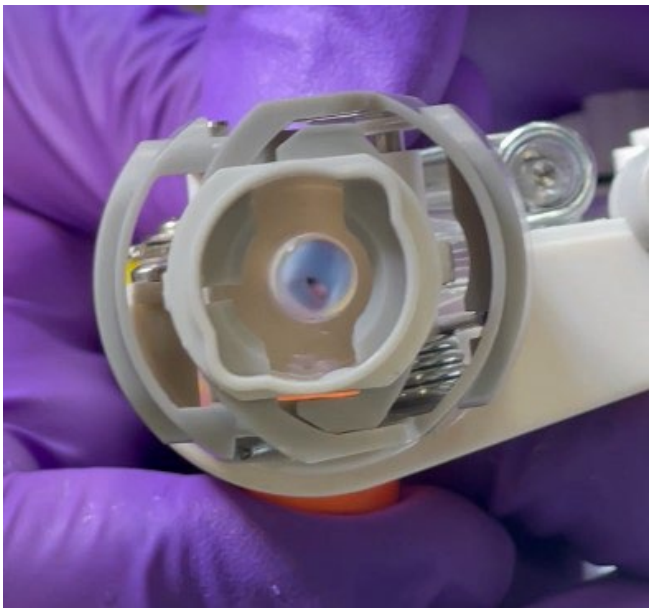
(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)



(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve constricted.)



(Internal image of hemostasis valve with filaments encircling and constricting tubular member.)

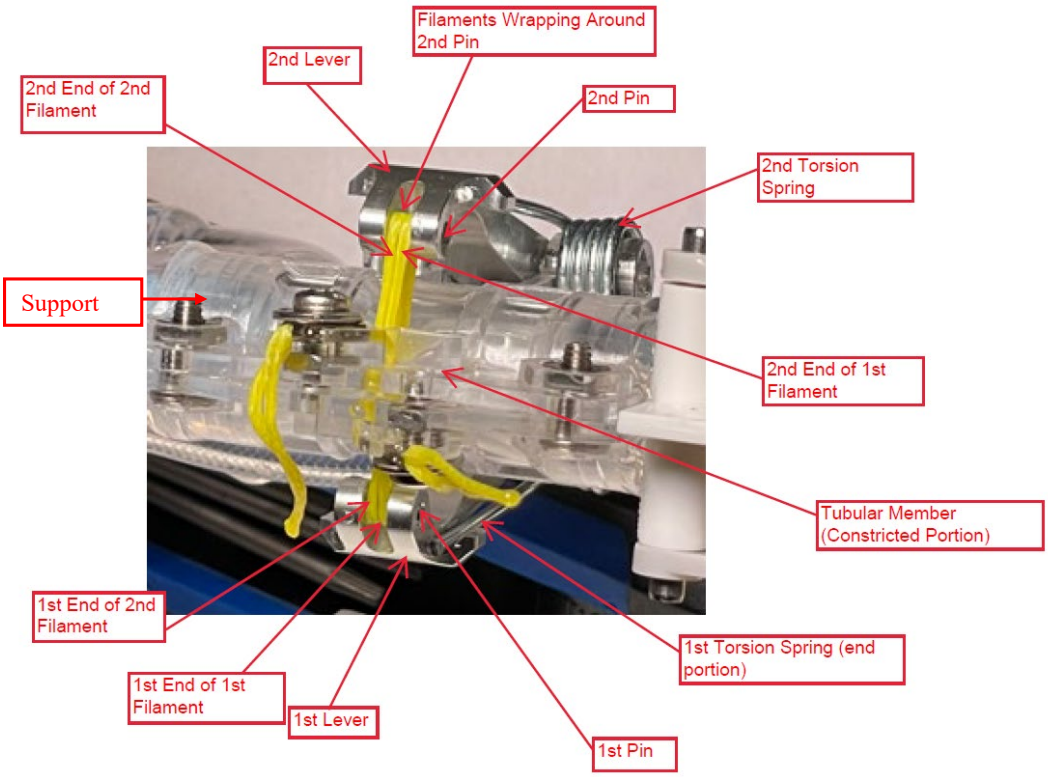


(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve open.)

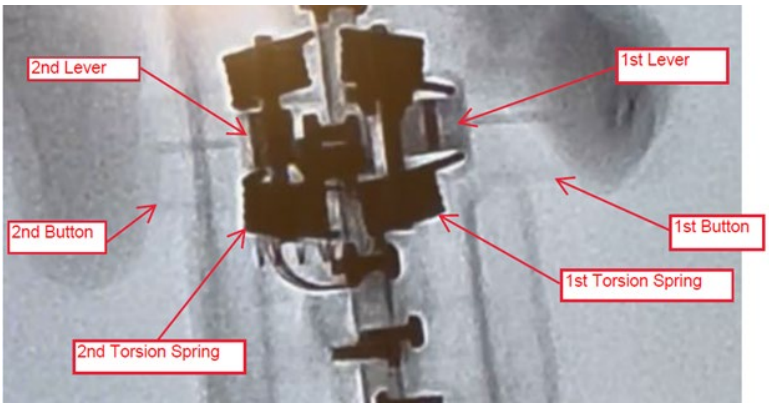
218. ~~215.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member," as can be seen in Exhibit S. As can be seen in the preceding paragraph, the hemostasis valves include a first filament and a second filament that are looped around the tubular sidewall of the tubular member

of the hemostasis valve, and the filament lines both have a first end portion that extends from the loop to couple to the first pin of the first lever of the first actuator member.

219. ~~216.~~ The hemostasis valves of the Symphony system practice the requirements of claim 1, including "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," as can be seen in Exhibit S. The hemostasis valve of the Symphony handles includes a first torsion spring that pushes against the first lever, biasing the first member to a first position (closed/constricted with an undepressed first button) and a second torsion spring that pushes against the second lever biasing the second member to the first position. There are two torsion springs for each lever.



(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs.)

220. ~~217.~~ Defendant directly infringes claims of the '291 Patent, including claim 1, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures using the hemostasis valves) Symphony system products.

221. ~~218.~~ Defendant induces infringement of claims of the '291 Patent, including claim 1 by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems that practice claim 1. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

222. ~~219.~~ Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-

product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

223. ~~220.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '291 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

224. ~~221.~~ Defendant's infringement is with knowledge of the '291 Patent and its claims. Specifically, as described above, Inari notified Defendant that the Symphony system might infringe the allowed claims of United States Patent Application 18/142,518, which has since issued as the '291 Patent, by letter dated September 29, 2023. Inari further explained, in its letter dated April 24, 2024, that a teardown of the hemostasis valves in the Symphony system showed that they infringe Inari's patents, including claim 1 of the '291 Patent.

225. ~~222.~~ At a minimum, Defendant has notice of the '291 Patent through the filing of the original Complaint.

226. ~~223.~~ Defendant has continued its infringing activities, despite knowledge of the '291 Patent (including knowledge from correspondence with Inari and through the original Complaint), and such infringement has been and continues to be egregious and willful.

227. ~~224.~~ To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '291 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

228. ~~225.~~ The requirements of 35 U.S.C. § 154(d) have been met for the allowed claims of the '518 Application from September 29, 2023, to the issuance of the '291 Patent.

229. ~~226.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 8: INFRINGEMENT OF THE '580 PATENT

230. ~~227.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

231. ~~228.~~ The '580 Patent is titled "Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods." The '580 Patent discloses improved clot-removing methods for intravascular treatment of clot materials that solve problems with prior art clot-removal devices and methods. The '580 Patent solves these problems through its inventions and combination of inventions that include, for example, pre-charging a vacuum in a pressure source, connecting the pressure source to an elongated shaft, e.g., a catheter, to aspirate a first portion of a clot, opening an attachment member at the proximal end, and advancing an interventional device to engage a second portion of the clot remaining after the aspiration pass. (Ex. J at cl. 1.) The interventional device is a mechanical structure that can engage the clot material, and retain it, as the interventional device is withdrawn through the catheter. (*See id.*) The '580 Patent teaches that the using a guide aspiration catheter to advance the interventional device allows for multiple passes (repeated deployments and withdrawals) with the interventional device to remove more clot material. (*See id.* at Fig. 10, 3:45-62.)

232. ~~229.~~ The '580 Patent further solves problems in the art through a clot reservoir container with a removable filter. (*E.g.*, *id.* at Fig. 3B, Fig. 3C, cls. 18-20.) The '580 Patent teaches that the clot reservoir and filter capture clot material within a housing, while filtered blood is allowed to flow through. (*Id.* at Figs. 3A-3C, 8:60-9:58.) This allows the treating physician to see the captured clot material to help determine whether additional passes are necessary and to remove clot that has been collected by removing and emptying the filter housing. (*Id.*)

233. ~~230.~~ Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claims 18 and 19 of the '580 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

//

//

234. ~~231.~~ Specifically, claim 1 of the '580 Patent recites:

> [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.

235. ~~232.~~ Dependent claim 18 of the '580 Patent recites:

> [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.

236. ~~233.~~ Dependent claim 19 of the '580 Patent recites:

> [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.

237. ~~234.~~ Performing thrombectomy using the Truvic Symphony system including its ProHelix device practices each limitation of at least claims 1 (from which claims 18 and 19 depend), 18, and 19 of the '580 Patent, as can be seen in the '580 Patent claim chart, attached as Exhibit T.

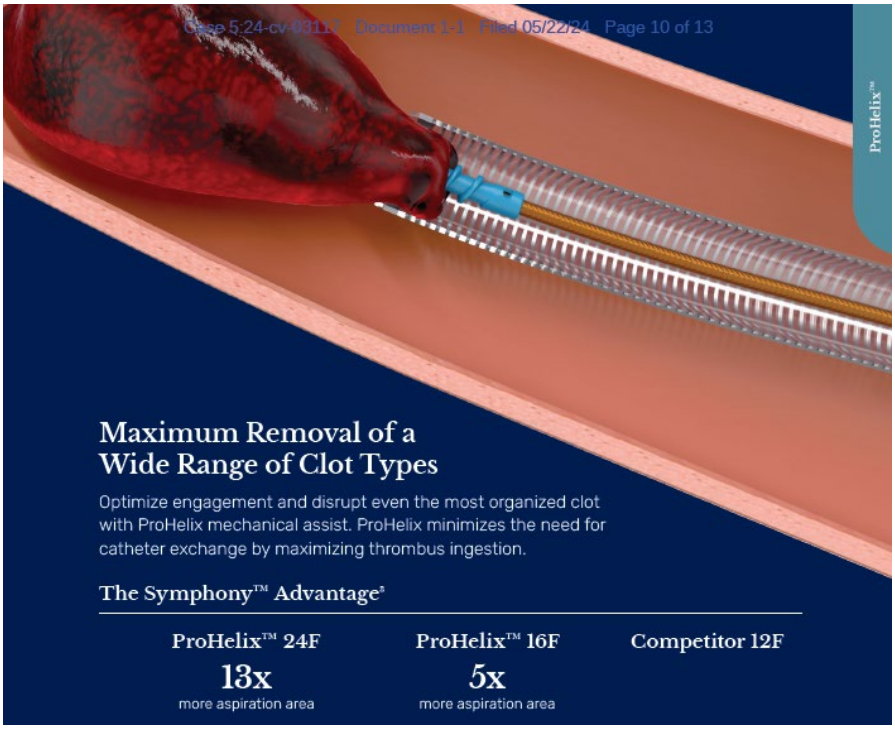
238. ~~235.~~ To the extent the preamble of claim 1 is construed to be limiting, thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the requirements of the preamble, "[a] method for the intravascular treatment of clot material within a blood vessel, the method comprising," as can be seen in Exhibit T. For

example, according to Truvic's Symphony Brochure, Symphony employs "next generation thrombus removal" with "powerful, focused aspiration" for treating (*e.g.*, removing) clot material from within a blood vessel. (*See* Ex. A at 2-4.) The Symphony Instructions for Use further instruct that the system "is indicated for: [t]he non-surgical removal of fresh, soft emboli and thrombi from blood vessels." (Ex. B at 12.) In addition, Symphony's product website includes a video detailing a method of using the Symphony system to treat clot material within a blood vessel of a human patient using vacuum aspiration. (*See* https://www.truvic.com/symphony-product.)

239. ~~236.~~ Symphony's Instructions for Use further teach users to advance a 16F or 24F ProHelix device within a catheter to engage the clot:

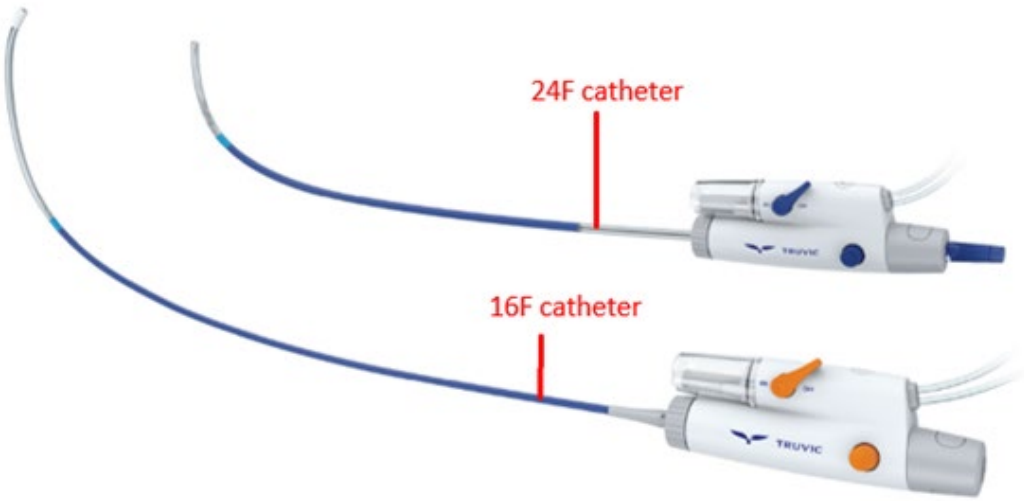
> As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter.

(Ex. B at 1.) Truvic's Symphony Brochure shows this as well:

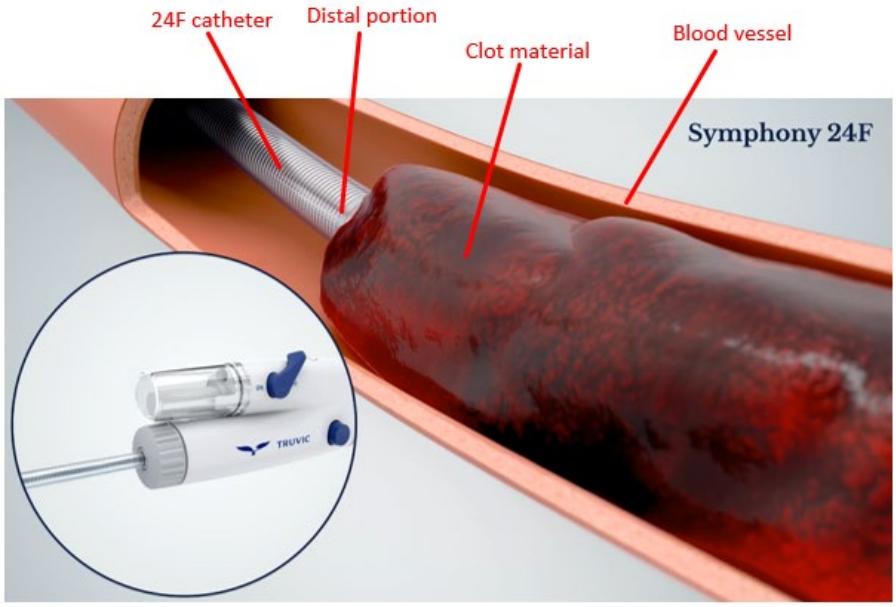


(Ex. A at 10.)

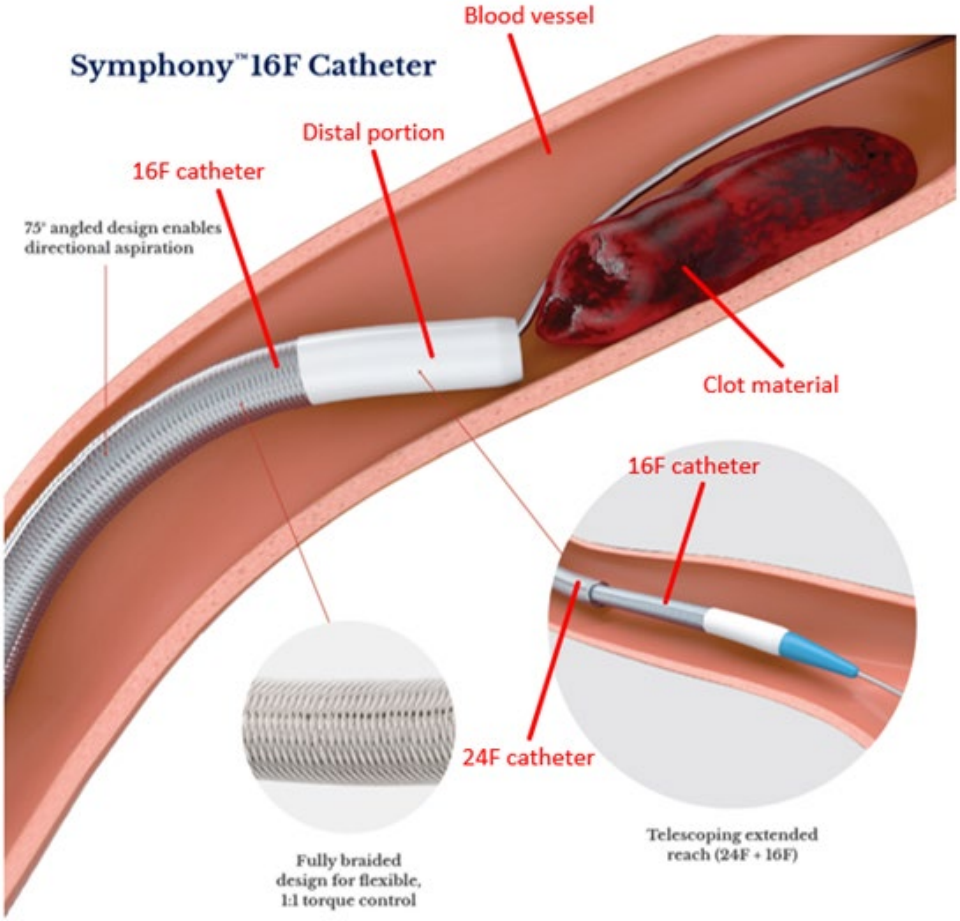
240. ~~237.~~ Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 1, including "a positioning a distal portion of an elongated shaft proximate to the clot material within the blood vessel," as can be seen in Exhibit T. The Symphony system includes a 24F catheter (a "first catheter") and a 16F catheter (a "second catheter"). (*Id.* at 2, 4.) These catheters can be used as aspiration catheters, and the Truvic Symphony system is "intended for use in the peripheral vasculature," such as for deep vein thrombosis.



(Ex. A at 2 (annotations added).)

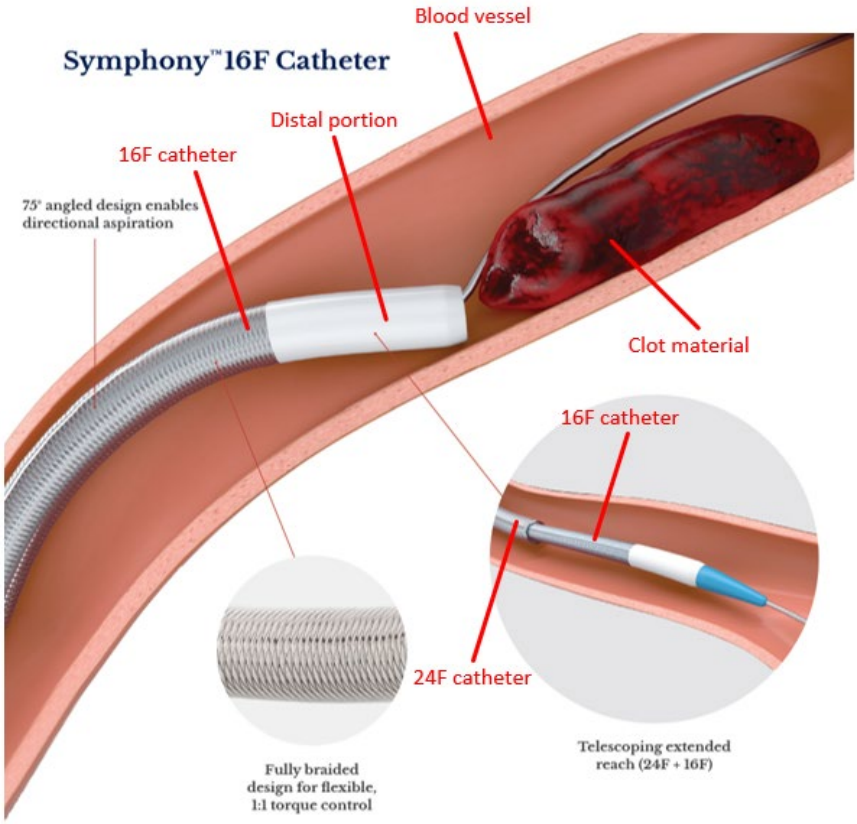


(Annotated screen capture from Symphony product video.)

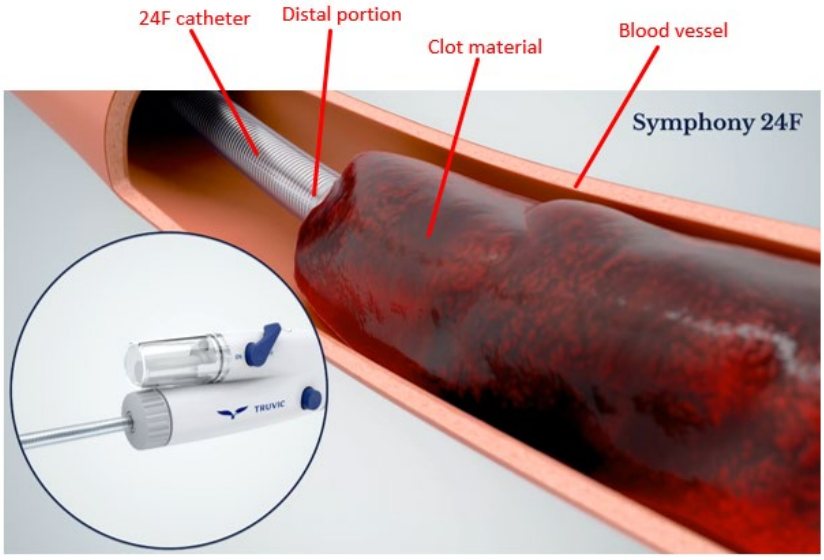


(Ex. A at 4 (annotations added).)

241. ~~238.~~ In thrombectomy operations, the 16F second catheter can be advanced, including through the 24F first catheter and out of the 24F first catheter, through the vasculature of a patient over a guidewire and/or with a dilator positioned therein (as shown in the image below) until a distal portion of the 16F second catheter is positioned just proximal of clot material within a blood vessel of the vasculature. (*See id.* at 4.) The 24F catheter can also be advanced to a position proximal to the clot material within a blood vessel of the patient's vasculature. Upon information and belief, practitioners using the Symphony system are intended to and regularly do use this feature.



(Ex. A at 4 (annotations added).)



(Annotated screen capture from Symphony product video.)

242. ~~239.~~ Thrombectomy with the Symphony system, including thrombectomy with a ProHelix device, practices the limitations of claim 1, including "pre-charging a vacuum in a

pressure source," as can be seen in Exhibit T. In the Symphony system, the 24F and 16F controller handles are coupled to a Truvic Generator and Truvic Canister, or another pressure source, which is a vacuum pressure source:

13. Confirm that both the 24F and 16F Handle vacuum levers are in the "OFF" position.

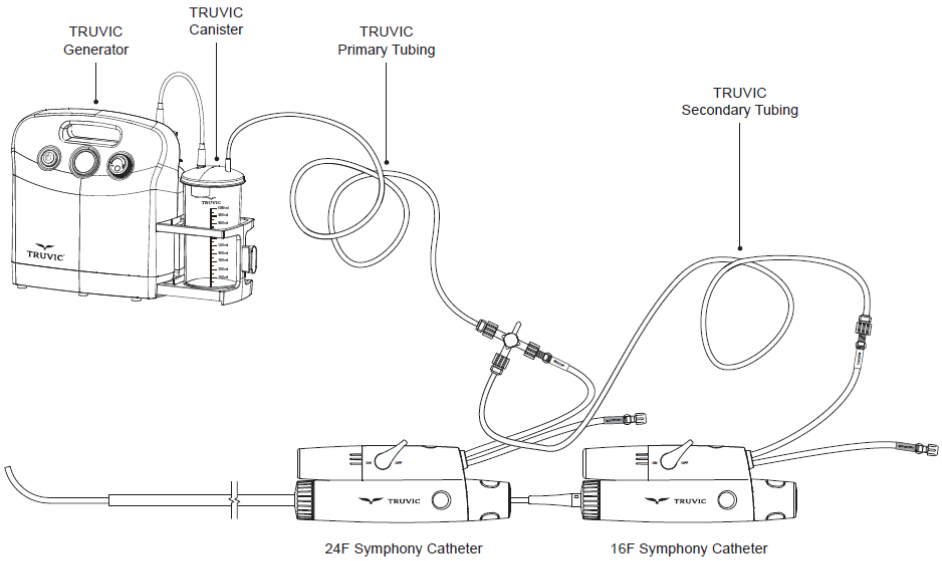
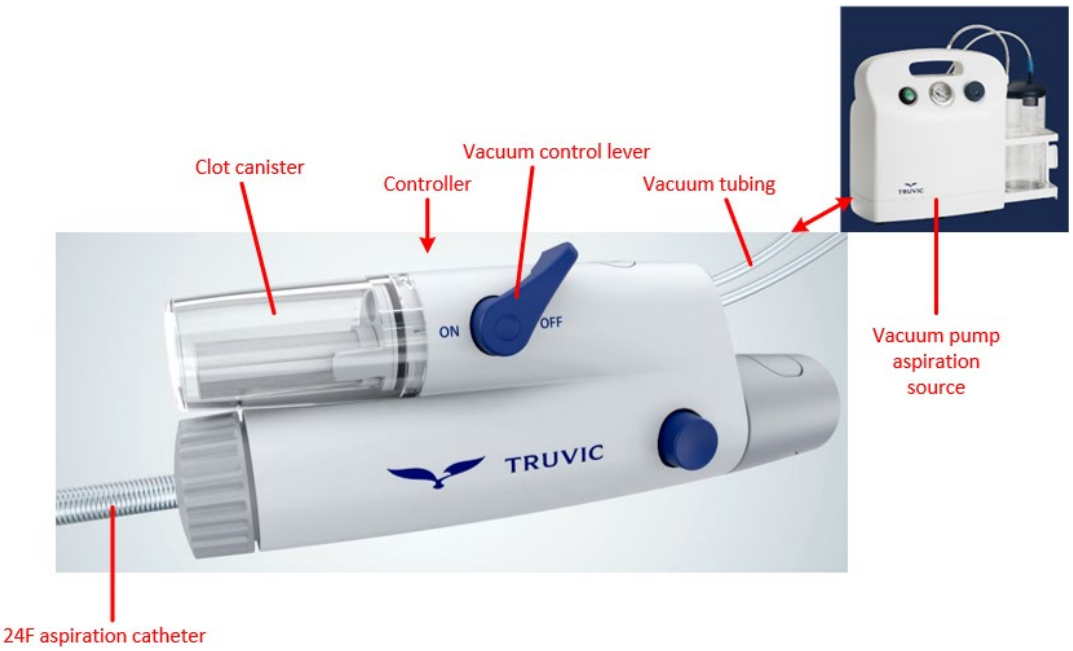


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

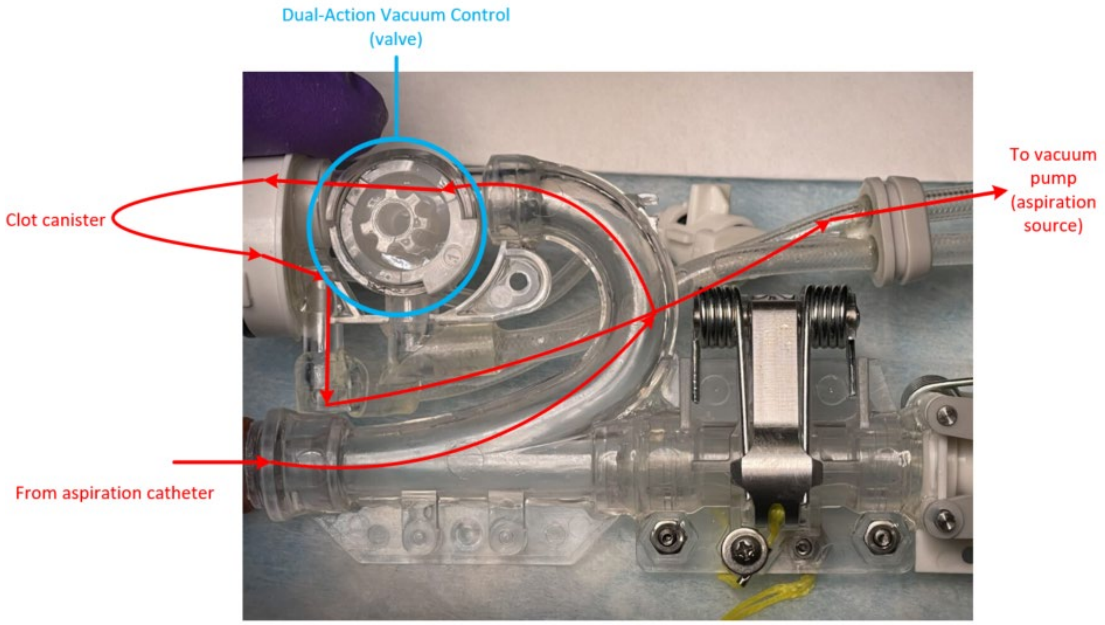
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

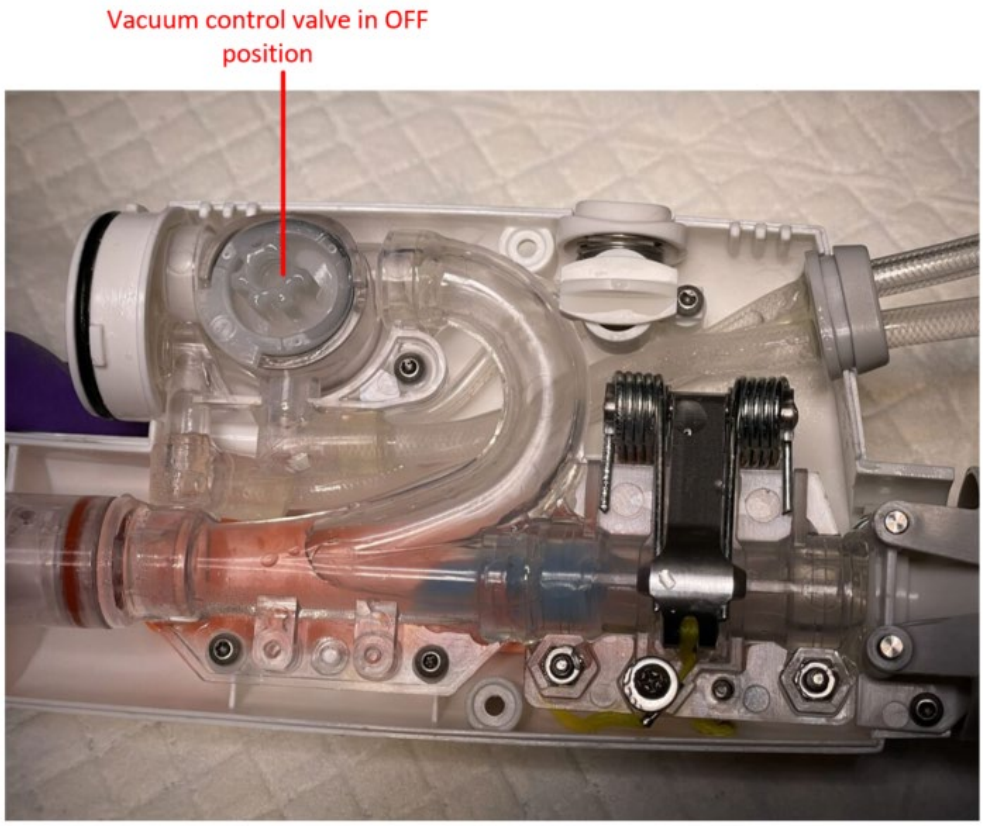
243. ~~240.~~ During thrombectomy using the Symphony system, the user initially sets the vacuum control lever on the 16F and/or 24F handles to the "OFF" position, which actuates a vacuum valve in the handle, ensuring that vacuum is not applied to the lumen of the 16F and/or 24F aspiration catheters:



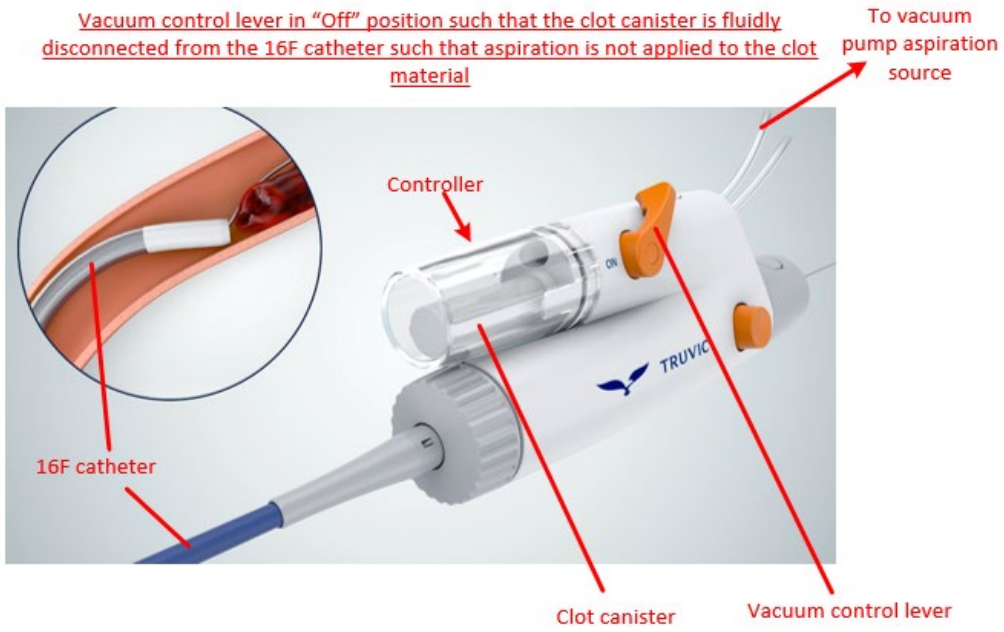
(Annotated diagram of Symphony system.)



(Annotated image of Symphony housing (internal).)



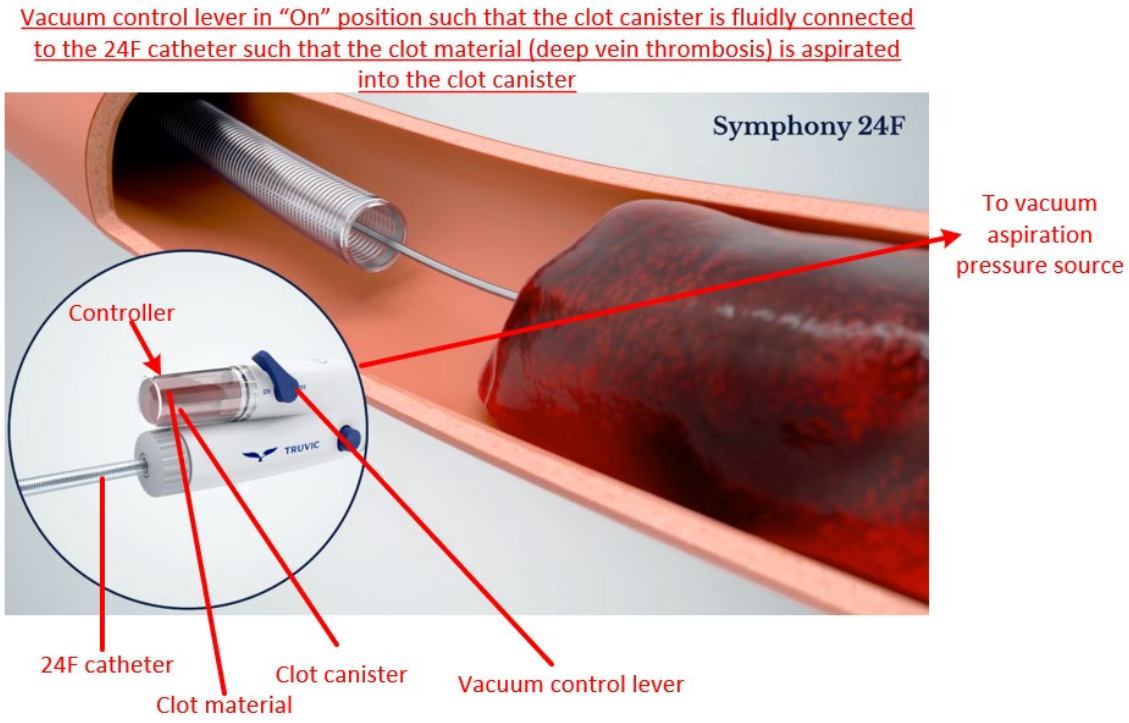
(Annotated image of Symphony housing (internal).)



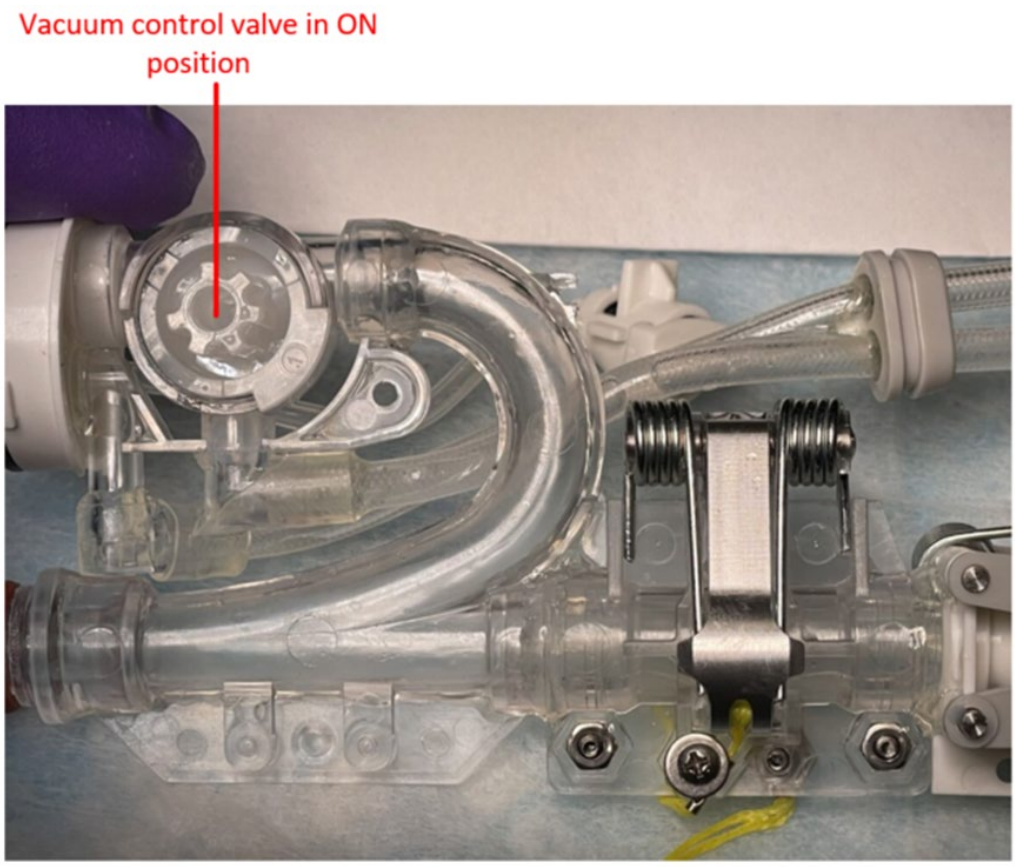
(Annotated screen capture from Symphony product video.)

244. ~~241.~~ Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 1, including "fluidly connecting the pressure

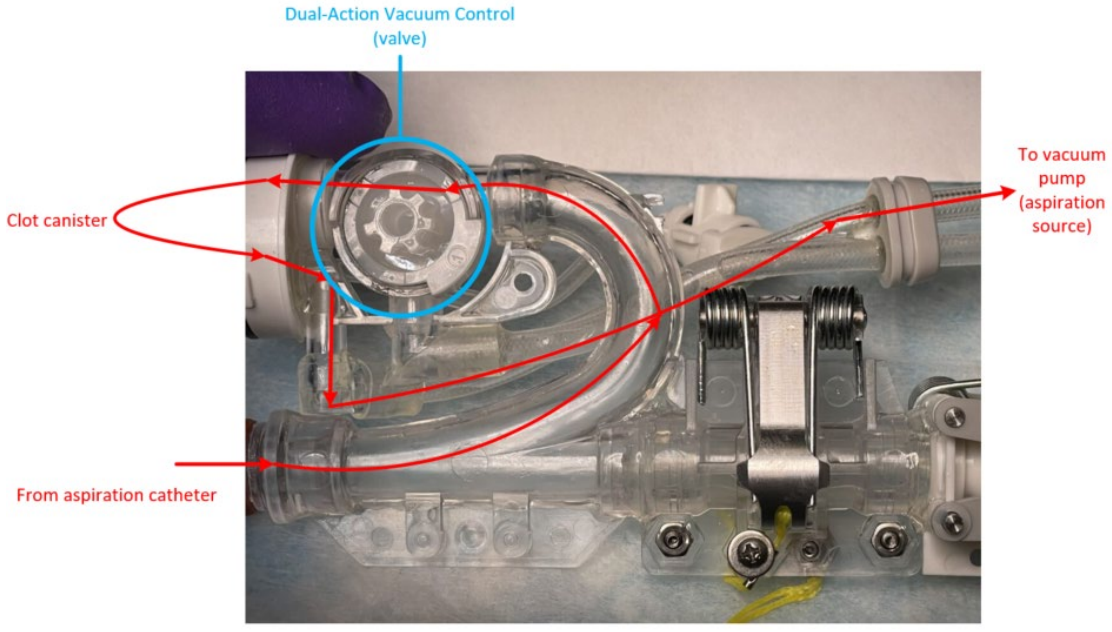
source to the elongated shaft to apply the pre-charged vacuum to the elongated shaft to aspirate a first portion of the clot material into the elongated shaft," as can be seen in Exhibit T. Specifically, during thrombectomy using the Symphony system, the user moves the vacuum lever on the 16F and/or 24F handles to the "ON" position, which actuates a valve in the handle, applying vacuum from the vacuum pump aspiration source (*e.g.*, the Truvic Generator and Truvic Canister) to the lumen of the 16F and/or 24F aspiration catheters to aspirate clot:



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)



(Annotated image of internal portion of controller handle housing.)

245. ~~242.~~ The Symphony IFU further teaches to fluidly connect the catheter to the stored vacuum by turning the vacuum lever to "on" to aspirate a portion of the clot.

12. Confirm the Handle vacuum lever is in the "OFF" position and open the stopcock on the Tubing.
13. Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
14. Confirm tip of the Symphony Catheter is in the desired location.
15. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.
16. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the "OFF" position.
17. If aspiration in another location is desired, reposition the tip of the Catheter using the Dilator, as necessary.
18. Confirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle.

(Ex. B at 5-6, 8-9.)

246. ~~243.~~ Thrombectomy with the Symphony system using a ProHelix device practices the limitations of claim 1, including "unsealing an attachment member coupled to a proximal portion of the elongated shaft," and "advancing an interventional device distally through the attachment member and the elongated shaft," as can be seen in Exhibit T. Specifically, when using the ProHelix device, Truvic teaches to push the buttons on the 24F or 16F Symphony Handle to release the hemostasis valve and then to advance the ProHelix device over the guidewire to the clot. (Ex. B at 2 ("Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device."), 5 ("Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle."), 6 ("During ProHelix movement, press the Hemostasis Valve buttons on the Handle to reduce friction.").)

247. ~~244.~~ Thrombectomy with the Symphony system using a ProHelix device practices the limitations of claim 1, including "engaging the interventional device with a second portion of the clot material remaining within the blood vessel," as can be seen in Exhibit T. Specifically,

the IFU teaches users to employ a ProHelix device during procedures to engage a lot and clear clot obstructing the catheter tip, "[t]o resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix."

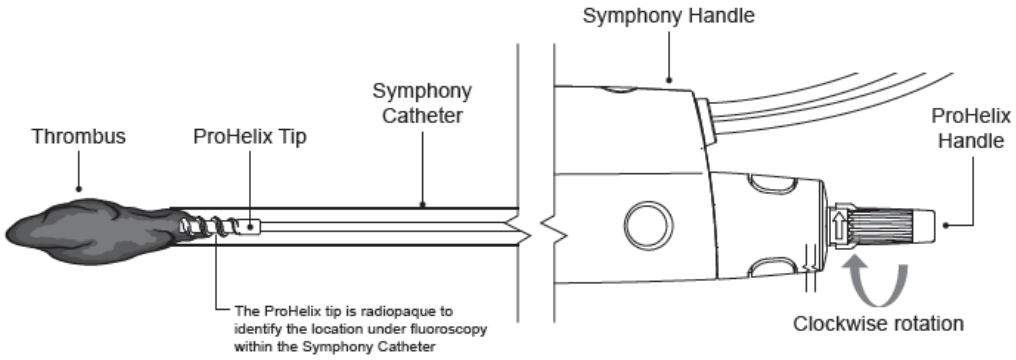
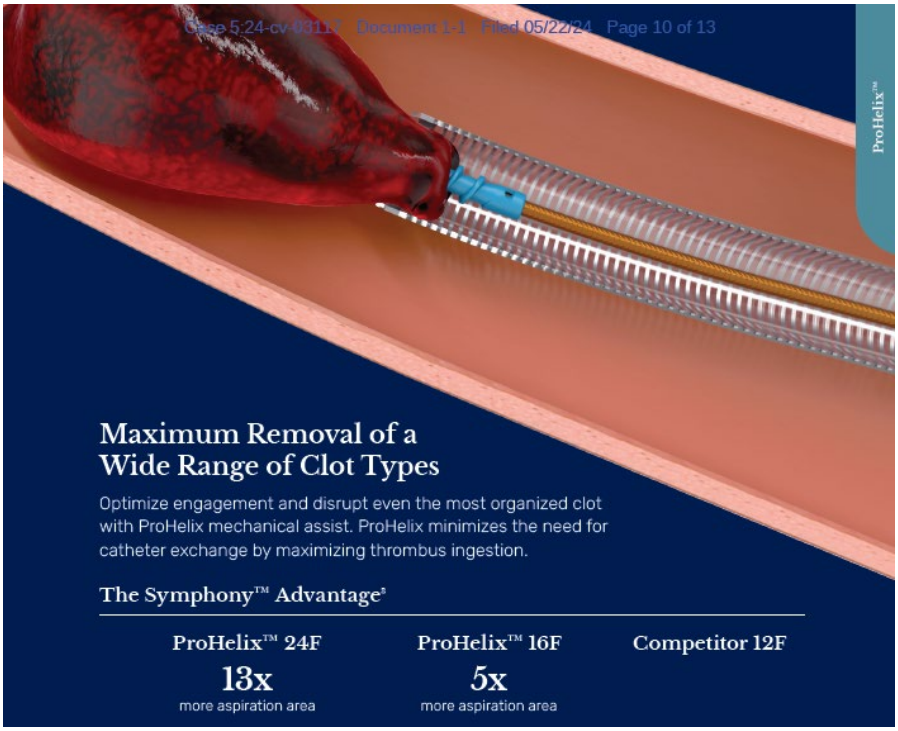


Figure 4: ProHelix engaged with thrombus

(Ex. B at 5.) Truvic's Symphony Brochure shows this as well, as does ~~Truvic's~~the Symphony



video.

(Ex. A at 10; *see also* https://vimeo.com/817718796.)

248. ~~245.~~ Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 18, including "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." Specifically, as can be seen in the images from page 4 of the IFU below, the Symphony system handle has a clot container with a filter chamber coupled between the Truvic Generator vacuum pump and the aspiration catheter that captures and filters clot material from blood during thrombectomy:

24F OR 16F SYMPHONY SYSTEM PREPARATION AND USE

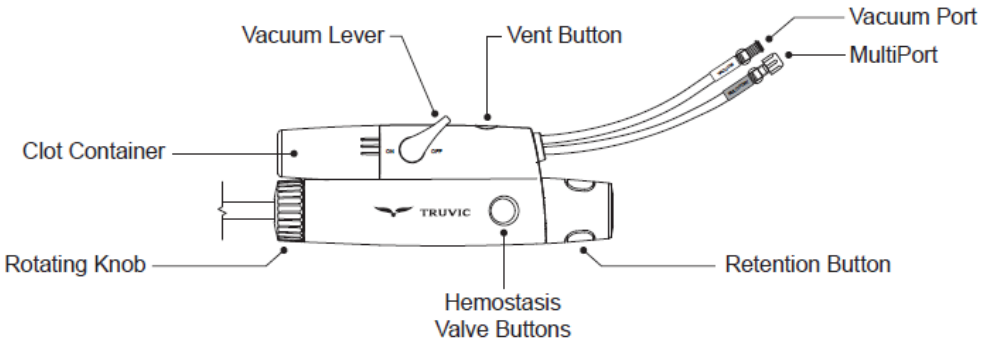
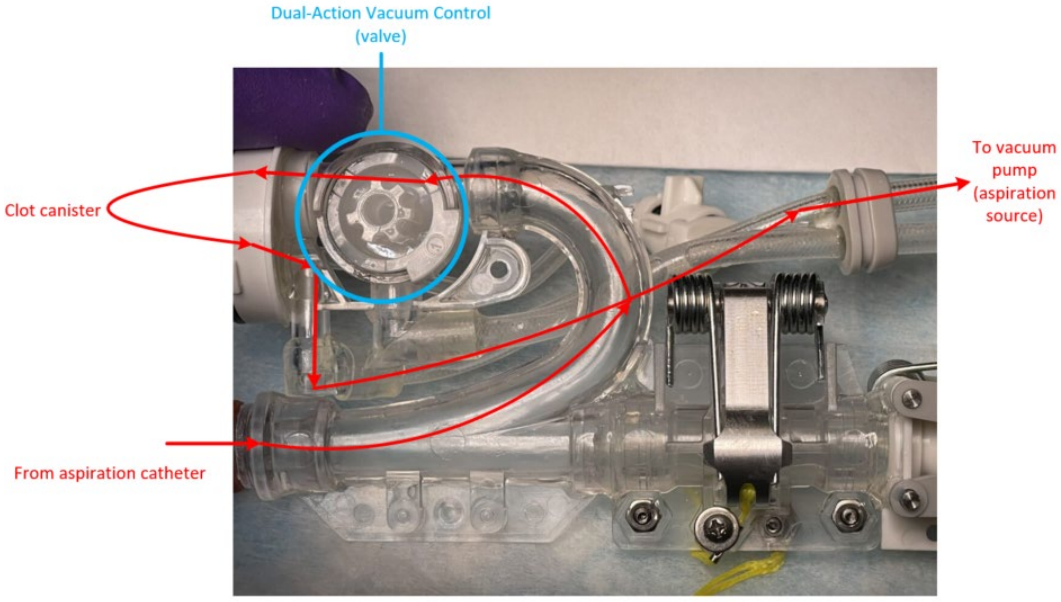


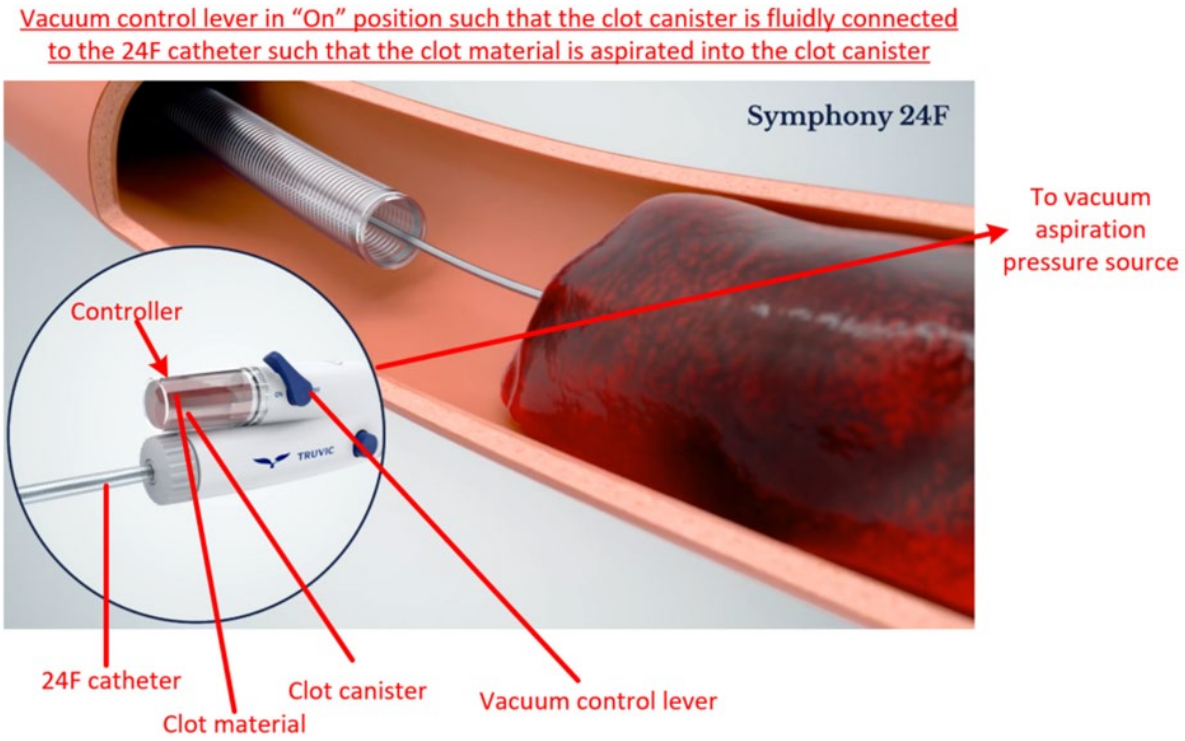
Figure 3: Symphony Catheter Handle, labeled

(Ex. B at 4.) The fluid path from the aspiration catheter, through the clot canister to the vacuum pump is labeled in the annotated teardown image below:

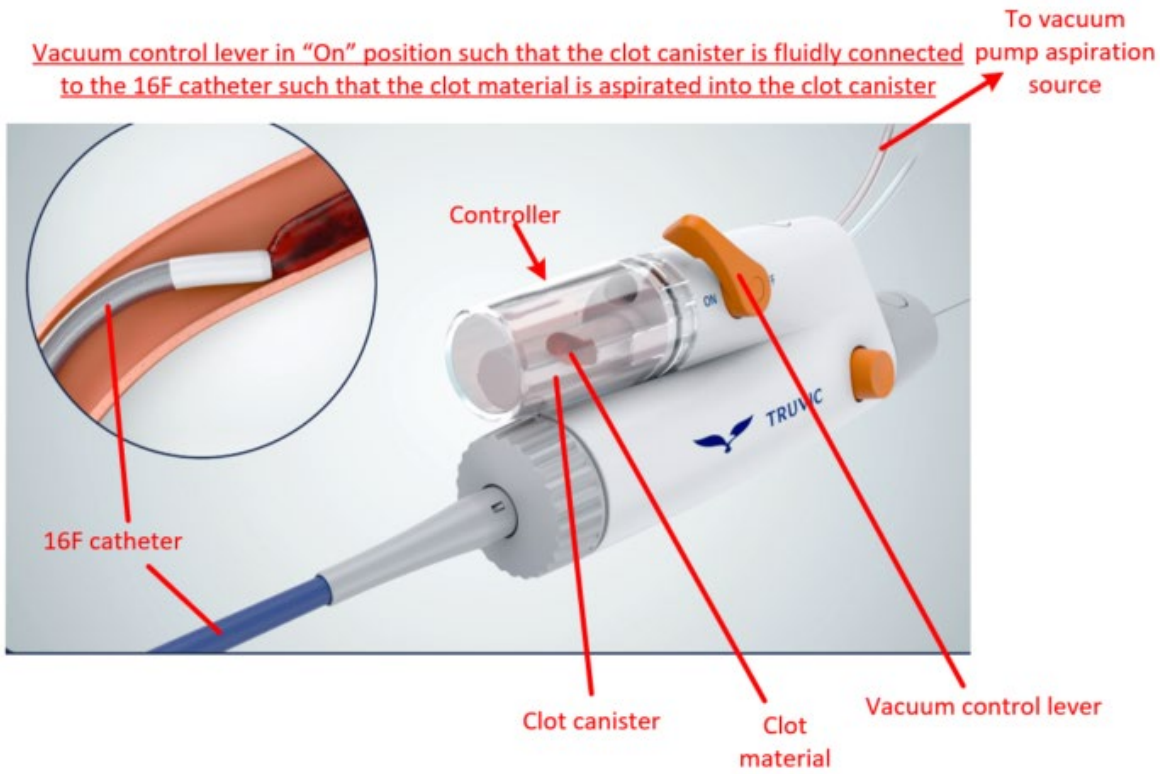


(Annotated image of internal portion of controller handle housing.) The clot container includes a removable filter chamber including a housing and removable filter, as can be seen in the

annotated images captured from of the Symphony video below:



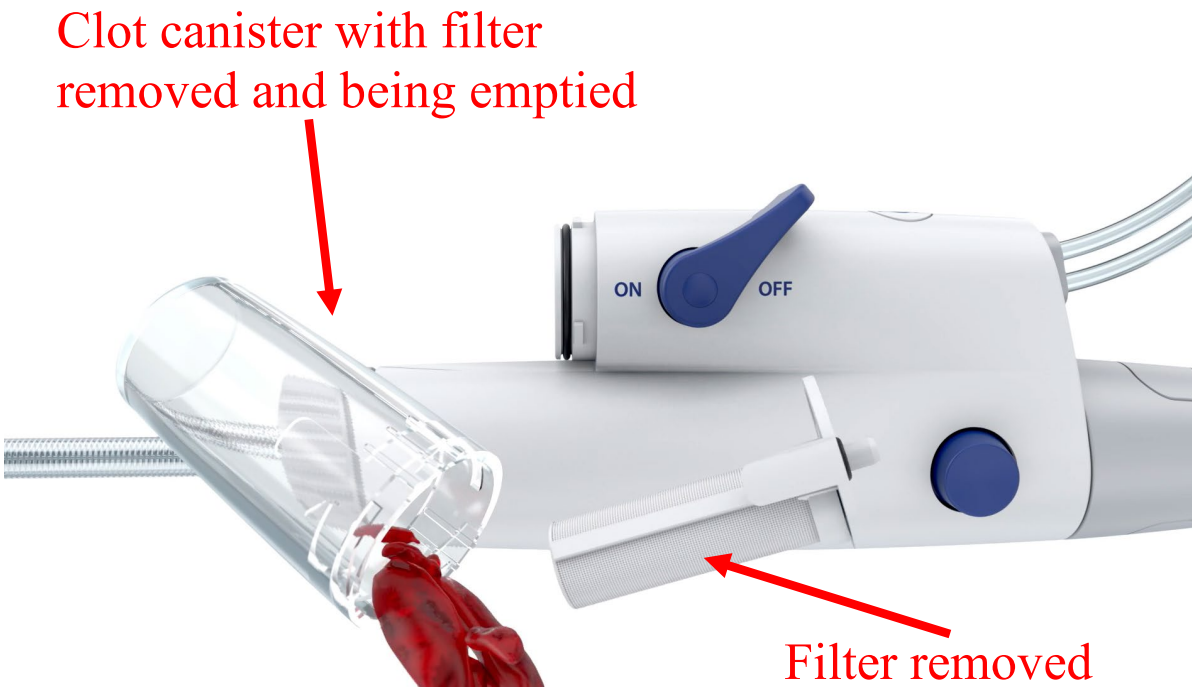
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:45 (~~https://www.truvic.com/symphony-product)~~https://www.truvic.com/symphony-product).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:55 (https://www.truvic.com/symphony-product).)

249. ~~246.~~ Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 19, including "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." Specifically, as can be seen in the annotated images from the Symphony video below, Symphony system's clot canister includes a removable filter chamber and a removable filter. To empty the collected clot from the clot canister, the operator removes the clot canister containing the clot and filter, and then removes the filter and the clot from the clot canister housing:

(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:18 (https://www.truvic.com/symphony-product).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

(Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

250. ~~247.~~ The clear clot container also allows visual access to the captured clot.

251. ~~248.~~ Defendant directly infringes claims of the '580 Patent, including claims 18 and 19 when Defendant or persons under its direction and control perform thrombectomy procedures using Symphony system with a ProHelix device. For example, Defendant directly infringes claims 18 and 19 when testing or using the Symphony system in patients.

252. ~~249.~~ Defendant induces infringement of claims of the '580 Patent, including claims 18 and 19 by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony systems in a manner that practices the methods of claims 18 and 19. Defendant actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures with the Truvic Symphony system using a ProHelix device in a manner that practices the limitations of claims of the '580 Patent, including claims 18 and 19. Defendant instructs and teaches users to perform methods that practice the limitations of claims 18 and 19 with knowledge and/or willful blindness that such acts constitute direct infringement of the '580 Patent.

253. ~~250.~~ Defendant, for example, provides Instructions For Use that state that the

"Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.… The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) The IFU further teaches users to employ a ProHelix device during procedures to engage a clot and clear clot material obstructing the catheter tip, "[t]o resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix."

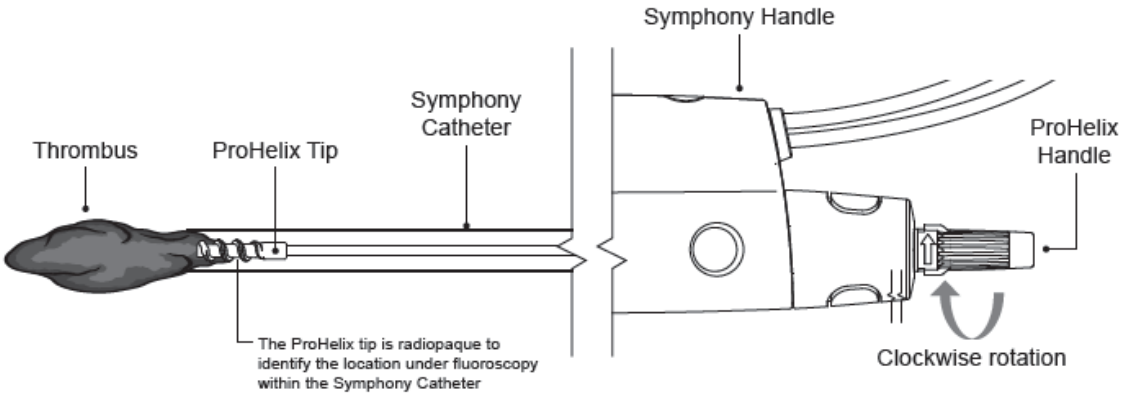


Figure 4: ProHelix engaged with thrombus

(Ex. B at 5.)

254. ~~251.~~ Defendant further provides brochures and other materials, including animation videos, that detail how to use the Truvic Symphony system in a manner that practices claims of the '580 Patent, including claims 18 and 19. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding methods of using the Truvic Symphony system, including methods of treating clots use a ProHelix device that practice the claims of the '580 Patent.

255. ~~252.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '580 Patent

and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

256. ~~253.~~ Defendant's infringement is with knowledge of the '580 Patent and its claims. Specifically, as described above, Inari notified Defendant, by letter dated September 29, 2023, that its products would infringe claims of United States Patent Application No. 17/498,642 ("the '642 Application"), when issued. Inari further attached the published version of this application (United States Published Application No. 2022/0240959) with claim 21, which later issued as claim 1 in identical or substantially identical form.

257. ~~254.~~ At a minimum, Defendant has notice of the '580 Patent through the filing of ~~this~~the First Amended Complaint, which was submitted to the Court just a few weeks after the '580 Patent issued.

258. ~~255.~~ Defendant has continued its infringing activities after the '580 Patent issued, despite knowledge of the '580 Patent (including knowledge from correspondence with Inari and from ~~this~~the First Amended Complaint), and such infringement has been and continues to be egregious and willful.

259. ~~256.~~ The requirements of 35 U.S.C. § 287(a) have been met for the '580 Patent. Because the '580 Patent contains only method claims, no marking is required.

260. ~~257.~~ The requirements of 35 U.S.C. § 154(d) have been met for the published claims of Publication No. 2022/0240959 from September 29, 2023, to the issuance of the '580 Patent.

261. ~~258.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 9: INFRINGEMENT OF THE '384 PATENT

262. ~~259.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

263. ~~260.~~ The '384 Patent, titled "Hemostasis Valves and Methods of Use," is part of the same family as the '921, '012, and '291 Patents, and shares the same specification. The '384 Patent discloses improved hemostasis valves and methods of their use. (*See, e.g.*, Ex. K at Abstract, 1:65-2:4.) Hemostasis valves are used to seal, *e.g.*, to seal around catheters, in order

to minimize blood loss, and maintain sterility within the body, such as in a blood vessel. (*Id.* at 1:36-51.) This is critical during surgical procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (*See id.* at 1:25-33.) Improved hemostasis valves are important to maximize patient outcomes, including by providing ease of use (*e.g.*, one-handed use) for doctors and practitioners and effective sealing. (*See id.* at 1:52-61, 5:55-6:6.)

264. ~~261.~~ The '384 Patent discloses hemostasis valves having an elongate tubular member defining a lumen, where the hemostasis valve further has a constricting mechanism that includes a first filament extending in a first loop, a second filament extending in a second loop, and a pair of actuators that are movable between a first position to tension the first and second filament and constrict the lumen of the tubular member and a second position to loosen the first and second filament and partially open the lumen of the tubular member. (*See id.* at cl. 1, Fig. 8, 3:1-18.) The '384 Patent further is directed to embodiments where one of the actuators acts on a first end portion of the first filament and the other actuator acts on a second end portion of the first filament, and the second filament similarly has one end portion acted on by the first actuator and a second end portion acted on by a second actuator. (*See id.* at cl. 1, cl. 3.)

265. ~~262.~~ Defendant directly and indirectly infringes—literally and/or under the doctrine of equivalents—at least claims 1 and 3 of the '384 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

266. ~~263.~~ Specifically, claim 1 recites:

> [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 the 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;

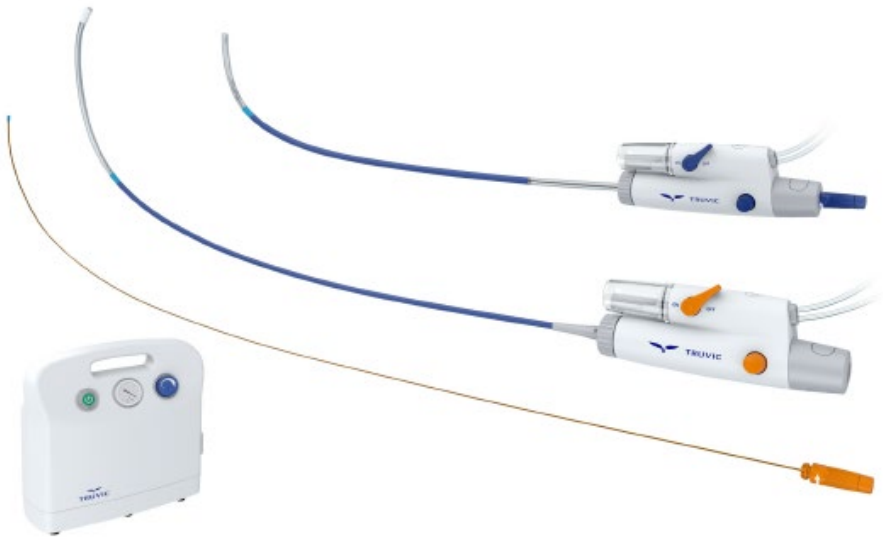
in the second position, the actuators are positioned to loosen the first filament and the second filament thereby permitting the tubular member to expand against the first loop and the second loop to increase the dimension of the first loop and the dimension of the second loop to at least partially open the lumen of the tubular member; and

the actuators are biased to the first position.

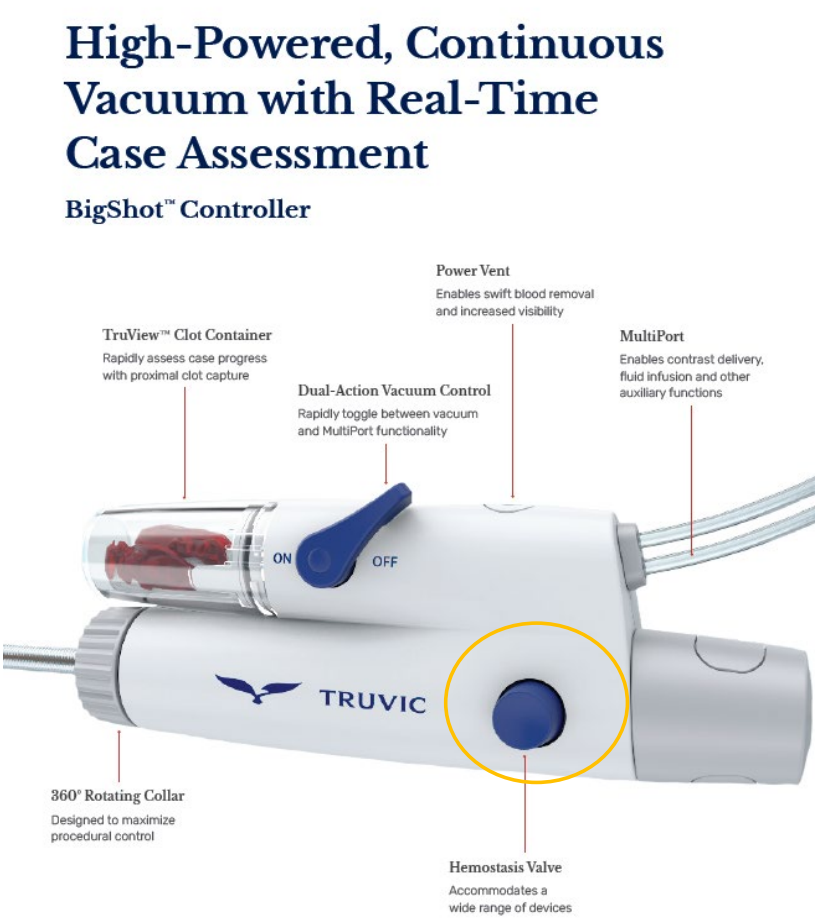
267. ~~264.~~ Dependent claim 3 recites:

> [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.

268. ~~265.~~ The hemostasis valves of the Symphony system practice the elements of claim 1, including the preamble, "[a] valve assembly comprising," as can be seen in Exhibit U. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle). Documentation for the Symphony system makes clear that the controller handles have a hemostasis valve, controlled by the buttons on the handles, as can be seen in the excerpts and the teardown photos below.



(Ex. A at 2.)

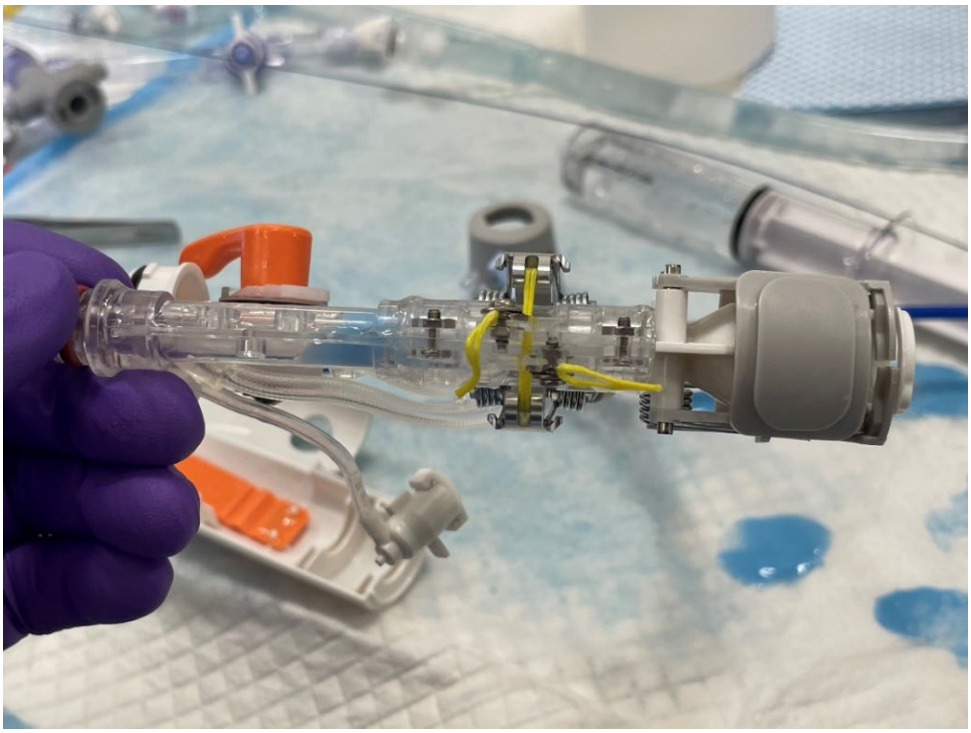

High-Powered, Continuous Vacuum with Real-Time Case Assessment
BigShot™ Controller
Power Vent
Enables swift blood removal and increased visibility
TruView™ Clot Container
Rapidly assess case progress with proximal clot capture
MultiPort
Enables contrast delivery, fluid infusion and other auxiliary functions
Dual-Action Vacuum Control
Rapidly toggle between vacuum and MultiPort functionality
ON
OFF
TRUVIC
360° Rotating Collar
Designed to maximize procedural control
Hemostasis Valve
Accommodates a wide range of devices

(Annotated Ex. A at 6.)

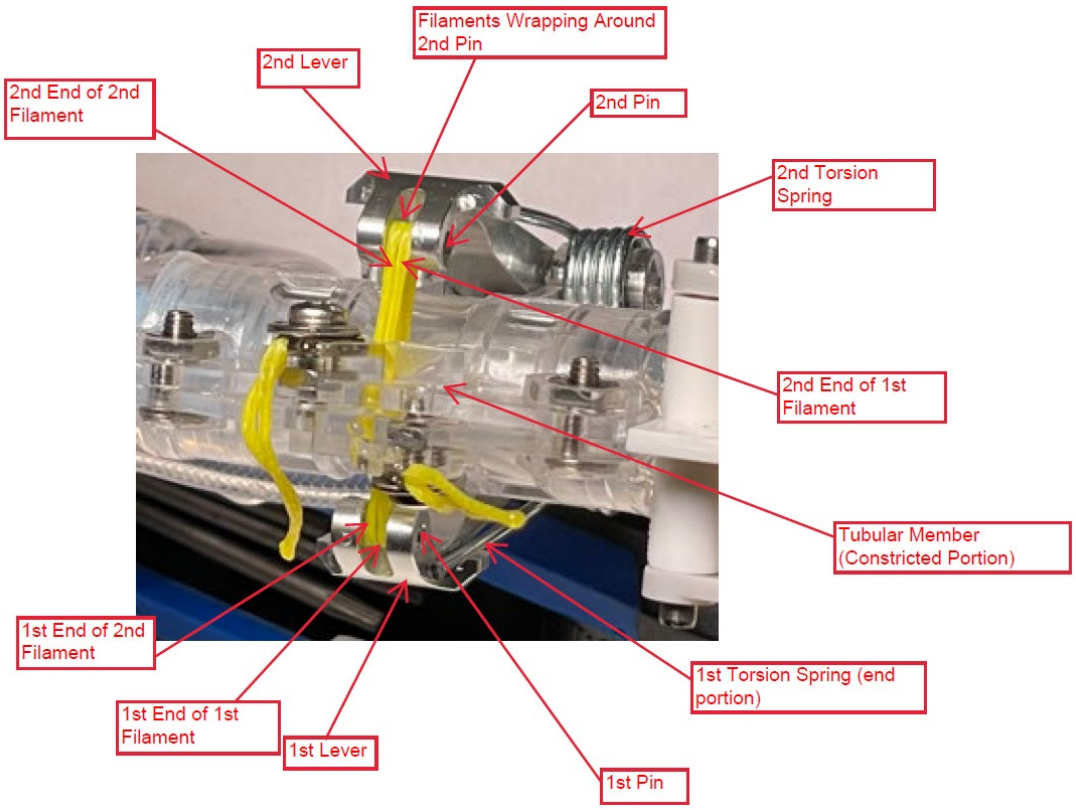
(Image of internal portion of housing with hemostasis valve.)

(Image of internal portion of housing zoomed in on hemostasis valve.)

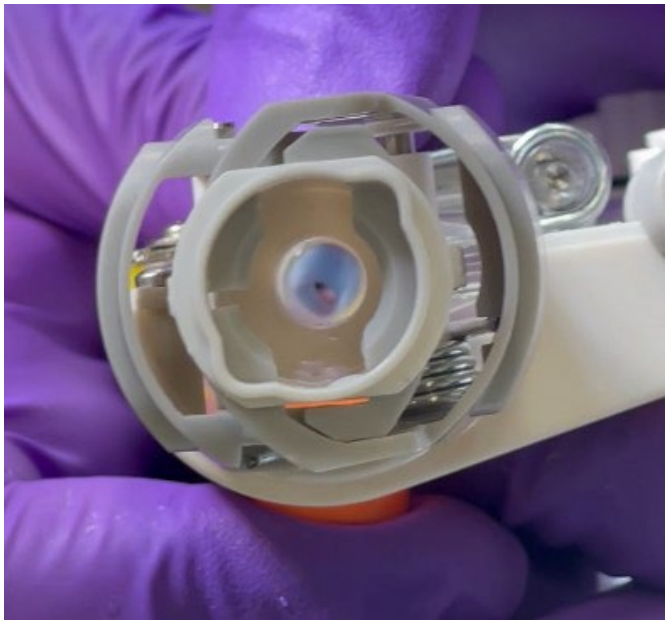
269. ~~266.~~ The Symphony system practices the limitations of claim 1, including "a tubular member defining a lumen," as can be seen in Exhibit U. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle) that include an elongate tubular member that defines a lumen, as can be seen in the teardown images below.



(Image of internal portion of housing with hemostasis valve.)

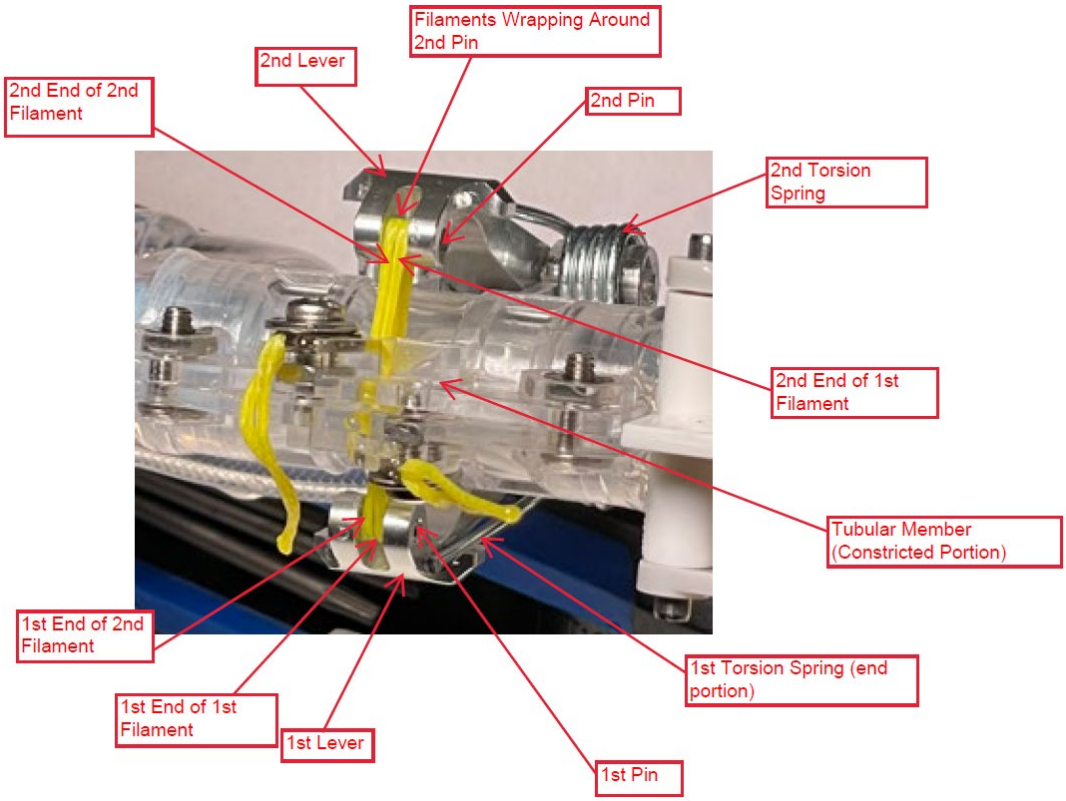


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

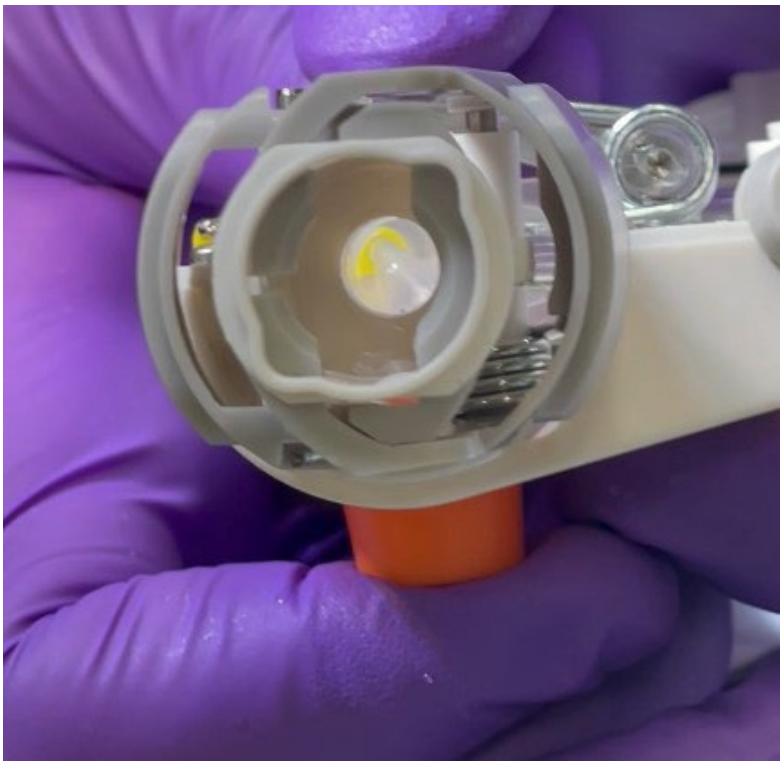


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

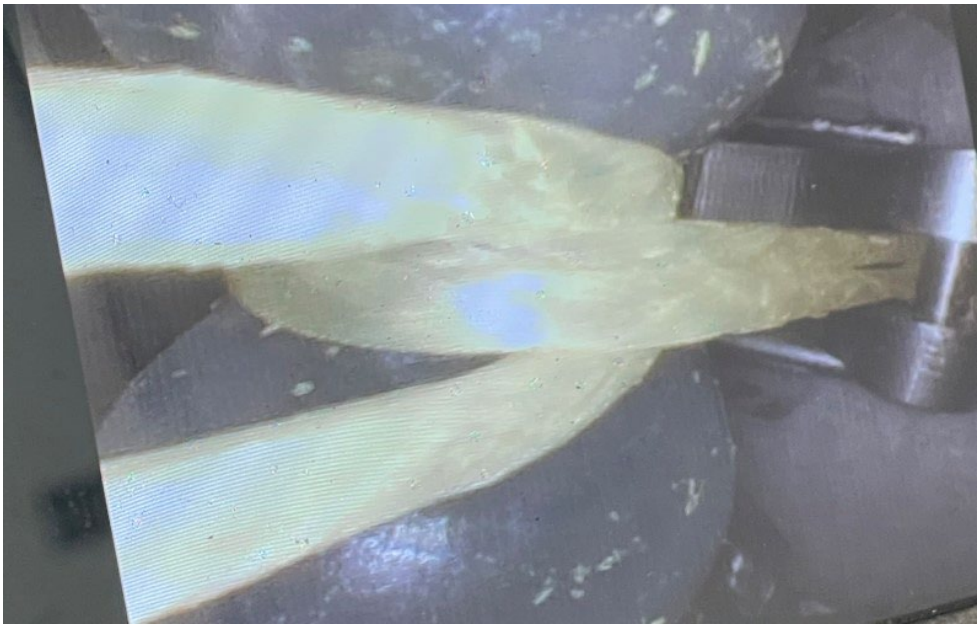
270. ~~267.~~ Thrombectomy with the Symphony system practices the limitations of claim 1, including "a first filament extending in a first loop around the tubular member, wherein the first filament is flexible," as can be seen in Exhibit U. Specifically, the controller handles of the Symphony system include a hemostasis valve with an active tensioning mechanism where a first and second button control first and second levers and first and second pins coupled to first and second lines (filaments) that loop around the valve's elongate tubular member defining a lumen, and the first and second filaments forming loops are flexible, as can be seen in the teardown images below. The first and second filaments are braided filament lines, which are flexible.



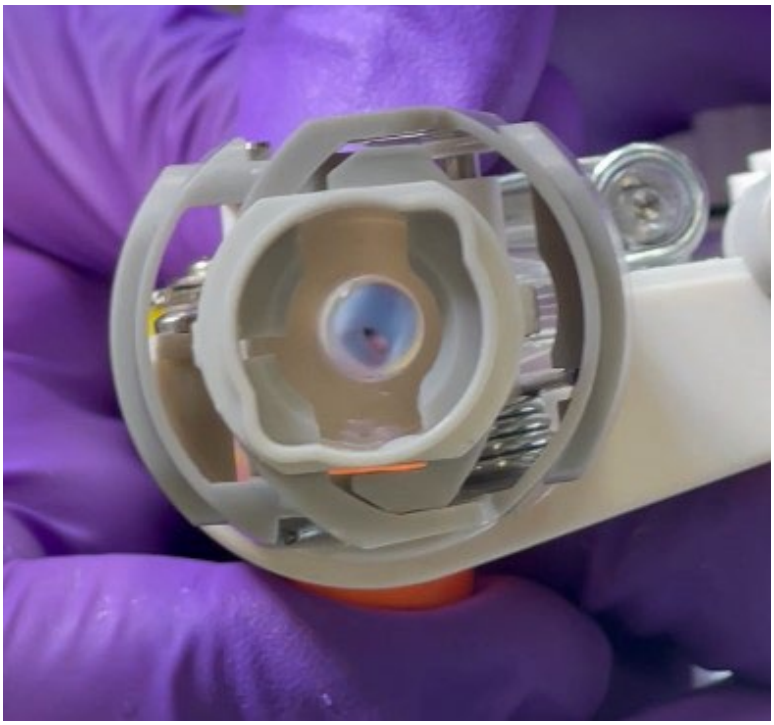
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

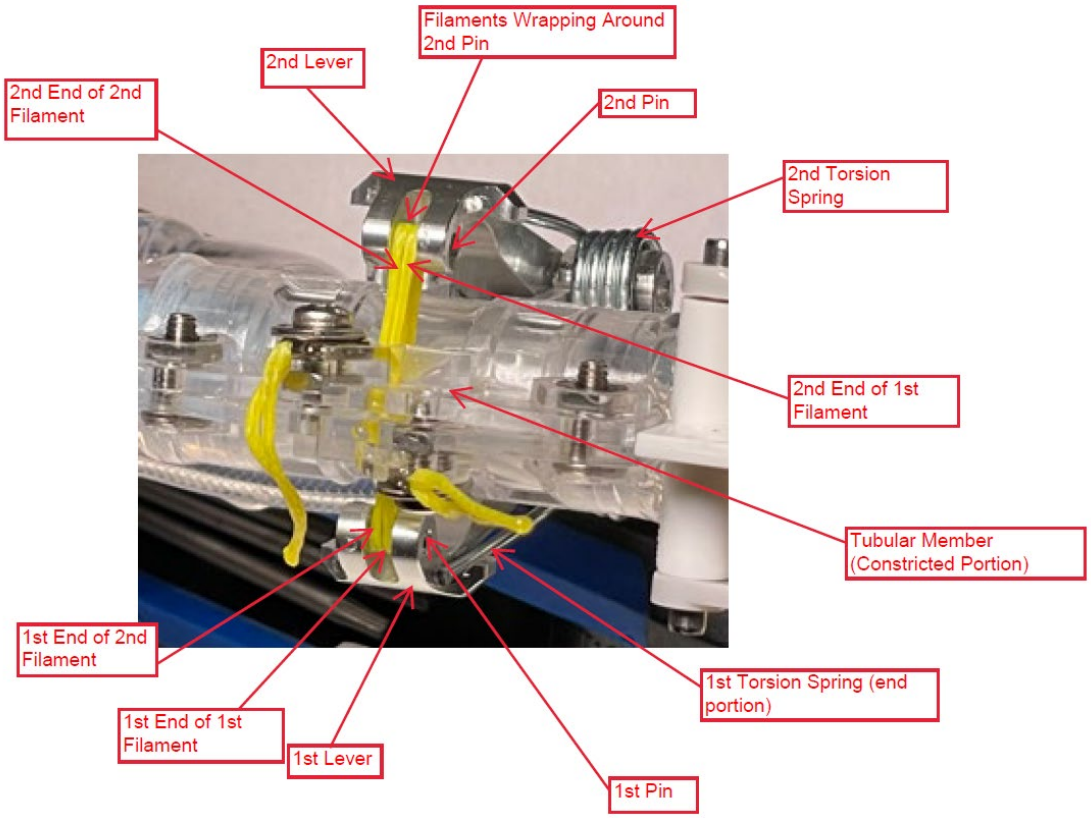


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

271. ~~268.~~ Thrombectomy with the Symphony system practices the limitations of claim 1, including "a second filament extending in a second loop around the tubular member, wherein the second filament is flexible," as can be seen in Exhibit U, and in the preceding limitation. The first and second filaments are braided filament lines, which are flexible.

272. ~~269.~~ The Symphony system practices the limitations of claim 1, including "a pair of actuators movable from a first position to a second position," as can be seen in Exhibit U. Specifically, the controller handles of the Symphony system include a hemostasis valve with an active tensioning mechanism with two actuators where a first and second button control first and second levers and first and second pins coupled to lines (filaments) that loop around the valve's elongate tubular member defining a lumen. The first actuator includes the first button/lever/pin to which the first ends of each of the first and the second filaments (lines) are wrapped around and the second actuator includes the second button/lever/pin to which the second ends of each of the first and the second filaments (lines) are wrapped around. The first and second actuators move between a first (undepressed button) position where the lumen of the valve is constricted

to a second (depressed button) position wherein the lumen is less constricted and at least partially open, as can be seen in the teardown images below.



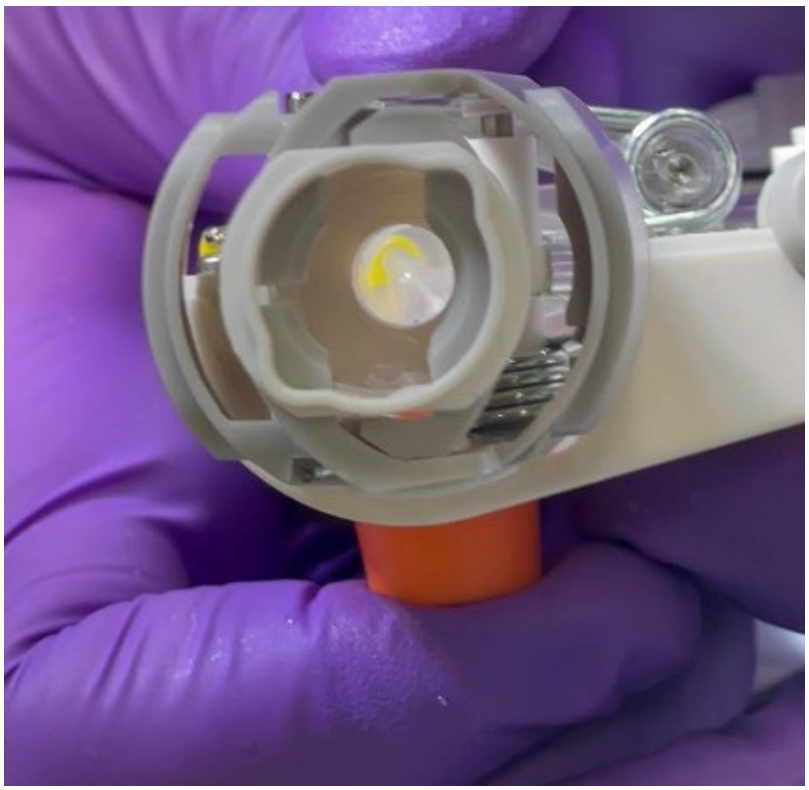
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

273. ~~270.~~ The Symphony system practices the limitations of claim 1, including "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," as can be seen in Exhibit U. Specifically, as can be seen in the teardown image above, the first end portion of the first filament is coupled to and acted upon by the first actuator (button/lever/pin), and the second end portion of the first filament is coupled to and acted upon by the second actuator (button/lever/pin).

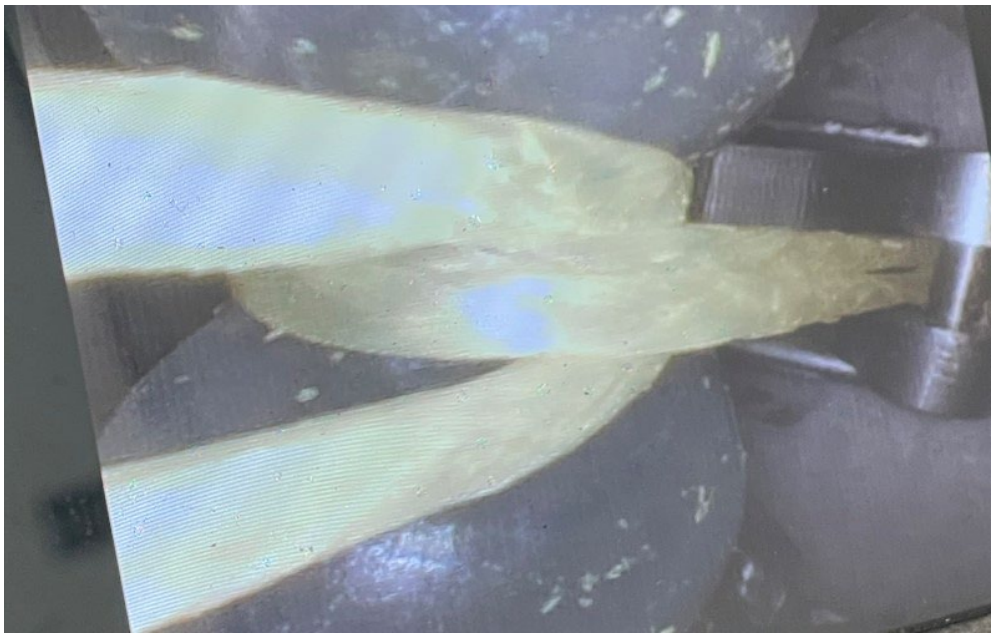
274. ~~271.~~ The Symphony system practices the limitations of claim 1, including "a second filament includes a first portion operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators," as can be seen in Exhibit U. Specifically, as can be seen in the teardown image above, the first end portion of the

second filament is coupled to and acted upon by the first actuator (button/lever/pin), and the second end portion of the second filament is coupled to and acted upon by the second actuator (button/lever/pin).

275. ~~272.~~ The Symphony system practices the limitations of claim 1, including "in the first position, the actuators are positioned to tension the first filament and the second filament thereby decreasing the dimension of the first loop and a dimension of the second loop to constrict the lumen of the tubular member," as can be seen in Exhibit U. Specifically, when the actuators are in the first (undepressed buttons) position, the actuators tension the first filament and the second filament, decreasing the dimension of the first loop in the first filament and the second loop in the second filament to constrict the tubular member, as can be seen in the teardown images below.

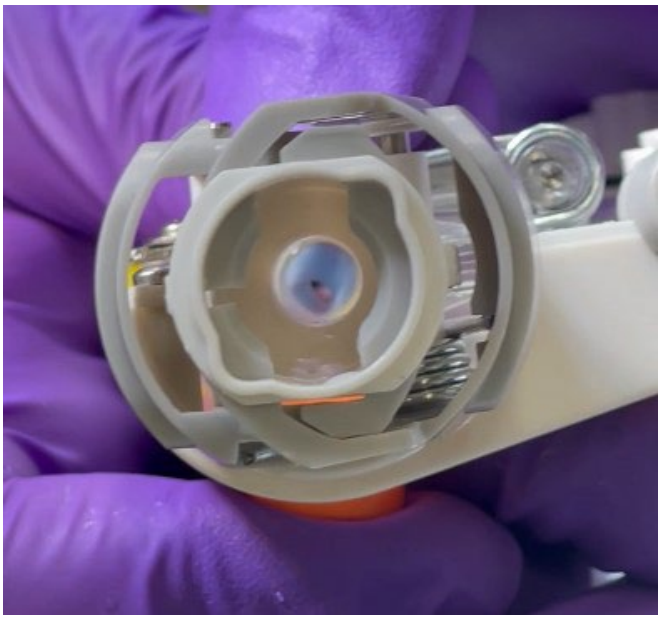


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



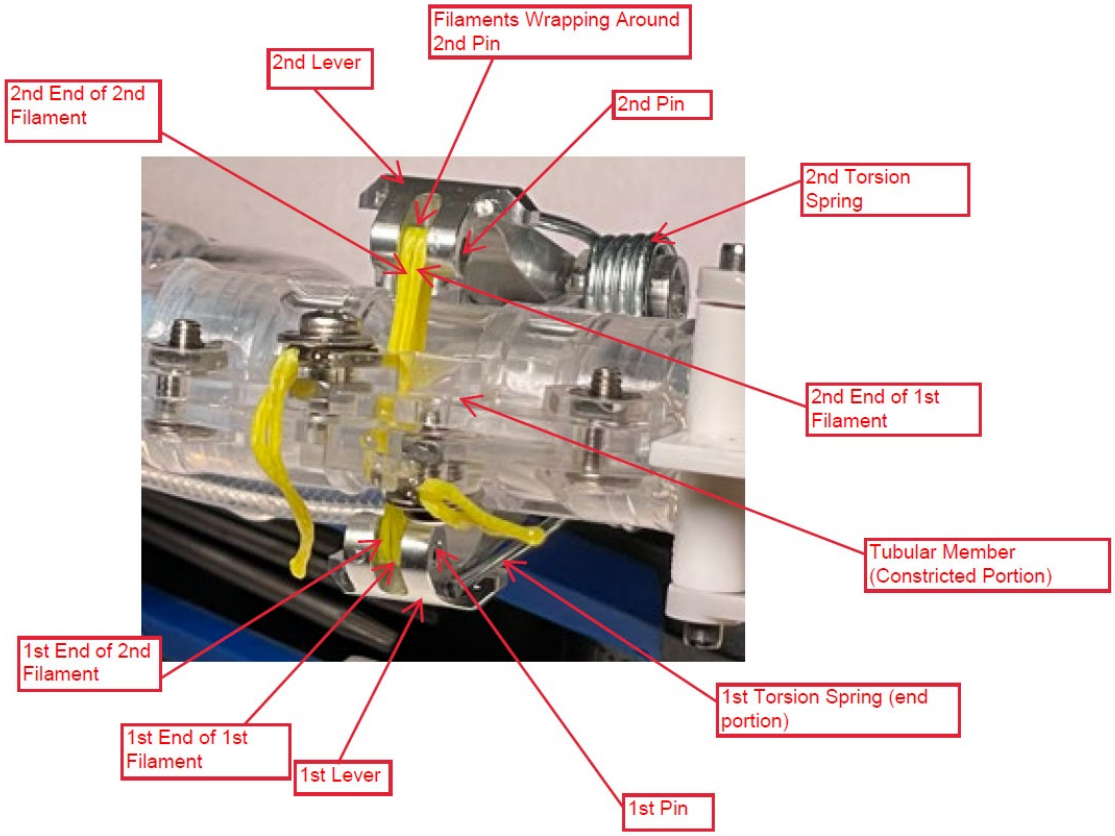
(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

276. ~~273.~~ The Symphony system practices the limitations of claim 1, including "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," as can be seen in Exhibit U. Specifically, when the actuators are in the second (depressed buttons) position, the actuators push and loosen tension on the first filament and the second filament, allowing the dimension of the first loop in the first filament and the second loop in the second filament to increase and at least partially open the tubular member, as can be seen in the teardown images below.

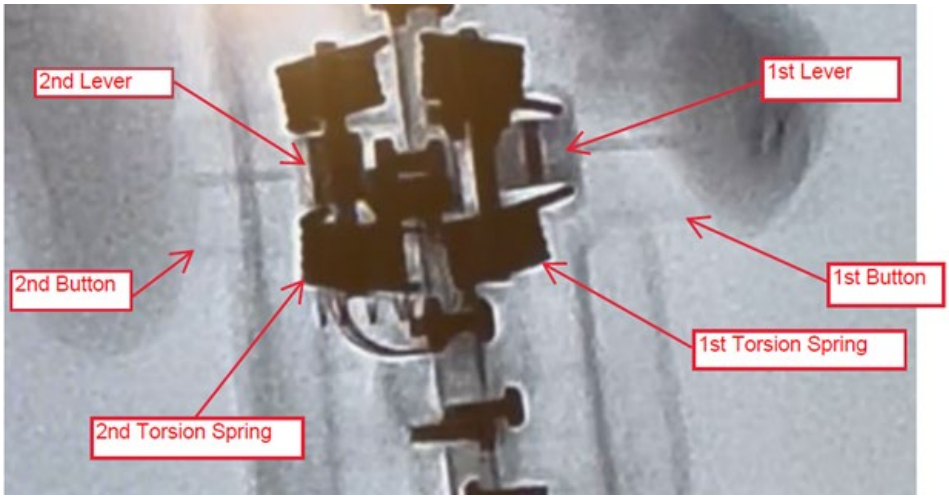


(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve open.)

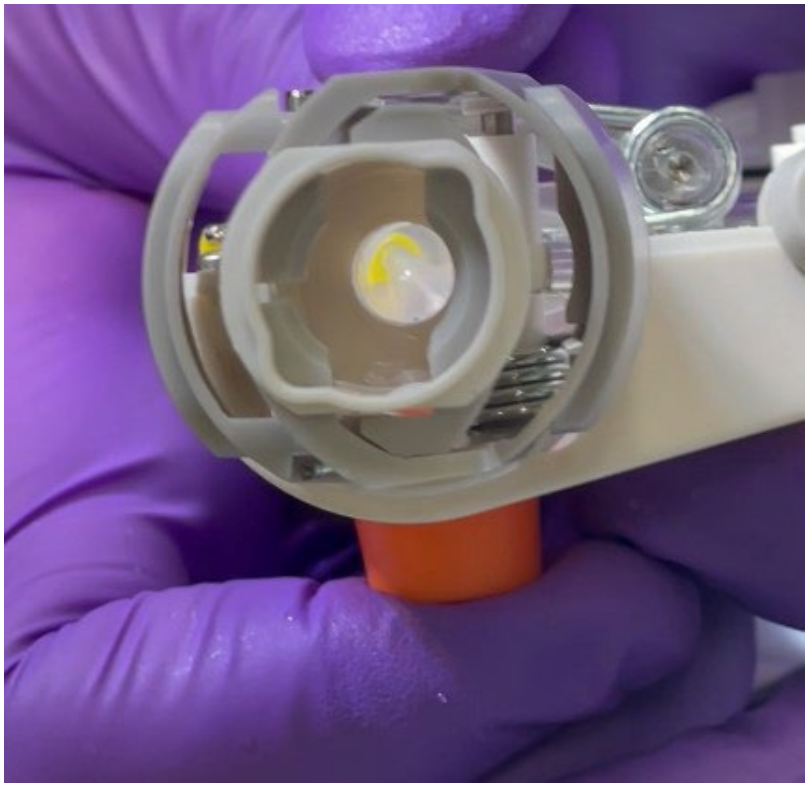
277. ~~274.~~ The Symphony system practices the limitations of claim 1, including "the actuators are biased to the first position," as can be seen in Exhibit U. Specifically, the first and the second actuators are driven outward/biased to the first (constricted, undepressed button) position by first and second sets of torsion springs that drive the first lever and the second lever outward, as can be seen in the teardown images below.



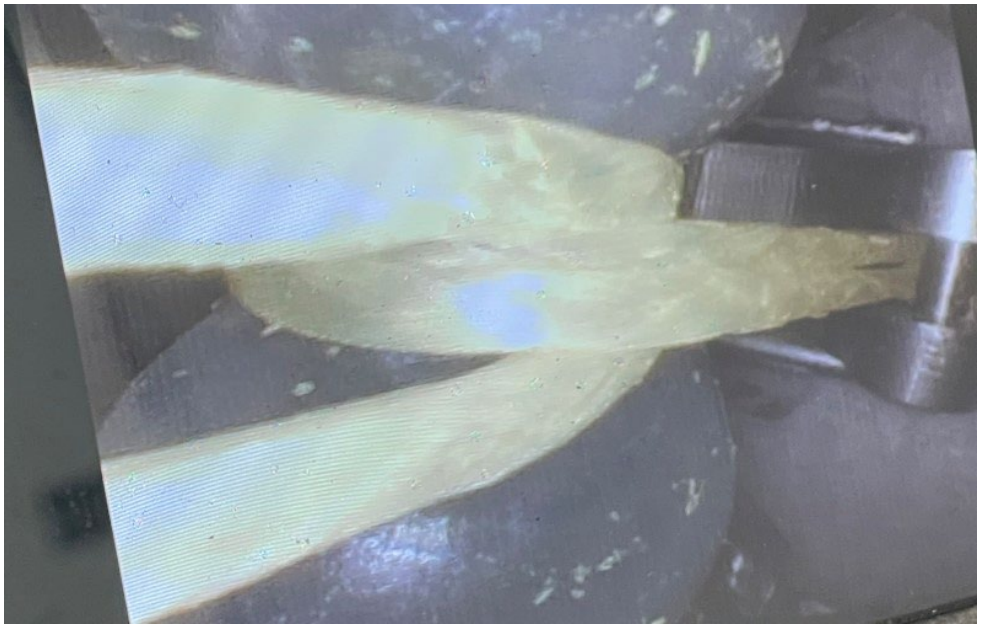
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs.)

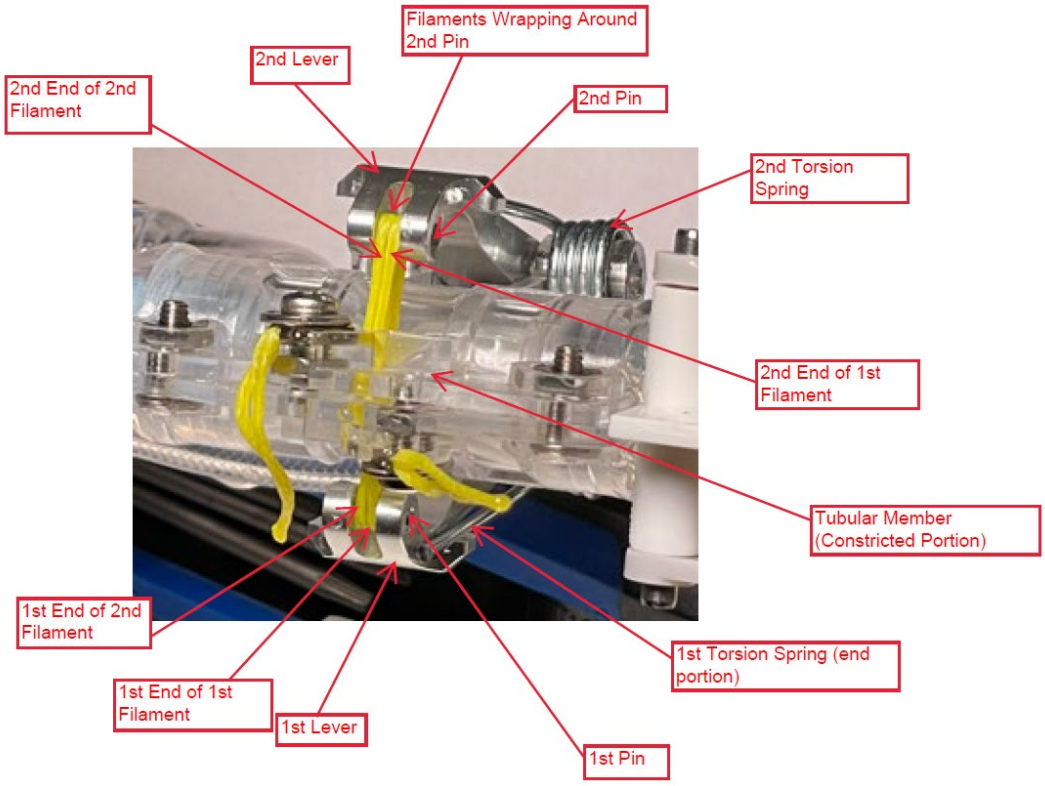


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)



(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

278. ~~275.~~ Thrombectomy with the Symphony system practices the limitations of claim 3, including "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," as can be seen in Exhibit U. Specifically, the first end portions of the first and second filaments are wrapped around and acted upon by the first actuator, as can be seen in the teardown images below.



(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

(Image of internal portion of housing with hemostasis valve.)

(Image of internal portion of housing zoomed in on hemostasis valve.)

279. ~~276.~~ Thrombectomy with the Symphony system practices the limitations of claim 3, including 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," as can be seen in Exhibit U. Specifically, the second end portions of the first and second filaments are wrapped around and acted upon by the second actuator, as can be seen in the teardown images above.

280. ~~277.~~ Defendant directly infringes claims of the '384 Patent, including claims 1 and 3, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures using the hemostasis valves) Symphony system products.

281. ~~278.~~ Defendant induces infringement of claims of the '384 Patent, including claims 1 and 3, by selling Symphony systems (and components thereof) and teaching or directing others, including physicians, to use the Symphony products that practice claims 1 and 3. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

282. ~~279.~~ Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels…. The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding method of using the Truvic Symphony system,

including on information and belief, methods of treating thrombi and emboli.

283. ~~280.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system (and components thereof), knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '384 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

284. ~~281.~~ At a minimum, Defendant has notice of the '384 Patent through the filing of ~~this~~the Second Amended Complaint. On information and belief, Defendant has had knowledge of the '384 Patent via monitoring and investigation of Inari's patent portfolio, including in response to the notice letters provided by Inari regarding many other patents, including family members of the '384 Patent.

285. ~~282.~~ Defendant has continued its infringing activities after the '384 Patent issued, despite knowledge of the '384 Patent (including from the Second Amended Complaint), and such infringement has been and continues to be egregious and willful.

286. ~~283.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 10: INFRINGEMENT OF THE '669 PATENT

287. ~~284.~~ Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

288. ~~285.~~ The '669 Patent, titled "Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods," is part of the same family as the '580 Patent and shares the same specification. The '669 Patent discloses improved clot-removing devices for intravascular treatment of clot materials that solve problems with prior art clot-removal devices and methods. The '669 Patent solves these problems through its inventions and combination of inventions that include, for example, a vacuum source that is coupled to both an elongated shaft, *e.g.*, a catheter, and a filter chamber via a flow controller and a first fluid path. (Ex. L at cl. 15.) The filter chamber includes a housing and filter, where the housing further includes a first port coupled to the catheter and a second port coupled to the vacuum source, and

the filter is in the housing along a first fluid path that includes a flow controller to couple the filter chamber and catheter. (*Id.*) A hemostasis valve is coupled to the catheter along a second fluid path that is at least partially different than the first, where the hemostasis valve inhibits flow along the second path when an interventional device is inserted. (*See id.*, Fig. 10, 3:53-4:3.)

289. ~~286.~~ The '669 Patent further solves problems in the art through a filter chamber, or clot reservoir container, having a removable filter. (*E.g.*, *id.* at Fig. 3B, Fig. 3C, cl. 22.) The '669 Patent teaches that the filter chamber/clot reservoir and filter capture clot material within a housing, while filtered blood is allowed to flow through. (*Id.* at Fig. 3A, Fig. 3B, Fig. 3C, 8:60-9:60.) A filter that is removable from within the housing allows the treating physician to visualize the captured clot material to help determine whether additional passes are necessary and to remove clot that has been collected by removing and emptying the filter housing. (*Id.*) As disclosed in other Inari patents, filtered blood can also be reintroduced to the patient's vasculature.

290. ~~287.~~ Defendant directly infringes and indirectly infringes—literally and/or under the doctrine of equivalents—at least claim 15 of the '669 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

291. ~~288.~~ Specifically, claim 15 of the '669 Patent recites:

> [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.

292. ~~289.~~ The Truvic Symphony system practices each limitation of at least claim 15 of the '669 Patent, as can be seen in the '669 Patent claim chart, attached as Exhibit V.

293. ~~290.~~ To the extent the preamble of claim 15 is construed to be limiting, the Symphony system practices the requirements of the preamble, "[a]n aspiration system, comprising," as can be seen in Exhibit V. For example, according to Truvic's Symphony Brochure, the Symphony system allows for "[p]owerful, focused Aspiration" that "[m]aximize[s] thrombus removal with high-powered, on-demand, continuous aspiration and in-hand TruView™ clot capture." (Ex. A at 2.) The Symphony Instructions for Use further states that "[t]he Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. The Symphony ProHelix may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter." (Ex. B at 1.) In addition, Symphony's product website includes a video detailing a method of using the Symphony system to treat clot material within a blood vessel of a human patient using vacuum aspiration. (*See* https://www.truvic.com/symphony-product.)

294. ~~291.~~ The Symphony system practices the limitations of claim 15, including "a vacuum source," as can be seen in Exhibit V. In the Symphony system, the 24F and/or 16F controller handles (shown in an optional telescoping configuration below) are coupled to a Truvic Generator and Truvic Canister, or another pressure source, which is a vacuum source.

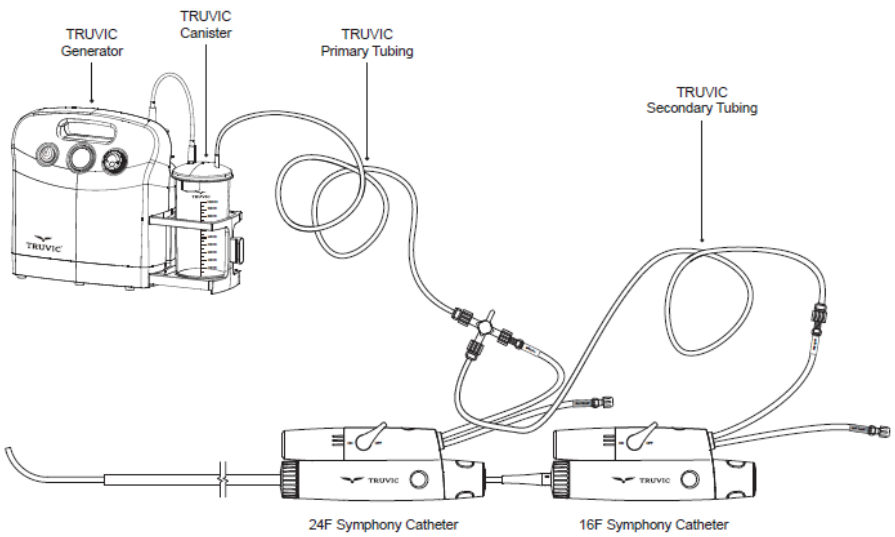


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy.
17. To begin aspiration, move the vacuum lever on the 16F Handle to the "ON" position.

(Ex. B at 8.)

295. ~~292.~~ Symphony's product website includes a video detailing a method of using the Symphony system to treat clot material within a blood vessel of a human patient using the Truvic Generator and Truvic Canister as a vacuum source. (*See* https://www.truvic.com/symphony-product.)

296. ~~293.~~ The Symphony system practices the limitations of claim 15, including "a catheter fluidically coupled to the vacuum source via a first fluid path," as can be seen in Exhibit V. Specifically, as can be seen in the images from page 8 of the IFU below, the Symphony system includes a catheter coupled to the Truvic Generator and Truvic Canister via the first fluid path through the Symphony system 16F and/or 24F handles (the BigShot Controller Handles).

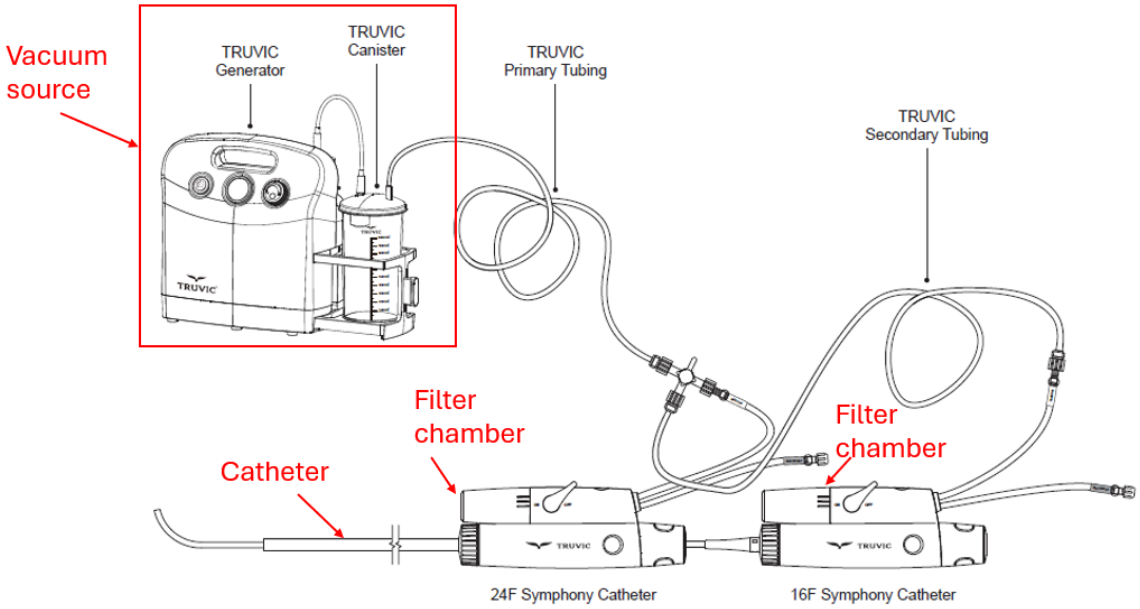
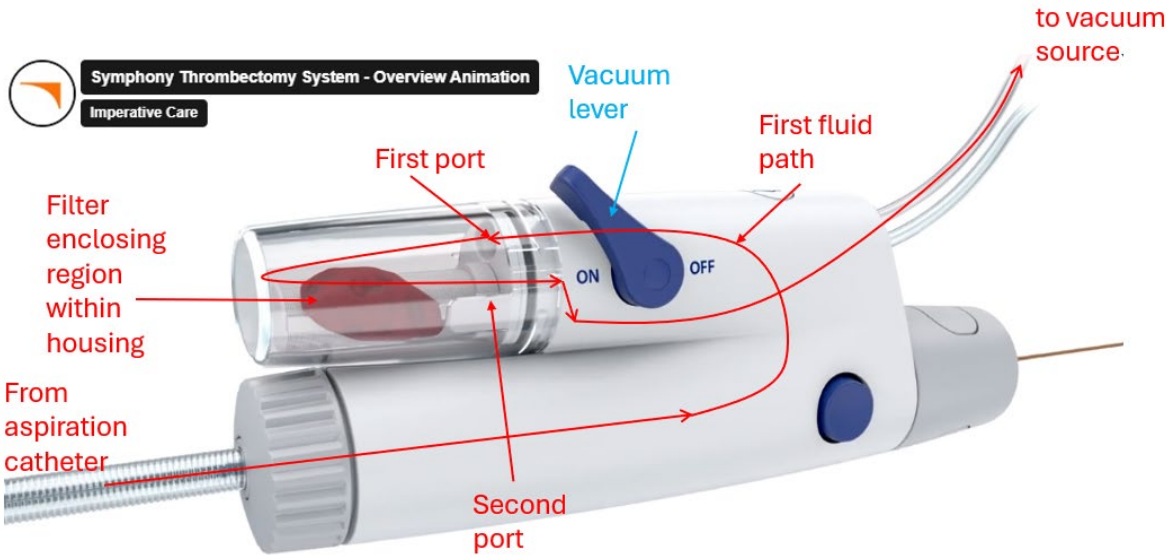
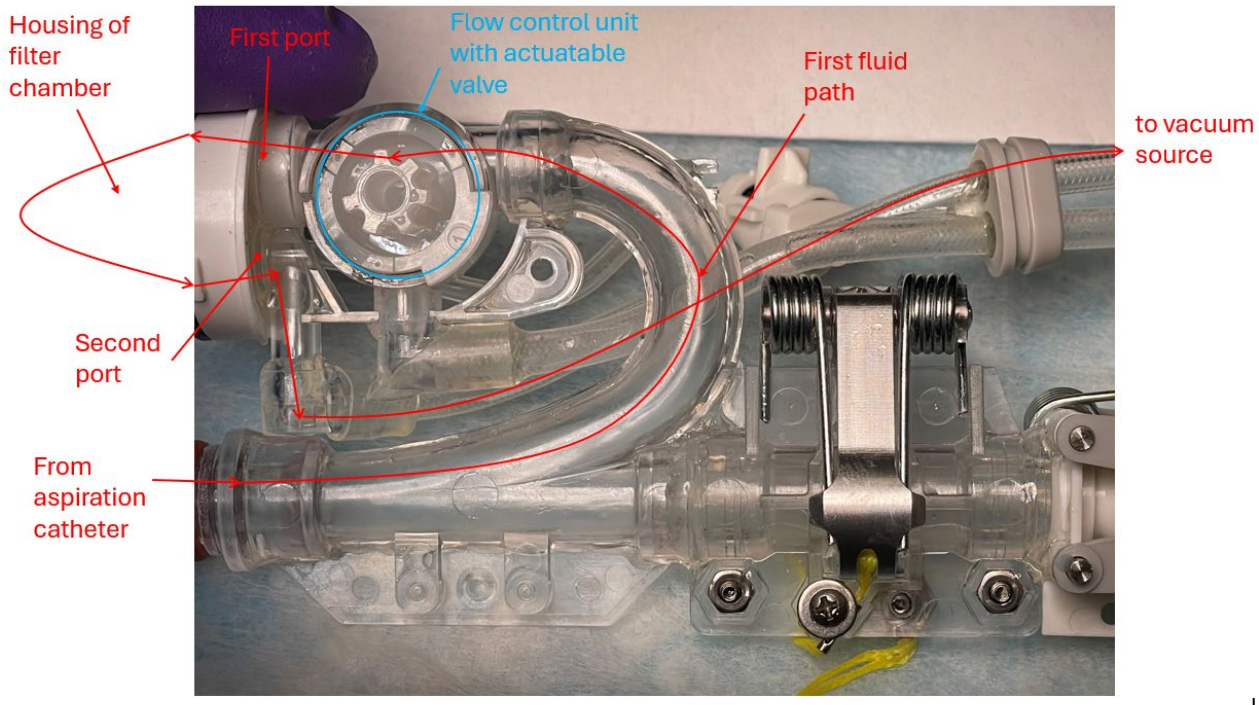


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Ex. B at 8 (annotated) (showing a telescoping configuration).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57 (https://www.truvic.com/symphony-product).)



(Annotated image of internal portion of controller handle housing with flow path.)

297. ~~294.~~ The Symphony system practices the limitations of claim 15, including "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," as can be seen in Exhibit V. Specifically, as can be seen from the images above and from page 4 of the IFU below, the Symphony system handle has a clot container with a filter chamber coupled to the Truvic Generator and Truvic Canister and the aspiration catheter that captures and filters clot material from blood during thrombectomy.

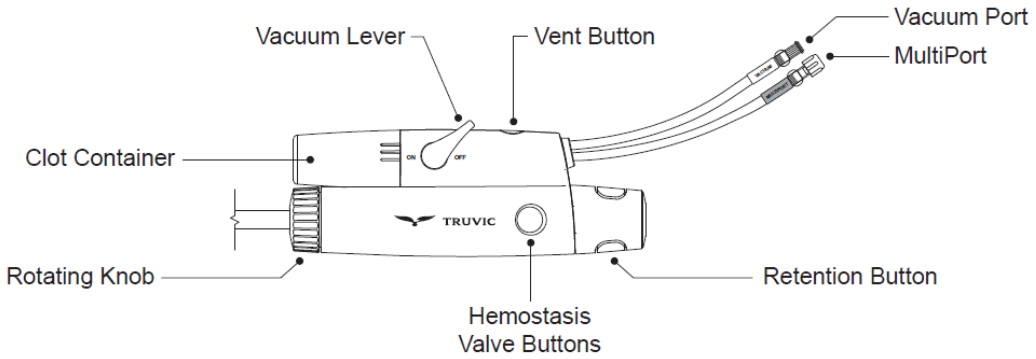


Figure 3: Symphony Catheter Handle, labeled

(Ex. B at 4.)

298. ~~295.~~ As can be seen from the images from page 8 of the IFU below, the Symphony system includes a filter chamber along the first fluid path that is spaced apart from the Truvic Generator and Truvic Canister (*e.g.*, vacuum source).

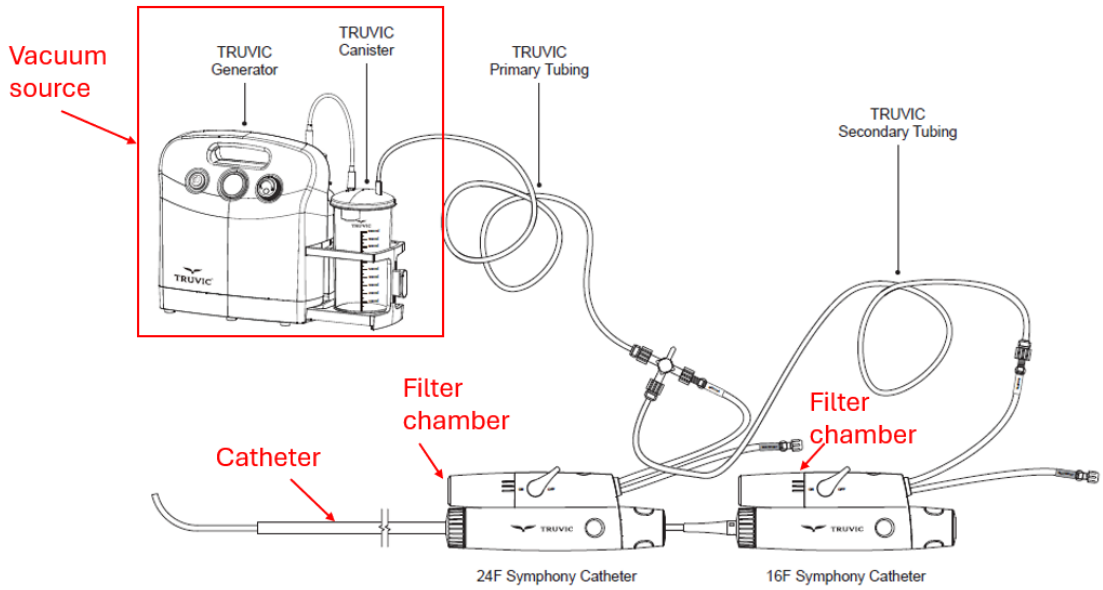
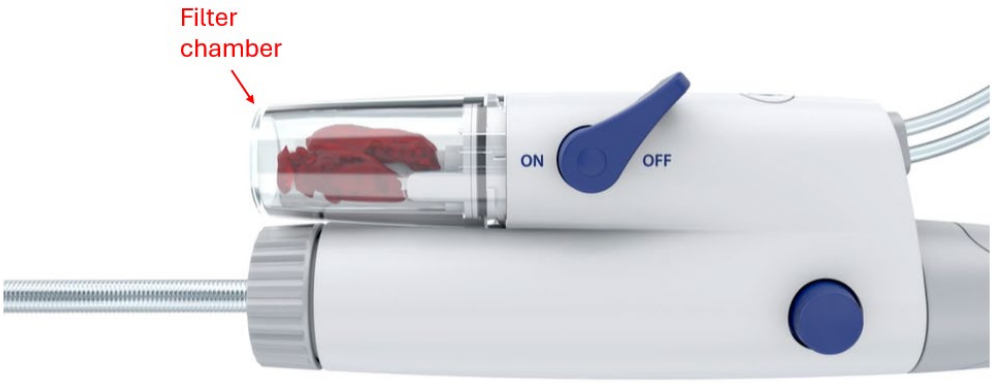


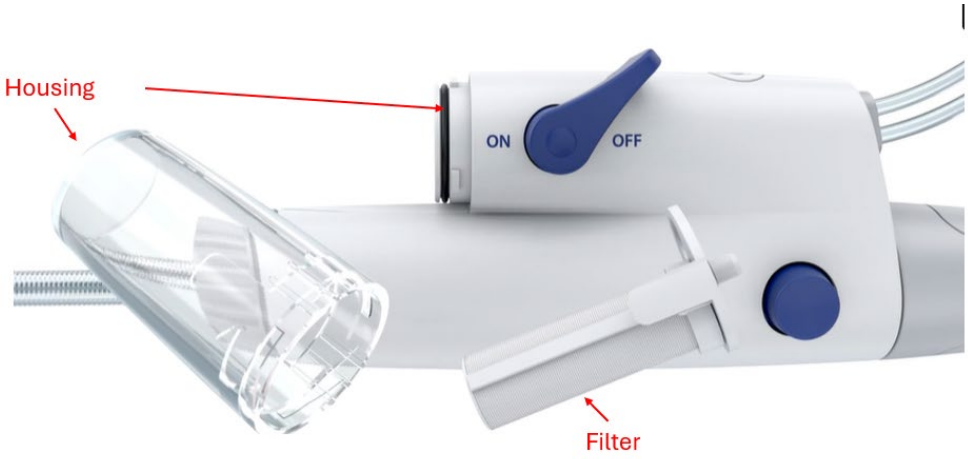
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Ex. B at 8 (annotated).)

299. ~~296.~~ As can be further seen from the annotated images from the Symphony video below, the Symphony system includes a filter chamber that has a housing and a filter within it.

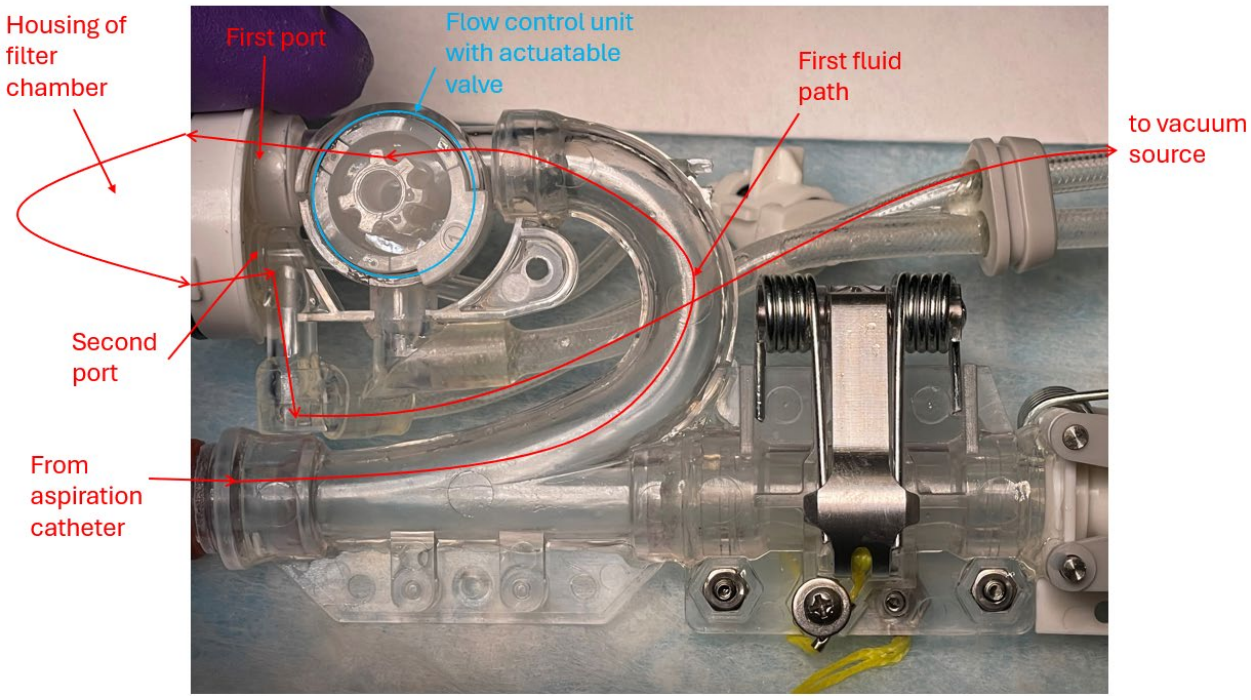


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:15 (https://www.truvic.com/symphony-product).)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

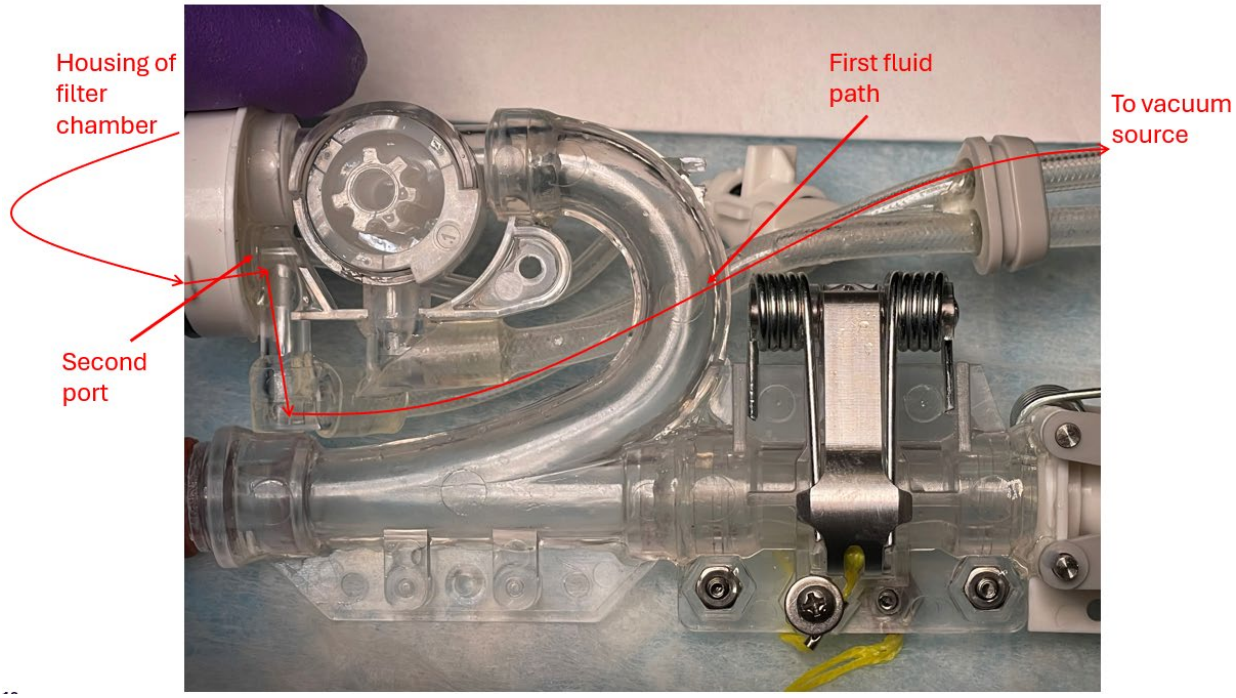
300. ~~297.~~ The Symphony system practices the limitations of claim 15, including "wherein the housing includes—a first port configured to be fluidically coupled to the catheter," as can be seen in Exhibit V. Specifically, the clot canister of the Symphony system includes a first port that is fluidly connected to the aspiration catheter, as shown in the teardown image



below.

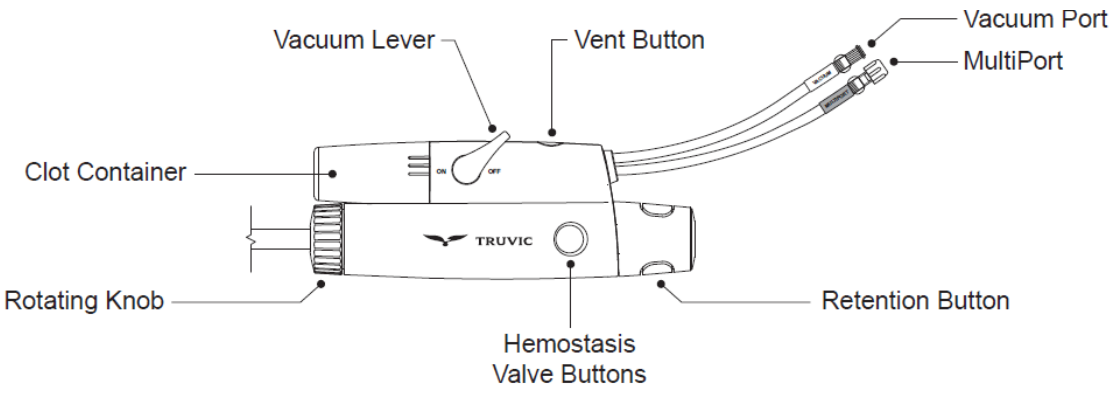
(Annotated image of internal portion of controller handle housing).

301. ~~298.~~ The Symphony system practices the limitations of claim 15, including "wherein the housing includes—…a second port configured to be fluidically coupled to the vacuum source," as can be seen in Exhibit V. Specifically, the clot canister of the Symphony system includes a second port that is fluidly connected to the Truvic Generator and Truvic Canister (*e.g.*, vacuum source), as shown in the teardown image below.



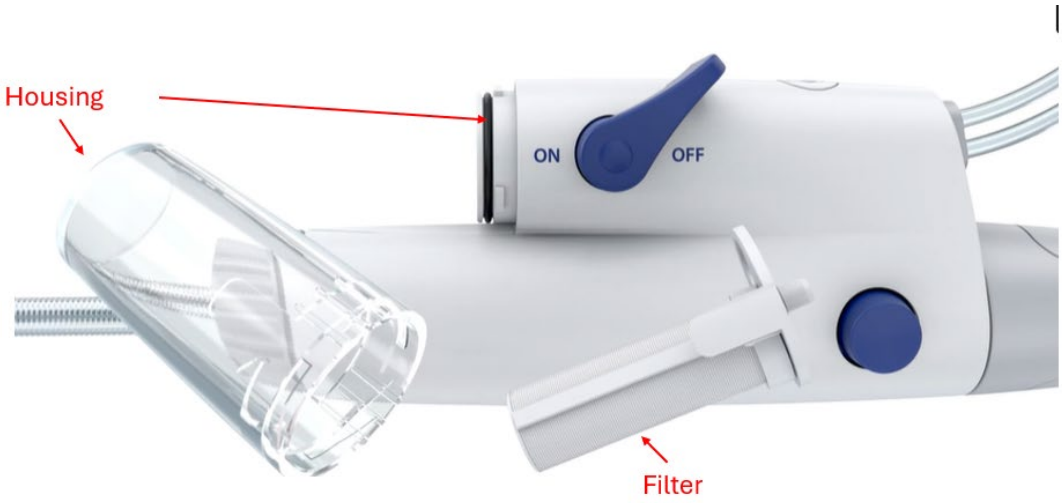
(Annotated image of internal portion of controller handle housing).

302. ~~299.~~ As can be seen from the images from page 4 of the IFU below, the Symphony system includes a vacuum port that fluidly connects the housing and vacuum source.



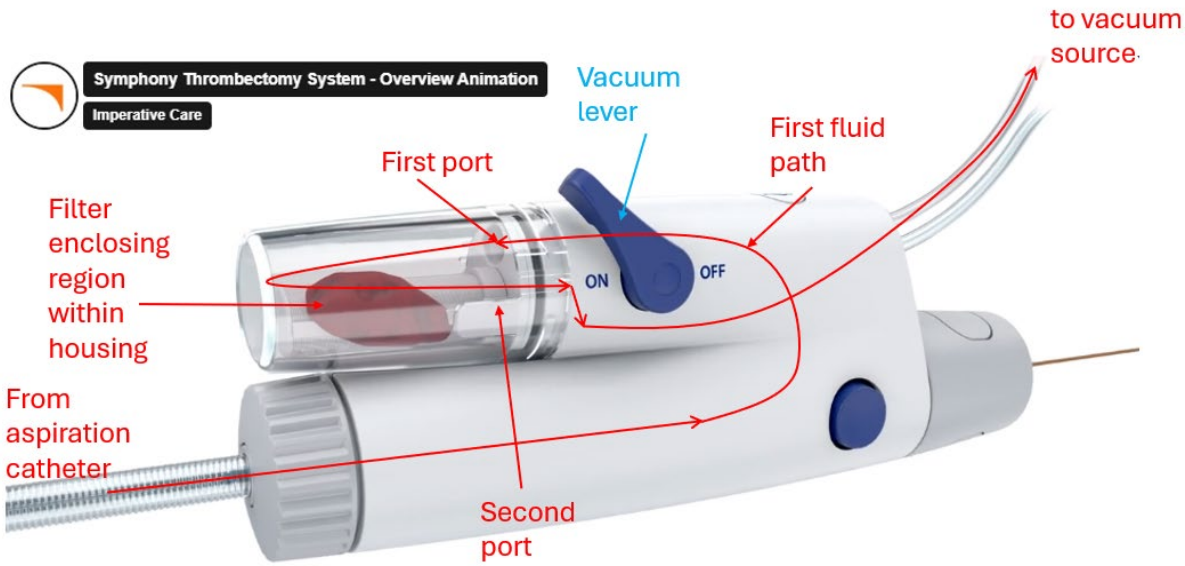
(Ex. B at 4.)

303. ~~300.~~ Thrombectomy with the Symphony system, including thrombectomy using a ProHelix device, practices the limitations of claim 15, including "wherein the filter is in the housing along the first fluid path between the first port and the second port," as can be seen in Exhibit V. Specifically, the clot canister of the Symphony system includes a removable filter that is along the first fluid path between the first port that fluidly couples the catheter and the second port that fluidly couples the vacuum source, as shown in the annotated images from the Symphony video below. The housing of the Symphony product receives the clot and blood from the human patient via the first port fluidly coupled to aspiration catheter, where the blood is



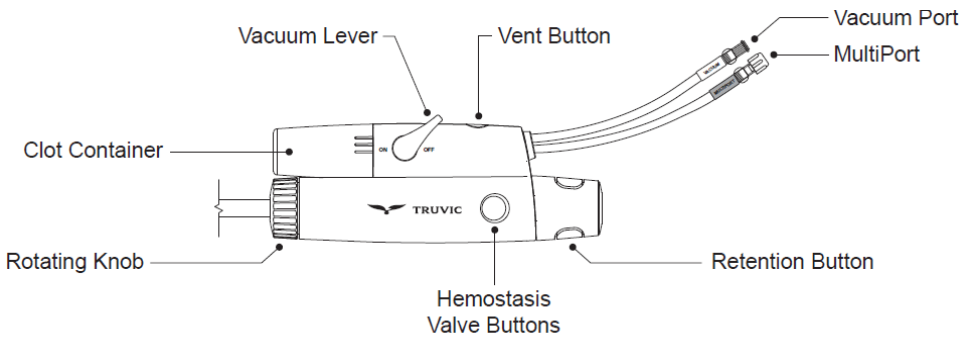
filtered out of the housing via the second port that is fluidly coupled to the vacuum source. (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57 (https://www.truvic.com/symphony-product).)

304. ~~301.~~ The filter contained within the housing is along the first fluid path.

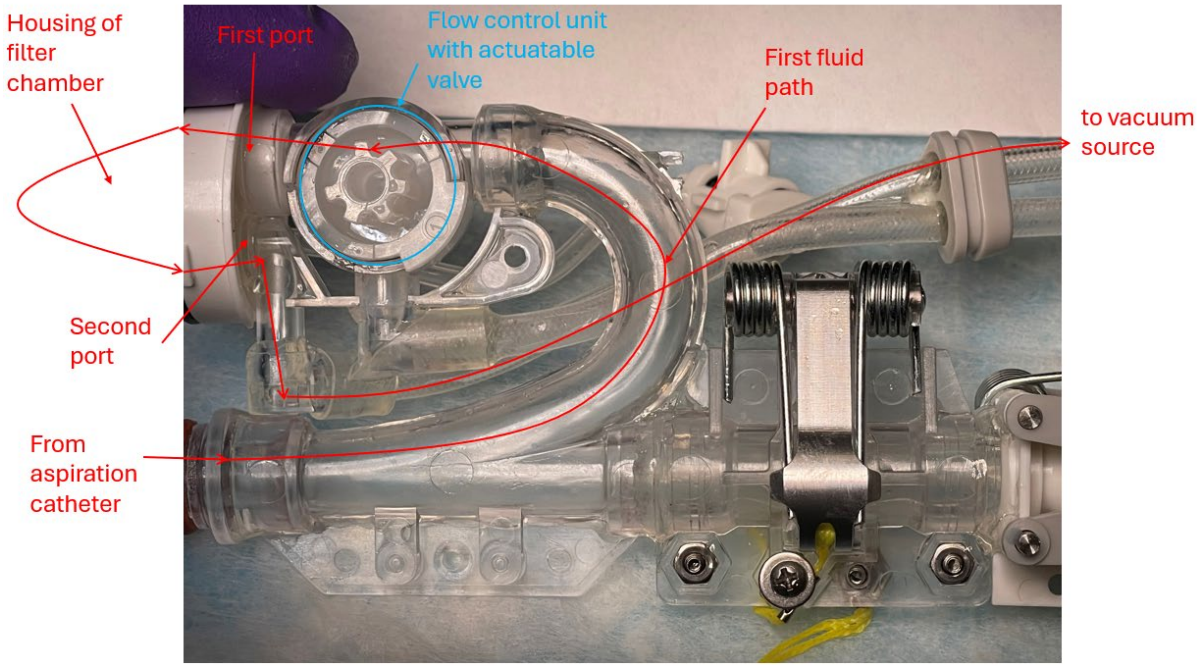


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https:www.truvic.com/symphony-product).)

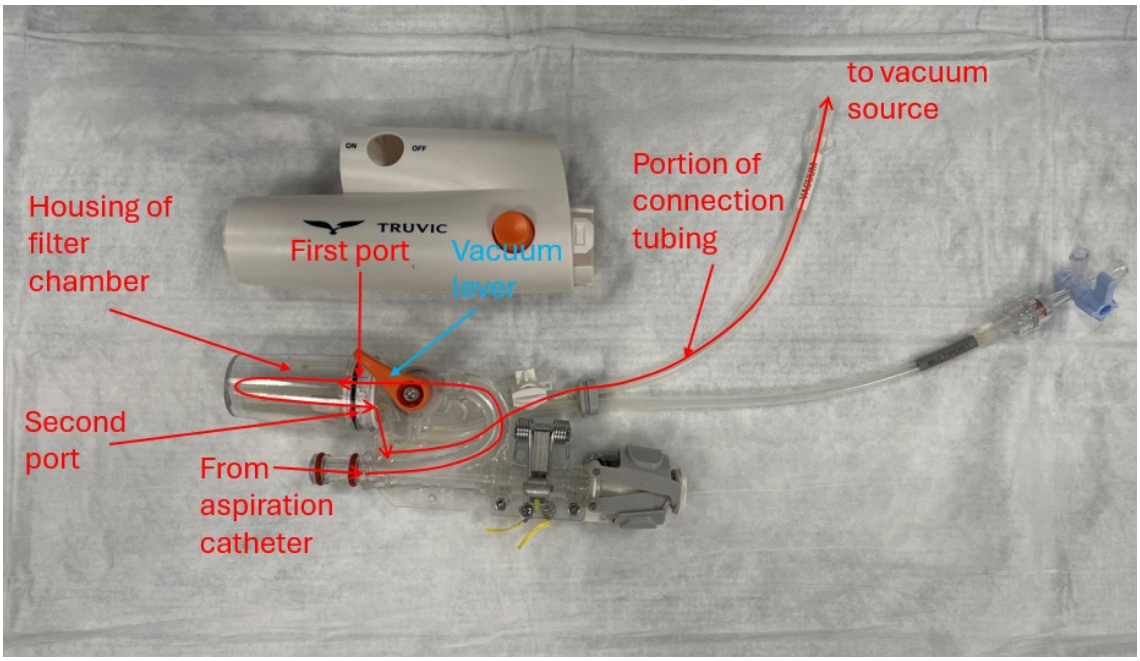
305. ~~302.~~ The Symphony system practices the limitations of claim 15, including "a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter," as can be seen in Exhibit V. Specifically, as can be seen from the images from page 4 of the IFU below the Symphony system handle includes a vacuum control valve and vacuum lever (*e.g.*, flow controller).



(Ex. B at 3.) As can be seen from the teardown image below, the flow controller is along the first fluid path and couples the filter chamber to the aspiration catheter.



(Annotated image of internal portion of controller handle housing.)



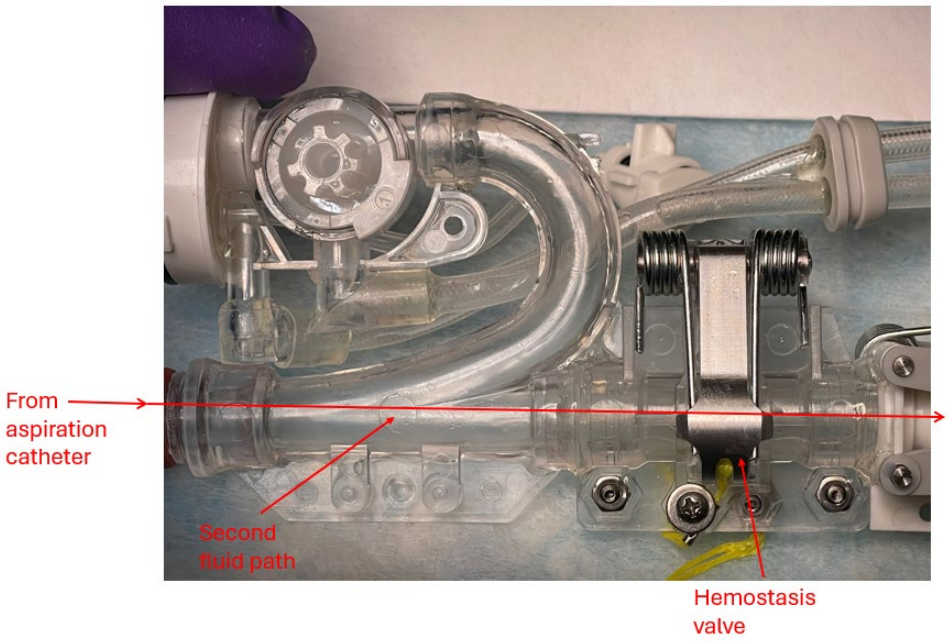
(Annotated image of internal portion of the controller housing with vacuum lever.)

306. ~~303.~~ As shown in the Symphony system animation video, when the vacuum lever is moved to an "On" position, the clot flows from the human patient, through the aspiration catheter along the first flow path to the housing of the filter chamber.

(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:55

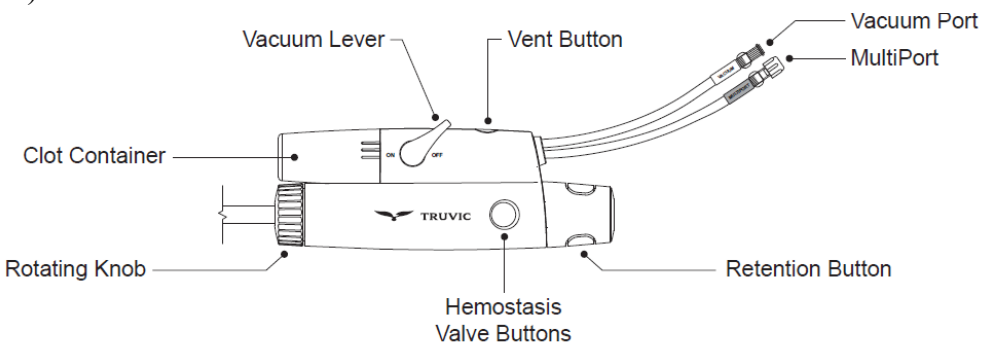
(https:www.truvic.com/symphony-product).)

307. ~~304.~~ The Symphony system practices the limitations of claim 15, including "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," as can be seen in Exhibit V. Specifically, as can be seen from the IFU and the teardown image below, the hemostasis valve of the Symphony system is fluidically coupled to the aspiration catheter along a second fluid path, that is at least partially different than the first fluid path (e.g., the portion of the second fluid path running from the hemostasis valve toward the aspiration catheter).



(Annotated image of internal portion of controller handle housing.)

(Ex. B. at 4)



308. ~~305.~~ The IFU teaches that the ProHelix device (the interventional device) can be inserted through the hemostasis valve and the catheter to reach the clot, demonstrating that the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second path (through the hemostasis valve) when an interventional device, such as a ProHelix is inserted through the valve and to the catheter.

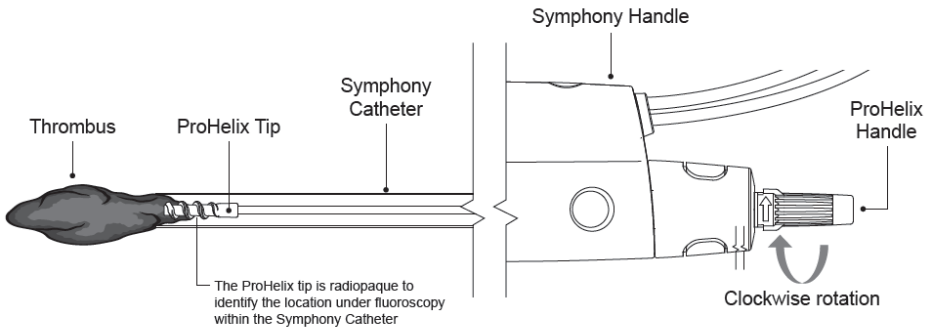


Figure 4: ProHelix engaged with thrombus

(Ex. B at 5.) Moreover, the buttons for the hemostasis valve on the 24F or 16F Symphony handle are configured to be pushed to release the hemostasis valve and then to advance a device, for example a ProHelix device (the interventional device), over the guidewire to the clot. (Ex. B at 5 ("Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle."), 6 ("During ProHelix movement, press the Hemostasis Valve buttons on the Handle to reduce friction.").) The buttons are configured to be released to seal the valve around the inserted device, such as a ProHelix, so that the Symphony hemostasis valve inhibits fluid flow along the second fluid path by clamping down on the inserted ProHelix device.

309. ~~306.~~ Defendant directly infringes claims of the '669 Patent, including claim 15, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures) Symphony system products, such as with a ProHelix device.

310. ~~307.~~ Defendant induces infringement of claims of the '669 Patent, including claim 15, by selling Symphony systems and teaching or directing others, including physicians, to use

the Symphony products that practice claim 15. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

311. ~~308.~~ Defendant teaches and/or directs others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels…. The Symphony Thrombectomy System is intended for use in the peripheral vasculature." (Ex. B at 2.) The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration." (*Id.* at 1.) Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. (*See, e.g.*, https://www.truvic.com/symphony-product.) Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding method of using the Truvic Symphony system, including on information and belief, methods of treating thrombi and emboli.

312. ~~309.~~ Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system, knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the '669 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

313. ~~310.~~ At a minimum, Defendant has notice of the '669 Patent through the filing of ~~this~~the Second Amended Complaint. On information and belief, Defendant has had knowledge of the '669 Patent via monitoring and investigation of Inari's patent portfolio, including in response to the notice letters provided by Inari regarding many other patents, including family members of the '669 Patent.

314. ~~311.~~ Defendant has continued its infringing activities after the '669 Patent issued, despite knowledge of the '669 Patent (including from the Second Amended Complaint), and such infringement has been and continues to be egregious and willful.

315. ~~312.~~ Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

COUNT 11: INFRINGEMENT OF THE 12-'333 PATENT

316. Inari realleges and incorporates by reference the preceding paragraphs as though fully set forth herein.

317. The 12-'333 Patent, titled "Single Insertion Delivery System for Treating Embolism and Associated Systems and Methods," is part of the same family as the '580 Patent and '669 Patent and shares the same specification. The 12-'333 Patent discloses improved clot-removing devices for intravascular treatment of clot materials that solve problems with prior art clot-removal devices and methods. The 12-'333 Patent solves these problems through its inventions and combination of inventions that include, for example, a clot collection reservoir with a partially transparent housing that defines a chamber, a first port connected to a catheter, and a second port connected to an aspiration source that generates negative pressure in the chamber, where the chamber includes a filter. Ex. W at cl. 1. The filter is substantially cylindrical and prevents clot material and not the blood (drawn in through the catheter) from passing through the filter body and out through the second port. *Id.* The 12-'333 Patent teaches that a transparent housing allows the doctor to see the clot material so they can at least partially determine whether additional passes with an interventional device are needed to remove more clot material. *Id.* at 9:57-64.

318. The 12-'333 Patent further solves problems in the art through a clot reservoir container with a removable filter. *E.g.*, *id.* at Fig. 3B, Fig. 3C, cl. 1. The 12-'333 Patent teaches that the filter chamber/clot reservoir and filter capture clot material within a housing, while filtered blood is allowed to flow through. *Id.* at Fig. 3A, Fig. 3B, Fig. 3C, 9:40-64. This also allows the treating physician to visualize the captured clot material to help determine whether additional passes are necessary and to remove clot material that has been collected by removing and emptying the filter housing. *Id.* As disclosed in other Inari patents, the filtered blood can also be reintroduced to the patient's vasculature to further mitigate blood loss during procedures.

319. Defendant directly and indirectly infringes—literally and/or under the doctrine of

equivalents—at least claim 1 of the 12-'333 Patent by making, using, selling, offering for sale, and/or importing into the United States its Symphony system and components thereof.

320. Specifically, claim 1 of the 12-'333 Patent recites:

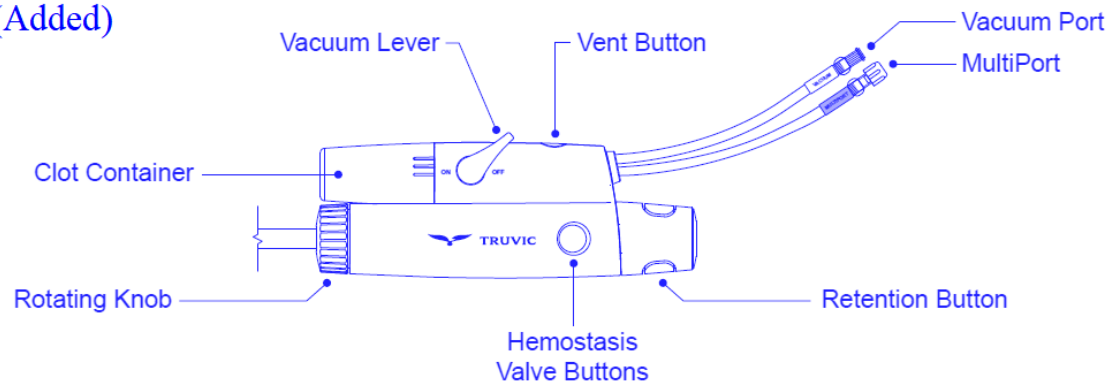
> [1] A clot collection reservoir, comprising:
>
> a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;
>
> a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber;
>
> a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber; and
>
> a filter removably positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter extends continuously about the first filter end portion such that the filter body encloses an interior region around the second port;
>
> wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the second port;
>
> wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and
>
> wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region.

321. The Truvic Symphony system practices each limitation of at least claim 1 of the 12-'333 Patent, as can be seen in the 12-'333 Patent claim chart, attached as Exhibit X.

322. To the extent the preamble of claim 1 is construed to be limiting, the Symphony system practices the requirements of the preamble, "[a] clot collection reservoir, comprising," as can be seen in Exhibit X. In the Symphony system, the 24F and 16F controller handles include a clot collection reservoir. For example, according to the Symphony Instructions for Use the Symphony system includes a clot collection reservoir where a user can "[c]onfirm clot removal

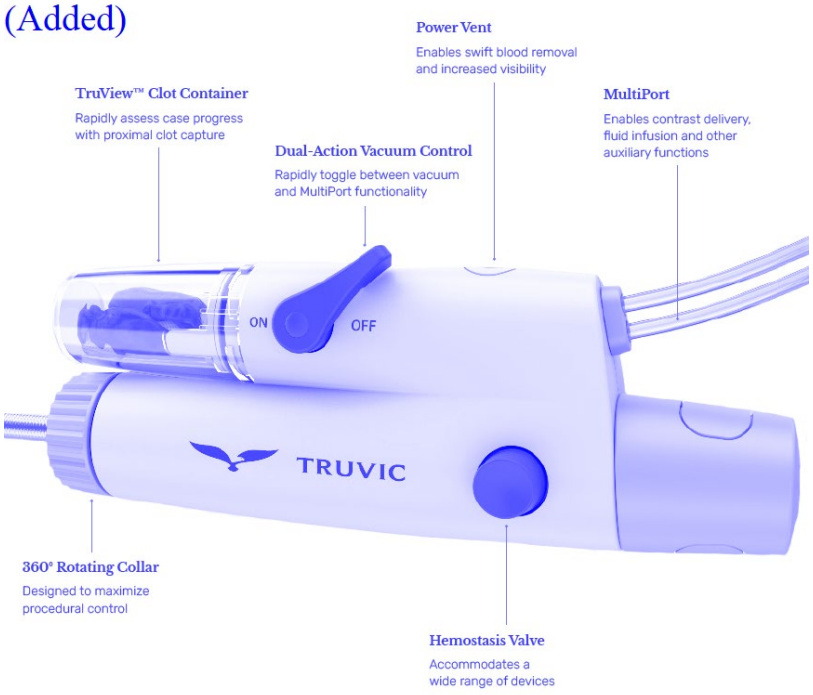
by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle." Ex. B at 5. The IFU depicts the clot collection reservoir of the Symphony system, as shown below.

(Added)



(*Id.* at 4.) Truvic's Symphony Brochure shows the clot collection reservoir as well.

(Added)

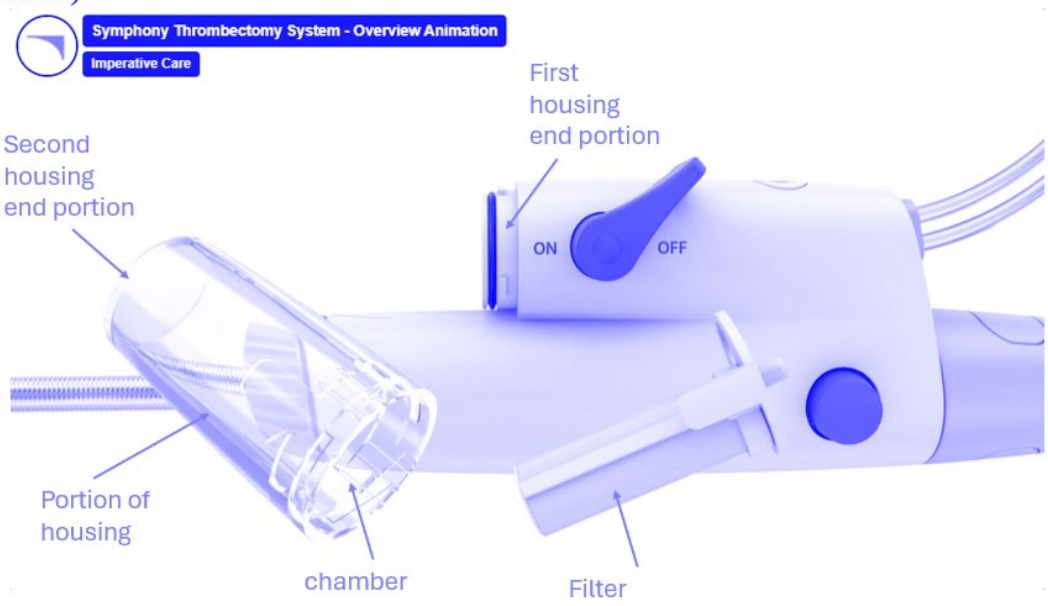


(Ex. A at 6.)

323. The Symphony system practices the limitations of claim 1, including "a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion," as can be seen in Exhibit X. The clot collection reservoir of the Symphony system includes a housing that defines a sealed chamber (*e.g.*, the interior of the housing) with a first housing end portion and a second housing end portion

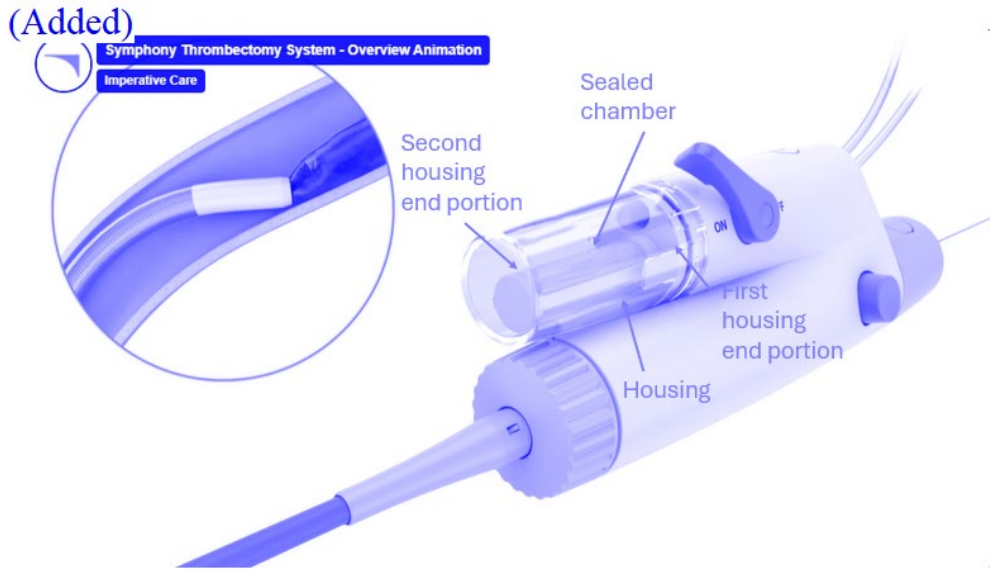
opposite the first, as can be seen in the annotated images of the Symphony overview animation video below.

(Added)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

(Added)

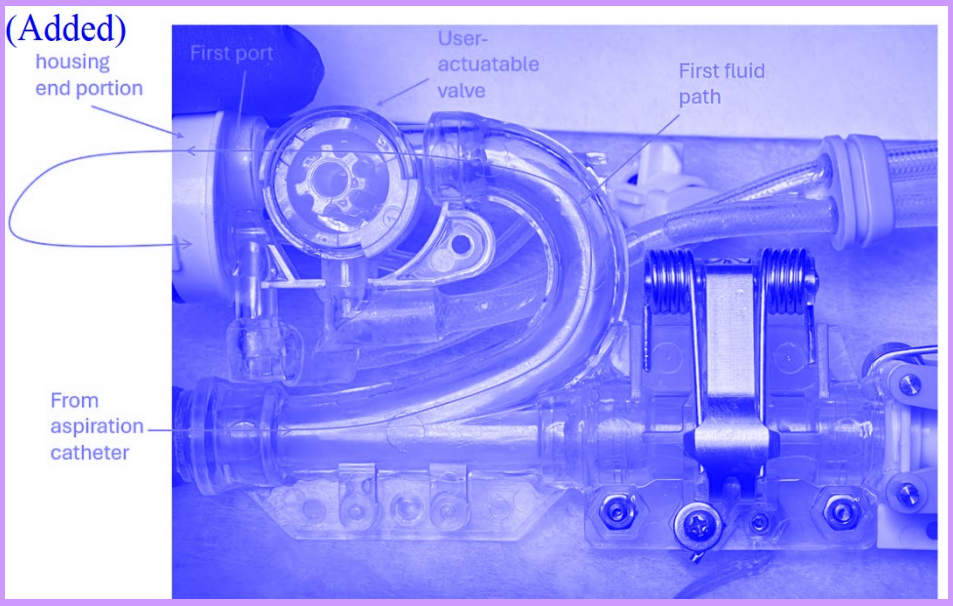


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:57 (https://www.truvic.com/symphony-product).)

324. The Symphony system practices the limitations of claim 1, including "a first port configured to be fluidly coupled to an aspiration catheter, wherein the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber," as can

be seen in Exhibit X. Specifically, the Symphony 24F and 16F controller handles include a clot collection reservoir with a first port fluidly coupled to an aspiration catheter, providing a fluid flow path to the chamber, as shown in the annotated teardown image below.

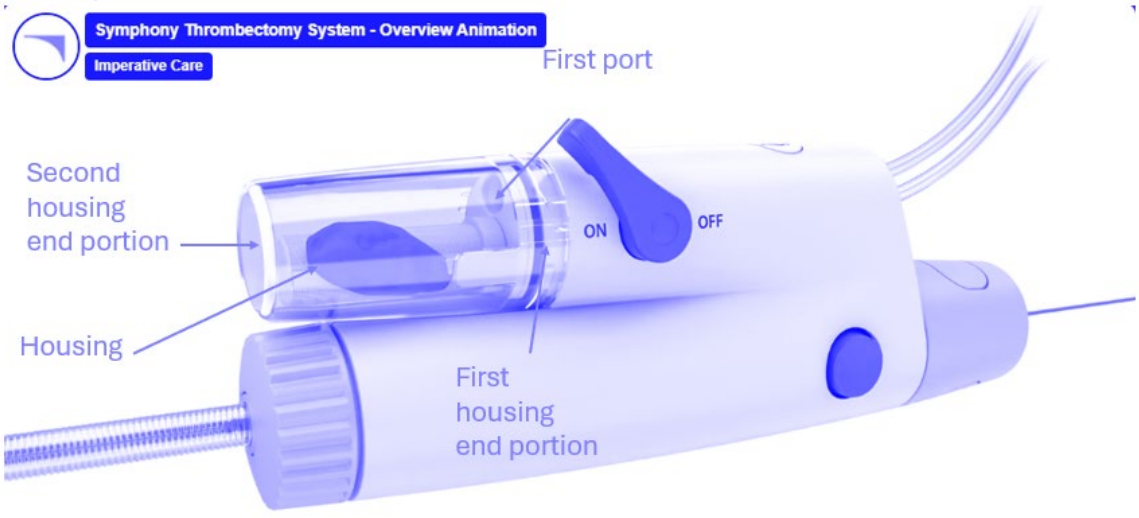
(Added)



(Annotated image of internal portion of controller handle housing)

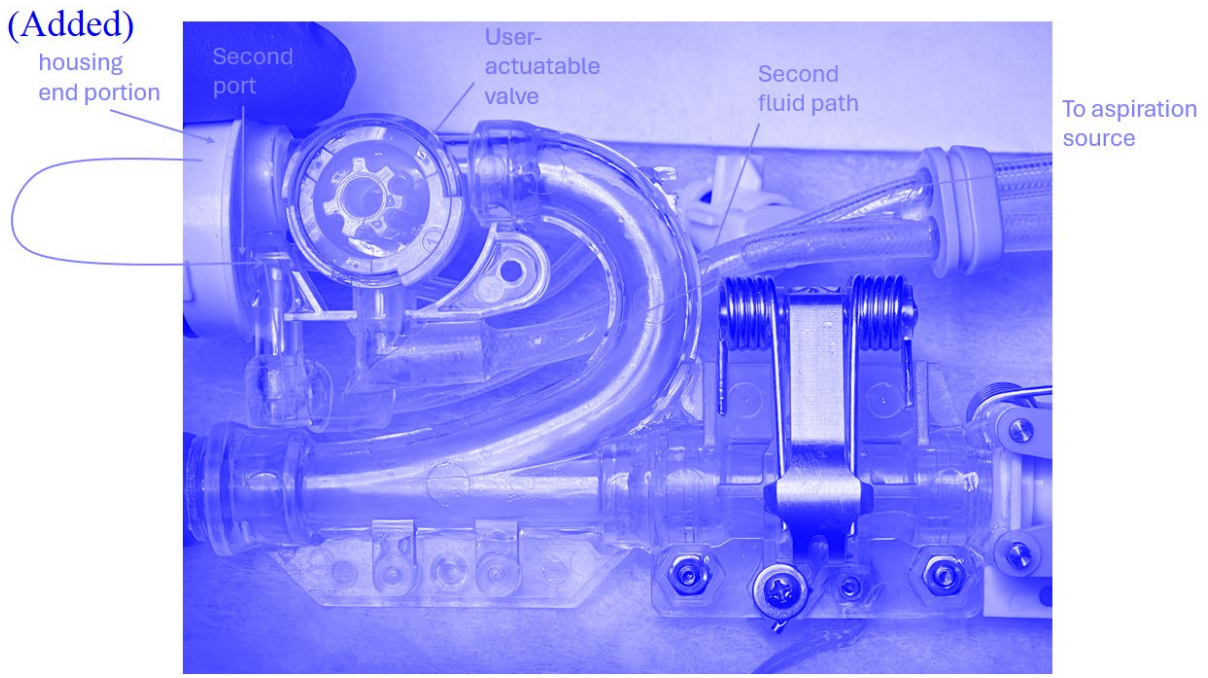
325. The first port of the clot collection reservoir is positioned proximate to the first housing end portion such that fluid flows through the first port to the chamber, as shown in the annotated images of the Symphony overview animation video below.

(Added)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57 (https://www.truvic.com/symphony-product).)

326. The Symphony system practices the limitations of claim 1, including "a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the chamber," as can be seen in Exhibit X. Specifically, the Symphony system 24F and 16F handles (BigShot Controller handles) include a clot collection reservoir with a second port fluidly coupled to an aspiration source (the Truvic Generator and Truvic Canister (*e.g.*, an aspiration source)) via a path through the handle, a tubeset, and ultimately to the Truvic Canister, as shown in the annotated teardown image below. The second port provides a second fluid path from the chamber, back through the handle, the tubeset, and ultimately to the aspiration source.



(Annotated image of internal portion of controller handle housing)

327. The Symphony IFU for the Symphony system confirms that the Truvic Generator and Truvic Canister are configured to be fluidly connected to the second port of the clot collection reservoir.

(Added)

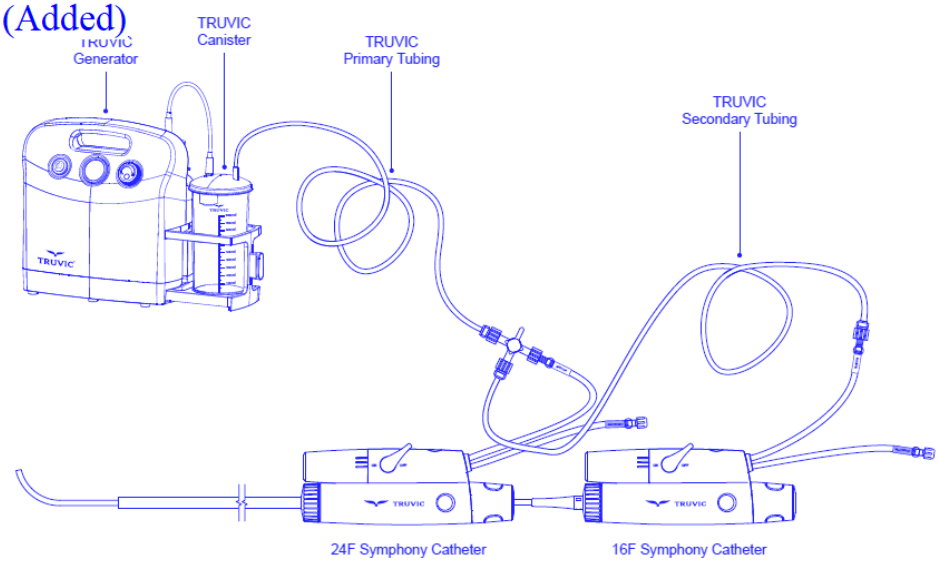
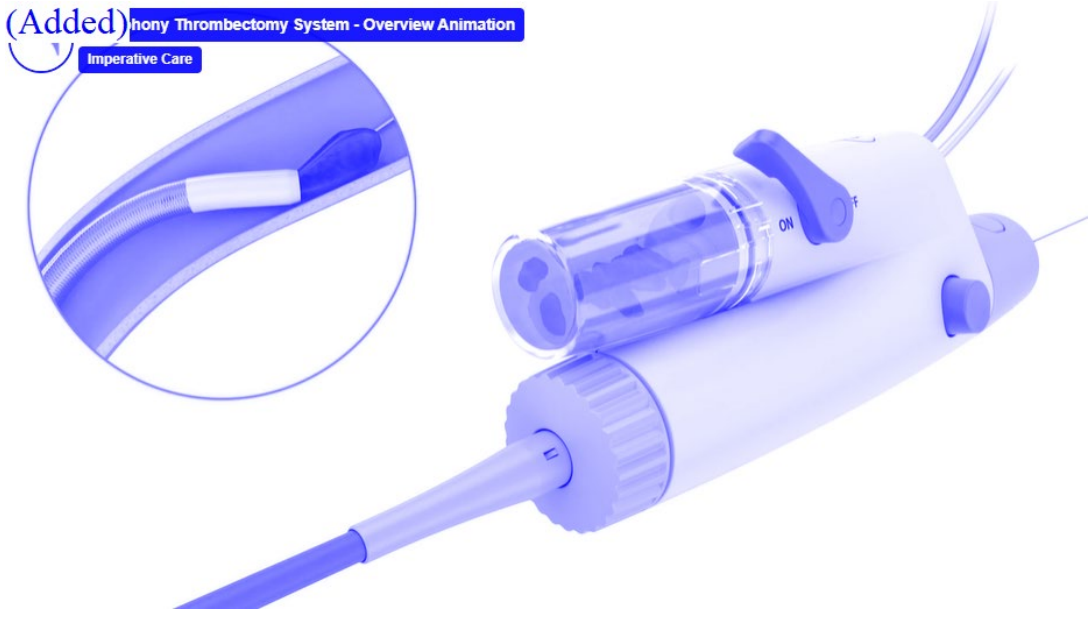


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Ex. B at 8.) And as shown in the Symphony overview video, the second port provides a second fluid path from the chamber for blood to be removed.

(Added)

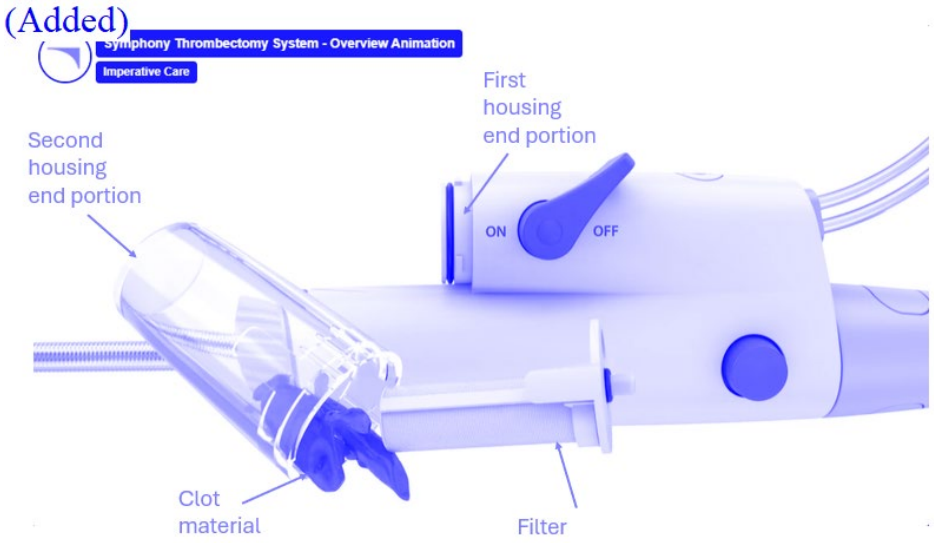


(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:03 (https://www.truvic.com/symphony-product).)

328. The Symphony IFU further confirms that the second port provides a second fluid path that allows blood to evacuate from the chamber. Ex. B at 5.

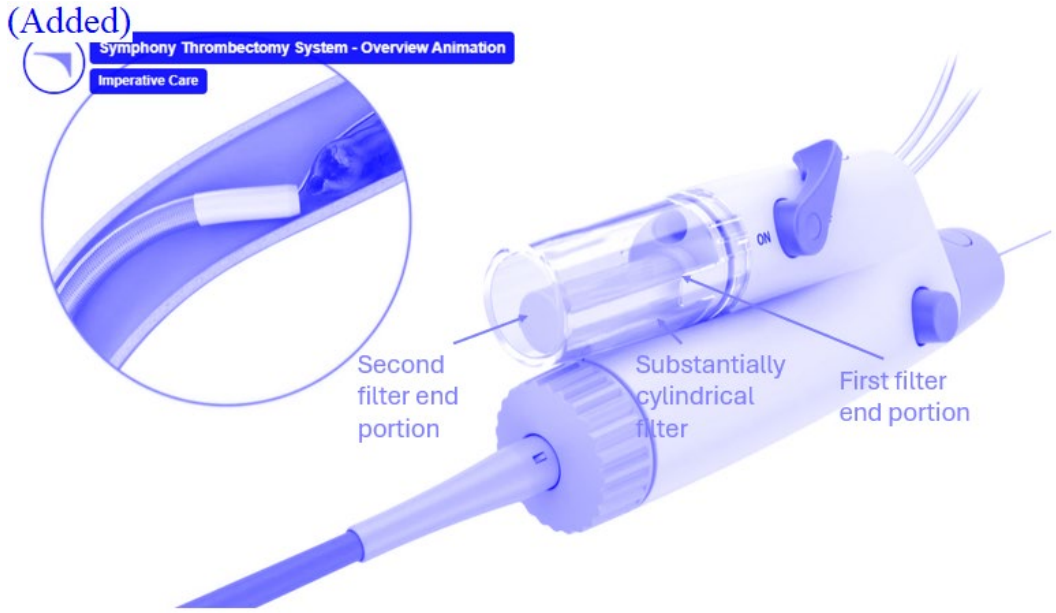
329. The Symphony system practices the limitations of claim 1, including "a filter removably positioned within the chamber, wherein the filter has a substantially cylindrical shape extending from a first filter end portion to a second filter end portion, and wherein the filter body extends continuously about the first filter end portion such that the filter encloses an interior region around the second port," as can be seen in Exhibit X. Specifically, the Symphony 24F and 16F controller handles include a clot collection reservoir that has a filter positioned within the chamber of the housing, where the filter body is substantially cylindrical in shape and removable, as shown in the annotated images of the Symphony overview animation video below.

(Added)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

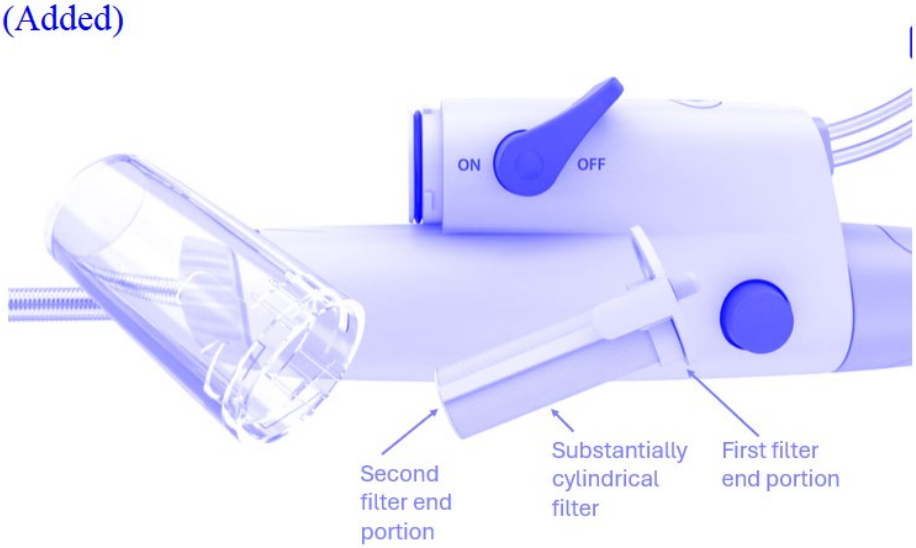
(Added)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:47 (https://www.truvic.com/symphony-product).)

330. The Symphony overview animation video (as can be seen in the annotated images below) confirms that the substantially cylindrical shape of the Symphony's filter extends from a first filter end portion to a second filter end portion, such that the substantially cylindrical filter body extends about the first filter end portion.

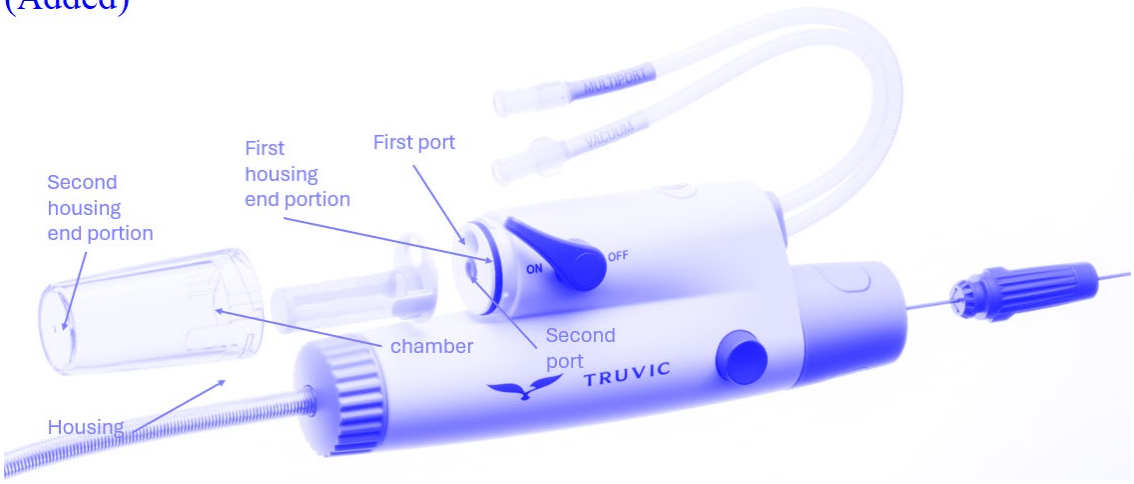
(Added)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21 (https://www.truvic.com/symphony-product).)

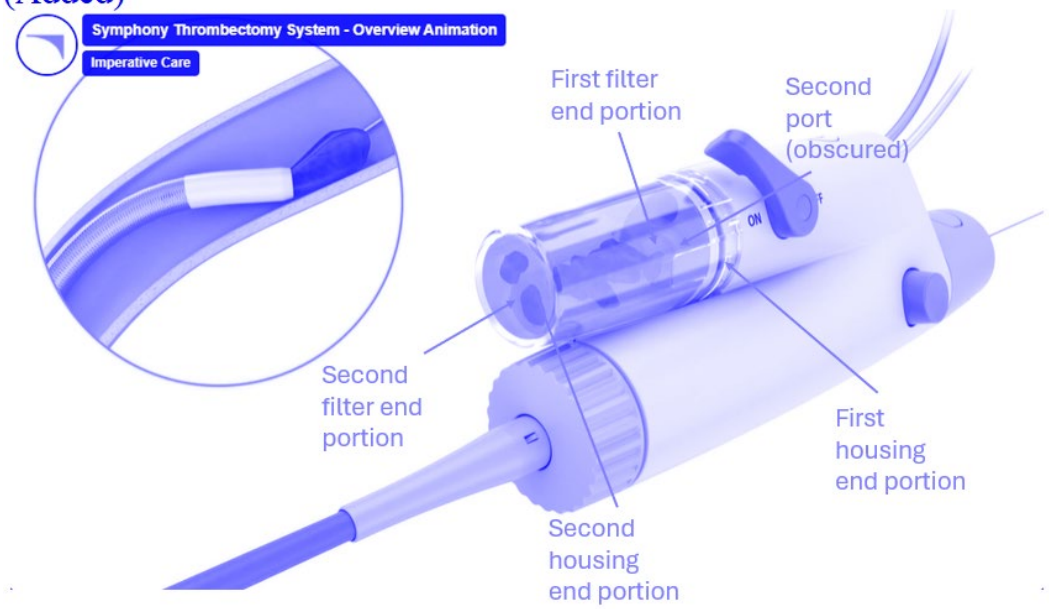
331. The Symphony IFU confirms that the filter encloses an interior region around the second port, where it teaches that blood can be evacuated through the second port, but the clot material remains due to the filter inhibiting the clot to pass through the second port. Ex. B at 5 ("Confirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle."). This is also shown in the image from Whipsaw and Symphony Thrombectomy System Overview Animation Video below:

(Added)



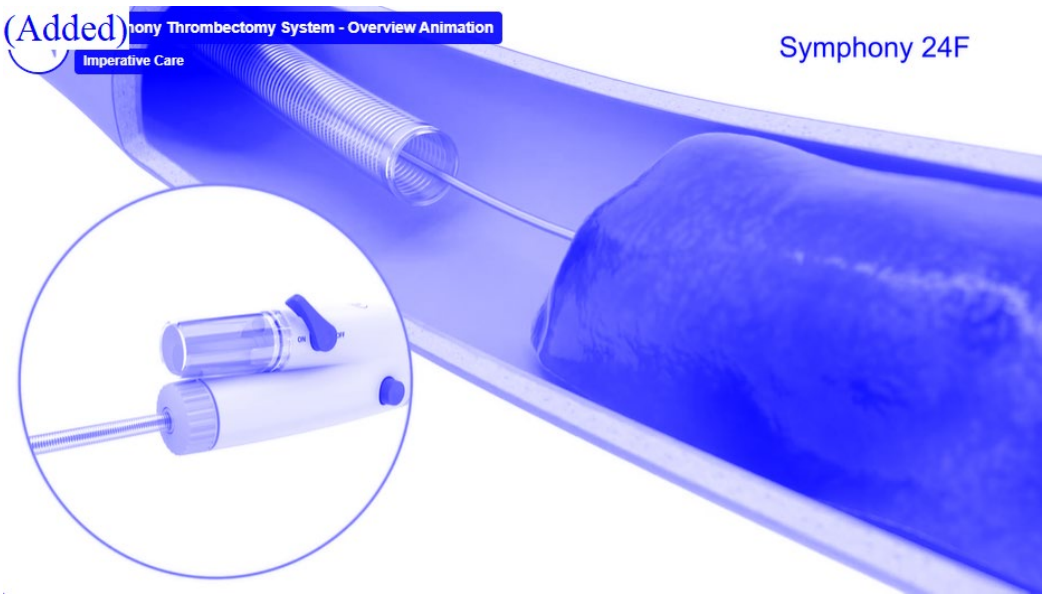
(Annotated image of handle including clot container from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)

(Added)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:03 (https://www.truvic.com/symphony-product).)

332. The Symphony system practices the limitations of claim 1, including "wherein the aspiration source is configured to generate negative pressure in the chamber via the second port to (a) draw blood and clot material from the aspiration catheter through the first port into the chamber and (b) draw blood through the filter into the interior region and through the interior region and through the second port," as can be seen in Exhibit X. Specifically, the Symphony IFU confirms that the Truvic Generator and Truvic Canister (*e.g.*, aspiration source) is configured to generate a negative pressure to begin aspiration of clot material and blood via the first port. Ex. B at 5 ("Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU). Confirm tip of the Symphony Catheter is in the desired location. To begin aspiration, move the vacuum lever on the Handle to the "ON" position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the "OFF" position."). The Symphony overview animation video further shows that clot material and blood are drawn through the first port into the chamber, as can be seen below.



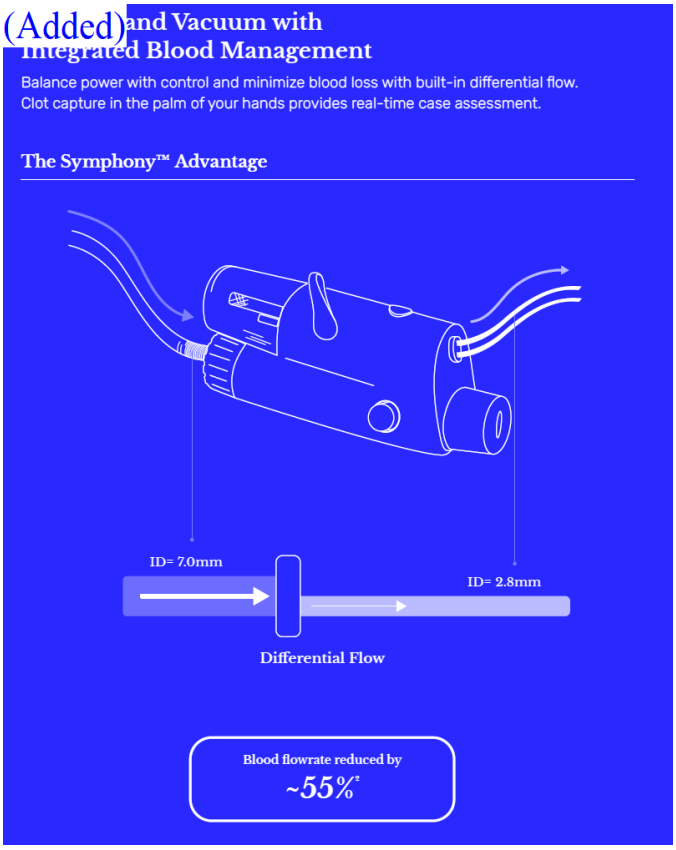
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:47 (https://www.truvic.com/symphony-product).)

333. The IFU also confirms that blood is drawn through the filter into the interior region of the filter and through the second port. Ex. B at 5. The Symphony overview animation video further shows that the blood is drawn through the interior of the filter and through the second port, which leaves the clot material remaining in the sealed chamber.

(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:03 (https://www.truvic.com/symphony-product).)

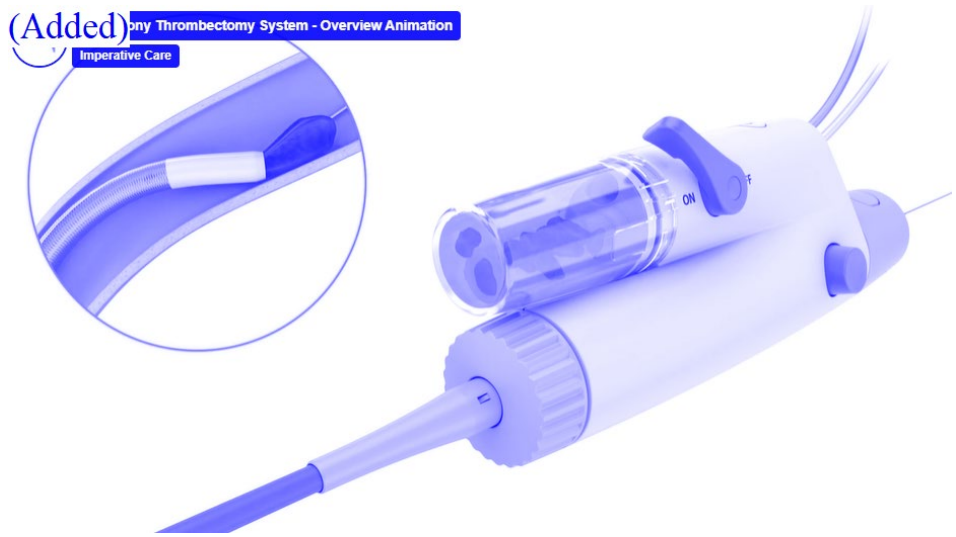
334. Truvic's Symphony Brochure confirms the flow of clot material and blood into the chamber and blood out of the chamber, capturing the clot in the clot container.

(Added)

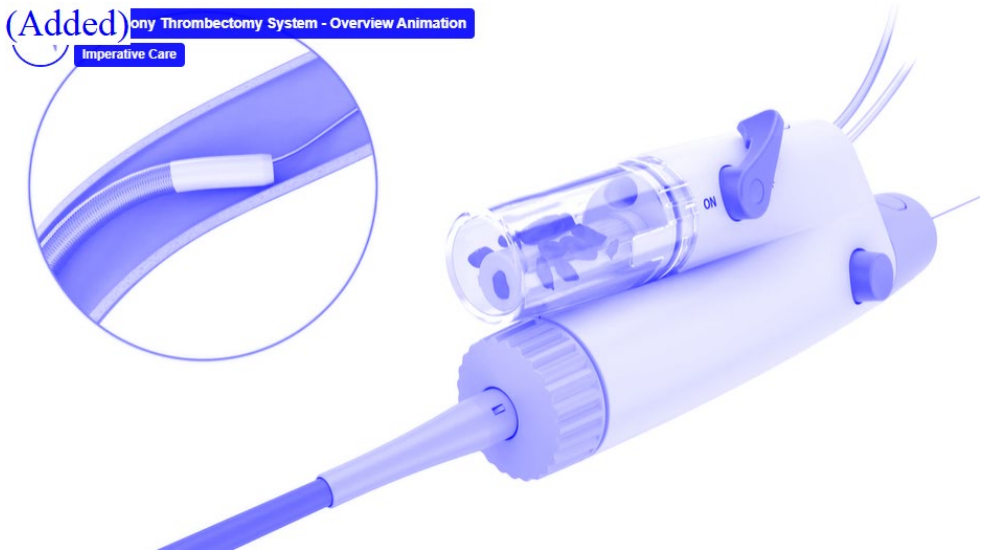


(Ex. A at 7.)

335. The Symphony system practices the limitations of claim 1, including "wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port," as can be seen in Exhibit X. Specifically, the Symphony overview animation video shows that the filter inhibits clot material from passing through its interior region and through the second port. Instead, as can be seen below, the clot material remains in the chamber.



(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:03 (https://www.truvic.com/symphony-product).)

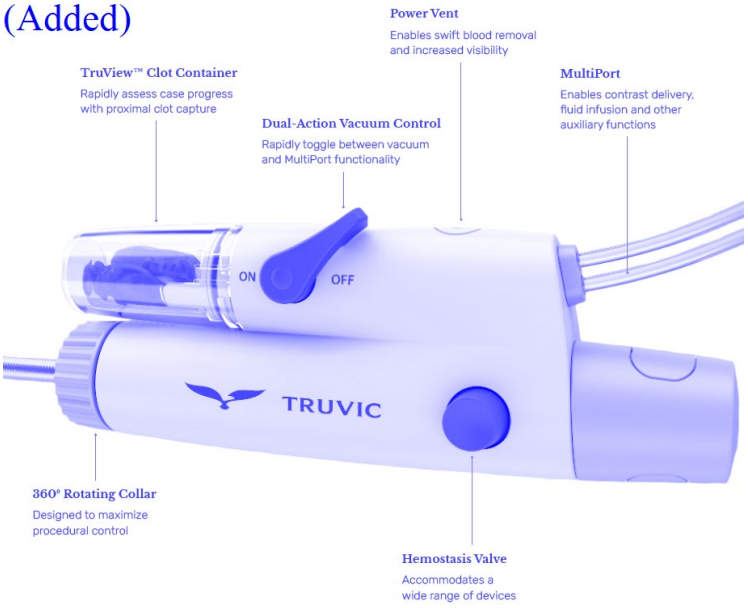


(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:05 (https://www.truvic.com/symphony-product).)

336. The Symphony IFU further confirms that the filter inhibits clot material from passing through its interior region and through the second port. Ex. B at 5.

337. The Symphony system practices the limitations of claim 1, including "wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior region," as can be seen in Exhibit X. Specifically, the Symphony IFU confirms that a user of the Symphony system can visualize the clot material in the chamber due to the partial transparency of the outer plastic portion of the clot collection reservoir. Ex. B at 5. Truvic's Symphony Brochure further confirms that the "TruView™ Clot Container" includes an at least partially transparent housing to permit visualization of the clot, as can be seen below.

(Added)



(Ex. A at 6.)

338. Defendant directly infringes claims of the 12-'333 Patent, including claim 1, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendant's direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures using the hemostasis valves) Symphony system products.

339. Defendant induces infringement of claims of the 12-'333 Patent, including claim 1, by selling Symphony systems and teaching or directing others, including physicians, to use the Symphony products that practice claim 1. Defendant actively induces users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

340. Defendant teaches and/or directs others to perform thrombectomy on, for example,

deep vein thrombosis using the Symphony system (and components thereof) and to use hemostasis valves of the system. Defendant, for example, provides Instructions for Use that state that the "Symphony Thrombectomy System is intended for: The non-surgical removal of fresh, soft emboli and thrombi from blood vessels…. The Symphony Thrombectomy System is intended for use in the peripheral vasculature." Ex. B at 2. The IFU further states that the "Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vascular using controlled aspiration." *Id.* at 1. Defendant further provides brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system. *See, e.g.*, https://www.truvic.com/symphony-product. Upon information and belief, Defendant's sales representatives additionally attend procedures and instruct physicians regarding method of using the Truvic Symphony system including on information and belief, methods of treating thrombi and emboli.

341. Defendant further engages in contributory infringement by offering to sell, selling, and/or importing into the United States the Symphony system, knowing that these are apparatuses for use in a patented process and constitute a material part of the invention that is especially made or adapted for infringement of the claims of the 12-'333 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

342. Defendant's infringement is with knowledge of the 12-'333 Patent and its claims. Specifically, as described above, Inari notified Defendant, by e-mail dated February 14, 2025, that its products would infringe claims of the 12-'333 Patent, when issued. Inari further notified Defendant that it intended to seek leave to add the 12-'333 Patent to the Complaint and would serve supplemental contentions for the 12-'333 Patent.

343. At a minimum, Defendant has notice of the 12-'333 Patent through the filing of this Complaint. On information and belief, Defendant has had knowledge of the application that would issue as the 12-'333 Patent via monitoring and investigation of Inari's patent portfolio, including in response to the notice letters provided by Inari regarding many other patents, including family members of the 12-'333 Patent.

344. Defendant has continued its infringing activities, despite knowledge of the 12-'333

Patent, and such infringement has been and continues to be egregious and willful.

345. Defendant's infringement has caused and will continue to cause Inari substantial and irreparable harm, entitling Inari to an award of damages and injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Inari requests the following relief:

A. A judgment that the Defendant has infringed one or more claims of each of the '910, 11-'333, '005, '691, '921, '012, '291, '580, '384, ~~and~~ '669, and 12-'333 Patents and that such infringement is willful;

B. A preliminary and permanent injunction enjoining Defendant and Defendant's officers, agents, servants, employees, attorneys and any other persons who are in active concert or participation with such persons, from making, selling, using, offering for sale or importing the Symphony Thrombectomy System and components thereof;

C. For an award of damages, including lost profits, no less than a reasonable royalty under 35 U.S.C. § 284, arising from such infringement;

D. For an award of reasonably royalties pursuant to 35 U.S.C. § 154(d) for provisional rights between the publication of a patent application and issuance of substantially identical claims;

E. For increased damages pursuant to 35 U.S.C. § 285 or as otherwise permitted by law;

F. For an award of attorneys' fees and costs pursuant to 35 U.S.C. § 285 or as otherwise permitted by law; and

G. For such other relief as the Court deems just and proper.

Dated: ~~February 7~~March 5, 2025

PERKINS COIE LLP

By: ~~/s/~~ *Daniel T. Keese*

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ATTORNEYS FOR PLAINTIFF INARI MEDICAL, INC.

Summary report: **Litera Compare for Word 11.9.1.1 Document comparison done on 3/5/2025 2:36:04 PM**	
Style name: Perkins	
Intelligent Table Comparison: Active	
Original DMS: iw://perkinscoie.cloudimanage.com/LEGAL/170765228/9	
Modified DMS: iw://perkinscoie.cloudimanage.com/LEGAL/180139626/3	
Changes:	
Add	451
~~Delete~~	275
~~Move From~~	0
Move To	0
Table Insert	1
~~Table Delete~~	0
Table moves to	0
~~Table moves from~~	0
Embedded Graphics (Visio, ChemDraw, Images etc.)	19
Embedded Excel	0
Format changes	0
Total Changes:	746

EXHIBIT 3

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/497,249	03/04/2025	12239333	111552.8023.US07	6832

25096 7590 02/12/2025

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

ISSUE NOTIFICATION

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

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

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

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

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

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

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

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

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

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

Inari Medical, Inc., Irvine, CA;

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

EXHIBIT 4

From: Tessar, Amanda (DEN)
To: Joshua Stowell
Cc: *Inari-Imperative; Lit TSPVL.107L; Joe Re
Subject: RE: Notice regarding new Inari patent
Date: Friday, February 21, 2025 3:07:13 PM

Thanks for providing Truvic's position, Josh. I'll send an invite for Thursday at 3 pm PT.

From: Joshua Stowell <Joshua.Stowell@knobbe.com>
Sent: Friday, February 21, 2025 2:38 PM
To: Tessar, Amanda (DEN) <ATessar@perkinscoie.com>
Cc: *Inari-Imperative <Inari-Imperative@perkinscoie.com>; Lit TSPVL.107L <LitTSPVL.107L@knobbe.com>; Joe Re <Joe.Re@knobbe.com>
Subject: RE: Notice regarding new Inari patent

Amanda,

Imperative Care opposes Inari's motion to add an eleventh patent to the case for several reasons. First, Inari has not provided any reason why it would need an eleventh patent. Inari has already asserted ten patents and almost 200 patent claims. Two of the ten patents were added to the case less than two weeks ago. Inari cannot possibly try the huge number of patent claims it has already asserted, let alone additional patent claims.

Second, given that Inari has already asserted far more claims than it can try, Inari's conduct reflects a goal to drive up the cost of the litigation and outspend Imperative Care. This conduct is reflected in Inari's recent discovery demands for access to future Imperative Care products having no relevance to this case, and Mr. Al-Salam's February 18 letter threatening Imperative Care with yet more patents. Inari's strategy to harass Imperative Care, unnecessarily complicate the case, exhaust Imperative Care and Court resources, and generally drive-up the cost of the litigation is improper.

Third, Inari's request to add an additional patent shortly before the parties begin exchanging claim construction positions would prejudice Imperative Care. The new patent Inari seeks to add does not even issue until March 4, 2025, yet the parties must exchange claim terms for construction on March 13, 2025. Such a short turnaround does not afford Imperative Care sufficient time to consider the new patent and its claims. Moreover, under the Patent Local Rules, Imperative Care should have 45 days from the date Inari serves infringement contentions to identify the claim terms in the new patent subject to 112(6). Yet, Imperative Care would receive only 9 days to make such a determination if Inari adds the patent on March 4. Further, Inari's proposal would force Imperative Care to engage in claim construction before it has completed its invalidity contentions, which is inconsistent with the local rules and would prejudice Imperative Care.

For at least these reasons, Imperative Care will oppose Inari's motion. Imperative Care believes

that the parties should proceed on the ten patents currently asserted in the case. I am available next Thursday, February 27 at 3 p.m. (PT) for a meet and confer if that works for you.

Best Regards,

Joshua Stowell
Partner
Joshua.Stowell@knobbe.com
949-721-5252 **Direct**
Knobbe Martens
2040 Main St., 14th Fl.
Irvine, CA 92614
www.knobbe.com/joshua-stowell

From: Tessar, Amanda (Perkins Coie) <ATessar@perkinscoie.com>
Sent: Friday, February 14, 2025 4:29 PM
To: Lit TSPVL.107L <LitTSPVL.107L@knobbe.com>
Cc: Inari-Imperative@perkinscoie.com
Subject: Notice regarding new Inari patent

Dear Joe, Josh, and Nick,

We write to provide notice that Inari received word this week that the Patent Office will issue United States Patent No. 12,239,333 on March 4, 2025. Inari intends to seek leave to add this patent to the case through a Third Amended Complaint as soon as it issues.

Please confirm that Imperative Care will not oppose the addition of this new patent to the case. Assuming not, and in the interest of permitting Imperative Care sufficient time to prepare its invalidity contentions, we would be happy to work with you on a schedule to provide infringement contentions for the '333 Patent in advance of its issuance and amendment of the complaint.

Regards,

--Amanda

Amanda Tessar
PARTNER | PERKINS COIE
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atessar@perkinscoie.com
perkinscoie.com

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

INARI MEDICAL, INC.,

Plaintiff,

v.

IMPERATIVE CARE, INC. ,

Defendant.

Case No. 4:24-cv-03117-EKL

[PROPOSED] ORDER GRANTING PLAINTIFF'S MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT

Hearing Date: May 29, 2025
Time: 1:30 p.m.
Location: San Jose Federal Courthouse, Courtroom 7, 4th Floor
Judge: Eumi K. Lee

Before the Court is Plaintiff's Motion for Leave to File Third Amended Complaint. The Court, having carefully considered the submission, the record, the applicable law, and any arguments related thereto, hereby GRANTS Plaintiff's motion. Plaintiff shall file its Third Amended Complaint, adding an additional count of patent infringement for U.S. Patent No. 12,239,333, on the docket within five days from the date of this order. The Court further grants Plaintiff leave to supplement its infringement contentions to address U.S. Patent No. 12,239,333.

Dated:

By: _____

Judge Eumi K. Lee
UNITED STATES DISTRICT JUDGE