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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. and TRUVIC MEDICAL, INC., Defendants.	Case No. 24-cv-3117 COMPLAINT FOR PATENT INFRINGEMENT DEMAND FOR JURY TRIAL

Inari-2013
Imperative Care, Inc. v. Inari Medical, Inc.
IPR2025-00289

1. Plaintiff Inari Medical, Inc. ("Inari") files this Complaint for Patent Infringement against Defendants Imperative Care, Inc. ("Imperative Care") and Truvic Medical, Inc. ("Truvic") (collectively, "Truvic" or "Defendants") 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.

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 eight patents: United States Patent Nos. 11,974,910, 11,969,333, 11,554,005, 11,744,691, 11,844,921, 11,697,011, 11,697,012, and 11,865,291.

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.

8. Defendant Truvic Medical, Inc. ("Truvic") is a Delaware corporation having its principal place of business and headquarters at 1359 Dell Avenue, Campbell, California. Truvic is a wholly-owned subsidiary of Imperative.[1]

JURISDICTION AND VENUE

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

10. 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.

11. 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

[1] In August 2023, Imperative Care announced that it had restructured its corporate organization and renamed Truvic as "Imperative Care Vascular." *See* https://www.businesswire.com/news/home/20230810499166/en/Imperative-Care-Unveils-New-Structure-to-Elevate-Care-for-Patients-with-Vascular-Diseases. As of the filing date of this Complaint, however, Truvic remains a wholly-owned subsidiary of Imperative Care that is registered in Delaware. "Imperative Care Vascular," by contrast, does not appear to be a registered business entity in any state, and so presumably must be a business unit of Imperative Care, rather than a separate company. For this reason, Inari names both Imperative Care and Truvic as defendants here.

and fairly anticipate being brought into court in this District.

12. This Court has personal jurisdiction over Truvic 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.

13. 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 Defendants have committed acts of patent infringement in this Judicial District and have 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

14. 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.

15. 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 50 United States patents and is in the process of allowing additional claims in multiple pending applications.

16. 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, 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.

17. 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 first version of FlowTriever includes 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 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. The FlowTriever system allows the removal of the FlowTriever Catheter from the patient without the simultaneous

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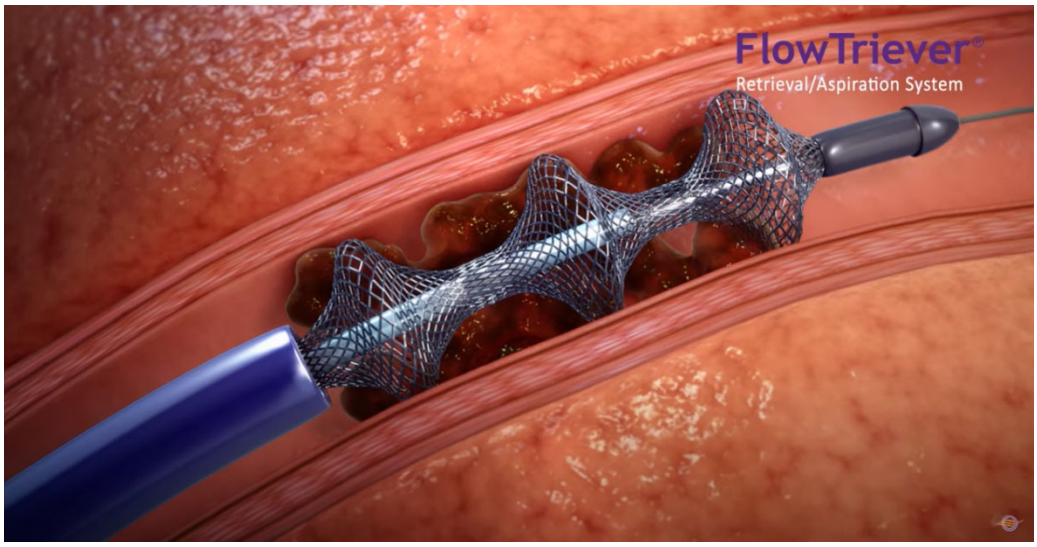
[2] *See* www.inarimedical.com/int/in-the-news.

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

removal of the Aspiration Guide Catheter.[4] A capture from a FlowTriever video depicting the distal end of a FlowTriever catheter is below:



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

18. 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]

19. 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]

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

[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://www.inarimedical.com/flowtriever-inari-fda-510k-clearance-treatment-pulmonary-embolism/.

20. 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 (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.

21. 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.

22. 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.

23. 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]

24. 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

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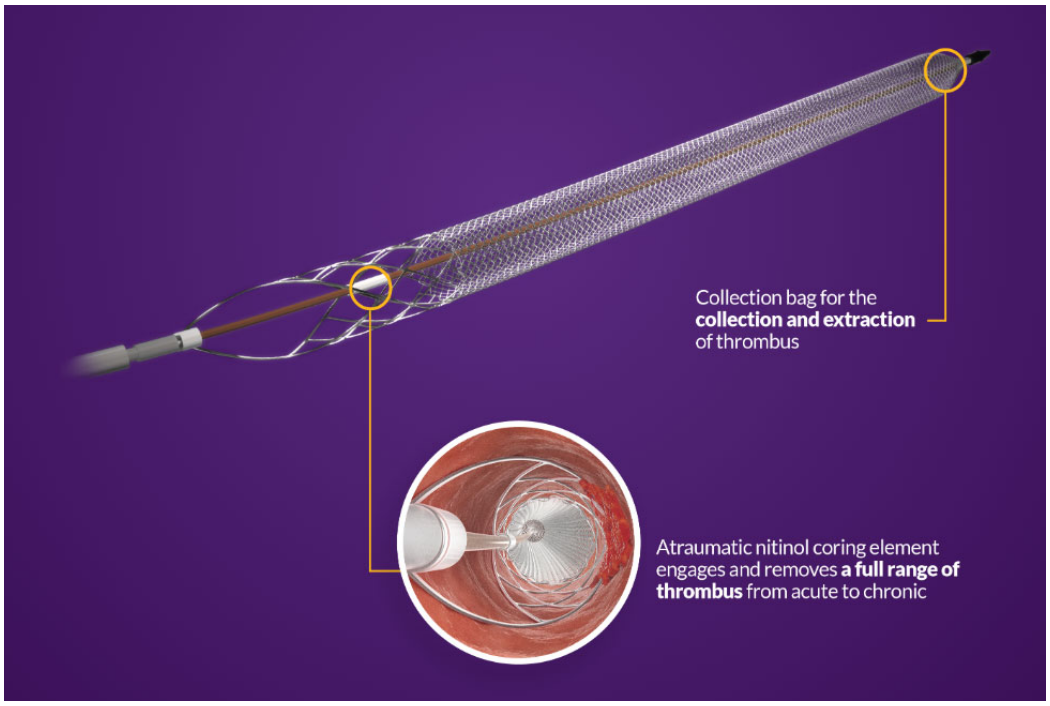
[8] *See* FDA 510(k) Premarket Notification K191710 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191710.pdf).

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

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. The expandable member and tissue collection bag. At the proximal end of the catheter is a handle used to enable expansion of the expandable member and net.

25. 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:



26. 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

[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).

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

Truvic's Copycat Devices

27. 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.

28. In July 2021, Imperative Care acquired Truvic,[14] a thrombectomy device developer that, based on recorded filings, was incorporated in 2020. Truvic 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.

29. 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 the 24F Symphony Catheter, 16F Symphony Catheter, 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. 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

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

[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.

disrupting the clot material. The Symphony Catheters and Symphony Dilators are introduced through a vascular 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 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]

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

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

35. 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.

36. 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.

37. 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

38. 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.

39. The '910 Patent is valid and enforceable.

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

41. The ’333 Patent is valid and enforceable.

42. 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]

43. The ’005 Patent is valid and enforceable.

44. 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]

45. The ’691 Patent is valid and enforceable.

46. On December19, 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.

47. The ’921 Patent is valid and enforceable.

48. On July 11, 2023, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,697,011 (“the ’011 Patent”), entitled “Hemostasis Valves and Methods of Use.” Inari owns all rights, title, and interest in and to the ’011 Patent and possesses all rights of recovery under the ’011 Patent. A true and accurate copy of the ’011 Patent is attached as Exhibit H.

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

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

49. The ’011 Patent is valid and enforceable.

50. 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 I.

51. The ’012 Patent is valid and enforceable.

52. 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 J.

53. The ’291 Patent is valid and enforceable.

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

54. 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 Defendants to inform them of Inari’s belief that Defendants were infringing at least United States Patent Nos. 11,559,382 and 11,744,691 and that Defendants would infringe other allowed claims of pending applications in the “System for Treating Embolism and Associate Devices and Methods” family 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, 11,697,011, 11,697,012, and allowed claims of Application No. 18/142,518 (later issued as United States Patent No. 11,865,291). 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 Defendants cease or delay their launch of their Symphony products until patent issues were resolved. Inari also invited a dialogue and asked Defendants to identify any genuine basis that they had for believing that they were not infringing Inari’s patents.

55. 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…."

56. 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.

57. 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 '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, '011, '012, and '291 Patents, as had been suggested was likely in Inari's September 2023 letter.

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

COUNT 1: INFRINGEMENT OF THE '910 PATENT

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

60. 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.

61. Defendants directly infringe—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 their Symphony system and components thereof.

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

63. 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:
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> a first clot aspiration assembly, including:
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> a first catheter;
>
> a first pressure source; and
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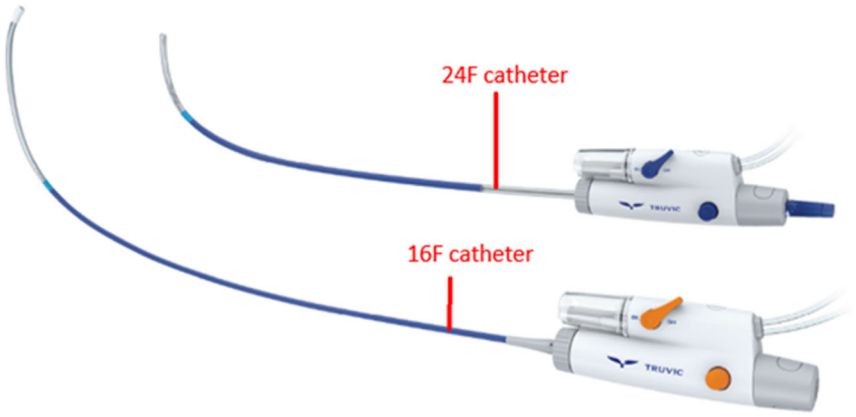
> a first fluid control device between the first catheter and the first pressure source,
>
> wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure 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.

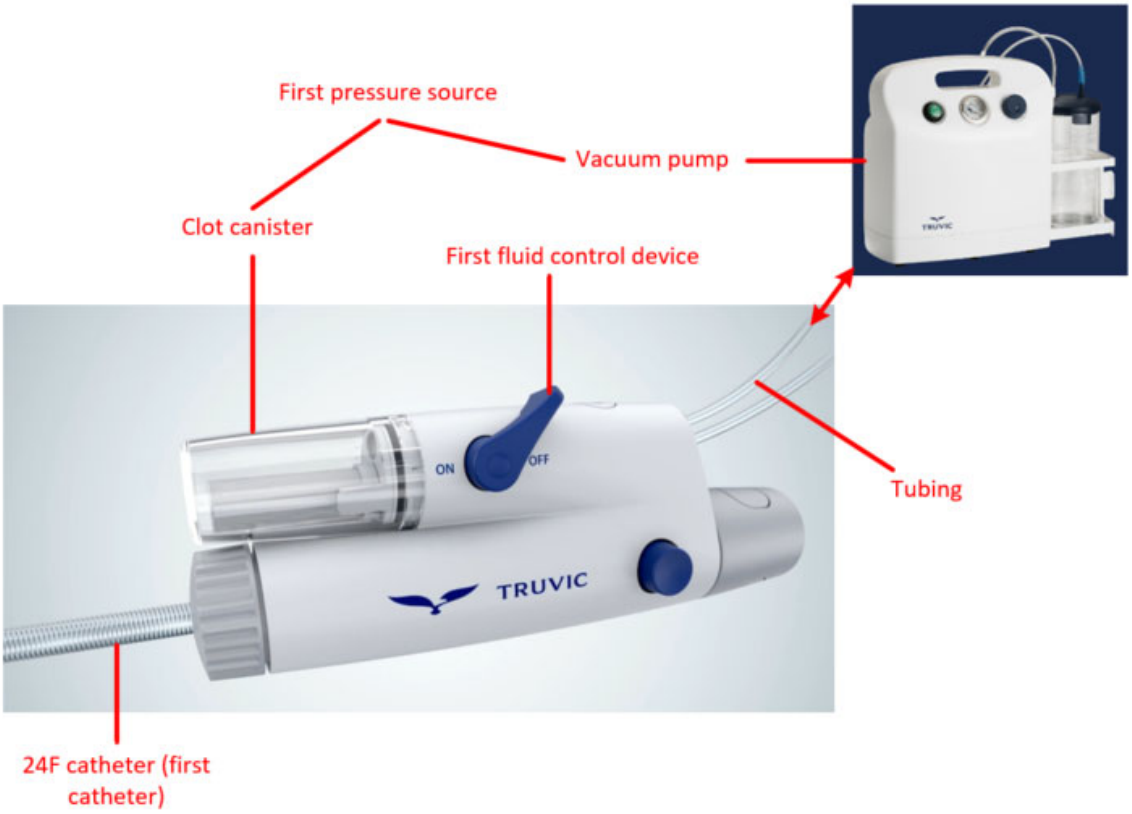
64. Claim 3 further recites: "[t]he clot treatment system of claim 1 wherein the first catheter has a size of 24 French, and wherein the size of the [] second catheter [] is 16 French."

65. 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 K. 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." (Symphony Brochure 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 Defendants 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).

66. 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 K. 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:

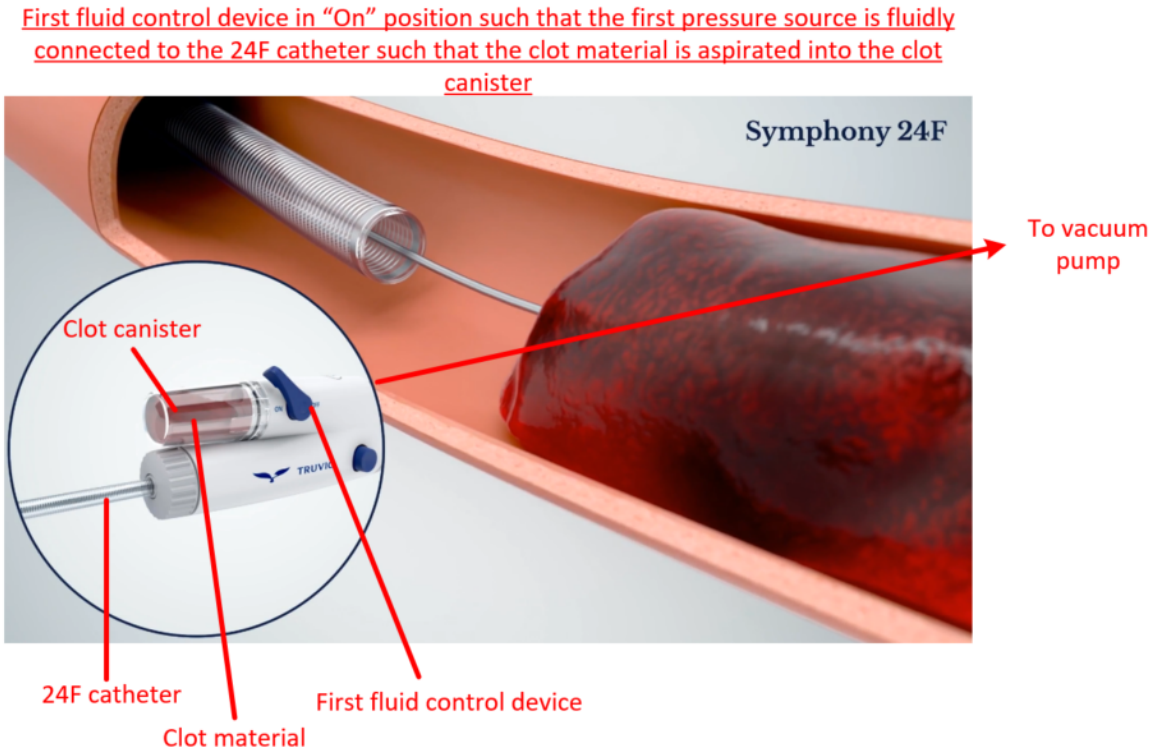


(Ex. A at 2 (annotations added).)

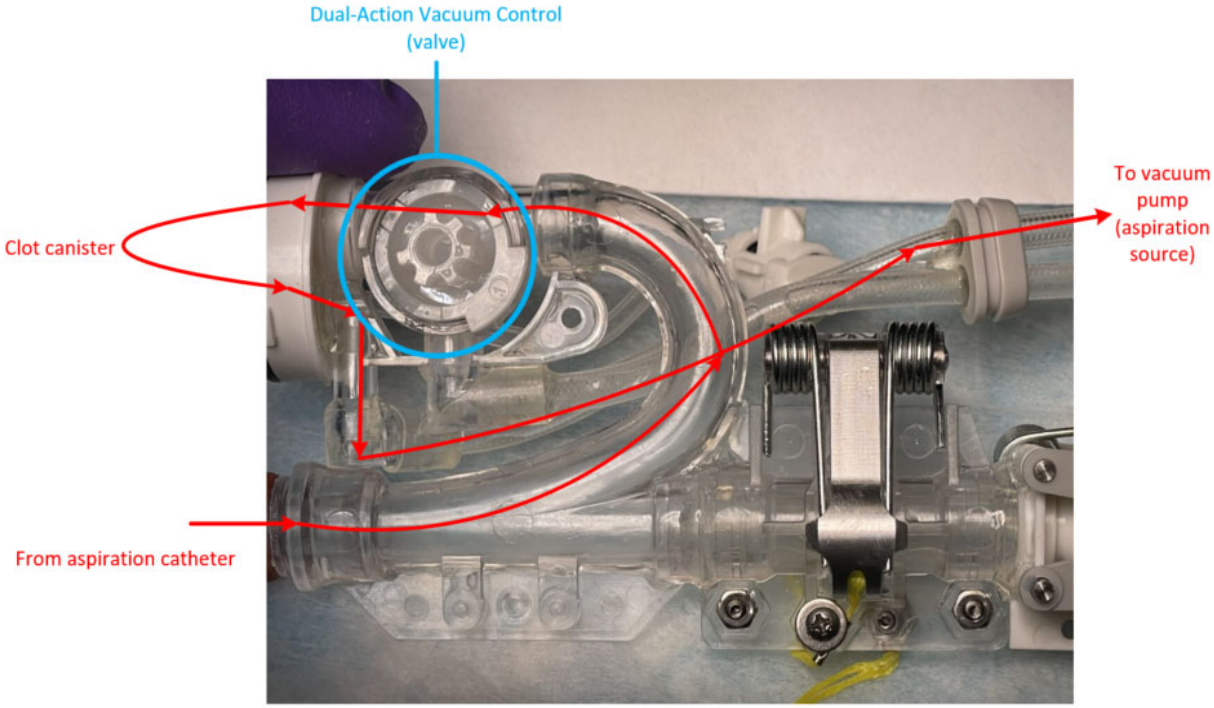


(Annotated diagram of Symphony system handle, including the first catheter, connection to a first pressure source (clot canister and vacuum pump), and a first fluid control device (the Dual-Action Vacuum Control operated by a lever).)

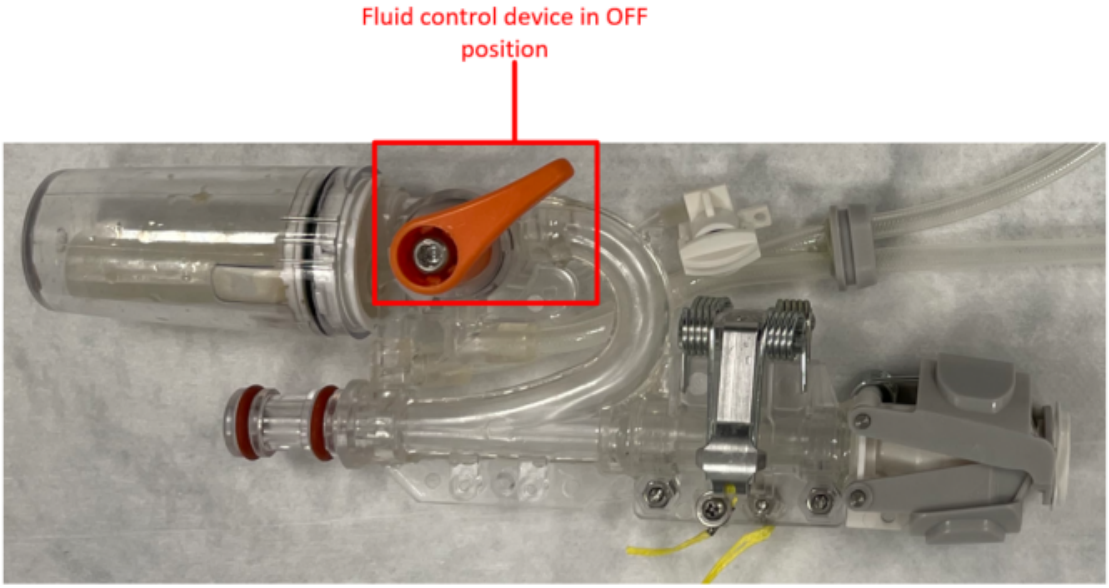
67. The Symphony system practices the limitations of claim 1, including "wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter," as can be seen in claim chart in Exhibit K. 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:



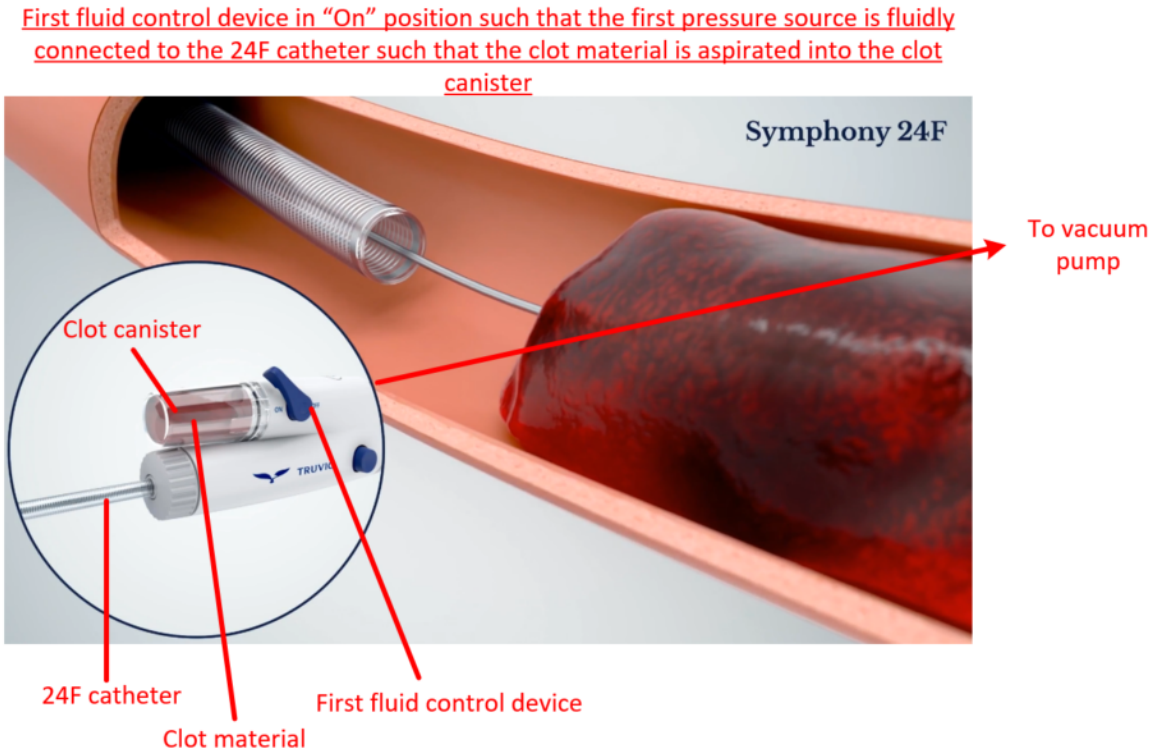
(Annotated screen capture from Symphony product video.)



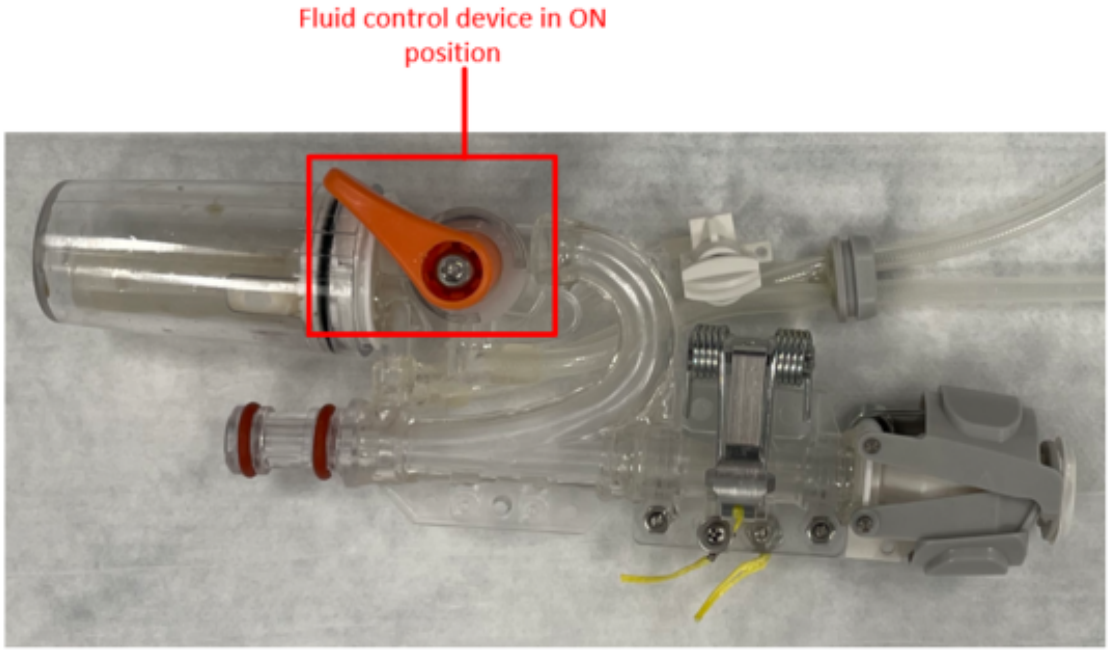
(Annotated image of internal portion of controller handle housing.)



(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)

68. 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 K. 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.

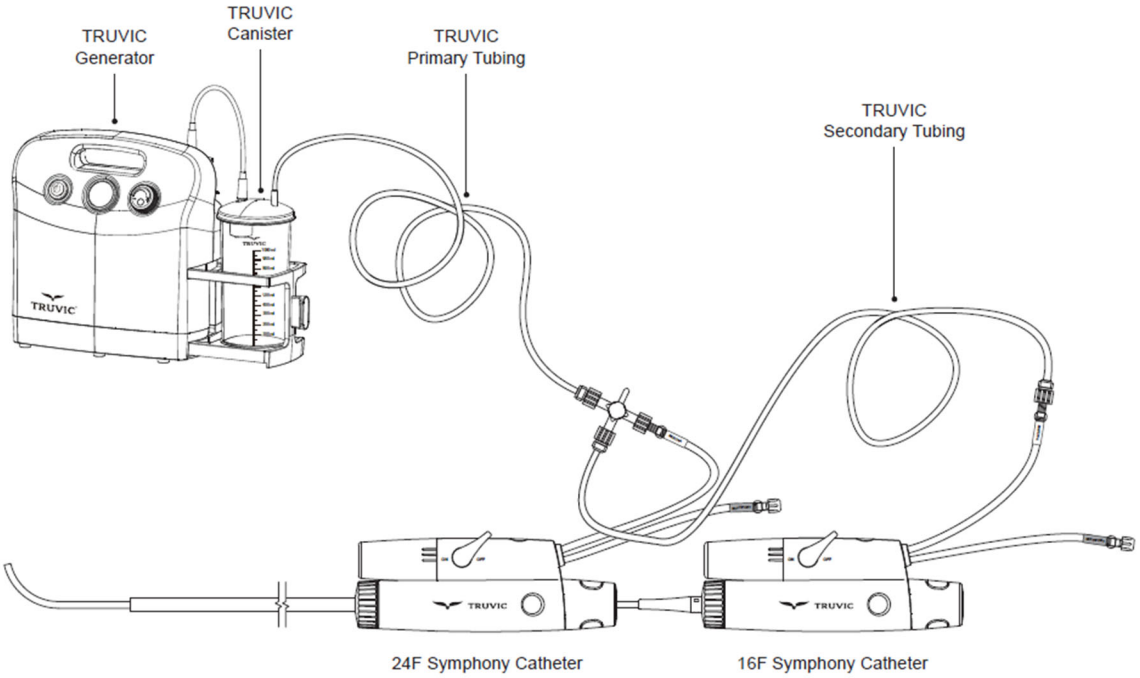


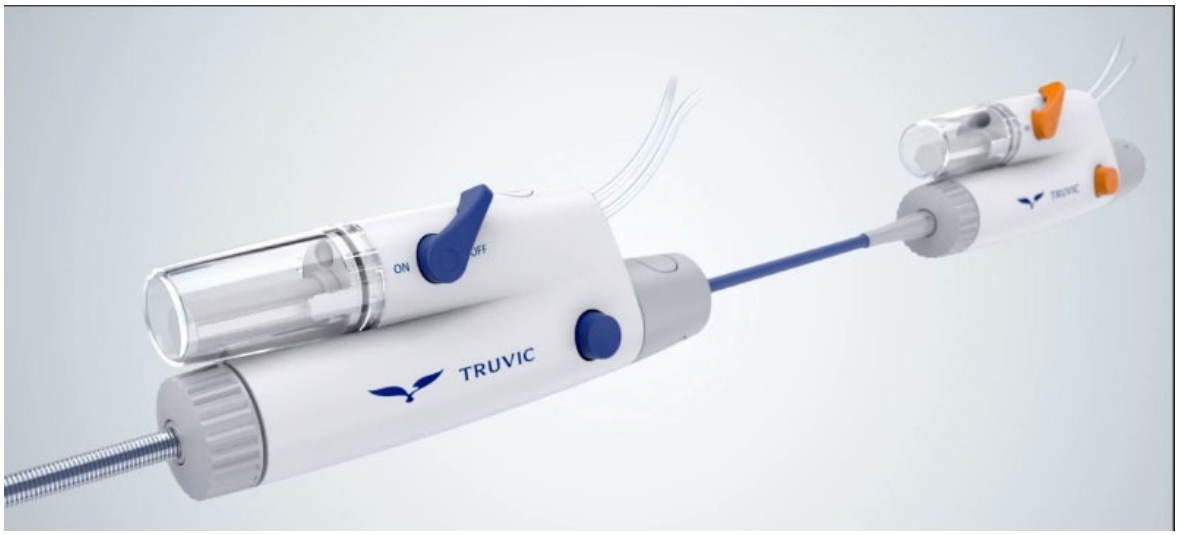
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

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.

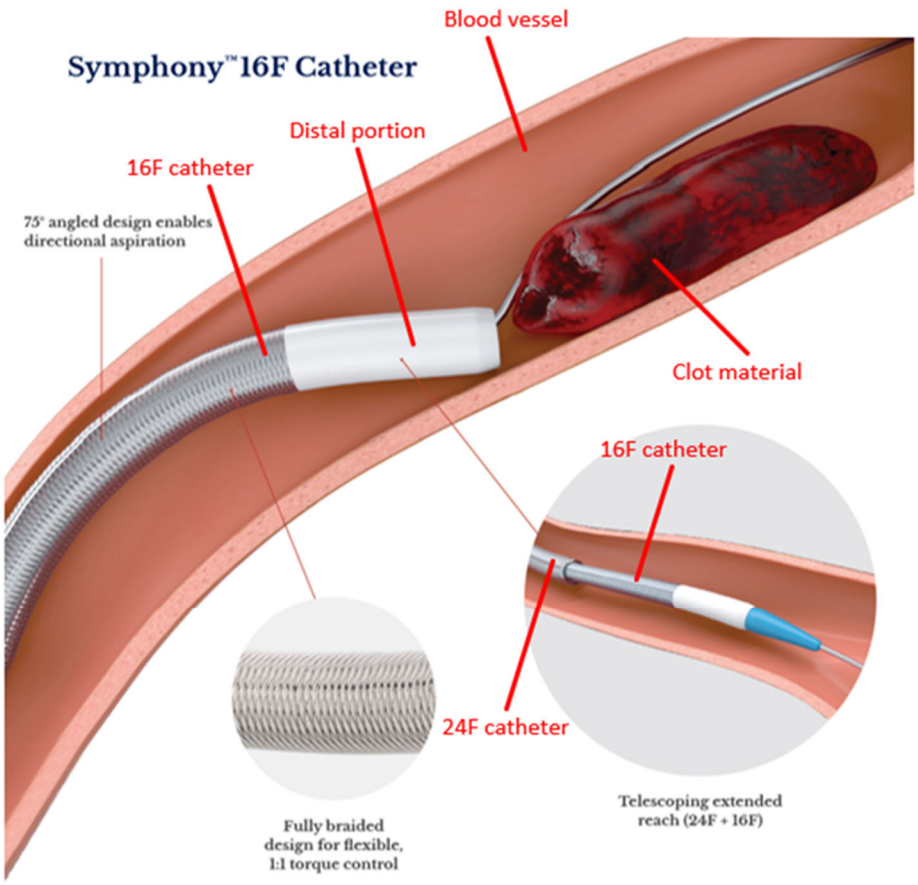
(Ex. B at 8.)

69. 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 K.

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:

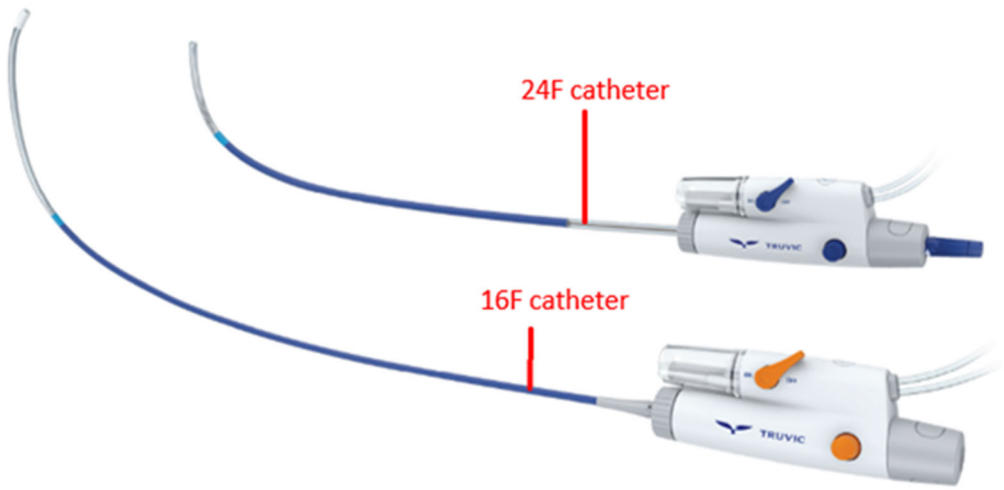


(Screen capture from Symphony product video.)

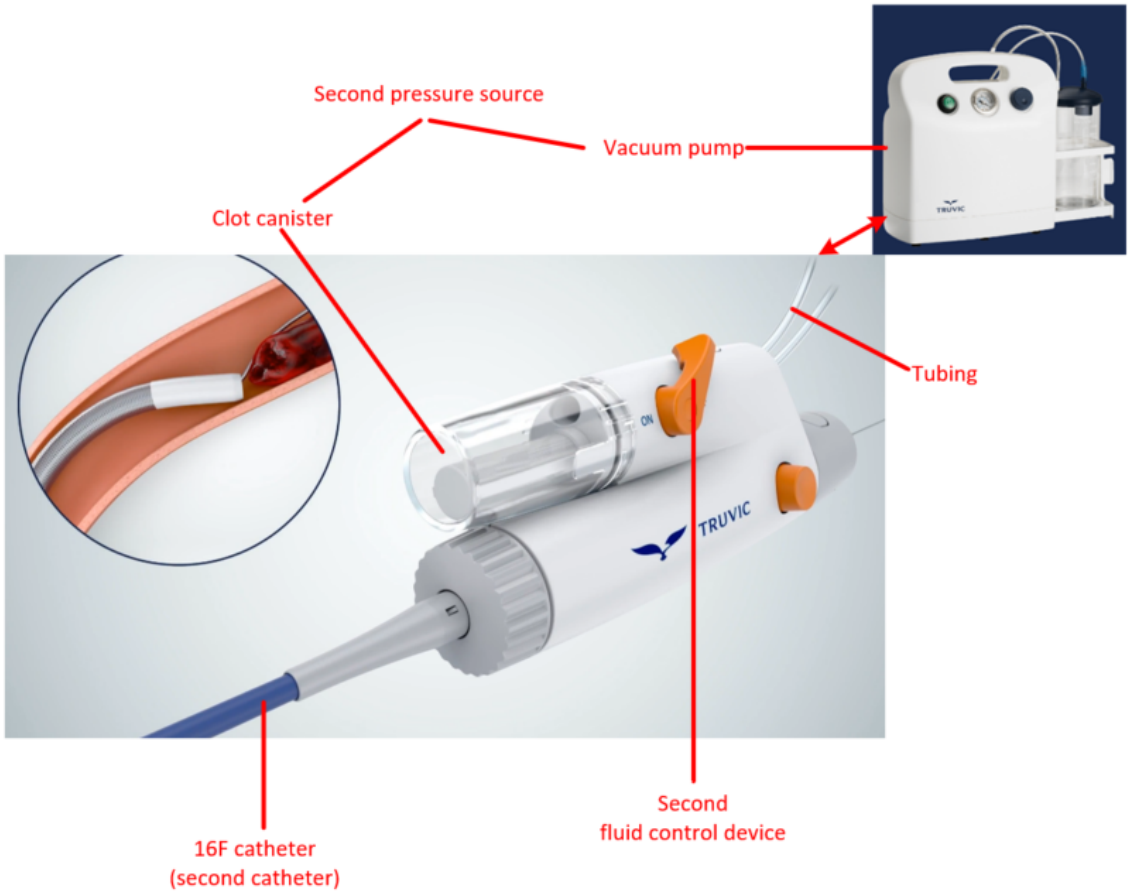


(Ex. A at 4 (annotations added).)

70. 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 K. 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:

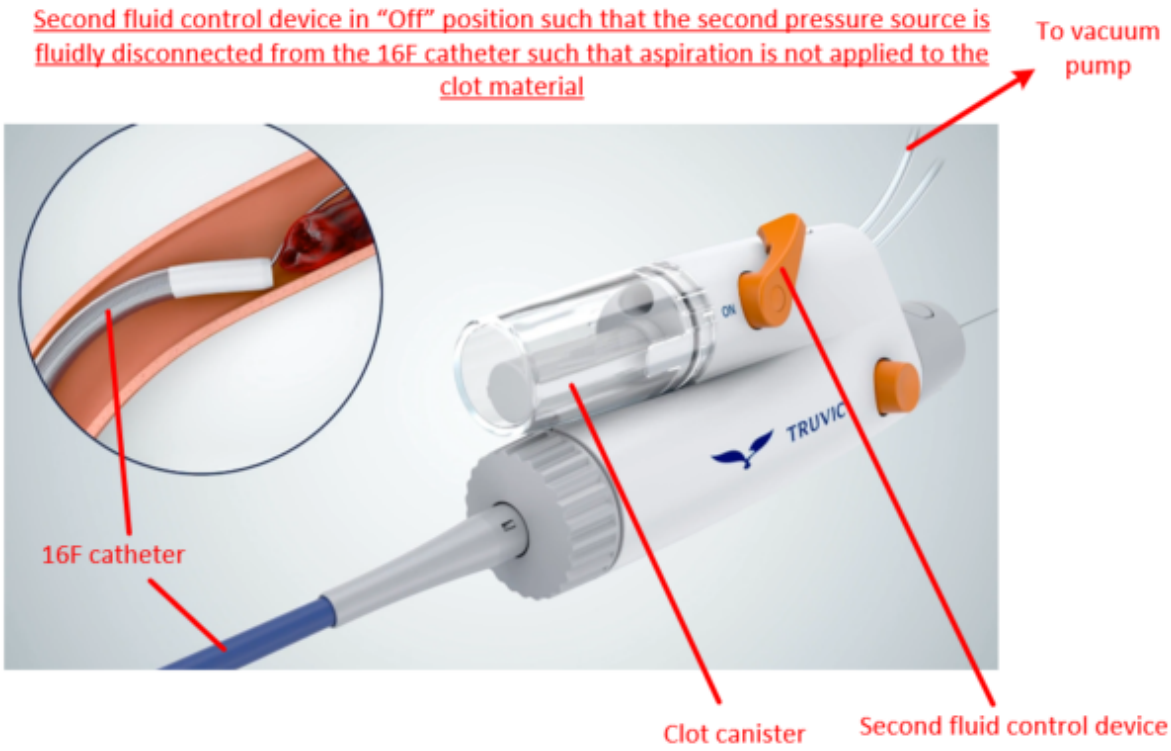


(Ex. A at 2 (annotations added).)

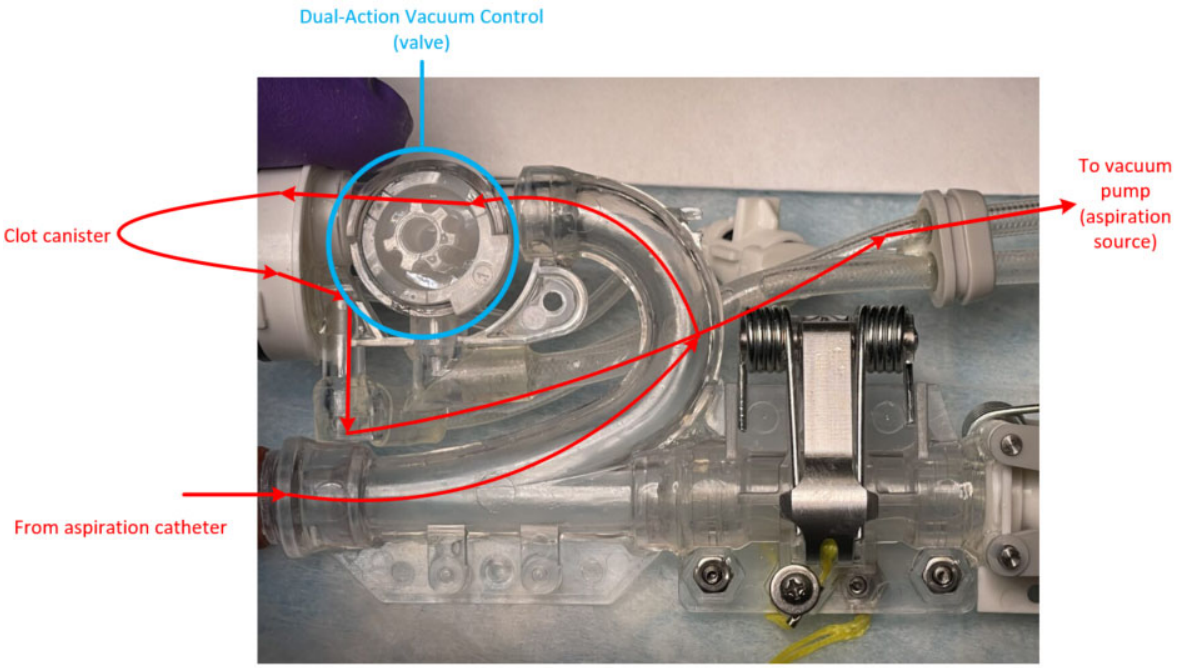


(Annotated diagram of Symphony system handle, including the second catheter, connection to a second pressure source (clot canister and vacuum pump), and a second fluid control device (the Dual-Action Vacuum Control operated by a lever).)

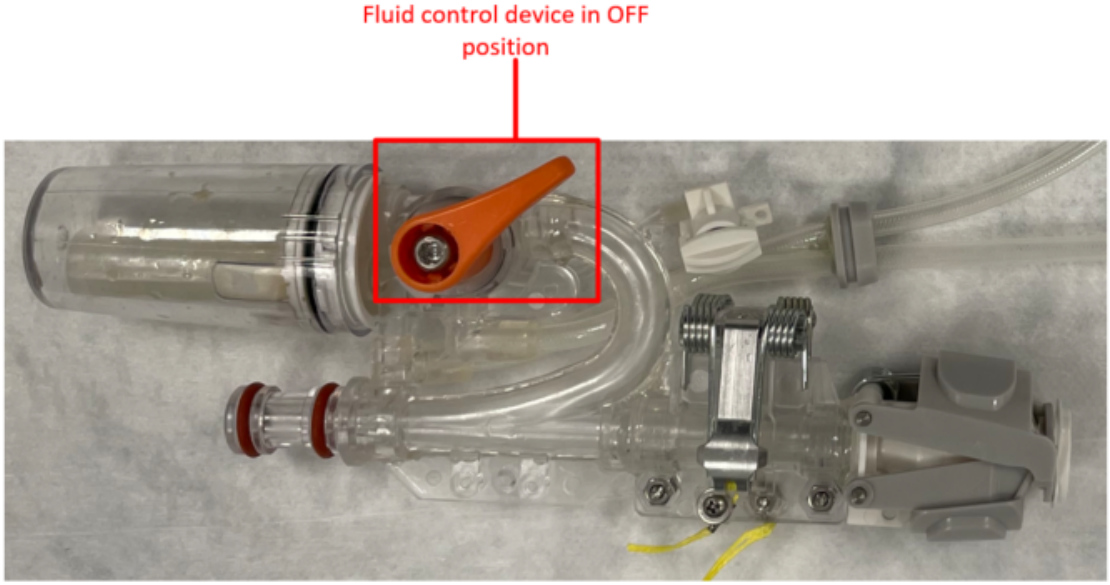
71. The vacuum control lever of the second fluid control device can be moved from the first (off) position where the second catheter is fluidly disconnected from the second pressure source to a second (on) position where the second catheter is fluidly connected to the second pressure source:



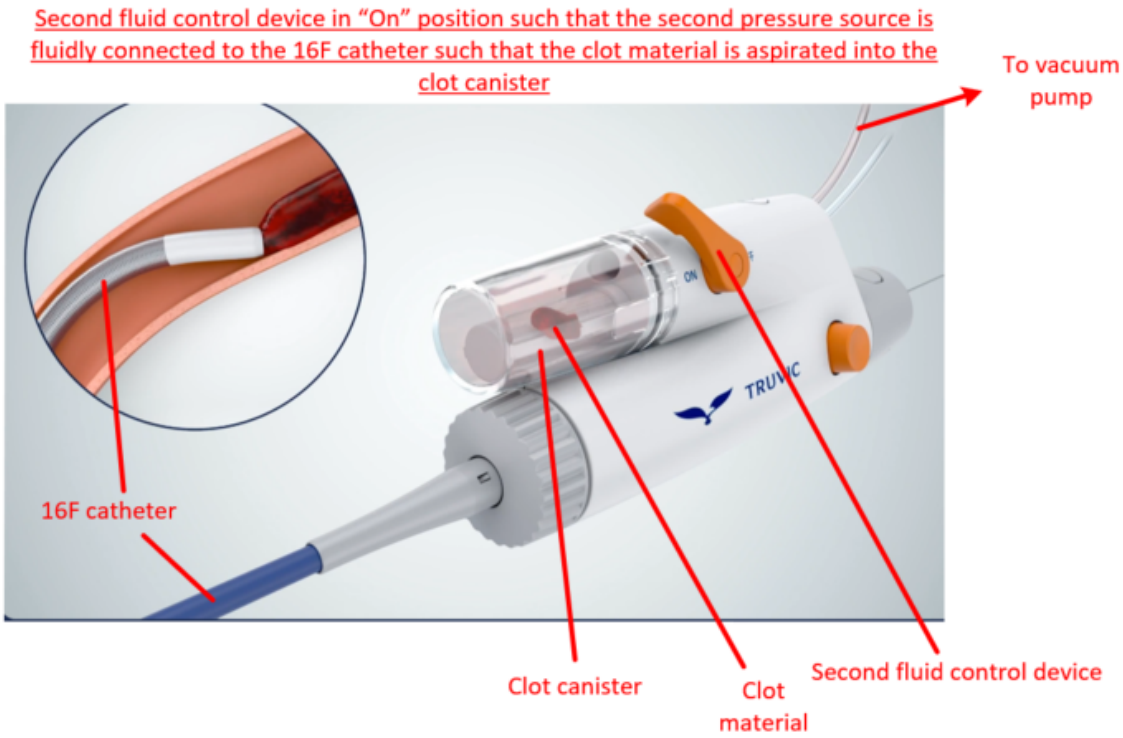
(Annotated screen capture from Symphony product video.)



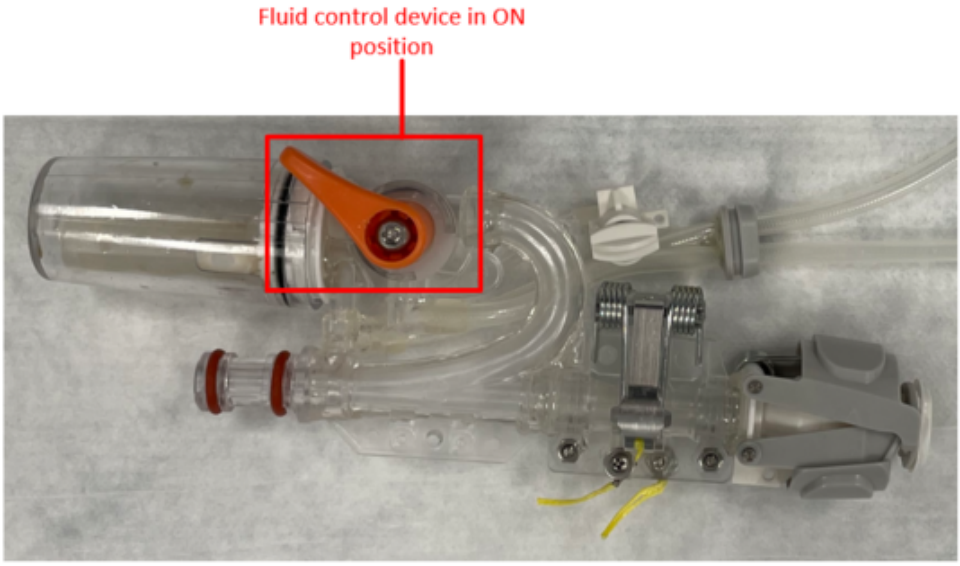
(Annotated image of internal portion of controller handle housing.)



(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)

72. 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 K. 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.

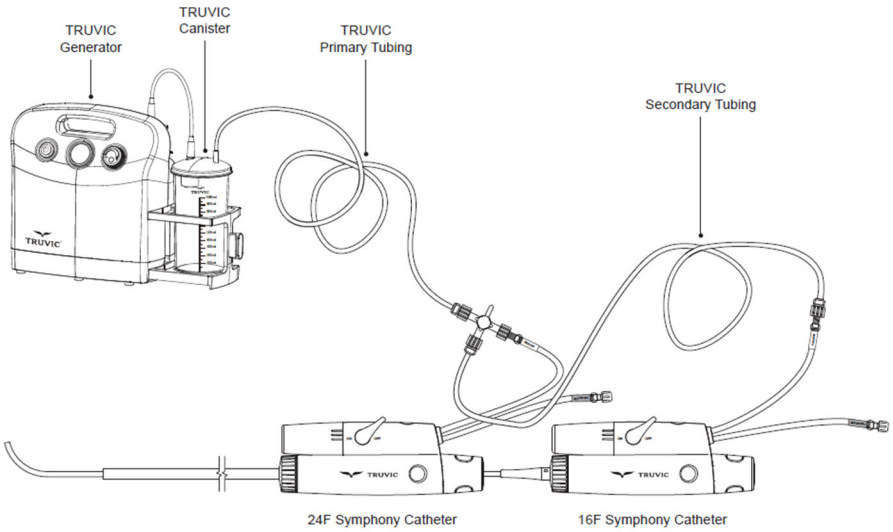


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

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.)

73. 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 K. 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.

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

75. Defendants induce 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. Defendants actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures on patients with pulmonary embolisms.

76. On information and belief, Defendants teach 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. Defendants, for example, provide instructions for use (“IFU”) 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. Defendants further provide 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, Defendants’ 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. Defendants additionally are in the process of seeking FDA clearance for the treatment of PE and have an announced intention to formally market their Symphony system to do so.

77. Defendants further engage 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.

78. Defendants’ infringement is with knowledge of the ’910 Patent and its claims. Specifically, as described above, Inari notified Defendants, 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.

79. At a minimum, Defendants have notice of the '910 Patent through the filing of this Complaint, which was submitted to the Court just a few weeks after the '910 Patent issued.

80. Defendants have continued their infringing activities after the '910 Patent issued, despite knowledge of the allowed claims (including knowledge from correspondence with Inari and through this Complaint), and such infringement has been and continues to be egregious and willful.

81. 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.

82. Defendants' 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 '333 PATENT

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

84. Defendants directly and indirectly infringe—literally and/or under the doctrine of equivalents—at least claims 20 and 22 of the '333 Patent by making, using, selling, offering for sale, and/or importing into the United States their Symphony system and components thereof.

85. The '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 '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 '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 '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 '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).

86. Specifically, claim 20 of the '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,

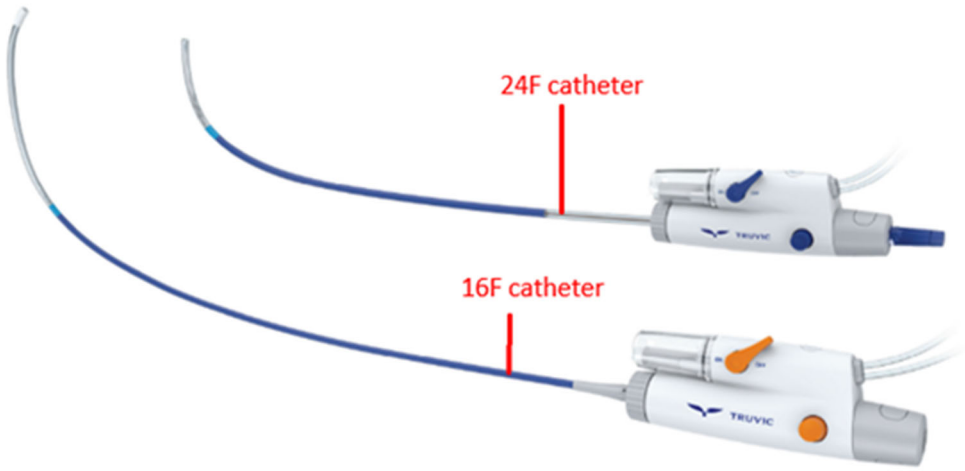
and wherein the clot canister includes a filter configured to filter the blood from the portion of the deep vein thrombosis.

87. Claim 22 of the '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."

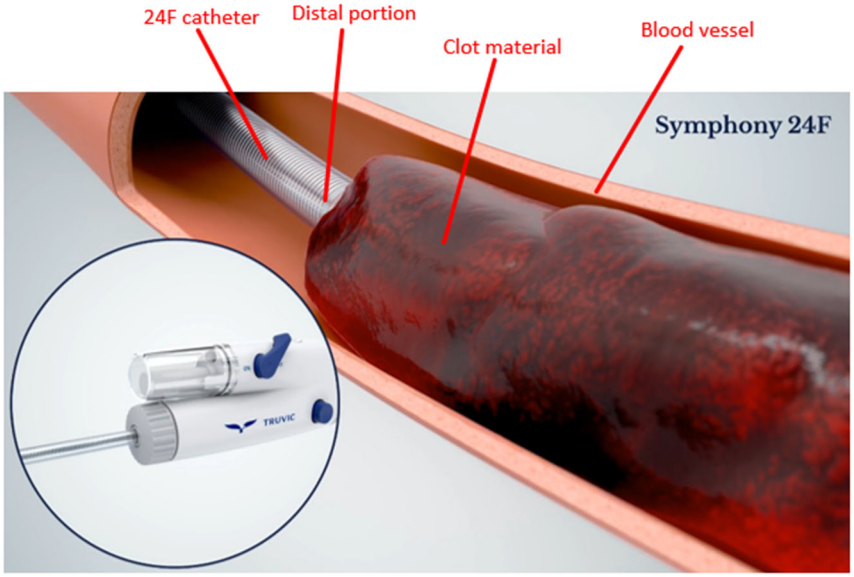
88. Performing thrombectomy on deep vein thrombosis using the Truvic Symphony system practices each limitation of at least claims 20 and 22 of the '333 Patent, as can be seen in the '333 Patent claim chart, attached as Exhibit L.

89. 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 L. 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.

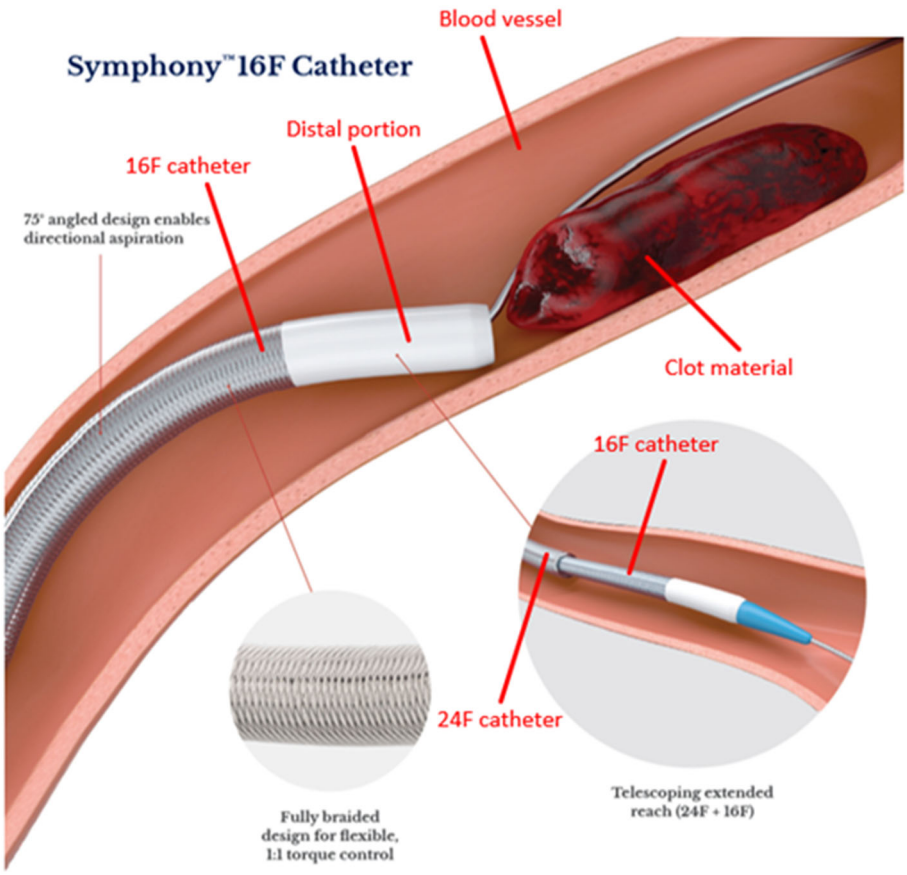
90. Thrombectomy with the Symphony system practices the limitations of claim 20, including "advancing an aspiration catheter at least partially through the vasculature of the patient such that a distal end portion of the aspiration catheter is positioned proximate to the deep vein thrombosis," as can be seen in Exhibit L. 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).)

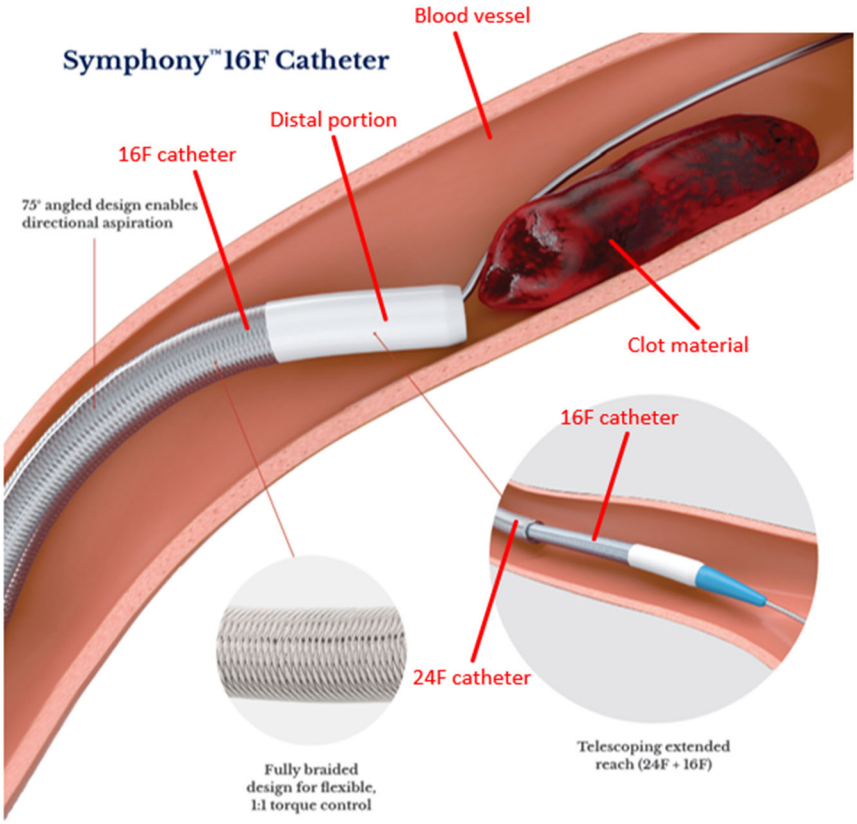


(Annotated screen capture from Symphony product video.)

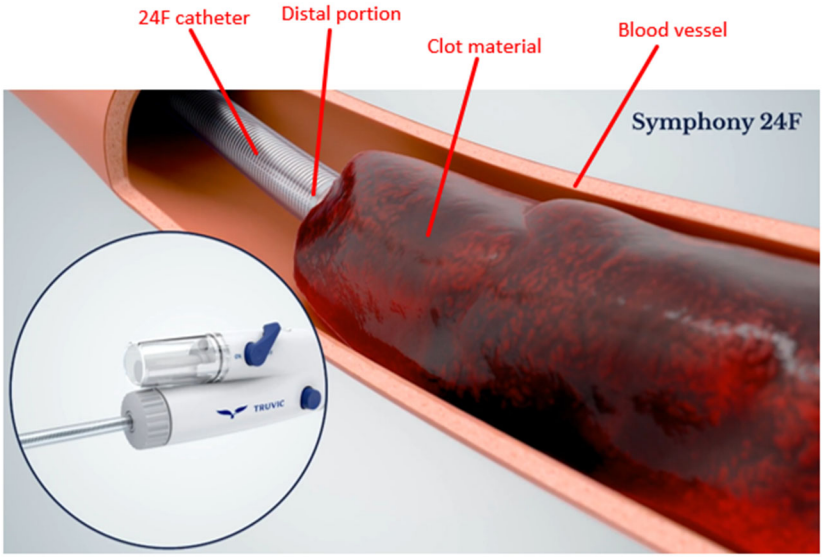


(Ex. A at 4 (annotations added).)

91. 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.



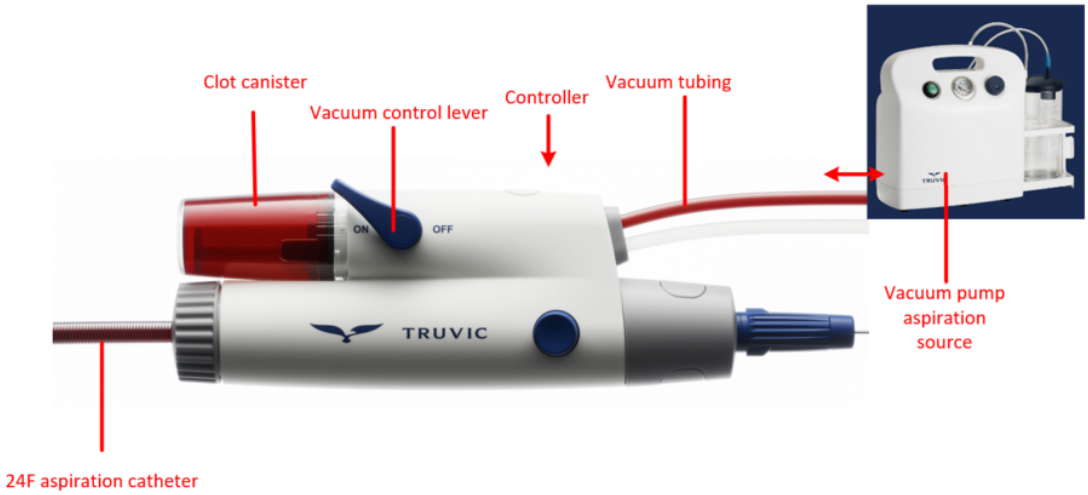
(Ex. A at 4 (annotations added).)



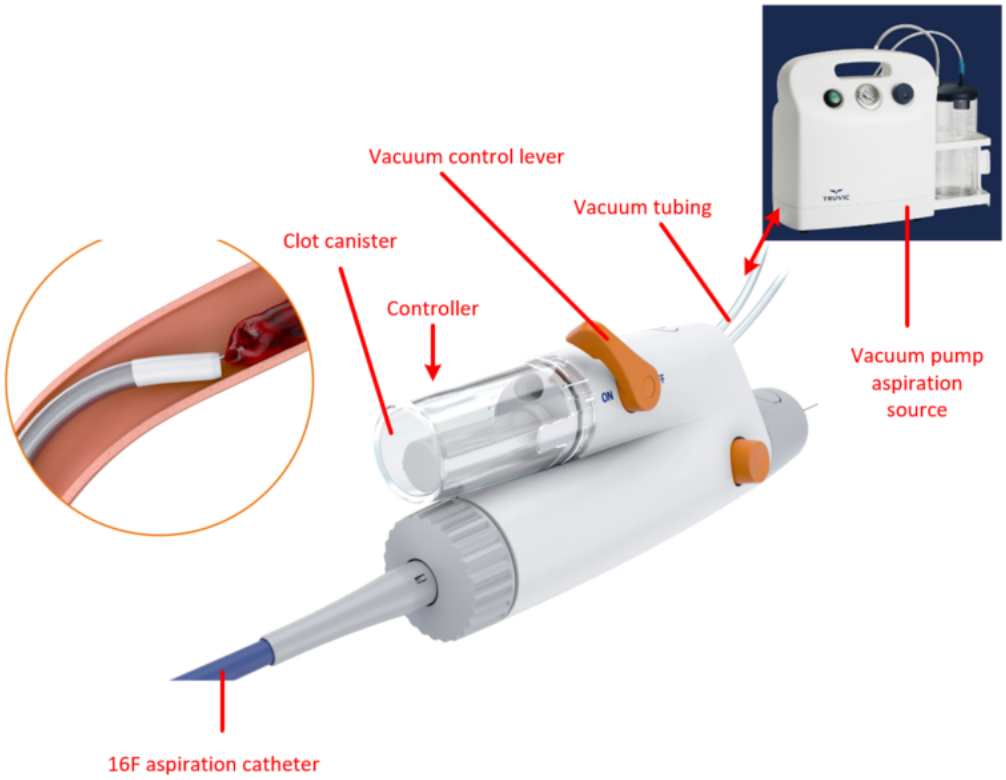
(Annotated screen capture from Symphony product video.)

92. 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

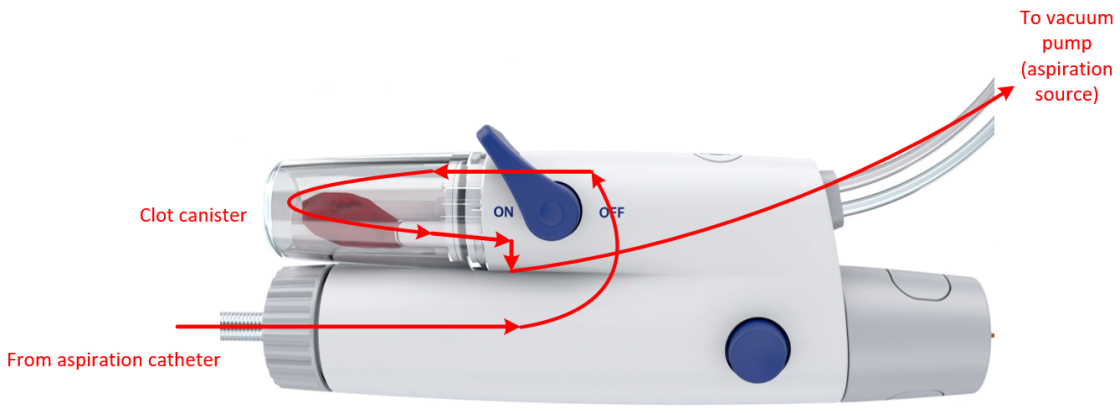
clot canister and an aspiration source proximal to the clot canister," as can be seen in Exhibit L. Specifically, in the Symphony system, the 24F and 16F catheters have lumens that are coupled along a fluid path in the controller handle, and then to an aspiration source that includes a vacuum pump that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



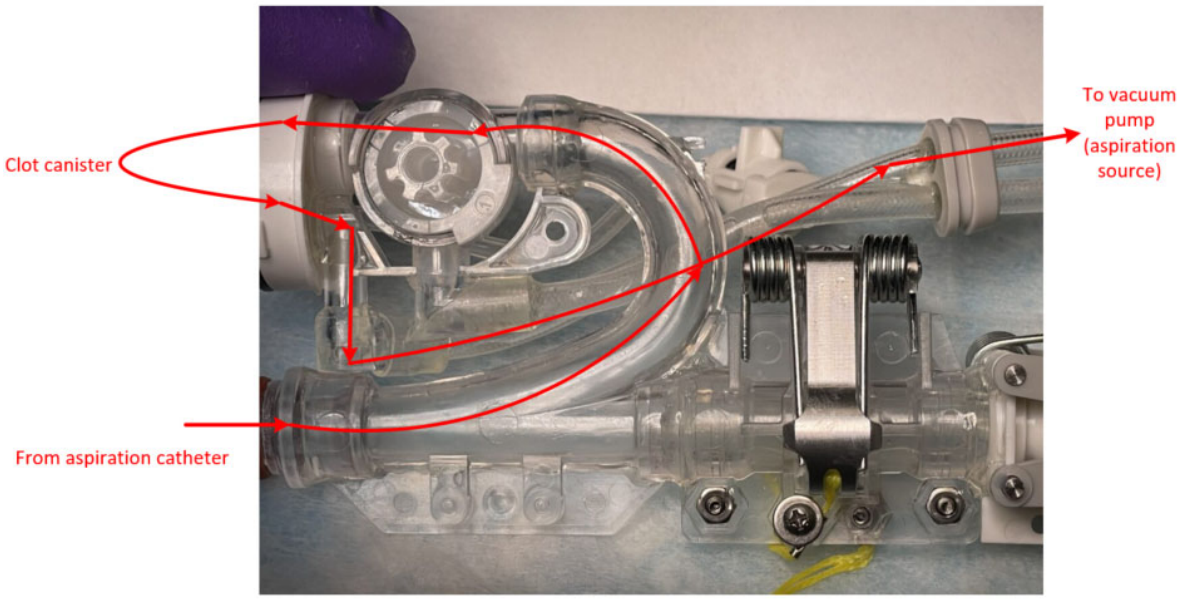
(Annotated diagram of Symphony system.)



(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.)

93. 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 L. 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.

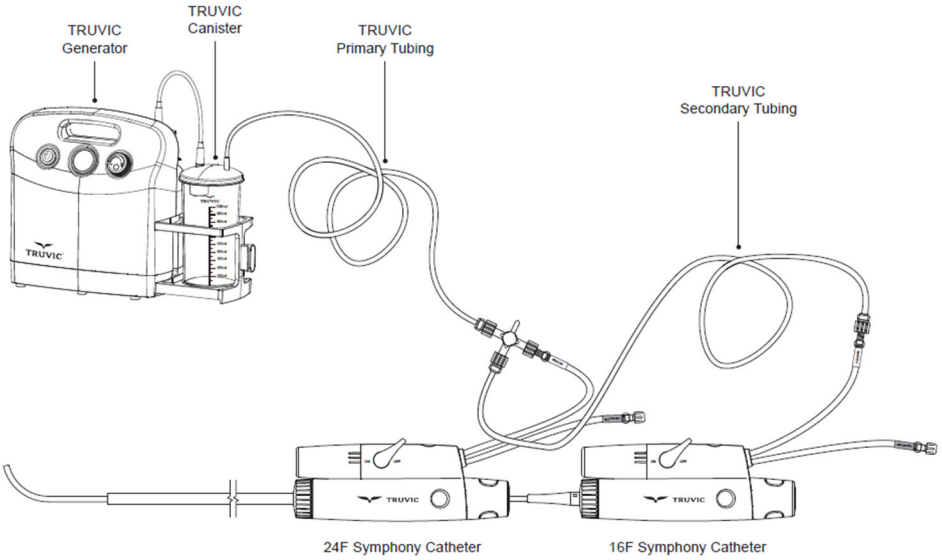
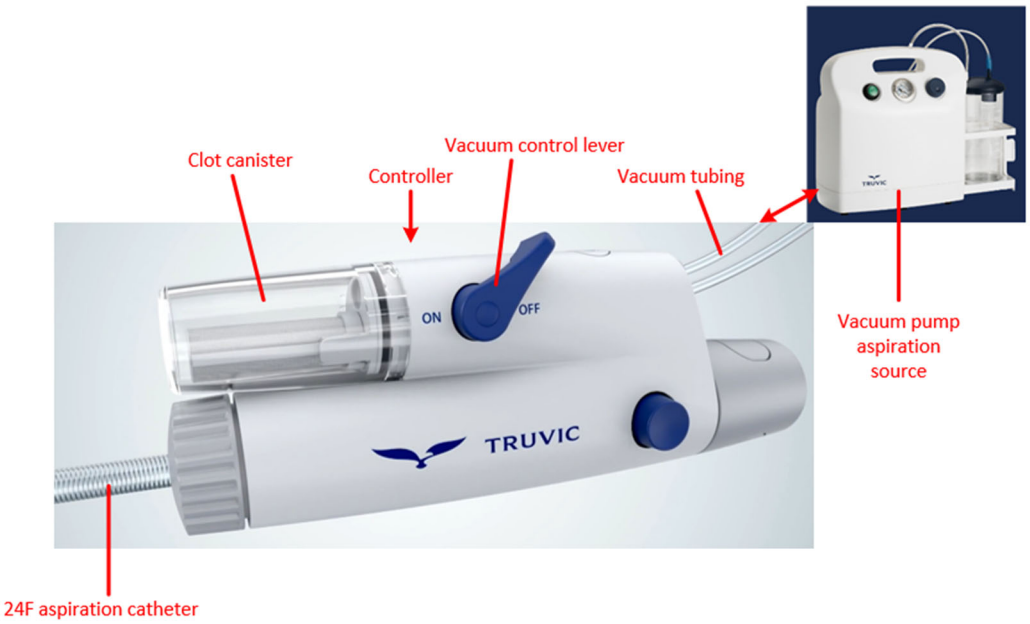


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

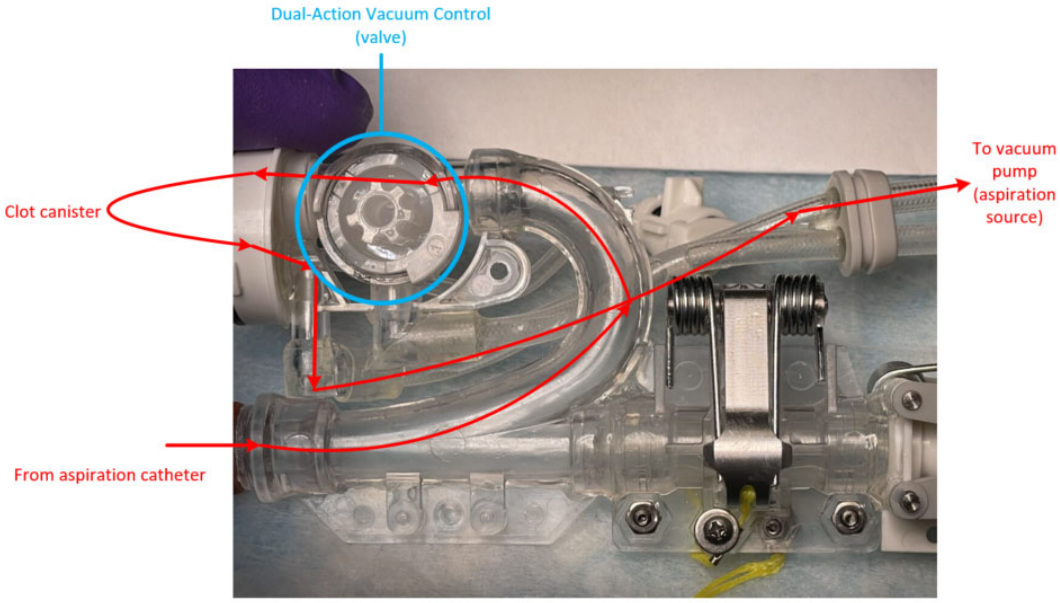
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the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

(Ex. B at 8.)

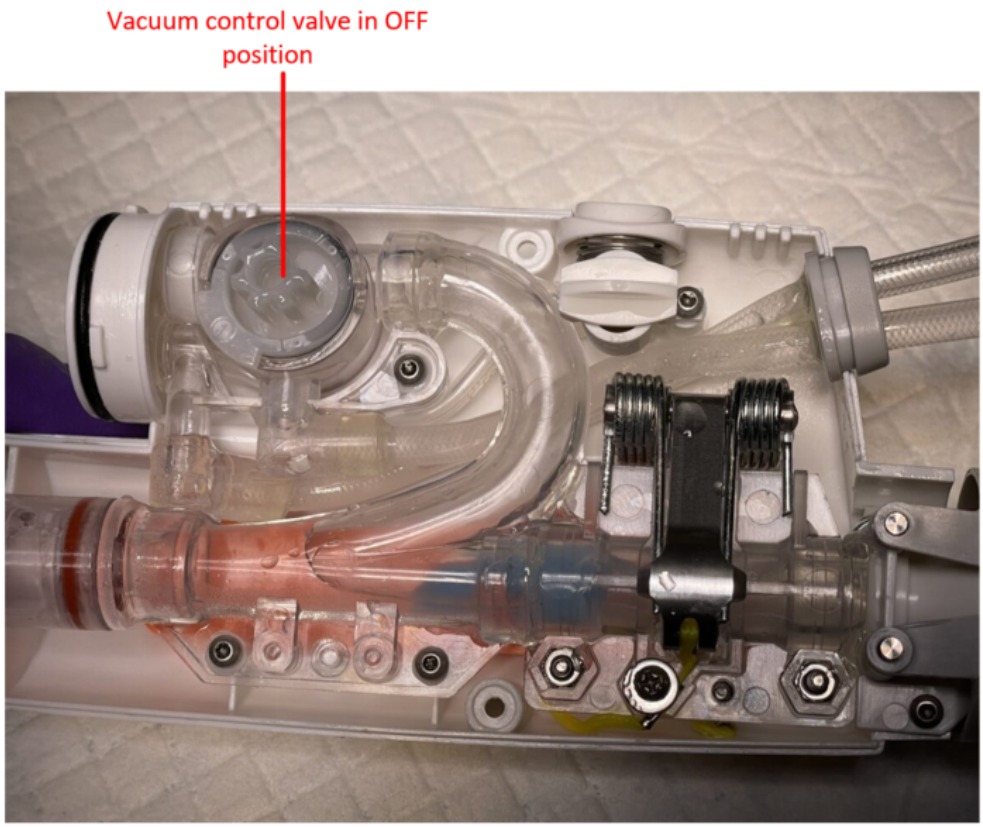
94. During thrombectomy using the Symphony system, the user initially sets the vacuum control lever on the 16F and/or 24F handles to the "OFF" position, which actuates a vacuum valve in the handle, ensuring that vacuum is not applied to the lumen of the 16F and/or 24F aspiration catheters:



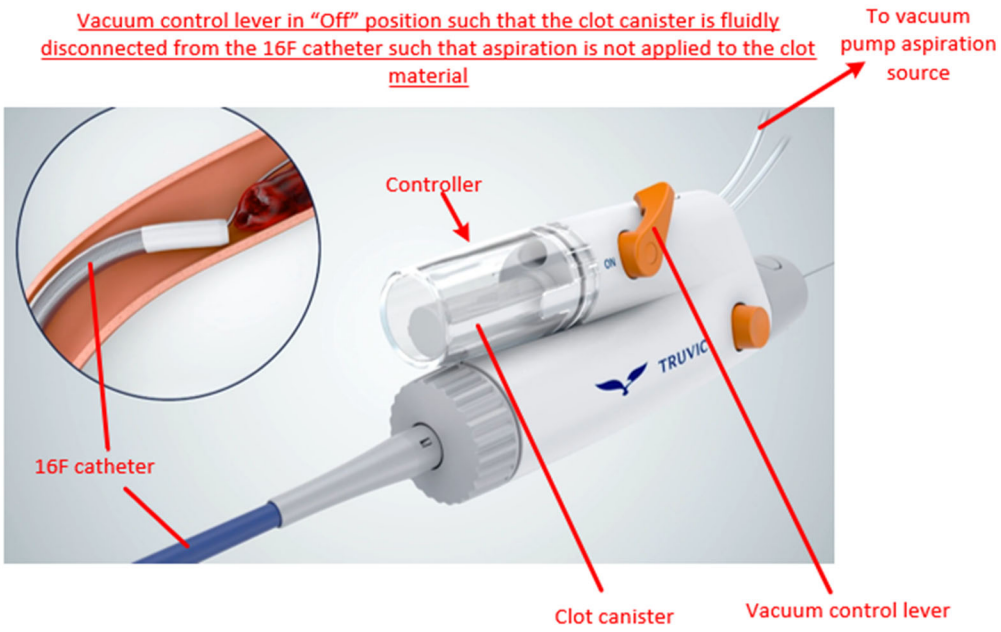
(Annotated diagram of Symphony system.)



(Annotated image of Symphony housing (internal).)



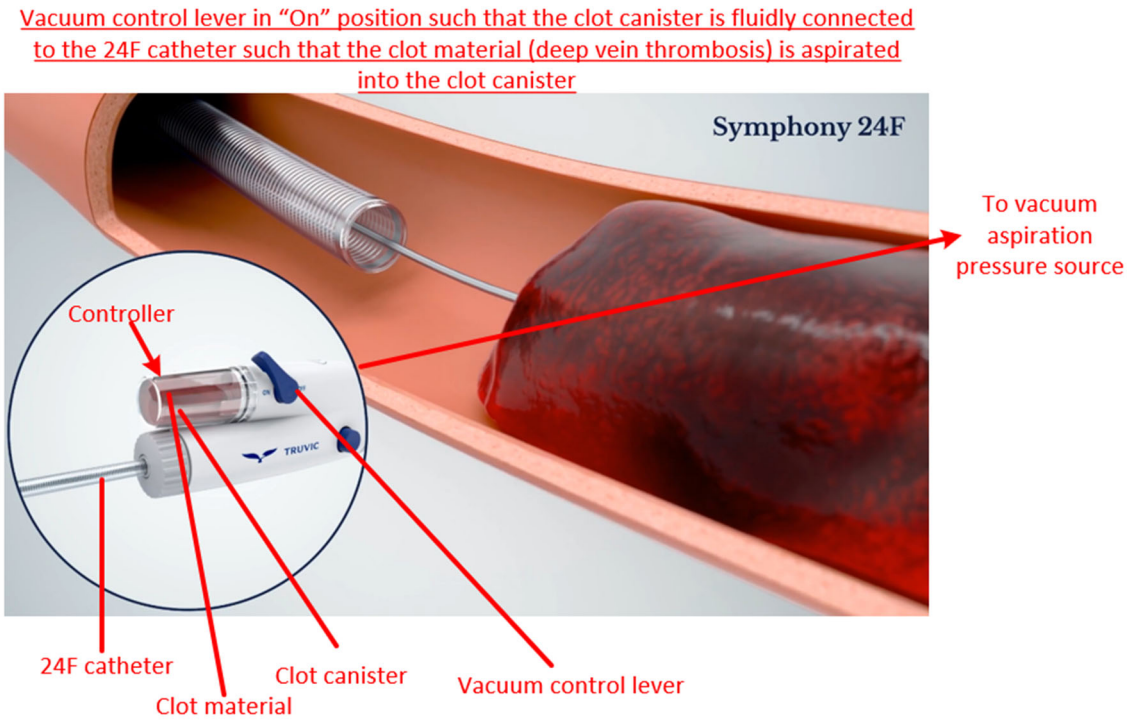
(Annotated image of Symphony housing (internal).)



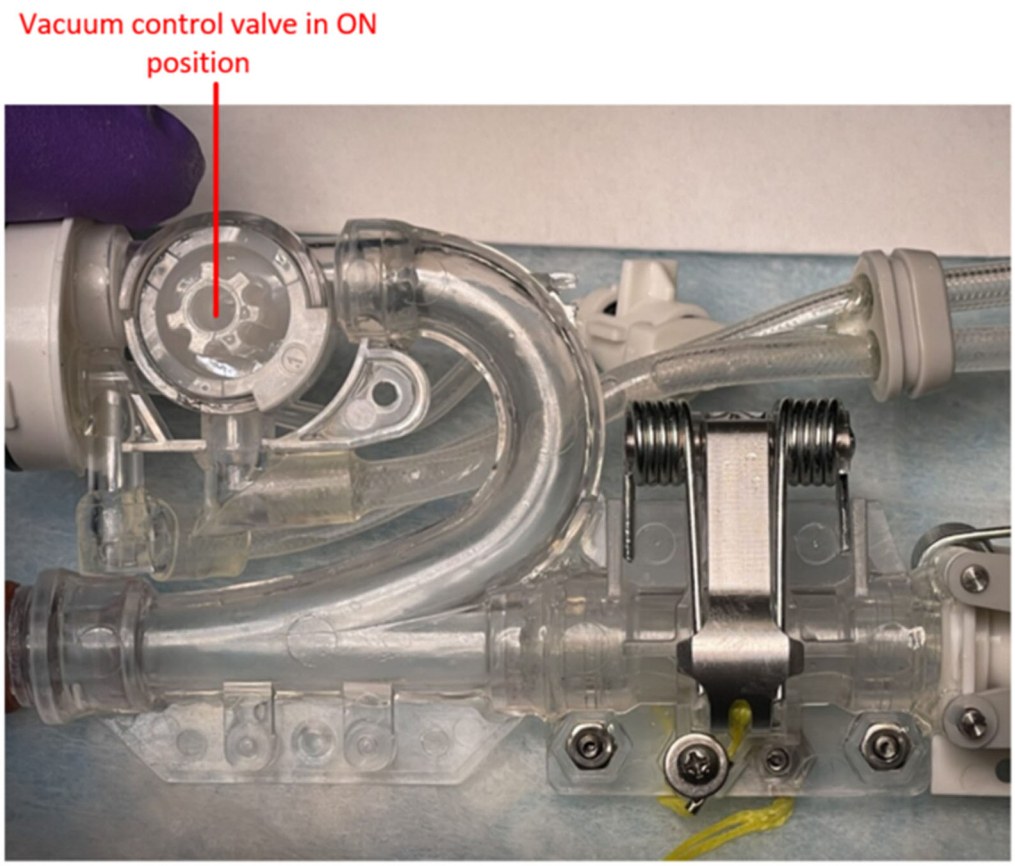
(Annotated screen capture from Symphony product video.)

95. 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,

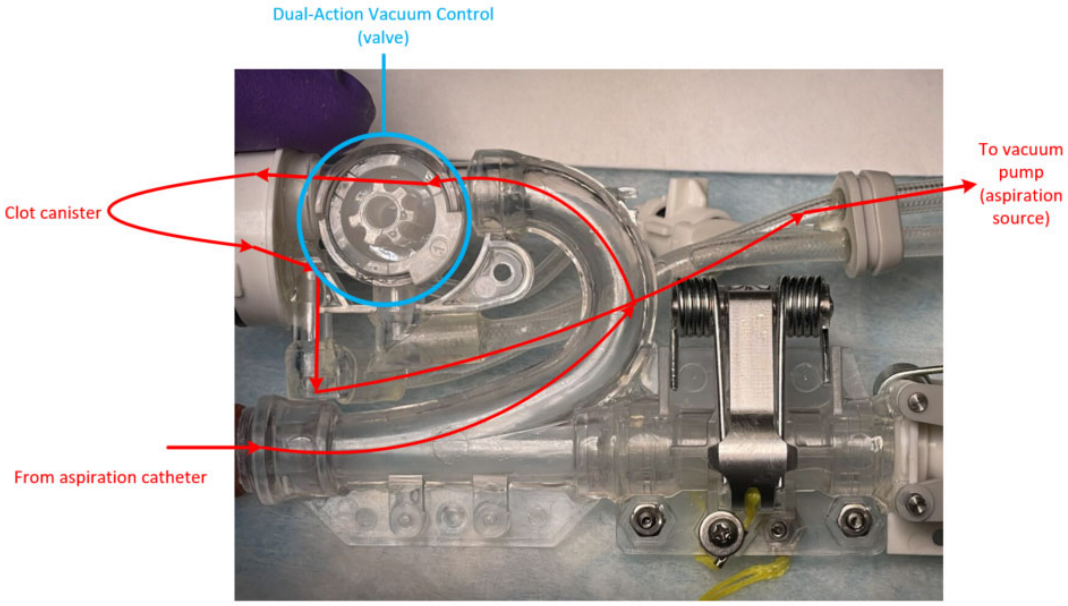
applying vacuum to the lumen of the 16F and/or 24F aspiration catheters:



(Annotated screen capture from Symphony product video.)

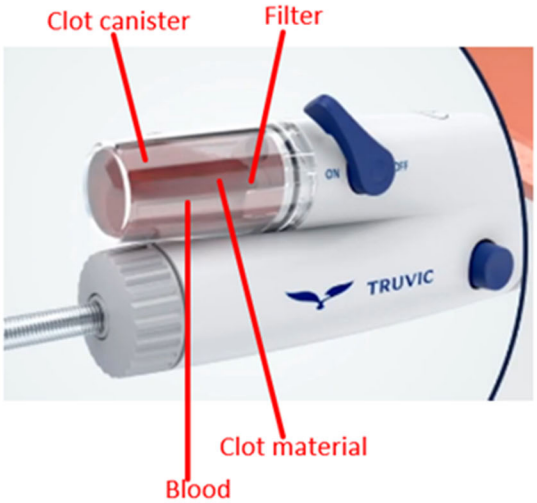


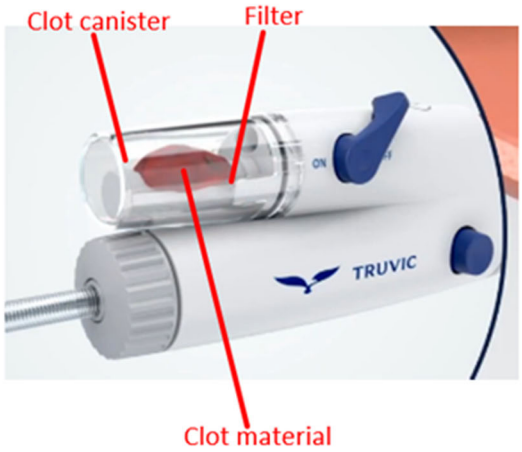
(Annotated image of Symphony housing (internal).)

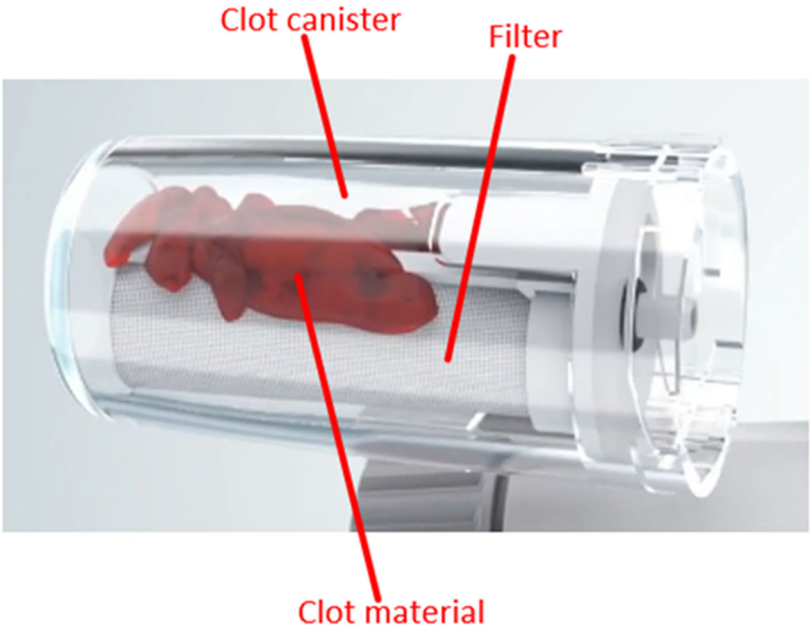


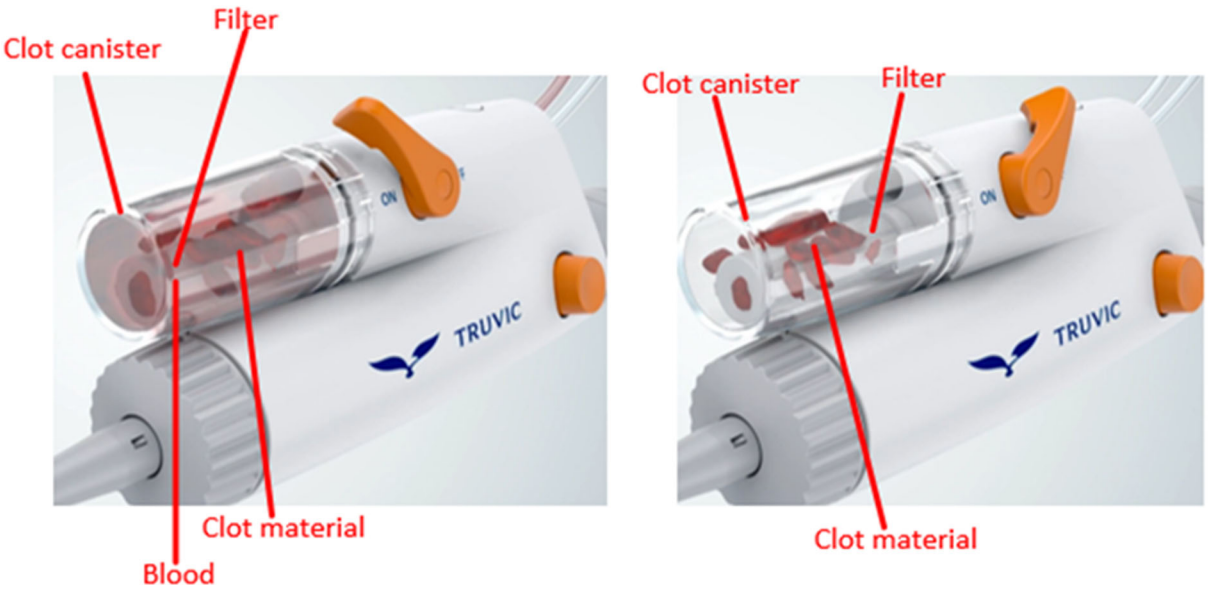
(Annotated image of internal portion of controller handle housing.)

96. 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 L. 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.



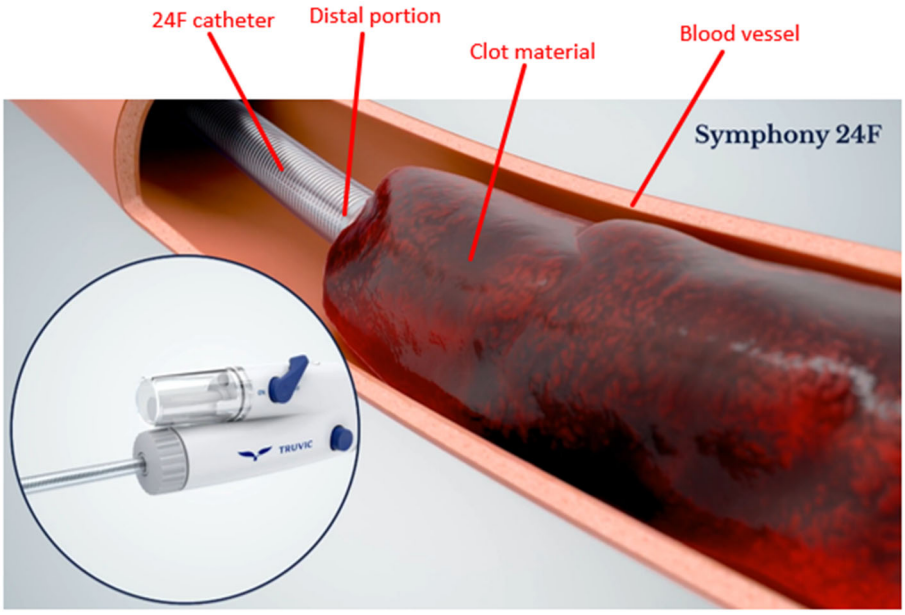






(Annotated screen captures from Symphony product video.)

97. Additionally, thrombectomy with the Symphony system practices claim 22 of the '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 L. 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.)

98. Defendants directly infringe claims of the '333 Patent, including claims 20 and 22, when Defendants or persons under their direction and control perform thrombectomy procedures on deep vein thromboses. For example, Defendants (individually and/or collectively) directly infringe claims 20 and 22 when testing or using the Symphony system in patients.

99. Defendants induce infringement of claims of the '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. Defendants actively induce 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 '333 Patent, including claims 20 and 22. Defendants instruct and teach 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 '333 Patent.

100. Defendants, for example, provide instructions for use ("IFU") 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. Defendants further provide brochures and other materials, including animations videos, that detail how to use the Truvic Symphony system in a manner that practices claims of the '333 Patent, including claims 20 and 22. *See, e.g.*, https://www.truvic.com/symphony-product. Upon information and belief, Defendants' 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 '333 Patent.

101. Defendants further engage 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 ’333 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

102. Defendants’ infringement is with knowledge of the ’333 Patent and its claims. Specifically, as described above, Inari notified Defendants, 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 ’333 Patent and further provided notice that claims 42 and 44 of the ’450 Application (renumbered as claims 20 and 22 of the ’333 Patent) read on the Symphony system and that Defendants would be infringing the ’333 Patent upon its issuance. Inari further attached the notice of allowance and the issue notification for the ’333 Patent.

103. At a minimum, Defendants have notice of the ’333 Patent through the filing of this Complaint, which was submitted to the Court just a few weeks after the ’333 Patent issued.

104. Defendants have continued their infringing activities after the ’333 Patent issued, despite knowledge of the ’333 Patent (including knowledge from correspondence with Inari and from this Complaint), and such infringement has been and continues to be egregious and willful.

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

106. Defendants’ 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

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

108. The ’005 Patent, titled “System for Treating Embolism and Associated Devices and Methods,” is part of the same family as the ’910 and’333 Patents, and shares the same specification. Similar to the ’910 and ’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.

109. Defendants directly infringe—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 their Symphony system and components thereof.

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

111. 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.

112. 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 M. 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.)

113. 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 M. The Symphony system includes controller handles (a housing), one for each of a 24F and 16F catheter:

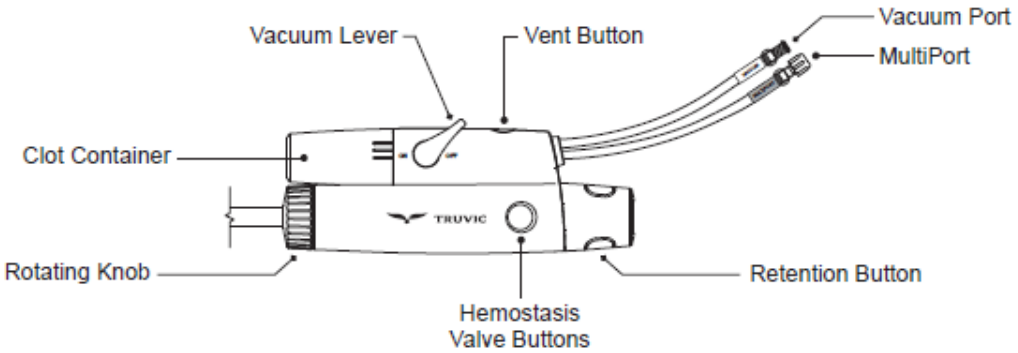
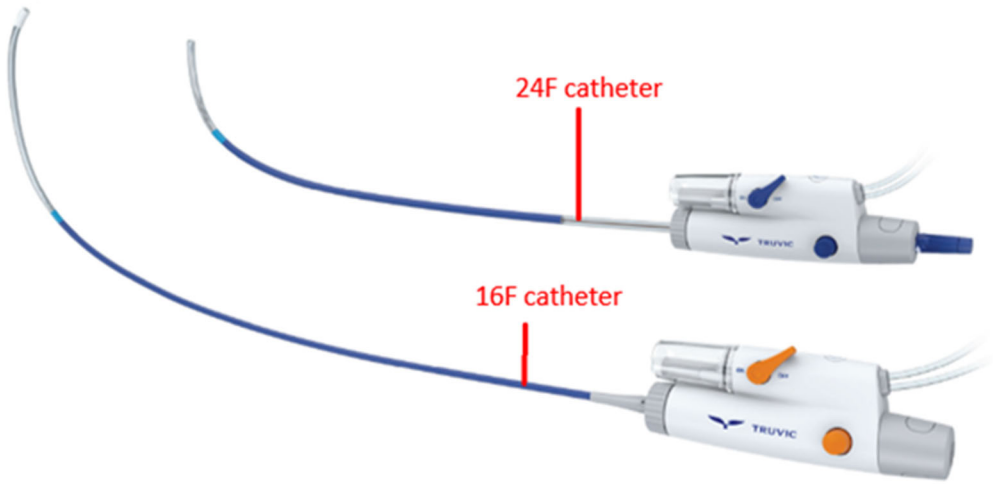


Figure 3: Symphony Catheter Handle, labeled

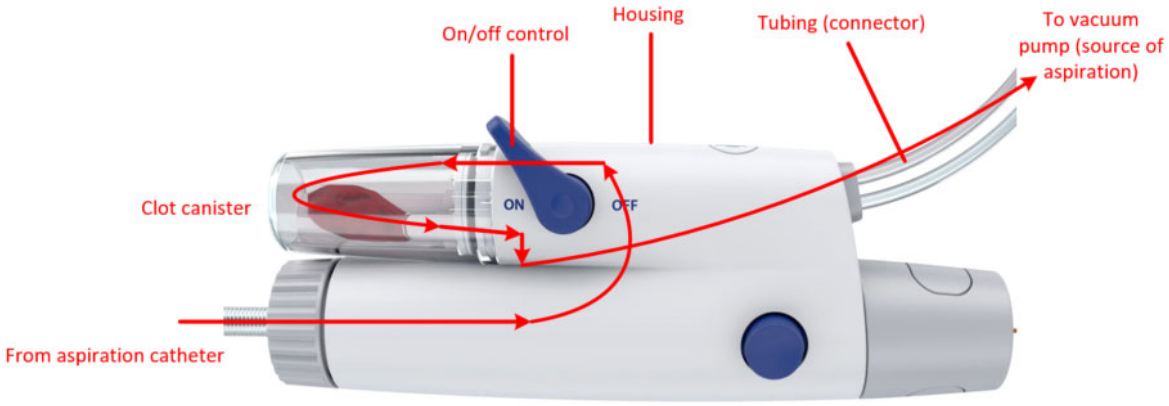
(Ex. B at 4.)



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

114. 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):

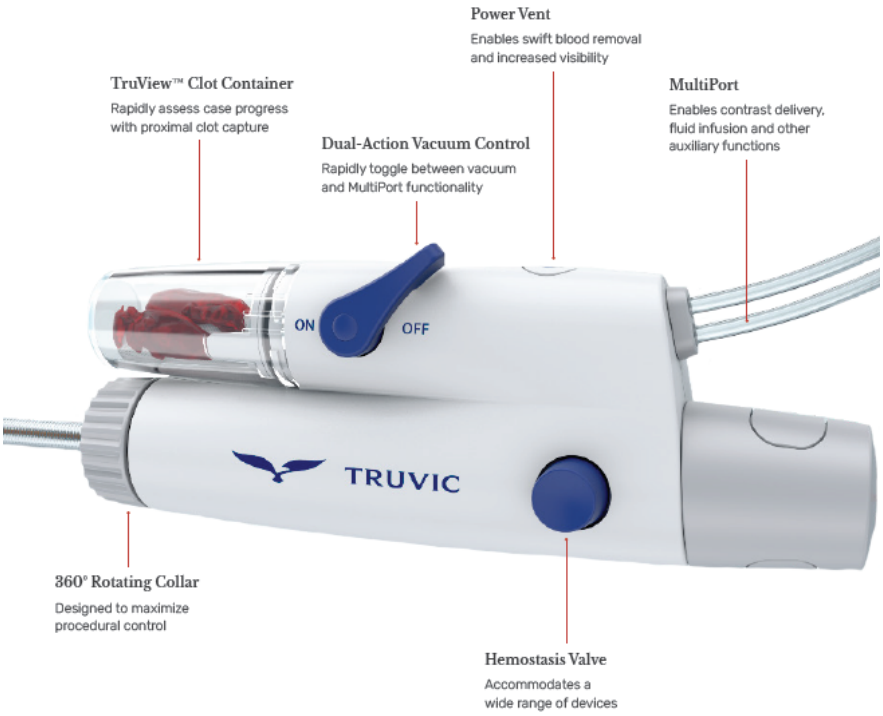


(Annotated diagram of Symphony housing with flow path.)

115. 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 M. The Symphony system includes a controller handle with a hemostasis valve in the controller housing:

High-Powered, Continuous Vacuum with Real-Time Case Assessment

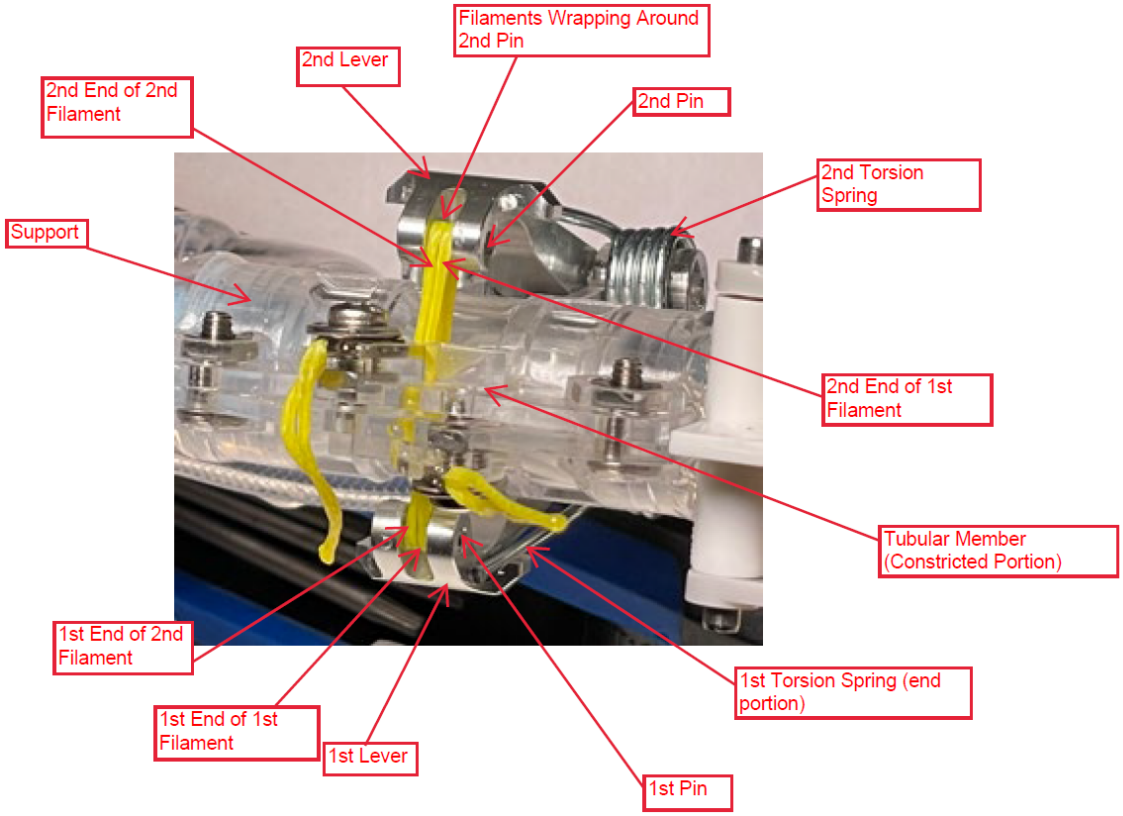
BigShot™ Controller



(Ex. A at 6.)

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

116. 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 M. 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.)

117. 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.

118. Defendants directly infringe 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 Defendants’ direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures) Symphony system products.

119. Defendants induce 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. Defendants actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

120. On information and belief, Defendants teach and/or direct others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof). Defendants, for example, provide instructions for use ("IFU") 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. Defendants further provide 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, Defendants' 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.

121. Defendants further engage 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.

122. Defendants' infringement is with knowledge of the '005 Patent and its claims. Specifically, as described above, Inari notified Defendants, 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.

123. At a minimum, Defendants have notice of the '005 Patent through the filing of this Complaint.

124. Defendants have continued their infringing activities, despite knowledge of the '005 Patent (including knowledge from correspondence with Inari and through this Complaint), and such infringement has been and continues to be egregious and willful.

125. 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.

126. Defendants' 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

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

128. The '691 Patent, titled "System for Treating Embolism and Associated Devices and Methods," is part of the same family as the '910, '333, and '005 Patents, and it shares the same specification. Similar to the '910, '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. E at cl. 14. Dependent claims further recite that the system is for treating deep vein thrombosis. *Id.* at cl. 22.

129. Defendants directly infringe—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 their Symphony system and components thereof.

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

131. 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.

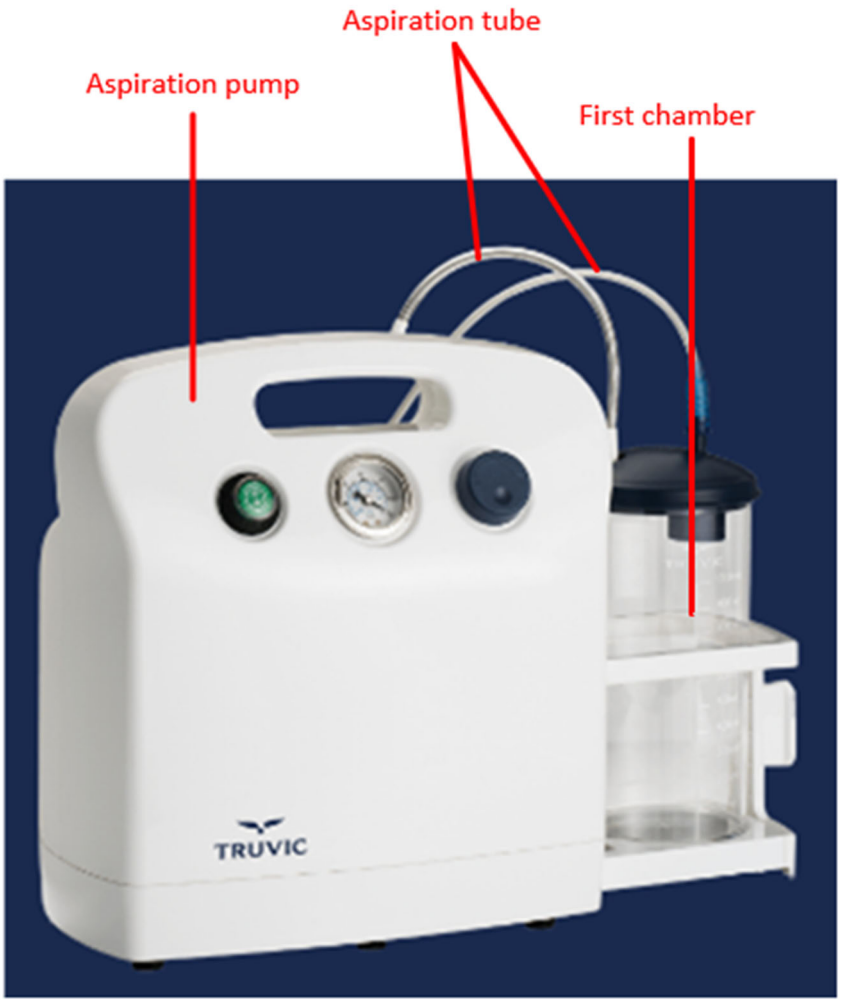
132. Claim 19 of the '691 Patent depends from claim 14 and further recites "[t]he aspiration system of claim 14 wherein the aspiration catheter is configured to be intravascularly positioned within a blood vessel of a patient."

133. 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."

134. 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."

135. 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 N. 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.).

136. 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 N. 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.

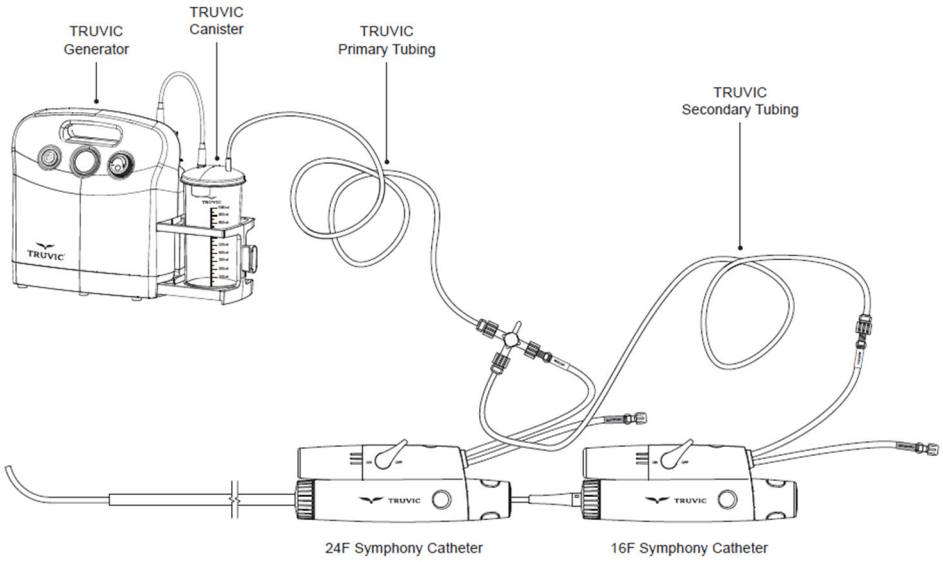
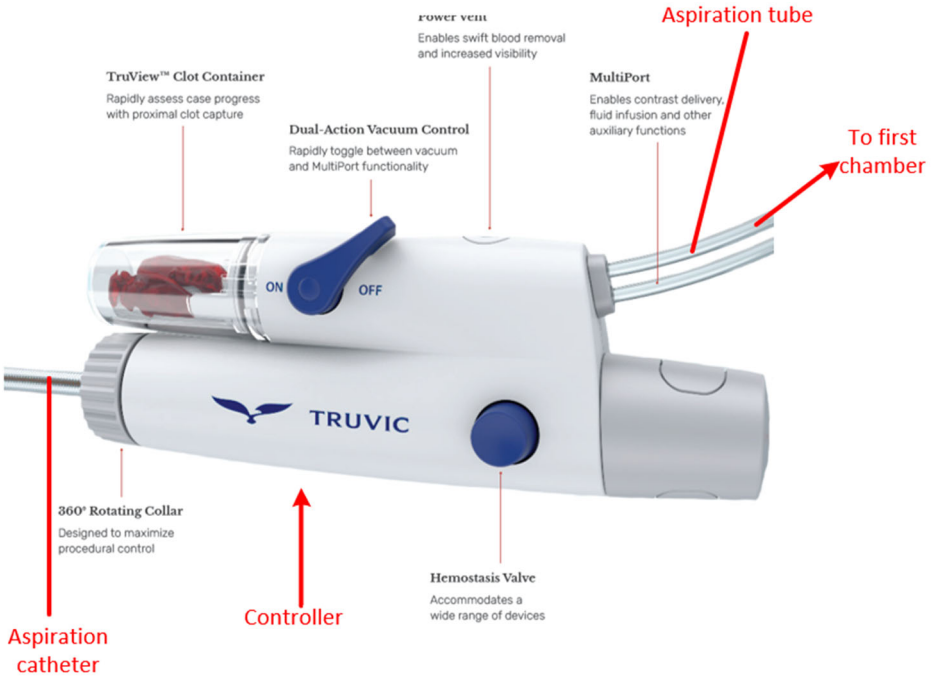


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

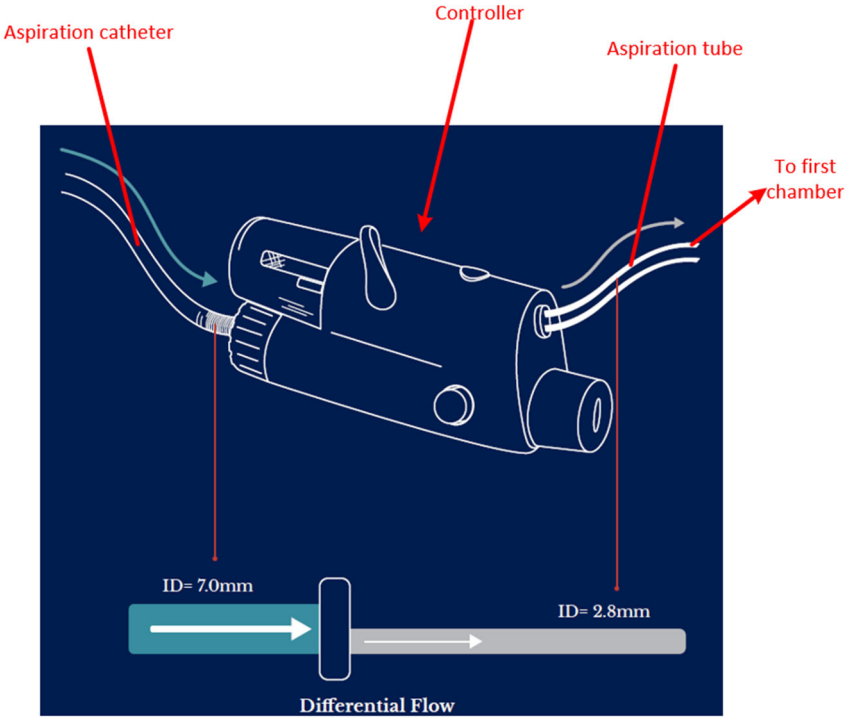
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the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

(Ex. B at 8.)

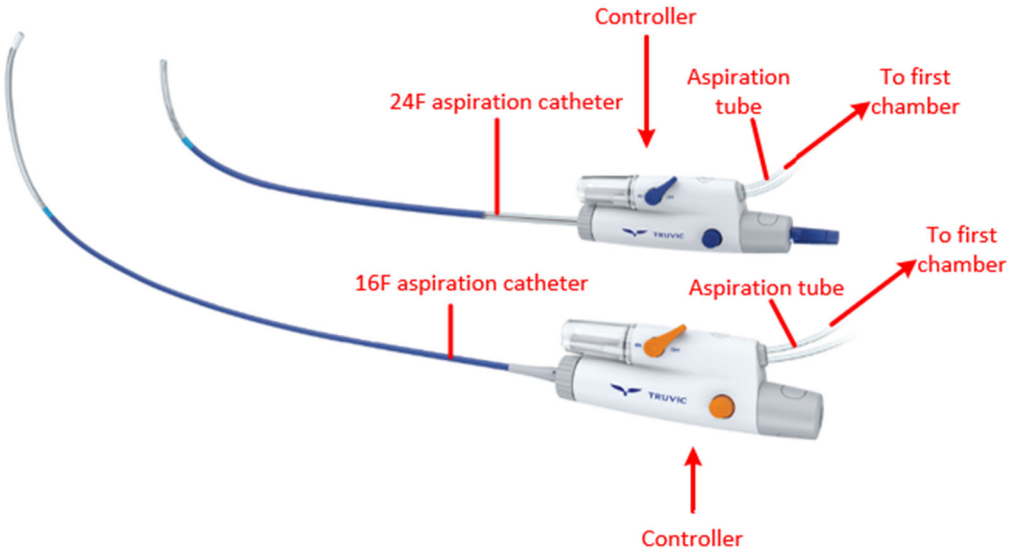
137. The Symphony system practices the limitations of claim 1, including "an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube," as can be seen in claim chart in Exhibit N. The Symphony system includes 24F and 16F catheters in fluid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



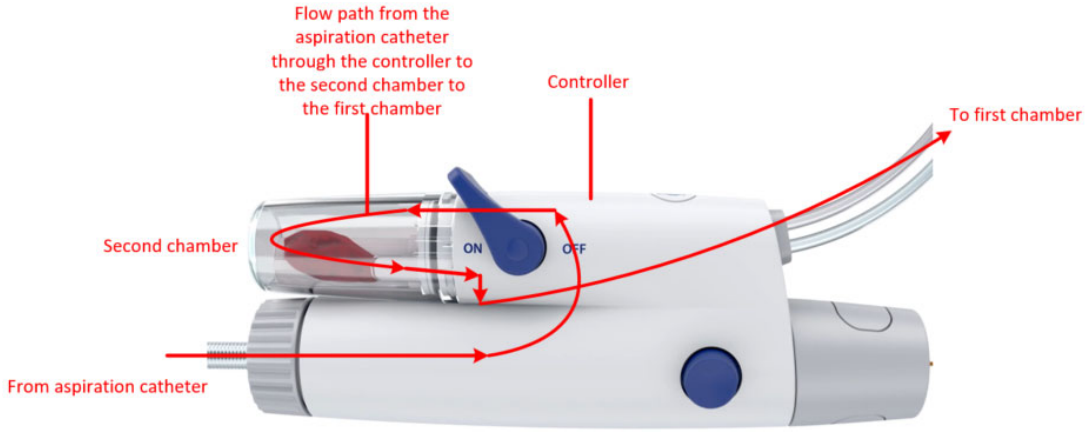
(Ex. A at 6 (annotations added).)



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

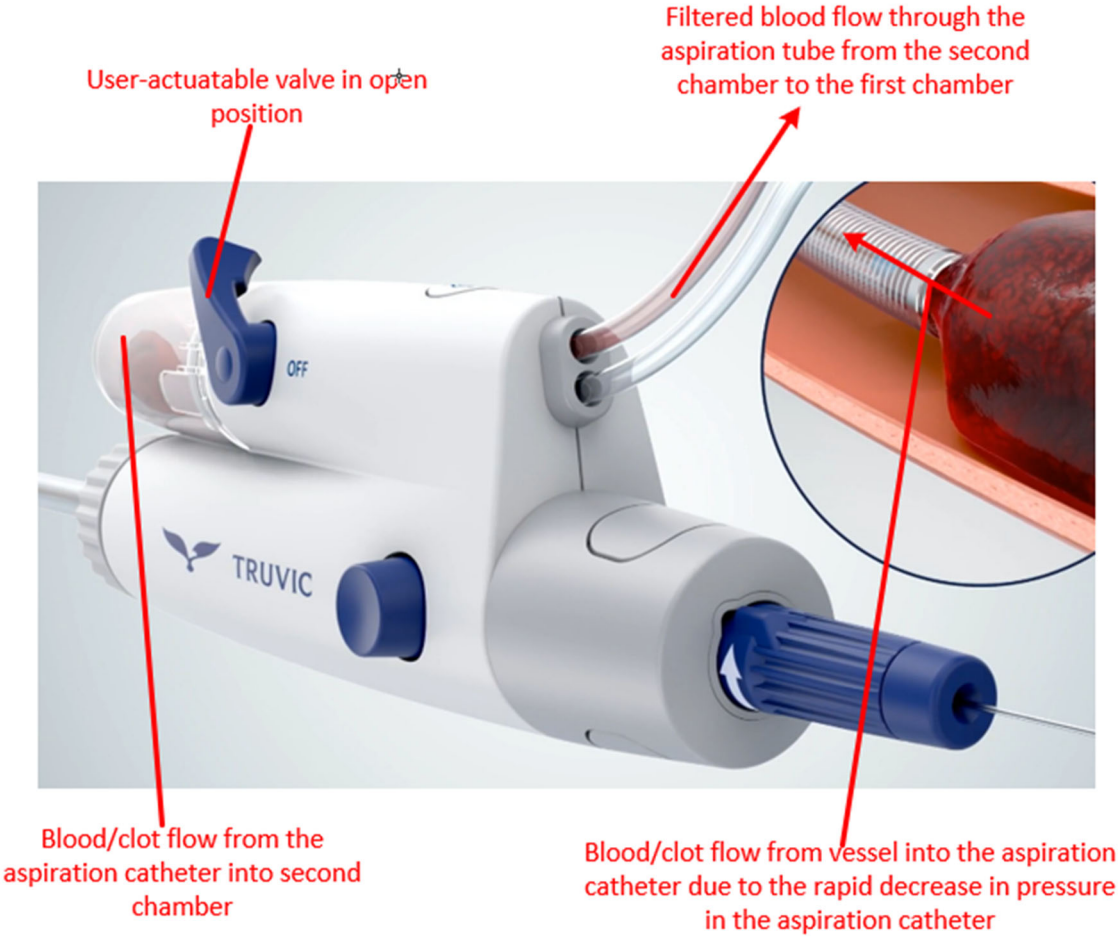


(Ex. A at 2 (annotations added).)

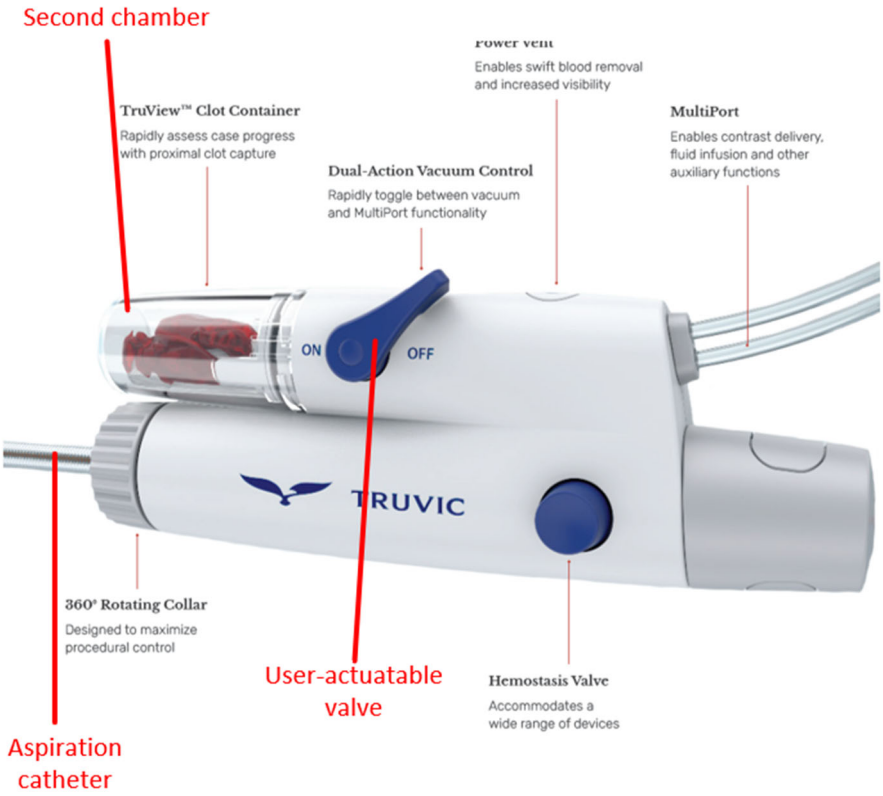


(Annotated diagram of Symphony housing with flow path.)

138. 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 N. 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.)

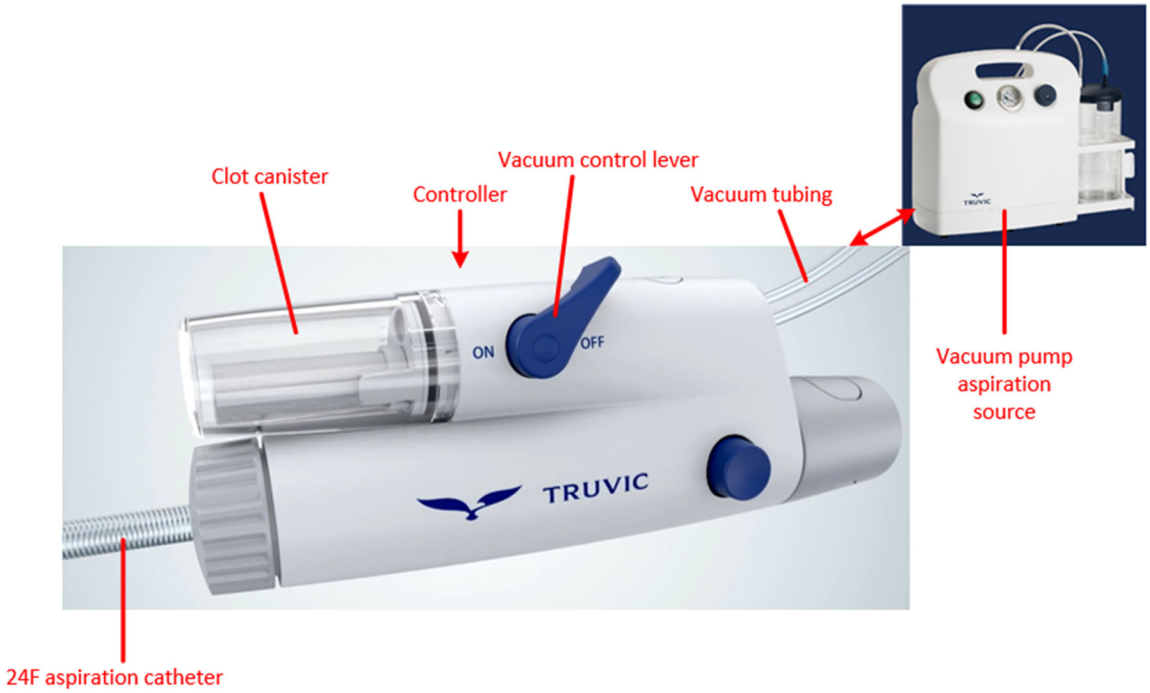


(Ex. A at 6 (annotations added).)

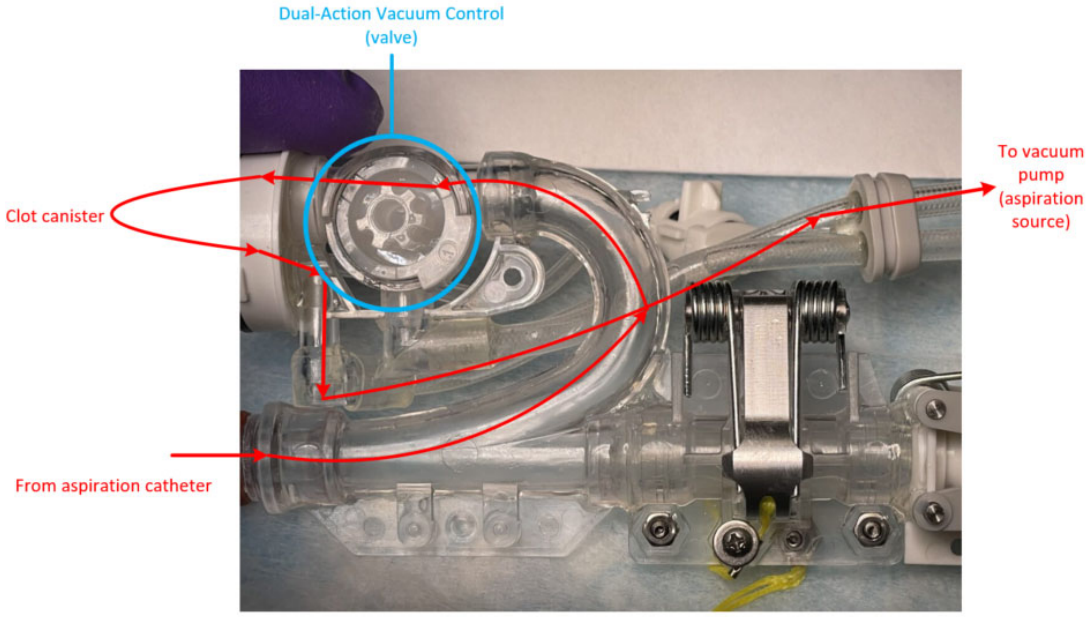
(Annotated screen captures from Symphony product video.)

139. 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

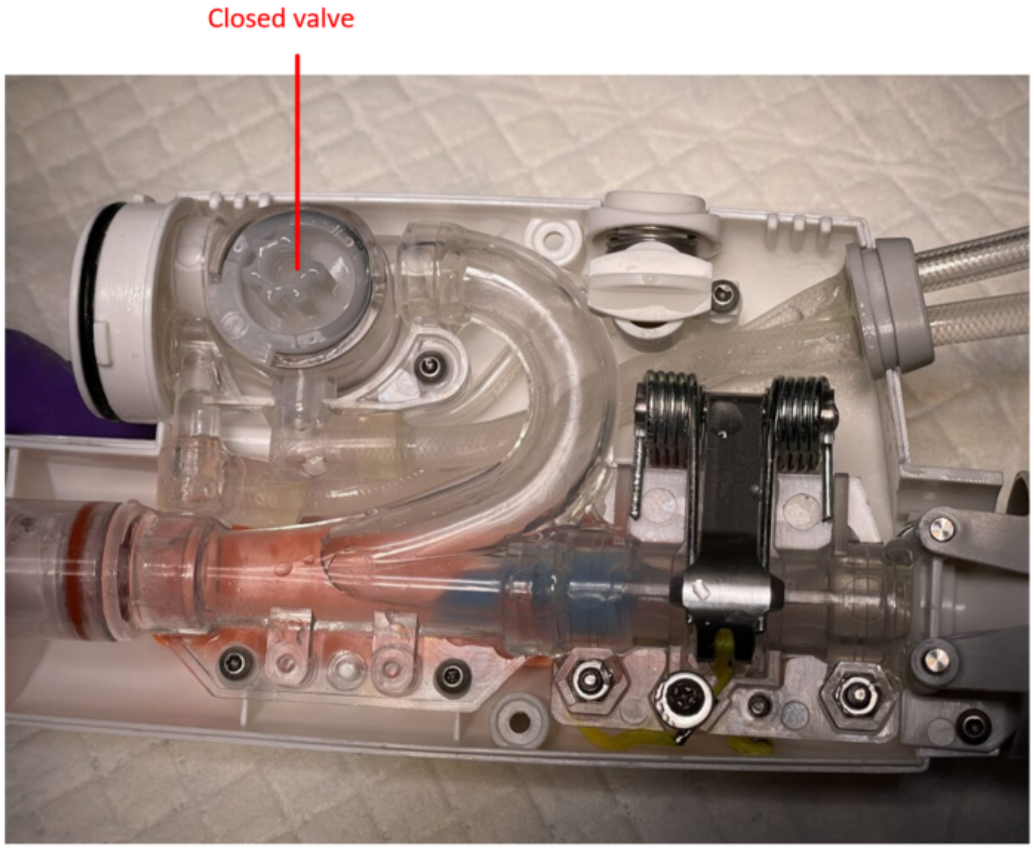
first and second chambers," as can be seen in claim chart in Exhibit N. The Symphony system includes a both the 24F and 16F handle controllers each having a user-actuatable valve in the controller that is controlled by the vacuum control lever on the handles, where negative pressure is generated in the 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"):



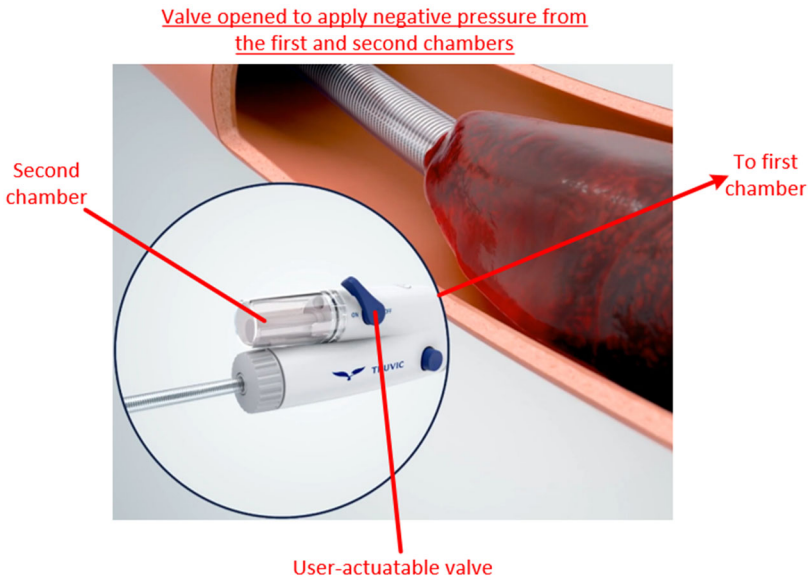
(Annotated diagram of Symphony system.)



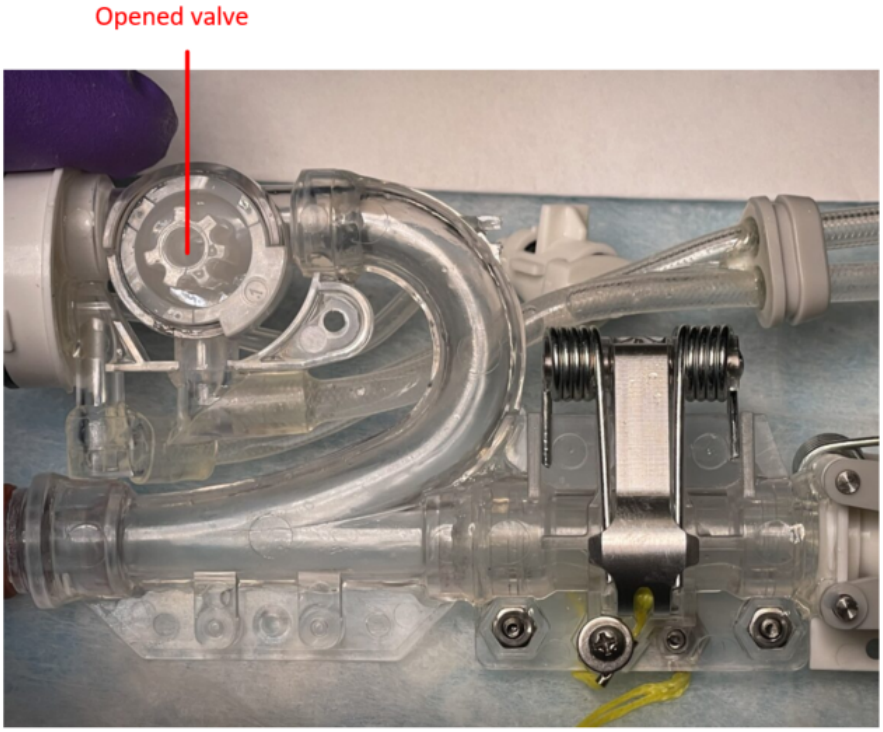
(Annotated image of internal portion of controller handle housing)



(Annotated image of Symphony housing (internal).)



(Annotated screen capture from Symphony product video.)



(Annotated image of Symphony housing (internal).)

140. 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.

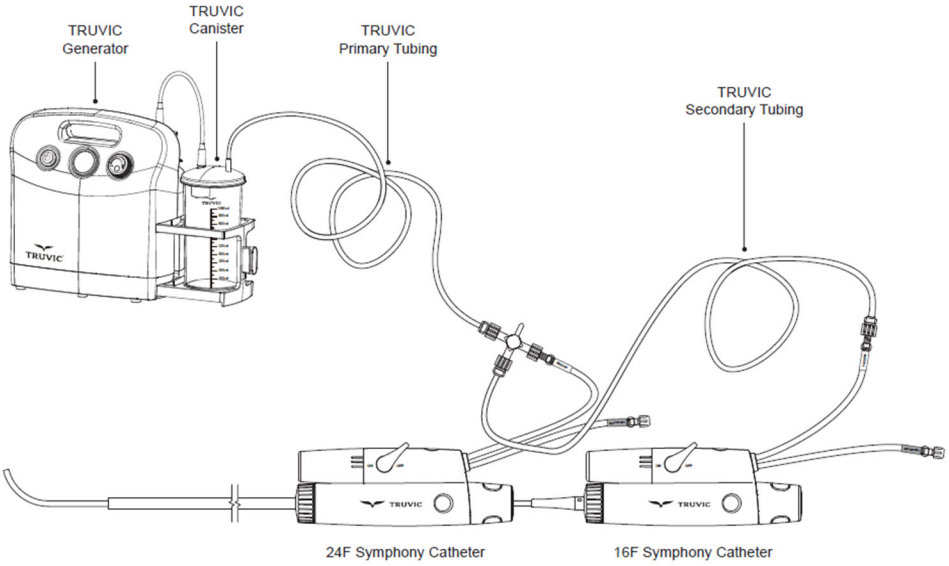


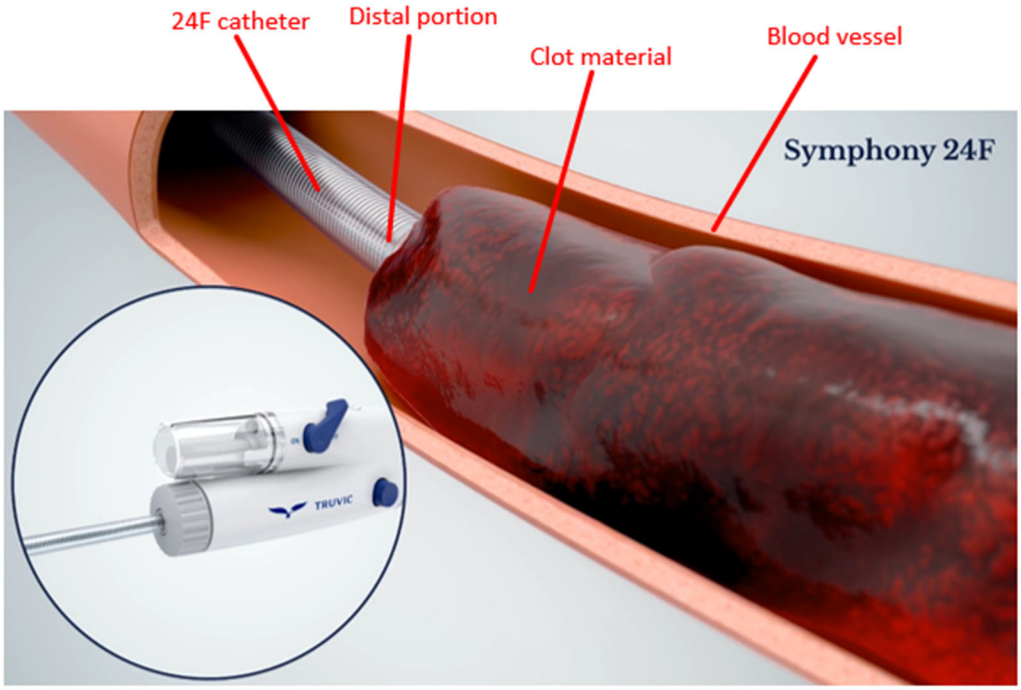
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

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.

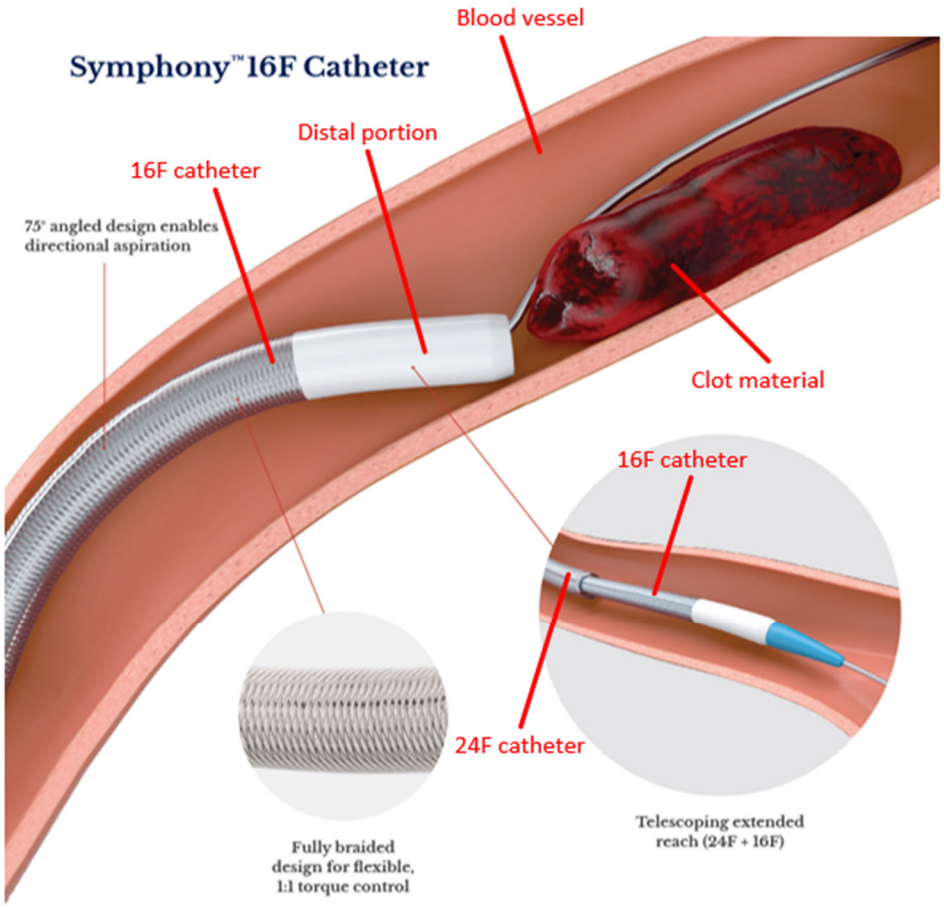
(Ex. B at 8.)

141. 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 N. 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 low 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.

142. 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 N. 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).)

143. 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 N. As discussed above with respect to claim 20 of the '333 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.

144. Defendants directly infringe 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 Defendants' direction and control make, sell, offer to sell, import and/or use (*e.g.*, to perform thrombectomy procedures) Symphony system products.

145. Defendants induce 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. Defendants actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system.

146. On information and belief, Defendants teach and/or direct others to perform thrombectomy on, for example, deep vein thrombosis using the Symphony system (and components thereof). Defendants, for example, provide instructions for use ("IFU") 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. Defendants further provide 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, Defendants' 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.

147. Defendants further engage 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.

148. Defendants' infringement is with knowledge of the '691 Patent and its claims. Specifically, as described above, Inari notified Defendants, by letter dated September 29, 2023, that the Symphony system infringes the '691 Patent. Inari further explained to Defendants, 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.

149. At a minimum, Defendants have notice of the '691 Patent through the filing of this Complaint, which was submitted to the Court just a few weeks after the '691 Patent issued.

150. Defendants have continued their infringing activities, despite knowledge of the '691 Patent (including knowledge from correspondence with Inari and through this Complaint), and such infringement has been and continues to be egregious and willful.

151. Defendants' 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

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

153. 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.

154. 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.

155. Defendants directly and indirectly infringe—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 their Symphony system and components thereof.

156. 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.

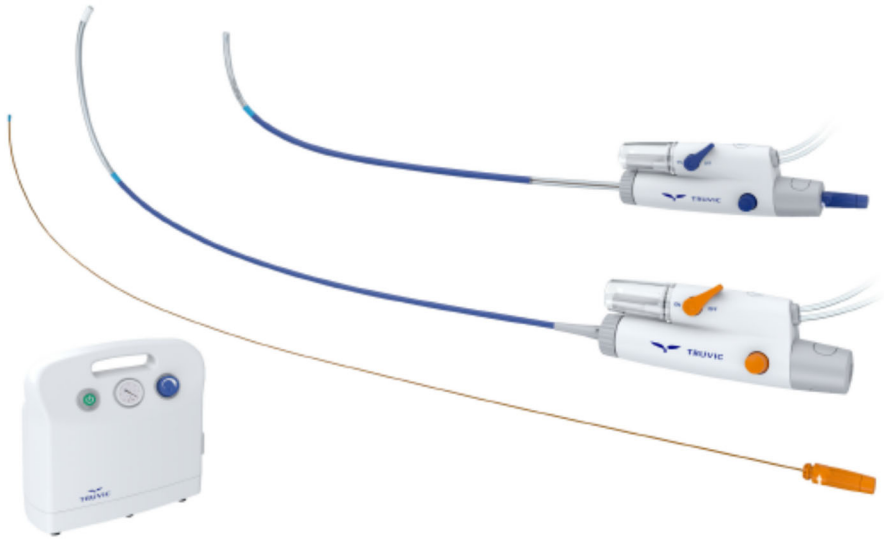
157. For example, claim 1 of the ’921 Patent recites:

> [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.

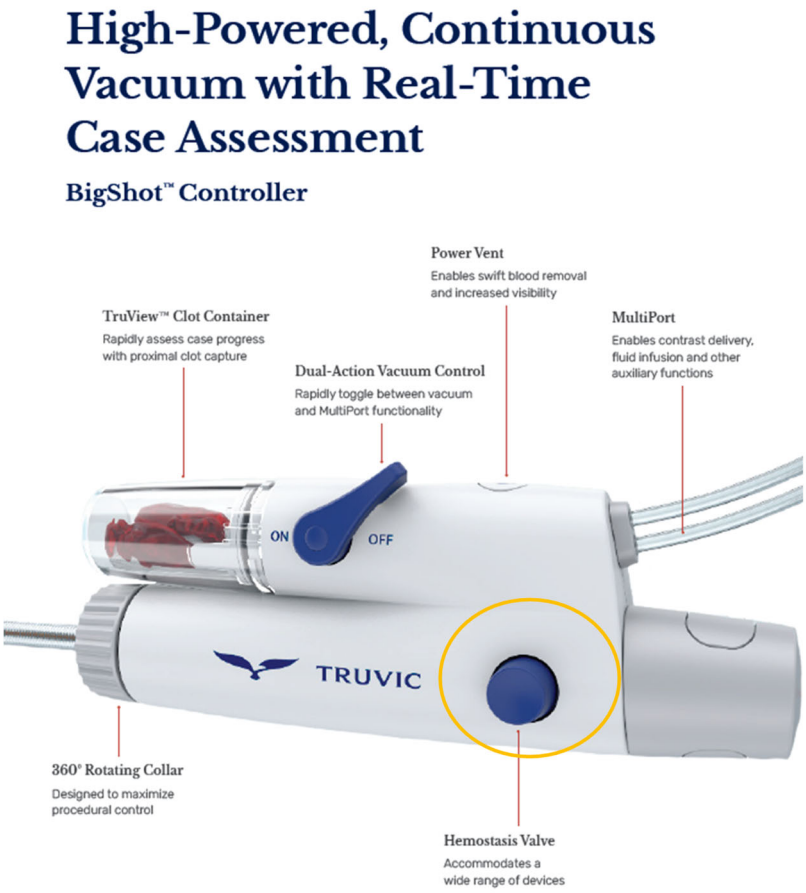
158. Claim 10 of the ’921 Patent further recites:

> [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.

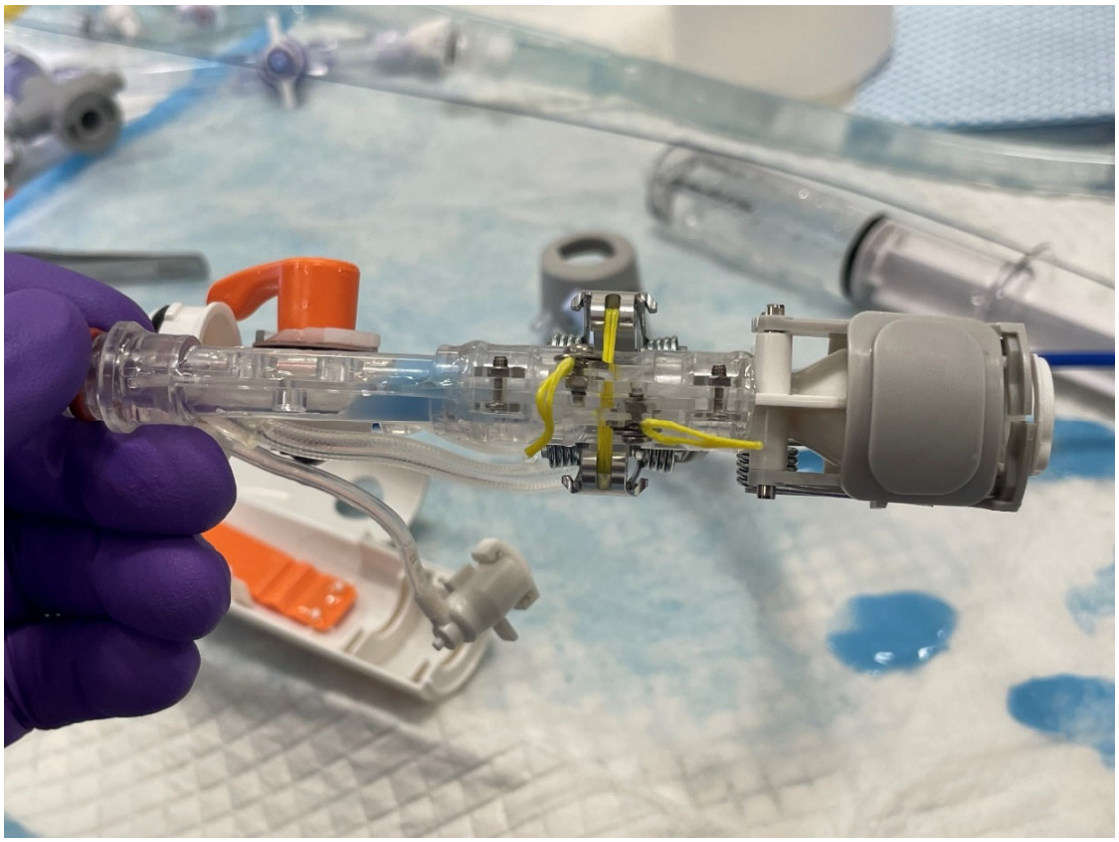
159. The hemostasis valves of the Symphony system practice the requirements of claim 1, including the preamble, “[a] valve, comprising,” as can be seen in Exhibit O. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and 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.)

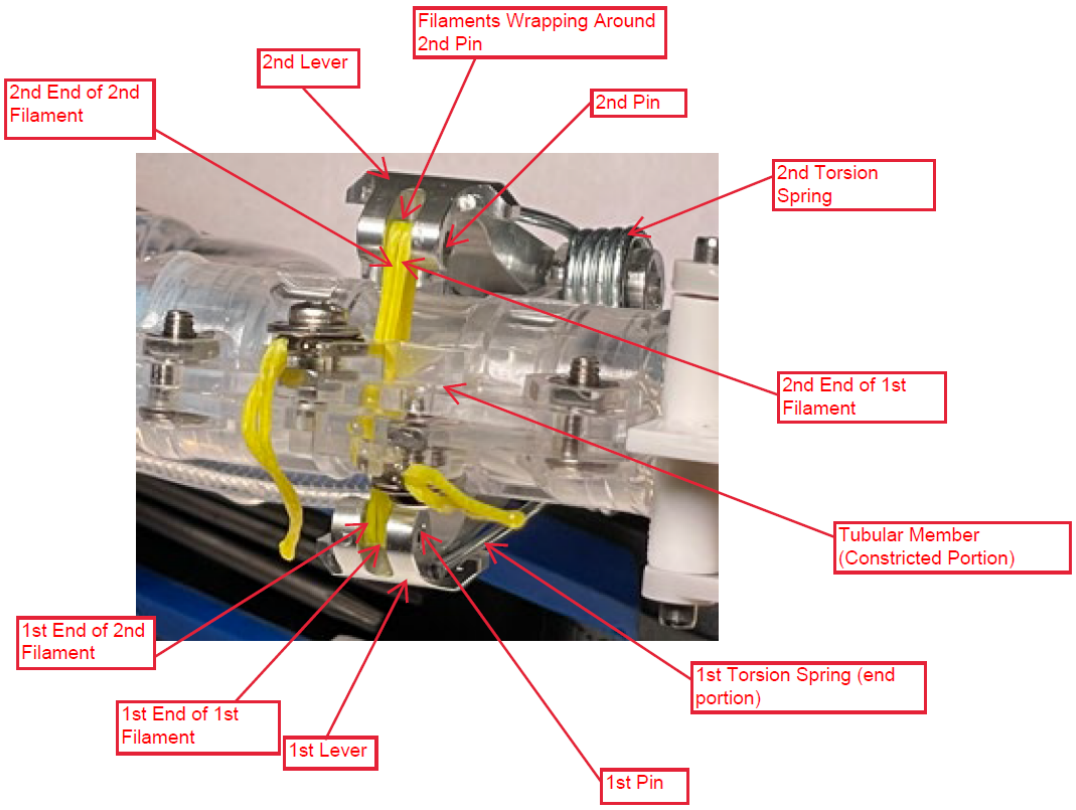


(Image of internal portion of housing with hemostasis valve.)

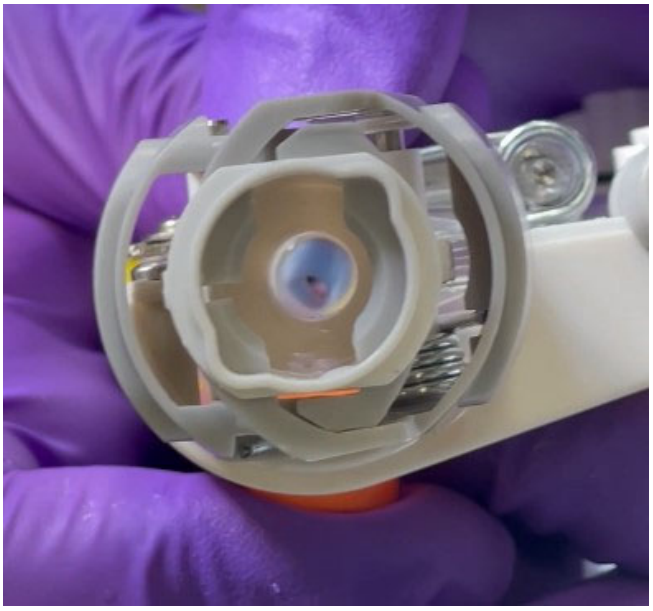
(Image of internal portion of housing zoomed in on hemostasis valve.)

160. 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 O. 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.)

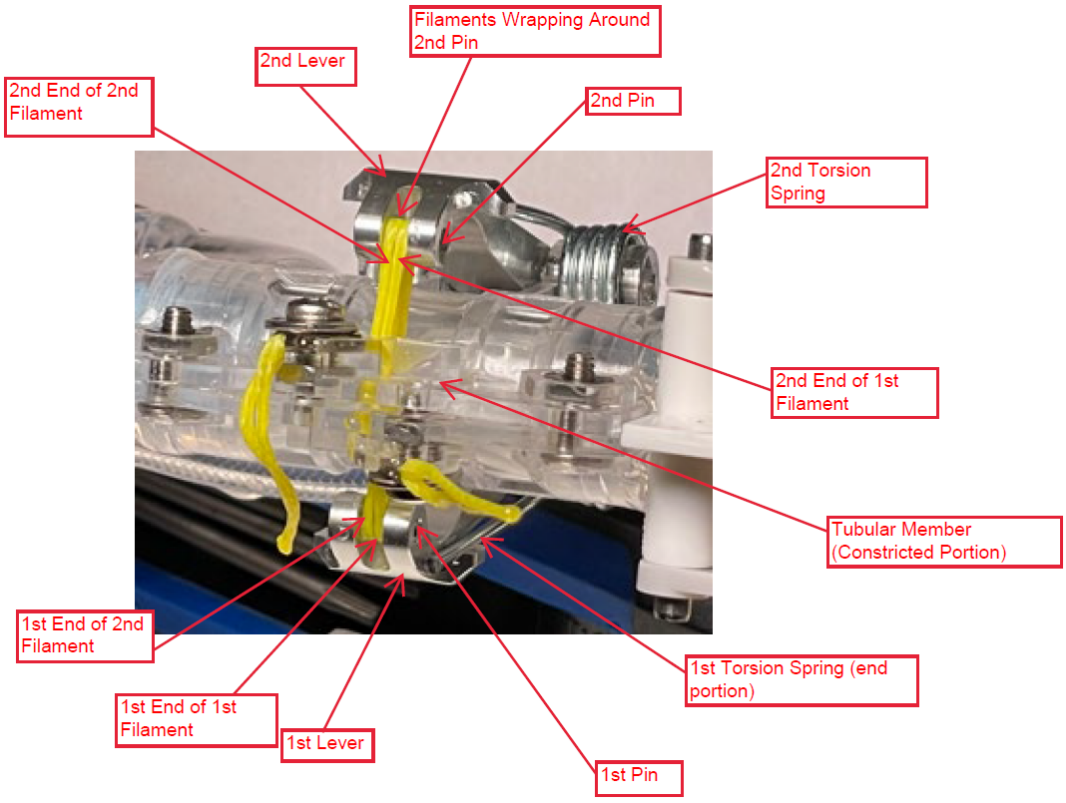


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



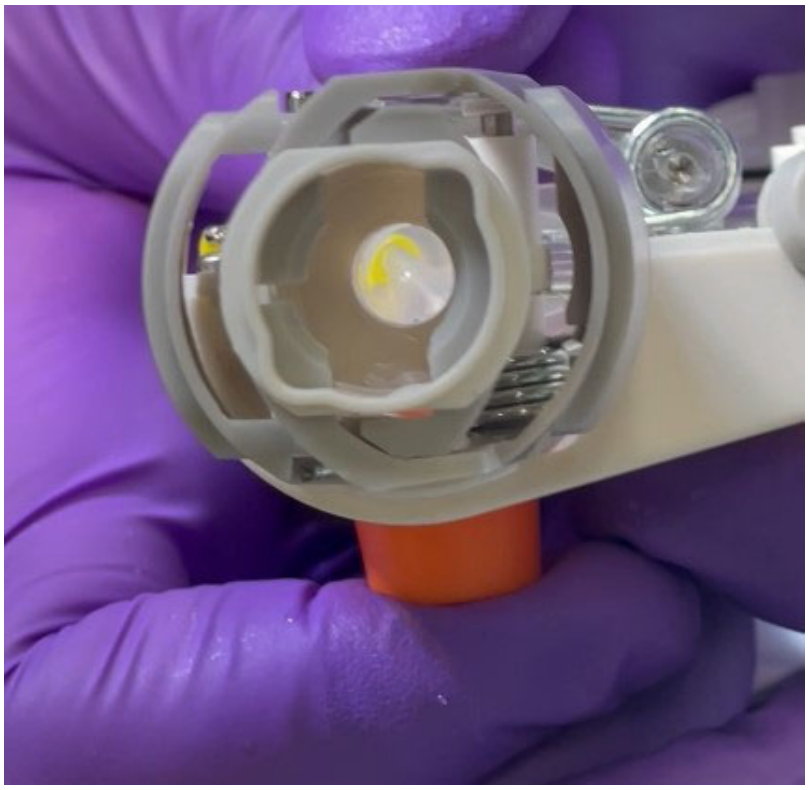
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

161. 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 O. 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.

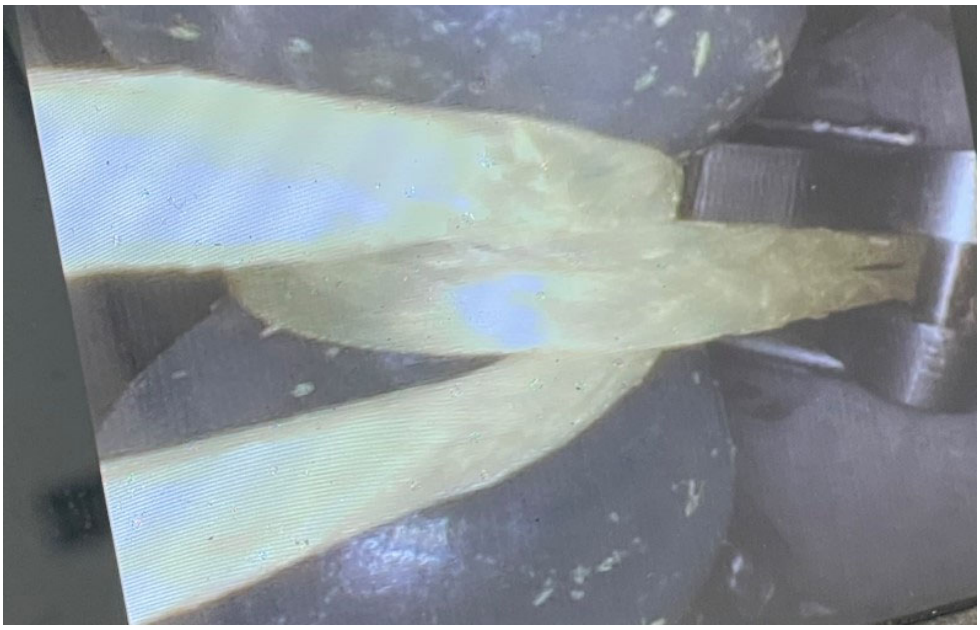


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)

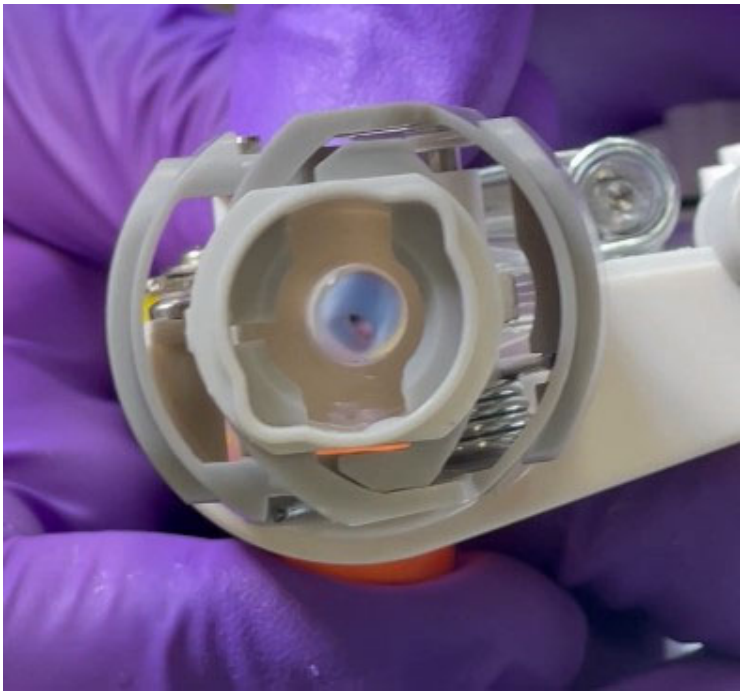
162. In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring(s), releasing tension on the filaments wrapped around the lever pin(s), which decreases the constriction on the lumen of the hemostasis valve. This allows 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.)



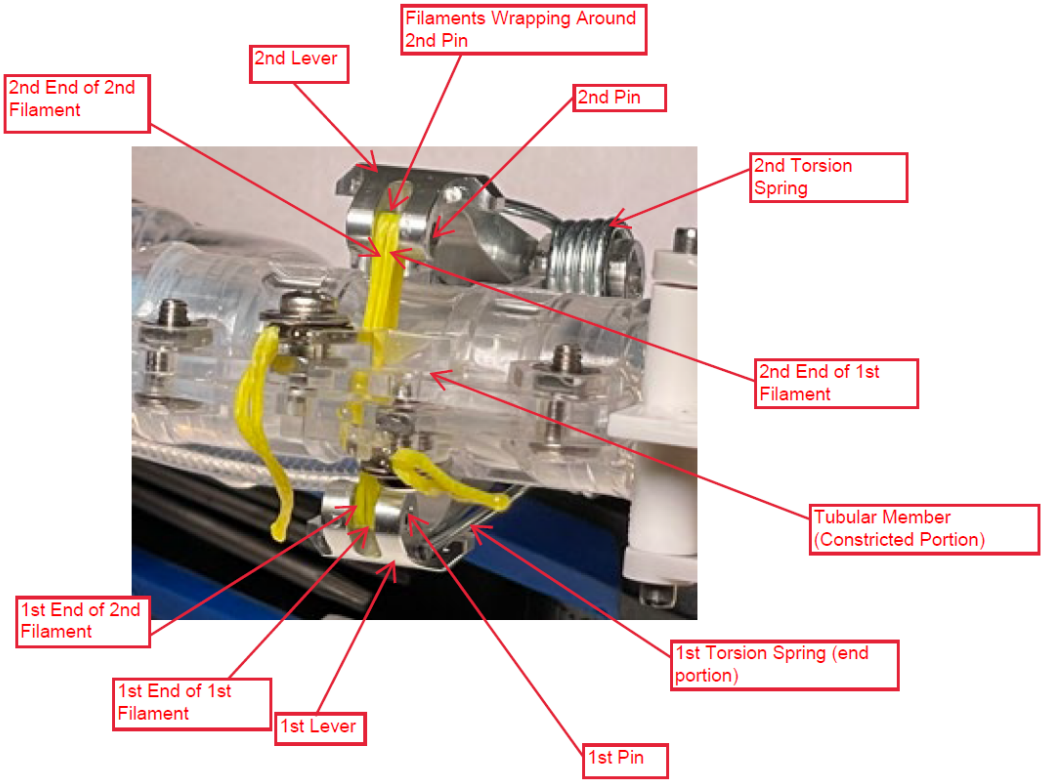
(Internal image of hemostasis valve with filaments encircling and constricting elongate member.)



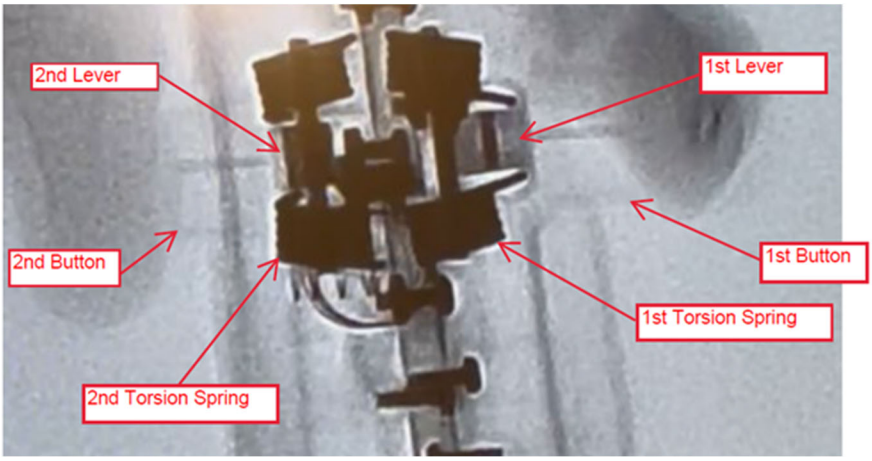
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

163. 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 O. 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.



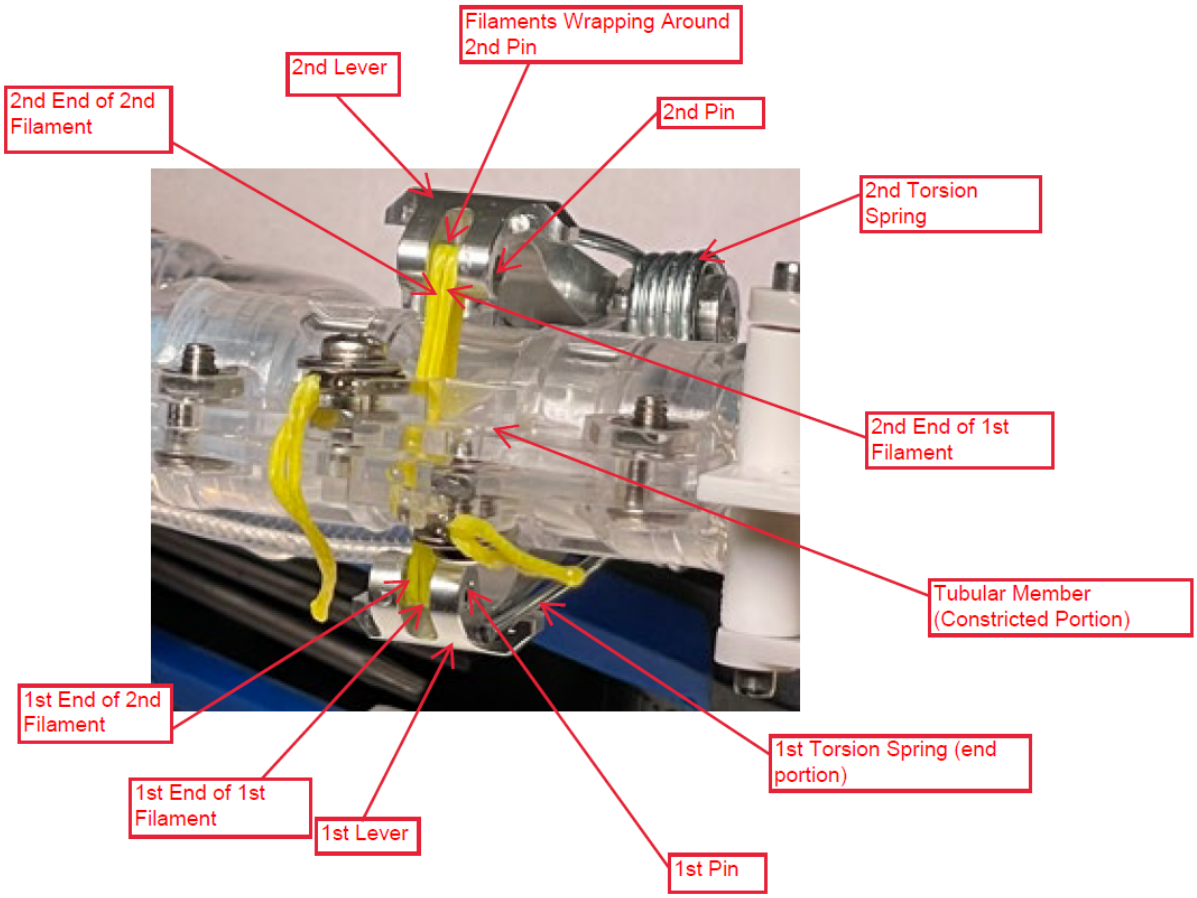
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



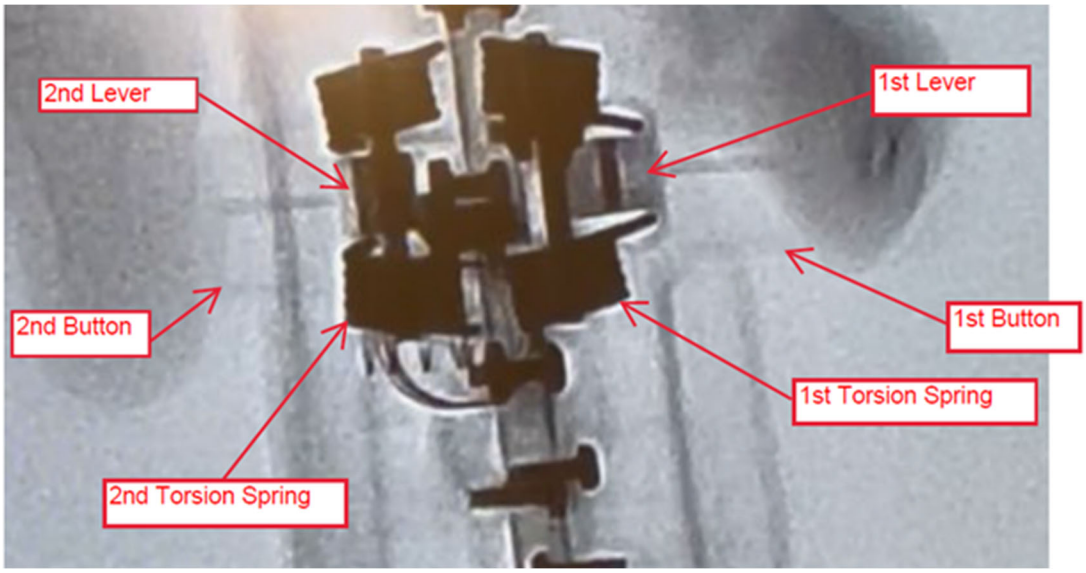
(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs.)

164. 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 O. The hemostasis valves of the Symphony system comprise a first actuator, as alleged above for claim 1.

165. 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 O. 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.)

166. 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 O. 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.

167. Defendants directly infringe 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 Defendants' 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.

168. Defendants induce 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. Defendants actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

169. On information and belief, Defendants teach and/or direct 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. Defendants, for example, provide instructions for use ("IFU") 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. Defendants further provide 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, Defendants' 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.

170. Defendants further engage 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.

171. Defendants have knowledge of the '921 Patent and its claims. Specifically, Inari notified Defendants 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.

172. At a minimum, Defendants have notice of the '921 Patent through the filing of this Complaint.

173. Defendants have continued their infringing activities, despite knowledge of the '921 Patent (including knowledge from correspondence with Inari and through this Complaint), and such infringement has been and continues to be egregious and willful.

174. 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.

175. Defendants' 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 '011 PATENT

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

177. The '011 Patent, titled "Hemostasis Valves and Methods of Use," is part of the same family as the '921 Patent and shares the same specification. The '011 Patent discloses improved hemostasis valves and methods of their use. *See, e.g.*, Ex. H at Abstract, 1:61-65. 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 1:30-46. 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 1:21-29. 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 1:48-57, 5:51-6:2.

178. The '011 Patent discloses hemostasis valves having an elongate tubular member with a lumen (an inner cavity through which something can be inserted) that is configured to slidably receive a catheter and that can be constricted and sealed by a filament wrapped at least partially around, *e.g.*, in a loop around, the elongate tubular member 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 to a first position to circumferentially constrict the elongate tube's lumen with the filament to create a seal, and moving the actuator 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) controls whether the valve is sealed. *See id.* at cl. 1, Fig. 7, 2:10-27. Some embodiments disclosed by the '011 Patent have multiple actuators, *i.e.*, a first actuator member comprising a first button and a second actuator member comprising a second button. *See id.* at cl. 1, cl. 4.

179. Defendants directly and indirectly infringe—literally and/or under the doctrine of equivalents—at least claim 1 of the '011 Patent by making, using, selling, offering for sale, and/or importing into the United States their Symphony system and components thereof.

180. The Symphony system practices each limitation of at least claim 1 of the '011 Patent.

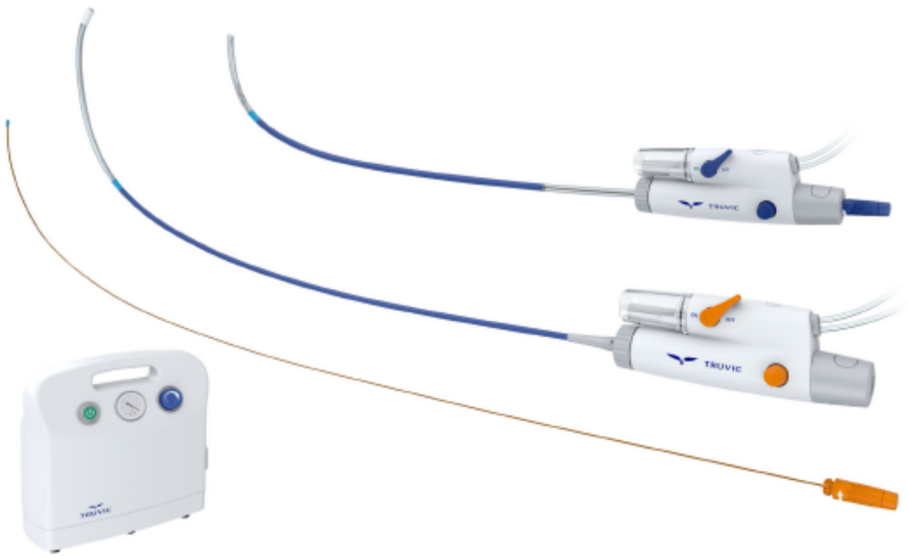
181. For example, claim 1 of the '011 Patent recites:

[1] A valve, comprising:

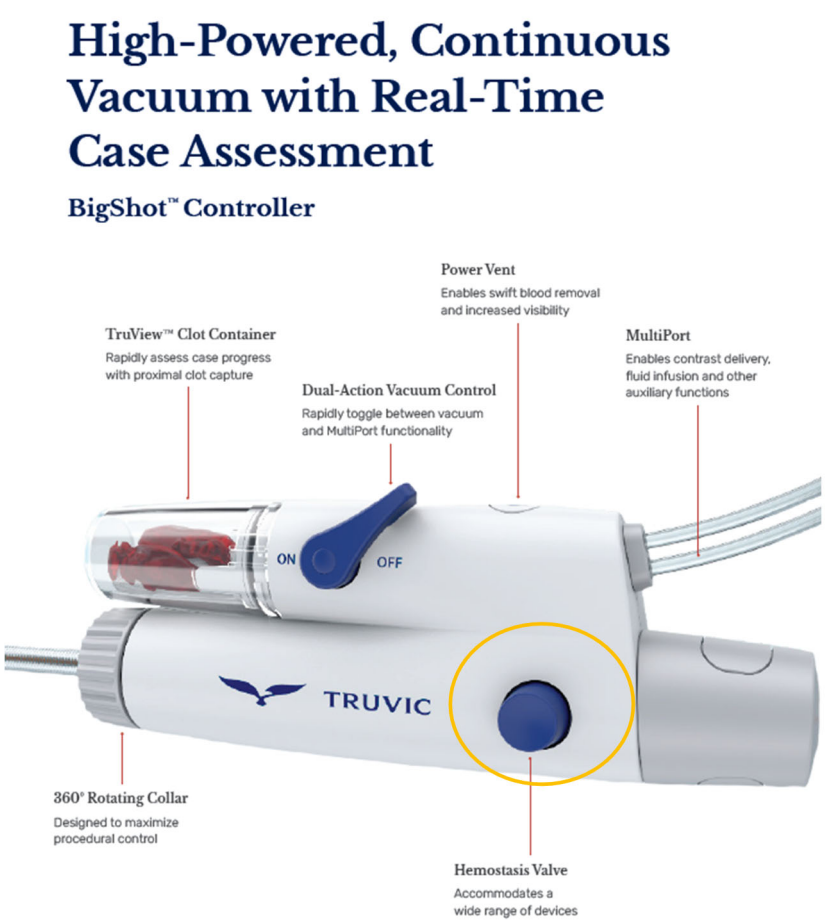
a tubular member defining a lumen configured to slidably receive a catheter;

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

182. 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 P. 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.)



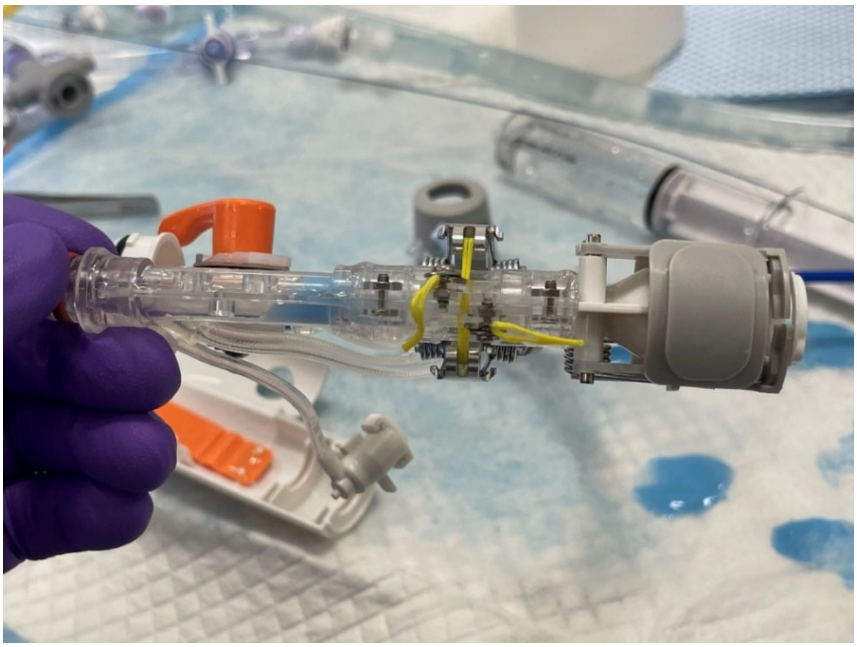
(Annotated Ex. A at 6.)

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

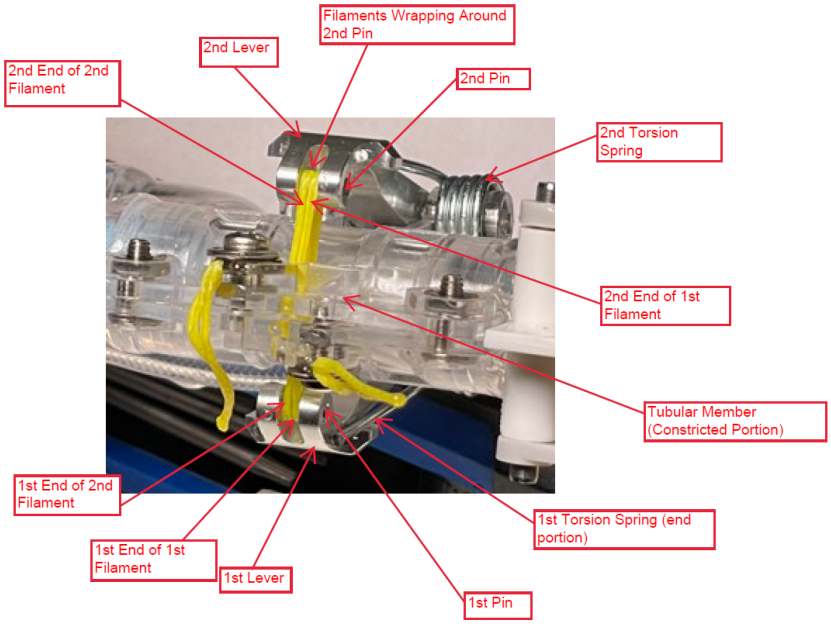
(Image of internal portion of housing zoomed in on hemostasis valve.)

183. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a tubular member defining a lumen configured to slidably receive a catheter," as

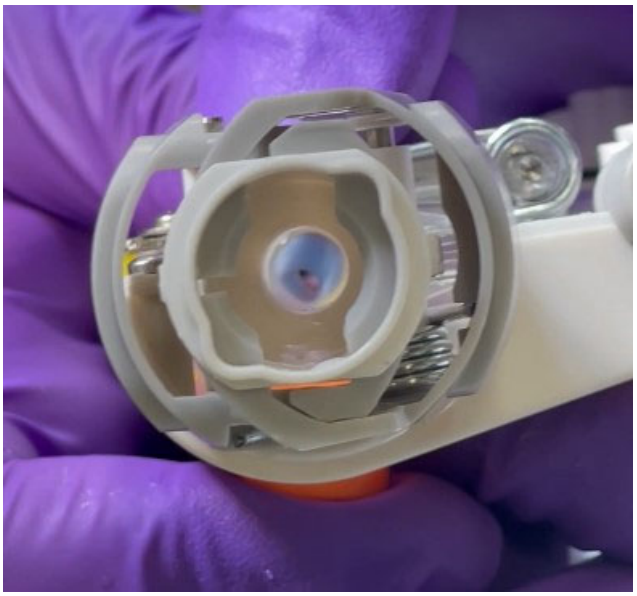
can be seen in Exhibit P. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle) that include an elongate member (tubular member) that defines a lumen. The valve's lumen is configured to 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.)



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

184. 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

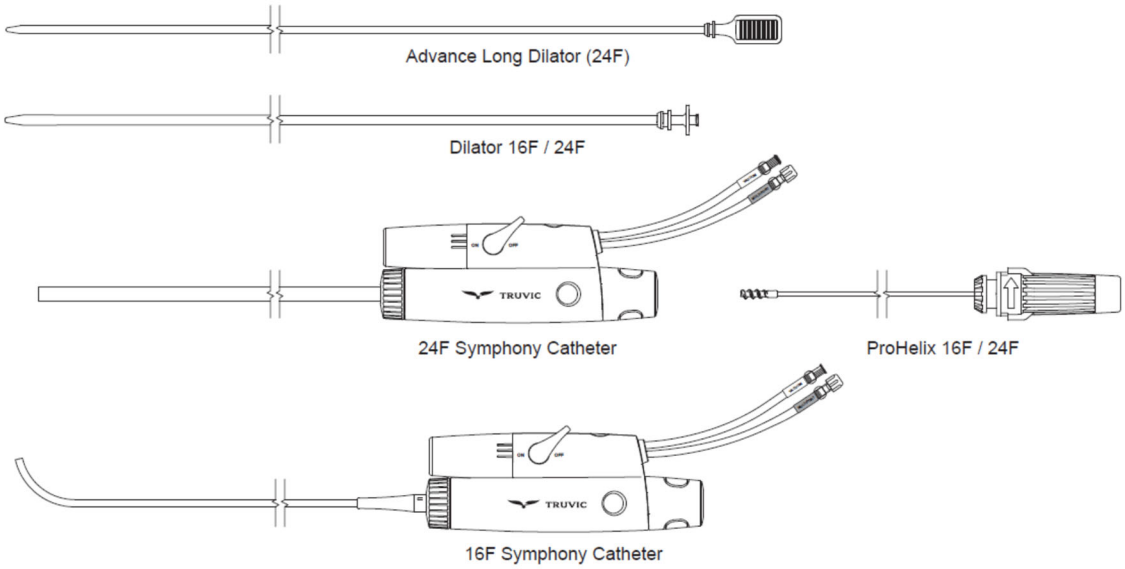


Figure 1: Symphony Thrombectomy System components

(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.

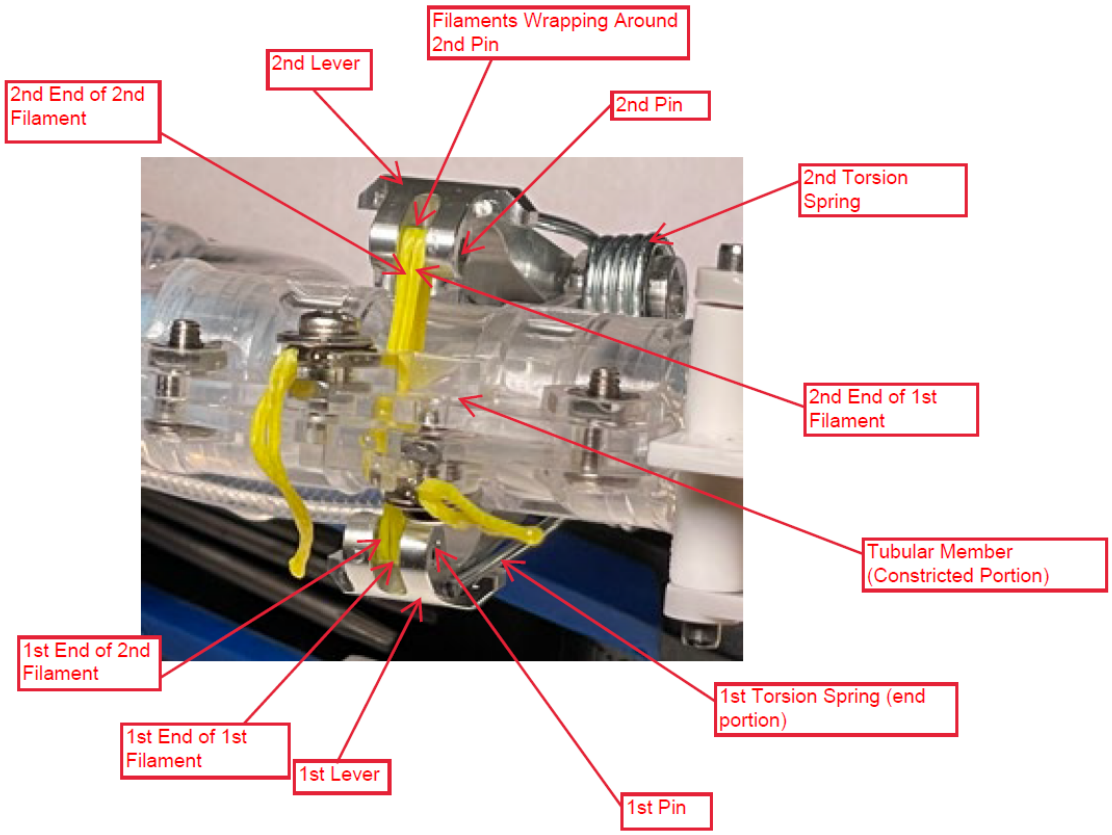
    ii. With the Advance Long Dilator, hold the dilator and guide wire in position and advance the catheter approximately 1 cm. Then press the Hemostasis Valve buttons on the Handle to reduce friction and advance the Catheter over the Dilator to the desired location. While pressing the Hemostasis Valve buttons,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

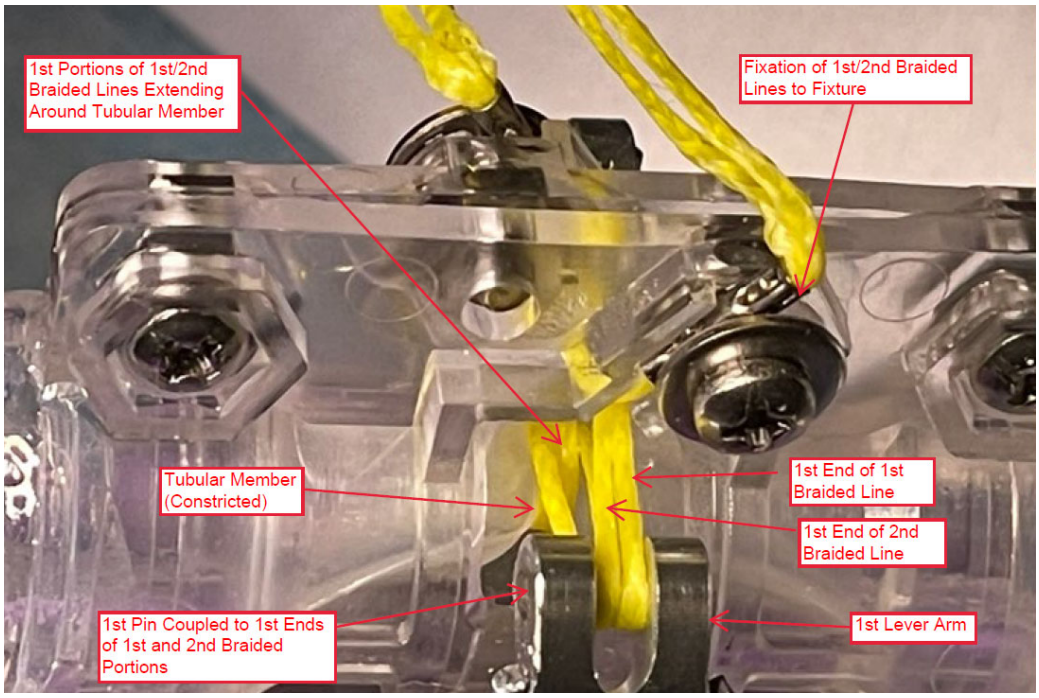
(Ex. B at 3-5.)

185. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially

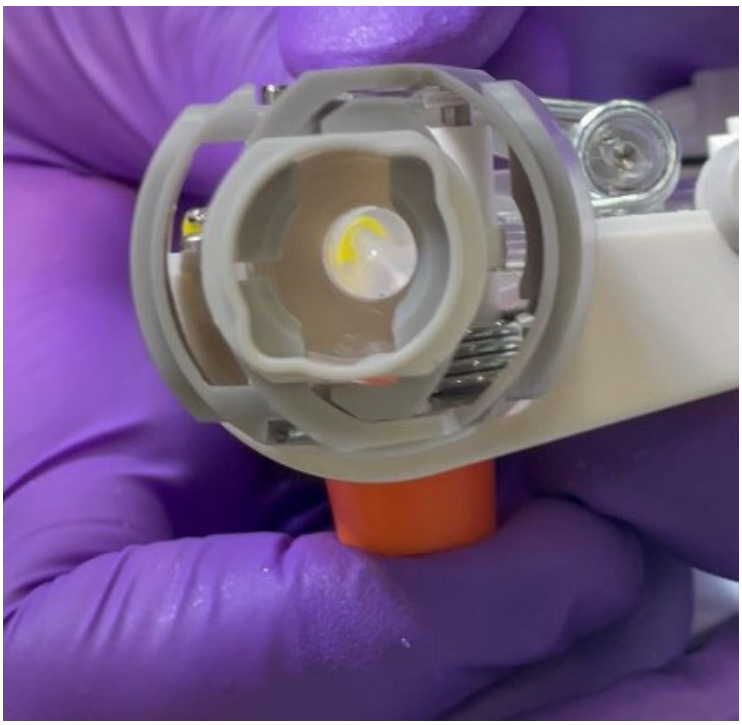
constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen," as can be seen in Exhibit P. Specifically, the controller handles of the Symphony system include a hemostasis valve with an constricting mechanism that constricts the lumen having an actuator mechanism including a first member and a second member (a first and second button that control first and second levers coupled to the ends of lines (filaments) that loop around the valve's elongate tubular member defining a lumen). The first member comprising a first button/lever/pin to which the first end of the filament line is coupled, and the second member comprising a second button/lever/pin to which the second end of the filament line is coupled are both 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.



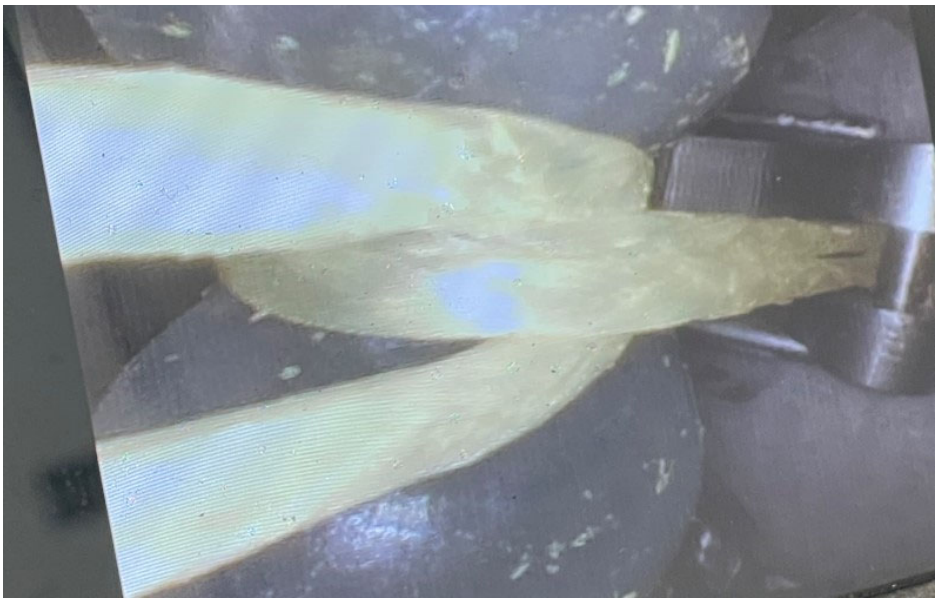
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



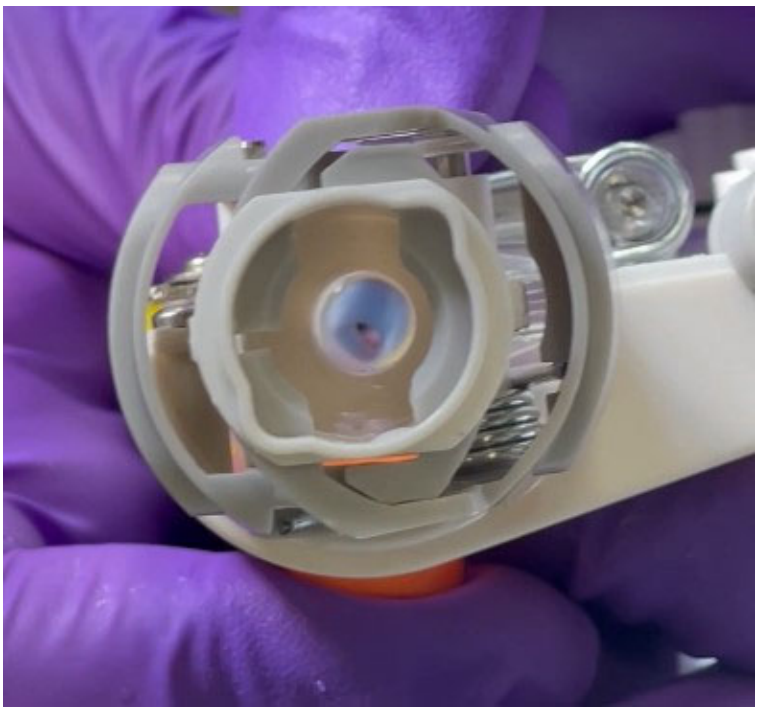
(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)



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



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

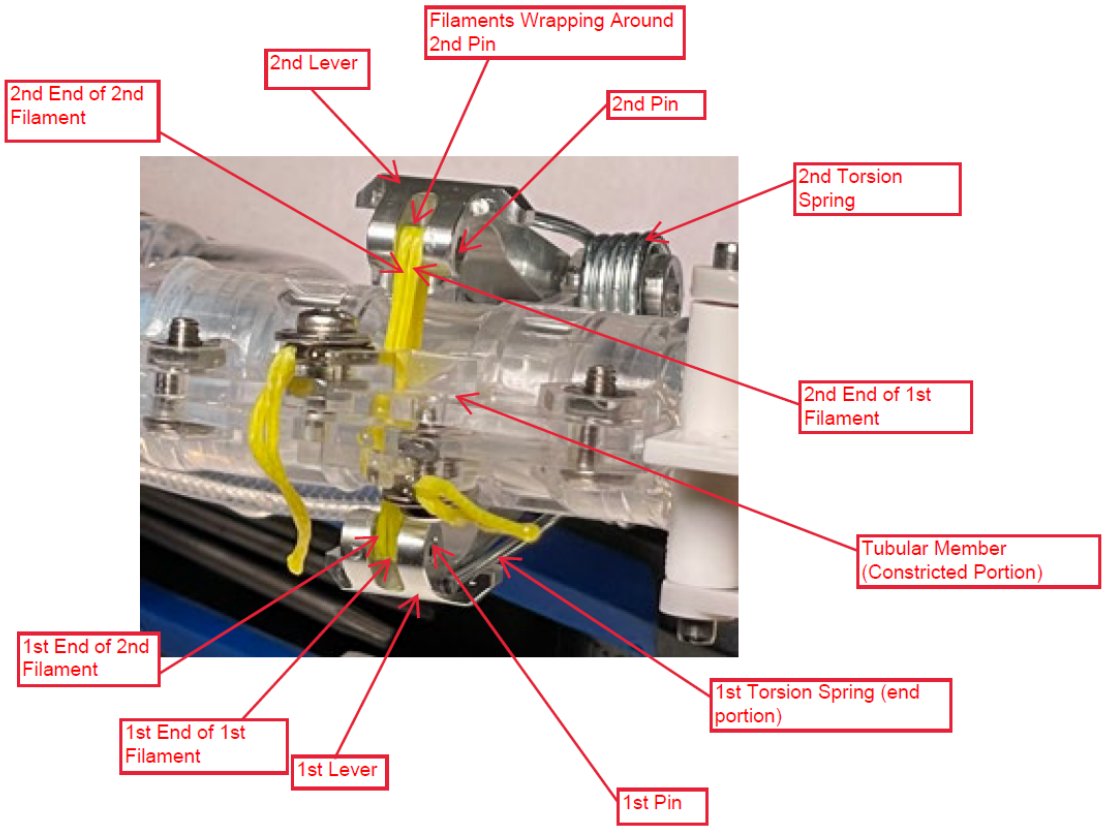


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

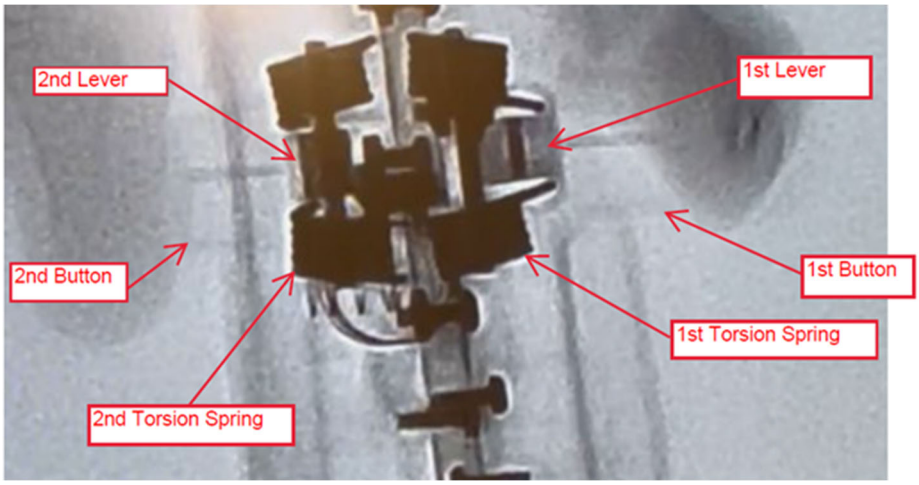
186. In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring(s), releasing tension on the

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.

187. The hemostasis valve of the Symphony system practices the requirements of claim 1, including "a biasing system configured to bias the first member and the second member to the first position," as can be seen in Exhibit P. 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(s) that pushes against the second lever biasing the second member to the first position. There are two 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.)

188. Defendants directly infringe claims of the '011 Patent, including claim 1, by making, using, selling, offering for sale, and/or importing Symphony system products, and when persons under Defendants' 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.

189. Defendants induce infringement of claims of the '011 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. Defendants actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

190. On information and belief, Defendants teach and/or direct 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. Defendants, for example, provide instructions for use ("IFU") 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. Defendants further provide 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, Defendants' 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.

191. Defendants further engage 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 '011 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing uses.

192. Defendants' infringement is with knowledge of the '011 Patent and its claims. Specifically, as described above, Inari notified Defendants that the Symphony system might infringe the '011 Patent by letter dated September 29, 2023. 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, including claim 1 of the '011 Patent.

193. At a minimum, Defendants have notice of the '011 Patent through the filing of this Complaint.

194. Defendants have continued their infringing activities, despite knowledge of the '011 Patent (including knowledge from correspondence with Inari and through this Complaint), and such infringement has been and continues to be egregious and willful.

195. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met for the '011 Patent, including through the use of Inari's virtual marking website: https://www.inarimedical.com/inari-patents.

196. Defendants' 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 '012 PATENT

197. Inari realleges and incorporates by reference the preceding paragraphs as though

fully set forth herein.

198. The ’012 Patent, titled “Hemostasis Valves and Methods of Use,” is part of the same family as the ’921 and ’011 Patents, and it shares the same specification. The ’012 Patent discloses improved hemostasis valves and methods of their use. *See, e.g.*, Ex. I 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.

199. 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.

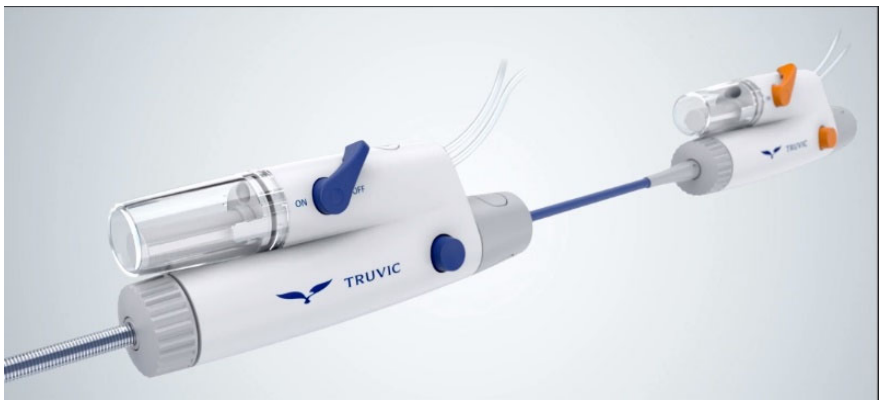
200. Defendants directly and indirectly infringe—literally and/or under the doctrine of equivalents—at least claim 1 of the ’012 Patent by making, using, selling, offering for sale, and/or importing into the United States their Symphony system and components thereof.

201. The Symphony system practices each limitation of at least claim 1 of the ’012 Patent.

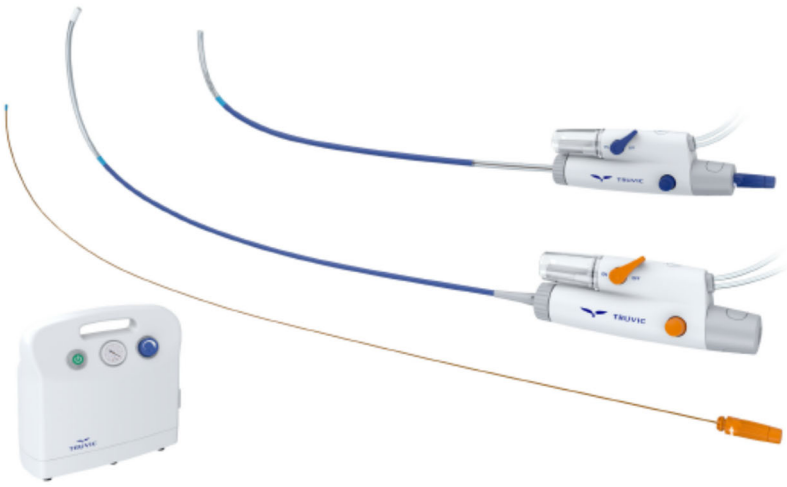
202. For example, claim 1 of the ’012 Patent recites:

> [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.

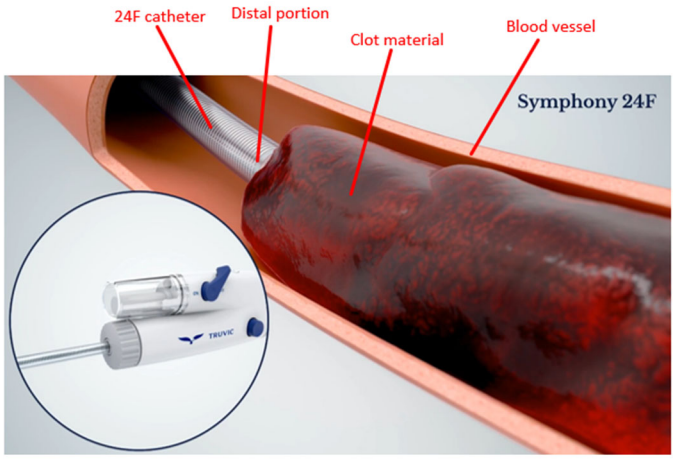
203. The Symphony system including the hemostasis valves practices the requirements of claim 1, including the preamble, "[a]n aspiration catheter, comprising," as can be seen in Exhibit Q. The Truvic Symphony system includes aspiration catheter systems for 24F and 16F catheters:



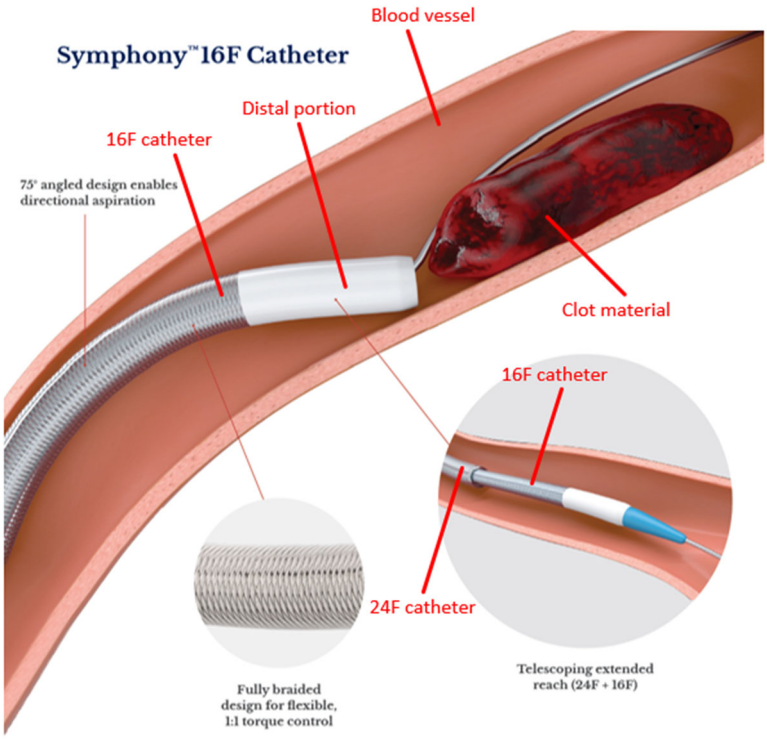
(Screen capture from Symphony product video.)



(Ex. A at 2.)



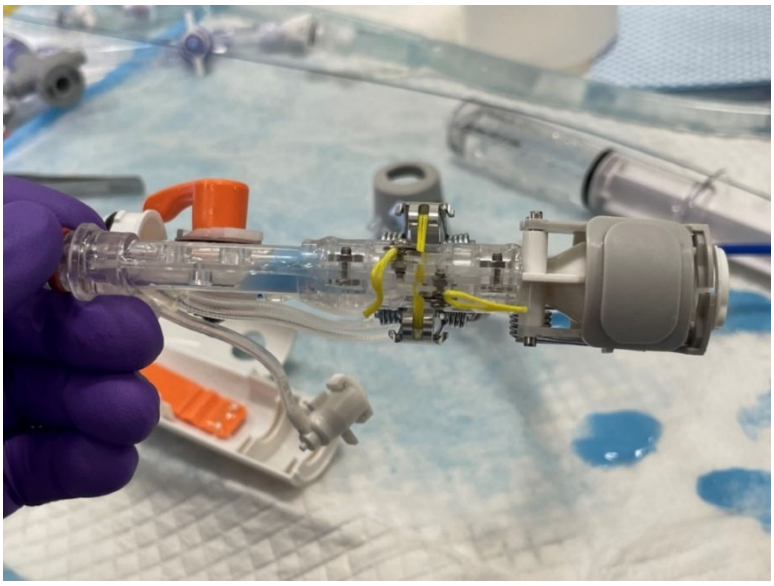
(Annotated screen capture from Symphony product video.)



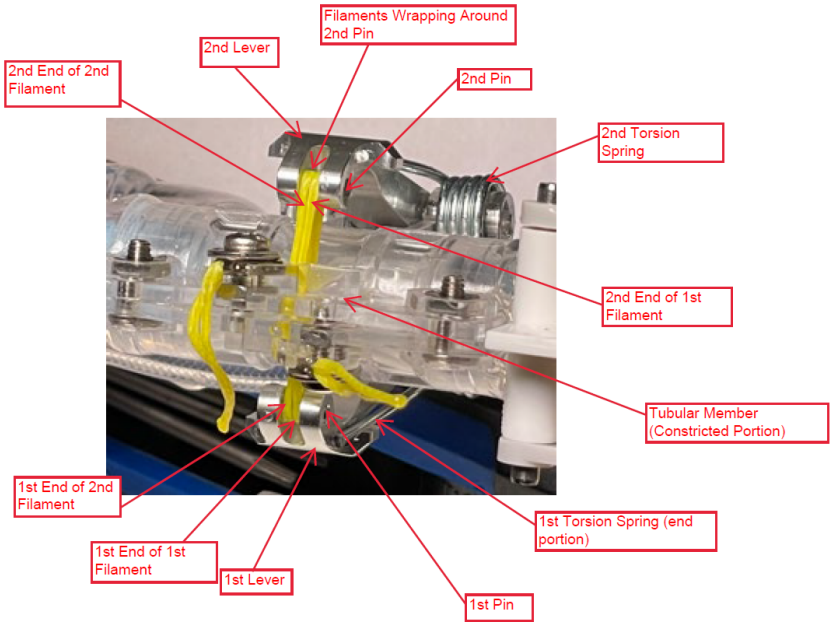
(Ex. A at 4 (annotations added) (showing a telescoping 16F and 24F catheter.)

204. 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 Q. 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.

205. 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 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 (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.)

206. 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

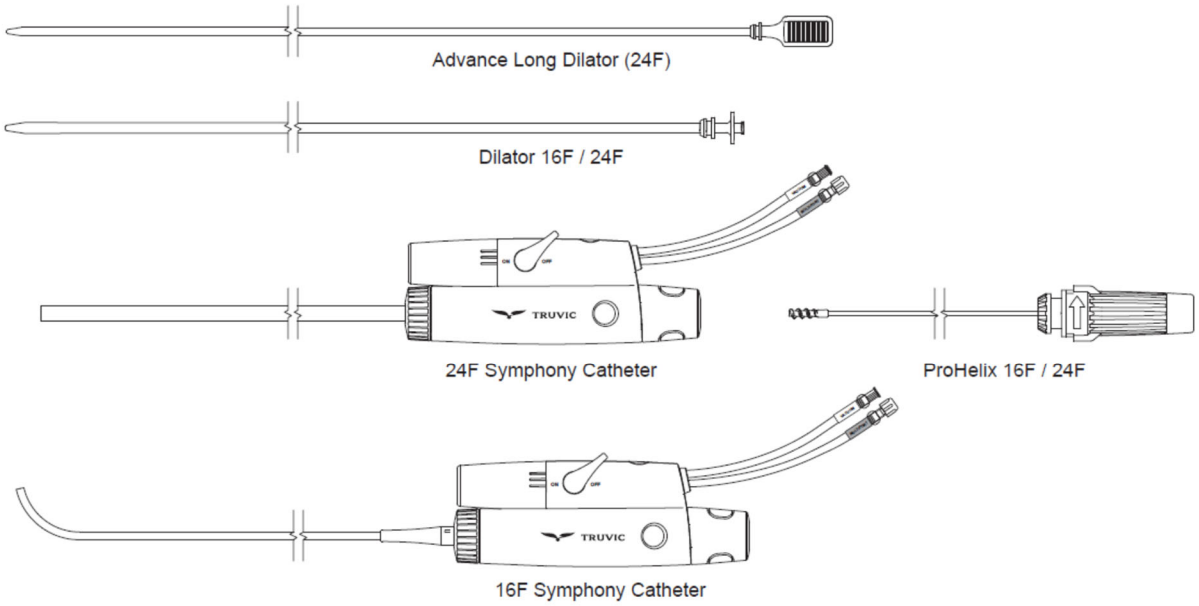


Figure 1: Symphony Thrombectomy System components

(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.

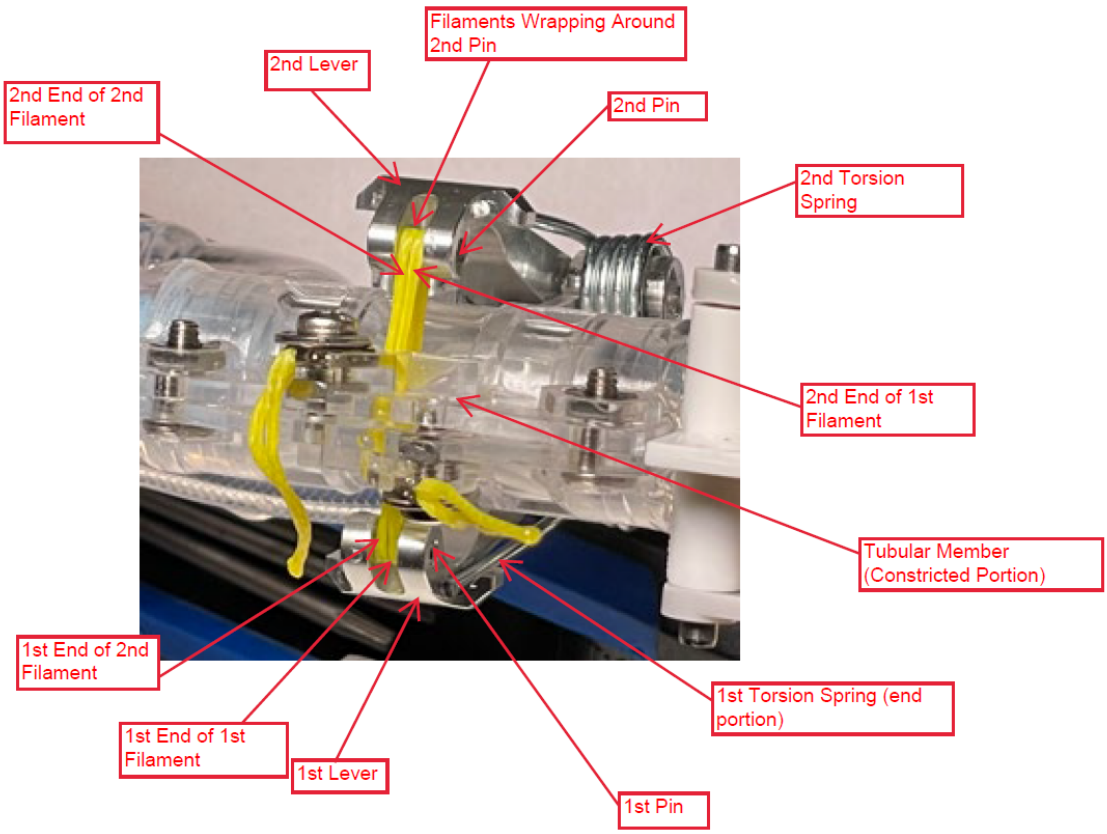
- Press the Hemostasis buttons to open the hemostasis valve and insert the Dilator through the open Hemostasis Valve of the Handle. Advance the Dilator through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
- If desired, attach a manifold or syringe to the stopcock on the 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.

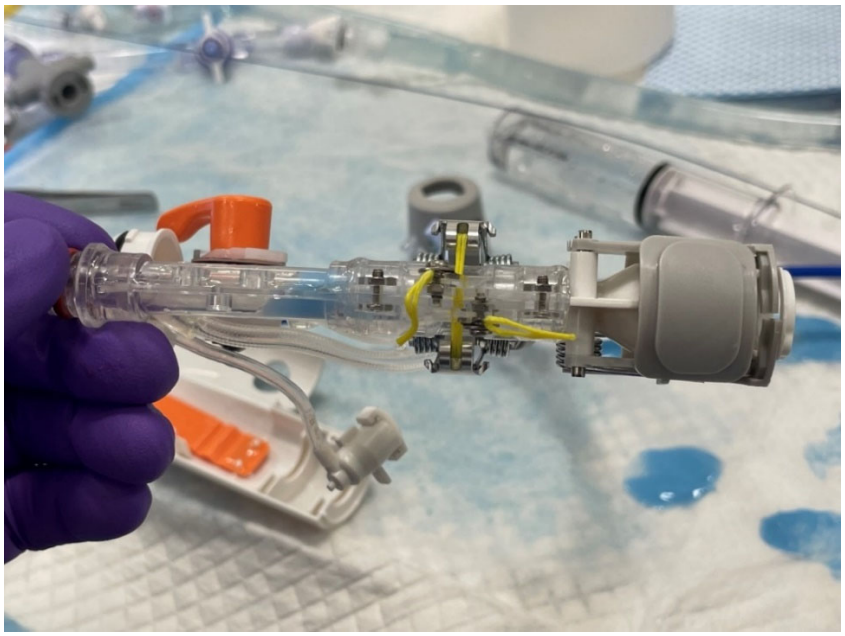
b. When using a 16F Symphony System, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the dilator while maintaining the Catheter and guidewire position.

(Ex. B at 3-5.)

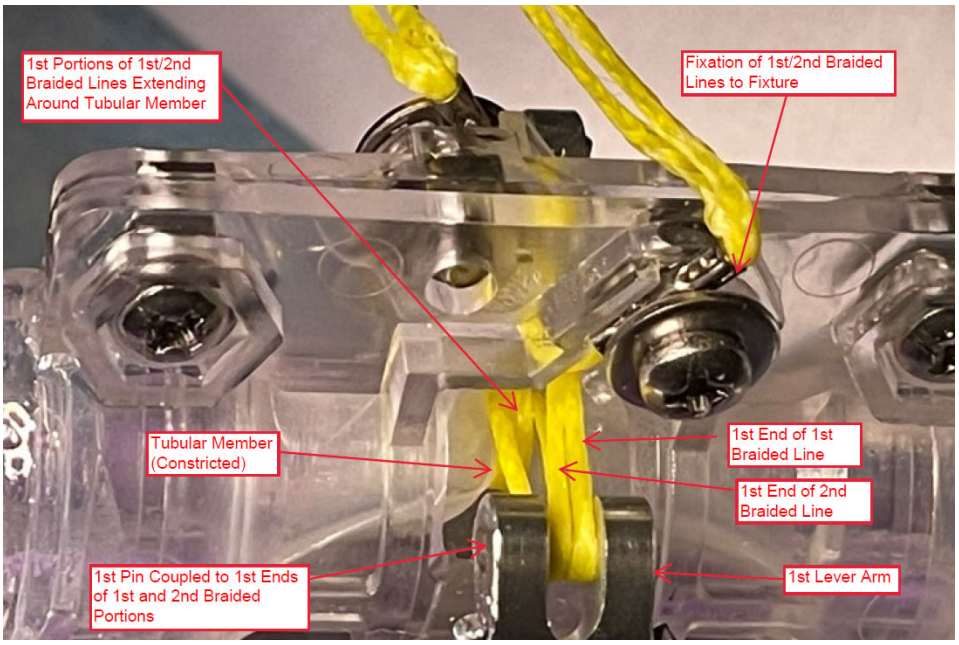
207. The Symphony system including the hemostasis valves practices the requirements of claim 1, including "a collapsible tubular sidewall defining a valve lumen in communication with the central lumen," as can be seen in Exhibit Q. The hemostasis valve in each of the 24F and the 16F handles of the Symphony 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.)

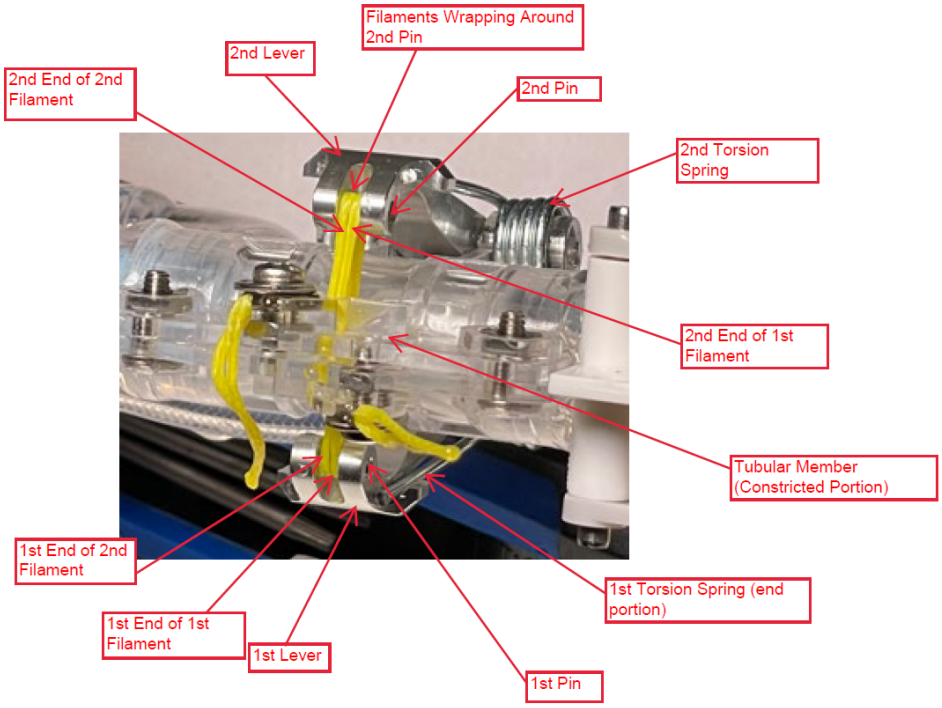


(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)

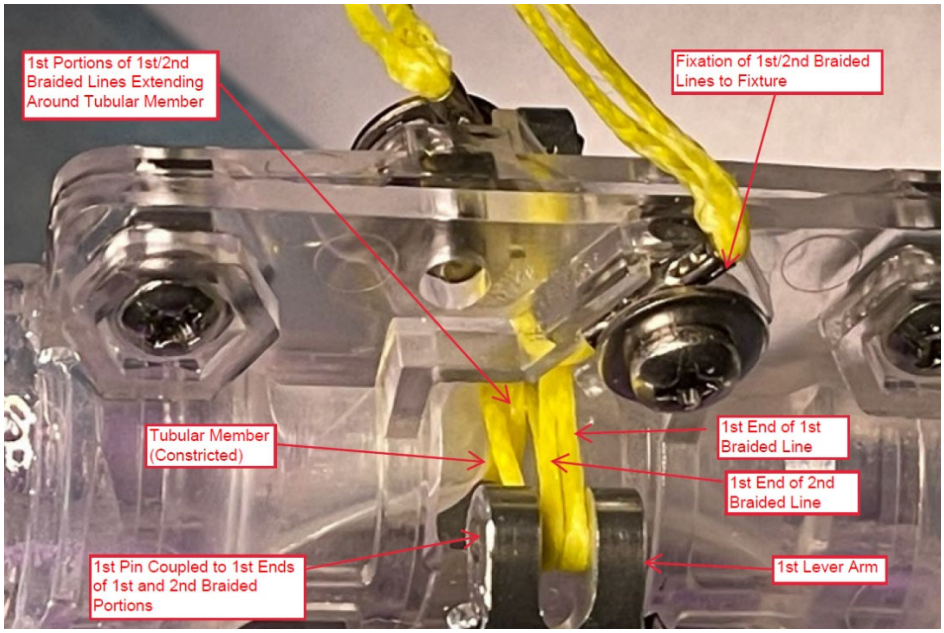
208. The hemostasis valve is in communication with the aspiration catheter, as can be seen above in the Symphony Instructions for Use directing users to advance 24F and/or 16F catheters through a hemostasis valve in the handle.

209. 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 Q. 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.



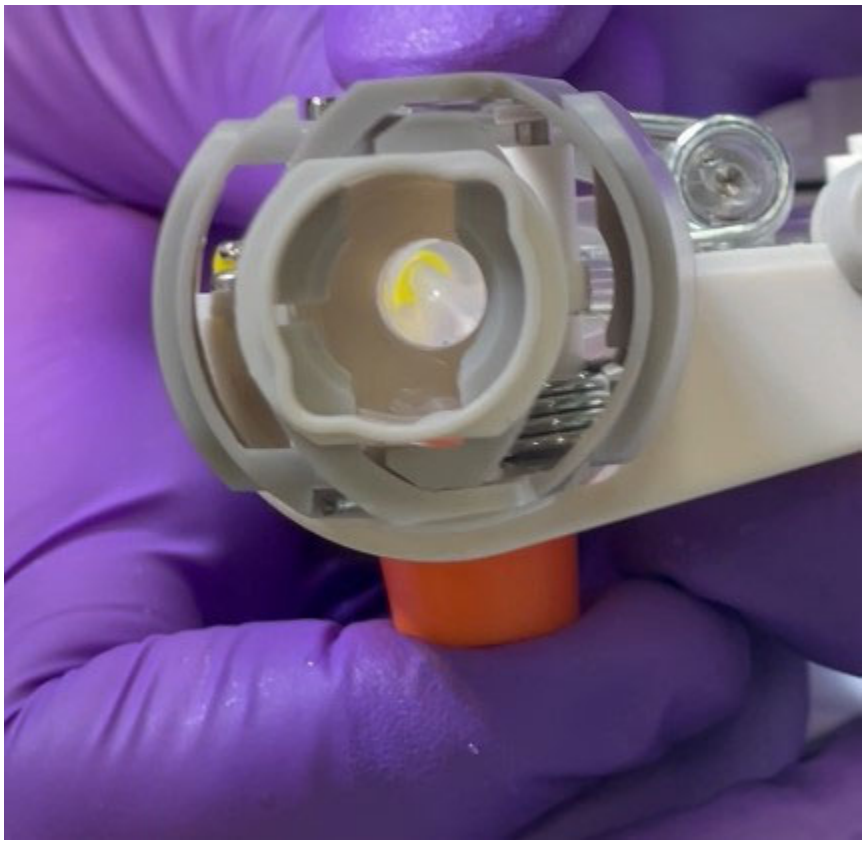
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



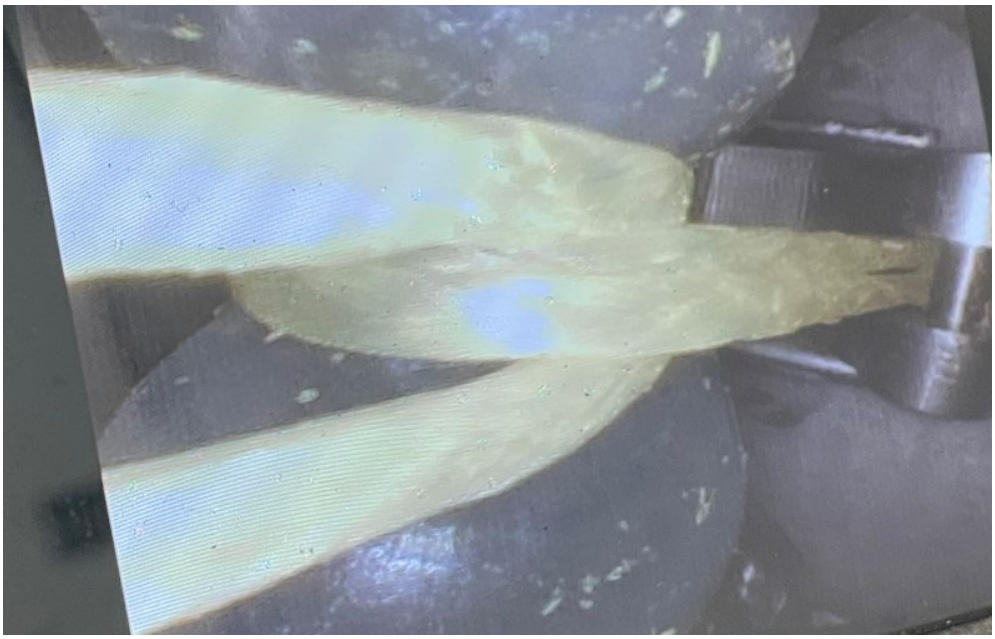
(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)

210. The Symphony system's hemostasis valves further include torsion spring(s)

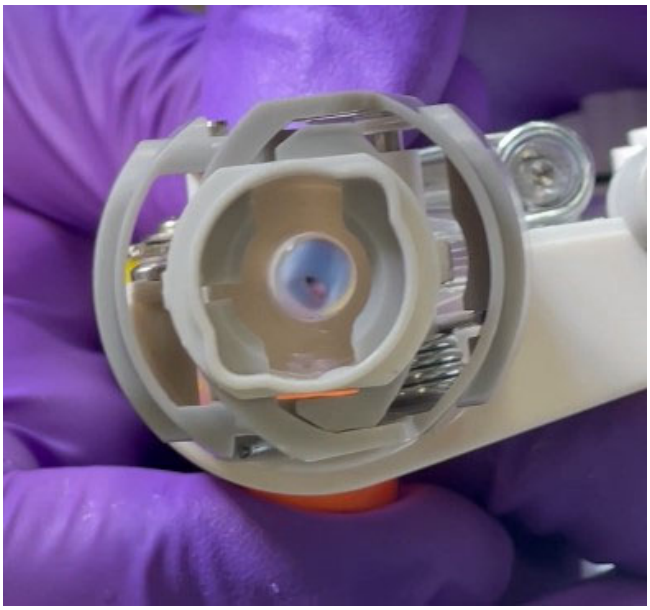
configured to move the first actuator's lever and pin outward, thus pulling the first end portion of the filament line, increasing the tension in the loop of the filament line around the valve lumen, thus decreasing the diameter of the valve lumen by constricting the loop to decrease the diameter of 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.)

211. Defendants directly infringe 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 Defendants’ 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.

212. Defendants induce 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. Defendants actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

213. On information and belief, Defendants teach and/or direct 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. Defendants, for example, provide instructions for use (“IFU”) 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. Defendants further provide 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, Defendants’ 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.

214. Defendants further engage 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.

215. Defendants’ infringement is with knowledge of the ’012 Patent and its claims. Specifically, as described above, Inari notified Defendants 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.

216. At a minimum, Defendants have notice of the ’012 Patent through the filing of this Complaint.

217. Defendants have continued their infringing activities, despite knowledge of the ’012 Patent (including knowledge from correspondence with Inari and through this Complaint), and such infringement has been and continues to be egregious and willful.

218. 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.

219. Defendants’ 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 ’291 PATENT

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

221. The ’291 Patent, titled “Hemostasis Valves and Methods of Use,” is part of the same family as the ’921, ’011, 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. J 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.

222. 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.

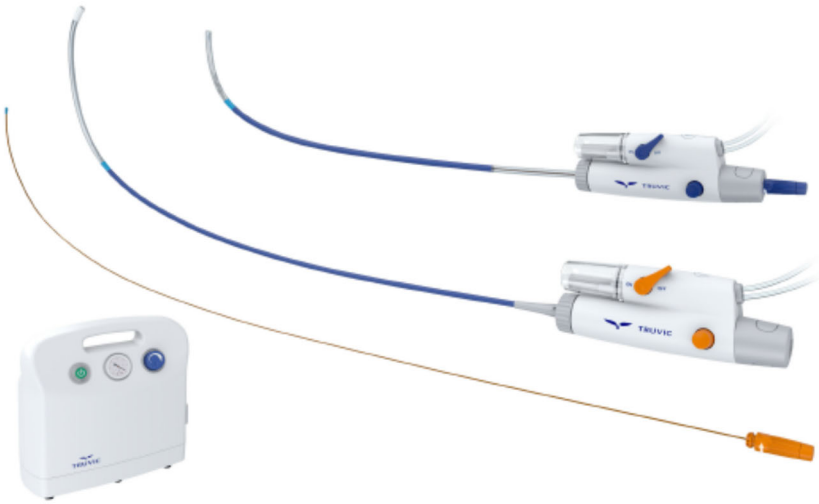
223. Defendants directly and indirectly infringe—literally and/or under the doctrine of equivalents—at least claim 1 of the '291 Patent by making, using, selling, offering for sale, and/or importing into the United States their Symphony system and components thereof.

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

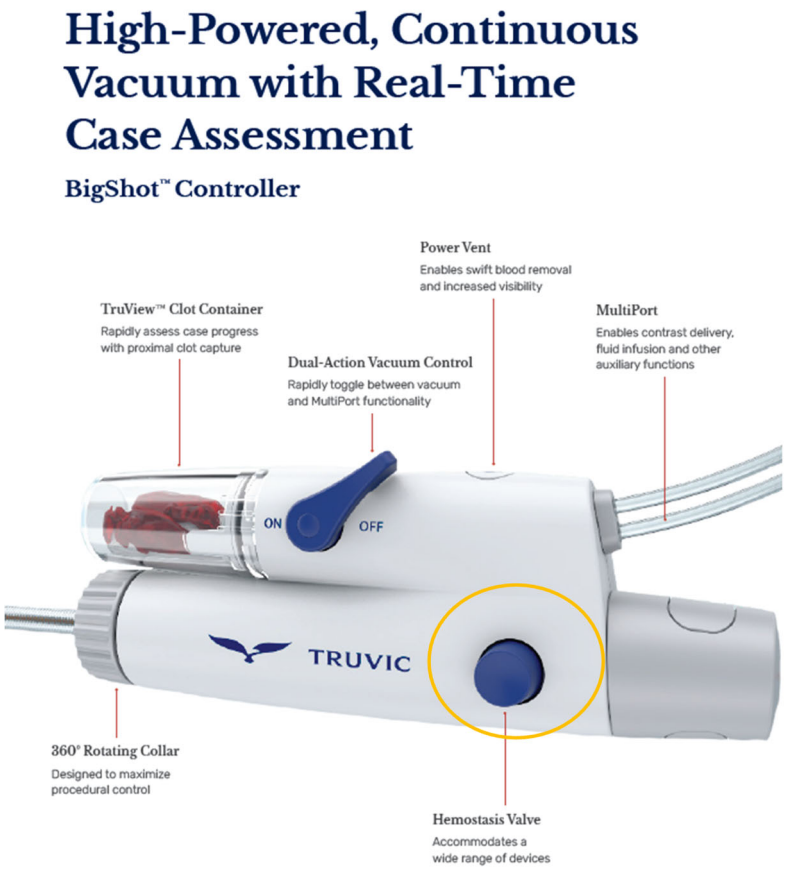
225. For example, claim 1 of the '291 Patent recites:

> [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.

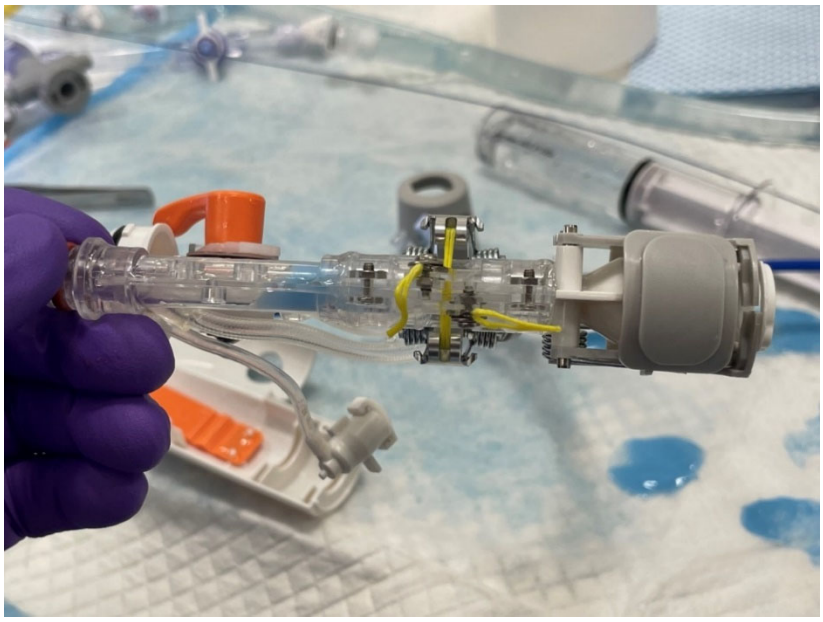
226. The hemostasis valves of the Symphony system practice the requirements of claim 1, including the preamble, "[a] valve, comprising," as can be seen in Exhibit R. Specifically, the controller handles of the Symphony system include a hemostasis valve operated by blue buttons (in the 24F handle) and orange buttons (in the 16F handle). 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.)

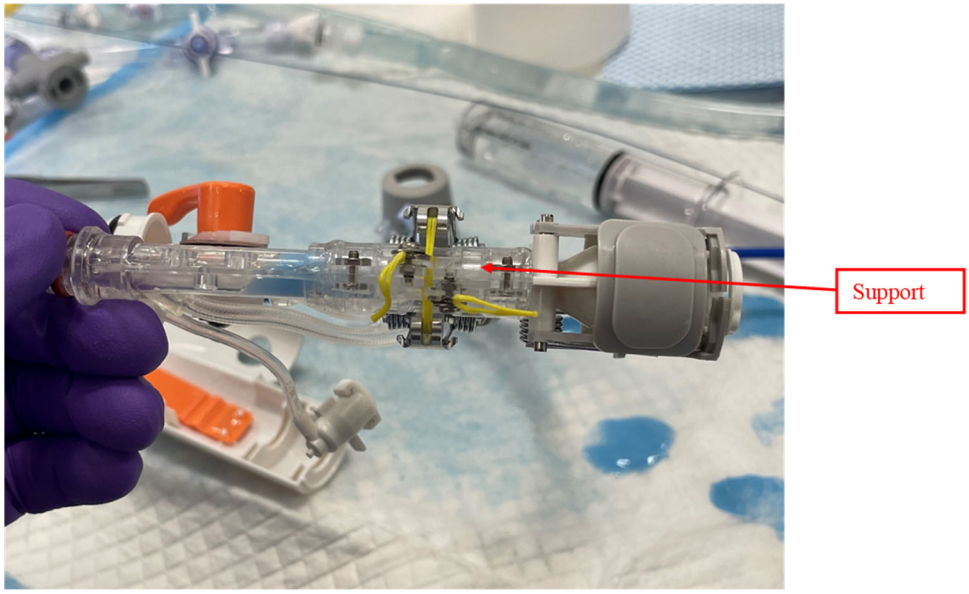


(Image of internal portion of handle housing with hemostasis valve.)

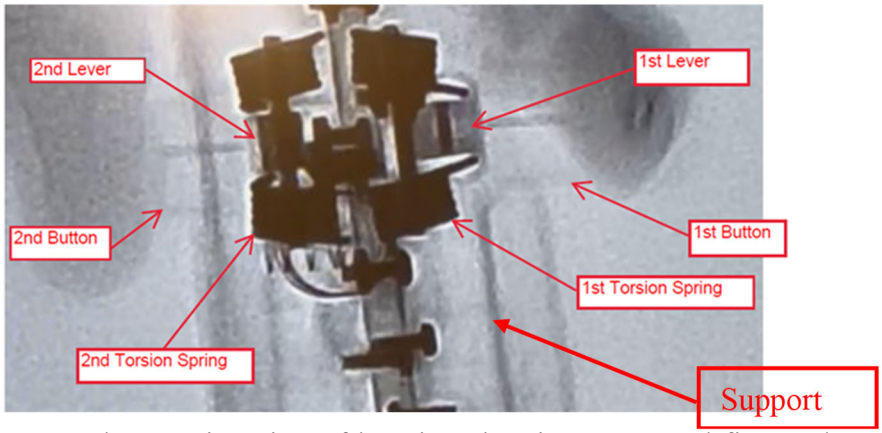
(Image of internal portion of housing zoomed in on hemostasis valve.)

227. 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 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 a clear plastic support that carries a tubular member and further has an

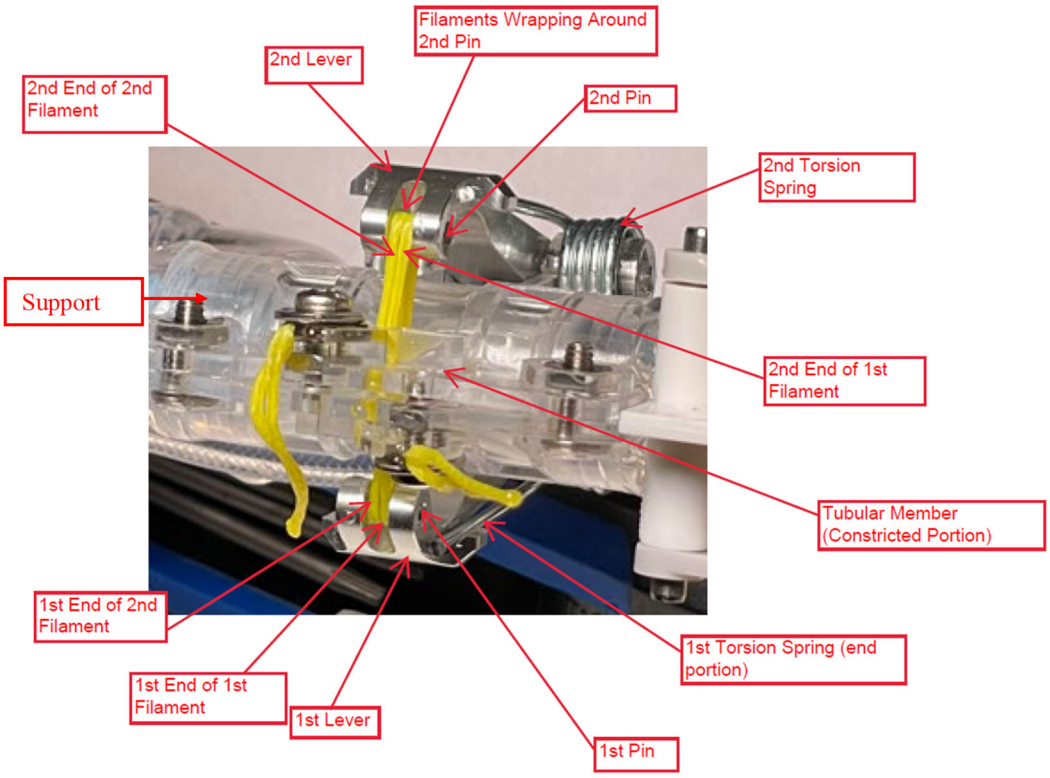
actuator with a first and second member coupled to the support.



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

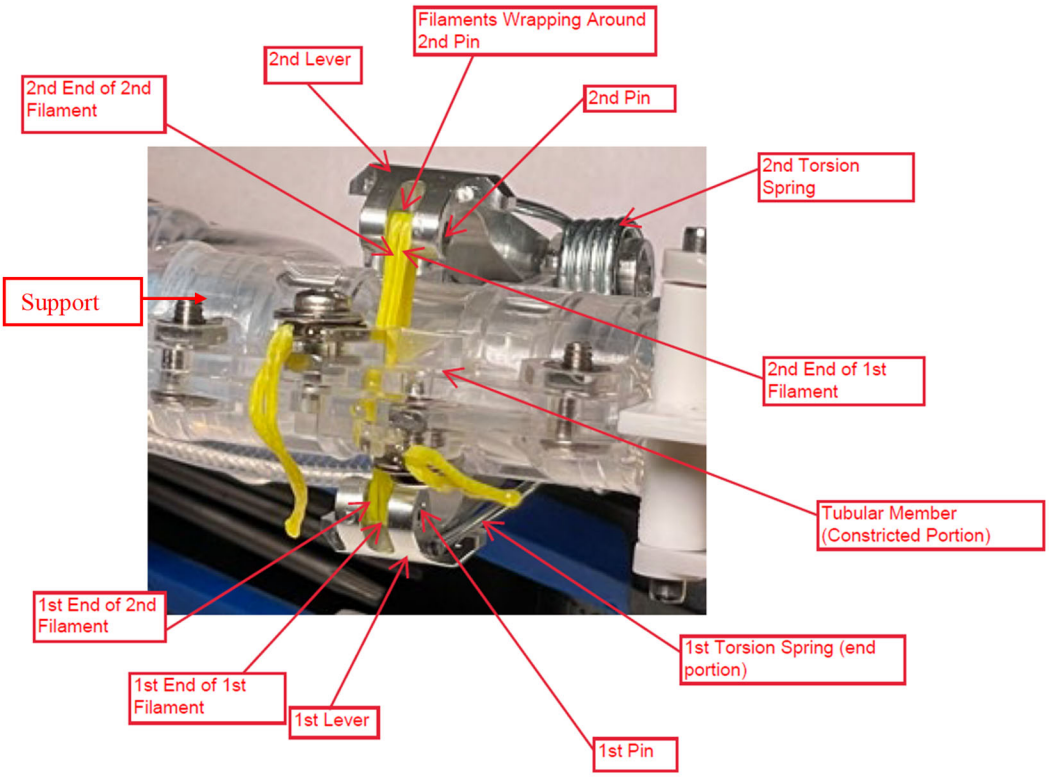


(Annotated X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of hemostasis valve in Symphony housing.)

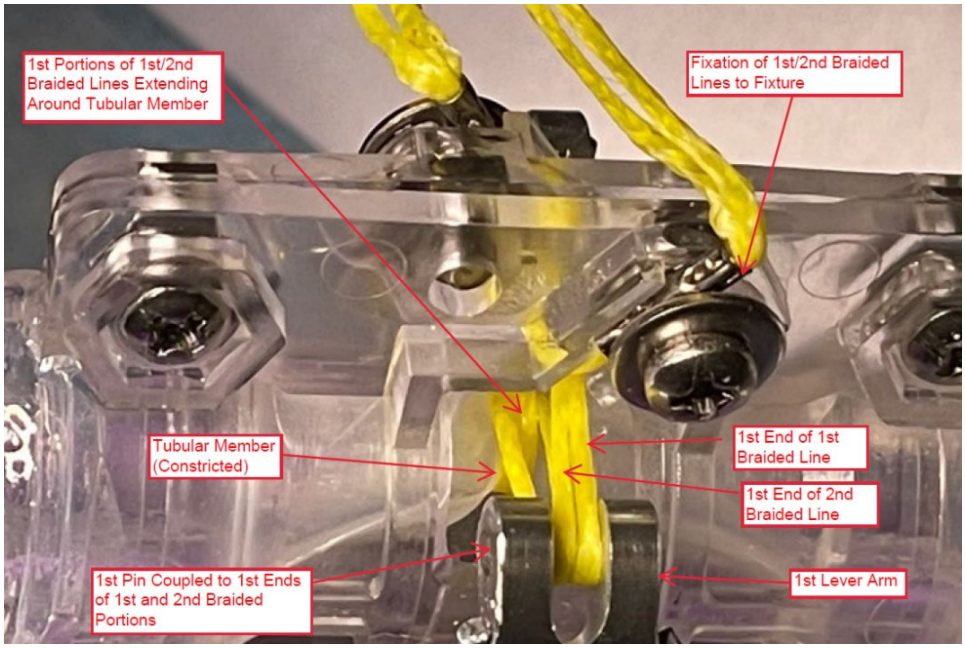


(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member and support.)

228. 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 R. 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.



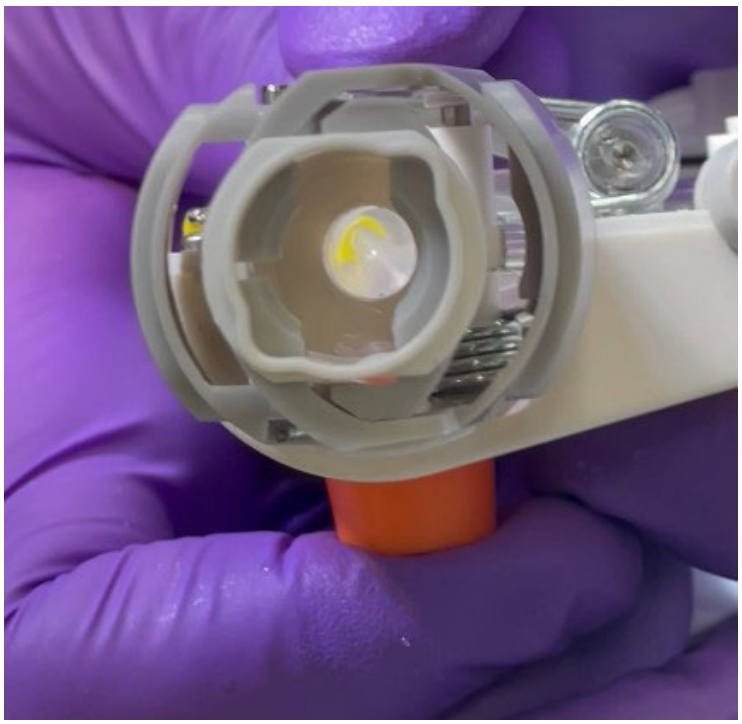
(Annotated image of internal portion of Symphony housing, including hemostasis valve with elongate tubular member.)



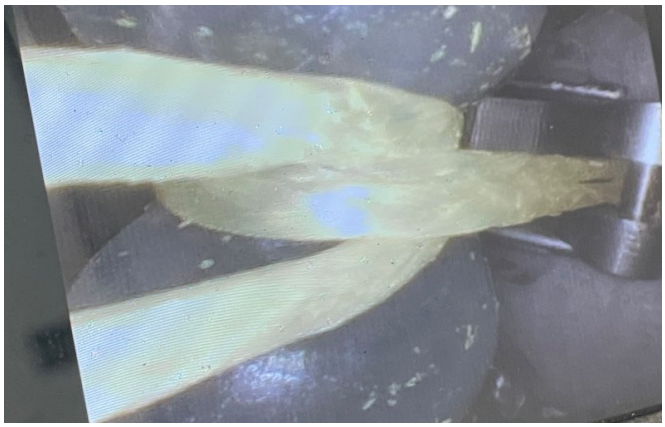
(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis

valve with tubular member and lines (filaments) extending around the tubular member.)

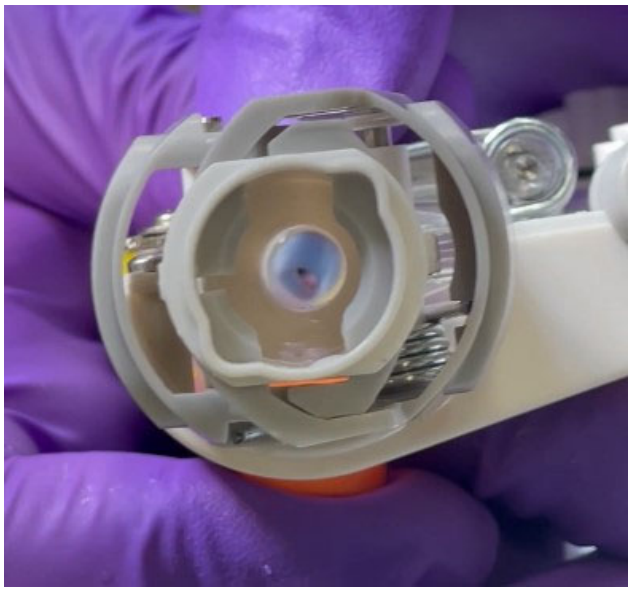
229. In operation, depressing the hemostasis valve button(s) of the Symphony system controller handles pushes the lever(s) against the torsion spring(s), releasing tension on the filaments wrapped around the lever pin(s), which decreases the constriction on the lumen of the hemostasis valve. This allows 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.)

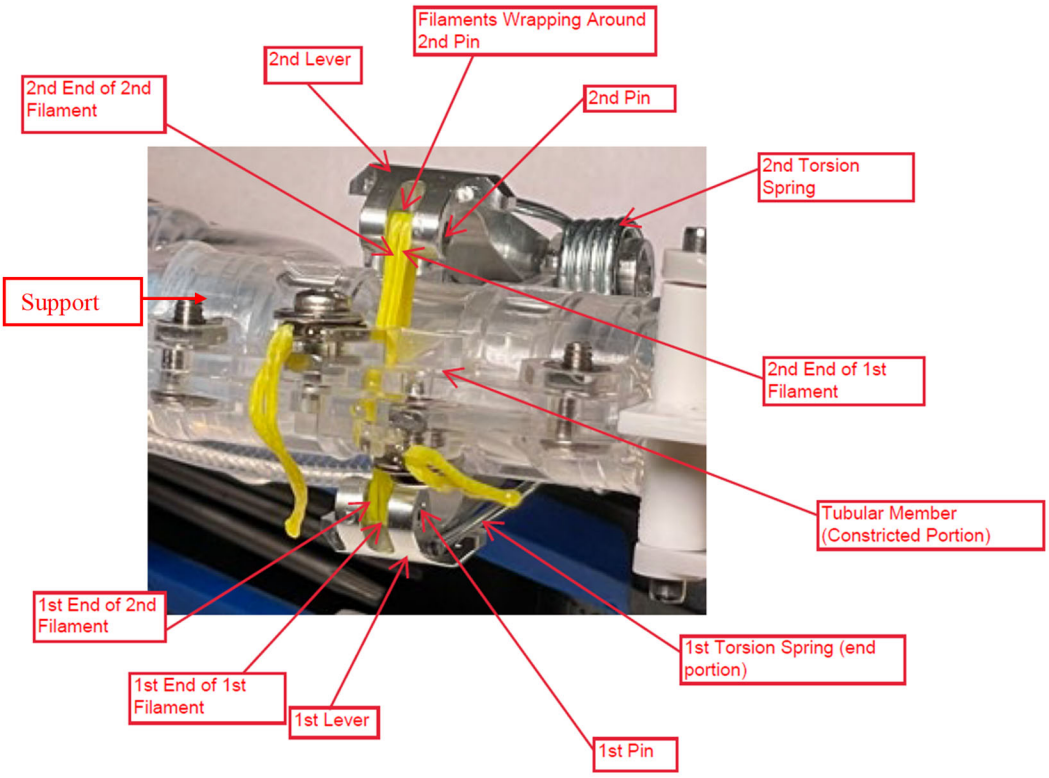


(Internal image of hemostasis valve with filaments encircling and constricting tubular member.)



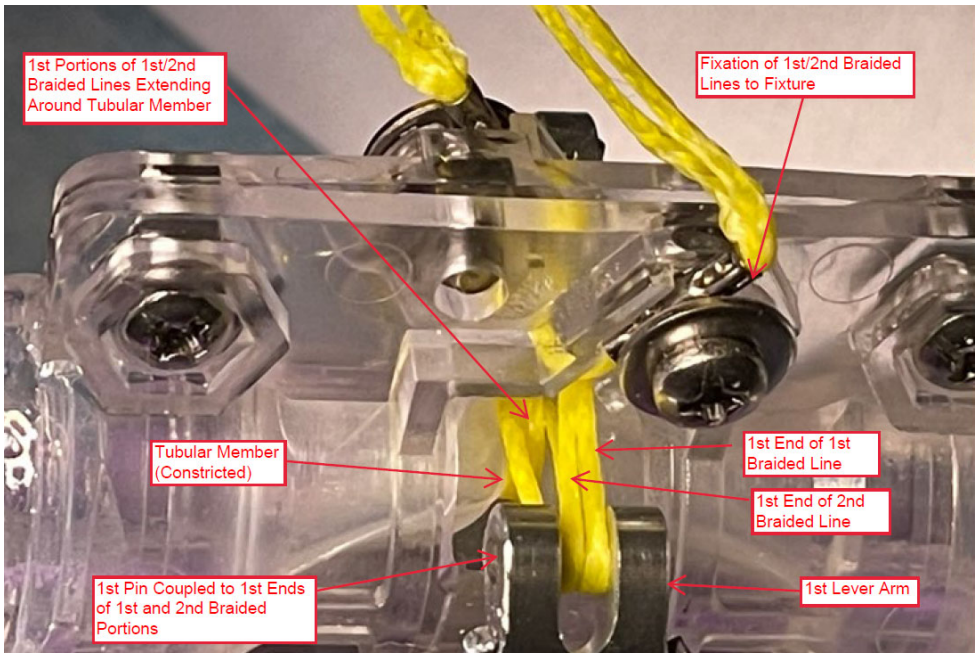
(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve open.)

230. 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 R. 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).

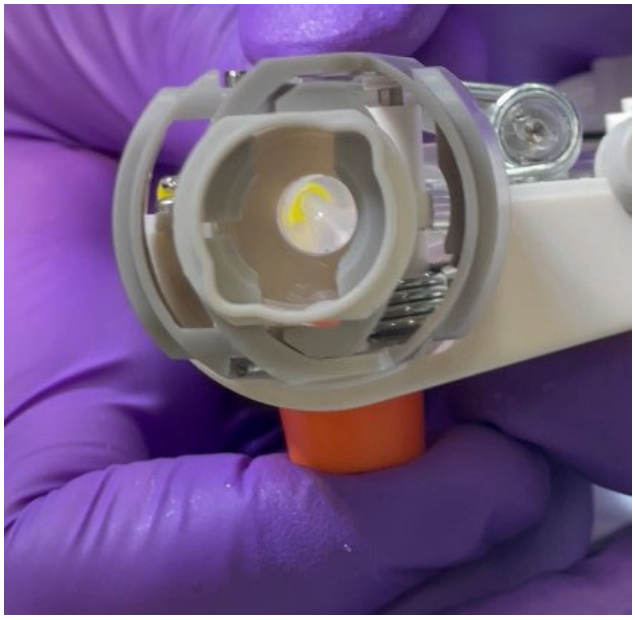


(Annotated image of internal portion of Symphony housing, including hemostasis valve with tubular member.)

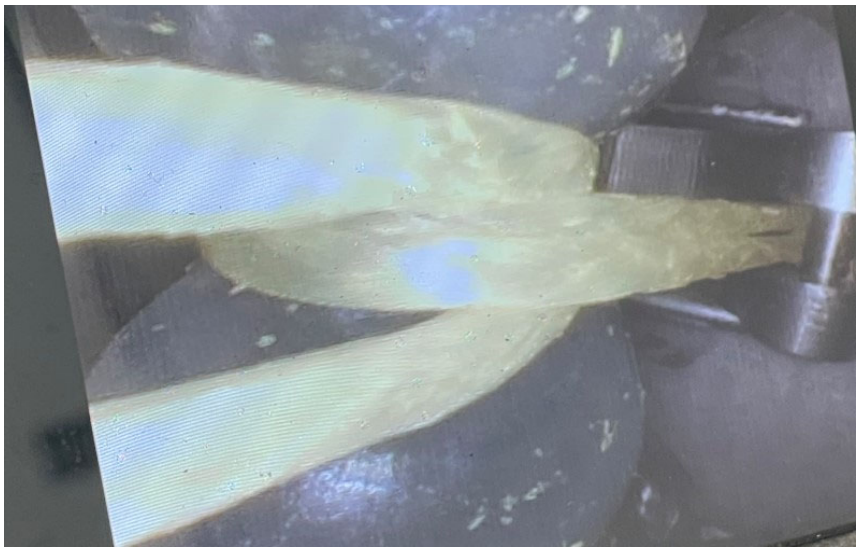
(Image of internal portion of housing with hemostasis valve.)



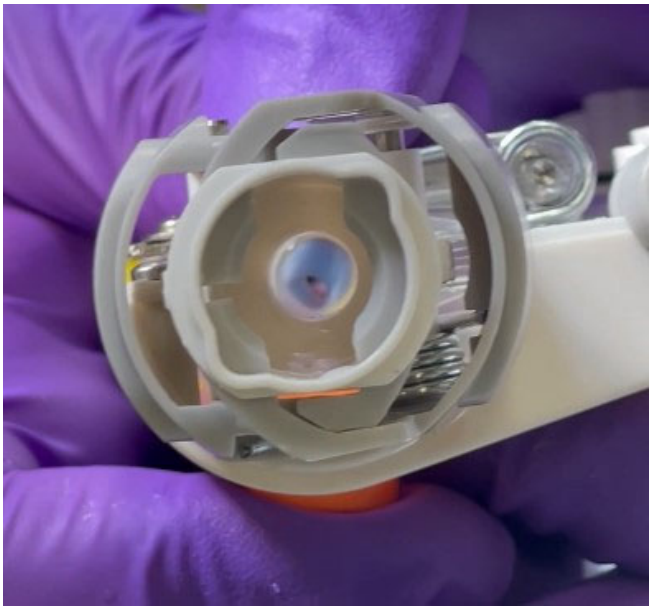
(Annotated image of zoomed in internal portion of Symphony housing, including hemostasis valve with tubular member and lines (filaments) extending around the tubular member.)



(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.)

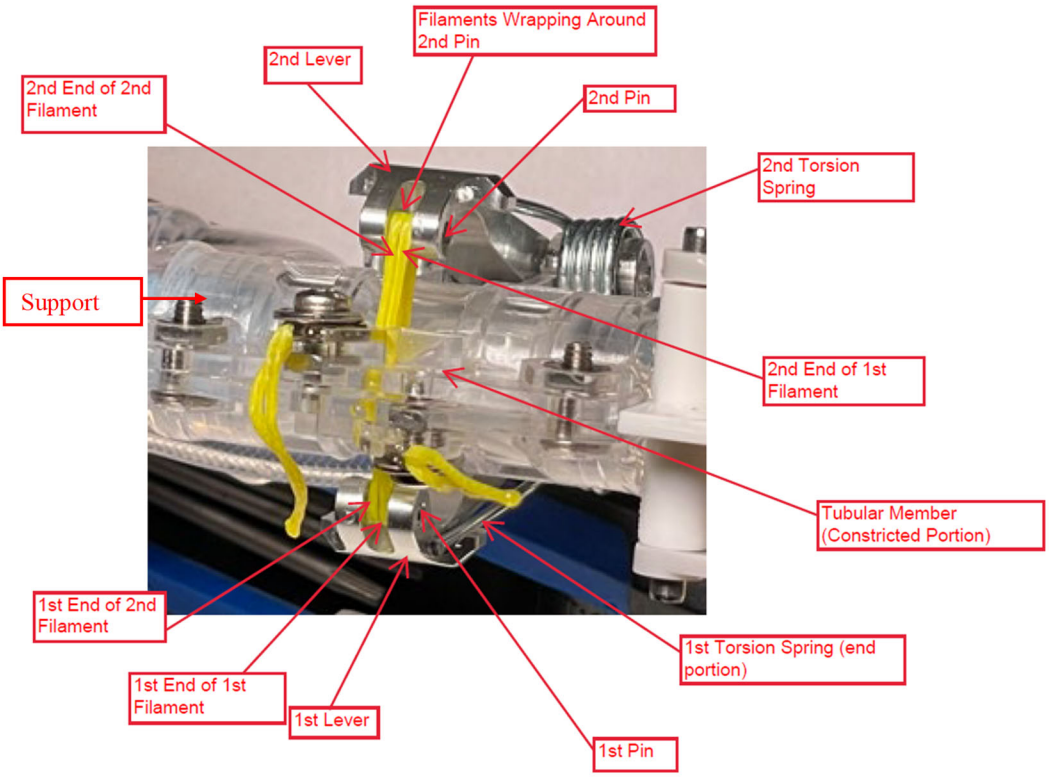


(Symphony handle with view down tubular member (lumen) of hemostasis valve with valve open.)

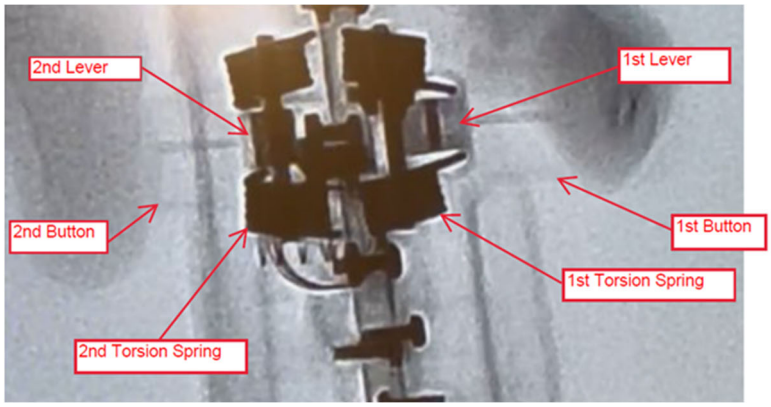
231. The hemostasis valves of the Symphony system practice the requirements of claim 1, including "a filament formed in a loop around the tubular sidewall, the filament having at least a first end portion extending away from the loop to the first member," as can be seen in Exhibit R. As can be seen in 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.

232. 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 R. 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.)

233. Defendants directly infringe 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 Defendants' 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.

234. Defendants induce 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. Defendants actively induce users of the system, *e.g.*, doctors, to perform thrombectomy procedures using the Symphony system that include use of infringing hemostasis valves.

235. On information and belief, Defendants teach and/or direct 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. Defendants, for example, provide instructions for use ("IFU") 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. Defendants further provide 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, Defendants' 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.

236. Defendants further engage 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.

237. Defendants' infringement is with knowledge of the '291 Patent and its claims. Specifically, as described above, Inari notified Defendants 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.

238. At a minimum, Defendants have notice of the '291 Patent through the filing of this Complaint.

239. Defendants have continued their infringing activities, despite knowledge of the '291 Patent (including knowledge from correspondence with Inari and through this Complaint), and such infringement has been and continues to be egregious and willful.

240. 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.

241. Defendants' 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 preliminary and permanent injunction enjoining Defendants, individually and

collectively, and Defendants' 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;

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

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

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

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

Dated: May 22, 2024

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