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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

INARI MEDICAL, INC., Plaintiff, v. IMPERATIVE CARE, INC., Defendant.	Case No. 4:24-cv-03117-YGR **DECLARATION OF BRIAN BROWN IN SUPPORT OF INARI'S MOTION FOR A PRELIMINARY INJUNCTION**

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I, Brian Brown, hereby declare as follows:

1. My name is Brian Brown. I am currently employed as President of Brown-Tech, LLC where I provide engineering expertise in the areas of Research and Development and Operations for medical device companies. I have been asked to provide an expert declaration on behalf of Inari Medical, Inc. ("Inari"). I understand that Inari alleges that the defendant in this case, Imperative Care, Inc. (which I refer to as "Truvic") has infringed United States Patent Nos. 11,974,910 ("'910 Patent"), 11,969,333 ("'333 Patent"), 11,554,005 ("'005 Patent"), 11,744,691 ("'691Patent"), 11,844,921 ("'921 Patent"), 11,697,011 ("'011 Patent"), 11,697,012 ("'012 Patent"),11,865,291 ("'291 Patent"), 12,016,580 ("'580 Patent").

2. I submit this declaration in support of Inari's Motion for Preliminary Injunction. I focus for purposes of this declaration on Claim 1 of the '910 Patent and Claim 10 (which depends from and therefore requires discussion of Claim 1) of the '921 Patent. I reserve the right to supplement or amend this declaration should additional data or other information that affect my opinions become available. I may testify at a hearing regarding the matters expressed in this declaration and any supplemental declaration(s) I may prepare. I also may prepare and rely on visual aids to demonstrate various aspects of my testimony at a hearing. If asked to do so, I may also testify with respect to matters raised by other witnesses, including experts retained by Truvic. If I am asked to testify at trial, I intend to prepare an expert report in compliance with Federal Rule of Civil Procedure 26(a)(2) according to any schedule set by the Court.

3. For my work in connection with this case, I am being compensated at my standard consulting rate of $500 per hour. My compensation is in no way contingent upon the outcome of the litigation or the specifics of my testimony or opinions.

I. BACKGROUND AND QUALIFICATIONS

4. A brief summary of my qualifications follows. I received a Bachelor of Science in Mechanical Engineering from North Dakota State University, with an emphasis on electro-mechanical automation. As part of my studies, I took classes covering many different engineering areas including chemistry, physics, advanced mathematics, statistics, software engineering and architecture, statics, dynamics, thermodynamics, robotics, technical writing,

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material science, fluid dynamics and engineering design. After my studies, I joined Hutchinson Technology as a machine design engineer. After a few years at Hutchinson, I joined Boston Scientific/SciMED in 1990 and began working with their medical device product lines, including stents and cardiovascular implants.

5. Beginning with my time at SciMED, I have over 30 years of research and development experience working in the cardiovascular and medical device industries across a wide variety of application areas including development of neurovascular, cardiovascular, peripheral vascular, and pulmonary aspiration thrombectomy devices.

6. For 24 years, I served in various roles at SciMED Life Systems and Boston Scientific, including multiple research and development engineering positions in various application areas including catheters, stents, guidewires, thrombectomy systems, and cardiovascular implants. For my final 10 years at Boston Scientific, I served as the global vice president of R&D Interventional Cardiology, where I was tasked to direct worldwide cardiovascular research and development activities for accelerated launches of implantable stents, drug delivery technologies, structural heart devices, disposable catheters, and adjunctive products.

7. Starting in 1991, in collaboration with Possis Medical and SciMED Life Systems, I designed and developed a drive unit to supply high pressure water jet and aspiration to a thrombectomy catheter. From 1992 to 1993, as part of my work, I developed and patented several thrombus removal catheters designed for aspiration, irrigation, and mechanical interaction with thrombi.

8. I also held various leadership roles at medical device and diagnostics companies, including Chief Technology Officer at OvaGene Oncology and Vice President of R&D and Operations at both Cogentix Medical, Inc. and Sunshine Heart, Inc, focused on advancing the medical device and diagnostics industries.

9. For the past 6 years, I have served as a technical consultant for various early-stage medical device companies as the founder and President of Brown-Tech, LLC, including QXMedical, Peytant Solutions, and CardioMech. I am also one of the founding partners for

Northern Nitinol, LLC, which is a company that focuses on nitinol design and prototyping for medical device components.

10. I was the two-time recipient of the Boston Scientific Patent of the Year award, recognized as one of Minnesota's leading inventors by Twin City Business Magazine in 2013, elected to College of Fellows, American Institute for Medical and Biological Engineering, and served as an Advisor to the University of Minnesota Office of Technology Commercialization. I also served as a mentor to students enrolled in the University of Minnesota Design of Medical Device program.

11. I am a named inventor on approximately sixty issued U.S. medical device patents covering a wide variety of technologies, including two aspiration thrombectomy patents and several others on stent geometries, nitinol, balloon catheters, infusion catheters, and ePTFE processing. I am an inventor of U.S. Patent No. 5,419,774 on a thrombus extraction device for quickly removing thrombus from a saphenous vein graft, and U.S. Patent No. 5,417,703 on an intravascular device for removing vascular occlusion material.

12. During my career, I developed a range of medical devices from low profile neurovascular catheters for the treatment of neurovascular disease and embolic stroke to large profile catheters for the treatment of peripheral vascular disease (PVD), deep vein thrombosis (DVT), pulmonary embolism (PE), and structural heart disease (SHD). Larger profile catheters were used for the treatment of PVD, DVT, PE, and SHD to accommodate the delivery of larger therapeutic devices (balloons, stents, valves) to the large diameter vessels. Many of the catheter systems I developed included hemostasis valves, of various designs, on the proximal end to facilitate the introduction of ancillary devices (guidewires, snares, ultrasound, etc.) and the coaxial introduction of a catheter within a catheter to cross challenging anatomy or to extend to distal treatment sites.

13. My Litigation History and my CV detailing my experiences above are attached to this Declaration as Appendix A and Appendix B.

II. LEGAL STANDARDS

14. Below is a summary of my understanding of certain legal principles relevant to

my analysis, as explained to me by counsel. I provide this solely as a context for the opinions I am providing in this case. In setting forth these legal standards, it is not my intention to testify about the law.

A. Overview

15. I understand that determining whether there is infringement of a patent involves two steps. First, each claim must be construed to determine its proper scope and meaning to one of ordinary skill in the art. Second, each element (or limitation) of the claims, as construed, is compared to the accused device or process to determine whether the element (or limitation) is found in the accused device or process.

16. I understand that Inari, as the party asserting infringement, has the burden of proving by a preponderance of the evidence that Truvic has infringed the asserted patent claims. I understand that a "preponderance of the evidence" is such evidence that causes a trier of fact to be persuaded that the fact sought to be proved is more likely than not to be true. I understand that proving a fact by a "preponderance of the evidence" is a lower burden than proving a fact by "clear and convincing evidence." I have applied the "preponderance of the evidence" standard throughout my Report.

17. To find infringement by an accused system or method, I understand that a patentee must show the presence of every element of a given claim (literal infringement) or its equivalent (infringement under the doctrine of equivalents) in the accused system or method.

18. I further understand that an accused system or method literally infringes a patent if all the elements of the claim, as properly construed by the Court, are present in the accused system or method. I also understand that if one or more claim elements are missing from the accused system or method then the claim is not literally infringed.

19. I also understand that a method claim is infringed if each step of the method is actually performed by the accused product. I further understand that a method claim cannot be infringed unless each step of the method is actually performed.

B. Claim Construction

20. I understand that claims are construed by the Court as a matter of law. I understand

that the language of patent claims is generally given its plain and ordinary meaning to a person of ordinary skill in the art ("POSITA" OR "POSA") to which the patent relates, as viewed in light of the surrounding claim language, the patent specification, and the rest of the intrinsic record, at the time of the invention. Except as explicitly noted below, I apply this meaning to all of the claim language in question. I understand that the claims of a patent define the scope of the rights conferred by the patent. The claims particularly point out and distinctly claim the subject matter which the patentee regards as their invention. I understand that preambles of claims are generally not limiting unless they recite essential structure or steps; are necessary to give life, meaning, and vitality to the claim; or contain phrases relied upon for antecedent basis.

C. Direct Infringement, Indirect Infringement and Doctrine of Equivalents

21. I understand that patent infringement can be direct or indirect. I understand that a person is liable for direct infringement when they make, sell, offer for sale, or import a product that meets the elements of the claims or practice each step of a patented method. I understand that indirect infringement occurs when the defendant is responsible for causing or encouraging another person or entity to directly infringe, or contributes to the infringement of another by, among other things, providing a product that has no substantial non-infringing use. I also understand that both direct and indirect infringement can occur both literally and by equivalents.

22. I understand that each construed claim should be compared to the accused device or process to determine whether every claim element is found in the accused device or process. I understand that a patent is literally infringed only when the accused product contains each and every claim limitation, or where a single party performs each and every step of a method claim. I am informed that if any claim limitation is absent from the accused device or method, there is no literal infringement as a matter of law.

23. I also understand that because dependent claims incorporate all the limitations of the independent claims from which they depend, dependent claims can only be literally infringed if every limitation from the independent claim is also present, in addition to the limitations of the dependent claims.

24. I understand that an accused product that does not infringe a claim literally may

still infringe that claim under the doctrine of equivalents if any differences between the accused product and the claimed elements are only insubstantial differences, or where the function, way, and result of the accused product would still be the same as the claimed element(s). I understand that analysis under the doctrine of equivalents must be performed on an element-by-element basis. I understand that equivalence must be viewed from the perspective of a person having ordinary skill in the art. I also understand that one test of whether any differences are insubstantial is whether an element of an accused product performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed element would if that element were literally present.

25. I understand that application of the doctrine of equivalents is subject to certain limitations. First, I understand that the doctrine of equivalents does not allow a claim element to be ignored entirely. Instead, each element of a claim must exist either literally or by an equivalent in the accused product or method. For instance, I understand that a claim element and its opposite cannot be equivalent to each other under the doctrine of equivalents. Likewise, I understand that the doctrine of equivalents cannot be used to make a claim cover prior art that was known at the time the application for the asserted patent was filed. I also understand that the doctrine of equivalents cannot be used to make a claim cover embodiments that were disclosed in the patent specification but were not claimed. I also understand that if a patent applicant adds an element to a patent claim in an amendment during prosecution of a patent for purposes of patentability, that element is not subject to the doctrine of equivalents, and that this rule is also known as prosecution history estoppel. An example of prosecution history estoppel occurs when the patent applicant amends a pending claim to overcome a prior art rejection. I understand that prosecution history estoppel does not work as an absolute rule, and that the patent holder can overcome this doctrine either by showing that the equivalent was not known or foreseeable at the time when the amendment was made or by showing that the rationale underlying the amendment bore no more than a tangential relationship to the equivalent in question, or that the patentee could not have been expected to describe the equivalent in question at the time when the amendment was made.

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D. Validity

26. I understand that a claim is invalid if the claimed invention was known or used by others in the United States, or patented or described in a printed publication in the United States or a foreign country, before the invention thereof by the applicant for a patent. I also understand that a claim is invalid if the invention was patented or described in a printed publication in the United States or a foreign country or in public use or on sale in the United States, more than one year prior to the date of the application for a patent in the United States.

27. I understand that each claim of an issued patent is presumed to be valid. I understand that the defendant ultimately bears the burden of providing invalidity by clear and convincing evidence at trial. I have been told that this means that the Court must be left with a clear conviction that the claims are invalid. I further understand that clear and convincing evidence falls between a preponderance of the evidence standard, in which proof need only be sufficient to tip the scale in favor of the party proving the fact and a beyond reasonable doubt standard, where the fact must be proven to a very high degree of certainty. For the purposes of supporting Inari's motion for a preliminary injunction only, however, I have been asked to affirmatively address validity in view of the prior art identified to-date, as discussed below. I do so despite the fact that, as I understand it, Truvic will have the burden of proving invalidity at trial.

28. I understand that in order for a patent claim to be valid, the claimed invention must be novel. I understand that if each and every element of a claim is disclosed in a single prior art product or reference, then the claimed invention is anticipated and the invention is not patentable. In order for the invention to be anticipated, all of the elements and limitations of a claim must be shown in a single prior art product or reference, arranged as in the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art product or reference. In order for a reference to inherently disclose a limitation, that claim limitation must necessarily be present in the product or reference.

29. I understand that obviousness under Section 103 is another basis for invalidity. I

understand that where a prior art product or reference does not disclose all of the limitations of a given patent claim, that patent claim is invalid if the differences between the claimed subject matter and the prior art product or reference are such that the claimed subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. Obviousness can be based on a single prior art product or reference or a combination of products and/or references that either expressly or inherently disclose all limitations of the claimed invention.

30. I understand that, in assessing the obviousness of the claimed subject matter, one should evaluate obviousness in light of the prior art from the perspective of a person having ordinary skill in the art at the time the alleged invention was made (and not from the perspective of either a layman or a genius in the art). It is my further understanding that the question of obviousness is to be determined based on:

- The scope and content of the prior art;
- The difference or differences between the subject matter of the claim and the prior art (whereby in assessing the possibility of obviousness one should consider the manner in which a patentee and/or a Court has construed the scope of a claim);
- The level of ordinary skill in the art at the time of the alleged invention of the subject matter of the claim;
- Any relevant objective factors (the "secondary considerations") indicating non-obviousness, including evidence of any of the following: (i) commercial success of the products or methods covered by the patent claims; (ii) a long-felt need for the alleged invention; (iii) failed attempts by others to make the alleged invention; (iv) copying of the alleged invention by others in the field; (v) unexpected results achieved by the alleged invention; (vi) praise of the alleged invention by the alleged infringer or others in the field; (vii) the taking of licenses under the patent by others and the nature of those licenses; (viii) expression of surprise by experts and those skilled in the art at the subject matter of the claim; and (ix) whether the patentee proceeded contrary to accepted wisdom of the prior art; and

- Any relative objective factors ("the secondary considerations") indicating obviousness, such as independent invention of the claimed invention by others before or at about the same time as the named inventor thought of it; and other evidence tending to show obviousness.

III. TECHNOLOGY BACKGROUND

31. The '910 and '921 Patents generally relate to methods and systems for performing thrombectomy (removing clots). The mechanical thrombectomy approach developed by Inari is to use aspiration (using vacuum pressure to suction clot material out of the body) and other mechanical interventional devices (e.g., using structures to engage, disrupt, and/or withdraw clot material) to remove clots in the large-diameter deep leg veins and pulmonary arteries. Before turning to a description of the innovations of the '910 and '921 Patents and my opinions on infringement and validity, I begin by providing a brief description of the problem of DVT and PE, historical treatment options for DVT and PE, and historical treatment options (including medical devices) for treatment of clots found in small arteries. I do so to clarify and explain the state of the art that forms part of the backdrop against which Inari has innovated.

32. Thrombi and emboli are blood clots that cause blockages (also called occlusions) of blood vessels or arteries. Blocking blood flow results in oxygen deprivation of tissues that results in tissue death. Clot blockages can cause many very serious health conditions if the clot is located in a critical blood vessel, including stroke (blocking blood flow to or from the brain), pulmonary embolism (blocking the flow of deoxygenated blood to the lungs), heart attacks (blocking blood flow to the heart), and other serious conditions. Venous thromboembolism and the related health conditions are a huge problem, affecting approximately 900,000 people in the United States every year. (*See* https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html.) Venous thromboembolism is, in fact, a leading cause of preventable hospital deaths in the United States and worldwide, causing 60,000-100,000 deaths per year in the United States alone. (*See* https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html.)

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33. A blood clot is essentially a living polymer, comprising a matrix of intertwined and cross-linked strands within which are situated red and white blood cells, platelets and numerous other proteins and components. The mechanical properties of a clot are influenced by the relative percentages of other materials and red blood cells, and clots that are highly fibrous (and highly organized) and have lower red blood cell content tend to be firmer and more cohesive than clots of a higher red cell content. Such clots have also been found to have a higher coefficient of friction, or in other words to be "stickier." These firm and sticky clots can be challenging to remove from a vessel. Clots that are less organized and with a high red cell content have been found to be less cohesive, more friable (i.e., more easily crumbled) and to have a lower coefficient of friction than the more organized and stickier clots previously described. Fresher (younger) clots are typically characterized as more friable, softer and less organized, whereas older (mature) clots are characterized as more organized, firmer, and stickier. These properties mean that fresher and softer clots may be easier to dislodge from the site of occlusion.

34. 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 hospital preventable death and disease worldwide. Pulmonary embolism ("PE") and deep vein thrombosis ("DVT") are common types of VTE.

35. Deep vein thrombosis ("DVT") is a type of blood clot (thrombus) that typically forms in the deep veins of a limb, such as the leg. Thromboembolism occurs when part or all of a thrombus breaks away from the blood vessel wall. This blood clot (now called an embolus) is then carried in the direction of blood flow. When the embolus travels from the vein towards the heart and then lungs, a pulmonary embolism ("PE") may result if such embolus lodges in an artery or branch thereof of the lungs. Because of their location and how they are formed DVT and PE clots tend to be larger, older, more highly organized, and more fibrous than arterial clots.

36. The diameter of the human body's various blood vessels varies from person to person, and every human has many different blood vessel sizes, from the largest veins and

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arteries to miniscule capillaries and venules. For example, the coronary arteries (the arteries that supply blood to the heart itself) are between about 1.5mm-5mm in diameter in most people, and the neurovascular arteries (which provide blood flow through the neck to the cerebral system) average between about 3-6mm in diameter. Some of the veins and arteries in the chest can be far larger, with the main trunk of the pulmonary artery (which supplies all the oxygen-poor blood from the heart to the pulmonary system, so that it can be oxygenated by the lungs to then distribute oxygen to the rest of the body) averaging about 27mm in diameter. In general, veins associated with DVT have much larger inner lumens (the opening in the inner part of the vein) than arteries of the heart or head, with the femoral vein deep in a person's legs typically 6mm-11mm in diameter.

A. Treatments for DVT and PE

37. PE and DVT are treated in a similar fashion to one another because the veins and pulmonary arteries are comparable in size, both being far larger than the majority of arteries supplying critical organs of the body (such as the brain and heart).

38. Inari's products, including FlowTriever and ClotTriever, are designed specifically for treating DVT and PE in patients. Treatment of PE and DVT has long been a challenge, with the existing methods of treatment failing to significantly improve patient mortality rates over the last five decades. Inari's devices, which employ percutaneously-introduced (i.e., inserted through a smaller opening from a needle puncture through the skin into a vessel) catheters to apply vacuum pressure and/or self-expanding nitinol structures to capture and remove clots, have improved patient outcomes and are a significant improvement over the traditional treatment methods.

39. Traditionally, PE and DVT have been treated with drugs, e.g., anticoagulants (also called blood thinners), streptokinase (also called SK manufactured by pharmaceutical makers including GSK and BBT Biotech GmbH), urokinase (also called Abbokinase or Kinlytic, manufactured by companies including Abbott Laboratories), or other drugs in a class of agents called "thrombolytics" (or just "lytics") that break down and dissolve the clot over hours or days, but do not physically remove the clot material from the body. Doctors can treat patients

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with lytics by introducing the drugs through an IV line or, more preferably for many cases, applying the lytics at the site of the clot using a perfusion catheter placed at the clot. To this day, the use of either anticoagulants or lytics (particularly for certain types of more acute cases) are the most common and recommended treatments for PE and DVT in guidelines by medical organizations such as the American College of Chest Physicians, European Society of Cardiology, American Heart Association, and the Society of Interventional Radiology.

40. Lytics have many disadvantages. First, they can take many hours to work. Second, because the clots are not actually removed from the body, portions of the clot can break off and travel to a different location within the body rather than being eliminated entirely. Additionally, using lytics can cause hemorrhages and serious risks of death, necessitating ICU stays for treatments and monitoring. Lytic treatments also are very expensive, as they require longer hospital stays, and they cannot be used for many patients because of conditions related to increased risk of bleeding (*e.g.*, active bleeding, recent brain bleed/hemorrhage, recent brain or spine surgery, severe hypertension, severe kidney disease, etc.).

41. Anticoagulant drugs also have many disadvantages. The side effects include bleeding risk and loss of bone density. Anticoagulants also are not effective against existing clots, merely preventing clots from forming or continuing to form (to some degree).

42. Increasingly over the past decade (and particularly the past few years with the introduction of Inari's devices and competitors), thrombectomy procedures have been used to treat PE and DVT. The term "thrombectomy" refers to physical removal of clotted blood (a thrombus or emboli) from the vasculature either surgically or percutaneously. While thrombectomy treatments have been growing in popularity, the majority of DVT and PE cases are still treated with lytics and anticoagulants.

43. The advantage of performing a procedure with a percutaneously inserted device over surgery is that it removes the thrombus from the vessel in a less invasive procedure to the patient than surgery while providing a more effective treatment option and lower cost than either surgery or lytics. Such a thrombectomy device offers the speed of (or even more speed than) surgical removal with the advantage of minimally invasive treatment.

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44. Catheter-based thrombectomy systems are used for the percutaneous removal of blood clots from vessels inside the body. Companies have developed many catheter-based thrombectomy systems for applications other than treating clots in the largest veins and arteries, in other words for applications besides PE and DVT. For example, companies have long produced catheter thrombectomy systems for treating clots in smaller arteries, including systems used to treat ST-elevated myocardial infarction (STEMI), a heart attack from one or more blocked coronary arteries, or blockages in the neurovascular system, such as ischemic stroke, a stroke caused by a clot blocking a carotid or other major artery supplying blood to the brain.

45. There are multiple types of catheter thrombectomy devices for treating blockages in smaller arteries, including aspiration catheters to vacuum the clot out of the vessel, lytic delivery catheters to infuse the clot with targeted thrombolytic drug treatment, and mechanical interventional devices that break up or engage the clot.

B. Mechanical Thrombectomy Devices, Including Aspiration-Based Devices, for Treatment of Clots

46. Mechanical thrombectomy devices offer many benefits in short-term therapy for patients, such as fast thrombus removal, no or low doses of thrombolytic agents, and short treatment times that translate into immediate and improved symptom relief, decreased complications, and highly effective patient care. As mentioned above, aspiration and other mechanical thrombectomy devices have long been used to remove blood clots from smaller vasculatures such as the cerebrovasculature and the coronary vasculature, but not for DVT and PE.

47. In the past decade, Inari and now followers like Truvic and Penumbra have developed mechanical (*e.g.*, aspiration-based) thrombectomy devices to remove blood clots from larger vasculatures such as the peripheral vasculature (DVT) and pulmonary vasculature (PE), which present different challenges to remove clot than smaller vasculatures and different requirements for the thrombectomy devices. Developing effective thrombectomy devices for treating DVT and PE was not easy or straightforward, however, as further discussed below.

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48. When a doctor performs a thrombectomy using a catheter, the treatment involves inserting a catheter into the patient's vasculature and advancing the catheter to the occlusive clot. If the doctor is using an aspiration-based mechanical thrombectomy system, then the clot is removed by generating vacuum pressure using a pressure source, such as syringe or vacuum pump, attached to the catheter, in an attempt to suck the clot into the catheter tip and out of the patient's vasculature. These treatments can be complicated and may require significant vacuum applied to the clot (dependent on clot location and other factors), which the treating physician may control (at least with devices currently on the market) by varying how the plunger of a syringe is withdrawn or by varying a pump setting. It typically requires a pressure drop of 500mmHg (19.7 inHg) to 760mmHg (29.9 inHg) (or "full" vacuum) to aspirate clot material, although the specifics again depend on a number of factors relating to the patient's size, medical condition, clot location, and clot "stickiness." But this amount of pressure drop generally creates a difference in pressure between the blood vessel in which the clot is situated and the interior of the catheter, i.e., a pressure gradient (which may exceed 760mmHg (29.9 inHg) because the patient's blood pressure is higher than atmospheric pressure) that suctions the clot into the catheter mouth.

49. The energy to deform the clot to fit into the catheter is effectively an extrusion energy as the catheter tip acts as a form of extrusion die for the clot. This extrusion energy is related to the fibrousness of the clot, with more highly organized clots requiring increased extrusion energy to aspirate the clot into the catheter. A conventional technique to aspirate clot material, particularly for softer and less-organized clots, involves applying a steady state (continuous) vacuum to the tip of the catheter; however, in many cases this does not provide sufficient energy to aspirate the clot fully into the catheter. This could cause embolization of thrombus debris that break off and travel downstream in the circulation. This risk can be significant, particularly with large and organized thrombi, a common occurrence in DVT and PE.

50. Aspirating clots in larger-diameter vessels is different and far more difficult than in smaller arteries, such as coronary or cerebral arteries, including for the following reasons:

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- As discussed above, treating newer clots with that are less fibrous (such as acute coronary or cerebral clots) is less difficult than treating more "mature" clots often found in DVT and PE cases, because clots generally become more organized and increase their fibrousness, organization, and stickiness as they age. Older clots are therefore much more difficult, requiring much more force over a larger area, to aspirate. Treating clots formed into DVT and PE necessitates a significantly larger suction area and more suction force to remove because the clots are not easy to deform and suck up in smaller globs.
- Clots formed into DVT and PE are also much larger than those found in coronary or cerebral vessels and in the case of PE the clot material can have a complex geometry that extends into branch vessels. So, in addition to generally being more difficult to remove because of the fibrousness of the clot material forming DVT and PE, another challenge of using aspiration to remove DVT and PE is complex size and geometry that make it more likely the clot material is anchored to the vasculature.
- Additionally, due to blood loss considerations and the geometry of the vessels compared to the size and shape of the clot material in PE and DVT applications, the clots in PE and DVT cases are generally much larger than the bore size of the catheter. As a result, only a portion of the clot material in PE and DVT applications is subject to the direct force of the aspiration flow making it more difficult to extrude other portions of the clot material into the catheter. Whereas in coronary and cerebral applications where the clot material occupies all or nearly all of the tubular vessel, the bore of the catheter more closely matches the diameter of the clot material such that the aspiration force is applied to more surface area of the clot material making it easier to extrude the entire clot into the catheter.

51. To aspirate a clot into a catheter, the clot often needs be deformed to fit into the catheter lumen because the diameter of a clot can be greater than the inner diameter of the catheter. Therefore, for such a clot to be aspirated into a catheter, the clot also must deform and elongate to fit into the catheter tip. The inner diameter of the catheter can vary but is inherently limited by the size of human physiology, the inner diameter of the vessels that the catheters are designed to treat, and the maximum diameter of the puncture site that can safely be sealed after

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the catheter is removed from the patient. This poses a design challenge in that the energy required to deform clots forming DVT and PE is not easily attained by aspiration alone.

52. Another issue with using vacuum to remove thrombus from the body is the clogging of catheters or tubing. Such clogging prevents the flow of fluids from the patient, through the catheter, to remove the matter.

53. PE clots, especially, also are not simple in their geometry, and often are shaped like the branching system of tree roots. The size and shape of DVT and PE clots increases the demand for suction over a larger area and for a catheter that doesn't clog as easily when treating large clots forming a PE or DVT, and often requires multiple aspiration attempts to pull out the clots. This is particularly true because the PE and DVT clots are often much larger in relation to an aspiration catheter (even large-bore catheters), making it more difficult to remove with aspiration because the vacuum force acts on a smaller part of the clot's total size.

54. Treating DVT and PE also requires the catheters to travel long tortuous distances through the twists and turns of the patient's body. For example, to get a catheter to the pulmonary artery, a physician will often place the insertion point at a location away from the lungs where vessels can be accessed more easily, requiring the catheter to travel a winding road, including through the heart, to reach the lungs. This increases the need for catheter reach, including reaching vessel locations having different diameters.

55. As discussed below, Inari developed a series of improvements, combined into a cohesive system that solved many of the design challenges to effective devices for aspiration-based thrombectomy of PE and DVT.

C. Hemostasis Valves

56. Percutaneous endovascular procedures (such as interventional thrombectomy procedures) require a doctor to puncture an insertion point through which medical devices (such as catheters) access the inside of the vasculature and perform desired treatment (such as removing blood clots). A catheter is essentially a flexible tube with a lumen (like a tunnel) extending through its center. In order to maintain the sterile environment within the patient, despite this lumen, doctors must prevent backflow of blood from the vasculature and prevent

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delivery of air (creating bubbles) into the vasculature through the catheter. Doctors also need to seal the catheter lumen to reduce blood loss. In other words, fluid flow through the catheter needs to be carefully controlled.

57. For decades, doctors have used different configurations of hemostasis valves to minimize blood loss and provide a sterile environment during several types of procedures that involve insertion of a catheter or other tool into the body. As an example, hemostasis valves are generally opened to allow a guidewire, catheter, or a tool to be inserted into a first catheter and into the body and then closed tightly around the inserted object to prevent blood loss and maintain a sterile environment in the patient while performing a procedure.

58. Preexisting percutaneous thrombectomy systems going back decades had hemostasis valves, usually a "Tuohy-Borst" hemostasis valve. In Tuohy-Borst valves, the valve is opened and closed by rotating a nub at the proximal end of the valve to compress or relax an o-ring style seal. Tuohy-Borst valves are obviously better than no hemostasis valve at all, but they are not adapted and optimized for treating DVT and PE (or other procedures employing large diameter catheters) because they may not seal adequately around all interventional applications or tools. They also require an amount of time to fully actuate between an open and closed position that can be material within the context of a PE or DVT thrombectomy procedure, and they can often be difficult to operate during procedures, frequently requiring the use of both of the doctors' hands such that a doctor needs to pause during insertion/withdrawal of a tool.

59. Traditional hemostasis valves are not ideal for closing from a large open diameter down to fully closed to provide tight seals, which is a problem in DVT and PE treatments where there is a potential for large blood loss, given the size of and flow rate for the blood in the deep leg veins and pulmonary arteries. These hemostasis valves are also not optimized for treating DVT or PE because they are not easy to open nor quickly return to a closed (sealed) configuration, often requiring both hands to actuate.

IV. <u>Inari's Aspiration-Based Mechanical Thrombectomy Systems</u>

60. Inari is the world's leading developer of catheter-based mechanical thrombectomy devices that treat PE and DVT. Inari has been at the forefront of changing the standard treatment

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approach for PE and DVT from lytics-based therapies and surgical thrombectomy to aspiration-based thrombectomy and/or thrombectomy combining aspiration with other mechanical interventions.

61. Unlike some of its competitors, Inari chose not to repurpose existing thrombectomy systems designed to treat clots in smaller arteries, including neurovascular or coronary aspiration-based thrombectomy systems, to treat PE or DVT. By contrast, one of Inari's competitors, Penumbra, adapted its existing thrombectomy designs for the removal of emboli/thrombi from smaller neurovascular, peripheral arteries, and coronary arteries to create a thrombectomy device for VTE. The resultant DVT/PE systems, the Penumbra Indigo Lightning System and Penumbra Indigo Lightning Flash System, use continuous vacuum with 7F, 8F, 12F, and more recently 16F aspiration catheters, and have shortcomings versus Inari's purpose-built systems that are specifically designed for larger vasculature with large-bore catheters and stored vacuum.

62. Redesigning a thrombectomy system designed to treat smaller arteries would have significant shortcomings, as shown by the Penumbra example. As described above, because of the size and location of the deep leg veins and the pulmonary arteries, clots found there are older and tend to be more fibrous and larger in size, requiring aspiration over a larger area with greater force. For example, if one used a smaller 7F, 8F, or 12F catheter, it is less likely that the full amount of clot material is removed unless the catheter is swept around the clot material. Second, in a system using continuous aspiration, there is a larger risk of too much blood loss while the smaller catheter is swept around the clot material.

63. Simply sizing up (increasing the diameter of) existing aspiration catheters by itself also was not an effective option for Inari. As catheters get larger in diameter, they become more rigid and have a larger minimum radii of curvature, but aspiration catheters for PE and DVT must be flexible enough to navigate long paths from an entry point (for example in an arm or leg) through many twists and turns to reach the clot, while still maintaining sufficient structure for the treating physician to advance the catheter along a winding path to where a clot is located. Catheter diameters also cannot be too large in diameter either, because catheters cannot be

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advanced through vessels that are significantly smaller in diameter than the catheter or navigate structurally sensitive elements of the heart in order to get to a larger diameter vessel, like a pulmonary artery (for example through the tricuspid valve of the heart).

64. For context, even 16F or 24F catheters, such as Inari's, occupy a smaller ratio of the cross-section area of the pulmonary arteries (or deep leg veins) than the ratio of the cross-sectional area of the coronary or cerebral arteries occupied by traditional 6F to 8F catheters used to remove clot from the smaller coronary and cerebral arteries.[1] For example, a 24F catheter inserted into the largest branch of the pulmonary artery (about 81F (27 mm in diameter)) the catheter occupies less than one tenth of the cross-sectional area of the main pulmonary artery (1:10 ratio). Whereas a 6F (2mm in diameter) or 8F (2.66mm in diameter) catheter inserted into a cerebral or coronary artery with a diameter of approximately 3mm-6mm occupies a much larger percentage of the vessel's cross-sectional area. In other words, a 6F or 8F catheter ranges from approximately the same size (1:1 ratio) to a quarter of the area of such an artery (1:4 ratio). This means that catheters for PE and DVT must be designed to account for the fact that the catheter cannot simply slide along the walls of the blood vessel proximate to the clot, which requires more control and trackability for the large, e.g., 16F to 24F catheters.

65. Using large cross-sectional 16F, 20F, and 24F aspiration catheters also dramatically increases the risk of blood loss, requiring stringent measures to minimize and mitigate blood loss. For example, an 8F catheter has only one ninth of the cross-sectional area as a 24F catheter, meaning that a 24F catheter allows up to 81 times as much blood to flow out of the body, according to the Hagen-Poiseuille equation (where volumetric flow rate "Q" is proportional to the radius of a pipe to the fourth power for long cylindrical pipes having constant cross-sectional area):

$$Q = \frac{\Delta P \pi r^4}{8 \mu L}$$

66. The blood flowing in the deep leg veins and pulmonary arteries, which can bleed out during a thrombectomy procedure, is critical to systems throughout the body. Any blood

[1] The "French" ("F") scale is commonly used to label the size (profile/diameter) of catheters. 1 French (1F) equals approximately 1/3 mm in diameter.

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that is lost from large veins and pulmonary arteries is typically blood that was bound for—and needed by—critical systems of the body. Inari, focused on purpose-built devices to treat PE and DVT, thus needed to come up with ways to significantly reduce blood loss in addition to the other challenges and concerns that it was balancing to ensure effective thrombi/emboli removal.

67. Over the past decade, Inari invented and continuously improved two lines of aspiration and interventional mechanical thrombectomy systems—FlowTriever and ClotTriever. Inari's thrombectomy systems have gained more widespread use in the medical field for their effective removal of blood clots. Inari has already received over 50 United States patents for these innovative solutions.

68. Inari received FDA clearance for its first product, the FlowTriever thrombectomy system, in February 2015 (then called "Retraction Aspirator"; rebranded as "FlowTriever" in November 2016) for non-surgical removal of clot material in the peripheral vasculature. This first version of FlowTriever includes an Aspiration Guide Catheter, a FlowTriever Catheter with an interventional device and a Retraction Aspirator, but did not yet have many of the advances discussed in more detail below that are the disclosed in the '910 and '921 Patents. In this version, the FlowTriever Catheter was inserted through the Aspiration Guide Catheter and advanced to the thrombus. An interventional device having self-expanding wireform disks was then deployed to engage the thrombus by retracting the outer delivery catheter. The hand-lever operated Retraction Aspirator then simultaneously applied pulses of aspiration and incrementally retracted wireform disks of the interventional device of the FlowTriever Catheter such that at least a portion of the thrombus was drawn into the Aspiration Guide Catheter and blood flow restored. This FlowTriever system was then redesigned with a mechanical intervention device within an aspiration guide and retraction catheter that allowed the removal of the FlowTriever Catheter from the patient without the simultaneous removal of the Aspiration Guide Catheter.[2] A capture from a FlowTriever video depicting the interventional device of a

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

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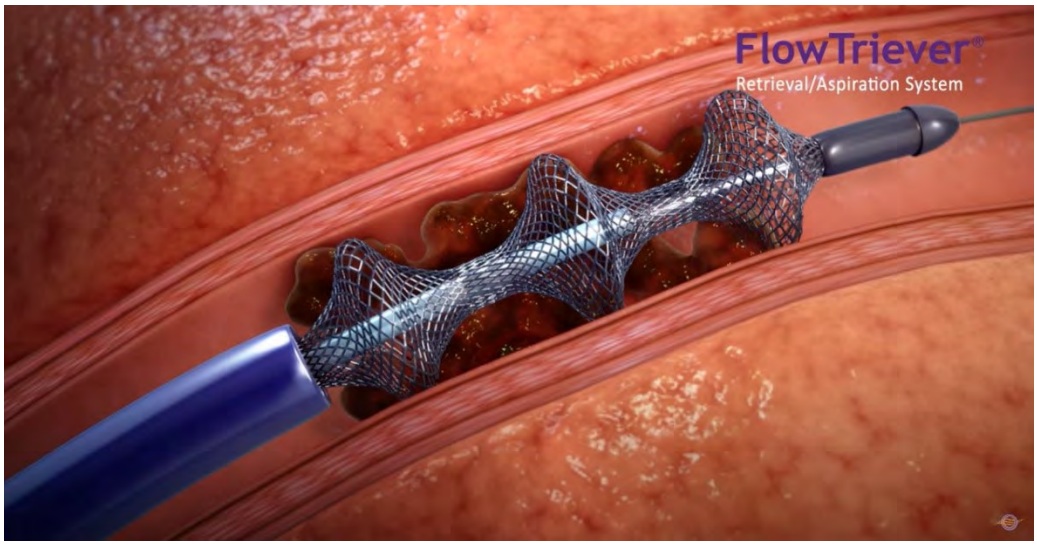
FlowTriever catheter is below, showing the Aspiration Guide Catheter in purple, the FlowTriever Catheter in pale blue, and the self-expanding wireform disks of the interventional device in grey:



69. Inari conducted the FlowTriever Pulmonary Embolectomy Clinical Study (the "FLARE" study) from April 2016 to November 2017 to evaluate the safety and effectiveness of percutaneous mechanical thrombectomy using the FlowTriever system in a prospective trial of patients with acute intermediate-risk PE. The results proved that percutaneous mechanical thrombectomy with FlowTriever was safe and effective in patients with acute intermediate-risk PE, with significant improvement in right ventricular to left ventricular diameter ratio and minimal major bleeding. FlowTriever provided many advantages over lytics treatment, including immediate thrombus removal, absence of thrombolytic complications, and reduced need for post-procedural critical care.[3] In May 2018, the strength of the results from the FLARE study led to an expanded FDA clearance to market FlowTriever for the treatment of PE.[4] This made FlowTriever the first FDA-approved aspiration-based mechanical thrombectomy system for treating PE.[5]

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

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

[5] *See* https://www.inarimedical.com/flowtriever-inari-fda-510k-clearance-treatment-pulmonary-embolism/.

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70. Inari developed purpose-built large diameter catheters for its aspiration system, including 24F, 20F, and 16F. Inari chose to create a system that has large diameter sizes partly because it minimizes clogging at the tip of the catheter and maximizes the vacuum energy applied to the thrombus for removal. As discussed above, this design choice imposed constraints on Inari's products that required other innovations, relating to aspects of the products such as the pressures used, blood loss mitigation features, and blood return systems, that would make the products safer and more effective.

71. These large-diameter catheters are introduced and guided over a guidewire through a vascular access sheath into the vasculature to the site of the thrombus. FlowTriever also optionally allowed a doctor to use mechanical intervention as well, by introducing self-expanding mesh disks to mechanically engage and disrupt clot materials.

72. To provide added reach and a second aspiration pass, by December 2018, Inari developed and received FDA clearance for a telescoping version of FlowTriever (an aspiration catheter within a larger aspiration catheter).[6] A FlowTriever system with telescoping kit includes, for example, the Triever16 Catheter (a 16F aspiration catheter), the Triever20 Catheter (a 20F aspiration catheter), the FlowTriever Catheter (interventional nitinol disks that engage and disrupt the clot), and two Large Bore 60cc Syringes to create aspiration force, one for Triever16 and one for Triever20. The Triever16 Catheter can be advanced through and past the distal end of the Triever20 Catheter in the blood vessel for extended reach to the thrombus. Each Triever Catheter is connected to a Large Bore 60cc Syringe for aspiration purposes.

73. 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 more effective for treating PE than using a single aspiration catheter.

74. Inari continued to improve the FlowTriever system, including developing more

[6] *See* FDA 510(k) Premarket Notification K183198 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183198.pdf).

catheter sizes for telescoping combinations. By September 2019, Inari developed and received FDA approval for Triever24, a 24F aspiration catheter.[7] This catheter can be used in a telescoping combination with Triever16.

75. Inari also received FDA approval for another line of thrombectomy system, ClotTriever, in February 2017. ClotTriever was designed for clot removal, including for acute and chronic clots (including DVT), using mesh forms to engage, trap, and then withdraw clots.[8]

76. The first version of ClotTriever consisted of the ClotTriever Sheath and the ClotTriever Catheter. The ClotTriever Sheath consisted of a polymeric sheath equipped with a self-expanding distal mesh funnel, a flush/aspiration port with tubing clamp, and a proximal hemostatic valve. The ClotTriever Catheter consisted of three preassembled polymeric coaxial catheters terminating in an expandable coring element and tissue collection net. The expandable coring element and tissue collection net at the distal end of the catheter was operated by a handle used to expand the expandable member and net. The expanded structures of the ClotTriever were drawn through the thrombus to capture clot and restore blood flow by "non-surgical removal of soft thrombi and emboli from blood vessels."[9]

77. As with FlowTriever, Inari continued and continues to improve ClotTriever over the years. For instance, by December 2017, Inari had developed and received FDA approval for replacing the tissue collection net with a collapsible clot collection bag.[10] A figure depicting this improved version of ClotTriever is shown below:

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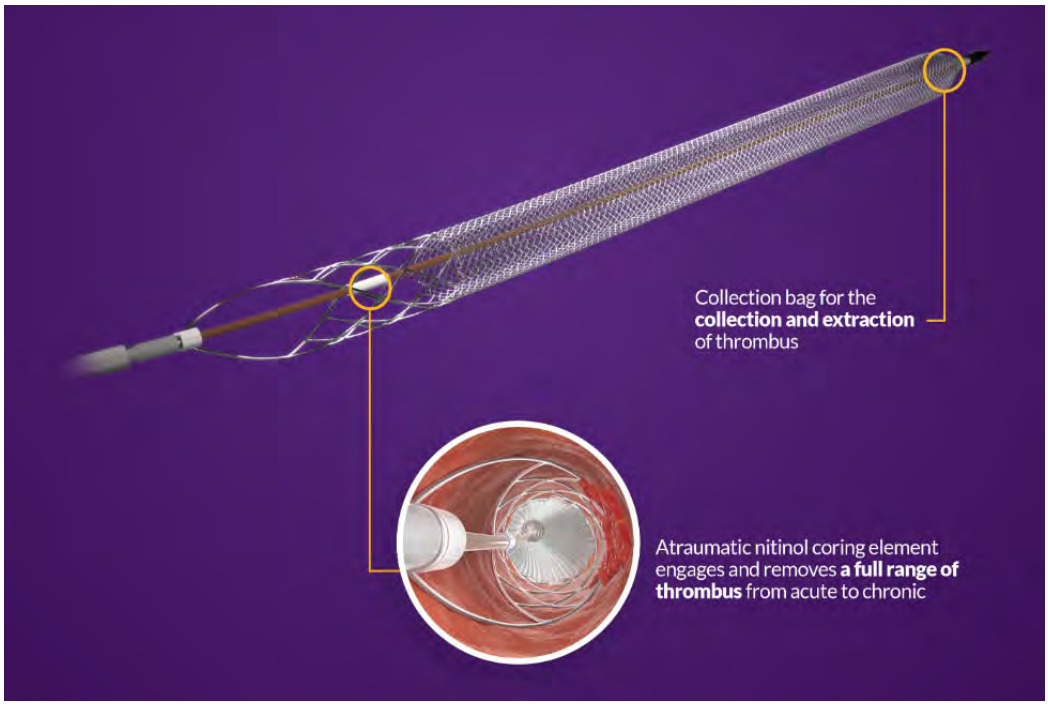
[7] *See* FDA 510(k) Premarket Notification K191710 (available at https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191710.pdf).

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

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

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



78. In September 2018, Inari started the ClotTriever Outcomes Registry Clinical Study (the "CLOUT" Registry) to assess the safety and effectiveness of the ClotTriever system for the treatment of acute and nonacute lower extremity DVT in all-comer patients. It is the largest prospective mechanical thrombectomy study in the field of DVT. Inari announced the interim results of the study on March 12, 2024, showing that thrombectomy procedures with ClotTriever resulted in rates of post thrombotic syndrome at two years that are significantly lower than rates reported in historical DVT trials.[11] On September 9, 2020, Inari received FDA clearance to market ClotTriever specifically for the treatment of DVT.[12]

V. Truvic's Thrombectomy Systems

79. Truvic, a medical device company focusing on the development of thrombectomy systems, was founded in 2020, which was years after Inari's invention and early popularization efforts for the FlowTriever and ClotTriever thrombectomy systems. Truvic has two lines of thrombectomy products—the Prodigy Thrombectomy system and the Symphony Thrombectomy system. Symphony directly competes with Inari's FlowTriever and ClotTriever

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

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

systems, while Prodigy targets clots in much smaller arteries. In July 2021, Imperative Care, a medical technology company founded in 2016, acquired Truvic.

80. Like FlowTriever and ClotTriever, the Symphony system is designed to remove thrombus/embolus from veins and large arteries using controlled aspiration and mechanical interaction. The Symphony system comprises the 24F Symphony Catheter, 16F Symphony Catheter, 24F Symphony Dilator, 16F Symphony Dilator, 24F Symphony Advance Long Dilator, BigShot Controller handles with an on/off valve controlled by a lever, Truvic Generator, Truvic Canister, Truvic Tubeset, 16F Symphony ProHelix, and 24F Symphony ProHelix, although not all parts of the system need to be or are used for every patient procedure. In operation, doctors connect the Symphony catheters to a Truvic generator via a BigShot Controller handle, Truvic tubeset, and Truvic Canister to aspirate thrombus by directing the aspiration force generated directly to the thrombus. Doctors introduce the Symphony catheters and dilators through a vascular access sheath into the vasculature and guide them over a guidewire to the site of the thrombus. The 16F Symphony catheter is capable of telescoping from (extending past the distal end of) the 24F Symphony catheter for extended reach to the thrombus. As needed, the Symphony ProHelix may be introduced through the Symphony catheter to facilitate aspiration and removal of the thrombus through the catheter by mechanically engaging and disrupting the clot material. The Symphony ProHelix is passed through a button-operated garrote-type hemostasis valve and then 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 catheter(s).

81. In February 2023, Truvic received FDA approval to market its Symphony system for DVT treatment.[13] Truvic began marketing and selling its Symphony system to physicians and hospitals by no later than late 2023.

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

82. It is common in the medical industry for doctors to use FDA-cleared devices in an "off-label" manner, i.e., to treat problems beyond those for which the devices are indicated. For instance, while Truvic can only market its Symphony system for DVT treatment, as stated in Symphony's Indications for Use, doctors might also use Symphony to treat PE even without the FDA clearance for PE.

83. In addition, in an October 2023 submission to ClinicalTrials.gov, Truvic stated that it will conduct a clinical study to evaluate the safety and efficacy of Symphony in the treatment of PE from December 2023 to April 2025.[14] Upon completion of this study, the FDA will presumably clear Truvic to market Symphony for the treatment of PE.

84. Given the date that it was founded, Truvic must have designed its Symphony system after Inari had invented, introduced to the market, improved, and popularized the FlowTriever system. The Symphony system's design, functions, features, and mechanisms significantly overlap with and even mirror those of the FlowTriever. Similarities include the telescoping large-bore aspiration catheters (such as extending the 16F catheter through the 24F catheter for access to PE and DVT clots), an intervening vacuum control valve mechanism enabling generating and storing a vacuum that can be applied to the aspiration catheter, the design of a hemostasis valve, and the design and stored vacuum function of the removable clot-filtering canister, and optionally implementing a mechanical engagement device (e.g., the Truvic ProHelix). Symphony also significantly overlaps and mirrors the hemostasis valve design of ClotTriever, which I understand uses the same basic design as the one used in FlowTriever.

VI. LEVEL OF ORDINARY SKILL IN THE ART

85. My opinion on the level of ordinary skill in the art is based upon my personal knowledge and experience as well as my consideration of such things as the education and experience level of persons of skill working in the field.

86. In my opinion, the field of invention is mechanical thrombectomy, including

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

aspiration-based mechanical thrombectomy, in peripheral and pulmonary vasculatures. One of skill in the art as of that date would have been (1) a person with a Bachelor of Science degree in engineering or an equivalent field, with two to four years of academic or industry experience in the mechanical thrombectomy industry or comparable industry experience who would, where necessary or desired, work or consult with others including a physician to develop thrombectomy devices (including for smaller arteries); or (2) an interventional radiologist or pulmonologist with at least three years of experience developing and/or using medical devices in thrombectomy procedures (including for smaller arteries), and who would, where necessary, work or consult with others including an engineer to develop such a medical device. A person with less education but more relevant practical experience, or more relevant education but less practical experience, may also meet this standard.

87. According to the standards set forth above, I was at least a person of ordinary skill in the art as of the priority date of the ’910 and ’921 Patents.

VII. CLAIM CONSTRUCTION

88. I understand that preambles of claims are generally not limiting unless they recite essential structure or steps; are necessary to give life, meaning, and vitality to the claim; or contain phrases relied upon for antecedent basis.

89. I understand that the ’910 and ’921 Patents have not been construed by the court in this case or by any other court in any other case. Save for the term “filament,” I do not propose any specific claim constructions, but interpret the patents according to their plain and ordinary meaning to a person of skill in the art in view of the claim language, the specification, and the file history. For “filament,” I expressly address the term because Truvic has proposed construing (and applying) this term in an overbroad manner that is contrary to its plain and ordinary meaning in an *inter partes* review challenging another patent in the same family as the ’921 Patent. Because of this, I believe that it will be helpful to explain what the actual plain and ordinary meaning of this term is.

90. In the context of the ’921 Patent, a person of ordinary skill in the art would understand the term “filament” to mean “a thin, flexible length of material formed by one or

more strands of material." The '921 Patent specification supports this construction, making clear that the filament(s) can be monofilament (a single strand) or multiple strands that can be, "twisted, woven, grouped, and/or fused to form the filament." '921 Patent at 4:3-6, 9:3-17. There further can be multiple filaments. *See id.* at Fig. 7. The filament(s) can further be made of variety of thin flexible materials. *Id.* at 9:15-17 ("the filament 150 can comprise one or several threads, lines, cords, rope, ribbon, flat wire, sheet, or tape.").

91. This meaning further is in keeping with conventional usage of filament in a mechanical sense: as thin, flexible pieces of material. *See, e.g.*, https://web.archive.org/web/20170818203220/https://www.merriam-webster.com/dictionary/filament ("a single thread or a thin flexible threadlike object, process, or appendage); https://web.archive.org/web/20170717183619/https:/www.dictionary.com/browse/filament ("a very fine thread or threadlike structure; a fiber or fibril:").

92. Truvic's proposed construction that includes of any structure having "at least 'one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes'" is not consistent with, and is broader than, the plain and ordinary meaning of the term "filament." Truvic's construction is premised on the argument that the '011 Patent, which shares a specification with the '921 Patent, applies "filament" more broadly than the plain and ordinary meaning. I disagree. Nothing in the '921 Patent's specification and the examples that the specification provides (*see id.* at 9:3-18) indicates that the '921 Patent is contradicting the plain meaning of the term filament. Construing "filament" to mean any structure that includes "one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes," as Truvic contends, would remove any meaning from the term and would cover structures, including rigid plastic or aluminum structures, that do not function as a thin, flexible material, such as a thin, flexible thread.

VIII. THE '910 AND '921 PATENTS

A. U.S. Patent 11,974,910 ("'910 Patent")

1. Claims and Specification of the '910 Patent

93. The '910 Patent is entitled "System for Treating Embolism and Associate Devices

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and Methods." It claims priority to provisional patent applications filed on August 13, 2018. It was issued on May 7, 2024. It identifies Inari as its assignee.

94. The '910 Patent is part of a family of patents claiming priority back to United States Application No. 16/536,185 filed on August 8, 2019 (now United States Patent No. 11,559,382) and two provisional applications filed on August 13, 2018. The family includes multiple patents, including the '910, '333, '005, and '691 Patents.

95. The '910 Patent is generally directed to improved thrombectomy systems and methods. The '910 Patent explains:

> Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A method in accordance with embodiments of the present technology can include, for example, positioning a distal portion of a catheter proximate to the clot material within the blood vessel. The method can further include coupling a pressure source to the catheter via a tubing subsystem including a valve or other fluid control device and, while the valve is closed, activating the pressure source to charge a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel and into the catheter.

('910 Patent at Abstract, 4:17-33.) The disclosed systems and methods include ones related to the so-called "Whoosh" method of treatment using aspiration. "Whoosh" is the name that Inari has given to the process of (a) positioning an aspiration catheter proximate to a clot to be removed from a patient body, (b) creating a stored volume of vacuum with a vacuum pressure source (for example, by pulling back the plunger of a syringe or using an electric pump to build vacuum pressure in a chamber) while a fluid control device (e.g., a valve) between the stored vacuum volume and the catheter is closed to disconnect the vacuum from the catheter, and then (c) opening the intervening fluid control device, e.g. valve, to rapidly apply the vacuum to the distal tip of the aspiration catheter to aspirate at least some of the clot (in other words to suck at least some clot into the catheter). Figure 8 of the '910 Patent describes one embodiment of this method:

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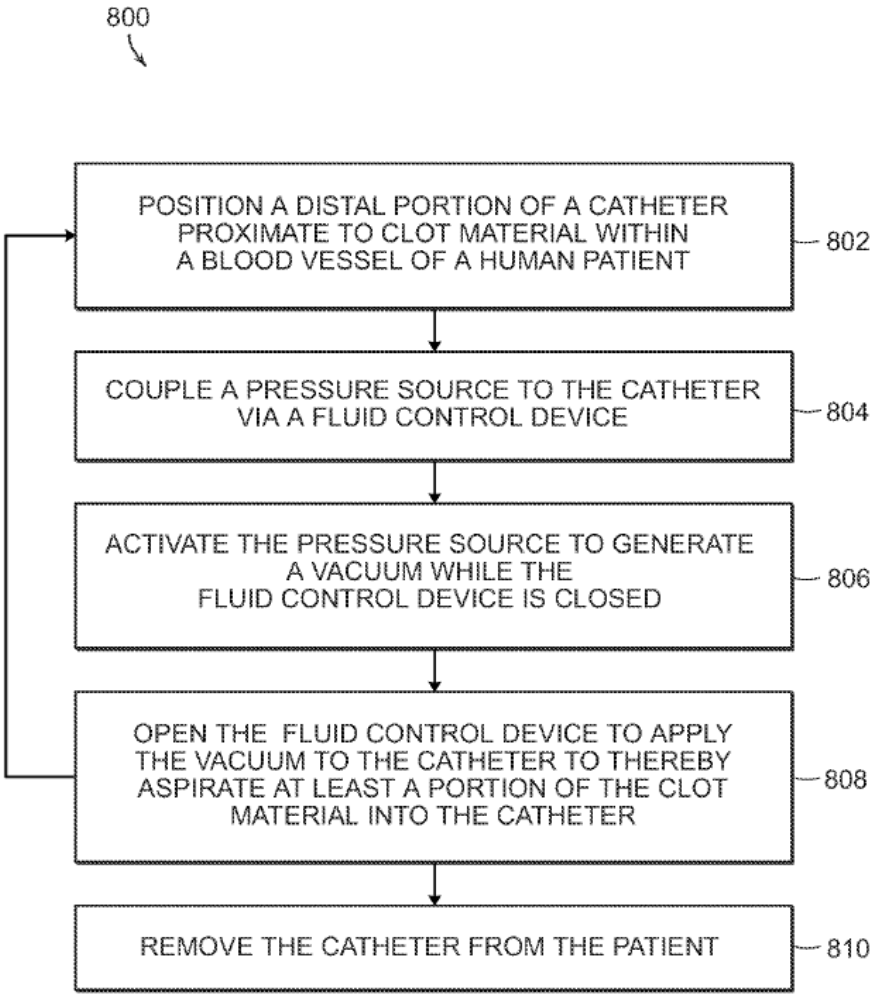

(Fig. 8.)

96. The claims, including Claims 1 and 10 recite particular systems for removing PE using a telescoping configuration. The improved systems and methods include, for example, a vacuum aspiration system that includes two aspiration assemblies (respectively, the first and second aspiration assembly). Each assembly includes an aspiration catheter, a pressure source, and a fluid control device controlling the fluid flow between the catheter and the pressure source. (*See, e.g.*, cl. 1.) The aspiration catheter of the second aspiration assembly is advanceable through, meaning it can be pushed within the inner lumen of, the aspiration catheter of the first aspiration assembly. (*See id.*) Figure 11 below shows such a telescoping configuration where the second aspiration catheter (1102) is advanced through the first aspiration catheter (1002).

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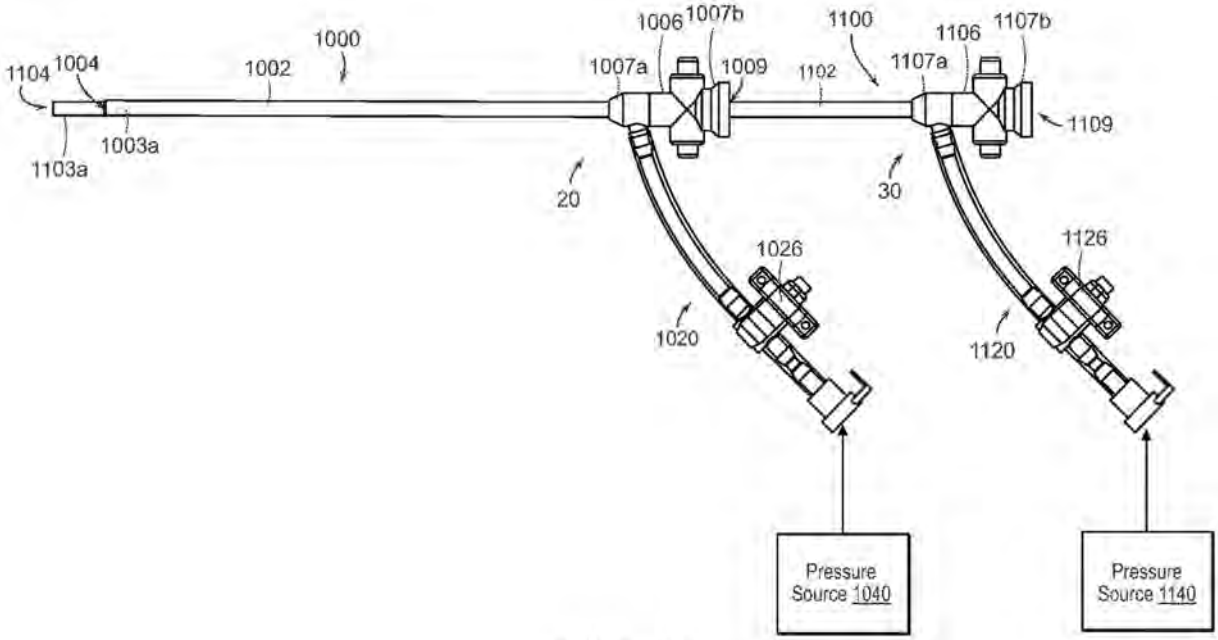

FIG. 11

97. Figure 12 of the ’910 Patent recites one specific method of using a telescoping configuration with a “Whoosh” aspiration. In Figure 12 the steps include advancing a second catheter through a first catheter in a telescoped configuration, connecting a vacuum pressure source to the second catheter with a fluid control device closed, generating a stored vacuum, and then opening the fluid control device of the second aspiration assembly to aspirate clot material using the second aspiration catheter:

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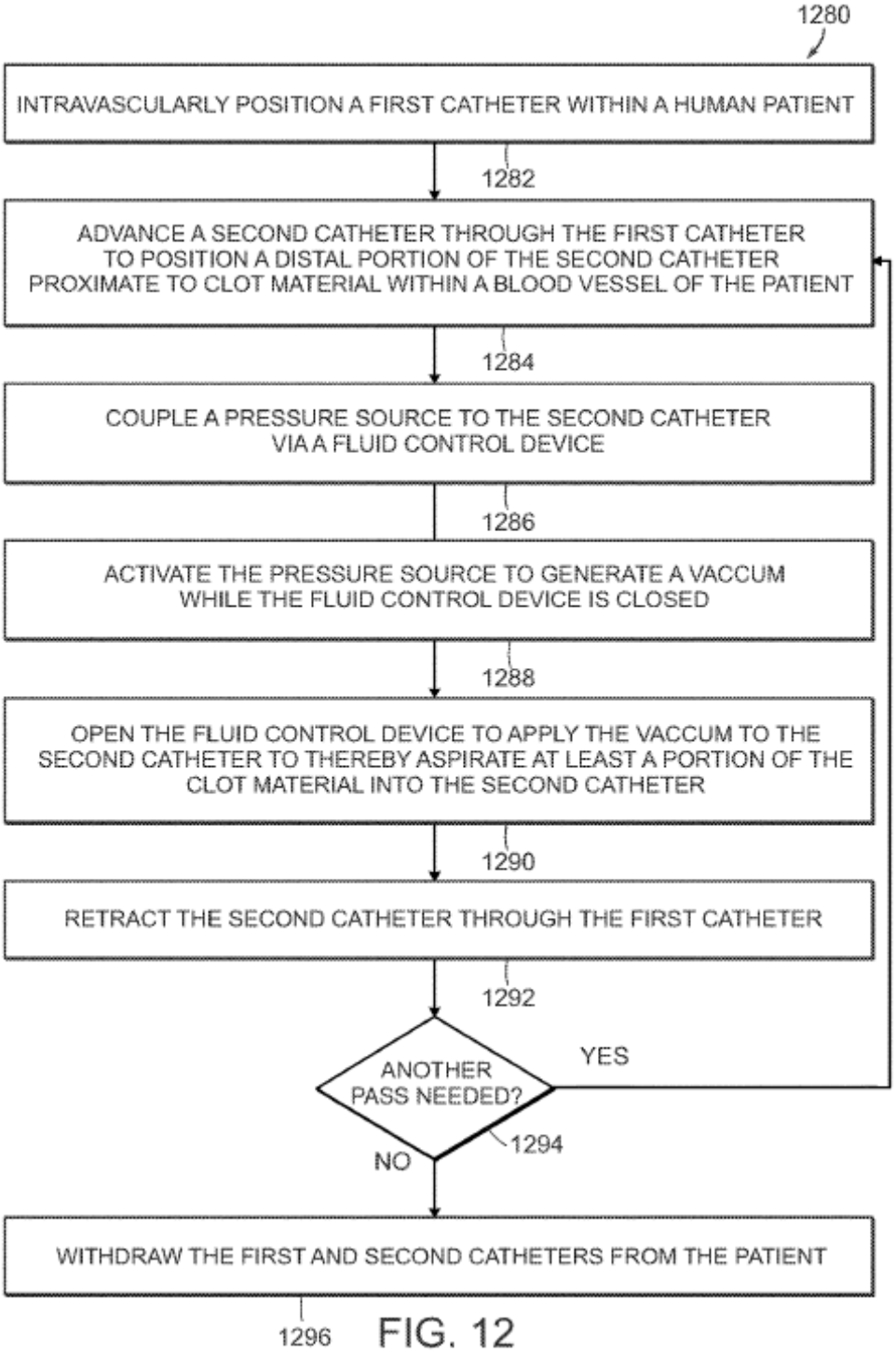

FIG. 12

(Fig. 12.)

98. The telescoping configuration can also be used to perform multiple aspiration passes involving aspiration by each of the two catheters in a telescoping configuration. Figure 15 of the '910 Patent discloses a method in which both catheters in the telescoping configuration are used for aspiration with employing a first vacuum pressure source and a first fluid control

device for the first aspiration catheter, and a second vacuum pressure source and a second fluid control device (not shown in Figure 15) for the second aspiration catheter:

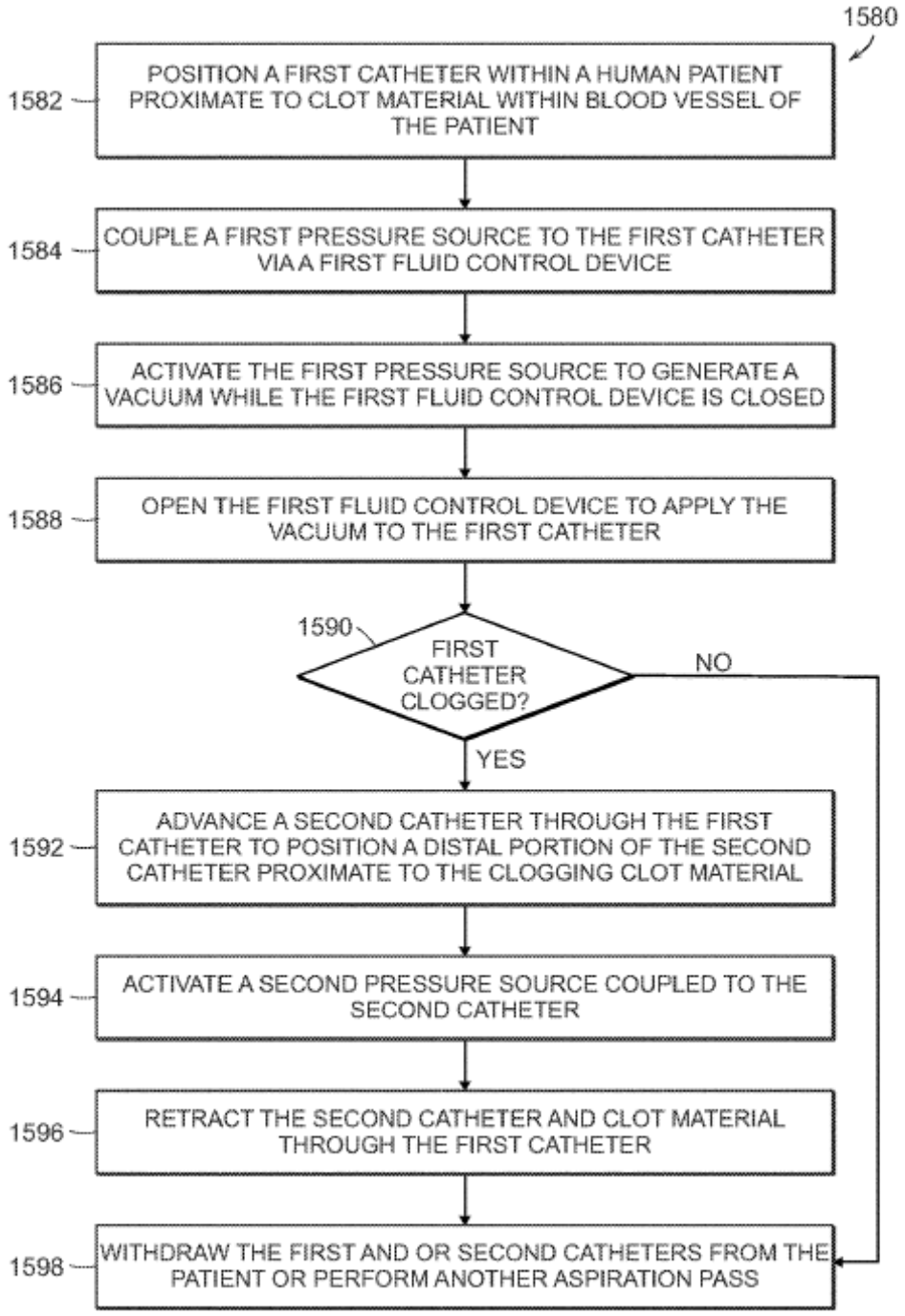

FIG. 15

(Fig. 15 (describing a method that includes performing aspiration with a first catheter connected to a first vacuum pressure source (1582-1588), and then advancing a second catheter through the first catheter in a telescoping configuration (1592) and activating as second pressure source to aspirate

clot material with the second catheter (1594).)

99. The aspiration catheter of each aspiration assembly in the telescoping configuration has a distal end that can be placed inside a blood vessel, *e.g.*, proximate to a PE clot, and a proximal end that can be connected to a pressure source. The fluid control device of each aspiration assembly can be moved between a first position where the pressure source is fluidly 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 applies suction at the distal end of the catheter in order to suck in the PE). (*See id.*) In this design, "the pressure source is configured to generate a vacuum and store the vacuum before the pressure source is fluidly connected to the catheter. Therefore, opening the fluid control device can instantaneously or nearly instantaneously apply the stored vacuum pressure to the catheter, thereby generating suction throughout the catheter. . . . Pre-charging or storing the vacuum before applying the vacuum to the catheter can generate greater and longer suction forces (and corresponding fluid flow velocities) at and/or near the distal portion of the catheter compared to, for example, simply activating the pressure source while it is fluidly connected to the catheter."

2. <u>File History of the '910 Patent</u>

100. I have reviewed the file history of the '910 Patent.

101. During prosecution, the examiner granted the application after a single office action dated November 6, 2023. The Examiner allowed original Claims 1-17 and 19-20, for reciting a telescoping ("a second catheter advanceable through the first catheter"), but rejected original claim 18, which did not require telescoping, for obviousness over United States Published Applications 20150173782 ("Garrison") and 20180054453 ("Garrison II"). (Nov. 6, 2023, Office Action at 2-3, 4- 6.)

> Garrison (US 20150173782 Al) teaches all of the limitations as discussed above and Garrison further teaches a second clot aspiration assembly (second aspiration assembly connected to line (2045), see Figure 33), including: a second catheter (flow line (2045)); and a second pressure source (3425) configured to be fluidly coupled to the second catheter (see Figure 33) and to generate suction at a distal portion of the second catheter (aspiration

> source (3425) provides suction to the distal portion of the flow line (2045), see Figure 33). However, Garrison fails to teach a second catheter advanceable through the first catheter. The second catheter (2045) does not advance through first catheter (2025), as shown in Figure 33. There is no reason to advance the second catheter through the first catheter of Garrison. Also Garrison does not explicitly disclose the flow lines (2025 and 2045) advancing through arterial access device (2010). It would be unreasonable to modify the flow lines to advance through the arterial access device (2010) because it would interfere with the thrombectomy device. Therefore, the limitations of claims 1 and 11 are considered allowable.

(Nov. 6, 2023, Office Action at 4.)

> However, Garrison et al. (US 20180064453 Al) fails to teach a second clot aspiration assembly, including: a second catheter advanceable through the first catheter; a second pressure source; and a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) an open position in which the second pressure source is fluidly connected to the second catheter and (b) a closed positioned in which the second pressure source is fluidly disconnected from the second catheter, wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the closed position, and wherein, upon movement of the second fluid control device from the open position to the closed position, the vacuum pressure is applied to the second catheter to generate suction at a distal portion of the second catheter.

(Nov. 6, 2023, Office Action at 6.)

102. In response, the applicant canceled original Claims 18 and 20. (Feb. 6, 2024, Amendment and Office Action response.) The applicant also amended the allowed claims (including current claim 1) to add the limitations reciting treatment for PE ("for treating clot material comprising a pulmonary embolism in the vasculature of a patient;") and large-bore catheter sizes ("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;" and "to aspirate blood and at least a portion of the pulmonary embolism into the second catheter."). The applicant also added new dependent Claims 21 and 22.

103. In the Amendment, the applicant noted that the new claims, now incorporating the PE and large catheter size limitations, would be patentable for reasons discussed in co-pending

Patent Application No. 18/329,450 (which issued as the '333 Patent).

> [I]ndependent claims 1 and 11, as amended, are further patentable over Garrison for at least the reasons discussed during the January 25th videoconference interview with the Examiner and his supervisor in related United States Patent Application No. 18/329,450, and specifically the Examiner's comments in the Applicant-Initiated Interview Summary mailed January 31, 2024 that "Attorney and Examiner agree that incorporating more structural claim language, i.e. diameter of the catheter, would make the claim 1 allowable over the prior art Garrison."

(*Id.* at 7-8.)

104. The examiner allowed the then-pending claims over the best prior art of record, including Garrison (US20150173782), citing these additional limitations as further making the claims patentable, stating that:

> Garrison fails to teach ["]a clot treatment system for treating clot material comprising a pulmonary embolism in the vasculature of a patient" and "wherein the second catheter has a size of 16 French or greater". The clot treatment device of Garrison is configured for a neurovascular application and not for larger vasculature such as pulmonary embolism. It would be unreasonable to modify the clot treatment of Garrison to be used for pulmonary embolisms. There is not prior art that teaches all of the limitations.

(March 13, 2024, Notice of Allowance at 2.)

3. <u>Claim 1 of the '910 Patent</u>

105. Claim 1 of the '910 Patent recites:

> 1. A clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient, comprising:
>
> a first clot aspiration assembly, including:
>
> a first catheter;
>
> a first pressure source; and
>
> a first fluid control device between the first catheter and the first pressure source,
>
> wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter,
>
> wherein the first pressure source is configured to generate vacuum pressure while the first fluid control device is in the first position, and wherein, upon movement of the first fluid control device from

> the first position to the second position, the vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first catheter; and
>
> a second clot aspiration assembly, including:
>
> a second catheter advanceable through the first catheter, wherein the second catheter has a distal portion, wherein the second catheter has a size of 16 French or greater, and wherein the second catheter is shaped to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the pulmonary embolism;
>
> a second pressure source; and
>
> a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter,
>
> wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and
>
> wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second catheter to generate suction at the distal portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism into the second catheter.

('910 Patent at 35:52-36:34.)

106. In sum, Claim 1 includes the concepts of treatment for pulmonary embolism using a system with telescoping large-diameter (16F or greater) catheters, a first and second vacuum pressure source, and creating a stored vacuum that can be used to perform "Whoosh" aspiration with the stored vacuum.

B. United States Patent 11,844,921 ("'921 Patent")

1. <u>Claims and Specification of the '921 Patent</u>

107. The '921 Patent is entitled "Hemostasis Valves and Methods of Use." It claims priority to provisional patent applications filed on September 6, 2017. It was issued on December 19, 2023. It identifies Inari as its assignee.

108. The '921 Patent is part of a family of patents claiming priority back to United States Application No. 16/117,519, filed on August 30, 2018 (now United States. Patent No.

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11,000,682) and a provisional application filed on September 6, 2017. The family includes multiple patents, including the '921, '011, '012 and '291 Patents.

109. The '921 Patent is generally directed to improved hemostasis valves and methods of their use. (*See, e.g.*, '921 Patent at Abstract, 1:58-62.) The '921 Patent discloses:

> Devices, systems, and methods for sealing medical devices, particularly during intravascular access, are disclosed herein. Some aspects relate to a hemostatic valve for sealing a wide range of medical devices, such as catheters, wires, embolectomy systems. The valve can include an elongate member having a first end, a second end, and a central lumen extending therebetween. … A tensioning mechanism is coupled to the shell and to the elongate member, the tensioning mechanism can be moveable between a first configuration wherein the tensioning mechanism is collapsed and the central lumen is sealed and a second configuration wherein the central lumen is open.

(Abstract, 1:58-2:7.)

110. Hemostasis valves are typically used in medical devices to seal around guidewires and catheters in order to minimize blood loss and maintain sterility within the body (such as in a blood vessel). (1:28-44.) This is critical during interventional procedures to prevent patients from losing blood unnecessarily, to prevent air from entering into the vasculature (which can cause bubbles), and to reduce infection. (1:18-26.)

111. As the '921 Patent discloses, 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. (1:45-54, 5:49-67.) To explain this point more fully, and as would be understood by one of ordinary skill in the art, there is a large volume of blood that flows through the large veins and pulmonary arteries. Removing clots from these vessels necessarily carries a risk of patient blood loss which, in certain scenarios, can be life-threatening for a patient. Hemostasis valves help to minimize patent blood loss. Hemostasis valves are one of the primary tools in a doctor's arsenal for achieving this result, making it a particularly important feature of any VTE thrombectomy device. Making the valve easy to operate (e.g., with one hand) further makes this feature accessible and desirable for the physicians who use it.

112. The '921 Patent discloses hemostasis valves having particular structures for

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garrote hemostasis valves, including an internal elongate and/or tubular member with a lumen (an inner cavity through which an object such as a catheter can be inserted), which can be circumferentially constricted and sealed by filaments wrapped around it. (5.49-6:18 ("This valve, also referred to herein as a garrote valve can seal…. Combined with single-handed operation, the garrote valve provides robust sealing either with or without a tool extending through the valve.").) The hemostasis valve further has an actuator (such as a button control mechanism) that can be activated to constrict the elongate member's lumen by pulling tight the filaments around the lumen, thereby closing/sealing the hemostasis valve. (cl. 1, 2:8-25.) Figure 1 below shows an example of such a garrote hemostasis valve (104) having an elongate tubular member (132) with a central lumen (138) that can be constricted with a constricting mechanism (141) (not shown in Figure 1) including an actuator (142) having one or more buttons (144-A and 144-B) and one or more filaments extending at least partially around the elongate tubular member (132).

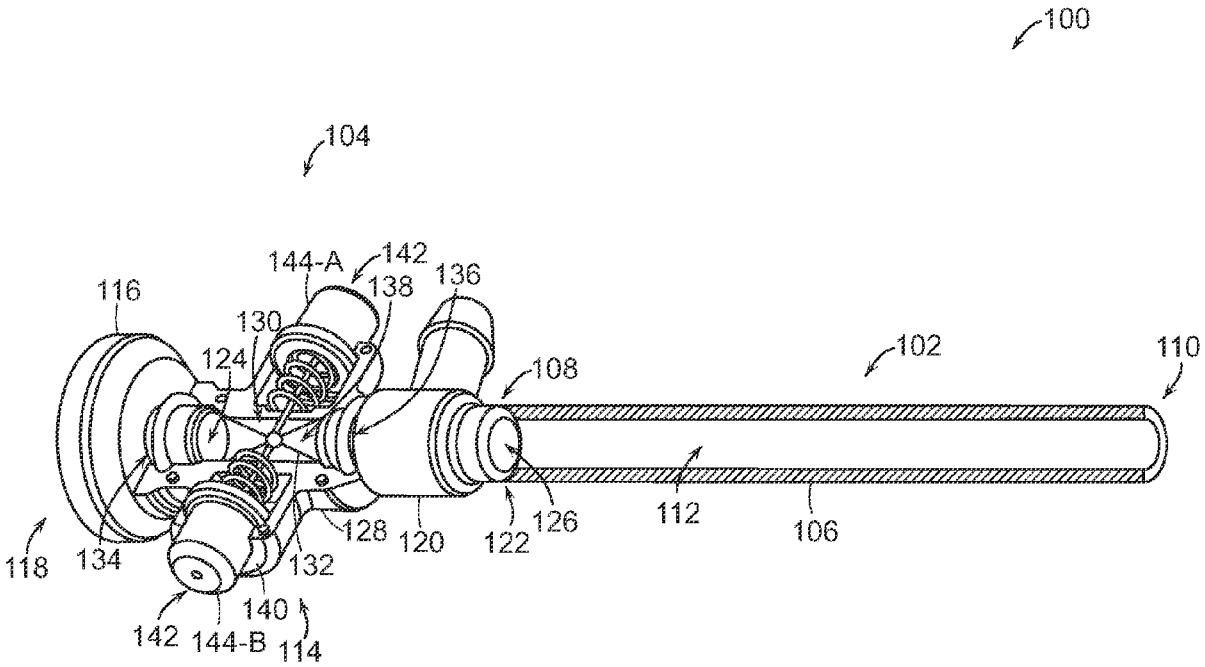

FIG. 1

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(Fig. 1, 6:19-8:34.)

113. Figure 2 of the '921 Patent depicts more details of the constricting mechanism (141), including the actuator(s) (142) where buttons are biased to a first undepressed (constricted) position and can be pressed to a second depressed (partially open) position because the buttons depress springs (148), the springs which bias the constricting mechanism toward the

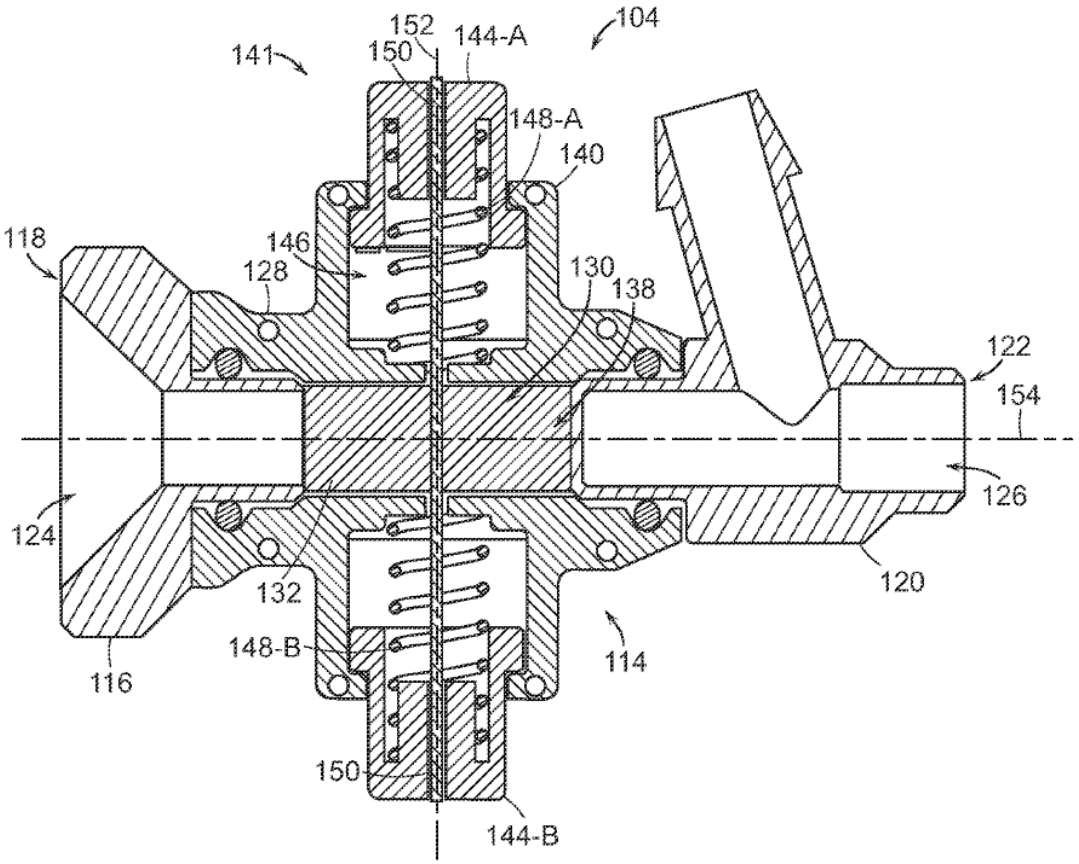

FIG. 2

first position corresponding to the first undepressed configuration.

(Fig. 2, 8:34-55.) The constricting mechanism further includes at least one filament (150) that extends at least partially around the elongate member of the valve (132), which can circumferentially constrict the elongate member to collapse and seal it. (Fig. 2, 9:1-47.) In embodiments the valve has multiple filaments. (Fig. 7, 2:45-51, 12:54-13:9.)

114. Figures 6-9 depict embodiments of the filament(s) used to constrict the hemostasis

valve, which can either be a single filament or multiple filaments either extending partially around the tubular member or completely around the tubular member. (Figs. 6-9, 12:37-14:27.) Figure 7 depicts a configuration with two filaments (150-A and 150-B), each looped completely around in a loop (704 and 706).

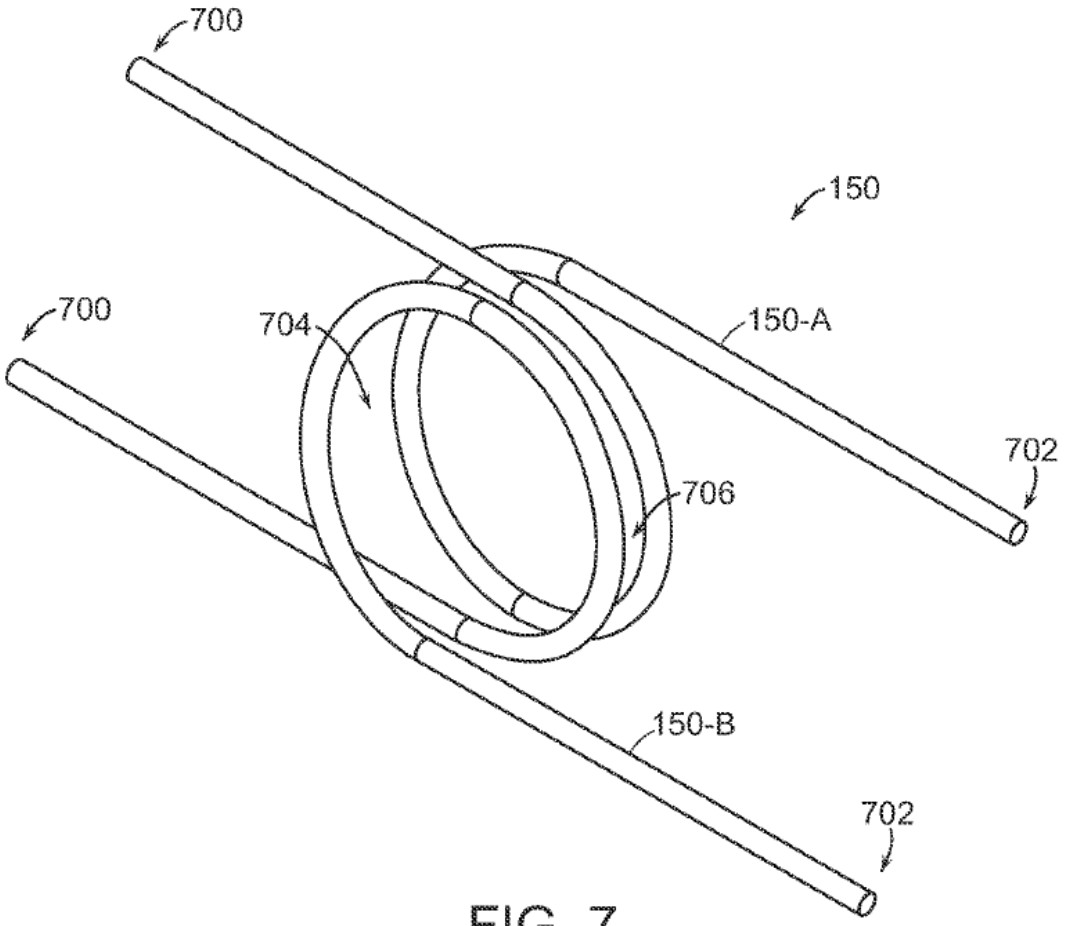

FIG. 7

(Fig. 7, 12:54-13:22.) The two ends of the filaments (700 and 702) can be coupled to one or more buttons and/or to a housing.

2. <u>File History of the ’921 Patent</u>

115. I have reviewed the file history of the ’921 Patent. During prosecution, the examiner granted the application with no office action.

116. The applicant filed preliminary amendments on June 11, 2021, and December 27, 2022. In the Notice of Allowance dated October 18, 2023, the Examiner entered an Examiner’s Amendment, pursuant to an interview conducted on May 5, 2023, making minor changes to

Claims 56 (renumbered as Claim 5) and 67 (renumbered as Claim 15), neither of which are a focus of this declaration. (October 18, 2023, Notice of Allowability at 2.) The Examiner explained that the claims were patentable over the "closest prior art of record … Hartley (US2003/0116731) [and] Williams et al (US3,438,607)" because:

> Regarding claim 52, Hartley discloses a valve 8 comprising: an elongate member 22 defining a lumen 3; an active tensioning mechanism including an actuator 12 coupled to the elongate member via a filament 20 extending at least partially around the elongate member, wherein the actuator is movable between a first position (Figs. 2 & 4), wherein the lumen constricted and sealed; a second position (Figs.1 & 3) wherein the lumen is at least partially open. Harley fails to disclose a biasing member configured to bias the actuator to the first position. Note: the spring 29 in Hartley is not configured to bias the actuator to the first position. A ball 28 loaded by the spring 29 to detent or hold in the housing 6. **********
> Regarding claim 77, the claim 77 requires two actuators coupled to the elongate member; and each of the actuator coupled to the elongate member via with respective to each of a first filament and a second filament. Meanwhile, the prior art Har[t]ley discloses only one actuator.

(October 18, 2023, Notice of Allowability at 3-4.)

117. Regarding the Williams reference, the Examiner noted that it did not disclose a filament constricting mechanism (a filament extending around the elongate member forming a lumen) for the valve, and that it did not disclose a first and second actuator or a first and second filament. (October 18, 2023, Notice of Allowability at 4.)

3. <u>Claim 1 of the '921 Patent</u>

118. 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.

(22:12-22.)

119. Claim 1 recites a garrote hemostasis valve with an elongate (*e.g.*, a tubular)

member and an active tensioning mechanism for constricting the elongate member with a filament at least partially around the elongate member, where the tensioning mechanism has an actuator coupled to a filament and that can be moved between a first (valve constricted) position, *e.g.*, with undepressed button(s), and a second (valve partially open) position, *e.g.*, with depressed button(s).

4. Claim 10 of the '921 Patent

120. Claim 10 of the '921 Patent recites:

> 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.

(22:53-64.) Claim 10 depends from Claim 1 and recites an additional second actuator and a second filament looped at least partially around the elongate member of the valve.

IX. Inari's Patents Cover Important Innovations

121. The '910 Patent, including Claim 1, relates to several important developments Inari invented and ultimately brought to market. For instance, Claim 1 recites a telescoping system where a second large diameter catheter (16F or greater) is advanced through (telescoped) a larger first catheter (e.g., a 20F of 24F catheter). As a starting point, Claim 1 recites large catheter sizes, which are important for many reasons, as discussed above. For example, large-bore catheters allow for greater suction over a greater area and removal of more clot material. The large catheters also may come closer to fitting the size of the larger vasculature for DVT and/or PE procedures, allowing for clot material to be more effectively sucked into the aspiration catheter during an aspiration pass.

122. Telescoping catheters is another important innovation in Inari's system because it allows for additional length or reach to get to clot material and because the relatively smaller

diameter catheter allows the system to reach into vasculature that may narrow to a smaller diameter than the larger first aspiration catheter, such as in the branching pulmonary arteries. The telescoping system additionally provides the chance for two aspiration passes with a single set of two aspiration catheters, which can remove additional clot material, as well as facilitating the clearing of a clogged catheter. The telescoping system provides additional versatility that is valuable in complicated thrombectomy procedures, such as in treatments for PE.

123. Claim 1 also recites the concept of a system configured to perform aspiration(s) using a stored vacuum, which Inari calls a "Whoosh." This technique allows for rapid aspiration using high levels of suction, a key requirement for treating PE.

124. Claim 1 of the '921 Patent also recites key innovations that Inari patented and brought to market for thrombectomy applications, including for pulmonary embolism, innovations that individually and as whole have improved the efficacy of thrombectomy treatments in large vasculature and that have improved patient outcomes over the existing treatments with thrombolytics, surgical procedures, and other mechanical procedures.

125. The '921 Patent, including Claims 1 and 10, relates to improved hemostasis valves through an improved garrote valve structure utilizing a circumferential constriction with one or more filaments controlled by an actuator biased to a closed (valve constricted) position. Improved design in the '921 Patent, including Claims 1 and 10, provides improved ergonomics and ease of use during procedures, allowing for one-handed operation while simultaneously providing a seal that maintains a vacuum, even for large diameter catheters.

126. The design in the '921 Patent improved the existing hemostasis valves by simplifying the system even for large diameter catheters. For large catheters, such as 16F or larger, a rotational valve is not desirable because of the number of actuations it takes to move from an open to closed position (or vice versa) for a valve that maintains a vacuum seal. This represented an important improvement to the existing technology, making it easier to deploy the large-diameter aspiration catheters needed for improved DVT and PE treatments.

X. THE SYMPHONY SYSTEM INFRINGES THE '910 AND '921 PATENTS

127. Based on the analysis I have conducted to date, and the materials that I have

reviewed, it is my opinion that the Symphony system practices Claim 1 of the ’910 Patent and Claims 1 and 10 of the ’921 Patent.

A. United States Patent 11,974,910 (“’910 Patent”)

128. I understand that in this lawsuit Inari is accusing Truvic of infringing the ’910 Patent. In particular, Inari alleges that Truvic infringes at least independent Claim 1 of the ’910 Patent. I have been asked to analyze the ’910 Patent and the Symphony system to provide technical opinions as to whether the Symphony system practices claims of the ’910 Patent.

129. As explained fully below, it is my opinion that the Symphony system practices at least Claim 1 of the ’910 Patent. My opinion is consistent with the points made in the claim chart attached as Ex. K to the Complaint and Amended Complaint and to the Motion for Preliminary Injunction as Ex. 17. I did not prepare this chart, but I agree with the analysis in it, adopt it as part of my opinions, and further explain the points made in it below.

1. <u>Claim 1</u>

130. I address the preamble and each element of the claim in turn below.

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

131. The preamble of Claim 1 recites a “clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient.” I am informed that the question of whether this preamble is limiting (i.e., must be met for there to be infringement) is a legal matter to be decided by the Court. I have not been asked to provide an opinion of whether this preamble is limiting at this stage. For the purposes of this declaration, however, and to be conservative, I have analyzed infringement assuming the preamble is limiting.

132. As can be seen in Ex. 17, the Symphony system practices the preamble because it is a clot treatment system that employs “next generation thrombus removal” with “powerful, focused aspiration” for treating (e.g., removing) clot material from within a blood vessel. (Ex. 7 at 2-4.) The Symphony system is for treating clot material comprising a pulmonary embolism in the vasculature of the patient, as it is currently being used in clinical trials for treatment of pulmonary embolism. In addition, Truvic is seeking FDA clearance for using the Symphony

system for treatment of pulmonary embolism. *See* SYMPHONY-PE Study for Treatment of Pulmonary Embolism (https://classic.clinicaltrials.gov/ct2/show/NCT06062329).

b. [1][a] 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,

133. Claim 1 recites "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."

134. As can be seen in Ex. 17, the Symphony system practices this limitation because it has a first clot aspiration assembly that includes a 24F aspiration catheter (first catheter), a first pressure source comprising a clot canister and vacuum pump, and a controller handle for the 24F aspiration catheter. The controller handle includes a Dual-Action Vacuum Control operated by a lever (first fluid control device) between the 24F aspiration catheter (first catheter) and the first pressure source.

135. Specifically, the 24F aspiration catheter (first catheter) is coupled to the controller handle labeled as the "BigShot Controller" in the image below. The controller handle includes a Dual-Action Vacuum Control operated by a lever (first fluid control device). The handle further includes a clot canister labeled as the "TruView Clot Container" in the image below.

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(Ex. 7 at 6.)

136. As shown in the annotated figure below, the clot canister is fluidly coupled to a vacuum pump via tubing. There is a first pressure source comprising the clot canister and vacuum pump. The Dual-Action Vacuum Control operated by a lever (first fluid control device) is between the 24F aspiration catheter (first catheter) and the first pressure source. The 24F aspiration catheter (first catheter), Dual-Action Vacuum Control operated by a lever (first fluid control device), and first pressure source are part of the first clot aspiration assembly.

c. [1][b] 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,

137. Claim 1 further recites "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."

138. As can be seen in Ex. 17, the Symphony system practices this limitation because it includes a Dual-Action Vacuum Control operated by a lever (first fluid control device) between the 24F aspiration catheter (first catheter) and the first pressure source comprising the clot canister and the vacuum pump. The first fluid control device is movable between an "Off" position (first position) in which the first fluid control device fluidly disconnects the first pressure source from the 24F aspiration catheter, and an "On" position (second position) in which the first fluid control device fluidly connects the first pressure source to the 24F aspiration

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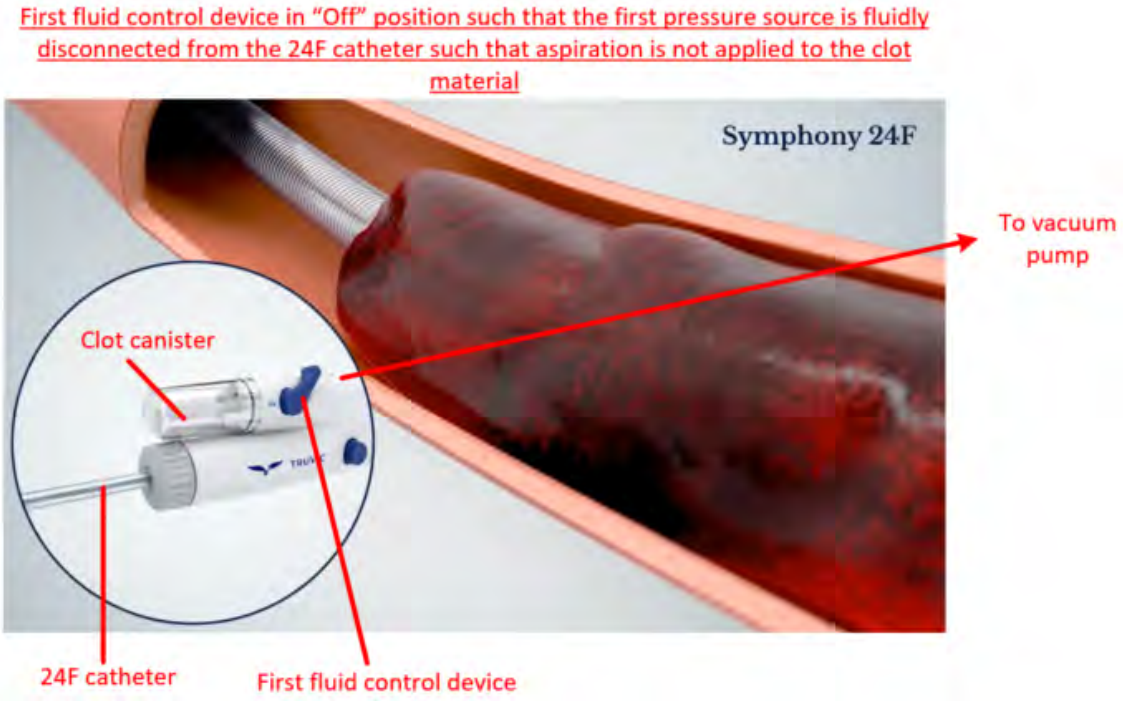
catheter (first catheter), applying suction to the catheter and ultimately to the distal end of the catheter.

139. Specifically, the Dual-Action Vacuum Control operated by a lever (first fluid control device) can be moved between an "Off" position (first position) and an "On" position (second position) by moving the lever. As shown in the annotated figure below, moving the lever of the first fluid control device to the "Off" position (first position) operates the first fluid control device to fluidly disconnect the first pressure source from the lumen of the 24F aspiration catheter (first catheter), thereby inhibiting fluid flow along the fluid path from the lumen of the 24F aspiration catheter (first catheter) to the clot canister.



140. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (first fluid control device). In the annotated photo below, the first fluid control device is in the "Off" position (first position).

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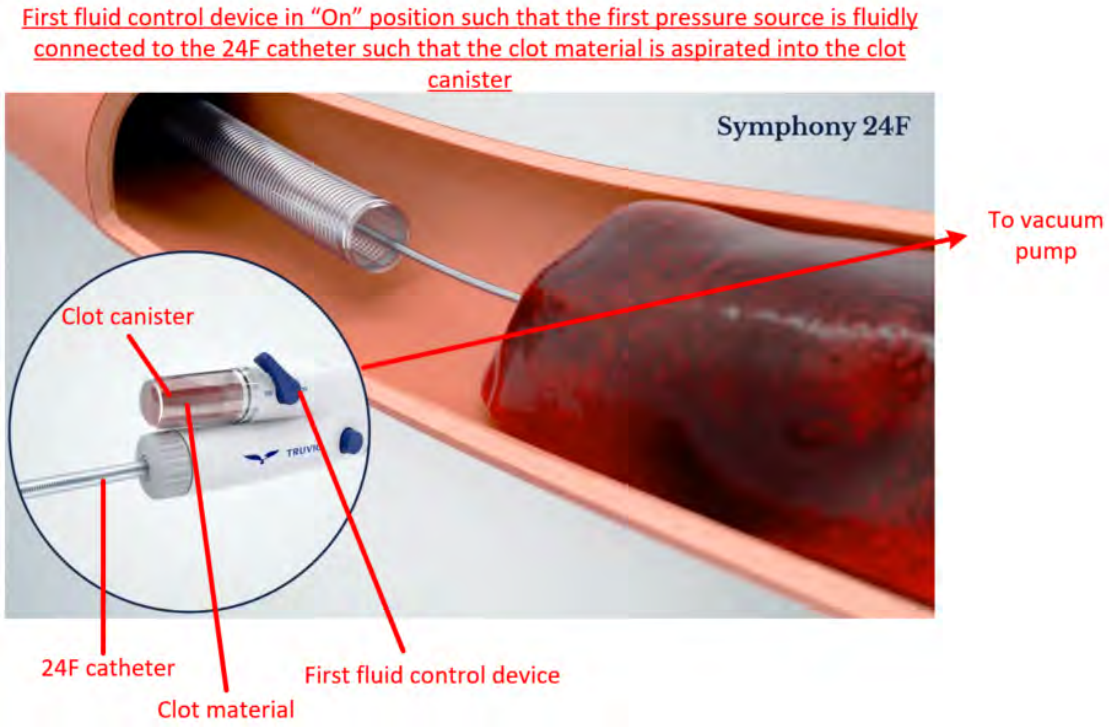
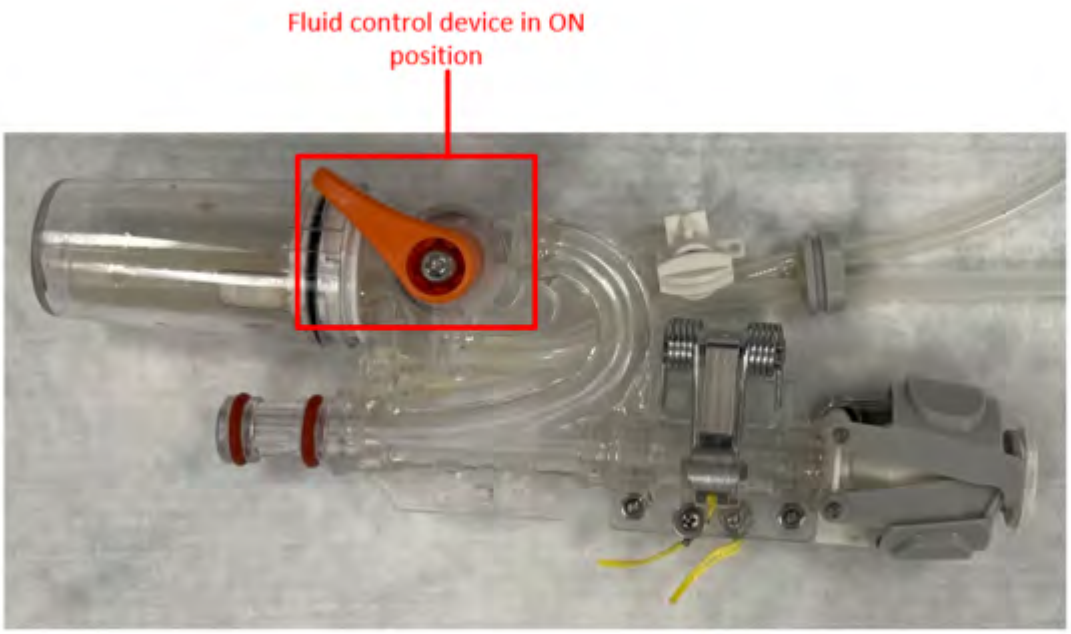
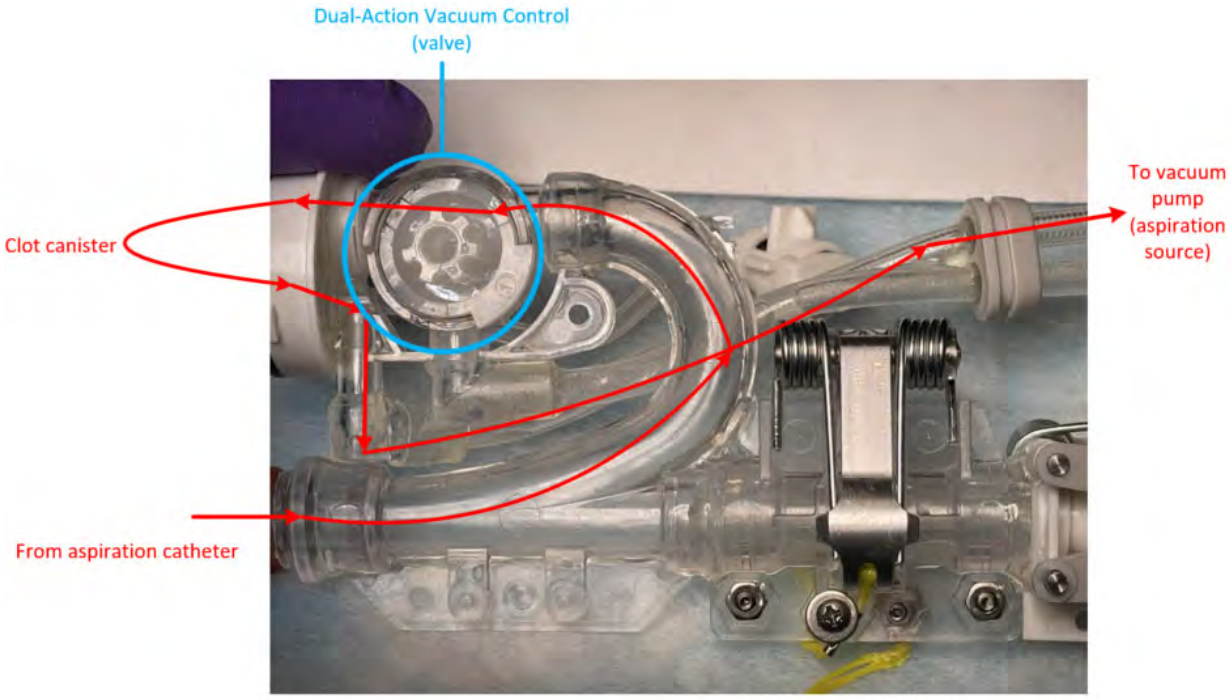
141. As shown in the annotated figure below, moving the lever of the first fluid control device to the "On" position (second position) operates the first fluid control device to fluidly connect the first pressure source to the lumen of the 24F aspiration catheter (first catheter), thereby permitting fluid flow along the fluid path from the lumen of the 24F aspiration catheter (first catheter) to the clot canister.



142. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (first fluid control device). The first fluid control device is moved to the on position (second position).



143. The annotated photo below shows the fluid path between the 24F aspiration catheter (first catheter) to the first pressure source comprising the clot canister and the vacuum pump.



d. [1][c] 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;

144. Claim 1 also recites "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."

145. As can be seen in Ex. 17, the Symphony system practices this limitation because the Symphony system's first fluid control device is movable between an "Off" position (first position) in which the first fluid control device fluidly disconnects the first pressure source from the 24F aspiration catheter (first catheter), and an "On" position (second position) in which the first fluid control device fluidly connects the first pressure source to the 24F aspiration catheter (first catheter). While the first fluid control device is in the "Off" position (first position), the first pressure source comprising the clot canister and vacuum pump generates vacuum pressure,

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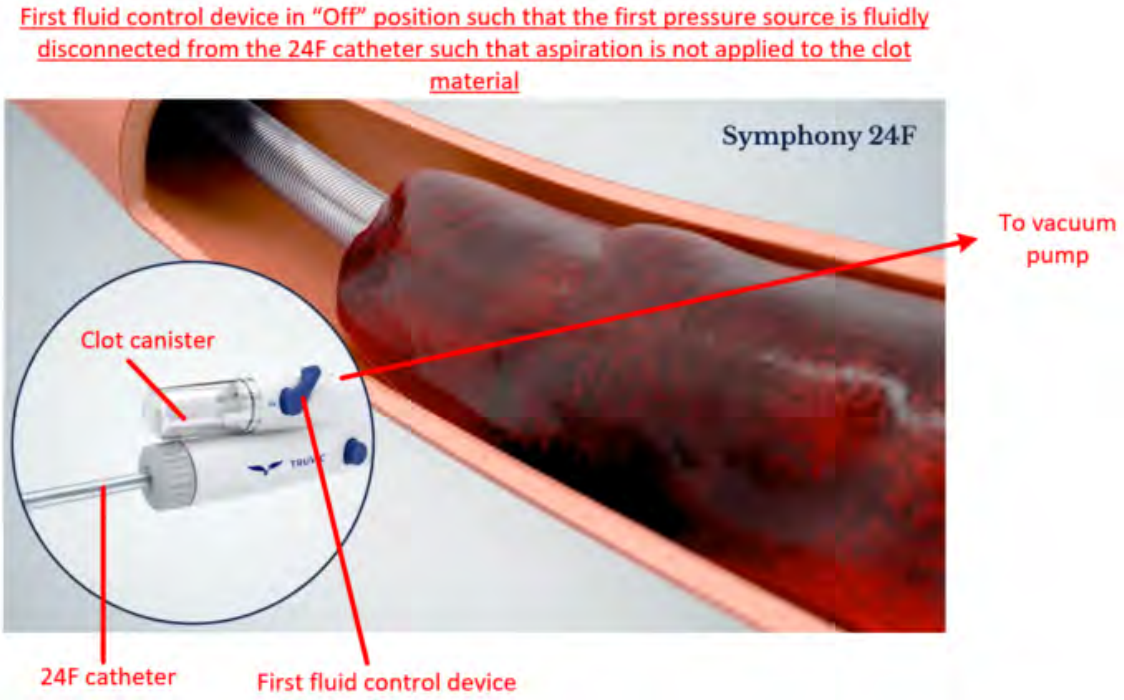
including in the clot canister. Upon movement of the first fluid control device from the "Off" position (first position) to the "On" position (second position), the vacuum pressure is applied to the 24F aspiration catheter (first catheter) to generate suction at the distal portion of the 24F aspiration catheter (first catheter) positioned near the clot material.

146. Specifically, as shown in the annotated figure below, while the first fluid control device is in the "Off" position (first position), vacuum pressure is generated, including in the clot canister, by the first pressure source comprising the clot canister and vacuum pump.



147. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (first fluid control device). In the annotated figure below, the first fluid control device is in the "Off" position (first position).

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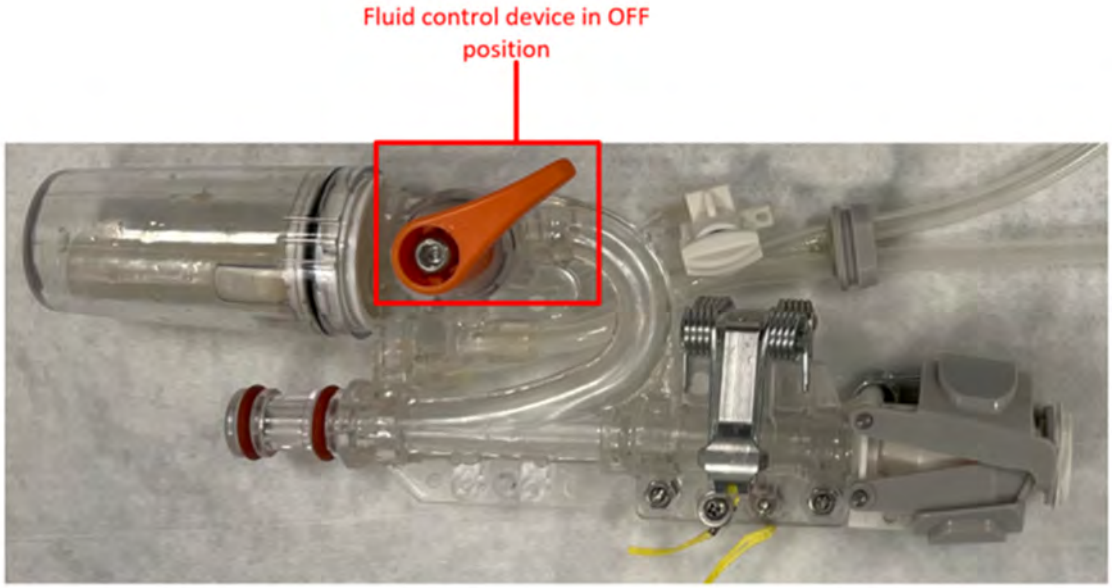
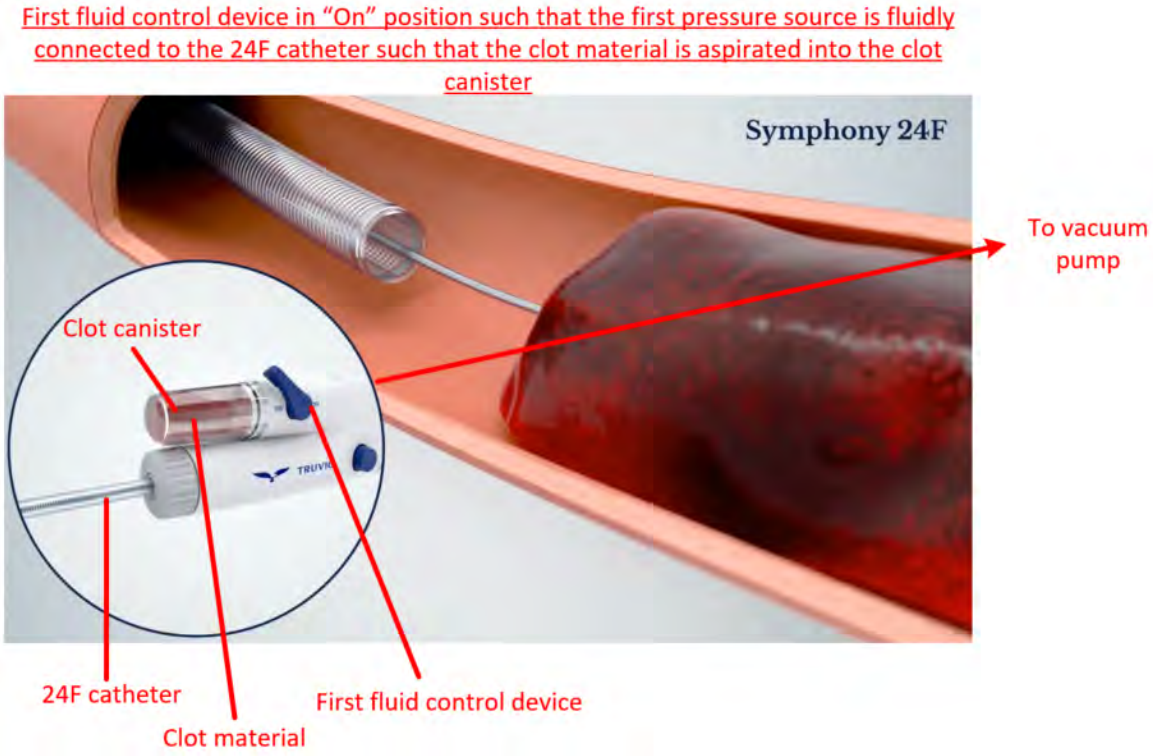


148. As shown in the annotated figure below, moving the first fluid control device from the "Off" position (first position) to the "On" position (second position) applies the vacuum pressure, including in the clot canister to the 24F aspiration catheter (first catheter) to generate suction at a distal portion of the 24F aspiration catheter (first catheter) to aspirate the clot material and blood into the clot canister.



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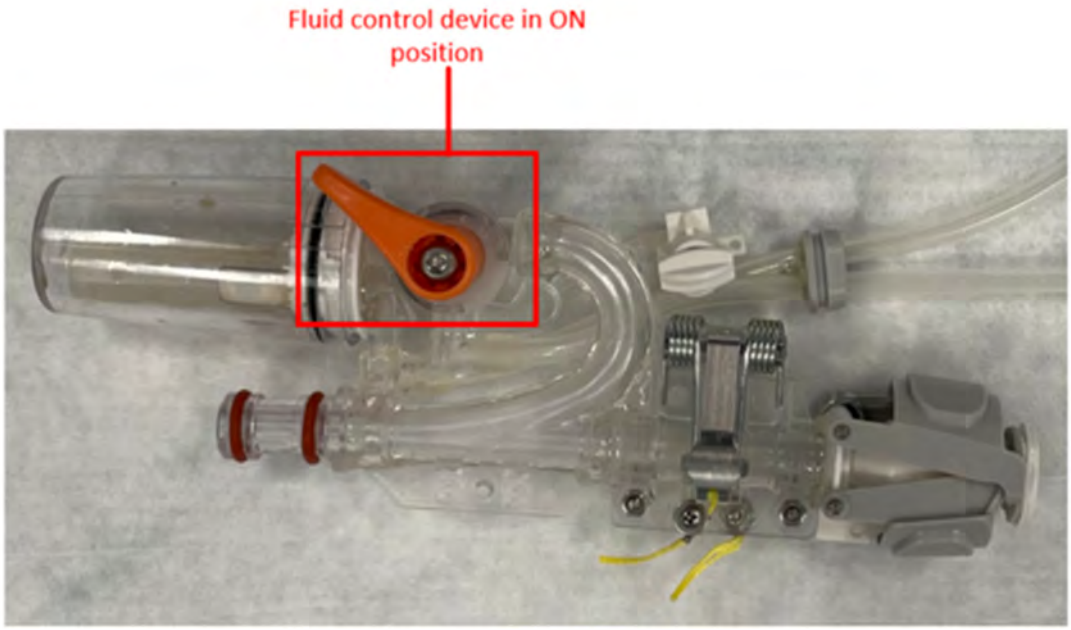
149. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (first fluid control device). In the annotated photo below, the first fluid control device is moved to the "On" position (second position).



150. In addition, page 5 of the Symphony system Instructions for Use (shown below) describes that while the first fluid control device is in the "Off" position (first position), the first pressure source is configured to generate vacuum pressure of at least -20 inHg. To apply the vacuum pressure to the 24F aspiration catheter (first catheter) in order to begin aspiration (apply suction) at a distal portion of the 24F aspiration catheter (first catheter), the first fluid control device is moved to the "On" position (second position).

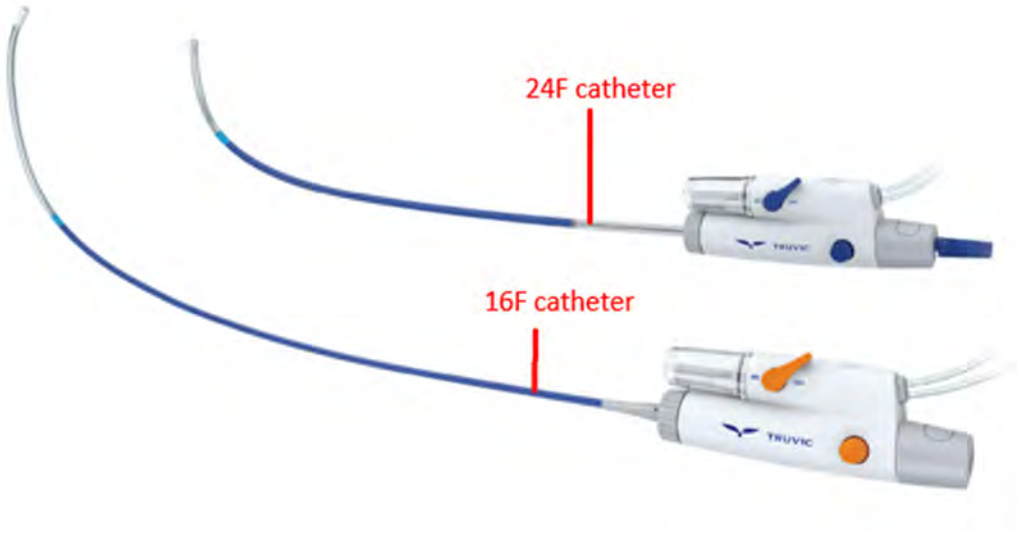
12. Confirm the Handle vacuum lever is in the "OFF" position and open the stopcock on the Tubing.
13. Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
14. Confirm tip of the Symphony Catheter is in the desired location.
15. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

e. [1][d] 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;

151. Claim 1 also recites "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."

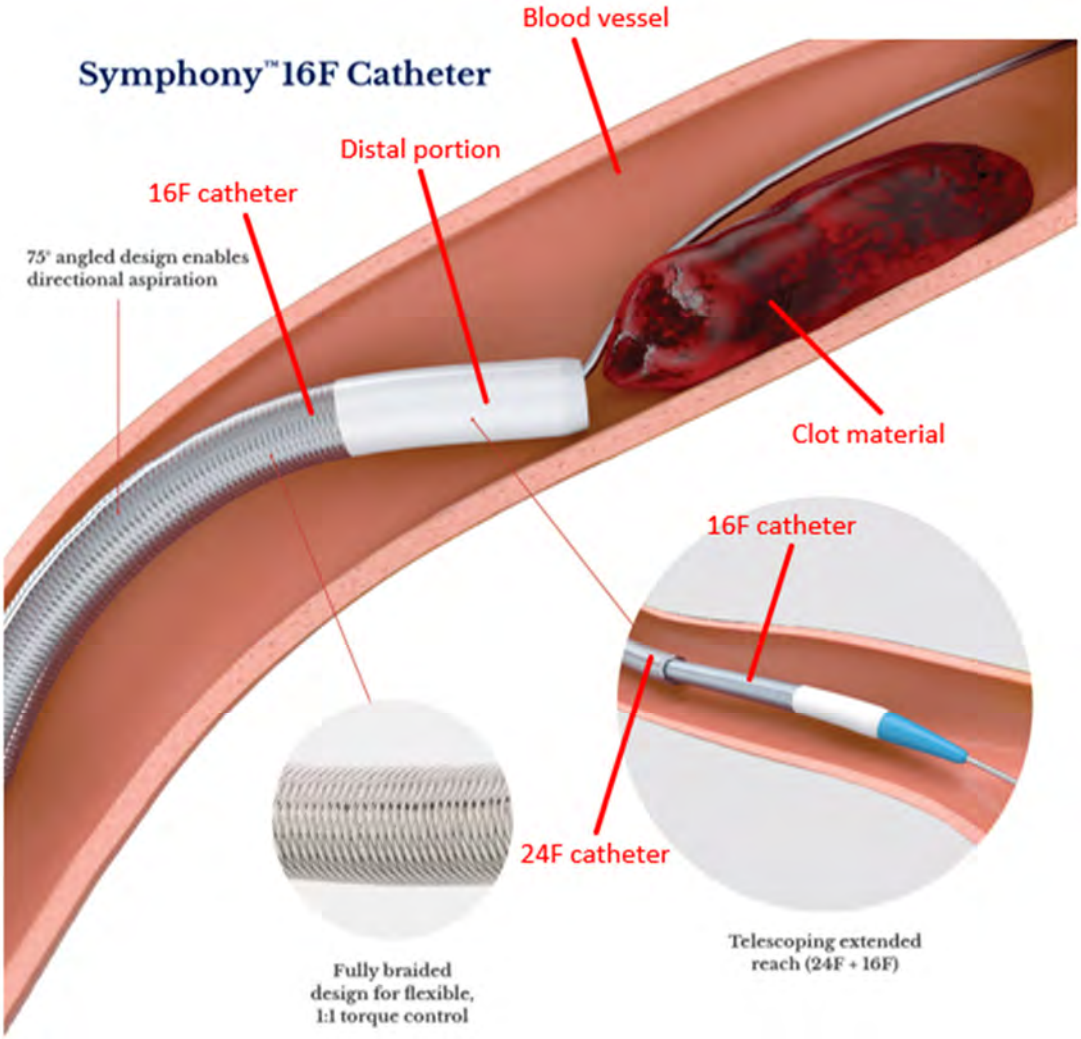
152. As can be seen in Ex. 17, the Symphony system practices this limitation because it has a second aspiration assembly that includes a 16F aspiration catheter (second catheter) advanceable through the 24F aspiration catheter (first catheter). The 16F aspiration catheter (second catheter) is shaped to be telescoped through the 24F aspiration catheter (first catheter) and advanced through a patient's vasculature such that the distal portion of the 16F aspiration catheter (second catheter) is positioned proximate to clot material, e.g., a pulmonary embolism.

153. Specifically, as shown in the annotated figure below, the Symphony system includes two clot aspiration assemblies. The first clot aspiration assembly includes a 24F aspiration catheter (first catheter), and the second clot aspiration assembly includes a 16F aspiration catheter (second catheter).



154. Furthermore, as shown in the figures below, the two clot aspiration assemblies can

be deployed in a telescoping configuration where the 16F aspiration catheter (second catheter) is telescoped (advanced) through the 24F aspiration catheter (first catheter) and out of the 24F aspiration catheter (first catheter) through the vasculature of the patient until the distal portion of the 16F aspiration catheter (second catheter) is positioned proximate to clot material, e.g., a pulmonary embolism, within the blood vessel.



(Annotated Ex. 7 at 4.)

f. [1][e] 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,

155. Claim 1 also recites "a second pressure source; and a second fluid control device between the second catheter and the second pressure source, wherein the second fluid control

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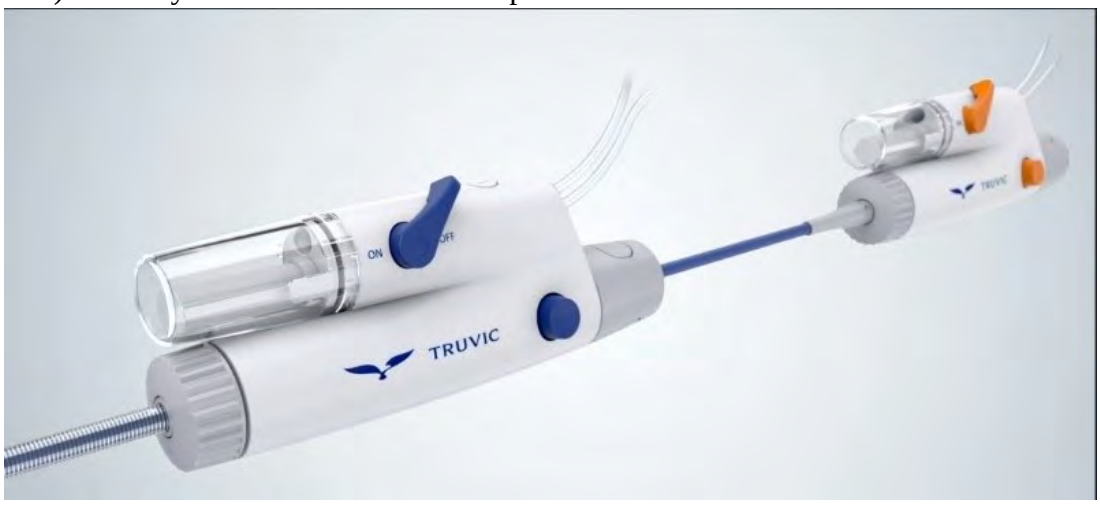
device is movable between (a) a first position in which the second pressure source is fluidly disconnected from the second catheter and (b) a second position in which the second pressure source is fluidly connected to the second catheter."

156. As can be seen in Ex. 17, the Symphony system practices this limitation because it includes a 16F aspiration catheter (second catheter), a controller handle for the 16F aspiration catheter, and a vacuum pump. The controller handle includes a clot canister. The second pressure source comprises a vacuum pump and a clot canister. The controller handle further includes a Dual-Action Vacuum Control operated by a lever (second fluid control device) between the 16F aspiration catheter (second catheter) and the second pressure source. The second fluid control device is movable between an "Off" position (first position) in which the 16F aspiration catheter (second catheter) is fluidly disconnected from the second pressure source, and an "On" position (second position) in which the 16F aspiration catheter (second catheter) is fluidly connected to the second pressure source.



157. Specifically, the 16F aspiration catheter (second catheter) is coupled to the controller handle labeled as the "BigShot Controller" in the image below. The controller handle includes a Dual-Action Vacuum Control operated by a lever (second fluid control device). The handle further includes a clot canister labeled as the "TruView Clot Container" in the image below.

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(Ex. 7 at 6.)

158. As shown in the annotated figure below, the clot canister is fluidly coupled to a vacuum pump via tubing. There is a second pressure source comprising the clot canister and vacuum pump. The Dual-Action Vacuum Control operated by a lever (second fluid control device) is between the 16F aspiration catheter (second catheter) and the second pressure source.

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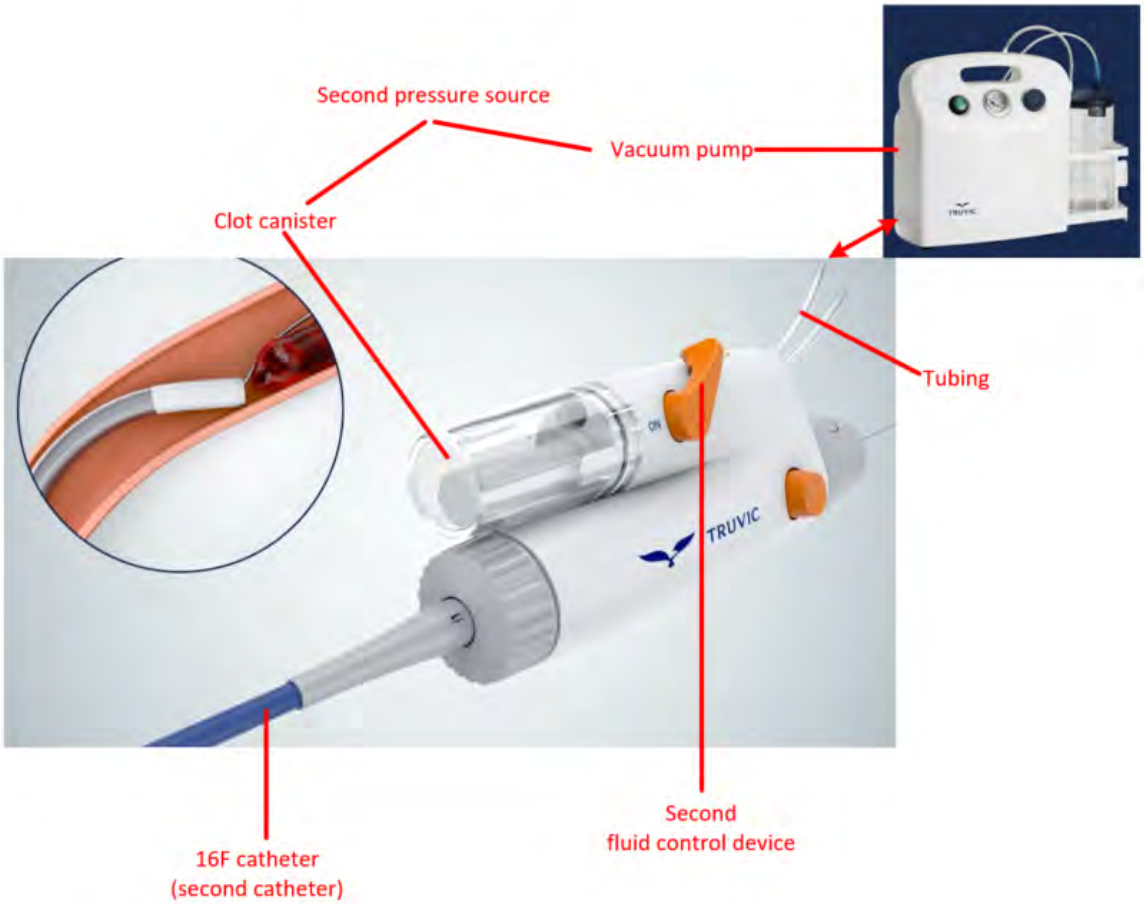

159. The Dual-Action Vacuum Control operated by a lever (second fluid control device) can be moved between an "Off" position (first position) and an "On" position (second position) by moving the lever. As shown in the annotated figure below, moving the lever of the second fluid control device to the "Off" position (first position) operates the second fluid control device to fluidly disconnect the second pressure source from the lumen of the 16F aspiration catheter (second catheter), thereby inhibiting fluid flow along the fluid path from the lumen of the 16F aspiration catheter (second catheter) to the clot canister.

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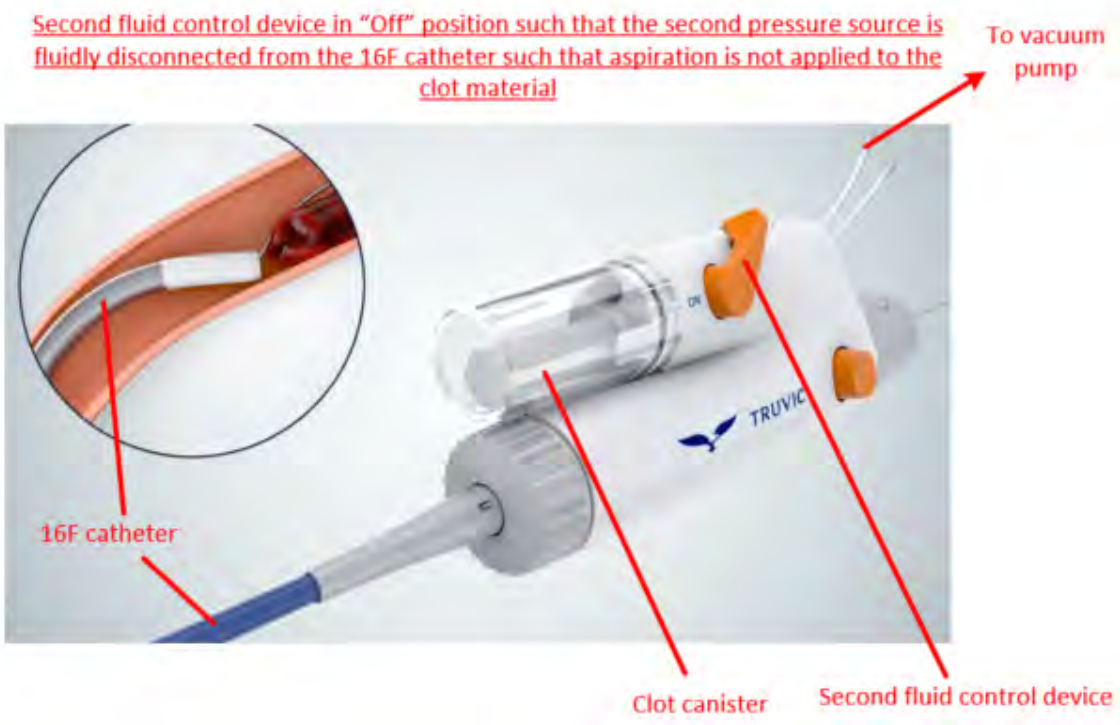
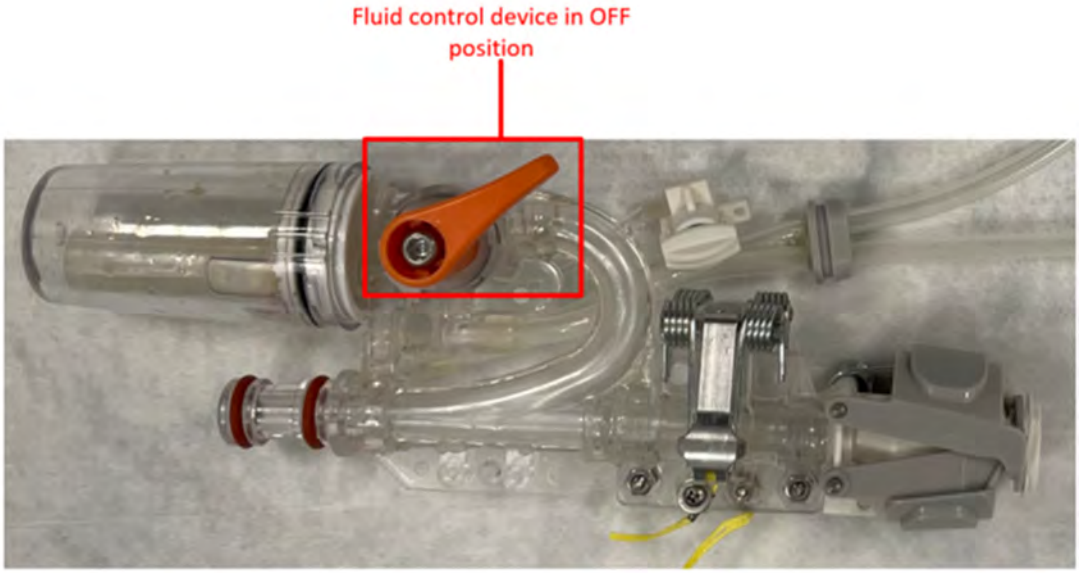


160. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (second fluid control device). In the annotated photo below, the second fluid control device is in the "Off" position (first position).



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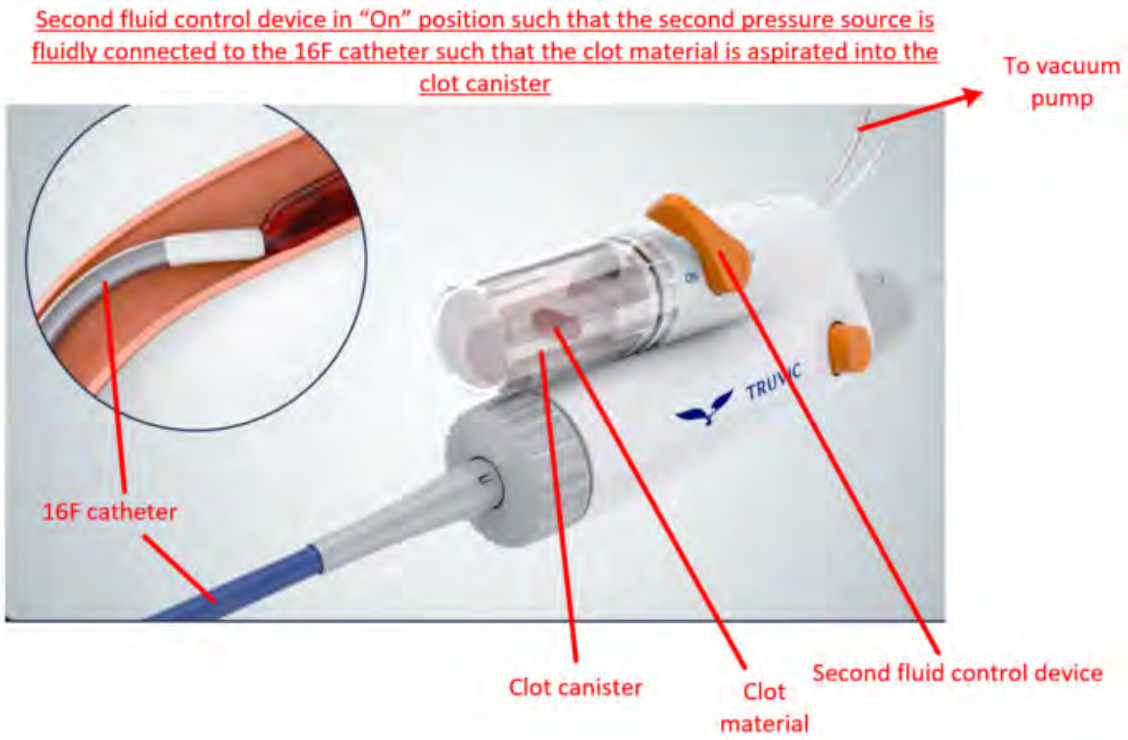
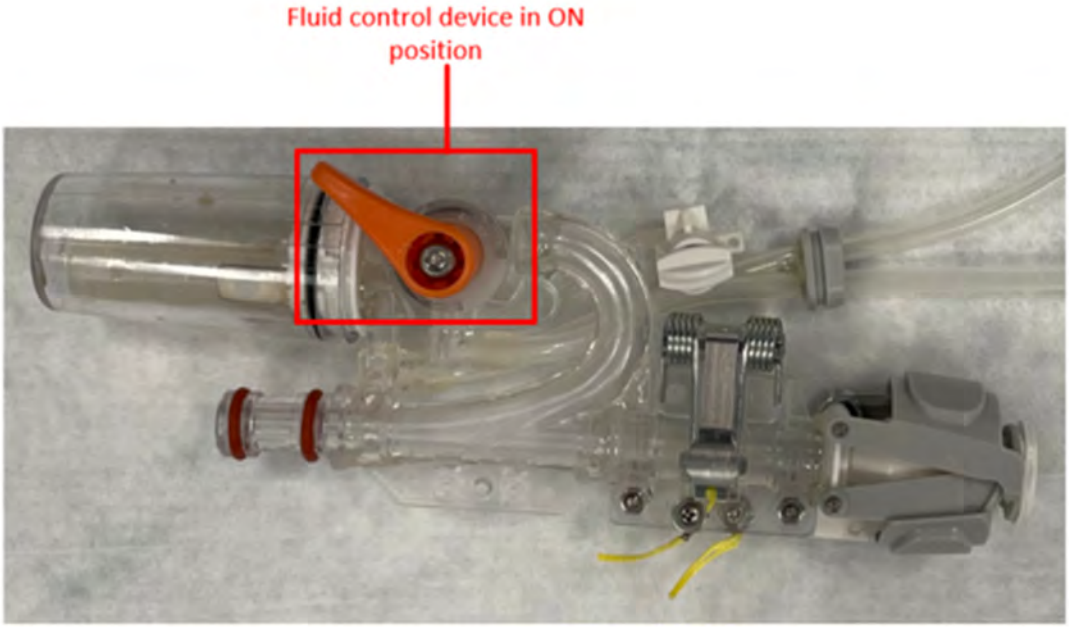
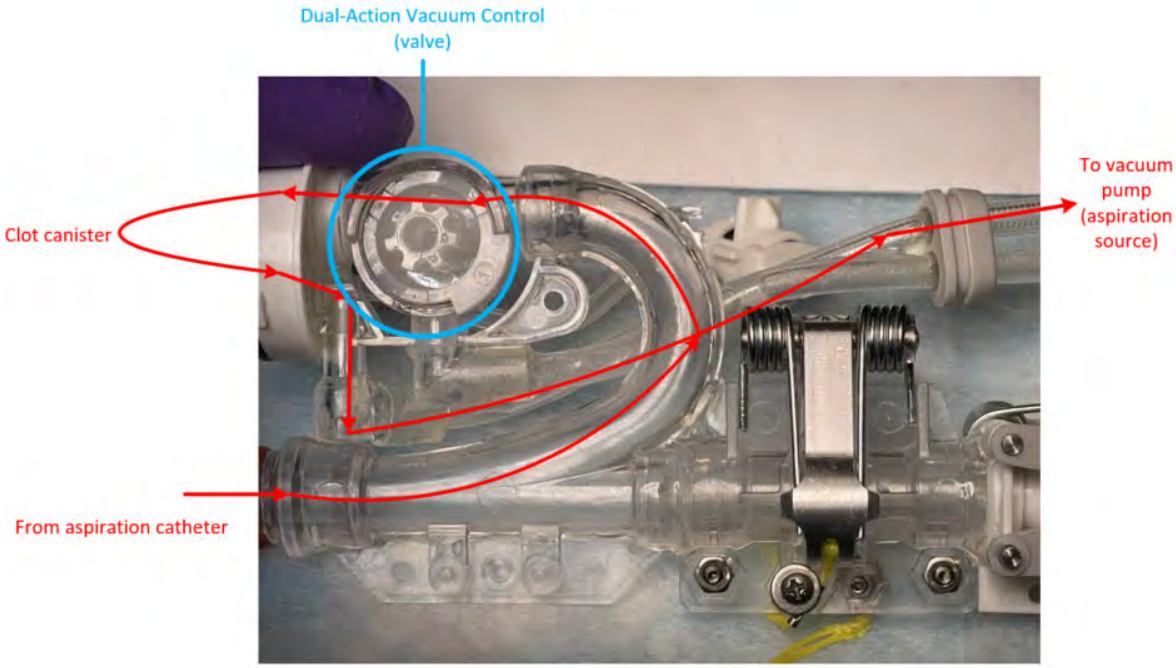
161. As shown in the annotated figure below, moving the lever of the second fluid control device to the "On" position (second position) operates the second fluid control device to fluidly connect the second pressure source to the lumen of the 16F aspiration catheter (second catheter), thereby permitting fluid flow along the fluid path from the lumen of the 16F aspiration catheter (second catheter) to the clot canister.



162. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (second fluid control device). In the annotated photo below, the second fluid control device is in the "On" position (second position).



163. The annotated photo below shows the fluid path between the 16F aspiration catheter (second catheter) to the second pressure source comprising the clot canister and the vacuum pump.



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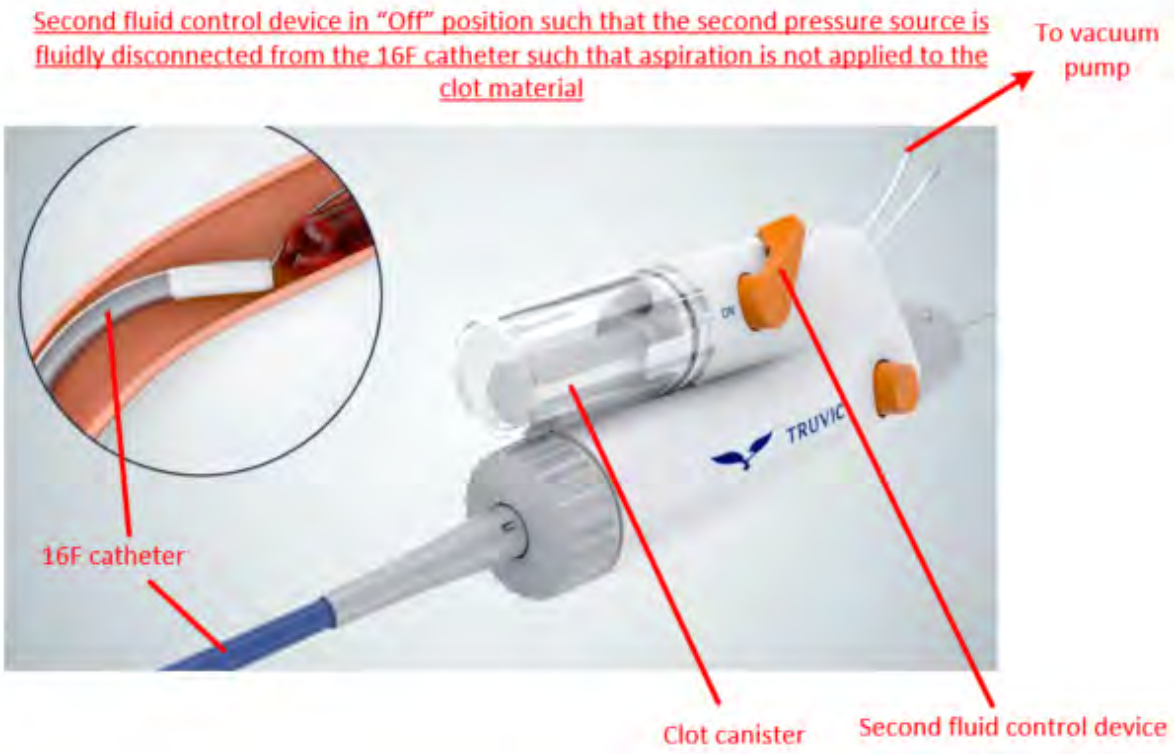
g. [1][f] wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure is applied to the second 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.

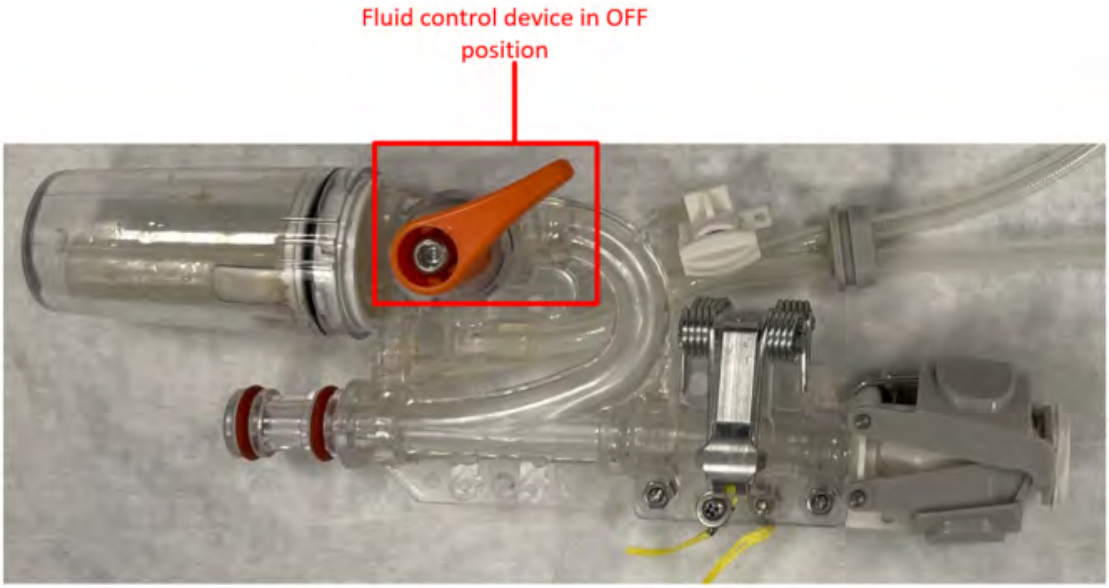
164. Claim 1 additionally recites "wherein the second pressure source is configured to generate vacuum pressure while the second fluid control device is in the first position, and wherein, upon movement of the second fluid control device from the first position to the second position, the vacuum pressure 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."

165. As can be seen in Ex. 17, the Symphony system practices this limitation because Symphony system's second fluid control device is movable between an "Off" position (first position) in which the second fluid control device fluidly disconnects the second pressure source from the 16F aspiration catheter (second catheter), and an "On" position (second position) in which the second fluid control device fluidly connects the second pressure source to the 16F aspiration catheter (first catheter). While the second fluid control device is in "Off" position (first position), the second pressure source comprising the clot canister and vacuum pump generates vacuum pressure, including in the clot canister. Upon movement of the second fluid control device from the "Off" position (first position) to the "On" position (second position), the vacuum pressure, including from the clot canister, is applied to the 16F aspiration catheter (second catheter) to generate suction at the distal portion of the 16F aspiration catheter (second catheter) positioned near the clot material (e.g., pulmonary embolism) to aspirate blood and at least a portion of the clot material (e.g., pulmonary embolism) into the 16F aspiration catheter (second catheter).

166. Specifically, as shown in the annotated figure below, while the second fluid control device is in the "Off" position (first position), vacuum pressure is generated, including in the clot canister, by the second pressure source comprising the clot canister and vacuum pump.



167. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (second fluid control device). The second fluid control device is moved to the off position (first position).



168. As shown in the annotated figures below, moving the second fluid control device from the "Off" position (first position) to the "On" position (second position) applies the

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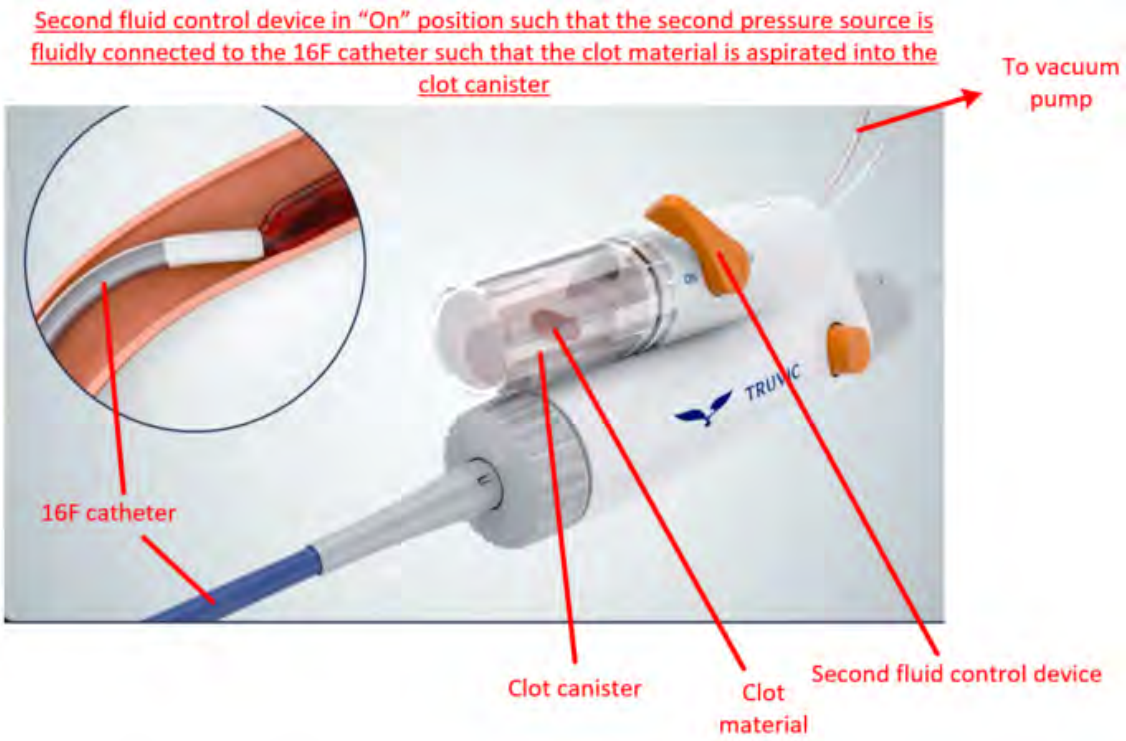
vacuum pressure in the clot canister to the 16F aspiration catheter (second catheter) to generate suction at a distal portion of the 16F aspiration catheter (second catheter) to aspirate blood and at least a portion of the clot material (e.g., pulmonary embolism) into the 16F aspiration catheter (second catheter).



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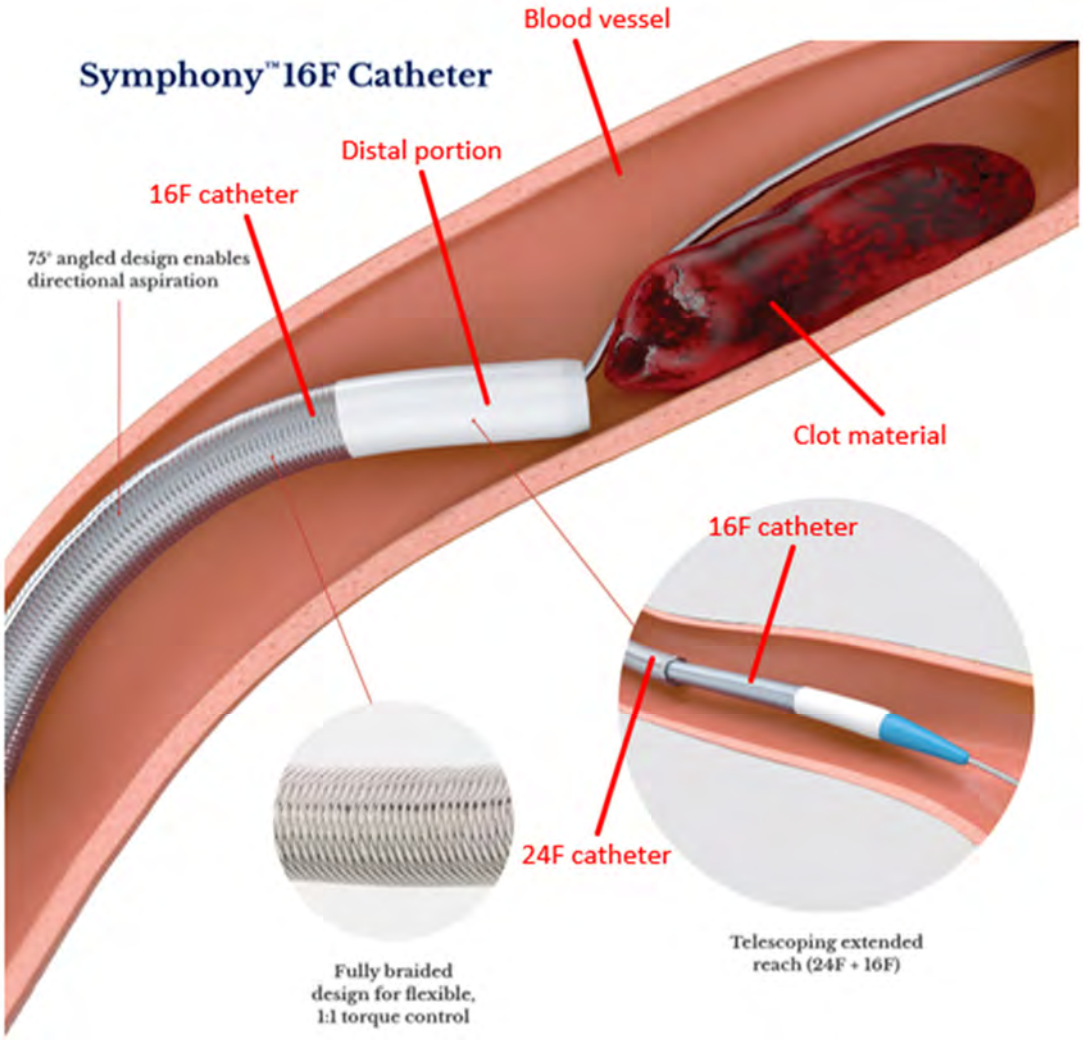

(Annotated Ex. 7 at 4.)

169. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (second fluid control device). In the annotated photo below, the second fluid control device is moved to the "On" position (second position).

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170. In addition, page 8 of the Symphony system Instructions for Use (shown below) describes that while the second fluid control device is in the "Off" position (first position), the second pressure source is configured to generate vacuum pressure of at least -20 inHg. To apply the vacuum pressure to the 16F aspiration catheter (second catheter) in order to begin aspiration (generate suction) at a distal portion of the 16F aspiration catheter (second catheter), the second fluid control device is moved to the "On" position (second position).

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

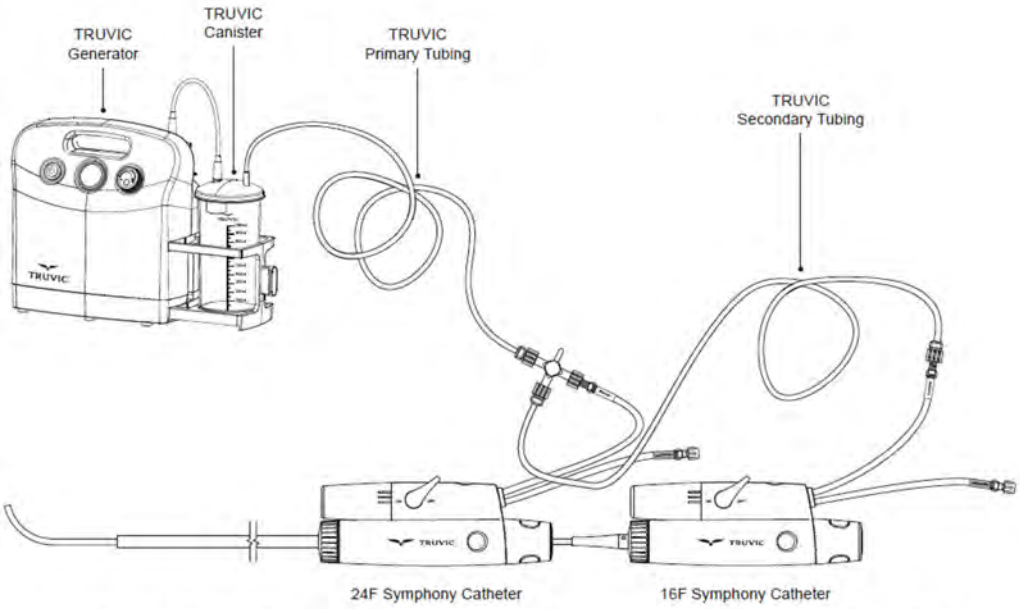

Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

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. 8 at 8.)

171. The Symphony system, specifically the telescoping configuration, practices each limitation of Claim 1 of the '910 Patent.

B. United States Patent 11,844,921 ("'921 Patent")

172. I understand that in this lawsuit Inari is accusing Truvic of infringing the '921 Patent. In particular, Inari alleges that Truvic infringes at least independent Claim 10 of the '921 Patent. I have been asked to analyze the '921 Patent and the Symphony system to provide technical opinions as to whether the Symphony system practices claims of the '921 Patent.

173. As explained below, it is my opinion that the Symphony system practices at least Claim 10 of the '921 Patent. My opinion is consistent with the points made in the claim chart

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attached as Ex. O to the Complaint and Amended Complaint and to the Motion for Preliminary Injunction as Ex. 18. I did not prepare this chart, but I agree with the analysis in it, adopt it as part of my opinions, and further explain the points made in it below.

1. <u>Claim 1</u>

174. I address the preamble and each element of the claims in turn below. Claim 10 depends from Claim 1, so Claim 10 incorporates each and every limitation of Claim 1.

a. 1[pre] A valve, comprising:

175. The preamble of Claim 1 recites a "valve, comprising." I am informed that the question of whether this preamble is limiting (i.e., must be met for there to be infringement) is a legal matter to be decided by the Court. I have not been asked to provide an opinion of whether this preamble is limiting at this stage. For the purposes of this declaration, however, and to be conservative, I have analyzed infringement assuming the preamble is limiting.

176. As can be seen in Ex. 18, the Symphony system practices the preamble because it includes a valve, specifically a hemostasis valve in each of the Symphony handles. These hemostasis valves are used to seal around catheters and/or tools inserted through the handle. The hemostasis valve can be seen in the Symphony documentation, including page 6 of the Symphony Brochure (Ex.7), images of which are annotated below to circle the hemostasis valve:

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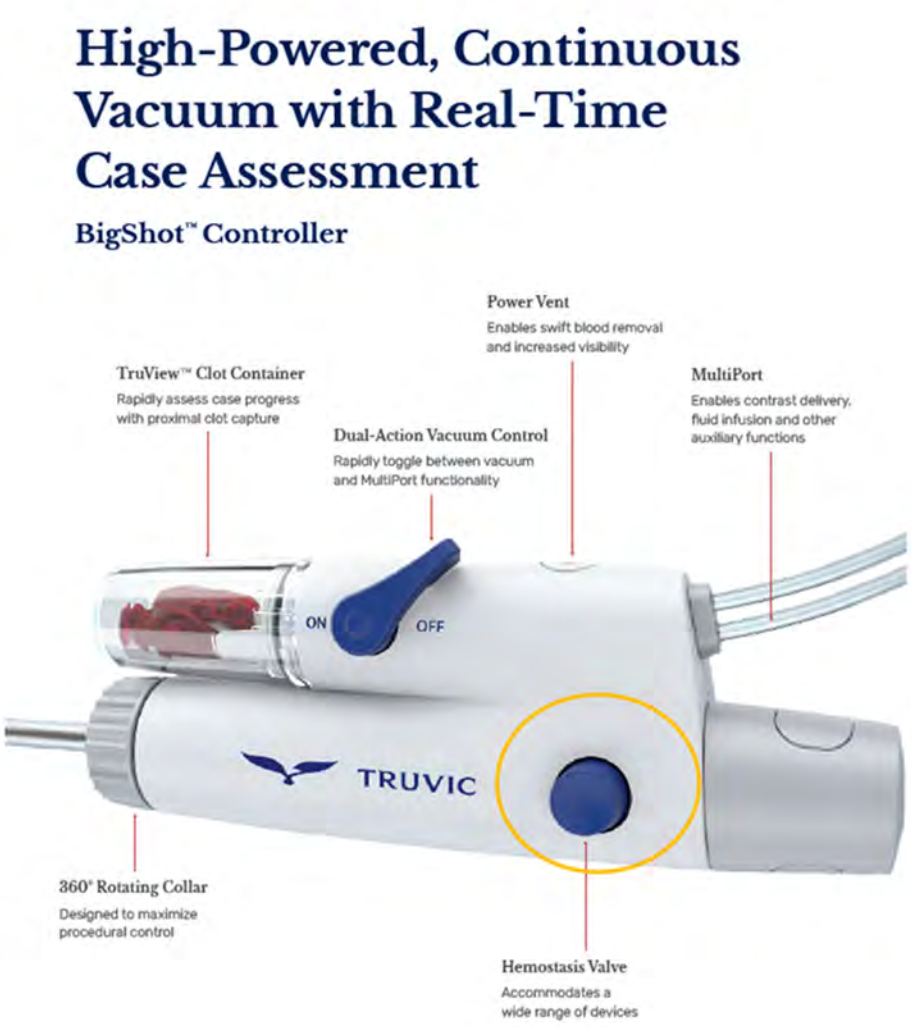

(Annotated Ex. 7 at 2.)

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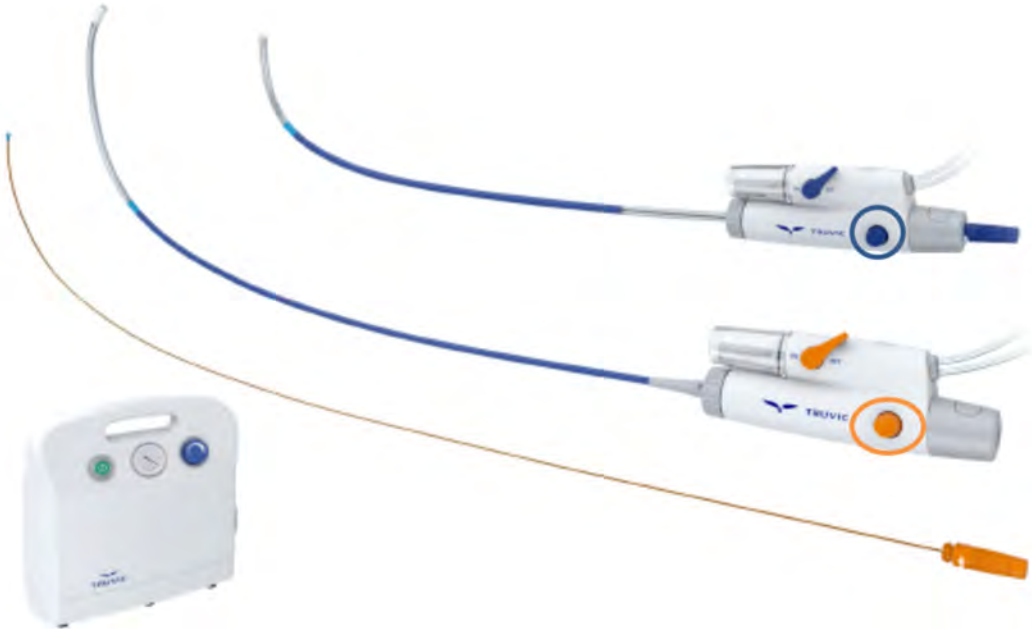

177. Images of the internal portion of the handle with the outer grey/white plastic housing removed and showing the hemostasis valve are below:

(Image of internal portion of housing with hemostasis valve.

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(Internal portion of housing zoomed in on hemostasis valve.)

b. 1[a] an elongate member defining a lumen;

178. Claim 1 recites "an elongate member defining a lumen."

179. As can be seen in Ex. 18, the Symphony system practices this limitation because the hemostasis valve in the Symphony handles is a garrote valve with an elongate tube-shaped portion that is constricted or opened via filaments by actuating the valve. This can be seen in the annotated images of the internal portions of the Symphony handle below:

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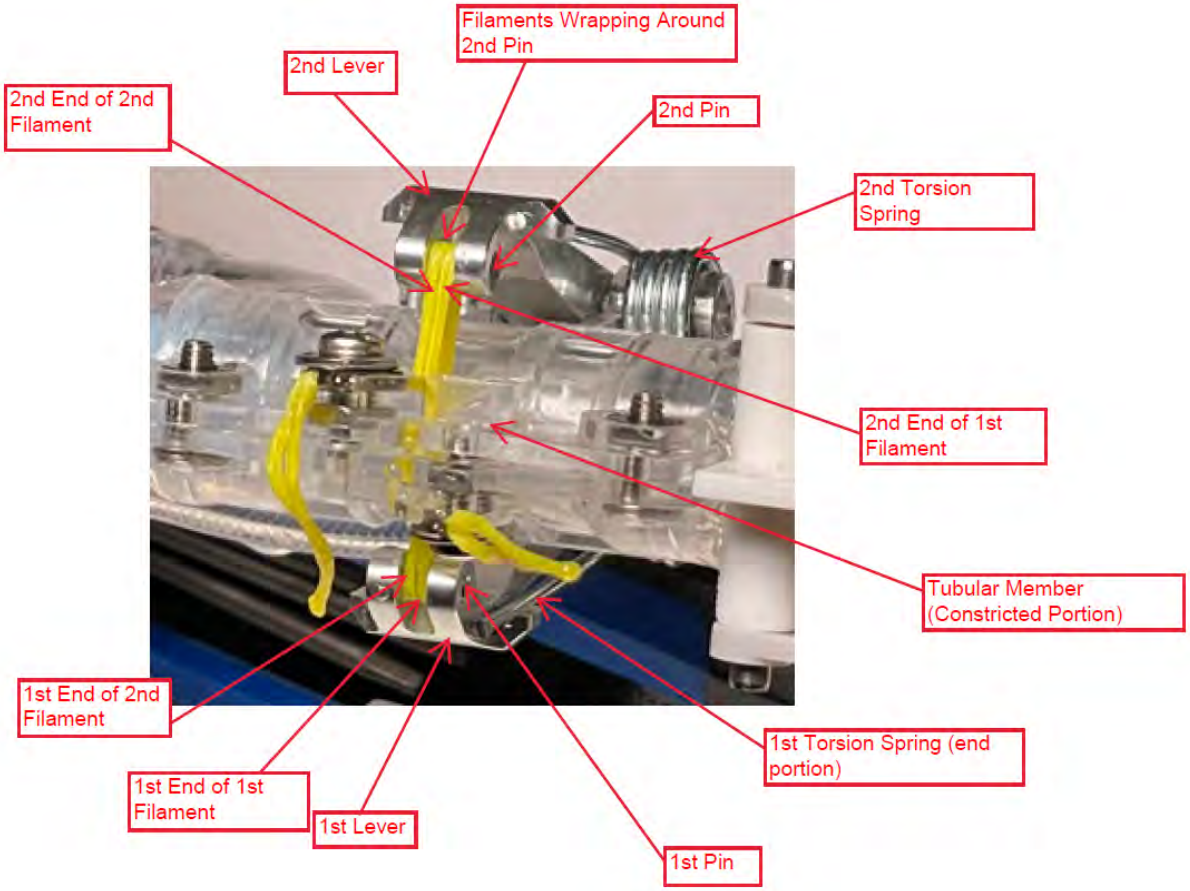

(Annotated image of internal portion of Symphony system handle zoomed in on the hemostasis valve, including the elongate (tubular) member.)

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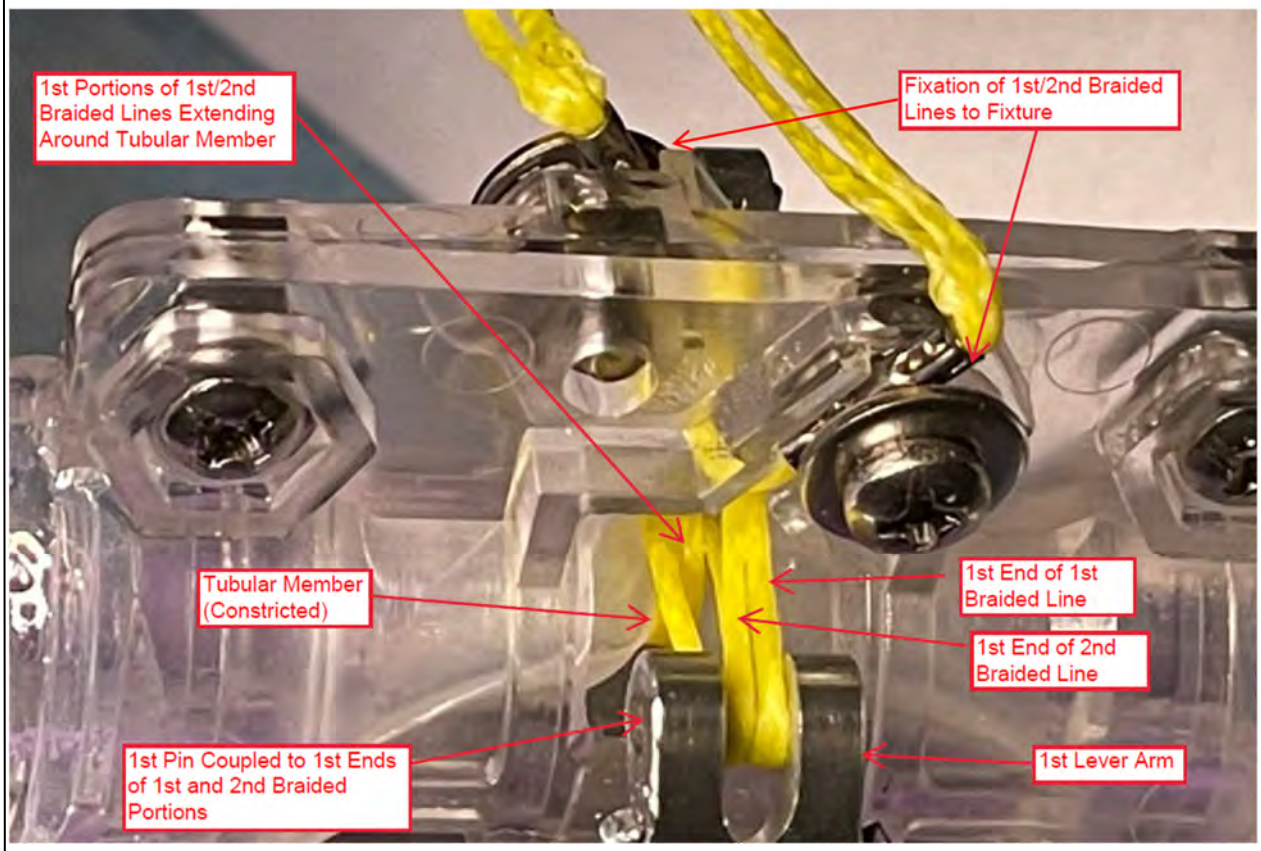

(Annotated image of zoomed in internal portion of Symphony system handle, including a partial view of the hemostasis valve, including the elongate (tubular) member and yellow filaments extending around it.)

180. The lumen of the elongate member can be seen in images looking down the Symphony handle lengthwise, as can be seen below. The yellow filaments wrapped around the outside of the lumen can be seen with the lumen in a constricted (button undepressed) position.

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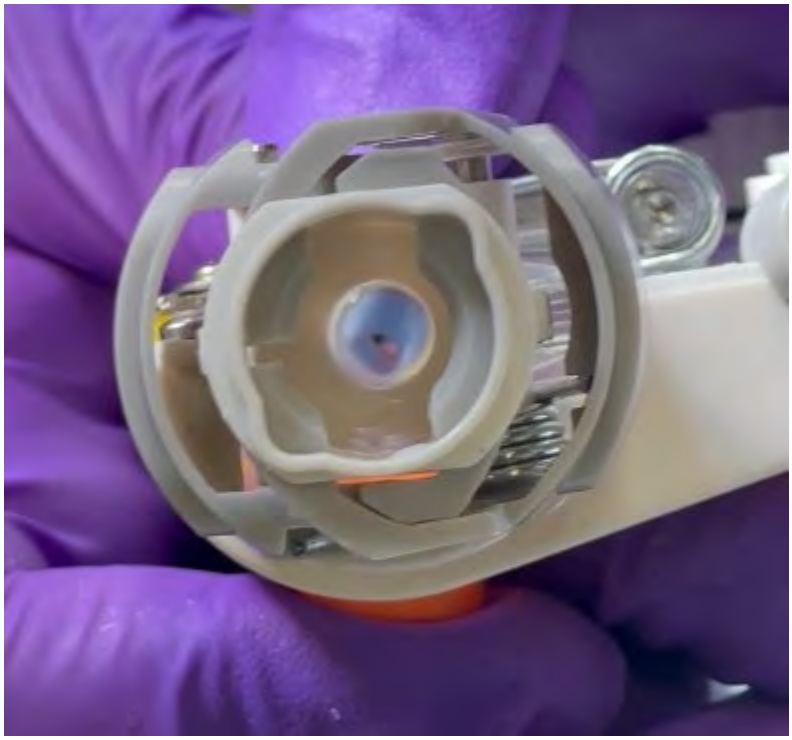
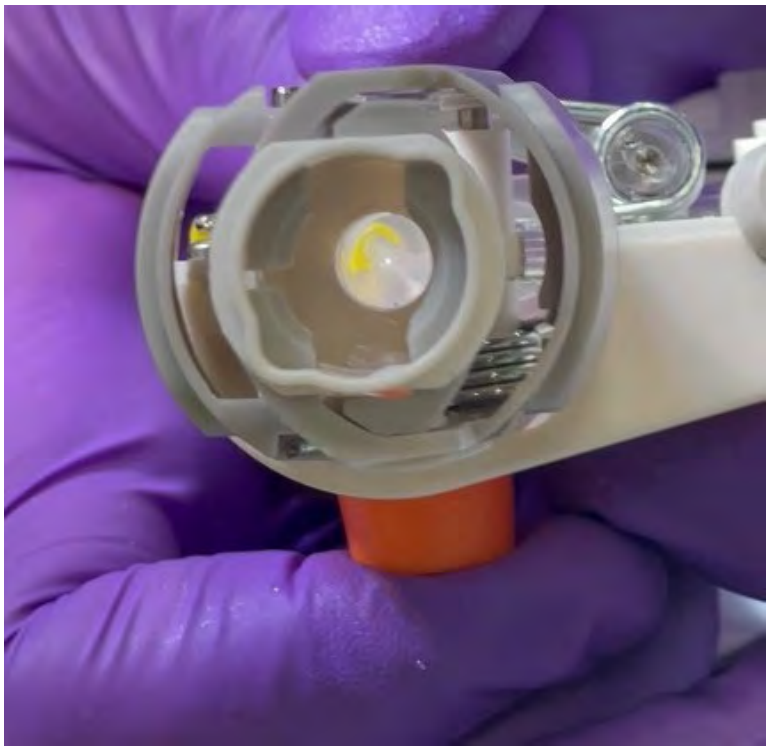


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)



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

c. 1[b] 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;

181. Claim 1 further recites "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."

182. As can be seen in Ex. 18, the Symphony system practices this limitation because the hemostasis valve in the Symphony handle has an active tensioning mechanism including a first actuator (a first button, first lever, and first pin) that is coupled to the elongate member via a first filament that wraps around the elongate member, and the filament wraps around the first pin in the first actuator. The first actuator (first button, first lever, and first pin) are moveable between a first position (undepressed button) where the lumen of the elongate member is constricted (by the filament(s) being pulled tighter) and a second position (depressed button) where the lumen of the elongate member is at least partially open (by depressing the first button the first lever is pushed against a set of torsion springs, decreasing the tension on the filament(s) and at least partially opening the lumen). (The active tensioning mechanism for the Symphony system hemostasis valve comprises two actuators, and, as will be discussed below, includes both a second filament, and a second actuator (a second button, second lever, and second pin).) This active tensioning mechanism can be seen in the annotated images of the Symphony Handle below, although in some of the images the buttons are not shown because the outer plastic portion of the Symphony handle was removed in order to capture images of the internal portion of the handle with the hemostasis valve structures:

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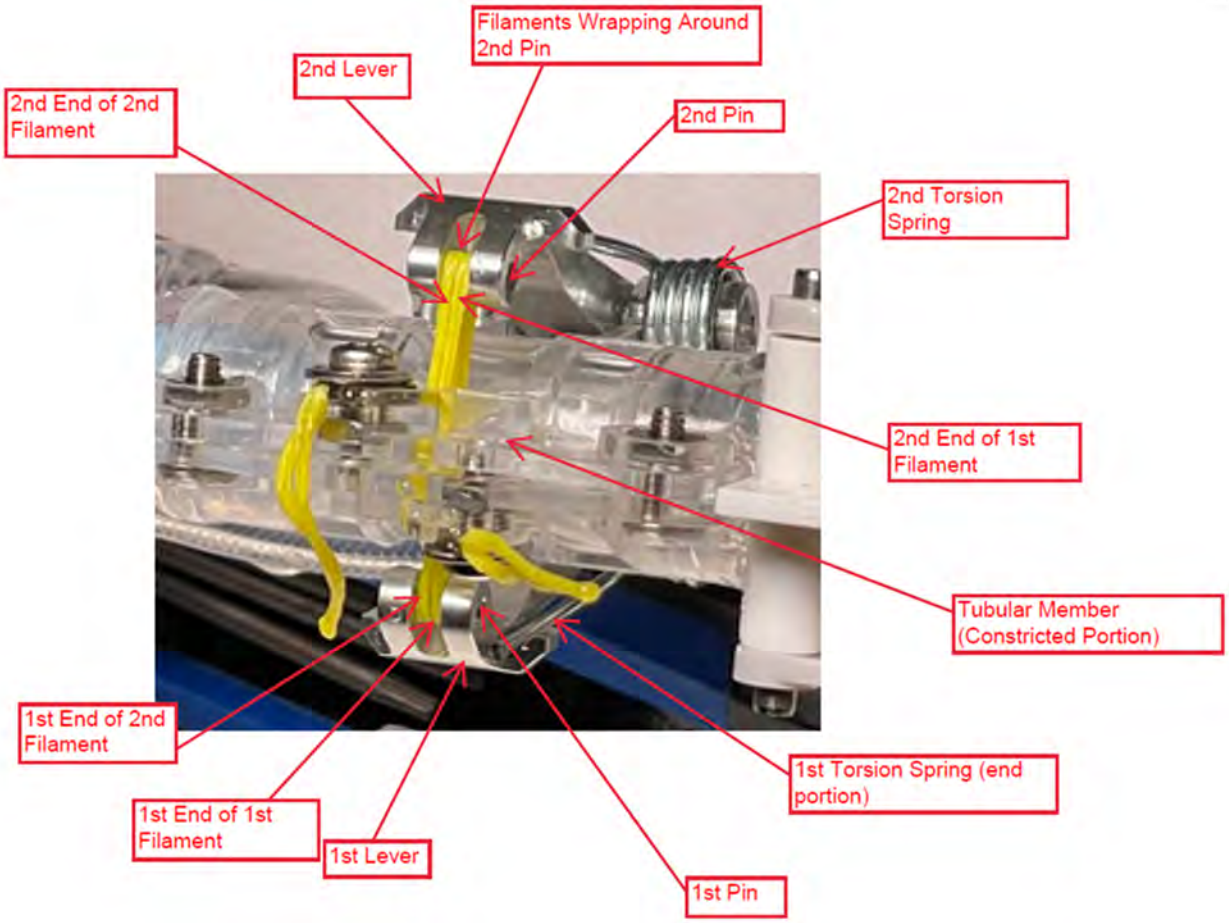

(Annotated image of internal portion of Symphony system handle zoomed in on the hemostasis valve, including the first lever and first pin of the first actuator coupled via filaments to the elongate (tubular) member of the valve.)

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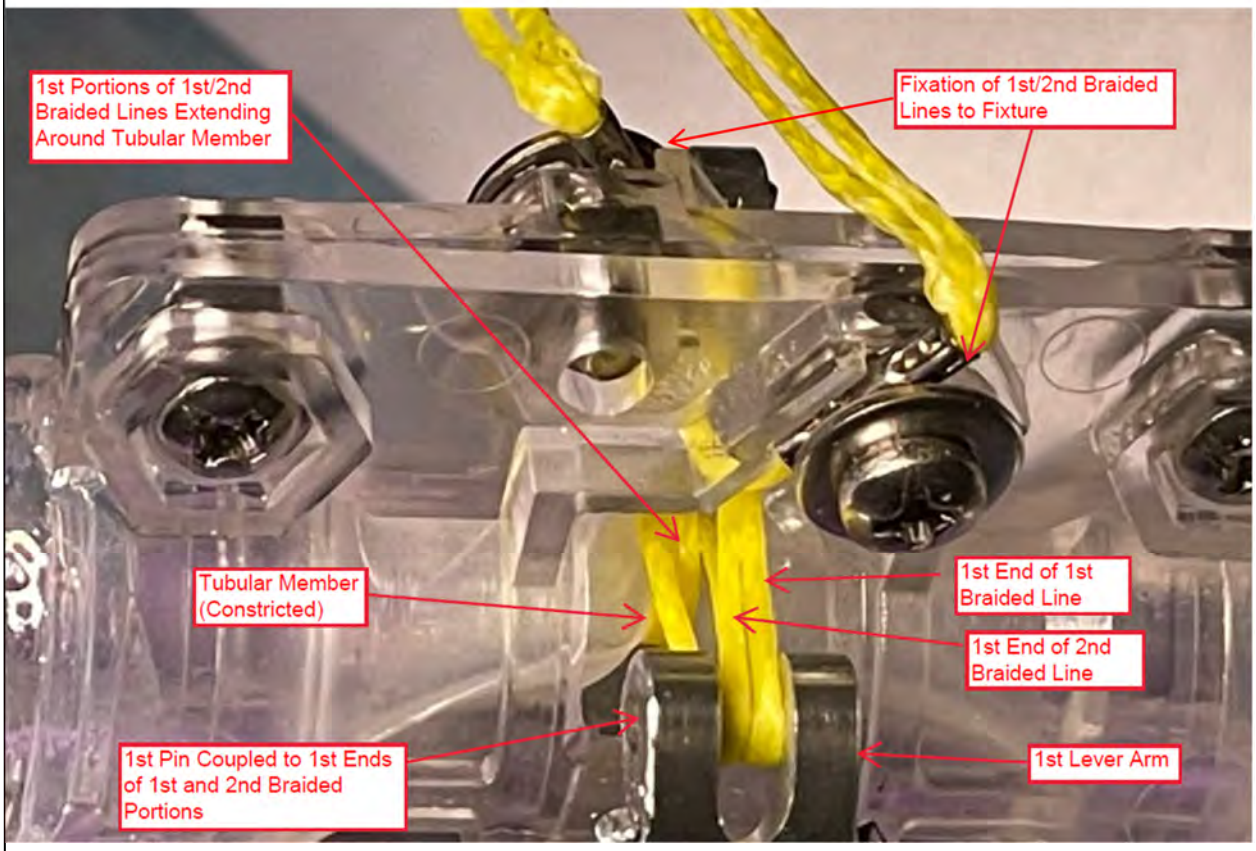

(Annotated image of internal portion of Symphony system handle zoomed in on a partial view of the hemostasis valve, including the end of first lever and first pin of the first actuator coupled via filaments to the elongate (tubular) member of the valve.)

183. The lumen of the elongate member can be seen in images looking down the Symphony handle lengthwise, as can be seen below. In the first position (undepressed button) the hemostasis valve is constricted by the yellow filaments wrapped around the outside of the lumen. In the second position (depressed button) the lumen of the hemostasis valve is not as constricted and is at least partially open.

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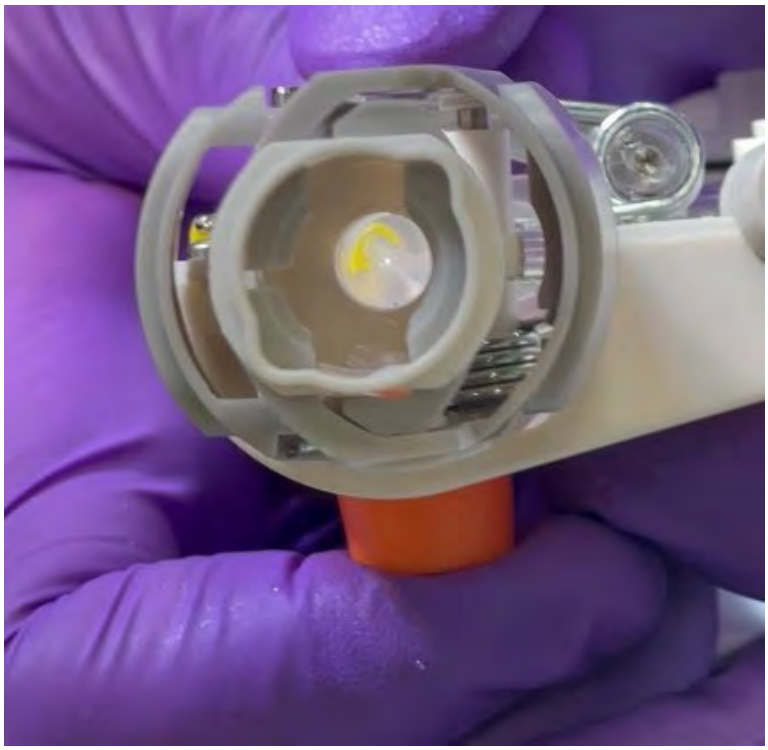
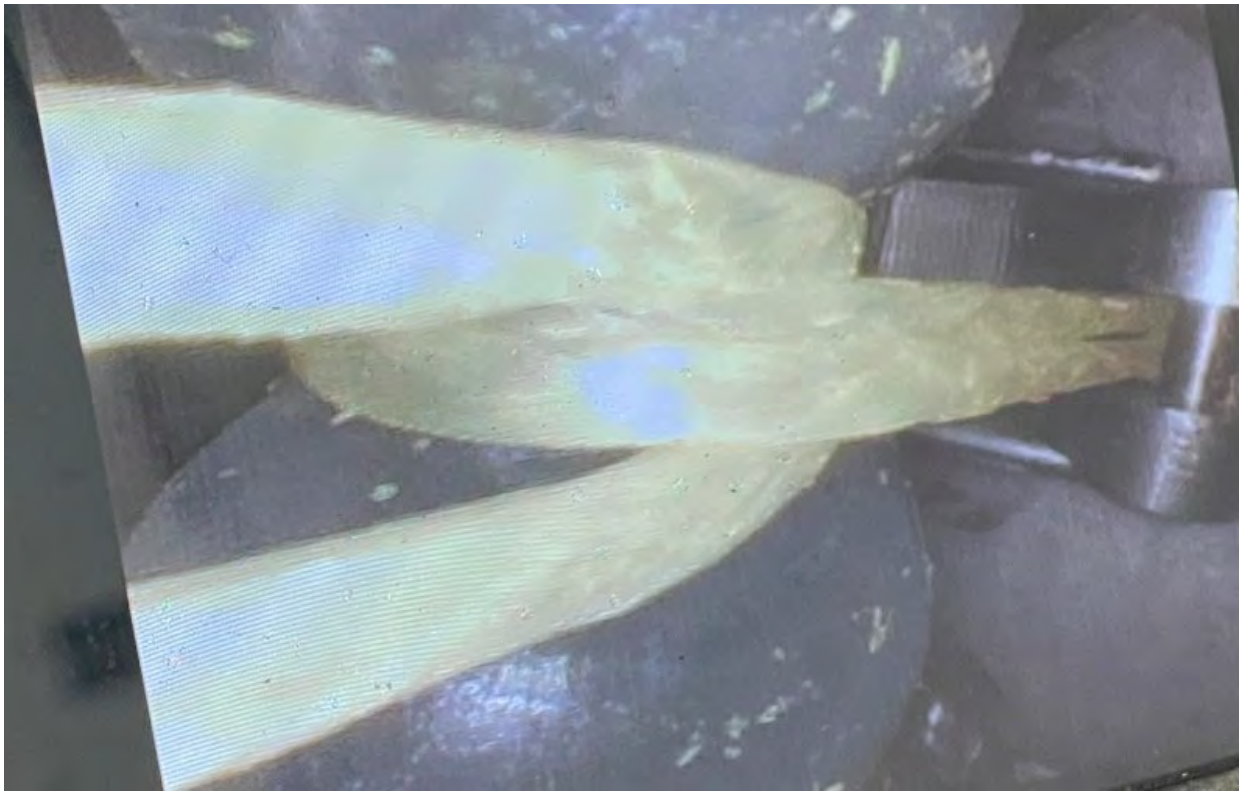


(Symphony handle with view down lumen of hemostasis valve with valve lumen constricted.)



(Internal image of side view of elongate (tubular) member of the hemostasis valve with filaments encircling and constricting elongate member.)

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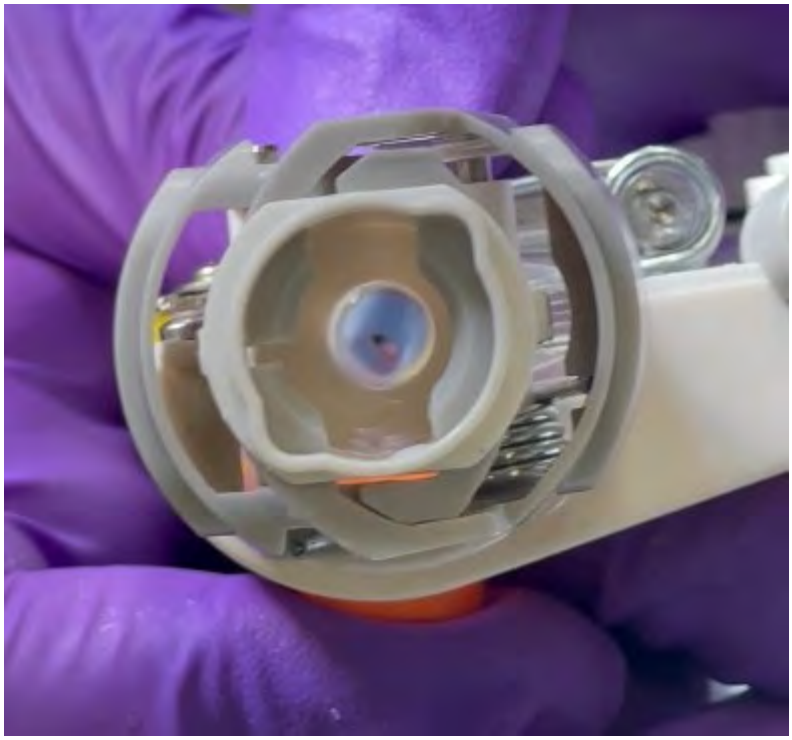
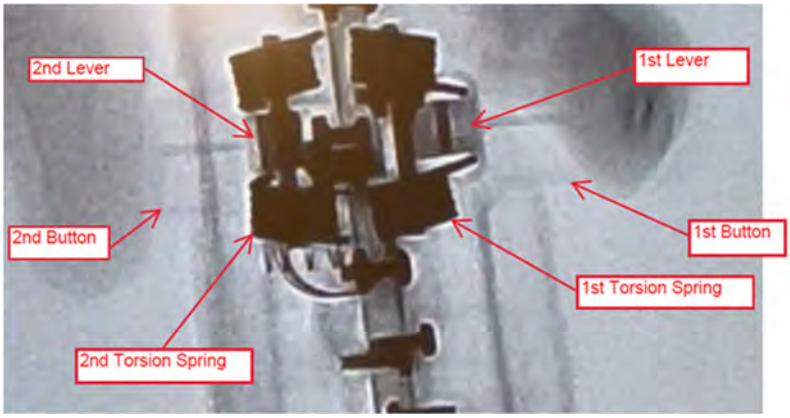


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

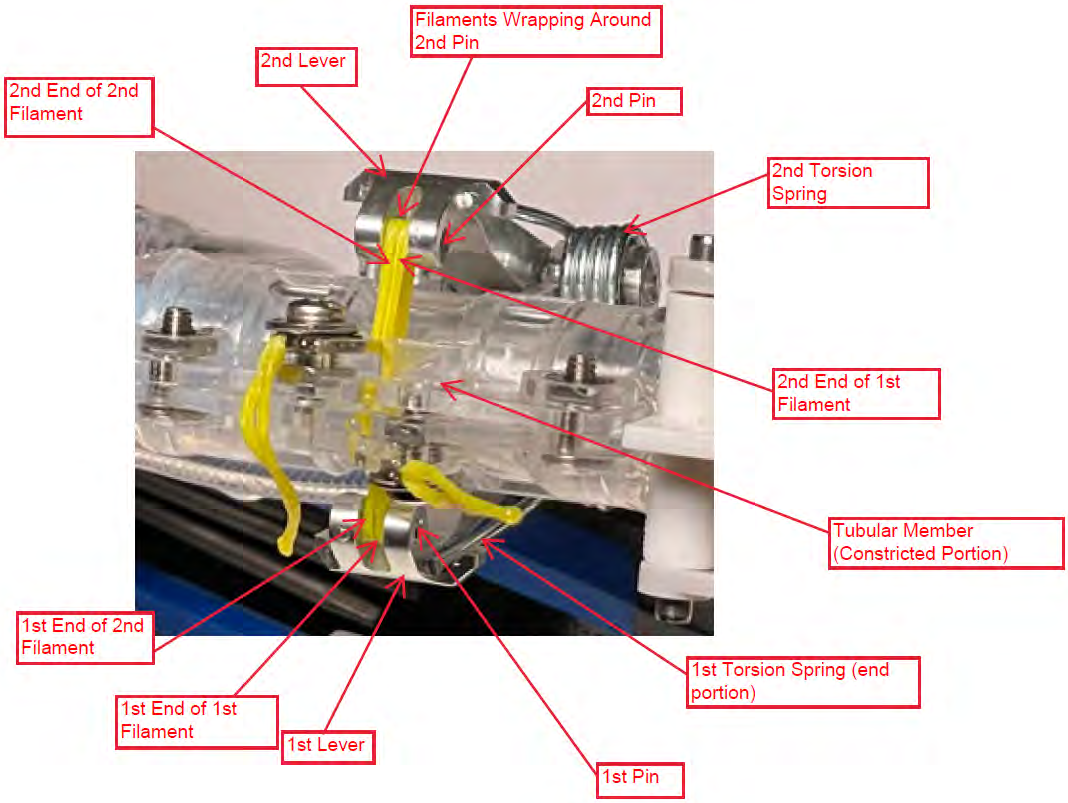
d. 1[c] a biasing member configured to bias the actuator to the first position.

184. Claim 1 also recites "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."

185. As can be seen in Ex. 18, the Symphony system practices this limitation because the hemostasis valve in the Symphony handles has a first biasing member, first torsion spring(s) (there are two torsion springs for each of the first actuator and the second actuator) that pushes the first lever of the first actuator outward thus pulling on the filaments and constricting the lumen of the hemostasis valve. The torsion springs drive the first lever outward to the first position (undepressed button). This can be seen in the annotated images below:



(X-ray imaging of Symphony handle showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs, as part of active tensioning mechanism with the first button in the first (undepressed, constricted) position.)



(Annotated image of internal portion of Symphony system housing zoomed in on the hemostasis valve, showing a portion of the first torsion springs for the first lever, and the first lever and the second lever of the first and the second actuators biased to the first (constricted, undepressed button) position.)

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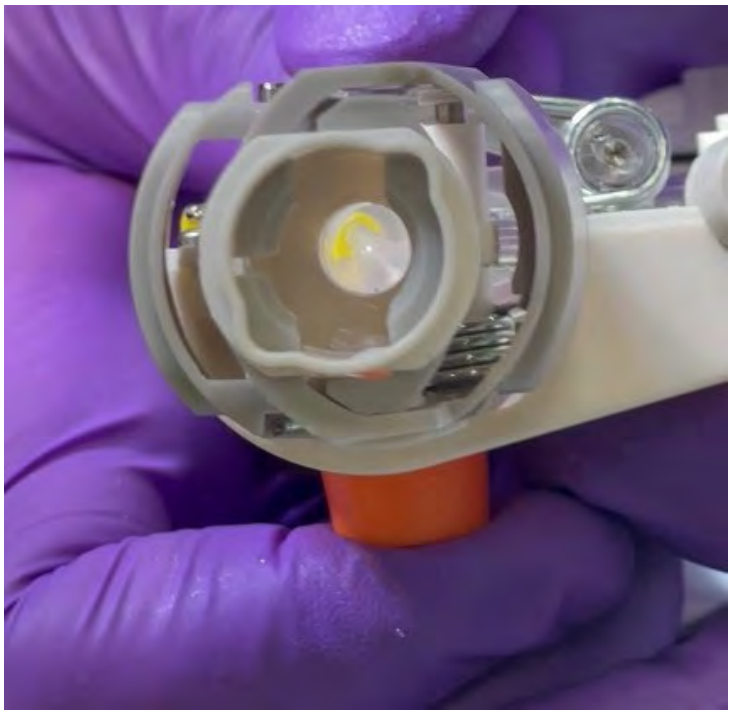
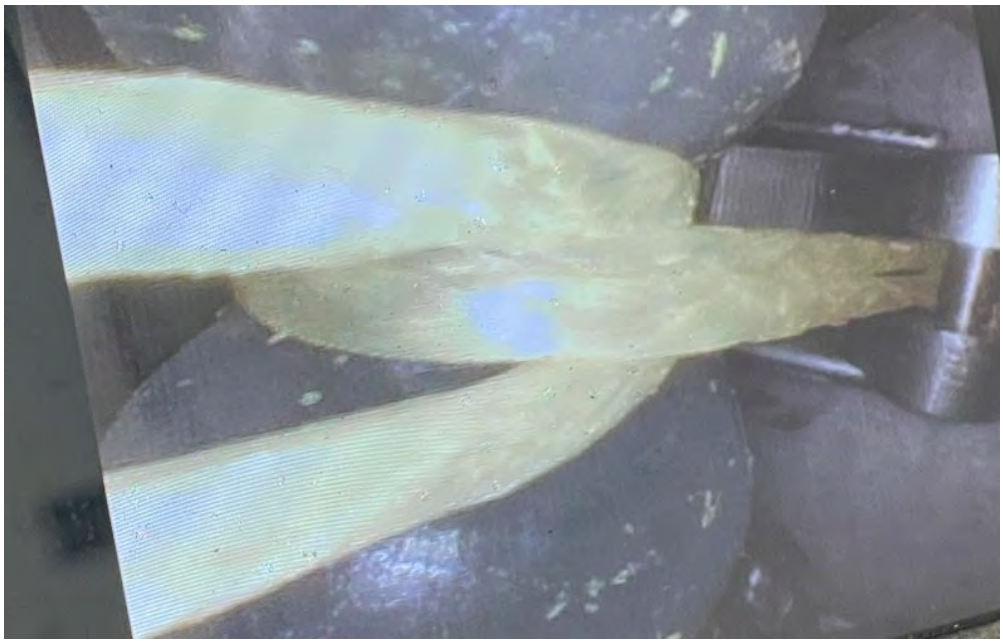


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted and the first actuator (the first button, first lever and first pin biased to the first position (constricted, button undepressed).)



(Internal image of side view of elongate (tubular) member of the hemostasis valve with filaments encircling and constricting elongate member in the first (undepressed button) position.)

186. The Symphony system, specifically the hemostasis valve of the Symphony handle

practices each limitation of Claim 1 of the '921 Patent.

2. Claim 10

a. 10[a] 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:

187. Claim 10 of the '921 Patent depends from Claim 1 and incorporates all elements of Claim 1. Claim 10 recites, "[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…."

188. As set forth above with respect to Claim 1, and as shown in Ex. 18, the Symphony system practices the preamble of Claim 10 because the hemostasis valve in the Symphony system includes a first actuator (a first button, a first lever, and first pin) as part of an active tensioning mechanism having a first biasing member (the first torsion springs driving the first lever), and a first (yellow braided line) filament that wraps around the first pin and wraps around the elongate (tubular) member of the hemostasis valve. As discussed below, the Symphony system further has a second actuator (a second button, second lever, and second pin) as part of the active tensioning mechanism having a second biasing member (the second torsion springs driving the second lever), and a second filament (yellow braided line) that wraps around the second pin and around the elongate tubular member of the hemostasis valve.

b. 10[b] 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;

189. Claim 10 further recites, "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."

190. As can be seen in Ex. 18, the Symphony system practices this limitation because the hemostasis valve in the Symphony handles has an active tensioning mechanism including a

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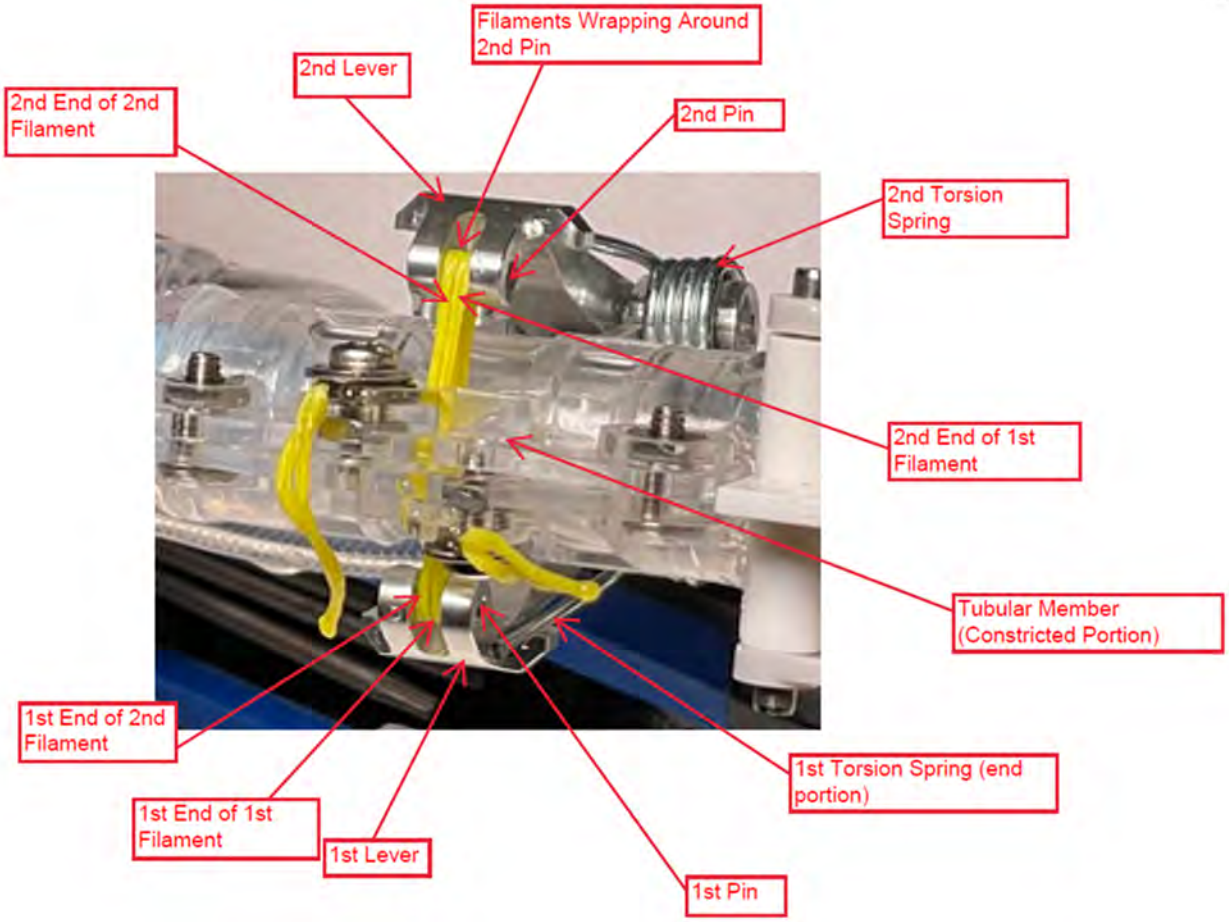
first actuator (a first button, first lever, and first pin) that is discussed above, and a second actuator that is coupled to the elongate member via a second filament that wraps around the elongate member, and the filament wraps around the second pin in the second actuator. The second actuator (second button, second lever, and second pin) are moveable between a first position (undepressed button) where the lumen of the elongate member is constricted (by the filament(s) being pulled tighter) and a second position (depressed button) where the lumen of the elongate member is at least partially open (by depressing the first button, the first lever is pushed against a set of torsion springs, decreasing the tension on the filament(s) and at least partially opening the lumen). This active tensioning mechanism can be seen in the annotated images of the Symphony Handle below, although in some of the images the buttons are not shown because the outer plastic portion of the Symphony handle was removed in order to capture images of the internal portion of the handle with the hemostasis valve structures:



(Annotated image of internal portion of Symphony system handle zoomed in on the hemostasis

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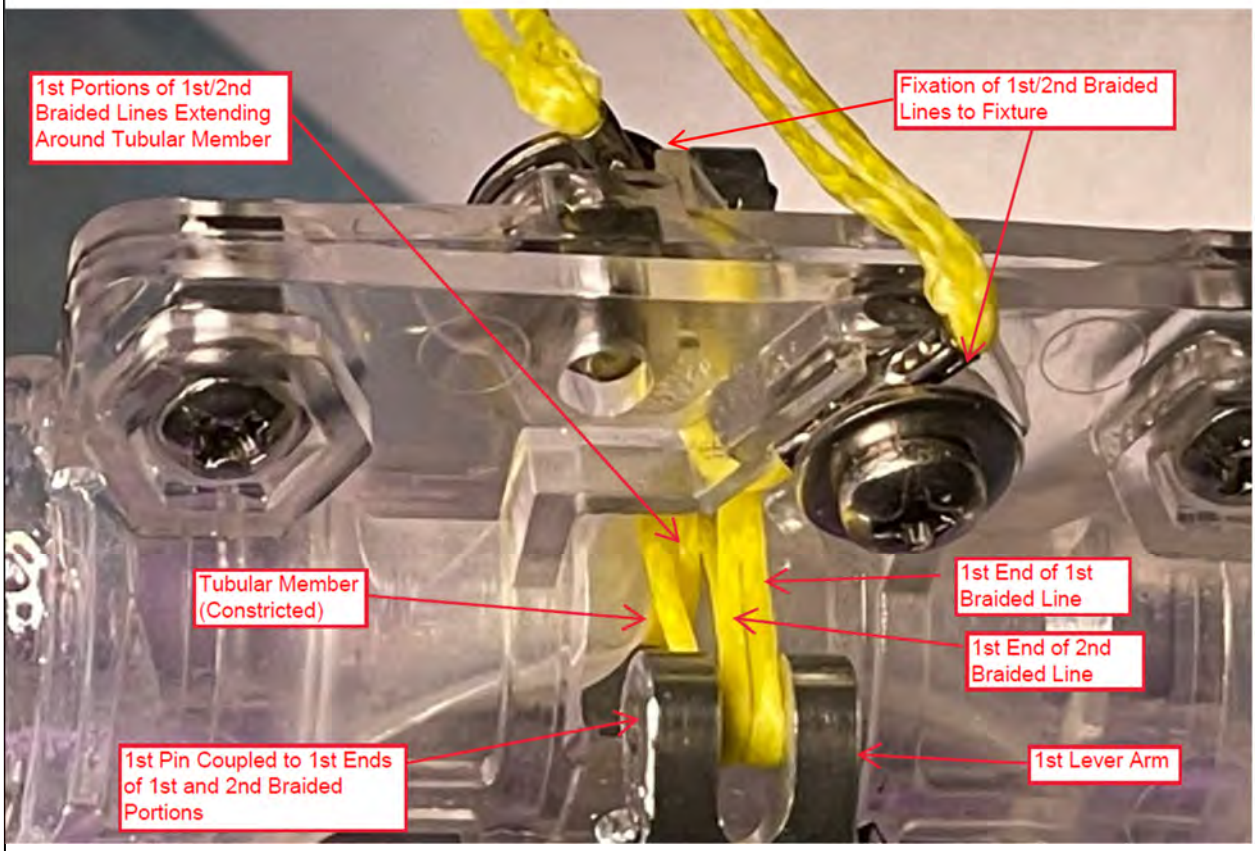
valve, including the first lever and first pin of the first actuator coupled via filaments to the elongate (tubular) member of the valve.)



(Annotated image of internal portion of Symphony system handle zoomed in on a partial view of the hemostasis valve, showing a portion of the first actuator and the first and second filaments wrapped around the first pin of the first actuator and the second pin of the second actuator (not shown).)

191. The lumen of the elongate member can be seen in images looking down the Symphony handle lengthwise, as can be seen below. In the first position (undepressed button) the hemostasis valve is constricted by the yellow filaments wrapped around the outside of the lumen. In the second position (depressed button) the lumen of the hemostasis valve is not as constricted and is at least partially open.

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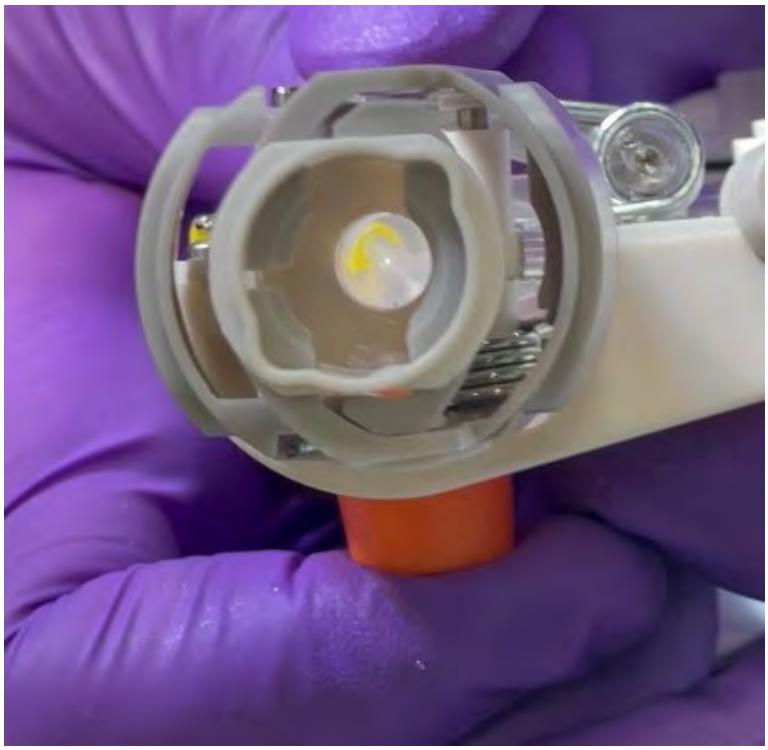
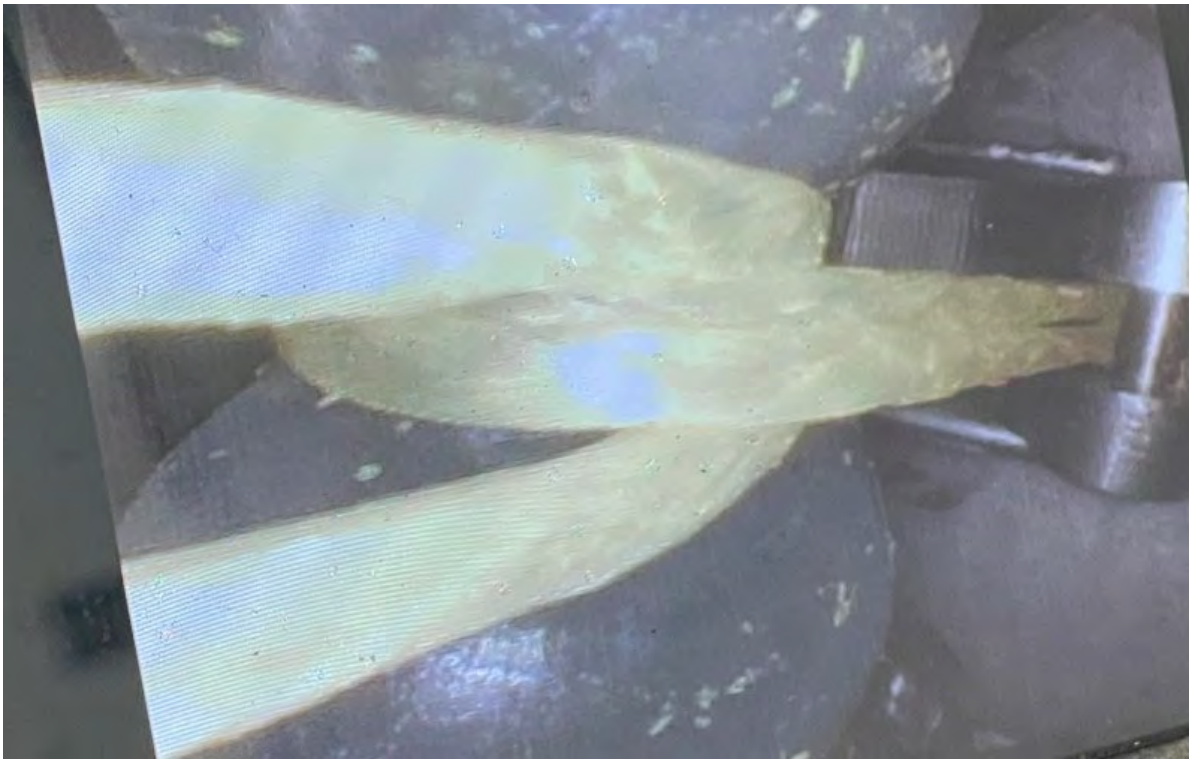
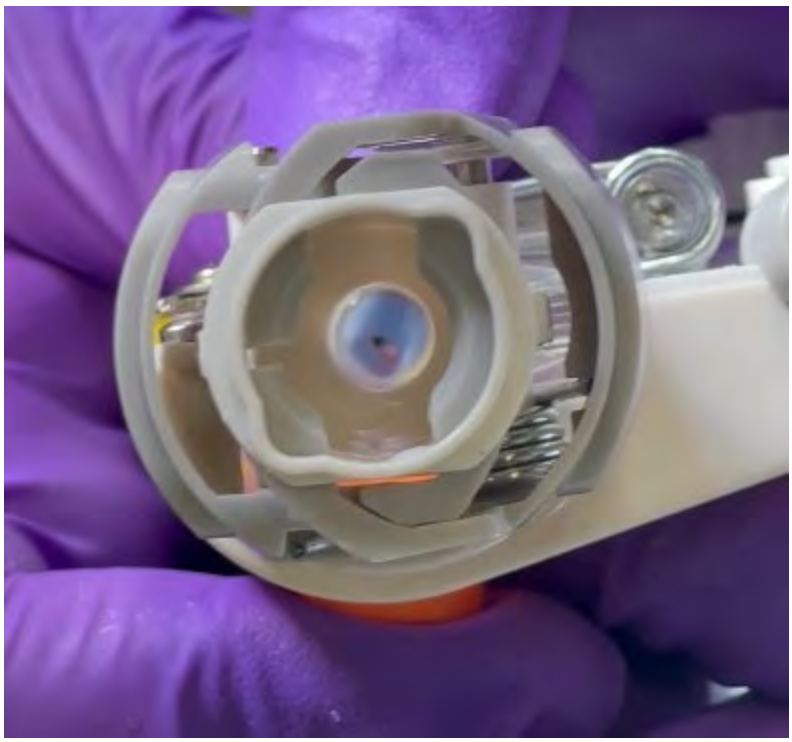


(Symphony handle with view down lumen of hemostasis valve with valve lumen constricted.)



(Internal image of side view of elongate (tubular) member of the hemostasis valve with first and second filaments encircling and constricting elongate member.)

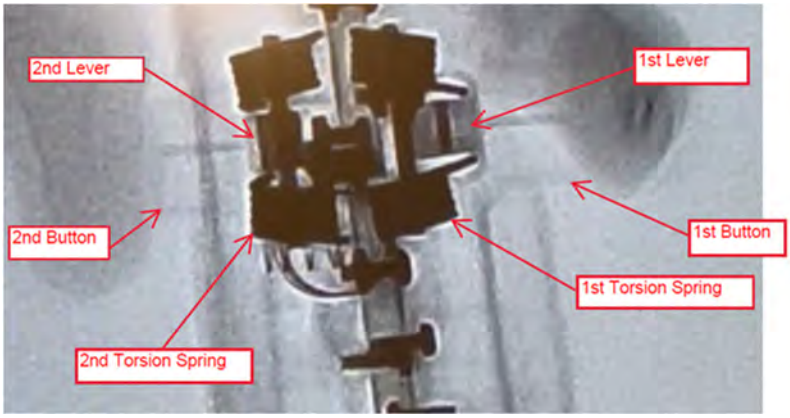


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve lumen open.)

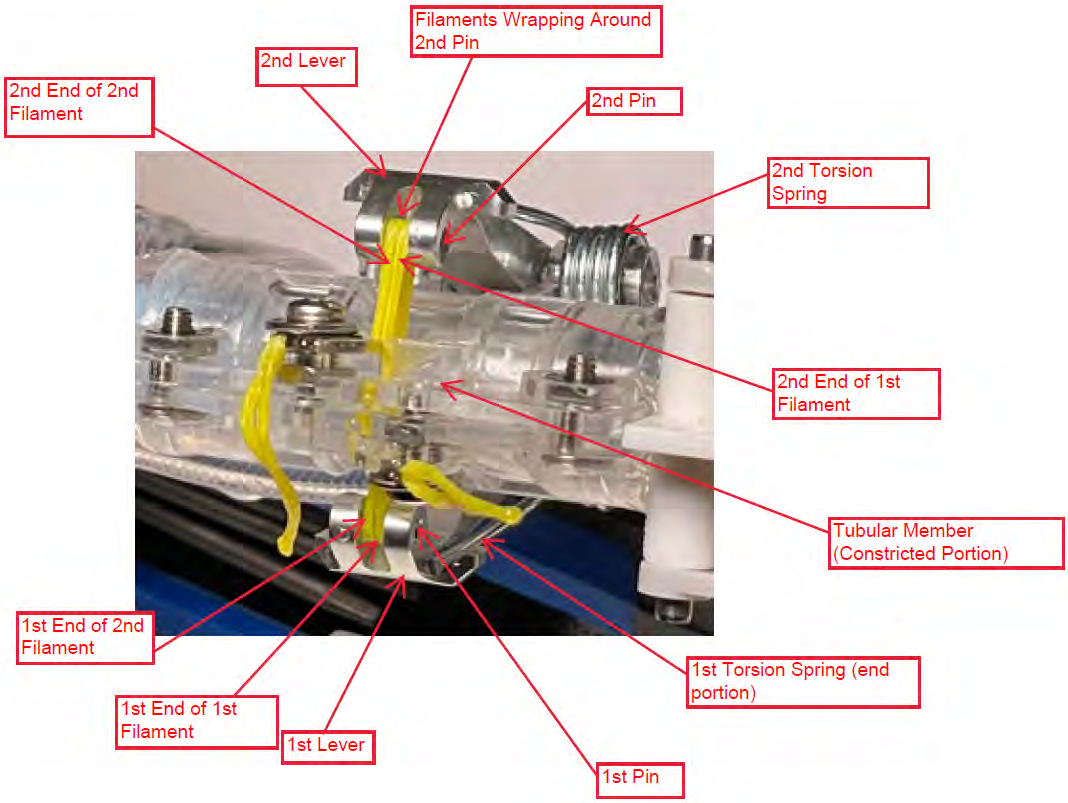
c. 10[c] a second biasing member configured to bias the second actuator to the first position.

192. Claim 10 additionally recites, "a second biasing member configured to bias the second actuator to the first position."

193. As can be seen in Ex. 18, the Symphony system practices this limitation because the hemostasis valve in the Symphony handles has an active tensioning mechanism with a second actuator and a second biasing member, second torsion spring(s) (there are two torsion springs for each of the first actuator and the second actuator) that pushes the second lever of the second actuator outward thus pulling on the filaments and constricting the lumen of the elongate member of the hemostasis valve. The torsion springs drive the second lever outward to the first position (undepressed button). This can be seen in the annotated images below:



(X-ray imaging of Symphony handle showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs, as part of active tensioning mechanism with the first and second buttons in the first (undepressed, constricted) position.)



(Annotated image of internal portion of Symphony system housing zoomed in on the hemostasis valve, showing a portion of the first torsion springs for the first lever, and the first lever and the second lever of the first and the second actuators biased to the first (constricted, undepressed button) position.)

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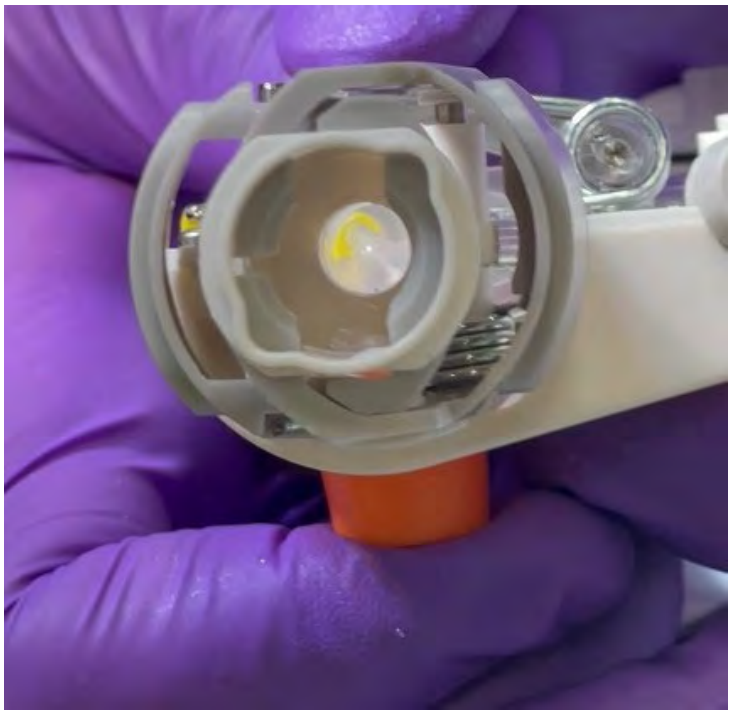
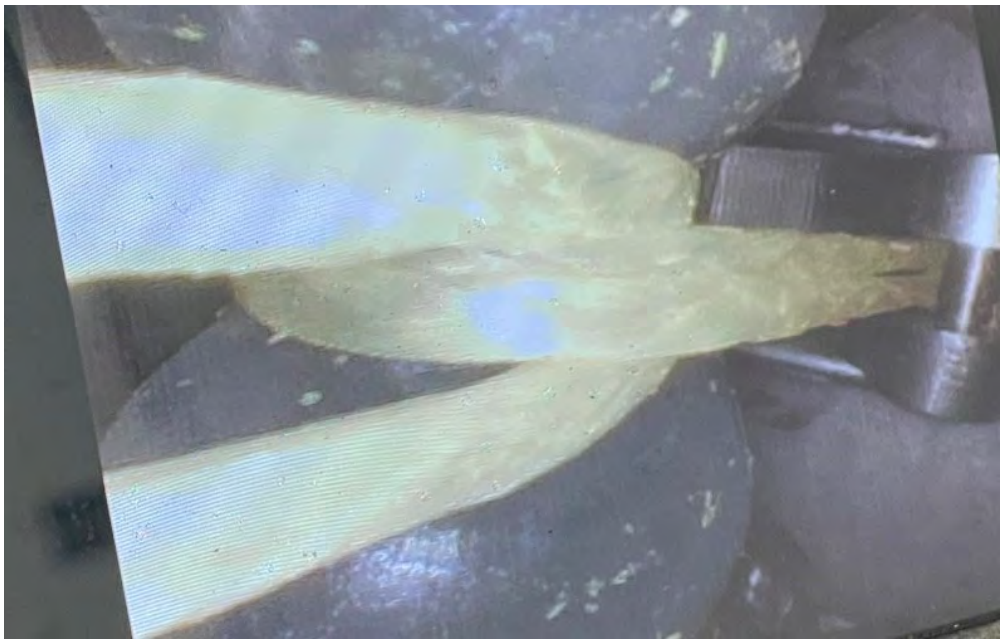


(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted and the second actuator (the second button (removed for picture), second lever and second pin biased to the first position (constricted, button undepressed).)



(Internal image of side view of elongate (tubular) member of the hemostasis valve with filaments encircling and constricting elongate member in the first (undepressed button) position.)

194. The Symphony system, specifically the hemostasis valve of the Symphony handle

practices each limitation of Claims 1 and 10 of the ’921 Patent.

XI. VALIDITY OPINIONS

195. I have further been asked to evaluate whether the ’910 Patent and the ’921 Patent are valid, including over the prior art identified by Truvic to date. Based on the information currently available to me and my knowledge as a person of extraordinary skill in the art, and recognizing that I have not yet received any full statement of Truvic’s invalidity contentions, it is my opinion at this time that Claim 1 of the ’921 Patent and Claims 1 and 10 of the ’910 Patent are valid. Additionally, I have seen nothing that suggests that there is any “substantial question of invalidity,” which is what I understand that Truvic must show in the context of a preliminary injunction motion. In reaching these opinions, I have reviewed and considered all prior art references that I am informed that Truvic has identified to date, and none of those references change my opinion that the three claims involved here are not anticipated or obvious.

196. I understand that Inari communicated with Truvic to put Truvic on notice of potential infringement of Inari’s patents before filing this lawsuit. I further understand that Truvic identified certain prior art in response. Specifically, Truvic identified United States Published Application No. 2015/0173782 (“Garrison I”) and 2016/0220741 (“Garrison III”) as supposedly better than any prior art of record in patents related to the ’910 Patent and that Truvic identified United States Patent Publication No. 2003/0116731 (“Hartley”) and/or United States Published Application No. 2003/0225379 (“Schaffer”) as supposedly better than any prior art of record in the ’921 Patent or other patents related to it. I discuss these references below, in addition to commenting more generally on Inari’s innovations over the available thrombectomy devices at the time that Inari began its work.

197. I further understand that Truvic has filed an *inter partes* review challenging the validity of the ’011 Patent, which is related to the ’921 Patent, asserting that Schaffer alone, Schaffer in combination with Hartley or U.S. Patent No. 9,980,813 (“Eller”), and Hartley in combination with Eller, invalidates claims of the ’011 Patent. I address the Eller reference below as well.

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A. The '910 Patent

1. Challenges Faced by Inari

198. Before Inari's development of large catheter aspiration-based mechanical thrombectomy devices, nearly all of the FDA-approved aspiration and mechanical thrombectomy devices on the market were designed for removing clots from smaller vasculatures such as the neurovasculature, including the cerebral arteries, and the coronary vasculature. In fact, I am not aware of any aspiration-based thrombectomy devices marketed specifically for VTE before Inari launched its FlowTriever and ClotTriever products.

199. As discussed in Technology Background section above, neurovascular arteries average between about 3-6mm in diameter, while coronary arteries are between about 1.5-5mm in diameter in most people. These vasculatures are very small compared to deep leg veins and pulmonary vasculatures, with the main trunk of the pulmonary artery averaging about 27mm in diameter and peripheral vasculatures associated with DVT averaging about 6-11mm in diameter. A cylindrical blood vessel that has twice the cross-sectional diameter has approximately four times the cross-sectional area. Interventional thrombectomy in large vasculatures pose different challenges than that in small vasculatures, so smaller diameter catheter thrombectomy devices designed for neurovascular applications and coronary vasculature cannot be easily adapted for peripheral and pulmonary vasculatures.

200. For example, as mentioned in Technology Background section above, clots in cerebral and coronary arteries are, by necessity, typically diagnosed and removed soon after they form, while clots in peripheral and pulmonary vasculatures typically remain in the blood vessels for quite a while before they are diagnosed and removed. Newer, softer clots are less fibrous and sticky, but as a clot remains in place it becomes more organized, more fibrous, and stickier, and strongly adheres to the vessel walls. This means that treating the typically older, larger, and more organized DVT and PE clots strongly benefit from a significantly larger suction area (a catheter with larger cross-sectional area) and more suction force to remove because the clots are not easy to deform and suck up in smaller globs.

201. In addition, the location of DVT and PE as well as the structure of the peripheral

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and pulmonary vasculatures mean that these blood clots can be harder to reach and remove. For example, DVT are often located deep in the veins of the limbs, while pulmonary vasculatures branch like a tree, resulting in clots in multiple vessels with complex geometries that are unlike smaller arterial or neuro clots. In the case of PE, the catheter needs to be advanced through multiple chambers of the heart before reaching the pulmonary vasculature. This means that the larger catheters to remove DVT and PE must also be more flexible yet more sturdy and "pushable" catheters that can be smoothly maneuvered through the twists and turns of the branching vessels of varying sizes deep in the legs or through the chambers of the heart to reach the DVT and PE. The greater distance between the pressure source and the clots is yet another reason that aspiration for DVT and PE require larger suction force compared to aspiration for clots in smaller vasculatures. Therefore, considerations as to the type, timing, and amount of pressure needed to aspirate clots in peripheral and pulmonary vasculature differ significantly from smaller vasculature.

202. Another challenge faced by large catheter thrombectomy is that larger catheters risk far more blood loss than smaller catheters. For example, as also described above, a 24F catheter has three times the circumference of an 8F catheter, meaning it has nine times the cross-sectional area, and, as discussed above, up to eighty-one times the blood flow. The larger suction area and suction force mean that blood is aspirated from the vessel at a much faster rate, which is a significant safety risk considering that DVT and PE are located in veins that return blood to the heart and lungs, and pulmonary arteries that supply blood to be oxygenated and then distributed to the entire body. Therefore, excessive blood loss during DVT and PE thrombectomy procedures create different (and often) greater subsidiary risks than for some of arterial thrombectomy procedures.

203. These challenges mean that preexisting small catheter thrombectomy devices designed for small vasculatures cannot be easily adapted for peripheral and pulmonary vasculatures. In other words, small catheter thrombectomy devices cannot just be paired with bigger catheters and work for DVT and PE. For these and other reasons, there have been only limited developments in the treatment of DVT and PE over the past five decades before Inari's

design.

2. Innovation over Prior Art

204. Inari overcame these challenges and the juggling act that they require by implementing various innovative features that work particularly well in Inari's unique patented combinations, including accelerated and pre-charged aspiration (such as Whoosh) (sometimes with multiple passes), telescoping catheters, and measures to minimize and mitigate blood loss such as improved hemostasis valves, blood filtration, and blood return. When aspiration alone is insufficient to remove the clots, a combination of aspiration and mechanical intervention devices that engage and break up the clots is used. Many of these innovations are captured in the claims of the patents that are the subject of this declaration, and it is my opinion that these claims are valid. They represent a significant leap forward in the treatment of VTE.

205. My opinions are also supported by secondary indicia of nonobviousness, which I have been asked to consider. It is my opinion that Inari's invention satisfies a long-felt need in the industry, namely efficient and safe aspiration percutaneous mechanical thrombectomy devices with large catheters for peripheral and pulmonary vasculature enabling improved patient outcomes and improved mortality rates. Most notably, before Inari implemented its invention in its own products, mortality rates for high-risk PE had remained mostly unchanged for fifty years.

206. While Inari's products now have several competitors in the market for mechanical thrombectomy devices, including aspiration-based devices, for DVT (and one in the PE market), none of them has the same advantages as Inari's products and none of which has experienced the degree of success that Inari has. For example, Penumbra's DVT and PE thrombectomy devices, referred to as "Indigo Lightning." was adapted from its thrombectomy device designed for removing clots from small neurovasculatures and therefore uses smaller catheters or sheaths (7F, 8F and 12F, and most recently a 16F sheath for the Lightning Flash System) than Inari's (16F, 20F, and 24F). It also uses computer-actuated suction, which Inari's products do not. The Penumbra devices do not use telescoping large catheters, do not have blood filtering and return, and use conventional Tuohy-Borst hemostasis valves. Boston

Scientific's "AngioJet" uses small catheters (3F to 8F), requires a large control console, and uses water jets to remove clots, and also bears a FDA warning against use for PE. AngioDynamics's "AlphaVac" has a complex design that takes many steps to be inserted into the vasculature and even more steps to remove the clot. The effectiveness of Inari's invention is unexpected because of various challenges, many of which are mentioned above, for adapting small catheter thrombectomy devices for large vasculatures.

3. Specific Prior Art Identified By Truvic And During Prosecution

207. I do not yet have the benefit of Truvic's invalidity arguments, but I understand (as mentioned above) that Truvic did cite a few prior art references during its pre-suit correspondence with Inari. I have been asked to consider those references and whether they affect my opinion that the claims considered in this declaration. They do not change my opinion on validity.

208. The Primary Patent Office Examiner who evaluated Inari's '910 Patent Application considered many prior art references that contemplated thrombectomy devices designed for removing clots from smaller vasculatures such as the cerebral and coronary arteries. These include Garrison I and Garrison III.

209. The list of prior art that was provided to the patent office during prosecution is extensive, with nine pages of references listed for the '910 Patent alone, including over 1,000 patent and non-patent literature references. I understand this to mean that the Examiner conducted a thorough search and considered many references.

210. Garrison I and Garrison III were both of record during the prosecution of the '910 Patent, and both appear on the face of the patent (along with several other Garrison references, including United States Published Application No. 2018/0064453, "Garrison II"). Garrison I was extensively considered and discussed at length during the prosecution of the '910 Patent.

211. The closest prior art identified during prosecution was the Garrison I reference. (November 6, 2023, Non-final Rejection (rejecting only then-pending Claim 18 in view of Garrison I).) I understand that Truvic raised Garrison I in its pre-suit correspondence with Inari, and argued that Garrison I invalidated some of Inari's claims. But the Examiner, after

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considering Garrison I at length, noted that the remaining claims were allowable over Garrison I because the claims recited telescoping, which Garrison I did not: "Garrison fails to teach a second catheter advanceable through the first catheter. The second catheter (2045) does not advance through first catheter (2025), as shown in Figure 33." (November 6, 2023, Non-final Rejection at 5-6 (allowing then-pending Claims 1-17 and 19-20). The Examiner further explained that, although Garrison I did teach a separate second catheter, "[i]t would be unreasonable to modify the flow lines to advance through the arterial access device (2010) because it would interfere with the thrombectomy device."

212. I agree with the Examiner that Garrison I fails to disclose a telescoping configuration, and indeed teaches against doing so by teaching a second, separate catheter that is not advanced through the first catheter. Issued Claim 1 of the '910 Patent requires a telescoping configuration, with the second catheter of the second aspiration assembly advanceable through the first catheter of the first aspiration assembly. Claim 1 is not obvious or anticipated by Garrison I for this reason, as the Examiner correctly determined during prosecution.

213. After the Examiner allowed then-pending Claim 1 during prosecution, the applicant amended the (already-allowed) claim to recite that the clot treatment system was "for treating clot material comprising a pulmonary embolism" and reciting that the second catheter was "16 French or greater" in size, and further explained that the claims were also patentable over Garrison I for the reasons discussed during an interview with the Examiner in a related patent application. (February 2, 2024 Amendment and Office Action Response.)

214. On March 12, 2024, the Examiner entered an Examiner's Amendment fixing two minor issues in the claim and a Notice of Allowance agreeing with the additional reasons for patentability over Garrison I raised by the applicant, including that the claims were not anticipated or obvious over Garrison I because it would not be reasonable to modify the clot treatment device of Garrison I to be used for pulmonary embolisms, *e.g.*, including because of the need for larger catheters:

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

215. Again, I agree with the Examiner's reasoning. The addition of the claim language reciting large catheter sizes for treatment of pulmonary embolisms is another reason why the issued claims, including Claim 1 is not anticipated or obvious in view of Garrison I. Specifically, it would not be obvious to modify a neurovascular system with far smaller catheters designed for the much smaller veins in the neurological system (*e.g.*, 6F and/or 8F catheter sizes) to provide far larger catheters (16F is 4 times the cross-sectional area of an 8F catheter) needed to effectively target and aspirate the larger and deeper clots in the pulmonary vasculature. This is not a matter of simply making an obvious jump up in size. Treatments for PE (and for DVT) are significantly different than neurovascular treatments, at least because of the size of the catheter required for aspiration, and because the clots, especially for PE, are much larger and more complex in shape. The large diameter catheter requires significantly different design choices, including because advancing a conventional large catheter the large distance to a pulmonary embolism would not work.

216. The Garrison III reference was not explicitly cited by the Examiner during prosecution, presumably because it does not disclose as many components of Claim 1 as Garrison I. For instance, while Garrison III still has the limitations of Garrison I, discussed above, it does not even disclose a second aspiration assembly including a second catheter, much less a telescoping configuration. Like Garrison I, Garrison III also does not disclose or render obvious treating pulmonary embolisms or using larger catheter sizes. Neither Garrison I nor Garrison III anticipates or renders obvious the system of Claim 1 of the '910 Patent.

217. In my years of experience in the field of art for these devices, Inari was the first

company to develop a system as claimed in Claim 1 of the '910 Patent, an aspiration based thrombectomy system used in removing pulmonary embolisms, especially one with a 16F or greater aspiration catheter size that is advanced in a telescoping configuration through an even larger aspiration catheter. The Inari FlowTriever systems with large catheters and telescoping represented a significant development that was not an obvious development in the market.

B. The '921 Patent

1. <u>Challenges Faced by Inari</u>

218. As mentioned in the Technology Background section above, the traditional hemostasis valves with a Tuohy-Borst design can result in significant blood loss because of poor sealing ability for large diameter openings. They can also be difficult to operate during procedures, often requiring the use of both hands.

219. These challenges are exacerbated when using larger catheters and the increased vacuum forces needed to aspirate DVT and PE clots, while also dealing with larger blood vessels that carry a larger volume of blood. Larger catheters with higher flow rates are more prone to excessive blood loss. In addition, the number of rotations or the degree of rotation required to seal a larger Tuohy-Borst valve (that can admit a larger catheter) is greater than that required to seal a smaller Tuohy-Borst valve, resulting in longer time to properly seal the larger catheter and greater risk of blood loss. Therefore, Inari needed a different hemostasis valve design for its large catheter thrombectomy devices.

2. <u>Innovation over Prior Art</u>

220. Inari invented a new structure for a garrote hemostasis valve. Inari's solution is to bias the valve towards a closed position, meaning that it is closed unless a user actuates the valve to transition to an open position. Compressing the buttons against the springs that drive the buttons outward loosens the filaments wrapped around the tubular member of the hemostasis valve to open it, while releasing the buttons causes the springs to drive the buttons outward to rapidly return the buttons to the decompressed position which tightens the filaments to close the valve. Not only does this unique structure of hemostasis valve have the advantage over conventional hemostasis valves (better sealing at the proximal end of the catheter to prevent

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blood backflow), but it also allows for faster sealing and single-hand operation because of the ease to operate the buttons with one hand while the user's other hand can insert a catheter or tool through the opened hemostasis valve. Such benefits are especially important to large catheter thrombectomy devices.

3. Specific Prior Art Identified By Truvic And During Prosecution

221. The Primary Examiner for Inari's '921 Patent considered the field of art and determined that it disclosed and claimed a non-obvious innovation to hemostasis valves, including over United States Application No. US20030116731 ("Hartley"), which the Examiner considered and discussed at length. The Eller reference was also disclosed during prosecution and is listed on the '921 Patent, along with Hartley.

222. I have been asked to evaluate the validity of the '921 Patent in view of the identified prior art, including Hartley and Schaffer (a combination that I understand was identified by Truvic in pre-suit correspondence), as well as Eller (a reference identified in an *inter partes* review challenging the '011 Patent filed by Truvic in combination with Hartley and in combination with Schaffer).

223. At the outset, I note that Hartley and Eller were of record during the prosecution of the '921 Patent. As can be seen on the face of the patent, both the Hartley and Eller references have an asterisk, which indicates that the reference was specifically cited by the Examiner during prosecution. This means that the Examiner specifically focused on, discussed, and addressed this reference during prosecution; there can be no serious contention that this reference was overlooked in any way.

224. The list of prior art that was provided to the Patent Office during prosecution is extensive, with over nine pages of references listed for the '921 Patent, including over 1,000 patent and non-patent literature references. This is because Inari provided a large amount of prior art to the Examiner during prosecution, so the Examiner had many references readily available to consider. Nevertheless, the Examiner deemed that Inari was entitled to the claims of the '921 Patent that issued.

225. The closest prior art identified during prosecution was the Hartley

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(US2003/0116731) reference, which Truvic identified in its pre-suit letter in connection with patents related to the '921 Patent, as well as the Williams et al (US3,438,607) reference. (October 18, 2023, Notice of Allowability at 3-4.) For these, the Examiner noted that the remaining claims were allowable over Hartley because the claims recited a biasing member that biases the actuator to the first (valve constricted) position, which Hartley does not disclose: "Hartley fails to disclose a biasing member configured to bias the actuator to the first position. Note: the spring 29 in Hartley is not configured to bias the actuator to the first position.") (October 18, 2023, Notice of Allowability at 3.) The Examiner also explained that Hartley did not disclose a second actuator, only a single actuator: "claim 77 requires two actuators coupled to the elongate member; and each of the actuator coupled to the elongate member via with respective to each of a first filament and a second filament. Meanwhile, the prior art Har[t]ley discloses only one actuator." (October 18, 2023, Notice of Allowability at 4.) The Examiner identified Hartley, Williams, Eller, and some other references as "cited by Examiner" in the list of such references concurrent with the Notice of Allowability. (October 18, 2023, List of References Cited.)

226. I agree with the Examiner that Hartley fails to disclose a biasing member that is configured to bias the actuator of the valve to a first (constricted) position. Issued Claim 1 of the '921 Patent requires such a biasing member as a key limitation defining a valve biased to be closed and that is open when actuated. Claim 1 is not obvious or anticipated by Hartley for this reason, as the Examiner correctly determined during prosecution. I also agree with the Examiner that Hartley fails to disclose the valve having a second actuator coupled to the elongate member, as Hartley has only a single actuator. For this additional reason, Claim 10 is not obvious in view of or anticipated by Hartley. I further agree with the Examiner finding that the claims were allowable over Eller.

227. Neither would modifying Hartley in view of Schaffer render the claims obvious. Schaffer, like the Williams reference considered by the Examiner during prosecution, discloses a biasing member, but fails to disclose a filament constricting mechanism. Like with Williams, it would not have been obvious to modify the Hartley valve rotary actuator, to add a biasing

member, such as a spring mechanism like the one disclosed in Schaffer, to bias the system to a constricted position. The Schaffer and Hartley valves function differently, and modifying the Hartley valve to have a spring biasing mechanism that provided for rapid closure of the valve would necessitate springs that would override the ball/recess structure in Hartley. Modifying Hartley's structure in this way (adding a spring mechanism to bias the actuator) would also negate a key feature of Hartley, the ability to retain incremental positions as opposed to just the fully closed position.

228. Schaffer itself also does not disclose circumferential constriction of the valve using a filament, instead using rigid U-shaped actuators, as opposed to a flexible filament required by the claims, which allows for circumferential restrictions. In the challenge filed by Truvic against the '011 Patent, Truvic argued that the rigid U-shaped members in Figure 32 of Schaffer are filaments, but that defies the plain and ordinary meaning of "filament," including because Schaffer's U-shaped members are not thin or flexible. Truvic appears to stretch the meaning of filament to make embodiments in Schaffer appear closer to the inventions disclosed in the '011 Patent (and the '921 Patent) than they are. It would not be obvious to substitute flexible filaments for the U-shaped rigid members disclosed by Schaffer because the flexible filament would not engage and disengage the containment structure in the manner taught by Schaffer to open and close the resilient member, and would instead engage with a circumferential motion and relax while still maintaining engagement with the containment structure, allowing the containment structure in Schaffer to expand and open during engagement with the filament. This is further true because the assembly procedure disclosed by Schaffer (in paragraph [0083]) requires the two buttons to fully deconstrict without relaxation and maintaining engagement in order to insert the seal module through the housing and between each of the buttons. If flexible filaments were substituted in Schaffer for the rigid U-shaped member, the assembly process would become unnecessarily cumbersome and expensive in terms of manufacturing time, and person of skill in the art would not be motivated to modify Schaffer in a manner that would incur these costs.

229. Eller, somewhat similar to Hartley, discloses a hemostasis valve with a rotatable

actuator. Eller additionally discloses an optional biasing member, such as a torsion spring, that can bias the valve towards a second configuration. Eller at 19:22-30. Similar to Hartley, Eller discloses only a single rotatable actuator (and Eller discloses only a single biasing member). For at least the same reasons discussed above a person of skill would not add a biasing member such as is disclosed in Eller to Hartley and further would not modify Schaffer to use a flexible filament for constricting the valve.

230. In my years of experience in the field of art for these devices, Inari was the first company to develop a hemostasis valve as claimed in Claims 1 and 10 of the ’921 Patent. The Inari FlowTriever systems using the improved hemostasis valves was not an obvious development in the market.

XII. INARI’S DEVICES ALSO PRACTICE THE CLAIMS

A. U.S. Patent 11,974,910 (“’910 Patent”) – Claim 1

231. In addition to offering my opinion that Truvic’s Symphony system infringe, I have also been asked to opine on whether Inari’s own FlowTriever system practices Claim 1 of the ’910 Patent and Claim 10 of the ’921 Patent. I do so in this section, and it is my opinion that it does.

232. I have reviewed Inari Medical’s FlowTriever documentation, including the Triever24 and Triever16 documentation. It is my opinion that FlowTriever practices Claim 1 of the ’910 Patent when used in a telescoping configuration with a Triever16 catheter telescoped through a Triever24 or Triever20 catheter for treatment of pulmonary embolism.

233. I understand that Inari’s FlowTriever system is used for treating thromboembolisms, including for treating pulmonary embolism. I further understand that the majority of treatments for pulmonary embolisms (PE) use a telescoping configuration. FlowTriever therefore is a “clot treatment system for treating clot material comprising a pulmonary embolism in a vasculature of a patient,” as recited in Claim 1 of the ’910 Patent.

234. In a telescoping configuration, FlowTriever includes “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 recited in the claims. Specifically,

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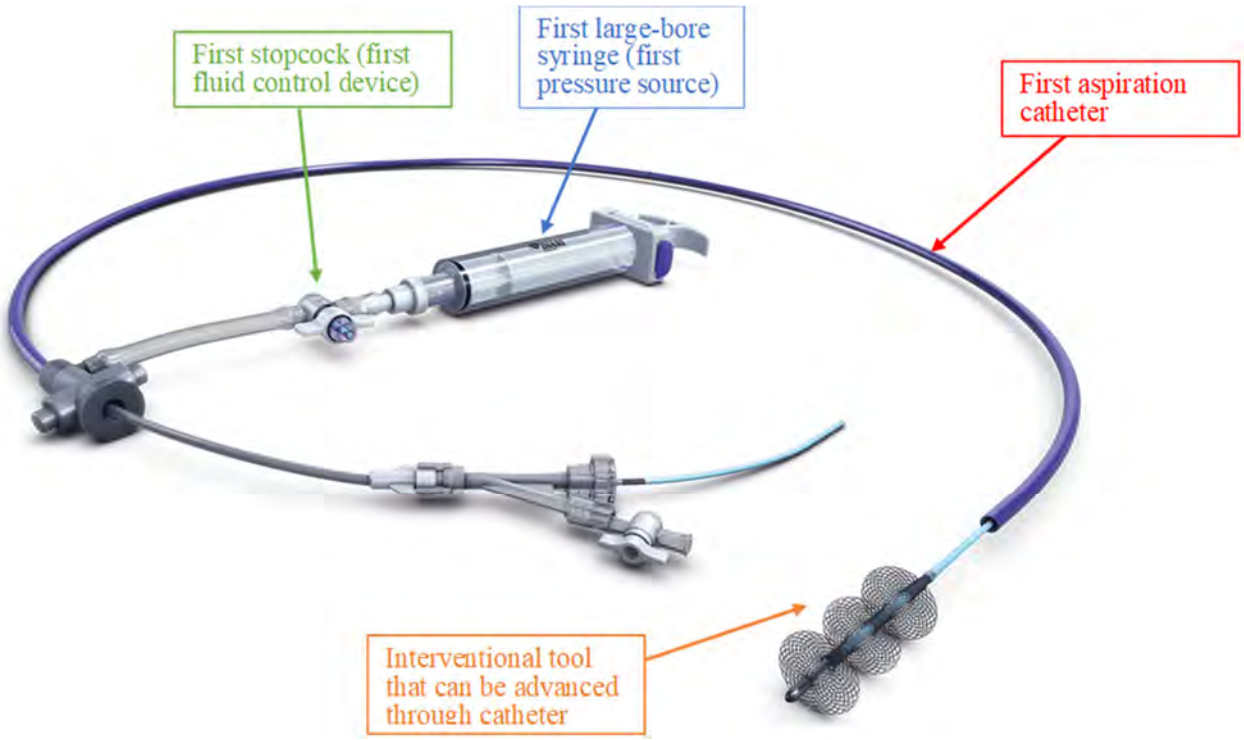
FlowTriever in a telescoping configuration includes (1) a Triever24 catheter or Triever20 catheter (first catheter), (2) a first pressure source (a first syringe), and (3) a first fluid control device between the Triever24 catheter or Triever20 catheter and the first syringe (a first stopcock). This can be seen below:



(Annotated image of FlowTriever assembly from Inari website, https://www.inarimedical.com/)

235. In a telescoping configuration a second, smaller diameter aspiration catheter (*e.g.*, a Triever16 aspiration catheter) is advanced through the larger-bore Triever24 catheter or Triever20 catheter.

236. The first fluid control device (first stopcock) is moveable between a first position (with the stopcock rotated to the closed position in which the stopcock tab/lever is perpendicular to the fluid path from the catheter to the syringe) in which the fluid control device is closed and the first syringe (first pressure source) is fluidly disconnected from the Triever24 catheter or Triever20 catheter (either being the first catheter) and a second position (open, with the stopcock rotated 90 degrees to where the stopcock tab/lever is parallel to the fluid path) in which the first syringe (first pressure source) is fluidly connected to the Triever24 catheter or Triever20 catheter:

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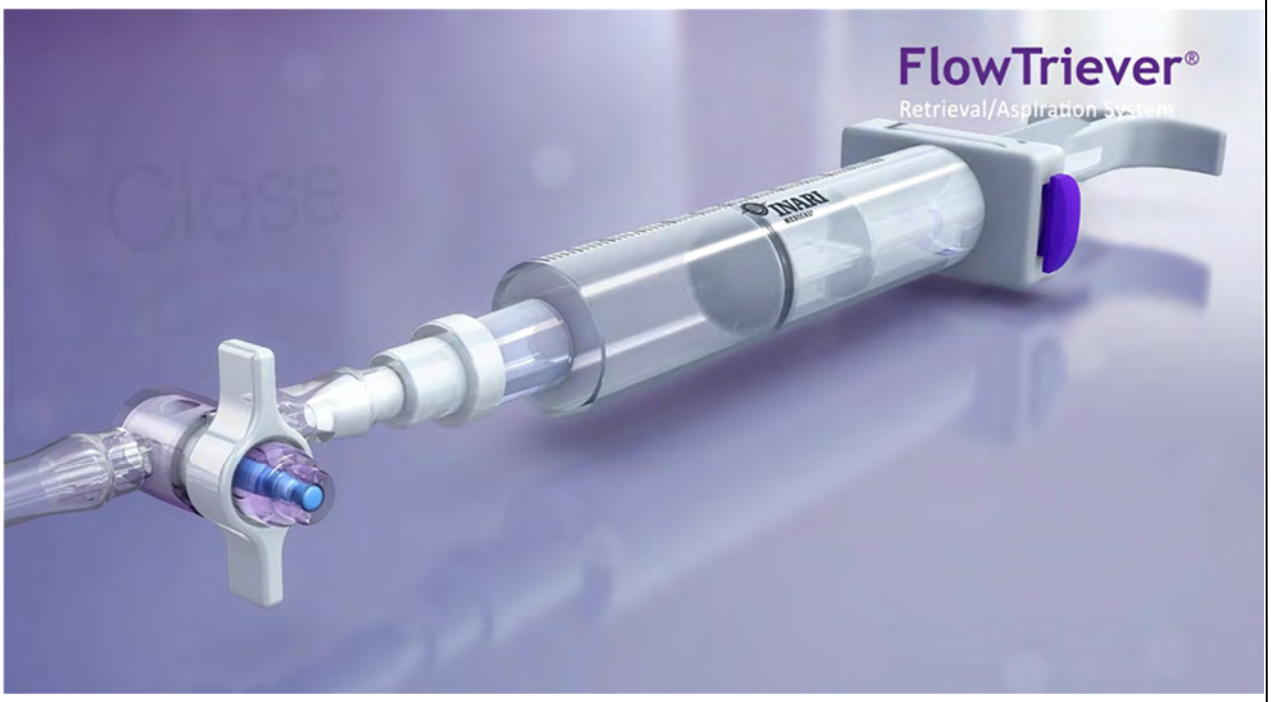
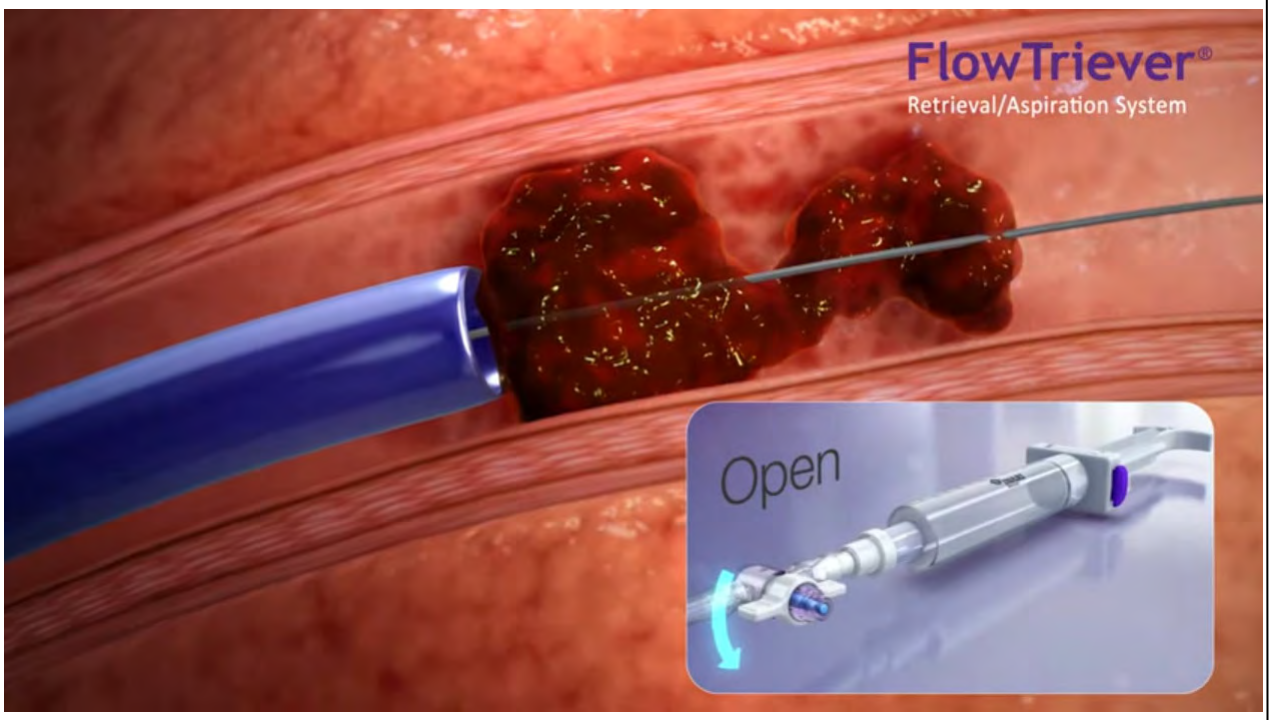


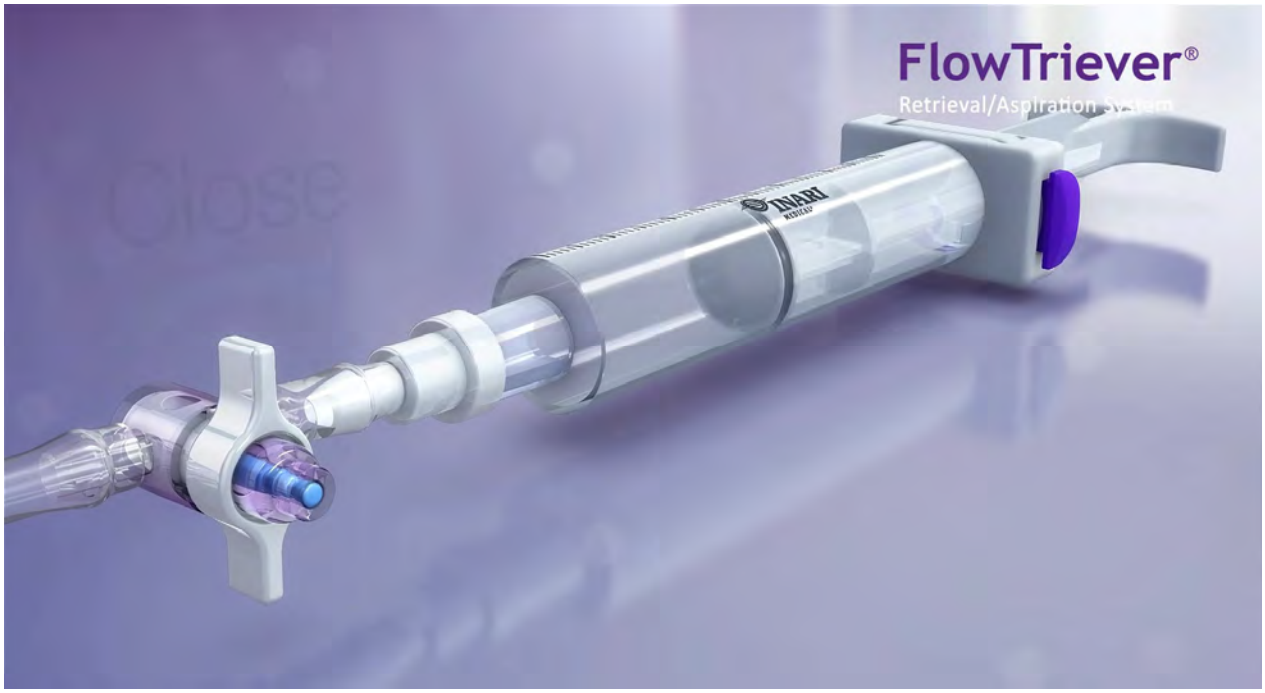
(Video screenshot showing the stopcock in the closed position.)



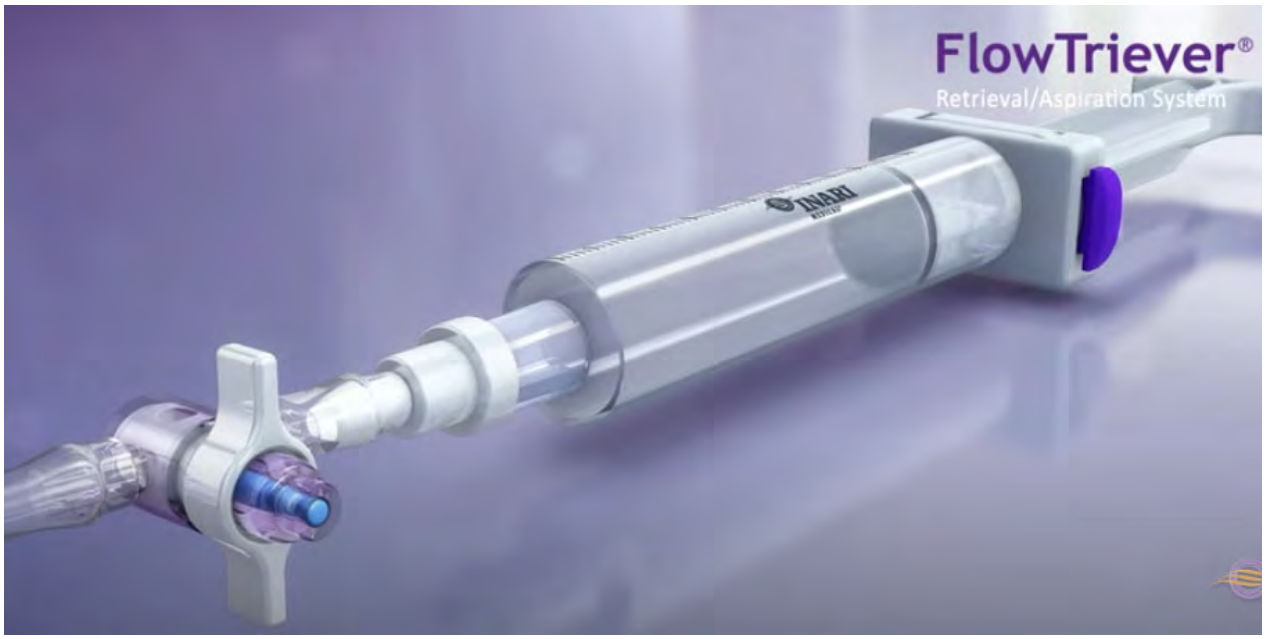
(Video screenshot showing the stopcock in the open position.)

237. The FlowTriever Triever24 or Triever20 assembly is configured to have the first syringe generate vacuum pressure by withdrawing the syringe plunger while the stopcock (first fluid control device) is closed (in the first position with the stopcock rotated to the closed

position in which the stopcock tab/lever is perpendicular to the fluid path from the catheter to the syringe) and, then, when the stopcock is rotated 90 degrees to the second position (open, with the stopcock parallel to the fluid flow path) the vacuum stored in the syringe is applied through the catheter to the distal end of the Triever24 catheter or Triever20 catheter.



(Video screenshot showing the stopcock in the closed position.)



(Video screenshot showing vacuum pressure being generated by the syringe when the stopcock is in the closed position.)

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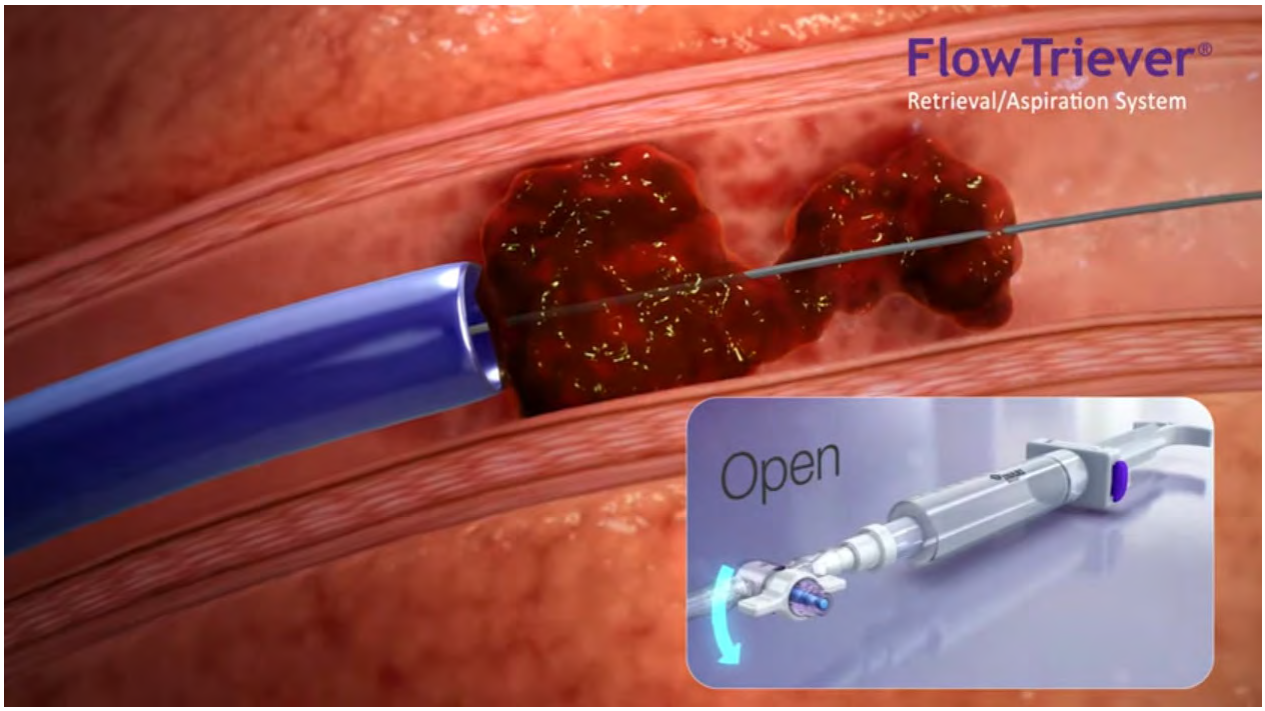
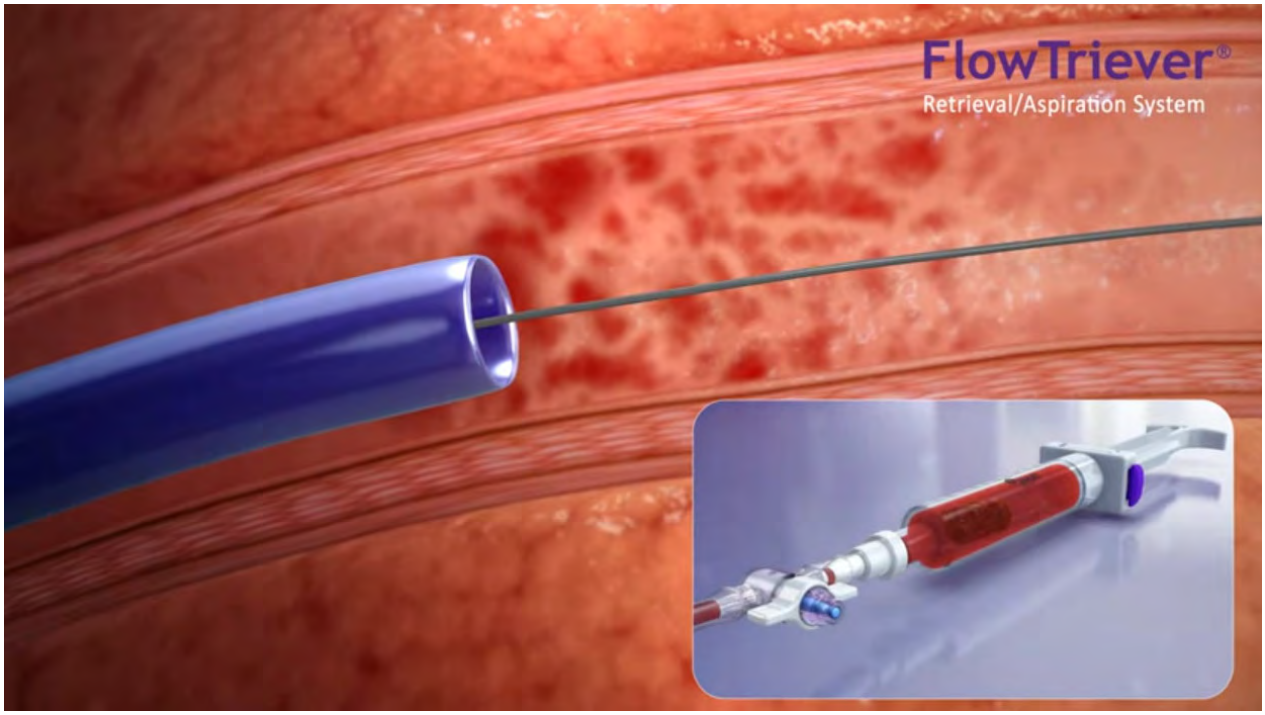


(Video screenshot showing the stopcock in the open position.)



(Video screenshot showing the vacuum from the syringe being applied to the distal end of the aspiration catheter when stopcock in the open position.)

238. In a telescoping configuration, FlowTriever includes a "a second clot aspiration assembly," including: a second catheter; a second pressure source; and a second fluid control

device between the second catheter and the second pressure source," as recited in the claims. Specifically, FlowTriever in a telescoping configuration includes a Triever16 catheter, such as pictured in the diagram below (second catheter) advanced through a larger Triever24 catheter or Triever20 that is not pictured in figure 1 below (or a Triever20 advanced through a Triever24 catheter), a second pressure source (a second syringe), and a second fluid control device (a second stopcock) between the Triever16 catheter and the second syringe. This can be seen in Ex. 19 (Triever16 Instructions for Use) below (a diagram of a telescoping configuration is provided by Figure 11 of the '910 Patent, discussed above in paragraph 96):

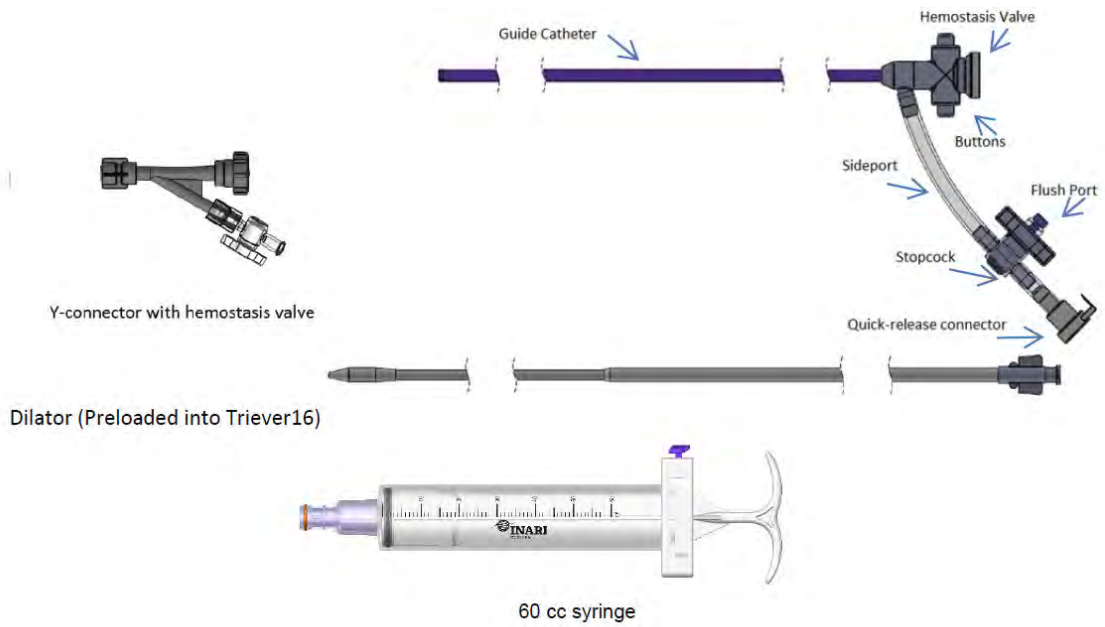


Figure 1: Triever16

(Ex. 19 at 2.)

239. As shown in Ex. 19, the Triever16 catheter is advanceable through the Triever24 catheter or Triever20 catheter and is designed to be intravascularly advanced through the vasculature of the patient such that the distal portion of the second catheter is positioned proximate to the clot material (e.g., pulmonary embolism).

Triever16 Co-axial Procedure with Triever20

12. Place the Triever16 over the guidewire. This step can be performed before and/or after the manual FlowTriever Catheter retraction through Triever20 or Triever24. To advance the Triever16 through the Triever20 or Triever24, loosen the Triever16's Dilator Y-connector hemostasis valve and insert the Triever16 over the pre-placed guidewire.
13. Advance the Triever16 through the Triever20 or Triever24 by pressing on the Triever20's hemostasis valve buttons.

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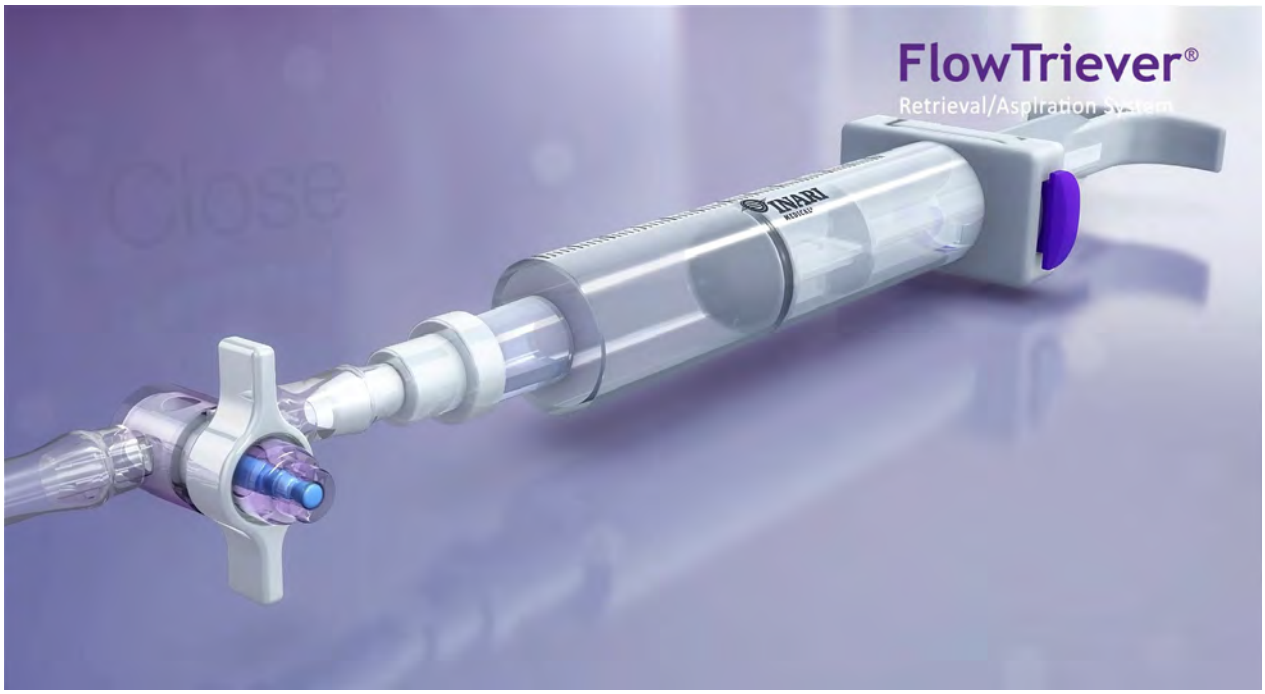
(Ex. 19 at 5.)

240. The second fluid control device (second stopcock) is moveable between a first position (with the stopcock rotated to the closed position in which the stopcock tab/lever is

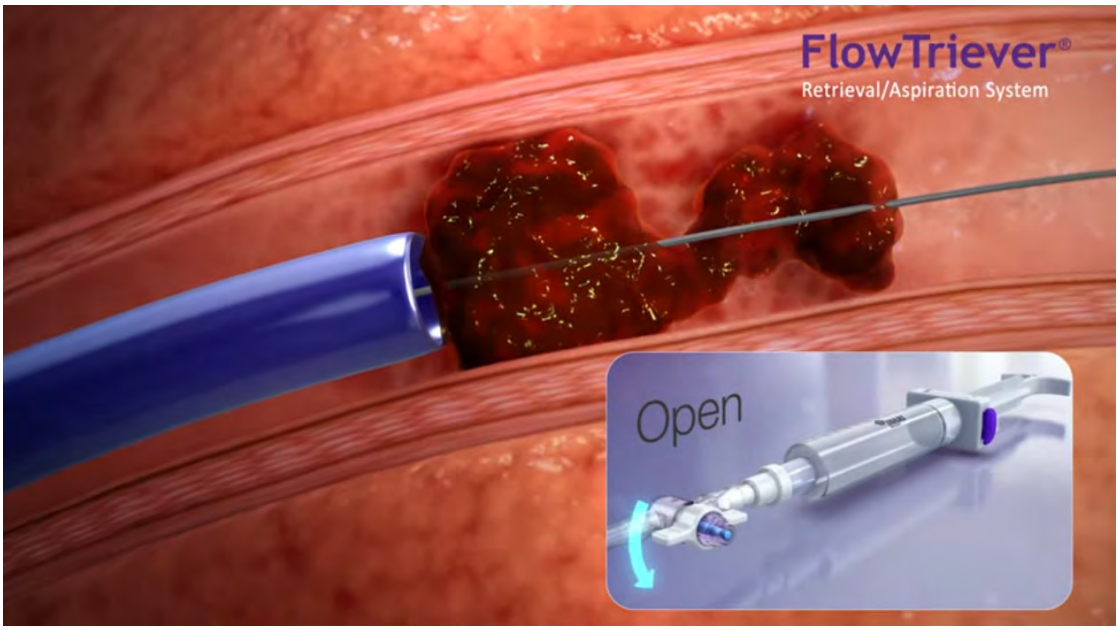
Triever16 Placement

5. Insert the Triever16 over the guidewire and advance proximal to the clot using fluoroscopic visualization.

perpendicular to the fluid path from the catheter to the syringe) where the fluid control device is closed and the first syringe (first pressure source) is not fluidly connected to the Triever16 catheter and a second position (with the stopcock rotated 90 degrees to where the stopcock is parallel to the fluid flow path) and the first syringe is fluidly connected to the Triever16 catheter:

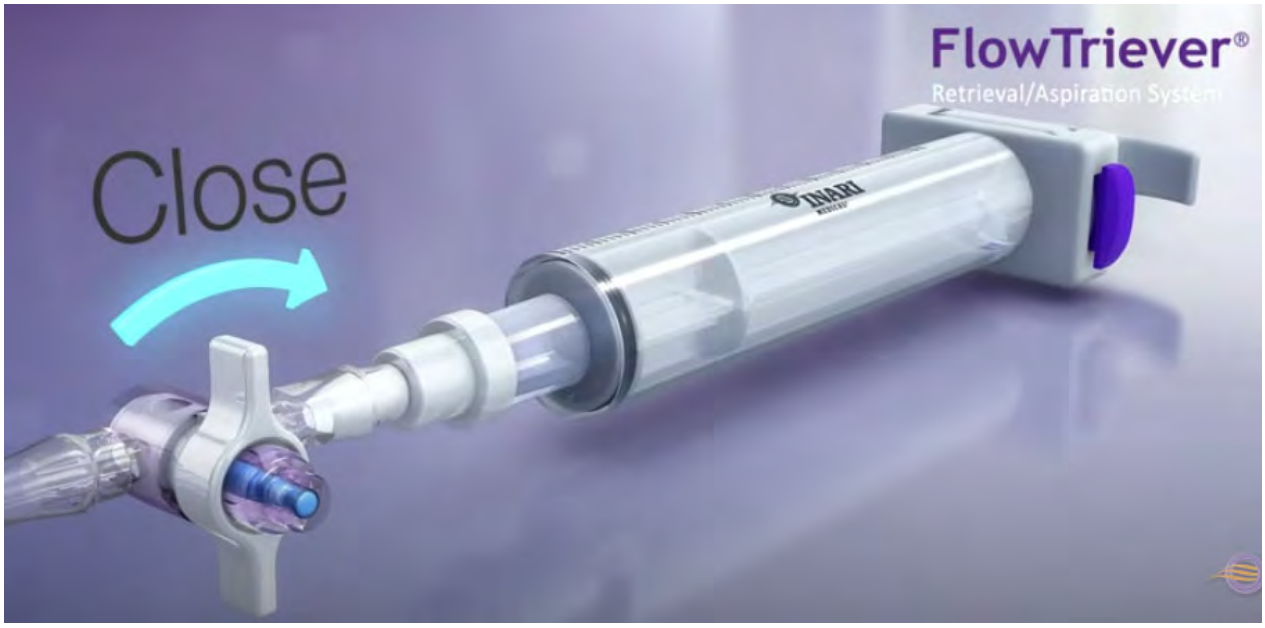


(Video screenshot showing the stopcock in the closed position.)



(Video screenshot showing the stopcock in the open position.)

241. The FlowTriever Triever16 assembly is configured to have the second syringe generate vacuum pressure by withdrawing the syringe plunger with the stopcock (second fluid control device) closed (in the first position with the stopcock rotated up) and, then, when the stopcock is rotated to the second position (open, with the stopcock parallel) the vacuum from the syringe is applied through the catheter to the distal end of the Triever16 catheter).



(Video screenshot showing the stopcock in the closed position.)

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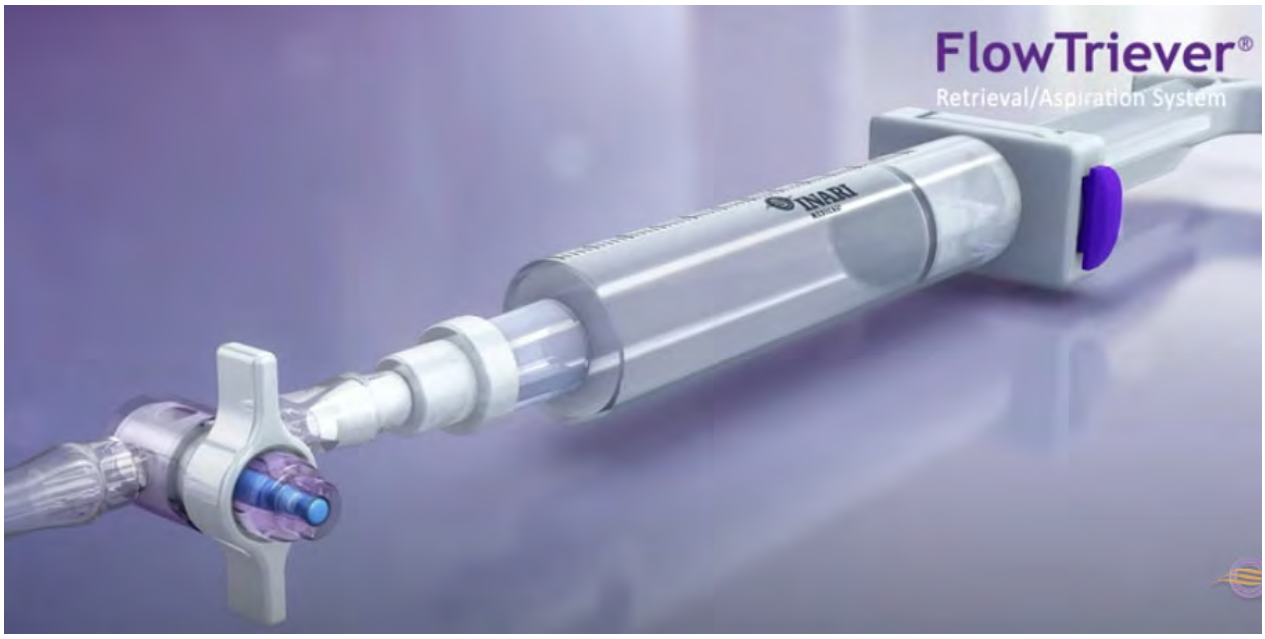
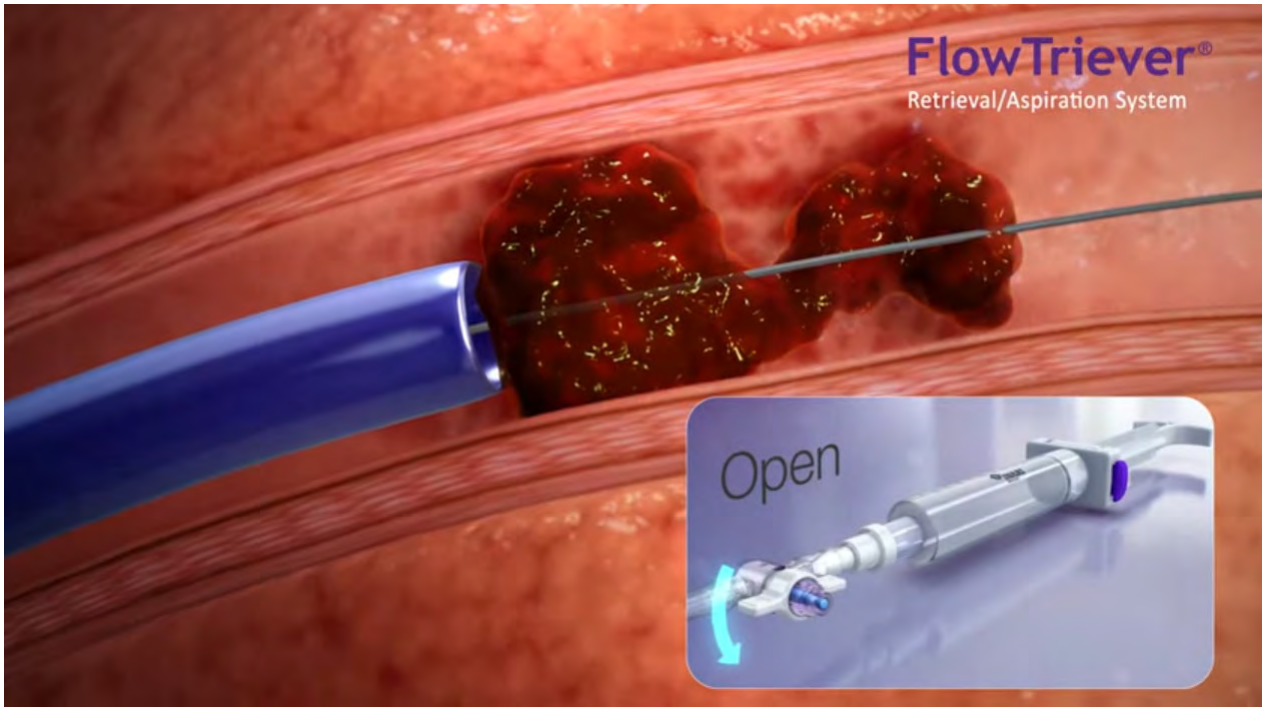
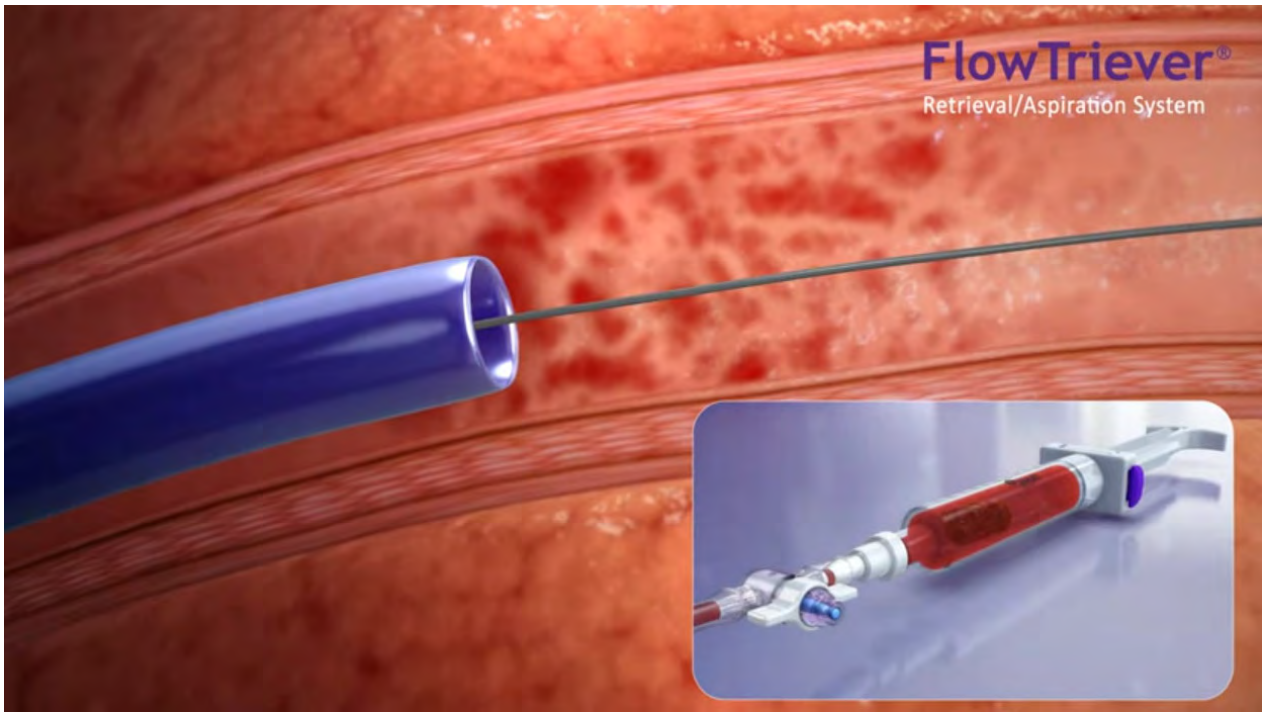


(Video screenshot showing vacuum pressure being generated by the syringe when the stopcock in the closed position.)



(Video screenshot showing the stopcock in the open position.)



(Video screenshot showing the vacuum from the syringe being applied to the distal end of the aspiration catheter when stopcock in the open position.)

242. Specifically, the FlowTriever system in a telescoping configuration for treating pulmonary embolism practices each and every limitation of Claim 1 of the ’910 Patent.

B. U.S. Patent 11844,921 (“’921 Patent”)

1. <u>Claim 1</u>

243. I have also reviewed Inari Medical’s Triever catheter assembly documents showing aspects of the garrote hemostasis valve in the Triever24 and Triever16 assemblies (Exs. 20, 21.) It is my opinion that Inari’s Triever24 and Triever16 assemblies used in the FlowTriever Retrieval/Aspiration system practices Claims 1 and 10 of the ’921 Patent. Specifically, the garrote hemostasis valve in the Triever catheter assemblies practices each and every limitation of Claims 1 and 10.

244. The hemostasis valve in the Triever catheter assembly is a garrote hemostasis valve (a valve) that includes an elongate tubular member defining a lumen (labeled below), an active tensioning mechanism including a first filament looped over the elongate tubular member, the first filament is connected to a first actuator (a first button) that is moveable from

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a first position (undepressed button, constricted valve lumen) in which the biasing member (a compression spring) pushes the button outward, pulling the filament to constrict the elongate tubular member, to a second position (depressed button, valve at least partially open) in which the filament is not pulled as tight against the elongate tubular member. The compression spring biases the first actuator to the first position (undepressed button, constricted valve lumen). This can be seen in annotated Ex. 20 (Triever24 Catheter Assembly Diagram) below.

[redacted]

245. The annotated image from Ex. 21 (Triever24 Assembly Procedure) below shows a valve during assembly with the top plastic piece (labeled 7 above) removed to show the internal structure of the valve.

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[redacted]

246. In the first position (undepressed button, valve constricted), the first compression spring (first spring) pushes against the first button, pulling the first filament tightly around the elongate member. The spring biases the first actuator (first button) to the first position (undepressed button, valve constricted). When the first button is pushed, the first spring is compressed, which moves the button to the second position (depressed button, valve open), loosening the tension on the first filament, at least partially opening the valve.

2. <u>Claim 10</u>

247. As can be seen in the annotated diagrams above, the Triever Catheter Assemblies also include an active tensioning mechanism having a second actuator (the second button) that is coupled to the elongate tubular member by a second filament that is connected to the second

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button and is looped around the elongate tubular member. The second actuator (second button) is biased to a first position (undepressed button, valve closed) by a second compression spring. The second actuator is moveable from the first position (undepressed button, valve closed) to a second position (depressed button, at least partially open valve) by pushing the second button downward.

248. In the first position (undepressed button, valve constricted),the second compression spring (second spring) pushes against the second button, pulling the first filament tightly around the elongate member. The spring biases the second actuator (second button) to the first position (undepressed button, valve closed with the lumen constricted). When the second button is pushed, the second spring is compressed, which moves the button to the second position (depressed button, valve open), loosening the tension on the second filament, at least partially opening the valve.

249. I confirm that the contents of this Declaration are true to the best of my knowledge and belief insofar as it states facts and that it contains my honest opinions on the matters upon which I have been asked to give them.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: July 23, 2024

By:

Brian Brown

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APPENDIX A
BRIAN J. BROWN
LITIGATION HISTORY

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Brian J. Brown

C (763) 458-8551 bb.browntech@gmail.com

Litigation History

QX Medical, LLC **Sept 2017- Present**

- Represented by Saul Ewing Arnstein & Lehr LLP, Minneapolis, MN
- QX Medical, LLC (Plaintiff and Counterclaim-Defendant) vs Vascular Solutions, Inc. (Teleflex)
- Patent Infringement Case, guide extension catheter
- Case No. 0:17-cv-01969 (PJS/TNL)
- USDC, for the District of MN

Produced Documents

- Claim Construction, Expert Declaration
- Invalidity Expert Report
- Non-Infringement Expert Report, including available non-infringing alternatives
- Expert Rebuttal
- Bench Testing and Test Reports
  - Accused device
  - Alternative commercial devices

Courtroom

- Marksman Hearing
- Summary Judgement Hearing

Depositions / Testimony

- Deposed on Non-Infringement and Invalidity Reports

Abbott Laboratory and Cardiovascular Systems **Sept 2017 – Nov 2020**

- Represented by McAndrews Held & Malloy, Chicago, IL
- Fischell(s), Plaintiffs vs Cordis Corporation, Defendant. Abbott Laboratory, Intervenor
- Patent Contract Dispute
- Civil Action No. 16-928 (PGS) (LHG)
- USDC, for the District of New Jersey

Produced Documents

- Claim Construction Brief, Expert Declaration
- Inter Partes Review, Expert Declaration
- Inter Partes Review Response, Expert Declaration
- Fabrication of court exhibits (stent models)

Courtroom

- Settled prior to court

Depositions / Testimony

- N/A

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Seshadri Raju, M.D., P.A. **Nov 2019 – Apr 2021**

- Represented by Kellum Law Firm, Jackson, MS
- Raju, Plaintiffs vs Erin Murphy, M.D. and Medtronic, Defendant.
- Misappropriation of Trade Secret(s)
- Civil Action No. 3:17-cv-00357-CWR-FKB
- USDC, for the Southern District of Mississippi Northern Division

Actions and Produced Documents

- Review of Discovery Phase documents
- Expert Declaration #1, Misappropriation of Trade Secret(s)
- Expert Declaration #2, Misappropriation of Trade Secret(s)
- Supplemental Expert Opinion
- Expert Affidavit

Courtroom

- Preliminary Judgement decision

Depositions / Testimony

- N/A

Penumbra Medical **Nov 2020 – Sept 2023**

- Represented by Baker Bott L.L.P, San Francisco, CA
- Inter Partes Review of U.S. Patent(s)
- US Patent Trial and Appeal Board

Actions and Produced Documents

- IPR, Expert Declaration, Patent #1
- IPR, Expert Declaration, Patent #2
- IPR, Supplemental Declaration, Patent #2

Depositions / Testimony

- Deposed on IPR, Expert Declaration, Patent #1
- Deposed on IPR, Expert Declaration, Patent #2
- Deposed on IPR, Supplemental Expert Declaration, Patent #2

Boston Scientific Corporation **1990 – 2013**

- Company employee (R&D Engineer, Vice President R&D)

Depositions

- Deposed approximately 10 times related to various patent litigation cases
  - Patent Inventor
  - Company 30(b)(6)

Courtroom Testimony

- Testified as designer of a product at issue, MDT vs BSC, Jervis Patent (nitinol properties)

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APPENDIX B
BRIAN J. BROWN
PROFESSIONAL EXPERIENCE

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Brian J. Brown

C (763) 458-8551 bb.browntech@gmail.com

Professional Experience

Brown-Tech , LLC. Hanover, MN **Sept 2017-Present**
President

- Technical Consultant for early stage medical device companies in the areas of product design and intellectual property development (clients: Peytant Solutions, QXMedical, CardioMech)
- Subject Matter Expert for Medical Device patent cases ranging from litigation to Inter Partes Reviews. Responsible for case document reviews, product testing, testing reports, POSA declarations, depositions and testimony.

Brown-Tech , LLC. (Nitinol) Maple Plain, MN **Mar 2018-July 2020**
President

- Specialized contract Nitinol design and prototyping for small to large nitinol projects.
- Expertise in the areas of design, laser cutting, shape setting, grit blasting, electro-polishing, passivation and testing.
- Over 25 years of expertise with nitinol stents, guidewires, structural heart, heart failure and misc. components.

Cogentix Medical Inc. Minnetonka, MN **Nov 2016 – June 2017**
VP of R&D and Operations

Pelvic Health medical device company developing and commercializing neurostimulators, endoscopes and sphincter bulking agents.

- Responsible for production, R&D, supply chain, planning, QC and Customer Care in MN, NY, and MA
- Owned cross functional leadership of New Business Development and Strategic Growth activities
- Provided oversight of Corporate intellectual property portfolio, outside counsel activities, and patents

OvaGene Oncology Irvine CA and Edina, MN **2016**
Chief Technology Officer

A Point of Care (POC) molecular diagnostic company focused on developing and commercializing a diagnostic (Dx) microfluidic chip capable of running self-contained, protein based diagnostic assays.

- Developed a commercial version of a research lab POC Dx prototype
- Sr. Staff member responsible for R&D, Intellectual Property, Operations, Quality, Regulatory, Facilities, and IT.

Sunshine Heart, Inc Eden Prairie, MN **June 2014 – Jan 2016**
Sr. Vice President Technology and Operations

An early-stage, publicly traded medical device company focused on developing, manufacturing and commercializing the C-Pulse System for the treatment of Class III and ambulatory Class IV heart failure.

- Sr. Staff member responsible for R&D, Operations, Facilities, and IT.
- Led the organizational development /optimization of electromechanical, mechanical, sensor and software components for a Class III permanent implant supported by an external controller.
- Led the portfolio planning and technology roadmap efforts for strategic planning
- Provided oversight of Corporate intellectual property portfolio, outside counsel activities, and patents

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Boston Scientific Corporation / SciMED, Maple Grove, MN **Feb 1990 – Jan 2014**
R&D, Vice President, Cardiovascular (2004-2014)
Directed worldwide Cardiovascular research and development activities for accelerated launches of implantable stents, drug delivery technologies, structural heart devices, disposable catheters and adjunctive products.

- Developed, sustained, and optimized a $200M/yr. international R&D organization to bring the right new technologies / products to the market
- Aligned company's technology development, M&A activities, and IP portfolio
- Initiated Bio Design partnerships with regional / global research institutions to identify / develop disruptive technologies to fuel future growth.

R&D, Sr. Director, Stents
Created R&D stent and drug elution centers of excellence in MN and Ireland (2001- 2004)

- Championed / built a stent organization bringing BSC's first internally developed nitinol and stainless steel stents to the market.
- Constructed / maintained a world class dual site drug elution organization capturing 70% of the global market launching the Taxus and Promus portfolio of stent products.
- Identified / engaged the technical assessment of business opportunities and integration of new licenses / acquisitions.

Prior History

Previously at Boston Scientific / SciMED held positions of R&D Director Catheters, R&D Director / Manager Stents, Operations Manager Guidewires, Sr. Process Development Engineer, and Sr. Machine Design Engineer. Highlights included developing BSC's core competency in nitinol, stent design, laser cutting, electropolishing, crimping, and fatigue testing. Many ground breaking design, clinical and regulatory competencies were developed to support Boston Scientific's first cardiovascular permanent implants.
Hutchinson Technology (Sep 1984-Jan 1990) as Machine Design Engineer / Supervisor responsible for building and leading equipment / process automation for a rapidly growing company. Examples include automated passivation lines, plating lines, photochemical etching lines, and laser equipment.

Education / Affiliations

North Dakota State University, Fargo, ND
Bachelor of Science, Mechanical Engineering with an emphasis on electro-mechanical automation.

Notable Achievements

- **~60 issued US Patents** in stent geometries, nitinol, balloon catheters, thrombectomy catheters, infusion catheters, and ePTFE processing.
- **Boston Scientific Patent of the Year award, two-time winner**
- **Recognized as one of Minnesota's leading inventors** by the Twin Cities Business Magazine (Jan 13)
- **Developed Boston Scientific's first product development process and design control tools.**
- **Elected to College of Fellows,** American Institute for Medical and Biological Engineering
- **Advisor to University of MN Office of Technology Commercialization** to advance the commercialization of university developed ideas
- **Mentor** for students enrolled in the University of MN Design of Medical Device program.

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USA PATENT NUMBER	TITLE	Listed Inventor	GRANT DATE
5358493	VASCULAR ACCESS CATHETER AND METHODS FOR MANUFACTURE THEREOF	Brian J Brown	25-Oct-94
5417703	THROMBECTOMY DEVICES AND METHODS OF USING SAME	Brian J Brown	23-May-95
5419774	THROMBUS EXTRACTION DEVICE	Brian J Brown	30-May-95
5507995	PROCESS FOR MAKING A CATHETER	Brian J Brown	16-Apr-96
5800517	STENT DELIVERY SYSTEM WITH STORAGE SLEEVE	Brian J Brown	1-Sep-98
6013091	STENT CONFIGURATIONS	Brian J Brown	11-Jan-00
6059810	ENDOVASCULAR STENT AND METHOD	Brian J Brown	9-May-00
6096056	FUGITIVE STENT SECUREMENT MEANS	Brian J Brown	1-Aug-00
6123720	STENT DELIVERY SYSTEM WITH STORAGE SLEEVE	Brian J Brown	26-Sep-00
6261319	STENT	Brian J Brown	17-Jul-01
6348060	FUGITIVE STENT SECUREMENT MEANS	Brian J Brown	19-Feb-02
6348065	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	19-Feb-02
6409753	FLEXIBLE STENT	Brian J Brown	25-Jun-02
6416538	STENT CONFIGURATIONS	Brian J Brown	9-Jul-02
6428569	MICRO STRUCTURE STENT CONFIGURATIONS	Brian J Brown	6-Aug-02
6451052	TISSUE SUPPORTING DEVICES	Brian J Brown	17-Sep-02
6471672	SELECTIVE HIGH PRESSURE DILATION BALLOON	Brian J Brown	29-Oct-02
6478816	STENT	Brian J Brown	12-Nov-02
6551351	SPIRAL WOUND STENT	Brian J Brown	22-Apr-03
6582461	IMPROVED TISSUE SUPPORTING DEVICES	Brian J Brown	24-Jun-03
6602226	LOW-PROFILE STENT DELIVERY SYSTEM AND APPARATUS	Brian J Brown	5-Aug-03
6638468	METHOD OF REDUCING THE WALL THICKNESS OF A PTFE TUBE	Brian J Brown	28-Oct-03
6702843	STENT DELIVERY DEVICE WITH BALLOONS	Brian J Brown	9-Mar-04
6776793	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	17-Aug-04
6818014	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	16-Nov-04
6852123	MICRO STRUCTURE STENT CONFIGURATIONS	Brian J Brown	8-Feb-05
6911038	MATCHED BALLOON TO STENT SHORTENING	Brian J Brown	28-Jun-05
6913619	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	5-Jul-05
6939119	METHOD OF REDUCING THE WALL THICKNESS OF A PTFE TUBE AND PRODUCT FORMED THEREBY	Brian J Brown	6-Sep-05
6945993	STENT	Brian J Brown	20-Sep-05
6962603	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	8-Nov-05
6970734	FLEXIBLE MARKER BANDS	Brian J Brown	29-Nov-05
6981985	STENT BUMPER STRUTS	Brian J Brown	3-Jan-06
6981986	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	3-Jan-06
7060089	MULTI-LAYER STENT	Brian J Brown	13-Jun-06
7204848	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	17-Apr-07
7229470	FLEXIBLE STENT	Brian J Brown	12-Jun-07
7318836	COVERED STENT	Brian J Brown	15-Jan-08
7326243	AN IMPROVED STENT	Brian J Brown	5-Feb-08
7331986	INTRALUMINAL MEDICAL DEVICE HAVING IMPROVED VISIBILITY	Brian J Brown	19-Feb-08
7335225	[IMPROVED] STENT CONFIGURATIONS	Brian J Brown	26-Feb-08
7488343	MEDICAL DEVICES	Brian J Brown	10-Feb-09
7491225	SYSTEM AND METHOD FOR DEPLOYING A DRUG-ELUTING EXTERNAL BODY AND TISSUE SCAFFOLD	Brian J Brown	17-Feb-09

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USA PATENT NUMBER	TITLE	Listed Inventor	GRANT DATE
7637938	FLEXIBLE STENT	Brian J Brown	29-Dec-09
7731746	AN IMPROVED STENT	Brian J Brown	8-Jun-10
7879082	MICRO STRUCTURE STENT CONFIGURATIONS	Brian J Brown	1-Feb-11
7914570	NON-SHORTENING HELICAL STENT	Brian J Brown	29-Mar-11
7951187	[IMPROVED] STENT CONFIGURATIONS	Brian J Brown	31-May-11
7988717	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	2-Aug-11
7988720	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	2-Aug-11
8038705	INTRALUMINAL MEDICAL DEVICE HAVING IMPROVED VISIBILITY	Brian J Brown	18-Oct-11
8043366	OVERLAPPING STENT	Brian J Brown	25-Oct-11
8114146	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	14-Feb-12
8147538	COVERED STENT	Brian J Brown	3-Apr-12
8206432	STENT	Brian J Brown	26-Jun-12
8221491	IMPROVED TISSUE SUPPORTING DEVICES	Brian J Brown	17-Jul-12
8348992	IMPROVED LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	8-Jan-13
8377111	MEDICAL DEVICES	Brian J Brown	19-Feb-13
8449597	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	28-May-13
8668731	STENT	Brian J Brown	11-Mar-14
8685053	TETHER EQUIPPED CATHETER	Brian J Brown	1-Apr-14
8728147	LONGITUDINALLY FLEXIBLE EXPANDABLE STENT	Brian J Brown	20-May-14