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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**

1 I, Brian Brown, hereby declare as follows:

2 1. My name is Brian Brown. I am currently employed as President of Brown-Tech,
3 LLC where I provide engineering expertise in the areas of Research and Development and
4 Operations for medical device companies. I have been asked to provide an expert declaration
5 on behalf of Inari Medical, Inc. (“Inari”). I understand that Inari alleges that the defendant in
6 this case, Imperative Care, Inc. (which I refer to as “Truvic”) has infringed United States Patent
7 Nos. 11,974,910 (“’910 Patent”), 11,969,333 (“’333 Patent”), 11,554,005 (“’005 Patent”),
8 11,744,691 (“’691 Patent”), 11,844,921 (“’921 Patent”), 11,697,011 (“’011 Patent”),
9 11,697,012 (“’012 Patent”), 11,865,291 (“’291 Patent”), 12,016,580 (“’580 Patent”).

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

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

23 **I. BACKGROUND AND QUALIFICATIONS**

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

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

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

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

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

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

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

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

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

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

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

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

27 **II. LEGAL STANDARDS**

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

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

4 **A. Overview**

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

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

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

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

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

27 **B. Claim Construction**

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

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

10 **C. Direct Infringement, Indirect Infringement and Doctrine of Equivalents**

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

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

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

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

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

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

1 **D. Validity**

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

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

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

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

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

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

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

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

5
6 **III. TECHNOLOGY BACKGROUND**

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

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

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

15 34. Venous thromboembolism (“VTE”) is a disease caused by blood clot formation in
16 the veins of the body, and is, unfortunately, a leading cause of both hospital preventable death
17 and disease worldwide. Pulmonary embolism (“PE”) and deep vein thrombosis (“DVT”) are
18 common types of VTE.

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

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

1 arteries to miniscule capillaries and venules. For example, the coronary arteries (the arteries
2 that supply blood to the heart itself) are between about 1.5mm-5mm in diameter in most people,
3 and the neurovascular arteries (which provide blood flow through the neck to the cerebral
4 system) average between about 3-6mm in diameter. Some of the veins and arteries in the chest
5 can be far larger, with the main trunk of the pulmonary artery (which supplies all the oxygen-
6 poor blood from the heart to the pulmonary system, so that it can be oxygenated by the lungs to
7 then distribute oxygen to the rest of the body) averaging about 27mm in diameter. In general,
8 veins associated with DVT have much larger inner lumens (the opening in the inner part of the
9 vein) than arteries of the heart or head, with the femoral vein deep in a person's legs typically
10 6mm-11mm in diameter.

11 **A. Treatments for DVT and PE**

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

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

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

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

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

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

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

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

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

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

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

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

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

1 48. When a doctor performs a thrombectomy using a catheter, the treatment involves
2 inserting a catheter into the patient’s vasculature and advancing the catheter to the occlusive
3 clot. If the doctor is using an aspiration-based mechanical thrombectomy system, then the clot
4 is removed by generating vacuum pressure using a pressure source, such as syringe or vacuum
5 pump, attached to the catheter, in an attempt to suck the clot into the catheter tip and out of the
6 patient’s vasculature. These treatments can be complicated and may require significant vacuum
7 applied to the clot (dependent on clot location and other factors), which the treating physician
8 may control (at least with devices currently on the market) by varying how the plunger of a
9 syringe is withdrawn or by varying a pump setting. It typically requires a pressure drop of
10 500mmHg (19.7 inHg) to 760mmHg (29.9 inHg) (or “full” vacuum) to aspirate clot material,
11 although the specifics again depend on a number of factors relating to the patient’s size, medical
12 condition, clot location, and clot “stickiness.” But this amount of pressure drop generally
13 creates a difference in pressure between the blood vessel in which the clot is situated and the
14 interior of the catheter, i.e., a pressure gradient (which may exceed 760mmHg (29.9 inHg)
15 because the patient’s blood pressure is higher than atmospheric pressure) that suctions the clot
16 into the catheter mouth.

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

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

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

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

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

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

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

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

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

22 **C. Hemostasis Valves**

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

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

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

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

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

26 **IV. Inari’s Aspiration-Based Mechanical Thrombectomy Systems**

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

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

4 61. Unlike some of its competitors, Inari chose not to repurpose existing
5 thrombectomy systems designed to treat clots in smaller arteries, including neurovascular or
6 coronary aspiration-based thrombectomy systems, to treat PE or DVT. By contrast, one of
7 Inari's competitors, Penumbra, adapted its existing thrombectomy designs for the removal of
8 emboli/thrombi from smaller neurovascular, peripheral arteries, and coronary arteries to create
9 a thrombectomy device for VTE. The resultant DVT/PE systems, the Penumbra Indigo
10 Lightning System and Penumbra Indigo Lightning Flash System, use continuous vacuum with
11 7F, 8F, 12F, and more recently 16F aspiration catheters, and have shortcomings versus Inari's
12 purpose-built systems that are specifically designed for larger vasculature with large-bore
13 catheters and stored vacuum.

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

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

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

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

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

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

24
25 66. The blood flowing in the deep leg veins and pulmonary arteries, which can bleed
26 out during a thrombectomy procedure, is critical to systems throughout the body. Any blood
27

28 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.

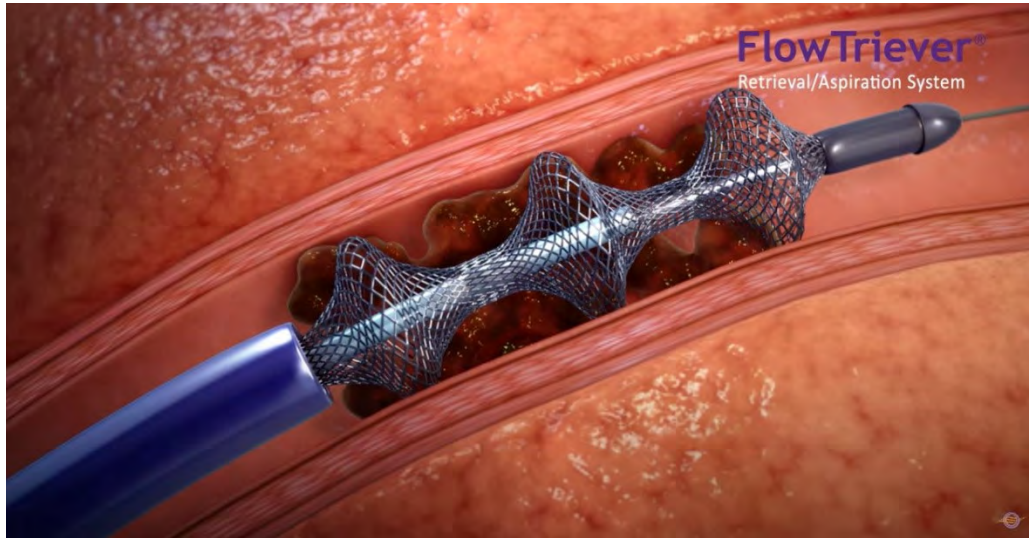
1 that is lost from large veins and pulmonary arteries is typically blood that was bound for—and
2 needed by—critical systems of the body. Inari, focused on purpose-built devices to treat PE
3 and DVT, thus needed to come up with ways to significantly reduce blood loss in addition to
4 the other challenges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

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

11 68. Inari received FDA clearance for its first product, the FlowTrievers thrombectomy
12 system, in February 2015 (then called “Retraction Aspirator”; rebranded as “FlowTrievers” in
13 November 2016) for non-surgical removal of clot material in the peripheral vasculature. This
14 first version of FlowTrievers includes an Aspiration Guide Catheter, a FlowTrievers Catheter with
15 an interventional device and a Retraction Aspirator, but did not yet have many of the advances
16 discussed in more detail below that are disclosed in the ’910 and ’921 Patents. In this
17 version, the FlowTrievers Catheter was inserted through the Aspiration Guide Catheter and
18 advanced to the thrombus. An interventional device having self-expanding wireform disks was
19 then deployed to engage the thrombus by retracting the outer delivery catheter. The hand-lever
20 operated Retraction Aspirator then simultaneously applied pulses of aspiration and
21 incrementally retracted wireform disks of the interventional device of the FlowTrievers Catheter
22 such that at least a portion of the thrombus was drawn into the Aspiration Guide Catheter and
23 blood flow restored. This FlowTrievers system was then redesigned with a mechanical
24 intervention device within an aspiration guide and retraction catheter that allowed the removal
25 of the FlowTrievers Catheter from the patient without the simultaneous removal of the Aspiration
26 Guide Catheter.² A capture from a FlowTrievers video depicting the interventional device of a
27

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

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



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

25
26 ³ See <https://www.clinicaltrials.gov/study/NCT02692586?rank=8&lead=Inari%20Medical>.

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

28 ⁵ See <https://www.inarimedical.com/flowtrievers-inari-fda-510k-clearance-treatment-pulmonary-embolism/>.

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

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

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

21 73. From December 2018 to February 2019, Inari conducted a limited market release
22 of the telescoping FlowTrievers and gathered physician feedback according to a clinical
23 evaluation plan. The positive evaluation results proved the telescoping combination of
24 Triever16 and Triever20 to be more effective for treating PE than using a single aspiration
25 catheter.

26 74. Inari continued to improve the FlowTrievers system, including developing more
27

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

1 catheter sizes for telescoping combinations. By September 2019, Inari developed and received
2 FDA approval for Trierer24, a 24F aspiration catheter.⁷ This catheter can be used in a
3 telescoping combination with Trierer16.

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

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

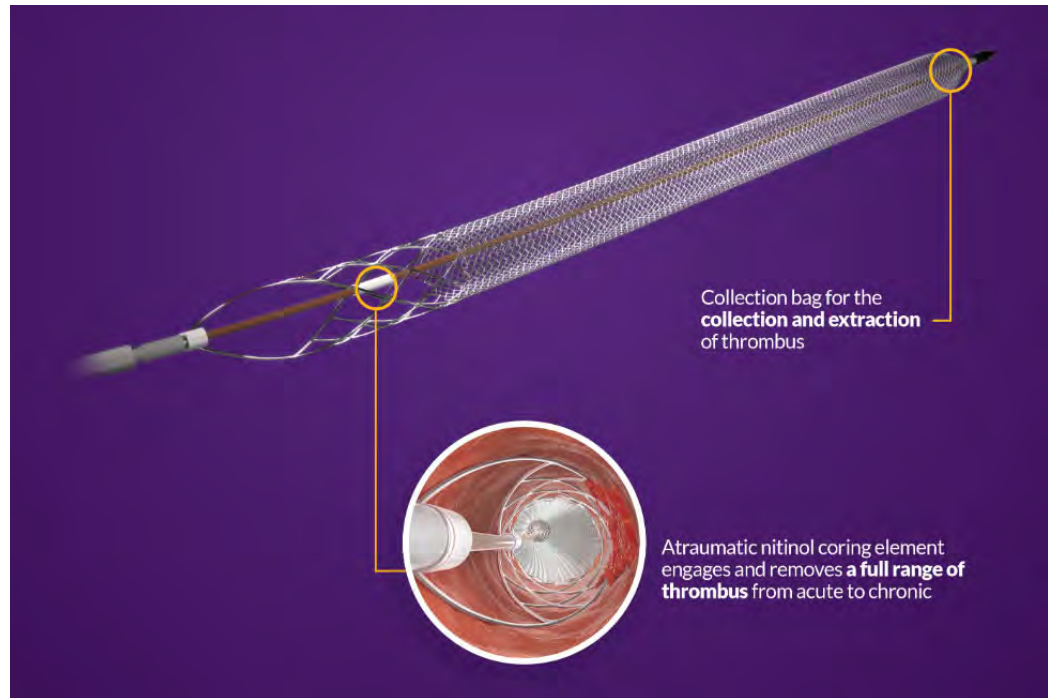
16 77. As with FlowTrierer, Inari continued and continues to improve ClotTrierer over
17 the years. For instance, by December 2017, Inari had developed and received FDA approval
18 for replacing the tissue collection net with a collapsible clot collection bag.¹⁰ A figure depicting
19 this improved version of ClotTrierer is shown below:
20
21
22
23

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

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

28 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).



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

21 V. Truvic’s Thrombectomy Systems

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

27 ¹¹ See <https://ir.inarimedical.com/node/10506/pdf>.

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

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

3 80. Like FlowTrieve and ClotTrieve, the Symphony system is designed to remove
4 thrombus/embolus from veins and large arteries using controlled aspiration and mechanical
5 interaction. The Symphony system comprises the 24F Symphony Catheter, 16F Symphony
6 Catheter, 24F Symphony Dilator, 16F Symphony Dilator, 24F Symphony Advance Long
7 Dilator, BigShot Controller handles with an on/off valve controlled by a lever, Truvic
8 Generator, Truvic Canister, Truvic Tubeset, 16F Symphony ProHelix, and 24F Symphony
9 ProHelix, although not all parts of the system need to be or are used for every patient procedure.
10 In operation, doctors connect the Symphony catheters to a Truvic generator via a BigShot
11 Controller handle, Truvic tubeset, and Truvic Canister to aspirate thrombus by directing the
12 aspiration force generated directly to the thrombus. Doctors introduce the Symphony catheters
13 and dilators through a vascular access sheath into the vasculature and guide them over a
14 guidewire to the site of the thrombus. The 16F Symphony catheter is capable of telescoping
15 from (extending past the distal end of) the 24F Symphony catheter for extended reach to the
16 thrombus. As needed, the Symphony ProHelix may be introduced through the Symphony
17 catheter to facilitate aspiration and removal of the thrombus through the catheter by
18 mechanically engaging and disrupting the clot material. The Symphony ProHelix is passed
19 through a button-operated garrote-type hemostasis valve and then manually advanced through
20 the Symphony catheter over a guidewire, remaining inside the Symphony catheter during the
21 procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is
22 manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus
23 removal through the catheter(s).

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

27
28 ¹³ See 510(k) Premarket Notification K223216 (available at
https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223216.pdf).

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

6 83. In addition, in an October 2023 submission to ClinicalTrials.gov, Truvic stated
7 that it will conduct a clinical study to evaluate the safety and efficacy of Symphony in the
8 treatment of PE from December 2023 to April 2025.¹⁴ Upon completion of this study, the FDA
9 will presumably clear Truvic to market Symphony for the treatment of PE.

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

22 **VI. LEVEL OF ORDINARY SKILL IN THE ART**

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

26 86. In my opinion, the field of invention is mechanical thrombectomy, including
27

28 ¹⁴ See <https://www.clinicaltrials.gov/study/NCT06062329?rank=1&lead=Imperative%20Care,%20Inc>.

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

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

14 VII. CLAIM CONSTRUCTION

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

18 89. I understand that the '910 and '921 Patents have not been construed by the court
19 in this case or by any other court in any other case. Save for the term "filament," I do not
20 propose any specific claim constructions, but interpret the patents according to their plain and
21 ordinary meaning to a person of skill in the art in view of the claim language, the specification,
22 and the file history. For "filament," I expressly address the term because Truvic has proposed
23 construing (and applying) this term in an overbroad manner that is contrary to its plain and
24 ordinary meaning in an *inter partes* review challenging another patent in the same family as the
25 '921 Patent. Because of this, I believe that it will be helpful to explain what the actual plain
26 and ordinary meaning of this term is.

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

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

7 91. This meaning further is in keeping with conventional usage of filament in a
8 mechanical sense: as thin, flexible pieces of material. *See, e.g.,*
9 [https://web.archive.org/web/20170818203220/https://www.merriam-webster.com/dictionary/f](https://web.archive.org/web/20170818203220/https://www.merriam-webster.com/dictionary/filament)
10 [ilament](https://web.archive.org/web/20170717183619/https://www.dictionary.com/browse/filament) (“a single thread or a thin flexible threadlike object, process, or appendage);
11 <https://web.archive.org/web/20170717183619/https://www.dictionary.com/browse/filament> (“a
12 very fine thread or threadlike structure; a fiber or fibril:”).

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

25 **VIII. THE ’910 AND ’921 PATENTS**

26 **A. U.S. Patent 11,974,910 (“’910 Patent”)**

27 **1. Claims and Specification of the ’910 Patent**

28 93. The ’910 Patent is entitled “System for Treating Embolism and Associate Devices

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

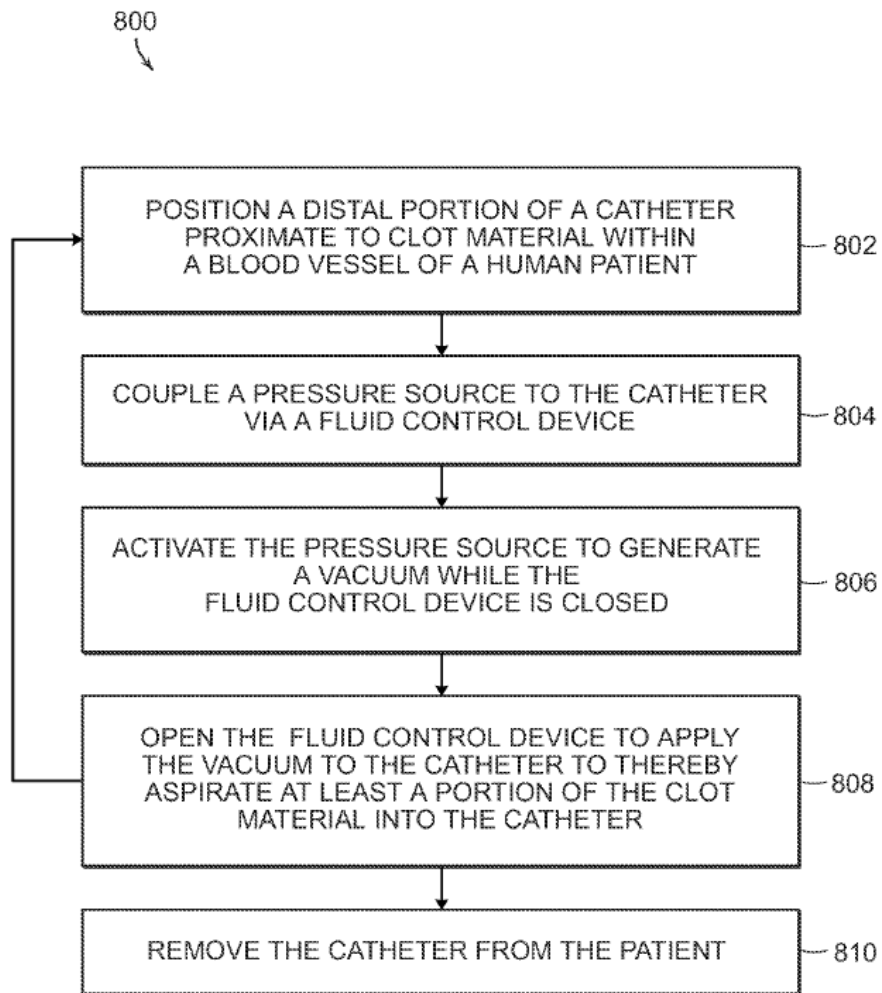
3 94. The '910 Patent is part of a family of patents claiming priority back to United
4 States Application No. 16/536,185 filed on August 8, 2019 (now United States Patent No.
5 11,559,382) and two provisional applications filed on August 13, 2018. The family includes
6 multiple patents, including the '910, '333, '005, and '691 Patents.

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

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

15 ('910 Patent at Abstract, 4:17-33.) The disclosed systems and methods include ones related to
16 the so-called “Whoosh” method of treatment using aspiration. “Whoosh” is the name that Inari
17 has given to the process of (a) positioning an aspiration catheter proximate to a clot to be removed
18 from a patient body, (b) creating a stored volume of vacuum with a vacuum pressure source (for
19 example, by pulling back the plunger of a syringe or using an electric pump to build vacuum
20 pressure in a chamber) while a fluid control device (e.g., a valve) between the stored vacuum
21 volume and the catheter is closed to disconnect the vacuum from the catheter, and then (c) opening
22 the intervening fluid control device, e.g. valve, to rapidly apply the vacuum to the distal tip of the
23 aspiration catheter to aspirate at least some of the clot (in other words to suck at least some clot
24 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).

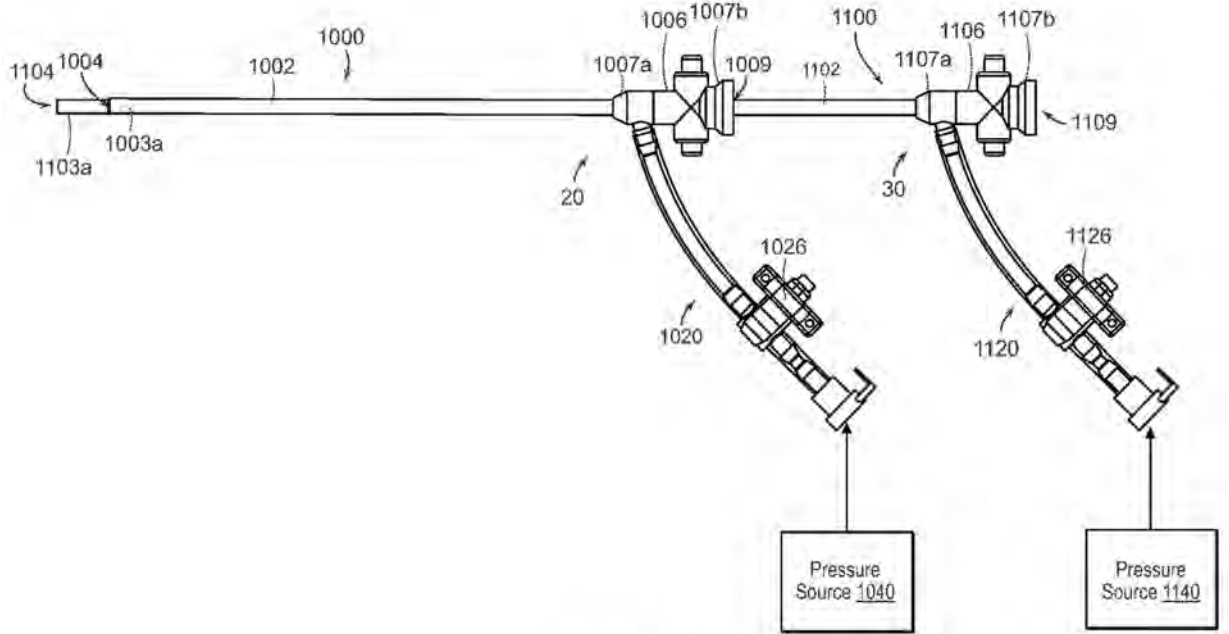
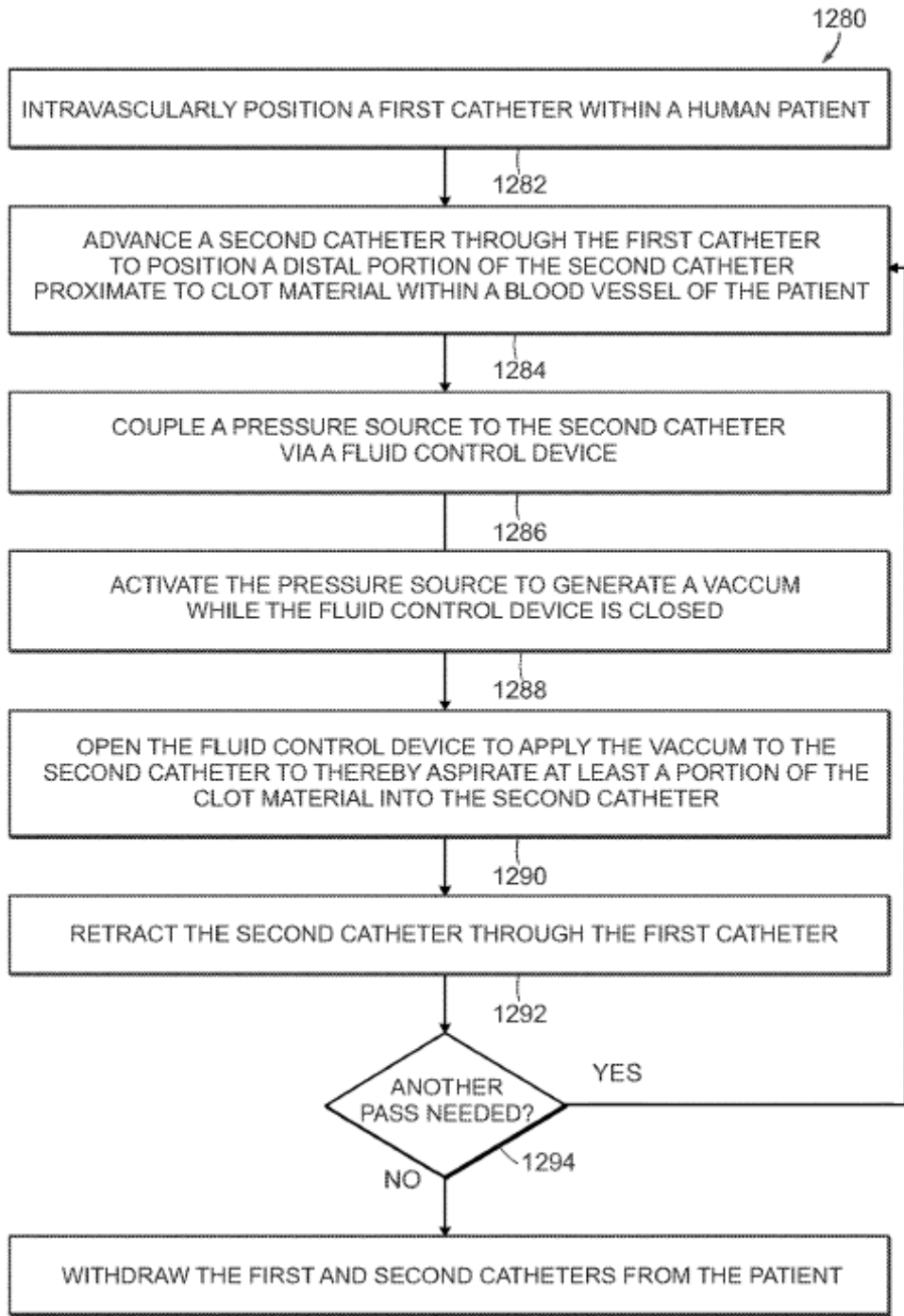


FIG. 11

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

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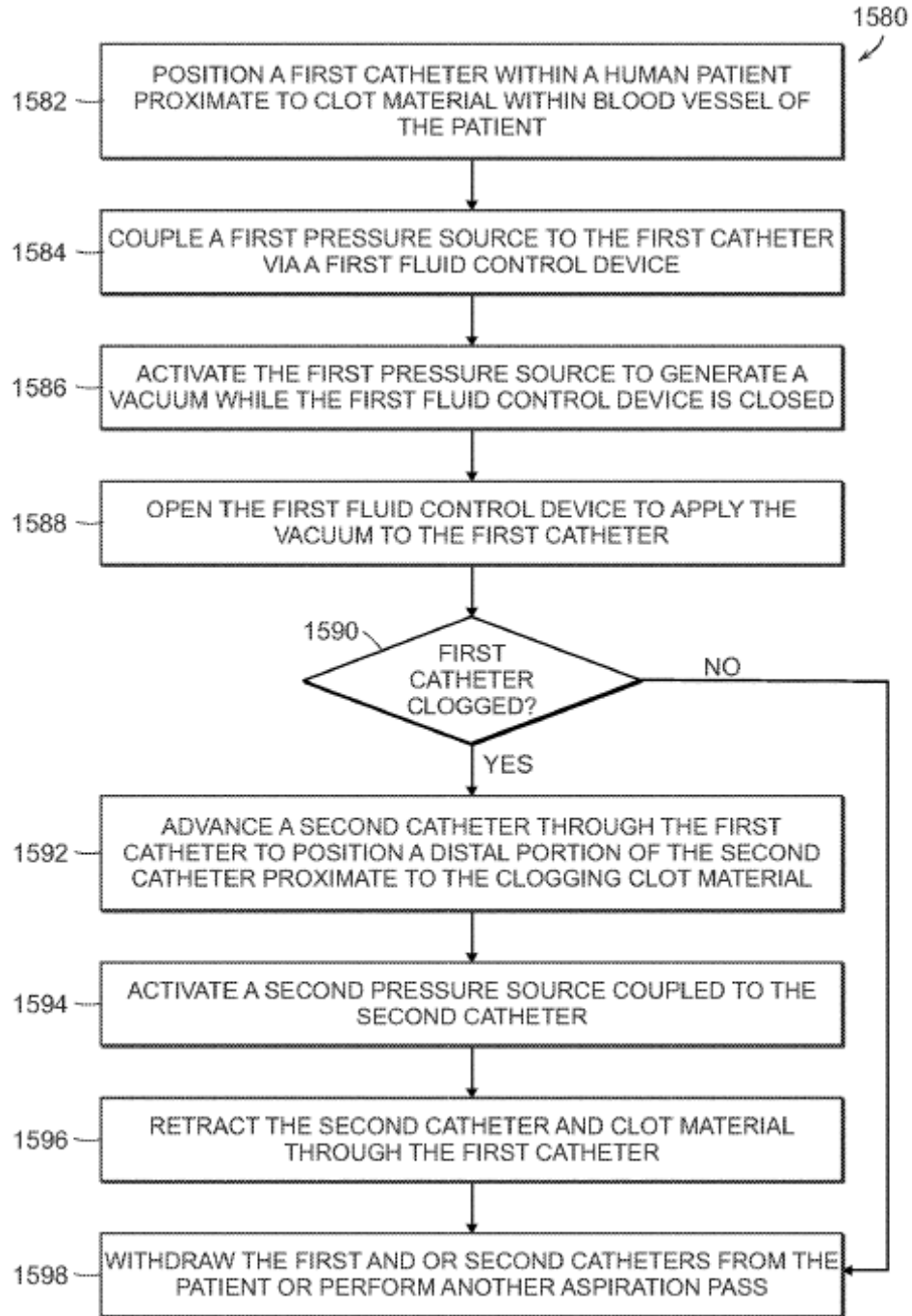


1296 FIG. 12

(Fig. 12.)

25 98. The telescoping configuration can also be used to perform multiple aspiration
26 passes involving aspiration by each of the two catheters in a telescoping configuration. Figure
27 15 of the '910 Patent discloses a method in which both catheters in the telescoping configuration
28 are used for aspiration with employing a first vacuum pressure source and a first fluid control

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



25 FIG. 15

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

1 clot material with the second catheter (1594.)

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

17 **2. File History of the '910 Patent**

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

19 101. During prosecution, the examiner granted the application after a single office
20 action dated November 6, 2023. The Examiner allowed original Claims 1-17 and 19-20, for
21 reciting a telescoping (“a second catheter advanceable through the first catheter”), but rejected
22 original claim 18, which did not require telescoping, for obviousness over United States
23 Published Applications 20150173782 (“Garrison”) and 20180054453 (“Garrison II”). (Nov. 6,
24 2023, Office Action at 2-3, 4- 6.)

25 Garrison (US 20150173782 A1) teaches all of the limitations as
26 discussed above and Garrison further teaches a second clot
27 aspiration assembly (second aspiration assembly connected to line
28 (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

1 source (3425) provides suction to the distal portion of the flow line
2 (2045), see Figure 33). However, Garrison fails to teach a second
3 catheter advanceable through the first catheter. The second catheter
4 (2045) does not advance through first catheter (2025), as shown in
5 Figure 33. There is no reason to advance the second catheter
6 through the first catheter of Garrison. Also Garrison does not
7 explicitly disclose the flow lines (2025 and 2045) advancing
8 through arterial access device (2010). It would be unreasonable to
9 modify the flow lines to advance through the arterial access device
10 (2010) because it would interfere with the thrombectomy device.
11 Therefore, the limitations of claims 1 and 11 are considered
12 allowable.

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

14 However, Garrison et al. (US 20180064453 A1) fails to teach a
15 second clot aspiration assembly, including: a second catheter
16 advanceable through the first catheter; a second pressure source; and
17 a second fluid control device between the second catheter and the
18 second pressure source, wherein the second fluid control device is
19 movable between (a) an open position in which the second pressure
20 source is fluidly connected to the second catheter and (b) a closed
21 positioned in which the second pressure source is fluidly
22 disconnected from the second catheter, wherein the second pressure
23 source is configured to generate vacuum pressure while the second
24 fluid control device is in the closed position, and wherein, upon
25 movement of the second fluid control device from the open position
26 to the closed position, the vacuum pressure is applied to the second
27 catheter to generate suction at a distal portion of the second catheter.

28 (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

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

2 [I]ndependent claims 1 and 11, as amended, are further patentable
3 over Garrison for at least the reasons discussed during the January
4 25th videoconference interview with the Examiner and his
5 supervisor in related United States Patent Application No.
6 18/329,450, and specifically the Examiner's comments in the
7 Applicant-Initiated Interview Summary mailed January 31, 2024
8 that "Attorney and Examiner agree that incorporating more
9 structural claim language, i.e. diameter of the catheter, would make
10 the claim 1 allowable over the prior art Garrison."

11 (*Id.* at 7-8.)

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

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

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

24 **3. Claim 1 of the '910 Patent**

25 105. Claim 1 of the '910 Patent recites:

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

28 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

1 the first position to the second position, the vacuum pressure is
2 applied to the first catheter to generate suction at a distal portion of
the first catheter; and

3 a second clot aspiration assembly, including:

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

8 a second pressure source; and

9 a second fluid control device between the second catheter and the
10 second pressure source, wherein the second fluid control device is
movable between (a) a first position in which the second pressure
11 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,

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

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

17 ('910 Patent at 35:52-36:34.)

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

22 **B. United States Patent 11,844,921 (“’921 Patent”)**

23 **1. Claims and Specification of the ’921 Patent**

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

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

1 11,000,682) and a provisional application filed on September 6, 2017. The family includes
2 multiple patents, including the '921, '011, '012 and '291 Patents.

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

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

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

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

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

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

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

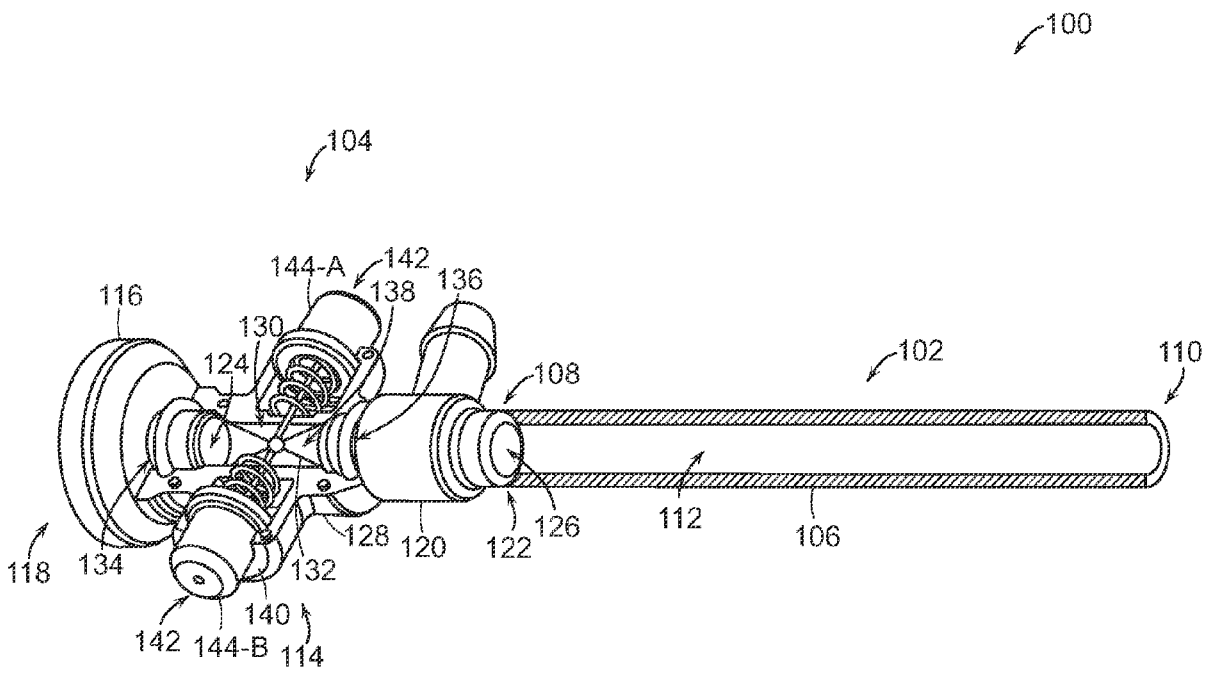
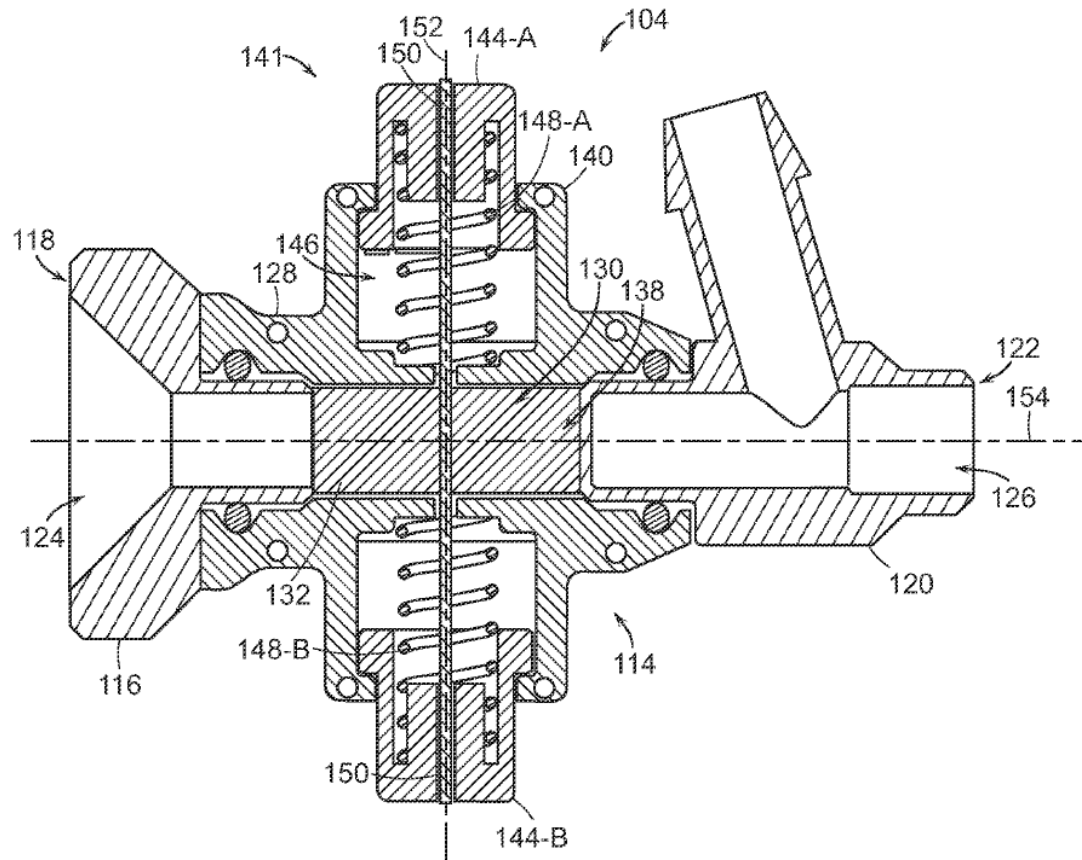


FIG. 1

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

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

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

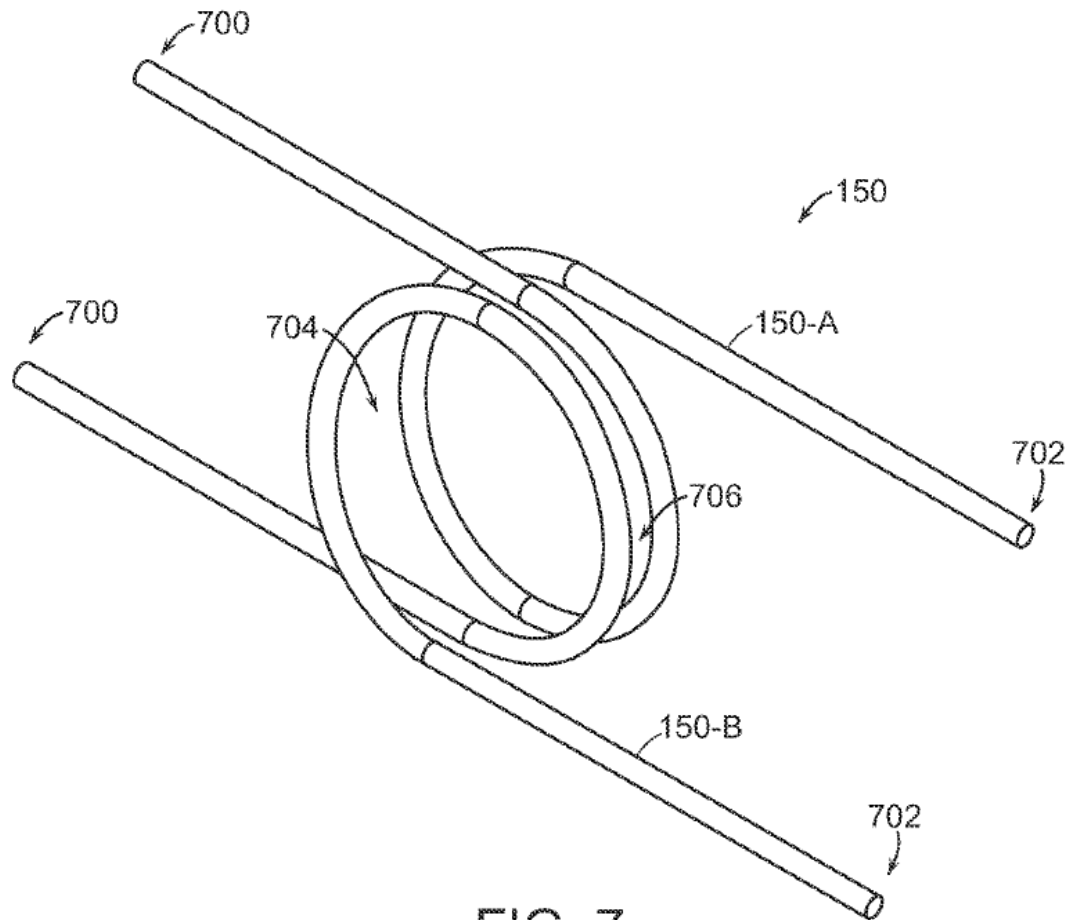


FIG. 7

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

23 **2. File History of the '921 Patent**

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

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

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

5 Regarding claim 52, Hartley discloses a valve 8 comprising: an
6 elongate member 22 defining a lumen 3; an active tensioning
7 mechanism including an actuator 12 coupled to the elongate
8 member via a filament 20 extending at least partially around the
9 elongate member, wherein the actuator is movable between a first
10 position (Figs. 2 & 4), wherein the lumen constricted and sealed; a
11 second position (Figs.1 & 3) wherein the lumen is at least partially
12 open. Harley fails to disclose a biasing member configured to bias
13 the actuator to the first position. Note: the spring 29 in Hartley is
14 not configured to bias the actuator to the first position. A ball 28
15 loaded by the spring 29 to detent or hold in the housing 6.
16 *****

17 Regarding claim 77, the claim 77 requires two actuators coupled to
18 the elongate member; and each of the actuator coupled to the
19 elongate member via with respective to each of a first filament and
20 a second filament. Meanwhile, the prior art Har[t]ley discloses only
21 one actuator.

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

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

27 **3. Claim 1 of the '921 Patent**

28 118. 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)

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

6 **4. Claim 10 of the '921 Patent**

7 120. Claim 10 of the '921 Patent recites:

8 The valve of claim 1 wherein the actuator is a first actuator, wherein
9 the filament is a first filament, wherein the biasing member is a first
10 biasing member, and wherein the active tensioning mechanism
11 further comprises:

12 a second actuator coupled to the elongate member via a second
13 filament extending at least partially around the elongate member,
14 wherein the second actuator is moveable between (a) a first position
15 wherein the lumen is constricted and sealed and (b) a second
16 position wherein the lumen is at least partially open; and

17 a second biasing member configured to bias the second actuator to
18 the first position.

19 (22:53-64.) Claim 10 depends from Claim 1 and recites an additional second actuator and a
20 second filament looped at least partially around the elongate member of the valve.

21 **IX. Inari's Patents Cover Important Innovations**

22 121. The '910 Patent, including Claim 1, relates to several important developments
23 Inari invented and ultimately brought to market. For instance, Claim 1 recites a telescoping
24 system where a second large diameter catheter (16F or greater) is advanced through (telescoped)
25 a larger first catheter (*e.g.*, a 20F or 24F catheter). As a starting point, Claim 1 recites large
26 catheter sizes, which are important for many reasons, as discussed above. For example, large-
27 bore catheters allow for greater suction over a greater area and removal of more clot material.
28 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

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

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

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

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

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

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

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

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

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

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

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

13 **1. Claim 1**

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

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

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

23 132. As can be seen in Ex. 17, the Symphony system practices the preamble because it
24 is a clot treatment system that employs “next generation thrombus removal” with “powerful,
25 focused aspiration” for treating (e.g., removing) clot material from within a blood vessel. (Ex.
26 7 at 2-4.) The Symphony system is for treating clot material comprising a pulmonary embolism
27 in the vasculature of the patient, as it is currently being used in clinical trials for treatment of
28 pulmonary embolism. In addition, Truvic is seeking FDA clearance for using the Symphony

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

3 **b. [1][a] a first clot aspiration assembly, including: a first catheter; a first**
4 **pressure source; and a first fluid control device between the first**
5 **catheter and the first pressure source,**

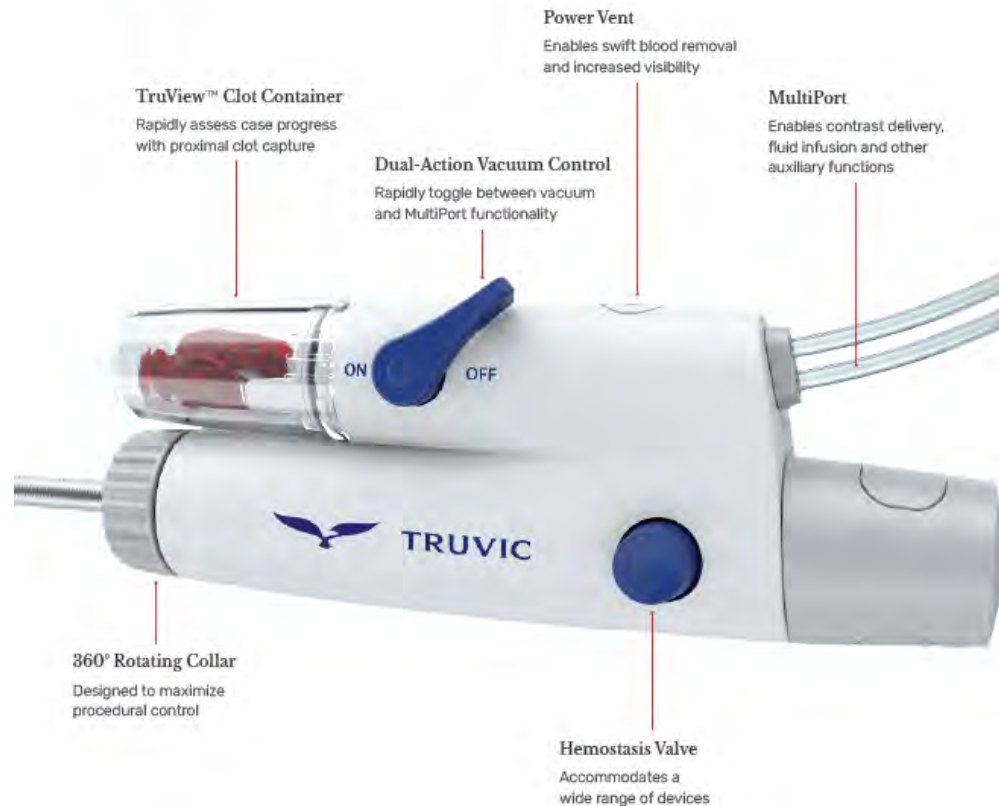
6 133. Claim 1 recites “a first clot aspiration assembly, including: a first catheter; a first
7 pressure source; and a first fluid control device between the first catheter and the first pressure
8 source.”

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

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



(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.



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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,

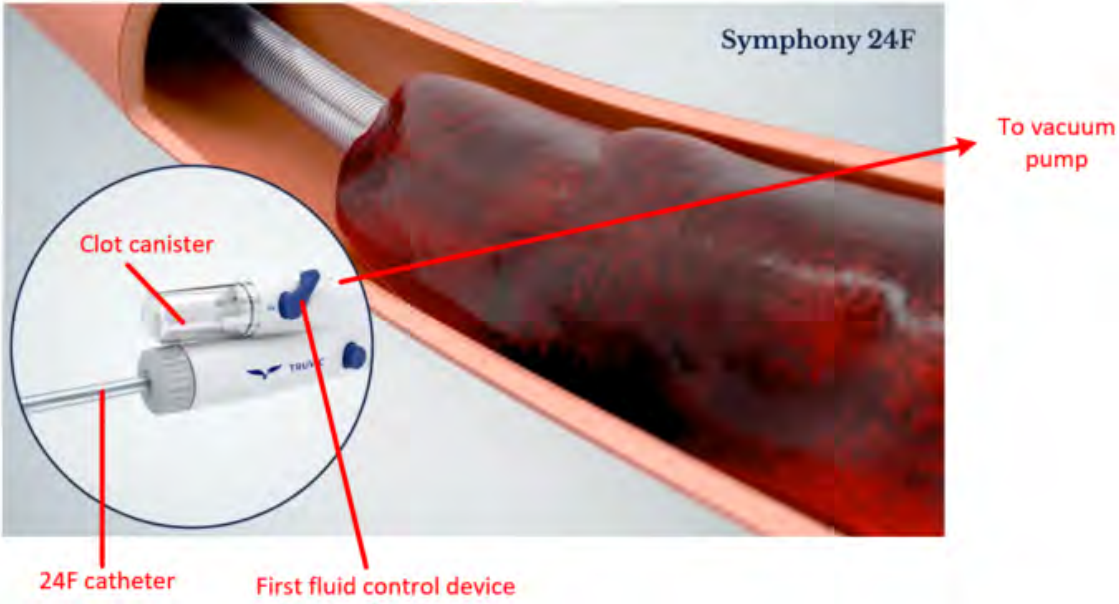
137. Claim 1 further recites “wherein the first fluid control device is movable between (a) a first position in which the first pressure source is fluidly disconnected from the first catheter and (b) a second position in which the first pressure source is fluidly connected to the first catheter.”

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

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

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

10 First fluid control device in “Off” position such that the first pressure source is fluidly
11 disconnected from the 24F catheter such that aspiration is not applied to the clot
12 material



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

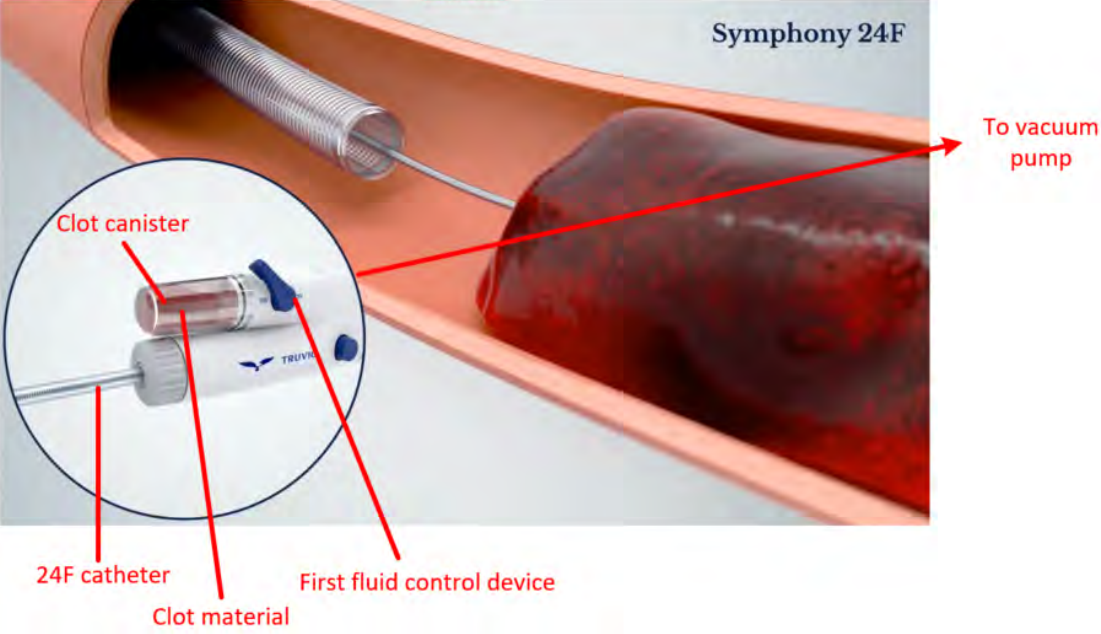
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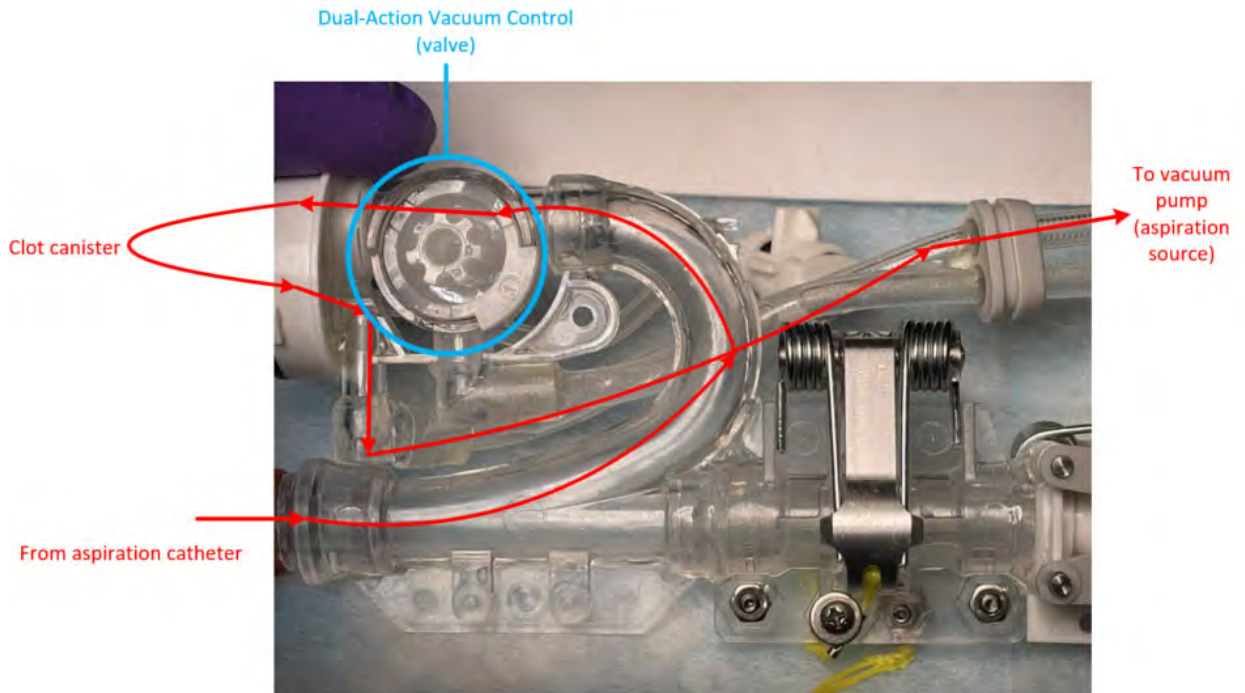
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141. As shown in the annotated figure below, moving the lever of the first fluid control device to the “On” position (second position) operates the first fluid control device to fluidly connect the first pressure source to the lumen of the 24F aspiration 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.

First fluid control device in “On” position such that the first pressure source is fluidly connected to the 24F catheter such that the clot material is aspirated into the clot canister





14 d. [1][c] wherein the first pressure source is configured to generate
15 vacuum pressure while the first fluid control device is in the first
16 position, and wherein, upon movement of the first fluid control device
17 from the first position to the second position, the vacuum pressure is
18 applied to the first catheter to generate suction at a distal portion of
19 the first catheter;

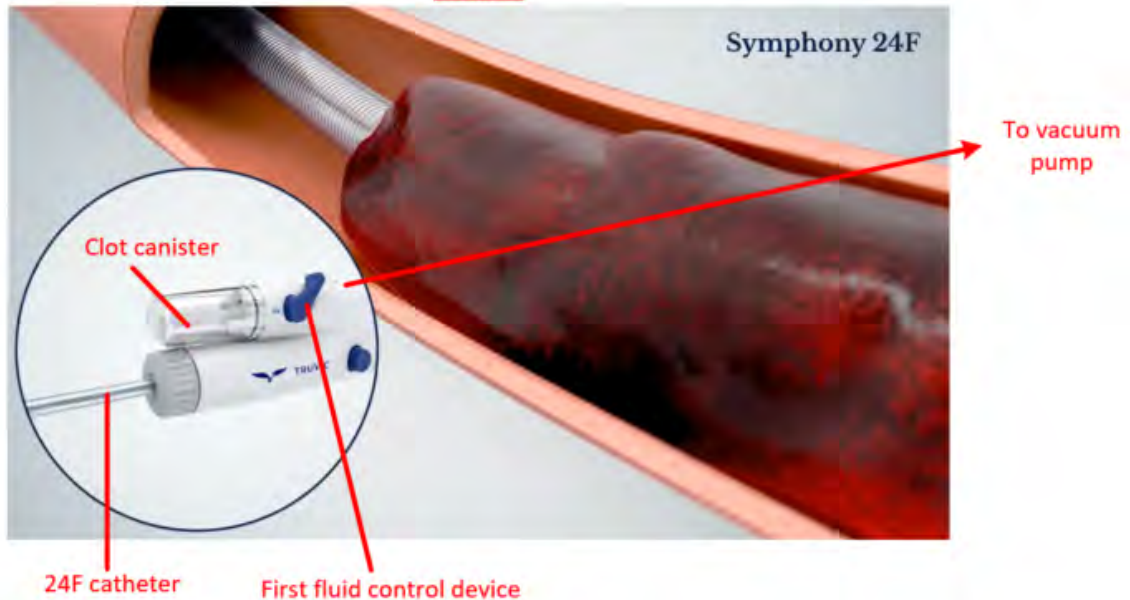
20 144. Claim 1 also recites “wherein the first pressure source is configured to generate
21 vacuum pressure while the first fluid control device is in the first position, and wherein, upon
22 movement of the first fluid control device from the first position to the second position, the
23 vacuum pressure is applied to the first catheter to generate suction at a distal portion of the first
24 catheter.”

25 145. As can be seen in Ex. 17, the Symphony system practices this limitation because
26 the Symphony system’s first fluid control device is movable between an “Off” position (first
27 position) in which the first fluid control device fluidly disconnects the first pressure source from
28 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,

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

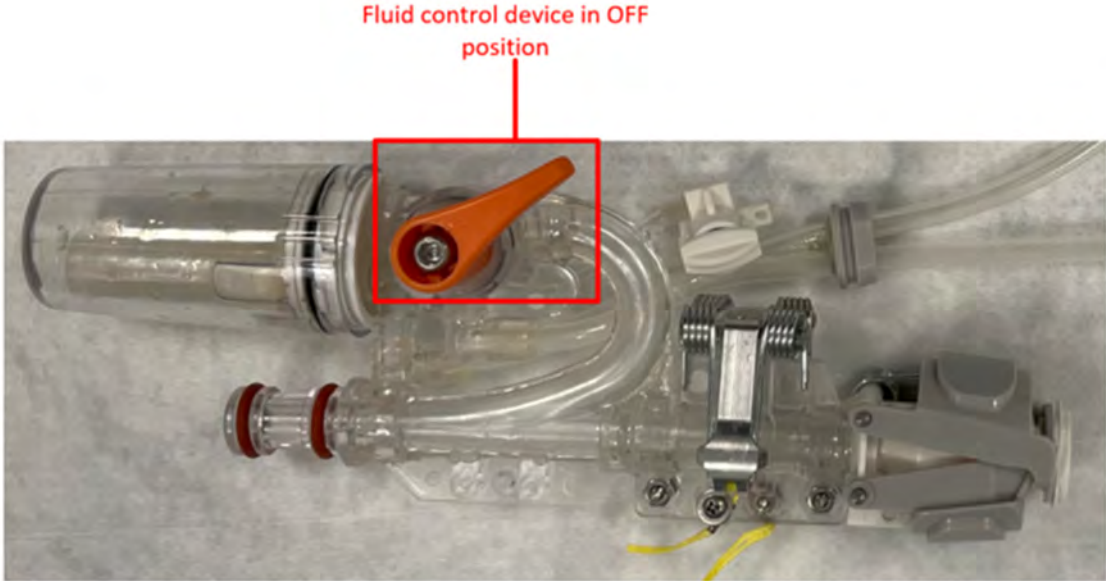
5 146. Specifically, as shown in the annotated figure below, while the first fluid control
6 device is in the “Off” position (first position), vacuum pressure is generated, including in the
7 clot canister, by the first pressure source comprising the clot canister and vacuum pump.

8 First fluid control device in “Off” position such that the first pressure source is fluidly
9 disconnected from the 24F catheter such that aspiration is not applied to the clot
10 material



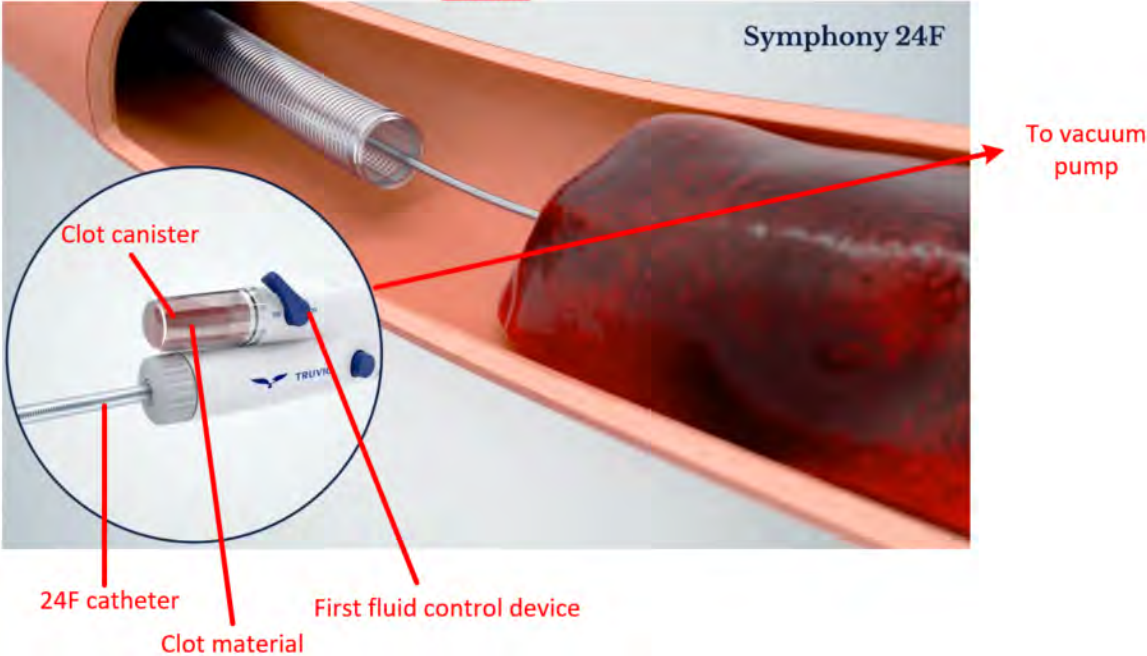
147. The annotated photo below shows the internal structure of the controller handle
which includes the Dual-Action Vacuum Control operated by a lever (first fluid control device).
In the annotated figure below, the first fluid control device is in the “Off” position (first
position).

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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.

First fluid control device in "On" position such that the first pressure source is fluidly connected to the 24F catheter such that the clot material is aspirated into the clot canister

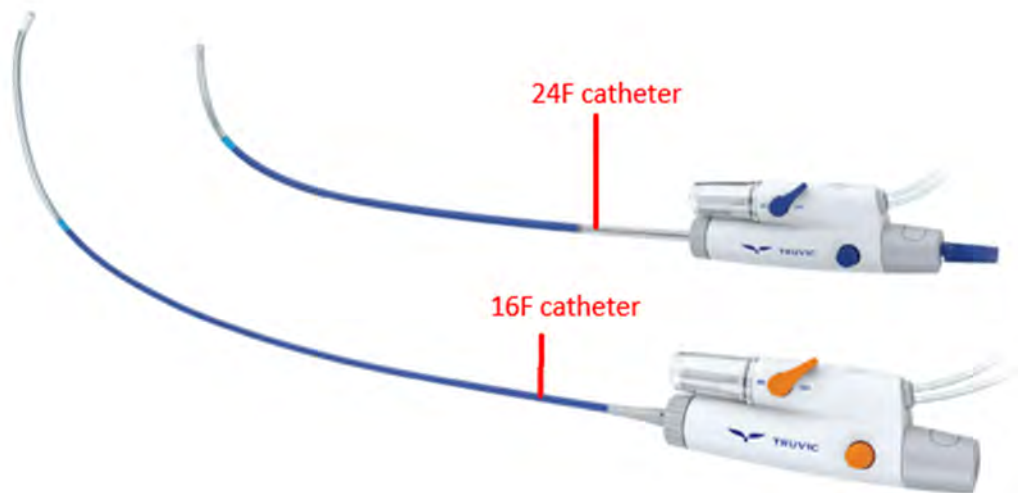


1 e. [1][d] and a second clot aspiration assembly, including: a second
2 catheter advanceable through the first catheter, wherein the second
3 catheter has a distal portion, wherein the second catheter has a size of
4 16 French or greater, and wherein the second catheter is shaped to be
intravascularly advanced through the vasculature of the patient such
that the distal portion of the second catheter is positioned proximate
to the pulmonary embolism;

5 151. Claim 1 also recites “a second clot aspiration assembly, including: a second
6 catheter advanceable through the first catheter, wherein the second catheter has a distal portion,
7 wherein the second catheter has a size of 16 French or greater, and wherein the second catheter
8 is shaped to be intravascularly advanced through the vasculature of the patient such that the
9 distal portion of the second catheter is positioned proximate to the pulmonary embolism.”

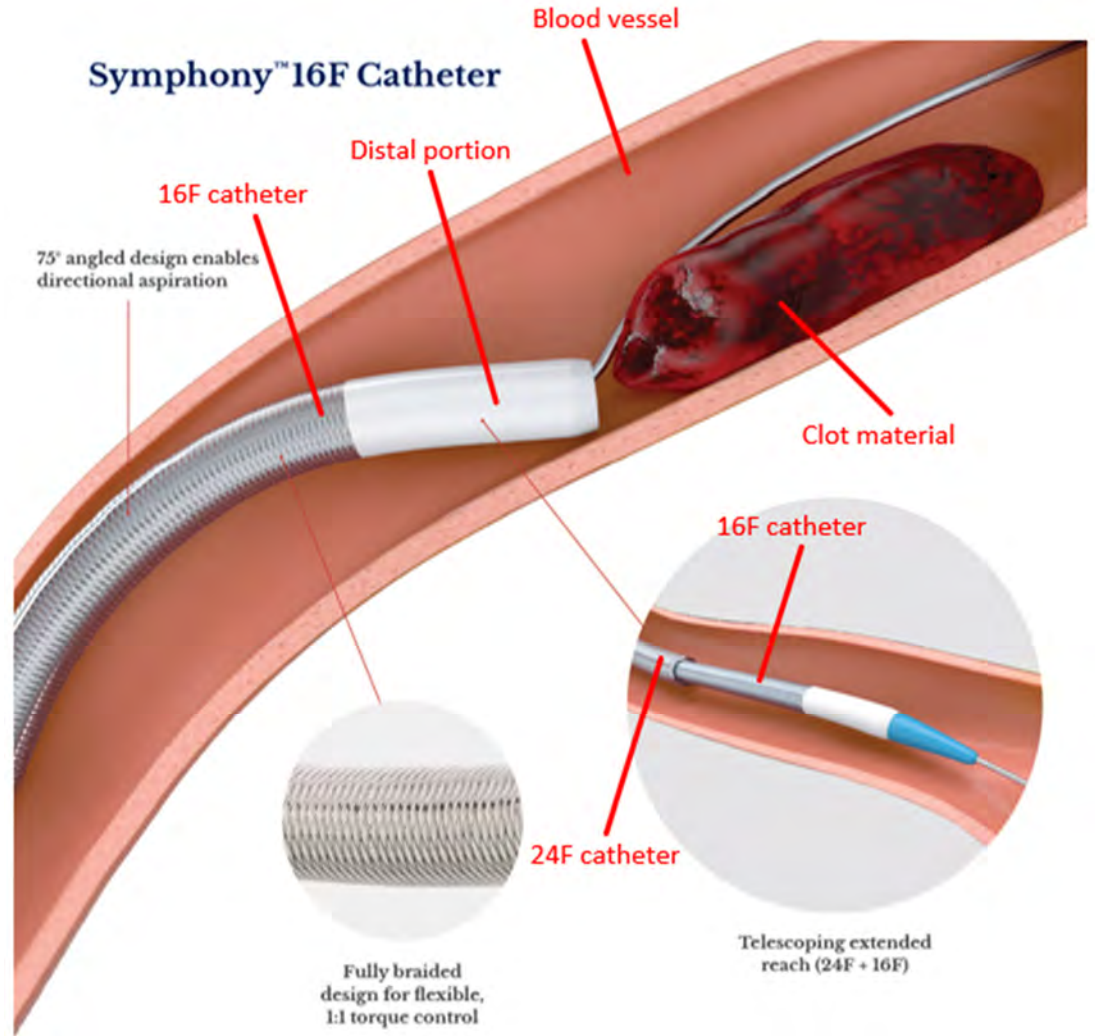
10 152. As can be seen in Ex. 17, the Symphony system practices this limitation because
11 it has a second aspiration assembly that includes a 16F aspiration catheter (second catheter)
12 advanceable through the 24F aspiration catheter (first catheter). The 16F aspiration catheter
13 (second catheter)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

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



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

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



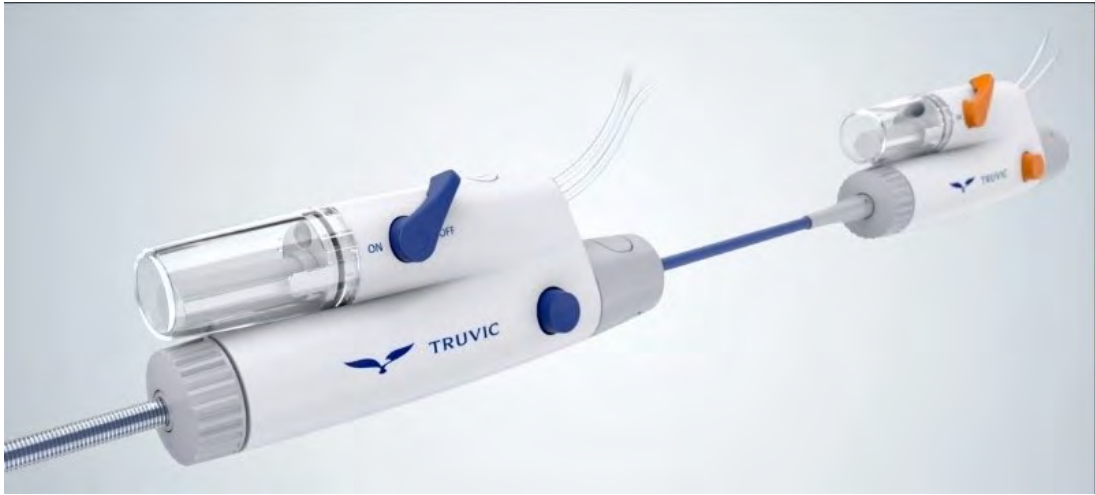
(Annotated Ex. 7 at 4.)

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

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

4 156. As can be seen in Ex. 17, the Symphony system practices this limitation because
5 it includes a 16F aspiration catheter (second catheter), a controller handle for the 16F aspiration
6 catheter, and a vacuum pump. The controller handle includes a clot canister. The second
7 pressure source comprises a vacuum pump and a clot canister. The controller handle further
8 includes a Dual-Action Vacuum Control operated by a lever (second fluid control device)
9 between the 16F aspiration catheter (second catheter) and the second pressure source. The
10 second fluid control device is movable between an “Off” position (first position) in which the
11 16F aspiration catheter (second catheter) is fluidly disconnected from the second pressure
12 source, and an “On” position (second position) in which the 16F aspiration catheter (second
13 catheter) is fluidly connected to the second pressure source.



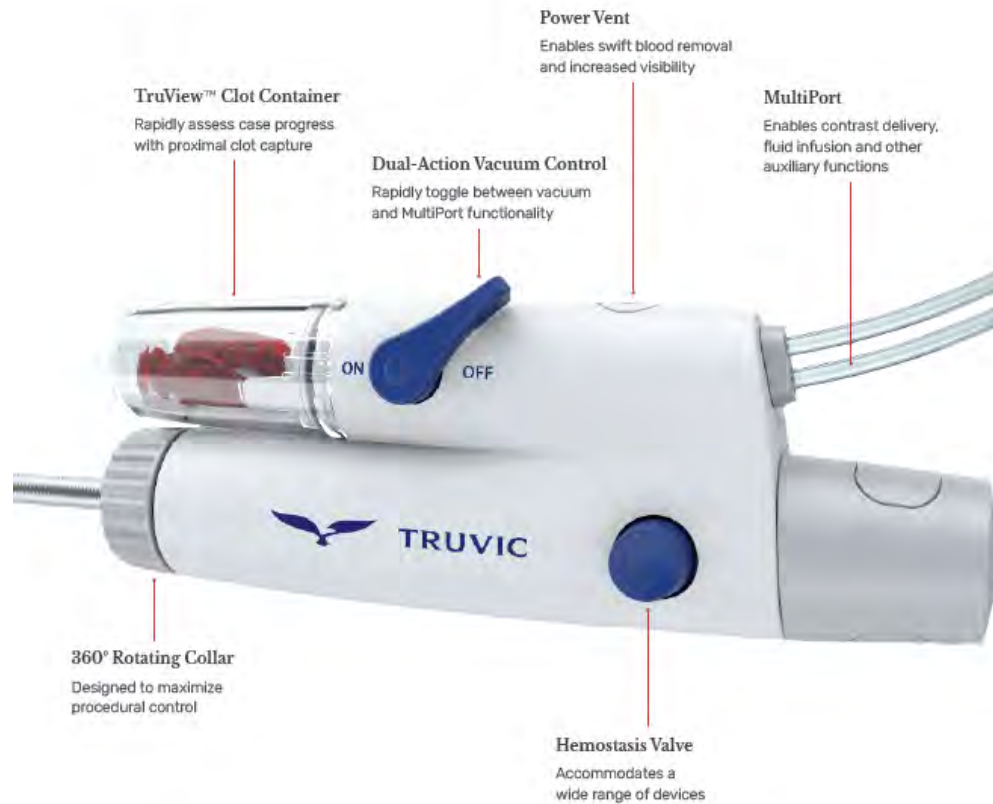
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22 157. Specifically, the 16F aspiration catheter (second catheter) is coupled to the
23 controller handle labeled as the “BigShot Controller” in the image below. The controller handle
24 includes a Dual-Action Vacuum Control operated by a lever (second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

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

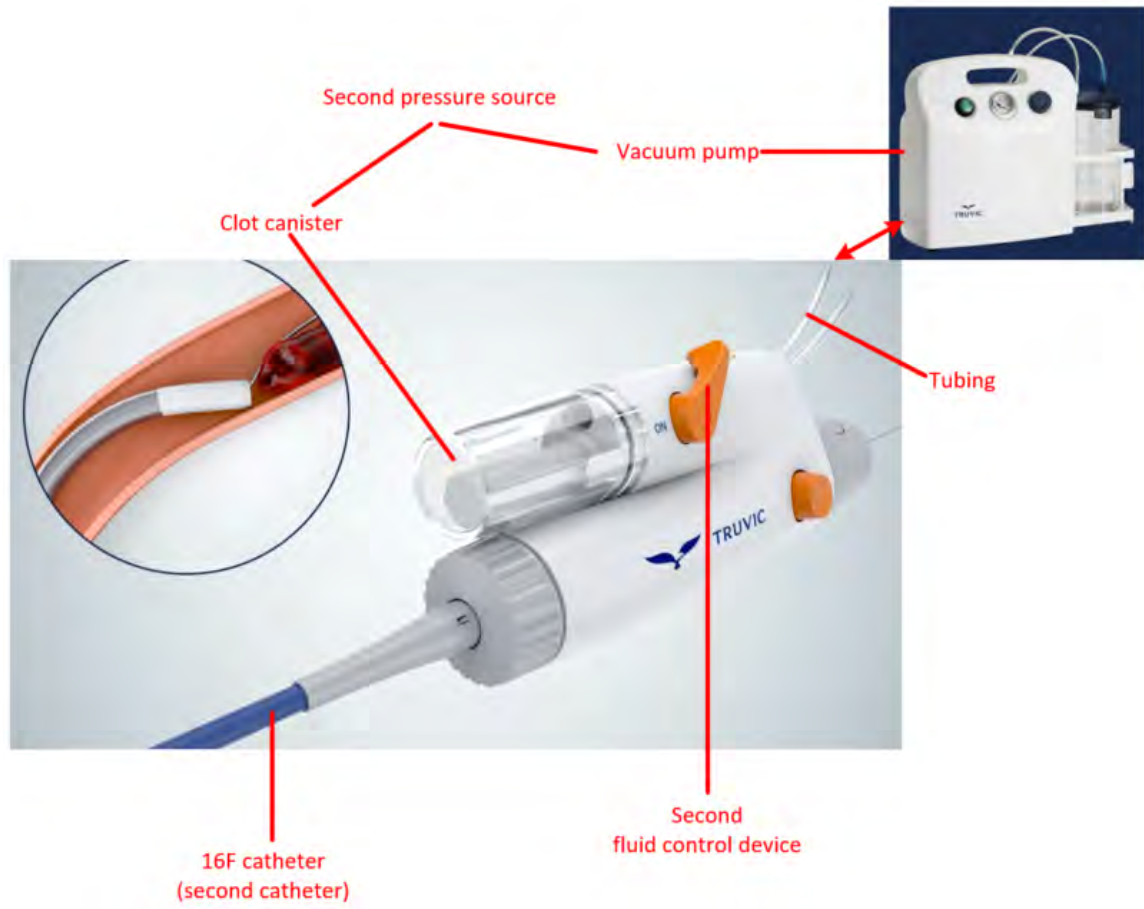
BigShot™ Controller



(Ex. 7 at 6.)

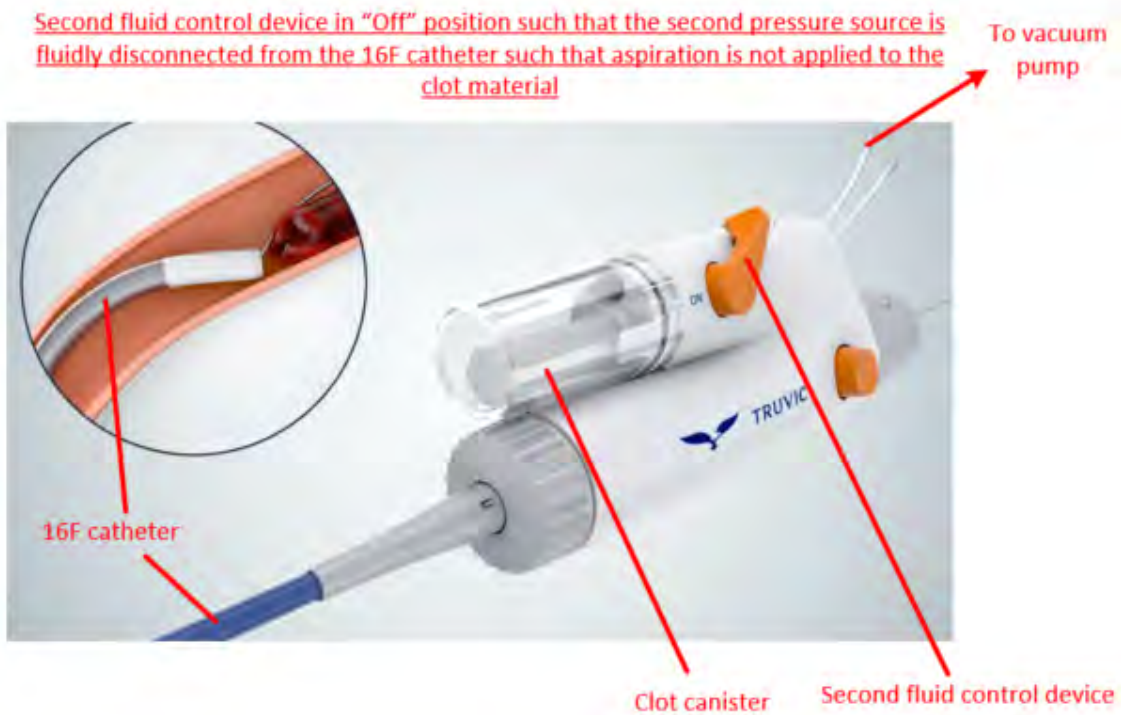
158. As shown in the annotated figure below, the clot canister is fluidly coupled to a vacuum pump via tubing. There is a second pressure source comprising the clot canister and vacuum pump. The Dual-Action Vacuum Control operated by a lever (second fluid control device) is between the 16F aspiration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

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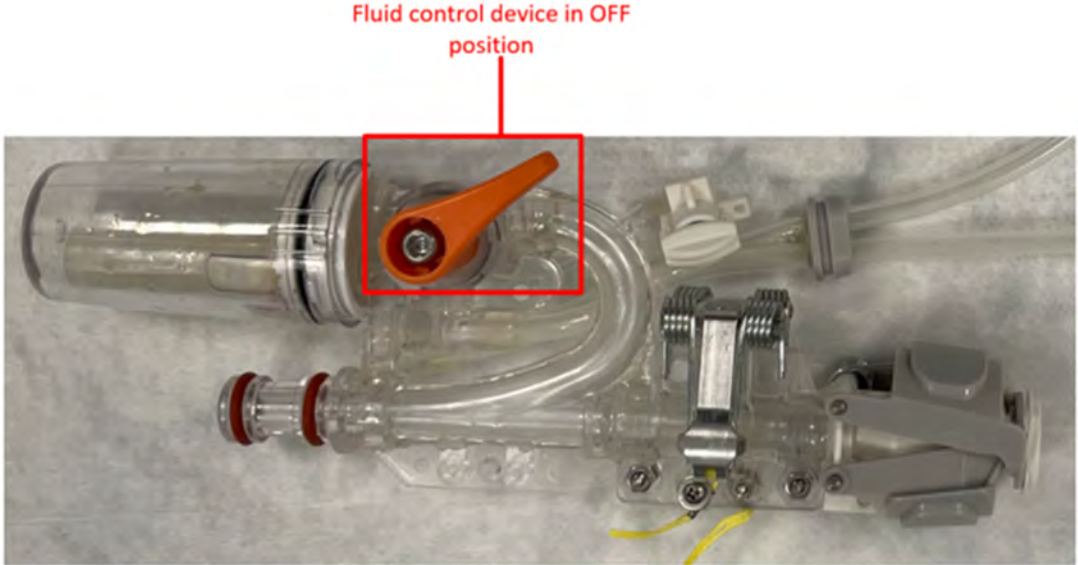


159. The Dual-Action Vacuum Control operated by a lever (second fluid control device) can be moved between an “Off” position (first position) and an “On” position (second position) by moving the lever. As shown in the annotated figure below, moving the lever of the second fluid control device to the “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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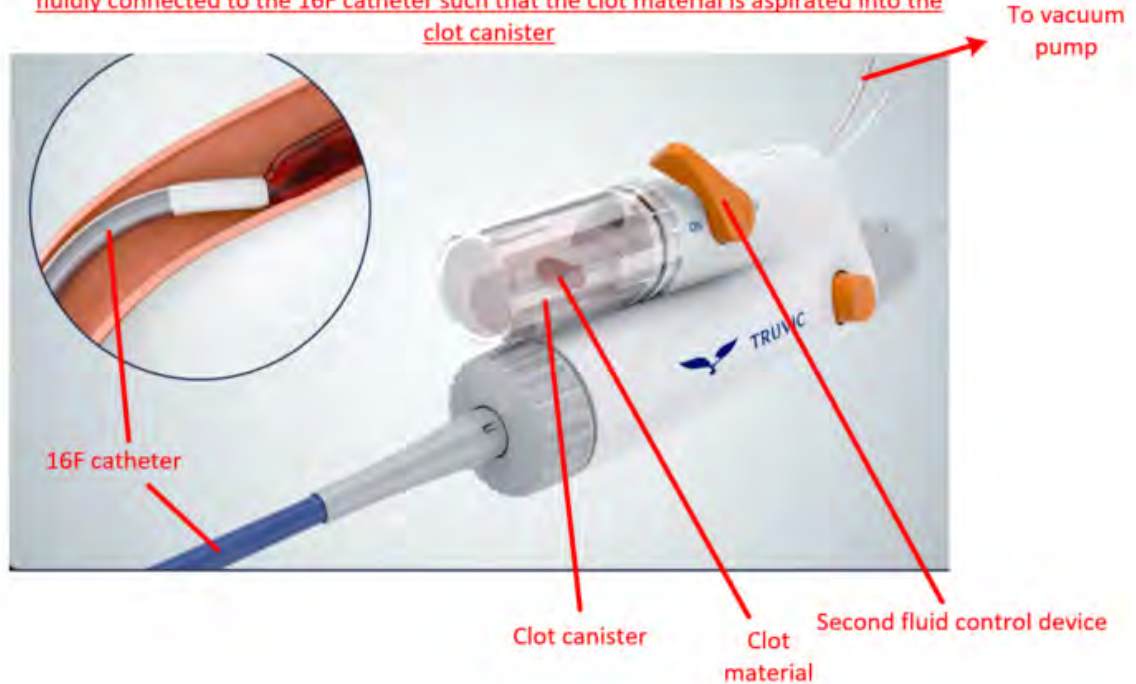


160. The annotated photo below shows the internal structure of the controller handle which includes the Dual-Action Vacuum Control operated by a lever (second fluid control device). In the annotated photo below, the second fluid control device is in the "Off" position (first position).



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

6 Second fluid control device in “On” position such that the second pressure source is
7 fluidly connected to the 16F catheter such that the clot material is aspirated into the
8 clot canister

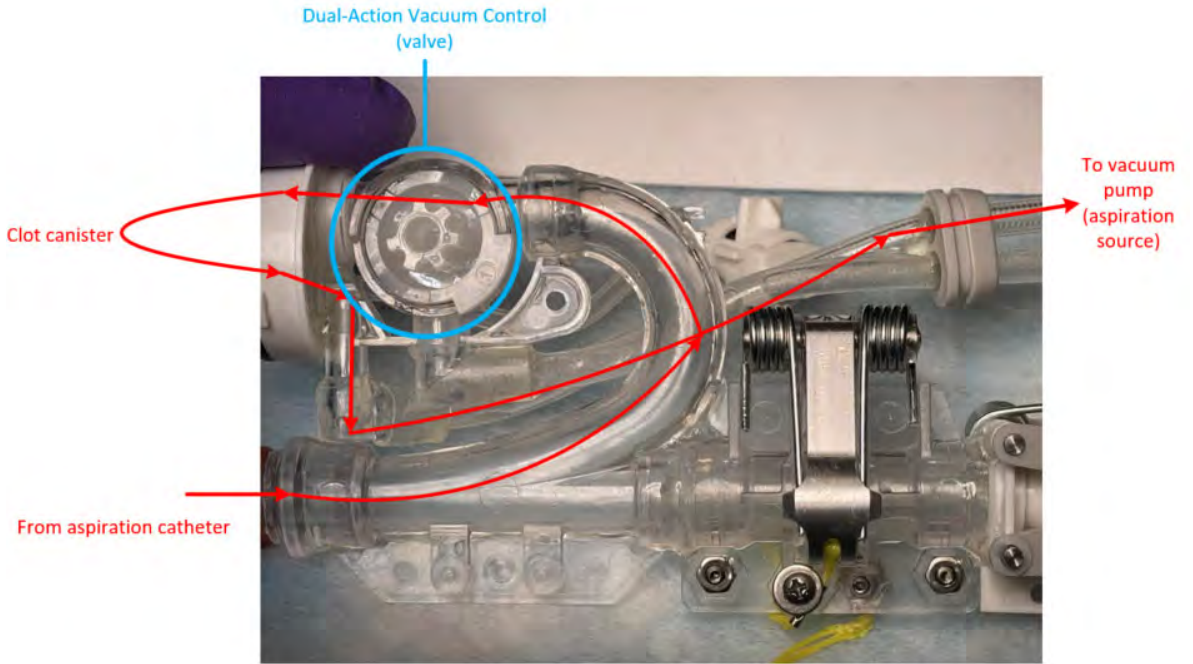


18 162. The annotated photo below shows the internal structure of the controller handle
19 which includes the Dual-Action Vacuum Control operated by a lever (second fluid control
20 device). In the annotated photo below, the second fluid control device is in the “On” position
21 (second position).

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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.



1 g. **[1][f] wherein the second pressure source is configured to generate**
2 **vacuum pressure while the second fluid control device is in the first**
3 **position, and wherein, upon movement of the second fluid control**
4 **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.

5 164. Claim 1 additionally recites “wherein the second pressure source is configured to
6 generate vacuum pressure while the second fluid control device is in the first position, and
7 wherein, upon movement of the second fluid control device from the first position to the second
8 position, the vacuum pressure is applied to the second catheter to generate suction at the distal
9 portion of the second catheter to aspirate blood and at least a portion of the pulmonary embolism
10 into the second catheter.”

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

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

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Second fluid control device in "Off" position such that the second pressure source is fluidly disconnected from the 16F catheter such that aspiration is not applied to the clot material To 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).

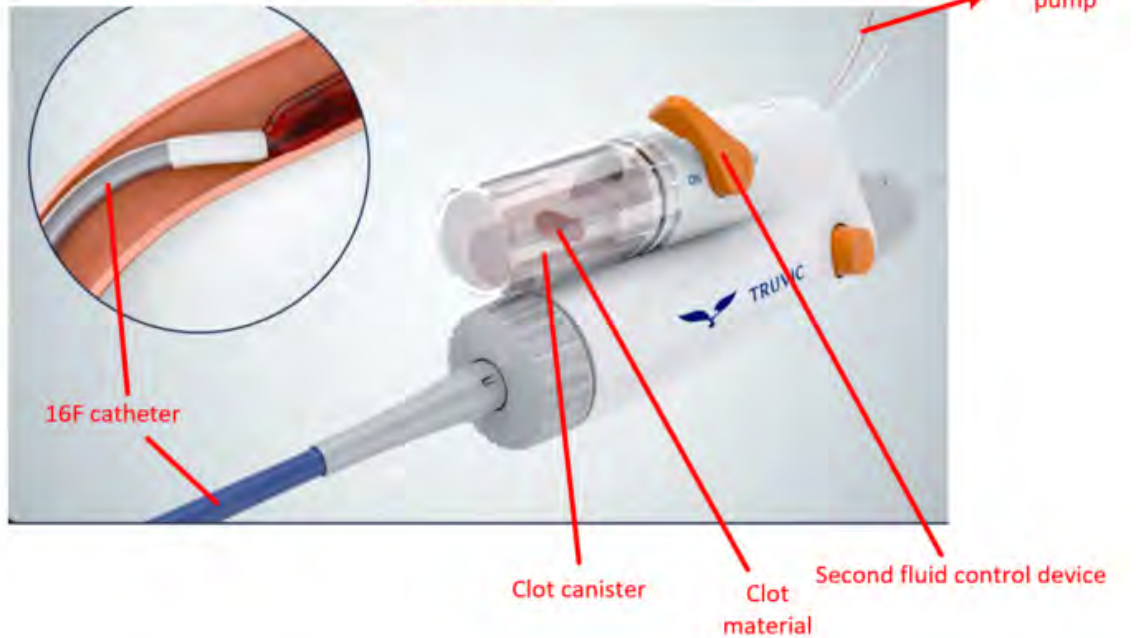
Fluid control device in OFF position



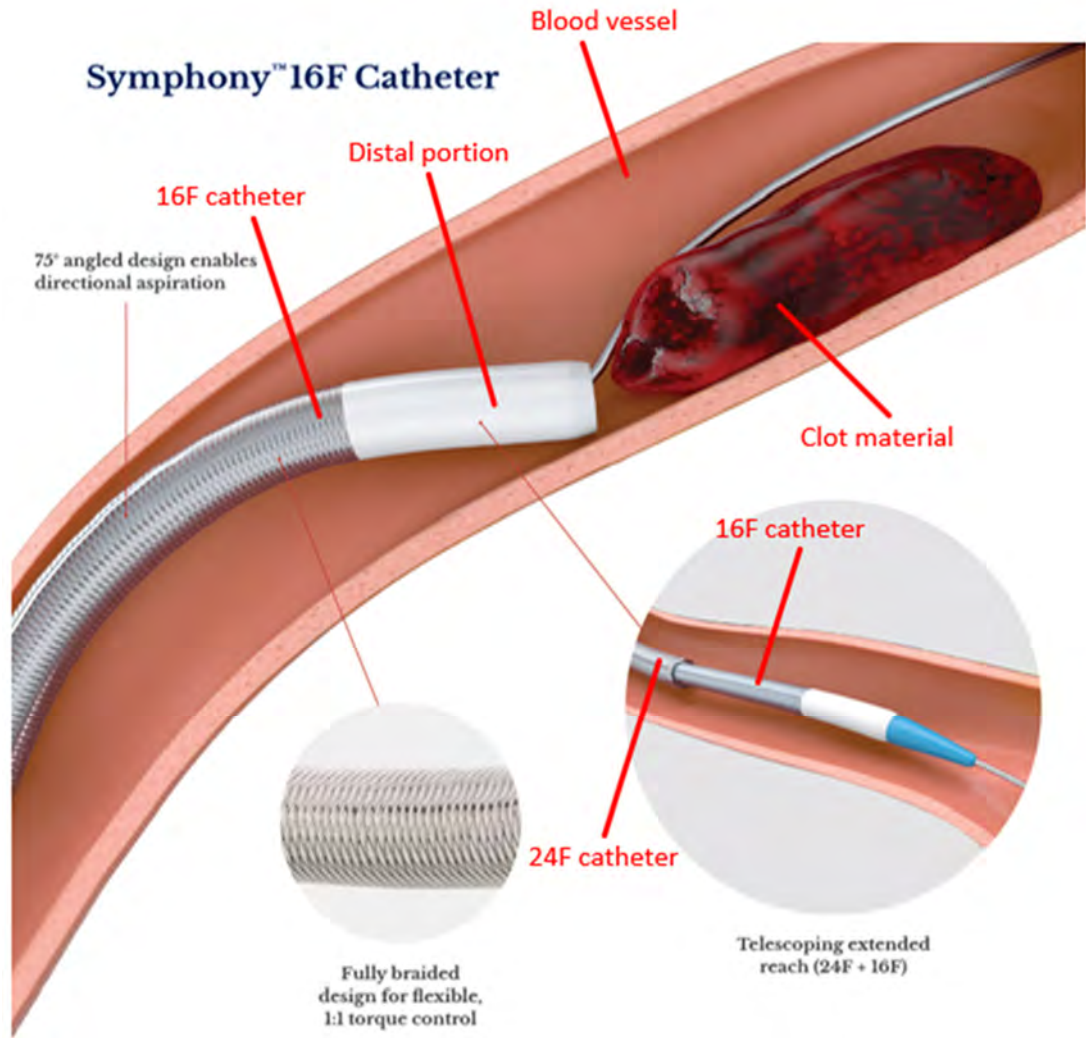
168. As shown in the annotated figures below, moving the second fluid control device from the "Off" position (first position) to the "On" position (second position) applies the

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

5 Second fluid control device in "On" position such that the second pressure source is
6 fluidly connected to the 16F catheter such that the clot material is aspirated into the
7 clot canister



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19 (Annotated Ex. 7 at 4.)

20 169. The annotated photo below shows the internal structure of the controller handle
21 which includes the Dual-Action Vacuum Control operated by a lever (second fluid control
22 device). In the annotated photo below, the second fluid control device is moved to the “On”
23 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.

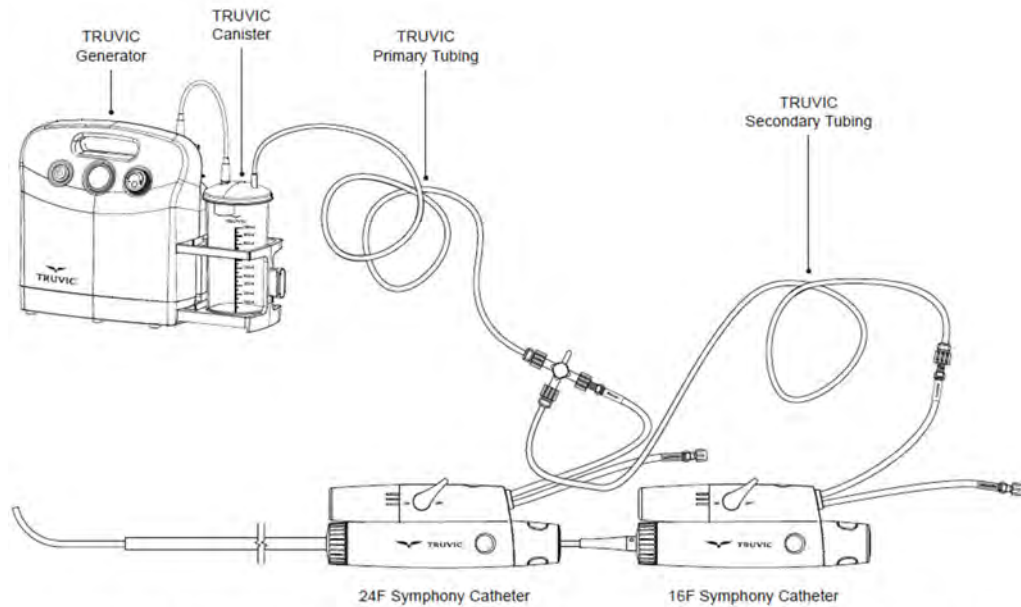


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

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

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

4 **1. Claim 1**

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

7 **a. 1[pre] A valve, comprising:**

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

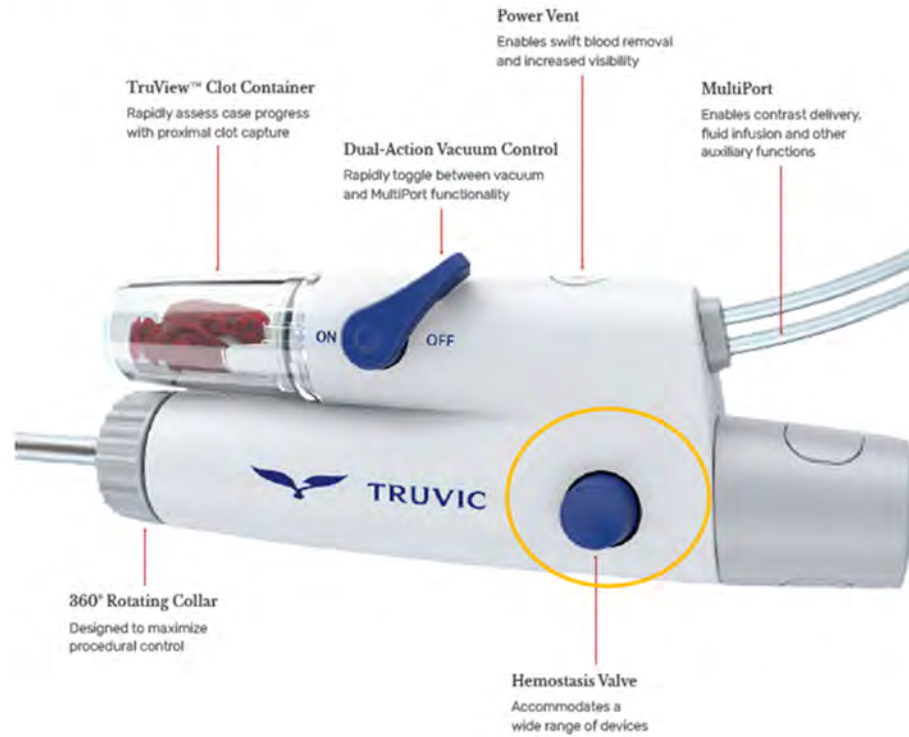
13 176. As can be seen in Ex. 18, the Symphony system practices the preamble because it
14 includes a valve, specifically a hemostasis valve in each of the Symphony handles. These
15 hemostasis valves are used to seal around catheters and/or tools inserted through the handle.
16 The hemostasis valve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

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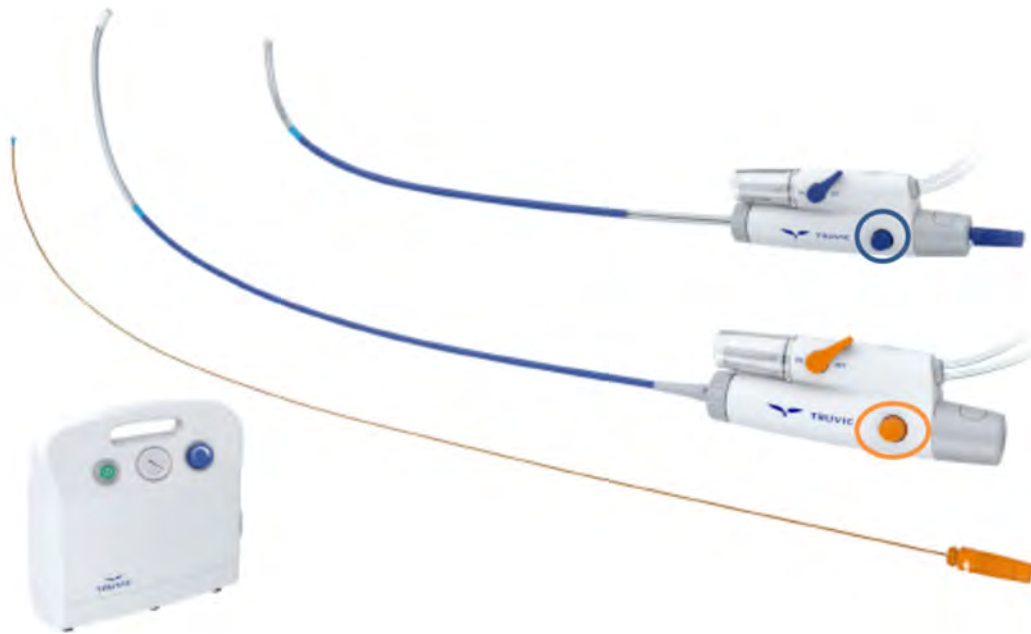
High-Powered, Continuous Vacuum with Real-Time Case Assessment

BigShot™ Controller



(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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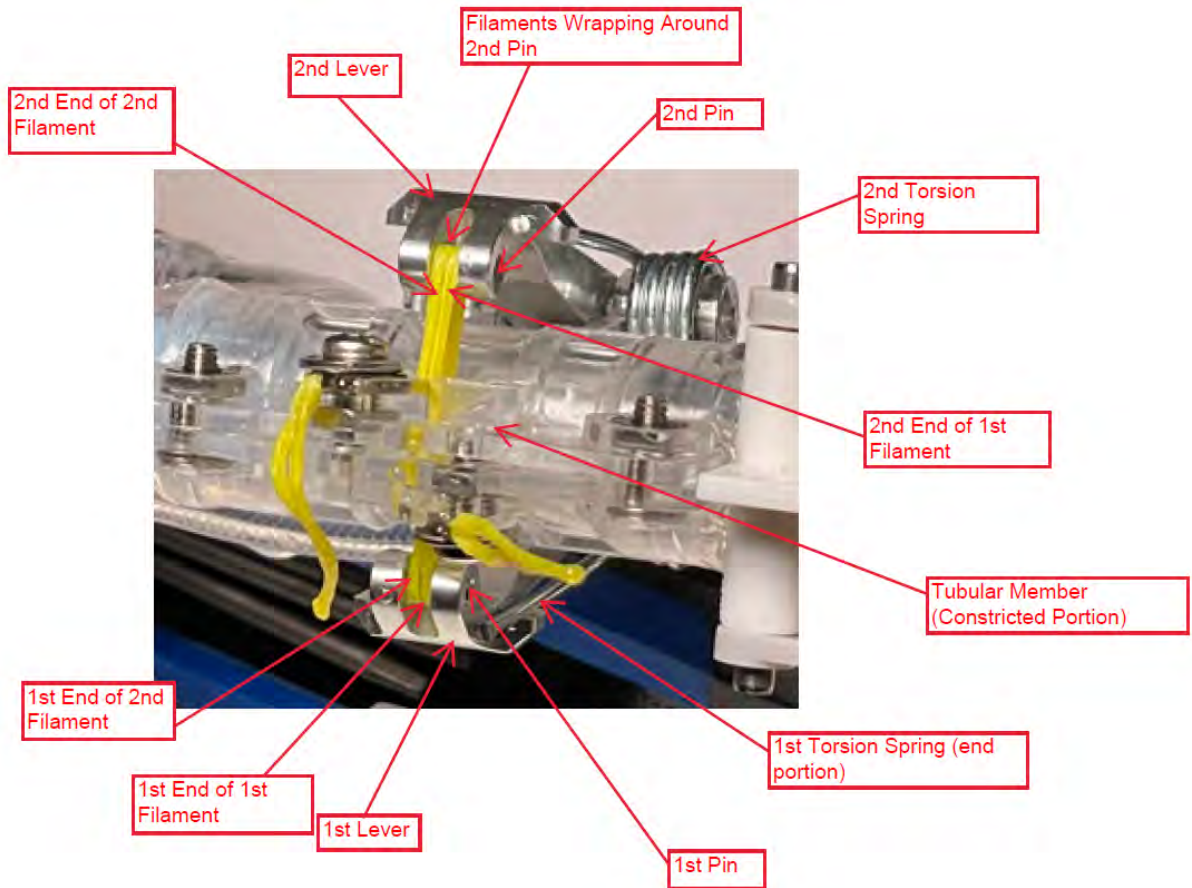


(Internal portion of housing zoomed in on hemostasis valve.)

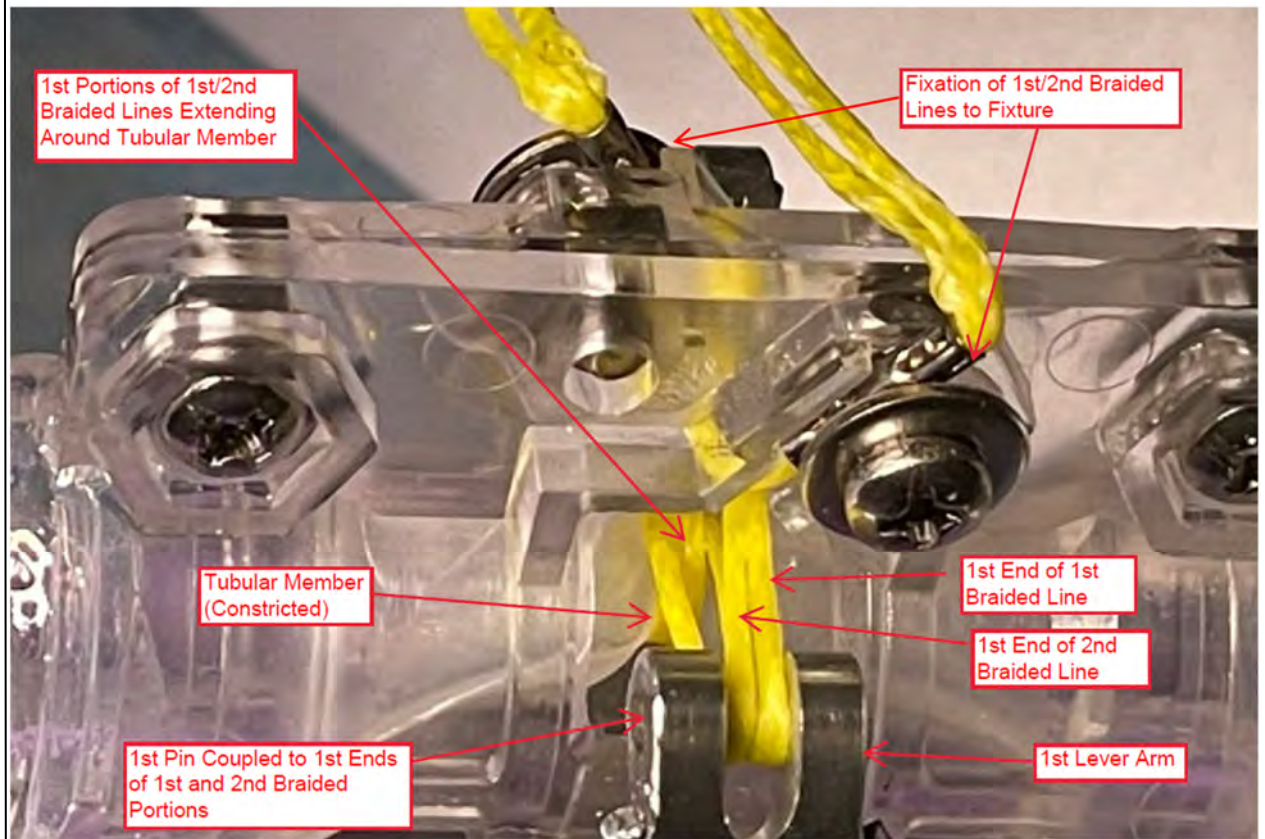
b. 1[a] an elongate member defining a lumen;

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:



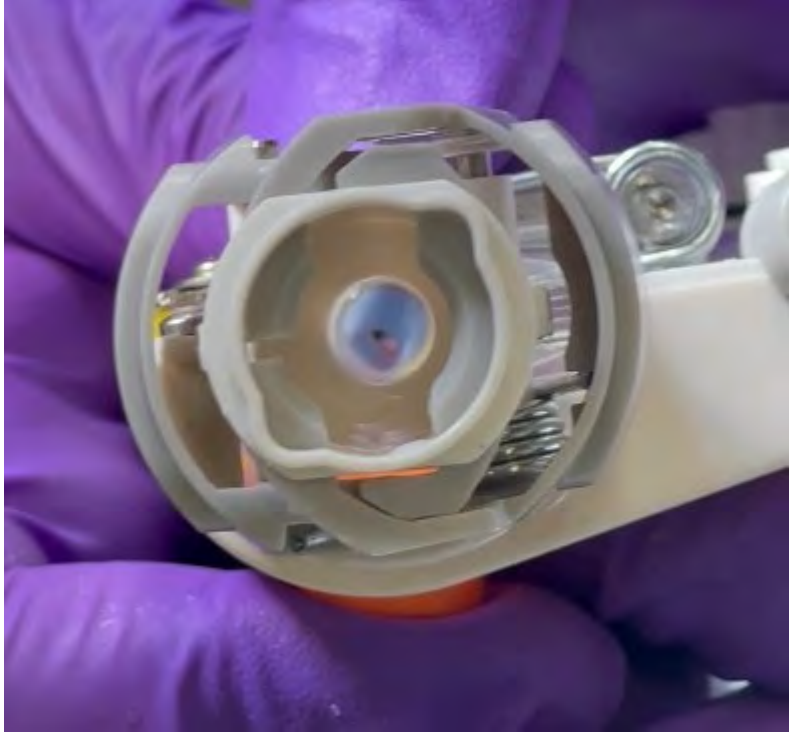
(Annotated image of internal portion of Symphony system handle zoomed in on the hemostasis valve, including the elongate (tubular) member.)



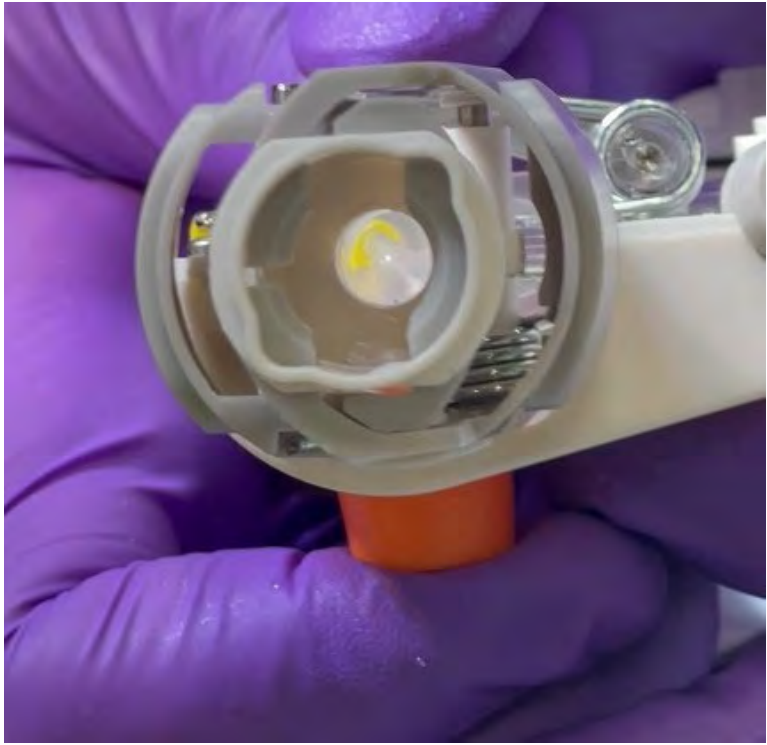
15 (Annotated image of zoomed in internal portion of Symphony system handle, including a partial
16 view of the hemostasis valve, including the elongate (tubular) member and yellow filaments
17 extending around it.)

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

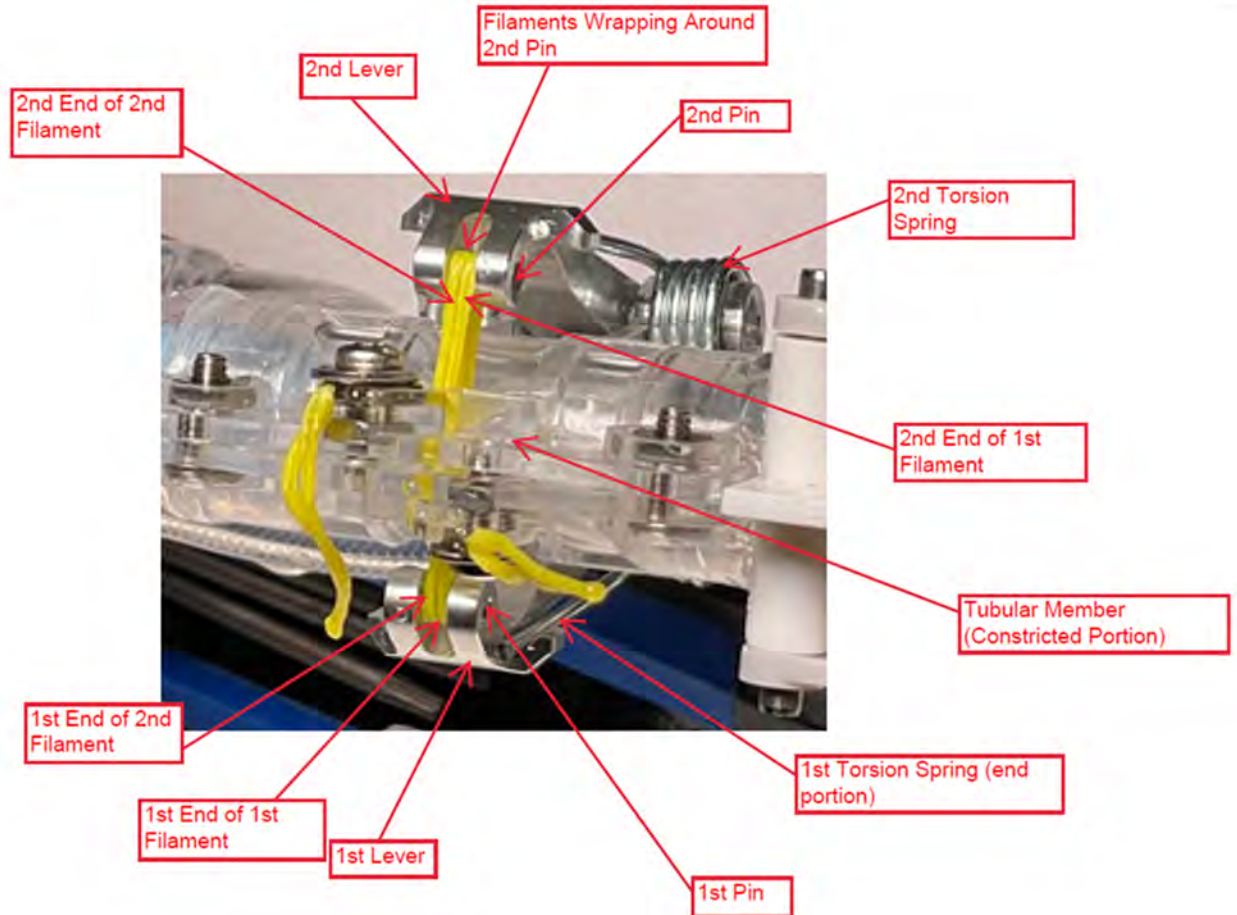
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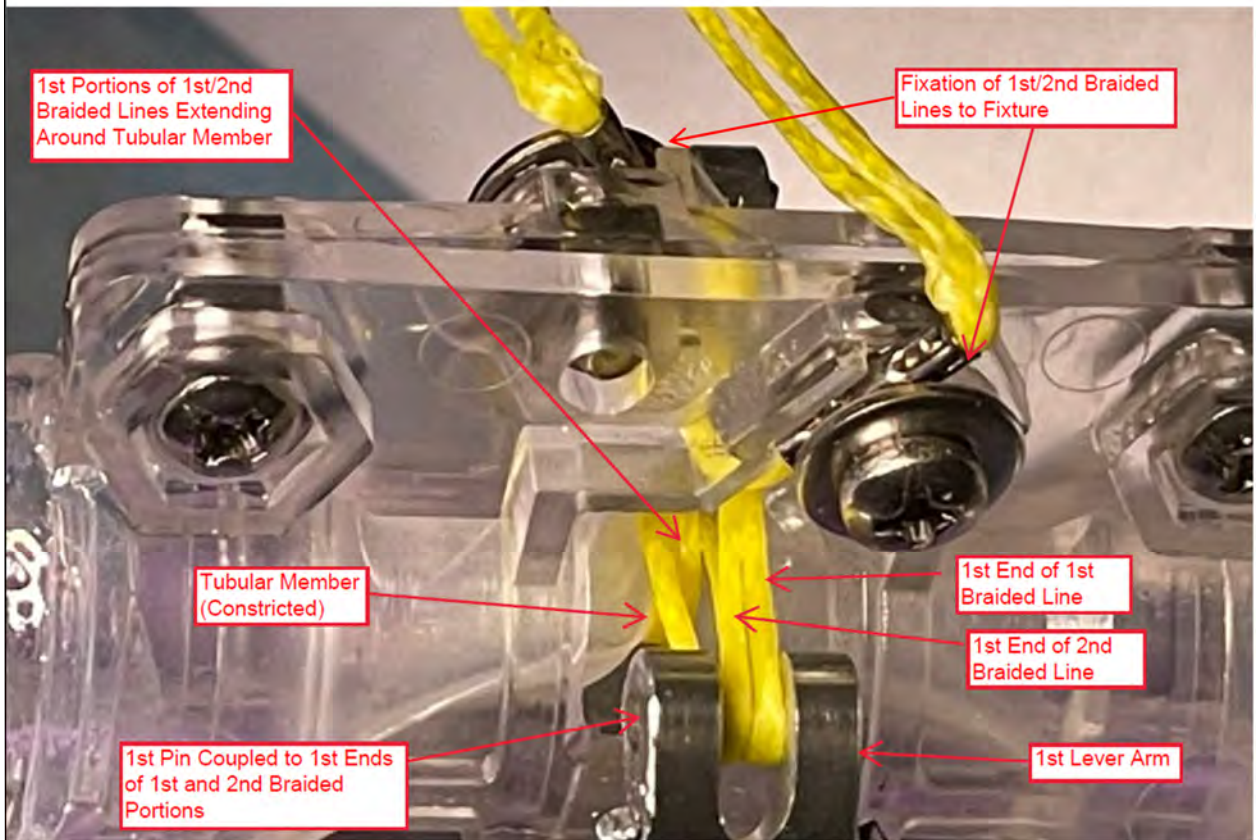
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)



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



(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.)

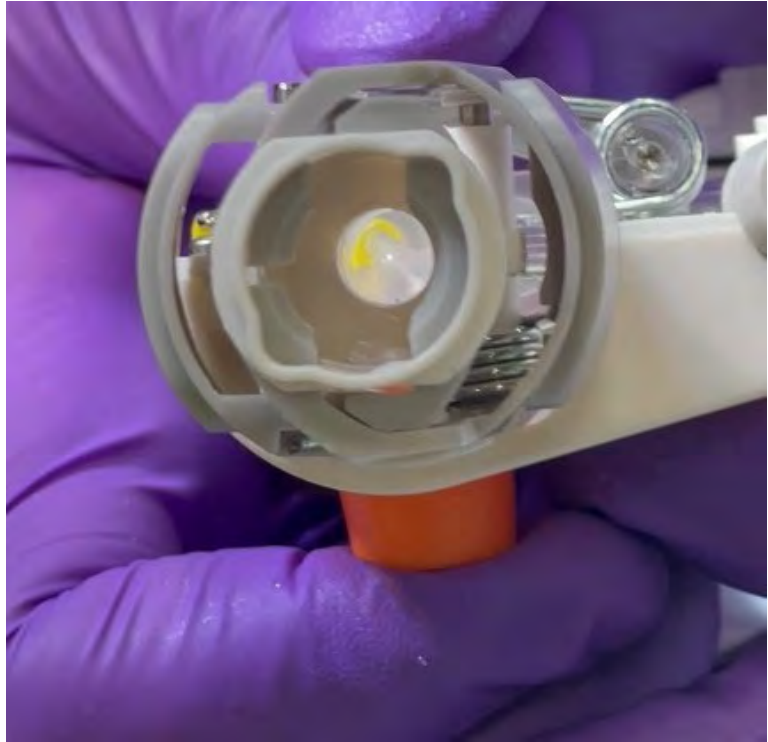


15 (Annotated image of internal portion of Symphony system handle zoomed in on a partial view of
16 the hemostasis valve, including the end of first lever and first pin of the first actuator coupled via
17 filaments to the elongate (tubular) member of the valve.)

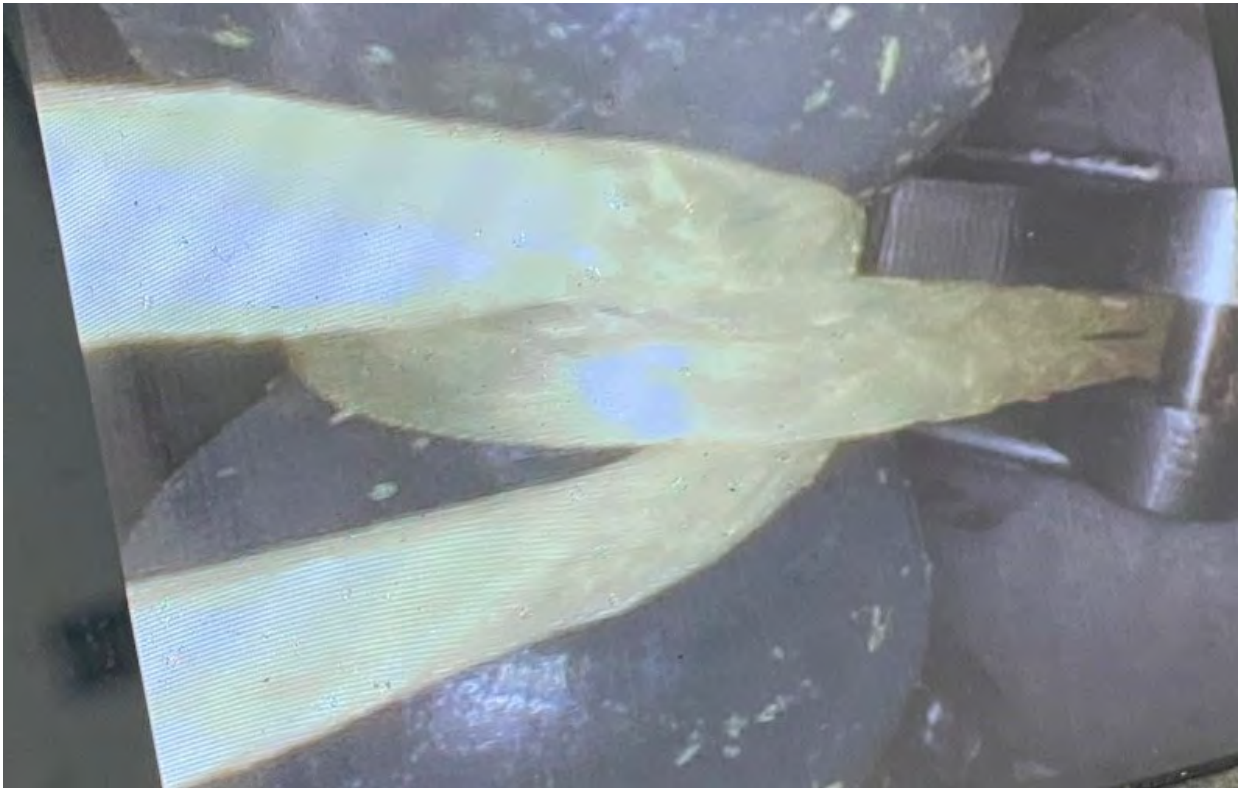
18 183. The lumen of the elongate member can be seen in images looking down the
19 Symphony handle lengthwise, as can be seen below. In the first position (undepressed button)
20 the hemostasis valve is constricted by the yellow filaments wrapped around the outside of the
21 lumen. In the second position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

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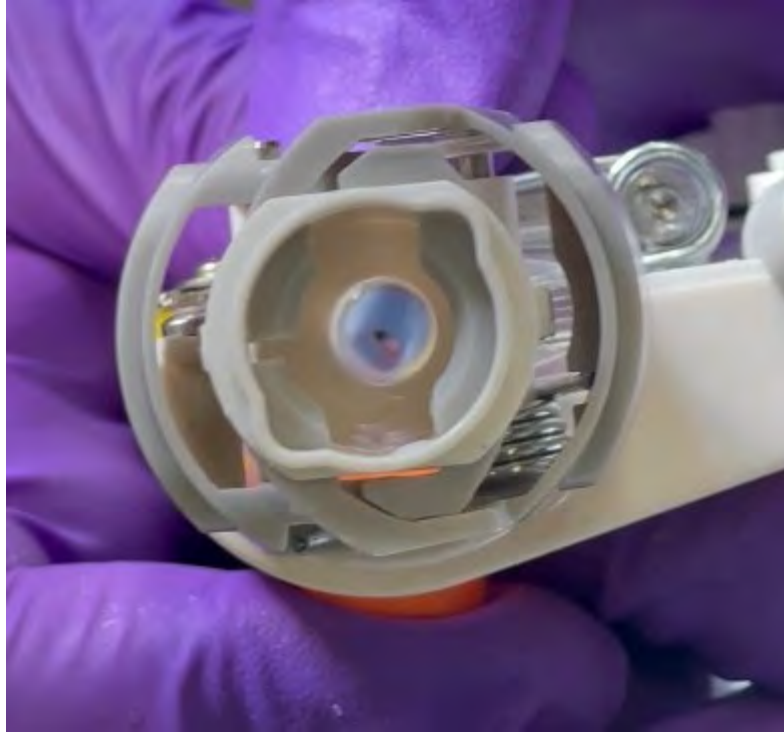


(Symphony handle with view down lumen of hemostasis valve with valve lumen constricted.)



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

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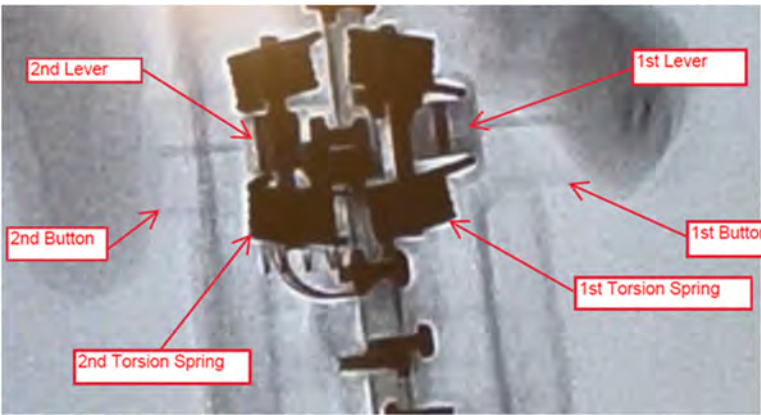
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

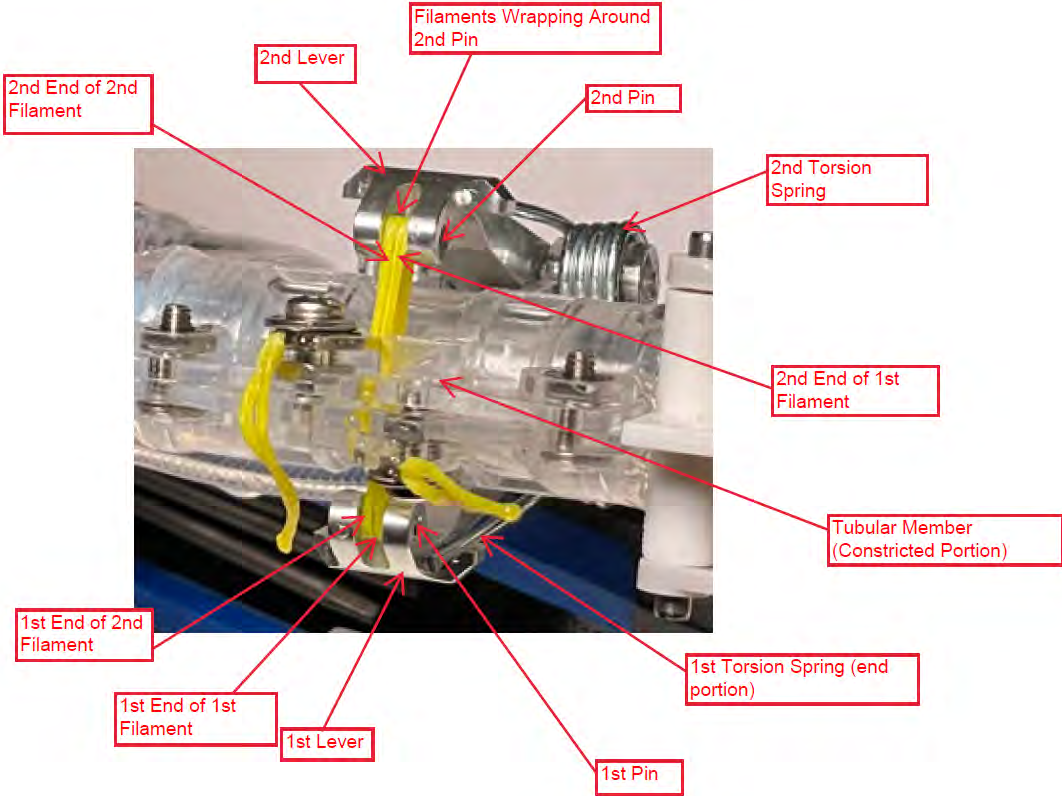
184. Claim 1 also recites “an active tensioning mechanism including an actuator coupled to the elongate member via a filament extending at least partially around the elongate member, wherein the actuator is moveable between (a) a first position wherein the lumen is constricted and sealed and (b) a second 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:

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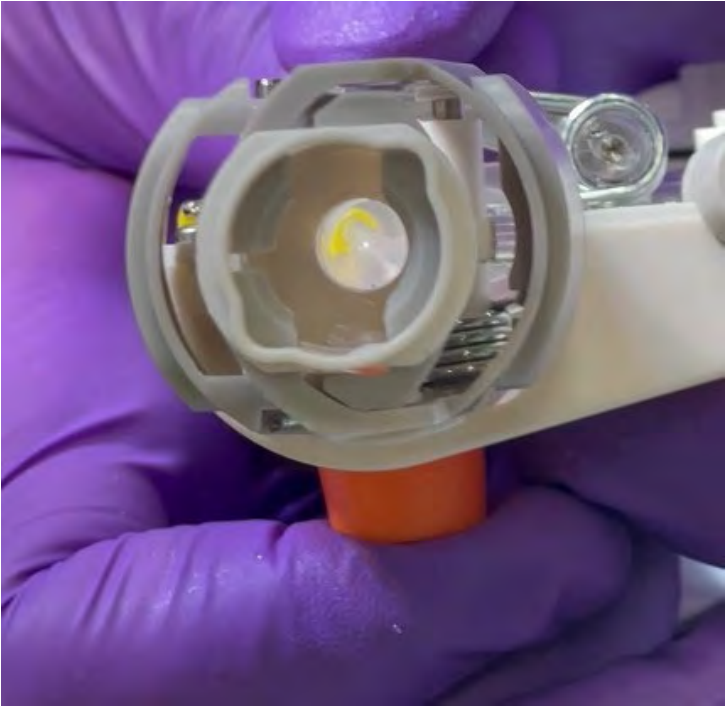


(X-ray imaging of Symphony handle showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs, as part of active tensioning mechanism with the first button in the first (undepressed, constricted) position.)

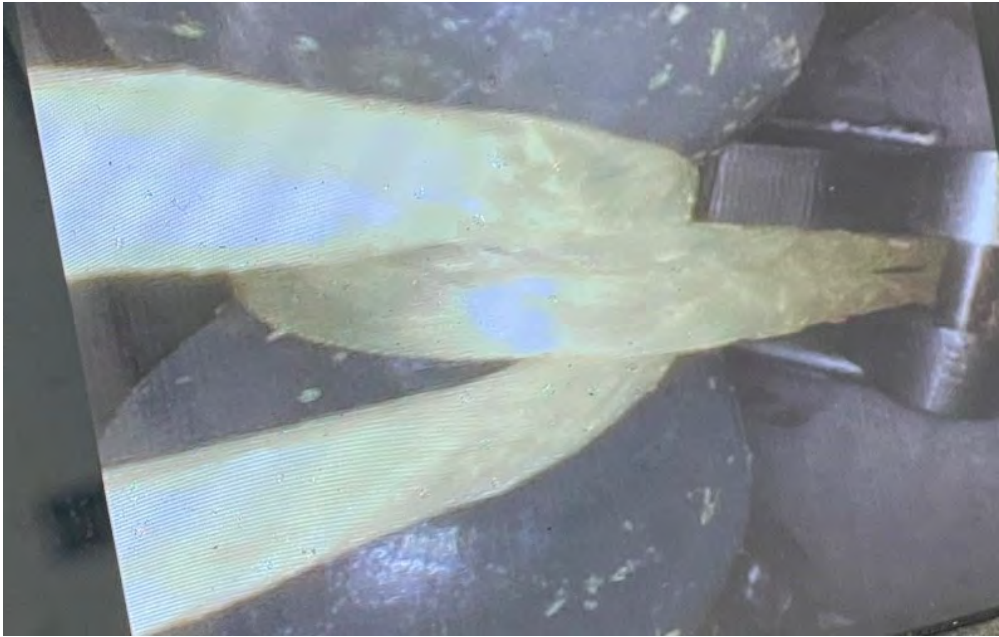


(Annotated image of internal portion of Symphony system housing zoomed in on the hemostasis valve, showing a portion of the first torsion springs for the first lever, and the first lever and the second lever of the first and the second actuators biased to the first (constricted, undepressed button) position.)

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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

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

2 **2. Claim 10**

- 3 **a. 10[a] The valve of claim 1 wherein the actuator is a first actuator,**
4 **wherein the filament is a first filament, wherein the biasing member is**
5 **a first biasing member, and wherein the active tensioning mechanism**
6 **further comprises:**

7 187. Claim 10 of the '921 Patent depends from Claim 1 and incorporates all elements
8 of Claim 1. Claim 10 recites, “[t]he valve of claim 1 wherein the actuator is a first actuator,
9 wherein the filament is a first filament, wherein the biasing member is a first biasing member,
10 and wherein the active tensioning mechanism further comprises....”

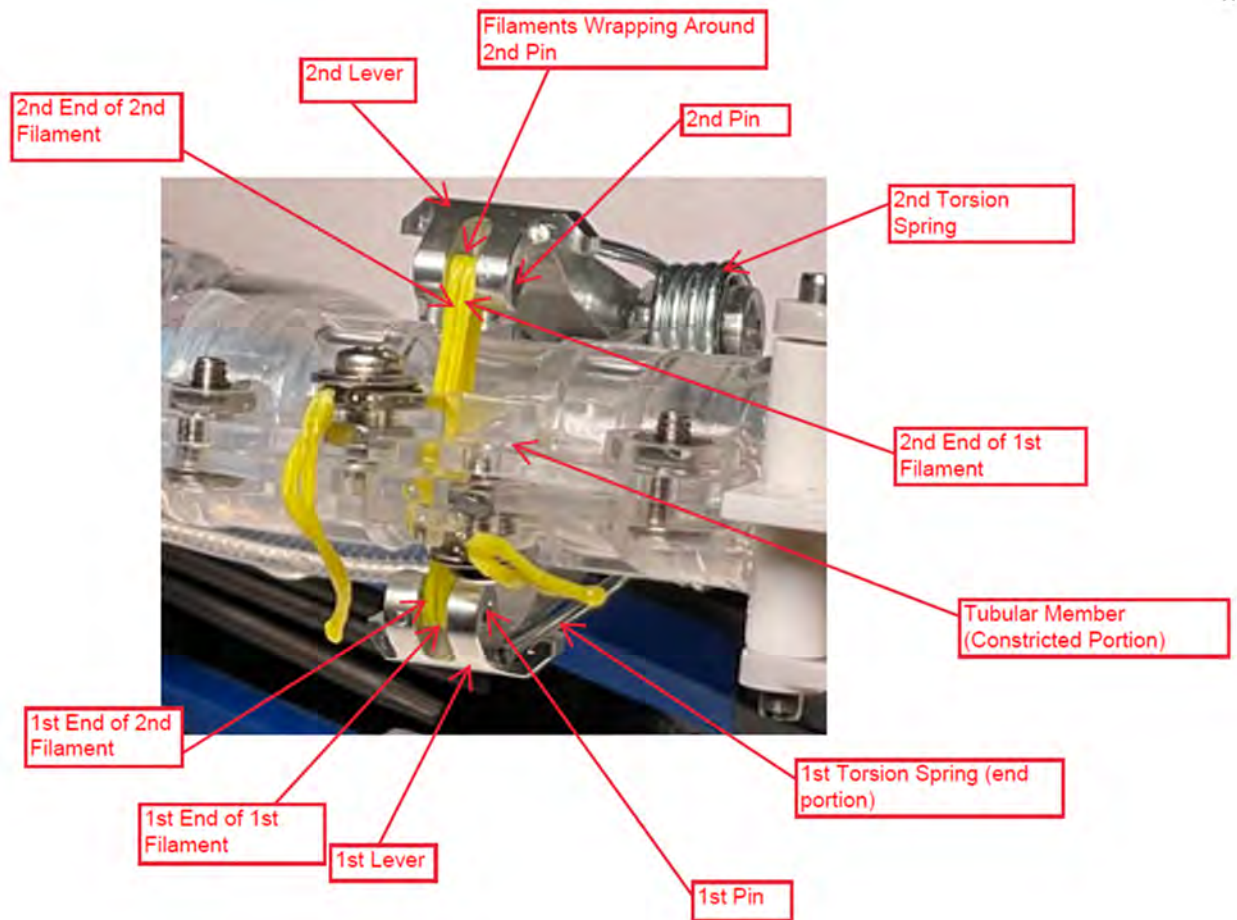
11 188. As set forth above with respect to Claim 1, and as shown in Ex. 18, the Symphony
12 system practices the preamble of Claim 10 because the hemostasis valve in the Symphony
13 system includes a first actuator (a first button, a first lever, and first pin) as part of an active
14 tensioning mechanism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

- 21 **b. 10[b] a second actuator coupled to the elongate member via a second**
22 **filament extending at least partially around the elongate member,**
23 **wherein the second actuator is moveable between (a) a first position**
24 **wherein the lumen is constricted and sealed and (b) a second position**
25 **wherein the lumen is at least partially open;**

26 189. Claim 10 further recites, “a second actuator coupled to the elongate member via a
27 second filament extending at least partially around the elongate member, wherein the second
28 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.”

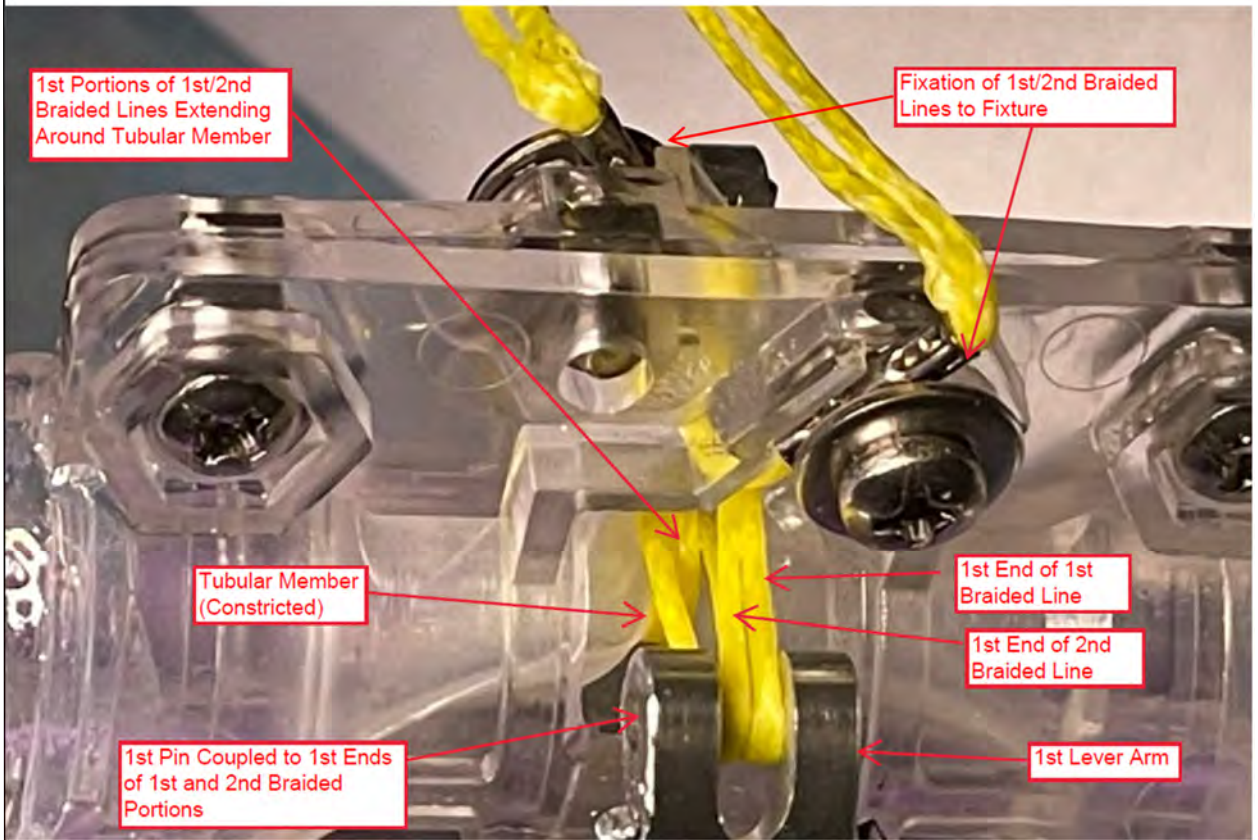
190. As can be seen in Ex. 18, the Symphony system practices this limitation because
the hemostasis valve in the Symphony handles has an active tensioning mechanism including a

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



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

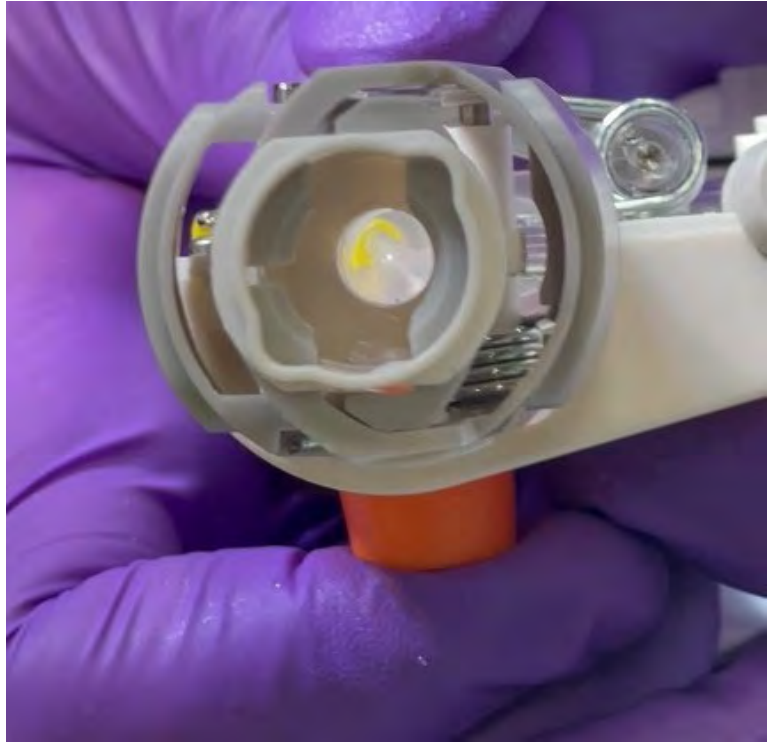
1 valve, including the first lever and first pin of the first actuator coupled via filaments to the
2 elongate (tubular) member of the valve.)



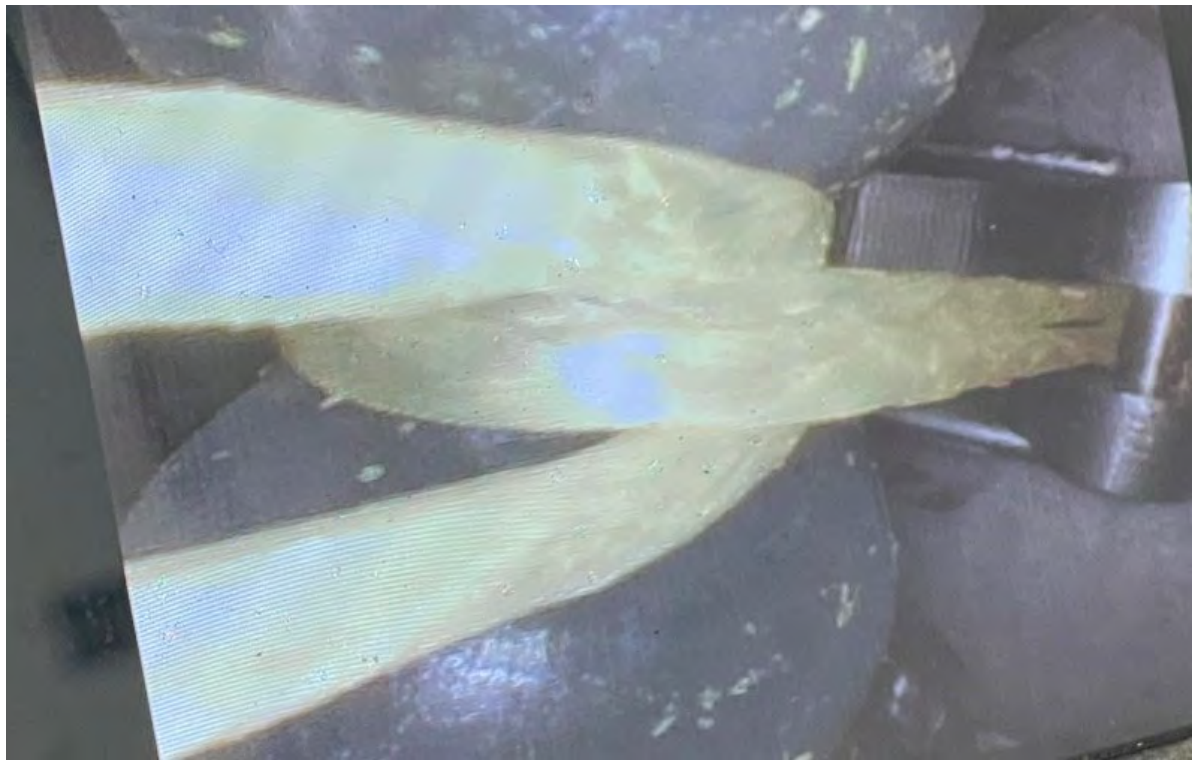
17 (Annotated image of internal portion of Symphony system handle zoomed in on a partial view of
18 the hemostasis valve, showing a portion of the first actuator and the first and second filaments
19 wrapped around the first pin of the first actuator and the second pin of the second actuator (not
20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

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

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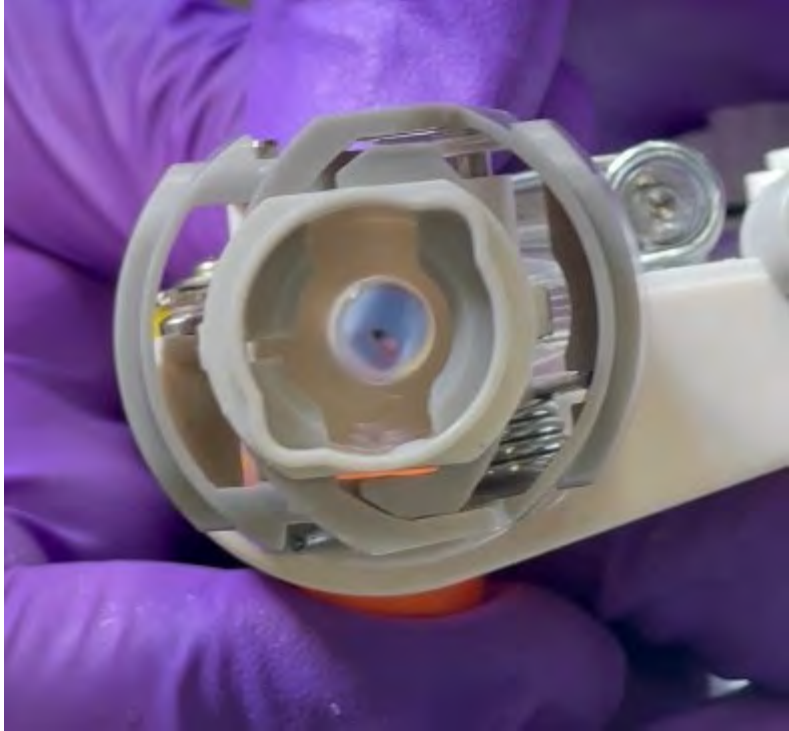


(Symphony handle with view down lumen of hemostasis valve with valve lumen constricted.)



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

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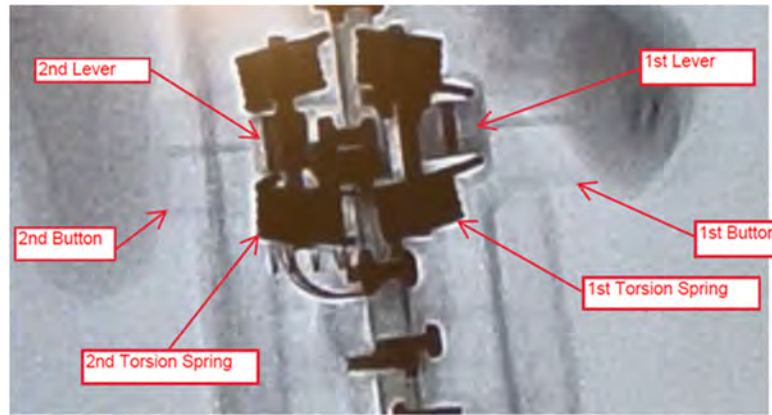
(Symphony handle with view down elongate member (lumen) of hemostasis valve with valve lumen open.)

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

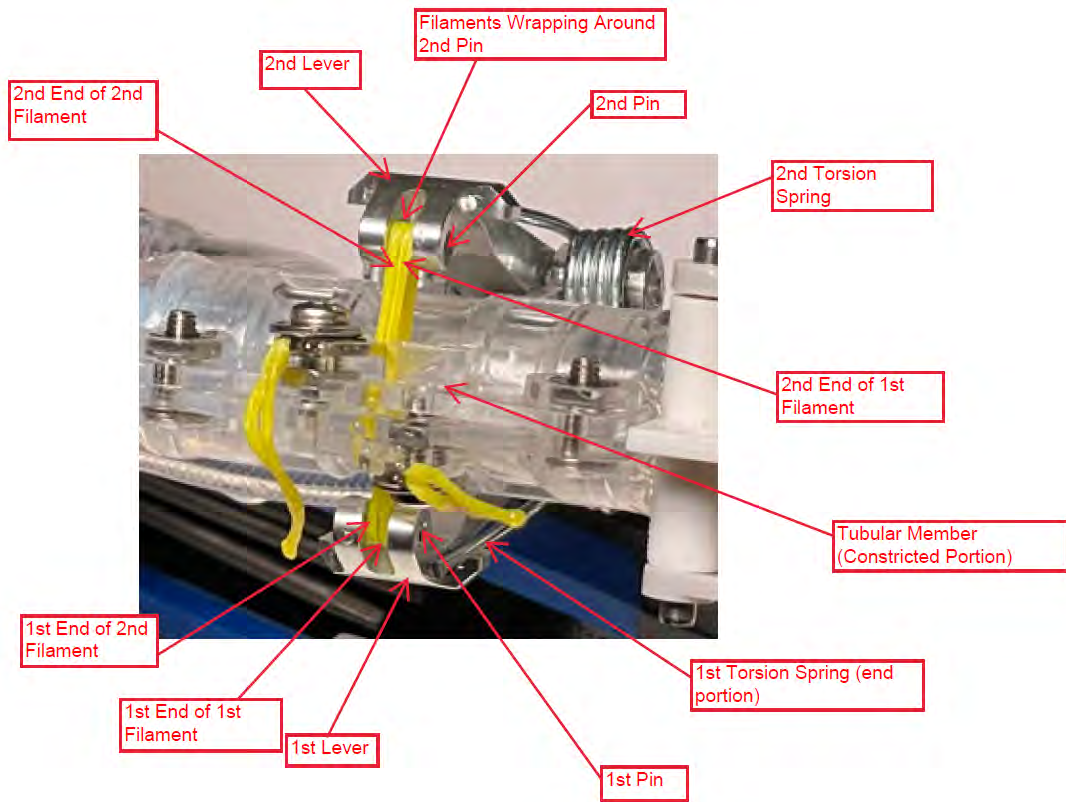
192. Claim 10 additionally recites, “a second biasing member configured to bias the second actuator to the first position.”

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:

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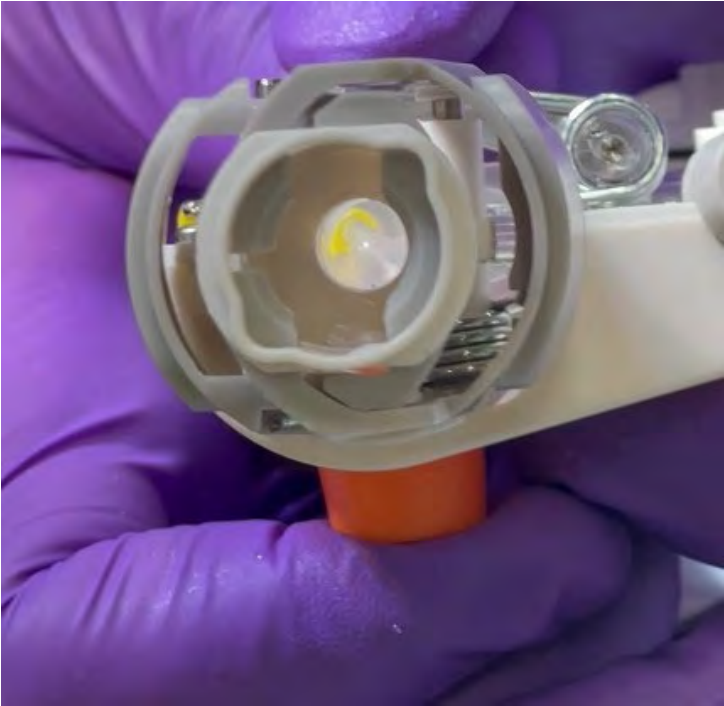


(X-ray imaging of Symphony handle showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs, as part of active tensioning mechanism with the first and second buttons in the first (undepressed, constricted) position.)



(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

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

2 **XI. VALIDITY OPINIONS**

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

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

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

28

1 **A. The '910 Patent**

2 **1. Challenges Faced by Inari**

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

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

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

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

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

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

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

1 design.

2 **2. Innovation over Prior Art**

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

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

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

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

7 **3. Specific Prior Art Identified By Truvic And During Prosecution**

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

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

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

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

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

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

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

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

22 214. On March 12, 2024, the Examiner entered an Examiner’s Amendment fixing two
23 minor issues in the claim and a Notice of Allowance agreeing with the additional reasons for
24 patentability over Garrison I raised by the applicant, including that the claims were not
25 anticipated or obvious over Garrison I because it would not be reasonable to modify the clot
26 treatment device of Garrison I to be used for pulmonary embolisms, *e.g.*, including because of
27 the need for larger catheters:
28

1 Garrison (US 20150173782 A1) teaches all of the limitations as
2 discussed previously in Non-Final Rejection filed on 11/06/2023.
3 However, Garrison fails to teach a clot treatment system for treating
4 clot material comprising a pulmonary embolism in the vasculature
5 of a patient" and "wherein the second catheter has a size of 16
6 French or greater". The clot treatment device of Garrison is
7 configured for a neurovascular application and not for larger
8 vasculature such as pulmonary embolism. It would be unreasonable
9 to modify the clot treatment device of Garrison to be used for
10 pulmonary embolisms. There is no prior art that teaches all of the
11 limitations. Therefore, claims 1 and 11 are allowable. Claims 2-10
12 and 22 are allowable for depending on claim 1. Claims 12-17, 19,
13 and 21 are allowable for depending on claim 11.

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

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

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

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

6 **B. The '921 Patent**

7 **1. Challenges Faced by Inari**

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

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

20 **2. Innovation over Prior Art**

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

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

5 **3. Specific Prior Art Identified By Truvic And During Prosecution**

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **XII. INARI'S DEVICES ALSO PRACTICE THE CLAIMS**

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

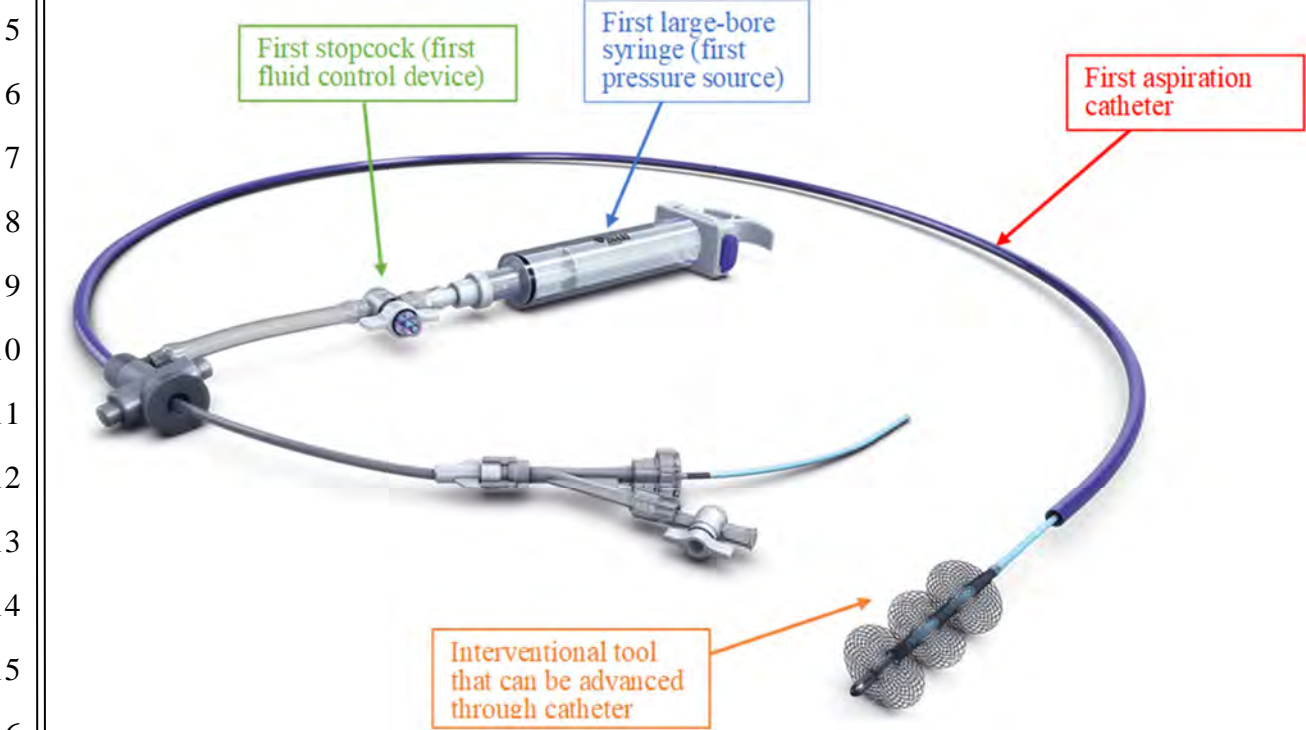
13 231. In addition to offering my opinion that Truvis's Symphony system infringe, I have
14 also been asked to opine on whether Inari's own FlowTrievers system practices Claim 1 of the
15 '910 Patent and Claim 10 of the '921 Patent. I do so in this section, and it is my opinion that it
16 does.

17 232. I have reviewed Inari Medical's FlowTrievers documentation, including the
18 Trievers24 and Trievers16 documentation. It is my opinion that FlowTrievers practices Claim 1
19 of the '910 Patent when used in a telescoping configuration with a Trievers16 catheter telescoped
20 through a Trievers24 or Trievers20 catheter for treatment of pulmonary embolism.

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

26 234. In a telescoping configuration, FlowTrievers includes “a first clot aspiration
27 assembly,” including: a first catheter; a first pressure source; and a first fluid control device
28 between the first catheter and the first pressure source,” as recited in the claims. Specifically,

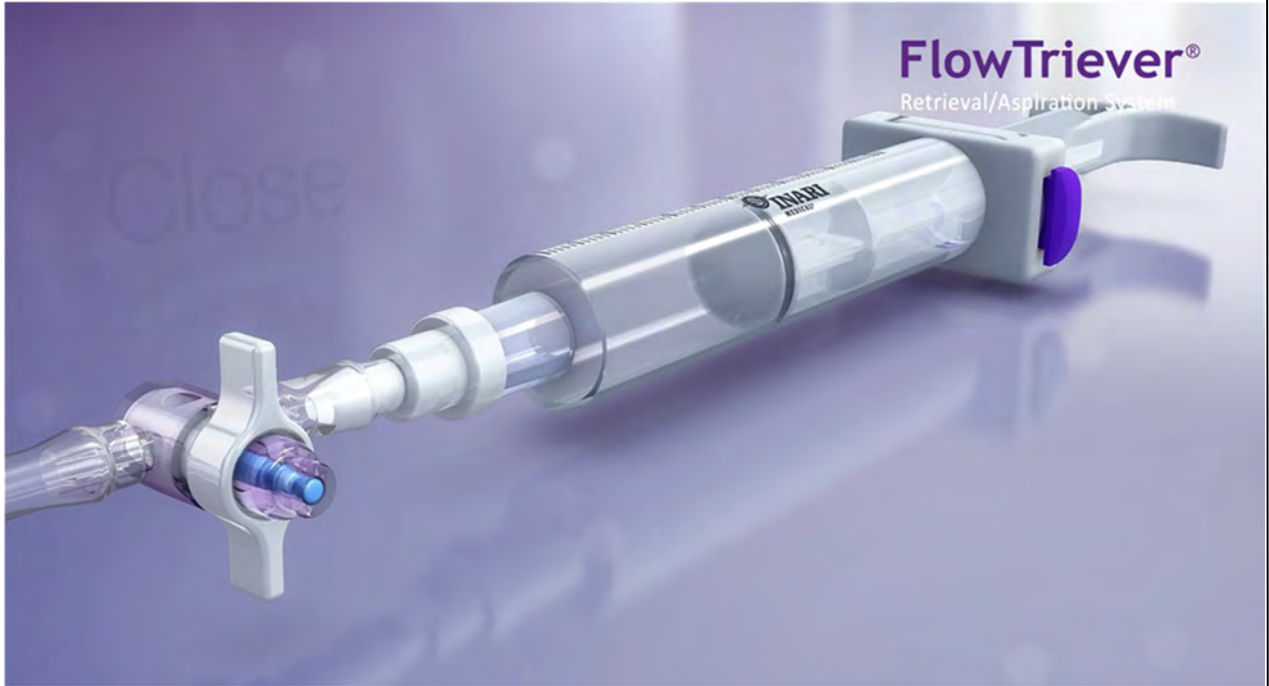
1 FlowTrievers in a telescoping configuration includes (1) a Trievers24 catheter or Trievers20
2 catheter (first catheter), (2) a first pressure source (a first syringe), and (3) a first fluid control
3 device between the Trievers24 catheter or Trievers20 catheter and the first syringe (a first
4 stopcock). This can be seen below:



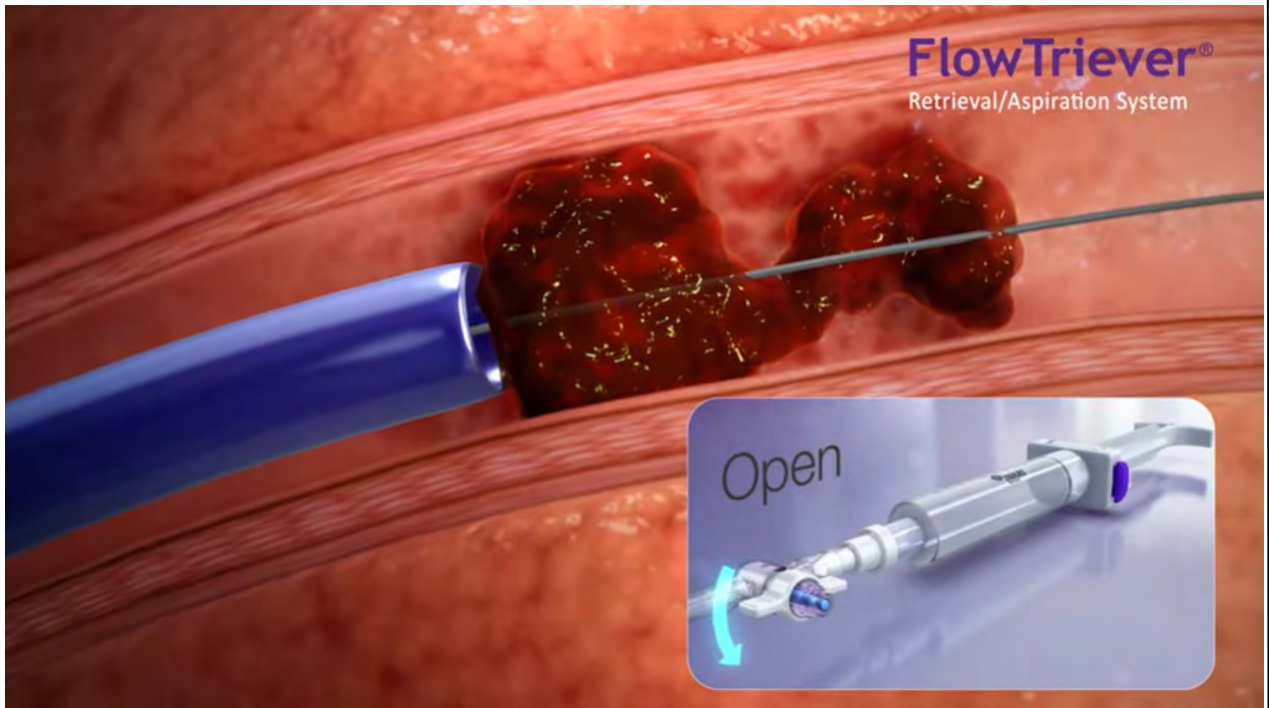
17 (Annotated image of FlowTrievers assembly from Inari website, <https://www.inarimedical.com/>)

18 235. In a telescoping configuration a second, smaller diameter aspiration catheter (*e.g.*,
19 a Trievers16 aspiration catheter) is advanced through the larger-bore Trievers24 catheter or
20 Trievers20 catheter.

21 236. The first fluid control device (first stopcock) is moveable between a first position
22 (with the stopcock rotated to the closed position in which the stopcock tab/lever is perpendicular
23 to the fluid path from the catheter to the syringe) in which the fluid control device is closed and
24 the first syringe (first pressure source) is fluidly disconnected from the Trievers24 catheter or
25 Trievers20 catheter (either being the first catheter) and a second position (open, with the stopcock
26 rotated 90 degrees to where the stopcock tab/lever is parallel to the fluid path) in which the first
27 syringe (first pressure source) is fluidly connected to the Trievers24 catheter or Trievers20
28 catheter:



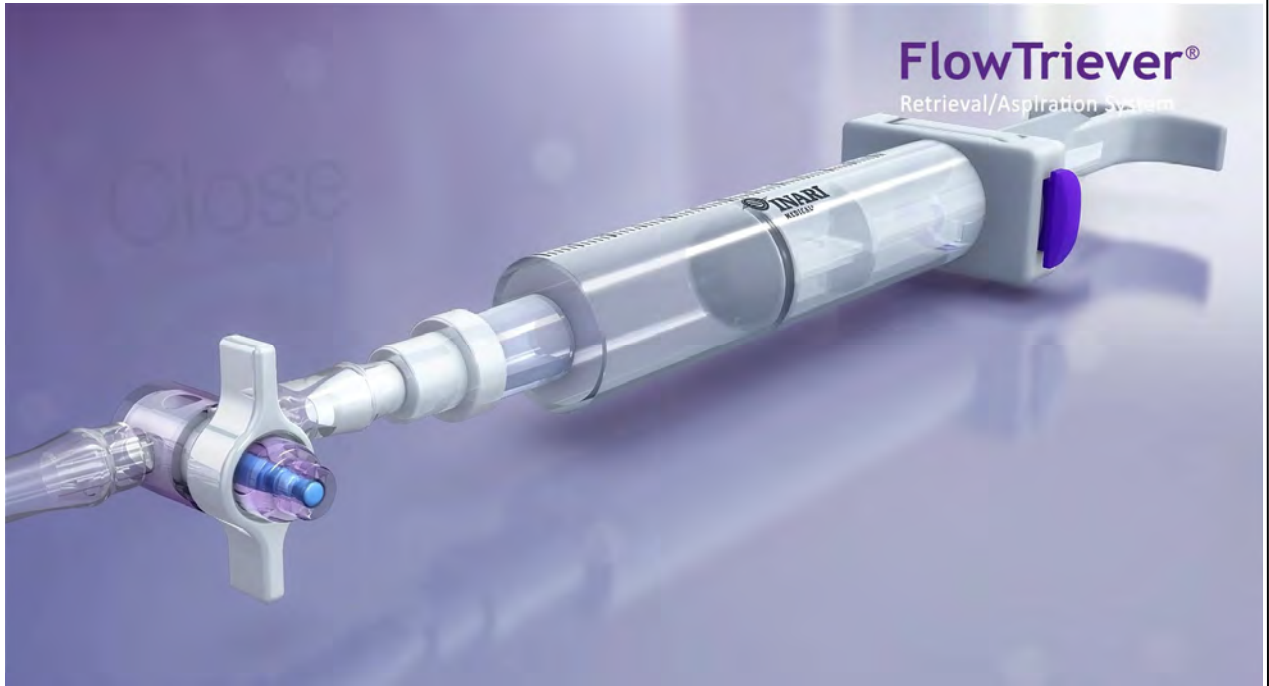
12 (Video screenshot showing the stopcock in the closed position.)



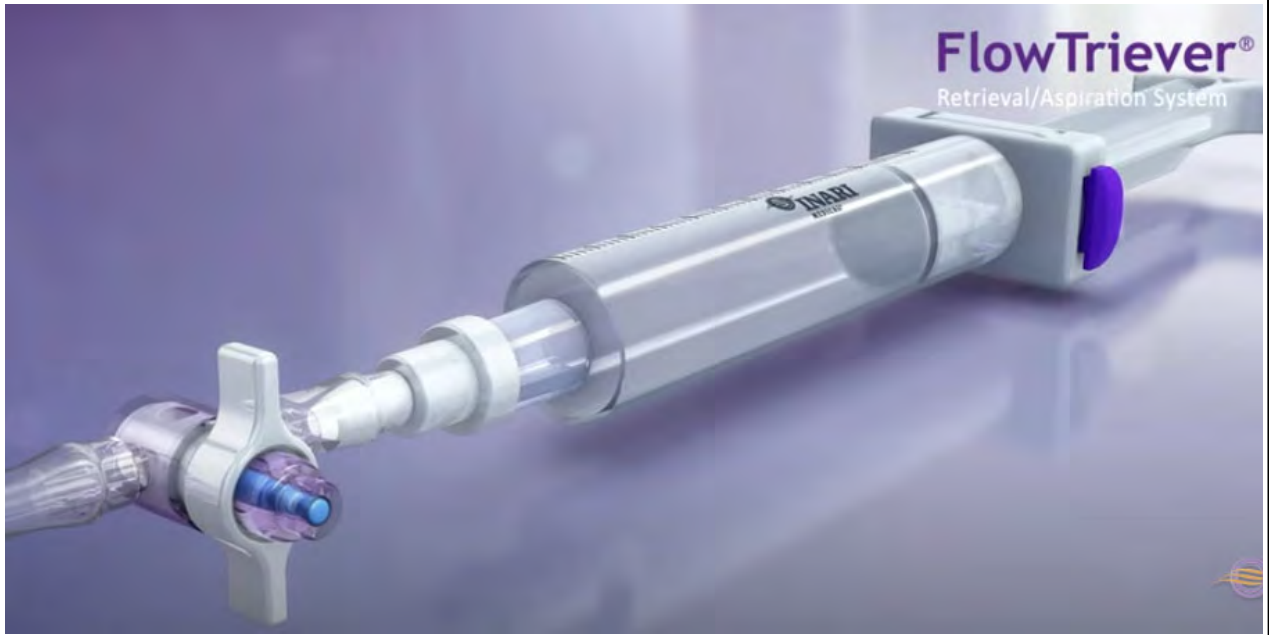
25 (Video screenshot showing the stopcock in the open position.)

26 237. The FlowTrievers Trierer24 or Trierer20 assembly is configured to have the first
27 syringe generate vacuum pressure by withdrawing the syringe plunger while the stopcock (first
28 fluid control device) is closed (in the first position with the stopcock rotated to the closed

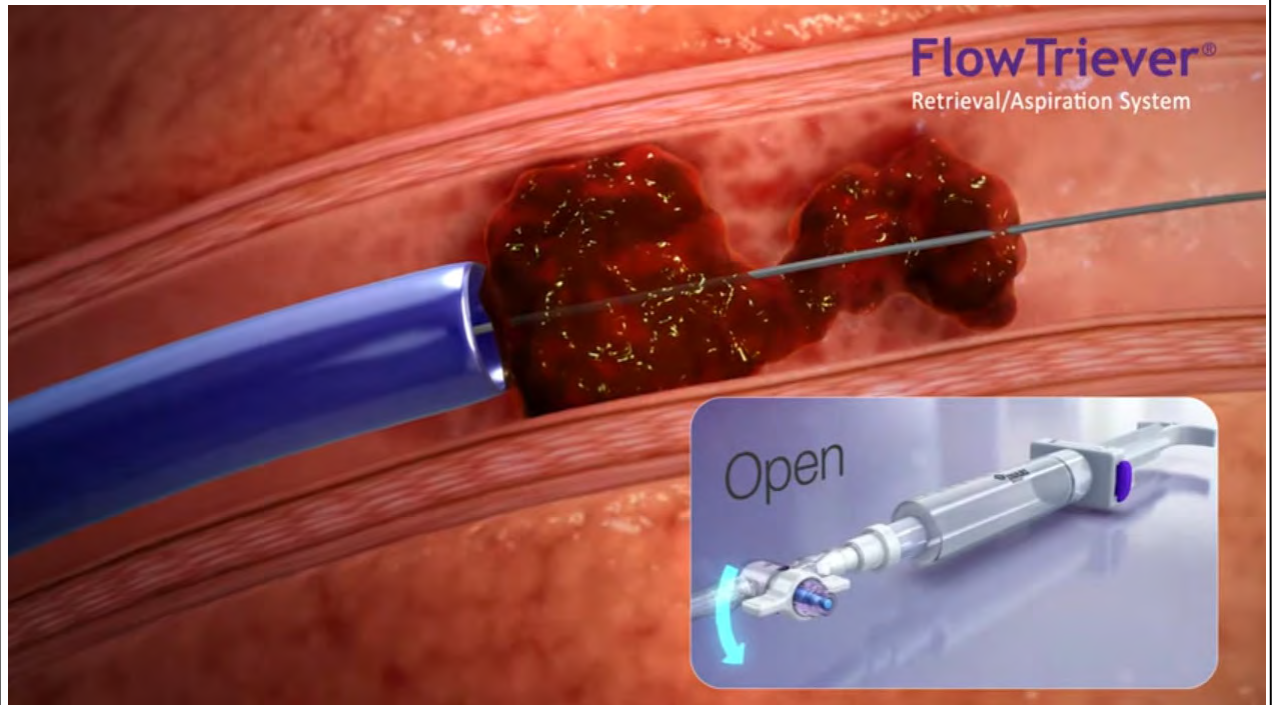
1 position in which the stopcock tab/lever is perpendicular to the fluid path from the catheter to
2 the syringe) and, then, when the stopcock is rotated 90 degrees to the second position (open,
3 with the stopcock parallel to the fluid flow path) the vacuum stored in the syringe is applied
4 through the catheter to the distal end of the Trierer24 catheter or Trierer20 catheter.



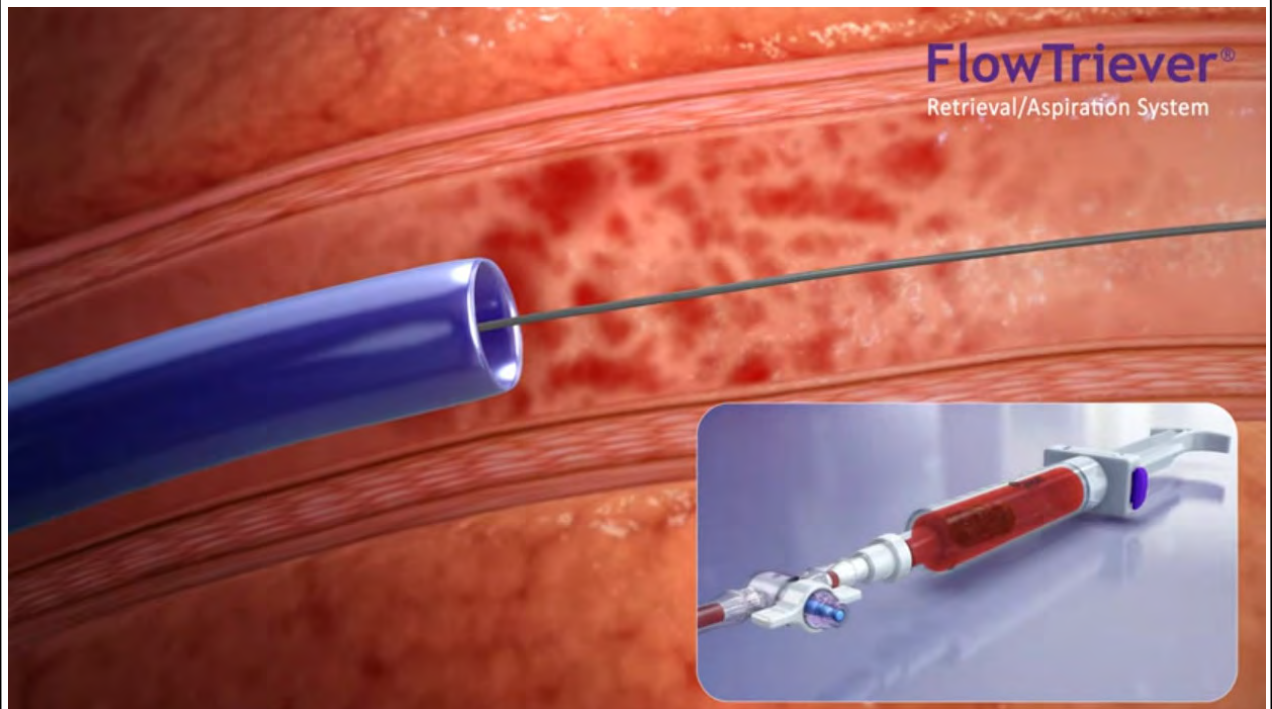
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16 (Video screenshot showing the stopcock in the closed position.)



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



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



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

27 238. In a telescoping configuration, FlowTrievers includes a “a second clot aspiration
28 assembly,” including: a second catheter; a second pressure source; and a second fluid control

1 device between the second catheter and the second pressure source,” as recited in the claims.
2 Specifically, FlowTrierer in a telescoping configuration includes a Trierer16 catheter, such as
3 pictured in the diagram below (second catheter) advanced through a larger Trierer24 catheter
4 or Trierer20 that is not pictured in figure 1 below (or a Trierer20 advanced through a Trierer24
5 catheter), a second pressure source (a second syringe), and a second fluid control device (a
6 second stopcock) between the Trierer16 catheter and the second syringe. This can be seen in
7 Ex. 19 (Trierer16 Instructions for Use) below (a diagram of a telescoping configuration is
8 provided by Figure 11 of the '910 Patent, discussed above in paragraph 96):

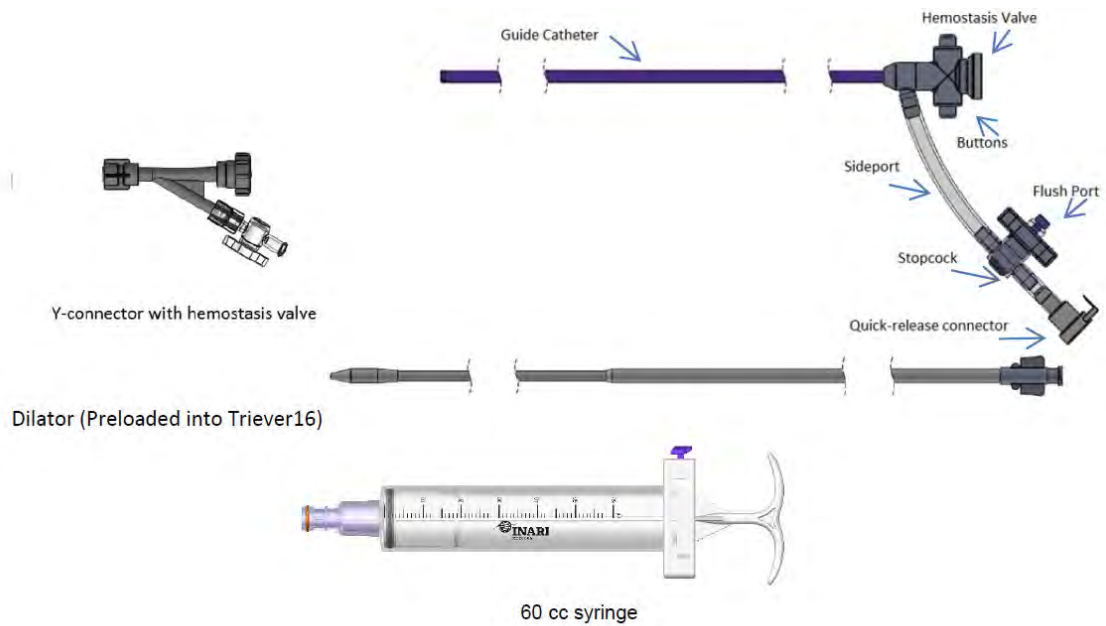


Figure 1: Trierer16

(Ex. 19 at 2.)

239. As shown in Ex. 19, the Trierer16 catheter is advanceable through the Trierer24
catheter or Trierer20 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).

Trierer16 Co-axial Procedure with Trierer20

12. Place the Trierer16 over the guidewire. This step can be performed before and/or after the manual FlowTrierer Catheter retraction through Trierer20 or Trierer24. To advance the Trierer16 through the Trierer20 or Trierer24, loosen the Trierer16's Dilator Y-connector hemostasis valve and insert the Trierer16 over the pre-placed guidewire.
13. Advance the Trierer16 through the Trierer20 or Trierer24 by pressing on the Trierer20's hemostasis valve buttons.

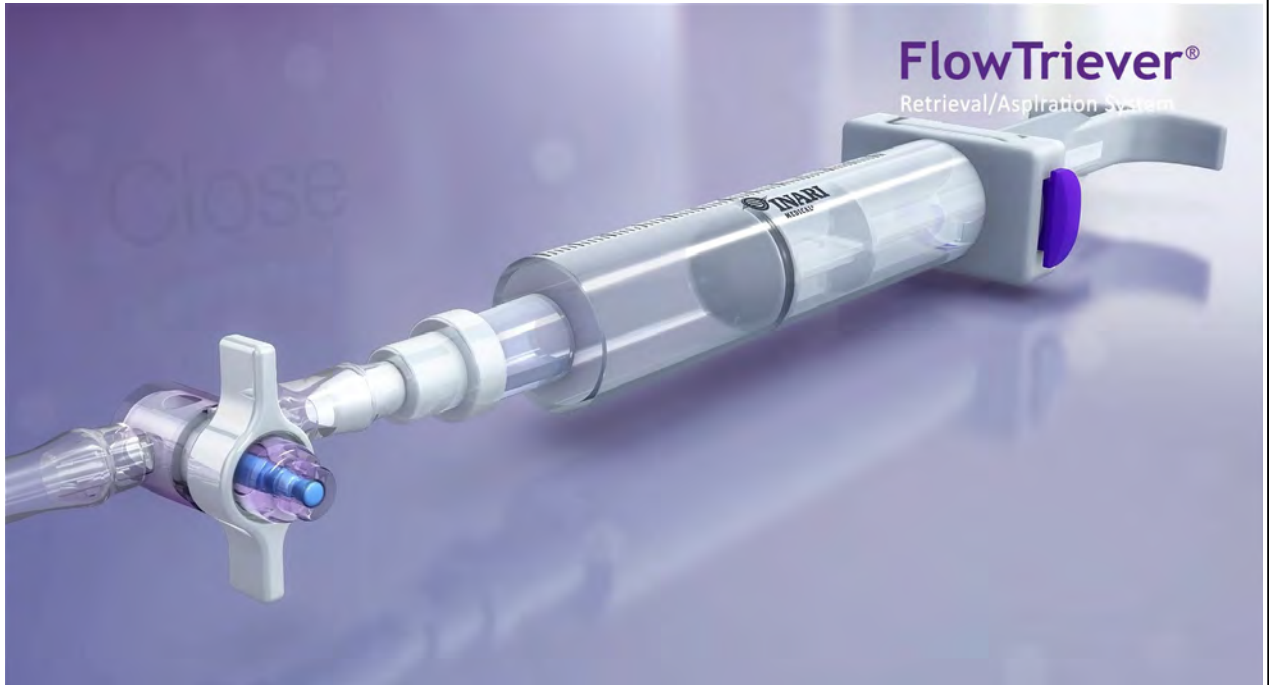
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(Ex. 19 at 5.)

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

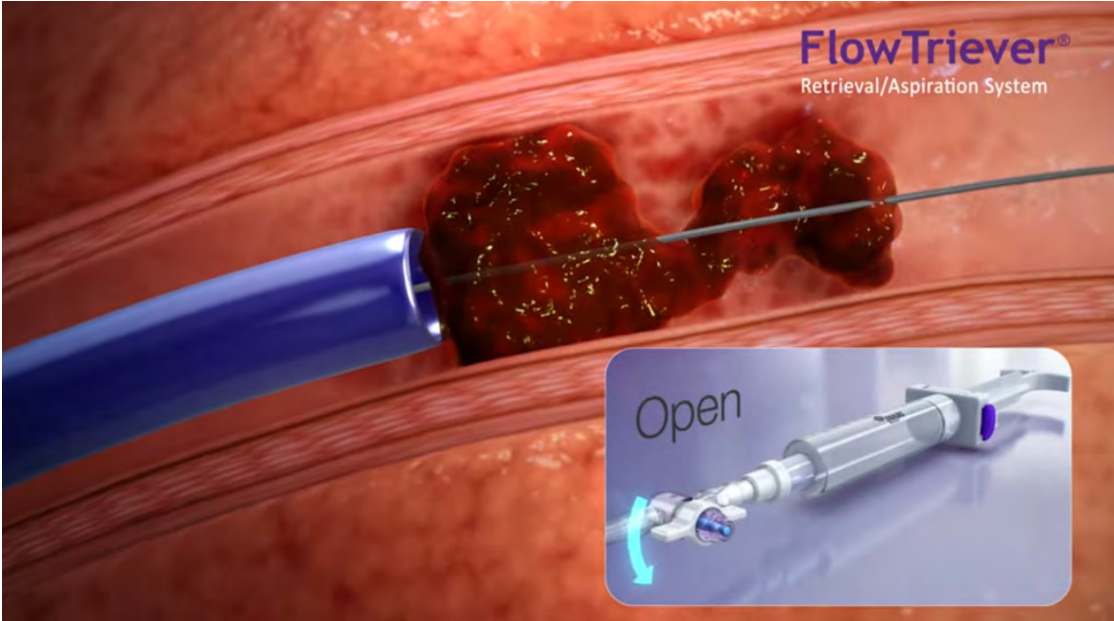
Triever16 Placement

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:



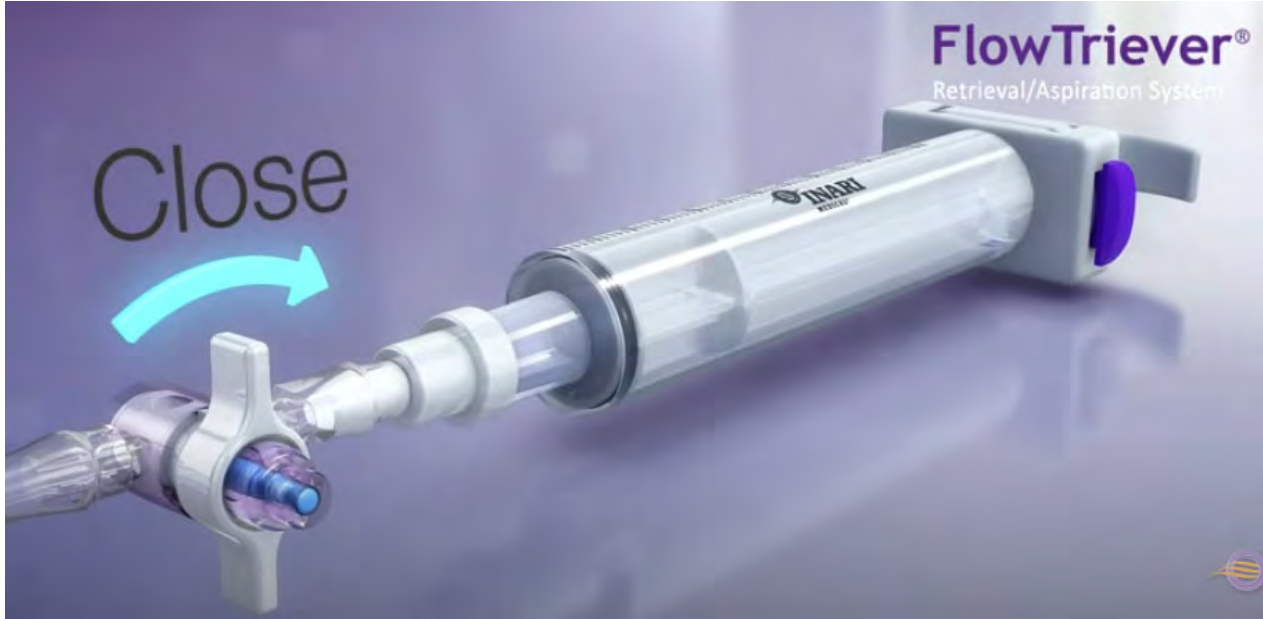
(Video screenshot showing the stopcock in the closed position.)

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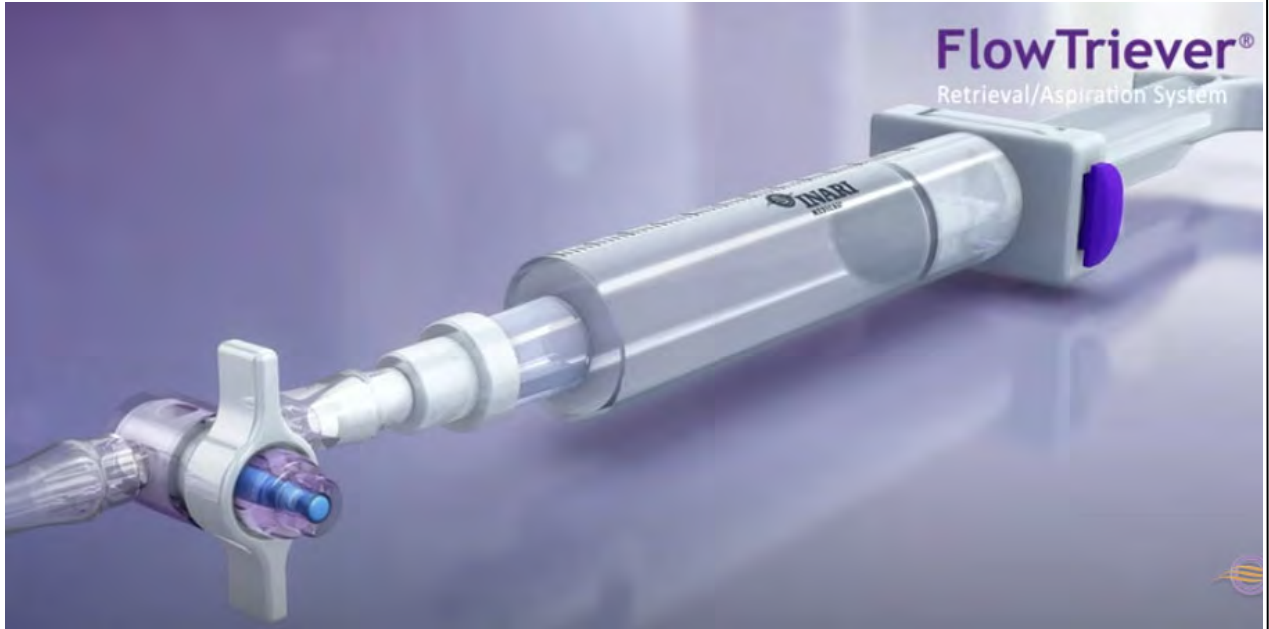
(Video screenshot showing the stopcock in the open position.)

241. The FlowTriever Trierer16 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 Trierer16 catheter).

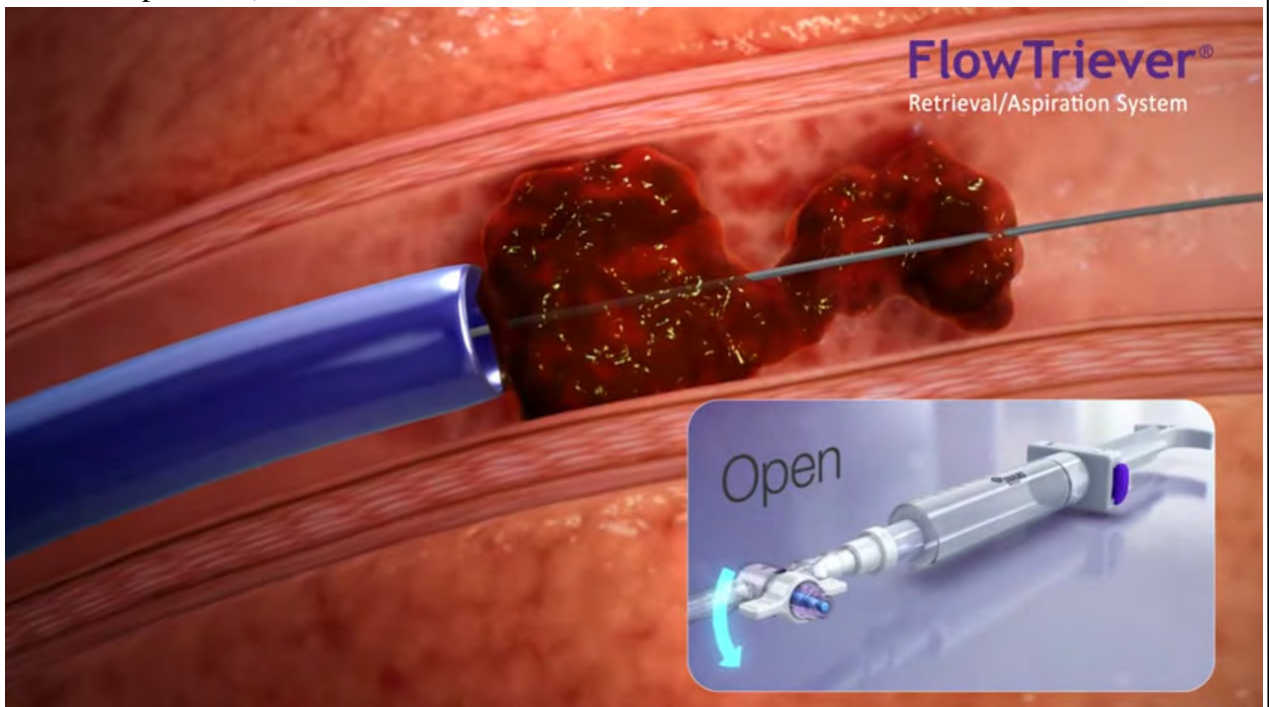


(Video screenshot showing the stopcock in the closed position.)

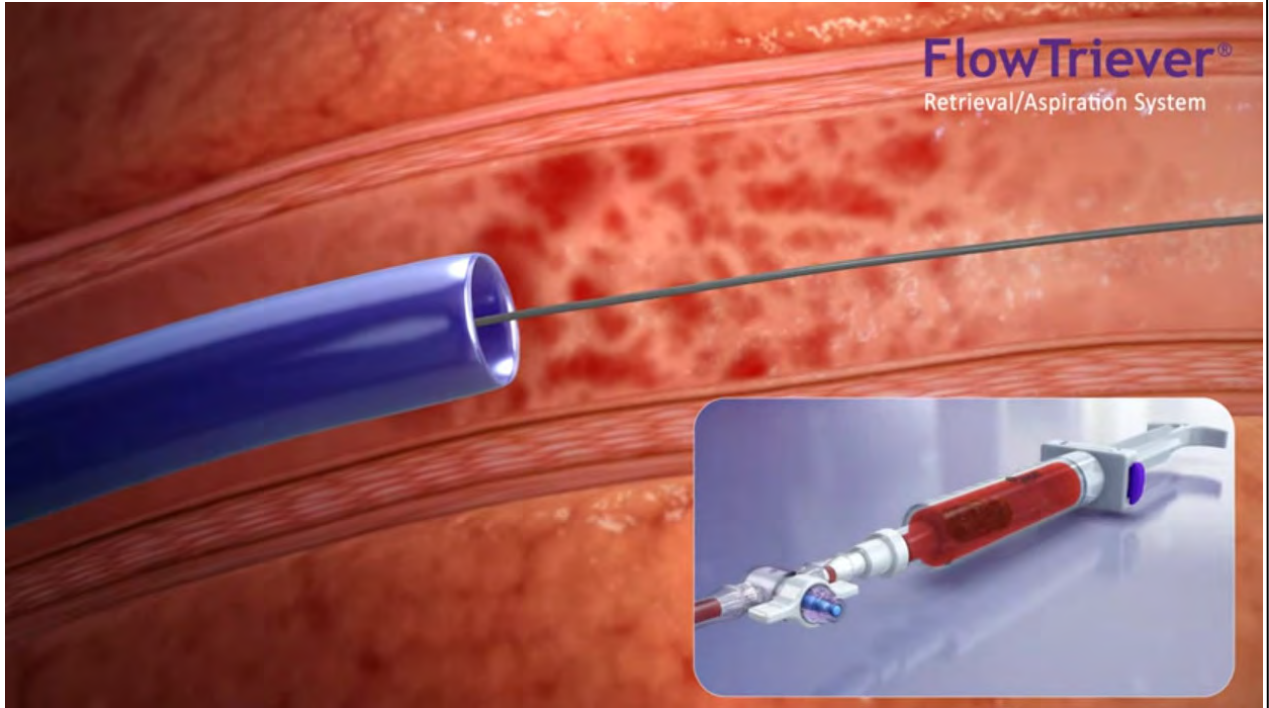
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(Video screenshot showing vacuum pressure being generated by the syringe when the stopcock in the closed position.)



(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 FlowTrievers system in a telescoping configuration for treating pulmonary embolism practices each and every limitation of Claim 1 of the '910 Patent.

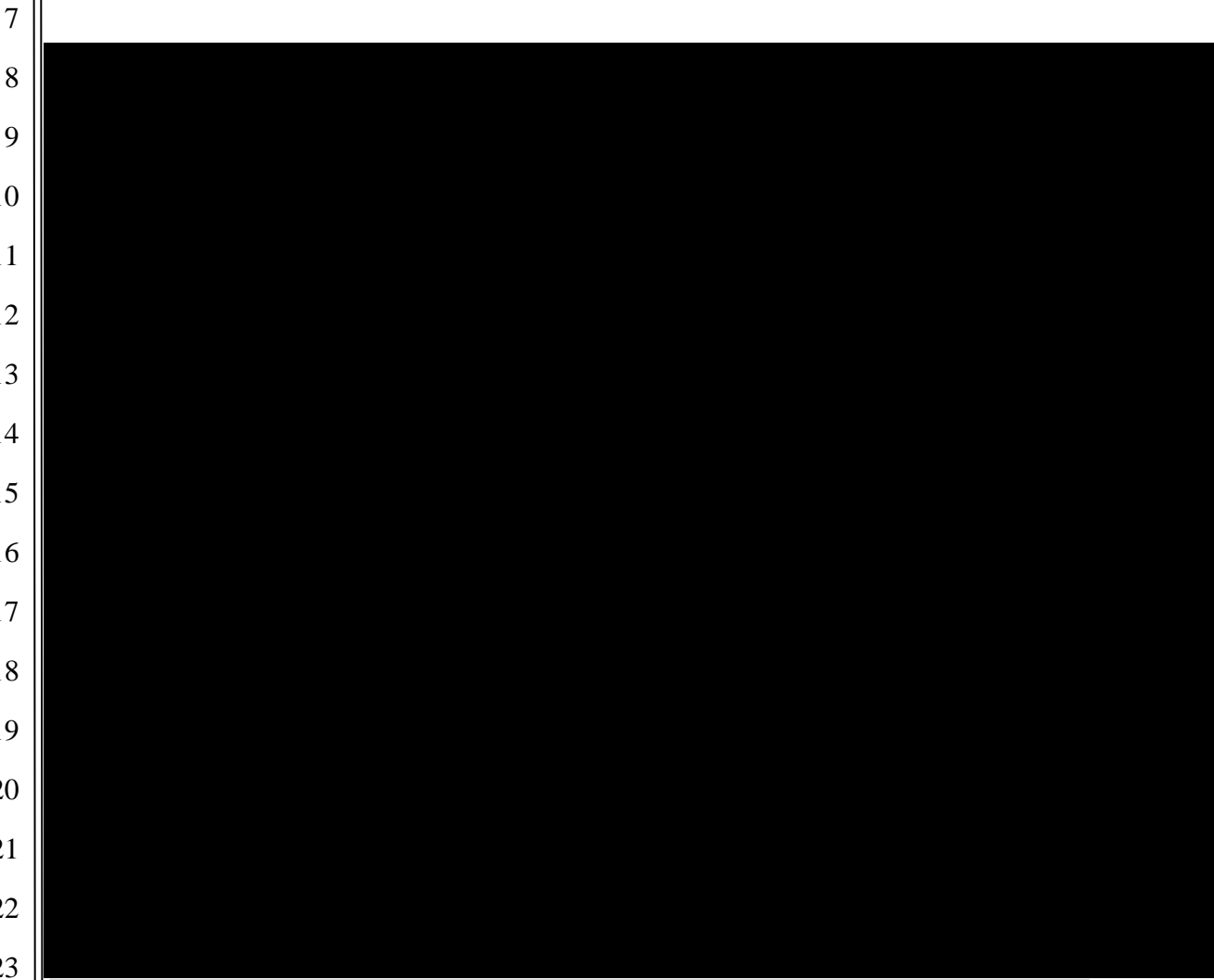
B. U.S. Patent 11844,921 (“921 Patent”)

1. Claim 1

243. I have also reviewed Inari Medical’s Trierer catheter assembly documents showing aspects of the garrote hemostasis valve in the Trierer24 and Trierer16 assemblies (Exs. 20, 21.) It is my opinion that Inari’s Trierer24 and Trierer16 assemblies used in the FlowTrievers Retrieval/Aspiration system practices Claims 1 and 10 of the '921 Patent. Specifically, the garrote hemostasis valve in the Trierer catheter assemblies practices each and every limitation of Claims 1 and 10.

244. The hemostasis valve in the Trierer 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

1 a first position (undeformed button, constricted valve lumen) in which the biasing member (a
2 compression spring) pushes the button outward, pulling the filament to constrict the elongate
3 tubular member, to a second position (depressed button, valve at least partially open) in which
4 the filament is not pulled as tight against the elongate tubular member. The compression spring
5 biases the first actuator to the first position (undeformed button, constricted valve lumen). This
6 can be seen in annotated Ex. 20 (Trievery24 Catheter Assembly Diagram) below.



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25 245. The annotated image from Ex. 21 (Trievery24 Assembly Procedure) below shows
26 a valve during assembly with the top plastic piece (labeled 7 above) removed to show the
27 internal structure of the valve.
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246. In the first position (undeepressed 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 (undeepressed 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. Claim 10

247. As can be seen in the annotated diagrams above, the Trierer 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

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

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

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

16
17 I declare under penalty of perjury under the laws of the United States of America that the
18 foregoing is true and correct.

19 Dated: July 23, 2024

20 By: 
21 Brian Brown

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APPENDIX A
BRIAN J. BROWN
LITIGATION HISTORY

Brian J. Brown

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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

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)

APPENDIX B
BRIAN J. BROWN
PROFESSIONAL EXPERIENCE

Brian J. Brown

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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

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.

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

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