Ramsey M. Al-Salam, Bar No. 109506
RAlSalam@perkinscoie.com
PERKINS COIE LLP
1201 Third Avenue, Suite 4900
Seattle, Washington 98101-3099
Telephone: +1.206.359.8000
Facsimile: +1.206.359.9000

Amanda Tessar, Bar No. 33173 (admitted *pro hac vice*)
ATessar@perkinscoie.com
PERKINS COIE LLP
1900 Sixteenth Street, Suite 1400
Denver, Colorado 80202-5255
Telephone: +1.303.291.2357
Facsimile: +1.303.291.2457

Daniel T. Keese, Bar No. 280683
PERKINS COIE LLP
1120 NW Couch Street, Tenth Floor
Portland, OR 97209-4128
Telephone: 503-727-2000
Facsimile: 503-727-2222
DKeese@perkinscoie.com

ATTORNEYS FOR PLAINTIFF
INARI MEDICAL, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

INARI MEDICAL, INC., Plaintiff, v. IMPERATIVE CARE, INC., Defendant.	Case No. 5:24-cv-03117-EKL PLAINTIFF INARI'S SUPPLEMENTAL PRELIMINARY DISCLOSURE OF ASSERTED CLAIMS AND INFRINGEMENT CONTENTIONS PURSUANT TO PATENT LOCAL RULES 3-1 AND 3-2

Imperative Care v. Inari Medical
US Patent 11,969,333
Imperative Care Ex. 1042

Pursuant to Patent Local Rules ("PLR") 3-1 and 3-2 and the Court's Case Management & Scheduling Order providing leave to amend pleadings without motion (ECF No. 54), Plaintiff Inari Medical, Inc. ("Inari") hereby serves on Defendant Imperative Care, Inc. ("Truvic") the following Supplemental Disclosure of Asserted Claims and Infringement Contentions.

Inari contends that the Symphony Thrombectomy System and/or structures within and/or for use with the Symphony Thrombectomy System (collectively "the Accused Products") directly infringe the Inari patents asserted in this case: United States Patent Nos. 11,969,333 ("the '333 Patent"), 11,974,910 ("the '910 Patent"), 11,554,005 ("the '005 Patent"), 11,744,691 ("the '691 Patent"), 11,844,921 ("the '921 Patent"), 11,697,012 ("the '012 Patent"), 11,865,291 ("the '291 Patent"), 12,016,580 ("the '580 Patent"), 12,109,384 ("the '384 Patent"), and 12,156,669 ("the '669 Patent"). The '333, '910, '005, and '691 Patents are part of a family of patents related to, *inter alia*, thrombectomy systems using aspiration catheters to remove blood clots and thromboses found in large veins and the pulmonary arteries. The '921, '012, '291, and '384 Patents are part of a family of patents related to, *inter alia*, hemostasis valve designs for use with, *inter alia*, the types of systems described above. The '580 and '669 Patents are part of a family of patents related to thrombectomy systems employing aspiration catheters and interventional devices advanced through them, again with a focus on the removal of blood clots and thromboses found in large veins and the pulmonary arteries.

Inari's contentions are preliminary in nature, as discovery is ongoing, Inari has not completed its investigation of the facts related to this case, and Truvic has not provided complete product samples for Inari's evaluation. Such samples, as well as documents due from Truvic, will contain information pertaining to the structure, function, and operation of the Accused Products. For example, Inari has not yet received from Truvic a complete set of documents and discovery responses regarding the structure and functionalities of all accused products, including, but not limited to, whiteboard print outs, design documents, sketches, laboratory notebooks or workbooks, research notes, invention disclosure forms, technical manuals, whitepapers, datasheets, user guides, engineering drawings, schematics, structural and functional specifications, design documents, test data, and instructions for use. In addition, Inari has not yet

had the opportunity to depose any Truvic or third-party engineers and technicians, including without limitation Whipsaw engineers and technicians, who may be knowledgeable with respect to the relevant structure, function, and/or operation of the Accused Products.

Moreover, the Court has not yet construed any of the asserted claims of the Inari Patents, nor have expert reports been submitted. Inari's infringement contentions may ultimately be amended based upon the information revealed during discovery, the addition or withdrawal of patents and claims from the case, the Court's construction of the asserted claims, and the submission of expert reports directed to the issue of Truvic's infringement. This disclosure is therefore provided without prejudice to Inari's right to supplement and/or amend its disclosures.

INFRINGEMENT CONTENTIONS PURSUANT TO PLR 3-1

A. Identification of Asserted Claims – PLR 3-1(a): Requiring identification of "[e]ach claim of each patent in suit that is allegedly infringed by each opposing party, including for each claim the applicable statutory subsections of 35 U.S.C. §271 asserted."

As listed below, Truvic directly infringes the system and apparatus claims of the '910, '005, '691, '921, '012, '291, '384, and'669 Patents under 35 U.S.C. § 271(a) by making, using, selling, and offering for sale the Accused Products. Truvic directly infringes the asserted method claims of the '333 and '580 Patents under 35 U.S.C. § 271(a), including through its testing activities, as well as by directing its agents or contractors to perform procedures.

Truvic additionally indirectly infringes the asserted claims of claims of the '910, '005, '691, '921, '012, '291, '384, and '669 Patents under Sections 271(b) and/or 271(c) by inducing and contributing to doctors' and other users' direct infringement through their use of Truvic's Accused Products, assembly of components of Accused Products into infringing structures, and performance of Inari's patented methods of treatment, and/or by producing products especially made or adapted for assembly into infringing structures with no substantial noninfringing use. As listed below, Inari further contends that Truvic alone, and in combination with others, indirectly infringes the asserted method claims of the '333 and '580 Patents under 35 U.S.C. § 271(b) by inducing others (e.g., customers who are using the Accused Products and other end users of the Accused Products) to use the Accused Products to perform methods in a manner that directly

infringes these claims, and under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing components, materials, or apparatus that constitute a material part of the asserted method claims and that contribute to direct infringement by others (e.g., customers who are using the Accused Products and end users of the Accused Products) with the knowledge that the component, material, or apparatus is specially adapted for use in an infringement of the asserted method claims and that the component, material, or apparatus has no substantial noninfringing use.

PATENT	ASSERTED CLAIMS	STATUTORY SECTIONS	ACCUSED PRODUCTS
11,974,910	1-8, 11-15, 18-20	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Symphony System with 24F and 16F telescoping catheters
11,969,333	1-4, 6-12, 14-23, 25-31, 33-38	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Symphony System with 24F and/or 16F (117cm, and/or 82cm) catheters
11,554,005	1-7, 9-15	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Symphony System with 24F and 16F telescoping catheters
11,744,691	14-22	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Symphony System with 24F and/or 16F (117cm, and/or 82cm) catheters
11,844,921	1-3, 5-7, 9-10	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Truvic hemostasis valves in Symphony System 16F and 24F handles
11,697,012	1-7, 9	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Truvic hemostasis valves in Symphony System 16F and 24F catheter assemblies
11,865,291	1-8, 12-17, 19	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Truvic hemostasis valves in Symphony System 16F and 24F handles

PATENT	ASSERTED CLAIMS	STATUTORY SECTIONS	ACCUSED PRODUCTS
12,016,580	1, 5-6, 9-30, 33-34	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c);	Symphony System with 24F and/or 16F ProHelix Interventional Device(s)
12,109,384	1-4, 6-18, 20-30	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Truvic hemostasis valves in Symphony System 16F and 24F handles
12,156,669	1-5, 8, 10-12 14-19, 22, 24-28, 30	35 U.S.C. § 271(a); 35 U.S.C. § 271(b); 35 U.S.C. § 271(c)	Symphony System with 24F and/or 16F (117cm, and/or 82cm) catheters

B. Identification of Truvic's Infringing Products -- PLR 3-1(b): Requiring identification of, "[s]eparately for each asserted claim, each accused apparatus, product, device, process, method, act, or other instrumentality ("Accused Instrumentality") of each opposing party of which the party is aware.…"

See table in Section A above. Inari identifies the Symphony Thrombectomy System as infringing the asserted patents (e.g., for the '333, '691, '921, '012, '291, '384, and '669 Patents), identifies the Symphony Thrombectomy System with both 24F and 16F catheters as infringing the '910 and '005 Patents, and with 24F and/or 16F ProHelix device(s) as infringing the '580 Patent the Symphony Thrombectomy System. Discovery may show that additional or newer versions of Truvic products also infringe, and/or that Truvic's products infringe additional patents or claims beyond those listed above.

Inari requires more discovery on whiteboard printouts, design documents, sketches, laboratory notebooks or workbooks, research notes, invention disclosure forms, technical manuals, whitepapers, datasheets, user guides, engineering drawings, schematics, structural and functional specifications, design documents, test data, instructions for use, and other documentation sufficient to show the operation of the aspects and elements of the Accused Products identified above and in the claim charts. Inari reserves the right to supplement and amend its Infringement Contentions.

C. Claim Charts Demonstrating Truvic's Infringement Of The Asserted Claims Of The Asserted Patents – PLR 3-1(c): Requiring "[a] chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function."

Charts for each of the first set of Asserted Patents and Accused Products listed in the table above were previously served as Exhibits A-E and G-I (Inari has by its Second Amended Complaint removed its claims as to the '011 Patent), and charts for the additional two patents added to the case through Inari's Second Amended Complaint on February 7, 2025 are attached as Exhibits J-K. For each element of the Asserted Claims, the charts may provide just one example of multiple types or products and/or structures that meet the claim element. The charts are not intended to be exhaustive as to all products/structures that satisfy a given claim element of any claims asserted against Truvic; for example, the charts apply the asserted claims against the Accused Products, but discovery may show that other Truvic products infringe in additional ways, and the charts are not meant to include third-party products that also may infringe the Asserted Patents.

Inari does not presently contend that any claim language of the asserted claims is governed by 35 U.S.C. § 112, ¶ 6.

Inari reserves the right to supplement this response.

D. Truvic's Indirect Infringement Of The Asserted Claims – PLR 3-1(d): "For each claim which is alleged to have been indirectly infringed, an identification of any direct infringement and a description of the acts of the alleged indirect infringer that contribute to or are inducing that direct infringement. Insofar as alleged direct infringement is based on joint acts of multiple parties, the role of each such party in the direct infringement must be described."

Inari asserts method claims of the '333 and '580 Patents. Truvic induces infringement of these method claims under 35 U.S.C. § 271(b) because it sells products in the United States capable of practicing the method claims and being used in the systems in the United States along with materials, documentation, instruction (including attendance at patient procedures by its sales representatives), setup, and installation services, which enable Truvic's customers to directly infringe these claims by practicing the claimed methods. Truvic provides materials and personnel

that specifically instruct Truvic's customers in the practice of infringing methods. Truvic was aware of both the '333 Patent and the published application that matured into the '580 Patent, which had claims substantially identical to claims of the '580 Patent, before this litigation (*see* Section VIII below), and Truvic has indirectly infringed the '333 and '580 Patents after having such knowledge. Truvic engages in promotional, advertising, and instructional efforts that include, at a minimum, the maintenance and distribution of instructions for use, videos, guides, and/or manuals that instruct, direct, and encourage its customers and potential customers to use the patented methods of the '333 Patent because the materials teach treating pulmonary embolism and/or deep vein thrombosis using the Symphony System by, e.g., advancing an aspiration catheter proximate to clot material, generating a vacuum pressure within a clot canister while a valve is in a first position, and then moving the valve to a second position to apply vacuum pressure to the clot material. Truvic also engages in promotional, advertising, and instructional efforts that include, at a minimum, the maintenance and distribution of instructions for use, videos, guides, and/or manuals that instruct, direct, and encourage its customers and potential customers to use the patented methods of the '580 Patent because the materials teach treating blood clots using the Symphony Thrombectomy System by, e.g., advancing an aspiration catheter comprising an elongated shaft proximate to clot material, pre-charging a vacuum in a pressure source while a valve is in a first position, and then moving the valve to a second position to apply vacuum pressure to the clot material to aspirate a first portion of the clot material, and advancing an interventional device, such as a ProHelix, through the catheter and engaging a second portion of the clot material.

Truvic is also liable for contributory infringement of the asserted method claims of the '333 and '580 Patents under 35 U.S.C. § 271(c) because it sells the Accused Products, e.g., the Symphony System and components of that system, that have no other use, except to practice one or more of the claimed methods of the '333 and '580 Patents. Truvic is liable for contributory infringement, because the Accused Products are especially made or especially adapted for infringing use, and the Accused Products are not staple articles of commerce that there are capable of substantial noninfringing uses.

Additionally, Truvic also induces infringement and is liable for contributory infringement of the asserted system and/or apparatus claims of the asserted ’910, ’005, ’691, ’921, 012, ’291, ’384, and ’669 Patents. Truvic provides promotional, advertising, and instructional materials and information that include, at a minimum, the maintenance and distribution of instructions for use, videos, guides, and/or manuals, as well as the attendance of its personnel at patient procedures using the Symphony Thrombectomy System, that instruct, direct, and encourage its customers and potential customers to use its Symphony Thrombectomy System (i.e., their direct infringement). Truvic further sells Accused Products, *e.g.*, the Symphony Thrombectomy System and/or components thereof that are intended to and are combined into an operational system that have no other use except to practice one or more of the claims of the asserted ’910, ’005, ’691, ’921, 012, ’291, ’384, and ’669 Patents. The Accused Products are especially made or especially adapted for infringing use by incorporation into infringing structures, and the Accused Products are not staple articles of commerce that there are capable of substantial noninfringing uses. As discussed further below, Truvic has continued to engage in such activities after being notified of its infringement of the asserted ’910, ’005, ’691, ’921, 012, ’291, ’384, and ’669 Patents, including by Inari’s letter and by Inari’s Complaint (ECF 1), First Amended Complaint (ECF 20), and/or Second Amended Complaint.

E. Doctrine Of Equivalents – PLR 3-1(e): Requiring identification of “[w]hether each limitation of each asserted claim is alleged to be literally present or present under the doctrine of equivalents in the Accused Instrumentality.”

Inari contends that all elements of the asserted claims are literally present in each Accused Product. Inari has, in the alternative, identified certain structures that will infringe under the doctrine of equivalents, to the extent Truvic argues that the claimed limitations are not literally met by the cited structures. Inari further reserves the right to assert that any element that is not literally present in an Accused Product is present under the doctrine of equivalents. Inari may supplement to include explanation of the doctrine of equivalents based on the Court’s claim construction or the other orders of the Court, based on new information through discovery or other investigation, or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

To the extent any claim is not found to be literally infringed, the claim is infringed under the doctrine of equivalents because (a) the accused product, method, or system has substantially the same overall function, operates in substantially the same way, and achieves substantially the same result or qualities as the product, method, or system disclosed in the patent claim; and (b) every element of the patent claim either is literally present or has some substantially equivalent corresponding element in the accused product, method, or system. For example, some of the Asserted Claims require elements such as one or more (a) "aspiration source" or "pressure source"; (b) "clot canister"; and/or (c) the tubular member extending along a first axis and member(s) of one or more actuators or members of actuators movable along another axis orthogonal to the first axis. All of these limitations of the Asserted Claims are literally met in the Accused Products. To the extent, however, that Truvic ***contends*** that the claim language corresponding to these limitations is not literally met (for example: if Truvic contends that the identified aspiration source(s) and/or pressure sources(s) are not literally met by the Asserted Claims, such as because the only aspiration source/pressure source is a single pump and cannot be part of both a first pressure source and a second pressure source and/or because the pressure sources/aspiration sources are limited to a syringe embodiment; if Truvic contends that the clot container of the Symphony System handles is not a clot canister; or if Truvic contends that the longitudinal axis of the tubular portion of the Symphony hemostasis valves is not orthogonal to the longitudinal axis of the motion of the actuator(s)'s member(s)), then the claim language is satisfied under the doctrine of equivalents because the Symphony Thrombectomy System and/or components thereof performs substantially the same function as the recited structure, in substantially the same way, to yield substantially the same result.

F. Priority Dates – PLR 3-1(f): Requiring identification, "[f[or any patent that claims priority to an earlier application, the priority date to which each asserted claim allegedly is entitled."

The '333, '910, '005, and '691 Patents claim priority to and are entitled to the priority dates of Application No. 16/536,185 (Patent No. 11,559,382), filed on August 8, 2019, and Provisional Application Nos. 62/718,248 and 62/718,269, both filed on August 13, 2018.

The ’921, ’012, ’291, and ’384 Patents claim priority to and are entitled to the priority dates of Application No. 16/117,519 (Patent No. 11,000,682), filed on August 20, 2018, and Provisional Application No. 62/554,931, filed on September 6, 2017.

The ’580 and ’669 Patents claim priority to and is entitled to the priority dates of Application No. 16/258,344 (Patent No. 11,154,314), filed on January 25, 2019, and Provisional Application No. 62/622,691, filed on January 26, 2018.

G. Inari’s Products That Practice The Asserted Patents – PLR 3-1(g): “If a party claiming patent infringement wishes to preserve the right to rely, for any purpose, on the assertion that its own apparatus, product, device, process, method, act, or other instrumentality practices the claimed invention, the party shall identify, separately for each asserted claim, each such apparatus, product, device, process, method, act, or other instrumentality that incorporates or reflects that particular claim.”

Inari’s products practice at least the following asserted claims of the Asserted Patents. Inari reserves the right to later amend this disclosure to identify additional claims practiced by Inari products, including based on Truvic’s interpretation of the claims or based on the Court’s construction of terms of the Asserted Claims. Inari products practice at least the following:

PATENT	ASSERTED CLAIMS	INARI PRODUCTS
11,974,910	1, 2, 6-8, 11, 15	Inari FlowTriever with 16F and 24F, 16F and 20F, and/or 20F and 24F Triever aspiration catheters
	3, 12	Inari FlowTriever with 16F and 24F Triever aspiration catheters
11,554,005	10-11	Inari FlowTriever with 16F and 24F, 16F and 20F, and/or 20F and 24F Triever aspiration catheters
11,844,921	1-3, 5-7, 9-10	Inari FlowTriever; Inari ClotTriever; Inari ProTrieve
11,697,012	1	Inari FlowTriever; Inari ClotTriever; Inari ProTrieve
11,865,291	1-2, 7-8, 12-14	Inari FlowTriever; Inari ClotTriever; Inari ProTrieve

PATENT	ASSERTED CLAIMS	INARI PRODUCTS
12,016,580	1, 5-6, 9-17, 30, 33-34	Inari FlowTriever with 16F, 20F, and/or 24F Triever aspiration catheter(s) and FlowTriever catheter (disk device) or FlowTriever2 catheter (laser cut interventional element)

Information and documents about the FlowTriever, ClotTriever, and ProTrieve can be found at Inari's website https://www.inarimedical.com/, and were produced at least at bates numbers INARI_021684-INARI_023166 and INARI_023277- INARI_024530.

H. Damages Period – PLR 3-1(h): "Identify the timing of the point of first infringement, the start of claimed damages, and the end of claimed damages."

As set forth in Inari's charts, the damages period, to Inari's current understanding based on representations of by Truvic of when it gained clearance and began marketing Symphony Thrombectomy System is March 2023-present. For patents that issued after March 2023, the damages period runs at least from the date of issuance (or sooner, in some instances, as permitted by 35 USC 154(d)) to the present. For instance, for the '910 Patent, which issued on May 7, 2024, the damages period is from no later than April 24, 2024 (when Inari specifically notified Truvic of infringement of the then-allowed claims of the soon-to-issue '910 Patent by letter) until the present. For the '333 Patent, which issued on April 30, 2024, the damages period is from no later than April 24, 2024 (when Inari specifically notified Truvic of infringement of the then-allowed claims of the soon-to-issue '333 Patent by letter) until the present. For the '005 Patent, which issued on January 17, 2023, the damages period is at least from March 2023, when Truvic began to market the Symphony System, to the present. For the '691 Patent, which issued on September 5, 2023, the damages period is from September 5, 2023 to the present. For the '921 Patent, which issued on December 19, 2023, the damages period is from December 19, 2023 to the present. For the '012 Patent, which issued on July 11, 2023, the damages period is from July 11, 2023 to the present. For the '291 Patent, which issued on January 9, 2024, the damages period is from September 29, 2023 (when Inari specifically notified Truvic of infringement of the then-allowed and later issued claims of Patent Application 18/142,518) to the present. For the '580 Patent, which issued on June 25, 2024, the damages period is from September 29, 2023 (when Inari

specifically notified Truvic of infringement of the published claims of Patent Application 17/498,642, which are substantially identical to issued claims that issued June 25, 2024) to the present. For the '384 Patent, which issued on October 8, 2024, the damages period is at least from October 8, 2024 to the present. For the '669 Patent, which issued on December 3, 2024, the damages period is from December 3, 2024 to the present.

Inari additionally provides notice of its patents under Section 287 through its virtual marking webpage, found at https://www.inarimedical.com/inari-patents.

I. Truvic's Willful Infringement – PLR 3-1(i): Requiring identification, "*[i]f a party claiming patent infringement alleges willful infringement, the basis for such allegation.*"

Truvic's infringement of Inari's Asserted Patents is and has been willful and intentional, with knowledge of the Asserted Patents, and knowledge of, intent, and/or at least willful blindness of its infringement. Truvic has been aware of the Asserted Patents and its infringement of those patents at least since September 29, 2023, when Inari provided notice that the Symphony Thrombectomy System infringes Inari's patents, including specifically that it was infringing patents from each of the three families Inari has asserted. Inari's September 29, 2023 letter specifically raised and attached a copy of: (a) the '005 Patent, (b) the '691 Patent, (c) the '012 Patent, (d) the allowed claims of Application No. 18/142,518, later issued as the '291 Patent, and (e) the published claims of Application No. 17/498,642, including claims issued in substantially identical form as the '580 Patent. When, on January 15, 2024, Truvic finally responded as to the substance of the allegations Inari raised, after delays and refusing to provide a sample of the Symphony System, Truvic did not raise even a single noninfringement arguments for any of the Inari patents asserted in this litigation.

Inari wrote Truvic another letter on April 24, 2024, informing Truvic of its infringement of additional patents, including: (g) the '921 Patent; (h) the '333 Patent; and (i) the allowed claims of Application No 18/342,553, which were later issued as the '910 Patent. Inari's letter also: (a) confirmed that a tear-down of a Truvic device obtained by Inari had conclusively demonstrated infringement of the '921, 012, and '291 Patents by the Symphony Thrombectomy System's

hemostasis valves; and (b) disputed the validity arguments raised in Truvic's letter, explaining that the prior art that Truvic cited had largely been expressly considered by the Patent Office.

After this litigation began, additional Inari patents have continued to issue. The '669 Patent issued on December 3, 2024, and the '384 Patent issued on October 8, 2024. On February 7, 2024, Inari added these patents via a Second Amended Complaint. Truvic has been aware of the '384 Patent at least since November 8, 2024 because Truvic included discussion of and attached the '384 Patent to a petition for *inter partes* review that Truvic filed on November 8, 2024. Truvic has had knowledge of the '669 Patent at least since February 7, 2025, when Inari provided express notice via its Second Amended Complaint.

Inari further alleges that discovery will show that Truvic was aware of Inari's intellectual property relating to aspiration systems, hemostasis valves, and systems that employ aspiration and an interventional device, including without limitation one or more the Asserted Patents before receiving express notice from Inari, including because Truvic and Inari are competitors in the industry, Truvic monitors Inari's patent filings and issuances, Truvic was and remains aware of and/or copied one or more aspects Inari's patented devices and knew that they were likely to be subject to patent protection, and because Truvic has engaged in a practice of hiring persons employed by Inari and knowledgeable about Inari's products, customers, and intellectual property in order to obtain a competitive advantage.

Despite Truvic's knowledge of the Asserted Patents and its infringement, including from correspondence with Inari, Truvic has continued to make, have made, use, sell, and/or offer to sell infringing devices, which constitutes willful and intentional infringement. This includes willful infringement following Truvic's continued infringement after being served with Inari's Complaint (ECF 1), Amended Complaint (ECF 20), and Second Amended Complaint (ECF 67).

Inari may supplement these contentions to include further explanation regarding willful infringement based on new information through discovery or other investigation, or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

DOCUMENT PRODUCTION PURSUANT TO PLR 3-2

A. PLR 3-2(a): "Documents (e.g., contracts, purchase orders, invoices, advertisements, marketing materials, offer letters, beta site testing agreements, and third party or joint development agreements) sufficient to evidence each discussion with, disclosure to, or other manner of providing to a third party, or sale of or offer to sell, or any public use of, the claimed invention prior to the date of application for the patent in suit. A party's production of a document as required herein shall not constitute an admission that such document evidences or is prior art under 35 U.S.C. § 102."

Inari identifies under PLR 3-2(a) at least the documents produced concurrently with Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_021675-INARI_021683, as well as additional documents being produced concurrently with these supplemental preliminary infringement contentions that are Bates-labeled INARI_034267-INARI_034305.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

B. PLR 3-2(b): "All documents evidencing the conception, reduction to practice, design, and development of each claimed invention, which were created on or before the date of application for the patent in suit or the priority date identified pursuant to Patent L.R. 3-1(f), whichever is earlier."

Inari identifies under PLR 3-2(b) at least the documents produced concurrently with Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_021684-INARI_023166.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

C. PLR 3-2(c): "A copy of the file history for each patent in suit."

Inari identifies under PLR 3-2(c) at least the documents produced concurrently with these Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_000001-INARI_021674, as well as additional documents being produced concurrently with these supplemental preliminary infringement contentions that are Bates-labeled INARI_034316-INARI_039005.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

D. PLR 3-2(d): "All documents evidencing ownership of the patent rights by the party asserting patent infringement."

Inari identifies under PLR 3-2(d) at least the documents being concurrently with Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_023167-INARI_023276 as well as additional documents being produced concurrently with these supplemental preliminary infringement contentions that are Bates-labeled INARI_34313-INARI_34314.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

E. PLR 3-2(e): "If a party identifies instrumentalities pursuant to Patent L.R. 3-1(g), documents sufficient to show the operation of any aspects or elements of such instrumentalities the patent claimant relies upon as embodying any asserted claims."

Inari identifies under PLR 3-2(e) at least the documents produced concurrently with Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_023277- INARI_024530.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

F. PLR 3-2(f): "All agreements, including licenses, transferring an interest in any patent-in-suit."

Inari identifies under PLR 3-2(f) at least the documents produced concurrently with Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_024531-INARI_024887.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

G. PLR 3-2(g): "All agreements that the party asserting infringement contends are comparable to a license that would result from a hypothetical reasonable royalty negotiation."

Inari identifies under PLR 3-2(g) at least the documents produced concurrently with Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_024531-INARI_024887.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

H. PLR 3-2(h): "All agreements that otherwise may be used to support the party asserting infringement's damages case."

Inari identifies under PLR 3-2(h) at least the documents produced concurrently with Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_024888-INARI_034146.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

I. PLR 3-2(i): "If a party identifies instrumentalities pursuant to Patent L.R. 3-1(g), documents sufficient to show marking of such embodying accused instrumentalities and if it wants to preserve the right to recover lost profits based on such products, sales, revenues, costs and profits of such embodying accused instrumentalities."

Inari identifies under PLR 3-2(i) at least the documents produced concurrently with Inari's original preliminary infringement contentions, including specifically the documents Bates-labeled INARI_034147-034202.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

J. PLR 3-2(j): "All documents comprising or reflecting a F/RAND commitment or agreement with respect to the asserted patent(s)."

Inari is not currently aware of any such documents.

Inari may supplement its document production and/or its identification of Bates ranges based on new information uncovered through discovery or other investigation or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

RESERVATION OF RIGHTS

These contentions are preliminary in nature. Inari expects to supplement and amend them in light of claim construction, as information is learned and analyzed during discovery, or in any manner consistent with the Scheduling Order and applicable rules including the PLRs.

DATED: February 7, 2025

By: */s/ Daniel T. Keese*

Ramsey M. Al-Salam, Bar No. 109506
PERKINS COIE LLP
1201 Third Avenue, 49th Floor
Seattle, WA 98101
Tel: 206.359.8000
Fax: 206.359.9000
RAlSalam@perkinscoie.com

Amanda Tessar, Colorado Bar No. 33173
(admitted *pro hac vice*)
ATessar@perkinscoie.com
Perkins Coie LLP
1900 Sixteenth Street, Suite 1400
Denver, Colorado 80202-5255
Telephone: 303.291.2357
Facsimile: 303.291.2457

Daniel T. Keese, Bar No. 280683
PERKINS COIE LLP
1120 NW Couch Street, Tenth Floor
Portland, OR 97209-4128
Telephone: 503-727-2000
Facsimile: 503-727-2222
DKeese@perkinscoie.com

ATTORNEYS FOR PLAINTIFF INARI MEDICAL, INC.

CERTIFICATE OF SERVICE

I am a citizen of the United States of America and I am employed in Palo Alto, California. I am over the age of 18 and not a party to the within action. My business address is 3150 Porter Drive, Palo Alto, California.

On February 7, 2025, I served the foregoing: **INARI'S SUPPLEMENTAL PRELIMINARY INFRINGEMENT CONTENTIONS AND EXHIBITS J-K** on the parties or their counsel shown below, by transmitting it electronically to the addresses as follows:

VIA ELECTRONIC MAIL:

Joseph R. Re
joe.re@knobbe.com
Joshua J. Stowell
joshua.stowell@knobbe.com
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street. 14th Floor
Irvine, CA. 92614

Nicholas A. Belair
nick.belair@knobbe.com
KNOBBE, MARTENS, OLSON & BEAR, LLP
333 Bush St., 21st Fl.
San Francisco CA 94104

I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on February 7, 2025, at Madera, California.

/s/ Kate Rose
Kate Rose
Senior Paralegal

EXHIBIT J
INFRINGEMENT ANALYSIS FOR CLAIMS 1-4, 6-18, AND 20-30 OF UNITED STATES PATENT NO. 12,109,384
TRUVIC SYMPHONY THROMBECTOMY SYSTEM HEMOSTASIS VALVE

Pursuant to Patent Local Rule 3-1, this chart identifies specifically where and how each limitation of Asserted Claims 1-4, 6-18, and 20-30 of United States Patent No. 12,109,384 ("the '384 Patent") is found within the Imperative Care Symphony Thrombectomy System ("Symphony System"), specifically within the hemostasis valve of the 24F and 16F handles of the Symphony System. Collectively, these structures are referred to below as the "Symphony System."

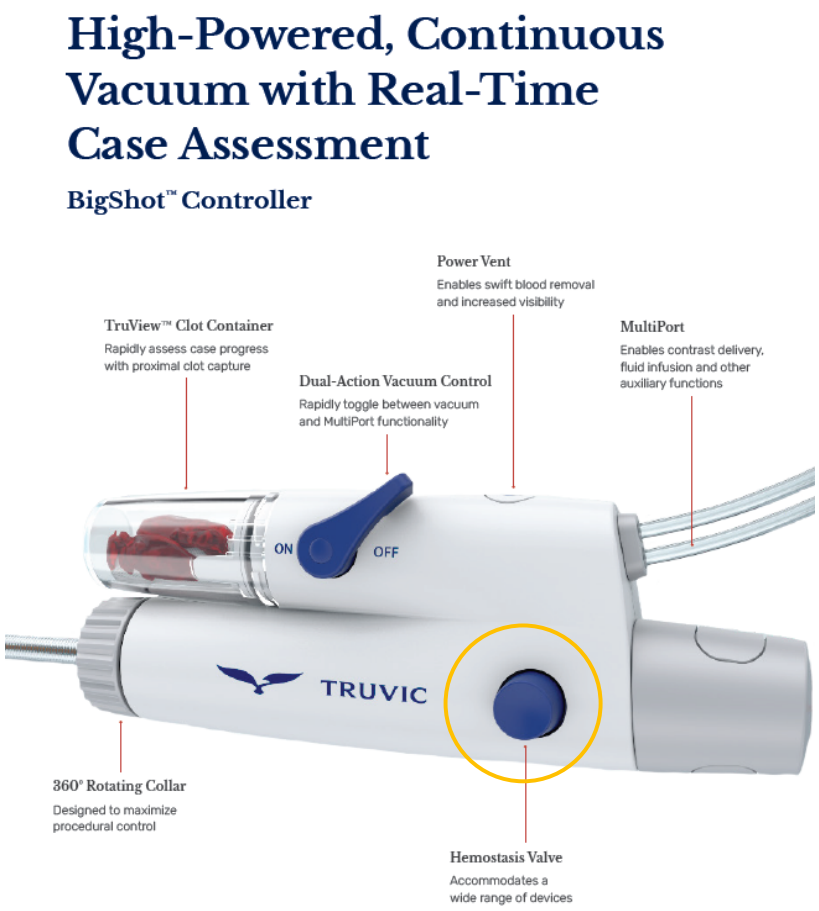
References Cited:

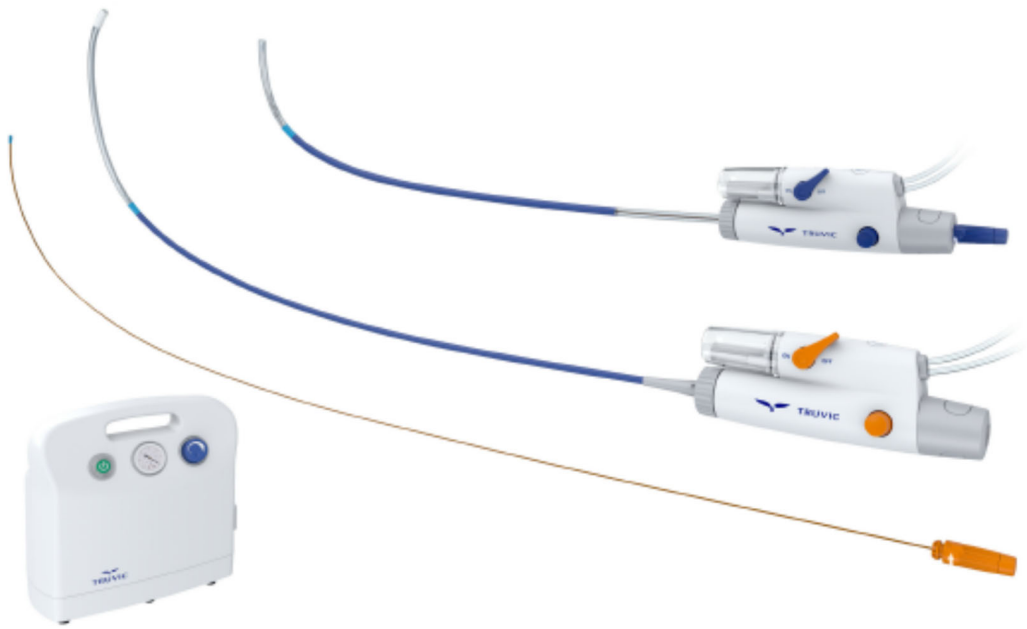
- Symphony Thrombectomy System Brochure (found at https://www.truvic.com/symphony-product; ECF 20-1 (First Amended Complaint Exhibit A); https://cdn.prod.website-files.com/65422b4be21822e711073c8a/65422b4be21822e711073cd1_M10132.A%20Symphony%20Brochure_single_Page.pdf)
- Instructions For Use Symphony Thrombectomy System (ECF 20-2 (First Amended Complaint Exhibit B); https://assets.website-files.com/5eeb7b9eeb1d5b0fb7c9d89a/644268627f5a6760b5e3ade2_LBL10001-02.B%20Truvic%20Symphony%20Thrombectomy%20System%20IFU.pdf)
- Symphony Thrombectomy System – Overview Animation Video (found at https://www.truvic.com/symphony-product; https://vimeo.com/817718796)
- Symphony System tear-down photos (produced at Bates numbers INARI_034203-INARI_034266, INARI_039006-INARI_039007)
- Whipsaw website discussion of Symphony (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system)
- Symphony System sample provided by Truvic
- M10147.C-Symphony-Product-Spec-Sheet.pdf (INARI_034312)
- Instructions For Use Symphony Thrombectomy System 16F, 82CM (INARI_034306- INARI_034311)

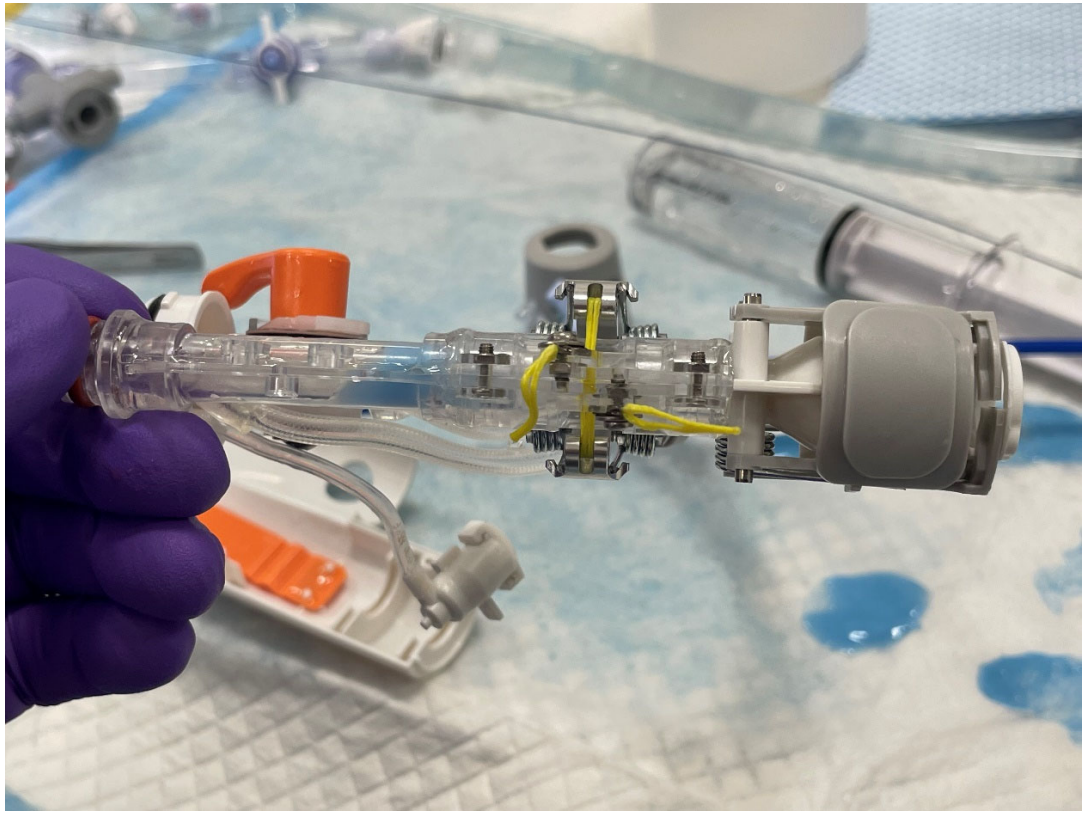
Infringing Acts:

- Imperative Care, including without limitation Imperative Care Vascular and/or Truvic (collectively, "Truvic"), has been making, having made, selling, offering for sale, and/or using Symphony System products since at least March of 2023. Truvic's filings admit that it received FDA clearance for the Symphony System in February of 2023 and began marketing in or before March of 2023. Since the issuance of the '384 Patent on October 8, 2024, these acts of making, having made, selling, offering for sale, and/or using the Symphony System, have infringed the '384 Patent.
- Truvic's Symphony System indirectly infringes by inducement and contributory infringement. Specifically, 16F/24F Bigshot Controller Handles and 16F/24F catheters are especially made to be used together with the hemostasis valve, and these components have no substantial noninfringing use. Further, Truvic specifically instructs intends for users to utilize 16F and 24F Bigshot Controller Handles, such that the hemostasis valve of the handle(s) are used.

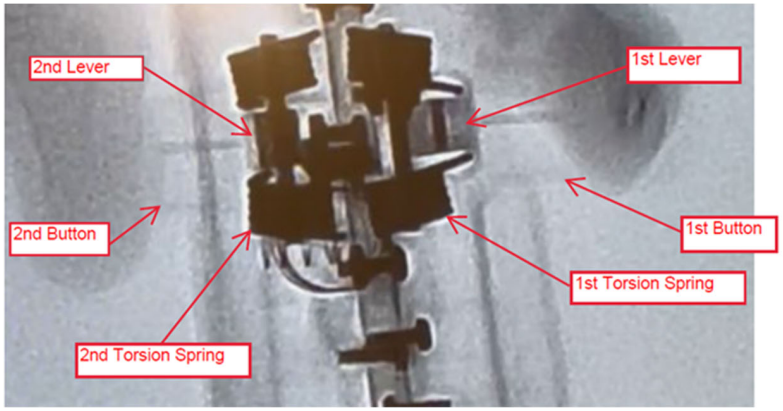
The citations to portions of any reference in this chart are exemplary only. Inari anticipates that it will rely on the entirety of the references cited in this chart, as well as other documents and testimony uncovered during discovery, to demonstrate that the Symphony System infringes the '384 Patent. Discovery is ongoing, and Inari reserves its right to update this chart as appropriate based on the results of its investigation, including pursuant to Local Patent Rule 3-6.

CLAIM ELEMENT	CORRESPONDING STRUCTURE
[1] A valve assembly, comprising:	The Symphony System has a hemostasis valve assembly.  (Annotated Symphony Thrombectomy System Brochure at 6.)

	A hemostasis valve is positioned within each of the two Symphony handles. The hemostasis valve is operated by two blue or two orange buttons, depending on the handle.  (Symphony Thrombectomy System Brochure at 2.)

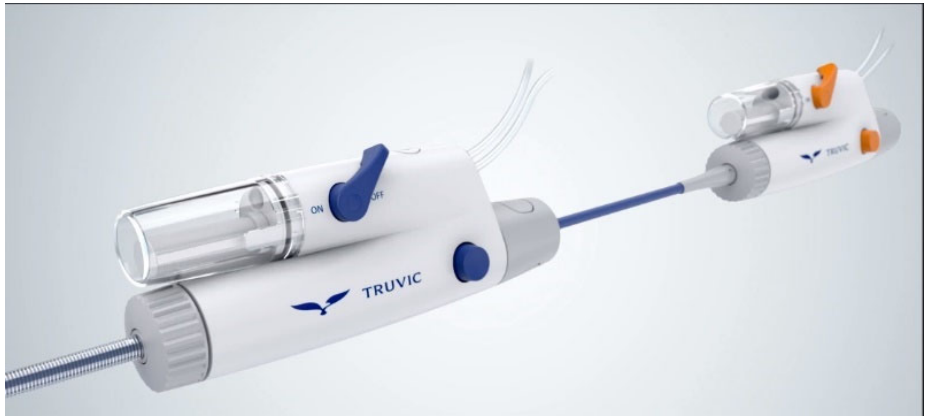
	 (Image of internal portion of housing with hemostasis valve.)

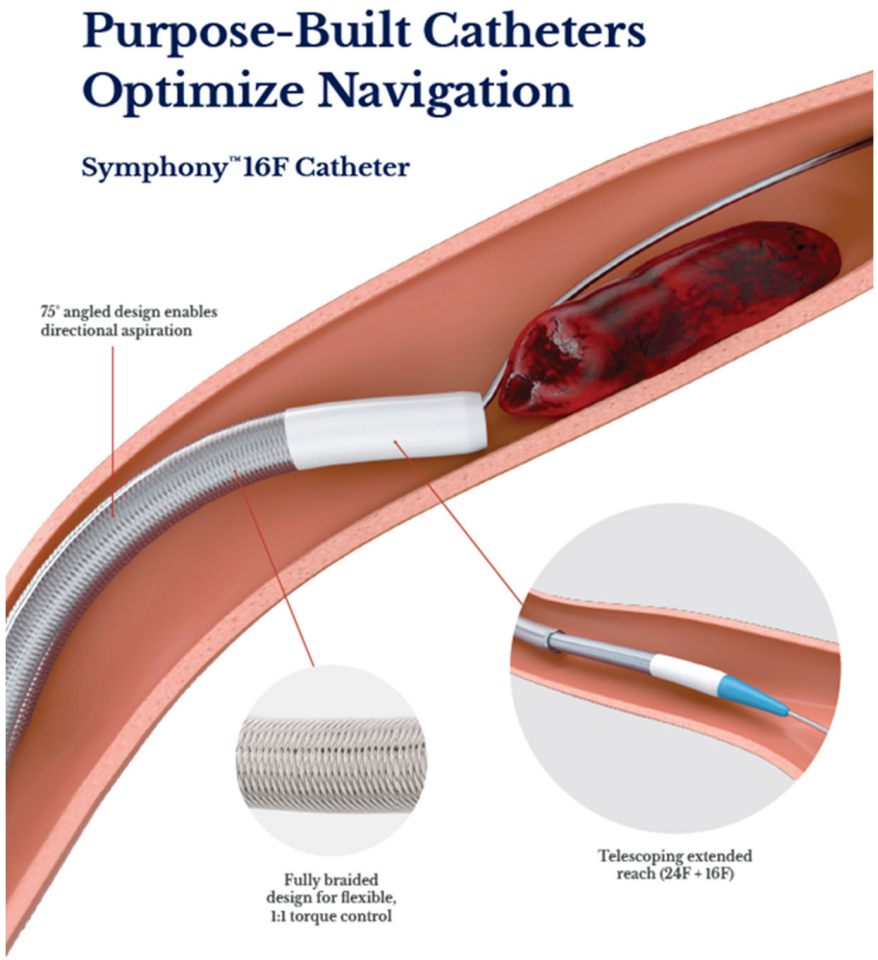
	 (Image of internal portion of housing zoomed-in on hemostasis valve.)



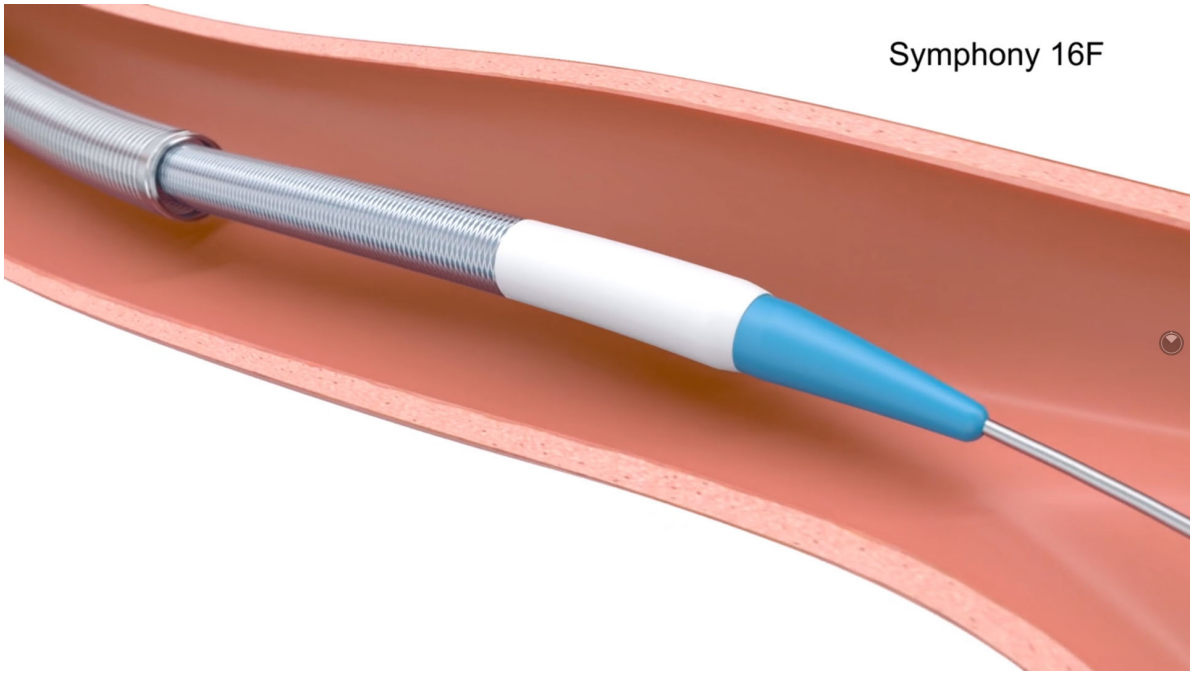
(Annotated x-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs (two for each lever), as part of tensioning mechanism for hemostasis valve in Symphony System housing.)

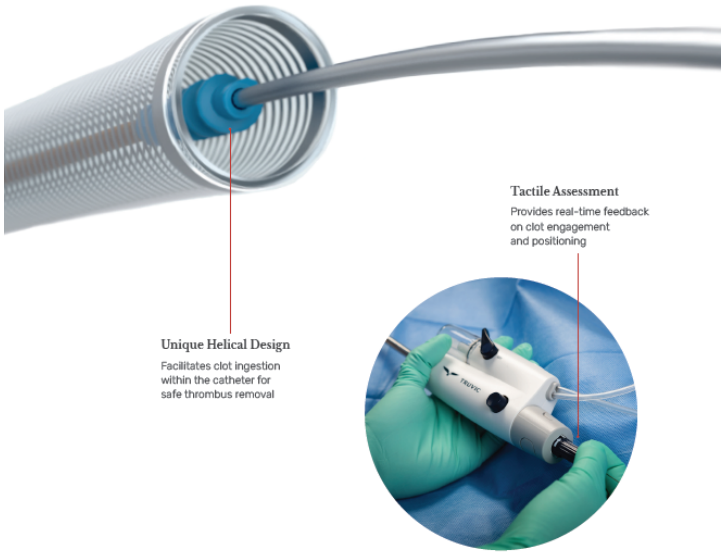
The hemostasis valve is configured to "accommodate a wide range of devices" (Symphony Thrombectomy System Brochure at 6), including a Truvic catheter, a

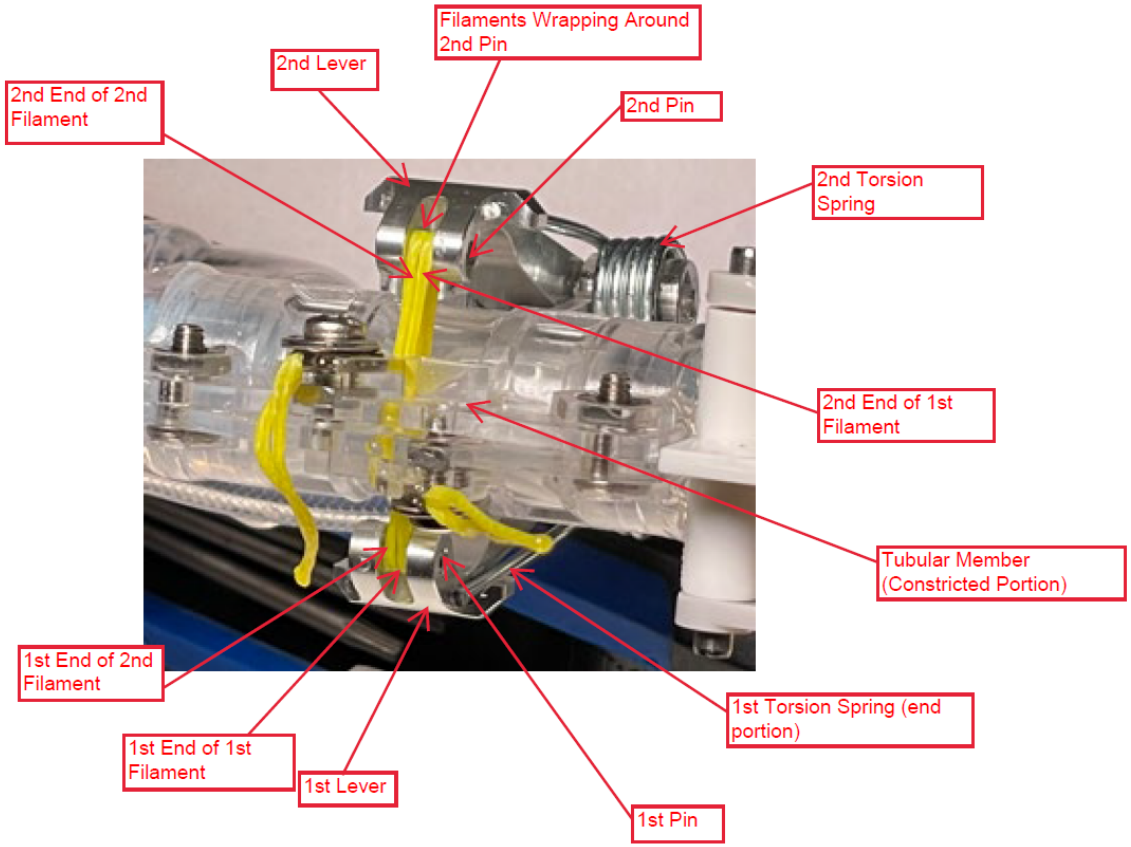
	ProHelix™ Mechanical Assist catheter and, in the case of at least the 24F handle or a second telescoping catheter, for use in procedures:  (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)

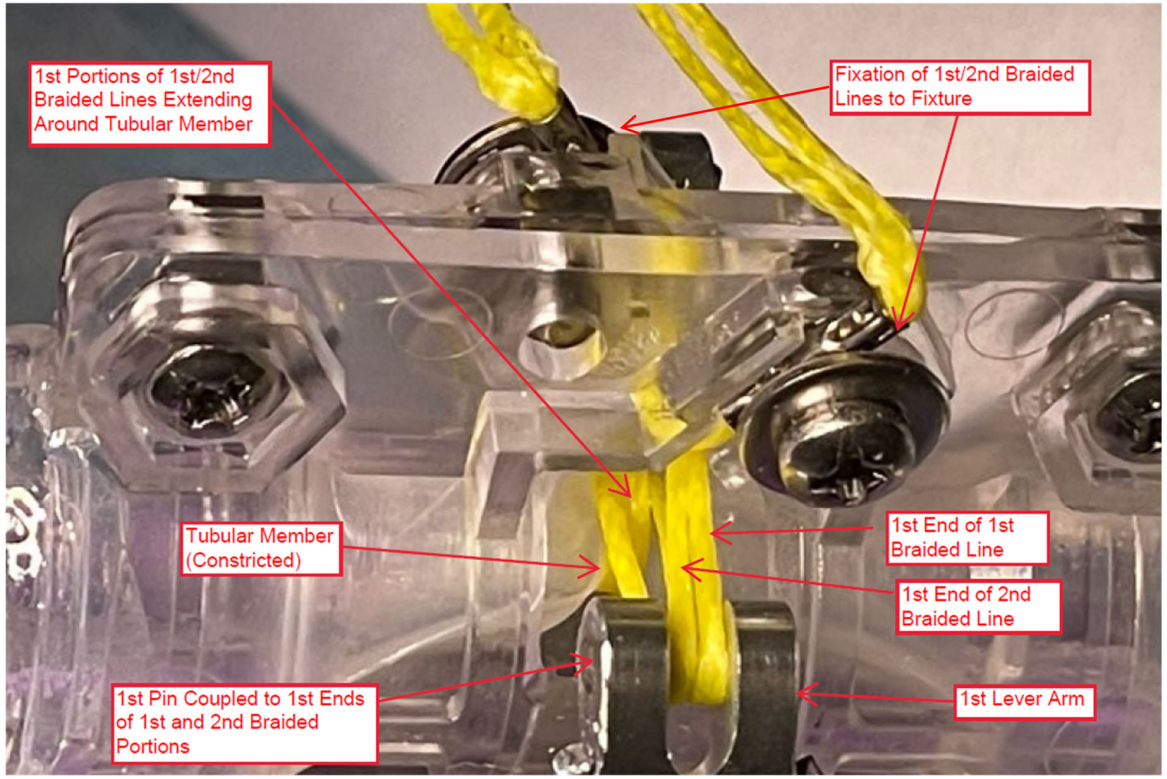


(Symphony Thrombectomy System Brochure at 4.)

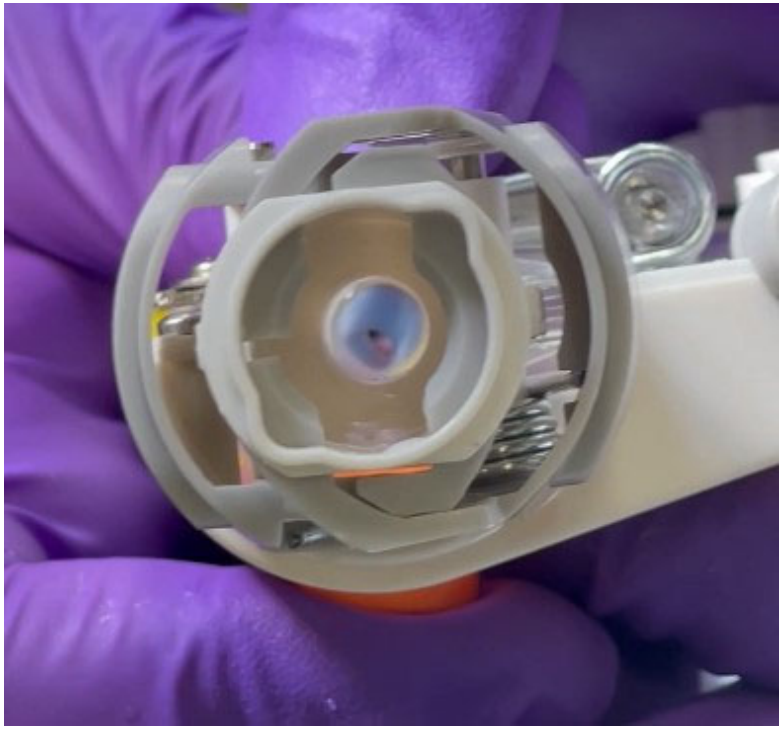
	 (Symphony Thrombectomy System – Overview Animation Video at 1:34 (https://vimeo.com/817718796).)

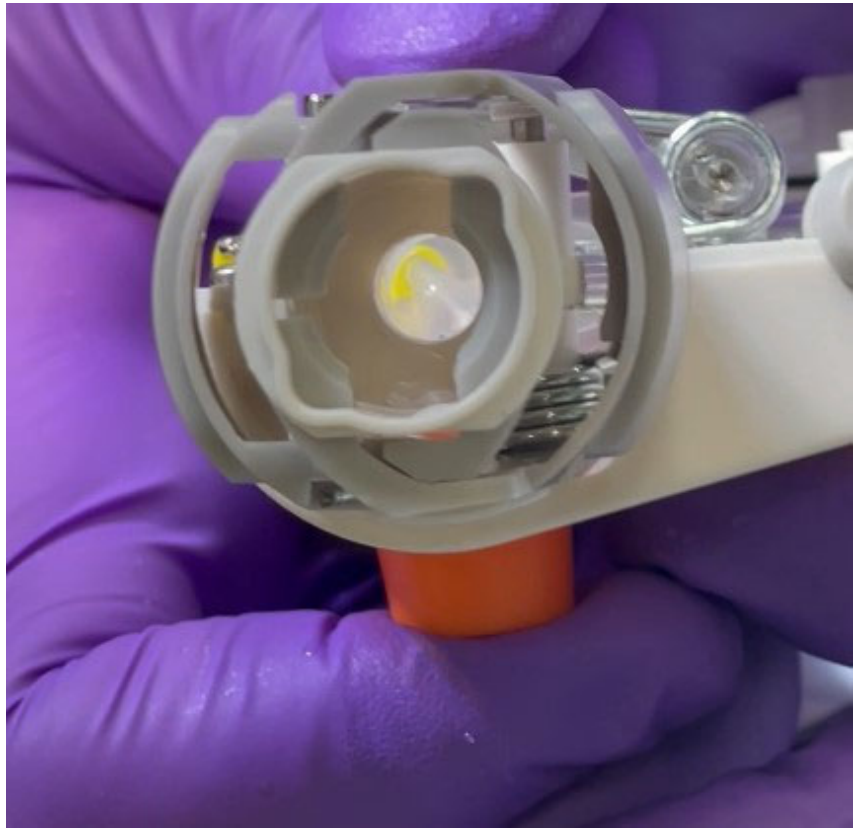
	SYMPHONY™ THROMBECTOMY SYSTEM **Mechanical Assist Optimizes Clot Engagement & Capture** **ProHelix™ Mechanical Assist**  (Symphony Thrombectomy System Brochure at 8.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a tubular member defining a lumen;	The Symphony System hemostasis valve has a collapsible elongate tubular member that defines a lumen (the "Tubular Member" annotated below). The valve lumen is shown below and is configured to "accommodate a wide range of

	devices." (Symphony brochure at 6). Therefore, the hemostasis valve has a tubular member defining a lumen.  (Annotated image of internal portion of Symphony System housing, including hemostasis valve with tubular member defining a lumen.)

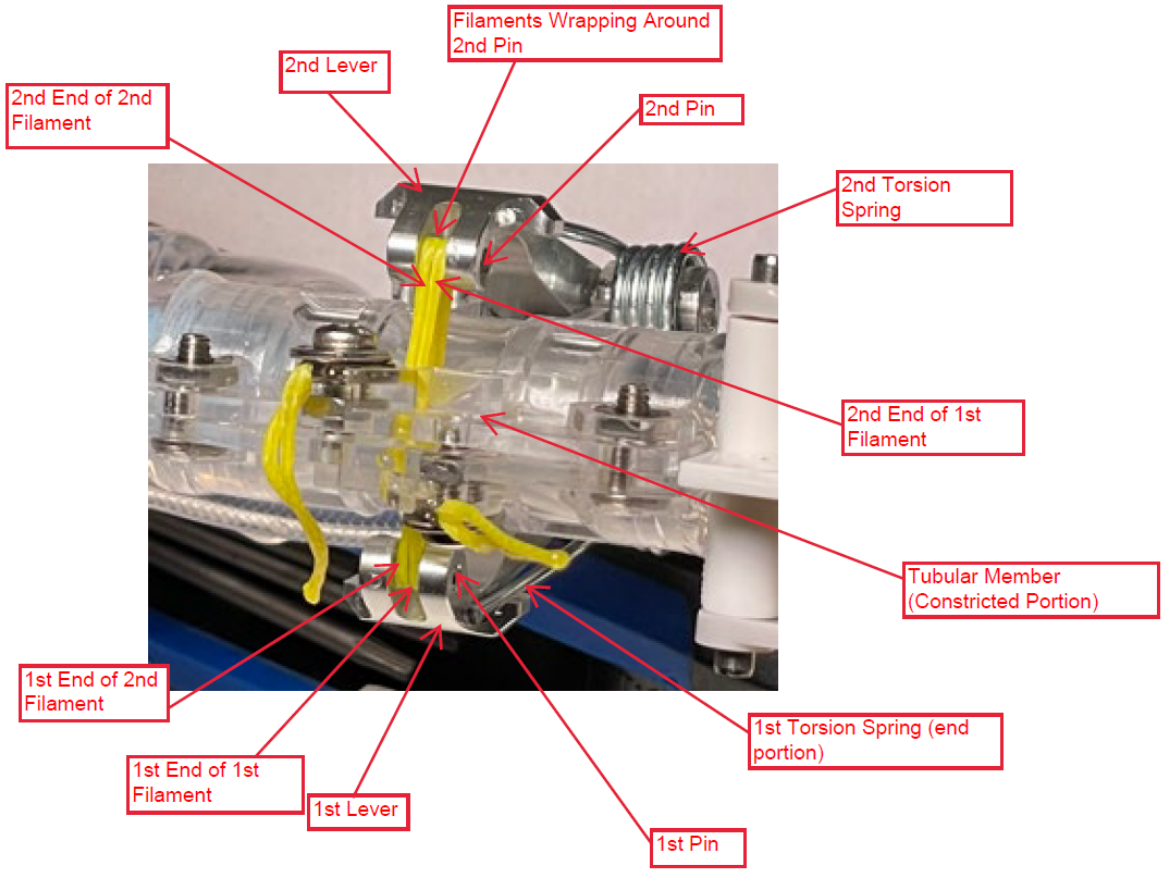


(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having a tubular member defining a lumen (tubular member) constricted and filaments extending around the tubular member.)

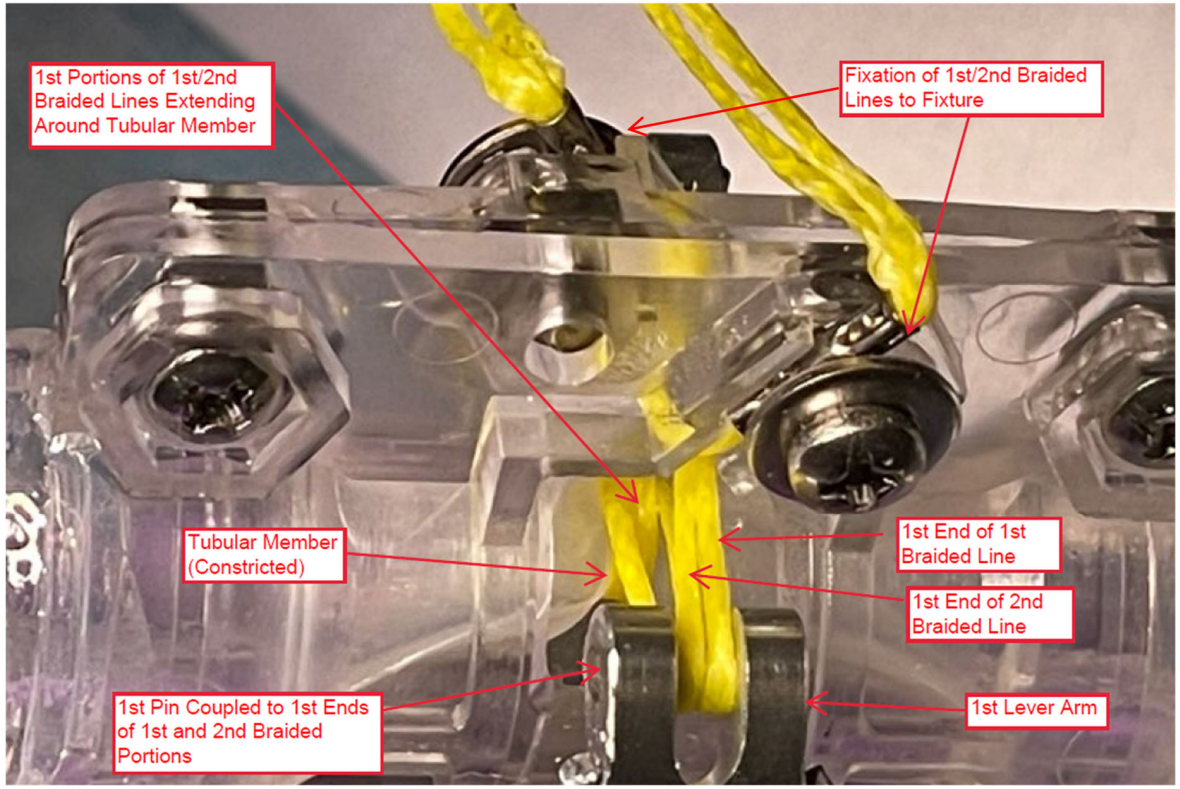
	 (Symphony handle with view down tubular member (lumen) of hemostasis valve with the valve open having the tubular member unconstricted.)

	 (Symphony handle with view down lumen of hemostasis valve with the tubular member of the valve constricted.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a first filament extending in a first loop around the tubular member, wherein the first filament is flexible;	The Symphony System hemostasis valve has a tensioning mechanism including a first filament and a second filament, each extending in a loop around the tubular member, each of the first and the second filaments being flexible. The loop of the first filament extends completely around the elongate member.

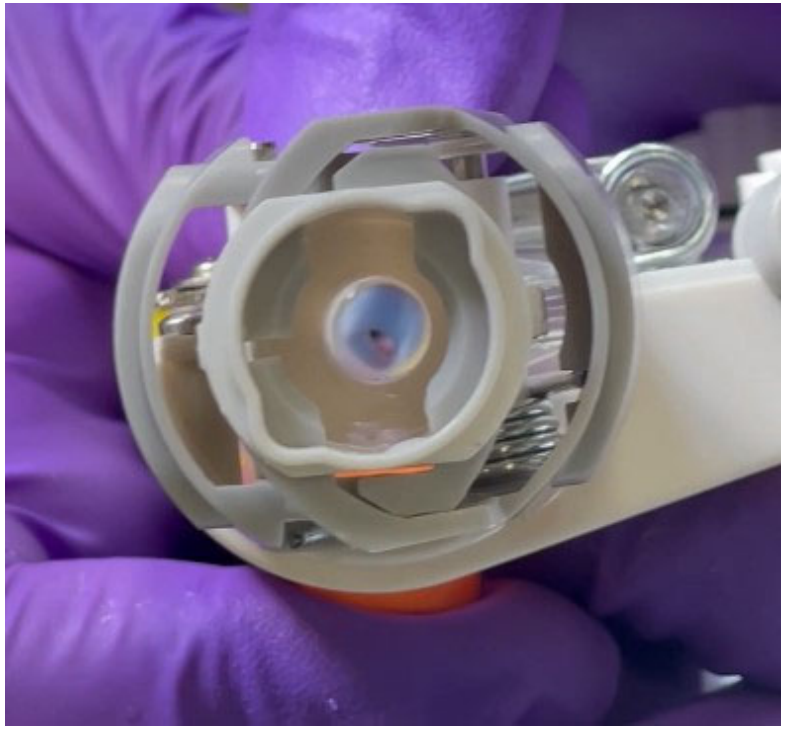
	 (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)

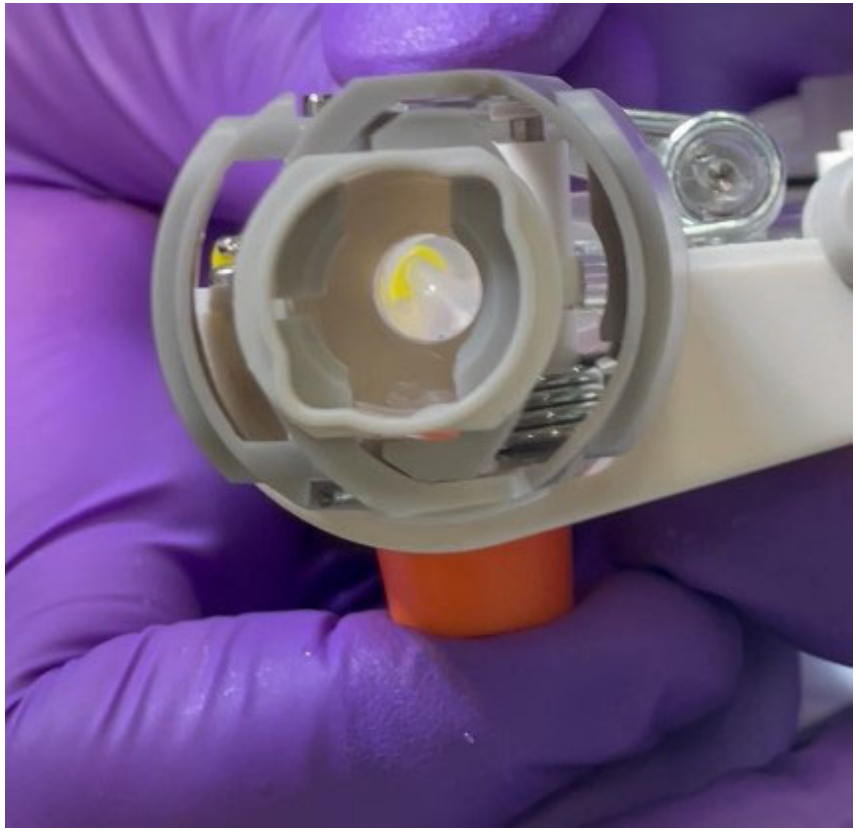


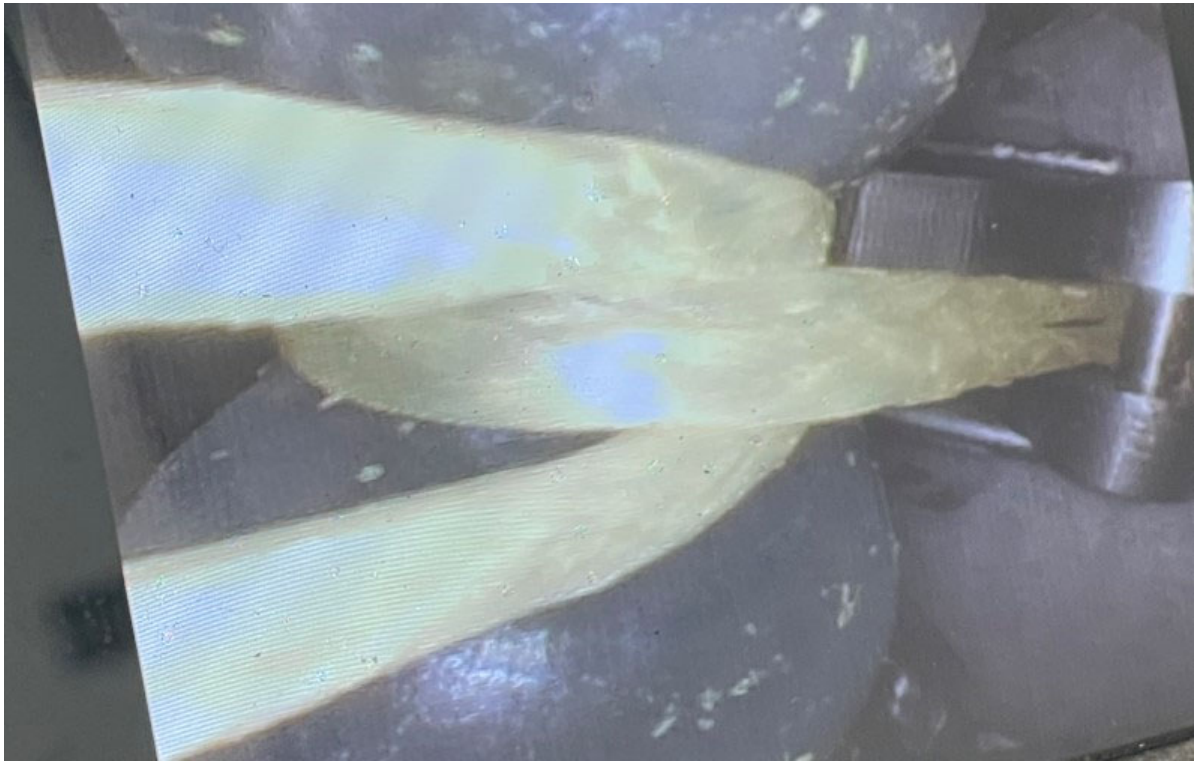
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)



(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

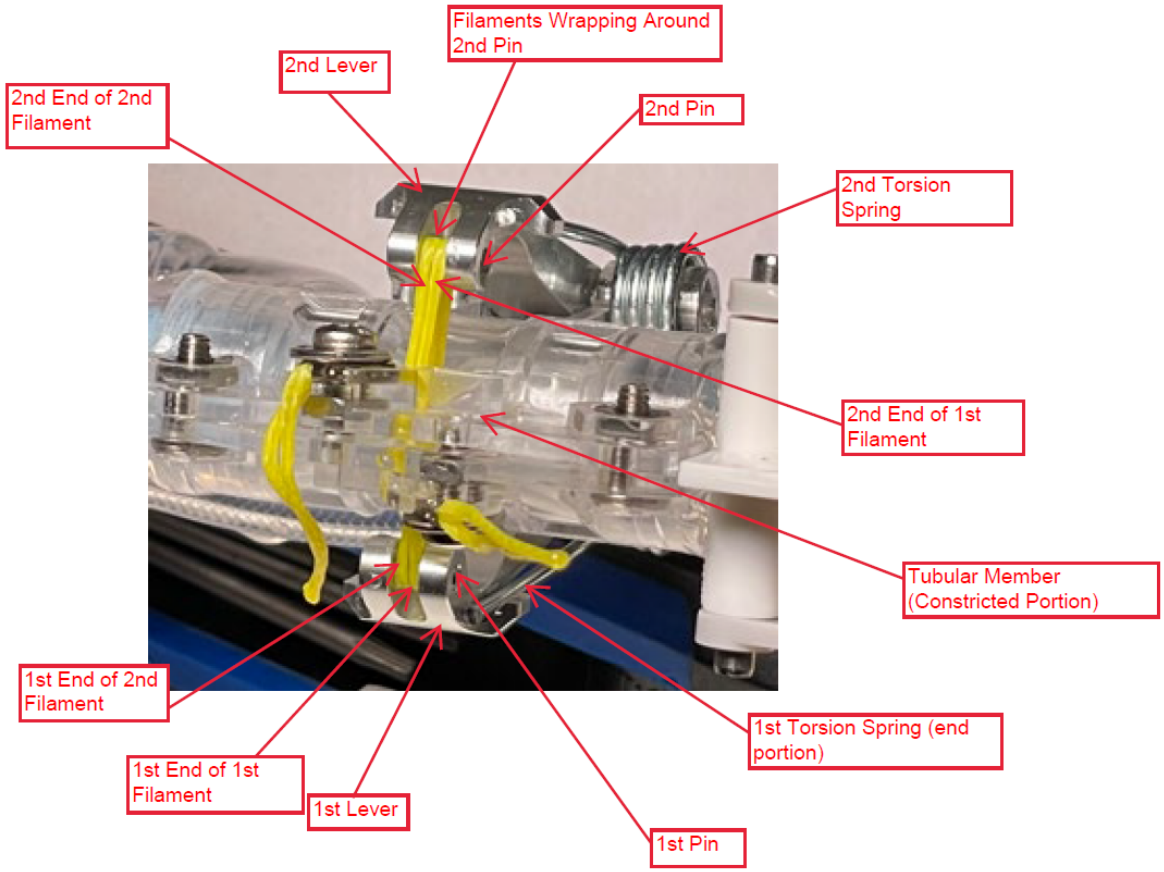
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

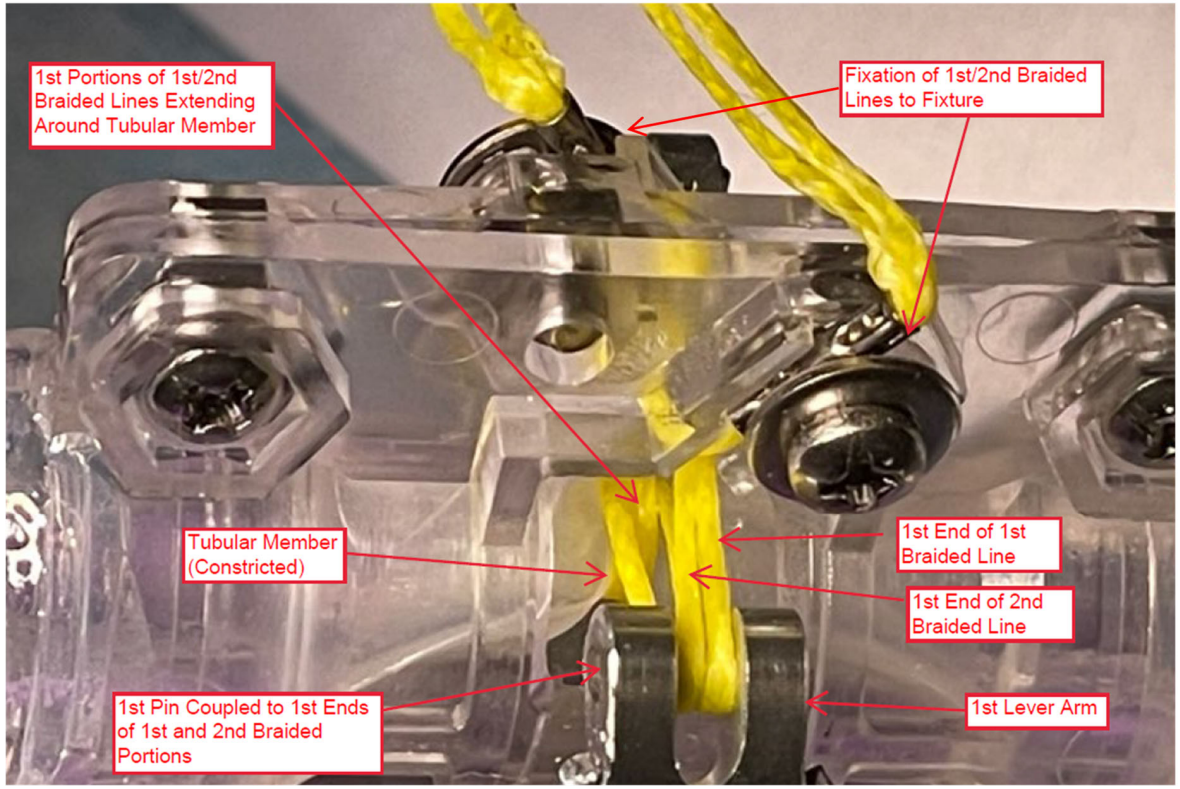
	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member.)

	 (Internal image of hemostasis valve with filaments encircling elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a second filament extending in a second loop around the tubular member, wherein the second filament is flexible;	The Symphony System hemostasis valve has a tensioning mechanism including a first filament and a second filament, each extending in a loop around the tubular member, each of the first and the second filaments being flexible. The loop of the second filament extends completely around the elongate member.

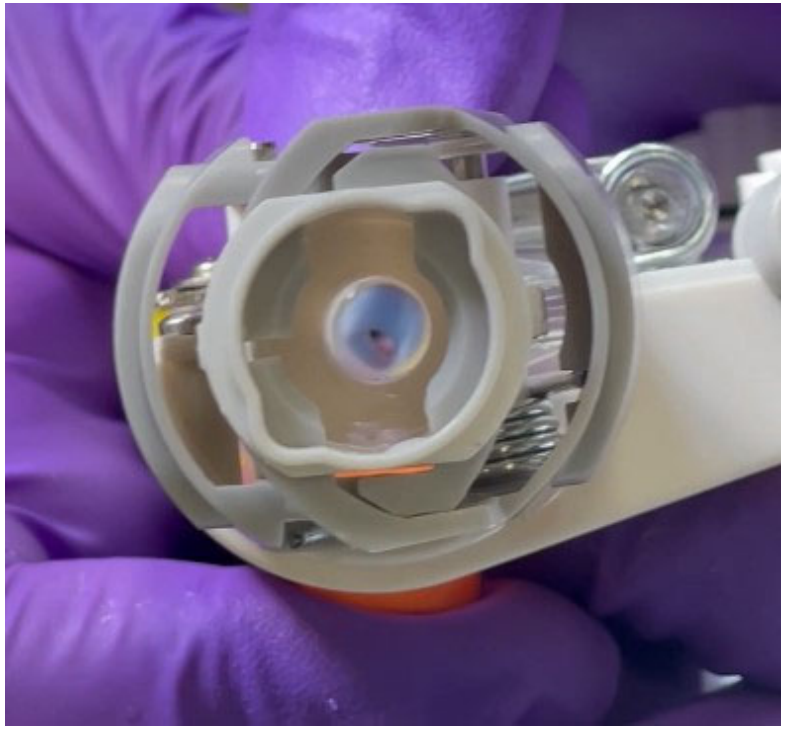
	 (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)

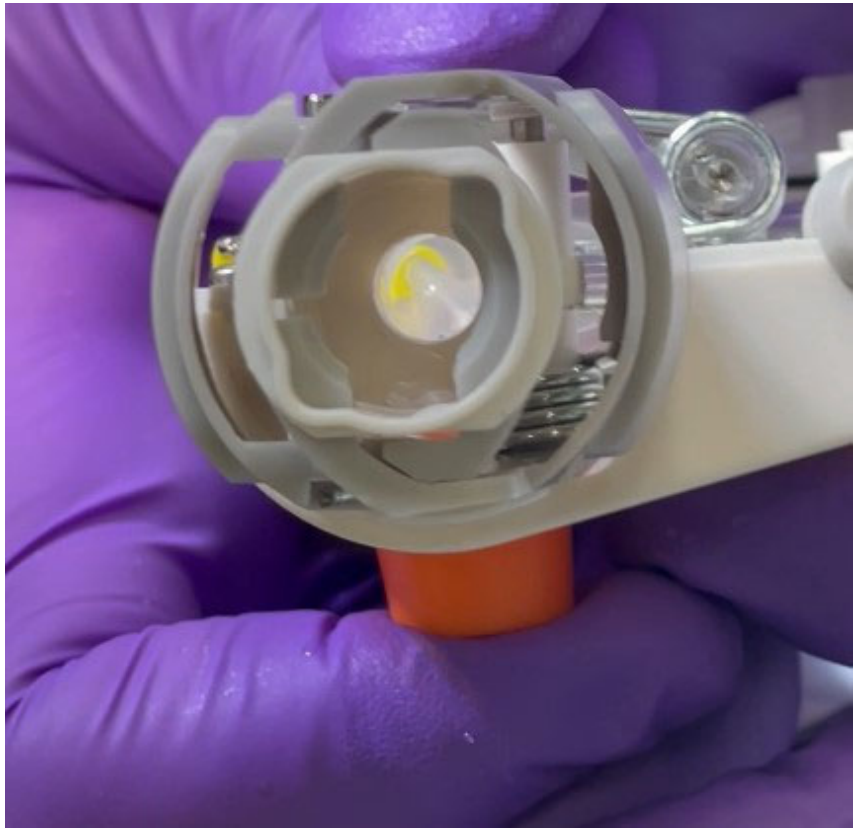


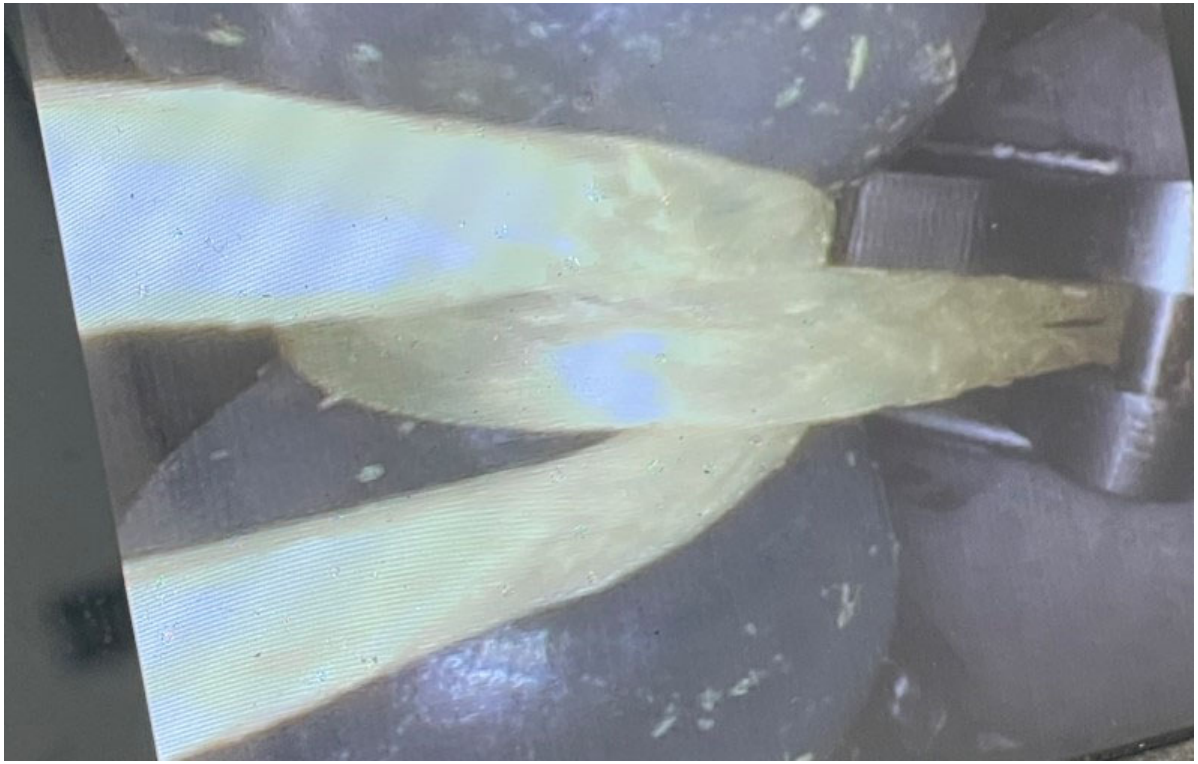
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)



(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

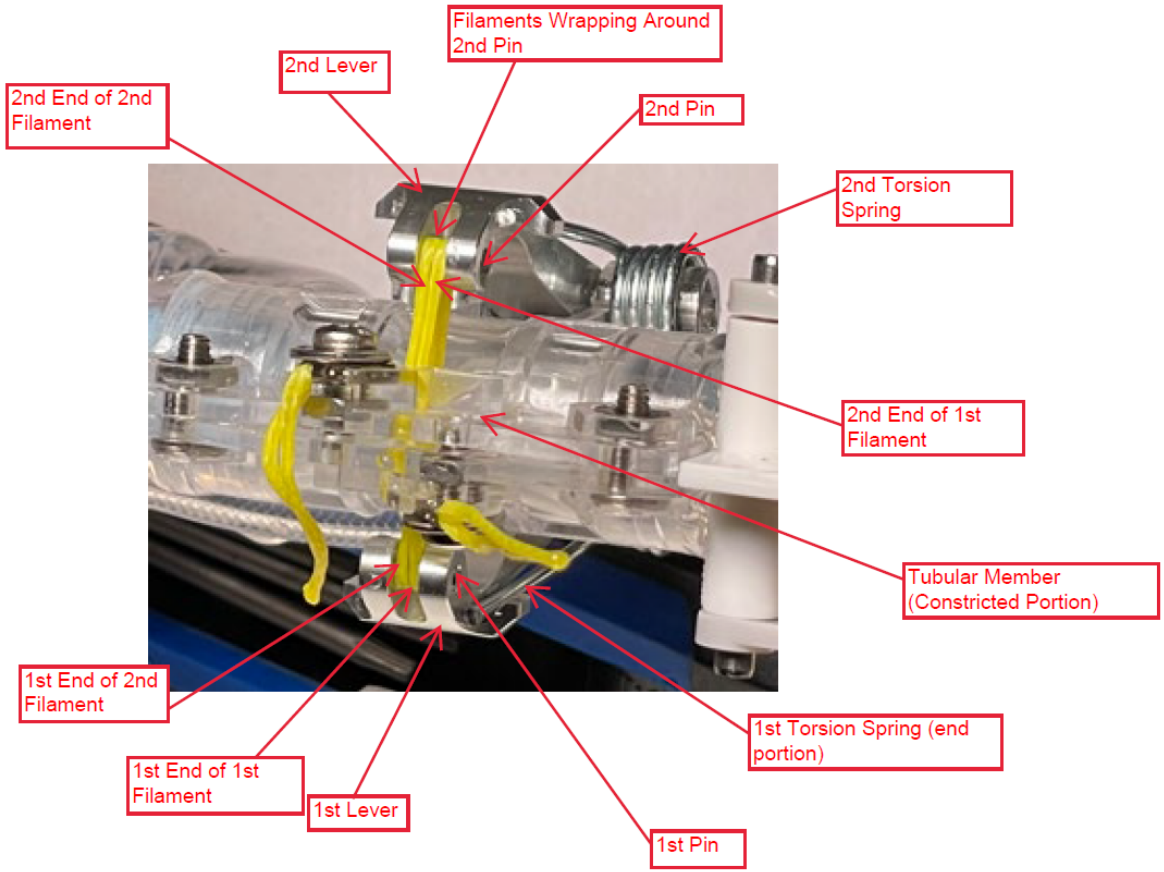
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

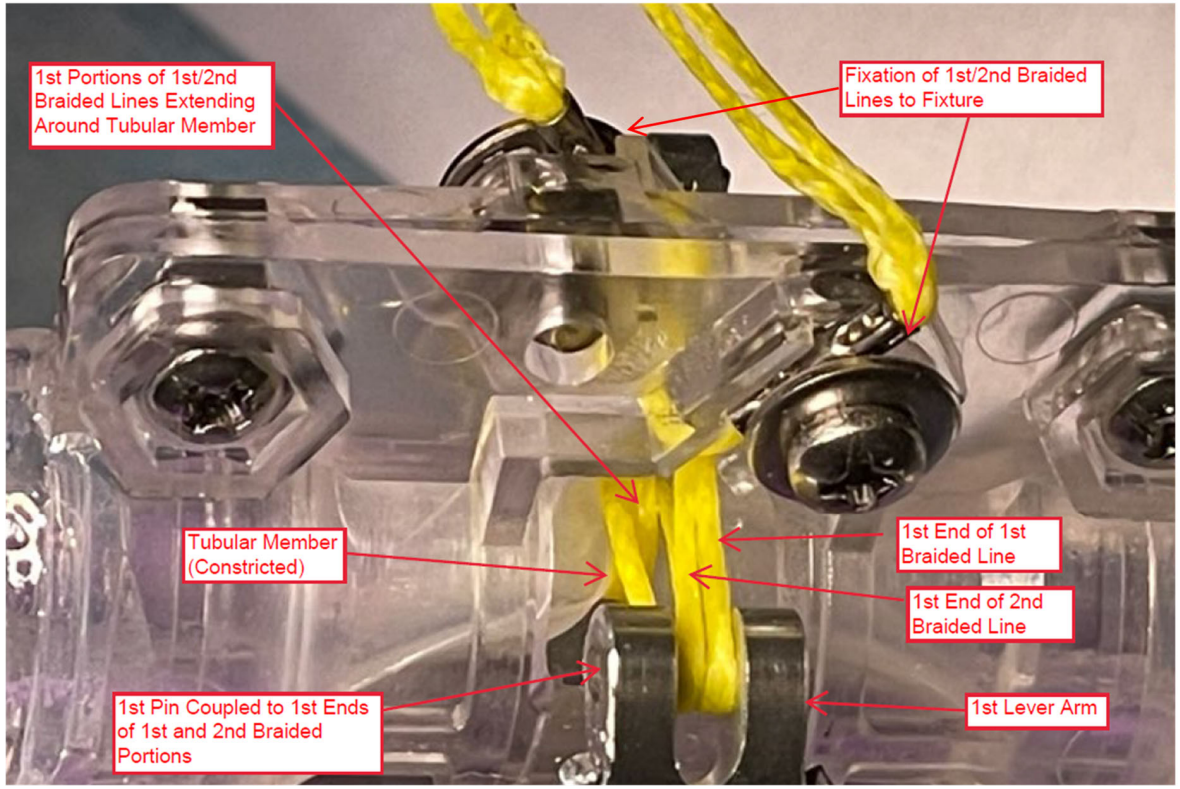
	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member.)

	 (Internal image of hemostasis valve with filaments encircling elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a pair of actuators movable from a first position to a second position, wherein—	The Symphony System hemostasis valve has a tensioning mechanism including a pair of actuators, specifically a first actuator comprising first torsion spring(s), a first button, a first lever, and a first pin, and a second actuator comprising second torsion spring(s), a second button, a second lever, and a second pin. The first actuator (e.g., the first button/lever/pin) and second actuator (e.g., the second button/lever/pin) are movable between (a) a first position (undepressed button) wherein the lumen is constricted and sealed by the torsion spring pulling the

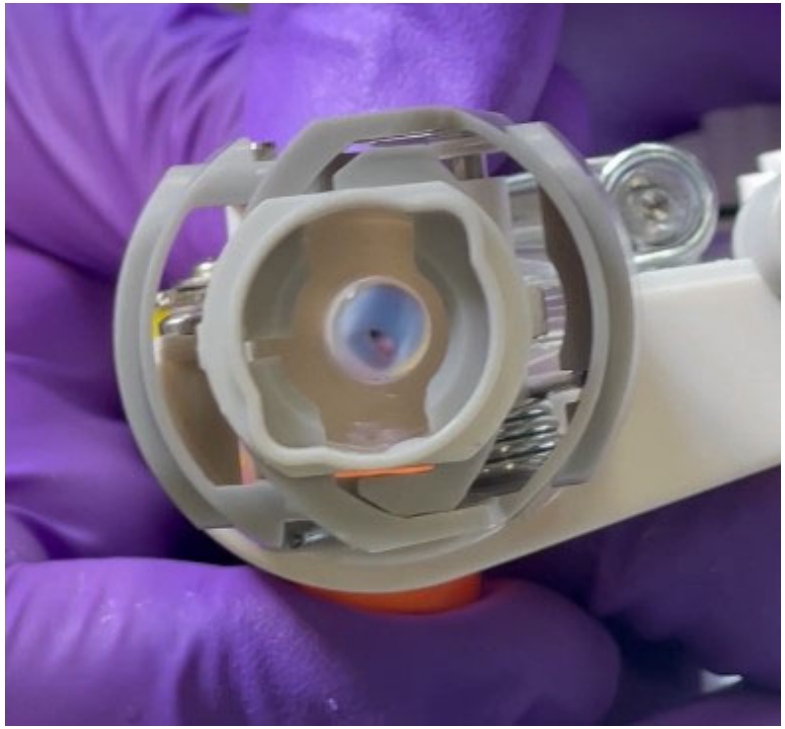
	filament to tighten the filament around the elongate member and (b) a second position (depressed button) wherein the lumen is at least partially open. (Image of internal portion of housing with hemostasis valve.)

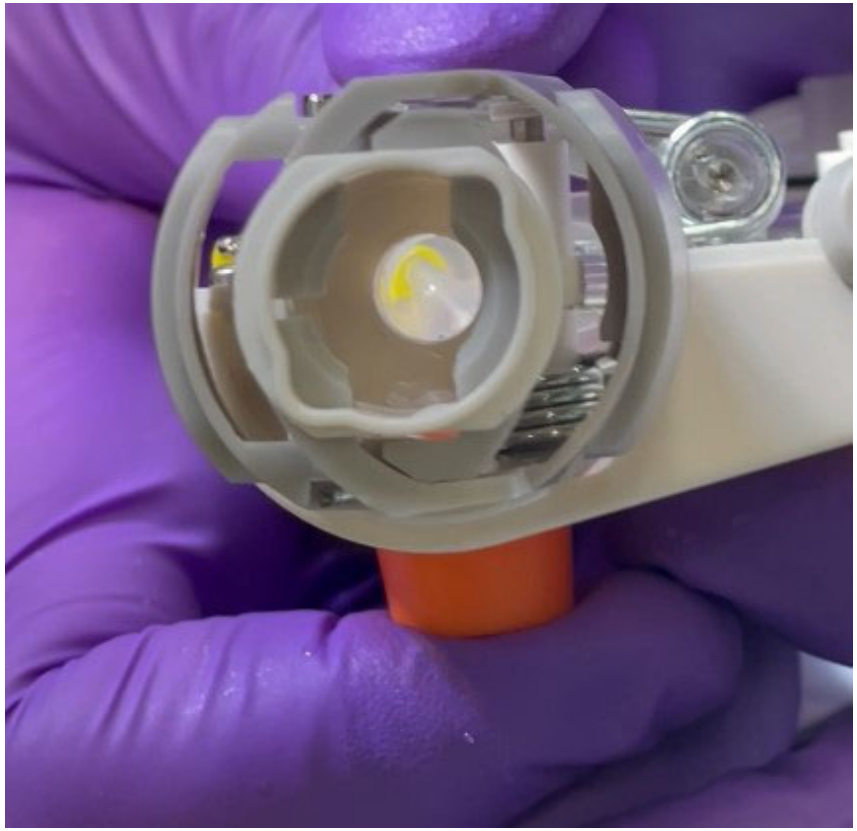


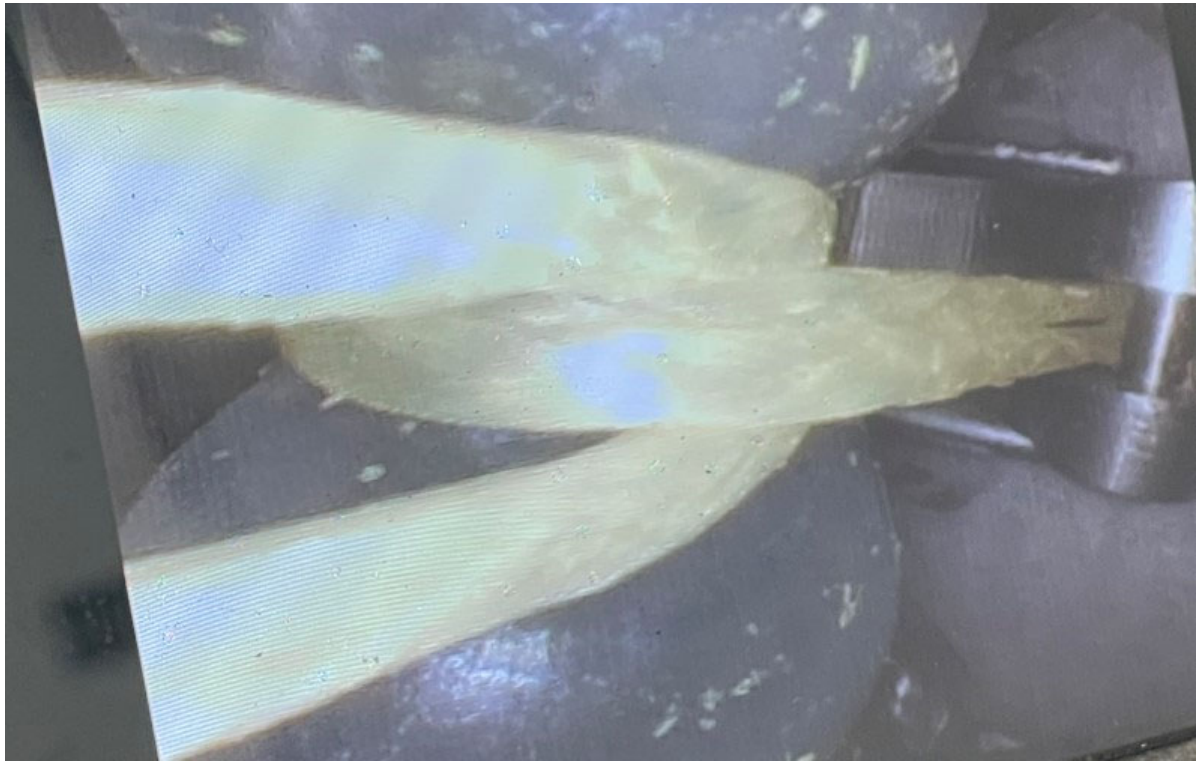
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and filaments extending around the elongate member.)

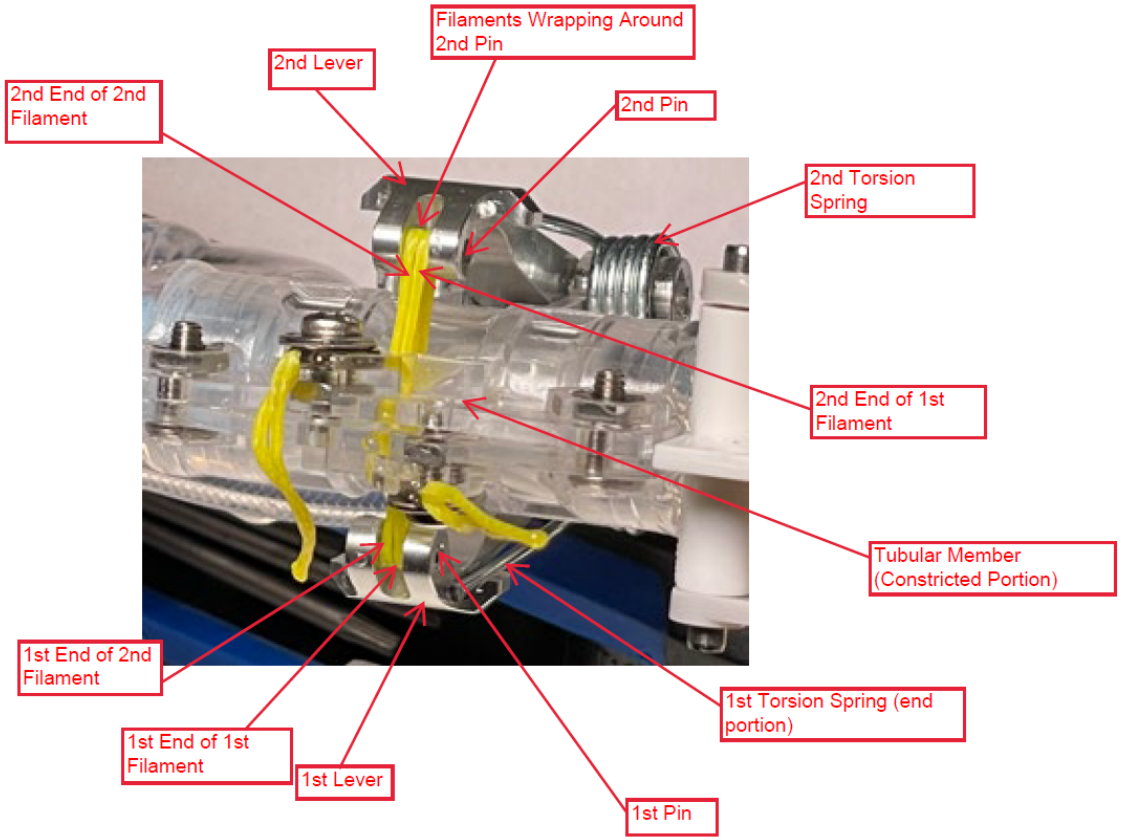


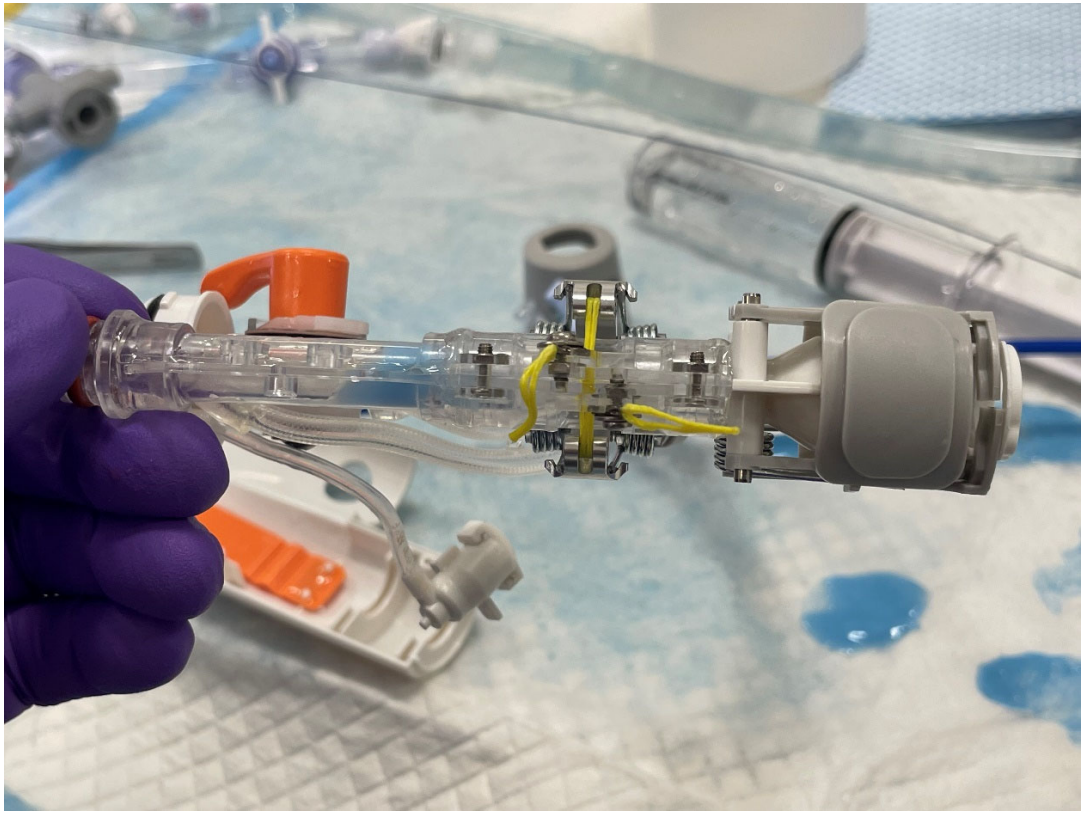
(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

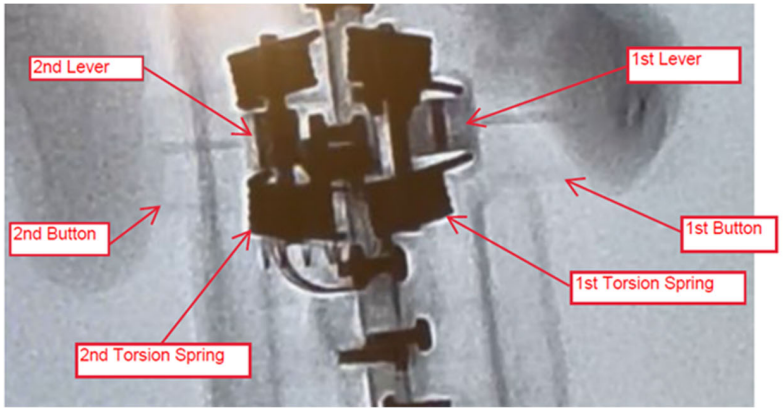
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

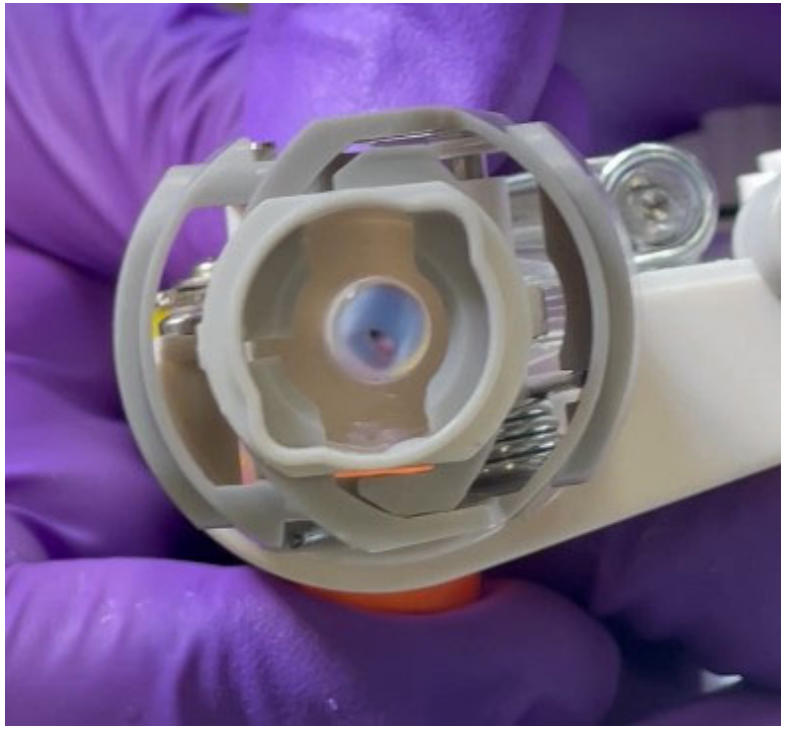
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

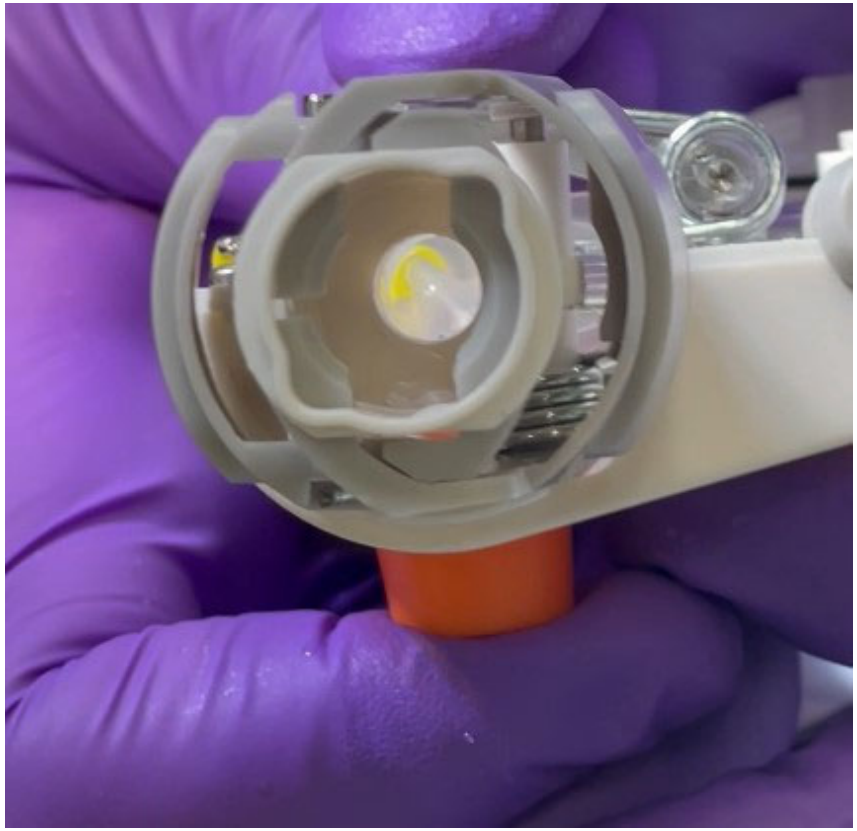
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
the first filament includes a first portion operably acted upon by a first one of the actuators and a second portion operably acted upon	The Symphony System hemostasis valve comprises a first actuator and a second actuator. The first actuator is defined by the first button/lever/pin. The second actuator has a second button, second lever, and second pin. The first actuator and second actuator are coupled to the elongate member via a first filament that extends at least partially around the elongate member. The filament extends completely in a loop around the elongate member, with the first end portion of

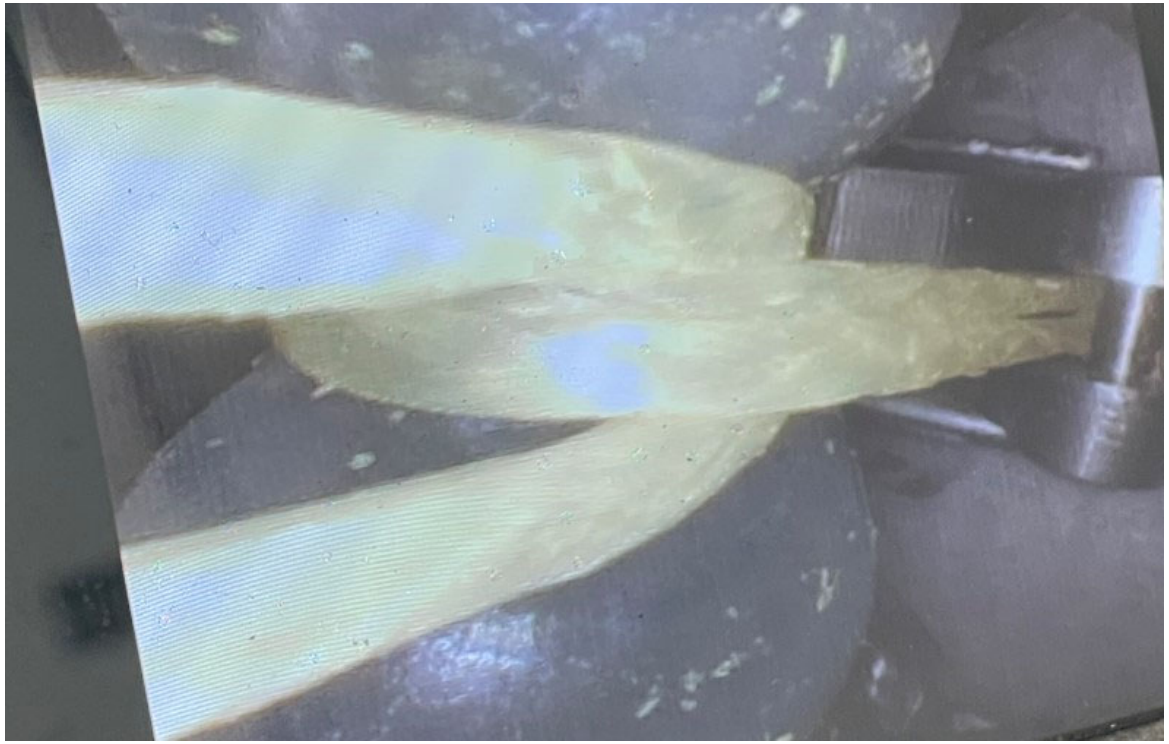
by a second one of the actuators;	the first filament coupled to and acted upon by the first actuator, and the second end portion of the first filament is coupled to and acted upon by the second actuator. The first actuator (e.g., the first button/lever/pin) and second actuator (e.g., the second button/lever/pin) are movable between (a) a first position (undepressed button) wherein the lumen is constricted and sealed by the torsion spring pulling the filament to tighten the filament around the elongate member and (b) a second position (depressed button) wherein the lumen is at least partially open.  (Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second

	filaments extending around the elongate member, with the first end of the first filament coupled to and acted on by the first actuator and the second end of the first filament coupled to and acted on by the second actuator.)  (Image of internal portion of housing with hemostasis valve.)

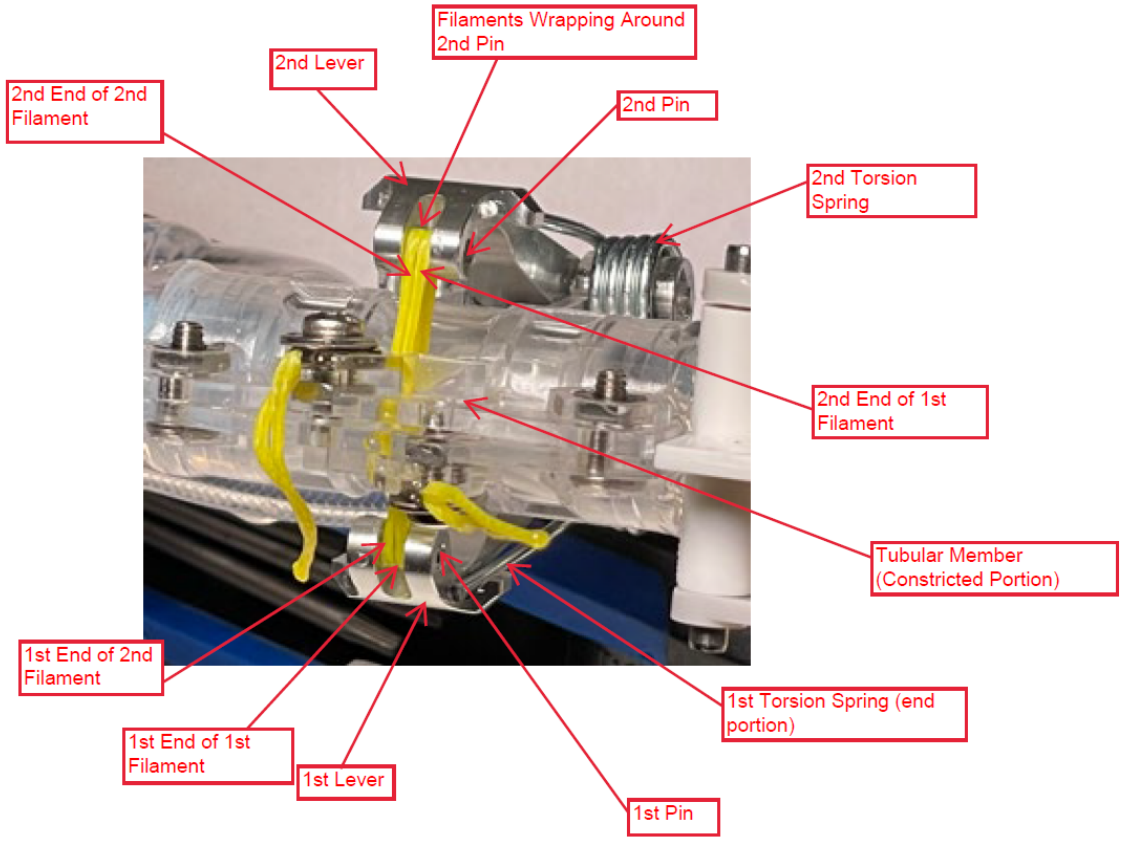
	 (X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of tensioning mechanism for hemostasis valve in Symphony System housing.)

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

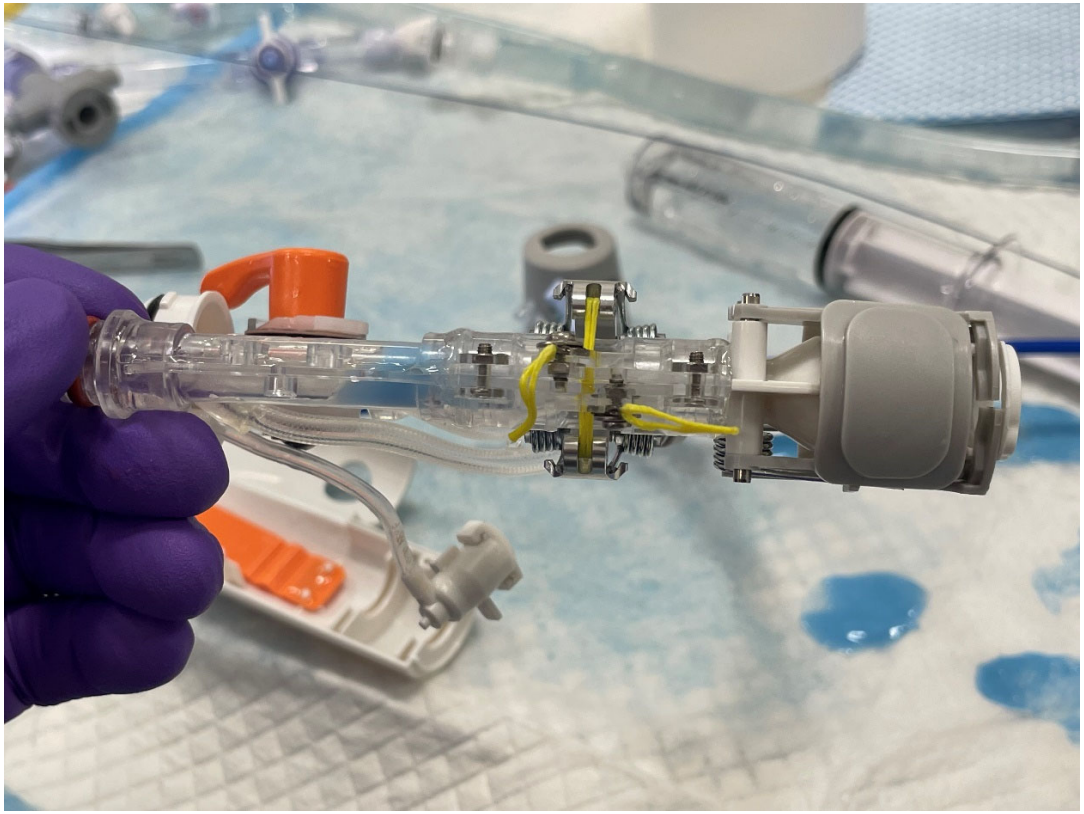
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

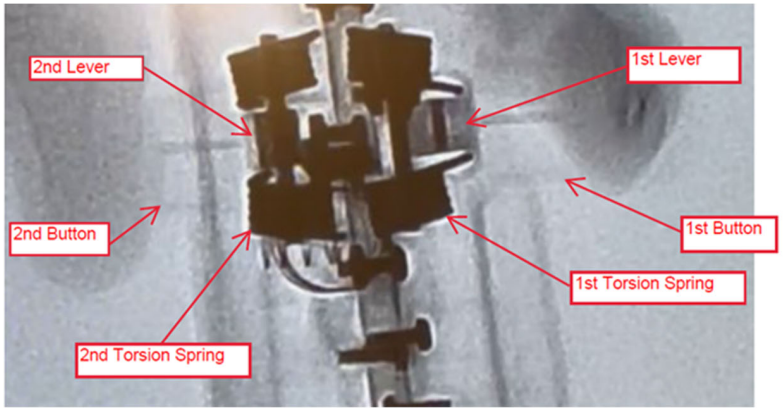
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
the second filament includes a first portion operably acted upon by the first one of the actuators and a second portion operably acted upon by the second one of the actuators;	The Symphony System hemostasis valve comprises a first actuator and a second actuator. The first actuator is defined by the first button/lever/pin. The second actuator has a second button, second lever, and second pin. The first actuator and second actuator are coupled to the elongate member via a second filament that extends at least partially around the elongate member. The second filament extends completely in a loop around the elongate member, with the first end portion of the second filament coupled to and acted upon by the first actuator, and

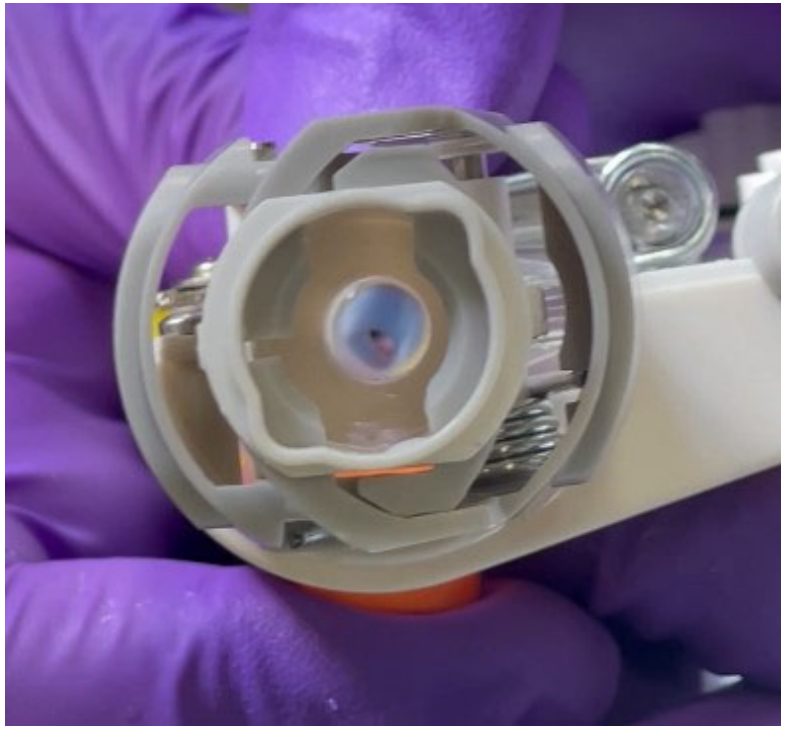
the second end portion of the second filament is coupled to and acted upon by the second actuator. The first actuator (e.g., the first button/lever/pin) and second actuator (e.g., the second button/lever/pin) are movable between (a) a first position (undepressed button) wherein the lumen is constricted and sealed by the torsion spring pulling the filament to tighten the filament around the elongate member and (b) a second position (depressed button) wherein the lumen is at least partially open.

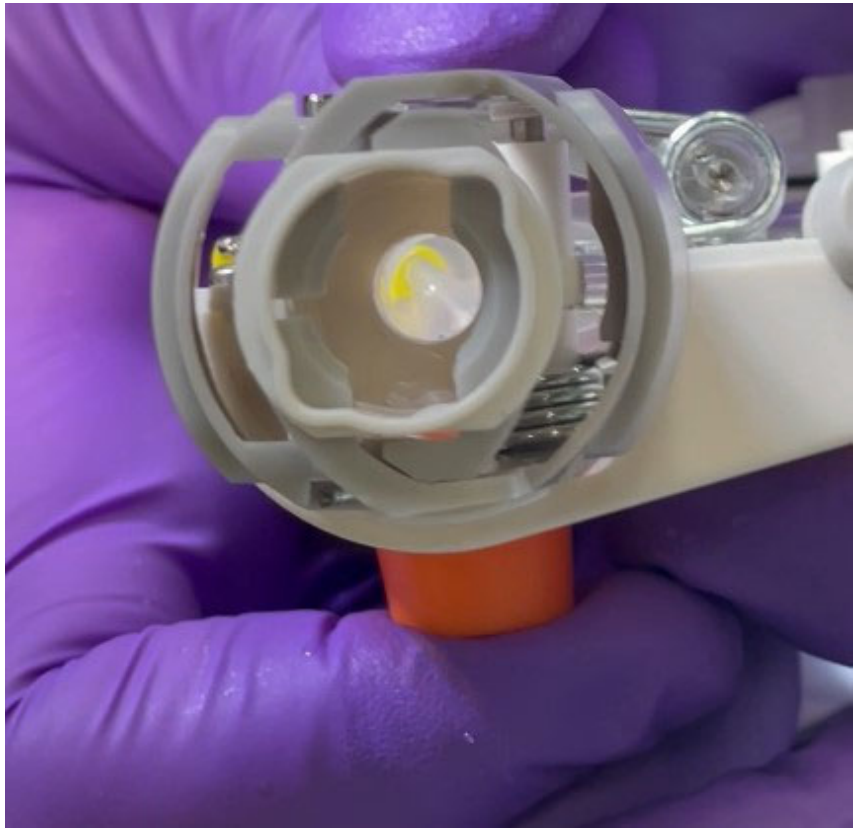


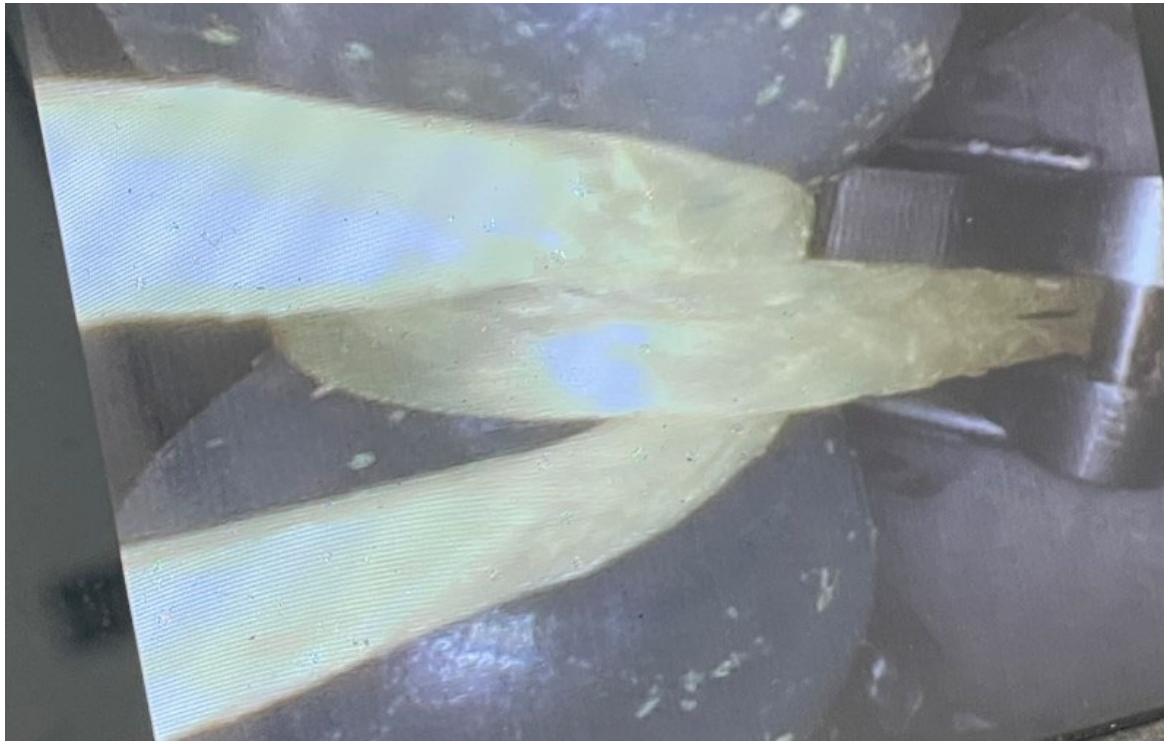
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first

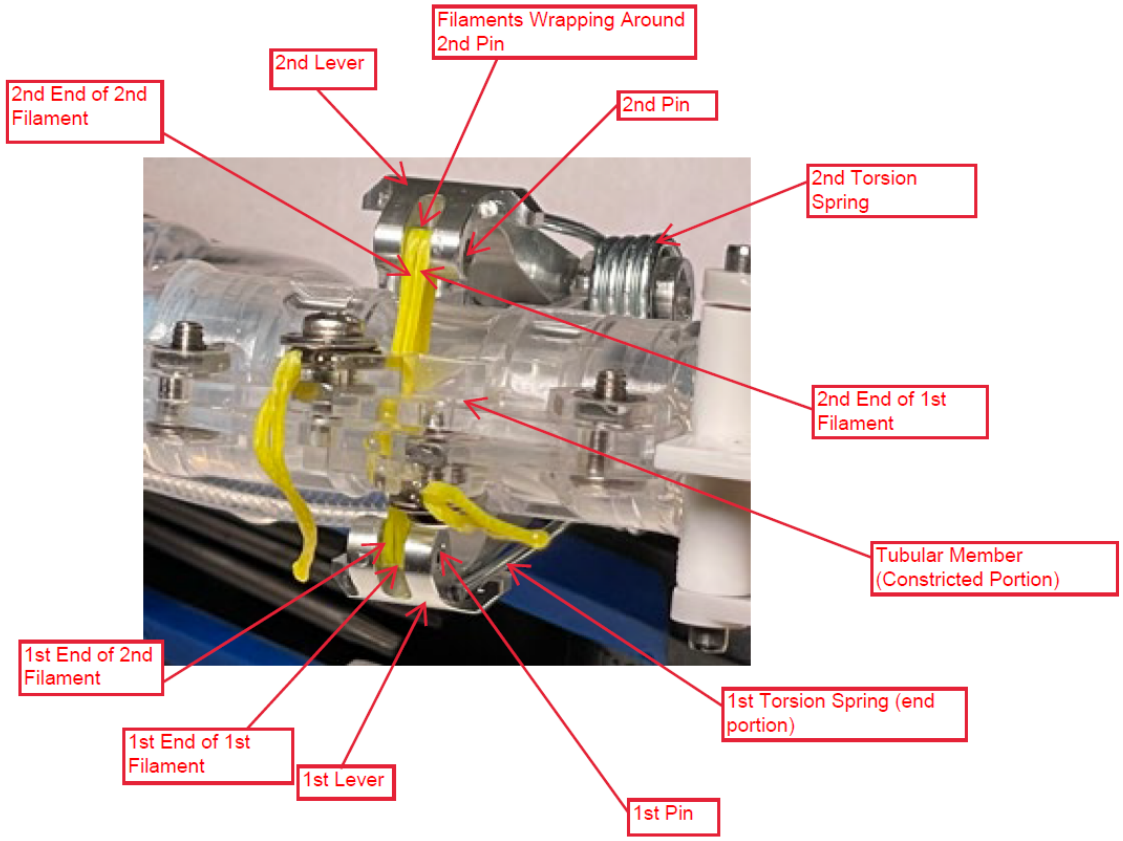
	filament coupled to and acted on by the first actuator and the second end of the first filament coupled to and acted on by the second actuator.)  (Image of internal portion of housing with hemostasis valve.)

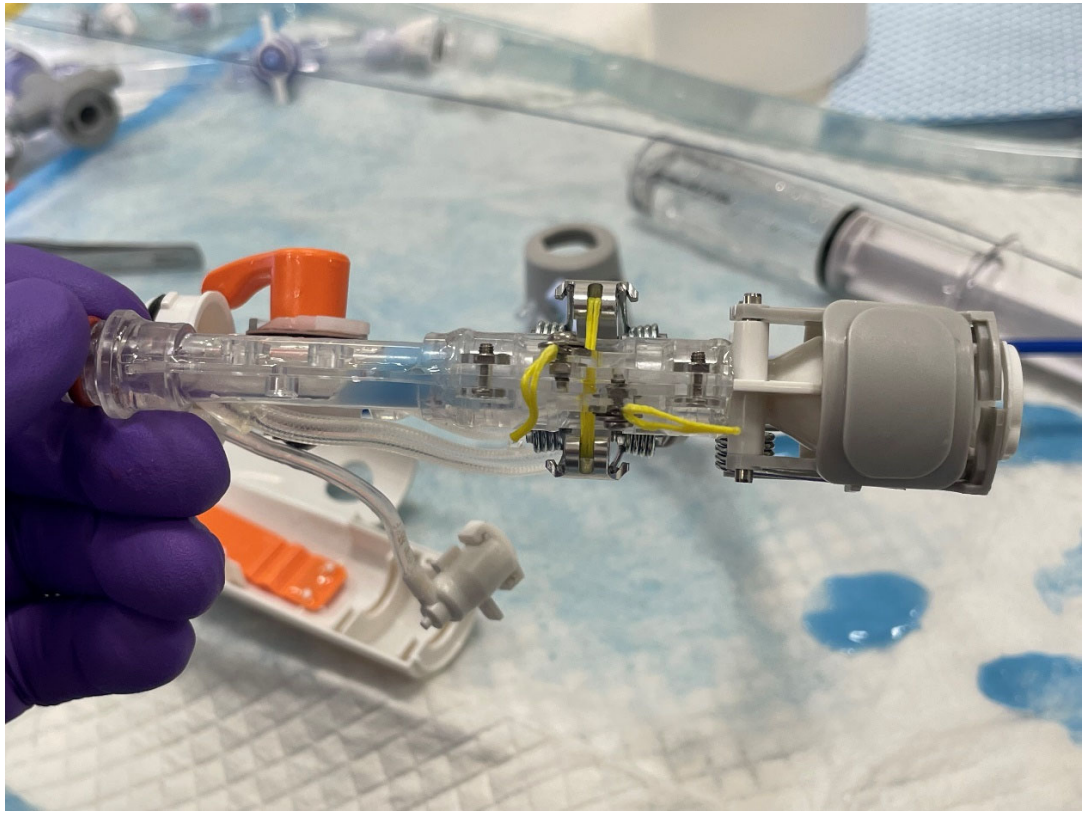
	 (X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of tensioning mechanism for hemostasis valve in Symphony System housing.)

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

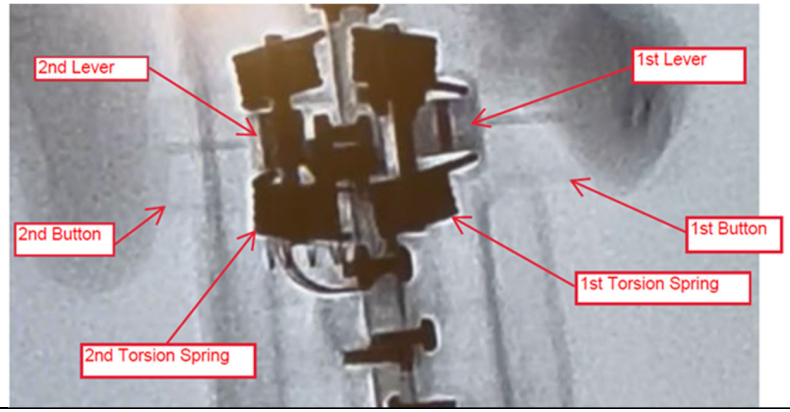
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

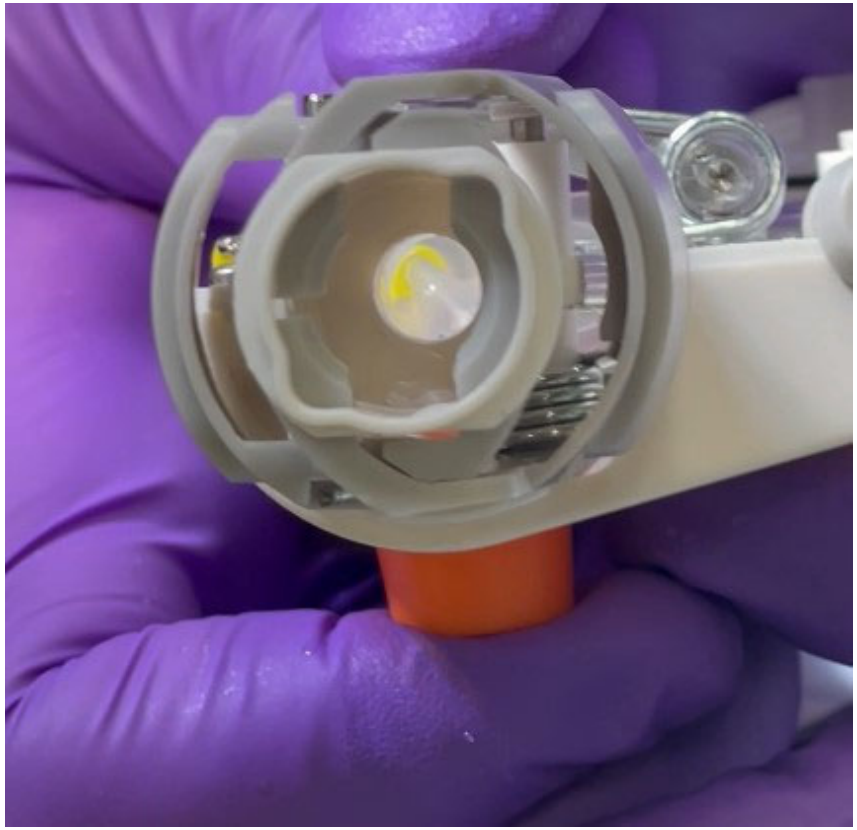
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
in the first position, the actuators are positioned to tension the first filament and the second filament thereby decreasing a dimension of the first loop and a dimension of the second loop to constrict	The Symphony System comprises a hemostasis valve in which, when the actuators are in the first position (constricted, buttons undepressed), the actuators are positioned to tension the first filament and the second filament, decreasing the dimension of first loop (in the first filament) and the dimension of the second loop (of the second filament) to constrict the lumen of the elongate tubular member, and constrict the valve.

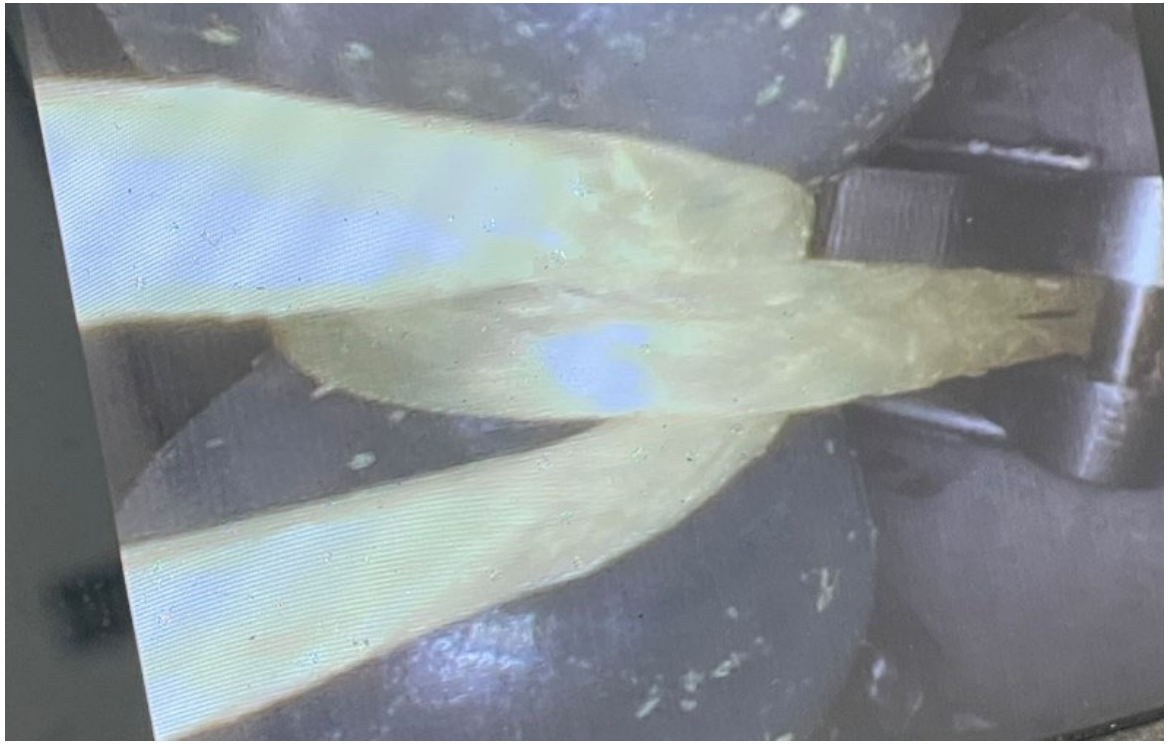
the lumen of the tubular member;	 (Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first filament coupled to and acted on by the first actuator and the second end of the first filament coupled to and acted on by the second actuator.)

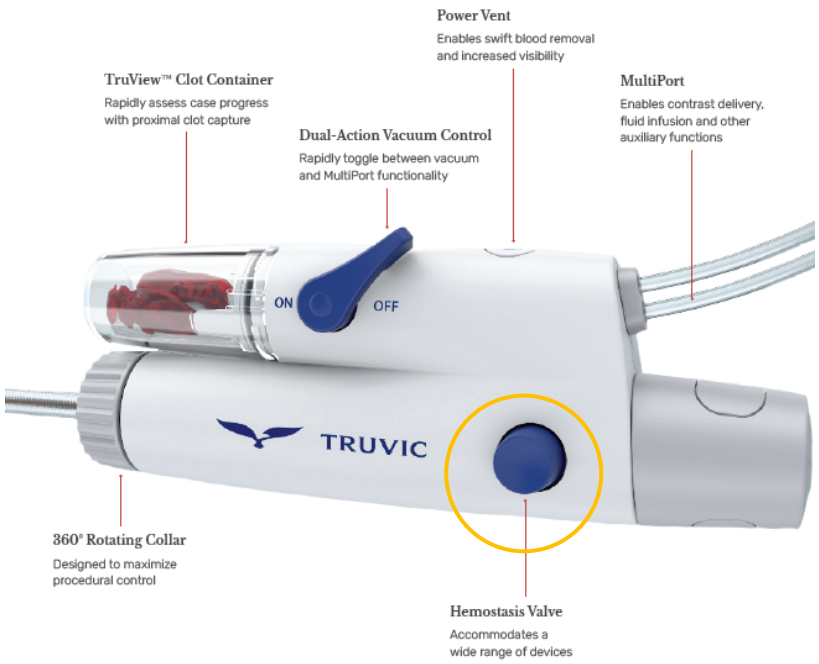


(Image of internal portion of housing with hemostasis valve.)

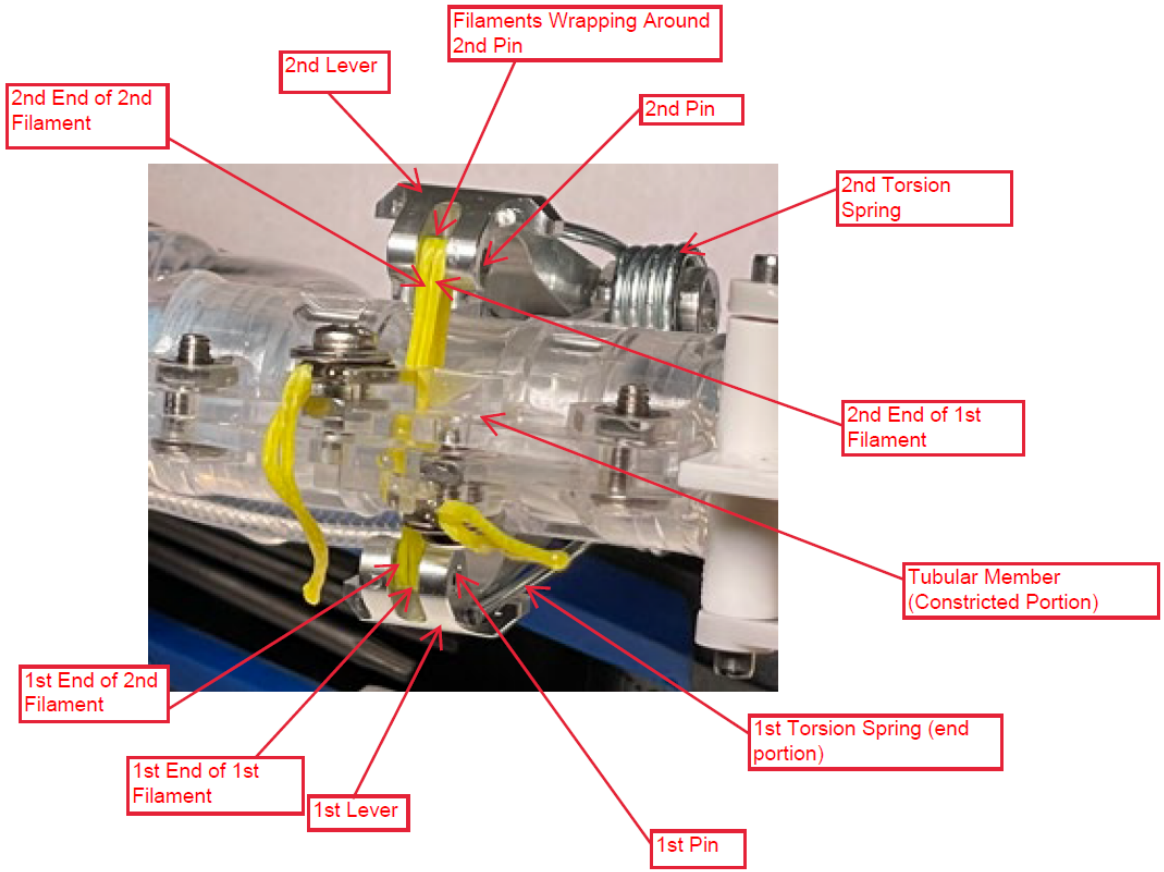


	(X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of tensioning mechanism for hemostasis valve in Symphony System housing.)  (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

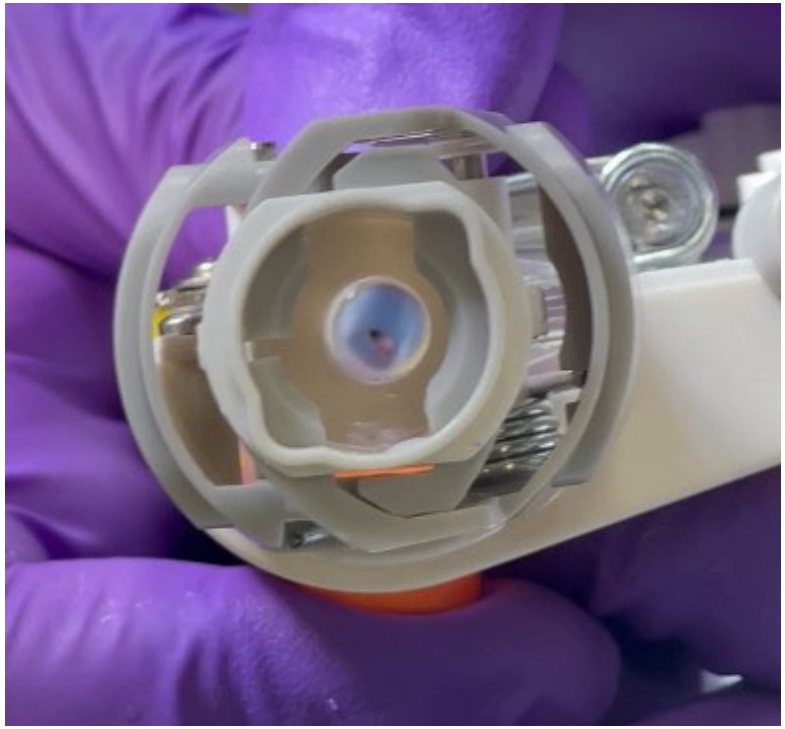
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
in the second position, the actuators are positioned to loosen the first filament and the second filament thereby permitting the tubular member to expand against the first loop and the second loop	The Symphony System comprises a hemostasis valve in which, when the actuators are in the second position (at least partially open, buttons depressed), the actuators are positioned to loosen the first filament and the second filament, thereby permitting the tubular member to expand against the first loop and the second loop, and increase to increase the dimension of first loop (in the first

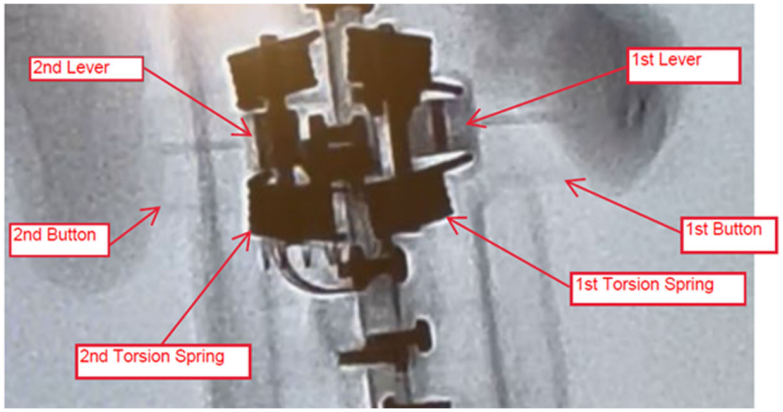
to increase the dimension of the first loop and the dimension of the second loop to at least partially open the lumen of the tubular member; and	filament) and the dimension of the second loop (of the second filament) to at least partially open the lumen of the tubular member. **High-Powered, Continuous Vacuum with Real-Time Case Assessment** **BigShot™ Controller**  (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

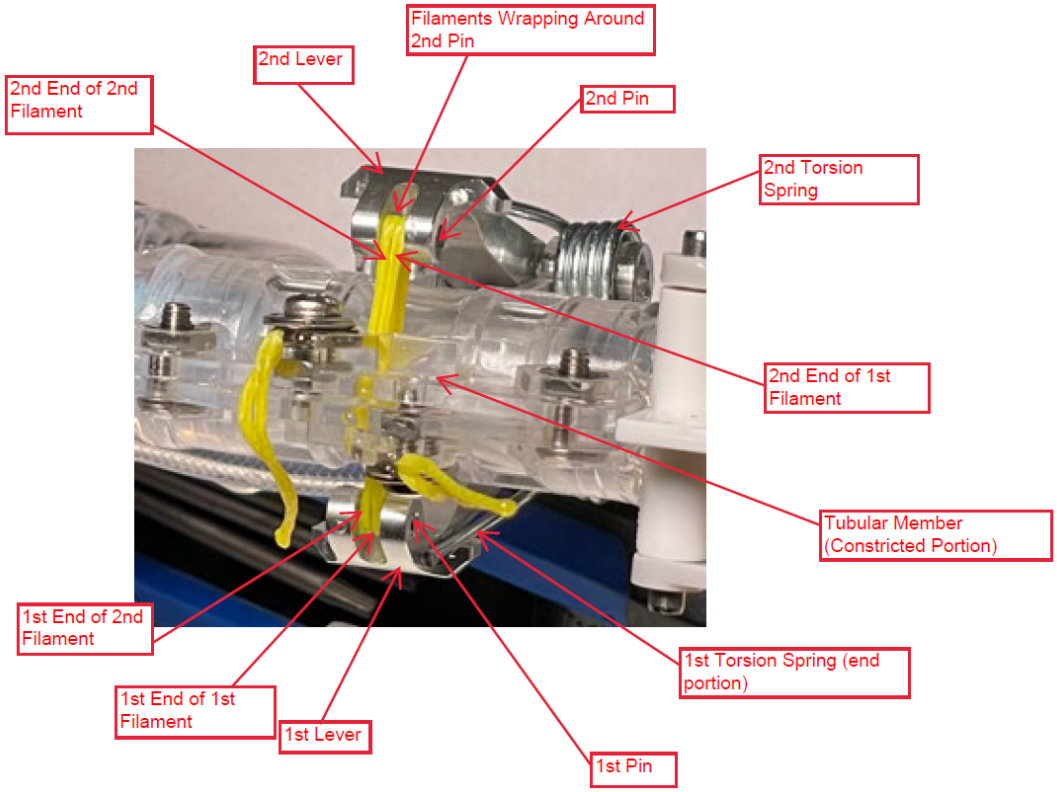
	 (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)



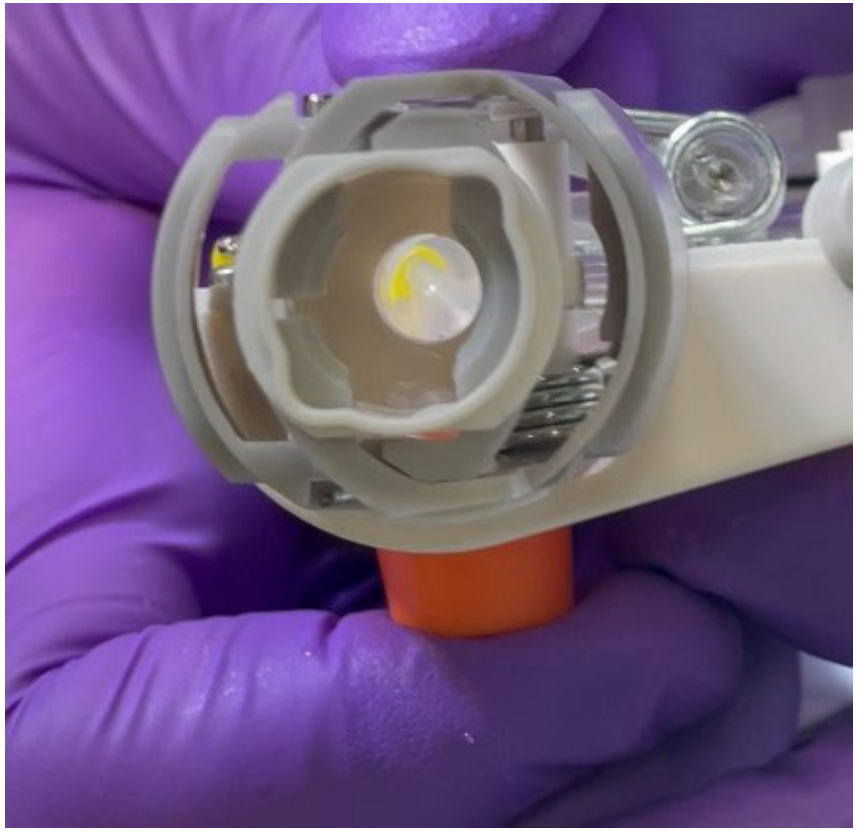
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)

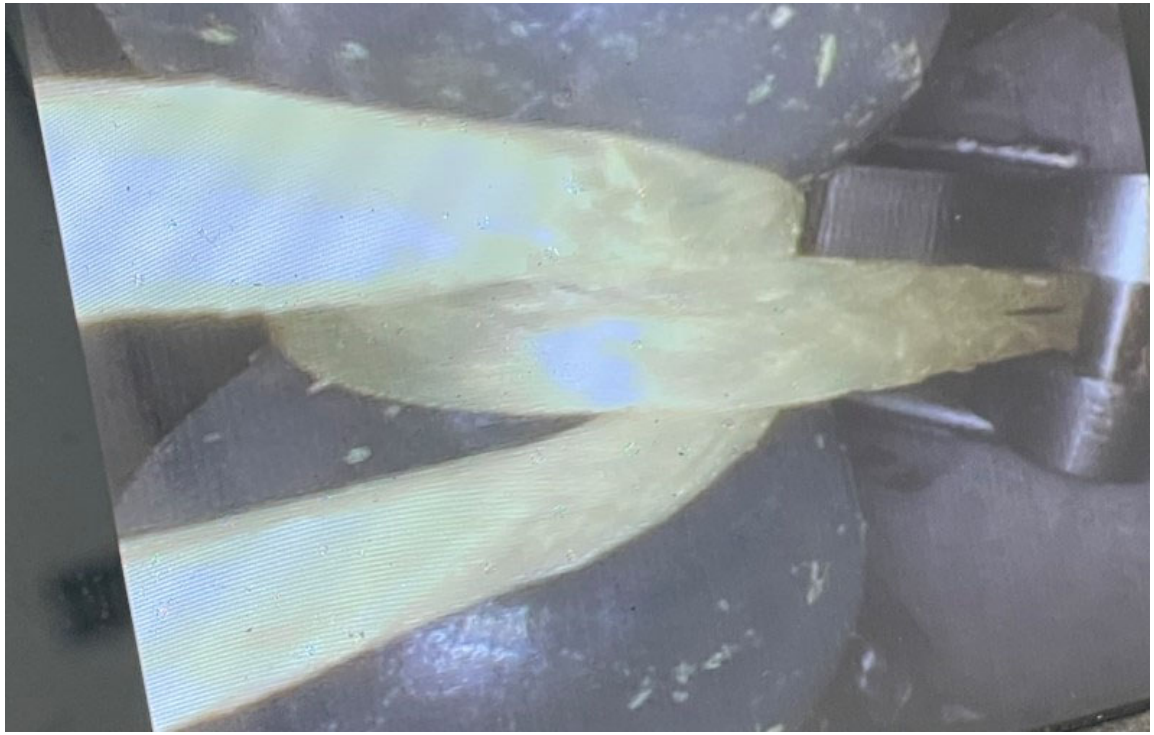
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
the actuators are biased to the first position.	The Symphony System comprises a hemostasis valve that has at least a first torsion spring(s) and a second torsion spring(s) (there are two for each lever) that biases the actuator(s) to the first position, pushing outward against the first lever, first pin, and first button, and the second lever, second pin and second button such that the actuators are in the first (constricted position) with the

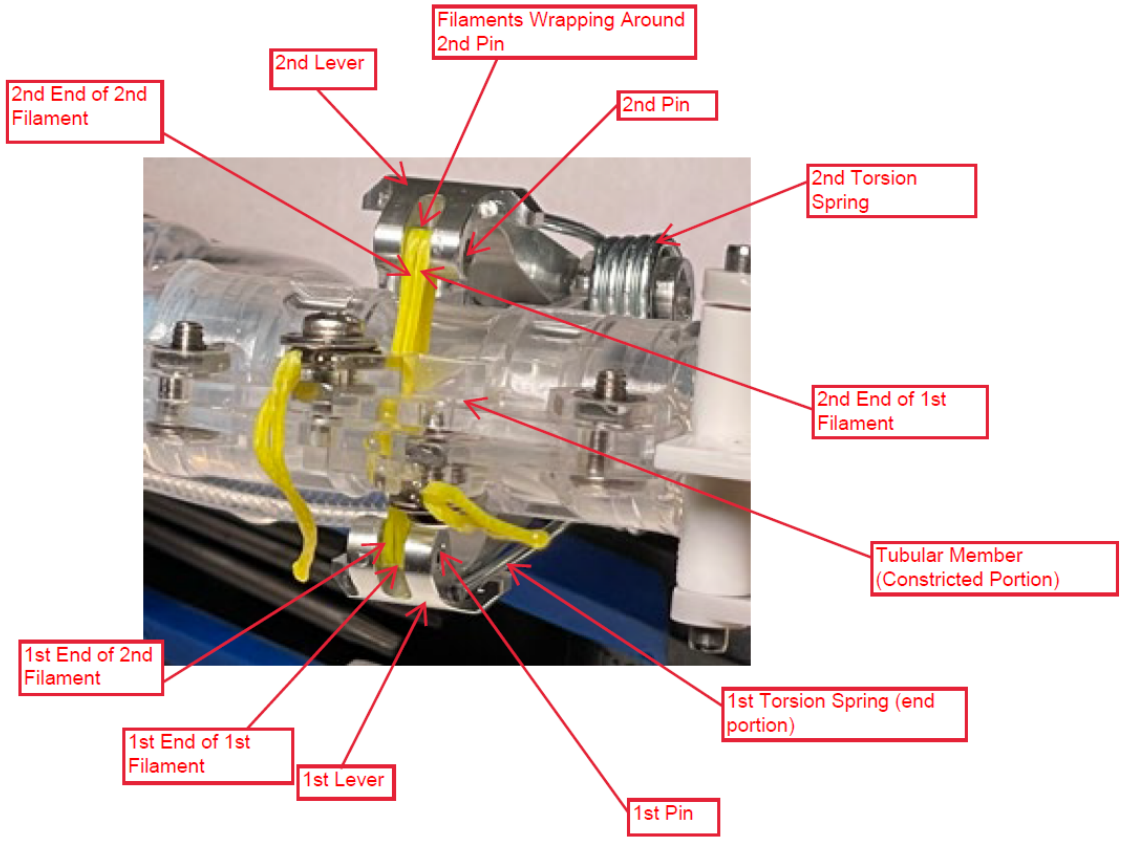
	buttons not depressed until the user presses the buttons and depresses the springs to move the actuators to the second position.  (X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of tensioning mechanism for hemostasis valve in Symphony System housing.)



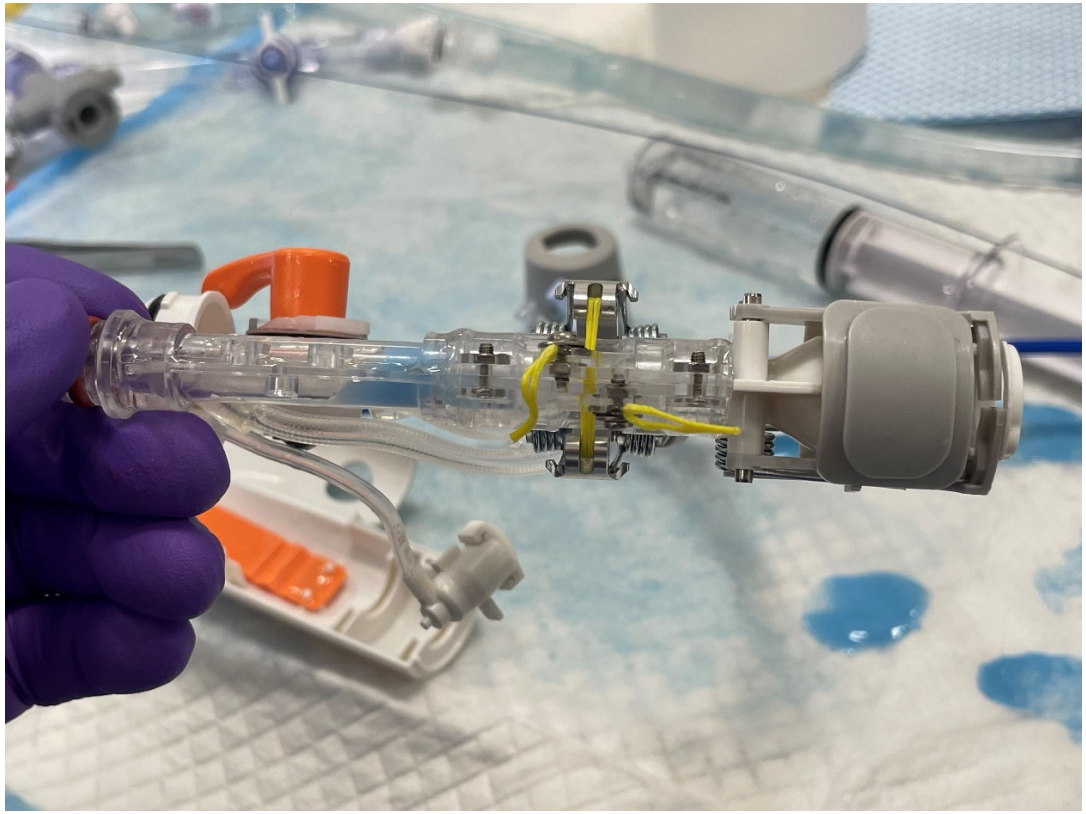
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member.)

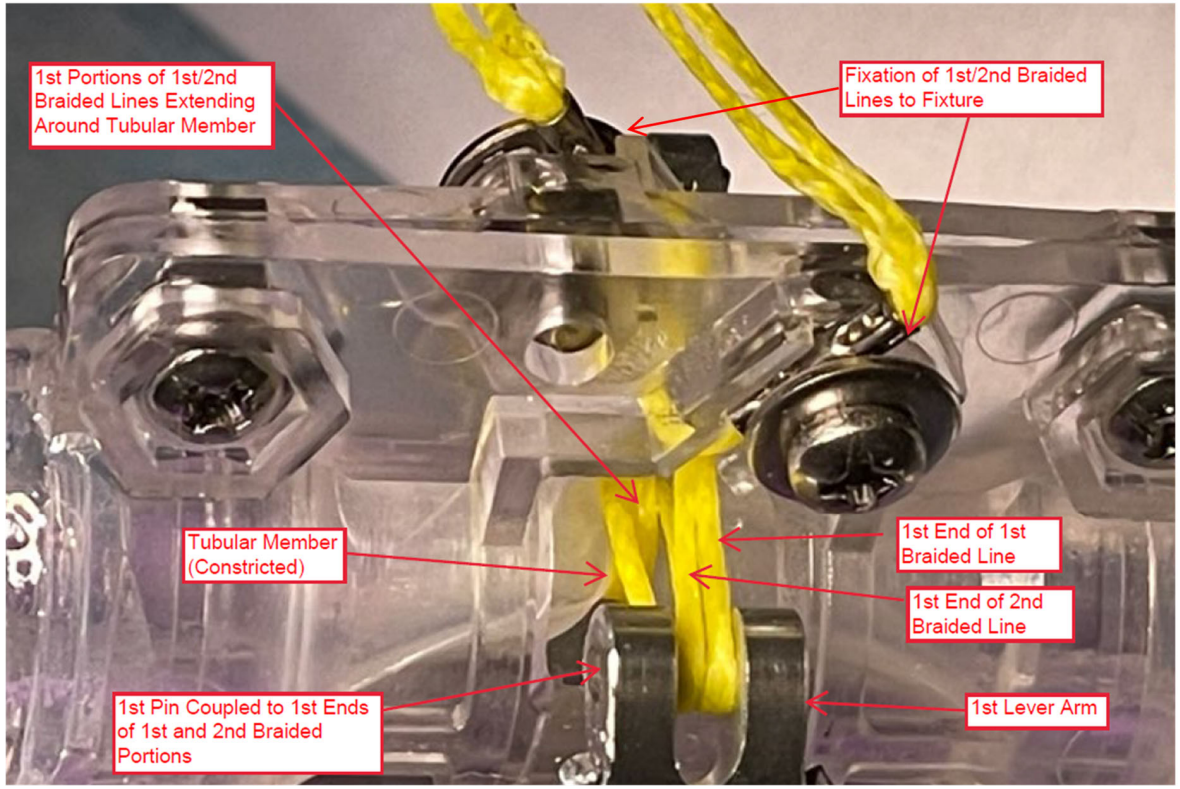
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[2] The valve assembly of claim 1 wherein the first loop extends completely around the tubular member, and wherein the second loop extends completely around the tubular member.	As can be seen above in the figures and photos with Claim 1, the Symphony System hemostasis valve has a first loop (in the first filament) and the second loop (in the second filament) that extend completely around the tubular (elongate) member.

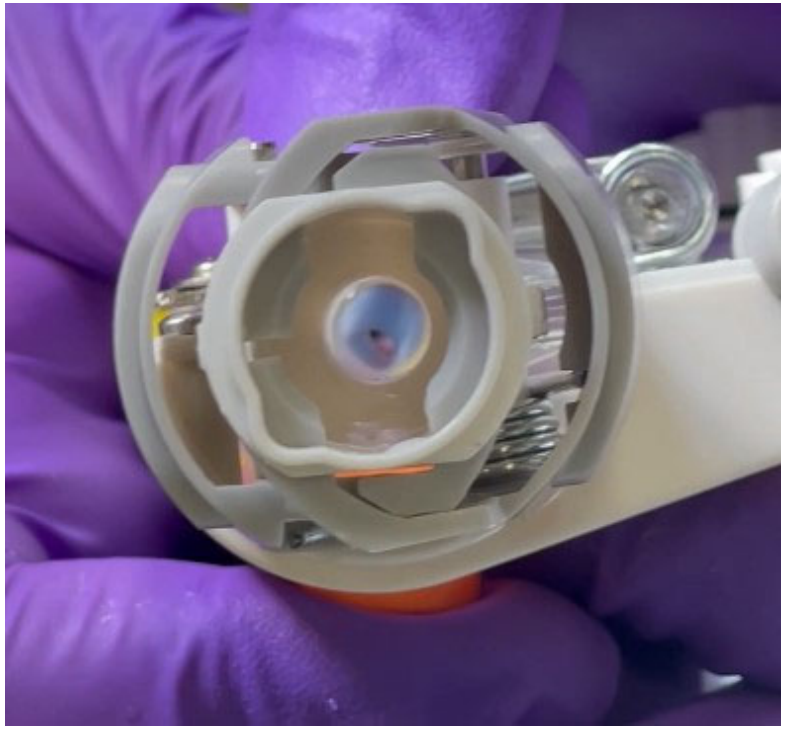


(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first filament coupled to and acted on by the first actuator and the second end of the first filament coupled to and acted on by the second actuator.)

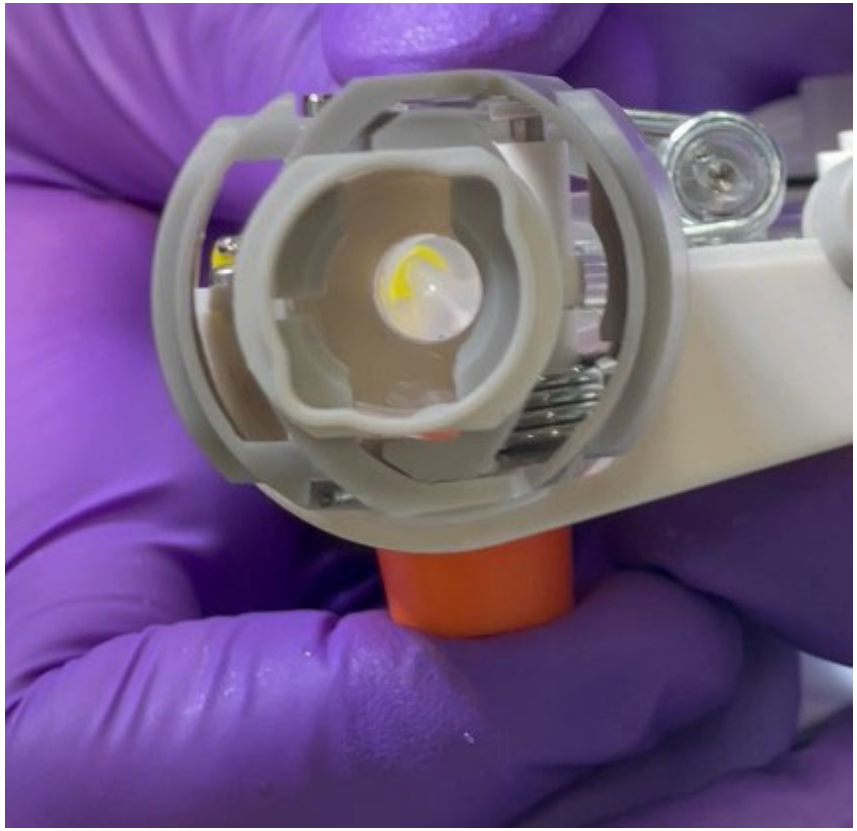
	 (Image of internal portion of housing with hemostasis valve.)

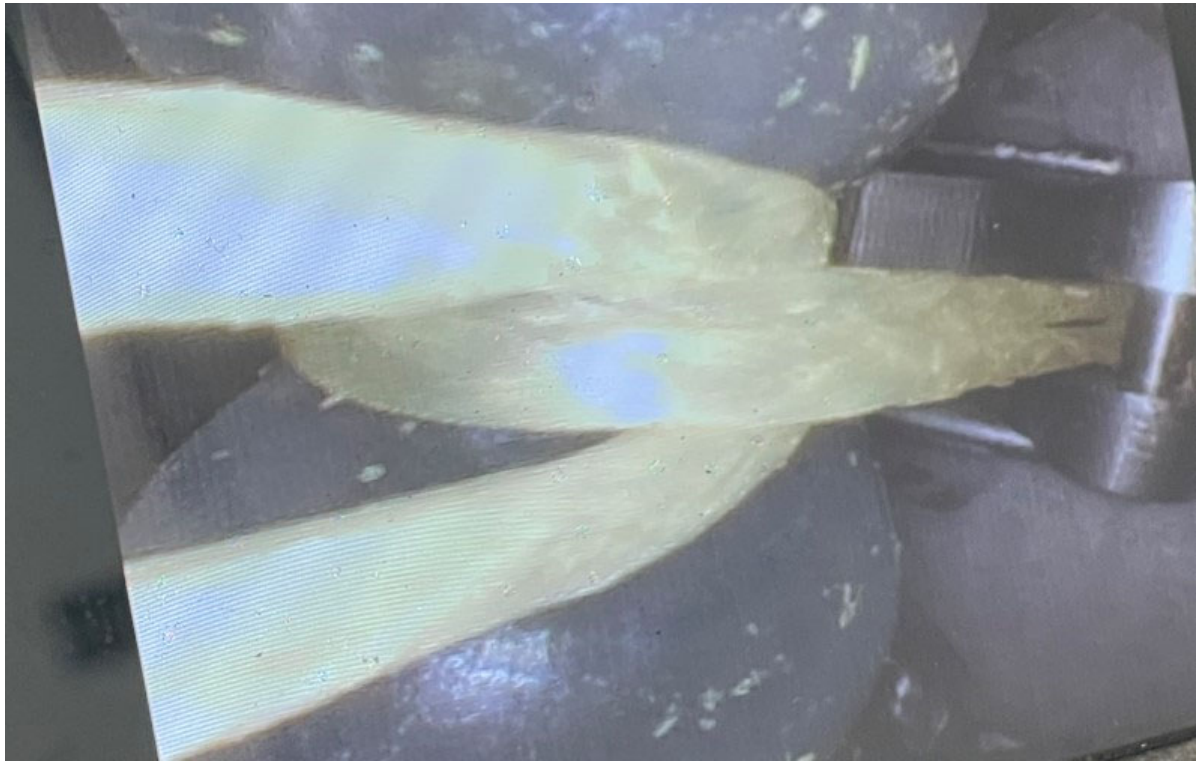


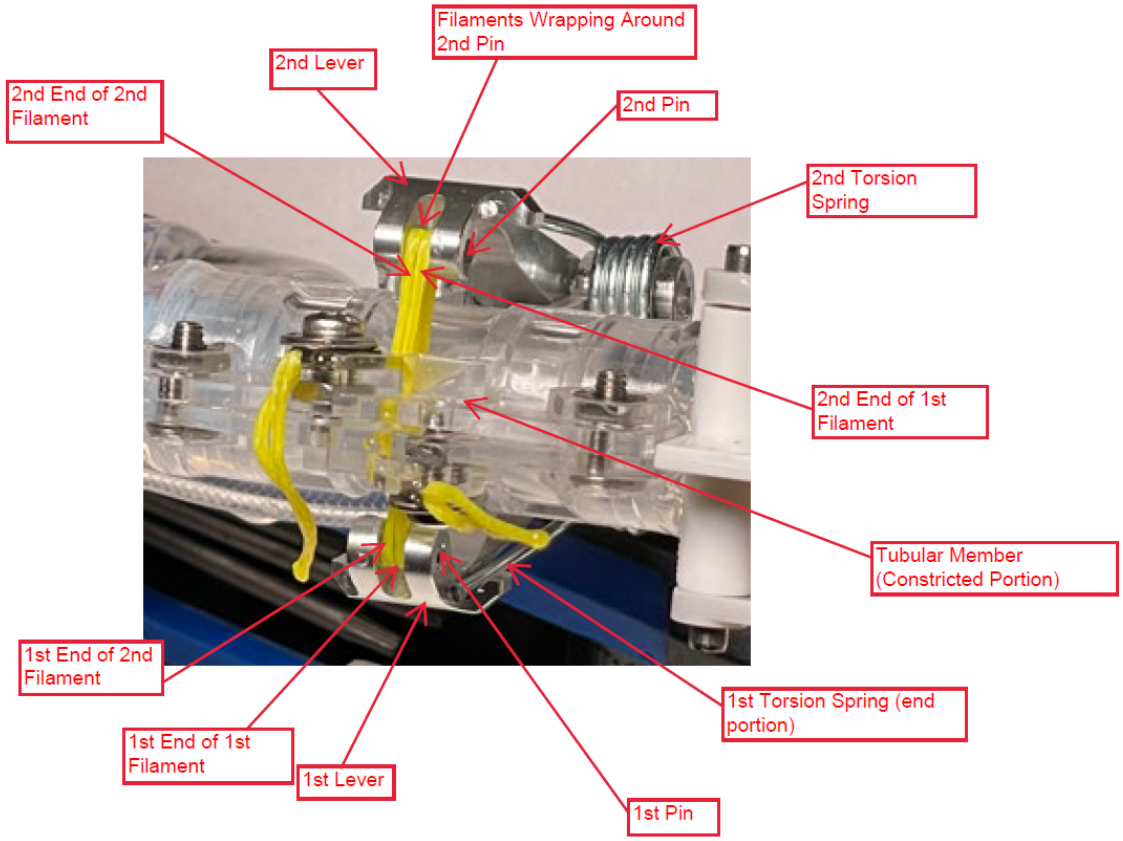
(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

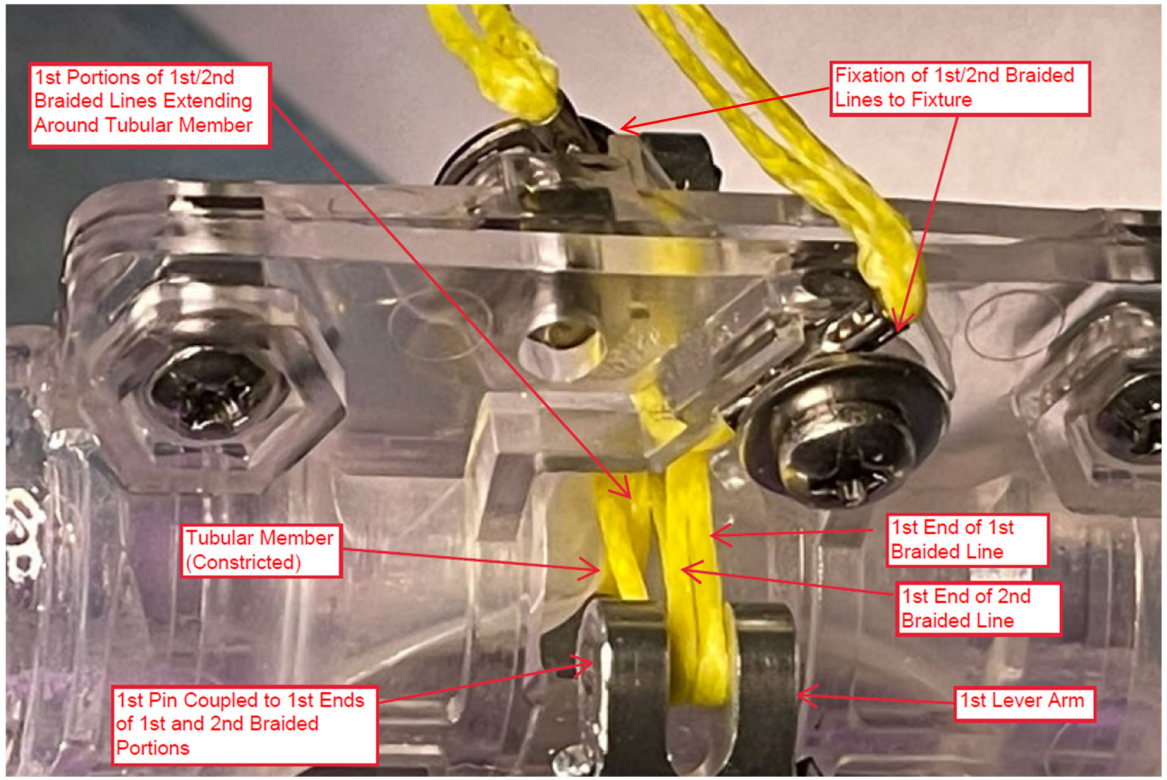
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

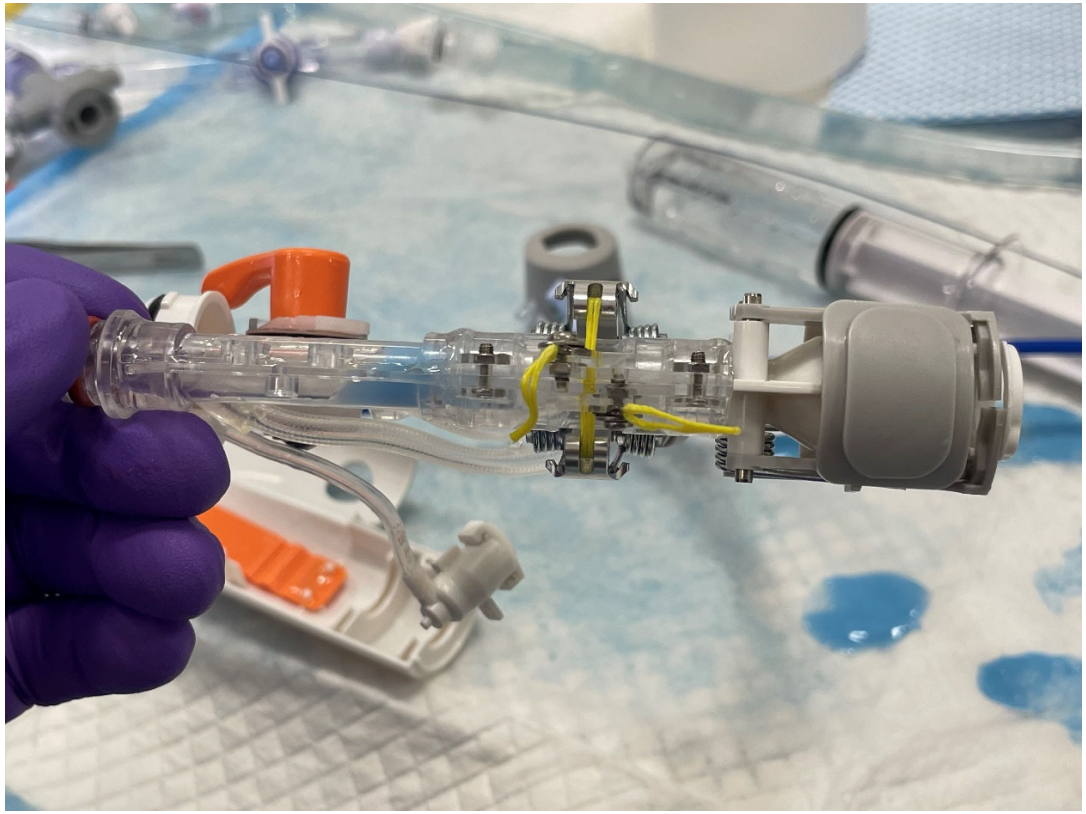
	 (Internal image of hemostasis valve with filaments encircling elongate member.)

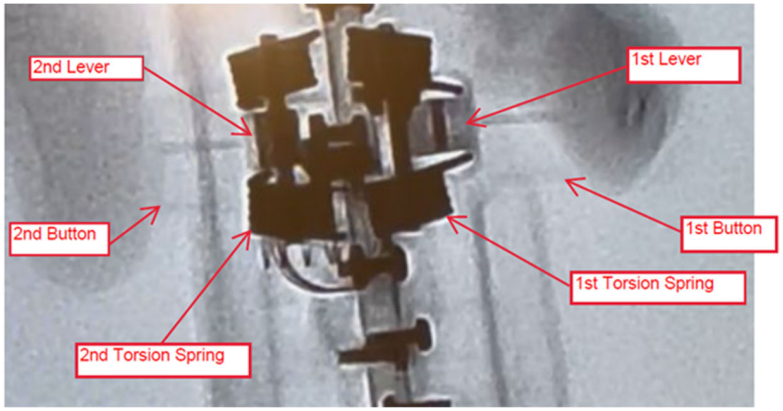
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

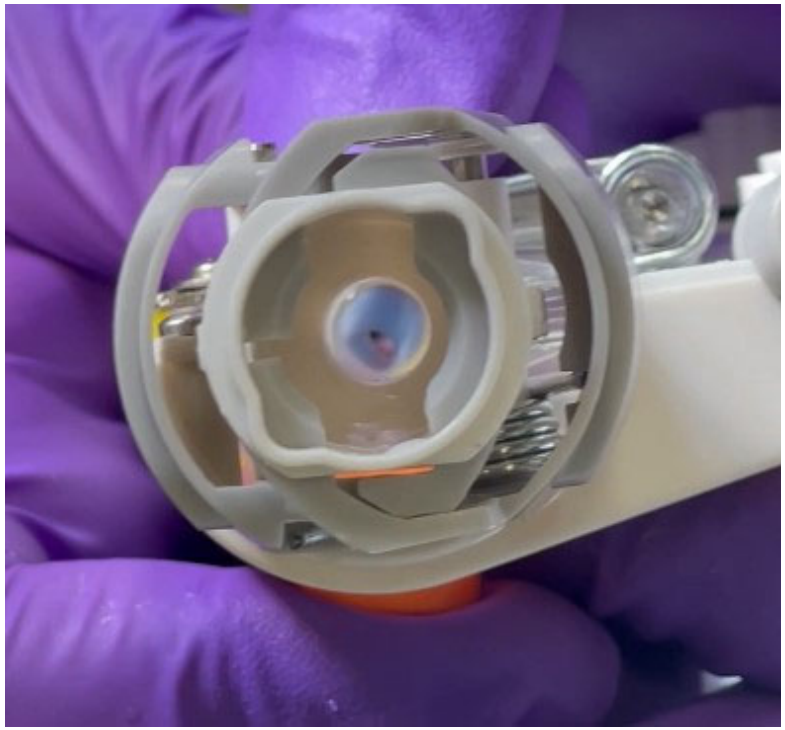
	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[3] The valve assembly of claim 1 wherein the first portion of the first filament is a first end portion of the first filament, wherein the second portion of the first filament is	As can be seen above in the figures and photos with Claim 1, the Symphony System hemostasis valve comprises a first actuator and a second actuator and a first filament and second filament that each have first end portions acted on by the first actuator and second end portions acted on by the second actuator. The first actuator is defined by the first button/lever/pin. The second actuator has a second button, second lever, and second pin. The first actuator and second

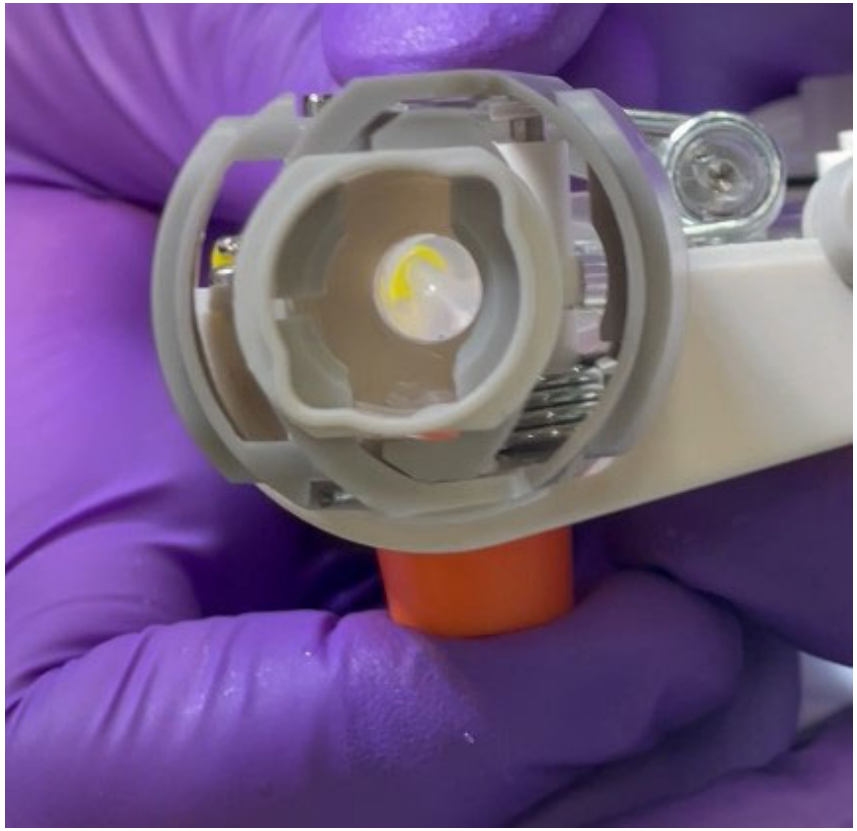
a second end portion of the first filament, wherein the first portion of the second filament is a first end portion of the second filament, and wherein the second portion of the second filament is a second end portion of the second filament.	actuator are coupled to the elongate member via first filament second filaments that extend at least partially around the elongate member. The first filament and second filament extend completely in a loop around the elongate member, with the first end portion of first filament and the first end portion of the second filament coupled to and acted upon by the first actuator, and the second end portion of the first filament and the second end portion of the second filament coupled to and acted upon by the second actuator.  (Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first

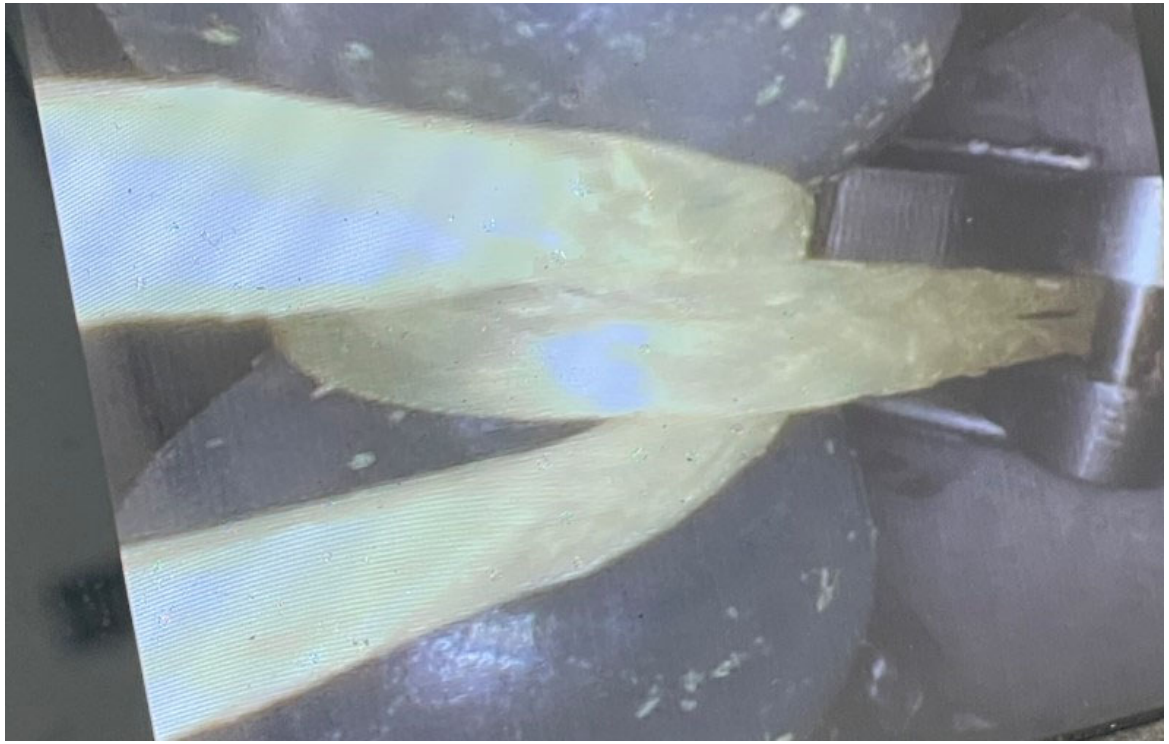
	filament and a first end of the second filament coupled to and acted on by the first actuator and the second end of the first filament and the second end of the second filament coupled to and acted on by the second actuator.)  (Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

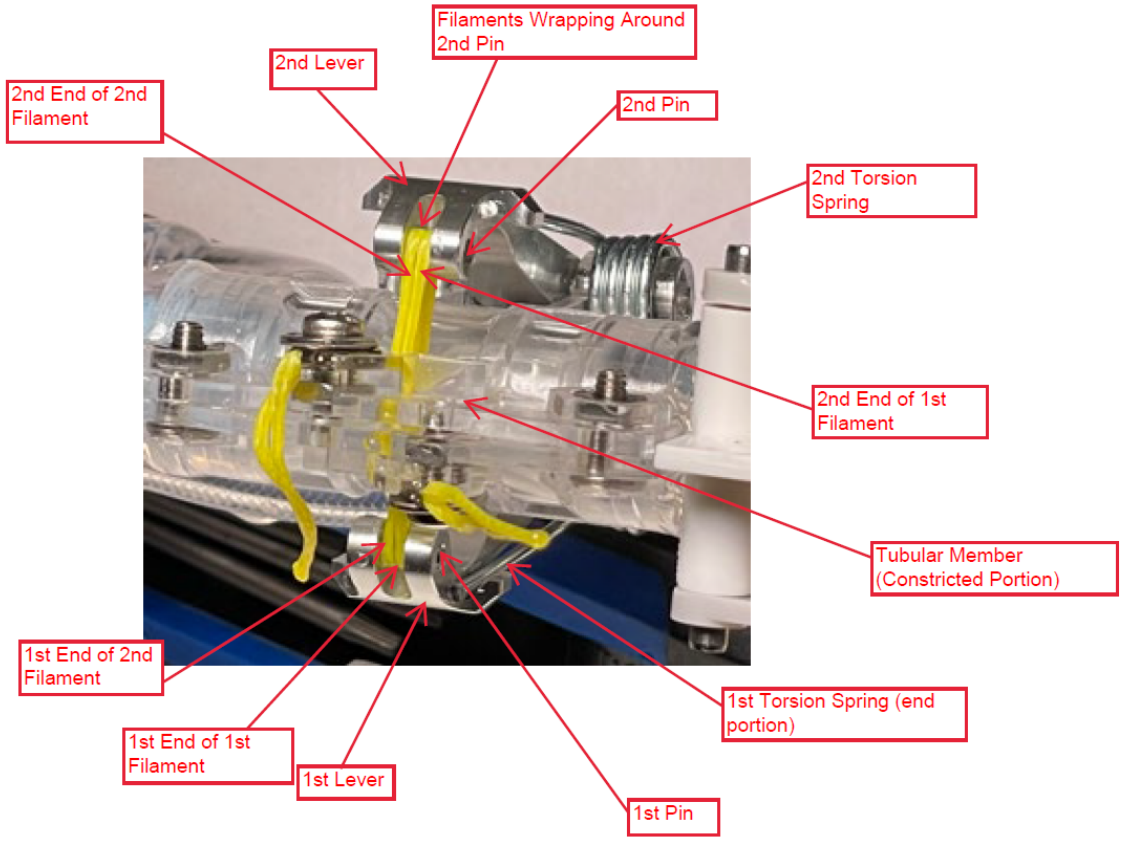
	 (Image of internal portion of housing with hemostasis valve.)

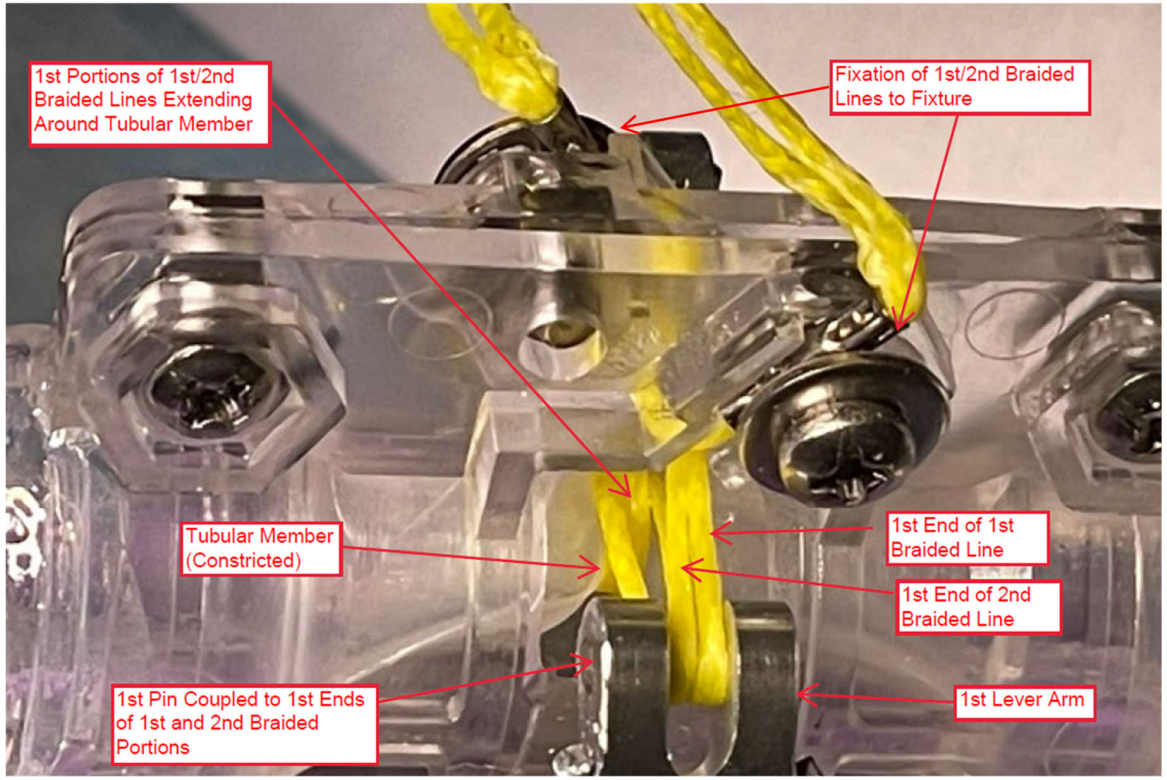
	 (X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of tensioning mechanism for hemostasis valve in Symphony System housing.)

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

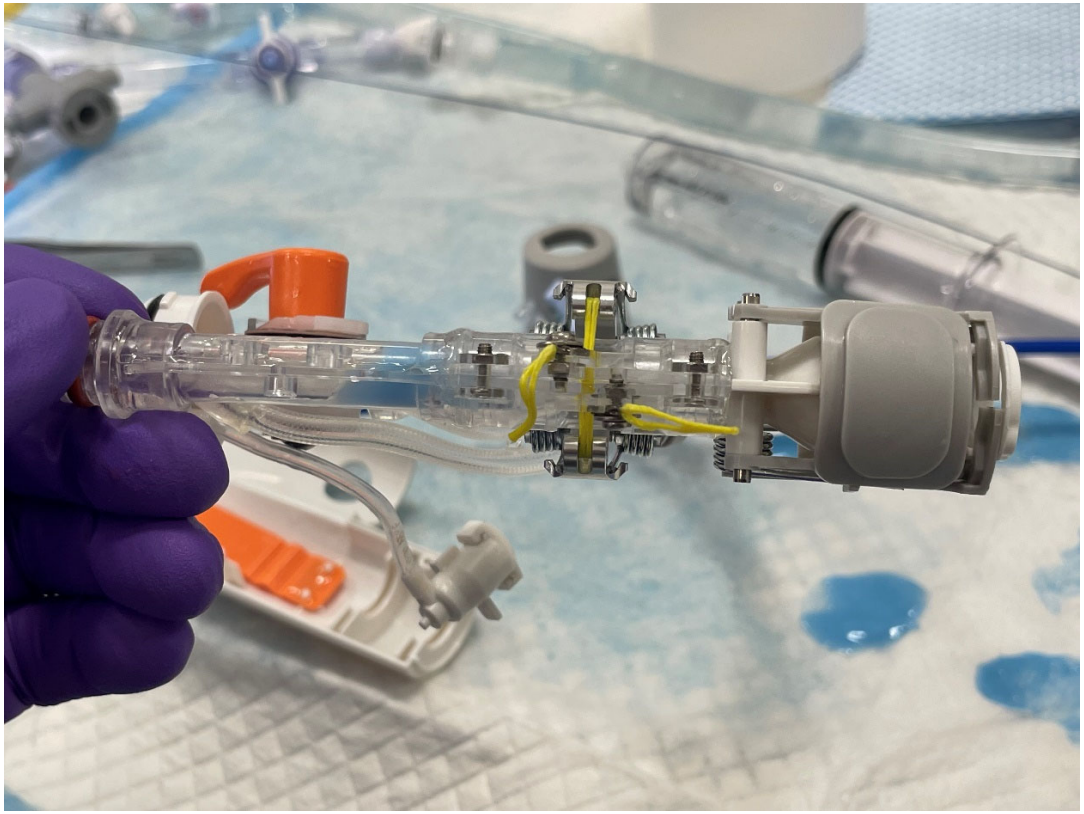
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

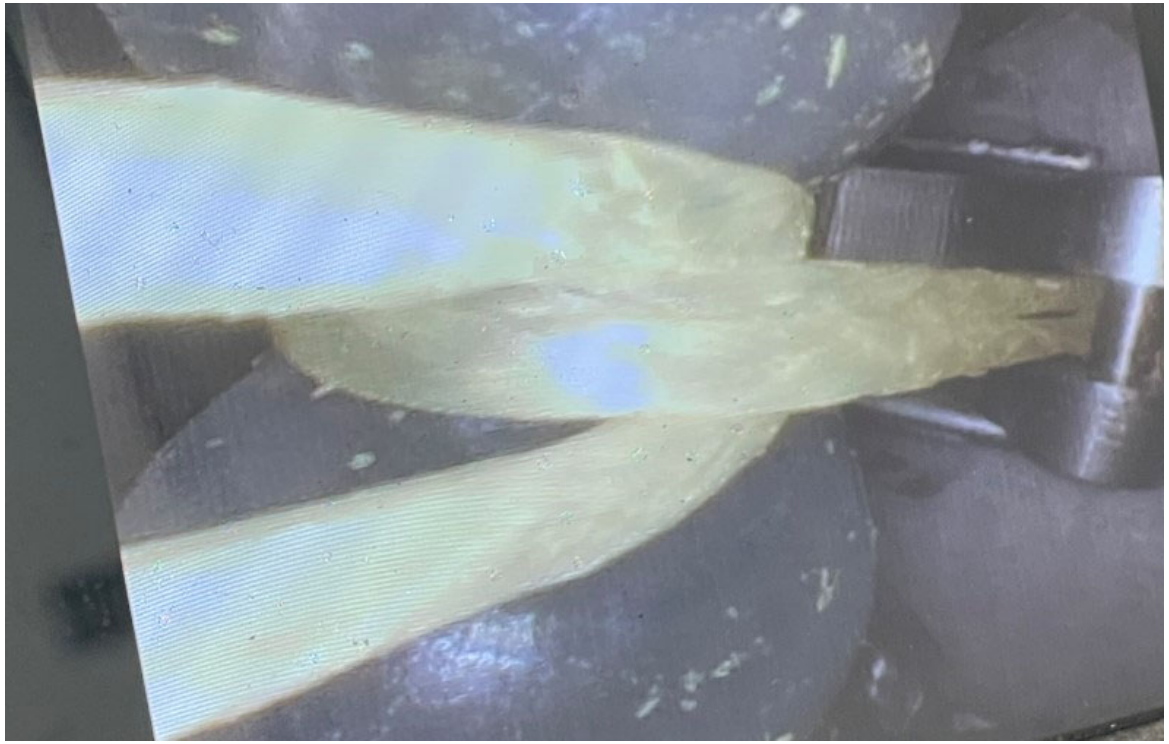
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[4] The valve assembly of claim 3 wherein the first end portion of first filament is directly attached to the first one of the actuators, wherein the second end portion of the first filament is directly	As can be seen above in the figures and photos with Claims 1 and 3, the Symphony System hemostasis valve comprises first end portions of the first and second filaments directly attached (looped around) the first one of the actuators, and second end portions of the first and second filaments directly attached (looped around) the second one of the actuators.

attached to the second one of the actuators, wherein the first end portion of the second filament is directly attached to the first one of the actuators, and wherein the second end portion of the second filament is directly attached to the second one of the actuators.	 (Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first filament and the first end of the second filament wrapped around the pin of and acted on by the first actuator and the second end of the first filament and the second end of the second filament wrapped around the pin of and acted on by the second actuator.)

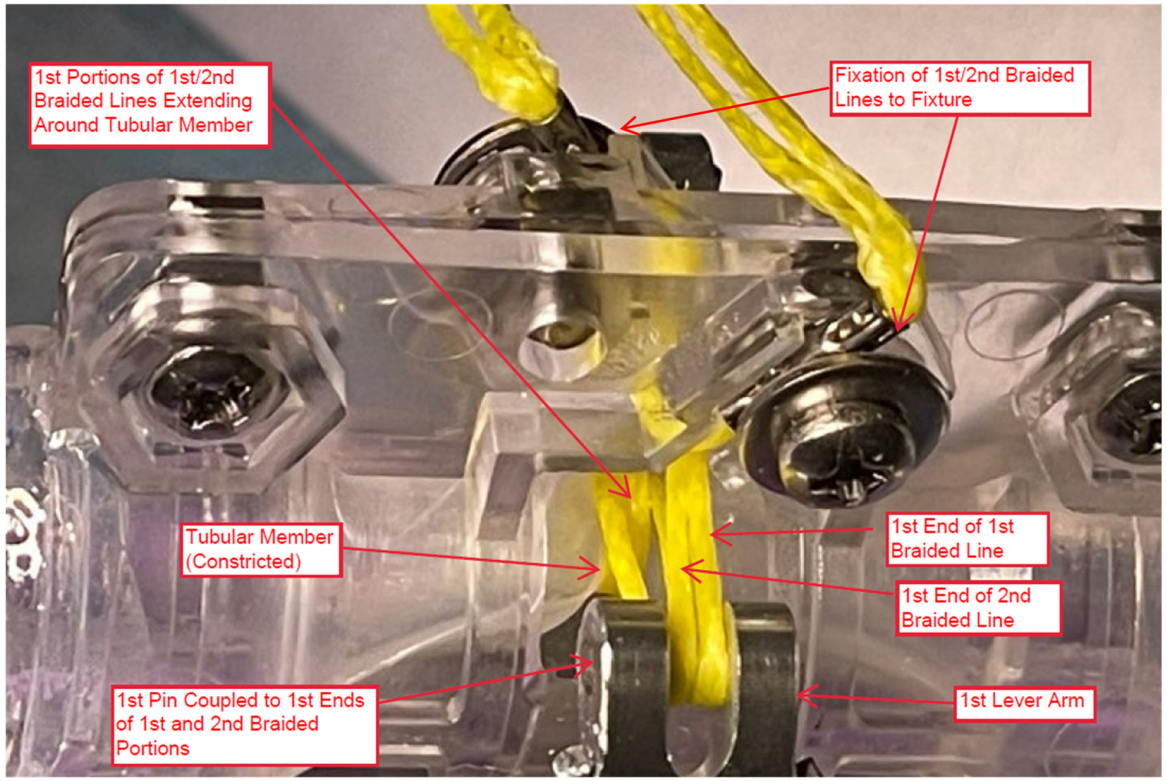


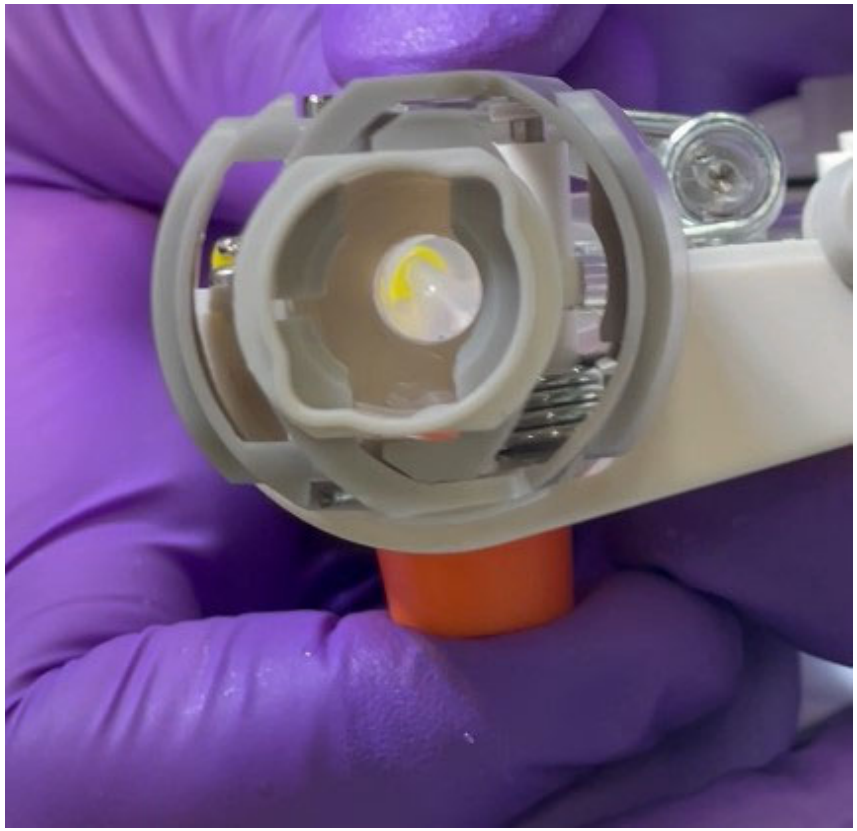
(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

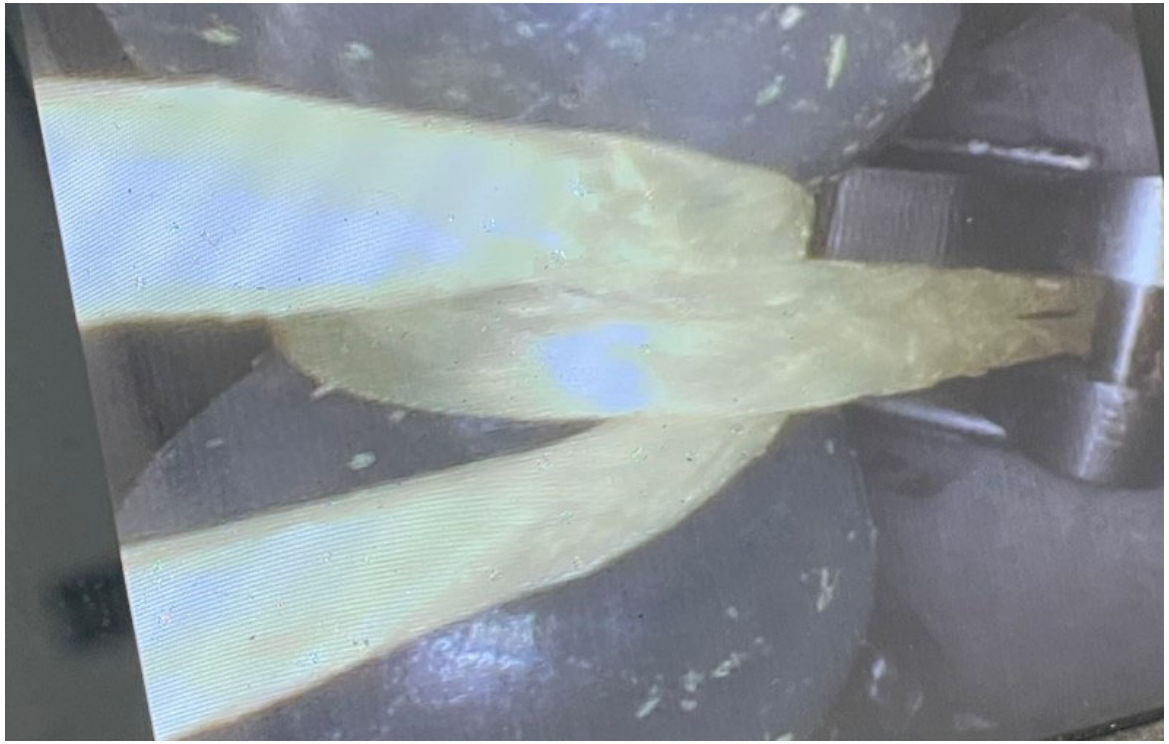
	 (Image of internal portion of housing with hemostasis valve.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[6] The valve assembly of claim 1 wherein the first filament and the second filament each comprise a plurality of strands woven together.	The Symphony System hemostasis valve comprises a first filament and a second filament, each being formed of a plurality of braided strands.

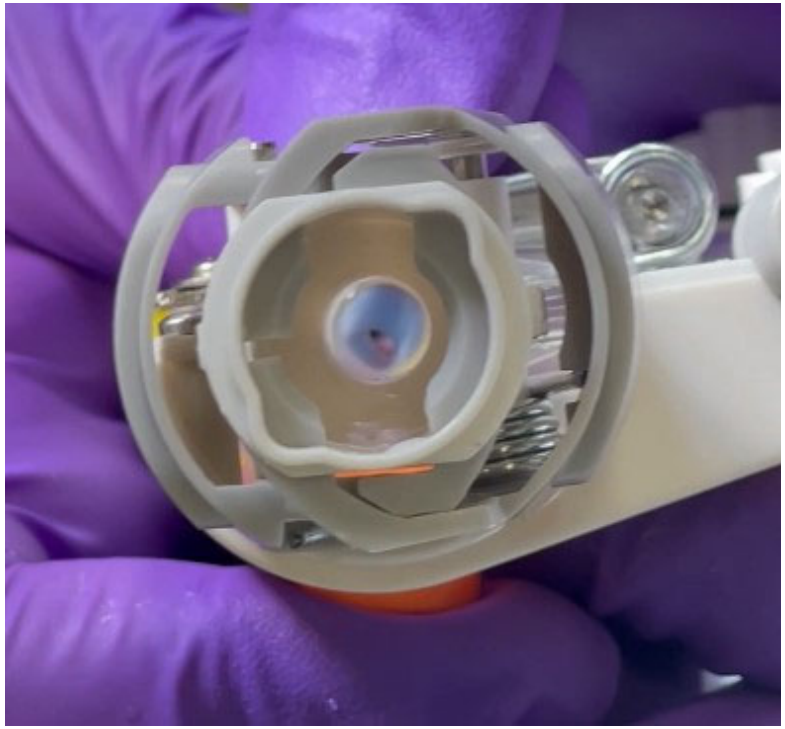
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

	 (Image of internal portion of housing zoomed-in on hemostasis valve, including braided yellow filament lines.)

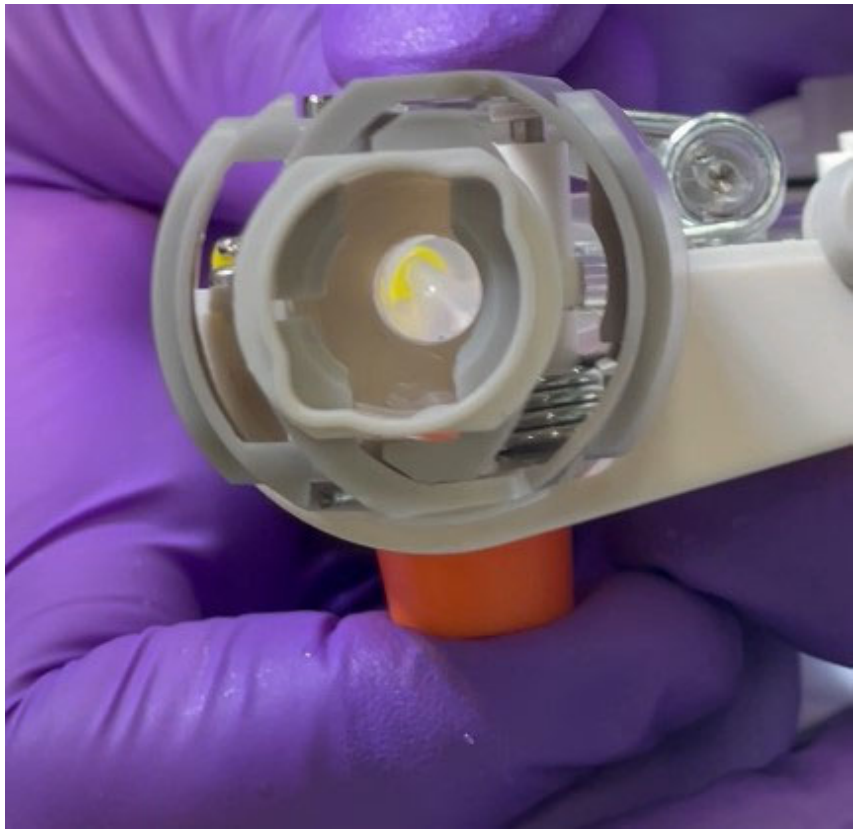
	 (Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[7] The valve assembly of claim 1 wherein the tubular member is elastically deformable.	As can be seen above in the figures and photos with Claim 1, the Symphony System hemostasis valve comprises a tubular elongate member defining a lumen that is elastically deformable to open and close. The elongate member is elastically constricted by the filament loops in the first position (constricted,

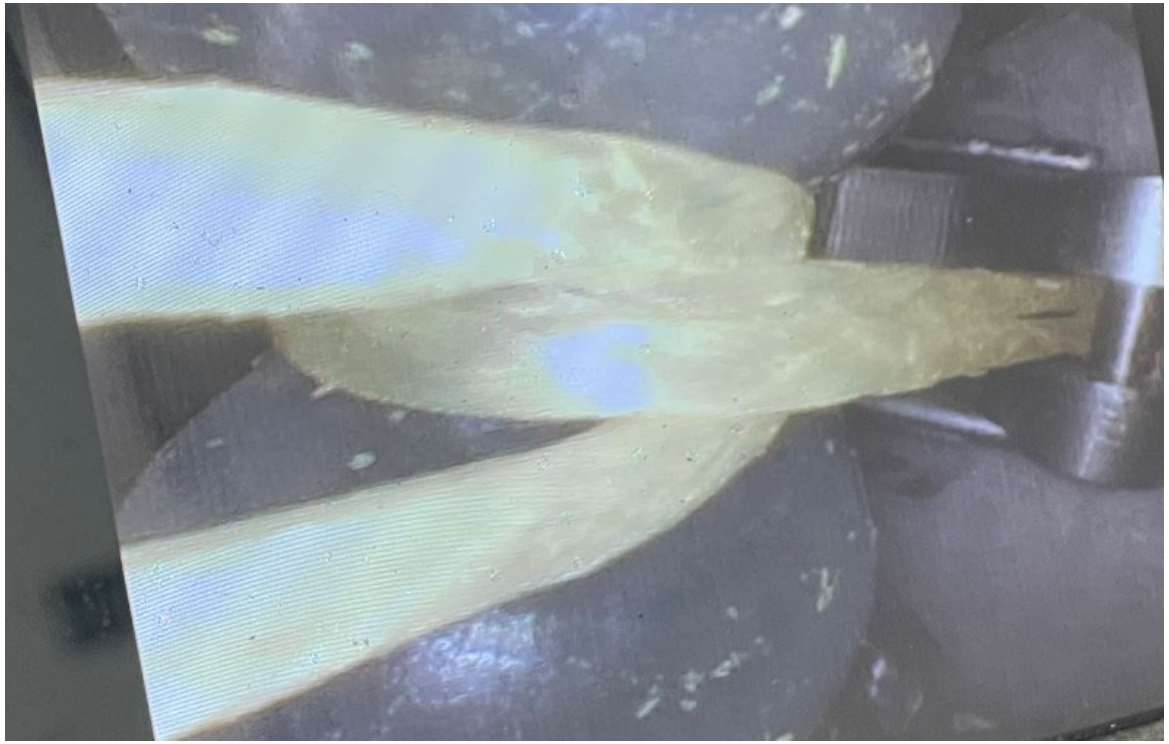
	undepressed buttons). It is allowed to elastically expand when the valve is in the second position (at least partially unconstricted, depressed buttons).  (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

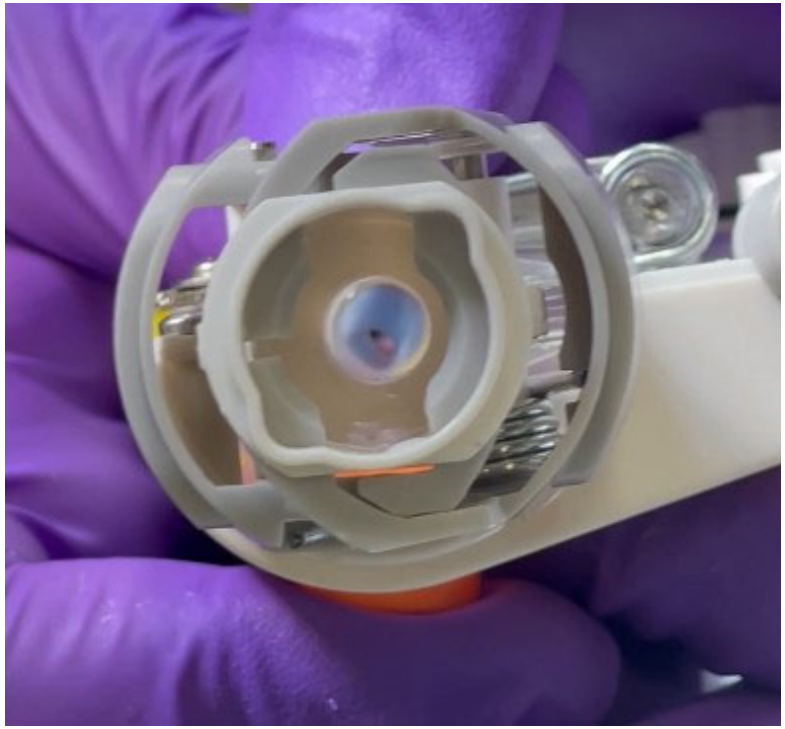
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

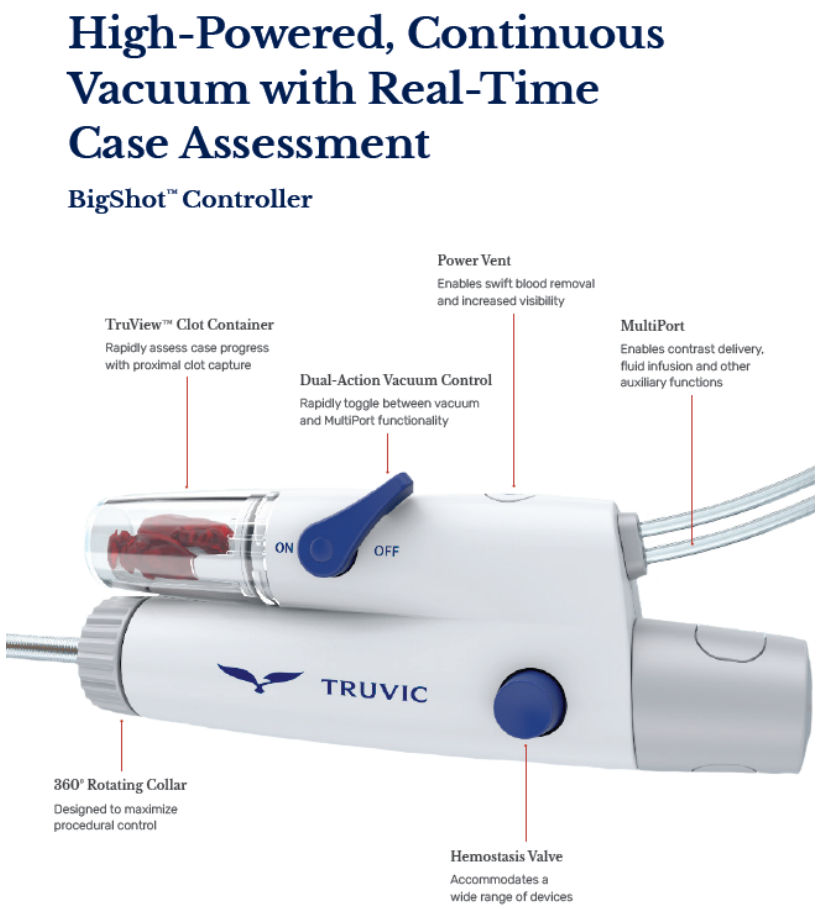
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

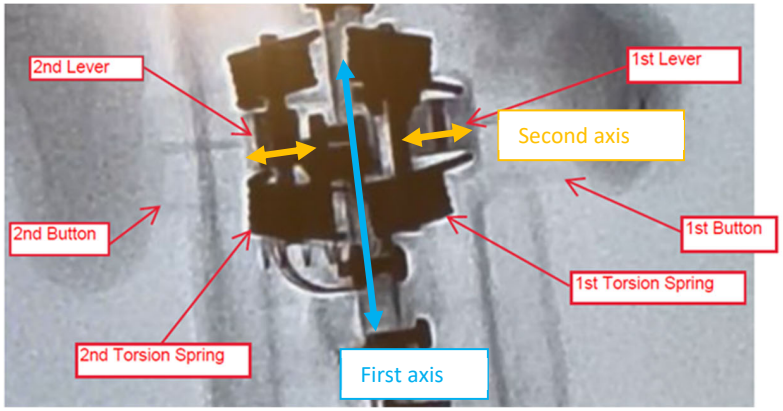
	 (Internal image of hemostasis valve with filaments encircling elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[8] The valve assembly of claim 1 wherein the tubular member is configured to resiliently expand.	As can be seen above in the figures and photos with Claims 1 and 7, the Symphony System hemostasis valve comprises a tubular elongate member defining a lumen that is configured to be elastically deformable to open and close. The elongate member is configured to, and does, resiliently and elastically expand against the filaments of the hemostasis valve when the valve is moved to the second position (at least partially unconstricted, depressed buttons) to at least partially open the valve.

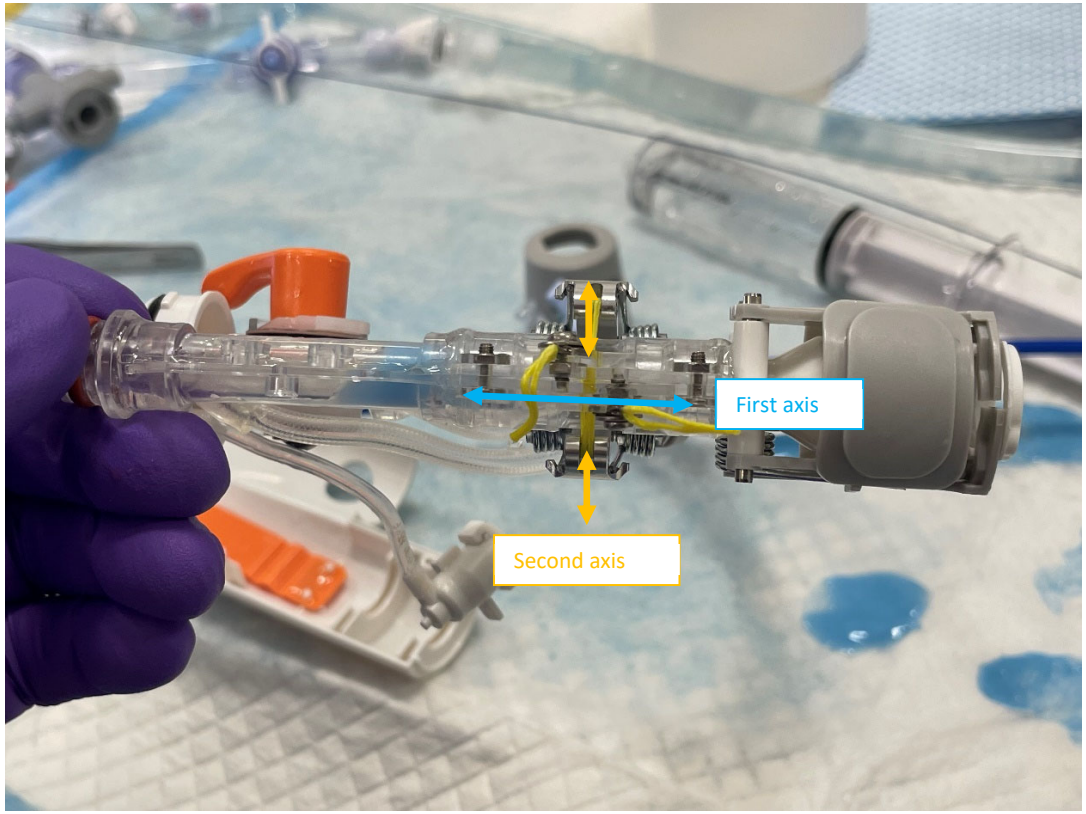
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

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

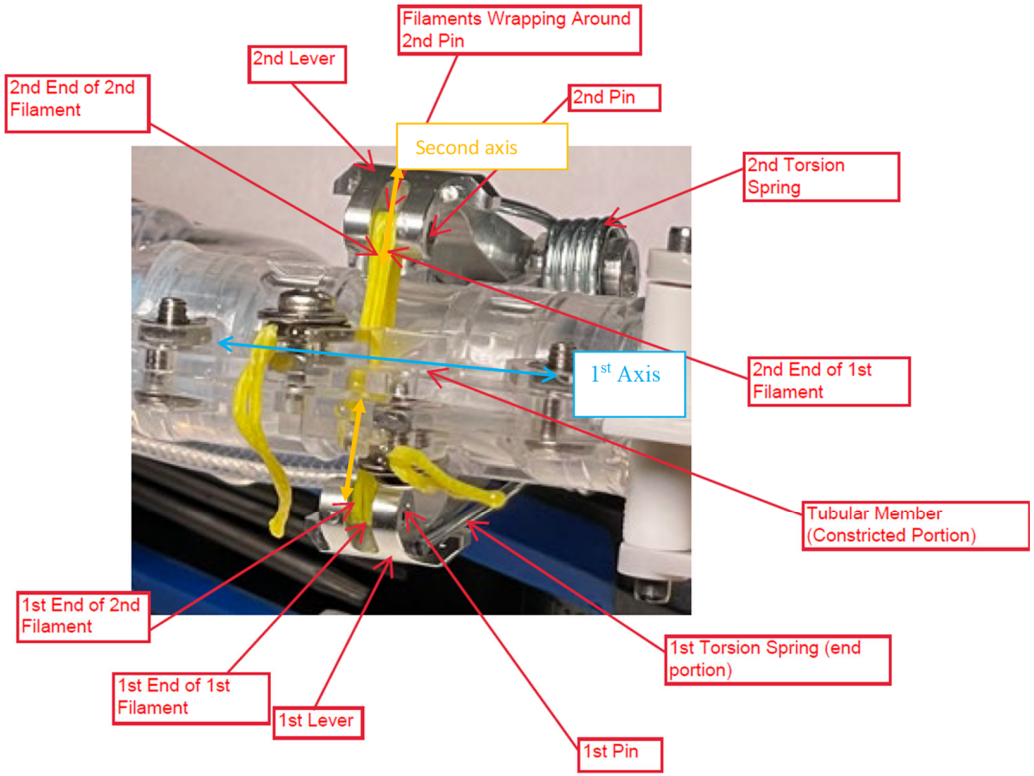
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[9] The valve assembly of claim 1, further comprising a rigid housing, wherein the tubular member, the first filament, and the second filament are positioned within the housing, and wherein the	The Symphony System hemostasis valve assemblies further include rigid plastic of the housing within the handle. The first and second filaments are positioned in the housing. The actuators are movably coupled to rigid plastic of the housing, and the buttons of the first and the second actuator can be depressed and released (undepressed) to move the first and second actuators between the first position (undepressed button) and second position (depressed button) along an axis towards and away from the tubular member. The buttons are depressed at

actuators are movably coupled to the housing.	approximately a 90-degree angle to the tubular member of the hemostasis valve's lumen.  (Annotated Symphony Thrombectomy System Brochure at 6.)

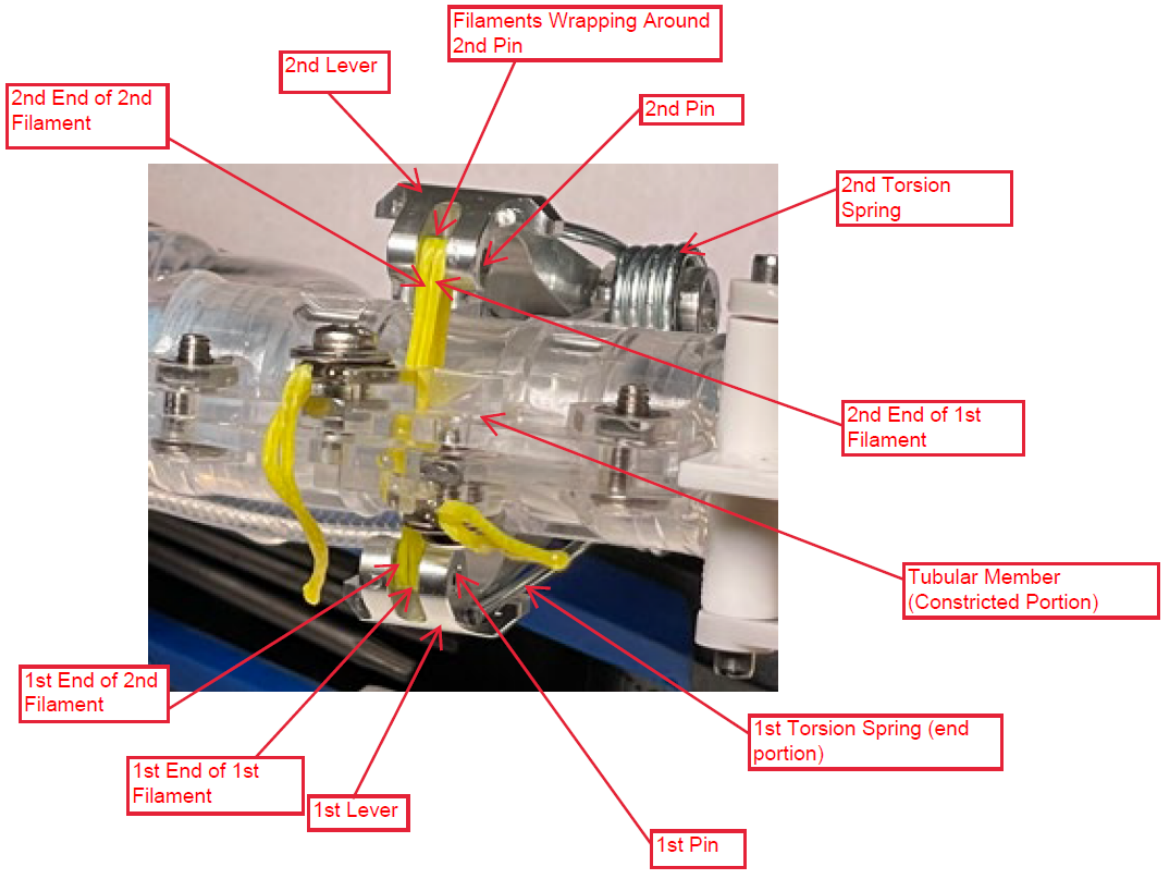
	 (X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs (two per lever), as part of tensioning mechanism for hemostasis valve in Symphony System housing.)



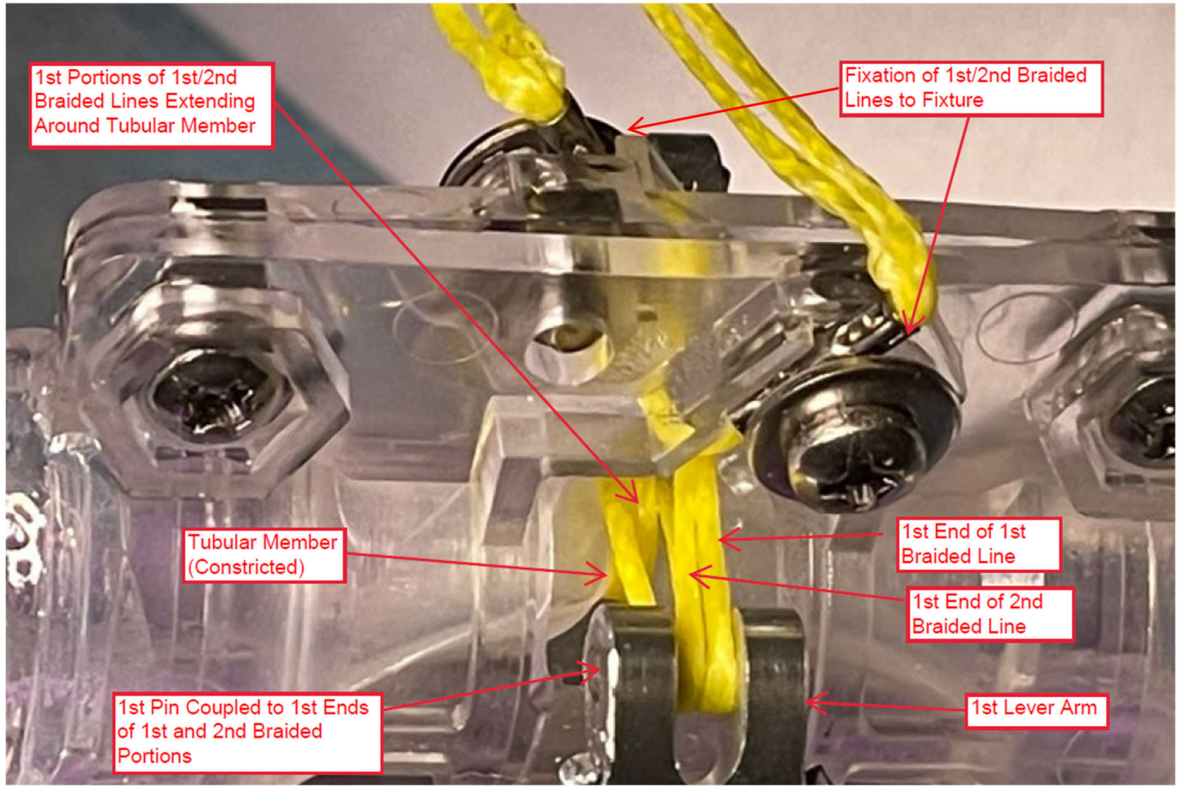
(Image of internal portion of housing with hemostasis valve with two filaments extending around the lumen of the hemostasis valve.)

	 (Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first actuator (first lever/pin/button) and second actuator (second lever/pin/button) movably coupled to the rigid plastic of the housing.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[10] The valve assembly of claim 1 wherein the actuators	The Symphony System hemostasis valve comprises a first actuator (first lever/pin/button) and second actuator (second lever/pin/button) that are depressed

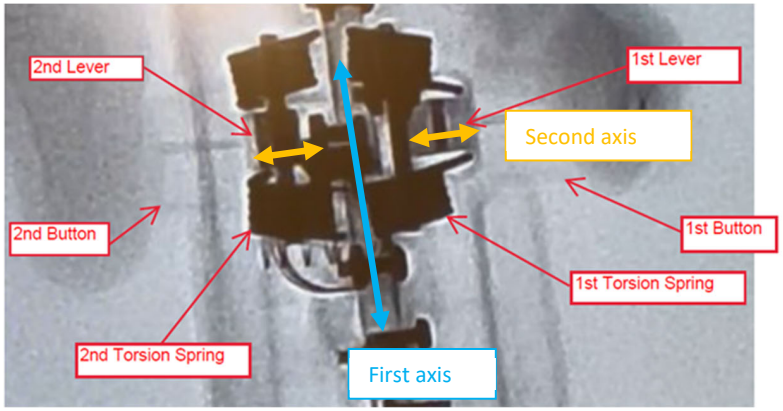
are depressed toward one another in the second position, and wherein the actuators are moved away from one another in the first position.	towards one another in the second position (unconstricted, buttons depressed). The first and second actuators are biased outwards from rigid plastic housing and the tubular member in the first position (constricted, button undepressed) and away from one another by first torsion spring(s) and second torsion spring(s). This biasing increases the tension in the first and second filament, decreasing the dimension of the first loop of the first filament and the second loop of the second filament, constricting and elastically deforming the tubular member defining a lumen. Pressing the first and second buttons inwards to the rigid plastic housing and tubular member along the second axis labeled in images below, moves the actuators toward each other and to the second position (unconstricted, buttons depressed). (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)

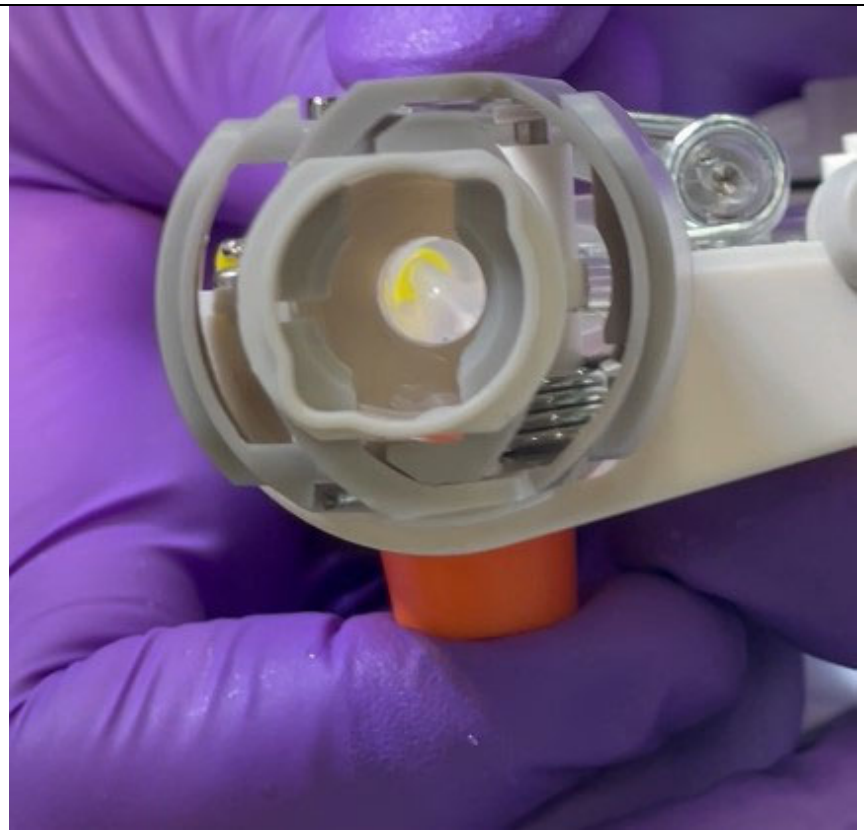


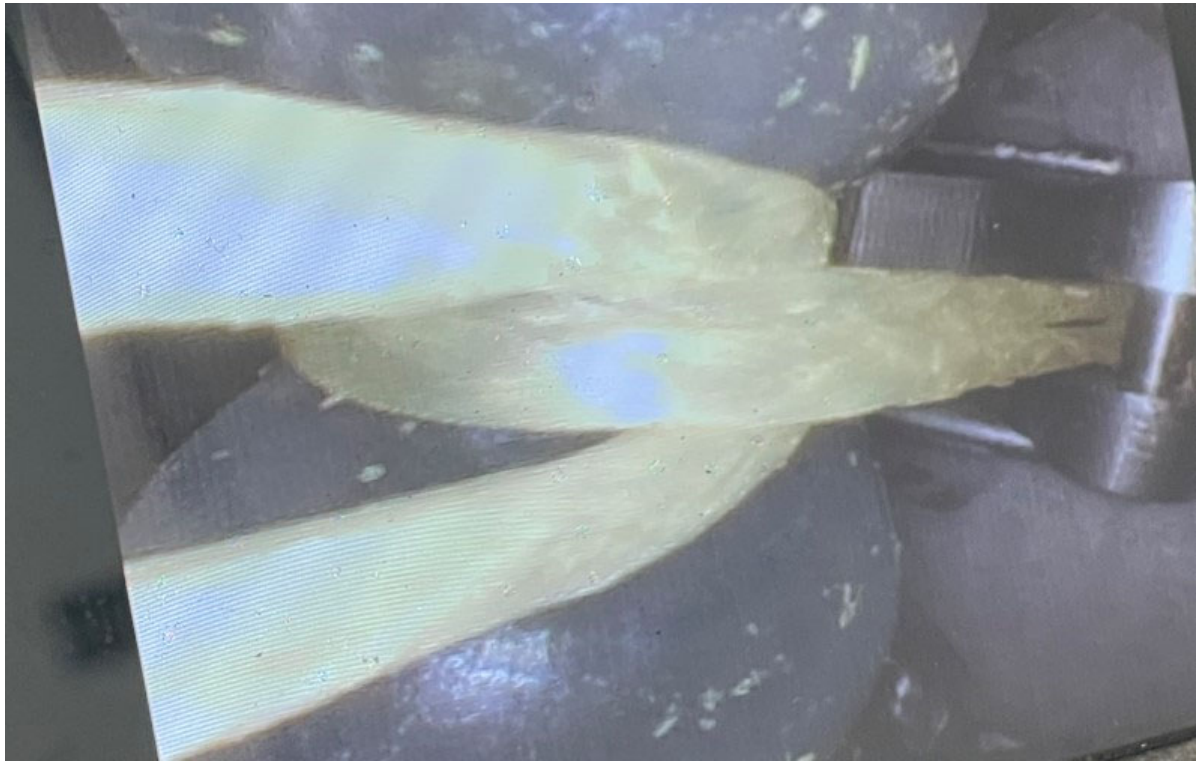
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)

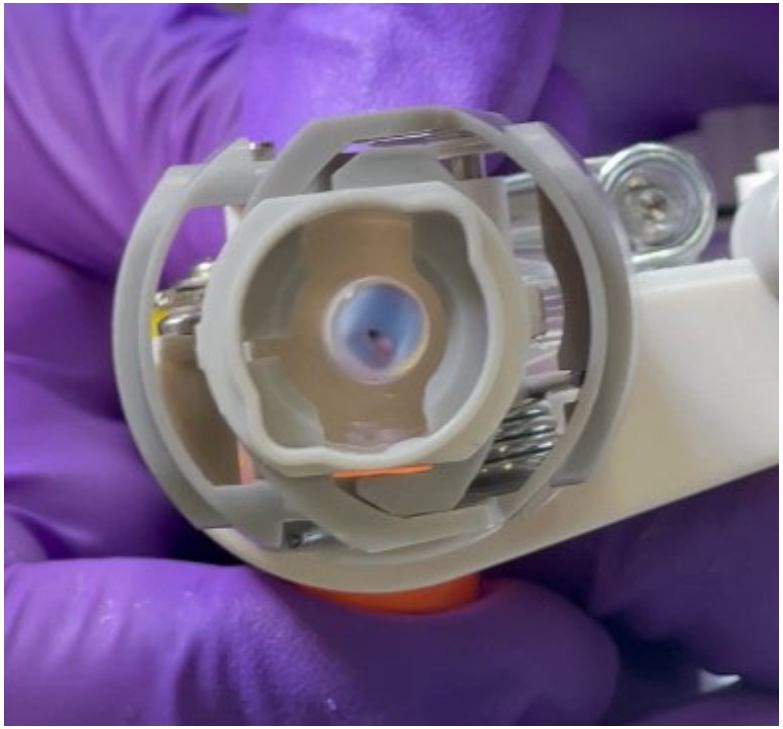


(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

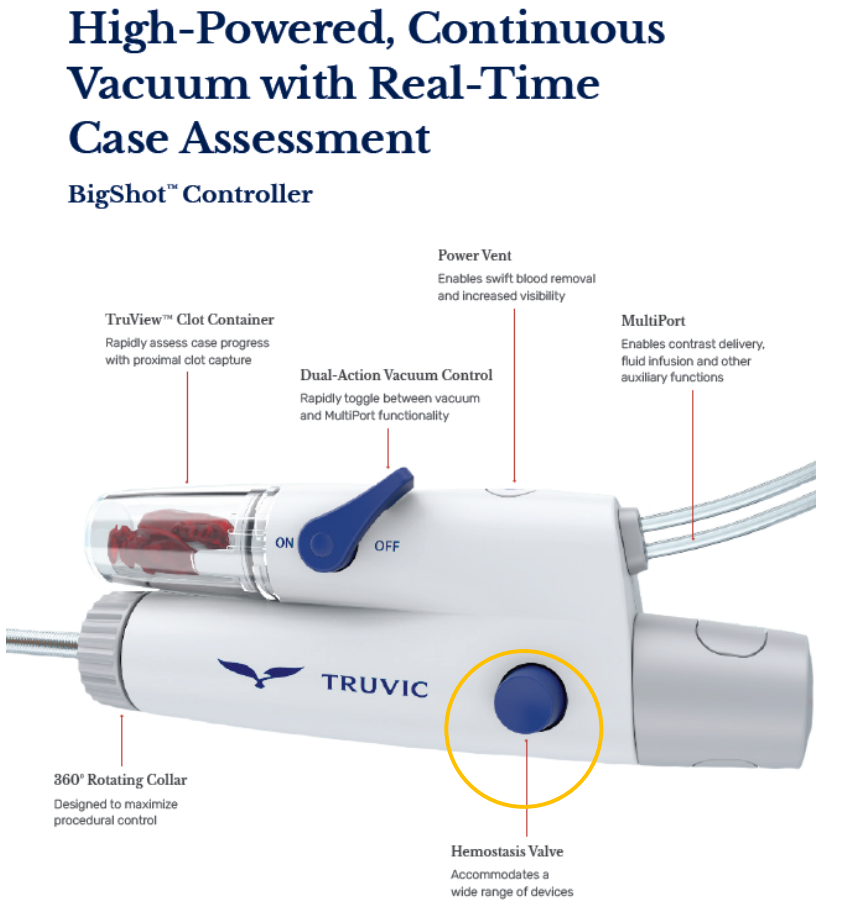
	 (Annotated x-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs (two for each lever), as part of tensioning mechanism for hemostasis valve in Symphony System housing.)

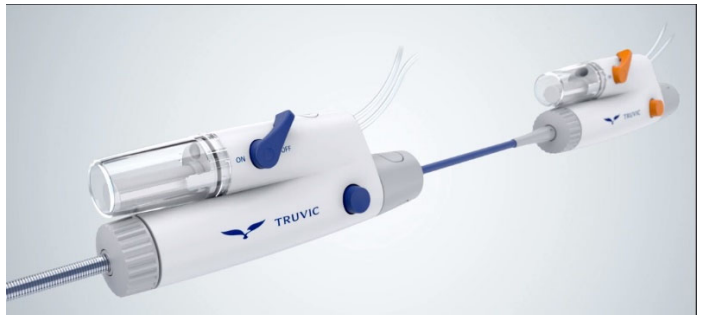
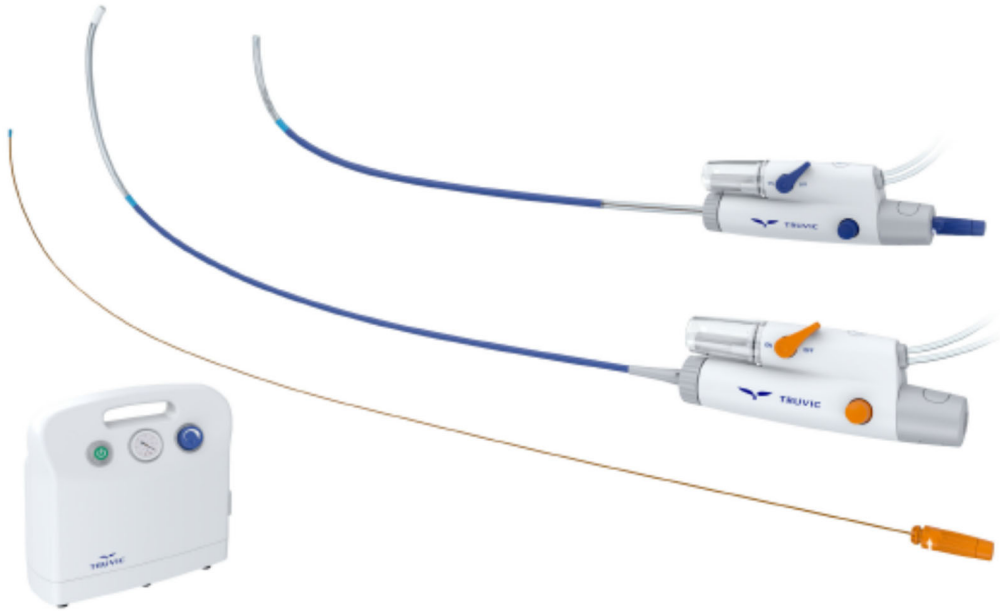
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member in the first position.)

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

	 (Internal image of hemostasis valve with filaments encircling elongate member in the second position.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents
[11] The valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 14 French.	The Symphony System hemostasis valves on both the 16F and 24F Symphony handles have a lumen diameter of more than 14 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the respective 16F or 24F dilator, 16F or 24F ProHelix (or a 16F catheter for the 24F handle), to pass through the hemostasis valve. 16 French and 24 French are both larger than 14 French.

	 (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

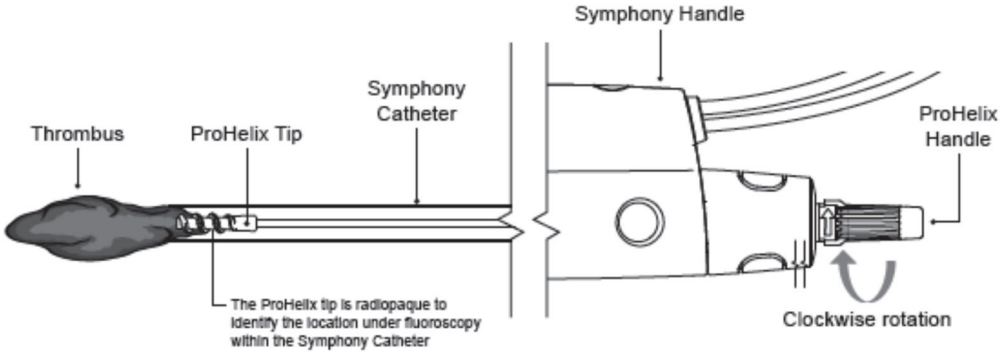


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

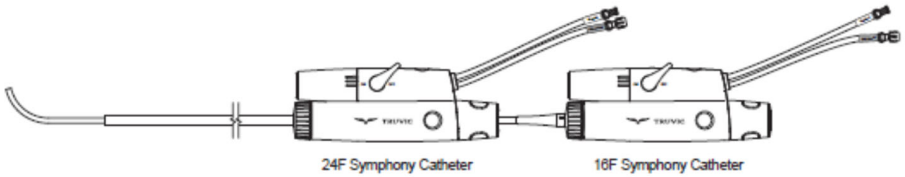
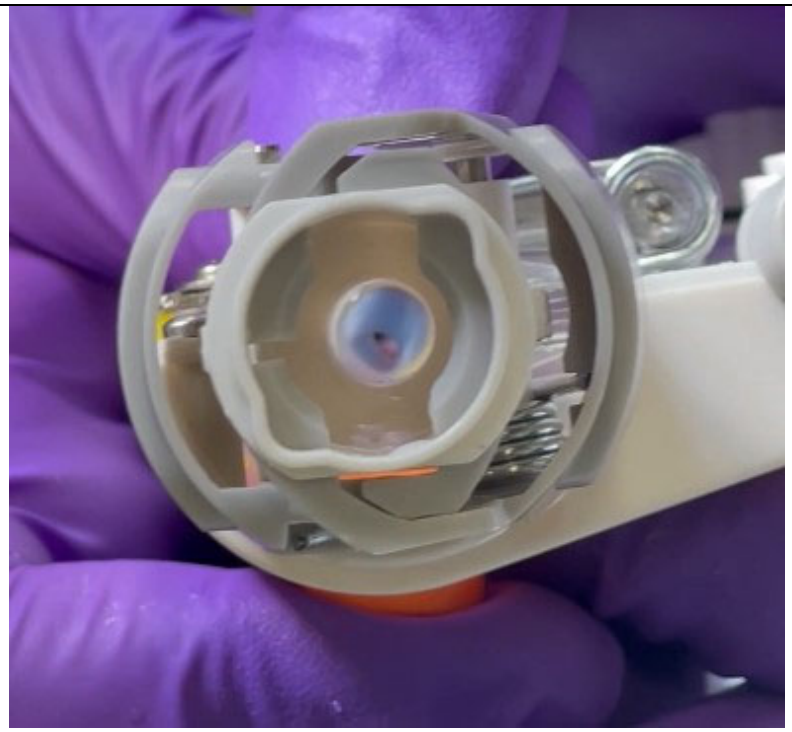
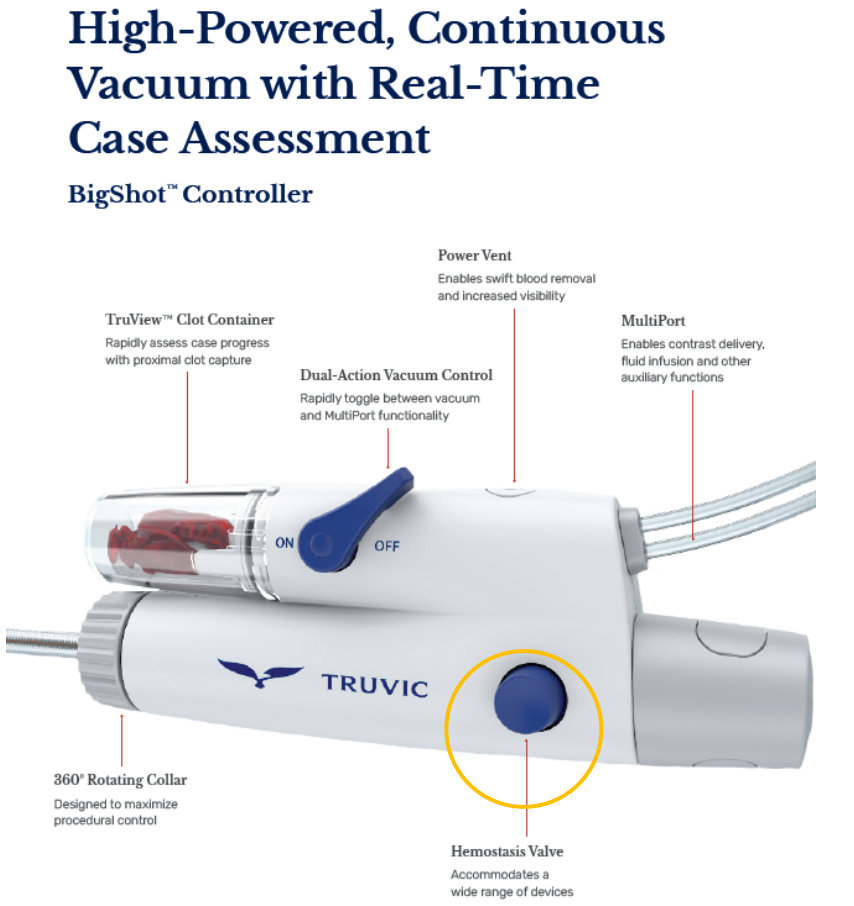
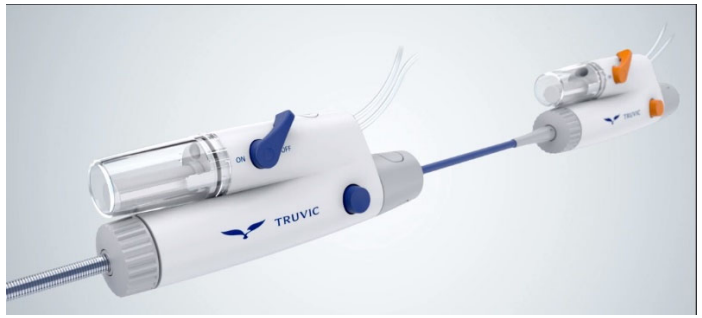
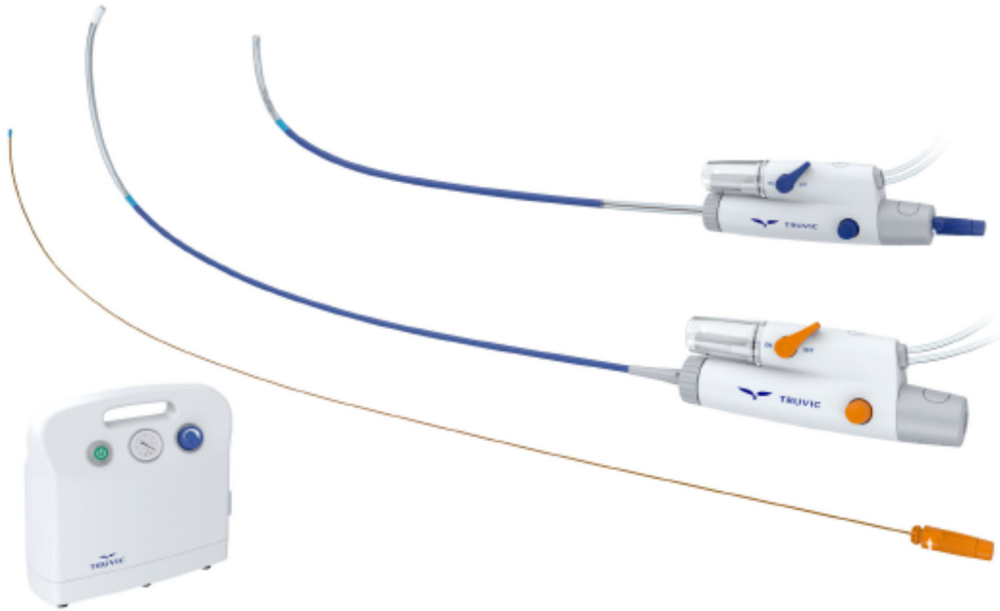


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[12] The valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 16 French.	The Symphony System hemostasis valves on both the 16F and 24F Symphony handles have a lumen diameter of at least 16 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the respective 16F or 24F dilator, 16F or 24F ProHelix (or a 16F catheter for the 24F handle), to pass through the hemostasis valve. 16 French and 24 French are both at least as 16 French.

	 (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

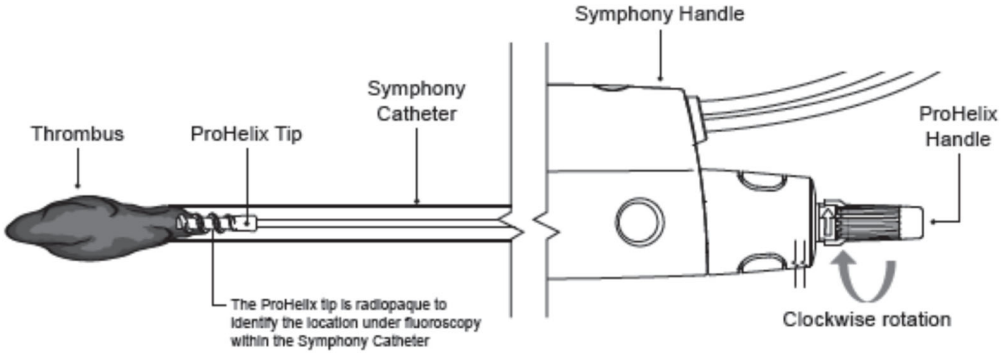


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

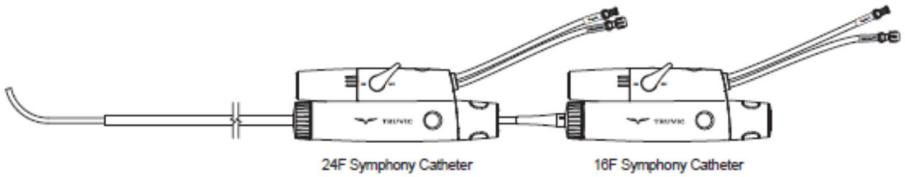
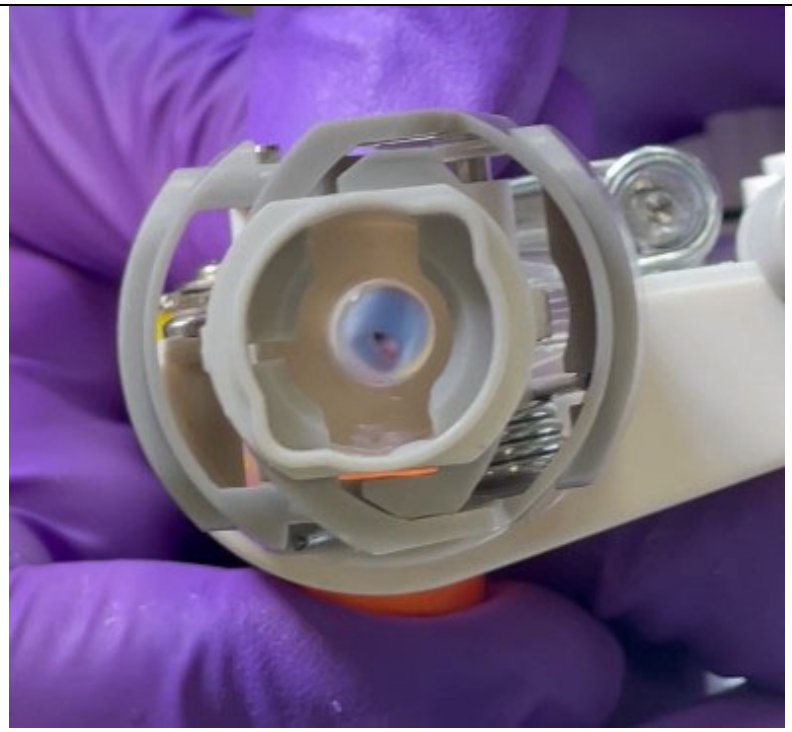
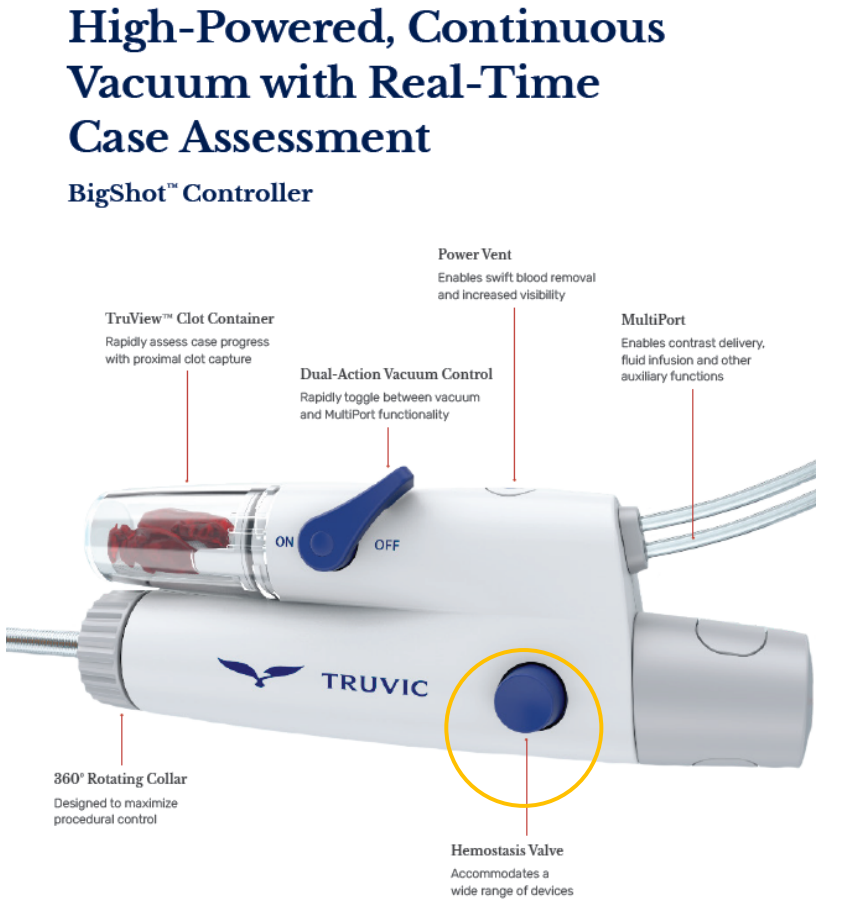
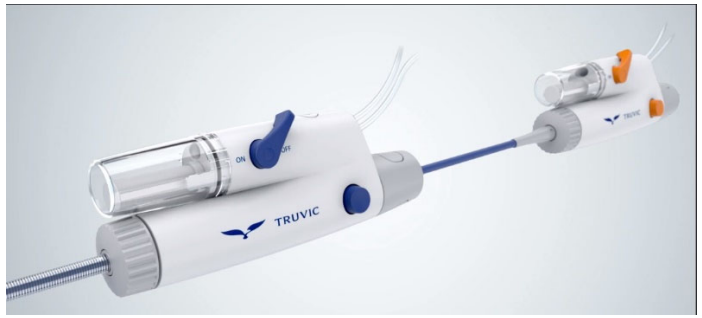
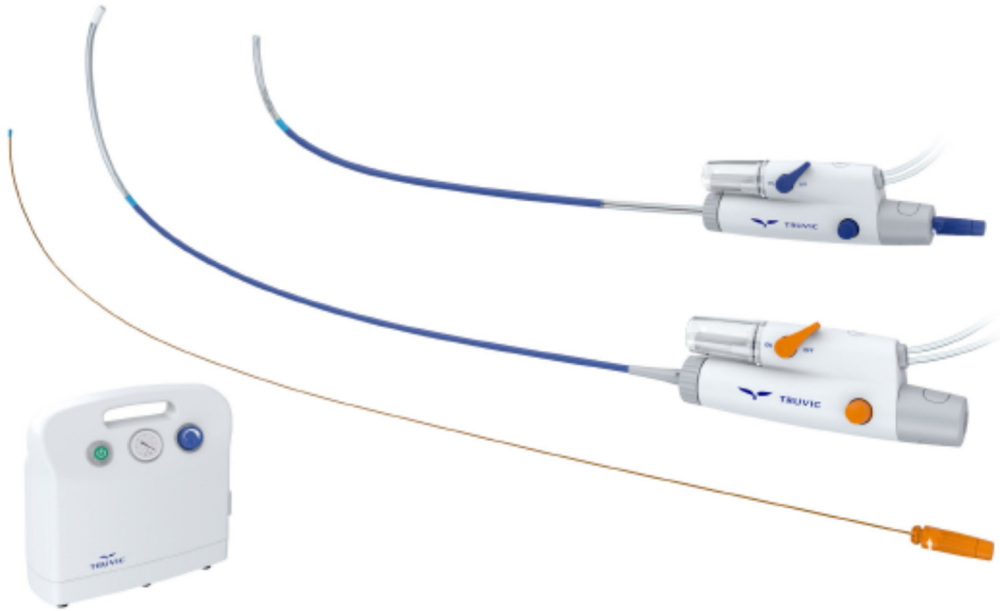


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[13] The valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 20 French.	The Symphony System hemostasis valve on the 24F Symphony handles have a lumen diameter of at least 20 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the 24F dilator, 24F ProHelix, or a 16F catheter, to pass through the hemostasis valve. 24 French is larger than 20 French.

	 (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

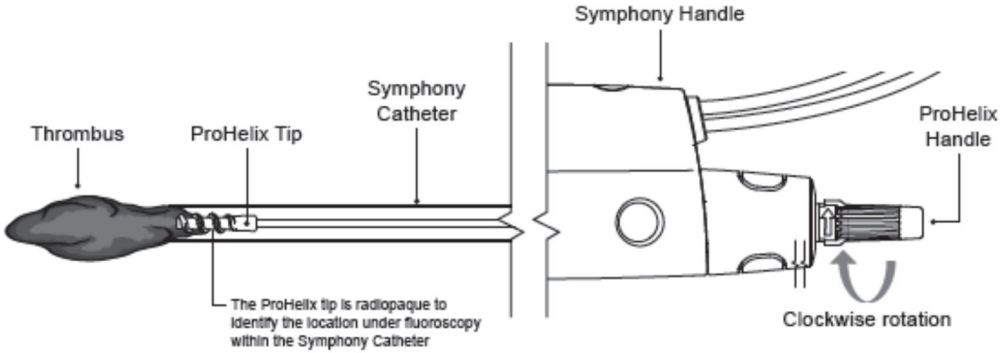


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

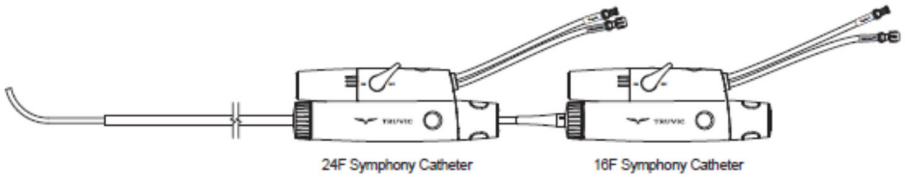
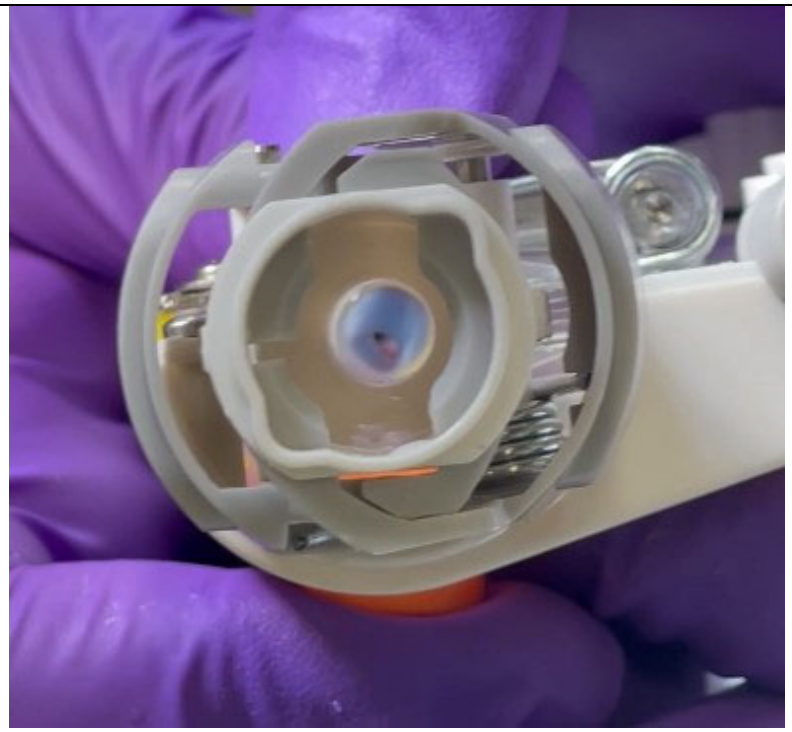
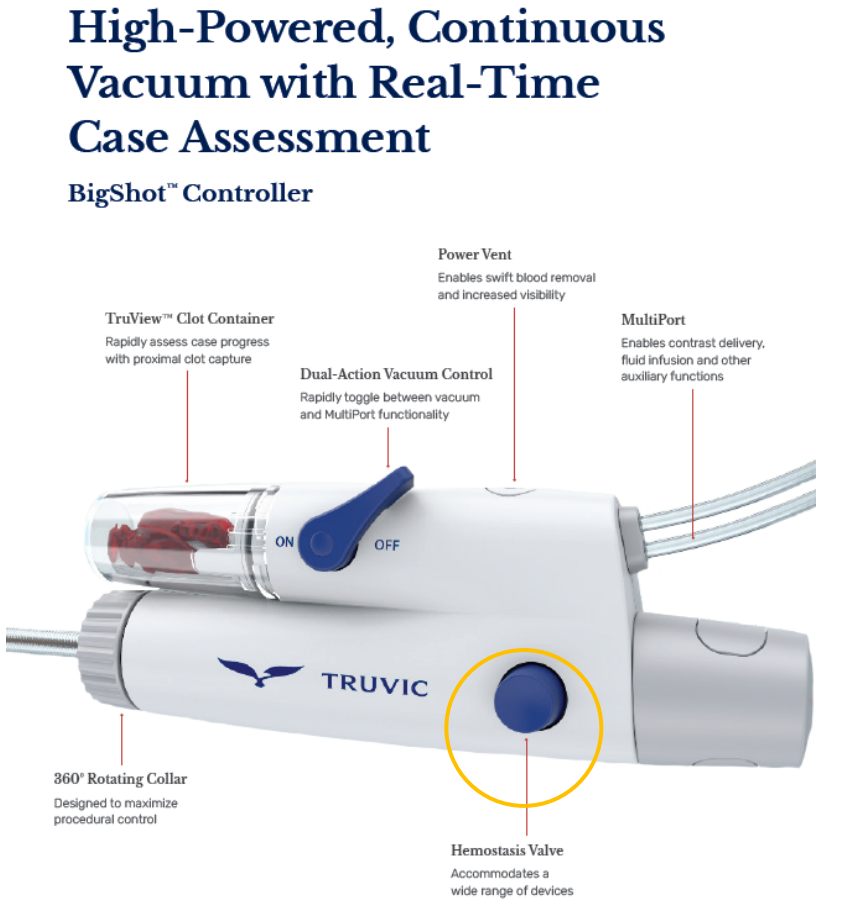
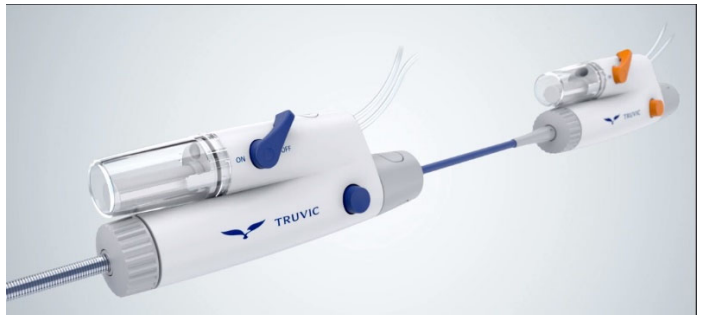
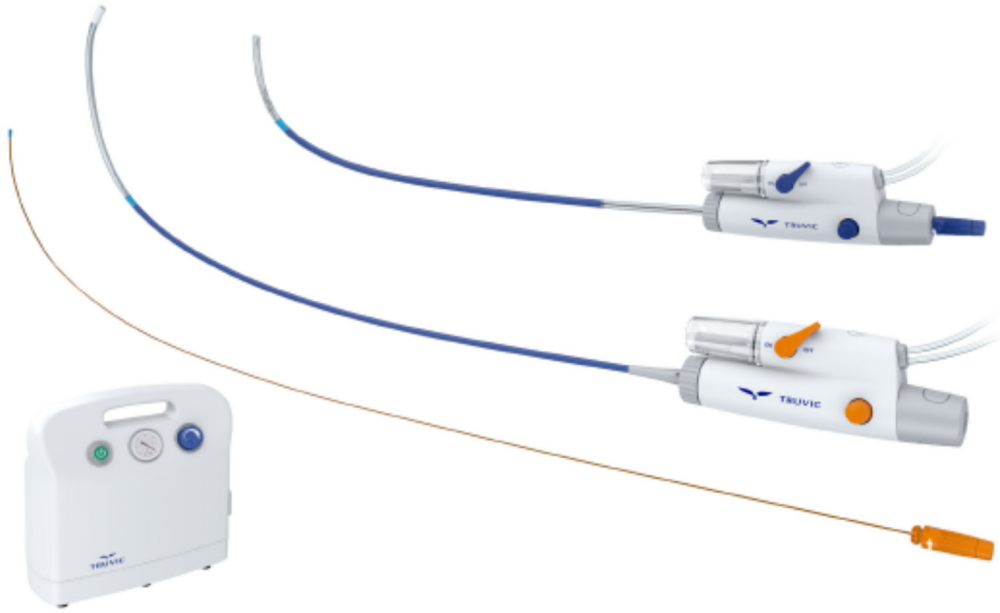


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[14] The valve assembly of claim 1 wherein, in the second position, the tubular member has a diameter of at least 24 French.	The Symphony System hemostasis valve on the 24F Symphony handles have a lumen diameter of at least 24 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the 24F dilator, 24F ProHelix, or a 16F catheter, to pass through the hemostasis valve. 24 French is at least 24 French.

	 (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

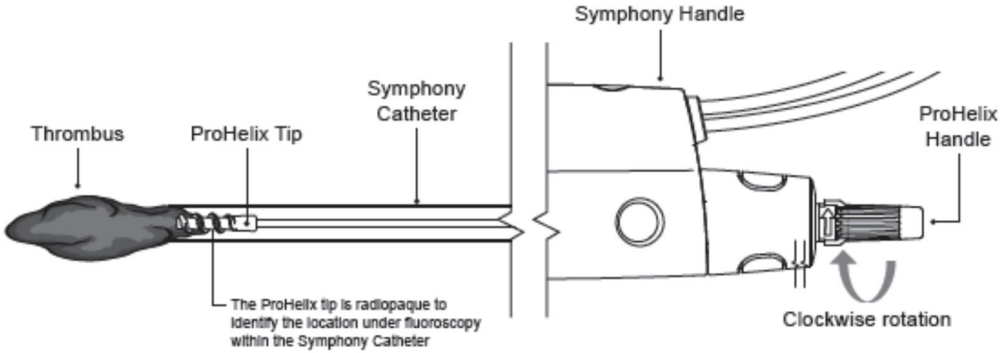


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

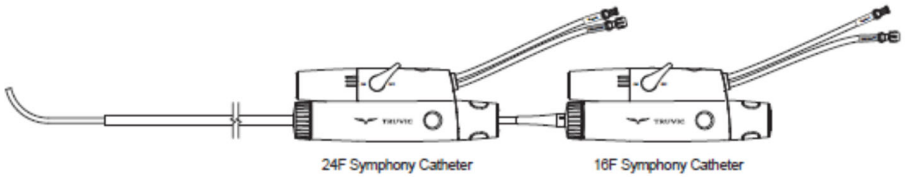
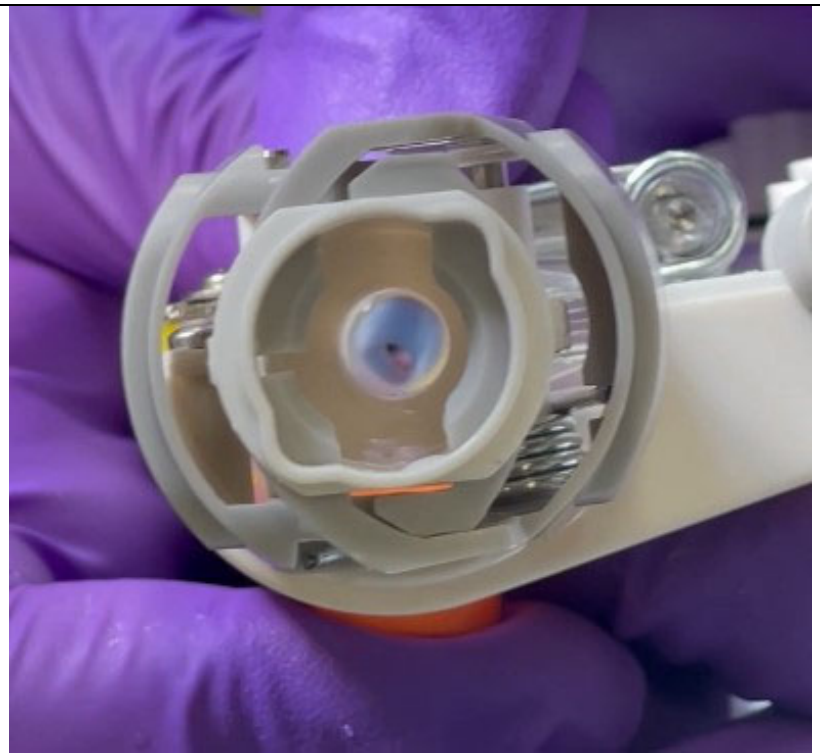
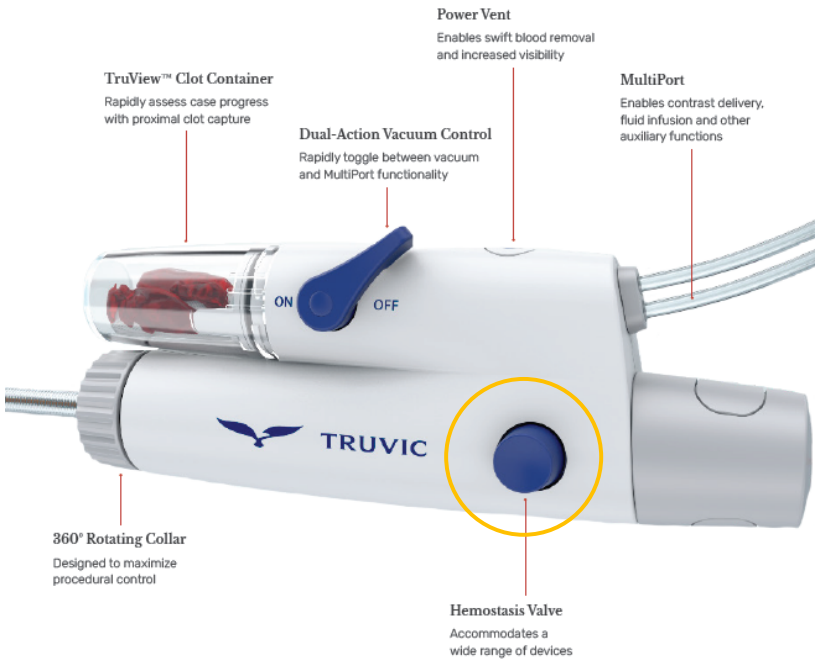
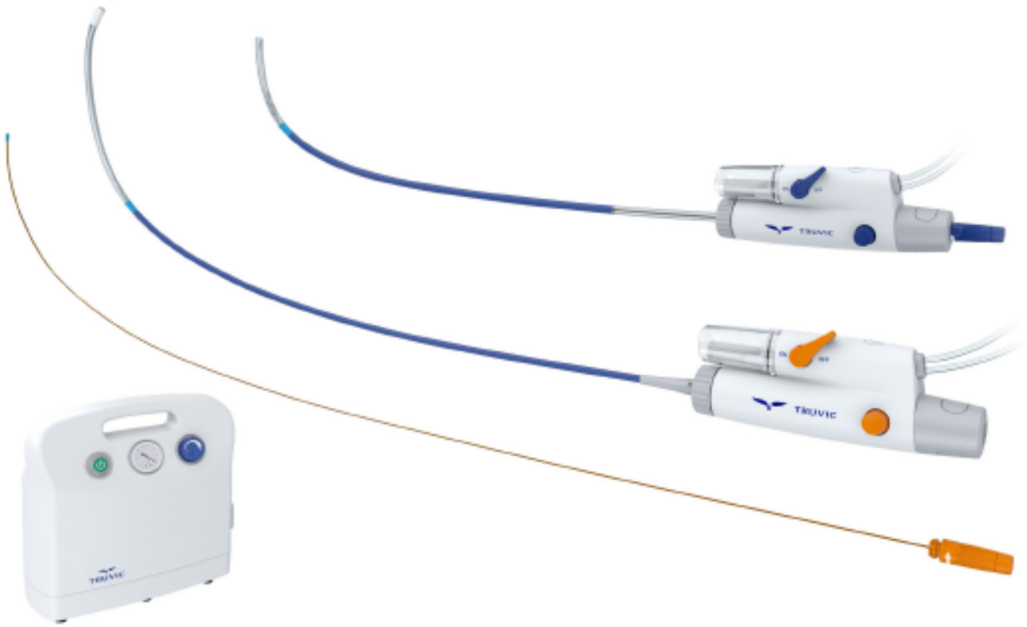


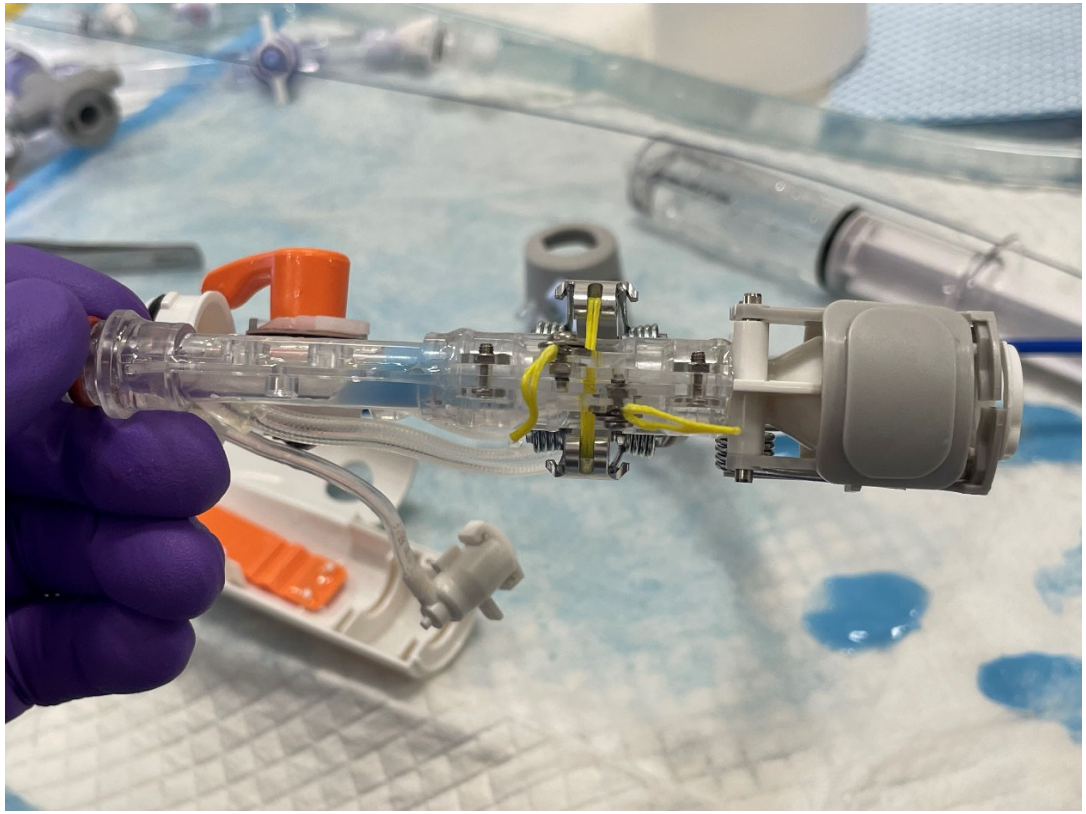
Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

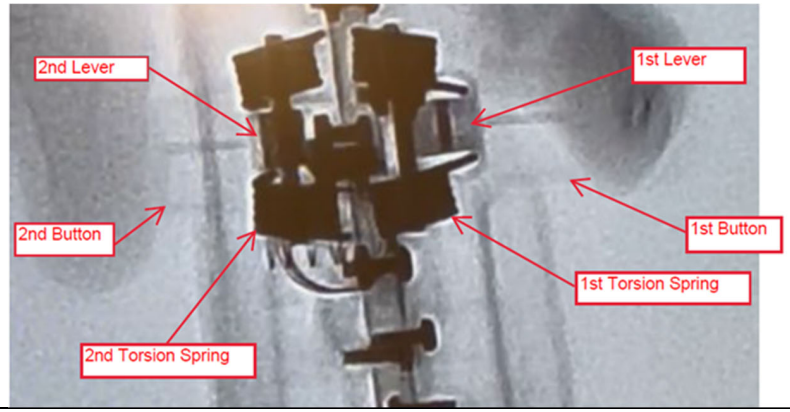
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

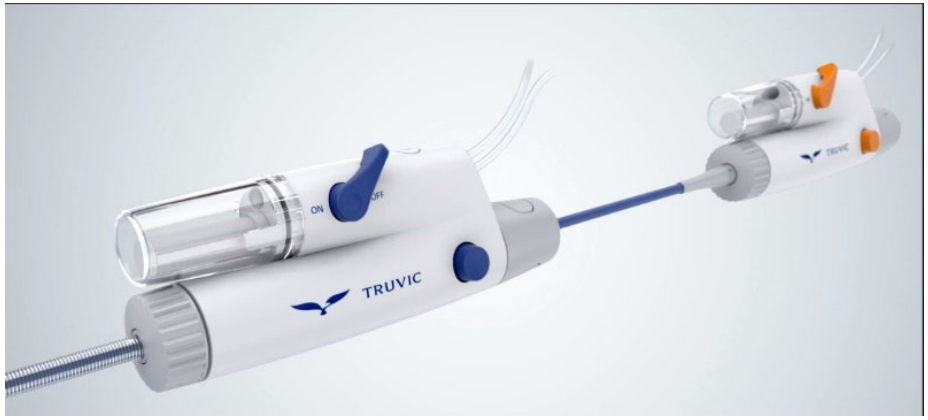
[15] A valve assembly, comprising:	The Symphony System has a hemostasis valve assembly. **High-Powered, Continuous Vacuum with Real-Time Case Assessment** **BigShot™ Controller**  (Annotated Symphony Thrombectomy System Brochure at 6.) A hemostasis valve is positioned within each of the two Symphony handles. The hemostasis valve is operated by two blue or two orange buttons, depending on the handle.

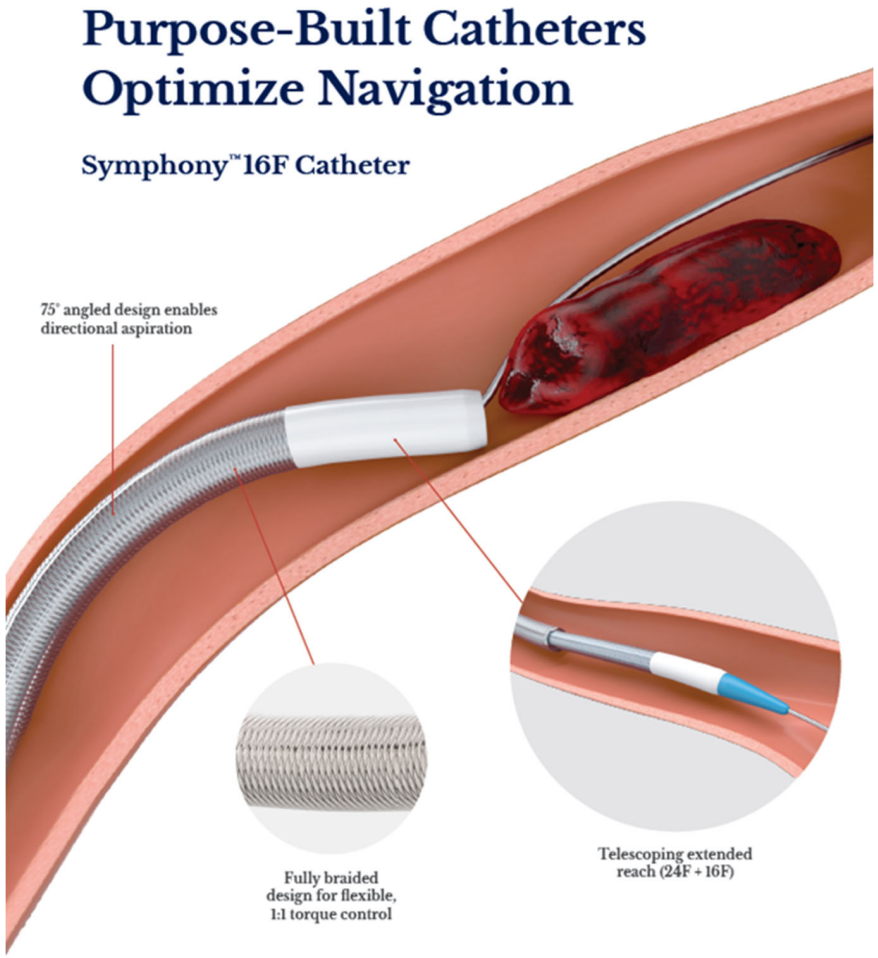
	 (Symphony Thrombectomy System Brochure at 2.)

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

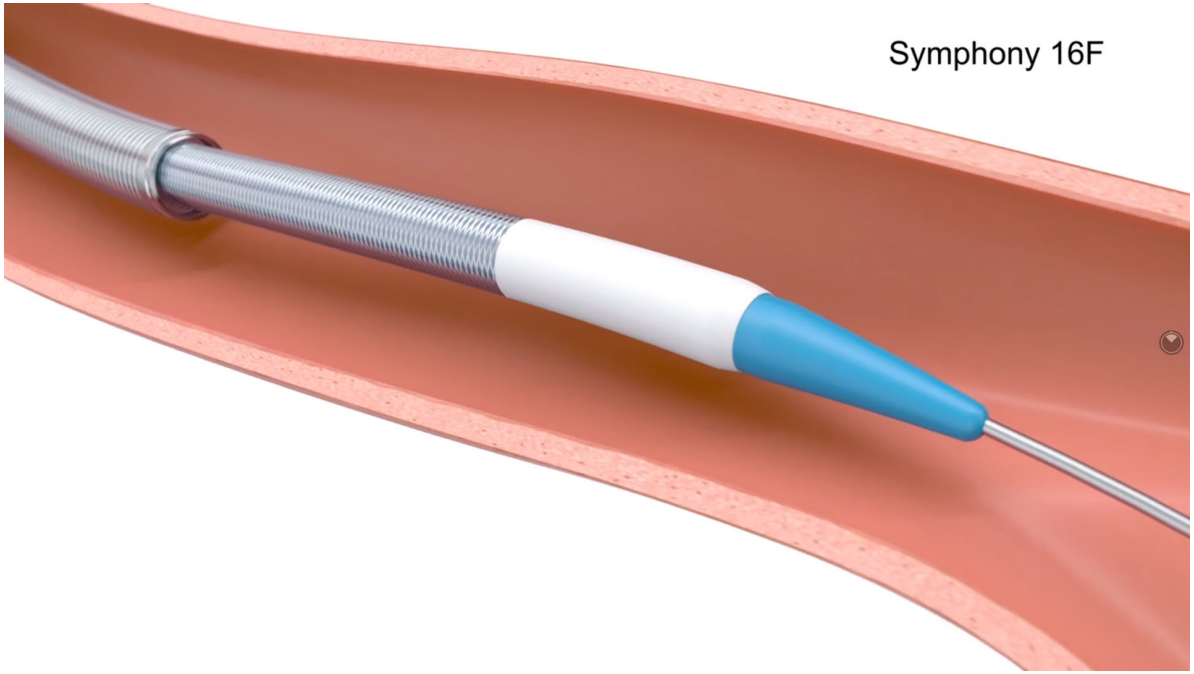
(Image of internal portion of housing zoomed-in on hemostasis valve.)

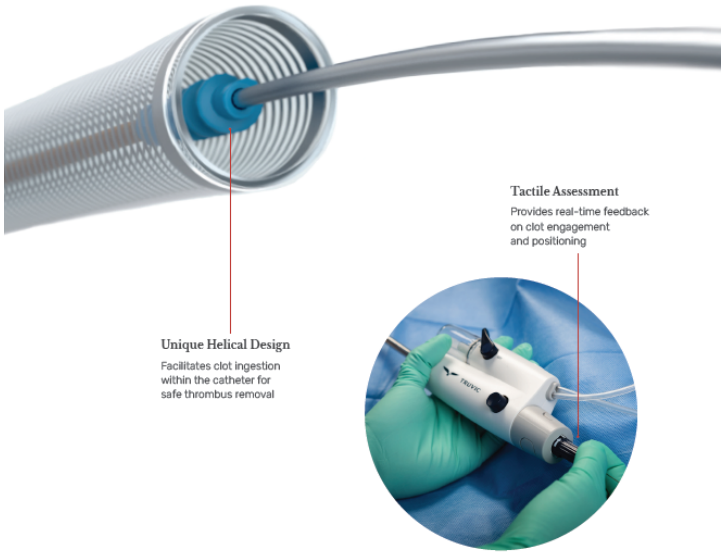


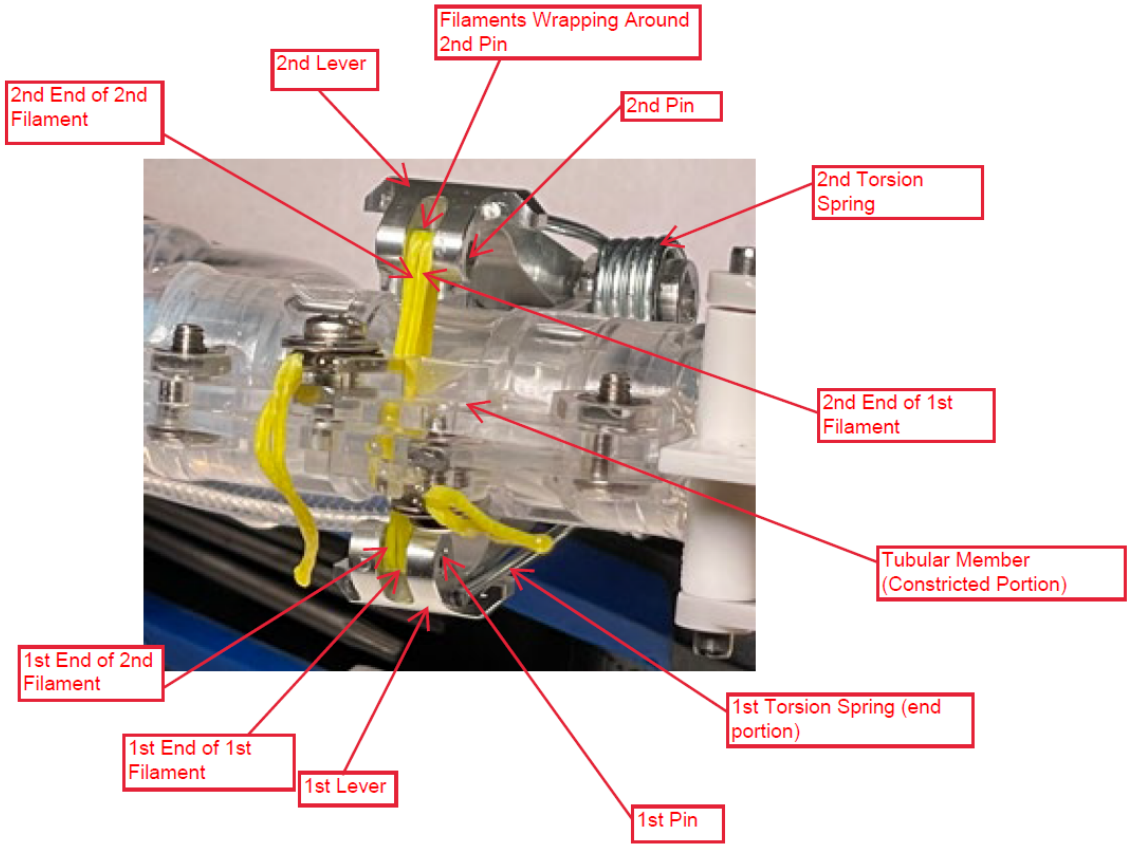
	(Annotated x-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs (two for each lever), as part of tensioning mechanism for hemostasis valve in Symphony System housing.) The hemostasis valve is configured to "accommodate a wide range of devices" (Symphony Thrombectomy System Brochure at 6), including a Truvic catheter, a ProHelix™ Mechanical Assist catheter and, in the case of at least the 24F handle or a second telescoping catheter, for use in procedures:  (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)

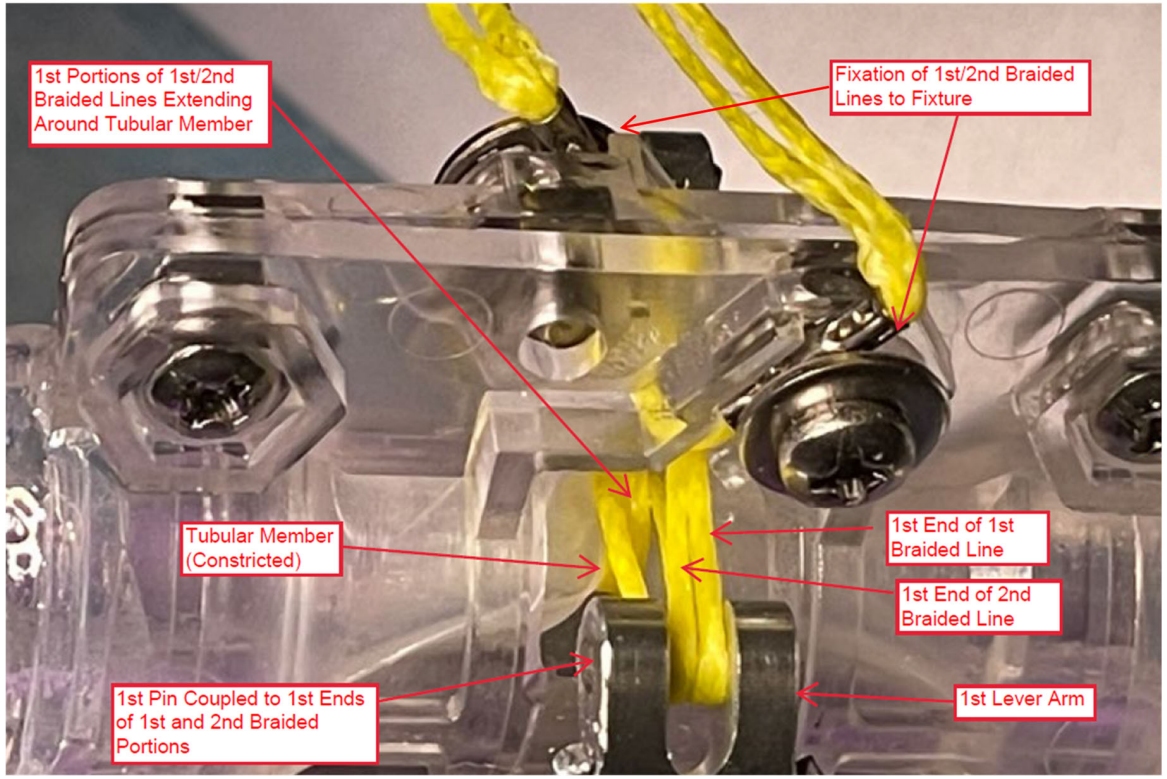


(Symphony Thrombectomy System Brochure at 4.)

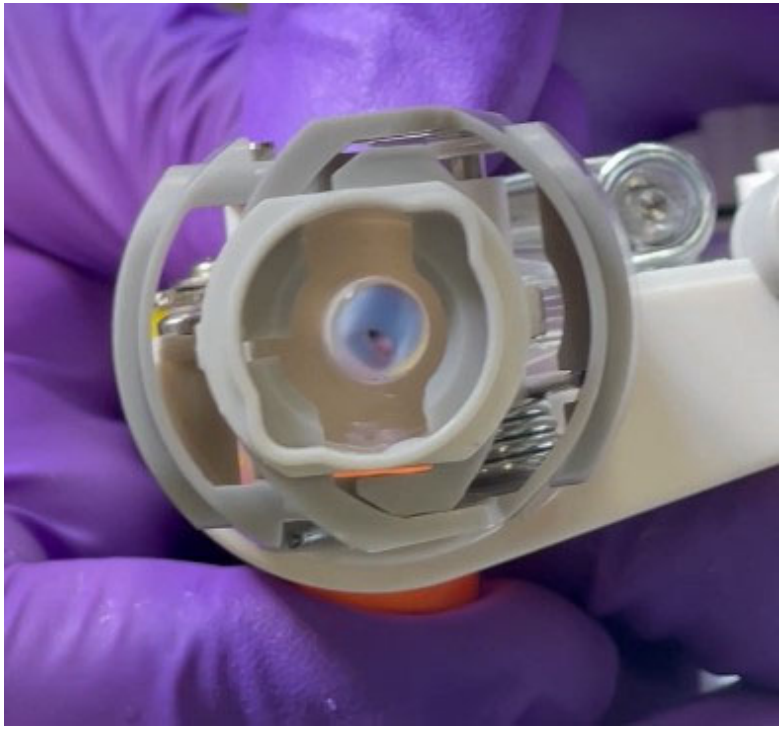
	 (Symphony Thrombectomy System – Overview Animation Video at 1:34 (https://vimeo.com/817718796).)

	SYMPHONY™ THROMBECTOMY SYSTEM **Mechanical Assist Optimizes Clot Engagement & Capture** **ProHelix™ Mechanical Assist**  (Symphony Thrombectomy System Brochure at 8.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a tubular member defining a lumen, wherein the tubular member is elastically deformable from a first position in which the lumen is	The Symphony System hemostasis valve has a collapsible elongate tubular member that defines a lumen (the "Tubular Member" annotated below). The valve lumen is shown below and is configured to "accommodate a wide range of devices." (Symphony brochure at 6). Therefore, the hemostasis valve has a tubular member defining a lumen. The tubular member is elastically deformable

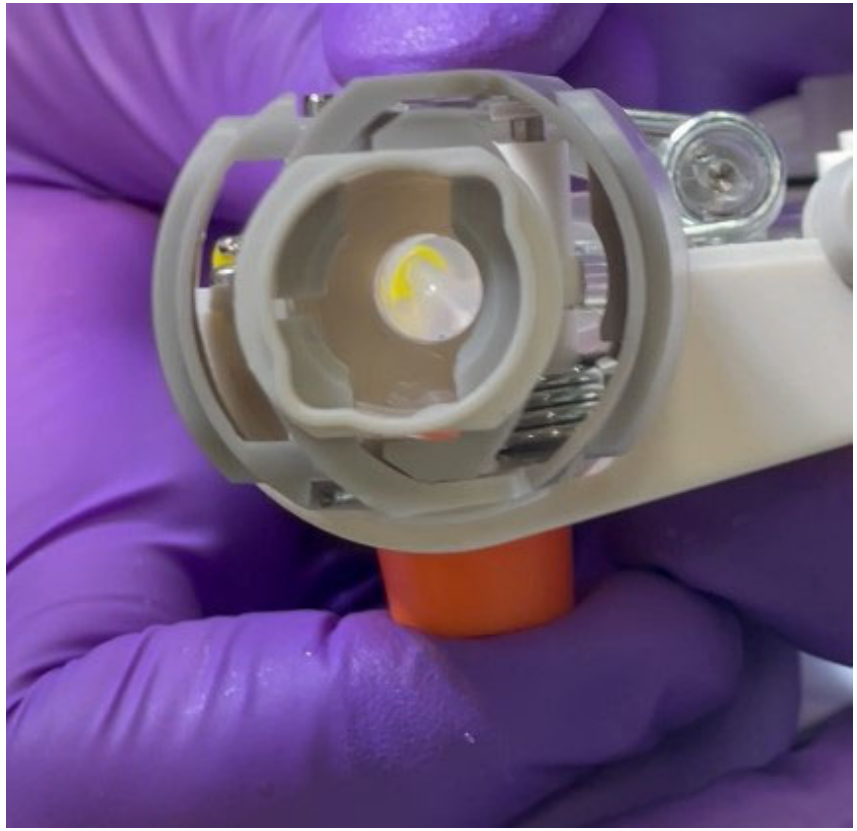
constricted to a second position in which the lumen is at least partially open;	in which, in a first position, the lumen is constricted, and in the second position the lumen is at least partially open.  (Annotated image of internal portion of Symphony System housing, including hemostasis valve with tubular member defining a lumen.)

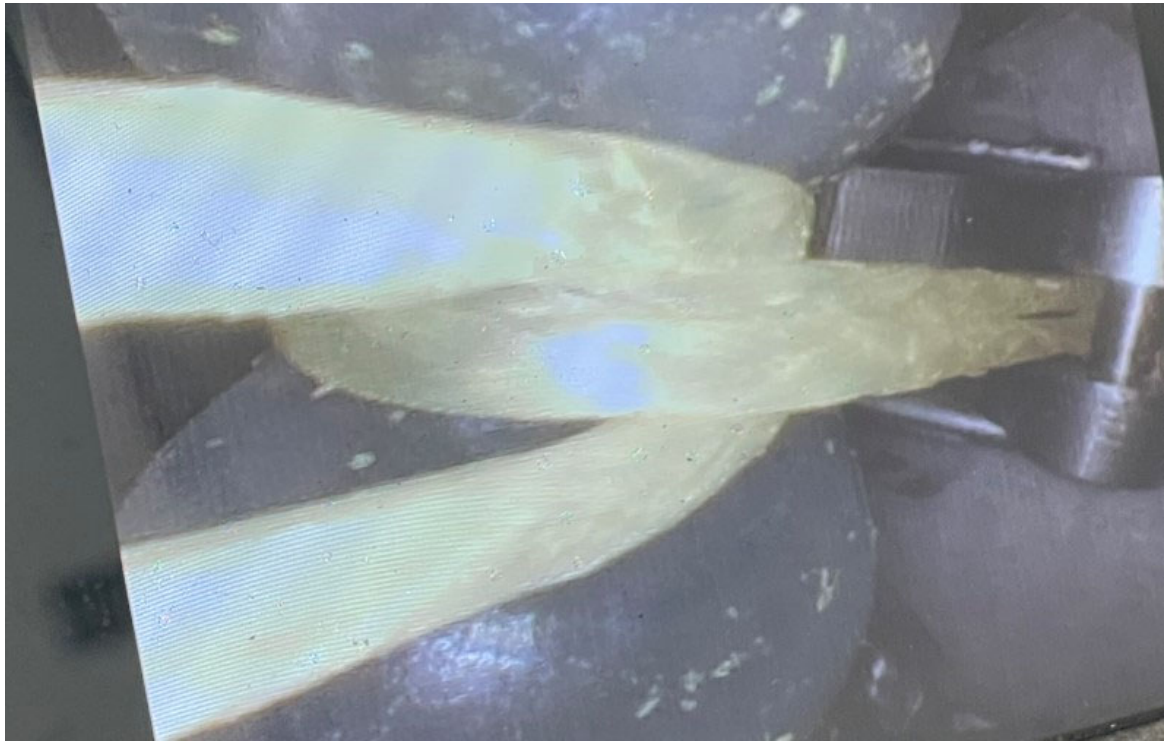


(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having a tubular member defining a lumen (tubular member) constricted and filaments extending around the tubular member.)

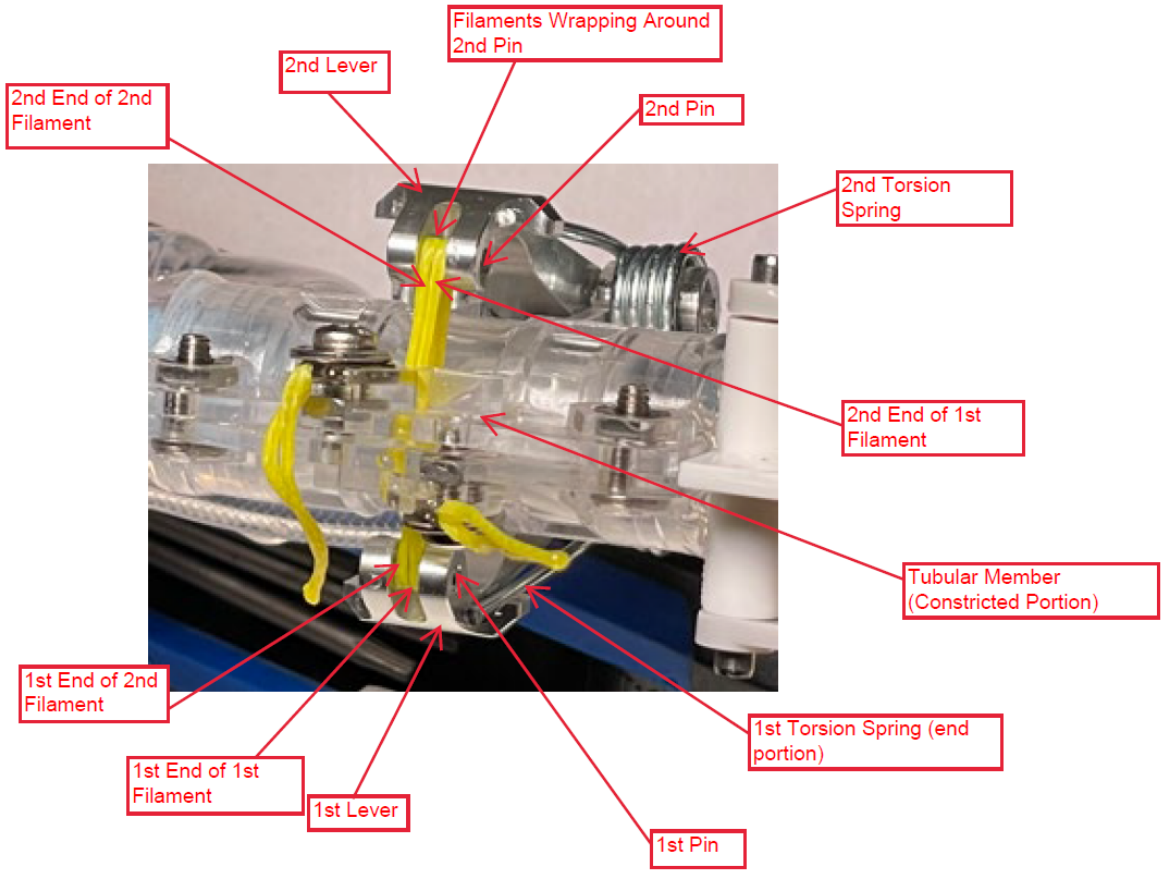
	 (Symphony handle with view down tubular member (lumen) of hemostasis valve with the valve open having the tubular member unconstricted.)

	 (Internal image of hemostasis valve with filaments encircling elongate member in the second position.)

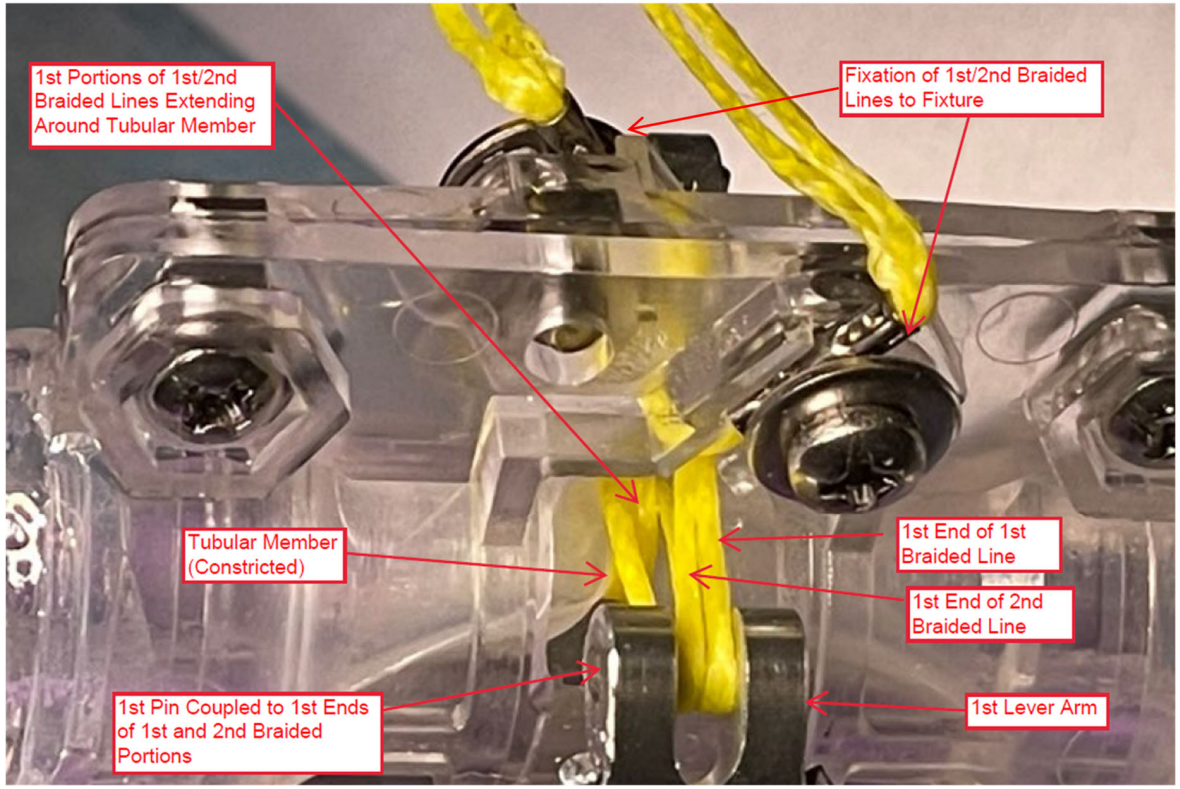
	 (Symphony handle with view down lumen of hemostasis valve with the tubular member of the valve constricted.)

	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member in the first position.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a first actuator;	The Symphony System hemostasis valve has a tensioning mechanism including a pair of actuators, specifically a first actuator comprising first torsion spring(s), a first button, a first lever, and a first pin, and a second actuator comprising second torsion spring(s), a second button, a second lever, and a second pin The first actuator (e.g., the first button/lever/pin) and second actuator (e.g., the second button/lever/pin) are movable between (a) a first position (undepressed button) wherein the lumen is constricted and sealed by the torsion spring pulling the

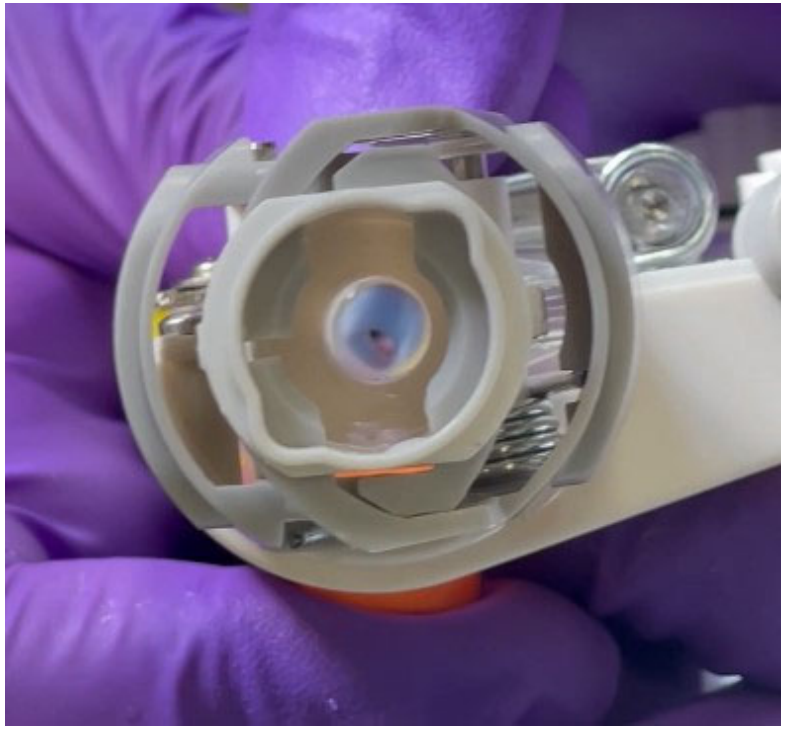
	filaments to tighten the filament around the elongate member and (b) a second position (depressed button) wherein the lumen is at least partially open. (Image of internal portion of housing with hemostasis valve.)

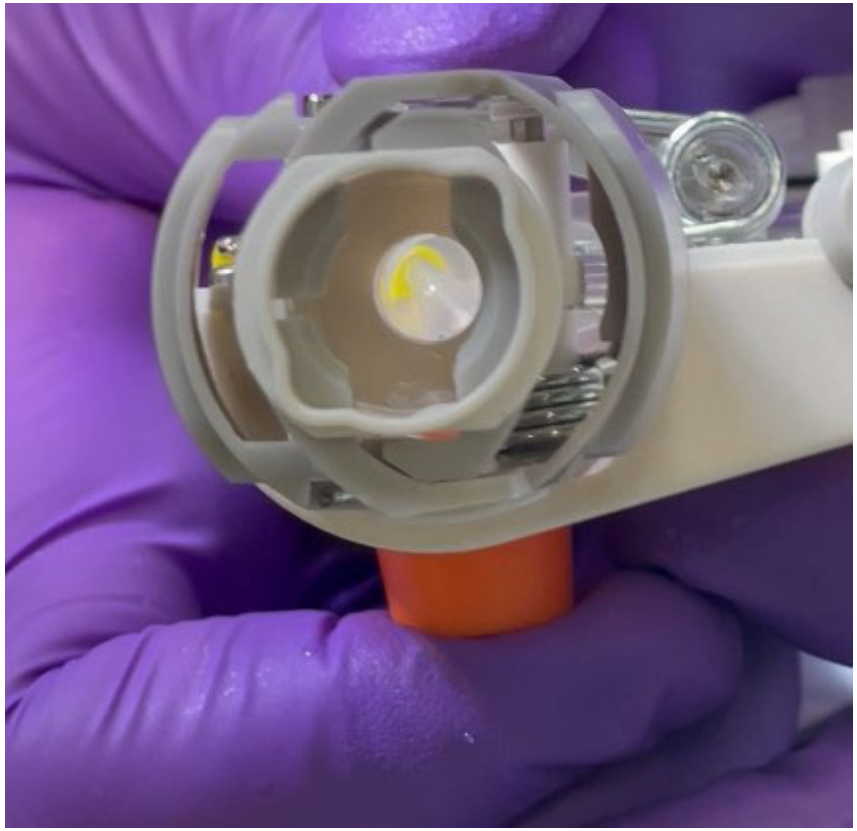


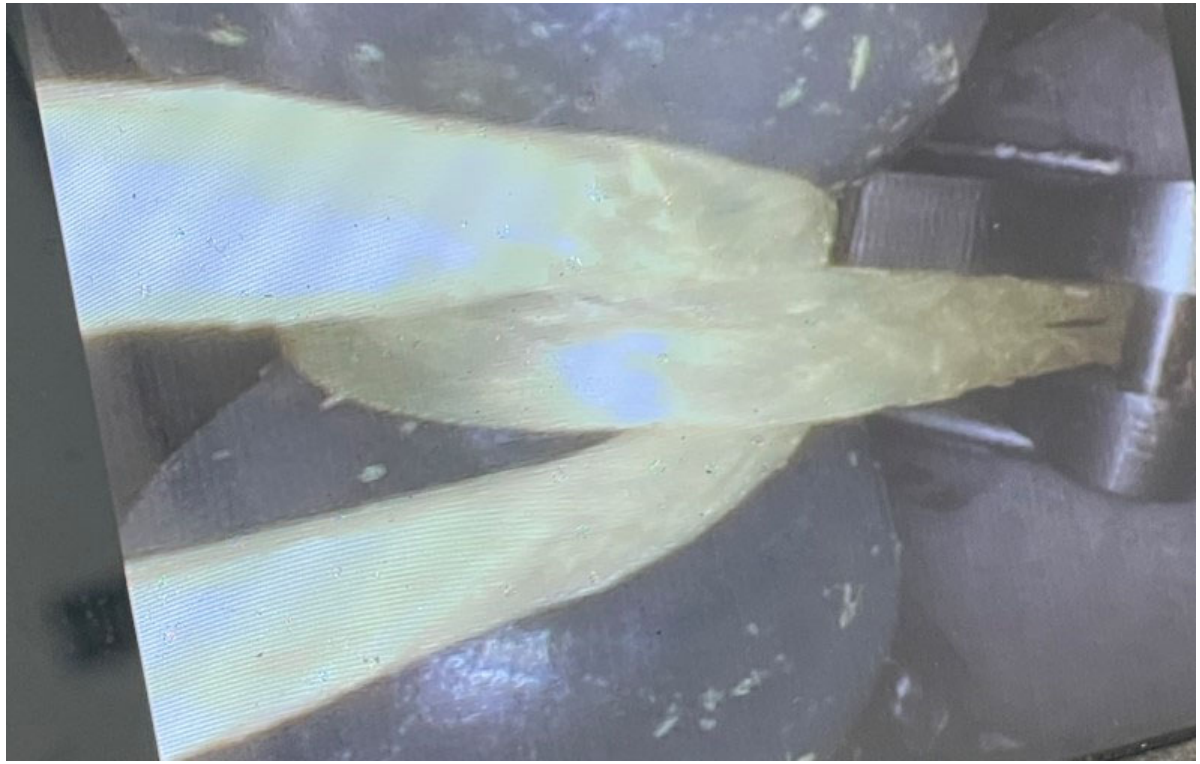
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and filaments extending around the elongate member.)



(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

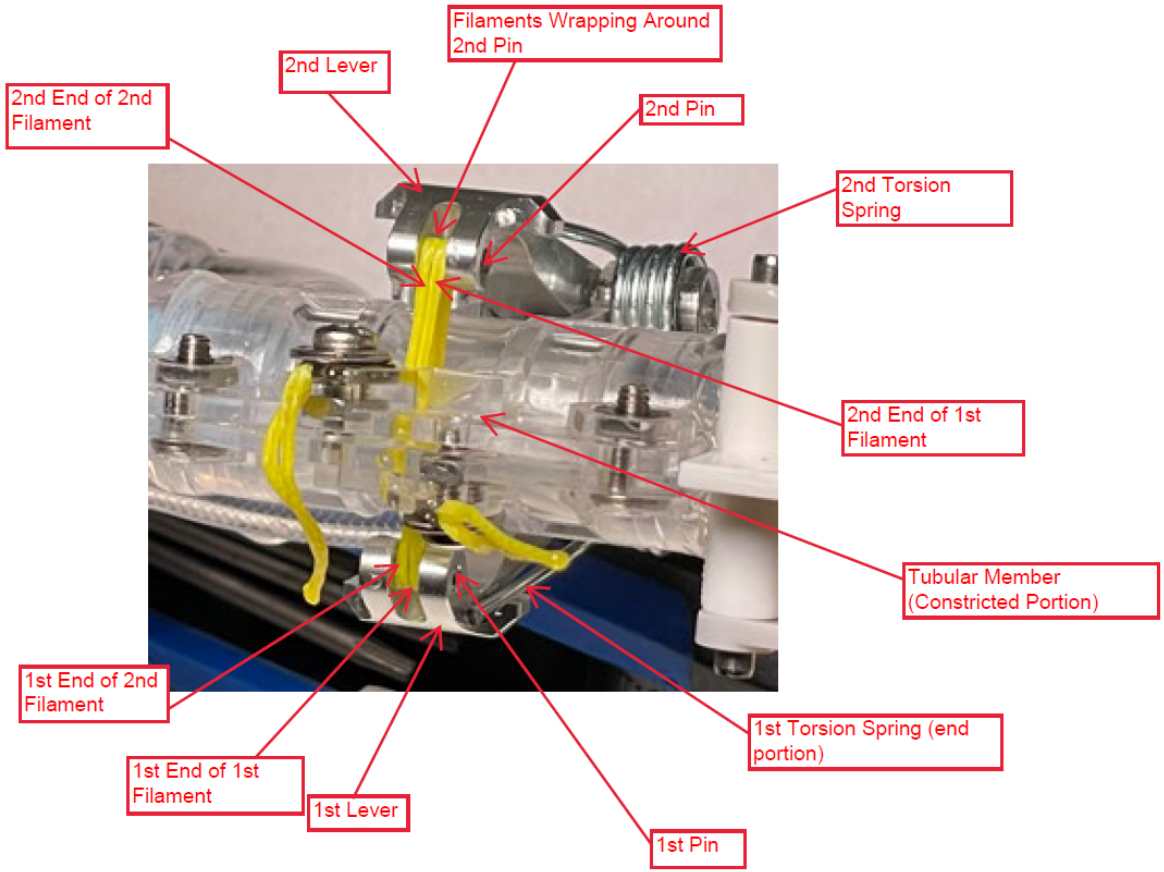
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

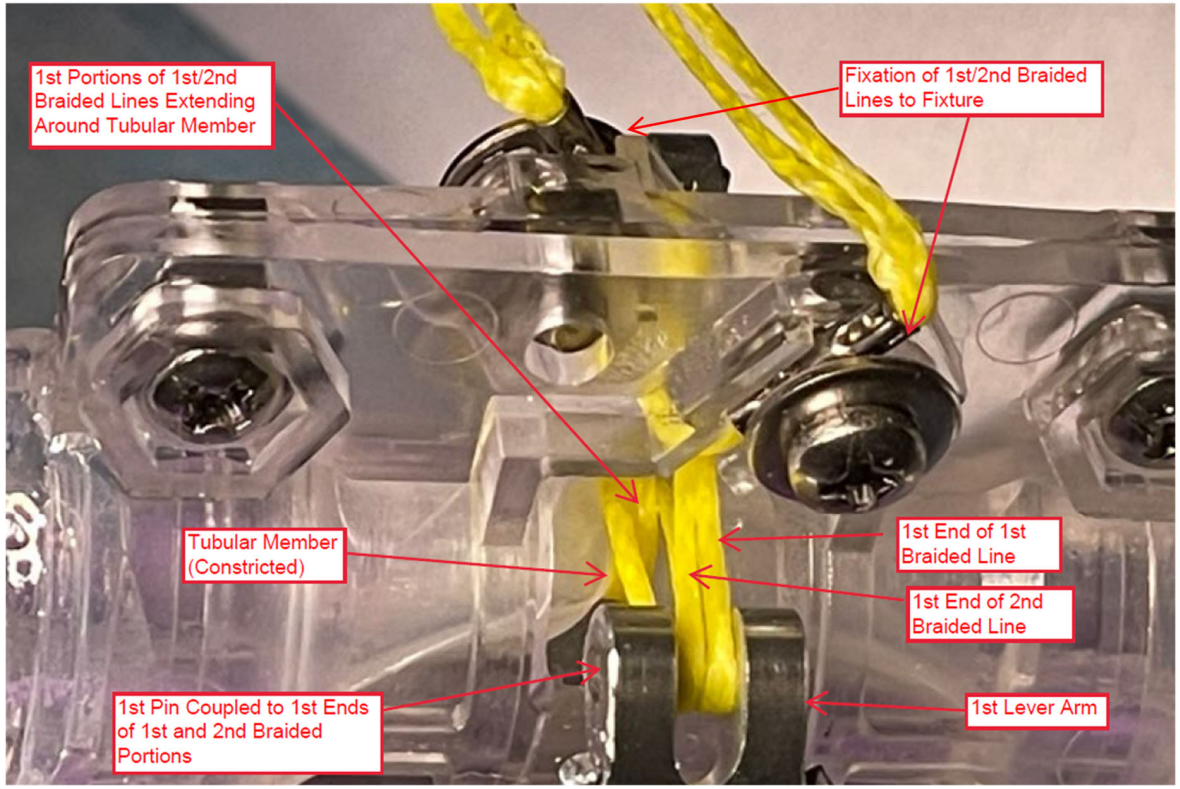
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a second actuator;	See previous limitation. The Symphony System hemostasis valve has a tensioning mechanism including a pair of actuators, specifically a first actuator comprising first torsion spring(s), a first button, a first lever and a first pin, and a second actuator comprising second torsion spring(s), a second button, a second lever, and a second pin The first actuator (e.g., the first button/lever/pin) and second actuator (e.g., the second button/lever/pin) are movable between (a) a first

	position (undepressed button) wherein the lumen is constricted and sealed by the torsion spring pulling the filament to tighten the filament around the elongate member and (b) a second position (depressed button) wherein the lumen is at least partially open. To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a first filament configured in a first loop completely around the tubular member and having a first portion extending from the first loop toward the first actuator and a second portion extending from the first loop toward the second actuator; and	The Symphony System hemostasis valve has a tensioning mechanism including a first filament and a second filament, each extending in a loop around the tubular member. The first loop of the first filament extends completely around the elongate member, and a first portion of the first filament extends from the first loop toward and then loops around the pin of the first actuator (first lever/pin/button), and a second portion of the first filament extends towards and then loops around the pin of the second actuator (second lever/pin/button).

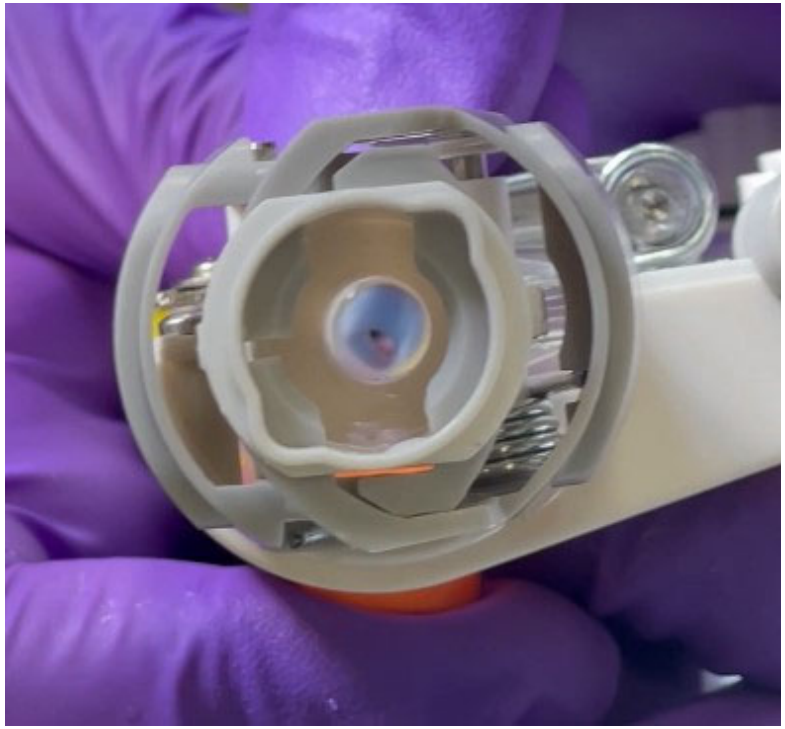
	 (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)



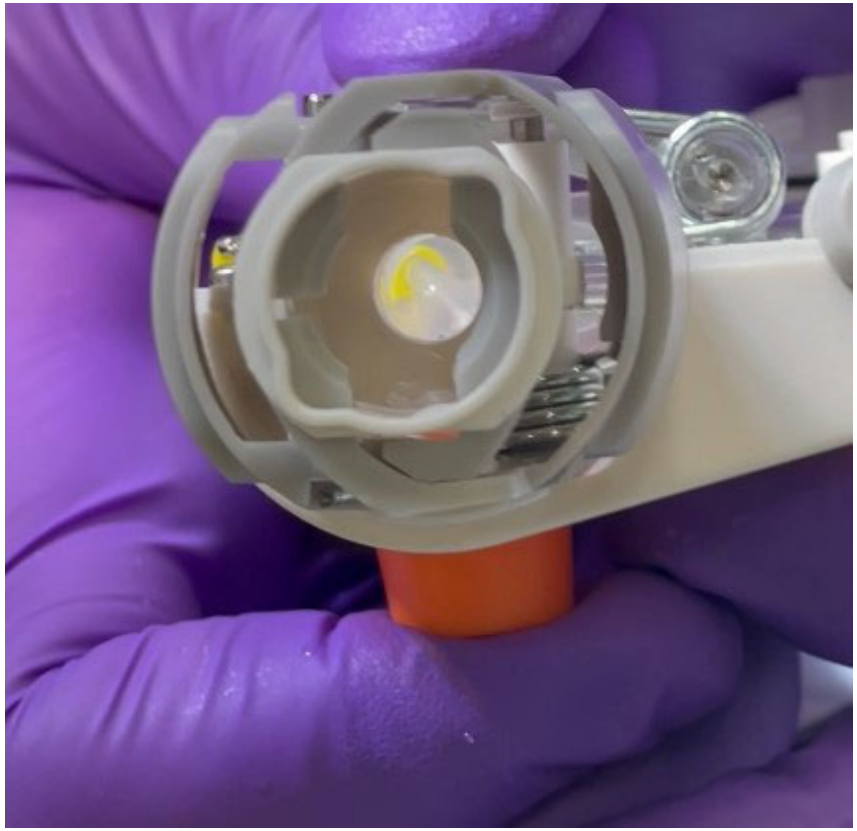
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)

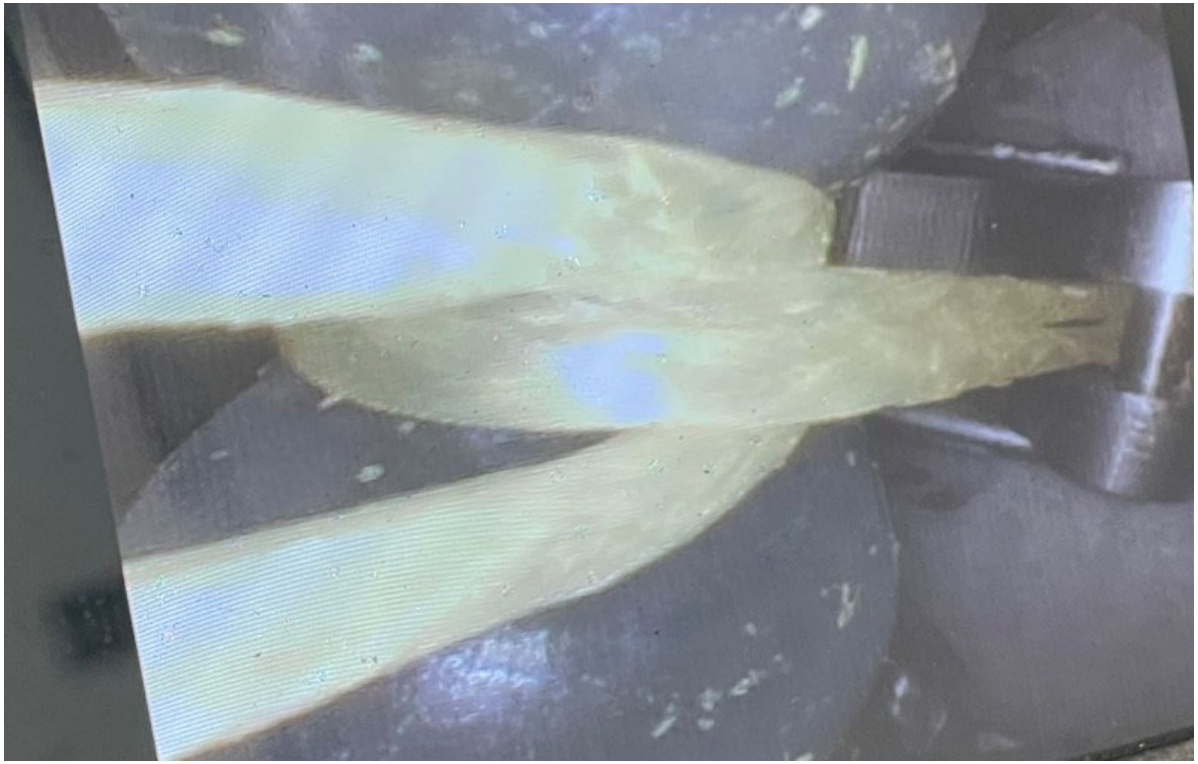


(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

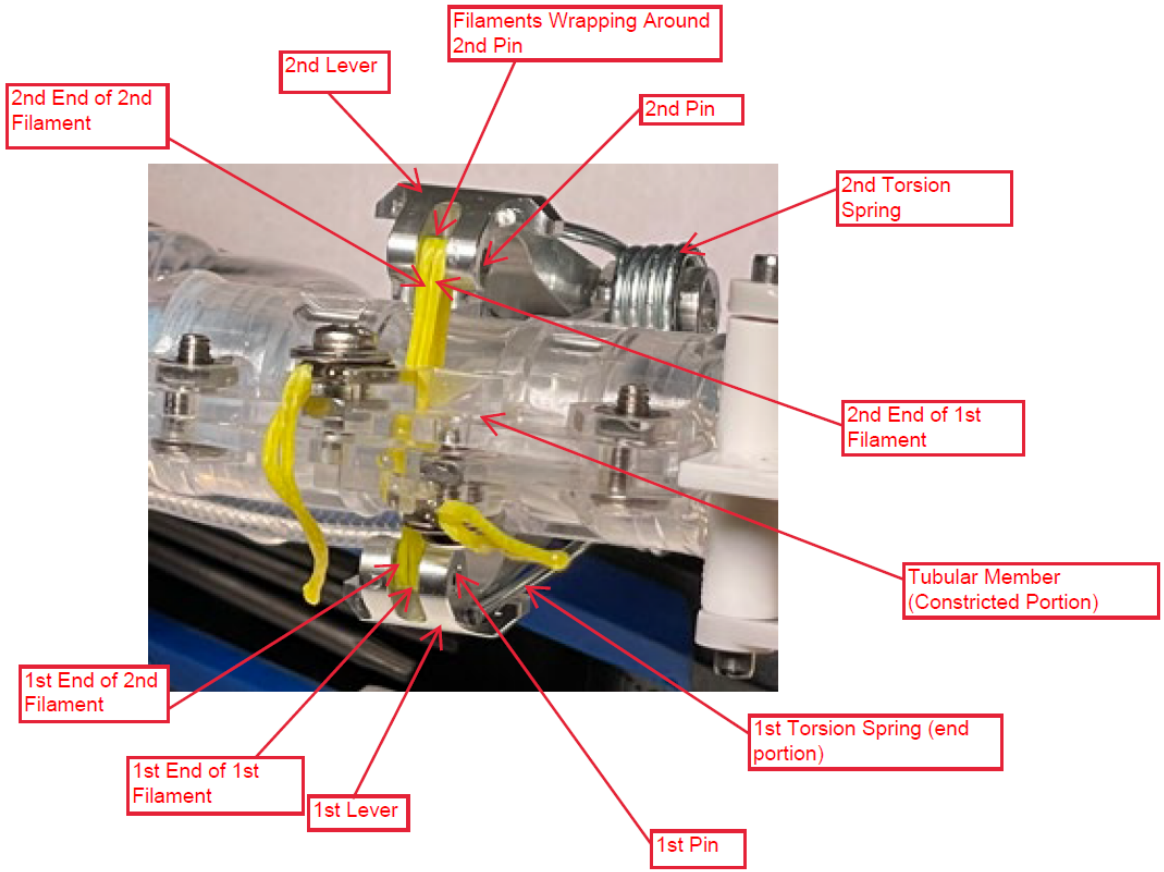
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

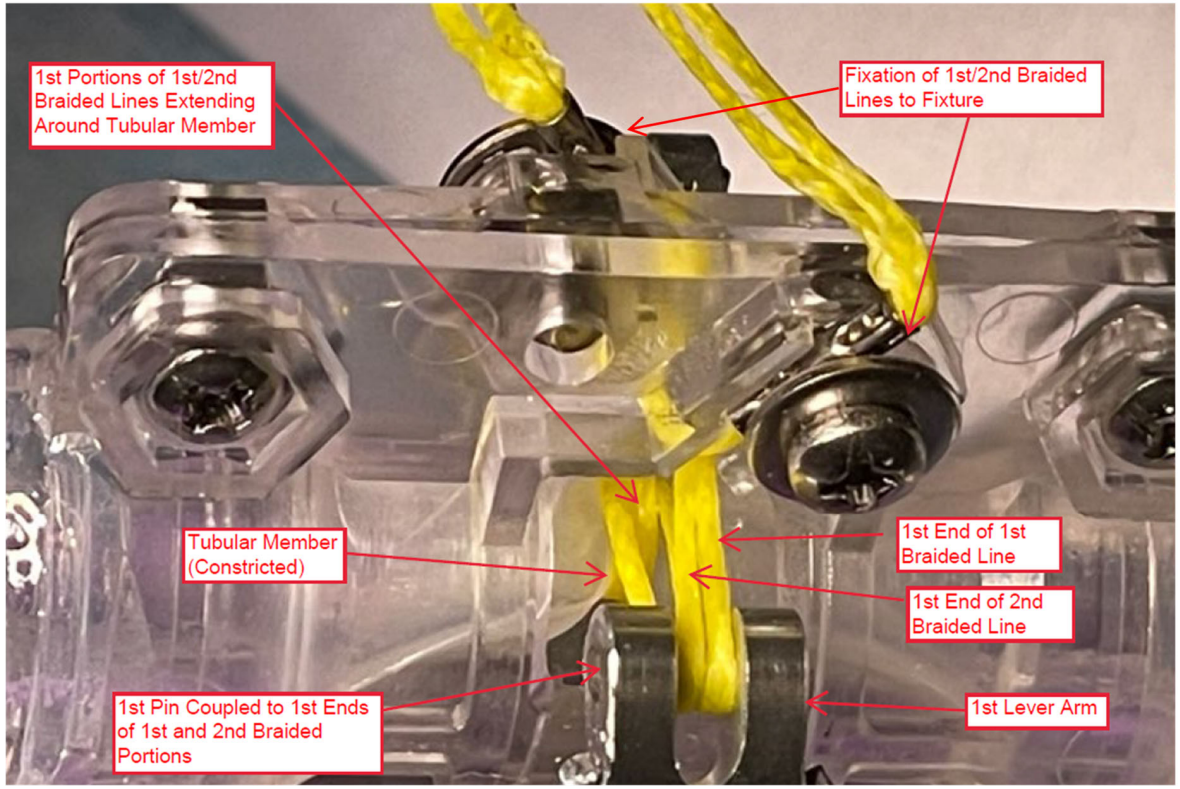
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a second filament configured in a second loop completely around the tubular member and having a first portion extending from the second loop toward the first actuator	The Symphony System hemostasis valve has a tensioning mechanism including a first filament and a second filament, each extending in a loop around the tubular member. The second loop of the second filament extends completely around the elongate member, and a first portion of the second filament extends from the first loop toward and then loops around the pin of the first actuator (first

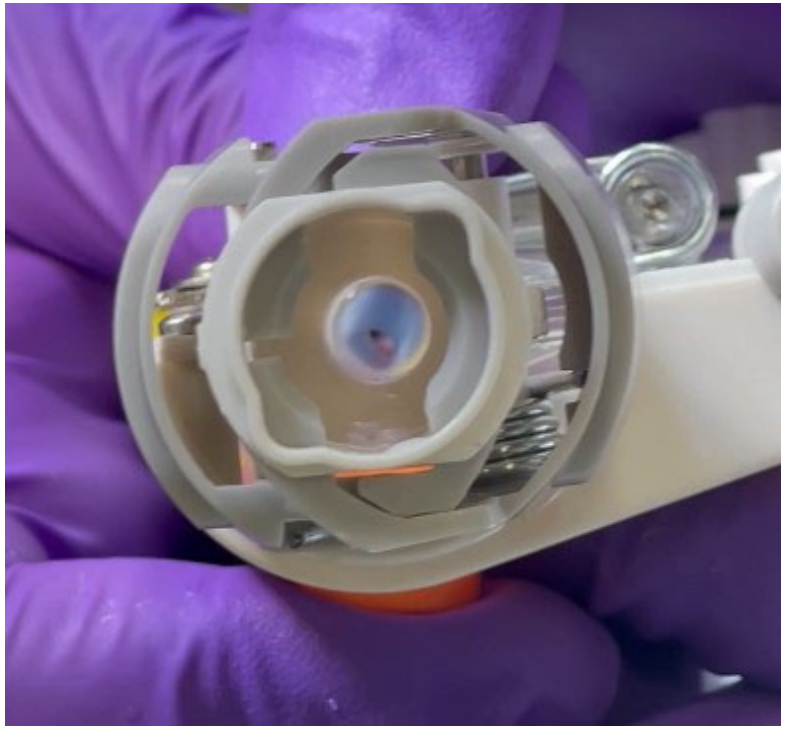
and a second portion extending from the second loop toward the second actuator;	lever/pin/button), and a second portion of the second filament extends towards and then loops around the pin of the second actuator (second lever/pin/button). (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)



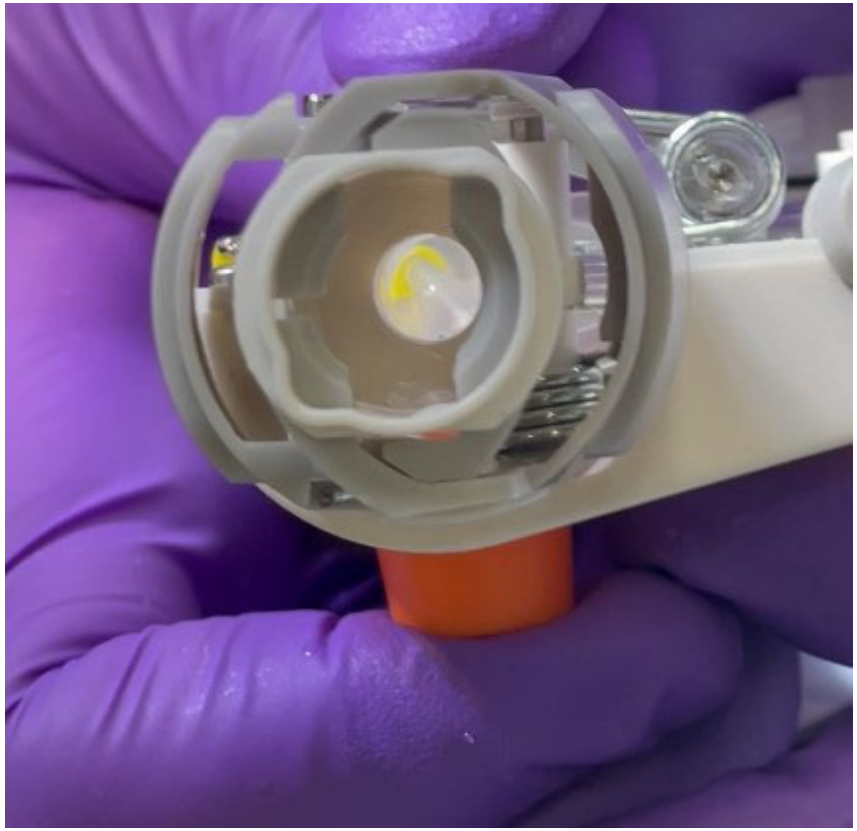
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)

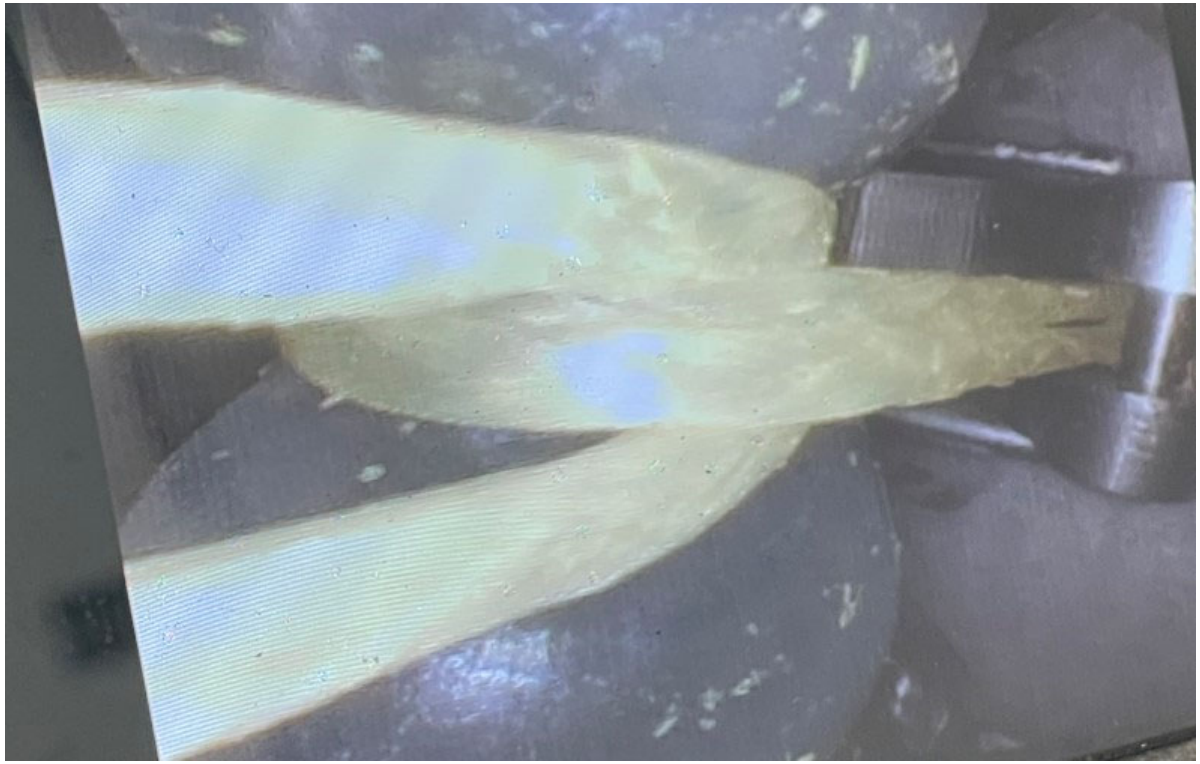


(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

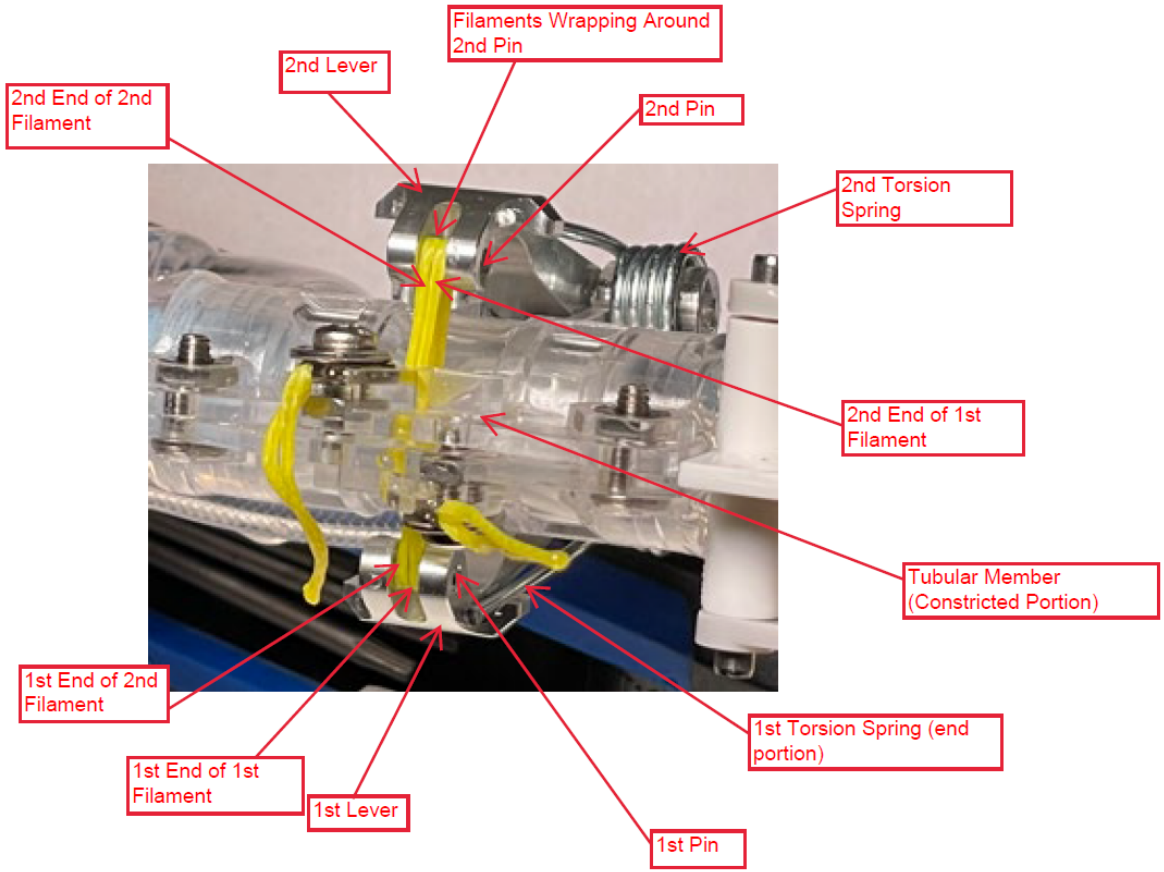
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

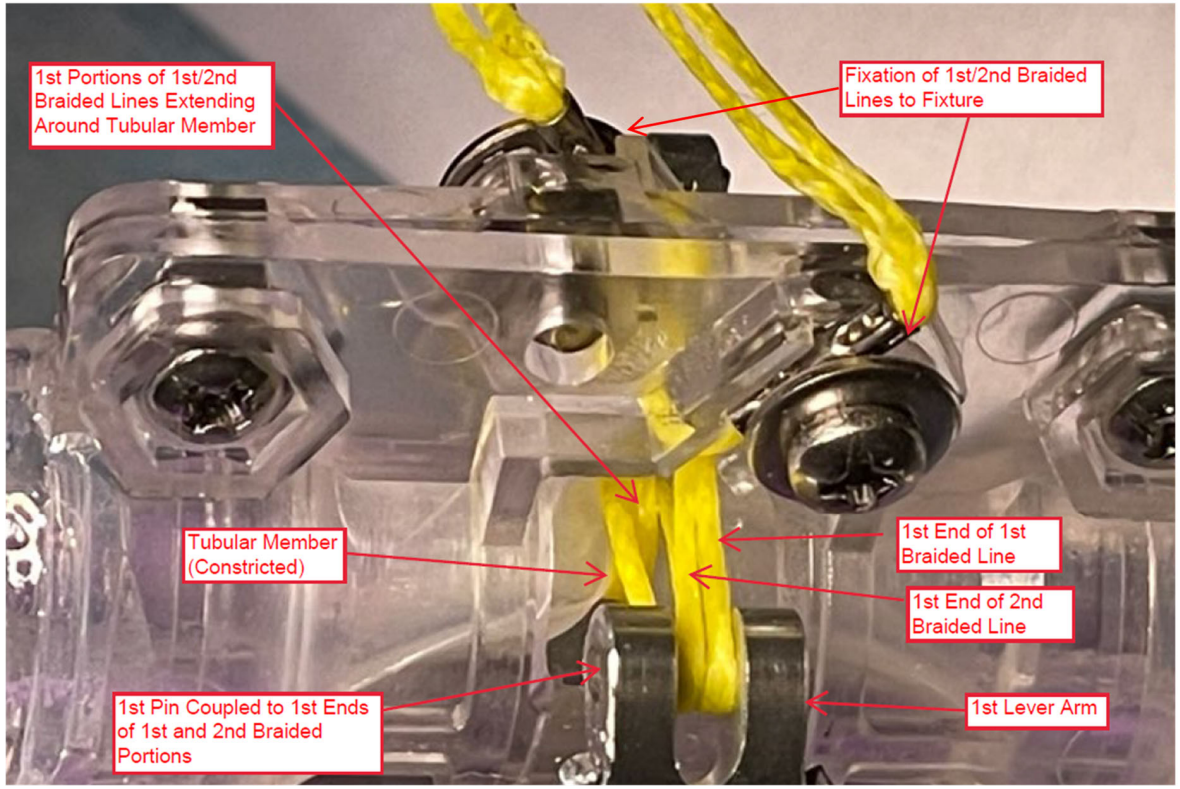
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
wherein— the first actuator and the second actuator are biased away from one another to elastically deform the tubular member to the first position by (a) increasing a	The Symphony System hemostasis valve comprises a first actuator (first lever/pin/button) and second actuator (second lever/pin/button) that are biased outwards from the rigid plastic housing and the tubular in the first position (constricted, button undepressed) and away from one another by first torsion spring(s) and second torsion spring(s). This biasing increases the tension in the first and second filament, decreasing the dimension of the first loop of the first

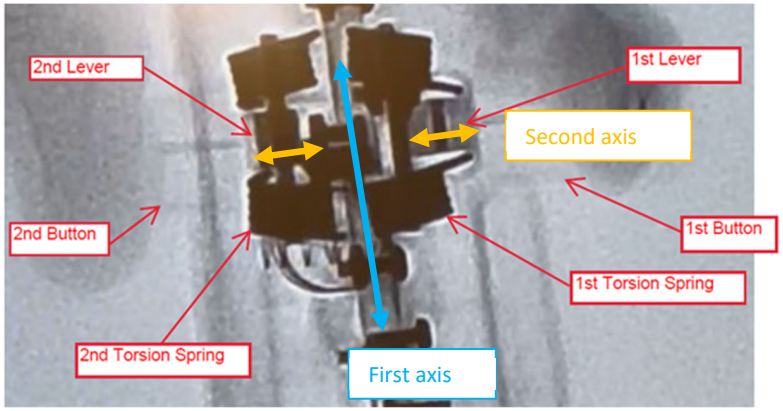
tension in the first filament to decrease a dimension of the first loop and (b) increasing a tension in the second filament to decrease a dimension of the second loop; and	filament and the second loop of the second filament, constricting and elastically deforming the tubular member defining a lumen. (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)

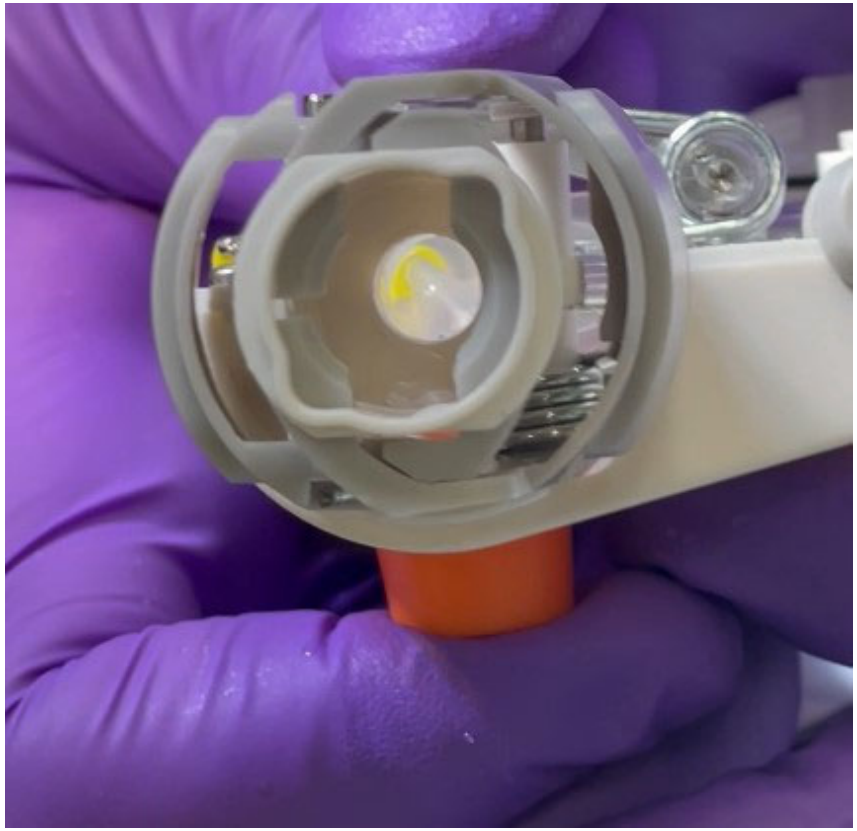


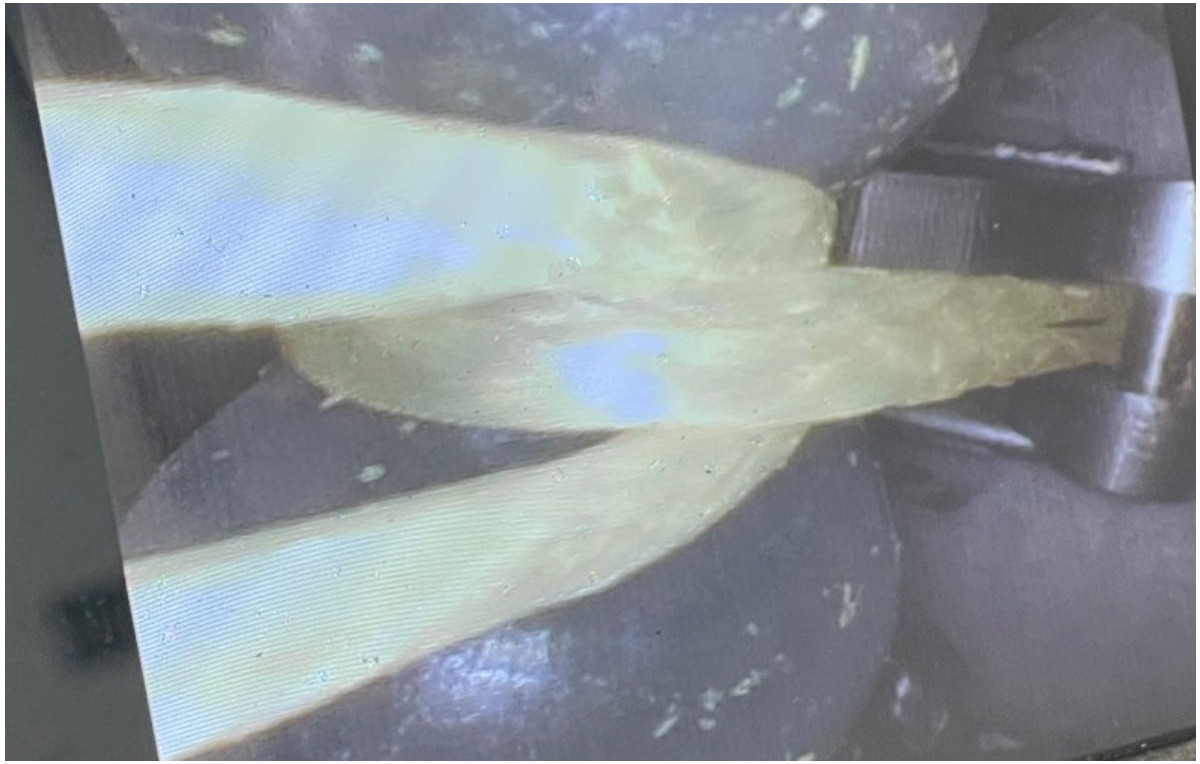
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)



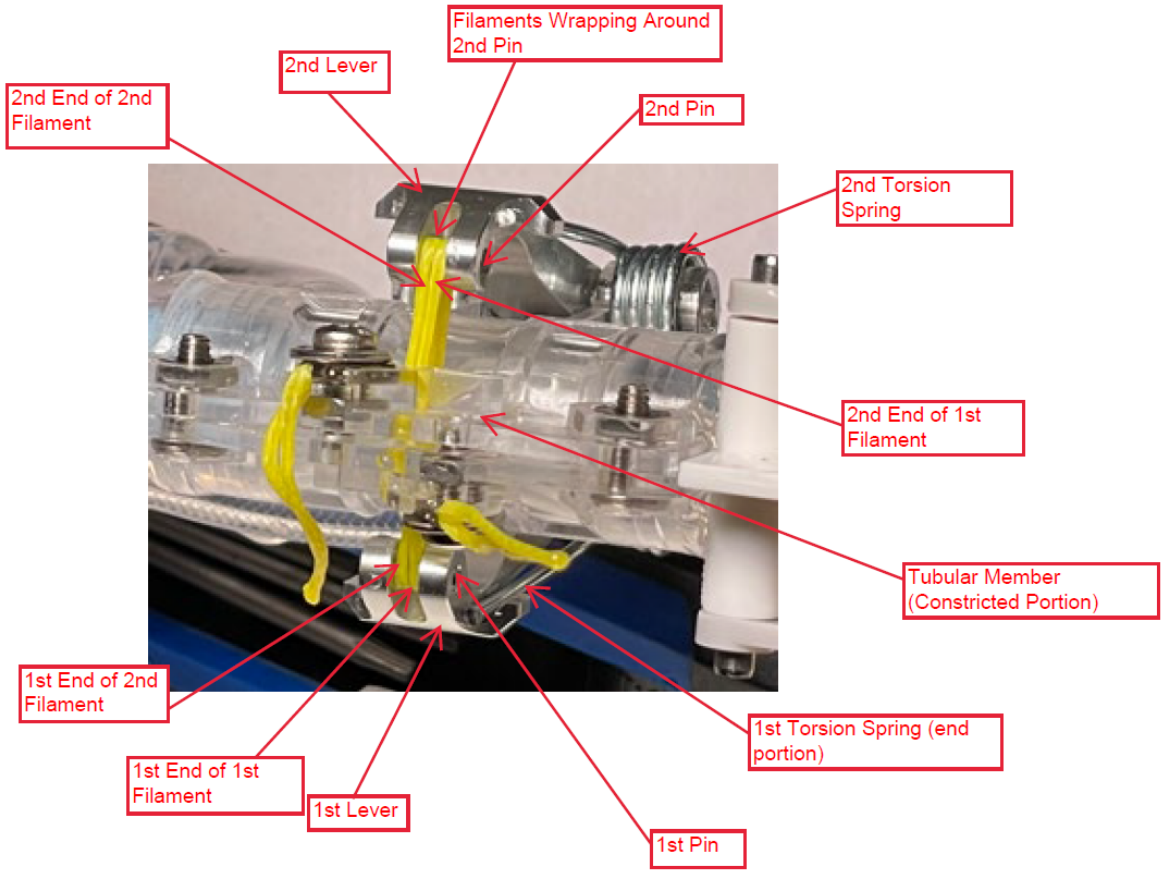
(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

	 (Annotated x-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs (two for each lever), as part of tensioning mechanism for hemostasis valve in Symphony System housing.)

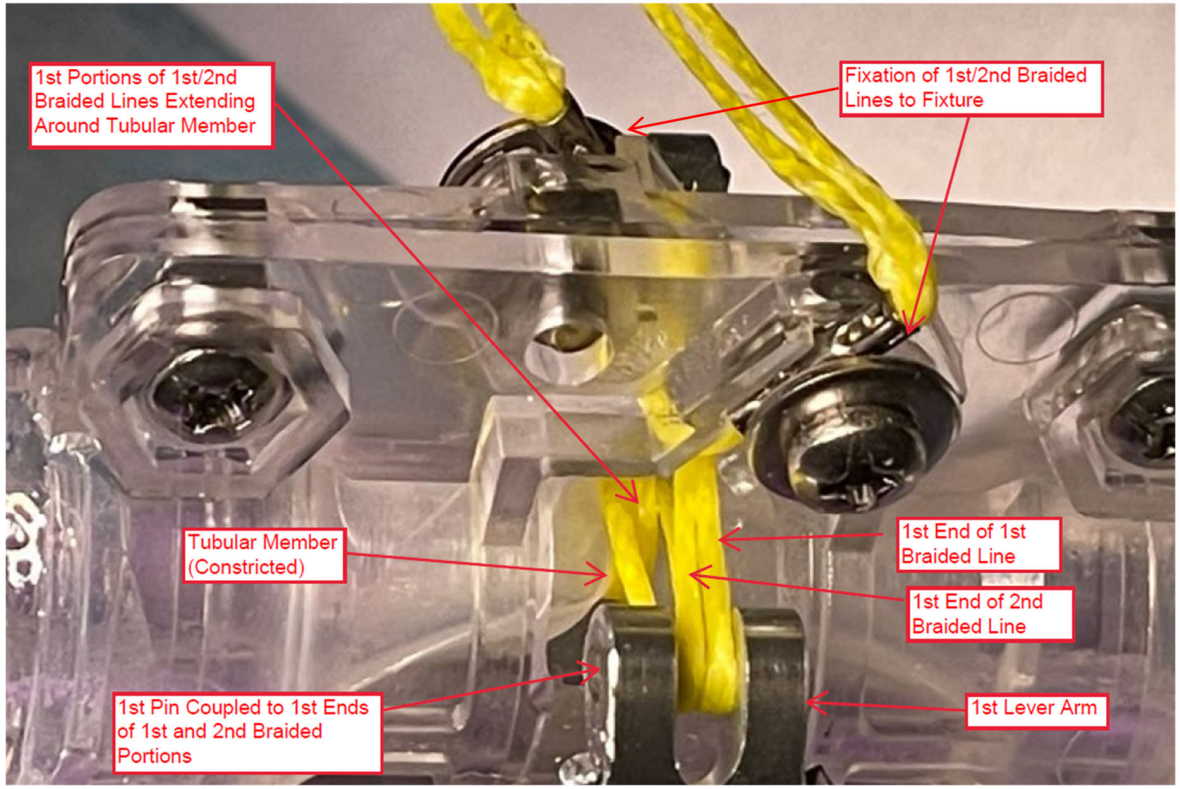
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member in the first position.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents
the first actuator and the second actuator are movable toward one another to permit the tubular member to return to the second position by (a) decreasing the tension in the	The Symphony System hemostasis valve comprises a first actuator (first lever/pin/button) and second actuator (second lever/pin/button) that are movable inwards to the rigid plastic of the handle/housing and the tubular member of the valve and towards one another to a second position (at least partially unconstricted, button depressed). Depressing the buttons (along the second access towards the tubular member) on the hemostasis valve decreases the tension

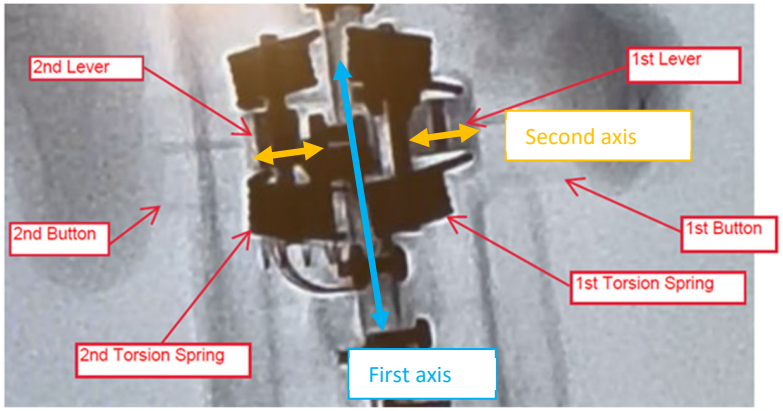
first filament and (b) decreasing the tension in the second filament.	in the first and second filament, allowing the dimension of the first loop of the first filament and the second loop of the second filament to increase, at least partially opening the tubular member defining a lumen. (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)

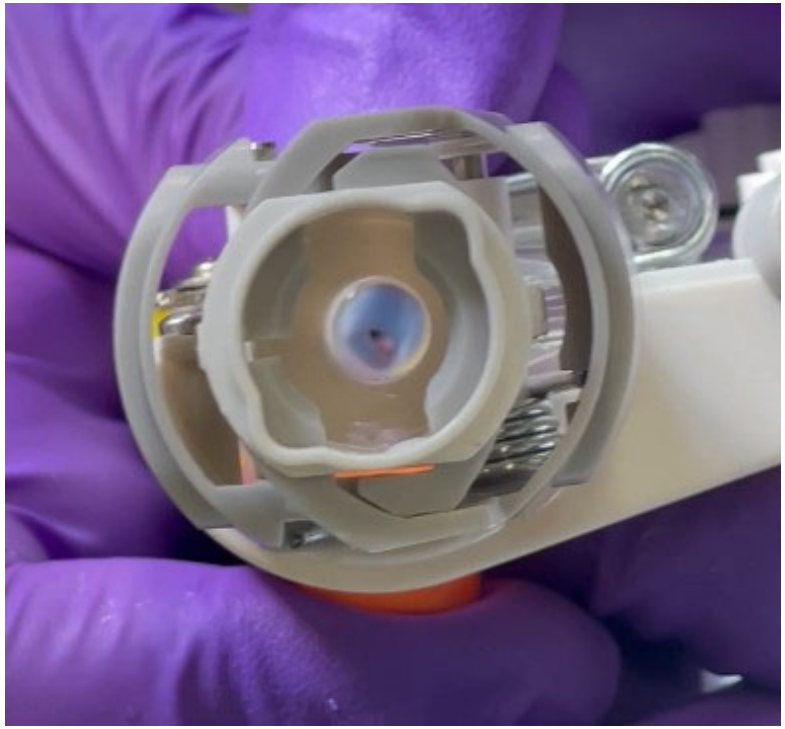


(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)



(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

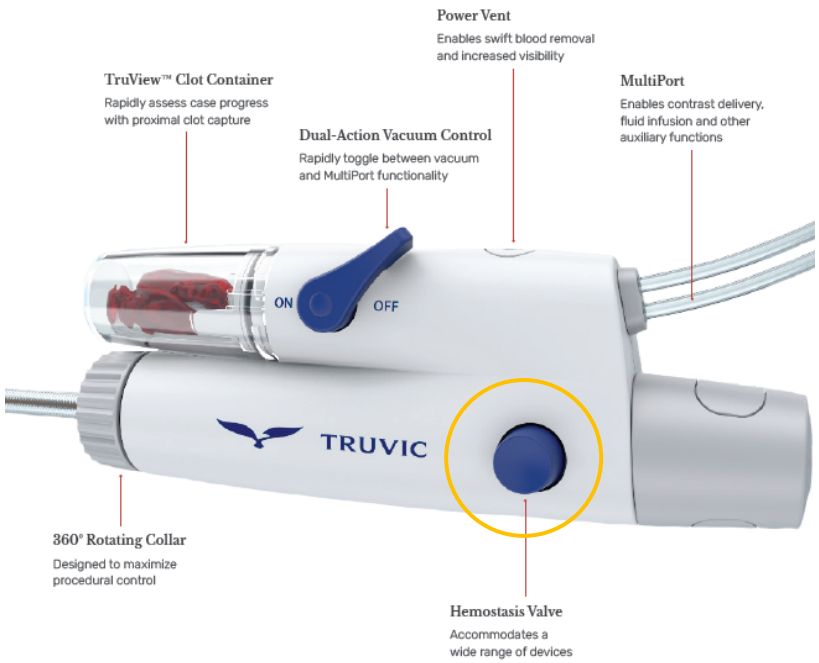
	 (Annotated x-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs (two for each lever), as part of tensioning mechanism for hemostasis valve in Symphony System housing.)

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

	 (Internal image of hemostasis valve with filaments encircling elongate member in the second position.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents
[16] The valve assembly of claim 15 wherein the first actuator and the second actuator each comprise a button.	As can be seen above in Claim 15, the Symphony System hemostasis valves comprise a first actuator and a second actuator that each comprise a button.

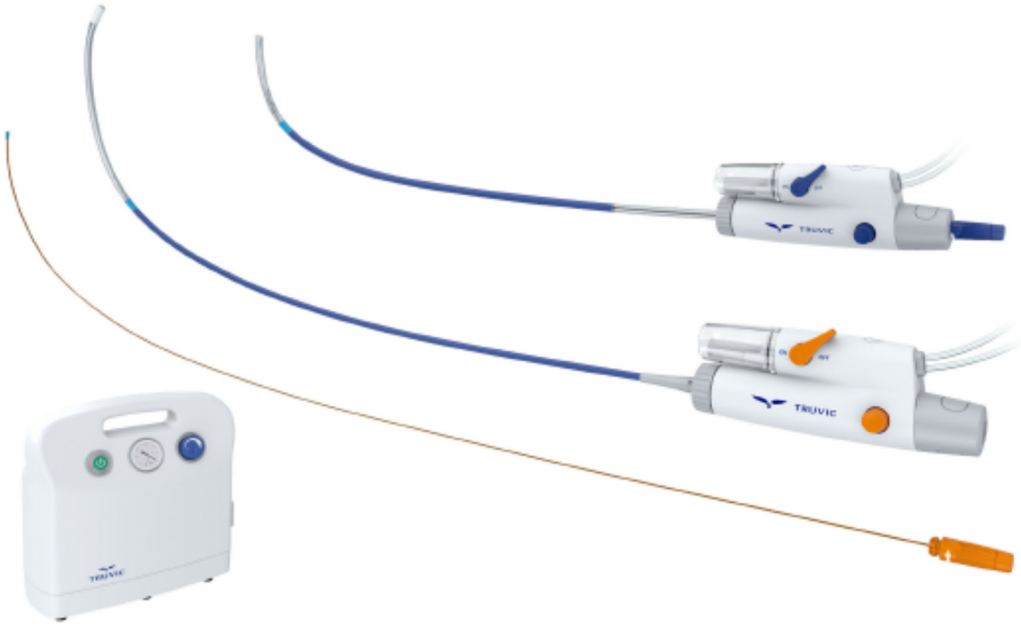
High-Powered, Continuous Vacuum with Real-Time Case Assessment

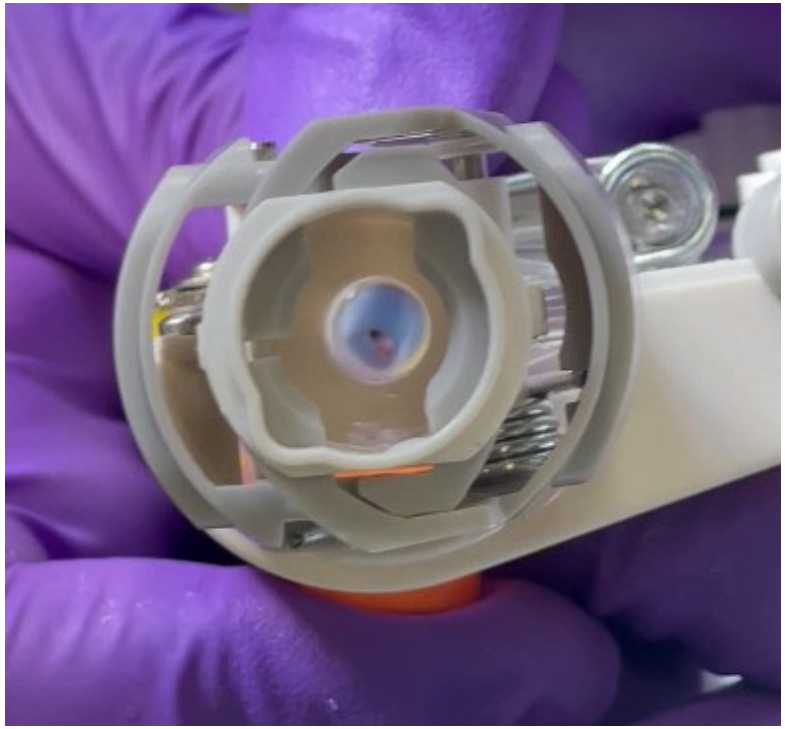
BigShot™ Controller

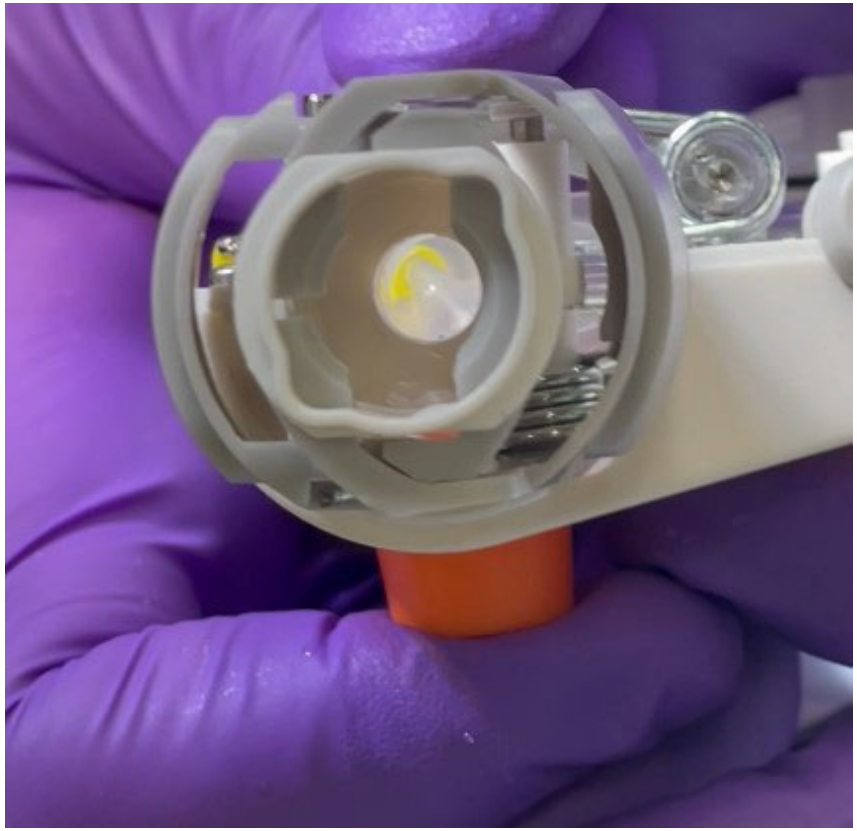


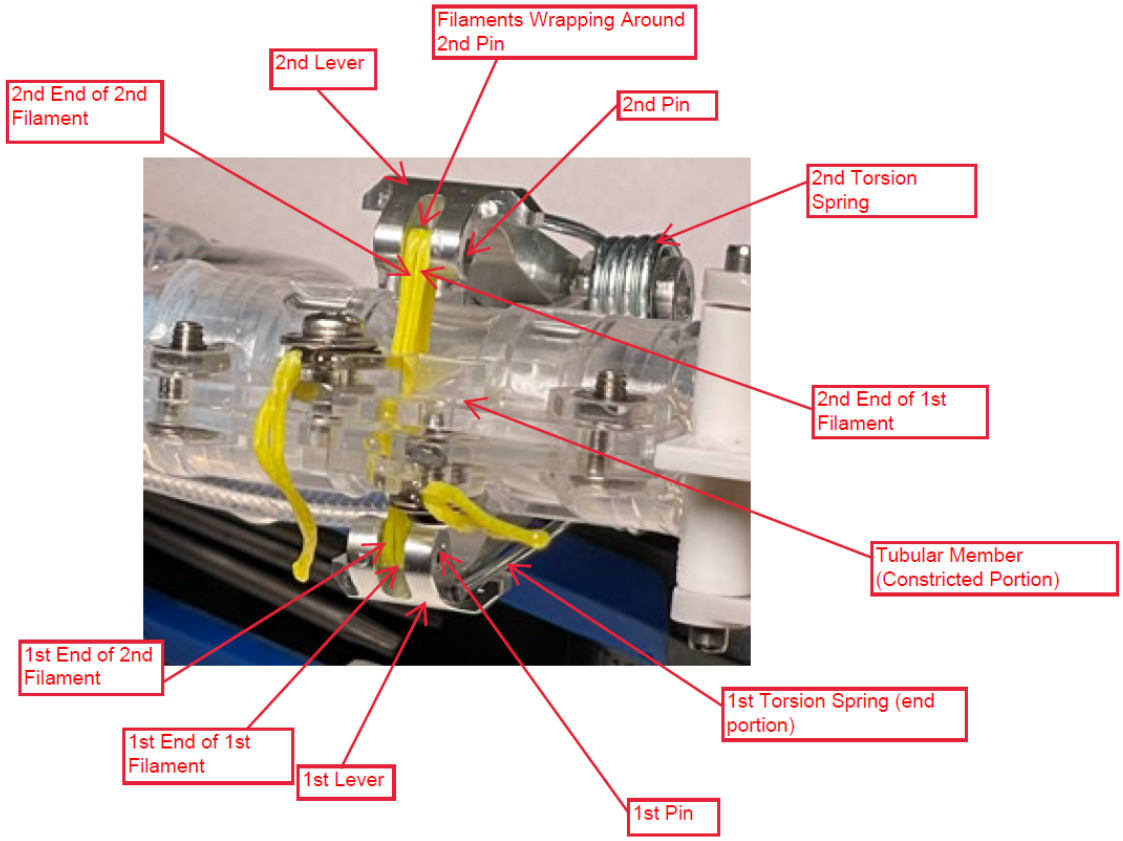
(Annotated Symphony Thrombectomy System Brochure at 6.)

A hemostasis valve is positioned within each of the two Symphony handles. The hemostasis valve is operated by two blue or two orange buttons, depending on the handle.

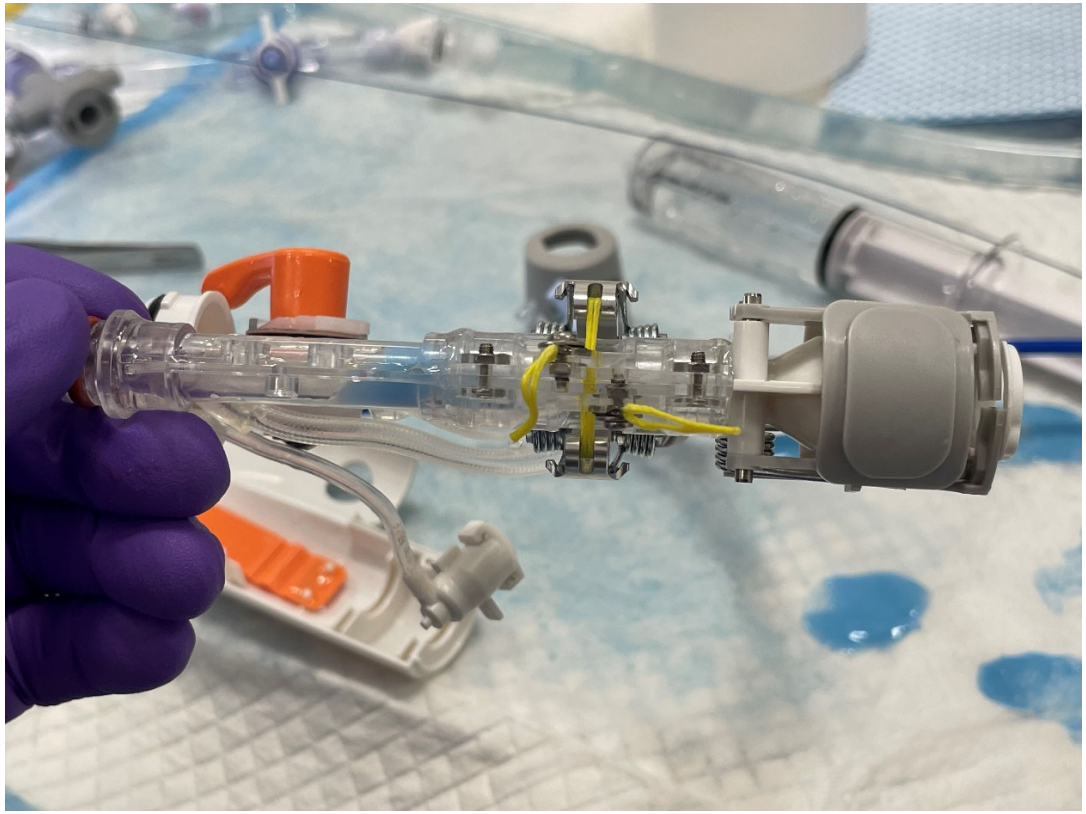
	 (Symphony Thrombectomy System Brochure at 2.)

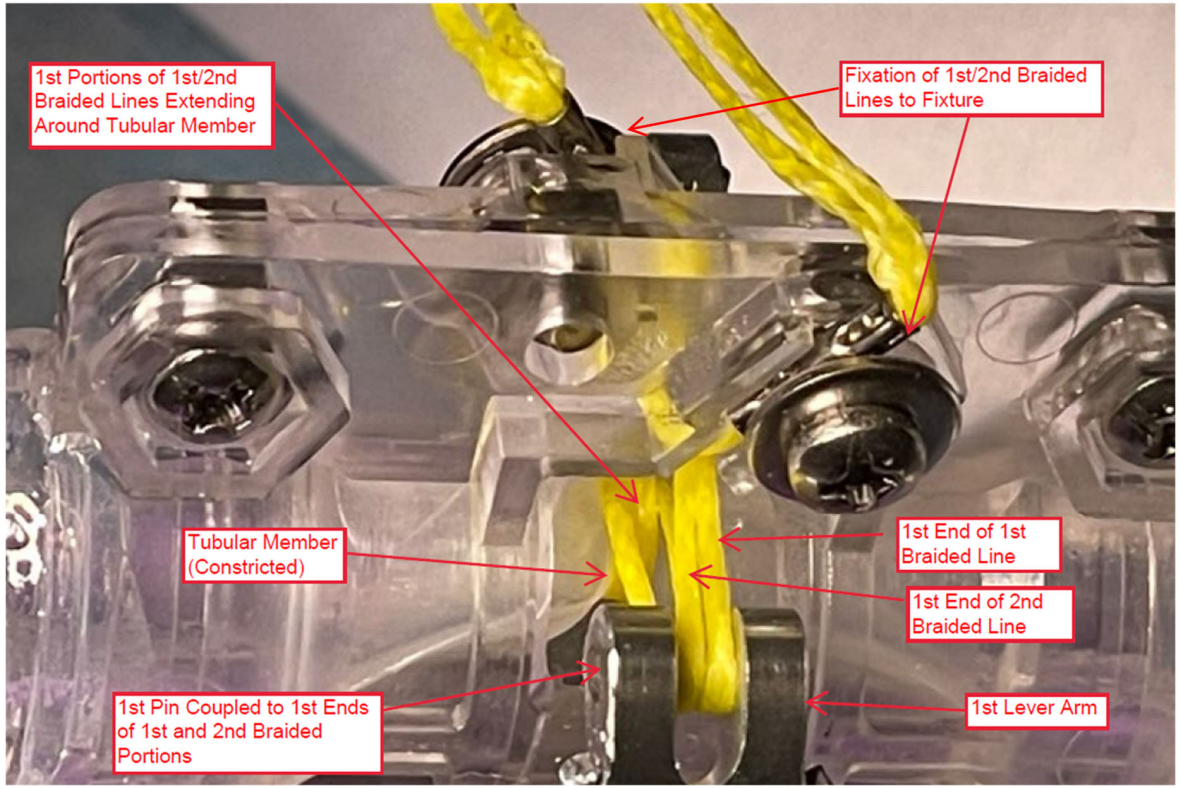
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[17] The valve assembly of claim 15 wherein the first filament is flexible, and wherein the second filament is flexible.	As can be seen above in Claims 1 and 15, the Symphony System has a flexible first filament with a first loop and a flexible second filament with a second loop that extend completely around the tubular (elongate) member.

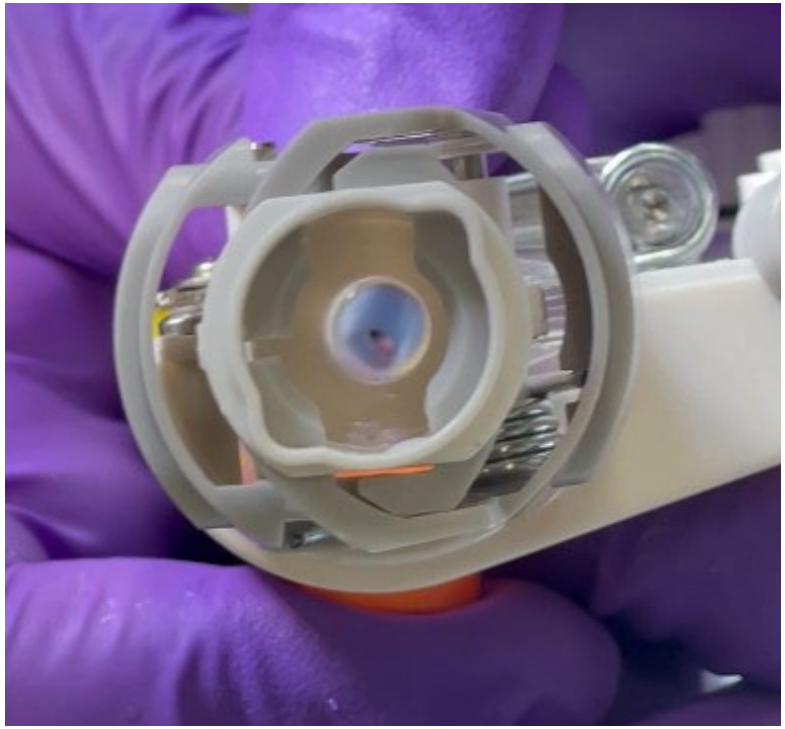


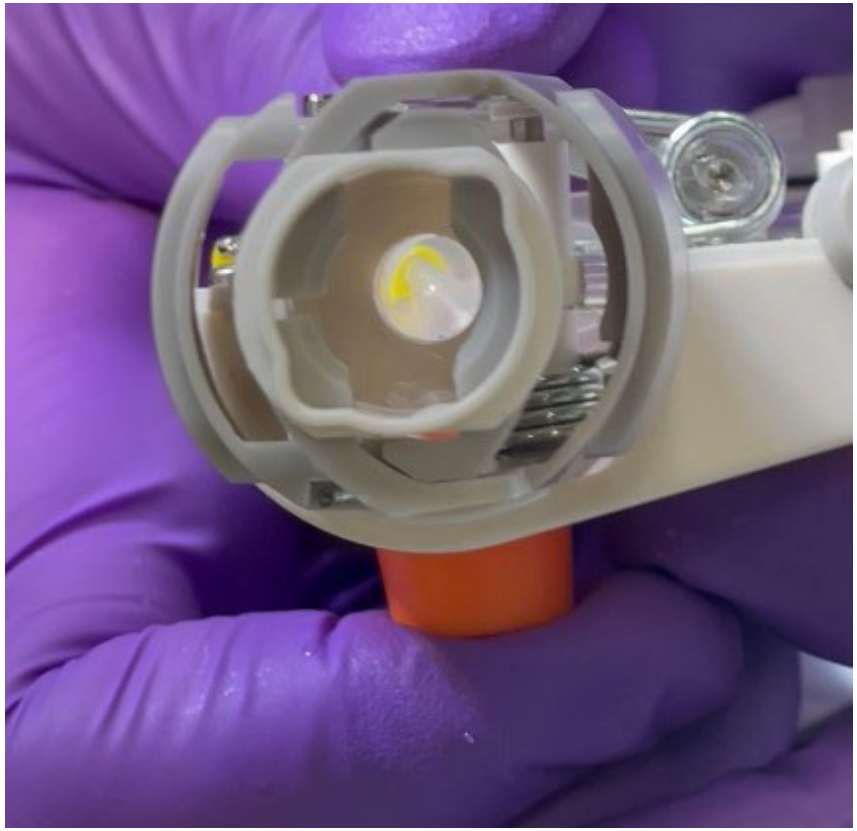
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first filament coupled to and acted on by the first actuator and the second end of the first filament coupled to and acted on by the second actuator.)

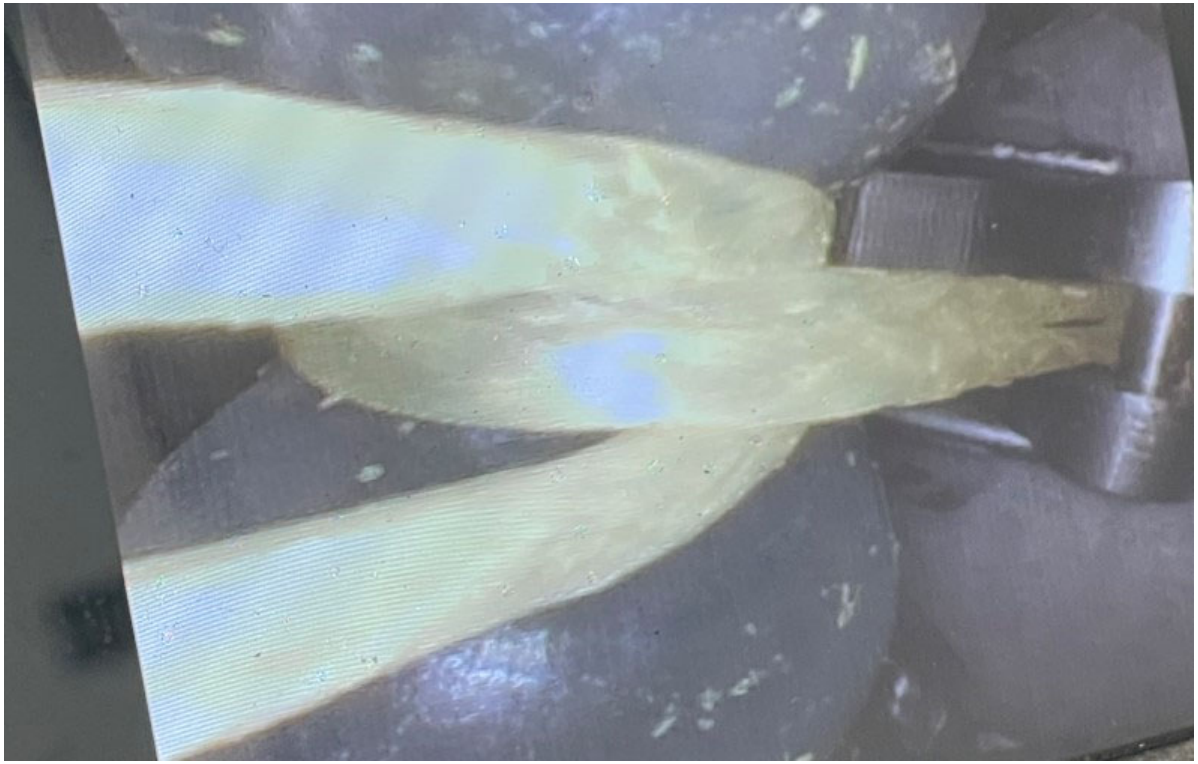
	 (Image of internal portion of housing with hemostasis valve.)



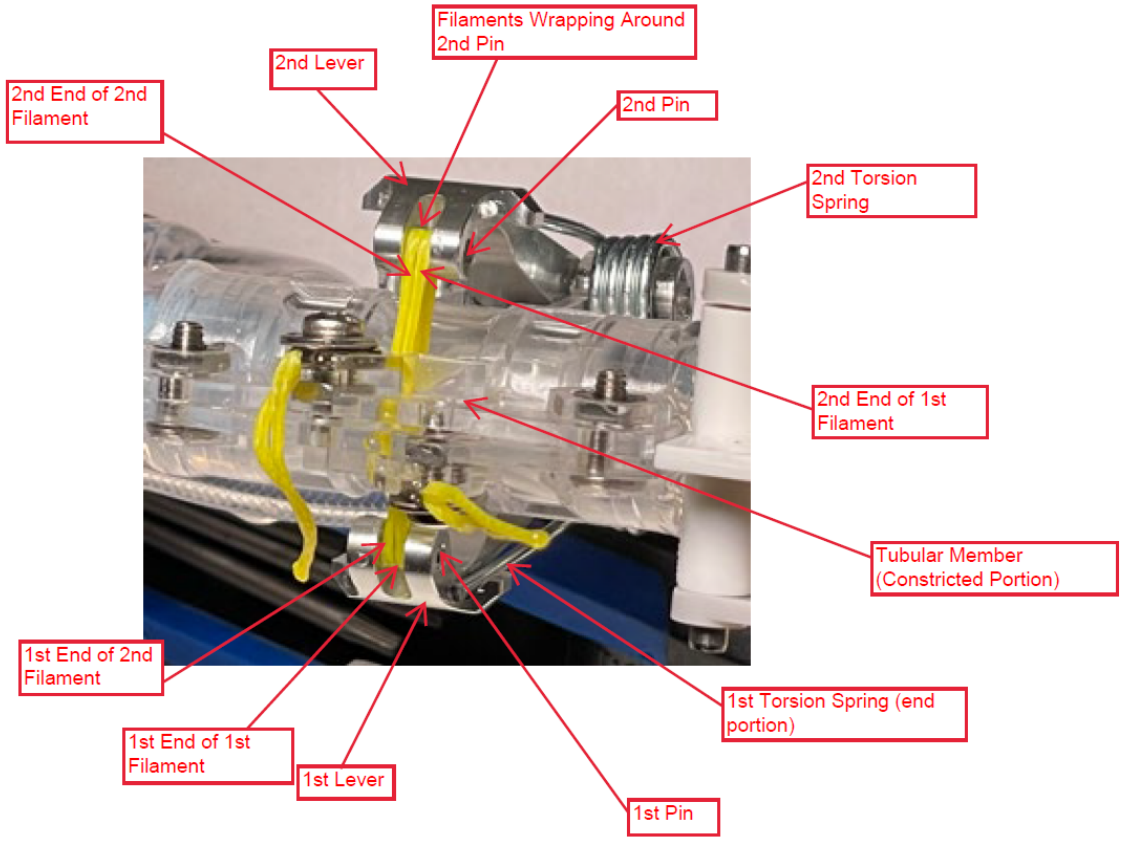
(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

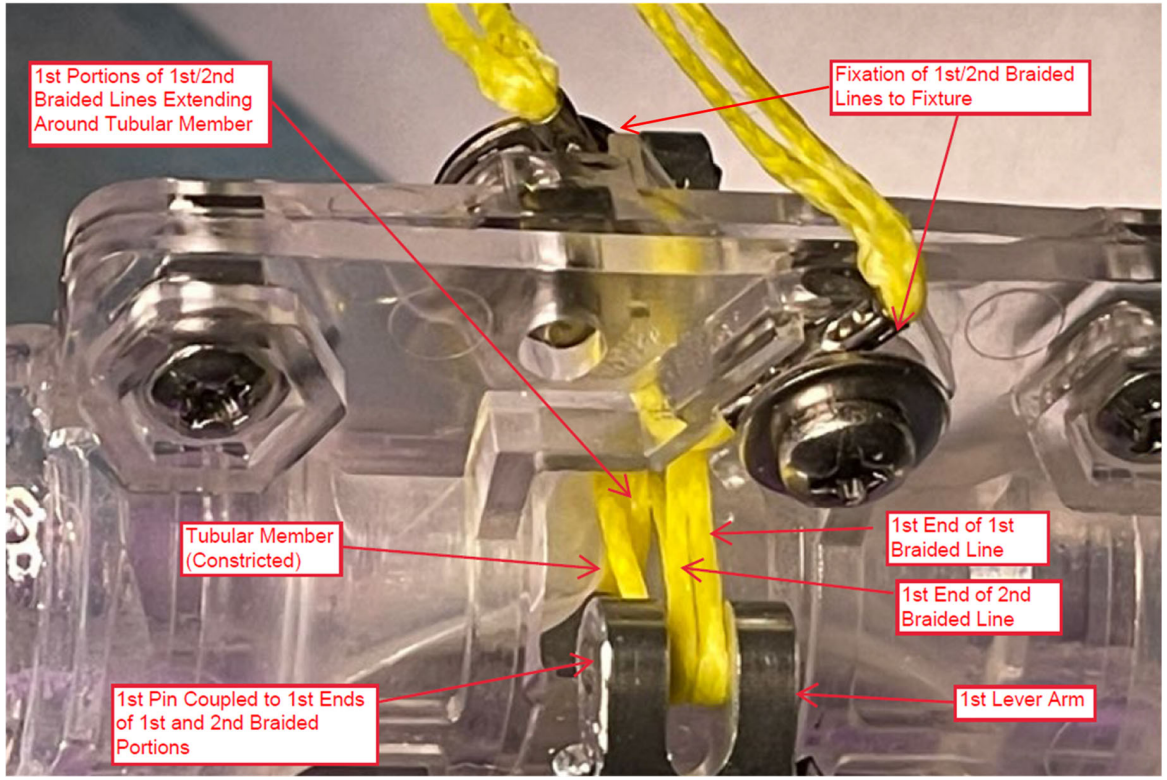
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

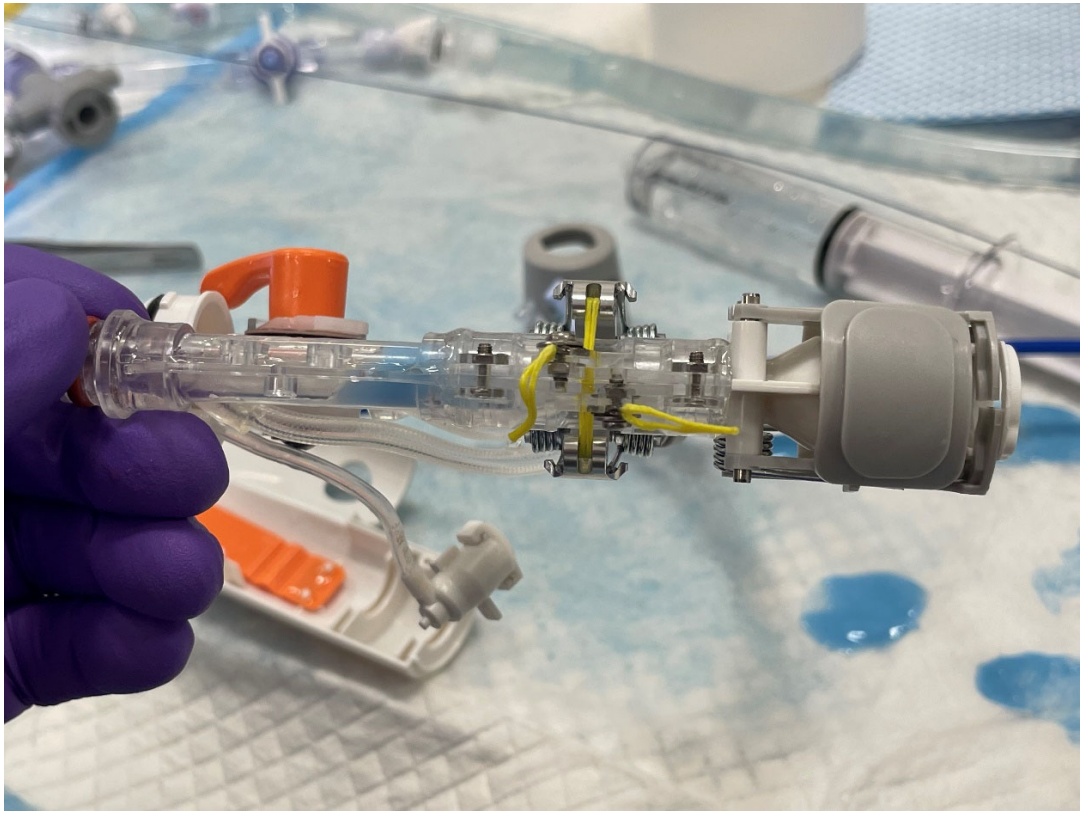
	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member.)

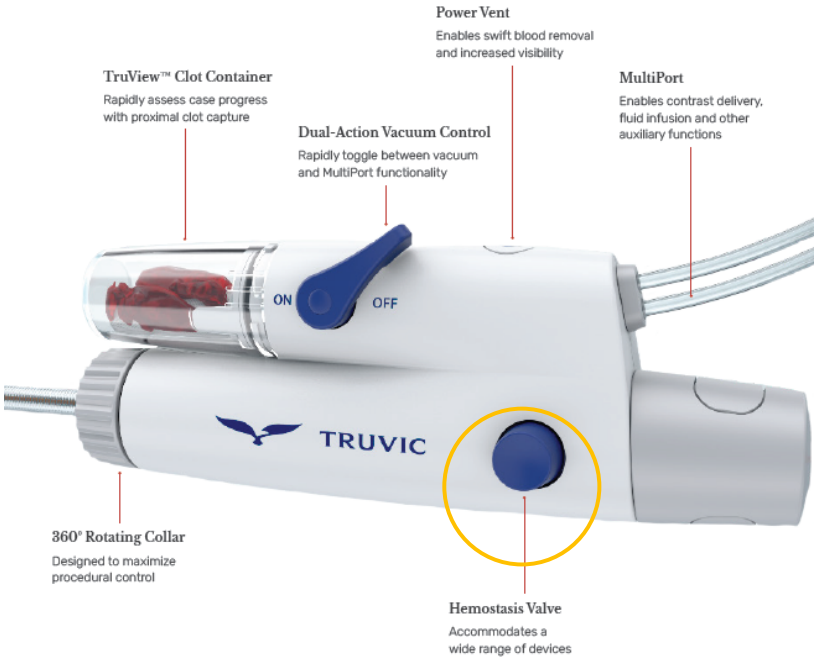
	 (Internal image of hemostasis valve with filaments encircling elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[18] The valve assembly of claim 15 wherein the first portion of first filament is directly attached to the first actuator, wherein the second portion of the first filament is directly attached to the second actuator, wherein the	As can be seen above in the figures and photos with Claims 1, 4, and 15, the Symphony System hemostasis valve comprises first end portions of the first and second filaments directly attached (looped around) the first one of the actuators, and second end portions of the first and second filaments directly attached (looped around) the second one of the actuators.

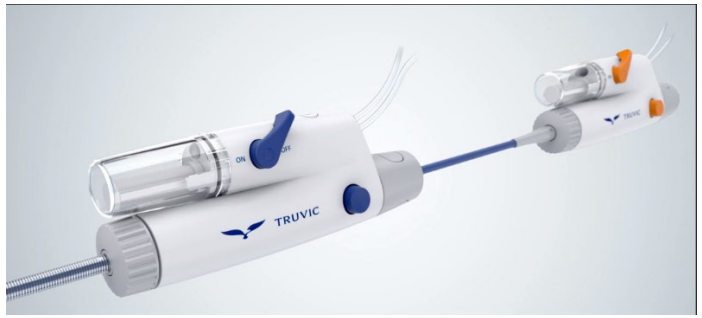
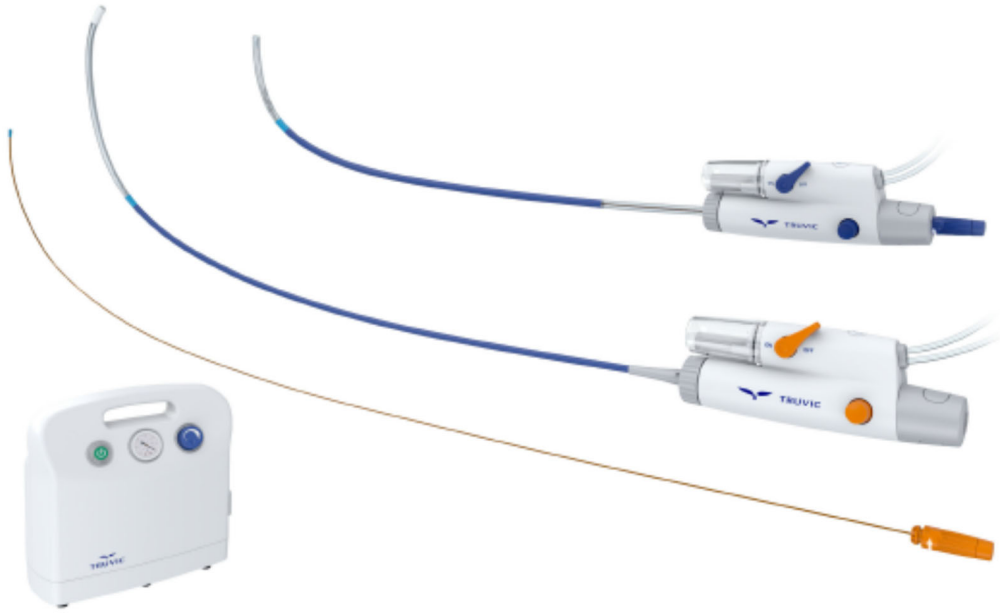
first portion of the second filament is directly attached to the first actuator, and wherein the second portion of the second filament is directly attached to the second actuator.	 (Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first filament and the first end of the second filament wrapped around the pin of and acted on by the first actuator and the second end of the first filament and the second end of the second filament wrapped around the pin of and acted on by the second actuator.)



(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

	 (Image of internal portion of housing with hemostasis valve.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[20] The valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 16 French.	The Symphony System hemostasis valves on both the 16F and 24F Symphony handles have a lumen diameter of at least 16 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the respective 16F or 24F dilator, 16F or 24F ProHelix (or a 16F catheter for the 24F

	handle), to pass through the hemostasis valve. 16 French and 24 French are both at least as 16 French. **High-Powered, Continuous Vacuum with Real-Time Case Assessment** **BigShot™ Controller**  (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

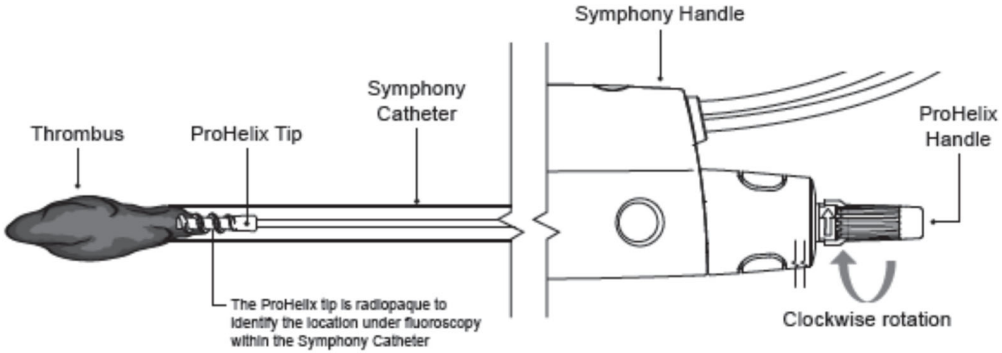


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

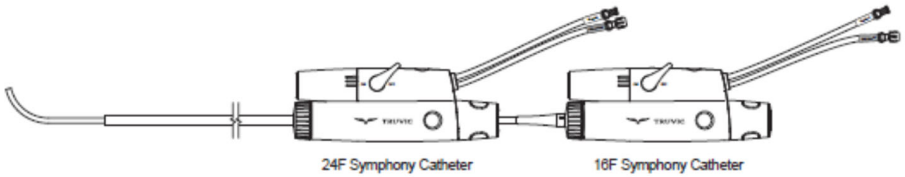
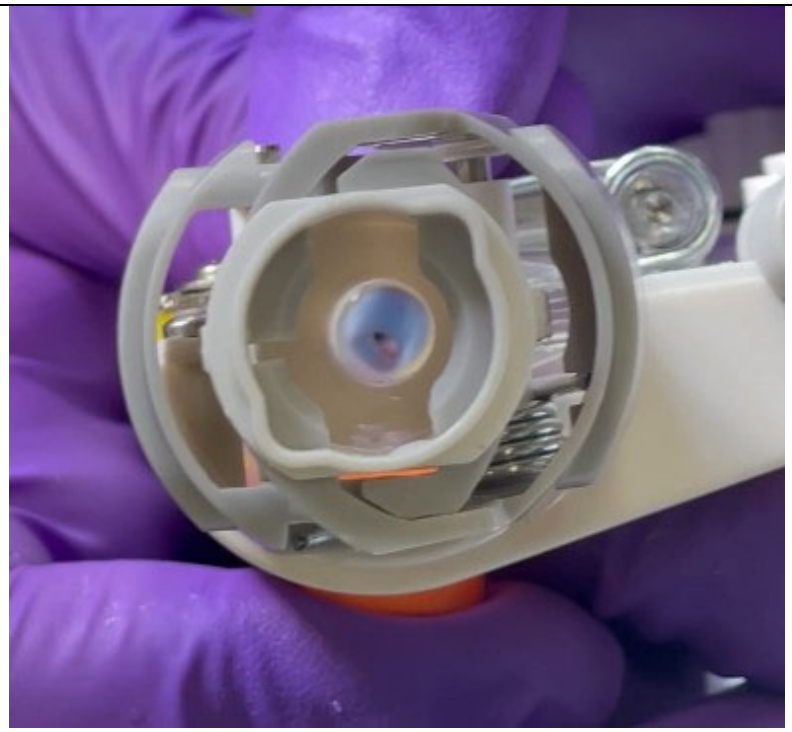
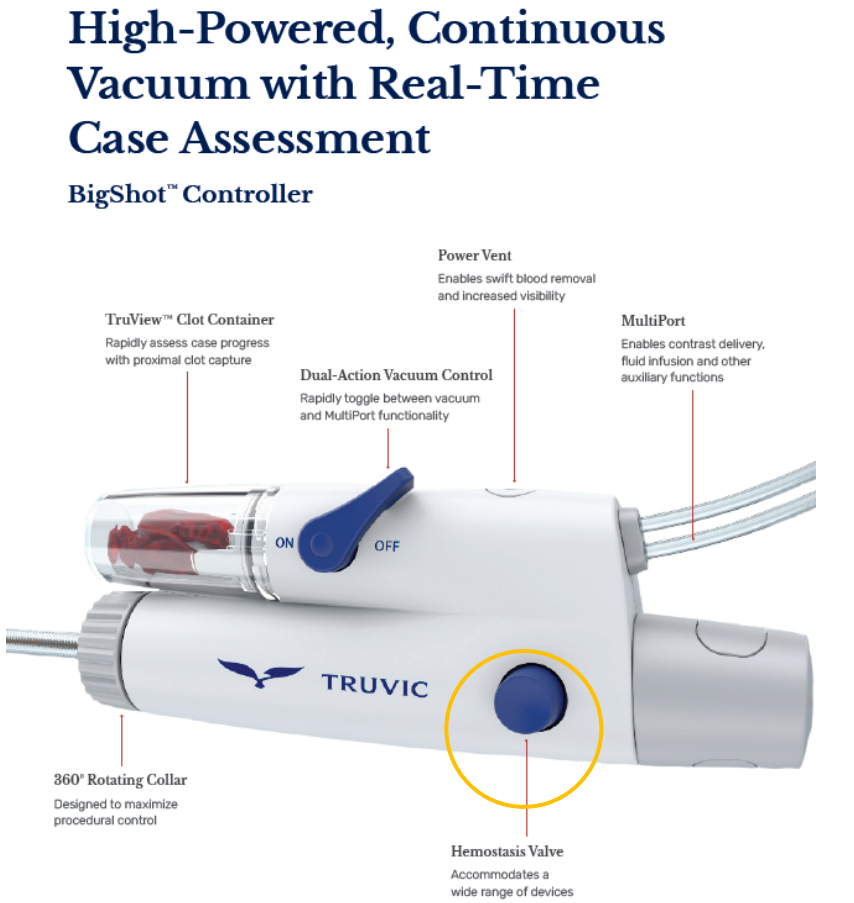
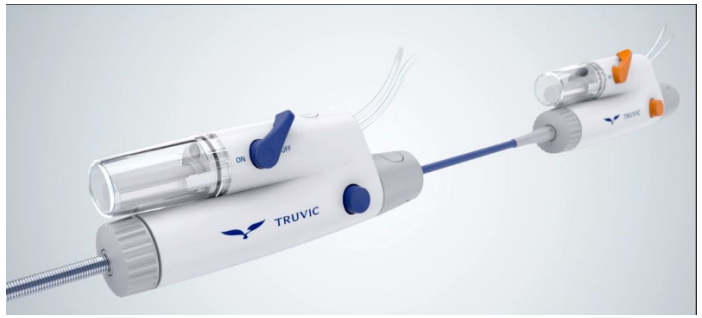
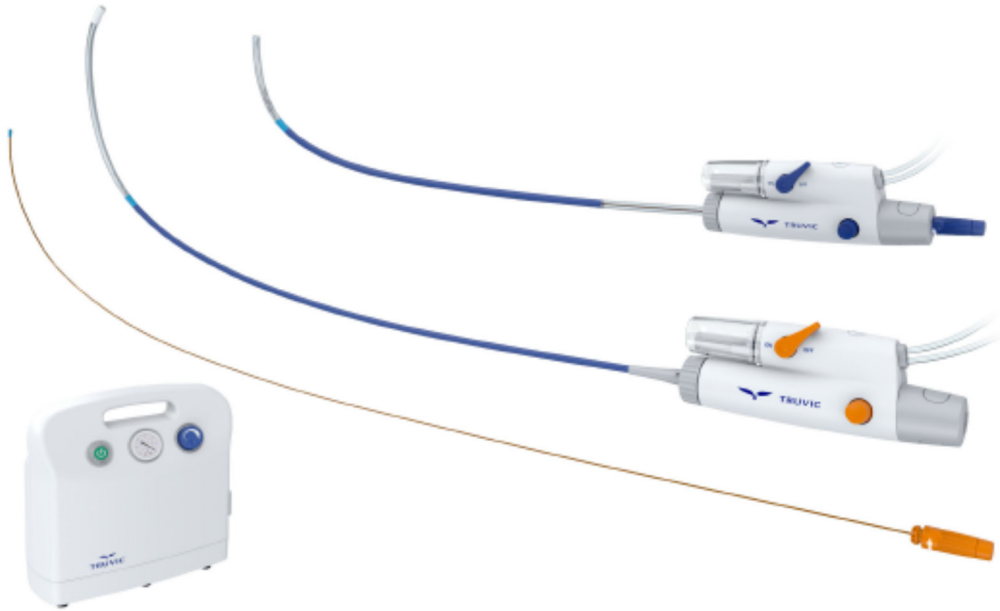


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[21] The valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 20 French.	The Symphony System hemostasis valve on the 24F Symphony handles have a lumen diameter of at least 20 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the 24F dilator, 24F ProHelix, or a 16F catheter, to pass through the hemostasis valve. 24 French is larger than 20 French.

	 (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

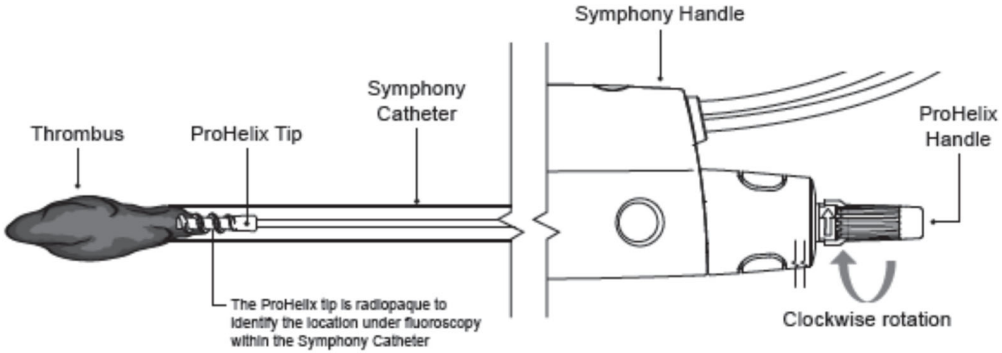


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

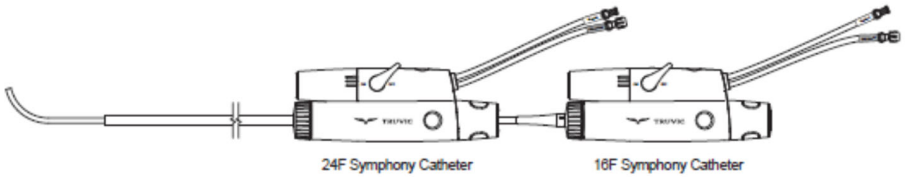
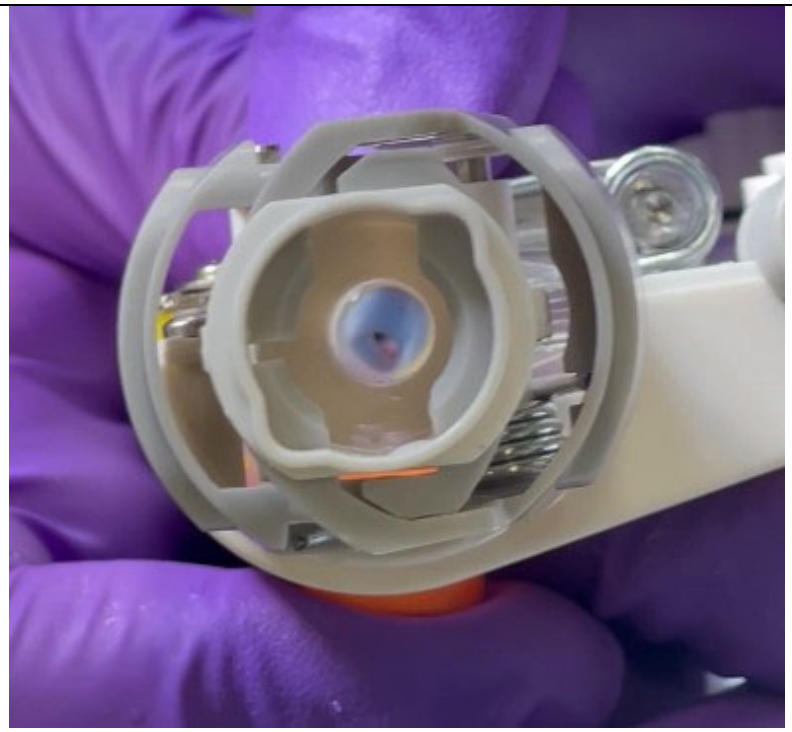
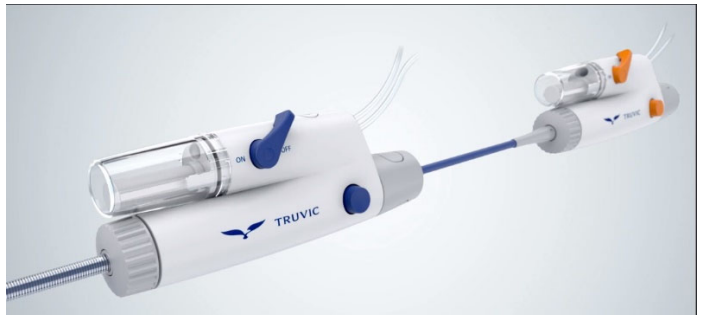
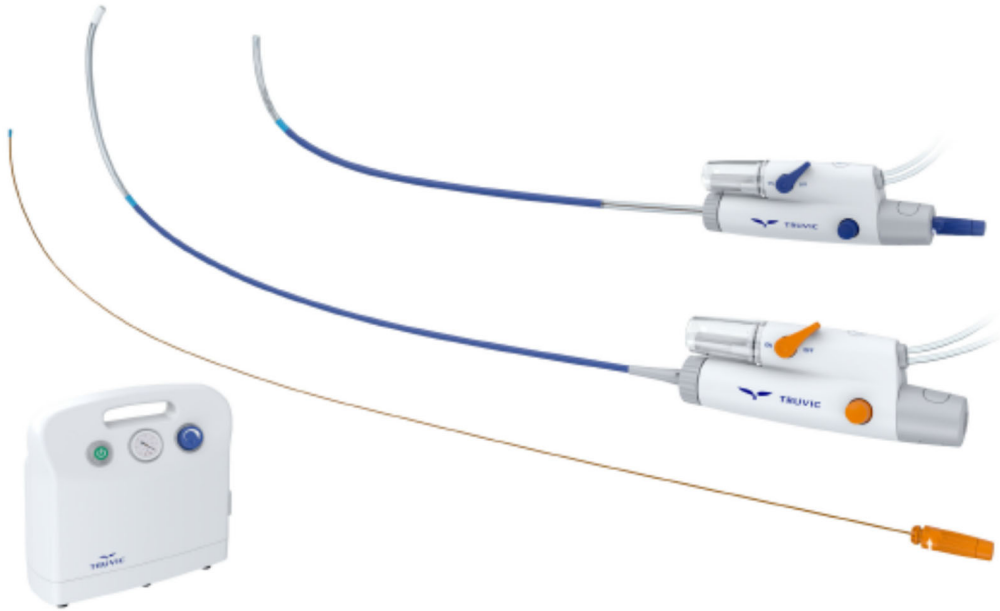


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[22] The valve assembly of claim 15 wherein, in the second position, the tubular member has a diameter of at least 24 French.	The Symphony System hemostasis valve on the 24F Symphony handles have a lumen diameter of at least 24 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the 24F dilator, 24F ProHelix, or a 16F catheter, to pass through the hemostasis valve. 24 French is at least 24 French.

(Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

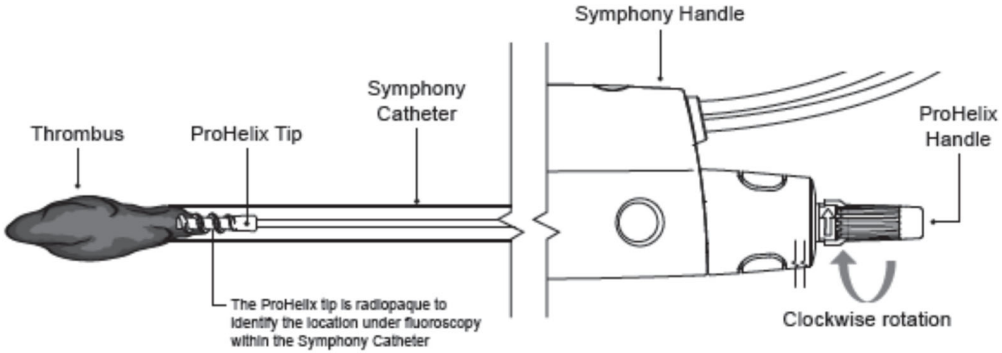


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

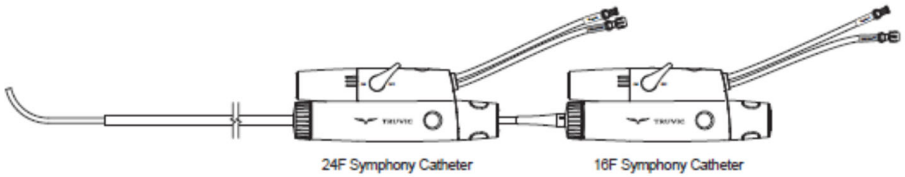
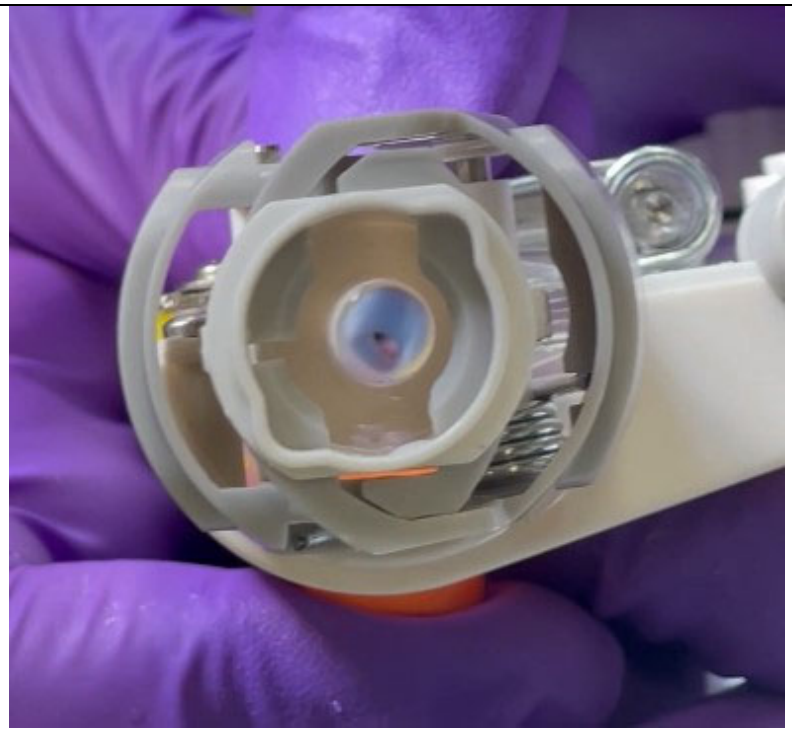
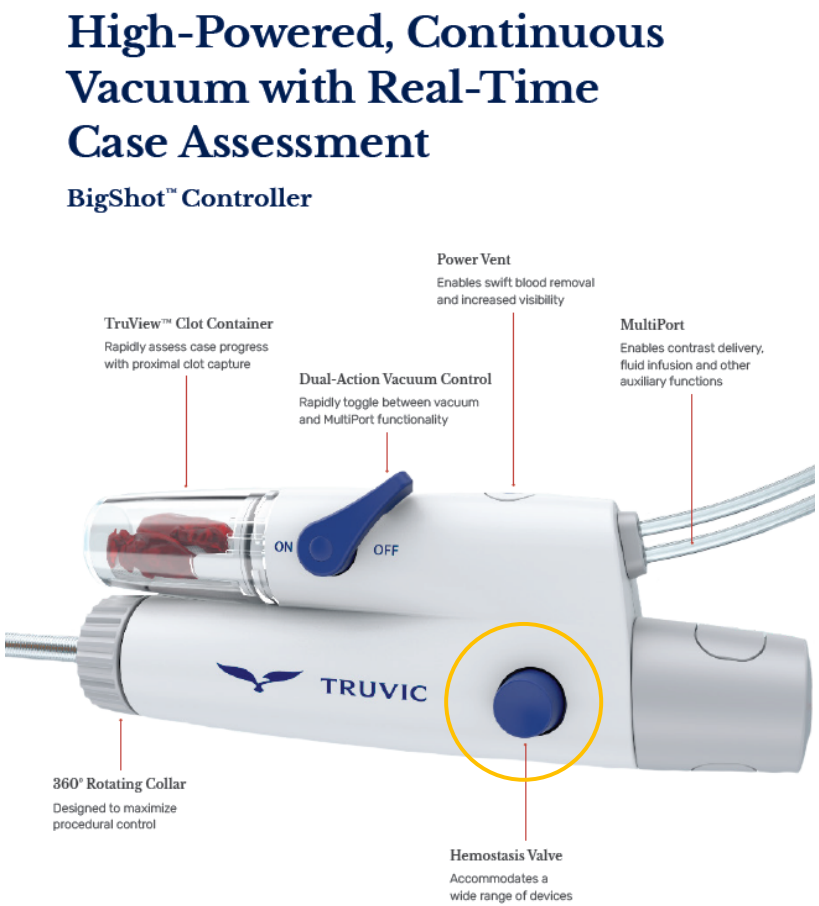
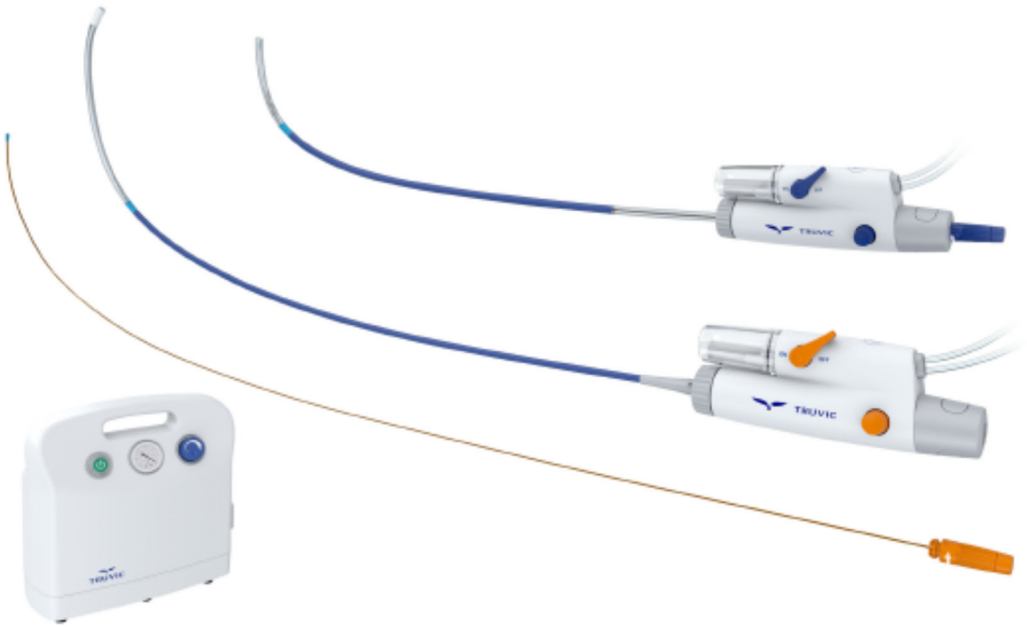


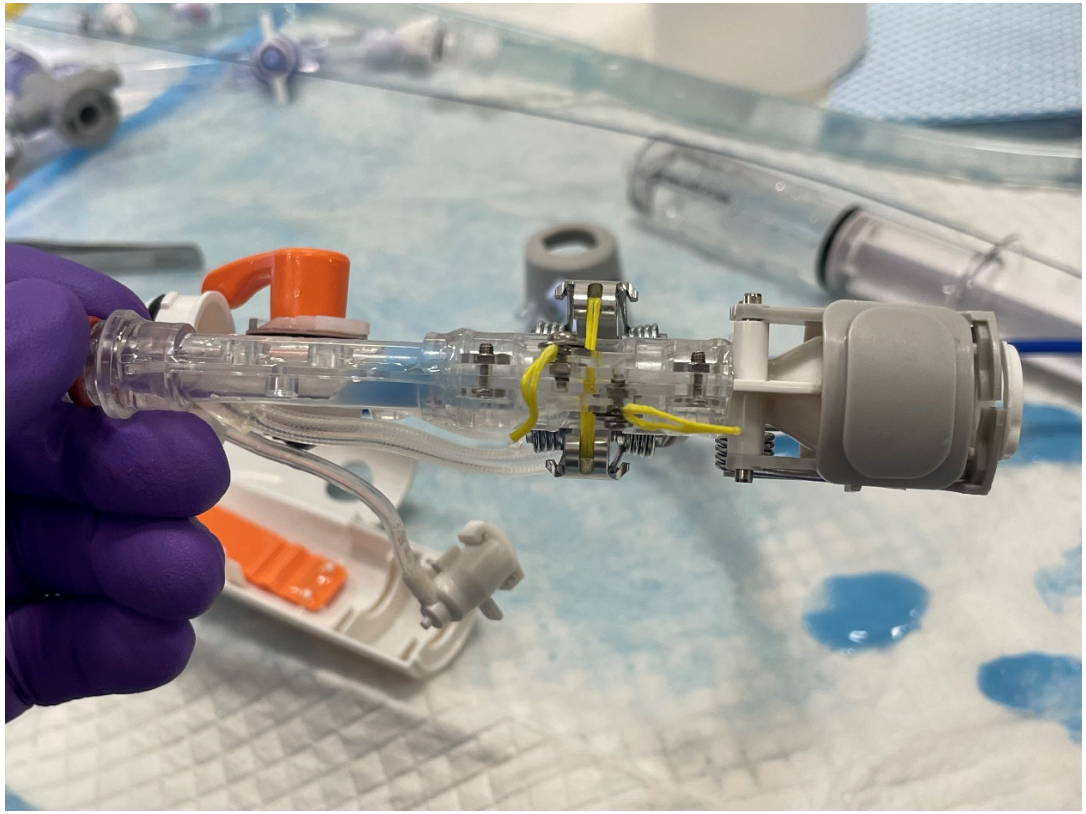
Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

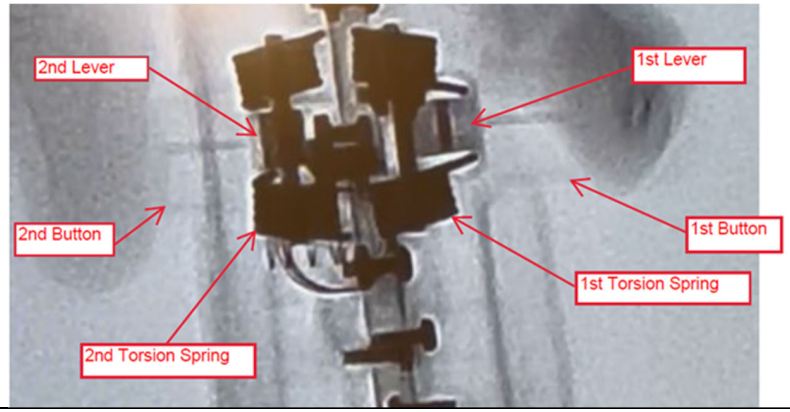
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

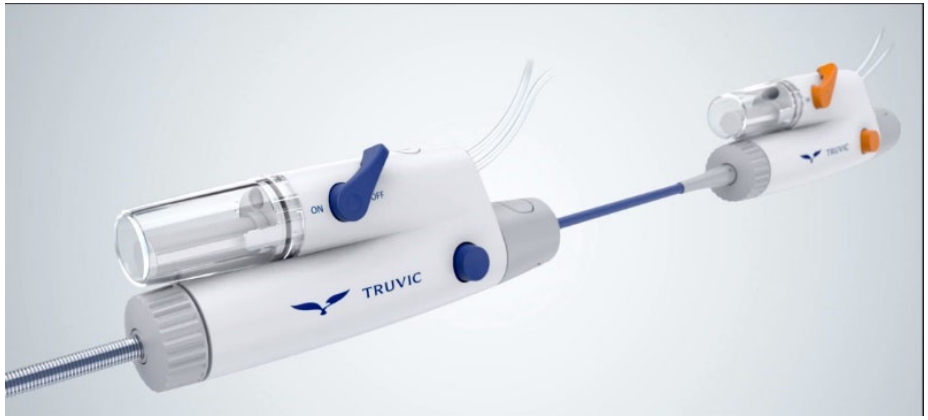
[23] A valve assembly, comprising:	The Symphony System has a hemostasis valve assembly.  (Annotated Symphony Thrombectomy System Brochure at 6.) A hemostasis valve is positioned within each of the two Symphony handles. The hemostasis valve is operated by two blue or two orange buttons, depending on the handle.

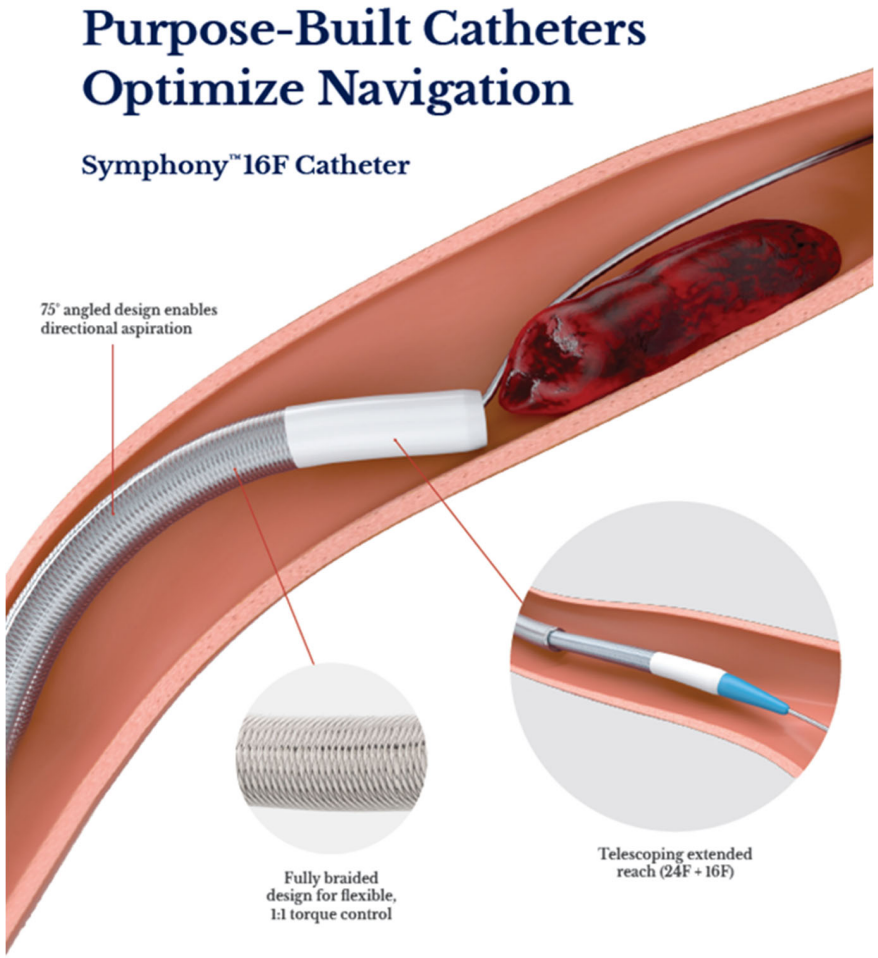
	 (Symphony Thrombectomy System Brochure at 2.)

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

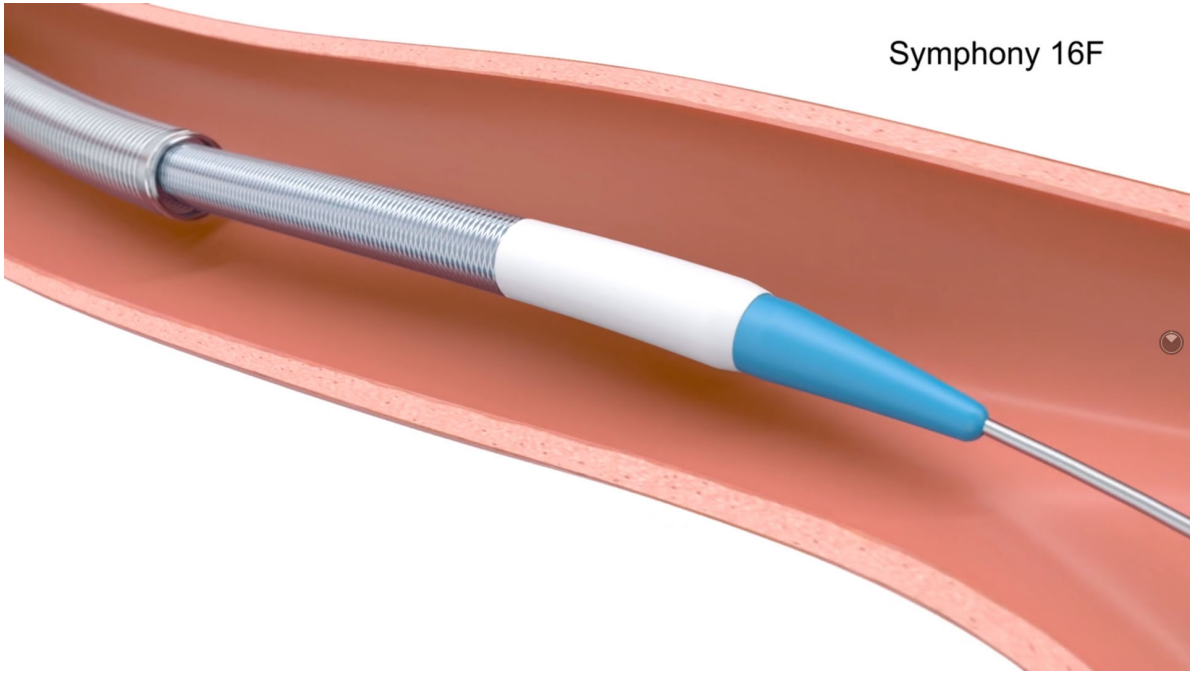
(Image of internal portion of housing zoomed-in on hemostasis valve.)

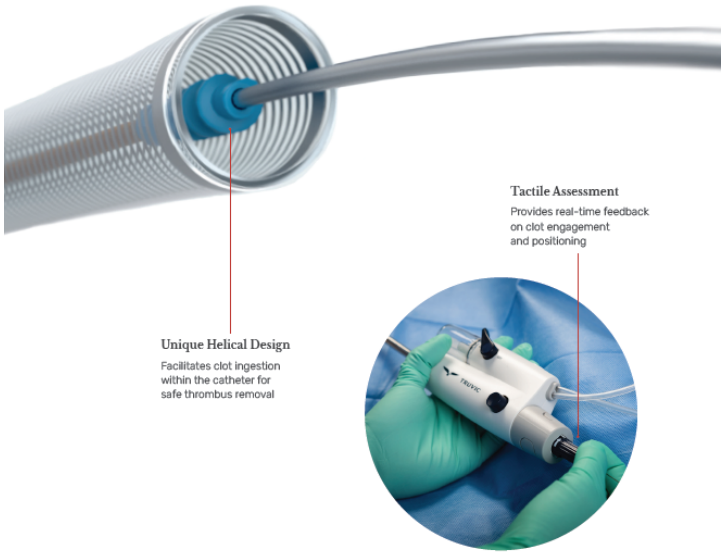


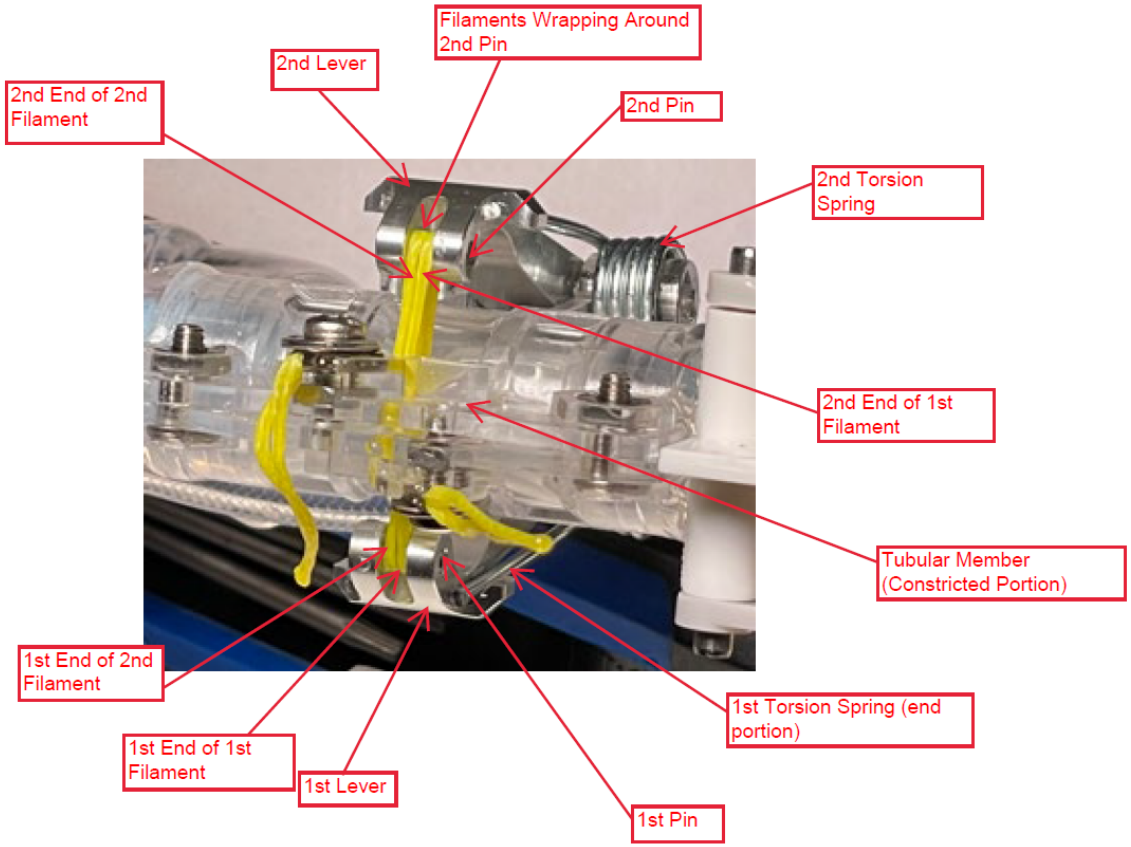
	(Annotated x-ray imaging of housing showing annotated first and second buttons, first and second levers, and first torsion springs and second torsion springs (two for each lever), as part of tensioning mechanism for hemostasis valve in Symphony System housing.) The hemostasis valve is configured to "accommodate a wide range of devices" (Symphony Thrombectomy System Brochure at 6), including a Truvic catheter, a ProHelix™ Mechanical Assist catheter and, in the case of at least the 24F handle or a second telescoping catheter, for use in procedures:  (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)



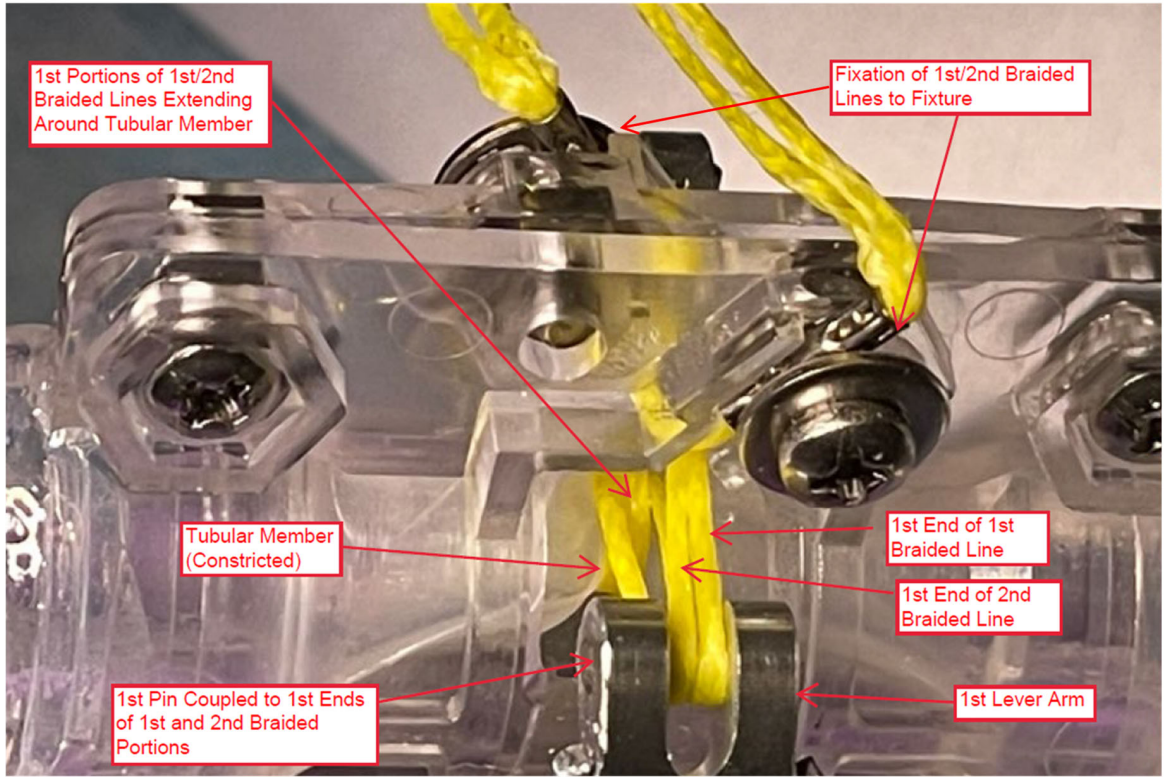
(Symphony Thrombectomy System Brochure at 4.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:34 (https://vimeo.com/817718796).)

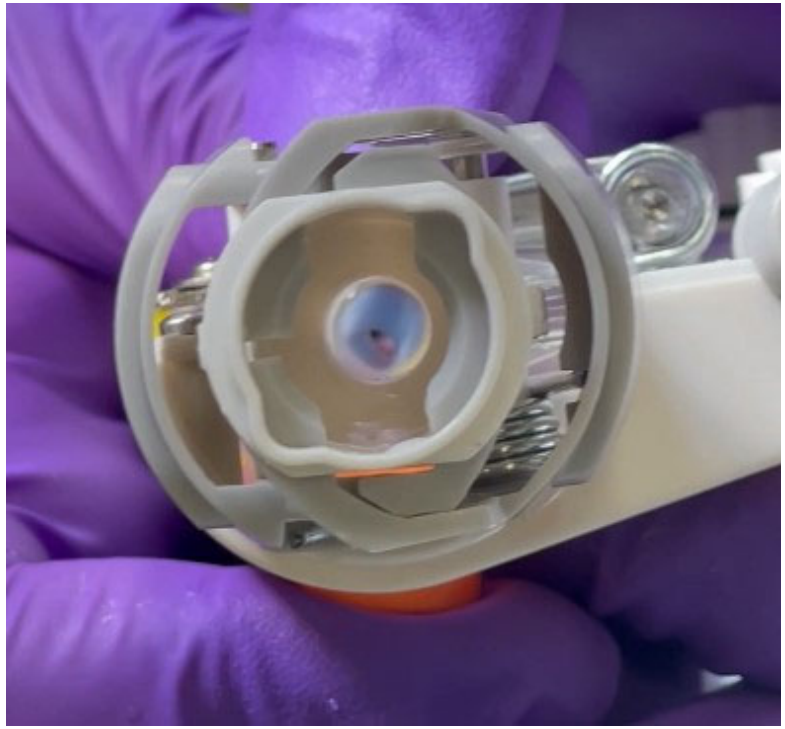
	SYMPHONY™ THROMBECTOMY SYSTEM **Mechanical Assist Optimizes Clot Engagement & Capture** **ProHelix™ Mechanical Assist**  (Symphony Thrombectomy System Brochure at 8.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a tubular member defining a lumen;	The Symphony System hemostasis valve has a collapsible elongate tubular member that defines a lumen (the "Tubular Member," annotated below). The valve lumen is shown below and is configured to "accommodate a wide range of devices." (Symphony brochure at 6). Therefore, the hemostasis valve has a tubular member defining a lumen.

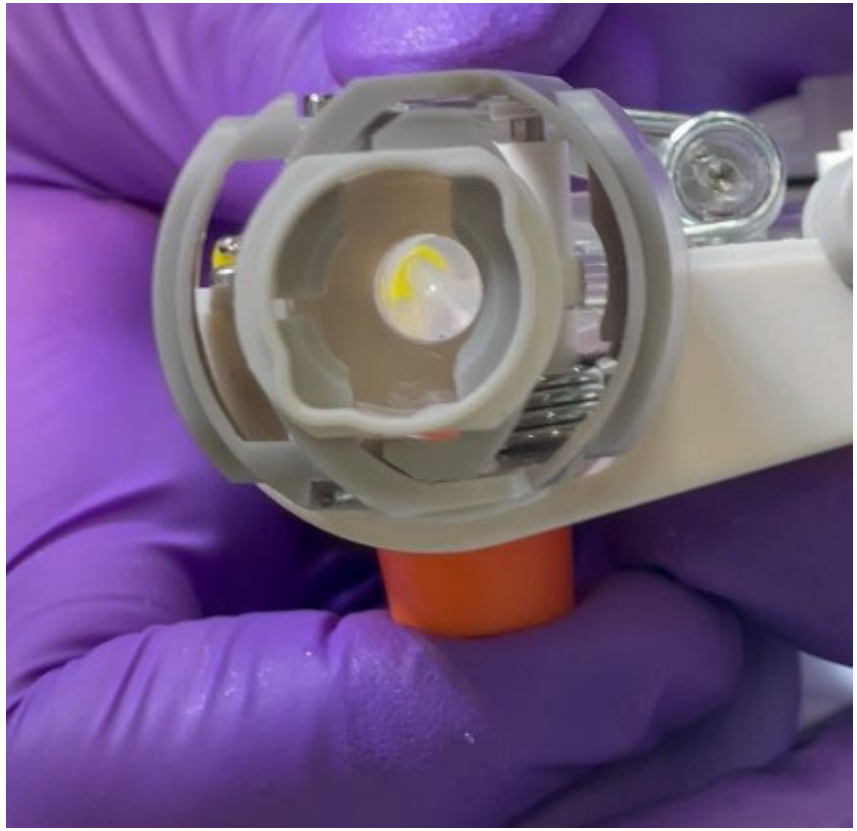


(Annotated image of internal portion of Symphony System housing, including hemostasis valve with tubular member defining a lumen.)

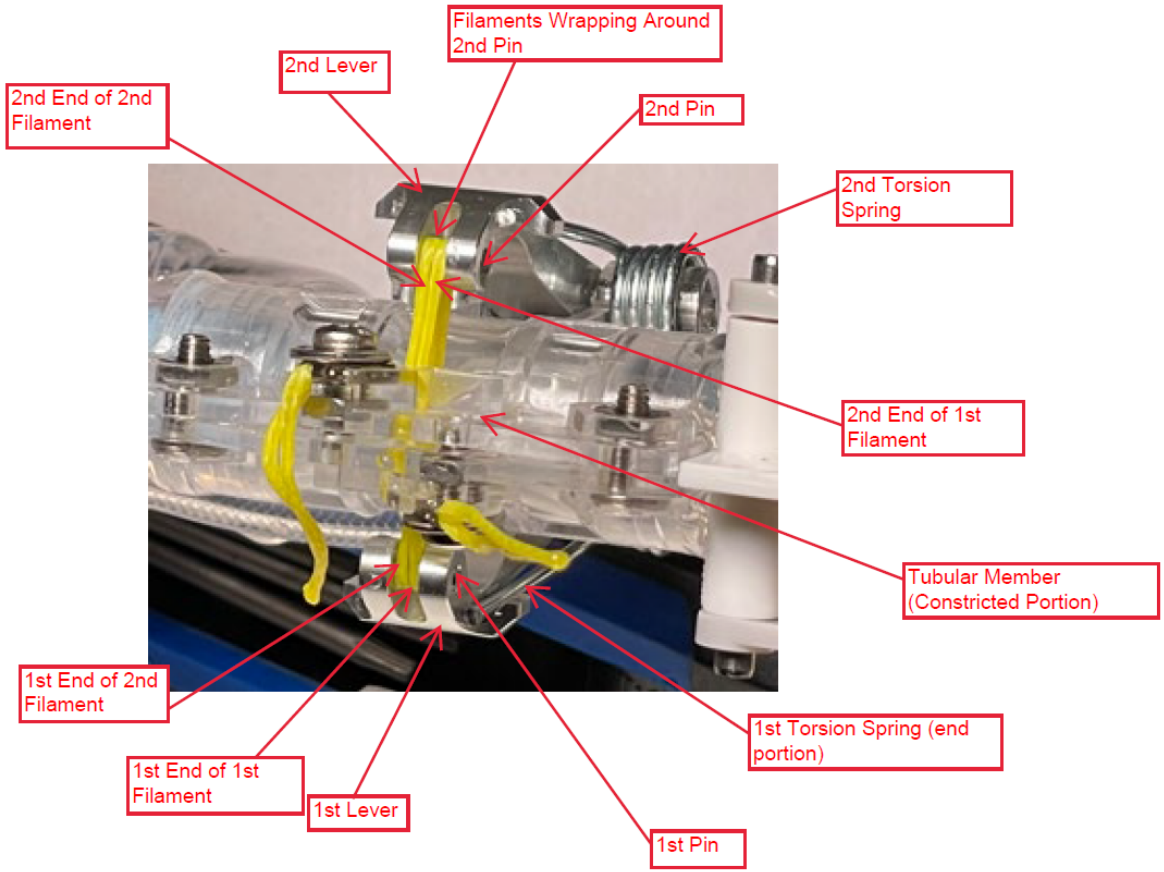


(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having a tubular member defining a lumen (tubular member) constricted and filaments extending around the tubular member.)

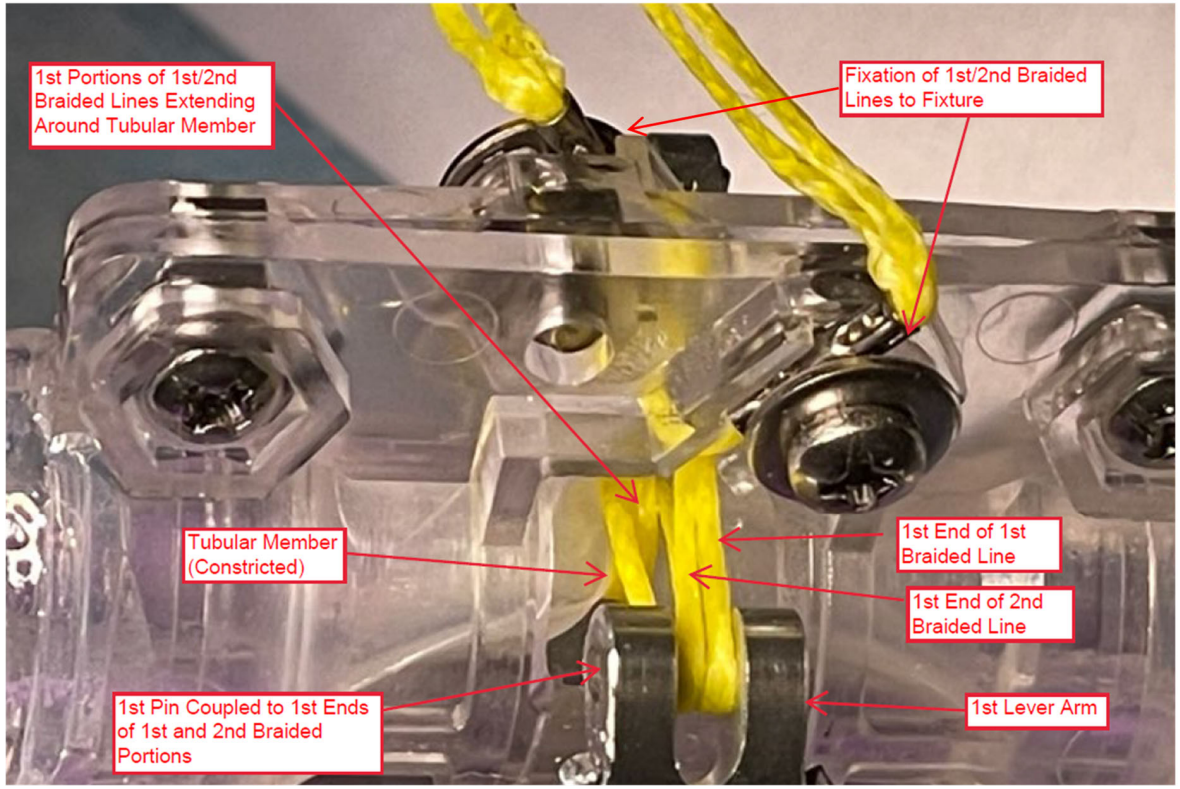
	 (Symphony handle with view down tubular member (lumen) of hemostasis valve with the valve open having the tubular member unconstricted.)

	 (Symphony handle with view down lumen of hemostasis valve with the tubular member of the valve constricted.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a first filament extending in a first loop around the tubular member;	The Symphony System hemostasis valve has a tensioning mechanism including a first filament and a second filament, each extending in a loop around the tubular member. The loop of the first filament extends completely around the elongate member.

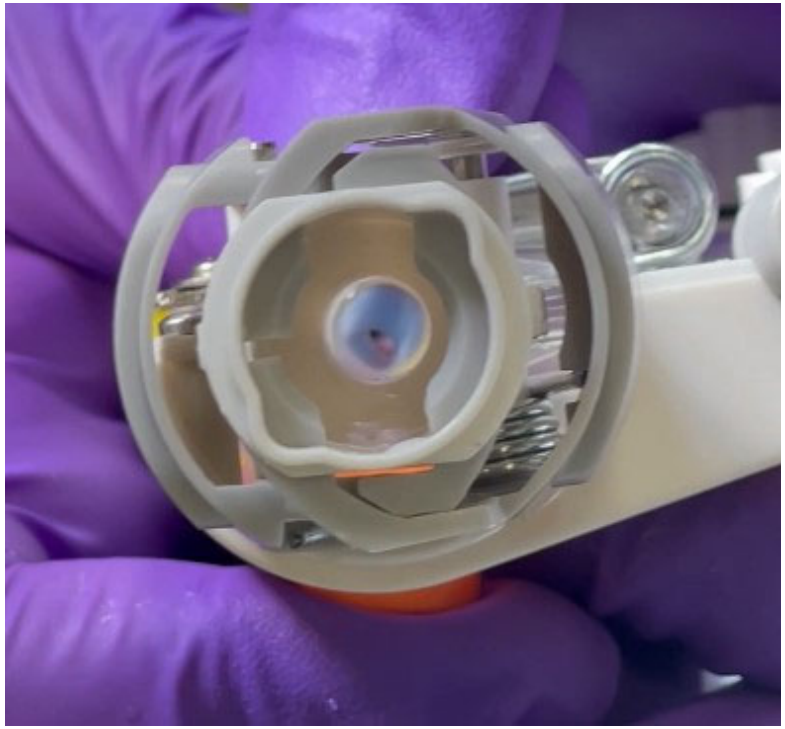
	 (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)

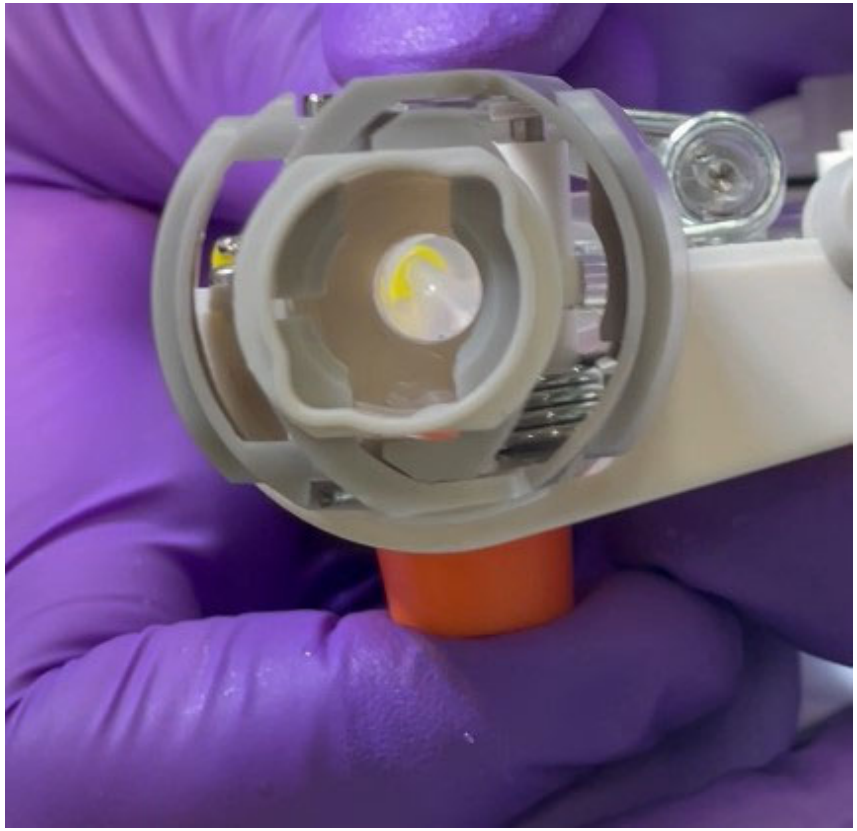


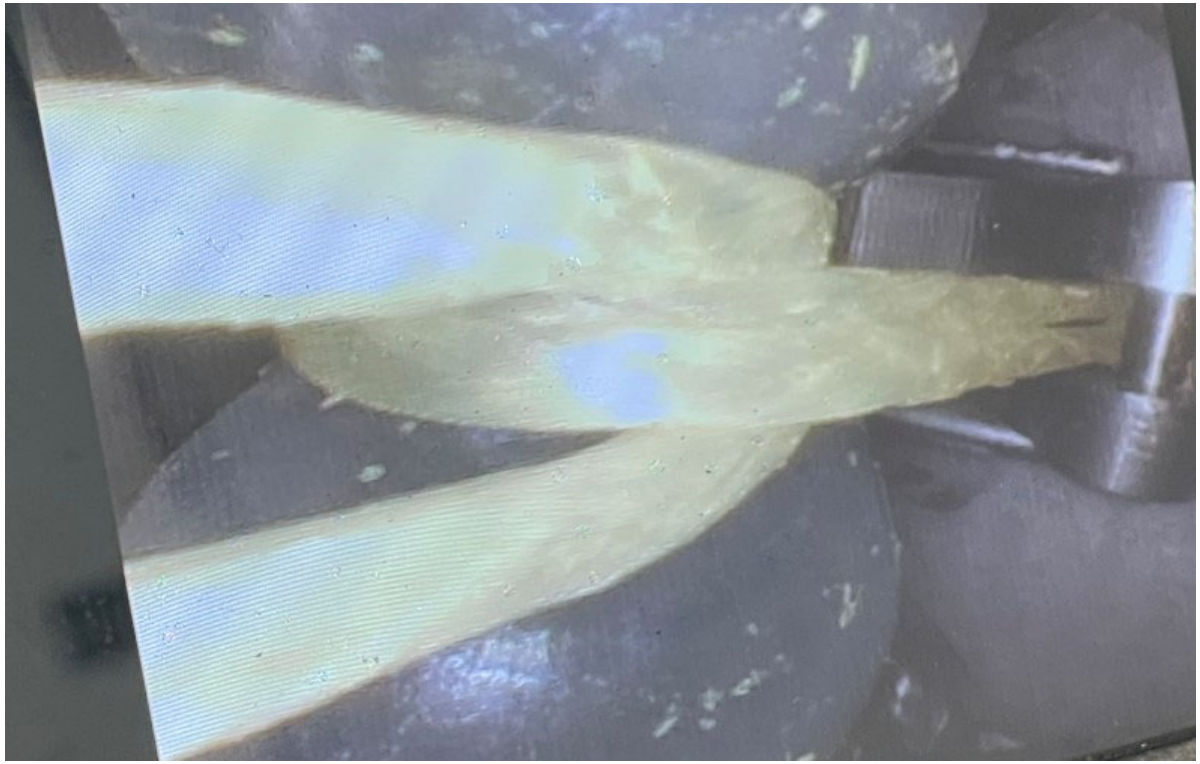
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)



(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

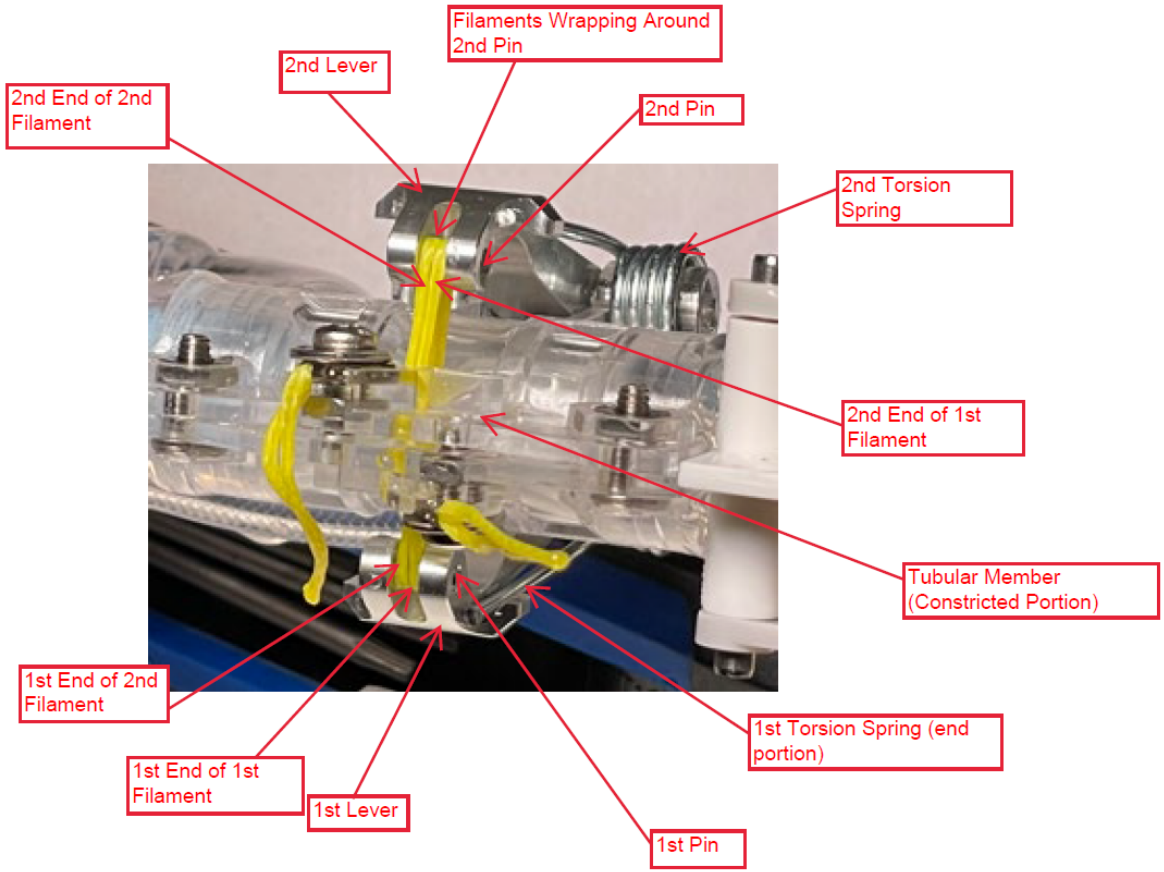
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

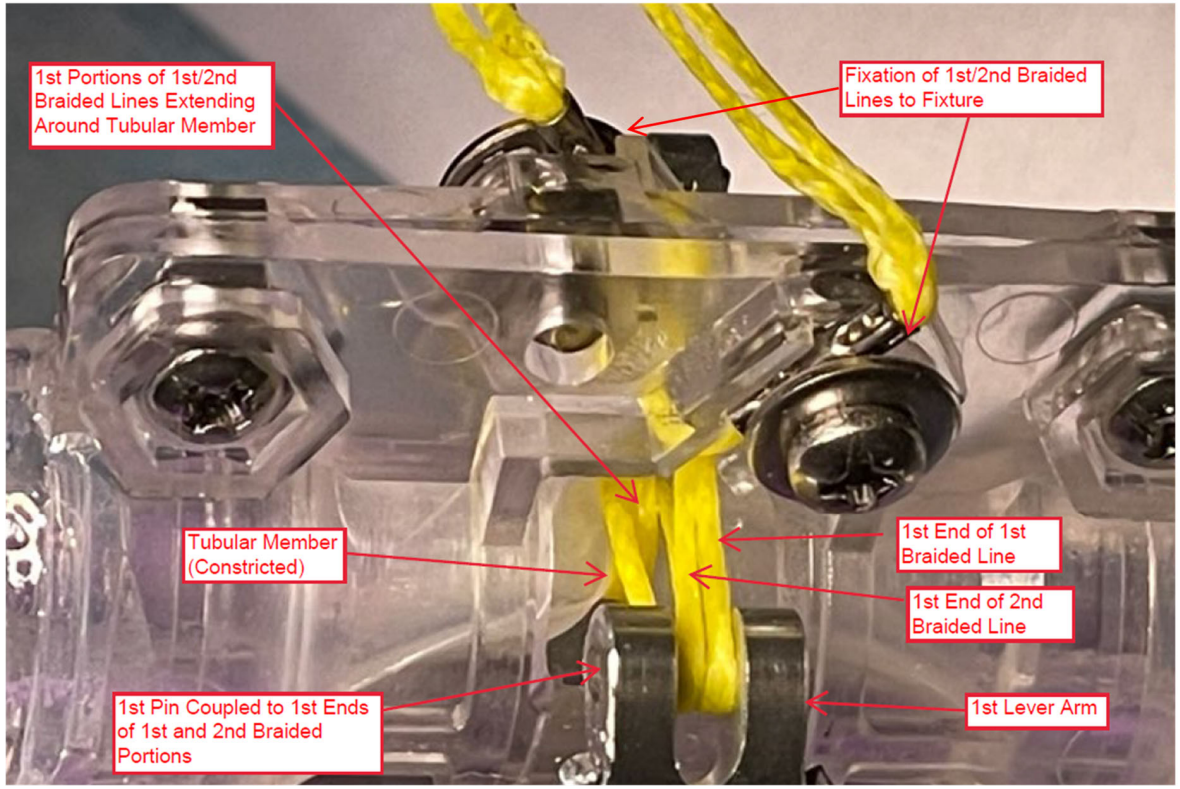
	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member.)

	 (Internal image of hemostasis valve with filaments encircling elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a second filament extending in a second loop around the tubular member; and	The Symphony System hemostasis valve has a tensioning mechanism including a first filament and a second filament, each extending in a loop around the tubular member. The loop of the second filament extends completely around the elongate member.

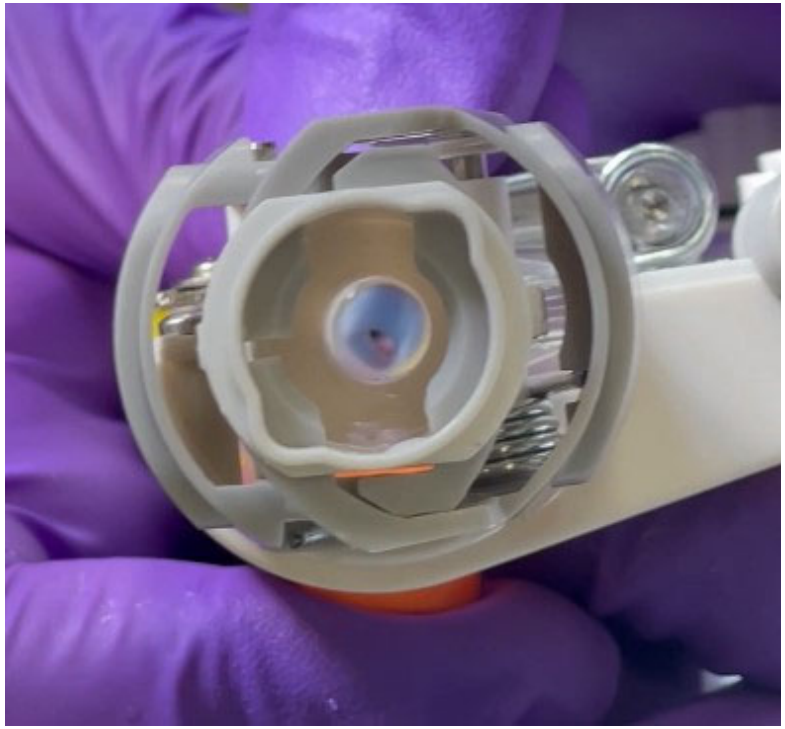
	 (Image of internal portion of housing with hemostasis valve with first filament and second filament visible.)

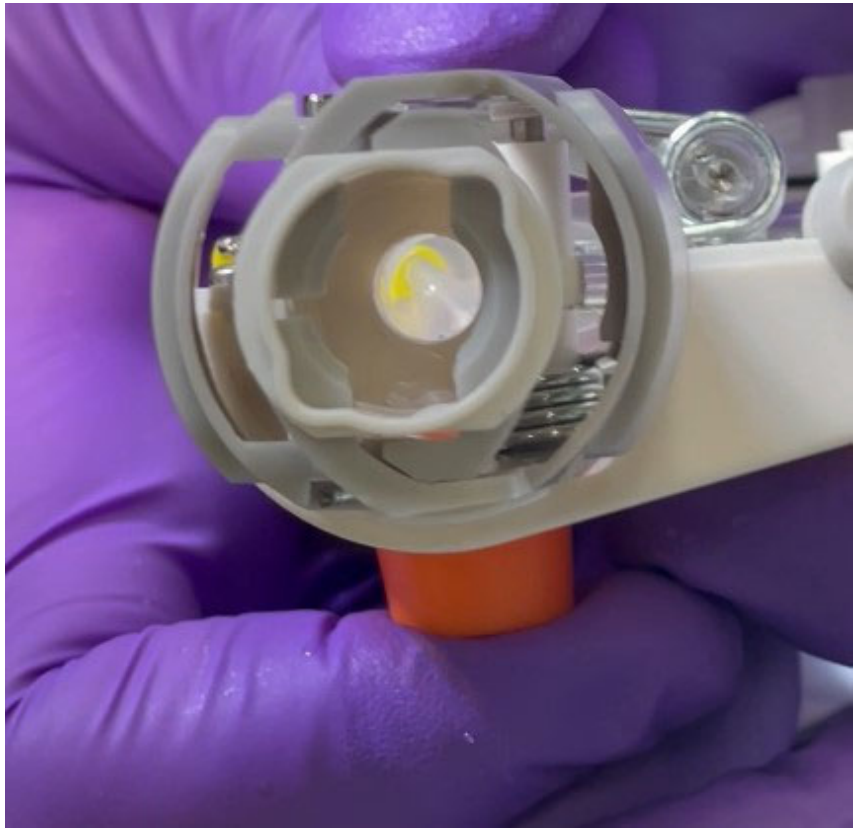


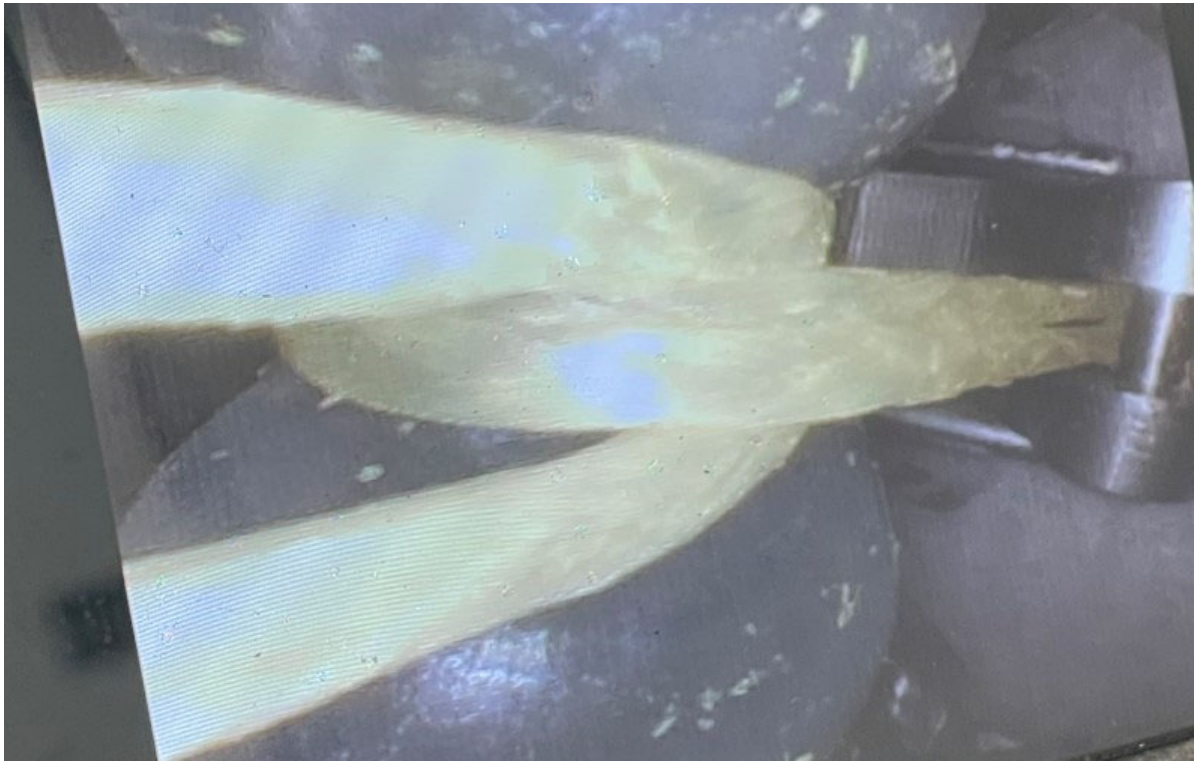
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments each extending in a loop around the elongate member.)



(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

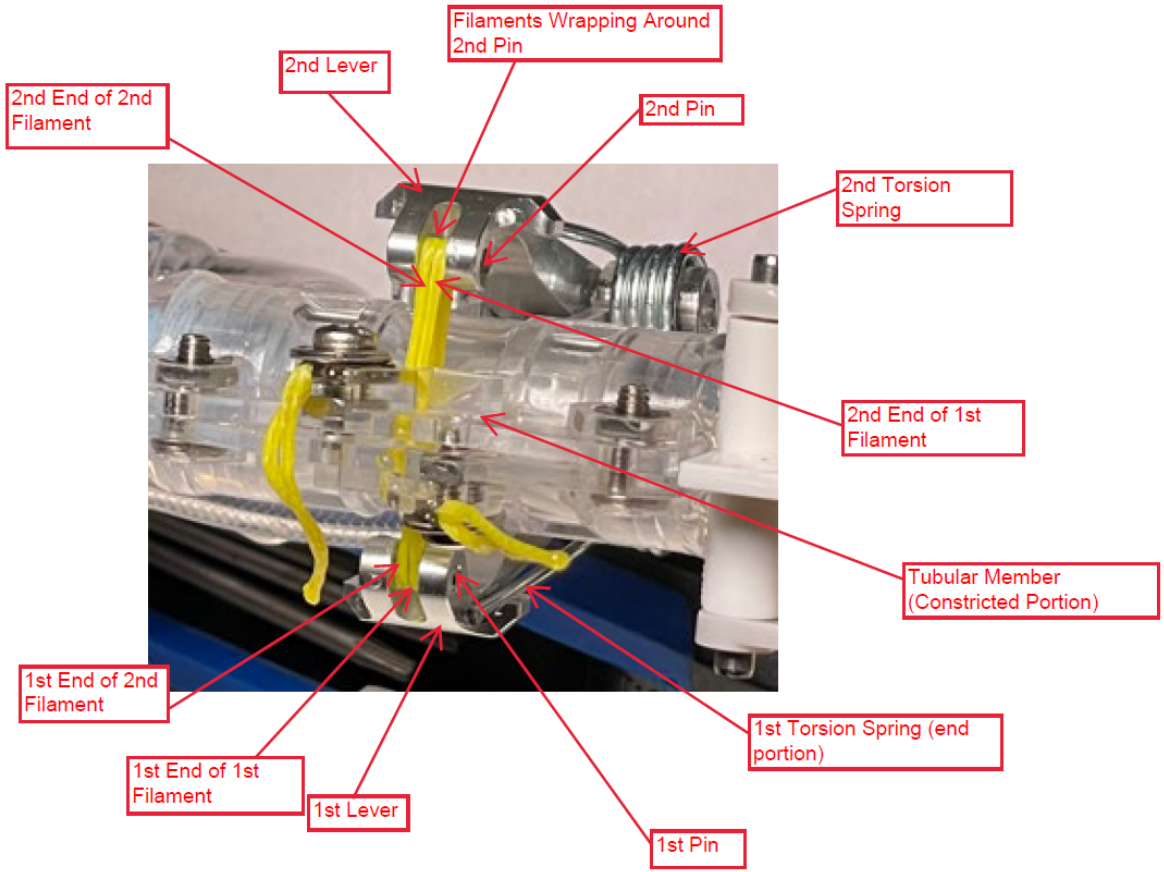
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

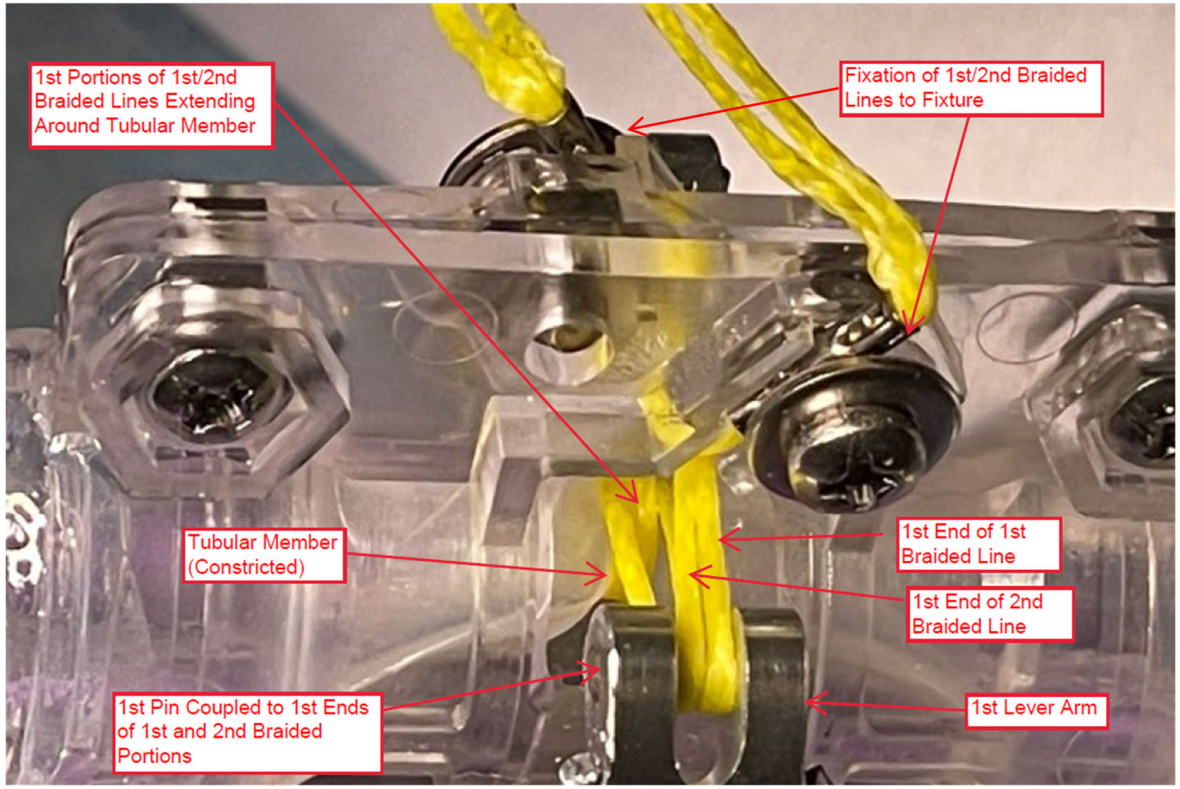
	 (Internal image of hemostasis valve with first and second filaments encircling and constricting elongate member.)

	 (Internal image of hemostasis valve with filaments encircling elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
a pair of actuators biased to circumferentially constrict the first loop and the second loop to elastically deform the tubular member to a first position in which the lumen is constricted, wherein at least one the actuators is movable to decrease a level of tension	The Symphony System hemostasis valve has a tensioning mechanism including a pair of actuators, specifically a first actuator comprising first torsion spring(s), a first button, a first lever and a first pin, and a second actuator comprising second torsion spring(s), a second button, a second lever, and a second pin. The first actuator (e.g., the first button/lever/pin) and second actuator (e.g., the second button/lever/pin) are movable between (a) a first position (undepressed button) wherein the lumen is constricted and sealed by the torsion spring pulling the actuators and the filaments to tighten the filaments around the elongate member and (b) a second position (depressed button) wherein the lumen is at least partially

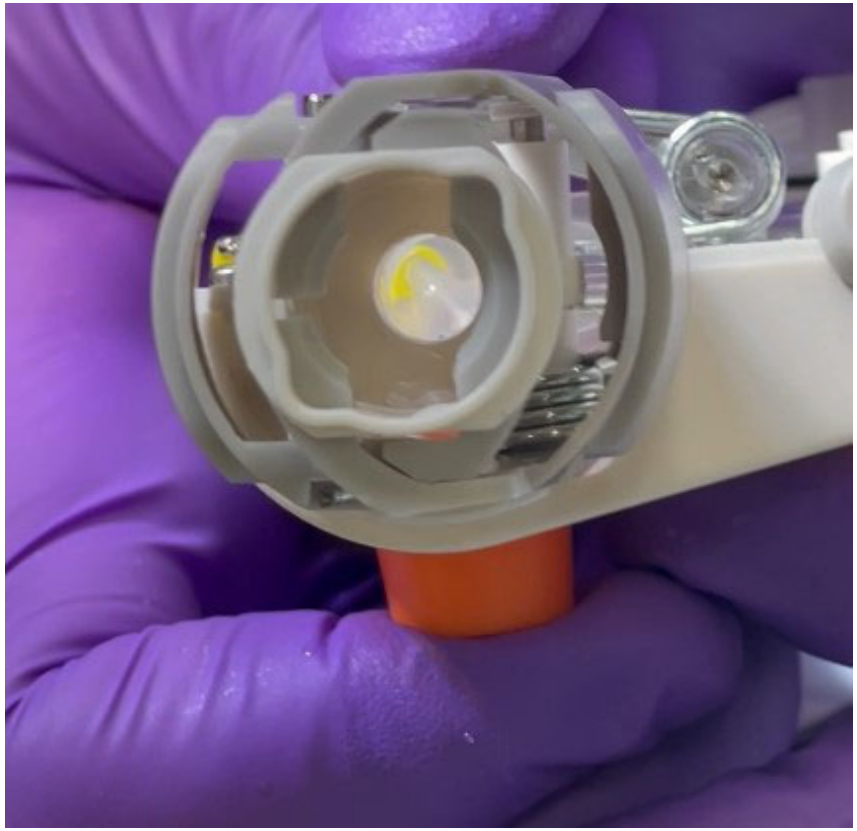
in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open.	open. The first and the second actuator are each biased towards the first position (constricted, button undepressed) by torsion springs, and, in the first position, the first and second actuators tension the first and second filaments to elastically deform and constrict the tubular member. Moving the first and second actuator from the first position (constricted, button undepressed) to the second position (at least partially open, button depressed) by pushing the buttons, decreases the tension in the first filament and the second filament, allowing the tubular member to expand against the first loop of the first filament and the second loop of the second filament, at least partially opening the lumen of the tubular member. (Image of internal portion of housing with hemostasis valve.)

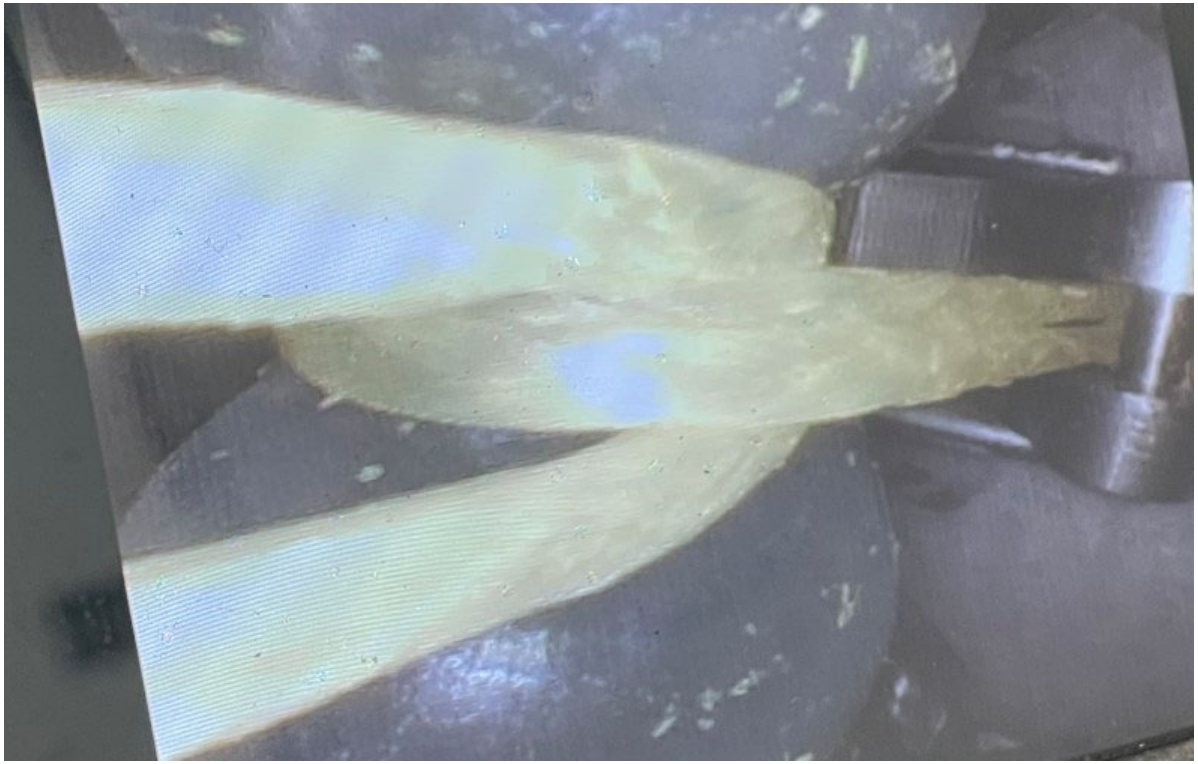


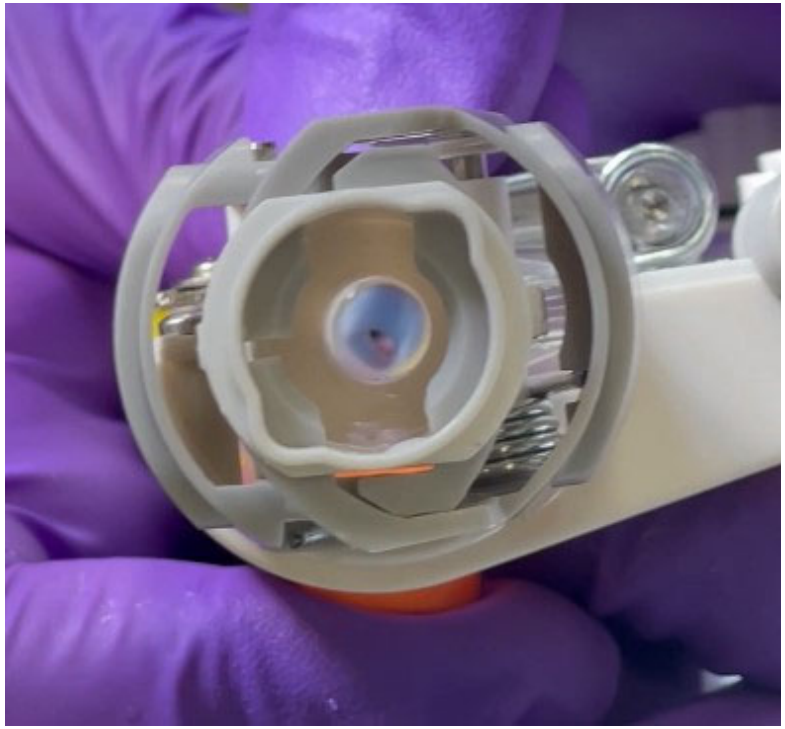
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and filaments extending around the elongate member.)



(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

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

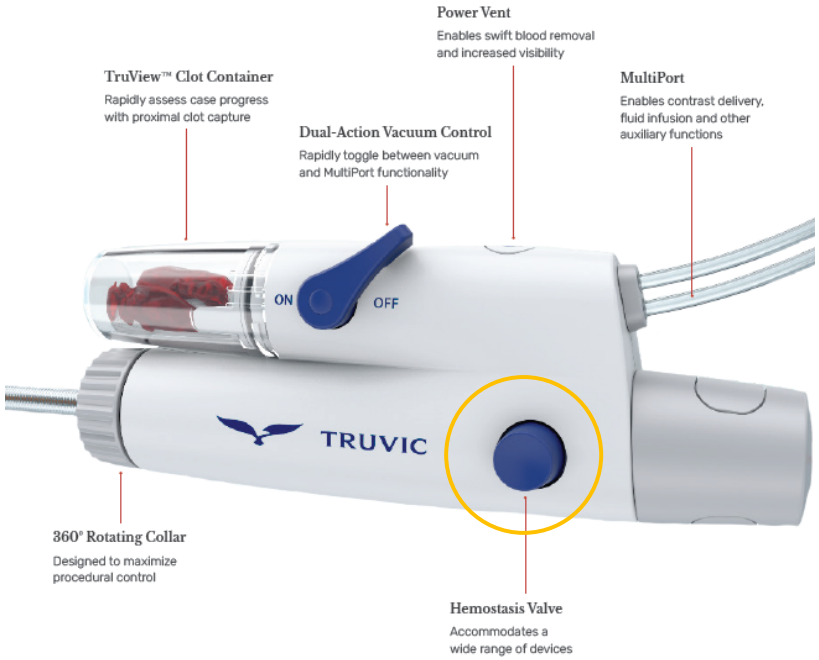
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.)

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

	 (Internal image of hemostasis valve with filaments encircling elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[24] The valve assembly of claim 23 wherein the actuators each comprise a button.	As can be seen above in the figures and photos with Claim 23, the Symphony System hemostasis valves comprise a first actuator and a second actuator that each comprise a button.

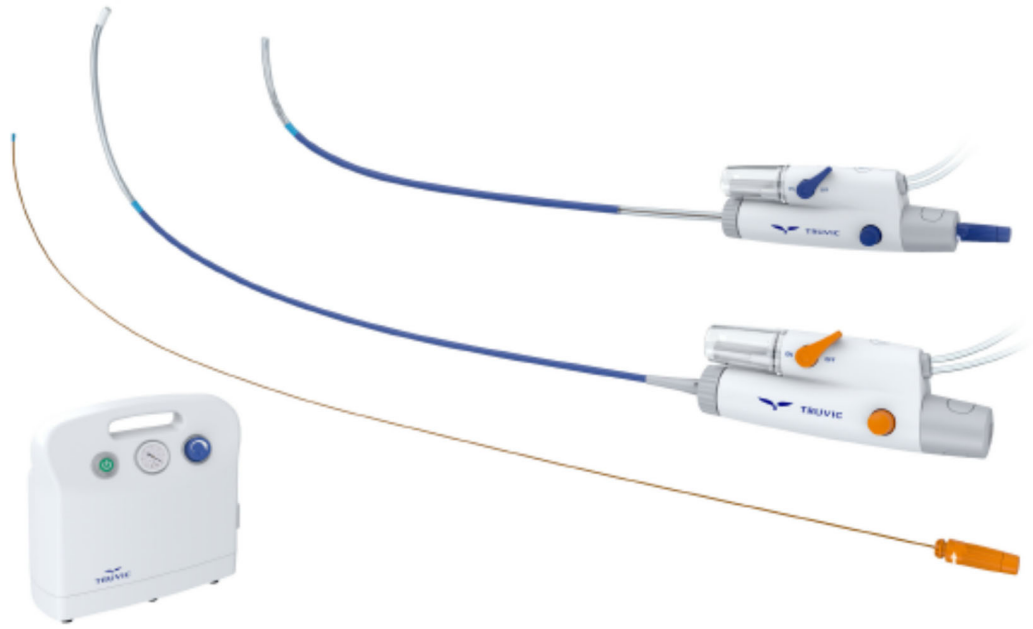
High-Powered, Continuous Vacuum with Real-Time Case Assessment

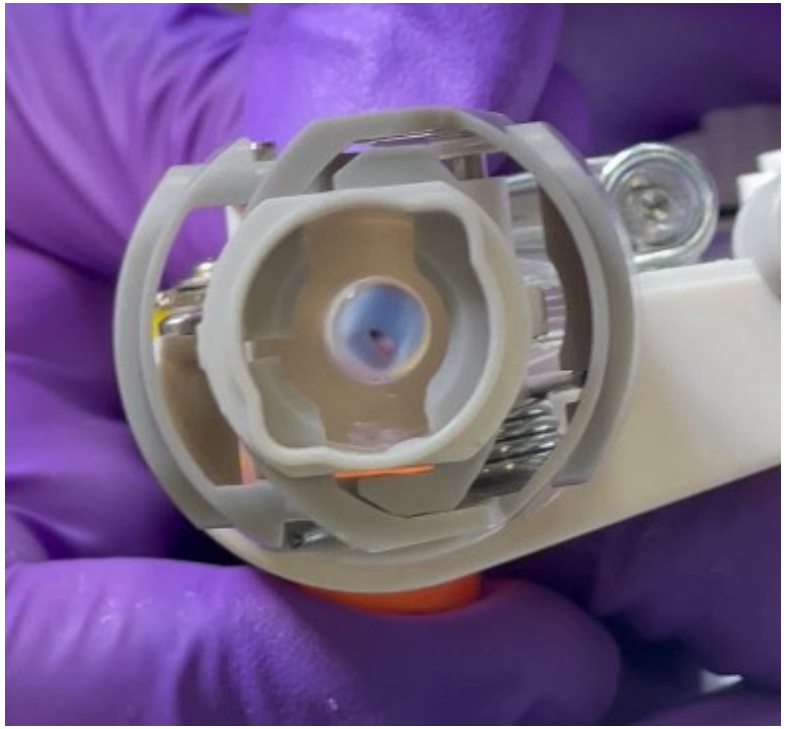
BigShot™ Controller

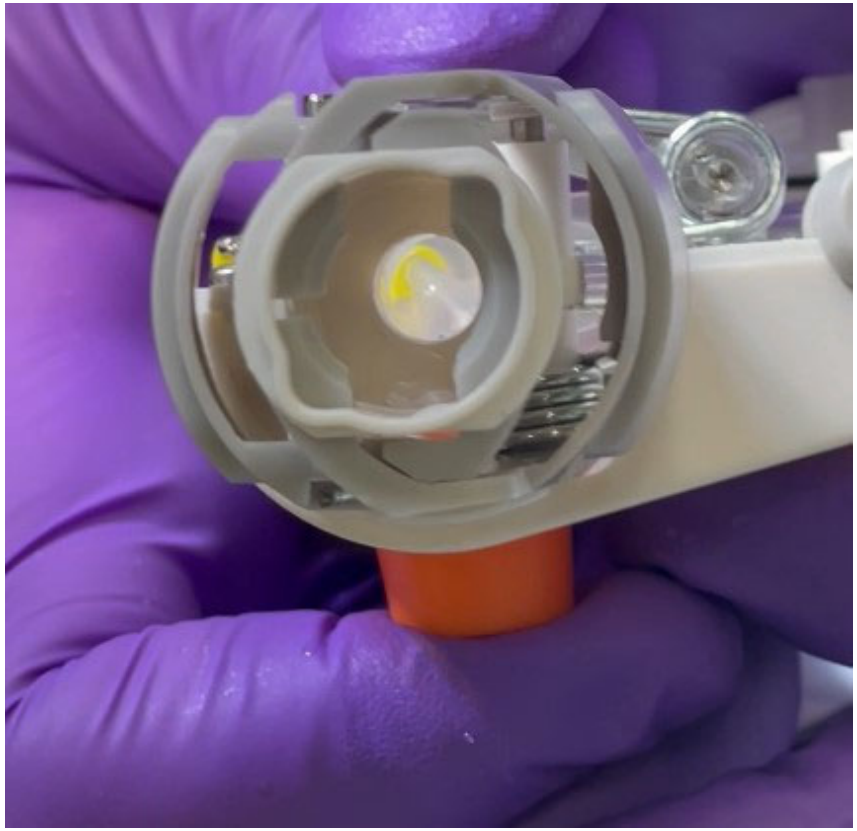


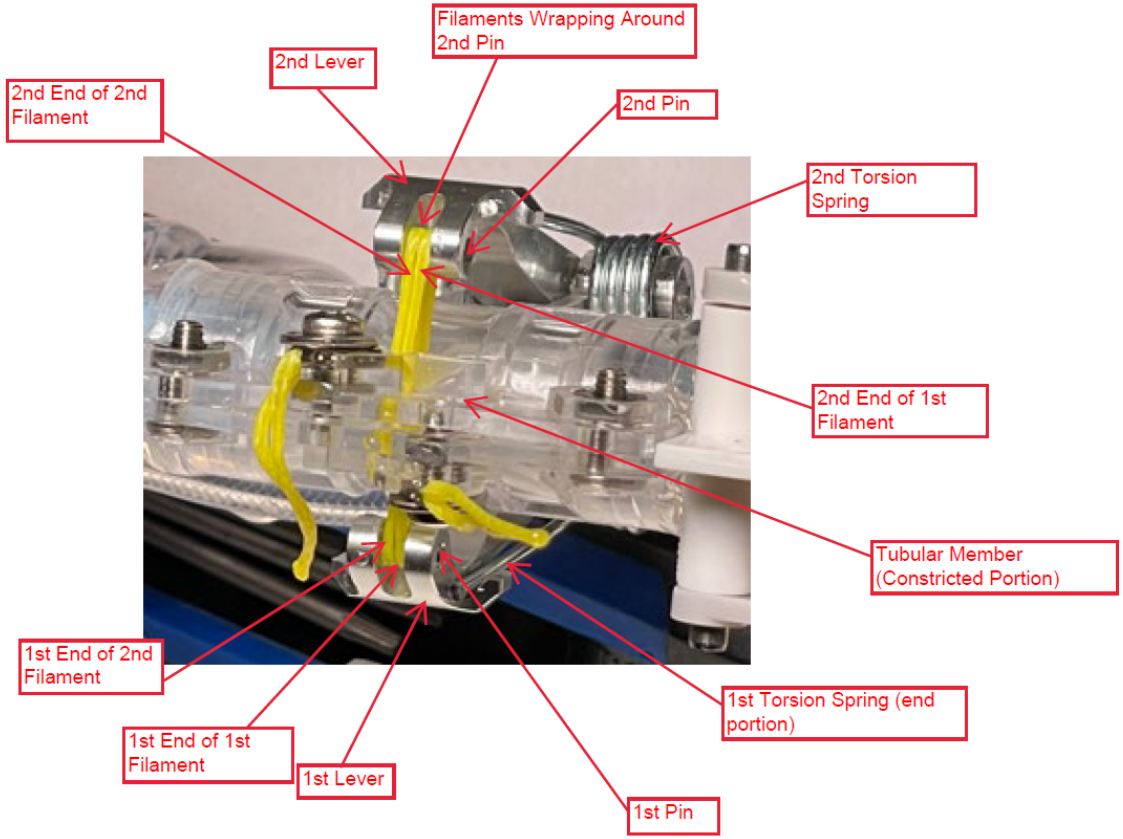
(Annotated Symphony Thrombectomy System Brochure at 6.)

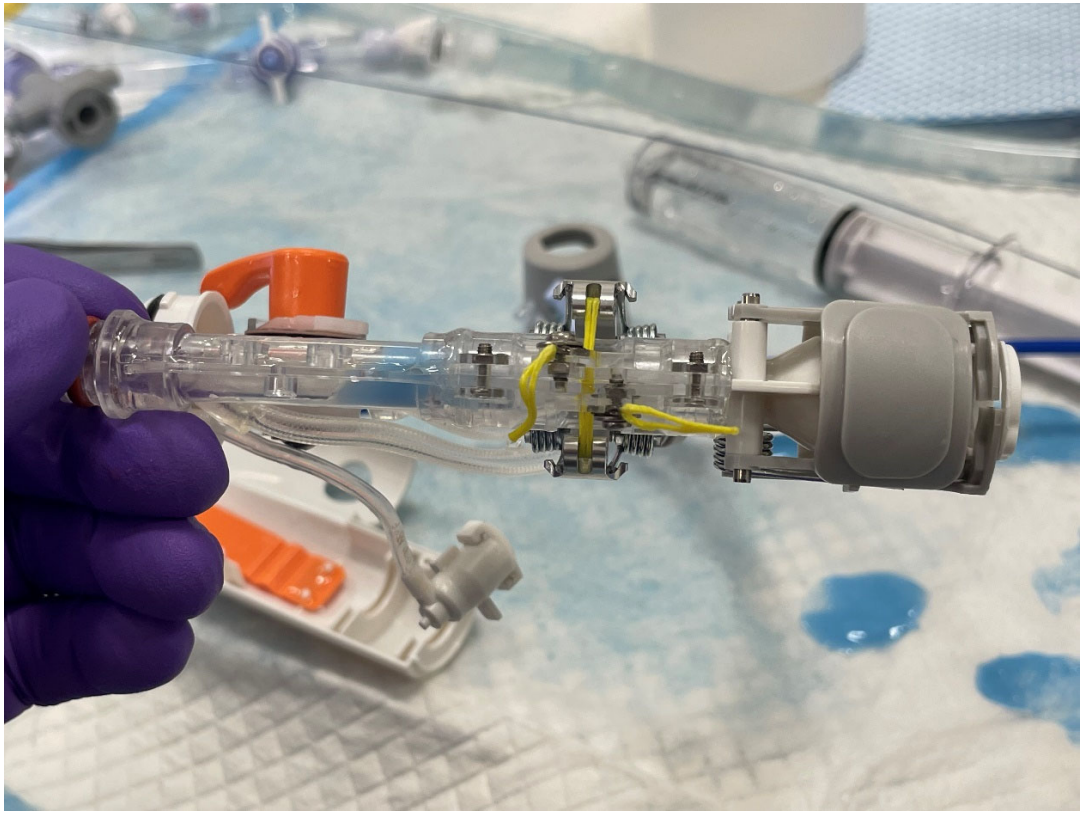
A hemostasis valve is positioned within each of the two Symphony handles. The hemostasis valve is operated by two blue or two orange buttons, depending on the handle.

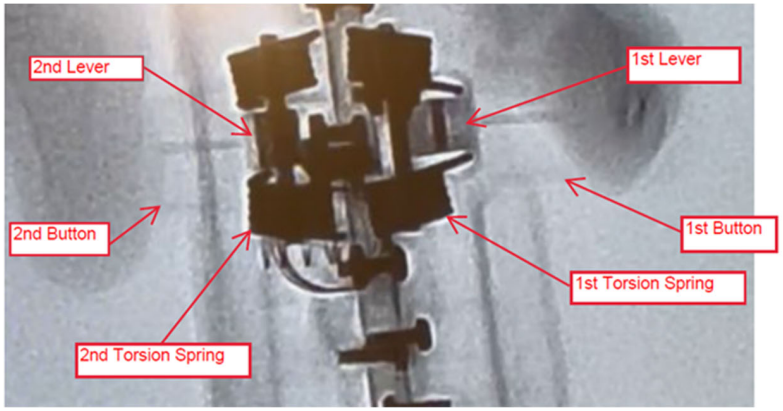
	 (Symphony Thrombectomy System Brochure at 2.)

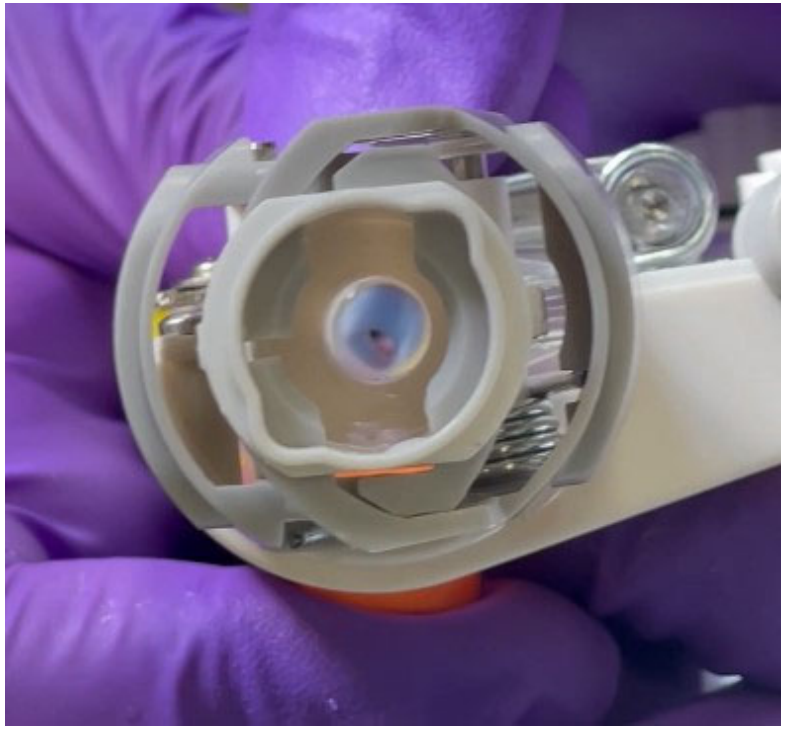
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

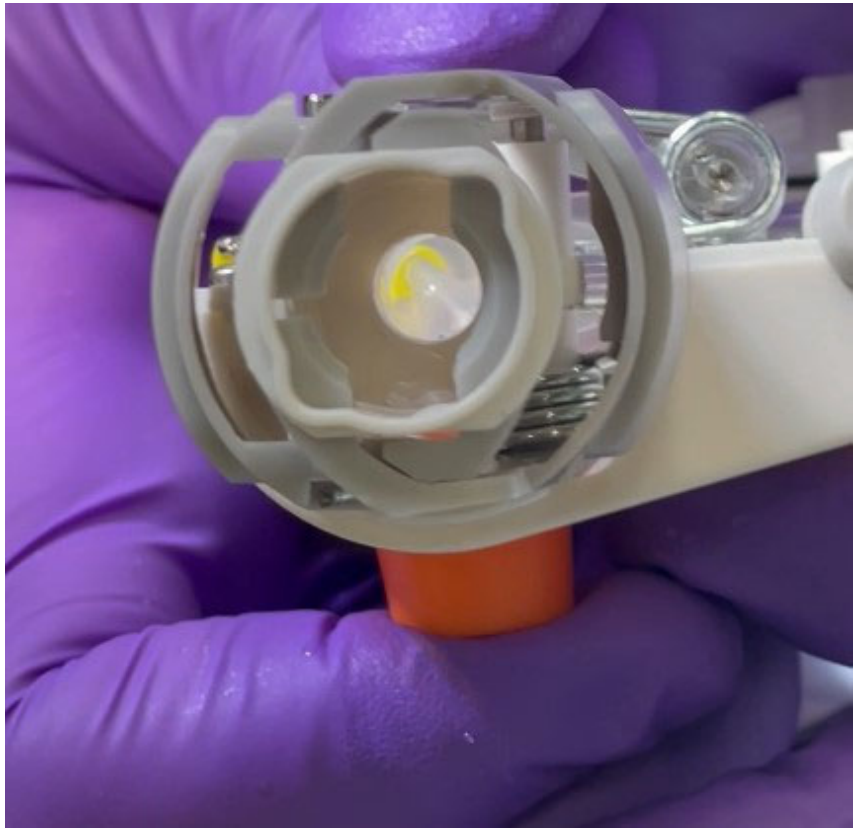
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[25] The valve assembly of claim 23 wherein the first filament includes a first portion operably coupled to a first one of the actuators and a	The Symphony System hemostasis valve comprises a first actuator and a second actuator. The first actuator is defined by the first button/lever/pin. The second actuator has a second button, second lever, and second pin. The first actuator and second actuator are coupled to the elongate member via a first filament and a second that extend at least partially around the elongate member. The first

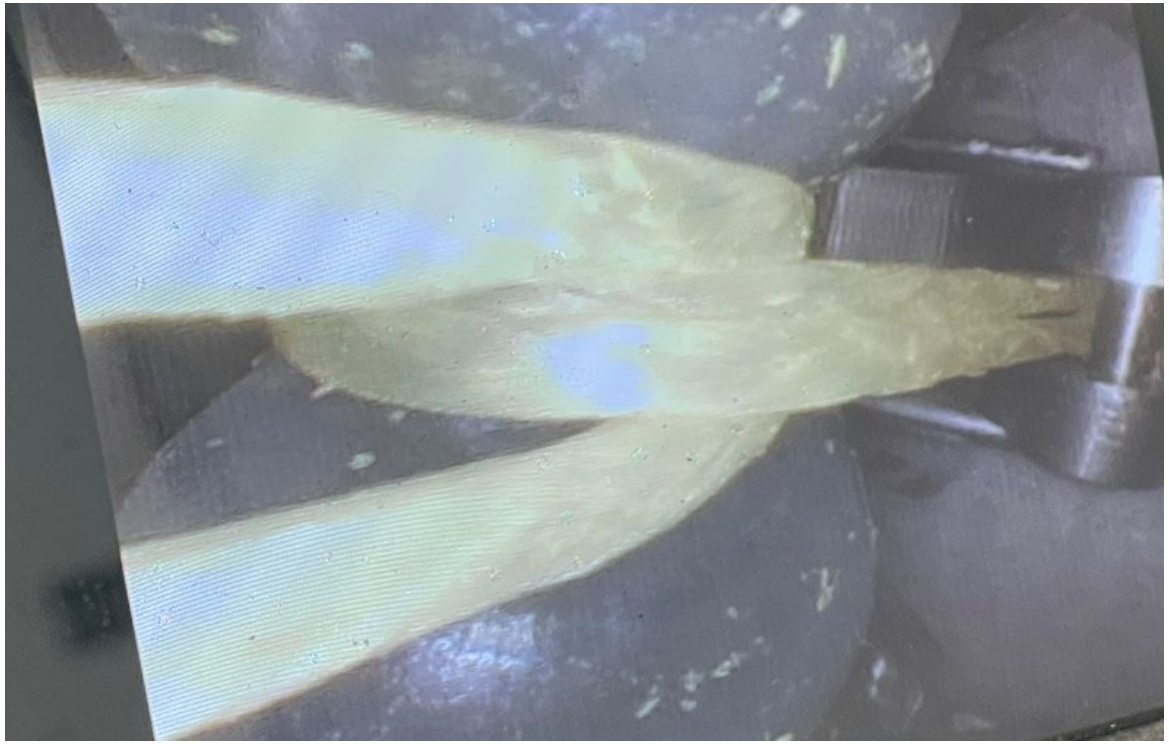
second portion operably coupled to a second one of the actuators, and wherein the second filament includes a first portion operably coupled to the first one of the actuators and a second portion operably coupled to the second one of the actuators.	filament and the second filament each extend completely in a loop around the elongate member, with the first end portion of the first filament and the first end portion of the second filament operably coupled to and acted upon by the first actuator, and the second end portion of the first filament and the second end portion of the second filament operably coupled to and acted upon by the second actuator.  (Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first

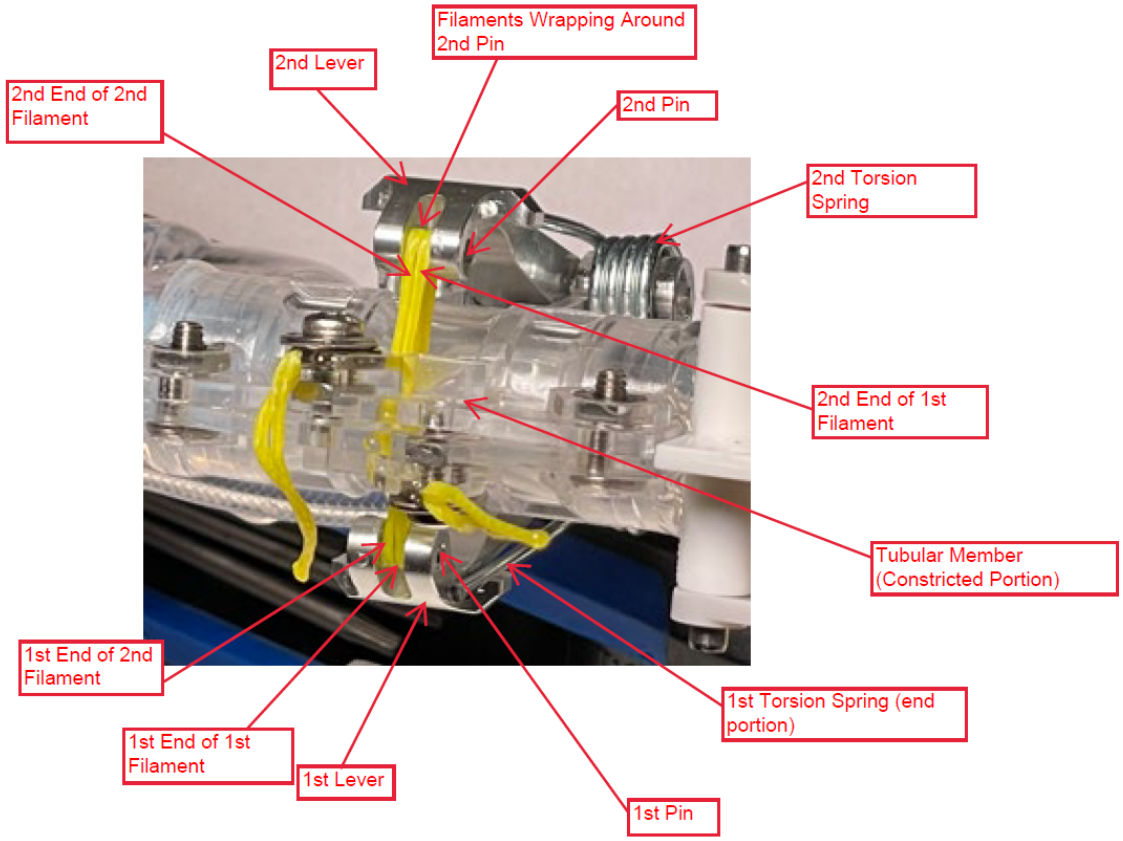
	filament coupled to and acted on by the first actuator and the second end of the first filament coupled to and acted on by the second actuator.)  (Image of internal portion of housing with hemostasis valve.)

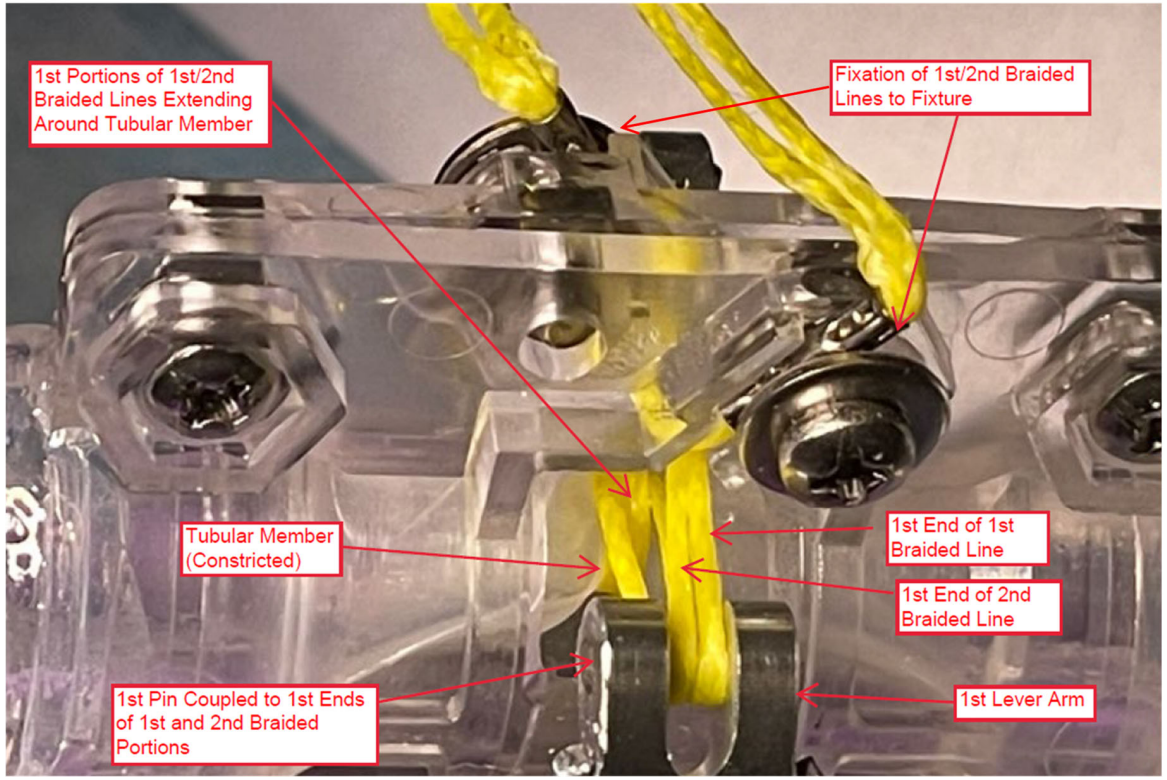
	 (X-ray imaging of housing showing annotated first and second buttons, first and second levers, and first and second torsion springs, as part of tensioning mechanism for hemostasis valve in Symphony System housing.)

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

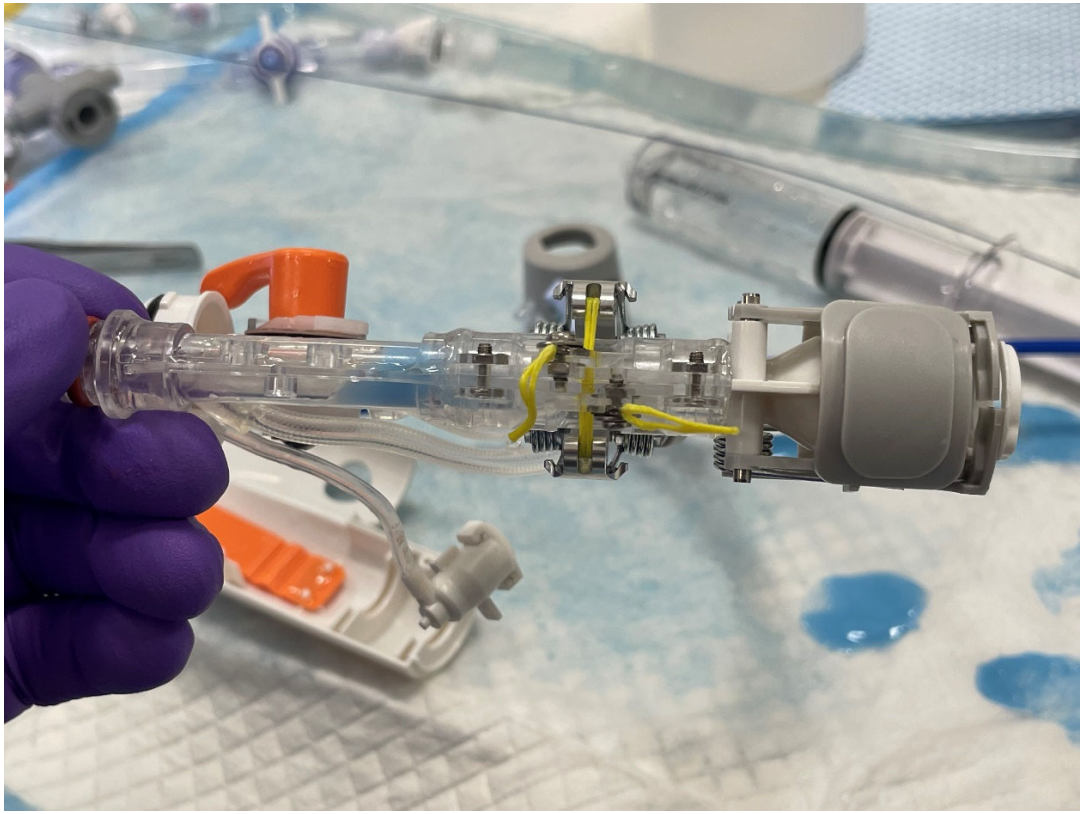
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve constricted.)

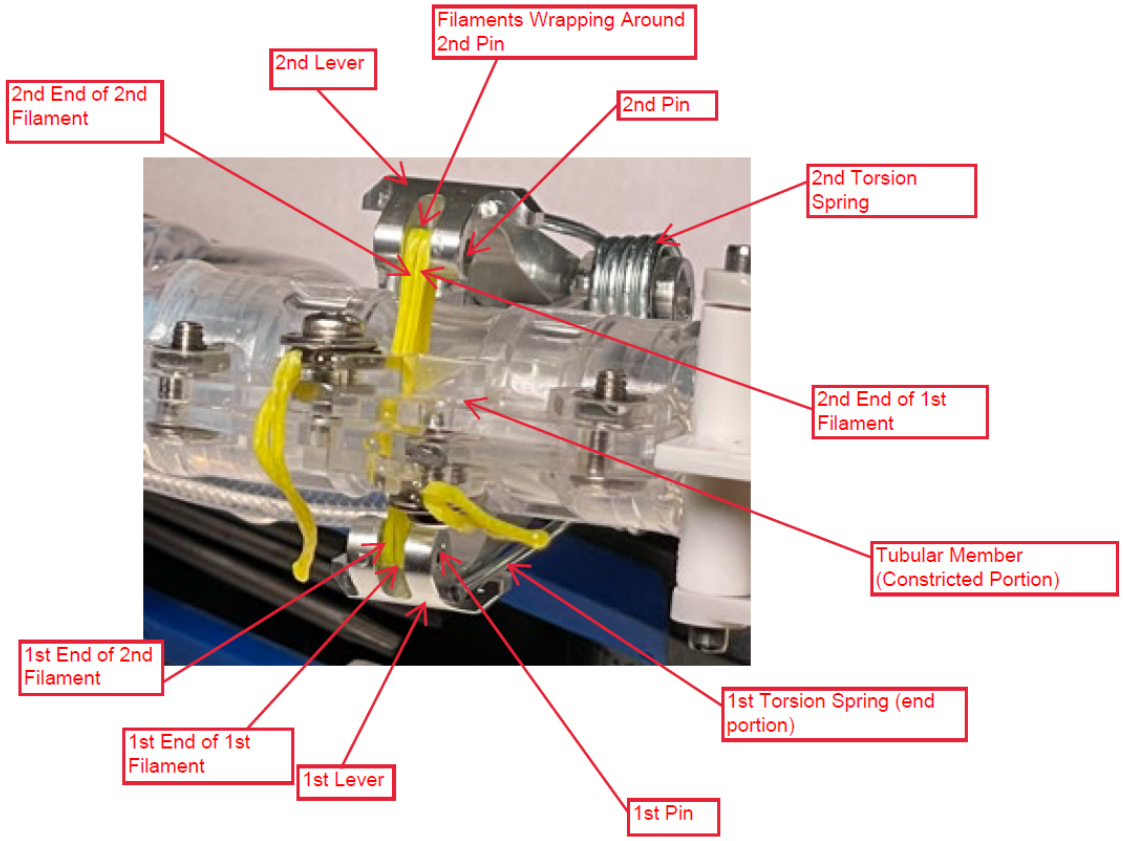
	 (Internal image of hemostasis valve with filaments encircling and constricting elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[26] The valve assembly of claim 25 wherein the first portion of first filament is directly attached to the first one of the actuators, wherein the second portion of the first filament is directly attached	As can be seen above in the figures and photos with Claims 1, 4, 15, and 18, the Symphony System hemostasis valve comprises first end portions of the first and second filaments directly attached (looped around) the first one of the actuators, and second end portions of the first and second filaments directly attached (looped around) the second one of the actuators.

to the second one of the actuators, wherein the first portion of the second filament is directly attached to the first one of the actuators, and wherein the second portion of the second filament is directly attached to the second one of the actuators.	 (Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first filament and the first end of the second filament wrapped around and acted on by the first actuator and the second end of the first filament and the second end of the second filament wrapped around and acted on by the second actuator.)

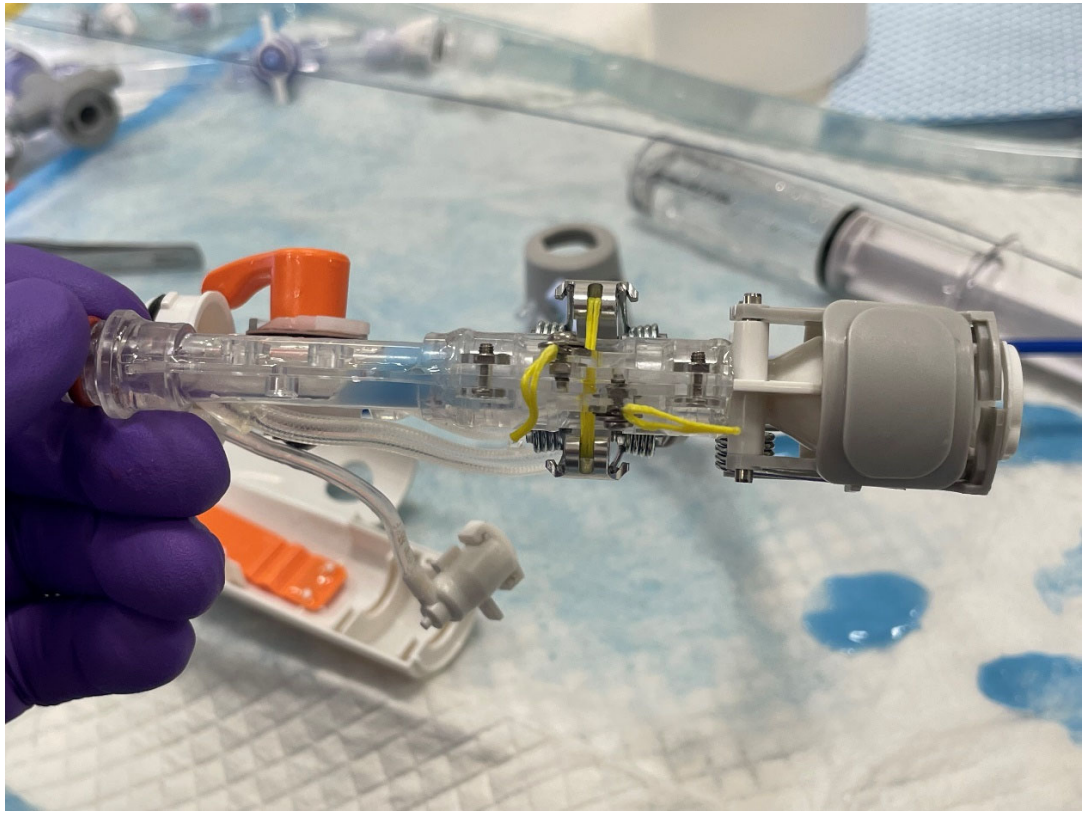


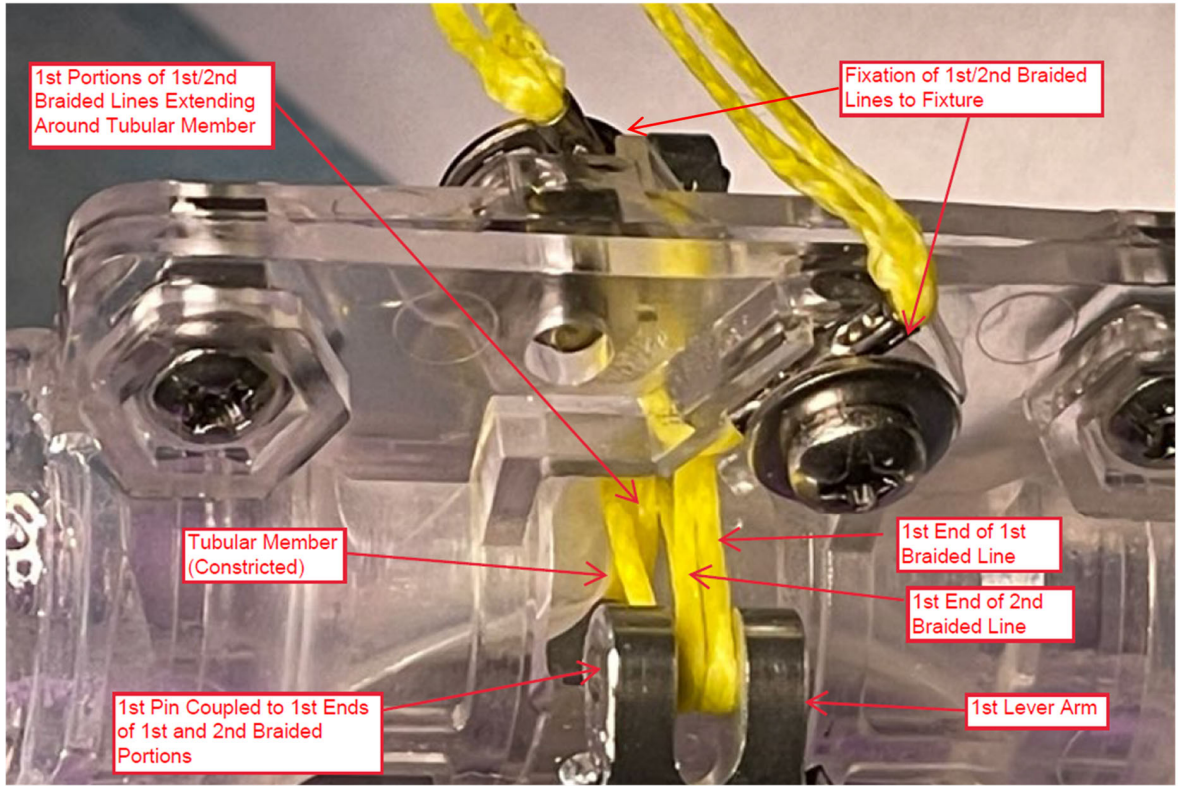
(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and filaments extending around the elongate member.)

	 (Image of internal portion of housing with hemostasis valve.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[27] The valve assembly of claim 23 wherein the first filament is flexible, and wherein the second filament is flexible.	As can be seen above in the figures and photos with Claims 1 and 17, the Symphony System has a flexible first filament with a first loop and a flexible second filament with a second loop that extend completely around the tubular (elongate) member.

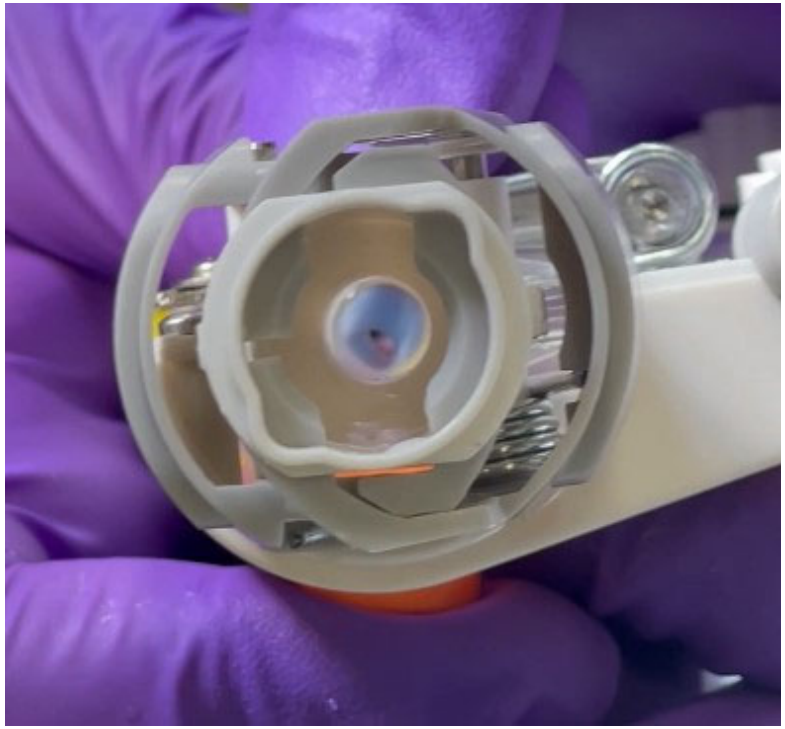


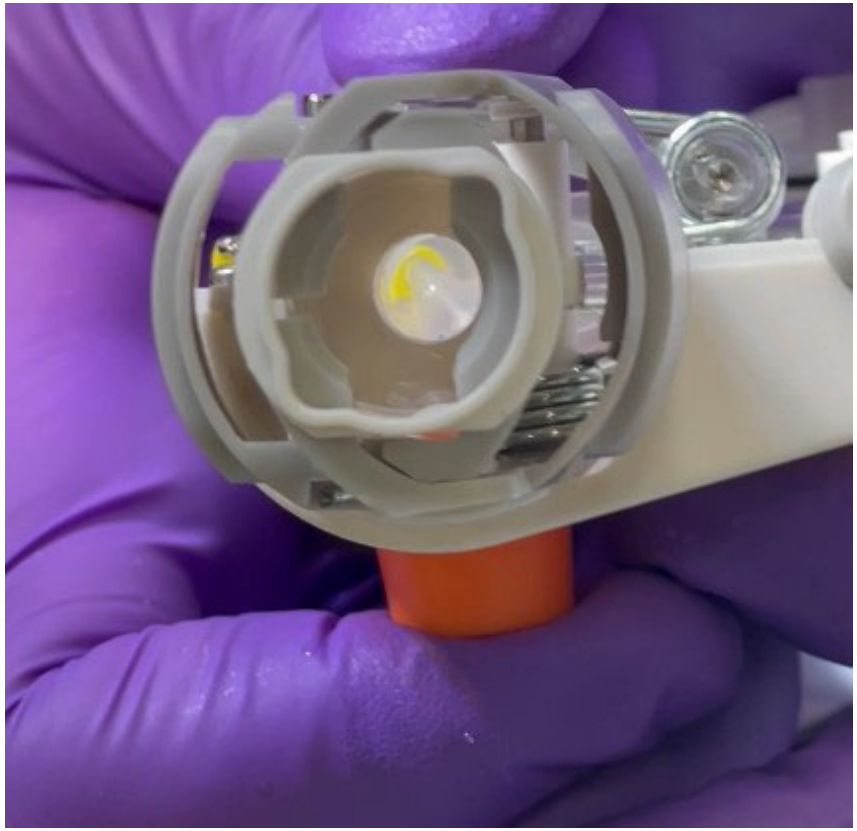
(Annotated image of internal portion of Symphony System housing, including hemostasis valve with elongate member (tubular member) and first and second filaments extending around the elongate member, with the first end of the first filament coupled to and acted on by the first actuator and the second end of the first filament coupled to and acted on by the second actuator.)

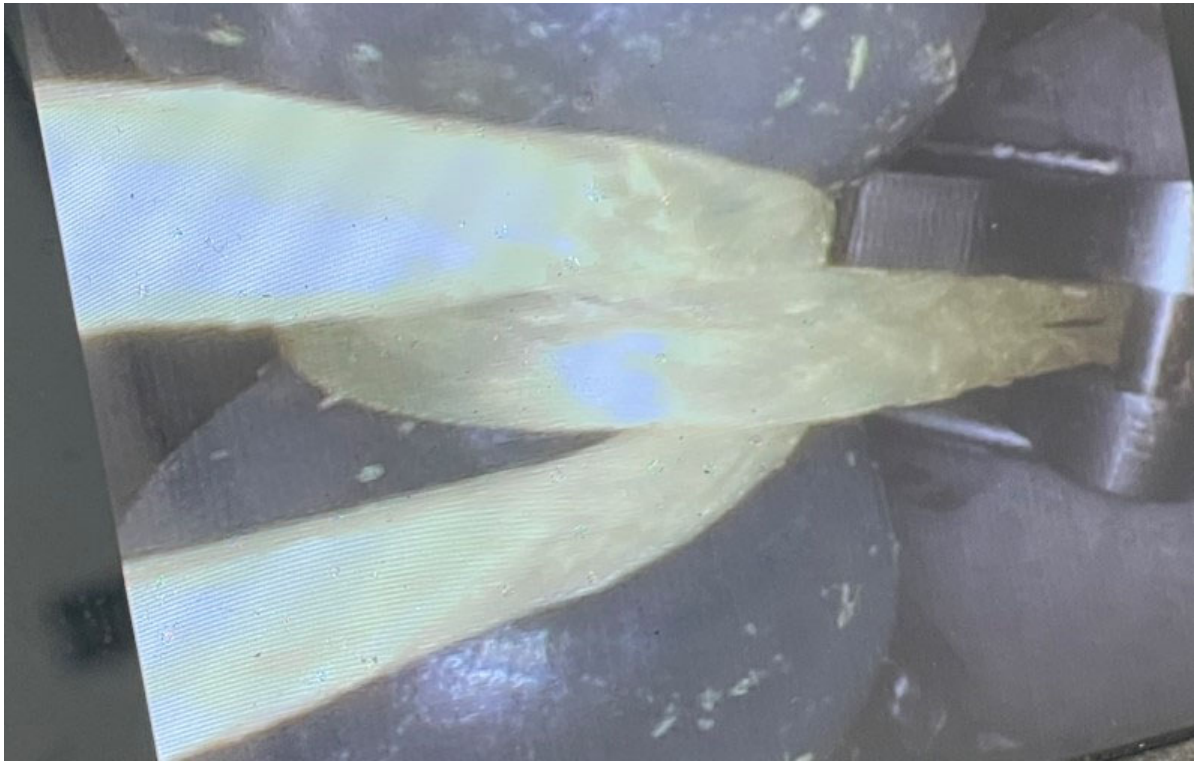
	 (Image of internal portion of housing with hemostasis valve.)



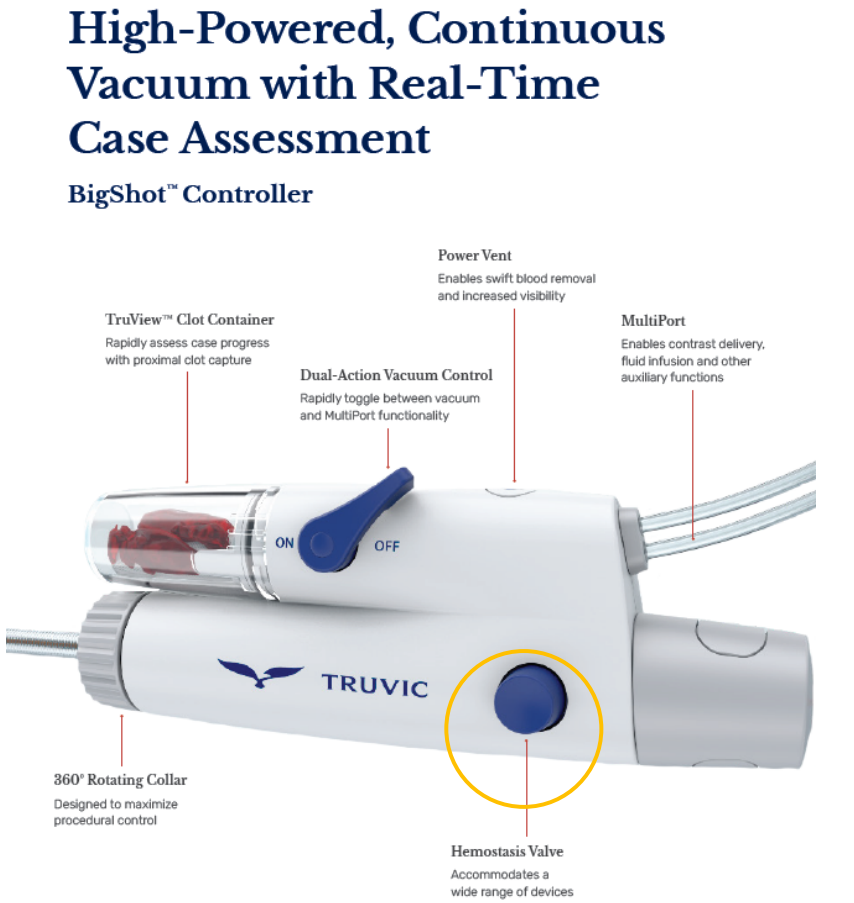
(Annotated image of zoomed-in internal portion of Symphony System housing, including a partial view of the hemostasis valve having an elongate member (tubular member) constricted and first and second filaments each extending in a loop around the elongate member.)

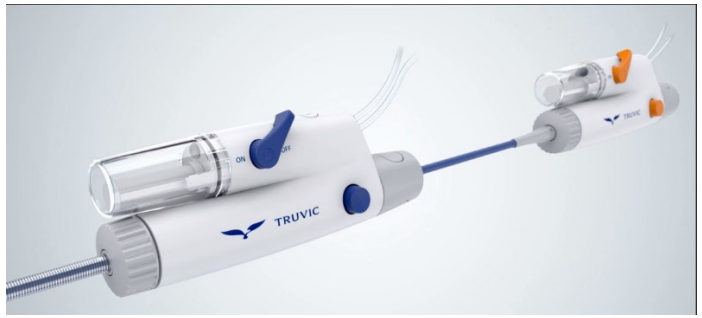
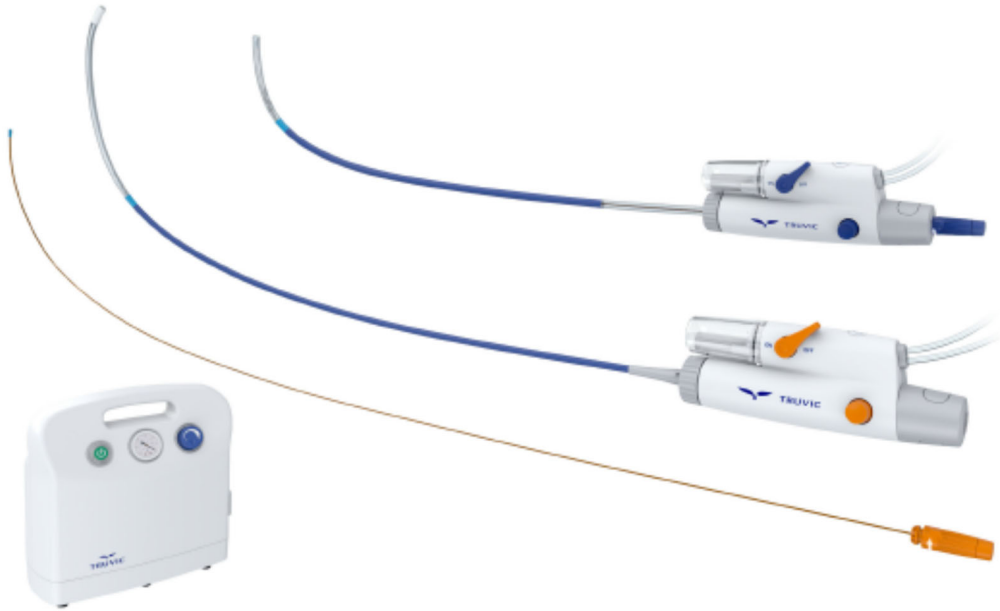
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.)

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

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

	 (Internal image of hemostasis valve with filaments encircling elongate member.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[28] The valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 16 French.	The Symphony System hemostasis valves on both the 16F and 24F Symphony handles have a lumen diameter of at least 16 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the respective 16F or 24F dilator, 16F or 24F ProHelix (or a 16F catheter for the 24F handle), to pass through the hemostasis valve. 16 French and 24 French are both at least as 16 French.

	 (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

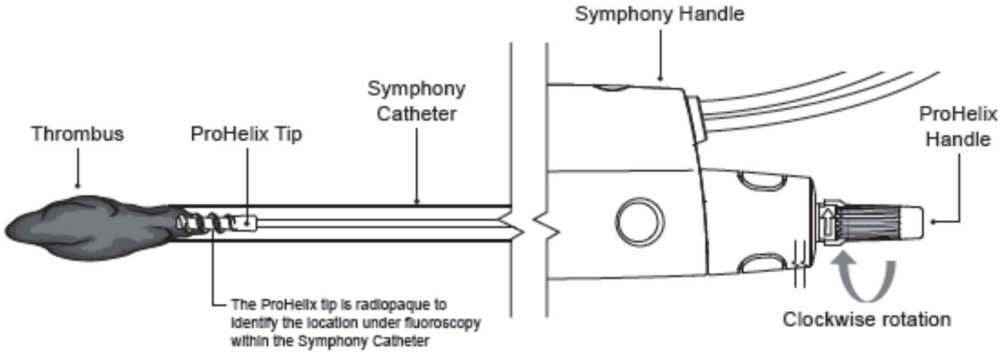


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

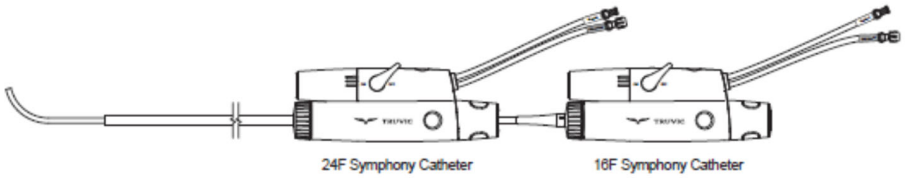
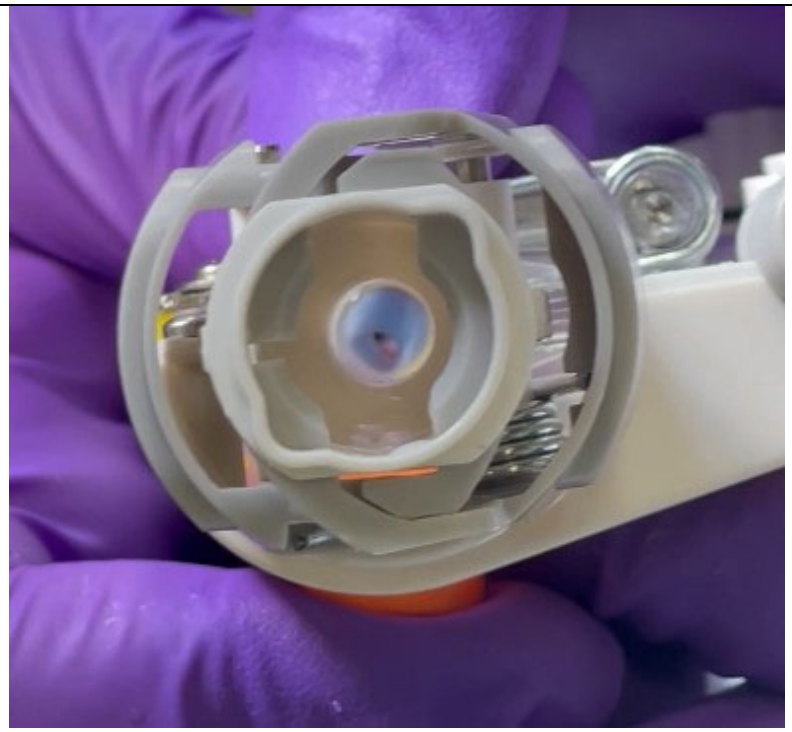
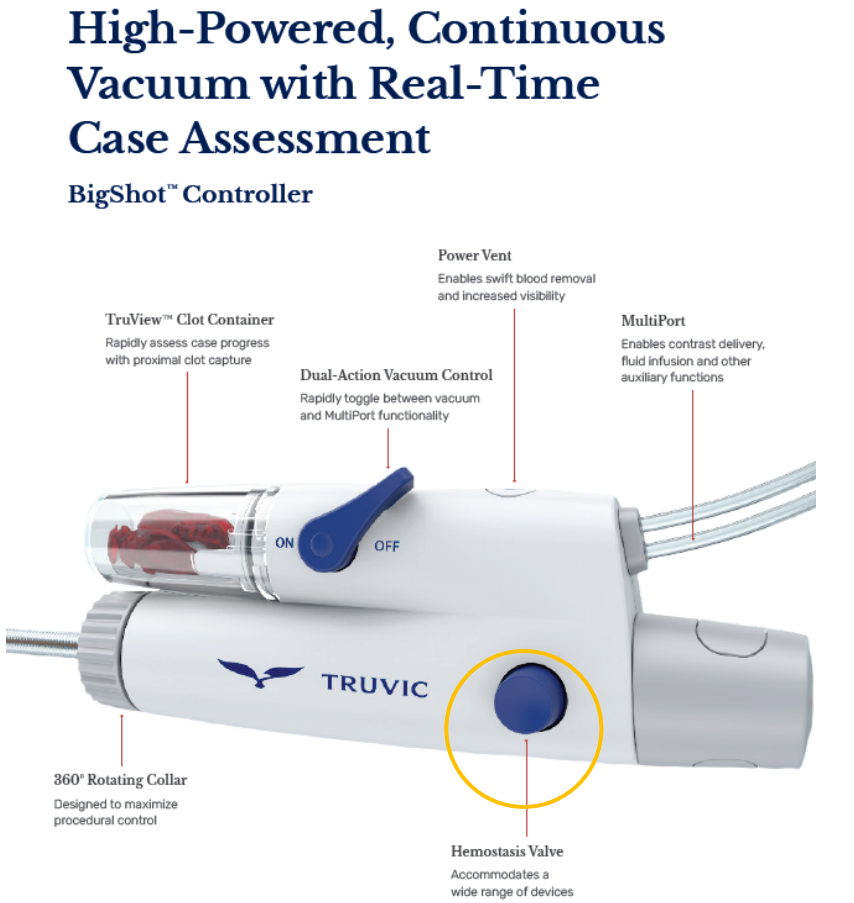
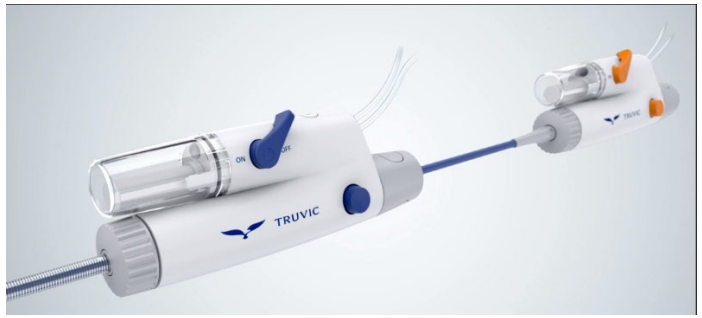
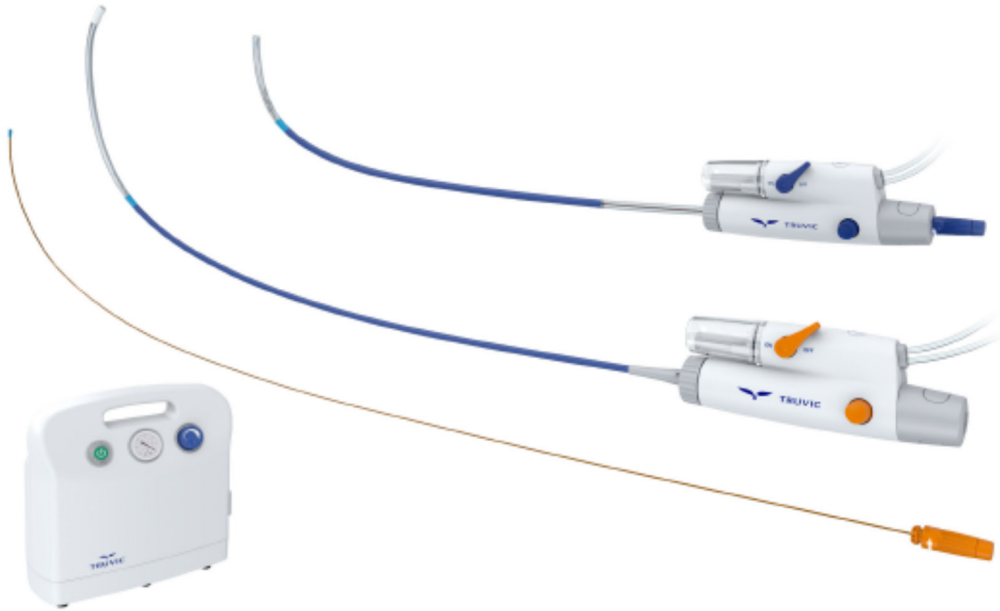


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[29] The valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 20 French.	The Symphony System hemostasis valve on the 24F Symphony handles have a lumen diameter of at least 20 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the 24F dilator, 24F ProHelix, or a 16F catheter, to pass through the hemostasis valve. 24 French is larger than 20 French.

	 (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

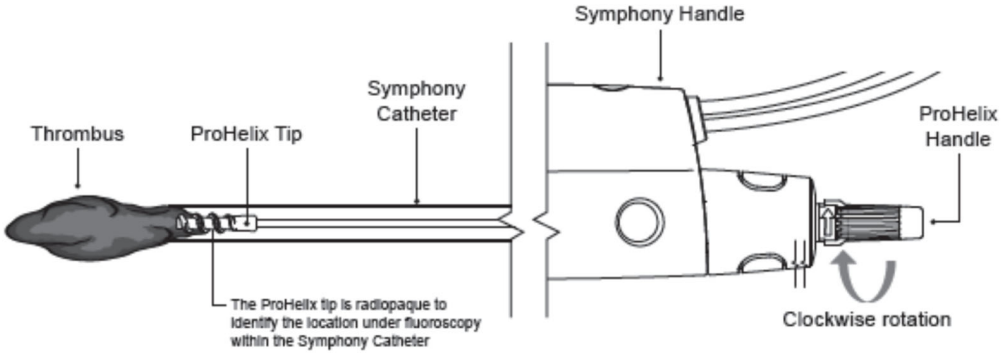


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

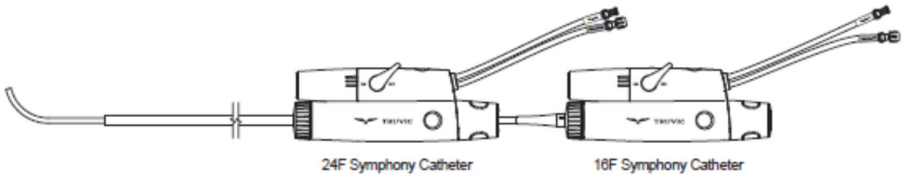
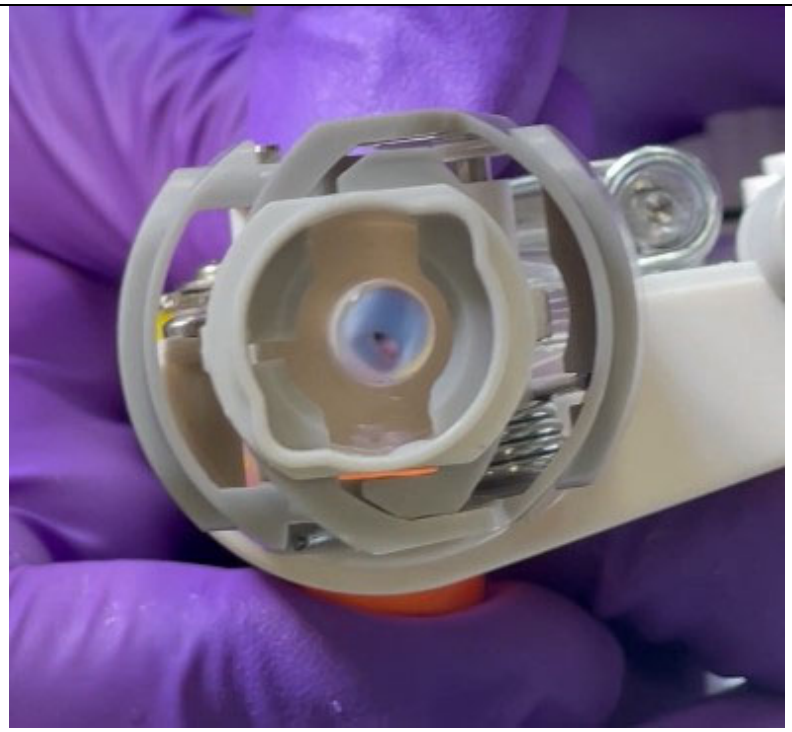
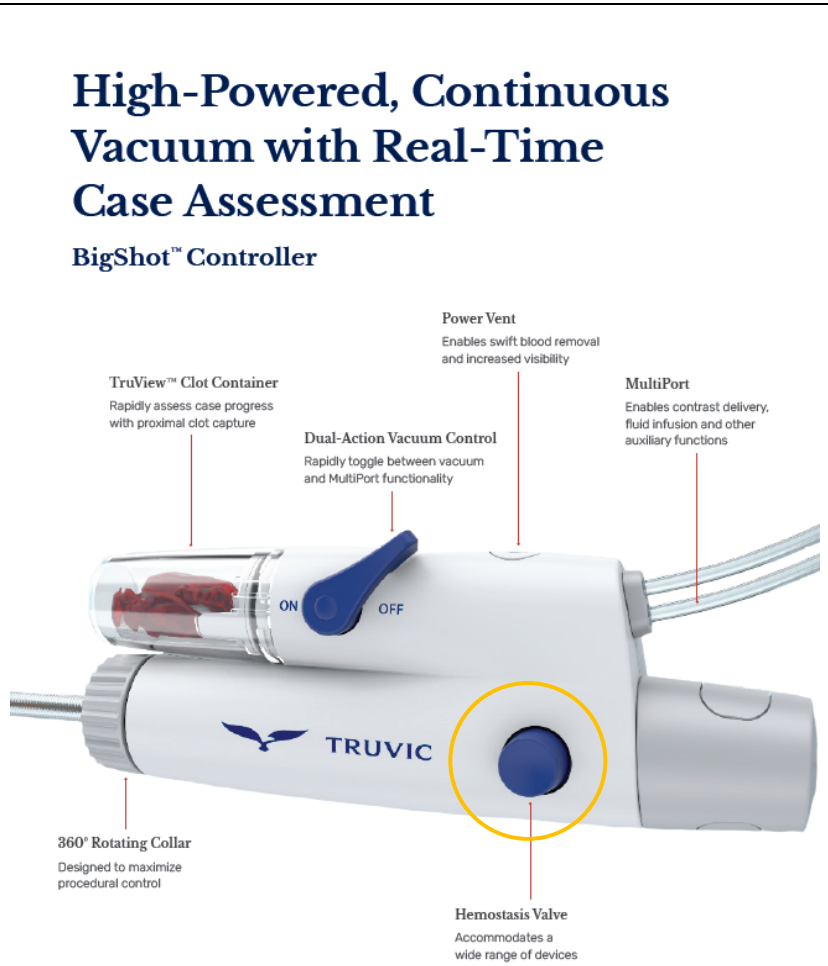
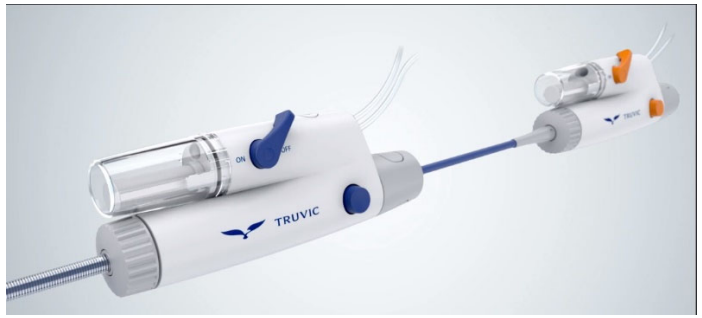
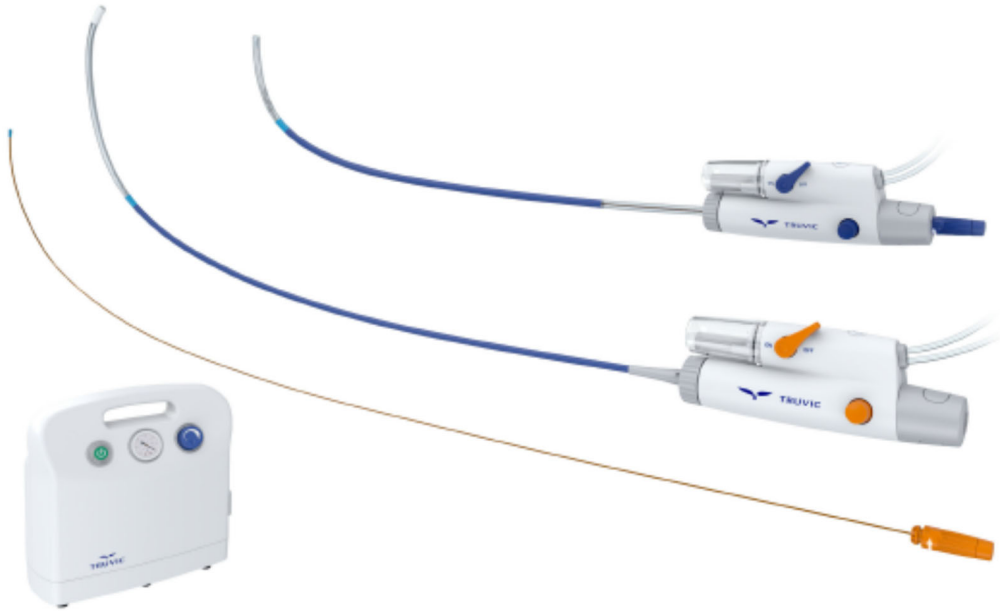


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
[30] The valve assembly of claim 23 wherein, in the second position, the tubular member has a diameter of at least 24 French.	The Symphony System hemostasis valve on the 24F Symphony handles have a lumen diameter of at least 24 French when the buttons are depressed (in the second, unconstricted position), allowing for an object, e.g., the 24F dilator, 24F ProHelix, or a 16F catheter, to pass through the hemostasis valve. 24 French is at least 24 French.

	 (Annotated Symphony Thrombectomy System Brochure at 6 pointing to button used to actuate hemostasis valve.)

	 (Symphony Thrombectomy System – Overview Animation Video at 1:45 (https://vimeo.com/817718796).)  (Symphony Brochure at 2.)

Symphony™

THROMBECTOMY SYSTEM

Product Ordering Information

Symphony Catheter	Model	Working Length	Guidewire Compatibility	Sheath Compatibility
16F Catheter	SYMPHONY16F	117 cm	0.038 in or less	16F
24F Catheter	SYMPHONY24F	85 cm	0.038 in or less	24F
24F Catheter+ Advance™ Long Dilator	SYMPHONY24F-A	85 cm	0.038 in or less	24F

Symphony Auxiliary Devices	Model
16F ProHelix	PROHELIX16F
24F ProHelix	PROHELIX24F

Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

(Symphony Brochure at 12.)

- Release the Dilator by pressing the Retention Clip buttons on the Handle.
  - When using a 24F Symphony System:
    - With the Dilator, withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the Catheter and guidewire position.

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

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

(Symphony IFU at 4-5.)

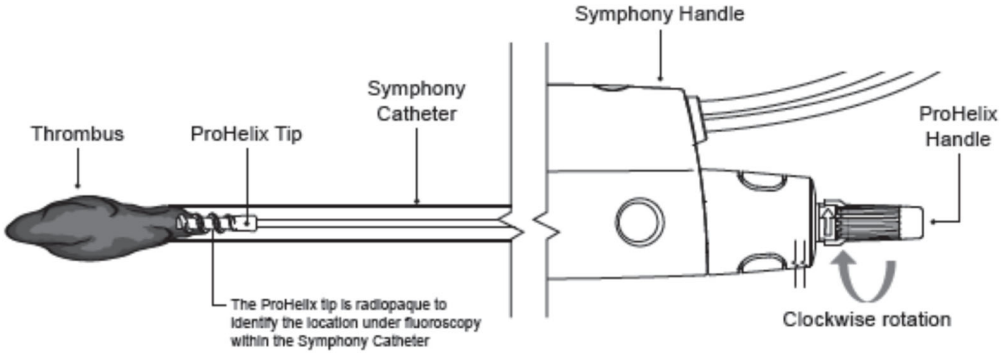


Figure 4: ProHelix engaged with thrombus

19. To resolve thrombus obstructing the Catheter tip, prepare and use the compatible Symphony ProHelix.
    a. Verify integrity of the ProHelix and flush the lumen with heparinized saline.
    b. Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle.
    c. To begin aspiration, move the vacuum lever on the Handle to the "ON" position.

(Symphony IFU at 5.)

TELESCOPING THE 16F SYMPHONY CATHETER THROUGH PREVIOUSLY PLACED 24F SYMPHONY CATHETER

1. Remove the Hemostasis Valve clip.
2. Flush the lumens of the Symphony Catheter and Dilator with heparinized saline. To flush the Symphony Catheter, confirm that the Vacuum Lever is in the "OFF" position, add a stopcock to the Handle injection port labelled "MultiPort" and flush saline through the Handle injection port until saline flows from the tip of the Symphony Catheter.
3. Hydrate the outer surfaces of the 16F Symphony Catheter and Dilator shafts.
4. Press the Hemostasis buttons to open the hemostasis valve and insert the 16F Symphony Dilator through the open Hemostasis Valve of the 16F Symphony Handle and advance through the Catheter until Dilator hub snaps into the Retention Clip of the Handle.
5. Insert a 0.035" guidewire at least 300 cm long into the Dilator with the guidewire tip retained within the Dilator.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled "MultiPort".
7. Press the Hemostasis buttons to open the Hemostasis Valve on the 24F Catheter Handle and advance the 16F System through the 24F Handle, until the Catheter tips are aligned under fluoroscopy.
   a. Note that the external markers on the 16F Catheter shaft provide an early indicator of approaching alignment of the 16F Catheter tip with the tip of the 24F Catheter.
   b. Alignment of the 16F Catheter tip with the tip of the 24F Catheter can be confirmed using fluoroscopic viewing of the radiopaque tip markers of the Catheters.
8. Extend the guidewire to the desired position to enable the 16F System to reach the target location.
9. Advance the 16F System over the guidewire to the target location.

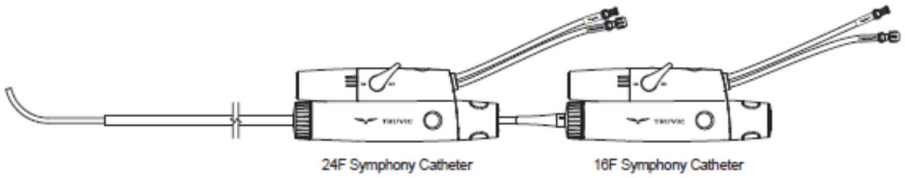


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony IFU at 7.)

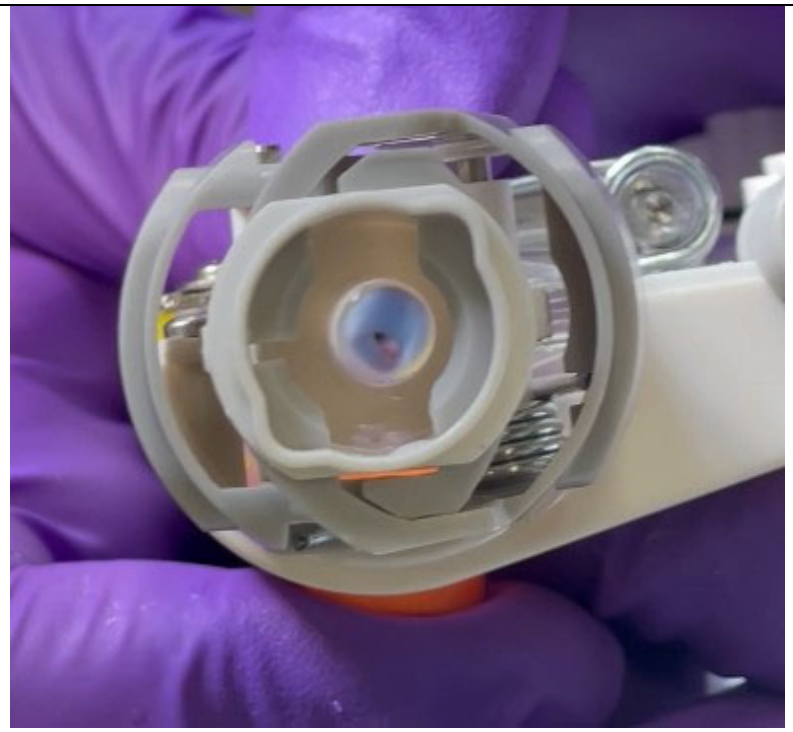
	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

EXHIBIT K
INFRINGEMENT ANALYSIS OF CLAIMS 1-5, 8, 10-12, 14-19, 22, 24-28, AND 30 OF UNITED STATES PATENT NO. 12,156,669
TRUVIC SYMPHONY THROMBECTOMY SYSTEM

Pursuant to Patent Local Rule 3-1, this chart identifies specifically where and how each limitation of Asserted Claims 1-5, 8, 10-12, 14-19, 22, 24-28, and 30 of United States Patent No. 12,156,669 ("the '669 Patent") is found within the Imperative Care Symphony Thrombectomy System ("Symphony System"), including parts and accessories of the 24F and 16F catheter assemblies, such as ProHelix devices of the Symphony System. Collectively, these structures are referred to below as the "Symphony System."

References Cited:

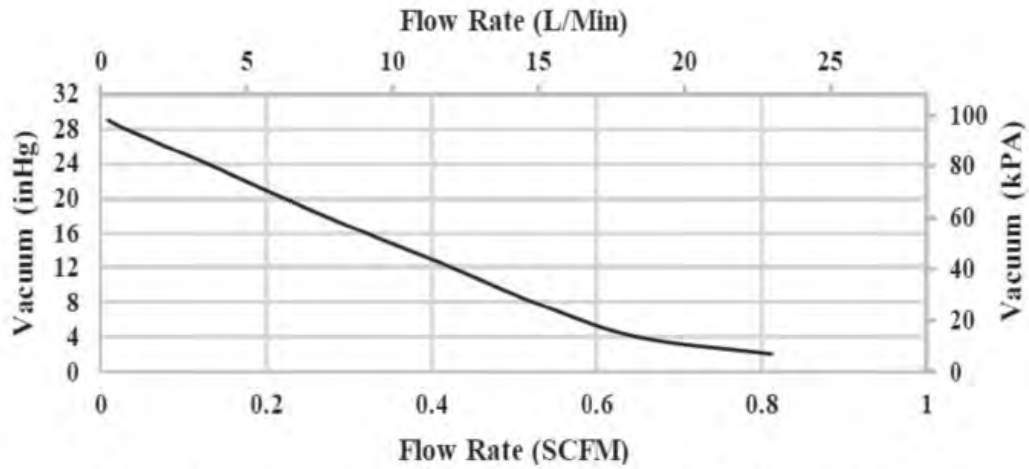
- Symphony Thrombectomy System Brochure (found at https://www.truvic.com/symphony-product; ECF 20-1 (First Amended Complaint Exhibit A); https://cdn.prod.website-files.com/65422b4be21822e711073c8a/65422b4be21822e711073cd1_M10132.A%20Symphony%20Brochure_single_Page.pdf)
- Instructions For Use Symphony Thrombectomy System (ECF 20-2 (First Amended Complaint Exhibit B); https://assets.website-files.com/5eeb7b9eeb1d5b0fb7c9d89a/644268627f5a6760b5e3ade2_LBL10001-02.B%20Truvic%20Symphony%20Thrombectomy%20System%20IFU.pdf)
- Symphony Thrombectomy System – Overview Animation Video (found at https://www.truvic.com/symphony-product; https://vimeo.com/817718796)
- Symphony System tear-down photos (produced at Bates numbers INARI_034203-INARI_034266, INARI_039006-INARI_039007)
- Whipsaw website discussion of Symphony (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system)
- Symphony System sample provided by Truvic
- M10147.C-Symphony-Product-Spec-Sheet.pdf (INARI_034312)
- Instructions For Use Symphony Thrombectomy System 16F, 82CM (INARI_034306-INARI_034311)

Infringing Acts:

- Imperative Care, including without limitation Imperative Care Vascular and/or Truvic (collectively, "Truvic"), has been making, having made, selling, offering for sale and/or using Symphony System products since at least March of 2023 to the present. Truvic's filings admit that it received FDA clearance for the Symphony System in February of 2023 and began marketing on or before March of 2023. Since the issuance of the '669 Patent on December 3, 2024, such making, having made, selling, offering for sale, and/or using the Symphony System, has infringed the '669 Patent.
- Truvic's Symphony System, including the 16F and 24F Bigshot Controller Handles and the 16F and 24F catheters, indirectly infringes by inducement and contributory infringement. Specifically, the Symphony System, including the 16F and 24F Bigshot Controller Handles and the 16F and 24F catheters are especially made to be used as an aspiration system to treat deep vein thrombosis and/or pulmonary embolism. Further, Truvic specifically instructs and intends for users to utilize the Symphony System as an aspiration system in a manner that infringes the '669 Patent. Additionally, the Symphony System is especially made and adapted for practicing the claims of the '669 Patent, forms a material part of the invention, and is not suitable for substantial non-infringing uses.

The citations to portions of any reference in this chart are exemplary only. Inari anticipates it will rely on the entirety of the references cited in this chart, as well as other documents and testimony that will be produced during discovery, to demonstrate that the Symphony System infringes the '669 Patent. Discovery is ongoing, and Inari reserves its right to update this chart as appropriate based on the results of its investigation, including pursuant to Local Patent Rule 3-6.

CLAIM ELEMENT	CORRESPONDING STRUCTURE
[1] An aspiration system, comprising:	The Symphony System is an aspiration system for treating blood clots in the vasculature of a patient. The Symphony System is system that provides "[p]owerful, [f]ocused [a]spiration to "[m]aximize thrombus removal with high-powered, on-demand continuous aspiration and in-hand TruView™ clot capture." (Symphony Thrombectomy System Brochure at 2-4.) It "is designed to remove thrombus/embolus … from the vasculature using controlled aspiration." (Symphony Thrombectomy System Instructions For Use at 1.) The Symphony System IFU also discloses that "[t]he Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. The Symphony ProHelix may also be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter." (Symphony Thrombectomy System Instructions For Use at 1; *see also* Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister to aspirate thrombus.").) Truvic includes a video on its website (https://www.truvic.com/symphony-product) detailing a method of using the Symphony System to treat clot material within a blood vessel of a human patient by aspirating clot material to remove thrombus.
a vacuum source;	The Symphony System includes a vacuum source. Specifically, the 24F and 16F Symphony Thrombectomy Catheters are verified for

	use with the Truvic Generator and Truvic Canister, which, together, is an example of a vacuum source. (Symphony Thrombectomy System Instructions For Use at 2.) "The TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve" shown below. (Symphony Thrombectomy System Instructions For Use at 2.)  **Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator** (Symphony Thrombectomy System Instructions For Use at 2.) The IFU depicts the Truvic Generator and Truvic Canister (*e.g.*, a vacuum source) connected to the 24F Symphony Catheter and/or 16F Symphony Catheter and includes instructions on how to turn on the Generator so that it can be used with the Truvic Canister as a vacuum source for aspiration. (Symphony Thrombectomy System Instructions For Use at 8.)

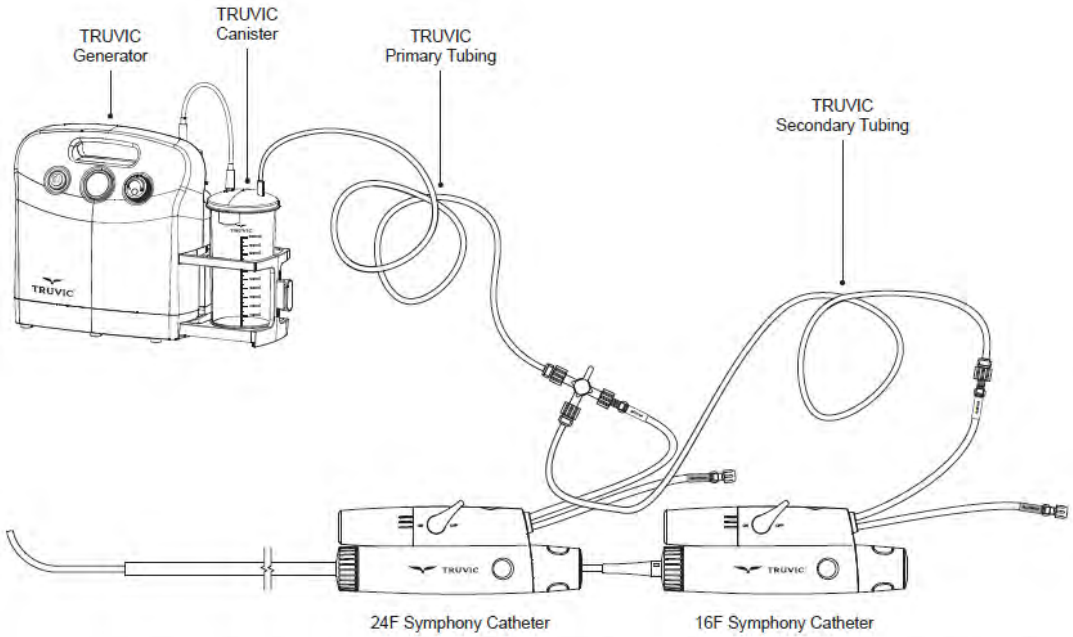
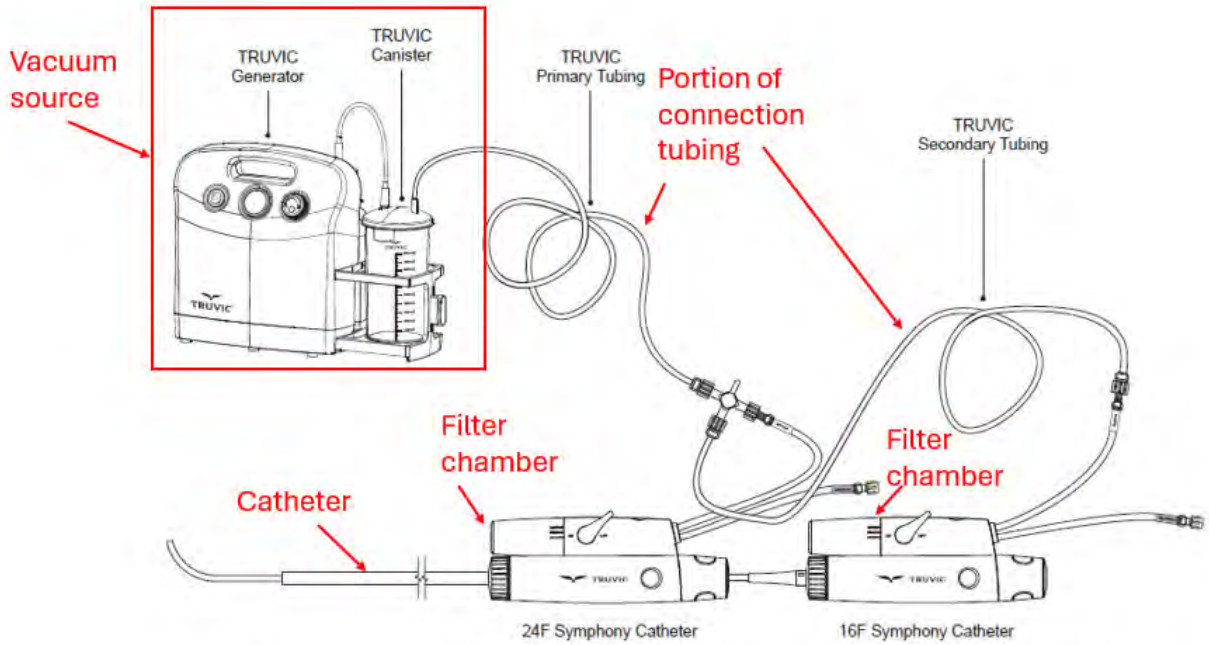
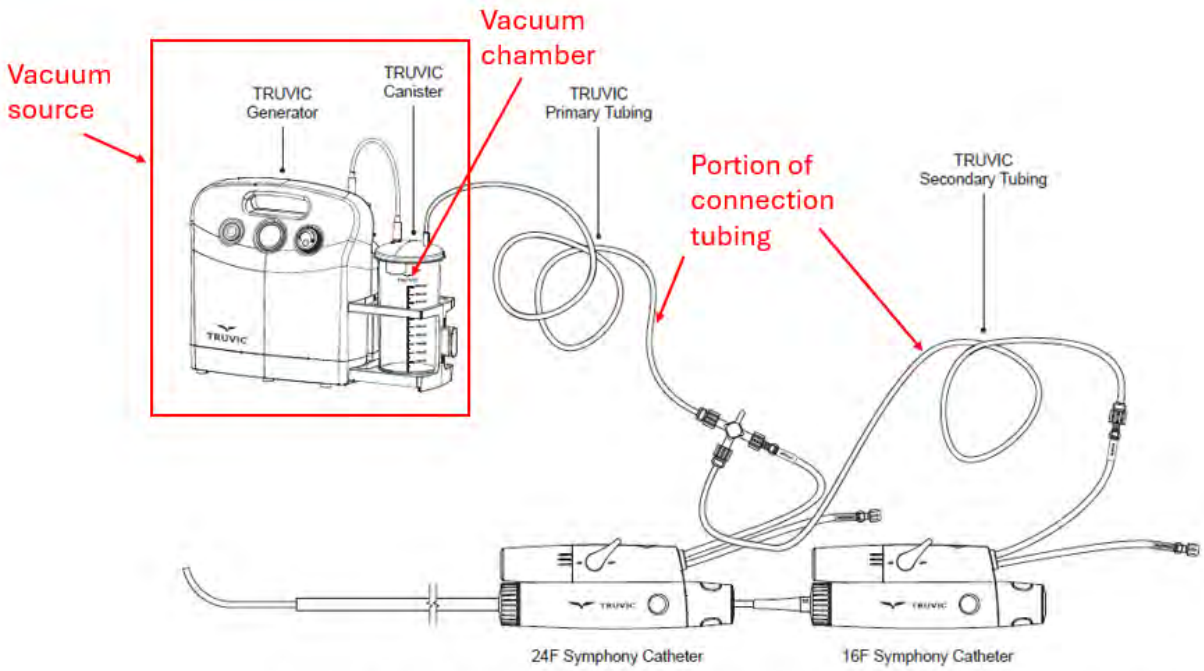


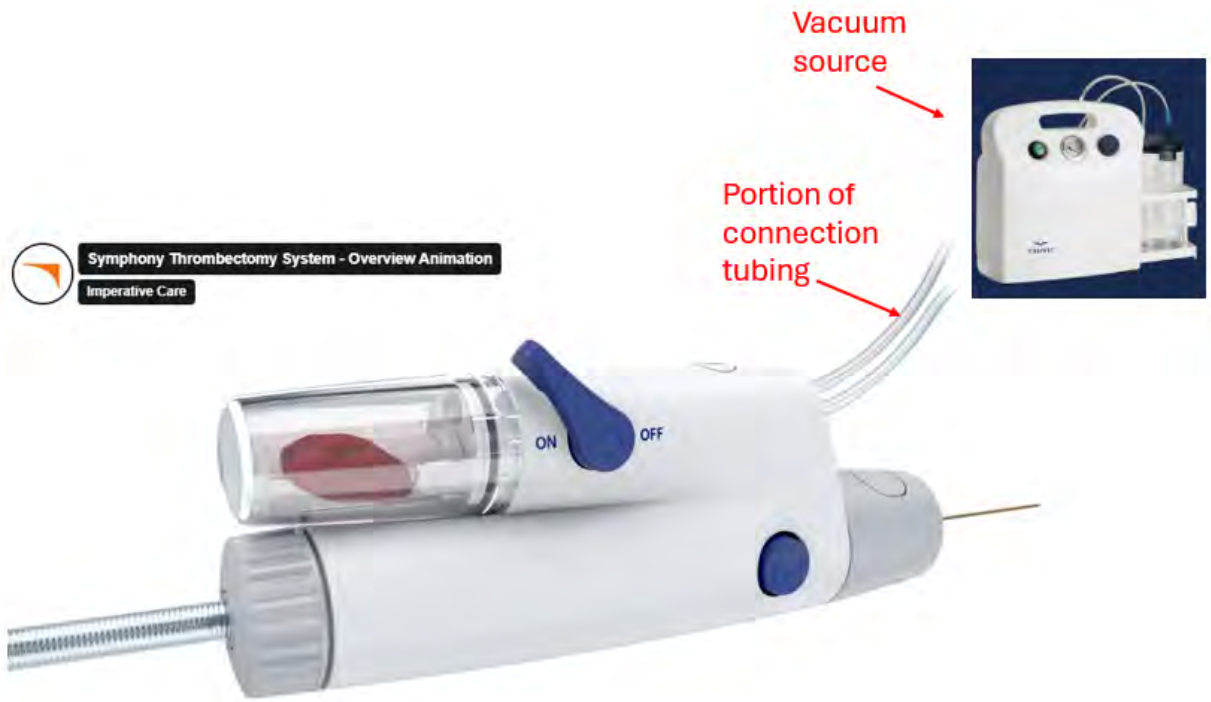
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

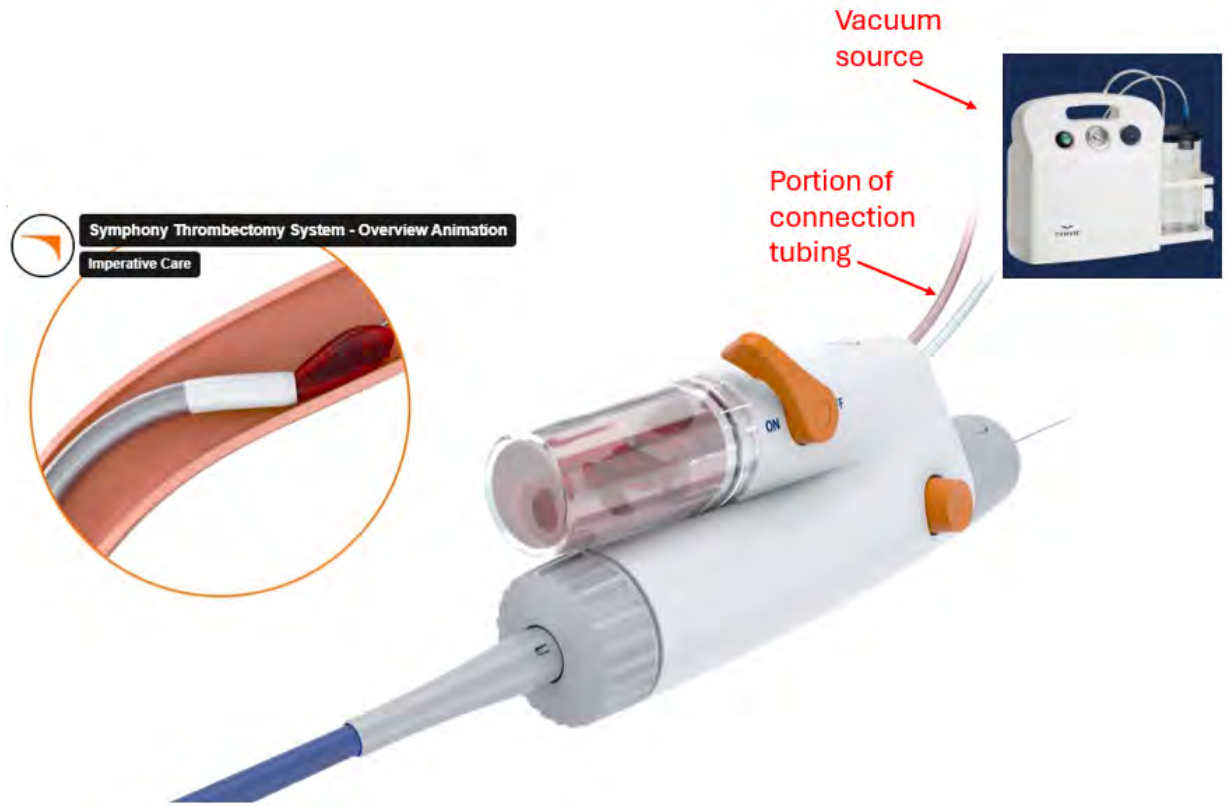
14. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).
15. Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected.
16. Confirm tip of the 16F Symphony Catheter is in the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

(Symphony Thrombectomy System Instructions For Use at 8.)

	 **Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister** (Symphony Thrombectomy System Instructions For Use at 8, annotated to show vacuum source.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
connection tubing fluidically coupled to the vacuum source;	The Symphony System includes connection tubing fluidically coupled to a vacuum source. Specifically, the Symphony System includes a Truvic Generator and Truvic Canister that are connected to the 24F and/or 16F Symphony Catheter handle via

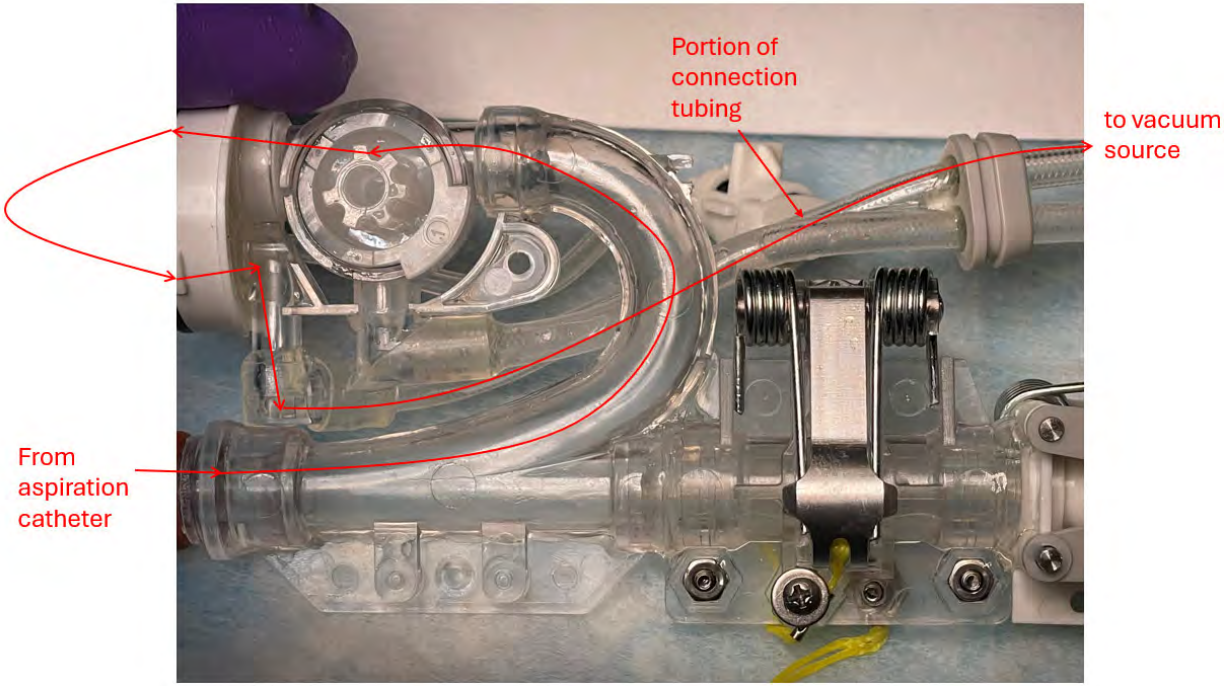
	primary or secondary tubing, as shown in Figure 6 from the Symphony System IFU, annotated below. A telescoping configuration is shown in Figure 6 below. But the Symphony System can be used in a non-telescoping manner, where the connection tubing is fluidically coupled to the Truvic Generator and Truvic Canister.  **Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister** (Symphony Thrombectomy System Instructions For Use at 8, annotated to show vacuum source and portion of connection tubing.)

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



(Annotated image of Symphony System.)

The Symphony System IFU directs users to "[c]onnect the Primary Tubing to the Handle tubing labelled 'Vacuum…'" and to "[a]ttach the other end of the Primary Tubing to the TRUVIC Canister." (Symphony Thrombectomy System Instructions For Use at 4; *see also* Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.").)

	The connection tubing continues within the 24 or 16F Symphony Catheter handle where the connection tubing is fluidically coupled to the vacuum source and is fluidically coupled to the fluid connector, as shown in the annotated teardown image below.  (Annotated image of internal portion of the controller housing.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

a catheter fluidically coupled to the vacuum source;	The Symphony System includes a catheter fluidically coupled to the vacuum source. Specifically, the Symphony System includes a 24F and/or 16F Symphony Catheter that is fluidically coupled to the Truvic Generator and Truvic Canister (*e.g.*, vacuum source). As shown in Figure 6 of the Symphony System IFU (annotated below), the Symphony System includes a 16F and/or 24F catheter coupled to the vacuum source via the 16F and/or 24F Symphony Catheter handle (including a first fluid path, including the Dual Action Vacuum Control valve, clot container, and tubing within the handle), the Truvic primary tubing for the 24F Symphony Catheter or the 16F Symphony Catheter and/or the Truvic secondary tubing for the 16F Symphony Catheter.

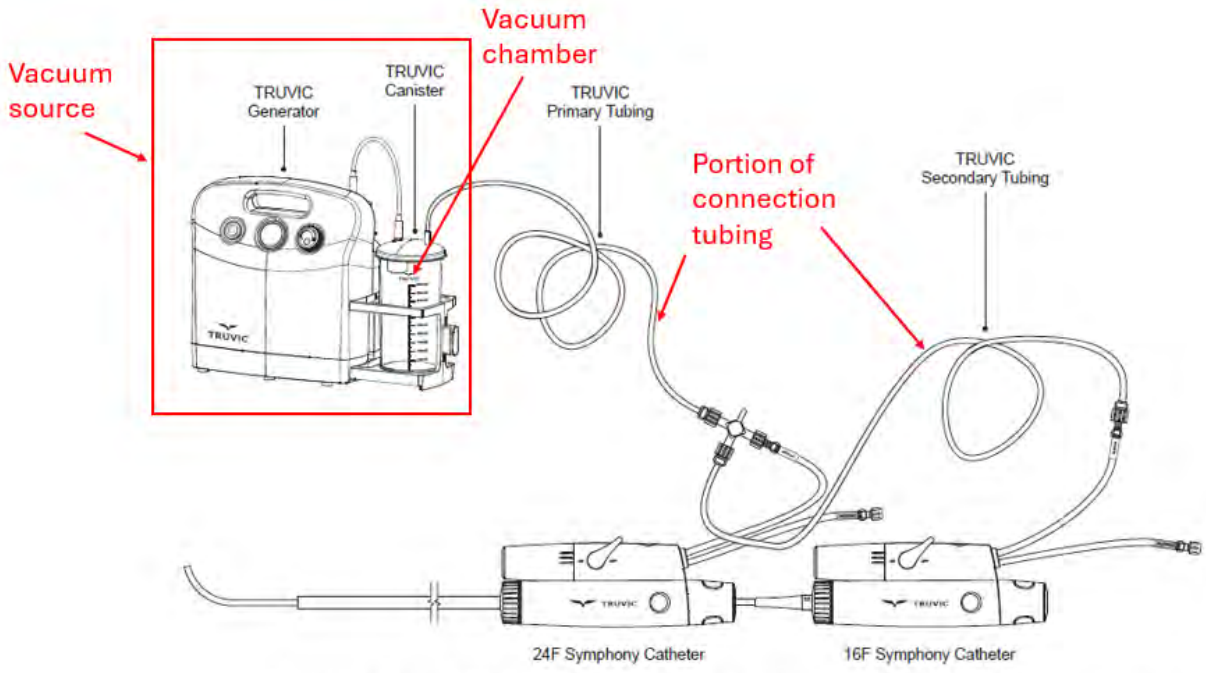
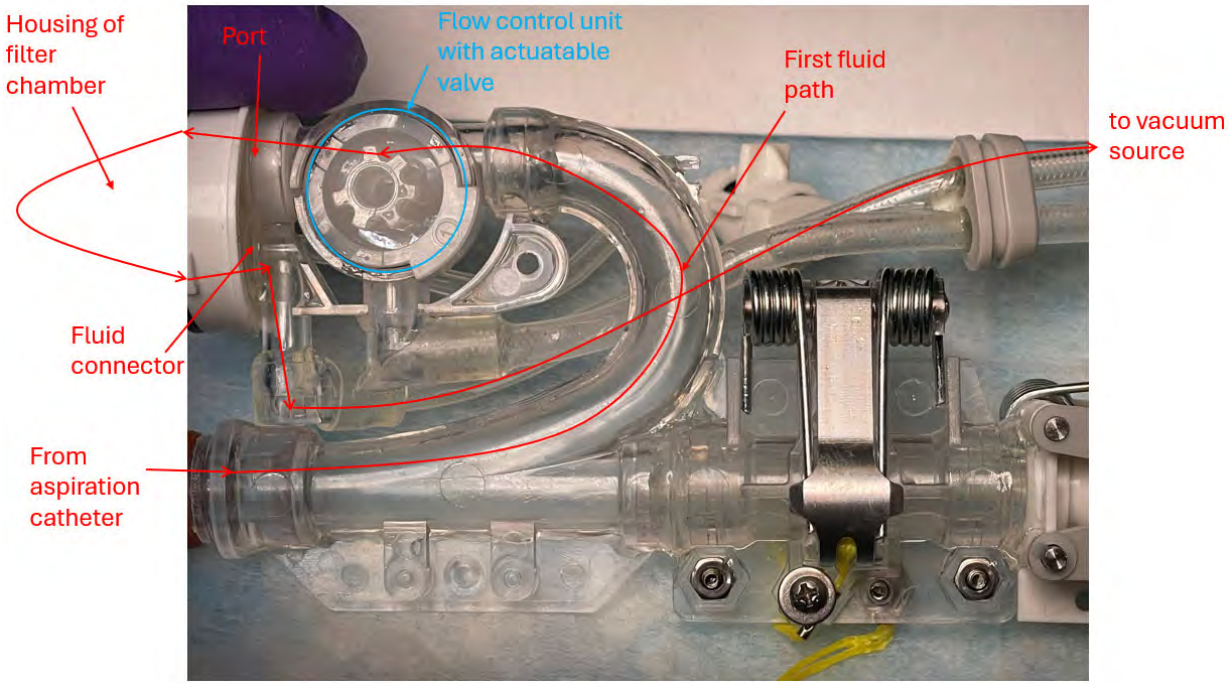


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Annotated Figure 6 of Symphony Thrombectomy System Instructions For Use at 8, showing catheter fluidically coupled to vacuum source.)



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

----------24F Aspiration Catheter----------

The 24F aspiration catheter is fluidically coupled to the Truvic Generator and Truvic Canister, as shown in Figure 3 of the Symphony System IFU, reproduced below.

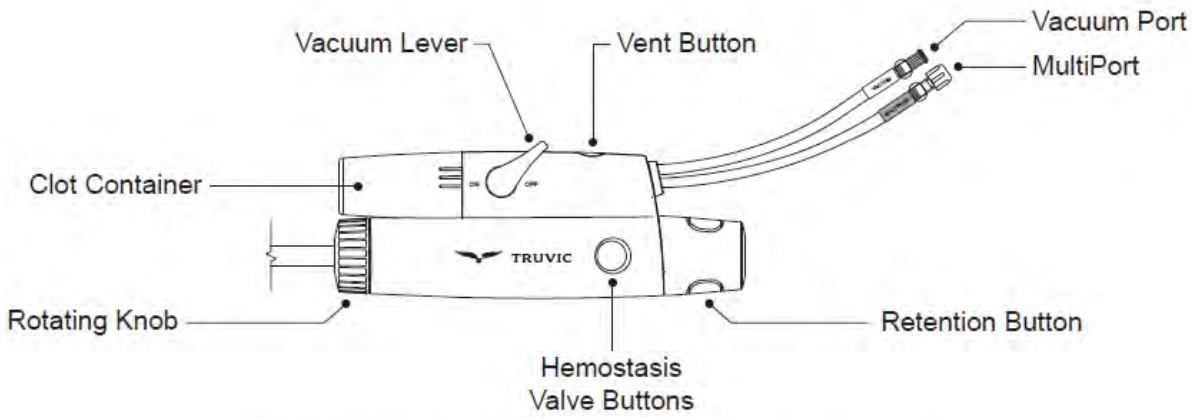


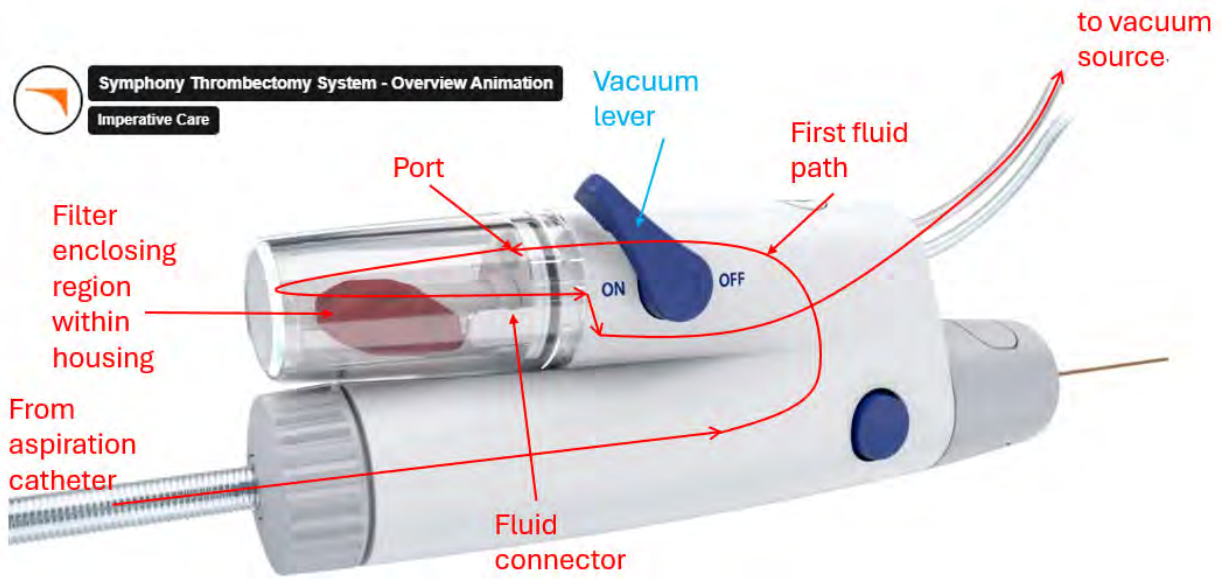
Figure 3: Symphony Catheter Handle, labeled

(Symphony Thrombectomy System Instructions For Use at 4, showing Symphony Catheter handle.)

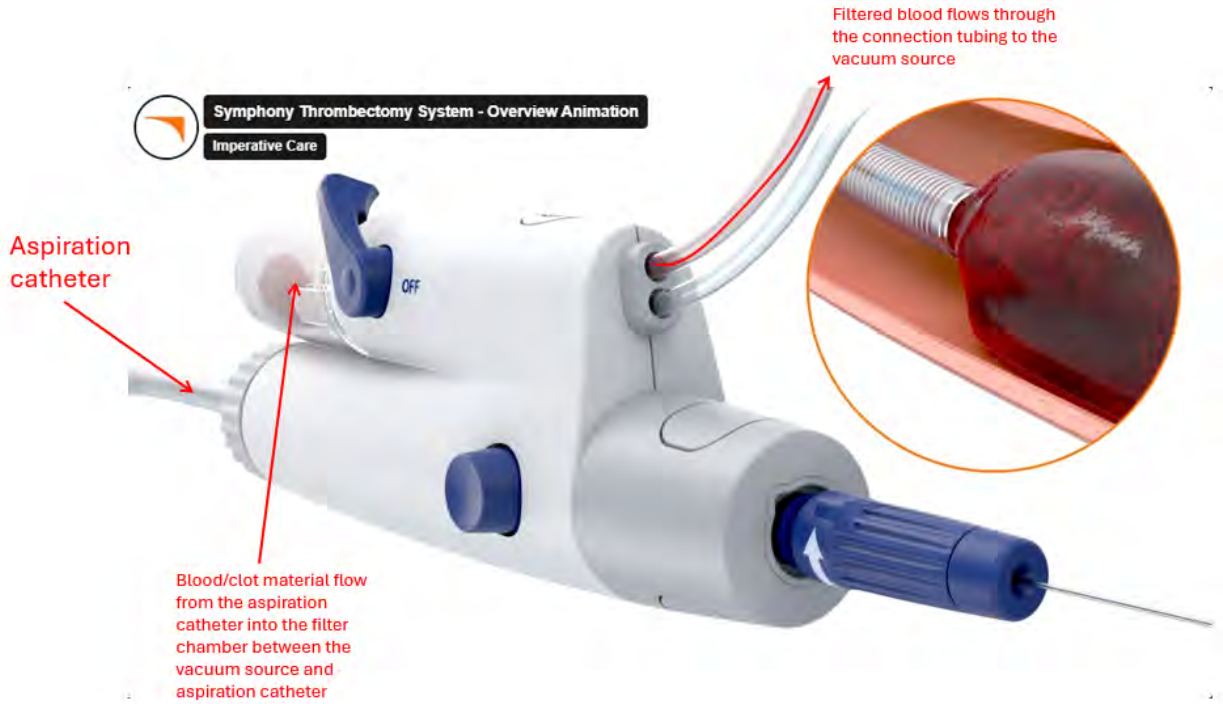
The Truvic primary tubing (portion of the connection tubing) connects the Truvic Generator and Truvic Canister to the Symphony Catheter handle via the vacuum port and tubing internal to the Symphony Catheter handle so that the Truvic Generator and Truvic Canister can provide negative pressure to the catheter. (*See* Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.").)

The Symphony Thrombectomy System – Overview Animation video demonstrates that blood and clot material from the human patient enter the catheter and flow to the clot container of the 24F Symphony Catheter handle. The clot container filters blood from the clot material, and the filtered blood flows out of the housing of the

	clot container toward the vacuum port. The blood then exits the Symphony Catheter handle through the vacuum port to be deposited in the Truvic Canister that is connected to the Truvic Generator. Blood exiting the Symphony Catheter handle toward the Truvic Canister is shown by the light red coloring of the connection tubing (upper tubing) in the 24F Symphony Catheter handle below. (Symphony Thrombectomy System – Overview Animation Video at 1:03.)

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

	 (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system, showing blood flow from catheter, through clot container and toward vacuum source.)



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:00.)

----------16F Aspiration Catheter----------

The 16F aspiration catheter is fluidically coupled to the Truvic Generator and Truvic Canister, as shown in Figure 3 of the Symphony System IFU, reproduced below.

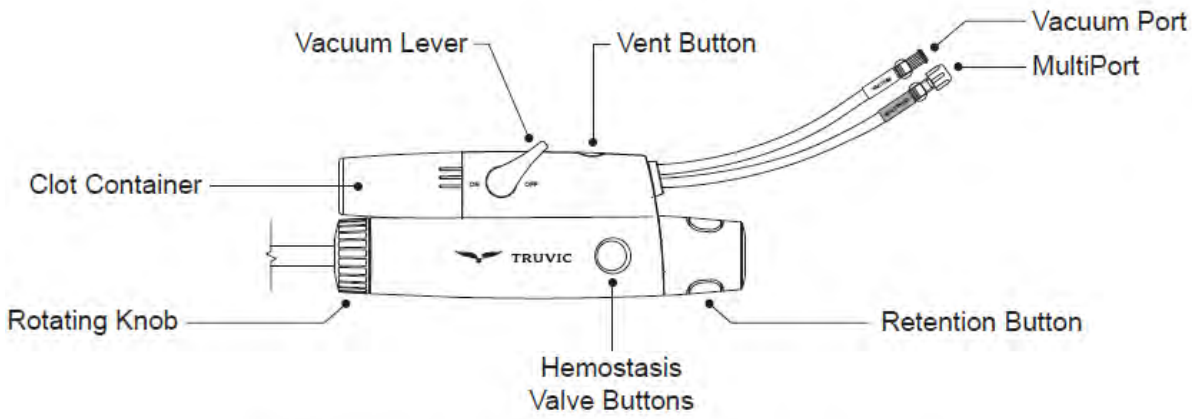
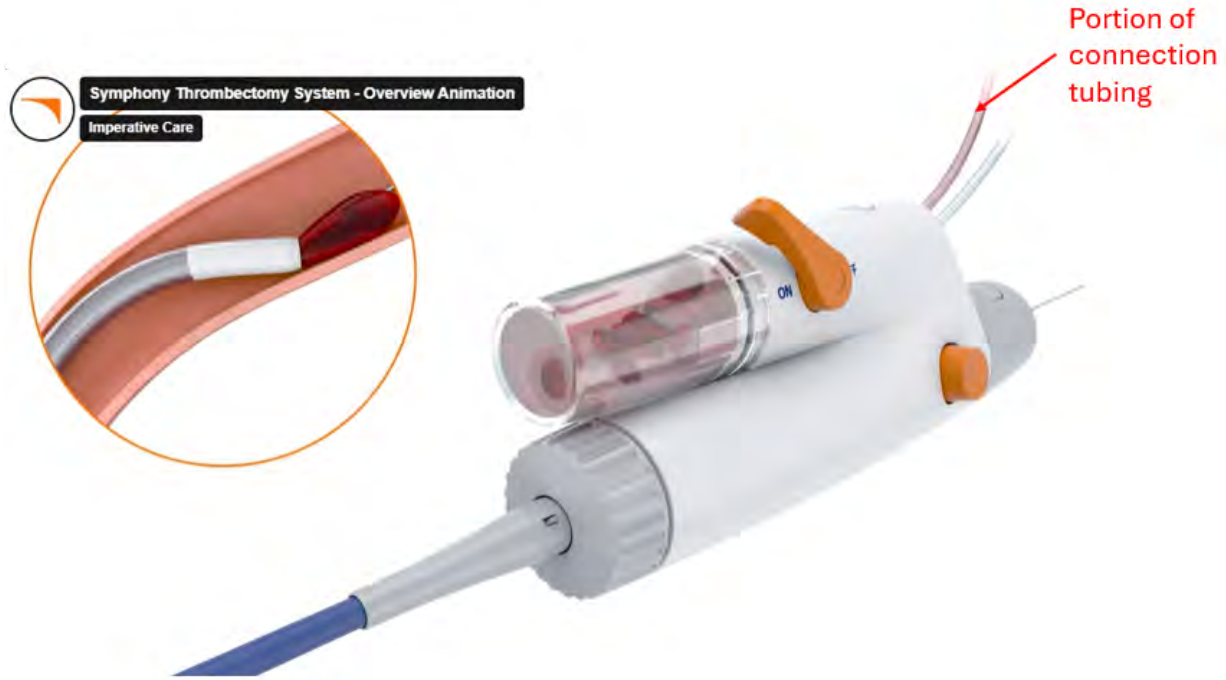


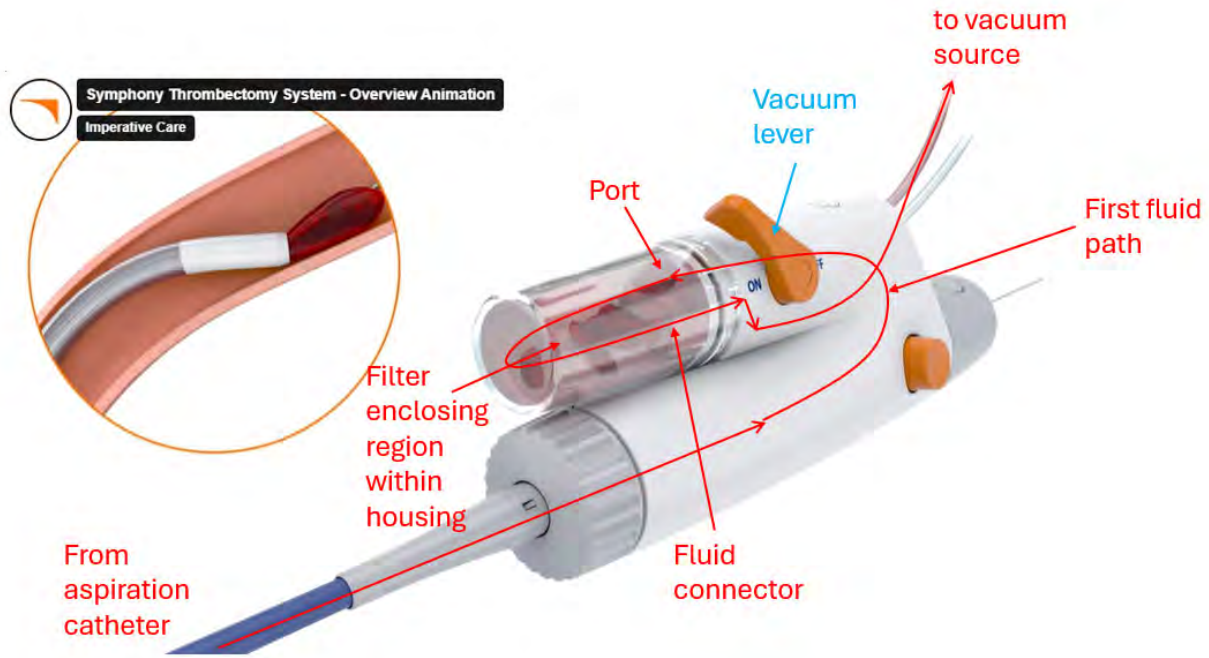
Figure 3: Symphony Catheter Handle, labeled

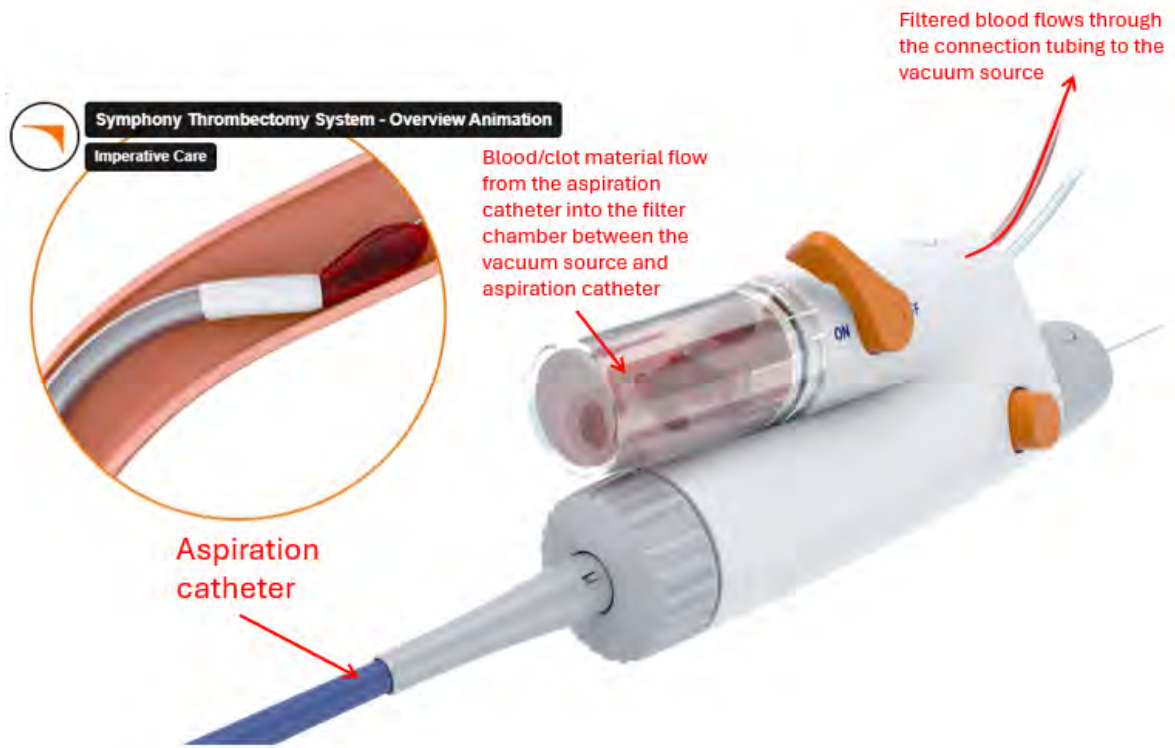
(Symphony Thrombectomy System Instructions For Use at 4, showing Symphony Catheter handle.)

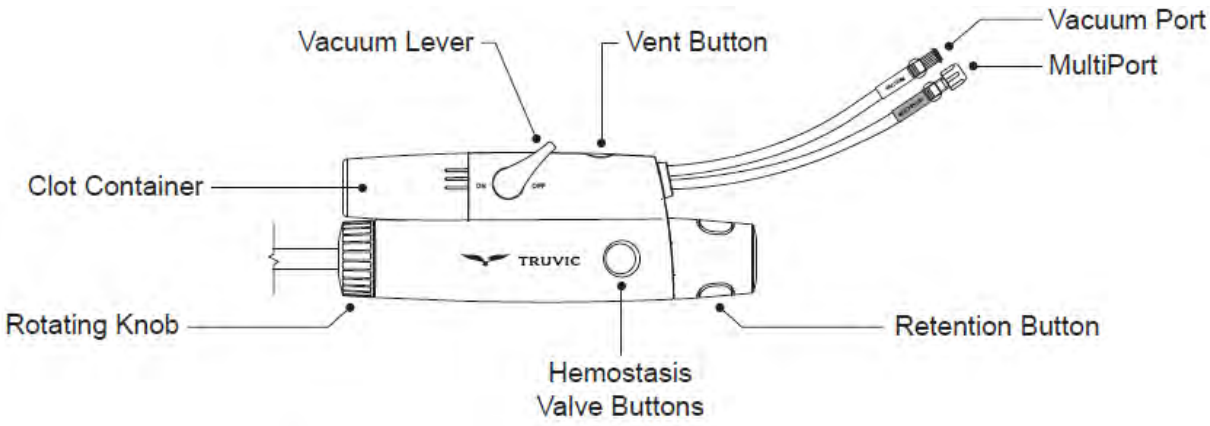
The Truvic primary or secondary tubing (portion of the connection tubing) connects the Truvic Generator and Truvic Canister to the Symphony Catheter handle via the vacuum port and tubing internal to the Symphony Catheter handle so that the Truvic Generator and Truvic Canister can provide negative pressure to the catheter. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.").)

The Symphony Thrombectomy System – Overview Animation video demonstrates that as blood and clot material from the human patient enter the catheter and flow to the clot container of the 16F Symphony Catheter handle. The clot container filters blood from the clot material, and the filtered blood flows out of the housing

	of the clot container toward the vacuum port. The blood then exits the Symphony Catheter handle through the vacuum port to be deposited in the Truvic Canister that is connected to the Truvic Generator. Blood exiting the Symphony Catheter handle toward the Truvic Canister is shown by the light red coloring of the connection tubing (upper tubing) in the 16F Symphony Catheter handle below.  (Symphony Thrombectomy System – Overview Animation Video at 2:02.)

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

	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

a filter chamber fluidically coupled to the connection tubing at a location apart from the vacuum source, wherein the filter chamber comprises a housing and a filter within the housing, and wherein the housing includes—	The Symphony System includes a filter chamber that is fluidically coupled to the connection tubing at a location apart from the vacuum source. The filter chamber comprises a housing and a filter within the housing. Specifically, the Symphony System includes a 24F Symphony Catheter handle and/or 16F Symphony Catheter handle that includes a clot container (*e.g.*, filter chamber) that is fluidically coupled to the connection tubing within the Symphony Catheter handle and vacuum port, as shown in Figure 3 of the IFU reproduced below.  **Figure 3: Symphony Catheter Handle, labeled** (Symphony Thrombectomy System Instructions For Use at 4, showing Symphony Catheter handle.) The internal tubing and vacuum port of the Symphony Catheter handle allow for the clot container of the Symphony Catheter handle to be fluidically coupled to Truvic Generator and Truvic Canister via the Truvic primary tubing (for the 24F

handle and/or 16F handle, below) and/or Truvic secondary tubing (for the 16F handle, below) (*e.g.*, a portion of the connection tubing). The clot container of the Symphony Catheter handle is fluidically coupled to the connection tubing at a location apart from the Truvic Generator and Truvic Canister (*e.g.*, vacuum source) of the Symphony System, as shown in Figure 6 of the Symphony System IFU reproduced and annotated below.

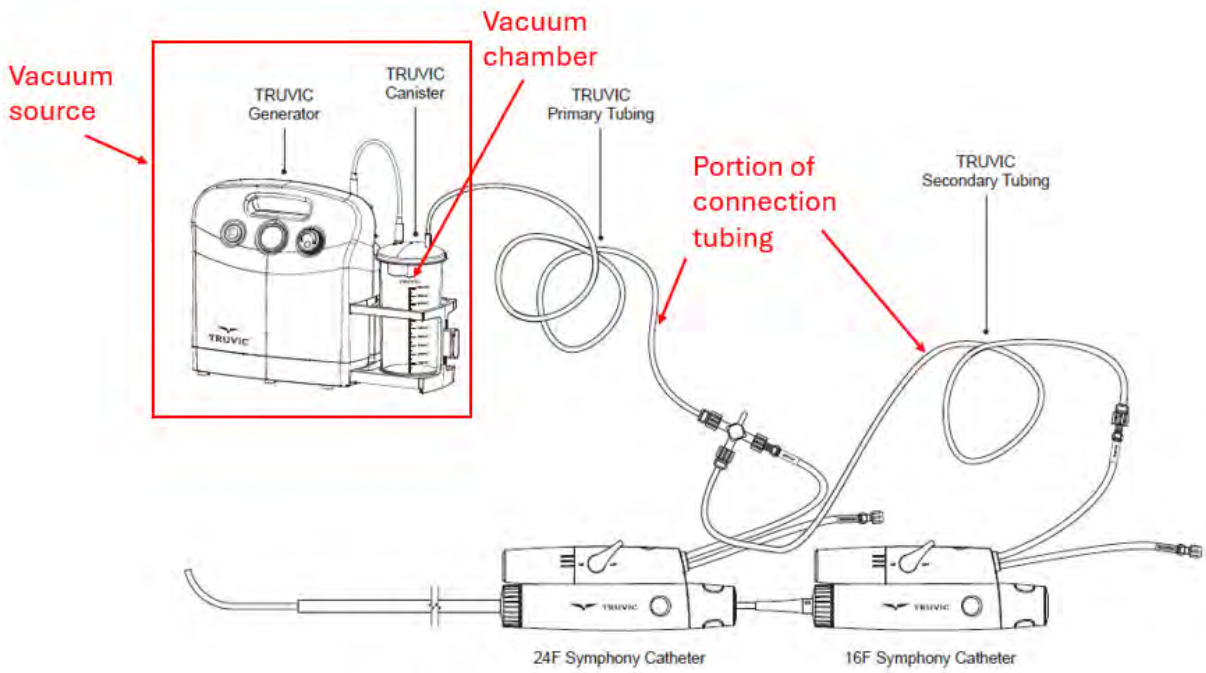
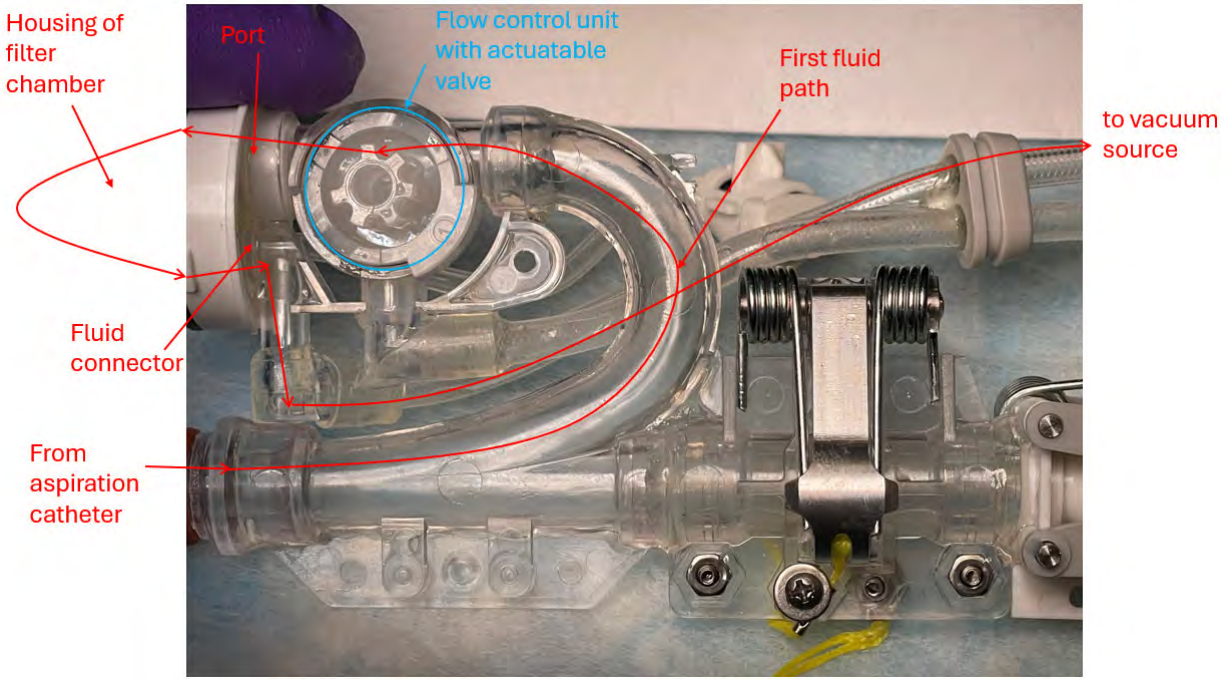


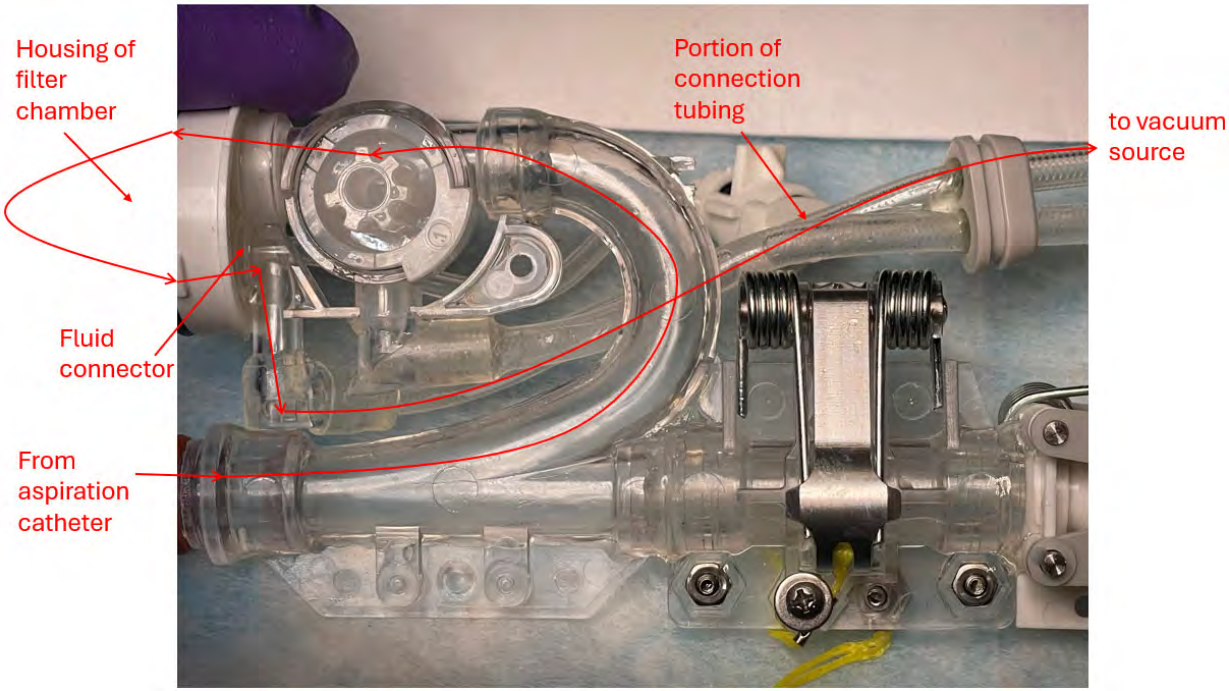
Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Annotated Symphony Thrombectomy System Instructions For Use at 8.)

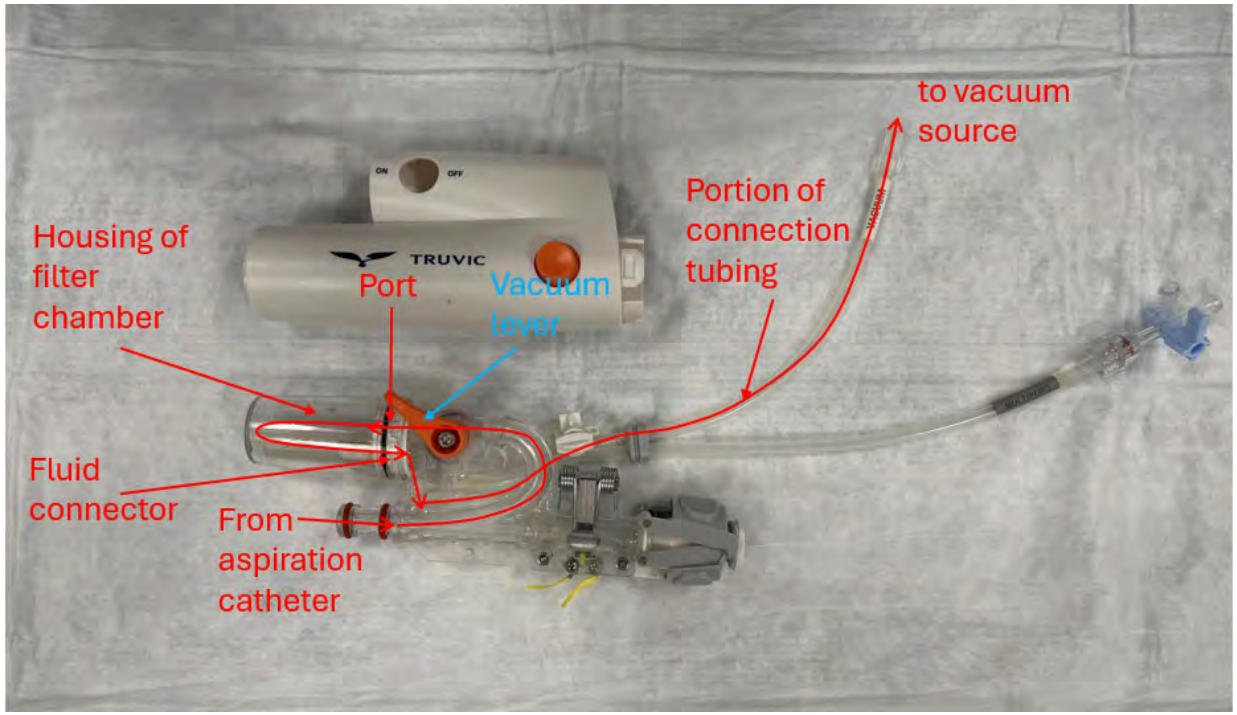
The annotated teardown images of the Symphony Catheter handle also show that the filter chamber is fluidically coupled to the connection tubing within the Symphony Catheter handle, which is a location apart from the Truvic Generator and Truvic Canister. The filter chamber and vacuum source are fluidically coupled via the connection tubing within the Symphony Catheter handle, vacuum port (shown in Figure 3 above) and Truvic primary and/or secondary tubing (shown in Figure 6 above).



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



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

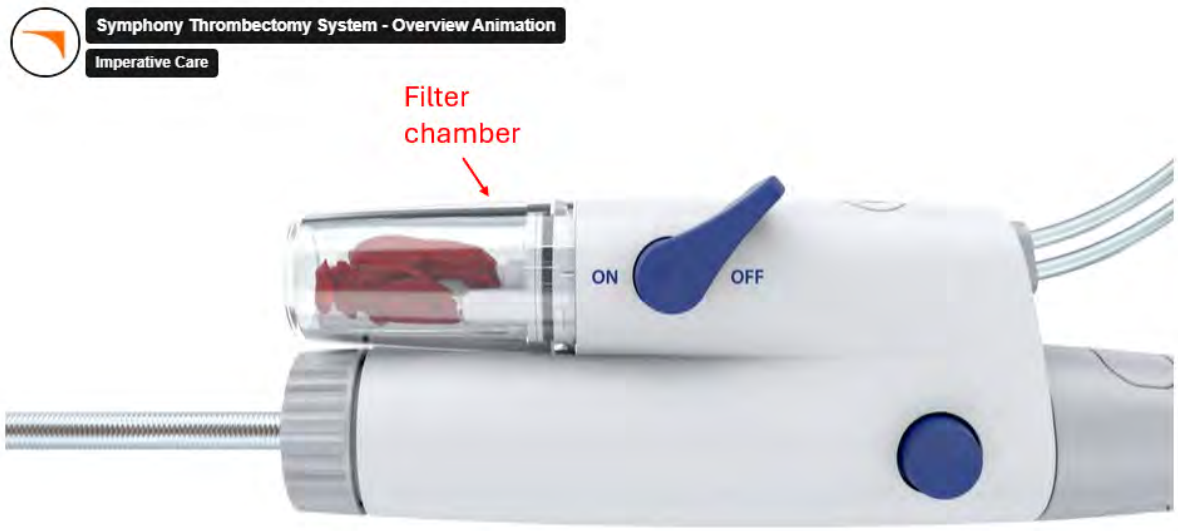


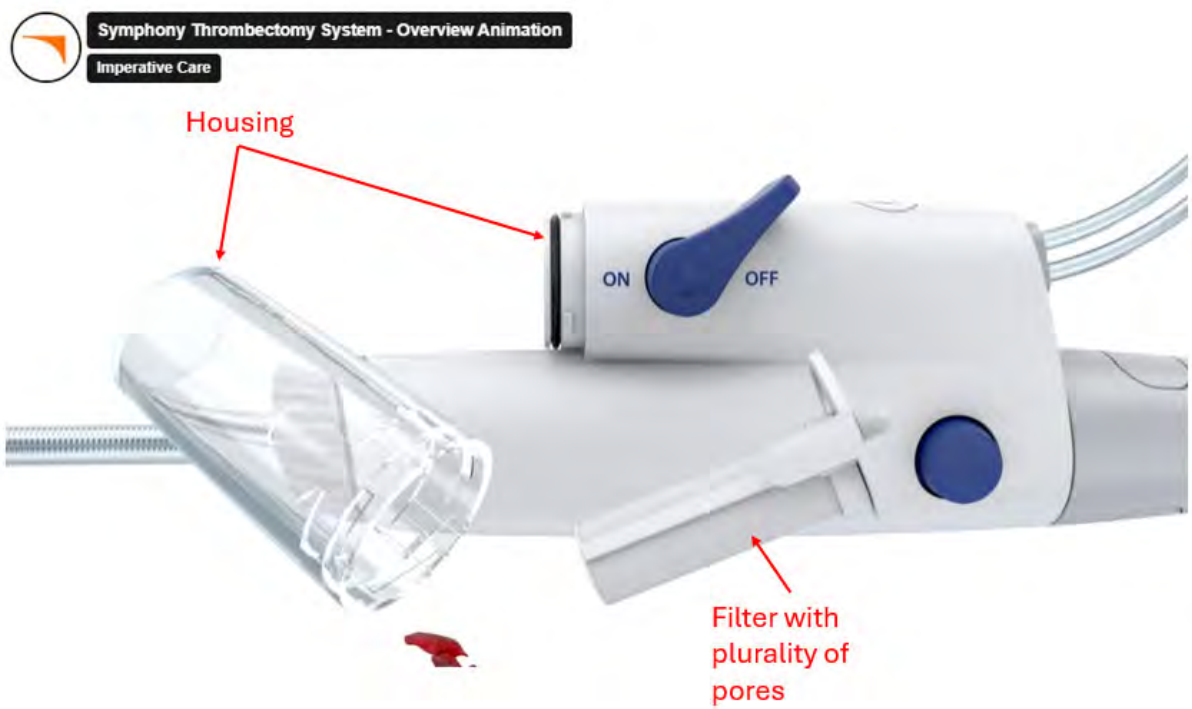
(Annotated image of internal portion of the controller housing with vacuum lever.)

The Symphony System IFU also discloses that the filter chamber of the 24F and/or 16F Symphony Catheter handle is fluidically coupled to the vacuum source via the connection tubing.

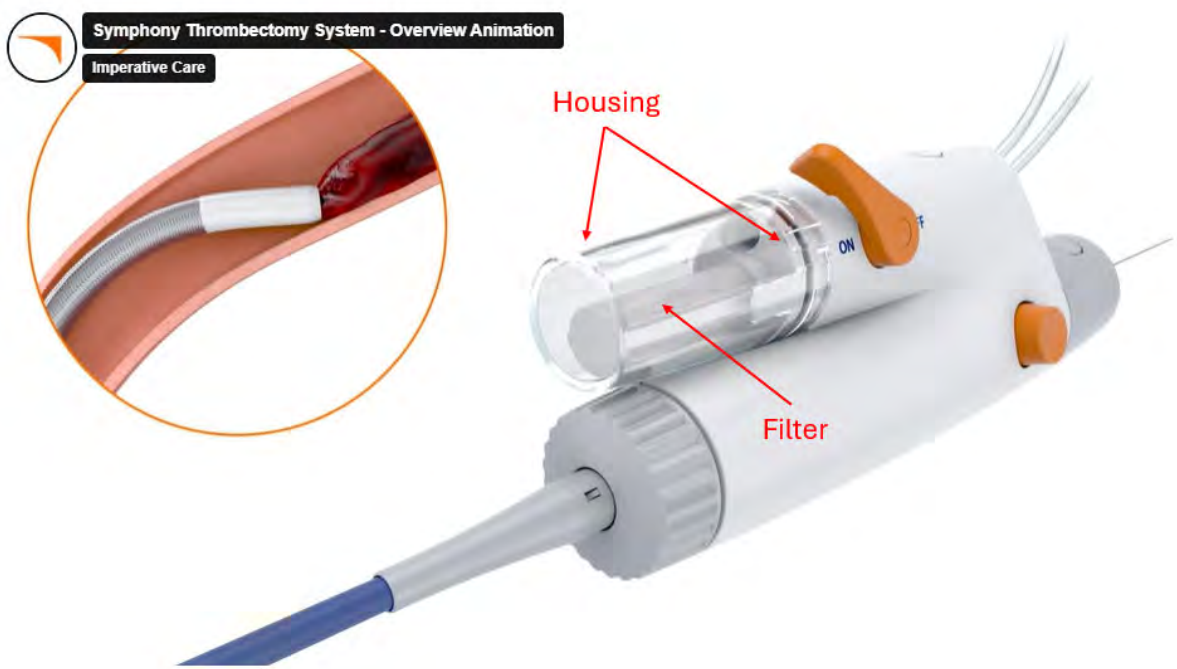
----------24F Aspiration Catheter----------

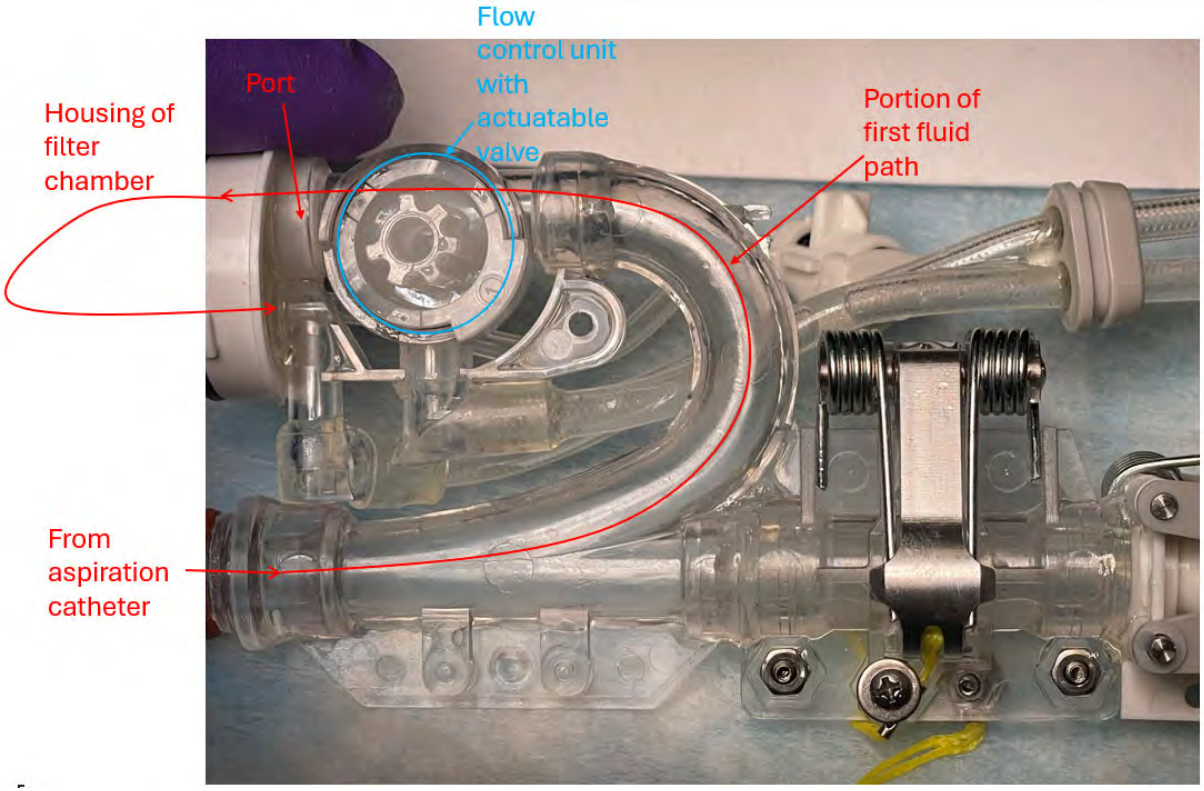
The 24F Symphony Catheter handle includes a filter chamber that comprises a housing with a removable cap and a filter within the housing, which is shown in

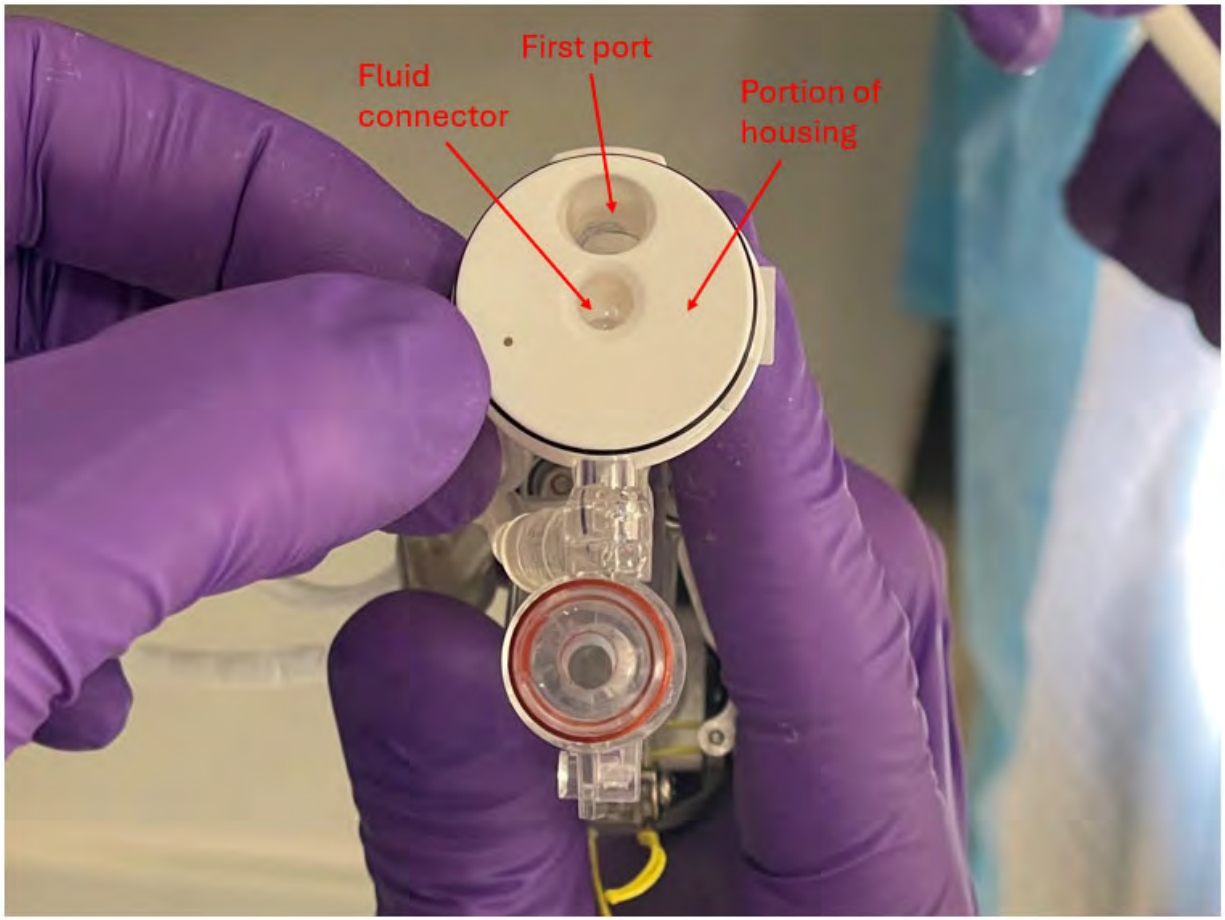
	the annotated images from the Symphony Thrombectomy System – Overview Animation video below.  (Annotated Symphony Thrombectomy System – Overview Animation Video at 1:15.)

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

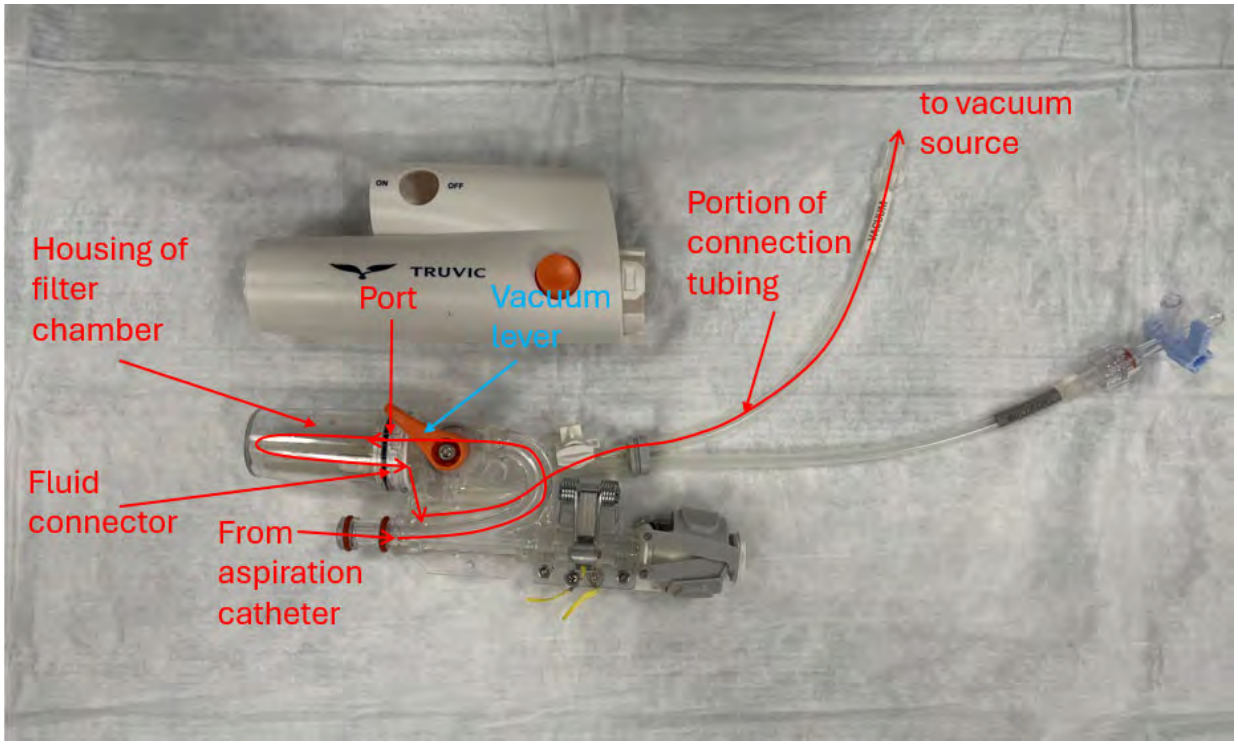
	 (Annotated image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) **----------16F Aspiration Catheter----------** The 16F Symphony Catheter handle includes a filter chamber that comprises a housing with a removable cap and a filter within the housing, which is shown in the annotated image from the Symphony Thrombectomy System – Overview Animation video below.

	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 1:55.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a port configured to be fluidically coupled to the catheter; and	The Symphony System includes a port configured to be fluidically coupled to the catheter. Specifically, the housing of the filter chamber of the 24F and/or 16F Symphony Catheter handle includes a port that is configured to be fluidically coupled to the

	aspiration catheter (via a portion of the first fluid path from the aspiration catheter through the vacuum control valve into the port), as shown in the teardown images of the Symphony Catheter handle below.  (Annotated image of internal portion of the controller housing.)



(Annotated image of controller housing showing port and fluid connector.)

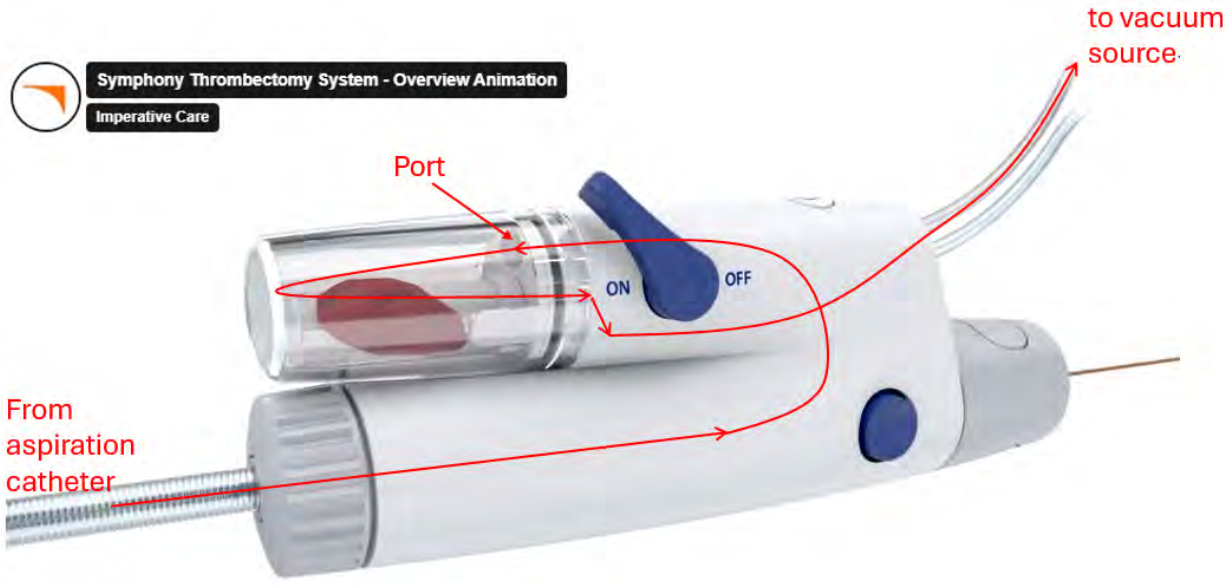


(Annotated image of internal portion of the controller housing with vacuum lever.)

----------24F Aspiration Catheter----------

The image below, which shows blood flowing from the aspiration catheter of the 24F Symphony Catheter handle through the port into the filter chamber confirms that the port is configured to be fluidically coupled to the catheter.

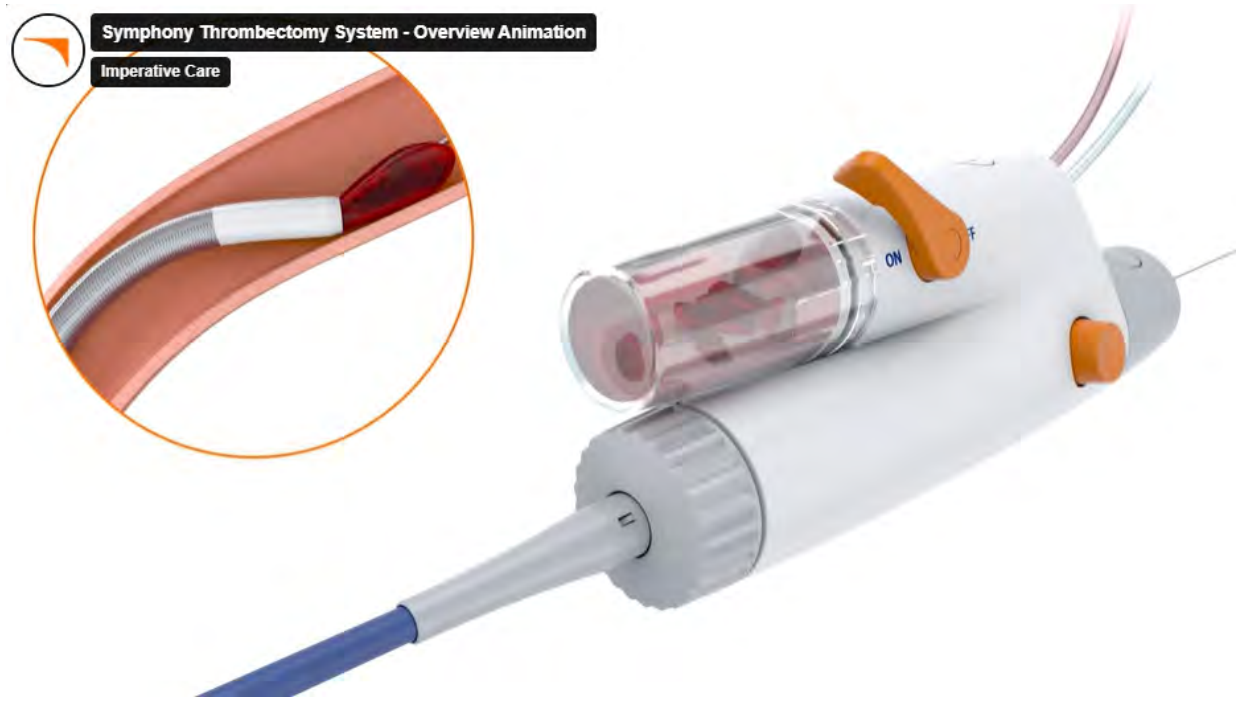
	 (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) Blood flows from the aspiration catheter through the port into the filter chamber via the flow path shown in the annotated image below.

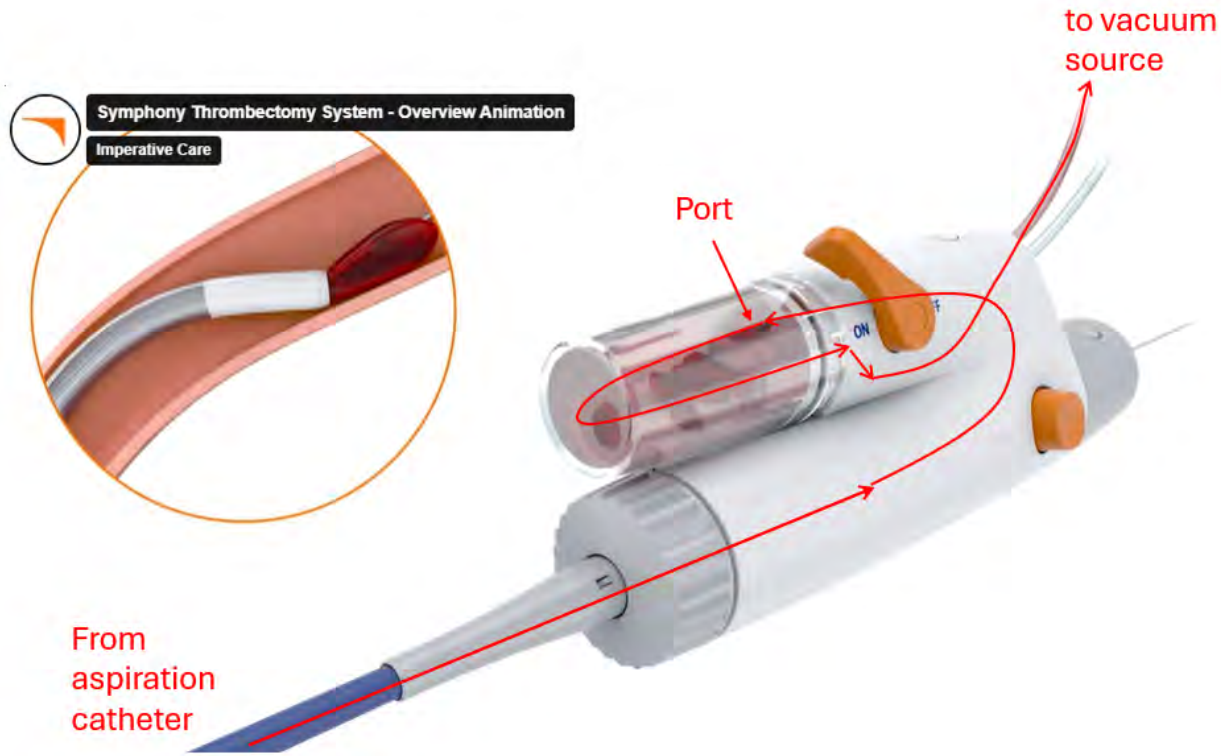


(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

----------16F Aspiration Catheter----------

The image below, which shows blood flowing from the aspiration catheter of the 16F Symphony Catheter handle through the port into the filter chamber, confirms that the port is configured to be fluidically coupled to the catheter.

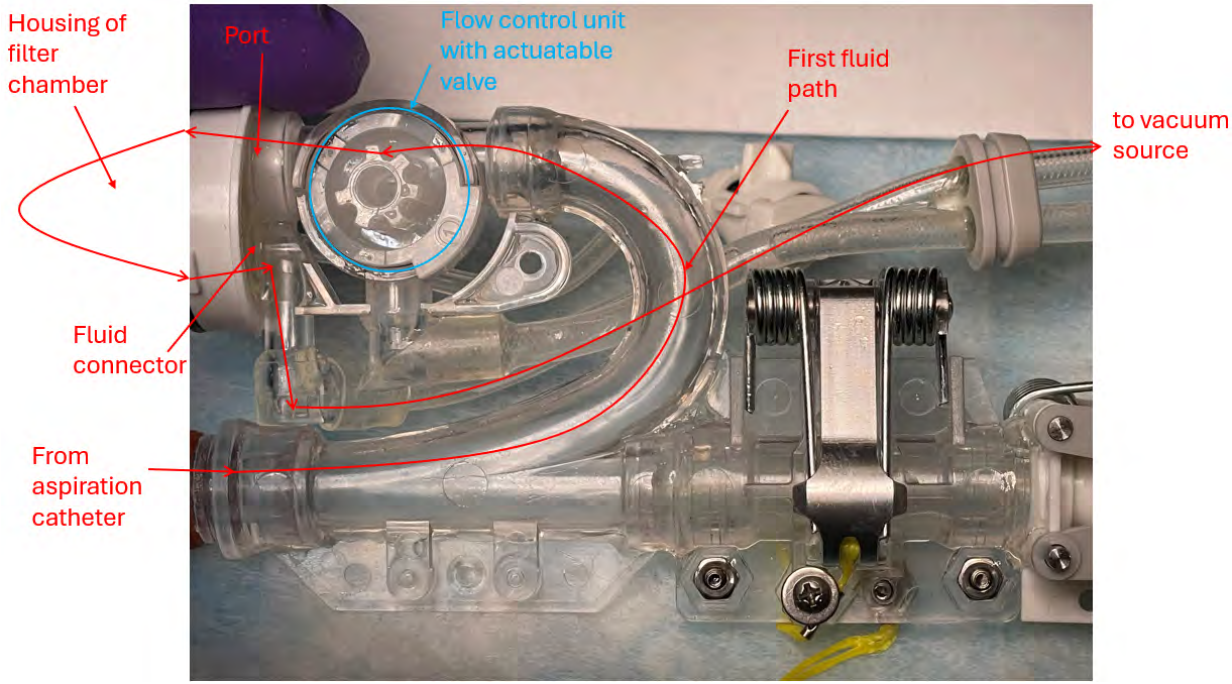
	 (Symphony Thrombectomy System – Overview Animation Video at 2:02.) Blood flows from the aspiration catheter through the port into the filter chamber via the flow path shown in the annotated image below.



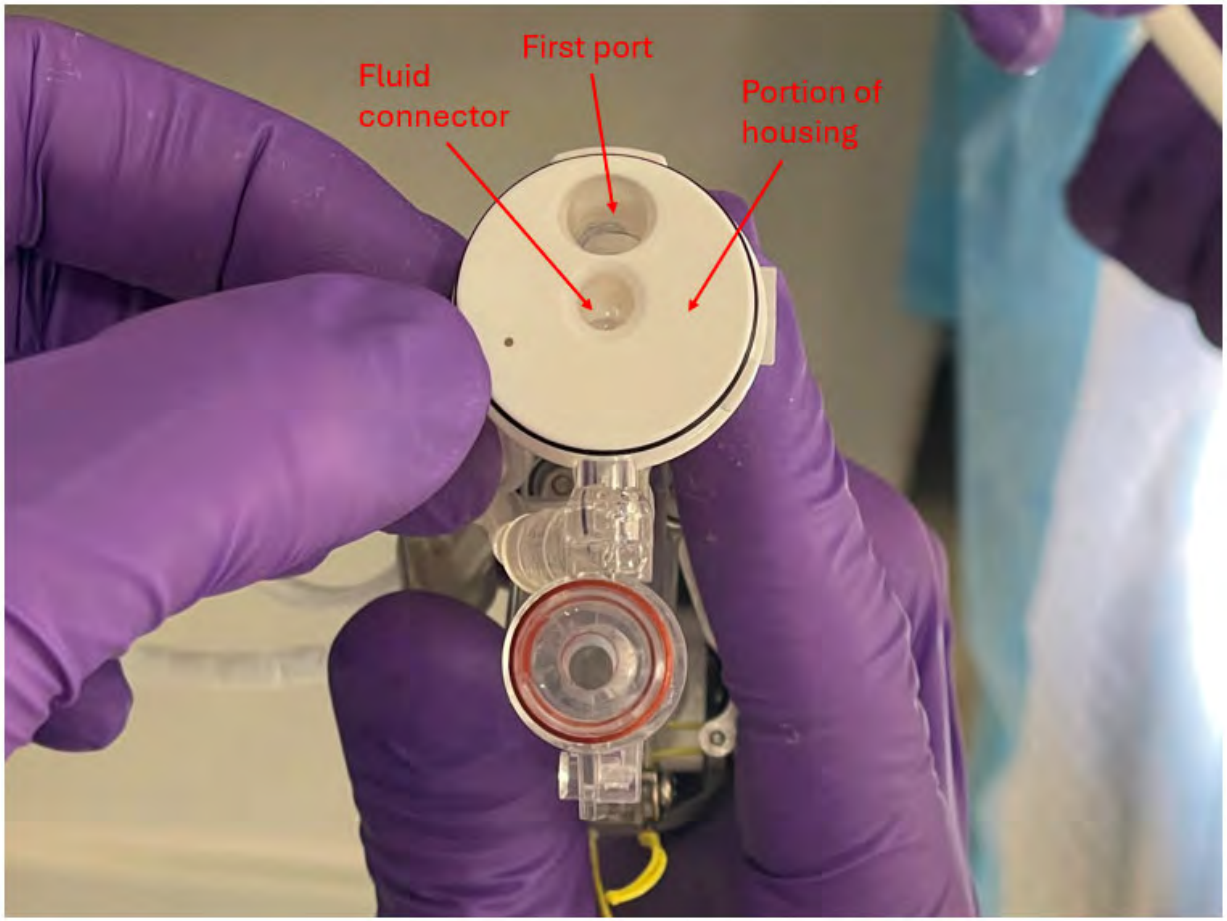
(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

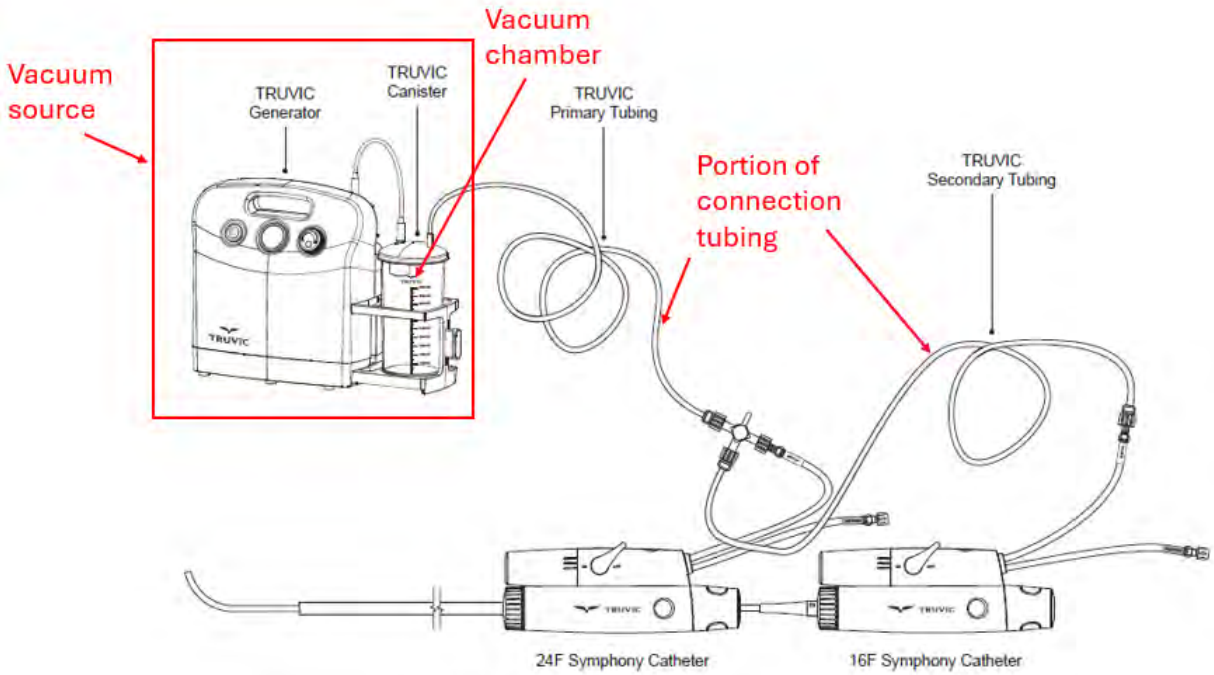
To the extent Truvic argues that the housing is limited to the removable clear portion of the housing of the Symphony Catheter handle such that housing cannot include the port, that is incorrect according to the dislcosure in the specification and claims 1 and 15, charted herein. If such a construction were adopted, however, the Symphony System will still meet this limitation under the doctrine of equivalents. For example, to the extent Truvic contends that the Symphony System housing does not include the port and instead the port is part of a structure separate

	from the housing, the Symphony System infringes under the doctirne of equivalents because the housing with a port proximate to it still performs the same function as the recited housing that includes a port, including fluidically coupling the housing to the catheter. This provides the same function as a housing that includes a port because it allows blood and clot material to enter the housing, where the blood is then filtered out of the housing with the clot material remaining in the housing.
a fluid connector configured to be fluidically coupled to the connection tubing; and	The Symphony System includes a fluid connector configured to be fluidically coupled to the connection tubing. Specifically, the housing of the filter chamber of the 24F and/or 16F Symphony Catheter handle includes a fluid connector that is configured to be fluidically coupled to the connection tubing (*e.g.*, the portion of the connection tubing that is internal to the Symphony Catheter handle), as shown in the teardown of the Symphony Catheter handle below.

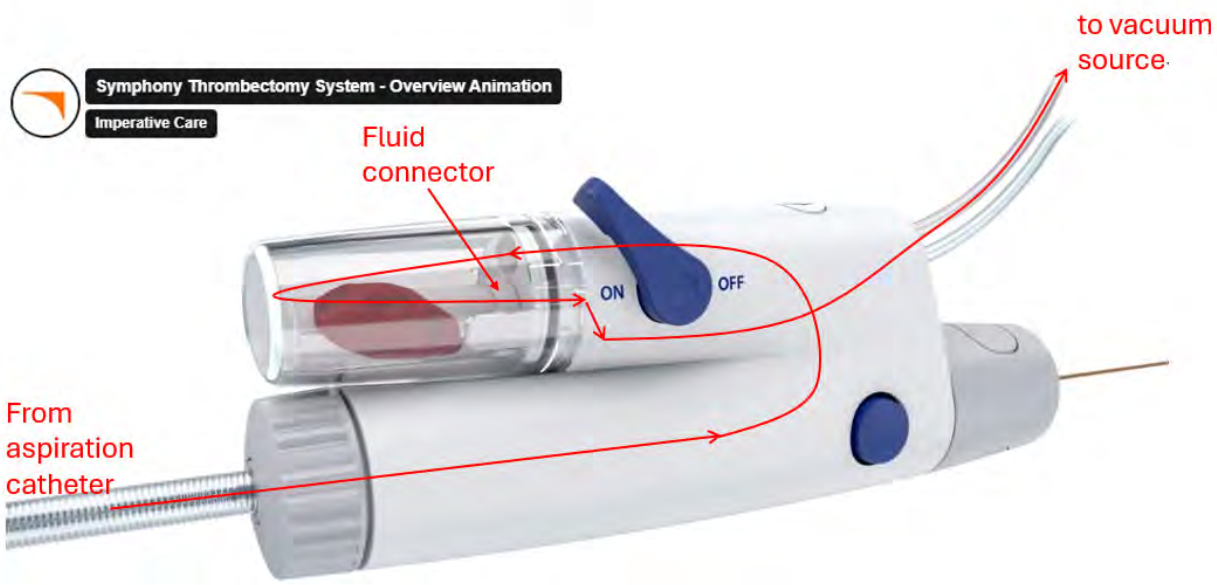


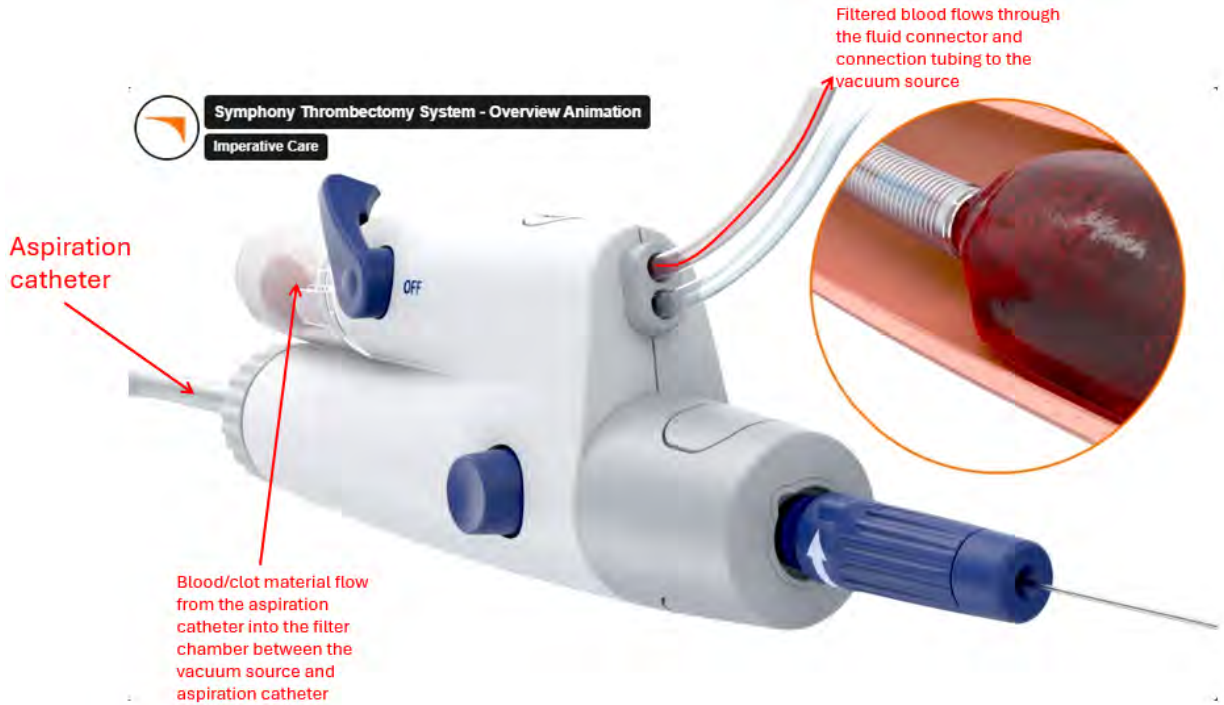
(Annotated image of internal portion of the controller housing.)

	 (Annotated image of controller housing showing port and fluid connector.) The Symphony System IFU confirms that the housing of the filter chamber includes a fluid connector that allows blood to flow through the connection tubing to the Truvic Canister and Truvic Generator. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC

	Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.”); Symphony Thrombectomy System Instructions For Use at 5 (“When unrestricted blood flow through the clot container and into the canister is observed, move the lever to the ‘OFF’ position.”).)  **Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister** (Annotated Symphony Thrombectomy System Instructions For Use at 8.) **----------24F Aspiration Catheter----------**

	The image below, which shows blood flowing from the aspiration catheter of the 24F Symphony Catheter handle through the port into the filter chamber and through the fluid connector into the connection tubing (eventually to the Truvic Canister), confirms that the fluid connector is configured to be fluidically coupled to the connection tubing. (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) Specifically, blood flows from the housing, through the removable filter and through the fluid connector, into the connection tubing (eventually flowing to the Truvic Canister) via the flow path shown in the annotated images below.

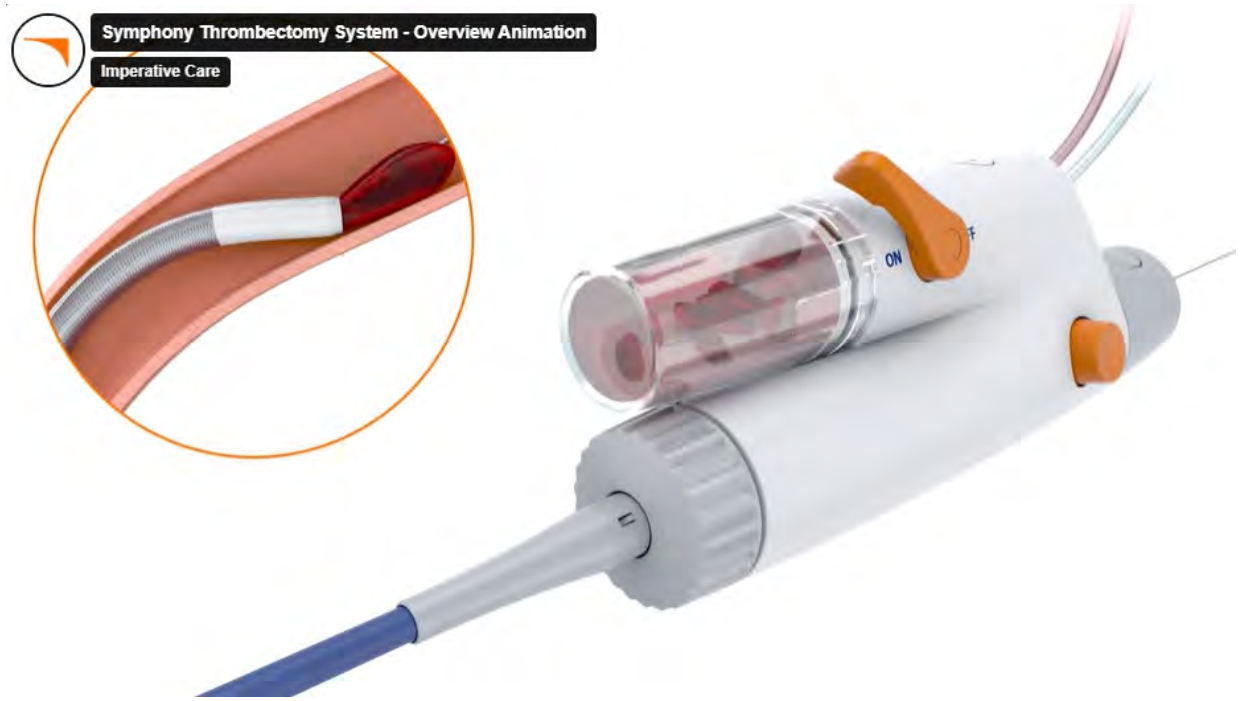
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

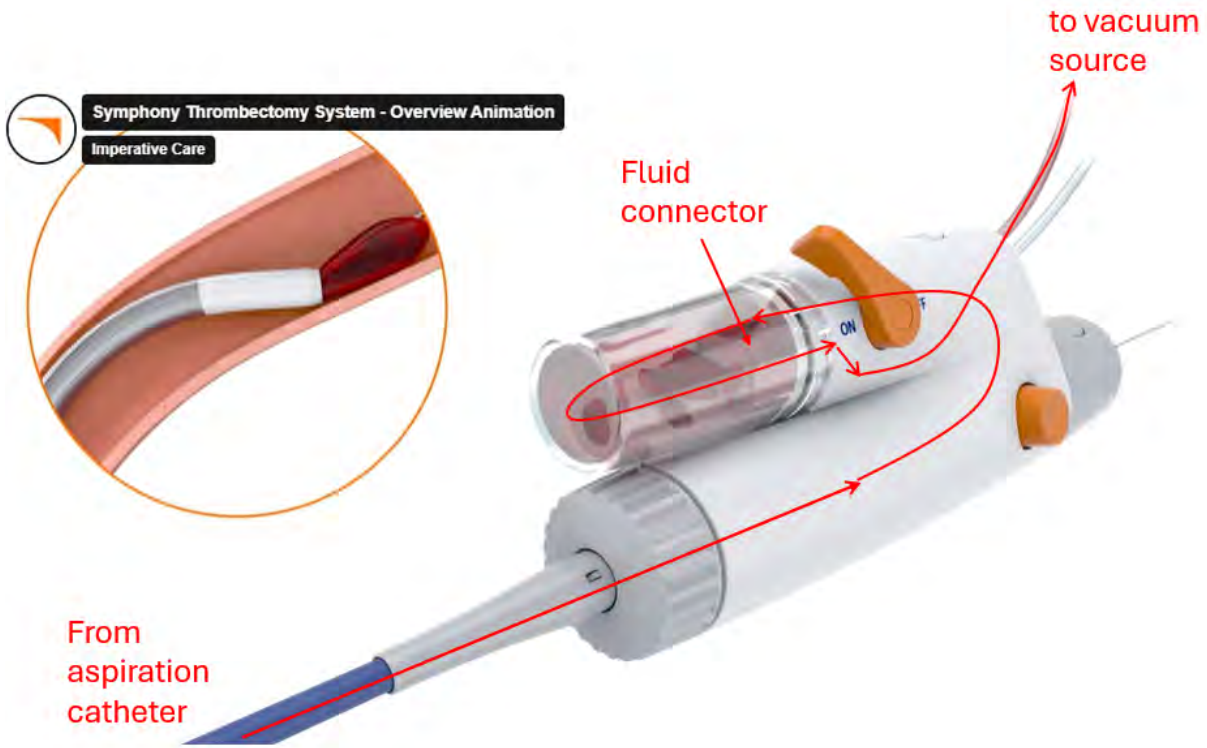


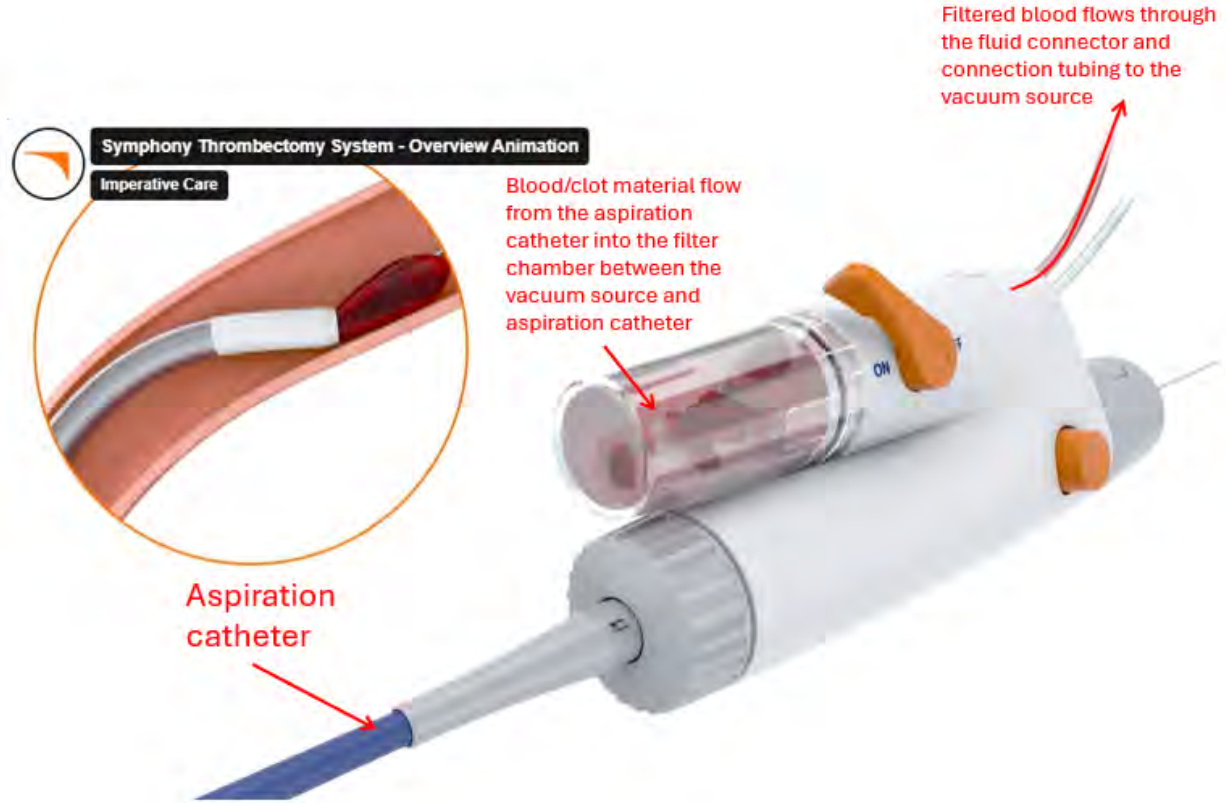
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:00.)

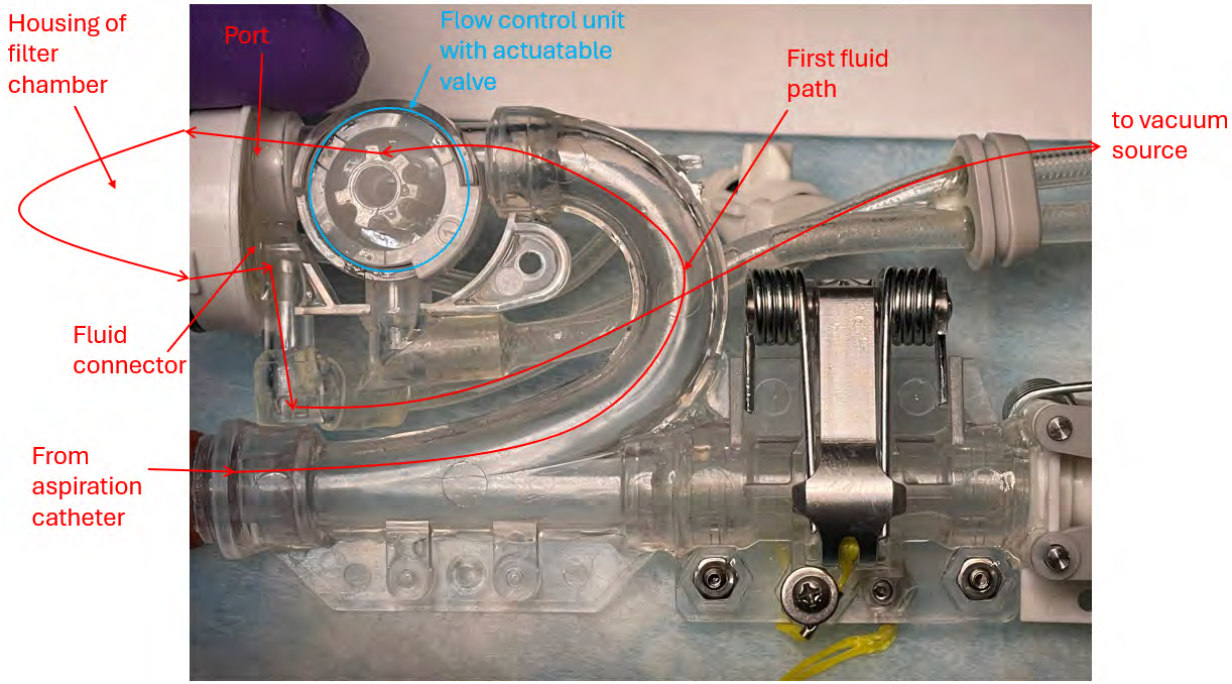
----------16F Aspiration Catheter----------

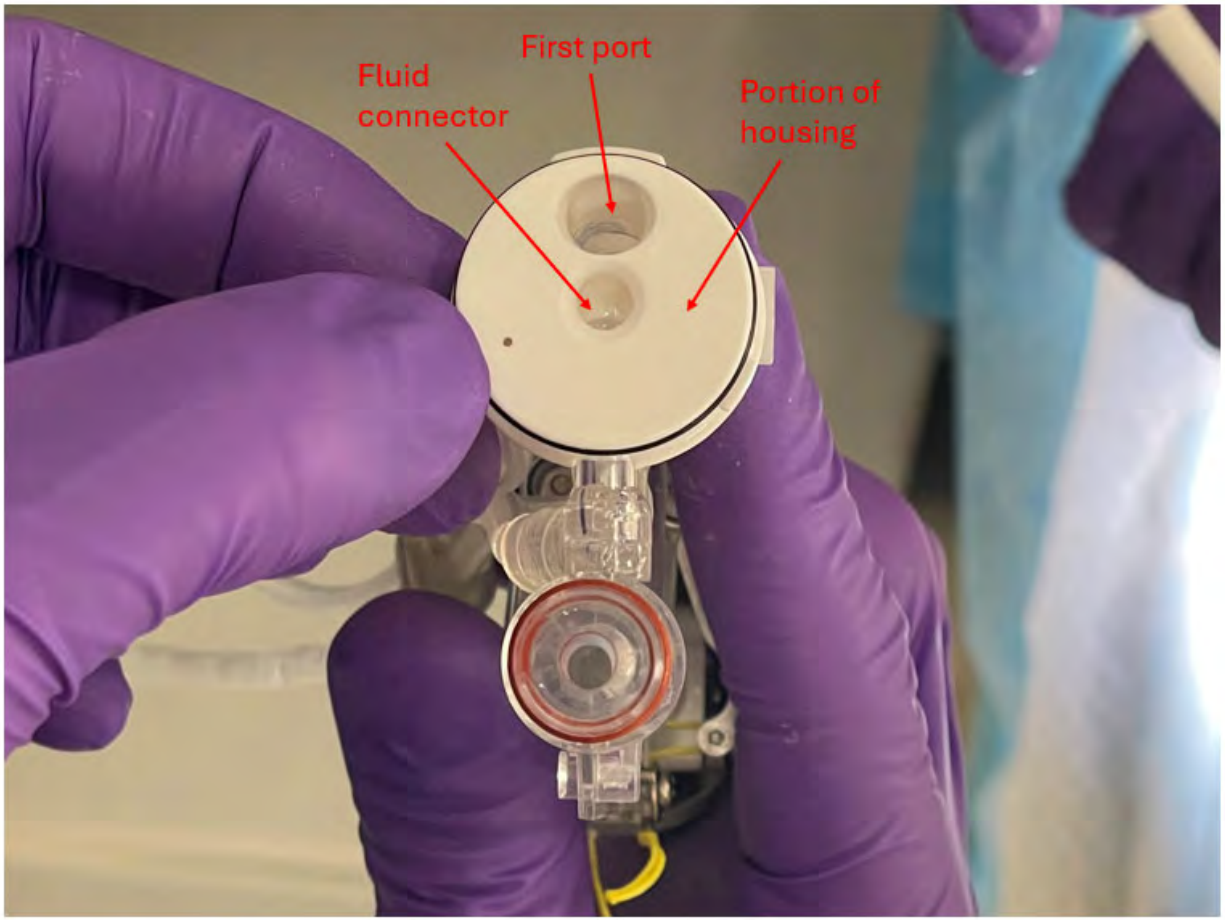
The image below, which shows blood flowing from the aspiration catheter of the 16F Symphony Catheter handle through the port into the filter chamber and through the fluid connector, into the connection tubing (eventually to the Truvic Canister), confirms that the fluid connector is configured to be fluidically coupled to the connection tubing.

	 (Symphony Thrombectomy System – Overview Animation Video at 2:02.) Specifically, blood flows from the housing, through the removable filter and through the fluid connector, into the connection tubing (eventually flowing to the Truvic Canister) via the flow path shown in the annotated images below.

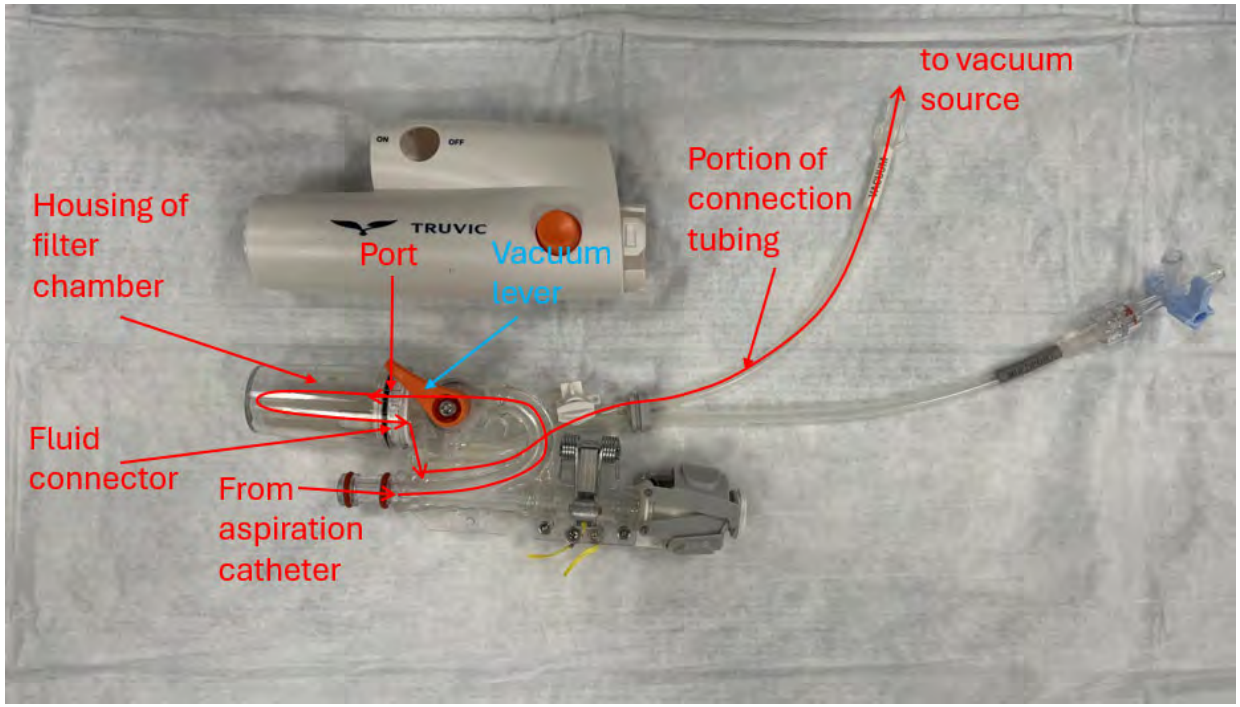
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
wherein the filter is in the housing along a first fluid path, wherein the	The Symphony Catheter handle of the Symphony System includes a filter in the housing of the filter chamber, where the first fluid path couples the port and fluid

first fluid path fluidically couples the port and the fluid connector, and wherein the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path;	connector and where the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path. Specifically, as shown in the annotated teardown image below, the first fluid path fluidically couples the port and fluid connector, such that the catheter is fluidically coupled to the vacuum source (Truvic Generator and Truvic Canister) via the filter chamber along the first fluid path.  (Annotated image of internal portion of the controller housing.)



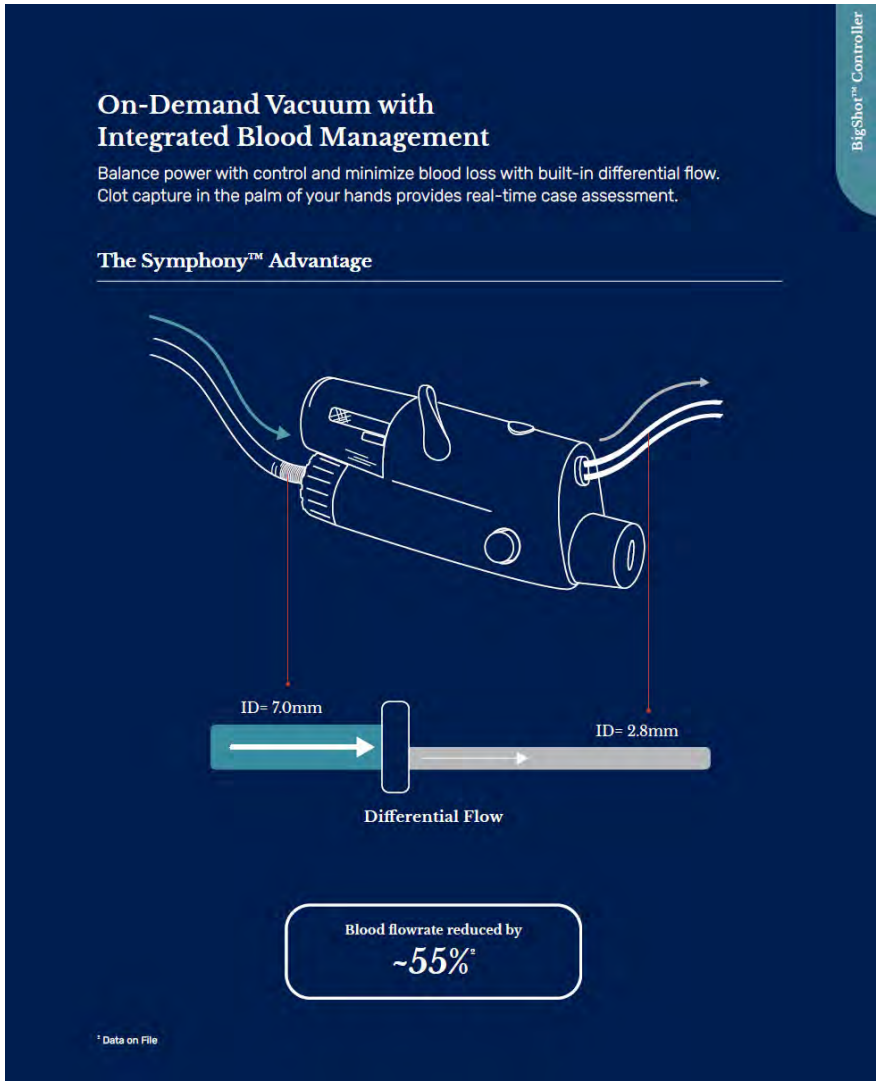
(Annotated image of controller housing showing port and fluid connector.)



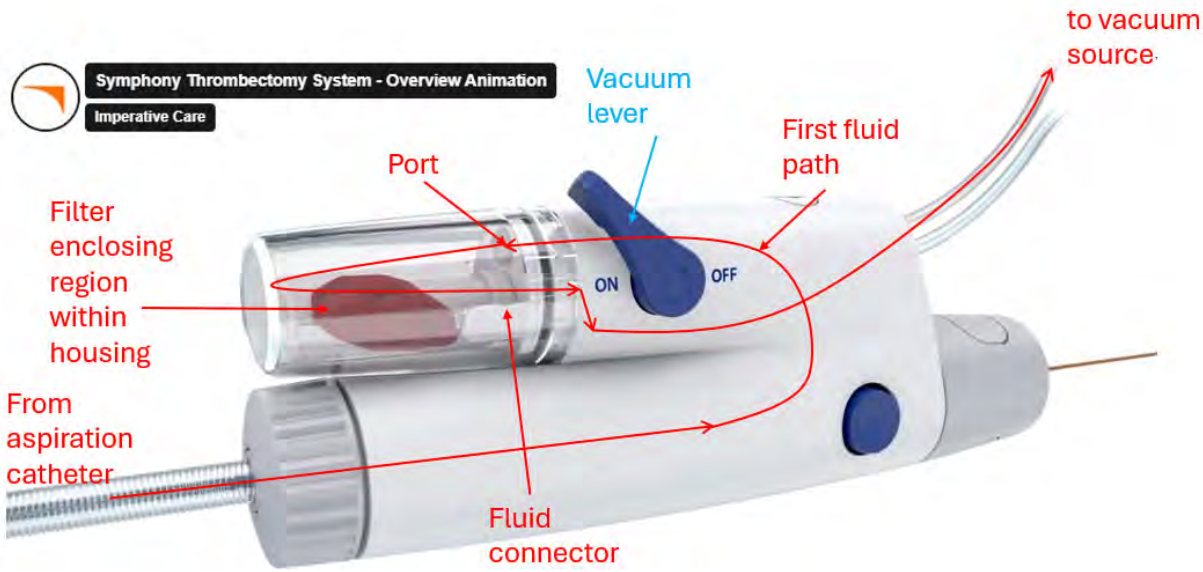
(Annotated image of internal portion of the controller housing with vacuum lever.)

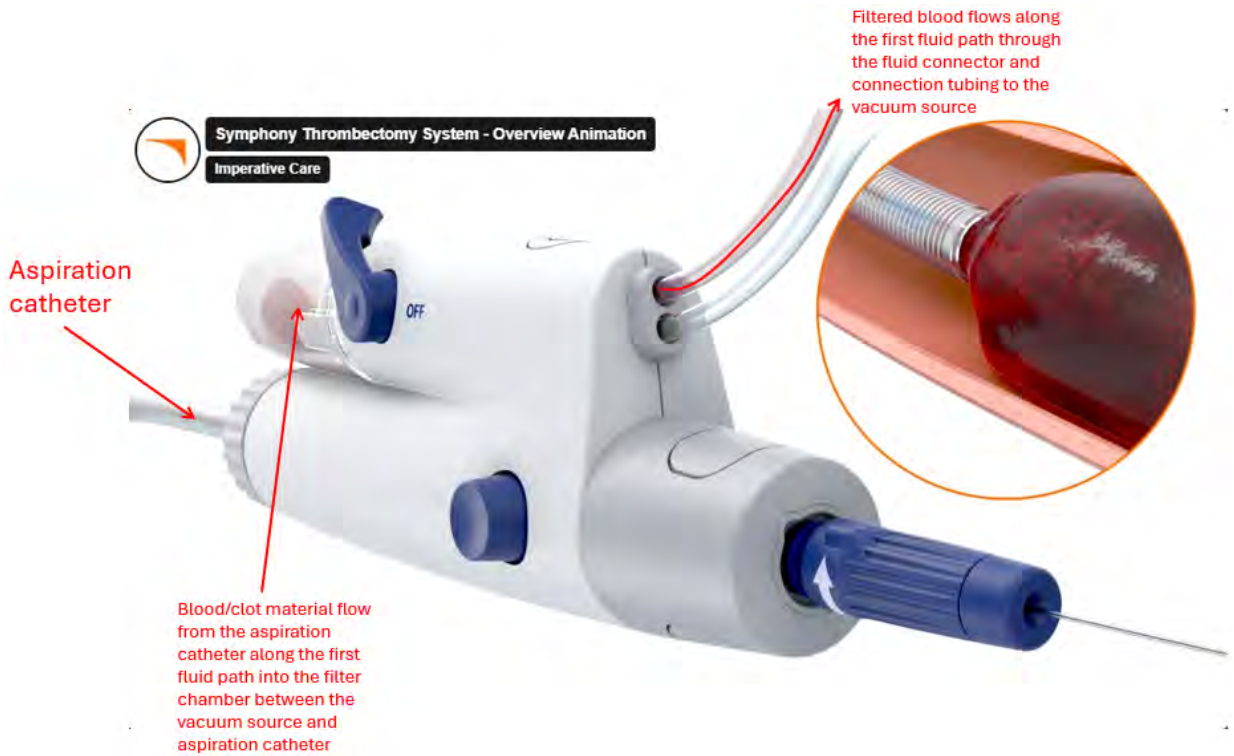
The Symphony System IFU confirms that the first fluid path couples the port and fluid connector such that the catheter is fluidically coupled to the vacuum source via the filter chamber along the first fluid path. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus."); Symphony Thrombectomy System Instructions For Use at 5 ("When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the 'OFF' position.").)

	The Symphony Thrombectomy System Brochure partially shows the first fluid path flowing from the aspiration catheter (blue arrow) into the Symphony Catheter handle and out toward the vacuum source.



(Symphony Thrombectomy System Brochure at 7.)

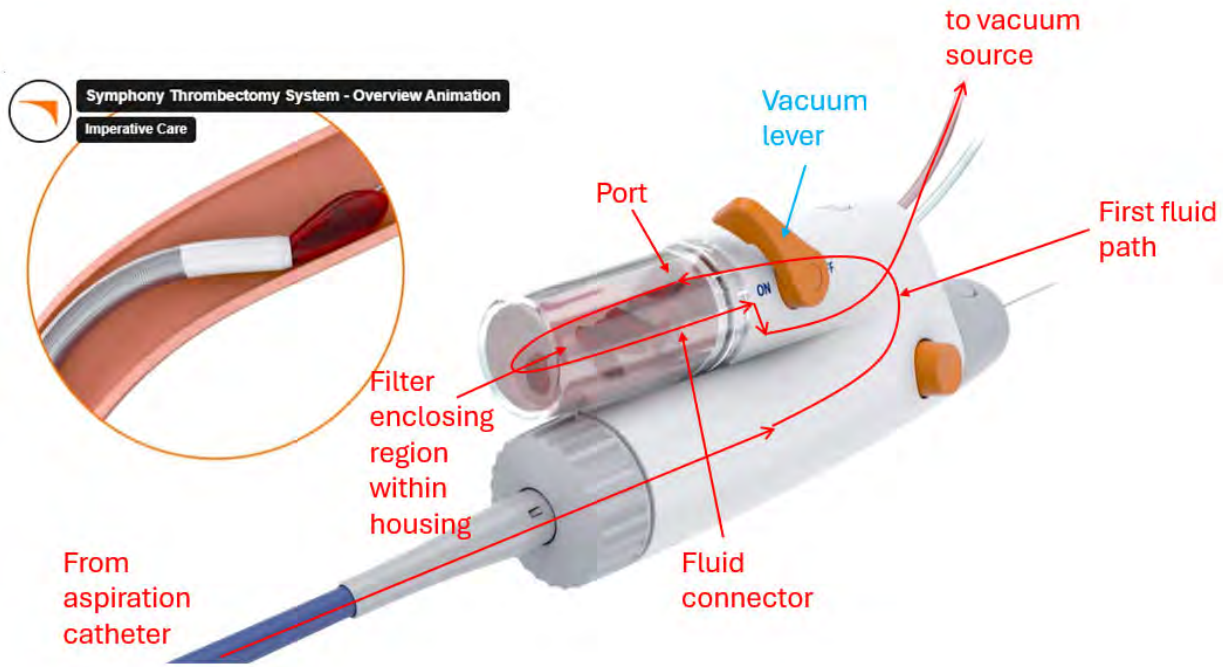
	----------24F Aspiration Catheter---------- The filter of the 24F Symphony Catheter handle is in the housing along the first fluid path, as shown in the annotated images below.  (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

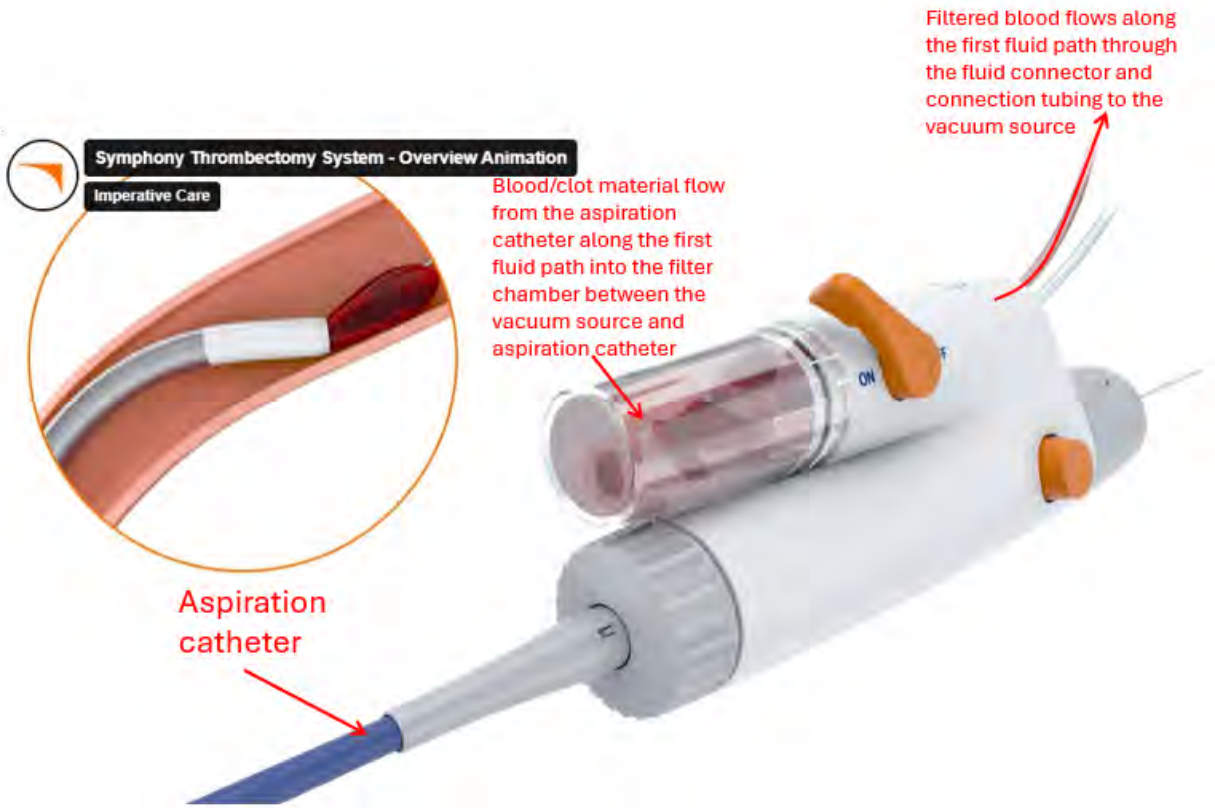


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:00.)

As shown in the Whipsaw image below, blood and clot material from the aspiration catheter flow along the first fluid path, through the port into the filter chamber. Blood then travels through the filter (where the clot material is unable to pass and, therefore, remains in the housing) and through the fluid connector along the first fluid path to the Truvic Canister (*e.g.*, part of the vacuum source) via the connection tubing.

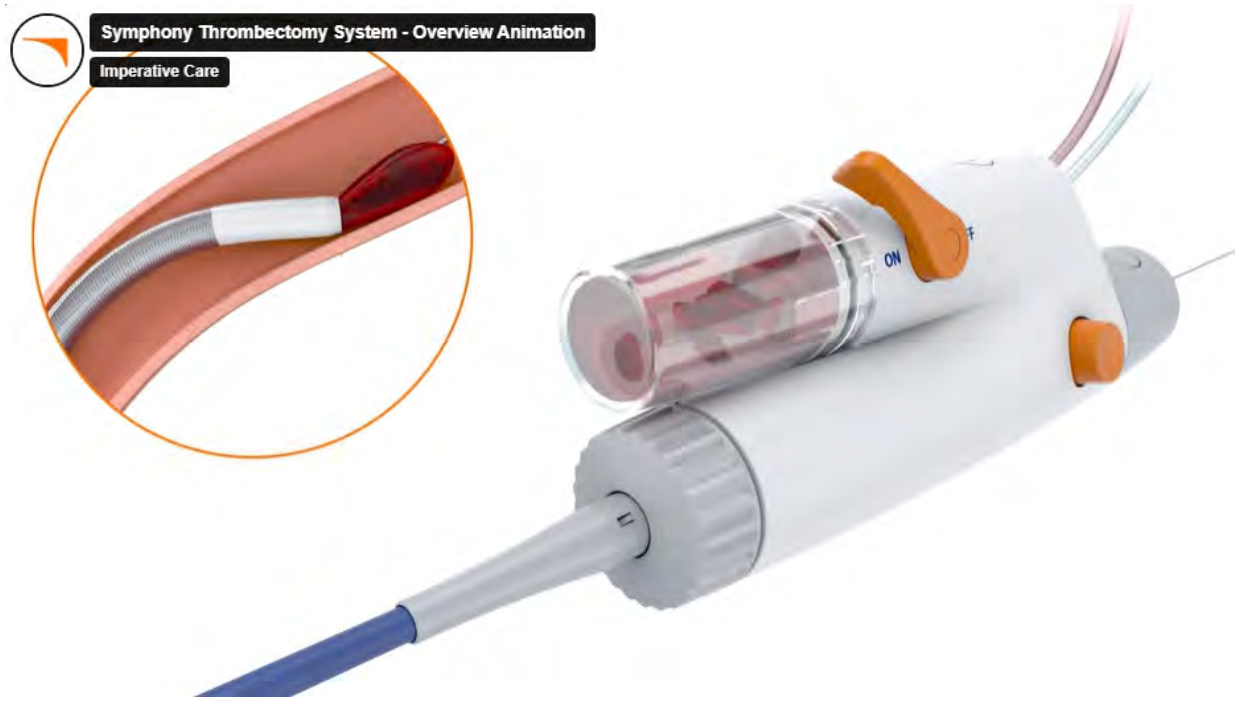
	 (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) **----------16F Aspiration Catheter----------** The filter of the 16F Symphony Catheter handle is in the housing along the first fluid path, as shown in the annotated images below.

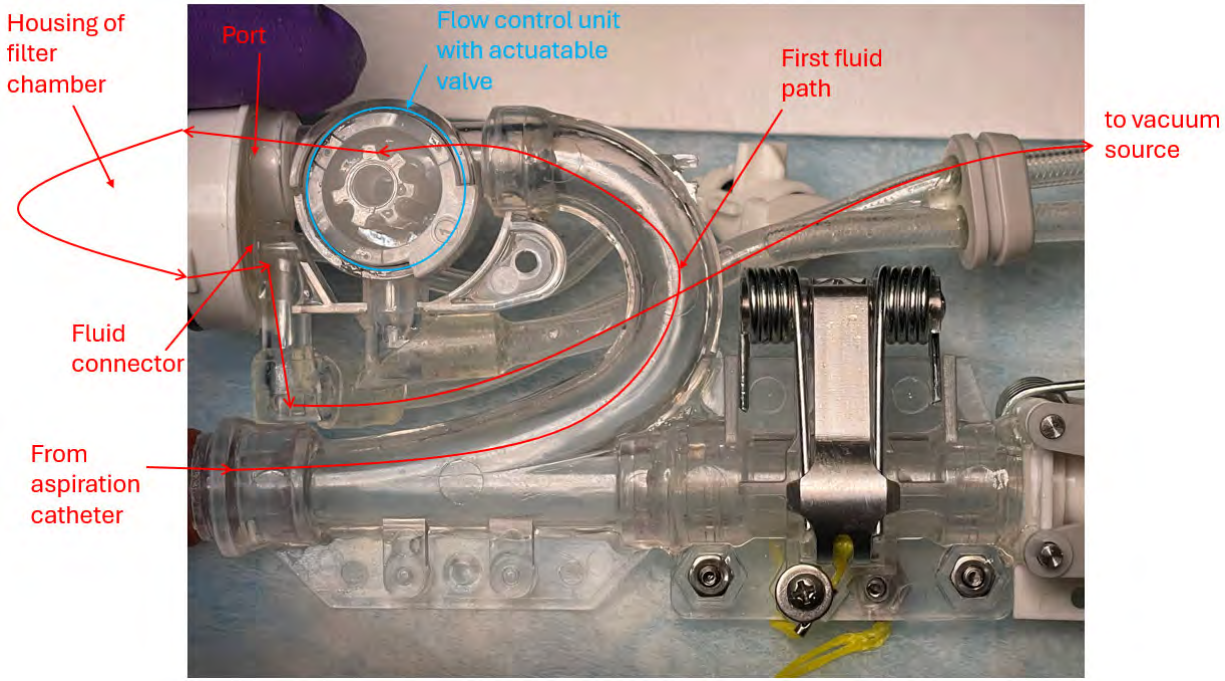
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

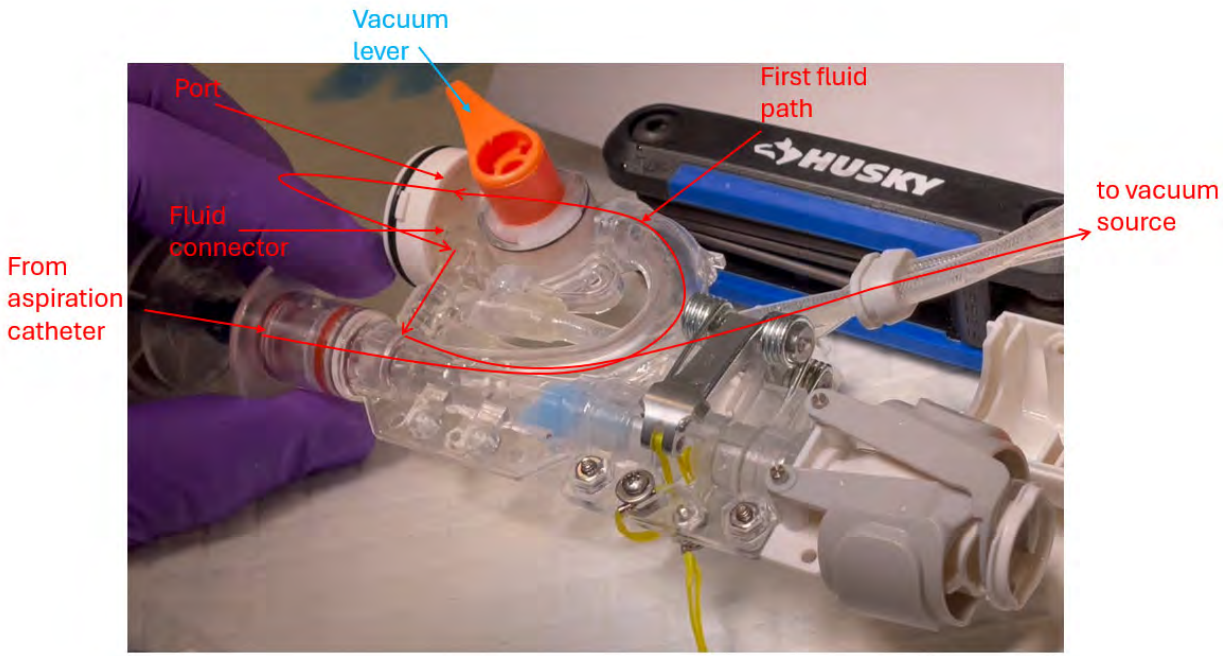


(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

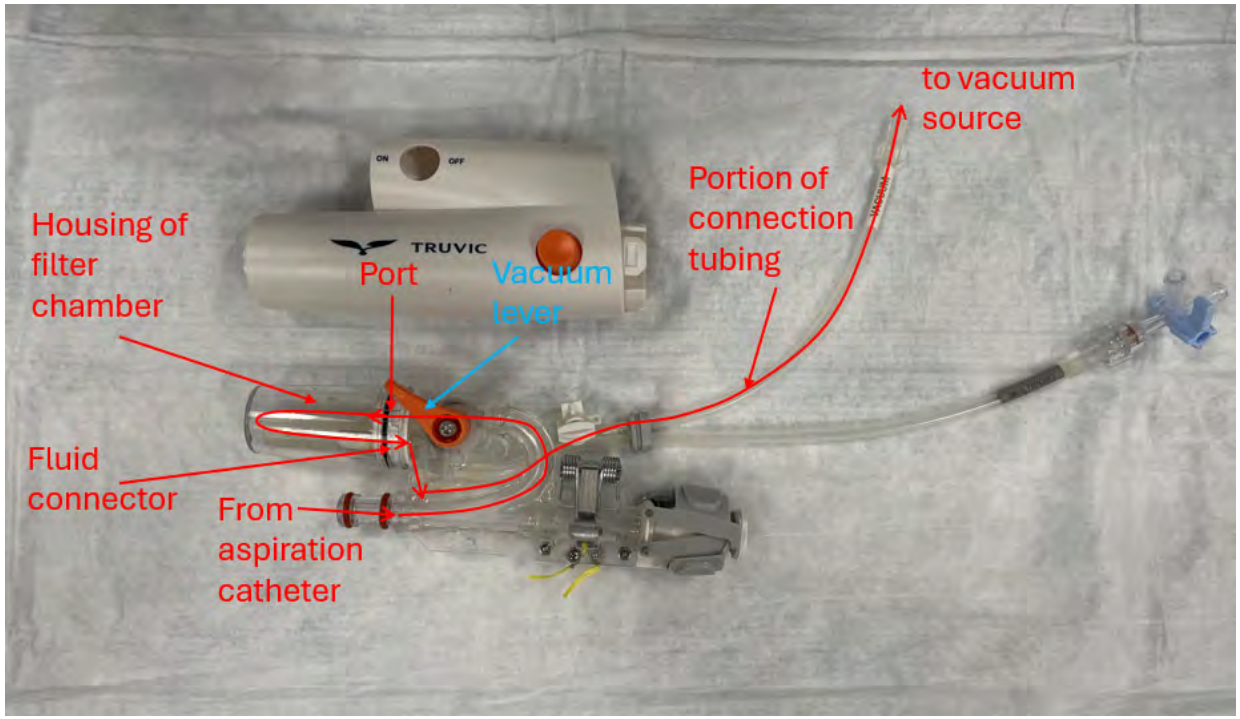
As shown in the image below, blood and clot material from the aspiration catheter flow along the first fluid path, through the port into the filter chamber. Blood then travels through the filter (where the clot material is unable to pass and, therefore, remains in the housing) and through the fluid connector along the first fluid path to the Truvic Canister (*e.g.*, part of the vacuum source) via the connection tubing.

	 (Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid path between the filter chamber and the catheter; and	The Symphony Catheter handle includes a flow controller fluidically coupling the filter chamber to the catheter, where the flow controller is along the first fluid path between the filter chamber and the catheter. Specifically, the 24F and 16F Symphony Catheter handle of the Symphony System includes a vacuum control valve and vacuum lever (*e.g.*, a flow controller) that fluidically couples the filter chamber to the catheter and is along the first fluid path

	between the filter chamber and catheter, as shown in the annotated teardown images below.  (Annotated image of internal portion of the controller housing.)



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

	 (Annotated image of internal portion of the controller housing with vacuum lever.) The Symphony System IFU depicts the vacuum lever, which is able to switch between an “ON” and “OFF” position.

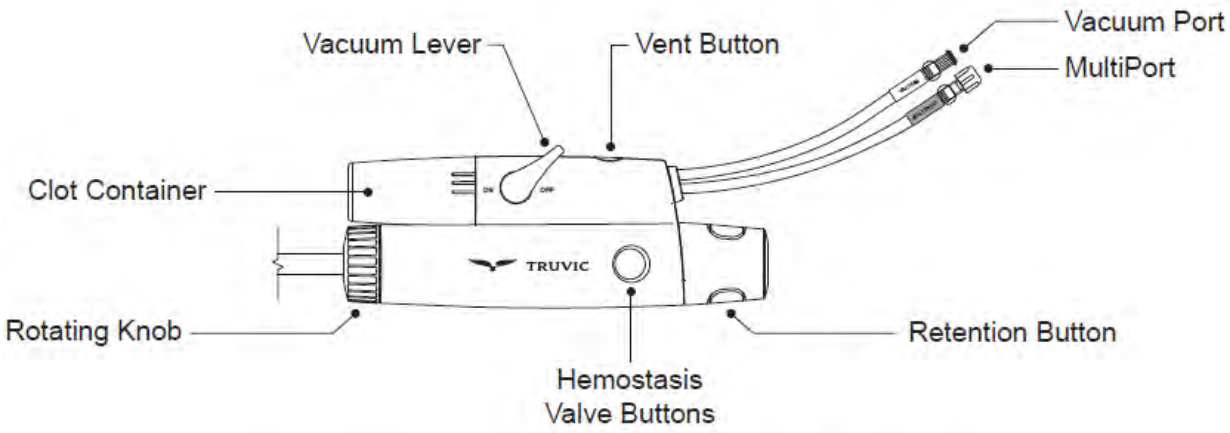


Figure 3: Symphony Catheter Handle, labeled

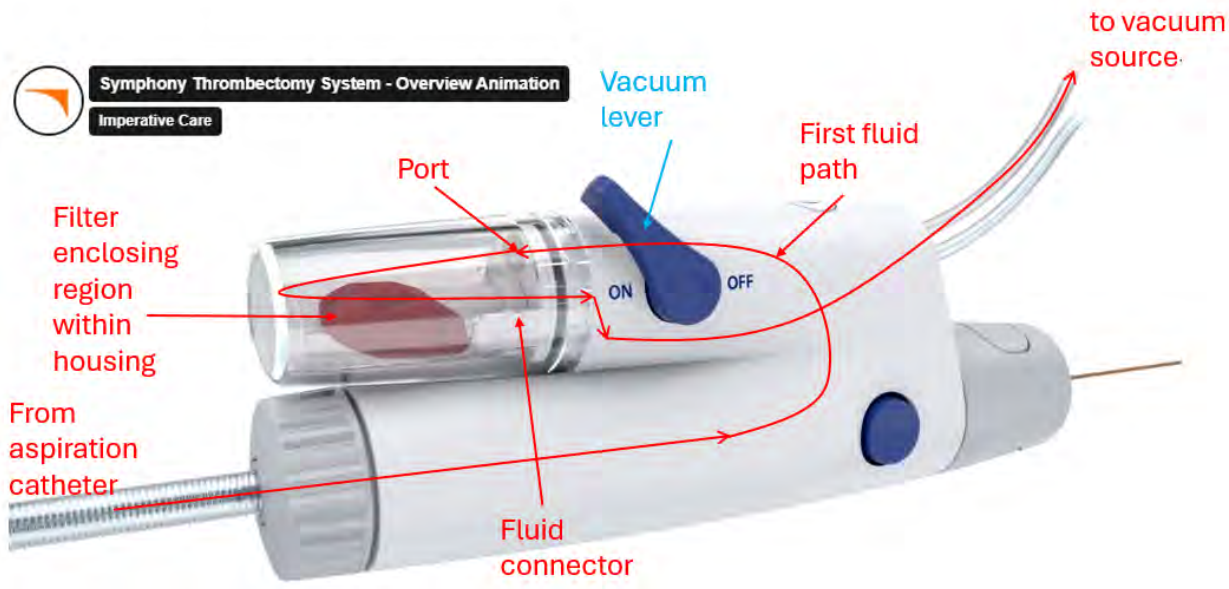
(Symphony Thrombectomy System Instructions For Use at 4.)

The Symphony System IFU confirms that the vacuum control valve (which is coupled to the vacuum lever) of the Symphony Catheter handle fluidically couples the filter chamber to the catheter, such that it allows for blood to move from the aspiration catheter to the clot container (and eventually to the Truvic Canister) via the first fluid path. (Symphony Thrombectomy System Instructions For Use at 5 ("To begin aspiration, move the vacuum lever on the Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the 'OFF' position."); *see also* Symphony Thrombectomy System Instructions For Use at 8 ("To begin aspiration, move the vacuum lever on the 16F Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the 16F Handle to the 'OFF' position."); Symphony Thrombectomy System Instructions For Use at 9 ("Ensure there is no thrombus remaining in the

24F Catheter by moving the vacuum lever to the 'ON' position and visualizing unrestricted blood flow through the clot container.").)

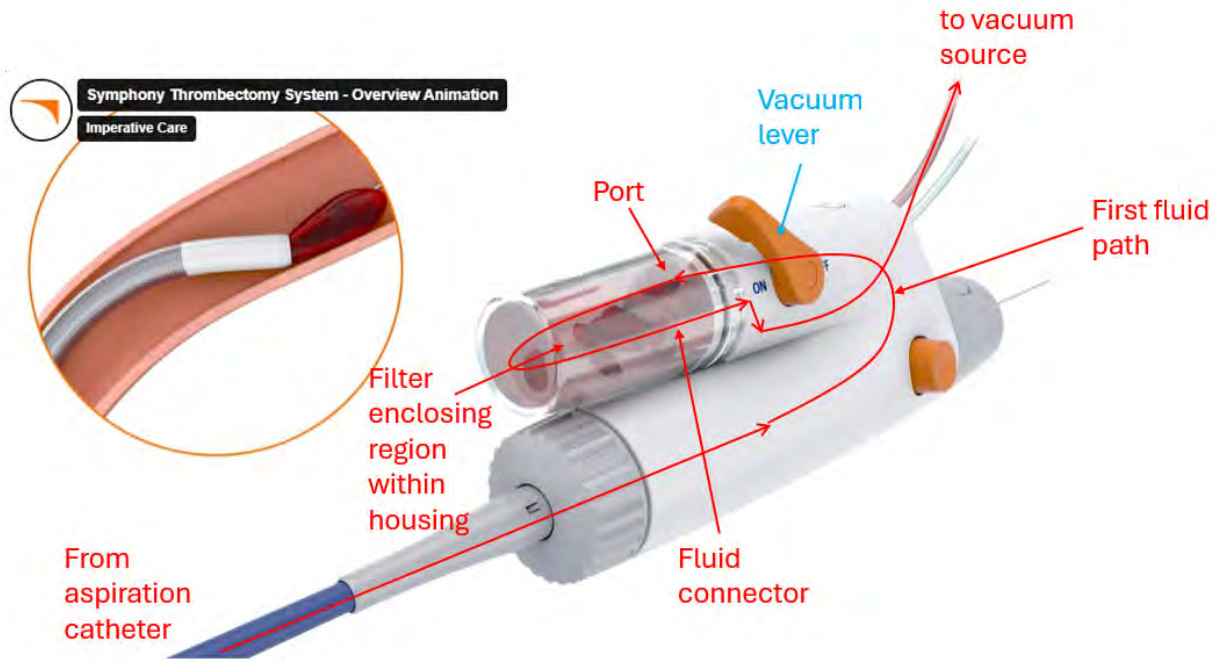
----------24F Aspiration Catheter----------

The flow controller of the 24F Symphony Catheter handle is along the first fluid path between the catheter and filter chamber, such that turning the vacuum lever to the "ON" position allows for the flow of blood and clot material from the aspiration catheter to the filter chamber, as shown in the annotated image of the 24F Symphony Catheter handle below.



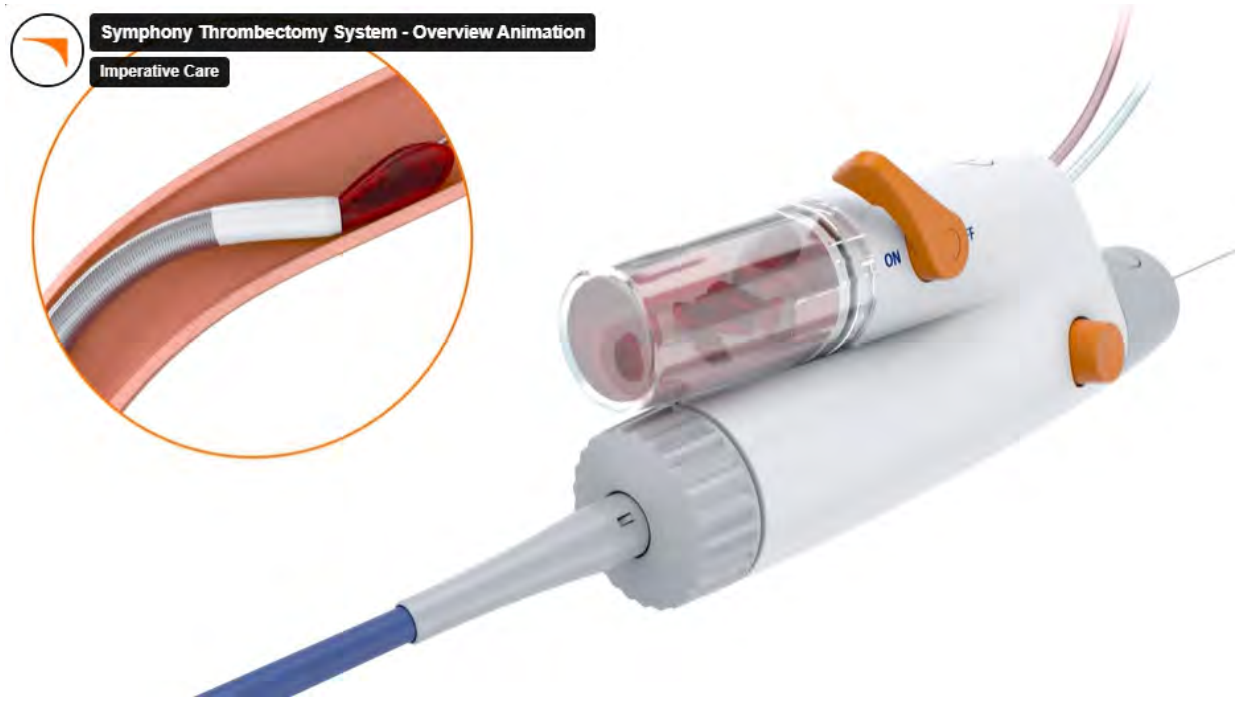
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

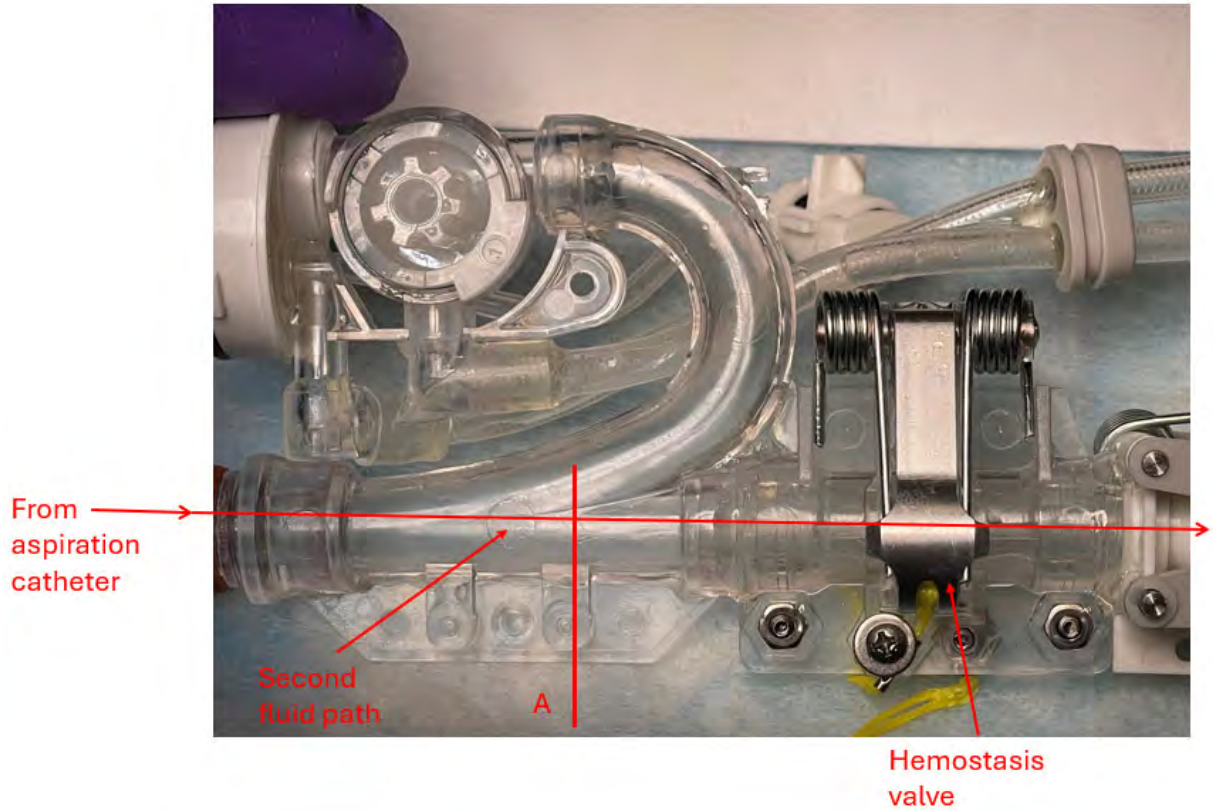
	The image below shows blood flowing from the aspiration catheter of the 24F Symphony Catheter handle to the filter chamber via the first fluid path (annotated above) when the vacuum lever is in the "ON" position, which confirms that the flow controller of the Symphony Catheter handle fluidically couples the filter chamber to the catheter. (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) **----------16F Aspiration Catheter----------** The flow controller of the 16F Symphony Catheter handle is along the first fluid path between the catheter and filter chamber, such that turning the vacuum lever to the "ON" position allows for the flow of blood and clot material from the aspiration catheter to the filter chamber, as shown in the annotated image of the 16F Symphony Catheter handle below.

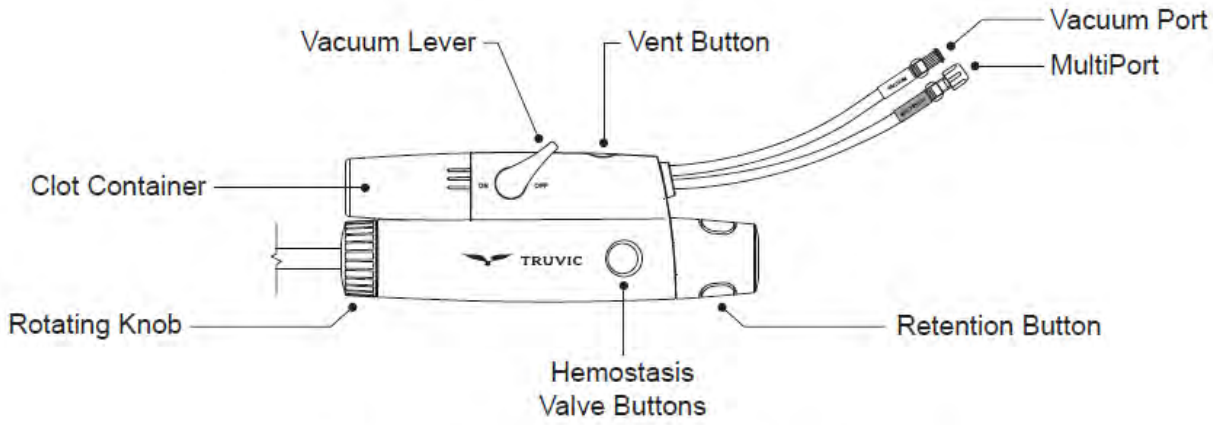


(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

The image below shows blood flowing from the aspiration catheter of the 16F Symphony Catheter handle to the filter chamber via the first fluid path (annotated above) when the vacuum lever is in the "ON" position, which confirms that the flow controller of the Symphony Catheter handle fluidically couples the filter chamber to the catheter.

	 (Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis	The Symphony Catheter handle includes a hemostasis valve fluidically coupled to the catheter along a second fluid path that is at least partially different than the first fluid path, where the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and catheter.

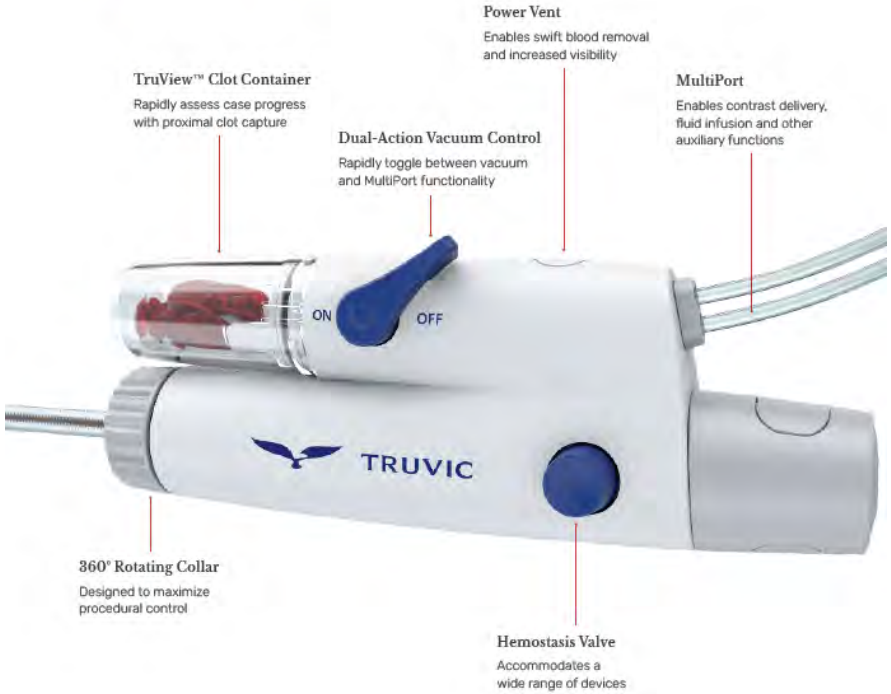
by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and catheter.	Specifically, the 24F and 16F Symphony Catheter handle include a hemostasis valve that is fluidically coupled to the catheter along a separate fluid path, which is at least partially different from the first fluid path, as shown in the annotated teardown image below. Specifically, the second fluid path is at least partially different from the first fluid path starting at approximately point A (annotated below) and running through the hemostasis valve.  (Annotated image of internal portion of controller handle housing.)

	The Symphony System IFU shows the outer shell of the Symphony Catheter handle that includes a button for the handle's hemostasis valve.  **Figure 3: Symphony Catheter Handle, labeled** (Symphony Thrombectomy System Instructions For Use at 4.) The Symphony Thrombectomy System Brochure similarly shows that the 24F Symphony Catheter handle includes a hemostasis valve.

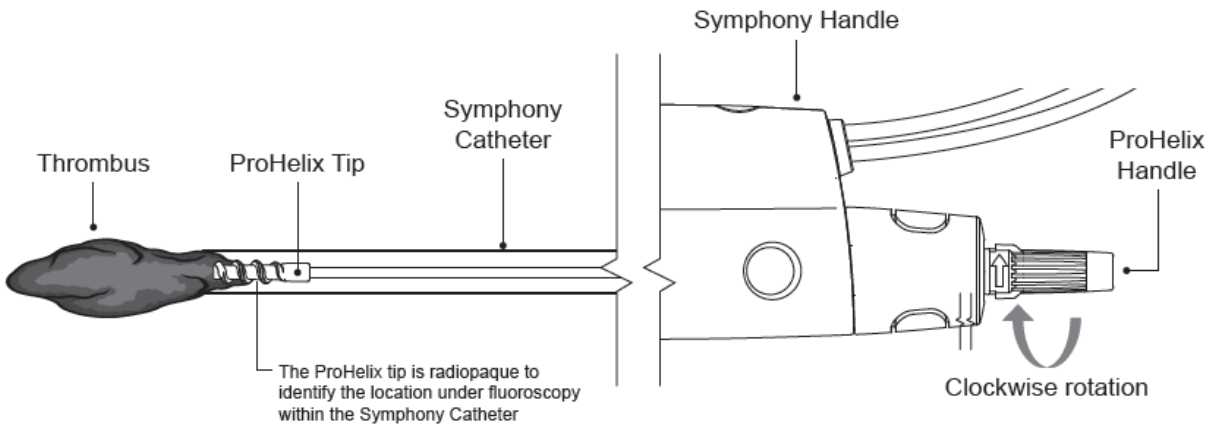
SYMPHONY™ THROMBECTOMY SYSTEM

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

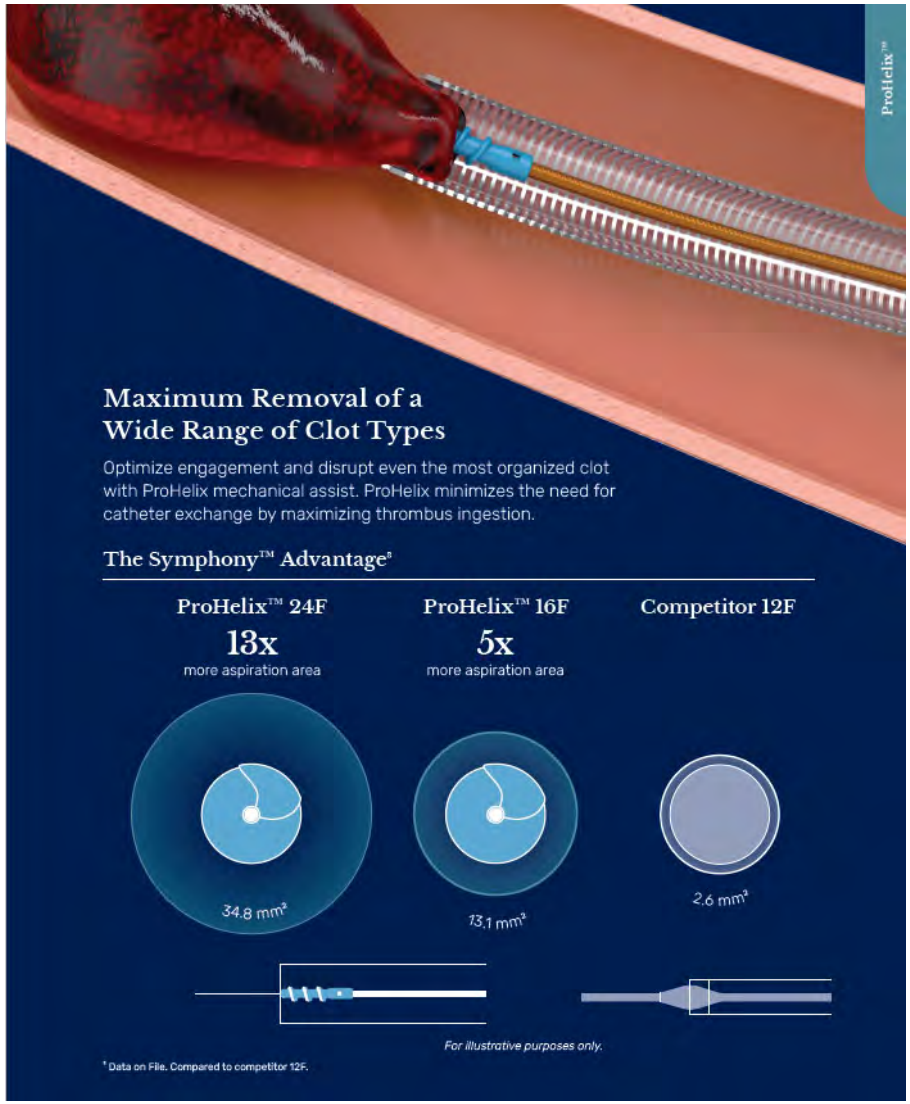
BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)

	The Symphony System IFU shows that a 24F or 16F Symphony ProHelix device (*e.g.*, an interventional device) can be inserted through the hemostasis valve and catheter to reach a clot within the human patient.  **Figure 4: ProHelix engaged with thrombus** (Symphony Thrombectomy System Instructions For Use at 5.) The Symphony System IFU describes the interventional nature of the ProHelix device and how it can be inserted through the hemostasis valve and into the catheter. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony ProHelix device may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter."); Symphony Thrombectomy System Instructions For Use at 1 ("As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the

	proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter.”); Symphony Thrombectomy System Instructions For Use at 5 (“Introduce the ProHelix over the previously placed 0.035” guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle. To begin aspiration, move the vacuum lever on the Handle to the ‘ON’ position. Slowly rotate the ProHelix handle as indicated by the arrow (clockwise direction). Upon feeling resistance to rotation, slowly retract the spring-loaded ProHelix handle up to 1 cm while rotating to assist with aspiration and removal of the thrombus.”); Symphony Thrombectomy System Instructions For Use at 8-9 (same for 16F Symphony Catheter handle); Symphony Thrombectomy System Instructions For Use at 5 (“When aspiration is complete, depress the Retention Clip buttons on the Handle and withdraw the ProHelix approximately 1 cm from the Catheter. Then press the Hemostasis Valve buttons on the Handle to reduce friction while withdrawing the ProHelix from the Catheter completely. Ensure the Hemostasis Valve buttons are completely depressed when pulling the ProHelix tip through the Valve.”).) The Symphony Thrombectomy System Brochure describes how the Symphony ProHelix (*e.g.*, an interventional device) can be used to extract clot material. (Symphony Thrombectomy System Brochure at 9 (“Optimize engagement and disrupt even the most organized clot with ProHelix mechanical assist. ProHelix minimizes the need for catheter exchange by maximizing thrombus ingestion.”).)

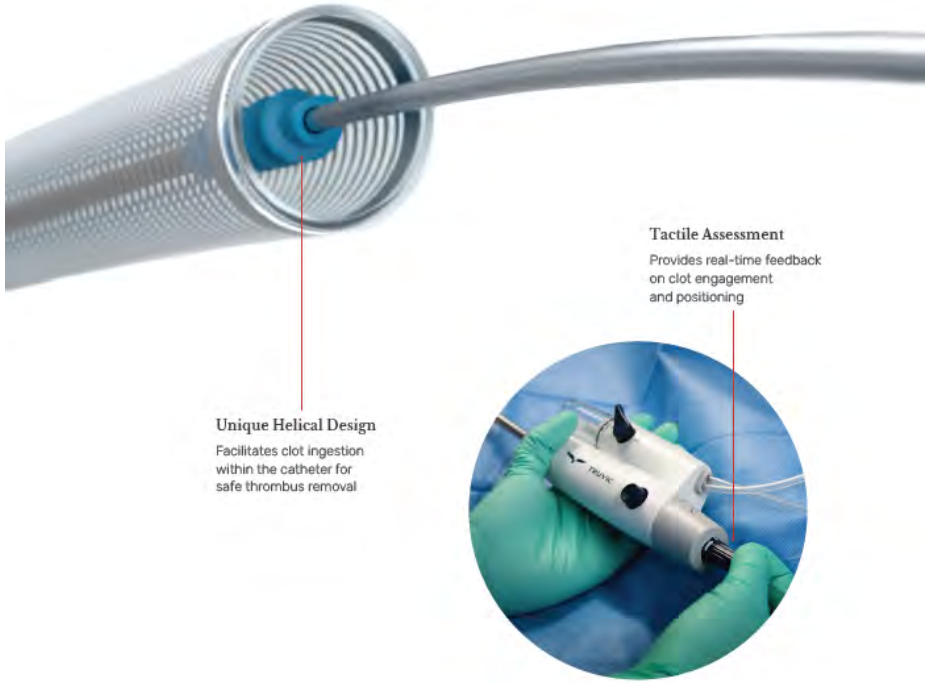


(Symphony Thrombectomy System Brochure at 9.)

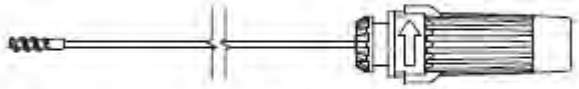
SYMPHONY™ THROMBECTOMY SYSTEM

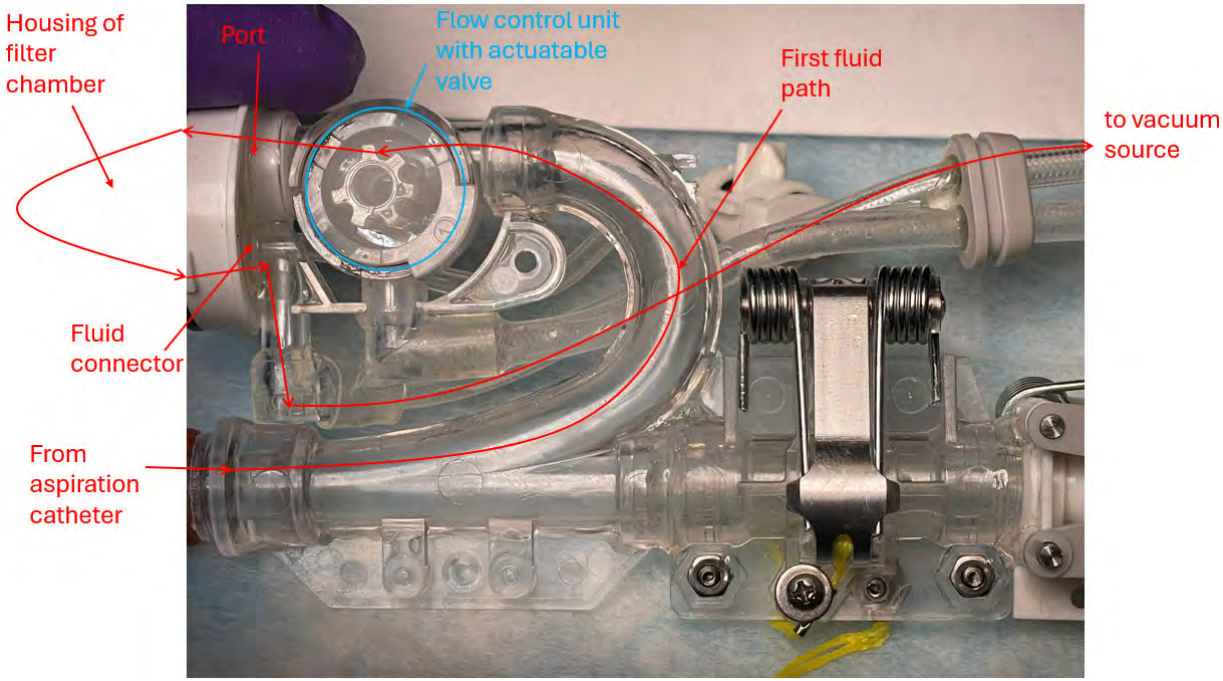
Mechanical Assist Optimizes Clot Engagement & Capture

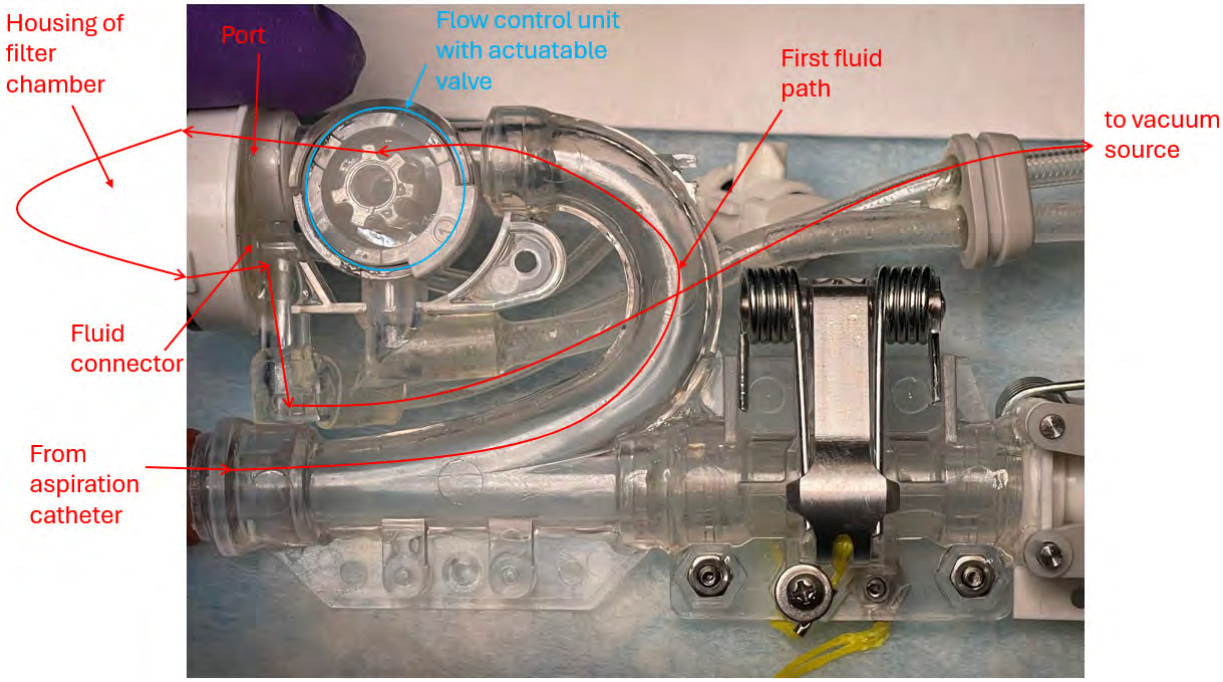
ProHelix™ Mechanical Assist

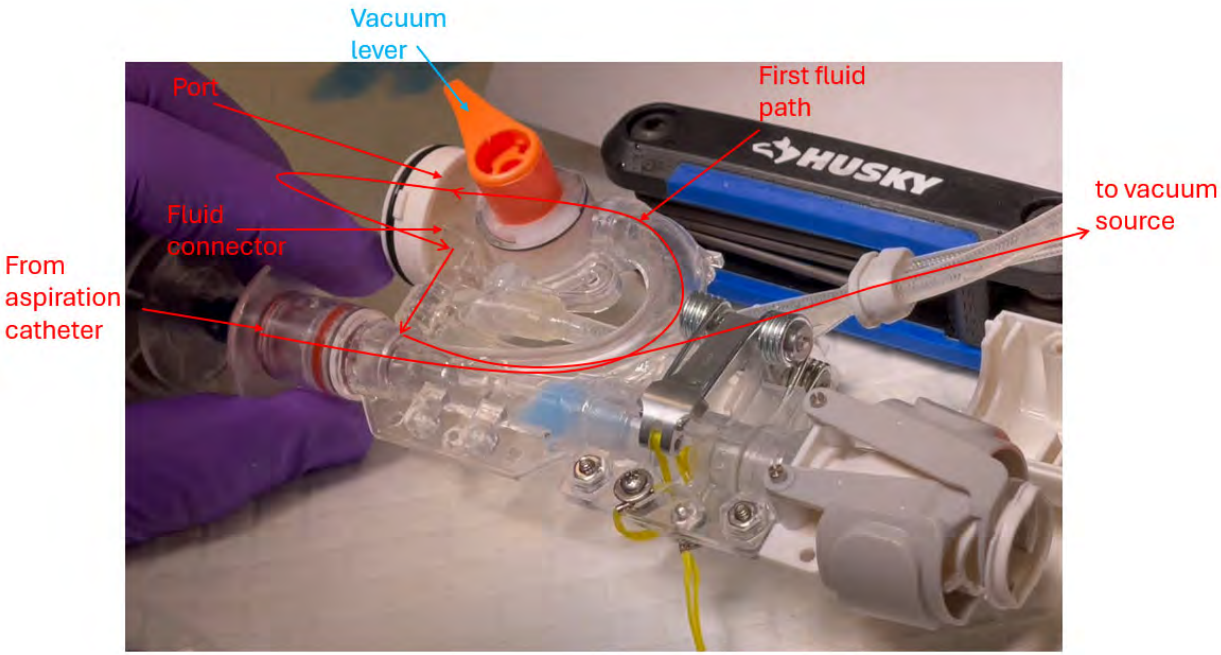


(Symphony Thrombectomy System Brochure at 8.)

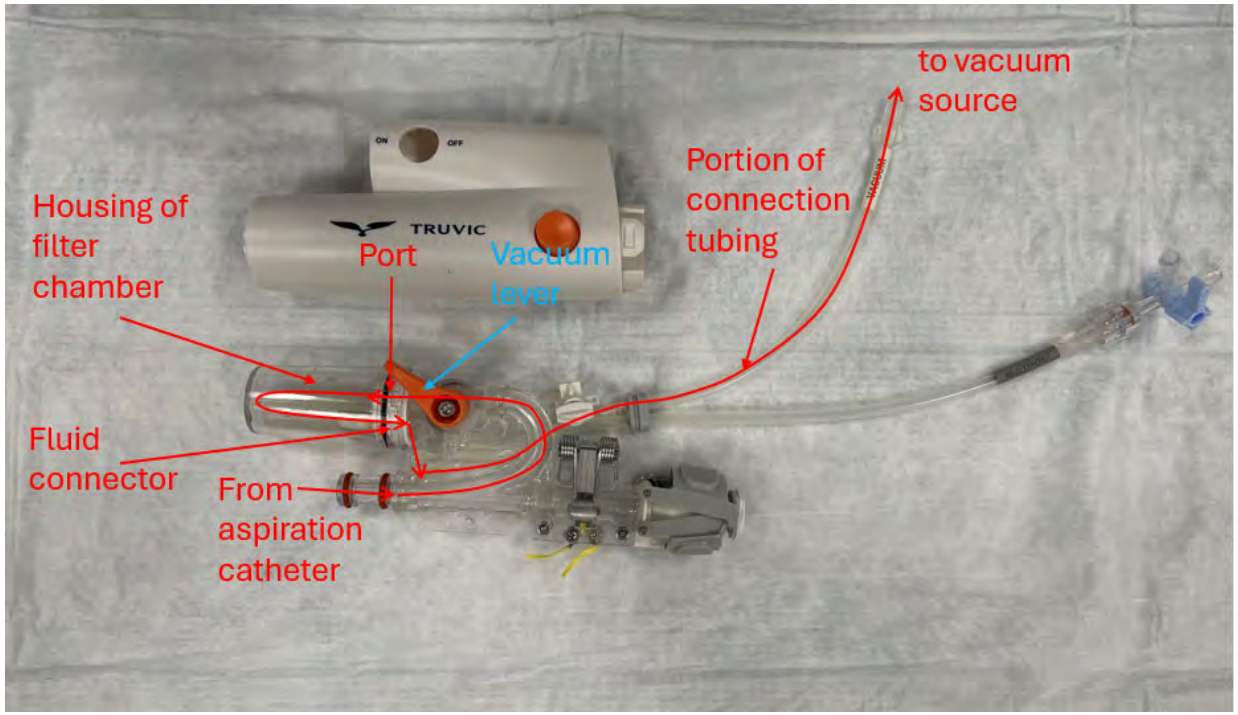
	 ProHelix 16F / 24F (Symphony Thrombectomy System Instructions For Use at 1.) The Symphony System IFU states to push the Hemostasis Valve Buttons on the 24F or 16F Symphony Catheter handle to release the hemostasis valve and then to advance the ProHelix device over the guidewire to the clot. (Symphony Thrombectomy System Instructions For Use at 2 ("Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device."); Symphony Thrombectomy System Instructions For Use at 5 ("Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle."), 6 ("During ProHelix movement, press the Hemostasis Valve buttons on the Handle to reduce friction.").) Hemostasis valves are used to inhibit proximal fluid flow from the catheter when an interventional device is inserted through the hemostasis valve and catheter. To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[2] The aspiration system of claim 1 wherein the flow controller	The Symphony System includes a flow controller that comprises a flow control unit between the filter chamber and the catheter.

comprises a flow control unit between the filter chamber and the catheter.	The Symphony System with a 24F and/or 16F Symphony Catheter handle include a flow controller that comprises a flow control unit (a vacuum control valve) between the filter chamber and the catheter, as shown in the annotated teardown image below. The flow control unit is along the first fluid path between the filter chamber and the aspiration catheter.  (Annotated image of internal portion of controller handle housing.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

[3] The aspiration system of claim 2 wherein the flow control unit comprises a user-actuatable valve.	The Symphony System includes a flow control unit that comprises a user-actuatable valve. Specifically, the flow control unit of the Symphony System with a 24F and/or 16F Symphony Catheter handle comprises a user-actuatable valve. As shown in the teardown image below, the flow control unit includes an actuatable valve that is controlled by rotating the vacuum lever between the "ON" and "OFF" position.  (Annotated image of internal portion of controller housing.)



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



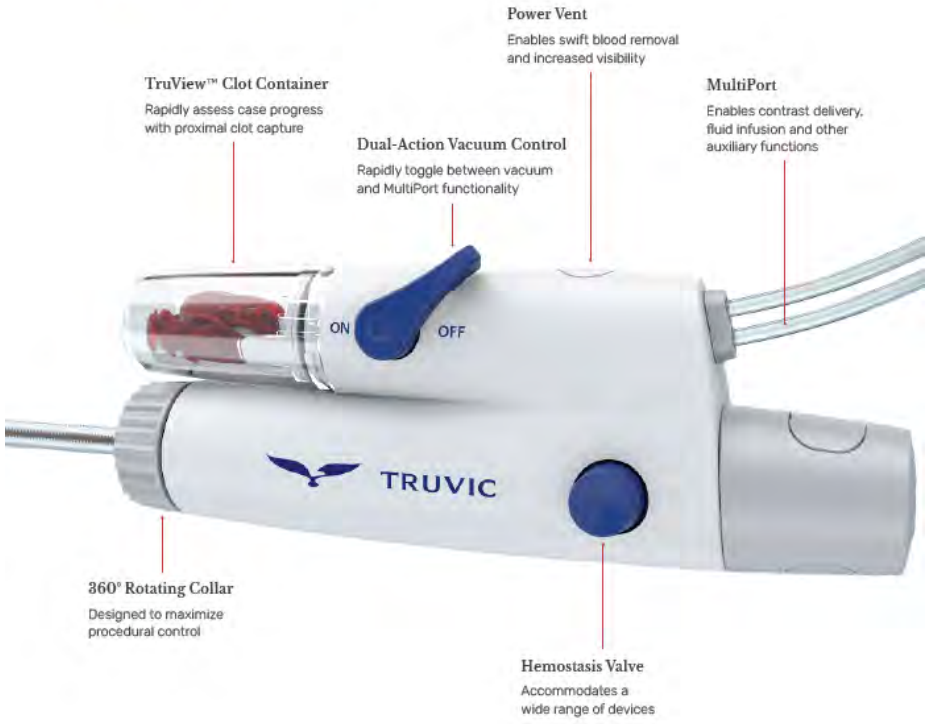
(Annotated image of internal portion of the controller housing with vacuum lever.)

The Symphony Thrombectomy System Brochure also shows how the valve is actuatable where it allows for a user to "[r]apidly toggle between the vacuum and MultiPort functionality." (Symphony Thrombectomy System Brochure at 6.)

SYMPHONY® THROMBECTOMY SYSTEM

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

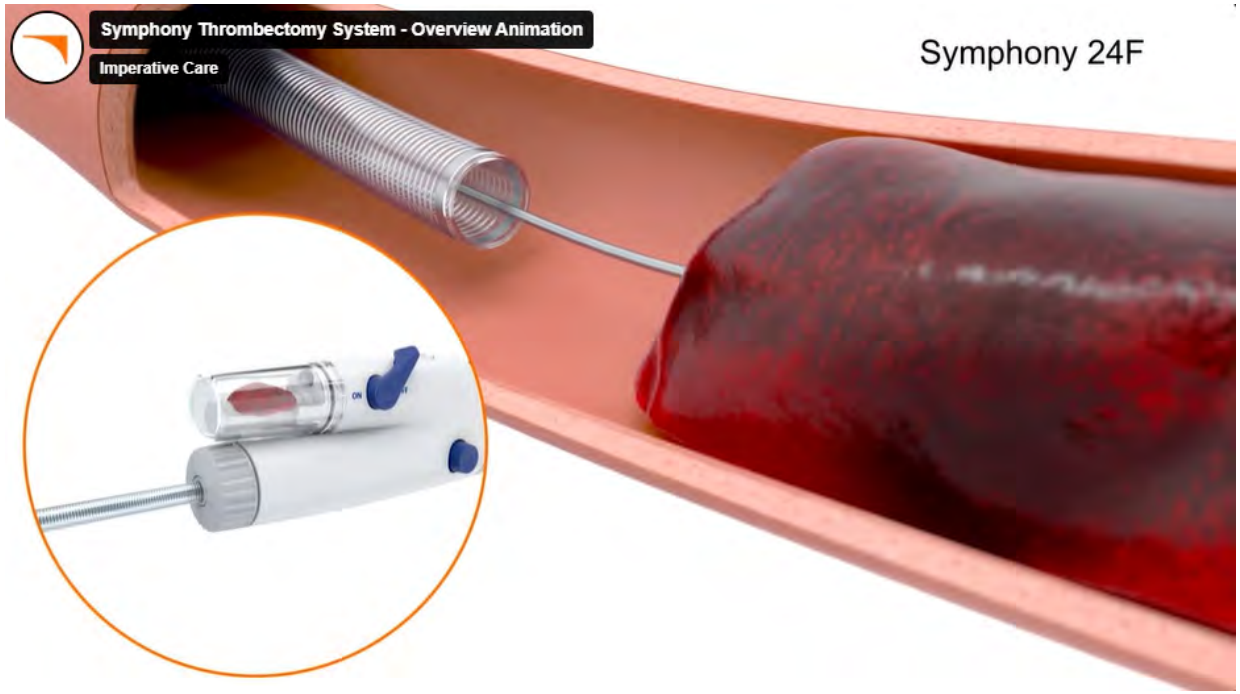
BigShot™ Controller

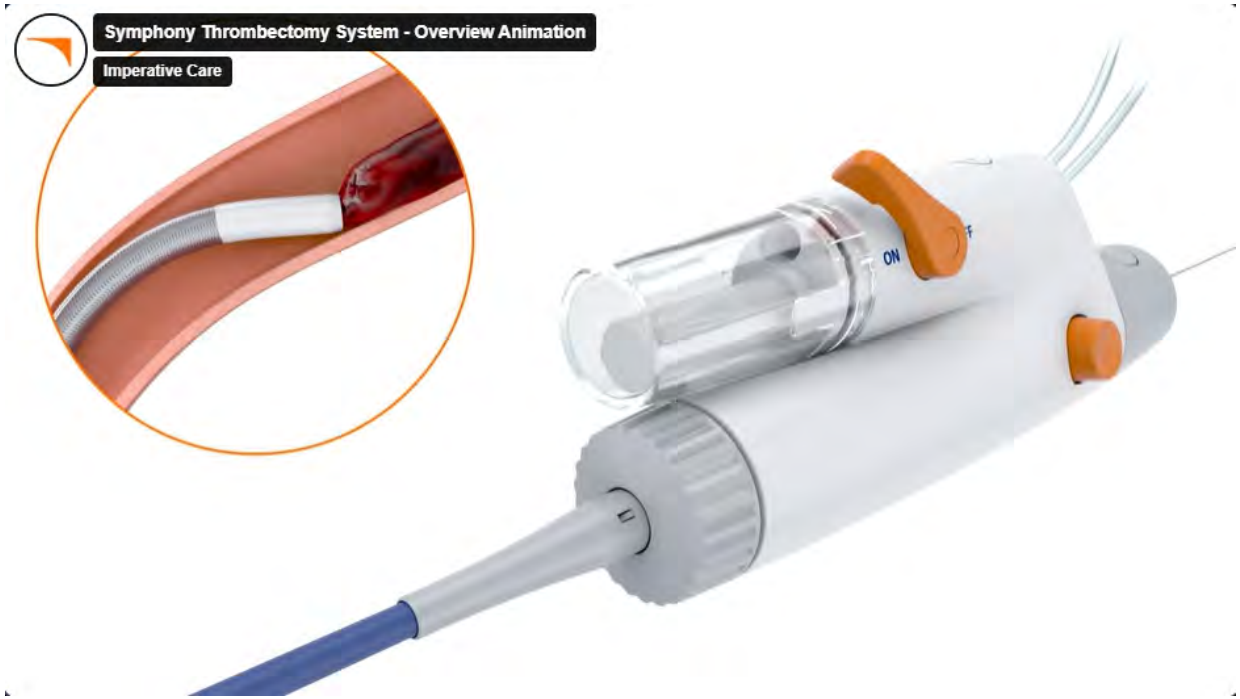


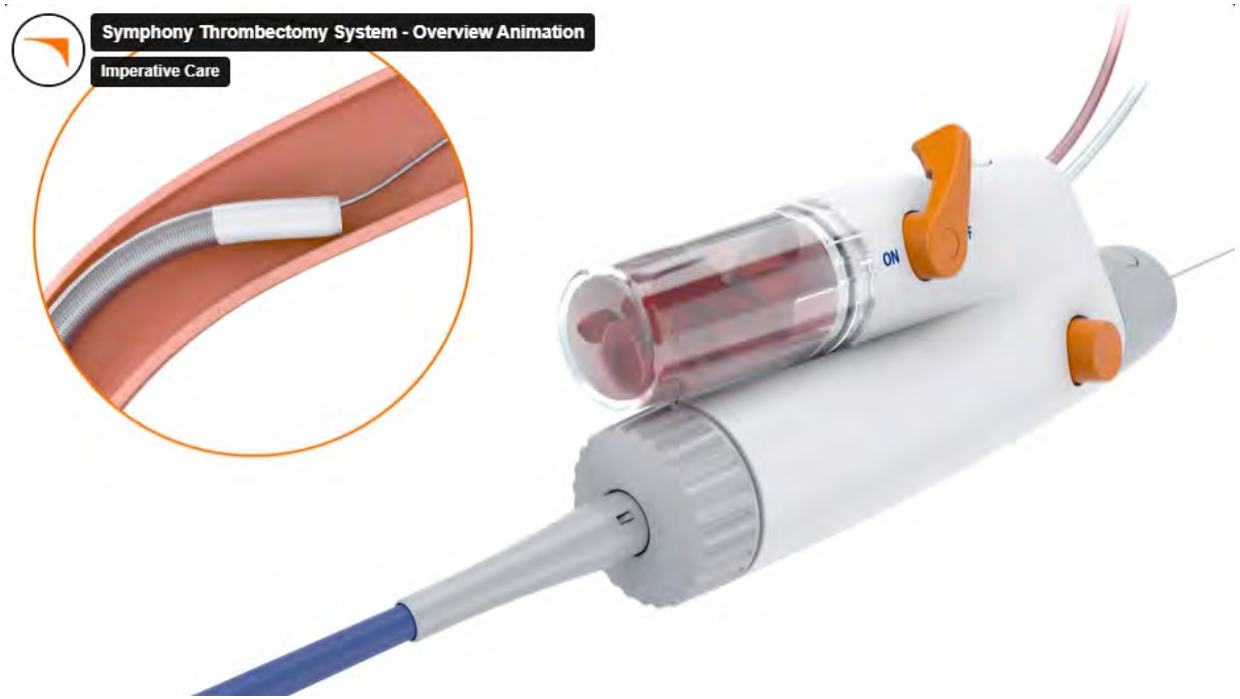
(Symphony Thrombectomy System Brochure at 6.)

	The Symphony System IFU discusses how the valve in the flow control unit is user-actuatable between an “ON” and “OFF” position when a user of the Symphony System manually moves the vacuum lever between the two positions. (Symphony Thrombectomy System Instructions For Use at 3 (“In order to minimize blood loss, ensure that the Symphony Catheter handle vacuum lever is in the ‘ON’ position for the minimum time needed to remove the thrombus.”); Symphony Thrombectomy System Instructions For Use at 5 (“To begin aspiration, move the vacuum lever on the Handle to the ‘ON’ position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the ‘OFF’ position.”); Symphony Thrombectomy System Instructions For Use at 8 (same for 16F Symphony Catheter handle).) The ability of the valve of the flow control unit to actuate between an “ON” and “OFF” position is shown for both the 24F and 16F Symphony Catheter handle in the Symphony Thrombectomy System Overview Animation Video.

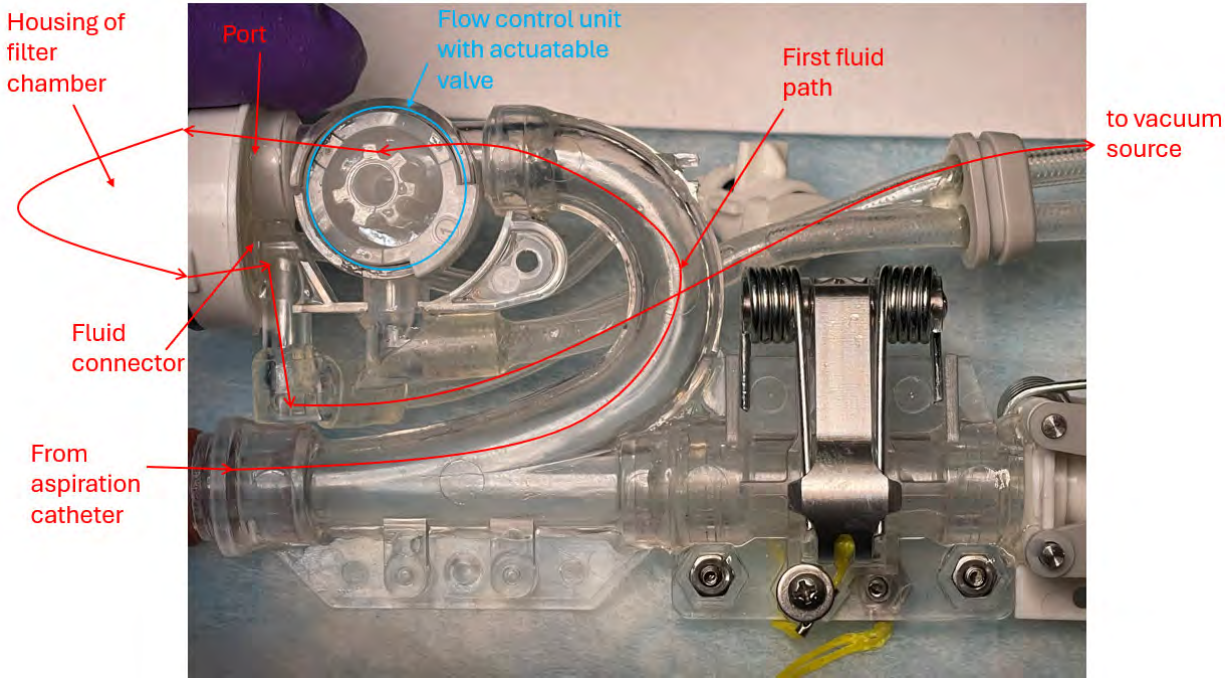
	 (Symphony Thrombectomy System – Overview Animation Video at 0:44.)

	 (Symphony Thrombectomy System – Overview Animation Video at 0:50.)

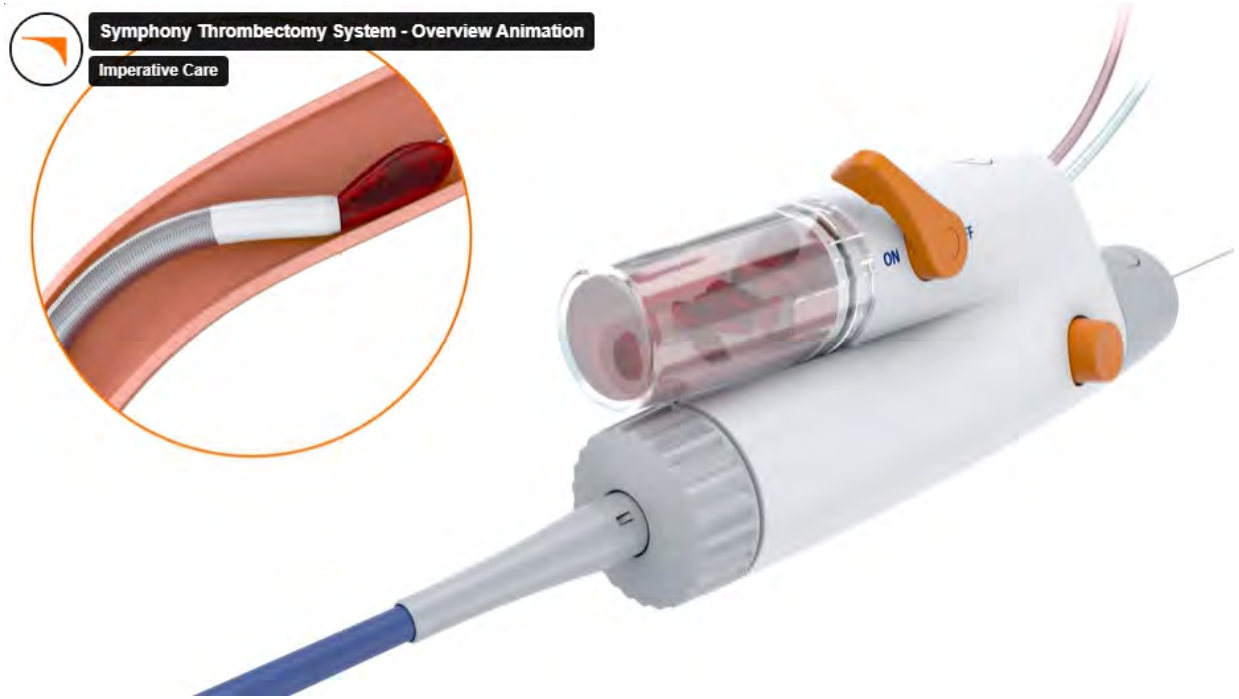
	 (Symphony Thrombectomy System – Overview Animation Video at 1:55.)

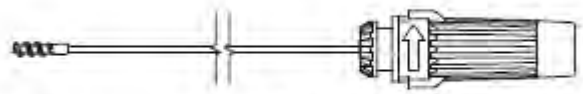
	 (Symphony Thrombectomy System – Overview Animation Video at 2:04.) The Symphony website shows that the valve of the flow control unit is user-actuated.

	 (Image from Truvic at https://www.truvic.com/symphony-product.) The Whipsaw website also confirms that the Symphony is a "handheld tool" that is used by a physician or other medical professional (*e.g.*, a user). (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

[4] The aspiration system of claim 1 wherein the catheter is fluidically coupled in serial to the filter chamber along the first fluid path.	The Symphony System includes a catheter that is fluidically coupled in serial to the filter chamber along the first fluid path. Specifically, the 24F catheter of the 24F Symphony Catheter handle and the 16F catheter of the 16F Symphony Catheter handle are fluidically coupled in serial to the filter chamber along the first filter path, as shown in the annotated teardown image below. The first fluid path starts at the aspiration catheter and runs to the filter chamber, which is serially coupled to the catheter.  (Annotated image of internal portion of controller housing.)

	----------24F Aspiration Catheter---------- The image of the 24F Symphony Catheter handle below shows blood flowing from the aspiration catheter of the 24F Symphony Catheter handle to the filter chamber via the first fluid path (annotated above) when the vacuum lever is in the "ON" position, which demonstrates that the catheter and filter chamber are fluidically coupled. (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) **----------16F Aspiration Catheter----------** The image of the 16F Symphony Catheter handle below shows blood flowing from the aspiration catheter of the 16F Symphony Catheter handle to the filter chamber via the first fluid path (annotated above) when the vacuum lever is in the "ON"

	position, which demonstrates that the catheter and filter chamber are fluidically coupled.  (Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[5] The aspiration system of claim 1, further comprising the interventional device.	The Symphony System can include an interventional device. Specifically, the Symphony System can include the 24F or 16F ProHelix device, which is an interventional device shown in the Symphony System IFU below.



(Symphony Thrombectomy System Instructions For Use at 1.)

The Symphony System IFU shows that a 24F or 16F Symphony ProHelix device (*e.g.*, an interventional device) is inserted through the hemostasis valve and catheter to reach a clot within the human patient.

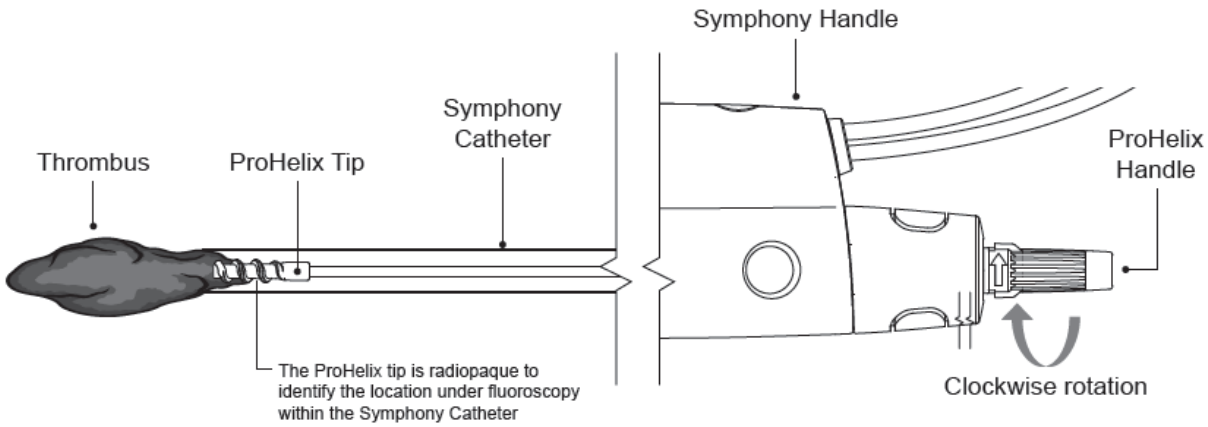


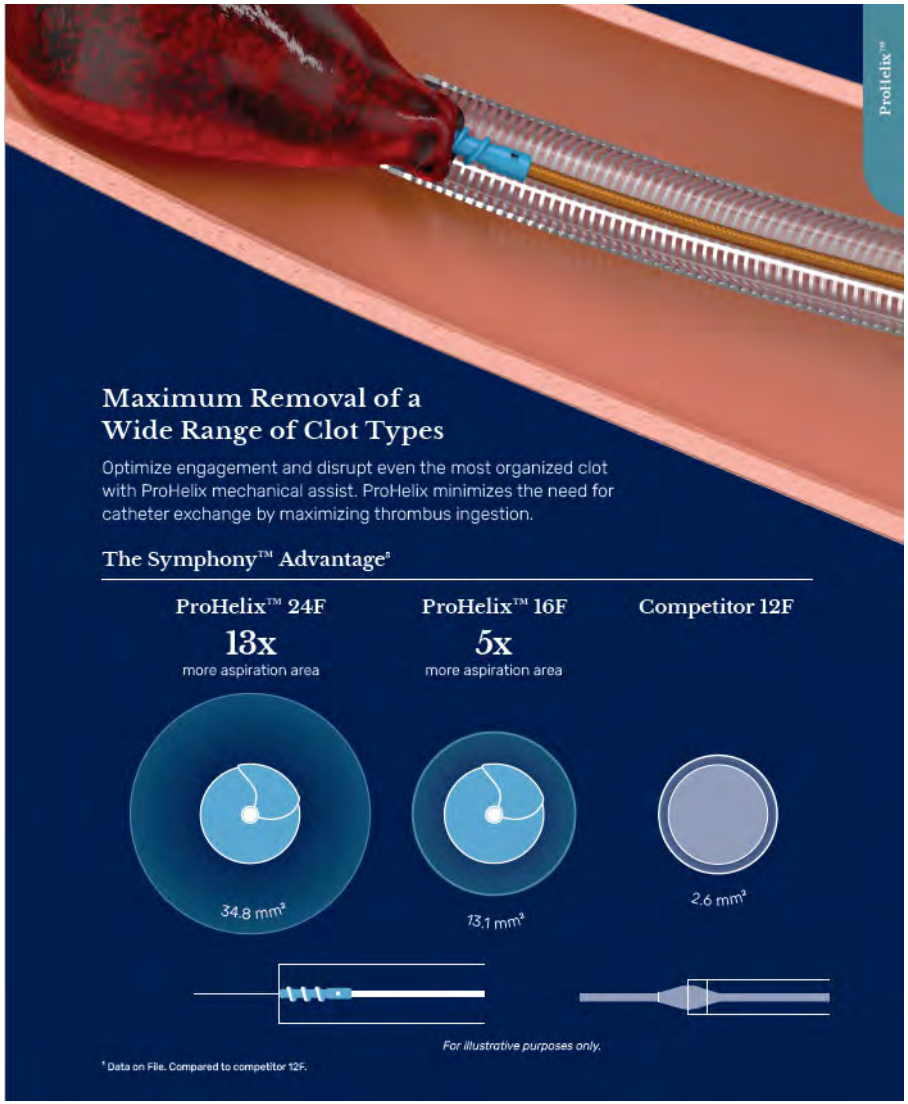
Figure 4: ProHelix engaged with thrombus

(Symphony Thrombectomy System Instructions For Use at 5.)

The Symphony System IFU describes the interventional nature of the ProHelix device and how it is inserted through the hemostasis valve and into the catheter.

	(Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony ProHelix device may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter."); Symphony Thrombectomy System Instructions For Use at 1 ("As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter."); Symphony Thrombectomy System Instructions For Use at 5 ("Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle. To begin aspiration, move the vacuum lever on the Handle to the 'ON' position. Slowly rotate the ProHelix handle as indicated by the arrow (clockwise direction). Upon feeling resistance to rotation, slowly retract the spring-loaded ProHelix handle up to 1 cm while rotating to assist with aspiration and removal of the thrombus."); Symphony Thrombectomy System Instructions For Use at 8-9 (same for 16F Symphony Catheter handle); Symphony Thrombectomy System Instructions For Use at 5 ("When aspiration is complete, depress the Retention Clip buttons on the Handle and withdraw the ProHelix approximately 1 cm from the Catheter. Then press the Hemostasis Valve buttons on the Handle to reduce friction while withdrawing the ProHelix from the Catheter completely. Ensure the Hemostasis Valve buttons are completely depressed when pulling the ProHelix tip through the Valve.").) The Symphony Thrombectomy System Brochure describes how the Symphony ProHelix (*e.g.*, an interventional device) can be used to extract clot material. (Symphony Thrombectomy System Brochure at 9 ("Optimize engagement and

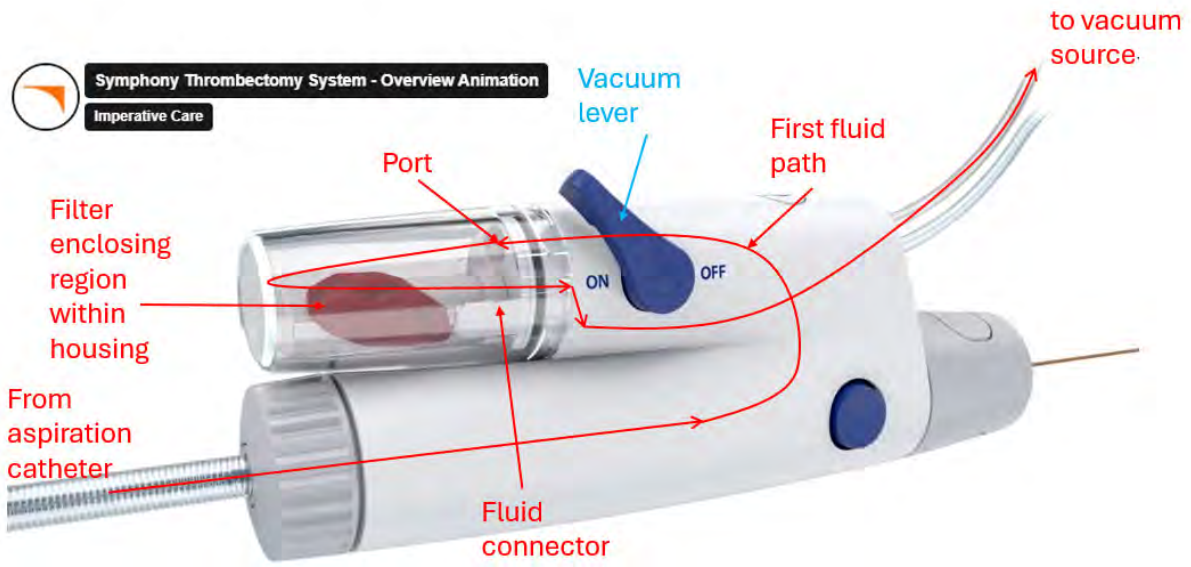
	disrupt even the most organized clot with ProHelix mechanical assist. ProHelix minimizes the need for catheter exchange by maximizing thrombus ingestion.”).)

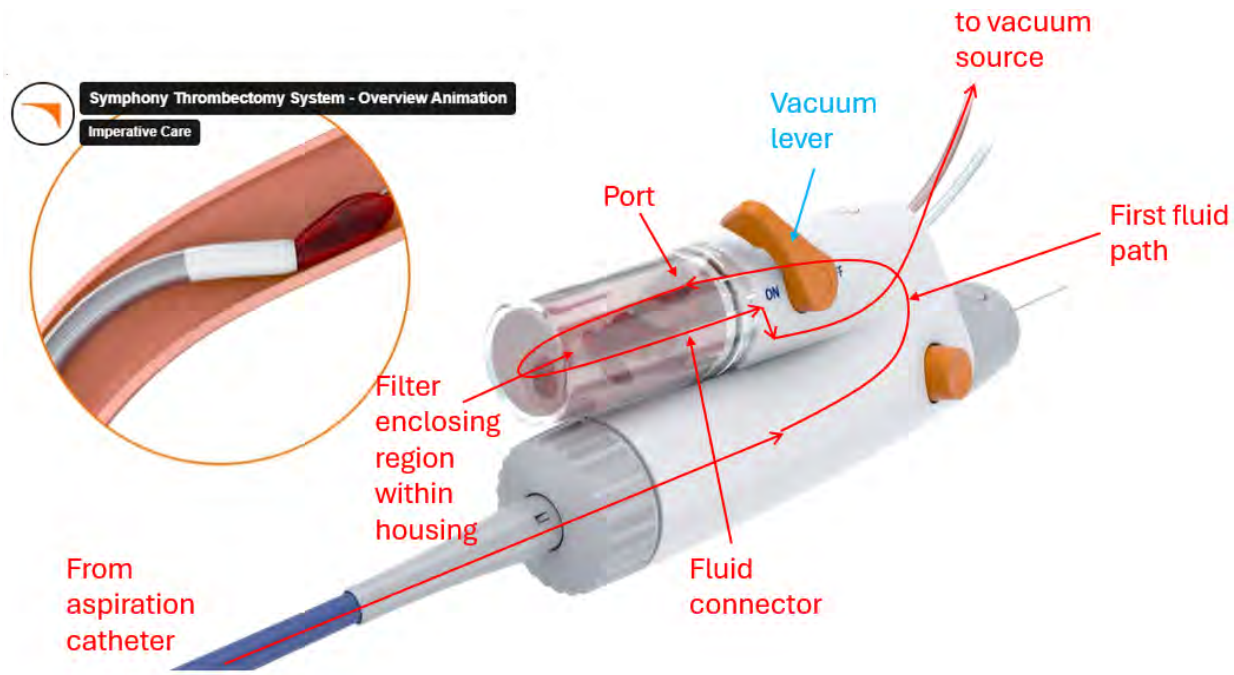


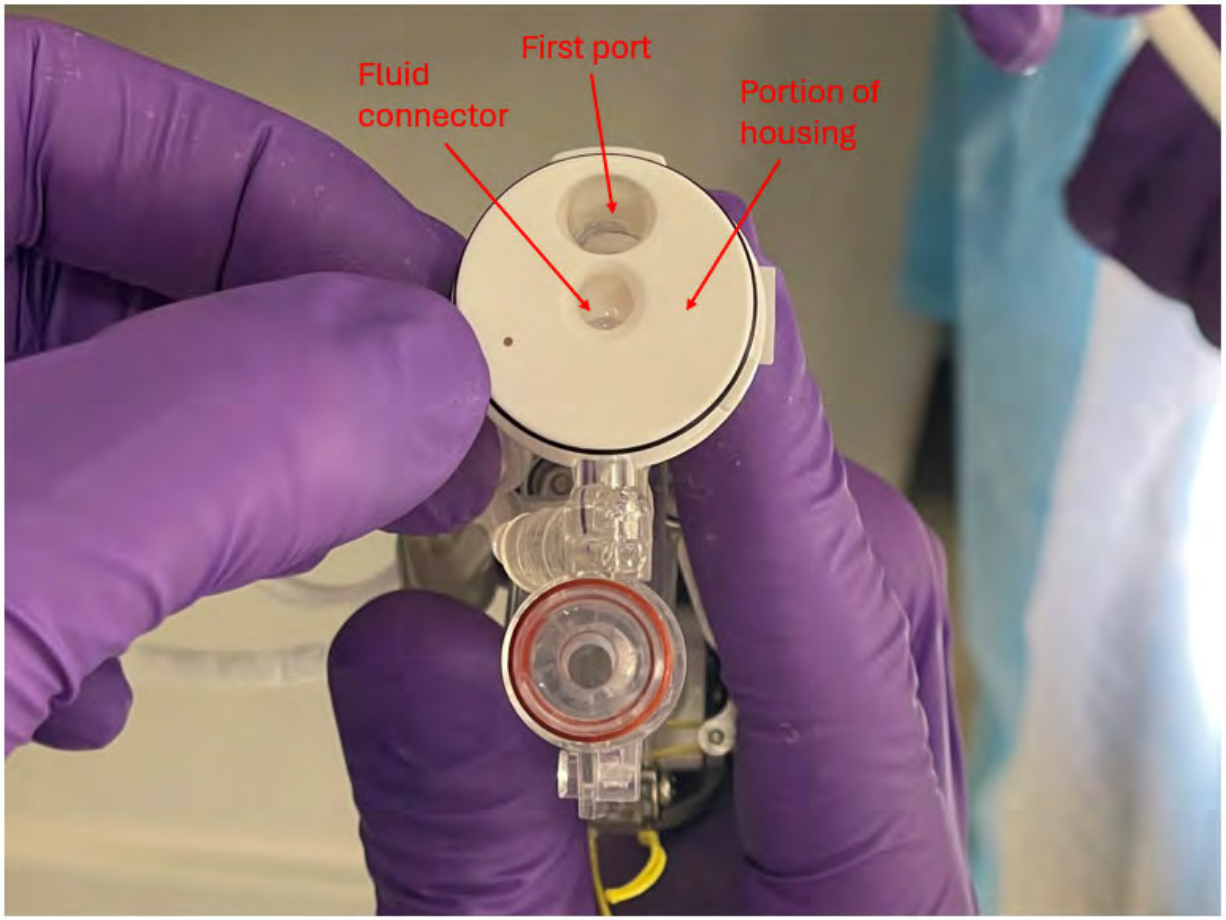
	(Symphony Thrombectomy System Brochure at 9.) (Symphony Thrombectomy System Brochure at 8.)

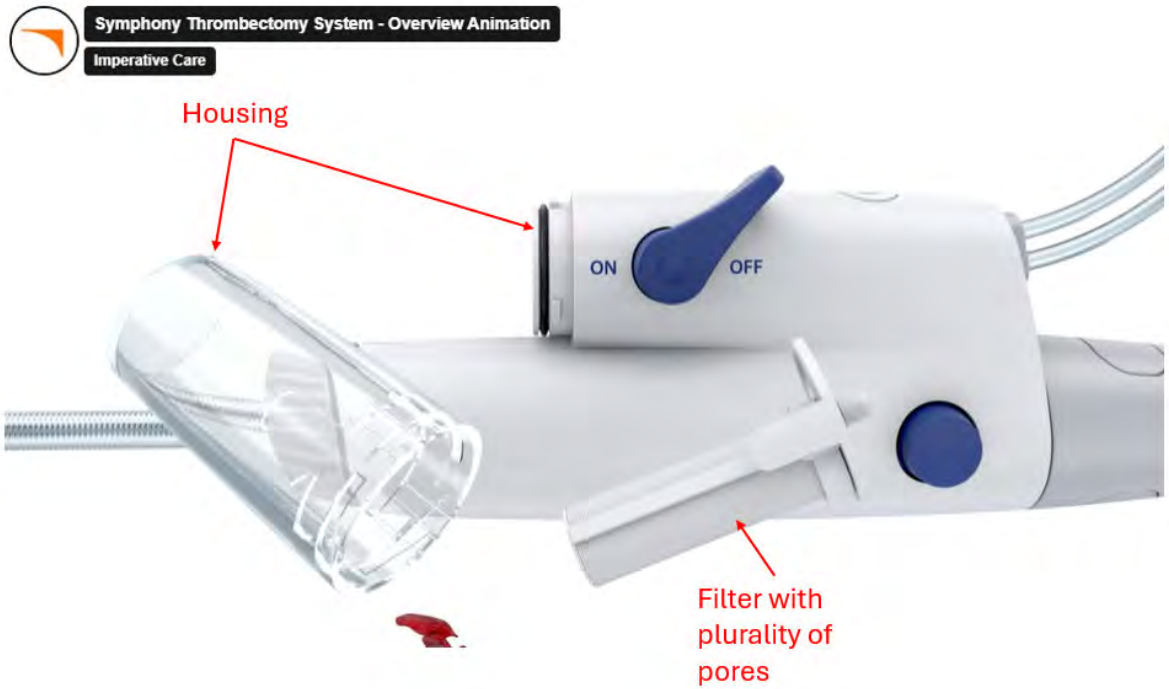
	To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[8] The aspiration system of claim 1 wherein the filter is removable from within the housing.	The Symphony System includes a filter that is removable from within the housing. Specifically, the filter of the 24F and/or 16F Symphony Catheter handle of the Symphony System is removable from within the housing, as shown in the Symphony Thrombectomy System Overview Animation Video, a screenshot of which is reproduced below.

	(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.) Whipsaw's website shows that the filter of the Symphony Catheter handle is removable from within the housing. (Annotated image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[10] The aspiration system of claim 1 wherein the filter encloses a region within the housing, wherein	The Symphony System include a filter that encloses a region within the housing and where the fluid connector is proximal to the enclosed region along the first

the fluid connector is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.	fluid path and where the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough. Specifically, the 24F and 16F Symphony Catheter handle includes a filter that encloses a region within the housing. As shown in the annotated images below, the fluid connector is proximal to the enclosed region along the first fluid path.  (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

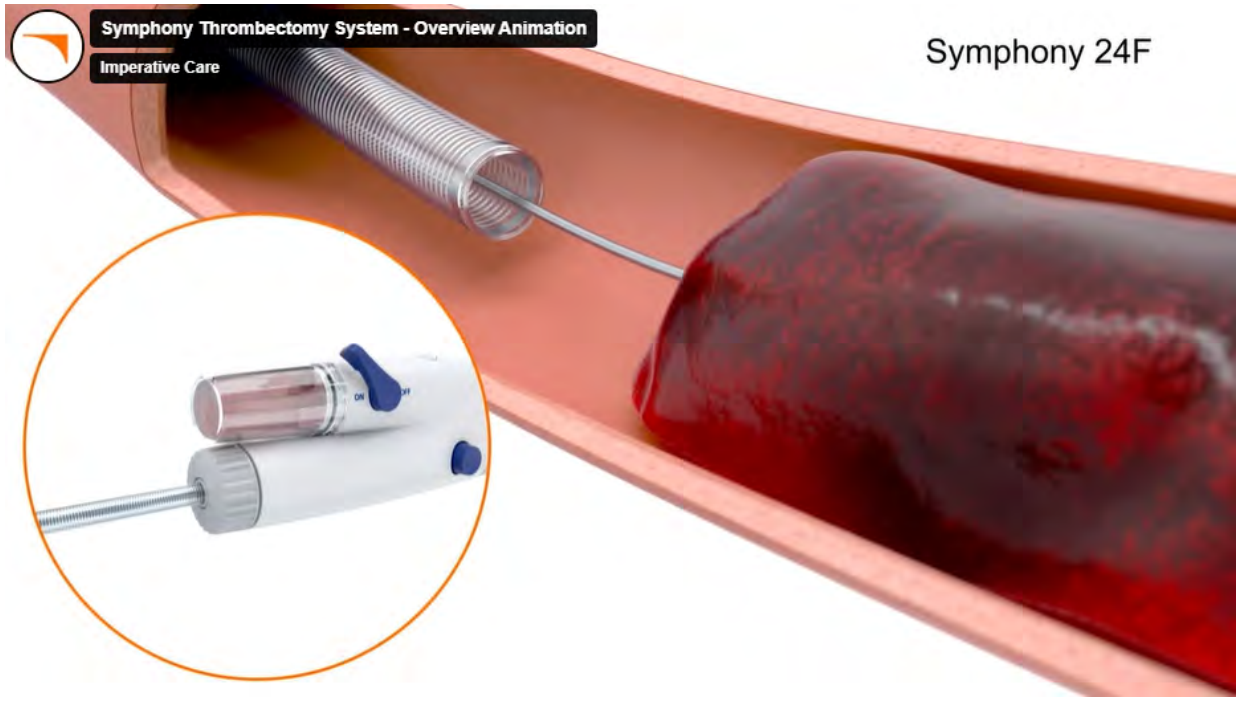
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

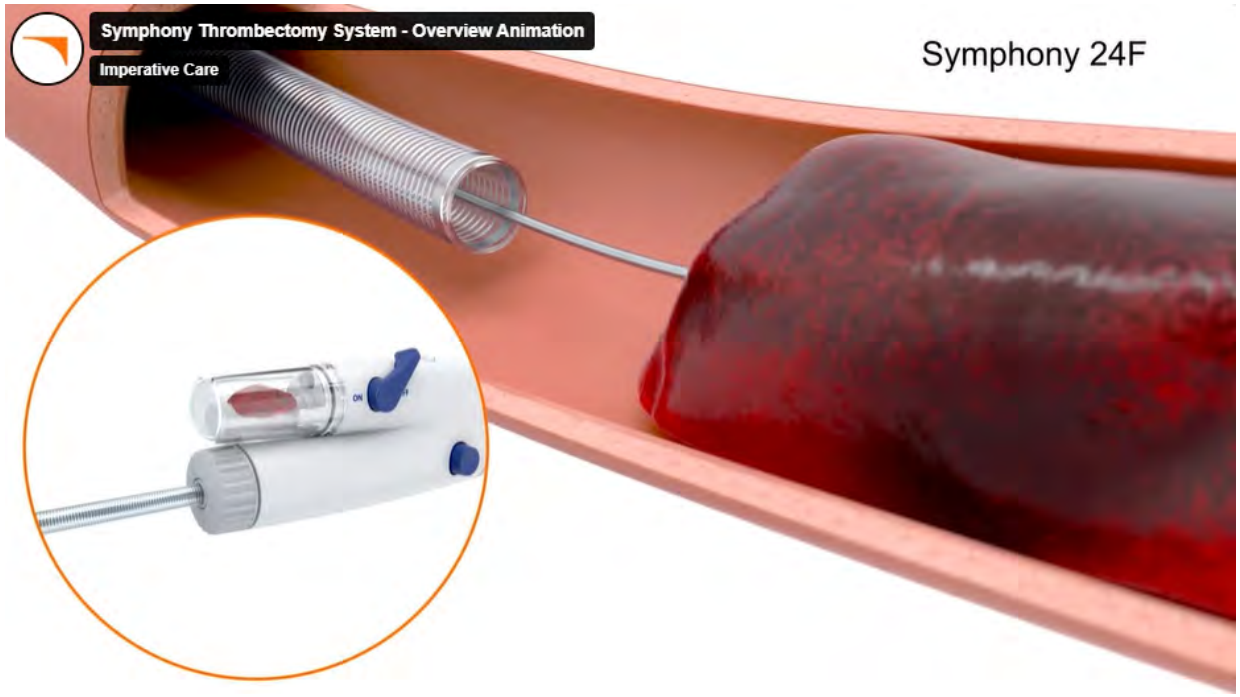
	 (Annotated image of controller housing showing port and fluid connector.) As shown in the annotated image below, the filter of the 24F and 16F Symphony Catheter handle includes a plurality of pores that are sized to inhibit clot material from flowing therethrough.

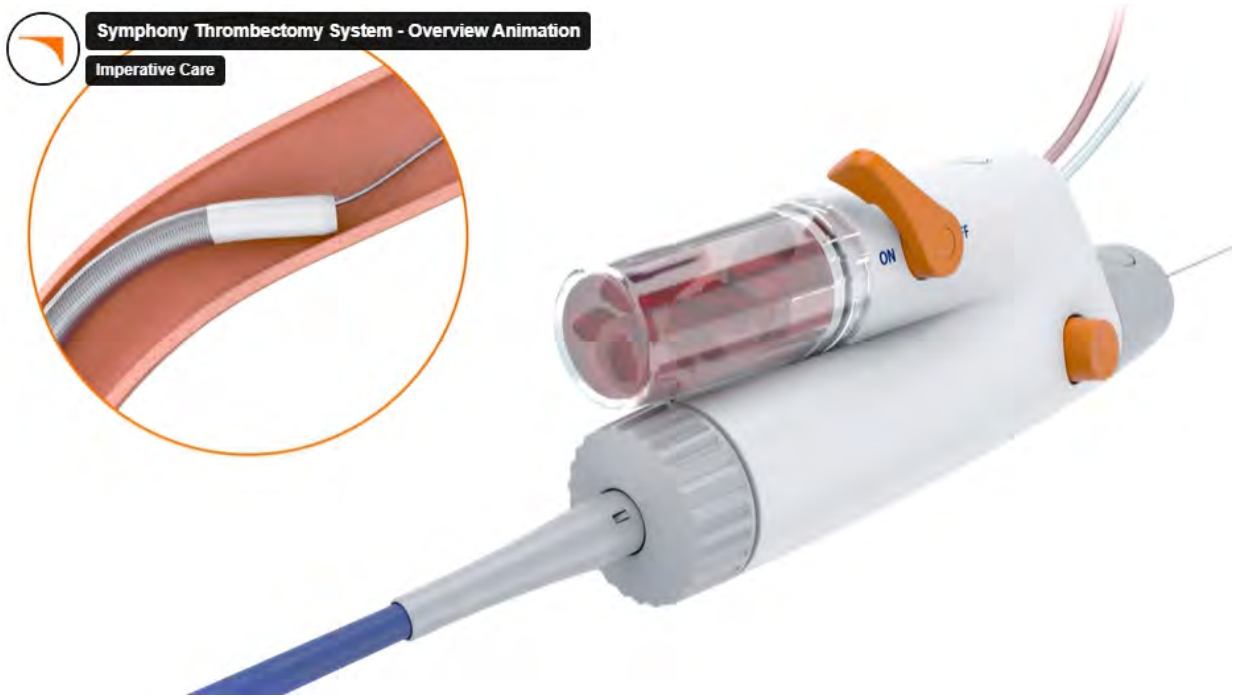


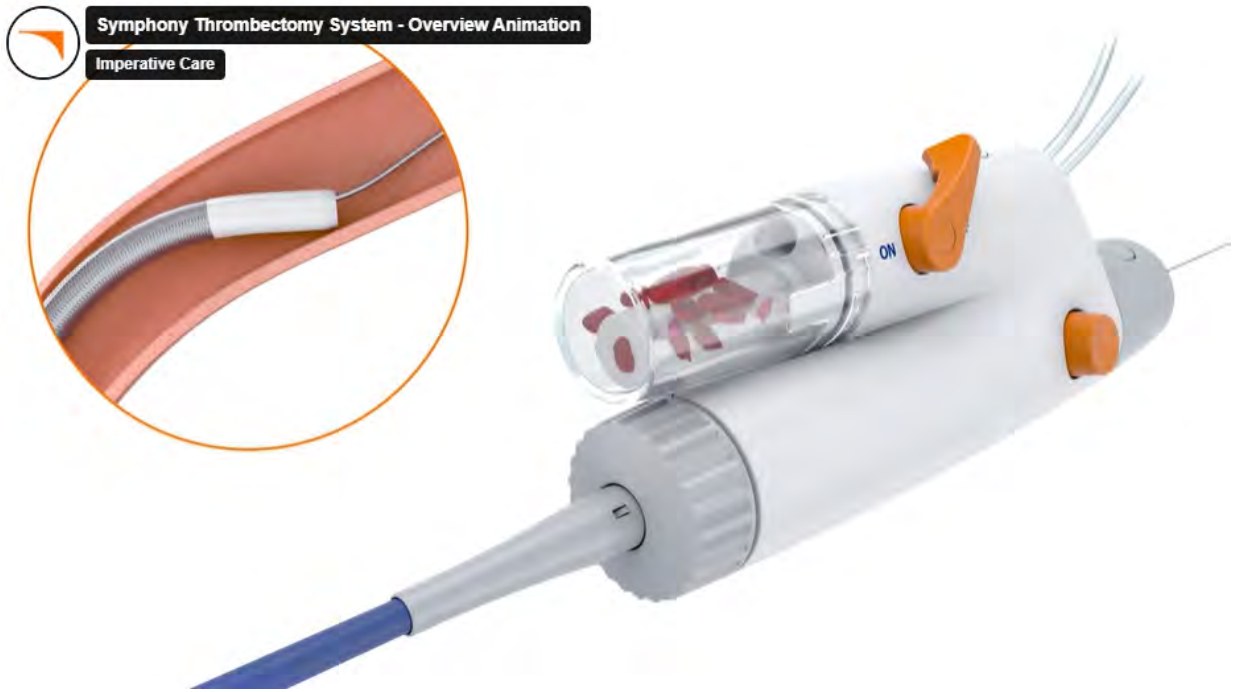
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

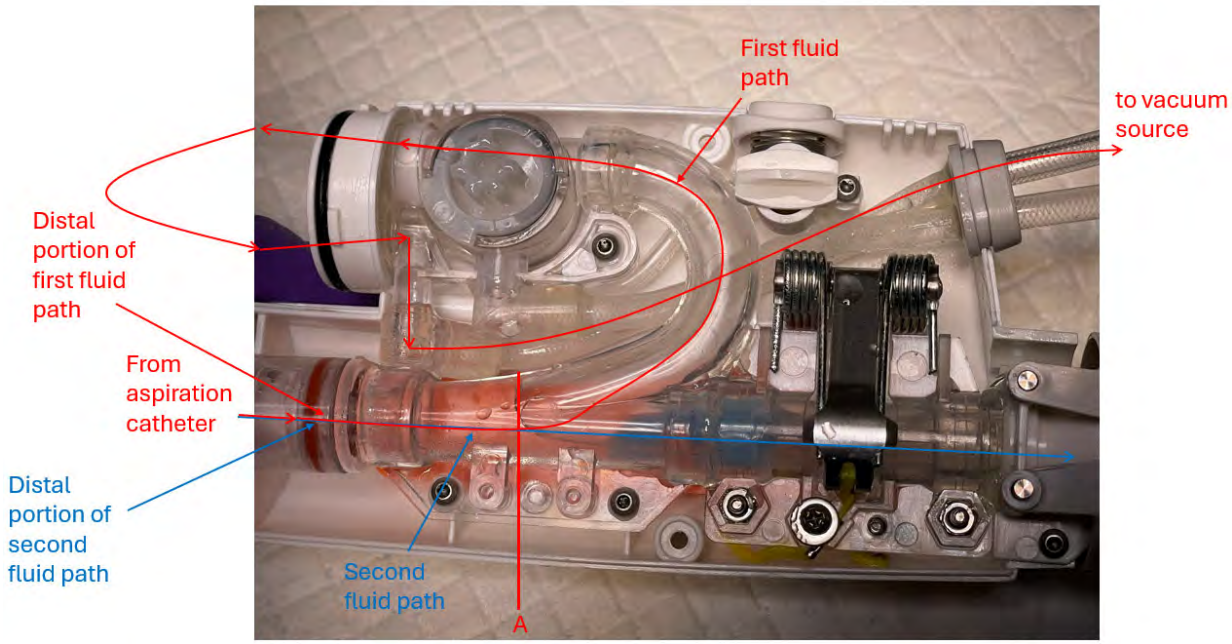
As shown the images from the Symphony Thrombectomy System Overview Animation Video, the plurality of pores of the filter permit blood to flow through the filter but inhibit clot material from flowing through the filter. Specifically, clot material and blood enter the filter chamber from the aspiration catheter and blood subsequently is filtered and exits the filter chamber leaving the clot material within the chamber.

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

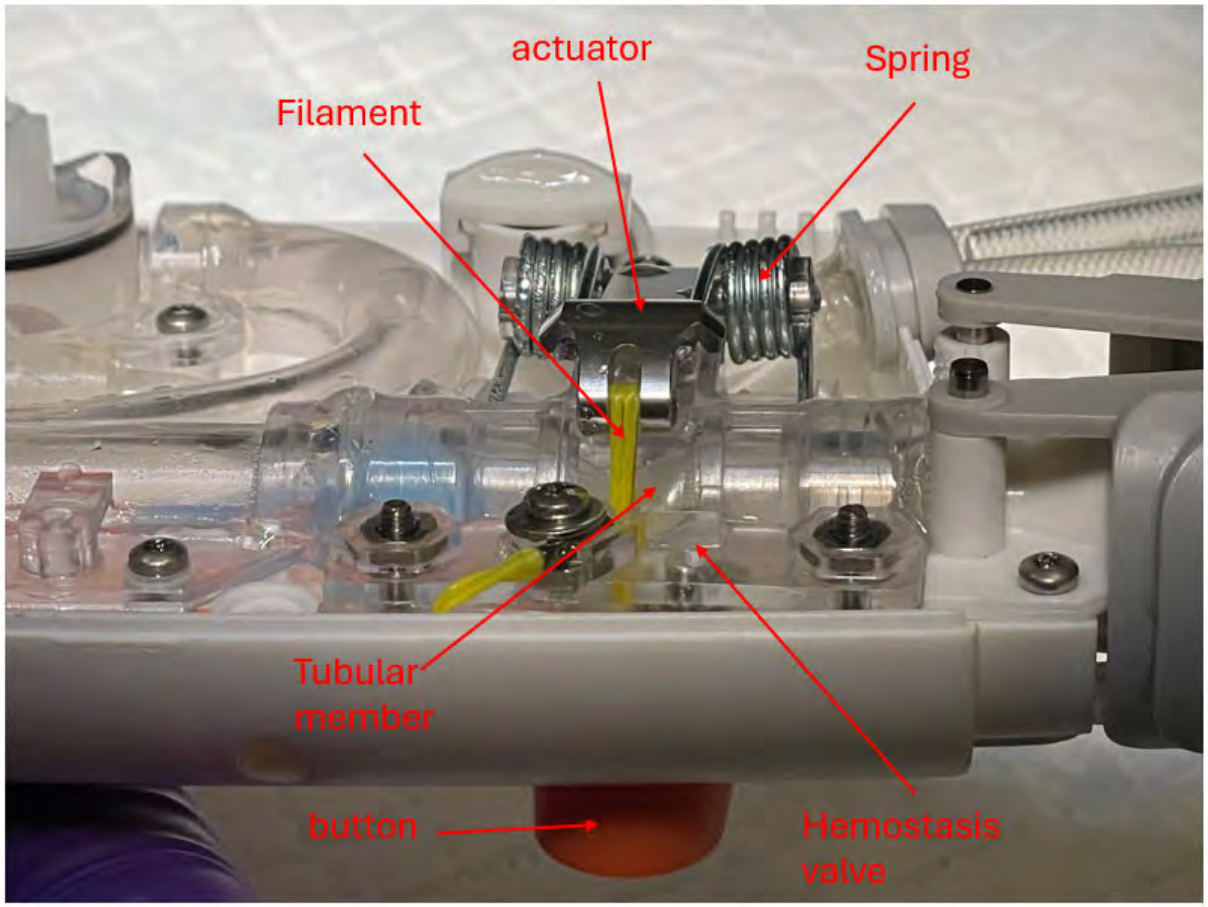
	 (Symphony Thrombectomy System – Overview Animation Video at 0:50.)

	 (Symphony Thrombectomy System – Overview Animation Video at 2:04.)

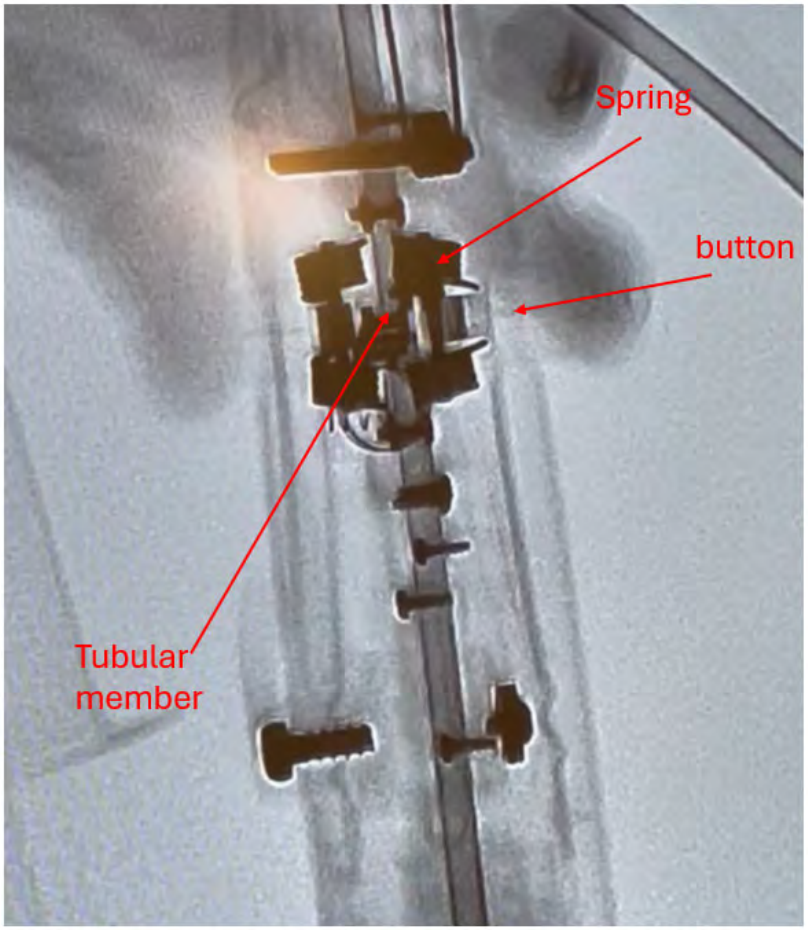
	 (Symphony Thrombectomy System – Overview Animation Video at 2:05.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[11] The aspiration system of claim 1 wherein the distal portion of the first fluid path and a distal portion of the second fluid path overlap.	The Symphony System includes a first and second fluid path where the distal portion of the first fluid path and the distal portion of the second fluid path overlap. Specifically, in the 24F and 16F Symphony Catheter handle of the Symphony System, the distal portion of the first fluid path and distal portion of the second

	fluid path (*e.g.*, the portion of each fluid path extending from the aspiration catheter to approximately point A) overlap, as shown in the annotated image below.  (Annotated image of internal portion of controller housing.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[12] The aspiration system of claim 1 wherein—the hemostasis valve comprises a tubular member, a button, a spring coupled to the button, and a filament coupled to	The Symphony System includes a hemostasis valve that comprises a tubular member, a button, a spring coupled to the button, and a filament coupled to the button and the tubular member.

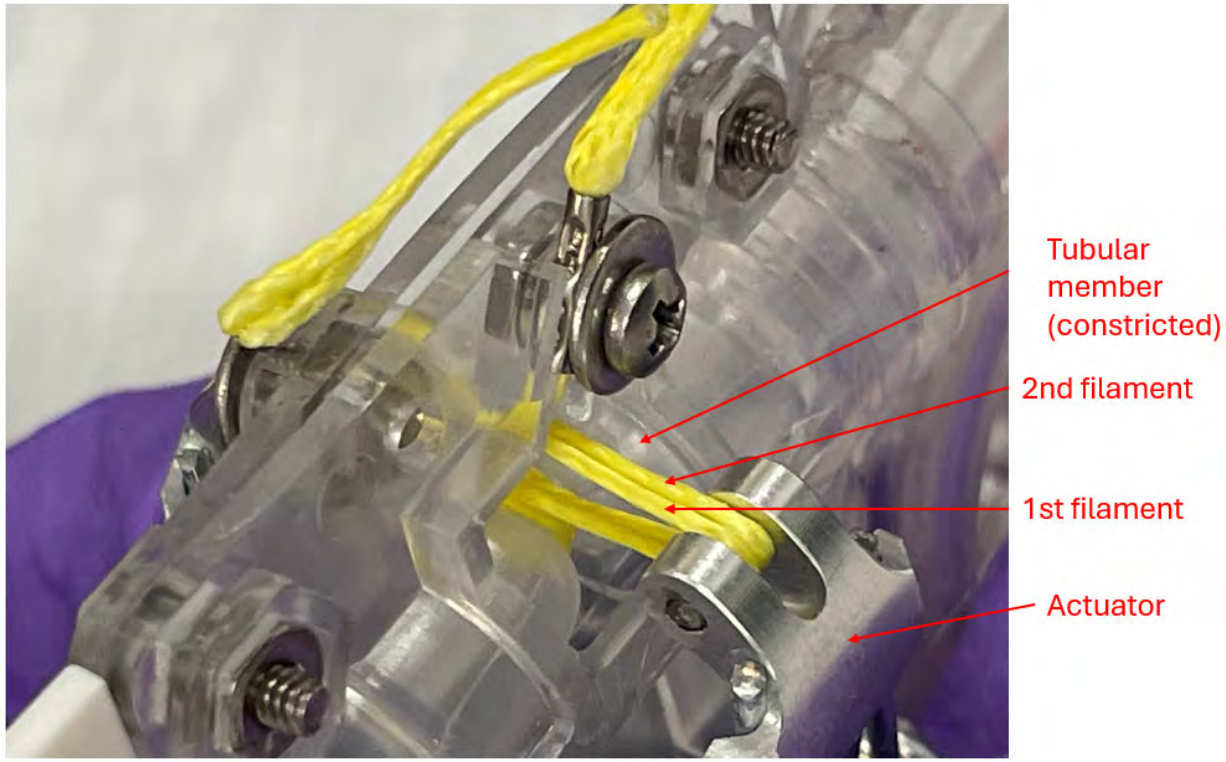
the button and the tubular member,	Specifically, the hemostasis valve of the 24F and 16F Symphony Catheter handle is comprised of a tubular (elongate) member, two buttons, torsion springs, and two filaments, coupled to the button via levers/pins depressed by the buttons and to the tubular member (the filaments are wrapped around the tubular member). The hemostasis has an actuator with a first member and a second member operated by buttons on the side of the 24F and 16F Symphony Catheter handles. The actuator mechanism includes a first button that pushes against a first lever on one side of the tubular member and a second button that pushes against a second lever on the other side of the tubular member. The levers and the buttons are driven outwardly by first torsion spring(s) and second torsion spring(s) (there are two per lever). The hemostasis valve also has first and second filaments. Each filament loops around the tubular sidewall and has a first end passing over a first pin at the end of a first lever and a second end passing over a second pin at the end of the second lever. In operation, the torsion springs drive the levers outward such that the pins tension the filaments and constrict the collapsible tubular member. Pressing the buttons pushes the levers inward, which releases tension in the filaments to allow the tubular member to expand.



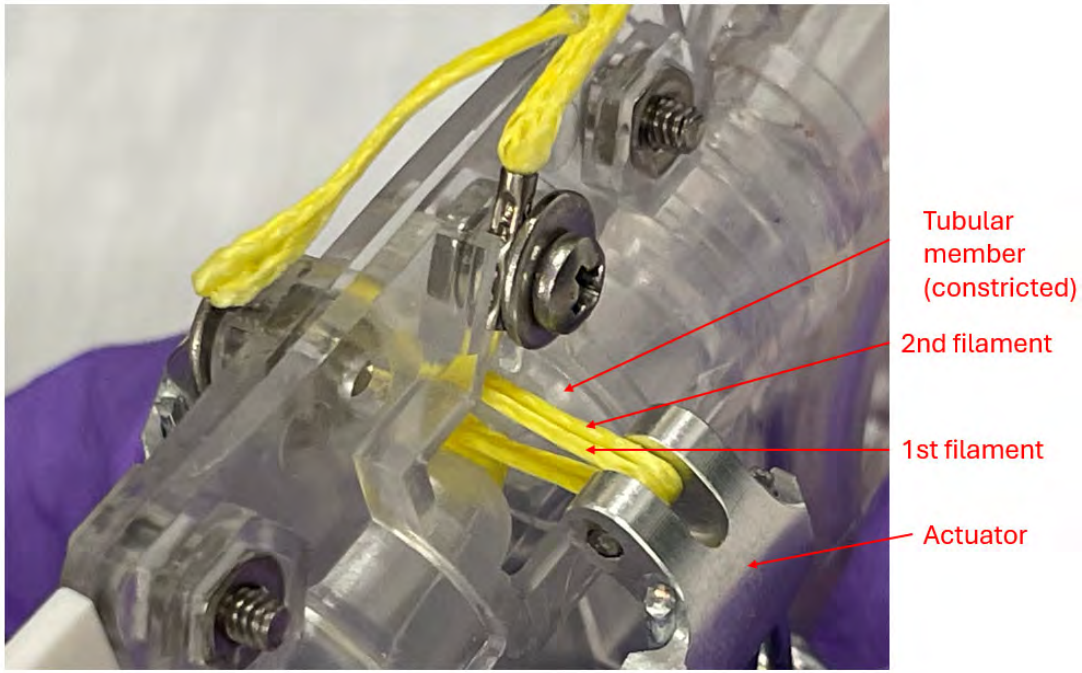
(Annotated image of internal portion of controller housing, showing hemostasis valve.)



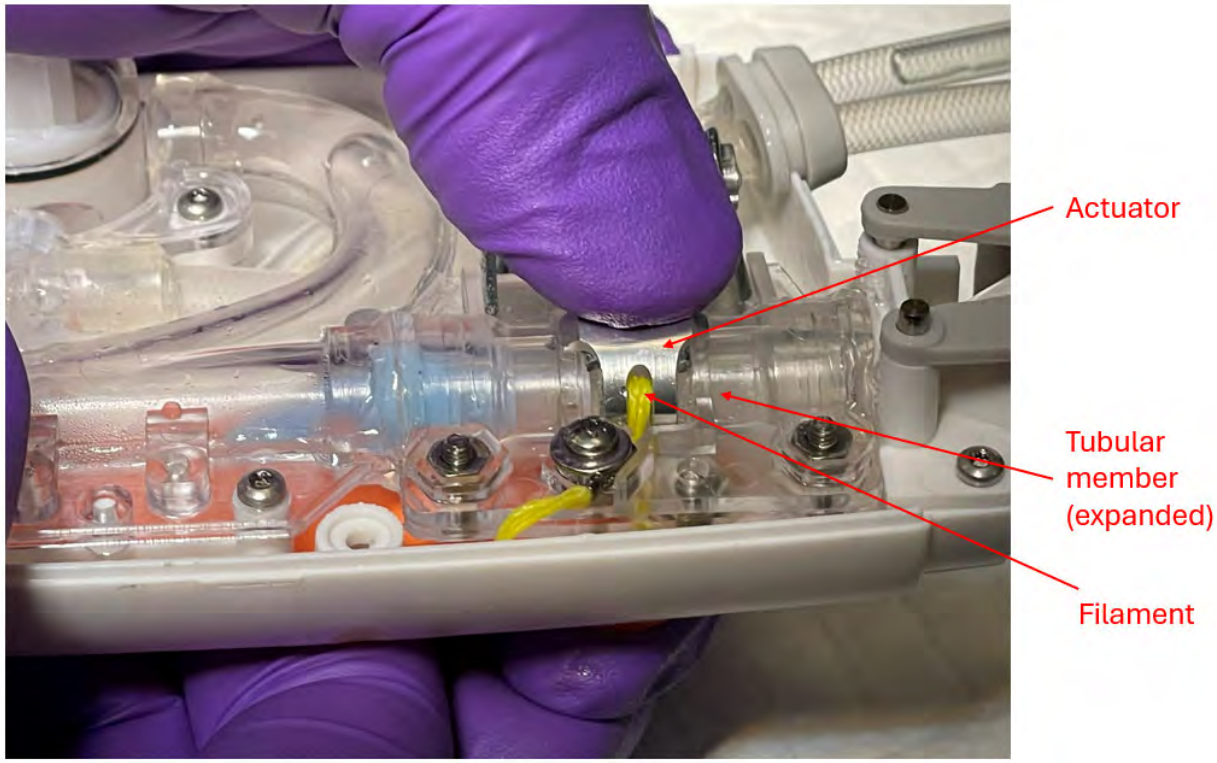
(Annotated x-ray imaging of housing, showing button, torsion spring, and tubular member.)

	 (Annotated image of internal portion of controller housing, showing hemostasis valve.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
the button is configured to be actuated from a first position to a second position to loosen the	The Symphony System includes a hemostasis valve with a pair of buttons, where each button is configured to be actuated from a first position (undepressed button position – tubular member constricted) to a second position (depressed button

filament to allow the tubular member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve,	position – tubular member unconstricted) to loosen the filaments, allowing the tubular member to expand to unseal the hemostasis valve. With the hemostasis valve unsealed, an interventional device can be inserted through the hemostasis valve. Specifically, the hemostasis valve has an actuator with a first member and a second member operated by buttons on the side of the 24F and 16F Symphony Catheter handles. The actuator mechanism includes a first button that pushes against a first lever on one side of the tubular member and a second button that pushes against a second lever on the other side of the tubular member. The levers and the buttons are driven outwardly by first torsion spring(s) and second torsion spring(s) (there are two per lever). The hemostasis valve also has first and second filaments. Each filament loops around the tubular sidewall and has a first end passing over a first pin at the end of the first lever and a second end passing over a second pin at the end of the second lever. In operation, in the first (buttons undepressed) position, the torsion springs drive the levers outward such that the pins tension the filaments and constrict the collapsible tubular member. Depressing the buttons (second position) pushes the levers inward, which releases tension in the filaments to allow the tubular member to expand.

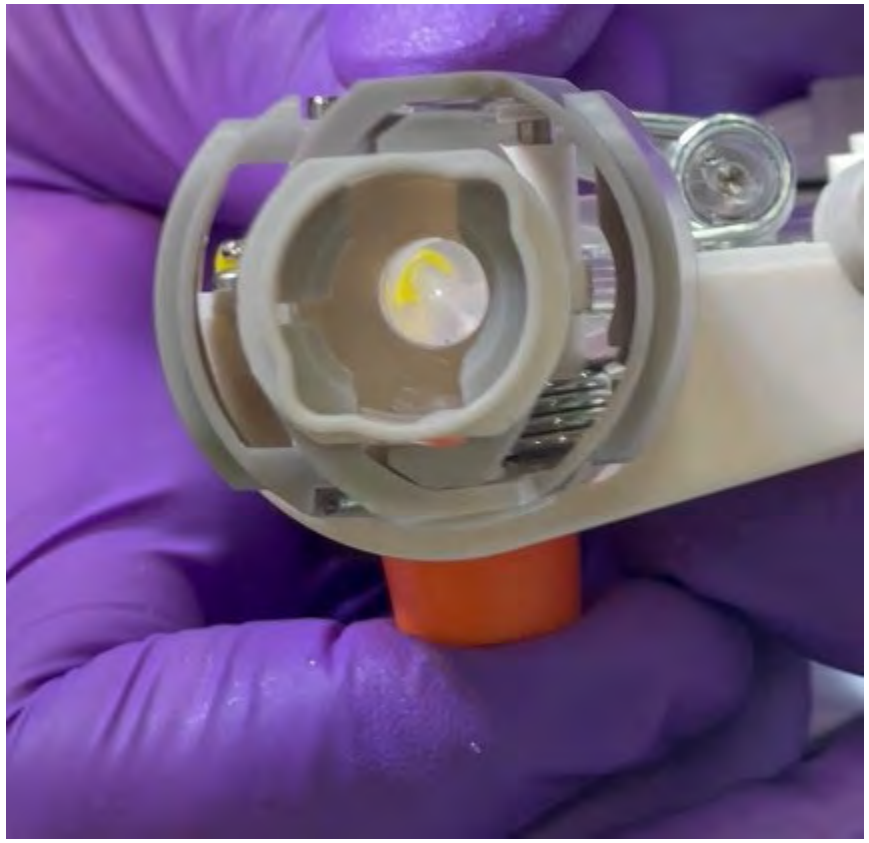


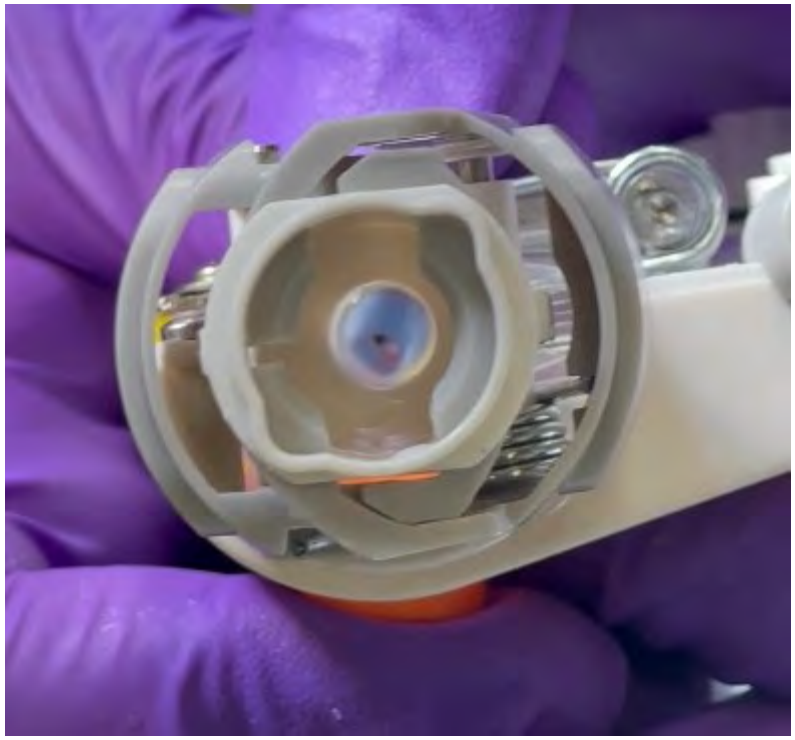
(Annotated image of internal portion of controller housing, showing hemostasis valve.)

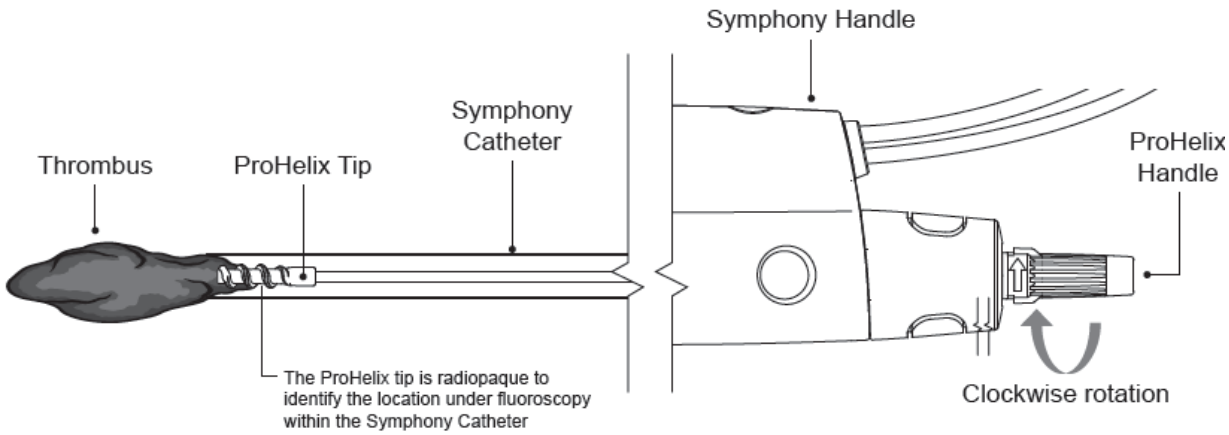


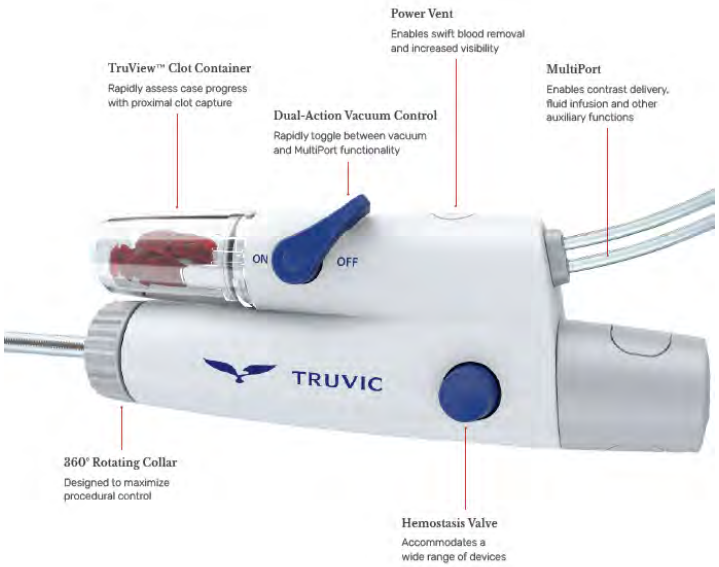
(Annotated image of internal portion of controller housing, showing hemostasis valve.)

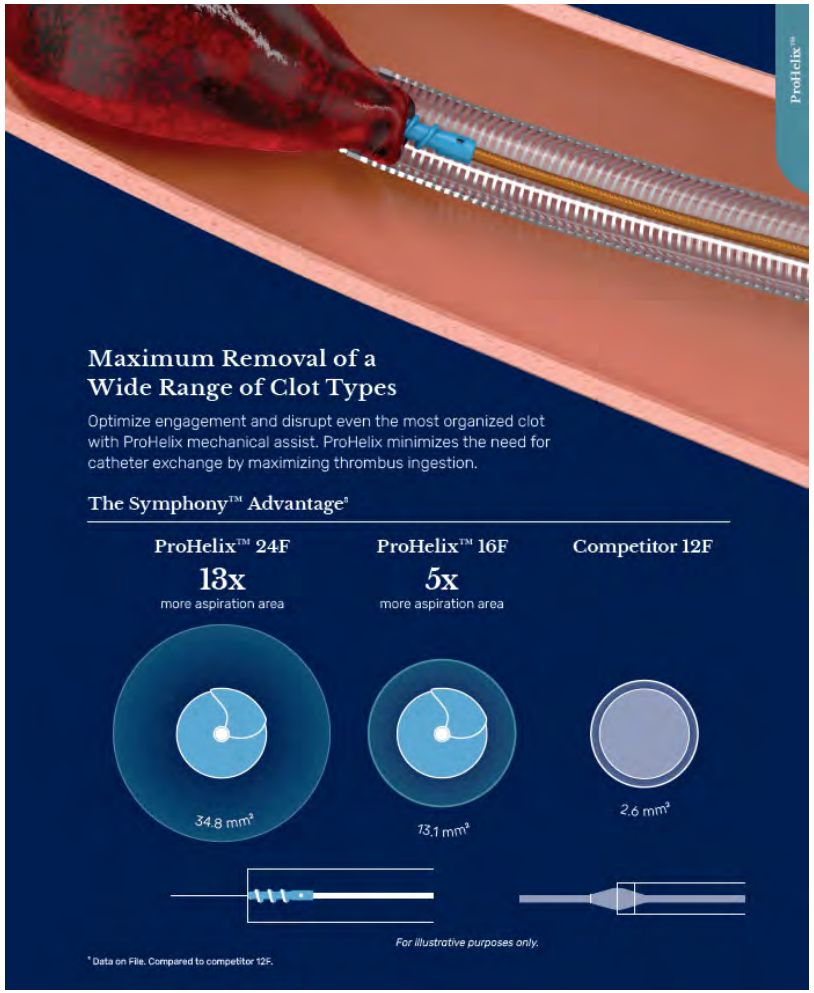
When the buttons of the 24F and 16F Symphony Catheter handle are depressed (second position), the tubular member moves from a closed position (due to constriction by the filaments) to an open position as shown in the images below.

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

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) The Symphony System IFU also describes that a user must actuate the hemostasis valve buttons to open the hemostasis valve and allow for insertion of a device (*e.g.*, an interventional device, such as the 24F or 16F Symphony ProHelix). (Symphony Thrombectomy System Instructions For Use at 2 ("Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the

	Hemostasis Valve may damage the valve or the device.”); Symphony Thrombectomy System Instructions For Use at 4 (“Press the Hemostasis buttons to open the hemostasis valve and insert the Dilator through the open Hemostasis Valve of the Handle.”); Symphony Thrombectomy System Instructions For Use at 6 (“When aspiration is complete, depress the Retention Clip buttons on the Handle and withdraw the ProHelix approximately 1 cm from the Catheter. Then press the Hemostasis Valve buttons on the Handle to reduce friction while withdrawing the ProHelix from the Catheter completely. Ensure the Hemostasis Valve buttons are completely depressed when pulling the ProHelix tip through the Valve.”).) Expansion of the hemostasis valve allows an interventional device, such as the 24F or 16F ProHelix to be inserted, as shown in Figure 4 of the Symphony System IFU, reproduced below.  **Figure 4: ProHelix engaged with thrombus** (Symphony Thrombectomy System Instructions For Use at 5.)

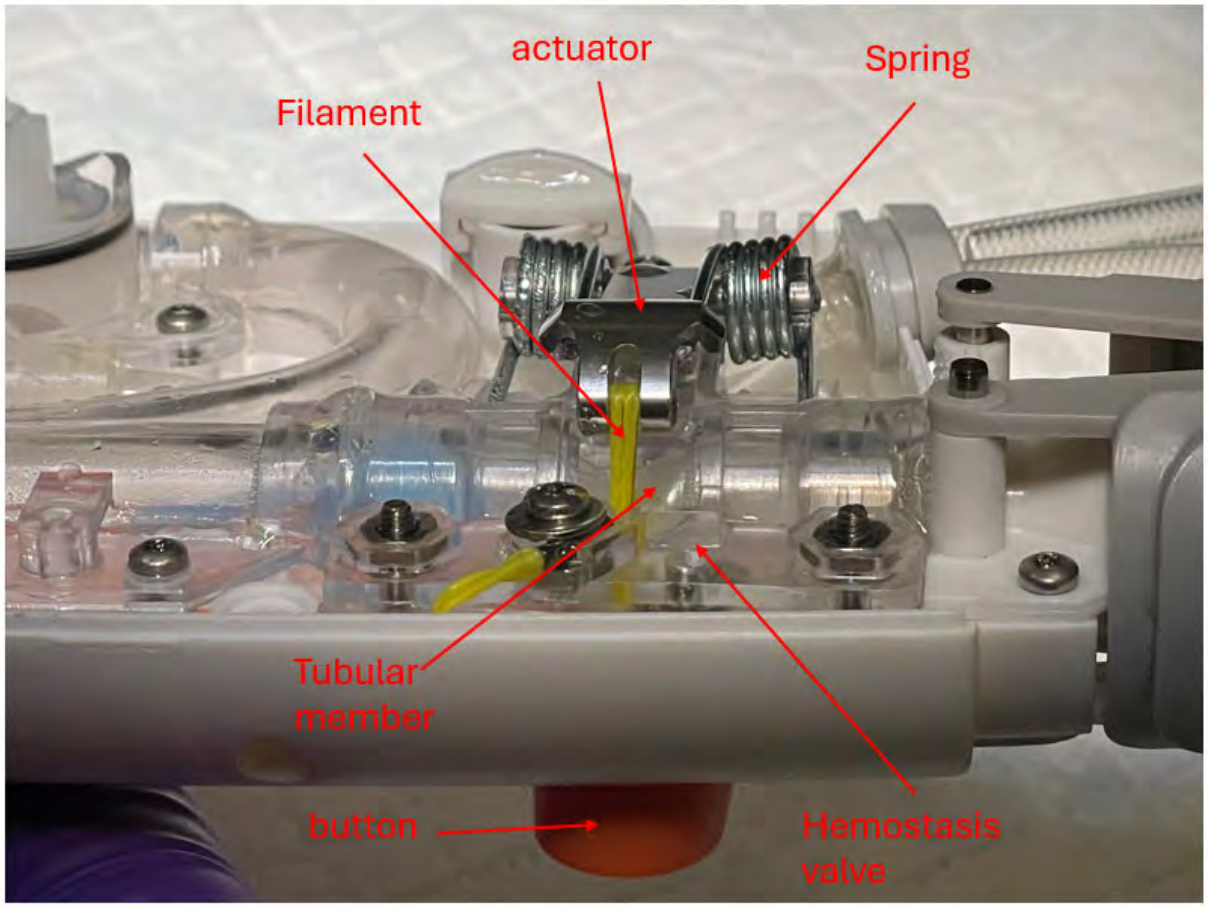
	The Symphony Thrombectomy System Brochure also depicts the ProHelix as an interventional device and the Symphony Catheter handle with hemostasis valve buttons that allow for the hemostasis valve to "[a]ccomodate[] a wide range of devices." SYMPHONY® THROMBECTOMY SYSTEM **High-Powered, Continuous Vacuum with Real-Time Case Assessment** **BigShot™ Controller**  (Symphony Thrombectomy System Brochure at 6.)



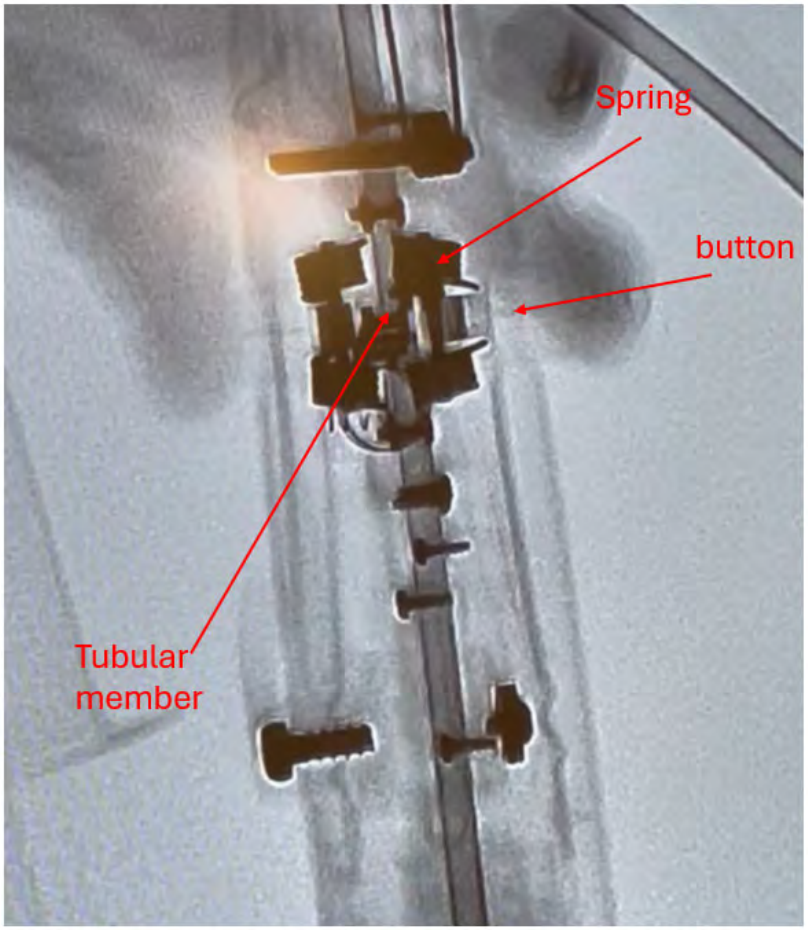
(Symphony Thrombectomy System Brochure at 9.)

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

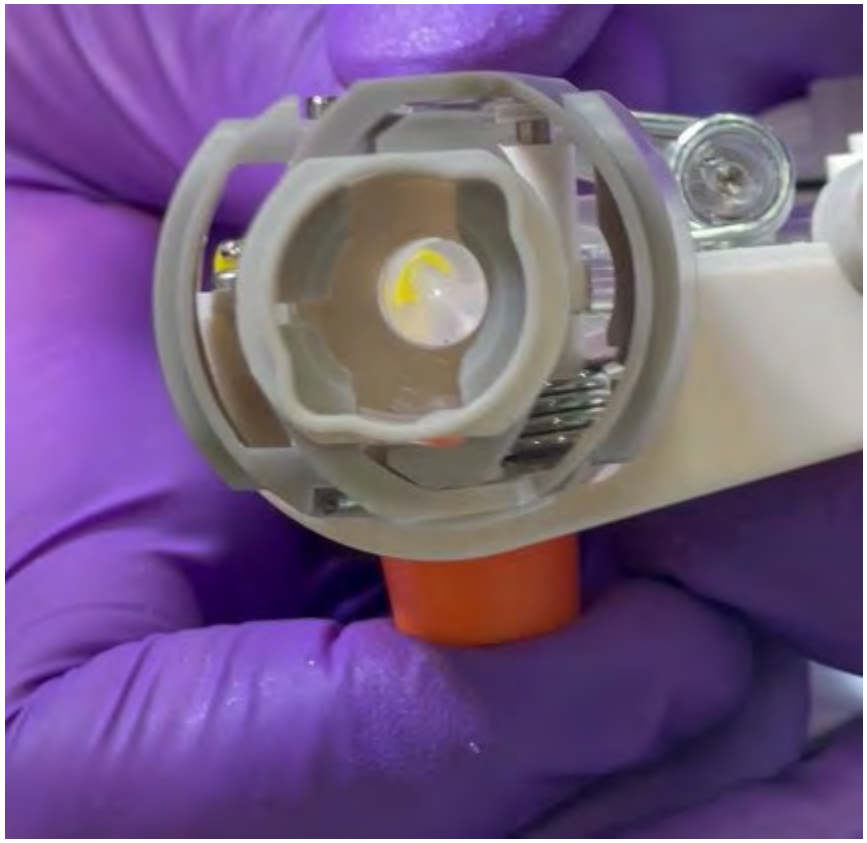
and the spring is configured to bias the button to the first position.	The Symphony System includes a hemostasis valve further comprises a spring configured to bias the button to a first position. Specifically, the hemostasis valve has an actuator with a first member and a second member operated by buttons on the side of the 24F and 16F Symphony Catheter handles. The actuator mechanism includes a first button that pushes against a first lever on one side of the tubular member and a second button that pushes against a second lever on the other side of the tubular member. The levers and the buttons are driven outwardly by first torsion spring(s) and second torsion spring(s) (there are two per lever). Particularly, in the biased position (e.g., first position – buttons undepressed), the springs drive the first and second members outward, reducing the diameter of the valve lumen by pulling the filaments to reduce the diameter of the looped portions of the filaments to constrict the tubular sidewall defining the valve lumen.

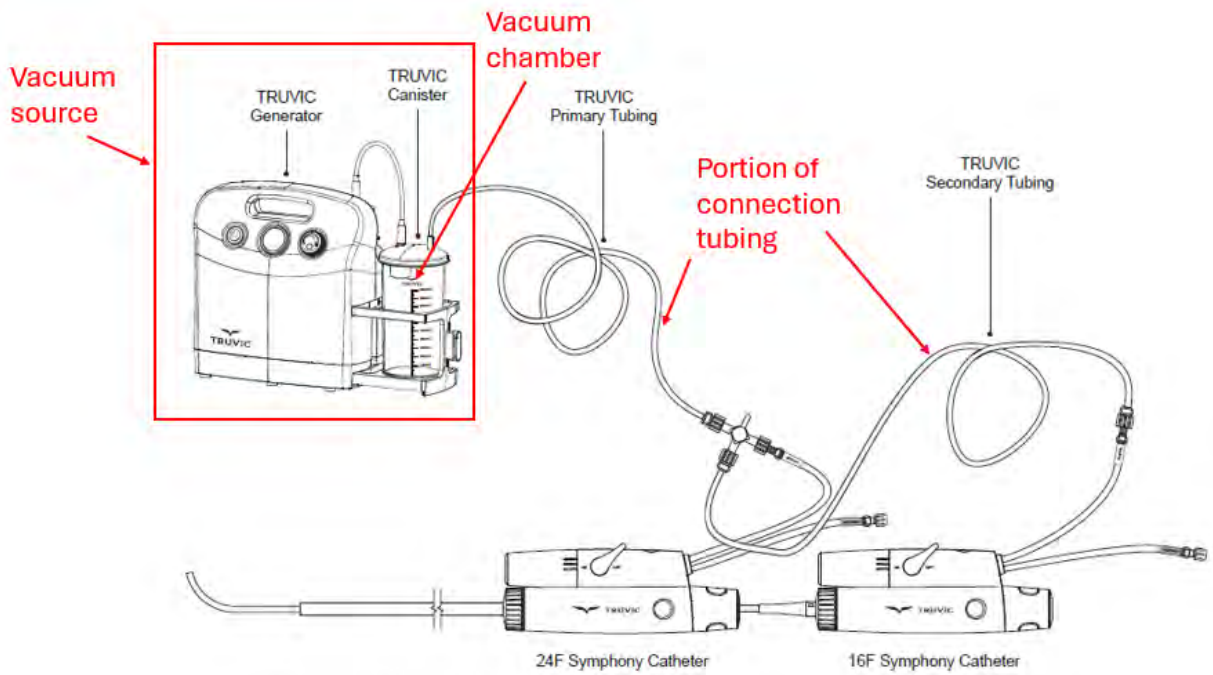


(Annotated image of internal portion of controller housing, showing hemostasis valve.)



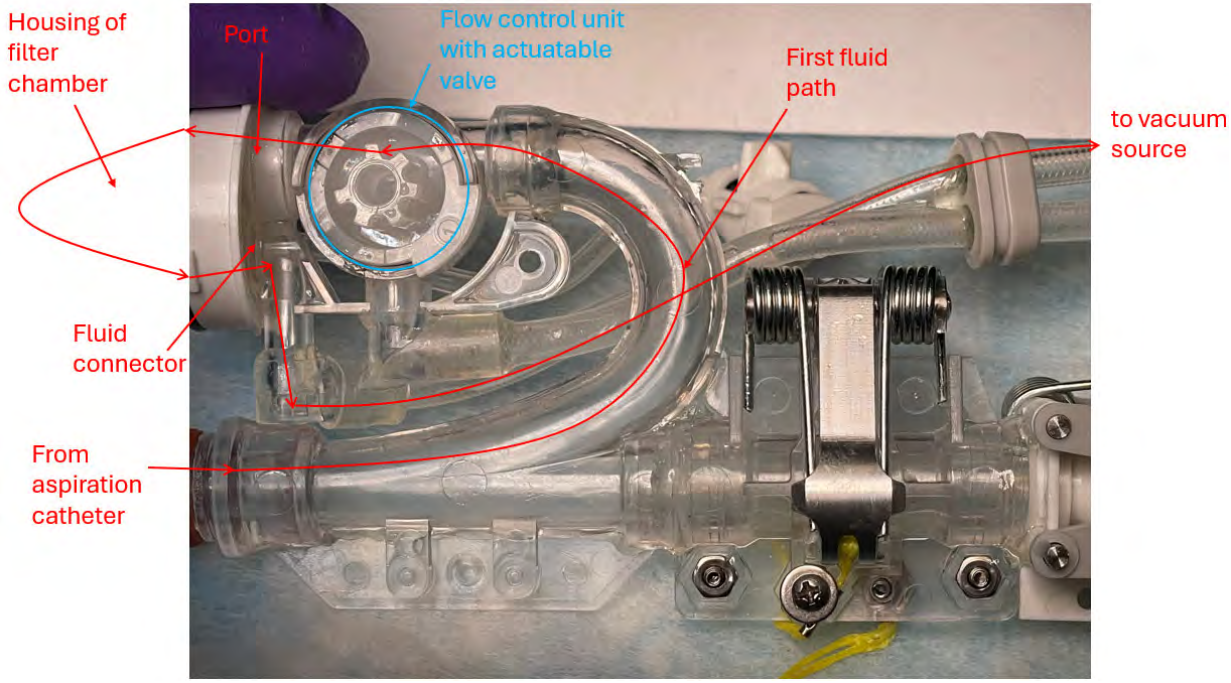
(Annotated x-ray imaging of housing, showing button, torsion spring, and tubular member.)

	 (Symphony handle with view down lumen of hemostasis valve with valve constricted.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[14] The aspiration system of claim 1 wherein the vacuum source	The Symphony System includes a vacuum source that comprises a vacuum chamber, where the connection tubing is fluidically coupled to the vacuum chamber

comprises a vacuum chamber, wherein the connection tubing is fluidically coupled to the vacuum chamber, and wherein the catheter is fluidically coupled to the vacuum chamber via the filter chamber along the first fluid path.	and where the catheter is fluidically coupled to the vacuum chamber via the filter chamber along the first fluid path. Specifically, the Truvic Generator and Truvic Canister (*e.g.*, vacuum source) comprise a vacuum chamber in the form of the Truvic Canister's container, which is connected to the Truvic primary tubing (for the 24F or 16F Symphony Catheter handle) and secondary tubing (for the 16F Symphony Catheter handle), both of which are a portion of the connection tubing, as shown in annotated Figure 6 of the Symphony System IFU below.  **Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister**

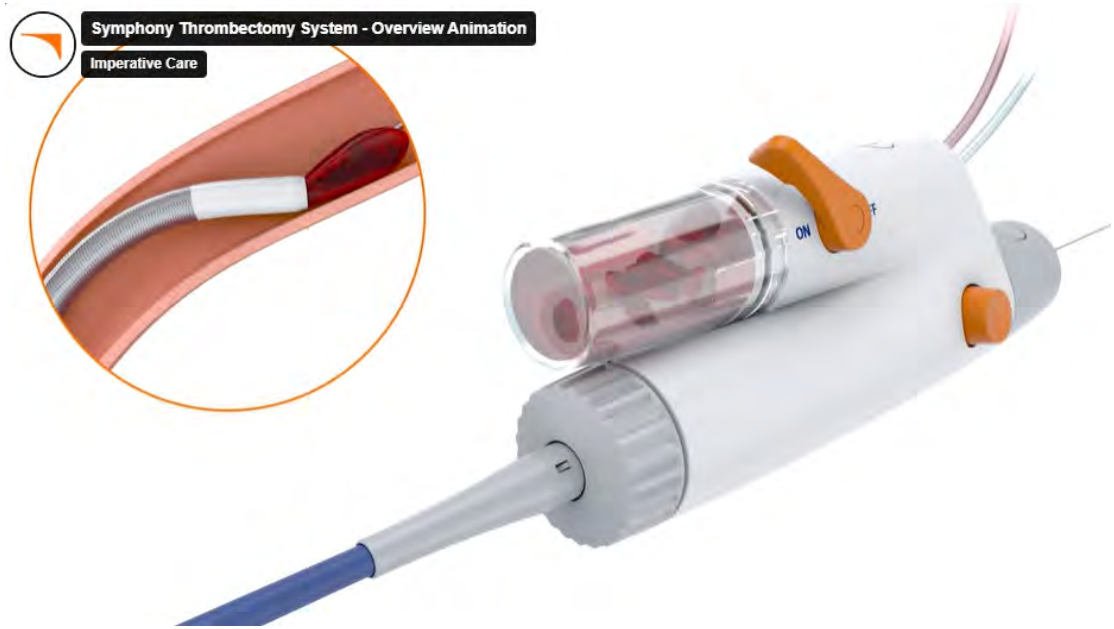
(Annotated Symphony Thrombectomy System Instructions For Use at 8.)

The catheter is fluidically coupled to the vacuum chamber via the filter chamber along the first fluid path. Specifically, blood and clot material from the human patient follow the first fluid path within the Symphony Catheter handle to the filter chamber as shown in the teardown image below. Blood is filtered and exits the filter chamber through the fluid connector and flows through the connection tubing to the Truvic Canister.

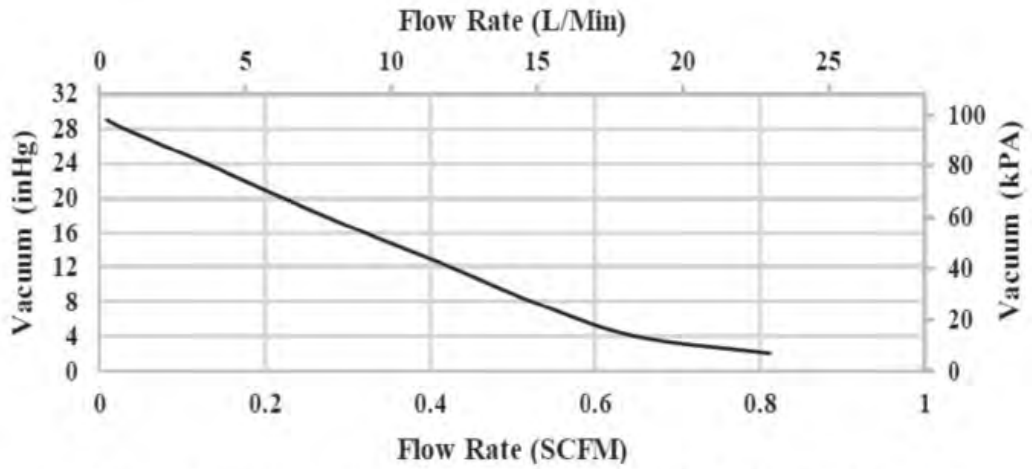


(Annotated image of internal portion of controller housing.)

	----------24F Aspiration Catheter---------- The image of the 24F Symphony Catheter handle below, which shows blood flowing from the aspiration catheter, along the first fluid path, into the filter chamber, out of the filter chamber and to the Truvic Canister via the connection tubing, confirms that the catheter is fluidically coupled to the vacuum chamber via the filter chamber of the first fluid path. (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) The Symphony System IFU confirms that the catheter is fluidically coupled to the vacuum chamber via the filter chamber of the first fluid path. (Symphony Thrombectomy System Instructions For Use at 5 ("To begin aspiration, move the vacuum lever on the Handle to the 'ON' position. When unrestricted blood flow

	through the clot container and into the canister is observed, move the lever on the Handle to the 'OFF' position.").) **----------16F Aspiration Catheter----------** The image of the 16F Symphony Catheter handle below, which shows blood flowing from the aspiration catheter, along the first fluid path, into the filter chamber, out of the filter chamber and to the Truvic Canister via the connection tubing, confirms that the catheter is fluidically coupled to the vacuum chamber via the filter chamber of the first fluid path.  (Symphony Thrombectomy System – Overview Animation at 2:02.)

	The Symphony System IFU confirms that the catheter is fluidically coupled to the vacuum chamber via the filter chamber of the first fluid path. (Symphony Thrombectomy System Instructions For Use at 8 ("To begin aspiration, move the vacuum lever on the 16F Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the 16F Handle to the 'OFF' position.").) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[15] An aspiration system, comprising:	The Symphony System is an aspiration system for treating blood clots in the vasculature of a patient. The Symphony System is system that provides "[p]owerful, [f]ocused [a]spiration to "[m]aximize thrombus removal with high-powered, on-demand continuous aspiration and in-hand TruView™ clot capture." (Symphony Thrombectomy System Brochure at 2.) It is "designed to remove thrombus/embolus … from the vasculature using controlled aspiration." (Symphony Thrombectomy System Instructions For Use at 1.). The Symphony System IFU also discloses that "[t]he Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. The Symphony ProHelix may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter." (Symphony Thrombectomy System Instructions For Use at 1; *see also* Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister to aspirate thrombus.").)

	Truvic includes a video on its website (https://www.truvic.com/symphony-product) detailing a method of using the Symphony System to treat clot material within a blood vessel of a human patient by aspiring clot material to remove thrombus.
a vacuum source;	The Symphony System includes a vacuum source. Specifically, the 24F and 16F Symphony Thrombectomy Catheters are verified for use with the Truvic Generator and Truvic Canister, which, together, is an example of a vacuum source. (Symphony Thrombectomy System Instructions For Use at 2.) The Symphony IFU discloses that "[t]he TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve" shown below. (Symphony Thrombectomy System Instructions For Use at 2.)  Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

	(Symphony Thrombectomy System Instructions For Use at 2.) The IFU depicts the Truvic Generator and Truvic Canister (*e.g.*, a vacuum source) connected to the 24F Symphony Catheter and/or 16F Symphony Catheter and includes instructions on how to turn on the Generator so that it can be used as a vacuum source for aspiration. (Symphony Thrombectomy System Instructions For Use at 8.)

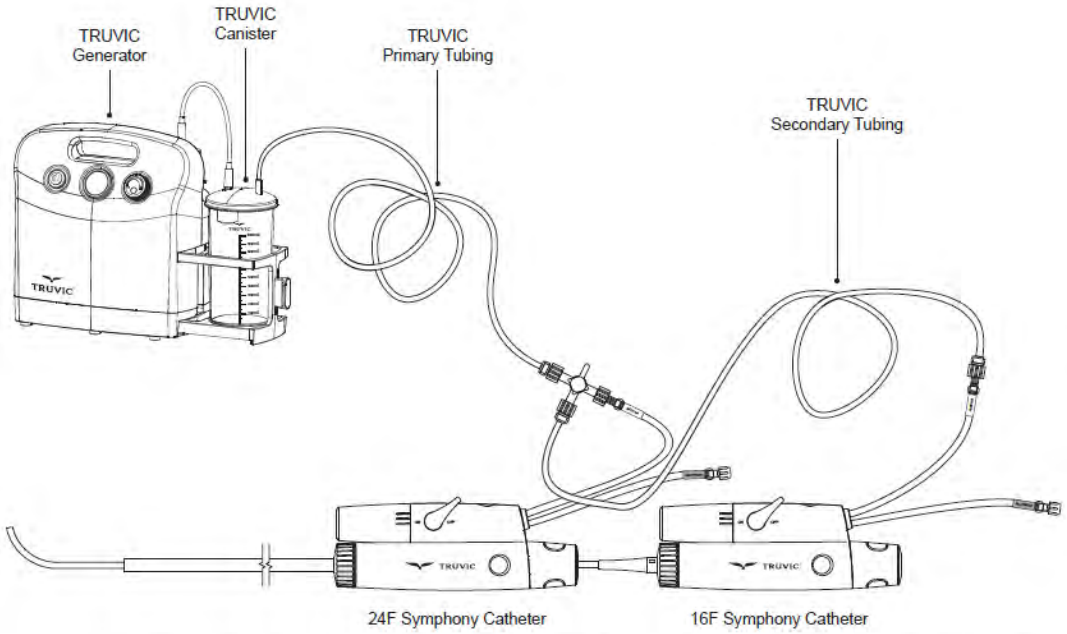
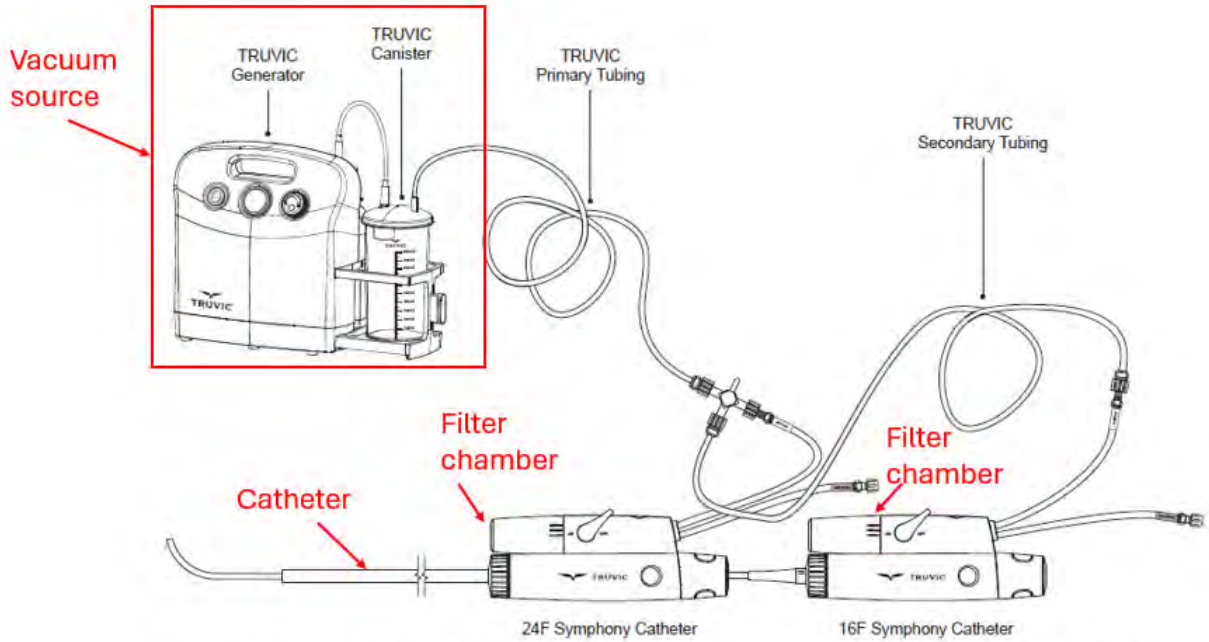


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

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.

(Symphony Thrombectomy System Instructions For Use at 8.)

	Truvic also includes a video on its website detailing a method of using the Symphony System to treat clot material within a blood vessel of a human patient using the Truvic Generator (along with the Truvic Canister) as a vacuum source.  **Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister** (Symphony Thrombectomy System Instructions For Use at 8, annotated to show vacuum source.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

a catheter fluidically coupled to the vacuum source via a first fluid path;	The Symphony System includes a catheter fluidically coupled to the vacuum source via a first fluid path. Specifically, the Symphony System includes a 24F and/or 16F Symphony Catheter that is fluidically coupled to the Truvic Generator and Truvic Canister (*e.g.*, vacuum source). As shown in Figure 6 of the Symphony System IFU (annotated below), the Symphony System includes a catheter coupled to the vacuum source via the first fluid path and the Truvic primary tubing for the 24F or 16F Symphony Catheter and/or the Truvic secondary tubing for the 16F Symphony Catheter.

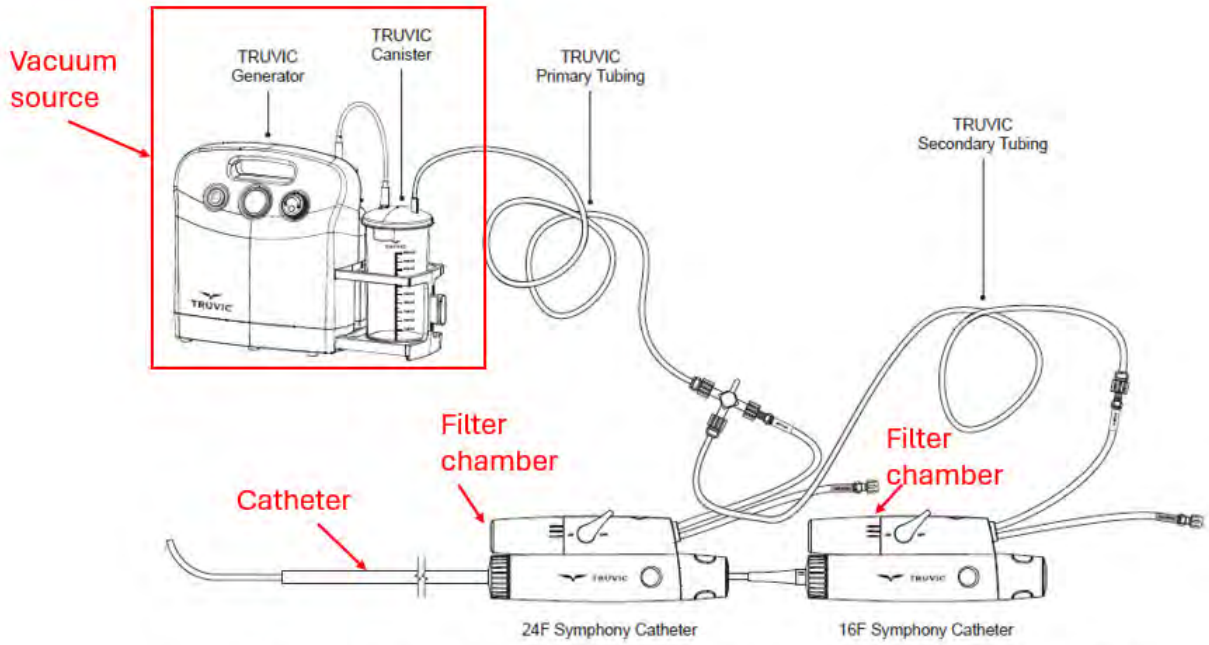
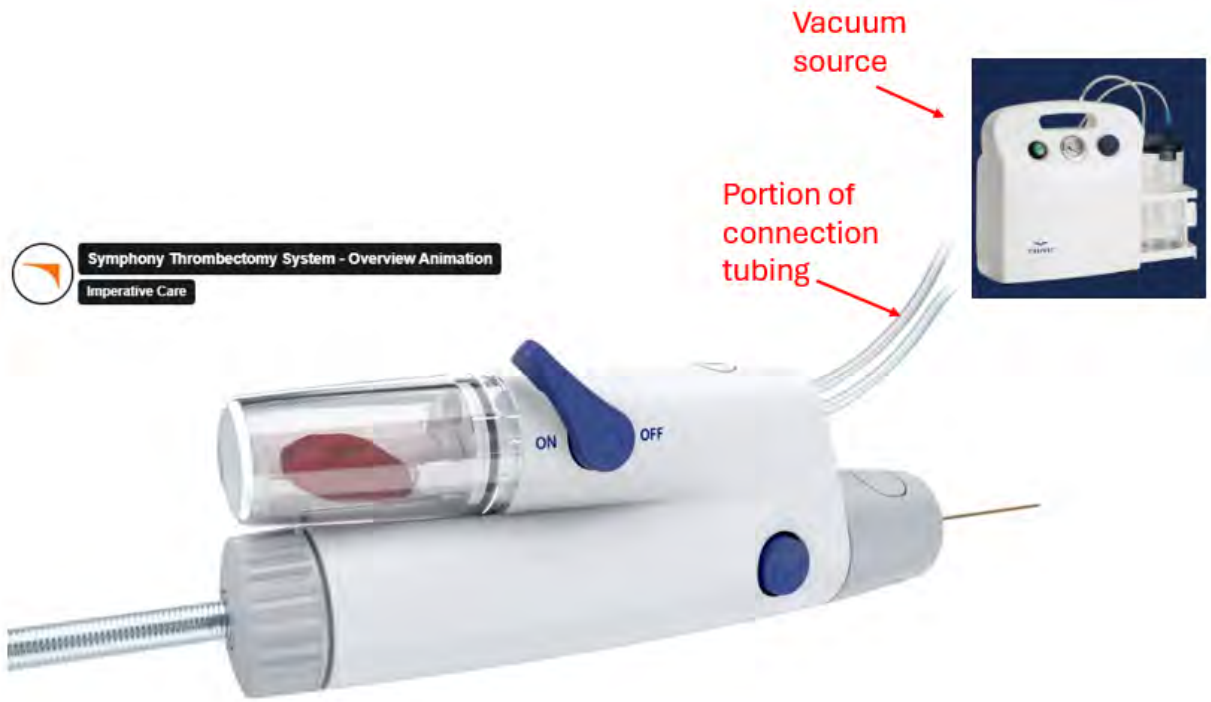
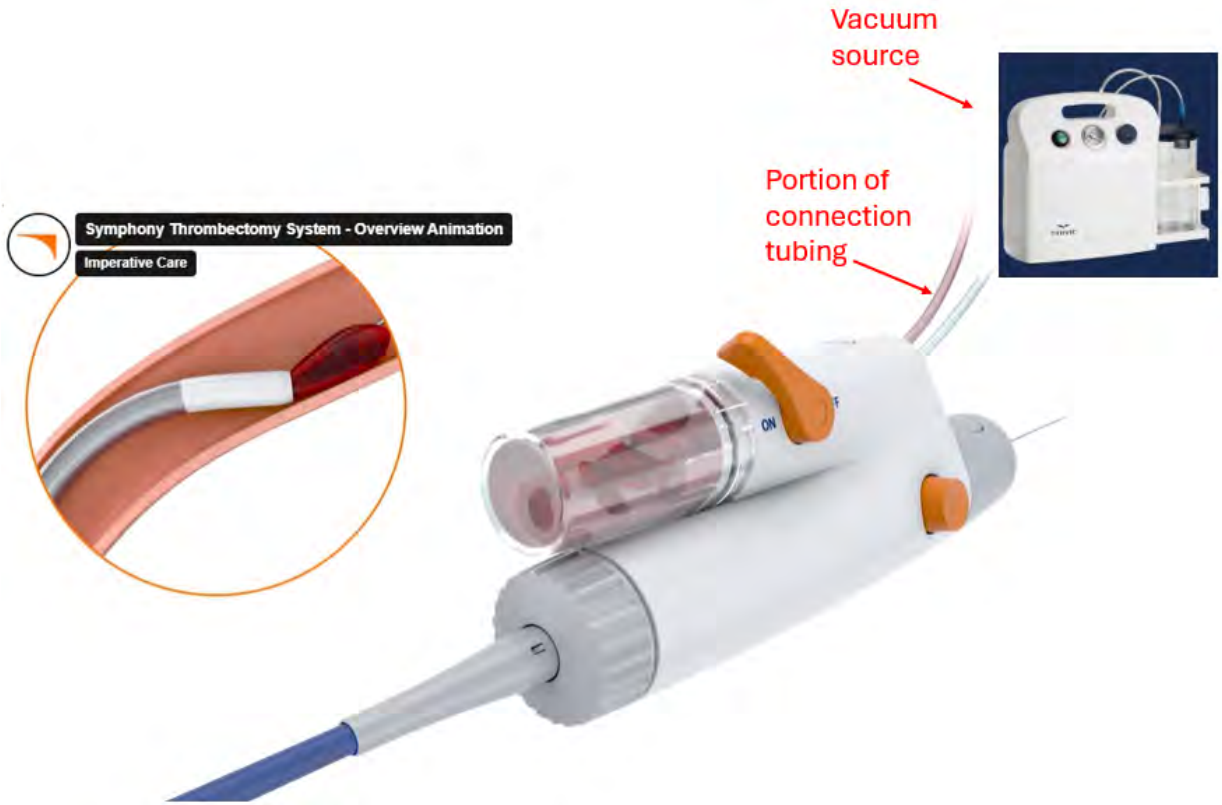
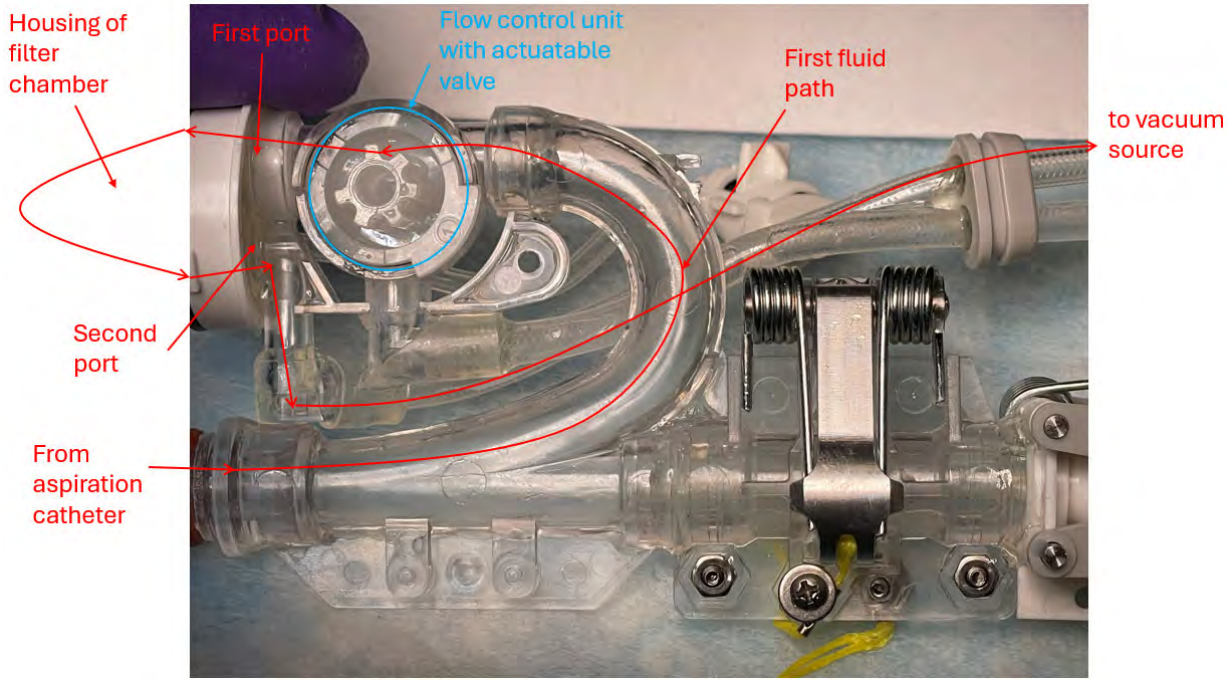


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Symphony Thrombectomy System Instructions For Use at 8.)

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

	 (Annotated image of Symphony System.)



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

----------24F Aspiration Catheter----------

The 24F aspiration catheter is fluidically coupled to the Truvic Generator and Truvic Canister, as shown in Figure 3 of the Symphony System IFU, reproduced below.

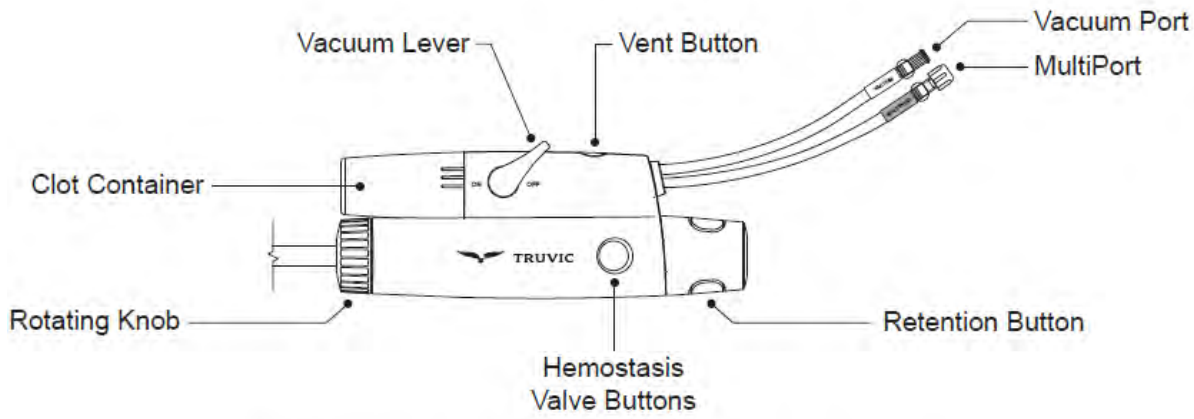
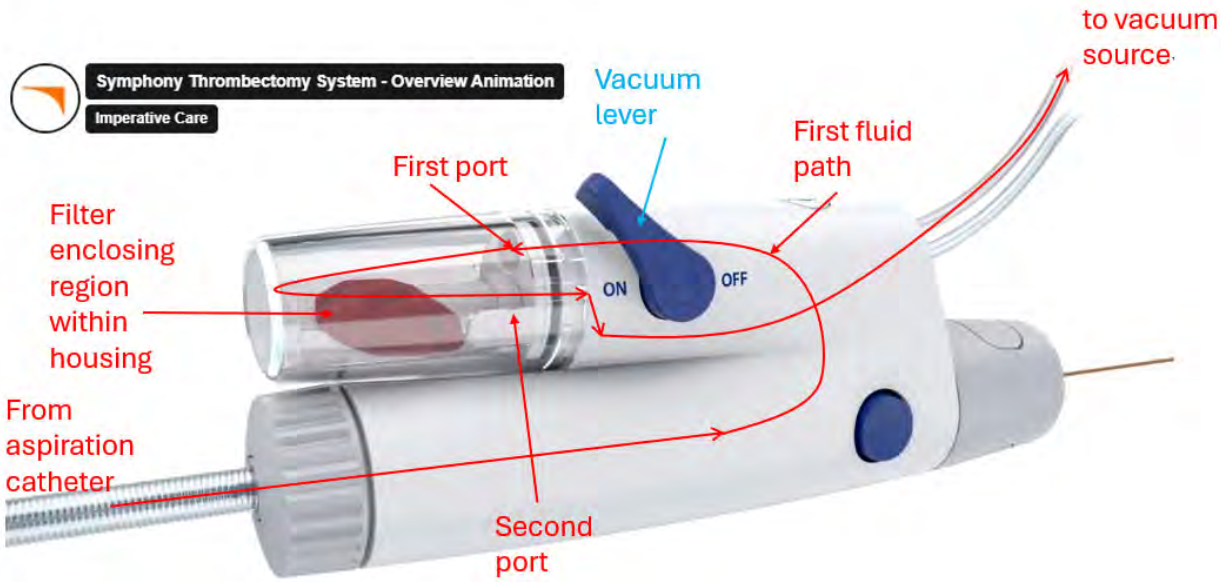
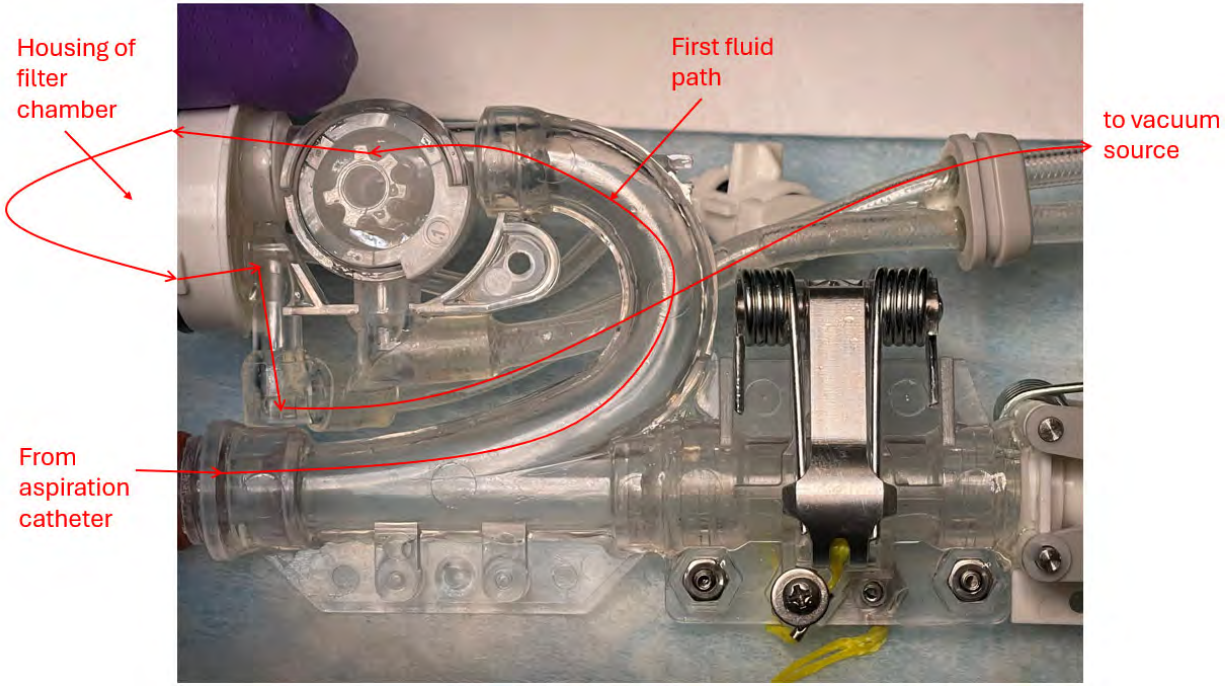


Figure 3: Symphony Catheter Handle, labeled

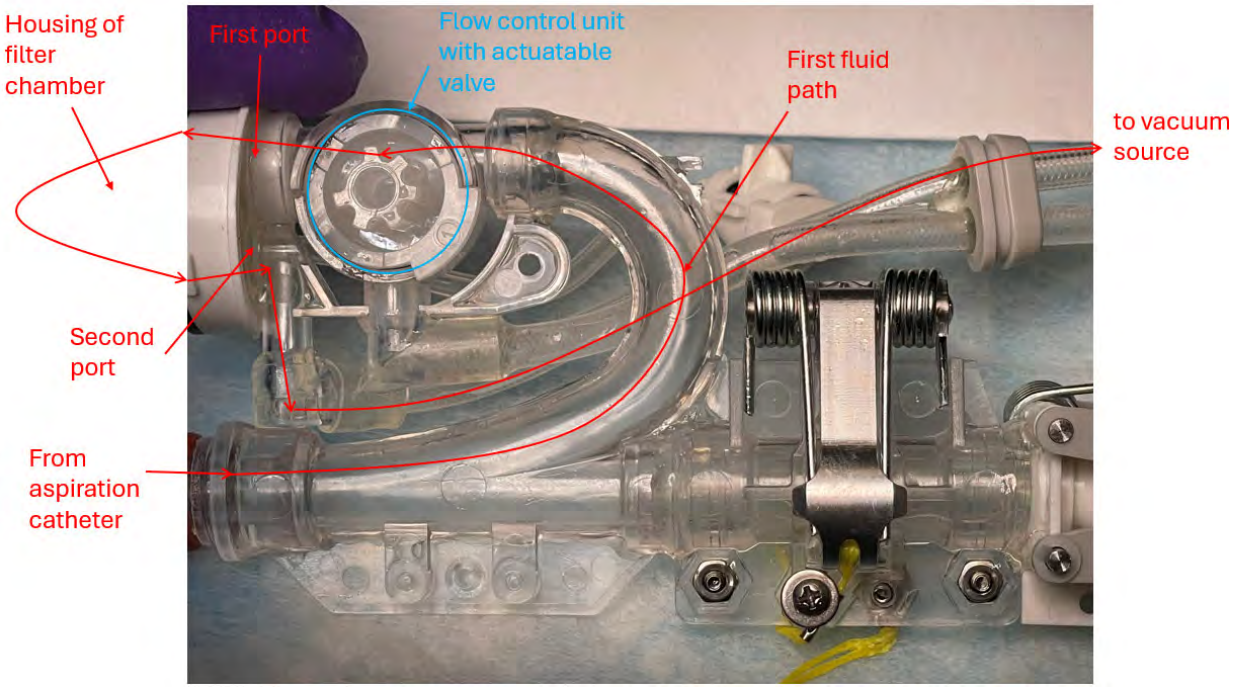
(Symphony Thrombectomy System Instructions For Use at 4.)

The Truvic primary tubing connects the Truvic Generator and Truvic Canister to the Symphony Catheter handle via the vacuum port and tubing internal to the Symphony Catheter handle so that the Truvic Generator and Truvic Canister can provide negative pressure to the catheter via the first fluid path shown in the annotated diagram of the Symphony Catheter handle and annotated teardown images of the handle. (*See* Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.").)

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

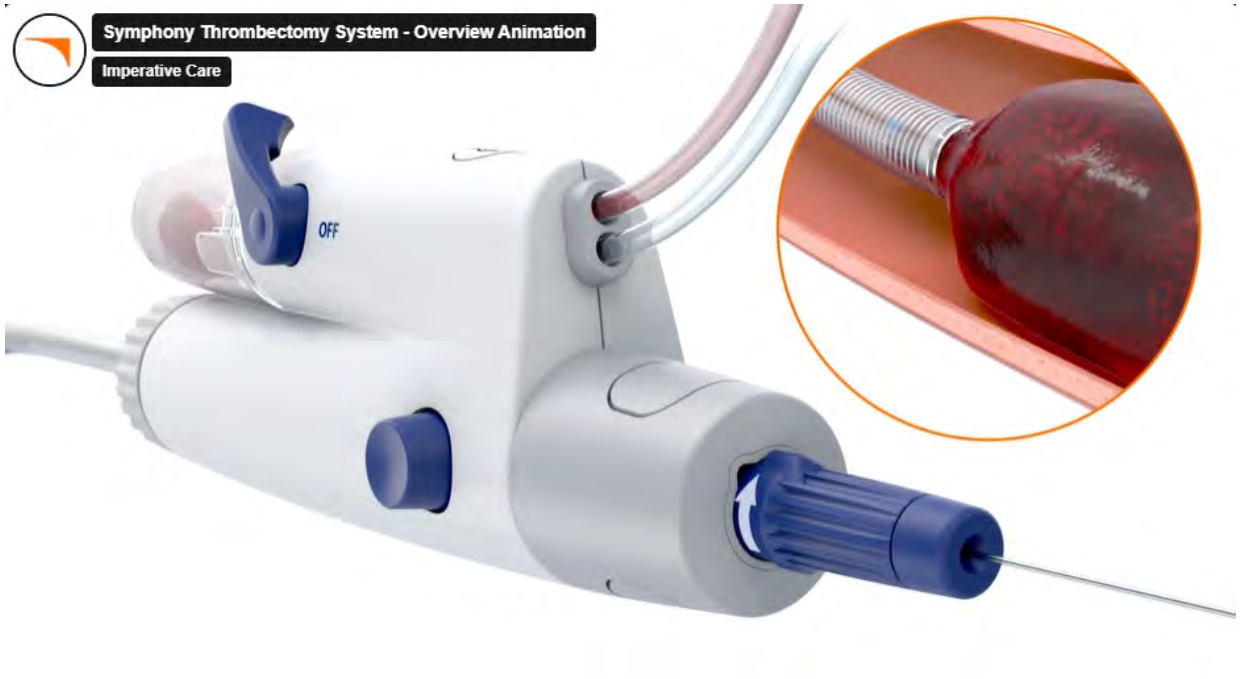


(Annotated image of internal portion of controller housing.)

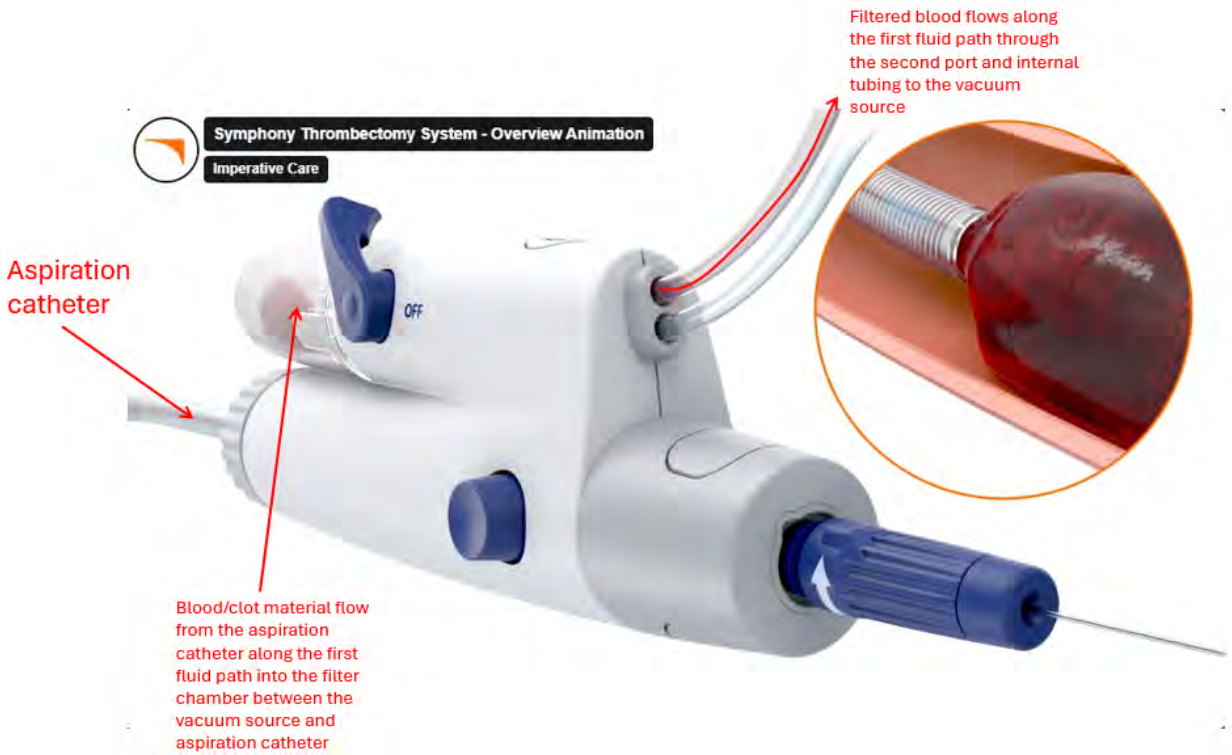


(Annotated image of internal portion of the controller housing.)

The Symphony Thrombectomy System – Overview Animation video demonstrates that as blood and clot material from the human patient enter the catheter and flow to the clot container of the 24F Symphony Catheter handle. The clot container filters blood from the clot material and the filtered blood flows out of the housing of the clot container toward the vacuum port. The blood then exits the Symphony Catheter handle through the vacuum port to be deposited in the Truvic Canister that is connected to the Truvic Generator. Blood exiting the Symphony Catheter handle toward the Truvic Canister is shown by the light red coloring of the connection tubing (upper tubing) in the 24F Symphony Catheter handle below.

	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 1:03.)

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



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:00.)

----------16F Aspiration Catheter----------

The 16F aspiration catheter is fluidically coupled to the Truvic Generator and Truvic Canister, as shown in Figure 3 of the Symphony System IFU, reproduced below.

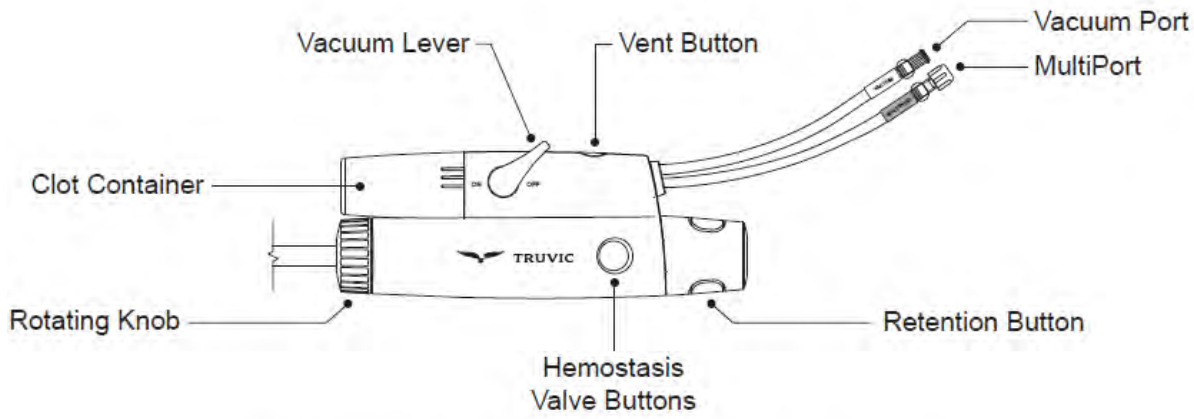
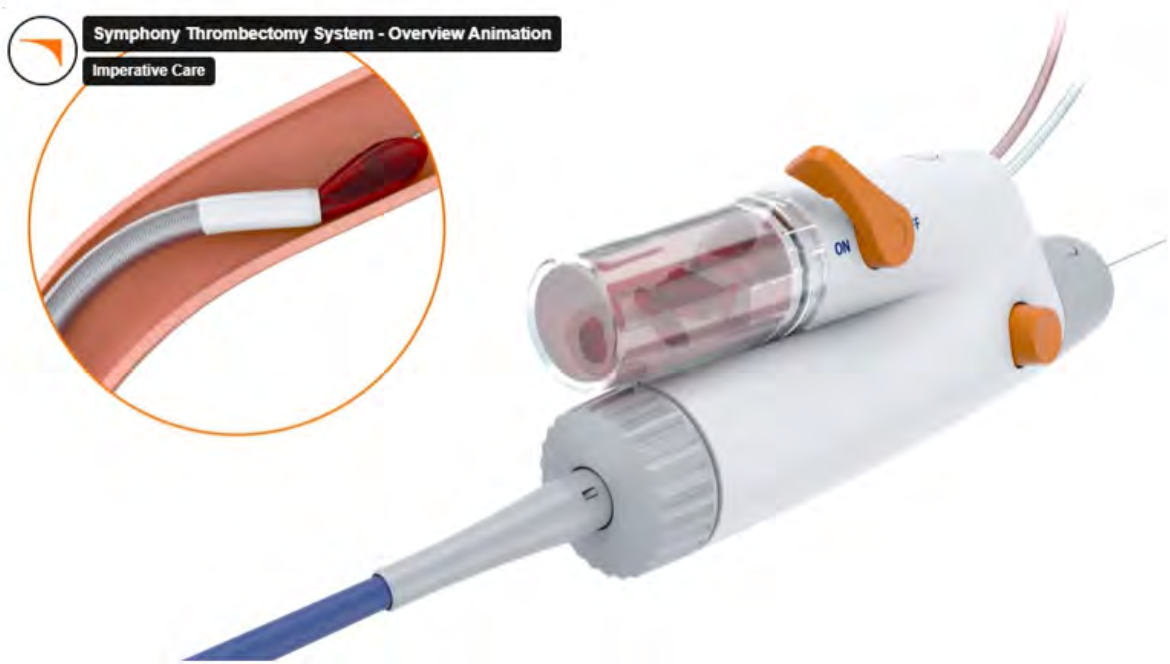


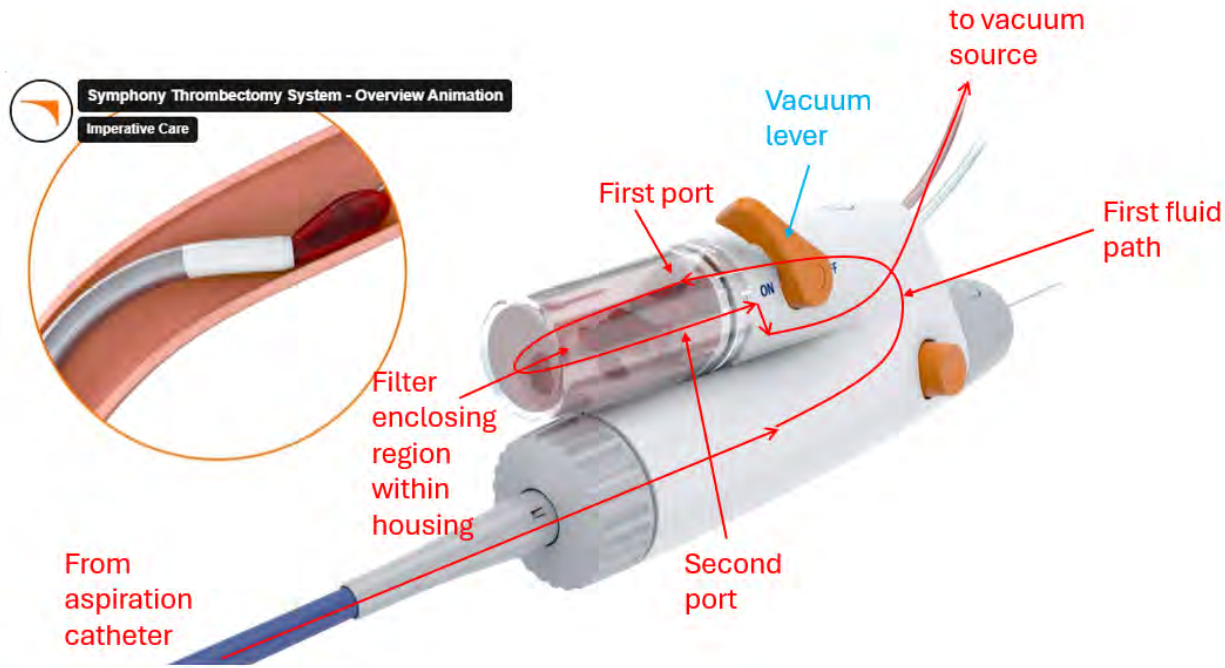
Figure 3: Symphony Catheter Handle, labeled

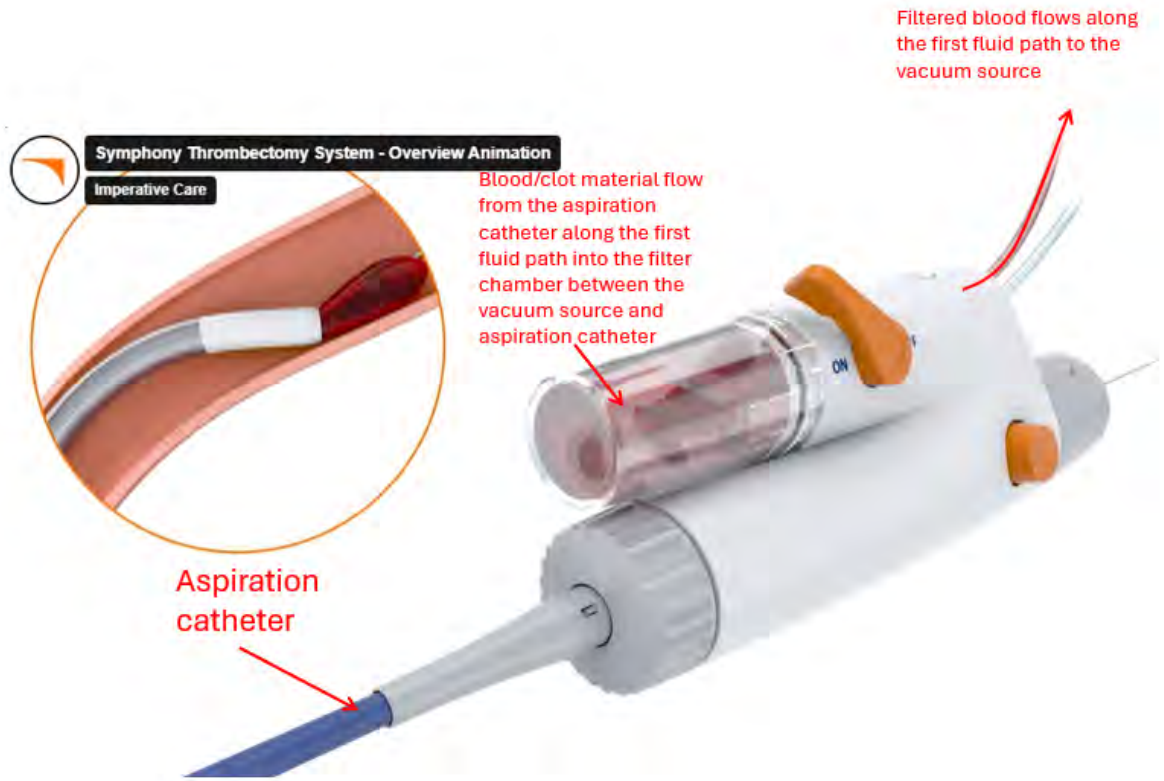
(Symphony Thrombectomy System Instructions For Use at 4.)

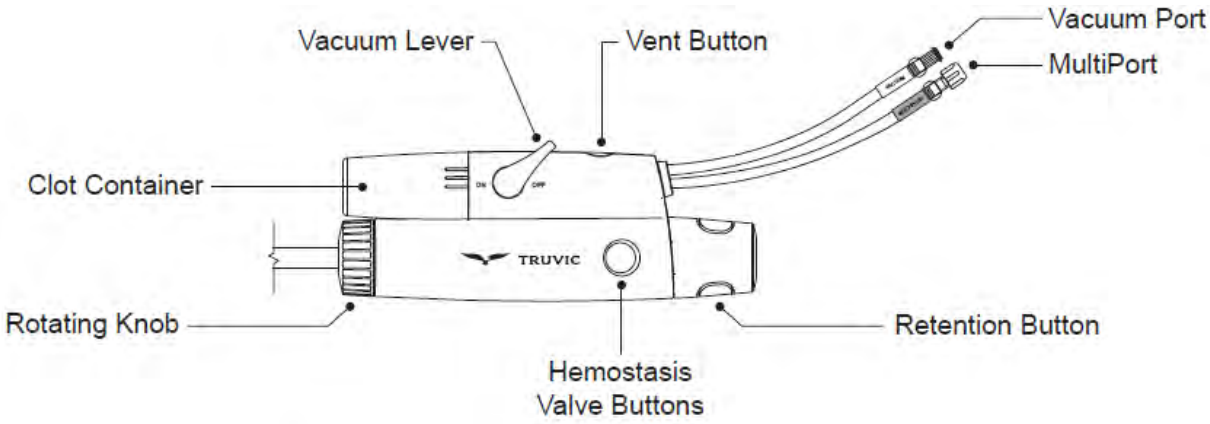
The Truvic primary or secondary tubing connects the Truvic Generator and Truvic Canister to the Symphony Catheter handle via the vacuum port and tubing internal to the Symphony Catheter handle so that the Truvic Generator and Truvic Canister can provide negative pressure to the catheter. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.").)

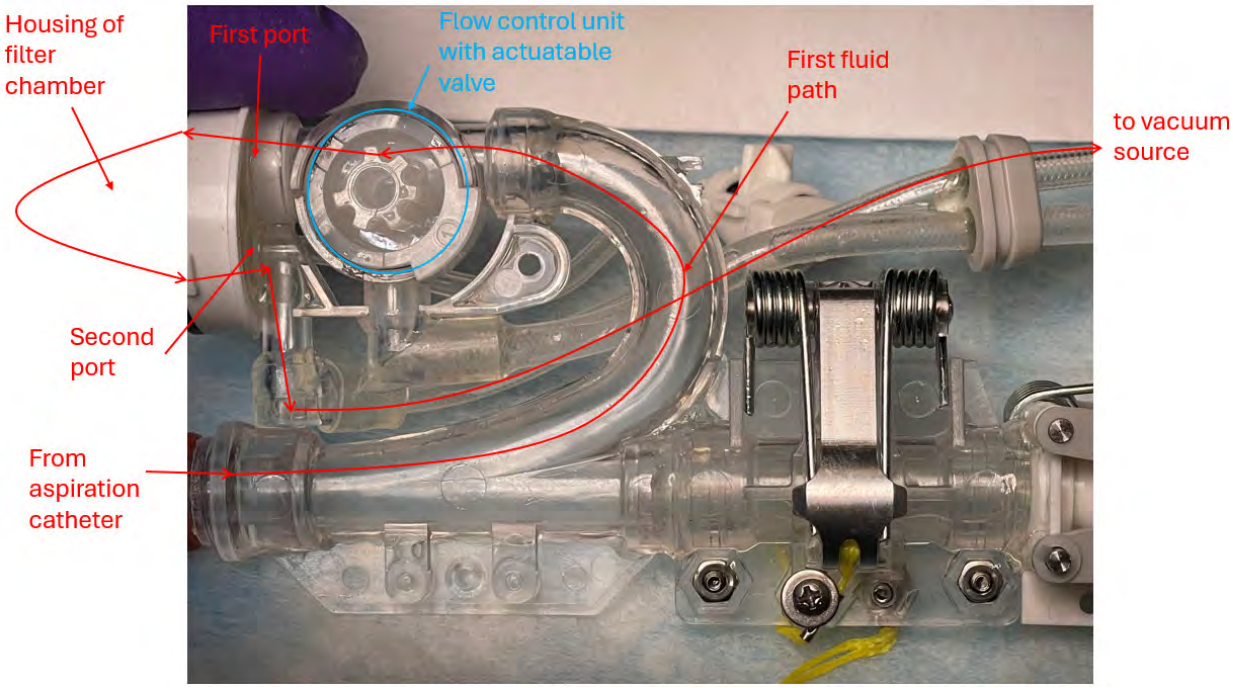
The Symphony Thrombectomy System – Overview Animation Video demonstrates that as blood and clot material from the human patient enter the catheter and flow to the clot container of the 16F Symphony Catheter handle. The clot container filters blood from the clot material, and the filtered blood flows out of the housing of the clot container toward the vacuum port. The blood then exits

	the Symphony Catheter handle. through the vacuum port to be deposited in the Truvic Canister that is connected to the Truvic Generator. Blood exiting the Symphony Catheter handle toward then Truvic Canister is shown by the light red coloring of the connection tubing (upper tubing) in the 16F Symphony Catheter handle below.  (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

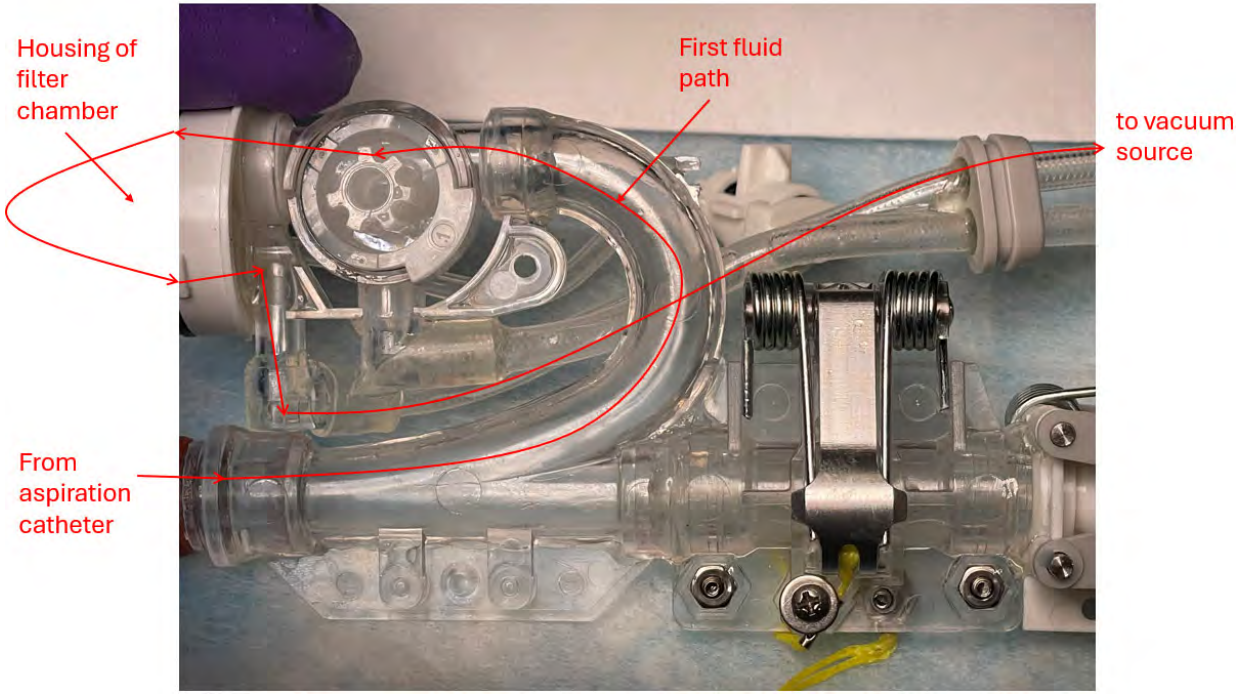
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a filter chamber along the first fluid path and spaced apart from the vacuum source, wherein the filter	The Symphony System includes a filter chamber along the first fluid path and spaced apart from the vacuum source, where the filter chamber comprises a housing and a filter within the housing.

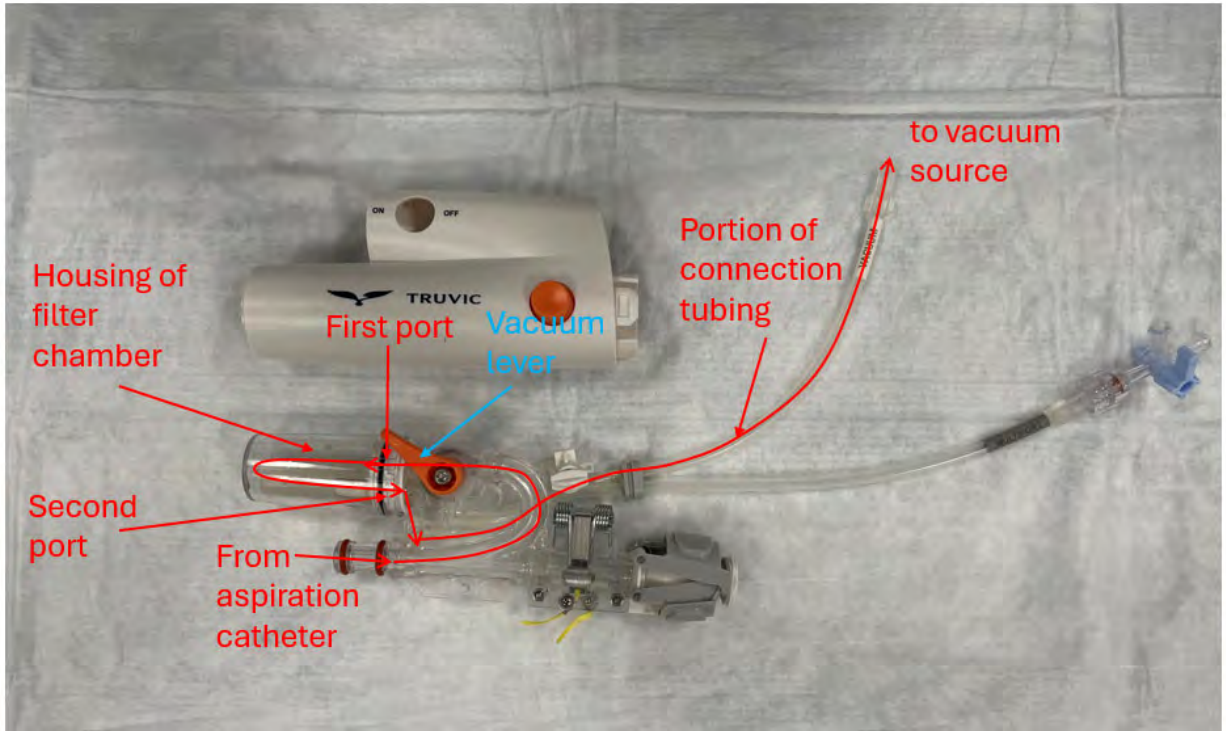
chamber comprises a housing and a filter within the housing, and wherein the housing includes—	Specifically, the Symphony System includes a 24F Symphony Catheter handle and/or 16F Symphony Catheter handle that includes a clot container (*e.g.*, filter chamber) that is fluidically coupled to the tubing within the Symphony Catheter handle and vacuum port along the first fluid path, as shown in Figure 3 of the IFU reproduced below.  **Figure 3: Symphony Catheter Handle, labeled** (Symphony Thrombectomy System Instructions For Use at 4.) The clot container (*e.g.*, filter chamber) is along the first fluid path, as shown in the annotated teardown image below.



(Annotated image of internal portion of controller housing.)



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



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

The internal tubing and vacuum port of the Symphony Catheter handle allow for the clot container of the Symphony Catheter handle to be fluidically coupled to the Truvic Generator and Truvic Canister (*e.g.*, vacuum source) of the Symphony System via the Truvic primary tubing (for the 24F handle and/or 16F handle, below) and/or Truvic secondary tubing (for the 16F handle, below). The clot container of the Symphony Catheter handle is apart from the Truvic Generator and Truvic Canister of the Symphony System, as shown in Figure 6 of the Symphony System IFU reproduced and annotated below.

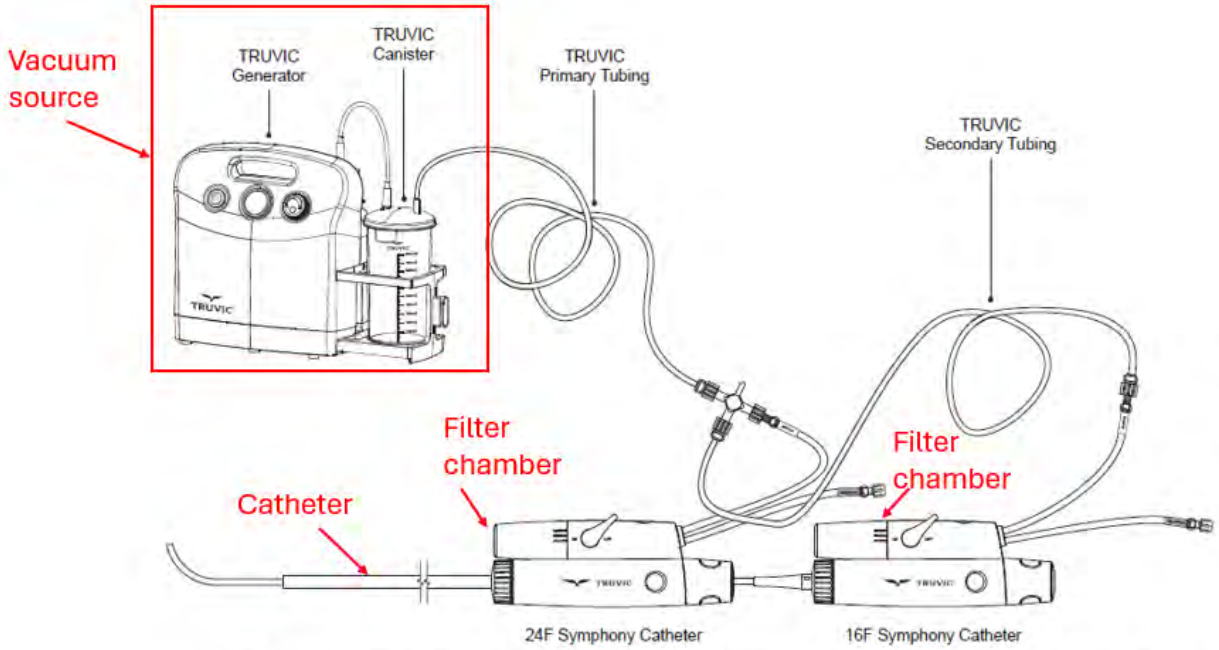
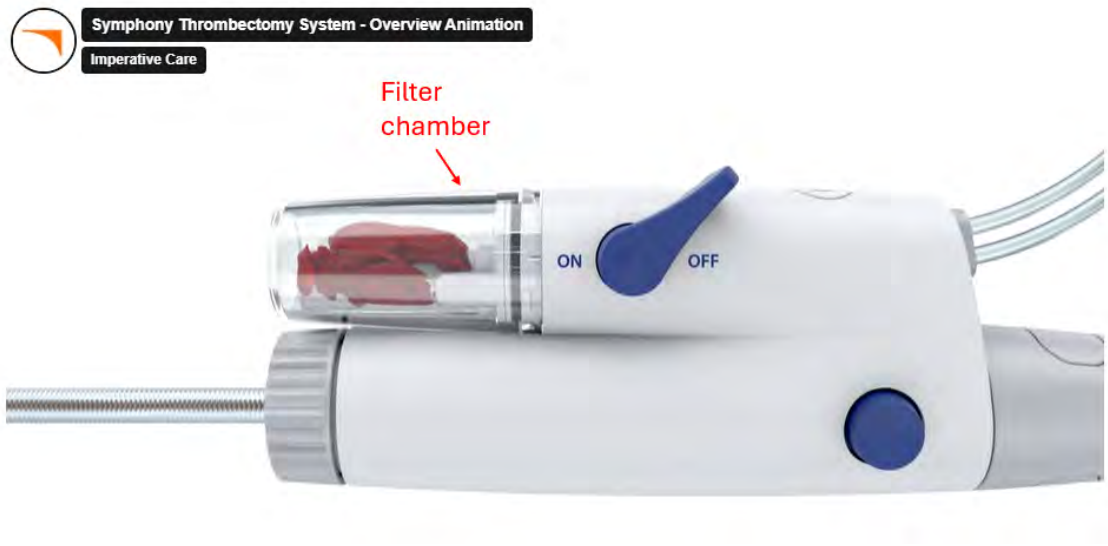


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Symphony Thrombectomy System Instructions For Use at 8.)

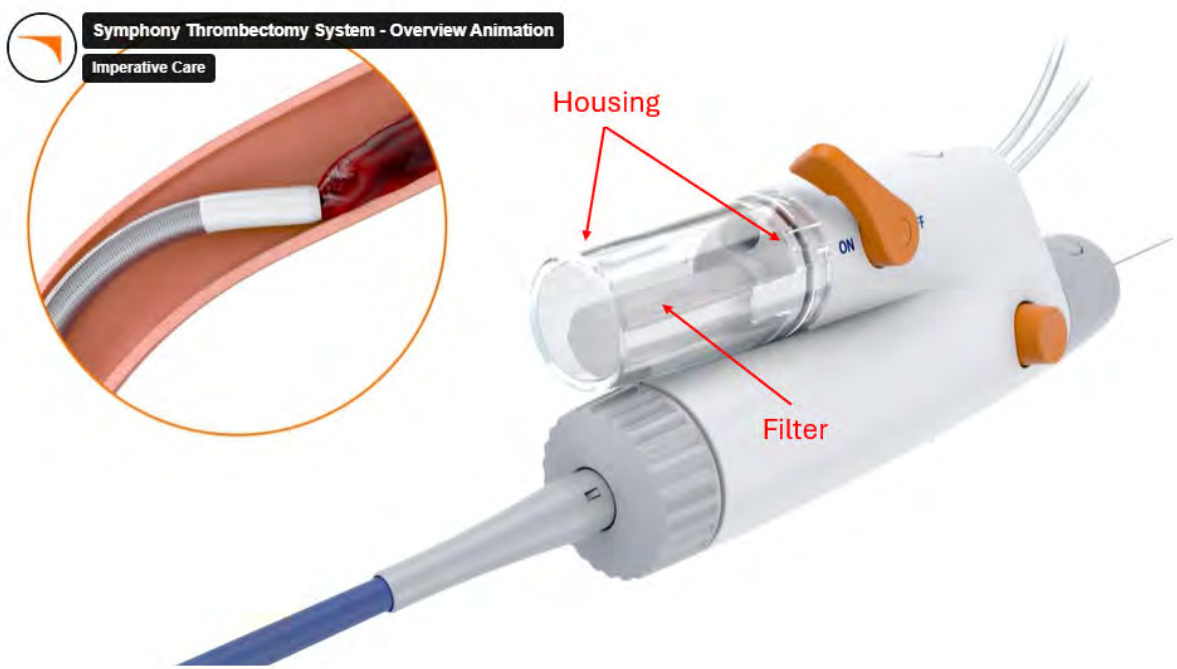
----------24F Aspiration Catheter----------

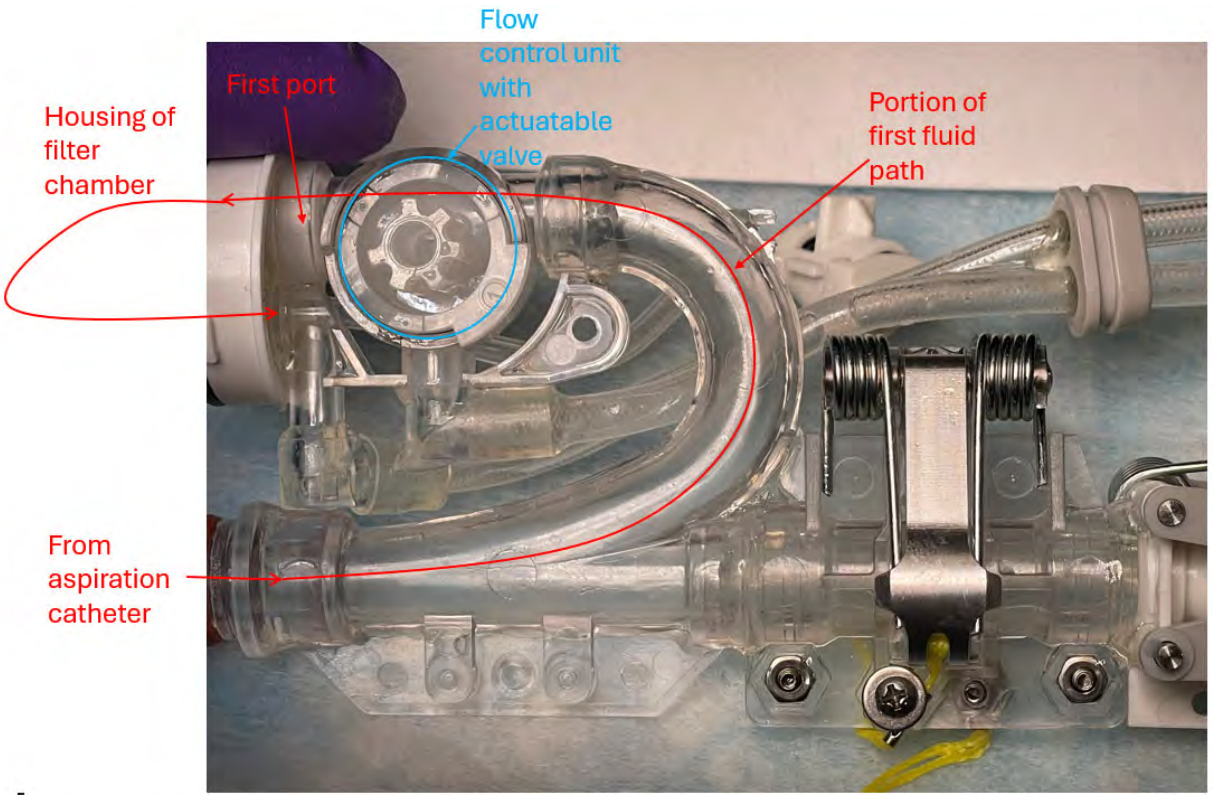
The 24F Symphony Catheter handle includes a filter chamber that comprises a housing with a removable cap and a filter within the housing, which is shown in the annotated images from the Symphony Thrombectomy System – Overview Animation video below.

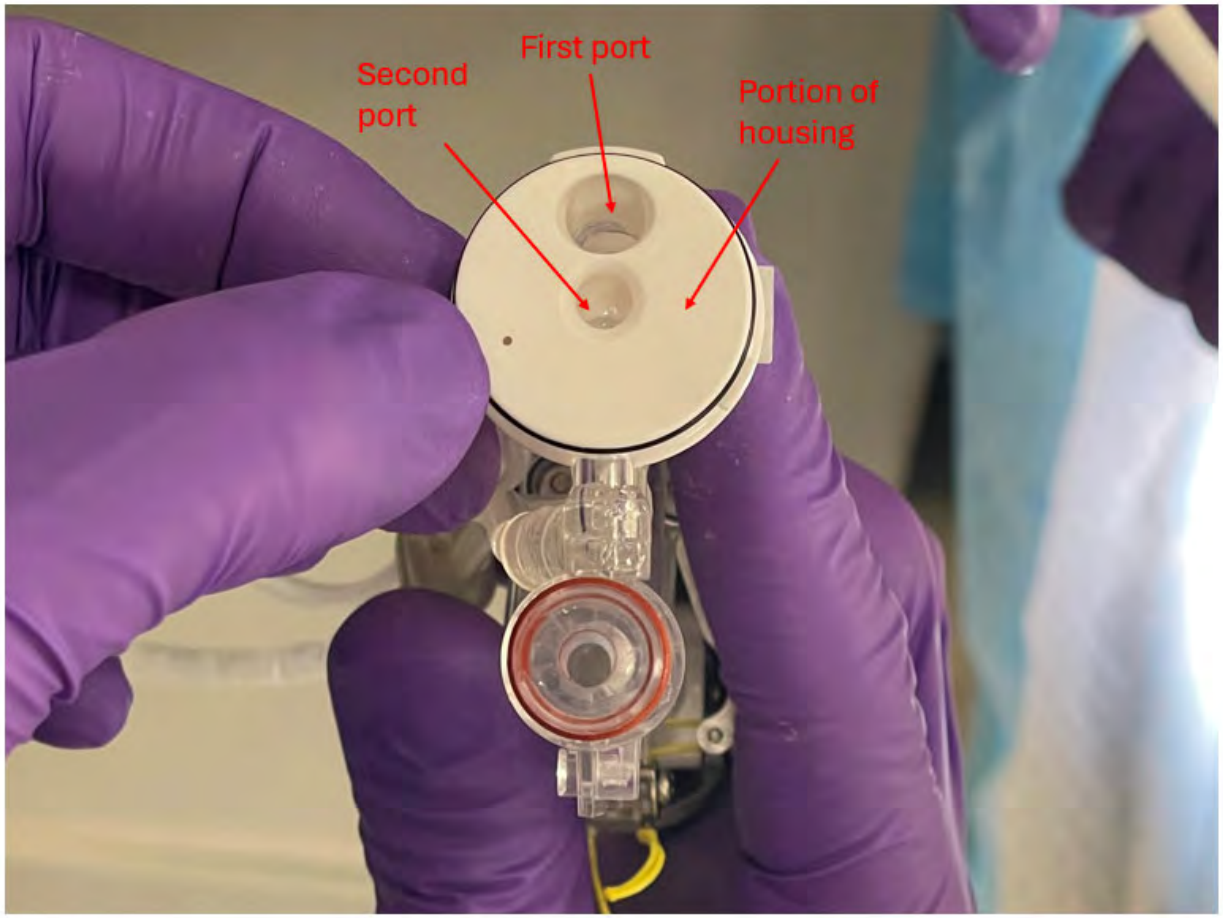
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 1:15.)

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

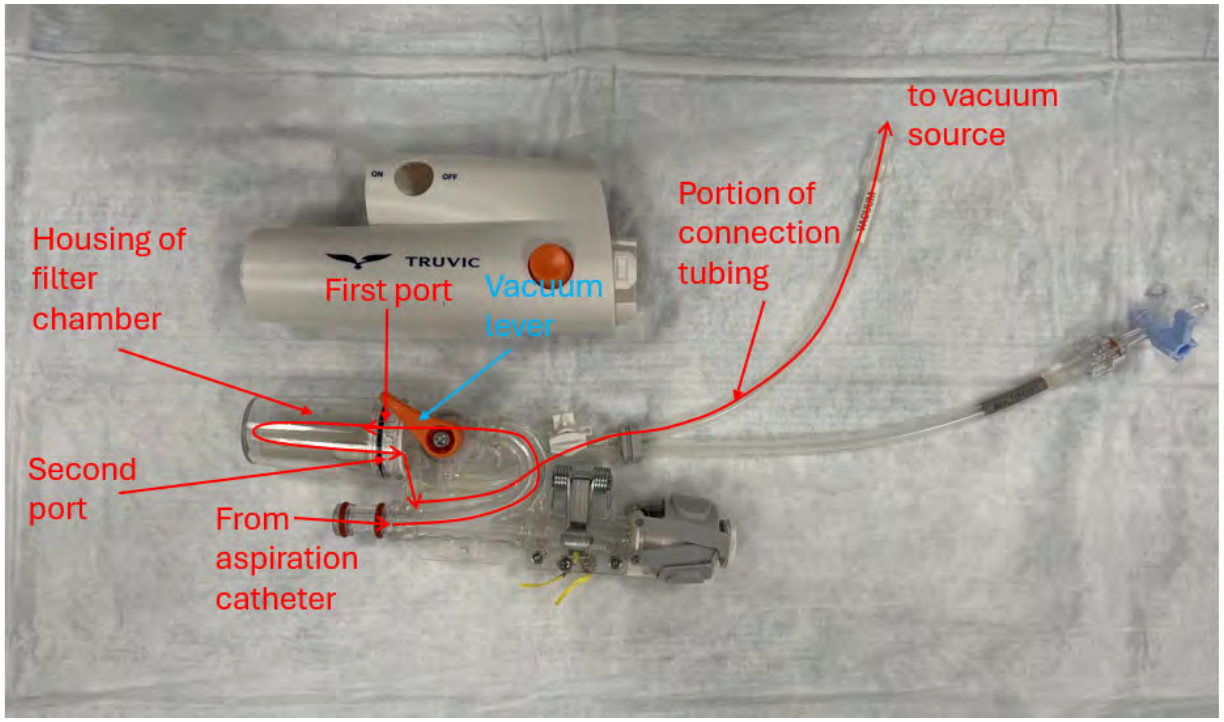
	 (Annotated image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) **----------16F Aspiration Catheter----------** The 16F Symphony Catheter handle includes a filter chamber that comprises a housing with a removable cap and a filter within the housing, which is shown in the annotated images from the Symphony Thrombectomy System – Overview Animation Video below.

	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 1:55.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a first port configured to be fluidically coupled to the catheter;	The Symphony System includes a first port configured to be fluidically coupled to the catheter. Specifically, the housing of the filter chamber of the 24F or 16F Symphony Catheter handle includes a first port that is configured to be fluidically coupled to

	the aspiration catheter (via a portion of the first fluid path from the aspiration catheter through the vacuum control valve into the first port), as shown in the teardown images of the Symphony Catheter handle below.  - (Annotated image of internal portion of controller housing.)



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

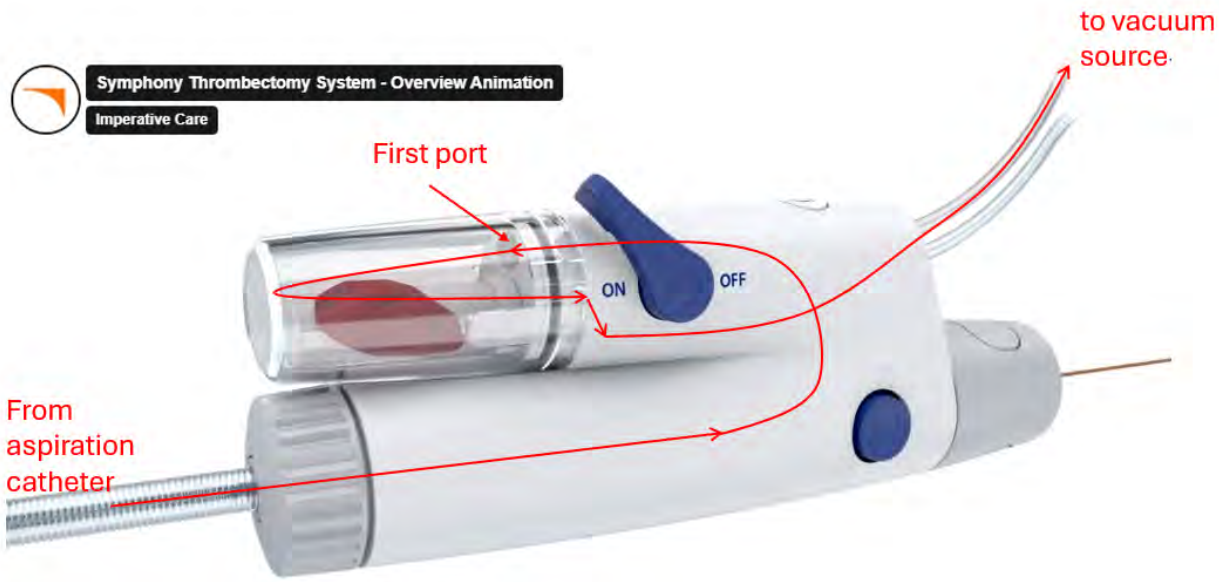


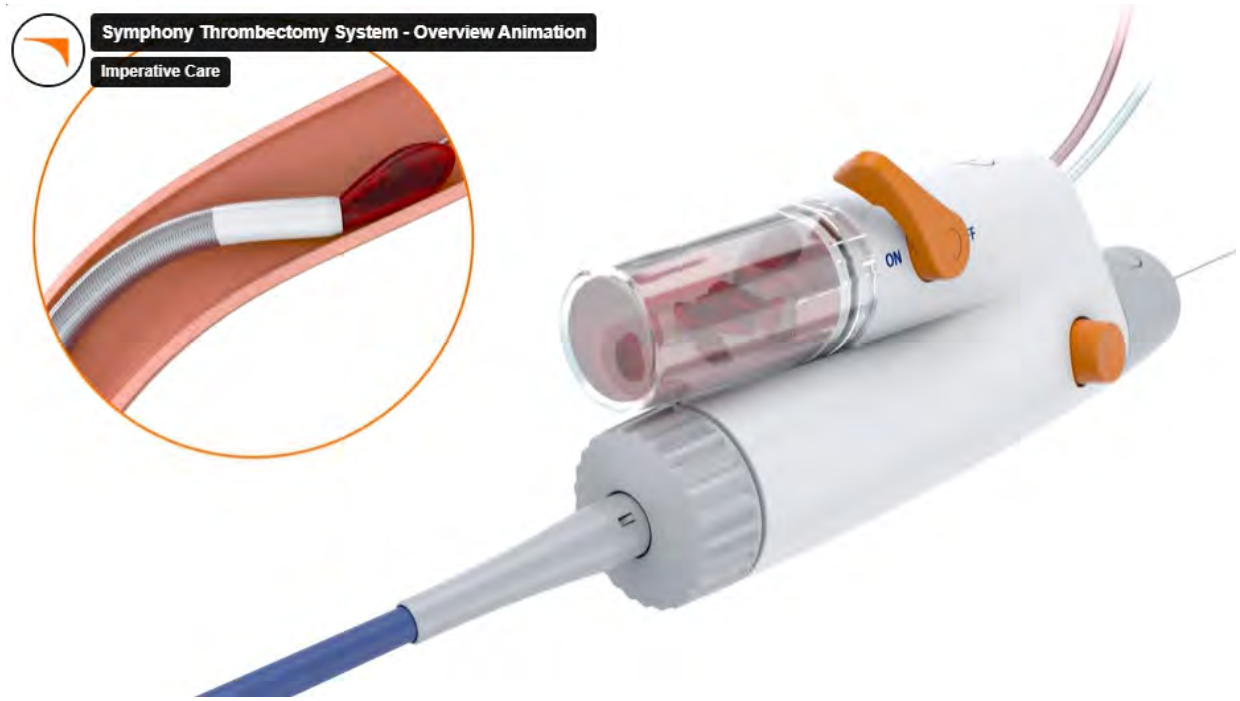
(Annotated image of internal portion of the controller housing with vacuum lever.)

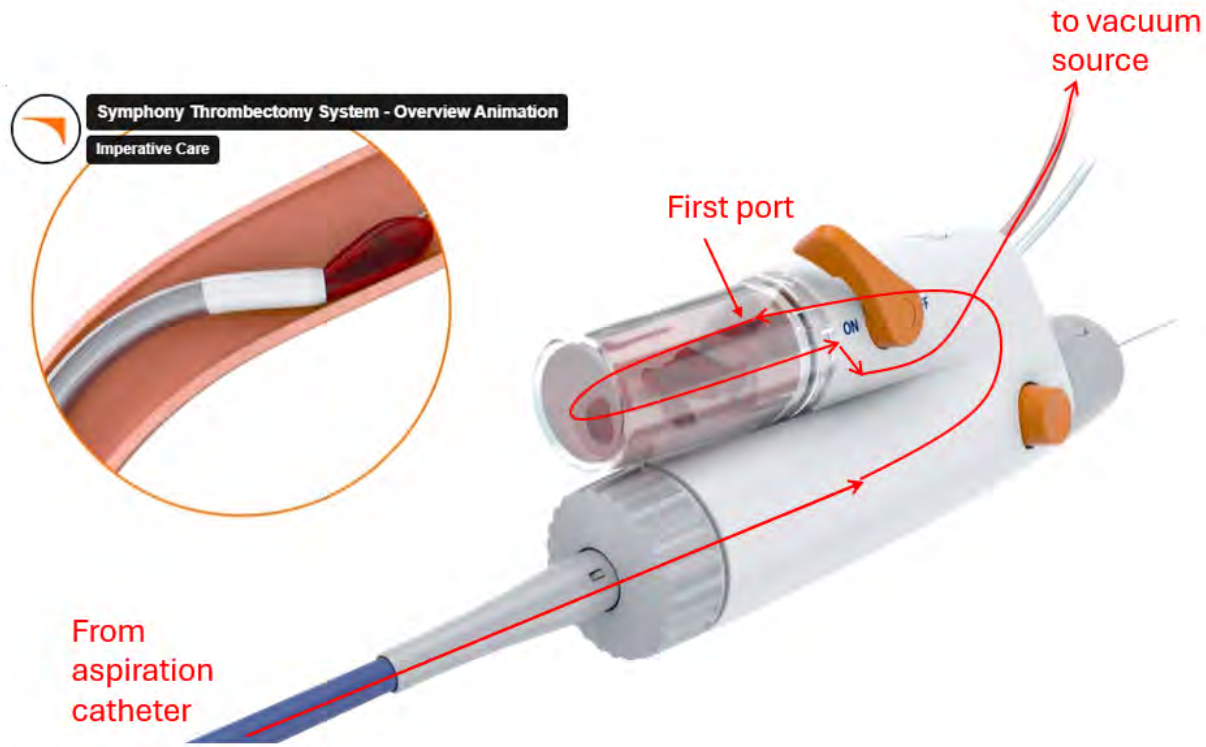
----------24F Aspiration Catheter----------

The image below, which shows blood flowing from the aspiration catheter of the 24F Symphony Catheter handle through the first port into the filter chamber confirms that the first port is configured to be fluidically coupled to the catheter.

	 (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) Blood flows from the aspiration catheter through the first port into the filter chamber via the flow path shown in the annotated image below.

	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.) **----------16F Aspiration Catheter----------** The image below, which shows blood flowing from the aspiration catheter of the 16F Symphony Catheter handle through the first port into the filter chamber, confirms that the first port is configured to be fluidically coupled to the catheter.

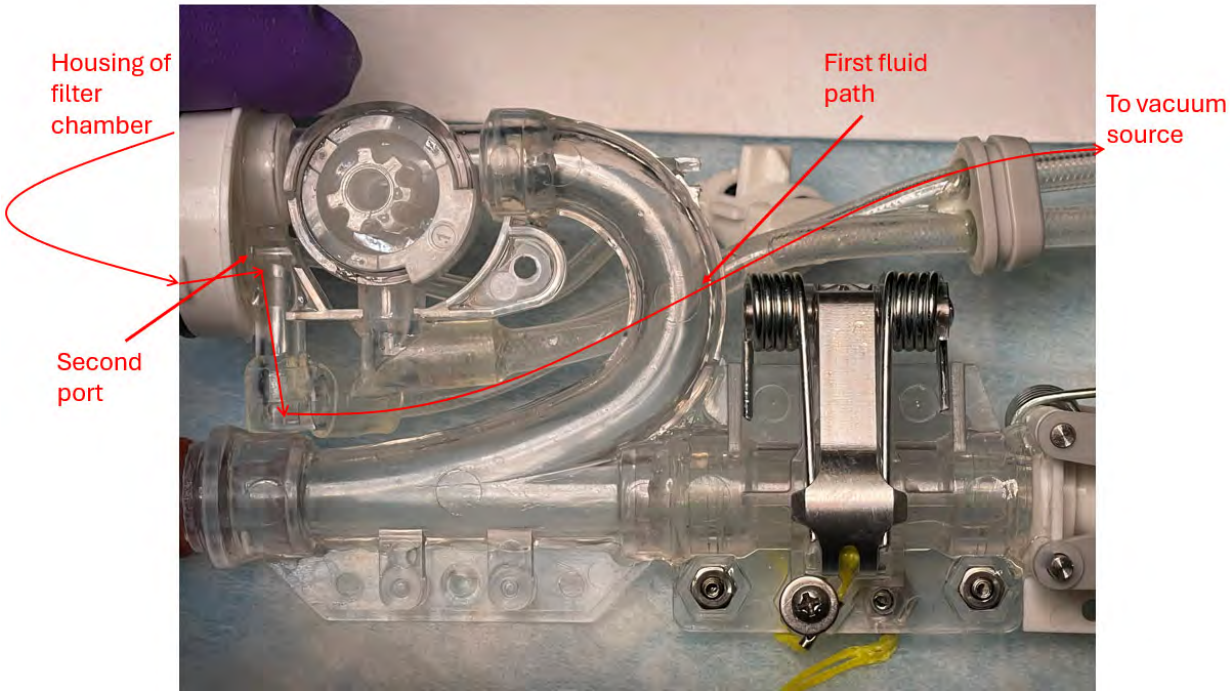
	 (Symphony Thrombectomy System – Overview Animation Video at 2:02.) Blood flows from the aspiration catheter through the first port into the filter chamber via the flow path shown in the annotated image below.



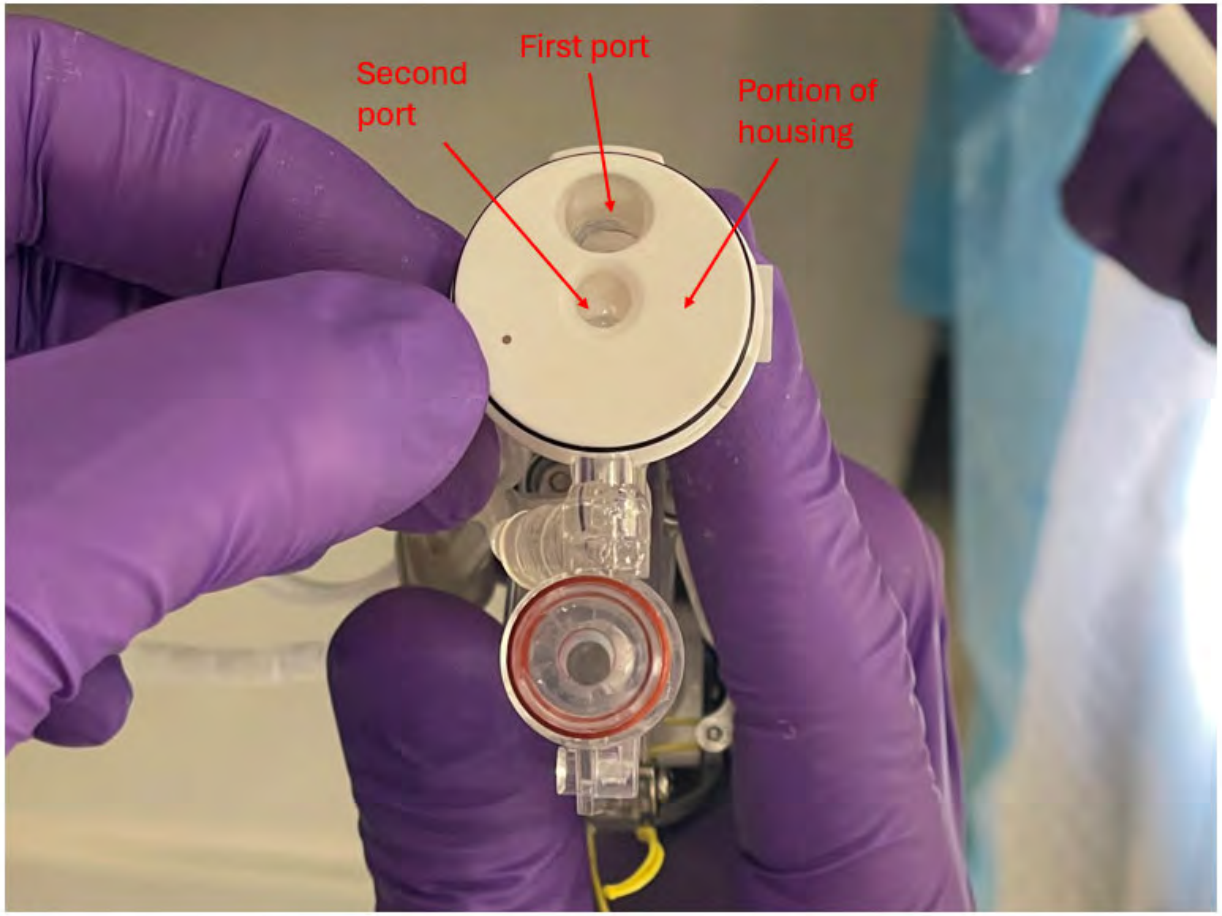
(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

To the extent Truvic argues that the housing is limited to the removable clear portion of the housing of the Symphony Catheter handle such that housing cannot include the first port, that is incorrect according to the dislcosure in the specification and claims 1 and 15, charted herein. If such a construction were adopted, however, the Symphony System will still meet this limitation under the doctrine of equivalents. For example, to the extent Truvic contends that the Symphony System housing does not include the first port and instead the first port is part of a structure

	separate from the housing, the Symphony System infringes under the doctirne of equivalents because the housing with a first port proximate to it still performs the same function as the recited housing that includes a first port, including fluidically coupling the housing to the catheter. This provides the same function as a housing that includes a first port because it allows blood and clot material to enter the housing, where the blood is then filtered out of the housing with the clot material remaining in the housing.
a second port configured to be fluidically coupled to the vacuum source; and	The Symphony System includes a second port configured to be fluidically coupled to the vacuum source. Specifically, the housing of the filter chamber of the 24F and 16F Symphony Catheter handle includes a second port that is configured to be fluidically coupled to the Truvic Generator and Truvic Canister (*e.g.*, vacuum source) via the first fluid path and vacuum port (which connects to the Truvic Generator and Truvic Canister via the Truvic primary tubing for a 24F or 16F handle or Truvic secondary tubing for a 16F handle) of the Symphony Catheter handle, as shown in the teardown images of the Symphony Catheter handle below.



(Annotated image of internal portion of controller housing.)

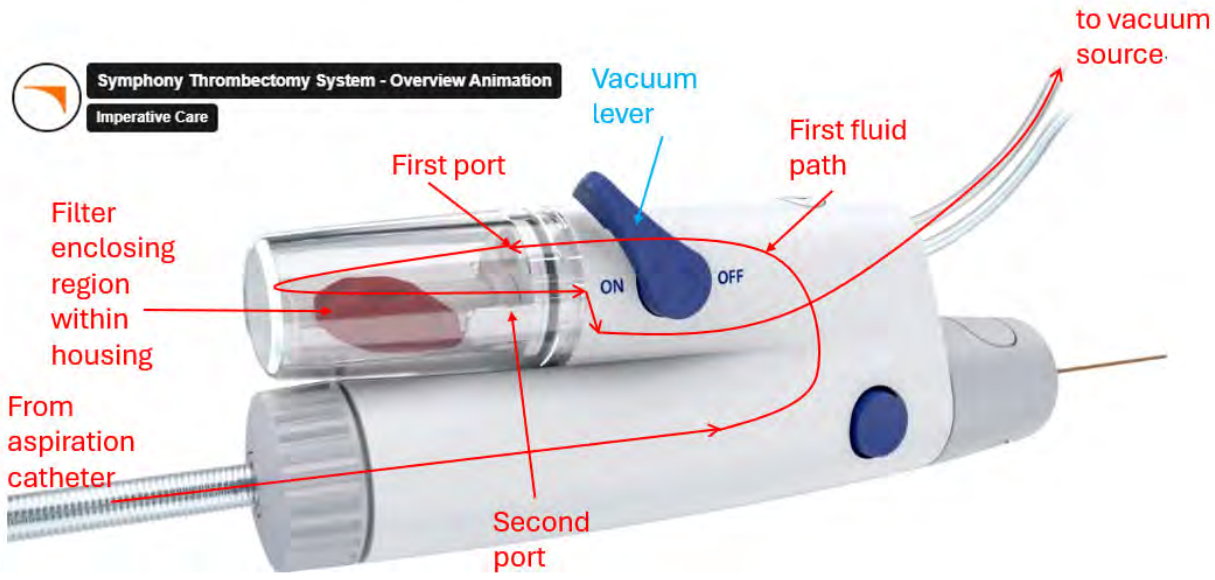


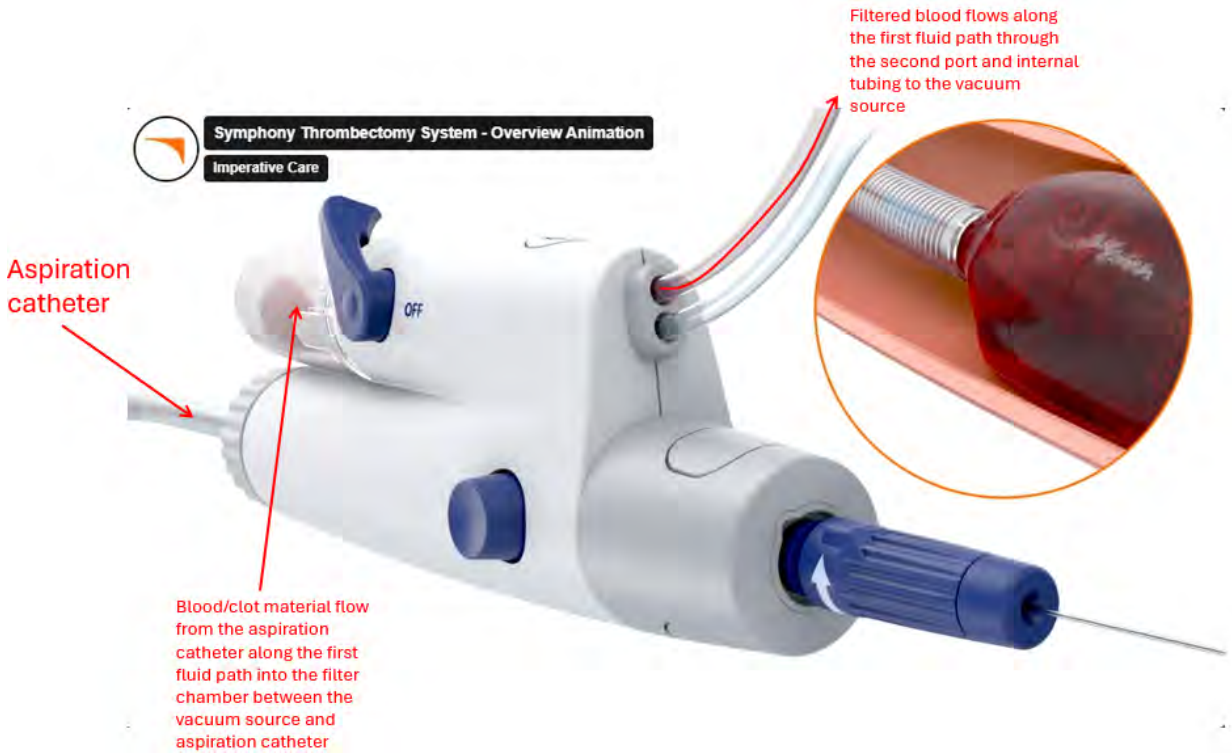
(Annotated image of controller housing showing first and second ports.)

----------24F Aspiration Catheter----------

The image below, which shows blood flowing from the housing of the 24F Symphony Catheter handle through the second port and tubing internal to the

	handle, through the vacuum port and eventually to the Truvic Canister, confirms that the second port is configured to be fluidically coupled to the vacuum source. (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) Blood flows from the housing of the filter chamber via the first fluid path, through the second port and the tubing internal to the handle, and out the vacuum port of the Symphony Catheter handle toward to the Truvic Canister via the Truvic primary tubing, as shown in the annotated images below.

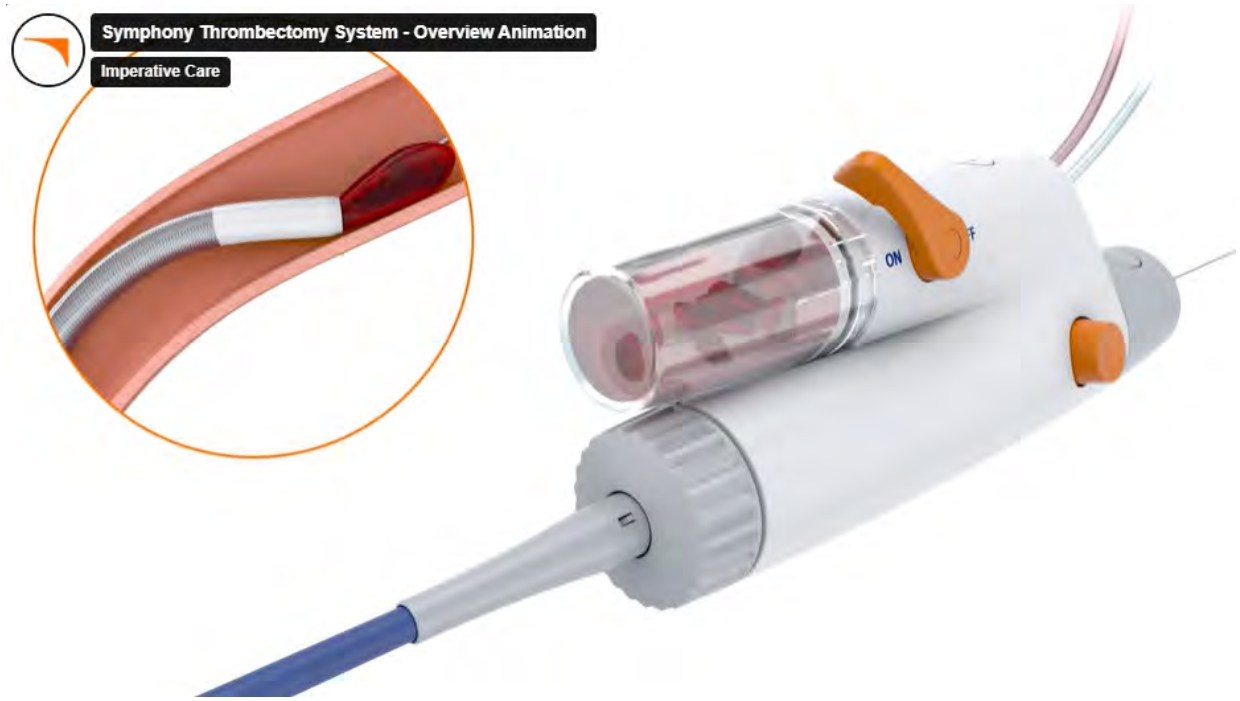
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

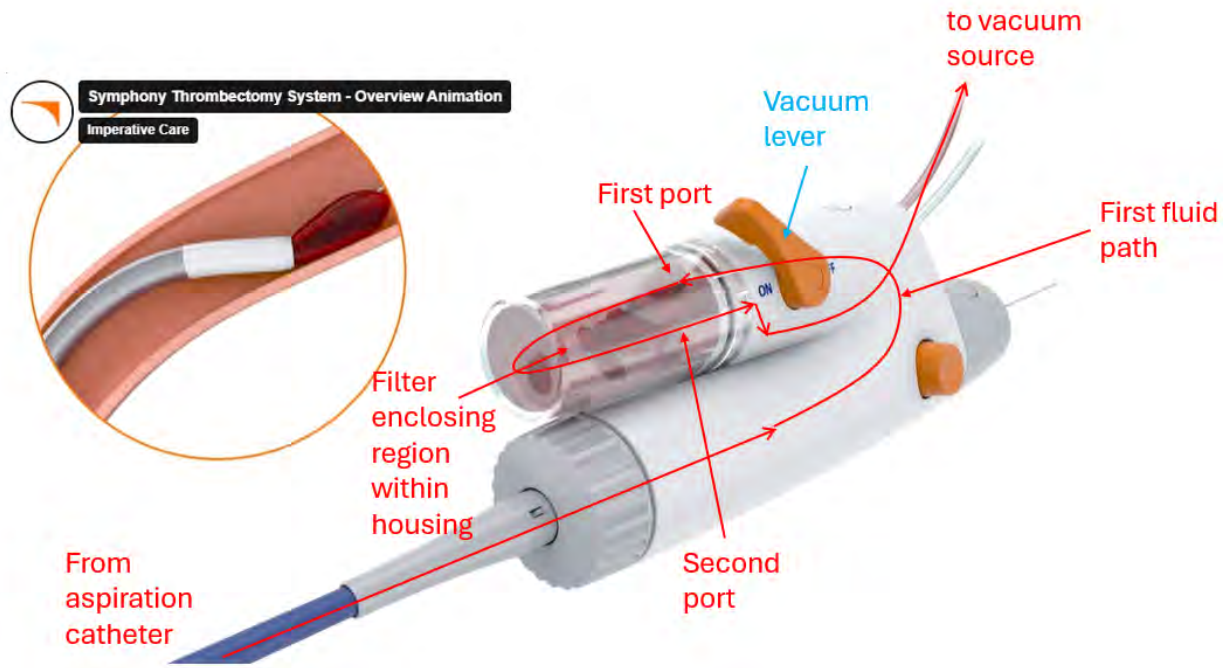


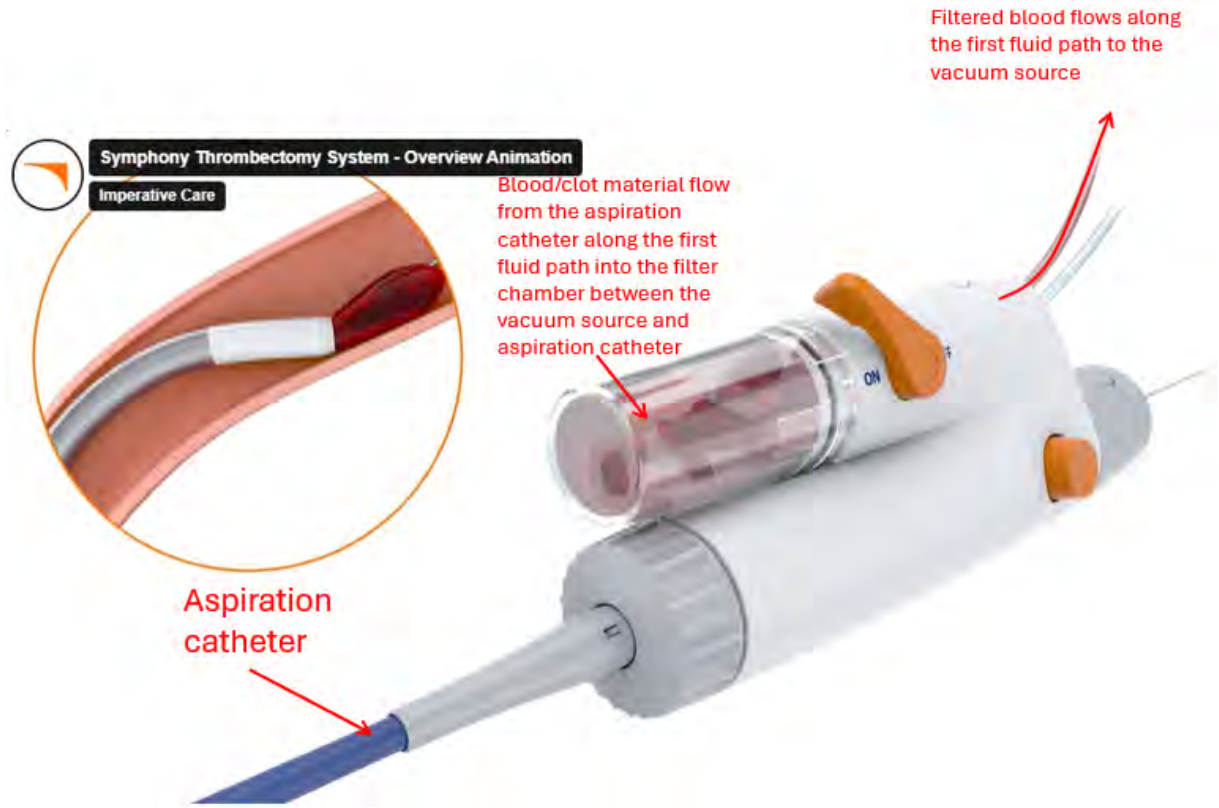
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:00.)

----------16F Aspiration Catheter----------

The image below, which shows blood flowing from the housing of the 16F Symphony Catheter handle through the second port and tubing internal to the handle and out of the vacuum port and to the Truvic Canister, confirms that the second port is configured to be fluidically coupled to the vacuum source.

	 (Symphony Thrombectomy System – Overview Animation Video at 2:02.) Blood flows from the housing of the filter chamber via the first fluid path, through the second port and the tubing internal to the handle, and out the vacuum port of the Symphony Catheter handle toward to the Truvic Canister via the Truvic primary or secondary tubing, as shown in the annotated images below.

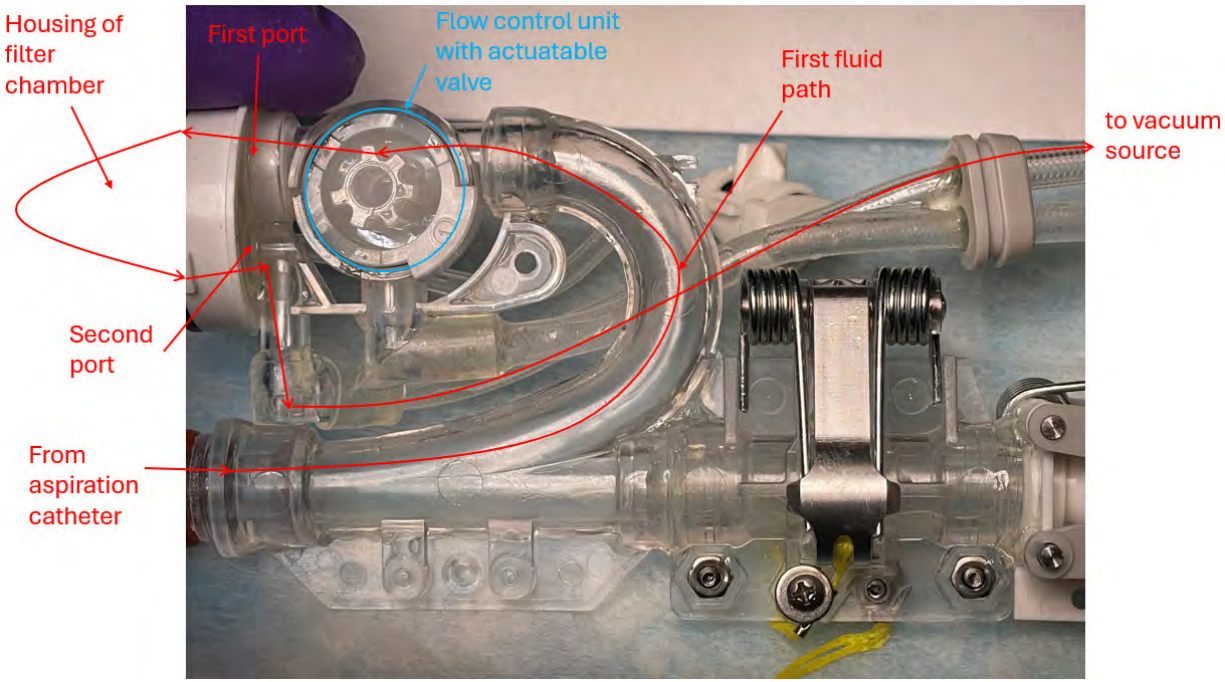
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)



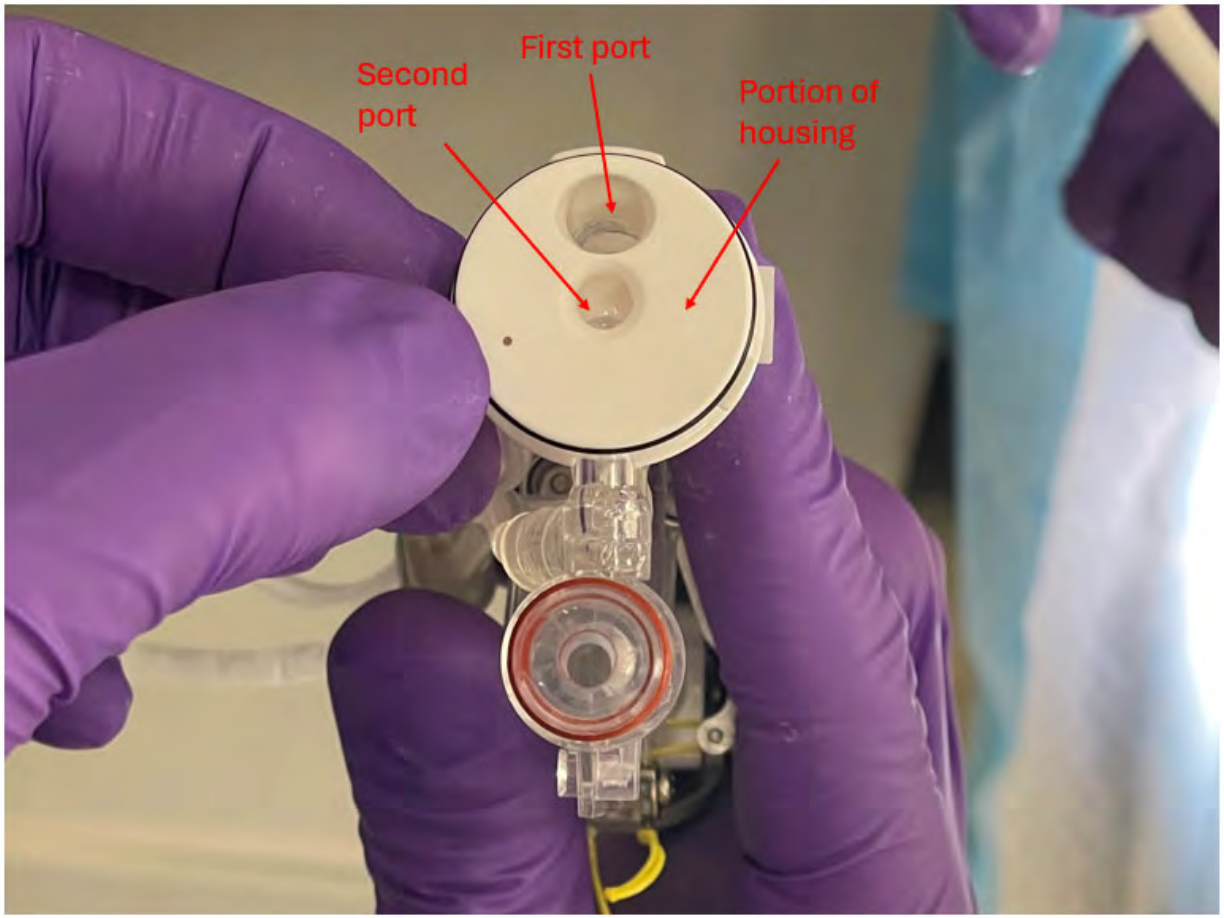
(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

To the extent Truvic argues that the housing is limited to the removable clear portion of the housing of the Symphony Catheter handle such that housing cannot include the second port, that is incorrect according to the dislcosure in the specification and claims 1 and 15, charted herein. If such a construction were adopted, however, the Symphony System will still meet this limitation under the

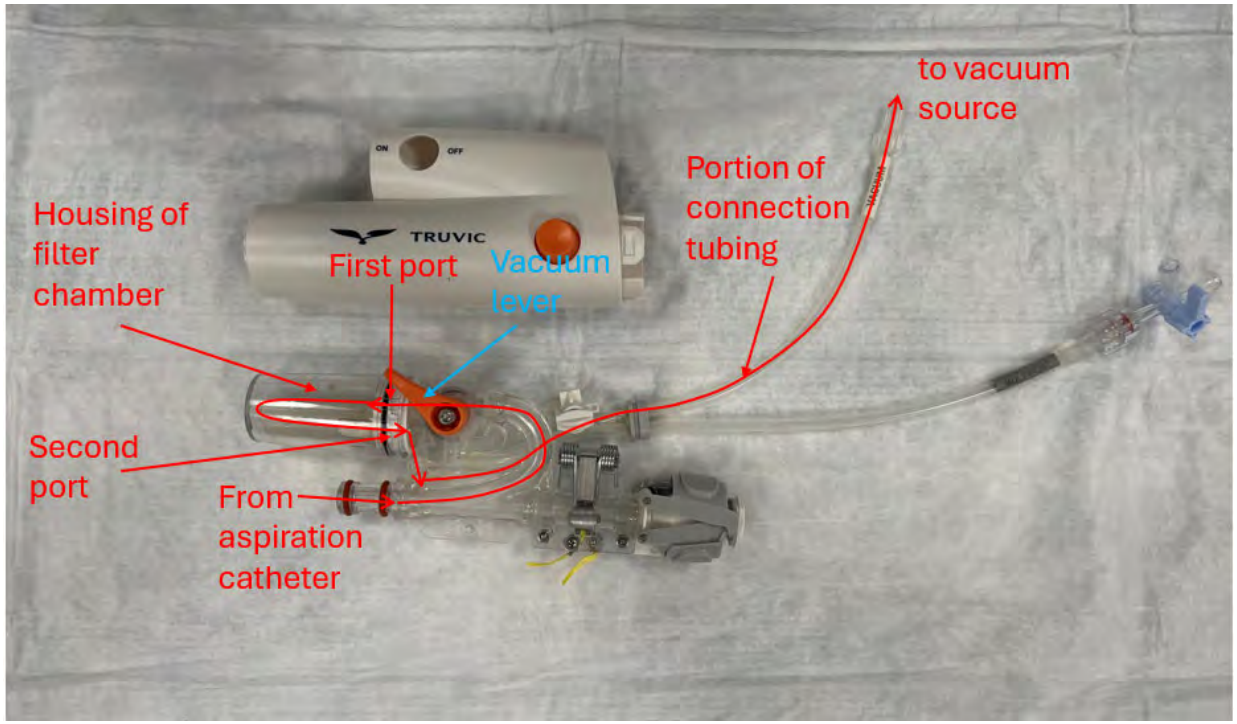
	doctrine of equivalents. For example, to the extent Truvic contends that the Symphony System housing does not include the second port and instead the first second is part of a structure separate from the housing, the Symphony System infringes under the doctirne of equivalents because the housing with a second port proximate to it still performs the same function as the recited housing that includes a second port, including fluidically coupling the housing to the vacuum source. This provides the same function as a housing that includes a second port because it allows blood to exit the housing through the filter with the clot material remaining in the housing.
wherein the filter is in the housing along the first fluid path between the first port and the second port;	The Symphony System includes a filter in the housing along the first fluid path between the first port and the second port. Specifically, the Symphony Catheter handle of the Symphony System includes a filter in the housing of the filter chamber. As shown in the annotated teardown images below, the filter is along the first fluid path between the first and the second port.

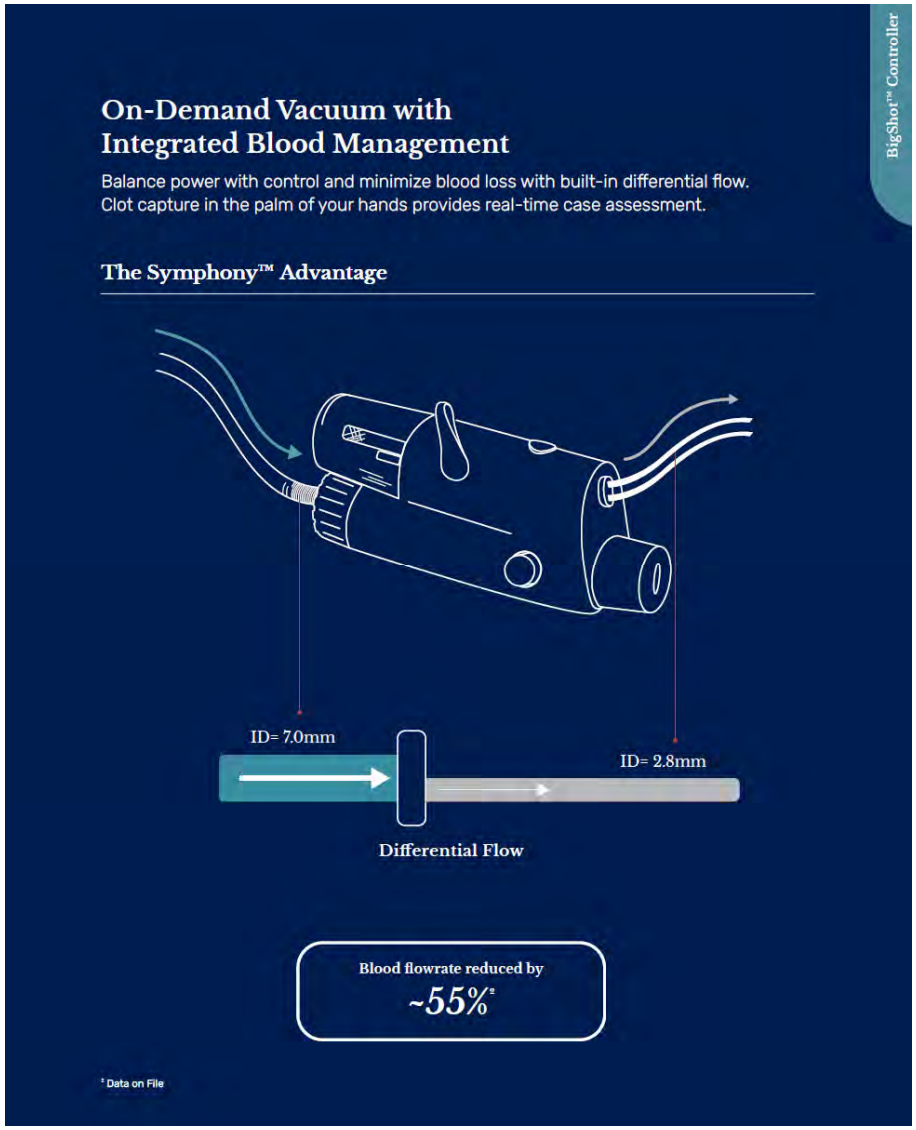


(Annotated image of internal portion of controller housing.)

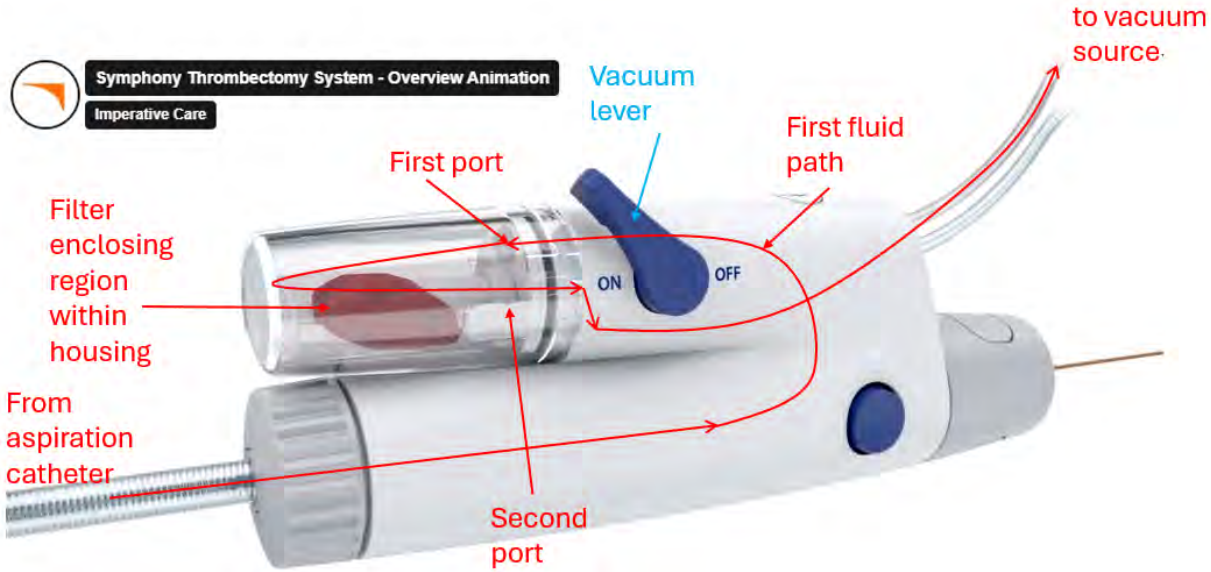


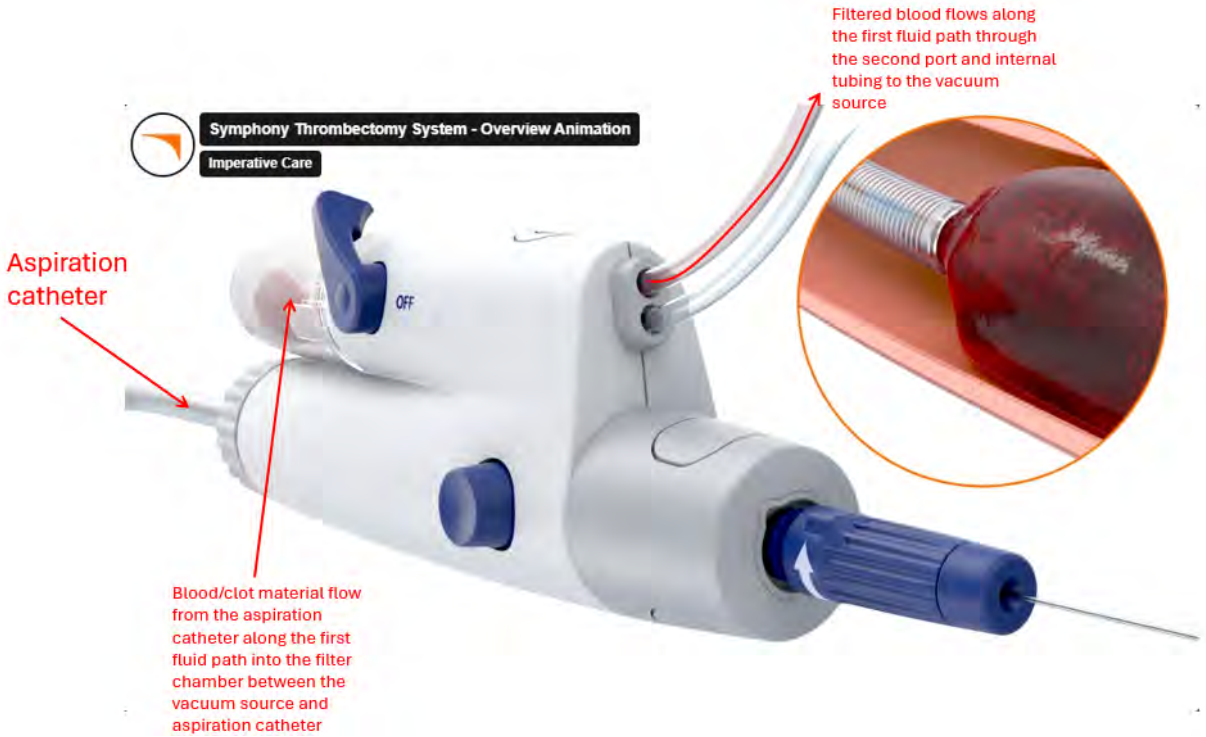
(Annotated image of controller housing showing first and second ports.)

	 (Annotated image of internal portion of the controller housing with vacuum lever.) The Symphony Thrombectomy System Brochure also partially shows the first fluid path flowing from the aspiration catheter (blue arrow) into the Symphony Catheter handle and out toward the vacuum source.



(Symphony Thrombectomy System Brochure at 7.)

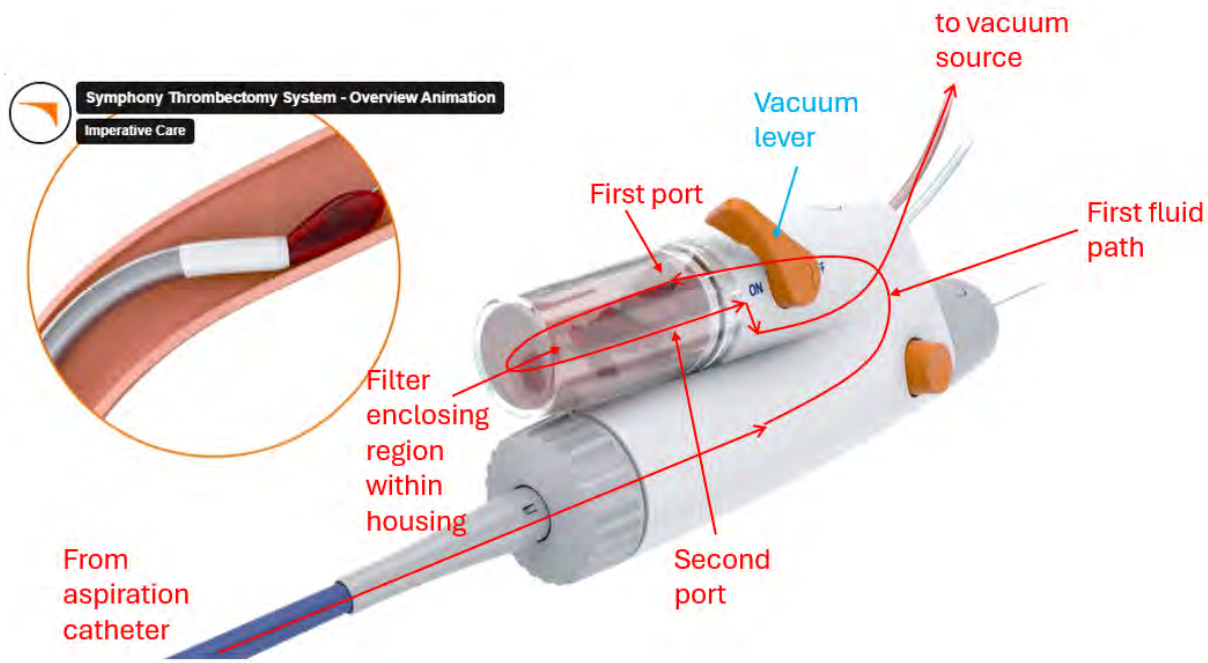
	----------24F Aspiration Catheter---------- The filter of the 24F Symphony Catheter handle is in the housing along the first fluid path, as shown in the annotated images below, and is along the first fluid path between the first and second ports.  (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

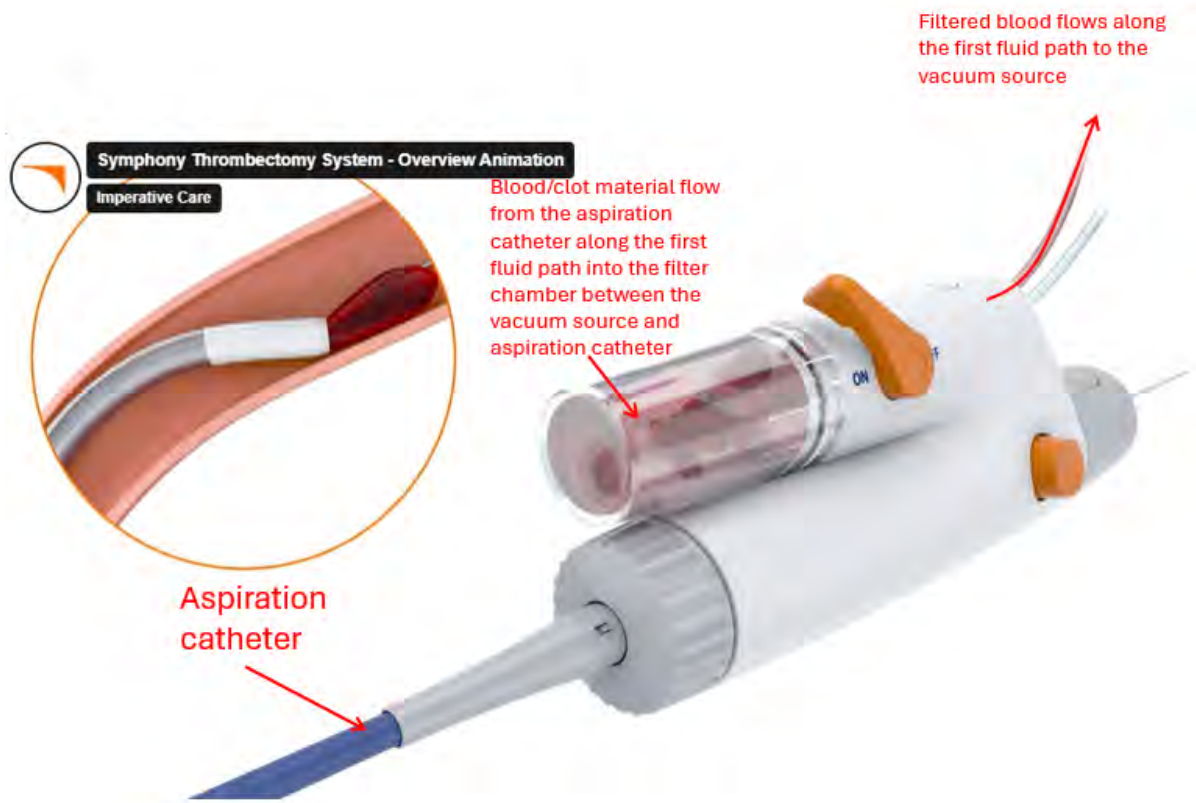


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:00.)

As shown in the image below, blood and clot material from the aspiration catheter flow along the first fluid path, through the first port into the filter chamber. Blood then travels through the filter (where the clot material is unable to pass and, therefore, remains in the housing) and through the second port along the first fluid path to the Truvic Canister (*e.g.*, part of the vacuum source) via the Truvic primary tubing.

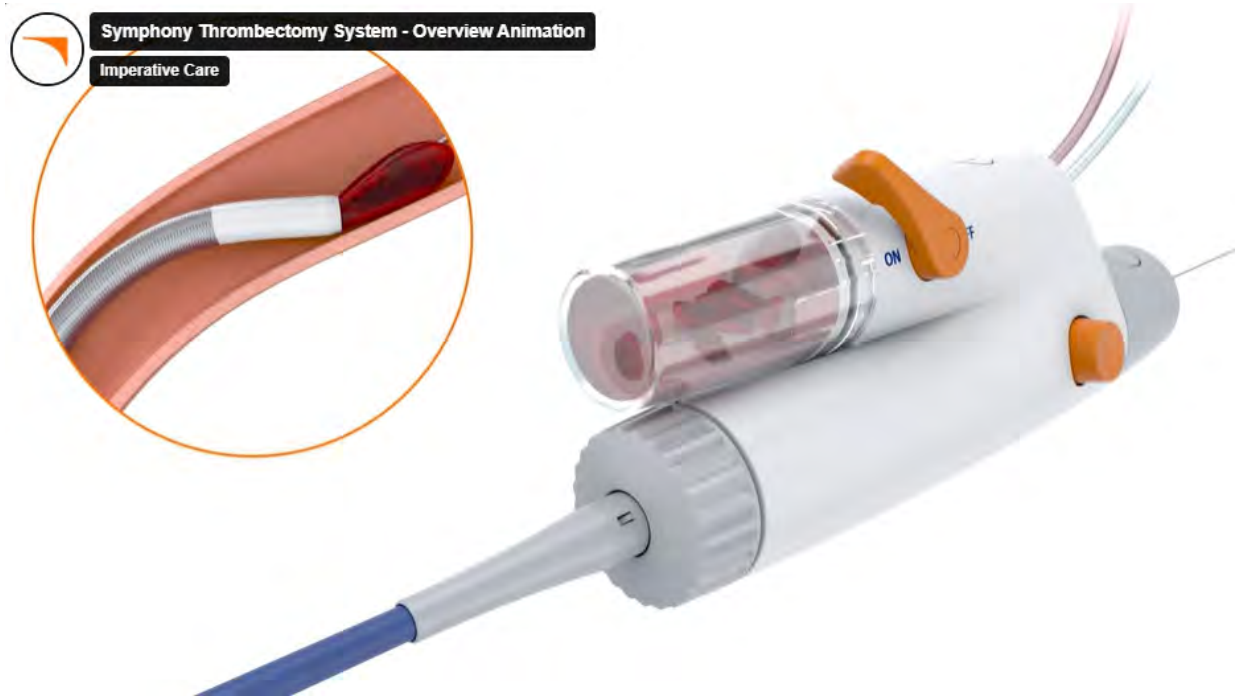
	  (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) **----------16F Aspiration Catheter----------** The filter of the 16F Symphony Catheter handle is in the housing along the first fluid path between the first and second ports, as shown in the annotated images below.

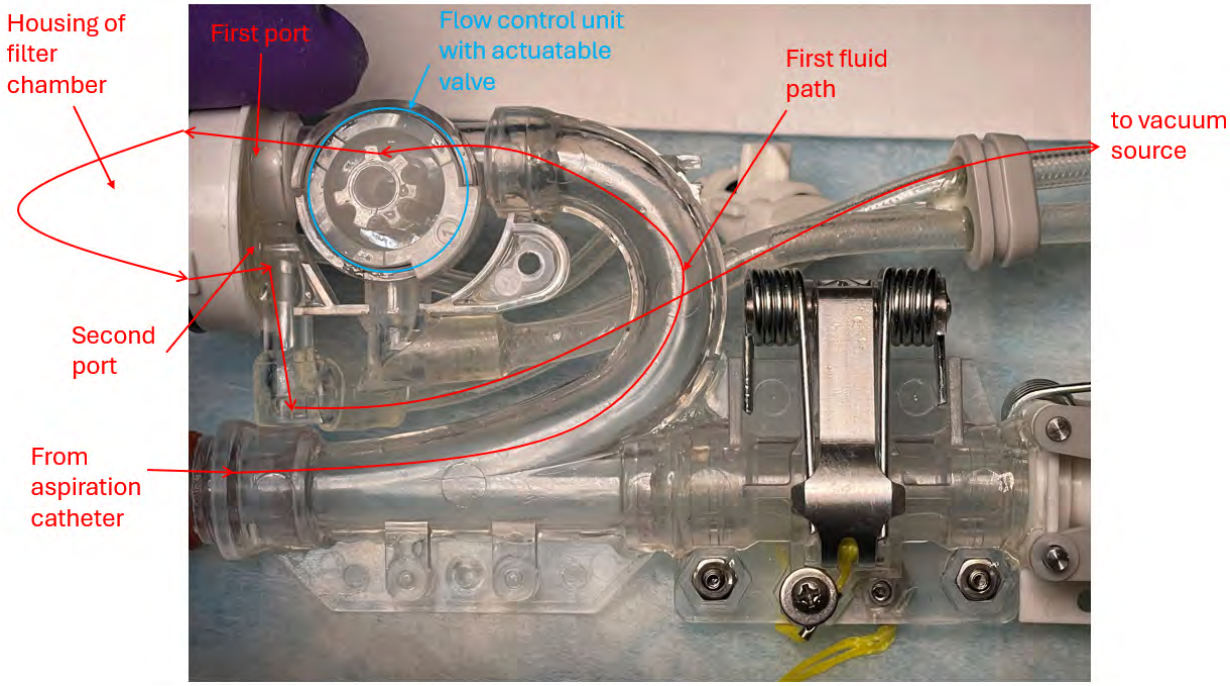
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

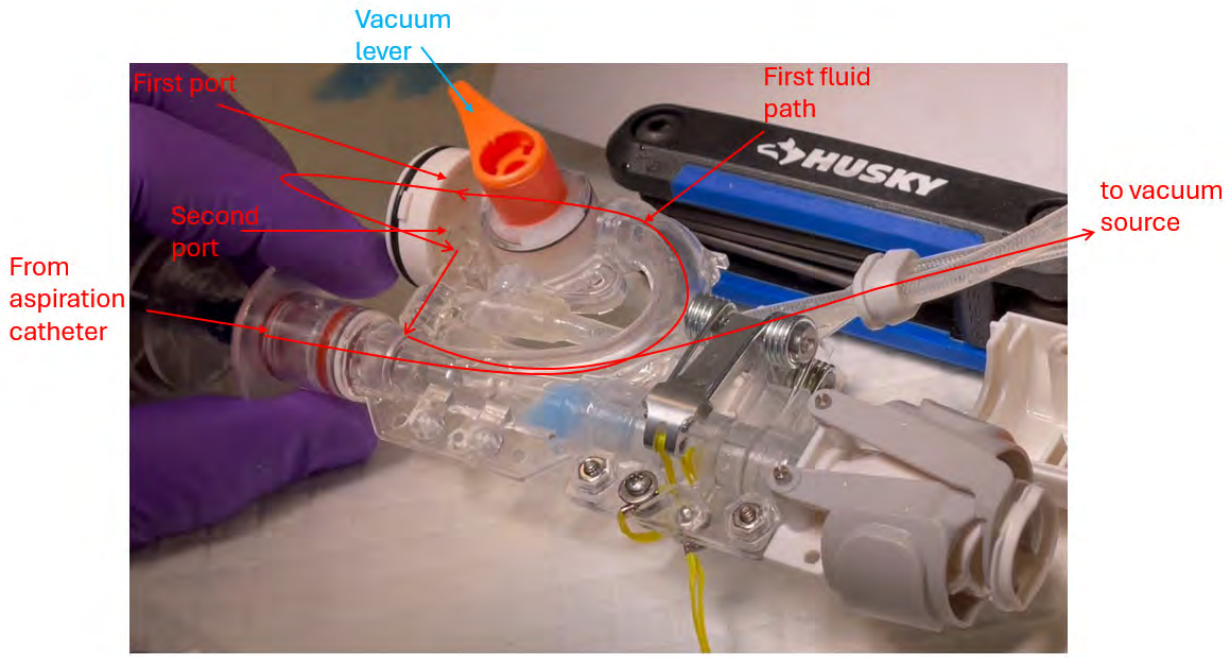


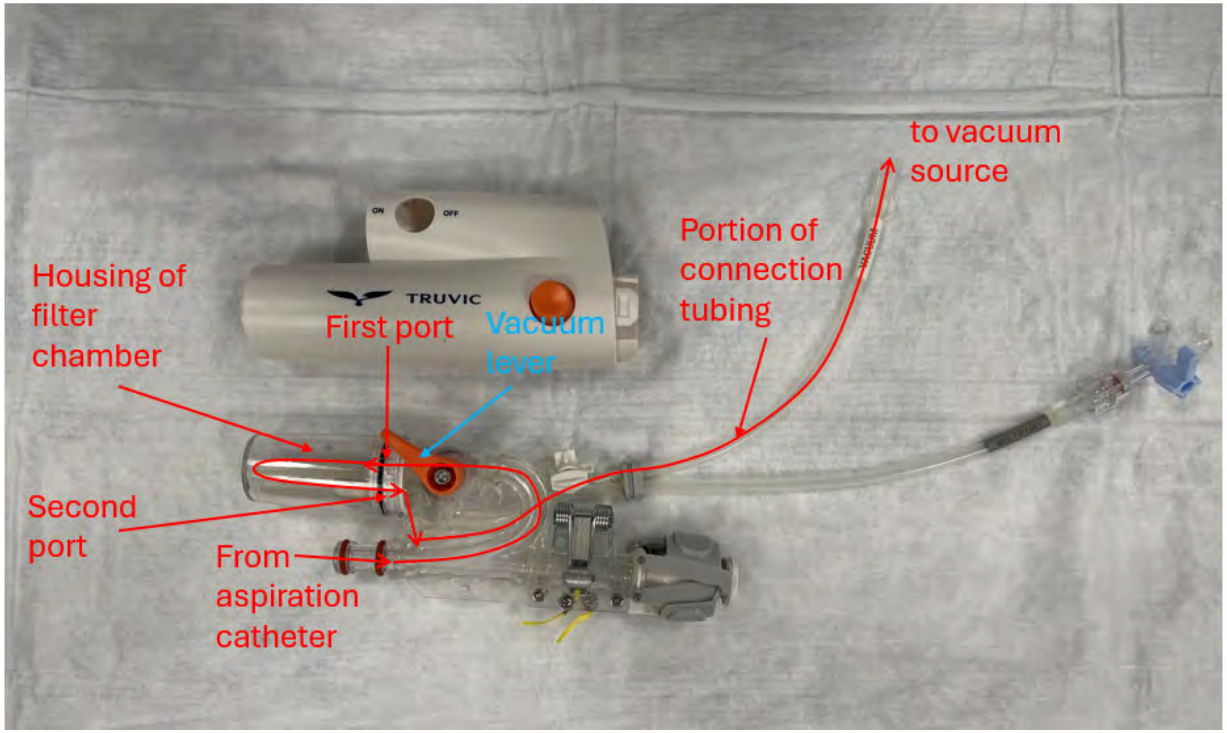
(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

As shown in the image below, blood and clot material from the aspiration catheter flow along the first fluid path, through the first port into the filter chamber. Blood then travels through the filter (where the clot material is unable to pass and, therefore, remains in the housing) and through the second port along the first fluid

	path to the Truvic Canister (*e.g.*, part of the vacuum source) via the Truvic primary or secondary tubing.  (Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a flow controller fluidically coupling the filter chamber to the catheter, wherein the flow controller is along the first fluid	The Symphony System includes a flow controller fluidically coupling the filter chamber to the catheter, where the flow controller is along the first fluid path between the filter chamber and the catheter.

path between the filter chamber and the catheter; and	Specifically, the 24F and 16F Symphony Catheter handles of the Symphony System include a vacuum control valve and vacuum lever (*e.g.*, a flow controller) that fluidically couples the filter chamber to the catheter and is along the first fluid path between the filter chamber and catheter, as shown in the annotated teardown images below.  (Annotated image of internal portion of controller housing.)

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

	 (Annotated image of internal portion of the controller housing with vacuum lever.) The Symphony System IFU depicts the vacuum lever, which is able to switch between an “ON” and “OFF” position.

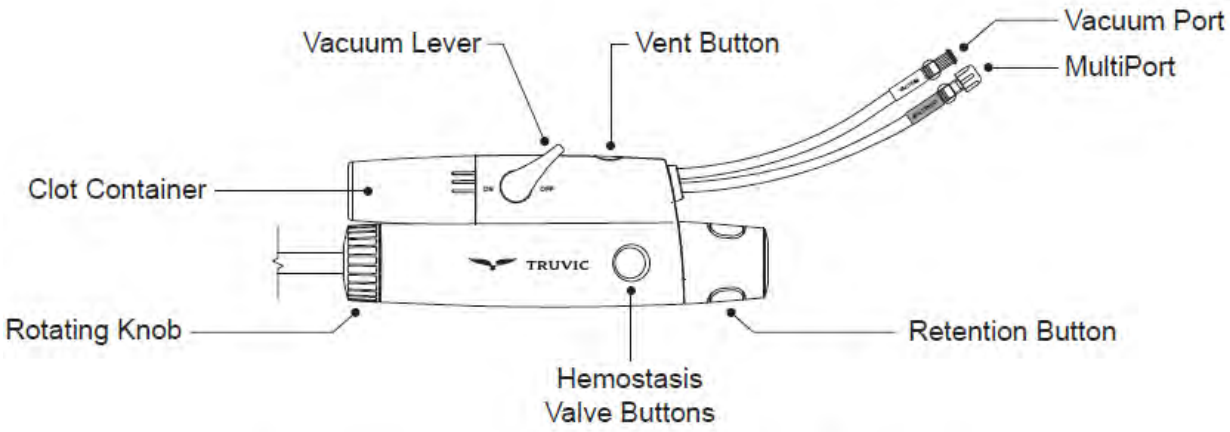
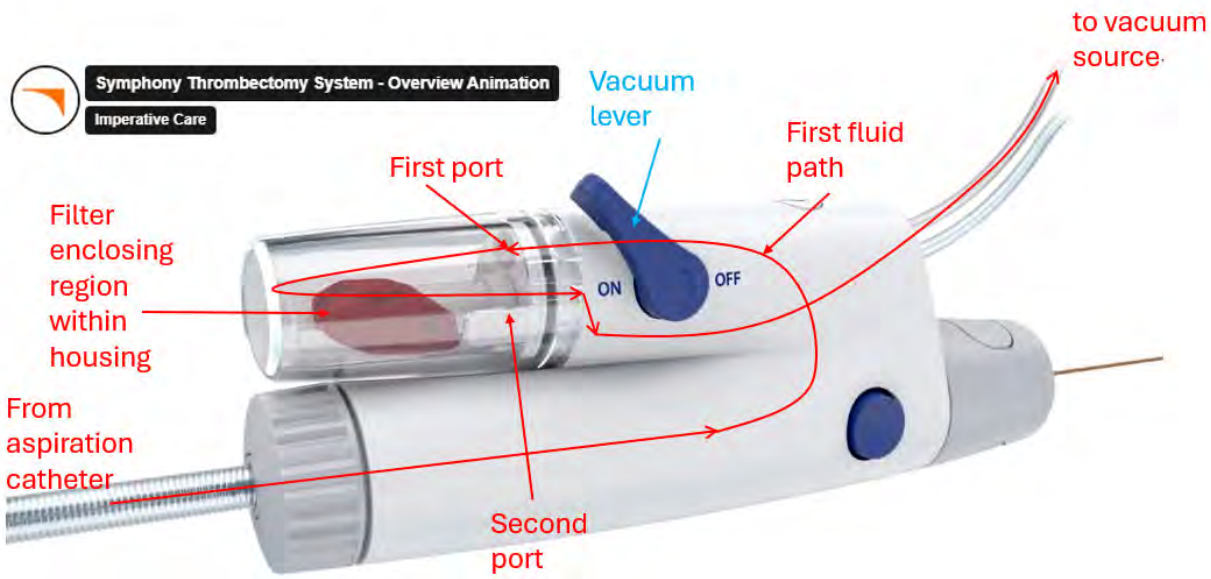


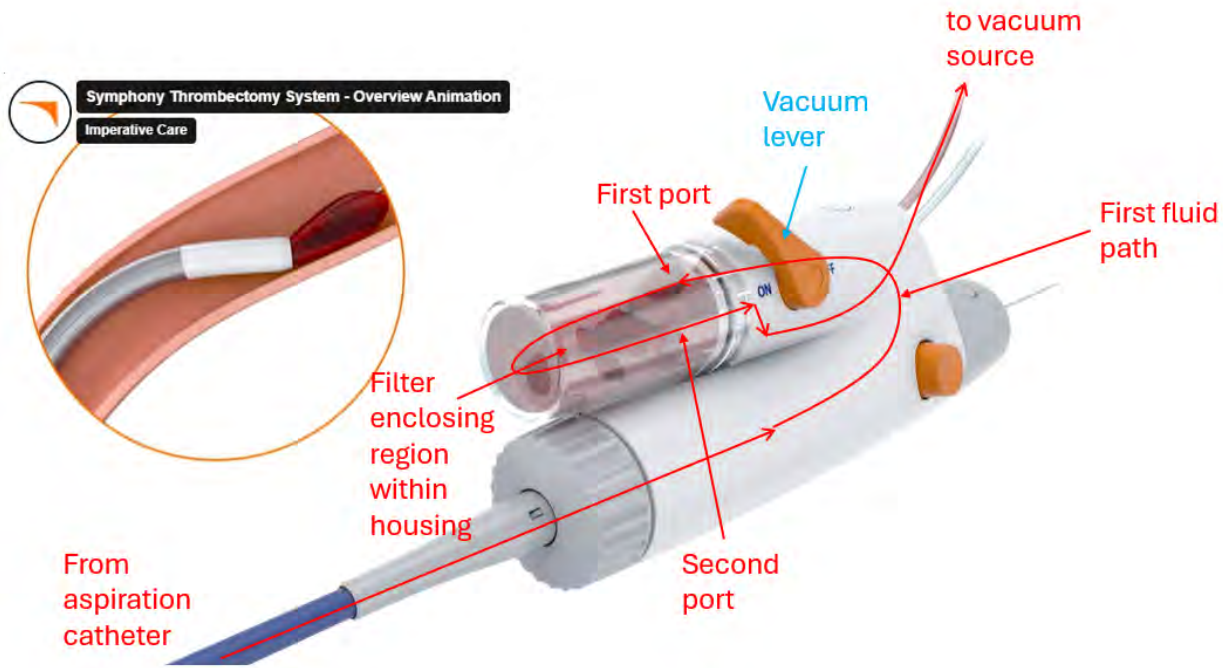
Figure 3: Symphony Catheter Handle, labeled

(Symphony Thrombectomy System Instructions For Use at 4.)

The Symphony System IFU confirms that the vacuum control valve (which is coupled to the vacuum lever) of the Symphony Catheter handle fluidically couples the filter chamber to the catheter, such that it allows for blood to move from the aspiration catheter to the clot container (and eventually to the Truvic Canister) via the first fluid path. (Symphony Thrombectomy System Instructions For Use at 5 ("To begin aspiration, move the vacuum lever on the Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the 'OFF' position."); *see also* Symphony Thrombectomy System Instructions For Use at 8 ("To begin aspiration, move the vacuum lever on the 16F Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the 16F Handle to the 'OFF' position."); Symphony Thrombectomy System Instructions For Use at 9 ("Ensure there is no thrombus remaining in the

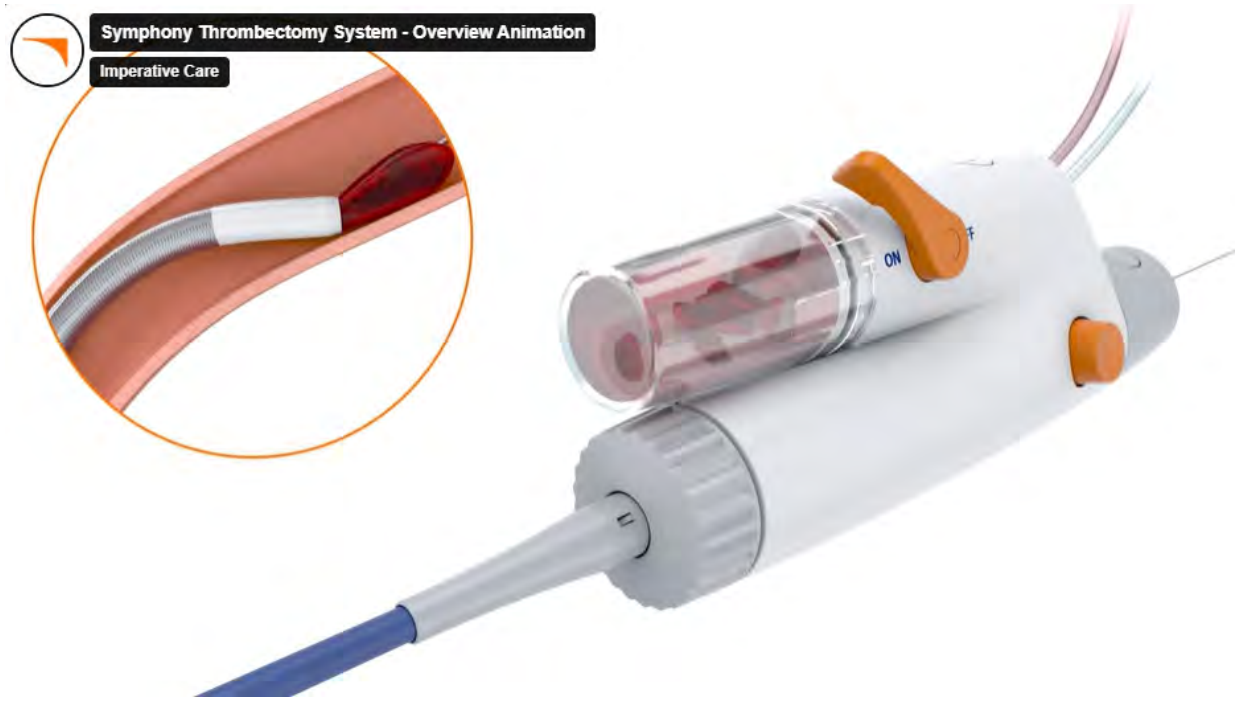
	24F Catheter by moving the vacuum lever to the 'ON' position and visualizing unrestricted blood flow through the clot container.").) **----------24F Aspiration Catheter----------** The flow controller of the 24F Symphony Catheter handle is along the first fluid path between the catheter and filter chamber, such that turning the vacuum lever to the "ON" position allows for the flow of blood and clot material from the aspiration catheter to the filter chamber, as shown in the annotated image of the 24F Symphony Catheter handle below.  (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

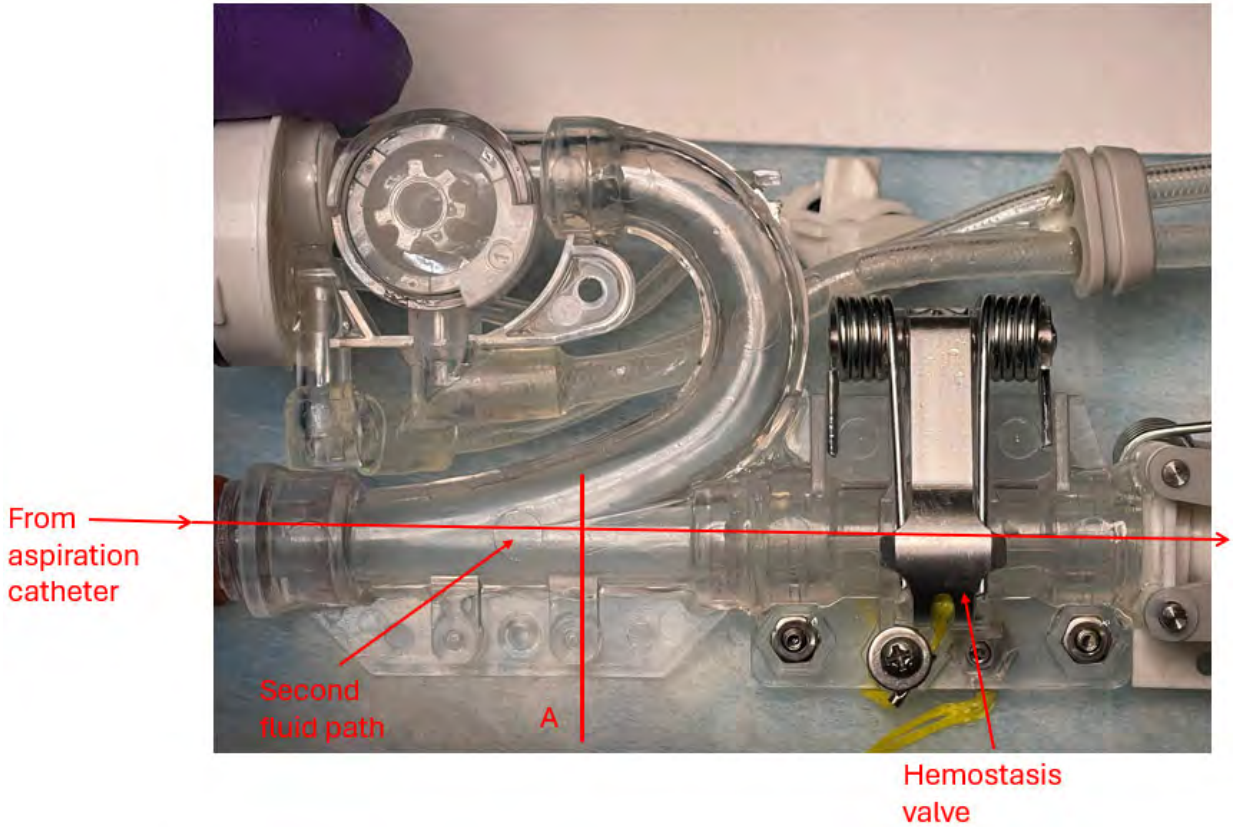
	The image below shows blood flowing from the aspiration catheter of the 24F Symphony Catheter handle to the filter chamber via the first fluid path (annotated above) when the vacuum lever is in the "ON" position, which further confirms that the flow controller of the Symphony Catheter handle fluidically couples the filter chamber to the catheter. (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) **----------16F Aspiration Catheter----------** The flow controller of the 16F Symphony Catheter handle is along the first fluid path between the catheter and filter chamber, such that turning the vacuum lever to the "ON" position allows for the flow of blood and clot material from the aspiration catheter to the filter chamber, as shown in the annotated image of the 16F Symphony Catheter handle below.

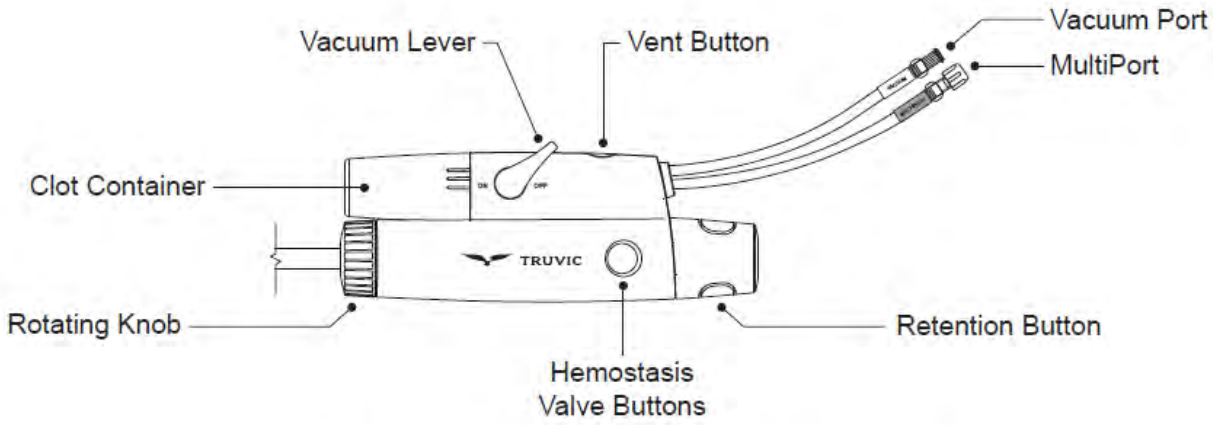


(Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

The image below shows blood flowing from the aspiration catheter of the 16F Symphony Catheter handle to the filter chamber via the first fluid path (annotated above) when the vacuum lever is in the "ON" position, which further confirms that the flow controller of the Symphony Catheter handle fluidically couples the filter chamber to the catheter.

	 (Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
a hemostasis valve fluidically coupled to the catheter along a second fluid path at least partially different than the first fluid path, wherein the hemostasis valve is configured to maintain hemostasis	The Symphony System includes a hemostasis valve fluidically coupled to the catheter along a second fluid path that is at least partially different than the first fluid path, where the hemostasis valve is configured to maintain hemostasis by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and catheter.

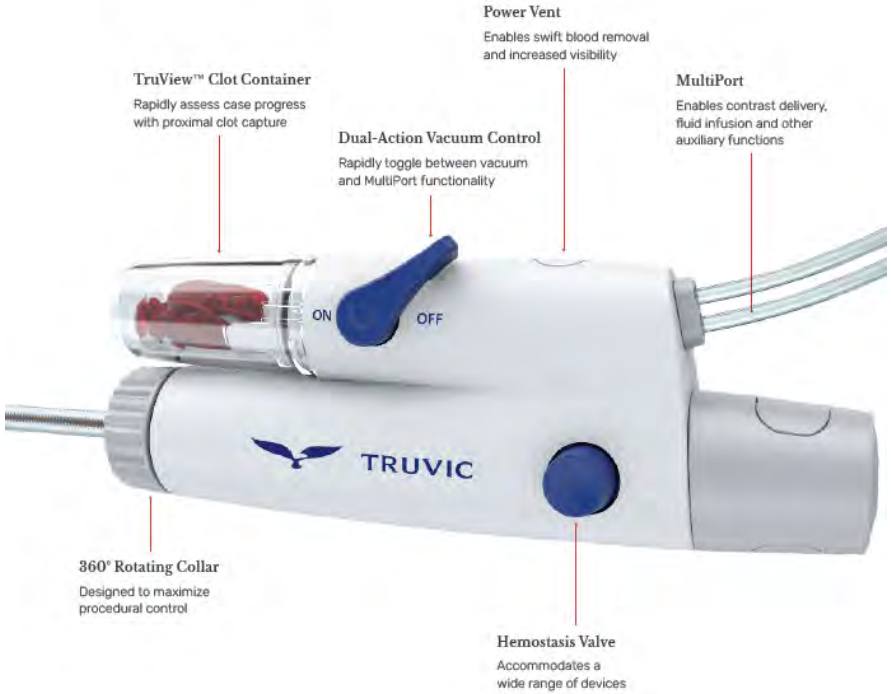
by inhibiting proximal fluid flow along the second fluid path when an interventional device is inserted through the hemostasis valve and the catheter.	Specifically, the 24F and 16F Symphony Catheter handle include a hemostasis valve that is fluidically coupled to the catheter along a second fluid path, which is at least partially different from the first fluid path, as shown in the annotated teardown image below. The second fluid path is at least partially different from the first fluid path starting at approximately point A (annotated below) and running through the hemostasis valve.  (Annotated image of internal portion of controller handle housing.)

	The Symphony System IFU shows the outer shell of the Symphony Catheter handle that includes a button for the handle's hemostasis valve.  **Figure 3: Symphony Catheter Handle, labeled** (Symphony Thrombectomy System Instructions For Use at 4.) The Symphony Thrombectomy System Brochure shows that the 24F Symphony Catheter handle includes a hemostasis valve.

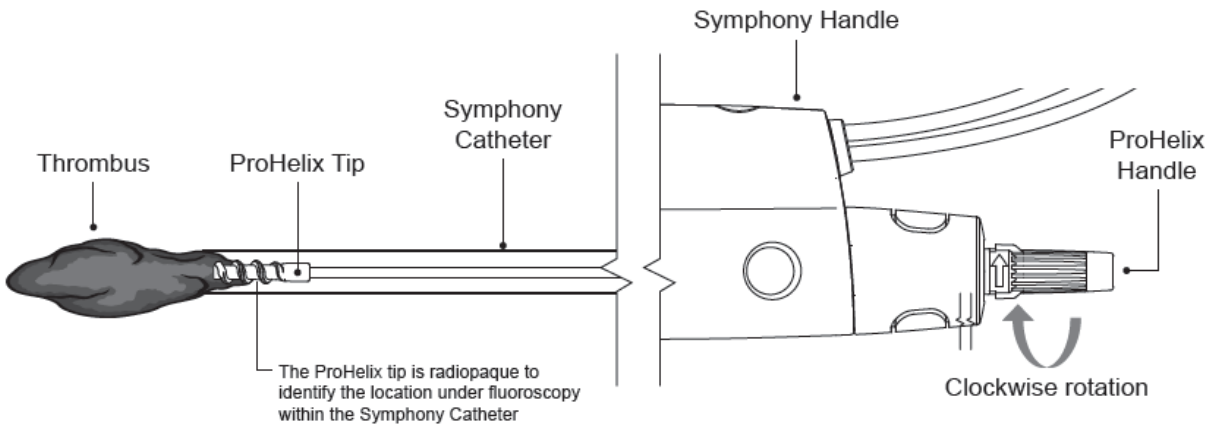
SYMPHONY™ THROMBECTOMY SYSTEM

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

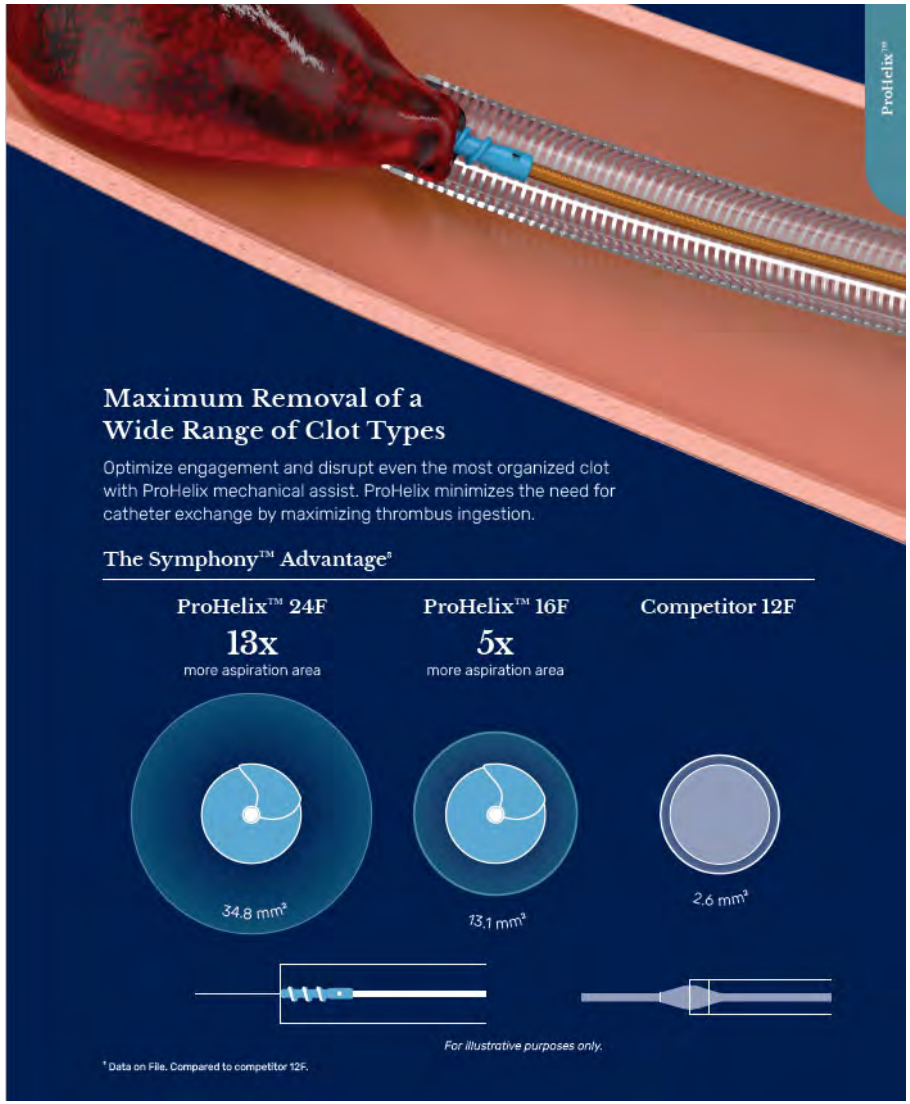
BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)

	The Symphony System IFU shows that a 24F or 16F Symphony ProHelix device (*e.g.*, an interventional device) can be inserted through the hemostasis valve and catheter to reach a clot within the human patient.  **Figure 4: ProHelix engaged with thrombus** (Symphony Thrombectomy System Instructions For Use at 5.) The Symphony System IFU describes the interventional nature of the ProHelix device and how it can be inserted through the hemostasis valve and into the catheter. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony ProHelix device may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter."); Symphony Thrombectomy System Instructions For Use at 1 ("As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the

	proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter.”); Symphony Thrombectomy System Instructions For Use at 5 (“Introduce the ProHelix over the previously placed 0.035” guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle. To begin aspiration, move the vacuum lever on the Handle to the ‘ON’ position. Slowly rotate the ProHelix handle as indicated by the arrow (clockwise direction). Upon feeling resistance to rotation, slowly retract the spring-loaded ProHelix handle up to 1 cm while rotating to assist with aspiration and removal of the thrombus.”); Symphony Thrombectomy System Instructions For Use at 8-9 (same for 16F Symphony Catheter handle); Symphony Thrombectomy System Instructions For Use at 5 (“When aspiration is complete, depress the Retention Clip buttons on the Handle and withdraw the ProHelix approximately 1 cm from the Catheter. Then press the Hemostasis Valve buttons on the Handle to reduce friction while withdrawing the ProHelix from the Catheter completely. Ensure the Hemostasis Valve buttons are completely depressed when pulling the ProHelix tip through the Valve.”).) The Symphony Thrombectomy System Brochure describes how the Symphony ProHelix (*e.g.*, an interventional device) can be used to extract clot material. (Symphony Thrombectomy System Brochure at 9 (“Optimize engagement and disrupt even the most organized clot with ProHelix mechanical assist. ProHelix minimizes the need for catheter exchange by maximizing thrombus ingestion.”).)

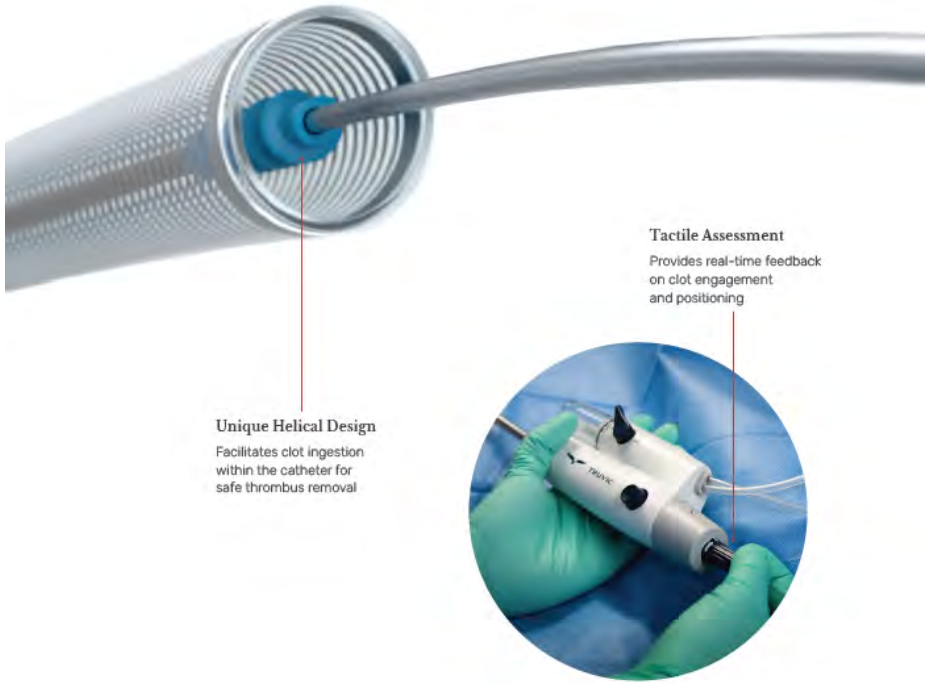


(Symphony Thrombectomy System Brochure at 9.)

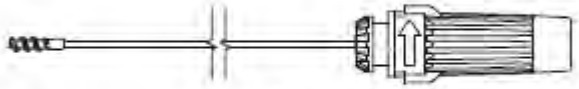
SYMPHONY™ THROMBECTOMY SYSTEM

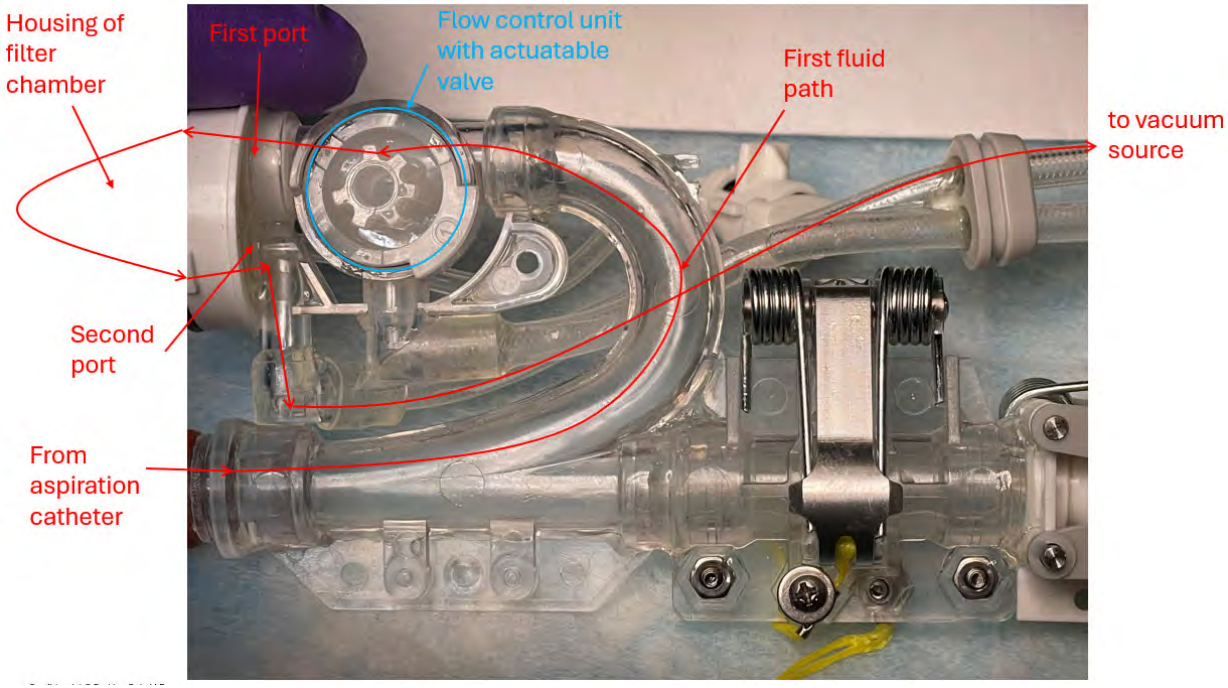
Mechanical Assist Optimizes Clot Engagement & Capture

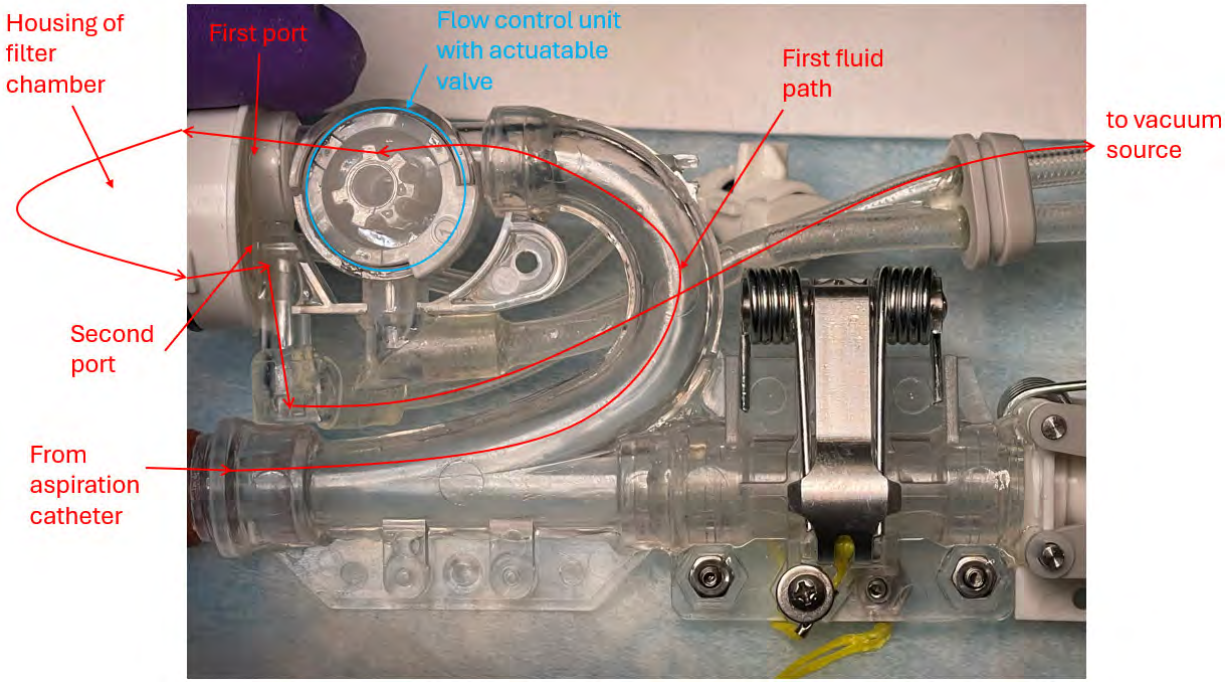
ProHelix™ Mechanical Assist

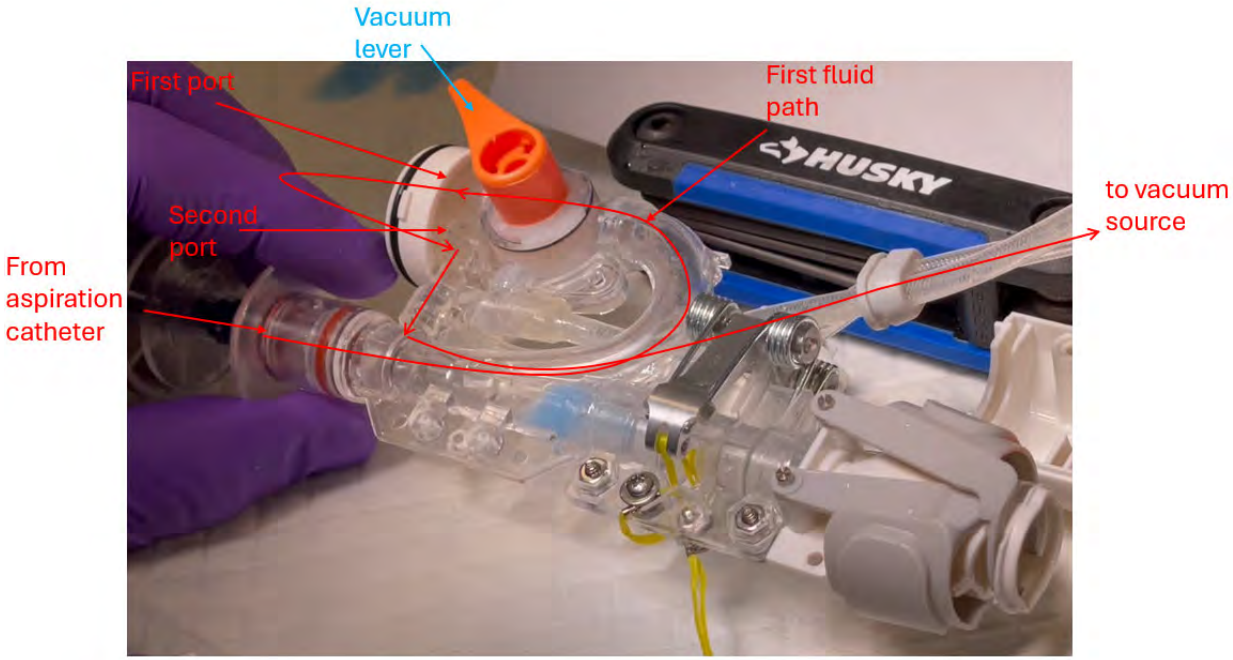


(Symphony Thrombectomy System Brochure at 8.)

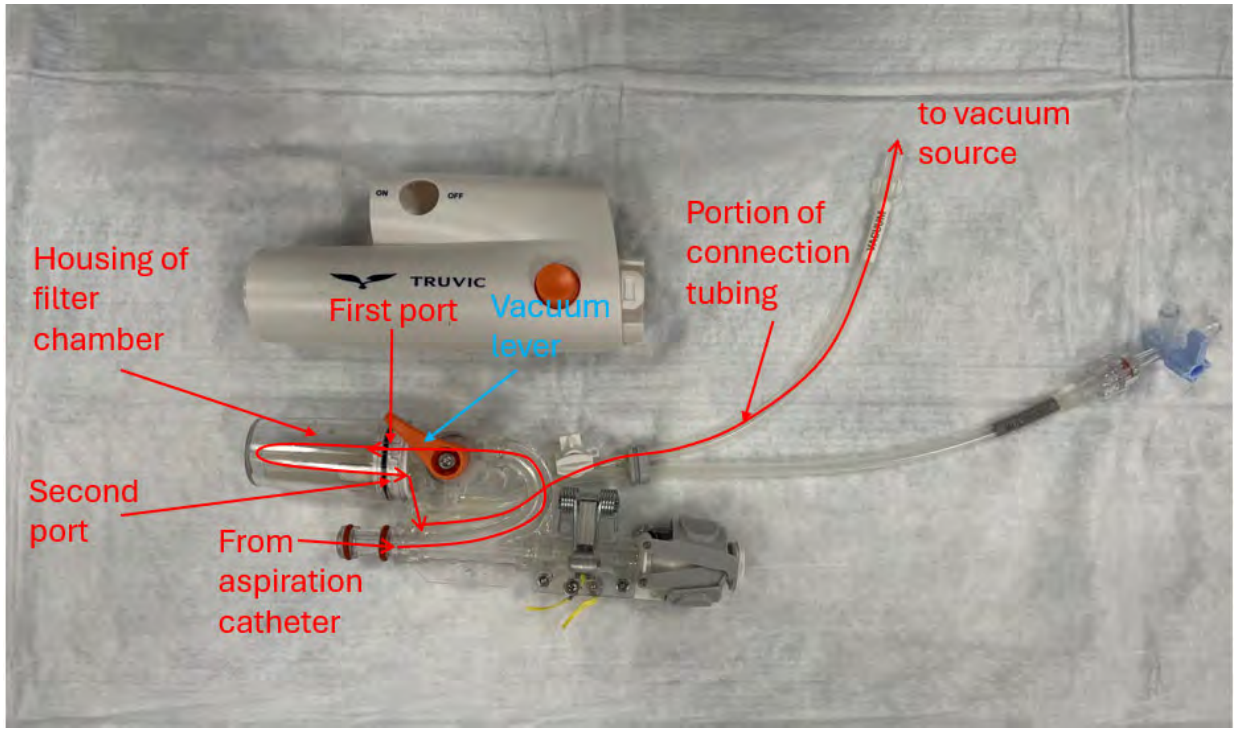
	 ProHelix 16F / 24F (Symphony Thrombectomy System Instructions For Use at 1.) The Symphony System IFU states to push the Hemostasis Valve Buttons on the 24F or 16F Symphony Catheter handle to release the hemostasis valve and then to advance the ProHelix device over the guidewire to the clot. (Symphony Thrombectomy System Instructions For Use at 2 ("Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device."); Symphony Thrombectomy System Instructions For Use at 5 ("Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle."), 6 ("During ProHelix movement, press the Hemostasis Valve buttons on the Handle to reduce friction.").) Hemostasis valves are used to inhibit proximal fluid flow from the catheter when an interventional device is inserted through the hemostasis valve and catheter. To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[16] The aspiration system of claim 15 wherein the flow controller	The Symphony System includes a flow controller that comprises a flow control unit between the filter chamber and the catheter.

comprises a flow control unit between the filter chamber and the catheter.	Specifically, the Symphony System with a 24F and/or 16F Symphony Catheter handle include a flow controller that comprises a flow control unit (a vacuum control valve) between the filter chamber and the catheter, as shown in the annotated teardown image below. The flow control unit is along the first fluid path between the filter chamber and the aspiration catheter.  (Annotated image of internal portion of controller housing.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

[17] The aspiration system of claim 16 wherein the flow control unit comprises a user-actuatable valve.	The Symphony System includes a flow control unit that comprises a user-actuatable valve. Specifically, the flow control unit of the Symphony System with a 24F and/or 16F Symphony Catheter handle comprises a user-actuatable valve. As shown in the teardown image below, the flow control unit includes an actuatable valve that is controlled by rotating the vacuum lever between the "ON" and "OFF" position.  (Annotated image of internal portion of controller housing.)



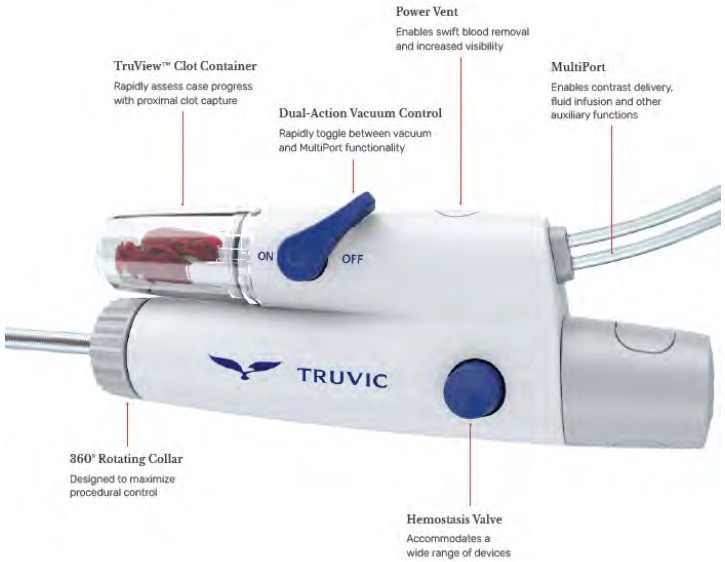
(Annotated image of internal portion of controller housing with vacuum lever.)

	 (Annotated image of internal portion of the controller housing with vacuum lever.) The Symphony Thrombectomy System Brochure also shows how the valve is actuatable where it allows for a user to "[r]apidly toggle between the vacuum and MultiPort functionality." (Symphony Thrombectomy System Brochure at 6.)

SYMPHONY™ THROMBECTOMY SYSTEM

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

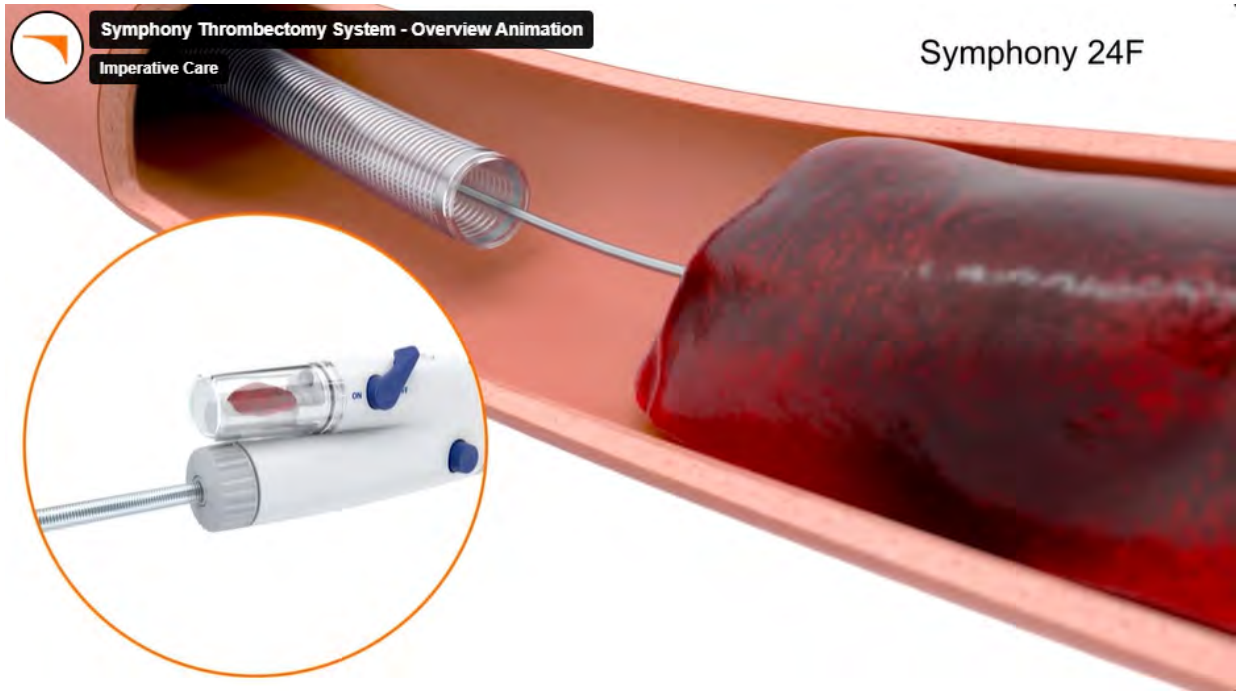
BigShot™ Controller

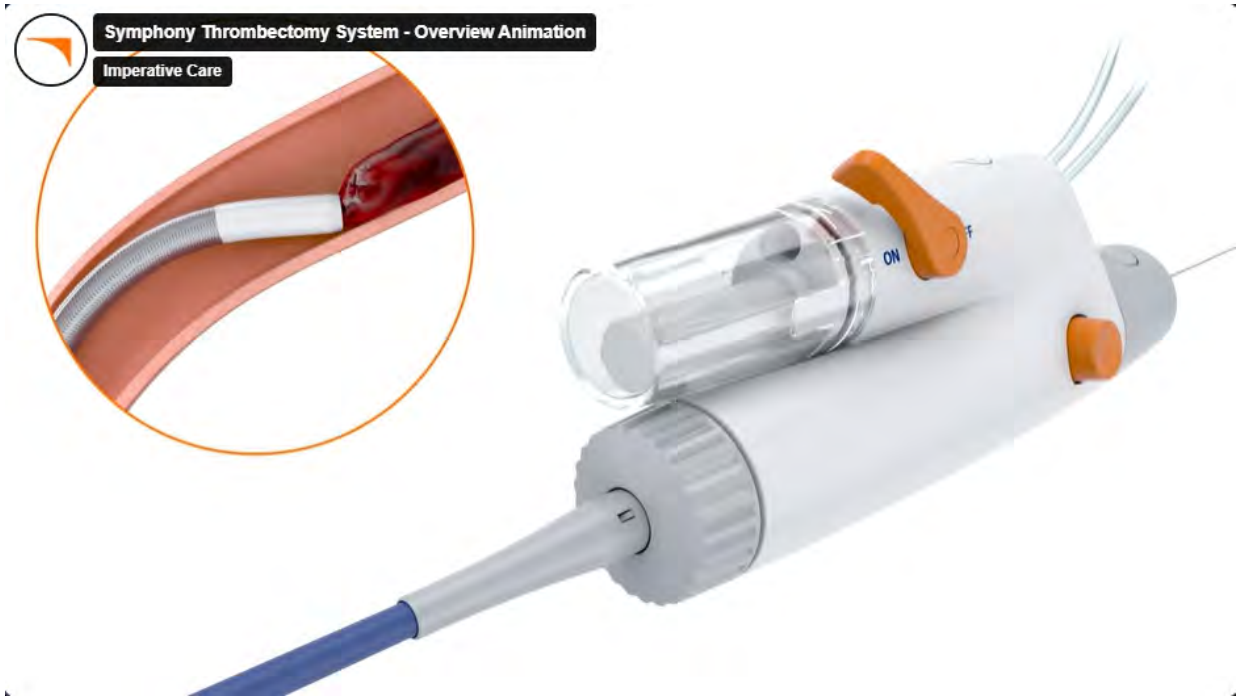


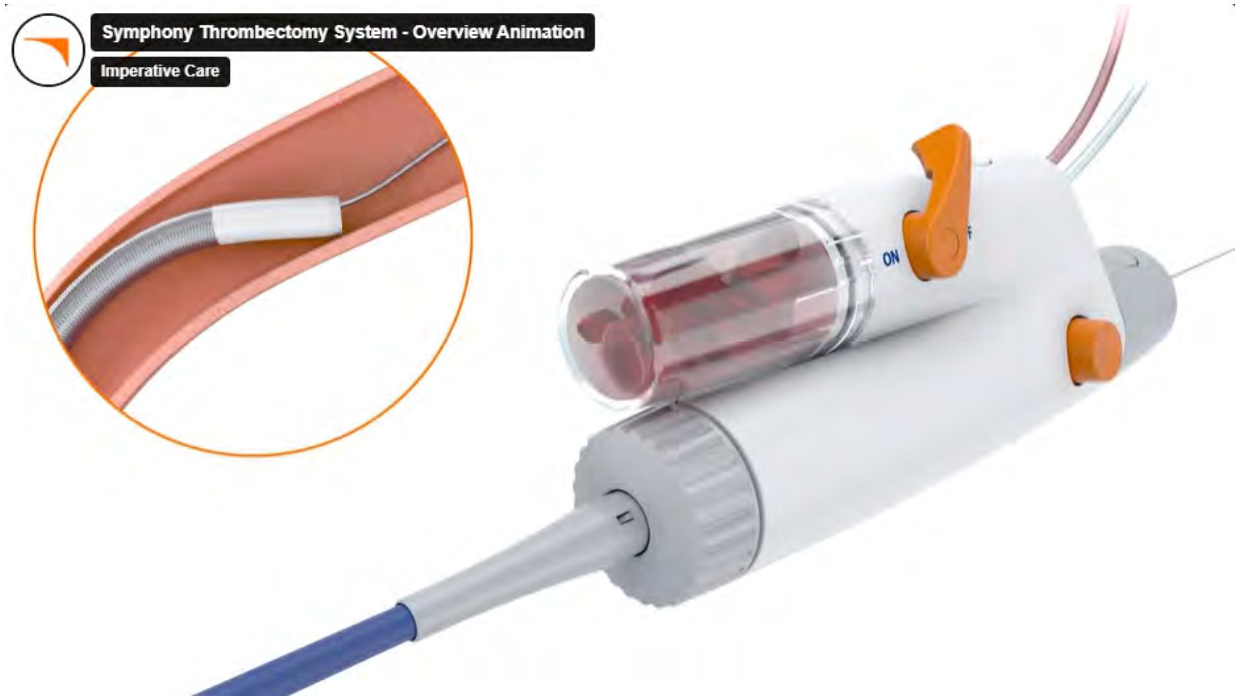
(Symphony Thrombectomy System Brochure at 6.)

The Symphony System IFU discusses how the valve in the flow control unit is user-actuatable between an "ON" and "OFF" position when a user of the Symphony System manually moves the vacuum lever between the two positions. (Symphony Thrombectomy System Instructions For Use at 3 ("In order to minimize blood loss, ensure that the Symphony Catheter handle vacuum lever is in the 'ON' position for

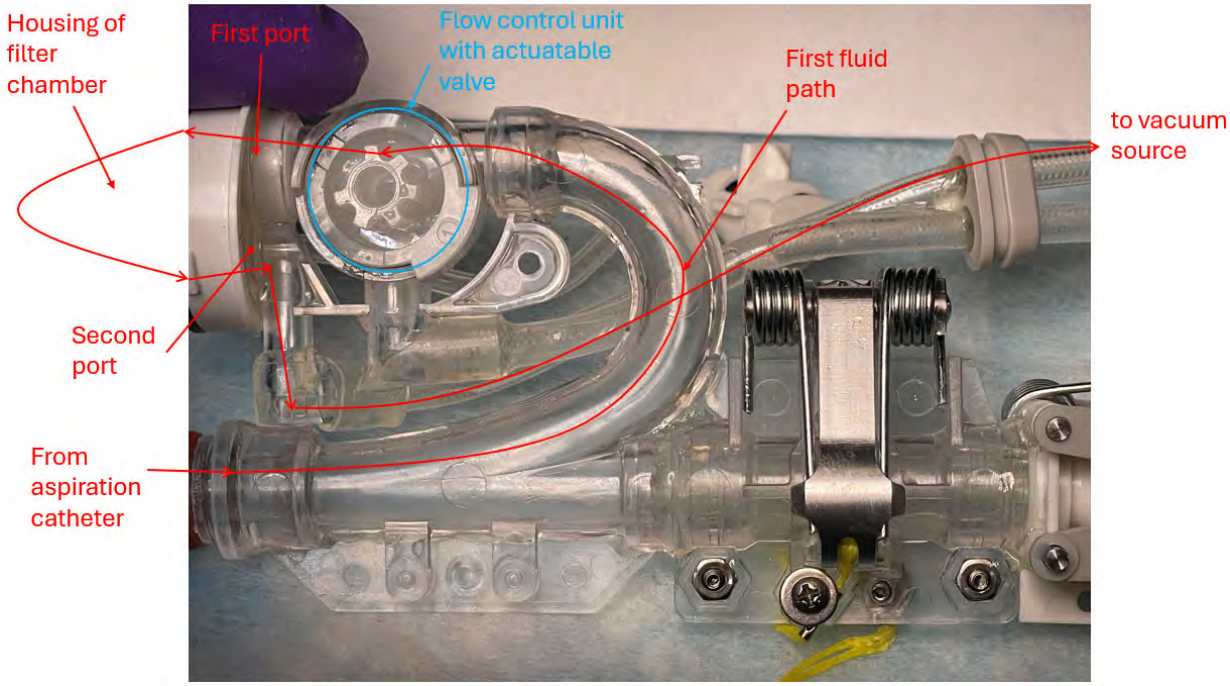
	the minimum time needed to remove the thrombus.”); Symphony Thrombectomy System Instructions For Use at 5 (“To begin aspiration, move the vacuum lever on the Handle to the ‘ON’ position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the ‘OFF’ position.”); Symphony Thrombectomy System Instructions For Use at 8 (same for 16F Symphony Catheter handle).) The ability of the valve of the flow control unit to actuate between an “ON” and “OFF” position is also shown for both the 24F and 16F Symphony Catheter handle in the Symphony Thrombectomy System Overview Animation Video. (Symphony Thrombectomy System – Overview Animation Video at 0:44.)

	 (Symphony Thrombectomy System – Overview Animation Video at 0:50.)

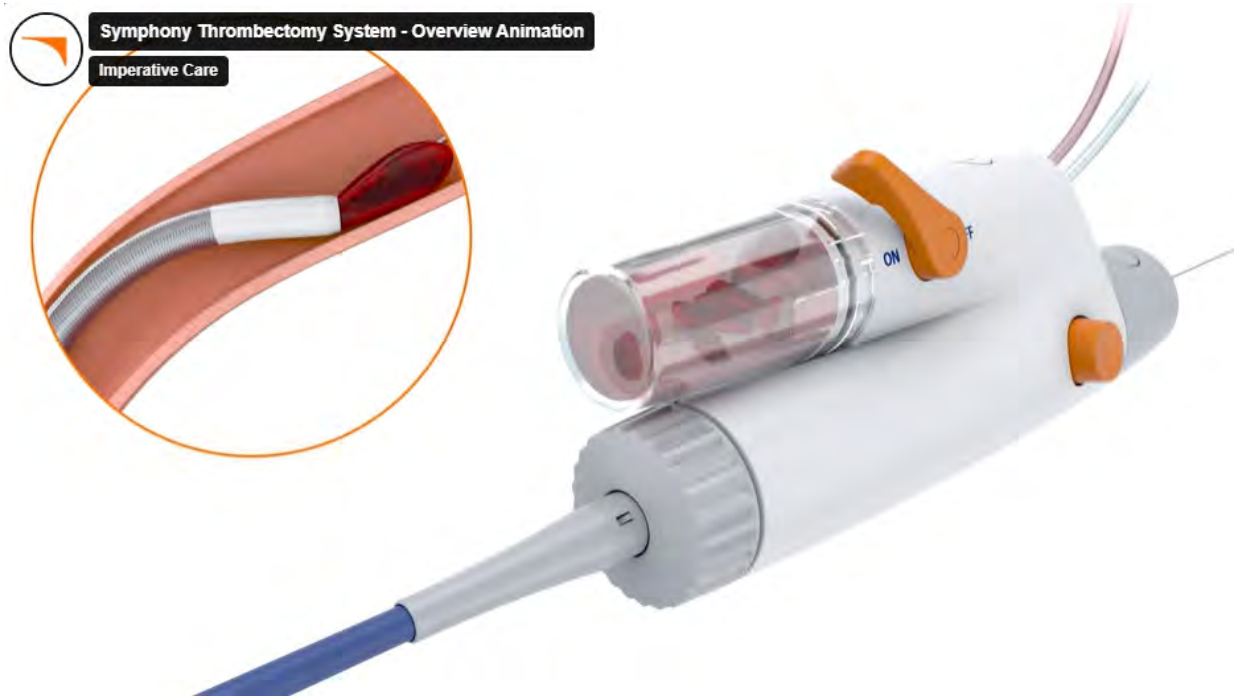
	 (Symphony Thrombectomy System – Overview Animation Video at 1:55.)

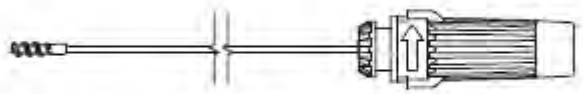
	 (Symphony Thrombectomy System – Overview Animation Video at 2:04.) The Symphony website shows that the valve of the flow control unit is user-actuated.

	  (Image from Truvic at https://www.truvic.com/symphony-product.) The Whipsaw website also confirms that the Symphony is a "handheld tool" that is used by a physician or other medical professional (*e.g.*, a user). (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

[18] The aspiration system of claim 15 wherein the catheter is fluidically connected in serial to the filter chamber along the first fluid path.	The Symphony System includes a catheter that is fluidically connected in serial to the filter chamber along the first fluid path. Specifically, the 24F catheter of the 24F Symphony Catheter handle and the 16F catheter of the 16F Symphony Catheter handle are fluidically coupled in serial to the filter chamber along the first filter path, as shown in the annotated teardown image below. Specifically, the first fluid path starts at the aspiration catheter and runs to the filter chamber, which is serially coupled to the catheter.  (Annotated image of internal portion of controller housing.)

	----------24F Aspiration Catheter---------- The image of the 24F Symphony Catheter handle below shows blood flowing from the aspiration catheter of the 24F Symphony Catheter handle to the filter chamber via the first fluid path (annotated above) when the vacuum lever is in the "ON" position, which demonstrates that the catheter and filter chamber are fluidically coupled. (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) **----------16F Aspiration Catheter----------** The image of the 16F Symphony Catheter handle below shows blood flowing from the aspiration catheter of the 16F Symphony Catheter handle to the filter chamber via the first fluid path (annotated above) when the vacuum lever is in the "ON"

	position, which demonstrates that the catheter and filter chamber are fluidically coupled.  (Symphony Thrombectomy System – Overview Animation Video at 2:02.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[19] The aspiration system of claim 15, further comprising the interventional device.	The Symphony System can include an interventional device. Specifically, the Symphony System can include the 24F or 16F ProHelix device, which is an interventional device shown in the Symphony System IFU below.



(Symphony Thrombectomy System Instructions For Use at 1.)

The Symphony System IFU shows that a 24F or 16F Symphony ProHelix device (*e.g.*, an interventional device) can be inserted through the hemostasis valve and catheter to reach a clot within the human patient.

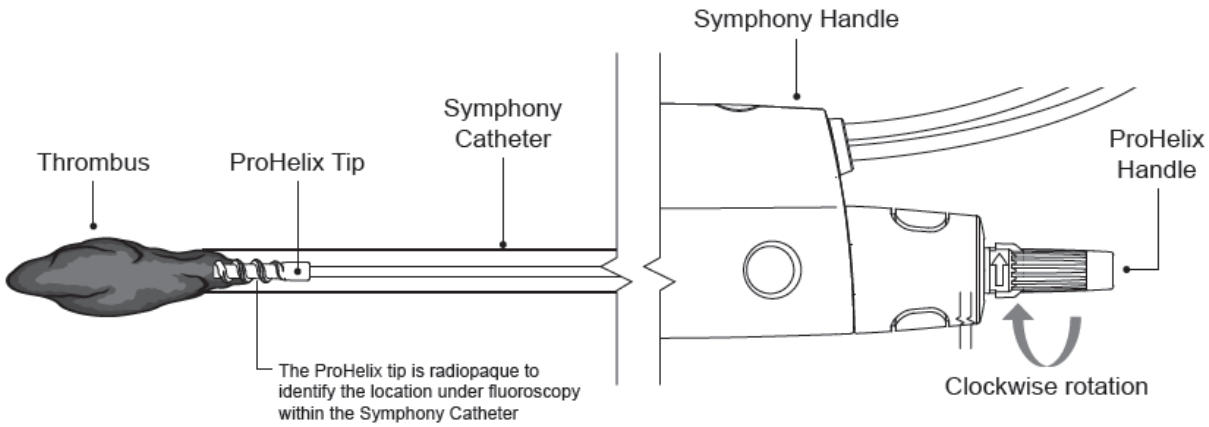


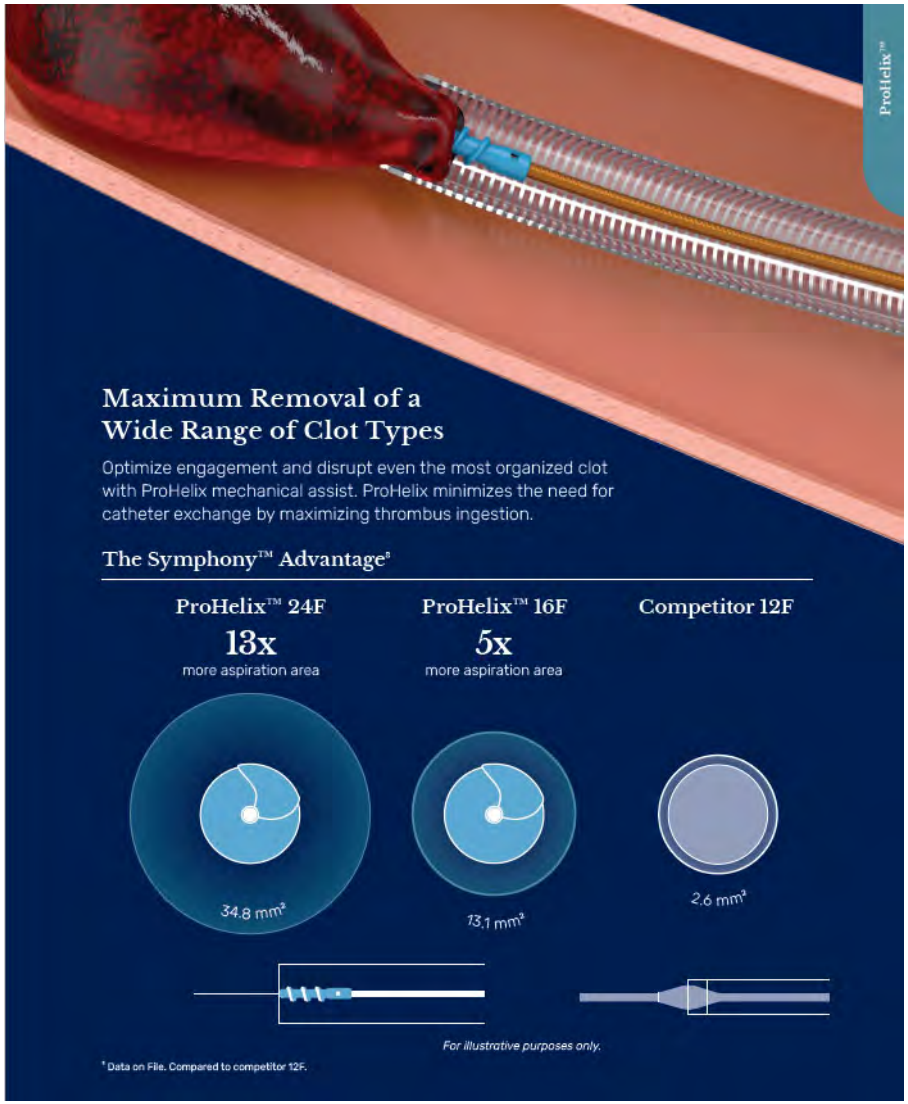
Figure 4: ProHelix engaged with thrombus

(Symphony Thrombectomy System Instructions For Use at 5.)

The Symphony System IFU describes the interventional nature of the ProHelix device and how it can be inserted through the hemostasis valve and into the

	catheter. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony ProHelix device may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter."); Symphony Thrombectomy System Instructions For Use at 1 ("As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter."); Symphony Thrombectomy System Instructions For Use at 5 ("Introduce the ProHelix over the previously placed 0.035" guidewire and through the Hemostasis Valve of the Handle until the handle of the ProHelix snaps into the Retention Clip of the Handle. To begin aspiration, move the vacuum lever on the Handle to the 'ON' position. Slowly rotate the ProHelix handle as indicated by the arrow (clockwise direction). Upon feeling resistance to rotation, slowly retract the spring-loaded ProHelix handle up to 1 cm while rotating to assist with aspiration and removal of the thrombus."); Symphony Thrombectomy System Instructions For Use at 8-9 (same for 16F Symphony Catheter handle); Symphony Thrombectomy System Instructions For Use at 5 ("When aspiration is complete, depress the Retention Clip buttons on the Handle and withdraw the ProHelix approximately 1 cm from the Catheter. Then press the Hemostasis Valve buttons on the Handle to reduce friction while withdrawing the ProHelix from the Catheter completely. Ensure the Hemostasis Valve buttons are completely depressed when pulling the ProHelix tip through the Valve.").) The Symphony Thrombectomy System Brochure describes how the Symphony ProHelix (*e.g.*, an interventional device) can be used to extract clot material. (Symphony Thrombectomy System Brochure at 9 ("Optimize engagement and

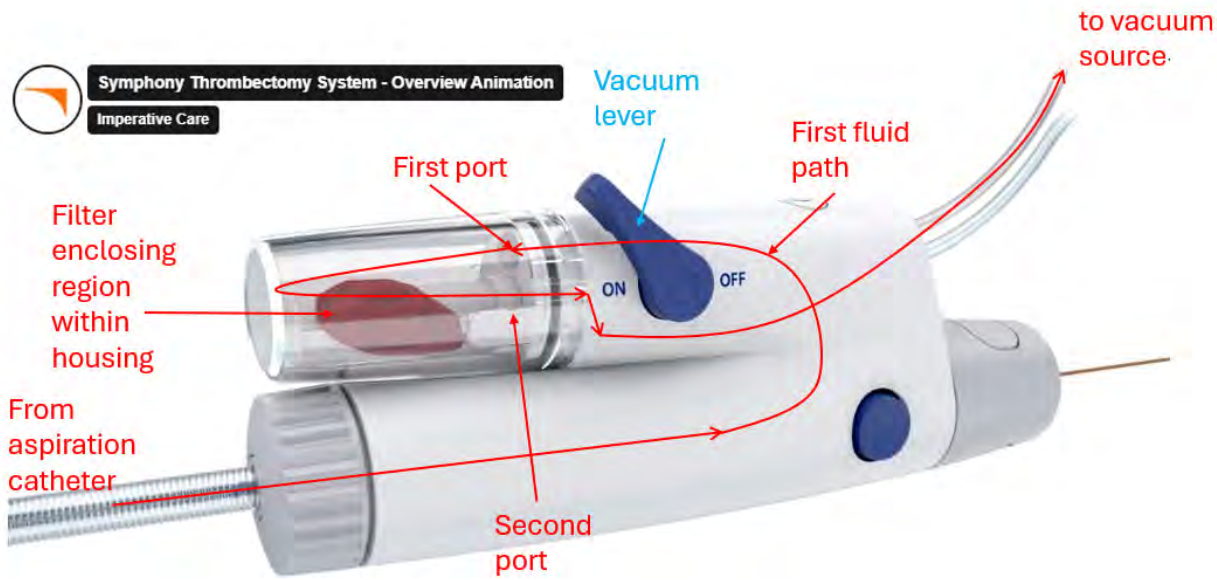
	disrupt even the most organized clot with ProHelix mechanical assist. ProHelix minimizes the need for catheter exchange by maximizing thrombus ingestion.”).)

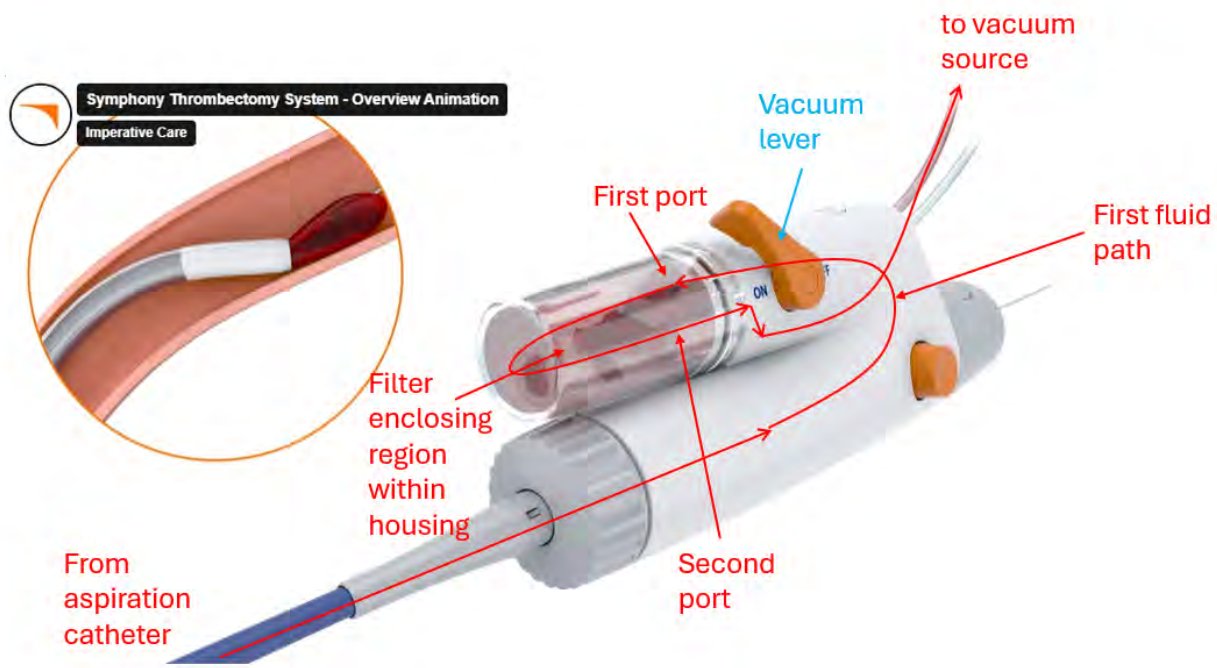


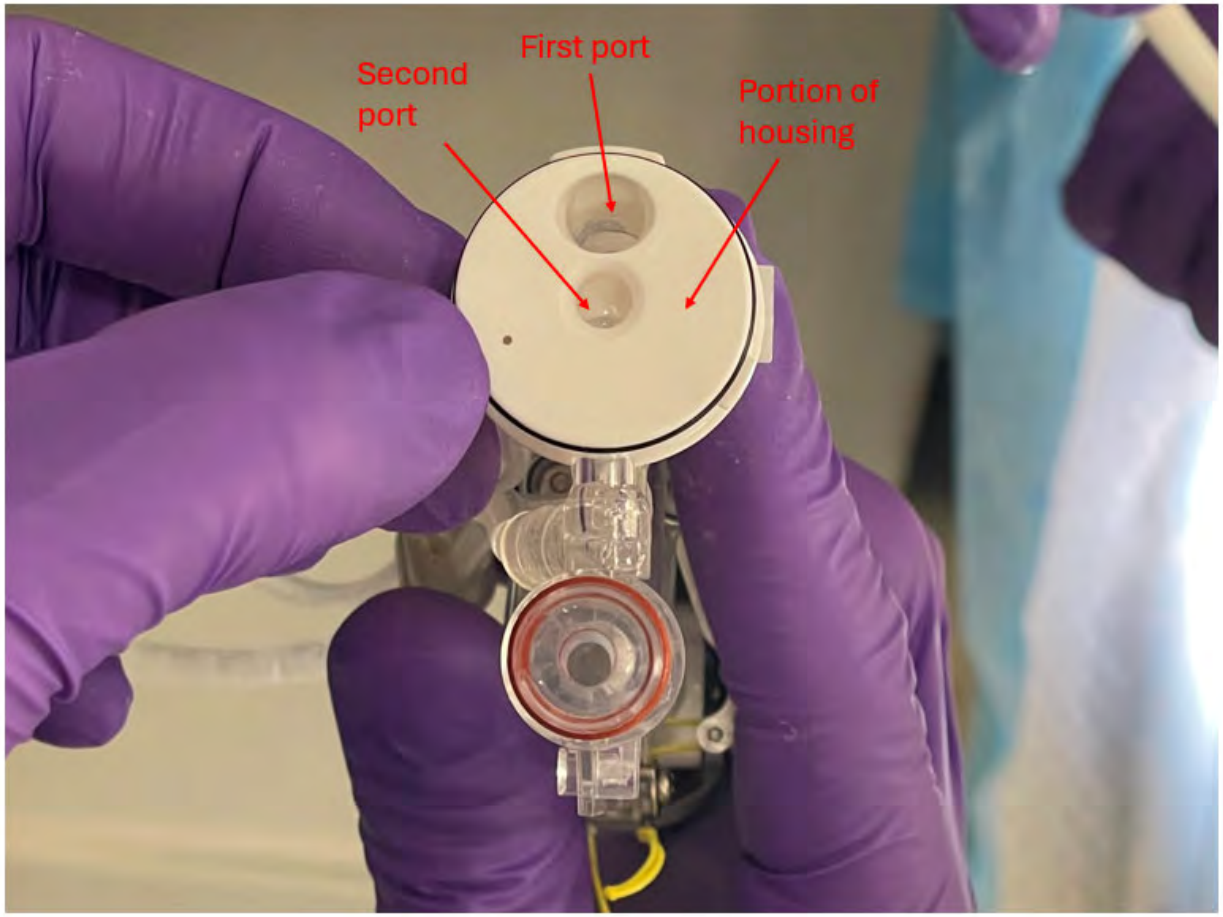
	(Symphony Thrombectomy System Brochure at 9.) (Symphony Thrombectomy System Brochure at 8.)

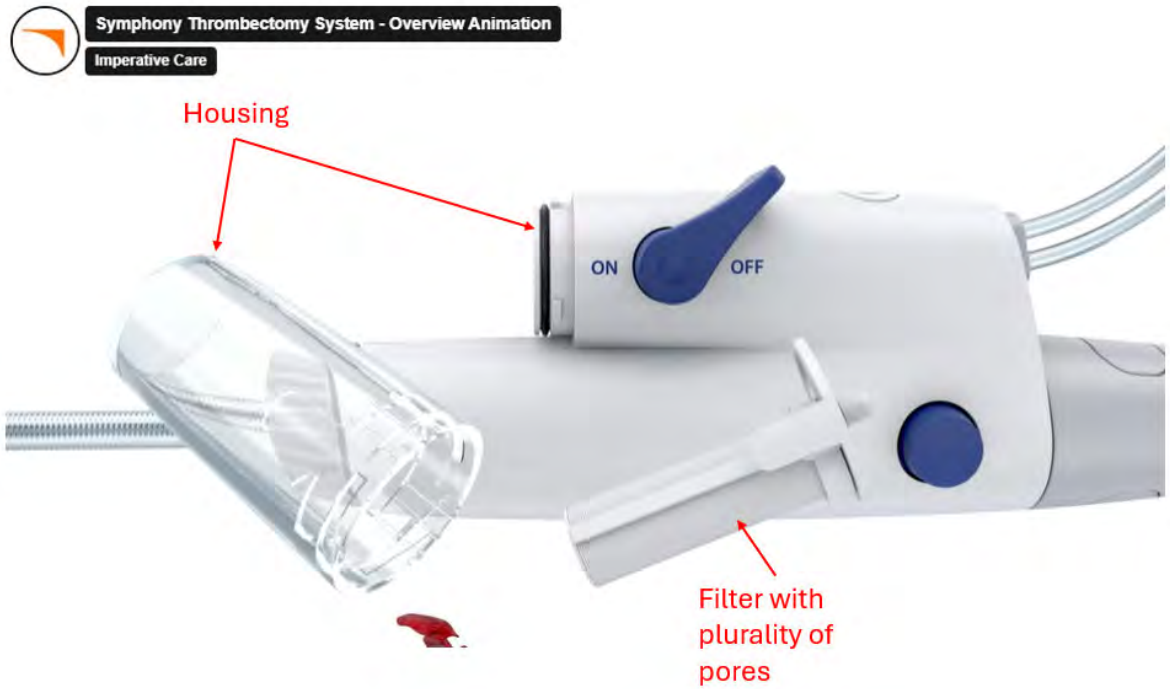
	To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[22] The aspiration system of claim 15 wherein the filter is removable from within the housing.	The Symphony System includes a filter that is removable from within the housing. The filter of the 24F and/or 16F Symphony Catheter handle of the Symphony System is removable from within the housing, as shown in the Symphony Thrombectomy System Overview Animation Video, a screenshot of which is reproduced below.

	(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.) Whipsaw's website similarly shows that the filter of the Symphony Catheter handle is removable from within the housing. (Image from Whipsaw at https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[24] The aspiration system of claim 15 wherein the filter encloses a	The Symphony System include a filter that encloses a region within the housing and where the second port is proximal to the enclosed region along the first fluid

region within the housing, wherein the second port is proximal to the enclosed region along the first fluid path, and wherein the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough.	path and where the filter includes a plurality of pores sized to inhibit clot material from flowing therethrough and to permit blood to flow therethrough. Specifically, the 24F and 16F Symphony Catheter handle includes a filter that encloses a region within the housing. As shown in the annotated images below, the second port is proximal to the enclosed region along the first fluid path.  (Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)

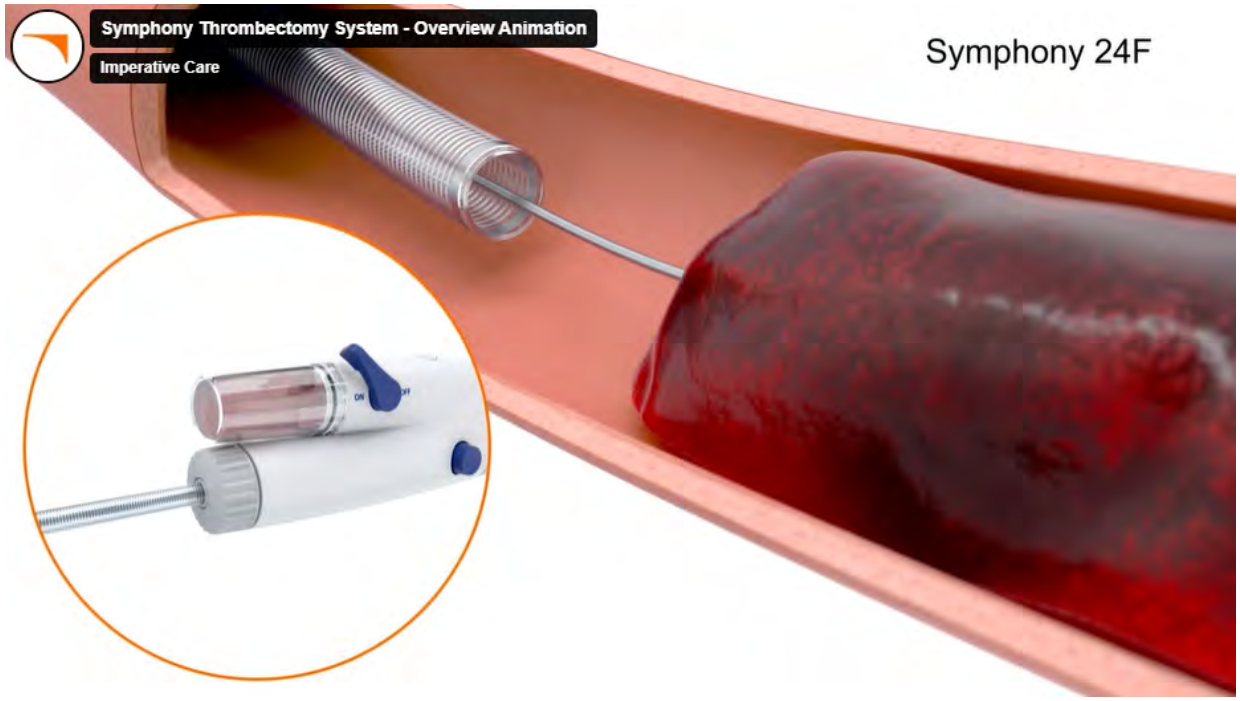
	 (Annotated Symphony Thrombectomy System – Overview Animation Video at 2:02.)

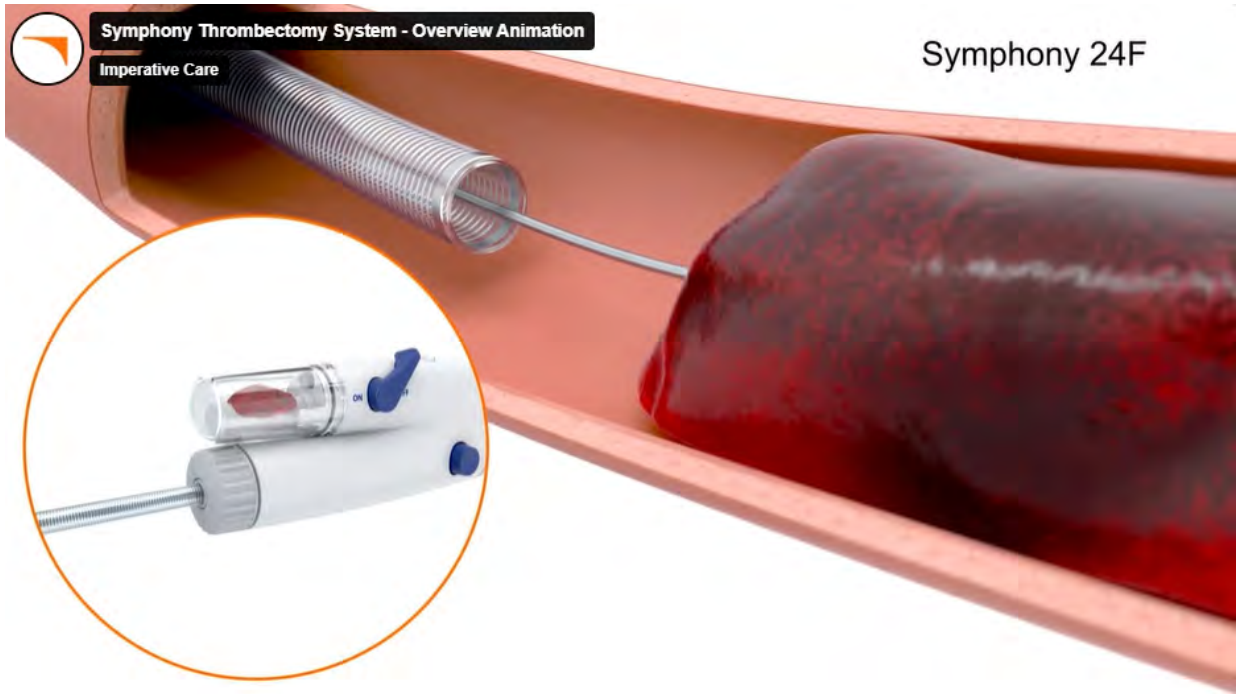
	 (Annotated image of controller housing showing first and second port.) As shown in the annotated image below, the filter of the 24F and 16F Symphony Catheter handle includes a plurality of pores that are sized to inhibit clot material from flowing therethrough.

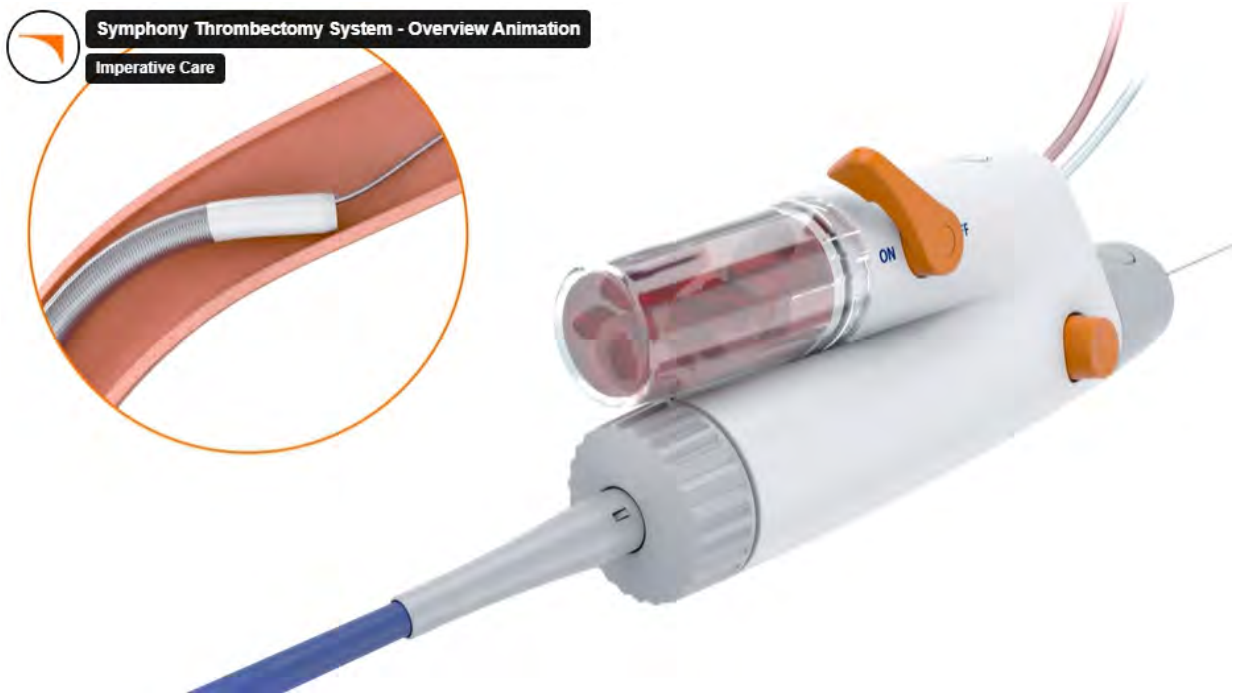


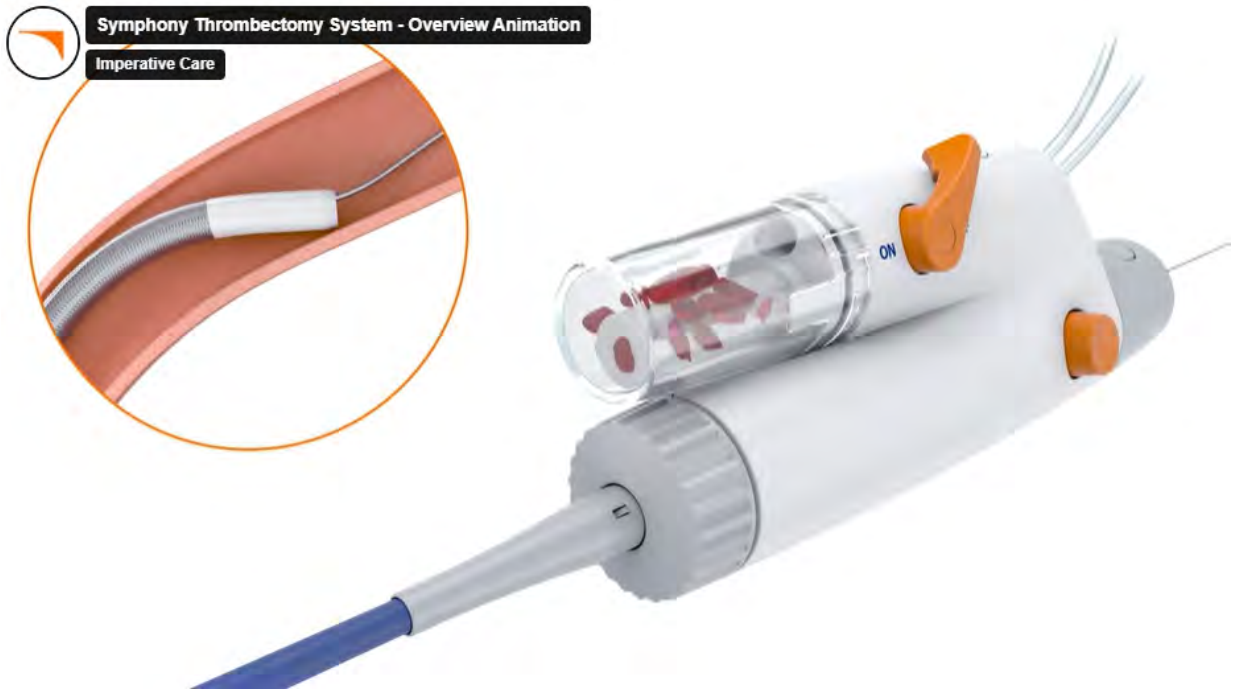
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

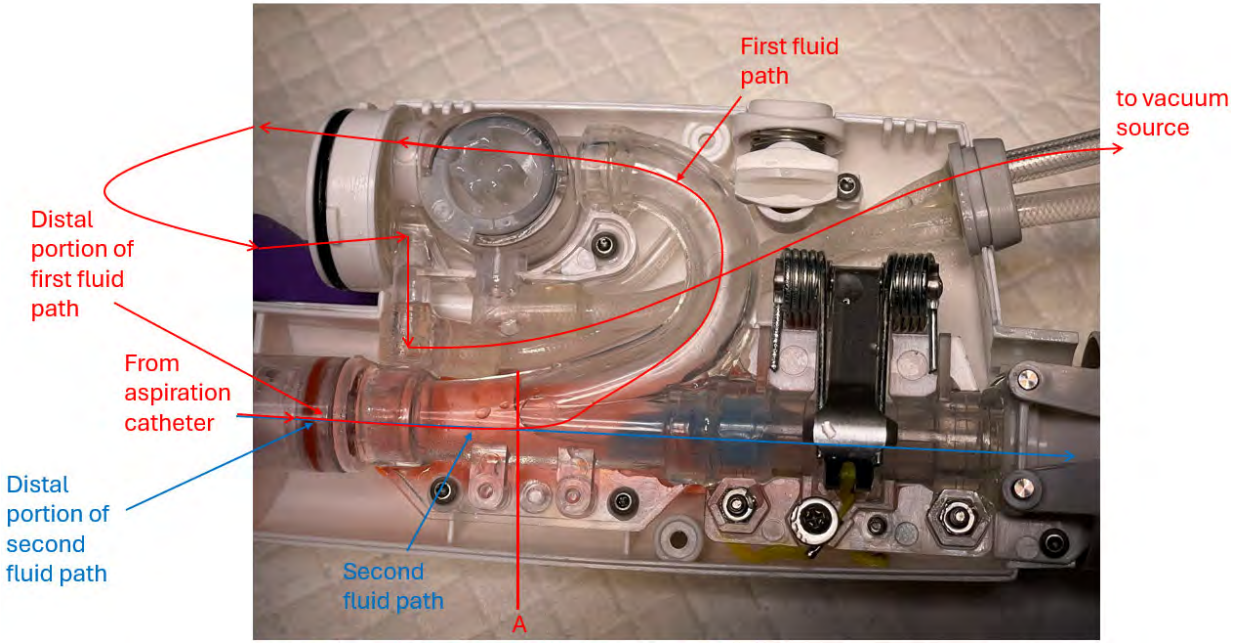
As shown the images from the Symphony Thrombectomy System Overview Animation Video, the plurality of pores of the filter permit blood to flow through the filter but inhibit clot material from flowing through the filter. Specifically, clot material and blood enter the filter chamber from the aspiration catheter and blood subsequently is filtered and exits the filter chamber leaving the clot material within the chamber.

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

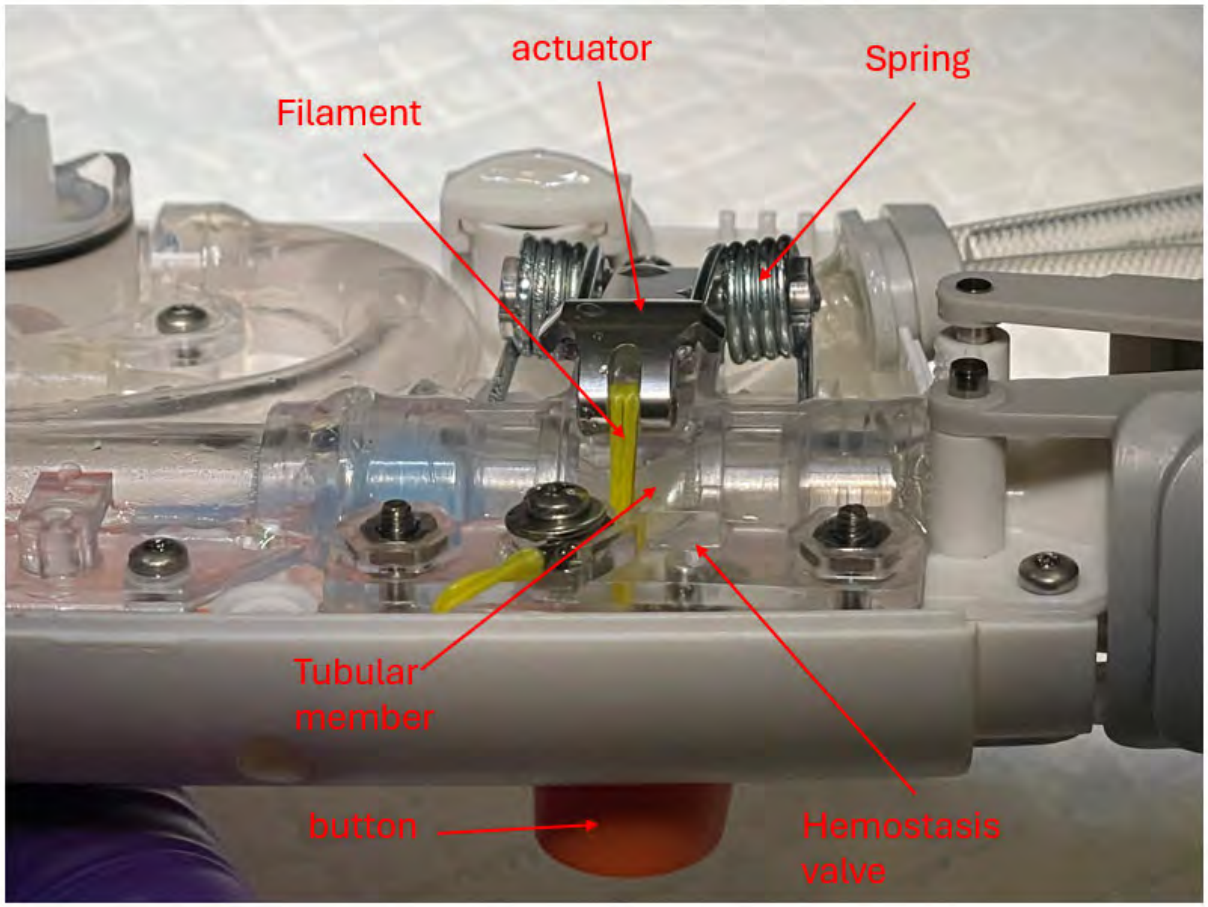
	 (Symphony Thrombectomy System – Overview Animation Video at 0:50.)

	 (Symphony Thrombectomy System – Overview Animation Video at 2:04.)

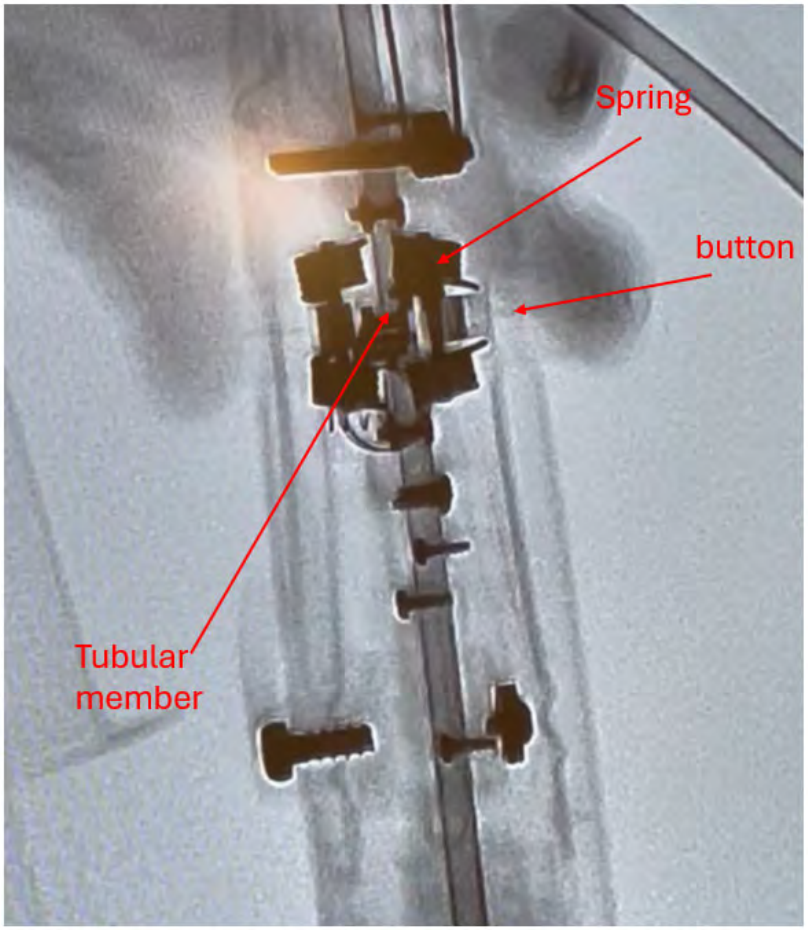
	 (Symphony Thrombectomy System – Overview Animation Video at 2:05.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[25] The aspiration system of claim 15 wherein a distal portion of the first fluid path and a distal portion of the second fluid path overlap.	The Symphony System includes a first and second fluid path where the distal portion of the first fluid path and the distal portion of the second fluid path overlap. Specifically, in the 24F and 16F Symphony Catheter handle of the Symphony System, the distal portion of the first fluid path and distal portion of the second

	fluid path (*e.g.*, the portion of each fluid path extending from the aspiration catheter to approximately point A) overlap, as shown in the annotated image below.  (Annotated image of internal portion of controller housing.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[26] The aspiration system of claim 15 wherein the hemostasis valve comprises a tubular member, a button, and a filament coupled to the button and the tubular member	The Symphony System includes a hemostasis valve that comprises a tubular member, a button, and a filament coupled to the button and the tubular member. Specifically, the hemostasis valve of the 24F and 16F Symphony Catheter handle is comprised of a tubular (elongate) member, two buttons, torsion springs and two

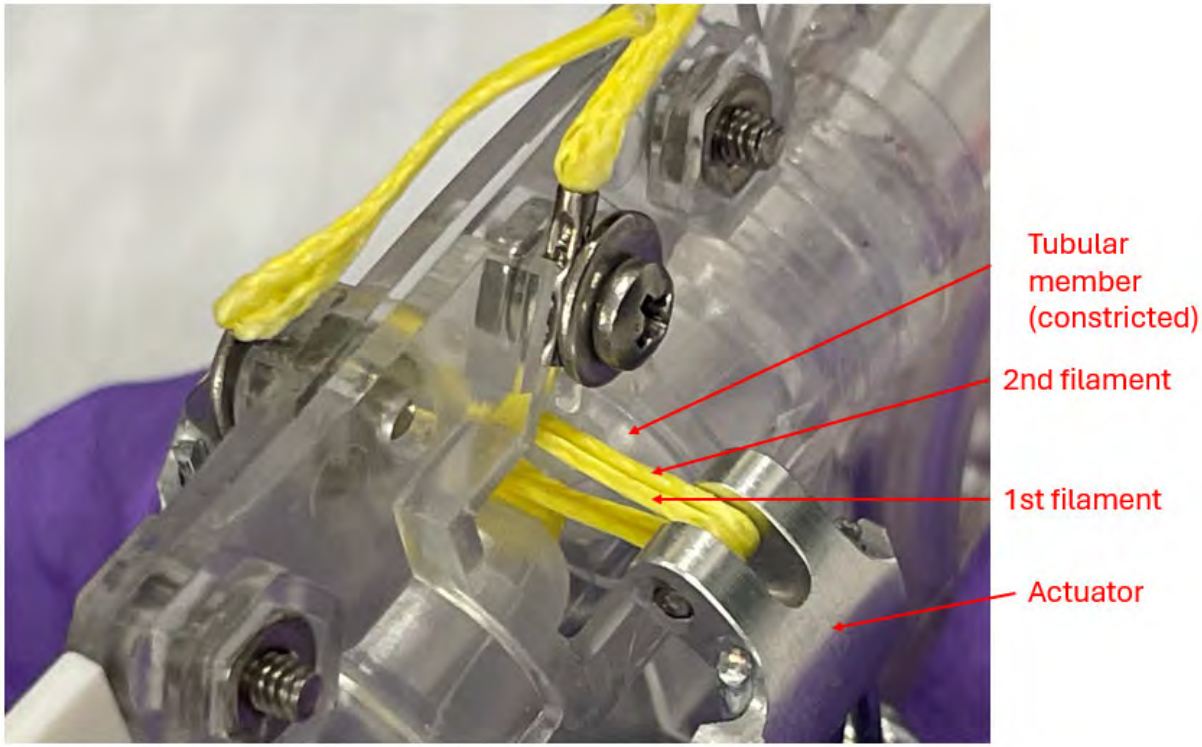
and	filaments, coupled to the button via levers/pins depressed by the buttons and to the tubular member (the filaments are wrapped around the tubular member). The hemostasis valve has an actuator with a first member and a second member operated by buttons on the side of the 24F and 16F Symphony Catheter handles. The actuator mechanism includes a first button that pushes against a first lever on one side of the tubular member and a second button that pushes against a second lever on the other side of the tubular member. The levers and the buttons are driven outwardly by first torsion spring(s) and second torsion spring(s) (there are two per lever). The hemostasis valve also has first and second filaments. Each filament loops around the tubular sidewall and has a first end passing over a first pin at the end of a first lever and a second end passing over a second pin at the end of the second lever. In operation, the torsion springs drive the levers outward such that the pins tension the filaments and constrict the collapsible tubular member. Pressing the buttons pushes the levers inward, which releases tension in the filaments to allow the tubular member to expand.



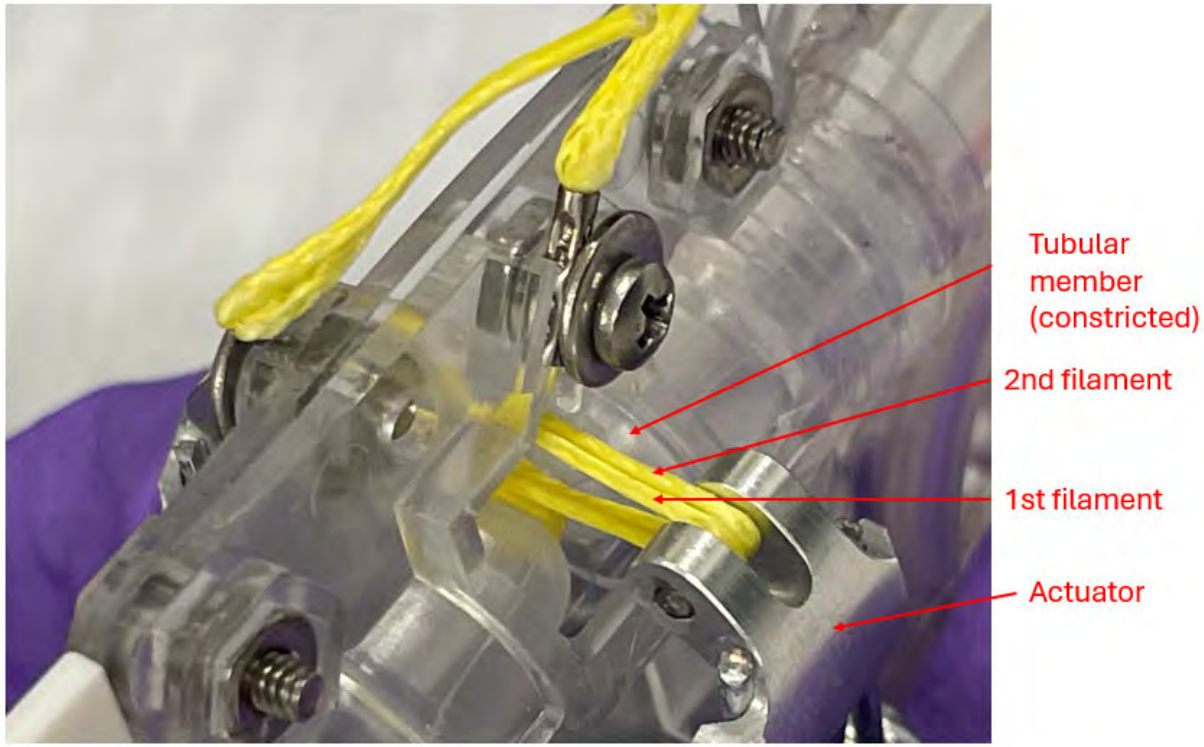
(Annotated image of internal portion of controller housing, showing hemostasis valve.)



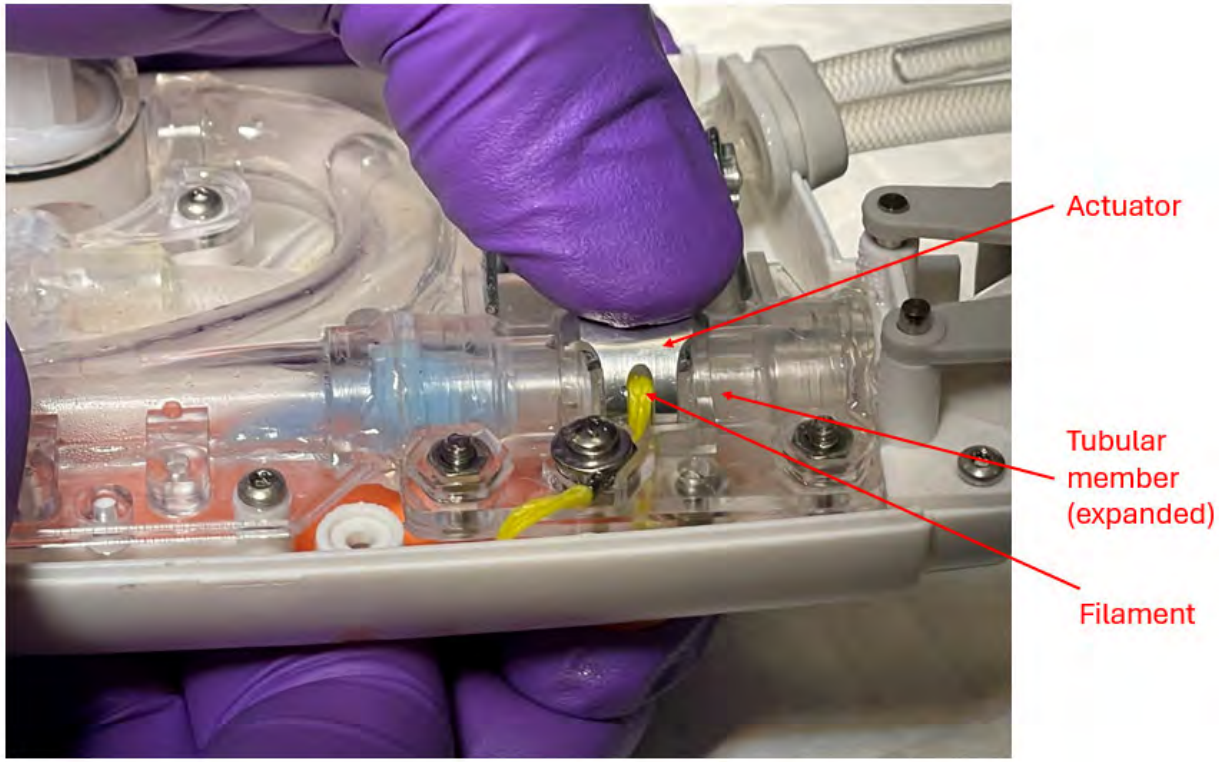
(Annotated x-ray imaging of housing, showing button, torsion spring, and tubular member.)

	 (Annotated image of internal portion of controller housing, showing hemostasis valve.) To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.
wherein the button is configured to be actuated from a first position to a second position to loosen the filament to allow the tubular	The Symphony System includes a hemostasis valve with a pair of buttons, where each button is configured to be actuated from a first position (undepressed button position – tubular member constricted) to a second position (depressed button position – tubular member unconstricted) to loosen the filaments, allowing the

member to expand to unseal the hemostasis valve to allow the interventional device to be inserted through the hemostasis valve.	tubular member to expand to unseal the hemostasis valve. With the hemostasis valve unsealed, and the interventional device can be inserted through the hemostasis valve. Specifically, the hemostasis valve has an actuator with a first member and a second member operated by buttons on the side of the 24F and 16F Symphony Catheter handles. The actuator mechanism includes a first button that pushes against a first lever on one side of the tubular member and a second button that pushes against a second lever on the other side of the tubular member. The levers and the buttons are driven outwardly by first torsion spring(s) and second torsion spring(s) (there are two per lever). The hemostasis valve also has first and second filaments. Each filament loops around the tubular sidewall and has a first end passing over a first pin at the end of the first lever and a second end passing over a second pin at the end of the second lever. In operation, in the first (buttons undepressed) position, the torsion springs drive the levers outward such that the pins tension the filaments and constrict the collapsible tubular member. Depressing the buttons (second position) pushes the levers inward, which releases tension in the filaments to allow the tubular member to expand.

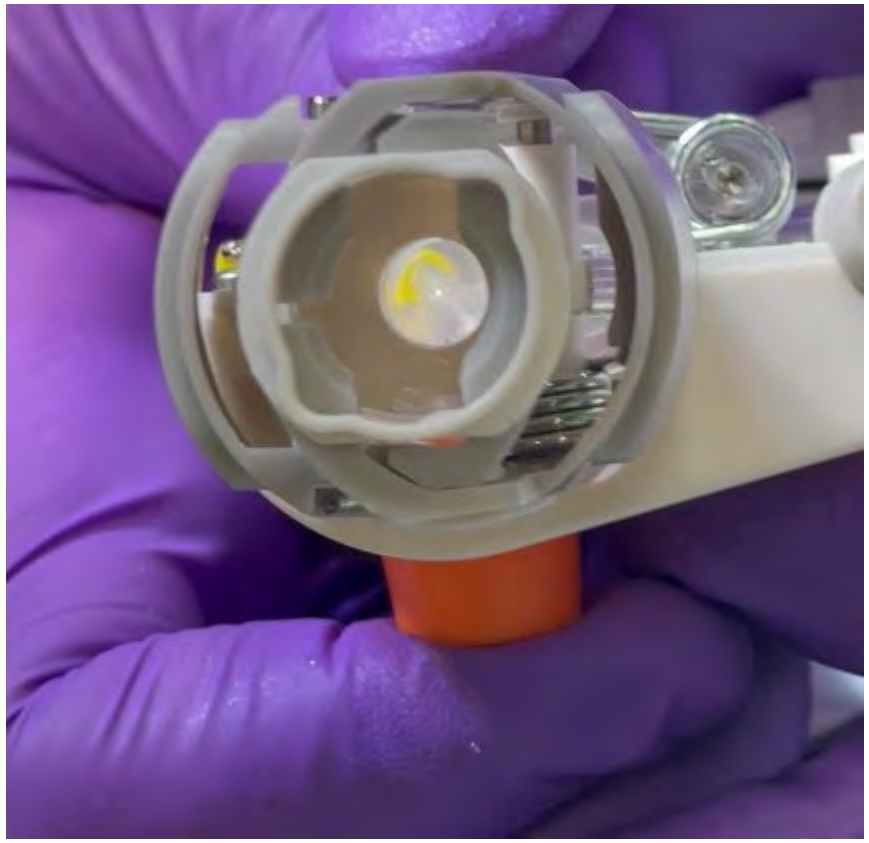


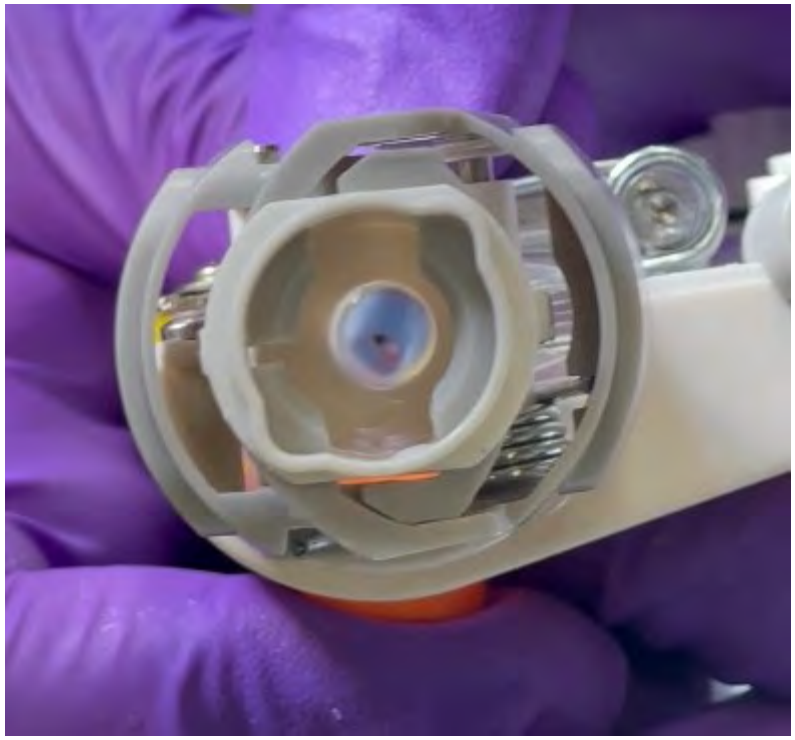
(Annotated image of internal portion of controller housing, showing hemostasis valve.)

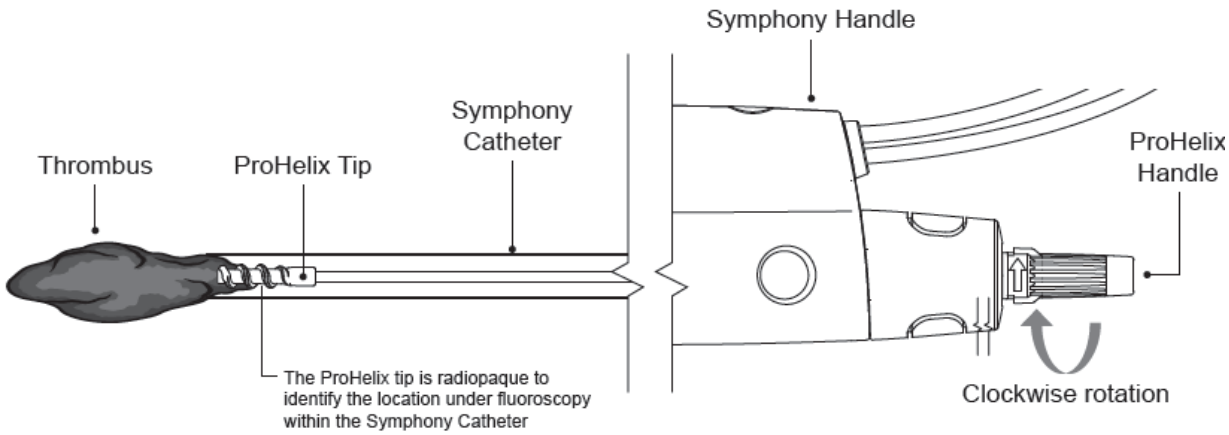


(Annotated image of internal portion of controller housing, showing hemostasis valve.)

When the buttons of the 24F and 16F Symphony Catheter handle are depressed (second position), the tubular member moves from a closed position (due to constriction by the filaments) to an open position as shown in the images below.

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

	 (Symphony handle with view down elongate member (lumen) of hemostasis valve with valve open.) The Symphony System IFU also describes that a user must actuate the hemostasis valve buttons to open the hemostasis valve and allow for insertion of a device (*e.g.*, an interventional device, such as the 24F or 16F Symphony ProHelix). (Symphony Thrombectomy System Instructions For Use at 2 ("Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the

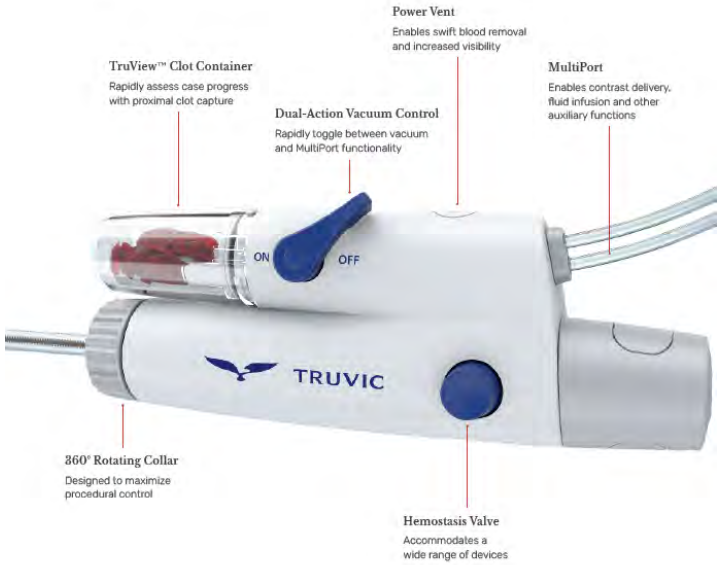
	Hemostasis Valve may damage the valve or the device.”); Symphony Thrombectomy System Instructions For Use at 4 (“Press the Hemostasis buttons to open the hemostasis valve and insert the Dilator through the open Hemostasis Valve of the Handle.”); Symphony Thrombectomy System Instructions For Use at 6 (“When aspiration is complete, depress the Retention Clip buttons on the Handle and withdraw the ProHelix approximately 1 cm from the Catheter. Then press the Hemostasis Valve buttons on the Handle to reduce friction while withdrawing the ProHelix from the Catheter completely. Ensure the Hemostasis Valve buttons are completely depressed when pulling the ProHelix tip through the Valve.”).) Expansion of the hemostasis valve allows an interventional device, such as the 24F or 16F ProHelix to be inserted, as shown in Figure 4 of the Symphony System IFU, reproduced below.  **Figure 4: ProHelix engaged with thrombus** (Symphony Thrombectomy System Instructions For Use at 5.)

	The Symphony System IFU describes the Symphony ProHelix as an interventional device. (Symphony Thrombectomy System Information For Use at 1 ("As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter.").) The Symphony Thrombectomy System Brochure also depicts the ProHelix as an interventional device and the Symphony Catheter handle with hemostasis valve buttons that allow for the hemostasis valve to "[a]ccomodate[] a wide range of devices."

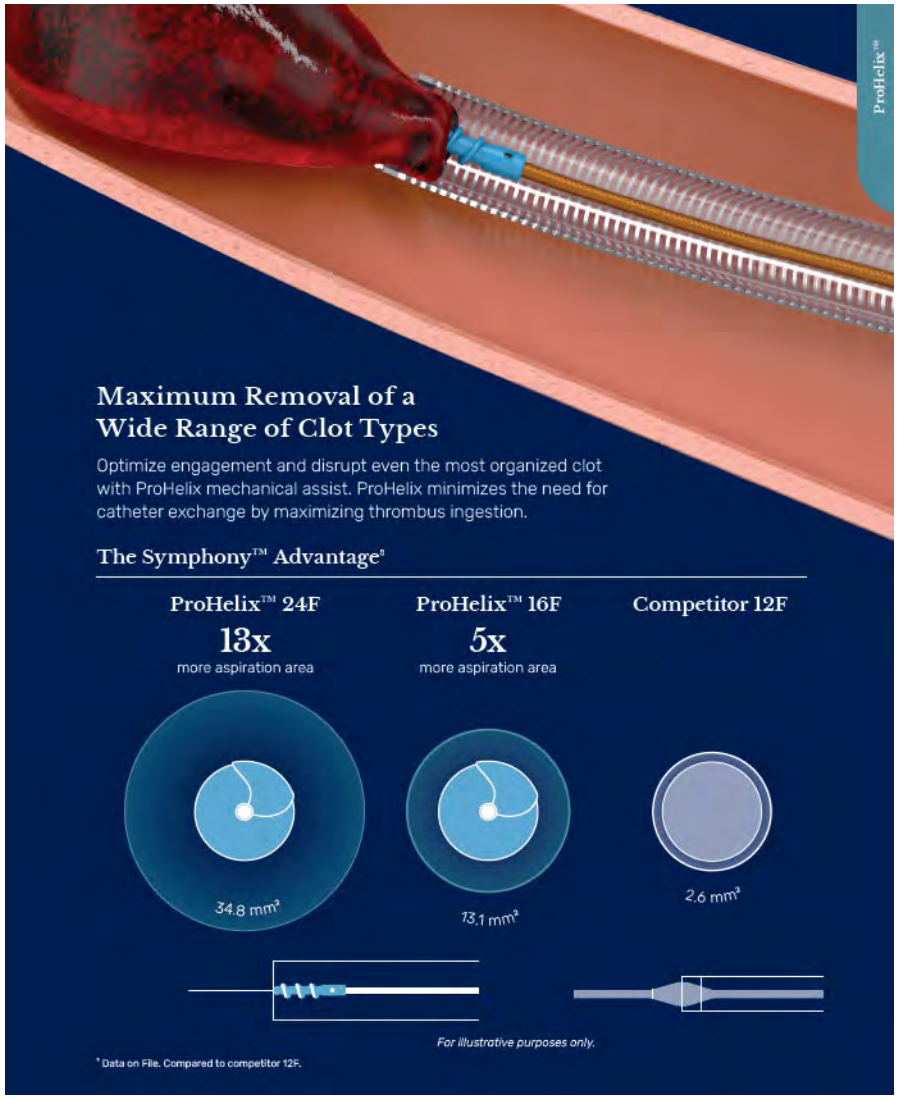
SYMPHONY® THROMBECTOMY SYSTEM

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

BigShot™ Controller

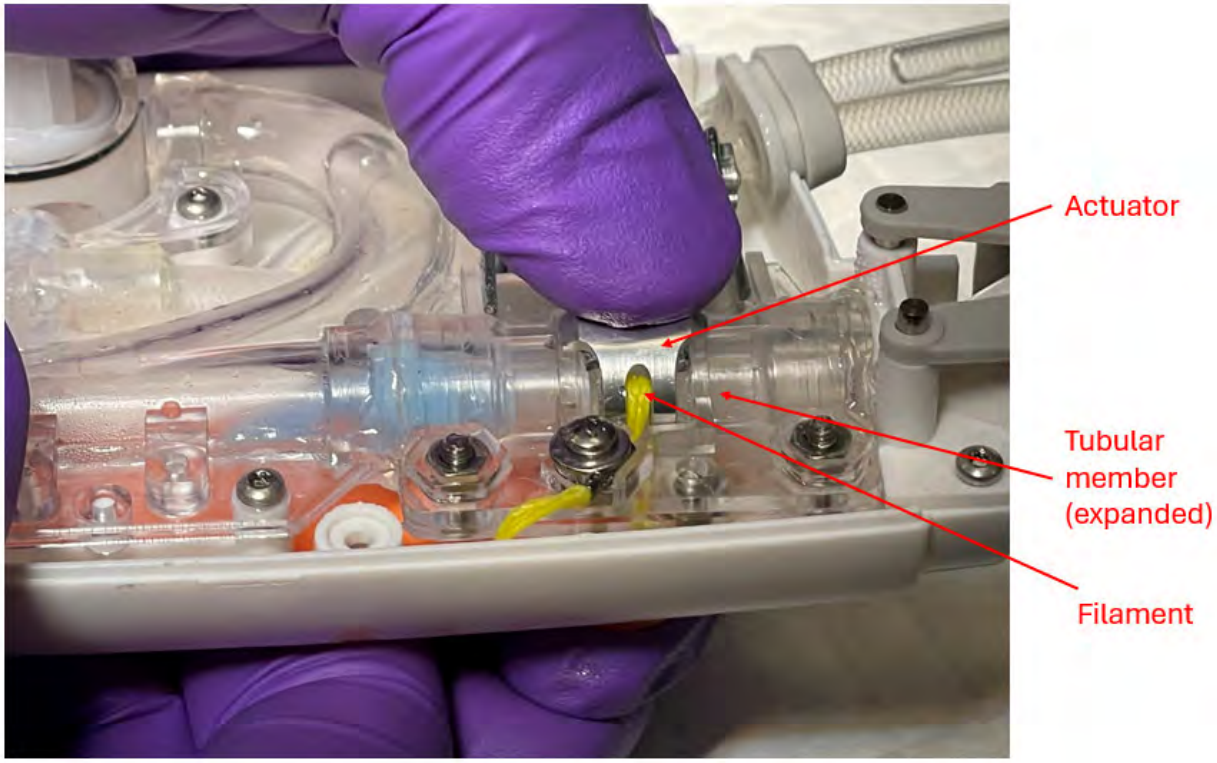


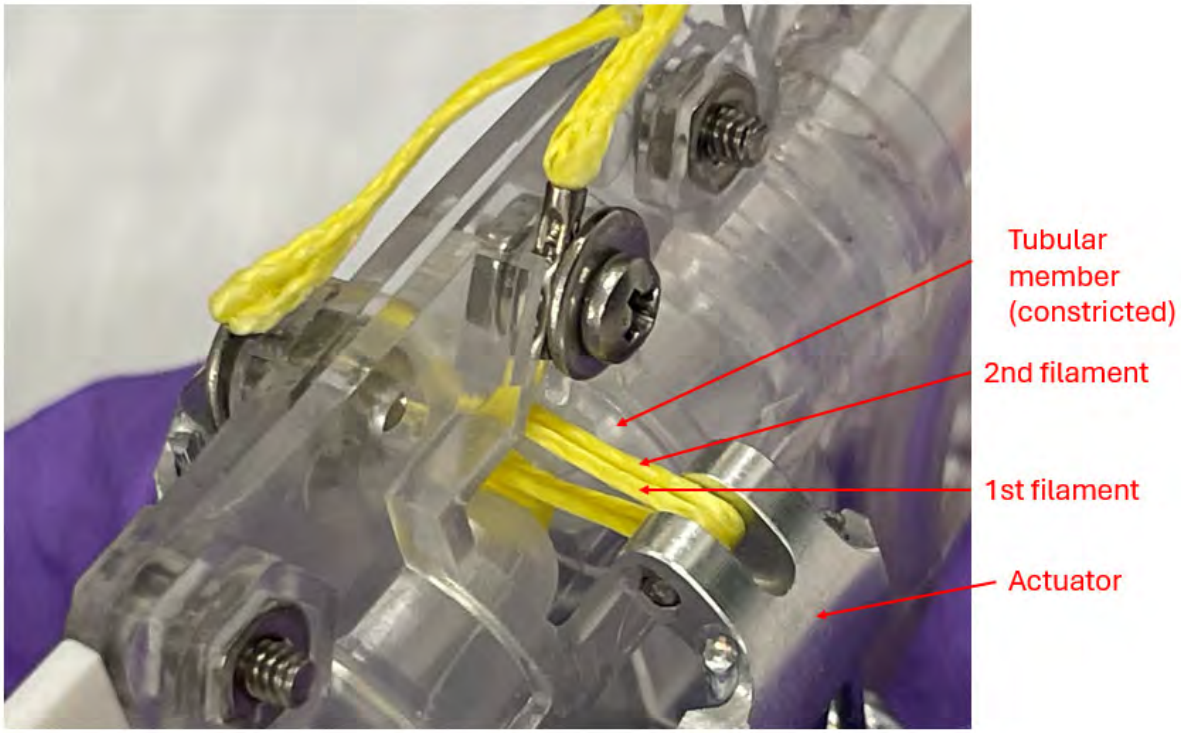
(Symphony Thrombectomy System Brochure at 6.)



(Symphony Thrombectomy System Brochure at 9.)

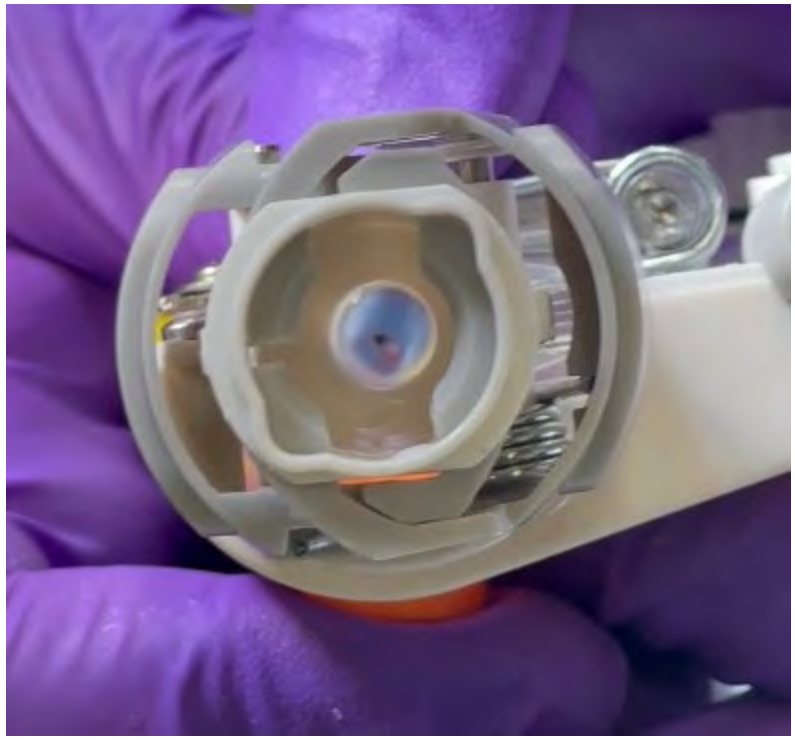
[27] The aspiration system of claim 26 wherein the button is movable from the second position to the first position to tighten the filament to allow the tubular member to collapse and seal about a portion of the interventional device.	The Symphony System includes a hemostasis valve with a pair of buttons, where each button is configured to be actuated from a second position (depressed button position – tubular member unconstricted) to a first position (undepressed button position – tubular member constricted) to tighten the filaments, allowing the tubular member to collapse and seal about a portion of the interventional device. Specifically, the hemostasis valve has an actuator with a first member and a second member operated by buttons on the sides of the 24F and 16F Symphony Catheter handles. The actuator mechanism includes a first button that pushes against a first lever on one side of the tubular sidewall and a second button that pushes against a second lever on the other side of the tubular body. The levers and the buttons are driven outwardly by first torsion spring(s) and second torsion spring(s) (there are two per lever). The hemostasis valve also has first and second filaments. Each filament loops around the tubular sidewall and has a first end passing over a first pin at the end of a first lever and a second end passing over a second pin at the end of the second lever. In operation, in the first (buttons undepressed) position, the torsion springs drive the levers outward such that the pins tension the filaments and constrict the collapsible tubular member. Depressing the buttons (second position) pushes the levers inward, which releases tension in the filaments to allow the tubular member to expand. When the button is depressed (*e.g.* in a second position), the filament that loops around the tubular member loosens, which allows the flexible tubular member to expand.

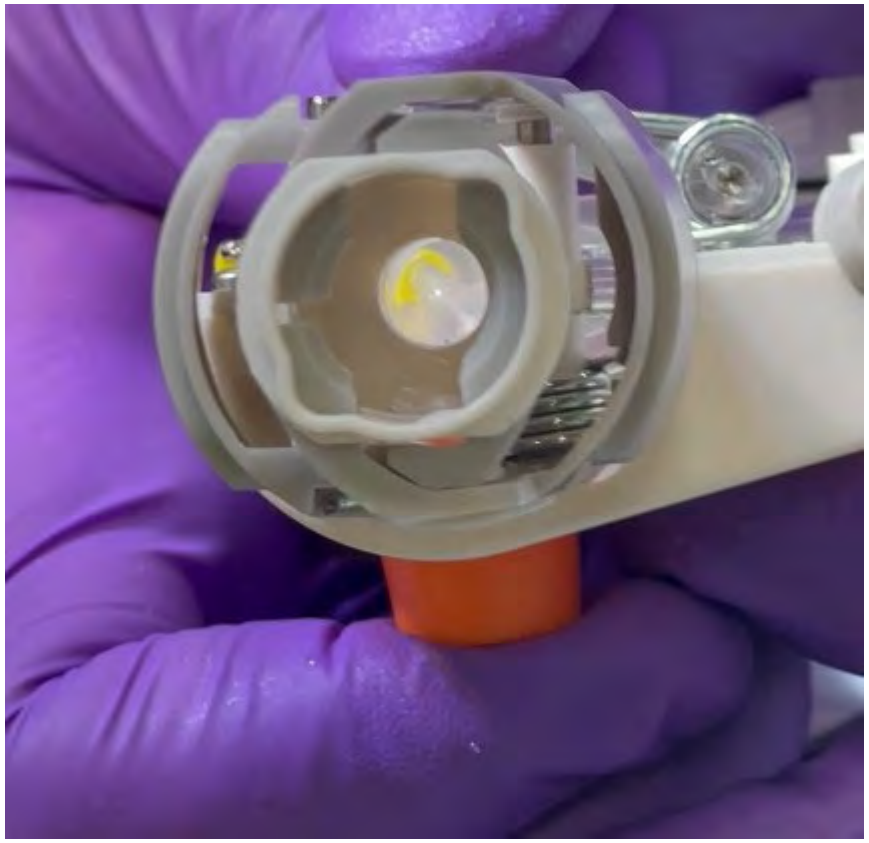
	 (Annotated image of internal portion of controller housing, showing hemostasis valve.)



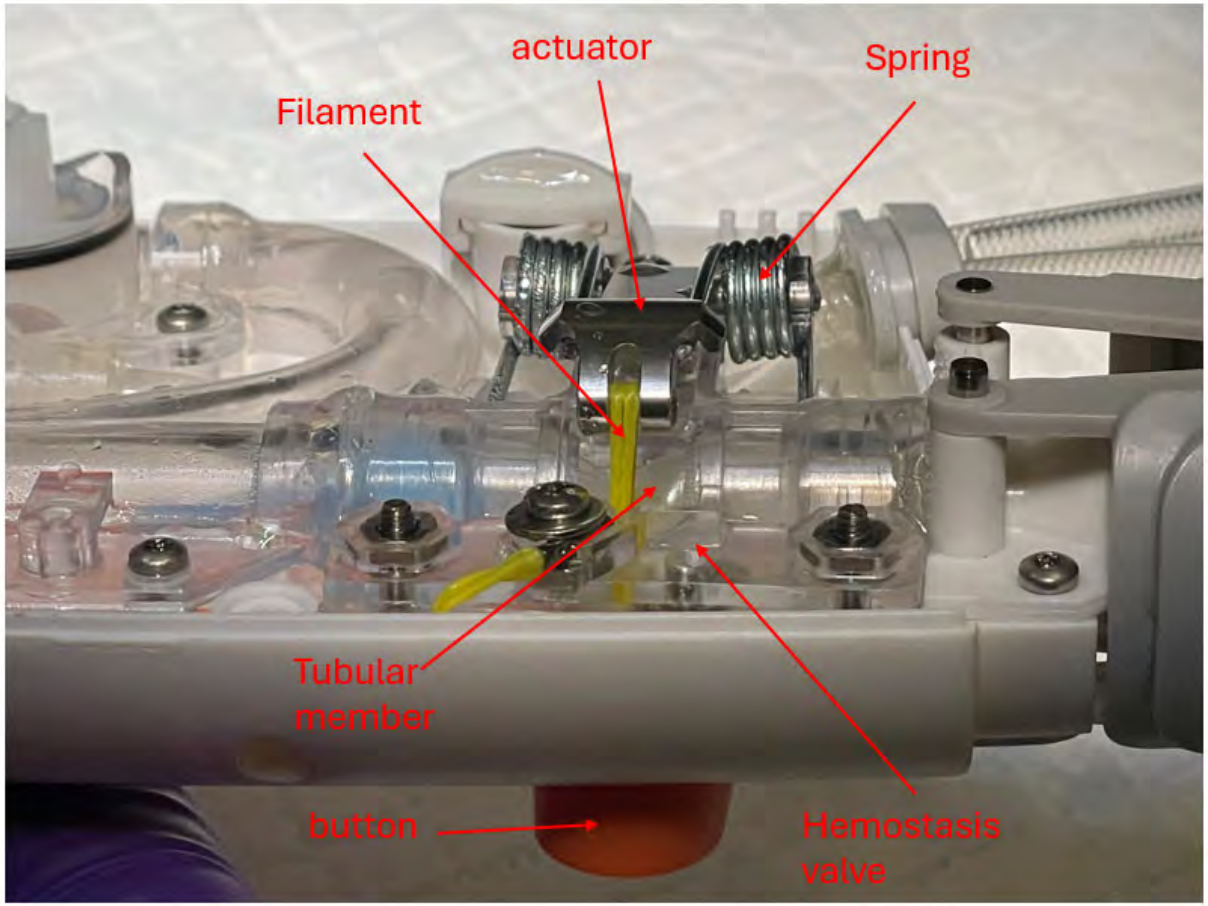
(Annotated image of internal portion of controller housing, showing hemostasis valve.)

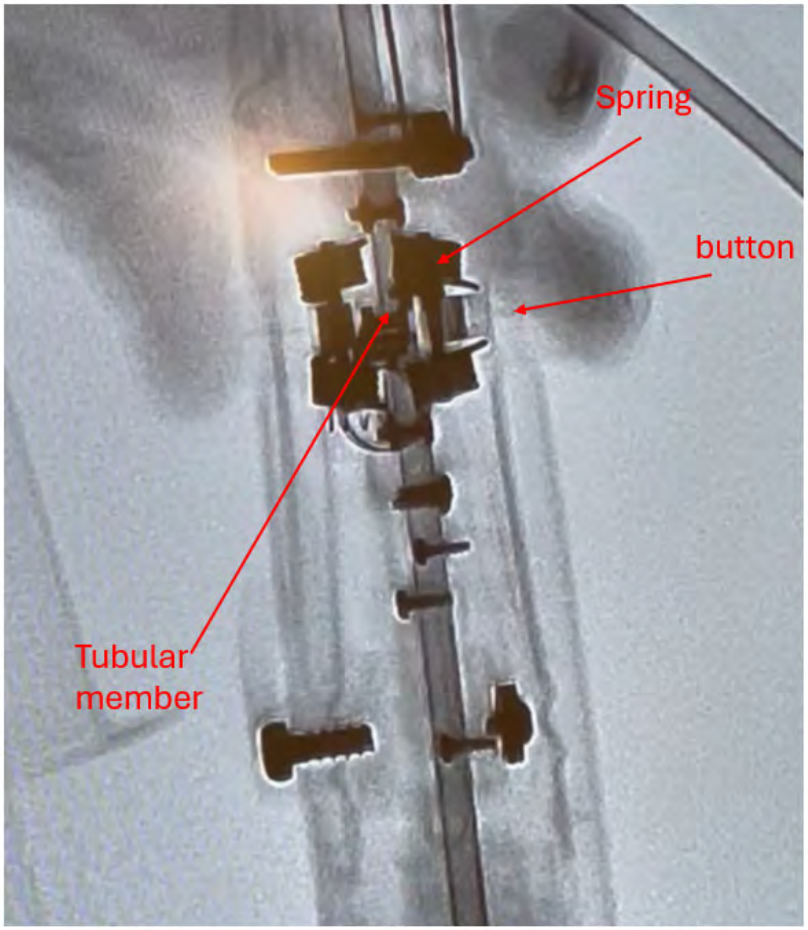
When the buttons of the 24F and 16F Symphony Catheter handle are undepressed (first position), the tubular member moves from an open position to a closed position (due to constriction by the filaments).

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

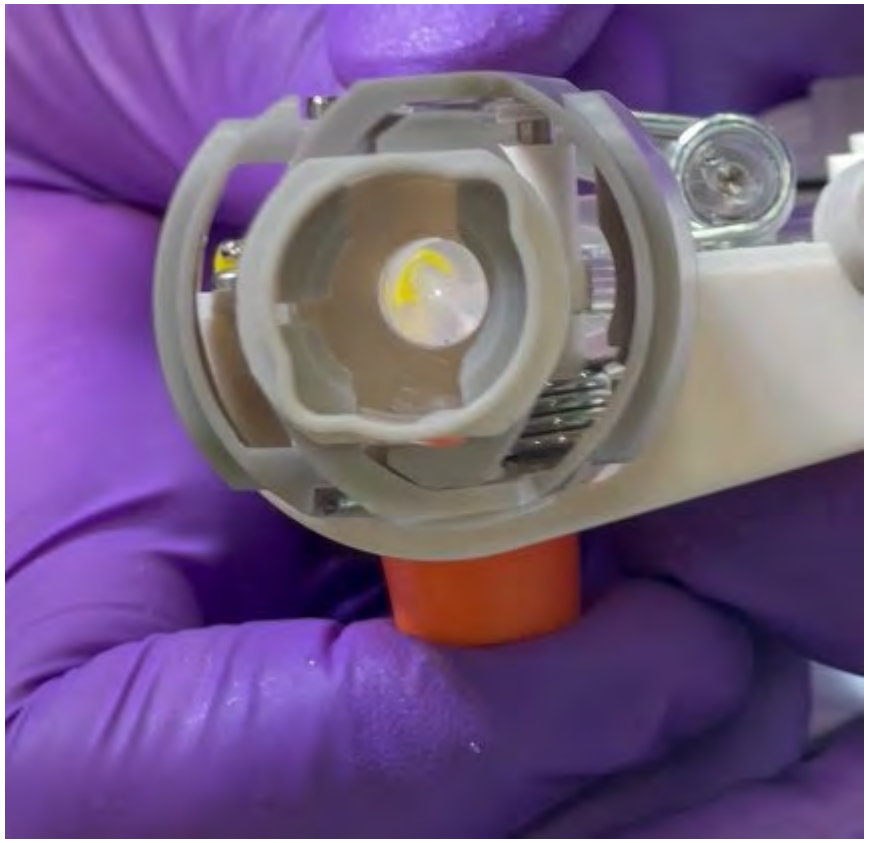
	 (Symphony handle with view down lumen of hemostasis valve with valve constricted.) The Symphony System IFU also describes that a user must actuate the hemostasis valve buttons to open the hemostasis valve and allow for insertion of a device (*e.g.*, an interventional device, such as the 24F or 16F Symphony ProHelix). Conversely, if the buttons are undepressed, the tubular member of the hemostasis valve collapses on the device and seals around a portion of the device. (Symphony

	Thrombectomy System Instructions For Use at 2 ("Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device."); Symphony Thrombectomy System Instructions For Use at 4 ("Press the Hemostasis buttons to open the hemostasis valve and insert the Dilator through the open Hemostasis Valve of the Handle."); Symphony Thrombectomy System Instructions For Use at 6 ("When aspiration is complete, depress the Retention Clip buttons on the Handle and withdraw the ProHelix approximately 1 cm from the Catheter. Then press the Hemostasis Valve buttons on the Handle to reduce friction while withdrawing the ProHelix from the Catheter completely. Ensure the Hemostasis Valve buttons are completely depressed when pulling the ProHelix tip through the Valve.").) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.
[28] The aspiration system of claim 27 wherein the hemostasis valve further comprises a spring configured to bias the button to the first position.	The Symphony System includes a hemostasis valve further comprises a spring configured to bias the button to a first position. Specifically, the hemostasis valve has an actuator with a first member and a second member operated by buttons on the side of the 24F and 16F Symphony Catheter handles. The actuator mechanism includes a first button that pushes against a first lever on one side of the tubular member and a second button that pushes against a second lever on the other side of the tubular member. The levers and the buttons are driven outwardly by first torsion spring(s) and second torsion spring(s) (there are two per lever). Particularly, in the biased position (e.g., first position – buttons undepressed), the springs drive the first and second members outward, reducing the diameter of the valve lumen by pulling the filaments to reduce the diameter of the

	looped portions of the filaments to constrict the tubular sidewall defining the valve lumen.  (Annotated image of internal portion of controller housing, showing hemostasis valve.)



(Annotated x-ray imaging of housing, showing button, torsion spring, and tubular member.)

	 (Symphony handle with view down lumen of hemostasis valve with valve constricted.) To the extent that the Symphony System does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.

[30] The aspiration system of claim 15 wherein the vacuum source comprises a vacuum chamber, and wherein the catheter is fluidically coupled to the vacuum chamber via the first fluid path.	The Symphony System includes a vacuum source that comprises a vacuum chamber where the catheter is fluidically coupled to the vacuum chamber via the first fluid path. Specifically, the Truvic Generator and Truvic Canister (*e.g.*, vacuum source) comprise a vacuum chamber in the form of the Truvic Canister's container, which is coupled to the catheter via the first fluid path and the Truvic primary tubing (for the 24F or 16F Symphony Catheter handle) and secondary tubing (for the 16F Symphony Catheter handle), as shown in annotated Figure 6 of the Symphony System IFU below.

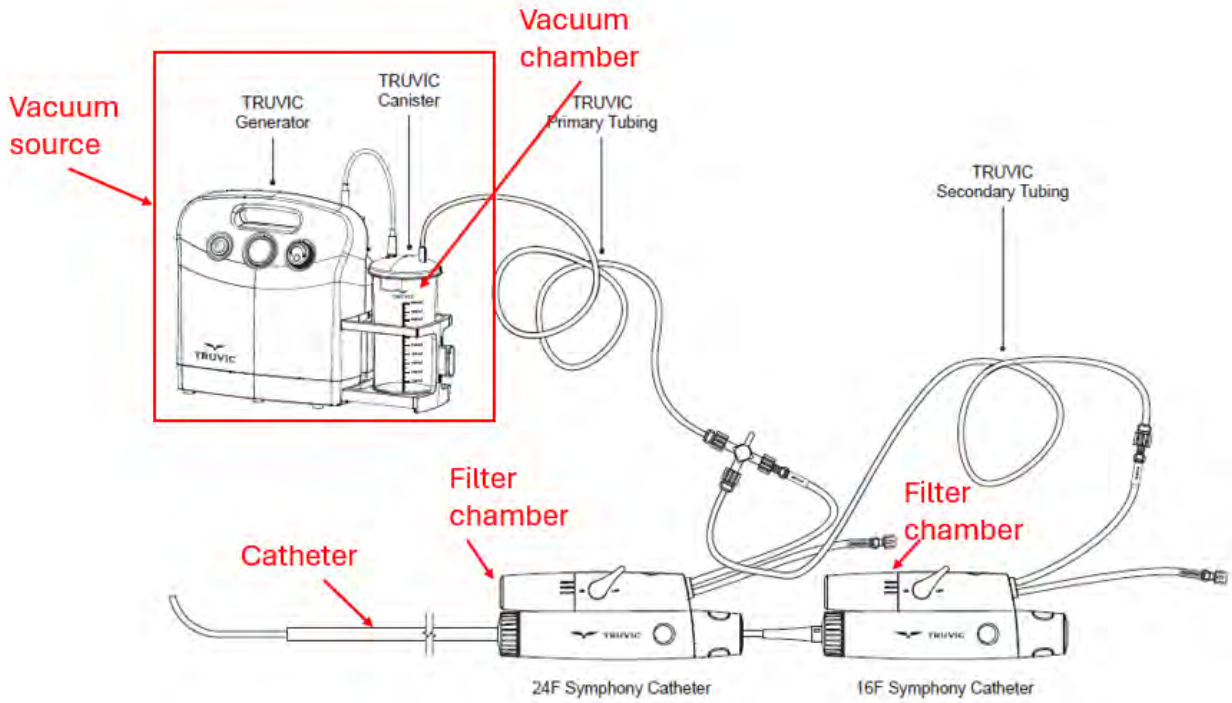
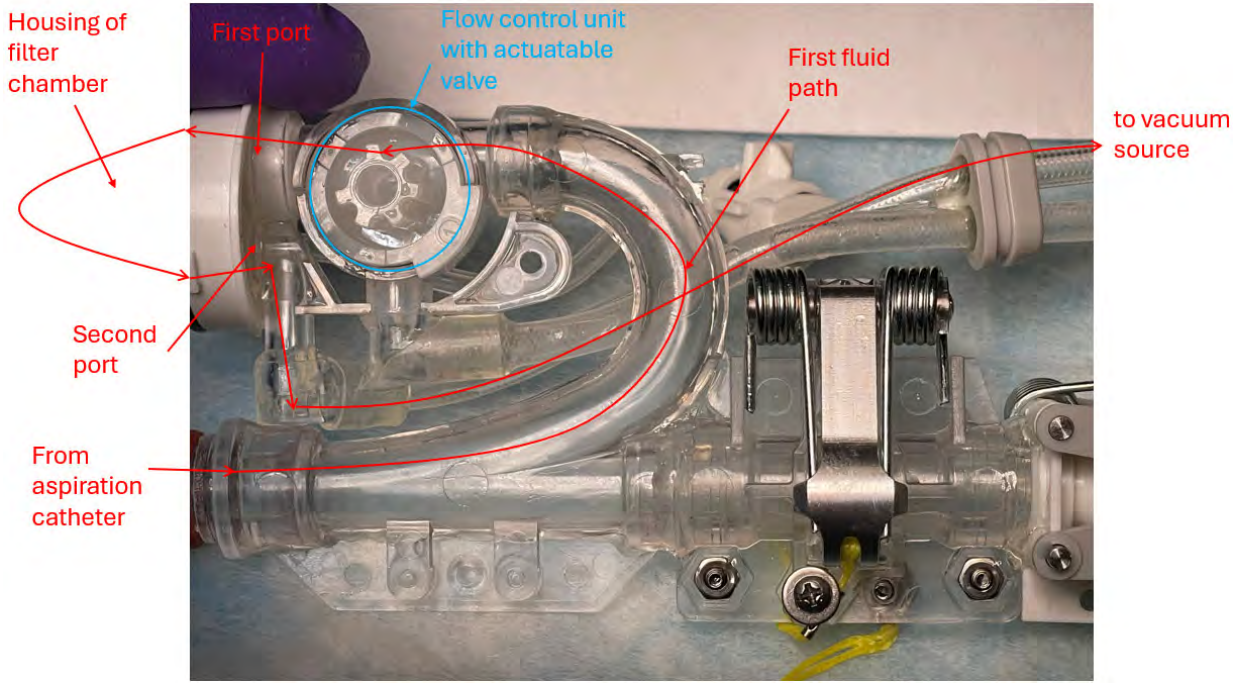


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Annotated Symphony Thrombectomy System Instructions For Use at 8.)

The catheter is fluidically coupled to the vacuum chamber via the filter chamber along the first fluid path. Specifically, blood and clot material from the human patient follows the first fluid path within the Symphony Catheter handle to the filter chamber, as shown in the teardown image below. Blood is filtered and exits the filter chamber through the second port and flows through the handle's internal tubing to the Truvic Canister.



(Annotated image of internal portion of controller housing.)

----------24F Aspiration Catheter----------

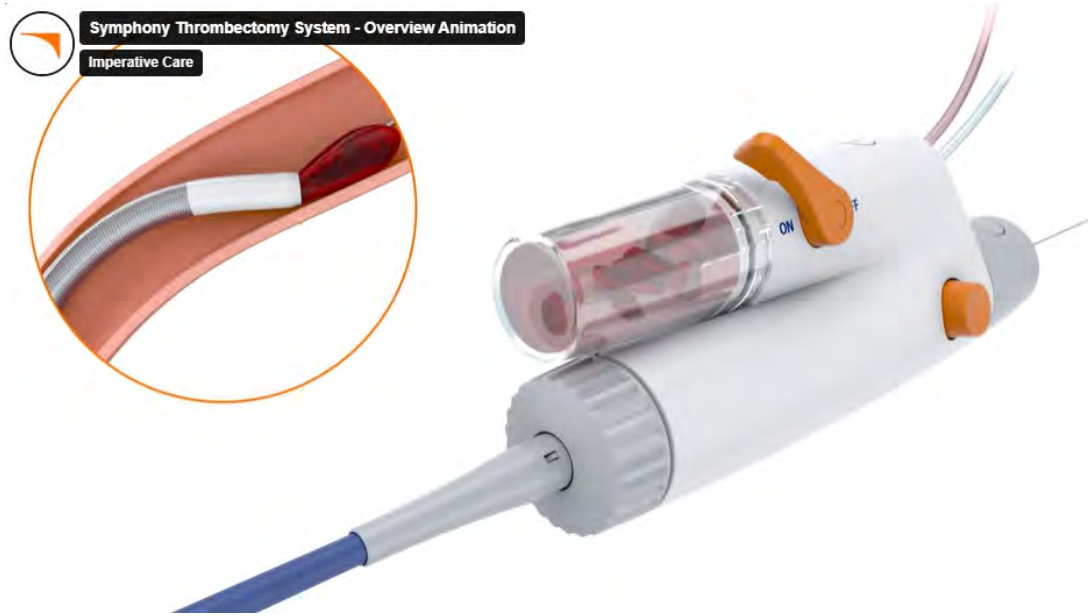
The image of the 24F Symphony Catheter handle below, which shows blood flowing from the aspiration catheter, along the first fluid path, into the filter chamber, out of the filter chamber and to the Truvic Canister along the first fluid path, confirms that the catheter is fluidically coupled to the vacuum chamber via the first fluid path.

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

The Symphony System IFU confirms that the catheter is fluidically coupled to the vacuum chamber via the filter chamber of the first fluid path. (Symphony Thrombectomy System Instructions For Use at 5 ("To begin aspiration, move the vacuum lever on the Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the 'OFF' position.").)

----------16F Aspiration Catheter----------

The image of the 16F Symphony Catheter handle below, which shows blood flowing from the aspiration catheter, along the first fluid path, into the filter chamber, out of the filter chamber and to the Truvic Canister via the first fluid path,

	confirms that the catheter is fluidically coupled to the vacuum chamber via the first fluid path.  (Symphony Thrombectomy System – Overview Animation at 2:02.) The Symphony System IFU confirms that the catheter is fluidically coupled to the vacuum chamber via the filter chamber of the first fluid path. (Symphony Thrombectomy System Instructions For Use at 8 ("To begin aspiration, move the vacuum lever on the 16F Handle to the 'ON' position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the 16F Handle to the 'OFF' position.").) To the extent that the Symphony fSystem does not literally meet this limtation, the Symphony System meets this limitation under the doctrine of equivalents.