

EXHIBIT L
INFRINGEMENT ANALYSIS OF CLAIMS 1, 4-5, 7, 10-11, 13, 15-28 OF UNITED STATES PATENT NO.
12,239,333
TRUVIC SYMPHONY THROMBECTOMY SYSTEM

Pursuant to Patent Local Rule 3-1, this chart identifies specifically where and how each limitation of Asserted Claims 1, 4-5, 7, 10-11, 13 and 15-28 of United States Patent No. 12,239,333 (“the 12-’333 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.”

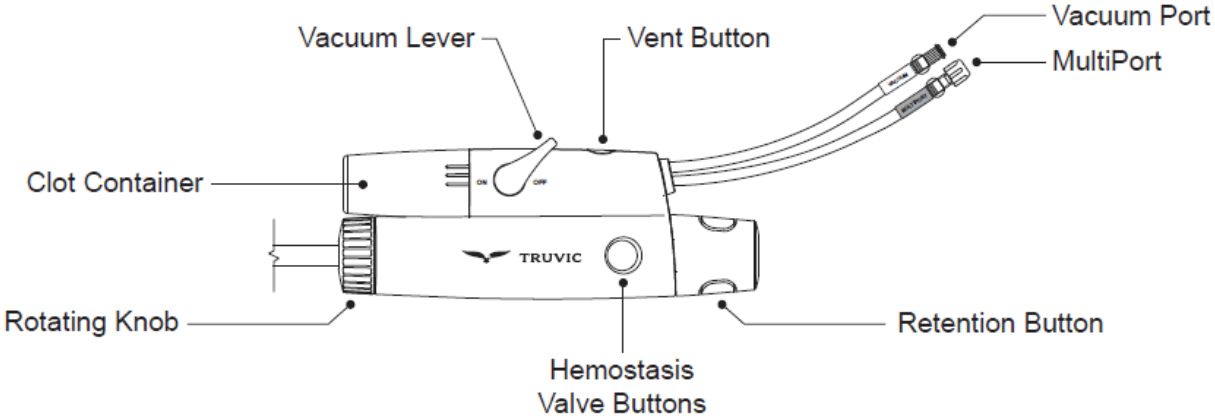
References Cited:

- Symphony Thrombectomy System Brochure (found at <https://www.truvic.com/symphony-product>; ECF 20-1 (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 (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)
- Whipsaw website discussion of Symphony (<https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>)
- Symphony System sample provided by Truvic
- Symphony Thrombectomy System Product Specifications Sheet (found at <https://imperativecare.com/wp-content/uploads/sites/4/2024/09/M10147.C-Symphony-Product-Spec-Sheet.pdf>)

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 12-’333 Patent on March 4, 2025, such making, having made, selling, offering for sale, and/or using the Symphony System has infringed the 12-’333 Patent.
- Truvic has further indirectly infringed the claims of the 12-’333 Patent under Sections 271(b) and 271(c) of Title 35 of the United States Code through the actions of its Symphony System customer/users that employ the Symphony System, including with ProHelix devices in treating blood clots. Truvic specifically instructs and intends users to employ the Symphony System, including with ProHelix devices in treatment procedures that practice the claims of the 12-’333 Patent, for instance by treating deep vein thrombosis and/or pulmonary embolism using the Symphony System with knowledge of the 12-’333 Patent since Inari’s filing of the Second Amended Complaint and that such use practices the claims. Additionally, the Symphony System is especially made and adapted for practicing the claims of the 12-’333 Patent, forms a material part of the invention, and is not suitable for substantial non-infringing uses.

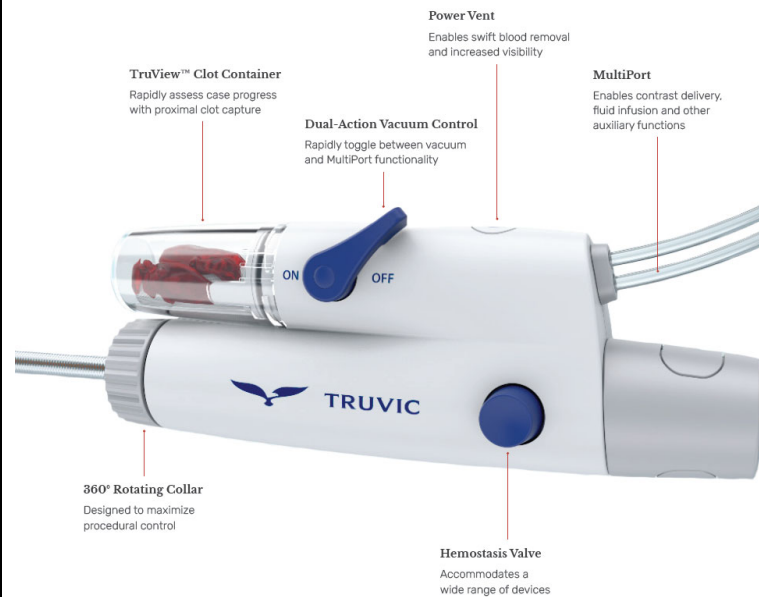
The citations to portions of any reference in this chart are exemplary only. Inari anticipates it will rely on the entirety of the references cited in this chart, as well as other documents and testimony that will be produced during discovery, to demonstrate that the Symphony System infringes the 12-’333 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
<p>[1] A clot collection reservoir, comprising:</p>	<p>The Symphony System includes a clot collection reservoir (including a “clot container” connected to the Symphony Bigshot Controller handle).</p> <p>Specifically, the 24F and 16F Symphony Catheter handles of the Symphony System includes a clot collection reservoir where a user can “[c]onfirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle.” (Symphony Thrombectomy System Instructions For Use at 5; Symphony Thrombectomy System Instructions For Use at 6 (same); Symphony Thrombectomy System Instructions For Use at 8 (same).) The clot container of the 24F and 16F Symphony Catheter handle is shown in the Symphony System IFU below.</p>  <p style="text-align: center;">Figure 3: Symphony Catheter Handle, labeled</p>

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

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

BigShot™ Controller

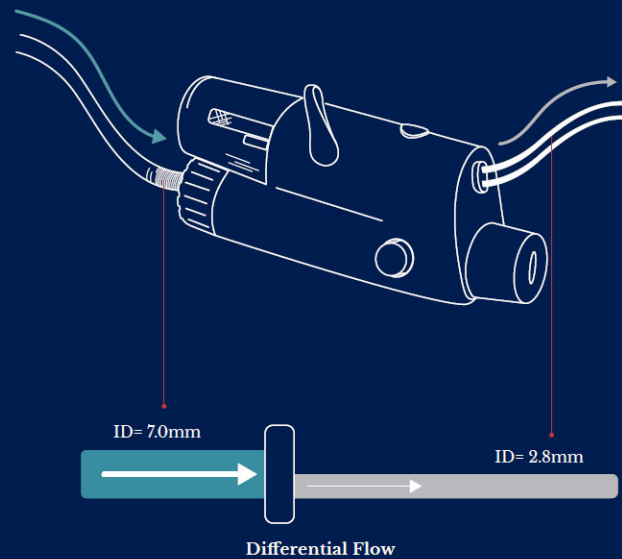


(Symphony Thrombectomy System Brochure at 6.)

On-Demand Vacuum with Integrated Blood Management

Balance power with control and minimize blood loss with built-in differential flow. Clot capture in the palm of your hands provides real-time case assessment.

The Symphony™ Advantage



Blood flowrate reduced by
~55%[‡]

[‡] Data on File

(Symphony Thrombectomy System Brochure at 7.)

The clot collection reservoir of the Symphony Catheter handle is also shown on the Whipsaw website.



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



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

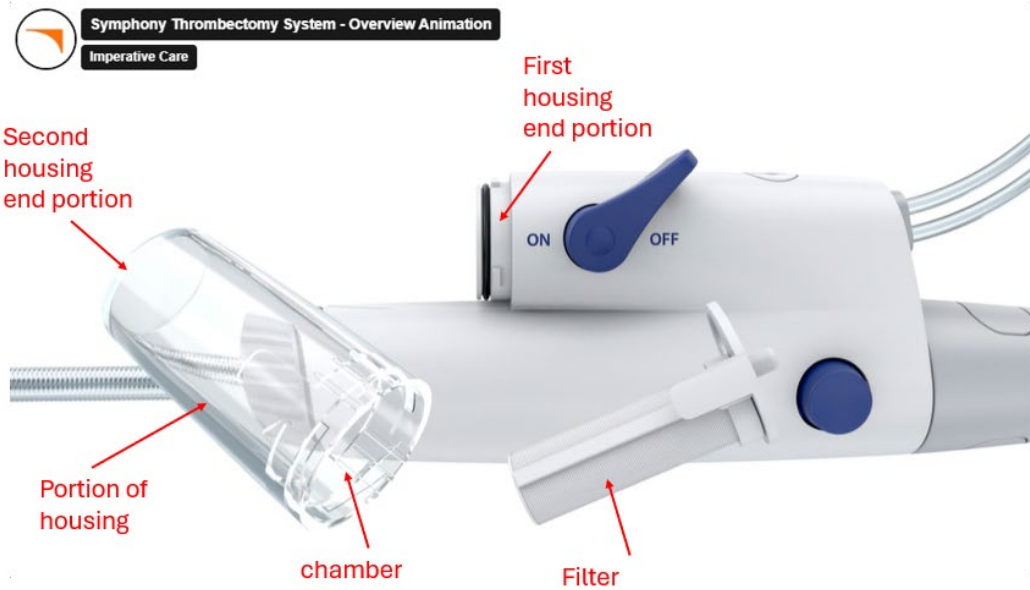


(Image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

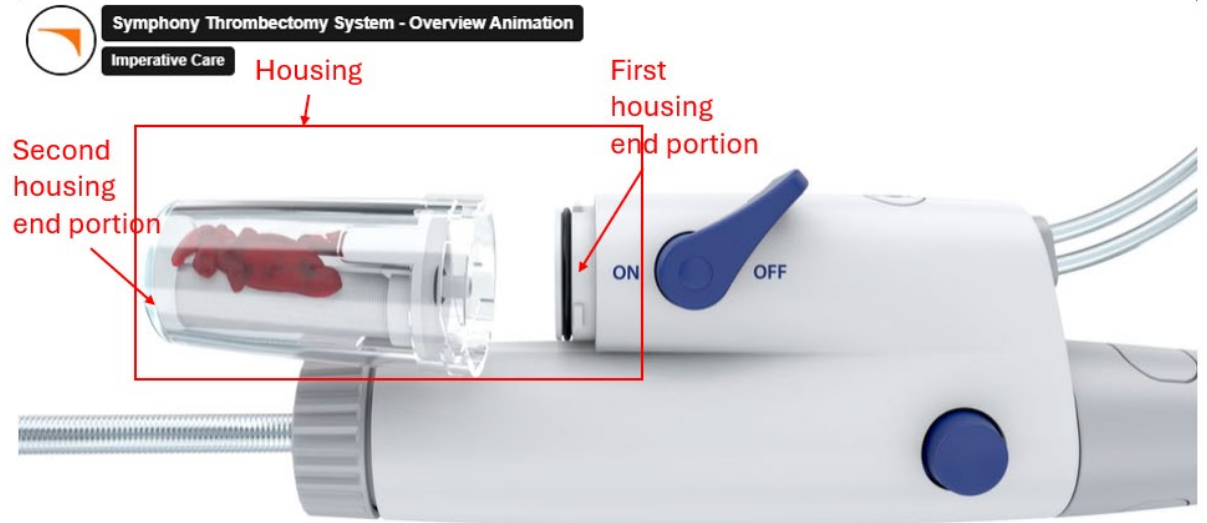
a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;

The clot collection reservoir of the Symphony System includes a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.

The clot collection reservoir and the 24F and 16F Catheter Handles includes a housing, which defines a sealed chamber and has a first housing end portion and a second housing end portion opposite the first, as shown in the annotated image below. The removable portion of the clot collection reservoir housing removably attaches to the portion of the housing connected to the 24F and 16F Catheter Handles.

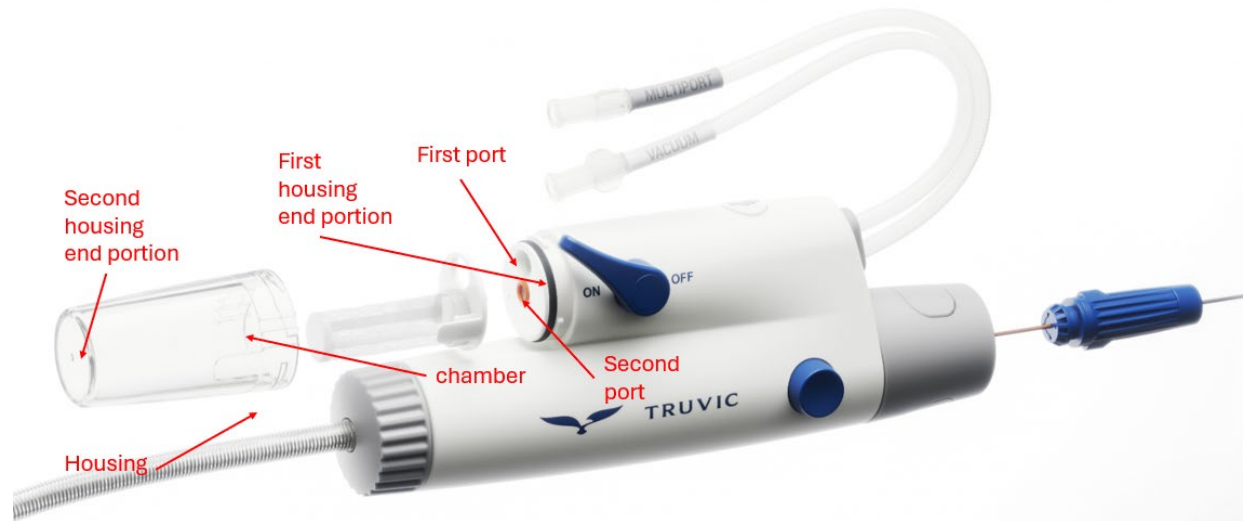


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

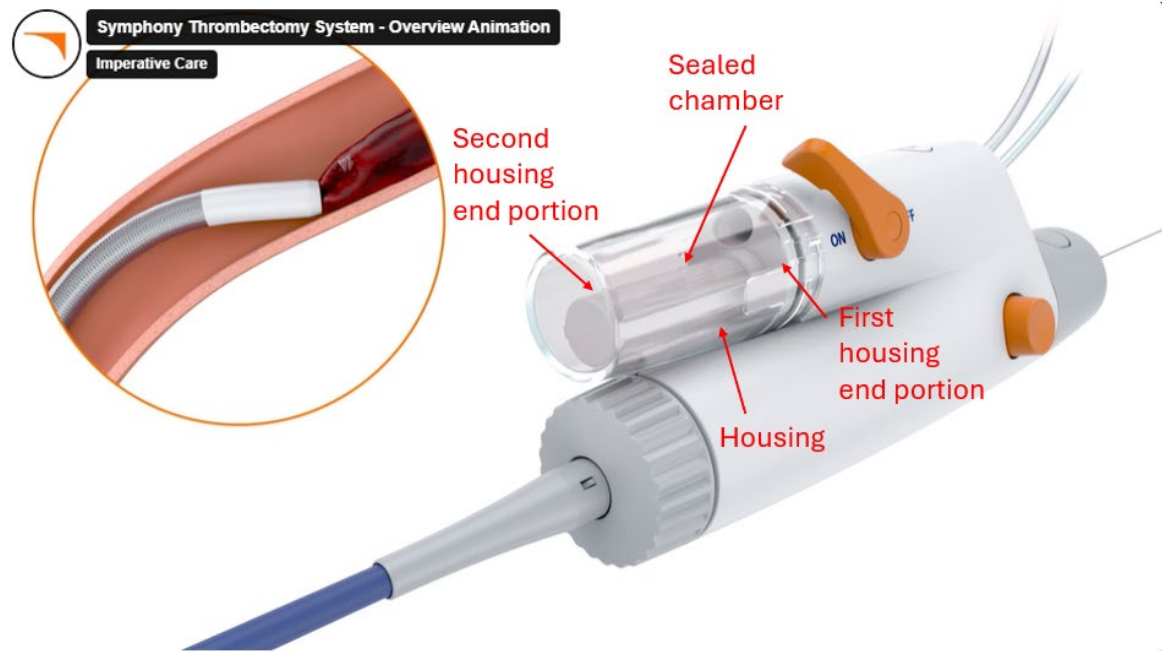


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:19.)

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



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



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:57.)

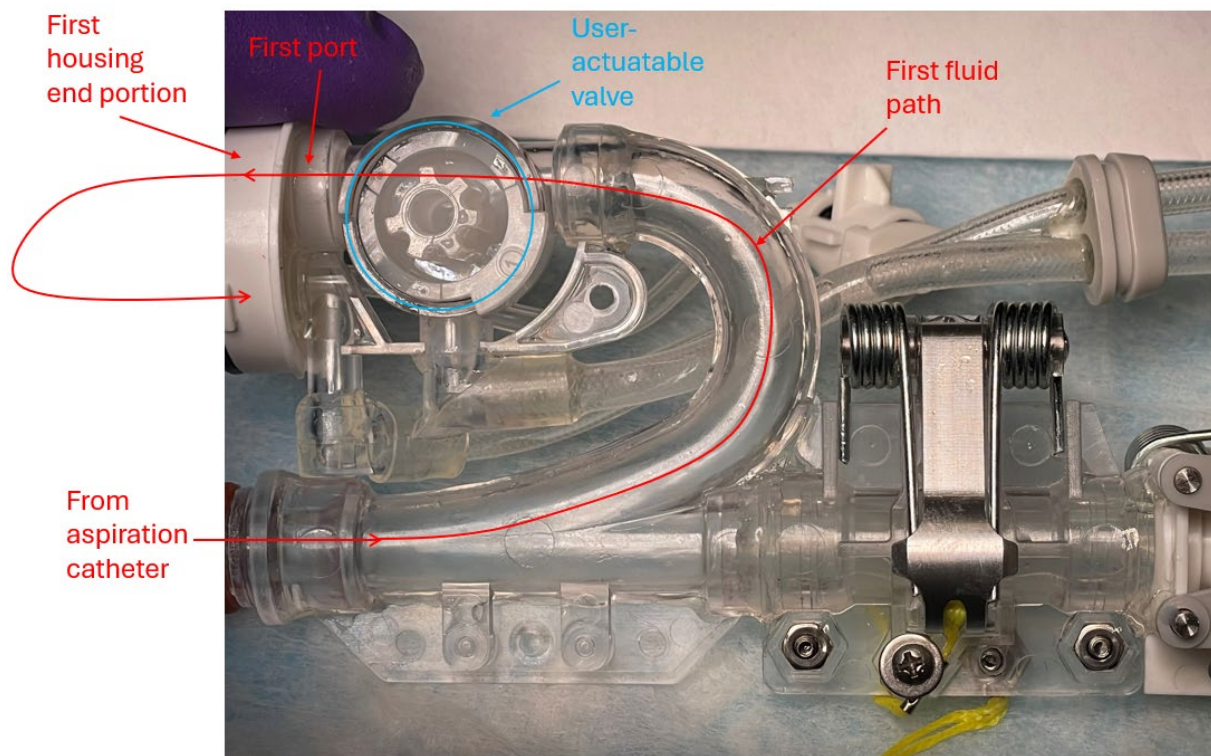
To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

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

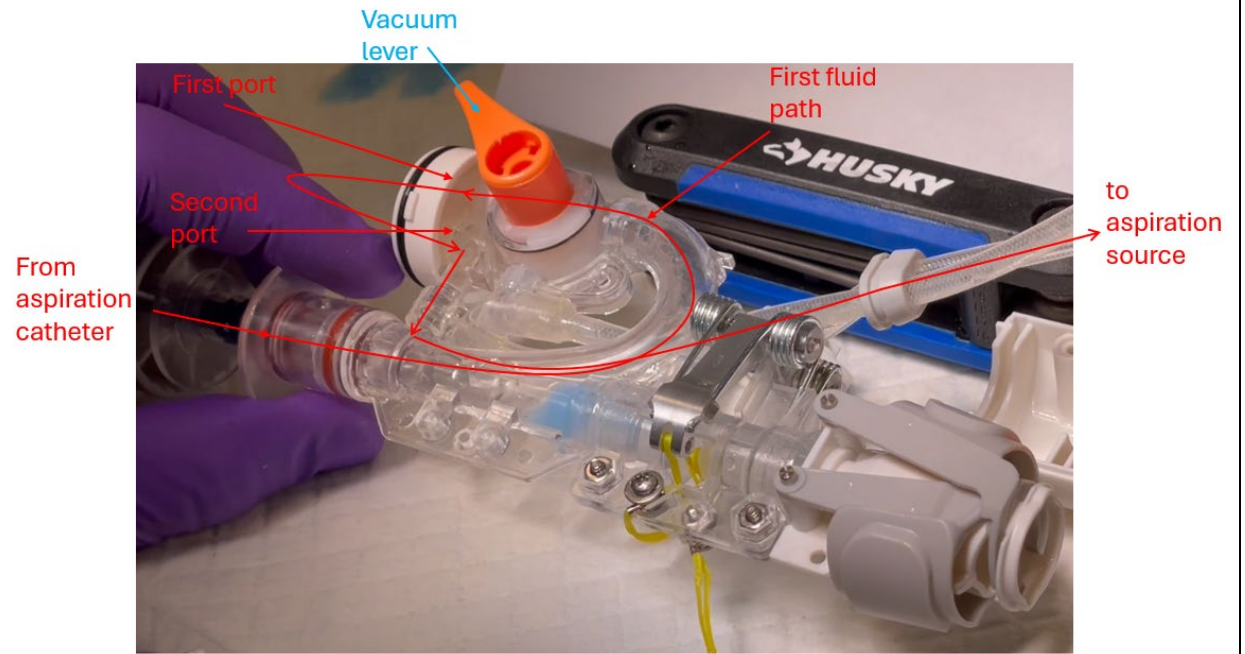
The clot collection reservoir of the Symphony System includes a first port configured to be fluidly coupled to an aspiration catheter, where the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber.

path to the chamber;

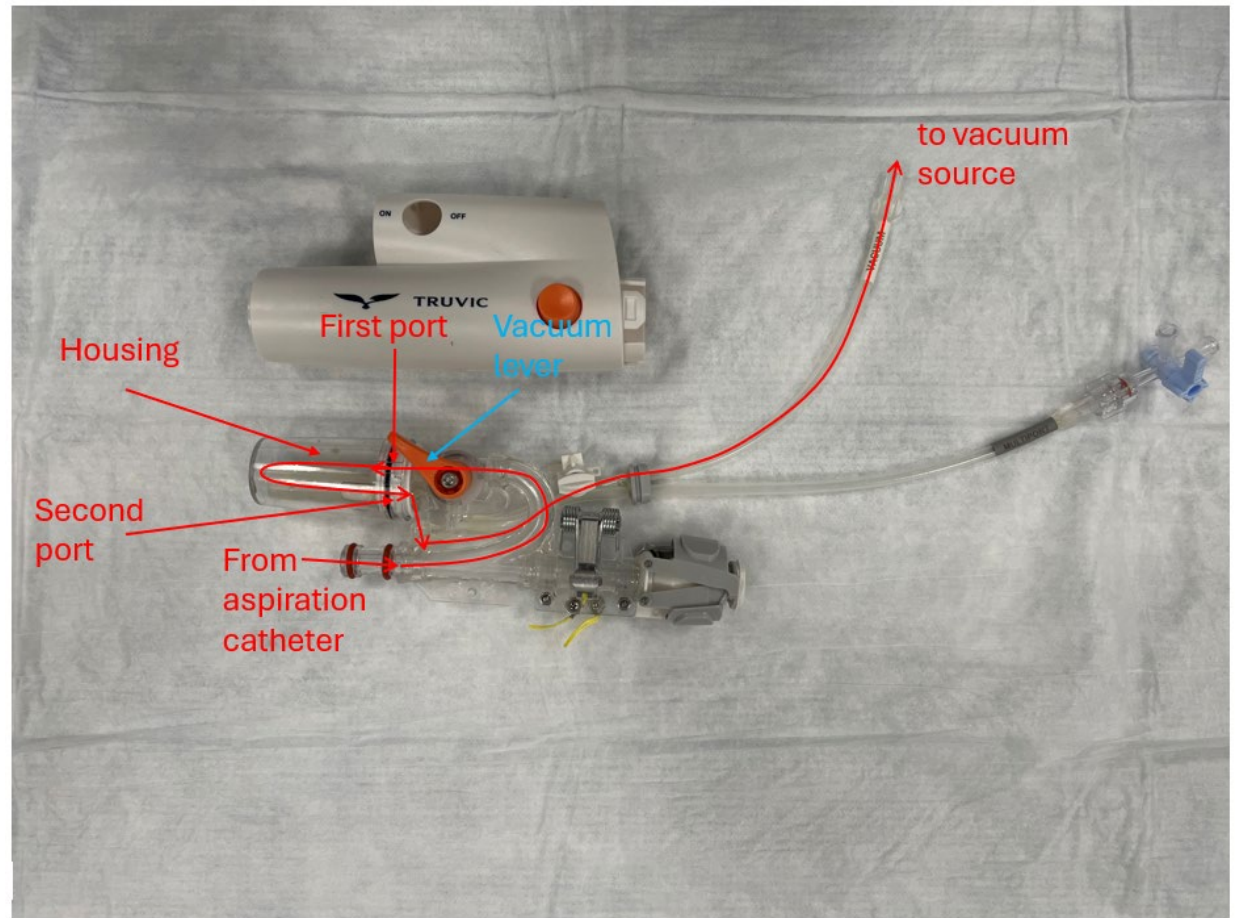
Specifically, the clot collection reservoir of the 24F and 16F Symphony Catheter handles includes a first port proximate to the first housing end portion that is coupled to an aspiration catheter when the valve is in the ON position, as shown in the annotated teardown images below.



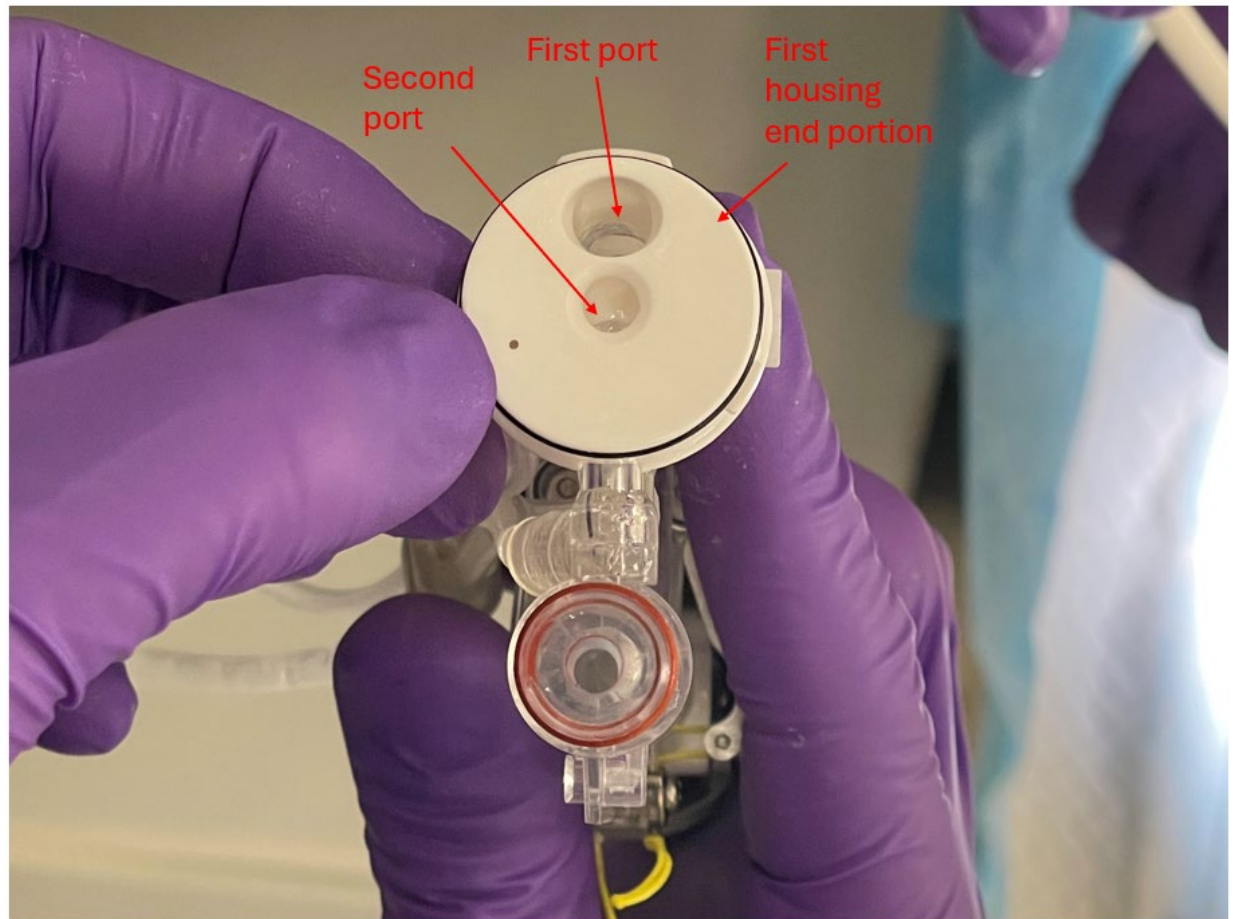
(Annotated image of internal portion of the controller housing.)



(Annotated image of internal portion of controller housing.)

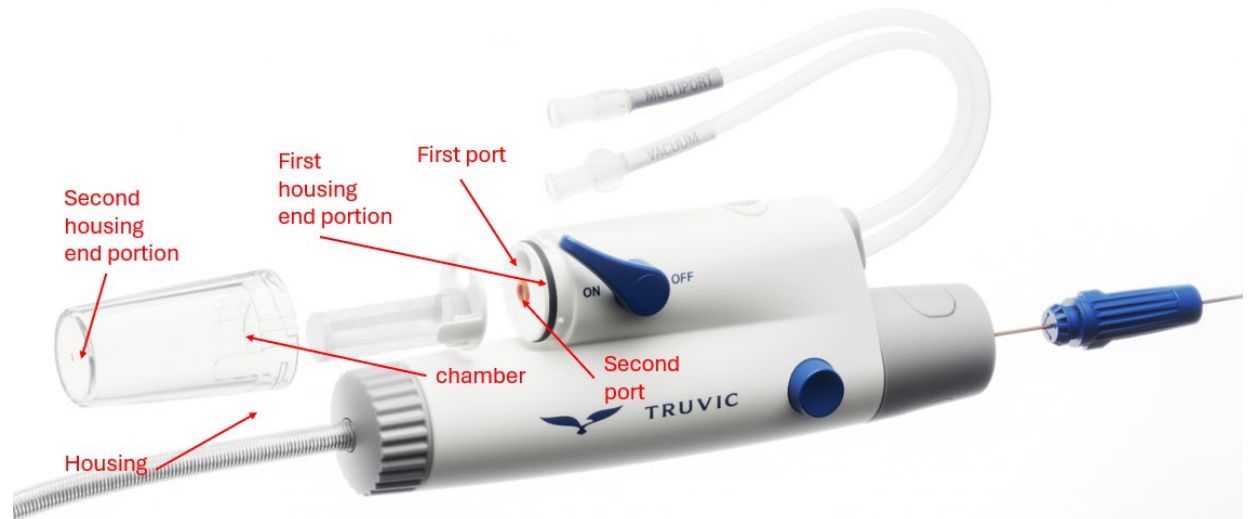


(Annotated image of internal portion of controller housing.)



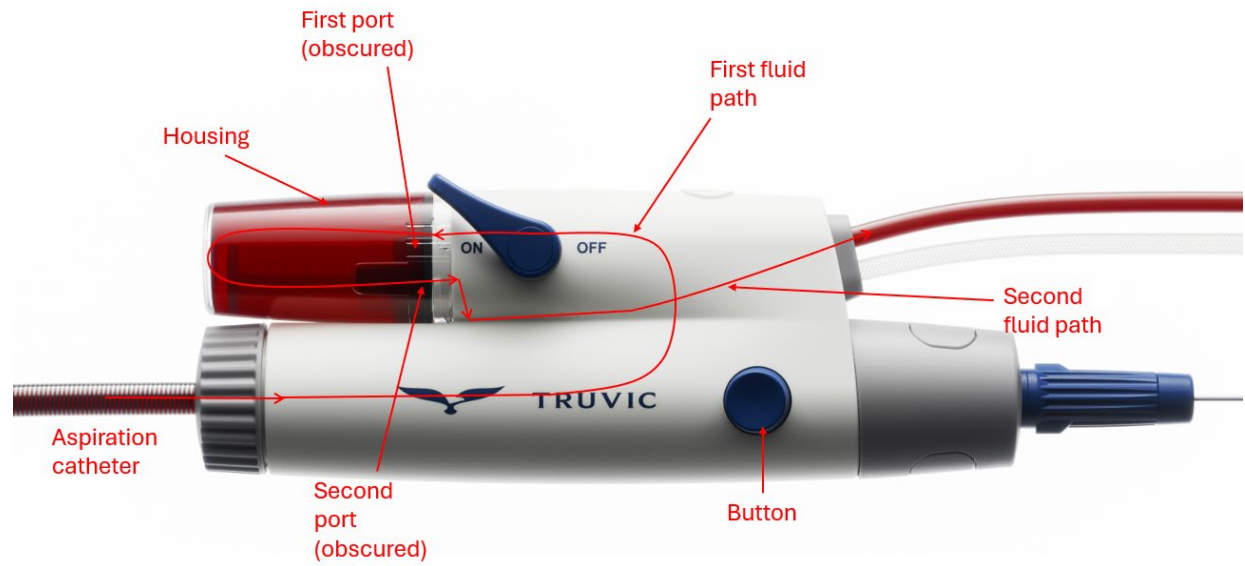
(Annotated image of controller housing showing first and second ports.)

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



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

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

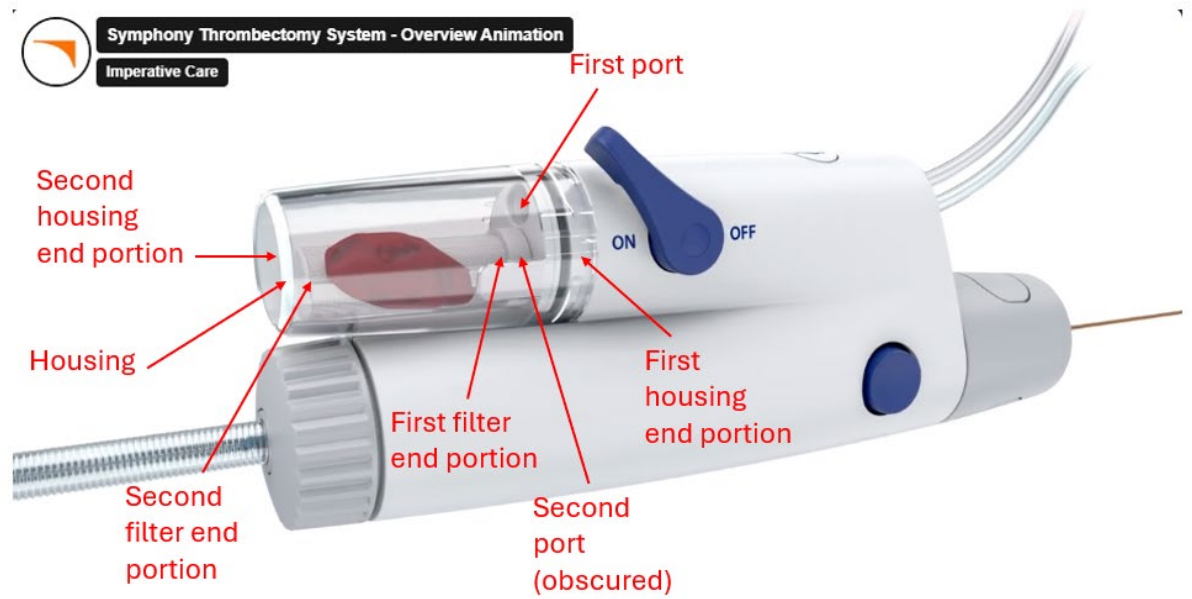


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

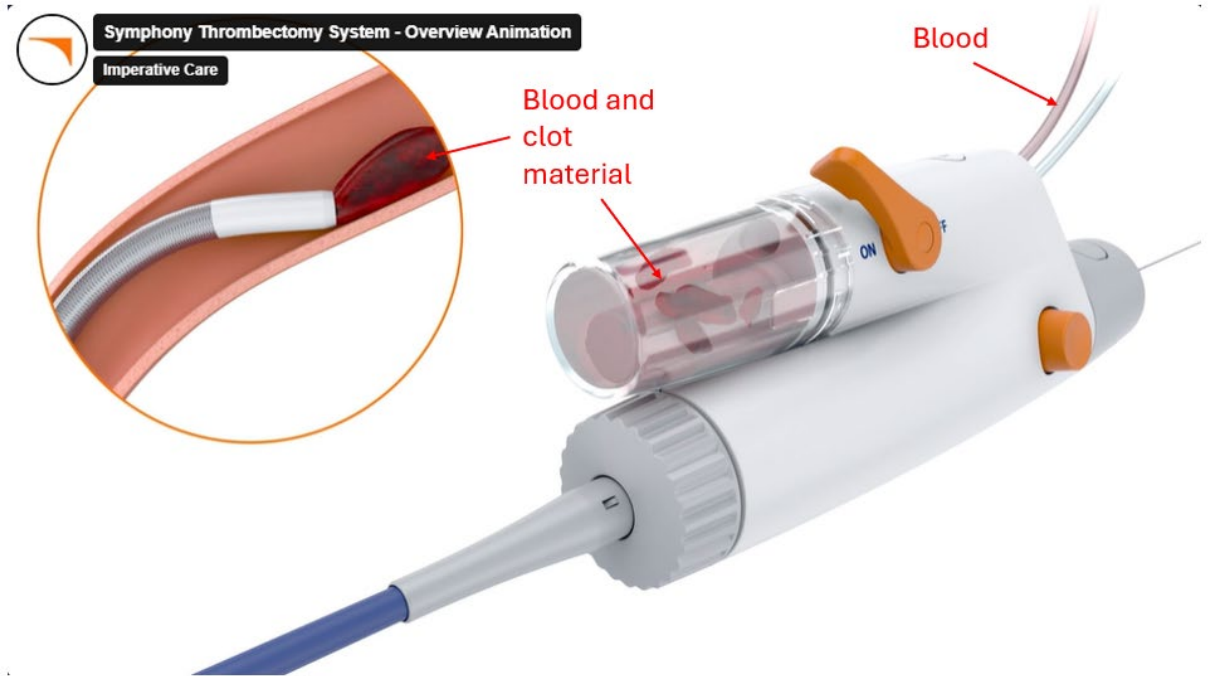
The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration catheters, travels through the first fluid path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot collection reservoir.



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



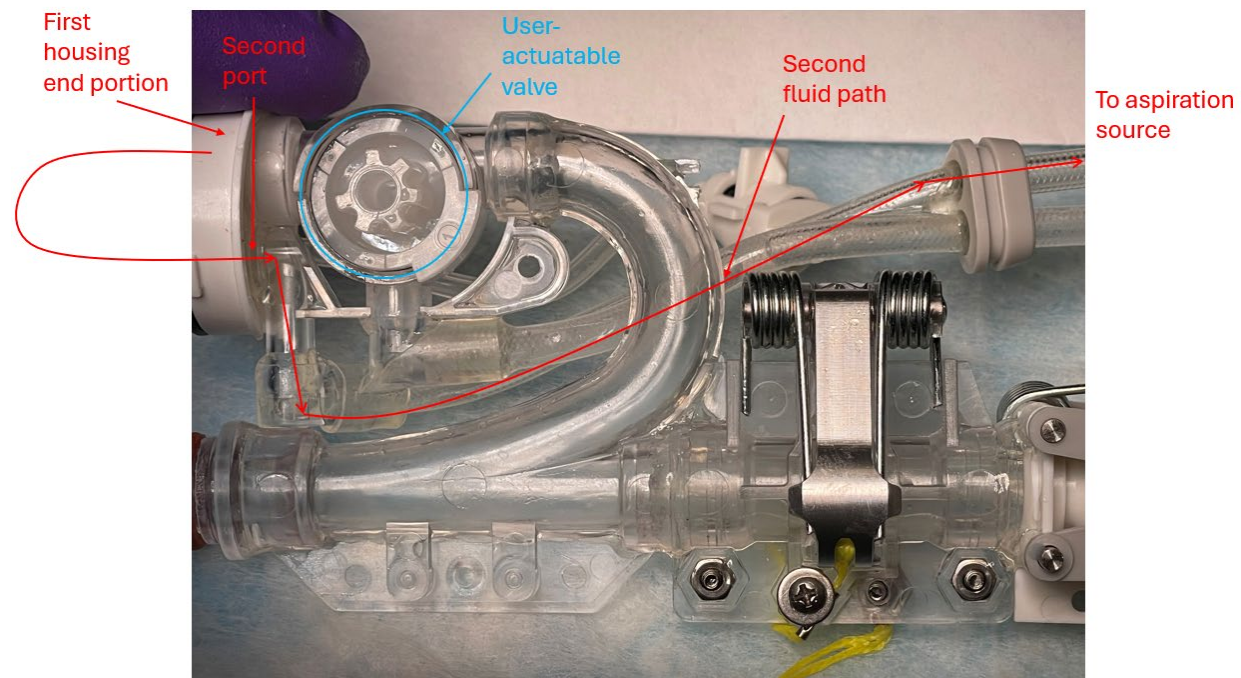
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)



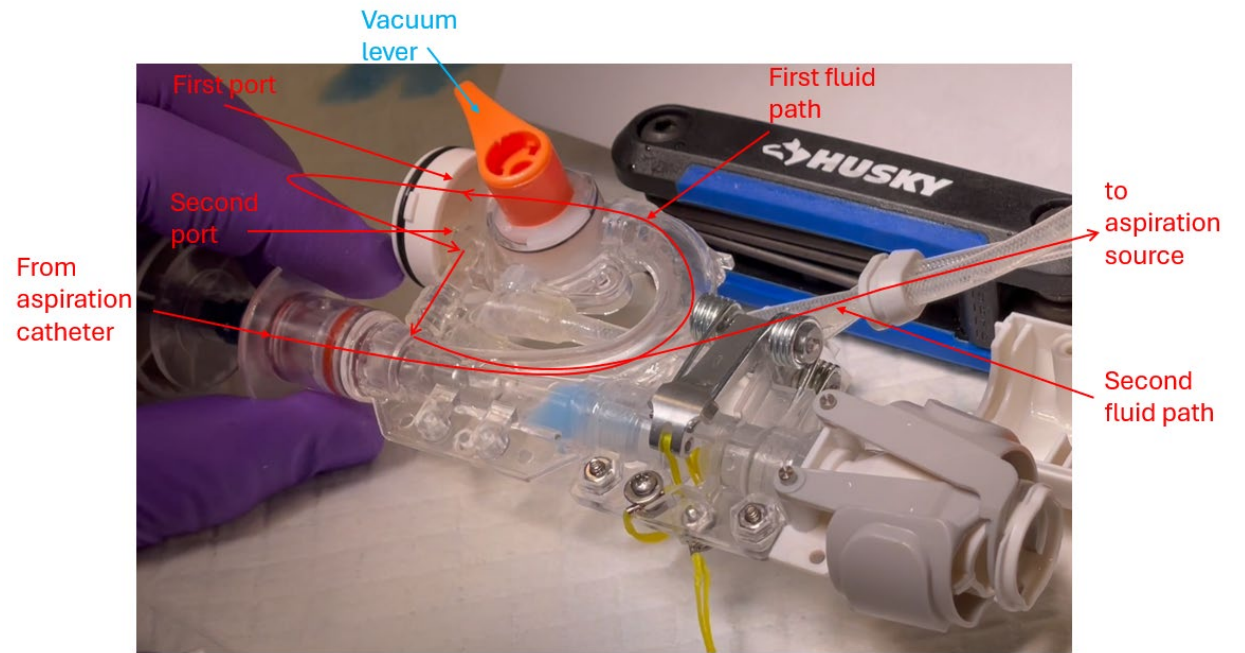
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

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

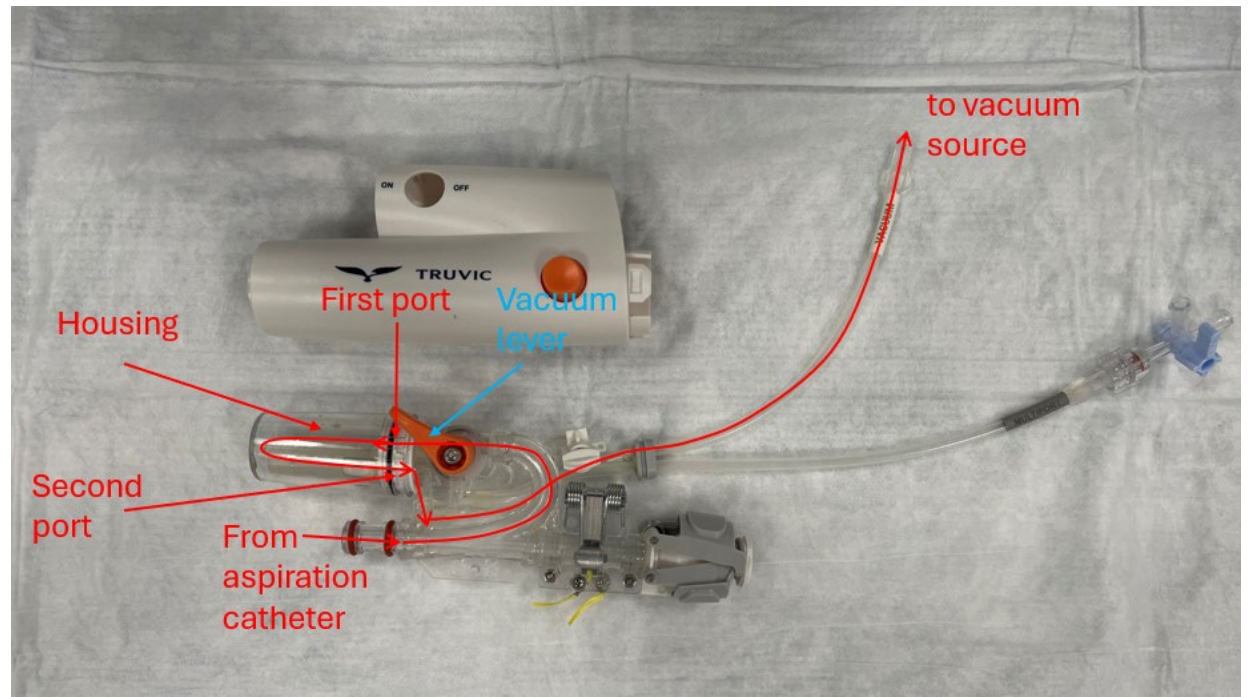
	<p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>a second port configured to be fluidly coupled to an aspiration source, wherein the second port provides a second fluid path from the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



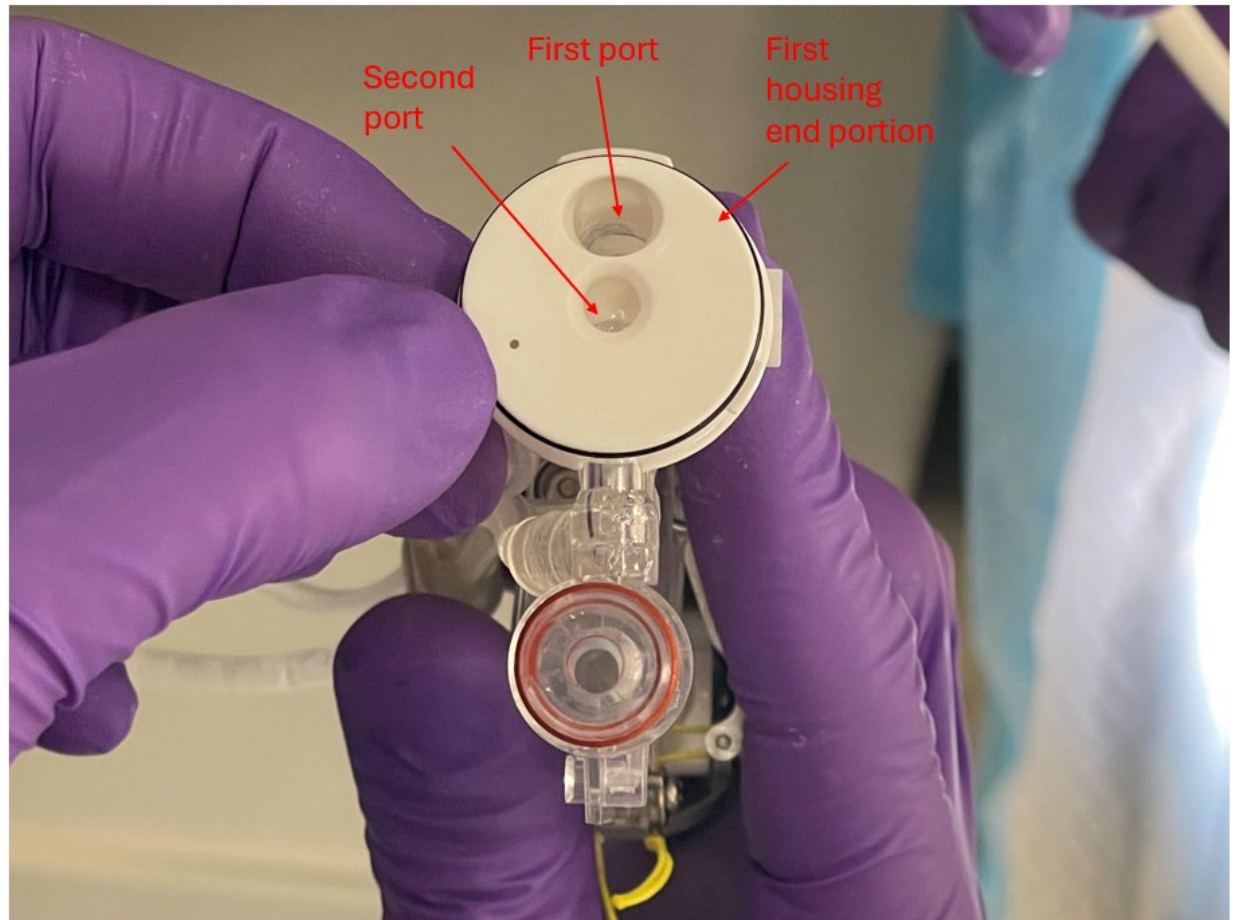
(Annotated image of internal portion of the controller housing.)



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



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



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

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

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

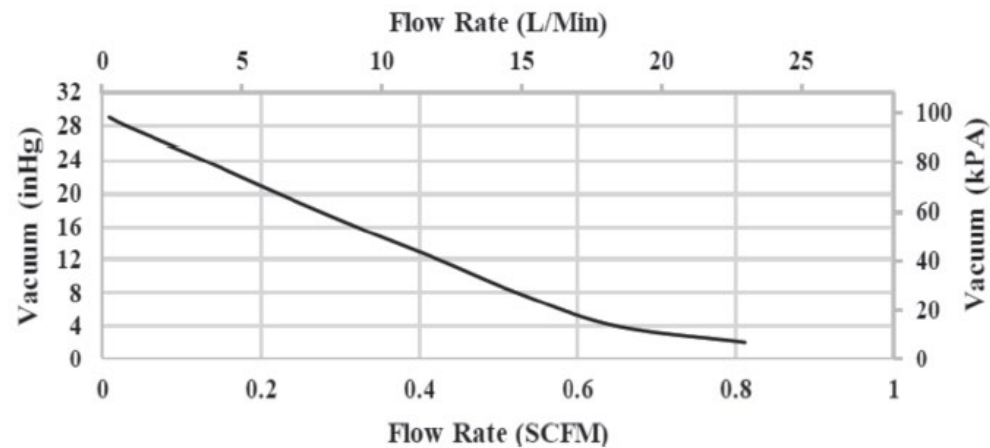
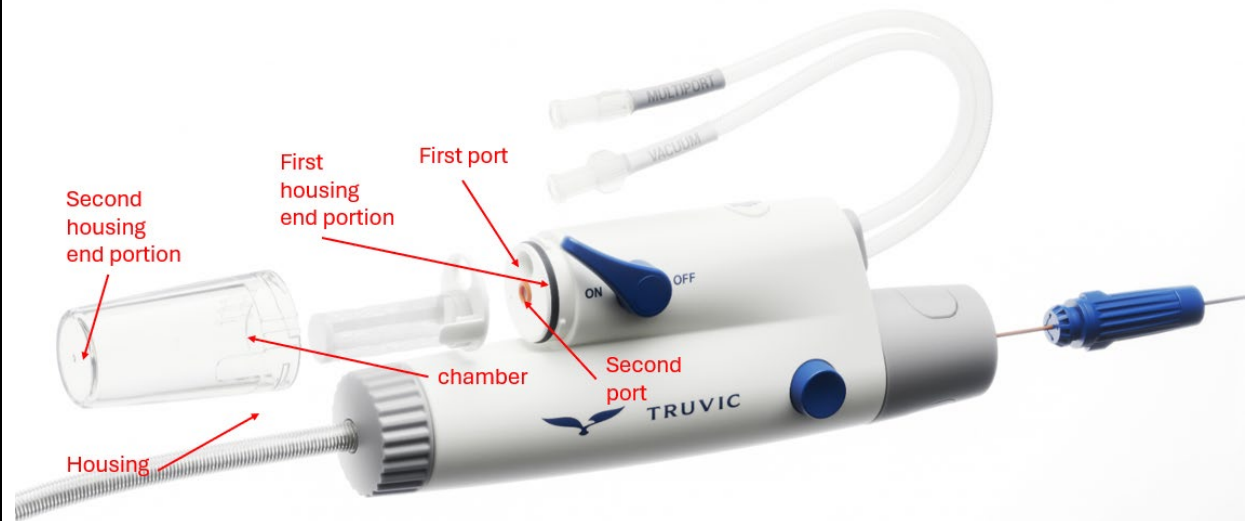


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

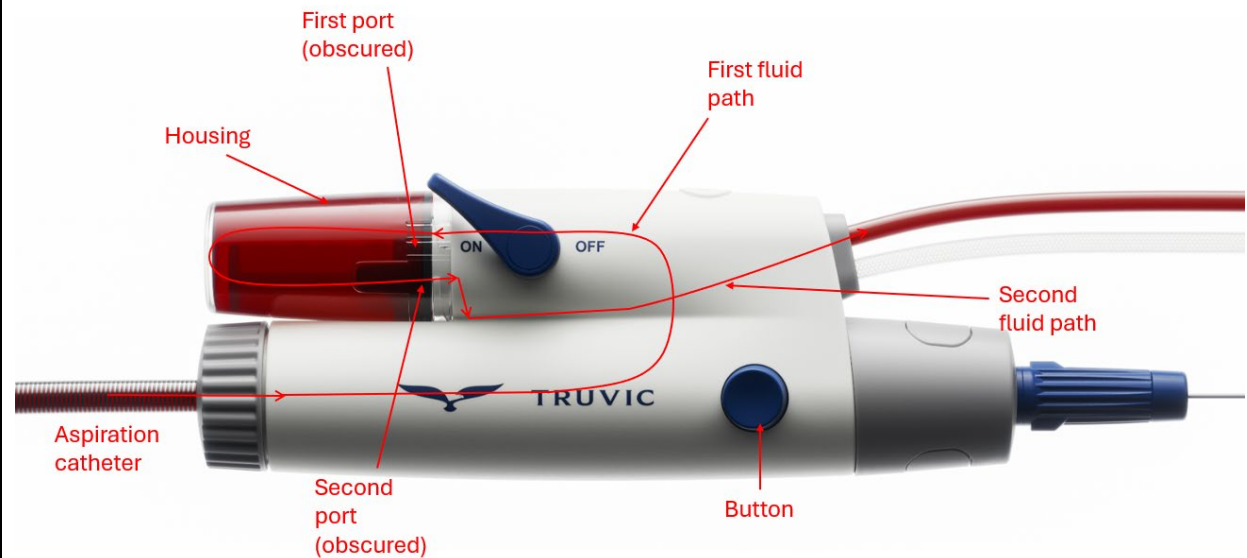
The second port can also be seen in the exploded image from the Whipsaw website of a 24F Symphony Catheter handle with a disassembled clot collection reservoir, which is annotated and reproduced below.



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

The second port provides a second fluid path from the clot container of the 24F and 16F Symphony Catheter handles, as shown in the annotated image from Whipsaw's website below. Specifically, blood and clot material enters the aspiration catheter and travels along the first fluid path through the first port and into the chamber of the clot container. Blood then passes through the filter, through the second port and along the second fluid path where blood flows through internal tubing within

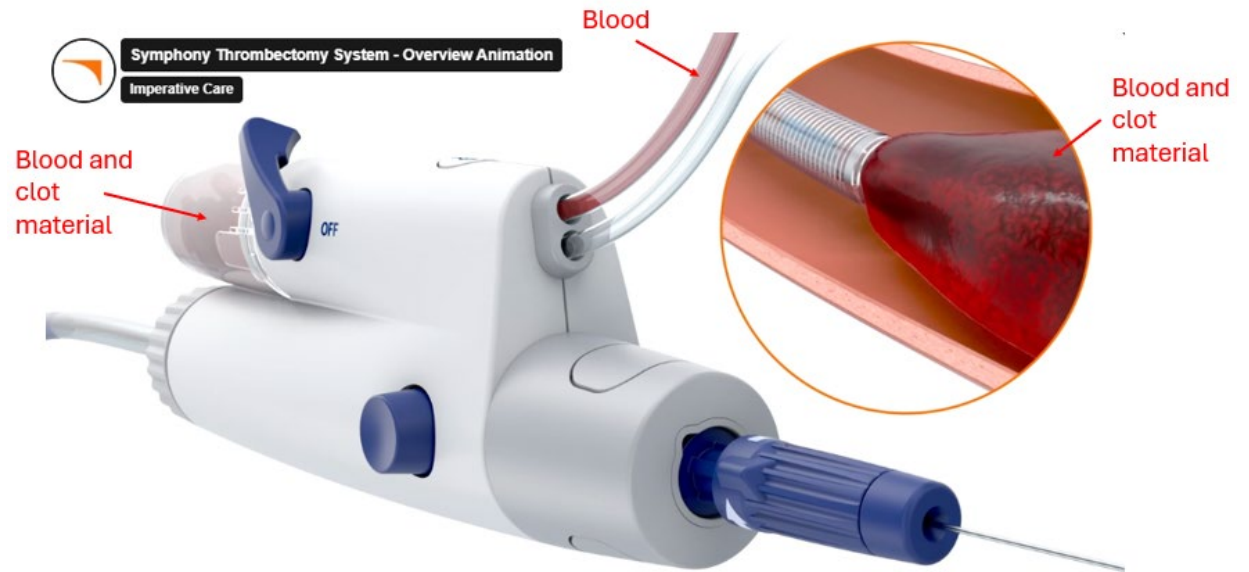
the handle toward the Truvic Generator and Truvic Canister (e.g., aspiration source, not shown).



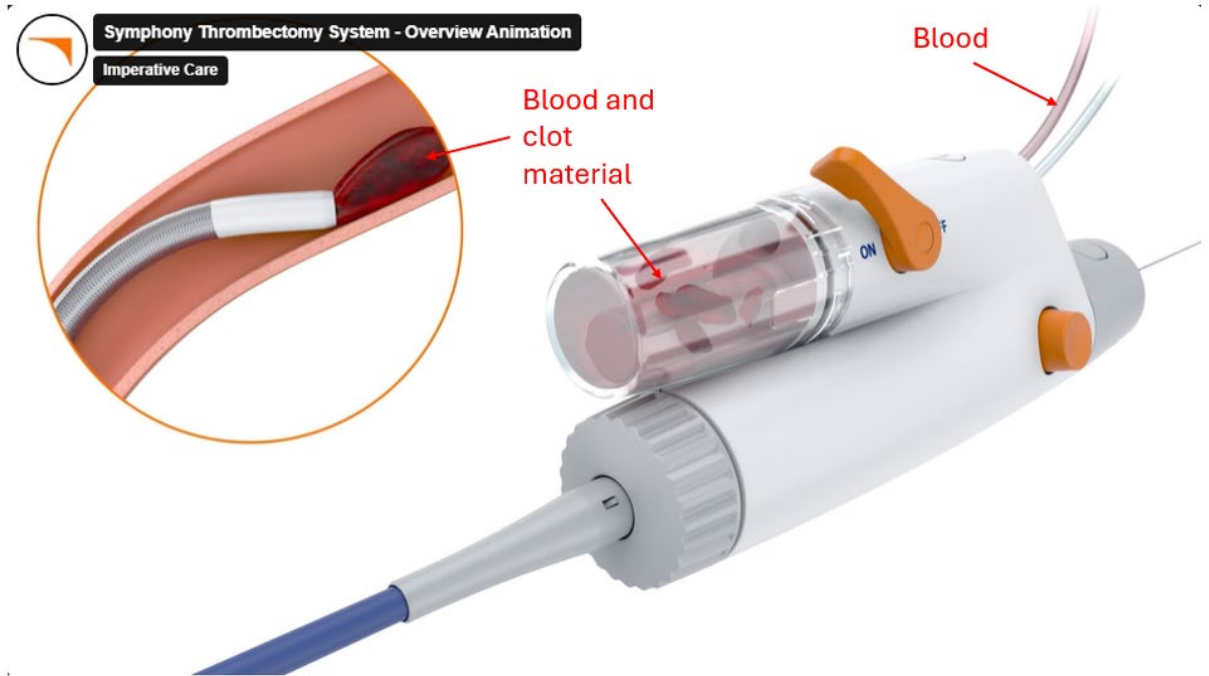
(Annotated image of handle including clot container from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration catheters, travels through the first fluid path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot container. Blood then flows through the filter, through the second port that provides a second fluid path from

the chamber of the clot container towards the tubest and then toward the aspiration source.



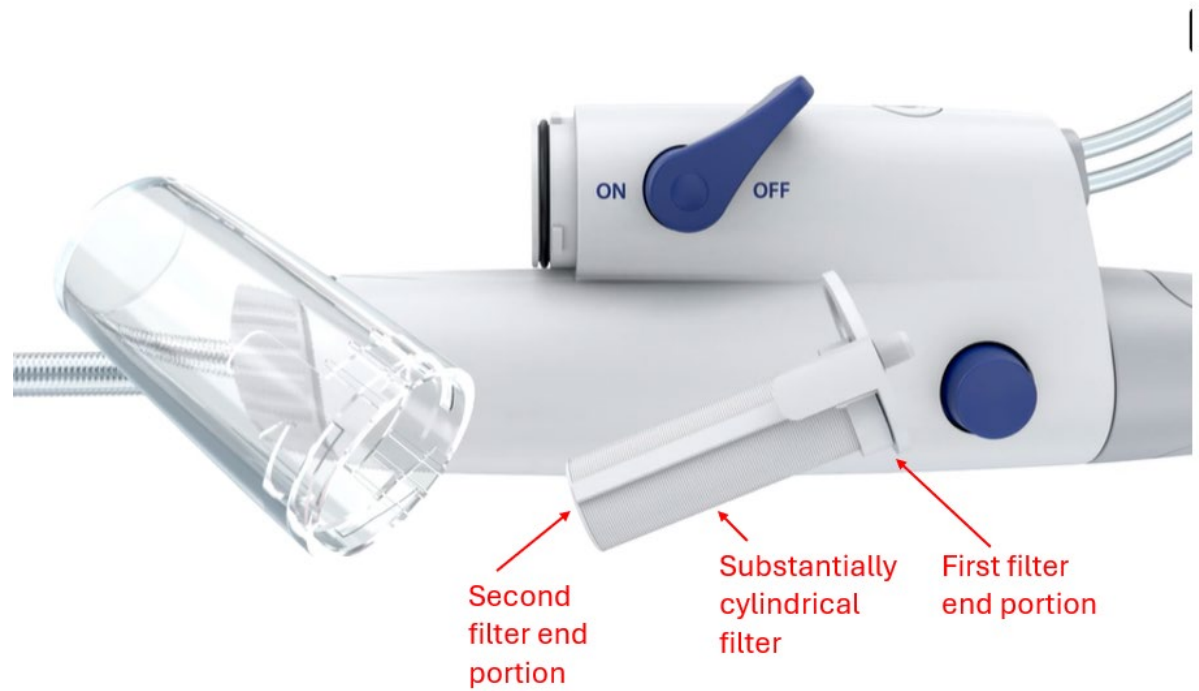
(Symphony Thrombectomy System – Overview Animation Video at 1:09.)



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

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

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

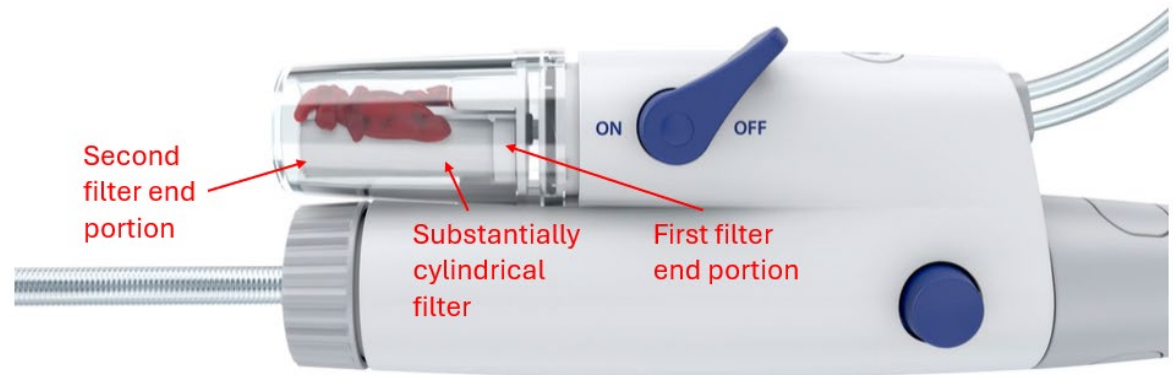


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

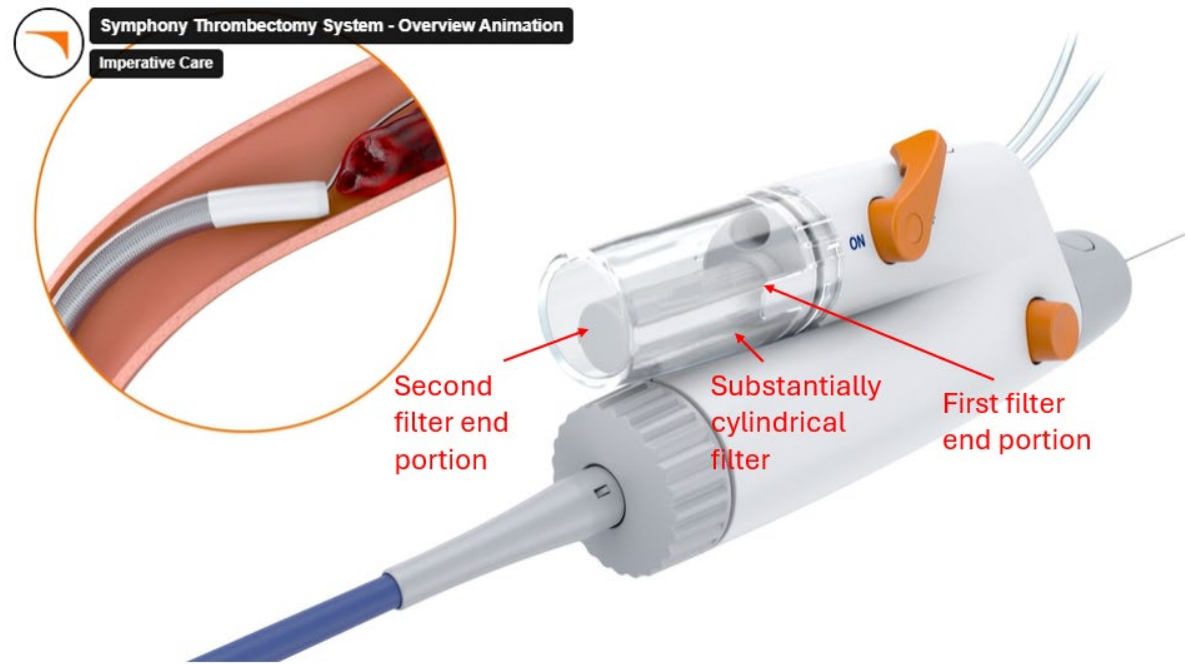


Symphony Thrombectomy System - Overview Animation

Imperative Care

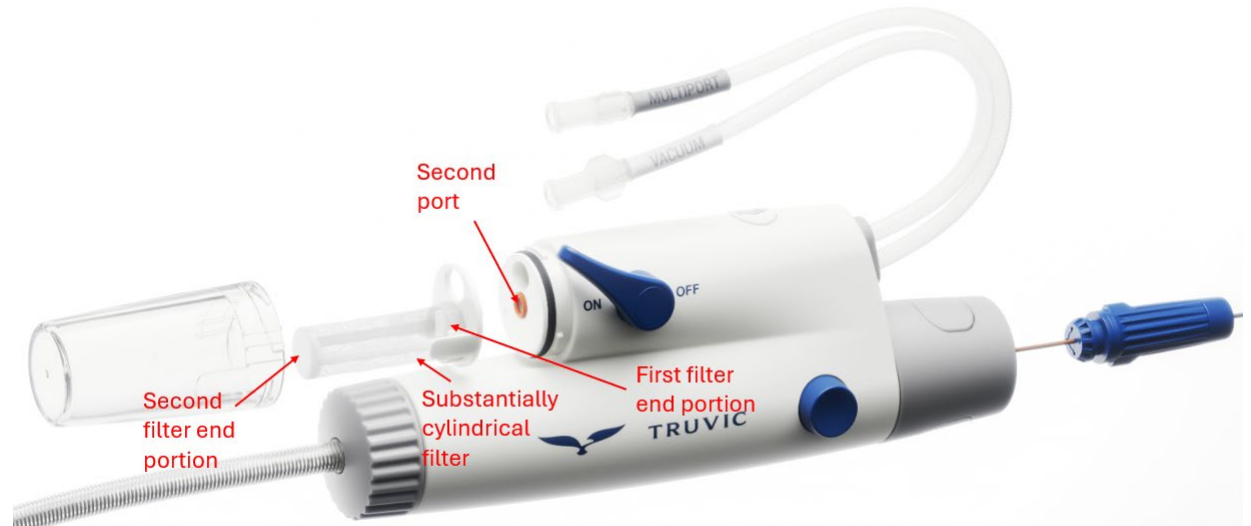


(Symphony Thrombectomy System – Overview Animation Video at 1:18.)



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

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



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

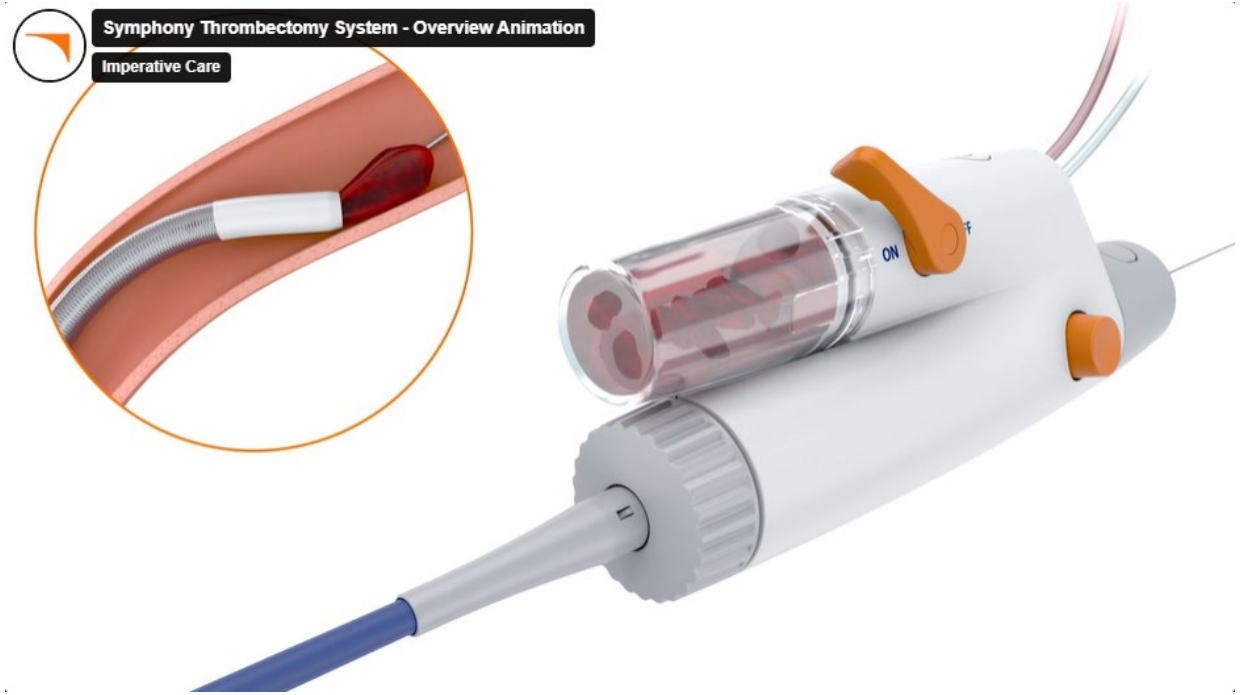
The substantially cylindrical filter encloses an interior region around the second port, such that it prevents clot material from entering the second port. Instead, the filter permits blood to flow through the second port and toward the aspiration source via the second fluid path, as shown in the images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



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



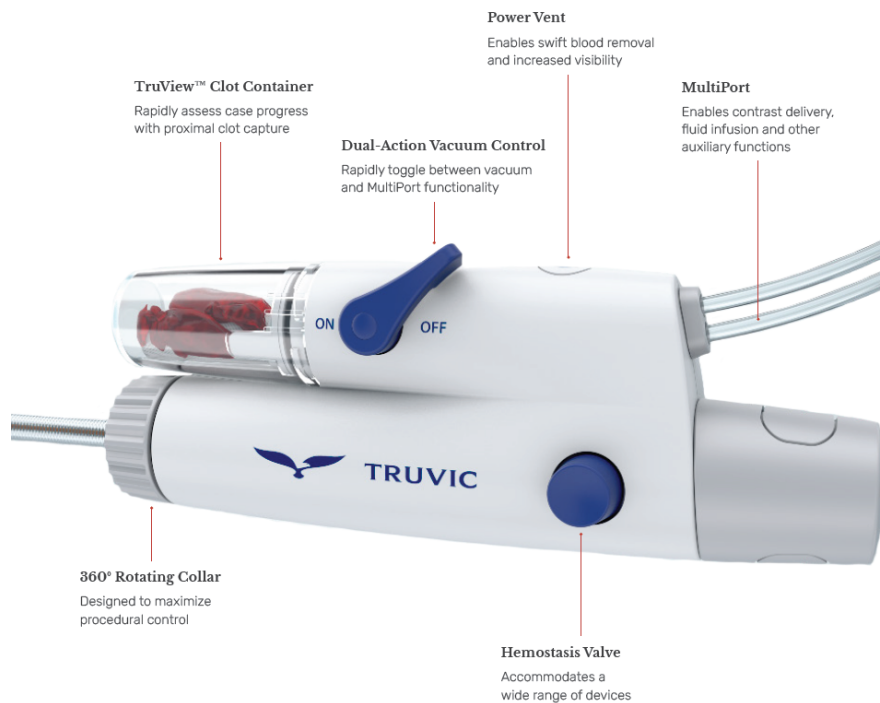
(Symphony Thrombectomy System – Overview Animation Video at 1:08.)



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

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

BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)

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

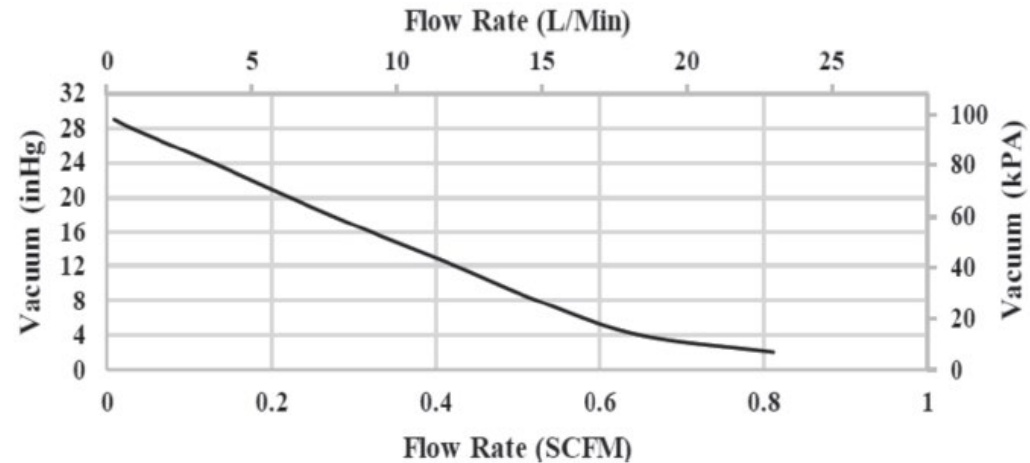
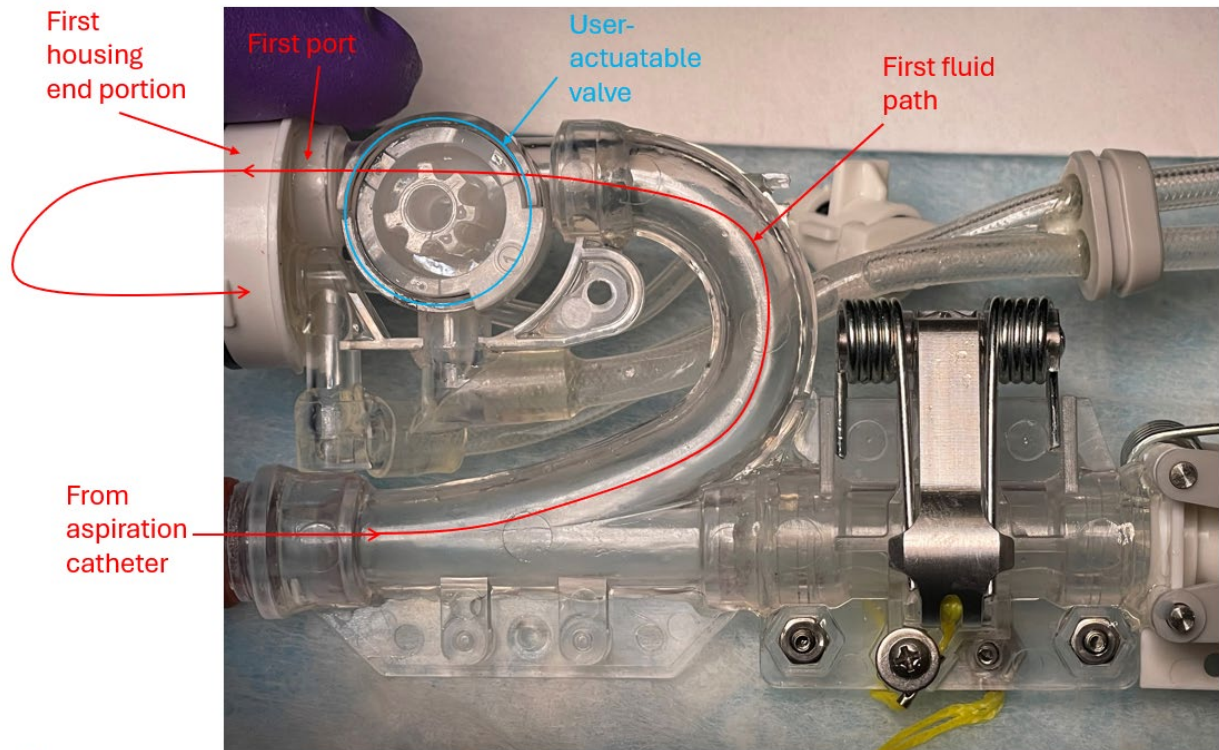


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

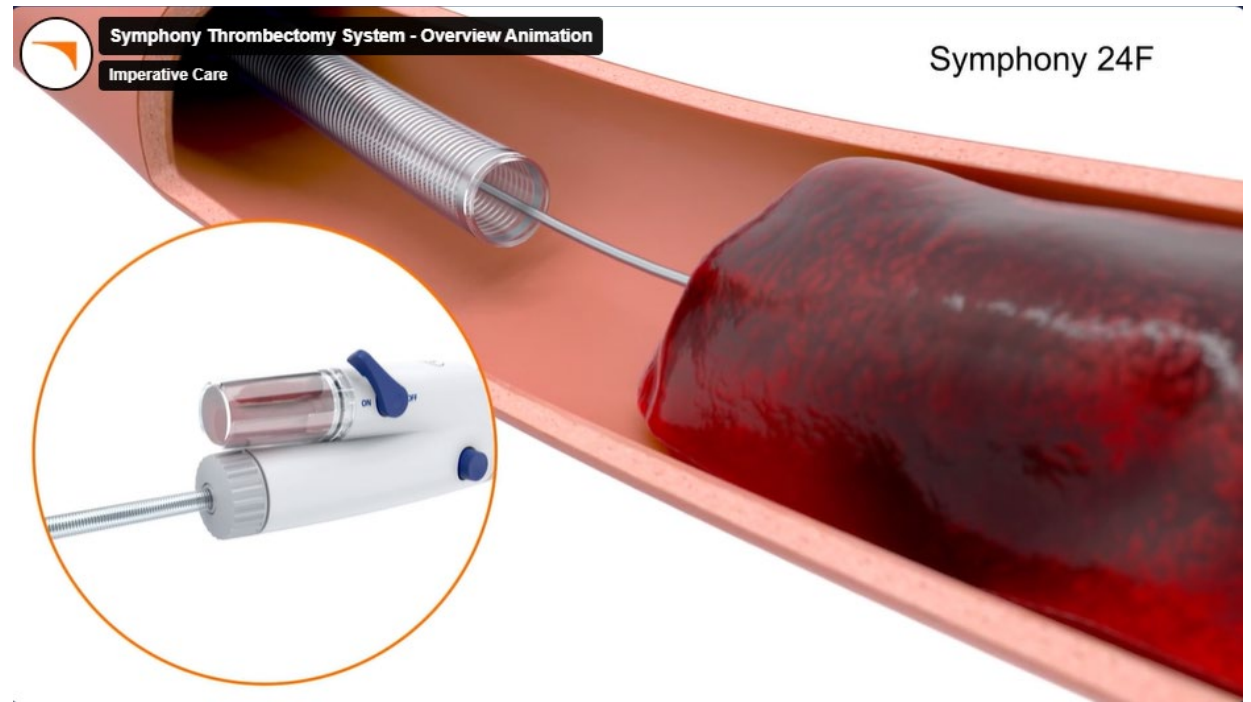
When negative pressure is generated in the chamber of the clot container by the aspiration source (*e.g.* the Truvic Generator and Truvic Canister) and then the vacuum lever is turned to on to connect the aspiration catheter, it causes blood and clot material to be drawn from the human patient, through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

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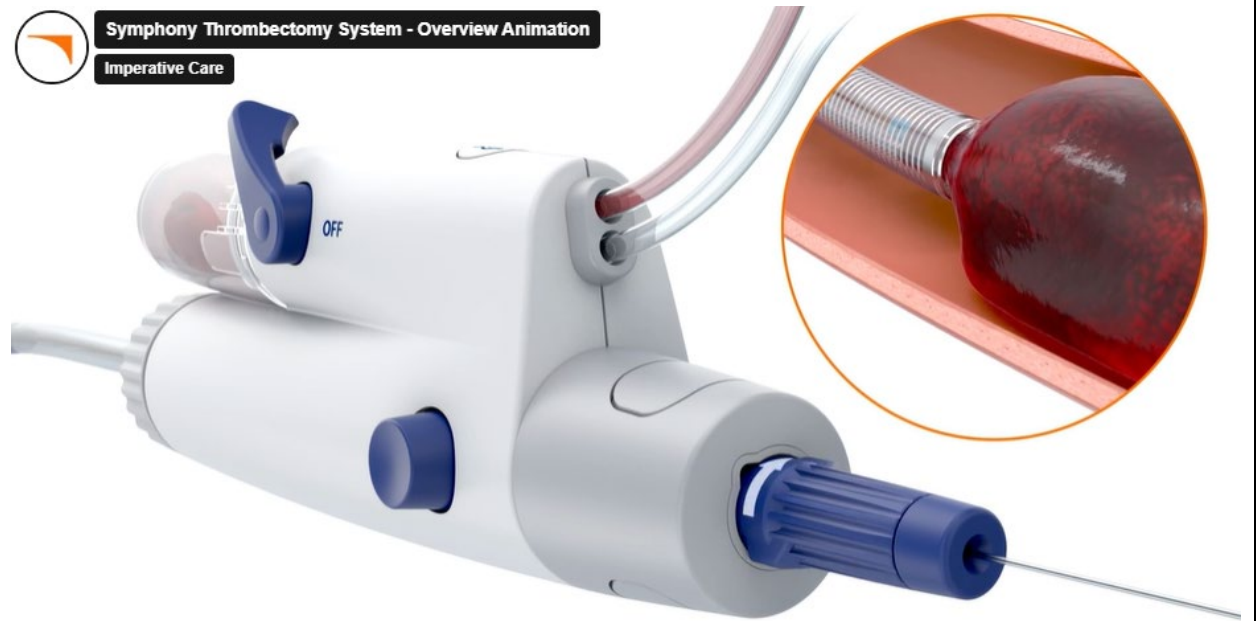


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(Annotated image of internal portion of the controller housing.)

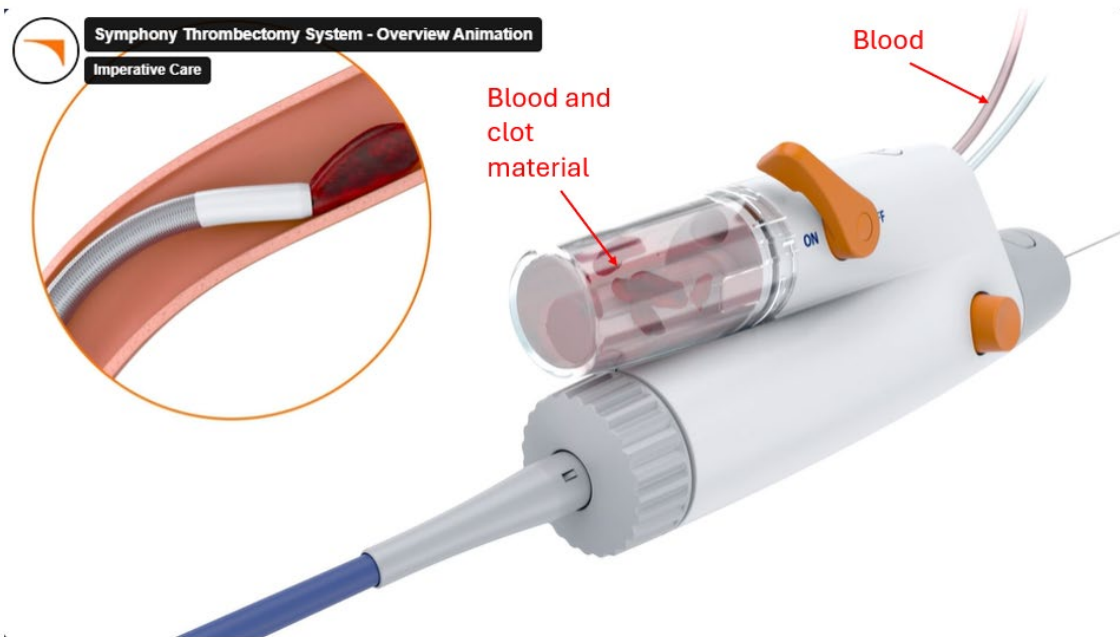
The Symphony Thrombectomy System Overview Animation Video also depicts blood and clot material flowing from the aspiration catheter, through the first port, and into the chamber of the clot container.



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

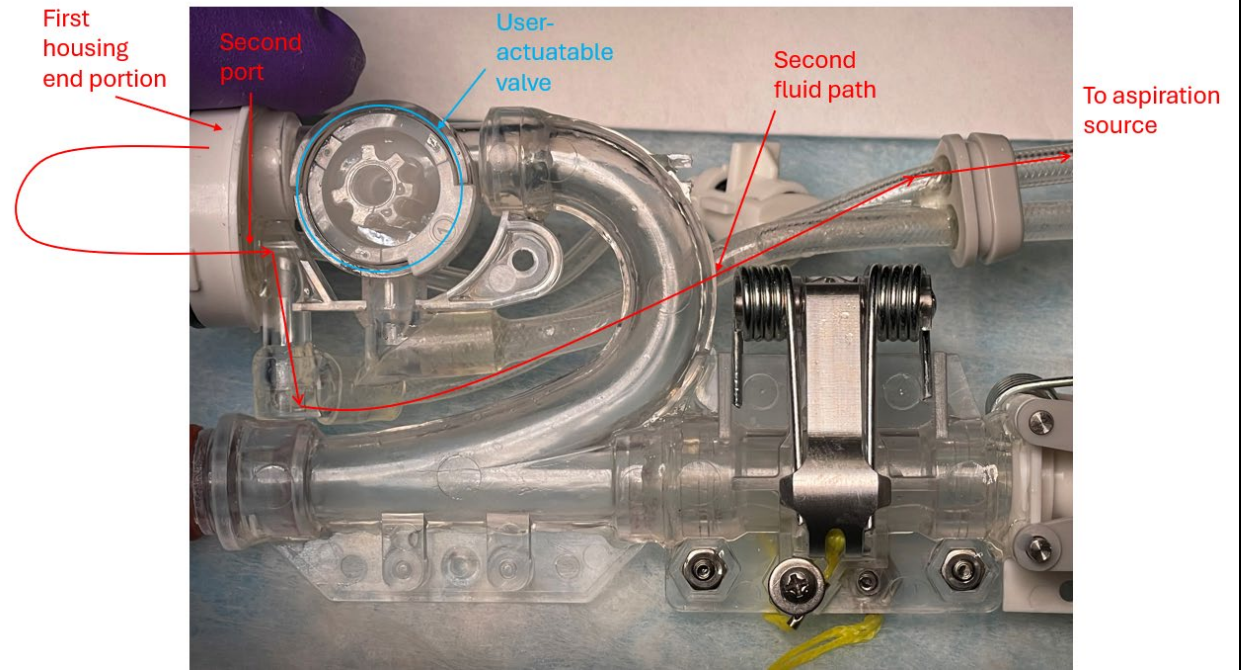


(Symphony Thrombectomy System – Overview Animation Video at 1:05.)



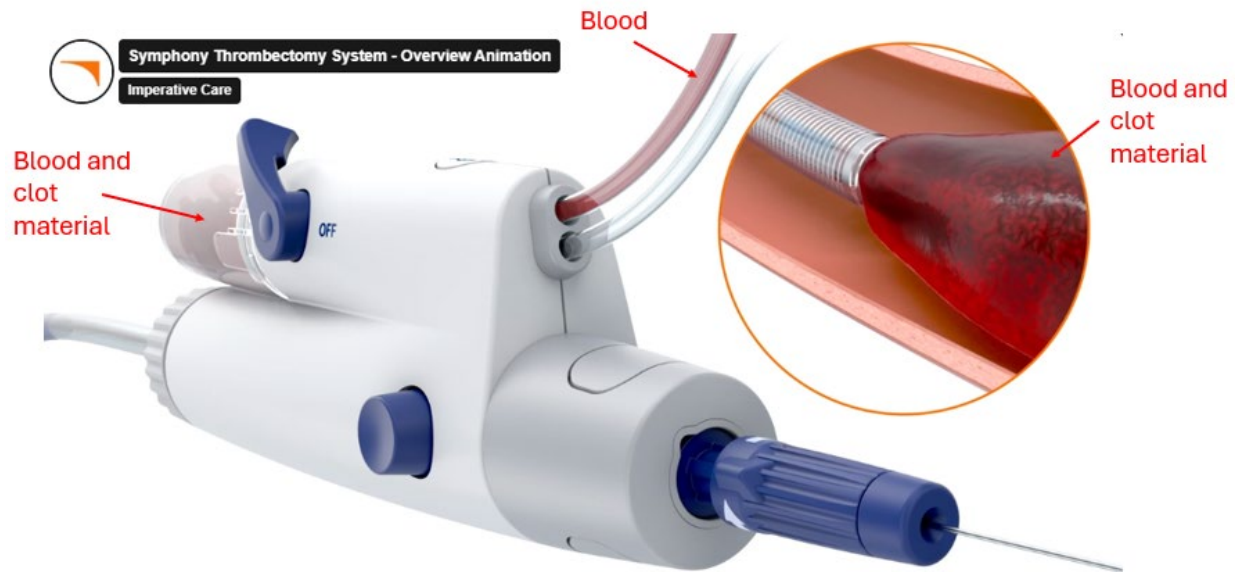
(Symphony Thrombectomy System – Overview Animation Video at 2:01.)

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

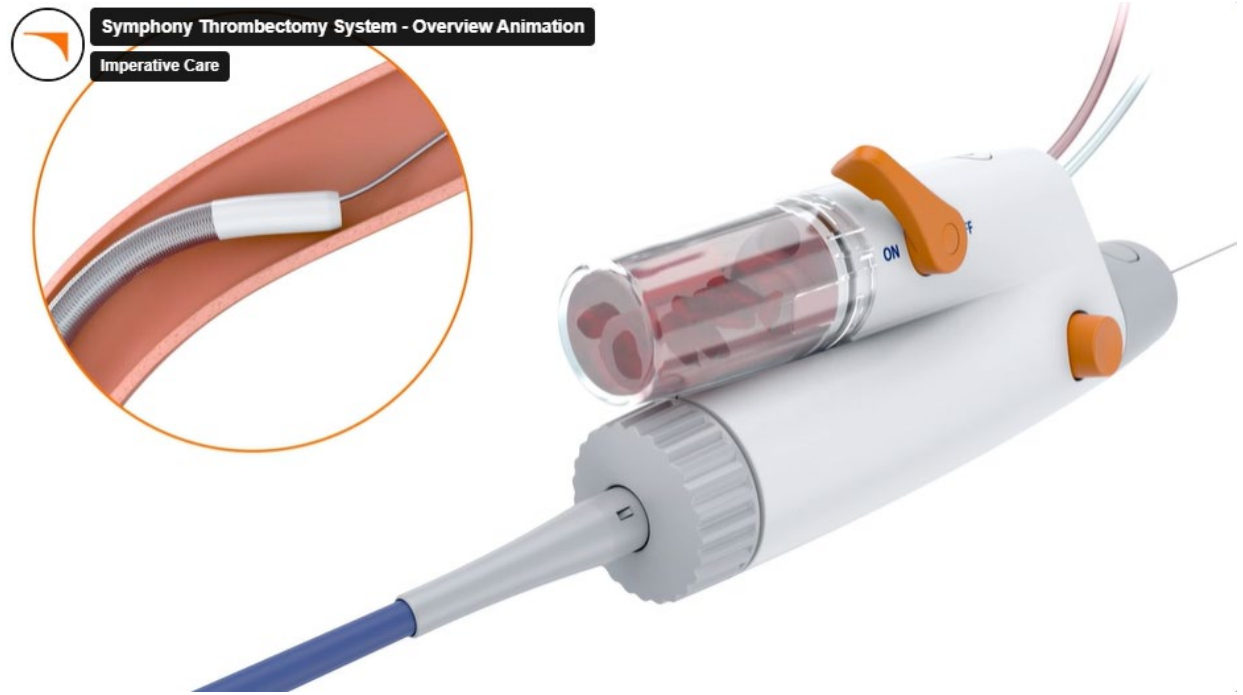


(Annotated image of internal portion of the controller housing.)

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



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



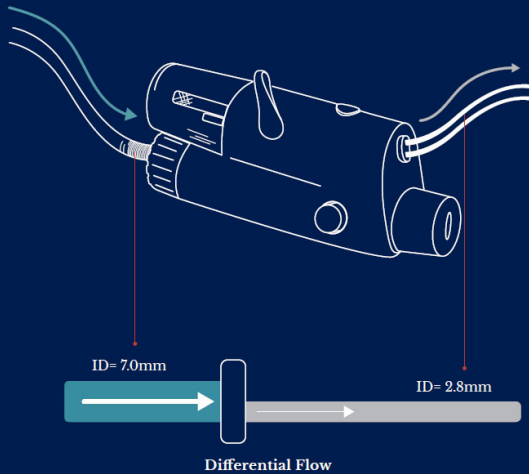
(Symphony Thrombectomy System – Overview Animation Video at 2:03.)

The Symphony Thrombectomy System Brochure also shows the flow of clot and blood into the chamber and shows blood flowing out of the chamber.

On-Demand Vacuum with Integrated Blood Management

Balance power with control and minimize blood loss with built-in differential flow. Clot capture in the palm of your hands provides real-time case assessment.

The Symphony™ Advantage



ID= 7.0mm

ID= 2.8mm

Differential Flow

Blood flowrate reduced by
~55%

* Data on File

BigShot™ Controller

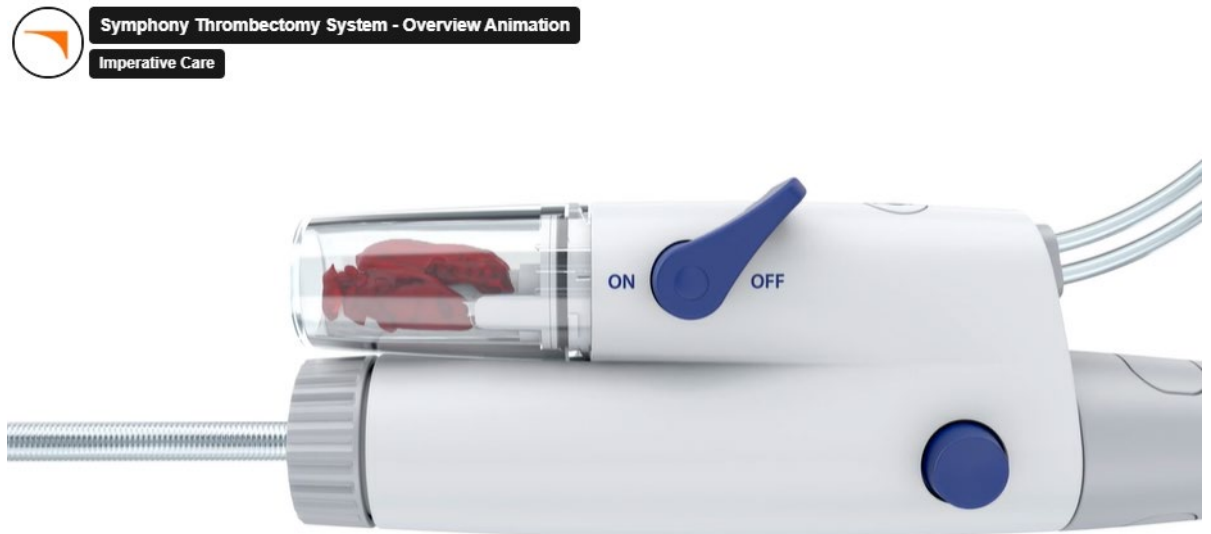
(Symphony Thrombectomy System Brochure at 7.)

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

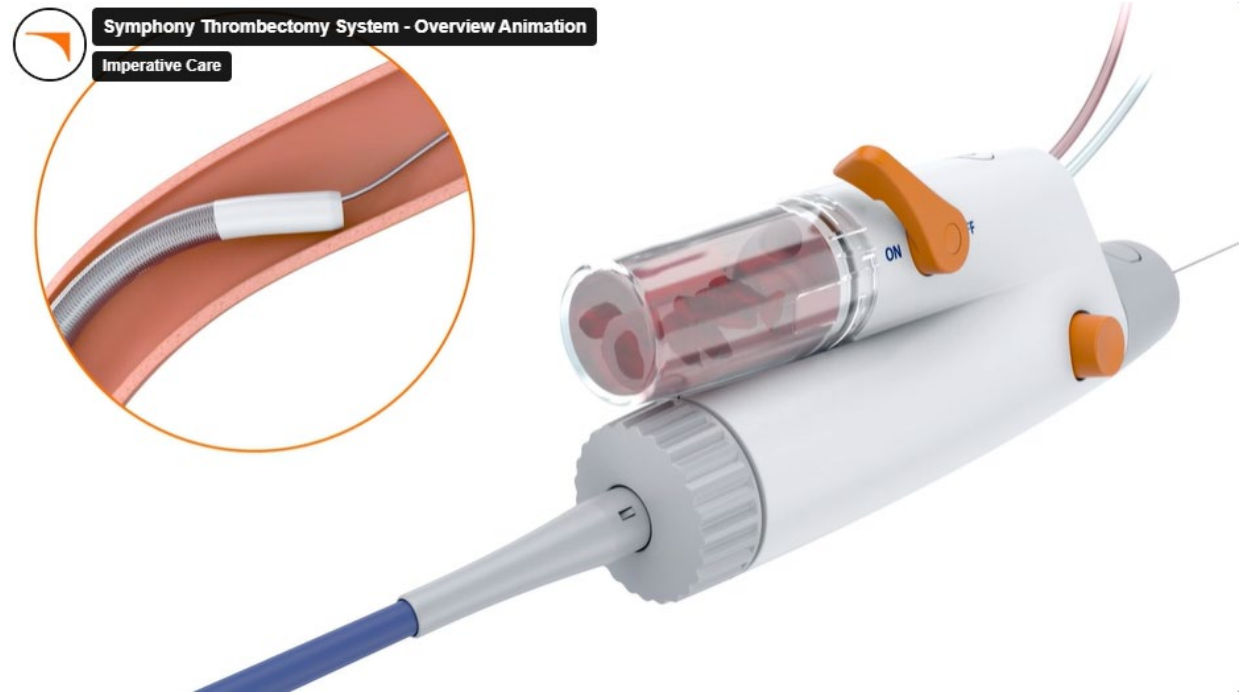
wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and

The clot collection reservoir of the Symphony System includes a filter that is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.

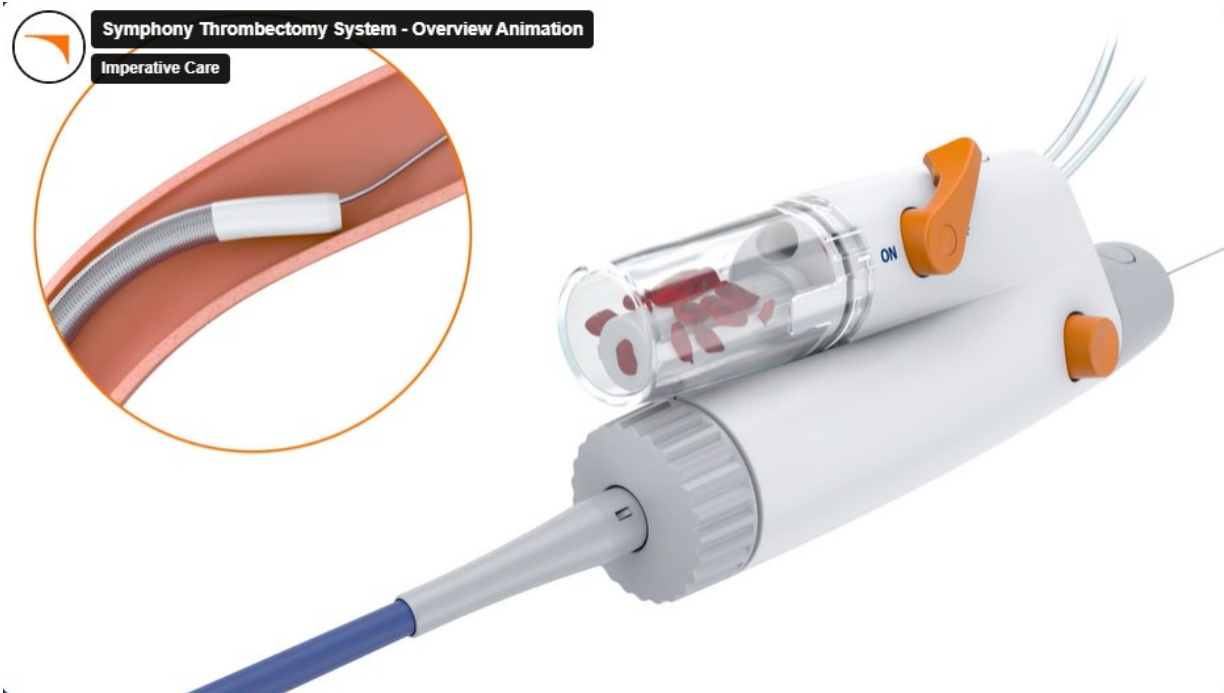
Specifically, as shown in the images from the Symphony Thrombectomy System Overview Animation Video, the filter of the clot container of the 24F and 16F Symphony Catheter handles is configured to and does inhibit clot material from passing through the filter, into its interior region, and through the second port, thus trapping clot material in the chamber of the clot container.



(Symphony Thrombectomy System – Overview Animation Video at 1:16.)



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



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

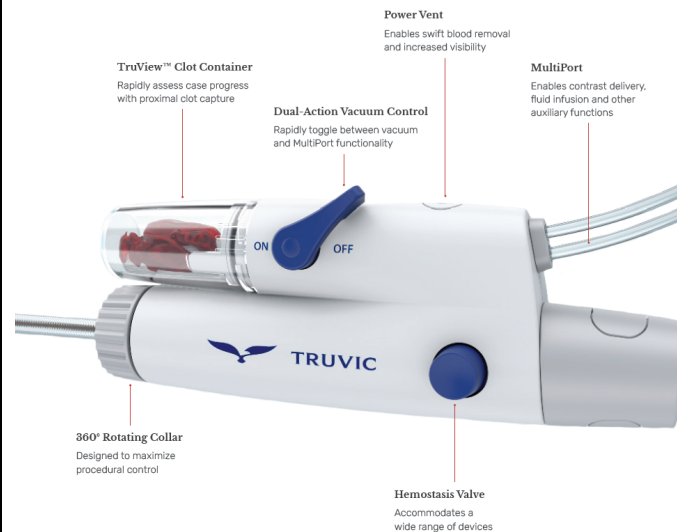
The Symphony System IFU confirms that the filter inhibits clot material from flowing into its interior, and instead allows for blood to flow through its interior and through the second port. (Symphony Thrombectomy System Instructions For Use at 5, 8.) Physical inspection of the Symphony System’s filter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

The Symphony Thrombectomy System Brochure also depicts clot material remaining in the chamber of the clot container so that the physician or user can view the clot and assess progress.

SYMPHONY™ THROMBECTOMY SYSTEM

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

BigShot™ Controller



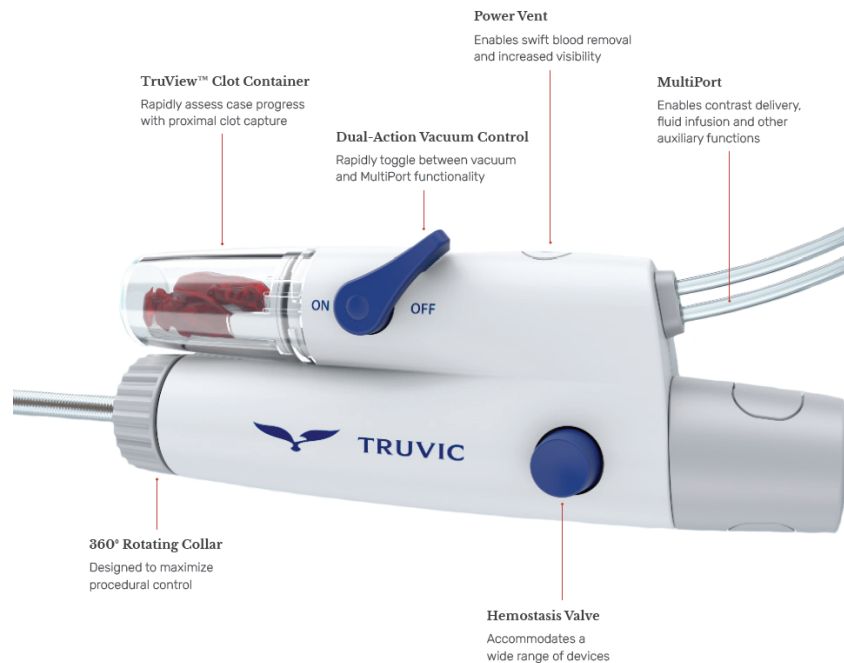
(Symphony Thrombectomy System Brochure at 6.)

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

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

BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)

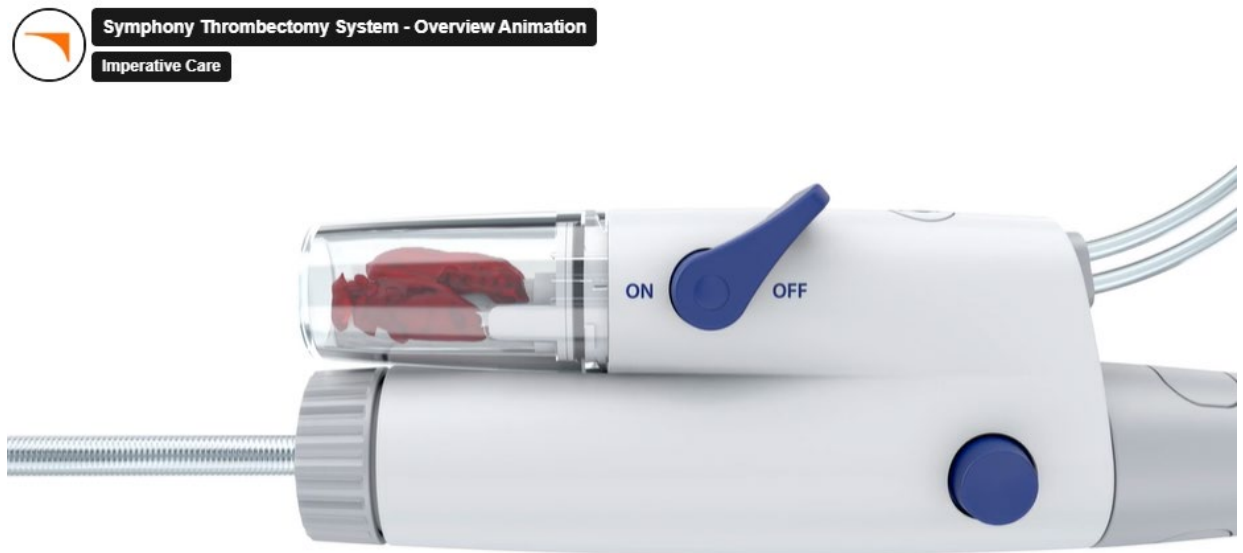


(X-ray image showing material in outer plastic portion of the clot collection reservoir.)

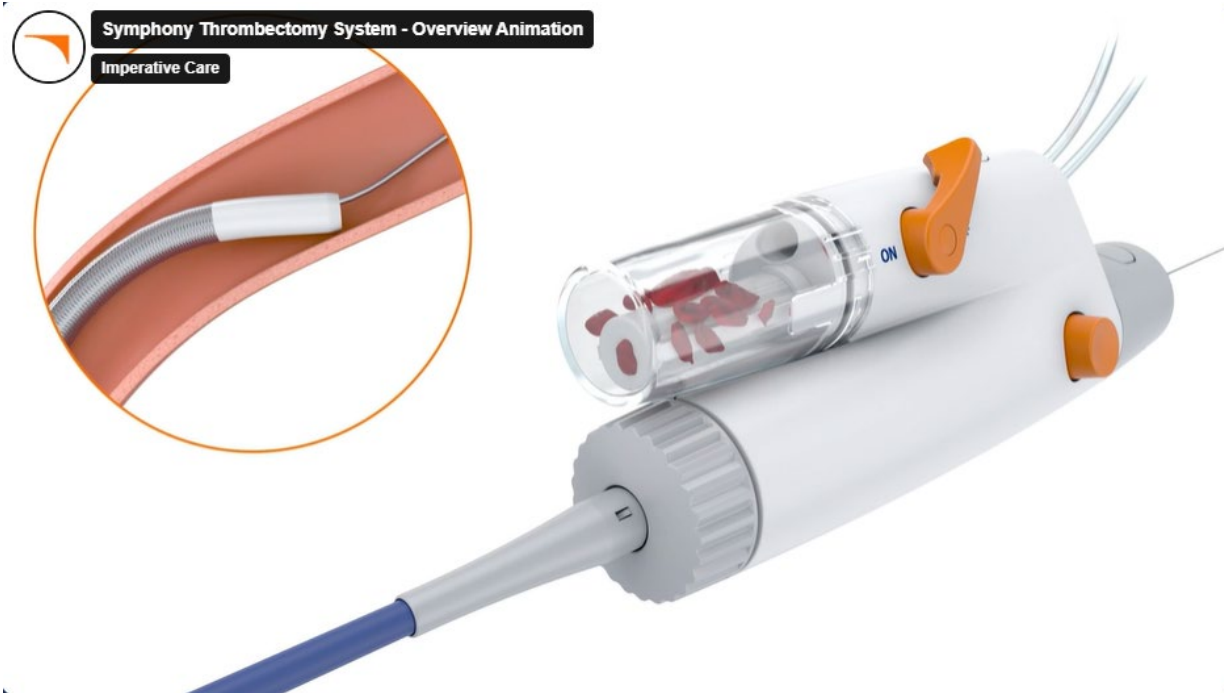
Specifically, the Symphony Thrombectomy System Brochure touts the Symphony System's "TruView™" clot capture. (Symphony Thrombectomy System Brochure at 2.)

The Symphony System IFU confirms that a user is able to visualize the clot material in the chamber of the clot container after blood is evacuated.

The images below from the Symphony Thrombectomy System Overview Animation Video further confirms that the housing of the clot container for both the 24F and 16F Symphony Catheter handles includes an outer plastic portion that is partially transparent to allow for a user to visualize the clot material.



(Symphony Thrombectomy System – Overview Animation Video at 1:16 (showing a clear portion of the housing that allows a user to visualize the clot).)



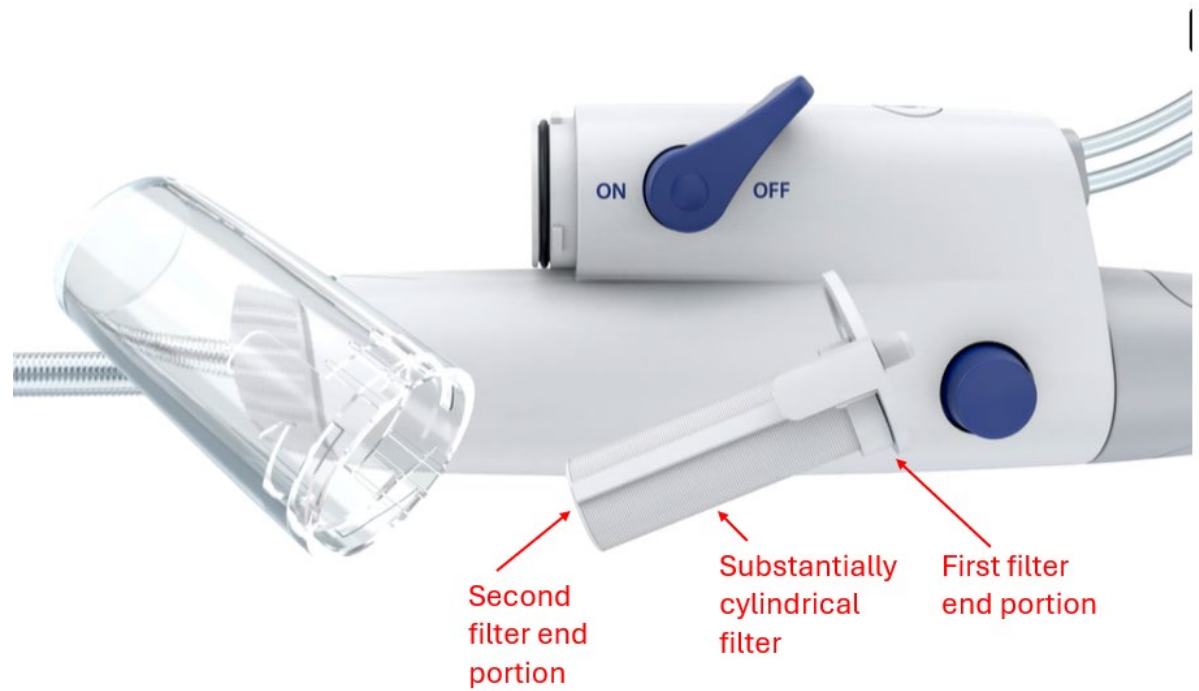
(Symphony Thrombectomy System – Overview Animation Video at 2:05 (showing a clear portion of the housing that allows a user to visualize the clot).)

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

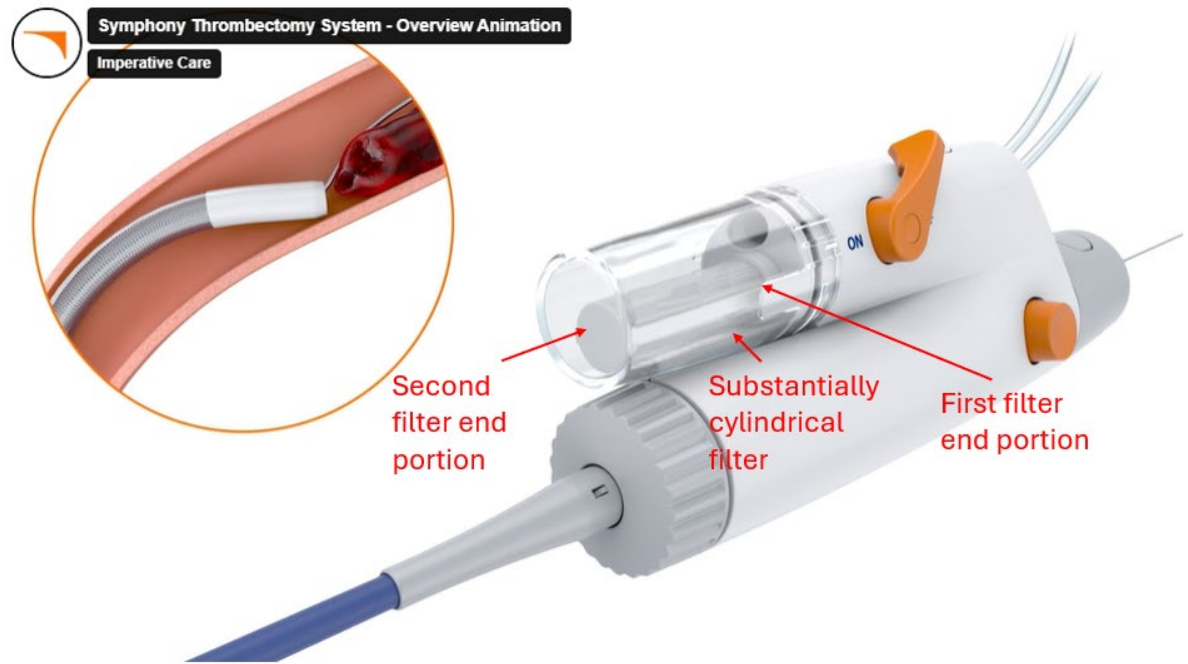
[4] The clot collection reservoir of claim 1 wherein the first filter end portion is curved.

The clot collection reservoir of the Symphony System includes a first filter end portion that is curved.

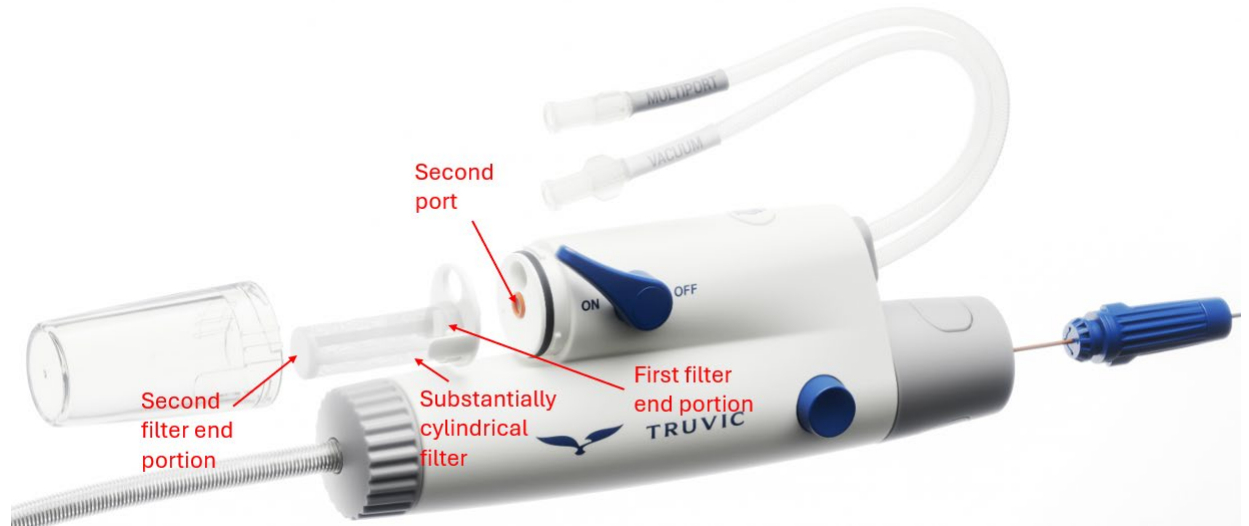
The first filter end portion of the 24F and 16F Symphony Catheter handle's filter is circular and therefore curved, as shown in the annotated images below.



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



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



(Annotated image of handle 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 limitation, the Symphony System meets this limitation under the doctrine of equivalents.

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

The Symphony System includes an aspiration source that is configured to generate negative pressure in the chamber via the second port to draw the clot material against the first filter end portion.

Specifically, the TruVic Generator and TruVic Canister (*e.g.* source of aspiration) is configured to generate negative pressure in the chamber of the clot container of the 24F and 16F Symphony Catheter handles, as described in the Symphony System IFU. (Symphony Thrombectomy System Instructions For Use at 2 (“The

TRUVIC Symphony Thrombectomy Catheters have been verified for use with the TRUVIC Tubeset and TRUVIC Generator. The TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 2.”.)

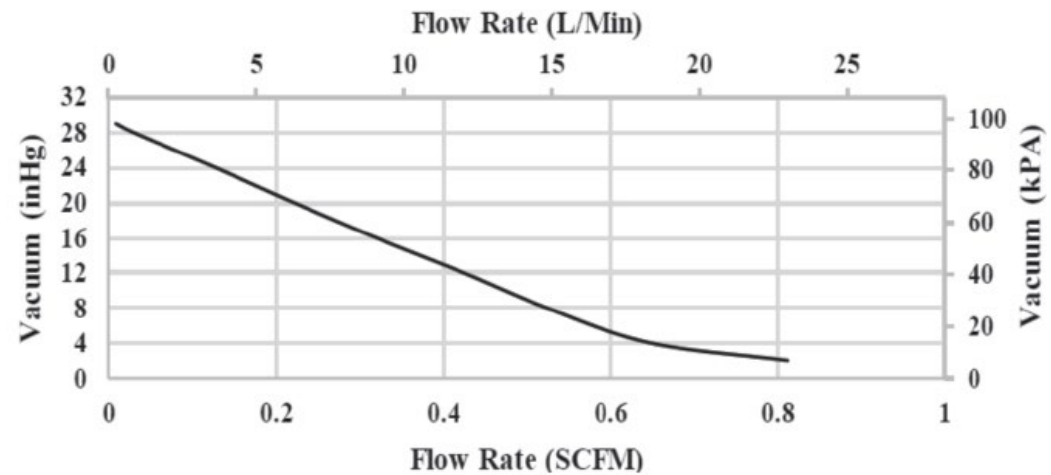
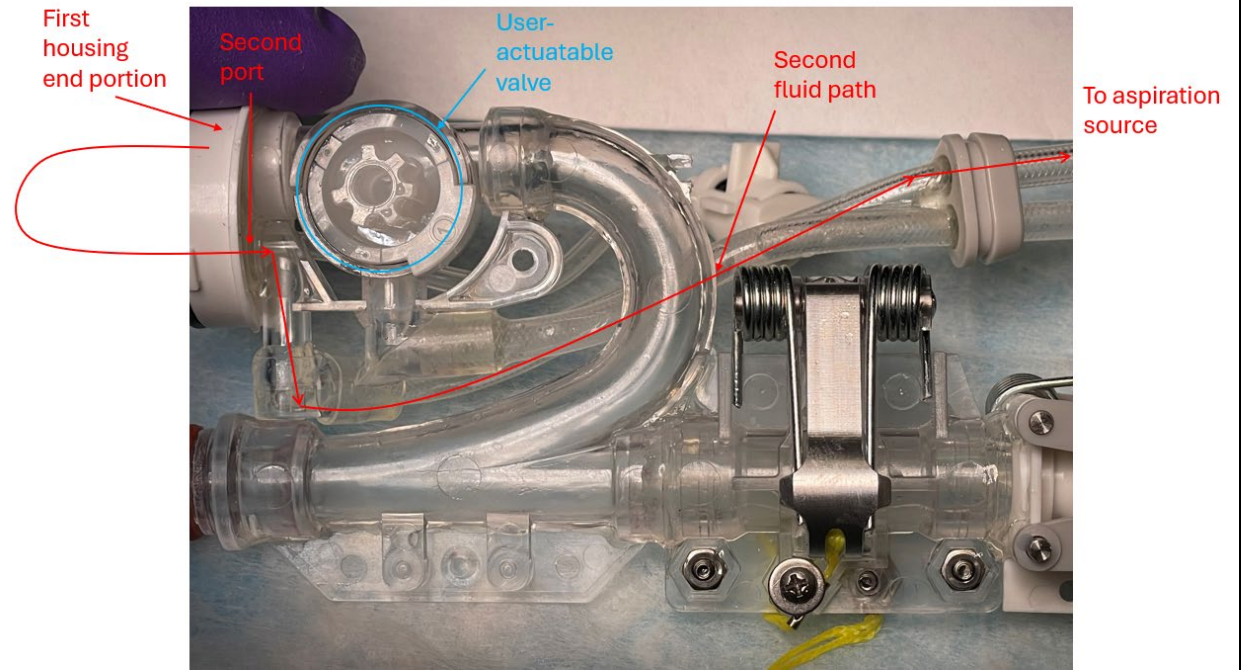


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

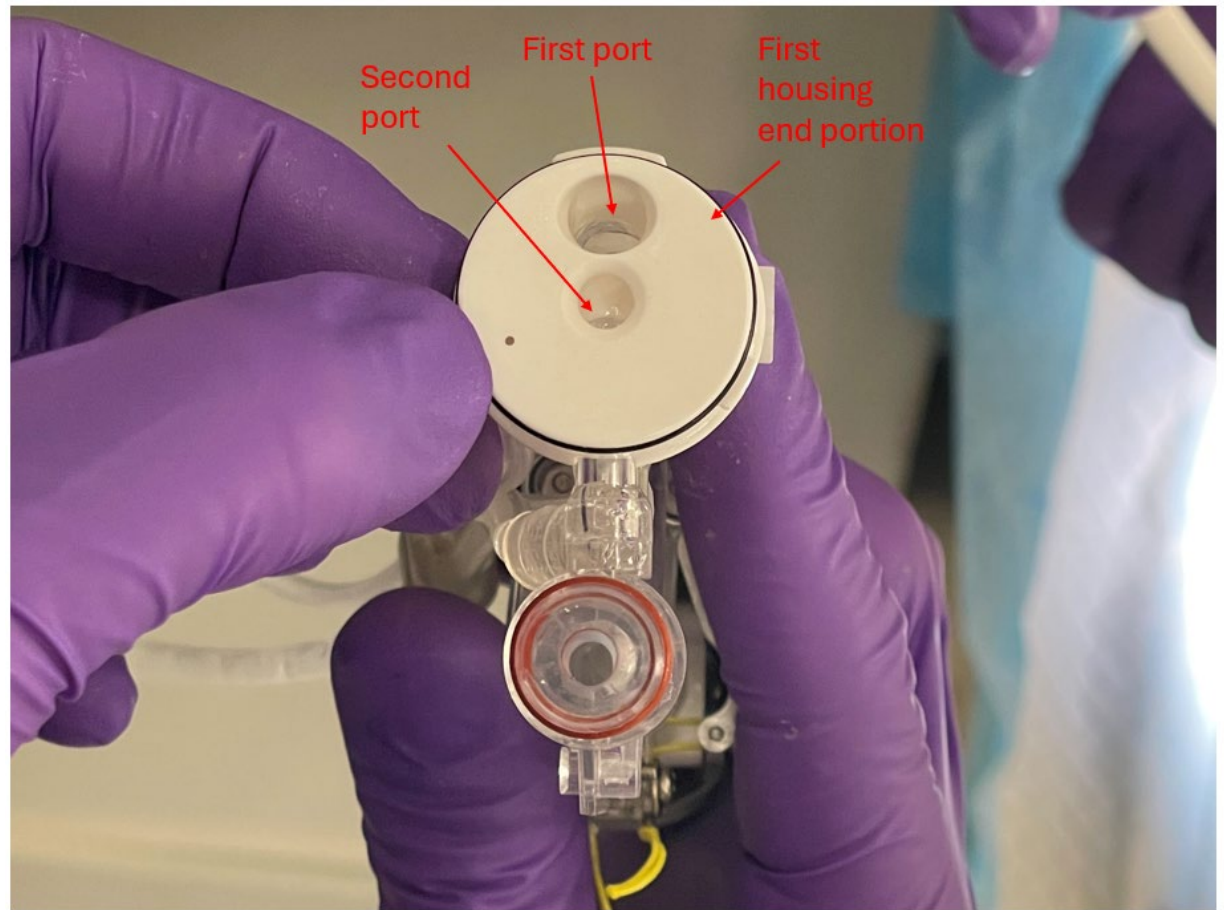
(Symphony Thrombectomy System Instructions For Use at 2 (showing vacuum pressure and flow rate for aspiration source).)

The Symphony System IFU further describes how the negative pressure generated by the Truvic Generator and Truvic Canister draws clot material against the first filter end portion. (Symphony Thrombectomy System Instructions For Use at 5 (“Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU). Confirm tip of the Symphony Catheter is in the desired location. To begin aspiration, move the vacuum lever on the Handle to the ‘ON’ position. When unrestricted blood flow through the clot

	<p>container and into the canister is observed, move the lever on the Handle to the ‘OFF’ position.”); Symphony Thrombectomy System Instructions For Use at 8 (“Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU). Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy. To begin aspiration, move the vacuum lever on the 16F Handle to the ‘ON’ position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the 16F Handle to the ‘OFF’ position.”).)</p> <p>As shown in the teardown images below, the negative pressure flows from the Truvic Generator and Truvic Canister through the second port, such that it generates a negative pressure in the chamber of the clot container.</p>
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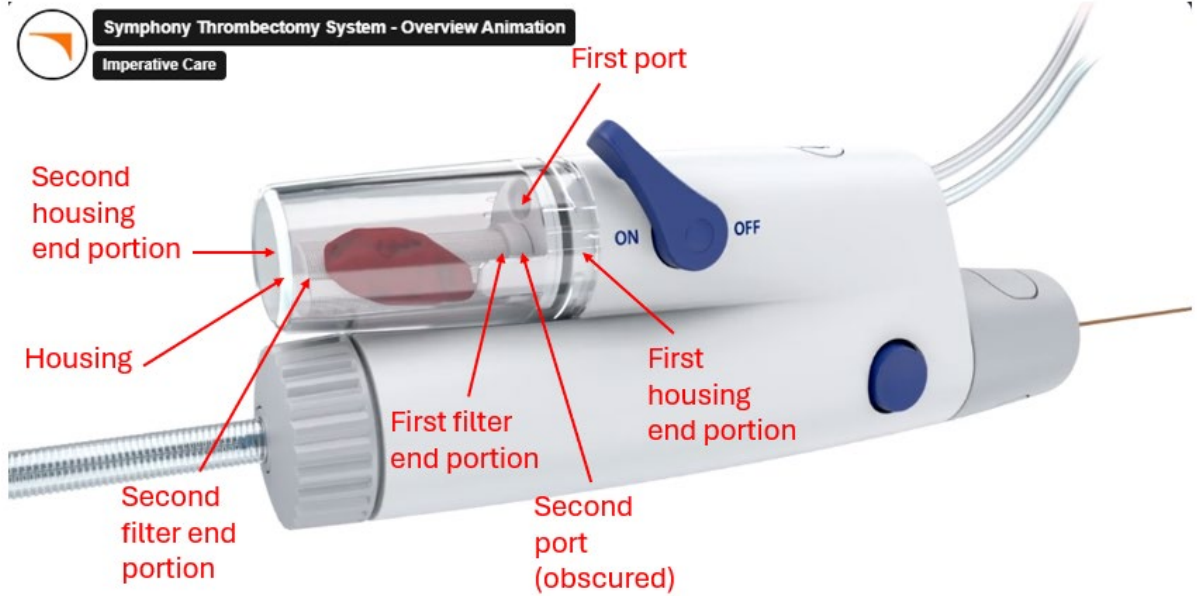


(Annotated image of internal portion of the controller housing.)

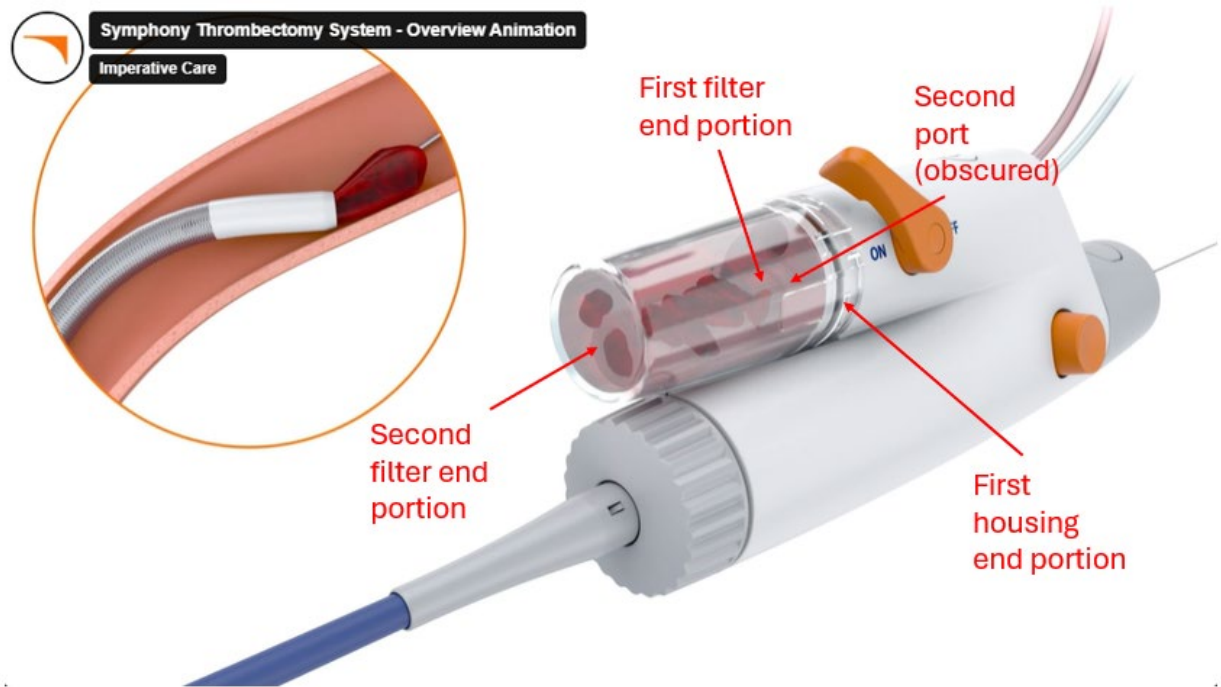


(Annotated image of controller housing showing first and second ports.)

As shown in the annotated images below, when the Truvic Generator and Truvic Canister generate negative pressure and the valve is rotated on to connect the aspiration catheter, clot material is drawn against the first filter end portion.



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



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

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

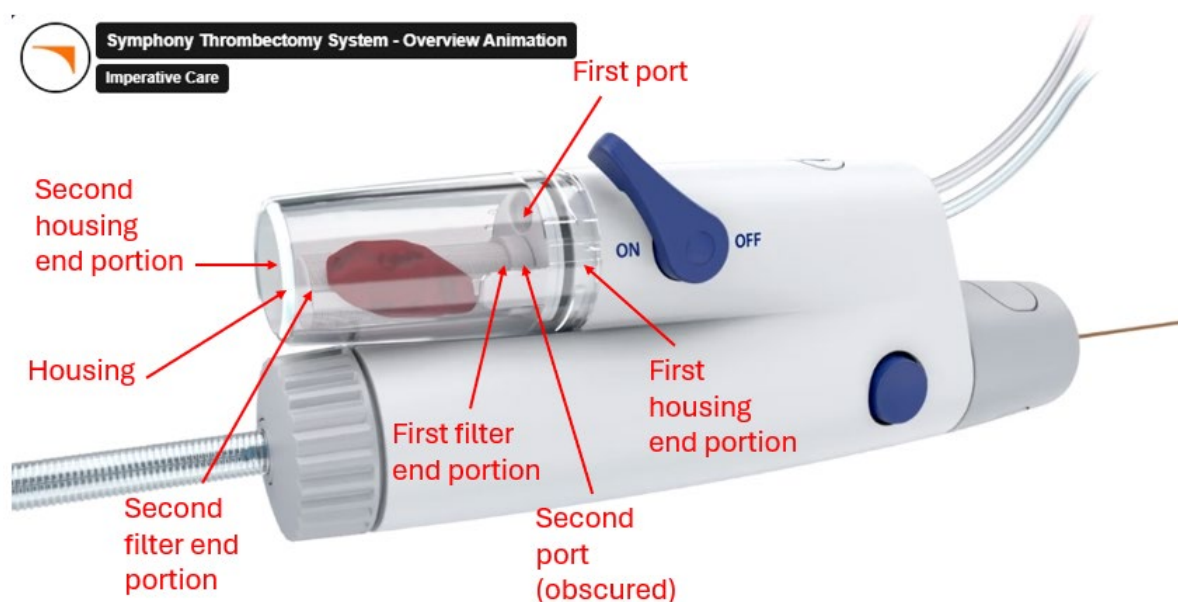
[7] The clot collection reservoir of claim 1 wherein the first filter end portion is positioned closer to the first housing end portion than the

The clot collection reservoir of the Symphony System's clot collection reservoir includes a filter where the first filter end portion is positioned closer to the first housing end portion than the second filter end portion, and where the second filter

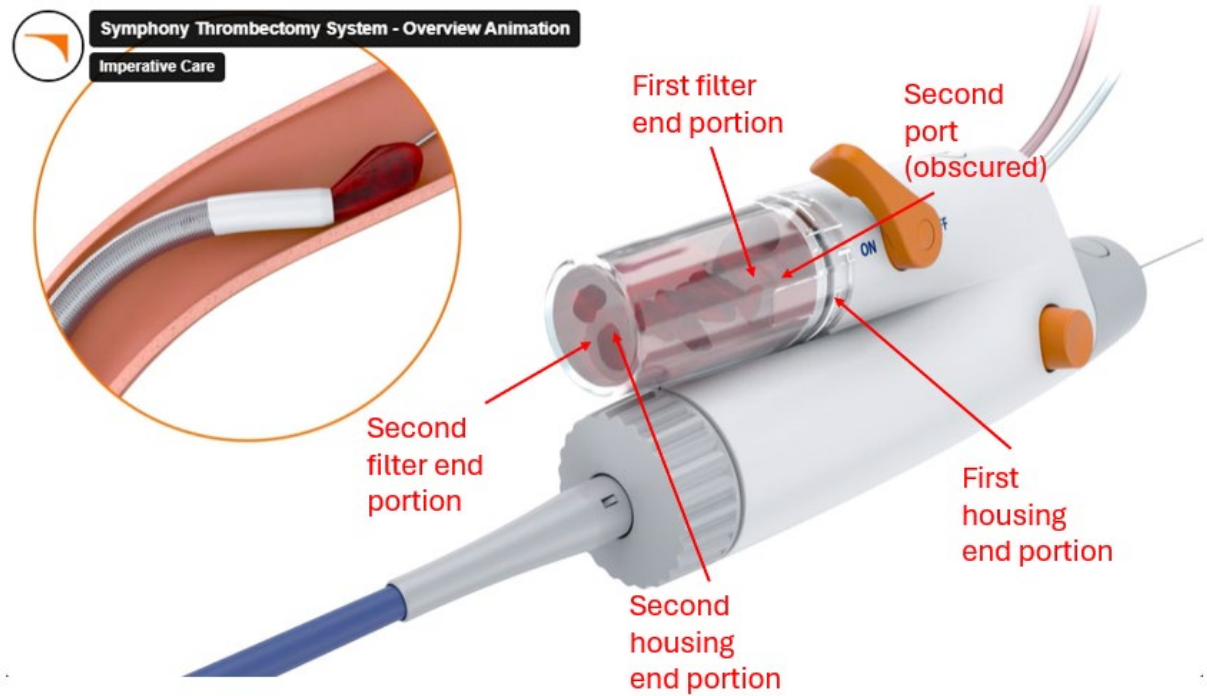
second filter end portion, and wherein the second filter end portion is positioned closer to the second housing end portion than the first filter end portion.

end portion is positioned closer to the second housing end portion than the first filter end portion.

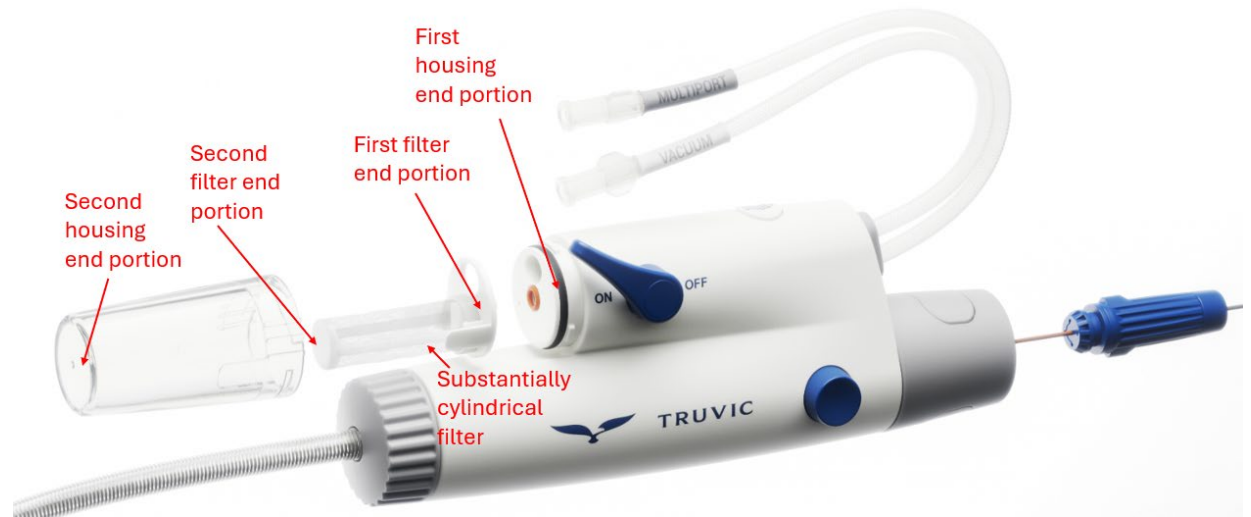
Specifically, the first filter end portion of the clot collection reservoir of the 24F and 16F Symphony Catheter handles is closer to the first housing end portion, while the second filter end portion is closer to the second housing end portion, as shown in the annotated images below.



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



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



(Annotated image of handle 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 limitation, the Symphony System meets this limitation under the doctrine of equivalents.

[10] A clot treatment system, comprising:

The Symphony System is a clot treatment system.

Specifically, “Symphony is a minimally invasive thrombectomy device that removes hazardous clots in patients’ veins via a catheter-based procedure. This handheld tool includes several innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a multifunction port for injecting medicine or contrast or measuring blood pressure, and a connection to a high-power vacuum source. The clot can also be ... withdrawn down through the catheter via vacuum where it is then trapped in a clear

	<p>filter container, allowing the clot to be seen and analyzed by the physician. Symphony is designed to make a thrombectomy procedure faster and less invasive.” (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system.)</p> <p>As stated in the Symphony System IFU, “[t]he Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration. The Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. 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.)</p> <p>To treat the clot, “[t]he Symphony Catheter and Symphony Dilator are introduced through a vascular access (introducer) sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and TRUVIC Canister, to aspirate thrombus.” (Symphony Thrombectomy System Instructions For Use at 1.)</p> <p>The Symphony System IFU also lists the intended purpose of the Symphony Thrombectomy System, which includes clot treatment.</p>
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	<p>The Symphony Thrombectomy System is intended for:</p> <ul style="list-style-type: none"> • The non-surgical removal of fresh, soft emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. <p>The Symphony Thrombectomy System is intended for use in the peripheral vasculature. It is not for use in the pulmonary vasculature.</p> <p>(Symphony Thrombectomy System Instructions For Use at 2.)</p> <p>The Symphony Thrombectomy System Brochure also discloses that it is a clot treatment and removal system.</p>
<p>an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient;</p>	<p>The Symphony System includes an aspiration catheter configured to be intravascularly positioned proximate to clot material within the blood vessel of a patient.</p> <p>Specifically, the Symphony System includes a 24F and/or 16F aspiration catheter that is intravascularly positioned proximate (<i>e.g.</i>, near) to clot material within the blood vessel of a human patient, as described on Whipsaw’s product development website. (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system) (“Symphony is a minimally invasive thrombectomy device that removes hazardous clots in patients’ veins via a catheter-based procedure. This handheld tool includes several innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a multifunction port for injecting medicine or contrast or measuring blood pressure, and a connection to a high-power vacuum source. The clot can also be ... withdrawn down through the catheter via vacuum where it is then trapped in a clear</p>

filter container, allowing the clot to be seen and analyzed by the physician. Symphony is designed to make a thrombectomy procedure faster and less invasive.”).)

Symphony™

THROMBECTOMY SYSTEM

Product Specifications

Symphony™ Catheters			
Product	Model	Working Length	Sheath Compatibility
16F Catheter, 82cm	SYMPHONY16F82	82 cm	16F
16F Catheter	SYMPHONY16F	117 cm	16F
24F Catheter	SYMPHONY24F	85 cm	24F

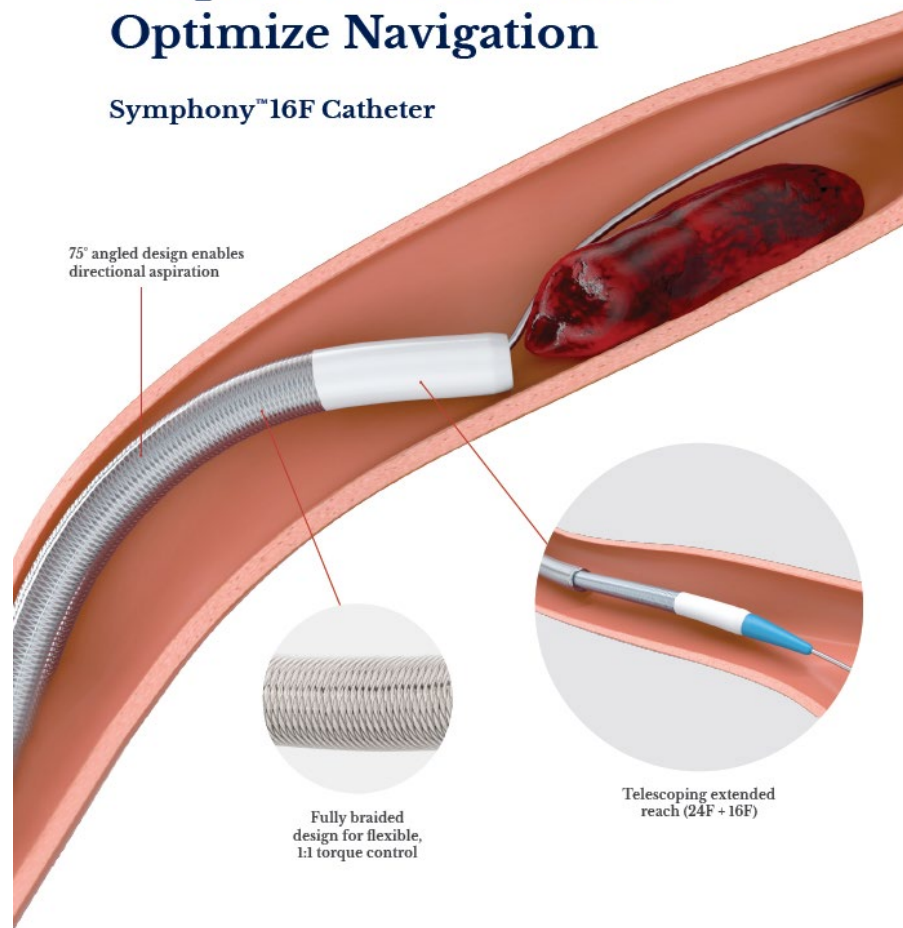
(Symphony Thrombectomy System Product Specifications Sheet at <https://imperativecare.com/wp-content/uploads/sites/4/2024/09/M10147.C-Symphony-Product-Spec-Sheet.pdf>.)

The Symphony Thrombectomy System Brochure shows how the 24F and/or 16F Symphony Catheter can navigate the blood vessel of a patient, such that it is positioned proximate to clot material.

SYMPHONY™ THROMBECTOMY SYSTEM

Purpose-Built Catheters Optimize Navigation

Symphony™ 16F Catheter



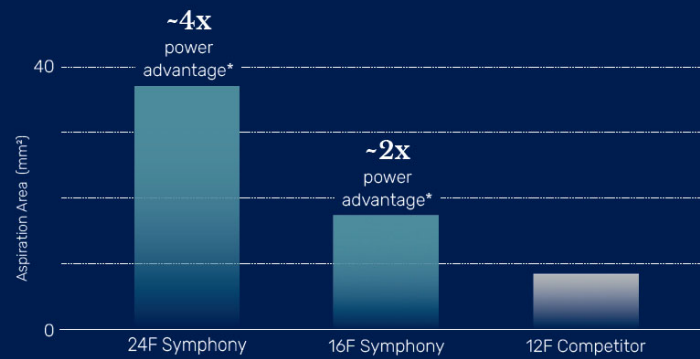
(Symphony Thrombectomy System Brochure at 4.)

Easily Directed for Precise Placement

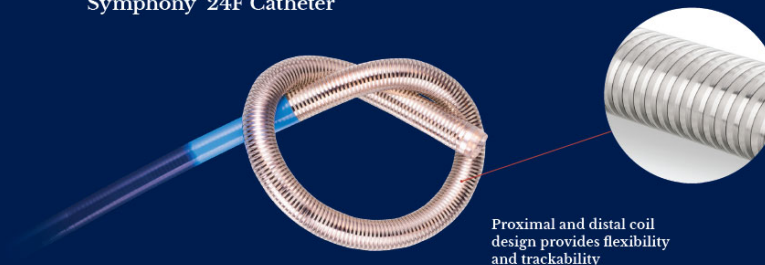
Highly flexible, radiopaque catheters optimize positioning and visibility.

The system's 16F catheter with angled design directs aspiration within the vessel.

The Symphony™ Advantage¹

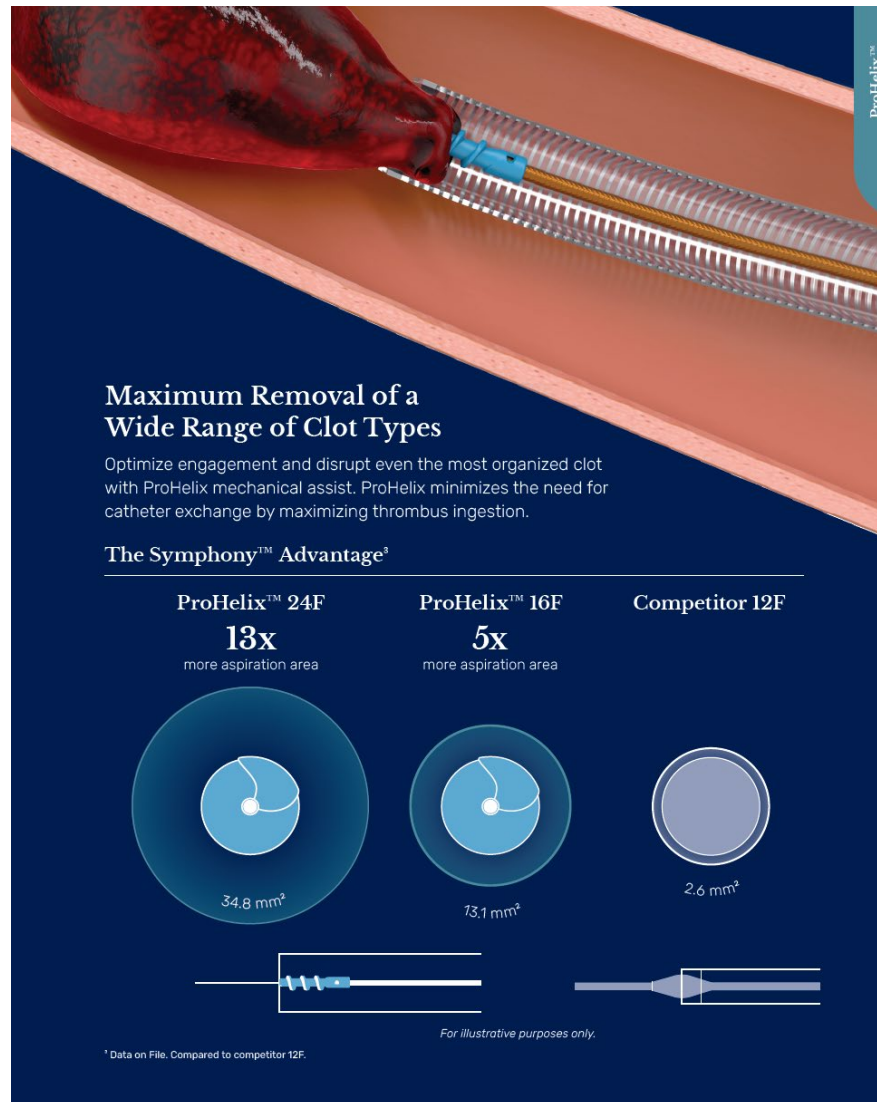


Symphony™ 24F Catheter



* Compared to 12F competitor. Aspiration Power: Force=Pressure x Area.
¹ Data on File

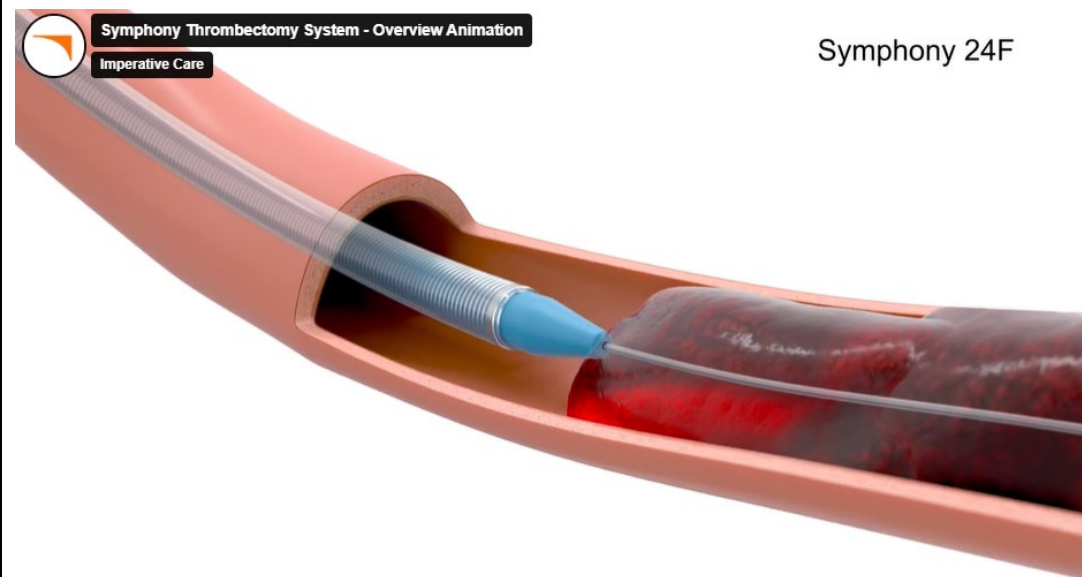
(Symphony Thrombectomy System Brochure at 5.)



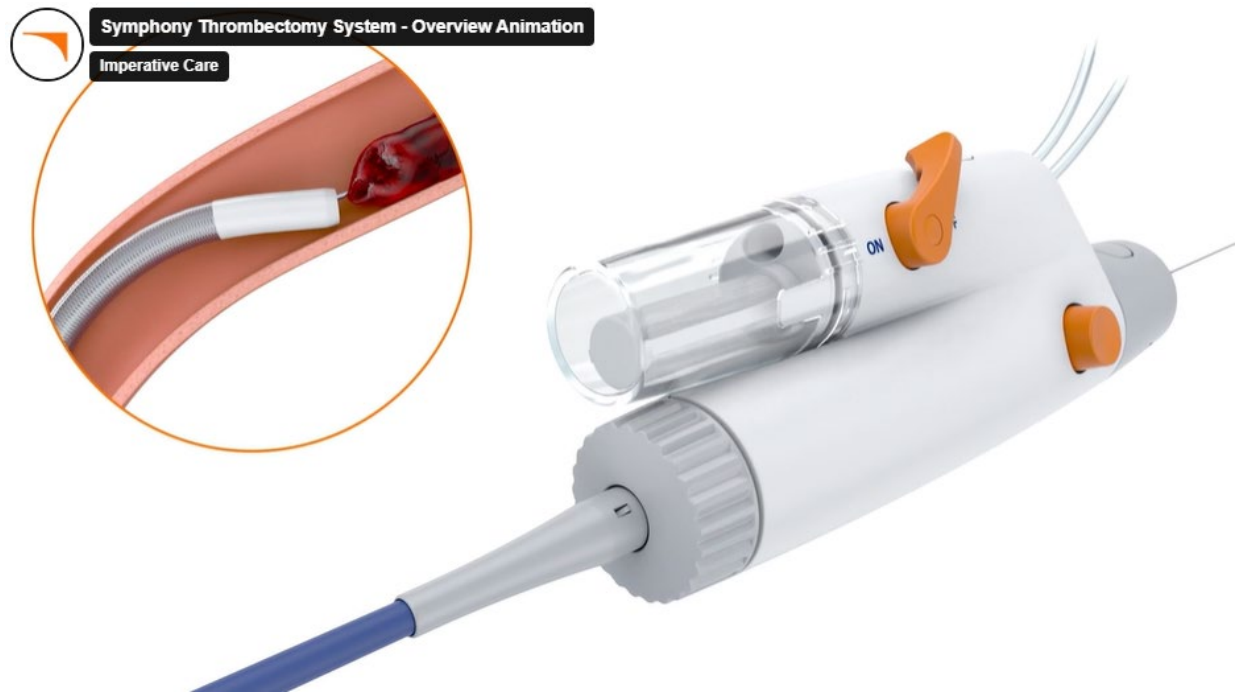
(Symphony Thrombectomy System Brochure at 9.)

The Symphony System IFU describes the aspiration catheter and how it is positioned proximate to clot material within a patient's blood vessel. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter has a lubricious hydrophilic coating on the distal 40 cm of the 24F catheter shaft, and distal 55 cm of the 16F catheter shaft. The Symphony Catheter and Symphony Dilator are introduced through a vascular access (introducer) sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.").)

The images of the 24F and 16F Symphony Catheters also demonstrate that it is positioned proximate to clot material in a patient's blood vessel during procedures.



(Symphony Thrombectomy System – Overview Animation Video at 0:37.)



(Symphony Thrombectomy System – Overview Animation Video at 1:54.)

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

an aspiration source; and

The Symphony System includes an aspiration source.

Specifically, the Symphony System Brochure describes the Truvic Generator and Truvic Canister that act as an aspiration source.

The Symphony System IFU describes how the 24F and 16F Symphony Catheter handles are designed to be used with the Truvic Generator and Truvic Canister for

aspiration. (Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration. The Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus.”); Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.”); Symphony Thrombectomy System Instructions For Use at 2 (“The TRUVIC Symphony Thrombectomy Catheters have been verified for use with the TRUVIC Tubeset and TRUVIC Generator. The TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 2.”).)

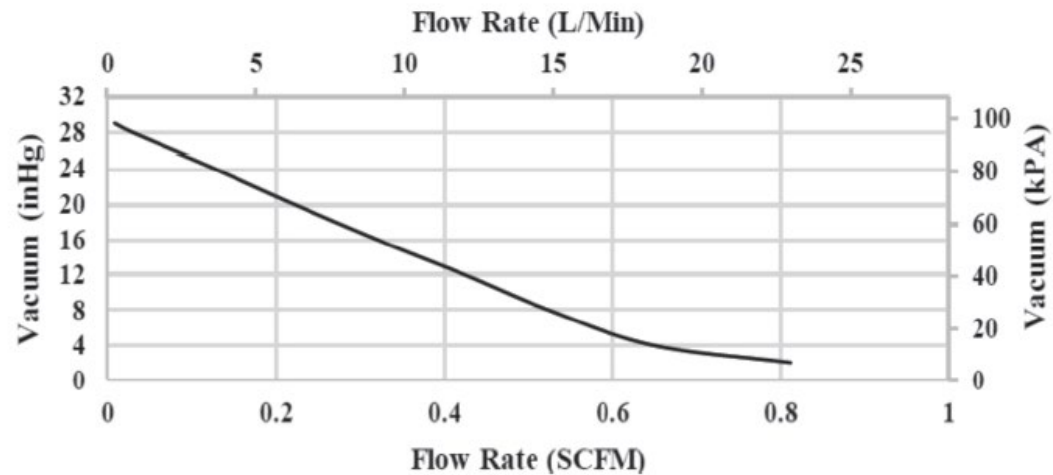


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

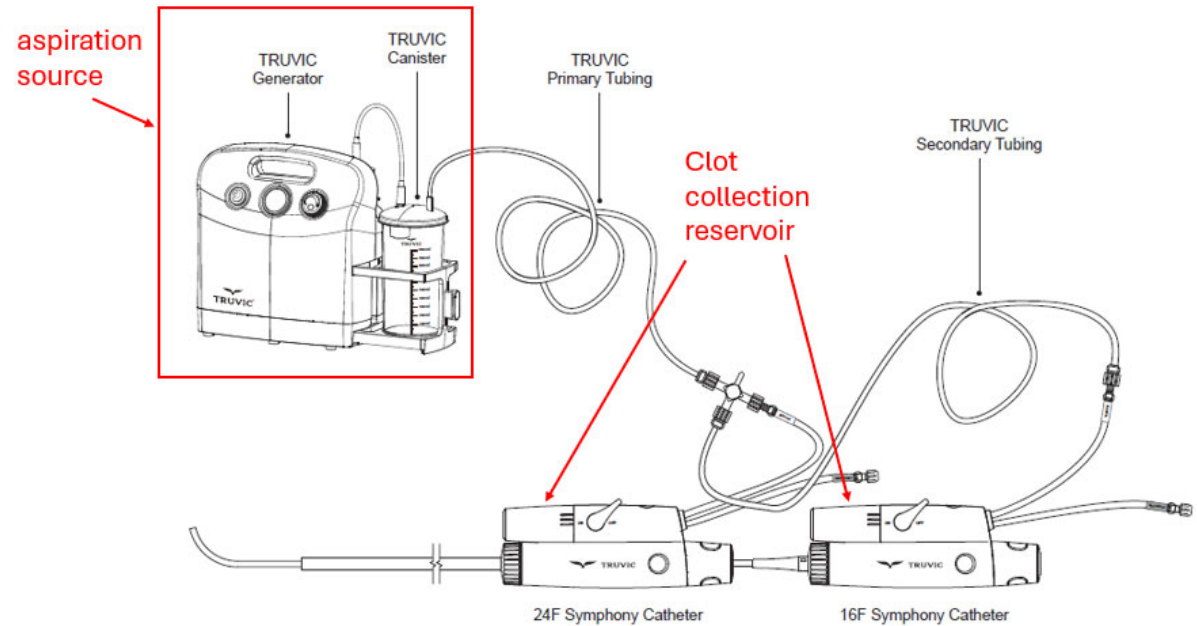


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

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

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 clot collection reservoir, comprising—

The Symphony System includes a clot collection reservoir (including a “Clot Container” connected to the Symphony Bigshot Controller handle).

Specifically, the 24F and 16F Symphony Catheter handles of the Symphony System includes a clot collection reservoir where a user can “[c]onfirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle.” (Symphony Thrombectomy System Instructions For Use at 5; Symphony Thrombectomy System Instructions For Use at 6 (same); Symphony Thrombectomy System Instructions For Use at 8 (same).) The clot container of the 24F and 16F Symphony Catheter handle is shown in the Symphony System IFU below.

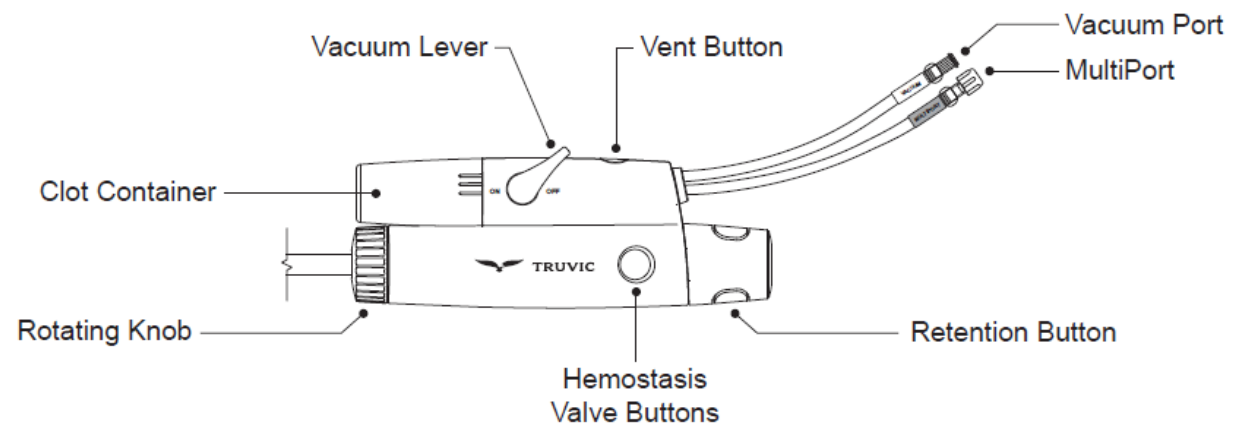
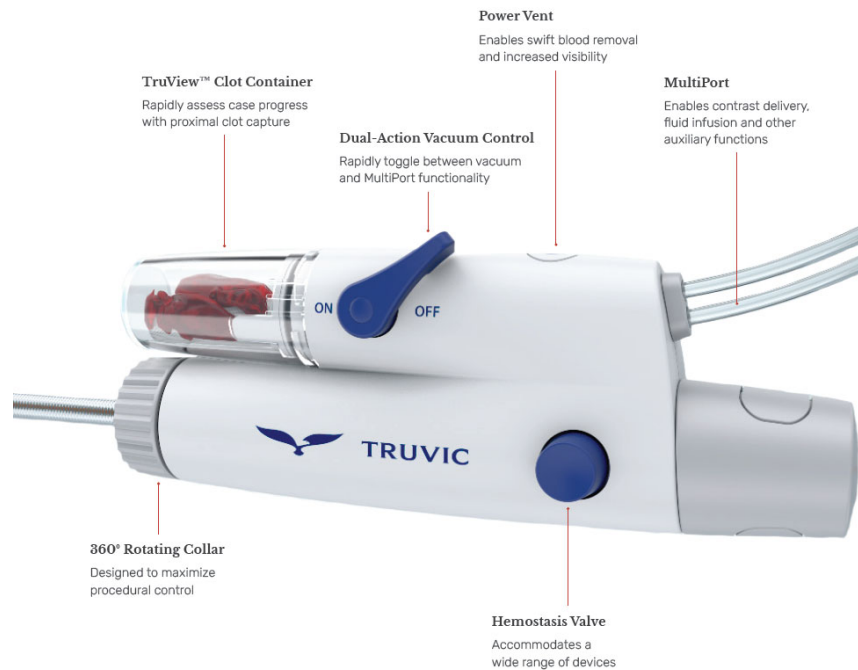


Figure 3: Symphony Catheter Handle, labeled

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

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

BigShot™ Controller

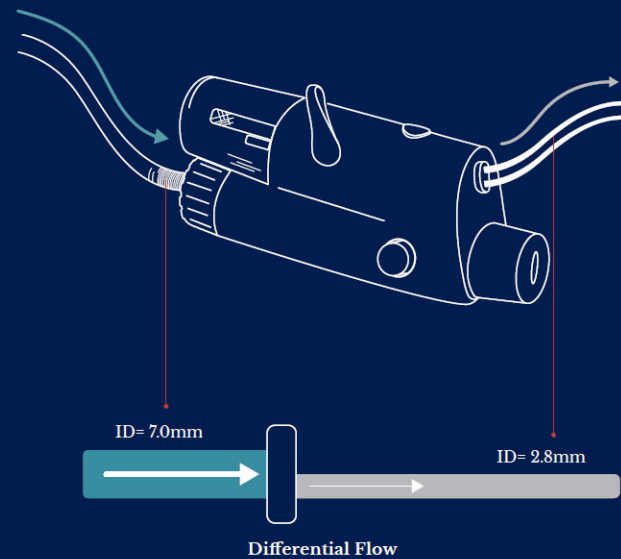


(Symphony Thrombectomy System Brochure at 6.)

On-Demand Vacuum with Integrated Blood Management

Balance power with control and minimize blood loss with built-in differential flow. Clot capture in the palm of your hands provides real-time case assessment.

The Symphony™ Advantage



Blood flowrate reduced by
~55%[‡]

[‡] Data on File

(Symphony Thrombectomy System Brochure at 7.)

The clot collection reservoir of the Symphony Catheter handle is also shown on the Whipsaw website.



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



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

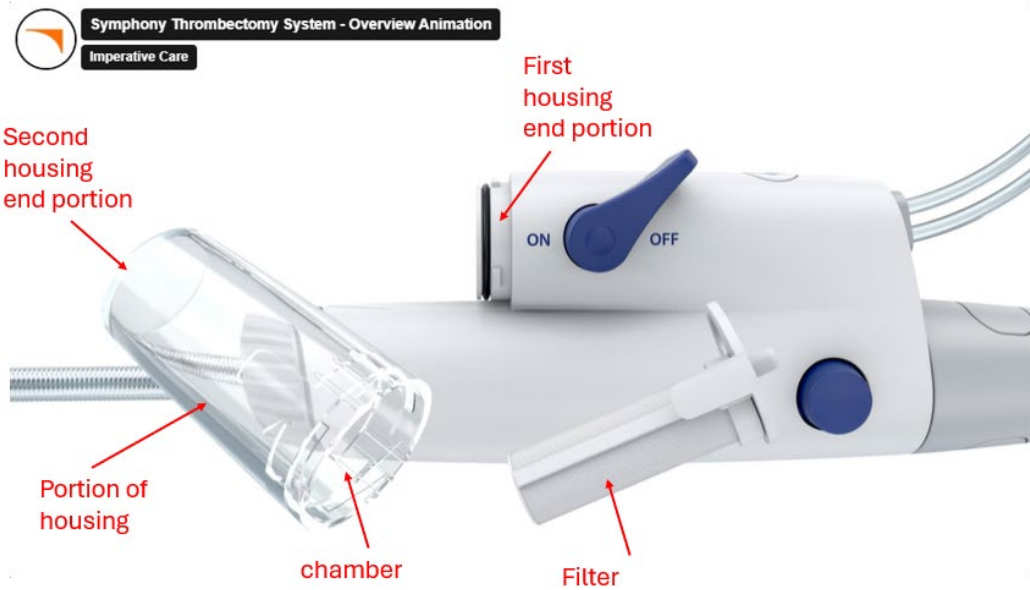


(Image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

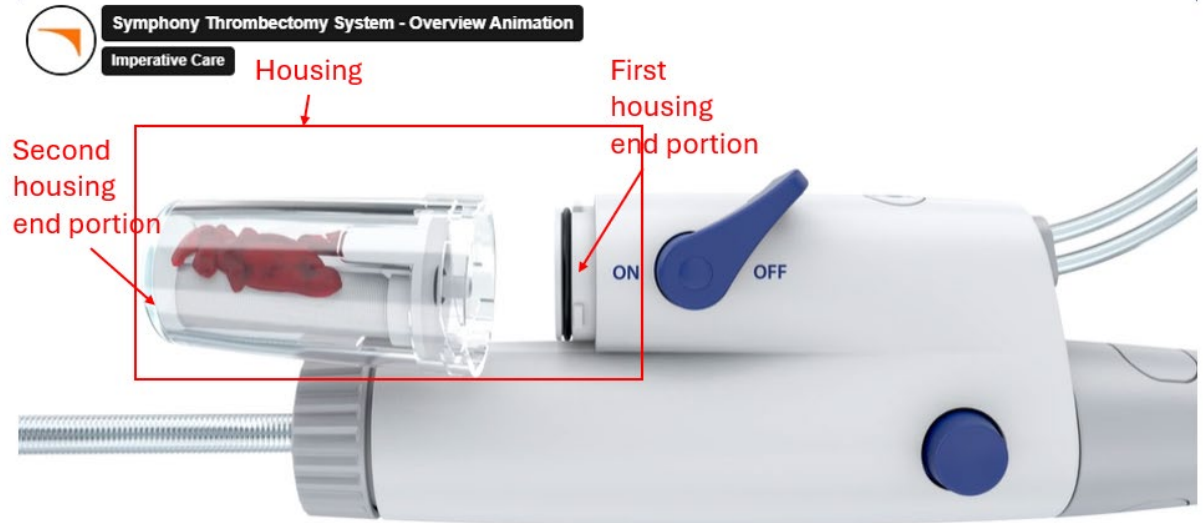
a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;

The clot collection reservoir of the Symphony System includes a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.

The clot collection reservoir and the 24F and 16F Catheter Handles includes a housing, which defines a sealed chamber and has a first housing end portion and a second housing end portion opposite the first, as shown in the annotated image below. The removable portion of the clot container housing removably attaches to the portion of the housing connected to the 24F and 16F Catheter Handles.

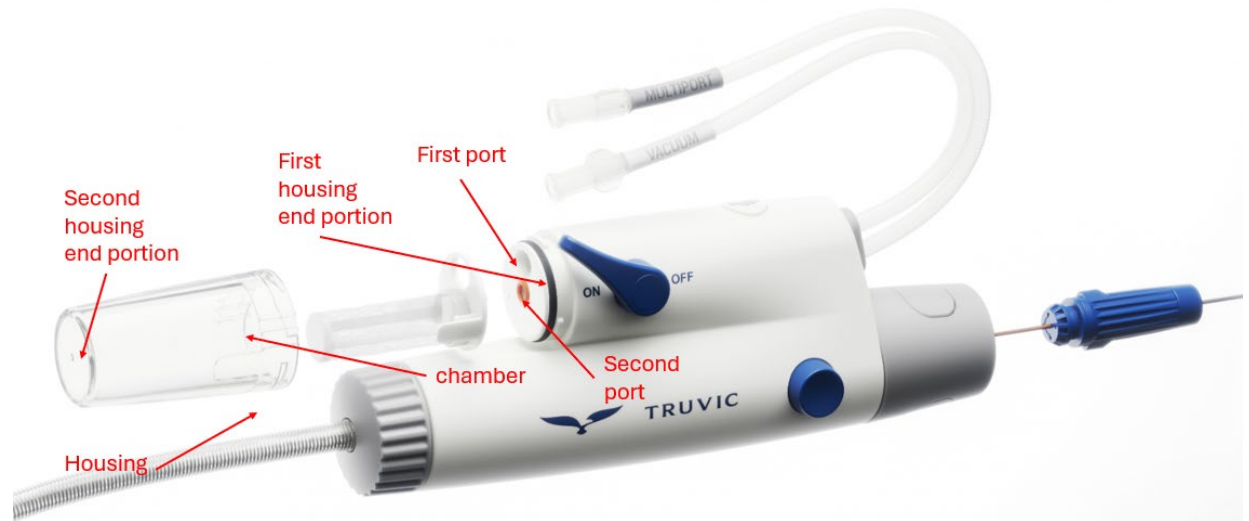


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

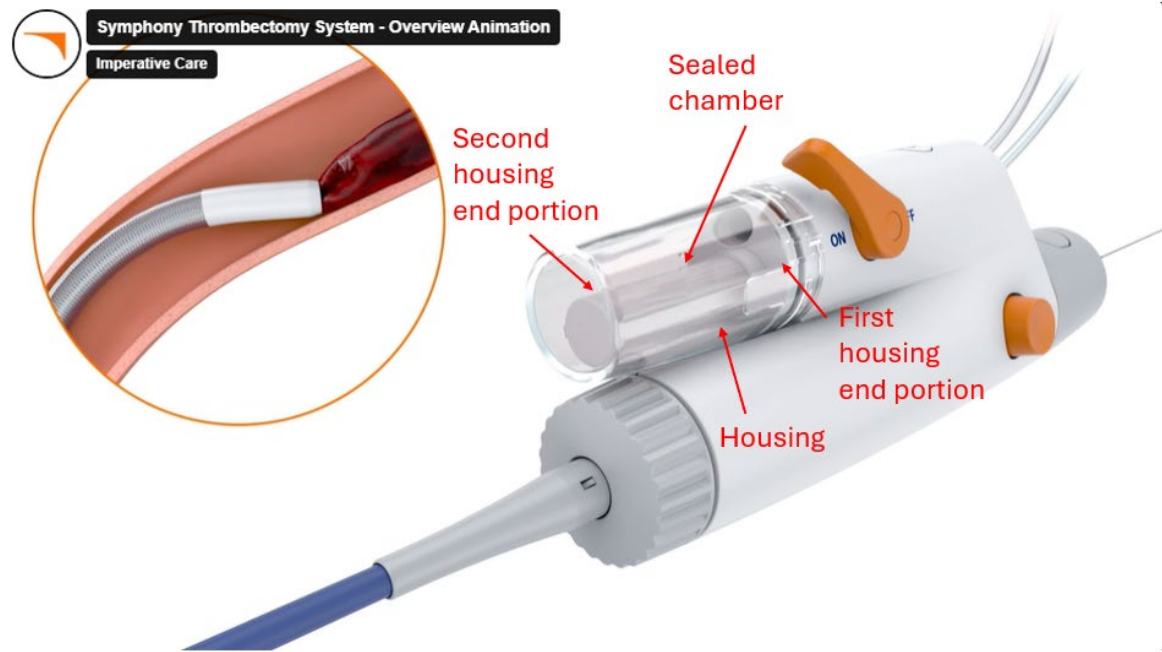


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:19.)

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



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



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:57.)

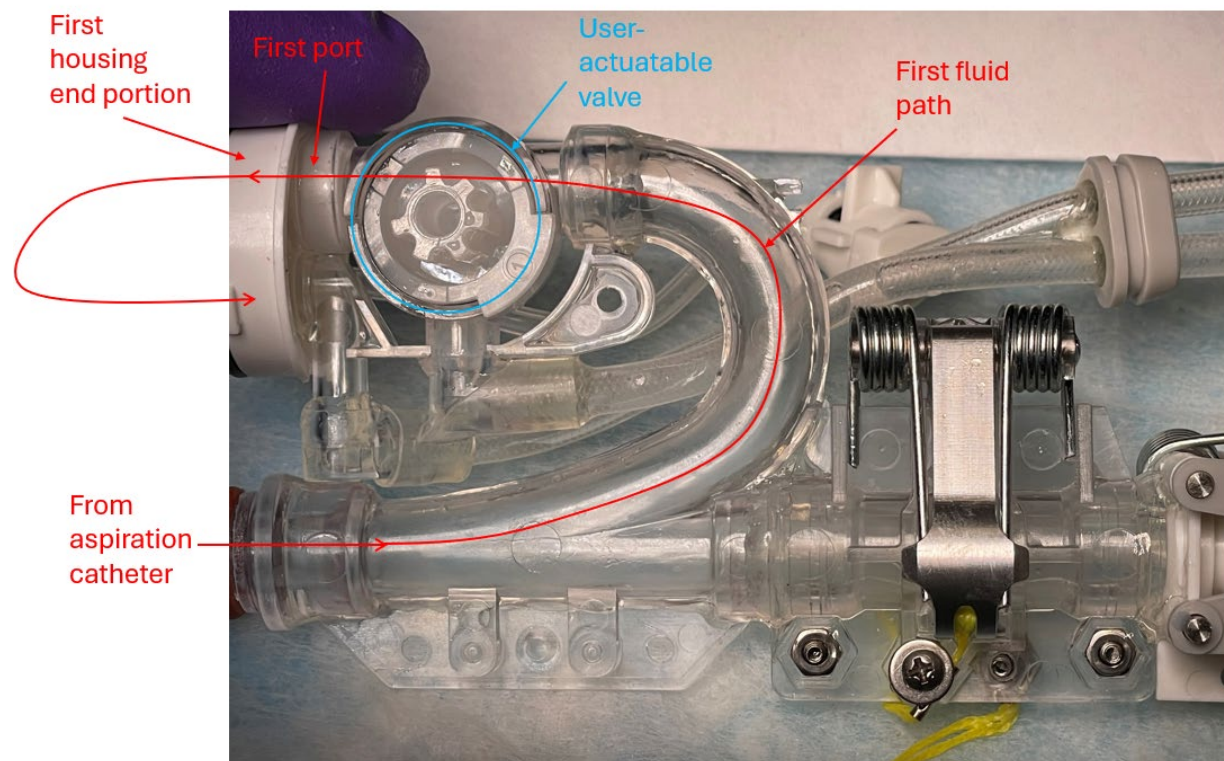
To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

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

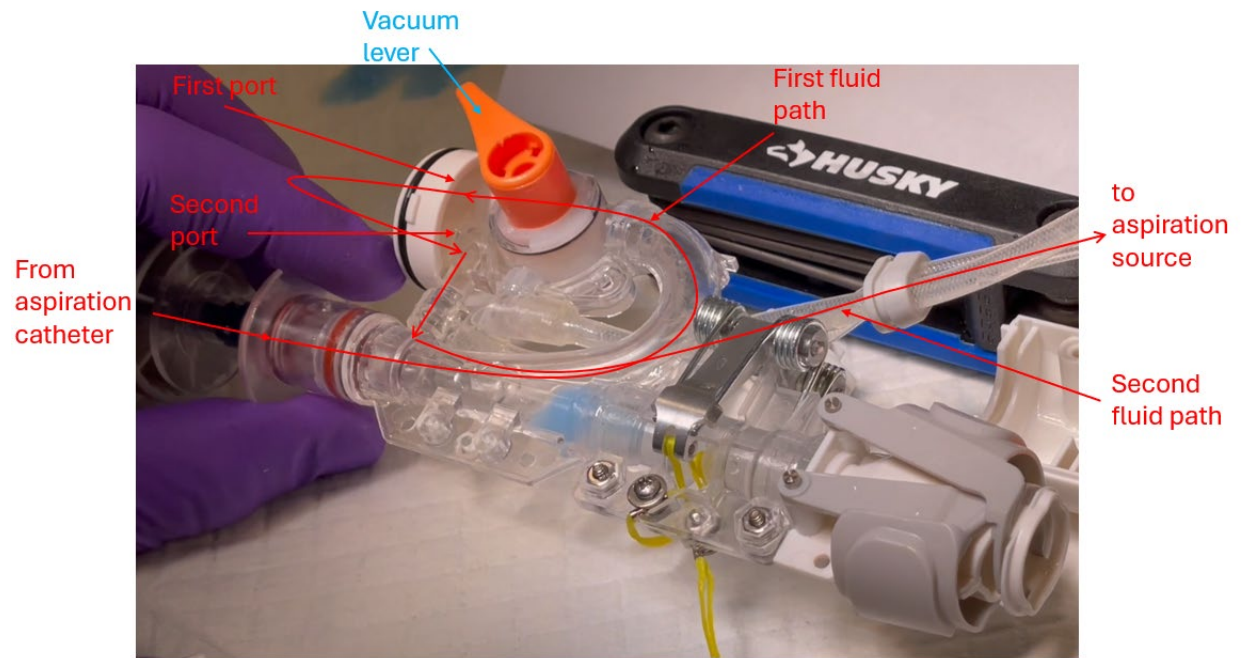
The clot collection reservoir of the Symphony System includes a first port configured to be fluidly coupled to an aspiration catheter, where the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber.

path to the chamber;

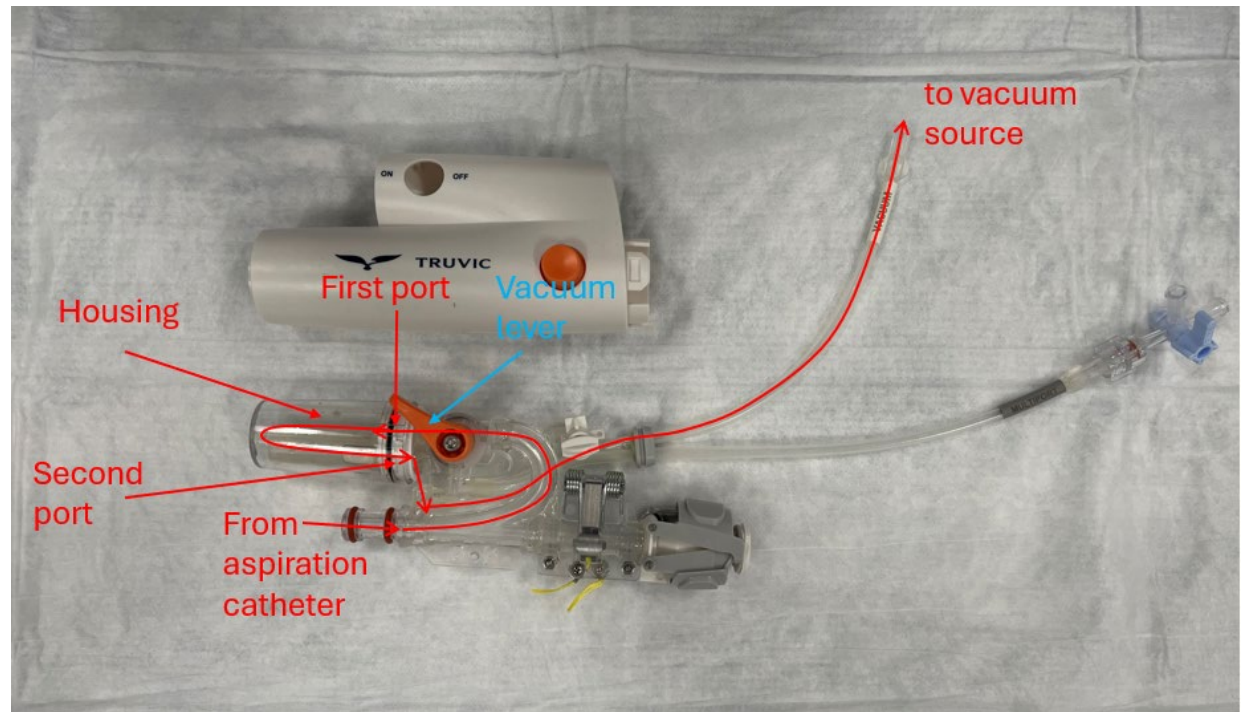
Specifically, the clot collection reservoir of the 24F and 16F Symphony Catheter handles includes a first port proximate to the first housing end portion that is coupled to an aspiration catheter when the valve is in the ON position, as shown in the annotated teardown images below.



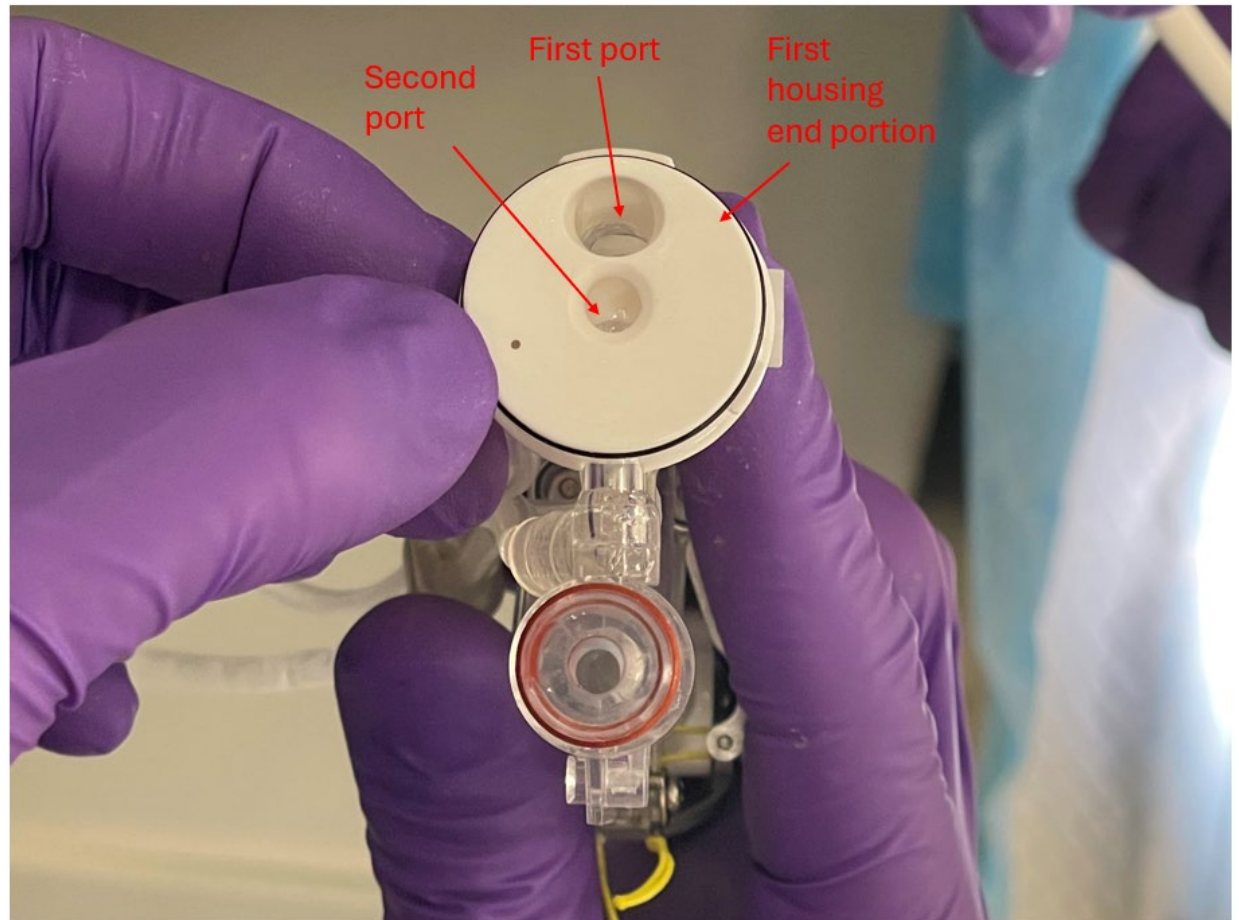
(Annotated image of internal portion of the controller housing.)



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

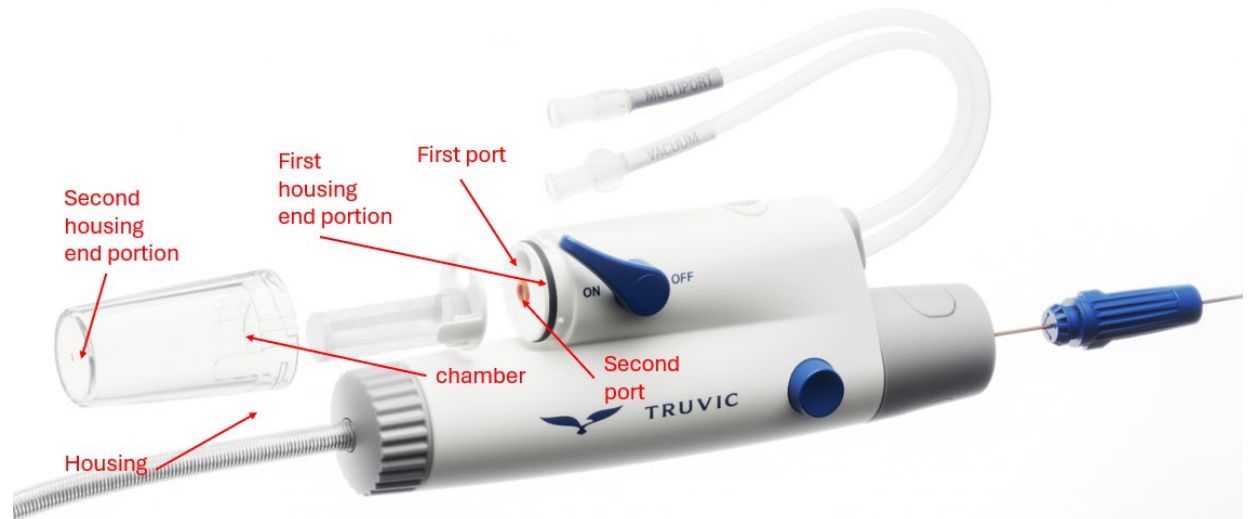


(Annotated image of internal portion of the controller housing.)



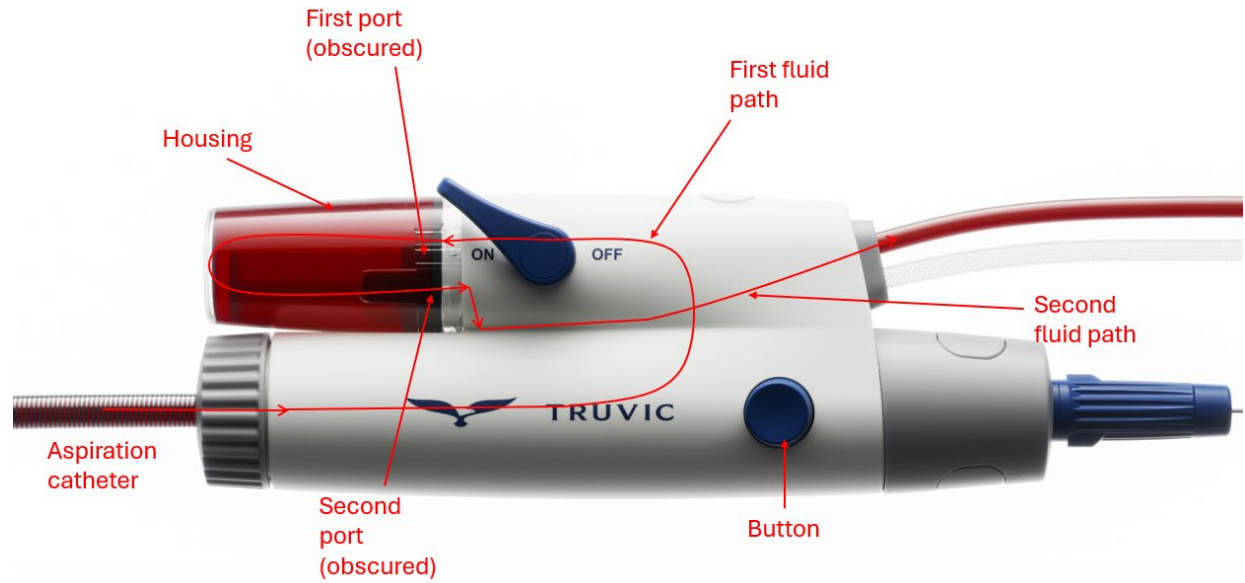
(Annotated image of controller housing showing first and second ports.)

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



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

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

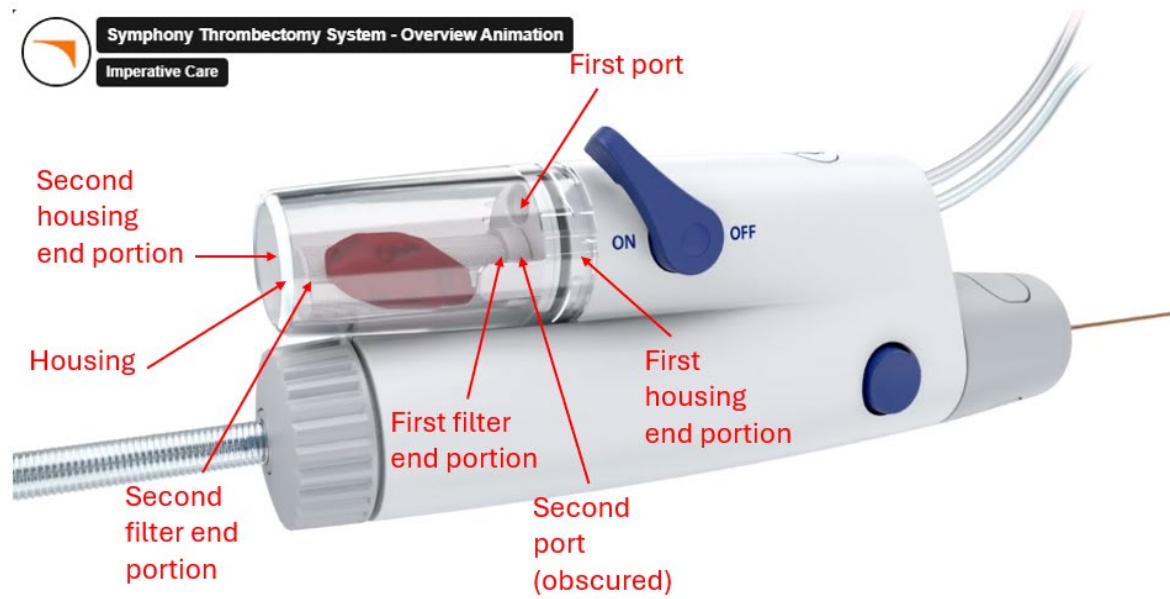


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

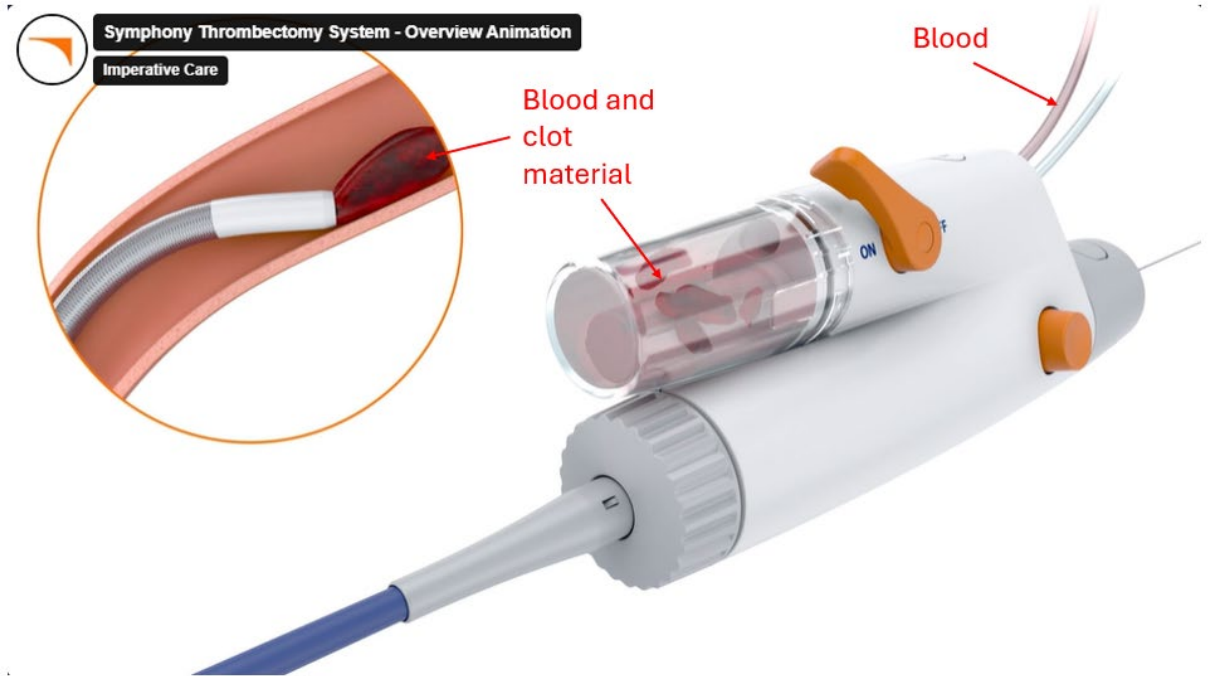
The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration catheters, travels through the first fluid path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot container.



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



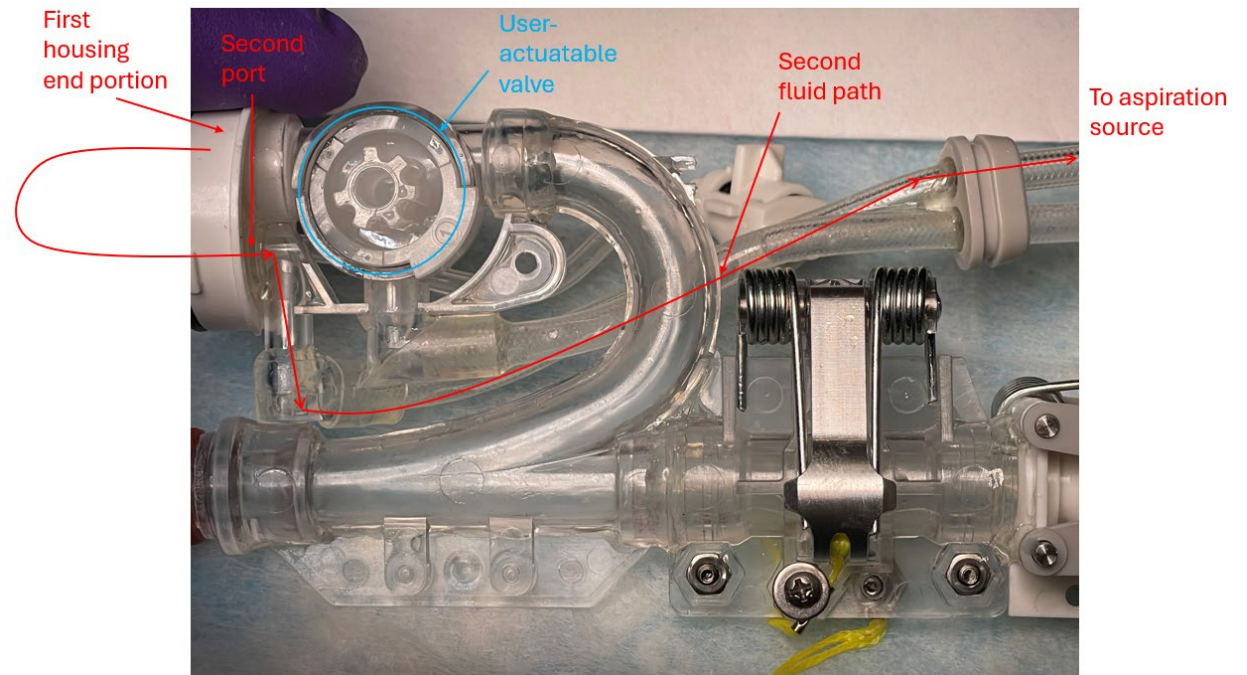
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)



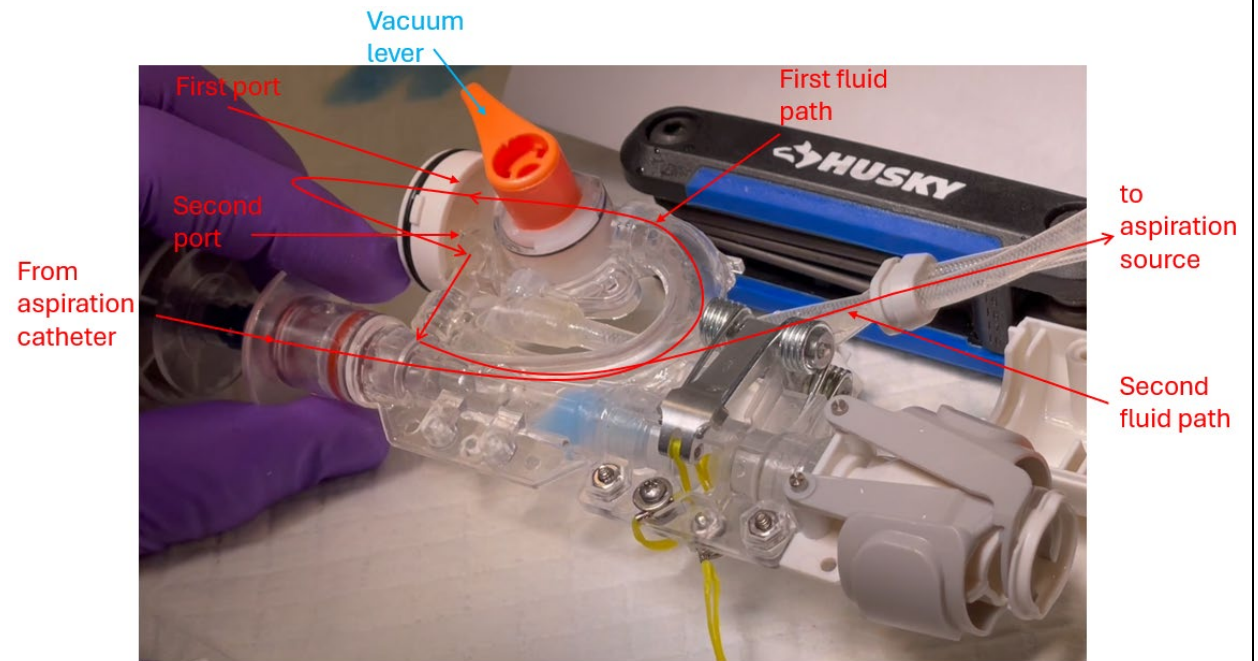
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

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

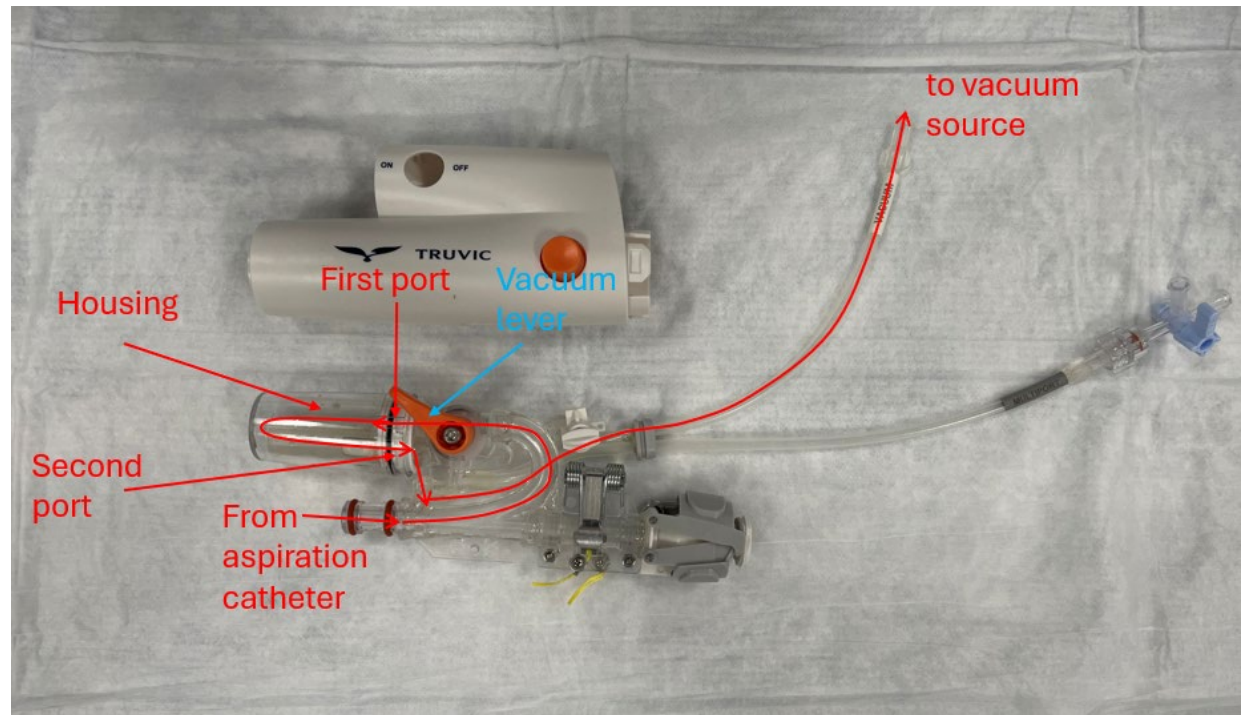
	<p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber;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



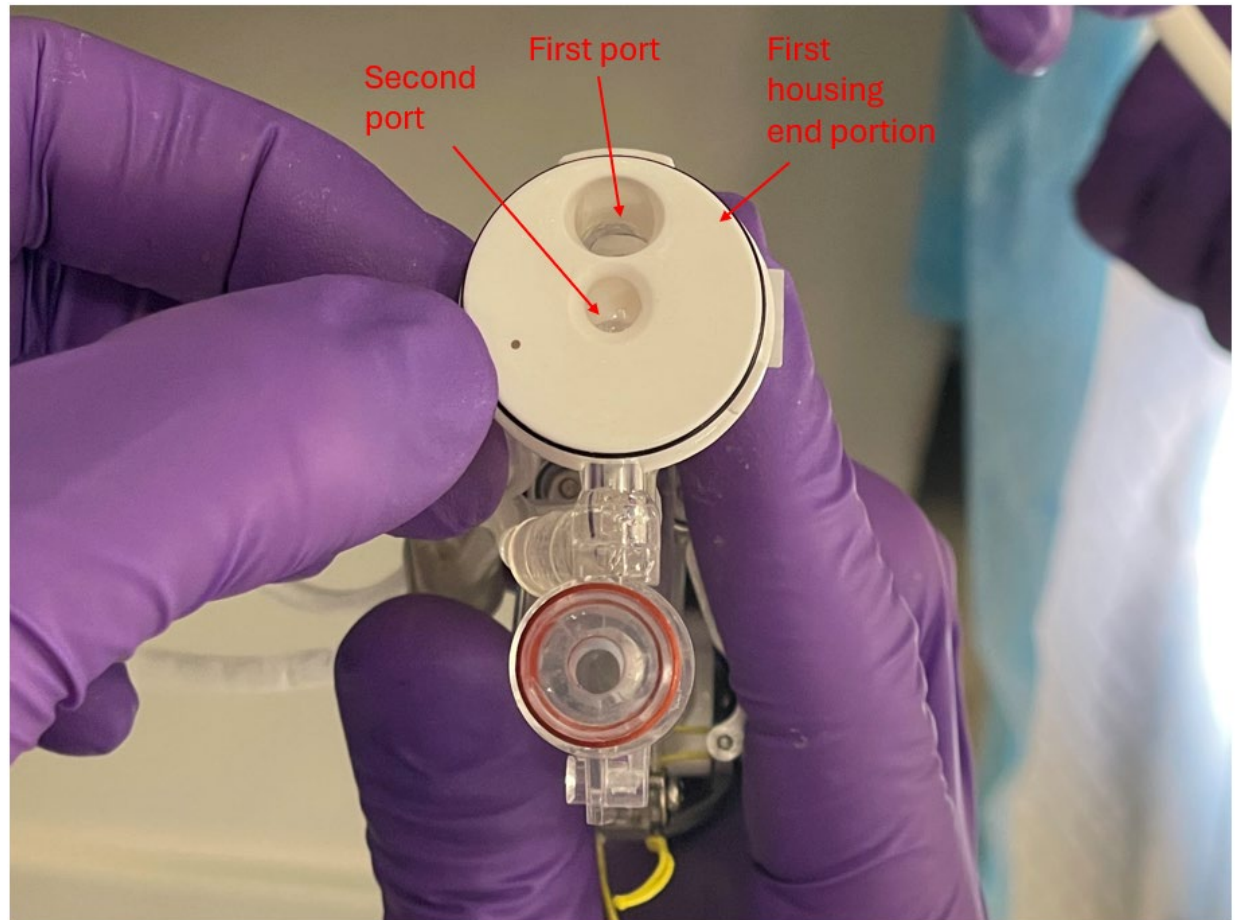
(Annotated image of internal portion of the controller housing.)



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



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



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

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

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

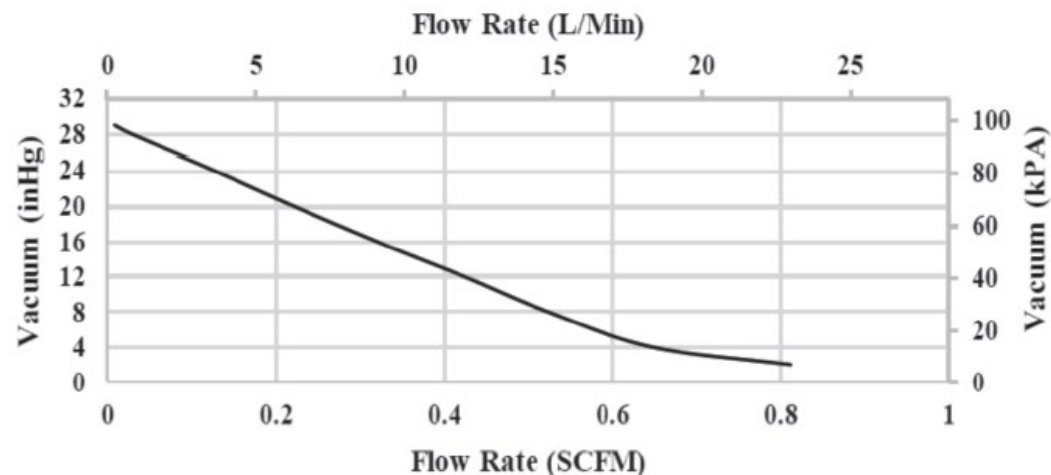
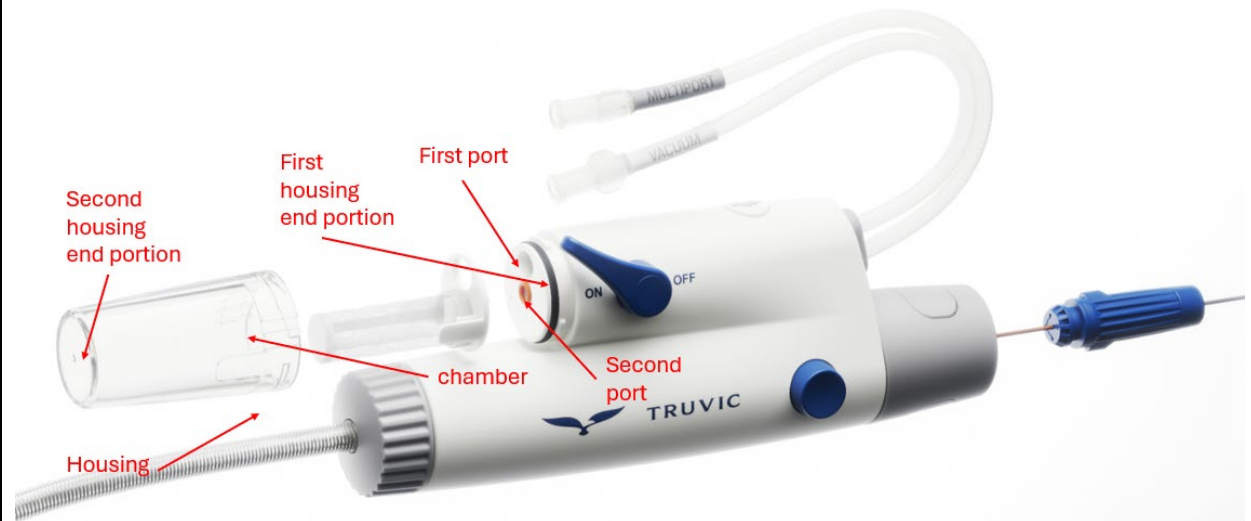


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

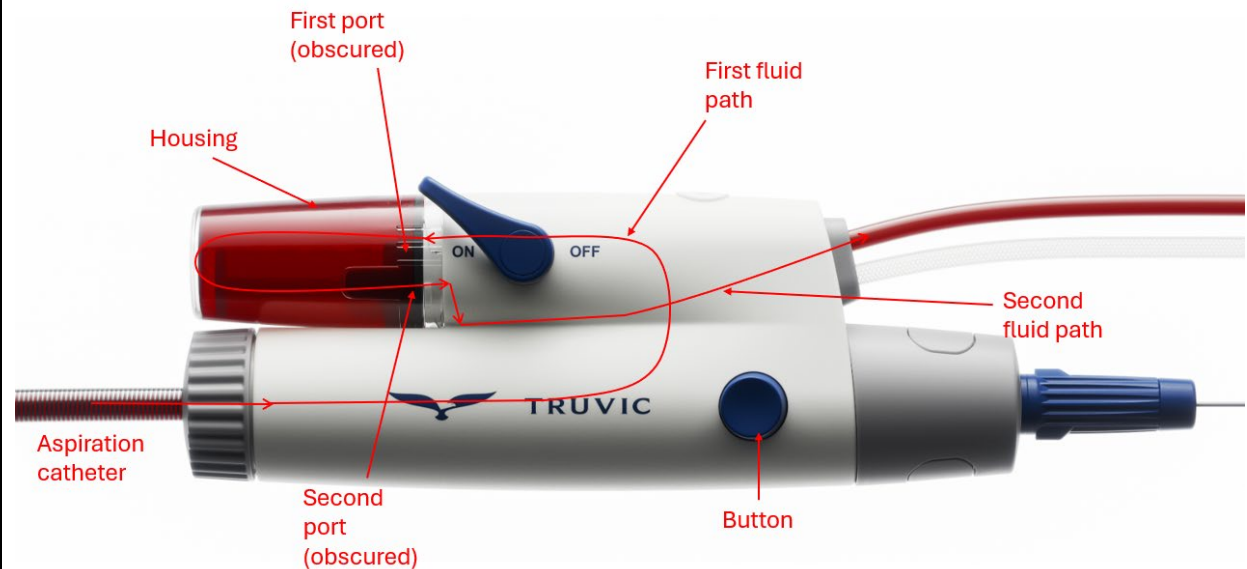
The second port can also be seen in the exploded image from the Whipsaw website of a 24F Symphony Catheter handle with a disassembled clot collection reservoir, which is annotated and reproduced below.



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

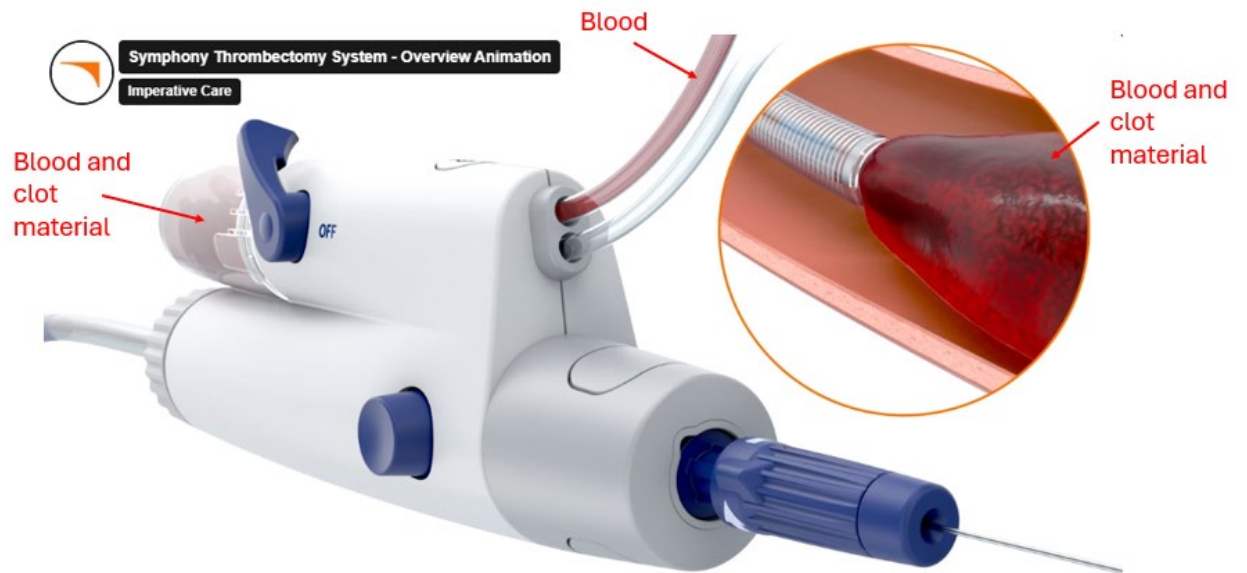
The second port provides a second fluid path from the clot container of the 24F and 16F Symphony Catheter handles, as shown in the annotated image from Whipsaw's website below. Specifically, blood and clot material enters the aspiration catheter and travels along the first fluid path through the first port and into the chamber of the clot container. Blood then passes through the filter, through the second port and along the second fluid path where it flows through tubing internal within the

handle toward the Truvic Generator and Truvic Canister (e.g., aspiration source, not shown).

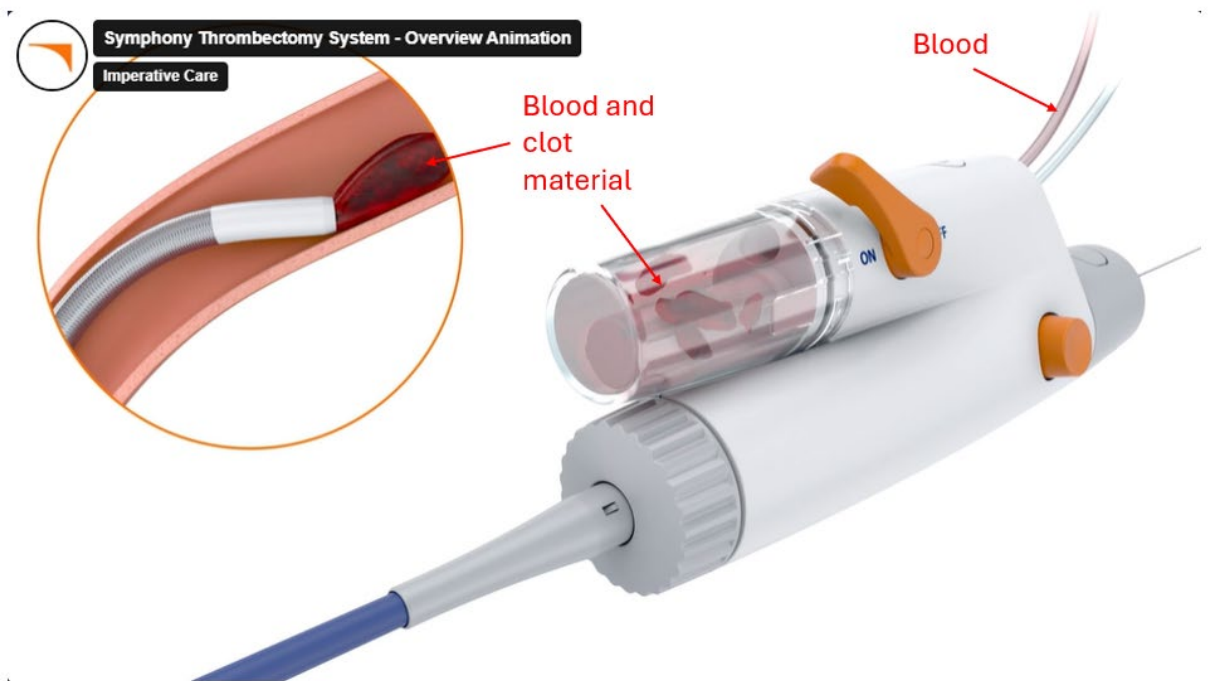


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration catheters, travels through the first fluid path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot container. Blood then flows through the filter, through the second port that provides the second fluid path from the chamber of the clot container towards the tubeset and then toward the aspiration source.



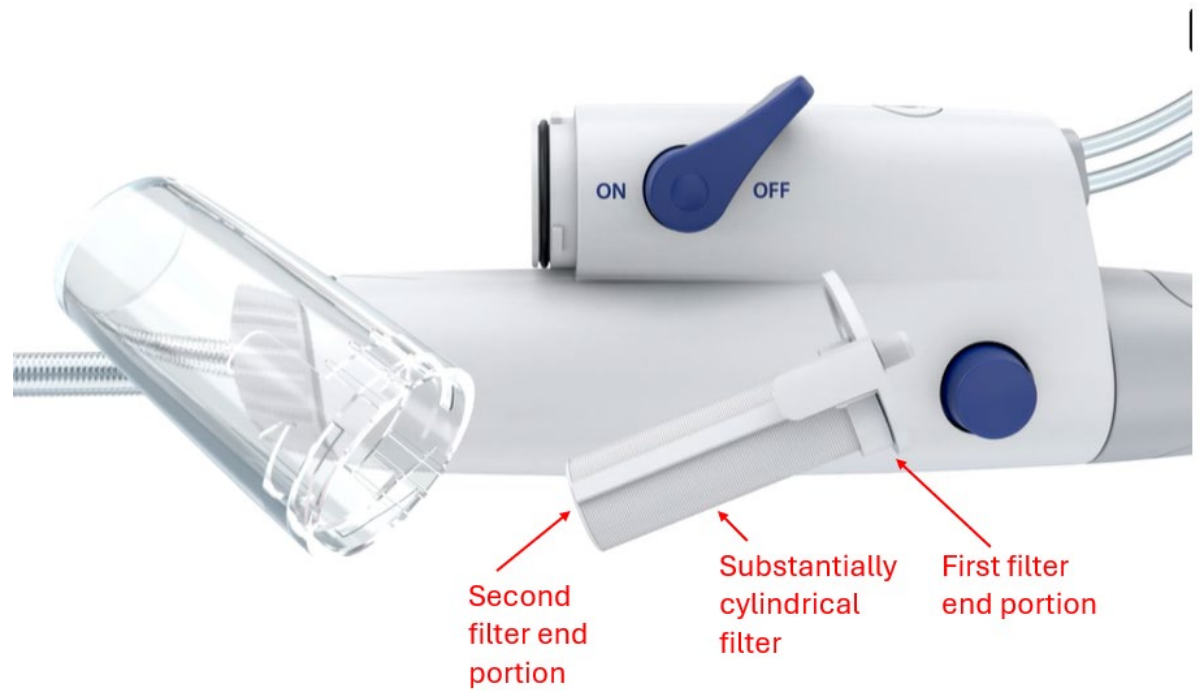
(Symphony Thrombectomy System – Overview Animation Video at 1:09.)



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

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

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

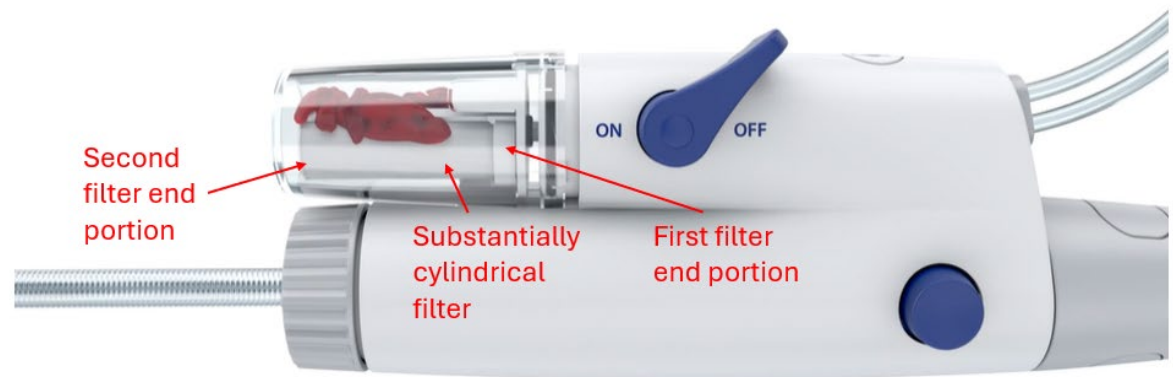


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

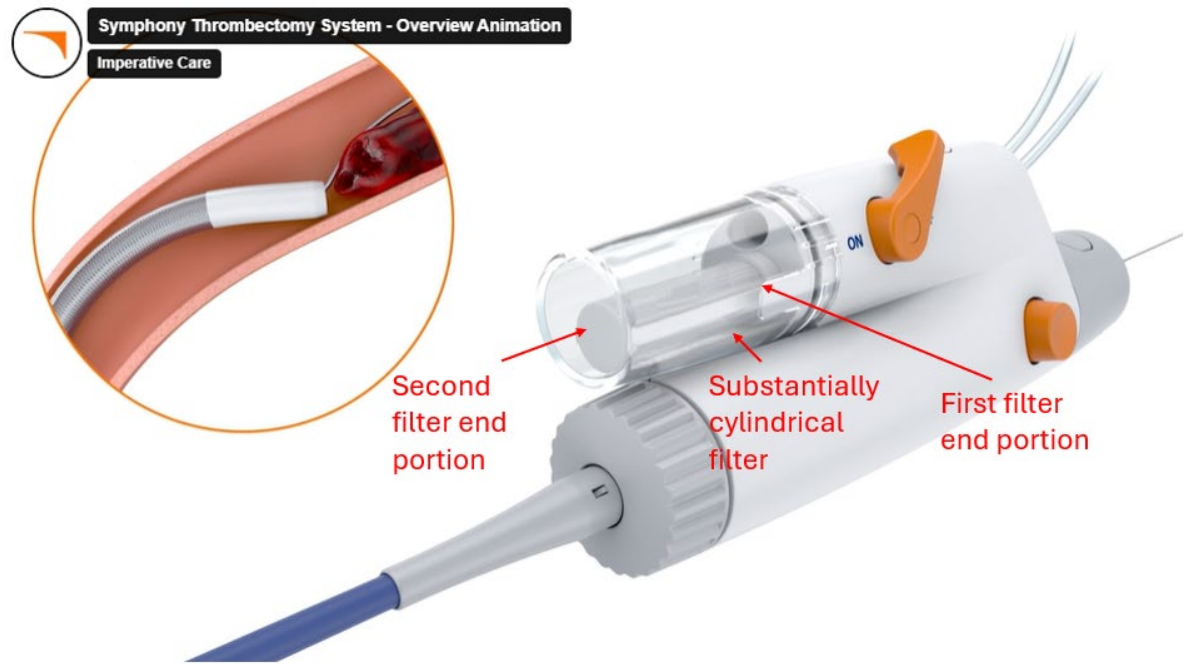


Symphony Thrombectomy System - Overview Animation

Imperative Care

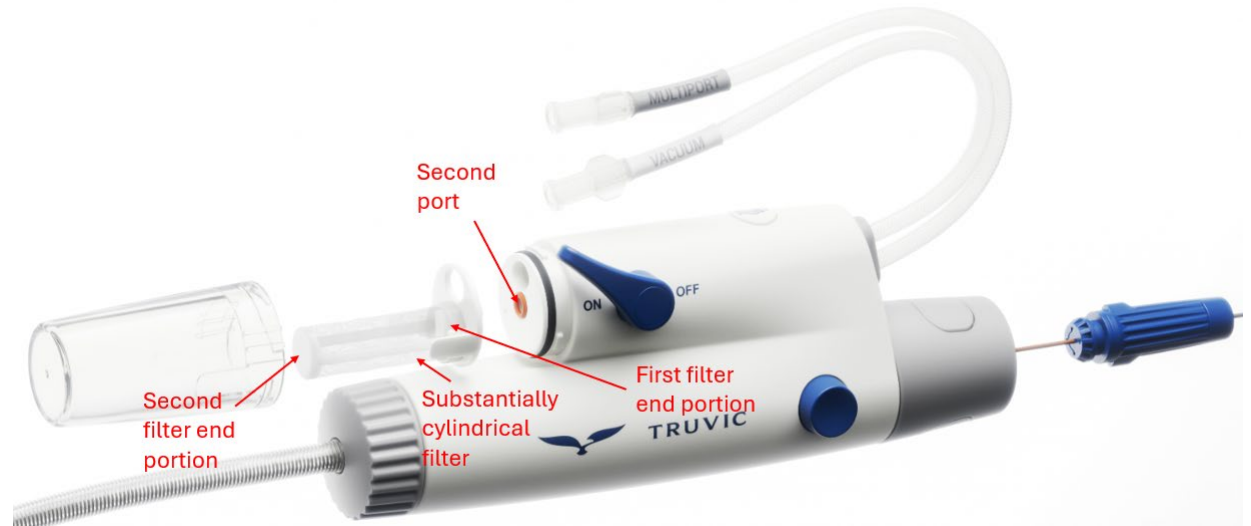


(Symphony Thrombectomy System – Overview Animation Video at 1:18.)



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

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

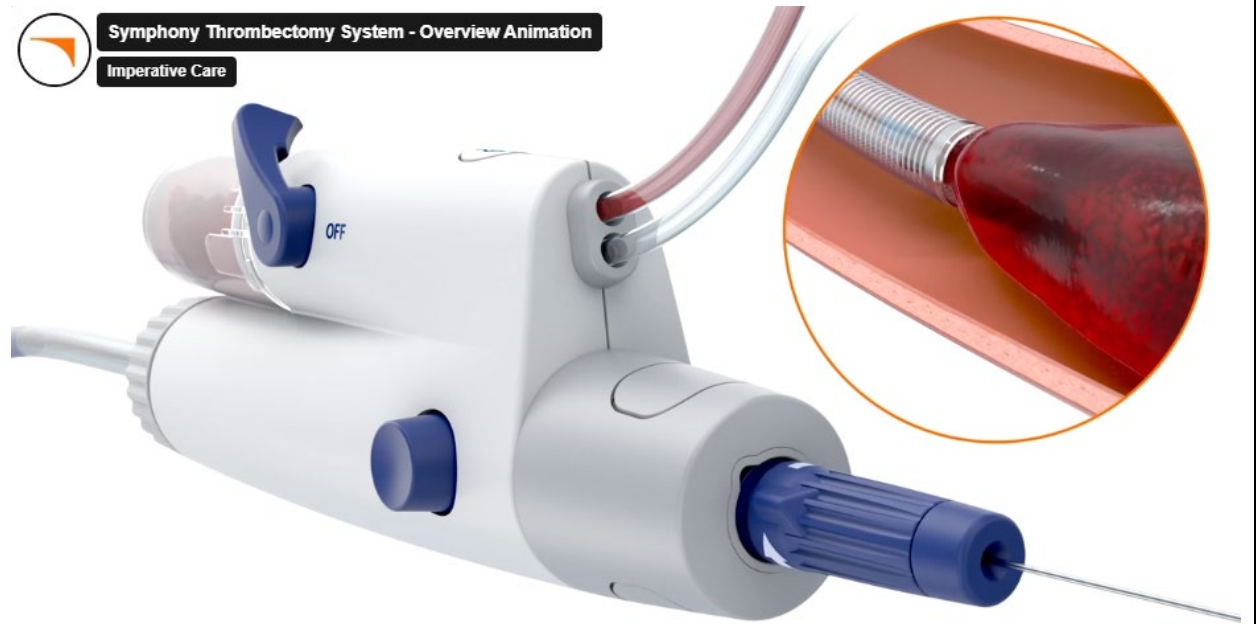


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

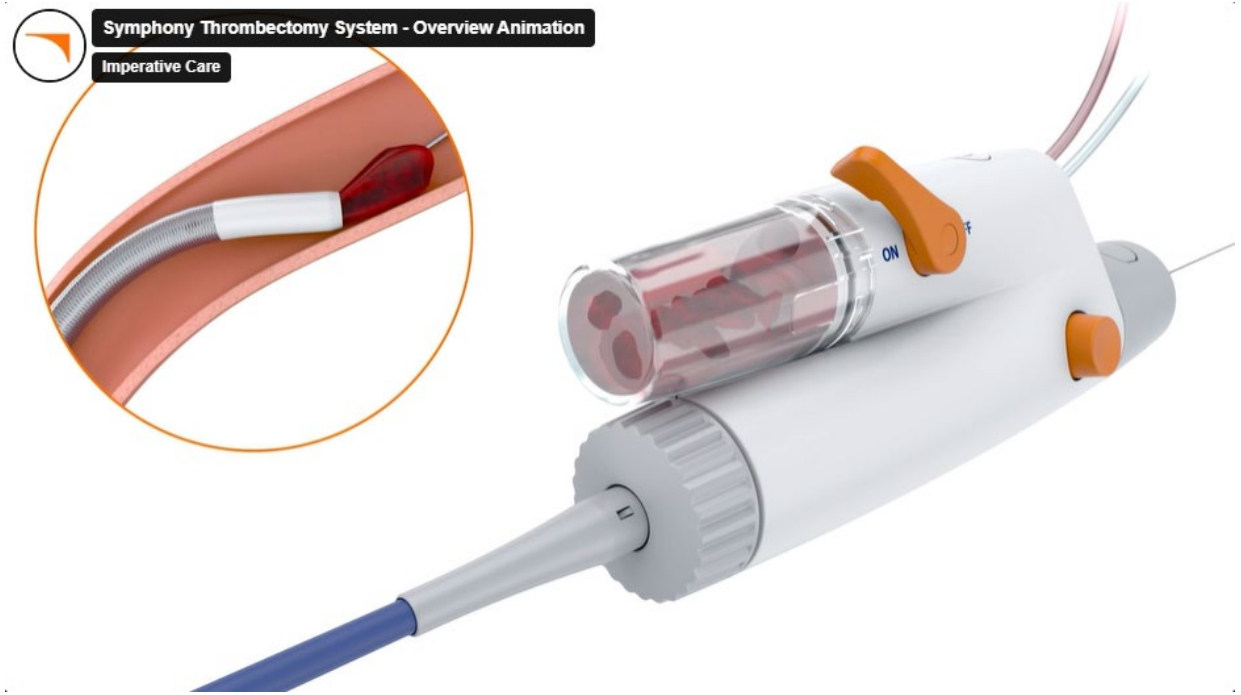
The substantially cylindrical filter encloses an interior region around the second port, such that it prevents clot material from entering the second port. Instead, the filter permits blood to flow through the second port and toward the aspiration source via the second fluid path, as shown in the images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



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



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

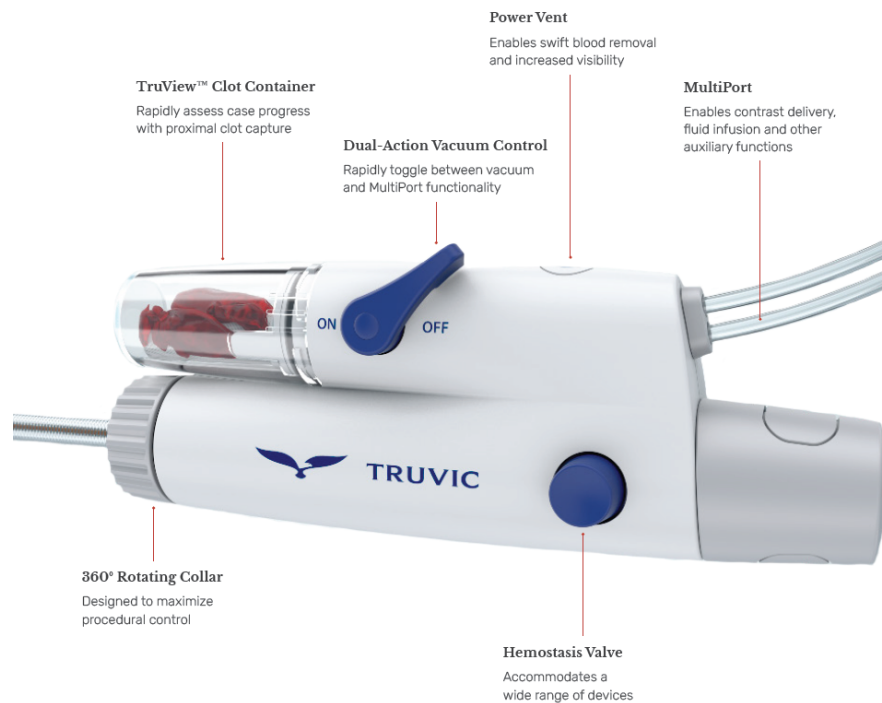


(Symphony Thrombectomy System – Overview Animation Video at 2:03.)

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(Symphony Thrombectomy System Brochure at 6.)

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

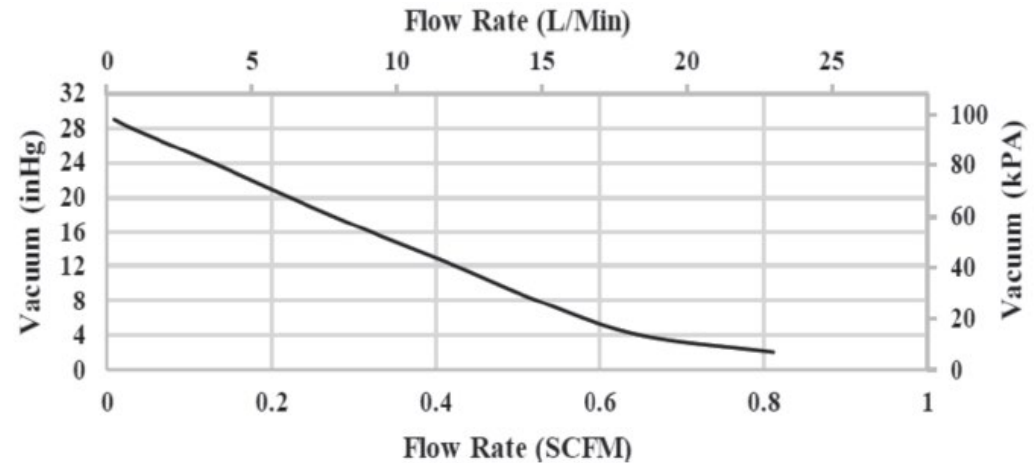
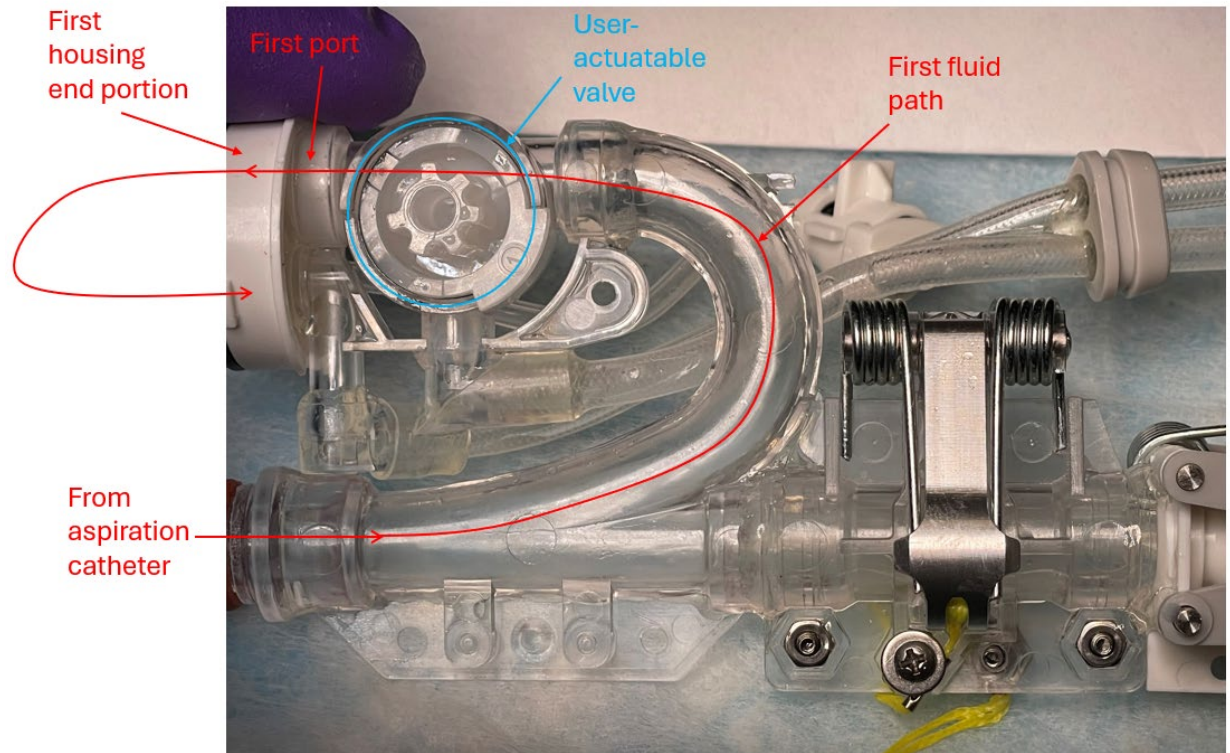


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

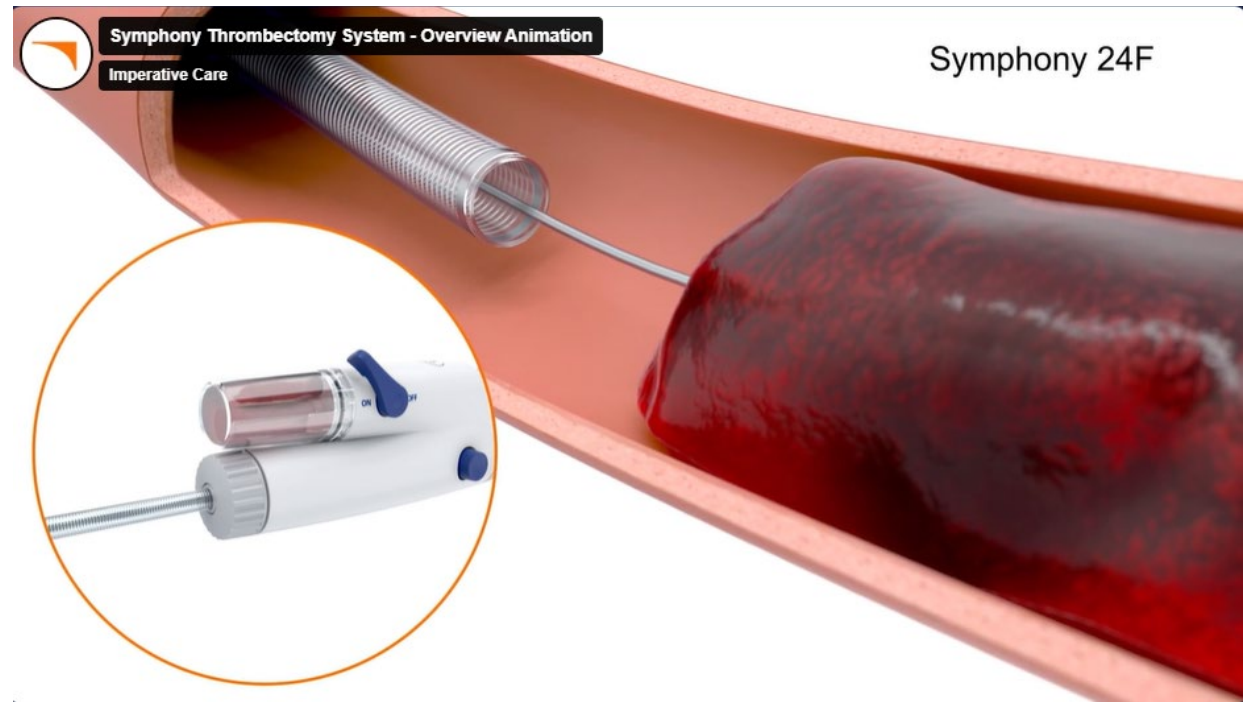
When negative pressure is generated in the chamber of the clot container by the aspiration source (e.g., the Truvic Generator and Truvic Canister) and then the vacuum lever is turned to on to connect the aspiration catheter, it causes blood and clot material to be drawn from the human patient, through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

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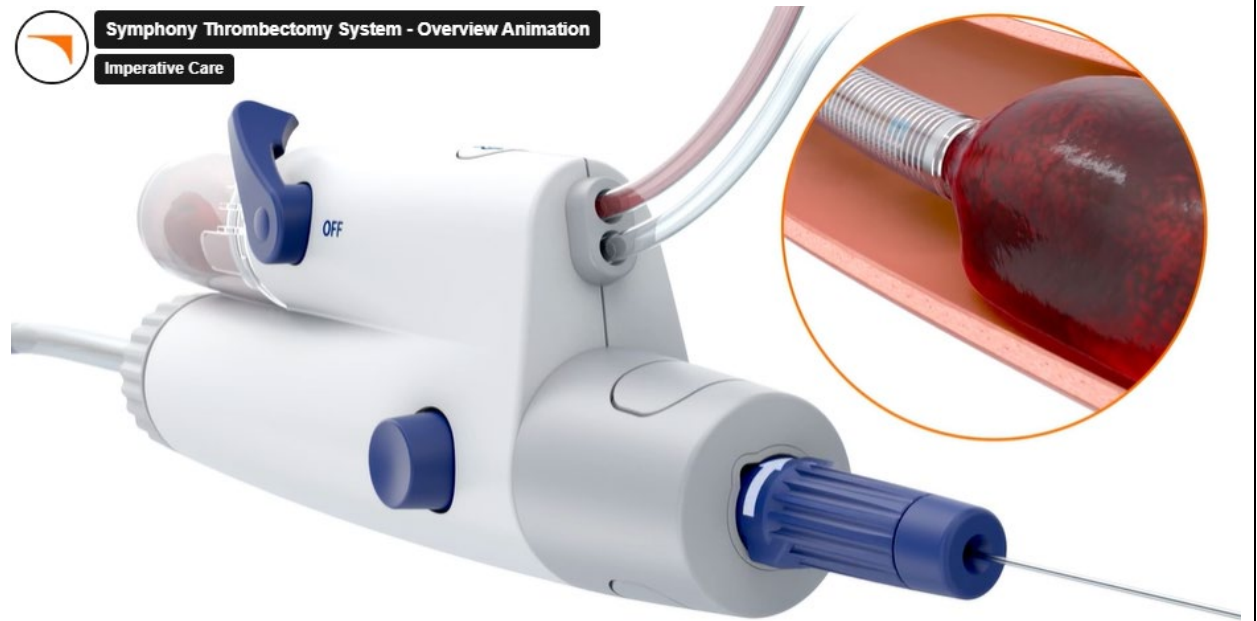


(Annotated image of internal portion of the controller housing.)

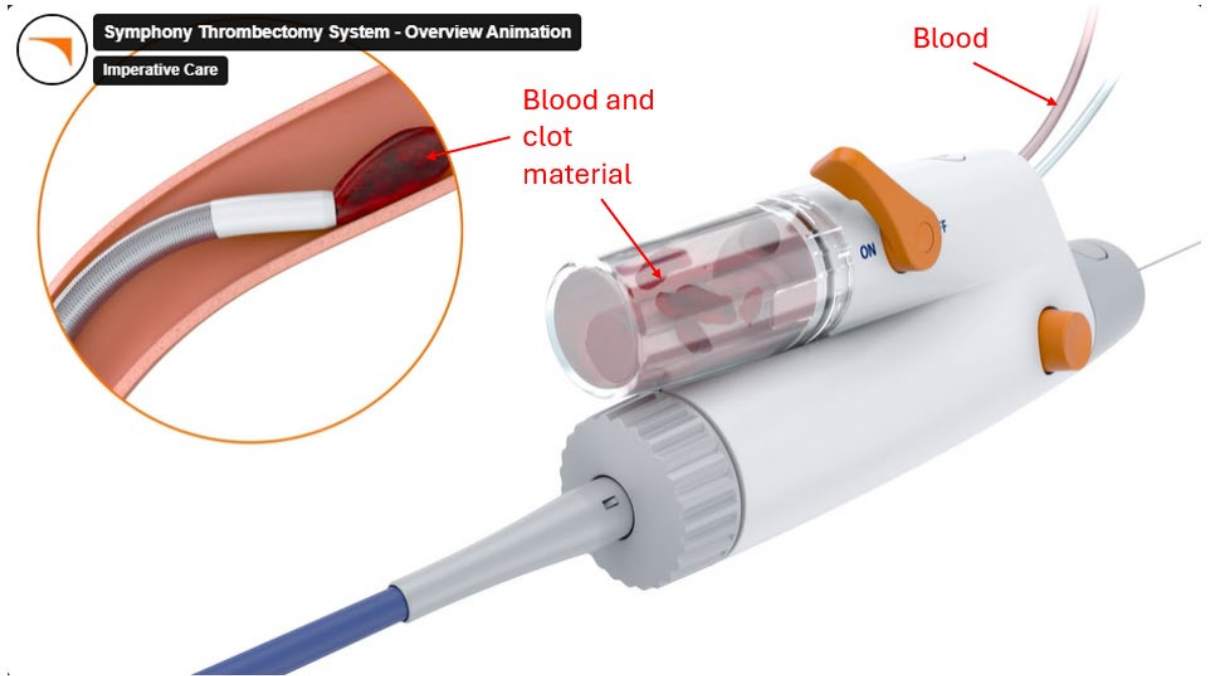
The Symphony Thrombectomy System Overview Animation Video also depicts blood and clot material flowing from the aspiration catheter, through the first port, and into the chamber of the clot container.



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

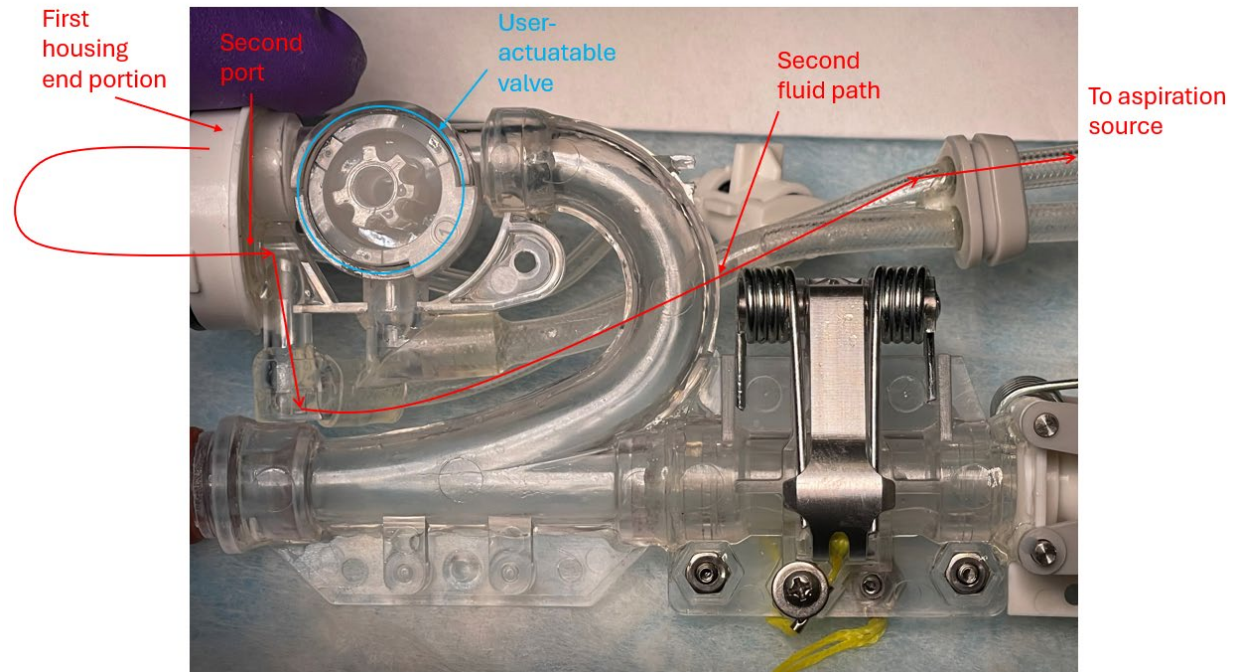


(Symphony Thrombectomy System – Overview Animation Video at 1:05.)



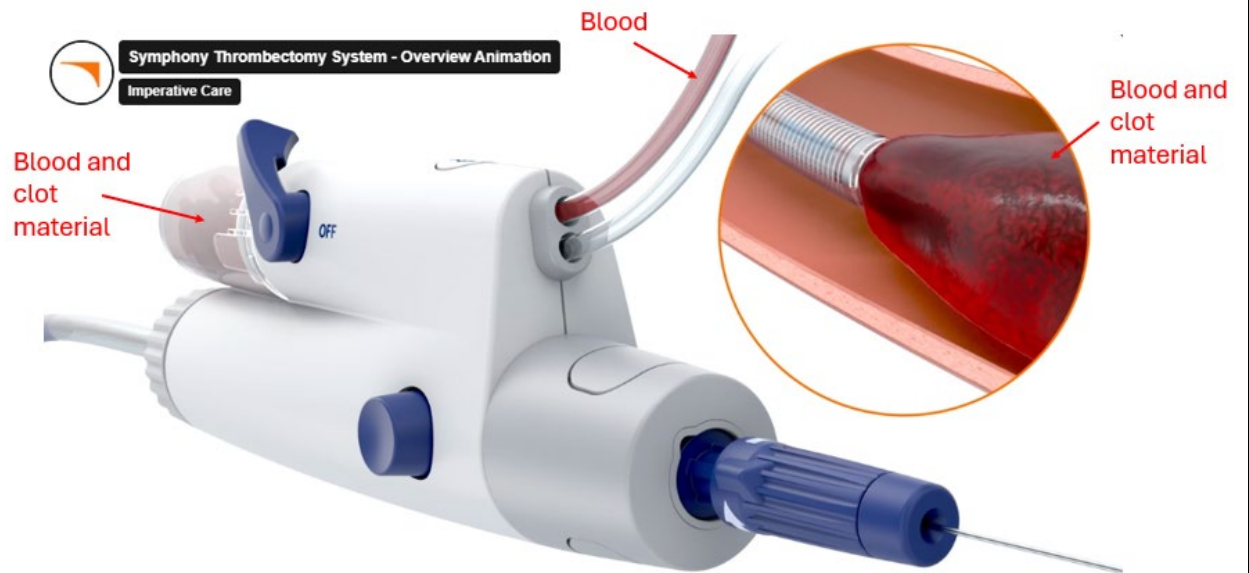
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

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

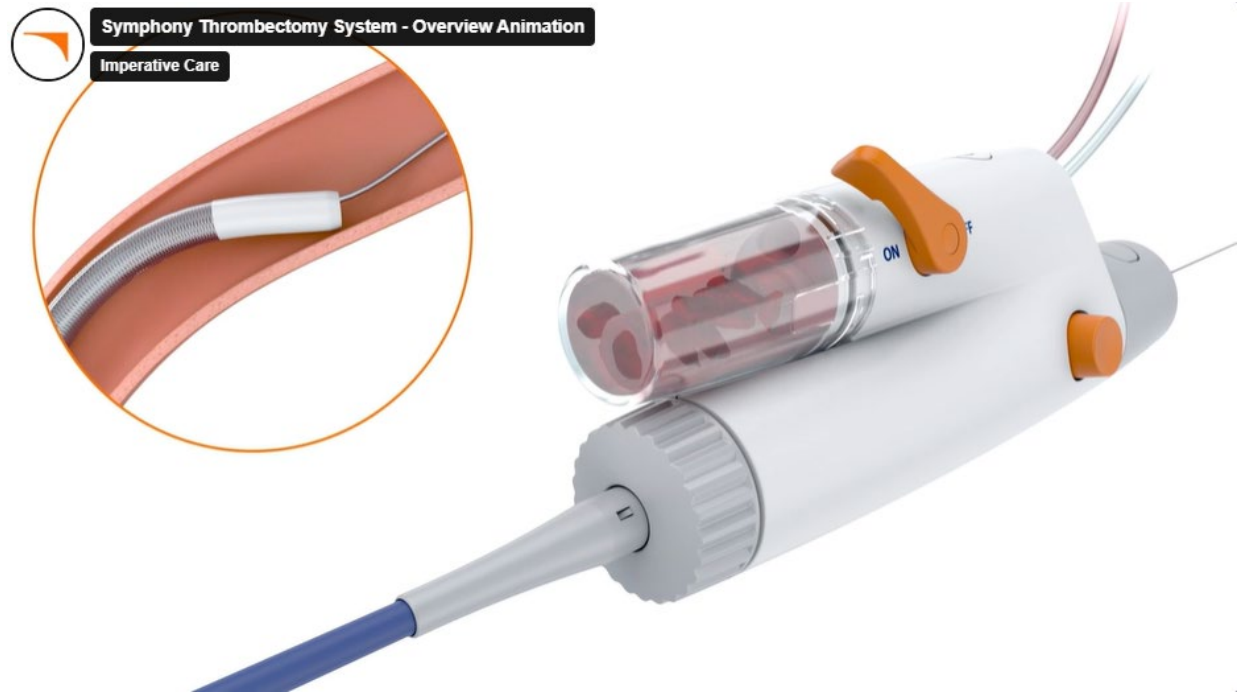


(Annotated image of internal portion of the controller housing.)

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



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



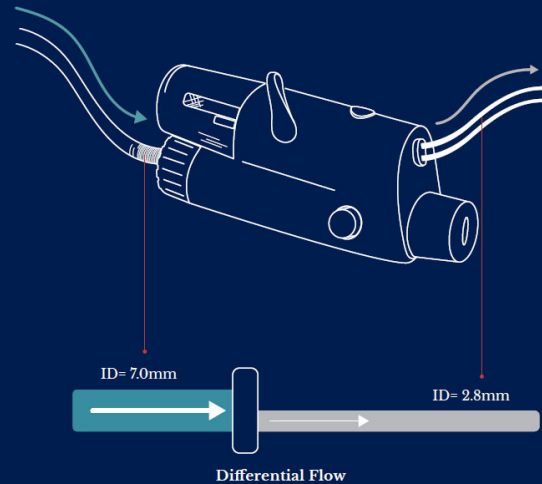
(Symphony Thrombectomy System – Overview Animation Video at 2:03.)

The Symphony Thrombectomy System Brochure also shows the flow of clot and blood into the chamber and shows blood flowing out of the chamber.

On-Demand Vacuum with Integrated Blood Management

Balance power with control and minimize blood loss with built-in differential flow. Clot capture in the palm of your hands provides real-time case assessment.

The Symphony™ Advantage



Blood flowrate reduced by

~55%*

* Data on File

BigShot™ Controller

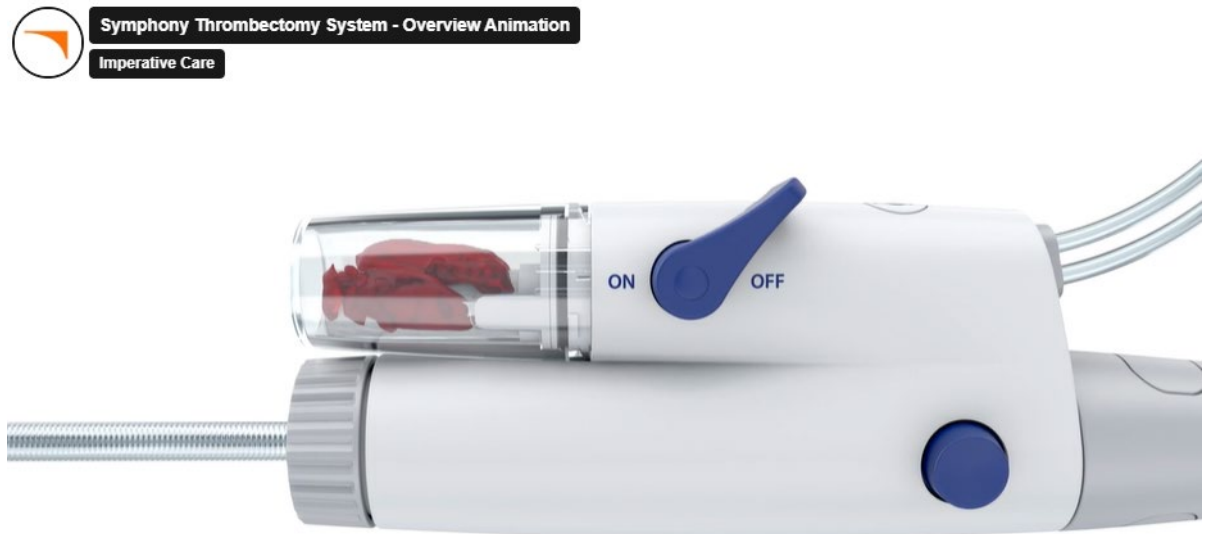
(Symphony Thrombectomy System Brochure at 7.)

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

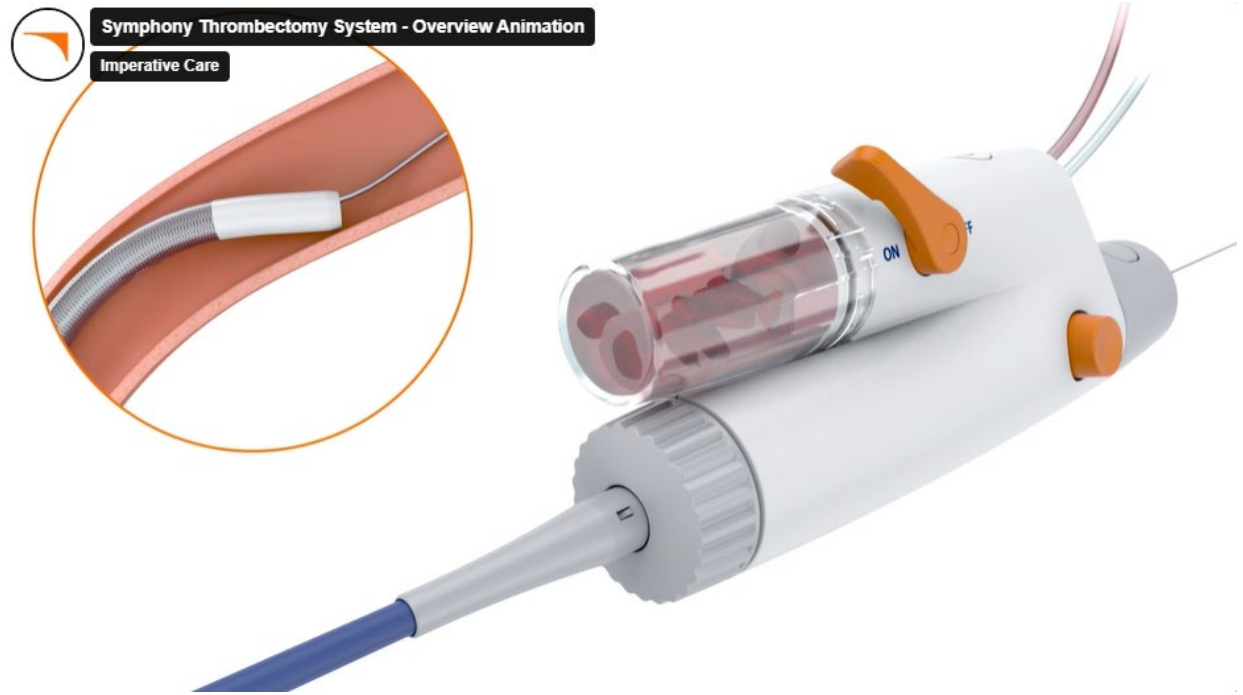
wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port; and

The clot collection reservoir of the Symphony System includes a filter that is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.

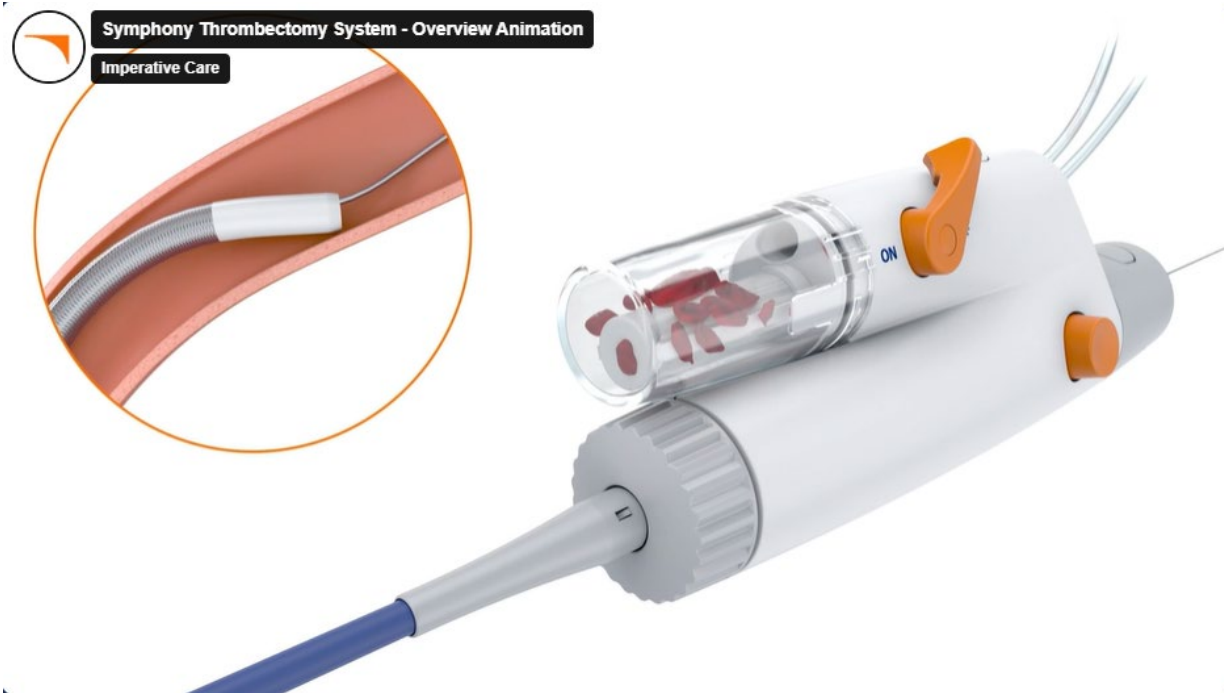
Specifically, as shown in the images from the Symphony Thrombectomy System Overview Animation Video, the filter of the clot container of the 24F and 16F Symphony Catheter handles is configured to and does inhibit clot material from passing through the filter, into its interior region, and through the second port, thus trapping clot material in the chamber of the clot container.



(Symphony Thrombectomy System – Overview Animation Video at 1:16.)



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



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

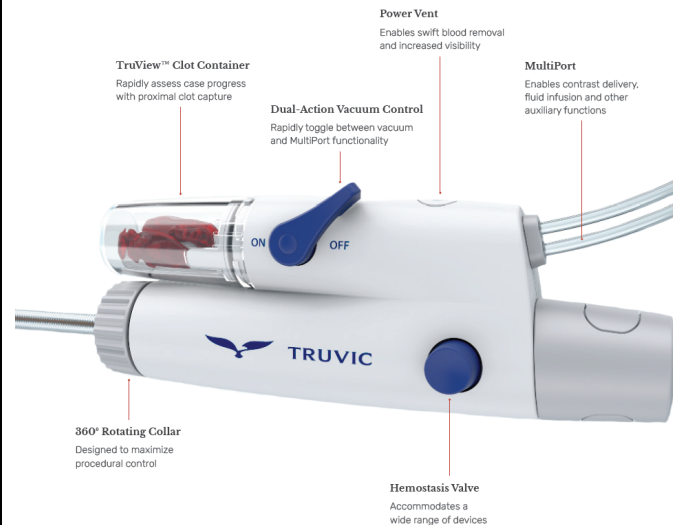
The Symphony System IFU confirms that the filter inhibits clot material from flowing into its interior, and instead allows for blood to flow through its interior and through the second port. (Symphony Thrombectomy System Instructions For Use at 5, 8.) Physical inspection of the Symphony System’s filter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

The Symphony Thrombectomy System Brochure also depicts clot material remaining in the chamber of the clot container so that the physician or user can view the clot and assess progress.

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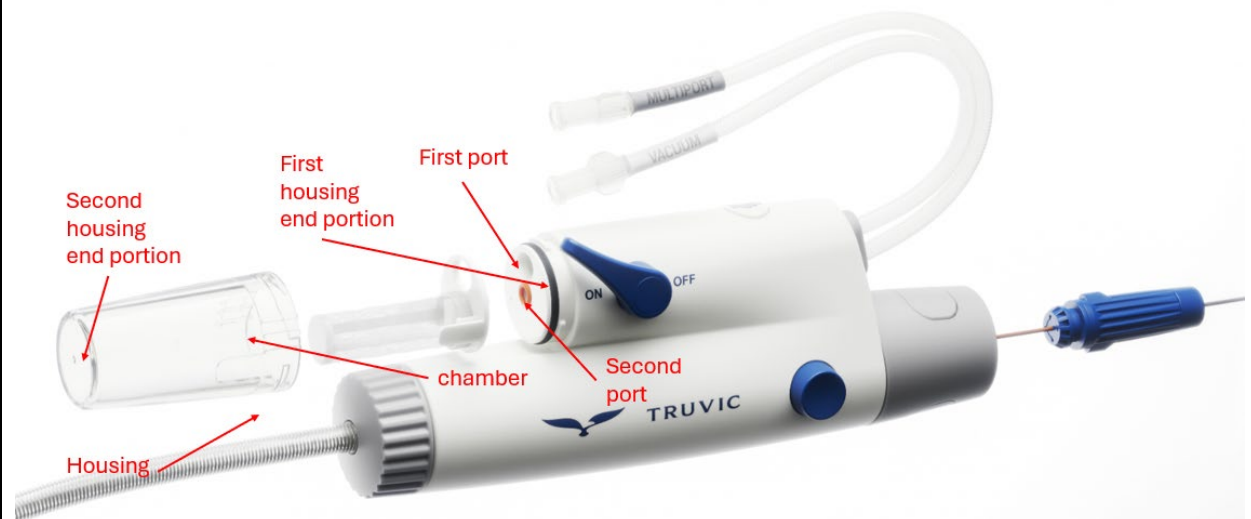
(Symphony Thrombectomy System Brochure at 6.)

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

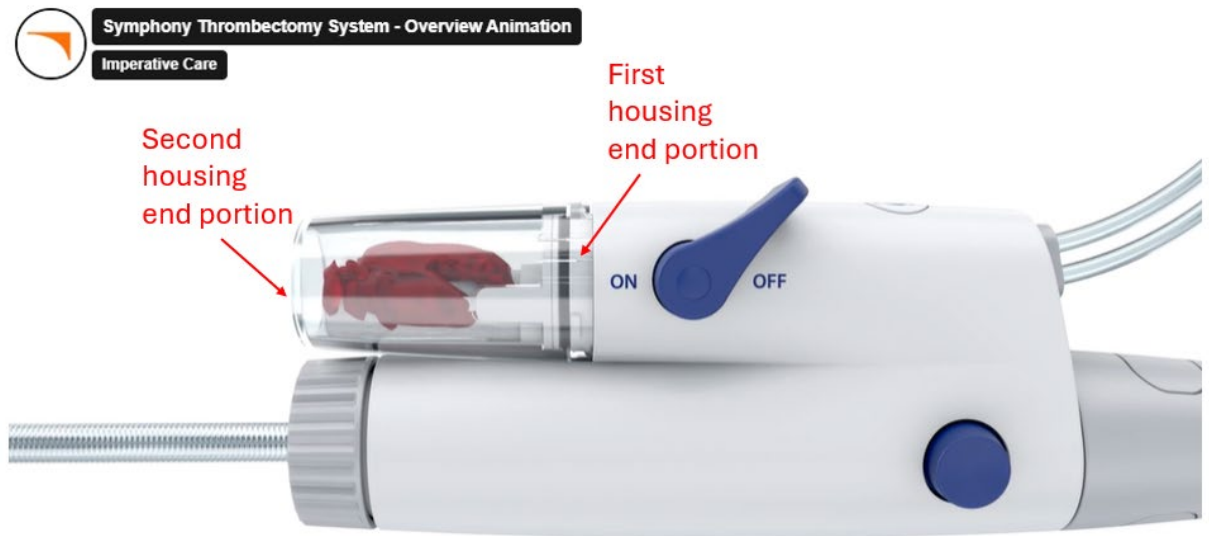
wherein the filter is removably positioned within the chamber to provide access to the clot material within the chamber.

The clot collection reservoir of the Symphony System includes a filter that is removably positioned within the chamber to provide access to the clot material within the chamber.

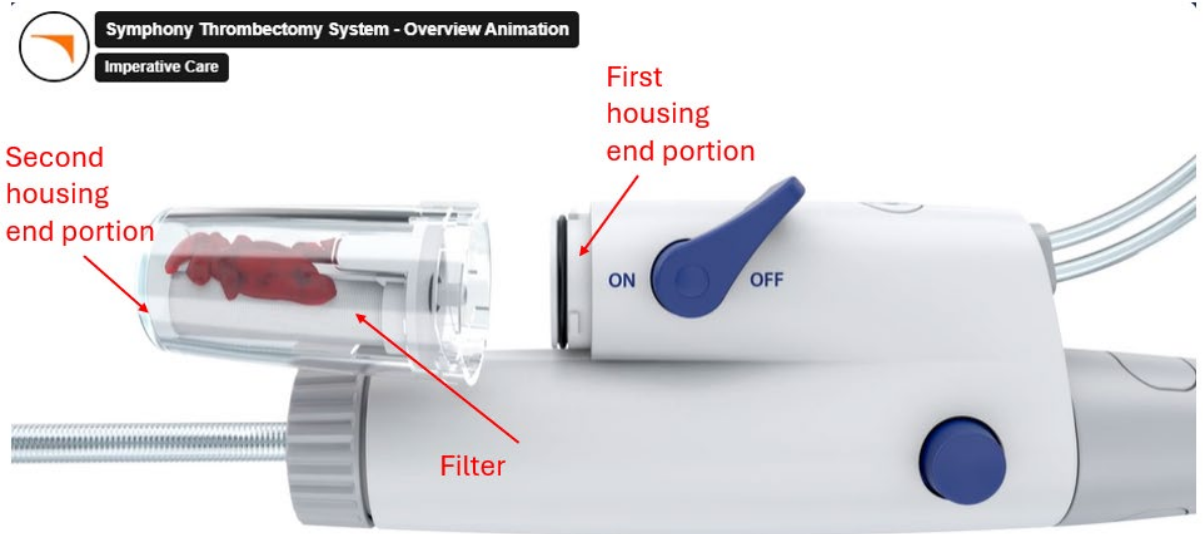
The clot collection reservoir of the 24F and 16F Symphony Catheter handles includes a filter that is removable from the housing to provide access to the clot material, as shown in the annotated figures below.



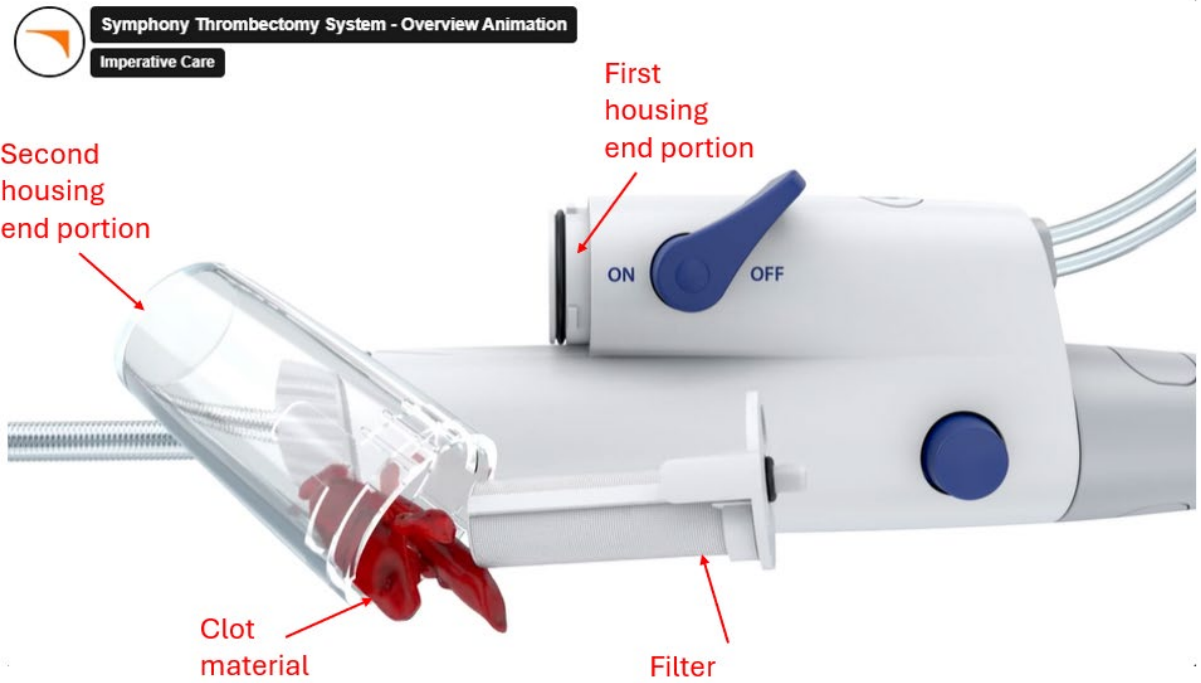
(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)



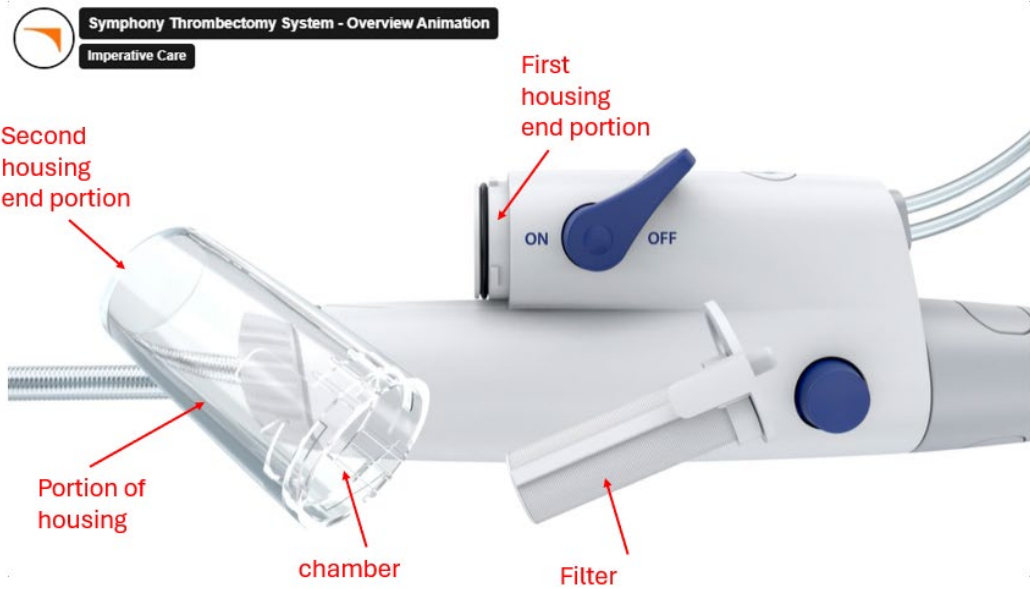
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:17.)



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



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

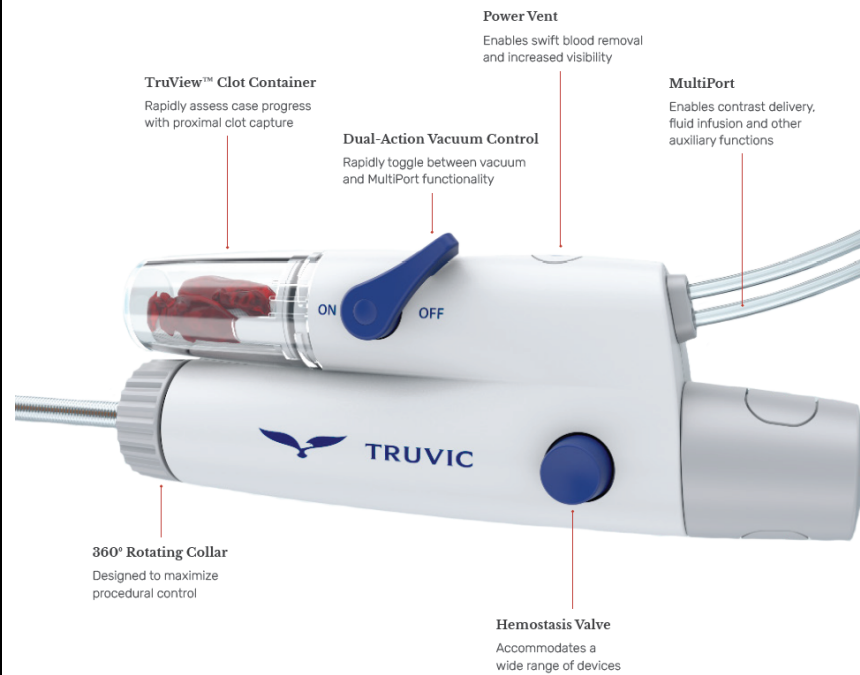
	 <p>(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents</p>
<p>[11] The clot treatment system of claim 10 wherein the housing is at least partially transparent to permit visualization of the clot material in the chamber outside the interior</p>	<p>The clot collection reservoir of the Symphony System includes a housing that is at least partially transparent to permit visualization of clot material in the chamber outside of the interior region.</p> <p>Specifically, the housing includes the outer plastic portion of the clot collection reservoir of the 24F and 16F Symphony Catheter handles that is clear (<i>e.g.</i>, at least</p>

region.	<p>partially transparent), which allows a user of the Symphony System to visualize the clot material in the chamber, outside the interior region of the filter as shown in the Symphony Thrombectomy System Brochure below. (<i>See also</i> https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system (“The clot can also be ... withdrawn down through the catheter via vacuum where it is then trapped in a clear filter container, allowing the clot to be seen and analyzed by the physician.”).</p>
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SYMPHONY™ THROMBECTOMY SYSTEM

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

BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)

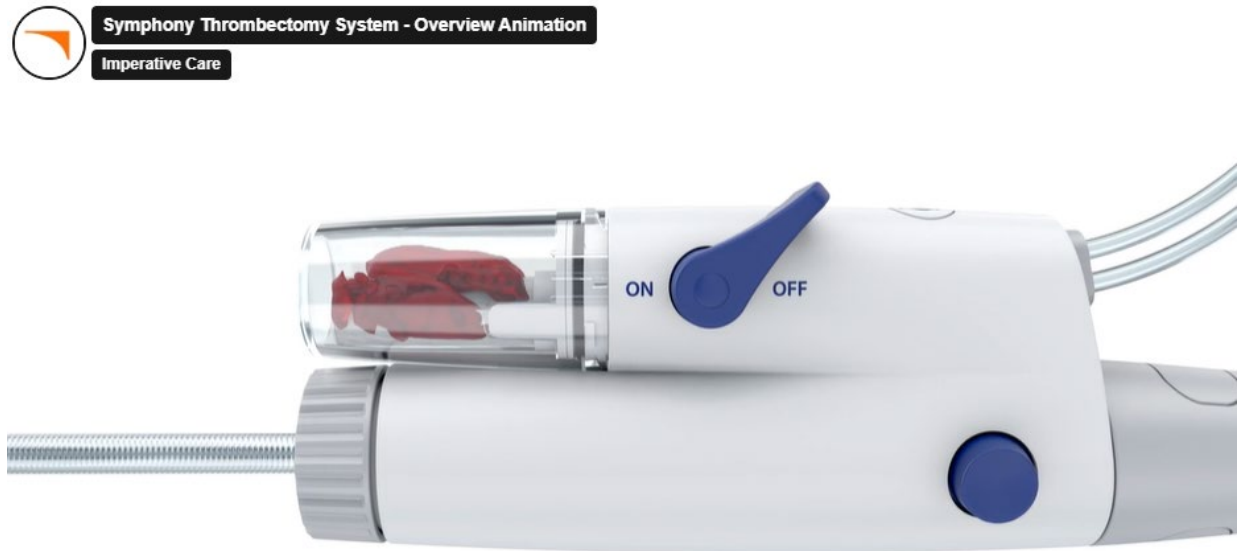


(X-ray image showing material in outer plastic portion of the clot collection reservoir.)

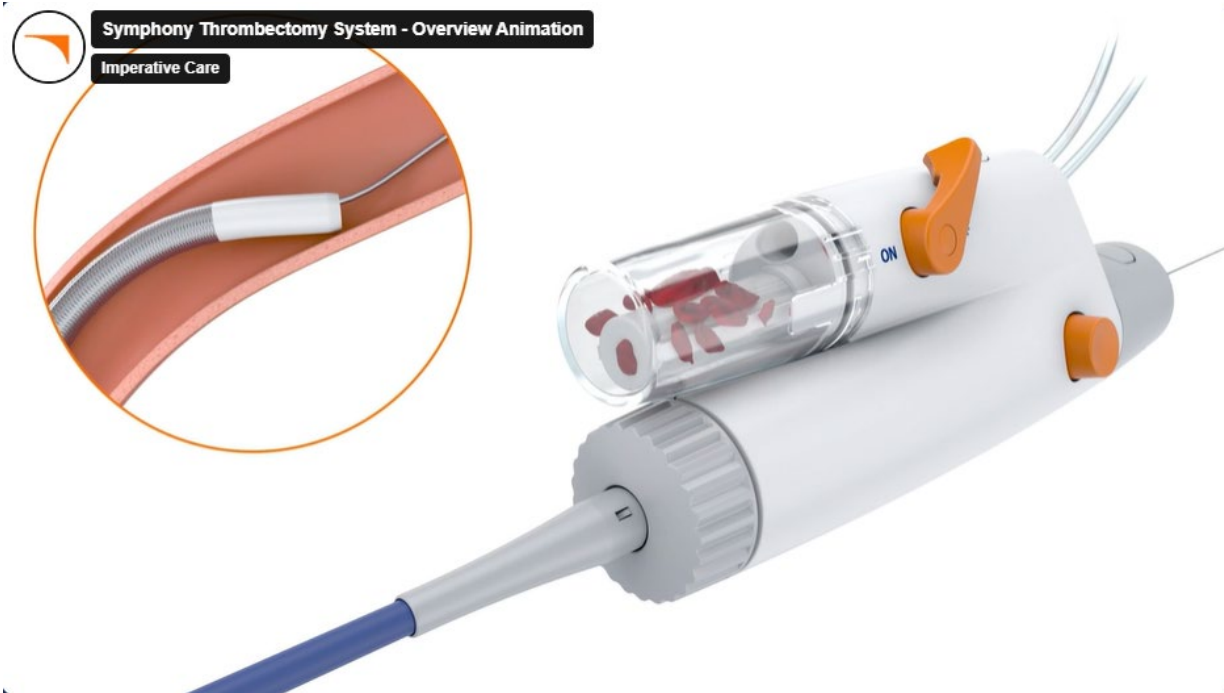
Specifically, the Symphony Thrombectomy System Brochure touts the Symphony System's "TruView™" clot capture. (Symphony Thrombectomy System Brochure at 2.)

The Symphony System IFU confirms that a user is able to visualize the clot material in the chamber of the clot container after blood is evacuated.

The images below from the Symphony Thrombectomy System Overview Animation Video further confirms that the housing of the clot container for both the 24F and 16F Symphony Catheter handles includes an outer plastic portion that is partially transparent to allow for a user to visualize the clot material.



(Symphony Thrombectomy System – Overview Animation Video at 1:16 (showing a clear portion of the housing that allows a user to visualize the clot).)



(Symphony Thrombectomy System – Overview Animation Video at 2:05 (showing a clear portion of the housing that allows a user to visualize the clot).)

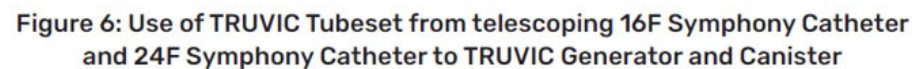
To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

[13] The clot treatment system of claim 10 wherein the clot collection reservoir is spaced apart from the aspiration source, and further comprising at least one tube

The Symphony System includes a clot collection reservoir that is spaced apart from the aspiration source and comprises at least one tube fluidly coupling the second port to the aspiration source.

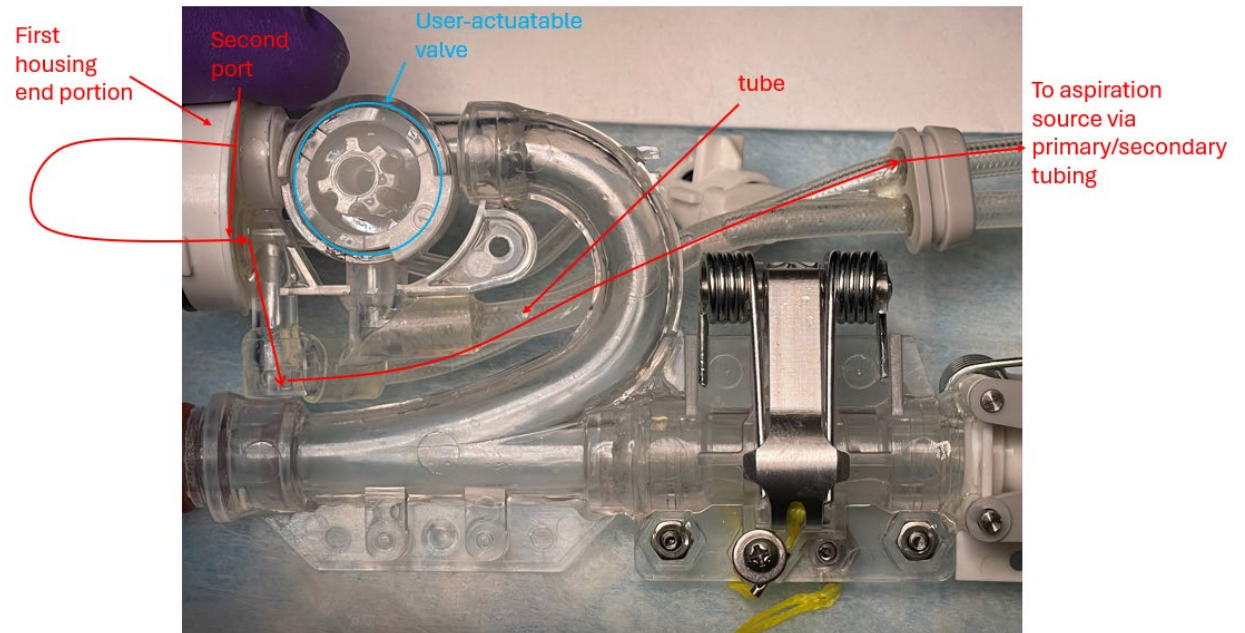
Specifically, the clot collection reservoir of the 24F and 16F Symphony Catheter handles is spaced apart from the Truvic Generator and Truvic Canister (*e.g.*, an

aspiration source), as shown in Figure 6 from the Symphony System IFU annotated and reproduced below.



As shown in annotated Figure 6 from the Symphony System IFU above, the TruViv Generator and TruViv Canister are fluidly coupled to the second port of the 24F and 16F Symphony Catheter handle via the TruViv Primary Tubing or TruViv Secondary Tubing above. As shown in the annotated teardown image below, the primary or secondary tubing is coupled to the second port via a tube pathway through and then out of the Bigshot Controller handle. (*See also* Symphony

Thrombectomy System Instructions For Use at 5 (“Connect the Primary Tubing to the Handle Tubing labelled ‘Vacuum’.”); Symphony Thrombectomy System Instructions For Use at 8 (“Connect one end of the TRUVIC Secondary Tubing to the 16F Handle tubing labelled ‘Vacuum’.”).)



(Annotated image of internal portion of the controller 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.

[15] A clot treatment system, comprising:

The Symphony System is a clot treatment system.

Specifically, “Symphony is a minimally invasive thrombectomy device that removes hazardous clots in patients’ veins via a catheter-based procedure. This handheld tool includes several innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a multifunction port for injecting medicine or contrast or measuring blood pressure, and a connection to a high-power vacuum source. The clot can also be ... withdrawn down through the catheter via vacuum where it is then trapped in a clear filter container, allowing the clot to be seen and analyzed by the physician. Symphony is designed to make a thrombectomy procedure faster and less invasive.” (<https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

As stated in the Symphony System IFU, “[t]he Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration. The Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. 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.)

To treat the clot, “[t]he Symphony Catheter and Symphony Dilator are introduced through a vascular access (introducer) sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and TRUVIC Canister, to aspirate thrombus.” (Symphony Thrombectomy System Instructions For Use at 1.)

	<p>The Symphony System IFU also lists the intended purpose of the Symphony Thrombectomy System, which includes clot treatment.</p> <p>The Symphony Thrombectomy System is intended for:</p> <ul style="list-style-type: none"> • The non-surgical removal of fresh, soft emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. <p>The Symphony Thrombectomy System is intended for use in the peripheral vasculature. It is not for use in the pulmonary vasculature.</p> <p>(Symphony Thrombectomy System Instructions For Use at 2.)</p> <p>The Symphony Thrombectomy System Brochure also discloses that it is a clot treatment and removal system.</p>
<p>an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient;</p>	<p>The Symphony System includes an aspiration catheter configured to be intravascularly positioned proximate to clot material within the blood vessel of a patient.</p> <p>Specifically, the Symphony System includes a 24F and/or 16F aspiration catheter that is intravascularly positioned proximate (<i>e.g.</i>, near) to clot material within the blood vessel of a human patient, as described on Whipsaw’s product development website. (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system) (“Symphony is a minimally invasive thrombectomy device that removes hazardous clots in patients’ veins via a catheter-based procedure. This handheld tool includes several innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a</p>

multifunction port for injecting medicine or contrast or measuring blood pressure, and a connection to a high-power vacuum source. The clot can also be ... withdrawn down through the catheter via vacuum where it is then trapped in a clear filter container, allowing the clot to be seen and analyzed by the physician. Symphony is designed to make a thrombectomy procedure faster and less invasive.”).)

Symphony™

THROMBECTOMY SYSTEM

Product Specifications

Symphony™ Catheters			
Product	Model	Working Length	Sheath Compatibility
16F Catheter, 82cm	SYMPHONY16F82	82 cm	16F
16F Catheter	SYMPHONY16F	117 cm	16F
24F Catheter	SYMPHONY24F	85 cm	24F

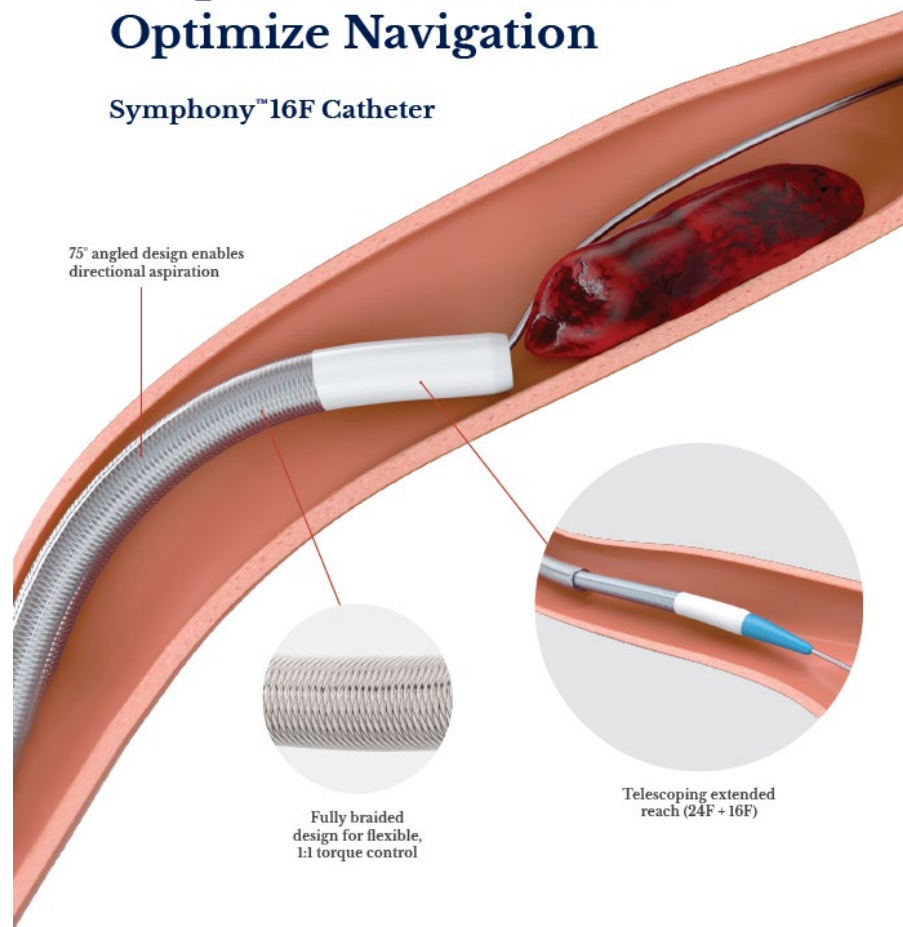
(Symphony Thrombectomy System Product Specifications Sheet at <https://imperativecare.com/wp-content/uploads/sites/4/2024/09/M10147.C-Symphony-Product-Spec-Sheet.pdf>.)

The Symphony Thrombectomy System Brochure shows how the 24F and/or 16F Symphony Catheter can navigate the blood vessel of a patient, such that it is positioned proximate to clot material.

SYMPHONY™ THROMBECTOMY SYSTEM

Purpose-Built Catheters Optimize Navigation

Symphony™ 16F Catheter



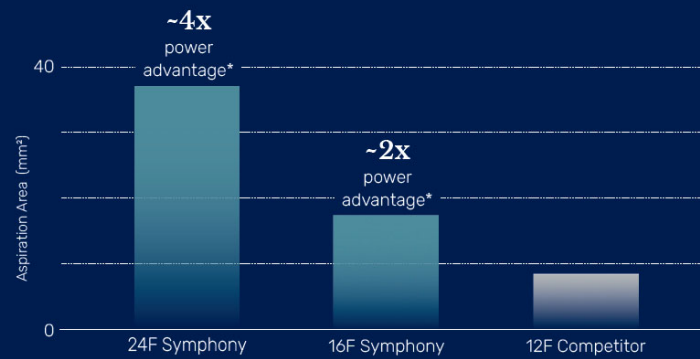
(Symphony Thrombectomy System Brochure at 4.)

Easily Directed for Precise Placement

Highly flexible, radiopaque catheters optimize positioning and visibility.

The system's 16F catheter with angled design directs aspiration within the vessel.

The Symphony™ Advantage¹



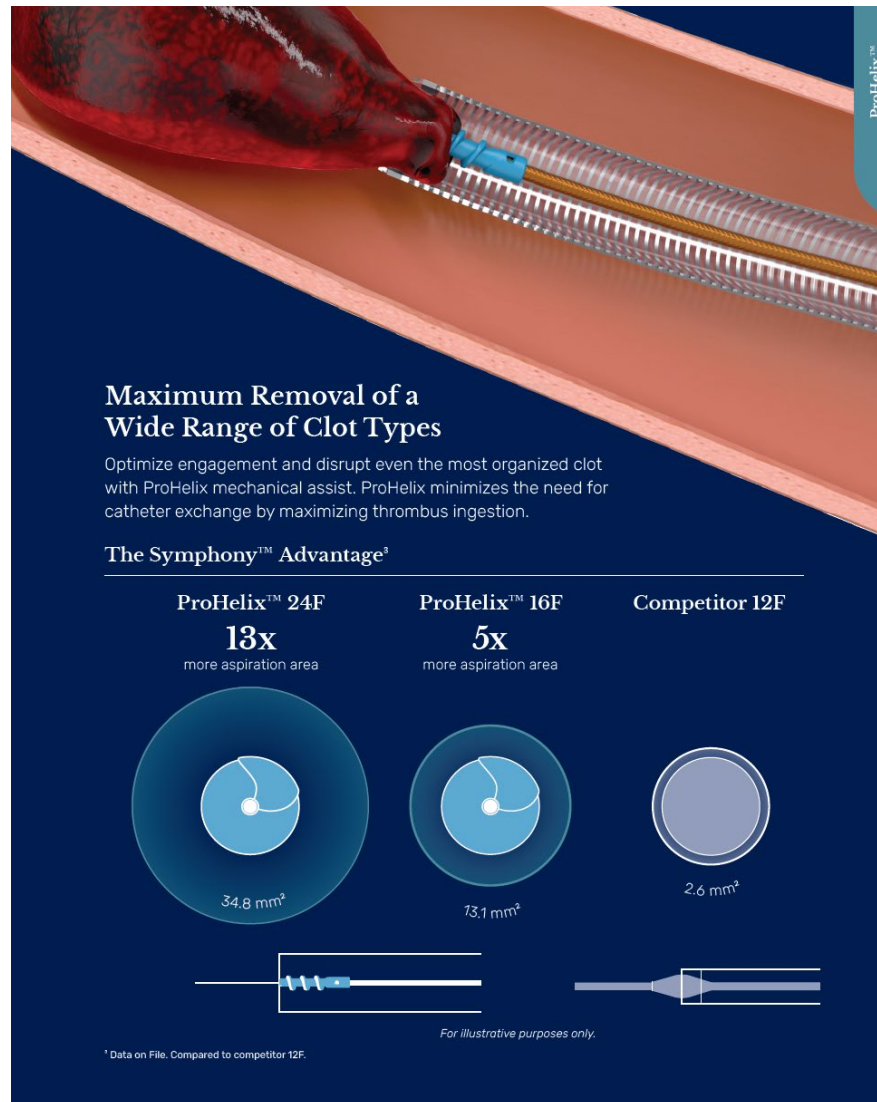
Symphony™ 24F Catheter



Proximal and distal coil design provides flexibility and trackability

* Compared to 12F competitor. Aspiration Power: Force=Pressure x Area.
¹ Data on File

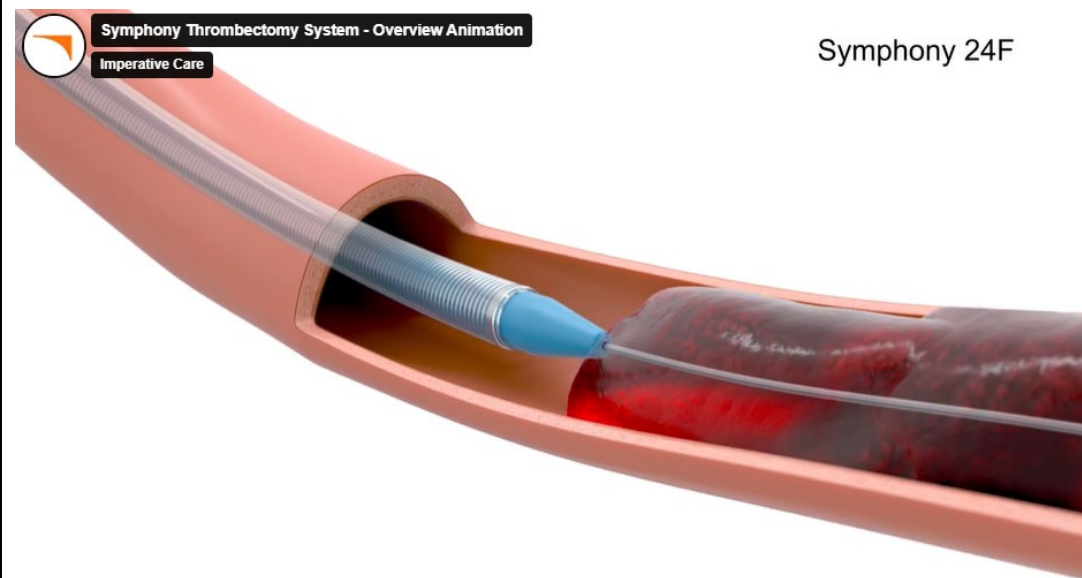
(Symphony Thrombectomy System Brochure at 5.)



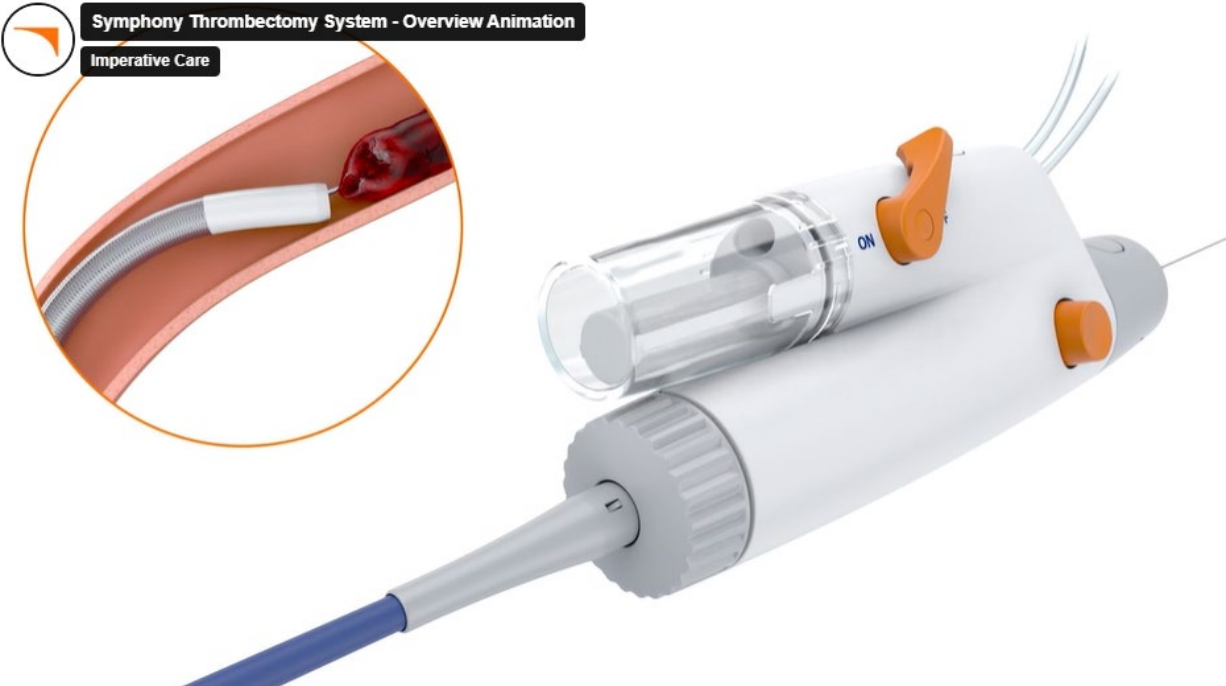
(Symphony Thrombectomy System Brochure at 9.)

The Symphony System IFU describes the aspiration catheter and how it is positioned proximate to clot material within a patient's blood vessel. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter has a lubricious hydrophilic coating on the distal 40 cm of the 24F catheter shaft, and distal 55 cm of the 16F catheter shaft. The Symphony Catheter and Symphony Dilator are introduced through a vascular access (introducer) sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.").)

The images of the 24F and 16F Symphony Catheters also demonstrate that it is positioned proximate to clot material in a patient's blood vessel.



(Symphony Thrombectomy System – Overview Animation Video at 0:37.)

	 <p>(Symphony Thrombectomy System – Overview Animation Video at 1:54.)</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>an aspiration source; and</p>	<p>The Symphony System includes an aspiration source.</p> <p>Specifically, the Symphony System Brochure describes the Truvic Generator and Truvic Canister as an aspiration source.</p> <p>The Symphony System IFU describes how the 24F and 16F Symphony Catheter handles are designed to be used with the Truvic Generator and Truvic Canister for</p>

aspiration. (Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration. The Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus.”); Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.”); Symphony Thrombectomy System Instructions For Use at 2 (“The TRUVIC Symphony Thrombectomy Catheters have been verified for use with the TRUVIC Tubeset and TRUVIC Generator. The TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 2.”).)

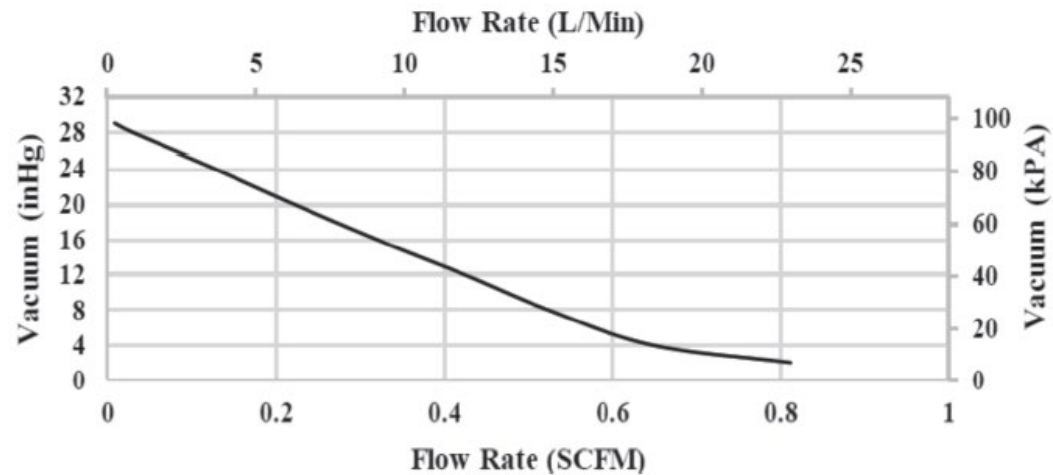


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

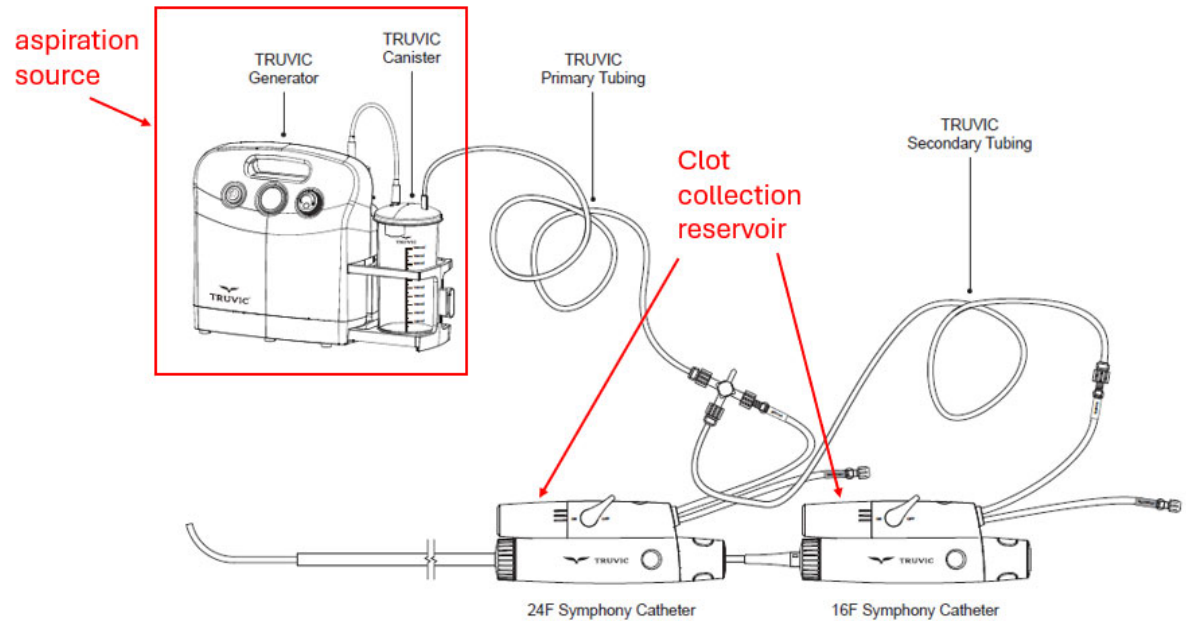


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Symphony Thrombectomy System Instructions For Use at 8.)

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 clot collection reservoir, comprising—

The Symphony System includes a clot collection reservoir (including a “clot container” connected to the Symphony Bigshot Controller handle).

Specifically, the 24F and 16F Symphony Catheter handles of the Symphony System includes a clot collection reservoir where a user can “[c]onfirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle.” (Symphony Thrombectomy System Instructions For Use at 5; Symphony Thrombectomy System Instructions For Use at 6 (same); Symphony Thrombectomy System Instructions For Use at 8 (same).) The clot container of the 24F and 16F Symphony Catheter handle is shown in the Symphony System IFU below.

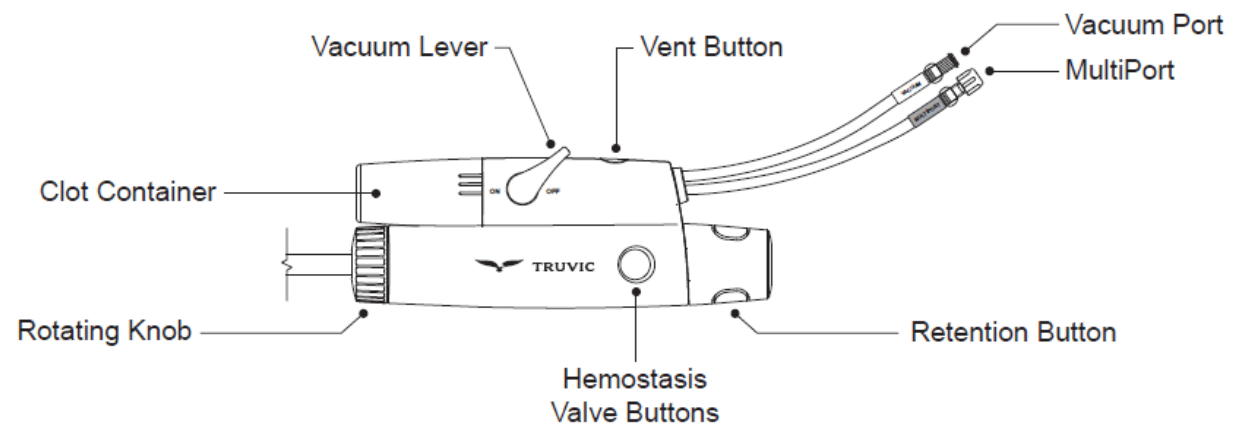
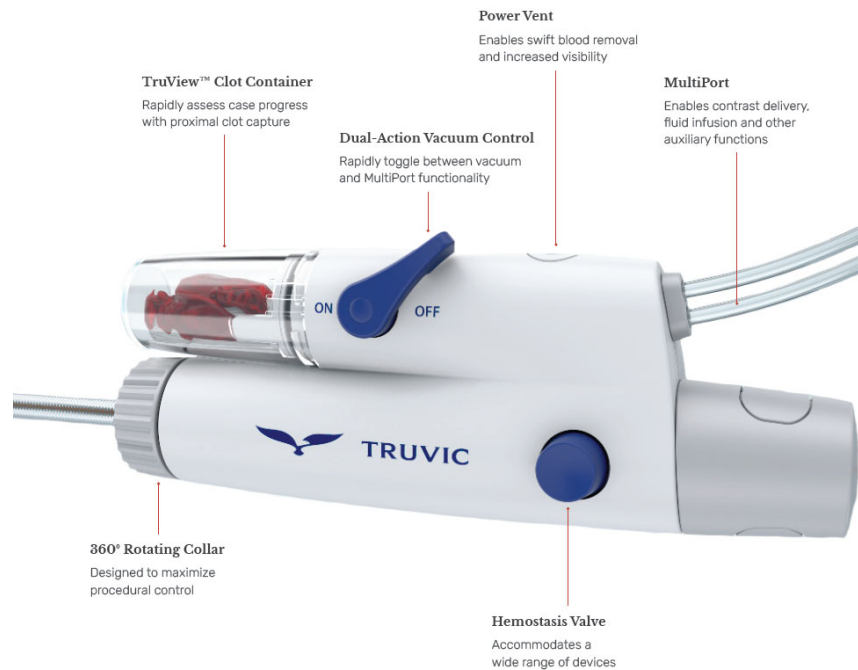


Figure 3: Symphony Catheter Handle, labeled

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

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

BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)

BigShot™ Contr

On-Demand Vacuum with Integrated Blood Management

Balance power with control and minimize blood loss with built-in differential flow. Clot capture in the palm of your hands provides real-time case assessment.

The Symphony™ Advantage

Diagram illustrating the Symphony™ Advantage, showing a catheter with a 7.0mm ID inlet and a 2.8mm ID outlet, demonstrating differential flow. The diagram shows a cross-section of the catheter with a thick blue arrow (7.0mm ID) entering from the left and a thinner grey arrow (2.8mm ID) exiting to the right, labeled "Differential Flow". A callout box states "Blood flowrate reduced by ~55%". A small note at the bottom left says "Data on File".

(Symphony Thrombectomy System Brochure at 7.)

The clot collection reservoir of the Symphony Catheter handle is also shown on the Whipsaw website.



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



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

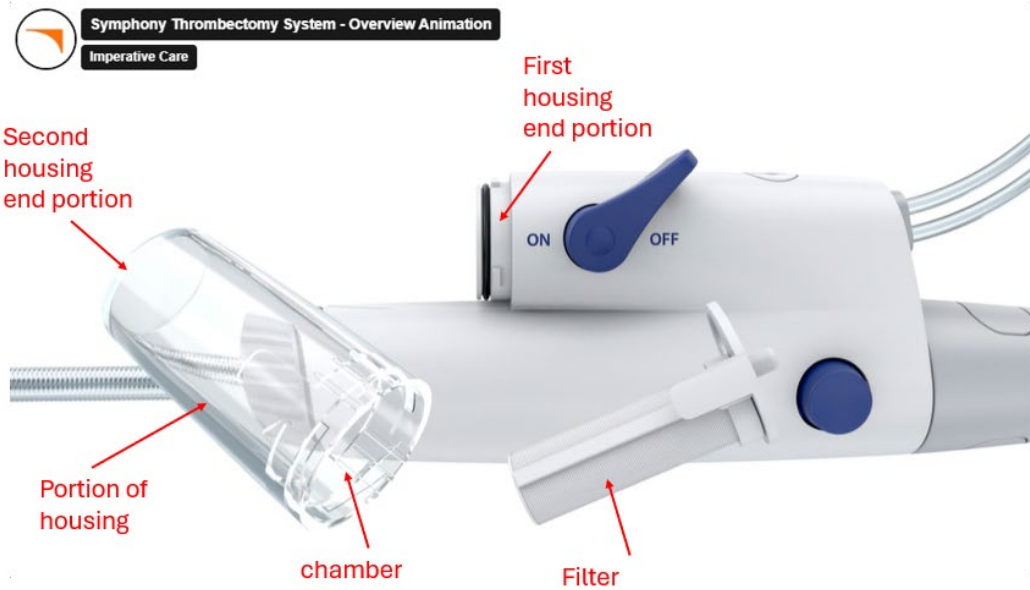


(Image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

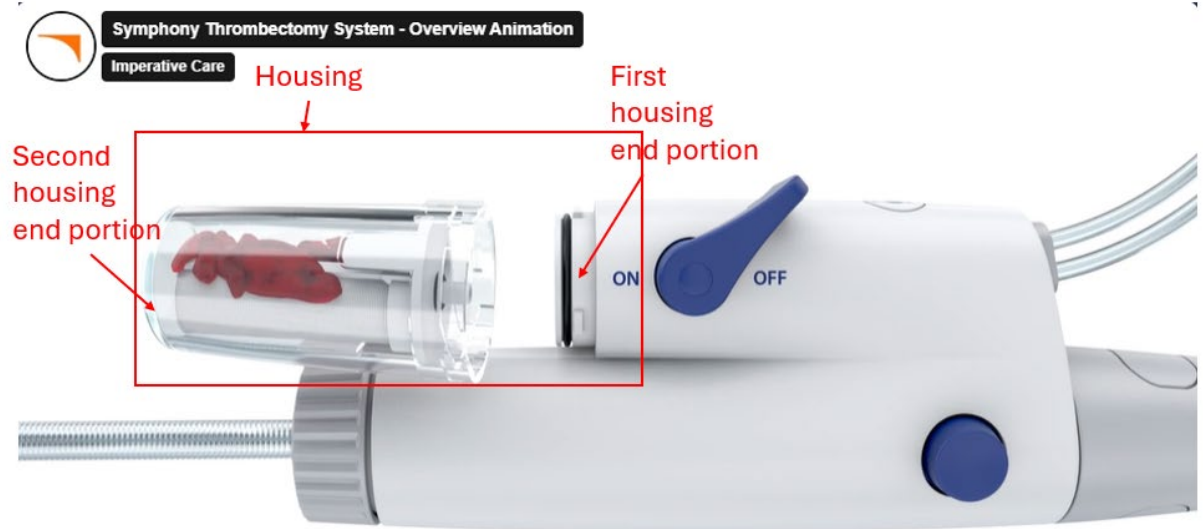
a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;

The clot collection reservoir of the Symphony System includes a housing defining a sealed chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.

The clot collection reservoir and the 24F and 16F Catheter Handles includes a housing, which defines a sealed chamber and has a first housing end portion and a second housing end portion opposite the first, as shown in the annotated image below. The removable portion of the clot collection reservoir housing removably attaches to the portion of the housing connected to the 24F and 16F Catheter Handles.

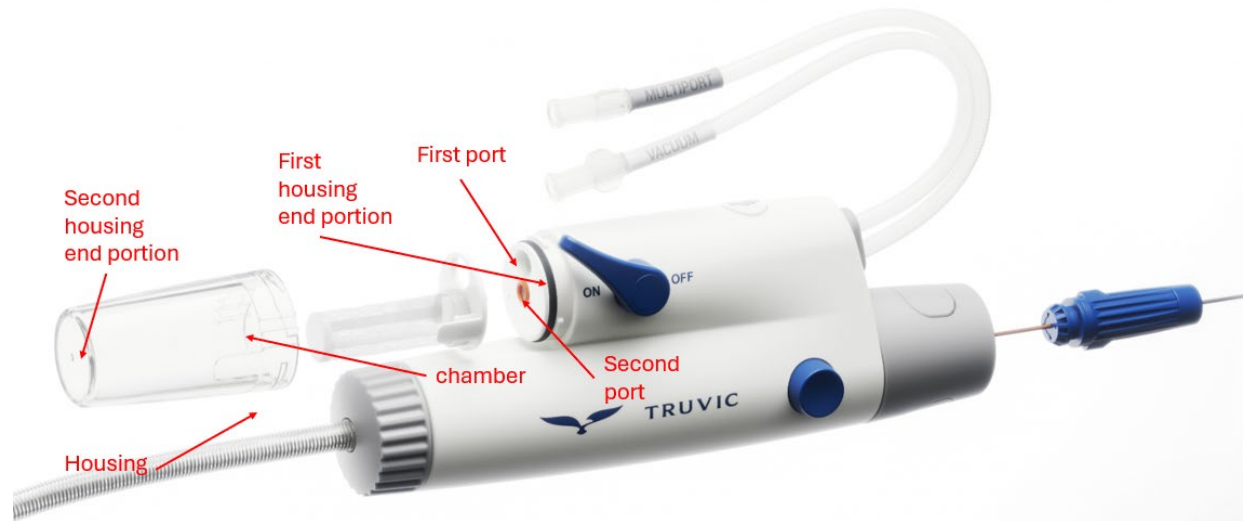


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

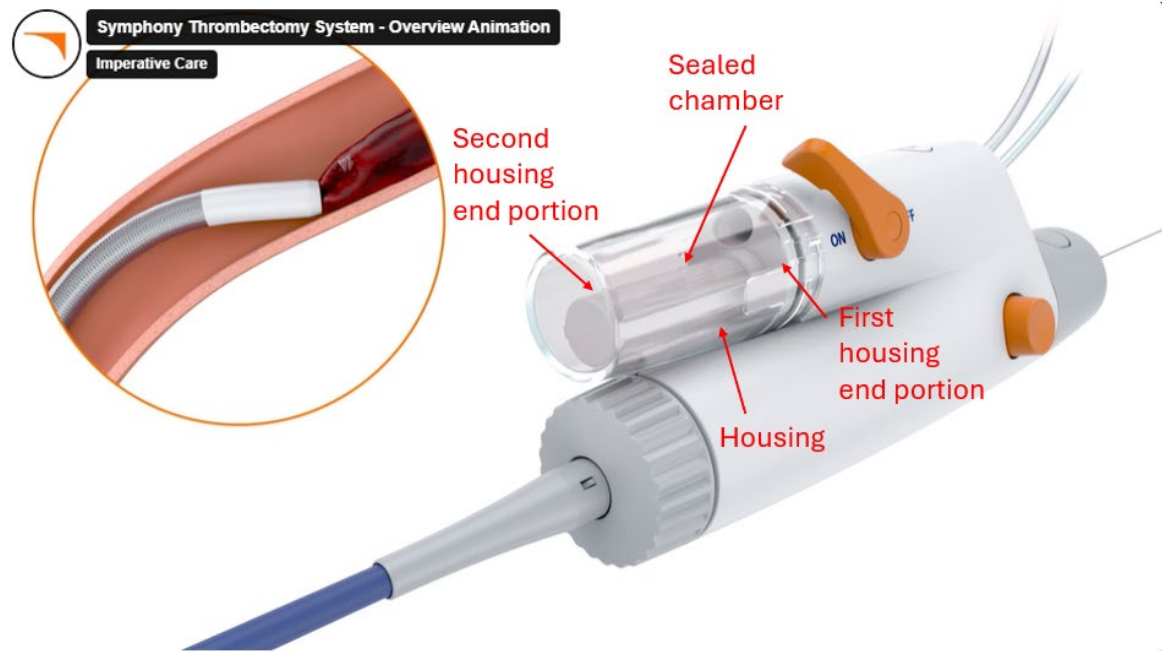


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:19.)

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



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



(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:57.)

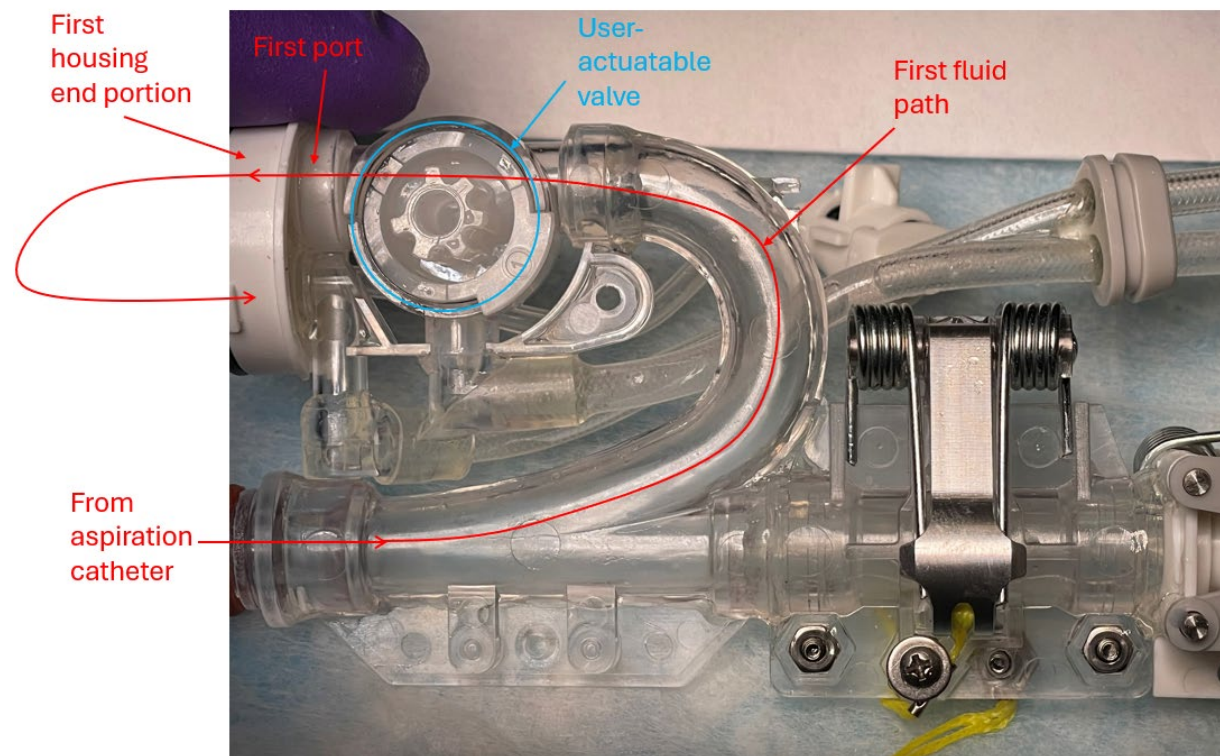
To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

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

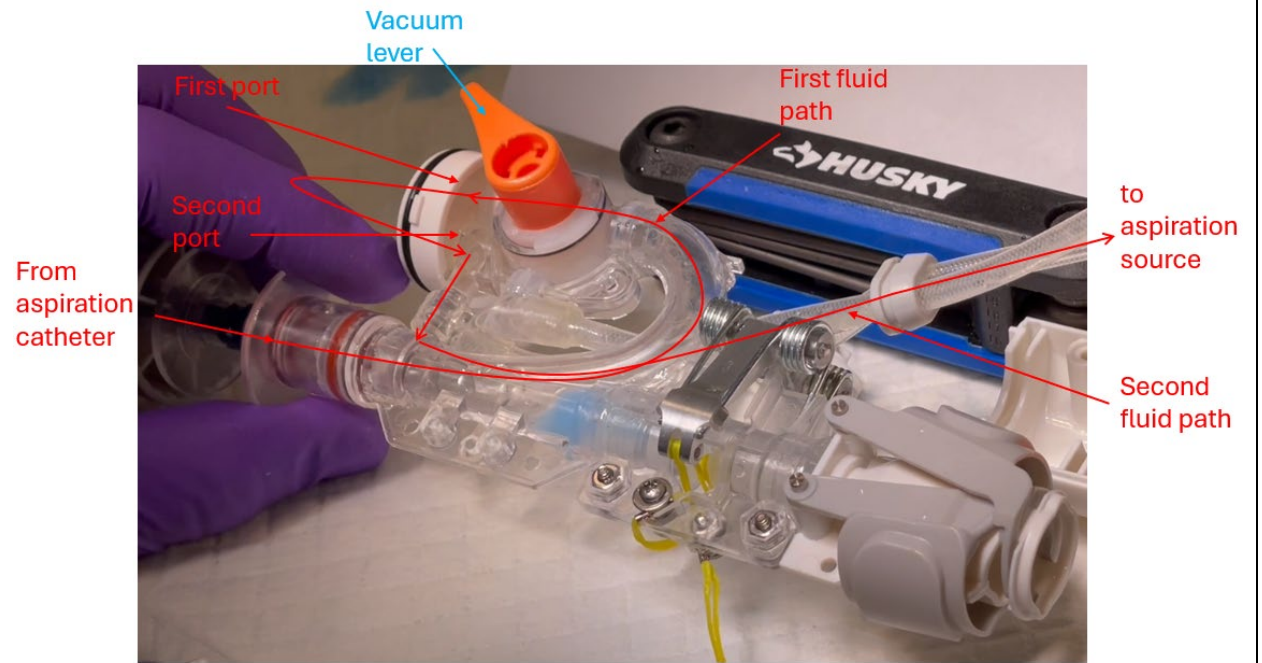
The clot collection reservoir of the Symphony System includes a first port configured to be fluidly coupled to an aspiration catheter, where the first port is positioned proximate to the first housing end portion and provides a first fluid path to the chamber.

path to the chamber;

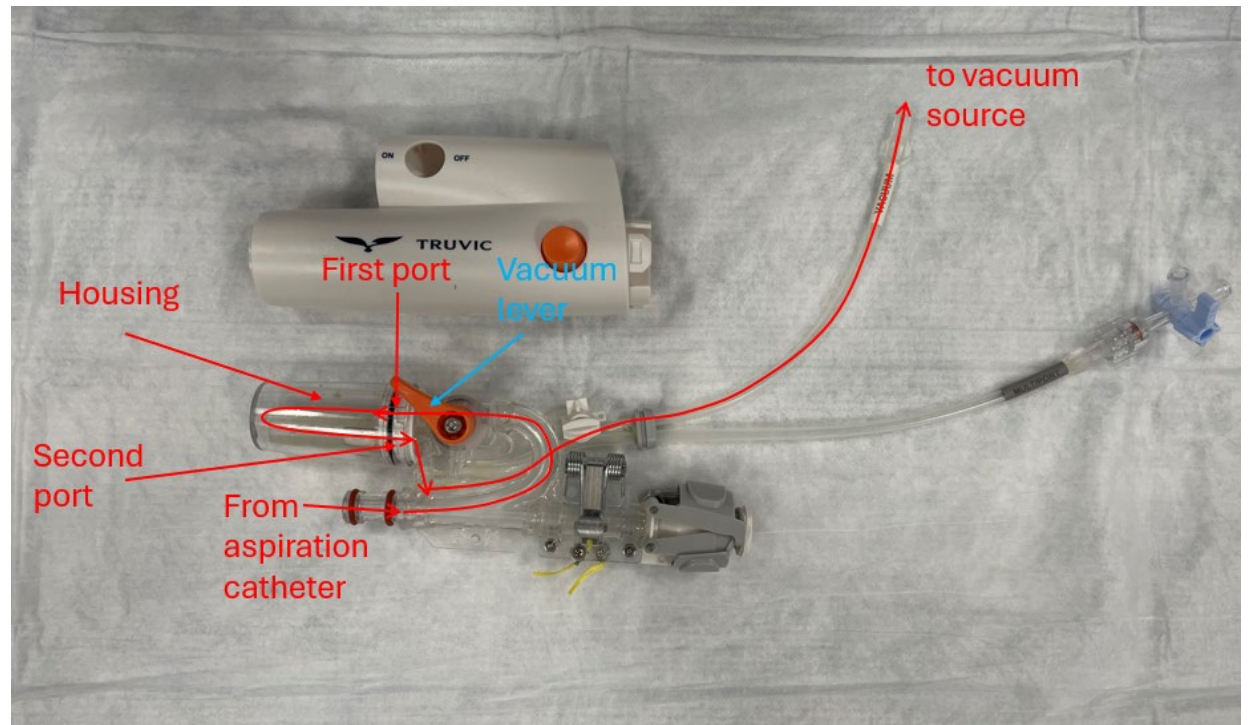
Specifically, the clot collection reservoir of the 24F and 16F Symphony Catheter handles includes a first port proximate to the first housing end portion that is coupled to an aspiration catheter when the valve is in the ON position, as shown in the annotated teardown images below.



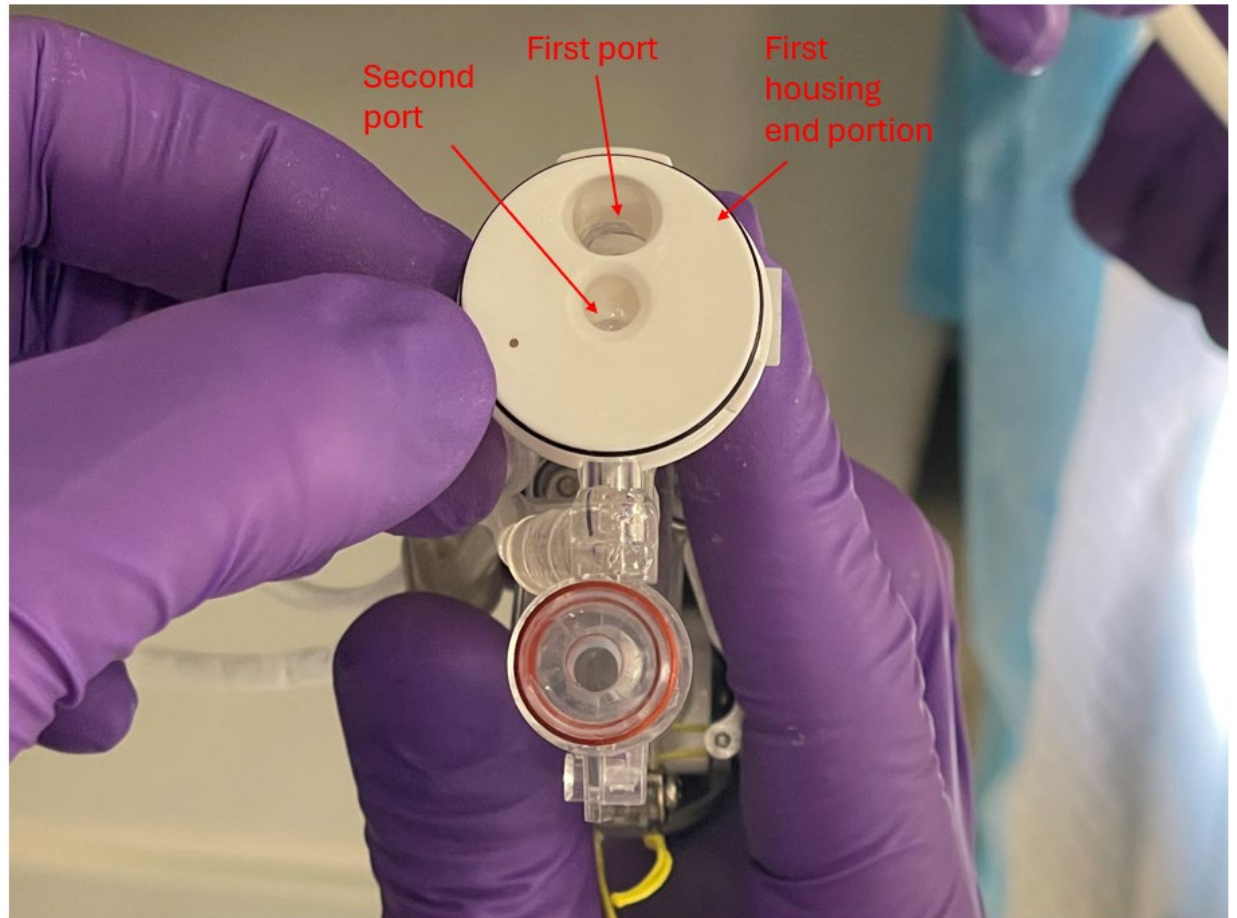
(Annotated image of internal portion of the controller housing.)



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

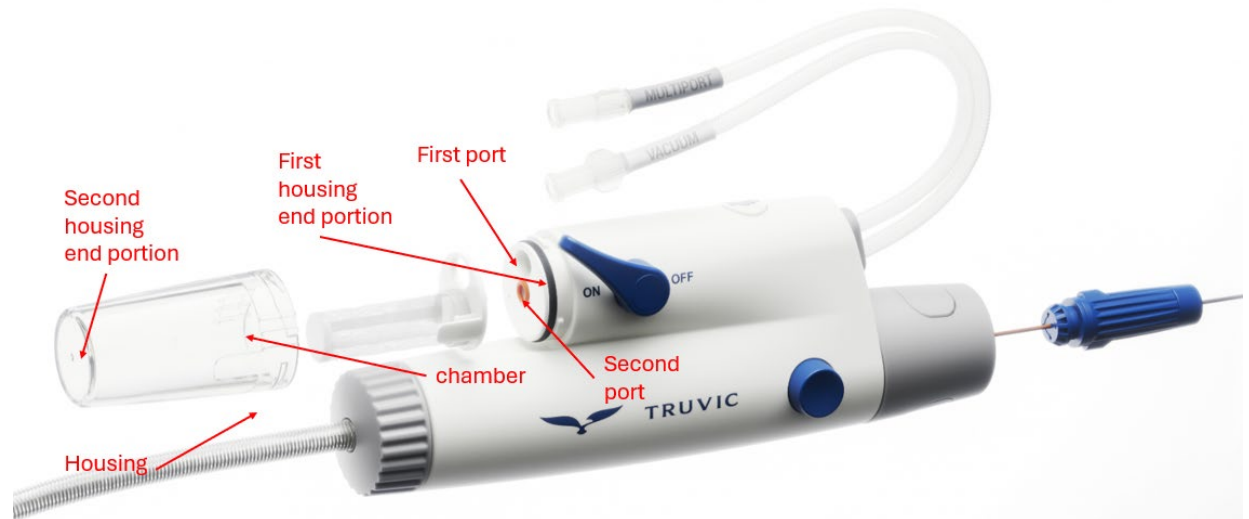


(Annotated image of internal portion of the controller housing.)



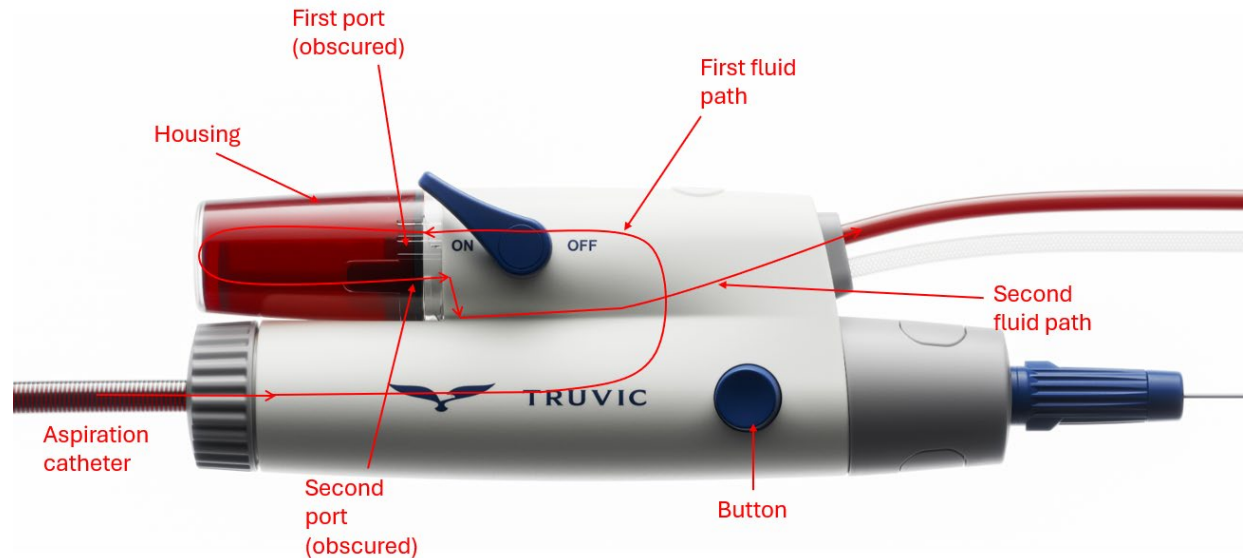
(Annotated image of controller housing showing first and second ports.)

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



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

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

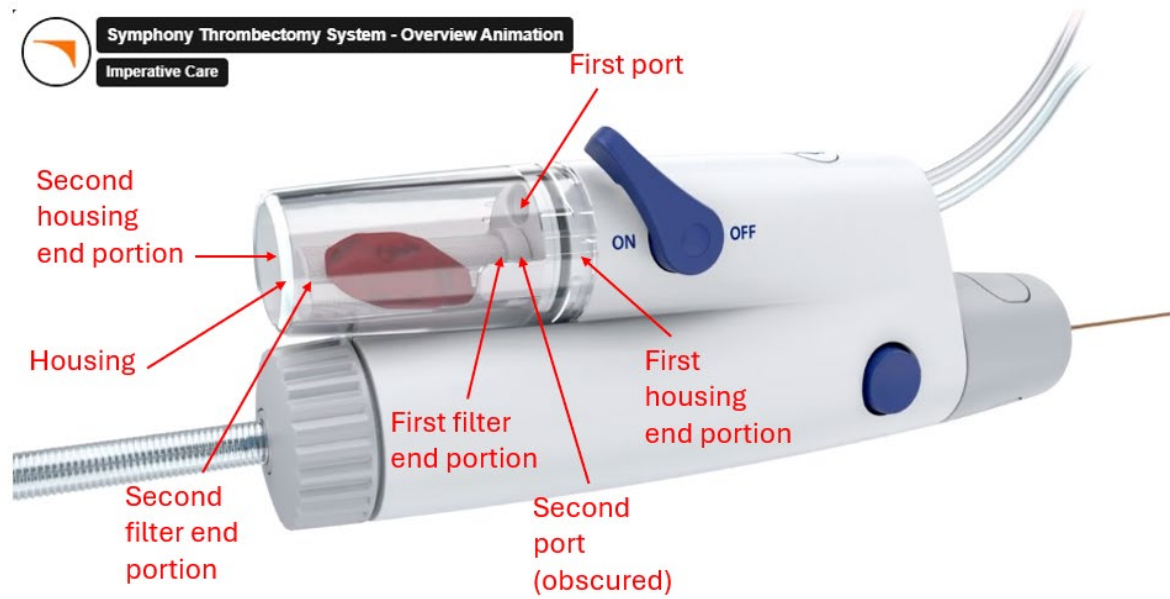


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

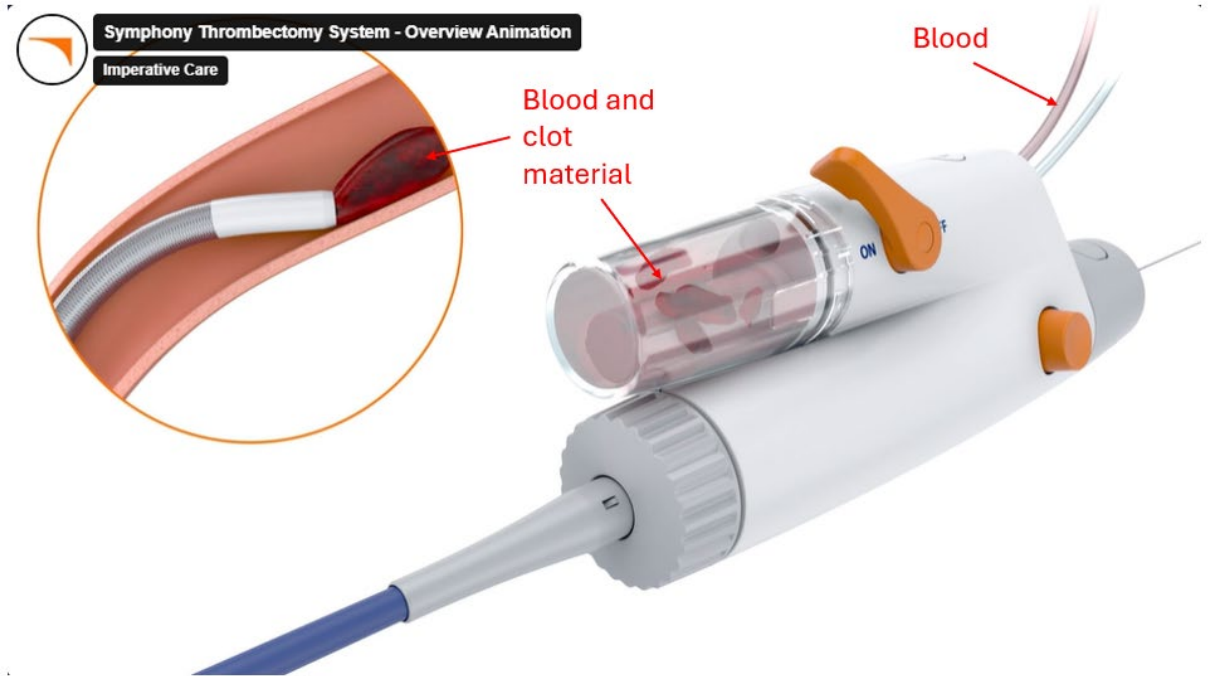
The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration catheters, travels through the first fluid path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot collection reservoir.



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



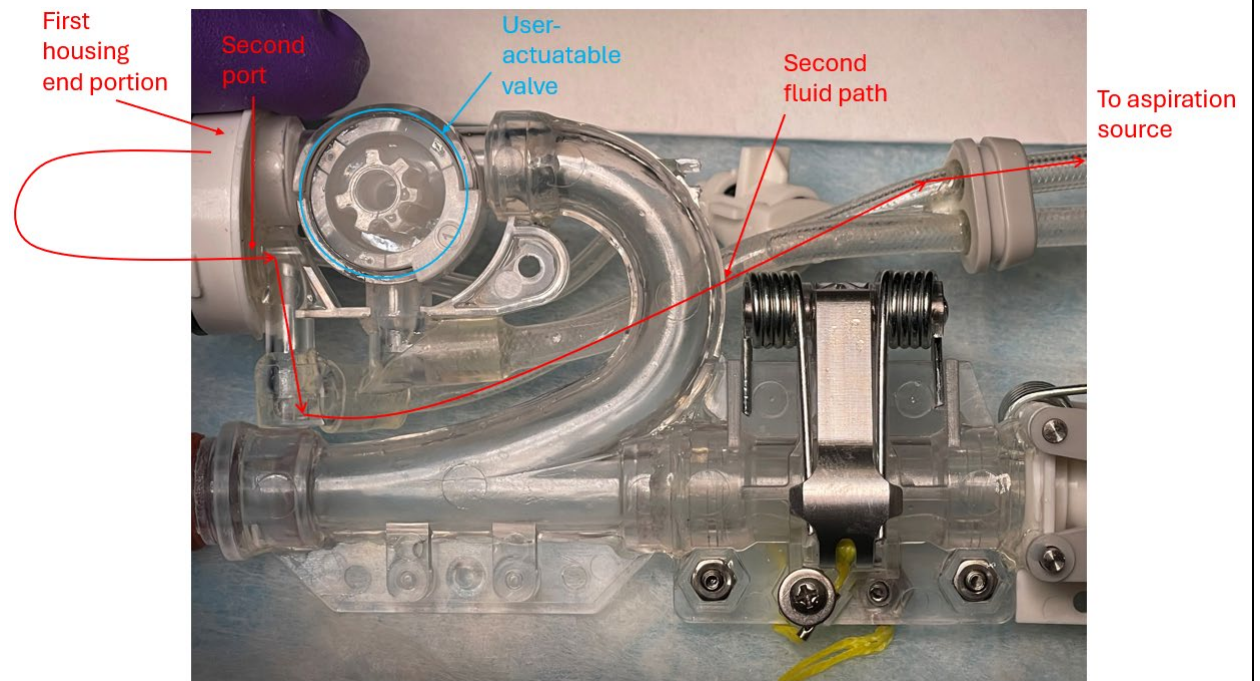
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)



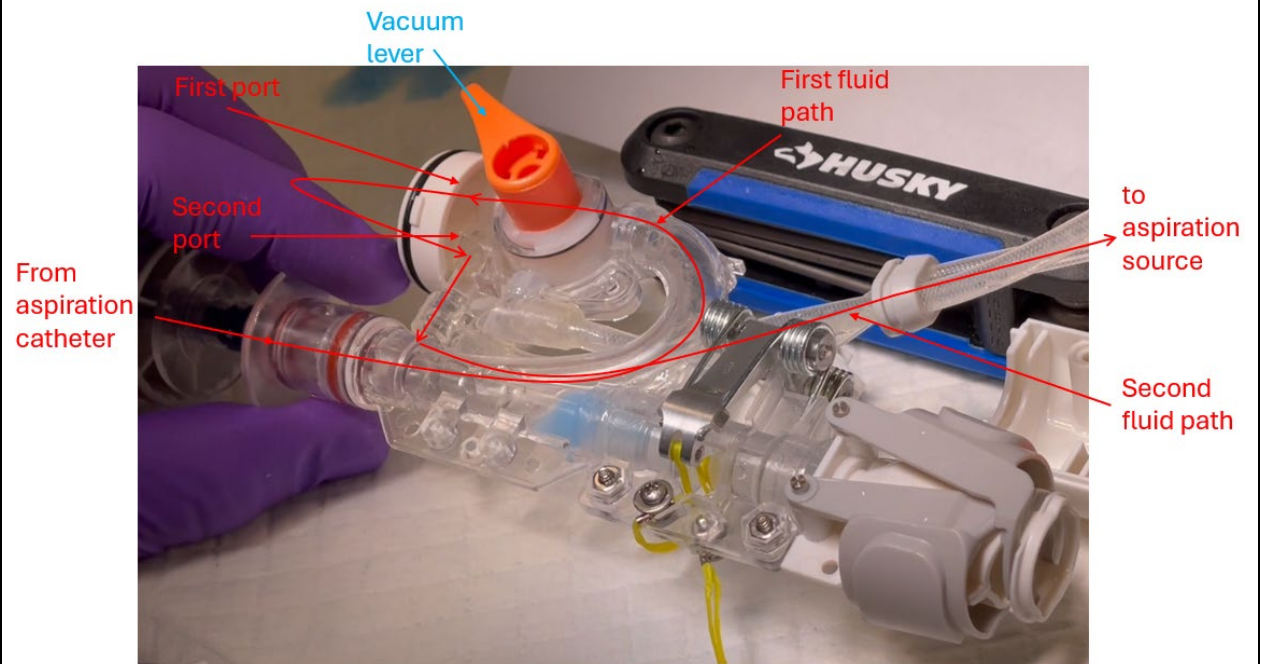
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

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

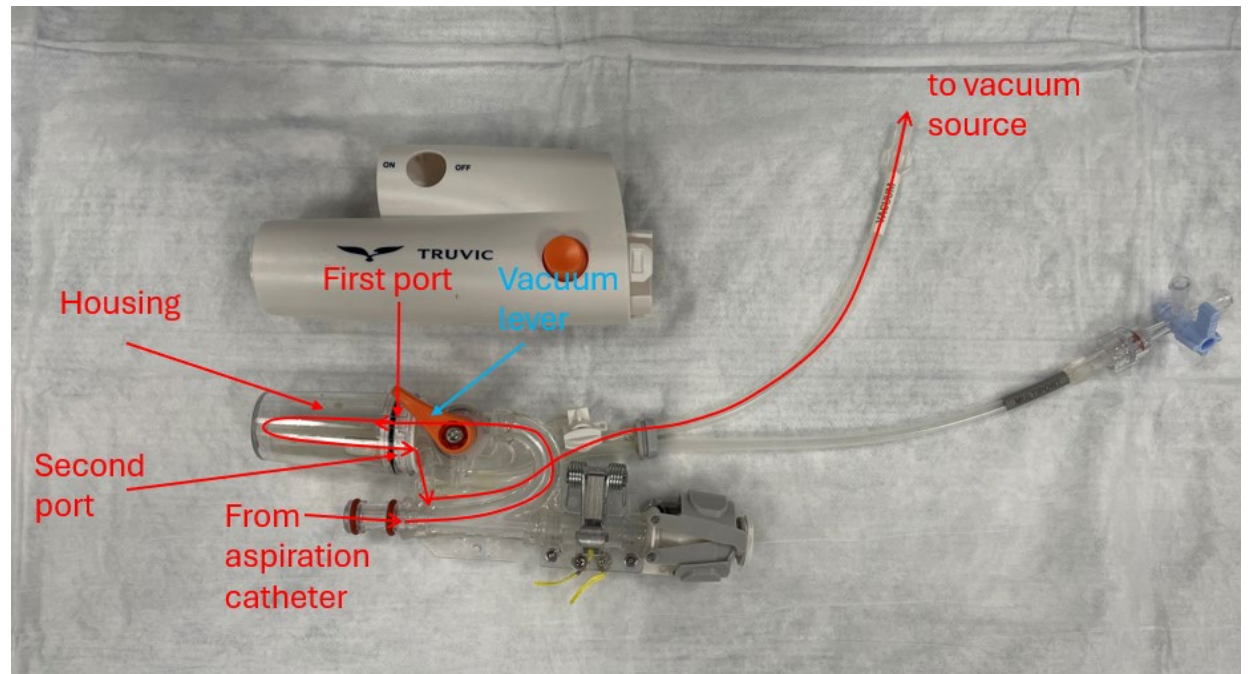
	<p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>a second port configured to be fluidly coupled to the aspiration source, wherein the second port provides a second fluid path to the chamber;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



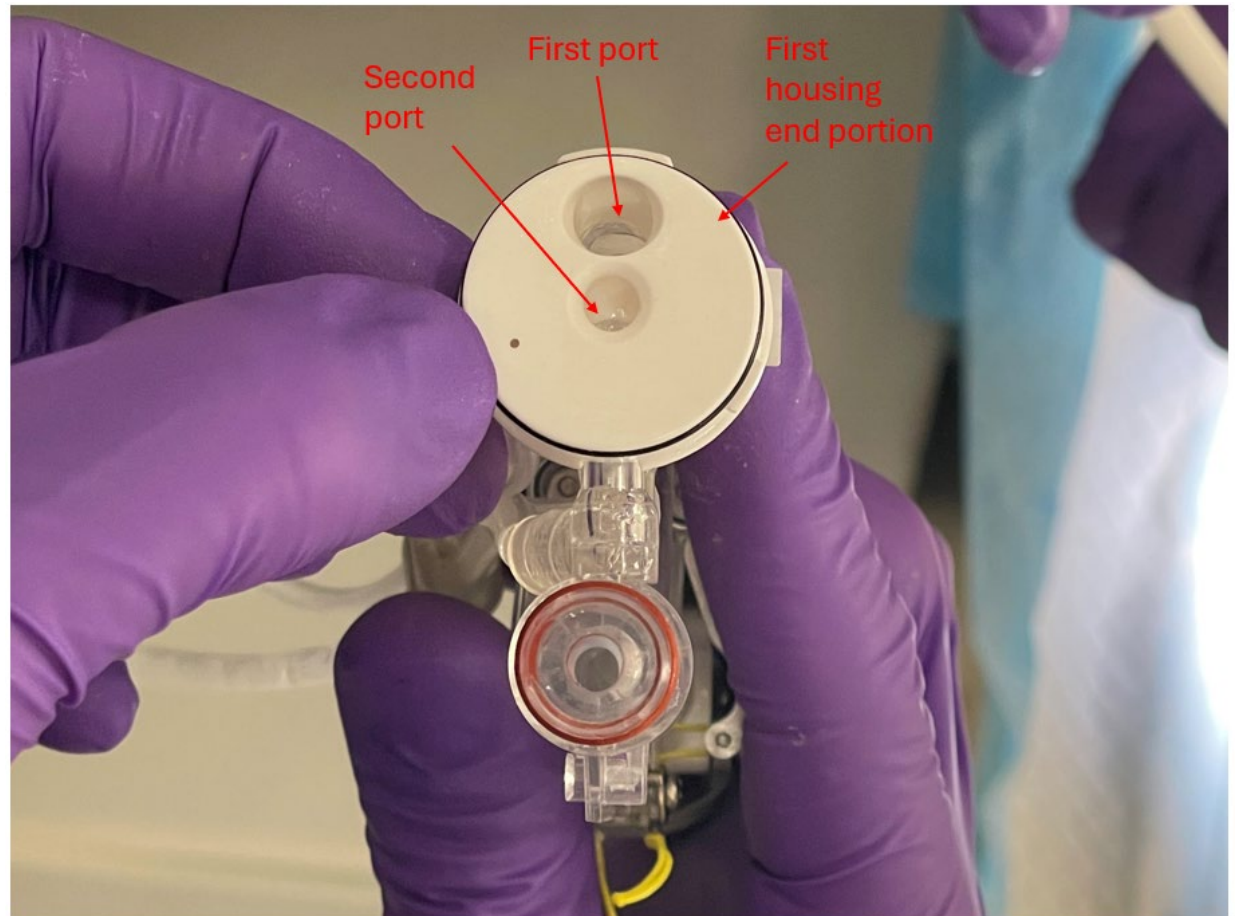
(Annotated image of internal portion of the controller housing.)



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



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



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

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

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

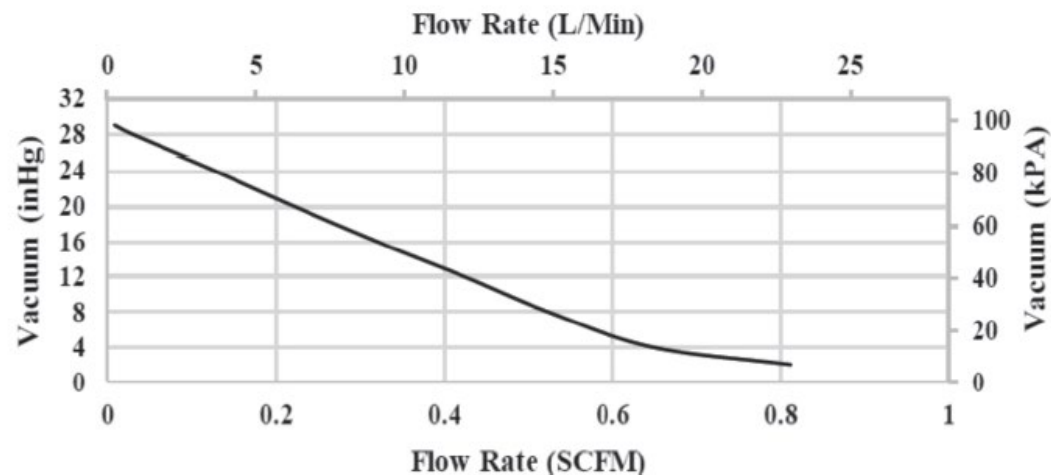
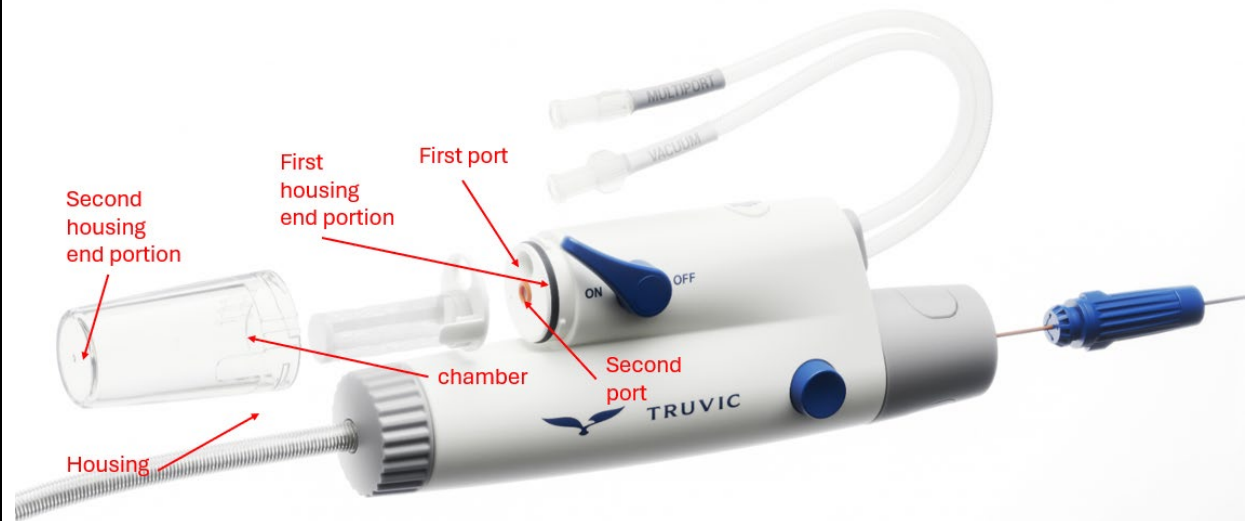


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

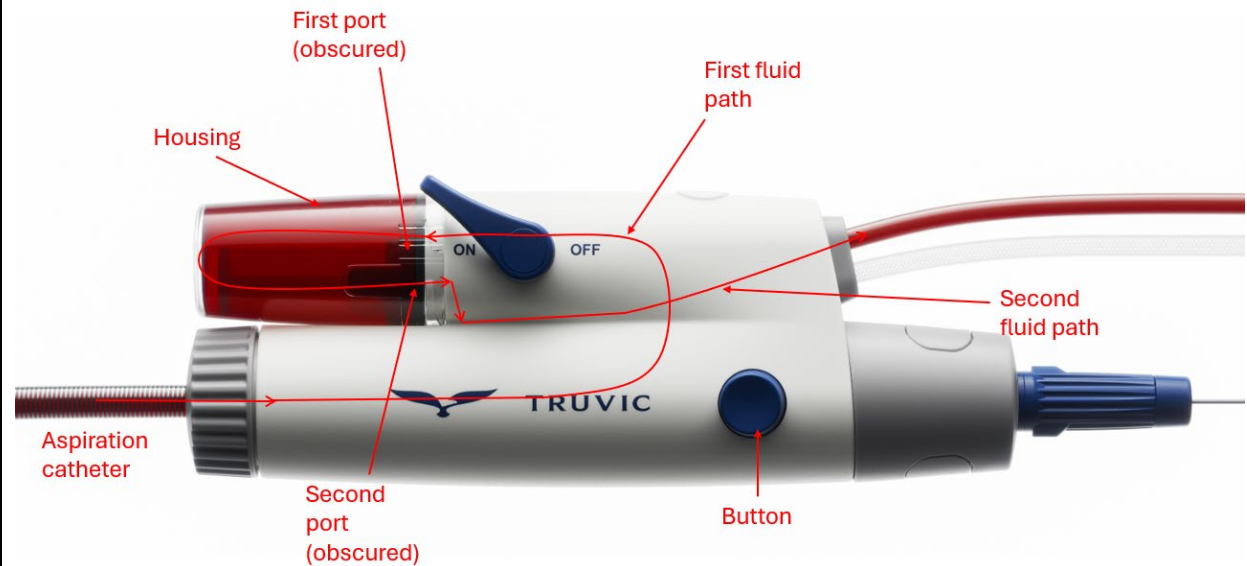
The second port can also be seen in the exploded image from the Whipsaw website of a 24F Symphony Catheter handle with a disassembled clot collection reservoir, which is annotated and reproduced below.



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

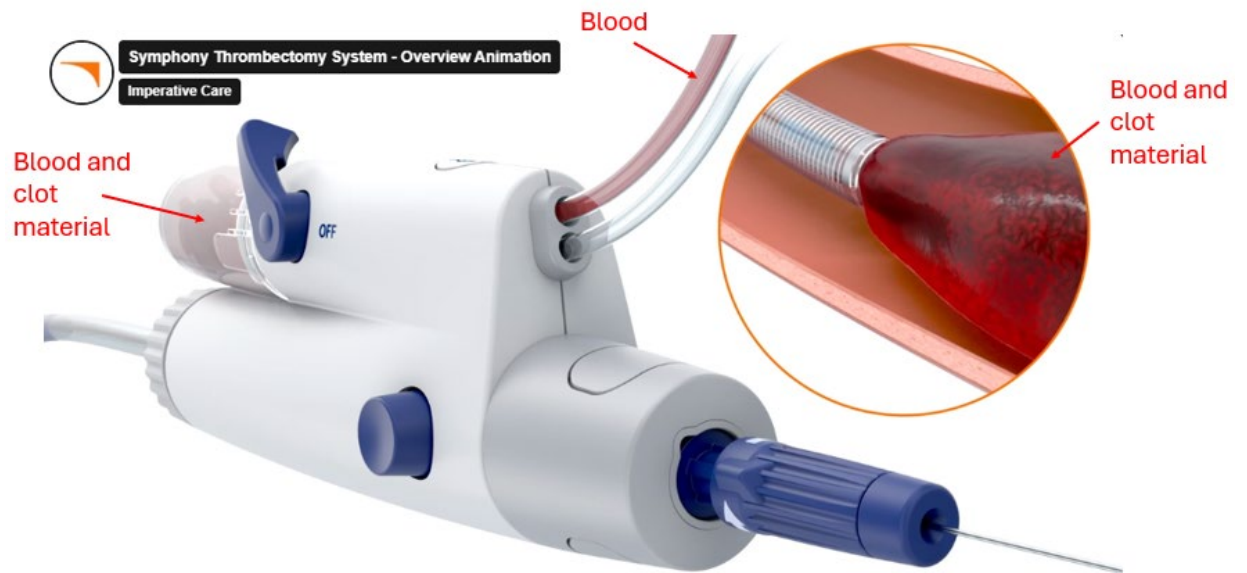
The second port provides a second fluid path from the clot container of the 24F and 16F Symphony Catheter handles, as shown in the annotated image from Whipsaw's website below. Specifically, blood and clot material enters the aspiration catheter and travels along the first fluid path through the first port and into the chamber of the clot container. Blood then passes through the filter, through the second port and along the second fluid path where it flows through tubing internal within the

handle toward the Truvic Generator and Truvic Canister (e.g., aspiration source, not shown).

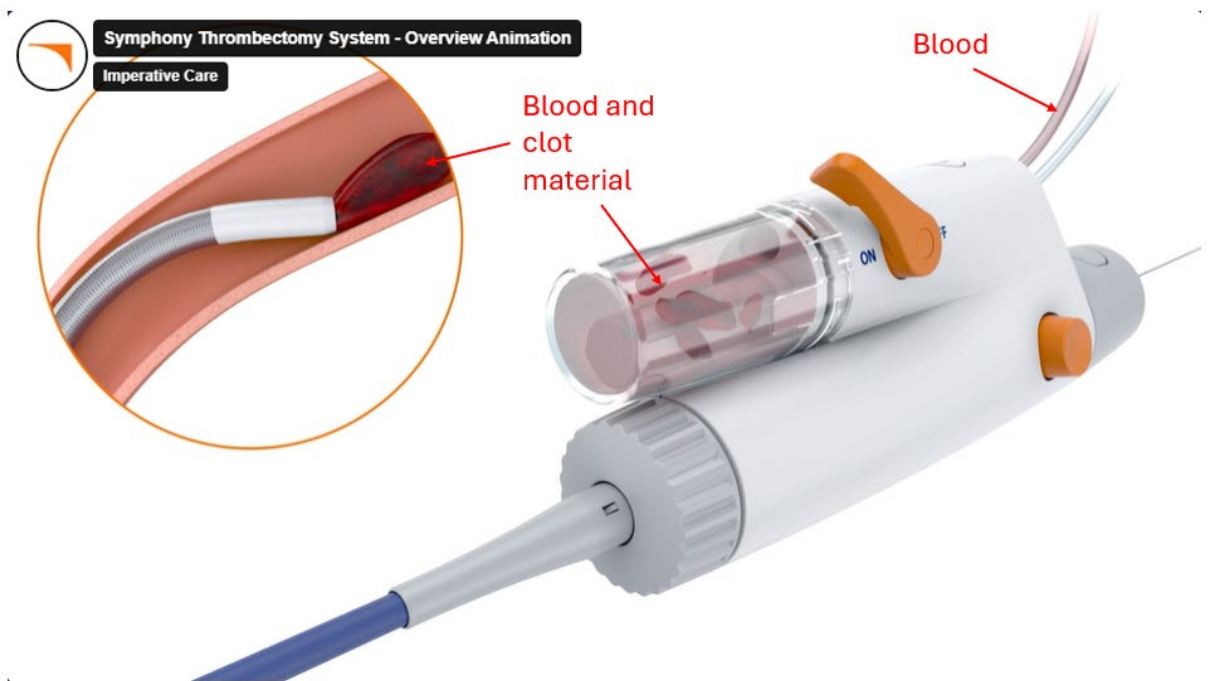


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration catheters, travels through the first fluid path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot container. Blood then flows through the filter, through the second port that provides a second fluid path from the chamber of the clot container towards the tubeset and then toward the aspiration source.



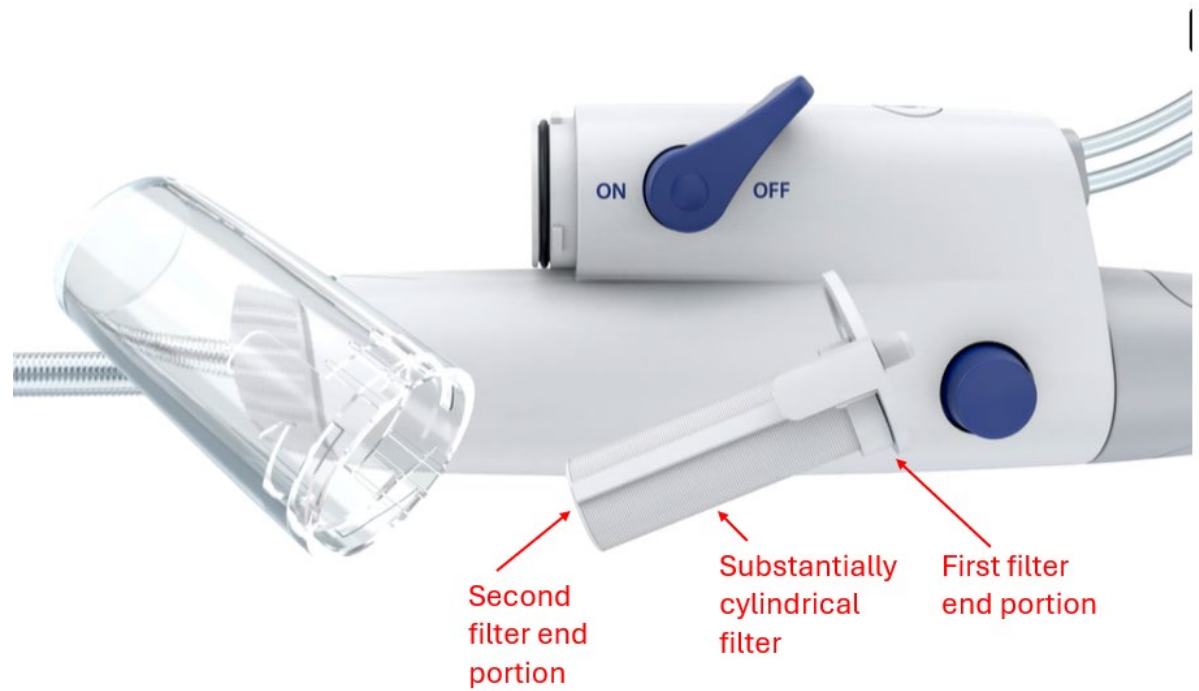
(Symphony Thrombectomy System – Overview Animation Video at 1:09.)



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

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

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

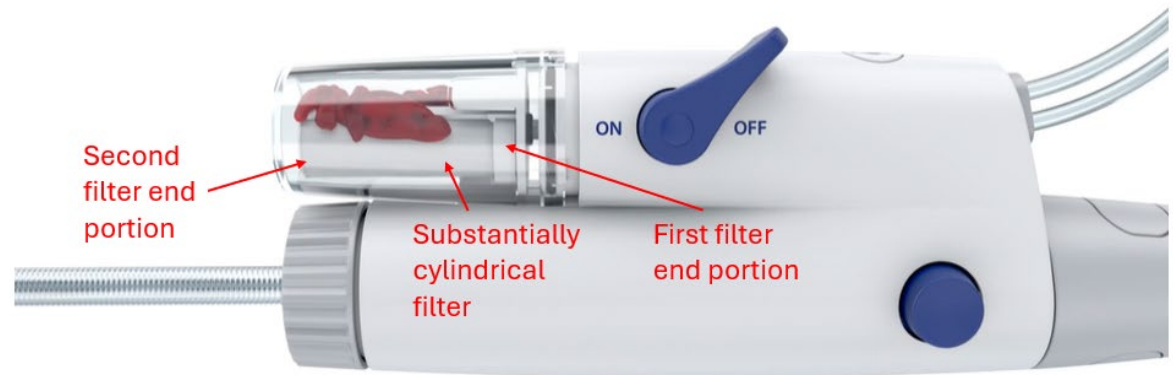


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

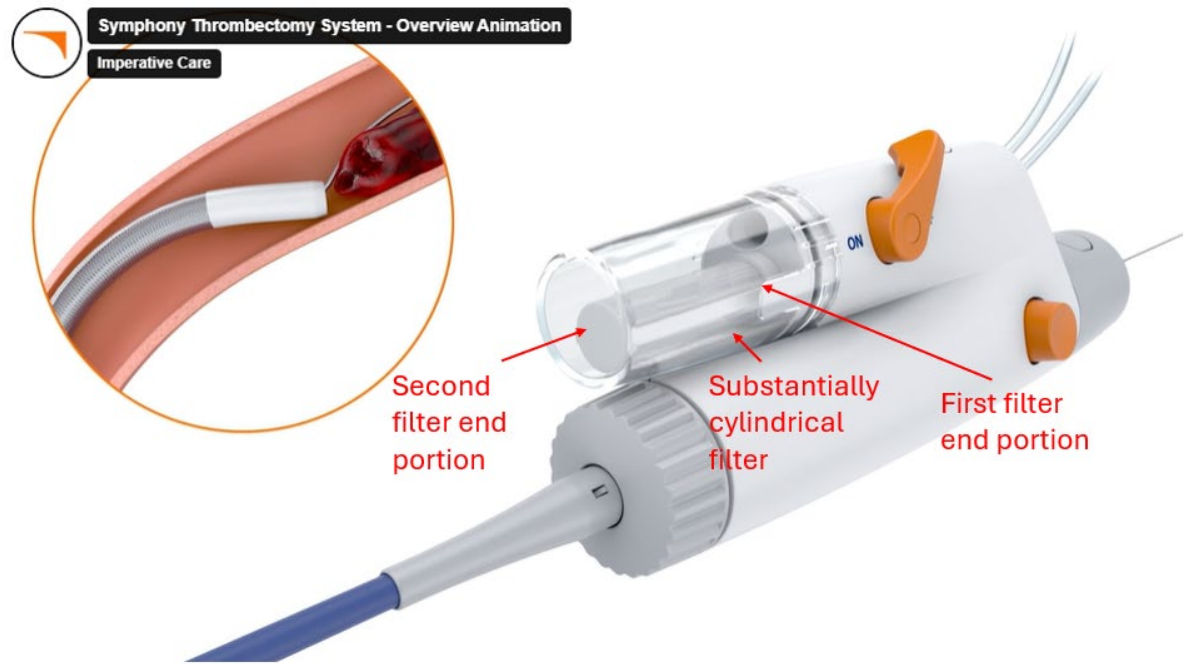


Symphony Thrombectomy System - Overview Animation

Imperative Care

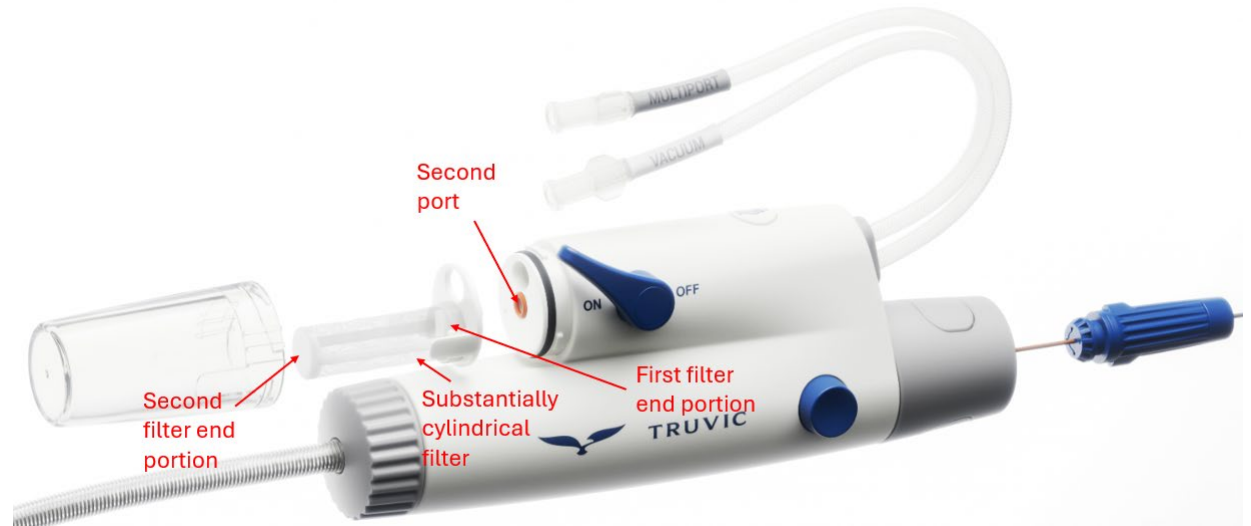


(Symphony Thrombectomy System – Overview Animation Video at 1:18.)



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

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

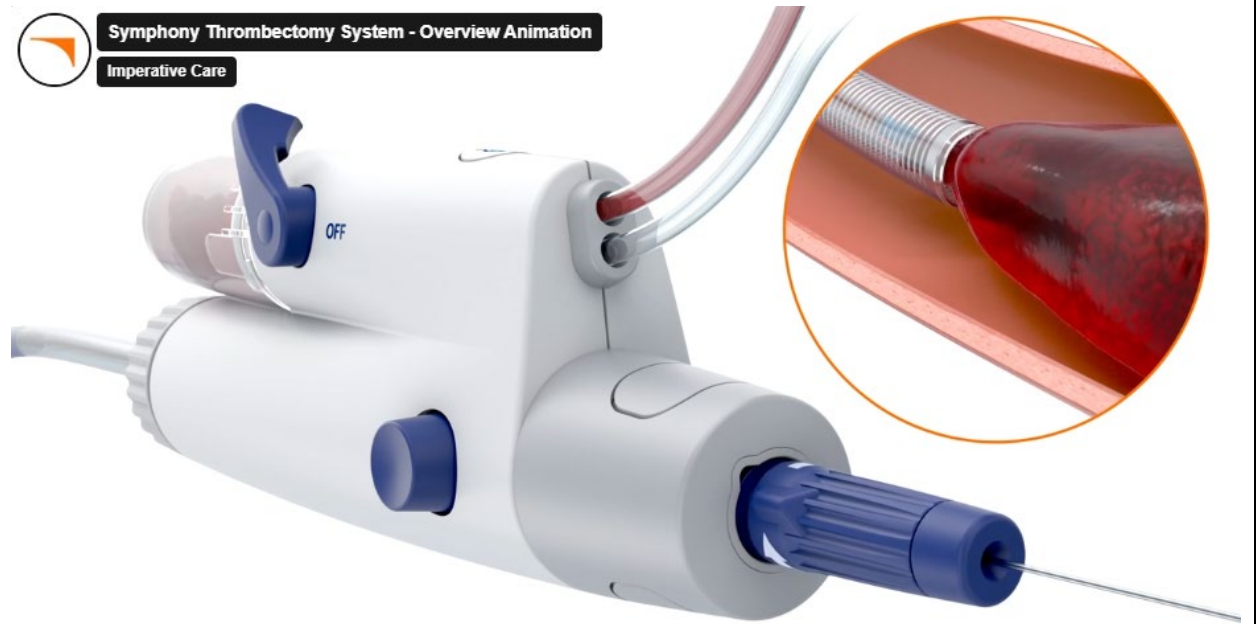


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

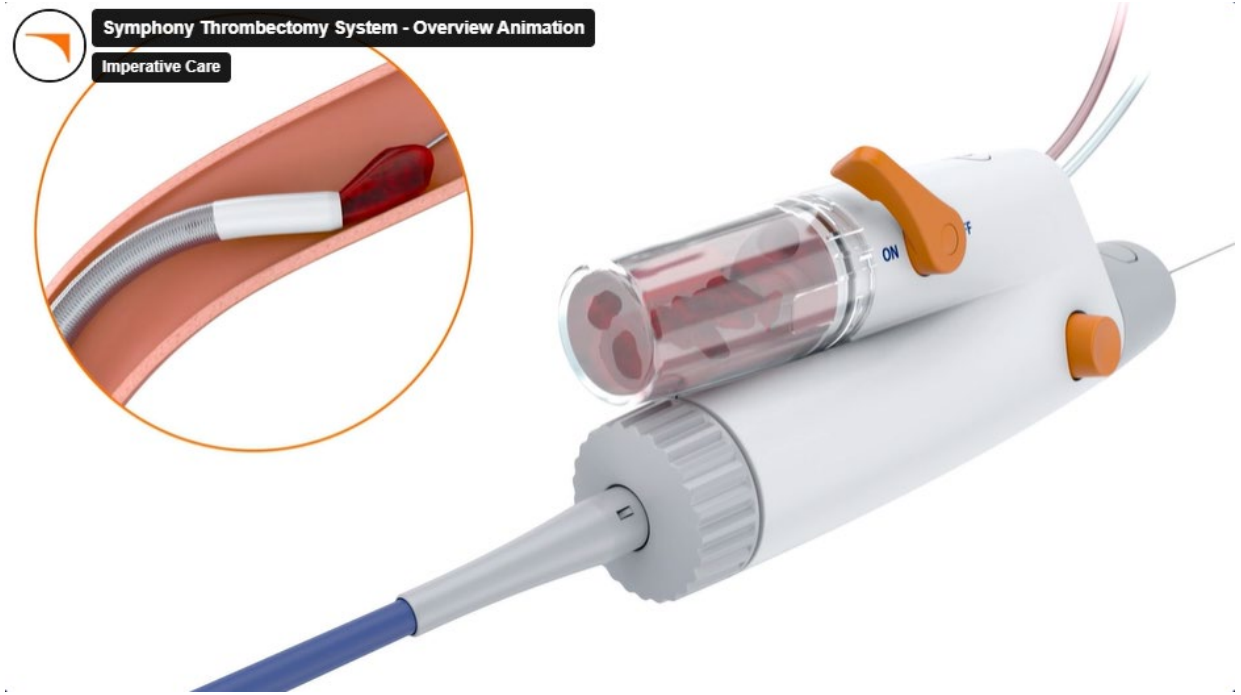
The substantially cylindrical filter encloses an interior region around the second port, such that it prevents clot material from entering the second port. Instead, the filter permits blood to flow through the second port and toward the aspiration source via the second fluid path, as shown in the images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



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



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

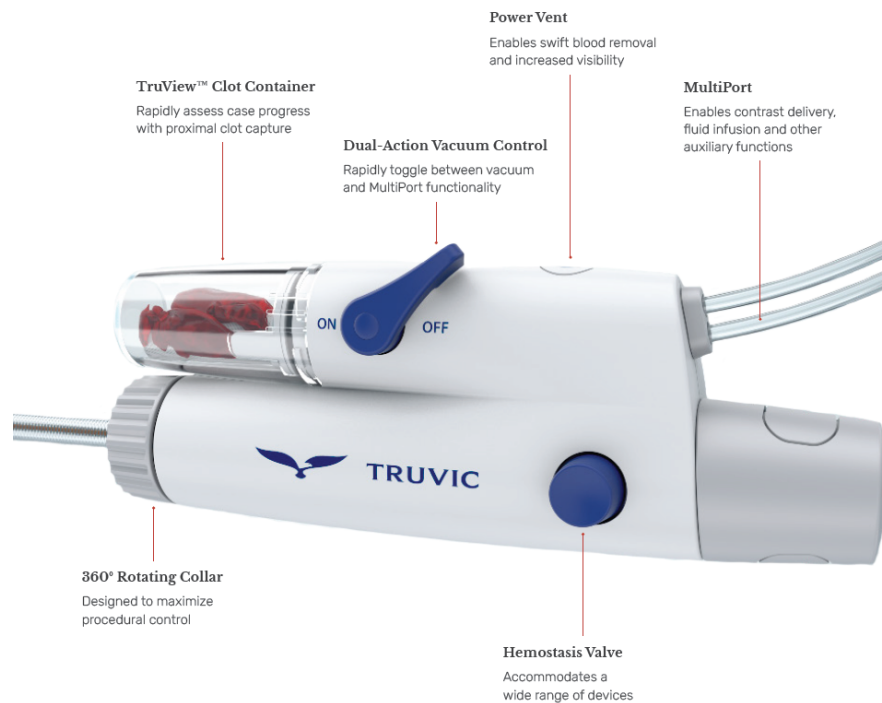


(Symphony Thrombectomy System – Overview Animation Video at 2:03.)

SYMPHONY™ THROMBECTOMY SYSTEM

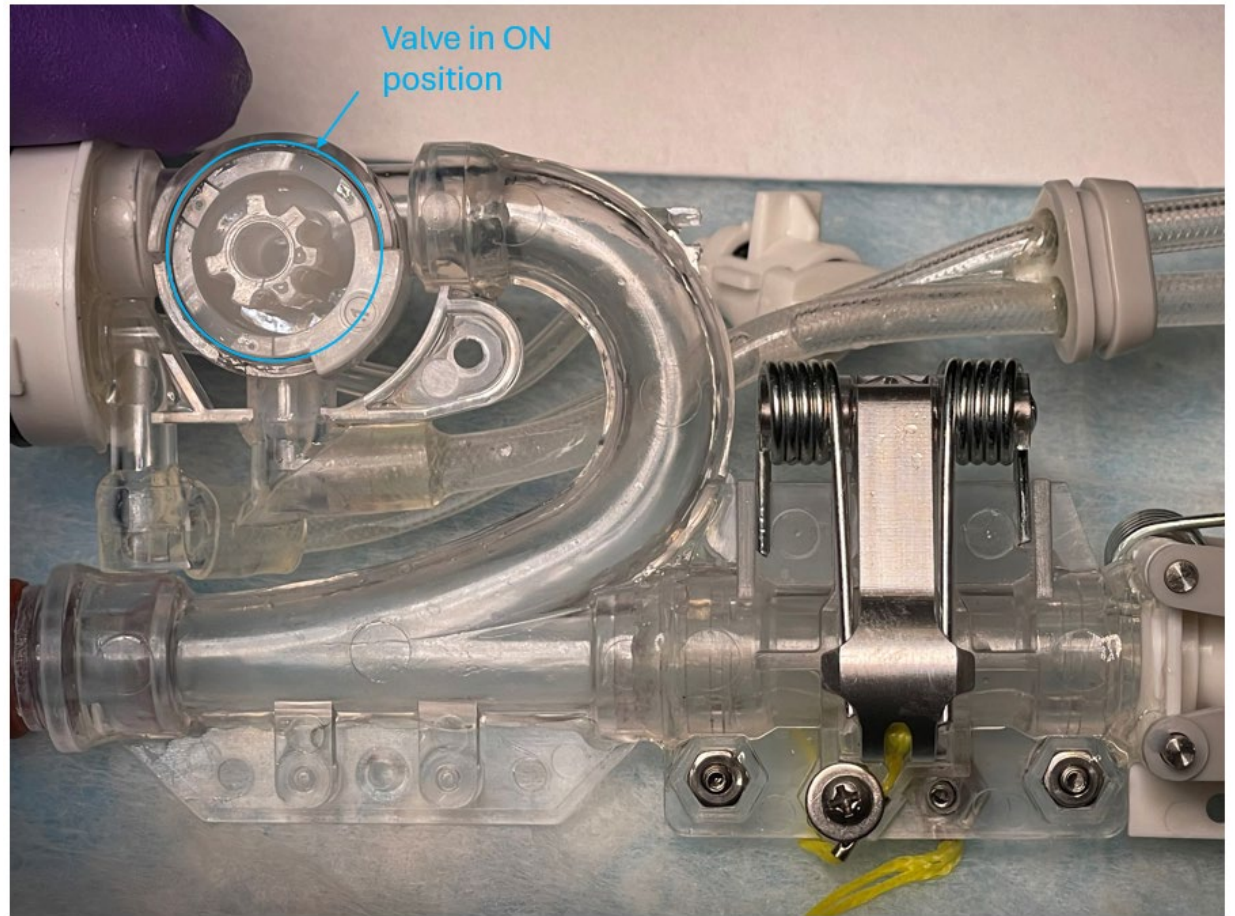
High-Powered, Continuous Vacuum with Real-Time Case Assessment

BigShot™ Controller

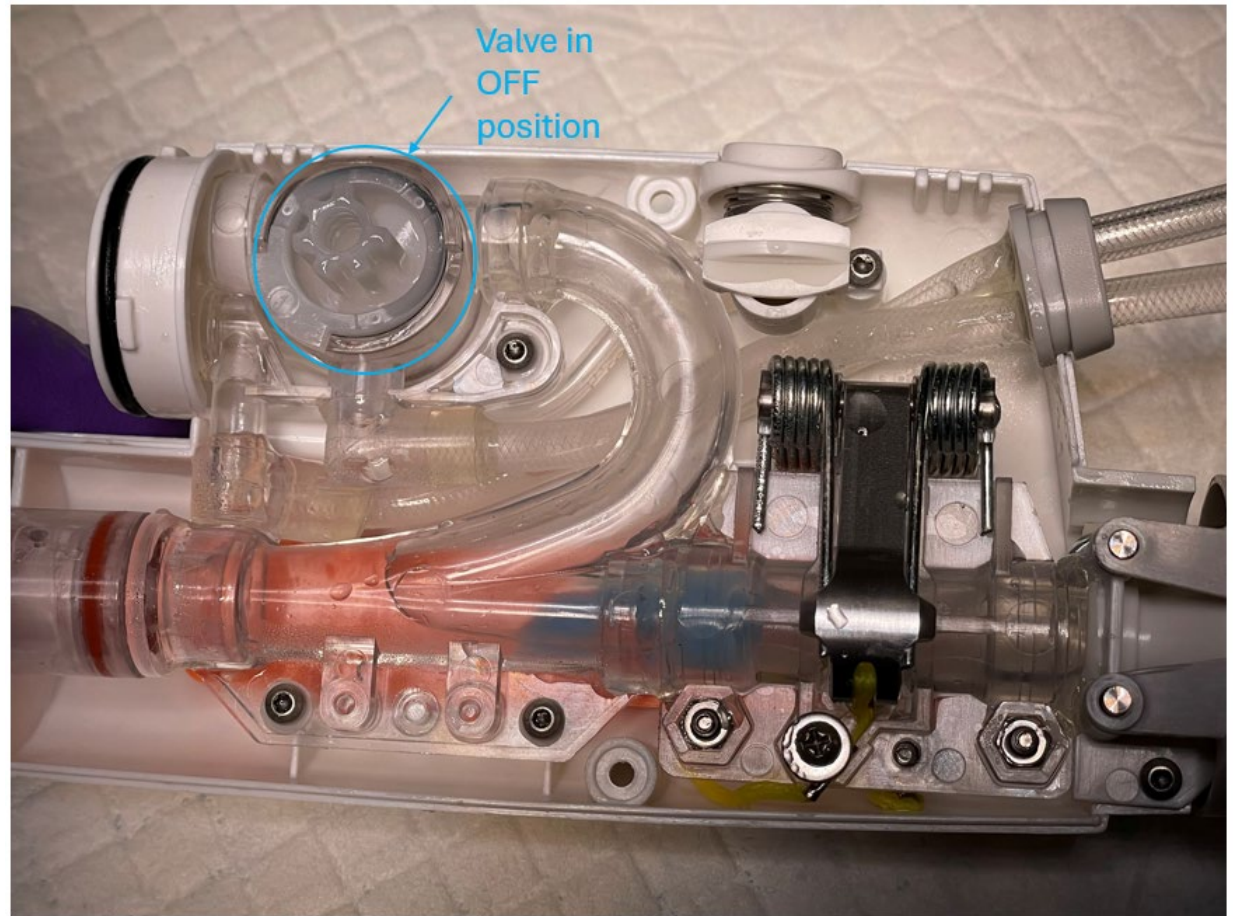


(Symphony Thrombectomy System Brochure at 6.)

	<p>The Symphony System IFU confirms that the filter extends continuously about the first filter end portion and encloses an interior region around the second port, where it describes that blood is allowed to pass through the filter, through the second port, along the second fluid path, and eventually into the TruVic Canister (which is part of the aspiration source). (Symphony Thrombectomy System Instructions For Use at 5 (“When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the handle to the ‘OFF’ position.”); Symphony Thrombectomy System Instructions For Use at 8 (same).)</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>a valve positioned between the clot collection reservoir and the aspiration catheter, wherein the valve is user-actuable to move between (a) an open position in which the first port is fluidly connected to the aspiration catheter and (b) a closed position in which the first port is fluidly disconnected from the aspiration catheter;</p>	<p>The Symphony System includes a valve positioned between the clot collection reservoir and the aspiration catheter, where the valve is user-actuable to move between an open position in which the first port is fluidly connected to the aspiration catheter and a closed position in which the first port is fluidly disconnected from the aspiration catheter.</p> <p>Specifically, the 24F and 16F Symphony Catheter handle includes a valve positioned between the clot collection reservoir and the aspiration catheter that is user-actuable. As shown in the teardown images below, the valve of the 24F and 16F Symphony Catheter handle is controlled by rotating the vacuum lever between the “ON” and “OFF” position.</p>



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



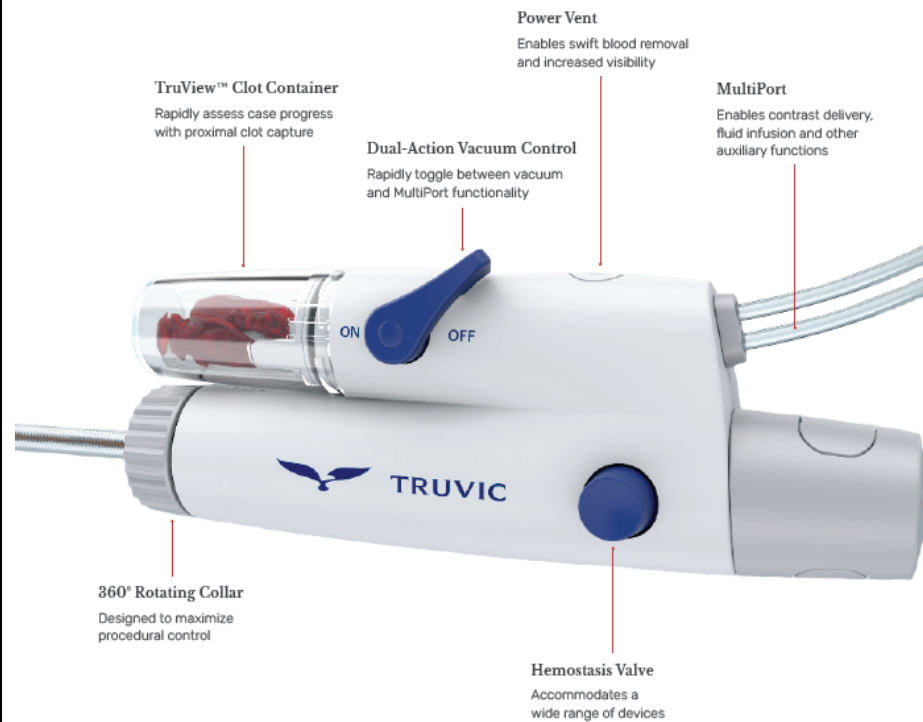
(Annotated image of internal portion of the controller housing.)

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

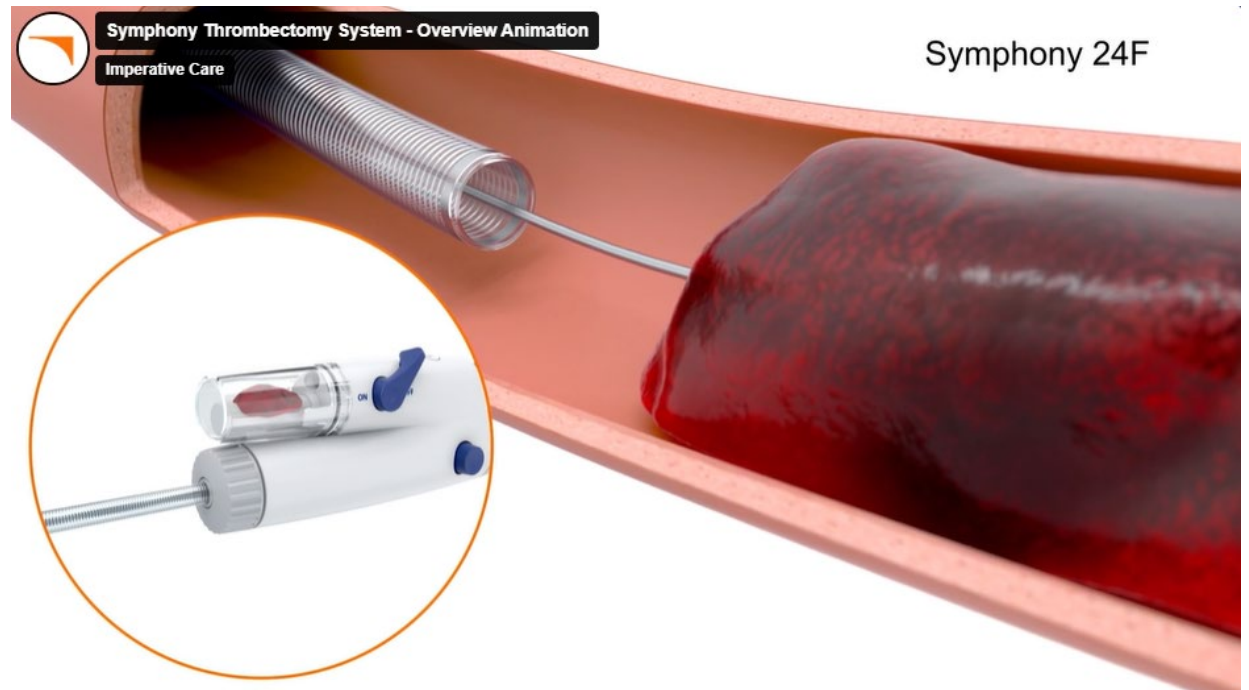


(Symphony Thrombectomy System Brochure at 6.)

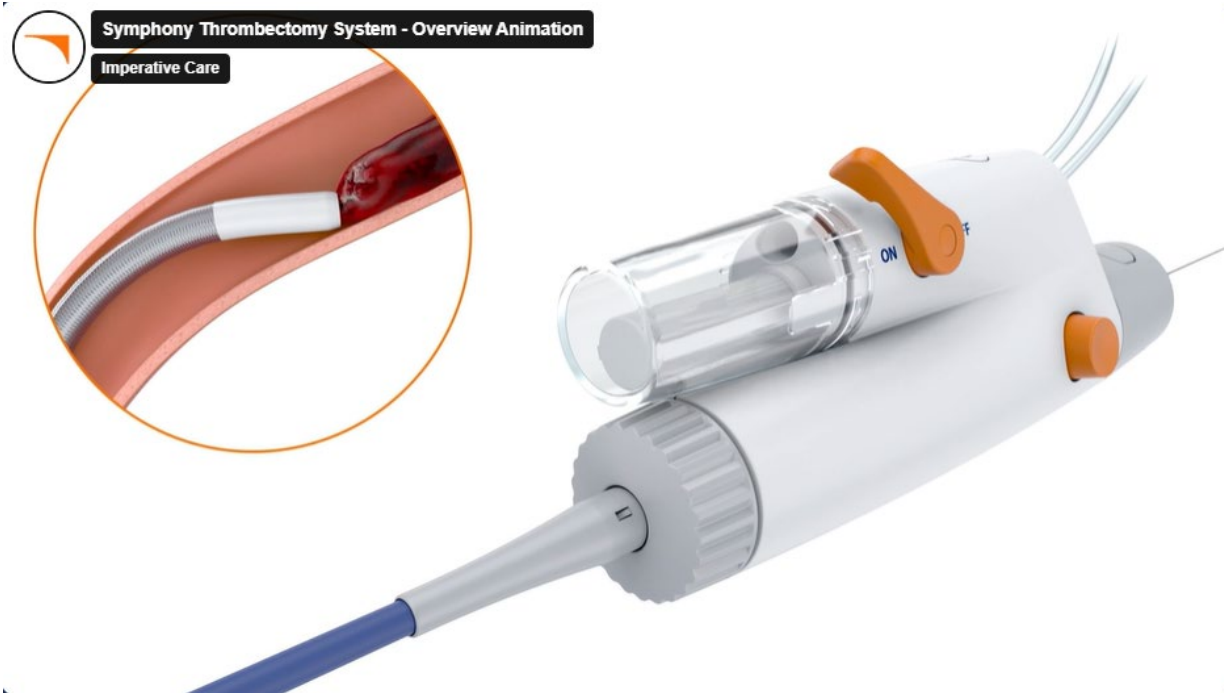
	<p>The Symphony System IFU discusses how the valve is actuatable between an “ON” and “OFF” position when a user of the Symphony System manually moves the vacuum lever between the two positions. When the valve is in the “ON” position, the first port is fluidly connected to the aspiration catheter such that blood and clot material can flow into the clot container. When the valve is in the “OFF” position, the first port is fluidly disconnected to the aspiration catheter such that blood and clot material cannot flow into the clot container. (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).</p> <p>The ability of the valve to actuate between an “ON” and “OFF” position is also shown for both the 24F and 16F Symphony Catheter handles.</p>
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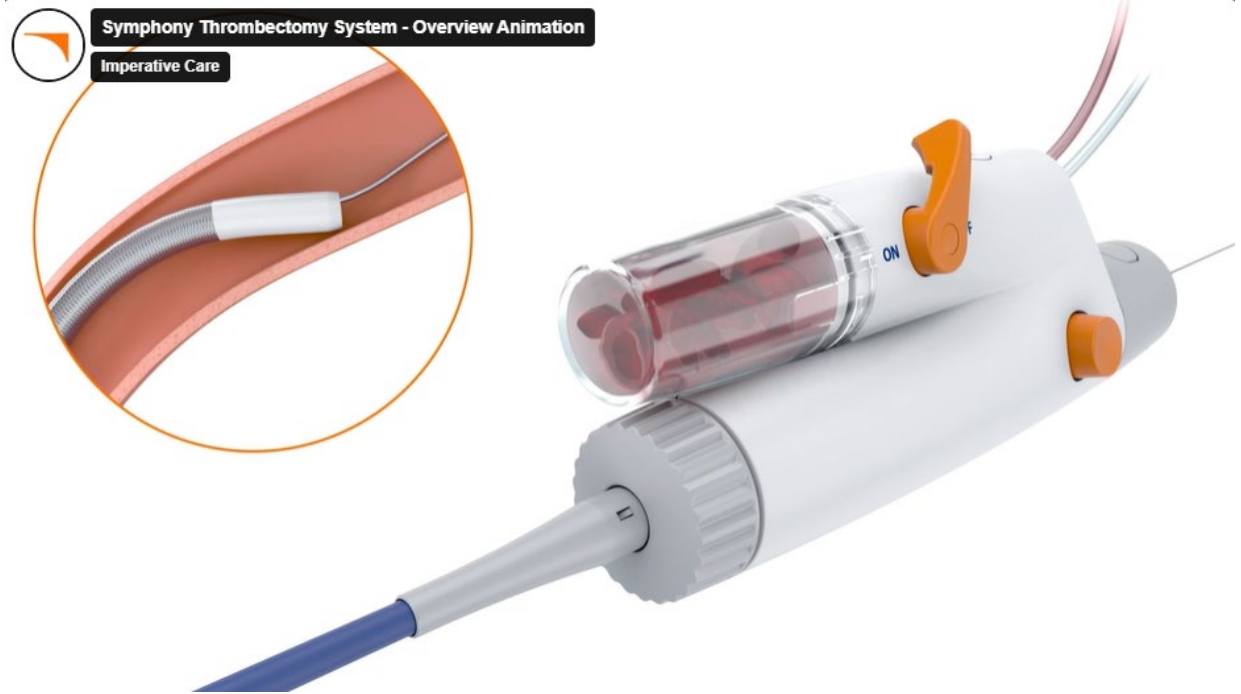
(Symphony Thrombectomy System – Overview Animation Video at 0:44.)



(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 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 limitation, the Symphony System meets this limitation under the doctrine of equivalents.

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

The Symphony System includes an aspiration source that is configured to generate negative pressure in the chamber via the second port to draw blood and clot material from the aspiration catheter through the first port into the chamber and draw blood through the filter into the interior region and through the second port.

Specifically, the Truvic Generator and Truvic Canister (*e.g.*, aspiration source) is configured to generate a negative pressure in the chamber of the clot collection reservoir of the 24F and 16F Symphony Catheter handles, as described in the Symphony System IFU. (Symphony Thrombectomy System Instructions For Use at 2 (“The TRUVIC Symphony Thrombectomy Catheters have been verified for use with the TRUVIC Tubeset and TRUVIC Generator. The TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 2.”).)

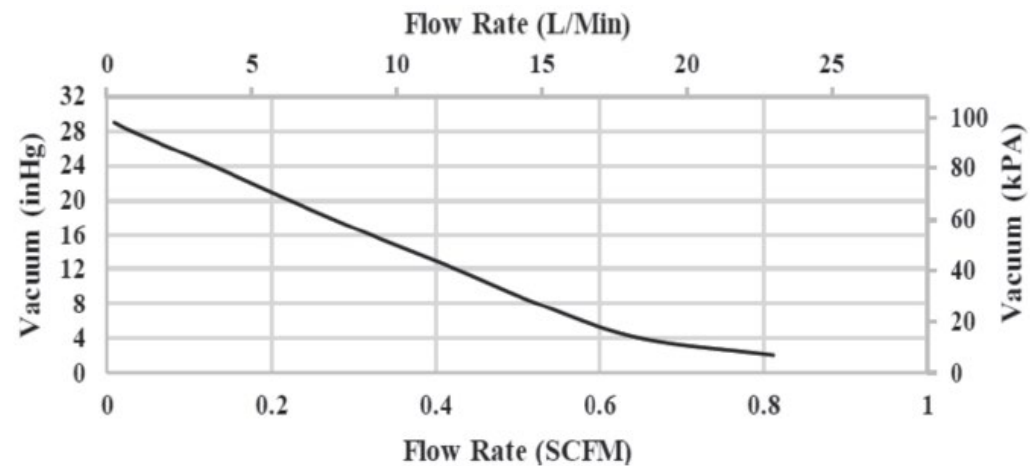
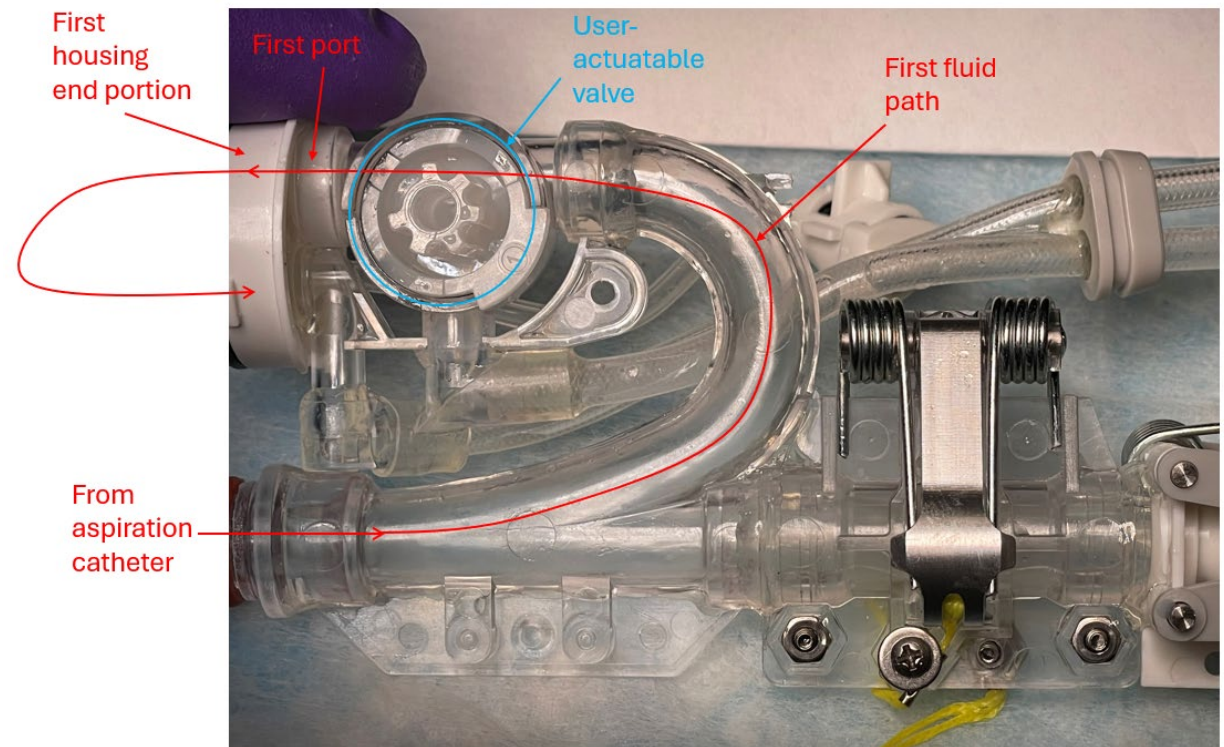


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

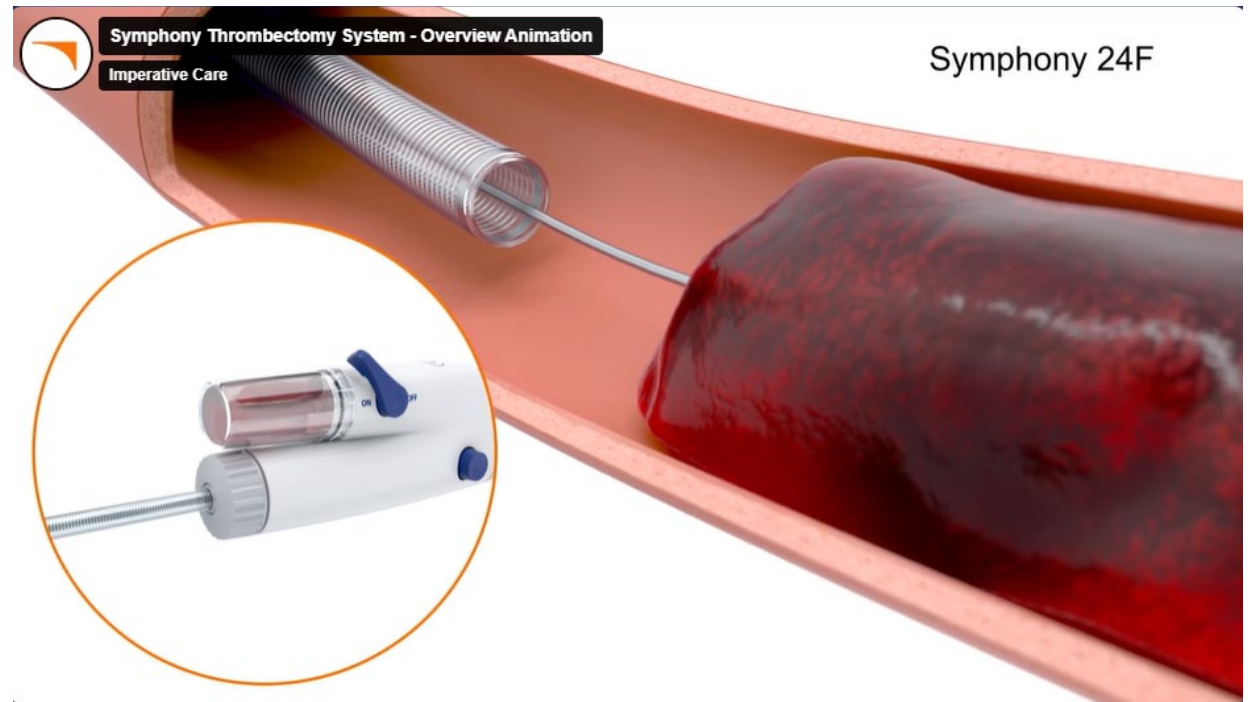
	<p>(Symphony Thrombectomy System Instructions For Use at 2 (showing vacuum pressure and flow rate for aspiration source).)</p> <p>When negative pressure is generated in the chamber of the clot container by the aspiration source (<i>e.g.</i>, Truvic Generator and Truvic Canister), and the vacuum lever is turned to on to connect the aspiration catheter, it causes blood and clot material to be drawn from the human patient, through the aspiration catheter, through the first port (along the first fluid path), and into the chamber of the clot container. Blood is then drawn through the interior region of the filter in the chamber and out through the second port, where it flows along the second fluid path and eventually to the Truvic Canister via the Truvic primary or secondary tubing. (Symphony Thrombectomy System Instructions For Use at 5 (“Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to Truvic Generator IFU). Confirm tip of the Symphony Catheter is in the desired location. To begin aspiration, move the vacuum lever on the Handle to the ‘ON’ position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the ‘OFF’ position.”); Symphony Thrombectomy System Instructions For Use at 8 (“Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU). Open the stopcock on the Tubeset to allow vacuum to both the 24F and 16F Systems and ensure no leaks are detected. Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy. To begin aspiration, move the vacuum lever on the 16F Handle to the ‘ON’ position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the 16F Handle to the ‘OFF’ position.”).)</p>
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The flow path of the blood and clot material (*i.e.*, from the aspiration catheter and through the first port into the chamber) is shown in the annotated teardown image below.

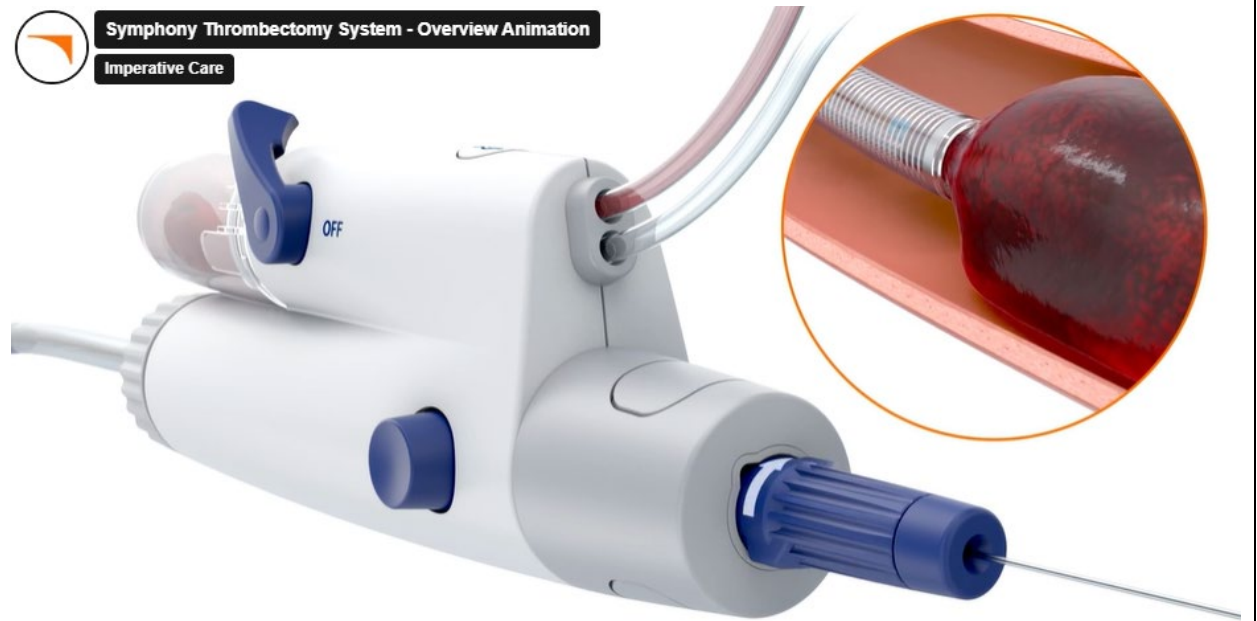


(Annotated image of internal portion of the controller housing.)

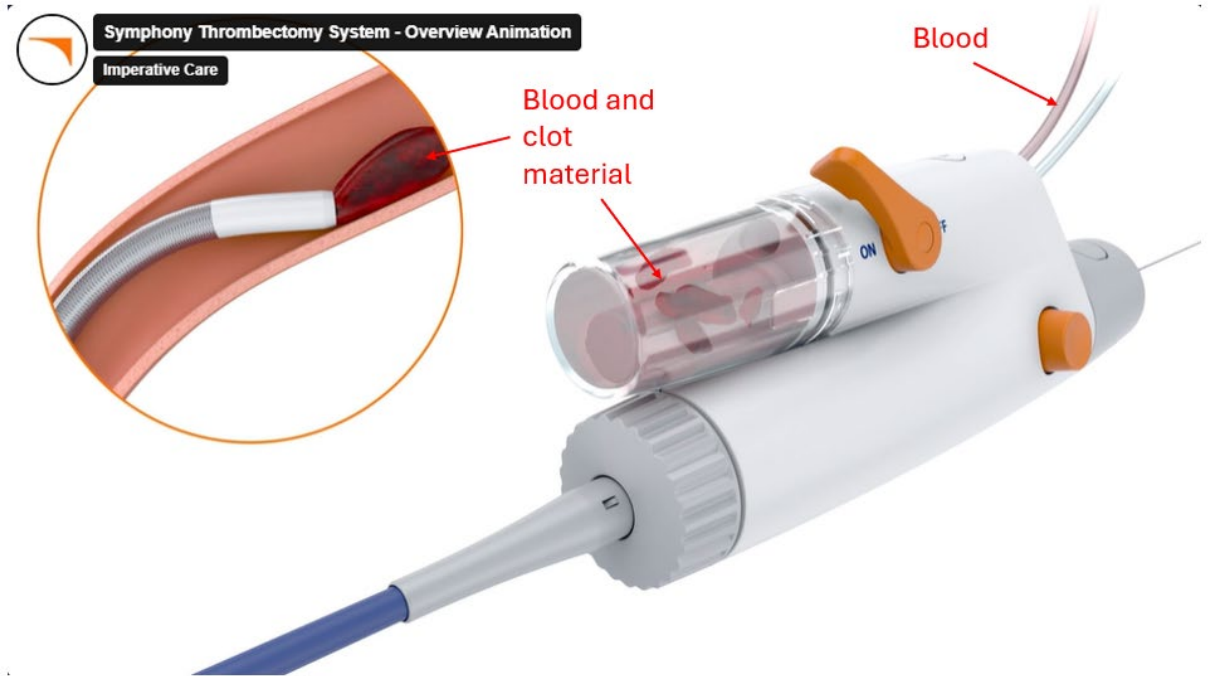
The Symphony Thrombectomy System Overview Animation Video also depicts blood and clot material flowing from the aspiration catheter, through the first port, and into the chamber of the clot container.



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

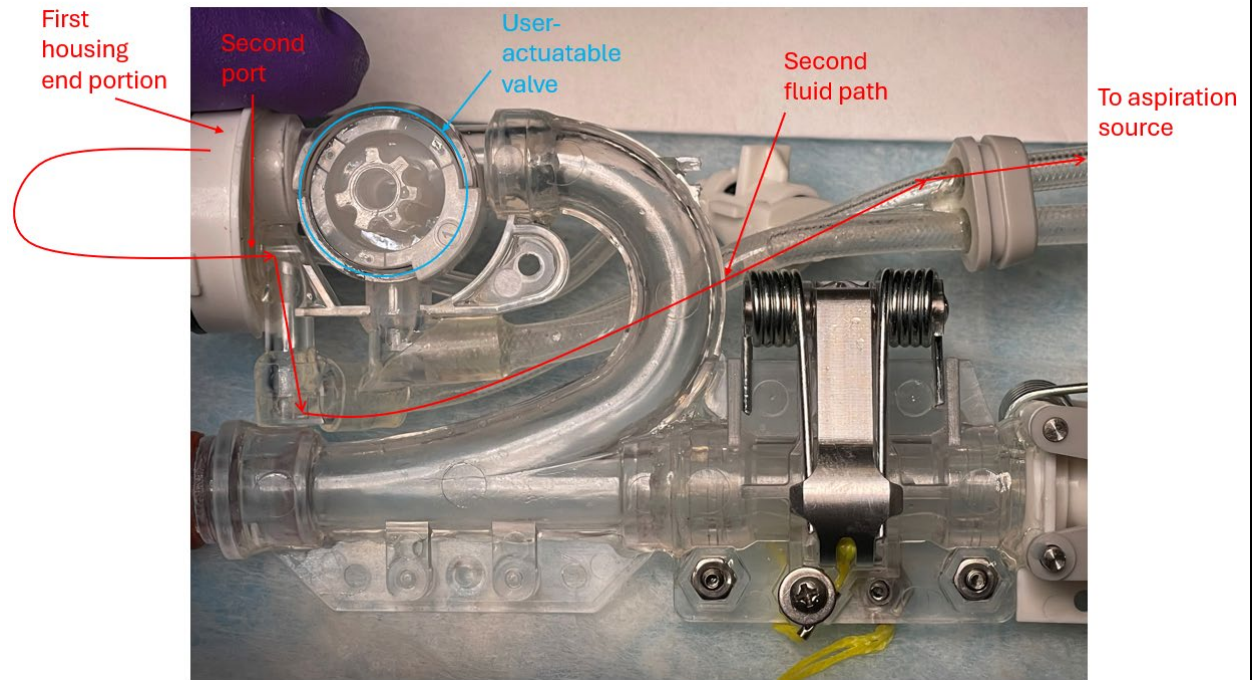


(Symphony Thrombectomy System – Overview Animation Video at 1:05.)



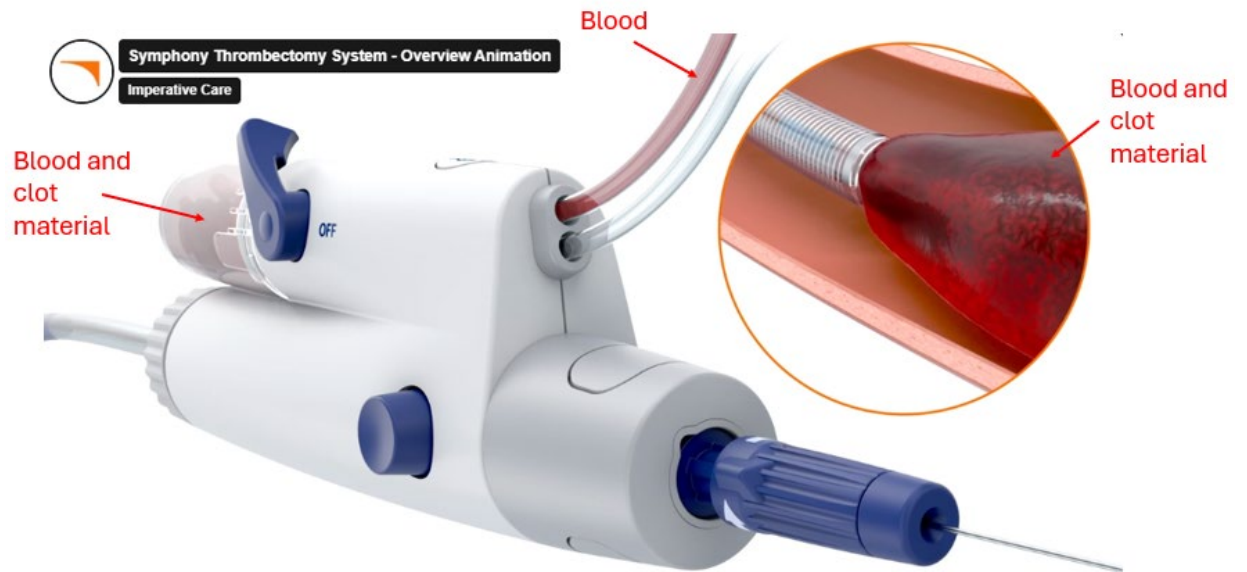
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

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

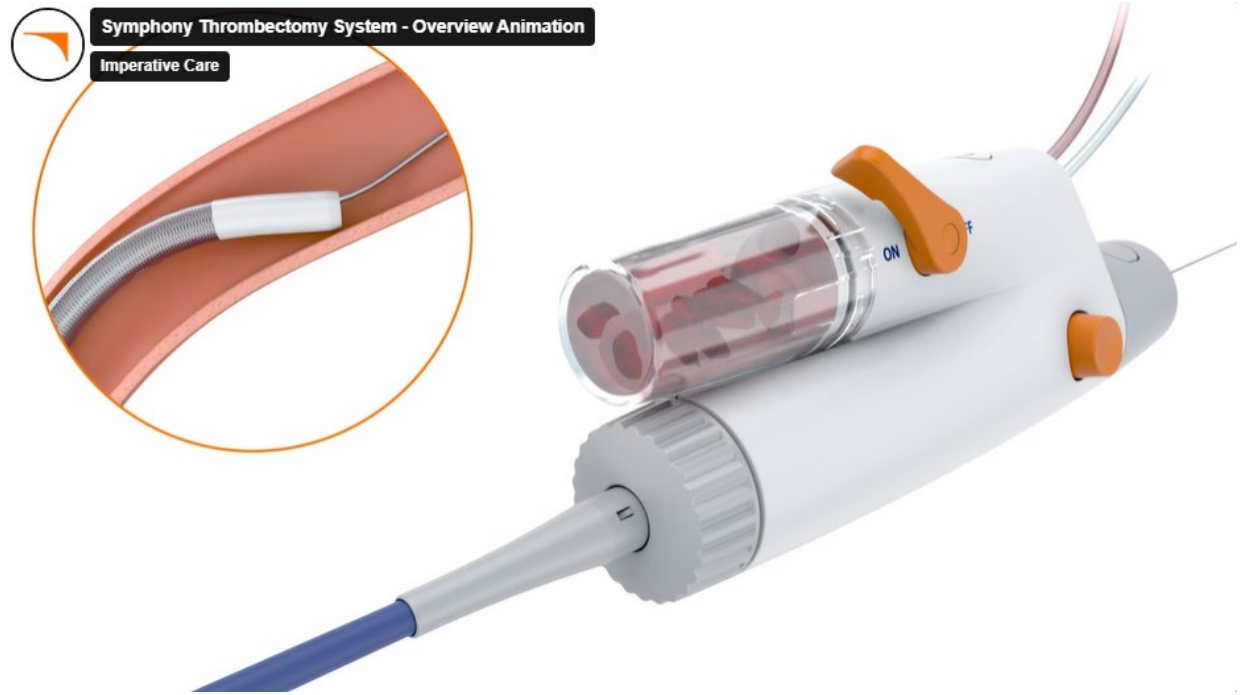


(Annotated image of internal portion of the controller housing.)

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



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



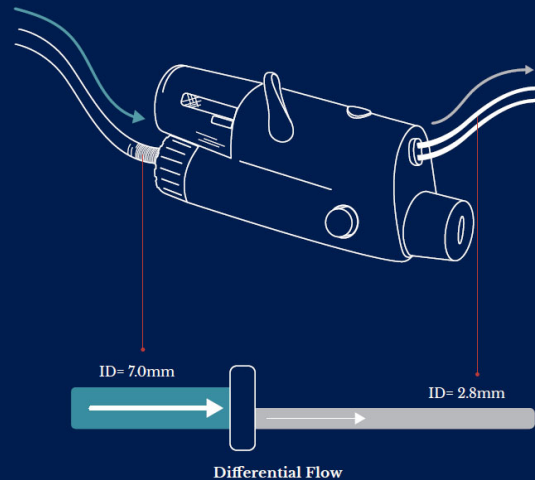
(Symphony Thrombectomy System – Overview Animation Video at 2:03.)

The Symphony Thrombectomy System Brochure also shows the flow of clot and blood into the chamber and shows blood flowing out of the chamber.

On-Demand Vacuum with Integrated Blood Management

Balance power with control and minimize blood loss with built-in differential flow. Clot capture in the palm of your hands provides real-time case assessment.

The Symphony™ Advantage



Blood flowrate reduced by
~55%*

* Data on File

BigShot™ Controller

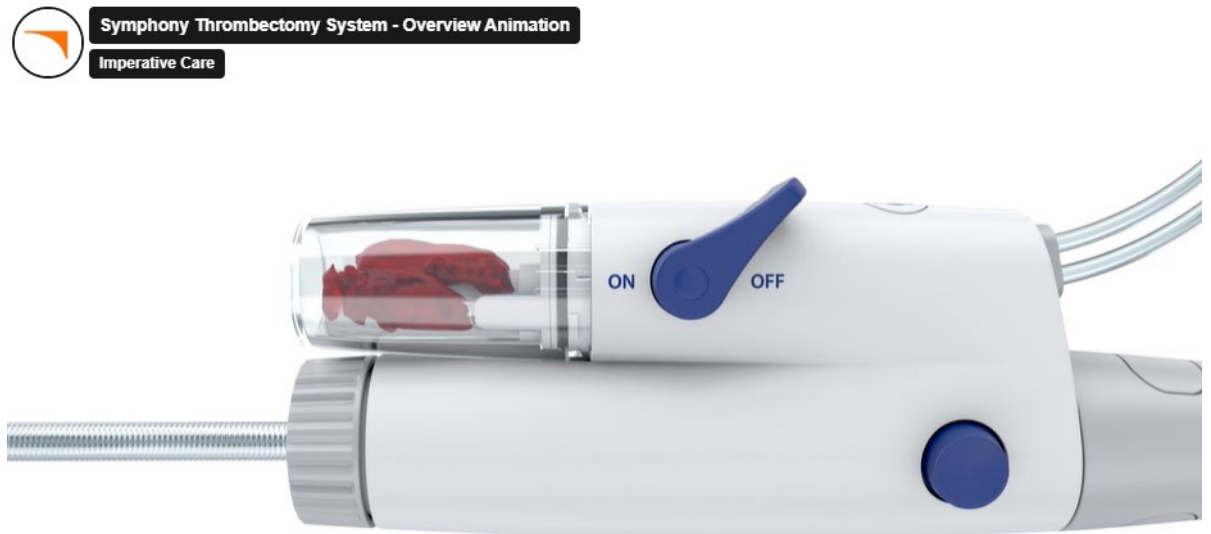
(Symphony Thrombectomy System Brochure at 7.)

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

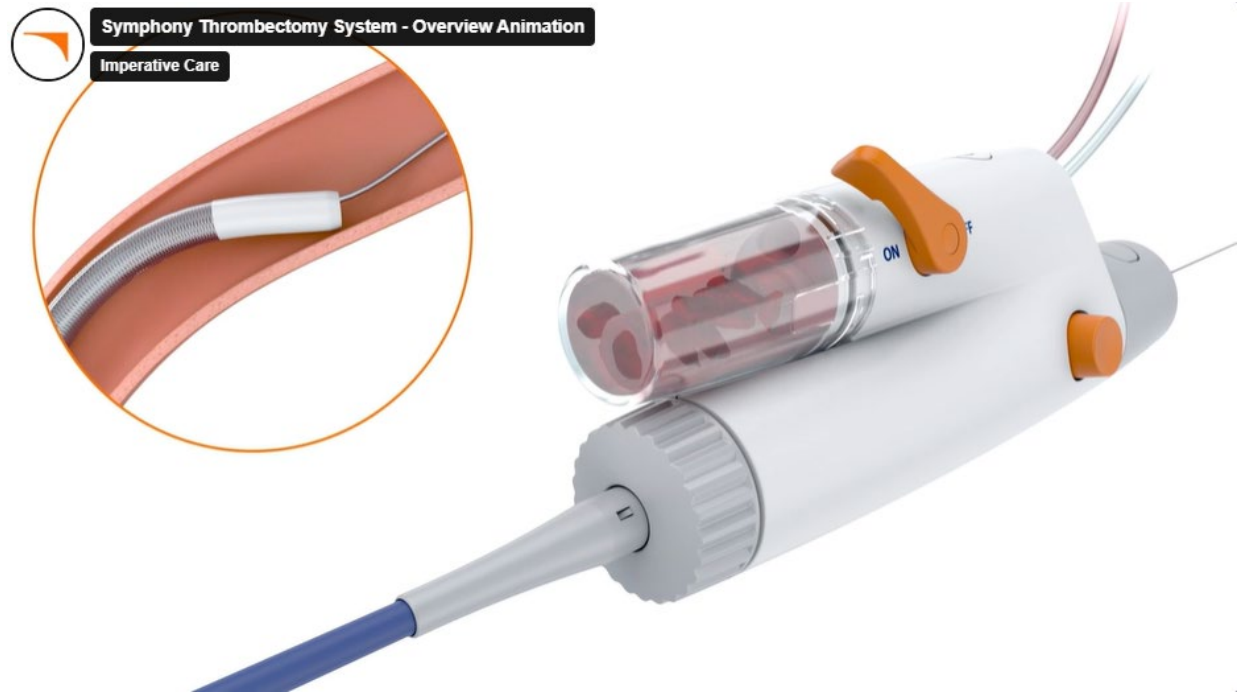
wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.

The clot collection reservoir of the Symphony System includes a filter that is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.

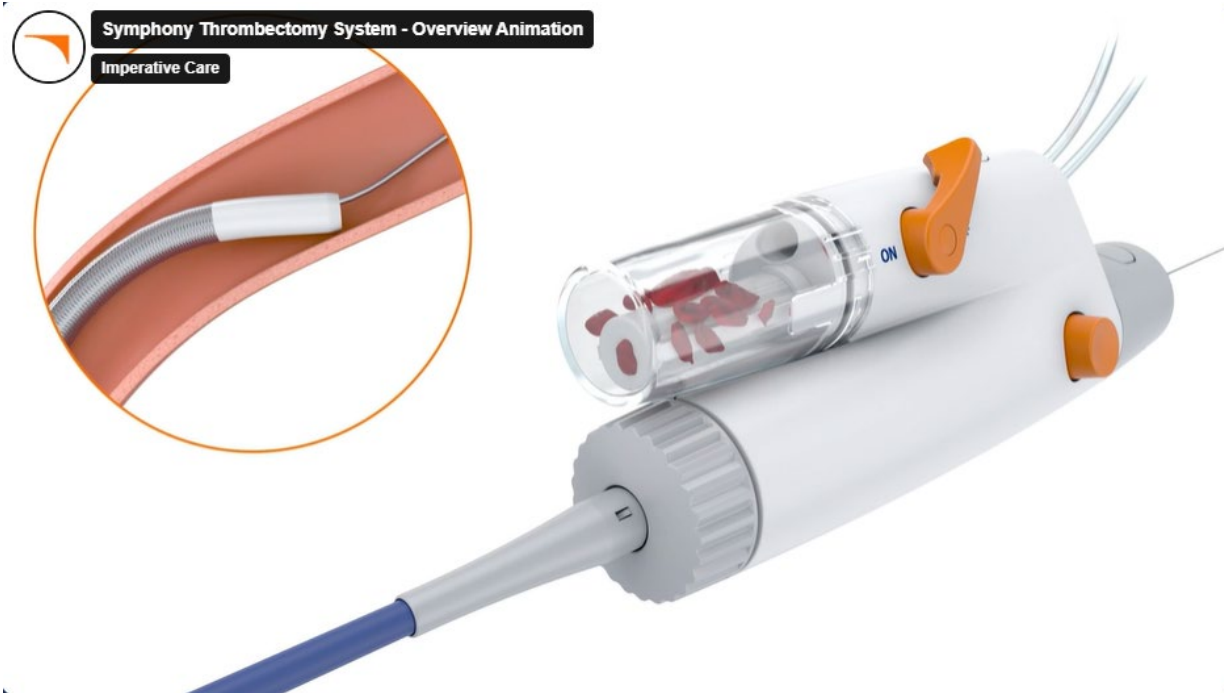
Specifically, as shown in the images from the Symphony Thrombectomy System Overview Animation Video, the filter of the clot container of the 24F and 16F Symphony Catheter handles is configured to and does inhibit clot material from passing through the filter, into its interior region, and through the second port, thus trapping clot material in the chamber of the clot container.



(Symphony Thrombectomy System – Overview Animation Video at 1:16.)



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



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

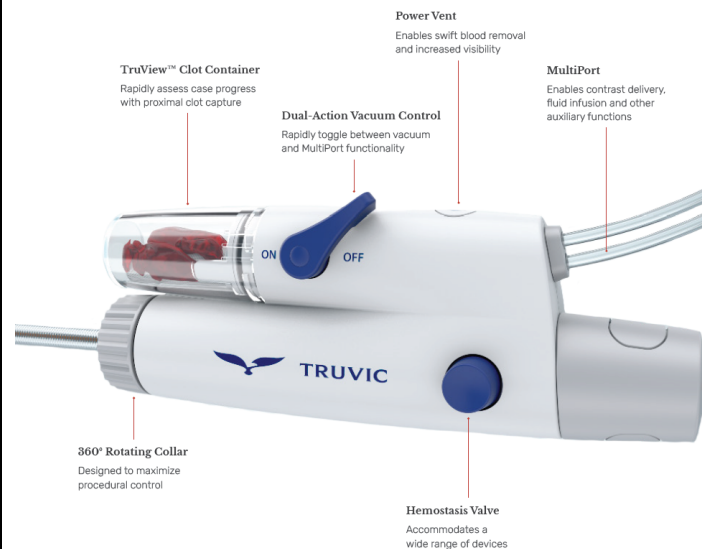
The Symphony System IFU confirms that the filter inhibits clot material from flowing into its interior, and instead allows for blood to flow through its interior and through the second port. (Symphony Thrombectomy System Instructions For Use at 5, 8.) Physical inspection of the Symphony System’s filter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

The Symphony Thrombectomy System Brochure also depicts clot material remaining in the chamber of the clot container so that the physician or user can view the clot and assess progress.

SYMPHONY™ THROMBECTOMY SYSTEM

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

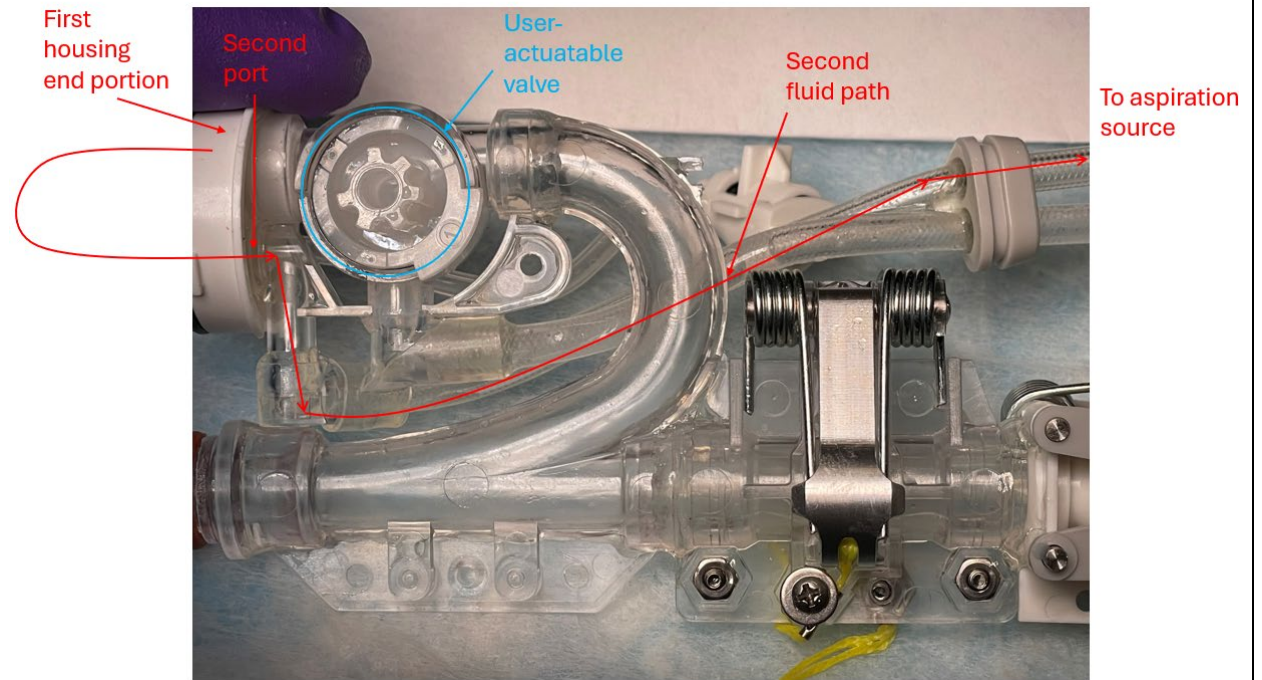
BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)

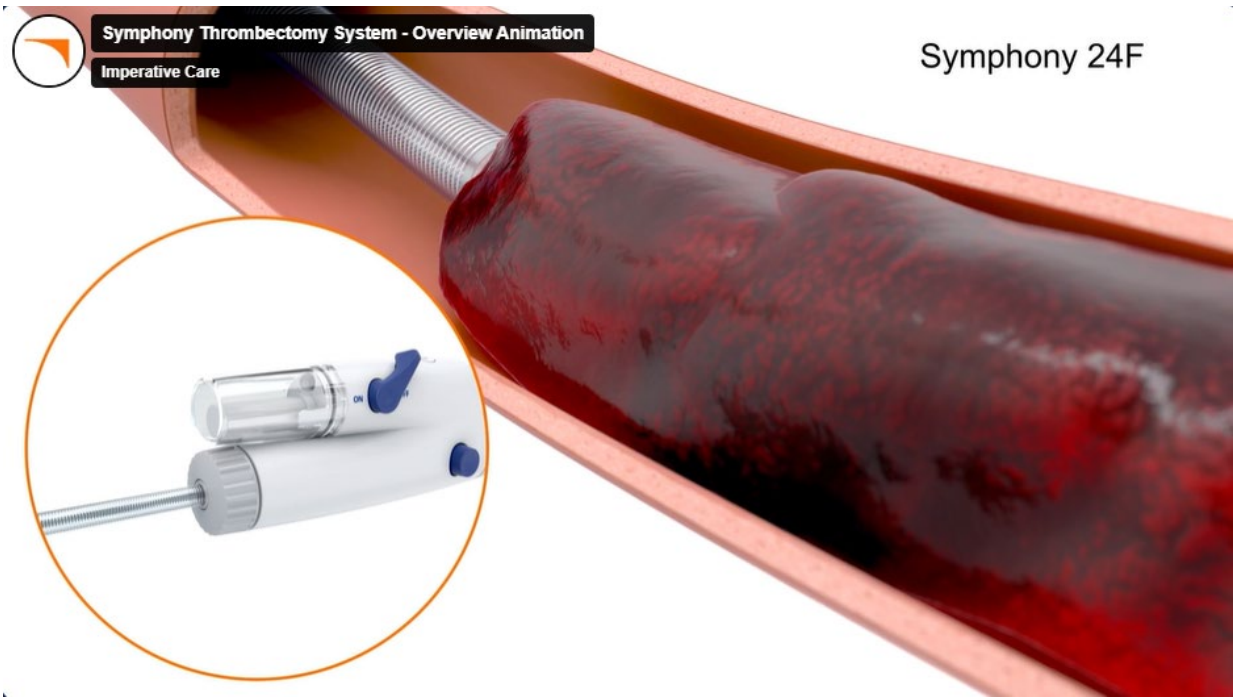
To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

<p>[16] The clot treatment system of claim 15 wherein the aspiration source is configured to generate the negative pressure in the chamber with the valve in a closed position, and wherein the valve is configured to be moved to the open position to apply the negative pressure to the aspiration catheter.</p>	<p>The Symphony System includes an aspiration source that is configured to generate negative pressure in the chamber with the valve in a closed position, where the valve is configured to move to an open position to apply the negative pressure to the aspiration catheter.</p> <p>Specifically, the Truvic Generator and Truvic Canister of the Symphony Thrombectomy System are configured to generate negative pressure in the chamber of the clot container of the 24F and 16F Symphony Catheter handles, the tubing within the Symphony Catheter handle, the Truvic primary and secondary tubing, and the Truvic Canister when the valve is in the “OFF” position before the valve is moved to the “ON” position such that negative pressure is applied to the aspiration catheter, as described in the Symphony Thrombectomy System IFU. (Symphony Thrombectomy System Instructions For Use at 5 (“Confirm the Handle vacuum lever is in the ‘OFF’ position and open the stopcock on the Tubing. Ensure the Generator is on and the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU). Confirm tip of the Symphony Catheter is in the desired location. To begin aspiration, move the vacuum lever on the Handle to the ‘ON’ position.”); Symphony Thrombectomy System Instructions For Use at 8 (“Confirm that both the 24F and 16F Handle vacuum levers are in the ‘OFF’ position. Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).... Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy. To begin aspiration, move the vacuum lever on the 16F Handle to ‘ON’ position.”).)</p> <p>When the valve is closed, the aspiration source generates negative pressure in the chamber of the clot container via the second port, as shown in the annotated teardown image below.</p>
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(Annotated image of internal portion of the controller housing.)

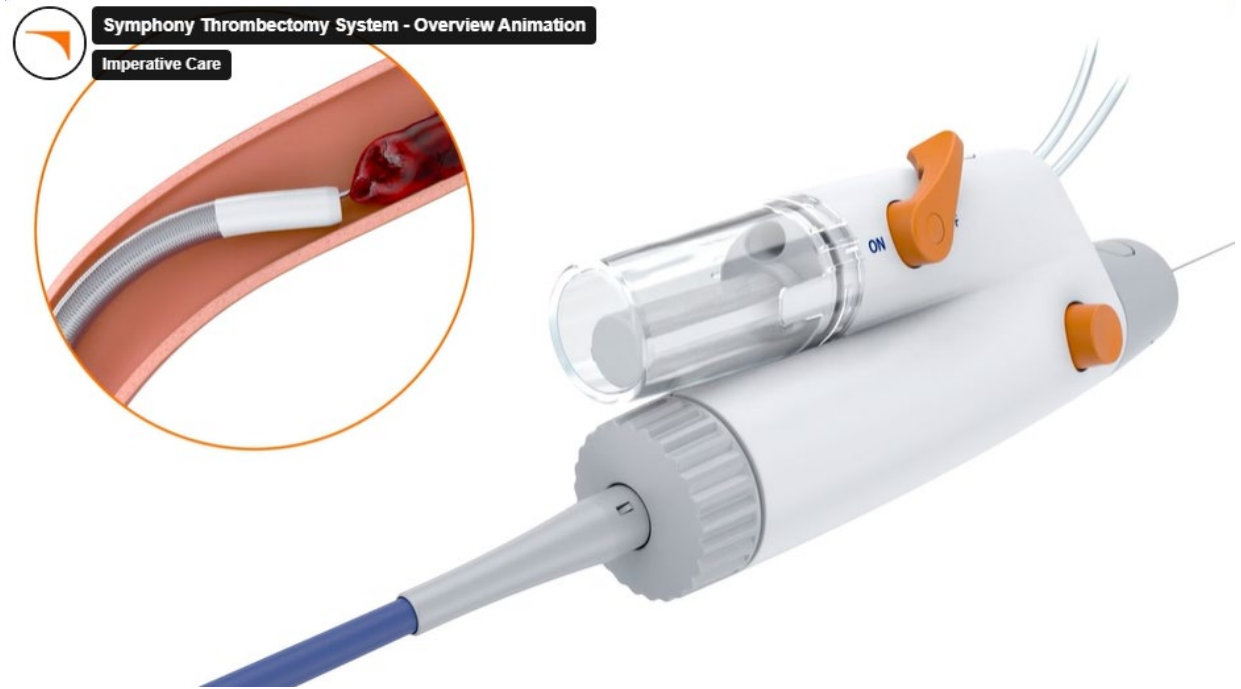
As shown in the images of the 24F and 16F Symphony Catheter handles below (from the Symphony Thrombectomy System Overview Animated Video), pressure builds in the chamber when the valve is in the “OFF” position. When the valve is moved to the “ON” position, that negative pressure is applied to the aspiration catheter.



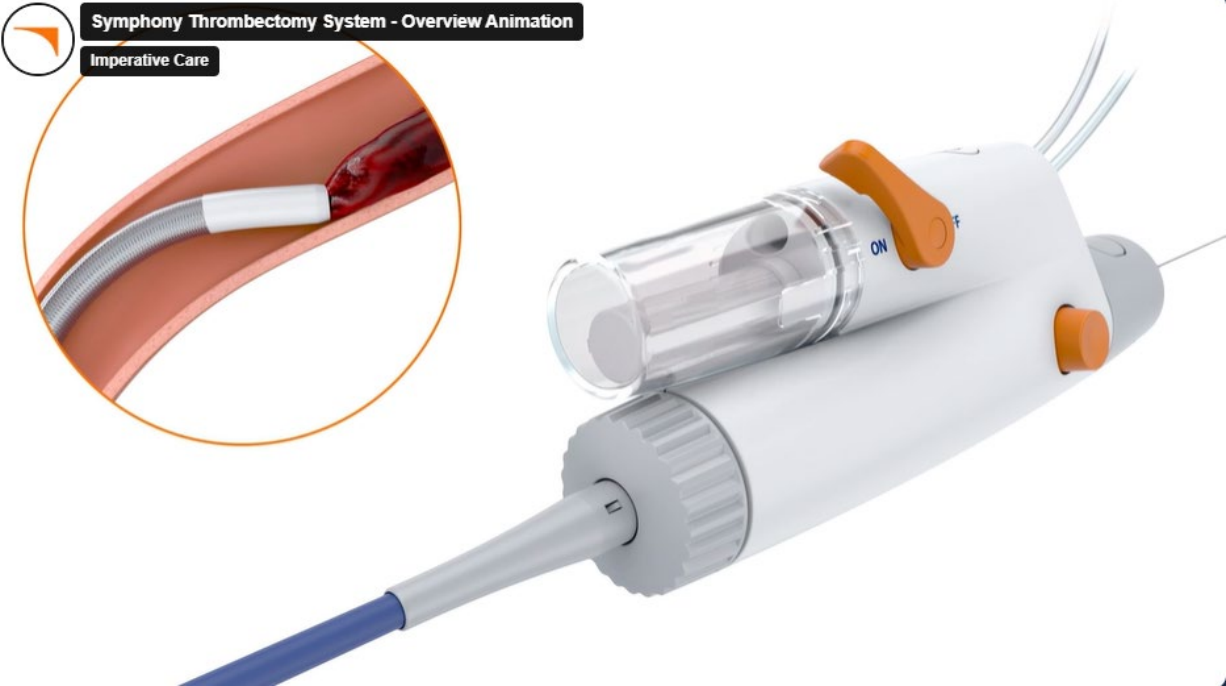
(Symphony Thrombectomy System – Overview Animation Video at 0:42.)



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



(Symphony Thrombectomy System – Overview Animation Video at 1:54.)

	 <p>The image shows a handheld medical device, the Symphony Thrombectomy System, which is white with orange accents. It has a long, thin catheter with a blue tip. An inset circular image shows a cross-section of a blood vessel with a red clot being treated by the device. Text overlays on the image include 'Symphony Thrombectomy System - Overview Animation' and 'Imperative Care'.</p> <p>(Symphony Thrombectomy System – Overview Animation Video at 1:56.)</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>[17] A clot treatment system, comprising:</p>	<p>The Symphony System is a clot treatment system.</p> <p>Specifically, “Symphony is a minimally invasive thrombectomy device that removes hazardous clots in patients’ veins via a catheter-based procedure. This handheld tool includes several innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a multifunction port for injecting medicine or contrast or measuring blood pressure,</p>

and a connection to a high-power vacuum source. The clot can also be ... withdrawn down through the catheter via vacuum where it is then trapped in a clear filter container, allowing the clot to be seen and analyzed by the physician. Symphony is designed to make a thrombectomy procedure faster and less invasive.” (<https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

As stated in the Symphony System IFU, “[t]he Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration. The Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. 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.)

To treat the clot, “[t]he Symphony Catheter and Symphony Dilator are introduced through a vascular access (introducer) sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and TRUVIC Canister, to aspirate thrombus.” (Symphony Thrombectomy System Instructions For Use at 1.)

The Symphony System IFU also lists the intended purpose of the Symphony Thrombectomy System, which includes clot treatment.

	<p>The Symphony Thrombectomy System is intended for:</p> <ul style="list-style-type: none"> • The non-surgical removal of fresh, soft emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. <p>The Symphony Thrombectomy System is intended for use in the peripheral vasculature. It is not for use in the pulmonary vasculature.</p> <p>(Symphony Thrombectomy System Instructions For Use at 2.)</p> <p>The Symphony Thrombectomy System Brochure also discloses that it is a clot treatment and removal system.</p>
<p>an aspiration catheter configured to be intravascularly positioned proximate to clot material within a blood vessel of a patient;</p>	<p>The Symphony System includes an aspiration catheter configured to be intravascularly positioned proximate to clot material within the blood vessel of a patient.</p> <p>Specifically, the Symphony System includes a 24F and/or 16F aspiration catheter that is intravascularly positioned proximate (<i>e.g.</i>, near) to clot material within the blood vessel of a human patient, as described on Whipsaw’s product development website. (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system) (“Symphony is a minimally invasive thrombectomy device that removes hazardous clots in patients’ veins via a catheter-based procedure. This handheld tool includes several innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a multifunction port for injecting medicine or contrast or measuring blood pressure, and a connection to a high-power vacuum source. The clot can also be ... withdrawn down through the catheter via vacuum where it is then trapped in a clear</p>

filter container, allowing the clot to be seen and analyzed by the physician. Symphony is designed to make a thrombectomy procedure faster and less invasive.”).)

Symphony™

THROMBECTOMY SYSTEM

Product Specifications

Symphony™ Catheters			
Product	Model	Working Length	Sheath Compatibility
16F Catheter, 82cm	SYMPHONY16F82	82 cm	16F
16F Catheter	SYMPHONY16F	117 cm	16F
24F Catheter	SYMPHONY24F	85 cm	24F

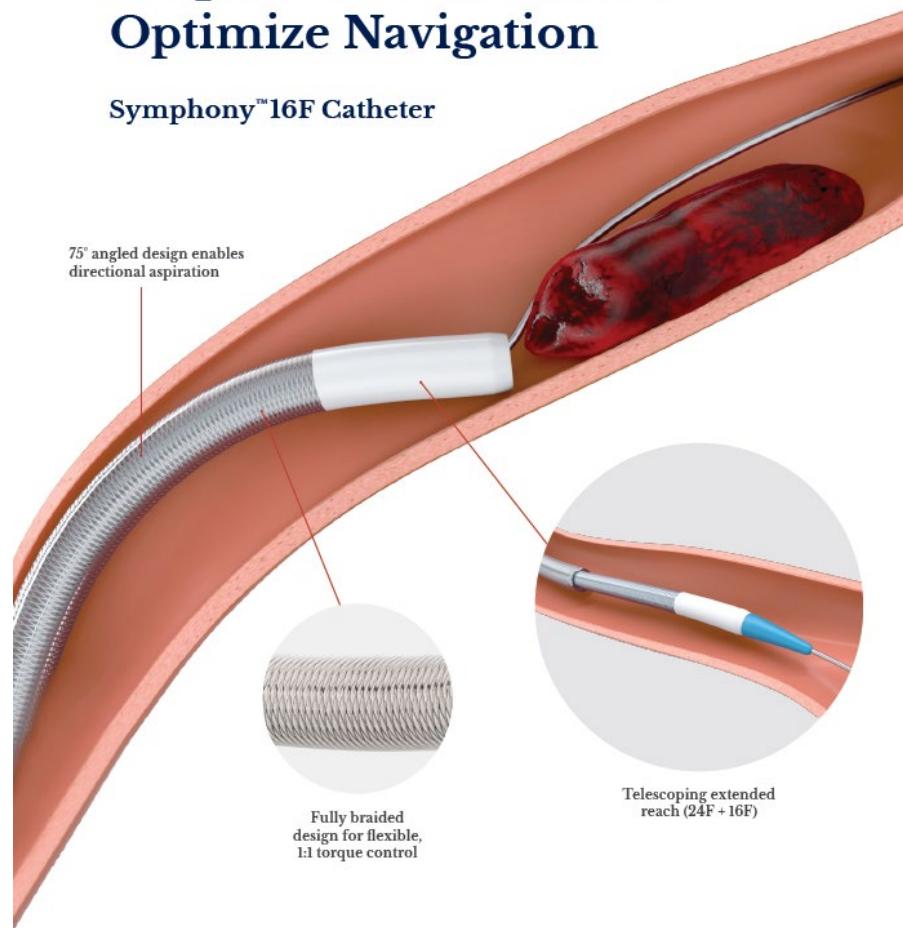
(Symphony Thrombectomy System Product Specifications Sheet at <https://imperativecare.com/wp-content/uploads/sites/4/2024/09/M10147.C-Symphony-Product-Spec-Sheet.pdf>.)

The Symphony Thrombectomy System Brochure shows how the 24F and/or 16F Symphony Catheter can navigate the blood vessel of a patient, such that it is positioned proximate to clot material.

SYMPHONY™ THROMBECTOMY SYSTEM

Purpose-Built Catheters Optimize Navigation

Symphony™ 16F Catheter



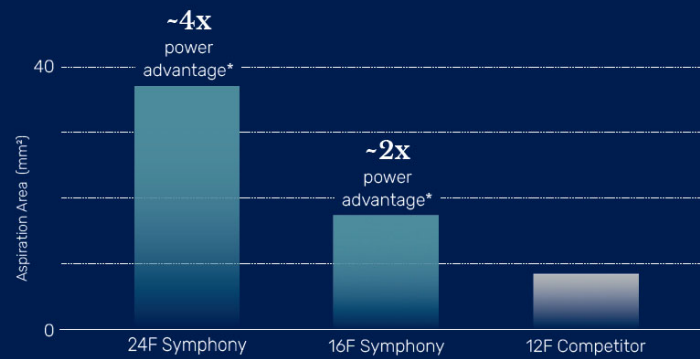
(Symphony Thrombectomy System Brochure at 4.)

Easily Directed for Precise Placement

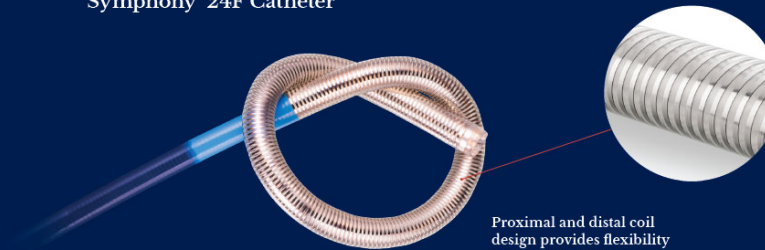
Highly flexible, radiopaque catheters optimize positioning and visibility.

The system's 16F catheter with angled design directs aspiration within the vessel.

The Symphony™ Advantage¹

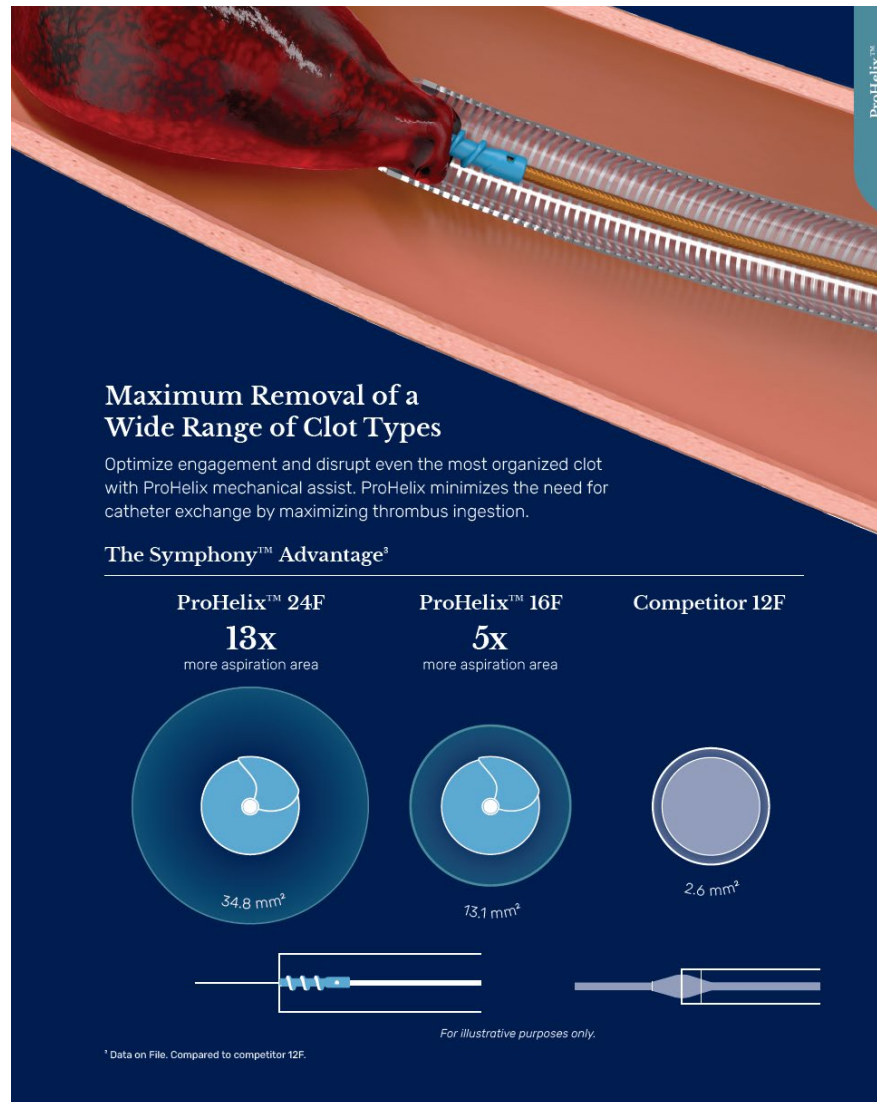


Symphony™ 24F Catheter



* Compared to 12F competitor. Aspiration Power: Force=Pressure x Area.
¹ Data on File

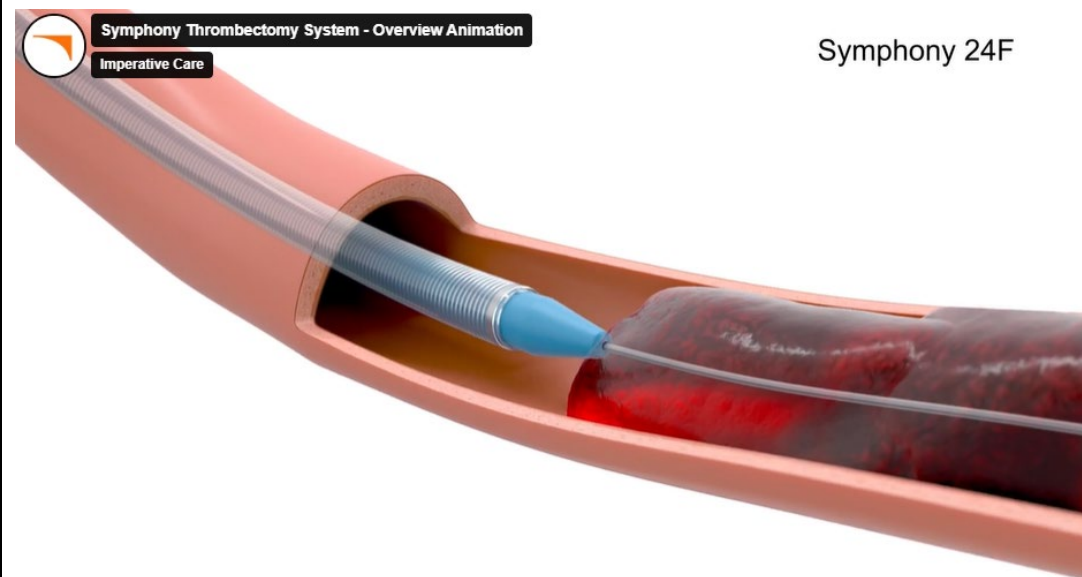
(Symphony Thrombectomy System Brochure at 5.)



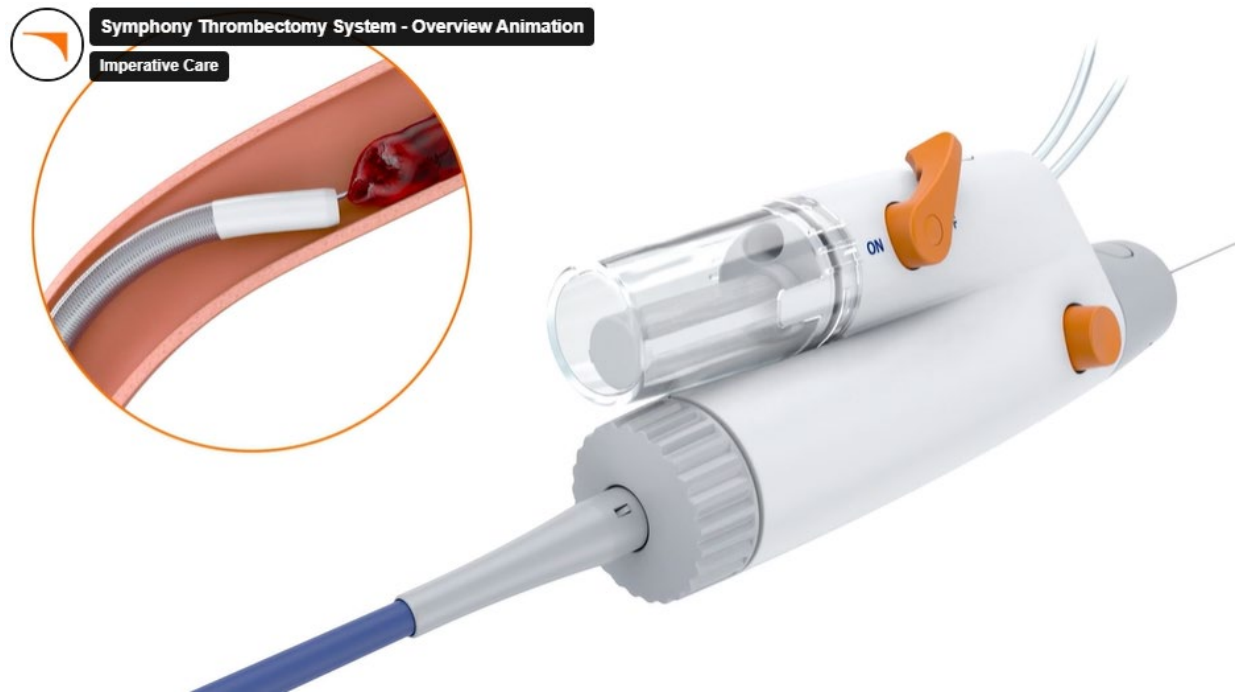
(Symphony Thrombectomy System Brochure at 9.)

The Symphony System IFU describes the aspiration catheter and how it is positioned proximate to clot material within a patient's blood vessel. (Symphony Thrombectomy System Instructions For Use at 1 ("The Symphony Catheter has a lubricious hydrophilic coating on the distal 40 cm of the 24F catheter shaft, and distal 55 cm of the 16F catheter shaft. The Symphony Catheter and Symphony Dilator are introduced through a vascular access (introducer) sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.").)

The images of the 24F and 16F Symphony Catheters also demonstrate that it is positioned proximate to clot material in a patient's blood vessel.



(Symphony Thrombectomy System – Overview Animation Video at 0:37.)



(Symphony Thrombectomy System – Overview Animation Video at 1:54.)

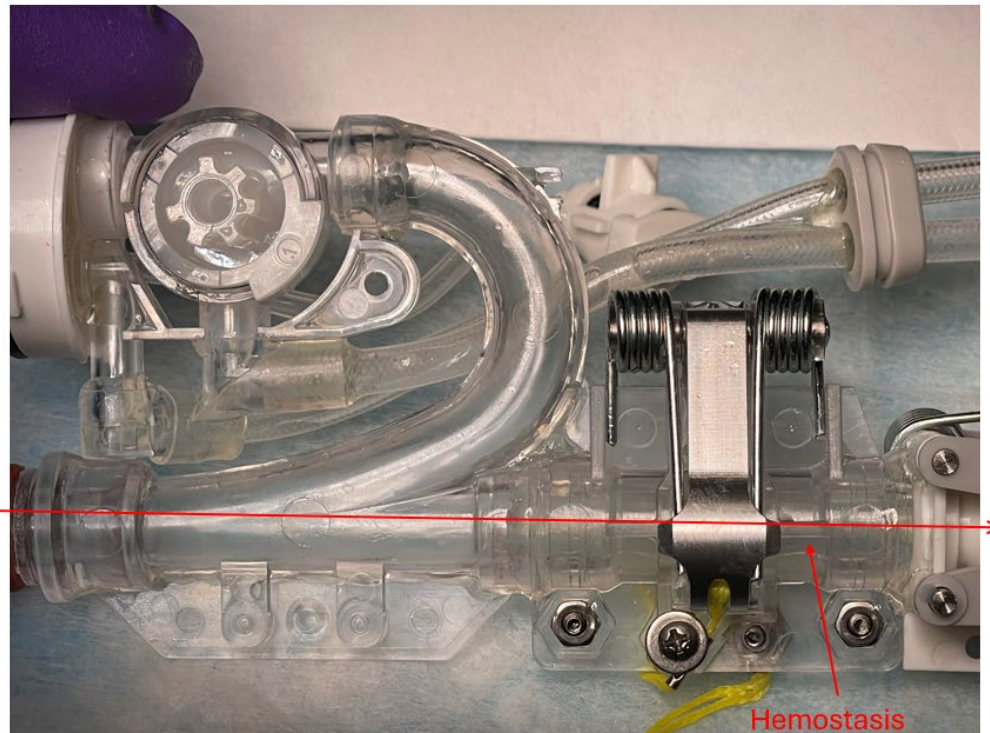
To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

a hemostasis valve coupled to a proximal portion of the aspiration catheter;

The Symphony System includes a hemostasis valve coupled to a proximal portion of the aspiration catheter.

Specifically, the 24F and 16F Symphony Catheter handle includes a hemostasis valve that is coupled to a proximal portion of the aspiration catheter, as shown below in the annotated teardown image.

From
aspiration
catheter



Hemostasis
valve

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

The Symphony System IFU shows the outer shell of the Symphony Catheter handles that includes a button for the Handle's hemostasis valve.

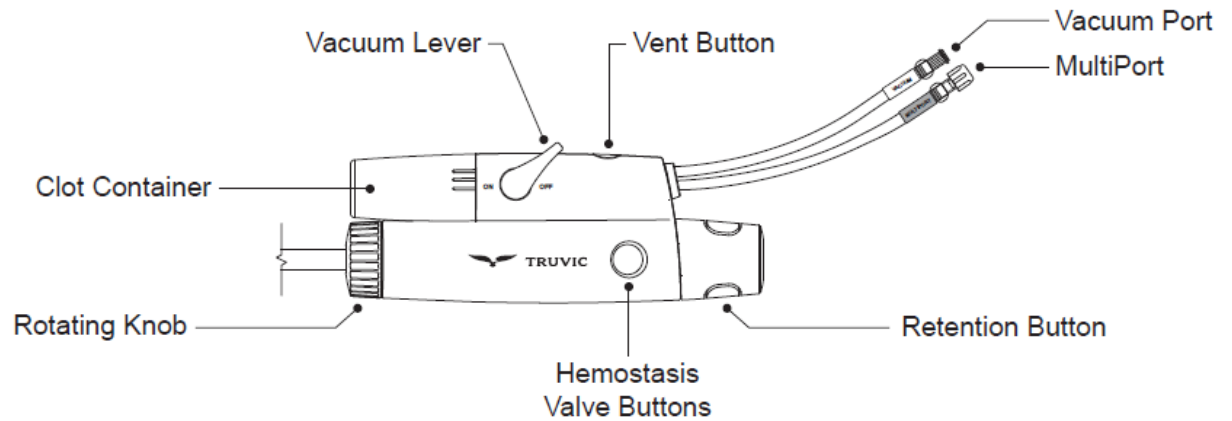


Figure 3: Symphony Catheter Handle, labeled

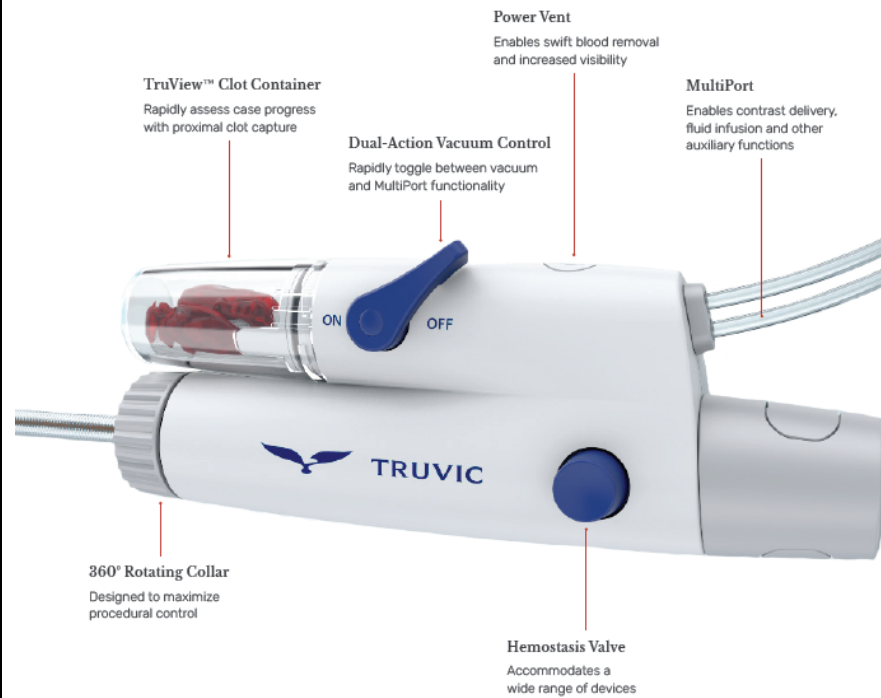
(Symphony Thrombectomy System Instructions For Use at 4; *see also* Symphony Thrombectomy System Instructions For Use at 2 (“Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device”).)

The Symphony Thrombectomy System Brochure shows that the 24F Symphony Catheter handles include a Hemostasis Valve.

SYMPHONY™ THROMBECTOMY SYSTEM

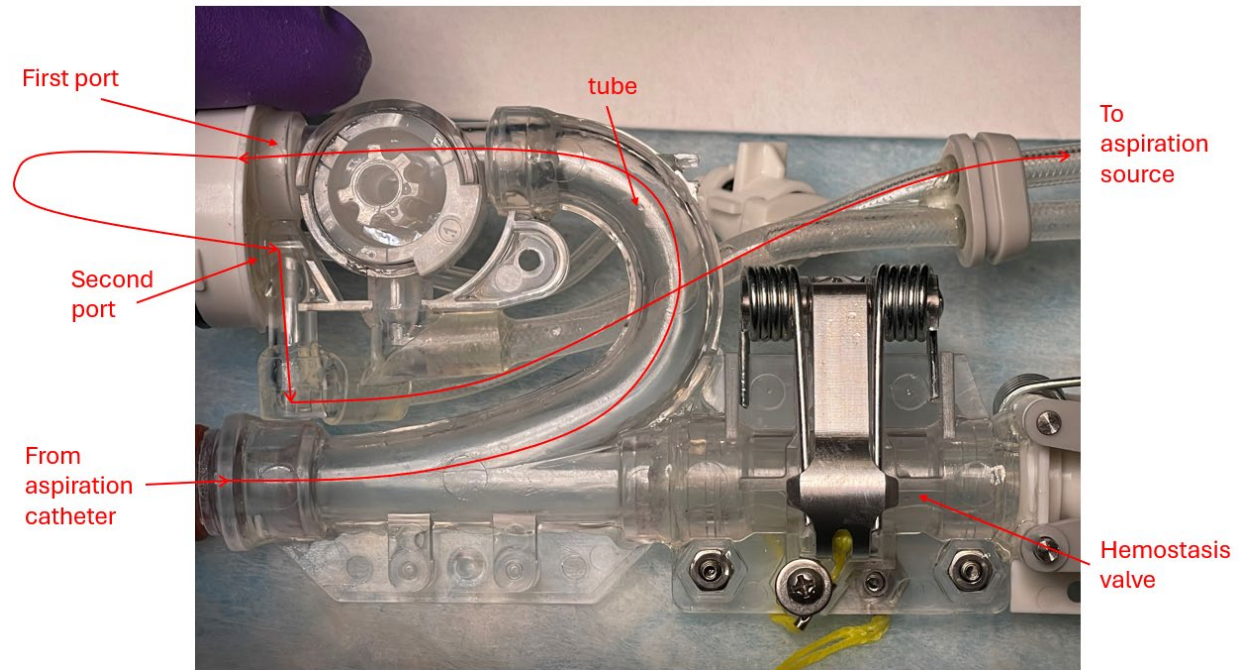
High-Powered, Continuous Vacuum with Real-Time Case Assessment

BigShot™ Controller



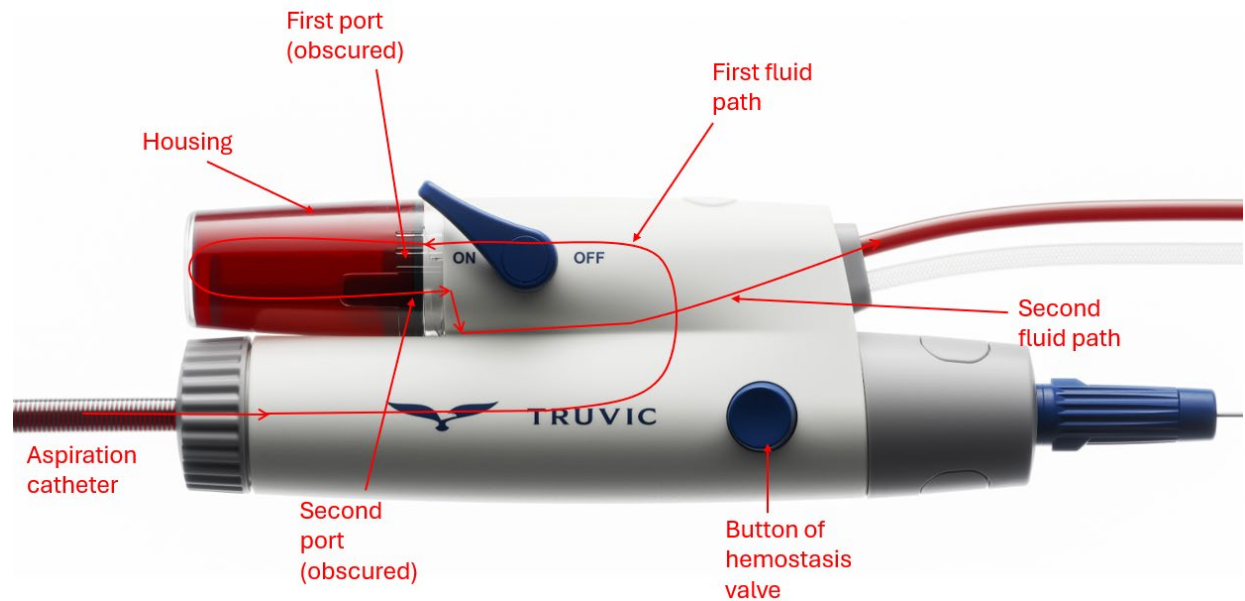
(Symphony Thrombectomy System Brochure at 6.)

	<p>The Whipsaw website also confirms that the 24F and 16F Symphony Catheter handles include a hemostasis valve. (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system (“This handheld tool includes several innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a multifunction port for injecting medicine or contrast or measuring blood pressure, and a connection to a high-power vacuum source.”)).</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
at least one tube fluidly coupling the first port to a portion of the aspiration catheter distal of the hemostasis valve;	<p>The Symphony System includes at least one tube coupling the first port to a portion of the aspiration catheter distal of the hemostasis valve.</p> <p>Specifically, the 24F and 16F Symphony Catheter handles include at least one tube fluidly coupling the first port to the aspiration catheter distal of the hemostasis valve, as shown in the annotated teardown image below.</p>



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

The annotated image from Whipsaw's website shows that the tube fluidly connects the aspiration catheter and first port, such that clot material and blood can flow from the aspiration catheter to the clot container.



(Annotated image of handle 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 limitation, the Symphony System meets this limitation under the doctrine of equivalents.

an aspiration source; and

The Symphony System includes an aspiration source.

Specifically, the Symphony System Brochure describes the Truvic Generator and Truvic Canister as an aspiration source.

The Symphony System IFU describes how the 24F and 16F Symphony Catheter handles are designed to be used with the Truvic Generator and Truvic Canister for

aspiration. (Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as ‘thrombus’ or ‘clot’) from the vasculature using controlled aspiration. The Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus.”); Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.”); Symphony Thrombectomy System Instructions For Use at 2 (“The TRUVIC Symphony Thrombectomy Catheters have been verified for use with the TRUVIC Tubeset and TRUVIC Generator. The TRUVIC Generator is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 2.”).)

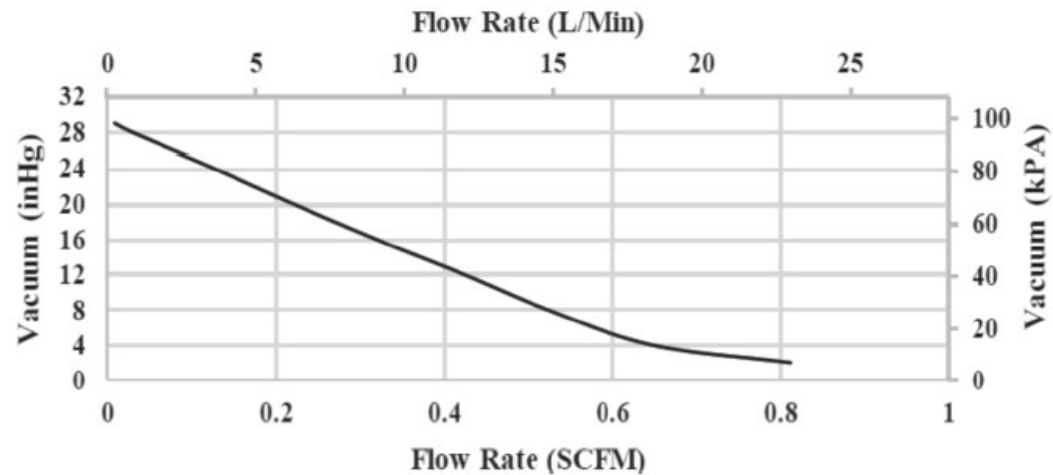


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

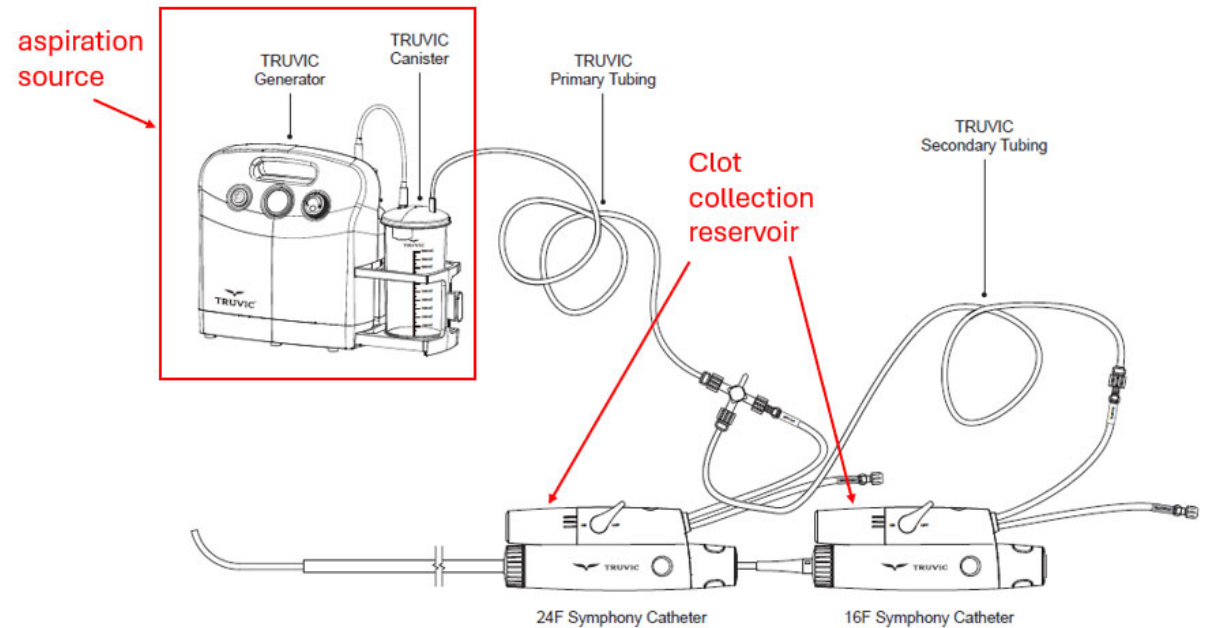


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Symphony Thrombectomy System Instructions For Use at 8.)

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 clot collection reservoir,
comprising—

The Symphony System includes a clot collection reservoir (including a “clot container” connected to the Symphony Bigshot Controller handle).

Specifically, the 24F and 16F Symphony Catheter handle of the Symphony System includes a clot collection reservoir where a user can “[c]onfirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle.” (Symphony Thrombectomy System Instructions For Use at 5; Symphony Thrombectomy System Instructions For Use at 6 (same); Symphony Thrombectomy System Instructions For Use at 8 (same).) The clot container of the 24F and 16F Symphony Catheter handles is shown in the Symphony System IFU below.

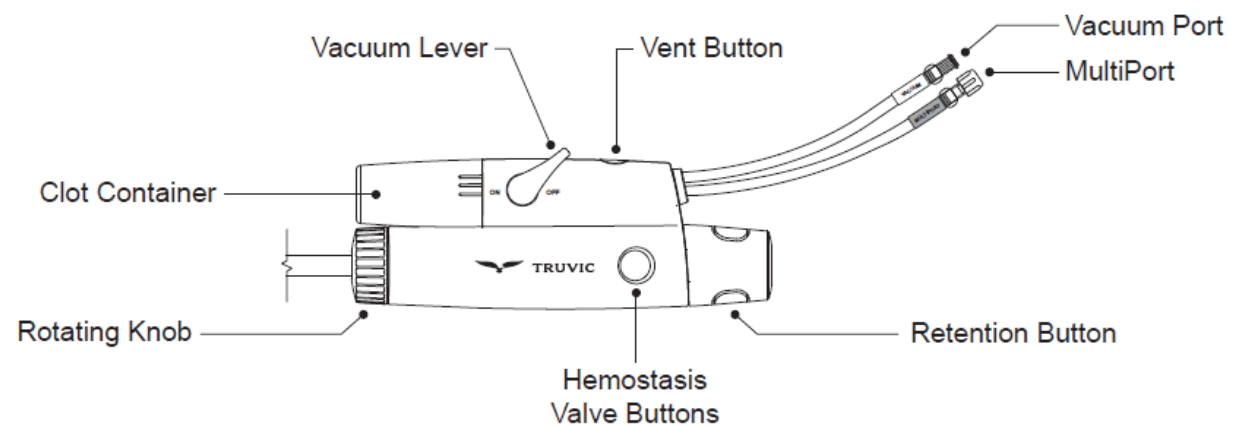
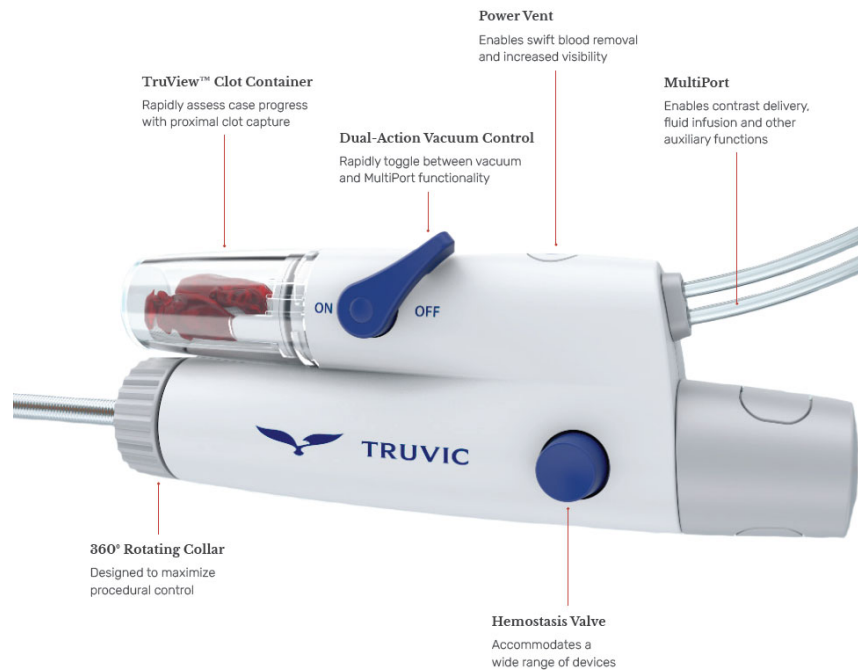


Figure 3: Symphony Catheter Handle, labeled

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

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

BigShot™ Controller

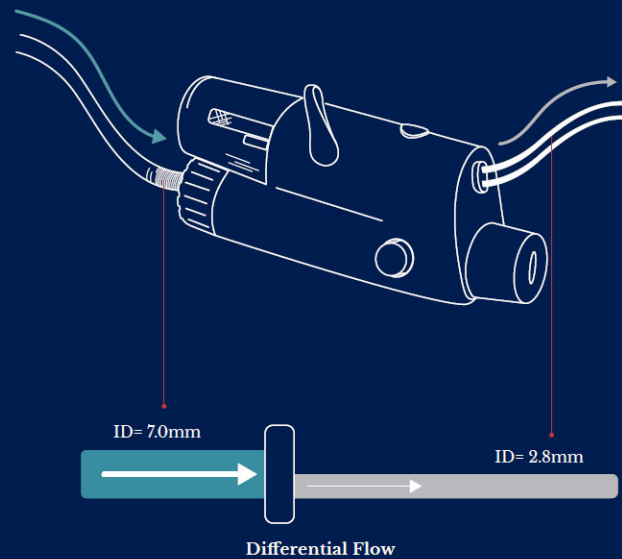


(Symphony Thrombectomy System Brochure at 6.)

On-Demand Vacuum with Integrated Blood Management

Balance power with control and minimize blood loss with built-in differential flow. Clot capture in the palm of your hands provides real-time case assessment.

The Symphony™ Advantage



Blood flowrate reduced by
~55%[‡]

[‡] Data on File

(Symphony Thrombectomy System Brochure at 7.)

The clot collection reservoir of the Symphony Catheter handle is also shown on the Whipsaw website.



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



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

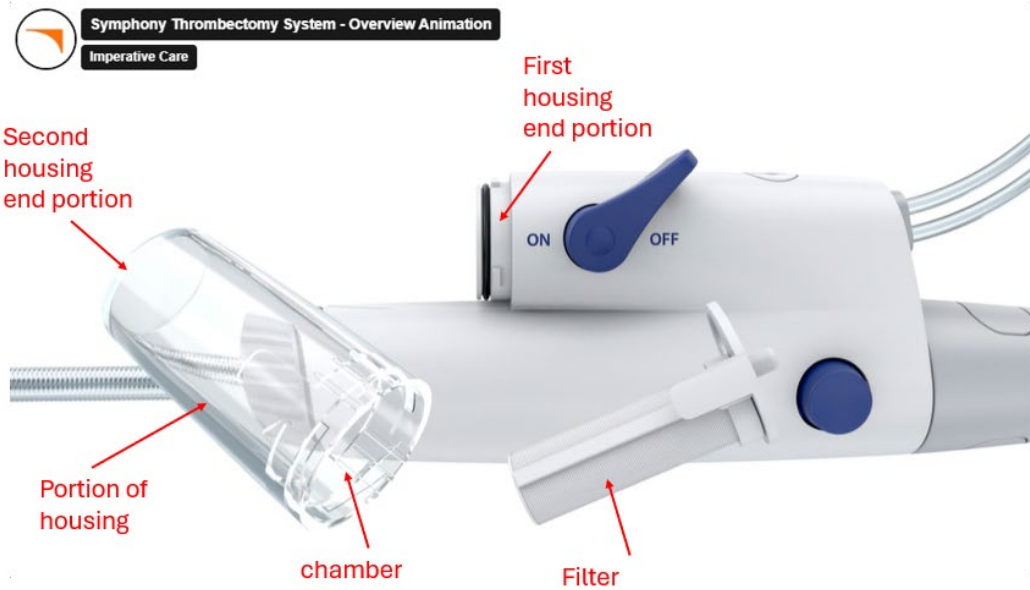


(Image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

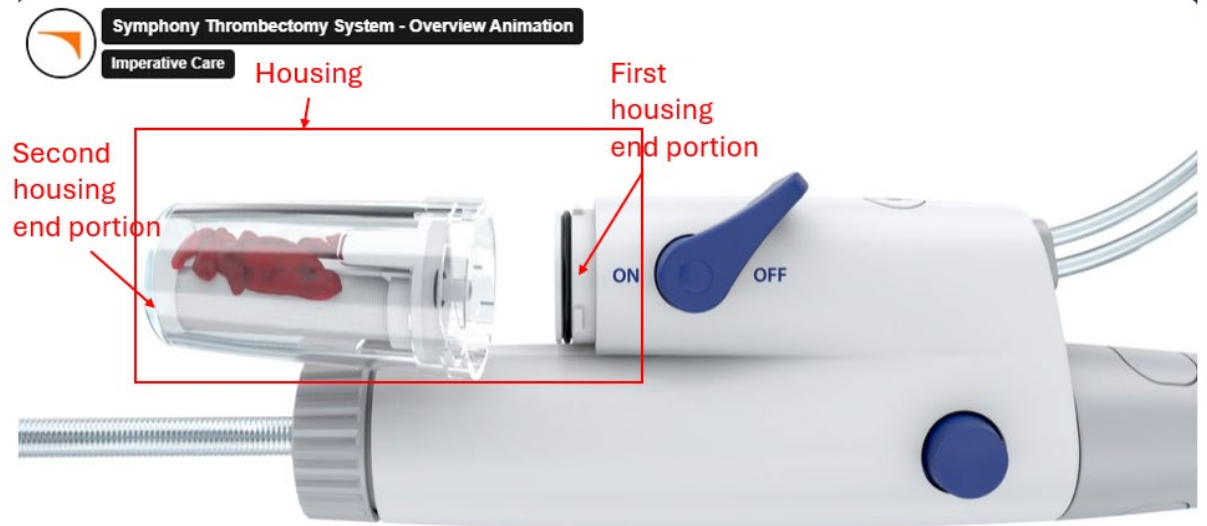
a housing defining a chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion;

The clot collection reservoir of the Symphony System includes a housing defining a chamber and having a first housing end portion and a second housing end portion opposite the first housing end portion.

The clot collection reservoir and the 24F and 16F Catheter Handles includes a housing, which defines a chamber and has a first housing end portion and a second housing end portion opposite the first, as shown in the annotated images below. The removable portion of the clot collection reservoir housing removably attaches to the portion of the housing connected to the 24F and 16F Catheter Handles.

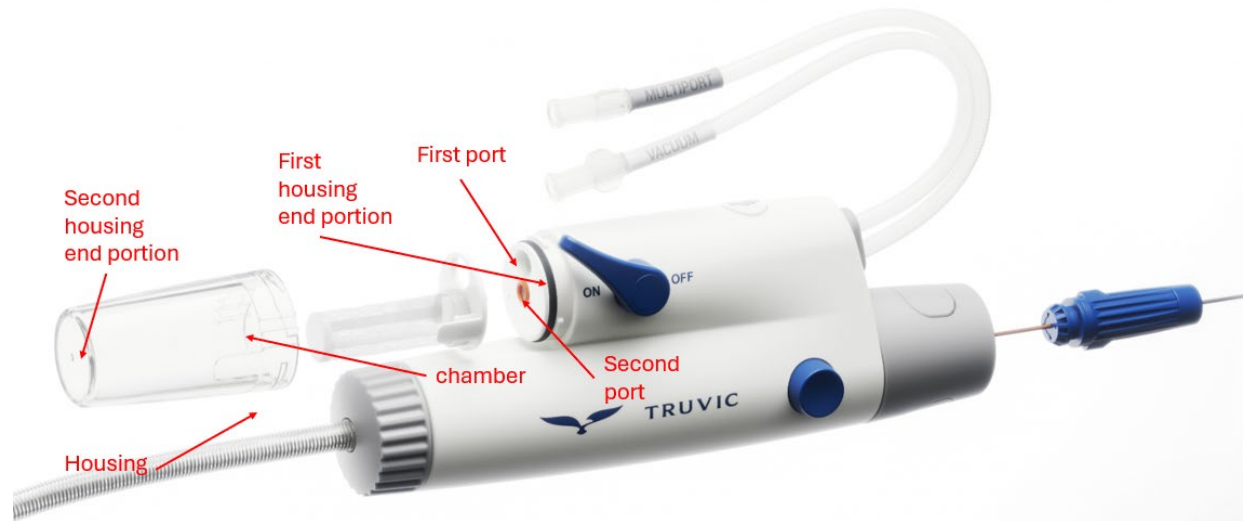


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

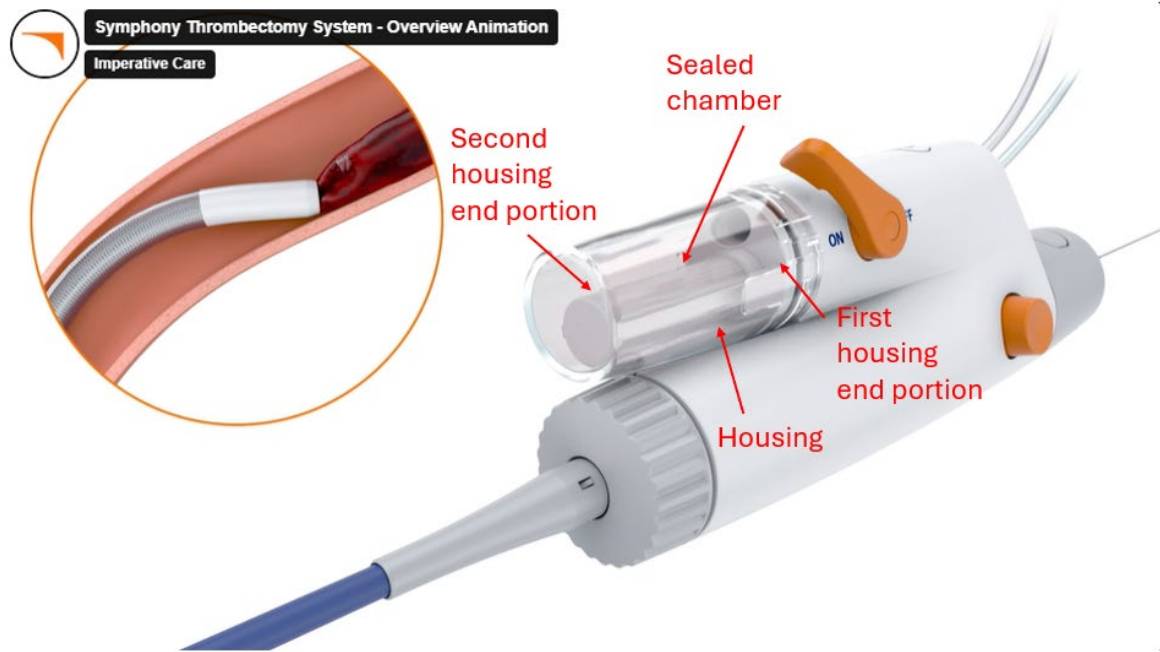


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:19.)

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



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



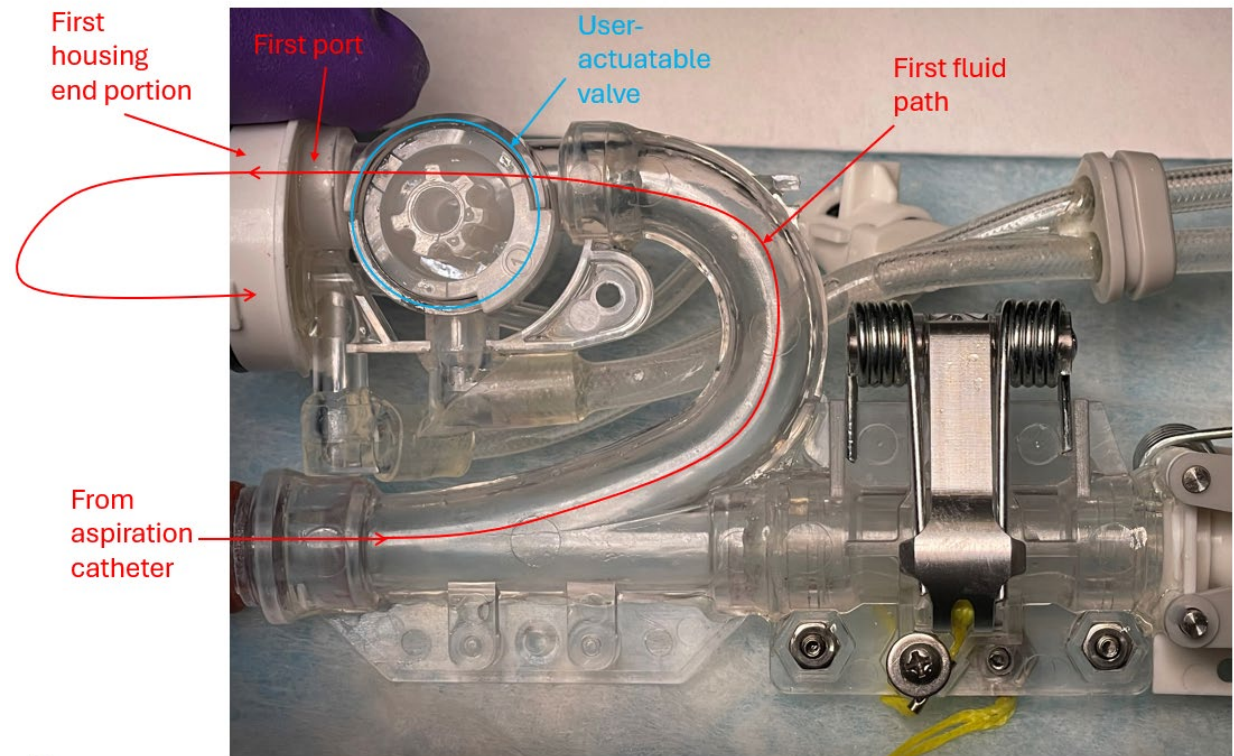
(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:57.)

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

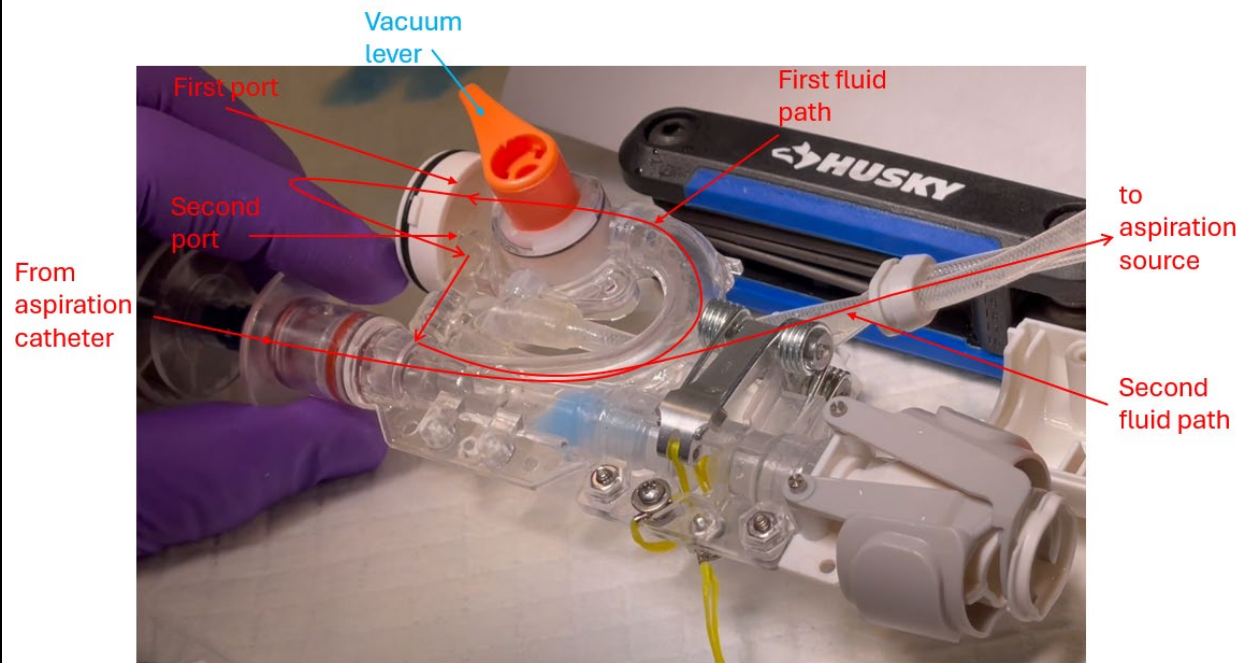
a first port configured to be fluidly coupled to the aspiration catheter, wherein the first port is positioned proximate to the first housing end portion;

The clot collection reservoir of the Symphony System includes a first port configured to be fluidly coupled to the aspiration catheter, where the first port is positioned proximate to the first housing end portion.

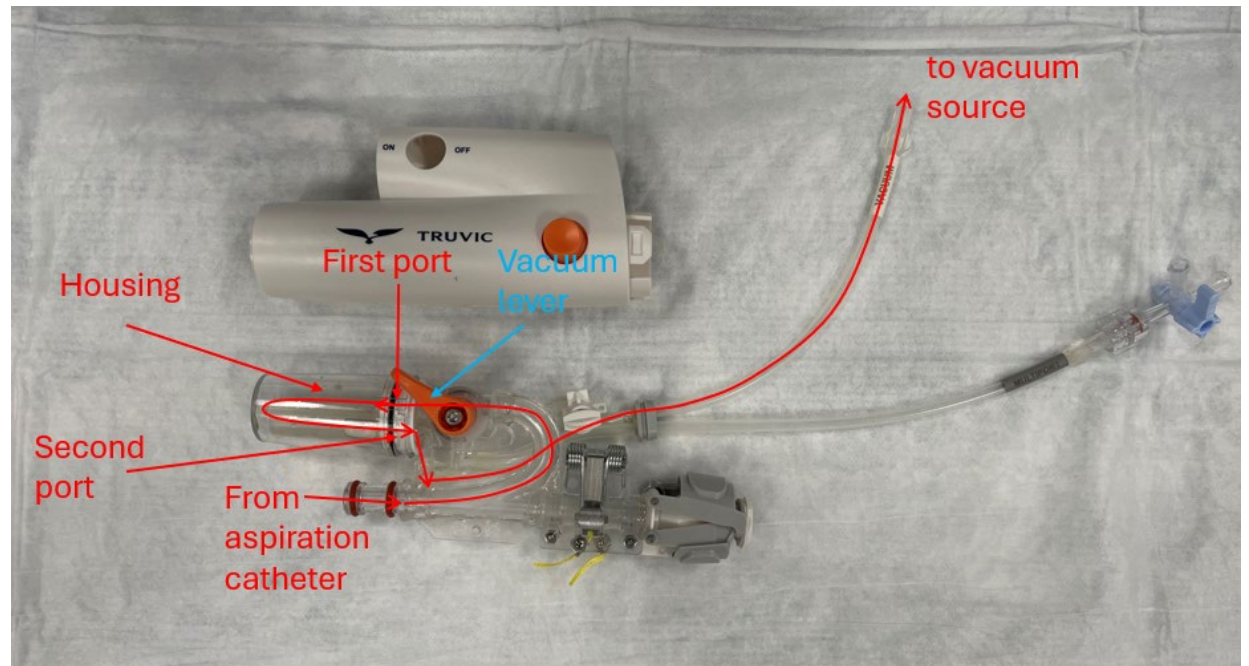
Specifically, the clot collection reservoir of the 24F and 16F Symphony Catheter handles includes a first port proximate to the first housing end portion that is coupled to an aspiration catheter when the valve is in the ON position, as shown in the annotated teardown images below.



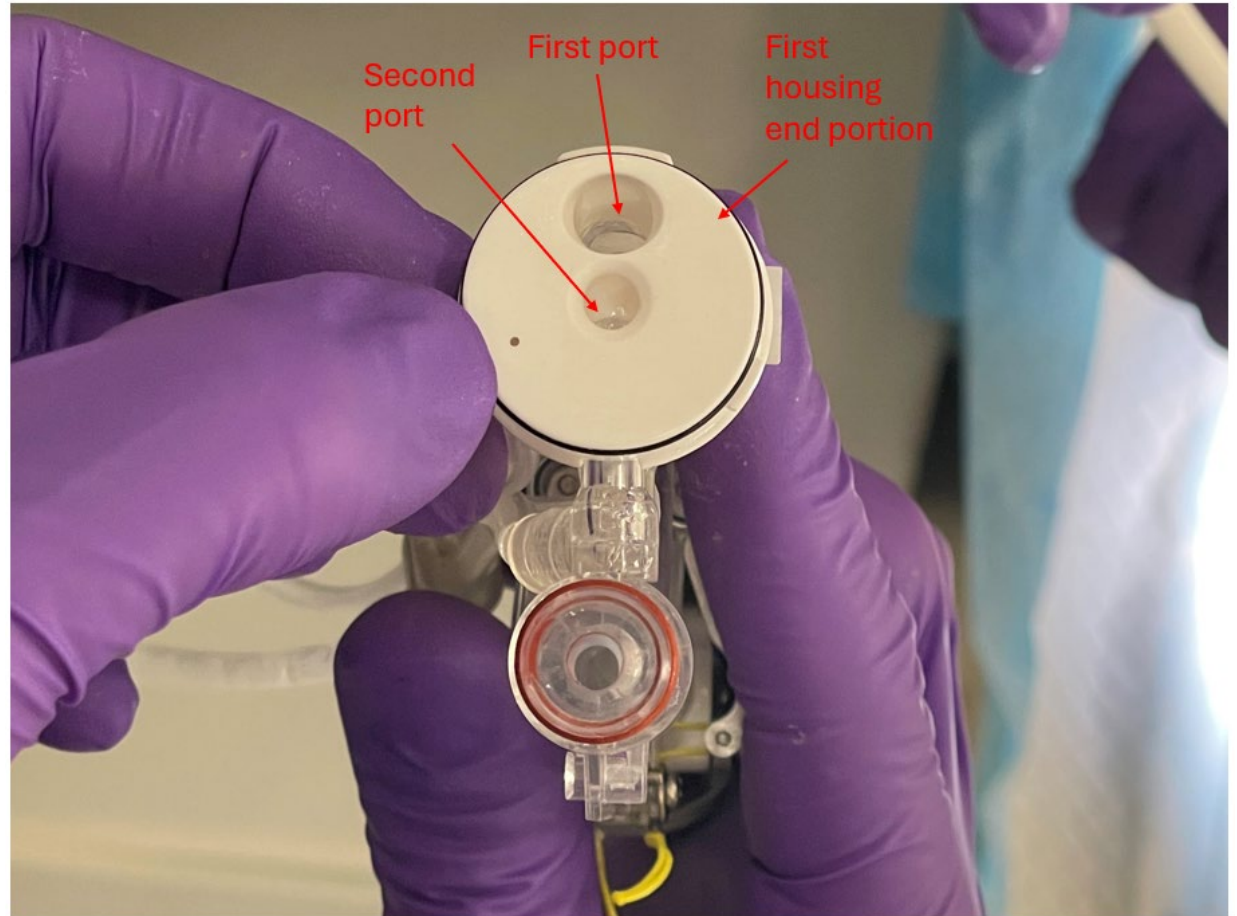
(Annotated image of internal portion of the controller housing.)



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

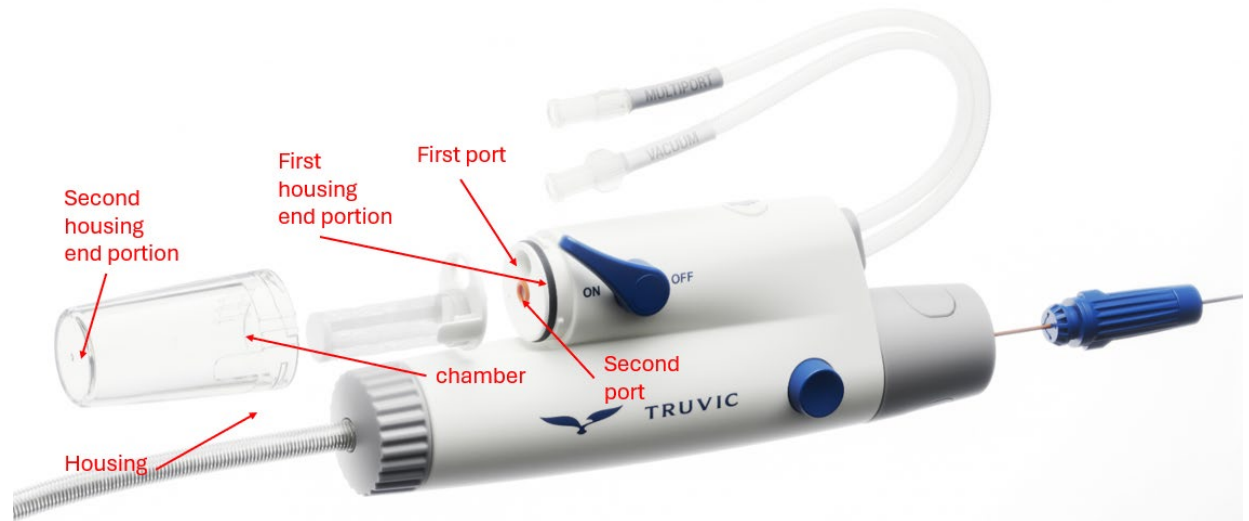


(Annotated image of internal portion of the controller housing.)



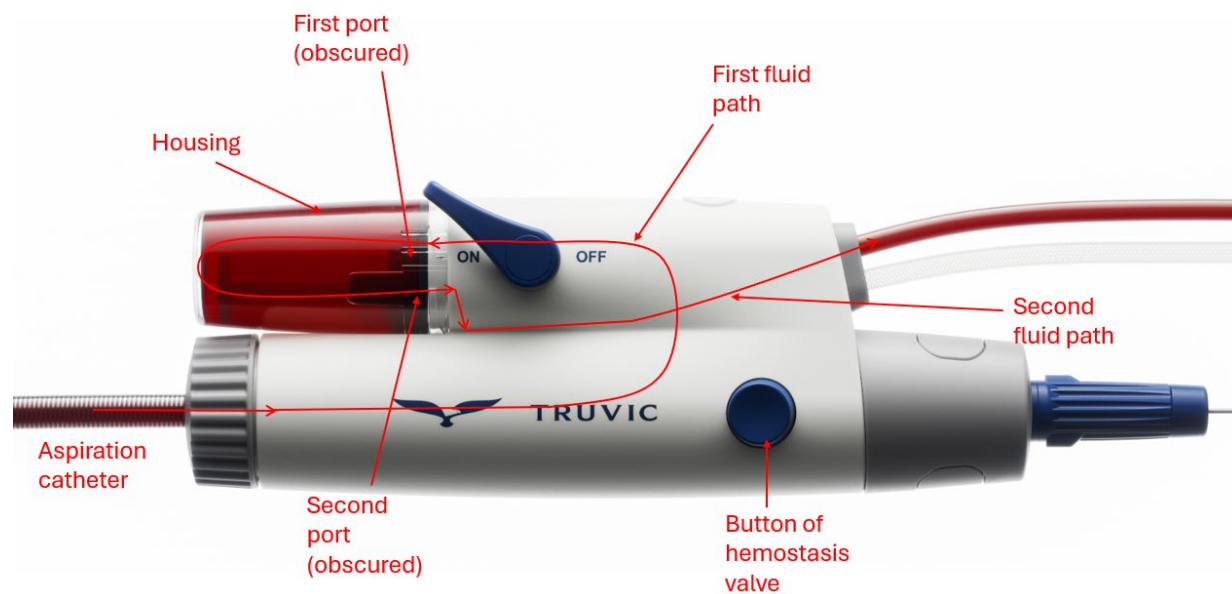
(Annotated image of controller housing showing first and second ports.)

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



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

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

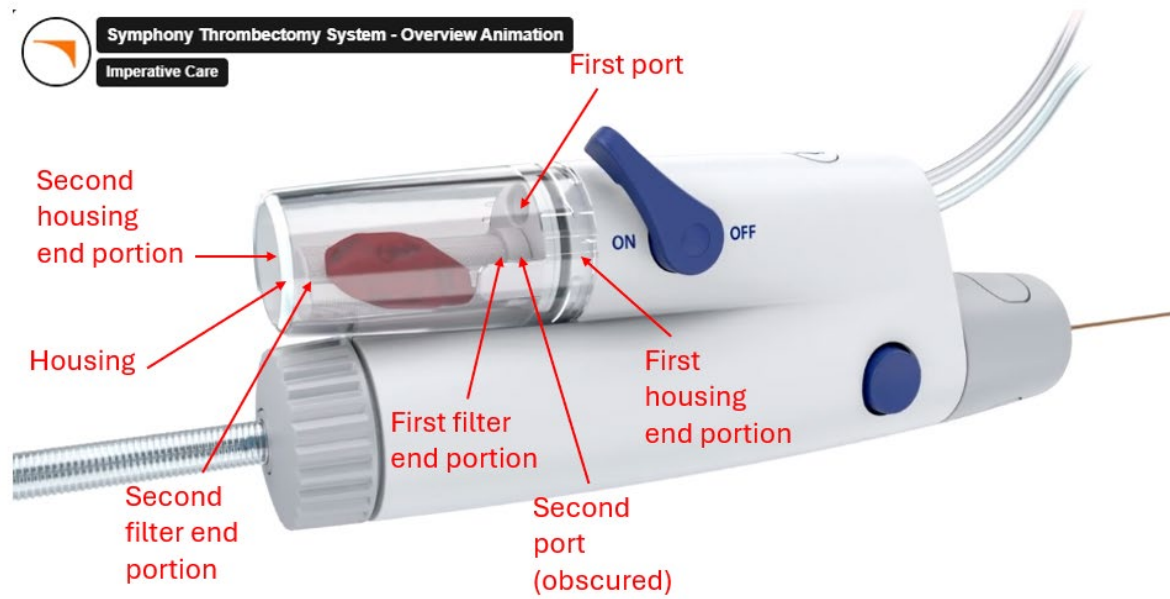


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

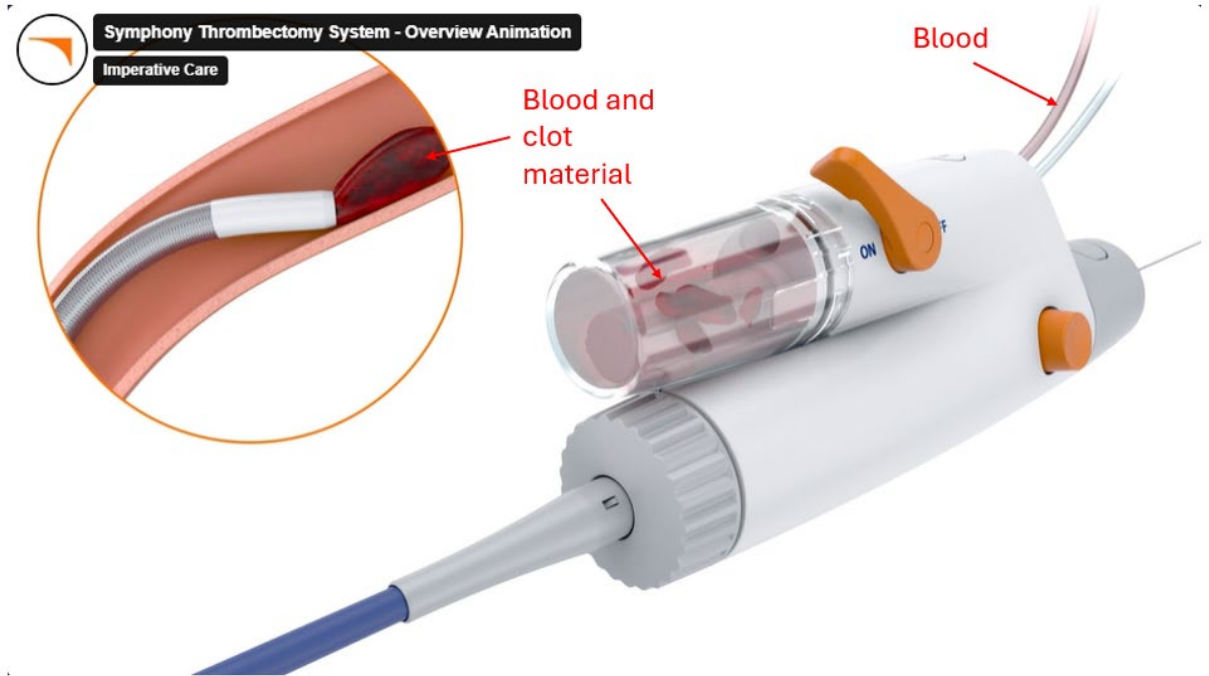
The Symphony Thrombectomy System Overview Animation Video shows that blood and clot material enters the 24F and 16F aspiration catheters, travels through the path of the 24F and 16F Symphony Catheter handles, through the first port, and into the chamber of the clot collection reservoir.



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



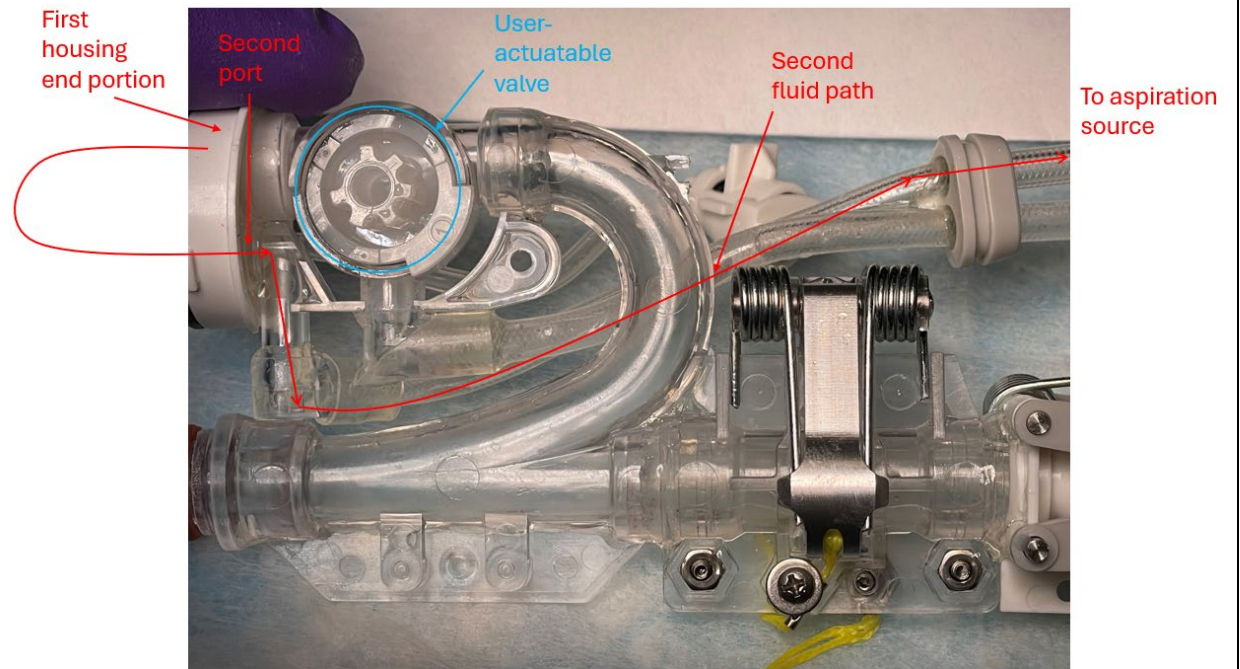
(Annotated Symphony Thrombectomy System – Overview Animation Video at 0:57.)



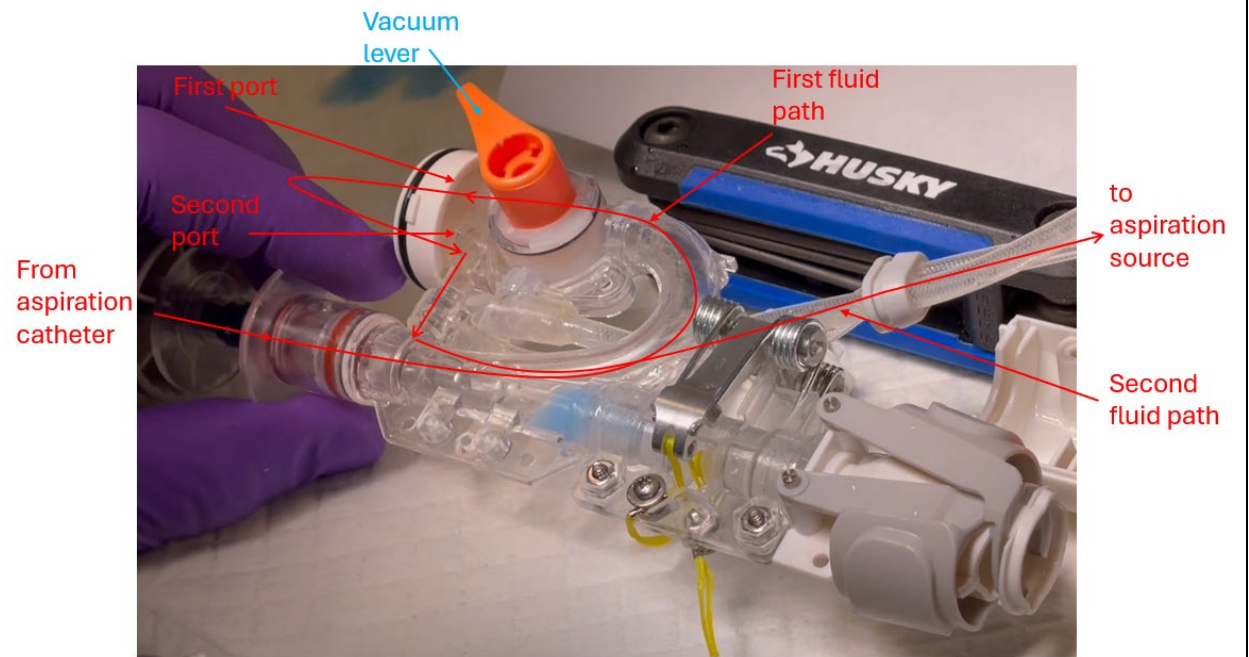
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

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

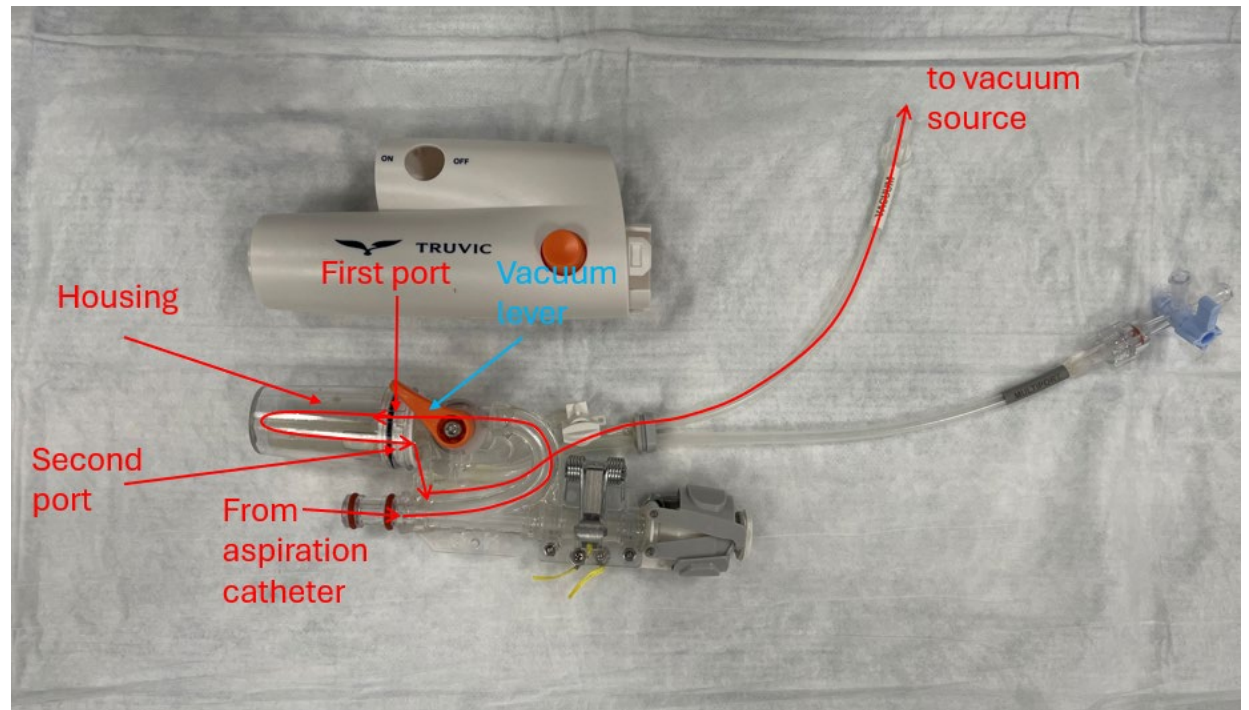
	<p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>a second port configured to be fluidly coupled to the aspiration source; and</p>	<p>The clot collection reservoir of the Symphony System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



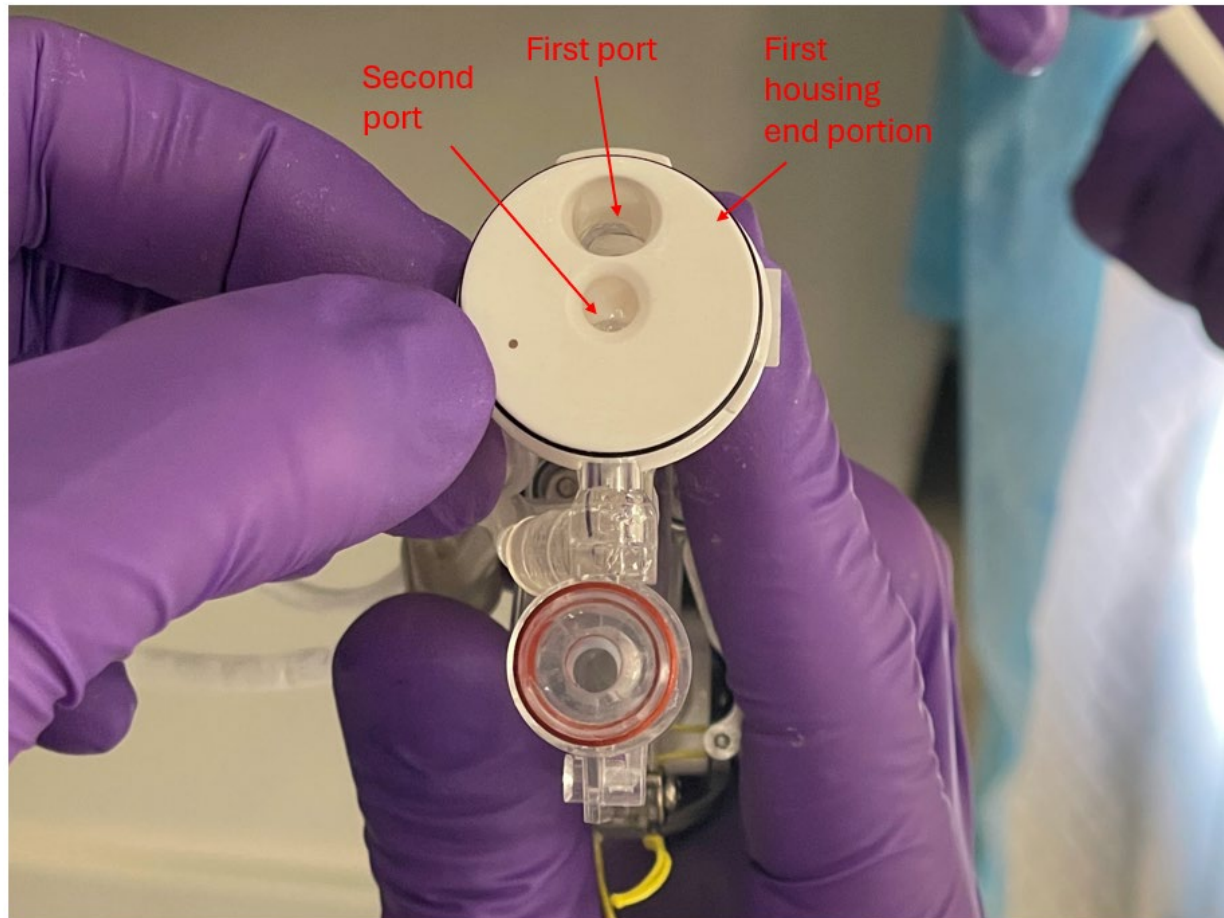
(Annotated image of internal portion of the controller housing.)



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

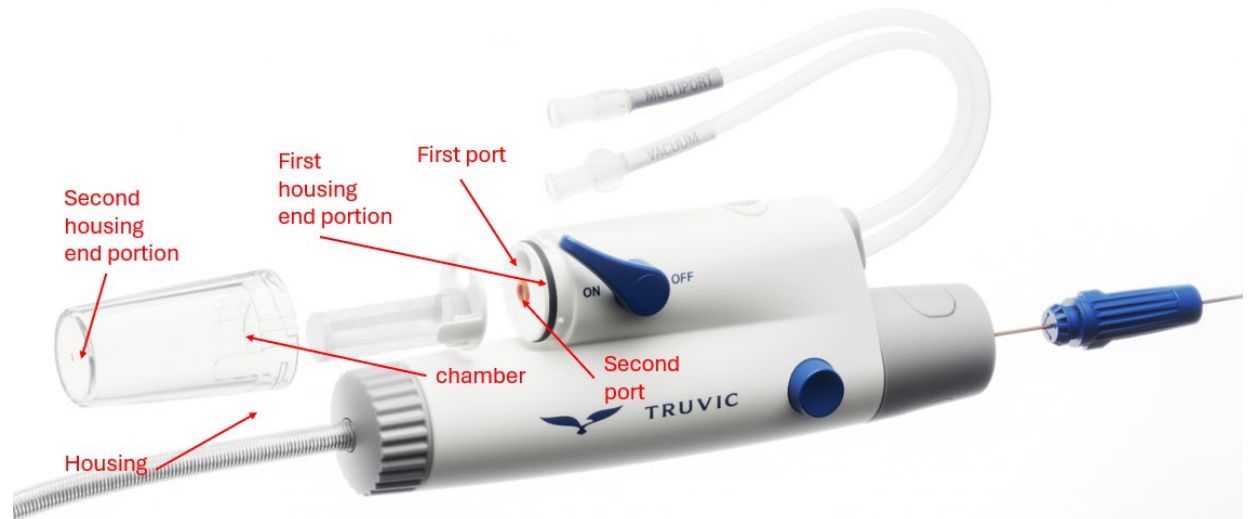


(Annotated image of internal portion of the controller housing.)



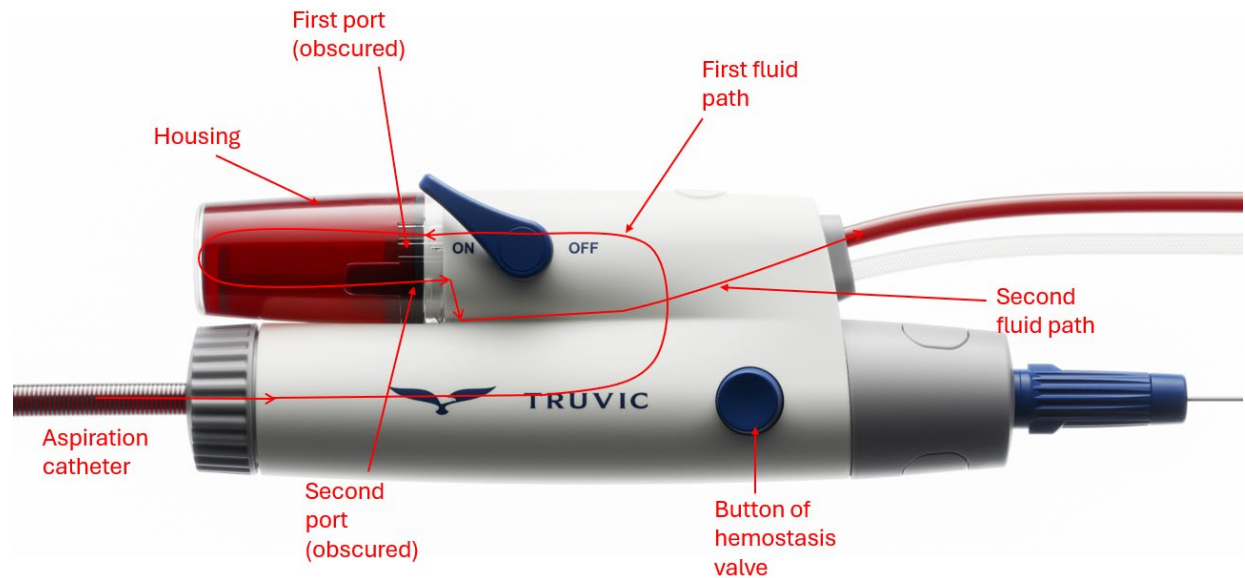
(Annotated image of controller housing showing first and second ports.)

The second port can also be seen in the exploded image from the Whipsaw website of a 24F Symphony Catheter handle with a disassembled clot collection reservoir, which is annotated and reproduced below.



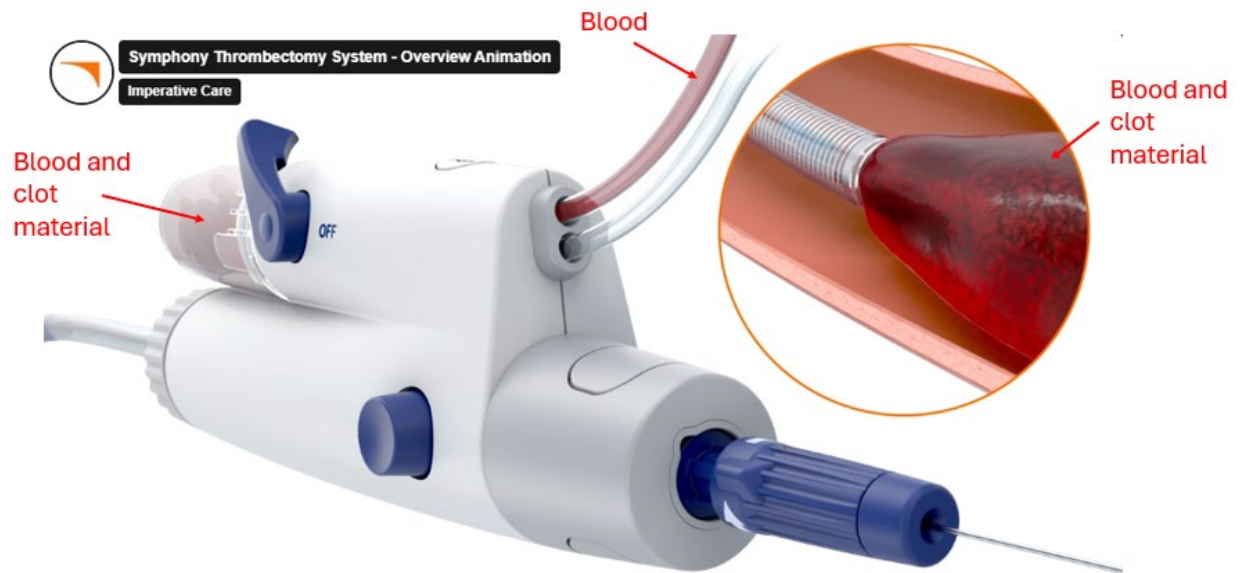
(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

The second port provides a path from the clot container of the 24F and 16F Symphony Catheter handles, as shown in the annotated image from Whipsaw's website below. Specifically, blood and clot material enters the aspiration catheter and travels along the path through the first port and into the chamber of the clot container. Blood then passes through the filter, through the second port and along the path where it flows through tubing internal within the handle toward the TruVid Generator and TruVid Canister (e.g., aspiration source, not shown).

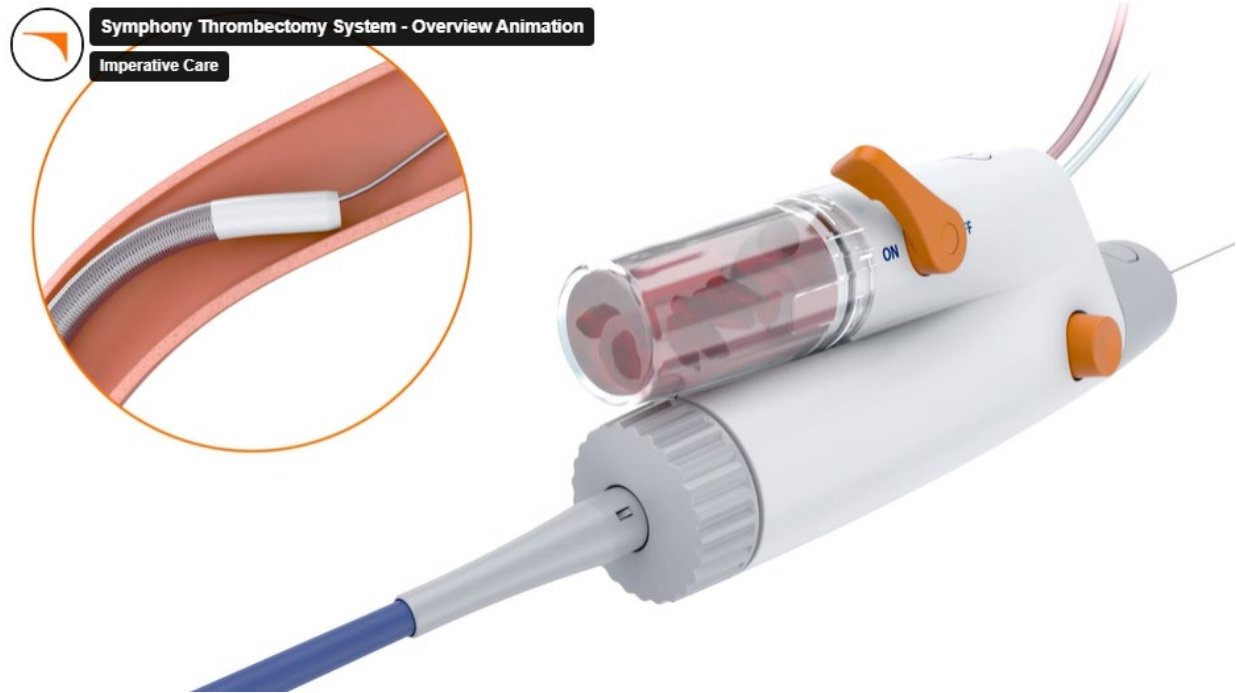


(Annotated image of handle from Whipsaw at <https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>.)

The Symphony Thrombectomy System Overview Animation Video similarly shows that blood and clot material enters the 24F and 16F aspiration catheters, travels through the first fluid path of the 24F and 16F Symphony Catheter handle, through the first port, and into the chamber of the clot container. Blood then flows through the filter, through the second port that provides a second fluid path from the chamber of the clot container towards the tubeset and then toward the aspiration source.



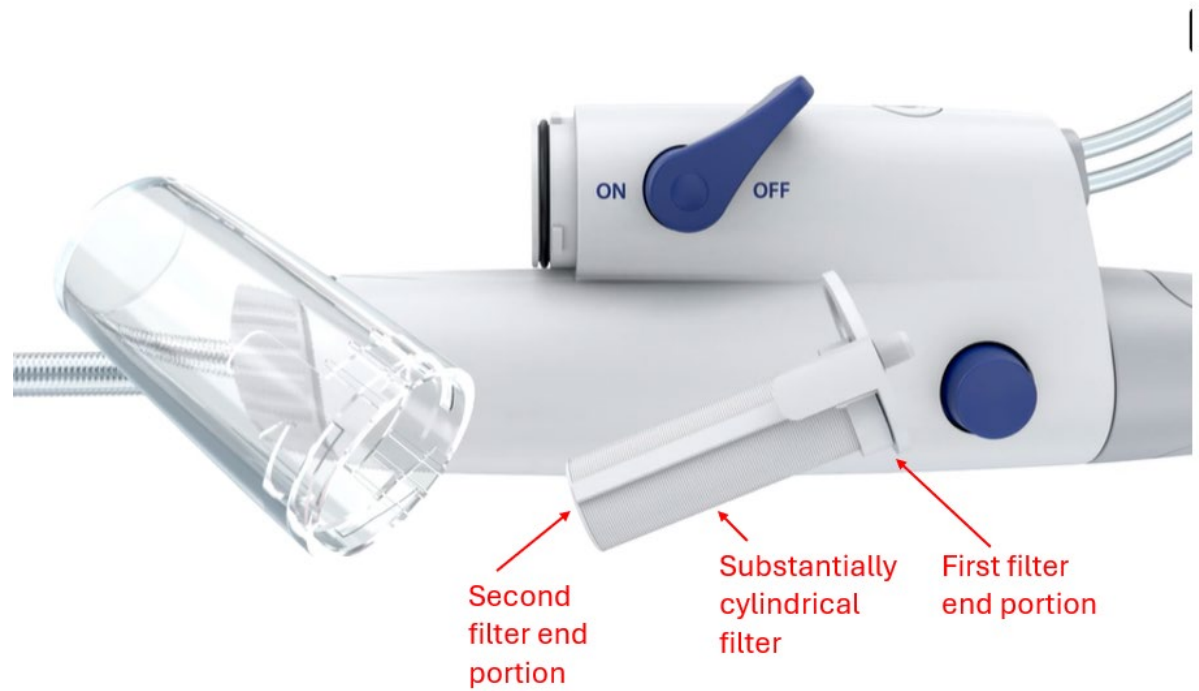
(Symphony Thrombectomy System – Overview Animation Video at 1:09.)



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

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

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

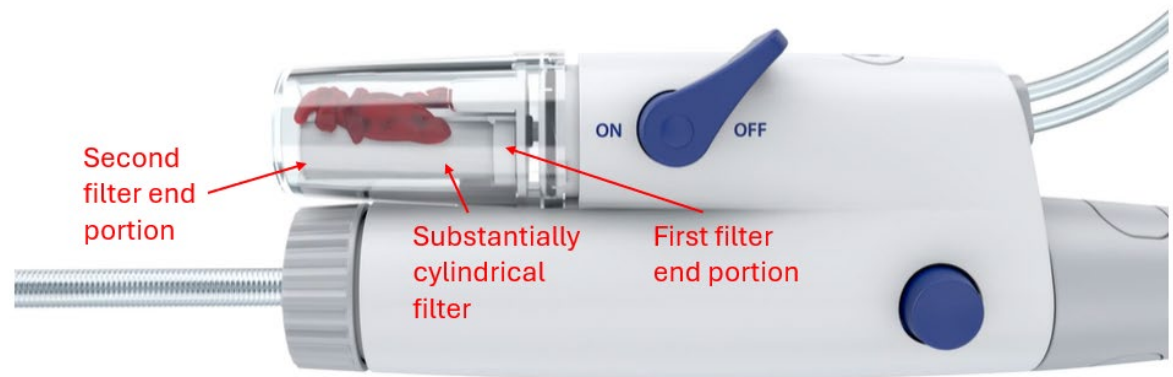


(Annotated Symphony Thrombectomy System – Overview Animation Video at 1:21.)

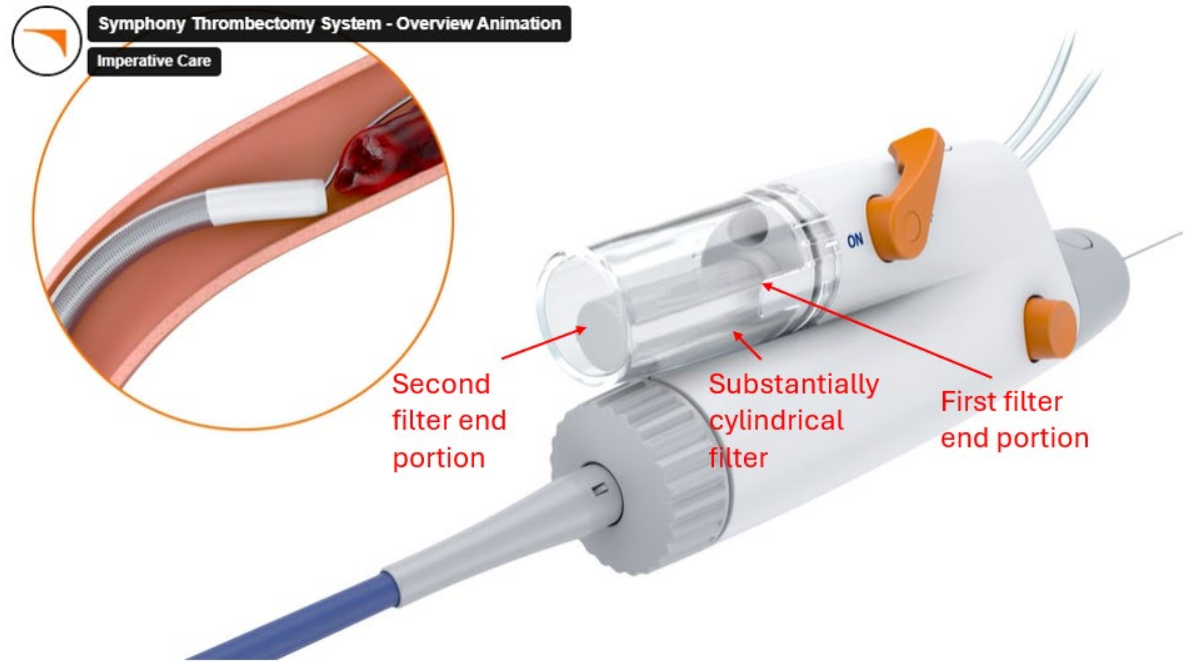


Symphony Thrombectomy System - Overview Animation

Imperative Care

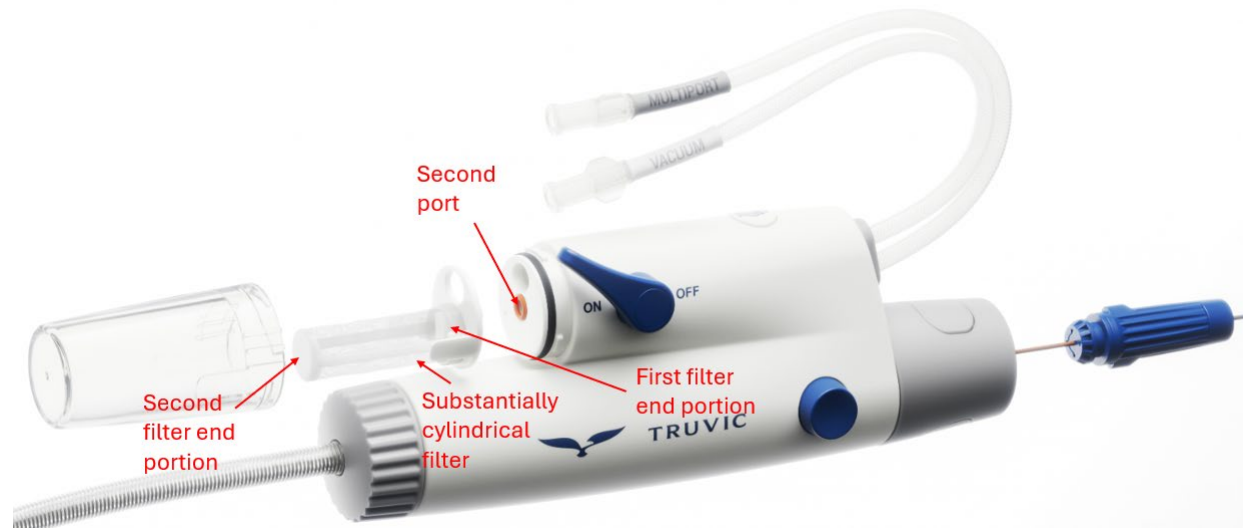


(Symphony Thrombectomy System – Overview Animation Video at 1:18.)



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

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



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

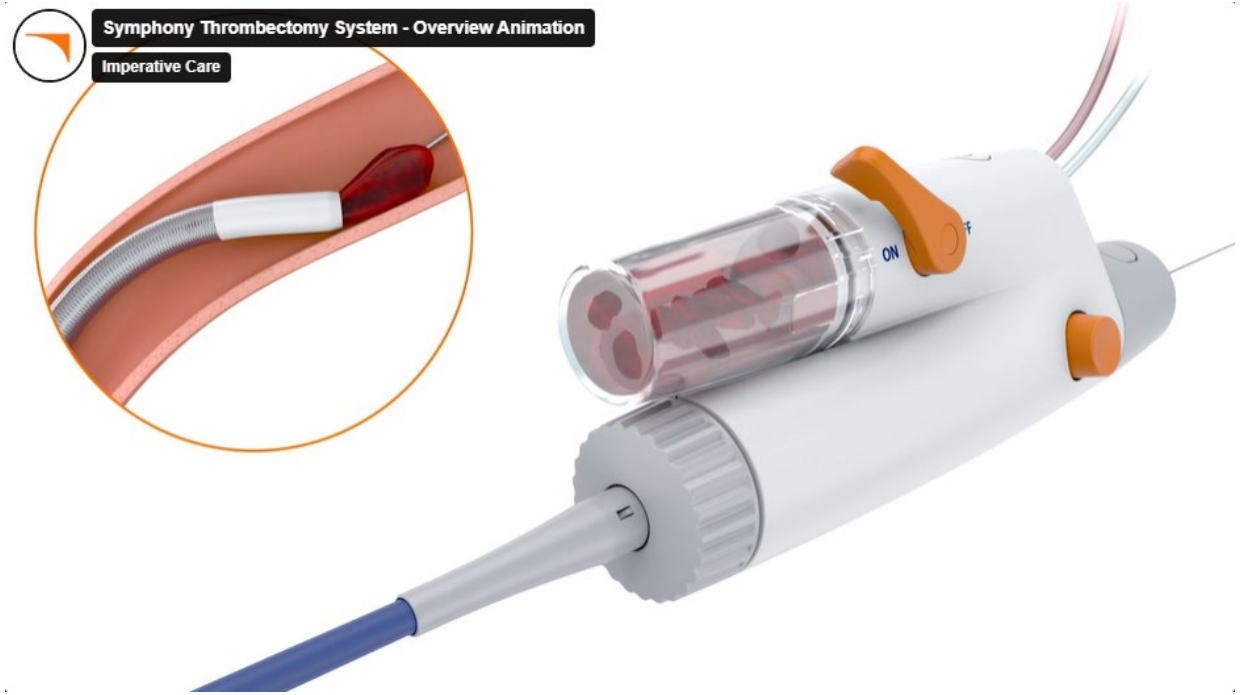
The substantially cylindrical filter encloses an interior region around the second port, such that it prevents clot material from entering the second port. Instead, the filter permits blood to flow through the second port and toward the aspiration source via the second fluid path, as shown in the images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



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



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

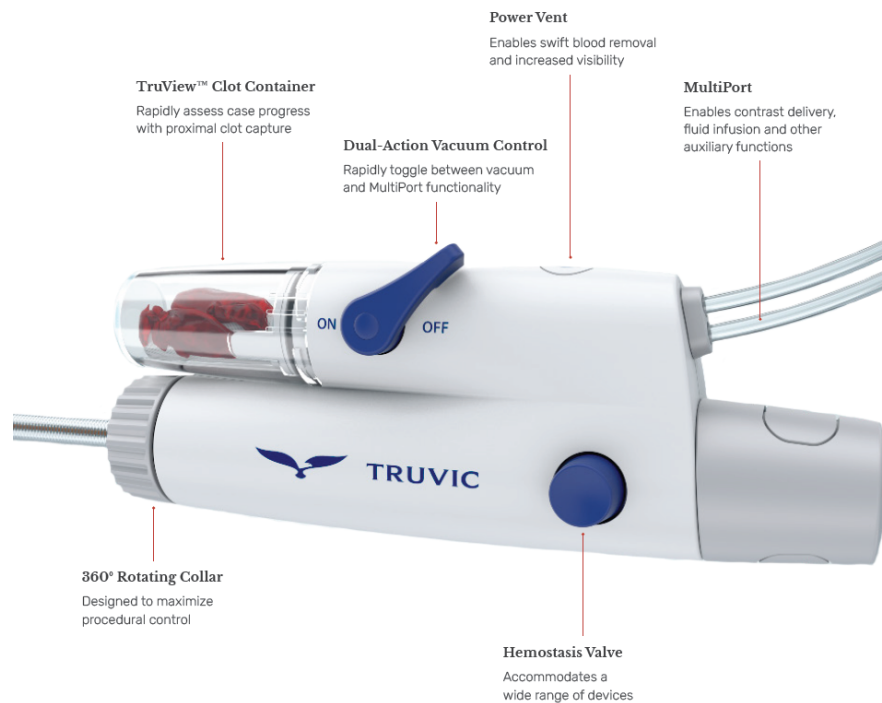


(Symphony Thrombectomy System – Overview Animation Video at 2:03.)

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BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)

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

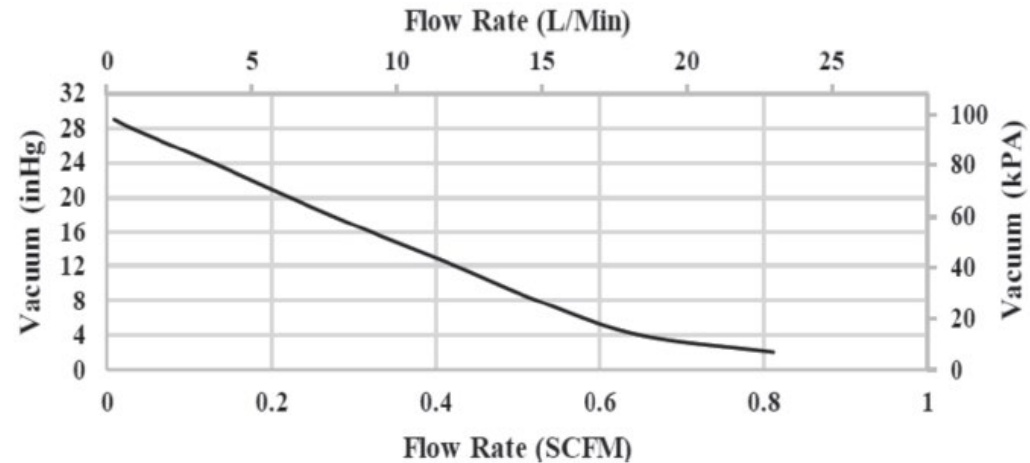
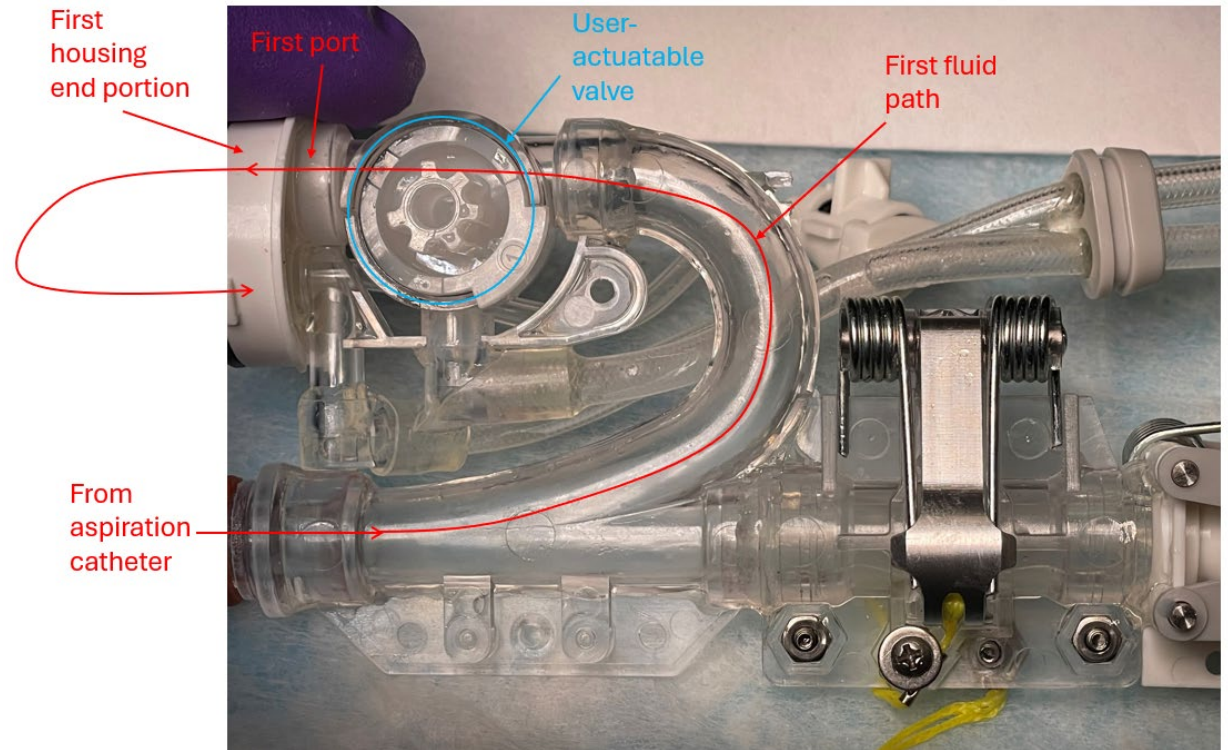


Figure 2 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator

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

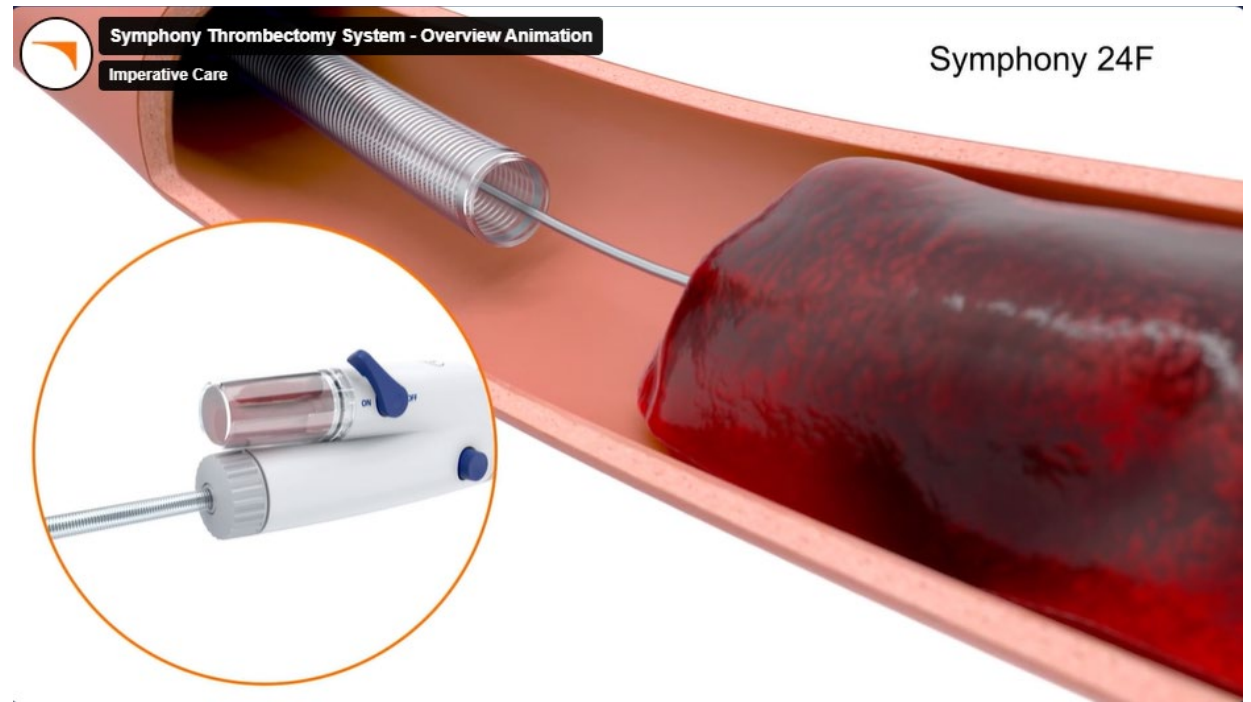
When negative pressure is generated in the chamber of the clot container by the aspiration source (e.g., Truvic Generator and Truvic Canister) and then the vacuum lever is turned to on to connect the aspiration catheter, it causes blood and clot material to be drawn from the human patient, through the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

	<p>position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the ‘OFF’ position.”); Symphony Thrombectomy System Instructions For Use at 8 (“Turn on the Generator and ensure that the Generator gauge reads -20 inHg or greater vacuum (refer to TRUVIC Generator IFU).... Confirm tip of the 16F Symphony Catheter is in the desired location under fluoroscopy. To begin aspiration, move the vacuum lever on the 16F Handle to the ‘ON’ position. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the 16F Handle to the ‘OFF’ position.”).)</p> <p>The flow path of the blood and clot material (<i>i.e.</i>, from the aspiration catheter and through the first port into the chamber) is shown in the annotated teardown image below.</p>
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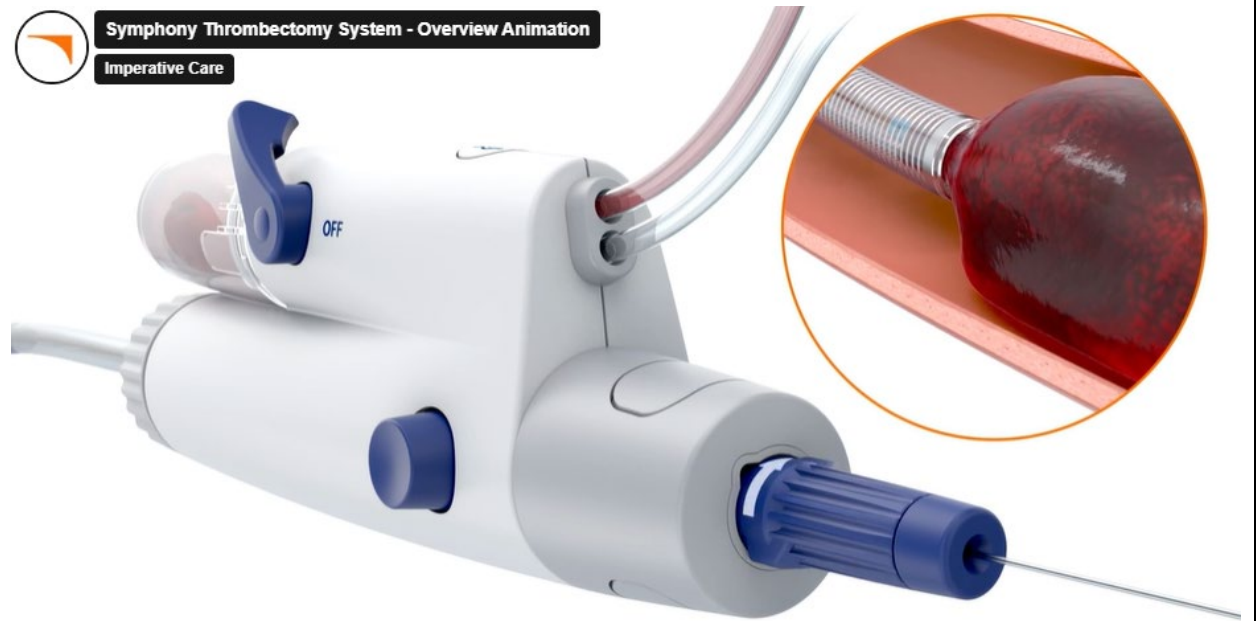


(Annotated image of internal portion of the controller housing.)

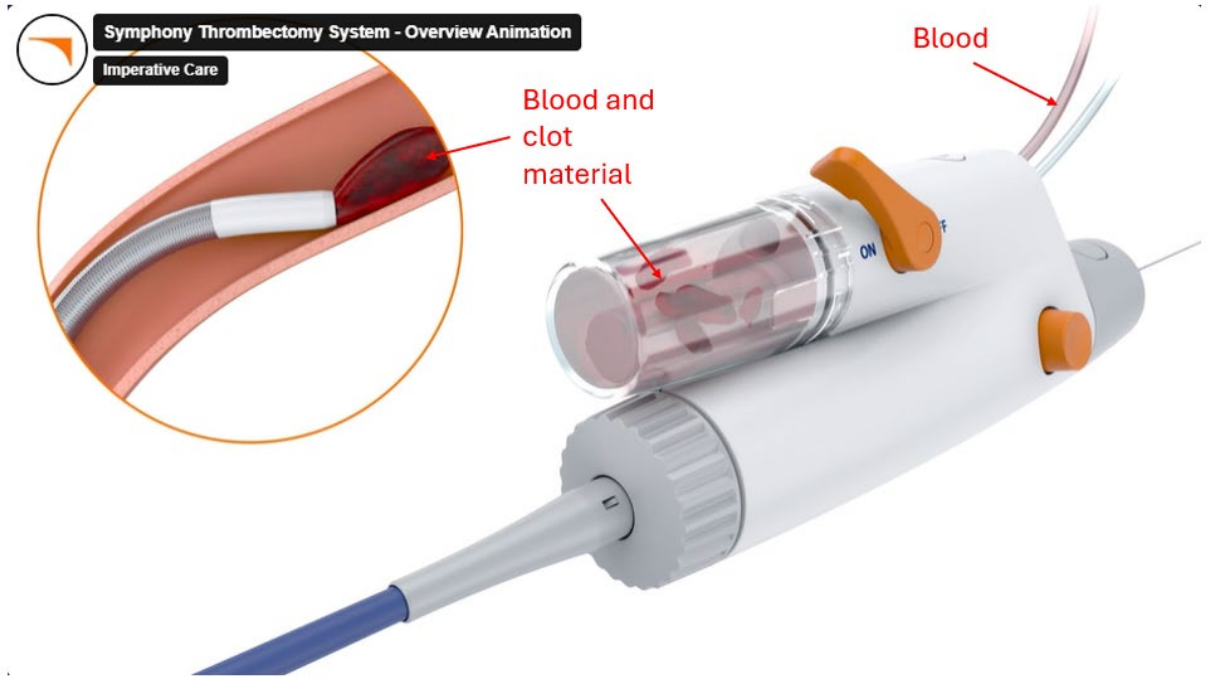
The Symphony Thrombectomy System Overview Animation Video also depicts blood and clot material flowing from the aspiration catheter, through the first port, and into the chamber of the clot container.



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

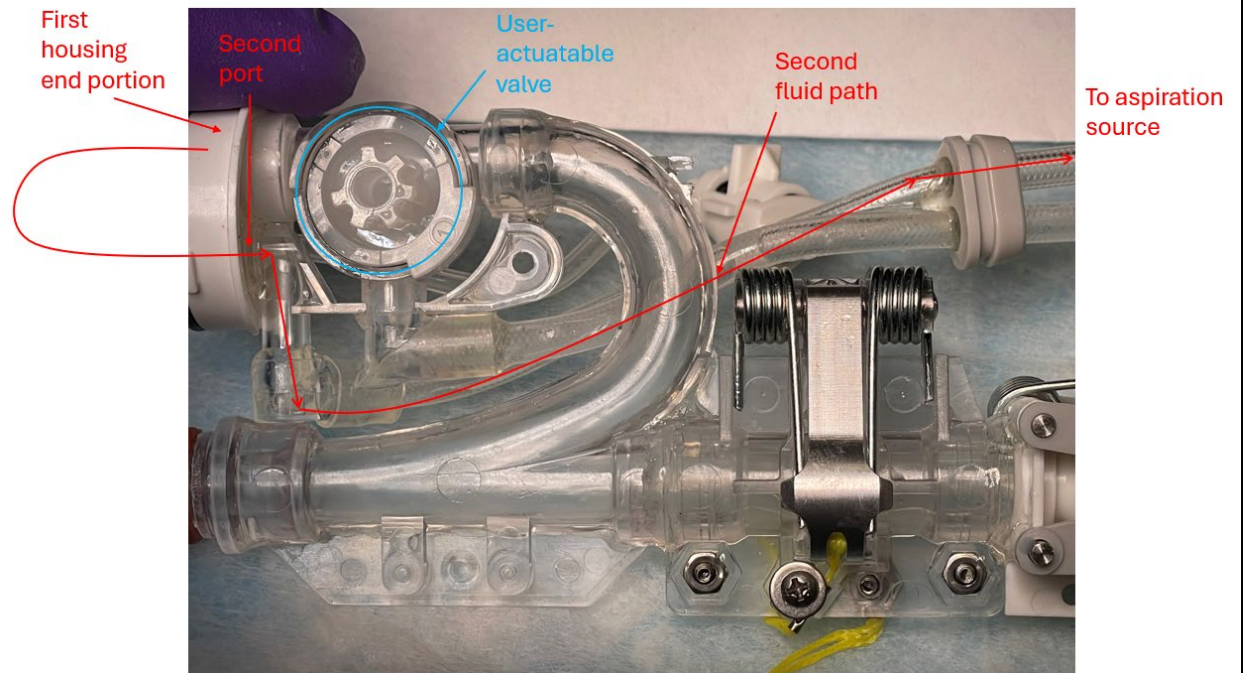


(Symphony Thrombectomy System – Overview Animation Video at 1:05.)



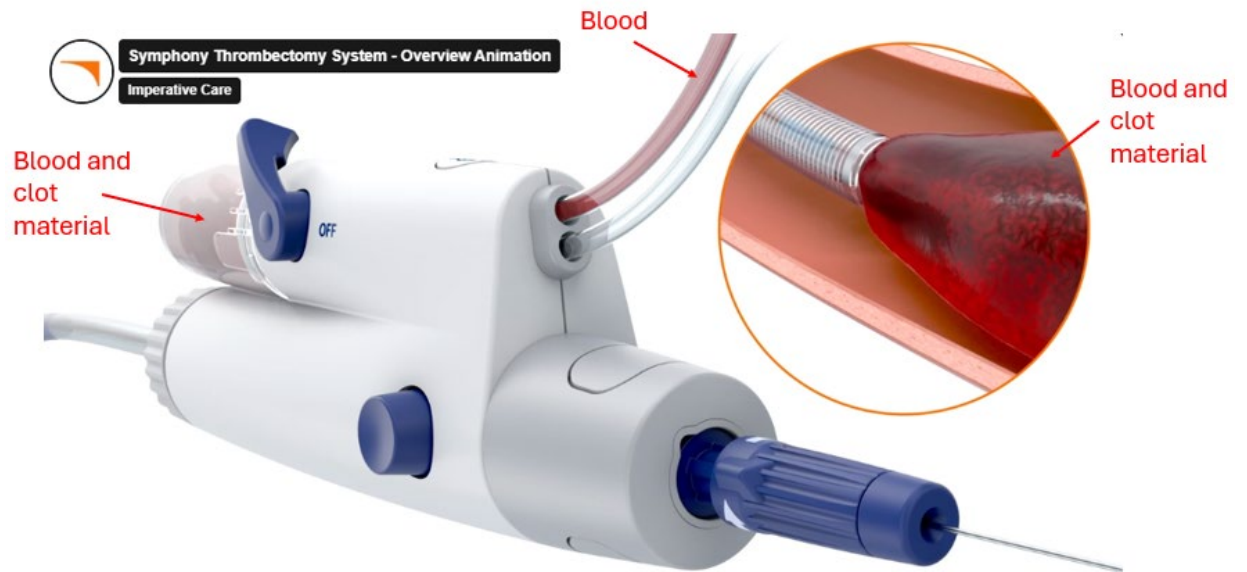
(Symphony Thrombectomy System – Overview Animation Video at 2:02.)

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

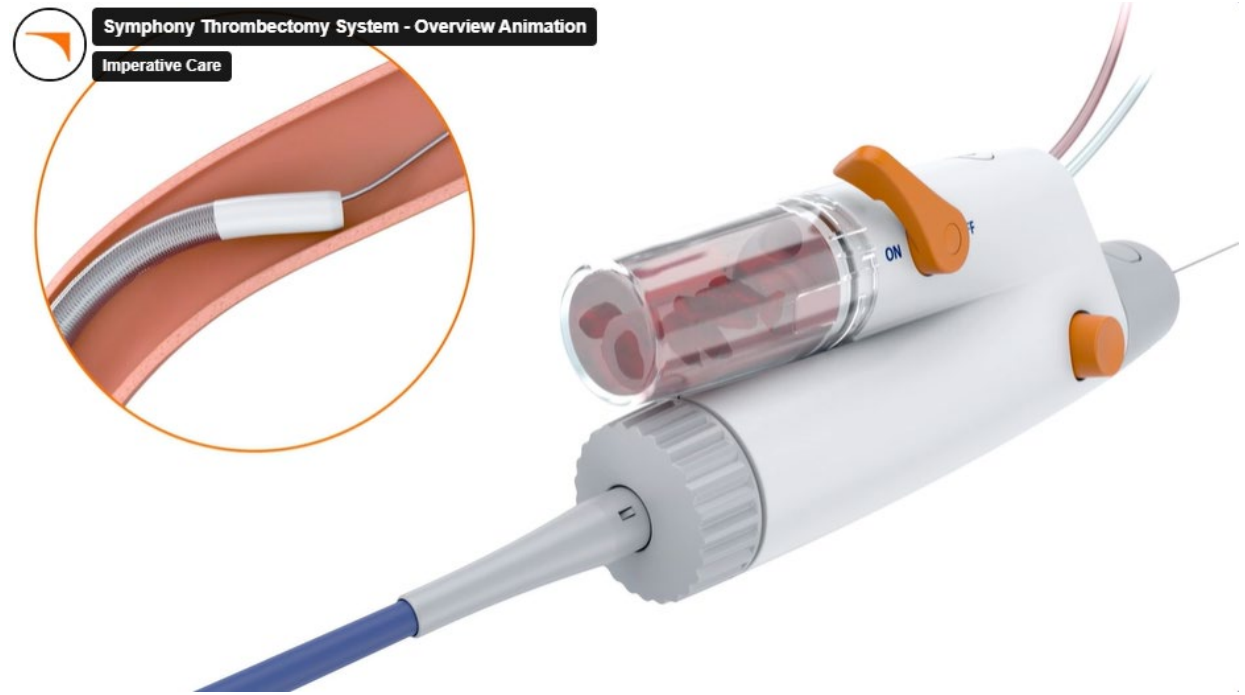


(Annotated image of internal portion of the controller housing.)

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



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



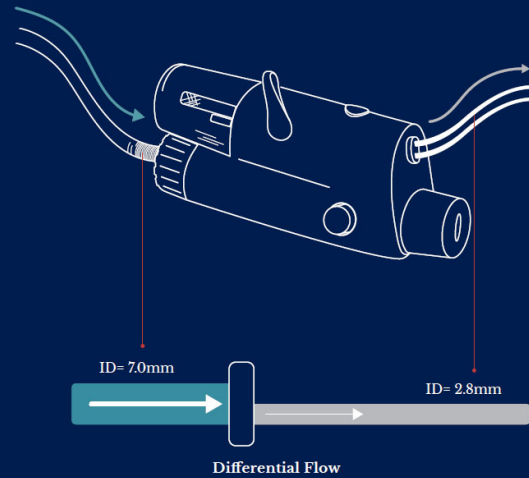
(Symphony Thrombectomy System – Overview Animation Video at 2:03.)

The Symphony Thrombectomy System Brochure also shows the flow of clot and blood into the chamber and shows blood flowing out of the chamber.

On-Demand Vacuum with Integrated Blood Management

Balance power with control and minimize blood loss with built-in differential flow. Clot capture in the palm of your hands provides real-time case assessment.

The Symphony™ Advantage



Blood flowrate reduced by

~55%

* Data on File

BigShot™ Controller

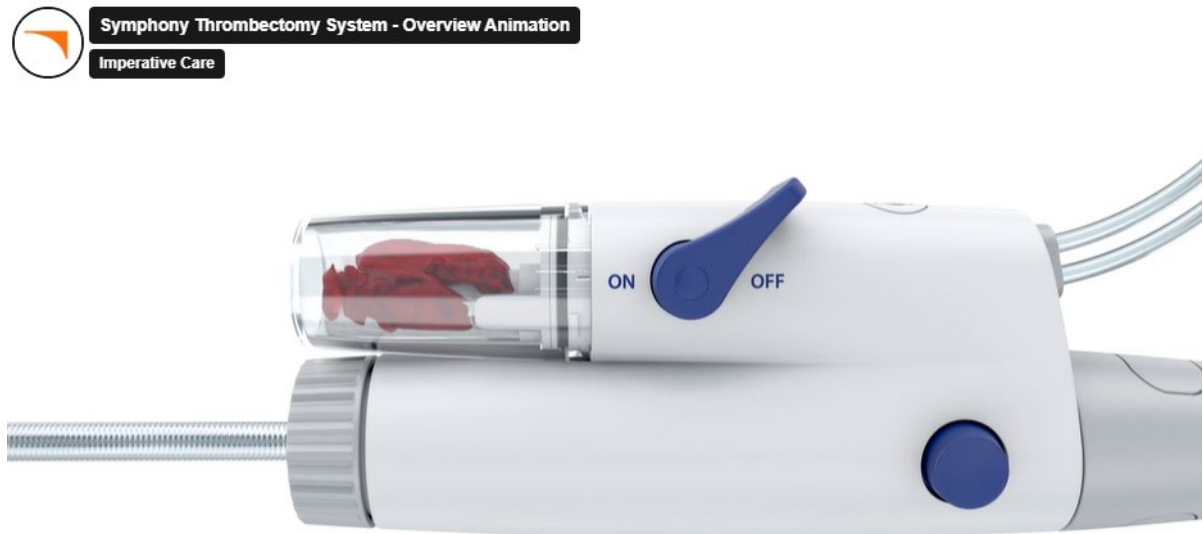
(Symphony Thrombectomy System Brochure at 7.)

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

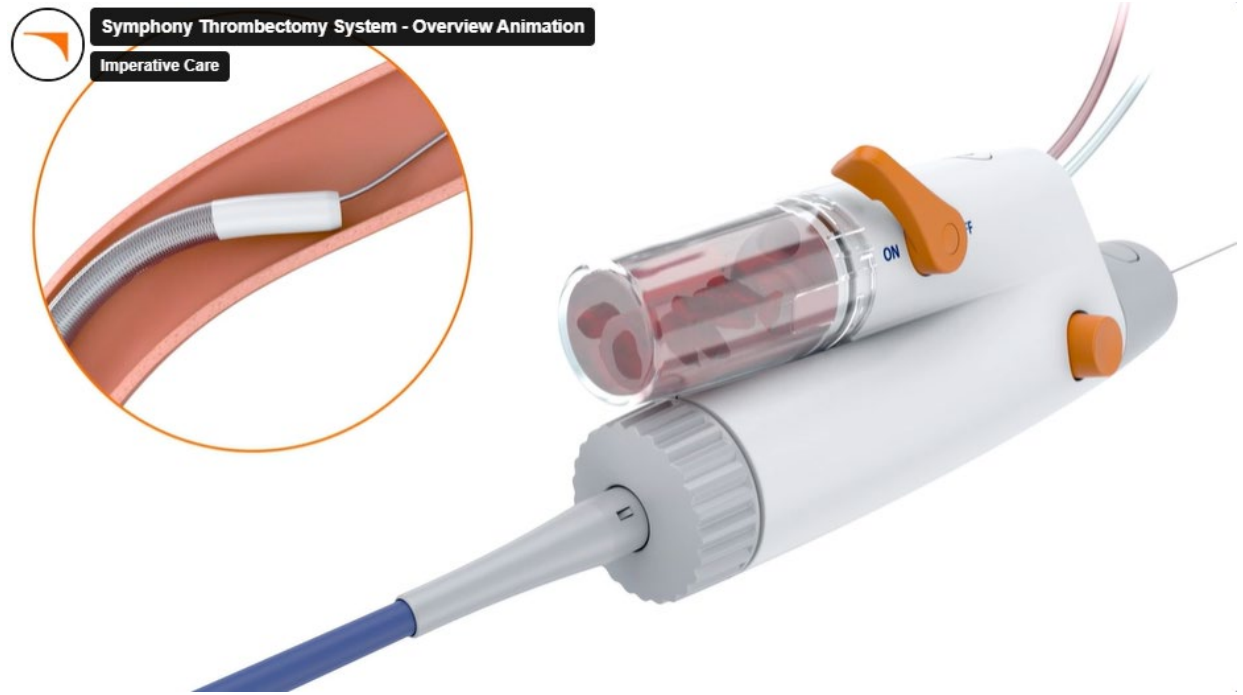
wherein the filter is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.

The clot collection reservoir of the Symphony System includes a filter that is configured to inhibit the clot material from passing through the filter into the interior region and through the second port.

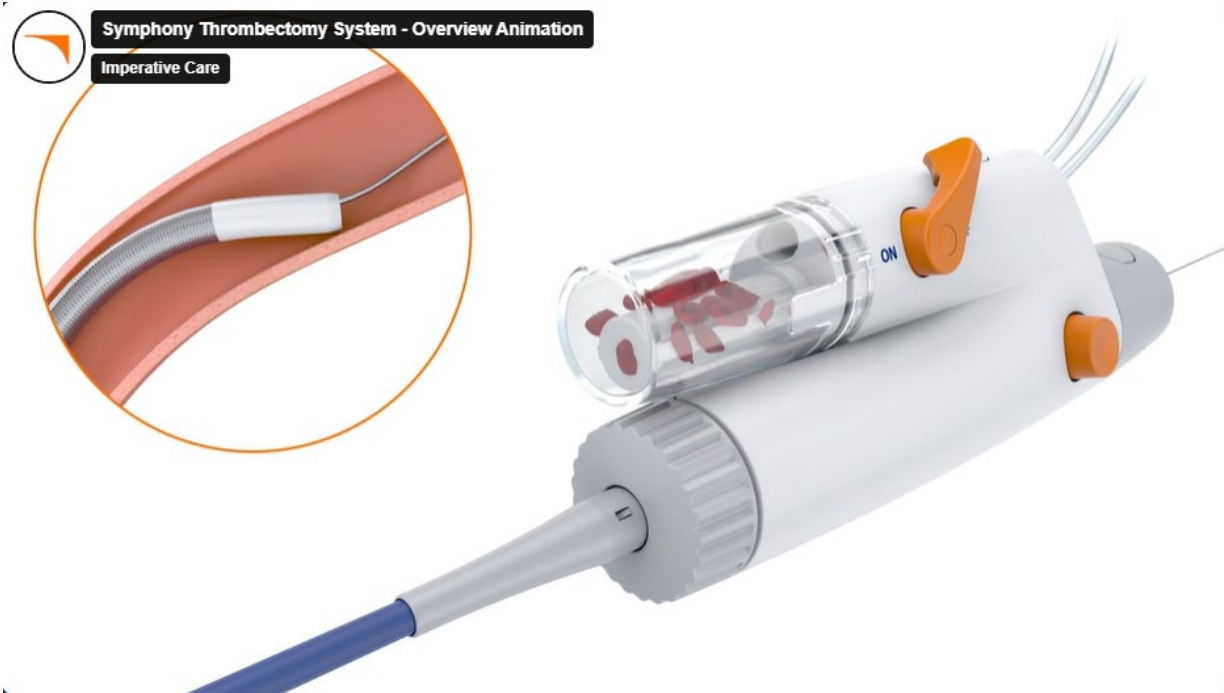
Specifically, as shown in the images from the Symphony Thrombectomy System Overview Animation Video, the filter of the clot container of the 24F and 16F Symphony Catheter handles is configured to and does inhibit clot material from passing through the filter, into its interior region, and through the second port, thus trapping clot material in the chamber of the clot container.



(Symphony Thrombectomy System – Overview Animation Video at 1:16.)



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



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

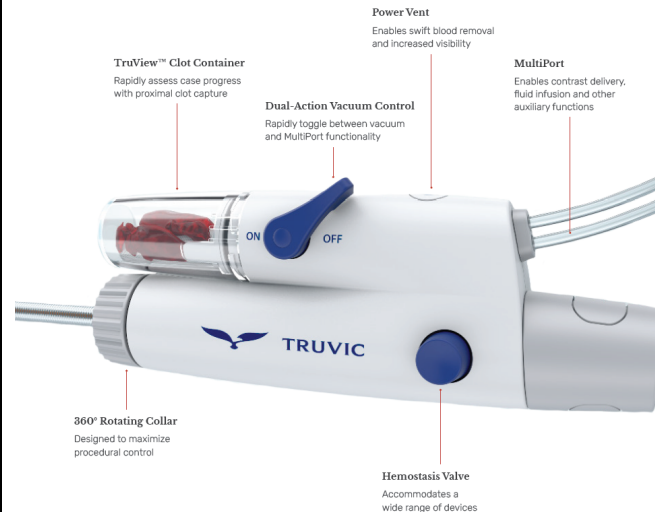
The Symphony System IFU confirms that the filter inhibits clot material from flowing into its interior, and instead allows for blood to flow through its interior and through the second port. (Symphony Thrombectomy System Instructions For Use at 5, 8.) Physical inspection of the Symphony System’s filter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

The Symphony Thrombectomy System Brochure also depicts clot material remaining in the chamber of the clot container so that the physician or user can view the clot and assess progress.

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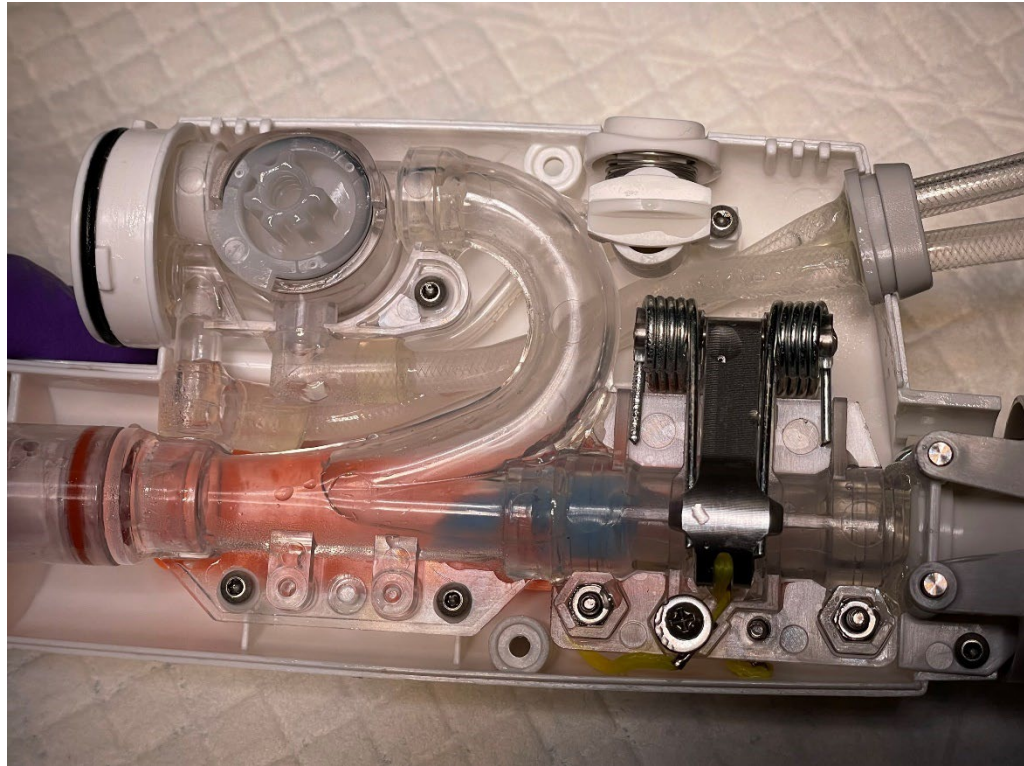
BigShot™ Controller



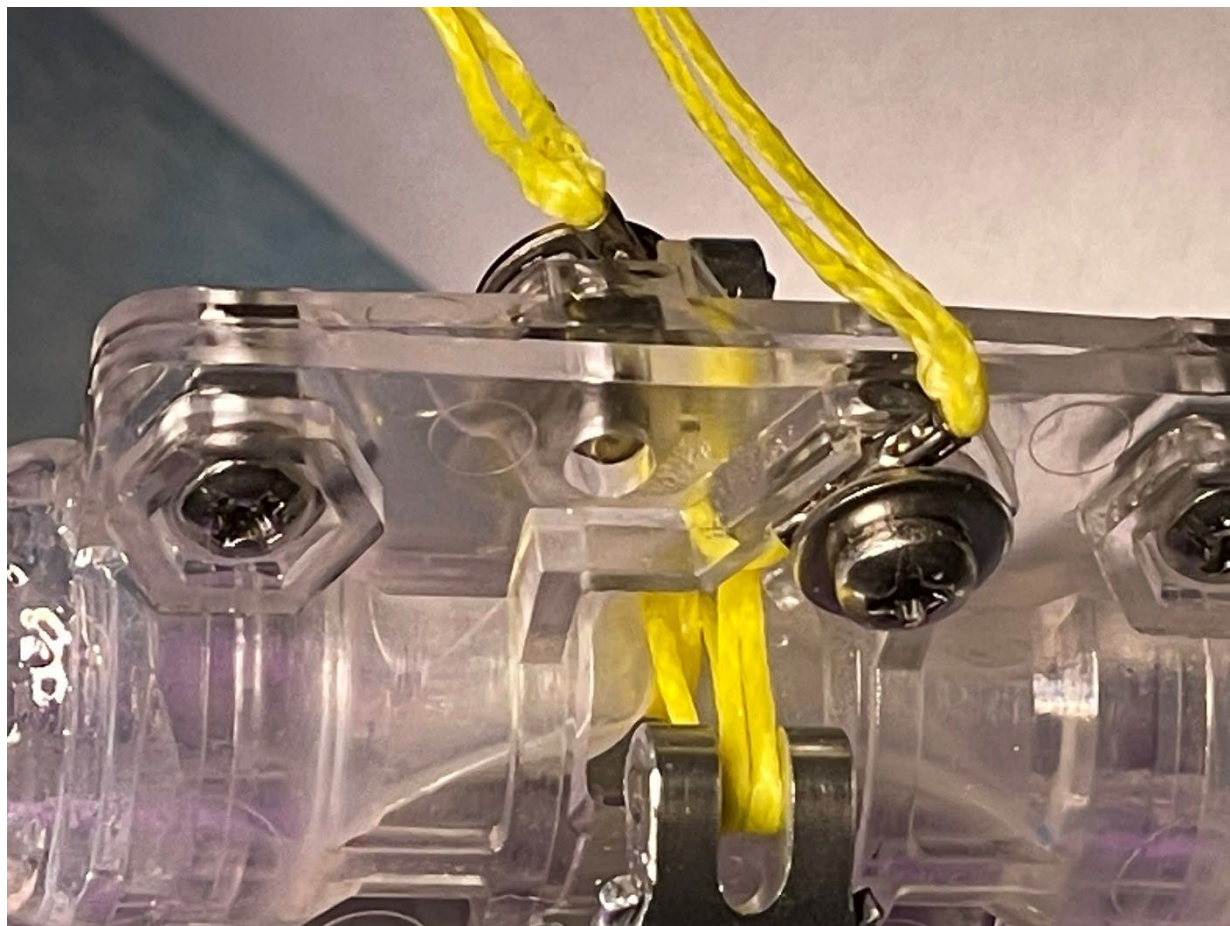
(Symphony Thrombectomy System Brochure at 6.)

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

<p>[18] The clot treatment system of claim 17 wherein the hemostasis valve comprises:</p>	<p>The Symphony System includes a hemostasis valve.</p> <p>Specifically, the hemostasis valve of the 24F and 16F Symphony Catheter handles 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 valve has a first actuator and a second actuator 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.</p> <p>The 24F and 16F Symphony Catheter Handles include a hemostasis valve, as shown in the teardown images below.</p>
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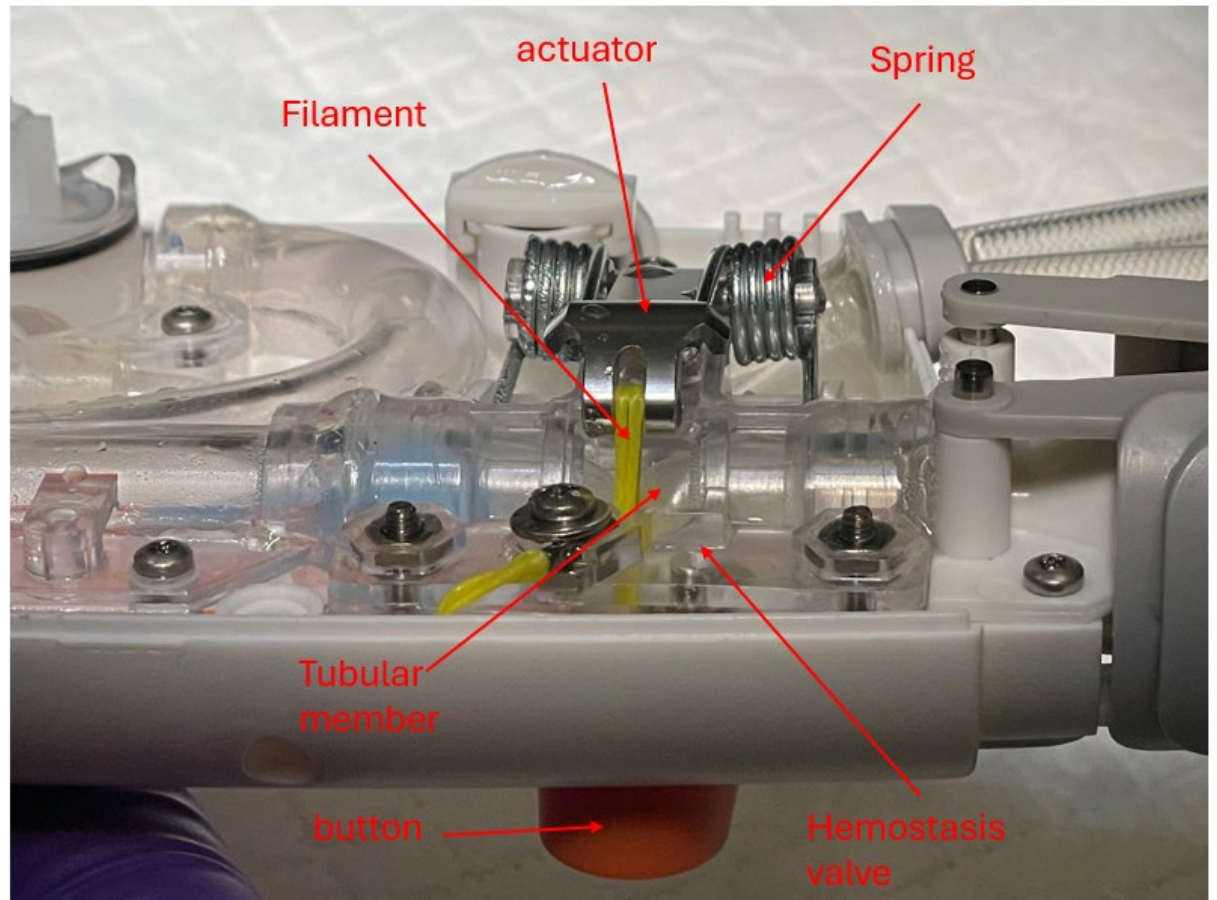
(Annotated image of internal portion of the controller housing.)



(Image of internal portion of the controller housing, focusing on hemostasis valve.)



(Image of internal portion of the controller housing, focusing on hemostasis valve.)



(Annotated image of internal portion of the controller housing, focusing on hemostasis valve.)

The Symphony System IFU shows the outer shell of the Symphony Catheter handles, which includes a button for the Handle's hemostasis valve.

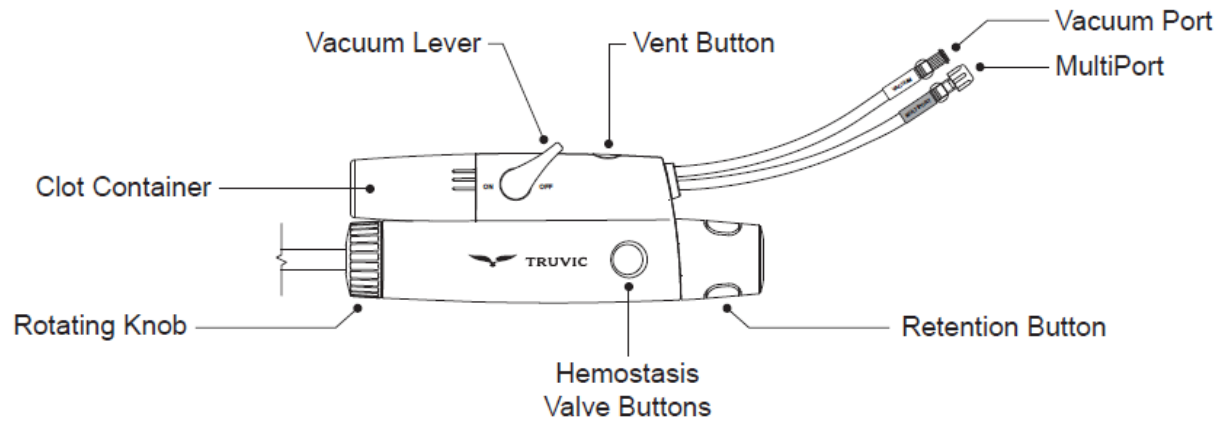


Figure 3: Symphony Catheter Handle, labeled

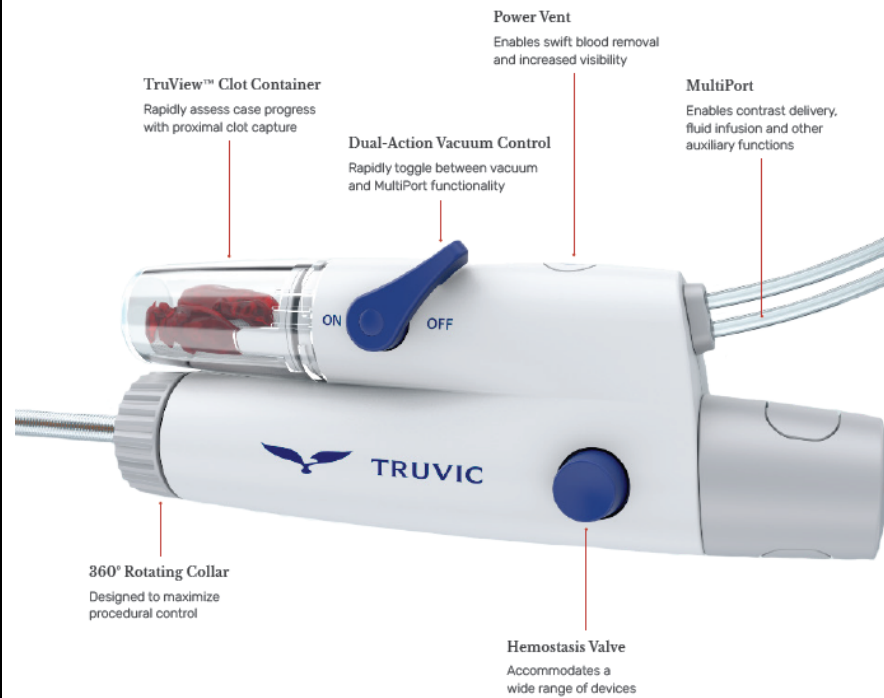
(Symphony Thrombectomy System Instructions For Use at 4; *see also* Symphony Thrombectomy System Instructions For Use at 2 (“Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device”).)

The Symphony Thrombectomy System Brochure similarly shows that the 24F Symphony Catheter handle includes a Hemostasis Valve.

SYMPHONY™ THROMBECTOMY SYSTEM

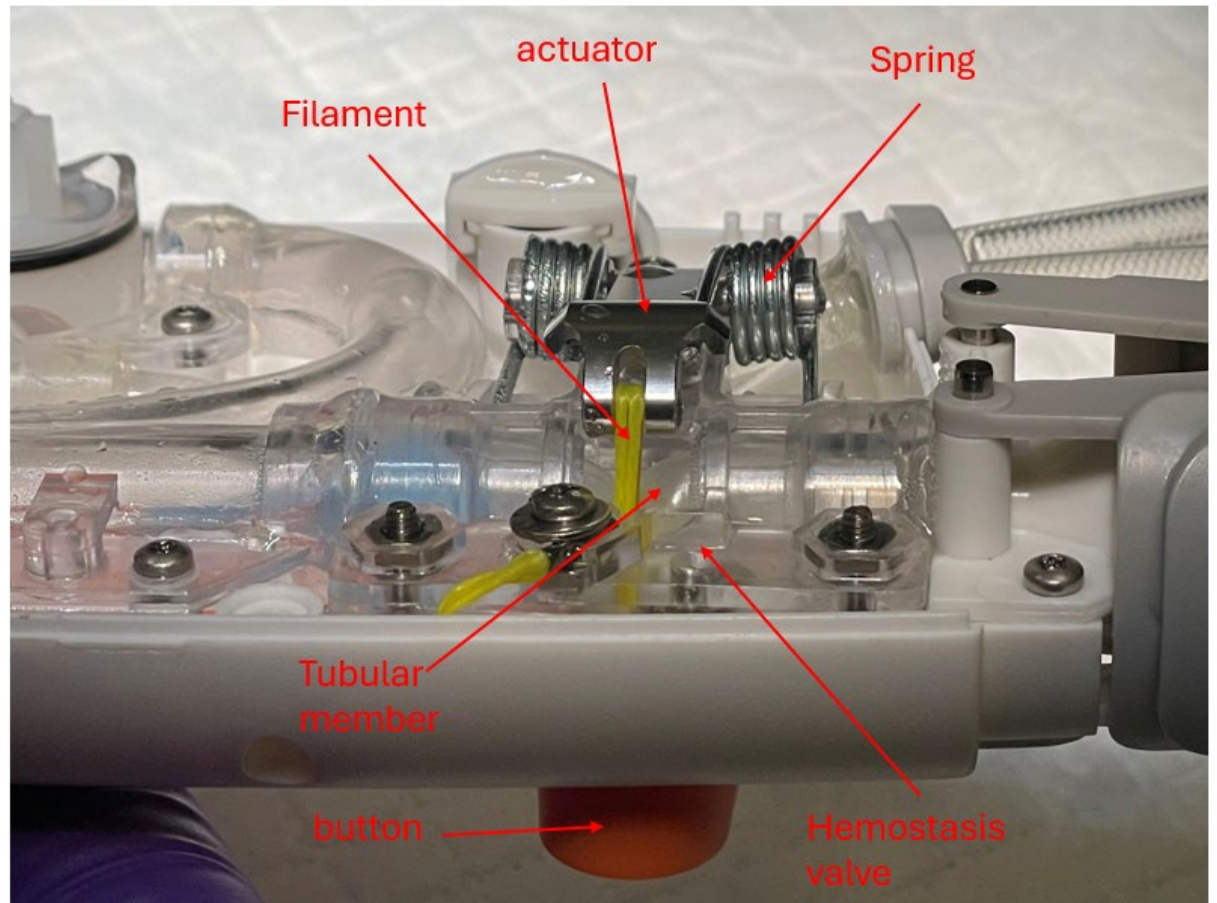
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(Symphony Thrombectomy System Brochure at 6.)

	<p>The Whipsaw website also confirms that the 24F and 16F Symphony Catheter handle includes a hemostasis valve. (https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system (“This handheld tool includes several innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a multifunction port for injecting medicine or contrast or measuring blood pressure, and a connection to a high-power vacuum source.”)).</p>
a tubular member;	<p>The Symphony System includes a hemostasis valve with a tubular member.</p> <p>Specifically, the 24F and 16F Symphony Catheter handles include a hemostasis valve with a tubular member, as shown in the annotated teardown images below.</p>

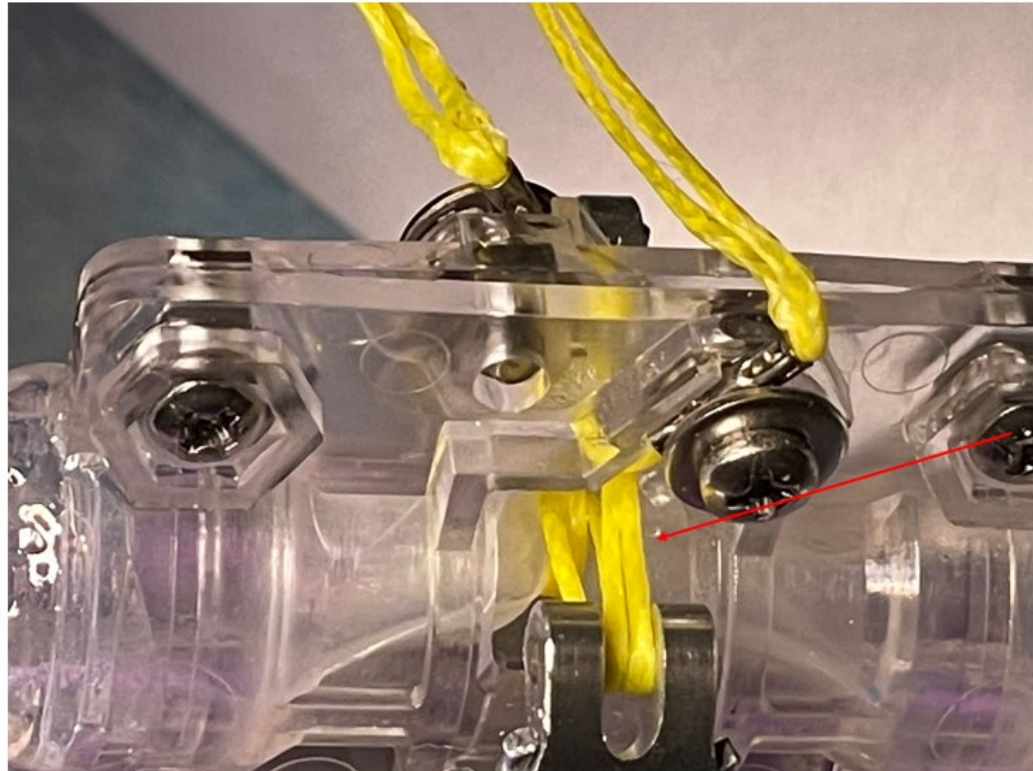


(Annotated image of internal portion of the controller housing.)



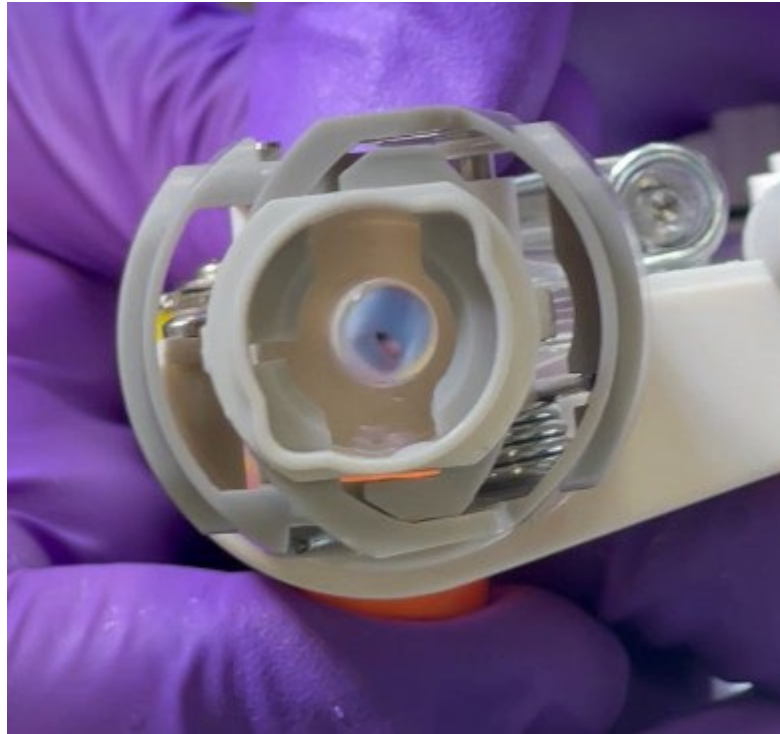
Tubular
member

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

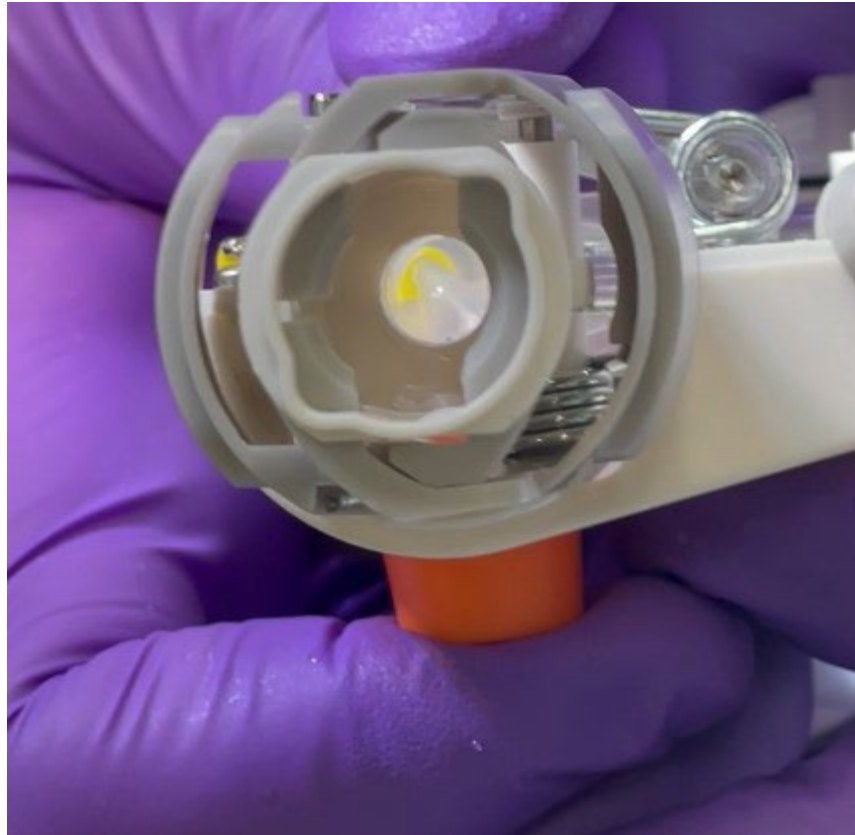


Tubular
member
(constricted)

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



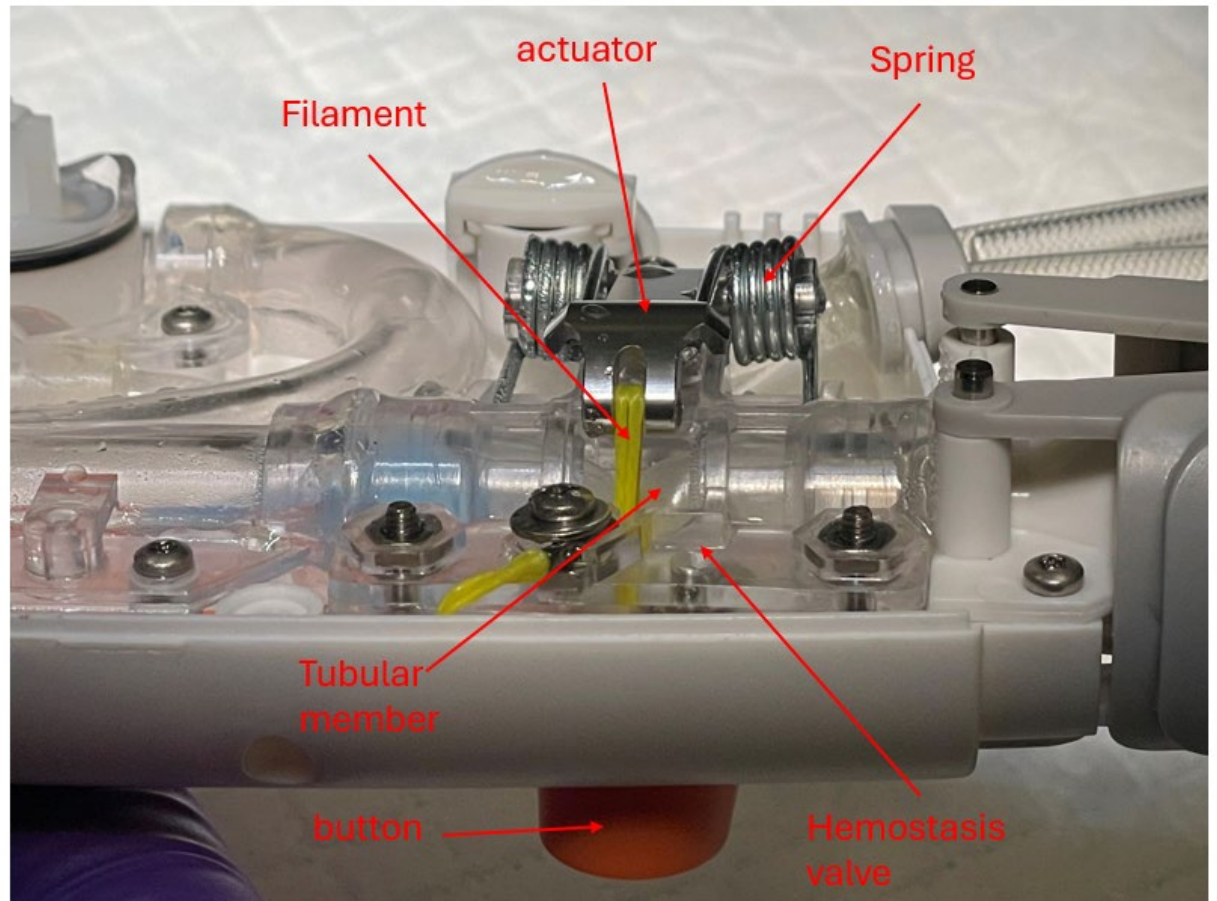
(Symphony handle with view down tubular member (lumen) of hemostasis valve with the valve open having the tubular member expanded.)



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

The Symphony System IFU describes the tubular member of the hemostasis valve, which can accommodate a wide range of devices, such as the 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

	<p>actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device”).</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
a button; and	<p>The Symphony System includes a hemostasis valve with a button.</p> <p>Specifically, the 24F and 16F Symphony Catheter handles include a hemostasis valve with a button, as shown in the annotated teardown image below.</p>



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

The Symphony System IFU describes how the button of the hemostasis valve is used to open and close (*i.e.*, actuate) the hemostasis valve. (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”).)

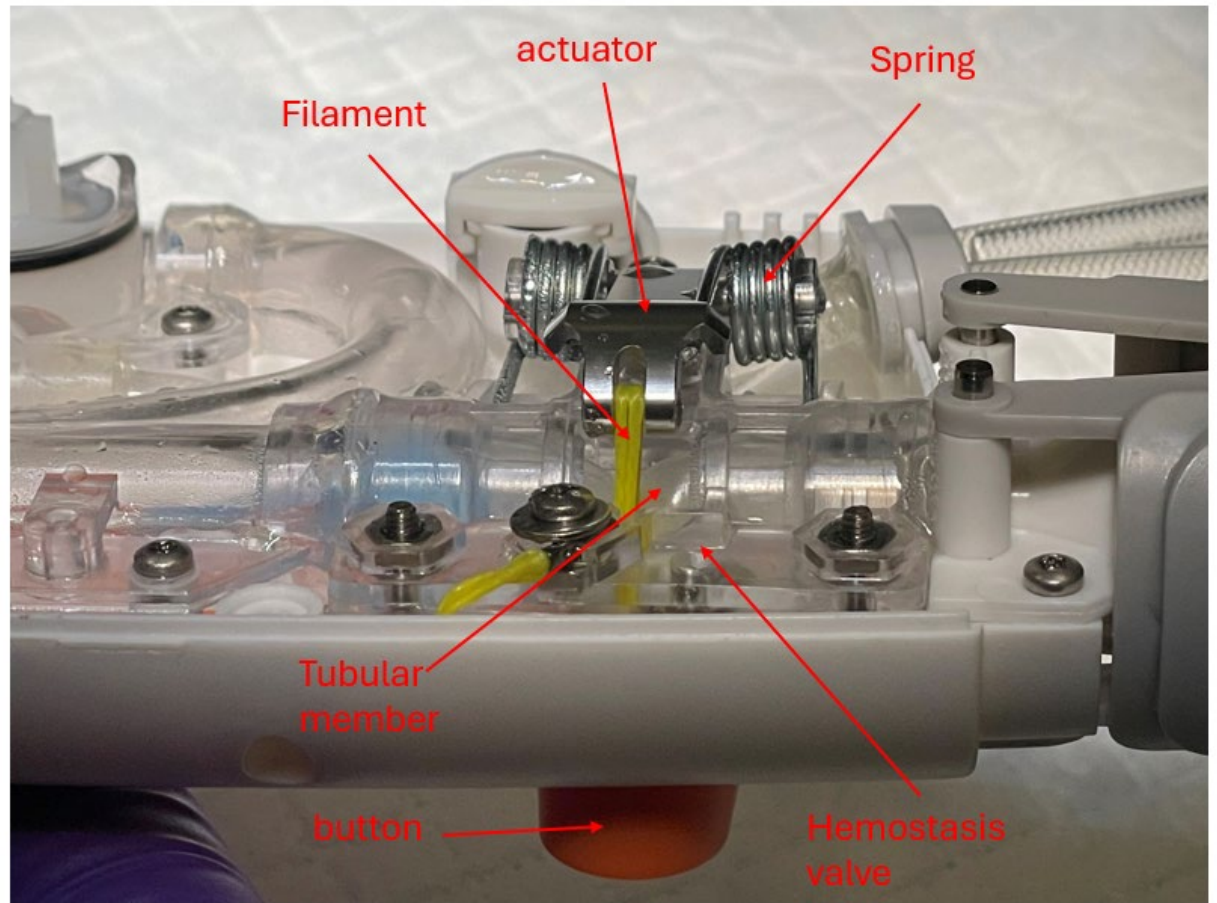
The Symphony Thrombectomy System Brochure similarly shows the hemostasis valve button, which allows the valve to “[a]ccommodate[] a wide range of devices.”



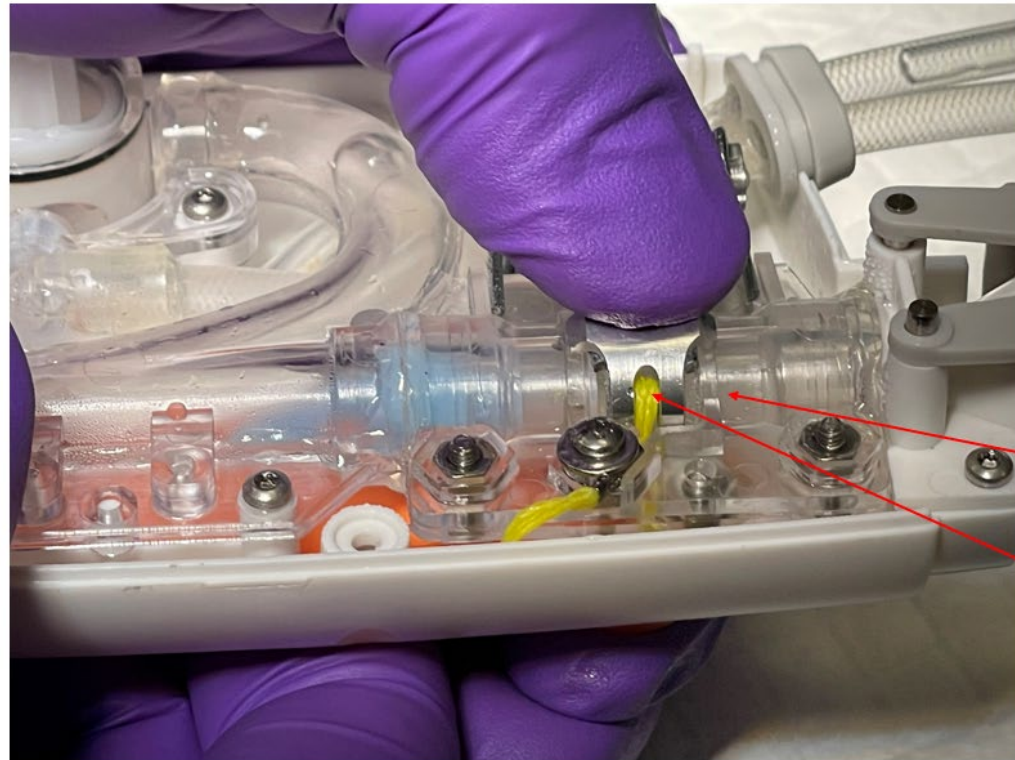
(Symphony Thrombectomy System Brochure at 6.)

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

<p>a filament coupled to the button and the tubular member, wherein the button is actuatable to loosen the filament to unseal the hemostasis valve.</p>	<p>The Symphony System includes a hemostasis valve with a filament coupled to the button and the tubular member, where the button is actuatable to loosen the filament to unseal the hemostasis valve.</p> <p>Specifically, the 24F and 16F Symphony Catheter handle includes a hemostasis valve with a first filament defined by a first braided line and an actuator defined by a first push-button, the first lever contacting the first push-button, and the first pin at the end of the first lever on one side and a second push-button, a second lever contacting the second push-button, and a second pin at the end of the second lever on the other side.</p> <p>The first filament has a portion looped fully around the tubular member and a first end extending from the loop in one direction toward the first lever/pin and a second end extending from the loop in an opposite direction toward the second lever/pin.</p> <p>The first pin at the end of the first arm is part of the first member of the actuator, and is coupled to the first end of the first filament. Specifically, the first end of the first filament wraps around the first pin. The lever arm/button are controlled by the first button, and couple the filament to the button.</p> <p>The first and second buttons/levers/pins are movably coupled to the support and movable between (a) a first position where the filaments circumferentially constrict the lumen of the tubular member to create a seal and (b) a second position wherein the filaments are moved to loosen the filament and unseal the lumen, as shown in the teardown images below.</p>
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(Annotated image of internal portion of the controller housing.)



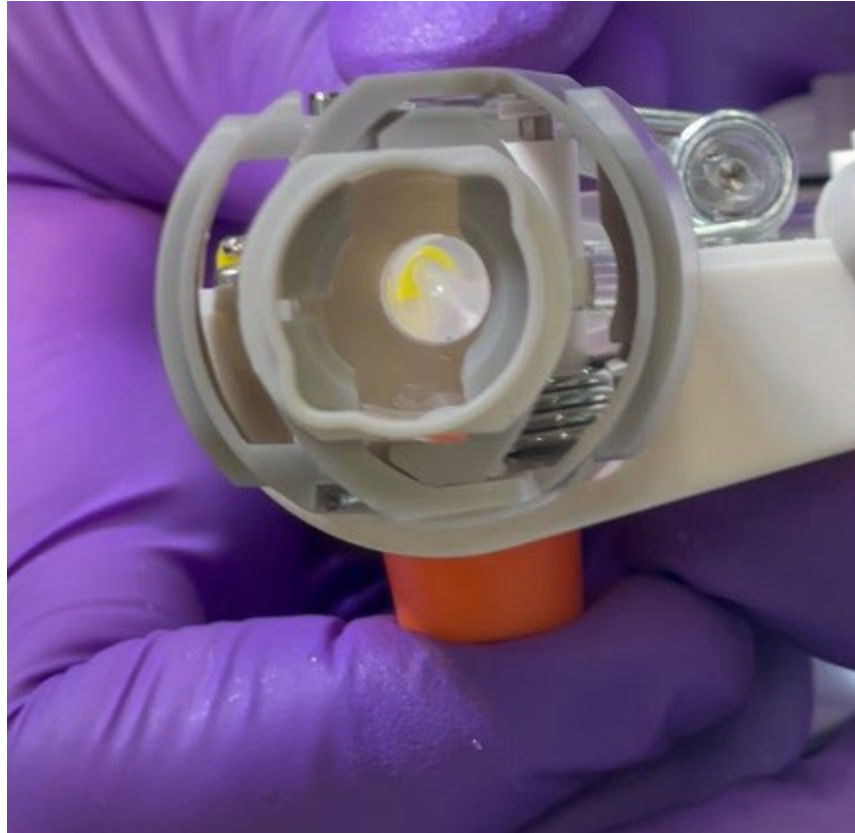
Tubular
member

Filament

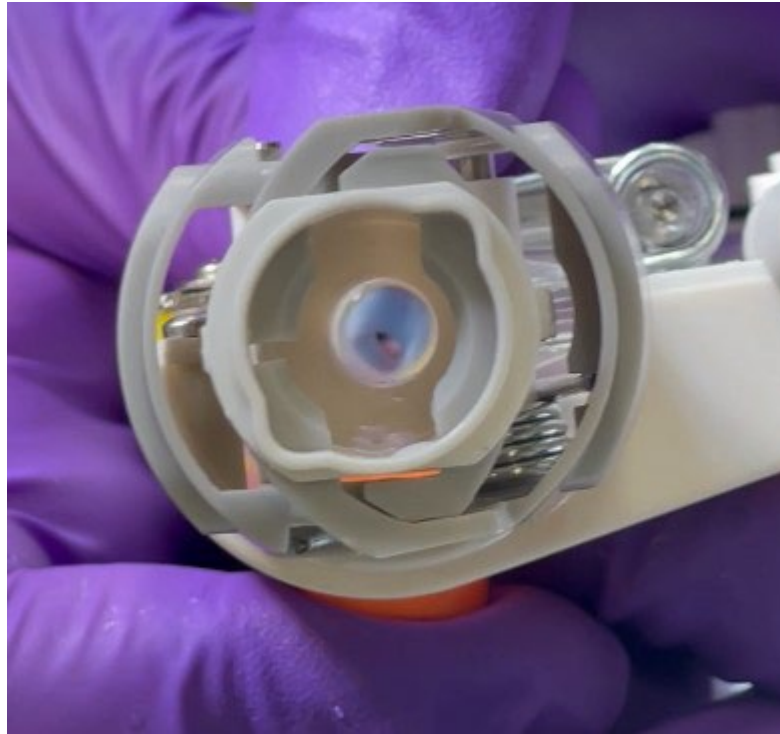
(Annotated image of internal portion of the controller housing.)



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



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



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

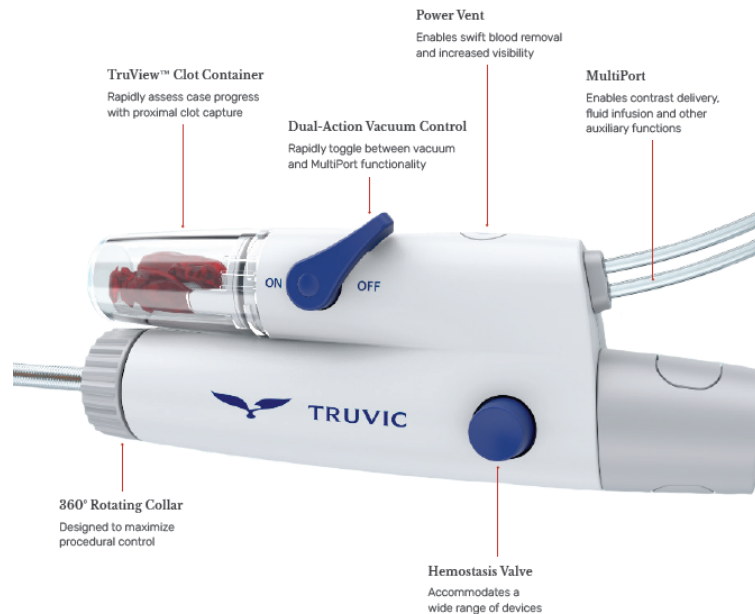
As shown above, when the button is actuatable to loosen the filament to unseal the hemostasis valve. The first annotated teardown image above shows the filament constricted around the tubular member of the hemostasis valve, such that the hemostasis valve is sealed. The second annotated teardown image above shows the button pressed (on the bottom of the Symphony Catheter handle and the actuator of the button depressed on the top of the Symphony Catheter handle), such that the filament is loosened, and the hemostasis valve is open.

	<p>The Symphony System IFU describes how the hemostasis valve button must be actuated when inserting or withdrawing a device to loosen the filament and open the hemostasis valve. (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 4 (“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.”); Symphony Thrombectomy System Instructions For Use at 7 (“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.”); Symphony Thrombectomy System Instructions For Use at 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.”).)</p> <p>The Symphony Thrombectomy System Brochure shows the hemostasis valve button, which allows the valve to “[a]ccommodate[] a wide range of devices.”</p>
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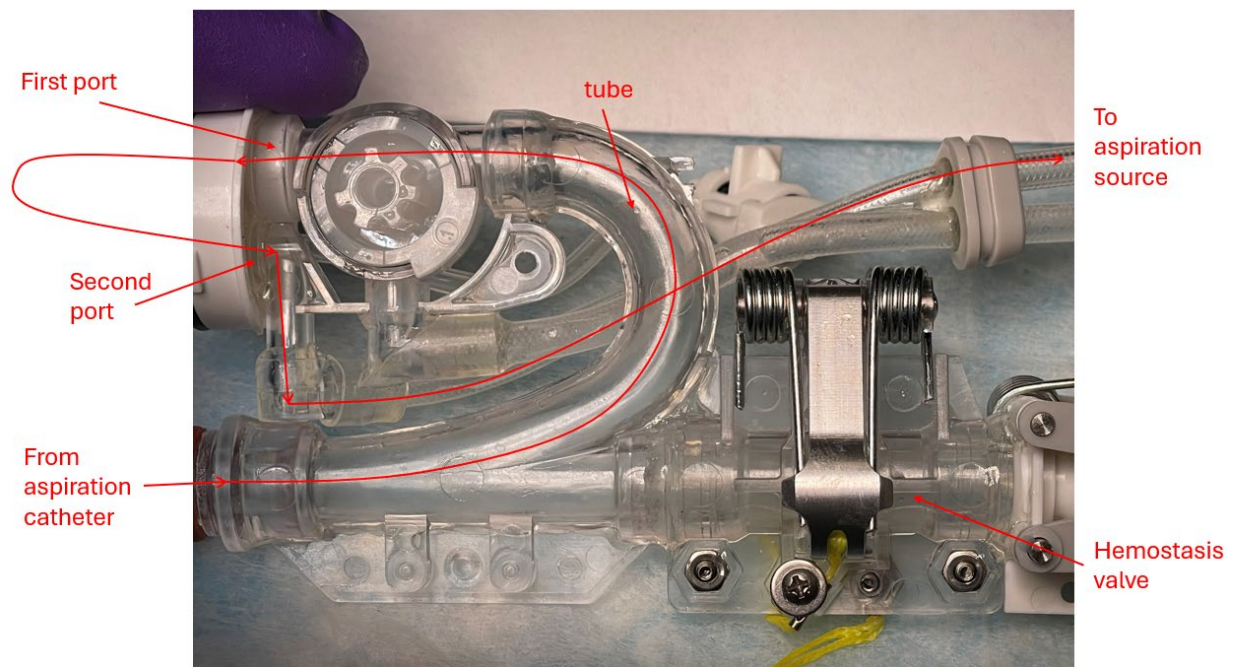
(Symphony Thrombectomy System Brochure at 6.)

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

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

The Symphony System includes an aspiration source that is fluidly coupled to the at least one tube.

Specifically, the Truvic Generator and Truvic Canister (e.g., the aspiration source) are fluidly coupled to the at least one tube via the clot container, as shown in the annotated teardown image below.



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

As shown in Figure 6 of the Symphony System IFU, the Truvic Canister and Truvic Generator are coupled to the 24F and/or 16F Symphony Catheter handle via the

TruVie Primary Tubing (for the 24F or 16F Symphony Catheter handle) or TruVie Secondary Tubing (for the 16F Symphony Catheter handle).

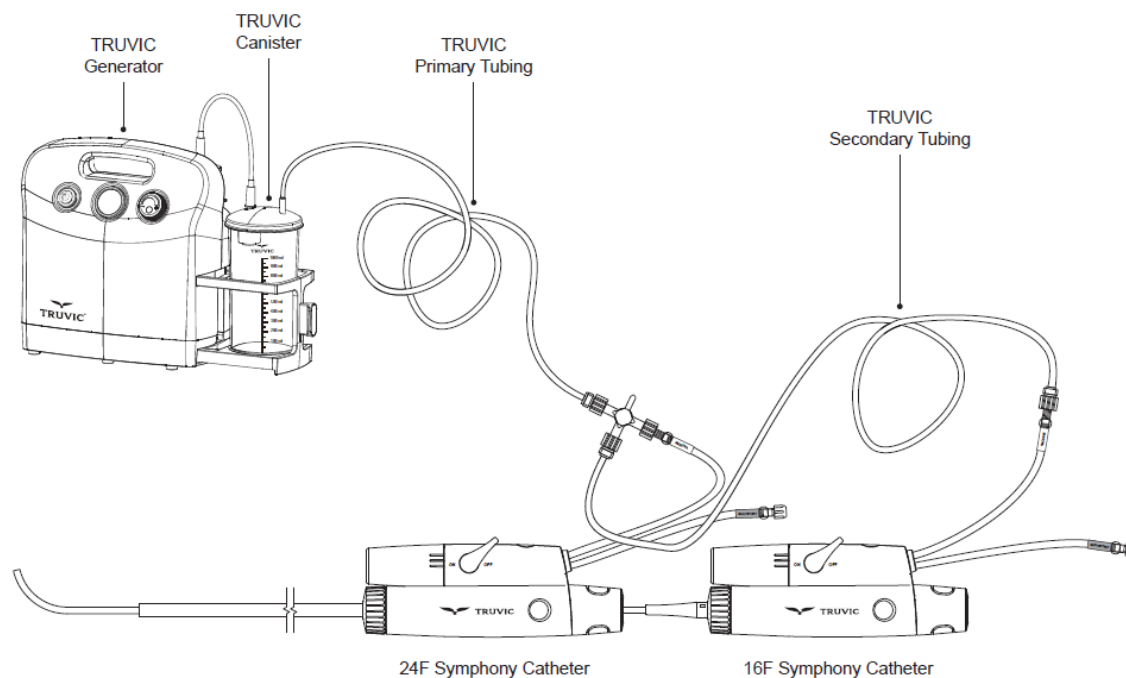


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Symphony Thrombectomy System Instructions For Use at 8.)

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

The Symphony System includes a hemostasis valve that is configured to receive an instrument therethrough.

Specifically, the hemostasis valve of the 24F and 16F Symphony Catheter handles is configured to receive an instrument, such as a Symphony ProHelix device, therethrough, as shown in Figure 4 of the Symphony System IFU.

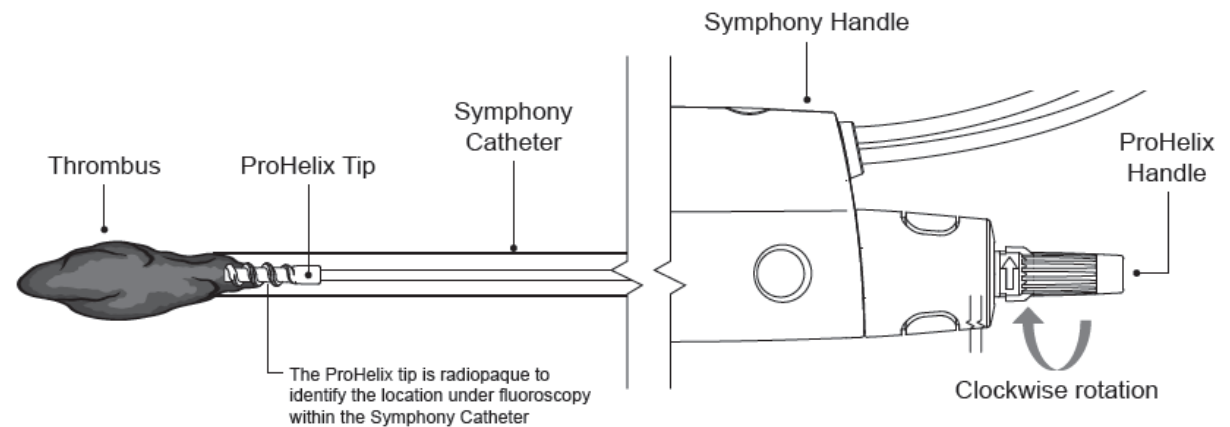


Figure 4: ProHelix engaged with thrombus

(Symphony Thrombectomy System Instructions For Use at 5.)

The Symphony System IFU further 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

	<p>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.”); Symphony Thrombectomy System Instructions For Use at 6 (“If reintroducing the Catheter with ProHelix, flush the Catheter and check the ProHelix tip for thrombus by visually inspecting the ProHelix tip. Rotate the handle of the ProHelix to align the safety wings with the open channels on the proximal end of the Catheter Handle. Press the Retention Clip buttons on the proximal end of the Catheter Handle and advance the ProHelix into the cleaning position. Remove any thrombus attached to the ProHelix tip. Press the retention clip buttons and withdraw ProHelix until the entire ProHelix handle is visible. Advance the ProHelix until the handle of the ProHelix snaps into</p>
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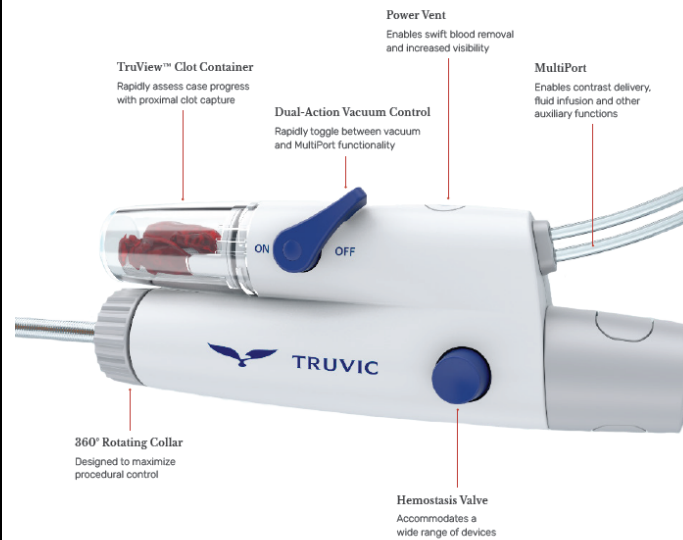
the retention clip of the Catheter Handle.”); Symphony Thrombectomy System Instructions For Use at 9 (same for 16F Symphony Catheter handle).)

The Symphony Thrombectomy System Brochure similarly depicts the hemostasis valve accepting an instrument, such as a Symphony ProHelix device.

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BigShot™ Controller

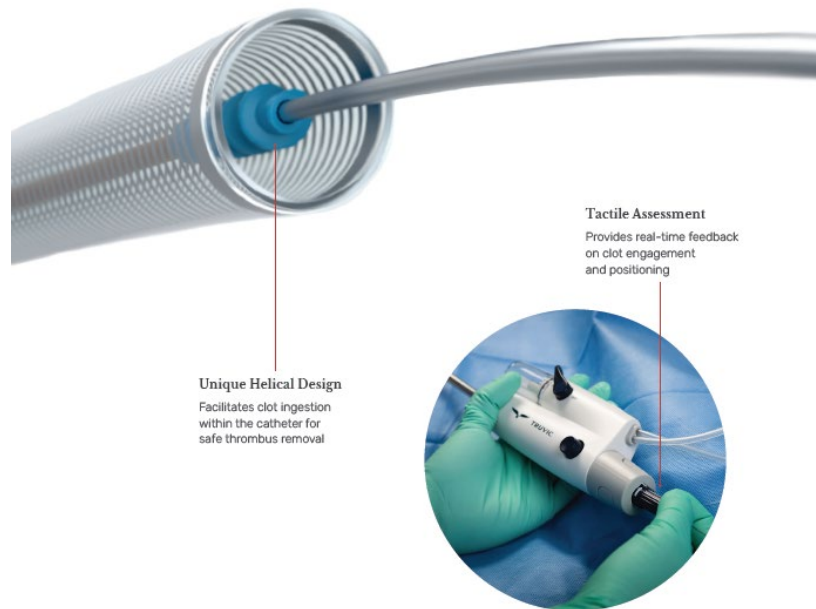


(Symphony Thrombectomy System Brochure at 6.)

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.

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

The Symphony System includes a hemostasis valve and aspiration catheter that are configured to receive and route an instrument therethrough.

Specifically, the hemostasis valve and aspiration catheter of the 24F and 16F Symphony Catheter handles is configured to receive an instrument, such as a Symphony ProHelix device, and route it through the hemostasis valve and aspiration catheter, as shown in Figure 4 of the Symphony System IFU.

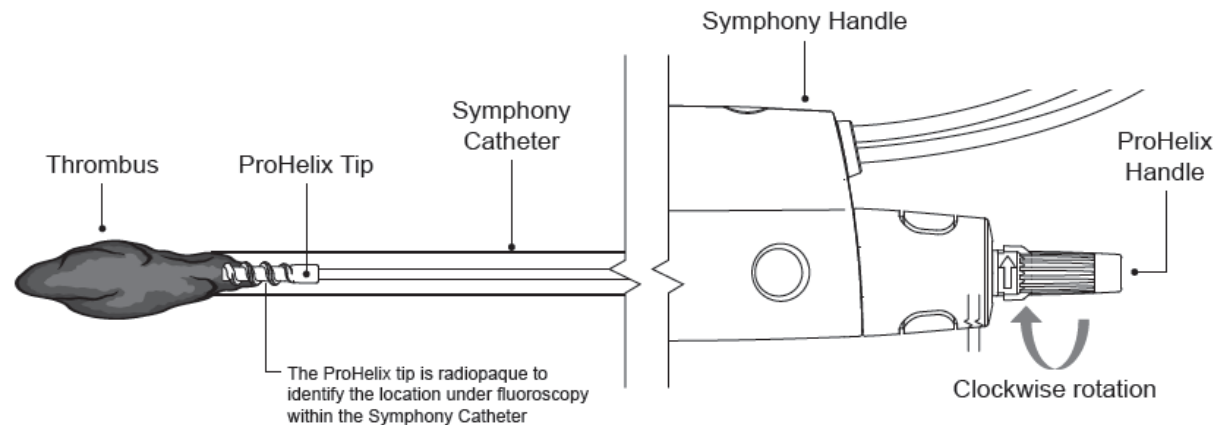


Figure 4: ProHelix engaged with thrombus

(Symphony Thrombectomy System Instructions For Use at 5.)

The Symphony System IFU further 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

	<p>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.”); Symphony Thrombectomy System Instructions For Use at 6 (“If reintroducing the Catheter with ProHelix, flush the Catheter and check the ProHelix tip for thrombus by visually inspecting the ProHelix tip. Rotate the handle of the ProHelix to align the safety wings with the open channels on the proximal end of the Catheter Handle. Press the Retention Clip buttons on the proximal end of the Catheter Handle and advance the ProHelix into the cleaning position. Remove any thrombus attached to the ProHelix tip. Press the retention clip buttons and withdraw ProHelix until the entire ProHelix</p>
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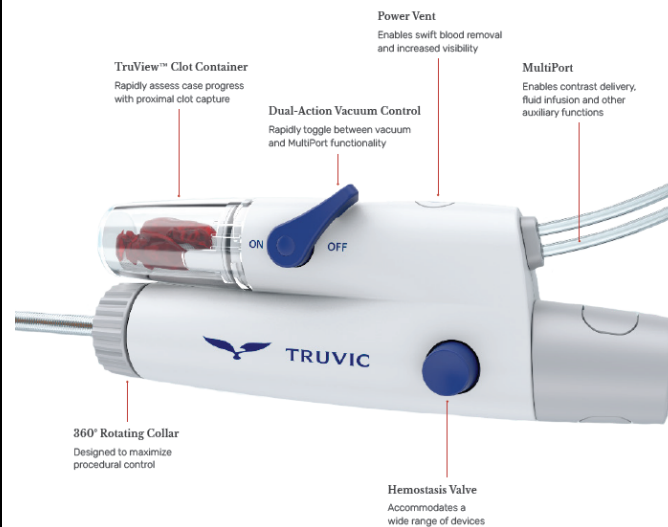
handle is visible. Advance the ProHelix until the handle of the ProHelix snaps into the retention clip of the Catheter Handle.”); Symphony Thrombectomy System Instructions For Use at 9 (same for 16F Symphony Catheter handle).)

The Symphony Thrombectomy System Brochure similarly depicts the hemostasis valve and aspiration catheter accepting an instrument, such as a Symphony ProHelix device.

SYMPHONY™ THROMBECTOMY SYSTEM

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

BigShot™ Controller

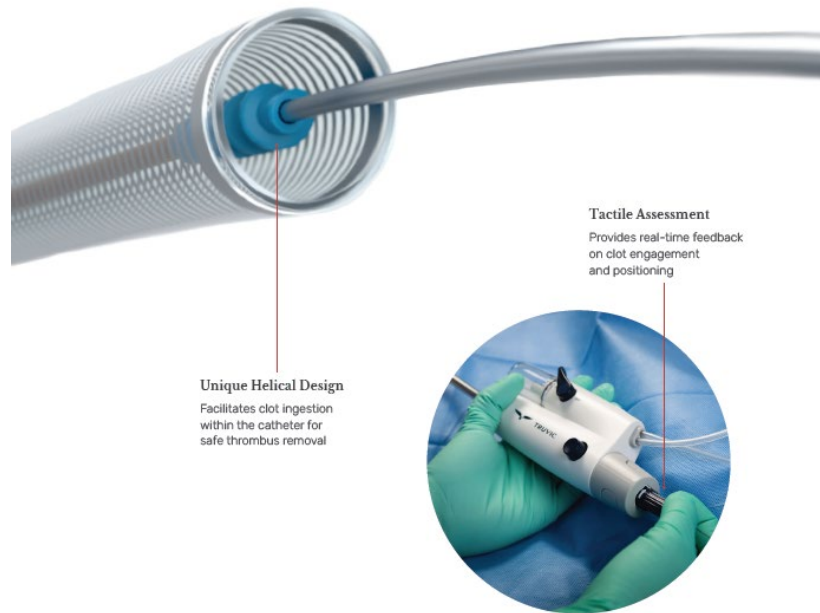


(Symphony Thrombectomy System Brochure at 6.)

SYMPHONY™ THROMBECTOMY SYSTEM

Mechanical Assist Optimizes Clot Engagement & Capture

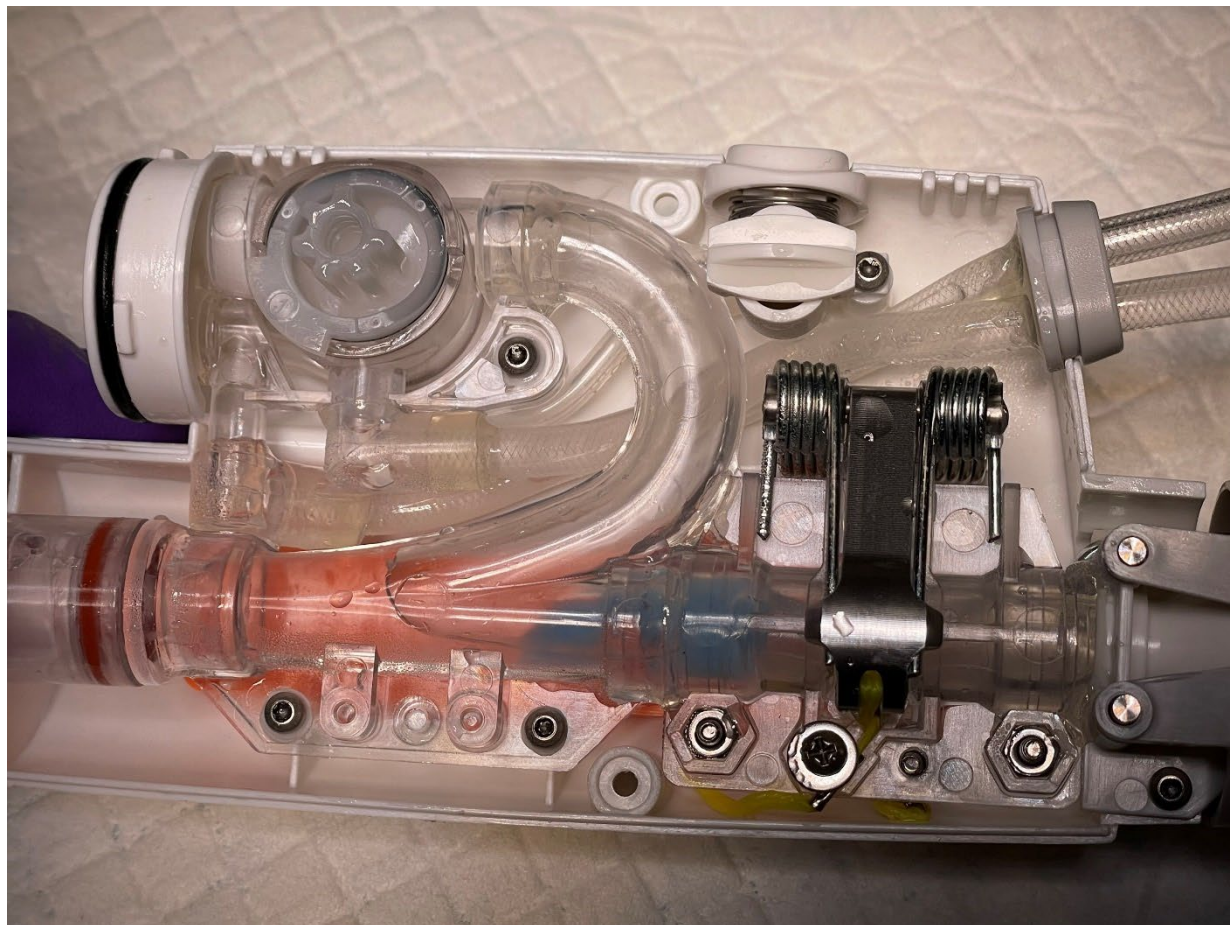
ProHelix™ Mechanical Assist



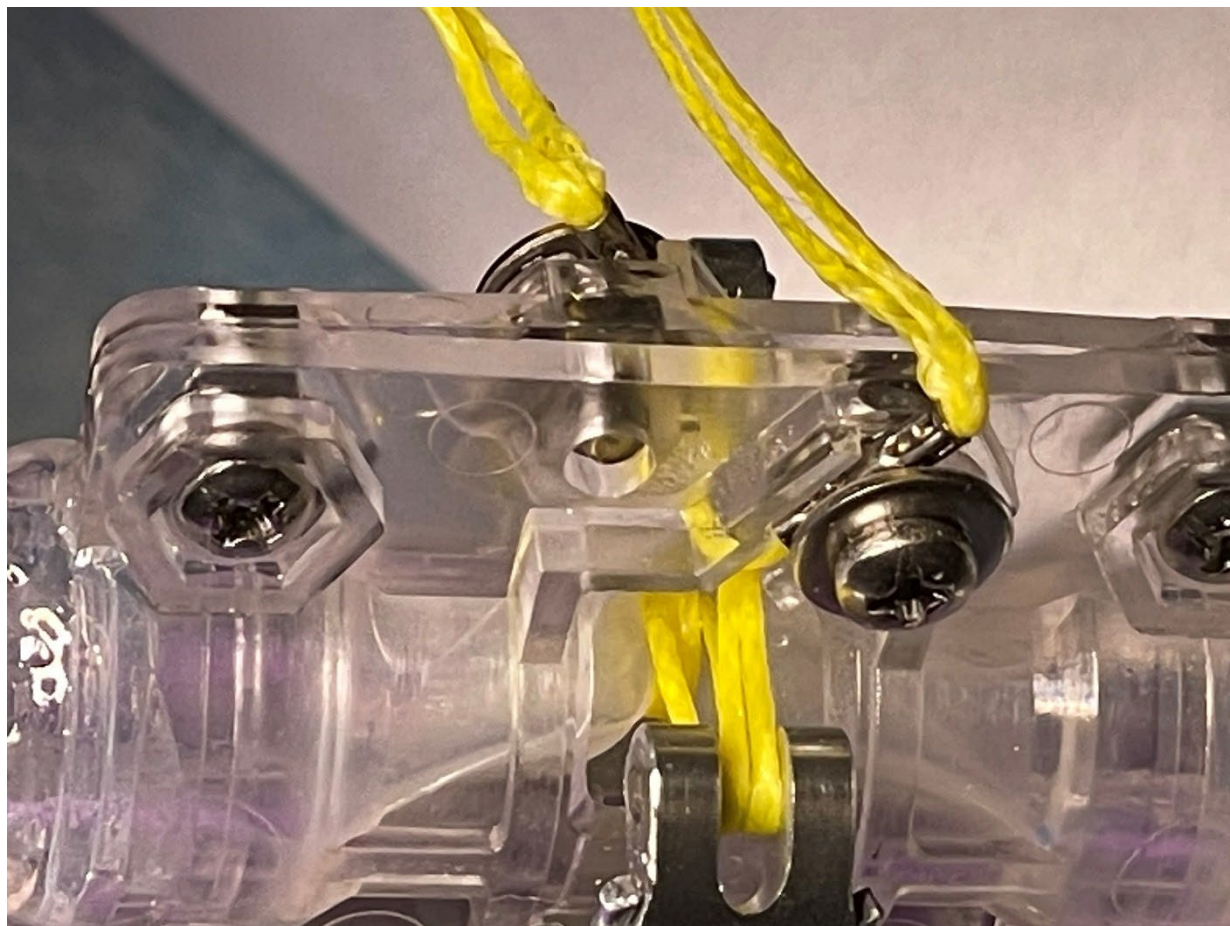
(Symphony Thrombectomy System Brochure at 8.)

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

<p>[22] The clot treatment system of claim 17 wherein the hemostasis valve comprises:</p>	<p>The Symphony System includes a hemostasis valve.</p> <p>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 valve has a pair of actuators, first actuator and a second actuator operated by buttons on the side of the 24F and 16F Symphony Catheter handles. The hemostasis valve 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 and elastically deform the collapsible tubular member. Pressing the buttons pushes the levers inward, which releases tension in the filaments to allow the tubular member to expand against the loops in the filaments.</p>
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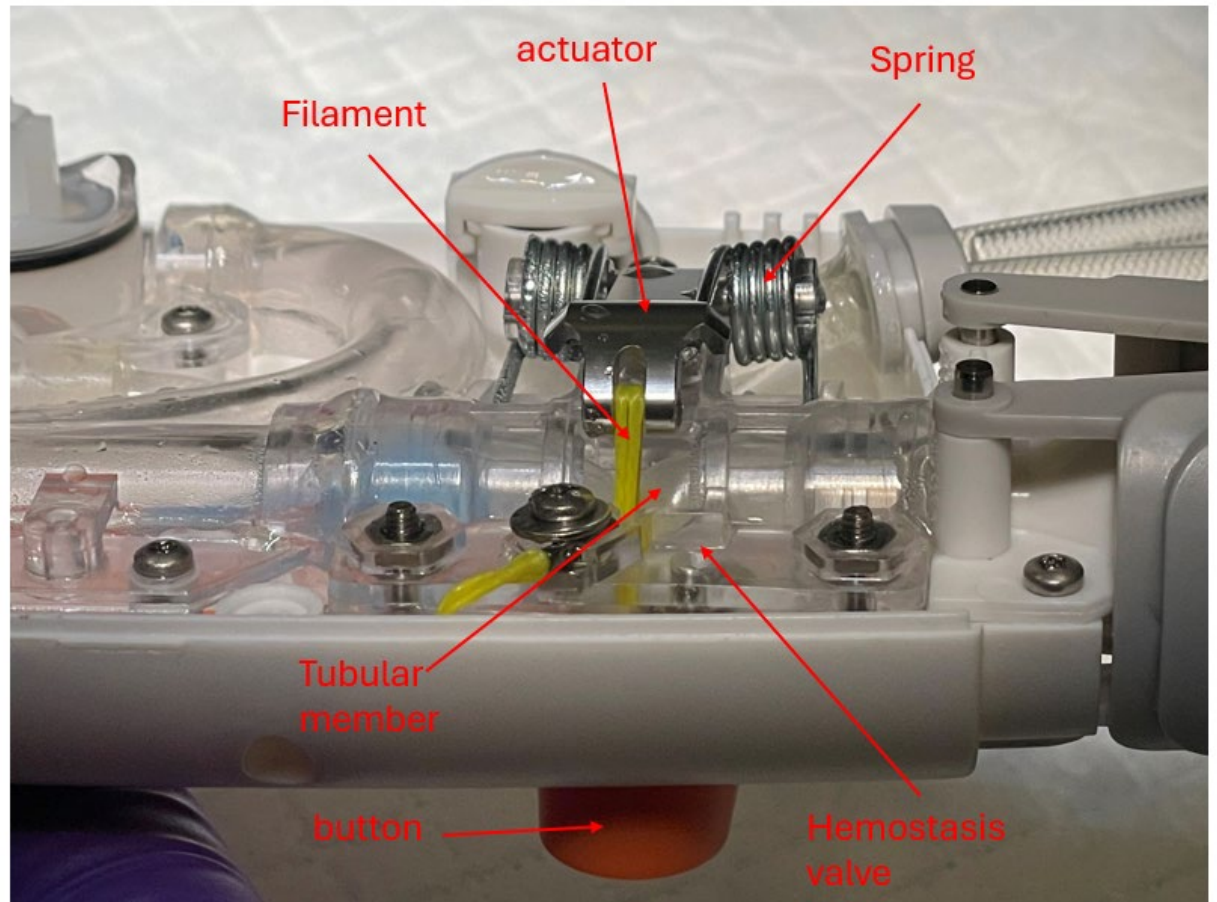
(Image of internal portion of the controller housing.)



(Image of internal portion of the controller housing, focusing on hemostasis valve.)



(Image of internal portion of the controller housing, focusing on hemostasis valve.)



(Annotated image of internal portion of the controller housing, focusing on hemostasis valve.)

The Symphony System IFU shows the outer shell of the Symphony Catheter handle that includes a button for the Handle's hemostasis valve.

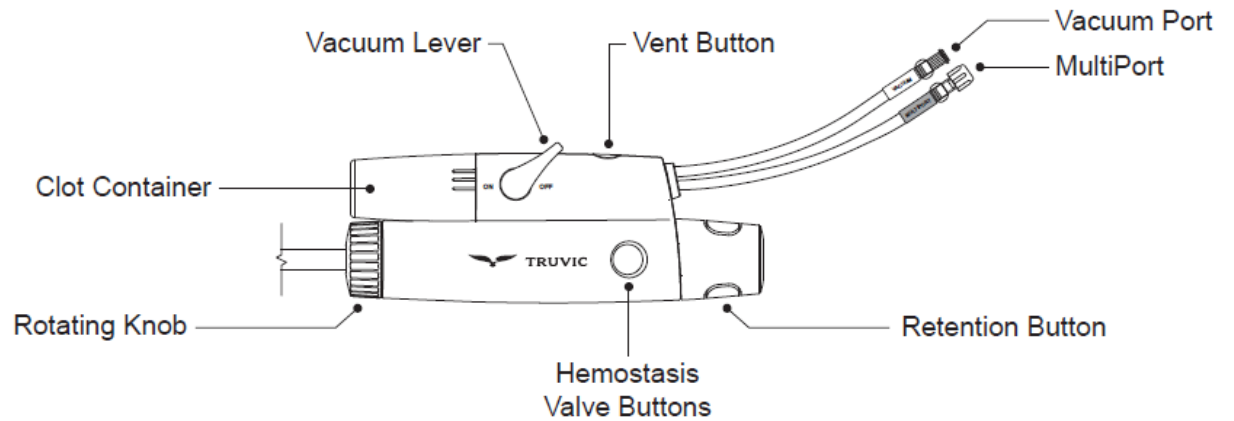


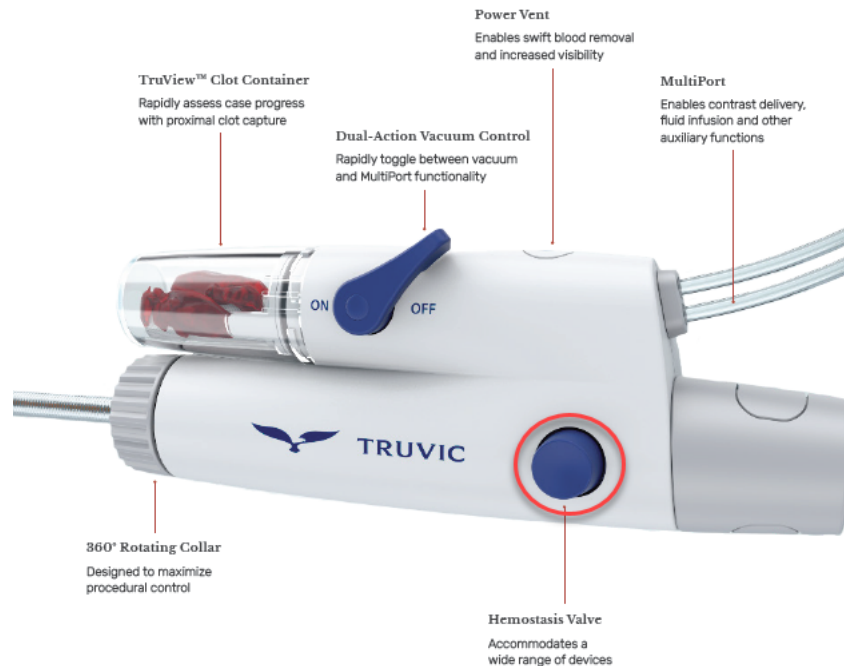
Figure 3: Symphony Catheter Handle, labeled

(Symphony Thrombectomy System Instructions For Use at 4; *see also* 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”).)

The Symphony Thrombectomy System Brochure similarly shows that the 24F Symphony Catheter handle includes a Hemostasis Valve.

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

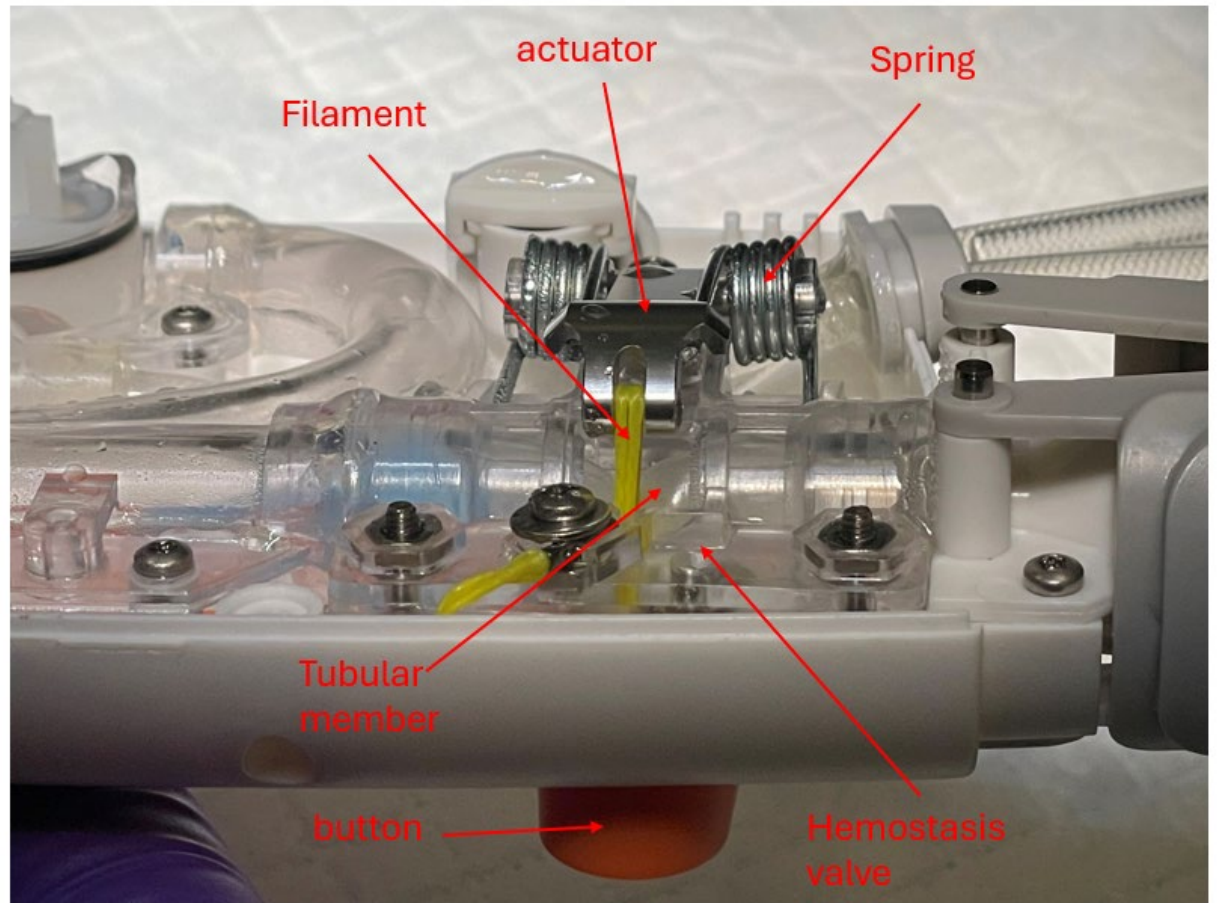
BigShot™ Controller



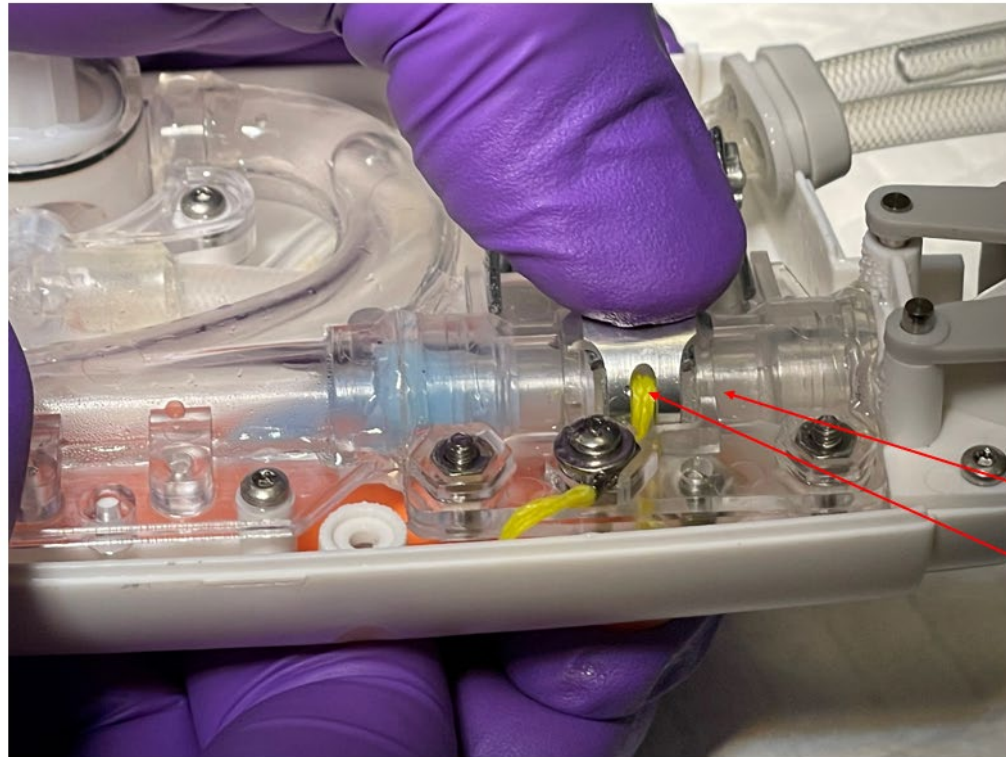
(Annotated Symphony Thrombectomy System Brochure at 6.)

The Whipsaw website also confirms that the 24F and 16F Symphony Catheter handle includes a hemostasis valve. (<https://www.whipsaw.com/work/imperative-care-symphony-thrombectomy-system>) (“This handheld tool includes several

	innovative features including a rotational function to orient the catheter tip to the clot, an aspiration valve, a hemostatic valve, a multifunction port for injecting medicine or contrast or measuring blood pressure, and a connection to a high-power vacuum source.”).
a tubular member defining a lumen;	<p>The Symphony System includes a hemostasis valve with a tubular member defining a lumen.</p> <p>Specifically, the 24F and 16F Symphony Catheter handle includes a hemostasis valve with a tubular member defining a lumen, as shown in the annotated teardown images below.</p>



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



Tubular
member
defining
lumen

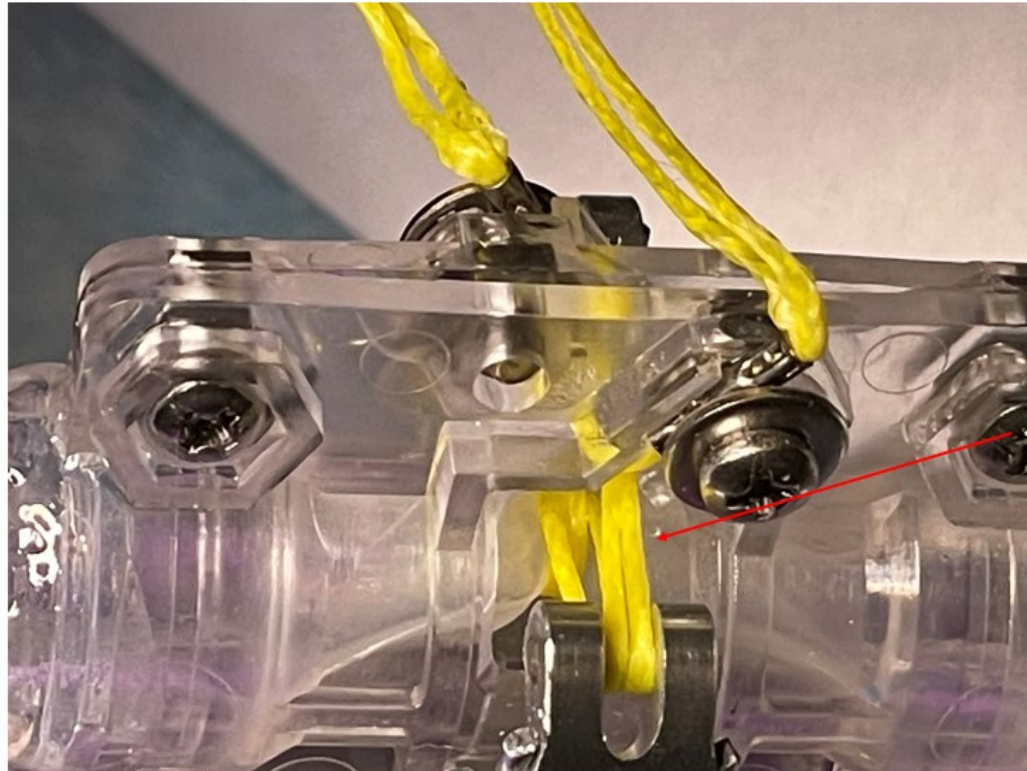
Filament

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

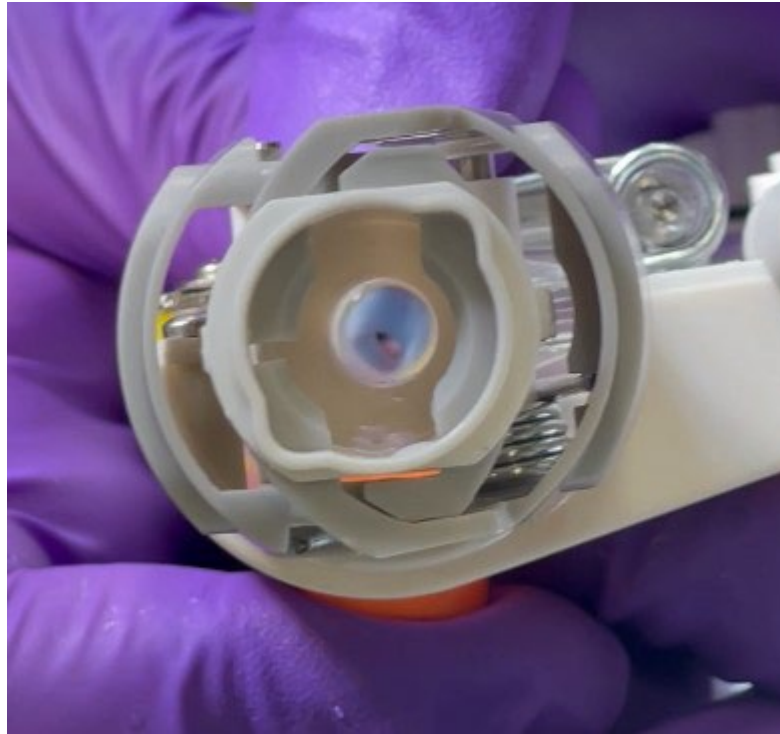


Tubular
member

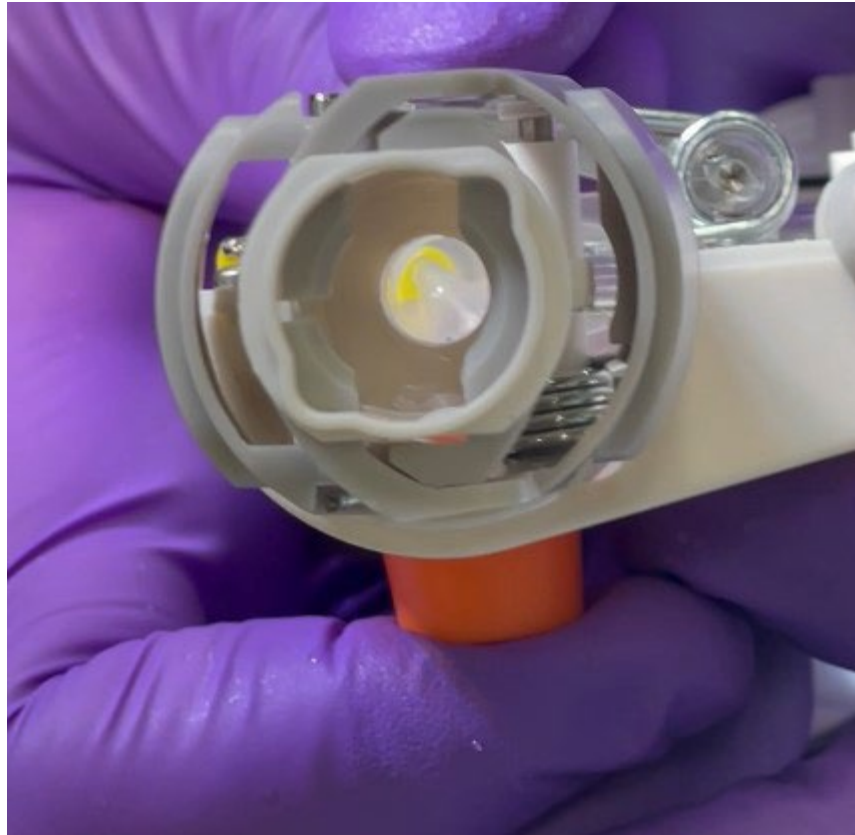
(Annotated image of internal portion of the controller housing.)



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



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

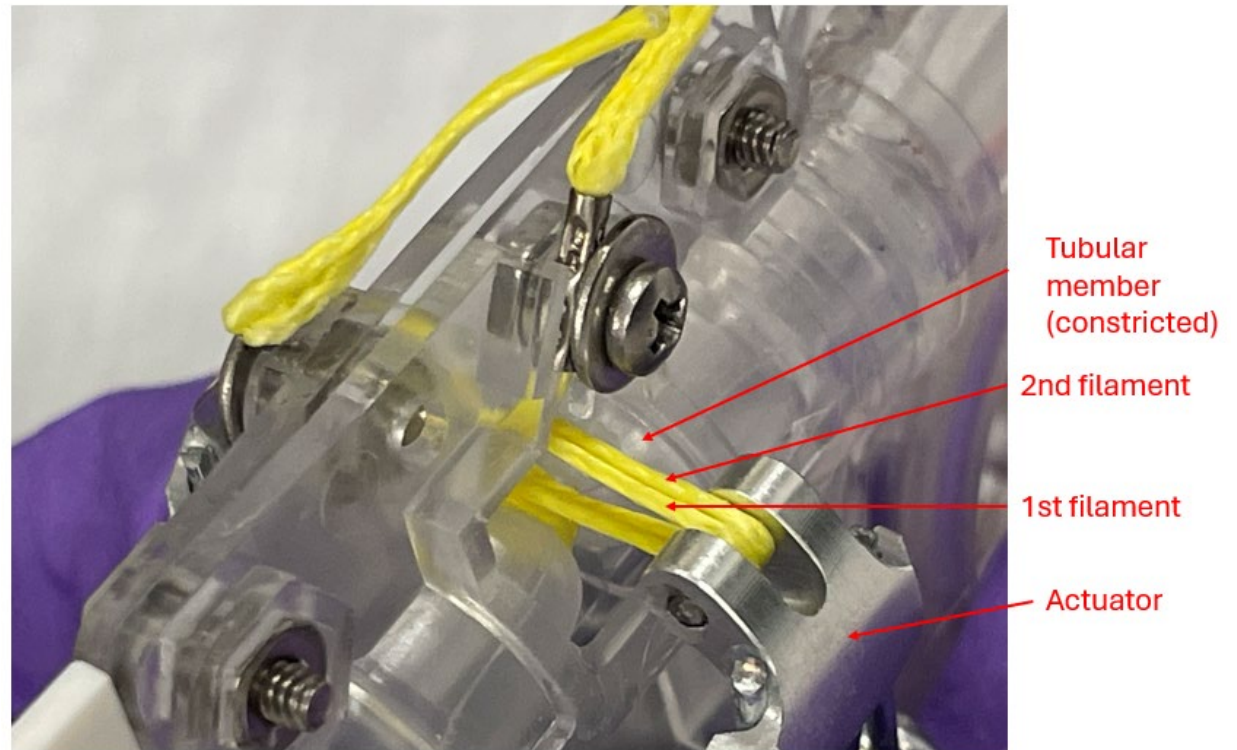


(Symphony handle with view down lumen of hemostasis valve with the tubular member of the valve constricted.)

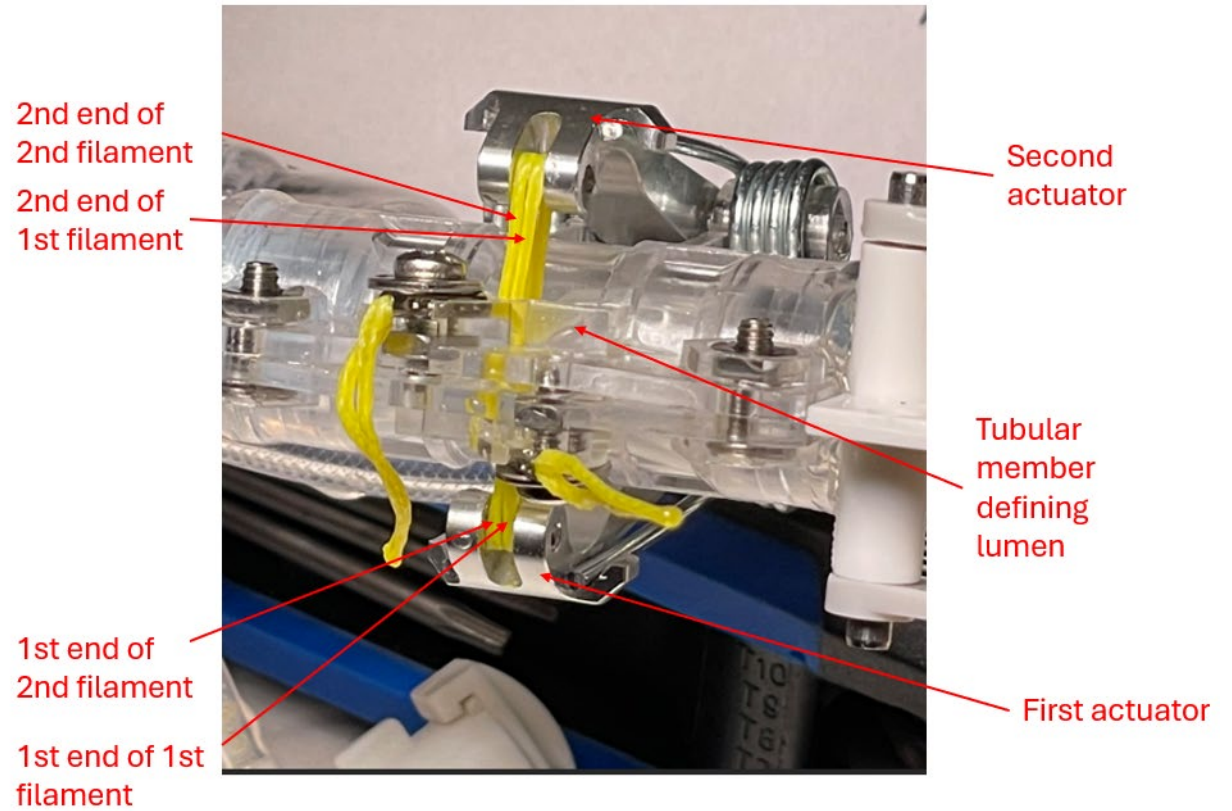
The Symphony System IFU also describes the tubular member of the hemostasis valve, which includes a lumen that can accept devices. (Symphony Thrombectomy System Instructions For Use at 2 (“Do not retract the Symphony ProHelix through the Hemostasis Valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve

	<p>buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device”).</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
a first filament extending in a first loop around the tubular member;	<p>The Symphony System includes a hemostasis valve with a first filament extending in a first loop around the tubular member.</p> <p>Specifically, the hemostasis valve of the 24F and 16F Symphony Catheter handle includes a first filament in a first loop around the tubular member. The hemostasis valve includes a first filament defined by a first braided line and a first actuator defined by a first push-button, the first lever contacting the first push-button, and the first pin at the end of the first lever on one side and a second actuator defined by a second push-button, a second lever contacting the second push-button, and a second pin at the end of the second lever on the other side.</p> <p>The first filament has a first portion looped fully around the tubular member and a first end extending from the loop in one direction toward the first lever/pin and a second end extending from the loop in an opposite direction toward the second lever/pin.</p> <p>The first pin at the end of the first arm is part of the first actuator, and is coupled to the first end of the first filament. Specifically, the first end of the first filament wraps around the first pin.</p> <p>The second pin at the end of the second arm is part of the second actuator, and is coupled to the second end of the first filament. Specifically, the second end of the first filament wraps around the second pin.</p>

The first and second buttons/levers/pins are movably coupled to the support and movable between (a) a first position where the filaments circumferentially constrict the lumen of the tubular member to create a seal and (b) a second position wherein the filaments are moved to at least partially open the lumen, as shown in the annotated images below.



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

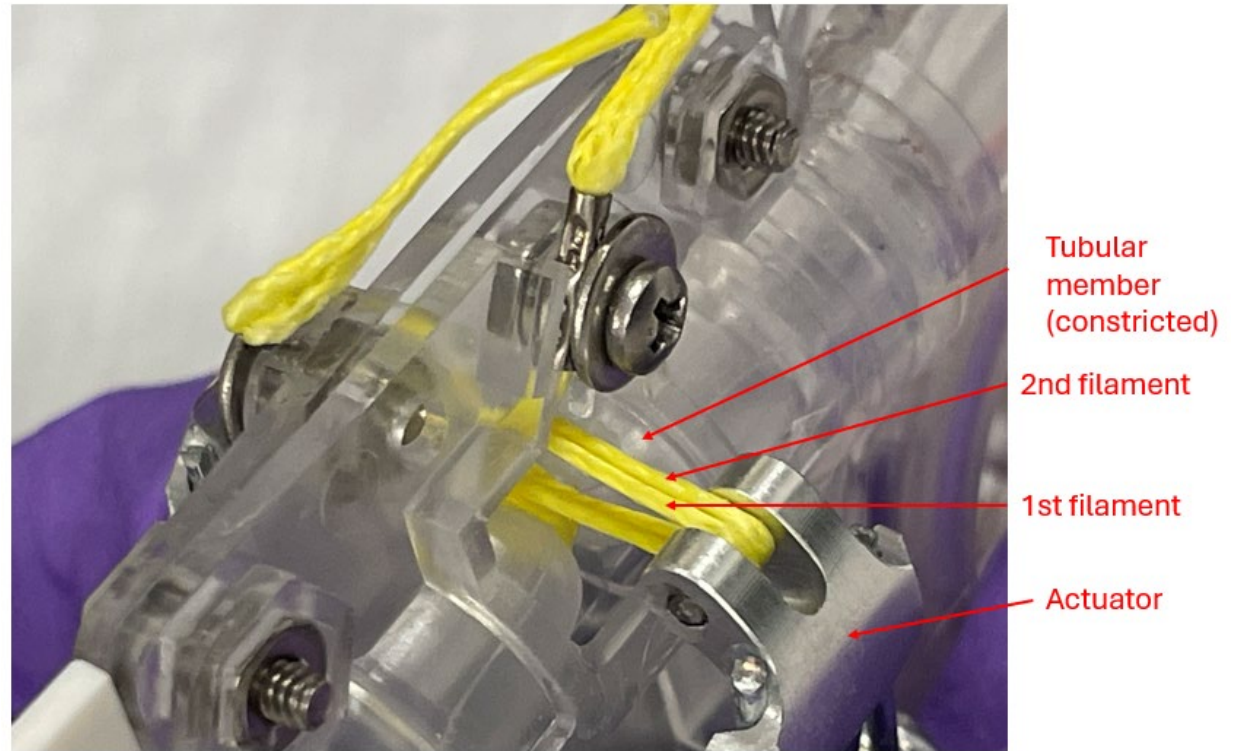


(Annotated image of internal portion of the controller housing.)

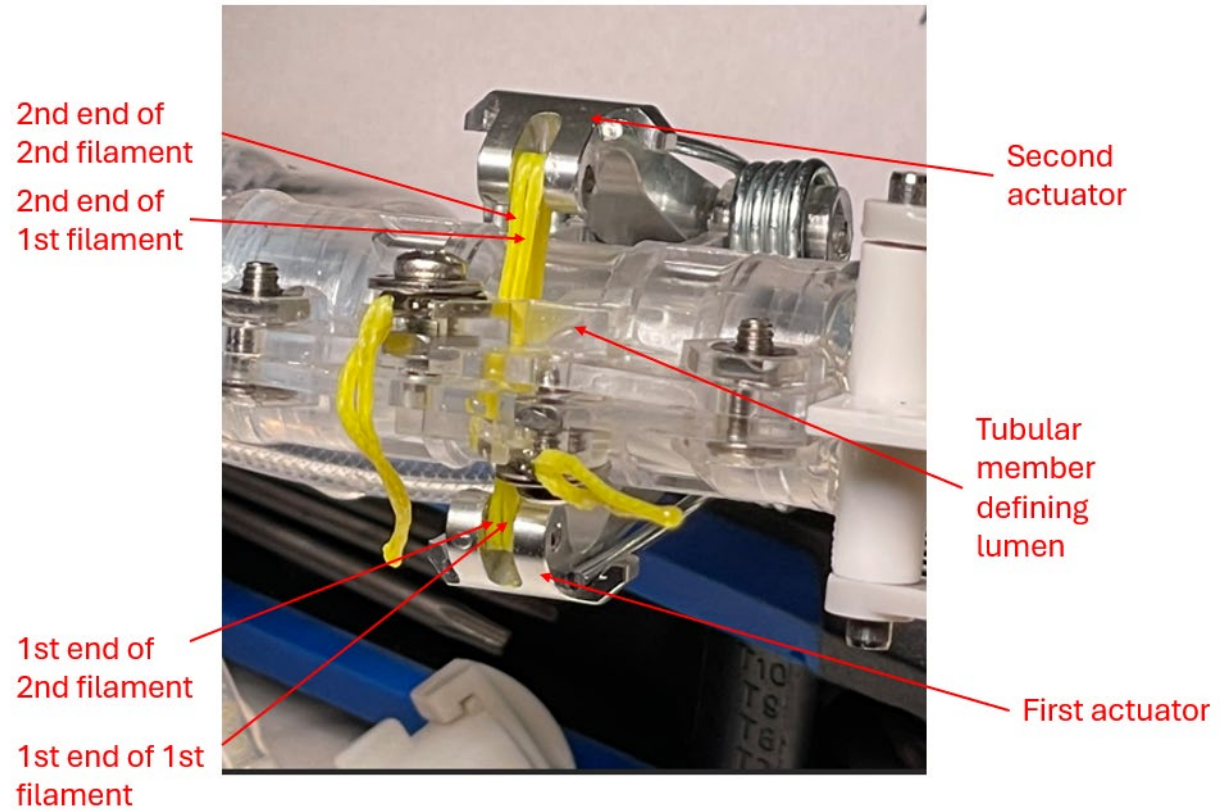
The first filament extends in a loop around the tubular member, as shown in the internal image of the Symphony Catheter handle hemostasis valve below.

	 <p>(Internal image of filament loop around tubular member.)</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>a second filament extending in a second loop around the tubular member; and</p>	<p>The Symphony System includes a hemostasis valve with a second filament extending in a second loop around the tubular member.</p> <p>Specifically, the hemostasis valve of the 24F and 16F Symphony Catheter handle includes a second filament in a second loop around the tubular member. The hemostasis valve includes a first filament defined by a first braided line and a first</p>

	<p>actuator defined by a first push-button, the first lever contacting the first push-button, and the first pin at the end of the first lever on one side and a second actuator defined by a second push-button, a second lever contacting the second push-button, and a second pin at the end of the second lever on the other side.</p> <p>The second filament has a portion looped fully around the tubular member and a first end extending from the loop in one direction toward the first lever/pin and a second end extending from the loop in an opposite direction toward the second lever/pin.</p> <p>The first pin at the end of the first arm is part of the first actuator, and is coupled to the first end of the second filament. Specifically, the first end of the second filament wraps around the first pin.</p> <p>The second pin at the end of the second arm is part of the second actuator, and is coupled to the first end of the second filament. Specifically, the second end of the second filament wraps around the second pin.</p> <p>The first and second buttons/levers/pins are movably coupled to the support and movable between (a) a first position where the filaments circumferentially constrict the lumen of the tubular member to create a seal and (b) a second position wherein the filaments are moved to at least partially open the lumen, as shown in the annotated images below.</p>
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(Annotated image of internal portion of the controller housing.)



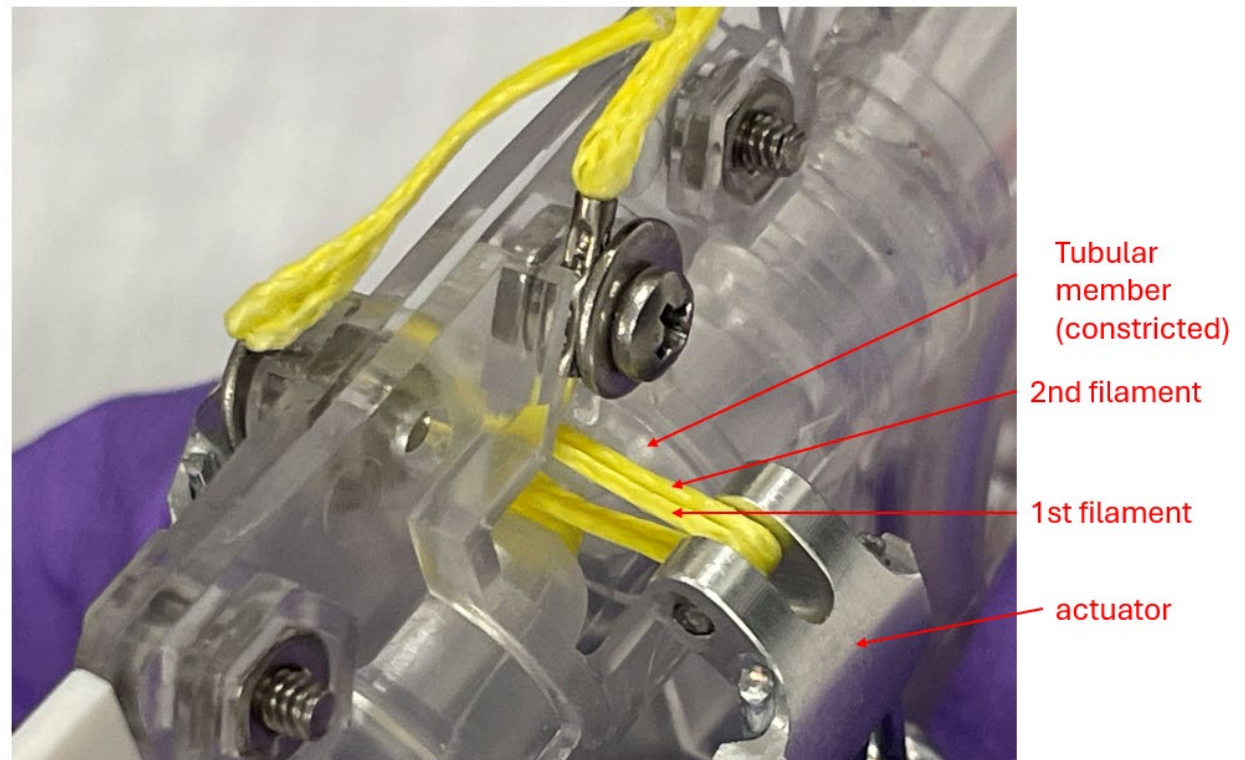
(Annotated image of internal portion of the controller housing.)

The second filament extends in a loop around the tubular member, as shown in the internal image of the Symphony Catheter handle hemostasis valve below.

	 <p>(Internal image of filament loop around tubular member.)</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>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</p>	<p>The Symphony System includes a hemostasis valve with 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, where at least one of the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member</p>

<p>least one [sic] the actuators is movable to decrease a level of tension in the first filament and a level of tension in the second filament to permit the tubular member to expand against the first loop and the second loop to a second position in which the lumen of the tubular member is at least partially open.</p>	<p>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.</p> <p>Specifically, the hemostasis valve of the 24F and 16F Symphony Catheter handle includes a pair of actuators that are biased to constrict the first and second filament loops, such that the tubular member is deformed in a position that constricts the lumen. The hemostasis valve has a first filament defined by a first braided line and a second filament defined by a second braided line, and a first actuator defined by a first push-button, the first lever contacting the first push-button, and the first pin at the end of the first lever on one side and a second actuator defined by a second push-button, a second lever contacting the second push-button, and a second pin at the end of the second lever on the other side.</p> <p>The first filament has a portion looped fully around the tubular member and a first end extending from the loop in one direction toward the first lever/pin and a second end extending from the loop in an opposite direction toward the second lever/pin.</p> <p>The second filament has a portion looped fully around the tubular member and a first end extending from the loop in one direction toward the first lever/pin and a second end extending from the loop in an opposite direction toward the second lever/pin.</p> <p>The first pin at the end of the first arm is part of the first actuator, and is coupled to the first end of the first and second filaments. Specifically, the first end of the first and second filaments wrap around the first pin.</p> <p>The second pin at the end of the second arm is part of the second actuator, and is coupled to the second end of the first and second filaments. Specifically, the second end of the first and second filaments wrap around the second pin.</p>
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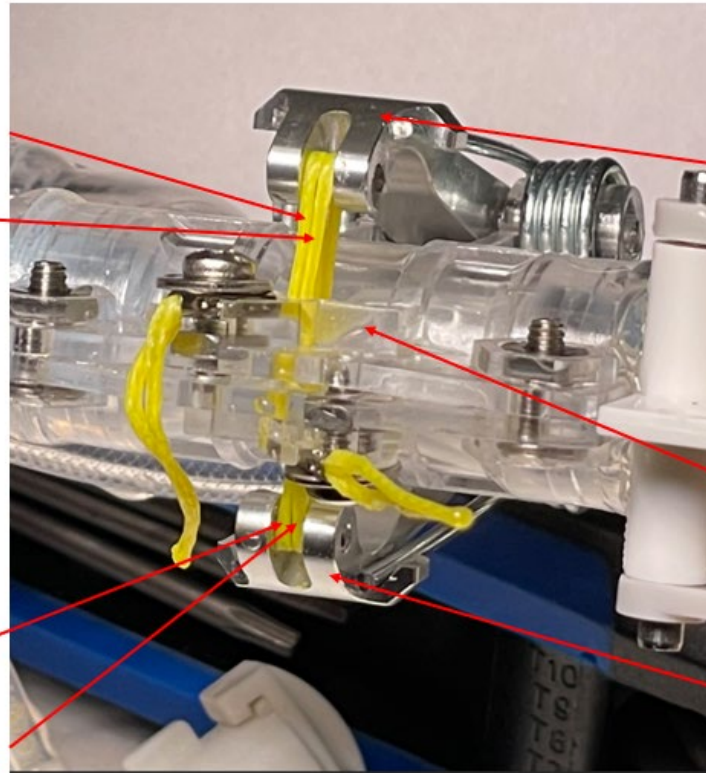
The first and second buttons/levers/pins are movably coupled to the support and movable between (a) a first position where the filaments circumferentially constrict the lumen of the tubular member by elastically deforming the tubular member to create a seal and (b) a second position wherein the filaments are moved to at least partially open the lumen by decreasing the level of tension in the first filament and the second filament to allow the tubular member to expand against the first and the second loop and expand, as shown in the annotated teardown images below.



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

2nd end of
2nd filament
2nd end of
1st filament

1st end of
2nd filament
1st end of 1st
filament



Second
actuator

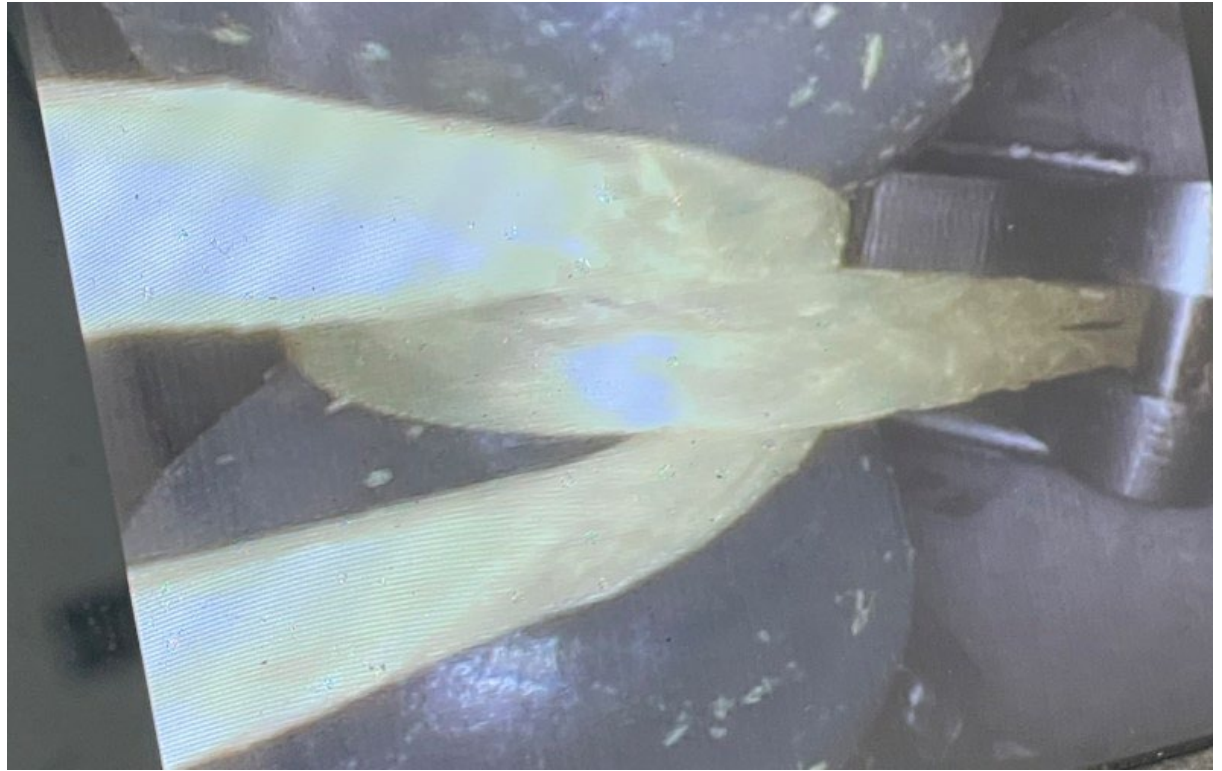
Tubular
member
defining
lumen

First actuator

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

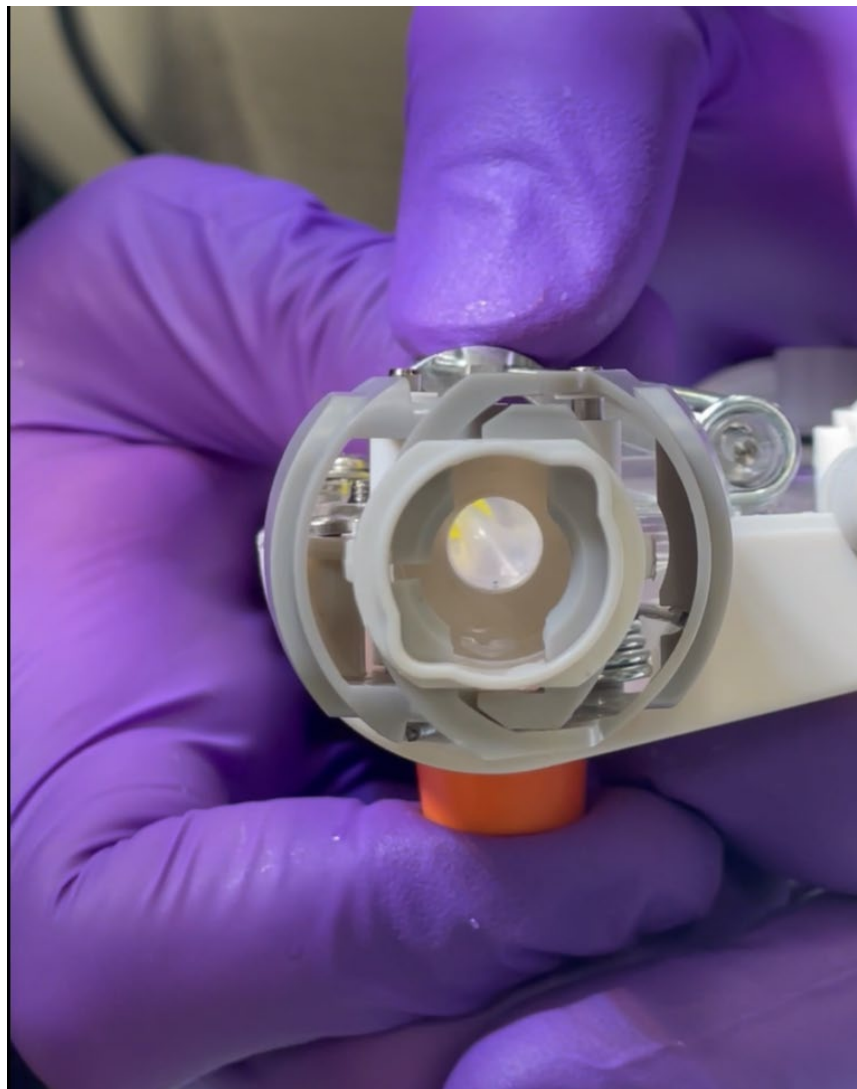


(Internal image of hemostasis valve with filaments encircling elongate member.)



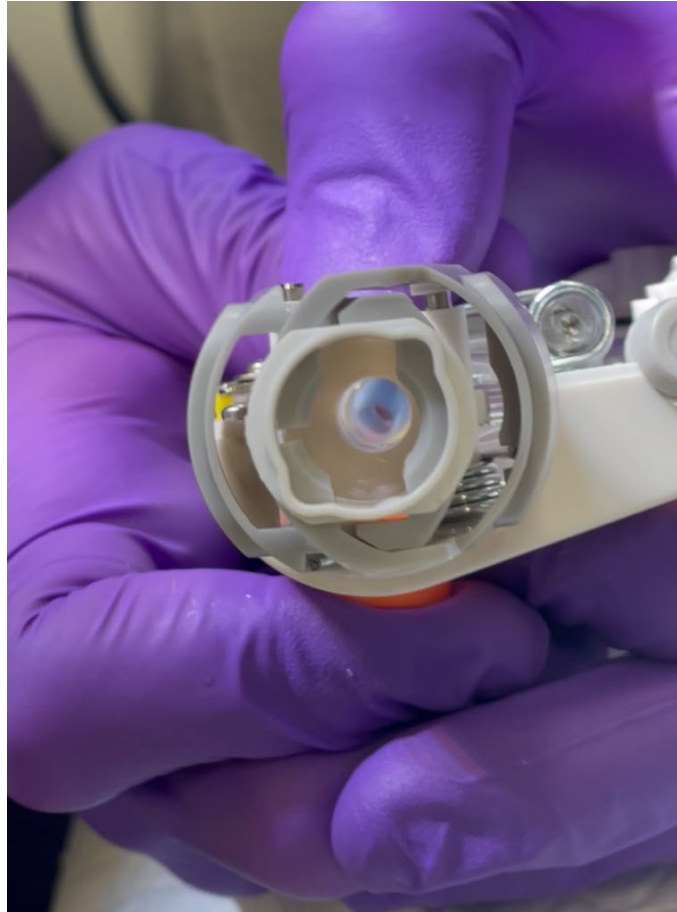
(Internal image of filament loops constricting tubular member.)

When the actuators are not engaged (*e.g.*, pressed down), the first and second loops of the first and second filaments elastically constrict the lumen.

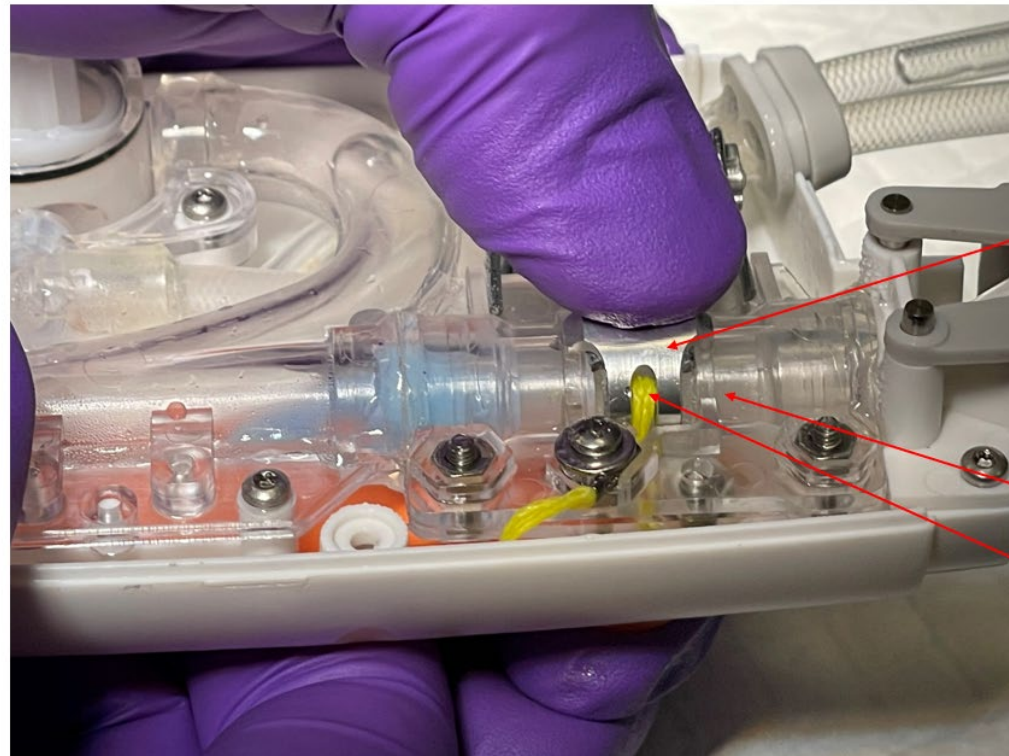


(Image of tubular member with lumen constricted by filaments.)

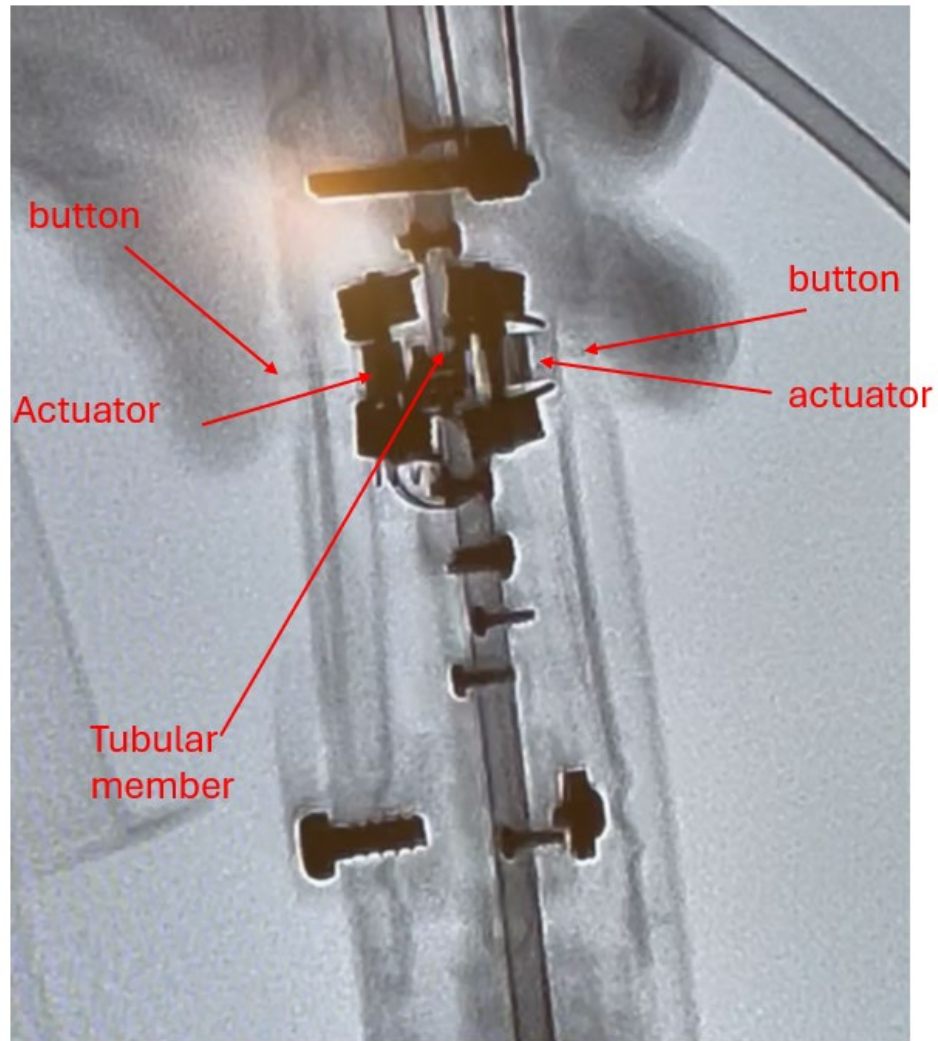
Both actuators of the Symphony Catheter handle are movable, where pressing the buttons cause the actuators to move, which decreases the level of tension in the first and second filaments and allows the lumen of the tubular member to expand against the loops in the filament and open, as shown in the images below.



(Image of tubular member with lumen not constricted by filaments.)



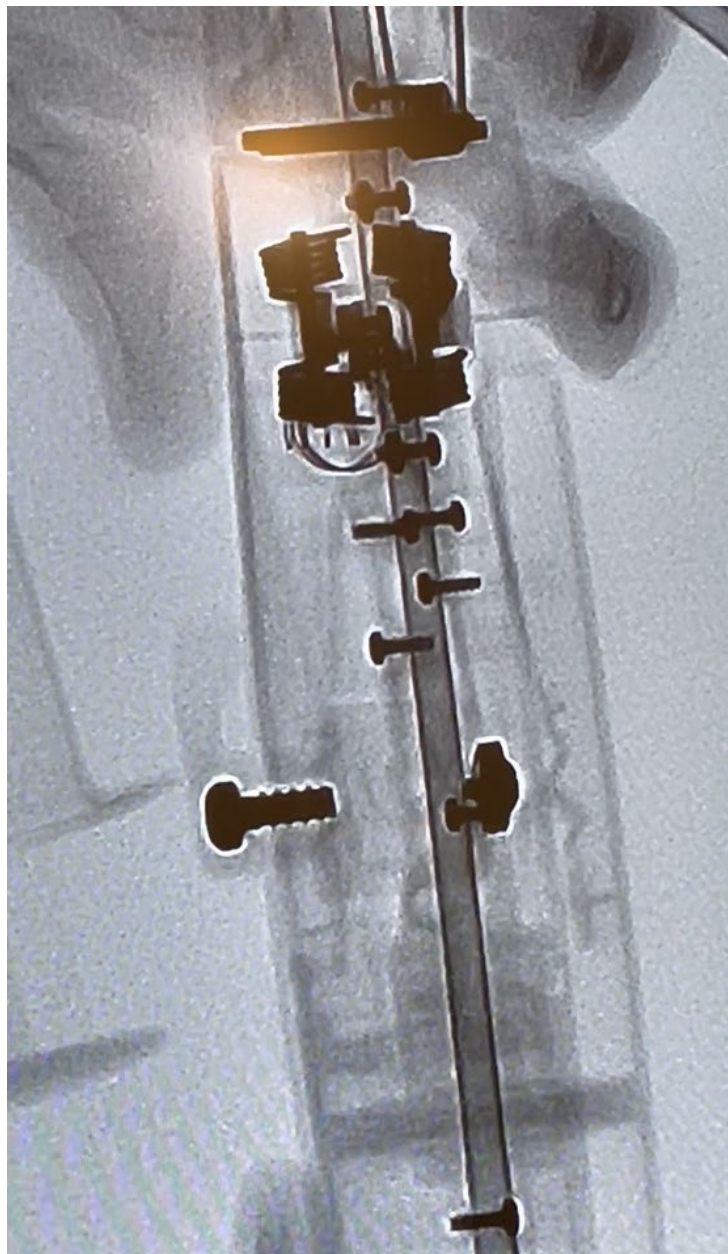
(Annotated image of internal portion of the controller housing.)



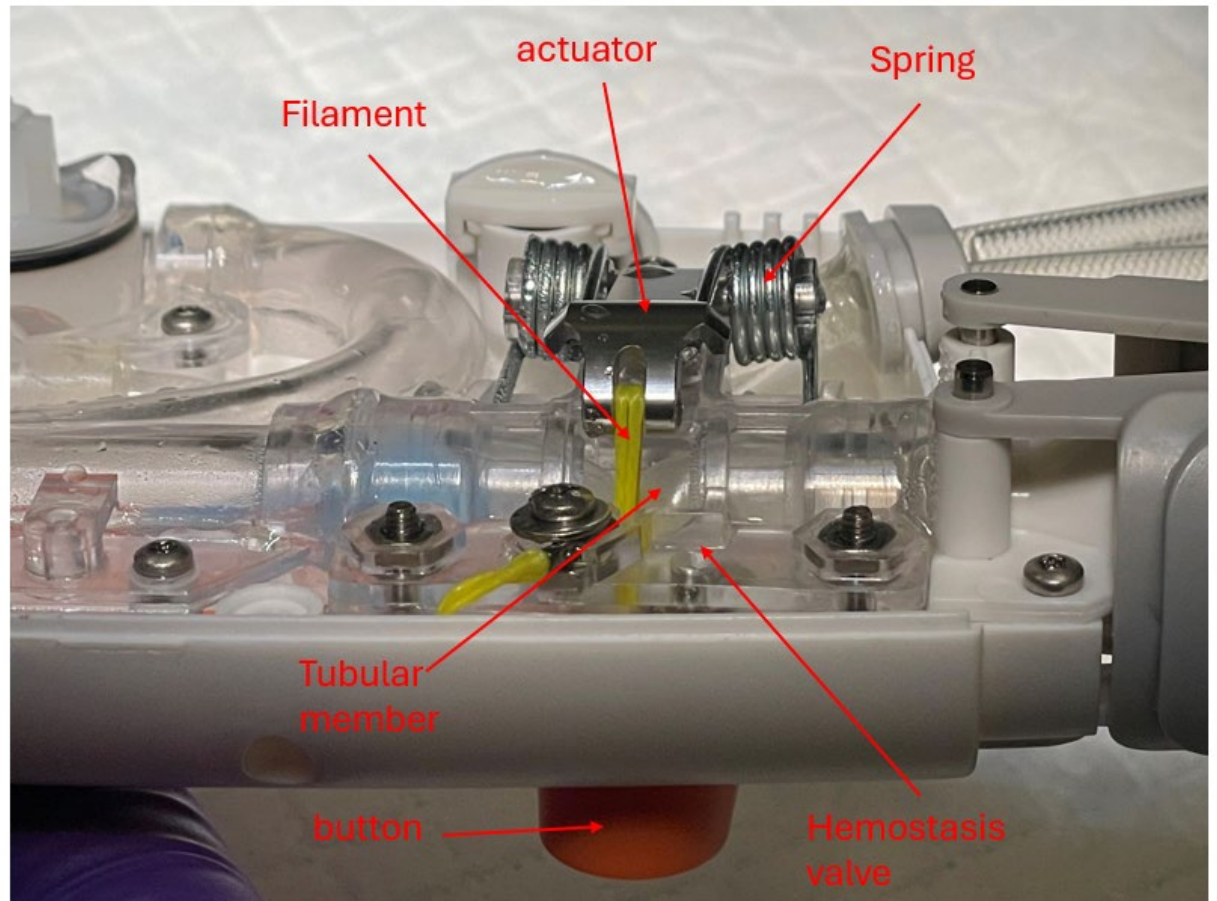
(Annotated x-ray image showing button and actuator.)



(X-ray image showing button and actuator when button undepressed.)



	<p>(X-ray image showing button and actuator when button is depressed.)</p> <p>The Symphony System IFU confirms that the pair of actuators of the hemostasis valve are movable, where engaging the actuators at least partially opens the lumen of the tubular member. (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 the 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.”).)</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
[23] The clot treatment system of claim 22 wherein the actuators each comprise a button.	<p>The Symphony System includes a hemostasis valve with a pair of actuators that each comprise a button.</p> <p>Specifically, the actuators of the hemostasis valve of the 24F and 16F Symphony Catheter handle comprise buttons, as shown in the annotated image below.</p>



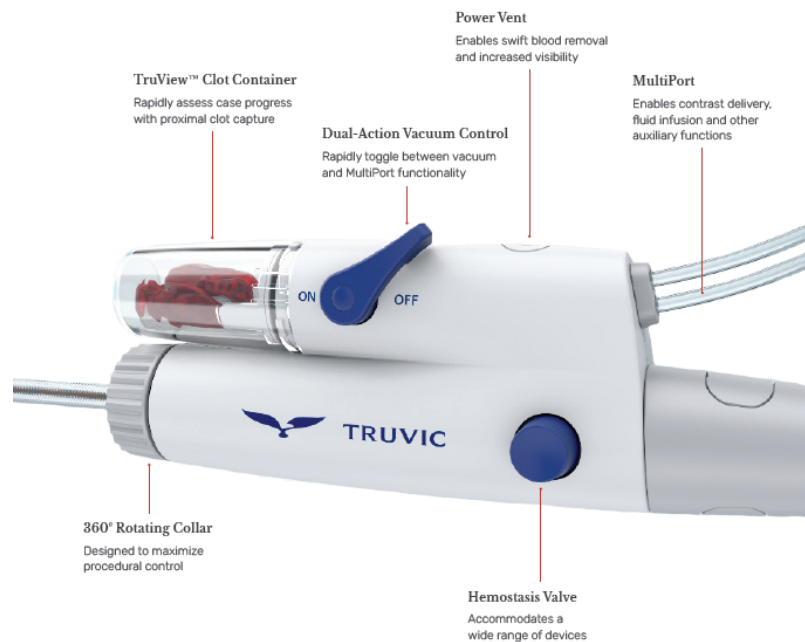
(Annotated image of internal portion of the controller housing.)

One of the buttons is shown in the Symphony Thrombectomy System Brochure, reproduced below.

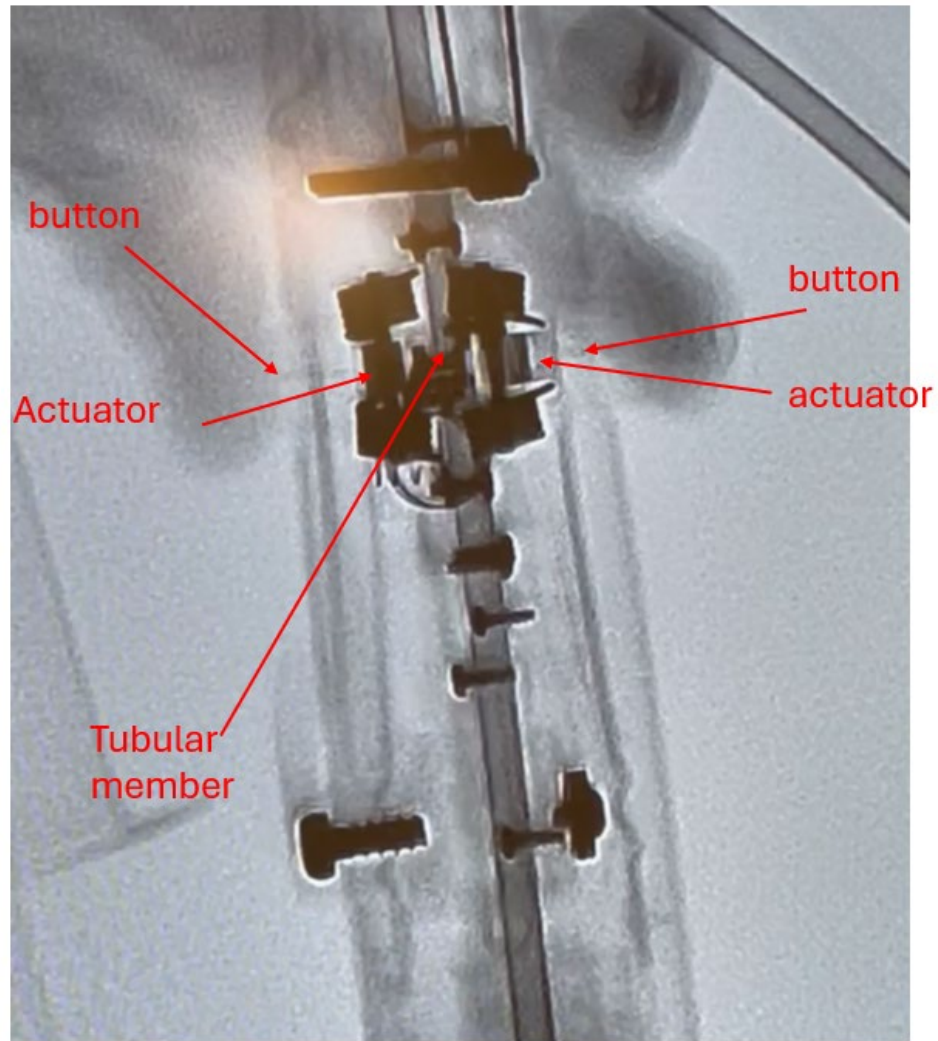
SYMPHONY™ THROMBECTOMY SYSTEM

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

BigShot™ Controller



(Symphony Thrombectomy System Brochure at 6.)



(Annotated x-ray image of housing showing button, actuator, and tubular member.)

The Symphony System IFU confirms that the actuators each comprise a button. (Symphony Thrombectomy System Instructions For Use at 2 (“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.”).)

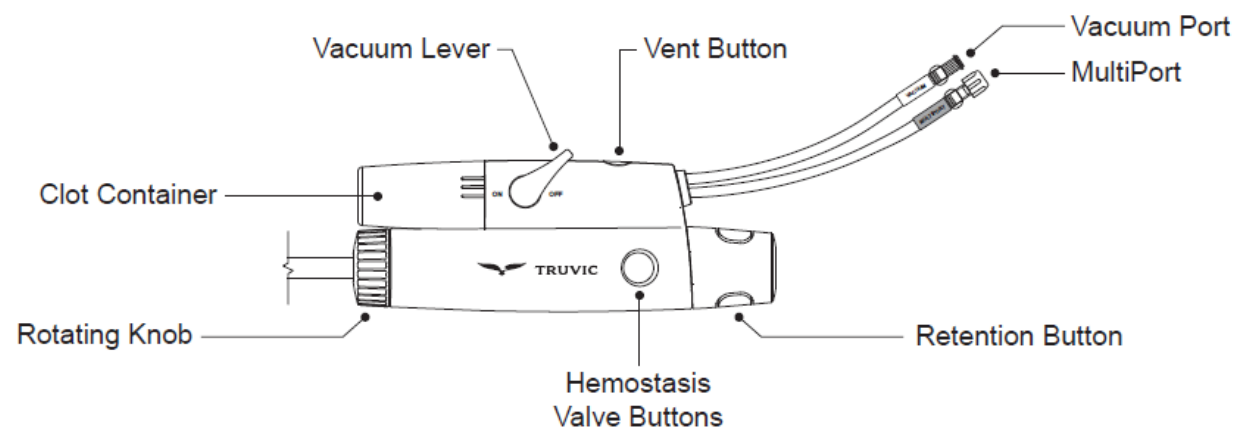


Figure 3: Symphony Catheter Handle, labeled

(Symphony Thrombectomy System Instructions For Use at 4.)

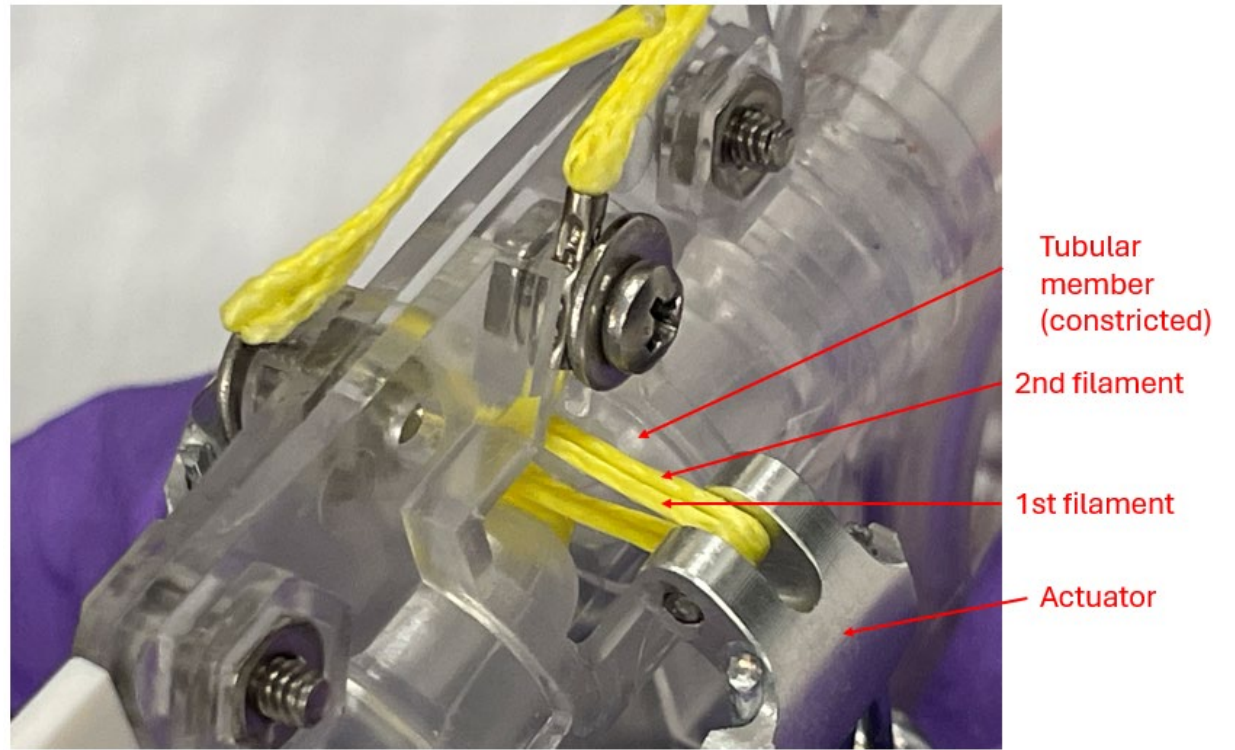
To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.

[24] The clot treatment system of claim 22 wherein the first filament

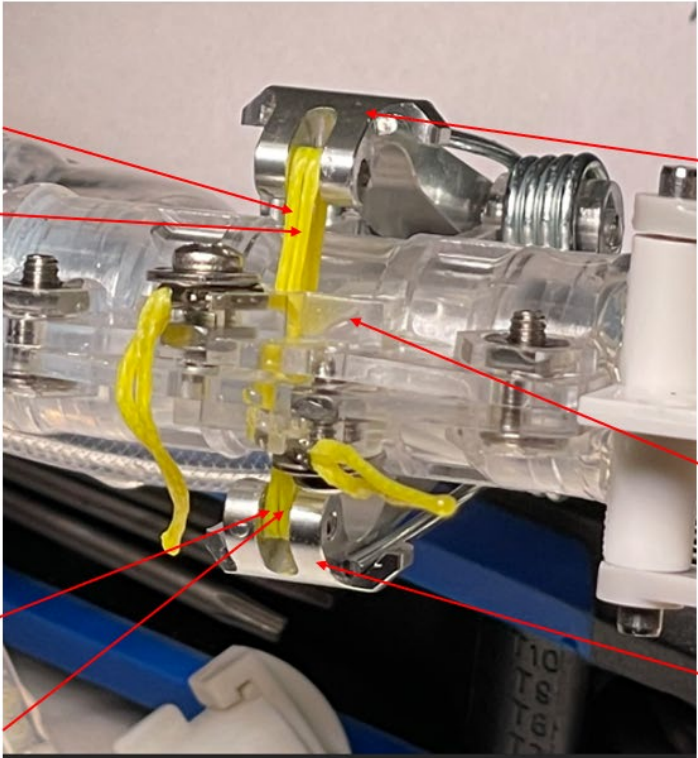
The Symphony System includes a hemostasis valve where the first filament includes a first portion operably coupled to a first one of the actuators and a second

<p>includes a first portion operably coupled to a first one of the actuators and a second portion operably coupled to a second one of the actuators, and wherein the second filament includes a first portion operably coupled to the first one of the actuators and a second portion operably coupled to the second one of the actuators.</p>	<p>portion coupled to the second one of the actuators and where the second filament includes a first portion operably coupled to the first one of the actuators and a second portion operably connected to the second one of the actuators.</p> <p>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 valve has a first and a second actuator 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.</p> <p>The hemostasis valve includes a first filament defined by a first braided line and a first actuator defined by a first push-button, the first lever contacting the first push-button, and the first pin at the end of the first lever on one side and a second actuator defined second push-button, a second lever contacting the second push-button, and a second pin at the end of the second lever on the other side.</p>
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	<p>The first filament has a portion looped fully around the tubular member and a first portion having a first end extending from the loop in one direction toward the first lever/pin and a second portion having a second end extending from the loop in an opposite direction toward the second lever/pin.</p> <p>The second filament has a portion looped fully around the tubular member and a first portion having a first end extending from the loop in one direction toward the first lever/pin and a second portion having a second end extending from the loop in an opposite direction toward the second lever/pin.</p> <p>The first pin at the end of the first arm is part of the first actuator, and is coupled to the first end of the first and second filaments. Specifically, the first end of the first filament and the second filament wraps around the first pin.</p> <p>The second pin at the end of the second arm is part of the second actuator, and is coupled to the second end of the first and second filaments. Specifically, the second end of the first filament and the second filament wraps around the second pin.</p> <p>The first and second buttons/levers/pins are movably coupled to the support and movable between (a) a first position where the filaments circumferentially constrict the lumen of the tubular member to create a seal and (b) a second position wherein the filaments are moved to at least partially open the lumen, as shown in the teardown images below.</p>
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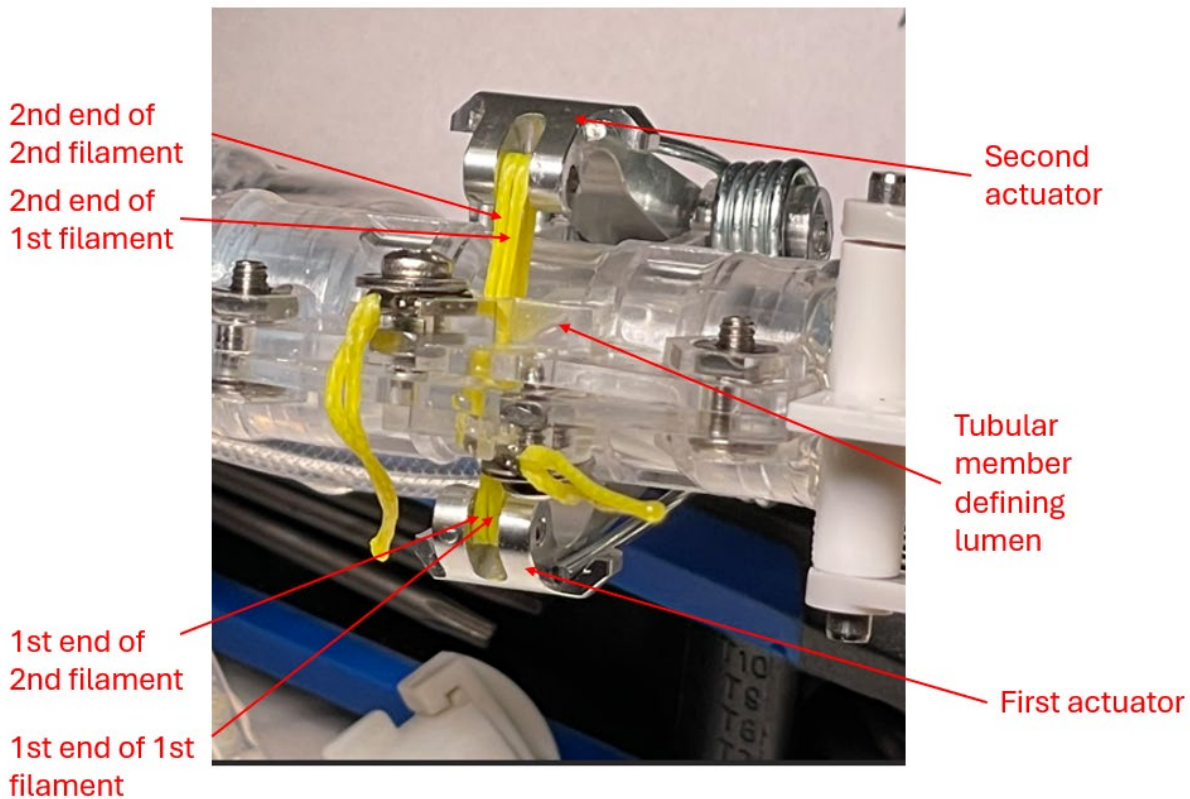


(Annotated image of internal portion of the controller housing.)

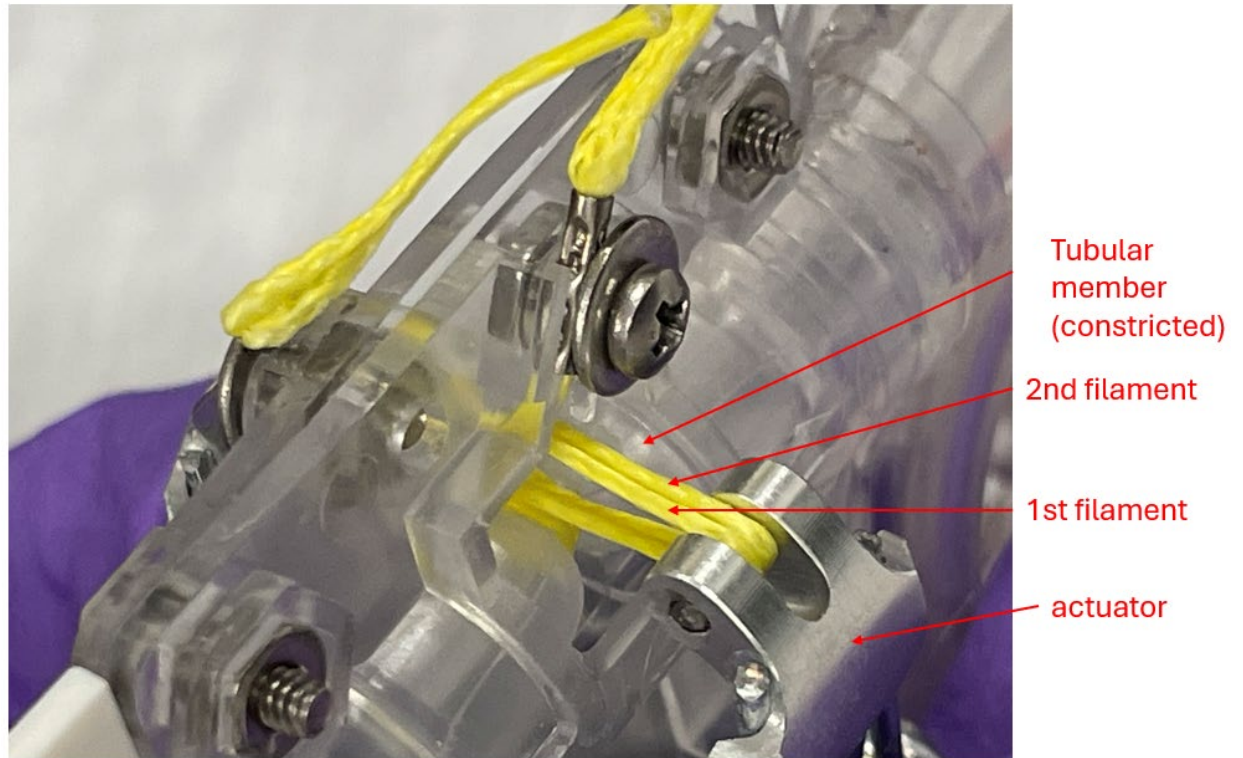
	<div data-bbox="781 230 1978 1023">  <p>2nd end of 2nd filament</p> <p>2nd end of 1st filament</p> <p>1st end of 2nd filament</p> <p>1st end of 1st filament</p> <p>Second actuator</p> <p>Tubular member defining lumen</p> <p>First actuator</p> </div> <p>(Annotated image of internal portion of the controller housing.)</p> <p>To the extent that the Symphony System does not literally meet this limitation, the Symphony System meets this limitation under the doctrine of equivalents.</p>
<p>[25] The clot treatment system of claim 22 wherein the first filament is flexible, and wherein the second</p>	<p>The Symphony System includes a hemostasis valve with a first filament that is flexible and a second filament that is flexible.</p>

filament is flexible.

Specifically, as shown in the annotated teardown images below, the first and second filaments of the hemostasis valve of the 24F and 16F Symphony Catheter handle are flexible, such that they can constrict the lumen of the tubular member or loosen to open the lumen.



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



(Annotated image of internal portion of the controller 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.

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

The Symphony System includes an aspiration catheter that has a size of at least 16 French.

Specifically, the Symphony System can include a 24F Catheter and/or 16F Catheter (either with a working length of 82 cm or 117 cm), as shown in the Symphony Thrombectomy System Brochure below.

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	Generator & Accessories		
16F ProHelix	PROHELIX16F	Generator	Model	
24F ProHelix	PROHELIX24F	Canister	Model	
		Tubaset	Model	

(Symphony Thrombectomy System Brochure at 11.)

Symphony™ Catheters

Product	Model	Working Length	Sheath Compatibility
16F Catheter, 82cm	SYMPHONY16F82	82 cm	16F
16F Catheter	SYMPHONY16F	117 cm	16F
24F Catheter	SYMPHONY24F	85 cm	24F

(Symphony System product specification sheet.)

The Symphony System IFU similarly instructs that the Symphony System can be used with a 24F Catheter and/or 16F Catheter.

DEVICE DESCRIPTION

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

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

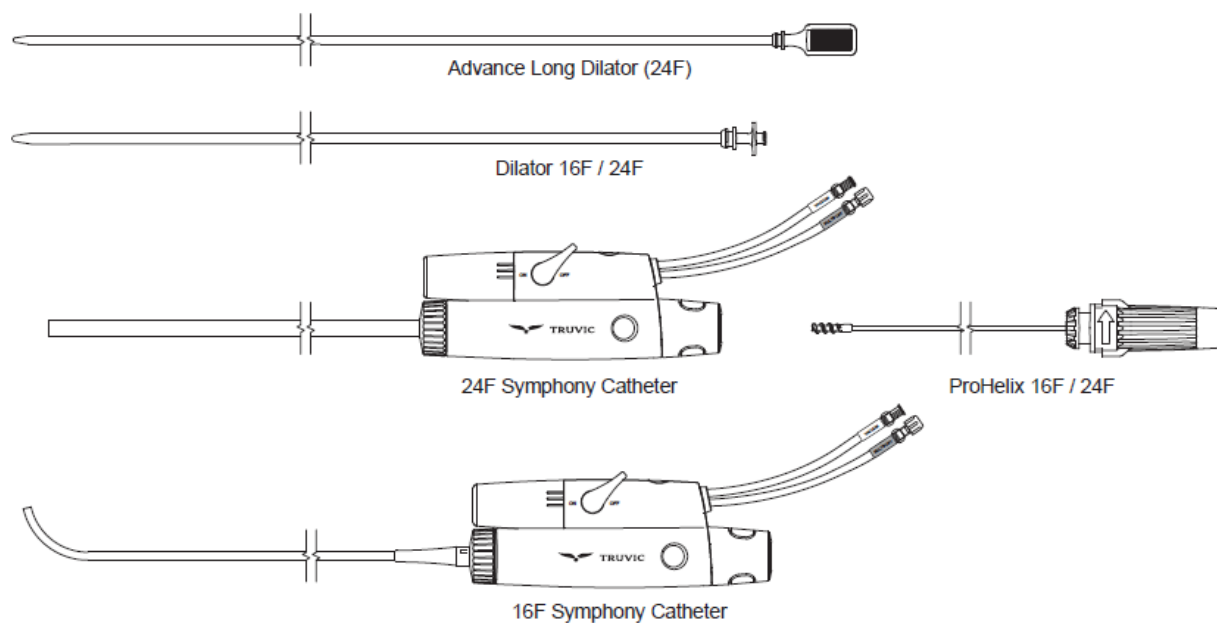


Figure 1: Symphony Thrombectomy System components

(Symphony Thrombectomy System Instructions For Use at 1.)

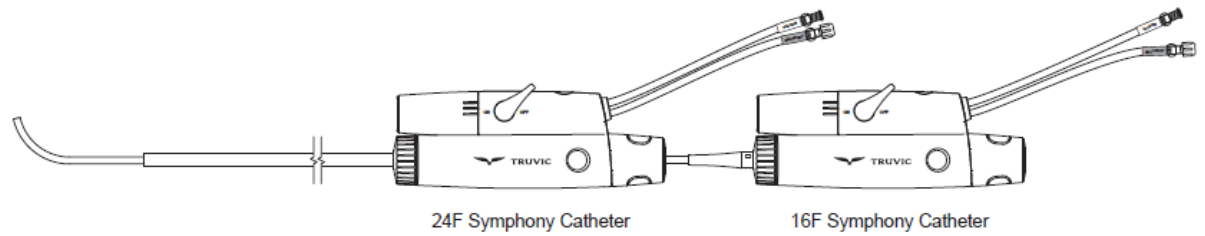


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony Thrombectomy System Instructions For Use at 7.)

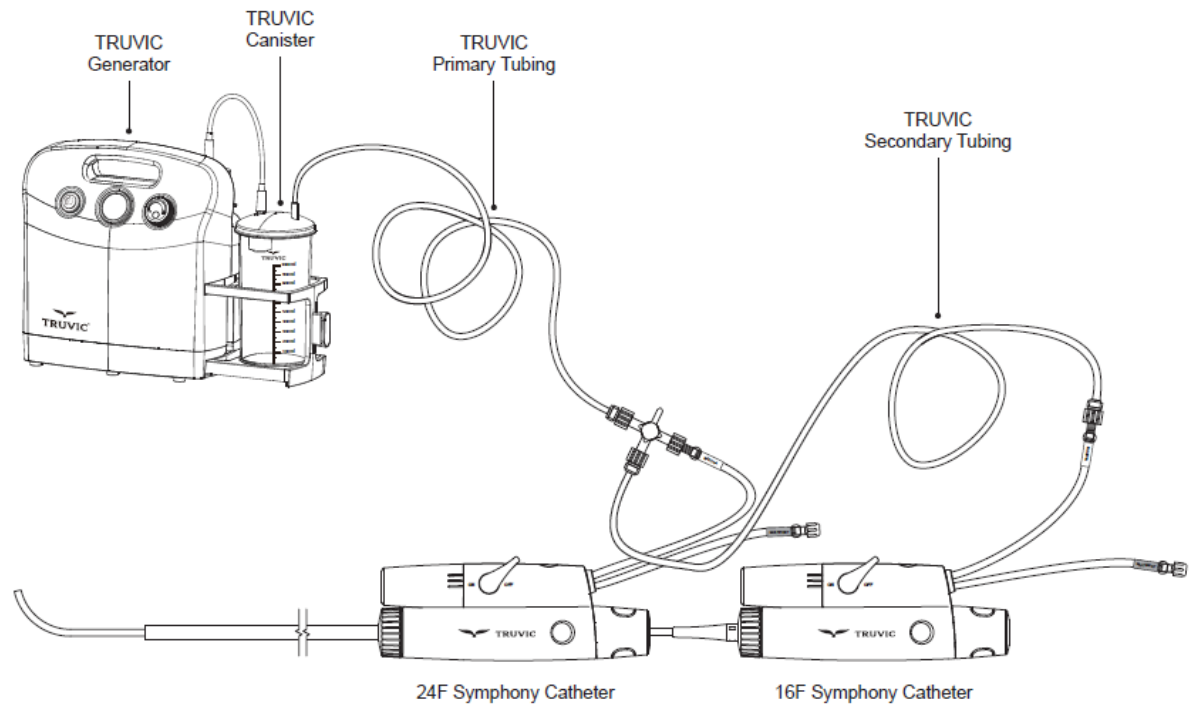


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Symphony Thrombectomy System Instructions For Use at 8; Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Catheter has a lubricious hydrophilic coating on the distal 40 cm of the 24F catheter shaft, and distal 55 cm of the 16F catheter shaft.”).)

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

The Symphony System includes an aspiration catheter that has size of at least 20 French.

Specifically, the Symphony System can include a 24F Catheter, as shown in the Symphony Thrombectomy System Brochure below.

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	Generator & Accessories		
16F ProHelix	PROHELIX16F	Generator	Model	
24F ProHelix	PROHELIX24F	Generator	PTG1B	
		Canister	PTC001B	
		Tubaset	PAT10261B	

(Symphony Thrombectomy System Brochure at 11.)

The Symphony System IFU similarly instructs that the Symphony System can be used with a 24F Catheter.

DEVICE DESCRIPTION

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

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

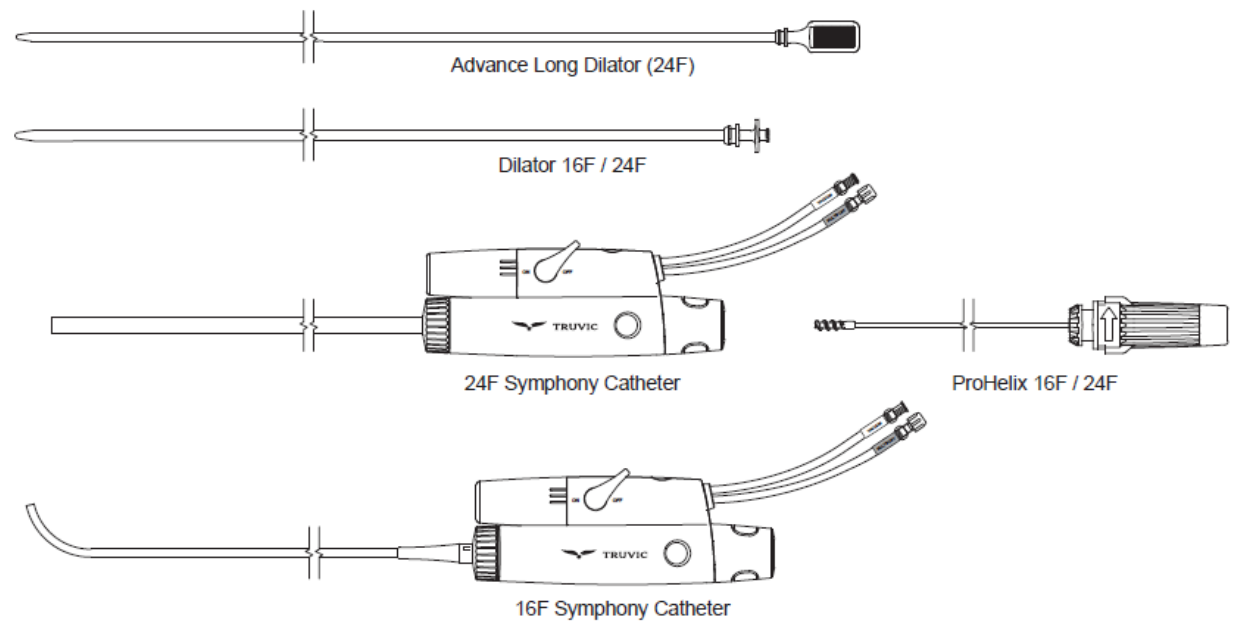


Figure 1: Symphony Thrombectomy System components

(Symphony Thrombectomy System Instructions For Use at 1.)

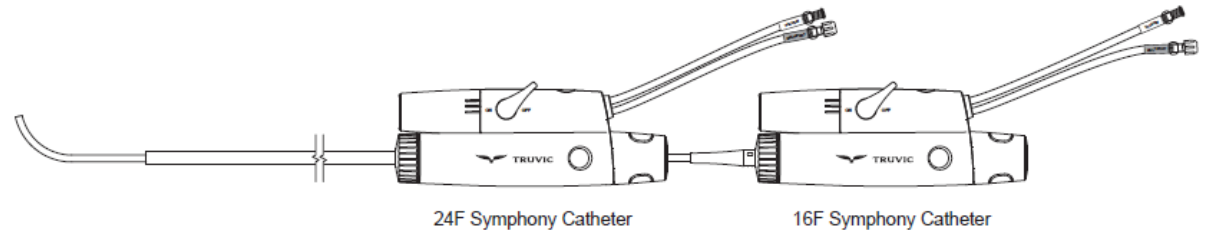


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony Thrombectomy System Instructions For Use at 7.)

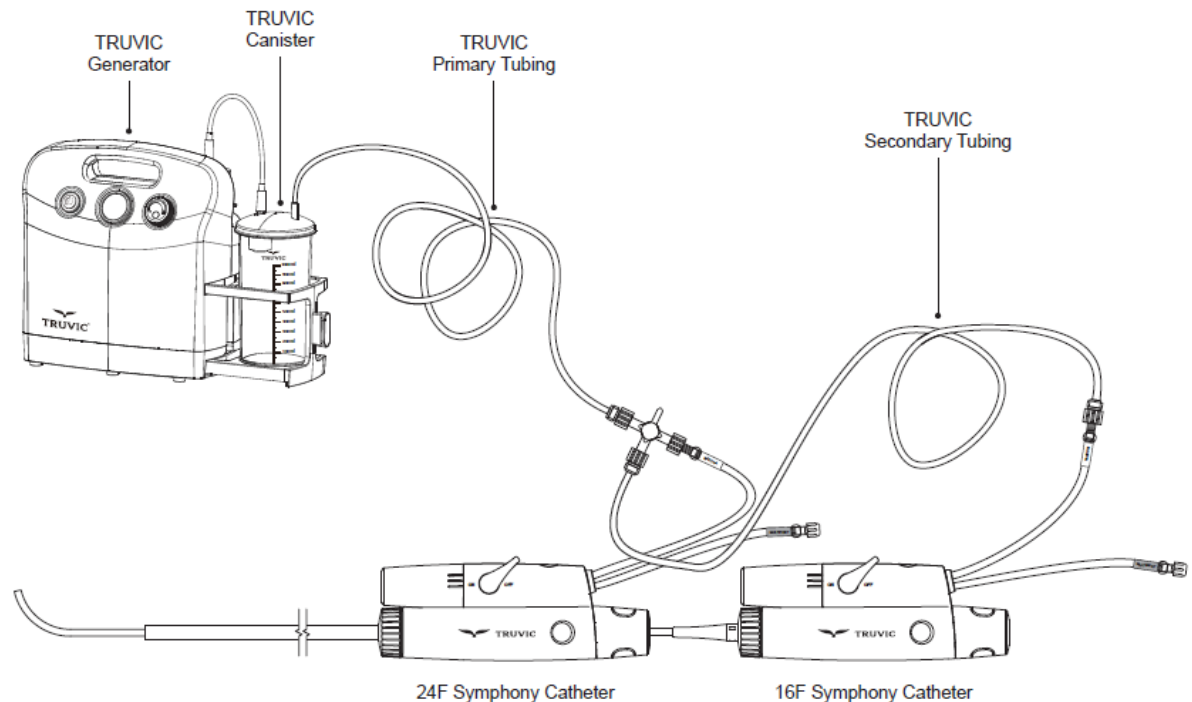


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Symphony Thrombectomy System Instructions For Use at 8; Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Catheter has a lubricious hydrophilic coating on the distal 40 cm of the 24F catheter shaft....”).)

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

The Symphony System includes an aspiration catheter that has a size of at least 22 French.

Specifically, the Symphony System can include a 24F Catheter, as shown in the Symphony Thrombectomy System Brochure below.

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	Generator & Accessories		
16F ProHelix	PROHELIX16F	Generator	Model	
24F ProHelix	PROHELIX24F	Generator	PTG1B	
		Canister	PTC001B	
		Tubaset	PAT10261B	

(Symphony Thrombectomy System Brochure at 11.)

The Symphony System IFU similarly instructs that the Symphony System can be used with a 24F Catheter.

DEVICE DESCRIPTION

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

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

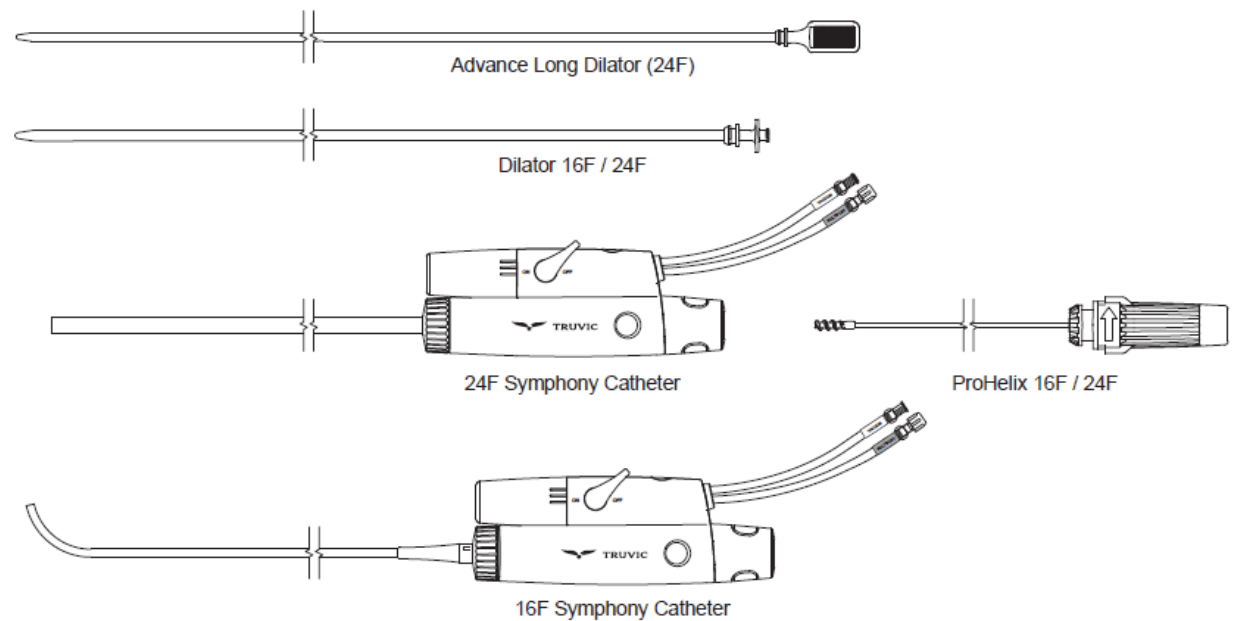


Figure 1: Symphony Thrombectomy System components

(Symphony Thrombectomy System Instructions For Use at 1.)

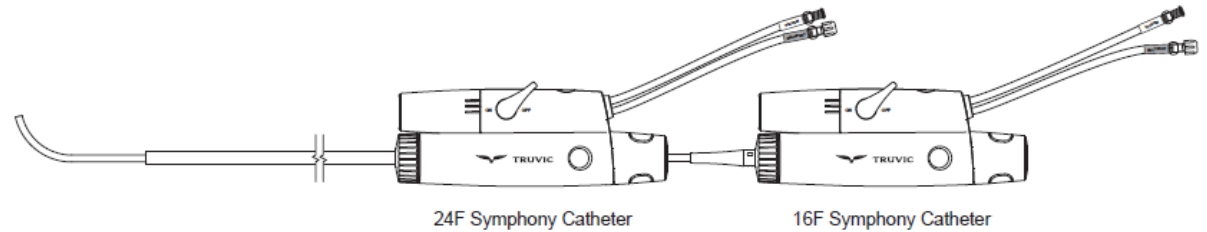


Figure 5: Telescoping a 16F Symphony Catheter into a 24F Symphony Catheter

(Symphony Thrombectomy System Instructions For Use at 7.)

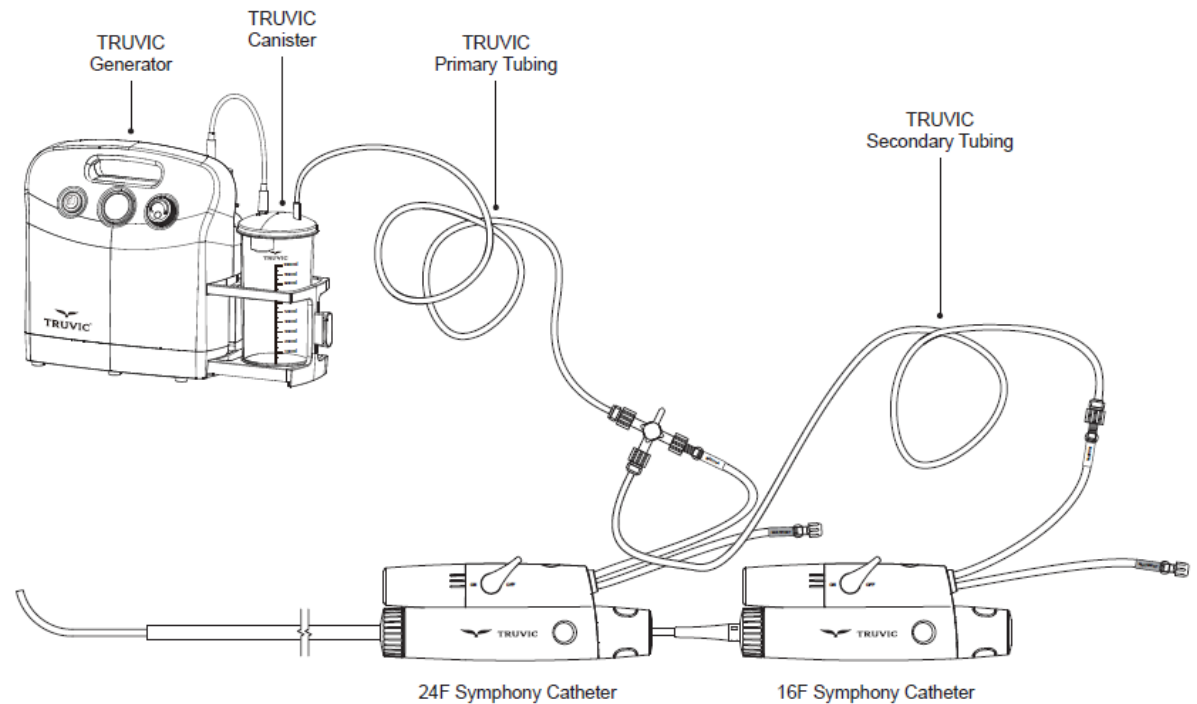


Figure 6: Use of TRUVIC Tubeset from telescoping 16F Symphony Catheter and 24F Symphony Catheter to TRUVIC Generator and Canister

(Symphony Thrombectomy System Instructions For Use at 8; Symphony Thrombectomy System Instructions For Use at 1 (“The Symphony Catheter has a lubricious hydrophilic coating on the distal 40 cm of the 24F catheter shaft....”).)

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