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(54) **DUAL HUB INTRODUCER SHEATH**

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(57)

**ABSTRACT**

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There is provided an introducer system for percutaneously delivering a first and a second medical device to a patient. The system may comprise an introducer sheath having a longitudinal axis and a lumen formed therein. The system may also comprise a hub coupled to a proximal end of the sheath. The hub may comprise a first arm having a first lumen and a first hemostasis valve for the passage of the first medical device. The hub may also comprise a second arm coupled to the first arm and having a second lumen and a second hemostasis valve for the passage of the second medical device. Further, the hub may comprise a connection port such that the first lumen and the second lumen are in communication with the lumen of the introducer sheath for the passage of at least one of the first and second medical devices through the introducer sheath for delivery to the patient.

**Related U.S. Application Data**

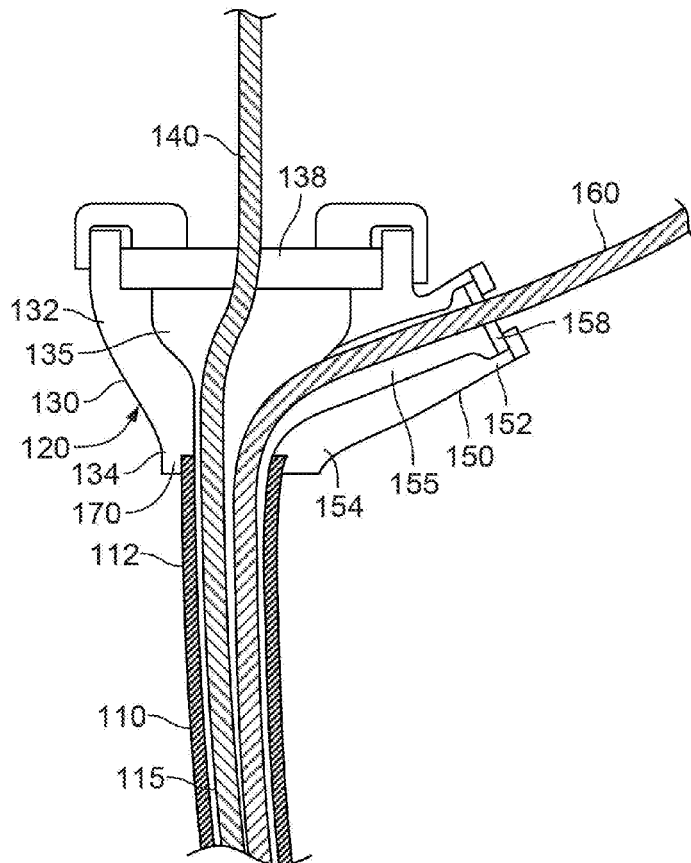
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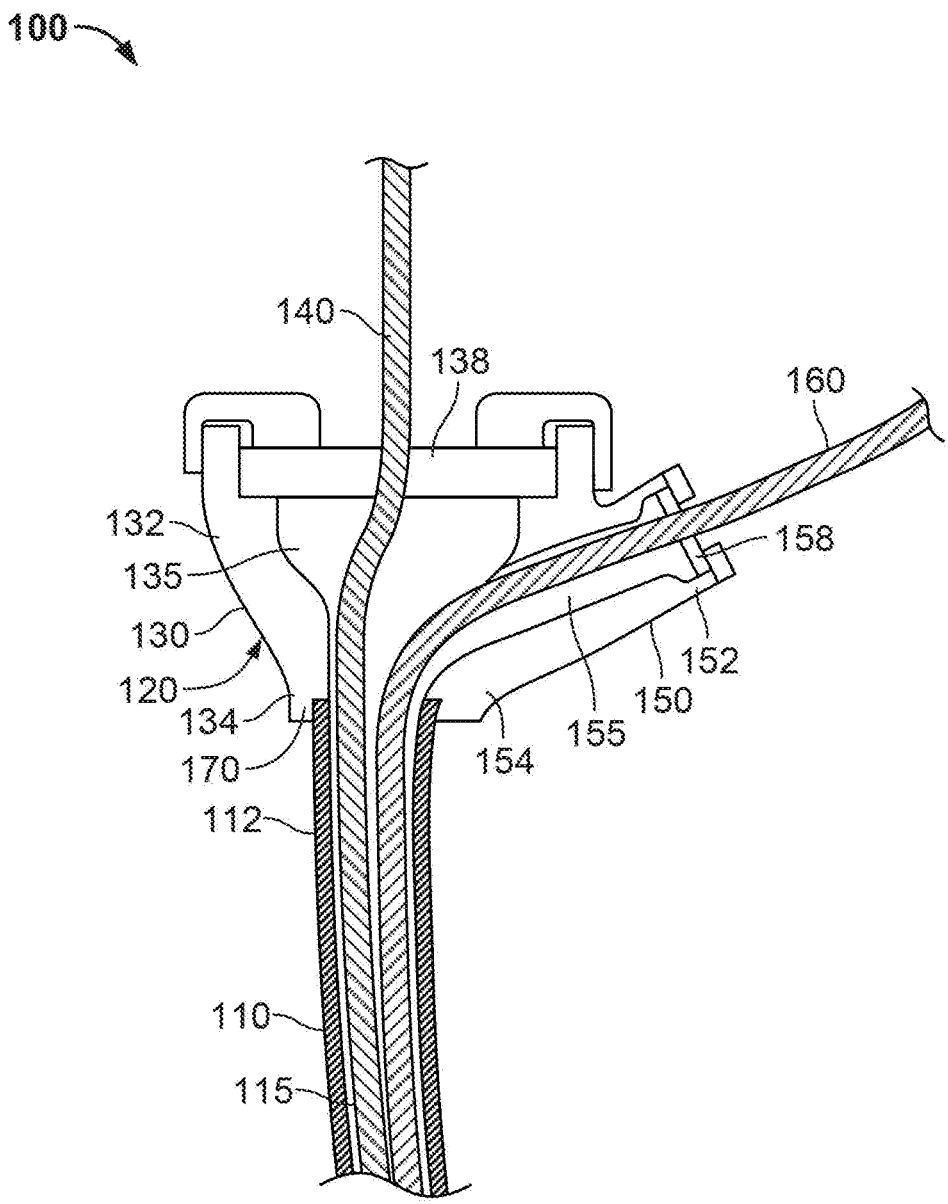


FIG. 1

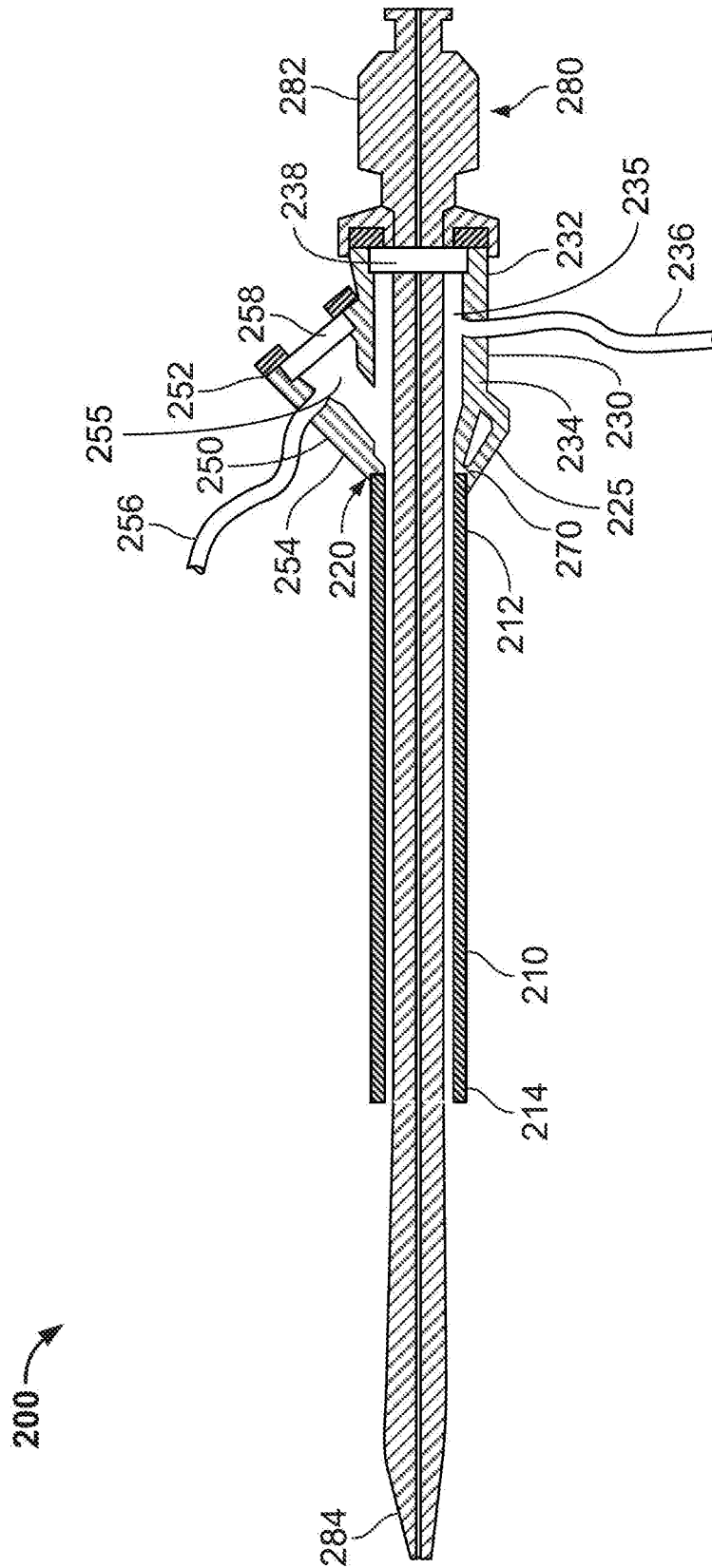


FIG. 2

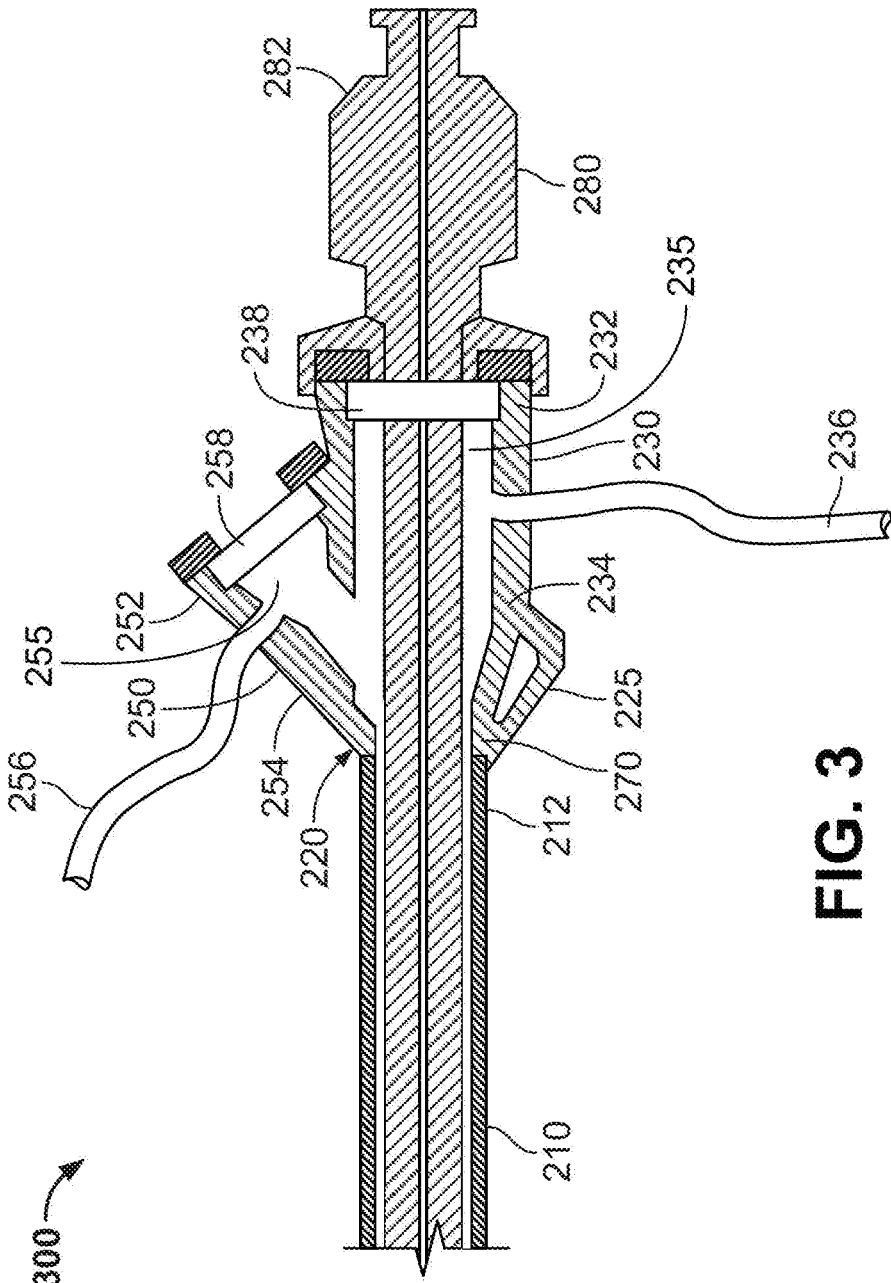


FIG. 3

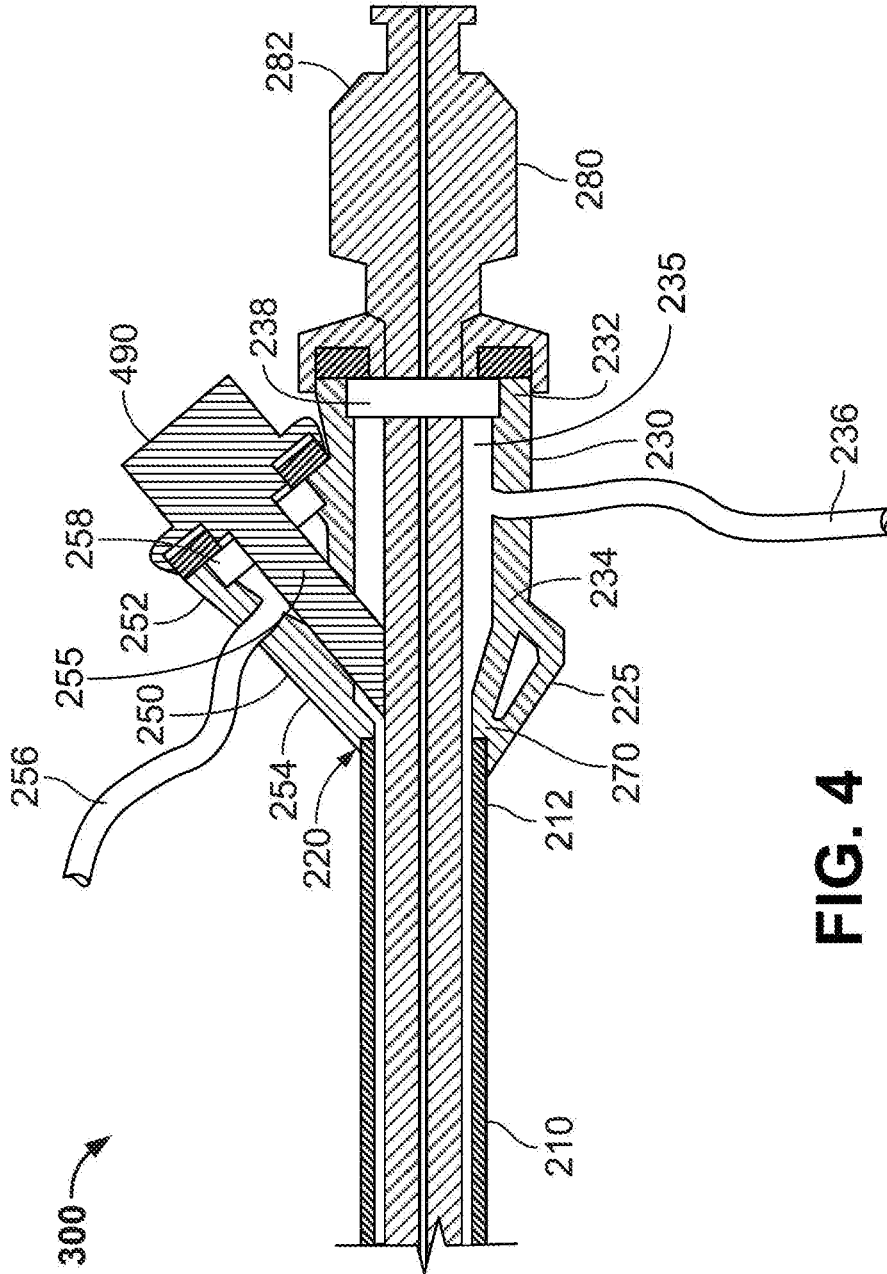
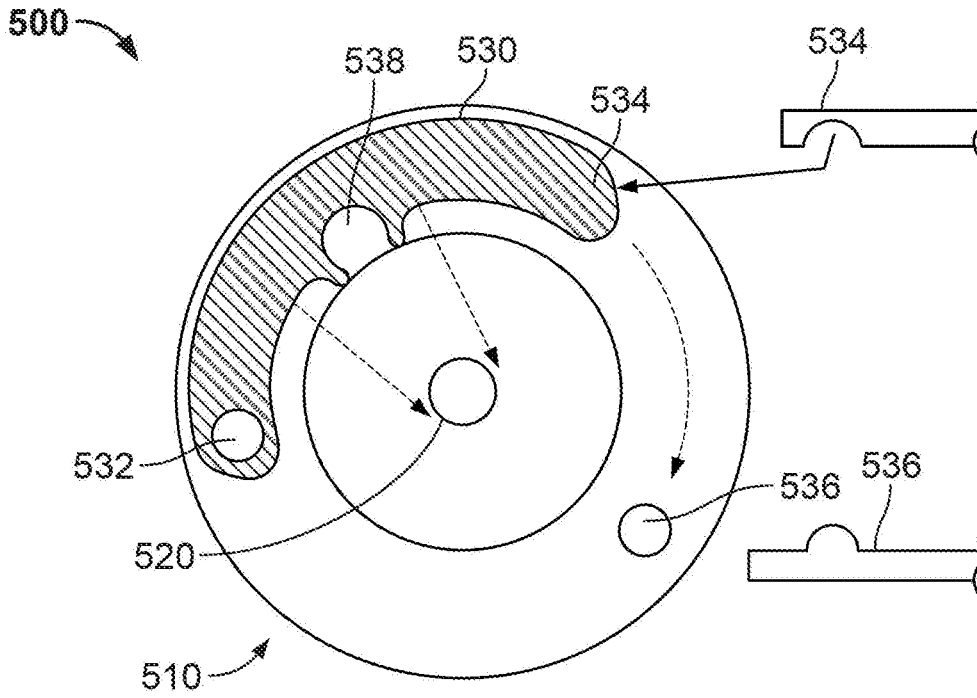
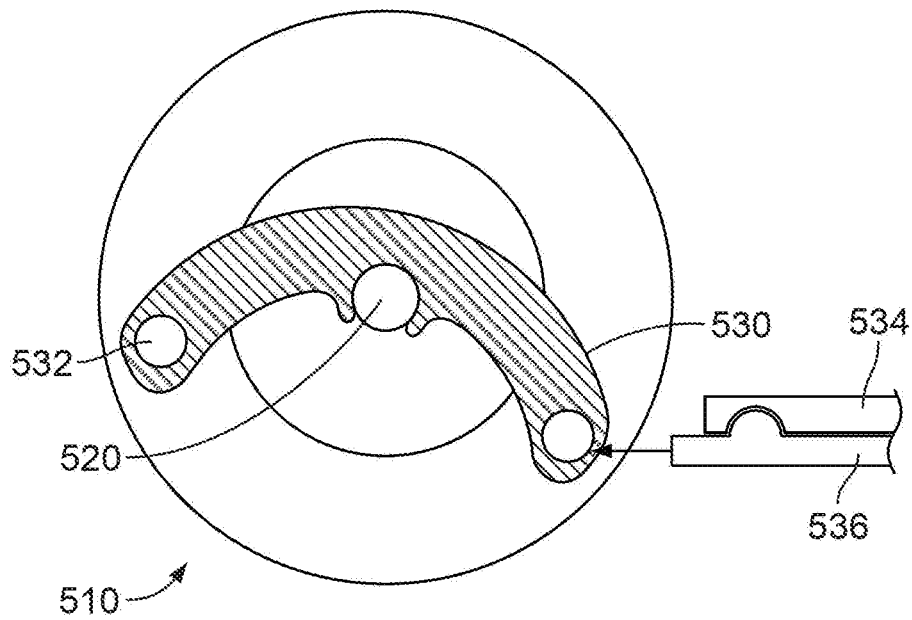


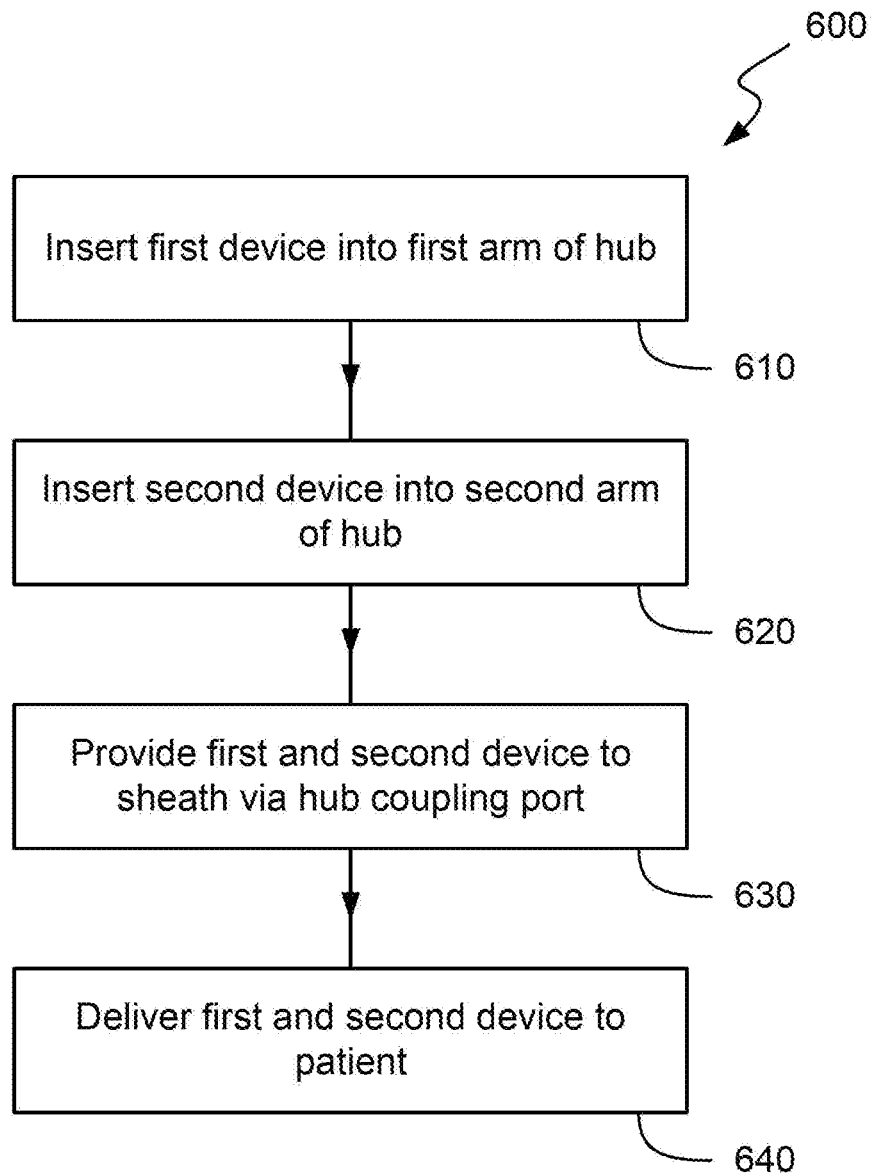
FIG. 4



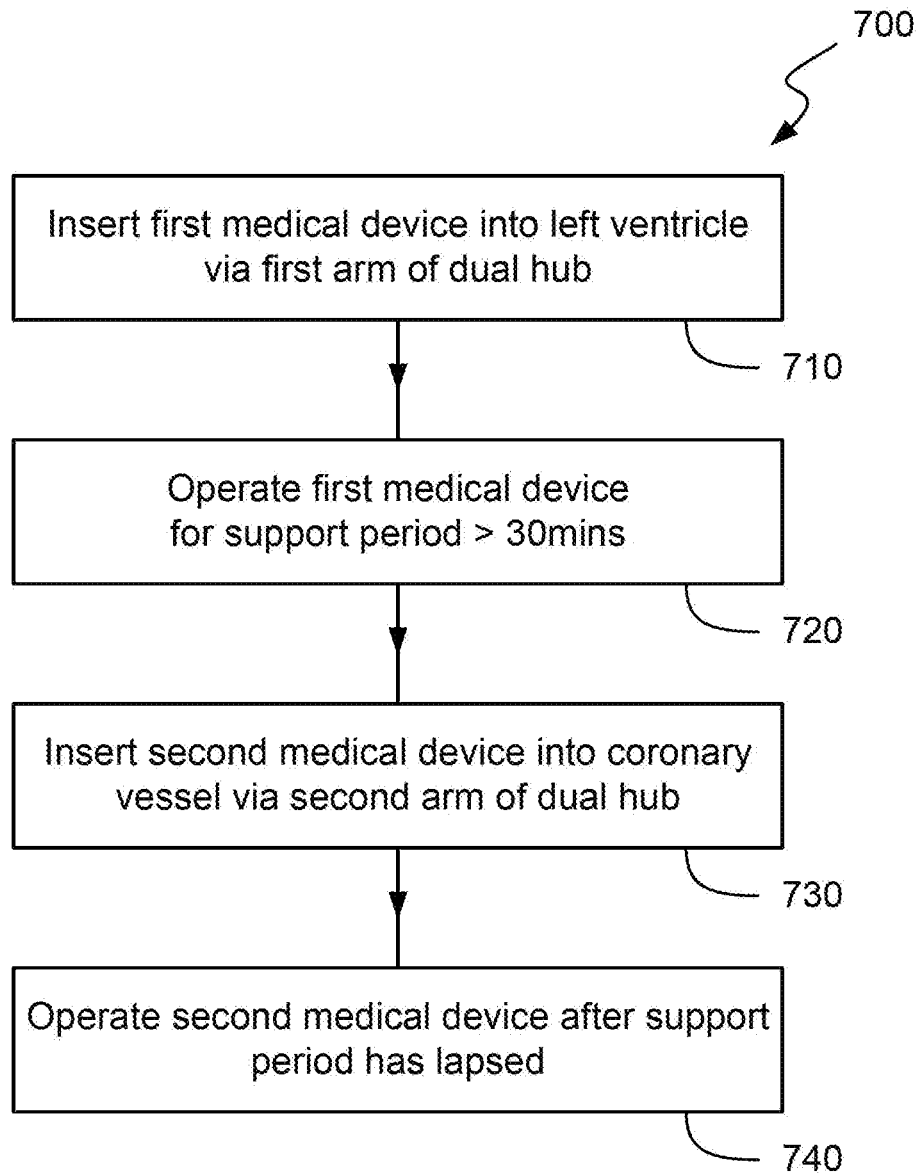
**FIG. 5A**



**FIG. 5B**



**FIG. 6**



**FIG. 7**



## DUAL HUB INTRODUCER SHEATH

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Application No. 62/817,901, filed Mar. 13, 2019, the contents of which are fully incorporated herein by reference.

### BACKGROUND

[0002] Currently, percutaneous mechanical support devices are leveraged for a variety of clinical indications. Such support devices may comprise, but are not limited to, an Impella® pump, an Extracorporeal Membrane Oxygenation (ECMO) pump, and a balloon pump. The Impella® pump may further comprise an Impella2.5® pump, an Impella5.0® pump, an Impella CP® pump and an Impella LD® pump, all of which are by Abiomed, Inc. of Danvers, Mass. Most often they are inserted into a patient percutaneously through a single access point (e.g., radial access, femoral access, axillary access) while other procedures, such as, for example, percutaneous coronary intervention (PCI) are performed through a second access point, such as a contralateral femoral or radial access point. The use of multiple devices on a patient at the same time therefore often requires multiple access sites which presents several challenges.

### BRIEF SUMMARY

[0003] The present technology relates to systems and methods for percutaneously delivering a first medical device and a second medical device to a patient.

[0004] In one aspect, the disclosure describes an introducer system comprising: an introducer sheath having a longitudinal axis and a lumen formed therein; and a hub coupled to a proximal end of the introducer sheath. The hub comprises: a first arm having a first lumen and a first hemostasis valve, the first lumen and the first hemostasis valve configured for the passage of a first medical device; a second arm coupled to the first arm and having a second lumen and a second hemostasis valve, the second lumen and the second hemostasis valve configured for the passage of a second medical device; and a connection port coupled to the introducer sheath and to the first arm and the second arm, such that the first lumen and the second lumen are in communication with the lumen of the introducer sheath to allow the passage of at least one of the first medical device and the second medical device through the introducer sheath for delivery to a patient. In some aspects, the first arm is arranged parallel to the longitudinal axis of the introducer sheath. In some aspects, the second arm is configured to branch off the first arm at an angle of no more than 90°. In some aspects, the first arm and the second arm are arranged in a Y-shaped configuration with respect to the introducer sheath. In some aspects, the second arm is located proximal to the connection port. In some aspects, the first arm and the second arm each has a proximal end and a distal end, and the distal end of the first arm is positioned distal of the proximal end of the second arm. In some aspects, the second lumen merges with the first lumen within the hub. In some aspects, the introducer sheath comprises a single lumen for the passage of the first and second medical devices. In some aspects, the first lumen and the second lumen are maintained

as separate lumens within the hub. In some aspects, the introducer sheath comprises a dual lumen sheath such that the first lumen is in communication with one of the lumens of the dual lumen sheath, and the second lumen is in communication with the other lumen of the dual lumen sheath. In some aspects, the introducer sheath is an expandable sheath. In some aspects, the introducer sheath is a peel-away sheath. In addition, the hub may further comprise tabs to enable separation of the hub and the peel-away sheath. In some aspects, the first and second hemostasis valves are configured to seal the respective first and second lumens. In some aspects, the first and second hemostasis valves are each configured to be penetrable by the first or second medical device. In some aspects, the hub further comprises at least one suture ring. In some aspects, the first arm and the second arm each comprise at least one side-port. In addition, the side-port may comprise an irrigation port configured to be supplied with an irrigation fluid. In some aspects, at least one of the first arm and the second arm comprises a locking mechanism configured to prevent axial movement of one or both of the first medical device and the second medical device within the introducer sheath after delivery to the patient. In some aspects, the locking mechanism comprises at least one of: a Tuohy-Borst adaptor, an inflatable balloon, and a locking lever arm. In some aspects, the locking mechanism is biased in a state that is configured to prevent axial movement of one or both of the first medical device and the second medical device within the introducer sheath. In some aspects, the introducer sheath comprises at least one of: a polyether block amide; a polyethylene material; a polytetrafluoroethylene (PTFE) material; a high-density polyethylene (HDPE) material; a medium-density polyethylene (MDPE) material; or a low-density polyethylene (LDPE) material. In some aspects, the hub comprises at least one of: ethylene-vinyl acetate (EVA); styrene-butadiene copolymer (SBC); styrene ethylene butylene styrene (SEBS); a high-density polyethylene (HDPE) material; a medium-density polyethylene (MDPE) material; a low-density polyethylene (LDPE) material; polyether ether ketone (PEEK); a polyether block amide; an elastomer; synthetic rubber; or a polyethylene, polyurethane, or polycarbonate material with an elastic modulus of about 40 ksi. In some aspects, the first medical device is a mechanical circulatory support device, and the second medical device is a coronary reperfusion therapy device for providing the patient with percutaneous coronary intervention (PCI). In some aspects, the coronary reperfusion therapy device is a stent. In some aspects, the stent is configured for insertion through the second arm and introducer sheath by a catheter. In some aspects, the mechanical circulatory support device comprises at least one of: a blood pump; a transvalvular axial-flow (TV)-pump; an intra-aortic balloon pump; or an extracorporeal membrane oxygenation (ECMO) pump. In some aspects, the mechanical circulatory support device is a rotary blood pump having a cannula and a rotor and rotor housing. In some aspects, the first arm and the introducer sheath are configured to allow passage of the cannula of the rotary blood pump. In some aspects, the first arm and the introducer sheath are configured to allow passage of the rotor and rotor housing of the rotary blood pump. In some aspects, the hub comprises up to five second arms, each second arm configured with a hemostasis valve and a lumen in communication with the introducer sheath for the passage of the second medical device from a respective second arm into the

introducer sheath. In some aspects, the second arms are arranged in a radially symmetric manner about the first arm. In some aspects, the hub comprises two second arms. In some aspects, the introducer system may further comprise at least one third arm coupled to the first arm, each third arm having a third lumen and a third hemostasis valve, the third lumen and third hemostasis valve configured for the passage of a third medical device.

**[0005]** In another aspect, the disclosure describes a method comprising: inserting a first medical device into a first arm of an introducer hub, the first arm having a first lumen for the passage of the first medical device there-through; inserting a second medical device into a second arm attached to the first arm, the second arm having a second lumen for the passage of the second medical device there-through; providing the first medical device and the second medical device to an introducer sheath via a connector port of an introducer hub, the connector port coupled to a proximal end of the introducer sheath; and delivering the first medical device and the second medical device to a patient from a distal end of the introducer sheath. In some aspects, the method further comprises inserting the first and second medical devices into a lumen formed within the introducer sheath for delivery to the patient. In some aspects, the method further comprises inserting the first medical device into a first lumen formed within the introducer sheath for delivery to the patient, and inserting the second medical device into a second lumen formed within the introducer sheath for delivery to the patient, the first lumen isolated from the second lumen. In some aspects, the method further comprises attaching the introducer hub to the patient via a suture ring. In some aspects, the method further comprises providing one or both of the first lumen and the second lumen with an irrigation fluid via a side-port positioned on each of the first and second arms. In some aspects, the method further comprises activating a locking mechanism to prevent axial movement of one or both of the first medical device and the second medical device within the introducer sheath. In some aspects, the locking mechanism comprises at least one of: a Tuohy-Borst adaptor, an inflatable balloon, and a locking lever arm. In some aspects, the locking mechanism is biased in a state that prevents axial movement of one or both of the first medical device and the second medical device within the introducer sheath. In some aspects, the method further comprises inserting a third medical device into a third arm attached to the first arm, the third arm having a third lumen for the passage of the third medical device there-through for delivery to the patient. In some aspects, the method further comprises supporting the patient's heart that has sustained myocardial infarction. In some aspects, the method further comprises: inserting the first medical device through the first arm and through the introducer sheath into the patient's left ventricle; operating the first medical device for a support period of greater than 30 minutes at a rate of at least 2.5 L/min of blood flow; inserting the second medical device through the second arm and through the introducer sheath into a coronary vessel of the patient; and operating the second medical device after the support period has elapsed. In some aspects, the first device comprises a mechanical circulatory support device. In some aspects, the mechanical circulatory support device comprises at least one of: a blood pump, a transvalvular axial-flow (TV)-pump, an intra-aortic balloon pump, or an extracorporeal membrane oxygenation (ECMO) pump. In

some aspects, the second device comprises a coronary reperfusion therapy device for providing the patient with percutaneous coronary intervention (PCI). In some aspects, the mechanical circulatory support device is operated to pump blood from the patient's left ventricle into the patient's aorta during the support period. In some aspects, the second medical device is inserted through the second arm after the first medical device is positioned across the patient's aortic valve and is unloading the patient's left ventricle. In some aspects, the second medical device is inserted through the introducer sheath at least 15 minutes after the first medical device begins unloading the patient's left ventricle. In some aspects, the first medical device is positioned with a distal tip located within the patient's left ventricle and pumps blood from the patient's left ventricle into the patient's aorta. In some aspects, the introducer hub comprises up to five second arms, each second arm configured with a hemostasis valve and a lumen in communication with the introducer sheath for the passage of the second medical device from a respective second arm into the introducer sheath. In some aspects, the second arms are arranged in a radially symmetric manner about the first arm. In some aspects, the introducer hub comprises two second arms. In some aspects, the introducer hub further comprises at least one third arm coupled to the first arm, each third arm having a third lumen and a third hemostasis valve, the third lumen and third hemostasis valve configured for the passage of a third medical device.

**[0006]** In another aspect, the disclosure describes an introducer hub comprising: a first arm having a first lumen and a first hemostasis valve, the first lumen and first hemostasis valve configured for the passage of a first medical device; a second arm coupled to the first arm and having a second lumen and a second hemostasis valve, the second lumen and second hemostasis valve configured for the passage of a second medical device; and a connection port coupled to an introducer sheath and to the first arm and the second arm, such that the first lumen and the second lumen are in communication with the lumen of the introducer sheath to allow the passage of at least one of the first medical device and the second medical device through the introducer sheath for delivery to a patient. In some aspects, the first arm is arranged parallel to a longitudinal axis of the introducer sheath. In some aspects, the second arm is configured to branch off the first arm at an angle of no more than 90°. In some aspects, the first arm and the second arm are arranged in a Y-shaped configuration with respect to the introducer sheath. In some aspects, the second arm is located proximal to the connection port. In some aspects, the first arm and the second arm each has a proximal end and a distal end, and the distal end of the first arm is positioned distal of the proximal end of the second arm. In some aspects, the second lumen merges with the first lumen. In some aspects, the introducer sheath comprises a single lumen for the passage of the first and second medical devices. In some aspects, the first lumen and the second lumen are maintained as separate lumens. In some aspects, the introducer sheath comprises a dual lumen sheath such that the first lumen is in communication with one of the lumens of the dual lumen sheath, and the second lumen is in communication with the other lumen of the dual lumen sheath. In some aspects, the introducer sheath is an expandable sheath. In some aspects, the introducer sheath is a peel-away sheath. In some aspects, the introducer hub further comprises tabs to enable separation of the introducer

hub and the peel-away sheath. In some aspects, the first and second hemostasis valves are configured to seal the respective first and second lumens. In some aspects, the first and second hemostasis valves are each configured to be penetrable by the first or second medical device. In some aspects, the introducer hub further comprises at least one suture ring. In some aspects, the first arm and the second arm each comprise at least one side-port. In some aspects, the side-port comprises an irrigation port configured to be supplied with an irrigation fluid. In some aspects, at least one of the first arm and the second arm comprises a locking mechanism configured to prevent axial movement of one or both of the first medical device and the second medical device within the introducer sheath after delivery to the patient. In some aspects, the locking mechanism comprises at least one of: a Tuohy-Borst adaptor, an inflatable balloon, and a locking lever arm. In some aspects, the locking mechanism is biased in a state that is configured to prevent axial movement of one or both of the first medical device and the second medical device within the introducer sheath. In some aspects, the introducer hub comprises up to five second arms, each second arm configured with a hemostasis valve and a lumen in communication with the introducer sheath for the passage of the second medical device from a respective second arm into the introducer sheath. In some aspects, the second arms are arranged in a radially symmetric manner about the first arm. In some aspects, the introducer hub comprises two second arms. In some aspects, the introducer hub further comprises at least one third arm coupled to the first arm, each third arm having a third lumen and a third hemostasis valve, the third lumen and the third hemostasis valve configured for the passage of a third medical device. In some aspects, the introducer hub comprises at least one of: ethylene-vinyl acetate (EVA); styrene-butadiene copolymer (SBC); styrene ethylene butylene styrene (SEBS); a high-density polyethylene (HDPE) material; a medium-density polyethylene (HDPE) material; a low-density polyethylene (LDPE) material; polyether ether ketone (PEEK); a polyether block amide; an elastomer; synthetic rubber; or a polyethylene, polyurethane, or polycarbonate material with an elastic modulus of about 40 ksi.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The foregoing and other objects and advantages will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

[0008] FIG. 1 shows an illustrative cross section of a dual hub introducer sheath system used for delivering a first medical device and second medical device into an arteriotomy of a patient, according to aspects of the disclosure;

[0009] FIG. 2 shows a dual hub introducer sheath system with a dilator for insertion into the arteriotomy of the patient, according to aspects of the disclosure;

[0010] FIG. 3 shows a detailed view of the dual hub introducer sheath system of FIG. 2;

[0011] FIG. 4 shows a detailed view of the dual hub introducer sheath system of FIG. 2 with an occluder sealing a lumen in a side arm;

[0012] FIG. 5A shows an illustrative locking mechanism, in an open state, used in a dual hub introducer sheath system according to aspects of the disclosure;

[0013] FIG. 5B shows the locking mechanism of FIG. 5A in a locked state;

[0014] FIG. 6 shows an illustrative flowchart of a method of using a dual hub introducer sheath system according to aspects of the disclosure; and

[0015] FIG. 7 shows an illustrative flowchart of a method of using a dual hub introducer sheath system for unloading the left ventricle of the heart according to aspects of the disclosure.

#### DETAILED DESCRIPTION

[0016] To provide an overall understanding of the systems, devices and methods described herein, certain illustrative examples will be described. Although the examples and features described herein are specifically described for use in connection with dual hub introducer sheath for use in intravascular procedures involving catheter based ventricular assist devices, it will be understood that all the components and other features outlined below may be combined with one another in any suitable manner and may be adapted and applied to other types of procedures requiring a dual hub introducer sheath.

[0017] As mentioned above, while it is possible to use multiple devices on a patient at the same time using multiple access sites, this can be challenging for a variety of reasons. Firstly, the patient may not have two anatomically available access sites for the PCI procedural devices, in which, for example, two 6-7 Fr sheaths may be used to facilitate procedures such as ballooning and stenting. In addition, peripheral artery disease, vessel lumen size (too small), scar tissue from previous procedures, and other diseases may complicate gaining access to a percutaneous site for larger devices, e.g., mechanical support devices. Using multiple access sites may also increase the likelihood of encountering vascular access complications, which can correlate to increased mortality, added hospital costs, etc. Further, multiple access sites requires more procedural time since access needs to be gained more than once, and can lead to increased procedural costs due to requiring multiple vascular closure devices, additional introducers, etc. There is thus a significant need for reducing the complexity of procedures requiring the operation of multiple devices on a patient.

[0018] The systems, devices and methods described herein relate to a dual hub introducer sheath which enables a single access site for multiple devices. For purposes of illustration herein, but not by way of limitation, the devices are described as a mechanical assist device (such as, for example, an Impella device) and a device for the PCI procedure. However, one skilled in the art will understand that the present disclosure is not limited to any particular kind of percutaneously inserted device. In fact, the disclosure contemplates that, in some aspects of the technology, the multiple devices can be two of the same device. Until recently, such single access for multiple devices has not been apparently possible because physicians were unaware of the ability to fit both the PCI device and the Impella device through a single sheath without increasing the overall diameter of the sheath.

[0019] Successful insertion of PCI devices through the same access sheath as the Impella device to perform both PCI and Impella support in a single access site has recently been reported (M. L. Esposito et al., "Left Ventricular Unloading Before Reperfusion Promotes Functional Recovery After Acute Myocardial Infarction," Journal of the

American College of Cardiology, Elsevier, vol. 72, no. 5, May 2018). However, using the current solutions leads to issues with hemostasis from the introducer valve and pump migration into and out of the ventricle as PCI devices are exchanged and manipulated. These adverse effects arise because conventional introducer valves are simply not designed to be accessed by dual devices.

[0020] The devices and methods described herein relate to a dual hub introducer sheath having a longitudinal axis and a lumen formed therein. The sheath also comprises a hub coupled to a proximal end of the introducer sheath. The hub comprises a first arm having a first lumen and a first hemostasis valve, the first lumen and hemostasis valve configured for the passage of a first medical device. The hub also comprises a second arm coupled to the first arm and having a second lumen and a second hemostasis valve, the second lumen and hemostasis valve configured for the passage of a second medical device. Further, the hub comprises a connection port coupled to the introducer sheath and to the first arm and the second arm, such that the first lumen and the second lumen are in communication with the lumen of the introducer sheath to allow the passage of at least one of the first medical device and second medical device through the introducer sheath for delivery to the patient.

[0021] The dual hub introducer sheath of the present disclosure allows for both the PCI and Impella device to be inserted through it while maintaining appropriate and acceptable hemostasis. By leveraging a bifurcated hub, two separate valves can be implemented which are specifically designed to meet insertion force and leakage requirements for either the Impella device or the PCI device, noting that these requirements and designs are quite different. Additionally, the dual hub introducer sheath of the present disclosure has a locking mechanism isolated to an arm of the hub intended for the Impella device which the physician can activate to hold the Impella in place preventing it from advancing or retracting as the PCI procedure is performed.

[0022] FIG. 1 shows a dual hub introducer sheath delivery system 100 for percutaneously delivering a first medical device and a second medical device to a patient. System 100 comprises introducer sheath 110 that extends between a proximal end 112 and a distal end (not shown) along a longitudinal axis (not shown). Sheath 110 further comprises a lumen 115 that extends between the proximal end 112 and distal end for the passage of the first medical device and the second medical device. While FIG. 1 depicts a sheath 110 having a single lumen 115, in some aspects of the technology, sheath 110 may comprise two distinct lumens throughout the length of the sheath, for example. In other aspects of the technology, sheath 110 may comprise any number of distinct lumens. System 100 further comprises a hub 120 coupled to the proximal end 112 of the sheath 110.

[0023] Hub 120 comprises a first arm 130 having a proximal end 132 and a distal end 134, the first arm 130 defining a first lumen 135. A first valve 138 is provided at the proximal end 132 of the first arm 130 to seal the first lumen 135 from the ambient. The first valve 138 is penetrable by the first medical device 140. Hub 120 further comprises a second arm 150 attached to the first arm 130. As with the first arm 130, second arm 150 defines a second lumen 155 and comprises a proximal end 152 and a distal end 154. A second valve 158 is provided at the proximal end 152 of the second arm 150 to seal the second lumen 155 from the ambient. The second valve 158 is penetrable by the second

medical device 160. In some aspects of the technology, the first valve 138 and the second valve 158 may comprise hemostasis valves (also referred to as “hemostatic” valves), such as, for example the valve described in U.S. Pat. No. 10,576,258 entitled “Hemostatic Valve for Medical Device Introducer,” the entire contents of which are hereby incorporated by reference herein. While FIG. 1 shows a hub 120 comprising one second arm 150, it will be understood that the hub 120 may comprise any number of second arms arranged relative to the first arm 130.

[0024] The hub 120 further comprises a connection port 170 which connects to the first lumen 135 and the second lumen 155. The connection port 170 of the hub 120 is coupled to the proximal end 112 of the sheath 110 such that the first medical device 140 and the second medical device 160 may traverse the sheath 110 to be delivered to a patient when the sheath 110 is inserted in the patient. In some aspects of the technology, such coupling may be a friction fit, for example, in which the proximal end 112 of the sheath 110 is dimensioned such that a friction fit between the outer surface of the sheath 110 and the inner surface of the connection port 170 prevents the proximal end 112 of the sheath 110 from detaching from the hub 120. In other aspects of the technology, the coupling may be brought about by an external thread on the outer surface of the proximal end 112 of the sheath 110 which interacts with a complementary thread on the inner surface of the connection port 170, for example. In further aspects of the technology, the sheath 110 may be coupled to the connection port 170 in any manner that enables the first lumen 135 and the second lumen 155 to be fluidically connected to the lumen 115 of the sheath 110 via the connection port 170 of the hub 120. In some aspects of the technology, the hub 120 may be overmolded and press fit or compressed onto the proximal end 112 of the sheath 110.

[0025] In some aspects of the technology, the hub 120 may be fabricated such that the first lumen 135 and the second lumen 155 merge within the hub 120 before transitioning into the connection port 170, as shown in FIG. 1. In such cases, the hub 120 may be coupled to a single lumen sheath, such as sheath 110 in FIG. 1, where the lumen 115 of the sheath 110 is in fluid communication with the first lumen 135 and the second lumen 155 via the connection port 170 of the hub 120. Thus, when the first medical device 140 is inserted into the first arm 130 and the second medical device 160 is inserted into the second arm 150 of the hub 120, the medical devices share the same lumen 115 of the sheath 110 when traversing the sheath 110 for delivery to the patient. In other aspects of the technology, the hub 120 may be fabricated such that the first lumen 135 and the second lumen 155 are maintained as separate lumens throughout the hub 120. In such cases, the hub 120 may be coupled to a dual lumen sheath such that the first medical device 140 and the second medical device 160 are separated at all times while traversing the length of the sheath 110 for delivery into an arteriotomy of the patient.

[0026] As shown in FIG. 1 the second arm 150 may be arranged such that it branches off the first arm 130 at an angle relative to the first arm 130, and the first arm 130 may be axially aligned with the longitudinal axis of the sheath 110. In some aspects of the technology, this angle is not larger than 90°. In such cases, when the first medical device 140 is inserted into the first arm 130, it is maintained in a substantially straight shape within the hub 120 without

having to bend or kink; and when the second device **160** is inserted into the second arm **150**, the arrangement of the second arm **150** relative to the first arm **130** causes the second device **160** to bend such that it aligns with the first device **140** before exiting the hub **120** via the connector port **170** and traversing the lumen **115** of the sheath **110**.

[0027] In some aspects of the technology, the first arm **130** and the second arm **150** may be arranged such that they form a Y-shaped configuration with respect to the longitudinal axis of the introducer sheath **110**. In such cases, both the first medical device **140** and the second medical device **160** may bend within the hub **120** such that they are aligned with the longitudinal axis of the sheath **110** as they exit the connector port **170** and traverse the lumen **115** of the sheath **110**.

[0028] FIG. 2 shows the configuration of a dual hub introducer sheath system **200** according to aspects of the technology. Sheath system **200** is similar to sheath system **100** in that it comprises a sheath **210** having a proximal end **212** and a distal end **214** with a lumen extending between the proximal end **212** and the distal end **214** for the passage of at least one medical device, such as the first medical device **140** and the second medical device **160** of FIG. 1, for delivery to an arteriotomy of a patient. The proximal end **212** of the sheath **210** is coupled to a connector port **270** of a hub **220**. The hub **220** comprises a first arm **230** having a proximal end **232** and a distal end **234**, and a second arm **250** attached to the first arm **230** and having a proximal end **252** and a distal end **254**. The first arm **230** forms a first lumen **235** which is sealed from the ambient by a first valve **238**. Similarly, the second arm **250** forms a second lumen **255** which is sealed from the ambient by a second valve **258**. The first valve **238** and the second valve **258** may comprise a hemostasis valve, and may be penetrable by the first and second medical devices, as has been described in relation to FIG. 1. In some aspects of the technology, the second lumen **255** fluidically connects to the first lumen **235** within the hub **220**, as shown in FIG. 2. In other aspects of the technology, the first lumen **235** and the second lumen **255** may be maintained as separate lumens within the hub **220**. In some aspects of the technology, the first valve **238** and the second valve **258** may be inserted into position by a snap cap to secure their position within the hub **220**.

[0029] As shown in FIG. 2 (and the enlargement **300** in FIGS. 3 and 4) the first arm **230** further comprises a first side port **236** that is in fluid connection with the first lumen **235**. Similarly, the second arm **250** comprises a second side port **256** that is in fluid communication with the second lumen **255**. Side port **236** and side port **256** may each serve as an irrigation port through which irrigation fluid can be injected to free the lumens **235**, **255** within the hub **220** of any thrombus that may have formed during treatment of the patient. In other aspects of the technology, the side ports **236**, **256** may serve as inflation ports connected to inflatable balloons within the hub **220** that may be inflated with an inflation fluid to expand the balloons so as to anchor or lock the positions of the first medical device **140** and the second medical device **160** relative to the respective arms through which they are inserted. In such cases, the inflated balloon may compress the medical device against its respective arm so as to prevent axial movement of the medical device within the sheath once the device is deployed in the patient. Such locking mechanisms for securing the position of a medical first device to prevent axial motion during insertion or manipulation of a second medical device using internal

sheath balloons are known to those skilled in the art. For example, various locking mechanisms for securing the position of a first medical device to prevent axial motion during insertion or manipulation of a second medical device using internal sheath balloons are described in U.S. Provisional Patent Application No. 62/797,527, the entire contents of which are hereby incorporated by reference herein. Other locking mechanisms will be detailed in the foregoing sections. While only one side port is shown on each arm in FIGS. 2 and 3, any number of side ports may be used on each arm within the scope of the present disclosure.

[0030] As discussed above, the second arm **250** may be arranged on the first arm **230** and configured to branch off the first arm **230** at an angle of no more than 90° with respect to the longitudinal axis of the sheath **210**. Additionally, in some aspects of the technology, the distal end **254** of the second arm **250** may be positioned proximal to the connector port **270**, and the proximal end **232** of the first arm **230** may be positioned distal to the connector port **270**. In this manner the proximal end **252** of the second arm **250** may be sufficiently spaced apart from the proximal end **232** of the first arm **230** to allow the first and second medical devices to interact with the respective arms **230**, **250** without having to abut each other.

[0031] As seen in FIGS. 2 and 3, the hub **220** may optionally include a suture ring **225** to aid with the attachment of the hub **220** to the patient after the first and second medical devices have been inserted in the patient. In certain aspects of the technology, the suture ring **225** may be positioned proximal to the connector port **270** as the profile of the hub **220** in this location may be smaller than at locations proximal to either the first arm **230** or the second arm **250**. In other aspects of the technology, the suture ring **225** may be located at any location along the body of hub **220**. While only one suture ring is shown in FIGS. 2 and 3, it will be understood that any number of suture rings may be present to aid in securing the hub **220** to the patient.

[0032] In order to insert the introducer sheath **210** into the patient, a dilator **280** may be used in connection with the dual hub **220**. FIGS. 2 and 3 also show a dilator **280** that has been inserted into the first arm **230** of the hub **220**. The dilator **280** comprises a proximal end **282** and a distal end **284**. The length of the dilator is such that the distal end **284** extends beyond the distal end **214** of the sheath **210** when the dilator **280** is fully inserted into the **210**. As previously mentioned, while the first arm **230** and the second arm **250** may assume any configuration relative to the longitudinal axis of the sheath **210** (e.g., a Y-shaped configuration), where insertion of the introducer sheath **210** into the patient requires a dilator **280**, the first arm **230** may be axially aligned with the longitudinal axis of the sheath **210**. With this arrangement of the first arm **230**, the dilator does not need to bend when being inserted in to the hub **220**, which may allow for a greater force to be applied when inserting the sheath **210** into the patient. Once inserted, proximal end **282** of the dilator **280** may connect to the proximal end **232** of the first arm **230**. This may be accomplished by any suitable type of connection, such as through a press fit or a twist connection.

[0033] In some aspects of the technology, an occluder **490** may be inserted into the lumen **255** of the second arm **250**, as shown in FIG. 4. Such an occluder **490** may be inserted to prevent any backflow of fluid when the sheath **210** is inserted into the patient. This may be helpful in cases where

sheath **210** needs to be repositioned after the medical devices have been removed from the first arm **230** and the second arm **250**. In such situations, due to their prior use, the respective seals **238**, **258** may not be able to seal the lumens **235**, **255** from the ambient completely due to wear and tear. As with the dilator **280**, the occluder **490** may connect to the proximal end **252** of the second arm **250** by any suitable type of connection, such as through a press fit or a twist connection.

**[0034]** As mentioned in the foregoing, the first medical device **140** and the second medical device **160** may be axially constrained by a locking mechanism. In some aspects of the technology, a locking mechanism may be configured so that some action must be taken in order to lock and/or unlock it. In some aspects of the technology, a locking mechanism may have a bias. For example, in some aspects of the technology, a locking mechanism may be biased in an unlocked state such that it does not restrict movement of the medical device unless an action is taken to lock the locking mechanism. Conversely, in some aspects of the technology, a locking mechanism may be biased in a locked state such that it restricts movement of the medical device unless an action is taken to unlock the locking mechanism. In some aspects of the technology, the locking mechanism may comprise an internal balloon located within the first lumen **235** or the second lumen **255**, the internal balloon being inflated by a side arm **236**, **256**, as previously described. In some aspects of the technology, the locking mechanism may also comprise a locking lever arm as shown in FIGS. **5A** and **5B**. FIG. **5A** shows the cross section of a hub **510** similar to hubs **220** and **120** as described in the foregoing. Hub **510** is shown with a first medical device **520** traversing therethrough, although it will be appreciated that the hub **510** may be allow the passage of a plurality of medical devices. Hub **510** also comprises a lever arm **530** which may be a separate component which is positioned within the hub body. The lever arm **530** may be configured to have a semicircular shape as shown in FIGS. **5A** and **5B**, however any shape of arm may be used that is suitable to secure the medical device **520** and prevent axial motion thereof.

**[0035]** The lever arm **530** may be pivotally connected to the hub **510** at a point **532** as shown in FIG. **5A**. In the unlocked position, the lever arm **530** resides within the hub body. The lever arm may comprise an actuating mechanism such as a handle or tab (not shown) that is accessible from the exterior of the hub **510**. The lever arm **530** comprises a notch or catch **538** that is configured to fit around the external periphery of the medical device **520** when the lever arm **530** is in the locked position. In this position, as shown in FIG. **5B**, the notch **538** pinches the medical device **520** to increase axial friction. In some aspects of the technology, the notch **538** may bend the medical device **520** when the lever arm **530** is in the locked position. In some aspects of the technology, the lever arm **530** may be located at the respective hemostasis valves **238**, **258**. Additionally, to secure the lever arm in the locked position, the end **534** of the lever arm **530** may be configured with a recess on its distal surface that engages with a protrusion **536** located within the hub body. The side profiles of end **534** and protrusion **536** are shown in FIG. **5A**. Similarly, FIG. **5B** shows end **534** in engagement with protrusion **536**. In some aspects of the technology, the lever arm **530** may be overmolded with a high friction material such as a low-durometer polyurethane or a silicone.

**[0036]** In addition to, or as an alternative to, the locking mechanisms described in the foregoing, the dual hub of the present disclosure may also comprise a Tuohy Borst mechanism built into the first or second arms of the hub body. Such a mechanism comprises a silicone slug that reduces in inner diameter onto the first and/or second medical device traversing the respective arm, thereby securing the position of the medical device.

**[0037]** As noted above, in some aspects of the technology, the sheath **210** may comprise a dual lumen sheath. In such a case, when the dual lumen sheath is coupled to the hub **220**, the first lumen **235** of the hub **220** may be in fluid communication with one of the lumens of the dual lumen sheath, and the second lumen **255** of the hub **220** may be communication with the other lumen of the dual lumen sheath.

**[0038]** In some aspects of the technology, the sheath **210** may comprise an expandable sheath. Expandable sheaths are well known to those skilled in the art and are not described in detail herein. For example, various expandable sheaths are described in U.S. Provisional Patent Application No. 62/797,527, which has been incorporated by reference herein.

**[0039]** In some aspects of the technology, the sheath **210** may comprise a peel-away sheath. Peel-away sheaths are also well known to those skilled in the art and are not described in detail herein. For example, various peel-away sheaths are described in U.S. Provisional Patent Application No. 62/777,598, the entire contents of which are hereby incorporated by reference herein. Peel-away sheaths may comprise one or more lines of weakness that are formed within the sheath body and extend longitudinally along the sheath to allow the sheath to be pulled apart as needed during treatment of the patient.

**[0040]** In some aspects of the technology, the hub **220** may comprise tabs that enable the hub **220** itself to be separated when it is no longer needed, e.g., when one or more of the medical devices are positioned within the patient.

**[0041]** In some aspects of the technology, the sheath **210** may be extruded and/or laminated. In some aspects of the technology, the introducer sheath **110**, **210** may comprise at least one of: a polyether block amide (such as PEBAX® or PebaSlix®); a polyethylene material; a polytetrafluoroethylene (PTFE) material; a high-density polyethylene (HDPE) material; a medium-density polyethylene (MDPE) material; or a low-density polyethylene (LDPE) material.

**[0042]** Further, as described above, in some aspects of the technology, the hub **120**, **220** may be formed by overmolding. In some aspects of the technology, the hub **120**, **220** may comprise at least one of: ethylene-vinyl acetate (EVA); styrene-butadiene copolymer (SBC); styrene ethylene butylene styrene (SEBS); a high-density polyethylene (HDPE) material; a medium-density polyethylene (MDPE) material; a low-density polyethylene (LDPE) material; polyether ether ketone (PEEK); a polyether block amide (such as PEBAX® or PebaSlix®); an elastomer; synthetic rubber; a polyethylene, polyurethane, or polycarbonate material with an elastic modulus of about 40 ksi; a crack-resistant material; or a material with a low coefficient of friction.

**[0043]** As mentioned in the foregoing description, the dual hub introducer sheath of the present disclosure is designed to facilitate the traversal of catheter-based medical devices (such as the first medical device and the second medical device) within the lumen of an introducer sheath. In some

aspects of the technology, the first medical device is a mechanical circulatory support device, and the second medical device is a coronary reperfusion therapy device for providing the patient with percutaneous coronary intervention (PCI). These PCI procedures may involve the use of a coronary stent delivered into the distal left anterior descending artery (LAD). Examples of such coronary stents include, but are not limited to, the Promus PREMIER™ and the REBEL™ bare-metal Platinum Chromium Coronary Stents, and the SYNERGY™ Bioabsorbable Polymer Stent, all by Boston Scientific, Marlborough, Mass. In some aspects of the technology, the mechanical circulatory support device may comprise a rotary blood pump having a cannula, a rotor, and rotor housing. Examples of such blood pumps include, but are not limited to, an Impella® pump, an Extracorporeal Membrane Oxygenation (ECMO) pump, and a balloon pump. The Impella® pump may further comprise an Impella 2.5® pump, an Impella 5.0® pump, an Impella CP® pump, or an Impella LD® pump, all of which are by Abiomed, Inc. of Danvers, Mass.

**[0044]** In some aspects of the technology, the first medical device and the second medical device may be used with the dual hub introducer sheath as described in the foregoing in procedures where PCI and percutaneous ventricular assist devices are used in unison, such as, for example, the method of left ventricular unloading in treating myocardial infarction as described in U.S. patent application Ser. No. 16/244, 998, the entire contents of which are hereby incorporated by reference herein.

**[0045]** FIG. 6 illustrates an exemplary method 600 of using a dual hub introducer sheath, such as any of the introducer sheaths as described in the foregoing description, according to aspects of the technology. The method 600 will be described in relation to the exemplary systems depicted in FIGS. 1-5 above. Prior to using the dual hub introducer sheath, the sheath 210 is positioned into the arteriotomy of the patient (not indicated in FIG. 6). Prior to insertion of the sheath 210 into the patient, a connector port of the hub, such as connector port 270 of the hub 220 as described above, is coupled to a proximal end of an introducer sheath, such as end 212 of sheath 210 as described above. In some aspects of the technology, a dilator may be inserted into the lumen of the sheath before insertion into the patient, such as dilator 280 shown in FIGS. 2 and 3. The dilator assists with positioning the sheath in regions of the patient's body which are difficult to penetrate with the sheath alone. Once inserted, the dilator is removed from the lumen of the sheath.

**[0046]** In step 610, the first medical device 140 is inserted into a first arm 230 of the dual hub 220. Here, the first medical device 140 is pushed through the first hemostasis valve 238 and traverses the hub 220 towards the connector port 270. As with the first medical device 140, in step 620, the second medical device 160 is pushed through the second hemostasis valve 258 in the second arm 250, after which it also traverses hub 220 toward connector port 270. In step 630, the first and second medical devices are provided to the lumen of the sheath 210 via the connector port 270 of the hub 220. In step 640, the first and second medical devices are delivered into an arteriotomy of the patient by pushing the devices along the length of sheath 210 until they exit the distal end 214 of the sheath 210.

**[0047]** Once in position in the patient's arteriotomy, the medical devices can be used as desired to treat the patient. In some aspects of the technology, the dual hub introducer

sheath may be used to unload the left ventricle of the patient, as shown in the exemplary method 700 of FIG. 7. In such cases, the first medical device 140 may be a mechanical circulatory support device, and the second medical device 160 may be a coronary reperfusion therapy device for providing the patient with percutaneous coronary intervention (PCI). With respect to FIG. 7, in step 710, after the first medical device 140 has emerged from the distal end 214 of the sheath 210, it is advanced into position in the left ventricle of the heart. The first medical device 140 may then be locked in position via a locking mechanism located on the first arm 230 of the hub 220. As already discussed, such locking mechanisms may include any one of: a Tuohy-Borst adaptor, an inflatable balloon, and a locking lever arm. In step 720, the mechanical circulatory device is operated within the left ventricle for a support period in excess of 30 minutes. In some aspects of the technology, the mechanical circulatory device may be operated at 2.5 L/min of blood flow. In step 730, the second medical device 160 is positioned into a coronary vessel of the patient. The second medical device 160 may then also be locked in position via a locking mechanism located on the second arm 250 of the hub 220 as previously discussed. In step 740, after the support period has passed, reperfusion therapy is applied to the coronary vessel via a PCI device, as described above. The reperfusion therapy may be performed in parallel with operation of the mechanical circulatory device, or after operation of the mechanical circulatory device.

**[0048]** In some aspects of the technology, the various steps discussed above with respect to methods 600 and 700 of FIGS. 6 and 7 may be performed in a different order and/or concurrently with each other. Furthermore, if desired, one or more of the above described steps may be optional or may be combined.

**[0049]** The foregoing description is merely intended to be illustrative of the principles of the technology. As such, the devices and methods described herein can be practiced by other than the described implementations, which are presented for purposes of illustration and not of limitation. It is to be understood that the systems, devices and methods disclosed herein, while described with respect to certain procedures, may be applied in any context where access to an arteriotomy of a patient is desired without creating multiple access sites in the vasculature of the patient. In addition, the disclosed features may be implemented in any combination or subcombination (including multiple dependent combinations and subcombinations) with one or more other features described herein. The various features described or illustrated above, including any components thereof, may also be combined or integrated into other systems. Finally, certain features may be omitted or not implemented without departing from the spirit of the technology.

1. An introducer system comprising:
  - a hub configured to be coupled to a proximal end of an introducer sheath, the hub comprising:
    - a first arm having a first lumen and a first hemostasis valve, the first lumen and the first hemostasis valve configured for the passage of a first medical device;
    - a second arm coupled to the first arm and having a second lumen and a second hemostasis valve, the second lumen and the second hemostasis valve configured for the passage of a second medical device;
  - and

- a connection port configured to be coupled to the introducer sheath and to the first arm and the second arm, such that the first lumen and the second lumen are in communication with a lumen of the introducer sheath to allow the passage of at least one of the first medical device or the second medical device through the introducer sheath for delivery to a patient.
2. The introducer system of claim 1, further comprising the introducer sheath.
  3. The introducer system of claim 2, wherein the first arm is arranged parallel to a longitudinal axis of the introducer sheath.
  4. The introducer system of claim 2, wherein the first arm and the second arm are arranged in a Y-shaped configuration with respect to the introducer sheath.
  5. (canceled)
  6. (canceled)
  7. The introducer system of claim 1, wherein the second lumen merges with the first lumen within the hub.
  8. The introducer system of claim 2, wherein the introducer sheath comprises a single lumen for the passage of the first and second medical devices.
  9. The introducer system of claim 1, wherein the first lumen and the second lumen are maintained as separate lumens within the hub.
  10. The introducer system of claim 2, wherein the introducer sheath comprises a dual lumen sheath such that the first lumen is in communication with one of the lumens of the dual lumen sheath, and the second lumen is in communication with the other lumen of the dual lumen sheath.
  11. The introducer system of claim 2, wherein the introducer sheath is an expandable sheath.
  12. The introducer system of claim 2, wherein the introducer sheath is a peel-away sheath.
  13. The introducer system of claim 12, wherein the hub further comprises tabs to enable separation of the hub and the peel-away sheath.
  14. (canceled)
  15. (canceled)
  16. The introducer system of claim 1, wherein the hub further comprises at least one suture ring.
  17. The introducer system of claim 1, wherein the first arm and the second arm each comprise at least one side-port.
  18. The introducer system of claim 17, wherein the side-port comprises an irrigation port configured to be supplied with an irrigation fluid.
  19. The introducer system of claim 1, wherein at least one of the first arm or the second arm comprises a locking mechanism configured to prevent axial movement of one or both of the first medical device and the second medical device within the introducer sheath after delivery to the patient.
  20. The introducer system of claim 19, wherein the locking mechanism comprises at least one of: a Tuohy-Borst adaptor, an inflatable balloon, or a locking lever arm.
  21. The introducer system of claim 19, wherein the locking mechanism is biased in a state that is configured to prevent axial movement of one or both of the first medical device and the second medical device within the introducer sheath.
  22. The introducer system of claim 2, wherein the introducer sheath comprises at least one of: a polyether block amide; a polyethylene material; a polytetrafluoroethylene (PTFE) material; a high-density polyethylene (HDPE) material; a medium-density polyethylene (MDPE) material; or a low-density polyethylene (LDPE) material.
  23. The introducer system of claim 1, wherein the hub comprises at least one of: ethylene-vinyl acetate (EVA); styrene-butadiene copolymer (SBC); styrene ethylene butylene styrene (SEBS); a high-density polyethylene (HDPE) material; a medium-density polyethylene (MDPE) material; a low-density polyethylene (LDPE) material; polyether ether ketone (PEEK); a polyether block amide; an elastomer; synthetic rubber; or a polyethylene, polyurethane, or polycarbonate material with an elastic modulus of about 40 ksi.
  24. The introducer system of claim 1, wherein the first medical device is a mechanical circulatory support device, and the second medical device is a coronary reperfusion therapy device for providing the patient with percutaneous coronary intervention (PCI).
  25. The introducer system of claim 24, wherein the coronary reperfusion therapy device is a stent.
  26. The introducer system of claim 25, wherein the stent is configured for insertion through the second arm and introducer sheath by a catheter.
  27. The introducer system of claim 24, wherein the mechanical circulatory support device comprises at least one of: a blood pump; a transvalvular axial-flow (TV)-pump; an intra-aortic balloon pump; or an extracorporeal membrane oxygenation (ECMO) pump.
  28. The introducer system of claim 24, wherein the mechanical circulatory support device is a rotary blood pump having a cannula and a rotor and rotor housing.
  29. (canceled)
  30. (canceled)
  31. The introducer system of claim 1, wherein the hub comprises up to five second arms, each second arm configured with a hemostasis valve and a lumen in communication with the introducer sheath for the passage of the second medical device from a respective second arm into the introducer sheath.
  32. The introducer system of claim 31, wherein the second arms are arranged in a radially symmetric manner about the first arm.
  33. (canceled)
  34. (canceled)
  35. A method comprising:
    - inserting a first medical device into a first arm of an introducer hub, the first arm having a first lumen for the passage of the first medical device therethrough;
    - inserting a second medical device into a second arm attached to the first arm, the second arm having a second lumen for the passage of the second medical device therethrough;
    - providing the first medical device and the second medical device to an introducer sheath via a connector port of an introducer hub, the connector port coupled to a proximal end of the introducer sheath; and
    - delivering the first medical device and the second medical device to a patient from a distal end of the introducer sheath.
  - 36-44. (canceled)
  45. The method of claim 35, further comprising the steps of:
    - inserting the first medical device through the first arm and through the introducer sheath into a patient's left ventricle to support the patient's heart after myocardial



infarction, wherein the first medical device comprises a mechanical circulatory support device;  
operating the first medical device for a support period of greater than 30 minutes at a rate of at least 2.5 L/min of blood flow;  
inserting the second medical device through the second arm and through the introducer sheath into a coronary vessel of the patient; and  
operating the second medical device after the support period has elapsed.

**46-82.** (canceled)

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