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MEDICAL DEVICE DELIVERY SYSTEMS

Abstract

Delivery systems are used for medical devices. For example, this document describes delivery systems for implantable medical devices such as, but not limited to, prosthetic heart valves that are deliverable in a minimally invasive manner using a system of catheters. The delivery systems may include a valve stop member that establishes the longitudinal position of the prosthetic heart valve on a balloon member. Such a valve stop member can be constructed as a braided wire body or cellular body to provide multiple advantages.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application claims the benefit of U.S. Provisional Application Ser. No. 63/554,666 filed Feb. 16, 2024. The disclosure of the prior application is considered part of (and is incorporated by reference in) the disclosure of this application.

BACKGROUND
1. Technical Field
[0002] This document relates to delivery systems for medical devices and methods for their use. For example, this document relates to delivery systems for implantable medical devices such as prosthetic heart valves that are deliverable in a minimally invasive manner using a system of catheters.
2. Background Information
[0003] Some prosthetic heart valves can be delivered in a minimally invasive fashion to avoid open-heart surgery. Such prosthetic heart valves can be delivered using a system of catheters that are manipulated by a clinician using an actuator handle and/or other types of control mechanisms that remain positioned external to the patient. For example, in some such cases, a prosthetic heart valve is compressed into a delivery catheter or sheath, which may be manually deflectable by adjusting a mechanism located on an actuator handle.
[0004] Transcatheter aortic valve replacement (TAVR) delivery systems can be used to deliver a prosthetic aortic valve to a native aortic heart valve site. Clinicians occasionally encounter difficulty when delivering prosthetic aortic valves in a minimally invasive manner using such catheter-based delivery systems. One such area of difficulty pertains to the task of navigating, in an atraumatic manner, the prosthetic aortic valve through the aortic arch pathway on the way to the native aortic heart valve location.
SUMMARY
[0005] This document describes delivery systems for medical devices and methods for their use. For example, this document describes delivery systems for implantable medical devices such as, but not limited to, prosthetic heart valves that are deliverable in a minimally invasive manner using a system of catheters. In some embodiments, the delivery systems include a valve stop member that establishes the longitudinal position of the prosthetic heart valve on a balloon member. Such a valve stop member can be constructed as a braided wire body or cellular body to provide multiple advantages, as described further herein.
[0006] In one aspect, this disclosure is directed to a medical device (e.g., prosthetic heart valve) delivery system that includes an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter; and a valve stop member attached to the inner catheter shaft and located within the balloon member. The valve stop member comprises a braided body or a cellular body.
[0007] Particular embodiments of the medical device delivery system may optionally include or more of the following features. The body of the valve stop member may comprise a frustoconical outer profile. The body of the valve stop member may further comprise an inverted frustoconical portion located within the frustoconical outer profile. The valve stop member may comprise the

braided body, and the braided body may comprise a multi-element braided body. The multi-element braided body comprises at least 20 elements that are braided together. The valve stop member may comprise the cellular body, and the cellular body may comprise a laser-cut tube that is shape-set to have a frustoconical outer profile. The system may also include a nose cone attached to a distal end of the inner catheter shaft. In some embodiments, a distal end of the balloon member is attached to the nose cone. A proximal end of the balloon member may be attached to a distal end portion of the outer catheter shaft. The system may also include a steerable catheter defining a lumen and comprising a pull wire, wherein the catheter is slidably disposed within the lumen. A distal end portion of the valve stop member may be attached to the inner catheter shaft and a proximal end portion may be slidably coupled to the inner catheter shaft. A proximal end portion of the valve stop may comprise a polymeric tube that is slidably coupled to the inner catheter shaft.

[0008] In another aspect, this disclosure is directed to a method of assembling a prosthetic heart valve delivery system. The method can include: reducing an outer diameter of a valve stop member attached to an inner catheter shaft by longitudinally extending the valve stop member; passing a distal end portion of an inflatable balloon member over the valve stop member to position the valve stop member within the balloon member, wherein the outer diameter of the valve stop member expands after passing through the distal end portion of the balloon member; attaching the distal end portion of the balloon member to a nose cone that is attached to a distal end portion of the inner catheter shaft; and/or attaching a proximal end portion of the balloon member to an outer catheter shaft from which the inner catheter shaft distally extends.

[0009] Such a method of assembling a prosthetic heart valve delivery system may optionally include one or more of the following features. In some embodiments, the outer diameter of the valve stop member expands within the balloon member to a natural diameter that is greater than an inner diameter of the distal end portion of the balloon member. The valve stop member may comprise a braided body or a cellular body.

[0010] In another aspect, this disclosure is directed to a prosthetic heart valve delivery system. The system can include: an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter; and/or a valve stop member attached to the inner catheter shaft and located within the balloon member. The valve stop member defines an internal space within which a portion of the balloon member is located when a prosthetic heart valve is mounted on the balloon member in a position that is distally limited by the valve stop member.

[0011] Such a prosthetic heart valve delivery system may optionally include one or more of the following features. The valve stop member may comprise a braided body or a cellular body. In some embodiments, a body of the valve stop member comprises a frustoconical outer profile and an inverted frustoconical portion located within the frustoconical outer profile. The internal space may be defined within the inverted frustoconical portion.

[0012] In another aspect, this disclosure is directed to a prosthetic heart valve delivery system. The system includes an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter shaft, the balloon member having a distal opening with an inner diameter prior to being attached to the distal end portion of the catheter shaft; and a valve stop member attached to the inner catheter shaft and located within the balloon member. The valve stop member has an outer diameter that is adjustable between a contracted diameter that is less than the inner diameter and a natural diameter that is greater than the inner diameter.

[0013] Such a prosthetic heart valve delivery system may optionally include one or more of the following features. The valve stop member may comprise a braided body or a cellular body. The natural diameter may be adjustable to the contracted diameter by longitudinally stretching the braided body or the cellular body.

[0014] Particular embodiments of the subject matter described in this document can be implemented to realize one or more of the following advantages.

[0015] In some embodiments, the valve stop member is located within the balloon member and the braided or cellular structure of the valve stop member allows for a desired expansion process of the balloon member because the flow of the inflation medium is substantially uninhibited by the valve stop member.

[0016] In some embodiments, the flexibility of the braided or cellular structure of the valve stop member allows for tracking of valve stop member and prosthetic heart valve along a curved pathway in an advantageous manner. That is, internal portions of the valve stop member can flex while tracking along the curved pathway while other portions of the valve stop member against which the prosthetic heart valve is pressed do not substantially deform. Said another way, portions of the valve stop member can flex or extend while tracking along a curved path while a proximal section of the nose cone does not move relative to the crimped valve on the balloon member. Accordingly, a distal end of the prosthetic heart valve can remain reliably compressed against the valve stop member to provide positional control and to protect the blood vessel walls of the patient by keeping the distal end of the prosthetic heart valve concealed by the valve stop member during advancement.

[0017] In some embodiments, the braided or cellular structure of the valve stop member allows for an advantageous assembly process of the prosthetic heart valve delivery systems described herein. For example, the natural outer diameter of the braided or cellular structure of the valve stop member can be reduced by longitudinally stretching the valve stop member. The reduced outer diameter of the valve stop member allows the valve stop member to be placed within a balloon member that has an end opening that is smaller than the natural outer diameter of the valve stop member.

[0018] In some embodiments, the valve stop member defines an internal space within which a portion of the balloon member extend so that the prosthetic heart valve on the balloon member can be longitudinally located on the balloon member in a consistent and predictable manner.

[0019] In some embodiments, the valve stop member has a high level of radial compressive strength that, in some embodiments, can be advantageously used to radially expand a delivery sheath. Moreover, the valve stop member can also have a high level of longitudinal compressive strength that can be advantageously used to maintain the longitudinal position of the prosthetic heart valve on the balloon member. The longitudinal force of the valve stop enables the steerable shaft of the delivery system to be loaded under compressive forces, which also aids in the tracking mentioned above.

[0020] In some embodiments, the medical device delivery systems described herein are advantageously designed to enable rotary adjustments of the balloon catheter on which the prosthetic heart valve is mounted in order to facilitate a desired alignment the of prosthetic valve's structure with the commissures of the native heart valve. In some embodiments, a steerable catheter is included as part of the medical device delivery systems described herein, and such a steerable catheter can be controllably deflected by 180° or more. Such deflection is advantageous while navigating the catheters within the patient including, navigation of the aortic arch, for example. In some such embodiments, a deflection indicator is included on the control handle of the medical device delivery systems described herein. Such an indicator is advantageous to clinicians by providing a readily available indication of the amount of deflection of the catheters that are within the patient. In some embodiments, a locking mechanism is included on the control handle of the medical device delivery systems described herein. Such a locking mechanism can be activated to advantageously lock together (longitudinally) the catheters of the medical device delivery systems during the advancement and retraction steps of the medical device deployment process. Moreover, the locking mechanism can be unlocked to allow for relative movements of the catheters, as described herein.

[0021] Unless otherwise defined, all technical and scientific terms used herein have the same

meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. Although methods and materials similar or equivalent to those described herein can be used to practice the invention, suitable methods and materials are described herein. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.
[0022] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description herein. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

Description

DESCRIPTION OF THE DRAWINGS
[0023] FIG. **1** is a perspective view of an example medical device delivery system in accordance with some embodiments provided herein.
[0024] FIG. **2** is an enlarged perspective view of an example distal end portion of the medical device delivery system of FIG. **1**.
[0025] FIG. **3** is an enlarged perspective view of an example handle of the medical device delivery system of FIG. **1**.
[0026] FIG. **4** is a plan view of the distal end portion of the medical device delivery system of FIG. **1** in a delivery configuration.
[0027] FIG. **5** is a plan view of the distal end portion of the medical device delivery system of FIG. **1** in an intermediate configuration.
[0028] FIG. **6** is a plan view of the distal end portion of the medical device delivery system of FIG. **1** in an expanded configuration.
[0029] FIG. **7** is a perspective view of the distal end portion of the medical device delivery system of FIG. **1** without the implantable medical device.
[0030] FIG. **8** is a perspective view of an example valve stop member in accordance with some embodiments.
[0031] FIG. **9** is another perspective view of the valve stop member of FIG. **8**.
[0032] FIG. **10** is a perspective view of the braided body of the valve stop member of FIG. **8**.
[0033] FIG. **11** is a plan view of the braided body of the valve stop member of FIG. **8**.
[0034] FIG. **12** is a cross-sectional view of the valve stop member of FIG. **11**.
[0035] FIG. **13** is a plan view of an example balloon member of the medical device delivery systems in accordance with some embodiments.
[0036] FIG. **14** is a flowchart of an example method for the delivery of a medical device using the delivery systems described herein.
[0037] Like reference numbers represent corresponding parts throughout.
DETAILED DESCRIPTION
[0038] This document describes delivery systems for medical devices and methods for their use. For example, this document describes delivery systems for implantable medical devices such as, but not limited to, prosthetic heart valves that are deliverable in a minimally invasive manner using a system of catheters. In some embodiments, the delivery systems include a valve stop member that establishes the longitudinal position of the prosthetic heart valve on a balloon member. Such a valve stop member can be constructed as a braided wire body or cellular body to provide multiple advantages, as described further herein.
[0039] FIG. **1** illustrates an example transcatheter medical device delivery system **100**. In the depicted example, the medical device delivery system **100** is configured to deliver a prosthetic

heart valve to a native heart valve location by advancing the prosthetic heart valve to the heart via the vascular system of the patient. For example, in some embodiments the medical device delivery system **100** can be used to deliver a prosthetic aortic valve to a site of a native aortic valve via the aorta of the patient. This non-limiting type of use of the medical device delivery system **100** is used as an example herein to describe the functionality of the medical device delivery system **100**. In such a case, the medical device delivery system **100** may be inserted into a femoral artery via a sheath and then advanced to the aorta, through the aortic arch, and to the native aortic valve site. Alternative approaches, such as trans-subclavian, trans-carotid, trans-radial, and others are also envisioned using the medical device delivery system **100**.

[0040] Broadly speaking, the medical device delivery system **100** includes a clinician control handle **110** (or simply “handle **110**”), a steerable catheter **160**, and an elongate catheter **170** (referred to hereinafter as a balloon catheter **170**). The steerable catheter **160** and the balloon catheter **170** each extend distally from the handle **110**. The steerable catheter **160** and the balloon catheter **170** are each affixed to the handle **110**, but at different locations of the handle **110** (as described further below).

[0041] FIG. **2** shows an expanded view of a distal end portion of the steerable catheter **160** and the balloon catheter **170**. An example prosthetic heart valve **300** is mounted on the balloon catheter **170** in a low-profile delivery configuration.

[0042] The steerable catheter **160** defines a lumen in which the balloon catheter **170** is slidably disposed. That is, the balloon catheter **170** can be manipulated by the clinician (using the handle **110**) to advance and/or retract the balloon catheter **170** (and the prosthetic heart valve **300**) relative to the steerable catheter **160** by sliding the balloon catheter **170** within the lumen of the steerable catheter **160**. For example, in some cases the steerable catheter **160** can be proximally pulled back relative to the balloon catheter **170** and the prosthetic heart valve **300**, as described further below. The steerable catheter **160** is controllably deflectable or steerable by the clinician (using the handle **110** to manipulate a pull wire, as described further below in reference to FIG. **3**). In particular, a distal end portion of the steerable catheter **160** is controllably deflectable to any desired angle up to approximately 180°, or even more than 180° in some embodiments. When the steerable catheter **160** is deflected in that manner, the balloon catheter **170** also takes on the same extent of deflection (because the balloon catheter **170** is positioned within the lumen of the steerable catheter **160**). The deflection of the steerable catheter **160** (and the balloon catheter **170**) can be useful for navigating the aortic arch, for example. In some embodiments, the balloon catheter **170** (and the steerable catheter **160**) can be advanced over a pre-placed guidewire.

[0043] Still referring to FIG. **2**, the balloon catheter **170** includes an inner catheter shaft **172** and a balloon **174** mounted on a distal end portion of the balloon catheter **170**. The catheter shaft **172** defines an inflation lumen and one or more openings (not visible) through which an inflation fluid can be supplied and withdrawn in order to controllably inflate and/or deflate the balloon **174**. In addition, the inner catheter shaft **172** defines a central lumen by which the balloon catheter **170** (and the steerable catheter **160**) can be advanced over a guidewire.

[0044] In the depicted embodiment, a tapered nose cone **178** is attached to a distal end of the inner catheter shaft **172** and to the balloon **174**. The nose cone **178** extends distally from the balloon **174** and provides an atraumatic leading distal end of the medical device delivery system **100**.

[0045] The prosthetic heart valve **300** can be crimped on the balloon **174** in a radially compressed, low-profile delivery configuration. Then, as described further below, when the balloon **174** and the prosthetic heart valve **300** are positioned at a target location and in a desired orientation relative to the patient's anatomy, the balloon **174** can be inflated to radially expand the prosthetic heart valve into engagement with the native anatomy of the patient (e.g., into engagement with the annulus of a native heart valve such as the native aortic valve). Thereafter, the balloon **174** can be deflated and retracted from the prosthetic heart valve **300**. In some embodiments, radiopaque markers can be located on one or more locations of the steerable catheter **160** and/or the balloon catheter **170** to provide visualization of the steerable catheter **160** and/or the balloon catheter **170** under fluoroscopy.

[0046] FIG. **3** shows an enlarged view of an example handle **110** of the medical device delivery system **100**. The handle **110** remains external to the patient while the steerable catheter **160**, the balloon catheter **170**, and the prosthetic heart valve **300** extend internally to the patient (e.g., into the vasculature and/or heart of the patient). The handle **110** includes multiple control mechanisms by which a clinician operator can remotely manipulate various aspects of the steerable catheter **160** and the balloon catheter **170**, as described further below. The steerable catheter **160** is fixed to the handle **110**.

[0047] In this view of the handle **110**, the following components and/or control mechanisms of the handle **110** are in view. That is, the handle **110** includes a housing **112**, a rotatable first actuator knob **114**, a locking actuator **116**, a rotatable second actuator knob **118**, a balloon catheter pull rod **120**, a flush line **122**, and an optional deflection indicator **180**.

[0048] The first actuator knob **114**, the second actuator knob **118**, and the locking actuator **116** are each manually rotatable relative to the housing **112**. The steerable catheter **160** can be laterally deflected by rotation of the first actuator knob **114**. That is, manual rotations of the first actuator knob **114** can be used to control the extent of deflection of the steerable catheter **160** (and the balloon catheter **170** disposed therein) by tensioning or relaxing a pull wire (not shown). The deflection indicator **180** can provide an indication of the extent of deflection of the steerable catheter **160**. The second actuator knob **118** can be rotated to rotate the balloon catheter **170** (and the prosthetic heart valve **300**) relative to the steerable catheter **160**.

[0049] A proximal end of the balloon catheter **170** is affixed to the balloon catheter pull rod **120**. The balloon catheter pull rod **120** is manually translatable relative to the housing **112** (when the locking actuator **116** is in its unlocked position). The balloon catheter pull rod **120** can be extended and retracted relative to the housing **112** to extend and retract the balloon catheter **170** (and the prosthetic heart valve **300**) relative to the steerable catheter **160**. The locking actuator **116** can be used to lock and unlock the movability of the balloon catheter pull rod **120** relative to the housing **112**.

[0050] FIG. **4** provides another view of the distal end portion of the medical device delivery system **100**, including the steerable catheter **160** and the balloon catheter **170**. The prosthetic heart valve **300** is mounted on the balloon **174** of the balloon catheter **170**. The nose cone **178** and the inner catheter shaft **172** of the balloon catheter **170** are also visible. The depicted configuration is the delivery configuration that is used when advancing the distal end portion of the medical device delivery system **100** and the prosthetic heart valve **300** to a target location for deployment of the prosthetic heart valve **300** within a patient (e.g., to a native heart valve region).

[0051] In addition, a valve stop member **190** is shown. The valve stop member **190** is attached to the inner catheter shaft **172** and located within the balloon **174**. Additional features of the valve stop member **190** are described below.

[0052] In the depicted delivery configuration, the prosthetic heart valve **300** is longitudinally compressed and securely captured between a flared distal end **162** of the steerable catheter **160** and the valve stop member **190**. The flared distal end **162** defines an annular space that receives and covers an end portion of the prosthetic heart valve **300**. That is, an end portion of the prosthetic heart valve **300** (e.g., of the metallic stent frame of the prosthetic heart valve **300**) is concealed by the flared distal end **162** of the steerable catheter **160**. This arrangement helps to prevent the potential for vessel wall damage that the end portion of the prosthetic heart valve **300** may otherwise incur if the end portion was exposed (rather than being concealed by the flared distal end **162** of the steerable catheter **160**). Accordingly, during transvascular advancement of the depicted arrangement, the coverage of the end portion of the prosthetic heart valve **300** by the flared distal end **162** mitigates risks of vessel wall damage that could result if that end portion was to make contact with the vessel walls.

[0053] The other end of the prosthetic heart valve **300** is held in position by the valve stop member **190**. The valve stop member **190** prevents the prosthetic heart valve **300** from moving distally despite the longitudinal force from the flared distal end **162** of the steerable catheter **160** that would otherwise engender such distal movement. Accordingly, the prosthetic heart valve **300** is captured between the steerable catheter **160** and the valve stop member **190**.

[0054] More specifically, because the valve stop member **190** resides within the balloon **174**, a layer of the flexible wall material of the balloon **174** resides between the prosthetic heart valve **300** and the valve stop member **190**. That flexible wall material of the balloon **174** is compressed between the prosthetic heart valve **300** and the valve stop member **190** in the depicted delivery configuration. FIG. **5** depicts a latter stage of the delivery/deployment process of the prosthetic heart valve **300** using the medical device delivery system **100**. In comparison to the arrangement of FIG. **4**, here the steerable catheter **160** has been pulled proximally back in relation to the balloon catheter **170**, and in relation to the prosthetic heart valve **300** that is mounted on the balloon **174** of the balloon catheter **170**.

[0055] The depicted arrangement reveals that the balloon catheter **170** also includes an outer catheter shaft **173**. The inner catheter shaft **172** extends distally from the outer catheter shaft **173**. The proximal end of the balloon **174** is attached to a distal end portion of the outer catheter shaft **173**. The distal end of the balloon **174** is attached to the tapered nose cone **178**, which is attached to a distal end portion of the inner catheter shaft **172**. The valve stop member **190** is within the balloon **174** and longitudinally positioned between the outer catheter shaft **173** and the tapered nose cone **178**. The valve stop member **190** is close to the tapered nose cone **178** than to the distal end of the outer catheter shaft **173**.

[0056] FIG. **6** depicts yet another latter stage of the delivery/deployment process of the prosthetic heart valve **300** using the medical device delivery system **100**. In this arrangement, the balloon **174** has been inflated and the prosthetic heart valve **300** has been radially expanded as a result. This expansion of the prosthetic heart valve **300** may be performed, for example, once the prosthetic heart valve **300** has been longitudinally and/or rotationally positioned properly in relation to a native heart valve annulus. That is, the unexpanded prosthetic heart valve **300** can be properly positioned in relation to the native anatomy, and then the prosthetic heart valve **300** can be expanded by inflation of the balloon **174**.

[0057] FIG. **7** illustrates a distal end portion of the balloon catheter **170**. As shown, the balloon catheter **170** includes the inner catheter shaft **172**, the outer catheter shaft **173**, the balloon **174**, the tapered nose cone **178**, and the valve stop member **190**. Radiopaque markers **177** may be located on various positions of the inner catheter shaft **172** and the valve stop member **190**.

[0058] FIGS. **8** and **9** show the valve stop member **190** in isolation so that additional details of its construction are visible. The valve stop member **190** includes a distal hub **191**, an elongate proximal hub **192**, a frustoconical outer surface **194**, and an inner inverted frustoconical surface **196**.

[0059] The distal hub **191** is attached/affixed to the inner catheter shaft **172** such that it is held in a constant position. The elongate proximal hub **192**, however, is a polymeric or metallic tube that is slidable along the inner catheter shaft **172** rather than being attached to the inner catheter shaft **172**. More particularly, the elongate proximal hub **192** comprises an elongate tube that defines a lumen in which the inner catheter shaft **172** is slidably disposed. The elongate proximal hub **192** can slide along the inner catheter shaft **172**. As described further below, during the assembly of the balloon catheter **170** the elongate proximal hub **192** is forcibly slid along the inner catheter shaft **172** to longitudinally stretch the valve stop member **190** and to thereby reduce the outer diameter of the frustoconical outer surface **194** so that the balloon **174** can be moved into position over the valve stop member **190**.

[0060] Referring also to FIGS. **10-12**, the main body of the valve stop member **190** is made of an open structure that can be constructed in various ways such as, but not limited to, a braided wire structure, a laser-cut tube and expanded stent-like structure, and the like. In some embodiments, the structure can be heat-set in the depicted configuration so that the depicted configuration is the natural shape. Accordingly, if/when the shape is deformed for any reason it will rebound to the depicted natural shape when released from external forces.

[0061] In some embodiments, the main body of the valve stop member **190** (e.g., as depicted in FIGS. **10-12**) is a braided wire structure that is made of one or more wires, or multiple wires that are braided together. In other words, in some embodiments the main body of the valve stop member **190** may be a multi-element braided body. Such wires/elements may be made of various materials such as, but not limited to, nitinol (nickel titanium), stainless steel, other metal alloys, polymeric materials, and the like, and combinations thereof.

[0062] In some embodiments, the braided wire structure of the main body of the valve stop member **190** includes a single wire, or from one to ten wires, or from ten to twenty wires, or from twenty to thirty wires, or from thirty to forty wires, or more than forty wires. In some embodiments, the braided wire structure of the main body of the valve stop member **190** includes at least ten wires, or at least twenty wires, or at least thirty wires, or at least forty wires.

[0063] As best seen in FIG. **12**, the main body of the valve stop member **190** defines or includes the inverted frustoconical surface **196**. The inverted frustoconical surface **196** is radially within the frustoconical outer surface **194**. The open frustoconical space defined between the inverted frustoconical surface **196** and the elongate proximal hub **192** provides room for some of the flexible wall material of the balloon **174** to reside. That is, when the prosthetic heart valve **300** is captured between the steerable catheter **160** and the valve stop member **190** (e.g., as shown in FIG. **4**), some of the flexible wall material of the balloon **174** extends into the open frustoconical space defined between the inverted frustoconical surface **196** and the elongate proximal hub **192**. This is an advantageous arrangement because the prosthetic heart valve **300** can thereby abut against the valve stop member **190** (with two layers of the flexible wall material of the balloon **174** therebetween) in an orderly and predictable manner. In other words, the end of the prosthetic heart valve **300** will be predictably positioned away from the valve stop member **190** by a distance equal to the thickness of two layers of the flexible wall material of the balloon **174**. In some embodiments, the proximal edge of the elongate proximal hub **192** is within the open frustoconical space defined between the inverted frustoconical surface **196** and the elongate proximal hub **192**. This can allow for the frame of the prosthetic heart valve **300** to be crimped as radially small as possible and in a predictable manner.

[0064] The shape and open construction of the main body of the valve stop member **190** also provide advantages while the assembly is being advanced/tracked along a curved path (e.g., along the aortic arch). More specifically, the shape and wire construct of the inverted frustoconical surface **196** acts like a deflectable suspension while the assembly is being tracked along curved paths. Accordingly, the full circumference of the prosthetic heart valve **300** can remain reliably abutted against the valve stop member **190** (with two layers of the flexible wall material of the balloon **174** therebetween) as the assembly is being tracked along curved paths. This keeps the assembly in an atraumatic arrangement because no pointed edges of the prosthetic heart valve **300** that could injure a vessel wall become exposed as it travels along a curvature. Instead, the bending/flexure of the main body of the valve stop member **190** is performed by the inverted frustoconical surface **196**.

[0065] In some embodiments, the shape and open construction of the main body of the valve stop member **190** also provide advantages during manufacturing of the balloon catheter **170**. In particular, the main body of the valve stop member **190** can be longitudinally stretched to cause a reduction in the maximum natural outer diameter of the frustoconical outer surface **194**. That reduction in the outer diameter of the frustoconical outer surface **194** can allow the valve stop member **190** to pass through an opening of the balloon **174** that is smaller than the natural maximum outer diameter of the frustoconical outer surface **194**. Once the valve stop member **190** has been placed within the balloon **174**, then the main body of the valve stop member **190** will self-rebound to its natural configuration (as shown) in which the maximum outer diameter of the frustoconical outer surface **194** is larger than the opening of the balloon **174** it was passed through.

[0066] FIG. **13** shows the balloon **174** in its expanded configuration. The distal end **175** of the balloon **174** that gets attached to the tapered nose cone **178** (e.g., see FIGS. **4-7**) has an opening with an inner diameter D. The diameter D is smaller than the natural maximum outer diameter of the frustoconical outer surface **194**. However, when the main body of the valve stop member **190** is stretched, the maximum outer diameter of the frustoconical outer surface **194** can be made smaller than the diameter D. Accordingly, the valve stop member **190** can be placed inside of the balloon **174** by passing it through the opening of the distal end **175** of the balloon **174** while the main body of the valve stop member **190** is maintained in a stretched condition. After the placement of the valve stop member **190** inside of the balloon **174** and the relieving of the tension, the main body of the valve stop member **190** will relax and rebound to its natural configuration (as shown in FIGS. **4-12**) in which the maximum outer diameter of the frustoconical outer surface **194** is larger than the diameter D of the distal end **175** of the balloon **174**.

[0067] FIG. **14** is a flowchart of an example method **200** for the delivery and deployment of a medical device using the medical device delivery system **100**. In particular, the example method **200** is for delivering a prosthetic aortic valve (e.g., the prosthetic heart valve **300**) using the medical device delivery system **100**. Each step of the method **200** will be explained, and references will be made to other figures to describe how a clinician can manipulate the medical device delivery system **100** to perform the steps of the method **200**.

[0068] This method **200** can be performed by a clinician while using fluoroscopic imaging (and/or other types of imaging) in some cases. In addition, other conventional steps for preparing the medical device delivery system **100** (e.g., flushing, testing, etc.) may be performed prior to the first step **210**, but are not specifically included in the flowchart of FIG. **14**.

[0069] At the first step **210** of the method **200**, a guidewire is inserted into the patient. For example, in some embodiments the guidewire is inserted into a femoral artery and then navigated into the aorta, over the aortic arch, and across the aortic valve. A distal end portion of the guidewire is located in the left ventricle of the patient.

[0070] At step **220**, with the locking actuator **116** (FIG. **3**) in the locked position, the medical device delivery system **100** (with a prosthetic aortic valve **300** mounted in a radially compressed configuration on the balloon **174**) is advanced over the guidewire. As the balloon catheter **170** and steerable catheter **160** are advanced over the aortic arch, the clinician can deflect the steerable catheter **160** (and the balloon catheter **170** contained therein) accordingly. That is, the clinician can rotate the first actuator knob **114** relative to the housing **112** to add tension to the pull wire, resulting in deflection of the steerable catheter **160** (and the balloon catheter **170** contained therein) to help navigate the aortic arch. The advancement of step **220** can continue until the prosthetic aortic valve **300** is positioned generally within the native aortic valve.

[0071] At step **230**, with the prosthetic aortic valve **300** remaining positioned generally within the native aortic valve, the clinician can move the locking actuator **116** (FIG. **3**) to its unlocked position and then pull the housing **112** proximally while holding the balloon catheter pull rod **120** in a generally stationary position. These actions will pull back the steerable catheter **160** relative to the balloon catheter **170** (and the prosthetic heart valve **300** mounted thereon) as shown in FIG. **5**. The balloon catheter pull rod **120** will be extended into the housing **112** as a result.

[0072] Next, at step **240** and with the locking actuator **116** relocked, the clinician can rotate the balloon catheter **170** (and the prosthetic heart valve **300** mounted thereon) to align structural features of the prosthetic heart valve **300** relative to anatomical features of the native aortic valve. The clinician can perform this step by rotating the second actuator knob **118** relative to the housing **112**. The balloon catheter **170** will rotate in response to the rotations of second actuator knob **118**, but the steerable catheter **160** will remain stationary. The clinician can use fluoroscopic imaging to observe radiopaque markers on the prosthetic heart valve **300** to align the prosthetic heart valve **300** in a desired orientation relative to the native heart valve anatomy (e.g., relative to commissures of the native heart valve). With the desired orientation attained, the clinician can then manipulate the locking actuator **116** to its locked position.

[0073] At step **250** and with the locking actuator **116** in its locked position, the clinician can then advance or retract the medical device delivery system **100** (with the prosthetic heart valve **300** still mounted on the balloon **174** of the balloon catheter **170**) to position the prosthetic heart valve **300** in a desired longitudinal position relative to the annulus of the native aortic valve. In some embodiments, the prosthetic heart valve **300** can include a radiopaque marker that indicates where the prosthetic heart valve **300** should be longitudinally located relative to the annulus of the native aortic valve. The clinician can simply push the handle **110** distally or pull the handle **110** proximally to perform this step.

[0074] At step **260** and with the locking actuator **116** still in its locked position, the clinician can then initiate rapid pacing and when in optimal position, inflate the balloon **174** to expand the prosthetic heart valve **300** into contact with the annulus of the native aortic valve, as depicted in FIG. **6**. For example, the clinician can inject an inflation liquid (e.g., saline, a mixture of saline and a contrast media, etc.) into the inflation lumen of the balloon catheter **170** via a port **123** (FIG. **3**) extending from the balloon catheter pull rod **120** to inflate the balloon **174** (and expand the prosthetic heart valve **300**).

[0075] At step **270** and with the locking actuator **116** still in its locked position, the clinician can then deflate the balloon **174** (to uncouple the balloon **174** from the prosthetic heart valve **300** which remains engaged with the annulus of the native aortic heart valve). To deflate the balloon **174**, the clinician can withdraw the inflation liquid from the balloon **174** by performing the reverse of the injection step. After the deflation of the balloon **174** the pacing is ceased. In some cases, the clinician can then manipulate the locking actuator **116** to its unlocked position.

[0076] At step **280**, the clinician can retract the balloon catheter **170** and the steerable catheter **160** away from the prosthetic heart valve **300** (which remains engaged with the annulus of the native aortic heart valve) by pulling them proximally. The balloon **174** is proximally retracted at least far enough to allow the prosthetic heart valve **300** to begin to function. This can be performed by simultaneously pulling both the balloon catheter **170** and the steerable catheter **160** proximally, or by pulling the balloon catheter **170** proximally relative to the steerable catheter **160**. The balloon **174** is thereby removed from being within the prosthetic heart valve **300** and the prosthetic heart valve **300** will begin to function.

[0077] At step **282**, an assessment can be made by the clinician (or clinical team) to determine whether the prosthetic heart valve **300** should be expanded further. To make this assessment, the clinician can consider various factors. The factors that may be considered by the clinician can include, for example, the extent of calcification of the native valve annulus, the extent (if any) of paravalvular leakage (e.g., as visualized/indicated using Doppler ultrasound imaging), one or more fluoroscopic images of the prosthetic heart valve **300** relative to the anatomy, and the like. In some cases, one or more mathematical calculations may also be made to assist with the decision process.

[0078] If the assessment at step **282** indicates that additional expansion of the prosthetic heart valve **300** is desirable, the method **200** can return to step **260** for additional expansion of the balloon **174** and the prosthetic heart valve **300**. For example, in some cases an additional injection of ½ ml to 1 ml of inflation liquid (e.g., saline) beyond the originally injected amount can be delivered to cause a relatively small additional expansion of the balloon **174** and the prosthetic heart valve **300**. Thereafter, the method **200** can once again proceed to step **270** and so on.

[0079] If the assessment at step **282** indicates that no additional expansion of the prosthetic heart valve **300** is desirable, the method **200** can proceed to step **290**.

[0080] In some embodiments, the assessment at step **282** is skipped and, after repositioning the balloon **174** within the prosthetic heart valve **300**, inflation liquid is added to the inflate the balloon

174 to further expand the prosthetic heart valve **300** as a matter of standard procedure. For example, in some embodiments an additional amount (e.g., ½ ml or 1 ml) of inflation liquid (in addition to the originally injected amount of inflation liquid) may be added to expand the balloon **174** and the prosthetic heart valve **300** as a matter of standard procedure.

[0081] At step **290**, the clinician can then proximally retract the medical device delivery system **100** and the guidewire from the patient to complete the method **200**. The prosthetic heart valve **300** remains engaged with the annulus of the native aortic heart valve in a functional arrangement.

[0082] While this specification contains many specific implementation details, these should not be construed as limitations on the scope of any invention or of what may be claimed, but rather as descriptions of features that may be specific to particular embodiments of particular inventions. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described herein as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

[0083] Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. In certain circumstances, multitasking and parallel processing may be advantageous.

[0084] Particular embodiments of the subject matter have been described. Other embodiments are within the scope of the following claims. For example, the actions recited in the claims can be performed in a different order and still achieve desirable results. As one example, the processes depicted in the accompanying figures do not necessarily require the particular order shown, or sequential order, to achieve desirable results.

Claims

1. A prosthetic heart valve delivery system, the system comprising: an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter; and a valve stop member attached to the inner catheter shaft and located within the balloon member, wherein the valve stop member comprises a braided body or a cellular body, wherein the body of the valve stop member comprises a frustoconical outer profile, and wherein the body of the valve stop member further comprises an inverted frustoconical portion located within the frustoconical outer profile.

2. (canceled)

3. (canceled)

4. The system of claim 1, wherein the valve stop member comprises the braided body, and wherein the braided body comprises a multi-element braided body.

5. The system of claim 4, wherein the multi-element braided body comprises at least elements that are braided together.

6. The system of claim 1, wherein the valve stop member comprises the cellular body, and wherein the cellular body comprises a laser-cut tube that is shape-set to have a frustoconical outer profile.

7. The system of claim 1, further comprising a nose cone attached to a distal end of the inner catheter shaft.

8. The system of claim 7, wherein a distal end of the balloon member is attached to the nose cone.

9. The system of claim 8, wherein a proximal end of the balloon member is attached to a distal end portion of the outer catheter shaft.

10. The system of claim 1, further comprising a steerable catheter defining a lumen and comprising a pull wire, wherein the catheter is slidably disposed within the lumen.
11. The system of claim 1, wherein a distal end portion of the valve stop member is attached to the inner catheter shaft and a proximal end portion of the valve stop member is slidably coupled to the inner catheter shaft.
12. The system of claim 1, wherein a proximal end portion of the valve stop member comprises a polymeric tube that is slidably coupled to the inner catheter shaft.
13. A prosthetic heart valve delivery system, the system comprising: an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter; and a valve stop member attached to the inner catheter shaft and located within the balloon member, wherein the valve stop member defines an internal space within which a portion of the balloon member is located when a prosthetic heart valve is mounted on the balloon member in a position that is distally limited by the valve stop member.
14. The system of claim 13, wherein the valve stop member comprises a braided body or a cellular body.
15. The system of claim 13, wherein a body of the valve stop member comprises a frustoconical outer profile and an inverted frustoconical portion located within the frustoconical outer profile.
16. The system of claim 15, wherein the internal space is defined within the inverted frustoconical portion.
17. A prosthetic heart valve delivery system, the system comprising: an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter shaft, the balloon member having a distal opening with an inner diameter prior to being attached to the distal end portion of the catheter shaft; and a valve stop member attached to the inner catheter shaft and located within the balloon member, the valve stop member having an outer diameter that is adjustable between a contracted diameter that is less than the inner diameter and a natural diameter that is greater than the inner diameter.
18. The system of claim 17, wherein the valve stop member comprises a braided body or a cellular body.
19. The system of claim 18, wherein the natural diameter is adjustable to the contracted diameter by longitudinally stretching the braided body or the cellular body.
20. A prosthetic heart valve delivery system, the system comprising: an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter; and a valve stop member attached to the inner catheter shaft and located within the balloon member, wherein the valve stop member comprises a braided body or a cellular body, and wherein the valve stop member comprises the cellular body, and wherein the cellular body comprises a laser-cut tube that is shape-set to have a frustoconical outer profile.
21. The system of claim 20, wherein the body of the valve stop member further comprises an inverted frustoconical portion located within the frustoconical outer profile.
22. The system of claim 20, further comprising a nose cone attached to a distal end of the inner catheter shaft.
23. The system of claim 22, wherein a distal end of the balloon member is attached to the nose cone.
24. The system of claim 23, wherein a proximal end of the balloon member is attached to a distal end portion of the outer catheter shaft.
25. The system of claim 20, further comprising a steerable catheter defining a lumen and comprising a pull wire, wherein the catheter is slidably disposed within the lumen.
26. The system of claim 20, wherein a distal end portion of the valve stop member is attached to

the inner catheter shaft and a proximal end portion of the valve stop member is slidably coupled to the inner catheter shaft.
27. The system of claim 20, wherein a proximal end portion of the valve stop member comprises a polymeric tube that is slidably coupled to the inner catheter shaft.
28. A prosthetic heart valve delivery system, the system comprising: an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter; a valve stop member attached to the inner catheter shaft and located within the balloon member; and a nose cone attached to a distal end of the inner catheter shaft, wherein the valve stop member comprises a braided body or a cellular body.
29. The system of claim 28, wherein the body of the valve stop member comprises a frustoconical outer profile.
30. The system of claim 29, wherein the body of the valve stop member further comprises an inverted frustoconical portion located within the frustoconical outer profile.
31. The system of claim 28, wherein the valve stop member comprises the braided body, and wherein the braided body comprises a multi-element braided body.
32. The system of claim 31, wherein the multi-element braided body comprises at least 20 elements that are braided together.
33. The system of claim 28, wherein the valve stop member comprises the cellular body, and wherein the cellular body comprises a laser-cut tube that is shape-set to have a frustoconical outer profile.
34. The system of claim 28, wherein a distal end of the balloon member is attached to the nose cone.
35. The system of claim 34, wherein a proximal end of the balloon member is attached to a distal end portion of the outer catheter shaft.
36. The system of claim 28, further comprising a steerable catheter defining a lumen and comprising a pull wire, wherein the catheter is slidably disposed within the lumen.
37. The system of claim 28, wherein a distal end portion of the valve stop member is attached to the inner catheter shaft and a proximal end portion of the valve stop member is slidably coupled to the inner catheter shaft.
38. The system of claim 28, wherein a proximal end portion of the valve stop member comprises a polymeric tube that is slidably coupled to the inner catheter shaft.
39. A prosthetic heart valve delivery system, the system comprising: an elongate catheter comprising: (i) an outer catheter shaft and (ii) an inner catheter shaft extending distally beyond the outer catheter shaft; an inflatable balloon member attached at a distal end portion of the catheter; a valve stop member attached to the inner catheter shaft and located within the balloon member; and a steerable catheter defining a lumen and comprising a pull wire, wherein the catheter is slidably disposed within the lumen, wherein the valve stop member comprises a braided body or a cellular body.
40. The system of claim 39, wherein the body of the valve stop member comprises a frustoconical outer profile.
41. The system of claim 40, wherein the body of the valve stop member further comprises an inverted frustoconical portion located within the frustoconical outer profile.
42. The system of claim 39, wherein the valve stop member comprises the braided body, and wherein the braided body comprises a multi-element braided body.
43. The system of claim 42, wherein the multi-element braided body comprises at least 20 elements that are braided together.
44. The system of claim 39, wherein the valve stop member comprises the cellular body, and wherein the cellular body comprises a laser-cut tube that is shape-set to have a frustoconical outer profile.

45. The system of claim 39, further comprising a nose cone attached to a distal end of the inner catheter shaft.
46. The system of claim 45, wherein a distal end of the balloon member is attached to the nose cone.
47. The system of claim 46, wherein a proximal end of the balloon member is attached to a distal end portion of the outer catheter shaft.
48. The system of claim 39, further comprising a steerable catheter defining a lumen and comprising a pull wire, wherein the catheter is slidably disposed within the lumen.
49. The system of claim 39, wherein a distal end portion of the valve stop member is attached to the inner catheter shaft and a proximal end portion of the valve stop member is slidably coupled to the inner catheter shaft.
50. The system of claim 39, wherein a proximal end portion of the valve stop member comprises a polymeric tube that is slidably coupled to the inner catheter shaft.