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Catheter assembly

Abstract

Embodiments of a catheter assembly are disclosed. The catheter assembly comprises a shaft; a connector assembly comprising a first connector portion and a second connector portion, wherein the first connector portion is fixedly coupled to a distal end of the shaft, and is rotatably coupled to the second connector portion by at least one radially extending pin retained within at least one slot on the second connector portion, wherein the at least one slot has an oversized circumferential dimension that allows limited rotation of the second connector portion relative to the first connector portion about a longitudinal axis of the shaft.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATION (1) This application is a continuation of U.S. patent application Ser. No. 16/839,501, filed Apr. 3, 2020, which is a continuation of International Application No. PCT/US2018/053532, filed Sep. 28, 2018, which claims the benefit of U.S. Provisional Patent Application No. 62/573,883, filed Oct. 18, 2017. The foregoing applications are incorporated by reference in their entirety herein for all purposes.

FIELD
(1) The present disclosure concerns embodiments of a catheter assembly, such as a delivery apparatus for implanting a prosthetic heart valve.
BACKGROUND
(2) Endovascular delivery devices, such as catheters, are used in various procedures to deliver prosthetic medical devices or instruments to locations inside the body that are not readily accessible by surgery or where access without surgery is desirable. Access to a target location inside the body can be achieved by inserting and guiding the delivery device through a pathway or lumen in the

body, including, but not limited to, a blood vessel, an esophagus, a trachea, any portion of the gastrointestinal tract, a lymphatic vessel, to name a few. In one specific example, a prosthetic heart valve can be mounted in a crimped state on the distal end of a delivery device and advanced through the patient's vasculature (e.g., through a femoral artery and the aorta) until the prosthetic valve reaches the implantation site in the heart. The prosthetic valve is then expanded to its functional size such as by inflating a balloon on which the prosthetic valve is mounted, or by deploying the prosthetic valve from a sheath of the delivery device so that the prosthetic valve can self-expand to its functional size.

(3) The usefulness of delivery devices is largely limited by the ability of the device to successfully navigate through small vessels and around tight bends in the vasculature, such as around the aortic arch. Since the path through the patient's vasculature to the intended site is often long and tortuous, steering forces must be transmitted over great distances. It is preferably for a delivery catheter to have sufficient axial strength so that the physician can push through the patient's vasculature via a force applied at the proximal end of the catheter. In addition, the distal part of the delivery catheter preferably includes a steerable section having sufficient flexibility so that it can pass through tortuous anatomy without sacrificing rigidness of the catheter shaft. However, many delivery catheters are too stiff and are difficult to push through the vasculature. Hence, there is a continued need for improved delivery catheters with enhanced flexibility.

SUMMARY

(4) Disclosed herein are steerable catheter devices and related methods, which can be used to deliver a medical device, tools, agents, or other therapy to a location within a body of a subject. In some implementations, the steerable catheter devices can be used to deliver a medical device through the vasculature, such as to a heart of the subject.

(5) Certain embodiments of the disclosure concern a catheter assembly that includes a shaft and a connector assembly. The connector assembly can include a first connector portion and a second connector portion. The first connector portion can be fixedly coupled to a distal end of the shaft, and is rotatably coupled to the second connector portion by at least one radially extending pin retained within at least one slot on the second connector portion. The at least one slot can have an oversized circumferential dimension that allows limited rotation of the second connector portion relative to the first connector portion about a longitudinal axis of the shaft.

(6) In some embodiments, the at least one slot can be sized to allow limited tilting of the second connector portion with respect to the longitudinal axis of the shaft.

(7) In some embodiments, the at least one slot can have an oversized width in a direction along the longitudinal axis that allows limited axial movement of the first connector portion relative to the second connector portion.

(8) In some embodiments, the at least one slot can include first and second slots and the at least one pin comprises first and second pins disposed in the first and second slots, respectively.

(9) In some embodiments, each slot can have an arc length around the longitudinal axis of less than 180 degrees.

(10) In the foregoing embodiments, the first connector portion can include a distal end portion that extends into an axial bore of the second connector portion, and the at least one pin can extend radially outwardly from the distal end portion into the at least one slot in the second connector portion.

(11) In the foregoing embodiments, the second connector portion can include one or more attachment features configured to form a releasable attachment with corresponding retaining arms of an implantable medical device.

(12) In certain embodiments, the one or more attachment features can include one or more recesses configured to receive the one or more retaining arms of the implantable medical device.

(13) In certain embodiments, the catheter assembly can further include an outer sheath configured to extend over the connector assembly and the implantable medical device so as to retain the

implantable medical device in a radially compressed state within the sheath when the retaining arms are in engagement with the attachment features of the second connector portion.
(14) In the foregoing embodiments, the catheter assembly can further include another shaft having a proximal end connected to the second connector portion.
(15) Certain embodiments of the disclosure also concern a delivery apparatus for delivering an implantable device via a patient's vasculature. The delivery apparatus includes an outer sheath, a shaft extending through the outer sheath; and a connector assembly. The connector assembly can include a first connector portion and a second connector portion. The first connector portion can be fixedly coupled to a distal end of the shaft. The second connector portion can be coupled to the first connector portion such that the second connector portion can rotate relative to the first connector portion about a longitudinal axis of the shaft and can tilt with respect to the longitudinal axis of the shaft. The second connector portion can include one or more attachment features configured to form a releasable attachment with corresponding retaining arms of a radially expandable implantable medical device. The outer sheath can be configured to extend over the connector assembly and the implantable medical device so as to retain the implantable medical device in a radially compressed state within the sheath when the retaining arms of the implantable medical device are placed in engagement with the attachment features of the second connector portion.
(16) In some embodiments, the second connector portion can be coupled to the first connector portion such that the second connector portion can move axially relative to the first connector portion a limited amount in a direction parallel to the longitudinal axis.
(17) In some embodiments, the second connector portion can be coupled to the first connector portion by at least one radially extending pin retained within at least one slot on the second connector portion.
(18) In some embodiments, the second connector portion can be coupled to the first connector portion by at least one radially extending pin retained within at least one slot on the first connector portion.
(19) In some embodiments, the at least one slot can have an oversized circumferential dimension that allows limited rotation of the second connector portion relative to the first connector portion about the longitudinal axis of the shaft.
(20) In some embodiments, the at least one slot can be sized to allow limited tilting of the second connector portion with respect to the longitudinal axis of the shaft.
(21) In some embodiments, the at least one slot can have an oversized width in a direction along the longitudinal axis that allows limited axial movement of the first connector portion relative to the second connector portion.
(22) In some embodiments, the at least one slot can include first and second slots and the at least one pin can include first and second pins disposed in the first and second slots, respectively, and the first slot being opposite the second slot with respect to the longitudinal axis.
(23) In some embodiments, the attachment features of the second connector portion can include one or more recesses configured for receiving one or more retaining arms of the implantable device.
(24) Further, certain embodiments of the disclosure concern also concern an assembly including an outer sheath, a first shaft extending through the outer sheath, a second shaft extending through the first shaft, a nose cone mounted on a distal end portion of the second shaft, a connector assembly, and a radially expandable and compressible prosthetic heart valve. The connector assembly can include a proximal connector portion and a distal connector portion. The proximal connector portion can be fixedly coupled to a distal end of first shaft. The distal connector portion can be rotatably coupled to the proximal connector portion by at least a pin retained within a slot in the distal connector portion. The slot can have an oversized circumferential dimension that allows limited rotation of the distal connector portion relative to the proximal connector portion about a longitudinal axis of the first shaft, limited tilting of the distal connector portion with respect to the

longitudinal axis, and limited axial movement of the distal connector portion relative to the proximal connector portion in a direction parallel to the longitudinal axis. The distal connector portion can include one or more attachment features. The prosthetic heart valve can be retained in a radially compressed state within the sheath and having one or more retaining arms that engage respective attachment features of the distal connector portion.
(25) The foregoing and other objects, features, and advantages of the invention will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) FIG. **1** shows a side elevation view of a catheter assembly including a delivery apparatus and a prosthetic heart valve that is in a radially compressed state.
(2) FIG. **2** shows a top perspective view of a distal portion of the delivery apparatus depicted in FIG. **1**.
(3) FIG. **3** shows an expanded prosthetic heart valve along a distal portion of the catheter assembly of FIG. **1**.
(4) FIG. **4** shows a top perspective view of an exemplary connector assembly included in the delivery apparatus depicted in FIG. **2**.
(5) FIG. **5** shows a cross-sectional view of the connector assembly of FIG. **4** taken along line **3**-**3** of FIG. **4**.
(6) FIG. **6** shows another cross-sectional view of the connector assembly of FIG. **4** taken along line **4**-**4** of FIG. **4**.
(7) FIG. **7**A shows an enlarged view of the connector assembly and its coupling with a shaft of the delivery apparatus.
(8) FIG. **7**B shows another embodiment of the connector assembly and its coupling with a shaft of the delivery apparatus.
(9) FIG. **7**C shows an alternative embodiment of the connector assembly and its coupling with a shaft of the delivery apparatus.
(10) FIG. **8** shows a side elevation view of the connector assembly depicted in FIG. **2** and illustrates its tilting movement.
(11) FIG. **9** shows a cross-sectional view of the connector assembly depicted in FIG. **2** and illustrates its rotational movement.
DETAILED DESCRIPTION
(12) In particular embodiments, a delivery apparatus that can be used to deliver a medical device, tools, agents, or other therapy to a location within the body of a subject can include one or more steerable catheters and/or sheaths. Examples of procedures in which steerable catheters and sheaths are useful include cardiovascular, neurological, urological, gynecological, fertility (e.g., in vitro fertilization, artificial insemination), laparoscopic, arthroscopic, transesophageal, transvaginal, transvesical, transrectal, and procedures including access in any body duct or cavity. Particular examples include placing implants, including stents, grafts, embolic coils, and the like; positioning imaging devices and/or components thereof, including ultrasound transducers; and positioning energy sources, for example, for performing lithotripsy, RF sources, ultrasound emitters, electromagnetic sources, laser sources, thermal sources, and the like.
(13) In some embodiments, the delivery apparatus can include a steerable shaft such as a guide sheath having one or more delivery catheters coaxially disposed within the guide sheath. The delivery apparatus may comprise one or more eccentrically positioned pull wires configured to cause the steerable shaft to curve in a given direction, or to straighten. In some embodiments, the

delivery apparatus can be used to deliver a medical device through the vasculature, such as to a heart of the subject. In certain configurations, a balloon-inflatable or self-expandable prosthetic heart valve can be mounted on a distal portion of the delivery apparatus. Exemplary configurations of the prosthetic heart valve and implant catheter are further disclosed in U.S. Patent Application Publication Nos. 2013/0030519, 2012/0123529, 2010/0036484, 2010/0049313, 2010/0239142, 2009/0281619, 2008/0065011, and 2007/0005131, the disclosures of which are incorporated by reference in their entireties. In addition, it should be understood that the delivery apparatus can be used to deliver any of various other implantable devices, such as docking devices, leaflet clips, etc.

(14) As an exemplary embodiment, FIG. **1** shows a catheter assembly **10** that includes a prosthetic heart valve **80** mounted on a delivery apparatus **12**. FIG. **2** shows a distal portion of the delivery apparatus **12**, according to one exemplary embodiment.

(15) As shown, the delivery apparatus **12** can include a first shaft **14**, a connector assembly **20** that is coupled to a distal end portion of the first shaft **14**, an outer sheath **16** sized to extend over the first shaft **14** and the connector assembly **20**, a second shaft **18** (which can also be referred to as an "inner shaft" in the illustrated embodiment) extending through the first shaft **14** and the connector assembly **20**, and a nose cone **22** connected to a distal end **18***d* of the inner shaft **18**. A guide wire **76** can extend through the central lumen of the inner shaft **18** and the inner lumen of the nose cone **22**, so that the delivery apparatus **12** can be advanced over the guide wire **76** inside the patient's vasculature.

(16) The connector assembly **20** in the illustrated embodiment includes a first connector portion **26** and a second connector portion **28**, wherein the first connector portion **26** is positioned proximally relative to the second connector portion **28**. The first connector portion **26** (which can be referred to as a "proximal connector portion" in the illustrated embodiment) can be fixedly coupled to the distal end **14***d* of the first shaft **14**, and the first connector portion **26** can be generally coaxial with the first shaft **14**. The second connector portion **28** (which can be referred to as a "distal connector portion" in the illustrated embodiment) can be coupled to the first connector portion **26** so as to permit limited movement of the second connector portion relative to the first connector portion.

(17) As indicated in FIG. **2** and described more fully below, the second connector portion **28** can be configured to have multiple degrees of freedom to move relative to the first connector portion **26**. For example, with respect to the first connector portion **26**, the second connector portion **28** can translate axially (in the directions indicated by double-headed arrow A) along the longitudinal axis **24** of the first shaft **14**, rotate in a plane that is transverse to the longitudinal axis **24** (in the directions indicated by double-headed arrow R), and/or axially tilt with respect to the longitudinal axis **24** (in the directions indicated by arrow T).

(18) The delivery apparatus **12** can have a device retaining portion **78** located between the connector assembly **20** and the nose cone **22**. The device retaining portion **78** can be configured to accommodate an implantable medical device, such as a prosthetic heart valve **80** (see e.g., FIG. **1**), in a radially compressed state within the outer sheath **16**. As described herein, the prosthetic heart valve **80** can be balloon inflatable or self-expandable.

(19) As described more fully below, the outer sheath **16** can be configured to move axially relative to the first shaft **14** and the second shaft **18** between a first, distal position extending over the device retaining portion **78** and the implantable medical device for delivery through the vasculature of a patient (as shown in FIG. **1**) and a second, proximal position in which the distal end of the outer sheath is proximal to the device retaining portion **78** (as shown in FIG. **2**) to allow the implantable medical device to be expanded at the desired implantation site, as further described below.

(20) For example, as shown in FIGS. **1** and **3** and describe more fully below, the prosthetic heart valve **80** can have one or more retaining arms **84** that engage respective attachment features of the connector assembly **20**. When the prosthetic heart valve **80** is deployed from the sheath (e.g., by sliding the outer sheath **16** proximally or sliding the inner shaft **18** distally), the retaining arms **84**

can disengage from respective attachment features. Accordingly, the prosthetic heart valve **80** can be released from the device retaining portion **78**, and expanded to its functional size (see e.g., FIG. **3**) for deployment at the target site.

(21) In some embodiments, the prosthetic heart valve **80** can be self-expandable such that the prosthetic heart valve **80** automatically expands from the radially compressed state to a radially expanded state once it is deployed from the outer sheath **16**. In other embodiments, the prosthetic heart valve **80** can be configured to be expanded by an expansion device (e.g., an inflatable balloon) once deployed from the outer sheath **16**.

(22) As shown in FIG. **1**, the delivery apparatus **12** can include a handle **68** at a proximal end thereof. During delivery of the implantable medical device (e.g., the prosthetic heart valve **80**), the handle **68** can be maneuvered by a surgeon to advance and retract the delivery apparatus **12** through the patient's vasculature.

(23) In one exemplary, non-limiting embodiment illustrated in FIG. **1**, the handle **68** can include a plurality of knobs for controlling different components of the delivery apparatus **12**. For example, the proximal end **16***p* of the outer sheath **16** can be operatively coupled to a first knob **70**, the proximal end **14***p* of the first shaft **14** can be operatively coupled to a second knob **72**, and the proximal end **18***p* of the inner shaft **18** can be operatively coupled to a knob **74**.

(24) In some embodiments, operation (e.g., rotational or axial movement) of the first knob **70** can cause the outer sheath **16** to slide over and retain the implantable medical device (e.g., the prosthetic heart valve **80**) or withdraw proximally so as to expose and release the implantable medical device. In some embodiments, operation of the first knob **70** can cause rotational twisting of the outer sheath **16** relative to the first shaft **14** and the inner shaft **18**.

(25) In some embodiments, operation (e.g., rotational or axial movement) of the second knob **72** can cause the first shaft **14** to rotate about and/or slide along its longitudinal axis **24**. Because the distal end **14***d* of the first shaft **14** is fixedly coupled to the first connector portion **26**, operation of the second knob **72** can produce limited rotational and/or axial movement of the first connector portion **26** relative to the second connector portion **28**.

(26) In some embodiments, operation (e.g., rotational or axial movement) of the third knob **74** can cause the inner shaft **18** (and the nose cone) to slide longitudinally relative to the first shaft **14** and the outer sheath **16**. For example, in certain embodiments, the inner shaft **18** can be moved distally to move the nose cone **22** distally relative to the sheath **16** so that the implantable medical device can then be deployed from the sheath.

(27) Further details of the construction of the handle with knobs and the means for operating the handle and knobs are described in U.S. Patent Application Publication Nos. 2013/0030519, 2009/0281619, 2008/0065011, and 2007/0005131. Alternatively, different components of the delivery apparatus **12** can be controlled by different forms of actuation mechanism other than knobs, such as push buttons, joysticks, voice-controlled actuators, etc.

(28) FIG. **4** shows the connector assembly **20** in isolation without displaying other parts of the delivery apparatus **12**. As shown, the connector assembly **20** includes the first connector portion **26** and the second connector portion **28** that is distal to the first connector portion **26**. The first and second connector portions **26**, **28** can be generally cylindrical in shape. The first and second connector portions **26**, **28** can be rotatably coupled to each other by at least one radially extending pin **30** retained within at least one slot **40** formed in the second connector portion **28**.

(29) FIGS. **5-6** show one exemplary, non-limiting embodiment of the detailed structure of the connector assembly **20**. As shown, the first connector portion **26** can include a proximal end portion **42** and a distal end portion **44** connected by an intermediate portion **46**. The proximal end portion **42** can be fixedly coupled to the distal end portion **14***d* of the shaft **14**. Each portion **42**, **44**, **46** can have a generally cylindrical shape but can vary in cross-sectional area. It should be noted, however, each portion **42**, **44**, **46** can also have a non-cylindrical shape (e.g., the cross-sectional shape of the portion can be square, oval, hexagonal, etc.). The first connector portion **26** can

comprise a sidewall **48** defining a proximal lumen **50** along the proximal end portion **42** and a distal lumen **52** extending through the intermediate and distal end portions **44**, **46**. The proximal lumen **50** can have a larger interior dimension (e.g., diameter) than the distal lumen **52**. To affix the shaft **14** to the first connector portion **26**, the distal end portion **14***d* of the shaft **14** can extend into the proximal lumen **50** and can be secured in place, such as with an interference fit and/or a suitable adhesive.

(30) The second connector portion **28** can include a distal end portion **54** and a proximal end portion **56**. Each portion **54**, **56** can have a generally cylindrical shape. It should be noted, however, each portion **54**, **56** can also have a non-cylindrical shape (e.g., the cross-sectional shape of the portion can be square, oval, hexagonal, etc.). The outer surface of the distal end portion **54** can define a plurality of recesses **32** and optional bosses **34** extended therefrom, which form attachment features for forming a releasable connection with each of the retaining arms **84** of the prosthetic valve, as further described below. The second connector portion **28** can comprise a sidewall **58** defining a proximal lumen **62** along the proximal end portion **56** and a distal lumen **60** along the distal end portion **54**, wherein the proximal lumen **62** can have a larger interior dimension (e.g., diameter) than the distal lumen **60**.

(31) In the embodiment depicted in FIGS. **5-6**, the outer dimension of the distal end portion **44** of the first connector portion **26** is smaller than the interior dimension of the proximal lumen **62** of the second connector portion **28** such that there is a radial gap between the outer surface of the distal end portion **44** and the inner surface of the proximal lumen **62**. Accordingly, the distal end portion **44** of the first connector portion **26** can be inserted into the proximal lumen **62** (which can also be referred to as an "axial bore") of the second connector portion **28**. The respective lumens **50**, **52**, **62**, and **60** of the first and second connector portions **26**, **28** can collectively define a central passage for the inner shaft **18** to extend through.

(32) In the embodiment depicted in FIG. **6**, two pins **30**′, **30**″ extend radially outward from the distal end portion **44** of the first connector portion **26** respectively into two slots **40**′, **40**″ formed in the proximal end portion **56** of the second connector portion **28**.

(33) In some embodiments, the pins **30**′, **30**″ can be embedded in and extend radially outward from respective recesses **64**′, **64**″ located at the distal end portion **44** of the first connector portion **26**. The recesses **64**′, **64**″, which can be formed in the sidewall **48** at diametrically opposed locations. The radial inner end portions of the pins **30**, **30**″ can be secured in the recesses **64**′, **64**″, such as with an adhesive and/or a frictional fit. Alternatively, the sidewall **48** can be without recesses **64**′, **64**″ and the pins **30**′, **30**″ can be secured to the outer surface of the sidewall **48**. Alternatively, the pins **30**′, **30**″ can be formed as integral parts of the first connector portion **26** (i.e., they form a unitary piece) such that they protrude outward from the outer surface of the wall **48** without any recesses **64**′, **64**″. In the depicted embodiment, both slots **40**′, **40**″ extend through the sidewall **58** of the second connector portion **28**, and they are arranged on opposite sides of the sidewall **58** with respect to the longitudinal axis **24**. Each of the slots **40**′, **40**″ can have an arc length of less than 180 degrees.

(34) Although the exemplary embodiment described herein have two pins **30** in two slots **40**, it should be understood that any number of pins **30** and slots **40** (e.g., 1, 3, 4, etc.) can be used. Further, the slots **40** are not necessarily equally spaced circumferentially.

(35) In the embodiments shown in FIGS. **4-6**, the pins **30**′, **30**″ have a generally cylinder shape with a cross-sectional diameter D**1**. It should be noted, however, that the pins **30**′, **30**″ can have other cross-sectional shapes (e.g., square, oval, hexagonal, etc.) with a maximum cross-sectional dimension D**1**. Each of the slots **40**′, **40**″, which defines an opening in the sidewall **58** of the second connector portion **28**, has a circumferential dimension (or length) L measured circumferentially and an axial dimension (or width) W measured longitudinally over the outer surface of the second connector portion **28**.

(36) In some embodiments, the slot **40** can have an oversized circumferential dimension L (i.e.,

L>D**1**) or arc length (measured in degrees) that allows limited rotation (e.g., clockwise or counter-clockwise) of the second connector portion **28** relative to the first connector portion **26** about the longitudinal axis **24** of the shaft **14** (see e.g., FIGS. **2** and **9**). The degree of rotational movement of the second connector portion **28** relative to the first connector portion **26** can be limited by the length (L) of the slot **40**.

(37) In addition, the slot **40** can have an oversized width W (i.e., W>D**1**) in a direction along the longitudinal axis **24** that allows limited axial movement (e.g., distally or proximally) of the second connector portion **28** relative to the first connector portion **26**. The degree of axial movement of the second connector portion **28** relative to the first connector portion **26** can be limited by the width (W) of the slot **40**.

(38) The second connector portion **28** is also configured to tilt relative to the first connector portion **26** about a tilt axis **82** (FIG. **4**) defined by the pins **30**, **30**″ by virtue of the arrangement of the distal end portion **44** of the first connector portion **26** with respect to the axial bore **62**. In particular, as noted above, the axial bore **62** of the second connector portion **28** can be oversized (e.g., in cross-sectional dimension) relative to the distal end portion **44** of the first connector portion **26** (e.g., D**3**>D**2** as illustrated in FIG. **6**) such that there is an annular extending, radial gap between the adjacent surfaces of the first and second connector portions. This allows the second connector portion **28** to tilt about the tilt axis **82** (in the directions indicated by double-headed arrow T in FIG. **2**) wherein the tilt axis **82** extends through the pins **30**′, **30**″ perpendicular to the longitudinal axis **24**. In this manner, the pins **30**′, **30**″ function as a fulcrum, allowing the second connector portion **28** to tilt relative to the first connector portion **26** about the tilt axis **82**.

(39) In addition, since the width W of the slots **40**′, **40**″ is greater than the dimension D**1** of the pins **30**′, **30**″, the tilting motion of the second connector portion **28** relative to the first connector portion **26** is not necessarily limited to tilting motion about tilt axis **82** extending through the pins **30**′, **30**″. Explaining further, due to the width W being oversized relative to the dimension D**1** and the diameter D**3** being oversized relative to the diameter D**2**, the second connector portion **28** can "float" relative to the first connector portion **26** in three-dimensional space with movement of the second connector portion **28** being constrained by contact between the pins **30**, **30**″ with the sides of the slots **40**′, **40**″. As such, the second connector portion **28** can shift and/or tilt relative to the first connector portion such that the central axis **88** of the second connector portion **28** (FIG. **8**) deviates from the longitudinal axis **24** (i.e., movement of the second connector portion **28** causes the central axis **88** to become non-collinear with the longitudinal axis **24**). Accordingly, in some embodiments, the second connector portion **28** can tilt and/or shift in any direction relative to the first connector portion **26**, with movement of the second connector portion limited by the spacing between the axial bore **62** and the distal end portion **44** of the first connector portion **26** and the spacing between the pins **30**, **30**″ and the sides of the slots **40**′, **40**″.

(40) In some embodiments, as noted above, the second connector portion **28** can include one or more attachment features configured to form a releasable attachment with corresponding retaining arms of an implantable medical device, such as a prosthetic heart valve **80**, retained in the device retaining portion **78** (see, e.g., FIGS. **1** and **3**).

(41) One exemplary, non-limiting embodiment of attachment features are shown in FIGS. **1**-**6**. As depicted, the second connector portion **28** can have a plurality of circumferentially spaced recesses **32** formed in the outer surface of the distal end portion **54** and sized to receive respective retaining arms **84** of the prosthetic heart valve **80**. Optional radially-extending bosses or pins **34** can be disposed within the plurality of recesses **32**. Each boss **34** can be so complimentarily shaped and sized to engage with a corresponding aperture **86** in a retaining arm **84** of the prosthetic heart valve **80**. Thus, by extending through the corresponding apertures **86**, the bosses can serve as anchors to help secure the retaining arms **84** within the recesses. The distal end of the second connector portion can be formed with a flange **36** that has a slightly larger outer diameter than the section in which the recesses **32** are formed. The flange **36** can have one or more notches **38** along its

circumferential edge. The notches **38** are in communication with the recesses **32** such that the retaining arms **84** can extend through the notches.
(42) When the prosthetic heart valve **80** is in a radially compressed state and attached to the delivery apparatus for delivery into a patient's body, the prosthetic heart valve **80** is positioned distal to the flange **36** within the retaining portion **78**. The retaining arms **84** extend through the notches **32** in the flange **36** so as to position the end portions of the retaining arms **84** within respective recesses **32**. The sheath **16** is extended over the prosthetic heart valve **80** to retain the retaining arms **84** within recesses **32** and to retain the prosthetic heart valve **80** in the radially compressed state.
(43) Although FIG. **4** shows three recesses **32** (and three corresponding bosses **34** and notches **38**) that are equally spaced circumferentially around the outer surface of the second connector portion **28**, it should be understood that any number of recesses **32** (and corresponding bosses **34** and notches **38**) can be included so long as they collectively engage with the respective retaining arms **84** of the prosthetic heart valve **80**. Further, it should be understood that the attachment features can take any other forms so long as to enable releasable attachment with the implantable medical device. For example, in alternative embodiments, the attachment features can include a suture retention member and a slidable release member, as disclosed in US 2014/0343670, which is incorporated herein by reference.
(44) After attaching the prosthetic heart valve **80** to the delivery apparatus **12** as described above, the delivery apparatus can be inserted in the vasculature of a patient (e.g., a femoral artery and the aorta when delivering a prosthetic aortic valve in a retrograde delivery approach). Because the implantable medical device can be releasably attached to the second connector portion **28**, the connector assembly **20** in the illustrated embodiment supports limited, multiple degrees of movement of the implantable medical device retained within the outer sheath **16** at the device retaining portion **78**. As a result, the connector assembly **20** can function as a flexible self-tracking joint, such that when pushing the delivery apparatus **12** through a patient's vasculature, the distal portion of the delivery apparatus **12** (and the implantable medical device retained therein) can more easily track or follow the contour of the vasculature by passive deflections in at least three independent degrees of freedom (by limited tilting, rotation, and/or translation) against resistance from the vascular wall. Such self-tracking capability is advantageous because it allows the physician to more easily navigate the delivery apparatus **12** through a challenging vascular path, and in some embodiments reducing or even eliminating the need to operate control mechanisms for steering the delivery apparatus **12** (e.g., actively bending the distal portion through pull wires to achieve a desired curvature).
(45) FIG. **7**A shows an enlarged view of the connector assembly **20** and its coupling with the shaft **14** of the delivery apparatus **12** depicted in FIG. **2**.
(46) FIG. **7**B shows a connector assembly **100** incorporated in the delivery apparatus **12***b*, according to another embodiment. The connector assembly **100** comprises the first and second connector portions **102**, **104**, respectively. The first connector portion **102** is fixedly coupled to the shaft **14**, and the inner shaft **18** extends through the shaft **14** and the connector assembly **100**.
(47) In contrast to the connector assembly **20** described above, the second connector portion **104** has a proximal end portion **106** which has an outer diameter that is smaller than the interior diameter of a distal lumen **108** of the first connector portion **102**. Accordingly, the proximal end portion **106** of the second connector portion **104** can extend into the distal lumen **108** of the first connector portion **102**.
(48) In addition, the first and second connector portions **102**, **104** can be rotatably coupled to each other by one or more pins **30** extending radially outwardly from the second connector portion **104** and retained within respective slots **40** on the first connector portion **102**. Similarly, a distal lumen **108** of the first connector portion **102** can be oversized relative to a proximal end portion **106** of the second connector portion **28***b*, and the slots **40** can be oversized in length and width relative to the

cross-sectional dimensions of the pins **30** so that the second connector portion **104** can have a limited degree of freedom to rotate around the longitudinal axis **24**, and/or translate along the longitudinal axis **24**, and/or tilt in any direction relative to the first connector portion **102**.

(49) FIG. **7**C shows a connector assembly **200** incorporated in a delivery apparatus **12***c*, according to an alternative embodiment. The connector assembly **200** comprises a first connector portion **206** and a second connector portion **208**. The first connector portion can be fixedly coupled to a first shaft segment **202**, and the second connector portion can be fixedly coupled to a second shaft segment **204**. Similar to the connector assembly **20**, the first and second connector portions **206**, **208** can be rotatably coupled to each other by one or more pins **30** extending from the first connector portion **206** and retained within respective slots **40** on the second connector portion **208**.

(50) The connector assembly **200** can have the same configuration as the connector assembly **20** previously described, except that the second connector portion **208** is not formed with any retaining features for retaining an implantable medical device. Instead, the connector assembly **200** is used as a linkage between adjacent ends of two shaft segments of a catheter assembly. Similar to the connector assembly **20**, a proximal lumen of the second connector portion **208** can be oversized relative to a distal end portion of the first connector portion **206**, and the slots **40** can be oversized in length and width relative to the cross-sectional dimensions of the pins **30** so that the second connector portion **208** can have limited rotational, axial, and/or tilting movement relative to the first connector portion **206**. Because the second shaft segment **204** is fixedly coupled to the second connector portion **208**, any rotational, axial, and/or tilting movement of the second connector portion **208** can also cause corresponding rotational, axial, and/or tilting movement of the second shaft segment **204** relative to the first shaft segment. In this manner, the connector assembly **200** increases the flexibility of the shaft assembly along its length.

(51) Although only two shaft segments are shown, it should be understood that a shaft assembly can comprise any number of shaft segments coupled to end-to-end with respective connector assemblies **200** to enhance the flexibility of the shaft assembly along its length. Each shaft segment of the multi-segment hinged shaft assembly can have a limited degree of rotational, axial, and/or tilting movement relative to an attached connector assembly **200** and an adjacent shaft segment. In one implementation, connector assemblies can be used to interconnect relatively short, non-flexible shaft segments, such as metal shaft segments, to form a shaft assembly with a high degree of flexibility.

(52) In FIGS. **7**A-**7**C, the pins extend radially outwardly and are retained in respective outer slots. For example, in FIG. **7**A (and similarly in FIG. **7**C), because the distal end portion **44** of the first connector portion **26** is inserted into the proximal lumen **62** of the second connector portion **28**, the slots **40** retaining the pins **30** are positioned exterior to the distal end portion **44** from which the pins **30** extend radially outward. In FIG. **7**B, because the proximal end portion **106** of the second connector portion **104** is inserted into the distal lumen **108** of the first connector portion **102**, the slots **40** retaining the pins **30** are also positioned exterior to the proximal end portion **106** from which the pins **30** extend radially outward.

(53) Although not shown, it should be understood that the pin-in-slot configuration can be structured differently such that the pins can extend inwardly and are retained in respective inner slots. For example, the connector assembly can have an inner portion inserted into the central lumen of an outer portion, and the pins can extend radially inward from the outer portion and retained within corresponding inner slots located on the inner portion. The inner portion can be part of the first connector portion and the outer portion can be part of the second connector portion. Alternatively, the inner portion can be part of the second connector portion and the outer portion can be part of the first connector portion. Similarly, the inner slots can be oversized relative to the inwardly extending pins so that the second connector portion can have limited rotational, axial, and/or tilting movement relative to the first connector portion.

(54) General Considerations

(55) It should be understood that the disclosed embodiments can be adapted to deliver and implant prosthetic devices in any of the native annuluses of the heart (e.g., the pulmonary, mitral, and tricuspid annuluses), and can be used with any of various delivery approaches (e.g., retrograde, antegrade, transseptal, transventricular, transatrial, etc.) or other organs.
(56) For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatus, and systems should not be construed as being limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The methods, apparatus, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved. The technologies from any example can be combined with the technologies described in any one or more of the other examples. In view of the many possible embodiments to which the principles of the disclosed technology may be applied, it should be recognized that the illustrated embodiments are only preferred examples and should not be taken as limiting the scope of the disclosed technology.
(57) Although the operations of some of the disclosed embodiments are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. Additionally, the description sometimes uses terms like “provide” or “achieve” to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms may vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art.
(58) As used in this application and in the claims, the singular forms “a,” “an,” and “the” include the plural forms unless the context clearly dictates otherwise. Additionally, the term “includes” means “comprises.” Further, the terms “coupled” and “connected” generally mean electrically, electromagnetically, and/or physically (e.g., mechanically or chemically) coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.
(59) Directions and other relative references (e.g., inner, outer, upward, downward, interior, exterior, etc.) may be used to facilitate discussion of the drawings and principles herein, but are not intended to be limiting. For example, certain terms may be used such as “inside,” “outside,”, “top,” “down,” and the like. Such terms are used, where applicable, to provide some clarity of description when dealing with relative relationships, particularly with respect to the illustrated embodiments. Such terms are not, however, intended to imply absolute relationships, positions, and/or orientations. For example, with respect to an object, an “upper” part can become a “lower” part simply by turning the object over. Nevertheless, it is still the same part and the object remains the same. As used herein, “and/or” means “and” or “or”, as well as “and” and “or”.
(60) In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims. I therefore claim as my invention all that comes within the scope of these claims.

Claims

1. A catheter assembly comprising: a shaft; and a connector assembly comprising a first connector portion and a second connector portion, wherein the first connector portion is fixedly coupled to a distal end of the shaft, and is rotatably coupled to the second connector portion by at least one radially extending pin retained within at least one slot on the second connector portion, wherein the at least one slot has an oversized circumferential dimension that allows limited rotation of the second connector portion relative to the first connector portion about a longitudinal axis of the shaft, wherein the at least one slot extends circumferentially along a sidewall of the second connector portion, and wherein the at least one radially extending pin retained within the at least one slot prevents axial separation of the first connector portion from the second connector portion when the second connector portion rotates relative to the first connector portion, wherein a sidewall of the first connector portion defines a proximal lumen and a distal lumen, wherein the proximal lumen of the first connector portion has a larger diameter than the distal lumen of the first connector portion.
2. The catheter assembly of claim 1, wherein the distal end of the shaft is a terminal end.
3. The catheter assembly of claim 1, wherein the first connector portion and the second connector portion are axially offset from one another.
4. The catheter assembly of claim 1, wherein a distal end portion of the shaft extends into the proximal lumen of the first connector portion.
5. The catheter assembly of claim 1, wherein the sidewall of the second connector portion defines a proximal lumen and a distal lumen, wherein the proximal lumen of the second connector portion has a larger diameter than the distal lumen of the second connector portion.
6. The catheter assembly of claim 5, wherein a distal end portion of the first connector portion extends into the proximal lumen of the second connector portion, wherein the proximal lumen of the second connector portion is oversized relative to the distal end portion of the first connector portion to allow limited tilting of the second connector portion with respect to the longitudinal axis of the shaft.
7. The catheter assembly of claim 1, wherein the at least one slot comprises first and second slots and the at least one pin comprises first and second pins disposed in the first and second slots, respectively, wherein the first slot is positioned opposite to the second slot with respect to the longitudinal axis.
8. The catheter assembly of claim 1, wherein the shaft is a first shaft, the catheter assembly further comprising a second shaft extending through the first shaft and the connector assembly, wherein a distal end portion of the second shaft defines a valve retaining portion, around which a prosthetic heart valve can be mounted in a radially compressed state.
9. The catheter assembly of claim 8, wherein the second connector portion comprises one or more attachment features configured to form a releasable connection with the prosthetic heart valve.
10. The catheter assembly of claim 9, wherein the one or more attachment features comprise a plurality of circumferentially spaced recesses formed over an outer surface of the second connector portion, wherein the plurality of recesses is configured to receive a plurality of retaining arms of the prosthetic heart valve.
11. The catheter assembly of claim 10, wherein the second connector portion comprises a flange having a larger diameter than a section of the second connector portion in which the recesses are formed, wherein the flange comprises a plurality of notches that are in communication with the recesses such that the retaining arms can extend through the notches.
12. The catheter assembly of claim 8, further comprising an outer sheath configured to extend over the connector assembly, the valve retaining portion and the prosthetic heart valve so as to retain the prosthetic heart valve in the radially compressed state within the sheath.
13. A catheter assembly comprising: a first shaft; a connector assembly comprising a first connector portion and a second connector portion, the first connector portion being fixedly coupled to a distal

end of the first shaft, the second connector portion being coupled to the first connector portion such that the second connector portion can rotate relative to the first connector portion about a longitudinal axis of the first shaft and can tilt with respect to the longitudinal axis of the first shaft; and a second shaft extending through the first shaft and the connector assembly; wherein the second connector portion comprises one or more attachment features configured to form a releasable attachment with a prosthetic heart valve mounted over a distal end portion of the second shaft that is located distal to the connector assembly, wherein a distal end portion of the first shaft extends into a lumen of the first connector portion.

14. The catheter assembly of claim 13, wherein the second connector portion is coupled to the first connector portion by at least one pin radially extending from the first connector portion and retained within at least one slot located on the second connector portion.

15. The catheter assembly of claim 14, wherein the at least one slot has an oversized circumferential dimension that allows limited rotation of the second connector portion relative to the first connector portion about the longitudinal axis of the first shaft.

16. The catheter assembly of claim 13, wherein the second connector portion is coupled to the first connector portion by at least one pin radially extending from the second connector portion and retained within at least one slot located on the first connector portion.

17. The catheter assembly of claim 16, wherein the at least one slot has an oversized circumferential dimension that allows limited rotation of the second connector portion relative to the first connector portion about the longitudinal axis of the first shaft.

18. The catheter assembly of claim 13, wherein a distal end portion of the first connector portion is inserted into an axial bore of a proximal end portion of the second connector portion.

19. A catheter assembly comprising: a shaft; and a connector assembly comprising a first connector portion and a second connector portion, wherein the first connector portion is fixedly coupled to a distal end of the shaft, and is rotatably coupled to the second connector portion by at least one radially extending pin retained within at least one slot on the second connector portion, wherein the at least one slot has an oversized circumferential dimension that allows limited rotation of the second connector portion relative to the first connector portion about a longitudinal axis of the shaft, wherein the at least one slot extends circumferentially along a sidewall of the second connector portion, and wherein the at least one radially extending pin retained within the at least one slot prevents axial separation of the first connector portion from the second connector portion when the second connector portion rotates relative to the first connector portion, wherein the shaft is a first shaft, the catheter assembly further comprising a second shaft extending through the first shaft and the connector assembly, wherein a distal end portion of the second shaft defines a valve retaining portion, around which a prosthetic heart valve can be mounted in a radially compressed state, wherein the second connector portion comprises one or more attachment features configured to form a releasable connection with the prosthetic heart valve.