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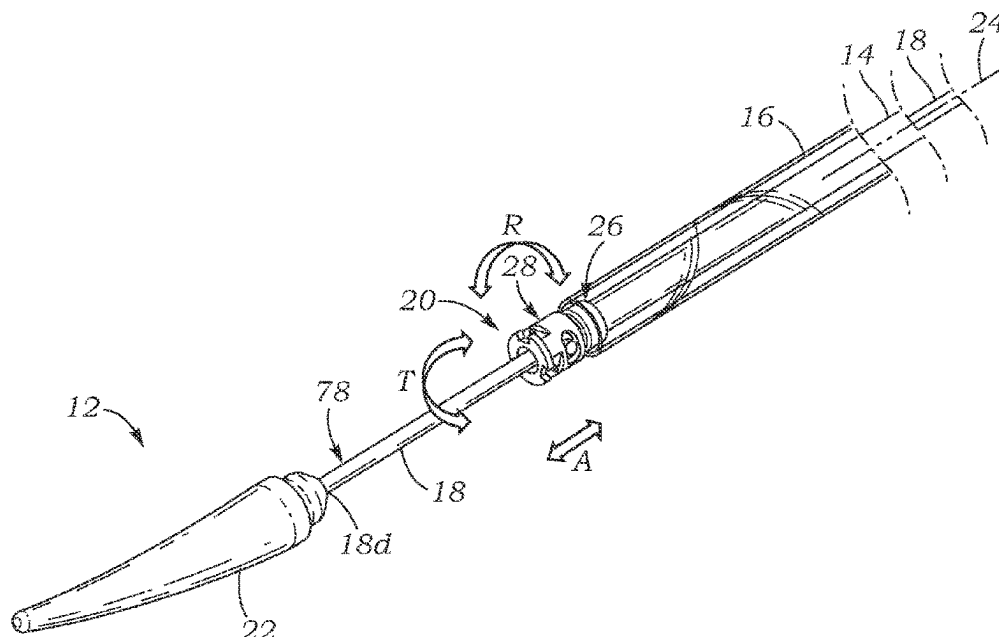
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ABSTRACT

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.

19 Claims, 6 Drawing Sheets

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See application file for complete search history.

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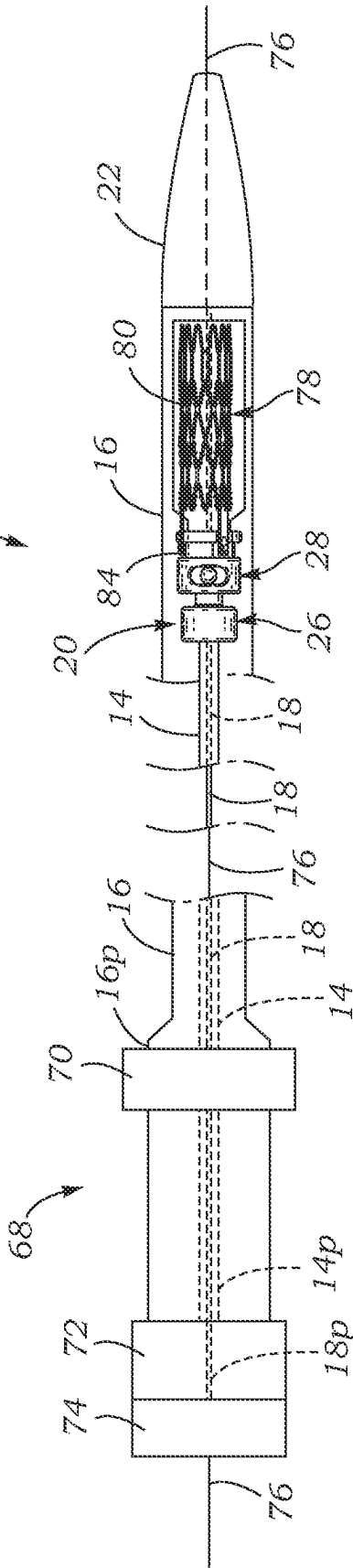
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Fig. 1



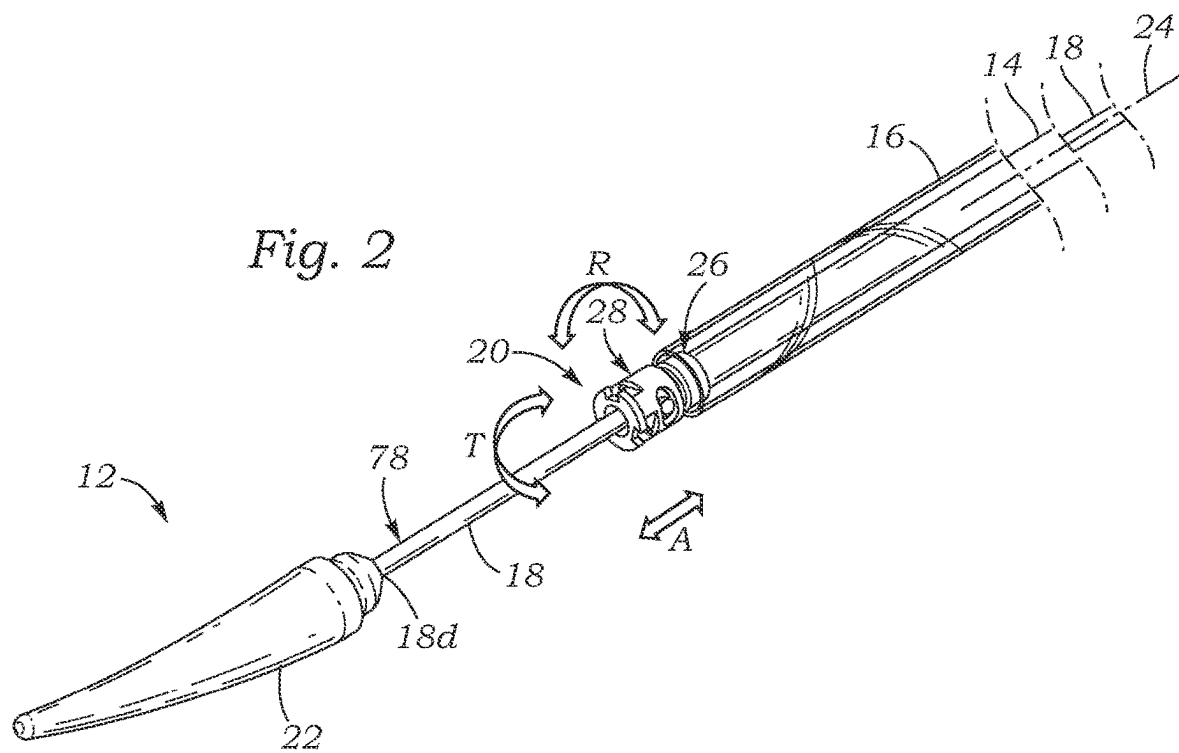


Fig. 3

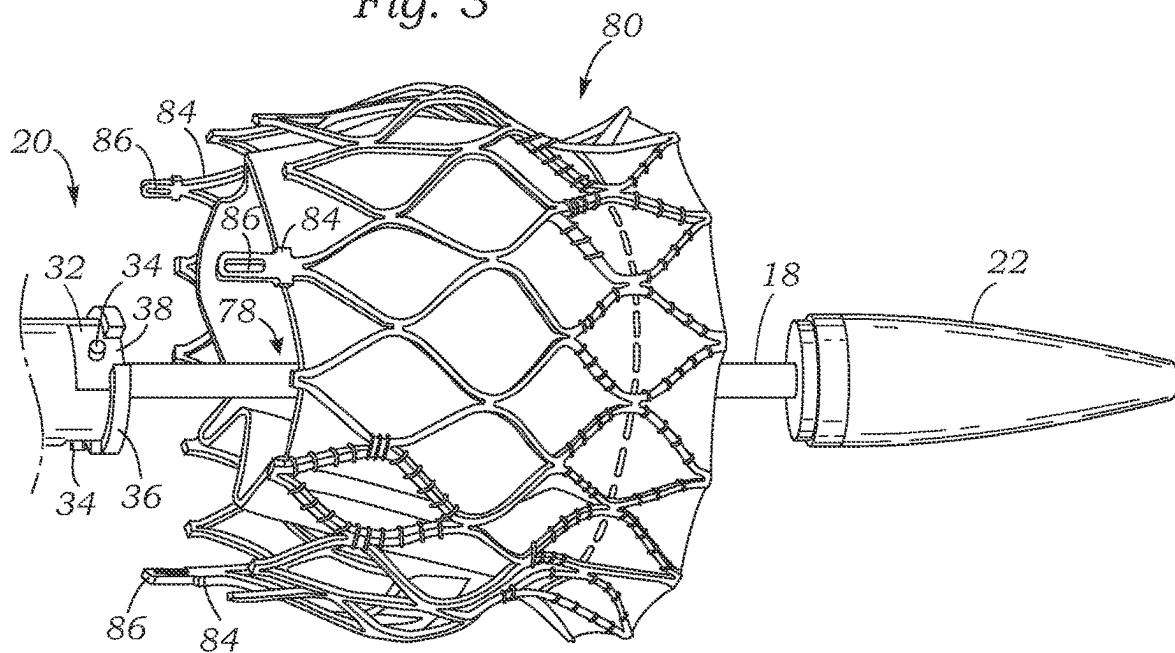


Fig. 4

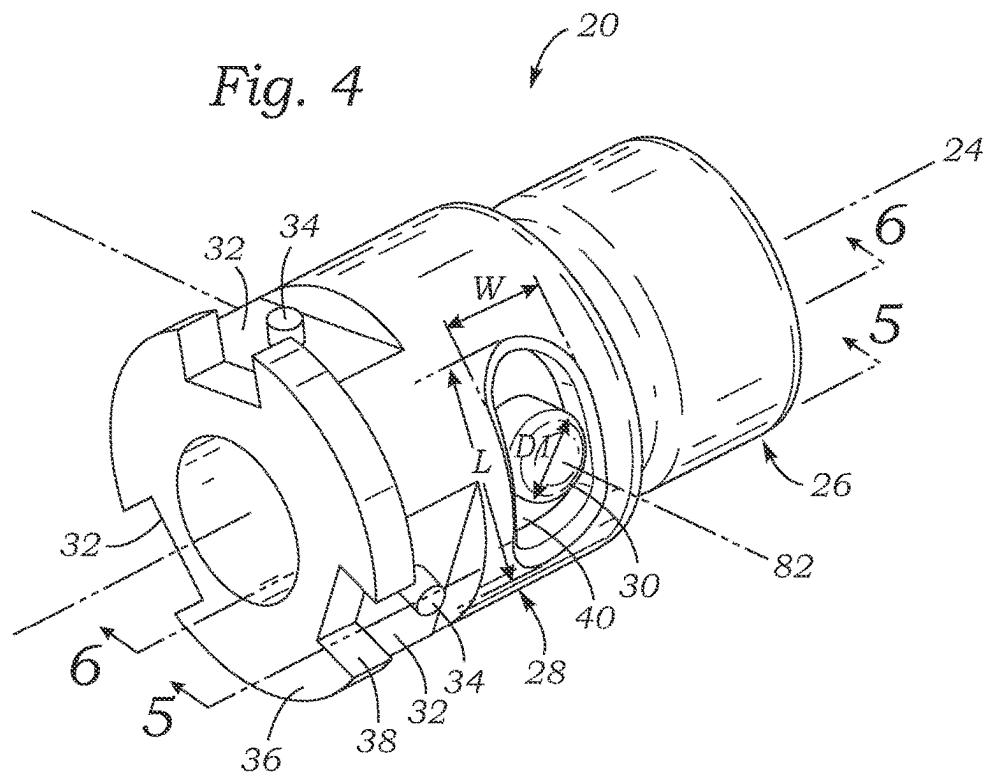


Fig. 5

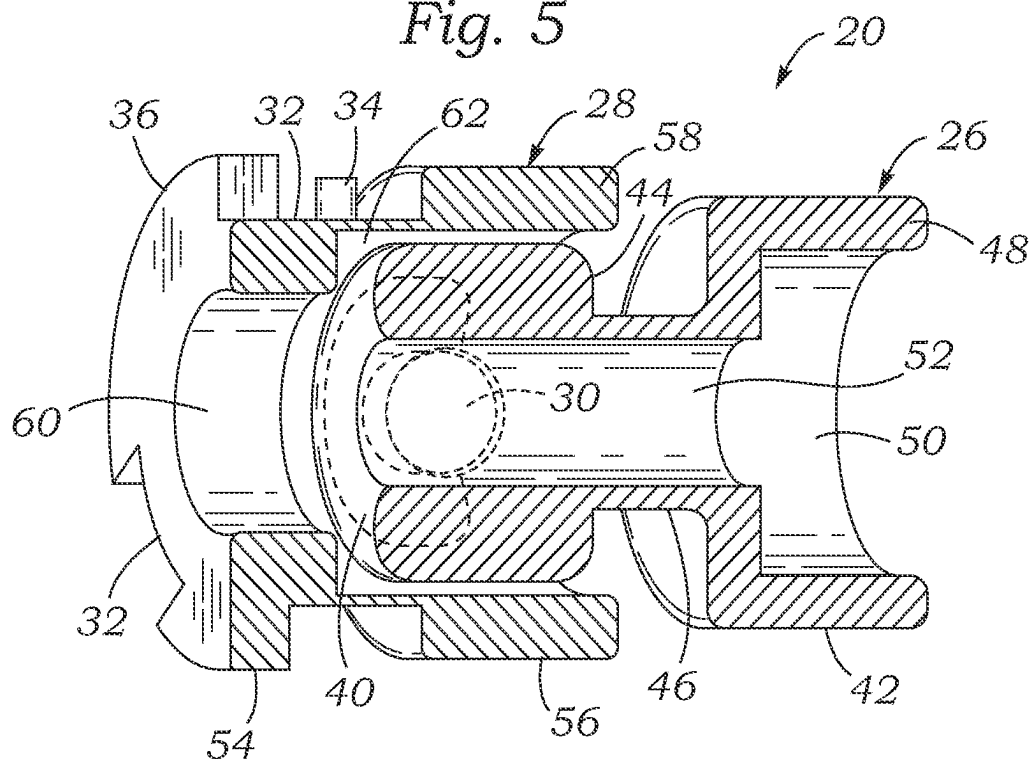
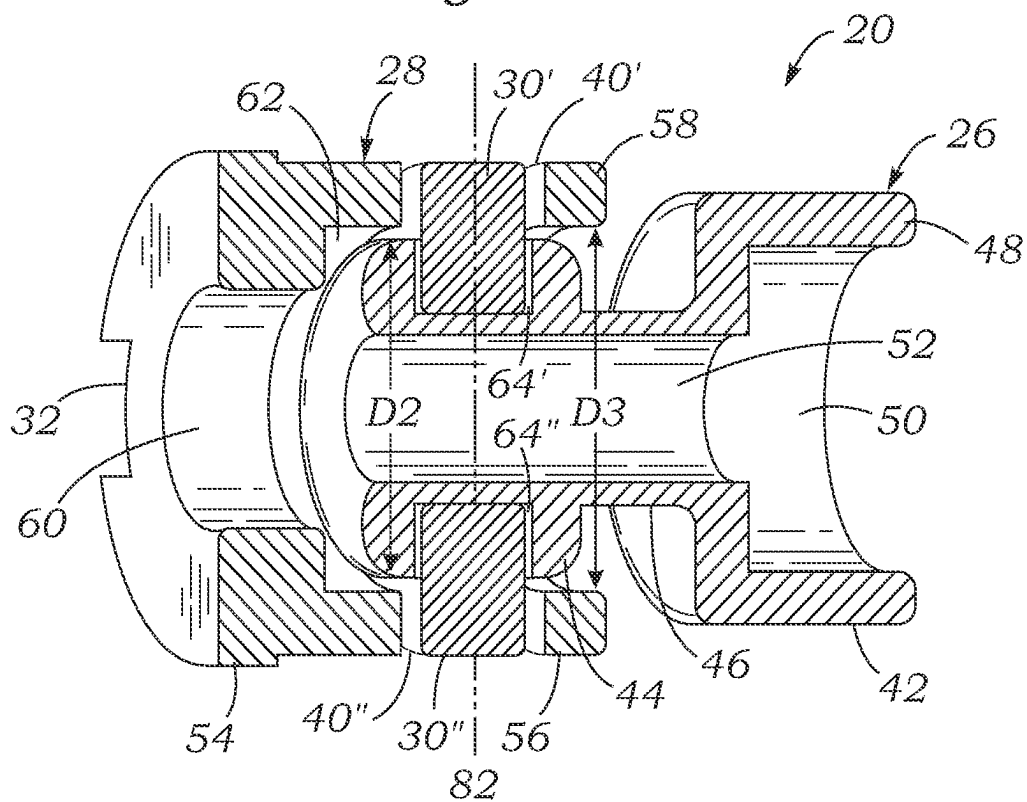
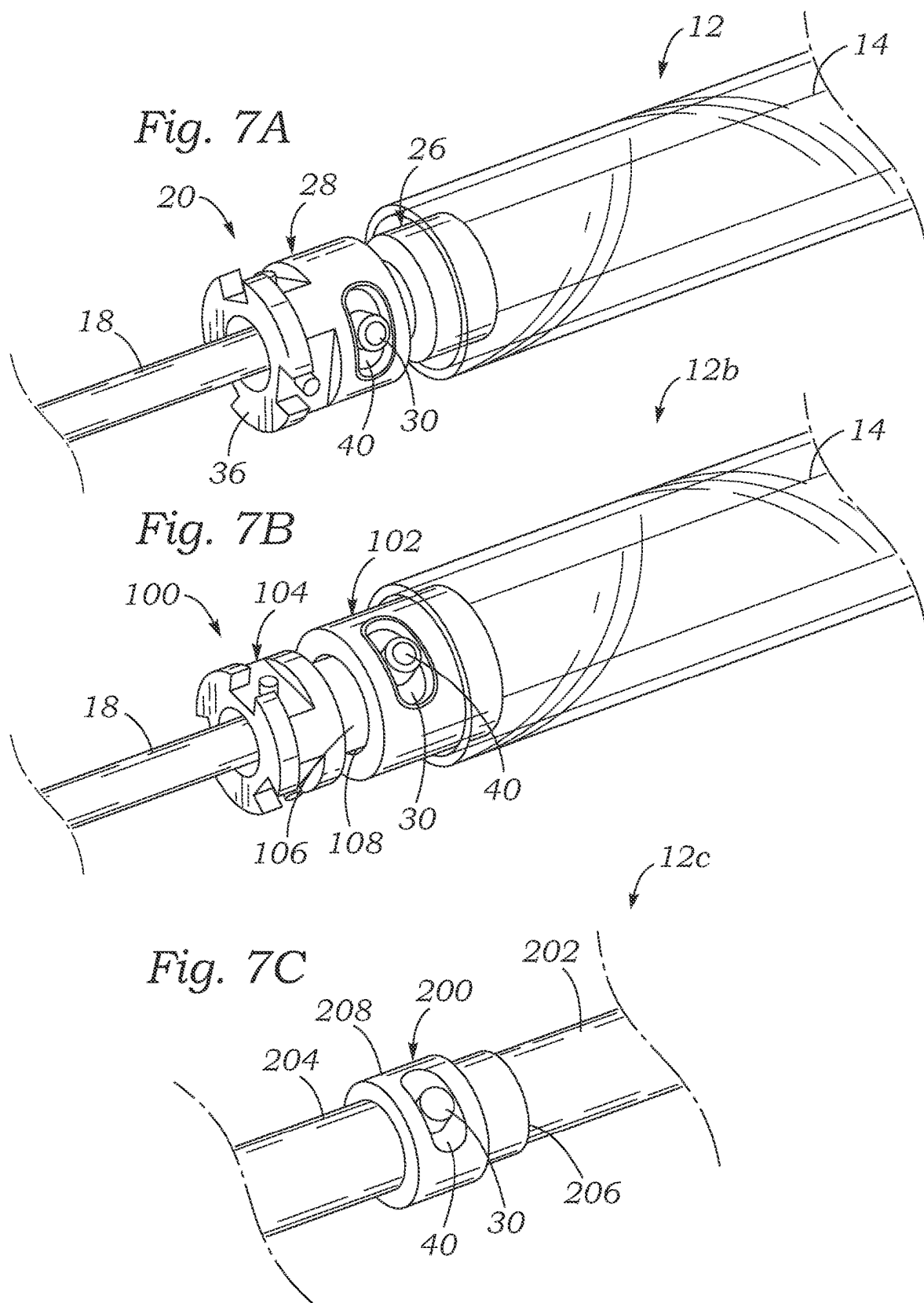
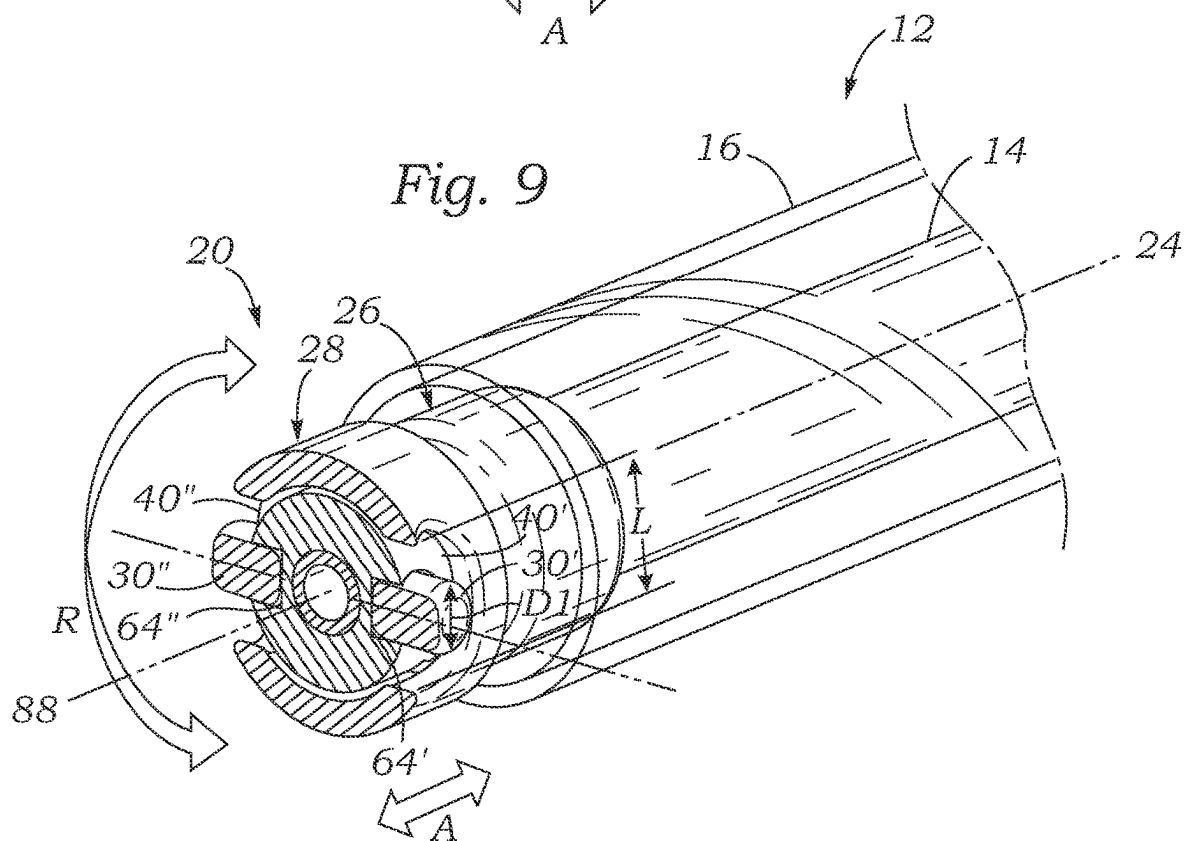
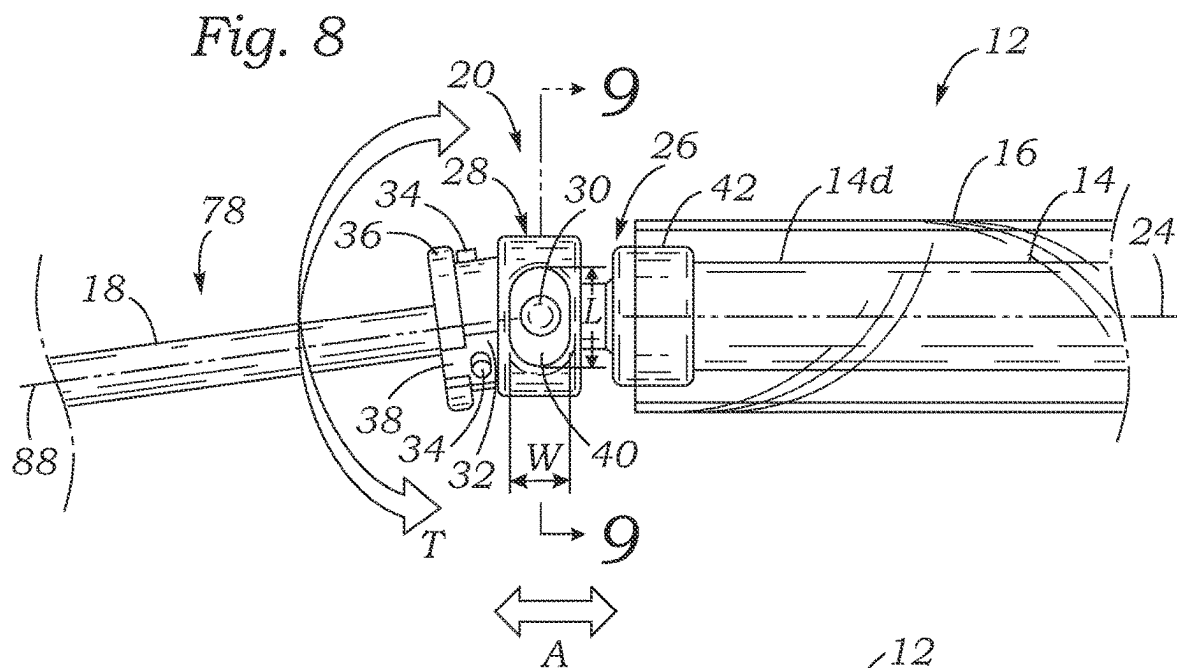


Fig. 6







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CATHETER ASSEMBLY**CROSS REFERENCE TO RELATED APPLICATION**

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

The present disclosure concerns embodiments of a catheter assembly, such as a delivery apparatus for implanting a prosthetic heart valve.

BACKGROUND

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.

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 rigidity 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

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.

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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.

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.

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.

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.

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

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.

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.

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.

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.

In the foregoing embodiments, the catheter assembly can further include another shaft having a proximal end connected to the second connector portion.

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

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of the implantable medical device are placed in engagement with the attachment features of the second connector portion.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

BRIEF DESCRIPTION OF THE DRAWINGS

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.

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FIG. 2 shows a top perspective view of a distal portion of the delivery apparatus depicted in FIG. 1.

FIG. 3 shows an expanded prosthetic heart valve along a distal portion of the catheter assembly of FIG. 1.

FIG. 4 shows a top perspective view of an exemplary connector assembly included in the delivery apparatus depicted in FIG. 2.

FIG. 5 shows a cross-sectional view of the connector assembly of FIG. 4 taken along line 3-3 of FIG. 4.

FIG. 6 shows another cross-sectional view of the connector assembly of FIG. 4 taken along line 4-4 of FIG. 4.

FIG. 7A shows an enlarged view of the connector assembly and its coupling with a shaft of the delivery apparatus.

FIG. 7B shows another embodiment of the connector assembly and its coupling with a shaft of the delivery apparatus.

FIG. 7C shows an alternative embodiment of the connector assembly and its coupling with a shaft of the delivery apparatus.

FIG. 8 shows a side elevation view of the connector assembly depicted in FIG. 2 and illustrates its tilting movement.

FIG. 9 shows a cross-sectional view of the connector assembly depicted in FIG. 2 and illustrates its rotational movement.

DETAILED DESCRIPTION

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.

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.

As an exemplary embodiment, FIG. 1 shows a catheter assembly 10 that includes a prosthetic heart valve 80

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mounted on a delivery apparatus 12. FIG. 2 shows a distal portion of the delivery apparatus 12, according to one exemplary embodiment.

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 18d 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.

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 14d 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.

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).

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.

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.

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

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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.

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.

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.

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 16p of the outer sheath 16 can be operatively coupled to a first knob 70, the proximal end 14p of the first shaft 14 can be operatively coupled to a second knob 72, and the proximal end 18p of the inner shaft 18 can be operatively coupled to a knob 74.

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.

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 14d 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.

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.

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.

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.

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 14d 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 14d 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.

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.

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.

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.

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.

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.

In the embodiments shown in FIGS. 4-6, the pins 30', 30" have a generally cylinder shape with a cross-sectional diameter D1. 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 D1. 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.

In some embodiments, the slot 40 can have an oversized circumferential dimension L (i.e., $L > D1$) 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.

In addition, the slot 40 can have an oversized width W (i.e., $W > D1$) 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.

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., $D3 > D2$ 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.

In addition, since the width W of the slots 40', 40" is greater than the dimension D1 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 D1 and the diameter D3 being oversized relative to the diameter D2, 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".

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).

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 complementarily 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.

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.

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.

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).

FIG. 7A 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.

FIG. 7B shows a connector assembly 100 incorporated in the delivery apparatus 12b, 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.

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.

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 28b, 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.

FIG. 7C shows a connector assembly 200 incorporated in a delivery apparatus 12c, 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.

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.

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.

In FIGS. 7A-7C, the pins extend radially outwardly and are retained in respective outer slots. For example, in FIG. 7A (and similarly in FIG. 7C), 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. 7B, 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.

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.

General Considerations

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.

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.

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.

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.

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”.

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

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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.

I claim:

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.

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entally 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

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within at least one slot on the second connector portion,
wherein the at least one slot has an oversized circum-
ferential dimension that allows limited rotation of the
second connector portion relative to the first connector
portion about a longitudinal axis of the shaft, 5
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 10
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 15
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 releas- 20
able connection with the prosthetic heart valve.

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