

Repositioning the prosthetic valve can be relatively more difficult in the expanded, functional state because the increased radial profile of the prosthetic valve can cause the prosthetic valve to engage the native anatomy (e.g., the native annulus) of the patient's heart, which can interfere or prevent the prosthetic valve from moving freely within the patient's heart. Retrieving the prosthetic valve can be relatively more difficult once the prosthetic valve is expanded because it can be difficult to exert sufficient radial force on the prosthetic valve to cause it to radially compress so that it can be retracted into a delivery cylinder.

[005] An additional challenge is that about fifty percent of self-expanding prosthetic valves require a balloon post-dilation procedure to expand the prosthetic valve to its nominal diameter and/or to reduce paravalvular leakage. This additional procedure can add undesirable steps and thus time to an implantation procedure.

[006] Thus, there is a continuing need for improved transcatheter prosthetic devices and delivery apparatuses for implanting such devices.

SUMMARY

[007] Embodiments of improved prosthetic implant delivery assemblies are disclosed herein, as well as related methods, apparatuses, and devices for such assemblies. In several embodiments, the disclosed assemblies are configured for delivering replacement heart valves into a heart of a patient. The disclosed assemblies, apparatuses, and methods can, for example, improve a physician's ability to control the expansion, repositioning, and/or retrieval of a prosthetic implant during an implantation procedure.

[008] In one representative embodiment, a prosthetic heart valve delivery assembly comprises an annular stent having a first plurality of apices spaced circumferentially around a first end portion of the stent, a second plurality of apices spaced circumferentially around a second end portion of the stent, and an intermediate portion disposed between the first and the second end portions, wherein the stent is configured to radially expand and axially foreshorten from a first state to a second state and to radially compress and axially elongate from the second state to the first state, an elongate shaft disposed radially within and extending axially through the stent and having a first manifold coupled to the shaft

distal to the first end of the stent, wherein the first manifold has a first plurality of openings, a second manifold located proximal to the first manifold of the shaft, wherein the second manifold has a second plurality of openings, a first plurality of sutures extending through at least some of the second plurality of openings of the second manifold, through the first plurality of openings of the first manifold, and through or around the first plurality of apices of the stent, wherein the first plurality of sutures is releasably coupled to the stent and configured such that increasing tension of the first plurality of sutures causes the first plurality of apices of the stent to radially converge, and a second plurality of sutures extending through at least some second plurality of openings of the second manifold and through or around the second plurality of apices of the stent, wherein the second plurality of sutures is releasably coupled to the stent and configured such that increasing tension of the second plurality of sutures causes the second plurality of apices of the stent to radially converge, wherein the intermediate portion of the stent can radially expand and axially foreshorten when the first and the second pluralities of apices radially converge.

[009] In some embodiments, a sheath which can be advanced distally over the stent to retain the stent in the first state and retracted proximally relative to the stent to permit radial expansion of the stent from the first state to the second state, wherein after the entirety of the stent is deployed from the sheath, the first and the second pluralities of apices of the stent can be radially converged, and the sheath can be advanced distally back over the stent to cause the stent to radially collapse to the first state as it is recaptured by the sheath.

[010] In some embodiments, the first and the second pluralities of sutures are configured to be independently movable relative to each other. In some embodiments, the second plurality of openings of the second manifold is an inner set of openings and an outer set of openings, the inner set of openings being spaced radially inward from the outer set of openings, and wherein the first plurality of sutures extend through the inner set of openings of the second manifold, and the second plurality of sutures extend through the outer set of openings of the second manifold.

[011] In some embodiments, the shaft is a first shaft, and the delivery assembly further comprises a second shaft to which the second manifold is coupled. In some

embodiments, the first shaft is a nose cone shaft which extends coaxially through the second shaft, and a nose cone is mounted on a distal end of the nose cone shaft. In some embodiments, the first manifold and the second manifold are configured to be axially movable relative to each other.

[012] In some embodiments, the delivery assembly is configured such that increasing a spacing between the first manifold and the second manifold causes the intermediate portion of the stent to axially elongate and to radially compress. In some embodiments, the delivery assembly is configured such that decreasing the spacing between the first manifold and the second manifold causes the intermediate portion of the stent to axially foreshorten and to radially expand. In some embodiments, the stent is configured to be self-expandable from the first state to the second state. In some embodiments, the delivery assembly further comprises at least one apex guide mounted on a suture of the first plurality of sutures or the second plurality of sutures.

[013] In another representative embodiment, a delivery apparatus for a prosthetic heart valve comprises a sheath, an elongate first shaft, a first manifold coupled to the first shaft, wherein the first manifold has a first plurality of openings, an elongate second shaft, and a second manifold coupled to the second shaft, wherein the second manifold has a second plurality of openings, wherein the first shaft extends coaxially through the second shaft and the second manifold, and the first manifold is disposed distal to the second manifold, and wherein the first manifold and the second manifold are configured to be axially movable relative to each other, wherein the first and the second manifolds are disposed radially within the sheath when delivering the prosthetic heart valve to an implantation location and wherein the first and second manifolds are exposed from the sheath when implanting the prosthetic heart valve at the implantation location.

[014] In some embodiments, the first shaft is a nose cone shaft.

[015] A method for delivering a prosthetic valve to a native annulus of a heart is disclosed. The method can comprise inserting an elongate delivery apparatus into a patient's body, advancing the delivery apparatus to an implantation location within the native annulus, retracting a delivery sheath of the

delivery apparatus relative to the prosthetic valve to expose the prosthetic valve from a distal end of the delivery sheath, and after the prosthetic valve is exposed from the delivery sheath, expanding the prosthetic valve from a radially compressed state to a radially expanded state by reducing axial tension on first and second ends of the prosthetic valve.

[016] In some embodiments, reducing axial tension on the first end of the prosthetic valve precedes reducing tension on the second end of the prosthetic valve. In some embodiments, reducing axial tension on the first end of the prosthetic valve and reducing tension on the second end of the prosthetic valve occur simultaneously.

[017] In some embodiments, reducing axial tension on the first and second ends of the prosthetic valve comprises reducing tension on a plurality of sutures of the delivery apparatus. In some embodiments, reducing axial tension on the first and second ends of the prosthetic valve comprises moving a first manifold of the delivery apparatus axially proximally toward a second manifold of the delivery apparatus.

[018] In some embodiments, the radially expanded state of the prosthetic valve is a first radially expanded state, and the method can further comprise expanding the prosthetic valve from the first radially expanded state to a second radially expanded state by radially converging the first and second ends of the prosthetic valve and axially compressing the first and second ends of the prosthetic valve by moving the first manifold of the delivery apparatus axially proximally toward the second manifold of the delivery apparatus, wherein the stent is radially larger in the second radially expanded state than in the first radially expanded state. In some embodiments, the method can further comprise radially compressing the prosthetic valve by moving the first manifold of the delivery apparatus axially distally away from the second manifold of the delivery apparatus.

[019] There is also disclosed a delivery assembly comprising an annular frame and a delivery apparatus. The annular frame includes a first plurality of apices spaced circumferentially around a first end portion of the frame, a second plurality of apices spaced circumferentially around a second end portion of the frame, and an

What is claimed is

1. A prosthetic heart valve delivery assembly, comprising:

an annular stent having a first plurality of apices spaced circumferentially around a first end portion of the stent, a second plurality of apices spaced circumferentially around a second end portion of the stent, and an intermediate portion disposed between the first and the second end portions, wherein the stent is configured to radially expand and axially foreshorten from a first state to a second state and to radially compress and axially elongate from the second state to the first state;

an elongate shaft disposed radially within and extending axially through the stent and having a first manifold coupled to the shaft distal to the first end of the stent, wherein the first manifold has a first plurality of openings;

a second manifold located proximal to the first manifold of the shaft, wherein the second manifold has a second plurality of openings;

a first plurality of sutures extending through at least some of the second plurality of openings of the second manifold, through the first plurality of openings of the first manifold, and through or around the first plurality of apices of the stent, wherein the first plurality of sutures is releasably coupled to the stent and configured such that increasing tension of the first plurality of sutures causes the first plurality of apices of the stent to radially converge; and

a second plurality of sutures extending through at least some second plurality of openings of the second manifold and through or around the second plurality of apices of the stent, wherein the second plurality of sutures is releasably coupled to the stent and configured such that increasing tension of the second plurality of sutures causes the second plurality of apices of the stent to radially converge,

wherein the intermediate portion of the stent can radially expand and axially foreshorten when the first and the second pluralities of apices radially converge.

2. The delivery assembly of claim 1 further comprising, a sheath which can be advanced distally over the stent to retain the stent in the first state and retracted proximally relative to the stent to permit radial expansion of the stent from the first state

to the second state, wherein after the entirety of the stent is deployed from the sheath, the first and the second pluralities of apices of the stent can be radially converged, and the sheath can be advanced distally back over the stent to cause the stent to radially collapse to the first state as it is recaptured by the sheath.

3. The delivery assembly of claim 1 or claim 2, wherein the first and the second pluralities of sutures are configured to be independently movable relative to each other.

4. The delivery assembly of any previous claim, wherein the second plurality of openings of the second manifold is an inner set of openings and an outer set of openings, the inner set of openings being spaced radially inward from the outer set of openings, and wherein the first plurality of sutures extend through the inner set of openings of the second manifold, and the second plurality of sutures extend through the outer set of openings of the second manifold.

5. The delivery assembly of any previous claim, wherein the shaft is a first shaft, and the delivery assembly further comprises a second shaft to which the second manifold is coupled.

6. The delivery assembly of claim 5, wherein the first shaft is a nose cone shaft which extends coaxially through the second shaft, and a nose cone is mounted on a distal end of the nose cone shaft.

7. The delivery assembly of any previous claim, wherein the first manifold and the second manifold are configured to be axially movable relative to each other.

8. The delivery assembly of claim 7, wherein the delivery assembly is configured such that increasing a spacing between the first manifold and the second

manifold causes the intermediate portion of the stent to axially elongate and to radially compress.

9. The delivery assembly of claim 8, wherein the delivery assembly is configured such that decreasing the spacing between the first manifold and the second manifold causes the intermediate portion of the stent to axially foreshorten and to radially expand.

10. The delivery assembly of any previous claim, wherein the stent is configured to be self-expandable from the first state to the second state.

11. The delivery assembly of any previous claim, further comprising at least one apex guide mounted on a suture of the first plurality of sutures or the second plurality of sutures.

12. A delivery apparatus for a prosthetic heart valve comprising:
a sheath;
an elongate first shaft;
a first manifold coupled to the first shaft, wherein the first manifold has a first plurality of openings;
an elongate second shaft; and
a second manifold coupled to the second shaft, wherein the second manifold has a second plurality of openings;
wherein the first shaft extends coaxially through the second shaft and the second manifold, and the first manifold is disposed distal to the second manifold, and
wherein the first manifold and the second manifold are configured to be axially movable relative to each other;
wherein the first and the second manifolds are disposed radially within the sheath when delivering the prosthetic heart valve to an implantation location; and

wherein the first and second manifolds are exposed from the sheath when implanting the prosthetic heart valve at the implantation location.

13. The delivery apparatus of claim 12, wherein the first shaft is a nose cone shaft.

14. The delivery apparatus of claim 12 or claim 13, wherein the first and second manifolds are suture guides.