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Transcatheter Prosthetic Heart Valve Delivery Device With Partial Deployment and Release Features and Methods

Abstract

A delivery device for percutaneously deploying a stented prosthetic heart valve, including a delivery sheath, an inner shaft, and a spindle. The inner shaft is slidably disposed within a lumen of the delivery sheath. The spindle is attached to the shaft and includes a hub defining at least one longitudinal slot sized to slidably receive a post of the stented valve. An outer surface of the hub forms a curved proximal segment. The device provides a loaded state in which the delivery sheath retains the stented valve over the inner shaft and coupled to the spindle via the slot. In a deployed state, the distal end of the delivery sheath is withdrawn from the prosthesis to permit the stented valve to release from the slot, sliding along the curved outer surface of the hub.

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1. A delivery device for percutaneously deploying a stented prosthetic heart valve including a stent frame to which a valve structure is attached, the device comprising: a delivery sheath assembly terminating at a distal end and defining a lumen; an inner shaft slidably disposed within the lumen; and a spindle attached to the shaft, the spindle including: a tubular base, a hub projecting radially outwardly relative to the base, wherein: the hub defines at least one longitudinal slot sized to slidably receive a corresponding post of a prosthetic heart valve stent frame, an outer surface of the hub forms a proximal segment and a distal segment, the proximal segment being curved in extension toward the distal segment; wherein the device is configured to provide a loaded state in which the delivery sheath assembly retains a stented prosthetic heart valve over the inner shaft and coupled to the spindle via the at least one slot, and a deployment state in which the distal end of the delivery sheath assembly is withdrawn from the prosthetic heart valve to permit the prosthetic heart valve to release from the at least one longitudinal slot.

2. The delivery device of claim 1, wherein the at least one longitudinal slot includes a plurality of circumferentially spaced longitudinal slots formed in the hub.

3. The delivery device of claim 2, wherein the plurality of longitudinal slots are equidistantly spaced from one another about a circumference of the hub.

4. The delivery device of claim 1, wherein the proximal segment defines a proximal face of the hub and the distal segment defines a distal face of the hub, and further wherein the at least one longitudinal slot is open at the proximal and distal faces.

5. The delivery device of claim 4, wherein the at least one longitudinal slot is defined by opposing side walls and a floor, and further wherein the tubular base includes a ring immediately proximal the hub, the ring having a surface aligned with the floor.

6. The delivery device of claim 5, wherein the spindle further includes a flange projecting radially outwardly relative to the base and proximally spaced from the hub by the ring.

7. The delivery device of claim 6, wherein an outer diameter of the flange approximates a maximum outer diameter of the hub.

8. The delivery device of claim 1, wherein the outer surface defines a convex curve in longitudinal extension along the proximal segment.

9. The delivery device of claim 1, wherein the outer surface, as collectively defined by the proximal and distal segments, approximates a semi-circle in longitudinal extension.

10. The delivery device of claim 1, further comprising: a release sheath assembly disposed between the delivery sheath assembly and the spindle in the loaded state, the release sheath assembly including a release sheath slidably received over at least the proximal segment of the hub in the loaded state.

11. The delivery device of claim 10, wherein the release sheath assembly is configured to proximally retract the release sheath relative to the hub with proximal retraction of the delivery sheath distal end from the release sheath.

12. The delivery device of claim 10, wherein the release sheath forms at least one longitudinal notch extending from a distal end of the release sheath, and further wherein upon final assembly in the loaded state, the at least one notch is longitudinally aligned with the at least one slot.

13. The delivery device of claim 12, wherein the at least one longitudinal slot includes a plurality of circumferentially spaced longitudinal slots, and the at least one notch includes a plurality of circumferentially spaced notches, and further wherein each of the slots is longitudinally aligned with a respective one of the notches.

14. The delivery device of claim 13, wherein the spindle further forms a circumferential trough between the hub and a flange formed proximal the hub, and further wherein the release sheath includes a plurality of fingers spaced from one another by the plurality of notches, and further wherein the loaded state includes the fingers extending across the circumferential trough.

15. A system for repairing a defective heart valve of a patient, the system comprising: a prosthetic heart valve having a stent frame and a valve structure attached to the stent frame, the stent frame defining a distal region and a proximal region, the proximal region forming at least one post; and a delivery device comprising: a delivery sheath assembly terminating at a distal end and defining a lumen, an inner shaft slidably disposed within the lumen, a spindle attached to the inner shaft, the spindle including: a tubular base, a hub projecting radially outwardly relative to the base and defining at least one longitudinal slot sized to slidably receive the at least one post, wherein the outer surface of the hub forms a proximal segment and a distal segment, the proximal segment being curved in extension toward the distal segment; wherein the system is configured to provide a loaded condition in which the prosthetic heart valve is retained between the delivery sheath assembly and the inner shaft, including the at least one post slidably captured within the at least one longitudinal slot.

16. The system of claim 15, wherein the at least one longitudinal slot includes a plurality of circumferentially spaced longitudinal slots, and further wherein the at least one post includes a plurality of posts corresponding with the plurality of longitudinal slots.

17. The system of claim 15, wherein the spindle further includes a flange projecting radially outwardly relative to the base and proximally spaced from the hub to define a circumferential trough.

18. The system of claim 17, wherein the at least one post includes a proximal shoulder and a distal head, the shoulder sized to slidably nest within the longitudinal slot and the head sized to slidably nest within the trough.

19. The system of claim 18, wherein a circumferential width of the head is larger than a circumferential width of the shoulder.

20. The system of claim 19, wherein the shoulder and the head collectively define a T-like shape.

21. The system of claim 15, wherein the system is further configured to provide a deployment condition in which the distal end of the delivery sheath assembly is proximal the hub to permit the post to release from the slot, including a head of the post sliding along the curved proximal segment of the hub outer surface.

22. The system of claim 21, wherein the stent frame is configured to radially self-expand from a compressed arrangement to a normal arrangement, and further wherein the loaded condition that includes the delivery sheath assembly compressively retaining the prosthetic heart valve in the compressed arrangement.

23. The system of claim 22, wherein the deployment condition includes the stent frame self-expanding to the normal arrangement.

24. The system of claim 15, wherein the delivery device further includes: a release sheath assembly disposed between the delivery sheath assembly and the spindle in the loaded state, the release sheath assembly including a release sheath slidably received over at least the proximal segment of the hub in the loaded state.

25. The system of claim 24, wherein the release sheath forms at least one longitudinal notch extending from a distal end of the release sheath, and further wherein upon final assembly in the loaded condition, the at least one notch is longitudinally aligned with the at least one slot.

26. The system of claim 25, wherein the system is further configured to provide a deployment condition includes the release sheath proximally retracted from the hub and the at least one post self-pivoting through the at least one slot and the at least one notch.

27. The system of claim 26, wherein the at least one post includes a distal shoulder and a proximal head, and further wherein the spindle forms a circumferential trough proximal the hub such that the loaded condition includes the shoulder disposed within the slot and the head disposed within the trough, the head being releasably captured within the trough by the release sheath.

28. A method of percutaneously deploying a stented prosthetic heart valve to an implantation site of a patient, the method comprising: receiving a delivery device loaded with a radially expandable prosthetic heart valve having a stent frame to which a valve structure is attached, the delivery device including a delivery sheath assembly containing the prosthetic heart valve in a compressed arrangement over an inner shaft in a loaded state of the device, and a spindle attached to the shaft, the spindle including: a tubular base, a hub projecting radially outwardly relative to the base and defining at least one longitudinal slot and an outer surface forming a proximal segment and a distal segment, the proximal segment being curved in extension toward the distal segment, wherein a post of the stent frame is slidably captured within the at least one slot in the loaded state; delivering the prosthetic heart valve in the compressed arrangement through a bodily lumen of the patient and to the implantation site via the delivery device in the loaded state; proximally retracting the delivery sheath assembly from the prosthetic heart valve; and permitting the post to release from the at least one slot, including a surface of the post sliding along the curved proximal segment of the hub outer surface such that the prosthetic heart valve deploys from the delivery device.

29. The method of claim 28, wherein the at least one longitudinal slot includes a plurality of circumferentially spaced longitudinal slots, and further wherein the at least one post includes a plurality of posts corresponding with the plurality of longitudinal slots.

30. The method of claim 28, wherein the stent frame is configured to radially self-expand from a compressed arrangement to a normal arrangement, and further wherein the loaded state includes the delivery sheath assembly compressively retaining the prosthetic heart valve in the compressed arrangement.

31. The method of claim 28, wherein the delivery device further includes: a release sheath assembly disposed between the delivery sheath assembly and the spindle in the loaded state, the release sheath assembly including a release sheath slidably received over at least the proximal segment of the hub.

32. The method of claim 31, wherein the release sheath forms at least one longitudinal notch extending from a distal end of the release sheath, and further wherein permitting the post to release from the at least one slot includes the post pivoting relative to the spindle such that a portion of the post moves through the at least one slot and a corresponding one of the at least one notch.

BACKGROUND

[0001] The present disclosure relates to systems, devices, and methods for percutaneous implantation of a prosthetic heart valve. More particularly, it relates to delivery systems, devices, and methods for transcatheter implantation of a stented prosthetic heart valve.

[0002] Diseased or otherwise deficient heart valves can be repaired or replaced with an implanted prosthetic heart valve. Conventionally, heart valve replacement surgery is an open-heart procedure conducted under general anesthesia, during which the heart is stopped and blood flow is controlled by a heart-lung bypass machine. Traditional open surgery inflicts significant patient trauma and discomfort, and exposes the patient to a number of potential risks, such as infection, stroke, renal failure, and adverse effects associated with the use of the heart-lung bypass machine, for example.

[0003] Due to the drawbacks of open-heart surgical procedures, there has been an increased interest in minimally invasive and percutaneous replacement of cardiac valves. With percutaneous transcatheter (or transluminal) techniques, a valve prosthesis is compacted for delivery in a catheter and then advanced, for example, through an opening in the femoral artery and through the descending aorta to the heart, where the prosthesis is then deployed in the annulus of the valve to be repaired (e.g., the aortic valve annulus). Although transcatheter techniques have attained widespread acceptance with respect to the delivery of conventional stents to restore vessel patency, only mixed results have been realized with percutaneous delivery of the more complex prosthetic heart valve.

[0004] Various types and configurations of prosthetic heart valves are available for percutaneous valve replacement procedures, and continue to be refined. The actual shape and configuration of any particular transcatheter prosthetic heart valve is dependent to some extent upon the native shape and size of the valve being repaired (i.e., mitral valve, tricuspid valve, aortic valve, or pulmonary valve). In general, prosthetic heart valve designs attempt to replicate the functions of the valve being replaced and thus will include valve leaflet-like structures. With a bioprostheses construction, the replacement valve may include a valved vein segment that is mounted in some manner within an expandable stent frame to make a valved stent (or "stented prosthetic heart valve"). For many percutaneous delivery and implantation devices, the stent frame of the valved stent is made of a self-expanding material and construction. With these devices, the valved stent is crimped down to a desired size and held in that compressed arrangement within an outer delivery sheath, for example. Retracting the sheath from the valved stent allows the stent to self-expand to a larger diameter, such as when the valved stent is in a desired position within a patient. In other percutaneous implantation devices, the valved stent can be initially provided in an expanded or uncrimped condition, then crimped or compressed on a balloon portion of catheter until it is as close to the diameter of the catheter as possible. The so-loaded balloon catheter is slidably disposed within an outer delivery sheath. Once delivered to the implantation site, the balloon is inflated to deploy the prosthesis. With either of these types of percutaneous stented prosthetic valve delivery devices, conventional sewing of the prosthetic heart valve to the patient's native tissue is typically not necessary.

[0005] It is imperative that the stented prosthetic heart valve be accurately located relative to the native annulus immediately prior to full deployment from the catheter as successful implantation requires the prosthetic heart valve intimately lodge and seal against the native annulus. If the prosthesis is incorrectly positioned relative to the native annulus, serious complications can result as the deployed device can leak and may even dislodge from the native valve implantation site. As a point of reference, this same concern does

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