

SUMMARY

[010] Described herein are embodiments of prosthetic devices that are primarily intended to be implanted at one of the mitral, aortic, tricuspid, or pulmonary valve regions of a human heart, as well as apparatuses and methods for implanting the same. The prosthetic devices can be used to help restore and/or replace the functionality of a defective native valve.

[010a] An aspect of the disclosure provides a clasp control mechanism for a delivery apparatus of an implantable prosthetic device; wherein the clasp control mechanism is releasably coupleable to clasp control members of the implantable prosthetic device; the clasp control members being releasably coupled to clasps of the prosthetic device; wherein the clasp control mechanism is configured such that the clasp control members can be actuated either simultaneously or separately; and wherein actuating the clasp control members moves the clasps of the prosthetic device between an open configuration and a closed configuration.

[010b] Another aspect of the disclosure provides a handle for a delivery apparatus, the handle comprising a housing; an actuation control mechanism; a clasp control mechanism; and a flushing mechanism; wherein the clasp control mechanism is releasably coupleable to clasp control members, the clasp control members being releasably coupled to clasps of an implantable prosthetic device; wherein actuating the clasp control members moves the clasps between an open configuration and a closed configuration; and wherein the clasp control mechanism is configured such that the clasp control members can be actuated either simultaneously or separately.

[010c] Another aspect of the disclosure provides a delivery system comprising an elongate shaft having a proximal portion and a distal portion; a handle connected to the proximal portion of the elongate shaft; a first clasp control member that extends into the distal portion of the elongate shaft, through at least a portion of the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle; a second clasp control member that extends into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle; an actuator coupled to the handle, the actuator comprising a first side portion connected to the first clasp control; and a second side portion connected to the second clasp control; wherein the

first side portion and the second side portion are releasably couplable such that when the first side portion and the second side portion are coupled, proximal movement of the actuator proximally pulls both the first clasp control member and the second clasp control member, and such that when the first side portion and the second side portion are uncoupled, individual proximal movements of the first side portion and the second side portion independently pull the first clasp control member and the second clasp control member, respectively.

[010d] Another aspect of the disclosure provides a delivery assembly comprising a first clasp that is moveable between an open position and a closed position, wherein the first clasp is configured to be securable to a first native valve leaflet by moving the first clasp from the open position to the closed position of the first clasp; a first clasp control member coupled to the first clasp, wherein applying tension to the first clasp control member moves the first clasp to the open position; a second clasp that is moveable between an open position and a closed position, wherein the second clasp is configured to secure a second native valve leaflet by moving the second clasp from the open position to the closed position of the second clasp; a second clasp control member coupled to the second clasp, wherein applying tension to the second clasp control member moves the second clasp to the open position; an elongate shaft having a proximal portion and a distal portion; a handle connected to the proximal portion of the elongate shaft; wherein the first clasp control member extends from the first clasp, into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle; wherein the second clasp control member extends from the second clasp, into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle; an actuator coupled to the handle, the actuator comprising a first side portion connected to the first clasp control member; and a second side portion connected to the second clasp control member; wherein the first side portion and the second side portion are releasably couplable such that when the first side portion and the second side portion are coupled, proximal movement of the actuator proximally tensions both the first clasp control member and the second clasp control member to move both the first and second clasps to the open position, and such that when the first side portion and the second side portions are uncoupled, individual proximal movements of the first side portion and the second side portion individually tension the

first clasp control member and the second clasp control member to independently open the first and second clasps, respectively.

[010e] Another aspect of the disclosure provides a delivery assembly comprising a pair of anchors that are moveable between an open position and a closed position; an anchor actuation shaft operably coupled to the pair of anchors; a first clasp that is moveable between an open position and a closed position; a first clasp control member coupled to the first clasp configured such that applying tension to the first clasp control member moves the first clasp to the open position; a second clasp that is moveable between an open position and a closed position, a second clasp control member coupled to the second clasp configured such that applying tension to the second clasp control member moves the second clasp to the open position; an elongate shaft having a proximal portion and a distal portion; a handle connected to the proximal portion of the elongate shaft; wherein the anchor actuation shaft extends into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and into the handle; wherein axial movement of the anchor actuation shaft relative to the elongate shaft moves the pair of anchors between the open position and the closed position; wherein the first clasp control member extends from the first clasp, into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle; wherein the second clasp control member extends from the second clasp, into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle; an actuator coupled to the handle, the actuator comprising a first side portion connected to the first clasp control member; and a second side portion connected to the second clasp control member; wherein the first side portion and the second side portion are releasably couplable such that when the first side portion and the second side portion are coupled, proximal movement of the actuator proximally tensions both the first clasp control member and the second clasp control member to move both the first and second clasps to the open position, and such that when the first side portion and the second side portions are uncoupled, individual proximal movements of the first side portion and the second side portion individually tension the first clasp control member and the second clasp control member to independently open the first and second clasps, respectively.

[011] An implantable prosthetic device can include a spacer member, a plurality of anchors, and a plurality of clasps. The spacer member can be configured to be disposed between native leaflets of a heart. The anchors can be coupled to the spacer member and configured to secure the native leaflets against the spacer member. The clasps can be coupled to a respective anchor and configured to secure the native leaflets to the anchors. The clasps can be independently movable between an open configuration and a closed configuration.

[012] In one representative embodiment, an implantable prosthetic device comprises a spacer member, a plurality of anchors, and a plurality of clasps. The spacer member is configured to be disposed between native leaflets of a heart. The anchors are coupled to the spacer member and configured to secure the native leaflets against the spacer member. The clasps are coupled to a respective anchor and are configured to secure the native leaflets to the anchors. The clasps are independently movable between an open configuration and a closed configuration.

[013] In some embodiments, the prosthetic device is movable between a compressed configuration, in which the spacer member is radially compressed and is axially spaced relative to at least a portion of the anchors, and an expanded configuration, in which the spacer member expands radially outwardly relative to the compressed configuration and overlaps the at least a portion of the anchors.

[014] In some embodiments, the anchors are pivotable relative to the spacer member between a first configuration and a second configuration. An angle between the first portions of the anchors and the spacer member is greater than approximately 120 degrees when the anchors are in the first configuration.

CLAIMS:

1. A clasp control mechanism for a delivery apparatus of an implantable prosthetic device;
wherein the clasp control mechanism is releasably coupleable to clasp control members of the implantable prosthetic device; the clasp control members being releasably coupled to clasps of the prosthetic device;
wherein the clasp control mechanism is configured such that the clasp control members can be actuated either simultaneously or separately; and
wherein actuating the clasp control members moves the clasps of the prosthetic device between an open configuration and a closed configuration.
2. The clasp control mechanism of claim 1, wherein the clasp control members comprise a first clasp control member and a second clasp control member and the clasp control mechanism comprises a first side portion a second side portion, and a removable pin selectively coupling the first and second side portions; and
wherein the first side portion is releasably coupleable to the first clasp control member, and the second side portion is releasably coupleable to the second side portion.
3. The clasp control mechanism of any claims 1 or 2, wherein the clasp control mechanism is coupleable to a main body of a handle of the delivery apparatus.
4. A handle for a delivery apparatus, the handle comprising:
a housing;
an actuation control mechanism;
a clasp control mechanism; and
a flushing mechanism;
wherein the clasp control mechanism is releasably coupleable to clasp control members, the clasp control members being releasably coupled to clasps of an implantable prosthetic device;
wherein actuating the clasp control members moves the clasps between an open configuration and a closed configuration; and
wherein the clasp control mechanism is configured such that the clasp control members can be actuated either simultaneously or separately.

5. The handle of claim 4, wherein the clasp control members comprise a first clasp control member and a second clasp control member and the clasp control mechanism comprises a first side portion a second side portion, and a removable pin selectively coupling the first and second side portions; and

wherein the first side portion is releasably coupleable to the first clasp control member, and the second side portion is releasably coupleable to the second side portion.

6. The handle of any of claims 4 or 5, wherein the actuation control mechanism is configured to be coupled to anchors of the implantable prosthetic device and to move the anchors between a closed configuration and an open configuration.

7. The handle of any of claims 4 to 6, further comprising a connection member coupled to a distal end portion of the housing and to a proximal end portion of an outer shaft of the delivery apparatus.

8. The handle of any of claims 4 to 6, wherein the housing comprises a main body and a nose portion coupled to a distal end portion of the main body.

9. The handle of claim 8, wherein the nose portion comprises a plurality of lumens including an actuation shaft lumen and control member lumens, and wherein the actuation shaft lumen is configured to receive a proximal end portion of an outer shaft of the delivery apparatus.

10. The clasp control mechanism of any of claims 2 or 3, or the handle of any of claims 5 to 9, wherein the connection between the first and second side portion is configured such that the first and second side portion can move axially but not rotationally relative to each other when the connecting pin is withdrawn.

11. The clasp control mechanism of any of claims 2, 3 or 10, or the handle of any of claims 5 to 10, wherein the first side portion is configured with a keyed slot or groove and the second side portion is configured with a keyed projection or tongue that corresponds to the keyed slot or groove of the first side portion.

12. The clasp control mechanism of any of claims 2, 3, 10 or 11 or the handle of any of claims 5 to 11, wherein the clasp control members are releasably coupled to the first and second side portion by locking members.

13. The clasp control mechanism of claim 12, or the handle of claim 12, wherein the first and second side portions include axially extending lumens, wherein distal ends of the lumens are configured to receive proximal end portions of control member tubes of the handle, and wherein proximal ends of the lumens are configured to receive portions of the locking members.

14. The clasp control mechanism of any of claims 12 or 13, or the handle of any of claims 12 or 13, wherein the locking members are configured to selectively control relative movement between a clasp control member of the clasp control members and the respective first or second side portion.

15. The clasp control mechanism of any of claims 12 to 14, or the handle of any of claims 12 to 14, wherein rotating a knob of a respective locking member in a first direction increases frictional engagement between the locking member on the corresponding clasp control member, and wherein rotating a knob of a respective locking member in a second direction decreases frictional engagement between the locking member on the corresponding clasp control member.

16. A delivery system comprising:
an elongate shaft having a proximal portion and a distal portion;
a handle connected to the proximal portion of the elongate shaft;
a first clasp control member that extends into the distal portion of the elongate shaft, through at least a portion of the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle;
a second clasp control member that extends into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle;
an actuator coupled to the handle, the actuator comprising

a first side portion connected to the first clasp control; and
a second side portion connected to the second clasp control;
wherein the first side portion and the second side portion are releasably couplable such that when the first side portion and the second side portion are coupled, proximal movement of the actuator proximally pulls both the first clasp control member and the second clasp control member, and such that when the first side portion and the second side portion are uncoupled, individual proximal movements of the first side portion and the second side portion independently pull the first clasp control member and the second clasp control member, respectively.

17. The delivery system of claim 16 wherein the first clasp control member comprises a suture.

18. The delivery system of claim 16 wherein the first side portion and the second side portion are releasably connected by a pin.

19. The delivery system of claim 16 wherein the first side portion and the second side portion are constrained to proximal and distal movement relative to one another when the first side portion and the second side portion are released.

20. The delivery system of claim 16 wherein the first clasp control member extends through a first control member lumen in the handle, and the second clasp control member extends through a second control member lumen in the handle.

21. The delivery system of claim 20 wherein at least a portion of the first control member lumen extends proximally at an angle toward the second control member lumen.

22. The delivery system of claim 16 wherein the elongate shaft is flexible.

23. The delivery system of claim 16 further comprising an anchor actuation shaft in a lumen of the elongate shaft, wherein the anchor actuation shaft extends out of

the proximal portion of the elongate shaft, and wherein the anchor actuation shaft extends out of the distal portion of the elongate shaft.

24. A delivery assembly comprising:
- a first clasp that is moveable between an open position and a closed position, wherein the first clasp is configured to be securable to a first native valve leaflet by moving the first clasp from the open position to the closed position of the first clasp;
 - a first clasp control member coupled to the first clasp, wherein applying tension to the first clasp control member moves the first clasp to the open position;
 - a second clasp that is moveable between an open position and a closed position, wherein the second clasp is configured to secure a second native valve leaflet by moving the second clasp from the open position to the closed position of the second clasp;
 - a second clasp control member coupled to the second clasp, wherein applying tension to the second clasp control member moves the second clasp to the open position;
 - an elongate shaft having a proximal portion and a distal portion;
 - a handle connected to the proximal portion of the elongate shaft;
 - wherein the first clasp control member extends from the first clasp, into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle;
 - wherein the second clasp control member extends from the second clasp, into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle;
 - an actuator coupled to the handle, the actuator comprising
 - a first side portion connected to the first clasp control member; and
 - a second side portion connected to the second clasp control member;
 - wherein the first side portion and the second side portion are releasably couplable such that when the first side portion and the second side portion are coupled, proximal movement of the actuator proximally tensions both the first clasp control member and the second clasp control member to move both the first and second clasps to the open position, and such that when the first side portion and the second side portions are uncoupled, individual proximal movements of the first side portion and the second side

portion individually tension the first clasp control member and the second clasp control member to independently open the first and second clasps, respectively.

25. The delivery assembly of claim 24 wherein the first clasp control member comprises a suture.

26. The delivery assembly of claim 24 wherein the first side portion and the second side portion are releasably connected by a pin.

27. The delivery assembly of claim 24 wherein the first side portion and the second side portion are constrained to proximal and distal movement relative to one another when the first side portion and the second side portion are released.

28. The delivery assembly of claim 24 wherein the first clasp control member extends through a first control member lumen in the handle, and the second clasp control member extends through a second control member lumen in the handle.

29. The delivery assembly of claim 28 wherein at least a portion of the first control member lumen extends proximally at an angle toward the second control member lumen.

30. The delivery assembly of claim 24 wherein the elongate shaft is flexible.

31. The delivery assembly of claim 24 wherein the first clasp and the second clasp are coupled to a spacer.

32. The delivery assembly of claim 24 further comprising an anchor actuation shaft in a lumen of the elongate shaft, wherein the anchor actuation shaft extends out of the proximal portion of the elongate shaft, and wherein the anchor actuation shaft extends out of the distal portion of the elongate shaft.

33. A delivery assembly comprising:

a pair of anchors that are moveable between an open position and a closed position;

an anchor actuation shaft operably coupled to the pair of anchors;

a first clasp that is moveable between an open position and a closed position;

a first clasp control member coupled to the first clasp configured such that applying tension to the first clasp control member moves the first clasp to the open position;

a second clasp that is moveable between an open position and a closed position,

a second clasp control member coupled to the second clasp configured such that applying tension to the second clasp control member moves the second clasp to the open position;

an elongate shaft having a proximal portion and a distal portion;

a handle connected to the proximal portion of the elongate shaft;

wherein the anchor actuation shaft extends into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and into the handle;

wherein axial movement of the anchor actuation shaft relative to the elongate shaft moves the pair of anchors between the open position and the closed position;

wherein the first clasp control member extends from the first clasp, into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle;

wherein the second clasp control member extends from the second clasp, into the distal portion of the elongate shaft, through the elongate shaft, out of the proximal portion of the elongate shaft, and through the handle;

an actuator coupled to the handle, the actuator comprising:

a first side portion connected to the first clasp control member; and

a second side portion connected to the second clasp control member;

wherein the first side portion and the second side portion are releasably couplable such that when the first side portion and the second side portion are coupled, proximal movement of the actuator proximally tensions both the first clasp control member and the second clasp control member to move both the first and second clasps to

the open position, and such that when the first side portion and the second side portions are uncoupled, individual proximal movements of the first side portion and the second side portion individually tension the first clasp control member and the second clasp control member to independently open the first and second clasps, respectively.

34. The delivery assembly of claim 33 wherein the first clasp control member extends through a first control member lumen in the handle, the second clasp control member extends through a second control member lumen in the handle, and at least a portion of the first control member lumen extends proximally at an angle toward the second control member lumen.

35. The delivery assembly of claim 33 wherein the first clasp control member extends through a first control member lumen in the handle;

wherein the second clasp control member extends through a second control member lumen in the handle;

wherein the anchor actuation shaft extends through an anchor actuation shaft lumen in the handle;

wherein a first portion of the first control member lumen is parallel to the anchor actuation shaft lumen; and

wherein a second portion of the first control member lumen extends at an angle relative to the anchor actuation shaft lumen.