

CLAIMS:

1. An implantable prosthetic device, comprising:
a spacer member configured to be disposed between native leaflets of a heart;
a plurality of anchors coupled to the spacer member and configured to secure the native leaflets against the spacer member; and
a plurality of clasps, wherein the clasps are coupled to a respective anchor and are configured to secure the native leaflets to the anchors, and wherein the clasps are independently movable between an open configuration and a closed configuration.
2. The prosthetic device of claim 1, wherein 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.
3. The prosthetic device of claim 1 or claim 2, wherein the anchors are pivotable relative to the spacer member between a first configuration and a second configuration, wherein an angle between first portions of the anchors and the spacer member is greater than approximately 120 degrees when the anchors are in the first configuration.
4. The prosthetic device of claim 1 or claim 2, wherein the anchors have first portions, second portions, and joint portions disposed between the first portions and the second portions, and wherein the first portions are coupled to the spacer member.
5. The prosthetic device of claim 2, wherein the at least a portion of the anchors is a second portion of the anchors.
6. The prosthetic device of claim 4, wherein the first portions are spaced relative to the second portions in the compressed configuration and overlap with the second portions in the expanded configuration.

7. The prosthetic device of claim 1 or claim 2, wherein the anchors are pivotable relative to the spacer member between a first configuration and a second configuration, wherein an angle between first portions of the anchors and the spacer member is approximately 180 degrees when the anchors are in the first configuration, and the angle between the first portions of the anchors and the spacer member is approximately 0 degrees when the anchors are in the second configuration.

8. The prosthetic device of any one of the previous claims, wherein the clasps comprise attachment portions and arm portions, the attachment portions are coupled to the anchors, and the arm portions are pivotable relative to the attachment portions between the open configuration and the closed configuration.

9. The prosthetic device of claim 8, wherein the clasps are configured to capture the native leaflets between the attachment portions and the arm portions.

10. The prosthetic device of any one of the previous claims, wherein the clasps are configured to be biased to the closed configuration.

11. The prosthetic device of any one of the previous claims, wherein the clasps are configured to have a preload when the clasps are in the closed configuration.

12. The prosthetic device of one of the previous claims, wherein the clasps comprise barbs configured to engage tissue of the native leaflets.

13. The prosthetic device of one of the previous claims, wherein the spacer member and the anchors are formed from a single, unitary piece of material.

14. The prosthetic device of one of the previous claims, wherein the spacer member and the anchors includes braided or woven material comprising nitinol.

15. The prosthetic device of one of the previous claims, wherein the prosthetic device is configured for implantation in a native mitral valve and to reduce mitral regurgitation.

16. An implantable prosthetic device, comprising:

a spacer member configured to be disposed between native leaflets of a heart;

a plurality of anchors coupled to the spacer member and configured to secure the native leaflets against the spacer member, wherein the anchors are pivotable relative to the spacer member between a first configuration and a second configuration, and wherein an angle between at least a portion of the anchors and the spacer member is approximately 180 degrees when the anchors are in the first configuration, and the angle between the at least a portion of the anchors and the spacer member is approximately 0 degrees when the anchors are in the second configuration; and

a plurality of clasps, wherein the clasps are coupled to a respective anchor and are configured to secure the native leaflets to the anchors, and wherein the clasps are movable between an open configuration and a closed configuration.

17. The prosthetic device of claim 16, wherein the anchors have first portions, second portions, and joint portions disposed between the first portions and the second portions, wherein the first portions are coupled to the spacer member, and wherein the at least a portion of the anchors is the first portions of the anchors.

18. The prosthetic device of claim 16 or claim 17, wherein the clasps are separately movable between the open configuration and the closed configuration.

19. An assembly, comprising:

an implantable prosthetic device having a spacer member, a plurality of anchors, a plurality of clasps, a first collar, and a second collar, wherein first end portions of the anchors are coupled to a first end portion of the spacer member, and second end portions of the anchors are coupled to the first collar, wherein the second collar is coupled to a second end portion of the spacer member, and the clasps are coupled to the anchors; and

a delivery apparatus having a first shaft, a second shaft, and a plurality of clasp control members, wherein the first shaft is releasably coupled to the first collar of the prosthetic device, the second shaft is releasably coupled to the second collar of the prosthetic device, and the clasp control members are releasably coupled to the clasps of

the prosthetic device, wherein actuating the clasp control members moves the clasps between an open configuration and a closed configuration.

20. The assembly of claim 19, wherein the delivery apparatus is configured such that moving the first shaft and the second shaft relative to each other moves the prosthetic device between a first configuration, in which anchors are in a radially compressed, axially elongate configuration, and a second configuration, in which the anchors are in a radially expanded, axially compressed configuration and at least partially overlap the spacer member to capture native leaflets between the anchors and the spacer member.

21. The assembly of claim 19 or claim 20, wherein the delivery apparatus further comprises a clasp control mechanism, and the clasp control members are releasably coupled to the clasp control mechanism, wherein the clasp control mechanism is configured such that the clasp control members can be actuated either simultaneously or separately.

22. The assembly of claim 21, wherein the clasp control members comprise a first clasp control member and a second clasp control member, wherein 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, wherein the first clasp control member is releasably coupled to the first side portion of the clasp control mechanism, and the second clasp control member is releasably coupled to the second side portion of the clasp control mechanism.

23. The assembly of any one of claims 19-22, wherein the delivery apparatus further comprises a locking mechanism coupled to the first shaft and the second shaft and configured to selectively prevent relative axial movement between the first shaft and the second shaft.

24. The assembly of claim 23, wherein the locking mechanism comprises a rotatable knob.

25. The assembly of claim 23 or claim 24, wherein the locking mechanism is configured to be selectively movable from a lock configuration to a release configuration, wherein the locking mechanism prevents relative axial movement between the first shaft and the second shaft in the lock configuration, and the locking mechanism allows relative axial movement between the first shaft and the second shaft in the release configuration.

26. The assembly of claim 23, wherein the locking mechanism comprises a knob, a drive screw, and a guide pin, wherein the knob is rotatably coupled to the second shaft and the drive screw, the drive screw is coupled to the first shaft, and the guide pin is coupled to the second shaft and configured to prevent relative rotational movement between the knob and the drive screw, and wherein rotating the knob relative to the second shaft and the drive screw results in relative axial movement between the first shaft and the second shaft.

27. The assembly of any one of claims 19-26, wherein the first shaft and the first collar are threadably coupled.

28. The assembly of any one of claims 19-26, wherein the first collar comprises a lumen, wherein the first shaft comprises a radially-expandable portion disposed at a distal end portion of the first shaft, and wherein the radially-expandable portion is configured such that the radially-expandable portion can be inserted through the lumen of the first collar when the radially-expandable portion is in a compressed state and such that the radially-expandable portion cannot be withdrawn through the lumen of the first collar when the radially-expandable portion is inserted through the lumen of the first collar and the radially-expandable portion is in an expanded state.

29. An implantable prosthetic device, comprising:
a spacer member configured to be disposed between native leaflets of a heart;
a plurality of anchors coupled to the spacer member and configured to secure the native leaflets against the spacer member; and
a plurality of clasps configured to secure the native leaflets to the anchors and having fixed end portions and free end portions, wherein the fixed end portions are coupled to the anchors, wherein the free end portions have barbs, wherein the free end

portions are pivotable relative to the fixed end portions between an open configuration and a closed configuration, and wherein the free end portions are axially movable in the open configuration from a first position in which the barbs engage tissue of the native leaflets to a second position in which the barbs disengage the tissue of the native leaflets.

30. An implantable prosthetic device, comprising:

a spacer member configured to be disposed between native mitral valve leaflets of a heart;

a plurality of anchors coupled to the spacer member, wherein the anchors are configured to secure the native mitral valve leaflets against the spacer member during ventricular systole and to allow the native mitral valve leaflet to move away from the spacer member during ventricular diastole; and

a plurality of clasps, wherein the clasps are coupled to a respective anchor and are configured to secure the native leaflets to the anchors, and wherein the clasps are movable between an open configuration and a closed configuration.

31. An implantable prosthetic device, comprising:

a spacer member configured to be disposed between native leaflets of a heart;

a sleeve coupled to and disposed radially within the spacer member;

a plurality of anchors configured to secure the native leaflets against the spacer member and having first end portions and second end portions, wherein the first end portions are coupled to the spacer member, and wherein the anchors are movable between an elongate configuration and a foreshortened configuration;

a piston coupled to the second end portions of the anchors, wherein the piston is axially movable relative to the cylinder between a first configuration and a second configuration, wherein the anchors are in the elongate configuration when the piston is in the first configuration, and wherein the anchors are in the foreshortened configuration when the piston is in the second configuration.

32. An assembly comprising the prosthetic device of claim 31 and a delivery apparatus, comprising:

an outer shaft having a first lumen and a plurality of second lumens disposed radially outwardly from the first lumen;

an actuation shaft extending through the first lumen, wherein the actuation shaft is axially movable relative the outer shaft and releasably coupled to the piston of the prosthetic device;

a plurality of tethers extending through the second lumens and releasably coupled to the prosthetic device, wherein tensioning the tethers moves the prosthetic device and the outer shaft toward each other, and wherein slackening the tethers allows the prosthetic device and the outer shaft to be space from each other.

33. The assembly of claim 32, wherein each of the tethers is disposed in two of the second lumens that are circumferentially offset by approximately 180 degrees.

34. The assembly of claim 32 or claim 33, wherein:

the prosthetic device further comprises a plurality of clasps, wherein the clasps are coupled to a respective anchor and are configured to secure the native leaflets to the anchors, and wherein the clasps are movable between an open configuration and a closed configuration;

the outer shaft of the delivery apparatus further comprises a plurality of third lumens disposed radially outwardly from the first lumen; and

the delivery apparatus further comprises a plurality of control members extending through the third lumens and releasably coupled to the clasps of the prosthetic device, wherein tensioning the control members move the clasps to the open configuration, and wherein slackening the control members allows the clasps to move to the closed configuration.

35. The assembly of claim 34, wherein each of the control members is disposed in two of the third lumens that are circumferentially offset by approximately 180 degrees.

36. The assembly of claim 34 or claim 35, wherein each of the second lumens is circumferentially offset relative to an adjacent second lumen by approximately 90 degrees, wherein each of the third lumens is circumferentially offset relative to an adjacent third lumen by approximately 90 degrees, and wherein each of the second lumens is circumferentially offset relative to an adjacent third lumen by approximately 45 degrees.

37. An assembly, comprising:

an implantable prosthetic device having a spacer member, a plurality of anchors, a plurality of clasps, a first collar, and a second collar, wherein first end portions of the anchors are coupled to a first end portion of the spacer member, and second end portions of the anchors are coupled to the first collar, wherein the second collar is coupled to a second end portion of the spacer member, and the clasps are coupled to the anchors and are independently movable between an open configuration and a closed configuration; and

a delivery apparatus having a first shaft, a second shaft, a plurality of tethers, and a plurality of clasp control members, wherein the first shaft is releasably coupled to the first collar of the prosthetic device by the tethers, the second shaft is releasably coupled to the second collar of the prosthetic device, and the clasp control members are releasably coupled to the clasps of the prosthetic device,

wherein actuating the clasp control members moves the clasps between an open configuration and a closed configuration, and

wherein tensioning the tethers moves the prosthetic device and the first shaft toward each other, and slackening the tethers allows the prosthetic device and the first shaft to be spaced from each other.

38. A handle for a delivery apparatus, comprising:

a main body; and

an anchor actuation mechanism coupled to the main body, wherein the anchor actuation mechanism is configured to be coupled to anchors of a prosthetic spacer device and to move the anchors of the prosthetic spacer device between a closed configuration and an open configuration, wherein the anchor actuation mechanism includes a knob and a mode selector button configured to move the anchors actuation mechanism between a first mode of operation and a second mode of operation,

wherein when the anchor actuation mechanism is in the first mode of operation, the knob is rotatable relative to the main body, and rotation of the knob moves the anchors of the prosthetic spacer device between the closed configuration and the open configuration, and

wherein when the anchor actuation mechanism is in the second mode of operation, the knob is axially slidable relative to the main body, and axially sliding the knob moves

the anchors of the prosthetic spacer device between the closed configuration and the open configuration.

39. The handle of claim 38, further comprising a clasp actuation mechanism coupled to the main body, wherein the clasp actuation mechanism is configured to be coupled to clasps of the prosthetic spacer device and configured to move the clasps of the prosthetic spacer device between a closed configuration and an open configuration.

40. A positioning tool for a delivery apparatus, comprising:
a main body, wherein the main body is configured to be releasably coupled to a first portion of a handle of the delivery apparatus; and
one or more projections extending from the main body, wherein the projections are configured to releasably engage a second portion of the handle of the delivery apparatus,
wherein the positioning tool prevents relative movement between the first and second portions of the handle of the delivery apparatus when the positioning tool is coupled thereto.