CLAIMS

What is claimed is:

1. A device for delivering an implant to a native valve of a patient's heart, comprising:

a flexible hollow tube extending from a proximal end to a distal end, wherein the flexible hollow tube comprises:

a first flexible portion extending from the proximal end to a middle portion;

a second flexible portion extending from the middle portion to the distal end;

a first pull wire extending through the first flexible portion to attach to the middle portion, the first pull wire extending along a first side of the flexible hollow tube, wherein applying tension to the first pull wire in a proximal direction creates a first bend in the first flexible portion in a first direction;

a second pull wire extending through the first and second flexible portions to attach to the distal end, the second pull wire extending along a second side of the flexible hollow tube, wherein applying tension to the second pull wire in a proximal direction creates a second bend in the second flexible portion in a second direction;

wherein the second side is offset from the first side by an offset angle so that the second direction of the second bend is also offset from the first direction of the first bend by the offset angle; and

wherein the offset angle is in a range of about 160 degrees to about 200 degrees.

2. The device of claim 1, wherein the middle portion comprises a first pull ring and the distal end comprises a second pull ring.

3. The device of claim 2, wherein the first pull ring is integrally formed with the middle portion.

4. The device of claim 2 or claim 3, wherein the second pull ring is integrally formed with the distal end.

5. The device of any of claims 1–4, further comprising:

a first conduit embedded within and extending along the first side of the flexible tube, wherein the first conduit extends through the first flexible portion and at least a

portion of the middle portion, and wherein the first pull wire extends through the first conduit; and

a second conduit embedded within and extending along the second side of the flexible tube offset from the first conduit by the offset angle, wherein the second conduit extends through the first flexible portion, the middle portion, and the second flexible portion, and wherein the second pull wire extends through the second conduit.

6. The device of any of claims 1–5, wherein:

a proximal end of the first pull wire is connected to a first control mechanism for controlling tension to the first pull wire; and

a proximal end of the second pull wire is connected to a second control mechanism for controlling tension to the second pull wire.

7. The device of any of claims 1–6, wherein the first bend forms an angle of between zero and 180 degrees, and the second bend forms an angle of between zero and 60 degrees.

8. The device of any of claims 1–6, wherein the first bend forms an angle of between zero and 90 degrees, and the second bend forms an angle of between zero and 45 degrees.

9. The device of any of claims 6–8, wherein:

the first control mechanism comprises a first shaft, the first shaft being rotatable to wind the first pull wire to apply tension to the first pull wire; and

the second control mechanism comprises a second shaft, the second shaft being rotatable to wind the second pull wire to apply tension to the second pull wire.

10. The device of any of claims 1–9, wherein a proximal end of the first pull wire and a proximal end of the second pull wire are connected to a shaft of a control mechanism.

11. The device of any of claims 1–10, wherein:

the second pull wire comprises a slack portion when the flexible hollow tube is in a straight configuration;

the slack portion is reduced when tension is first applied to the second pull wire; and

the slack portion is eliminated after continued application of tension to the second pull wire creates the second bend.

12. The device of claim 10 or claim 11, wherein:

the shaft of the control mechanism has a first portion having a first diameter and a second portion having a second diameter, the first diameter being greater than the second diameter;

the first pull wire is connected to the first portion and the second pull wire is connected to the second portion; and

a rotation of the shaft increases a tension on the first pull wire at a greater rate than the rotation increases a tension on the second pull wire.

13. The device of claim 10 or claim 11, wherein:

the shaft of the control mechanism has a first portion comprising a first thread pitch and a second portion comprising a second thread pitch, the first thread pitch being greater than the second thread pitch;

the first pull wire is connected to the first portion and the second pull wire is connected to the second portion; and

a rotation of the shaft increases a tension on the first pull wire at a greater rate than the rotation increases a tension on the second pull wire.

14. The device of any of claims 1–8, further comprising:

a proximal end of the first pull wire that is connected to a first shaft of a control mechanism;

a proximal end of the second pull wire that is connected to a second shaft of the control mechanism;

a clutch connecting the first shaft and the second shaft, the clutch having a disengaged position and an engaged position;

wherein when the clutch is in the disengaged position and the control mechanism is actuated, a tension on the first pull wire is increased; and

wherein when the clutch is in the engaged position and the control mechanism is actuated, the tension on the first pull wire and a tension on the second pull wire are increased.

15. The device of any of claims 1–14, further comprising:

a first increased stiffness region extending longitudinally along at least a portion of the first flexible portion; and

a second increased stiffness region extending longitudinally along at least a portion of the second flexible portion.

16. The device of claim 15, wherein:

a longitudinally oriented center of the first increased stiffness region is circumferentially offset from the first pull wire by 180 degrees; and

a longitudinally oriented center of the second increased stiffness region is circumferentially offset from the second pull wire by 180 degrees.

17. The device of claim 15 or claim 16, wherein:

the first increased stiffness region extends around a first arc of a circumference of the flexible tube, the first arc having an angle between about 45 and about 135 degrees; and

the second increased stiffness region extends around a second arc of the circumference of the flexible tube, the second arc having an angle between about 45 and about 135 degrees.

18. The device of claim 17, wherein:

the angle of the first arc is between about 60 and about 120 degrees; and

the angle of the second arc is between about 60 and about 120 degrees.

19. The device of claim 17 or claim 18, wherein:

the angle of the first arc is between about 85 and about 95 degrees; and

the angle of the second arc is between about 85 and about 95 degrees.

20. The device of any of claims 15–19, wherein:

a ratio of a first Shore D hardness of the first increased stiffness region to the flexible hollow tube is greater than a ratio of a second Shore D hardness of the second increased stiffness region to the flexible hollow tube.

21. The device of claim 20, wherein the ratio of the Shore D hardness of the first increased stiffness region to the flexible hollow tube is between 1.5:1 and 5:1.

22. The device of claim 20 or claim 21, wherein the ratio of the Shore D hardness of the first increased stiffness region to the flexible hollow tube is between 2.5:1 and 3.5:1.

23. The device of any of claims 1–22, wherein tension can first be applied to the first pull wire and then the second pull wire.

24. The device of any of claims 1–22, wherein tension can be simultaneously applied to the first pull wire and the second pull wire.

25. The device of any of claims 1–22, wherein tension can first be applied to the second pull wire and then to the first pull wire.

26. A method of manufacturing a device for delivering an implant to a native valve of a patient's heart, the method comprising:

providing a flexible hollow tube extending from a proximal end to a distal end, the flexible hollow tube including a middle portion disposed between the proximal end and distal end;

cutting a plurality of first slots into the flexible hollow tube between the proximal end and the middle portion to form a first flexible portion extending from the proximal end to the middle portion;

cutting a plurality of second slots into the flexible hollow tube between the middle portion and the distal end to form a second flexible portion extending from the middle portion to the distal end;

attaching a first pull wire to the middle portion, the first pull wire extending through the first flexible portion along a first side of the flexible hollow tube, wherein applying tension to the first pull wire in a proximal direction creates a first bend in the first flexible portion in a first direction; and

attaching a second pull wire to the distal end, the second pull wire extending through the first and second flexible portions along a second side of the flexible hollow tube, wherein applying tension to the second pull wire in a proximal direction creates a second bend in the second flexible portion in a second direction;

wherein the second side is offset from the first side by an offset angle so that the second direction of the second bend is also offset from the first direction of the first bend by the offset angle; and

wherein the offset angle is in a range of about 160 degrees to about 200 degrees.

27. The method of claim 26, wherein the cutting steps are performed with a laser cutter.

28. The method of claim 26, wherein the device is the device of any of claims 1–25.

29. A device for delivering an implant to a native valve of a patient's heart, comprising:

a flexible hollow tube having a proximal region and a distal region, wherein the distal region of the flexible hollow tube comprises a distal section and a proximal section;

a first pull wire fixed to a distal end of the distal section; and

a second pull wire fixed to a distal end of the proximal section;

wherein the second pull wire is offset from the first pull wire;

wherein applying tension to the first pull wire in a proximal direction creates a first bend in the distal section in a first direction, and

wherein applying tension to the second pull wire in a proximal direction creates a second bend in the proximal section in a second direction different from the first direction.

30. The device of claim 29, wherein tension can first be applied to the first pull wire and then the second pull wire.

31. The device of any of claims 29 and 30, wherein tension can be simultaneously applied to the first pull wire and the second pull wire.

32. The device of any of claims 29-31, wherein the distal end of the distal section comprises a first pull ring, and the distal end of the proximal section comprises a second pull ring.

33. The device of any of claims 29-32, wherein the first pull wire extends through a first conduit that is within and extends along a top of the flexible hollow tube through the distal section and the proximal section, and wherein the second pull wire extends through a second conduit that is within and extends along a bottom of the flexible hollow tube through the proximal section.

34. The device of any of claims 29-33, wherein a proximal end of the first pull wire is connected to a first control mechanism and a proximal end of the second pull wire is connected to a second control mechanism, wherein the first control mechanism controls the tension to the first pull wire, and wherein the second control mechanism controls the tension to the second pull wire.

35. The device of any of claims 29-31, wherein the first bend forms an angle of between zero and 180 degrees, and the second bend forms an angle of between zero and 60 degrees.

36. The device of claim 35 wherein the first bend forms an angle of between zero and 90 degrees, and the second bend forms an angle of between zero and 45 degrees.

37. The device of any of claims 29-36, wherein a proximal end of the first pull wire and a proximal end of the second control wire are connected to a single control mechanism.

38. The device of claim 37 wherein the single control mechanism comprises a first shaft and a second shaft, and wherein the first shaft is rotatable to wind the first pull wire to apply tension to the first pull wire, and the second shaft is rotatable to wind the second pull wire to apply tension to the second pull wire.

39. The device of any of claims 37-38 wherein when the flexible hollow tube is in a straight configuration, the first and second control wires are slack, wherein an initial

actuation of the single control mechanism tensions the first pull wire to create the first bend and reduces the slack in the second wire, and wherein a continued actuation of the single control mechanism tensions the second pull wire to create the second bend.

40. The device of claim 38 wherein the first shaft has a first diameter and the second shaft has a second diameter, wherein the first diameter is greater than the second diameter.

41. The device of claim 40, wherein the first pull wire is connected to the first shaft and the second pull wire is connected to the second shaft, and wherein a rotation of the first and second shafts together increases a tension on the first pull wire at a greater rate than the rotation increases a tension on the second pull wire.

42. The device of claim 38 wherein the first shaft has a first thread pitch and a second shaft has a second thread pitch, wherein the first thread pitch is greater than the second thread pitch, wherein the first pull wire is connected to the first shaft and the second pull wire is connected to the second shaft.

43. The device of claim 42 wherein a rotation of the first and second shafts together increases a tension on the first pull wire at a greater rate than the rotation increases a tension on the second pull wire.

44. The device of any of claims 29-43 wherein a proximal end of the first pull wire is connected to a first shaft of a control mechanism, wherein a proximal end of the second pull wire is connected to a second shaft of the control mechanism, wherein the first shaft and second shaft are connected by a clutch, the clutch having a disengaged position and an engaged position, wherein when the clutch is in the disengaged position and the control mechanism is actuated, a tension on the first pull wire is increased, and wherein when the clutch is in the engaged position and the control mechanism is actuated, the tension on the first pull wire and a tension on the second pull wire are increased.

45. The device of claim 44 wherein the distal section comprises a first increased stiffness region and the proximal section comprises a second increased stiffness region.

46. The device of claim 45 wherein a longitudinally oriented center of the first increased stiffness region is circumferentially offset from the first pull wire by 180 degrees, and a longitudinally oriented center of the second increased stiffness region is circumferentially offset from the second pull wire by 180 degrees.

47. The device of any of claims 45-46, wherein the first increased stiffness region extends around a first arc of a circumference of the flexible tube, wherein the first arc is between 45 and 135 degrees, and wherein the second increased stiffness region extends around a second arc of the circumference of the flexible tube, wherein the second arc is between 45 and 135 degrees.

48. The device of claim 47 wherein the first arc is between 60 and 120 degrees and the second arc is between 60 and 120 degrees.

49. The device of claim 47 wherein the first arc is between 85 and 95 degrees and the second arc is between 85 and 95 degrees.

50. The device of claim 46 wherein a ratio of Shore D hardness of the first increased stiffness region to the flexible hollow tube is greater than a ratio of Shore D hardness of the second increased stiffness region to the flexible hollow tube.

51. The device of claim 50 wherein the ratio of Shore D hardness of the first increased stiffness region to the flexible hollow tube is between 1.5:1 and 5:1.

52. The device of claim 51 wherein the ratio of Shore D hardness of the first increased stiffness region to the flexible hollow tube is between 2.5:1 and 3.5:1.

53. The device of any one of claims 29-53, wherein the second pull wire is offset from the first pull wire by 180 degrees.

54. The device of any one of claims 29-54, wherein the second direction is opposite to the first direction.

55. A device for delivering an implant to a native valve of a patient's heart, comprising:

a flexible hollow tube having a proximal region and a distal region, wherein the distal region of the flexible hollow tube comprises a distal section and a proximal section;

a first pull wire fixed to the distal end of the distal section; and

a second pull wire fixed to a distal end of the proximal section;

wherein the second pull wire is offset from the first pull wire by about 180 degrees;

wherein applying tension to the first pull wire in a proximal direction creates a first bend in the distal section in a first direction, and

wherein applying tension to the second pull wire in a proximal direction creates a second bend in the proximal section in a second direction that is substantially opposite to the first direction.

56. The device of claim 55, wherein the distal end of the distal section comprises a first pull ring, and the distal end of the proximal section comprises a second pull ring.

57. The device of any of claims 55-56, wherein the first pull wire extends through a first conduit that is within and extends along a top of the flexible hollow tube through the distal section and the proximal section, and wherein the second pull wire extends through a second conduit that is within and extends along a bottom of the flexible hollow tube through the proximal section.

58. The device of any of claims 55-57, wherein a proximal end of the first pull wire is connected to a first control mechanism and a proximal end of the second pull wire is connected to a second control mechanism, wherein the first control mechanism controls the tension to the first pull wire, and wherein the second control mechanism controls the tension to the second pull wire.

59. The device of any of claims 55-58, wherein the first bend forms an angle of between zero and 180 degrees, and the second bend forms an angle of between zero and 60 degrees.

60. The device of any of claims 55-59, wherein a proximal end of the first pull wire and a proximal end of the second control wire are connected to a single control mechanism.

61. The device of claim 60, wherein the single control mechanism comprises a first shaft and a second shaft, and wherein the first shaft is rotatable to wind the first pull wire to apply tension to the first pull wire, and the second shaft is rotatable to wind the second pull wire to apply tension to the second pull wire.

62. The device of any of claims 60-61 wherein when the flexible hollow tube is in a straight configuration, the first and second control wires are slack, wherein an initial actuation of the single control mechanism tensions the first pull wire to create the first bend and reduces the slack in the second wire, and wherein a continued actuation of the single control mechanism tensions the second pull wire to create the second bend.

63. The device of claim 61 wherein the first shaft has a first thread pitch and a second shaft has a second thread pitch, wherein the first thread pitch is greater than the second thread pitch, wherein the first pull wire is connected to the first shaft and the second pull wire is connected to the second shaft.

64. The device of any of claims 55-63 wherein a proximal end of the first pull wire is connected to a first shaft of a control mechanism, wherein a proximal end of the second pull wire is connected to a second shaft of the control mechanism, wherein the first shaft and second shaft are connected by a clutch, the clutch having a disengaged position and an engaged position, wherein when the clutch is in the disengaged position and the control mechanism is actuated, a tension on the first pull wire is increased, and wherein when the clutch is in the engaged position and the control mechanism is actuated, the tension on the first pull wire and a tension on the second pull wire are increased.