

CLAIMS:

1. A balloon assembly, comprising:
an inflatable balloon having an inflated state and a deflated state, wherein the inflatable balloon in the deflated state comprises:
a valve retaining portion having a generally cylindrical shape and one or more axial folds;
a distal tapered portion connected to a distal end of the valve retaining portion, a proximal end of the distal tapered portion having a larger diameter than a distal end of the distal tapered portion and the valve retaining portion;
a proximal tapered portion connected to a proximal end of the valve retaining portion, a distal end of the proximal tapered portion having a larger diameter than a proximal end of the proximal tapered portion and the valve retaining portion;
a distal leg connected to the distal end of the distal tapered portion; and
a proximal leg connected to the proximal end of the proximal tapered portion;
wherein the distal tapered portion comprises one or more axial folds, the proximal tapered portion comprises one or more axial folds, and
wherein the proximal end of the distal tapered portion comprises a first radial fold connected to a second radial fold, the first and second radial folds forming a pocket extending distally at the proximal end of the distal tapered portion.
2. The balloon assembly of claim 1, further comprising a restraining member extending around an outer surface of the valve retaining portion so as to prevent the one or more axial folds of the valve retaining portion from unfolding.

3. The balloon assembly of any of claims 1-2, further comprising a cover that encloses the inflatable balloon, wherein the cover comprises a proximal end portion, a distal end portion, and an intermediate portion between the proximal end portion and the distal end portion, wherein the proximal end portion defines a proximal recess that is shaped to substantially match a shape of the proximal tapered portion of the inflatable balloon, the distal end portion defines a distal recess that is shaped to substantially match a shape of the distal tapered portion of the inflatable balloon, and the intermediate portion defines an intermediate recess that is shaped to substantially match a shape of the valve retaining portion of the inflatable balloon.

4. The balloon assembly of claim 3, wherein the cover comprises a first cover piece and a second cover piece that are complementarily structured such that they can be matingly assembled together for enclosing the inflatable balloon in the deflated state.

5. The balloon assembly of claim 4, further comprising an outer sleeve extending over the cover so as to prevent the first and second cover pieces from separating from each other.

6. The balloon assembly of any of claims 1-5, wherein the inflatable balloon comprises an internal lumen extending through the tapered proximal portion, the valve retaining portion, and the tapered distal portion.

7. The balloon assembly of any of claims 1-6, wherein the proximal tapered portion of the inflatable balloon comprises a proximal end portion, wherein the one or more axial folds of the proximal tapered portion do not extend into the proximal end portion of the proximal tapered portion.

8. The balloon assembly of any of claims 1-7, wherein the distal tapered portion of the inflatable balloon comprises a distal end portion, wherein the one or more axial folds of the distal tapered portion do not extend into the distal end portion of the distal tapered portion.

9. The balloon assembly of any of claims 1-8, wherein the distal end of the proximal tapered portion comprises a radial fold that forms an obtuse or right angle relative to the valve retaining portion.

10. The balloon assembly of any of claims 1-9, wherein the first radial fold at the proximal end of the distal tapered portion forms an obtuse or right angle relative to the valve retaining portion, and the second radial fold forms an acute angle relative to the valve retaining portion.

11. A balloon assembly, comprising:

- an inflatable balloon having an inflated state and a deflated state, wherein the inflatable balloon in the deflated state comprises:
 - a valve retaining portion having a generally cylindrical shape and one or more axial folds;
 - a distal tapered portion connected to a distal end of the valve retaining portion, a proximal end of the distal tapered portion having a larger diameter than a distal end of the distal tapered portion and the valve retaining portion;
 - a proximal tapered portion connected to a proximal end of the valve retaining portion, a distal end of the proximal tapered portion having a larger diameter than a proximal end of the proximal tapered portion and the valve retaining portion;
 - one or more axially extending folds along at least sections of the distal tapered portion and the proximal tapered portion;
 - a distal leg connected to the distal end of the distal tapered portion; and

a proximal leg connected to the proximal end of the proximal tapered portion;
wherein the inflatable balloon is in an unassembled state apart from a delivery catheter.

12. The balloon assembly of claim 11, further comprising a restraining member extending around an outer surface of the valve retaining portion so as to prevent the one or more axial folds of the valve retaining portion from unfolding.

13. The balloon assembly of any of claims 11-12, further comprising a cover that encloses the inflatable balloon, wherein the cover comprises a proximal end portion, a distal end portion, and an intermediate portion between the proximal end portion and the distal end portion, wherein the proximal end portion defines a proximal recess that is shaped to substantially match a shape of the proximal tapered portion of the inflatable balloon, and the distal end portion defines a distal recess that is shaped to substantially match a shape of the distal tapered portion of the inflatable balloon.

14. The balloon assembly of claim 13, wherein the cover comprises a first cover piece and a second cover piece that are complementarily structured such that they can be matingly assembled together for enclosing the inflatable balloon.

15. The balloon assembly of claim 14, further comprising an outer sleeve extending over the cover so as to prevent the first and second cover pieces from separating from each other.

16. The balloon assembly of any of claims 11-15, wherein the inflatable balloon comprises an internal lumen extending through the tapered proximal portion, the valve retaining portion, and the tapered distal portion.

17. The balloon assembly of any of claims 11-16, wherein the one or more axially extending folds do not extend into a proximal end portion of the proximal tapered portion.

18. The balloon assembly of any of claims 11-17, wherein the one or more axially extending folds do not extend into a distal end portion of the distal tapered portion.

19. The balloon assembly of any of claims 11-18, wherein the proximal end of the distal tapered portion comprises a first radial fold connected to a second radial fold, the first and second radial folds forming a pocket extending distally at the proximal end of the distal tapered portion.

20. The balloon assembly of claim 19, wherein the first radial fold at the proximal end of the distal tapered portion forms an obtuse or right angle relative to the valve retaining portion, and the second radial fold forms an acute angle relative to the valve retaining portion.

21. A method for forming a balloon for a delivery device, the method comprising:
forming an inflatable balloon in a deflated state, the balloon in the deflated state having a valve retaining portion, a distal tapered portion connected to a distal end of the valve retaining portion, a proximal tapered portion connected to a proximal end of the valve retaining portion, a distal leg connected to a distal end of the distal tapered portion, and a proximal leg connected to a proximal end of the proximal tapered portion;

inserting a distal shoulder mounted on a first shaft of the delivery device through the distal leg and into the distal tapered portion of the inflatable balloon;

inserting a proximal shoulder mounted on a second shaft of the delivery device through the proximal leg and into the proximal tapered portion of the inflatable balloon;

securing the distal leg of the inflatable balloon to the distal shoulder; and

securing the proximal leg of the inflatable balloon to the second shaft and/or the proximal shoulder.

22. The method of claim 21, further comprising placing a restraining member around the valve retaining portion.

23. The method of any of claims 21-22, further comprising enclosing the inflatable balloon with a cover, wherein the cover comprises a first cover piece and a second cover piece that are complementarily structured such that they can be matingly assembled together for enclosing the inflatable balloon, and wherein the cover defines an internal recess whose geometry substantially matches a shape of the inflatable balloon in the deflated state.

24. The method of claim 23, further comprising placing a sleeve over the cover to prevent the first and second cover pieces from separating from each other.

25. The method of any of claims 21-24, wherein a proximal end of the distal shoulder has a larger diameter than a diameter of the distal leg, and inserting the distal shoulder through the distal leg comprises radially compressing the proximal end of the distal shoulder .

26. The method of any of claims 21-25, wherein a distal end of the proximal shoulder has a larger diameter than a diameter of the proximal leg, and inserting the proximal shoulder through the proximal leg comprises radially compressing the distal end of the proximal shoulder.

27. The method of any of claims 21-26, wherein forming the inflatable balloon comprises forming the valve retaining portion in a generally cylindrical shape, the diameter

of which being smaller than both a diameter of a proximal end of the distal tapered portion and a diameter of a distal end of the proximal tapered portion.

28. The method of claim 27, wherein forming the inflatable balloon comprises forming one or more axially extending folds along at least sections of the distal tapered portion and the proximal tapered portion.

29. The method of claim 28, wherein forming the inflatable balloon comprises forming a distal end portion of the distal tapered portion, wherein the distal end portion is free of any of the one or more axially extending folds.

30. The method of any of claims 28-29, wherein forming the inflatable balloon comprises forming a proximal end portion of the proximal tapered portion, wherein the proximal end portion is free of any of the one or more axially extending folds.

31. The method of any of claims 27-30, wherein forming the inflatable balloon comprises forming a radial fold at the distal end of the proximal tapered portion, the radial fold forming an obtuse or right angle relative to the valve retaining portion.

32. The method of any of claims 27-31, wherein forming the inflatable balloon comprises forming a radial fold at the proximal end of the distal tapered portion, the radial fold forming an obtuse or right angle relative to the valve retaining portion.

33. The method of any of claims 27-31, wherein forming the inflatable balloon comprises forming a first radial fold connected to a second radial fold at the proximal end of the distal tapered portion, the first and second radial folds forming a pocket extending distally at the proximal end of the distal tapered portion.

34. The method of any of claims 28-33, wherein the distal shoulder comprises one or more distal shoulder fins extending at least partially radially outwardly, and inserting the distal shoulder assembly into the distal tapered portion comprises snugly placing the one or more distal shoulder fins adjacent to at least some of the one or more axially extending folds in the distal tapered portion.

35. The method of any of claims 28-34, wherein the proximal shoulder comprises one or more proximal shoulder fins extending at least partially radially outwardly, and inserting the proximal shoulder assembly into the proximal tapered portion comprises snugly placing the one or more proximal shoulder fins adjacent to at least some of the one or more axially extending folds in the proximal tapered portion.

36. The method of any of claims 21-35, wherein inserting the distal shoulder into the distal tapered portion comprises aligning a marker located on the first shaft with a predefined position on the valve retaining portion of the inflatable balloon or the proximal shoulder.

37. A method for forming a balloon for a delivery device, the method comprising:
forming an inflatable balloon in a deflated state, the balloon in the deflated state having a distal portion, a proximal portion, and a valve retaining portion between the distal portion and the proximal portion;

forming a plurality of axially extending folds along at least sections of the distal and proximal portions of the inflatable balloon; and

after forming the inflatable balloon and forming the plurality of axially extending folds, mounting the inflatable balloon in the deflated state on a delivery device.

38. The method of claim 37, wherein mounting the inflatable balloon on the delivery device comprises inserting a distal shoulder mounted on a first shaft of the delivery device through a distal leg of the balloon and inserting a proximal shoulder mounted on a second shaft of the delivery device through a proximal leg of the balloon, wherein the distal leg is connected to a distal end of a tapered portion of the distal portion of the inflatable balloon, and the proximal leg is connected to a proximal end of a tapered portion of the proximal portion of the inflatable balloon.

39. The method of claim 38, wherein a proximal end of the distal shoulder has a larger diameter than a diameter of the distal leg, and inserting the distal shoulder through the distal leg comprises radially compressing the proximal end of the distal shoulder .

40. The method of any of claims 38-39, wherein a distal end of the proximal shoulder has a larger diameter than a diameter of the proximal leg, and inserting the proximal shoulder through the proximal leg comprises radially compressing the distal end of the proximal shoulder.

41. The method of any of claims 38-39, wherein mounting the inflatable balloon on the delivery device comprises inserting the distal shoulder into the tapered portion of the distal portion of the inflatable balloon, and inserting the proximal shoulder into the tapered portion of the proximal portion of the inflatable balloon.

42. The method of claim 41, wherein the distal shoulder comprises one or more distal shoulder fins extending at least partially radially outwardly, and inserting the distal shoulder into the tapered portion of the distal portion comprises snugly placing the one or more distal shoulder fins adjacent to at least some of the plurality of axially extending folds in the tapered portion of the distal portion.

43. The method of any of claims 41-42, wherein the proximal shoulder comprises one or more proximal shoulder fins extending at least partially radially outwardly, and inserting the proximal shoulder into the tapered portion of the proximal portion comprises snugly placing the one or more proximal shoulder fins adjacent to at least some of the plurality of axially extending folds in the tapered portion of the proximal portion.

44. The method of any of claims 41-43, wherein inserting the distal shoulder into the tapered portion of the distal portion comprises aligning a marker on the first shaft with a predefined position on the valve retaining portion of the inflatable balloon or the proximal shoulder.

45. The method of any of the claims 37-44, wherein forming the inflatable balloon comprises forming a distal end portion of the distal portion, wherein the distal end portion is free of any of the plurality of axially extending folds.

46. The method of any of the claims 37-45, wherein forming the inflatable balloon comprises forming a proximal end portion of the proximal portion, wherein the proximal end portion is free of any of the plurality of axially extending folds.

47. The method of any of claims 37-46, wherein forming the inflatable balloon comprises forming the valve retaining portion in a generally cylindrical shape, the diameter of which being smaller than both a diameter of a proximal end of the distal portion and a diameter of a distal end of the proximal portion.

48. The method of claim 47, wherein forming the inflatable balloon comprises forming a radial fold at the distal end of the proximal portion, the radial fold forming an obtuse or right angle relative to the valve retaining portion.

49. The method of any of claims 47-48, wherein forming the inflatable balloon comprises forming a radial fold at the proximal end of the distal portion, the radial fold forming an obtuse or right angle relative to the valve retaining portion.

50. The method of any of claims 47-48, wherein forming the inflatable balloon comprises forming a first radial fold connected to a second radial fold at the proximal end of the distal portion, the first and second radial folds forming a pocket extending distally at the proximal end of the distal portion.

51. The method of any of the claims 38-50, wherein mounting the inflatable balloon on the delivery device comprises securing the distal leg to the distal shoulder, and securing the proximal leg to the second shaft and/or the proximal shoulder.

52. The method of any of claims 37-51, further comprising placing a restraining member around the valve retaining portion.

53. The method of any of claims 37-52, further comprising enclosing the inflatable balloon with a cover, wherein the cover comprises a first cover piece and a second cover piece that are complementarily structured such that they can be matingly assembled together for enclosing the inflatable balloon, and wherein the cover defines an internal recess whose geometry substantially matches a shape of the inflatable balloon in the deflated state.

54. The method of claim 53, further comprising placing a sleeve around the cover to prevent the first and second cover pieces from separating from each other.

55. A prosthetic valve delivery assembly, comprising:
a delivery device comprising:

a shaft; and

an inflatable balloon mounted on the shaft in a deflated state;

wherein the balloon in the deflated state comprises a valve retaining portion having a generally cylindrical shape, a distal tapered portion connected to a distal end of the valve retaining portion, a proximal tapered portion connected to a proximal end of the valve retaining portion; and

wherein the proximal end of the distal tapered portion comprises a first radial fold connected to a second radial fold, the first and second radial folds forming a pocket extending distally at the proximal end of the distal tapered portion.

56. The prosthetic valve delivery assembly of claim 55, further comprising a restraining member extending around an outer surface of the valve retaining portion.

57. The prosthetic valve delivery assembly of any of claims 55-56, further comprising a cover, wherein the cover comprises a first cover piece and a second cover piece that are complementarily structured such that they can be matingly assembled together for enclosing the inflatable balloon, and wherein the cover defines an internal recess whose geometry substantially matches a shape of the inflatable balloon in the deflated state.

58. The prosthetic valve delivery assembly of claim 57, further comprising an outer sleeve extending over the cover so as to prevent the first and second cover pieces from separating from each other.

59. The prosthetic valve delivery assembly of any of claims 55-58, wherein the balloon in the deflated state comprises one or more axially extending folds along at least sections of the distal tapered portion and the proximal tapered portion.

60. The prosthetic valve delivery assembly of claim 59, wherein the distal tapered portion comprises a distal end portion that is free of any of the one or more axially extending folds.

61. The prosthetic valve delivery assembly of any of claims 55-60, wherein the balloon further comprises a distal leg connected to a distal end of the distal tapered portion and a proximal leg connected to a proximal end of the proximal tapered portion.

62. The prosthetic valve delivery assembly of claim 61, wherein the delivery device comprises a distal shoulder mounted on the first shaft extending through the distal leg and into the distal tapered portion of the inflatable balloon, and a proximal shoulder mounted on a second shaft of the delivery device extending through the proximal leg and into the proximal tapered portion of the inflatable balloon.

63. The prosthetic valve delivery assembly of claim 62, wherein the distal leg is secured to the distal shoulder and the proximal leg is secured to the second shaft or the proximal shoulder.

64. The prosthetic valve delivery assembly of any of claims 62-63, wherein a proximal end of the distal shoulder has a larger diameter than a diameter of the distal leg, and a distal end of the proximal shoulder has a larger diameter than a diameter of the proximal leg.

65. The prosthetic valve delivery assembly of any of claims 62-64, wherein the distal shoulder comprises one or more distal shoulder fins which extend at least partially radially outwardly and are adjacent to at least some of the one or more axially extending folds in the distal tapered portion, and wherein the proximal shoulder comprises one or more

proximal shoulder fins extending at least partially radially outwardly and are adjacent to at least some of the one or more axially extending folds in the proximal tapered portion.

66. The prosthetic valve delivery assembly of any of claims 62-65, wherein the first shaft comprises a marker that aligns with a predefined position on the valve retaining portion of the inflatable balloon.

67. The prosthetic valve delivery assembly of any of claims 62-66, wherein the first shaft extends through the valve retaining portion, and the first shaft is separated from the valve retaining portion by an axially extending gap.

68. The prosthetic valve delivery assembly of any of claims 55-67, wherein the distal end of the proximal tapered portion comprises a radial fold that forms an obtuse or right angle relative to the valve retaining portion.

69. The prosthetic valve delivery assembly of any of claims 55-68, wherein the first radial fold at the proximal end of the distal tapered portion forms an obtuse or right angle relative to the valve retaining portion, and the second radial fold forms an acute angle relative to the valve retaining portion.