

We claim:

1. A balloon shoulder assembly for a balloon catheter, comprising:
a proximal balloon shoulder including a proximal collar portion that extends radially outward from a proximal shaft portion, relative to a central axis of the balloon shoulder assembly; and
a distal balloon shoulder including a distal collar portion that extends radially outward from a distal shaft portion, wherein each of the proximal balloon shoulder and the distal balloon shoulder are hollow and comprise a compressible, blow molded material.
2. The balloon shoulder assembly of claim 1, wherein outer walls of the proximal balloon shoulder and outer walls of the distal balloon shoulder are configured to compress or stretch under applied pressure and return back to an uncompressed or unstretched state upon removal of the applied pressure.
3. The balloon shoulder assembly of any of the preceding claims, wherein the proximal collar portion is spaced away from the distal collar portion, in an axial direction relative to the central axis.
4. The balloon shoulder assembly of any of the preceding claims, wherein the proximal balloon shoulder and the distal balloon shoulder are molded as one piece with a central connecting portion, the central connecting portion arranged between and connecting the proximal collar portion and the distal collar portion.
5. The balloon shoulder assembly of claim 4, wherein the proximal balloon shoulder further includes a proximal transition portion extending between and connecting the proximal collar portion and the central connecting portion, the proximal transition portion narrowing in diameter from the proximal collar portion to the central connecting portion and wherein the distal balloon shoulder further includes a distal transition portion extending between and connecting the distal collar portion and the central connecting portion, the distal transition portion narrowing in diameter from the distal collar portion to the central connecting portion.

6. The balloon shoulder assembly of any of claims 1-3, wherein the proximal balloon shoulder and the distal balloon shoulder are molded separately, as two separate pieces.

7. The balloon shoulder assembly of any of the preceding claims, wherein each of the proximal balloon shoulder and the distal balloon shoulder are inflatable.

8. The balloon shoulder assembly of any of the preceding claims, wherein the proximal balloon shoulder and the distal balloon shoulder are not fluidly coupled with one another and are individually inflatable.

9. The balloon shoulder assembly of any of claims 1-6, wherein each of the proximal balloon shoulder and the distal balloon shoulder are not inflatable.

10. The balloon shoulder assembly of claim 9, wherein each of the proximal balloon shoulder and the distal balloon shoulder have a wall thickness in a range of .0001 inch to .01 inch.

11. The balloon shoulder assembly of any of claims 9-10, wherein the proximal collar portion has an open end facing an open end of the distal collar portion.

12. The balloon shoulder assembly of any of the preceding claims, wherein each of the proximal collar portion and the distal collar portion are funnel-shaped with a wider end that flares radially outward from a narrower end, wherein the narrower end of the proximal collar portion is connected to the proximal shaft portion, wherein the narrower end of the distal collar portion is connected to the distal shaft portion, and wherein the wider ends of each of the proximal collar portion and the distal collar portion face one another and are arranged normal to the central axis.

13. The balloon shoulder assembly of any of claims 1-11, wherein each of the proximal collar portion and the distal collar portion have a bulbous shape with a wider, central portion that narrows to two opposite ends.

14. The balloon shoulder assembly of any of claims 1-11, wherein one or more of the proximal collar portion and the distal collar portion includes a central, cylindrical body arranged between a first tapered end portion and a second tapered end portion, the first tapered end portion and the second tapered end portion tapering, in opposite directions, from the central, cylindrical body to one of the central connecting portion or a corresponding one of the proximal shaft portion or the distal shaft portion.

15. The balloon shoulder assembly of any of claims 1-11, wherein one or more of the proximal collar portion and the distal collar portion includes a curved, central portion positioned between a first tapered end portion and a second tapered end portion, the first tapered end portion and the second tapered end portion tapering, in opposite directions, from the central portion to one of the central connecting portion or a corresponding one of the proximal shaft portion or the distal shaft portion.

16. The balloon shoulder assembly of any of claims 1-11, wherein one or more of the proximal collar portion and the distal collar portion includes an elongate tapered portion, a shorter tapered portion, and a central ring portion positioned between the elongate tapered portion and the shorter tapered portion.

17. The balloon shoulder assembly of any of the preceding claims, wherein the balloon catheter is part of a transcatheter heart valve delivery system.

18. The balloon shoulder assembly of any of the preceding claims, wherein the proximal balloon shoulder and the distal balloon shoulder are configured to be positioned within and support an inflatable, main balloon of the balloon catheter.

19. A method of manufacturing a balloon catheter, comprising:

blow molding a balloon shoulder assembly including a proximal balloon shoulder and a distal balloon shoulder; and

installing the blow molded balloon shoulder assembly in the balloon catheter by positioning the balloon shoulder assembly within an inflatable, main balloon of the balloon catheter.

20. The method of claim 19, wherein the proximal balloon shoulder and the distal balloon shoulder are spaced apart from one another, in an axial direction relative to a central axis of the balloon catheter.

21. The method of either claim 19 or claim 20, wherein positioning the balloon shoulder assembly within the main balloon forms a device retaining portion on the main balloon, in a space that separates the proximal balloon shoulder and the distal balloon shoulder.

22. The method of claim 21, wherein the device retaining portion is adapted to receive a prosthetic medical device thereon.

23. The method of claim 22, wherein the prosthetic medical device is a prosthetic heart valve.

24. The method of any of claims 19-23, wherein blow molding the balloon shoulder assembly includes blow molding the proximal balloon shoulder and the distal balloon shoulder as one piece with a central connecting portion of the balloon shoulder assembly, the central connecting portion arranged between the proximal balloon shoulder and the distal balloon shoulder.

25. The method of any of claims 19-23, wherein blow molding the balloon shoulder assembly includes blow molding the proximal balloon shoulder and the distal balloon shoulder as separate pieces.

26. The method of any of claims 19-25, wherein blow molding the balloon shoulder assembly includes forming the proximal balloon shoulder and the distal balloon shoulder to be fully inflatable, with ends that are adapted to be sealed around one or more shafts of the balloon catheter during manufacturing and contain pressure therein.

27. The method of any of claims 19-25, wherein blow molding the balloon shoulder assembly includes forming each of the proximal balloon shoulder and the distal balloon shoulder to be at least partially open and not inflatable.

28. The method of any of claims 19-27, further comprising mounting the balloon shoulder assembly to one or more shafts of the balloon catheter, prior to positioning the balloon shoulder assembly within the main balloon.

29. The method of claim 28, wherein mounting the balloon shoulder assembly to the one or more shafts of the balloon catheter includes mounting the proximal balloon shoulder to an outer shaft of the balloon catheter and mounting the distal balloon shoulder to an inner shaft of the balloon catheter.

30. The method of claim 28, wherein mounting the balloon shoulder assembly to the one or more shafts of the balloon catheter includes mounting the proximal balloon shoulder to an outer shaft of the balloon catheter and mounting the distal balloon shoulder to a nosecone of the balloon catheter.

31. The method of claim 28, wherein mounting the balloon shoulder assembly to the one or more shafts of the balloon catheter includes mounting the proximal balloon shoulder to an inner shaft of the balloon catheter and mounting the distal balloon shoulder to a nosecone of the balloon catheter.

32. The method of claim 28, wherein mounting the balloon shoulder assembly to the one or more shafts of the balloon catheter includes mounting the proximal balloon

shoulder to an inner shaft of the balloon catheter and mounting the distal balloon shoulder to the inner shaft.

33. The method of any of claims 19-32, further comprising inflating the proximal balloon shoulder and the distal balloon shoulder from a deflated state to an inflated state, after positioning the balloon shoulder assembly within the main balloon.

34. The method of claim 33, wherein inflating the proximal balloon shoulder and the distal balloon shoulder includes delivering a fluid to an interior of the proximal balloon shoulder and an interior of the distal balloon shoulder.

35. The method of claim 34, wherein the fluid includes at least one of saline, a contrast mixture, a biocompatible media, a curable material, and a non-curable material.

36. The method of any of claims 19-35, wherein the balloon catheter is part of a transcatheter heart valve delivery system and wherein positioning the balloon shoulder assembly within the main balloon of the balloon catheter includes creating a valve sitting pocket on the main balloon, in a space between the proximal balloon shoulder and the distal balloon shoulder, for a prosthetic heart valve and that reduces movement of the prosthetic heart valve during an implantation procedure with the transcatheter heart valve delivery system.

37. A balloon catheter for an endovascular delivery system, comprising:
a proximal balloon shoulder mounted on an inner shaft of the balloon catheter, the proximal balloon shoulder comprising a compressible, hollow shell;
a distal balloon shoulder mounted on the inner shaft, the distal balloon shoulder comprising a compressible, hollow shell; and
an inflatable, main balloon that encloses the proximal balloon shoulder and the distal balloon shoulder.

38. The balloon catheter of claim 37, wherein the proximal balloon shoulder and the distal balloon shoulder are blow molded together as one piece with a central connection portion extending therebetween.

39. The balloon catheter of claim 37, wherein the proximal balloon shoulder and the distal balloon shoulder are each blow molded as a separate piece and are spaced axially apart from one another.

40. The balloon catheter of any of claims 37-39, wherein the proximal balloon shoulder and the distal balloon shoulder are each fully enclosed and sealed around the inner shaft and inflatable.

41. The balloon catheter of any of claims 37-39, wherein each of the proximal balloon shoulder and the distal balloon shoulder has an open, non-sealed end around the inner shaft.

42. The balloon catheter of any of claims 37-41, wherein the proximal balloon shoulder and the distal balloon shoulder each include a collar portion and a shaft portion, the collar portion extending radially outward from the shaft portion.

43. The balloon catheter of claim 42, wherein the collar portion has one of a funnel, conical, ellipsoid, or spheroid shape.

44. The balloon catheter of claim 42, wherein the collar portion has a central portion arranged between tapered end portions, the central portion having one of a cylindrical, ring, or bulbous, curved shape.

45. The balloon catheter of any of claims 37-44, wherein the main balloon is adapted to receive a prosthetic heat valve crimped thereon, between the proximal balloon shoulder and the distal balloon shoulder.

46. The balloon catheter of any of claims 37-45, wherein the inner shaft extends distally beyond an outer shaft of the balloon catheter and through the main balloon.

47. A balloon catheter for an endovascular delivery system, comprising:
a proximal balloon shoulder mounted on an outer shaft of the balloon catheter, the proximal balloon shoulder comprising a compressible, hollow shell;
a distal balloon shoulder mounted on an inner shaft of the balloon catheter, the distal balloon shoulder comprising a compressible, hollow shell; and
an inflatable, main balloon that encloses the proximal balloon shoulder and the distal balloon shoulder.

48. The balloon catheter of claim 47, wherein the proximal balloon shoulder and the distal balloon shoulder are blow molded together as one piece with a central connection portion extending therebetween.

49. The balloon catheter of claim 47, wherein the proximal balloon shoulder and the distal balloon shoulder are each blow molded as a separate piece and are spaced axially apart from one another.

50. The balloon catheter of any of claims 47-49, wherein the proximal balloon shoulder is fully enclosed and sealed around the outer shaft and is inflatable and wherein the distal balloon shoulder is fully enclosed and sealed around the inner shaft and is inflatable.

51. The balloon catheter of any of claims 47-49, wherein the proximal balloon shoulder has an open, non-sealed end around the outer shaft and wherein the distal balloon shoulder has an open, non-sealed end around the inner shaft.

52. The balloon catheter of any of claims 47-51, wherein the proximal balloon shoulder and the distal balloon shoulder each include a collar portion and a shaft portion, the collar portion extending radially outward from the shaft portion.

53. The balloon catheter of claim 52, wherein the collar portion has one of a funnel, conical, ellipsoid, or spheroid shape.

54. The balloon catheter of claim 52, wherein the collar portion has a central portion arranged between tapered end portions, the central portion having one of a cylindrical, ring, or bulbous, curved shape.

55. The balloon catheter of any of claims 47-54, wherein the main balloon is adapted to receive a prosthetic heat valve crimped thereon, between the proximal balloon shoulder and the distal balloon shoulder.

56. The balloon catheter of any of claims 47-55, wherein the inner shaft extends distally beyond the outer shaft of the balloon catheter and through the main balloon.

57. A balloon catheter for an endovascular delivery system, comprising:
a proximal balloon shoulder mounted on an outer shaft of the balloon catheter, the proximal balloon shoulder comprising a compressible, hollow shell;
a distal balloon shoulder mounted on a nosecone of the balloon catheter, the distal balloon shoulder comprising a compressible, hollow shell; and
an inflatable, main balloon that encloses the proximal balloon shoulder and the distal balloon shoulder.

58. The balloon catheter of claim 57, wherein the proximal balloon shoulder and the distal balloon shoulder are blow molded together as one piece with a central connection portion extending therebetween.

59. The balloon catheter of claim 57, wherein the proximal balloon shoulder and the distal balloon shoulder are each blow molded as a separate piece and are spaced axially apart from one another.

60. The balloon catheter of any of claims 57-59, wherein the proximal balloon shoulder is fully enclosed and sealed around the outer shaft and is inflatable and wherein the distal balloon shoulder is fully enclosed and sealed around the nosecone and is inflatable.

61. The balloon catheter of any of claims 57-59, wherein the proximal balloon shoulder has an open, non-sealed end around the outer shaft and wherein the distal balloon shoulder has an open, non-sealed end around the nosecone.

62. The balloon catheter of any of claims 57-61, wherein the proximal balloon shoulder and the distal balloon shoulder each include a collar portion and a shaft portion, the collar portion extending radially outward from the shaft portion.

63. The balloon catheter of claim 62, wherein the collar portion has one of a funnel, conical, ellipsoid, or spheroid shape.

64. The balloon catheter of claim 62, wherein the collar portion has a central portion arranged between tapered end portions, the central portion having one of a cylindrical, ring, or bulbous, curved shape.

65. The balloon catheter of any of claims 57-64, wherein the main balloon is adapted to receive a prosthetic heat valve crimped thereon, between the proximal balloon shoulder and the distal balloon shoulder.

66. The balloon catheter of any of claims 57-65, wherein an inner shaft of the balloon catheter extends distally beyond the outer shaft of the balloon catheter and through the main balloon and wherein the nosecone is coupled to a distal end of the inner shaft.

67. A balloon catheter for an endovascular delivery system, comprising:
a proximal balloon shoulder mounted on an inner shaft of the balloon catheter, the proximal balloon shoulder comprising a compressible, hollow shell;

a distal balloon shoulder mounted on a nosecone of the balloon catheter, the distal balloon shoulder comprising a compressible, hollow shell; and
an inflatable, main balloon that encloses the proximal balloon shoulder and the distal balloon shoulder.

68. The balloon catheter of claim 67, wherein the proximal balloon shoulder and the distal balloon shoulder are blow molded together as one piece with a central connection portion extending therebetween.

69. The balloon catheter of claim 67, wherein the proximal balloon shoulder and the distal balloon shoulder are each blow molded as a separate piece and are spaced axially apart from one another.

70. The balloon catheter of any of claims 67-69, wherein the proximal balloon shoulder is fully enclosed and sealed around the inner shaft and is inflatable and wherein the distal balloon shoulder is fully enclosed and sealed around the nosecone and is inflatable.

71. The balloon catheter of any of claims 67-69, wherein the proximal balloon shoulder has an open, non-sealed end around the inner shaft and wherein the distal balloon shoulder has an open, non-sealed end around the nosecone.

72. The balloon catheter of any of claims 67-71, wherein the proximal balloon shoulder and the distal balloon shoulder each include a collar portion and a shaft portion, the collar portion extending radially outward from the shaft portion.

73. The balloon catheter of claim 72, wherein the collar portion has one of a funnel, conical, ellipsoid, or spheroid shape.

74. The balloon catheter of claim 72, wherein the collar portion has a central portion arranged between tapered end portions, the central portion having one of a cylindrical, ring, or bulbous, curved shape.

75. The balloon catheter of any of claims 67-74, wherein the main balloon is adapted to receive a prosthetic heat valve crimped thereon, between the proximal balloon shoulder and the distal balloon shoulder.

76. The balloon catheter of any of claims 67-75, wherein the inner shaft extends distally beyond an outer shaft of the balloon catheter and through the main balloon and wherein the nosecone is coupled to a distal end of the inner shaft.