

Claims

- ~~1. — An expandable docking station for an expandable valve comprising:

— a valve seat that is substantially unexpandable beyond a deployed size;

— one or more sealing portions connected to the valve seat that are constructed to expand radially outward of the valve seat and provide a seal over a range of sizes; and

— one or more retaining portions connected to the one or more sealing portions that are configured to retain the docking station at a deployed position.~~
- ~~2. — The expandable docking station of claim 1 wherein the valve seat is not expanded radially outwardly by a radially outward force of an expandable valve.~~
- ~~3. — The expandable docking station of any of claims 1-2 wherein the range of sizes comprises 27mm to 38mm.~~
- ~~4. — The expandable docking station of any of claims 1-3 wherein the docking station is configured to expand radially outwardly to varying degrees along its length L.~~
- ~~5. — The expandable docking station of any of claims 1-4 wherein the valve seat and the one or more sealing portions act as an isolator that reduces or prevents radial outward forces of an expandable valve in the valve seat from being transferred to the one or more sealing portions or the one or more retaining portions.~~
- ~~6. — The expandable docking station of any of claims 1-5 wherein the docking station is configured such that pressure of blood enhances the retention by the retaining portions.~~
- ~~7. — The expandable docking station of any of claims 1-6 wherein the one or more retaining portions are configured such that force applied by at least one of the one or more~~

~~retaining portions at the deployed position is in proportion to the pressure of blood acting on the docking station.~~

~~8. — The expandable docking station of any of claims 1-7 wherein the one or more retaining portions are configured such that force applied by at least one of the one or more retaining portions is greater when the heart is in a diastolic phase than when the heart is in the systolic phase.~~

~~9. — The expandable docking station of any of claims 1-8 wherein the valve seat is formed by a suture.~~

~~10. — The expandable docking station of any of claims 1-9 wherein the sealing portion comprises a portion of a metal frame covered with a fabric.~~

~~11. — The expandable docking station of any of claims 1-10 wherein the sealing portion comprises an open-cell foam.~~

~~12. — The expandable docking station of any of claims 1-11 wherein a portion of the docking station is permeable to blood and a portion of the docking station is impermeable to blood.~~

~~13. — The expandable docking station of claim 11 or 12 wherein the portion of the docking station that is impermeable to blood extends from at least the valve seat to at least the sealing portion.~~

~~14. — The expandable docking station of any of claims 1-13 wherein the docking station is adjustable in length.~~

~~15. — The expandable docking station of claim 14 wherein the docking station includes a first half that a second half of the docking station can adjustably extend into to adjust the length.~~

~~16. The expandable docking station of any of claims 1-15 wherein the one or more retaining portions extend radially outward of the one or more sealing portions when the docking station is in an unconstrained state.~~

~~17. A system comprising:~~

~~— an expandable docking station that includes:~~

~~— a valve seat that expands to a deployed size;~~

~~— one or more sealing portions connected to the valve seat that are constructed to expand radially outward of the valve seat and provide a seal over a range of sizes of expansion; and~~

~~— one or more retaining portions connected to the one or more sealing portions that are configured to retain the docking station at a deployed position;~~

~~— an expandable valve that comprises:~~

~~— an expandable frame that is expandable to engage the valve seat of the docking station;~~

~~— a valve element connected to the expandable frame;~~

~~— wherein the expandable docking station and expandable valve are configured such that, when implanted in a portion of a circulatory system, a radial outward force applied by the sealing portions to the portion of the circulatory system when within the range of sizes is less than ½ of a radial outward force applied by the expandable frame to the valve seat.~~

~~18. The system of claim 17 wherein the expandable docking station is configured such that, when implanted in the portion of the circulatory system, the diameter of the valve seat~~

is not increased more than 3mm by the radial outward force applied by the expandable frame to the valve seat.

~~19. The system of any of claims 17-18 wherein the range of sizes comprises 27mm to 38mm.~~

~~20. The system of any of claims 17-19 wherein the expandable docking station is configured to expand radially outwardly to varying degrees along its length L when implanted in the portion of the circulatory system.~~

~~21. The system of any of claims 17-20 wherein the expandable docking station is configured such that, when implanted in the portion of the circulatory system, pressure of blood on the expandable docking station enhances retention by the retaining portions.~~

~~22. The system of any of claims 17-21 wherein the expandable docking station is configured such that force applied by the retaining portions, when implanted in the portion of the circulatory system, is in proportion to the pressure of blood acting on the system.~~

~~23. The system of any of claims 17-22 wherein the expandable docking station is configured such that force applied by the retaining portions, when implanted in the portion of the circulatory system, is greater when the heart is in a diastolic phase than when the heart is in the systolic phase.~~

~~24. The system of any of claims 17-23 wherein the valve seat is formed by a suture.~~

~~25. The system of any of claims 17-24 wherein the sealing portion comprises a portion of a metal frame covered with a fabric.~~

~~26. The system of any of claims 17-25 wherein the sealing portion comprises an open cell foam.~~

~~27. — The system of any of claims 17-26 wherein a portion of the docking station is permeable to blood and a portion of the docking station is impermeable to blood.~~

~~28. — The system of claim 27 wherein the portion of the docking station that is impermeable to blood extends from at least the valve seat to at least the sealing portion.~~

~~29. — The system of any of claims 17-28 wherein the docking station has an overall length that is adjustable.~~

~~30. — The system of claim 29 wherein the docking station includes a first half that a second half of the docking station can adjustably extend into to adjust the overall length.~~

~~31. — The system of any of claims 17-30 wherein the one or more retaining portions extend radially outward of the one or more sealing portion when the docking station is in an unconstrained state.~~

~~32. — A method of implanting an expandable valve in a docking station comprising:~~

~~—— expanding a docking station such that a valve seat of the docking station expands to a valve seat deployed size and a sealing portion expands to a sealing size that is within a range of sealing sizes;~~

~~—— expanding a frame of an expandable valve to engage the valve seat of the docking station; and~~

~~—— wherein a radial outward force applied by the sealing portions over the range of sealing sizes is less than 1/2 of a radial outward force applied by the expandable frame to the valve seat after expanding the frame.——~~

~~33. — The method of claim 32 wherein a diameter of the valve seat is not increased more than 2mm by the radial outward force applied by the expandable frame to the valve seat.~~

~~34. The method of any of claims 32-33 wherein the range of sealing sizes comprises 27mm to 38mm.~~

~~35. The method of any of claims 32-34 wherein the valve seat is formed by a suture.~~

~~36. A system comprising:~~

~~— an expandable docking station that includes:~~

~~— a valve seat that expands to a deployed size;~~

~~— one or more sealing portions connected to the valve seat that are constructed to expand radially outward of the valve seat and provide a seal over a range of sizes of expansion; and~~

~~— one or more retaining portions connected to the one or more sealing portions that are configured to retain the docking station at a deployed position;~~

~~— an expandable valve that comprises:~~

~~— an expandable frame that is expandable to engage the valve seat of the docking station;~~

~~— a valve element connected to the expandable frame;~~

~~— wherein a pressure of blood acting on the valve and docking station enhances retention by the retaining portions at the deployed position.~~

~~37. The system of claim 36 wherein the valve seat is not substantially expanded radially outwardly by a radially outward force of the expandable valve.~~

~~38. The system of any of claims 36-37 wherein the range of sizes comprises 27mm to 38mm.~~

~~39. — The system of any of claims 36-38 wherein the docking station is configured to expand radially outwardly to varying degrees along its length L.~~

~~40. — The system of any of claims 36-39 wherein force applied by the retaining portions is in proportion to the pressure of blood acting on the system.~~

~~41. — The system of any of claims 36-40 wherein force applied by the retaining portions is greater when the heart is in a diastolic phase than when the heart is in the systolic phase.~~

~~42. — The system of any of claims 36-41 wherein the valve seat is formed by a suture.~~

~~43. — The system of any of claims 36-42 wherein the sealing portion comprises a portion of a metal frame covered with a fabric.~~

~~44. — The system of any of claims 36-43 wherein the sealing portion comprises an open cell foam.~~

~~45. — The system of any of claims 36-44 wherein a portion of the docking station is permeable to blood and a portion of the docking station is impermeable to blood.~~

~~46. — The system of claim 45 wherein a the portion that is impermeable to blood extends from at least the valve seat to at least the sealing portion.~~

~~47. — The system of any of claims 36-46 wherein the docking station is adjustable in length.~~

~~48. — The system of claim 47 wherein the docking station includes a first half that a second half extends into.~~

~~49. — The system of any of claims 36-48 wherein the one or more retaining portions extend radially outward of the one or more sealing portion when the docking station is in an unconstrained state.~~

~~50. A method of installing an expandable valve in a docking station comprising:~~

~~—expanding a docking station such that a valve seat of the docking station expands to a valve seat deployed size and a sealing portion expands to a sealing size in a predetermined range of sizes;~~

~~—expanding a frame of an expandable valve to engage the valve seat of the docking station; and~~

~~—wherein a pressure of blood acting on the valve and docking station enhances retention by the retaining portions at the deployed position.~~

~~51. The method of claim 50 wherein the valve seat is not substantially expanded radially outwardly by a radially outward force of an expandable valve.~~

~~52. The method of any of claims 50-51 wherein the predetermined range of sizes comprises 27mm to 38mm.~~

~~53. The method of any of claims 50-52 wherein the valve seat is formed by a suture.~~

~~54. An expandable docking station for an expandable valve comprising:~~

~~—a valve seat that is expandable to a deployed size;~~

~~—one or more sealing portions connected to the valve seat that extend radially outward of the valve seat, wherein the one or more sealing portions are constructed to expand outward of the valve seat and provide a seal over a range of sizes; and~~

~~—wherein a length of the docking station is adjustable.~~

~~55. The expandable docking station of claim 54 wherein the docking station includes a first half that a second half extends into.~~

~~56. — The expandable docking station of any of claims 54-55 wherein the valve seat is not substantially expanded radially outwardly by a radially outward force of an expandable valve.~~

~~57. — The expandable docking station of any of claims 54-56 wherein the range of sizes comprises 27mm to 38mm.~~

~~58. — The expandable docking station of any of claims 54-57 wherein the docking station is configured to expand radially outwardly to varying degrees along its length L.~~

~~59. — The expandable docking station of any of claims 54-58 wherein the valve seat and the one or more sealing portions act as an isolator that substantially prevents radial outward forces of an expandable valve from being transferred to the one or more sealing portions.~~

~~60. — The expandable docking station of any of claims 54-59 wherein the valve seat is formed by a suture.~~

~~61. — The expandable docking station of any of claims 54-60 wherein the sealing portion comprises a portion of a metal frame covered with a fabric.~~

~~62. — The expandable docking station of any of claims 54-61 wherein the sealing portion comprises an open cell foam.~~

~~63. — The expandable docking station of any of claims 54-62 wherein a portion of the docking station is permeable to blood and a portion of the docking station is impermeable to blood.~~

~~64. — A system comprising:~~

~~—— an expandable docking station that includes:~~

~~—— a valve seat that expands to a deployed size;~~

~~one or more sealing portions connected to the valve seat that are constructed to expand radially outward of the valve seat and provide a seal over a range of sizes of expansion; and~~

~~wherein a length of the docking station is adjustable;~~

~~an expandable valve that comprises:~~

~~an expandable frame that is expandable to engage the valve seat of the docking station;~~

~~a valve element connected to the expandable frame.~~

~~65. A system as is claim 64 wherein the docking station includes a first half that a second half extends into.~~

~~66. The system of any of claims 64-65 wherein the valve seat is not substantially expanded radially outwardly by a radially outward force of the expandable valve.~~

~~67. The system of any of claims 64-66 wherein the range of sizes comprises 27mm to 38mm.~~

~~68. The system of any of claims 64-67 wherein the docking station is configured to expand radially outwardly to varying degrees along its length L.~~

~~69. The system of any of claims 64-68 wherein the valve seat is formed by a suture.~~

~~70. The system of any of claims 64-69 wherein the sealing portion comprises a portion of a metal frame covered with a fabric.~~

~~71. The system of any of claims 64-70 wherein the sealing portion comprises an open cell foam.~~

~~72. The system of any of claims 64-71 wherein a portion of the docking station is permeable to blood and a portion of the docking station is impermeable to blood.~~

~~73. A method of installing an expandable valve in a docking station comprising:~~

~~—expanding a first docking station half;~~

~~—positioning a portion of a second docking station half in the first docking station half;~~

~~—expanding the second docking station half in the first docking station half to set a length of the docking station;~~

~~—wherein the docking station has a valve seat and a sealing portion;~~

~~—expanding a frame of an expandable valve to engage the valve seat of the docking station.~~

~~74. The method of claim 73 wherein the valve seat is not substantially expanded radially outwardly by a radially outward force of an expandable valve.~~

~~75. The method of any of claims 73-74 wherein a sealing portion has a predetermined range of sizes that comprises 27mm to 38mm.~~

~~76. The method of any of claims 73-75 wherein the valve seat is formed by a suture.~~

~~77. A delivery catheter comprising:~~

~~an outer tube having a distal opening, and~~

~~an inner tube disposed in the outer tube such that a gap is formed between the inner tube and the outer tube, wherein the inner tube has an opening at a proximal end and one or more side openings, and~~

~~wherein the delivery catheter is configured such that injecting flushing liquid into the proximal end of the inner tube flushes the flushing liquid through the inner tube with at least some of the flushing liquid exiting the inner tube through the one or more side openings to fill the gap and flush air out the distal opening of the outer tube.~~

~~78. — A delivery catheter as in claim 77 wherein the inner tube has a distal opening and the delivery catheter is configured such that the filling of the inner tube with the flushing liquid at the proximal end flushes the air out of the distal opening of the inner tube.~~

~~79. — A delivery catheter as in claim 78 wherein the inner tube is fillable with the flushing liquid at an opening for a guide wire at the proximal end of the inner tube.~~

~~80. — A delivery catheter as in claim 78 wherein the delivery catheter is configured such that the air in the inner tube can be flushed out through the distal opening of the inner tube and through an opening in a nosecone that is connected to the inner tube.~~

~~81. — A delivery catheter as in claim 79 wherein the delivery catheter is configured such that the air in the inner tube can be flushed out through the distal opening of the inner tube and through an opening in a nosecone that is connected to the inner tube.~~

~~82. — A method of flushing air from a delivery catheter comprising an outer tube having a distal opening, an inner tube that has a proximal opening at a proximal end of the inner tube and one or more side openings, and a gap formed in between the inner tube and the outer tube, the method comprising:~~

~~injecting flushing liquid into the proximal end of the inner tube, such that the flushing liquid flows through the inner tube and at least some of the flushing liquid exits the inner tube through the one or more side openings to fill the gap and flush air out the distal opening of the outer tube.~~

~~83. — The method of claim 82 wherein the inner tube has a distal opening and the method further comprises filling the inner tube with the flushing through the proximal opening,~~

~~wherein the proximal opening can also be used for passing a guide wire through the delivery catheter.~~

~~84. — The method of claim 83 wherein air in the inner tube is flushed out through the distal opening of the inner tube and through an opening in a nosecone that is connected to the inner tube.~~

~~85. — The method of any of claims 82-84 further comprising the step of inserting the delivery catheter into a blood vessel after the air has been flushed out.~~

~~86. — A catheter and docking station system comprising:~~

~~—— a sleeve;~~

~~—— a docking station retainer disposed in the sleeve, wherein the docking station retainer includes one or more retainer recesses;~~

~~—— a docking station disposed in the sleeve, wherein the docking station includes one or more extensions releasably attached to the docking station retainer, wherein each extension of the one or more extensions includes a head disposed in at least one of the one or more retainer recesses;~~

~~—— wherein each extension of the one or more docking extensions contacts the docking station retainer at only two points.~~

~~87. — The system of claim 86 wherein the head is triangular.~~

~~88. — The system of any of claims 86-87 wherein the one or more extensions consist of two extensions.~~

~~89. — The system of any of claims 86-88 wherein the one or more retainer recesses comprise a rectangular recess in the docking station retainer.~~

~~90. — The system of any of claims 86-89 wherein sides of the head extend away from one another at an angle of between 60 degrees and 120 degrees.~~

~~91. — The system of any of claims 86-90 wherein the sleeve engages the one or more extensions to retain the one or more heads in the retainer recess when the sleeve is positioned over the one or more extensions.~~

~~92. — The system of claim 91 wherein the one or more extensions spring radially outward relative to the docking station retainer when unconstrained by the sleeve to release the one or more extensions from the docking station retainer.~~

~~93. — The system of any of claims 86-92 wherein the one or more extensions are tiltable in the one or more recesses.~~

~~94. — A method of using a docking station comprising:~~

~~—— placing a head of a docking station extension in a recess of a docking station retainer, wherein the docking station extension contacts the docking station retainer at only two points;~~

~~—— placing the docking station and the docking station retainer in a sleeve, wherein the sleeve engages the docking station extension to retain the head of the docking station extension in the recess.~~

~~95. — The method of claim 94 wherein the head is triangular.~~

~~96. — The method of any of claims 94-95 wherein the recess comprises a rectangular recess in the docking station retainer.~~

~~97. — The method of any of claims 94-96 wherein sides of the head extend away from one another at an angle of between 60 degrees and 120 degrees.~~

~~98.~~—The method of any of claims 94-97 further comprising removing the retainer and the docking station from the sleeve such that the head of the docking station extension springs radially outward relative to the docking station retainer to release the docking station extension from the docking station retainer.

~~99.~~—The method of any of claims 94-98 further comprising tilting the extension in the recess.

~~100.~~—An system for deploying a docking station comprising:

a handle that includes:

—— a housing;

—— a drive member rotatably coupled to the housing; and

—— a driven member coupled to the drive member and the housing, such that rotation of the drive member moves the driven member linearly in the housing;

a catheter that includes:

—— an outer sleeve fixedly connected to the driven member; and

—— an inner sleeve disposed in the outer sleeve and fixedly connected to the housing;

wherein rotation of the drive member moves the outer sleeve relative to the inner sleeve.

~~101.~~—The system of claim 100 wherein the drive member comprises a wheel having a gear portion.

~~102.~~—The system of any of claims 100-101 wherein the drive member comprises an internally threaded member.

~~103.~~—The system of any of claims 100-102 wherein the driven member comprises a gear rack.

~~104.~~—The system of any of claims 100-103 wherein the driven member comprises an externally threaded member.

~~105.~~—The system of any of claims 100-104 further comprising a ratchet mechanism that is moveable from an engaged position to a disengaged position, wherein when the ratchet is in the engaged position the drive member is able to be rotated in only one direction.

~~106.~~—The system of any of claims 100-105 further comprising a luer port fixed to the inner sleeve, wherein the luer port and the inner sleeve are configured to accept a guide wire that extends through the inner shaft.

~~107.~~—A method of deploying a docking station comprising:

~~rotating a drive member relative to a housing to linearly move a driven member in the housing;~~

~~wherein an inner sleeve is fixed to the housing and an outer sleeve is fixed to the driven member such that the rotation of the drive member moves the outer sleeve relative to the inner sleeve.~~

~~108.~~—The method of claim 107 wherein the drive member linearly moves the driven member by engagement of gear teeth.

~~109.~~—The method of any of claims 107-108 wherein the drive member linearly moves the driven member by engagement of threads.

~~110.~~—The method of any of claims 107 further comprising only allowing the drive member to be rotated in one direction.

~~111. The method of any of claims 107 further comprising moving the first and second sleeves over a guide wire.~~

1. An expandable stent for implantation in a right ventricular outflow tract, the expandable stent comprising:

a frame including a plurality of struts that define a repeating pattern of cells, wherein the repeating pattern of cells comprises:

a column of exactly three generally diamond shaped cells positioned in end-to-end alignment;

a column of exactly two generally diamond shaped cells positioned in end-to-end alignment;

wherein the frame has a substantially hourglass shape with a narrow portion in between a proximal end portion and a distal end portion;

wherein the proximal end portion and the distal end portion are configured to expand radially outward to contact a right ventricular outflow tract;

wherein the distal end portion includes a first convex sealing portion for sealing engagement with an inner surface of the right ventricular outflow tract;

wherein the proximal end portion includes a flared retaining portion configured to engage the inner surface of the right ventricular outflow tract at an angle between 30° and 60°; and

wherein the proximal end portion includes a second convex sealing portion axially disposed between the narrow waist portion and the flared retaining portion.

2. The expandable stent of claim 1, further comprising a fabric cover secured to the narrow portion, the proximal end portion, and the distal end portion.

3. The expandable stent of claim 2, wherein the fabric cover is sewn to the frame.

4. The expandable stent of claim 1, wherein the narrow portion of the frame has an expanded diameter between 24 mm and 30 mm.

5. The expandable stent of claim 1, wherein the first convex sealing portion includes an outer radial portion oriented to sealingly engage the inner surface of the right ventricular outflow tract and a radially inward tapered portion extending axially away from the waist portion.

6. The expandable stent of claim 1, wherein the flared retaining portion is sized to expand into retaining engagement with a portion of the inner surface of the right ventricular outflow tract having a vessel diameter of up to 40 mm.

7. The expandable stent of claim 1, wherein the first convex sealing portion is sized to expand into sealing engagement with a portion of the inner surface of the right ventricular outflow tract having a vessel diameter of up to 40 mm.

8. The expandable stent of claim 1, wherein the distal end portion includes a second flared retaining portion configured to engage the inner surface of the right ventricular outflow tract at an angle between 30° and 60°.

9. The expandable stent of claim 8, wherein the distal end portion includes a concave portion extending between the first convex sealing portion and the second flared retaining portion.

10. A valve assembly for implantation in a right ventricular outflow tract, the valve assembly comprising a frame having a substantially hourglass shape with a narrow portion in between a proximal end portion and a distal end portion, and a prosthetic valve secured to the frame in the narrow portion, the frame comprising:

a plurality of struts that define a repeating pattern of cells, wherein the repeating pattern of cells comprises:

a column of exactly three generally diamond shaped cells positioned in end-to-end alignment;

a column of exactly two generally diamond shaped cells positioned in end-to-end alignment;

wherein the proximal end portion and the distal end portion are configured to expand radially outward to contact a right ventricular outflow tract;

wherein the distal end portion includes a first convex sealing portion for sealing engagement with an inner surface of the right ventricular outflow tract;

wherein the proximal end portion includes a flared retaining portion configured to engage the inner surface of the right ventricular outflow tract at an angle between 30° and 60°; and

wherein the proximal end portion includes a second convex sealing portion axially disposed between the narrow waist portion and the flared retaining portion.

11. The valve assembly of claim 10, further comprising a fabric cover secured to the narrow portion, the proximal end portion, and the distal end portion.

12. The valve assembly of claim 11, wherein the fabric cover is sewn to the frame.

13. The valve assembly of claim 10, wherein the narrow portion of the frame has an expanded diameter between 24 mm and 30 mm.

14. The valve assembly of claim 10, wherein the first convex sealing portion includes an outer radial portion oriented to sealingly engage the inner surface of the right ventricular outflow tract and a radially inward tapered portion extending axially away from the waist portion.

15. The valve assembly of claim 10, wherein the flared retaining portion is sized to expand into retaining engagement with a portion of the inner surface of the right ventricular outflow tract having a vessel diameter of up to 40 mm.

16. The valve assembly of claim 10, wherein the first convex sealing portion is sized to expand into sealing engagement with a portion of the inner surface of the right ventricular outflow tract having a vessel diameter of up to 40 mm.

17. The valve assembly of claim 10, wherein the distal end portion includes a second flared retaining portion configured to engage the inner surface of the right ventricular outflow tract at an angle between 30° and 60°.

18. The valve assembly of claim 17, wherein the distal end portion includes a concave portion extending between the first convex sealing portion and the second flared retaining portion.

19. A system comprising:

a catheter including a sleeve;

an expandable stent for implantation in a right ventricular outflow tract, wherein the expandable stent is disposed in the sleeve, the expandable stent comprising:

a frame including a plurality of struts that define a repeating pattern of cells, wherein the repeating pattern of cells comprises:

a column of exactly three generally diamond shaped cells positioned in end-to-end alignment;

a column of exactly two generally diamond shaped cells positioned in end-to-end alignment;

wherein the frame has a substantially hourglass shape with a narrow portion in between a proximal end portion and a distal end portion;

wherein the proximal end portion and the distal end portion are configured to expand radially outward to contact a right ventricular outflow tract;

wherein the distal end portion includes a first convex sealing portion for sealing engagement with an inner surface of the right ventricular outflow tract;

wherein the proximal end portion includes a flared retaining portion configured to engage the inner surface of the right ventricular outflow tract at an angle between 30° and 60°; and

wherein the proximal end portion includes a second convex sealing portion axially disposed between the narrow waist portion and the flared retaining portion.

20. The system of claim 19, further comprising a fabric cover secured to the narrow portion, the proximal end portion, and the distal end portion.

21. The system of claim 19, wherein the narrow portion of the frame has an expanded diameter between 24 mm and 30 mm.

22. The system of claim 19, wherein the first convex sealing portion includes an outer radial portion oriented to sealingly engage the inner surface of the right ventricular outflow tract and a radially inward tapered portion extending axially away from the waist portion.

23. The system of claim 19, wherein the flared retaining portion is sized to expand into retaining engagement with a portion of the inner surface of the right ventricular outflow tract having a vessel diameter of up to 40 mm.

24. The system of claim 19, wherein the first convex sealing portion is sized to expand into sealing engagement with a portion of the inner surface of the right ventricular outflow tract having a vessel diameter of up to 40 mm.

25. The system of claim 19, wherein the distal end portion includes a second flared retaining portion configured to engage the inner surface of the right ventricular outflow tract at an angle between 30° and 60°.

26. The system of claim 25, wherein the distal end portion includes a concave portion extending between the first convex sealing portion and the second flared retaining portion.