

WHAT IS CLAIMED IS:

1. An annuloplasty ring prosthesis comprising:
a frame comprising an outer surface; and
a cover surrounding the frame, the cover comprising a fixed, non-regenerative bioprosthetic tissue.
2. The annuloplasty ring prosthesis of claim 1, wherein the fixed, non-regenerative bioprosthetic tissue is selected from the group consisting of: pericardium, blood vessels, skin, dura mater, small intestinal submucosa, ligaments, tendons, muscle, ureter, urinary bladder, liver, and heart.
3. The annuloplasty ring prosthesis of claim 2, wherein the fixed, non-regenerative bioprosthetic tissue is a pericardium.
4. The annuloplasty ring prosthesis of any one of the preceding claims, wherein the fixed, non-regenerative bioprosthetic tissue is fixed with an aldehyde.
5. The annuloplasty ring prosthesis of claim 4, wherein the aldehyde is a glutaraldehyde.
6. The annuloplasty ring prosthesis of claim 4, wherein free aldehyde groups in the fixed, non-regenerative bioprosthetic tissue are subjected to a capping treatment comprising a capping agent.
7. The annuloplasty ring prosthesis of claim 6, wherein the capping agent comprises an amine.
8. The annuloplasty ring prosthesis of claim 7, wherein the capping treatment further comprises a reducing agent.
9. The annuloplasty ring prosthesis of claim 8, wherein the reducing agent is a borohydride.
10. The annuloplasty ring prosthesis of any one of the preceding claims, wherein the fixed, non-regenerative bioprosthetic tissue is plasticized.
11. The annuloplasty ring prosthesis of claim 10, wherein the fixed, non-regenerative bioprosthetic tissue is plasticized with a polyol.
12. The annuloplasty ring prosthesis of claim 11, wherein the polyol is a glycerol.

13. The annuloplasty ring prosthesis of any one of the preceding claims, wherein:
- the cover comprises a sheet having a first edge and a second edge;
- the sheet covers the outer surface of the frame; and
- the first edge and the second edge are joined together to form a seam.
14. The annuloplasty ring prosthesis of claim 13, wherein:
- the sheet is dimensioned to permit the first edge and the second edge of the sheet to fold or roll upon each other to form a lip; and
- the lip protrudes away from the outer surface of the frame.
15. The annuloplasty ring prosthesis of any one of the preceding claims, wherein the frame comprises one or both of a non-degradable polymer and a non-degradable metal or metal alloy.
16. The annuloplasty ring prosthesis of claim 15, wherein the frame comprises a non-degradable metal or metal alloy selected from the group consisting of: stainless steel, a nickel-based alloy, a cobalt-chromium alloy, a nickel-cobalt-chromium alloy, Nitinol, and combinations thereof.
17. An annuloplasty ring prosthesis comprising:
- a frame comprising an outer surface; and
- a cover surrounding the frame, the cover comprising a regenerative bioprosthetic tissue.
18. The annuloplasty ring prosthesis of claim 17, wherein the regenerative bioprosthetic tissue is a decellularized biological tissue.
19. The annuloplasty ring prosthesis of claim 18, wherein the decellularized tissue is selected from the group consisting of: pericardium, blood vessels, skin, dura mater, small intestinal submucosa, ligaments, tendons, muscle, ureter, urinary bladder, liver, and heart.
20. The annuloplasty ring prosthesis of claim 18, wherein the regenerative bioprosthetic tissue is an artificial scaffold.
21. The annuloplasty ring prosthesis of claim 20, wherein the artificial scaffold is a biodegradable polymer scaffold.
22. The annuloplasty ring prosthesis of claim 21, wherein the biodegradable polymer scaffold comprises a polyglycolic acid.

23. The annuloplasty ring prosthesis of any one of claims 20 to 22, wherein the artificial scaffold further comprises an extracellular matrix protein.

24. The annuloplasty ring prosthesis of claim 23, wherein the extracellular matrix protein is one or more proteins selected from the group consisting of: hydroxyproline, vitronectin, fibronectin, collagen I, collagen III, collagen IV, collagen VI, collagen XI, collagen XII, fibrillin I, tenascin, decorin, biglycan, versican, asporin, agrin, and combinations thereof.

25. The annuloplasty ring prosthesis of any one of claims 17 to 24, wherein:
the cover comprises a sheet having a first edge and a second edge;
the sheet covers the outer surface of the frame; and
the first edge and the second edge are joined together to form a seam.

26. The annuloplasty ring prosthesis of claim 25, wherein:
the sheet is dimensioned to permit the first edge and the second edge of the sheet
to fold or roll upon each other to form a lip; and
the lip protrudes away from the outer surface of the frame.

27. The annuloplasty ring prosthesis of any one of claims 17 to 26, wherein the frame comprises one or both of a non-degradable polymer and a non-degradable metal or metal alloy.

28. The annuloplasty ring prosthesis of claim 27, wherein the frame comprises a non-degradable metal or metal alloy selected from the group consisting of: stainless steel, a nickel-based alloy, a cobalt-chromium alloy, a nickel-cobalt-chromium alloy, Nitinol, and combinations thereof.

29. An annuloplasty ring prosthesis comprising:
a bioabsorbable frame comprising an outer surface; and
a cover surrounding the frame, the cover comprising a fixed, non-regenerative bioprosthetic tissue.

30. The annuloplasty ring prosthesis of claim 29, wherein the bioabsorbable frame comprises a metal or a metal alloy.

31. The annuloplasty ring prosthesis of claim 30, wherein the metal or the metal alloy comprises one or a combination selected from the group consisting of magnesium, aluminum, iron, and zinc.

32. The annuloplasty ring prosthesis of one of claims 30 or 31, wherein:

the metal or the metal alloy has an ultimate tensile strength of about 30 MPa to about 400 MPa; and

the metal or the metal alloy has an elongation of about 0.3 percent to about 170 percent.

33. The annuloplasty ring prosthesis of any one of claims 29 to 32, wherein the bioabsorbable frame is a bioabsorbable material.

34. The annuloplasty ring prosthesis of claim 33, wherein the bioabsorbable material is one or a combination of polymers selected from the group consisting of: poly(L-lactide), poly(D-lactide), polyglycolide, poly(L-lactide-co-glycolide), polyhydroxyalkonate, polysaccharides, polyesters, polyhydroxyalkanoates, polyalkelene esters, polyamides, polycaprolactone, polylactide-co-polycaprolactone, polyvinyl esters, polyamide esters, polyvinyl alcohols, modified derivatives of caprolactone polymers, polytrimethylene carbonate, polyacrylates, polyethylene glycol, terminal dials, poly(L-lactide-co-trimethylene carbonate), polyhydroxybutyrate, polyhydroxyvalerate, poly-orthoesters, poly-anhydrides, polyiminocarbonate, and copolymers.

35. The annuloplasty ring prosthesis of any one of claims 29 to 34, wherein the bioabsorbable frame is reinforced with a reinforcing composition.

36. The annuloplasty ring prosthesis of claim 35, wherein the reinforcing composition comprises magnesium or a magnesium alloy.

37. The annuloplasty ring prosthesis of any one of claims 29 to 36, wherein the fixed, non-regenerative bioprosthetic tissue is selected from the group consisting of: pericardium, blood vessels, skin, dura mater, small intestinal submucosa, ligaments, tendons, muscle, ureter, urinary bladder, liver, and heart.

38. The annuloplasty ring prosthesis of claim 36, wherein the fixed, non-regenerative bioprosthetic tissue is a pericardium.

39. The annuloplasty ring prosthesis of any one of claims 29 to 38, wherein the fixed, non-regenerative bioprosthetic tissue is fixed with an aldehyde.

40. The annuloplasty ring prosthesis of claim 39, wherein the aldehyde is a glutaraldehyde.

41. The annuloplasty ring prosthesis of any one of claims 39 or 40, wherein free aldehyde groups in the fixed, non-regenerative bioprosthetic tissue are subjected to a capping treatment comprising a capping agent.

42. The annuloplasty ring prosthesis of claim 41, wherein the capping agent comprises an amine.

43. The annuloplasty ring prosthesis of claim 42, wherein the capping treatment further comprises a reducing agent.

44. The annuloplasty ring prosthesis of claim 43, wherein the reducing agent is a borohydride.

45. The annuloplasty ring prosthesis of any one of claims 29 to 44, wherein the fixed, non-regenerative bioprosthetic tissue is plasticized.

46. The annuloplasty ring prosthesis of claim 45, wherein the fixed, non-regenerative bioprosthetic tissue is plasticized with a polyol.

47. The annuloplasty ring prosthesis of claim 46, wherein the polyol is a glycerol.

48. An annuloplasty ring prosthesis comprising:
a bioabsorbable frame comprising an outer surface; and
a cover surrounding the frame, the cover comprising a regenerative bioprosthetic tissue.

49. The annuloplasty ring prosthesis of claim 48, wherein the bioabsorbable frame comprises a metal or a metal alloy.

50. The annuloplasty ring prosthesis of claim 49, wherein the metal or the metal alloy comprises one or a combination selected from the group consisting of magnesium, aluminum, iron, and zinc.

51. The annuloplasty ring prosthesis of one of claims 49 or 50, wherein:
the metal or the metal alloy has an ultimate tensile strength of about 30 MPa to about 400 MPa; and
the metal or the metal alloy has an elongation of about 0.3 percent to about 170 percent.

52. The annuloplasty ring prosthesis of any one of claims 48 to 51 wherein the bioabsorbable frame is a bioabsorbable material.

53. The annuloplasty ring prosthesis of claim 52, wherein the bioabsorbable material is one or a combination of polymers selected from the group consisting of: poly(L-lactide), poly(D-lactide), polyglycolide, poly(L-lactide-co-glycolide), polyhydroxyalkonate, polysaccharides, polyesters, polyhydroxyalkanoates, polyalkelene

esters, polyamides, polycaprolactone, polylactide-co-polycaprolactone, polyvinyl esters, polyamide esters, polyvinyl alcohols, modified derivatives of caprolactone polymers, polytrimethylene carbonate, polyacrylates, polyethylene glycol, terminal dials, poly(L-lactide-co-trimethylene carbonate), polyhydroxybutyrate, polyhydroxyvalerate, poly-orthoesters, poly-anhydrides, polyiminocarbonate, and copolymers.

54. The annuloplasty ring prosthesis of any one of claims 48 to 53, wherein the bioabsorbable frame is reinforced with a reinforcing composition.

55. The annuloplasty ring prosthesis of claim 54, wherein the reinforcing composition comprises magnesium or a magnesium alloy.

56. The annuloplasty ring prosthesis of any one of claims 48 to 55, wherein the regenerative bioprosthetic tissue is a decellularized biological tissue.

57. The annuloplasty ring prosthesis of claim 56, wherein the decellularized tissue is selected from the group consisting of: pericardium, blood vessels, skin, dura mater, small intestinal submucosa, ligaments, tendons, muscle, ureter, urinary bladder, liver, and heart.

58. The annuloplasty ring prosthesis of claim 56, wherein the regenerative bioprosthetic tissue is an artificial scaffold.

59. The annuloplasty ring prosthesis of claim 58, wherein the artificial scaffold is a biodegradable polymer scaffold.

60. The annuloplasty ring prosthesis of claim 59, wherein the biodegradable polymer scaffold comprises a polyglycolic acid.

61. The annuloplasty ring prosthesis of any one of claims 58 to 60, wherein the artificial scaffold further comprises an extracellular matrix protein.

62. The annuloplasty ring prosthesis of claim 61, wherein the extracellular matrix protein is one or more proteins selected from the group consisting of: hydroxyproline, vitronectin, fibronectin, collagen I, collagen III, collagen IV, collagen VI, collagen XI, collagen XII, fibrillin I, tenascin, decorin, biglycan, versican, asporin, agrin, and combinations thereof.

63. The annuloplasty ring prosthesis of any one of claims 48 to 62, wherein:
the cover comprises a sheet having a first edge and a second edge;
the sheet covers the outer surface of the frame; and
the first edge and the second edge are joined together to form a seam.

64. The annuloplasty ring prosthesis of claim 63, wherein:
the sheet is dimensioned to permit the first edge and the second edge of the sheet
to fold or roll upon each other to form a lip; and
the lip protrudes away from the outer surface of the frame.
65. A sewing ring for a prosthetic heart valve, the sewing ring comprising:
a suture-permeable annular member comprising an outer surface; and
a cover surrounding the annular member;
wherein the cover comprises a bioprosthetic tissue.
66. The sewing ring of claim 65, wherein the bioprosthetic tissue is fixed and
non-regenerative.
67. The sewing ring of claim 66, wherein the fixed, non-regenerative
bioprosthetic tissue is selected from the group consisting of: pericardium, blood vessels,
skin, dura mater, small intestinal submucosa, ligaments, tendons, muscle, ureter,
urinary bladder, liver, and heart.
68. The sewing ring of claim 67, wherein the fixed, non-regenerative
bioprosthetic tissue is a pericardium.
69. The sewing ring of any one of claims 65 to 68, wherein the fixed, non-
regenerative bioprosthetic tissue is fixed with an aldehyde.
70. The sewing ring of claim 69, wherein the aldehyde is a glutaraldehyde.
71. The sewing ring of any one of claims 69 or 70, wherein free aldehyde
groups in the fixed, non-regenerative bioprosthetic tissue are subjected to a capping
treatment comprising a capping agent.
72. The sewing ring of claim 71, wherein the capping agent comprises an
amine.
73. The sewing ring of claim 72, wherein the capping treatment further
comprises a reducing agent.
74. The sewing ring of claim 73, wherein the reducing agent is a borohydride.
75. The sewing ring of any one of claims 65 to 74, wherein the fixed, non-
regenerative bioprosthetic tissue is plasticized.
76. The sewing ring of claim 75, wherein the fixed, non-regenerative
bioprosthetic tissue is plasticized with a polyol.

77. The annuloplasty ring prosthesis of claim 76, wherein the polyol is a glycerol.
78. The sewing ring of claim 65, wherein the bioprosthetic tissue is regenerative.
79. The sewing ring of claim 78, wherein the regenerative bioprosthetic tissue is a decellularized biological tissue.
80. The sewing ring of claim 79, wherein the decellularized tissue is selected from the group consisting of: pericardium, blood vessels, skin, dura mater, small intestinal submucosa, ligaments, tendons, muscle, ureter, urinary bladder, liver, and heart.
81. The sewing ring of claim 80, wherein the regenerative bioprosthetic tissue is an artificial scaffold.
82. The sewing ring of claim 81, wherein the artificial scaffold is a biodegradable polymer scaffold.
83. The sewing ring of claim 82, wherein the biodegradable polymer scaffold comprises a polyglycolic acid.
84. The sewing ring of any one of claims 81 to 83, wherein the artificial scaffold further comprises an extracellular matrix protein.
85. The sewing ring of claim 84, wherein the extracellular matrix protein is one or more proteins selected from the group consisting of: hydroxyproline, vitronectin, fibronectin, collagen I, collagen III, collagen IV, collagen VI, collagen XI, collagen XII, fibrillin I, tenascin, decorin, biglycan, versican, asporin, agrin, and combinations thereof.
86. The sewing ring of any one of claims 65 to 85, wherein:
the cover comprises a sheet having a first edge and a second edge;
the sheet covers an outer surface of the annular member; and
the first edge and the second edge are joined together to form a seam.
87. The sewing ring of claim 86, wherein:
the sheet is dimensioned to permit the first edge and the second edge of the sheet
to fold or roll upon each other to form a lip; and
the lip protrudes away from the outer surface of the annular member.

88. The sewing ring of any one of claims 65 to 87, wherein the annular member comprises a molded polymer.

89. The sewing ring of claim 88, wherein the molded polymer is selected from the group consisting of: silicone, polyurethane, and combinations thereof.

90. The sewing ring of any one of claims 65 to 89, wherein the prosthetic heart valve comprises:

a support frame defining an orifice about an axis along an inflow-outflow direction; and

a plurality of leaflets mounted for movement on the support frame to provide a one-way valve in the orifice;

wherein each of the plurality of leaflets comprises the bioprosthetic tissue; and

wherein the sewing ring is connected to and positioned around the support frame for attaching the heart valve to a valve annulus.

91. A ring prosthesis comprising:

an elongated rod member formed into a substantially ring shape, the elongated rod member having a rod body, first and second ends and a free edge between the first and second ends;

wherein the free edge is secured to the rod body; and

wherein the elongated rod member is formed from a substantially flat

bioprosthetic tissue having a length, a width, a first surface and a second surface opposing the first surface.

92. The ring prosthesis of claim 91, wherein the second surface of the bioprosthetic tissue has a texture that is smoother than the first surface of the bioprosthetic tissue.

93. The ring prosthesis of claim 91, wherein the first surface of the bioprosthetic tissue has a texture that is rougher than the second surface of the bioprosthetic tissue.

94. The ring prosthesis of any one of claims 91 to 93, wherein the first surface of the bioprosthetic tissue forms an external surface of the rod body.

95. The ring prosthesis of any one of claims 91 to 93, wherein the second surface of the bioprosthetic tissue forms an external surface of the rod body.

96. The ring prosthesis of any one of claims 91 to 95, wherein the free edge is secured to the rod body with sutures.

97. The ring prosthesis of claim 96, wherein the elongated rod member consists of the substantially flat bioprosthetic tissue and sutures.

98. The ring prosthesis of any one of claims 91 to 95, wherein the free edge is secured to the rod body with an adhesive.

99. The ring prosthesis of claim 98, wherein the elongated rod member consists of the substantially flat bioprosthetic tissue and the adhesive.

100. The ring prosthesis of any one of claims 91 to 99, wherein the ring prosthesis does not have a frame or a support.

101. The ring prosthesis of any one of claims 91 to 98, wherein the ring prosthesis consists essentially of the bioprosthetic tissue.

102. The ring prosthesis of any one of claims 91 to 98, wherein the elongated rod member consists essentially of the bioprosthetic tissue.

103. The ring prosthesis of any one of claims 91 to 102, wherein the first and second ends of the elongated rod member are spaced apart such that the ring prosthesis is an open ring.

104. The ring prosthesis of any one of claims 91 to 102, wherein the first and second ends of the elongated rod members are joined together such that the ring prosthesis is a closed ring.

105. The ring prosthesis of any one of claims 91 to 104, wherein the elongated rod member has a substantially cylindrical shape and wherein the substantially flat bioprosthetic tissue is rolled upon itself to form the substantially cylindrical shape.

106. The ring prosthesis of any one of claims 91 to 104, wherein the elongated rod member has a substantially triangular shape and wherein the substantially flat bioprosthetic tissue is folded upon itself to form the substantially triangular shape.

107. The ring prosthesis of any one of claims 91 to 104, wherein the elongated rod member has a substantially rectilinear shape and wherein the substantially flat bioprosthetic tissue is folded upon itself to form the substantially rectilinear shape.

108. The ring prosthesis of claim 107, wherein the substantially flat bioprosthetic tissue is folded upon itself in an alternating sequence to form the substantially rectilinear shape.

109. The ring prosthesis of any one of claims 91 to 108, wherein the bioprosthetic tissue is a decellularized tissue.

110. The ring prosthesis of any one of claims 91 to 108, wherein the bioprosthetic tissue is an artificial scaffold.

111. The ring prosthesis of any one of claims 91 to 108 wherein the bioprosthetic tissue is selected from the group consisting of: pericardium, blood vessels, skin, dura mater, small intestinal submucosa, ligaments, tendons, muscle, ureter, urinary bladder, liver, and heart.

112. The ring prosthesis of claim 111, wherein the bioprosthetic tissue is a pericardium.

113. The ring prosthesis of claim 112, wherein the bioprosthetic tissue is fixed with an aldehyde.

114. The ring prosthesis of claim 113, wherein the aldehyde is a glutaraldehyde.

115. The ring prosthesis of claim 113, wherein free aldehyde groups in the fixed bioprosthetic tissue are subjected to a capping treatment with a capping agent.

116. The ring prosthesis of claim 115, wherein the capping agent comprises an amine.

117. The ring prosthesis of claim 116, wherein the capping treatment further comprises a reducing agent.

118. The ring prosthesis of claim 117, wherein the reducing agent is a borohydride.

119. The ring prosthesis of any one of claims 91 to 118, wherein the bioprosthetic tissue is plasticized.

120. The ring prosthesis of claim 119, wherein the bioprosthetic tissue is plasticized with a polyol.

121. The ring prosthesis of claim 120, wherein the polyol is a glycerol.

122. A method for simulating treating endocarditis in a simulated patient in need thereof, the method comprising simulating implanting the annuloplasty ring prosthesis of any one of claims 1 to 64 into a simulated patient having endocarditis.

123. A method for simulating treating endocarditis in a simulated patient in need thereof, the method comprising simulating implanting the sewing ring prosthesis of any one of claims 65 to 90 into a simulated patient having endocarditis.

124. A method for simulating treating endocarditis in a simulated patient in need thereof, the method comprising simulating implanting the ring prosthesis of any one of claims 91 to 121 into a simulated patient having endocarditis.

125. A method of manufacturing a ring prosthesis, the method comprising:
shaping a substantially flat bioprosthetic tissue to form an elongated rod,
wherein the bioprosthetic tissue has a length, a width, a first surface and
a second surface opposing the first surface,
wherein the rod comprises a body having first and second ends and a free
edge between the first and second ends;
securing the free edge of the rod onto the rod body; and
arranging the first and second ends of the rod body in proximity to one other such
that the rod is substantially shaped as a ring.

126. The method of claim 125, wherein the shaping comprises folding the substantially flat bioprosthetic tissue.

127. The method of claim 125, wherein the shaping comprises rolling the substantially flat bioprosthetic tissue.

128. The method of claim 125, wherein the first surface is rough or fibrous and the second surface is smoother than the first surface.

129. The method of claim 128, wherein the first surface forms an exposed surface of the elongated rod and the second surface forms an internal surface of the elongated rod.

130. The method of claim 128, wherein the second surface forms an exposed surface of the elongated rod and the first surface form an internal surface of the elongated rod.

131. The method of any one of claims 125 to 130, wherein the step of securing comprises suturing the free edge of the rod onto the rod body.

132. The method of any one of claims 125 to 130, wherein the step of securing comprises gluing the free edge of the rod onto the rod body.

133. The method of any one of claims 125 to 121, wherein the rod is substantially shaped as an open ring.

134. The method of any one of claims 114 to 131, wherein the first and second ends of the rod body are joined together to form a closed ring.

135. The method of claim 134, wherein the first and second ends are joined with sutures.

136. The method of claim 134, wherein the first and second ends are joined with an adhesive.

137. The method of any one of claims 125 to 136, wherein a cross-section of the rod body is substantially circular.

138. The method of any one of claims 125 to 136, wherein a cross-section of the rod body is substantially triangular.

139. The method of any one of claims 125 to 136, wherein a cross-section of the rod body is substantially rectangular.

140. The method of any one of claims 125 to 139, further comprising decellularizing the bioprosthetic tissue.

141. The method of any one of claims 125 to 140, wherein the bioprosthetic tissue is selected from the group consisting of: pericardium, blood vessels, skin, dura mater, small intestinal submucosa, ligaments, tendons, muscle, ureter, urinary bladder, liver, and heart.

142. The ring prosthesis of claim 141, wherein the bioprosthetic tissue is a pericardium.

143. The ring prosthesis of any one of claims 125 to 141, wherein the bioprosthetic tissue is fixed with an aldehyde.

144. The ring prosthesis of claim 143, wherein the aldehyde is a glutaraldehyde.

145. The ring prosthesis of claim 144, wherein free aldehyde groups in the fixed bioprosthetic tissue are subjected to a capping treatment with a capping agent.

146. The ring prosthesis of claim 145, wherein the capping agent comprises an amine.

147. The ring prosthesis of claim 146, wherein the capping treatment further comprises a reducing agent.

148. The ring prosthesis of claim 147, wherein the reducing agent is a borohydride.

149. The ring prosthesis of any one of claims 125 to 148, wherein the bioprosthetic tissue is plasticized.

150. The ring prosthesis of claim 149, wherein the bioprosthetic tissue is plasticized with a polyol.

151. The ring prosthesis of claim 150, wherein the polyol is a glycerol.