

## CLAIMS

What is claimed is:

1. An assembly, comprising:  
a prosthetic heart valve including:

5                                   a frame; and  
                                  a tissue leaflet assembly attached to the frame;  
                  a percutaneously insertable valve delivery mechanism, wherein the prosthetic heart valve  
is releasably mounted onto the percutaneously insertable valve delivery mechanism; and  
                  sterile packaging containing the prosthetic heart valve releasably mounted onto the  
10 percutaneously insertable valve delivery mechanism.

2. The assembly of Claim 1, wherein the percutaneously insertable valve delivery  
mechanism comprises a balloon catheter.

3. The assembly of Claim 2, wherein the balloon catheter is a 12 to 14 French  
balloon catheter.

15       4. The assembly of Claim 2, wherein the balloon catheter is less than about 12  
French.

5. The assembly of Claim 2, wherein the balloon catheter is between about 5 to 12  
French.

20       6. The assembly of Claim 1, wherein the percutaneously insertable valve delivery  
mechanism comprises a mandrel.

7. The assembly of Claim 1, wherein tissue forming the tissue leaflet assembly  
within the sterile packaging is at least one of hydrated and not substantially dry.

8. The assembly of Claim 1, wherein tissue forming the tissue leaflet assembly  
within the sterile packaging is substantially dry.

25       9. The assembly of Claim 1, wherein the frame comprises a stent.

10. The assembly of Claim 1, wherein tissue forming the tissue leaflet assembly  
comprises treated pericardium tissue.

11. A pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve  
ready for implantation in a patient, comprising:

30                                   a frame; and  
                                  a tissue leaflet assembly attached to the frame, the tissue leaflet assembly comprising a  
substantially dry tissue.

12. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve  
of Claim 11, wherein the substantially dry tissue comprises treated pericardium tissue.

13. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the substantially dry tissue comprises a water moisture content of less than about 40% by weight of the substantially dry tissue.

14. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the frame and the tissue leaflet assembly attached thereto are operably associated with a 12 to 14 French balloon catheter.

15. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the frame and the tissue leaflet assembly attached thereto are operably associated with a balloon catheter having a size of less than about 12 French.

16. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the frame and the tissue leaflet assembly attached thereto are operably associated with a balloon catheter having a size of between about 5 to 12 French.

17. An assembly for use with a patient, comprising:  
a sealed sterile package containing a delivery system for percutaneously deploying a heart valve in the patient, the heart valve including:

a frame releasably mounted on the delivery system within the sealed sterile package; and

a tissue leaflet assembly attached to the frame.

18. The assembly of Claim 17, wherein the tissue leaflet assembly comprises a treated pericardium tissue.

19. The assembly of Claim 17, wherein the delivery system includes a percutaneously insertable balloon catheter.

20. The assembly of Claim 19, wherein the balloon catheter is a 12 to 14 French balloon catheter.

21. The assembly of Claim 19, wherein the balloon catheter is less than about 12 French.

22. The assembly of Claim 19, wherein the balloon catheter is between about 5 to 12 French.

23. The assembly of Claim 17, wherein the delivery system includes a percutaneously insertable mandrel.

24. The assembly of Claim 17, wherein the tissue leaflet assembly within the sealed sterile package is at least one of partially hydrated and not substantially dry.

25. The assembly of Claim 17, wherein the tissue leaflet assembly within the sealed sterile package is substantially dry.

26. The assembly of Claim 17, wherein the frame comprises a stent.

27. An article adapted for implantation in a patient, comprising:  
a prosthetic heart valve further comprising a treated tissue attached to a frame, wherein  
the treated tissue comprises a water content of less than about 60% by weight of the treated  
tissue.

5 28. The article of Claim 27, wherein the treated tissue comprises a section of treated  
pericardium tissue having an ultimate tensile strength of greater than about 12 MegaPascals.

29. The article of Claim 28, wherein the section of pericardium tissue comprises a  
thickness of between about 50 to 300 micrometers.

10 30. The article of Claim 27, wherein the water content of the treated tissue is less  
than about 40% by weight of the treated tissue.

31. An article adapted for trans-catheter delivery into a patient, comprising:  
a prosthetic heart valve further comprising a treated tissue attached to a frame, wherein  
the treated tissue comprises a thickness of about 50 to 500 micrometers and an ultimate tensile  
strength of greater than about 15 MegaPascals when at a water content of less than about 50%  
15 by weight of the treated tissue.

32. The article of Claim 31, wherein the treated tissue comprises a treated  
pericardium tissue.

33. The article of Claim 31, wherein the water content of the treated tissue is less  
than about 40% by weight of the treated tissue.

20 34. The article of Claim 31, wherein the ultimate tensile strength is greater than about  
20 MegaPascals.

35. The article of Claim 31, wherein the treated tissue does not include a matrix that  
has been exposed to a polymer infiltrate.

36. A method, comprising:  
25 partially compressing and mounting a prosthetic heart valve upon a delivery catheter, the  
prosthetic heart valve comprising a tissue;  
allowing the tissue to at least partially dry;  
further compressing and mounting the prosthetic heart valve upon the delivery catheter;  
and

30 sterilizing and packaging the prosthetic heart valve and delivery catheter.

37. The method of Claim 36, further comprising transporting the sterilized and  
packaged prosthetic heart valve and delivery catheter.

38. The method of Claim 36, wherein the tissue comprises a treated pericardium  
tissue.

39. The method of Claim 36, wherein prior to partially compressing and mounting the prosthetic heart valve upon the delivery catheter, the tissue is at least one of (a) not substantially dry, and (b) at least partially hydrated.

40. A method, comprising:

5 attaching a tissue to a frame;  
partially compressing and mounting the frame, with the tissue attached thereto, upon a delivery catheter;  
allowing the tissue to at least partially dry;  
further compressing and mounting the frame, with the tissue attached thereto, upon the  
10 delivery catheter; and  
sterilizing and packaging the frame and delivery catheter, with the tissue attached thereto.

41. The method of Claim 40, wherein prior to partially compressing and mounting the frame, the tissue is at least one of (a) not substantially dry, and (b) at least partially hydrated.

15 42. The method of Claim 40, further comprising transporting the sterilized and packaged frame, with the tissue attached thereto, mounted upon the delivery catheter, to a surgical or medical procedure facility.

43. The method of Claim 40, wherein prior to attaching the tissue to the frame the tissue is folded to form a tissue leaflet assembly.

20 44. The method of Claim 43, wherein the tissue leaflet assembly comprises at least one cuff and at least one pleat.

45. The method of Claim 40, wherein the tissue comprises a treated pericardium tissue.

25 46. A method of preparing a percutaneous, trans-catheter prosthetic heart valve, comprising:

providing a membrane tissue from an organism;  
treating the membrane tissue with at least one chemical to produce a treated membrane tissue;

drying the treated membrane tissue until it is a substantially dry tissue;

30 attaching the substantially dry tissue to a frame;

rehydrating the substantially dry tissue that is attached to the frame to form a rehydrated tissue;

collapsing the frame with the rehydrated tissue attached thereto; and

35 drying the rehydrated tissue attached to the collapsed frame until it is a substantially dry tissue.

47. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, further comprising compressing and mounting the frame, with the tissue attached thereto, upon a delivery catheter.

48. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 47, further comprising sterilizing and packaging the frame, with the substantially dry tissue attached thereto, mounted upon the delivery catheter.

49. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 48, further comprising at least one of transporting and shipping the sterilized and packaged frame with the substantially dry tissue attached thereto, mounted upon the delivery catheter, to a surgical or medical procedure facility.

50. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 49, further comprising implanting the frame with the substantially dry tissue attached thereto into a patient.

51. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein the frame comprises a stent.

52. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein prior to the attaching step the dry tissue is not folded with a cuff and a pleat.

53. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein prior to the attaching step the dry tissue is folded to form a tissue leaflet assembly.

54. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, wherein the tissue leaflet assembly comprises at least one cuff and at least one pleat.

55. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a 12 to 14 French balloon catheter.

56. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a balloon catheter having a size of less than about 12 French.

57. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a balloon catheter having a size of between about 5 to 12 French.

58. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, further comprising mounting the frame and the tissue leaflet assembly attached thereto on a mandrel.

59. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, further comprising sterilizing the frame with the substantially dry tissue attached thereto with exposure to at least one of ethylene oxide, a proton beam, and gamma radiation.

60. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1 – 37.5% formalin solution for between about 3 days to 3 weeks.

61. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1 – 37.5% formalin solution for between about 3 days to 5 weeks.

62. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1 - 37.5% formalin solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

63. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1 - 37.5% formalin solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

64. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in 100% glycerol for greater than about 3 weeks.

65. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a 0.1 - 25% glutaraldehyde solution for between about 3 days to 3 weeks.

66. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a 0.1 - 25% glutaraldehyde solution for between about 3 days to 5 weeks.

67. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a 0.1 - 25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

68. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a 0.1 - 25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

69. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1 - 25% glutaraldehyde solution for between about 3 days to 3 weeks.

70. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1 - 25% glutaraldehyde solution for between about 3 days to 5 weeks.

71. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1 - 25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

72. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1 - 25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

73. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein the membrane tissue comprises a treated pericardium tissue.

## CLAIMS

1. A method, comprising:  
partially compressing and mounting a prosthetic heart valve upon a delivery catheter, the prosthetic heart valve comprising a tissue;  
allowing the tissue to at least partially dry;  
further compressing and mounting the prosthetic heart valve upon the delivery catheter; and  
sterilizing and packaging the prosthetic heart valve and delivery catheter.
2. The method of claim 1, further comprising transporting the sterilized and packaged prosthetic heart valve and delivery catheter.
3. The method of claim 1, wherein the tissue comprises a treated pericardium tissue.
4. The method of claim 1, wherein prior to partially compressing and mounting the prosthetic heart valve upon the delivery catheter, the tissue is at least one of (a) not substantially dry, and (b) at least partially hydrated.
5. A method, comprising:  
attaching a tissue to a frame;  
partially compressing and mounting the frame, with the tissue attached thereto, upon a delivery catheter;  
allowing the tissue to at least partially dry;  
further compressing and mounting the frame, with the tissue attached thereto, upon the delivery catheter; and  
sterilizing and packaging the frame and delivery catheter, with the tissue attached thereto.
6. The method of claim 5, wherein prior to partially compressing and mounting the frame, the tissue is at least one of (a) not substantially dry, and (b) at least partially hydrated.
7. The method of claim 5, further comprising transporting the sterilized and packaged frame, with the tissue attached thereto, mounted upon the delivery catheter, to a surgical or medical procedure facility.
8. The method of claim 5, wherein prior to attaching the tissue to the frame the tissue is folded

to form a tissue leaflet assembly.

9. The method of claim 8, wherein the tissue leaflet assembly comprises at least one cuff and at least one pleat.

10. The method of claim 5, wherein the tissue comprises a treated pericardium tissue.

11. A method of preparing a percutaneous, trans-catheter prosthetic heart valve, comprising:  
obtaining a membrane tissue from an organism;  
treating the membrane tissue with at least one chemical to produce a treated membrane tissue;  
drying the treated membrane tissue until it is a substantially dry tissue;  
attaching the substantially dry tissue to a frame;  
rehydrating the substantially dry tissue that is attached to the frame to form a rehydrated tissue;  
collapsing the frame with the rehydrated tissue attached thereto; and  
drying the rehydrated tissue attached to the collapsed frame until it is an again substantially dry tissue.

12. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, further comprising compressing and mounting the frame, with the again substantially dry tissue attached thereto, upon a delivery catheter.

13. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 12, further comprising sterilizing and packaging the frame, with the again substantially dry tissue attached thereto, mounted upon the delivery catheter.

14. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 13, further comprising at least one of transporting and shipping the sterilized and packaged frame with the again substantially dry tissue attached thereto, mounted upon the delivery catheter, to a surgical or medical procedure facility.

15. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 14, further comprising implanting the frame with the again substantially dry tissue attached thereto into a patient.

16. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein the frame comprises a stent.

17. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein prior to the attaching step the substantially dry tissue is not folded with a cuff and a pleat.
18. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein prior to the attaching step the substantially dry tissue is folded to form a tissue leaflet assembly.
19. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 18, wherein the tissue leaflet assembly comprises at least one cuff and at least one pleat.
20. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 18, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a 12 to 14 French balloon catheter.
21. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 18, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a balloon catheter having a size of less than about 12 French.
22. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 18, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a balloon catheter having a size of between about 5 to 12 French.
23. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 18, further comprising mounting the frame and the tissue leaflet assembly attached thereto on a mandrel.
24. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, further comprising sterilizing the frame with the again substantially dry tissue attached thereto with exposure to at least one of ethylene oxide, a proton beam, and gamma radiation.
25. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1-37.5% formalin solution for between about 3 days to 3 weeks.
26. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11,

wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1-37.5% formalin solution for between about 3 days to 5 weeks.

27. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1-37.5% formalin solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

28. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1-37.5% formalin solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

29. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in 100% glycerol for greater than about 3 weeks.

30. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in a 0.1-25% glutaraldehyde solution for between about 3 days to 3 weeks.

31. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in a 0.1-25% glutaraldehyde solution for between about 3 days to 5 weeks.

32. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in a 0.1-25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

33. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in a 0.1-25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

34. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1-25% glutaraldehyde solution for between about 3 days to 3 weeks.

35. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1-25% glutaraldehyde solution for between about 3 days to 5 weeks.

36. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1-25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

37. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1-25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

38. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of claim 11, wherein the membrane tissue comprises a pericardium tissue.