

CLAIMS

What is claimed is:

1. A transcatheter, percutaneously implantable, prosthetic heart valve, comprising:
a lattice frame; and

5 two or more integrated cusp and leaflet folded structures attached to the lattice frame, the two or more integrated cusp and leaflet folded structures each comprising a flat sheet of biocompatible membrane that is folded to include a mobile leaflet layer and a cusp wall layer, wherein the cusp wall layer located radially outside of the mobile leaflet layer, and wherein the cusp wall layer is further formed by joining apposing sides of the cusp wall layer along a seam.

10 2. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 1, wherein the two or more integrated cusp and leaflet folded structures are each attached along their respective seams to the lattice frame.

3. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 2, wherein the seams are oriented in a direction substantially parallel to an axis of the lattice frame.

15 4. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 1, wherein the flat sheet of biocompatible membrane forming at least one integrated cusp and leaflet folded structure of the two or more integrated cusp and leaflet folded structures comprises two or more pieces of biocompatible membrane material.

20 5. A transcatheter, percutaneously implantable, prosthetic heart valve, comprising:
a lattice frame; and

25 two or more integrated cusp and leaflet folded structures attached to the lattice frame, the two or more integrated cusp and leaflet folded structures each comprising a flat sheet of a biocompatible membrane that is folded to include a valve cusp according to a flat folding pattern, wherein the valve cusp is further formed by joining apposing sides of the valve cusp along a seam, and wherein the two or more integrated cusp and leaflet folded structures are each attached along their respective cusp seams to the lattice frame in a direction substantially parallel to an axis of the lattice frame.

30 6. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein two distal, downstream, vertices of each of the two or more integrated cusp and leaflet folded structures are folded over as vertex folds in a radially outward direction and fixed to the lattice frame such that the vertex folds of circumferentially adjacent leaflets are adjacent and define a degree of leaflet apposition at points corresponding to leaflet commissures.

35 7. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 6, wherein the two distal, downstream, vertices are fixed to the lattice frame by attachment not along an alignment with the vertex folds.

8. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein a vertex forming a proximal, upstream, tip of the valve cusp is folded over in a radially outward direction and attached to an inner portion of the lattice frame.

9. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the flat folding pattern is polygonal and includes extending portions that, when the cusp is mounted, extend circumferentially outward from an axial line of attachment of the cusp to the lattice frame so as to form, when joined and attached to corresponding extending portions of neighboring cusps, an integral, inner, luminal, circumferentially complete sealing cuff.

10. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the flat folding pattern is polygonal and includes extending portions that, when the two or more integrated cusp and leaflet folded structures are mounted, extend circumferentially outward from an axial line of attachment of the cusp to the lattice frame so as to form a circumferentially incomplete sealing cuff portion associated with each cusp.

11. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein a separate tubular cuff of biocompatible membrane is attached to an outer, abluminal surface of the lattice frame to form a sealing cuff.

12. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the lattice frame is collapsible and expandable and comprises a metal alloy substantially configured as tubular stent member.

13. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the biocompatible membrane comprises processed mammalian pericardium tissue.

14. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the biocompatible membrane does not comprise a treated tissue.

15. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the biocompatible membrane comprises a synthetic material.

16. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the cusp seams of the two or more integrated cusp and leaflet folded structures are each oriented along an axis of flow of the valve.

17. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the two or more integrated cusp and leaflet folded structures are each further attached to a circumferential portion of the lattice frame along at least a portion of their distal downstream edges.

18. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the two or more integrated cusp and leaflet folded structures are attached to the lattice frame at least at a non-commissural seam aligned with an axial flow direction of the valve.

19. A transcatheter, percutaneously implantable, prosthetic heart valve, comprising:
a lattice frame; and

two or more integrated cusp and leaflet structures attached to the lattice frame, the two or more integrated cusp and leaflet structures each comprising a flat sheet of biocompatible
5 membrane that is folded to include a mobile leaflet layer and a cusp wall layer, wherein with the mobile leaflet layer in a position corresponding to a closed operating configuration of the valve a transverse cross-sectional area of a cusp-sinus space decreases monotonically from a distal end to a proximal end of the mobile leaflet layer.

20. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim
10 19, wherein the cusp wall layer is located radially outside of the mobile leaflet layer.

21. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim
19, wherein the cusp wall layer is further formed by joining apposing sides of the cusp wall layer along a seam.

22. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim
15 19, wherein with the mobile leaflet layer in a position corresponding to a closed operating configuration of the valve a transverse cross-sectional length of the mobile leaflet layer decreases monotonically from a distal end to a proximal end of the mobile leaflet layer.

23. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim
20 19, wherein the mobile leaflet layer and the cusp wall layer of each integrated cusp and leaflet structure are a single continuous piece of biocompatible membrane.

24. In subcombination, an integrated cusp and leaflet structure for attachment to a
lattice frame to form a valve configured for implantation in a vascular system of a patient, the integrated cusp and leaflet structure comprising:

a flat sheet of a biocompatible membrane that is folded to include a mobile leaflet layer
25 and a cusp wall layer, wherein the cusp wall layer is divided along a seam, and wherein the mobile leaflet layer is continuous and apposes the cusp wall layer when the integrated cusp and leaflet structure is pressed substantially flat.

25. The subcombination of Claim 24, wherein the mobile leaflet layer and the cusp
30 wall layer of the integrated cusp and leaflet structure are a single continuous piece of biocompatible membrane.

26. The subcombination of Claim 24, wherein the biocompatible membrane
comprises processed mammalian pericardium tissue.

27. The subcombination of Claim 24, wherein the biocompatible membrane does not
comprise a treated tissue.

28. The subcombination of Claim 24, wherein the biocompatible membrane

comprises a synthetic material.

29. The subcombination of Claim 24, wherein the integrated cusp and leaflet structure further comprises at least one commissure tab.

30. The subcombination of Claim 29, wherein the at least one commissure tab is configured for engaging a slot within a member of the lattice frame.

31. A method of forming an integrated cusp and leaflet folded structure for use in an implantable valve having an axial flow direction, comprising:

folding a flat sheet of biocompatible membrane to form an integrated cusp and leaflet folded structure according to a flat folding pattern, wherein said folding includes making two diagonal folds in the flat sheet of biocompatible membrane, the two diagonal folds separating a mobile leaflet layer from a cusp wall layer of the integrated cusp and leaflet folded structure.

32. The method of forming the integrated cusp and leaflet folded structure of Claim 31, wherein said two diagonal folds are angled at between 10 to 80 degrees from the axial flow direction.

33. The method of forming an integrated cusp and leaflet folded structure of Claim 31, further comprising forming first and second cusp wall folds, wherein the cusp wall layer is further formed by joining apposing membrane portions adjacent the first and second cusp wall folds along a seam that is oriented substantially parallel with the axial flow direction.

34. A method of forming a transcatheter, percutaneously implantable, prosthetic heart valve, comprising:

folding a plurality of integrated cusp and leaflet folded structures, each integrated cusp and leaflet folded structure of the plurality of integrated cusp and leaflet folded structures comprising a flat sheet of biocompatible membrane that is folded to form a cusp according to a flat folding pattern, wherein the cusp is further formed by joining apposing sides of the cusp along a seam; and

attaching each integrated cusp and leaflet folded structure of the plurality of integrated cusp and leaflet folded structures to a lattice frame, wherein the two or more integrated cusp and leaflet folded structures are each attached along their respective seams to the lattice frame in a direction substantially parallel to an axis of the lattice frame.

CLAIMS

1. An invention not claimed in any divisional application.