

What is claimed is:

1. A valve for controlling fluid flow in a lumen having an annulus, the valve comprising:

a sewing ring having an inner portion and an outer portion, wherein the sewing ring is ~~substantially planar~~ in an unstressed position, wherein, in the unstressed position, the outer portion of the sewing ring defines an operative circumference of the sewing ring, wherein the diameter of the sewing ring in the unstressed position is larger than the diameter of the annulus, and wherein the outer portion of the sewing ring ~~and is~~ configured for attachment to the annulus in a biased position, ~~and wherein the diameter of the sewing ring is larger than the diameter of the annulus~~; and

~~at least one~~ a plurality of leaflets securely attached to the inner portion of the sewing ring, wherein, when the sewing ring is in the unstressed position, the plurality of leaflets are co-planar with the sewing ring and non-overlapping,

wherein, upon attachment of the sewing ring to the annulus in the biased position, the sewing ring is ~~substantially non-planar~~, the plurality of leaflets are non-planar and at least a portion of ~~each~~ at least one leaflet of the ~~at least one~~ plurality of leaflets is superposed relative to at least a portion of at least one of the adjacent leaflets of the ~~at least one~~ plurality of leaflets, wherein a distal end of each leaflet extends radially inwardly relative to the inner portion of the sewing ring generally toward a center point on the valve, and wherein at least a portion of the leaflets of the ~~at least one~~ plurality of leaflets comprises extracellular matrix material.

2. The valve of Claim 1, wherein at least a portion of the sewing ring comprises extracellular matrix material.

3. The valve of Claim 1, wherein the outer portion of the sewing ring is configured for attachment to an annulus in a heart of a subject.

4. The valve of Claim 3, wherein, upon attachment of the sewing ring to the annulus in the biased position, at least a portion of the valve is configured for communication with the circulation of the subject.

5. The valve of Claim 1, wherein the leaflets of the ~~at least one~~ plurality of leaflets are spaced ~~substantially~~ equally along the inner portion of the sewing ring.

6. The valve of Claim 1, wherein the sewing ring is configured to attach to the annulus such that at least a portion of ~~each~~ at least one leaflet of the ~~at least one~~ plurality of leaflets underlies at least a portion of at least one of the adjacent leaflets of the ~~at least one~~ plurality of leaflets.

7. The valve of Claim 1, wherein the sewing ring is further configured to attach to the annulus such that at least a portion of ~~each~~ at least one leaflet of the ~~at least one plurality of~~ leaflets overlies at least a portion of at least one of the adjacent leaflets of the ~~at least one~~ plurality of leaflets.
8. The valve of Claim 1, wherein the outer portion of the sewing ring is ~~substantially~~ circular.
- ~~9. The valve of Claim 1, wherein the at least one leaflet comprises a single leaflet.~~
- ~~10. The valve of Claim 1, wherein the at least one leaflet comprises a plurality of leaflets.~~
- ~~11. The valve of Claim 10, wherein the plurality of leaflets comprises two leaflets.~~
- ~~12. The valve of Claim 10, wherein the plurality of leaflets comprises three leaflets.~~
- ~~13. The valve of Claim 1, wherein the leaflets of the plurality of leaflets are configured to control blood flow through an annulus in a heart.~~
- ~~14. The valve of Claim 1, wherein the ratio of the diameter of the sewing ring to the diameter of the annulus is configured to range from about 1.01 : 1 to about 3.00: 1.~~
- ~~15. The valve of Claim 1, wherein the ratio of the diameter of the sewing ring to the diameter of the annulus is configured to range from about 1.70: 1 to about 2.10: 1.~~
- ~~16. The valve of Claim 1, wherein the diameter of the sewing ring ranges from about 20 mm to about 70 mm.~~
- ~~17. The valve of Claim 1, wherein the diameter of the sewing ring ranges from about 35 mm to about 45 mm.~~
- ~~18. The valve of Claim 1, wherein at least a portion of the sewing ring comprises metal.~~
- ~~19. The valve of Claim 1, wherein at least a portion of the sewing ring comprises a shape memory activated material.~~
- ~~20. The valve of Claim 2, wherein at least a portion of the sewing ring comprises a polymeric material.~~
- ~~21. The valve of Claim 18, wherein the extracellular matrix material is electrospun and applied to the polymeric material to produce the sewing ring.~~
20. The valve of Claim 1, wherein the sewing ring is integrally formed with the plurality of leaflets.
21. A valve for controlling fluid flow in a lumen having an annulus, the valve comprising:
a sewing ring having an inner portion and an outer portion, wherein the sewing ring is planar in an unstressed position, wherein, in the unstressed position, the outer portion of the sewing ring defines an operative circumference of the sewing ring, wherein the diameter of the sewing ring in the unstressed position is larger than the diameter of the annulus, and

wherein the outer portion of the sewing ring is configured for attachment to the annulus in a biased position; and

a plurality of leaflets securely attached to the inner portion of the sewing ring,
wherein, when the sewing ring is in the unstressed position, the plurality of leaflets are co-
planar with the sewing ring and non-overlapping; and

means for attaching the sewing ring to the annulus in the biased position, wherein , in
the biased position, the sewing ring is non-planar, the plurality of leaflets are non-planar and
at least a portion of at least one leaflet of the plurality of leaflets is superposed relative to at
least a portion of at least one of the adjacent leaflets of the plurality of leaflets, and wherein,
in the biased position, a distal end of each leaflet of the plurality of leaflets extends radially
inwardly relative to the inner portion of the sewing ring generally toward a center point on
the valve, and

wherein at least a portion of the leaflets of the plurality of leaflets comprises
extracellular matrix material.

~~22. A method of replacing a defective valve for controlling fluid flow in a lumen having an annulus, the method comprising:~~

~~providing a valve comprising:~~

~~a sewing ring having an inner portion and an outer portion, wherein the sewing ring is substantially planar in an unstressed position, wherein the outer portion of the sewing ring defines an operative circumference of the sewing ring and is configured for attachment to the annulus in a biased position, and wherein the diameter of the sewing ring is larger than the diameter of the annulus; and~~

~~at least one leaflet securely attached to the inner portion of the sewing ring,~~
~~wherein at least a portion of the leaflets of the at least one leaflet comprises~~
~~extracellular matrix material; and~~

~~securely attaching the outer portion of the sewing ring to the annulus in the biased position such that the sewing ring is substantially non-planar and at least a portion of each leaflet of the at least one leaflet is superposed relative to at least a portion of the adjacent leaflets of the at least one leaflet, wherein a distal end of each leaflet extends radially inwardly relative to the inner portion of the sewing ring generally toward a center point on the valve.~~

~~23. The method of Claim 22, wherein the step of securely attaching the outer portion of the sewing ring to the annulus comprises attaching the outer portion of the sewing ring to the annulus at a plurality of attachment points along the outer portion of the sewing ring.~~

24. The method of Claim 23, wherein the plurality of attachment points are substantially equally spaced along the outer portion of the sewing ring.
25. The method of Claim 23, wherein the plurality of attachment points comprises at least three attachment points.
26. The method of Claim 23, wherein the attachment points of the plurality of attachment points are substantially equally and continually spaced along the outer portion of the sewing ring.
27. The method of Claim 23, wherein the step of securely attaching the outer portion of the sewing ring to the annulus comprises attaching the outer portion of the sewing ring to the annulus in a heart with a blood supply, and wherein the leaflets of the at least one leaflet are configured to selectively control blood flow through the annulus in the heart.
28. A valve for controlling fluid flow in a lumen having an annulus, the valve and the annulus each having a circumference, the valve configured for attachment therein the annulus, wherein the valve is substantially planar in an unstressed position, wherein the valve is configured for attachment to the annulus in a biased position, and wherein an operative diameter of the valve is configured to be larger than the diameter of the annulus, the valve comprising:
- at least one leaflet disposed on the circumference of the valve such that each leaflet contacts adjacent leaflets,
- wherein a distal end of each leaflet extends radially inwardly generally toward a center point in the valve, wherein, upon attachment of the valve to the annulus in the biased position, the valve is substantially non-planar and at least a portion of each leaflet of the at least one leaflet is superposed relative to at least a portion of the adjacent leaflets of the at least one leaflet to be substantially planar before attachment therein the annulus and non-planar upon attachment therein the annulus, and wherein at least a portion of each leaflet of the at least one leaflet comprises extracellular matrix material.
29. The valve of Claim 28, wherein the ratio of the operative diameter of the valve to the diameter of the annulus is configured to range from about 1.01 : 1 to about 3.00 : 1.
30. The valve of Claim 28, wherein the ratio of the operative diameter of the valve to the diameter of the annulus is configured to range from about 1.70 : 1 to about 2.10 : 1.
31. The valve of Claim 28, wherein the operative diameter of the valve ranges from about 20 mm to about 70 mm.
32. The valve of Claim 28, wherein the operative diameter of the valve ranges from about 35 mm to about 45 mm.

33. The valve of Claim 28, wherein, upon attachment of the valve in the biased position, the valve is positioned along the circumference of the annulus in a substantially sinusoidal pattern.

34. The valve of Claim 28, wherein each leaflet of the at least one leaflet has an inner edge having an edge length corresponding to the total length of the inner edge of the leaflet that extends inwardly relative to the operative circumference of the valve toward the radial center of the valve, wherein the edge length of each leaflet ranges from about 20 mm to about 50 mm.

35. The valve of Claim 34, wherein each leaflet of the at least one leaflet has an apex corresponding to the point along the inner edge of the leaflet that is farthest from the operative circumference of the valve, wherein each leaflet of the at least one leaflet has a height corresponding to the distance between the apex of each leaflet and the operative circumference of the valve, and wherein the height of each leaflet ranges from about 8 mm to about 25 mm.

36. A method of replacing a defective valve for controlling fluid flow in a lumen having an annulus, the method comprising:

providing a substantially planar piece of extracellular matrix material, wherein the substantially planar piece of extracellular matrix material has a circumference;

removing selected portions of the substantially planar piece of extracellular matrix material to thereby define an outer edge portion and at least one leaflet of a valve, wherein the outer edge portion is positioned along the circumference of the substantially planar piece of extracellular matrix material, and wherein each leaflet of the valve has a distal end extending radially inwardly generally toward a center point in the valve;

folding the outer edge portion of the valve to create an attachment surface; and

securely attaching the attachment surface of the valve to the annulus in a biased position such that the valve is substantially non-planar and at least a portion of each leaflet of the at least one leaflet is superposed relative to at least a portion of the adjacent leaflets of the at least one leaflet.

37. The method of Claim 36, wherein the step of securely attaching the attachment surface of the valve to the annulus comprises attaching the attachment surface of the valve to the annulus in a substantially sinusoidal pattern.

38. The method of Claim 36, wherein the diameter of the valve after the step of folding the outer edge portion corresponds to an operative diameter of the valve, and wherein the operative diameter of the valve ranges from about 35 mm to about 45 mm.