

WE CLAIM:

1. A prosthetic heart valve comprising:

an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, wherein the frame comprises a plurality of struts defining openings;

a valvular structure mounted within the frame and comprising a plurality of leaflets that regulate the flow of blood through the frame, wherein each leaflet comprises an inflow surface, an outflow surface, and a cusp edge portion that is fixed relative to the frame;

a sealing member mounted on the frame and comprising an inner layer and an outer layer, wherein at least the outer layer is mounted on the outside of the frame, and the inner layer covers at least the openings in the frame between adjacent cusp edge portions of adjacent leaflets and the inner layer does not cover one or more openings in the frame at locations facing the outflow surfaces of the leaflets to permit retrograde blood to flow through the one or more uncovered openings in the frame and into space between the outer layer and the frame;

wherein:

(i) the inner layer does not cover any openings in the frame at locations facing the outflow surfaces of the leaflets;

(ii) the inner layer is formed with one or more openings along the portions of the inner layer that face the outflow surface of the leaflets to allow retrograde blood to flow through the frame at those locations; or

(iii) the inner layer is formed from a porous material that allows blood to flow through the inner layer and the inner layer is formed from a relatively more porous material than the outer layer.

2. The prosthetic heart valve of claim 1, wherein the cusp edge portions of the leaflets have a curved, scalloped shape and the inner layer of the sealing member comprises a plurality of triangular shaped portions that are mounted on the frame at locations between adjacent cusp edge portions of adjacent leaflets.

3. The prosthetic heart valve of any preceding claim, wherein the inner layer is mounted on the outer surface of the frame.

4. The prosthetic heart valve of claim 1 or 2, wherein the inner layer is mounted on the inner surface of the frame.

5. The prosthetic heart valve of any preceding claim, wherein the outer layer is shape set such that it extends radially away from the frame when the frame is in the radially expanded configuration.

6. The prosthetic heart valve of claim 5, wherein the outer layer comprises a shape set fabric.

7. The prosthetic heart valve of any preceding claim, wherein the outer layer comprises a lower tapered wall section that extends outwardly from the frame in a direction from the inflow end to the outflow end, an upper tapered wall section that extends outwardly from the frame in a direction from the outflow end to the inflow end, and a central wall section that extends between the lower and upper tapered wall sections.

8. The prosthetic heart valve of any preceding claim, wherein the cusp edge portion of each leaflet is fixed relative to the frame by a connecting skirt that is connected to and disposed between the frame and the cusp edge portion of the leaflet, wherein each connecting skirt is sutured to struts of the frame extending in a diagonal line from the inflow end to the outflow end of the frame.

9. The prosthetic heart valve of claim 8, wherein each connecting skirt comprises two layers of material sutured to the cusp edge portion of a leaflet and to struts of the frame.

10. The prosthetic heart valve of any preceding claim, wherein each leaflet comprises opposing upper tabs on opposite sides of the leaflet and opposing lower tabs on opposite sides of the leaflets below the upper tabs, wherein each upper tab is paired with an adjacent upper tab of an adjacent leaflet to form a plurality of commissures, and wherein each lower tab is folded to form at least one fold layer along the cusp edge portion of the respective leaflet.

11. The prosthetic heart valve of claim 10, wherein each leaflet is unattached to the frame at locations between the upper tabs and the lower tabs.

12. The prosthetic heart valve of claim 11, wherein each leaflet is formed with a gap between the upper tab and the lower tab on each side of the leaflet.

13. The prosthetic heart valve of any of claims 10-12, further comprising at least one reinforcing chord extending along the cusp edge portion of each leaflet and underneath each commissure.

14. The prosthetic heart valve of any of claims 10 to 13, wherein each leaflet has opposing edges between the upper tabs and the lower tabs that are unattached to the frame, the unattached edges being spaced radially inwardly of the frame, allowing blood to flow between the frame and the unattached edges.