ANNEX A2

825 Conditional Amendment 2

Claims

1. A system comprising:
a prosthetic heart valve (100) comprising:
a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body;
wherein the frame (102) is made of a nickel-cobalt-chromium-molybdenum alloy and comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114), the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells, wherein the frame (102) is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:
two opposing side struts (144) extending parallel to a flow axis of the valve (100),
a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging toward each other, and
a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and
a delivery catheter comprising an inflatable balloon;
wherein the prosthetic heart valve (100) is crimped in its radially compressed state on the balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic heart valve (100) at the desired deployment location, preferably within a native aortic valve,
wherein the frame (102) of the prosthetic heart valve (100) does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end (108) or an outflow end (110) of the frame (102) for mounting the frame (102) to the delivery catheter.

2. The system (100) of claim 1, wherein the frame (102) comprises four rows (112a, 112b, 112c, 112d) of angled struts (114) forming three rows of hexagonal cells, wherein a first row (112a) of angled struts (114) is located at an inflow end (108) of the frame (102), a second row (112b) of angled struts (114) is located adjacent the first row (112a) of angled struts (114) in a flow direction, a third row (112b) of angled struts (114) is located adjacent the second row (112a) of angled struts (114) in the flow direction, and a fourth row (112d) of angled struts (114) is located at an outflow end (110) of the frame (102), the flow direction extending along the flow axis from the inflow end (108) to the outflow end (110).

3. The system (100) of claim 2, wherein each cell of a first row of hexagonal shaped cells is formed by two opposing side struts (144) extending in the flow direction, a pair of lower angled struts (146) of the first row (112a) of angled struts (114) extending in a direction opposite the flow direction from respective lower ends of the two side struts (144) and converging to intersect each other at an apex (150), and a pair of upper angled struts (148) of the second row (112b) of angled

struts (114) extending in the flow direction from respective upper ends of the two side struts (144) and converging to intersect each other,

each cell of a second row of hexagonal shaped cells is formed by two opposing side struts (144) extending in the flow direction, a pair of lower angled struts (146) of the second row (112b) of angled struts (114) extending in a direction opposite the flow direction from respective lower ends of the two side struts (144) and converging to intersect each other, and a pair of upper angled struts (148) of the third row (112c) of angled struts (114) extending in the flow direction from respective upper ends of the two side struts (144) and converging to intersect each other, and wherein

each cell of a third row of hexagonal shaped cells is formed by two opposing side struts (144) extending in the flow direction, a pair of lower angled struts (146) of the third row (112c) of angled struts (114) extending in a direction opposite the flow direction from respective lower ends of the two side struts (144) and converging to intersect each other, and a pair of upper angled struts (148) of the fourth row (112c) of angled struts (114) extending in the flow direction from respective upper ends of the two side struts (144) and converging to intersect each other at an apex (152).

4. The system (100) of claim 3, wherein in each cell of the three rows of hexagonal cells, the pair of angled struts (146) extending in a direction opposite the flow direction from a respective lower end of the two side struts (144) and converging to intersect each other, form a U-shape at the intersection, and the pair of angled struts (148) extending in the flow direction from a respective upper end of the two side struts (144) and converging to intersect each other, form an inverted U-shape at the intersection.

~~5. The system (100) of any of the preceding claims, wherein the frame (102) is made of a plastically-expandable material, preferably selected from a group comprising stainless-steel, a nickel-based alloy, a nickel-cobalt chromium alloy, polymers or a combination thereof.~~

~~6~~5. The system (100) of any of the preceding claims, further comprising a leaflet structure comprising a plurality of leaflets (104), and a sealing skirt (106).

~~7~~6. The system (100) of claim ~~6~~5 when referred to claim 2, wherein the skirt (106) is positioned on the inside of the frame (102) and is sized to cover the openings of the frame (102) between the inflow end (108) and the third row (112c) of struts (114).

~~8~~7. The system (100) of claim ~~6~~5 or ~~7~~6, wherein the skirt (106) comprises a main annular body (126) that covers the openings in the frame (102) and plurality of commissure securement portions (128).

~~9~~8. The system (100) of claim ~~8~~7, wherein the main body (126) of the skirt (106) is secured to the frame (102) such that, when the frame (102) is in its radially expanded state, excess material is provided between an upper edge (130) and a lower edge (132) of the skirt (106), configured to protrude outwardly through the openings of the frame (102) when a pressure gradient is applied across the valve (100).

~~10~~9. The system (100) of any of claims ~~6~~5 to ~~9~~8, wherein each leaflet (104) has a scalloped lower edge portion (134) that is secured to the frame (102) and/or the skirt (106) by sutures.

~~11~~10. The system (100) of any of claims ~~6~~5 to ~~10~~9, wherein each leaflet (104) has a tab portion (116) adjacent an upper free edge of the leaflet (104).

~~12~~11. The system (100) of claim ~~11~~10, further comprising at least one reinforcement strip (118) that covers the tab portion (116) of a respective leaflet (104).

~~13~~12. The system (100) of any of claims ~~6~~5 to ~~12~~11, wherein the skirt (106) is made of a fabric, the fabric preferably made of PET or UHMWPE.