ANNEX B

181 Conditional Amendment 1

Specification

[0011]. The claimed invention is defined in independent claim 1 and relates to an implantable prosthetic valve that is radially collapsible to a collapsed configuration and radially expandable to an expandable configuration. Preferred configurations of the claimed invention are defined in dependent claims 2 to ~~13~~12. Certain aspects and/or particularly preferred configurations of the claimed invention are discussed hereafter for example in conjunction with Figs. 1-3 and 42-43. Also described herein are related aspects, examples, embodiments and arrangements useful for understanding the claimed invention.

Claims

1. An implantable prosthetic heart valve (10) that is radially collapsible to a collapsed configuration and radially expandable to an expanded configuration, the prosthetic valve (10) comprising:

an annular frame (12);

a leaflet structure (14) positioned within the frame (12);

an inner skirt (16); and

an annular outer skirt (18) positioned around an outer surface of the frame (12), the outer skirt (18) comprising an inflow edge (160) secured to the frame (12) at a first location, an outflow edge (162) secured to the frame (12) at a second location, and an intermediate portion between the inflow edge (160) and the outflow edge (162);

wherein when the valve is in the expanded configuration, the intermediate portion of the outer skirt (18) comprises slack in the axial direction between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18), and when the valve is collapsed to the collapsed configuration, the axial distance between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18) increases, reducing the slack in the outer skirt (18) in the axial direction.

2. The valve of claim 1, wherein the outer skirt (18) is not stretched in the axial direction when the valve is radially collapsed to the collapsed configuration and slack is removed from the intermediate portion of the outer skirt (18).

3. The valve of claim 1, wherein the outflow edge (162) of the outer skirt (18) comprises a plurality of alternating projections (164) and notches (166), the projections (164) being secured to the frame (12) at the second location, the outer skirt (18) being unsecured to the frame (12) at the notches (166).

4. The valve of any one of the preceding claims, wherein the outer skirt (18) is configured to fill in gaps between the frame (12) and a surrounding native annulus when the valve is deployed within the body.

5. The valve of any one of the preceding claims, wherein the slack between the lower and upper edges of the outer skirt (18) allows the frame (12) to elongate axially during crimping without

any resistance from the outer skirt (18) and the outer skirt (18) does not substantially affect the outer diameter of the prosthetic valve (10) in the crimped condition.

6. The valve of any one of the preceding claims, wherein the outer skirt (18) is formed of woven PET.

~~7. The valve of any one of the preceding claims, further comprising an inner skirt (16).~~

~~8~~7. The valve of any one of the preceding claim~~s 7~~, wherein the inflow edge (160) of the outer skirt (18) is sutured to an inflow edge of the inner skirt (16) at the inflow end of the valve.

~~9~~8. The valve of claim ~~8~~7, wherein the inflow edge (160) of the outer skirt (18) is substantially straight.

~~10~~9. The valve of any one of the preceding claims, wherein the frame (12) is made from a plastically-expandable material.

~~11~~10. The valve of claim ~~10~~9, wherein the frame (12) is configured to be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient by an inflatable balloon.

~~12~~11. The valve of any one of claims ~~10~~9 or ~~11~~10 wherein plastically-expandable material that is used to form the frame (12) includes stainless steel, a nickel based alloy, a cobalt-chromium alloy, a nickel-cobalt-chromium alloy, polymers, or combinations thereof; preferably wherein the frame (12) is made of a nickel-cobalt-chromium-molybdenum alloy.

~~13~~12. A delivery assembly for implanting an implantable prosthetic valve (10) in a patient's body comprising:

an implantable prosthetic valve (10) as defined in any one of claims ~~11~~10 or ~~12~~11; and

a delivery apparatus comprising an elongated shaft (180), the elongated shaft (180) comprising an inflatable balloon (182) for implanting the valve (10) within the patient's body;

wherein the inflatable balloon (182) is in a deflated state and the implantable prosthetic valve (10) is mounted over the deflated balloon (182) in a radially compressed configuration for delivery into the body.

ANNEX C

181 Conditional Amendment 2

Specification

[0011]. The claimed invention is defined in independent claim 1 and relates to an implantable prosthetic valve that is radially collapsible to a collapsed configuration and radially expandable to an expandable configuration. Preferred configurations of the claimed invention are defined in dependent claims 2 to ~~13~~11. Certain aspects and/or particularly preferred configurations of the claimed invention are discussed hereafter for example in conjunction with Figs. 1-3 and 42-43. Also described herein are related aspects, examples, embodiments and arrangements useful for understanding the claimed invention.

Claims

1. An implantable prosthetic heart valve (10) that is radially collapsible to a collapsed configuration and radially expandable to an expanded configuration, the prosthetic valve (10) comprising:

an annular frame (12);

a leaflet structure (14) positioned within the frame (12);

an inner skirt (16); and

an annular outer skirt (18) positioned around an outer surface of the frame (12), the outer skirt (18) comprising an inflow edge (160) secured to the frame (12) at a first location, an outflow edge (162) secured to the frame (12) at a second location, and an intermediate portion between the inflow edge (160) and the outflow edge (162);

wherein when the valve is in the expanded configuration, the intermediate portion of the outer skirt (18) comprises slack in the axial direction between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18), and when the valve is collapsed to the collapsed configuration, the axial distance between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18) increases, reducing the slack in the outer skirt (18) in the axial direction, and

wherein the inflow edge (160) of the outer skirt (18) is sutured to an inflow edge of the inner skirt (16) at the inflow end of the valve.

2. The valve of claim 1, wherein the outer skirt (18) is not stretched in the axial direction when the valve is radially collapsed to the collapsed configuration and slack is removed from the intermediate portion of the outer skirt (18).

3. The valve of claim 1, wherein the outflow edge (162) of the outer skirt (18) comprises a plurality of alternating projections (164) and notches (166), the projections (164) being secured to the frame (12) at the second location, the outer skirt (18) being unsecured to the frame (12) at the notches (166).

4. The valve of any one of the preceding claims, wherein the outer skirt (18) is configured to fill in gaps between the frame (12) and a surrounding native annulus when the valve is deployed within the body.

5. The valve of any one of the preceding claims, wherein the slack between the lower and upper edges of the outer skirt (18) allows the frame (12) to elongate axially during crimping without any resistance from the outer skirt (18) and the outer skirt (18) does not substantially affect the outer diameter of the prosthetic valve (10) in the crimped condition.

6. The valve of any one of the preceding claims, wherein the outer skirt (18) is formed of woven PET.

~~7. The valve of any one of the preceding claims, further comprising an inner skirt (16).~~

~~8. The valve of claim 7, wherein the inflow edge (160) of the outer skirt (18) is sutured to an inflow edge of the inner skirt (16) at the inflow end of the valve.~~

~~9~~7. The valve of ~~claim 8~~any one of the preceding claims, wherein the inflow edge (160) of the outer skirt (18) is substantially straight.

~~10~~8. The valve of any one of the preceding claims, wherein the frame (12) is made from a plastically-expandable material.

~~11~~9. The valve of claim ~~10~~8, wherein the frame (12) is configured to be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient by an inflatable balloon.

~~12~~10. The valve of any one of claims ~~10~~8 or ~~11~~9 wherein plastically-expandable material that is used to form the frame (12) includes stainless steel, a nickel based alloy, a cobalt-chromium alloy, a nickel-cobalt-chromium alloy, polymers, or combinations thereof; preferably wherein the frame (12) is made of a nickel-cobalt-chromium-molybdenum alloy.

~~13~~11. A delivery assembly for implanting an implantable prosthetic valve (10) in a patient's body comprising:

an implantable prosthetic valve (10) as defined in any one of claims ~~11~~9 or ~~12~~10; and

a delivery apparatus comprising an elongated shaft (180), the elongated shaft (180) comprising an inflatable balloon (182) for implanting the valve (10) within the patient's body;

wherein the inflatable balloon (182) is in a deflated state and the implantable prosthetic valve (10) is mounted over the deflated balloon (182) in a radially compressed configuration for delivery into the body.