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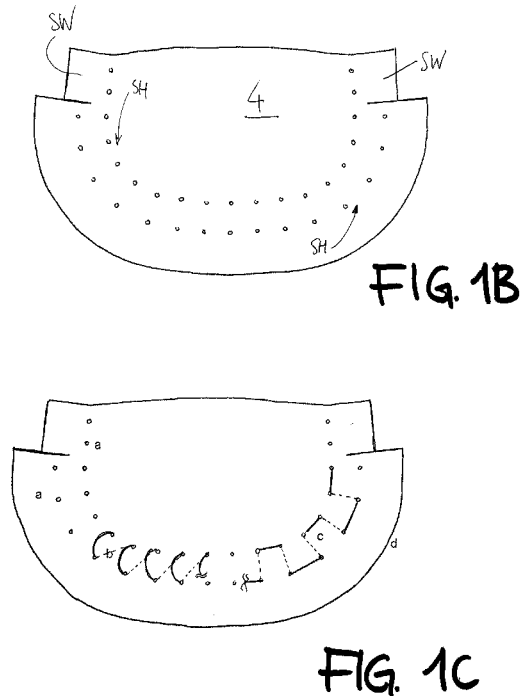
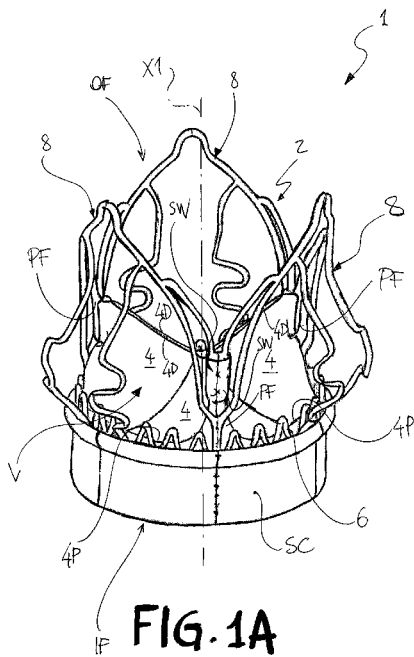
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(54) Title: A CARDIAC VALVE PROSTHESIS



(57) Abstract: A cardiac valve prosthesis including an armature for anchorage of the valve prosthesis at an implantation site. The armature defining a lumen for the passage of the blood flow and having a longitudinal axis, and a set of prosthetic valve leaflets supported by said armature and configured to move, under the action of blood flow, in a radially divaricated condition to enable the flow of blood through said lumen in a first direction, and in a radially contracted condition, in which said valve leaflets co-operate with one another and block the flow of blood through the prosthesis in the direction opposite said first direction. The armature including an annular part and a pattern of arched struts carried by said annular part, said pattern of arched struts having proximal ends connected to said annular part, and distal ends spaced axially from the proximal ends and opposite said annular part, a plurality of sets of anchoring formations configured to protrude radially outwardly of said annular part, each set being supported by at least one of said annular part



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"A cardiac valve prosthesis"

Field of the disclosure

The present disclosure relates to cardiac valve prosthesis. More specifically, the disclosure has been developed with reference to so-called "stented" cardiac valve prostheses, i.e. featuring a support structure and a prosthetic heart valve carried by the support structure, wherein the support structure is generally referred to as "armature" and is provided as a stent member.

Background

Some cardiac valve prostheses include a multi leaflet prosthetic heart valve sutured, stitched, or otherwise permanently connected to the armature, which defines a lumen for the passage of blood through the prosthesis. The armature is provided as a stent member, and as such it exhibits extensive deformation capabilities. Typically, an armature of a stented cardiac valve prosthesis features a radially collapsed configuration intended for delivery and positioning of the same to and at the implantation site (for example via a delivery instrument such as a catheter), and a radially expanded configuration which is intended to ensure that the prosthesis is withheld at the implantation site once implanted.

Sometimes, the prosthetic valve includes a set of prosthetic valve leaflets supported by the armature and configured to move, under the action of blood flow, in a radially divaricated condition to enable the flow of blood through the lumen in a first direction, and in a radially contracted condition, in which the valve leaflets co-operate with one another (so-called leaflet coaptation) and block the flow of blood through the prosthesis in the direction opposite said first direction.

As the prosthetic valve is coupled to the armature, there is a certain degree of structural interaction between the same, which results in the operation of the prosthetic valve being possibly affected by the structural condition the armature experiences at the end of the implantation procedure, with the valve sitting at the implantation site. The shape of the implantation site (the valve annulus) may affect the *in vivo* functionality of the valve. For example, a D-shaped annulus may encourage leaflet straightening, which in turn may end up with negatively affecting leaflet coaptation. This happens generally because the irregular shape of the annulus, meaning by this a deviation from the ideal circular shape. As a D-shaped annulus may notionally be regarded as a "flattened" circular annulus, the armature of the prosthesis will experience an irregular deformation pattern over the perimeter of the annulus, and especially over the "flattened" portion. This may result in a sensible change, for example, in relative position of support posts of the armature to which the prosthetic valve is attached, and especially an increase in the mutual distance between two supporting posts possibly located at the "flattened" side. Such an increase in distance causes the leaflet straightening referred to above, which in turn is susceptible of encouraging regurgitation of blood through the prosthesis. This is clearly an undesirable condition, in that functionality of the native heart valve replaced by the prosthesis will not be restored, not to mention the damage that this could cause to an already suffering patient.

Additionally, radially protruding anchoring formations possibly provided on the armature of the prosthesis may affect the resistance to bending when the prosthesis is implanted at sites such as the

annulus of a bicuspid valve, or a flat Valsalva Sinus. Accordingly, the prosthesis will be subject to a bending phenomenon known as "folding", which is another major source of risks and damage to the patient.

5

Summary

In a first example, a cardiac valve prosthesis comprising an armature for anchorage of the valve prosthesis at an implantation site. The armature
10 defining a lumen for the passage of the blood flow and having a longitudinal axis, and a set of prosthetic valve leaflets supported by said armature and configured to move, under the action of blood flow, in a radially divaricated condition to enable the flow of
15 blood through said lumen in a first direction, and in a radially contracted condition, in which said valve leaflets co-operate with one another and block the flow of blood through the prosthesis in the direction opposite said first direction. The armature comprising
20 an annular part and a pattern of arched struts carried by said annular part, said pattern of arched struts having proximal ends connected to said annular part, and distal ends spaced axially from the proximal ends and opposite said annular part. Where, a plurality of
25 sets of anchoring formations configured to protrude radially outwardly of said annular part, each set being supported by at least one of said annular part and a corresponding arched strut, and a plurality of support posts, each support post being supported by adjacent
30 arched struts. Where, the sets of anchoring formations alternate with the support posts around said longitudinal axis.

In a second example according to the first example, wherein each set of anchoring formations extends

bridge-wise between a corresponding arched strut and said annular part.

In a third example according to the first example or the second example, wherein each support post is
5 cantilevered to adjacent arched struts.

In a fourth example according to any of the previous examples, wherein each arched strut extends from a first proximal end, to a distal end, and then to a second proximal end.

10 In a fifth example according to the fourth example, wherein each set of anchoring formations extends bridge-wise from an arched strut to a portion of the annular part comprised between two proximal ends.

In a sixth example according to the fifth example,
15 wherein each set of anchoring formations comprises two anchoring formations.

In a seventh example according to the fifth example or the sixth example, wherein each anchoring formation comprises a serpentine, a weaving, or an apertured
20 pattern.

In an eighth example according to the fourth example, wherein each support post is angularly arranged between two adjacent arched struts at an inter-strut position, said inter-strut position corresponding to the position
25 of a proximal end shared between said two adjacent arched struts.

In a ninth example according to the third example or the eighth example, wherein said support post is cantilevered to said pair of arched struts by way of a
30 first and a second cantilever struts merging at the supporting post.

In a tenth example according to any of the previous examples, wherein said annular part is covered by a cuff to provide sealing at the implantation site, the

cuff being arranged outside of the lumen of the armature.

In an eleventh example according to the tenth example, wherein the cuff is separate from said set of
5 prosthetic valve leaflets.

In a twelfth example according to any of the previous examples, wherein said annular part includes one or more coupling elements configured to be engaged by valve loading or crimping facilities or instruments.

10 In a thirteenth example according to any of the previous examples, wherein said set of prosthetic valve leaflets define a prosthetic aortic valve, the cardiac valve prosthesis being an aortic valve prosthesis.

In a fourteenth example according to the first
15 example, wherein each arched strut includes a distal portion at the distal end thereof which is substantially C-shaped and is configured to mate with a valve holder or a carrier portion of a delivery instrument.

20 In a fifteenth example according to the first example or the fourteenth, wherein the pattern of arched struts includes inter-strut portions arranged at said proximal ends, and said annular part has a mesh structures including cells and nodes, said inter strut portions
25 having a Y-shape or a U-shape extending through nodes of the mesh of the annular part.

In a sixteenth example, a cardiac valve prosthesis comprising:

30 an armature for the valve prosthesis at an implantation site,

a set of prosthetic valve leaflets supported by said armature,

the armature comprising:

an annular part

a plurality of arched struts coupled to said annular part,

a plurality of support posts each having a free proximal end and a distal portion supported by adjacent
5 arched struts.

In a seventeenth example according to the sixteenth example, further including a plurality of sets of anchoring formations configured to protrude radially outwardly of said annular part, each set being
10 supported by at least one of said annular part and a corresponding arched strut.

In an eighteenth example according to the sixteenth example, the support posts are cantilevered to adjacent arched struts.

15 In a nineteenth example according to the seventeenth example, each set of anchoring formations extends bridge-wise between a corresponding arched strut and said annular part.

In a twentieth example according to the seventeenth example the sets of anchoring formations alternate with the support posts around a longitudinal axis of the prosthesis.

While multiple embodiments are disclosed, still other embodiments of the present disclosure will become
25 apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the disclosure. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not
30 restrictive.

Brief description of the figures

Further features and advantages of the disclosure will become apparent from the following description with reference to the annexed drawings, given purely by
35 way of non-limiting example, in which:

Figure 1A is a perspective view of a cardiac valve prosthesis, according to embodiments of the disclosure;

Figures 1B and 1C illustrate examples of trimmed portions of leaflet forming members, according to
5 embodiments of the disclosure;

Figure 2 is a perspective view of an armature of the prosthesis of Figure 1, according to embodiments of the disclosure;

Figure 3 is an orthogonal view of the armature of
10 Figure 2 according to III in Figure 2, according to embodiments of the disclosure;

Figure 4 is another orthogonal view of the armature of Figure 2 according to IV in Figure 2, according to embodiments of the disclosure;

Figure 5 is a further orthogonal view of the armature
15 of Figure 2 according to V in Figure 2, according to embodiments of the disclosure;

Figure 6 is yet a further orthogonal view of the
20 armature of Figure 2 according to VI in Figure 2, according to embodiments of the disclosure; and

Figure 7 is exemplary of an implantation of the heart valve prosthesis, according to embodiments of the disclosure.

While the disclosure is amenable to various
25 modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the disclosure to the particular embodiments described. On the contrary,
30 the disclosure is intended to cover all modifications, equivalents, and alternatives falling within the scope of the disclosure as defined by the appended claims.

Detailed description of embodiments

With reference to Figure 1A, reference number 1 designates as a whole a cardiac valve prosthesis according to various embodiments of the disclosure. The cardiac valve prosthesis 1 includes an armature 2 for anchorage of the valve prosthesis at an implantation site. The armature 2 defines a lumen for the passage of the blood flow and has a longitudinal axis X1.

The prosthesis 1 also includes a set of prosthetic valve leaflets 4 supported by the armature 2 and configured to move, under the action of blood flow (which has a main flow direction roughly corresponding to that of the axis X1): in a radially divaricated condition to enable the flow of blood through the lumen in a first direction, and in a radially contracted condition, in which the valve leaflets 4 co-operate with one another and block the flow of blood through the prosthesis 1 in the direction opposite the first direction. This is commonly referred to as leaflet coaptation.

With reference to Figures 2-5, in embodiments the armature 2 includes an annular part 6, and a pattern of arched struts 8 carried by the annular part 6. The annular part has a structure which can expand from a radially contracted condition, associated to delivery of the prosthesis to implantation site, to a radially expanded condition wherein the prosthesis is withheld at the implantation site. In these embodiments, the annular part may have a mesh structure including an annular pattern of multiple strut clusters (cells) having polygonal shape (hexagonal, rhomboidal, etc.).

As regards the construction of the set of leaflets 4 (also referred to as or valve sleeve), in various embodiments the prosthetic valve is made with three separate leaflets. Each leaflet is obtained from one sheet of pericardium trimmed accordingly to Figure 1B,

i.e., according to a substantially lobe-shaped figure. Each trimmed leaflet features two patterns of sewing holes SH and two side wings SW.

5 The patterns SH are sewn together forming a sewn stiffer fold which follows the leaflet profile at the root thereof, thereby forming the cusp.

10 The two side wings SW enable connection of the valve to supporting posts in the valve armature. The sewn fold has the purpose to bias the cusp inwardly thereby encouraging leaflet coaptation, and to avoid contact between the armature 2 and the valve leaflets 4 avoiding the risk of abrasion due to repeated impact against the armature 2, which, in some embodiments, is a metal material.

15 The two patterns of holes SH may be sewn together using a suture thread coated with a film of biocompatible material or PET thread or PTFE filament.

20 The sewing pattern may be varied to accommodate the directional differences in the forces exerted at each point of the stitches, prevent the stitches from triggering fatigue fracture lines.

25 Preferably the stitching follows the pattern identified by letter "C" in Figure 1C (alternate inner and outer surface stitches). The three leaflets 4 are then joined at the side wings SW and stitched together along the leaflet post line, i.e., at the interface of adjacent side wings SW, thereby forming a conical duct.

30 The side wings SW, which allow a slack of material that protrudes outwardly of the duct, are then fixed to the armature posts, which are fully wrapped by the side wings SW.

35 The extra tissue skirt below the stitching holes SH allows leaflet fixation to the inflow ring 6 of the stent, by mean of a stitching line. Additionally, in some embodiments one - preferably the lower one or both

of the patterns SH may be stitched to the armature at the annular part 6.

5 A strip of pericardium is finally stitched to the inflow ring 6 outwardly of the same, defining the sealing cuff SC. The strip can be folded on its outflow end to provide a sealing collar along the valve perimeter, or a second strip can be connected by means of a circumferential stitching line to the first strip, to realize a sealing circumferential collar.

10 The prosthetic leaflets 4 may be in any number compatible with operation as replacement heart valve. In some embodiments, the set includes a pair of leaflets. In some embodiments, such as that shown in the figures, the set includes three prosthetic valve leaflets 4 (e.g. for an aortic valve prosthesis). In some embodiments, the set may include four leaflets 4.

15 In embodiments, the leaflets 4 can be made of biological material such as, for instance, bovine or porcine pericardium. In other embodiments, the leaflets 20 4 can be made of non-biological material such as a non-biological woven or nonwoven fabric that exhibits hemocompatibility properties. An example of this is disclosed, for instance in EP application no. EP 16745505.4.

25 Each valve leaflet 4 includes a fluidodynamically proximal edge 4P with an arched pattern, which extends from a base portion at the upper pattern SH and along two adjacent pleat formations PF, and a fluidodynamically distal edge 4D which extends towards 30 the central orifice of the prosthesis 1 so as to be able to co-operate with the homologous edges of the other valve leaflets 4.

The terms "fluidodynamically proximal" and "fluidodynamically distal" as used herein refer to the 35 free flow direction of the blood through the

prosthesis, a direction that is bottom up as viewed in the figures of the annexed plate of drawings.

During operation (heart cycle) the valve leaflets 4 experience deformation, divaricating and moving up
5 towards the armature 2 so as to enable free flow of the blood through the prosthesis.

When the pressure gradient, and hence the direction of flow, of the blood through the prosthesis tends to be reversed, the valve leaflets 4 then move into the
10 position represented in Figure 1A, in which they prevent the back flow of the blood through the prosthesis.

The prosthetic valve including the valve leaflets 4 can be, for example, a glutaraldehyde fixed pericardium
15 valve which has three cusps that open distally to permit unidirectional blood flow.

The pattern of arched struts 8 includes proximal ends
10 connected to the annular part 6, and distal ends 12 spaced axially from the proximal ends 10 and arranged
20 at an end of the armature 2 opposite the annular part 6. In embodiments, the distal ends 12 coincide with distal ends of the armature 2, and in embodiments where the distal end of the armature 2 coincides with a distal end of the prosthesis 1 as a whole, the distal
25 ends 12 coincide with a distal end of the prosthesis as well (this is the case of at least some of the embodiments depicted in the figures).

Owing to this layout, in embodiments, the prosthesis 1 includes an inflow portion IF essentially
30 corresponding to the annular part 6 (whether or not covered by the sealing cuff SC), and an outflow portion OF corresponding essentially to the distal region of the armature, i.e. that where the distal ends 12 are arranged.

The armature 2 further includes a plurality of sets 14 of anchoring formations 16 configured to protrude radially outwardly of the annular part 6, each set 14 being supported by at least one of the annular part 6 and a corresponding arched strut 8, and a plurality of support posts 18, each supported by adjacent arched struts 8, wherein the sets 14 of anchoring formations 16 alternate with the support posts 18 around the longitudinal axis X1. In embodiments the support posts 18 are advantageously cantilevered to adjacent arched struts 8 and are configured as fixing locations for the prosthetic valve, specifically for the pleat formations PF at the commissural points of the valve. In this regard, the posts 18 are wrapped by adjacent side wings SW previously stitched together during assembly of the prosthetic valve.

Referring again to Figures 2-5, in embodiments each arched strut 8 extends from a first proximal end 10, to a distal end 12, then to a second proximal end 10 in a valley-peak-valley sequence, wherein valleys are located at the proximal ends 10, and peaks are located at the distal ends 12. In embodiments the pattern of arched struts includes three adjacent and preferably identical arched struts 8 (such as in the figures). With reference to Figure 5 and Figure 6, in embodiments, the arched struts 8 extend within the boundaries of the inner and outer surfaces of the armature 2, so as to be substantially free of any protrusion relative to those surfaces. In other embodiments the arched struts may have an offset from the inner and outer surfaces of the armature 2, meaning by this they may either protrude radially inwardly or radially outwardly of two cylinder surfaces tangent to the inner and outer surfaces of the armature 2 (in the view of Figure 6, this would correspond to a radially

inward or a radially outward offset from the circular perimeter of the lumen defined by the armature 2.

In embodiments, the arched struts are sized and dimensioned so as to have a variable curvature between
5 a proximal end 10 and a distal end 12, for example with the arched shape starting with a 45 degrees tangent at the proximal end 10, and ending up with an 80 degrees tangent at the distal end, the angle being measured relative to a direction parallel to the axis X1

10 In some embodiments, the arched struts 8 are sized and dimensioned so as to exhibit appreciable variations in curvature between proximal and distal ends 10, 12. The pattern of arched struts 8 includes distal portions 20 located at the distal ends 12, and inter-strut
15 portions 22 located at the proximal ends 10. The distal portions 20 may be shaped so as to provide a marked local variation in the shape of the strut, for example by exhibiting a C-shape as shown in the figures. The distal portions 20 may provide coupling locations for
20 other devices such as a valve holder or a hub of a carrier portion of a delivery catheter. In other embodiments, the distal portions 20 may be provided as closed-loop structures such as eyes or eyelets. Note also that closed loop structures may be provided at the
25 annular part 6 (either as part of the armature 2 or on the sealing cuff SC, for example as loops made of yarn and weaved through the cuff SC) as coupling elements intended to be engaged e.g. by valve loading or crimping facilities or instruments.

30 In embodiments, the inter-strut portions 22 are essentially V-shaped and are defined by the roots of the adjacent arched struts departing from the same proximal end 10. In some embodiments, the inter strut portions 22 may exhibit a Y-shape or a U-shape. An
35 example of a Y-shape is shown in the figures

(particularly Figures 2-5) wherein each inter-strut portion 22 extends through the mesh of the annular part 6. In these embodiments, the mesh of the annular part 6 is provided as a sequence of rhomboidal strut clusters (cells) sequentially connected to each other at endpoints of a diagonal line (such as the shortest diagonal) and exhibiting accordingly an identical circular pattern of free ends on opposite sides of a circumference extending through the sequence of the connection points. The Y-shaped inter-strut portion 22 is thus integrally formed at a selected connection point between two adjacent rhomboidal strut clusters, and may extend no further than the proximal end of the armature 2.

In embodiments the strut clusters may be arranged according to an arrow shape, i.e. defined by two axially staggered sinusoidal patterns, circumferentially in phase, bridged by longitudinal struts.

In embodiments, the support posts 18 are angularly arranged at an inter-strut location, i.e., a circumferential location arranged at an area where an inter-strut portion 22 (as well as - accordingly - a proximal end 10 shared by two adjacent arched struts 8) is provided. The support posts may be provided as cantilevered to both the adjacent arched struts 8 intervening at an inter-strut portion 22 via a first and a second cantilever struts 24, 26, each connected to a corresponding one of said adjacent arched struts 8 as shown in the figures. In some embodiments, each cantilever strut 24, 26 may be a twin strut.

The cantilever struts 24, 26 merge into each corresponding post 18 starting from locations on respective arched strut 8 approximately halfway through the portion of the arched strut 8 extending from a

proximal end 10 to a distal end 12. Note that in other embodiments the support posts 18 may be cantilevered to the annular part 6, for example by being formed integrally with the inter-strut portion 22 (which in this case will exhibit a trident shape).

The connection points at which the Y-shaped inter-strut portion 22 is formed may be chosen so that the same portions are evenly spaced (angular-wise) around the axis X1. The same applies to the support posts 18, which may be arranged so as to be evenly spaced (angular-wise) around the axis X1.

In some embodiments shown in the figures, the armature 2 comprises three arched struts 8, three posts 18 spaced 120° around the axis X1, and three sets 14, so that the sequence around the axis X1 is post 18 - set 14 - post 18 - set 14 - post 18 - set 14 (in this sense, even the struts 8 and the sets 14 do follow a 120degree-like distribution). In embodiments the three sets 14 include each a pair of anchoring formations 16, wherein each set 14 (and accordingly each anchoring formation 16) extends bridge-wise between the annular part 6 and the corresponding arched strut 8. In embodiments, each pair of anchoring formations 16 extend bridge wise at an intra-strut location, that is a location within an arched strut 8 and as such comprised between two proximal ends 10 of the same arched strut 8 and under a distal end 12/distal portion 20. In other words, each set 14 of anchoring formations 16 extends bridge-wise from the arched strut 8 to a portion of the annular part 6 comprised between two proximal ends 10.

The support posts 18, accordingly, are arranged at an inter-strut location (e.g. above the inter-strut portion 22 as shown in the figures) so that the sequence post 18 - set 14 - post 18 - set 14 - post 18

- set 14 is provided, location-wise, as inter-strut - intra-strut - inter-strut - intra-strut - inter-strut - intra-strut.

In embodiments, the support posts 18 are provided with bores 28 configured for receiving sutures or stitches that fix the commissural portions (pleat formations of the valvular sleeve) to the posts 18, hence fixing the prosthetic valve to the armature 2. In some embodiments, the prosthetic valve is fixed to the support posts 18 with the same being completely outside of the valve. Sutures or stitches are routed through the bores 28 and through the valve layers contacting the corresponding post 18 from inside of the lumen. In other embodiments, the posts 18 may be wrapped by the valve layers - particularly by the commissural points of the valve - so that the valve is at least partially "outside" of the posts 18.

In embodiments, the anchoring formations may include a serpentine or otherwise weaving portion between opposite ends thereof. Such a serpentine or otherwise weaving portion is intended to provide a larger footprint to the anchoring formation at the interface with a Valsalva Sinus, and additionally it enables the bulging of the anchoring formations to a diameter larger than the inflow diameter, typically 1.4 or 1.5 times the inflow diameter.

The prosthesis 1 shown in Figure 1A is particularly suitable as aortic valve prosthesis, i.e. for replacement of an aortic valve. To this end, the prosthetic valve includes three identical leaflets 4 and the armature 2 is designed as a whole - as described above - according to 120°- spacing (or, where appropriate, a 1/3 coverage) criteria: three posts 18 at 120° apart, three sets 14 evenly distributed around the axis X1, and three arched struts 8 covering

approximately one third of the circumferential extension of the annular part 6.

The prosthesis 1 may be implanted as shown in Figure 7, so that the inflow portion IF at the annular part 6 occupies a proximal position relative to the Valsalva sinus VS, including a native valve annulus, while the anchoring formations 16 extend into the lobes of the Valsalva sinus VS (one set 14 per each Sinus) to firmly anchor the prosthesis 1 in place. The pattern of arched struts 8 is configured to follow the contour of the Valsalva Sinus at the interface with the ascending aorta, distally of the Sinus itself. The distal portions 20 of the distal ends 12 in various embodiments are intended to sit just distally of the Sinus.

In embodiments, achieving this placement of the prosthesis 1 may include sizing and dimensioning the prosthesis according to the following specifications (all endpoints included in the ranges):

axial length of the annular part 6 (inflow portion IF): 7 to 10 mm;

total axial length of the prosthesis (e.g. measured from a proximal end of the inflow portion If to the distal portions 20): 25 to 37 mm;

expanded diameter of the inflow portion IF (outer diameter of annular part 6, including sealing collar SC: 23 to 33 mm; and

extended outer diameter of anchoring formations 16, measured at the most radially outward portion of the anchoring formations: 31 to 44 mm.

Additionally, the prosthetic valve carried by the armature 2 may be sized and dimensioned according to the following specifications:

ventricular protrusion: 5 to 8 mm; and

implantation diameter: 19 to 29 mm.

The paired anchoring formations 16 - especially when provided with a serpentine or otherwise weaving pattern as shown in the figures - favourably contact the Sinus to hold the prosthesis 1 in place by bulging radially outwardly of the armature 2. The anchoring formations 16 of each pair may advantageously be positioned on opposite sides of the coronary ostia in the respective sinuses of Valsalva, with the serpentine or otherwise generally weaving (or else aperture) structure thereof substantially avoiding interference with the coronary ostia.

The armature 2 of the prosthesis 1, according to embodiments, is manufactured by first cutting a blank part from a tube of a biocompatible metal (e.g., Nitinol, or a cobaltum-chromium alloy) having an outer diameter which is at an intermediate size between the fully radially contracted and the fully expanded device dimensions. For example, the tube may have an outer diameter of between about 10 mm to about 14 mm. In some embodiments, the tube has a diameter of about 12 mm. In some embodiments, the tube wall may vary between about 0.4 mm to about 0.6 mm, depending on the required stiffness required and the size of the prosthesis 1.

In embodiments, the final dimension and shape of the framework is achieved by a sequence of expansion cycles. A specific heat treatment is applied after each expansion cycle to homogenize and stress relieve the material, which allows the shape and properties of the structure of the armature 2 to be set. Although the number of forming steps may vary among devices, for the geometries described above with respect to the present disclosure, and using Nitinol for the tube blank, an exemplary number of forming steps is around three. Among these steps, the first two provide the final

diameter of the annular part 6. For example, if the fully-expanded diameter for implantation is 20.5 mm, the final cylindrical shape of the armature 2 can be achieved using a tube blank of about 12 mm in inner diameter, a first expansion from about 12 mm to about 15 mm, and a second expansion from about 15 mm to about 19.5 and a third expansion from about 19.5 to 21.5 mm. Optionally, the final diameter can be made slightly larger (e.g. about 21.5 mm in the previous example) in order to oversize the armature 2 with respect to the physiological annulus, thus imparting a radial force to the wall of the annulus at the nominal implant diameter.

All the forming steps are also aimed to impart the radially-extending shape of the anchoring formations such that they will fit and anchor within the Valsalva sinuses.

After the forming process is complete, the armature 2 may undergo one or more surface treatments, for example, sandblasting and electropolishing, to provide a sufficiently smooth surface and to remove the shallow defects. The armature 2 may thereafter be finally exposed to a carbon coating process in order to improve its hemocompatibility.

The final geometrical shape of the armature 2 will thus generally approximate the physiological shape and dimension of the aortic root, such that the anchoring formations 16 generally conform to the walls of the respective Valsalva sinuses VS.

The prosthesis 1 is delivered to the implantation site in a radially contracted condition, for example crimped and loaded into a delivery instrument such as a catheter. The prosthesis may be implanted using minimally invasive techniques or via conventional surgical techniques such as sternotomy or thoracotomy.

Once on site, the prosthesis 1 is released from the catheter so to allow the annular part 6 to expand to the radially expanded configuration and the anchoring formations 16 to settle into the Valsalva Sinus.

5 In embodiments, the provision of support posts 18 that are cantilevered to the arched struts 8 decouples the deformation pattern of the proximal portion of the prosthesis 1 - that is, the annular part 6 - from the deformation pattern of the distal portion of the same
10 prosthesis - that is, the portions of arched struts 8 converging to the distal ends 12. If the implantation site has an irregular shape (like a D-shape) such as to result in substantial alterations of leaflet functionality with prior art prostheses, the prosthesis
15 1 on the contrary allows the annular part to adapt to the shape of the implantation site without transmitting any of the deformations resulting therefrom to the support posts 18, which essentially maintain the advertised position on the armature 2 by remaining
20 spaced 120 degrees apart. In the case of an aortic implantation site, the deformation pattern of the annular part 6 may be largely variable on account of the shape of the site per se, and/or the size of calcium deposits possibly present at the implantation
25 site, while the deformation pattern of the arched struts 8 may be - instead - reasonably predictable and regular on account of a lesser variability of conditions at the locations concerned (Valsalva Sinus and ascending aorta). Therefore, the support posts 18
30 may take benefit from highly predictable and reasonably regular deformation of the portions of the armature it is attached to, thereby keeping the relative position thereof and allowing the prosthetic valve with the valve leaflets 4 to operate as efficiently as possible,

and ultimately independently of the shape and conditions of the implantation site.

Additionally, folding phenomena of the prosthesis are avoided owing to the armature design. Folding generally occurs on account of an inward rotation of the anchoring formations 16, wherein one rotates clockwise, and the other one rotates counterclockwise to jointly result in an inward displacement of annular part 6 . Anchoring formations 16 bridging two structural portions having a substantial axial extension and/or resistance to bending (relative to that of the anchoring formations) may encourage - undesirably - these phenomena, as the anchoring formations end up with accommodating a major share of deformations within the armature 2, which the structural portions above (e.g. two annular portions at opposite ends of the armature) inherently cannot accommodate.

Because the armature 2 features the pattern of arched struts 8, the anchoring formations 16 essentially bridge one structural portion, such as the annular part 6, that has a substantial axial extension and/or resistance to bending relative to the formations 16, and another structural portion such as the arched struts 8 which is subject to a binding structural constraint primarily at the proximal portions thereof (i.e. the proximal ends 10 and the inter-strut portions 22, while the distal portions 20 at the distal ends 12 are relatively free to accommodate deformations running through the armature from the proximal - stiffer - portions thereof (e.g. the inflow). This difference in strength or binding amount of the structural constraints the arched struts 8 are subject to allows to divert away from the anchoring formations the structural actions that would otherwise tend to rotate the anchoring formations 16. Diversion may occur, for

example, over the length of the arched struts and/or towards the distal ends 12 thereof.

In other words, the arched struts tend to compensate (essentially in that they have a lesser degree of
5 constraint to the remainder of the armature) the torsional forces on the anchoring formations 16, thereby keeping the same separate from one another and the armature 2 as a whole as close as possible to the intended shape.

10 Naturally, while the ideas and the principles of the disclosure remains the same, the details of construction and the embodiments may widely vary with respect to what has been described and illustrated by way of example, without departing from the scope of the
15 present disclosure.

Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present disclosure. For example, while the embodiments described above refer to
20 particular features, the scope of this disclosure also includes embodiments having different combinations of features and embodiments that do not include all of the described features. Accordingly, the scope of the present disclosure is intended to embrace all such
25 alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

CLAIMS:

1. A cardiac valve prosthesis comprising:

an armature for anchorage of the valve prosthesis at an implantation site, the armature defining a lumen for the passage of the blood flow and having a longitudinal axis; and

a set of prosthetic valve leaflets supported by the armature and configured to move, under the action of blood flow, in a radially divaricated condition to enable the flow of blood through the lumen in a first direction, and in a radially contracted condition, in which the set of prosthetic valve leaflets co-operate with one another and block the flow of blood through the prosthesis in the direction opposite the first direction,

the armature comprising:

an annular part;

a pattern of arched struts carried by the annular part, the pattern of arched struts having proximal ends connected to the annular part, and distal ends spaced axially from the proximal ends and opposite the annular part;

a plurality of sets of anchoring formations configured to protrude radially outwardly of the annular part to contact a valsalva sinus at the implantation site to anchor the valve prosthesis, each set being supported by at least one of the annular part and a corresponding arched strut; and

a plurality of support posts, each support post being supported by adjacent arched struts,

wherein the sets of anchoring formations alternate with the support posts around the longitudinal axis and each set of anchoring formations extends bridge-wise between a corresponding arched strut and the annular part.

2. The cardiac valve prosthesis of claim 1, wherein each support post is cantilevered to adjacent arched struts.

3. The cardiac valve prosthesis of claim 2, wherein the support post is cantilevered to the pair of arched struts by way of a first and a second cantilever struts merging at the supporting post.

4. The cardiac valve prosthesis of claim 1, wherein each arched strut extends from a first proximal end, to a distal end, then to a second proximal end.

5. The cardiac valve prosthesis of claim 4, wherein each set of anchoring formations extends bridge-wise from an arched strut to a portion of the annular part comprised between two proximal ends.

6. The cardiac valve prosthesis of claim 5, wherein each set of anchoring formations comprises two anchoring formations.

7. The cardiac valve prosthesis of claim 5, wherein each anchoring formation comprises a serpentine, a weaving, or an apertured pattern.

8. The cardiac valve prosthesis of claim 1, wherein the annular part is covered by a cuff to provide sealing at the implantation site, the cuff arranged outside of the lumen of the armature.

9. The cardiac valve prosthesis of claim 8, wherein the cuff is separate from the set of prosthetic valve leaflets.

10. The cardiac valve prosthesis of claim 1, wherein the annular part includes one or more coupling elements configured to be engaged by valve loading or crimping facilities or instruments.

11. The cardiac valve prosthesis of claim 1, wherein the set of prosthetic valve leaflets define an aortic valve prosthesis, the cardiac valve prosthesis being an aortic valve prosthesis.

12. A cardiac valve prosthesis comprising:

an armature for anchorage of the valve prosthesis at an implantation site, the armature defining a lumen for the passage of the blood flow and having a longitudinal axis; and

a set of prosthetic valve leaflets supported by the armature and configured to move, under the action of blood flow, in a radially divaricated condition to enable the flow of blood through the lumen in a first direction, and in a radially contracted condition, in which the set of prosthetic valve leaflets co-operate with one another and block the flow of blood through the prosthesis in the direction opposite the first direction,

the armature comprising:

an annular part;

a pattern of arched struts carried by the annular part, the pattern of arched struts having proximal ends connected to the annular part, and distal ends spaced axially from the proximal ends and opposite the annular part;

a plurality of sets of anchoring formations configured to protrude radially outwardly of the annular part, each set being supported by at least one of the annular part and a corresponding arched strut; and

a plurality of support posts, each support post being supported by adjacent arched struts,

wherein the sets of anchoring formations alternate with the support posts around the longitudinal axis, and wherein each support post is angularly arranged between two adjacent arched struts at an inter-strut position, the inter-

strut position corresponding to the position of a proximal end shared between the two adjacent arched struts.

13. A cardiac valve prosthesis comprising:

an armature for the valve prosthesis at an implantation site;

a set of prosthetic valve leaflets supported by the armature;

the armature comprising:

an annular part;

a plurality of arched struts coupled to the annular part;

a plurality of support posts supported by adjacent arched struts; and

a plurality of sets of anchoring formations configured to protrude radially outwardly of the annular part to contact a Valsalva sinus at the implantation site to anchor the valve prosthesis, each set being supported by at least one of the annular part and a corresponding arched strut;

wherein each arched strut includes a distal portion at a distal end thereof which is substantially C-shaped and is configured to mate with a valve holder or a carrier portion of a delivery instrument.

14. A cardiac valve prosthesis comprising:

an armature for the valve prosthesis at an implantation site;

a set of prosthetic valve leaflets supported by the armature;

the armature comprising:

an annular part;

a plurality of arched struts coupled to the annular part;

a plurality of support posts supported by adjacent arched struts; and

a plurality of sets of anchoring formations configured to protrude radially outwardly of the annular part, each set being supported by at least one of the annular part and a corresponding arched strut;

wherein the plurality of arched struts includes inter-strut portions arranged at proximal ends, and the annular part has a mesh structure including cells and nodes; and

wherein the inter strut portions have a Y-shape or a U-shape extending through the cells or nodes of the mesh structure of the annular part.

15. A cardiac valve prosthesis comprising:

an armature for the valve prosthesis at an implantation site;

a set of prosthetic valve leaflets supported by the armature;

the armature comprising:

an annular part;

a plurality of arched struts coupled to the annular part;

a plurality of support posts supported by adjacent arched struts; and

a plurality of sets of anchoring formations configured to protrude radially outwardly of the annular part to contact a Valsalva sinus at the implantation site to anchor the valve prosthesis, each set being supported by at least one of the annular part and a corresponding arched strut;

wherein each set of anchoring formations extends bridge-wise between a corresponding arched strut and the annular part.

16. The cardiac valve prosthesis of claim 15, wherein the support posts are cantilevered to adjacent arched struts.

17. The cardiac valve prosthesis of claim 16, wherein the sets of anchoring formations alternate with the support posts around a longitudinal axis of the prosthesis.

18. The cardiac valve prosthesis of claim 15, wherein the armature defines a lumen for the passage of the blood flow and having a longitudinal axis, and the annular part is covered by a cuff to provide sealing at the implantation site, the cuff being arranged outside of the lumen of the armature.

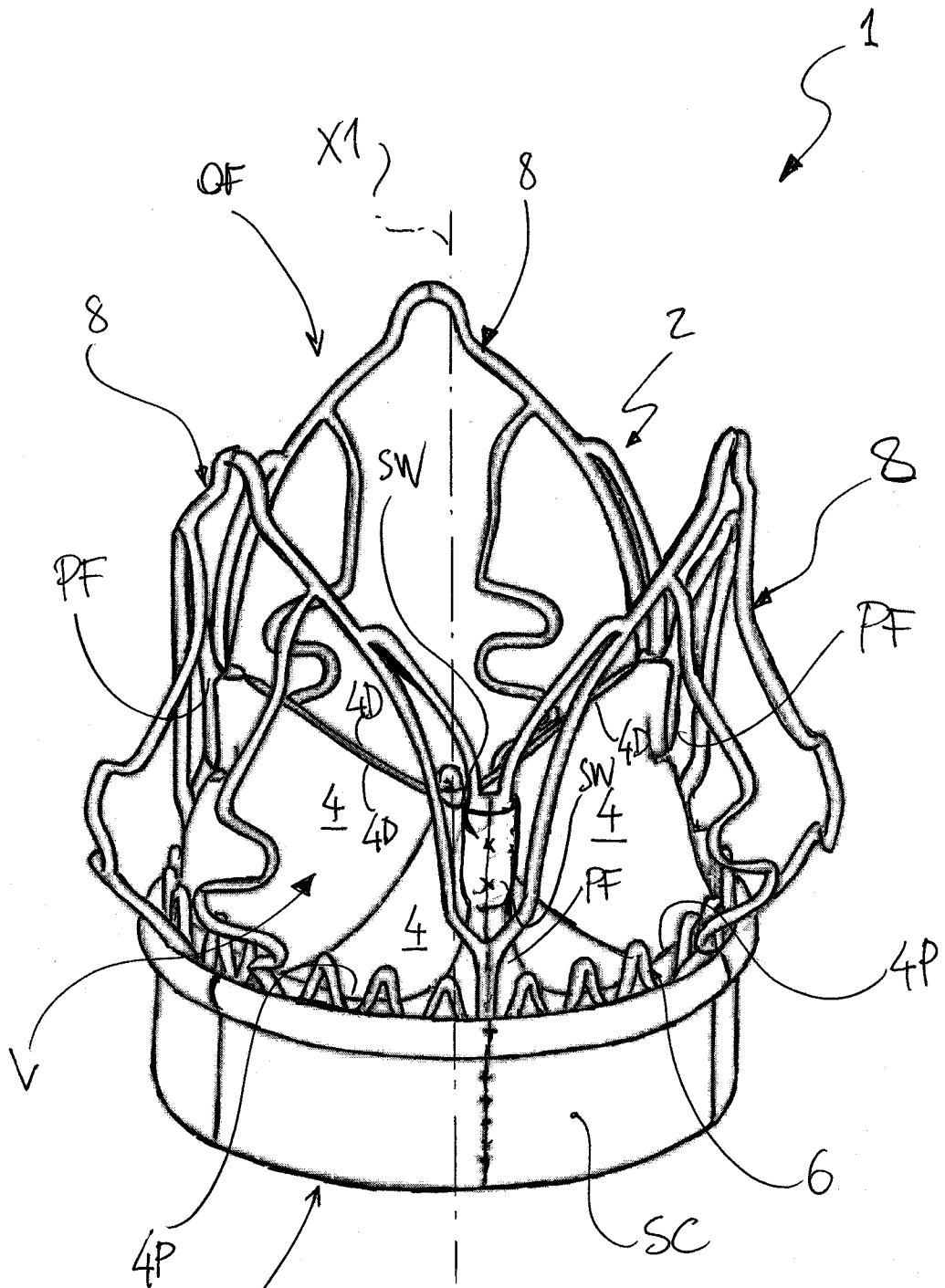


FIG. 1A

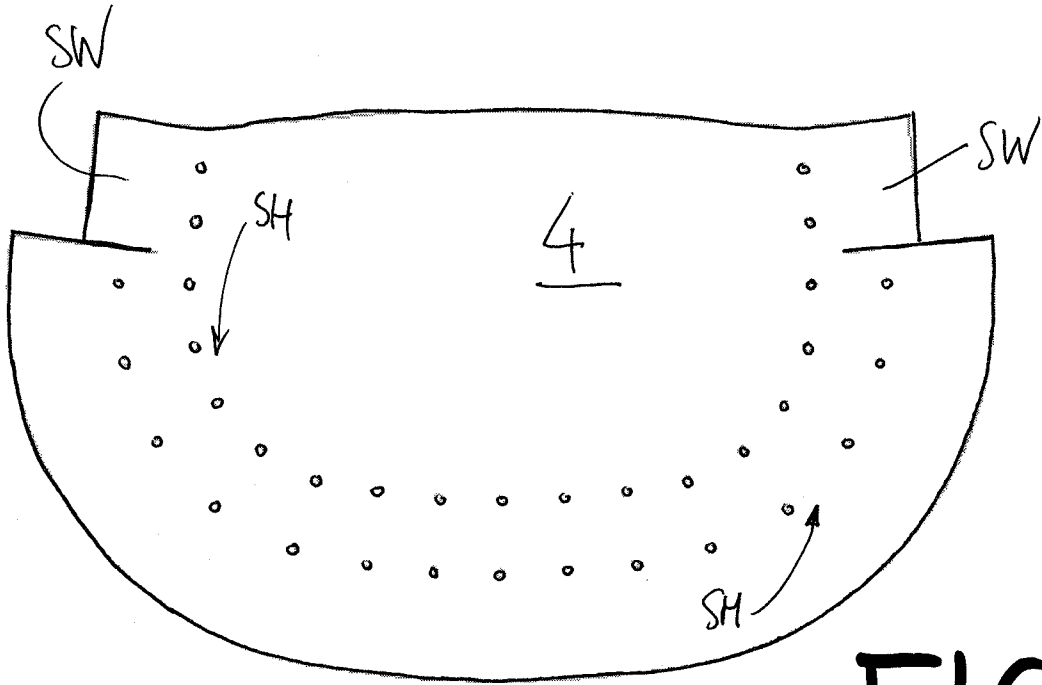


FIG. 1B

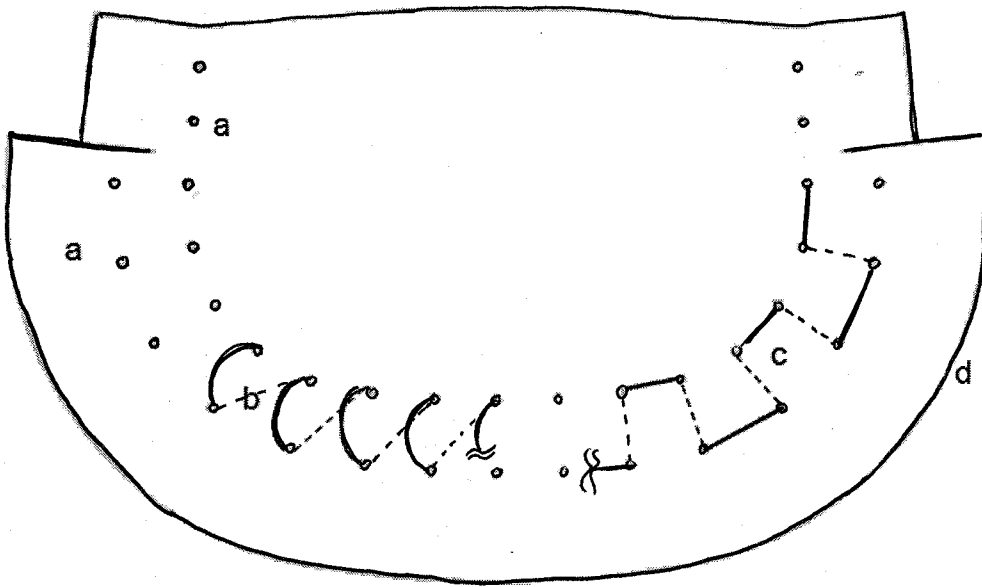


FIG. 1C

FIG. 2

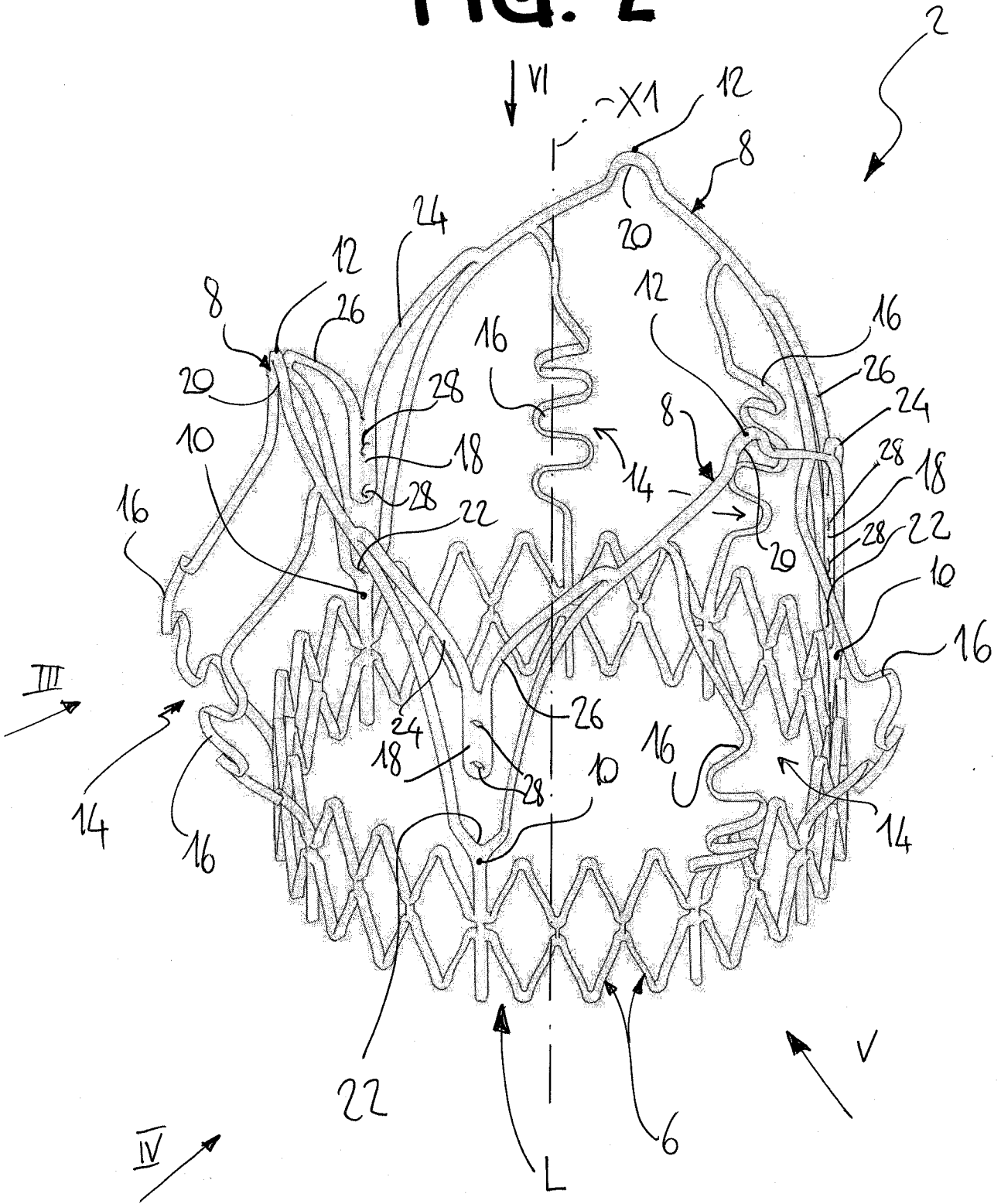


FIG. 3

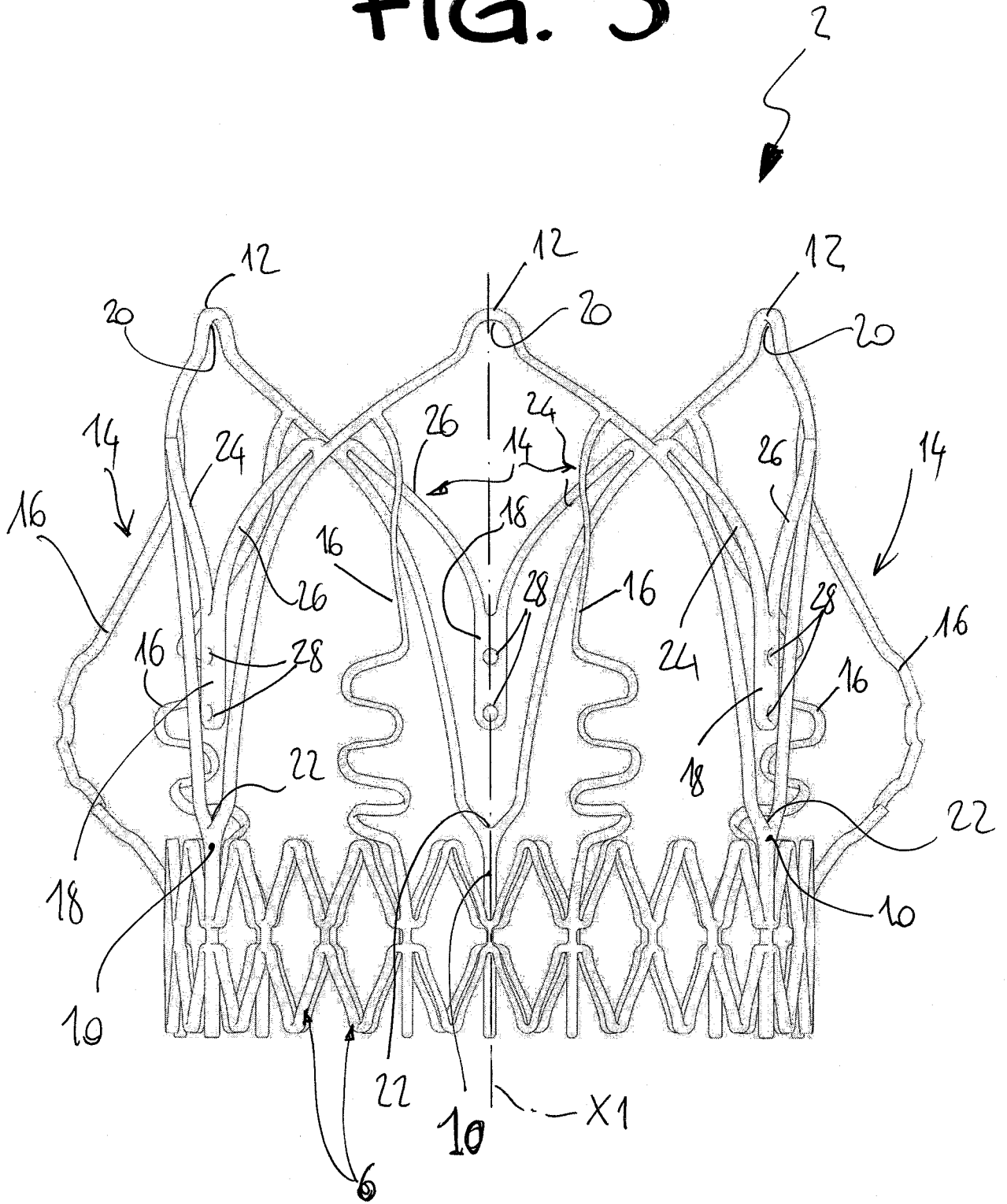
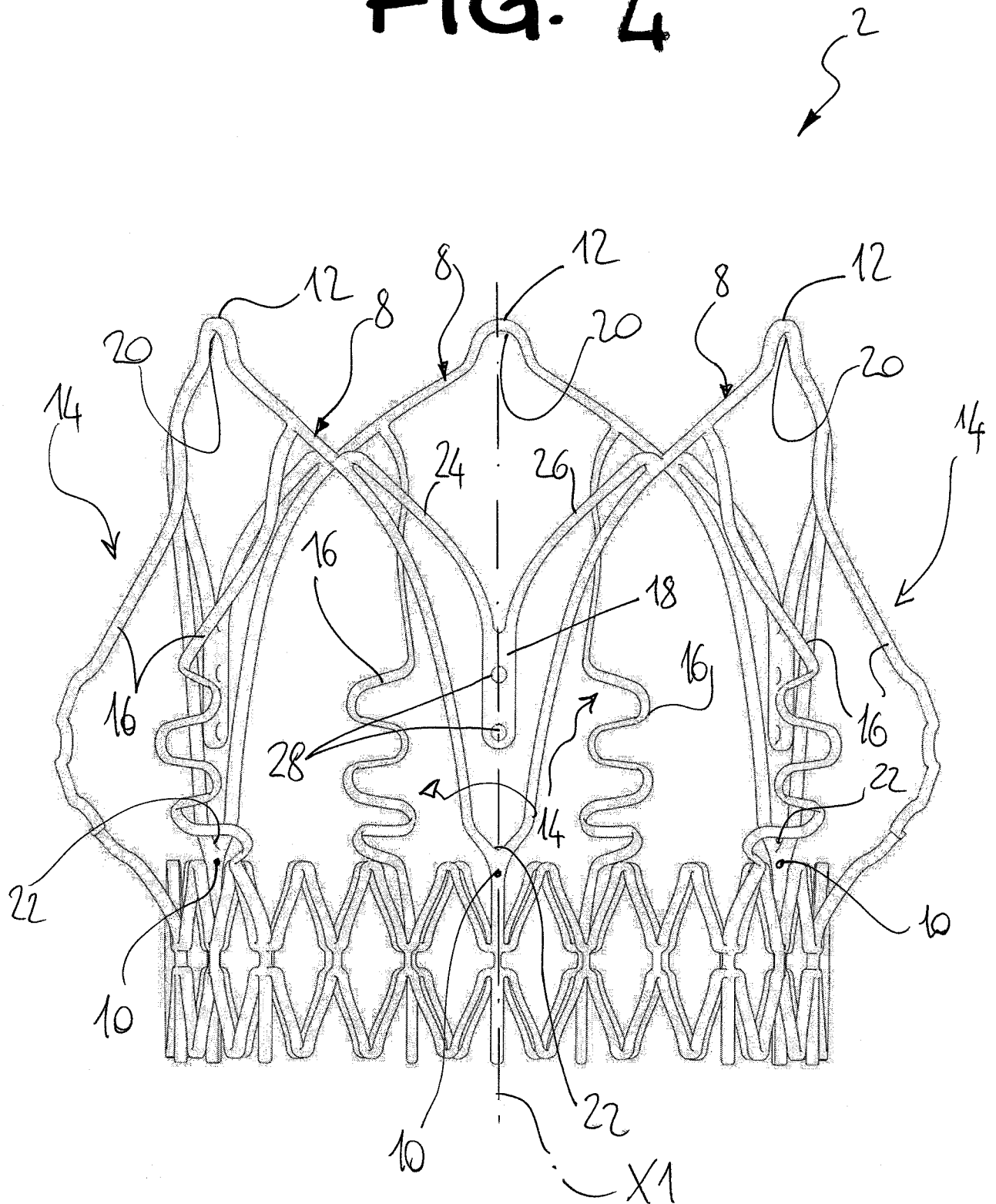


FIG. 4



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FIG. 5

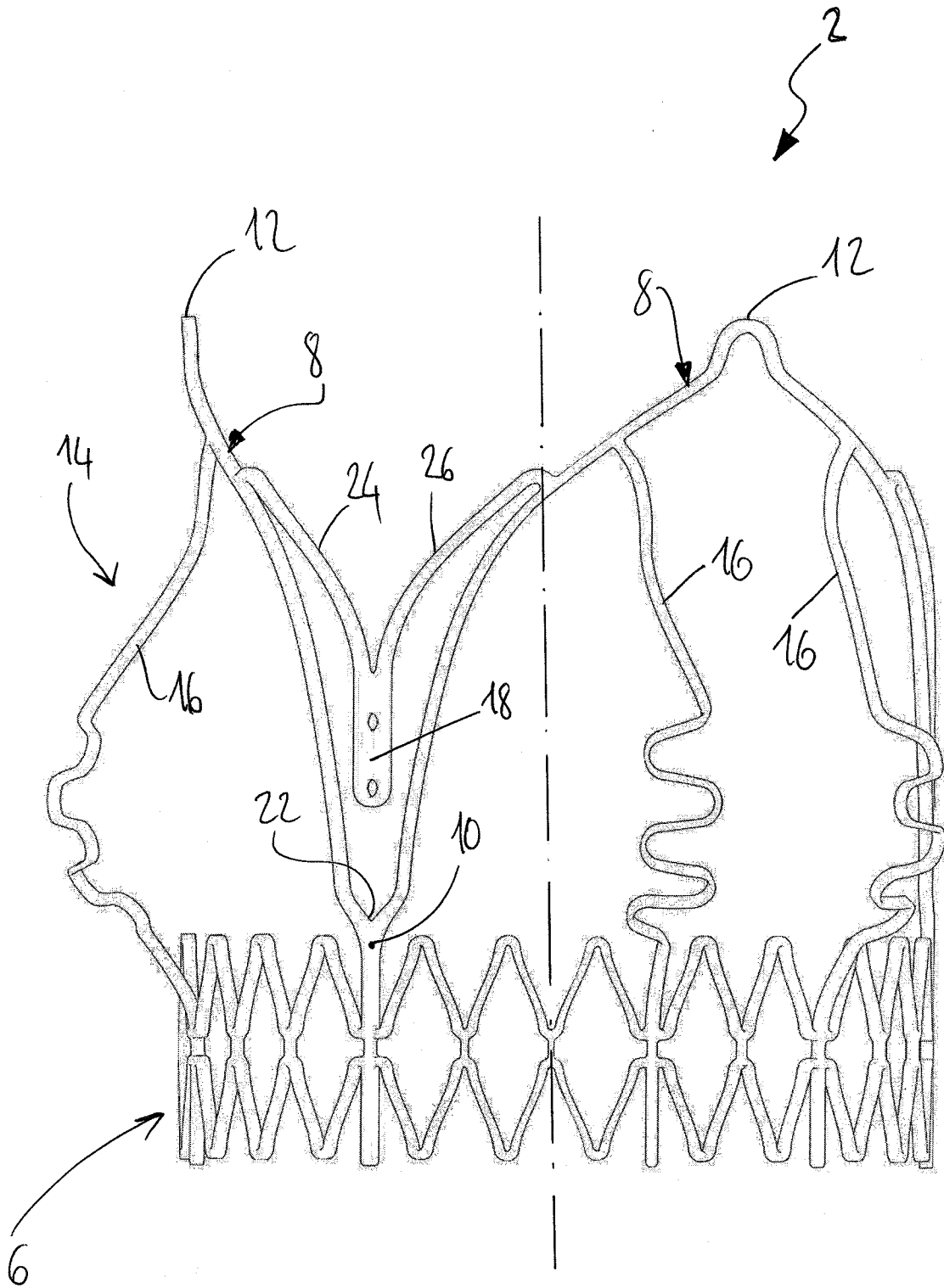
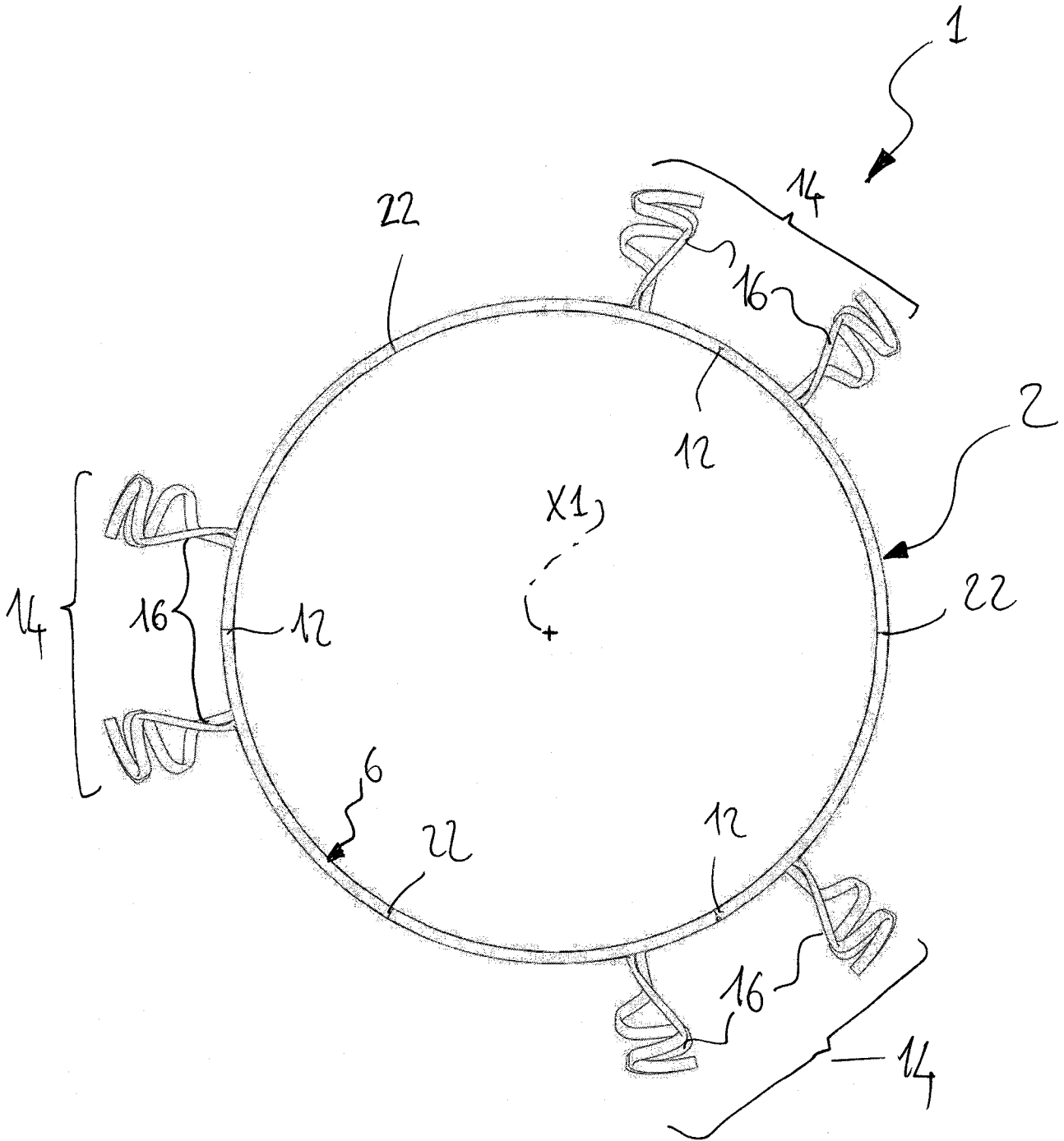


FIG. 6



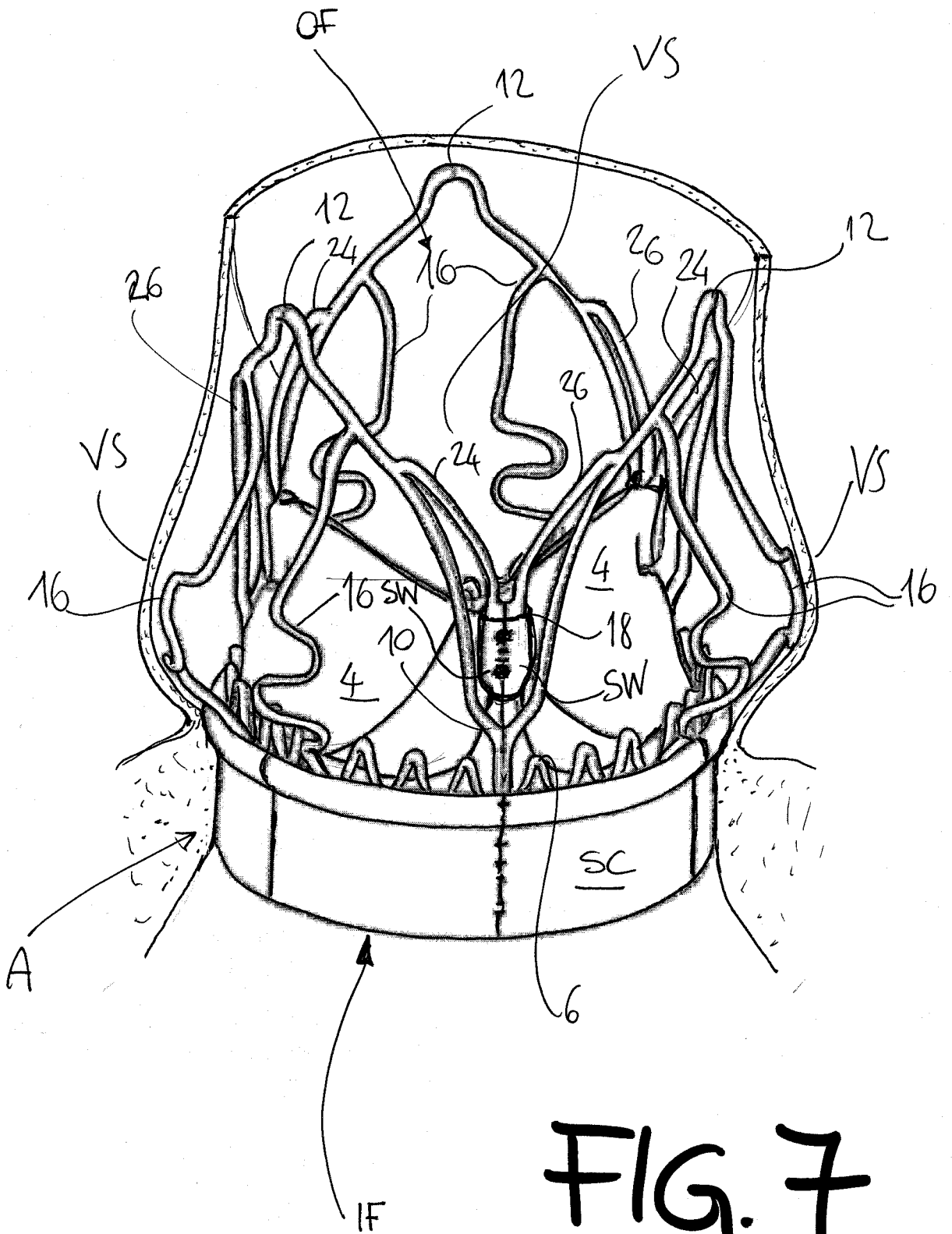


FIG. 7