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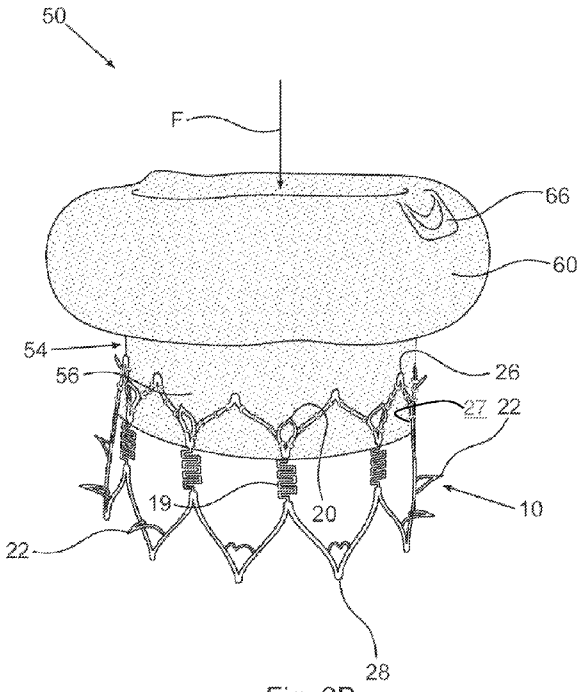

Fig. 3B

(57) Abstract: A prosthetic cardiac valve system is disclosed comprising a stent comprising a flexible tubular element having an upstream mesh section, a downstream mesh section, and a radially deformable intermediate section extending therebetween. The upstream mesh section is configured with a plurality of upstream tissue engaging spikes, and/or the downstream mesh section is configured with a plurality of downstream tissue engaging spikes. The upstream tissue engaging spikes and the downstream tissue engaging spikes are made of memory shape material and are configured, at a closed position to be coplanar with an outside surface of the stent, and at an expanded deployed position of the stent, after being introduced in situ and reaching a predefined temperature to deform to their memory shape to project radially outwards from an outside surface of the stent to their radially outwards deformed position, controlled by the inflation of the downstream inflatable tubular element. An upstream elastic sleeve may extend over at least a portion of the upstream mesh section. The upstream elastic sleeve can have an upstream inflatable tubular element disposed axially upstream of the upstream mesh section or downstream of the upstream mech section. A prosthetic cardiac valve can be configured to be secured within the upstream elastic sleeve after the stent is positioned in situ and the upstream inflatable tubular element of the upstream elastic sleeve is inflated. The prosthetic valve leaflets can be integrated as one piece within the prosthetic cardiac valve system.

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CARDIAC ANCHORING STENT, VALVE SYSTEM AND A METHOD FOR DEPLOYING SAME

TECHNOLOGICAL FIELD

The present disclosure is concerned with a cardiac valve, a personalized anchoring and sealing mechanism therefor, and a method for deploying and anchoring same.

BACKGROUND ART

Cardiac valve replacement may be necessary in cases where the valve is severely damaged or diseased. Replacement of a cardiac valve can often involve complications related with anatomic differences such as variable outlines and borders at the valve site.

References considered to be relevant as background to the presently disclosed subject matter: WO22201158; WO2017151566; US8,556,881; US2022241071; WO2022201158; US2009088836; WO2017151566.

Acknowledgement of the above references herein is not to be inferred as meaning that these are in any way relevant to the patentability of the presently disclosed subject matter.

BACKGROUND

WO22201158 discloses a supporting structure for accommodating a prosthetic valve aimed at replacing valve, a prosthetic valve system, a method for sealing between a native tissue and a prosthetic implant, a kit for implanting a prosthetic valve and a medium to be used with a supporting structure. The technique provides an implant structure with high compatibility with various anatomies while allowing optimal sealing and tissue anchoring, thus implementing personalized valve replacement procedures. This technique provides an accurate fitting for optimal sealing and anchoring to various complex anatomies necessitating a prosthesis.

WO2017151566 discloses methods, devices, and systems for anchoring and/or sealing a heart valve prosthesis and, in particular, a mitral valve prosthesis, wherein

inflatable elements are used to seal and anchor the mitral valve prosthesis and/or other elements associated with repairing a native mitral valve.

US2022104940 discloses prosthesis configured to grasp intraluminal tissue when deployed within a body cavity and prevent axial flow of fluid around an exterior of the prosthesis. The prosthesis can include an expandable frame configured to radially expand and contract for deployment within the body cavity and a valve body. The expandable frame can include a frame body and a supplemental frame. The valve body can include a plurality of leaflets and one or more intermediate components. The one or more intermediate components can couple at least a portion of the leaflets to the expandable frame. The prosthesis can include an annular flap positioned around an exterior of the expandable frame.

Acknowledgement of the above references herein is not to be inferred as meaning that these are in any way relevant to the patentability of the presently disclosed subject matter.

GENERAL DESCRIPTION

A first aspect of the disclosure is directed to a support structure for supporting a prosthetic cardiac valve, said support structure comprising a flexible tubular stent having an upstream mesh section and a downstream mesh section, with a radially deformable intermediate mesh section extending therebetween, and wherein the upstream mesh section is configured with a plurality of upstream tissue engaging spikes and/or the downstream mesh section is configured with a plurality of downstream tissue engaging spikes; wherein at an expanded position of the stent said upstream tissue engaging spikes and said downstream tissue engaging spikes project radially outwards from an outside surface of the stent; and an upstream elastic sleeve extending over at least a portion of said upstream mesh section; said upstream elastic sleeve having an upstream inflatable tubular element disposed axially upstream of said upstream mesh section.

The terms '*upstream*' and '*downstream*' as used herein in the specification and claims, correspond with normal hemodynamics flow directions, respectively. Accordingly, when considering a mitral valve blood flows in direction from the upstream left atrium towards the downstream left ventricle; when considering a tricuspid valve blood flows in direction from the upstream right atrium towards a downstream right ventricle; when discussing the aortic valve blood flows in direction from the upstream

left ventricle towards the downstream aorta, and; and when discussing the pulmonary valve blood flows in direction from the upstream right ventricle towards the downstream pulmonary artery.

The term *'valve'* as used herein the specification and claims denotes a prosthetic valve engageable within the elastic sleeve, and configurable as a one-way valve, facilitating blood flow in correspondence with hemodynamics flow directions.

The prosthetic valve is inherent with a carrier stent, wherein a nominal diameter of the stent of the prosthetic valve, at its deployed position, is greater than a nominal diameter of the stent at its deployed position, hence once deployed, the prosthetic valve is engageable within the elastic sleeve.

However, according to another example, the prosthetic valve can be directly secured within the elastic sleeve.

The support structure is configurable between a constricted, deploying position at which it is at a closed position, and an expanded, open position at which it assumes a radially expanded position, and wherein at the closed position the upstream tissue engaging spikes and the downstream tissue engaging spikes are coplanar with an outside surface of the stent.

Herein the specification and claims, the terms 'deployed', 'expanded' and 'nominal' positions can be used interchangeably, all of which refer to the stent/support structure at a position at which it assumes a maximal diameter. Likewise, the terms '*un-inflated*' and '*nominal'* position refer to the stent at its position at rest, prior to manipulating into its deployed position.

The support structure, at its closed position, can be received within a deploying catheter.

A second aspect of the disclosure is directed to a stent member for supporting a prosthetic cardiac valve, the stent member being a flexible tubular element having an upstream mesh section and a downstream mesh section, with a radially deformable intermediate section extending therebetween, and wherein the upstream mesh section is configured with a plurality of upstream tissue engaging spikes and/or the downstream mesh section is configured with a plurality of downstream tissue engaging spikes, whereby radially outwardly deforming the upstream mesh portion entails radial outwards deformation of the of upstream tissue engaging spikes, and radially outward deformation

of the intermediate section entails radially outwards deformation of the downstream mesh section and of the downstream tissue engaging spikes.

Radially outwardly deformation of the upstream mesh portion and of the downstream mesh section is imparted by an inflatable tubular element associated with the respective mesh portion.

The stent undergoes thermal treatment, whereby it obtains memory shape, so that once introduced into the body and deformed into its operative, expanded position it maintains said memory shape imparted thereto.

The stent is a tubular wire mesh, that can be made using different technologies, e.g. weaving a wire, welding, fine cutting techniques through a tubular element and other techniques used in the art of stent manufacturing, depending, among others, on final required mechanical properties.

The stent can be made of various biocompatible materials, such as metal (e.g. Nitinol -NiTi), polymeric materials, composite materials and others, however imparting the stent its unique property, namely the ability to be deformed from a closed position and return to its initial expanded shape upon exposure to heat or pressure, or upon cease of a restraint compacting force (in case of a self-expandable device). This allows the stent to be compressed for insertion through a small body incision, and then expand to the desired size and shape once manipulated in site.

Before deploying the stent into the body, the tissue engaging spikes remain flush with an outside surface of the stent. However, once the stent is deployed and reaches body temperature (approx. 37C°) the upstream tissue engaging spikes and said downstream tissue engaging spikes project radially outwards from an outside surface of the stent, as per predesigned memory shape thereof.

A third aspect of the disclosure is directed to a prosthetic cardiac valve system, comprising:

a support structure comprising a flexible tubular stent having an upstream mesh section and a downstream mesh section, with a radially deformable intermediate mesh section extending therebetween, and wherein the upstream mesh section is configured with a plurality of upstream tissue engaging spikes and/or the downstream mesh section is configured with a plurality of downstream tissue engaging spikes; wherein at an expanded position of the stent said upstream tissue engaging spikes and said downstream tissue engaging spikes project radially outwards from an outside surface of the stent;

an upstream elastic sleeve extending over at least a portion of an inside face of said upstream mesh section; said upstream elastic sleeve having an upstream inflatable tubular element disposed axially upstream of said upstream mesh section; and

a prosthetic cardiac valve engageable within the upstream elastic sleeve and downstream of the upstream inflatable tubular element, said valve configured to facilitate blood flow therethrough in direction from the upstream mesh section towards the downstream mesh section, corresponding with normal hemodynamics. The prosthetic cardiac valve can be configured to be secured within one or more of the mesh sections of the stent e.g., after the stent is positioned *in situ* and the upstream inflatable tubular element of the upstream elastic sleeve and the downstream inflatable tubular element of the downstream elastic sleeve are inflated.

Notably, the term *dock* is at times used in the art, as referring to a prosthetic cardiac valve support system.

The prosthetic cardiac valve is integrated in some embodiments with the stent. The prosthetic cardiac valve support system can comprise temporary valve leaflets attached to one or more mesh portions of the stent and/or to the upstream elastic sleeve configured. The prosthetic cardiac valve support system can be configured for attachment of the prosthetic cardiac valve by over-riding the temporary valve leaflets of the prosthetic cardiac valve support system, namely, the *dock*.

According to any of the aspects of the present disclosure, a downstream inflatable tubular element can be configured in association with the downstream mesh section and configured for deploying same radially outwards.

The prosthetic cardiac valve system according to the present disclosure can further be configured with an inflating mechanism for inflating and pressure regulating of the pressure within the upstream inflatable tubular element and the downstream inflatable tubular element). The respective inflating mechanism can be independently associated with each of the upstream inflatable tubular element and the downstream inflatable tubular element.

A fourth aspect of the disclosure is directed to a prosthetic cardiac valve kit comprising:

a support structure comprising a flexible tubular stent having an upstream mesh section and a downstream mesh section, with a radially deformable intermediate mesh section extending therebetween, and wherein the upstream mesh section is configured

with a plurality of upstream tissue engaging spikes and the downstream mesh section is configured with a plurality of downstream tissue engaging spikes; wherein at an expanded position of the stent said upstream tissue engaging spikes and said downstream tissue engaging spikes project radially outwards from an outside surface of the stent;

upstream elastic sleeve extending over at least a portion of an inside face of said upstream mesh section; said upstream elastic sleeve having an upstream inflatable tubular element disposed axially upstream of said upstream mesh section;

a prosthetic cardiac valve engageable within the upstream elastic sleeve and downstream of the upstream inflatable tubular element, said valve configured to facilitate blood flow therethrough in direction from the upstream mesh section towards the downstream mesh section, corresponding with normal hemodynamics;

an introducing and deploying system comprising a catheter and a guide wire, said catheter encapsulating the prosthetic cardiac valve system at a collapsed position and configured for deploying the prosthetic cardiac valve system *in situ*; and

an inflating mechanism for inflating the upstream tubular element and the downstream inflatable tubular element.

A fifth aspect of the disclosure is directed to a method of deploying a prosthetic cardiac valve system, or a fully functional prosthetic cardiac valve, (i.e., a prosthetic cardiac valve system), as disclosed herein above, the method comprising the following steps:

A. Introducing a guide wire with a distal capsule (*Over The Wire Delivery system*) containing the prosthetic cardiac valve support system (‘*dock*’), or the fully functional prosthetic cardiac valve (i.e. a prosthetic cardiac valve system), at a compressed position e.g., visualized under imaging;
B. Exposing the downstream inflatable element with the downstream mesh section of the stent at the sub annular level of the native valve, distal to the native leaflets coaptation line;
C. Inflating the downstream inflatable element, while upstream inflatable element is still crimped in the capsule;
D. Retrieving the capsule towards the upstream portion of the valve, allowing the downstream spikes to engage downstream of the native valve;
E. Unsheathing the upstream inflatable element under imaging;
F. Inflating the upstream inflatable element;

G. Withdrawing the capsule, while the guide wire optionally remains in place;

In some embodiments the method further comprises: introducing and guiding a compressed prosthetic valve over the guide wire *e.g.*, with a dedicated delivery system of the prosthetic valve into the prosthetic cardiac valve system; positioning the prosthetic valve within the inflated prosthetic cardiac valve system under imaging, between the upstream inflatable element and the downstream inflatable element; deploying the prosthetic valve; optionally, withdrawing the prosthetic valve's capsule; optionally, adjusting inflation level of the upstream inflatable element and/or the downstream inflatable element for para-prosthetic leaks elimination and sub annular adjustments, performed under imaging; detaching the inflating mechanism of the upstream inflatable element and the downstream inflatable element; and removing the guide wire.

In yet another aspect there is provided a method of deploying a prosthetic cardiac valve system, or a prosthetic cardiac valve support system, the method comprising: introducing a guide wire with a distal splitable capsule containing the prosthetic cardiac valve system at a compressed position e.g., visualized under imaging; splitting the distal portion pf the capsule for exposing an upstream inflatable element above native leaflets of a native valve while maintaining downstream portions and a stent of the prosthetic cardiac valve in a splitted portion of the distal capsule distal to the upstream inflatable element; inflating the upstream inflatable element; distally advancing the inflated upstream inflatable element and the splitted portion of the capsule to place the inflated upstream inflatable element over an annulus of the native vale and introducing the splitted portion of the capsule below the native leaflets of the native valve; distally advancing the splitted portion of the capsule for unsheathing the downstream portions and the stent of the prosthetic cardiac valve e.g., under imaging; inflating the downstream inflatable element for anchoring the stent sub-annularly *e.g.*, by upstream and/or downstream tissue engaging spikes of the stent; and withdrawing the capsule.

The method may comprise introducing over the guidewire a compressed insertable prosthetic cardiac valve into the prosthetic cardiac valve system, positioning the compressed insertable prosthetic valve within the inflated prosthetic cardiac valve system e.g., under imaging, deploying the insertable prosthetic valve, withdrawing the prosthetic valve's capsule.

By a specific configuration, there is disclosed a support structure for supporting a prosthetic mitral valve, said support structure having an elastic sleeve member comprising

an inflatable supra annular member and an inflatable sub annular member defining therebetween a flow space; and a flexible tubular mesh structure articulated at an outside face of the sleeve, the mesh structure having an atrial section and a ventricular portion, with a radially deformable section extending therebetween, and wherein the ventricular portion is configured with a plurality of sub annular tissue engaging spikes, whereby inflating the sub annular inflatable member entails radially outwards deformation of the downstream deformable section and of the radial deformation of the downstream engaging spikes, wherein a prosthetic valve is secured within the elastic sleeve, at the annular level thereof.

According to a particular design, the atrial portion of the mesh is configured with a plurality of supra-annular tissue engaging spikes.

According to an embodiment of any of the disclosed aspects, the support structure can further comprise a downstream elastic sleeve extending over at least a portion of an inside face of the intermediate mesh section; said downstream elastic sleeve having a downstream inflatable tubular element axially disposed in overlap over at least an inside portion of the intermediate mesh section and the portion of the downstream mesh section.

The support structure is configured for positioning and securing within a cardiac valve cavity wherein at its deployed, expanded position the upstream inflatable tubular element is configured for bearing over the annulus of the native cardiac valve, to thereby seal and prevent blood flow external to the sleeve.

Once the support structure is positioned and secured within a cardiac valve cavity, the stent is allowed to assume its expanded shape and bears against the native commissure, wherein the inflated upstream inflatable tubular element bears over the annulus of the native cardiac valve, and functions as a seal to prevent blood flow external to the sleeve.

The upstream mesh section and a downstream mesh section define between them a flow path in direction from the downstream mesh section to the upstream mesh section, in correspondence with normal hemodynamics, wherein a prosthetic valve is engageable within the elastic sleeve along said flow path.

A prosthetic cardiac valve is securable within the stent, said cardiac valve configurable for blood flow administration along the flow path, in direction from the upstream mesh section to the downstream mesh section in direction corresponding with normal hemodynamics.

In the case of a prosthetic cardiac valve support system, a temporary valve is configurable between the upstream and downstream mesh section at a non-deformable section of the support structure, for temporarily regulating blood flow, in the direction corresponding with the normal hemodynamics, during a procedure of positioning and deploying the support structure, whereby upon positioning and deploying the prosthetic valve within the support structure, said temporary valve is over-ridden by the prosthetic valve. In the case of a prosthetic cardiac valve system, valve leaflets are sutured and/or connected by various methods to the inner stent frame of the prosthetic cardiac valve system.

Any one or more of the following features, designs and configurations can be associated with any one or more of the aspects of the present disclosure, individually or in various combinations thereof:

- The upstream tissue engaging spikes and the downstream tissue engaging spikes face towards an upstream side of the stent;
- The intermediate mesh section can be configured as an undulating/serpentine-like section, axially extending between the upstream mesh section and the downstream mesh section;
- the intermediate section can be configured as axially extending posts or segments having a polygonal shape;
- The intermediate mesh section integrally extends with the upstream mesh section and the downstream mesh section:
- The upstream mesh section can extend in proximity below the downstream inflatable tubular element;
- the upstream mesh section extends in proximity above the upstream inflatable tubular element;
- The upstream inflatable tubular element can extend opposite at least a portion of the intermediate mesh section and a portion of the downstream mesh section;
- The stent can be cylindrical and however is sufficiently elastic to assume a shape of the respective cardiac valve cavity into which it is applied;
- The upstream elastic sleeve and the downstream elastic sleeve can be a homogeneous sleeve or independent sleeves;

- The sleeve member can be a continuous sleeve member comprising an intermediate portion extending between the upstream elastic sleeve and the downstream elastic sleeve;
- At its deployed, expanded position, the stent can have a frustoconical shape wherein a narrow portion thereof is the upstream section of the stent;
- The projecting spikes can have a pointed end facing the upstream end of the stent;
- The projecting spikes can be equally distributed about a perimeter of the stent;
- The projecting spikes can have a triangle/ teardrop or elongated loop shape;
- The inflatable tubular upstream element can be disposed within an annular pouch of the sleeve;
- The support structure is configurable for use as a cardiac valve support for any one of the mitral valve, the aortic valve, the tricuspid valve and the pulmonary valve.
- The arrangement is such that at a deployed position, when the upstream inflatable tubular element is inflated, it serves as an annular seal disposed upstream of the prosthetic cardiac valve, seal to restrict blood flow only through said prosthetic cardiac valve;
- The support structure is a valve support for a prosthetic mitral valve, wherein the upstream inflatable tubular element is configurable for supra-annular positioning and inflating, within the left atrium;
- The support structure is a valve support for a prosthetic aortic valve, wherein the upstream inflatable tubular element is configurable for sub-annular inflation;
- The support structure is configurable for use as a valve support for a prosthetic tricuspid valve, wherein the upstream inflatable tubular element is configurable for supra-annular positioning and inflating, within the right atrium;
- The support structure is configurable for use as a valve support for a prosthetic pulmonary valve, wherein the upstream inflatable tubular element is configurable for sub-annular inflation;

- At an initial, unstressed position, the stent be cylindric;
- The stent can be secured at an inside face of the flexible sleeve;
- The sleeve member can be made of any stretchable, biocompatible material, such as fabrics, polymeric sheets, metal sheet, etc.;
- The upstream inflatable tubular element and the downstream inflatable tubular element can each be configured as an annular pocket of the sleeve, accommodating an inflatable annular balloon;
- Each of the upstream inflatable tubular element and the downstream inflatable tubular element can be configured with a one-way inflating valve, including a possibility to deflate as well by various methods, if needed;
- The prosthetic cardiac valve kit can further comprise a detachable inflation tube detachably articulated with each of the upstream inflatable tubular element and the downstream inflatable tubular element;
- Each of the upstream inflatable tubular element and the downstream inflatable tubular element can be configured with an inflation valve, to which an inflation tube is detachably attachable to;
- One or both of the stent and the elastic sleeve and the prosthetic cardiac valve can be drug-eluting;
- The prosthetic cardiac valve is anchorable to the upstream mesh section or to the upstream elastic sleeve;
- The upstream inflatable tubular element and the downstream inflatable tubular element can be received within an enveloping portion of the upstream elastic sleeve and the downstream elastic sleeve, respectively.
- Each of the upstream inflatable tubular element and the downstream inflatable tubular element can comprise an inflation/deflation valve;
- The inflation/deflation valve can be detachable;
- The upstream inflatable tubular element and the downstream inflatable tubular element can be inflated by a compressed inflation fluid;
- The compressed inflation fluid can be a gaseous substance;
- The compressed inflation fluid can be a liquid, such as isotonic, hypertonic, hypotonic, isosmotic, hyperosmotic, hypoosmotic with various degrees of viscosities

- The compressed inflation fluid can be a liquid comprising a puncture sealing agent;
- At an inflated state the upstream inflatable tubular element extends radially beyond the free tips of the stent.
- The upstream elastic sleeve can be secured to an inside face of stent, or to an outside face thereof;
- The downstream elastic sleeve can be secured to an inside face of stent, or to an outside face thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to better understand the subject matter that is disclosed herein and to exemplify how it may be carried out in practice, embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1A is perspective view of a stent used in conjunction with a prosthetic cardiac valve support structure, according to an aspect of the disclosure, the stent at an un-deformed position;

Fig. 1B is a side view of Fig. 1A;

Fig. 1C is a top view of Fig. 1B;

Fig. 1D is a flattened planar view of the deformable intermediate mesh section of the stent at a manufacturing position, before compressing;

Fig. 1E is an enlarged view of the portion marked I in Fig. 1B;

Fig. 2A is a perspective view of the stent of Fig. 1A, illustrated at a deployed/expanded position prior to inflation of the downstream inflatable element;

Fig. 2B is a side view of Fig. 2A;

Fig. 2C is a top view of Fig. 2B;

Fig. 2D is an enlarged view of the portion marked II in Fig. 2B;

Fig. 3A is a perspective view illustrating an embodiment of prosthetic cardiac valve support structure, comprising an upstream flexible sleeve, the support structure at a deployed position, however with the inflatable tubular element deflated;

Fig. 3B illustrates the prosthetic cardiac valve support structure of Fig. 3A at a deployed/expanded position, upon inflating the upstream inflatable tubular element;

Fig. 4A is a perspective view illustrating another embodiment of prosthetic cardiac valve support structure, comprising an upstream flexible sleeve and a separate, downstream flexible sleeve, the support structure at a closed position, however with the inflatable tubular elements deflated;

Fig. 4B illustrates the prosthetic cardiac valve support structure of Fig. 4A at a deployed/expanded position, upon inflating both the inflatable tubular elements;

Fig. 5A is a perspective view illustrating an embodiment of prosthetic cardiac valve support structure, comprising an upstream flexible sleeve and an integrated, downstream flexible sleeve, the support illustrated prior to inflating the inflatable tubular elements, however with the inflatable tubular elements deflated;

Fig. 5B illustrates the prosthetic cardiac valve support structure of Fig. 5A at a deployed/expanded position, upon inflating both the inflatable tubular elements;

Fig. 5C is a longitudinal section along line 5C – 5C in Fig. 5B;

Fig. 6A is a side view illustrating only the stent used in the embodiment of Fig. 5B;

Fig. 6B is a top view of the stent of Fig. 6A;

Fig. 7A is a top view of the prosthetic cardiac valve support structure of Fig. 5B;

Fig. 7B is a bottom view of the prosthetic cardiac valve support structure of Fig. 5B;

Fig. 7C is an exploded view of a support structure and a prosthetic cardiac valve for use in conjunction therewith, constituting together a prosthetic cardiac valve system;

Fig. 7D is a sectioned view through a prosthetic cardiac valve system at a deployed position;

Fig. 7E illustrates the prosthetic cardiac valve system deployed within a human heart as a mitral valve;

Fig. 8A illustrates a heart implanted with a mitral prosthetic cardiac valve system and a tricuspid prosthetic cardiac valve system, according to an example of the disclosure;

Fig. 8B illustrates a prosthetic cardiac valve system according to an example of the disclosure, configured as a pulmonary valve;

Fig. 8C illustrates a prosthetic cardiac valve system according to an example of the disclosure, configured as an aortic valve;

Fig. 8D is an enlarged view of the portion marked 8D in Fig. 8C;

Fig. 9 is a flowchart of a method for deploying a prosthetic cardiac valve support system according to an embodiment of the disclosure, referring to steps A to N of the disclosed method;

Figs. 10A to **10E** illustrate steps of deploying and positioning the *dock* or the prosthetic cardiac valve system according to some of the embodiments described in flow chart of Fig. 9, wherein;

Fig. 10A illustrates the prosthetic cardiac valve system at a crimped position, over the guide wire;

Fig. 10B illustrates the device of Fig. 10A upon exposing the downstream inflatable element;

Fig. 10C illustrates the device of Fig. 10A upon inflating the downstream inflatable element;

Fig. 10D illustrates the device of Fig. 10C from a proximal end;

Fig. 10E illustrates the device of Fig. 10C from a distal end;

Fig. 11A illustrates the transseptal approach to the mitral valve of a heart, with the prosthetic cardiac valve system over the guide wire (Fig. 10A), at a crimped, delivery position;

Fig. 11B illustrates positioning the delivery system tip sub annularly;

Fig. 11C illustrates the system upon exposing the downstream inflatable element (Fig. 10B);

Fig. 11D illustrates the system upon inflating the downstream inflatable element (Fig. 10C – 10E);

Fig. 11E illustrates the system with the inflated downstream balloon being pulled back towards the annulus for anchoring by via stent's spikes grasping the native valve's leaflets;

Fig. 11F illustrates the upstream inflatable member deployed at its nominal size in location, prior to inflation;

Fig. 11G illustrates the upstream inflatable member positioned and while the inflation process ;

Fig. 11H illustrates the system at a deployed, operative position;

Figs. 12A to **12D** exemplify a prosthetic cardiac valve according to possible embodiments a set of leaflets integrated therein, wherein **Fig. 12A** shows a top view, **Fig.**

12B shows a top-perspective view, **Fig. 12C** shows a bottom view, and **Fig. 12D** shows a front view of a leaflet band usable for integration in the prosthetic cardiac valve;

Figs. 13A to **13G** demonstrates steps of placing a prosthetic cardiac valve according to possible embodiments;

Figs. 14A to **14C** schematically illustrate a stent according to other possible embodiments usable for a prosthetic cardiac valve and/or support structure thereof; wherein **Fig. 14A** shows the stent in a crimped state; **Fig. 14B** shows the stent in a deployed state, and **Fig. 14C** shows a flat view of the stent;

Figs. 15 schematically illustrate the stent of **Figs. 14A** to **14C** implemented with single-wire spikes; and

Figs. 16A to **16C** schematically illustrate different downstream (or upstream) spike configurations according to possible embodiments, wherein **Figs. 16A** shows a peg-like spike configuration, **Figs. 16B** shows an elongated loop spike configuration, and **Figs. 16A** shows an elongated tapering loop spike configuration; and

Figs. 17A to **17D** demonstrate a procedure for placing an insertable prosthetic valve in the prosthetic cardiac valve support structure according to possible embodiments.

DETAILED DESCRIPTION OF EMBODIMENTS

Attention is now made to the drawings, for better understanding the disclosure. In **Figs. 1A** to **1E** there is illustrated a stent member generally designated **10**, configured for supporting a prosthetic cardiac valve, as will be disclosed herein after in detail. In **Figs. 1A – 1E** the stent member **10** is at an un-deformed position, i.e. after cutting.

The stent member **10** is a tubular cylindrical wire/mesh-like element, which in the illustrated example is cut out of a cylindrical body, however, a stent can be made using different technologies, e.g. weaving a wire, welding, fine cutting techniques through a tubular element and other techniques used in the art of stent manufacturing, depending, among others, on final required mechanical properties. Optionally, but in some embodiments preferably, the stent undergoes thermal treatment, whereby it obtains memory shape, so that once introduced into the body and deformed into its operative, expanded/nominal position.

Accordingly, the stent can be configured to maintain said memory shape imparted thereto. The stent can be made of various biocompatible materials, such as metal (e.g. Nitinol -NiTi), polymeric materials, composite materials and others, or other suitable

material for imparting the stent its unique property, namely the ability to be deformed from a closed/crimped position and return to/restore its initial expanded shape upon exposure to heat or pressure, or upon cease of a restraint compacting force (in case of a self-expandable device). This allows the stent to be compressed for insertion through a small body incision, and then expand to the desired size and shape once manipulated *in situ*.

The stent **10** is a flexible tubular element having an upstream mesh section **12** and a downstream mesh section **14**, defining between them a flow path **F** in direction from the upstream mesh section **12** to the downstream mesh section **14**, in correspondence with normal hemodynamics.

It is to be noted that the terms '*upstream*' and '*downstream*' as used herein in the specification and claims, correspond with normal hemodynamics flow directions, respectively. Accordingly, when considering a mitral valve blood flows in direction from the upstream left atrium towards the downstream left ventricle; when considering a tricuspid valve blood flows in direction from the upstream right atrium towards a downstream right ventricle; when discussing the aortic valve blood flows in direction from the upstream left ventricle towards the downstream aorta, and; and when discussing the pulmonary valve blood flows in direction from the upstream right ventricle towards the downstream pulmonary artery.

The stent **10** is further configured with a radially deformable intermediate section **18** extending between the upstream mesh section **12** and the downstream mesh section **14**, and wherein the upstream mesh section **12** is configured with a plurality of upstream tissue engaging spikes **20** facing upstream, and the downstream mesh section **14** is configured with a plurality of downstream tissue engaging spikes **22** also facing upstream. It is however noted that in possible variants the stent **10** can be configured only with the downstream tissue engaging spikes **22** (or only with the upstream tissue engaging spikes **20**).

The upstream tissue engaging spikes **20** and the downstream tissue engaging spikes **22** are triangular/teardrop shaped having a pointed tip, wherein at an initial state (i.e. prior to exposure to predetermined temperature, optionally about 37°C) said spikes **20** and **22** extend coplanar with an outside surface of the stent, i.e. they do not radially project from an outside face **25** (see e.g., **Fig. 1C**) of the stent **10**. However, once introduced *in situ*, and as the stent reaches the predetermined temperature (body

temperature *e.g.*, of about 37°C) – said upstream tissue engaging spikes **20** and downstream tissue engaging spikes **22** deform to their memory shape projecting radially outwards from the outside face of the stent**.**

The spikes **20**, **22** are configured for projecting into the tissue of the native cardiac valve, for securing the stent **10** thereto, and in some embodiments also for securing a prosthetic cardiac valve system thereto, as will be discussed.

The free tips (ends) **26**, **28** of the stent **10**, at both respective axial ends thereof, are rounded, and said tips are also coplanar with the outside face **25** of the stent **10**.

The intermediate section **18** of the stent **10** connects between the upstream mesh section **12** and the downstream mesh section **14**, and has an undulating pattern **19**, imparting it flexibility for radially deforming so as to bear against inside walls of the native valve (as will be discussed herein below).

However, it is appreciated that the undulating pattern of the intermediate section **18** is a mere example and other design options are possible (e.g., having a sinusoidal, rectangular, or triangular, wavy pattern). For example, the intermediate section **18** can be configured as axially extending posits or segments having a polygonal shape.

Further attention is directed also to **Figs. 2A** to **2D** of the drawings, illustrating the stent **10** after it has been allowed to deform under thermal properties. Namely, pre-deploying the stent into the body (see **Figs. 1A – 1E**), the tissue engaging spikes remain flush with an outside surface of the stent. However, once the stent is deployed and reaches body temperature (approx. 37C°) the upstream tissue engaging spikes and said downstream tissue engaging spikes project radially outwards from the outside surface of the stent, as per predesigned memory shape thereof.

It is noted that the axial length of the stent **10** decreases, as it radially expands, and significantly wherein the upstream tissue engaging spikes **20** and the downstream tissue engaging spikes **22** now project radially outwards, i.e. project from the outside face **25** of the stent **10** (see **Fig. 2C**).

With further attention being made now also to **Figs. 3A** and **3B**, there is illustrated an example of a prosthetic cardiac valve system **50**, according to an aspect of the disclosure.

The prosthetic cardiac valve system **50** comprises a stent **10** of the kind disclosed hereinbefore, and wherein an upstream elastic sleeve **54** having a tubular section **56** extends over at least a portion of an inside face **27** of said upstream mesh section **12**, and

secured thereto, e.g. by adhering, welding, stitching, etc. The sleeve member **54** can be made of any stretchable, biocompatible material, such as fabrics, polymeric sheets, metal sheet, etc.

The upstream elastic sleeve **54** comprises an upstream inflatable tubular element **60** disposed axially beyond the free tips **26** of the stent, namely axially upstream of said upstream mesh section **12**, wherein the upstream inflatable tubular element **60** is a fluid-tight annular portion of the sleeve **54**, or it can be an inflatable bladder received within a pocket of the sleeve. The upstream inflatable tubular element **60** is configured with an inflating mechanism (e.g. tubing **64**) for inflating and pressure regulating of the pressure within the upstream inflatable tubular element **60**. The tubing **64** can be detachable from the inflatable tubular element with a suitable valve **66** (see **Fig. 3A**) provided. The inflatable tubular element **60** can be inflated by any inflating agent (gas or liquids), and a puncture sealing agent can be applied to the inflating agent. It is noted that the diameter of the inflated upstream inflatable tubular element **60** is greater than that of the prosthetic cardiac valve system **50** at its deployed position.

As can be noted in **Figs. 7A** and **7B**, the prosthetic cardiac valve system **50** comprises a unidirectional prosthetic cardiac valve **V** (secured within the upstream elastic sleeve however downstream of the upstream inflatable tubular element **60**). The valve **V** is configured to facilitate blood flow therethrough in direction of the flow path **F** (namely from the upstream mesh section **12** towards the downstream mesh section **14**), corresponding with normal hemodynamics. It is appreciated that the prosthetic cardiac valve **V** can be a leaf-type valve as illustrated in the drawings, or any other type.

In **Fig. 3A** the upstream inflatable tubular element **60** is deflated, whilst the upstream tissue engaging spikes **20** and the downstream tissue engaging spikes **22** are at their radially outwards deformed position, however with the stent **10** still at a cylindrical, undeformed state.

Once the upstream inflatable tubular element **60** is inflated (see **Fig. 3B**), it assumes an overall radii greater than that of the stent and the associated sleeve, hence it will bear over the annulus of the native cardiac valve, thereby sealing the valve external vicinity, i.e. preventing blood flow external to the sleeve so that blood flow takes place through the flow path **F** (through the valve).

Figs. 4A and **4B** illustrate a modification of the embodiment illustrated in **Figs. 3A** and **3B**. A prosthetic cardiac valve system **70** (also usable as prosthetic cardiac valve

support), according to an aspect of the disclosure comprises a stent **10** of the kind disclosed hereinbefore, and wherein an upstream elastic sleeve **74** having a tubular section **76** extends over at least a portion of an inside face **27** of said upstream mesh section **12**, and secured thereto as discussed hereinabove. The sleeve member **74** can be made of any stretchable, biocompatible material, such as fabrics, polymeric sheets, metal sheet, etc.

Similar to the arrangement of **Fig. 3A**, the upstream elastic sleeve **74** comprises an upstream inflatable tubular element **80** disposed axially beyond the free tips **26** of the stent, wherein the upstream inflatable tubular element **80** is a fluid-tight annular portion of the sleeve **74** (or it can be an inflatable bladder received within a pocket of the sleeve, as discussed herein before). The upstream inflatable tubular element **80** is configured with an inflating mechanism (e.g. tubing **84**) for inflating and pressure regulating of the pressure within the upstream inflatable tubular element **80**. Tubing **84** can be detachable from the inflatable tubular element with a suitable valve **86** (**Fig. 4A**) provided. The upstream inflatable tubular element **80** can be inflated by any inflating agent (gas or liquids), and a puncture sealing agent can be applied to the inflating agent. Once inflated, the upstream inflatable tubular element **80** radially expands to thereby assume a sealing position over the annulus of the native cardiac valve.

The prosthetic cardiac valve system **70** comprises a unidirectional prosthetic cardiac valve **V** (**Figs. 7A** and **7B**), that can be an integral part of the prosthetic valve system e.g., by sewing, welding, stitching etc., or it may be inserted separately during the procedure.

Unlike the embodiment of **Figs. 3A** and **3B**, the prosthetic cardiac valve system **70** exemplified in **Figs. 4A** and **4B** further comprises a downstream elastic sleeve **94**, made of any stretchable, biocompatible material, such as fabrics, polymeric sheets, metal sheet, etc. Downstream elastic sleeve **94** has a sleeve portion **96** secured (e.g. by adhering, welding, stitching, etc.) to an inside face **27'** of the downstream mesh section **14**. Downstream elastic sleeve **94** is further configured with a downstream inflatable tubular element **100** disposed axially internally i.e. upstream of the free tips **28** of the stent **10**.

The downstream inflatable tubular element **100** is a fluid-tight annular portion of the sleeve **94**, or it can be an inflatable bladder received within a pocket of the sleeve. The downstream inflatable tubular element **100** is configured with an inflating mechanism (**102**) for inflating and pressure regulating of the pressure within the

downstream inflatable tubular element **100**. The inflating arrangement can be common with the upstream inflatable tubular element **80**, for simultaneous inflation thereof, or each of the inflatable tubular element **80** and **100** can be fitted with an individual inflating arrangement. As mentioned before, the inflating mechanism can be detachable from the inflatable tubular element with a suitable valve **86** (**Fig. 4A**) provided and the inflation can take place by any inflating agent (gas or liquids), and a puncture sealing agent can be applied to the inflating agent.

In **Fig. 4A** the prosthetic cardiac valve system **70** is illustrated at an un-inflated, nominal stent position, wherein the upstream inflatable tubular element **80** and the downstream inflatable tubular element **100** are deflated, however with the upstream tissue engaging spikes **20** and the downstream tissue engaging spikes **22** of the stent disposed into the radially outwardly projecting position. This is the position upon introducing the prosthetic cardiac valve system **70** and positioning same within the native cardiac valve.

The arrangement is such that radially outwardly deforming the upstream mesh portion (e.g., by inflating the upstream inflatable tubular element **80**) and the downstream mesh section (e.g., by inflating the downstream inflatable tubular element **100**) will increase respective engagement of the radial outwards projecting upstream tissue engaging spikes **20** and/or of the downstream tissue engaging spikes **22**, wherein, as formerly explained, the tissue engaging spikes **20** and/or **22** deform to project radially outwards from the outside surface of the stent, upon reaching the predefined (e.g., body temperature of approximately 37°C), as per predesigned memory shape thereof. Accordingly, upon inflating the upstream inflatable tubular element **80** and/or the downstream inflatable tubular element **100** (shown in **Fig. 4B**), the prosthetic cardiac valve system **70** becomes arrested within the native cardiac valve, wherein the upstream inflatable tubular element **80** will bear over the annulus of the native cardiac valve (as seen in **Fig. 8A**), thereby sealing the valve external vicinity, i.e. preventing blood flow external to the sleeve so that blood flow takes place through the flow path **F** (through the valve), and wherein the downstream inflatable tubular element **100** applies radial force on the downstream mesh section **14**, resulting in outward deformation of the downstream mesh section **14**.

Yet an embodiment of the disclosure is disclosed with reference to **Figs. 5A** and **5B**). In fact, the prosthetic cardiac valve system **120** illustrated in **Figs. 5A** and **5B** is similar to the embodiment of **Figs. 4A** and **4B**, in that it also comprises an upstream elastic

sleeve **122** with an upstream inflatable tubular element **124**, and a downstream elastic sleeve **130** downstream inflatable tubular element **132**.

However, a distinguishing difference between the embodiments resides in that the upstream elastic sleeve **122** is integral (or integrated, e.g. by stitching, welding adhering, etc.) with the downstream elastic sleeve **130**, through coextending tubular section **126** and sleeve portion **134**.

The upstream inflatable tubular element **124** and the downstream inflatable tubular element **132** can be simultaneously inflated, or independently of one another, as mentioned hereinbefore.

The arrangement is such that deploying the system into the heart and upon reaching the nominal temperature (e.g., of 37C°) the upstream tissue engaging spikes **20**, and/or the downstream tissue engaging spikes **22** deform into radial projection from the external face of the stent, and wherein inflation of the inflatable tubular elements results in deformation of the downstream mesh portion **14**, entailing outward deformation of the intermediate section **18**, wherein the support structure securely bears against native heart tissue. Accordingly, upon inflating the upstream inflatable tubular element **124** and the downstream inflatable tubular element **132** (seen in **Fig. 5B**), the prosthetic cardiac valve system **120** becomes arrested within the native cardiac valve, wherein the upstream inflatable tubular element **124** will bear over the annulus of the native cardiac valve (as shown in **Fig. 8A**), thereby sealing the valve external vicinity, i.e. preventing blood flow external to the sleeve so that blood flow takes place through the flow path **F** (through the valve), and wherein the downstream inflatable tubular element **132** applies radial force on the downstream mesh section **14**, resulting in outward deformation of the downstream mesh section **14**.

In **Figs. 6A** and **6B** the stent **10** is isolated from other elements of the prosthetic cardiac valve/support system, however after it has been deformed into its expanded position, having a frustoconical shape, as explained hereinabove, with the upstream tissue engaging spikes **20** and/or the downstream tissue engaging spikes **22** at their radially outwards deformed position. As indicated hereinabove, the stent may comprise only the downstream tissue engaging spikes **22** (or only the upstream tissue engaging spikes **20**).

Figs 7C to **7E** illustrate in further detail a prosthetic cardiac valve system according to the disclosure, generally designated **140**. In **Fig. 7C** there is illustrated an insertable prosthetic valve generally designated **141** e.g., of known design, comprising a

set of valve leaflets **142** secured within a stent cage **143**. A nominal diameter **Dnv** of the insertable prosthetic valve **141** is slightly greater than a nominal diameter **Dns** of the support structure generally designated **145**. The arrangement is such that once the insertable prosthetic valve **141** is deployed within the deployed support structure **145**, the insertable prosthetic valve **141** is engaged there within (as shown in **Fig. 7D**). In the superimposed image of **Fig. 7D** the insertable prosthetic valve **141** is represented by thickened dashed lines. **Fig. 7E** illustrates a prosthetic cardiac valve system **140** deployed within a human heart **H** as a mitral valve.

Whilst hard to note in the drawings, it can be seen, best in **Fig. 7D**, that the support structure **145** is further configured in some embodiments with a set of temporary valve leaflets **148** positioned between the upstream and downstream mesh section at a non-deformable section of the support structure, said temporary valve leaflets **148** configured for temporarily regulating blood flow, in the flow direction **F** (corresponding with the normal hemodynamics), during a procedure of positioning and deploying the support structure **145** and until the insertable prosthetic valve **141** is positioned and anchored within the support structure **145**, whereby upon positioning and deploying the insertable prosthetic valve **141**, said temporary valve leaflets **148** are over-ridden by the stent cage **143** of the insertable prosthetic valve **141**.

Figs. 8A to **8C** exemplify use of a prosthetic cardiac valve system/ support structure with an insertable prosthetic valve according to the disclosure, at the different native valves in a human heart **H**.

In **Fig. 8A** a first prosthetic cardiac valve system/ support structure **150** is fitted at the mitral valve of heart **H**, and wherein arrow **F** illustrates the flow path in a normal hemodynamics flow direction, from the upstream left atrium **LA** towards the downstream left ventricle **LV**, and wherein the upstream inflatable tubular element **152** is inflated with the left atrium **LA** at a sealing position, and the downstream inflatable tubular element **153** is inflated sub-annularly within the left ventricle **LV** at a sealing position.

Also seen in **Fig. 8A**, a second prosthetic cardiac valve system/ support structure **160** is fitted at the tricuspid valve of heart **H**, and wherein arrow **F** illustrates the flow path in a normal hemodynamics flow direction, from the upstream right atrium **RA** towards the downstream right ventricle **RV**, and wherein the upstream inflatable tubular element **162** is inflated with the right atrium **RA** at a sealing position, and the downstream

inflatable tubular element **163** is inflated sub-annularly within the right ventricle **RV** at a sealing position.

In **Fig. 8B** a prosthetic cardiac valve system/support structure **170** is fitted at the pulmonary valve of heart **H**, and wherein arrow **F** illustrates the flow path in a normal hemodynamics flow direction, from the upstream right ventricle **RV** towards the downstream pulmonary artery **PA**, and wherein the upstream inflatable tubular element **172** is inflated sub annularly at a sealing position, and the downstream inflatable tubular element **173** is inflated supra annularly within the pulmonary artery **PA** at a sealing position.

In **Figs. 8C** and **8D** a prosthetic cardiac valve system **180** is fitted at the aortic valve of the heart **H**, and wherein arrow **F** illustrates the flow path in a normal hemodynamics flow direction, from the upstream left ventricle **LV** towards the downstream aorta **AO**, and wherein the upstream inflatable tubular element **182** is inflated sub annularly at a sealing position.

Turning now to **Figs. 9**, **10A** to **10E** and **11A** to **11H** of the drawings, there is described a method of deploying the prosthetic cardiac valve system/ support structure **120** according to an example of the present disclosure, the method comprising the following steps (step numbering corresponding with levels/steps in **Fig. 9**):

A. Introducing an assembly (delivery system - DS) **190** over a guide wire **191** received within a lumen (e.g., an insertion tube) **192** with a distal (full or splitable) capsule **194** (*Over The Wire Delivery system*) containing the prosthetic cardiac valve system **120** ('dock'/'prosthetic cardiac system') at a compressed position (see **Figs. 10A**, **11A**, **11B**), visualized under imaging;

B. Distally advancing the guide wire **191** through the atraumatic tip **196** at the distal end of the DS **190**, and exposing the downstream inflatable element **132** with the downstream mesh section **14** of the stent at the sub annular level of the native valve, distal to the native leaflets coaptation line (see **Figs. 10B**, **11C**);

C. Inflating the downstream inflatable element **132** (see **Figs. 10C** - **10E** and **11D**), while upstream inflatable element **124** is still crimped in the capsule **194**;

D. Retrieving the capsule **194** proximally (e.g., retrieving the delivery system **190**) towards the upstream portion of the valve, allowing the downstream spikes **22** to engage the sub annular apparatus of the native valve (see **Fig. 11E**);

E. Unsheathing the upstream inflatable element **124** under imaging (see **Fig. 11F**);

F. Inflating the upstream inflatable element **124** (see **Fig. 11G**);

G. Retrieving the entire DS **190** towards the upstream portion of the valve, allowing the downstream spikes to attach to the sub annular apparatus of the native valve;

H. withdrawing entire DS **190** and the capsule **194** e.g., while the guide wire **191** remains in place (**Fig. 11H**);

L. Inflation level adjustment of the inflatable tubular elements (upstream and downstream) for para valvular leaks elimination and sub annular adjustments performed under echocardiographic guidance;

M. Detaching the inflation tubes of the inflatable tubular elements (upstream and downstream);

N. Removing the guide wire;

O. The fully inflated docking system with the prosthetic cardiac valve are functioning as a whole unit.

In case of a support system, introducing and guiding the compressed insertable prosthetic valve over the guide wire **191** with a dedicated delivery system of the insertable prosthetic valve into the prosthetic cardiac valve system **120**;

In case of a support system, positioning the insertable prosthetic valve within the inflated prosthetic cardiac valve system under imaging, between the upstream inflatable element and the downstream inflatable element;

In case of a support system, deploying the insertable prosthetic valve;

Withdrawing the prosthetic valve's capsule;

Optionally, adjusting inflation level of the upstream inflatable element and/or of the downstream inflatable element for para-prosthetic leaks elimination and sub annular adjustments performed under echocardiographic guidance;

Detaching the inflating mechanism **64** of the upstream inflatable element and the downstream inflatable element; and

Removing the guide wire **191**.

If the capsule is a splitable capsule, the following steps are carried out:

B'. Unsheathing proximal capsule for upstream inflatable element exposure above native leaflets and inflating the upstream inflatable element;

C'. Distally advancing the inflated upstream inflatable element placing it supra annularly;

D'. Unsheathing distal capsule for downstream inflatable element exposure;

E'. Downstream inflatable element inflation for positioning and anchoring;

F'. Withdrawing the capsule;

And the above-described steps L, M N and O.

In case of a support system, inserting a prosthetic valve into a prosthetic valve support system of embodiments can be carried out as follows:

I. Positioning the prosthetic valve within the inflated docking system under fluoroscopic or echocardiography imaging, just between the upstream and downstream balloons;

J. Deploying the prosthetic valve (could be self-expandable or a balloon expandable prosthetic valve);

K. Withdrawing the prosthetic valve's DS;

L. Inflation level adjustment of the inflatable tubular elements (upstream and downstream) for para valvular leaks elimination, performed under echo guidance;

M. Detaching the inflation tubes of the inflatable tubular elements (upstream and downstream);

N. Removing the guide wire;

Q. The fully inflated docking system with the prosthetic cardiac valve are functioning as a whole unit.

Figs. 12A to **12D** exemplify a prosthetic cardiac valve **200** according to possible embodiments having a set of valve leaflets **148** integrated therein. **Figs. 12A** and **Fig. 12B** show the upstream inflatable tubular element **80** of the prosthetic cardiac valve **200** in an inflated sate. As seen in the top views of **Figs. 12A** and **Fig. 12B**, in this non-limiting example the upstream inflatable tubular element **80** located partially over the intermediate section (**18**) of the stent **10**, downstream from the upstream mesh section (**12**). **Fig. 12C** shows a bottom view of the prosthetic cardiac valve **200** with its upstream inflatable tubular element **80** and its downstream inflatable tubular element **100** in their inflated states.

The prosthetic cardiac valve **200** is configured to allow normal hemodynamics from/to the heart (**H**) via the valve leaflets **148** configured to permit blood flow there through in one direction only.

Fig. 12D shows a front view of a leaflet band **149** comprising a tethered set of three valve leaflets **148**. The valve leaflets **148** can be made from fabric, polymers, pericardium etc. ensuring optimal valve durability over time, and they can be attached to the stent **10** (or stent cage **143**) by adhering, welding, stitching, etc.

Figs. 13A to **13G** demonstrates a procedure of implanting a prosthetic cardiac valve according to possible embodiments by transseptal approach (*i.e.*, accessing the left atrium of the heart by puncturing the interatrial septum of the heart **H**). Of course, the procedure demonstrated in **Figs. 13A** to **13G** is not limited to transseptal approach, and it may be similarly carried out *mutatis mutandis* using other approach techniques into other parts of the heart **H** for implanting prosthetic cardiac valve(s) of embodiments hereof in other valves of the heart **H**.

Fig. 13A shows introducing an insertion tube **192** over a guide wire **191** through the septum, into the left atrium of the heart **H**. The insertion tube **192** comprises a distal capsule **194** coupled to its distal end and accommodating the prosthetic cardiac valve crimped thereinside. As seen, a distal end potion of the guide wire **191** is introduced into the left ventricle through the mitral valve **195** and the distal capsule **194** is located above the valve **195** prepared to deploy the prosthetic cardiac valve crimped thereinside. In this specific and non-limiting example the capsule **194** comprises separable main (**194b**) and auxiliary (**194a**) capsules portions. configured for carrying out a two-stage stepped deployment procedure (*e.g.*, as described in US Patent Publication No. 2021/0177593, the disclosure of which is incorporated herein by reference).

Next, as seen in **Fig. 13B**, the capsule is split to unsheathe the upstream inflatable tubular element **80** of the prosthetic cardiac valve and part of its inflation tube(s) **198**, that are distally discharged out of the auxiliary capsule portion **194a**. The upstream inflatable tubular element **80** is then inflated inside the atrium to assume its radially expanded stated, seen in **Fig. 13C**. The upstream inflatable tubular element **80** and the distal/main capsule portion **194b** are distally advanced to place the inflated tubular element **80** over the annulus of the native valve **195**, as seen in Fig. **13D**.

Thereafter, as seen in **Fig. 13E**, the distal/main capsule portion **194b** is further advanced below the native valve leaflets to expose and inflate the downstream inflatable element. As the downstream inflatable tubular element **100** is discharged out of the distal capsule portion **194b**, the stent (**10**) radially expands to assume its memorized open state, and as the stent elements take the body temperature of their new environment their

downstream tissue engaging spikes (**22**), and/or upstream tissue engaging spikes (**20**), radially project outwardly.

After the stent (**10**) assumes its expanded state, as shown in **Fig. 13F**, the downstream inflatable tubular element **100** is inflated to assume its expanded state, thereby further expanding the downstream mesh section (**14**) of the stent (**10**) and anchoring the prosthetic cardiac valve to the native leaflets of the native valve **195**, as the radially outwardly projecting downstream tissue engaging spikes **22** become embedded in the tissue of the natural valve **195**. The insertion tube **192** is then removed over guidewire **191** out of the heart **H**, and the guidewire **191** can be then also removed, as shown in **Fig. 13G**.

As also seen in **Fig. 13G**, immediately after exposure and inflation of the downstream tubular element, the valve becomes fully functional thereby permitting blood flow in one direction only in accordance with the hemodynamics flow direction. Namely, in this specific and non-limiting example, the leaflets **148'** permits blood flow from the left atrium into the left ventricle and prevent blood from flowing in the reverse direction.

The leaflets **148'** of the prosthetic cardiac valve can be either temporary valve leaflets, or a type of permanent biological leaflets (e.g., bovine or porcine pericardium) and/or polymeric leaflets, i.e., the prosthetic cardiac valve is configured as a fully functional valve. In possible embodiments, if the leaflets **148'** are temporary valve leaflets, the guidewire **191** can be further used to deliver thereover an insertable prosthetic valve (**141**) for mounting in the prosthetic cardiac valve e.g., using a dedicated delivery system. The prosthetic valve (**141**) is then mounted over the temporary valve leaflets of the prosthetic cardiac valve, and the guidewire **191** can be then removed from the body of the treated subject.

While in the procedure demonstrated in **Figs. 11A** to **11H** the downstream inflatable tubular element is exposed and inflated first, and thereafter the upstream inflatable tubular element is exposed and inflated, in the procedure demonstrated in **Figs. 13A** to **13G** the upstream inflatable tubular element is exposed and inflated first, and thereafter the downstream inflatable tubular element is exposed and inflated.

Figs. 14A to **14C** schematically illustrate a stent configuration **10'** according to other possible embodiments usable for a prosthetic cardiac valve and/or support structures thereof. **Fig. 14A** shows the stent **10'** in a crimped state, in which its upstream mesh section **12'**, comprised of a plurality elongated loop elements extending upwardly from

the intermediate section **18'**, and its downstream mesh section **14'**, comprised of a plurality of triangular elements extending downwardly from the intermediate section **18'**, are axially stretched. The intermediate section **18'** of the stent **10'** has an undulating pattern **19** configured to provide elasticity quick shape restoration, as in other stent embodiments disclosed herein. As also exemplified, in some embodiments the stents disclosed herein may include only the downstream tissue engaging spikes **22**.

Fig. 14B shows the stent **10'** in a deployed state, with its downstream tissue engaging spikes **22** radially projecting outwardly. **Fig. 14C** shows the stent **10'** in a flat (cut open) view. As seen, the downstream tissue engaging spikes **22** can be configured as elongated loop elements having a circular apertured base at the free tips **28**. **Fig. 15** schematically illustrates an embodiment of the stent **10''** wherein the downstream tissue engaging spikes **22** are configured in a form of solid peg **22'**.

Figs. 16A to **16C** schematically illustrate different downstream (or upstream) spike configurations according to possible embodiments. **Fig. 16A** shows a possible implementation of peg-like spikes **22'** having solid bases **22b'** at the free tips **28**. **Figs. 16B** shows a possible implementation of elongated loop-shaped spikes **22** having an aperture **22b** at the free tips **28**, the aperture's diameter being proportional to, or about the size of, the width of the spike. **Figs. 16C** shows a possible implementation of elongated tapering loop spikes **22''** having an aperture **22b''** at the free tips **28**, the aperture's diameter being proportional to, or about the size of, the width of the spike near the free tip **28**.

Figs. 17A to **17D** demonstrate a procedure for placing an insertable prosthetic valve **235** in the prosthetic cardiac valve support structure according to possible embodiments. **Fig. 17A** shows the delivery (*e.g.*, transseptal approach) of the insertable prosthetic valve **235** into the support structure situated in the mitral valve position in the heart **H** by a delivery system **230**. As seen, the insertable prosthetic valve **235** is advanced over the guidewire **191** into the prosthetic cardiac valve support system after it is placed *in situ* (*e.g.*, over a native cardiac valve of a treated subject) according to embodiments hereof.

Fig. 17B shows the deployment of the insertable prosthetic valve **235** inside the prosthetic cardiac valve support system, and **Fig. 17C** shows the insertable prosthetic valve **235** after it is fully deployed inside the prosthetic cardiac valve support system. The

delivery system **230** and guidewire **191** are then removed, allowing and permit blood flow therethrough in one direction corresponding with the normal hemodynamics.

As described hereinabove and shown in the associated figures the present application provides prosthetic cardiac valve configuration and related methods. While particular embodiments of the invention have been described, it will be understood, however, that the subject disclosed herein is not limited thereto, since modifications may be made by those skilled in the art, particularly in light of the foregoing teachings. As will be appreciated by the skilled person, the disclosed embodiments can be carried out in a great variety of ways, employing more than one technique from those described above, all without exceeding the scope of the claims.

CLAIMS:

1. A prosthetic cardiac valve system, comprising:

a stent comprising a flexible tubular element having an upstream mesh section, a downstream mesh section, and a radially deformable intermediate section extending therebetween, wherein the upstream mesh section is configured with a plurality of upstream tissue engaging spikes, and/or the downstream mesh section is configured with a plurality of downstream tissue engaging spikes; wherein said upstream tissue engaging spikes and said downstream tissue engaging spikes are made of memory shape material and are configured, at a closed position to be coplanar with an outside surface of the stent, and at an expanded deployed position of the stent, after being introduced *in situ* and reaching a predefined temperature to deform to their memory shape to project radially outwards from an outside surface of the stent to their radially outwards deformed position;

an upstream elastic sleeve extending over at least a portion of said upstream mesh section, said upstream elastic sleeve having an upstream inflatable tubular element disposed axially upstream of said upstream mesh section; and

a prosthetic cardiac valve secured within one or more of the mesh sections of said stent, after said stent is positioned *in situ* and the upstream and downstream inflatable tubular elements of said upstream and downstream elastic sleeves are inflated.

2. The prosthetic cardiac valve system of claim 1, wherein the prosthetic cardiac valve is integrated with the stent.

3. The prosthetic cardiac valve system of claim 1, comprising valve leaflets attached to the upstream elastic sleeve and/or one or more of the mesh sections.

4. The prosthetic cardiac valve system of any one of the preceding claims, wherein the stent is configured for positioning and securing within a cardiac valve cavity, wherein at its deployed, expanded position the upstream inflatable tubular element is configured for bearing over the annulus of a native cardiac valve, to thereby seal and prevent blood flow external to the sleeve.

5. The prosthetic cardiac valve system of any one of the preceding claims, wherein the stent is configurable for positioning and securing within a cardiac valve cavity, and wherein when the stent assumes its expanded shape and bears against the native annulus, the inflated upstream inflatable tubular element bears over the annulus of a native cardiac valve, and functions as a seal to prevent blood flow external to the sleeve.

6. The prosthetic cardiac valve system of claim 5, wherein at the deployed position, when the upstream inflatable tubular element is inflated, it serves as an annular seal disposed radially, surrounding the prosthetic cardiac valve, to restrict blood flow only through said prosthetic cardiac valve.

7. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the upstream mesh section and a downstream mesh section define between them a flow path in direction from the upstream mesh section to the downstream mesh section, in correspondence with normal hemodynamics.

8. The prosthetic cardiac valve system according to any one of the preceding claims, wherein a prosthetic cardiac valve is secured within the upstream mesh section of the stent, said cardiac valve being configured and operable for blood flow administration along the flow path, in direction from the upstream mesh section to the downstream mesh section in direction corresponding with normal hemodynamics.

9. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the stent further comprises a downstream elastic sleeve extending over at least a portion of an inside face of the intermediate mesh section, said downstream elastic sleeve having a downstream inflatable tubular element axially and radially disposed in overlap over at least an inside portion of the intermediate mesh section and the portion of the downstream mesh section.

10. The prosthetic cardiac valve system of claim 9, wherein the upstream elastic sleeve and the downstream elastic sleeve are a homogeneous sleeve or independent sleeves.

11. The prosthetic cardiac valve system of claim 9 or 10, wherein each of the upstream elastic sleeve and the downstream elastic sleeve are secured to either an inside face of stent, or to an outside face thereof.

12. The prosthetic cardiac valve system of any one of claims 9 to 11, wherein the sleeve member is a continuous sleeve member comprising an intermediate portion extending between the upstream elastic sleeve and the downstream elastic sleeve.

13. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the inflatable tubular element is configured with an inflating mechanism for inflating and pressure regulating of the volume and pressure within the inflatable tubular element.

14. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the inflatable tubular element is associated with an inflation/deflation port.

15. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the inflatable tubular element is disposed within an annular pouch of the sleeve.

16. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the inflatable tubular element is inflatable with a fluid comprising a puncture sealing agent.

17. The prosthetic cardiac valve system according to any one of claims 9 to 16, wherein the upstream inflatable tubular element and the downstream inflatable tubular element are received within an enveloping portion of the upstream elastic sleeve and a downstream elastic sleeve, respectively.

18. The prosthetic cardiac valve system according to any one of claims 9 to 17, wherein the upstream inflatable tubular element and the downstream inflatable tubular element are configured as an annular pocket of the sleeve, accommodating an inflatable supra and sub-annular balloon.

19. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the upstream tissue engaging spikes face towards a downstream side of the stent and the downstream tissue engaging spikes face towards an upstream side of the stent.

20. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the intermediate mesh section is configured and operable as an undulating section, axially extending between the upstream mesh section and the downstream mesh section.

21. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the intermediate mesh section integrally extends with the upstream mesh section and the downstream mesh section.

22. The prosthetic cardiac valve system according to any one of the preceding claims, having one of the following configurations: the upstream mesh section extends in proximity below the upstream inflatable tubular element; the upstream mesh section extends in proximity above the upstream inflatable tubular element.

23. The prosthetic cardiac valve system according to any one of claims 9 to 22, wherein the downstream inflatable tubular element extends opposite at least a portion of the intermediate mesh section and a portion of the downstream mesh section.

24. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the projecting downstream spikes have a pointed end facing an upstream end of the stent.

25. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the stent and the elastic sleeve and the prosthetic cardiac valve are configured and operable as drug-eluting.

26. The prosthetic cardiac valve system according to any one of the preceding claims, wherein a nominal diameter of the stent of the prosthetic valve, at its deployed position, is greater than a nominal diameter of the stent at its deployed position, hence once deployed, the prosthetic valve is engageable within the elastic sleeve.

27. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the prosthetic cardiac valve is secured to the upstream elastic sleeve.

28. The prosthetic cardiac valve system according to any one of the preceding claims, wherein the prosthetic cardiac valve is secured at an inside face of the elastic sleeve.

29. The prosthetic cardiac valve system according to any one of the preceding claims, further comprising an inflating mechanism for inflating one or both of an upstream inflatable tubular element and a downstream inflatable tubular element.

30. The prosthetic cardiac valve system according to any one of the preceding claims, further comprising a detachable inflation tube detachably articulated with each of the upstream inflatable tubular element and the downstream inflatable tubular element.

31. A support structure for supporting a prosthetic cardiac valve, wherein said support structure comprising a flexible tubular stent having an upstream mesh section and a downstream mesh section, with a radially deformable intermediate mesh section extending therebetween, and wherein the upstream mesh section is configured with a plurality of upstream tissue engaging spikes and/or the downstream mesh section is configured with a plurality of downstream tissue engaging spikes; wherein at an expanded position of the stent, said upstream tissue engaging spikes and said downstream tissue engaging spikes project radially outwards from an outside surface of the stent; and an upstream elastic sleeve extending over at least a portion of an inside/outside face of said upstream mesh section; said upstream elastic sleeve having an upstream inflatable tubular element disposed axially and radially upstream of said upstream mesh section.

32. The support structure of claim 31, being configured and operable between a constricted, deploying position at which it is at a closed position, and an expanded, open

position at which it assumes a radially expanded position, and wherein at the closed position the upstream tissue engaging spikes and the downstream tissue engaging spikes are coplanar with an outside surface of the stent.

33. The support structure of claim 31 or 32, being configured and operable for use as a cardiac valve support for any one of the following: mitral valve, aortic valve, tricuspid valve and pulmonary valve.

34. The support structure of any one of claims 31 to 33, for use in conjunction with a prosthetic cardiac valve system, wherein the support structure is a valve support for a prosthetic valve in the mitral position, and wherein the upstream inflatable tubular element is configurable for supra-annular positioning and inflating within the left atrium.

35. The support structure of any one of claims 31 to 34, for use in conjunction with a prosthetic cardiac valve system, wherein the support structure is a valve support for a prosthetic aortic valve, and wherein the upstream inflatable tubular element is configurable for sub-annular positioning and inflation.

36. The support structure of any one of claims 31 to 35, for use in conjunction with a prosthetic cardiac valve system, wherein the support structure is a valve support for a prosthetic tricuspid valve, wherein the upstream inflatable tubular element is configured and operable for supra-annular positioning and inflating within the right atrium.

37. The support structure of any one of claims 31 to 36, for use in conjunction with a prosthetic cardiac valve system, wherein the support structure is a valve support for a prosthetic pulmonary valve, wherein the upstream inflatable tubular element is configurable for sub-annular positioning and inflating within the right ventricle.

38. The support structure of any one of claims 31 to 37, further comprising a temporary valve positioned between the upstream and downstream mesh section at a non-deformable section of the support structure thereof, for temporarily regulating blood flow, in the direction corresponding with the normal hemodynamics, during a procedure of positioning and deploying the support structure, whereby upon positioning and deploying the prosthetic valve within the support structure, said temporary valve is over-ridden by the prosthetic valve.

39. A stent member for supporting a prosthetic cardiac valve, the stent member being a flexible tubular element having an upstream mesh section, a downstream mesh section and a radially deformable intermediate section extending therebetween, wherein the upstream mesh section is configured with a plurality of upstream tissue engaging spikes,

and/or the downstream mesh section is configured with a plurality of downstream tissue engaging spikes, wherein said upstream tissue engaging spikes and said downstream tissue engaging spikes are made of memory shape material and are configured, at a closed position to be coplanar with an outside surface of the stent, and at an expanded deployed position of the stent, after being introduced *in situ* and reaching a predefined temperature to deform to their memory shape to project radially outwards from an outside surface of the stent to their radially outwards deformed position.

40. The stent member according to claim 39, wherein at its deployed, expanded position, the stent assumes a frustoconical shape wherein a narrow portion thereof is the upstream section of the stent.

41. The stent member according to claim 39 or 40, wherein the projecting spikes can be equally distributed about a perimeter of the stent.

42. The stent member according to any one of claims 39 to 40, wherein the projecting spikes have a triangle/ teardrop or elongated loop shape.

43. The stent member according to any one of claims 39 to 42, wherein at an initial, unstressed position, the stent is cylindric.

44. A support structure for supporting a prosthetic mitral valve, said support structure having an elastic sleeve member comprising an inflatable supra annular member and an inflatable sub annular member defining therebetween a flow space; and a flexible tubular mesh structure articulated at an inside face of the sleeve, the mesh structure having an atrial section and a ventricular portion, with a radially deformable section extending therebetween, and wherein the atrial portion is configured with a plurality of annular/supra annular tissue engaging spikes and/or the ventricular portion is configured with a plurality of annular/sub annular tissue engaging spikes, whereby inflating the supranuclear portion entails radial deformation of the of annular/supra annular tissue engaging spikes, and inflating the sub annular portion entails radially outwards deformation of the deformable section and the sub annular portion, and radial deformation of the annular/sub annular tissue engaging spikes, wherein a prosthetic mitral valve is secured within the elastic sleeve thereof.

45. A prosthetic cardiac valve kit comprising:

a support structure comprising a flexible tubular stent having an upstream mesh section and a downstream mesh section, with a radially deformable intermediate mesh section extending therebetween, and wherein the upstream mesh section is configured

with a plurality of upstream tissue engaging spikes and/or the downstream mesh section is configured with a plurality of downstream tissue engaging spikes; wherein at an expanded position of the stent said upstream tissue engaging spikes and said downstream tissue engaging spikes project radially outwards from an outside surface of the stent;

an upstream elastic sleeve extending over at least a portion of an inside/outside face of said upstream mesh section; said upstream elastic sleeve having an upstream inflatable tubular element disposed axially and radially upstream of said upstream mesh section;

a prosthetic cardiac valve secured within the upstream elastic sleeve and downstream of the upstream inflatable tubular element.

46. The prosthetic cardiac valve kit of claim 45, further comprising an inflating mechanism for inflating one or both of an upstream inflatable tubular element and a downstream inflatable tubular element.

47. The prosthetic cardiac valve kit of claim 45 or 46, further comprising a detachable inflation tube detachably articulated with each of the upstream inflatable tubular element and the downstream inflatable tubular element.

48. A method of deploying a prosthetic cardiac valve support system, or a fully functional prosthetic cardiac valve, the method comprising the following steps:

A. introducing a guide wire with a distal capsule containing the prosthetic cardiac valve system, or the fully functional prosthetic cardiac valve, at a compressed position, visualized under imaging;

B. exposing the downstream inflatable element with the downstream mesh section of the stent at the sub annular level of the native valve, distal to the native leaflets coaptation line;

C. inflating the downstream inflatable element, while an upstream inflatable element is still crimped in the capsule;

D. retrieving the capsule towards the upstream portion of the valve, allowing the downstream spikes to engage downstream of the native valve;

E. unsheathing the upstream inflatable element under imaging;

F. inflating the upstream inflatable element;

G. withdrawing the capsule.

49. The method of claim 48 further comprising:

introducing and guiding a compressed prosthetic valve over the guide wire;

positioning the prosthetic valve within the inflated prosthetic cardiac valve system, between the upstream inflatable element and the downstream inflatable element;

deploying the prosthetic valve.

50. A method of deploying a prosthetic cardiac valve support system, or a prosthetic cardiac valve system, the method comprising the following steps:

introducing over a guide wire a distal capsule containing the prosthetic cardiac valve system at a compressed position;

splitting a proximal portion of the capsule for exposing an upstream inflatable element above native leaflets of a native valve while maintaining downstream portions and a stent of the prosthetic cardiac valve in a portion of said distal capsule distal to said upstream inflatable element;

inflating the upstream inflatable element;

distally advancing the inflated upstream inflatable element and said portion of the capsule to place said inflated upstream inflatable element over an annulus of said native valve and introducing said portion of the capsule below the native leaflets of said native valve;

distally advancing said portion of the capsule for unsheathing said downstream portions of the prosthetic cardiac valve under imaging;

inflating the downstream inflatable element for anchoring said stent inside said native valves by upstream and/or downstream tissue engaging spikes of said stent;

withdrawing the capsule.

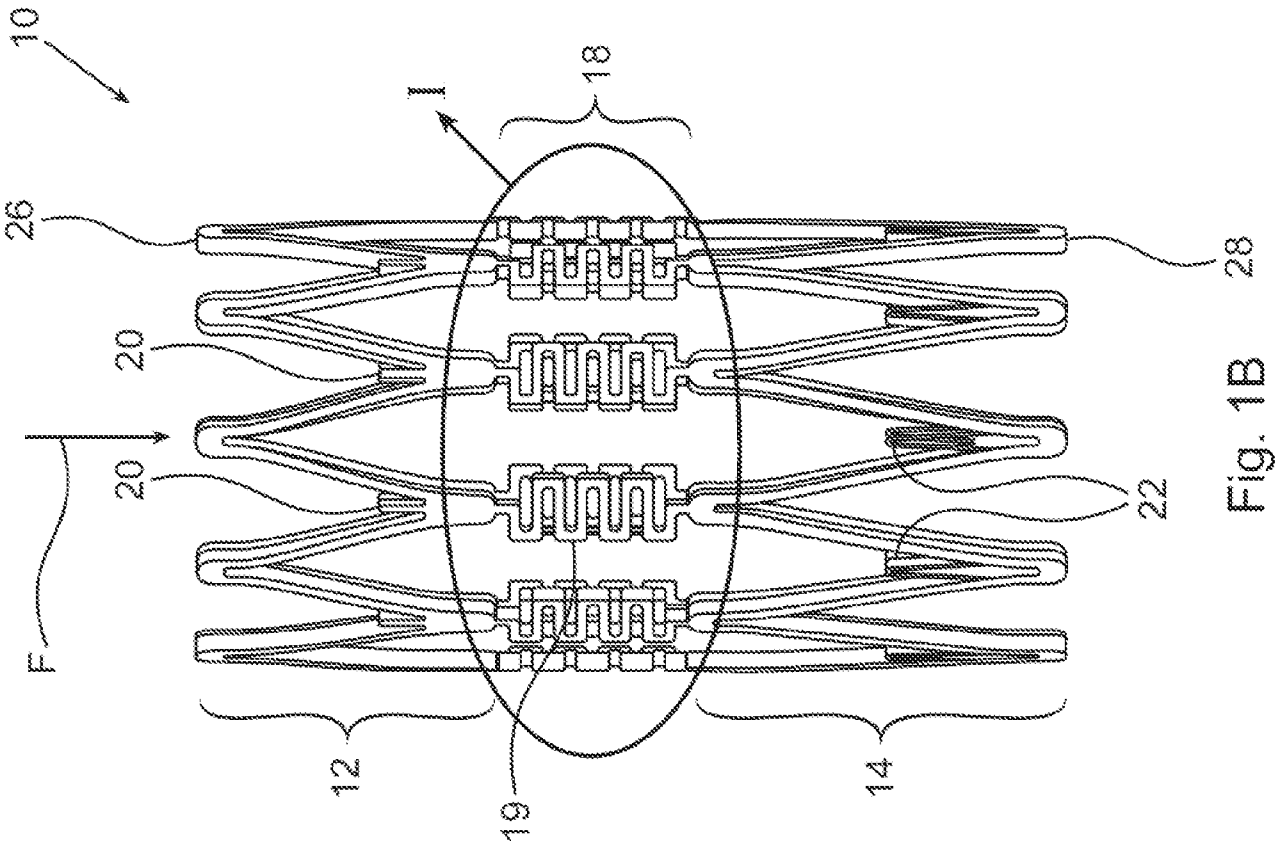

Fig. 1B

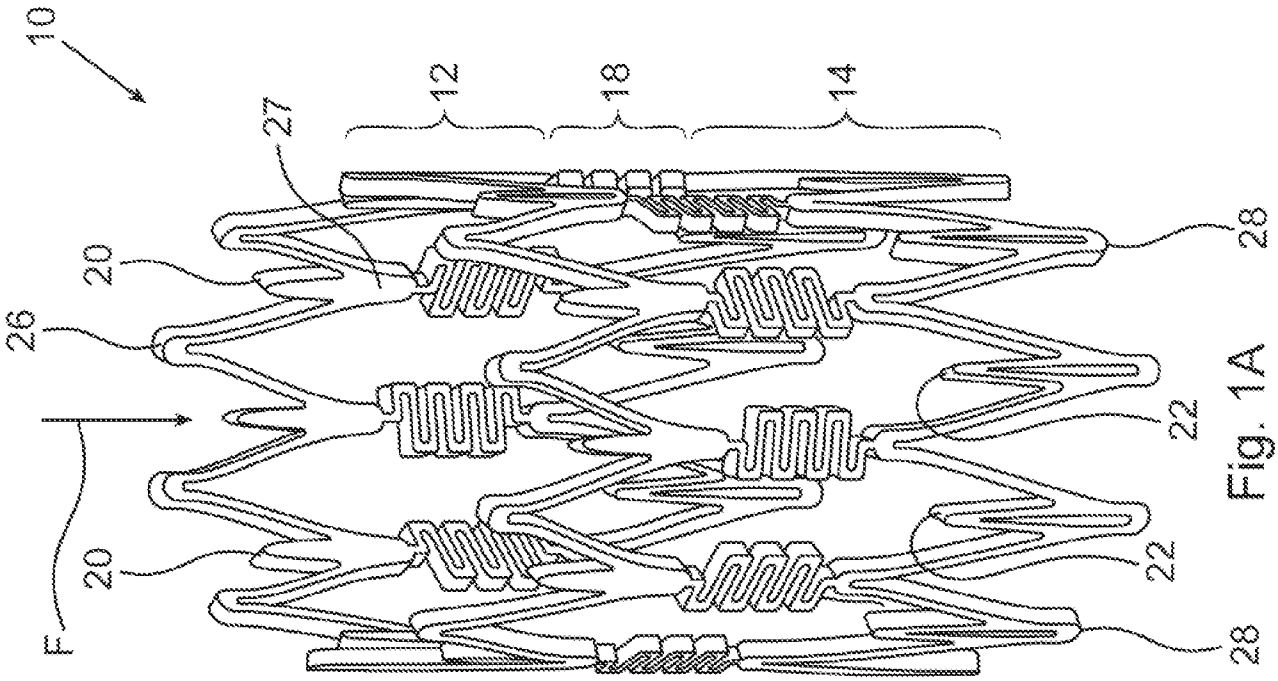

Fig. 1A

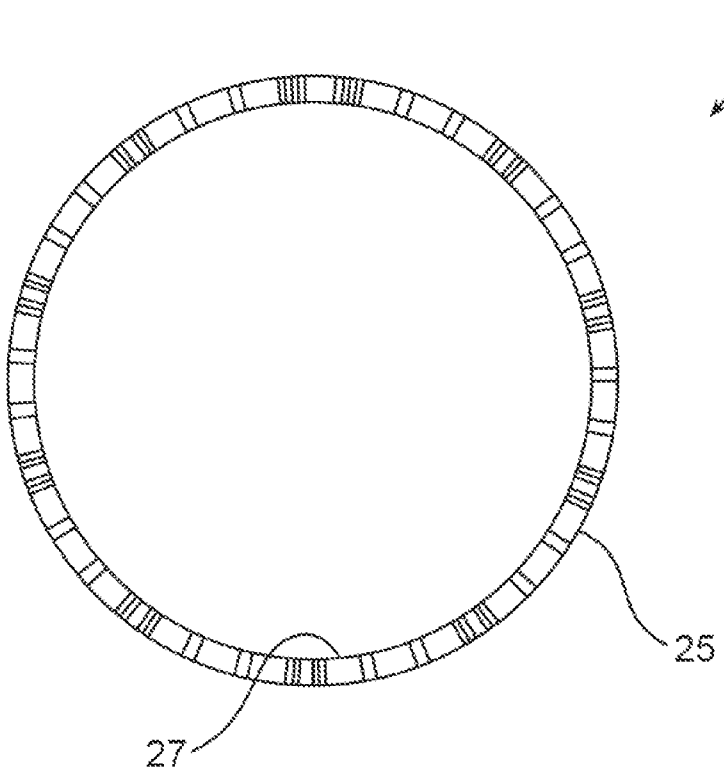

Fig. 1C

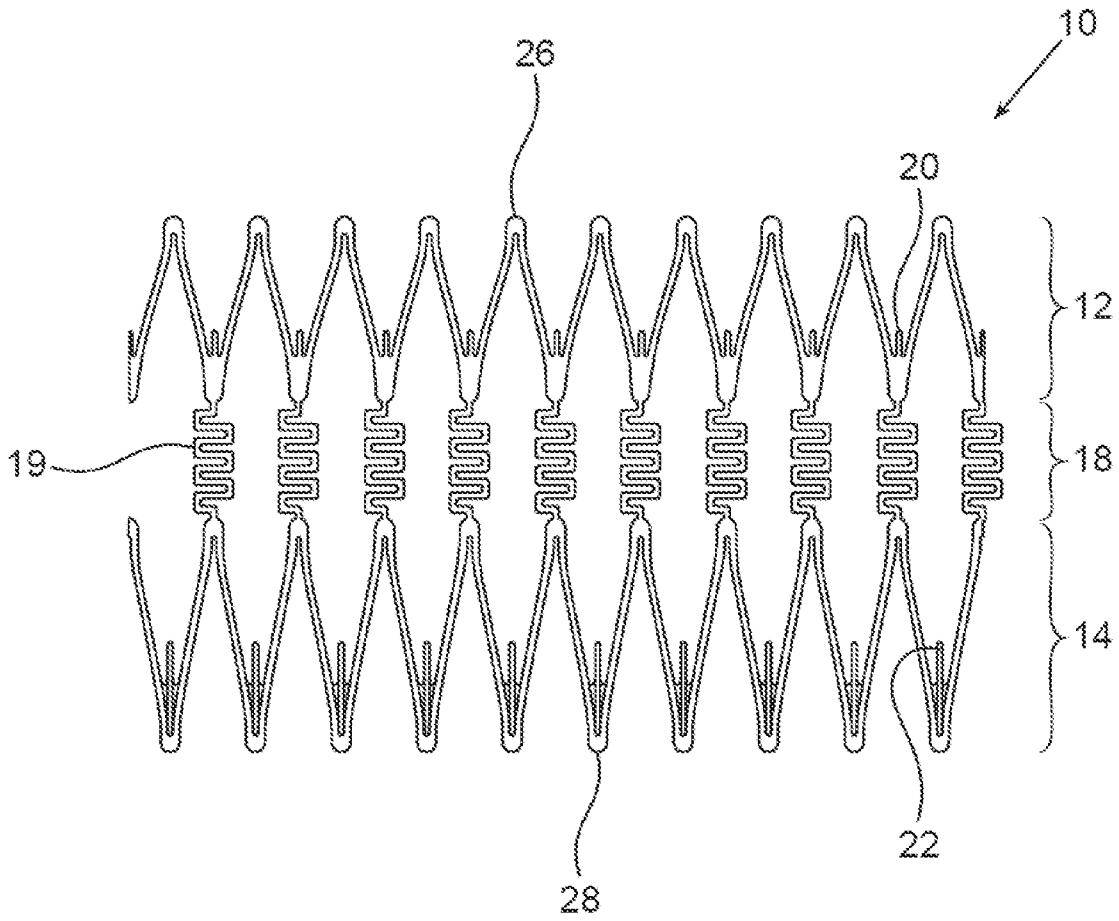

Fig. 1D

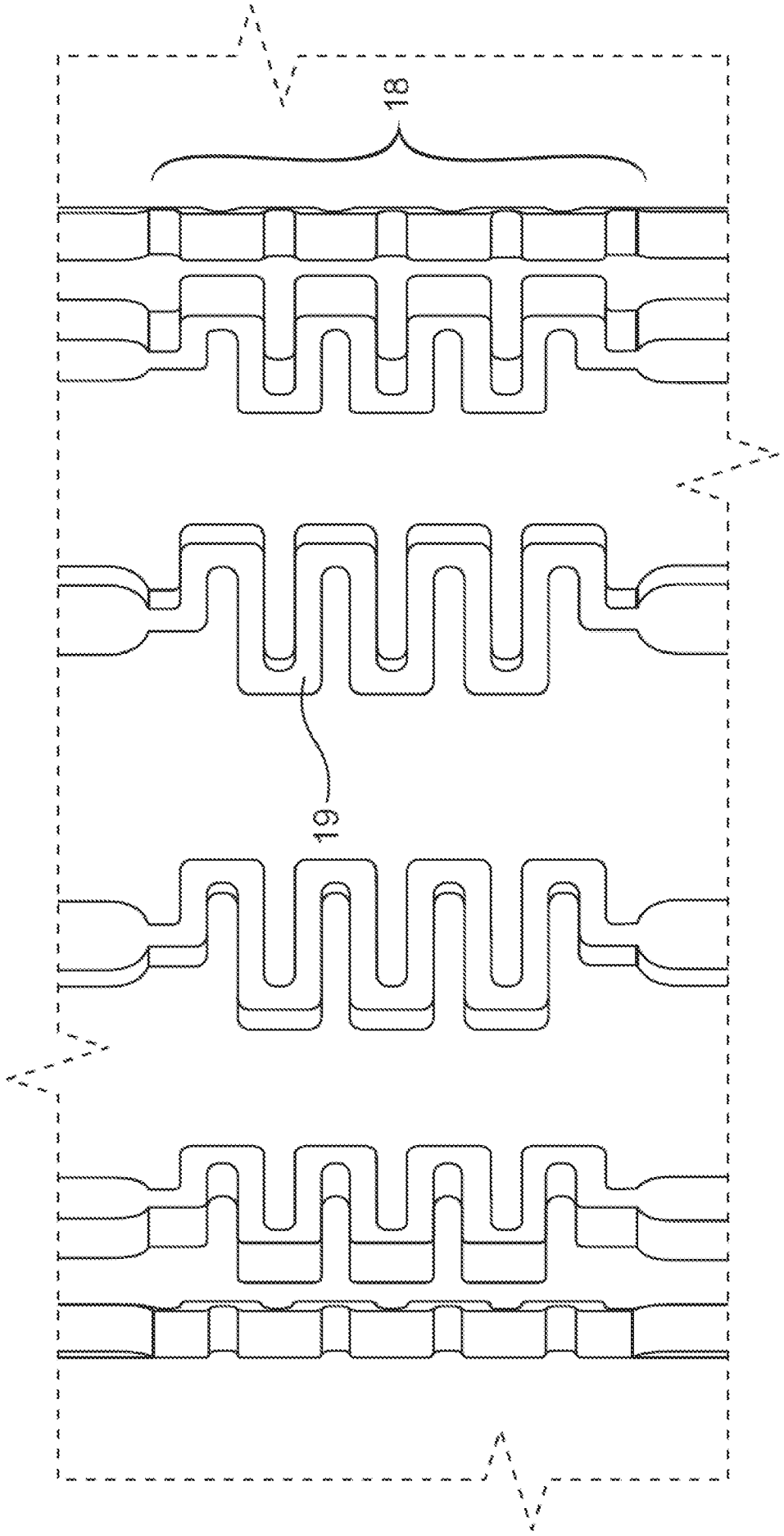

Fig. 1E

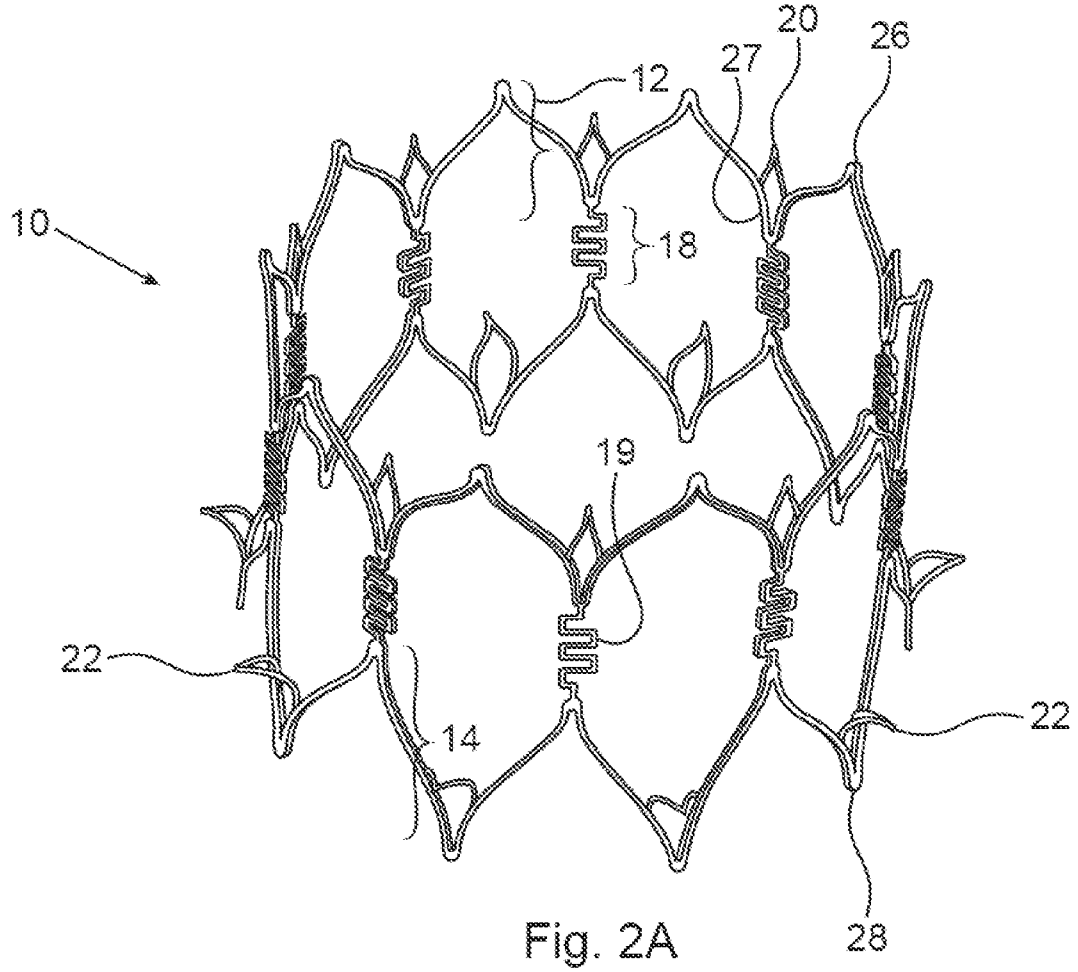

Fig. 2A

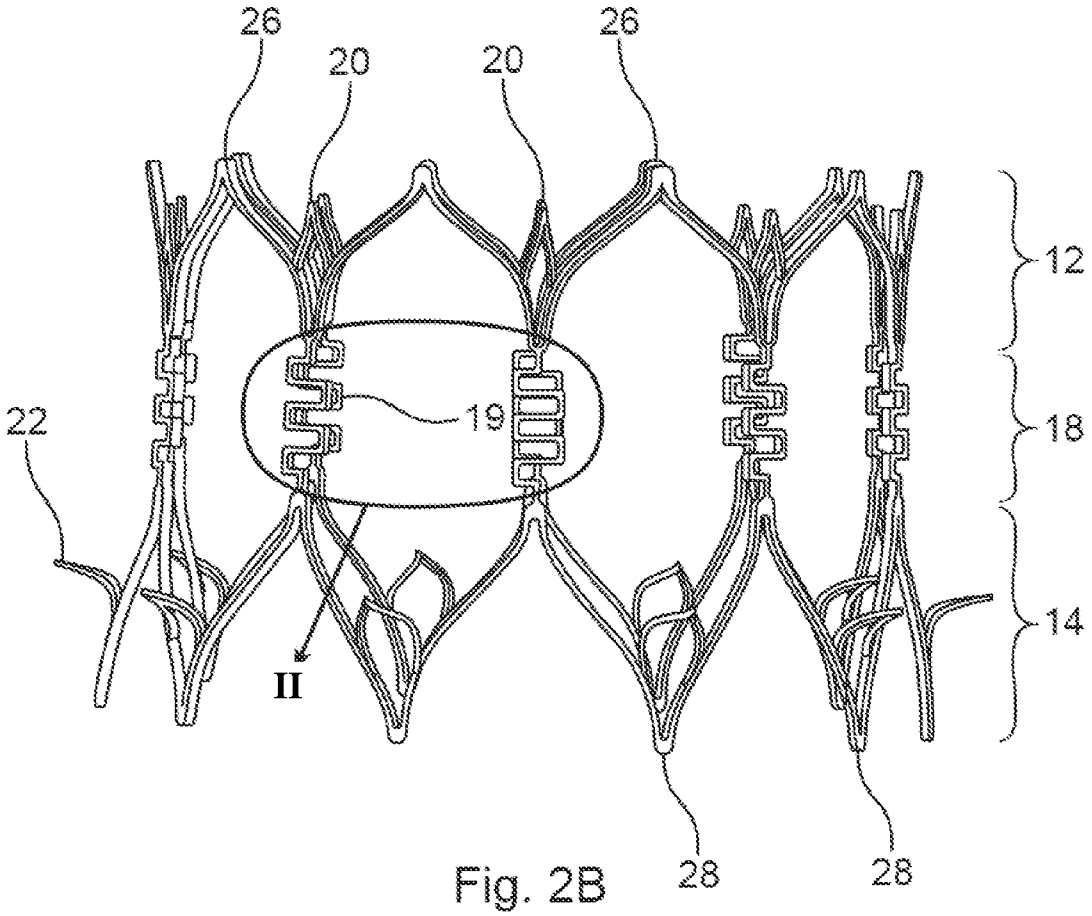

Fig. 2B

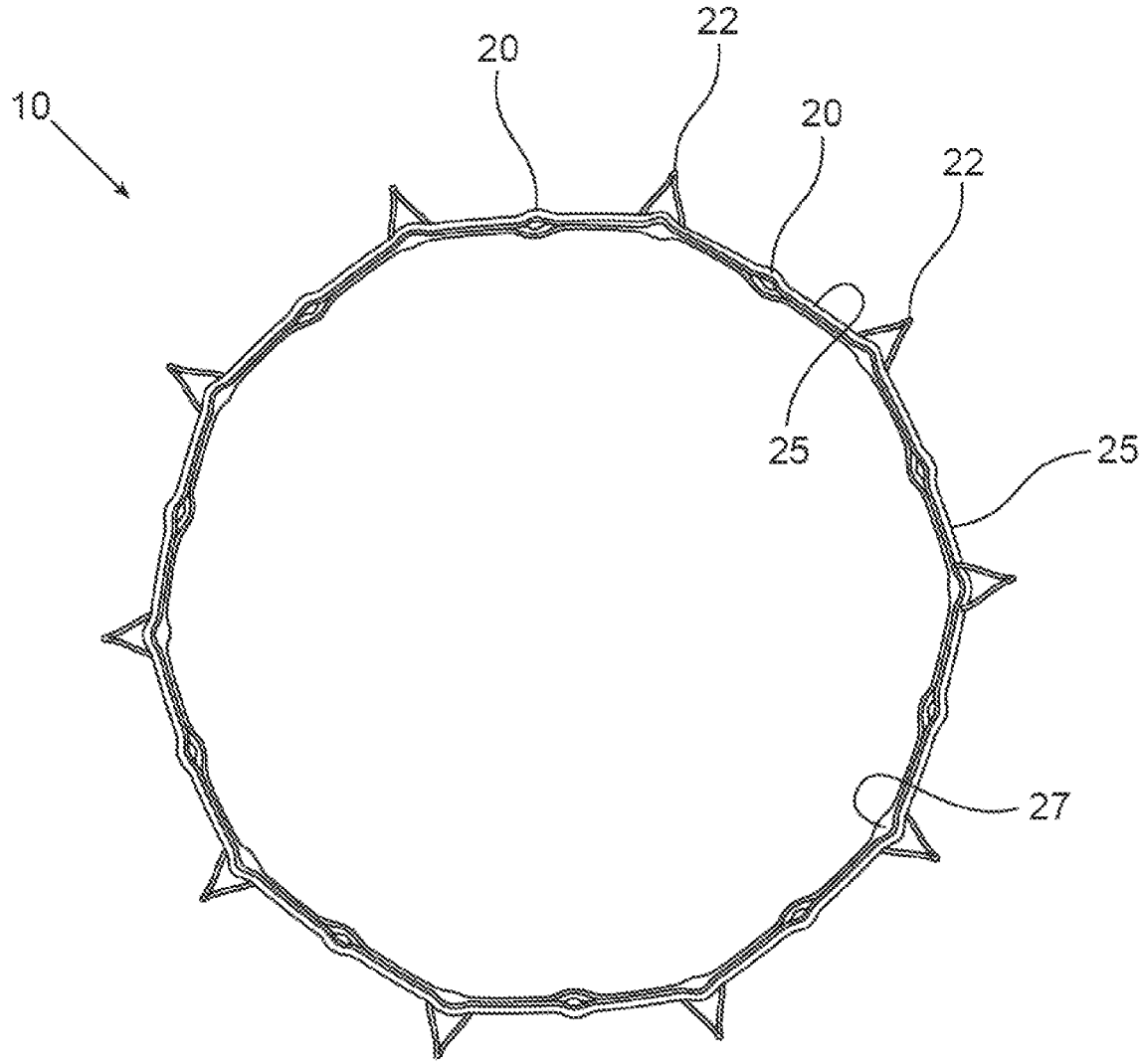

Fig. 2C

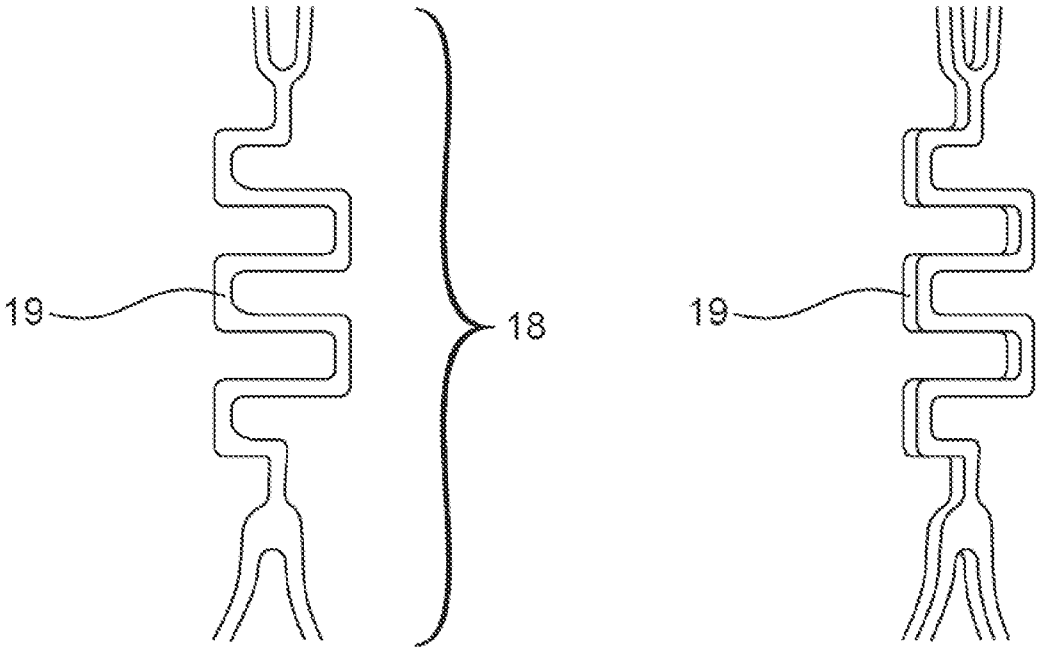

Fig. 2D

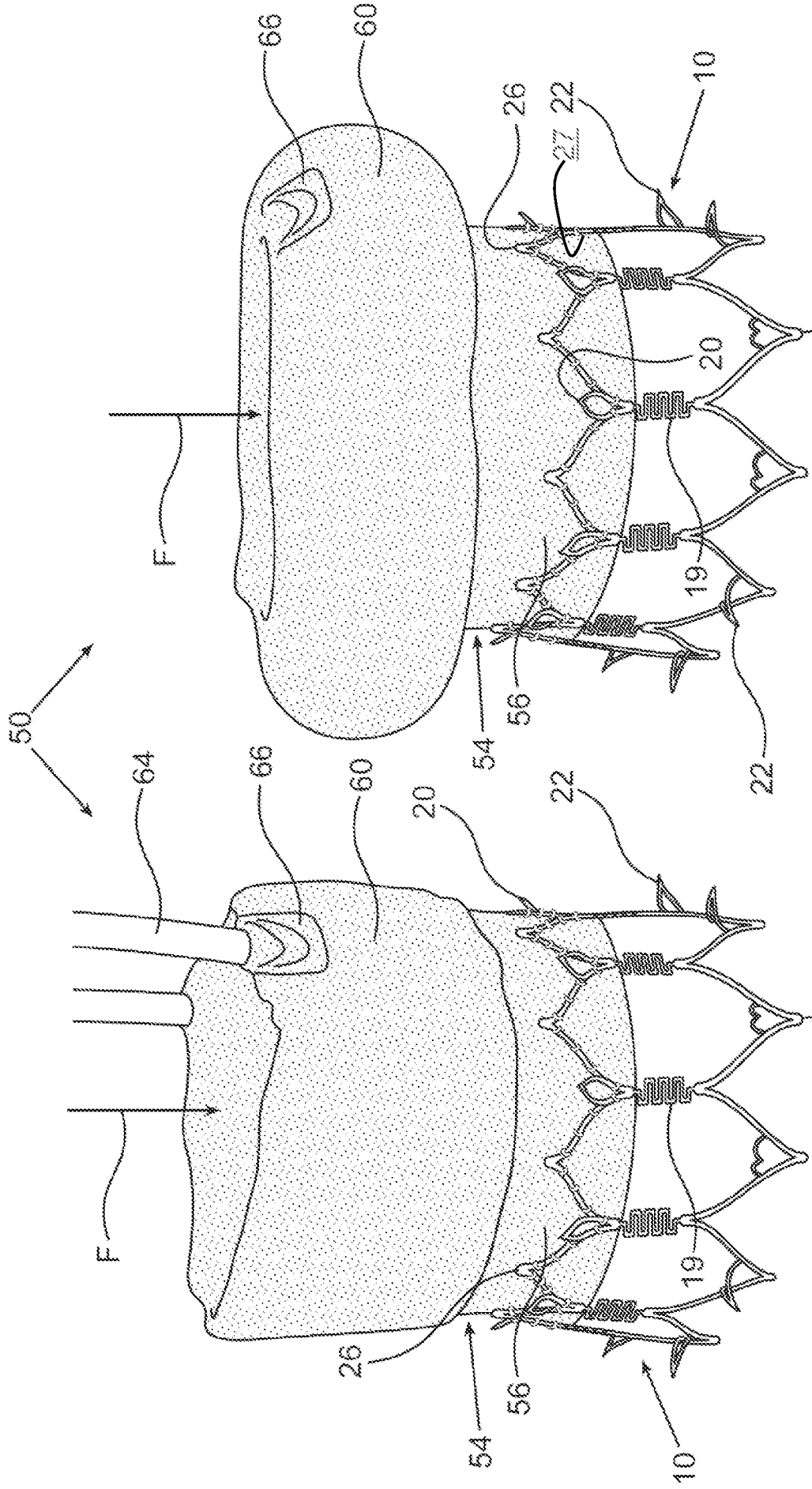
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Fig. 3A

Fig. 3B

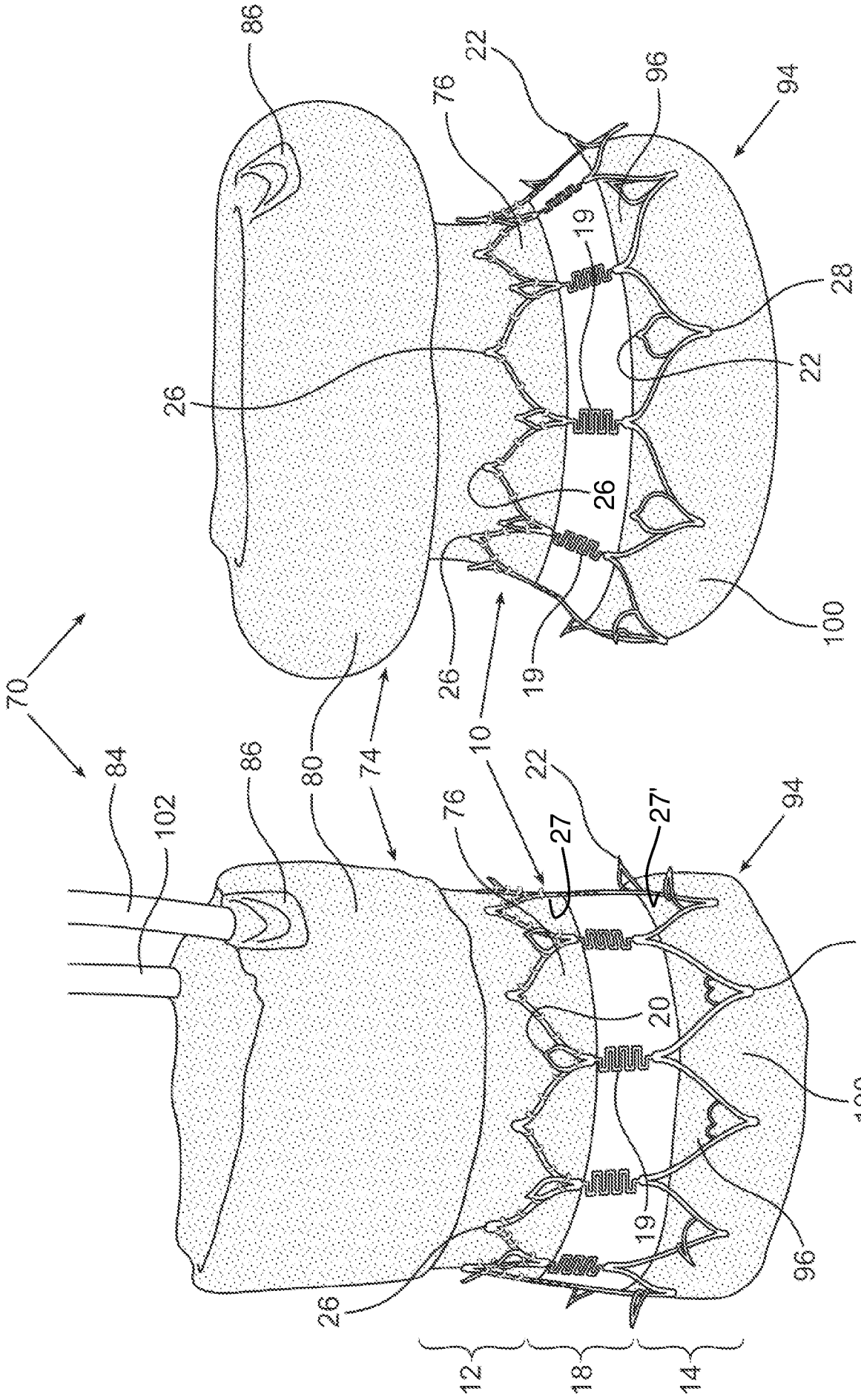
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Fig. 4B

Fig. 4A

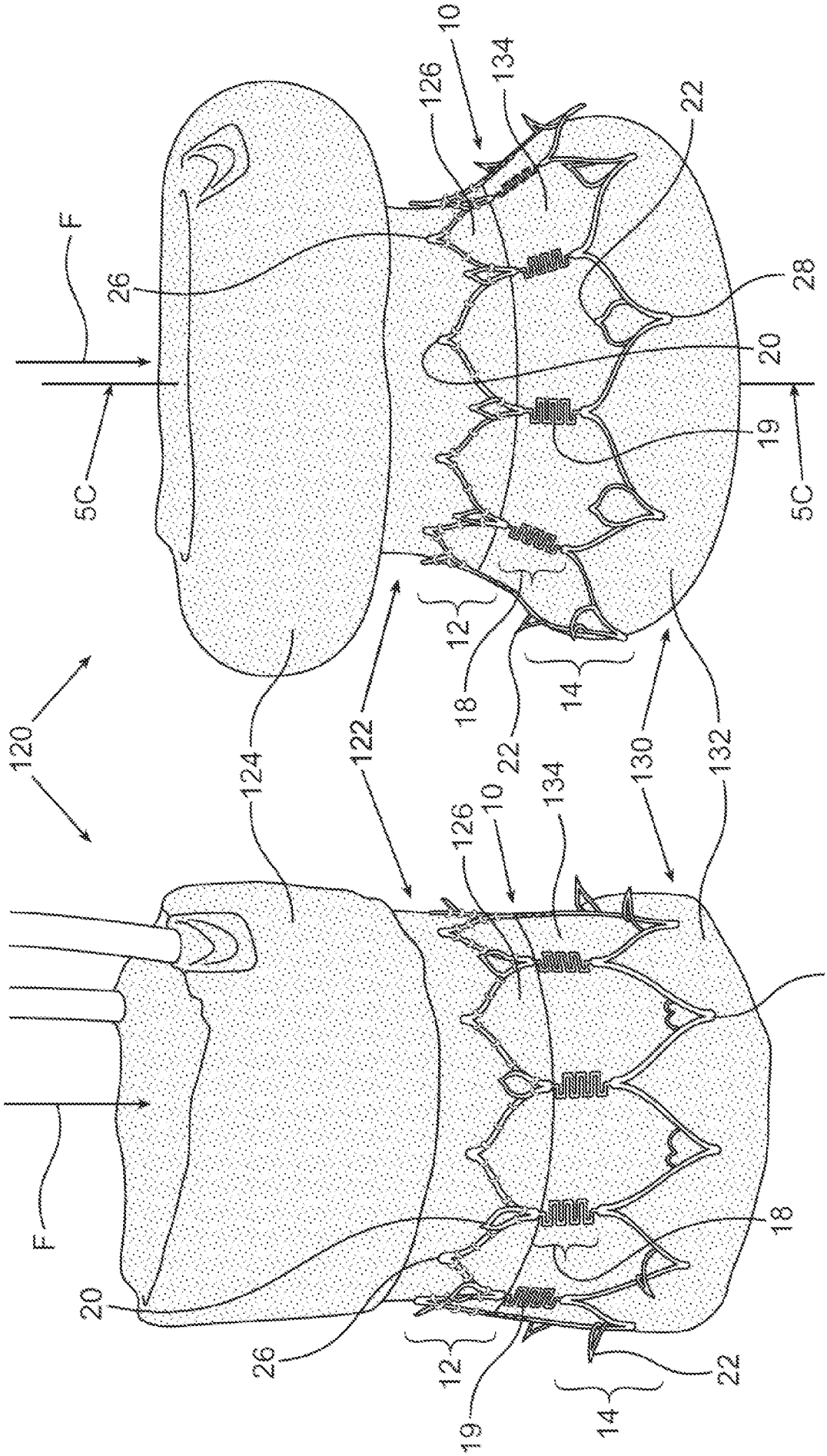
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Fig. 5B

Fig. 5A

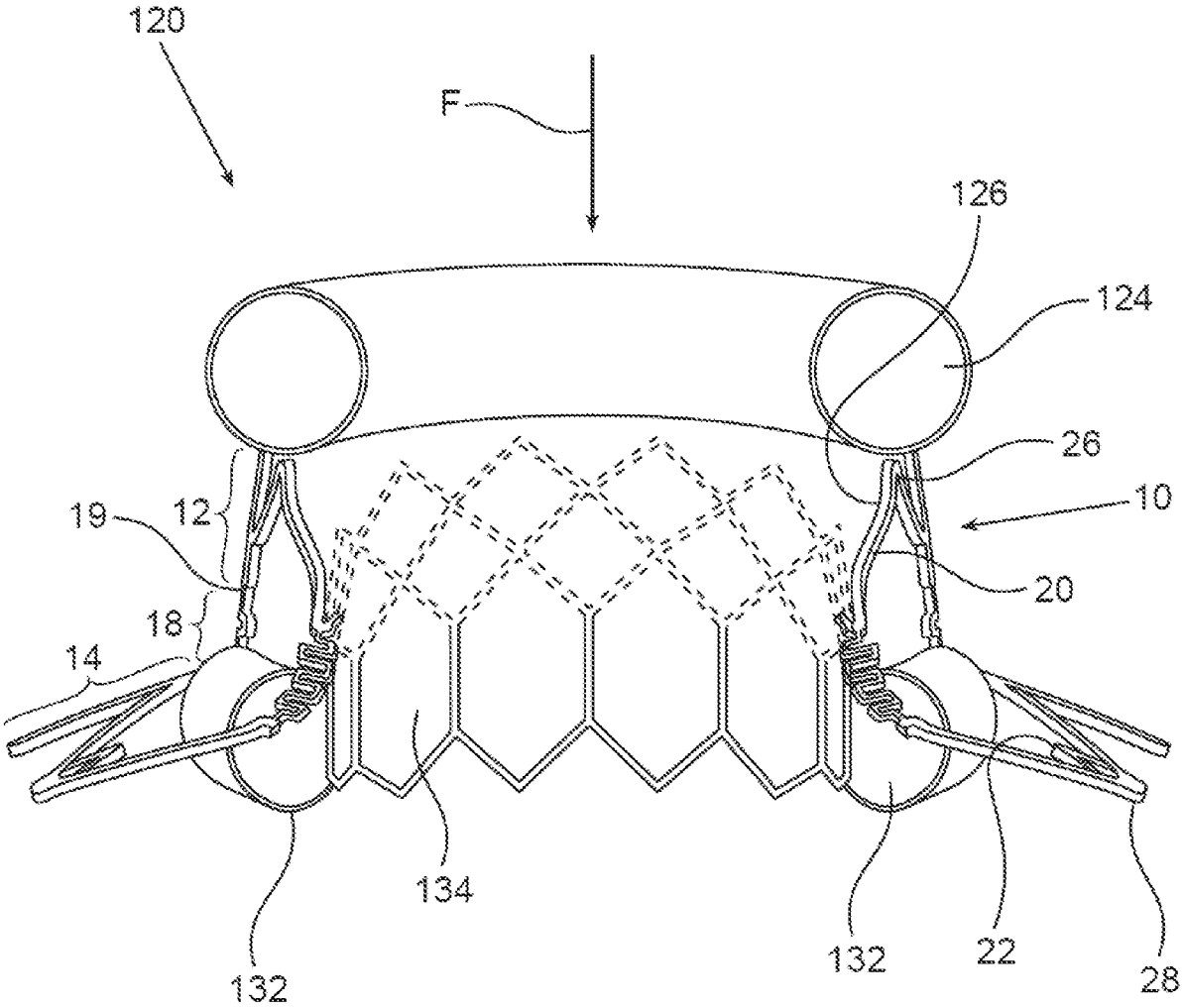

Fig. 5C

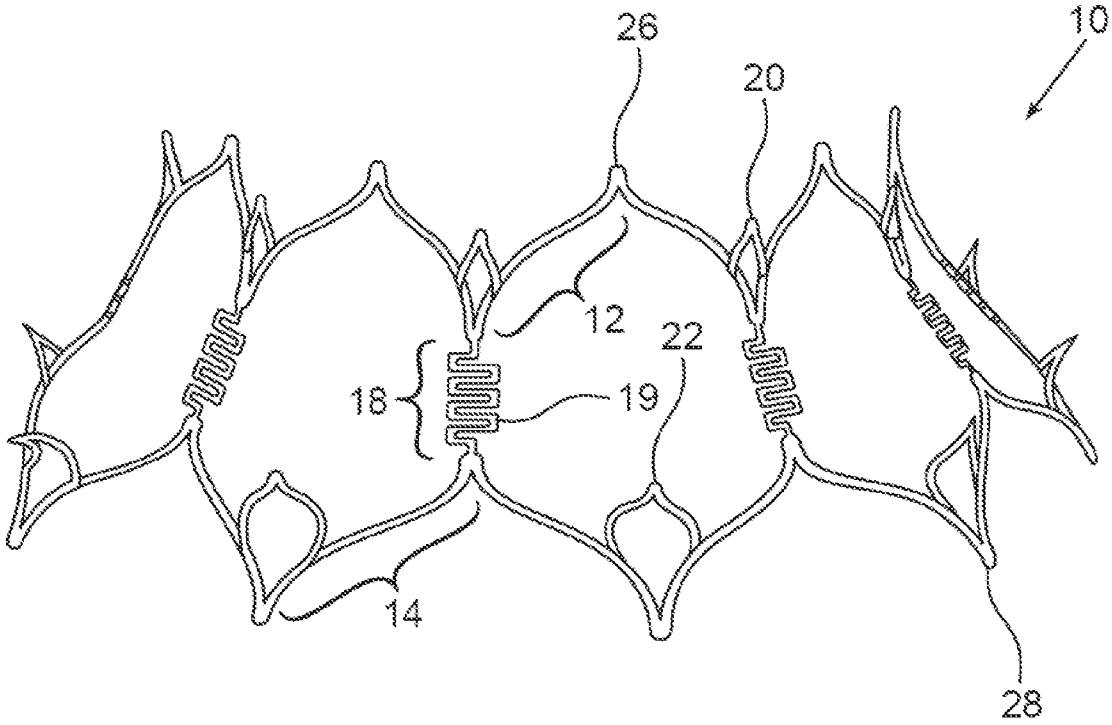

Fig. 6A

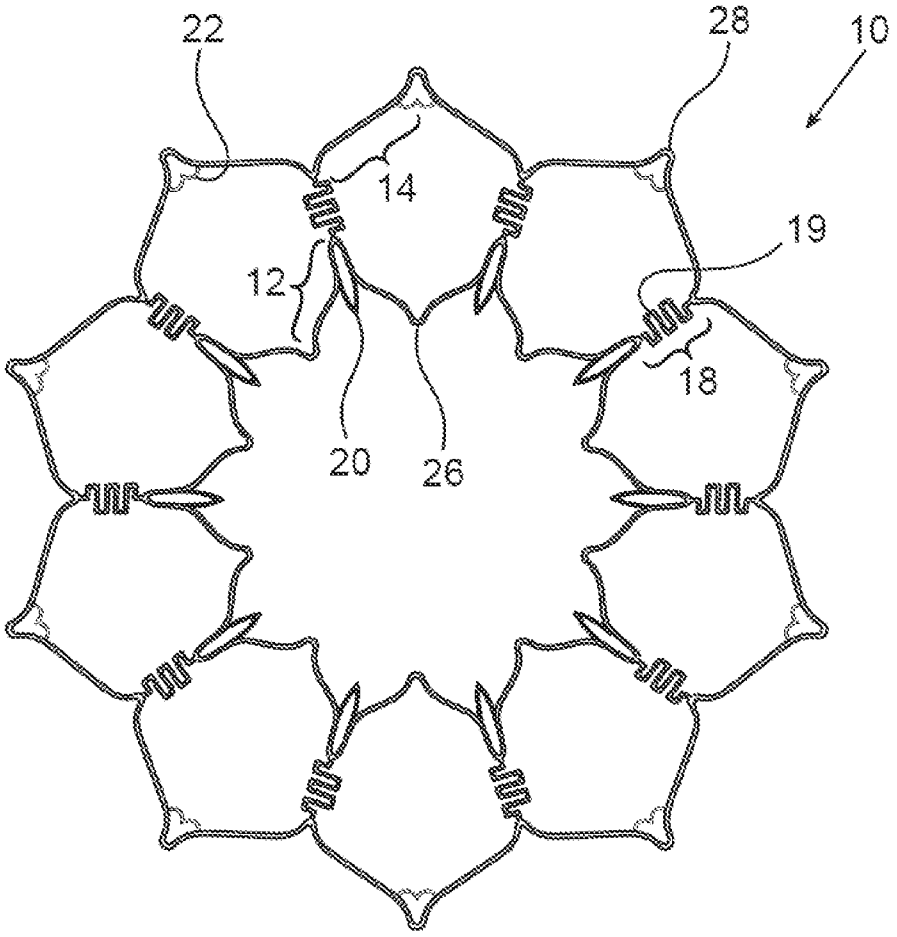

Fig. 6B

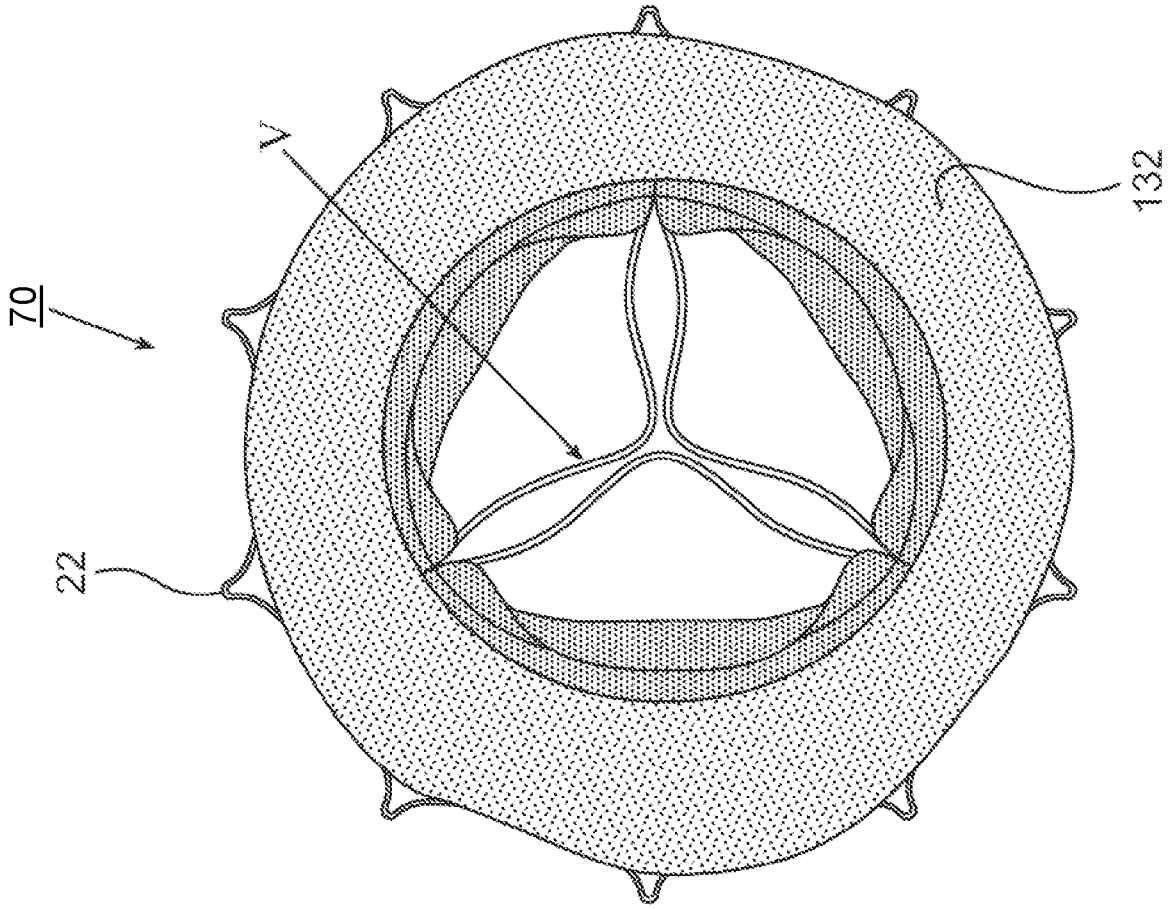

Fig. 7B

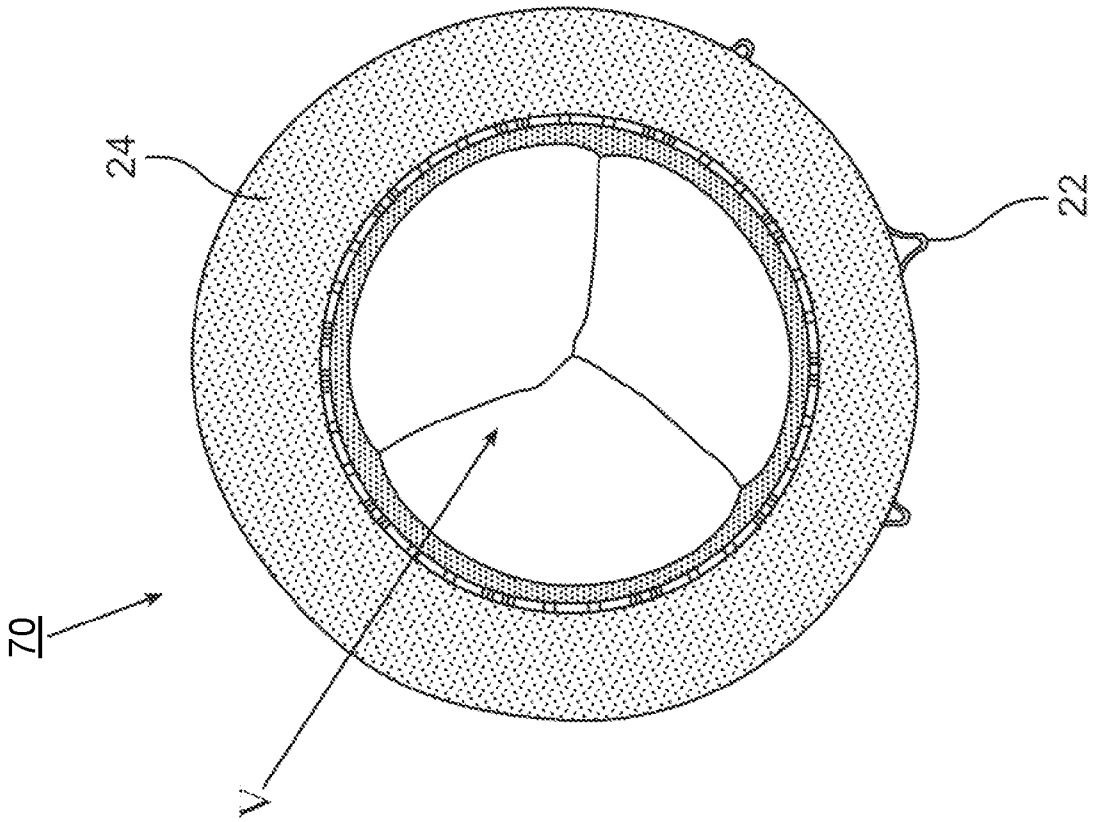

Fig. 7A

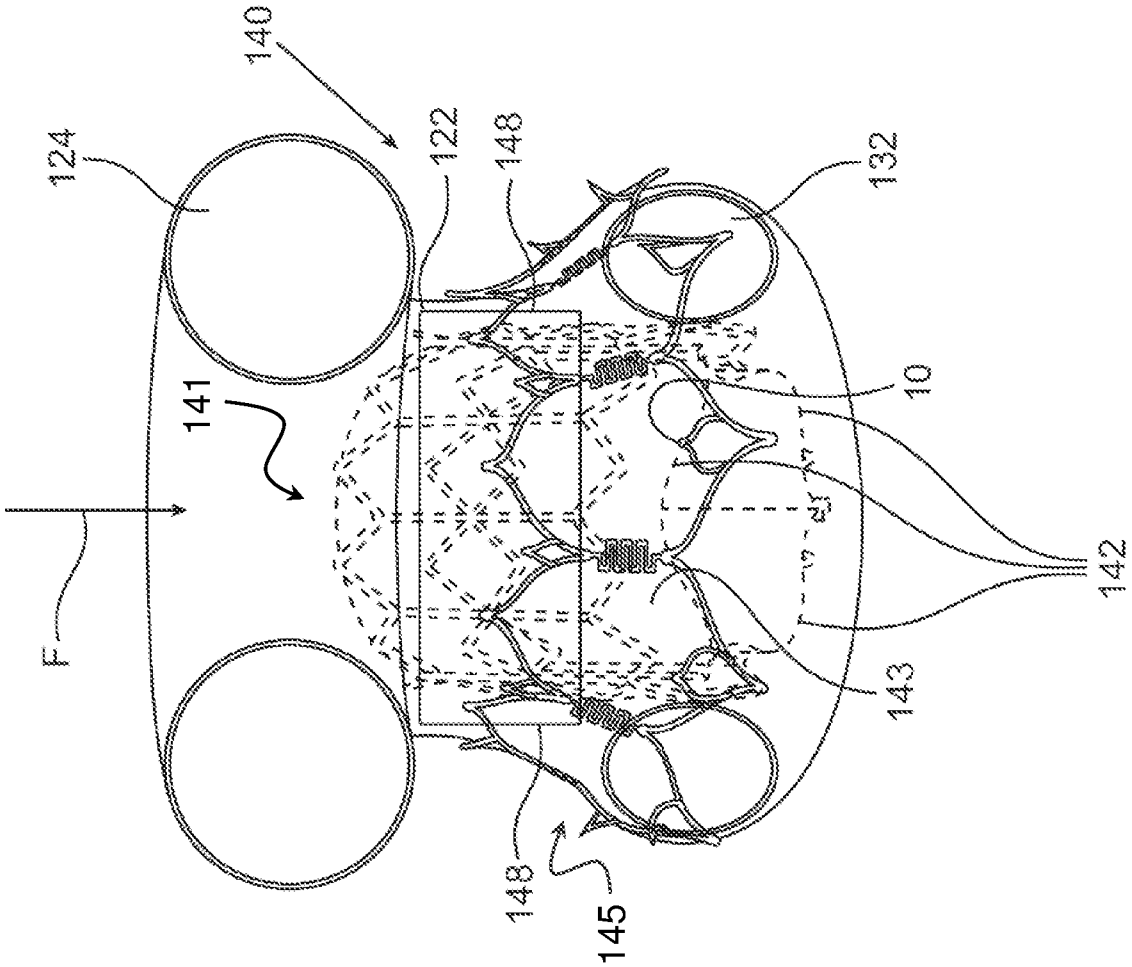
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Fig. 7D

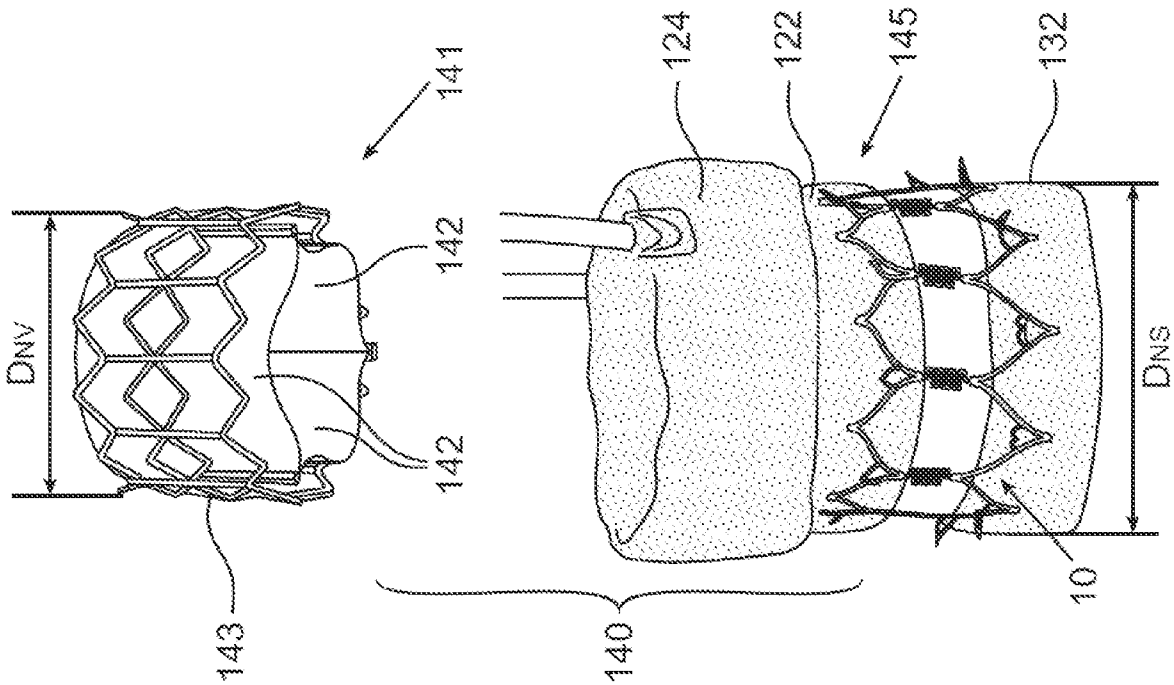
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Fig. 7C

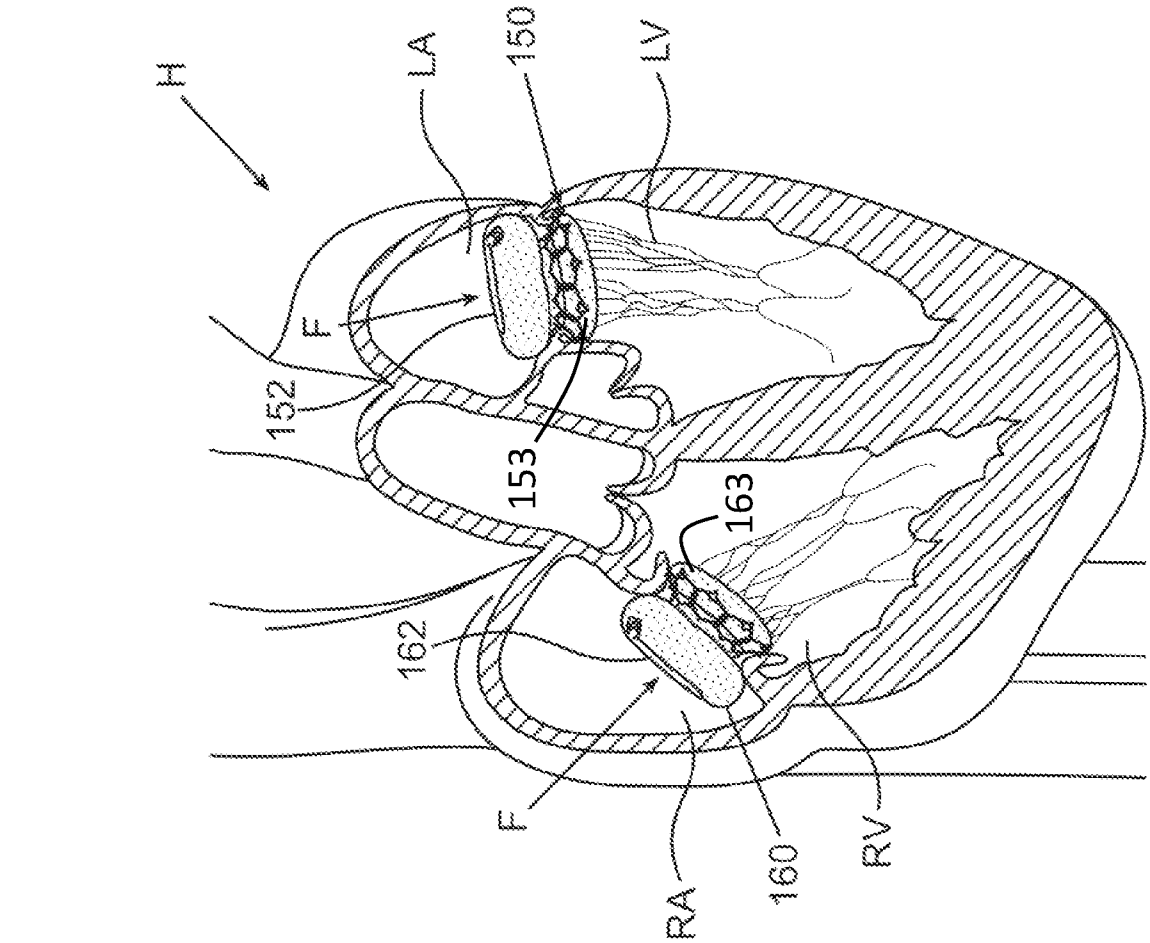

Fig. 8A

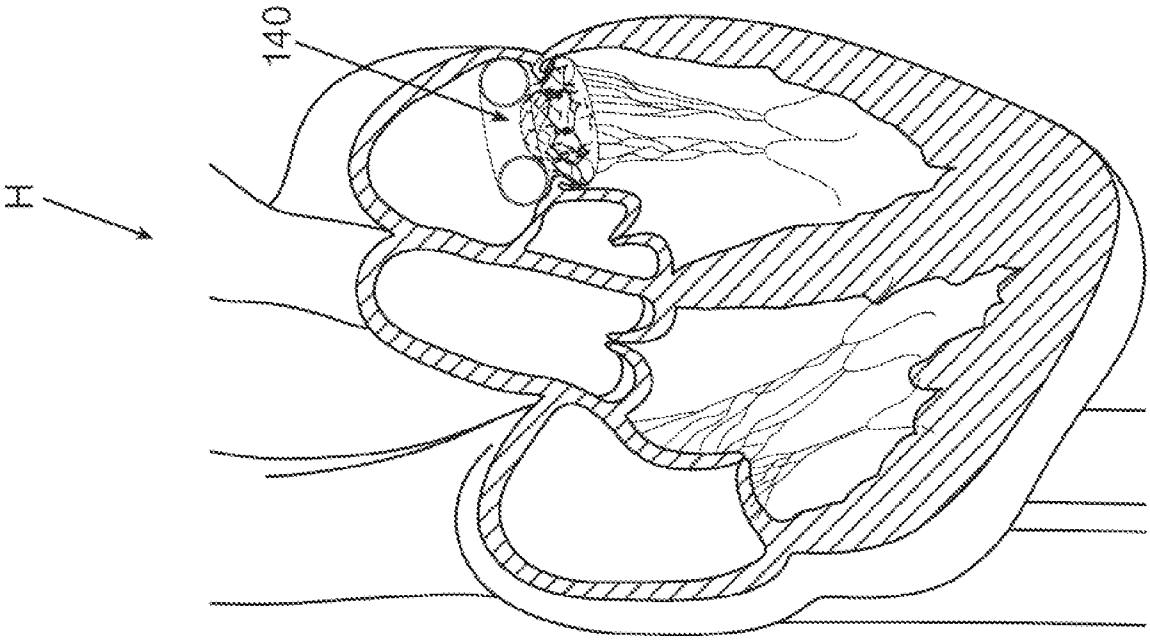

Fig. 7E

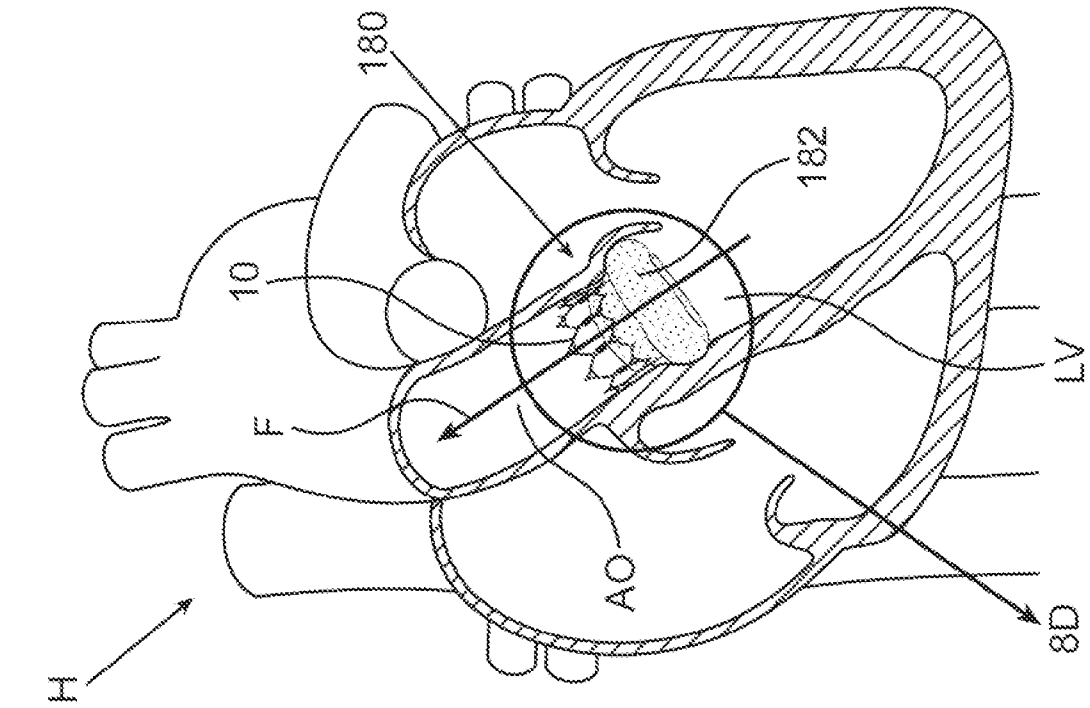

Fig. 8C

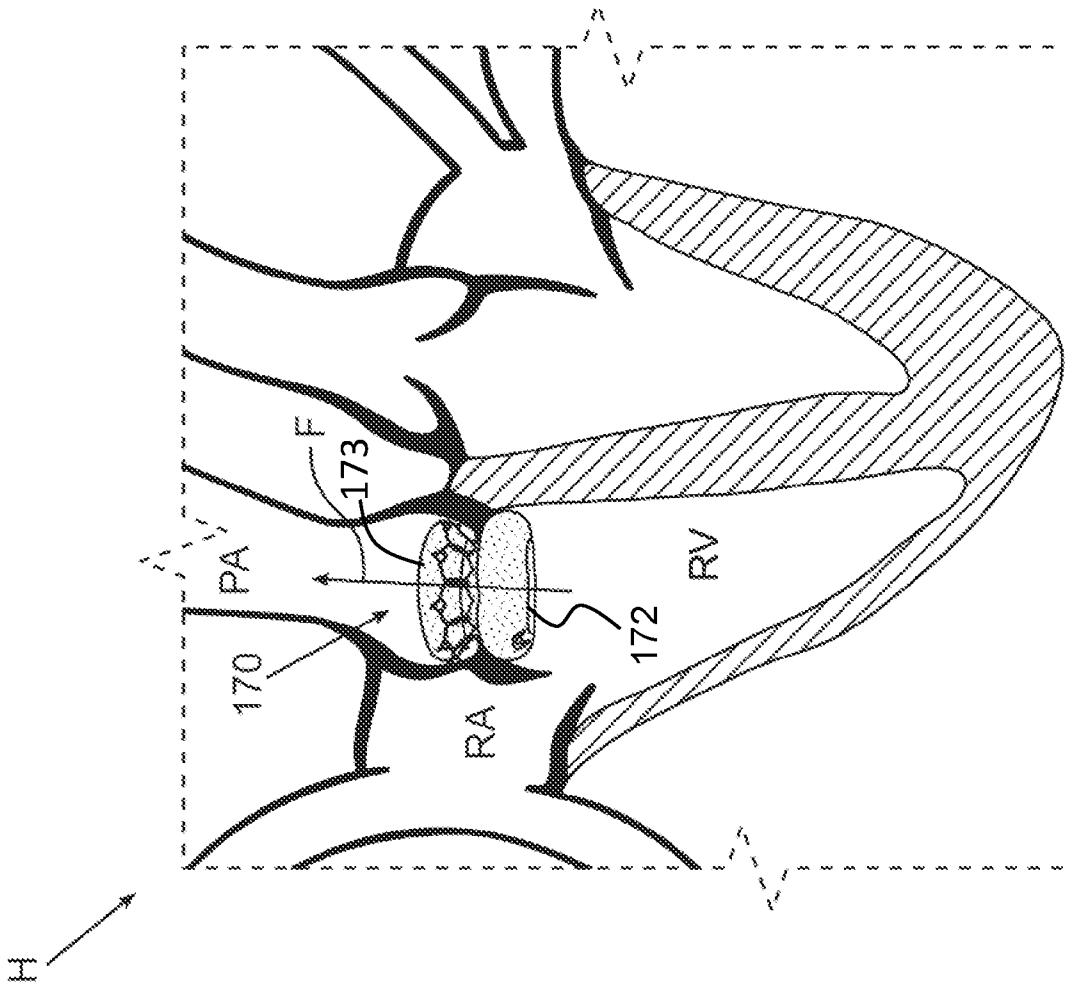

Fig. 8B

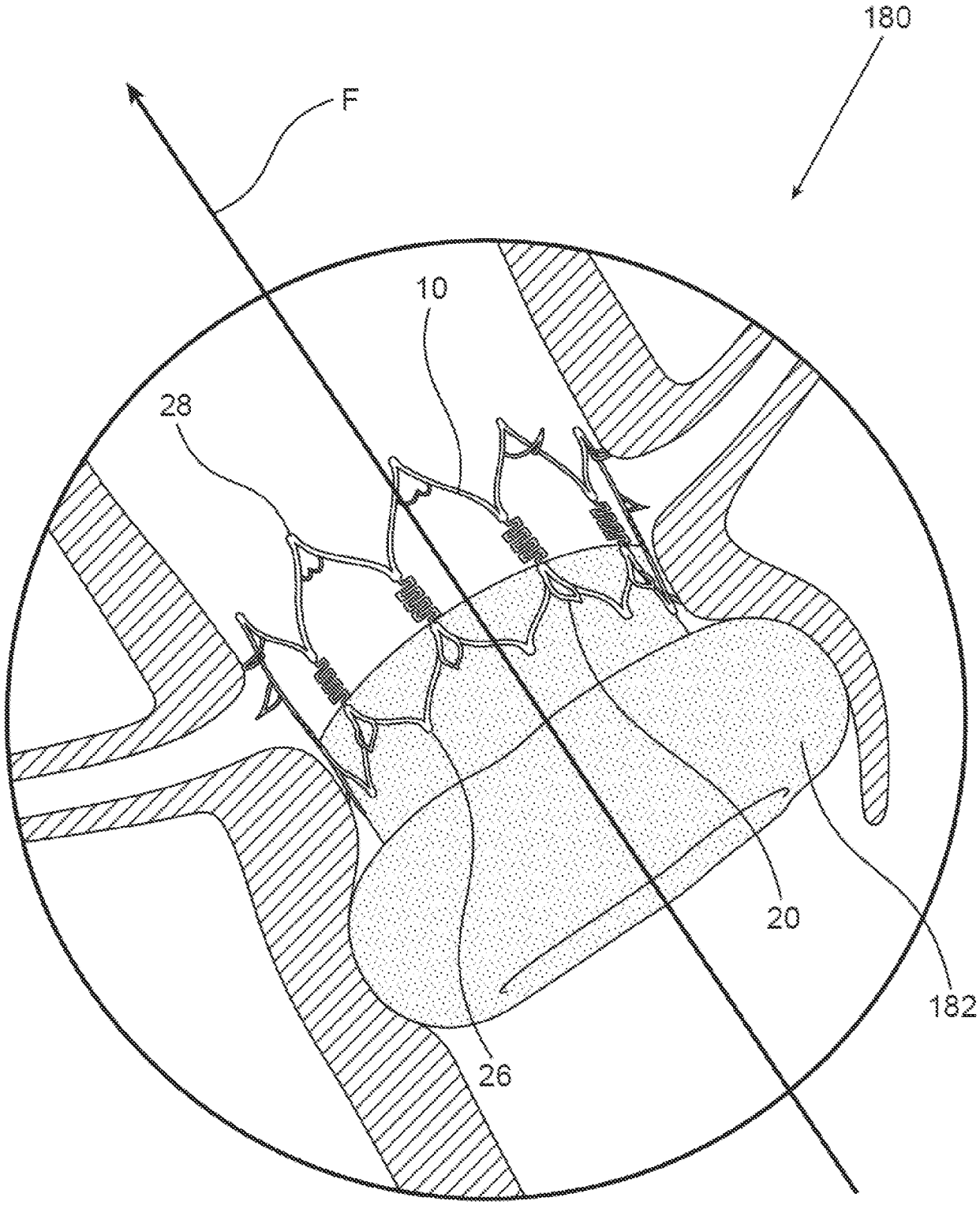

Fig. 8D

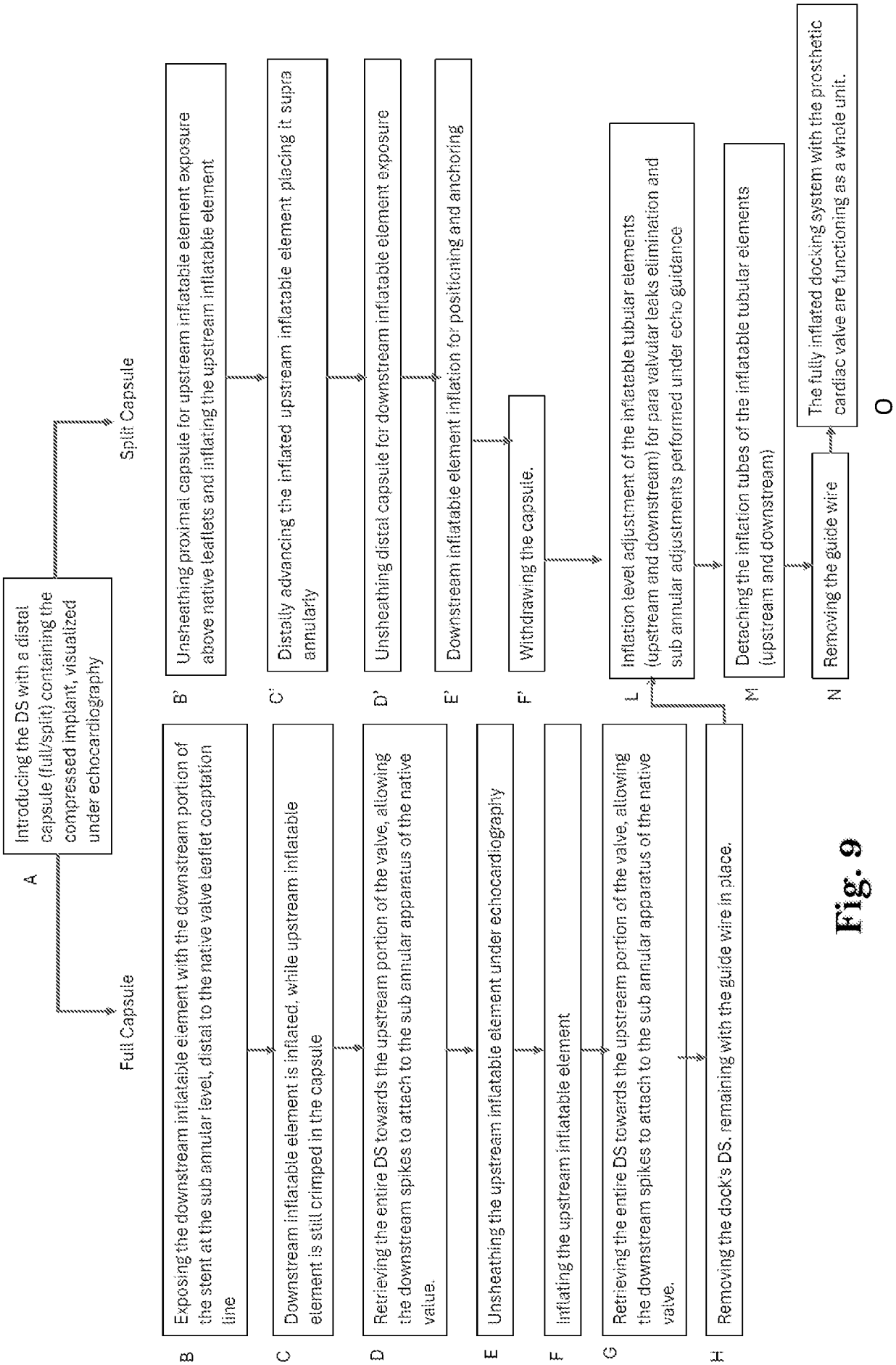
A
Introducing the DS with a distal capsule (full/split) containing the compressed implant, visualized under echocardiography
Full Capsule
Split Capsule
B
Exposing the downstream inflatable element with the downstream portion of the stent at the sub annular level, distal to the native valve leaflet coaptation line
C
Downstream inflatable element is inflated, while upstream inflatable element is still crimped in the capsule
D
Retrieving the entire DS towards the upstream portion of the valve, allowing the downstream spikes to attach to the sub annular apparatus of the native value.
E
Unsheathing the upstream inflatable element under echocardiography
F
Inflating the upstream inflatable element
G
Retrieving the entire DS towards the upstream portion of the valve, allowing the downstream spikes to attach to the sub annular apparatus of the native valve.
H
Removing the dock's DS, remaining with the guide wire in place.
B'
Unsheathing proximal capsule for upstream inflatable element exposure above native leaflets and inflating the upstream inflatable element
C'
Distally advancing the inflated upstream inflatable element placing it supra annularly
D'
Unsheathing distal capsule for downstream inflatable element exposure
E'
Downstream inflatable element inflation for positioning and anchoring
F'
Withdrawing the capsule.
L
Inflation level adjustment of the inflatable tubular elements (upstream and downstream) for para valvular leaks elimination and sub annular adjustments performed under echo guidance
M
Detaching the inflation tubes of the inflatable tubular elements (upstream and downstream)
N
Removing the guide wire
O
The fully inflated docking system with the prosthetic cardiac valve are functioning as a whole unit.

Fig. 9

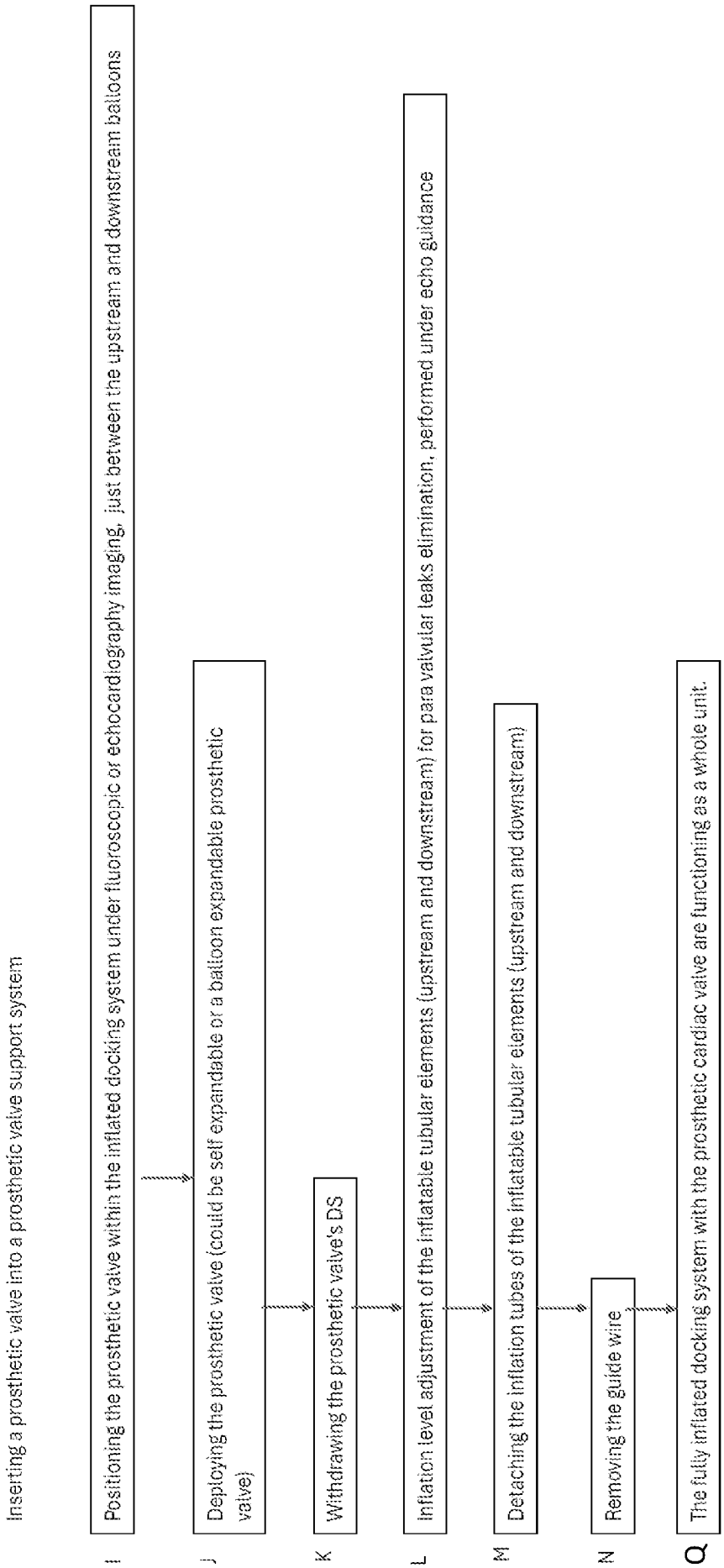

Fig. 9 (continued)

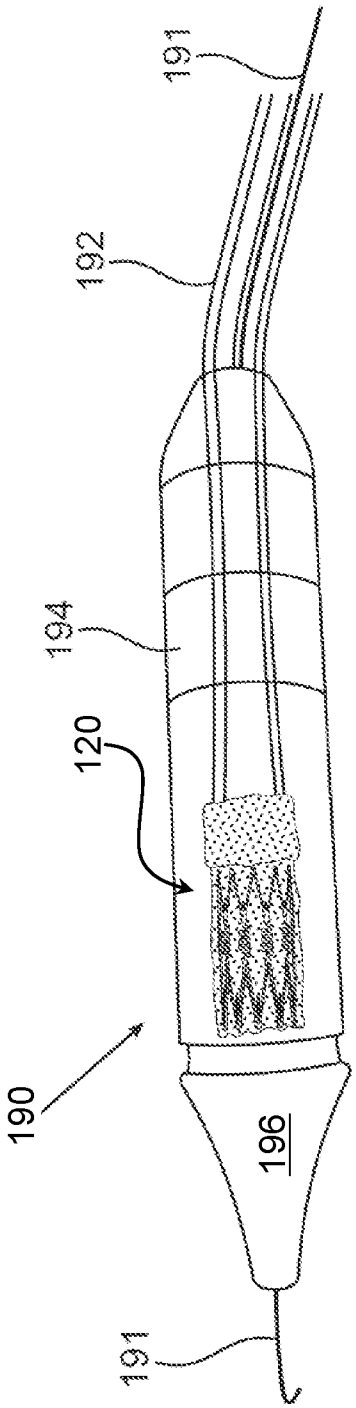

Fig. 10A

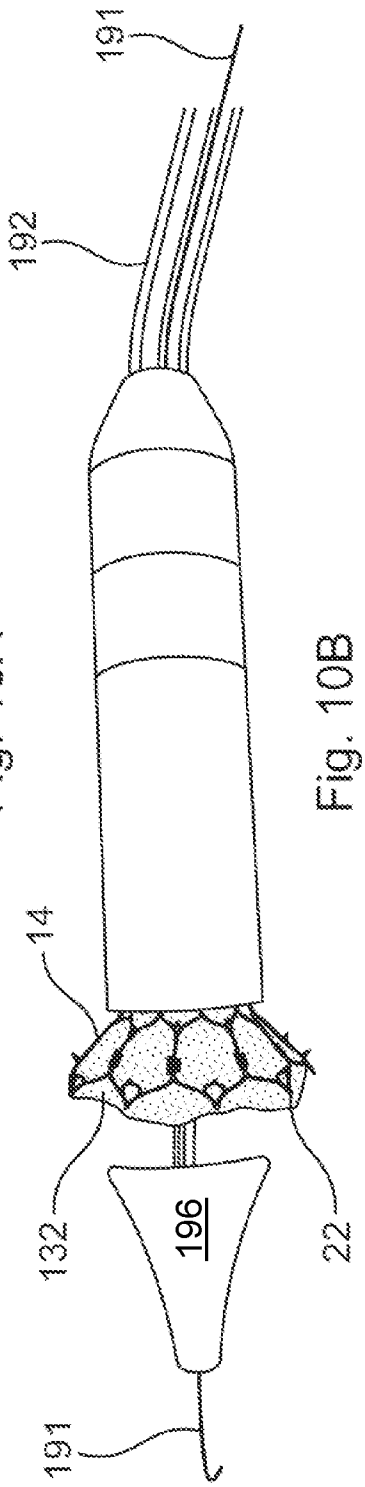

Fig. 10B

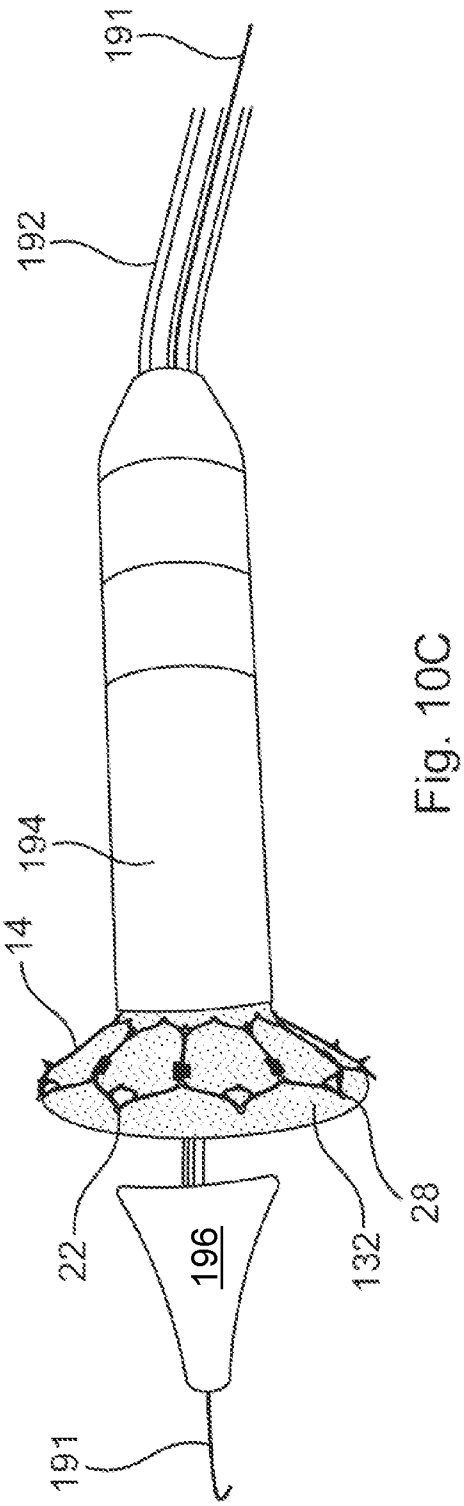

Fig. 10C

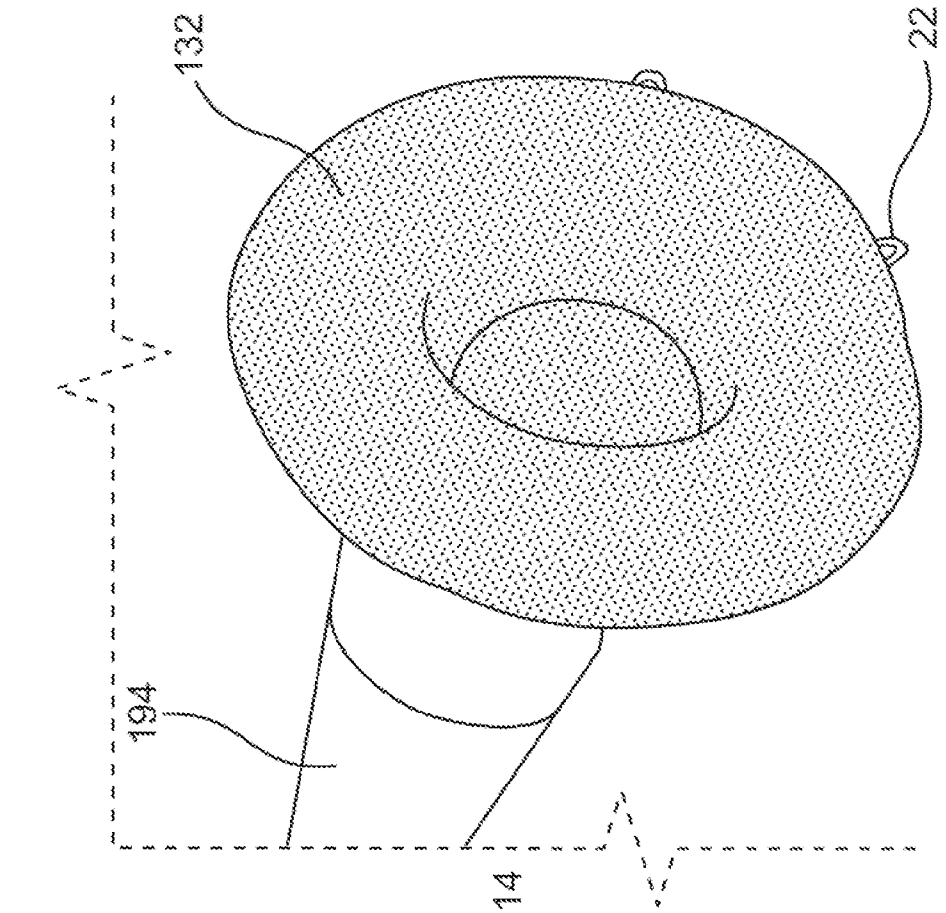

Fig. 10E

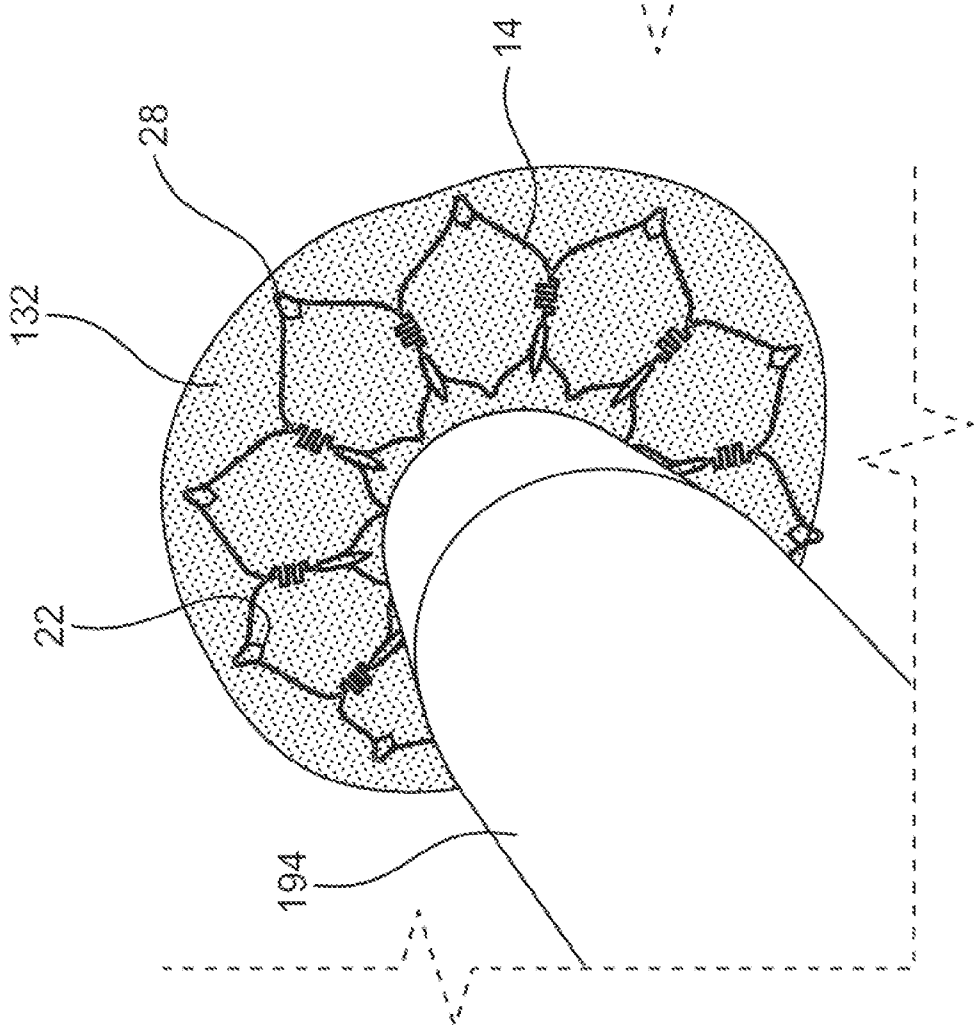

Fig. 10D

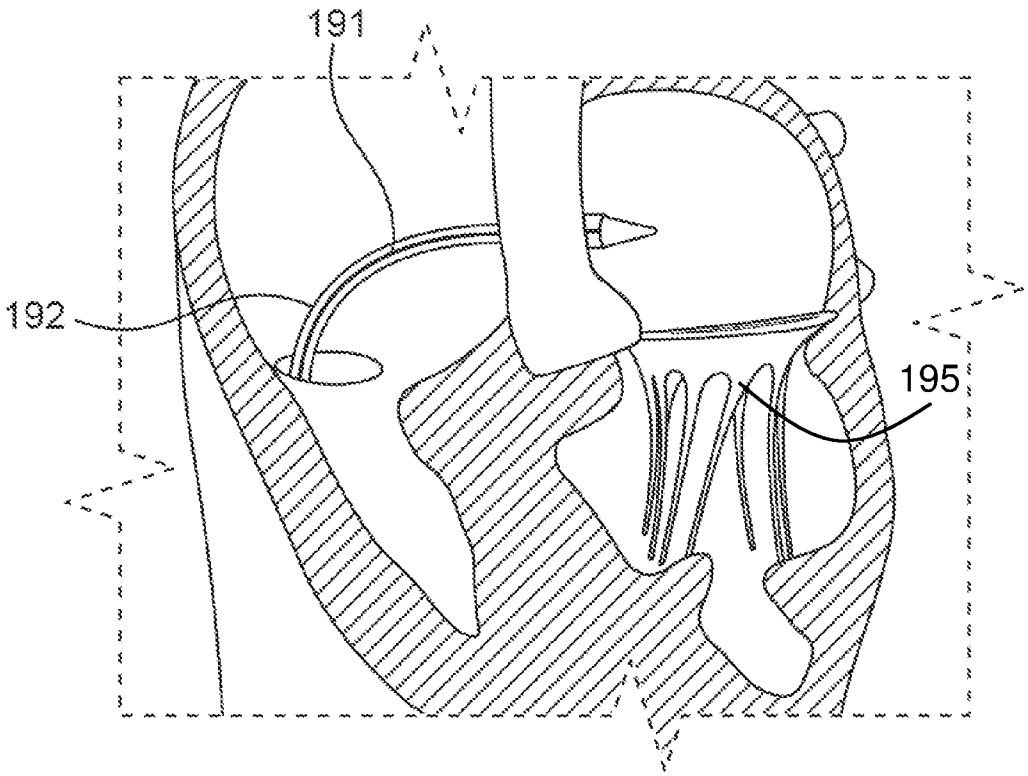

Fig. 11A

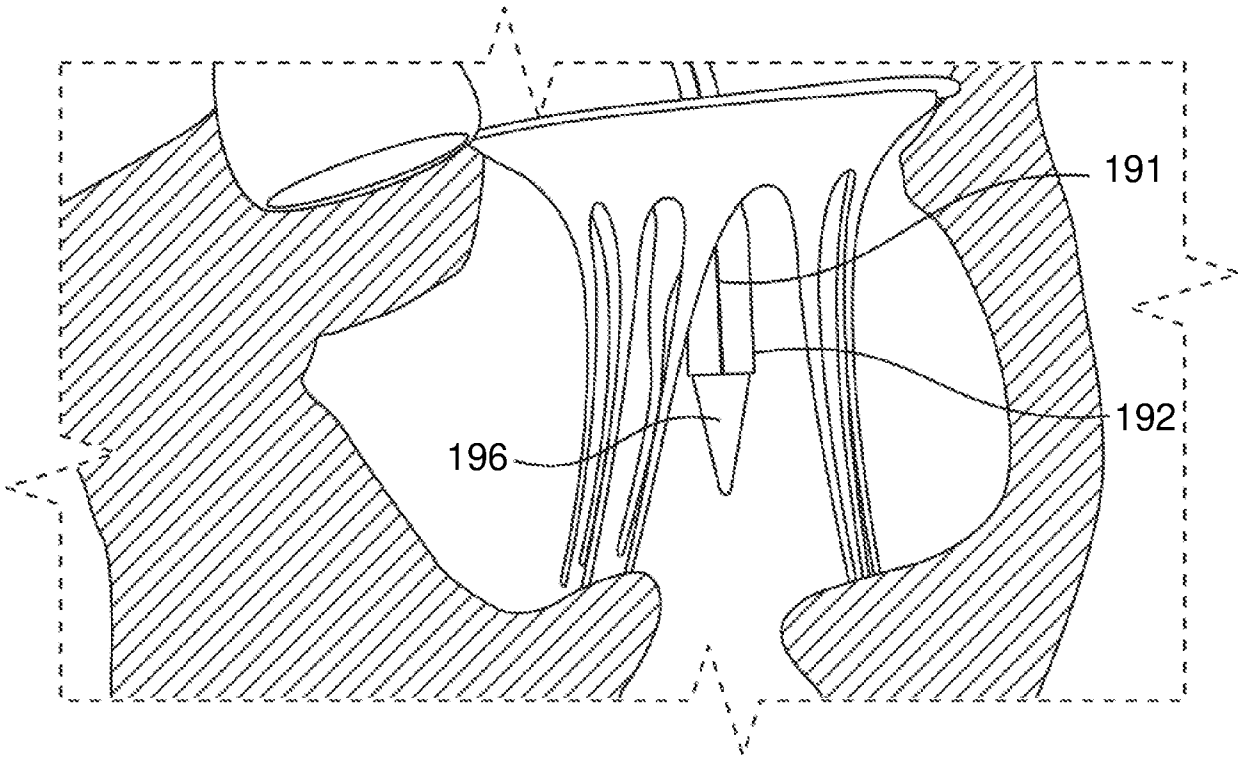

Fig. 11B

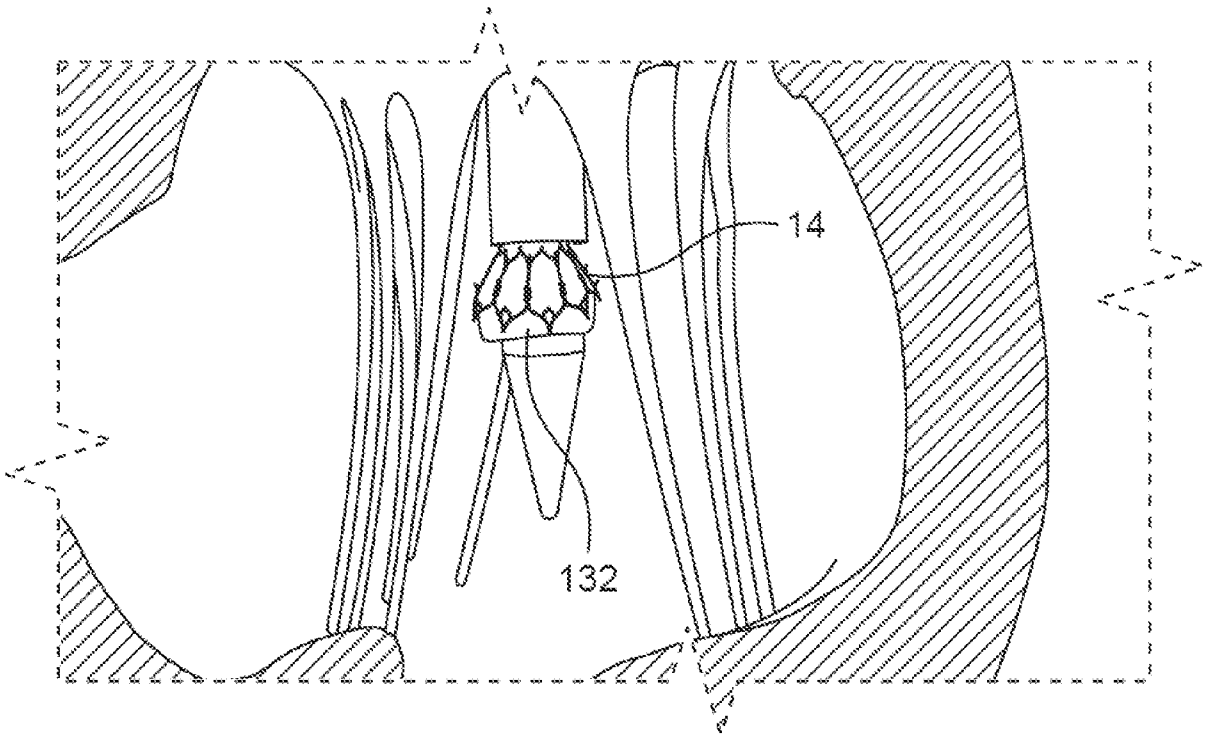

Fig. 11C

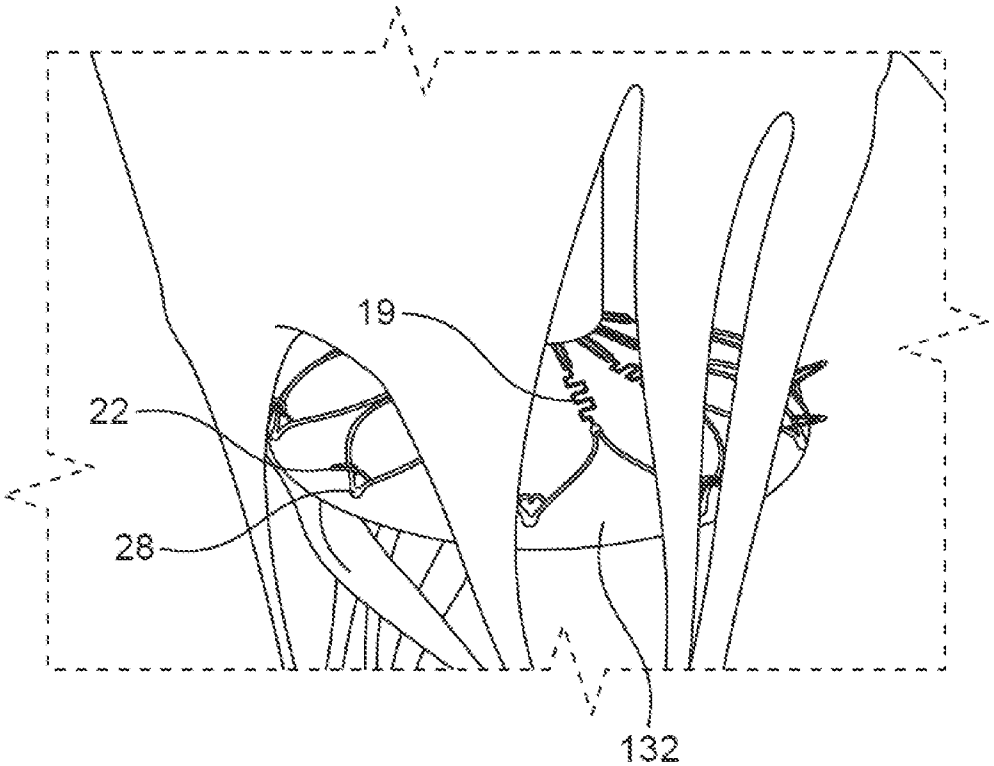

Fig. 11D

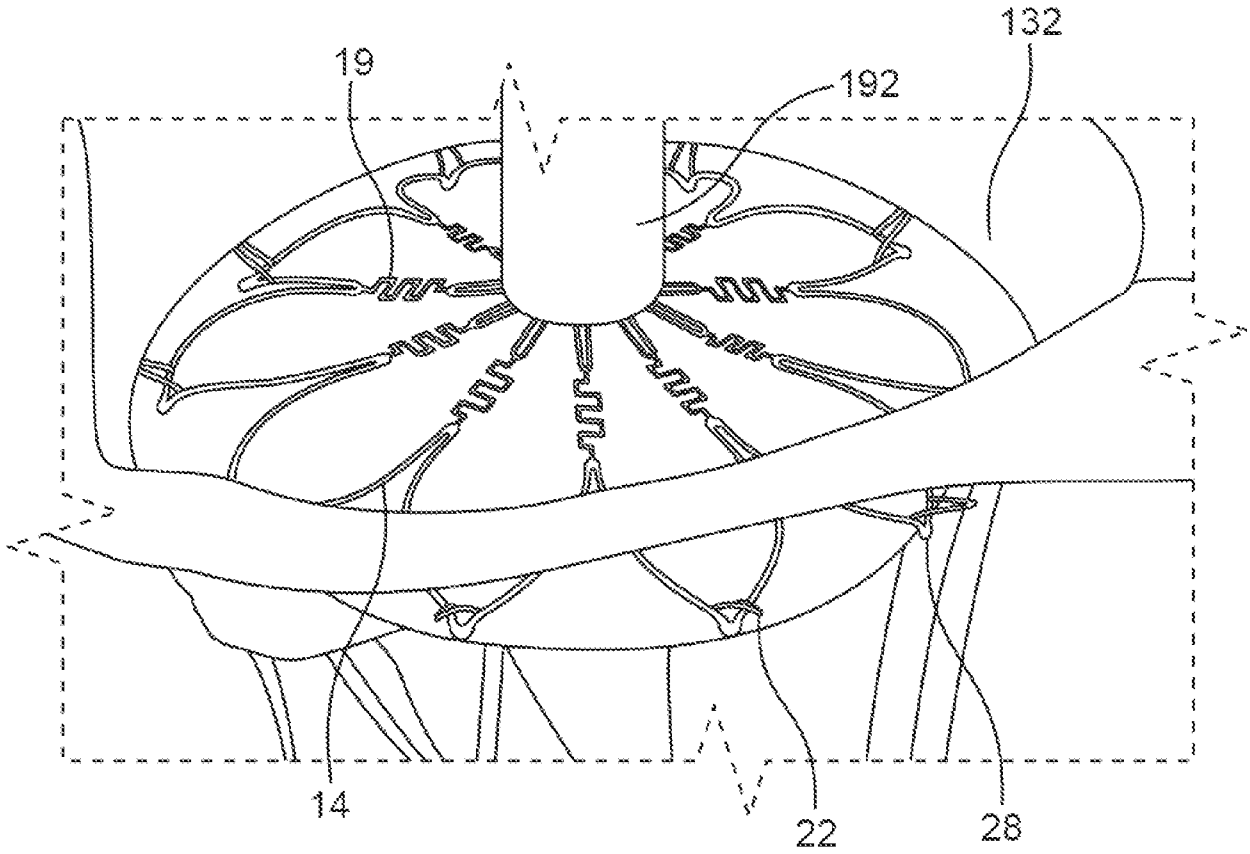

Fig. 11E

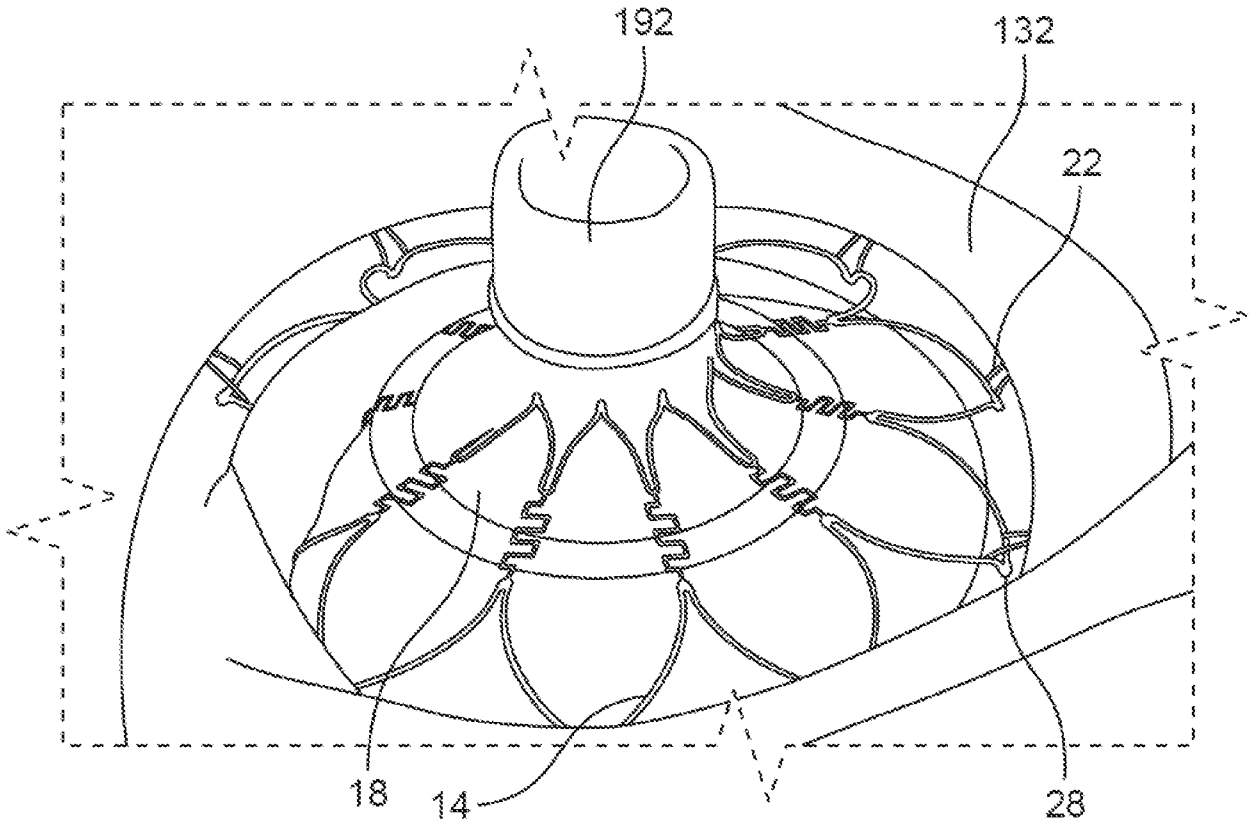

Fig. 11F

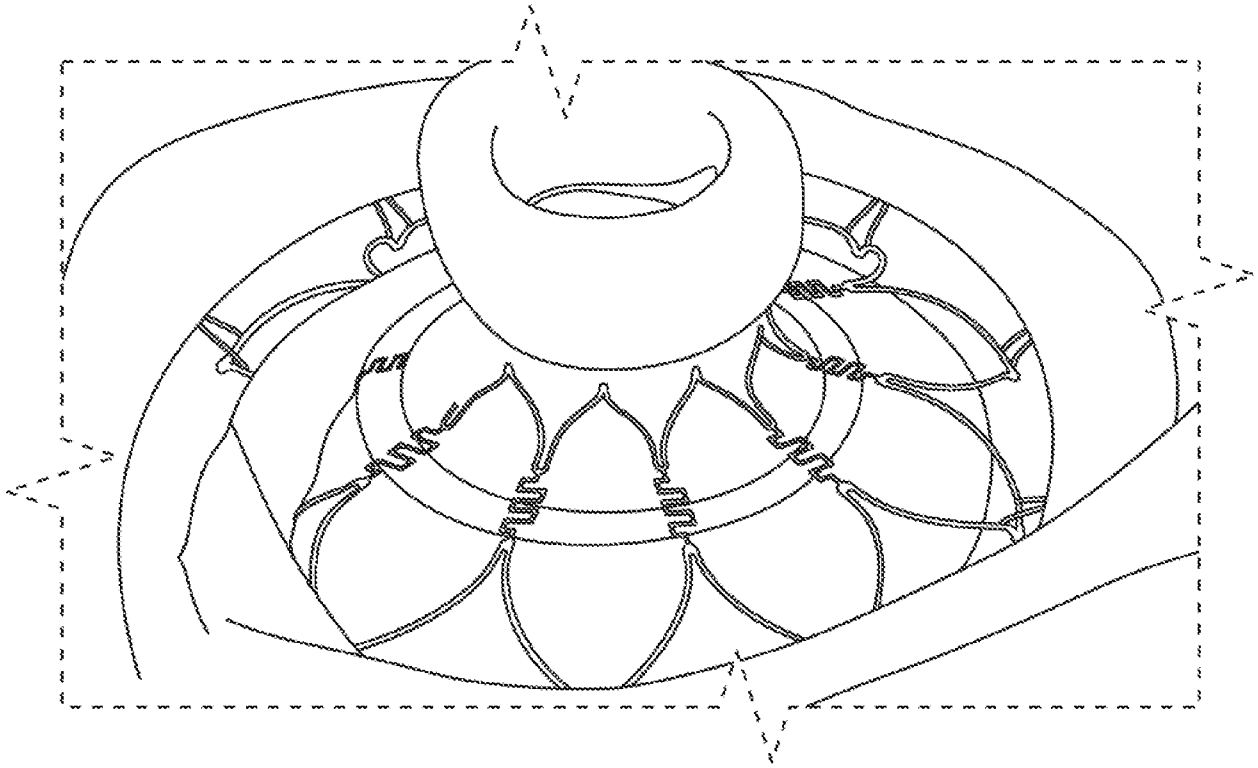

Fig. 11G

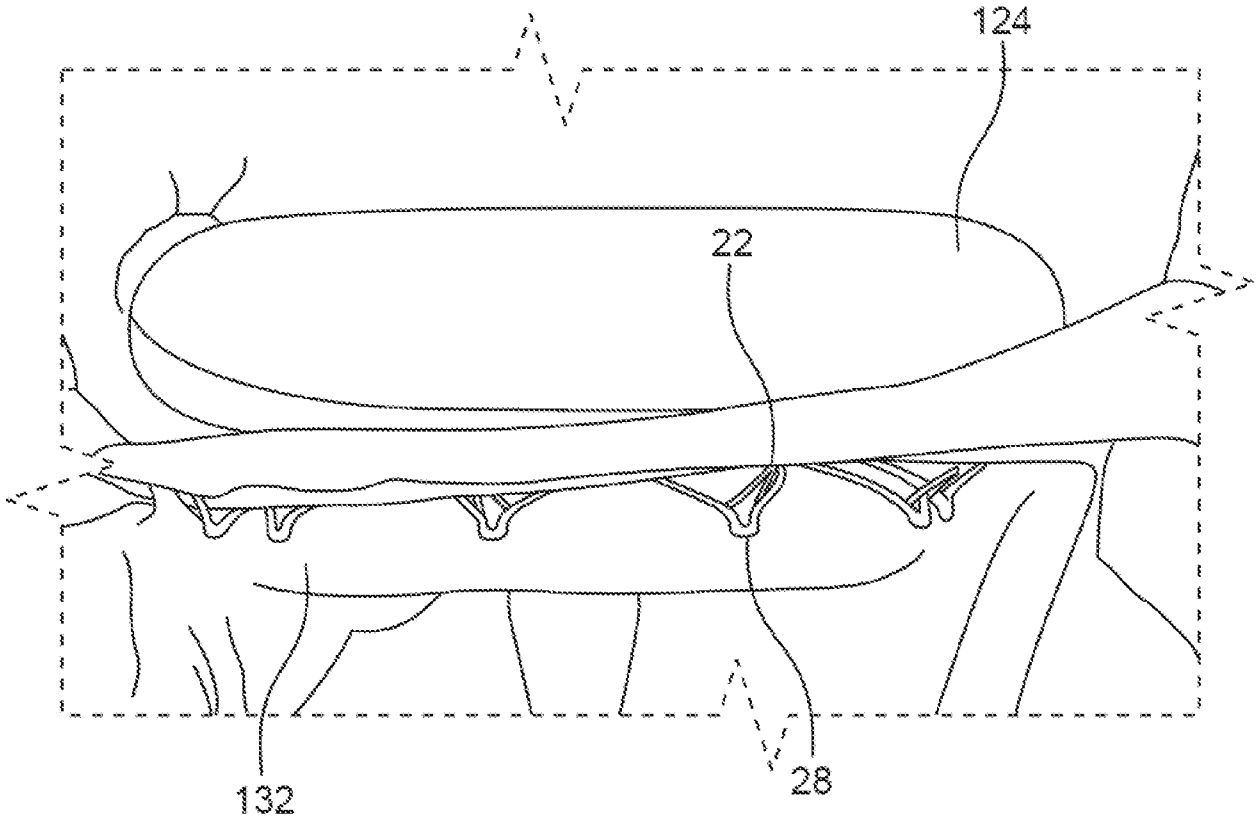

Fig. 11H

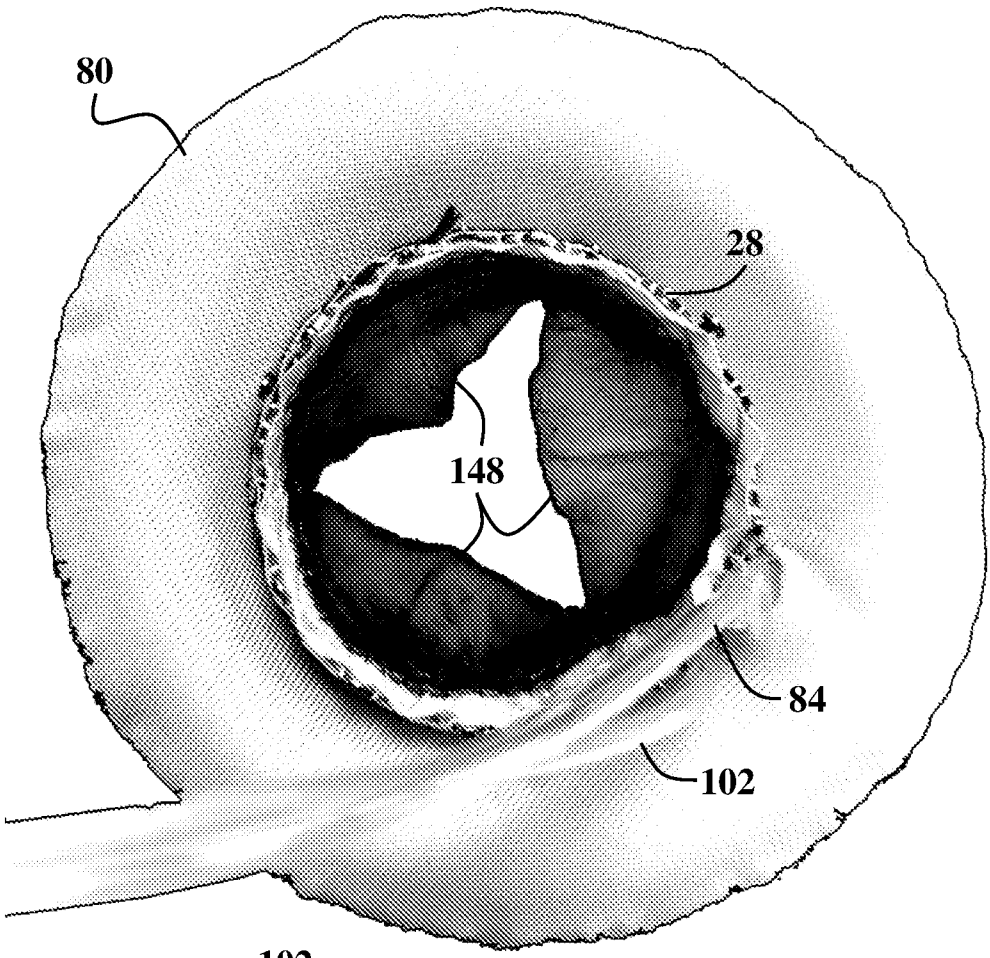

Fig.12A

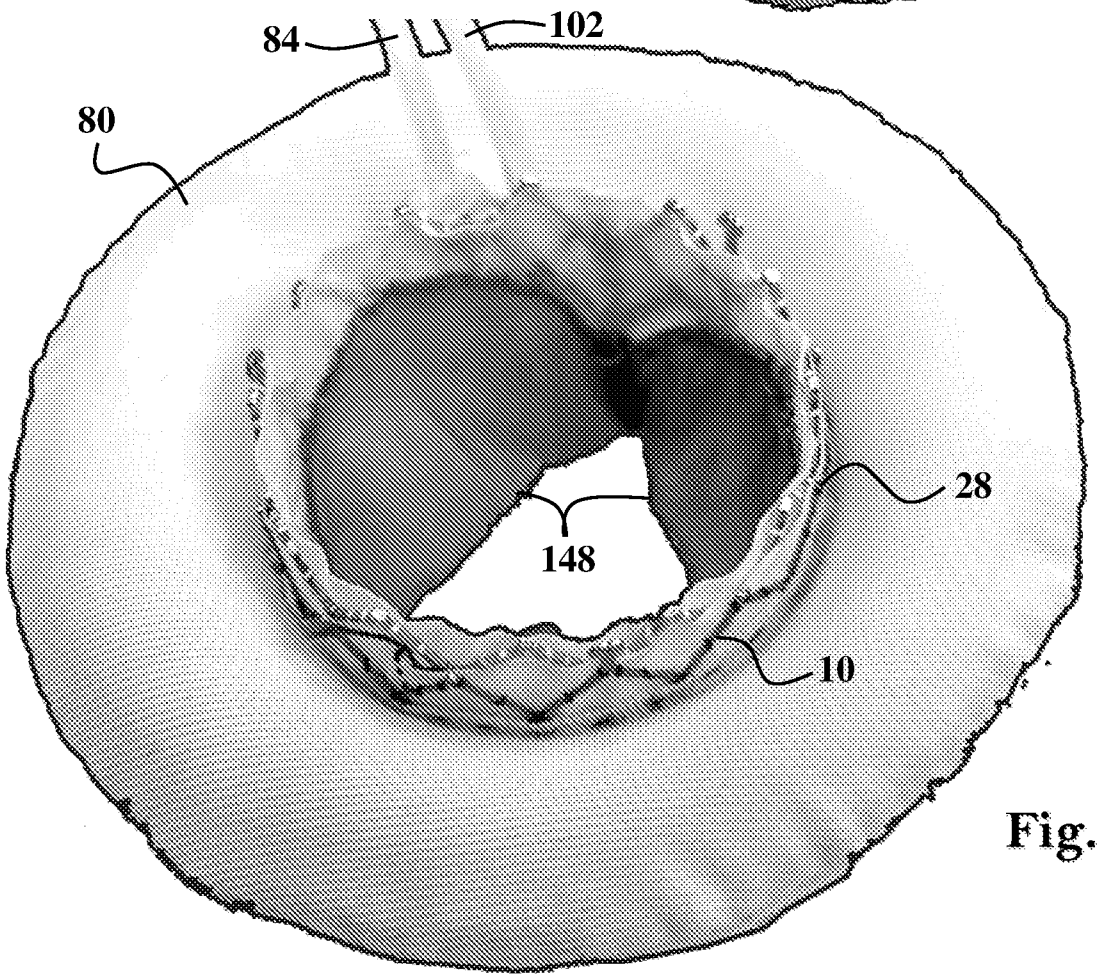

Fig.12B

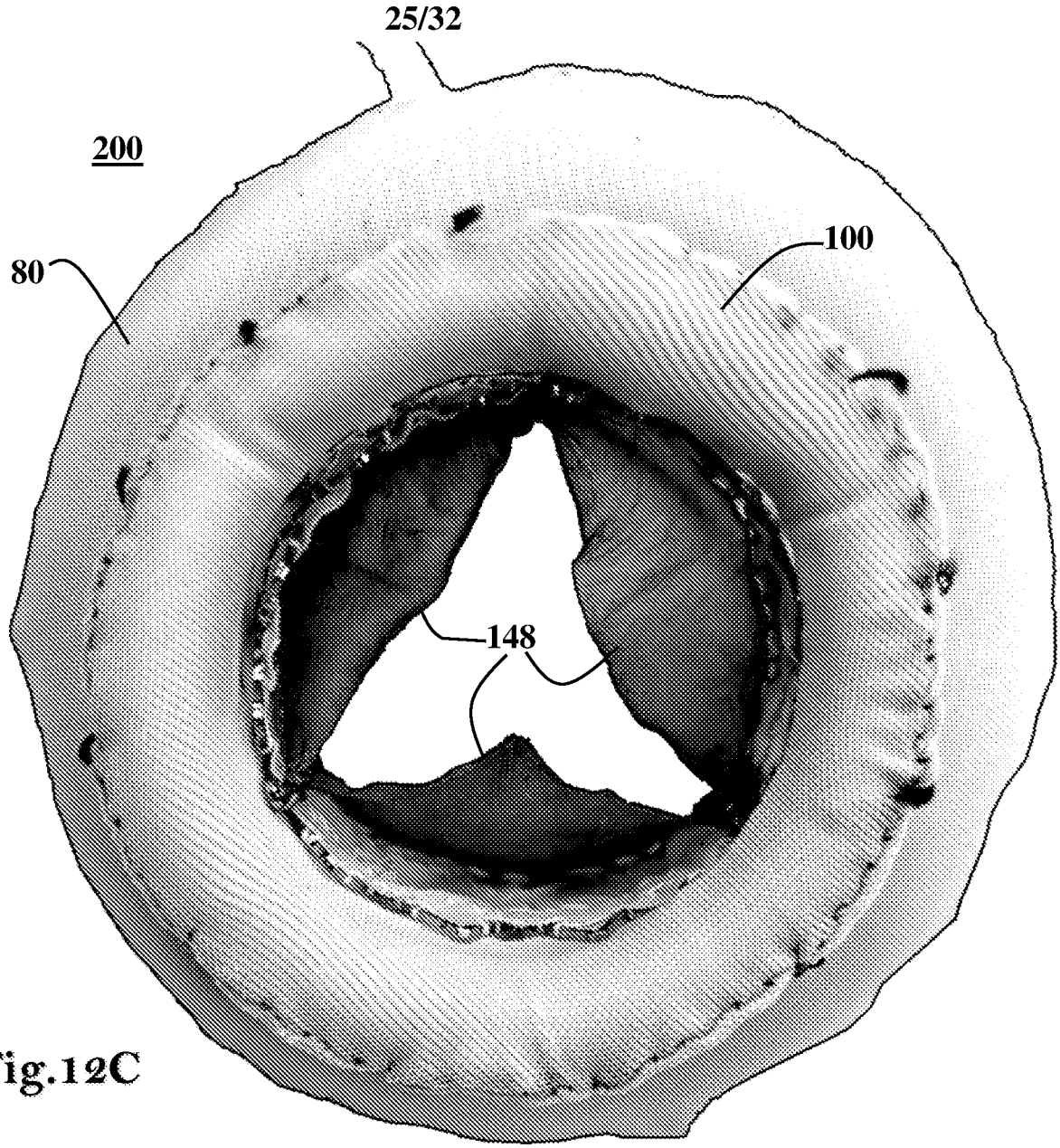

Fig.12C

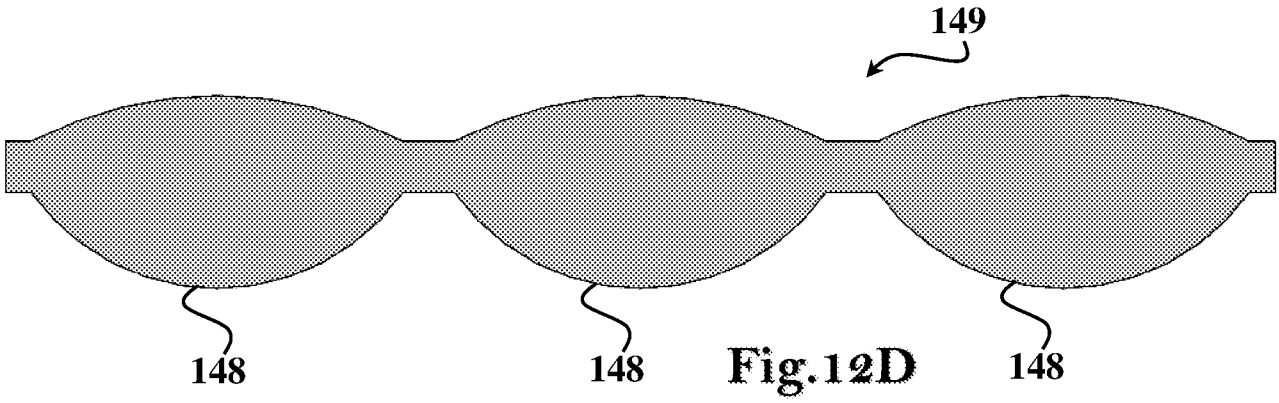

Fig.12D

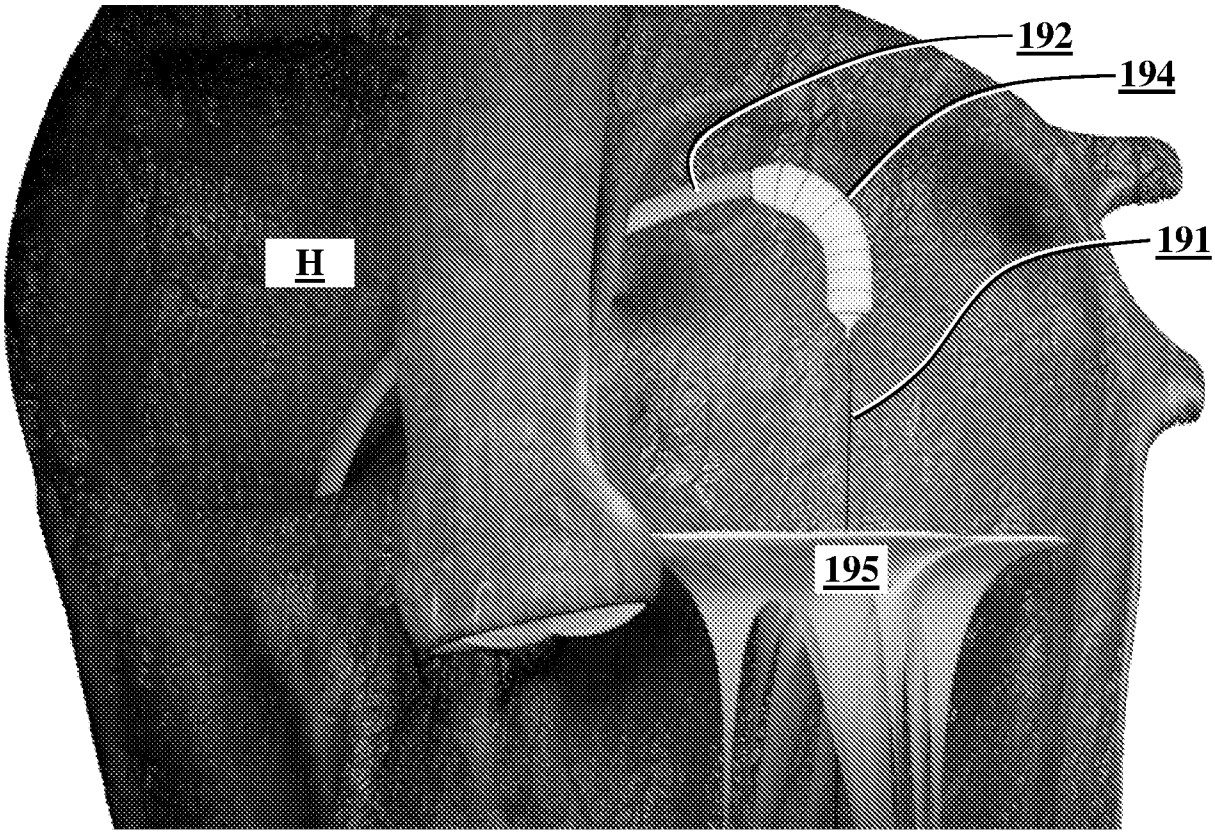

Fig.13A

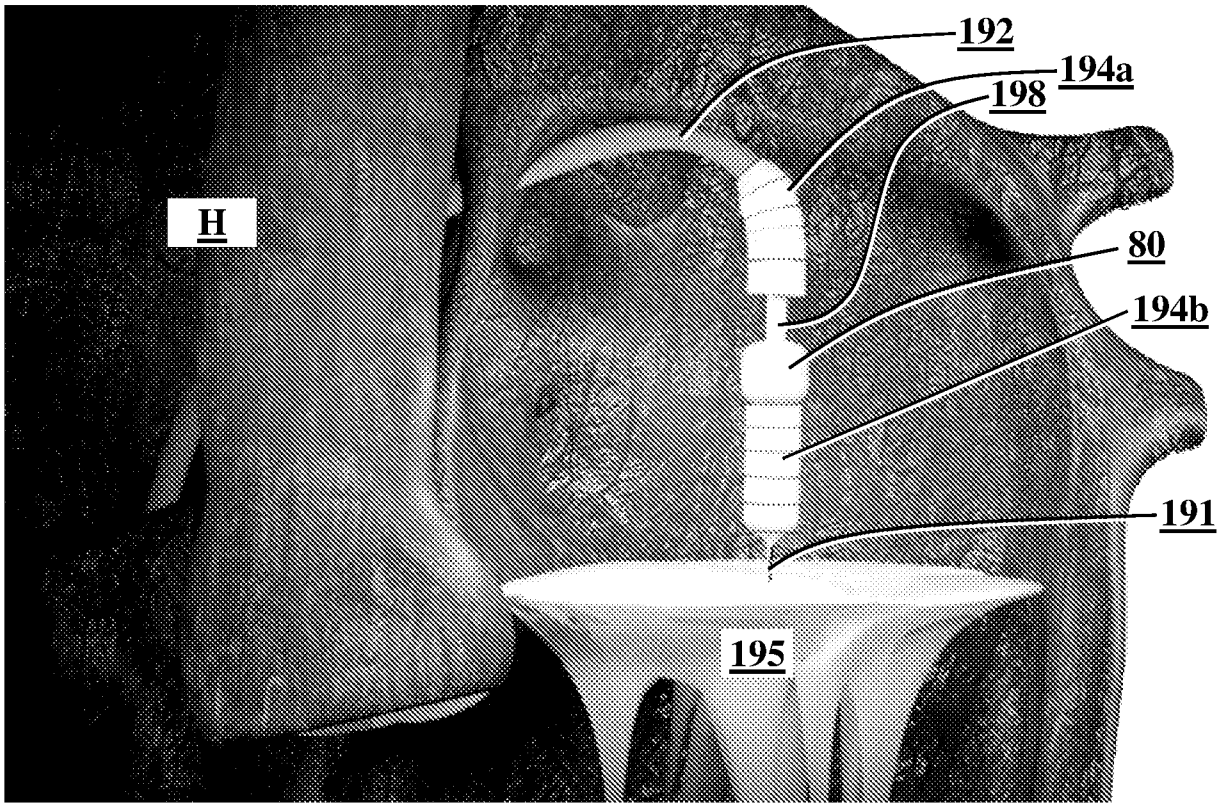

Fig.13B

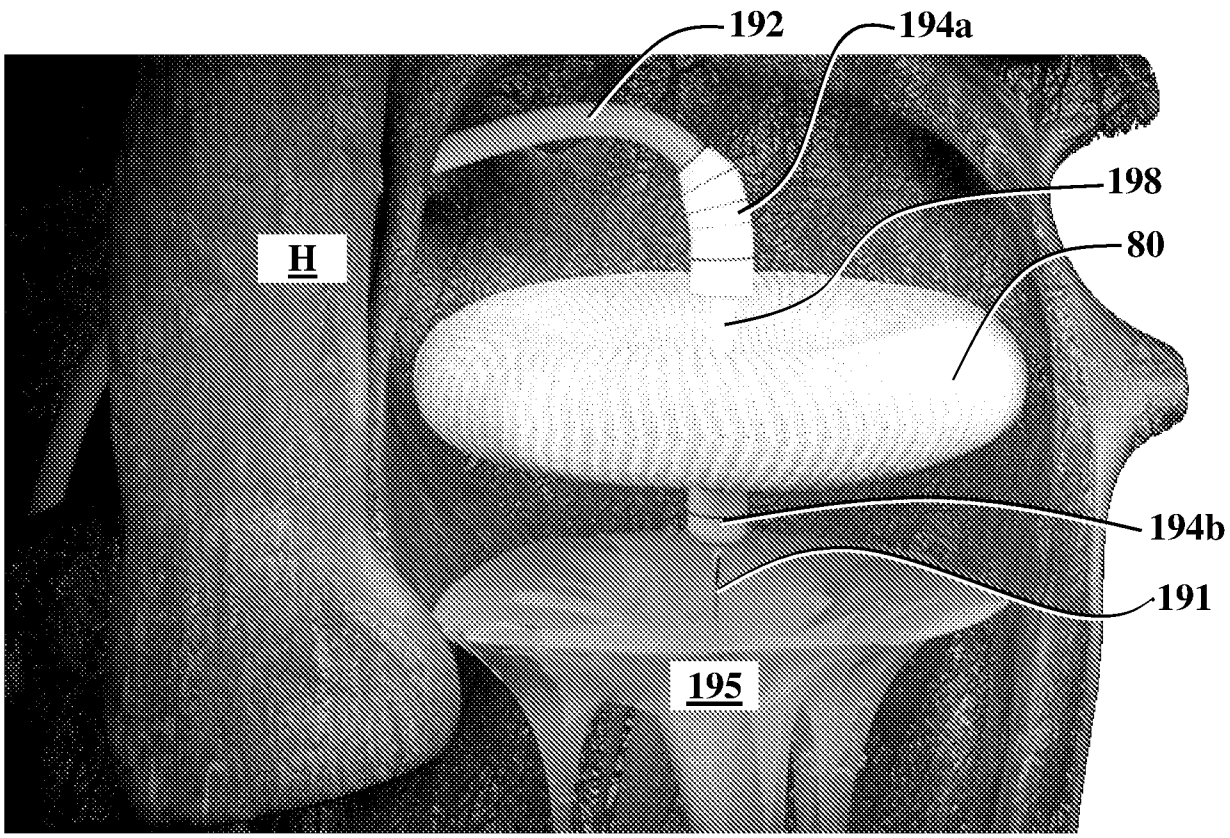

Fig.13C

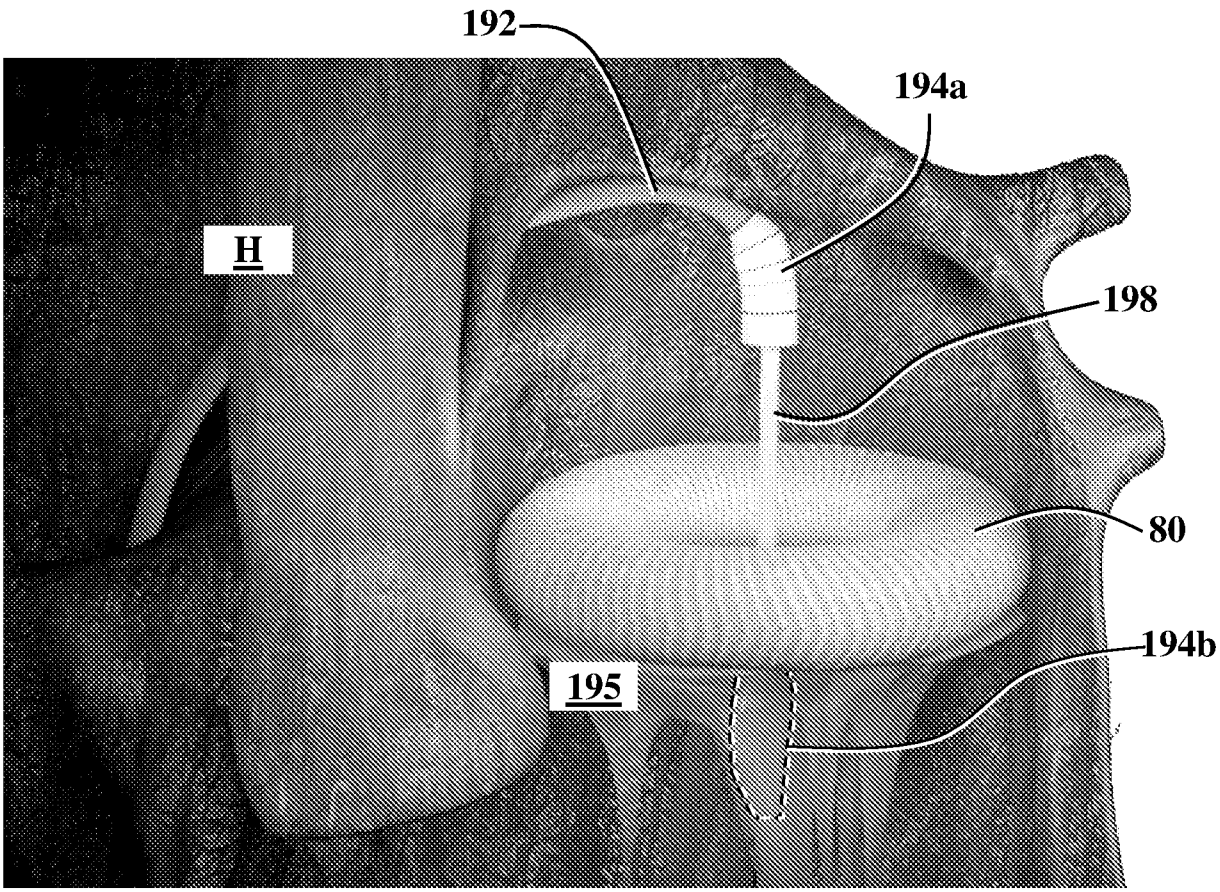

Fig.13D

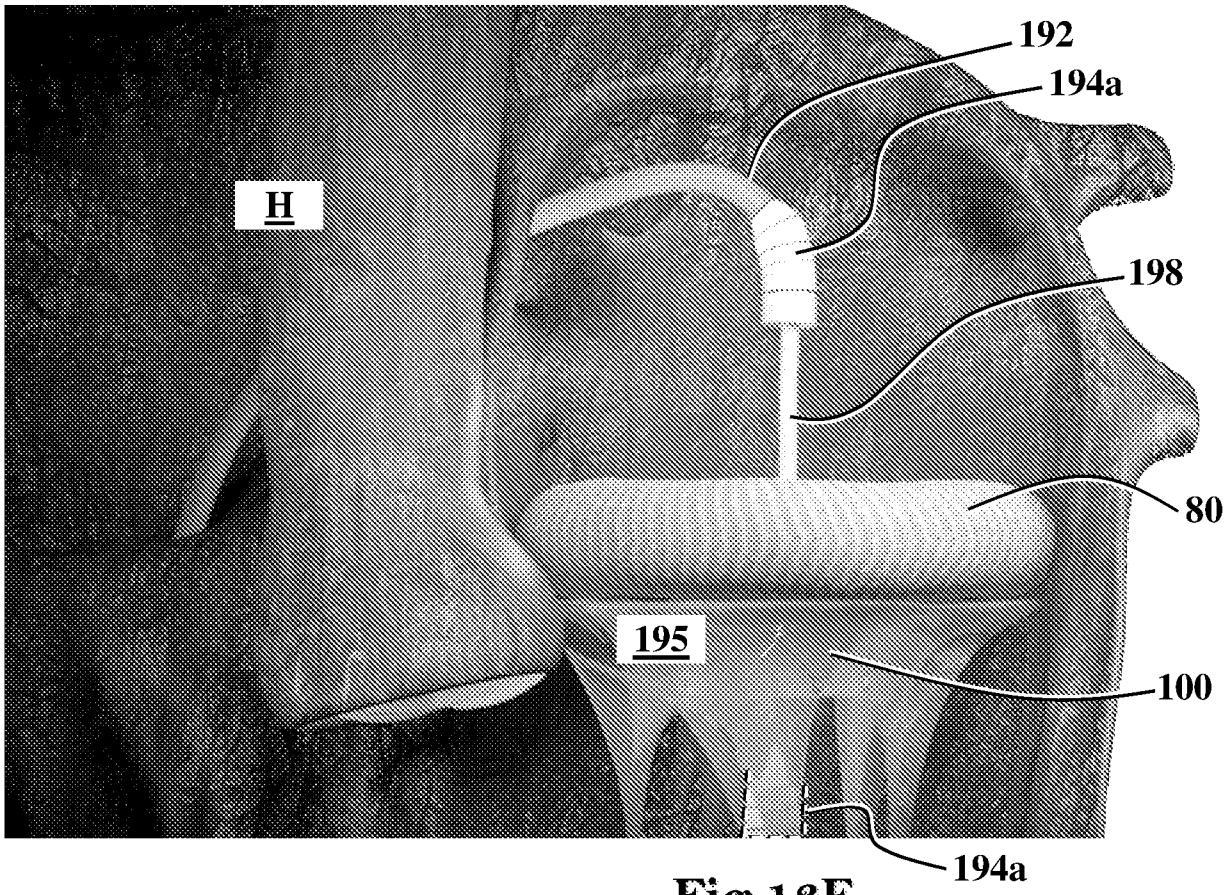

Fig.13E

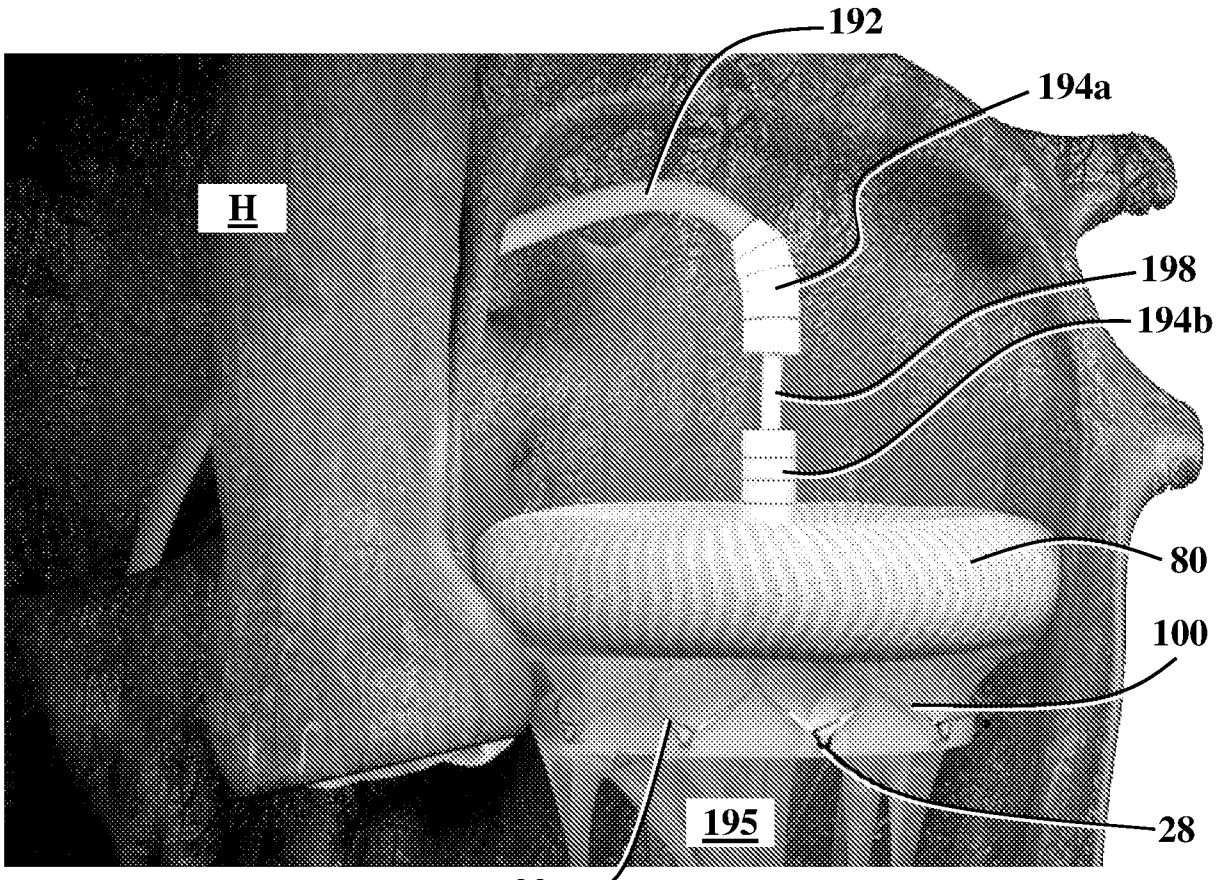

Fig.13F

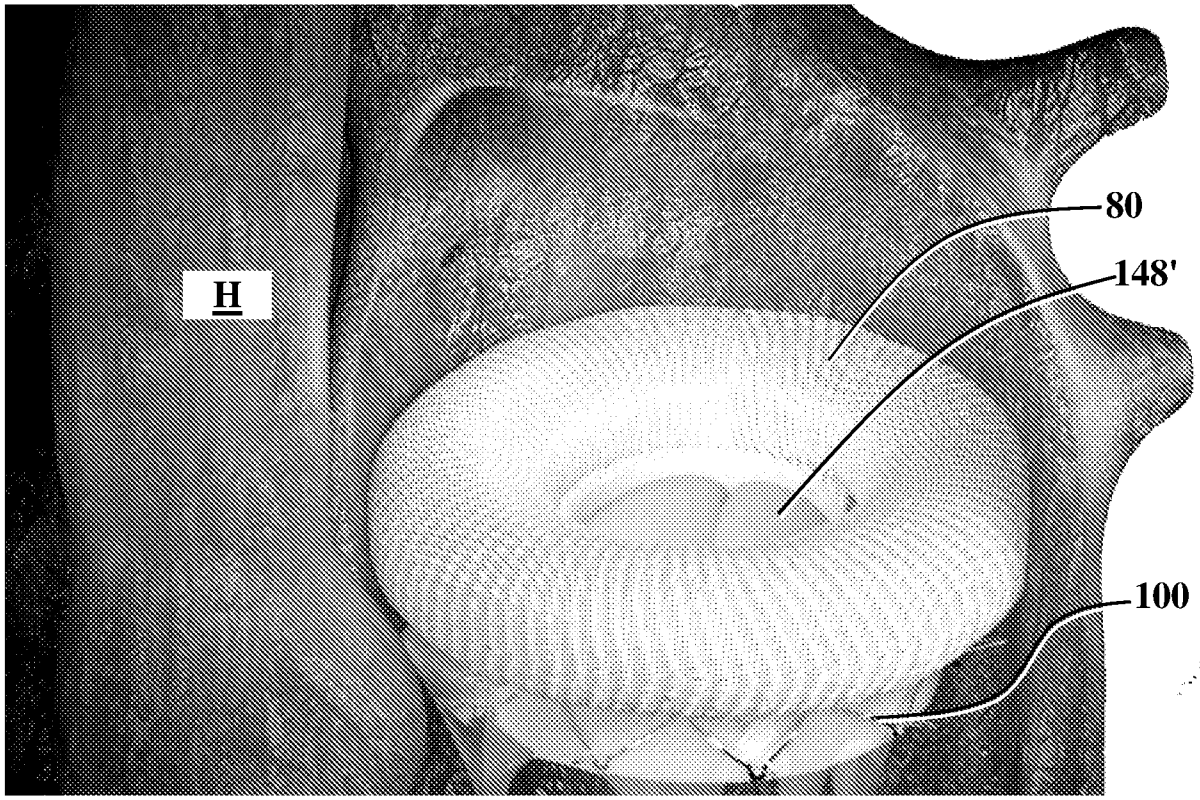

Fig.13G

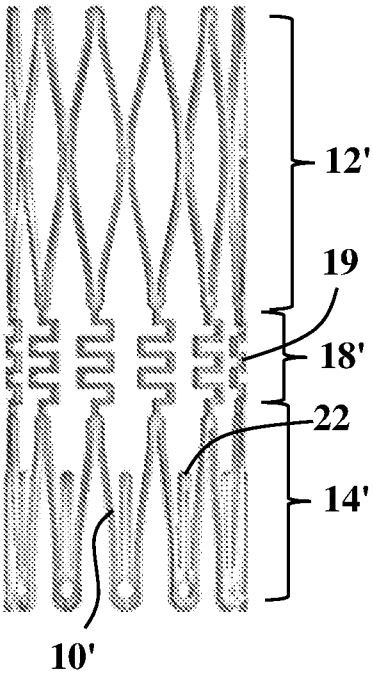

Fig.14A

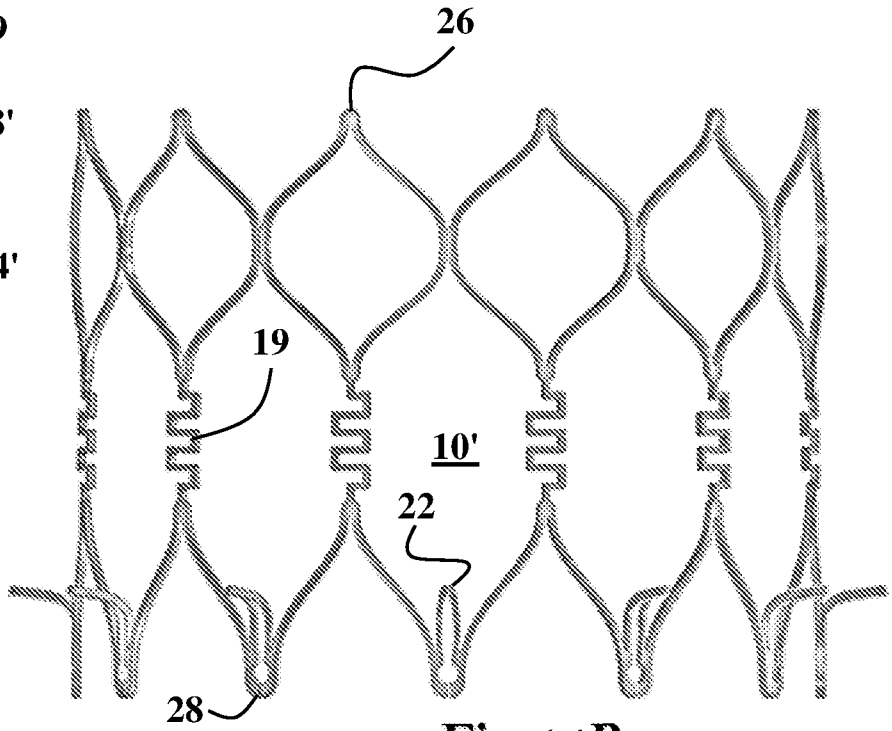

Fig.14B

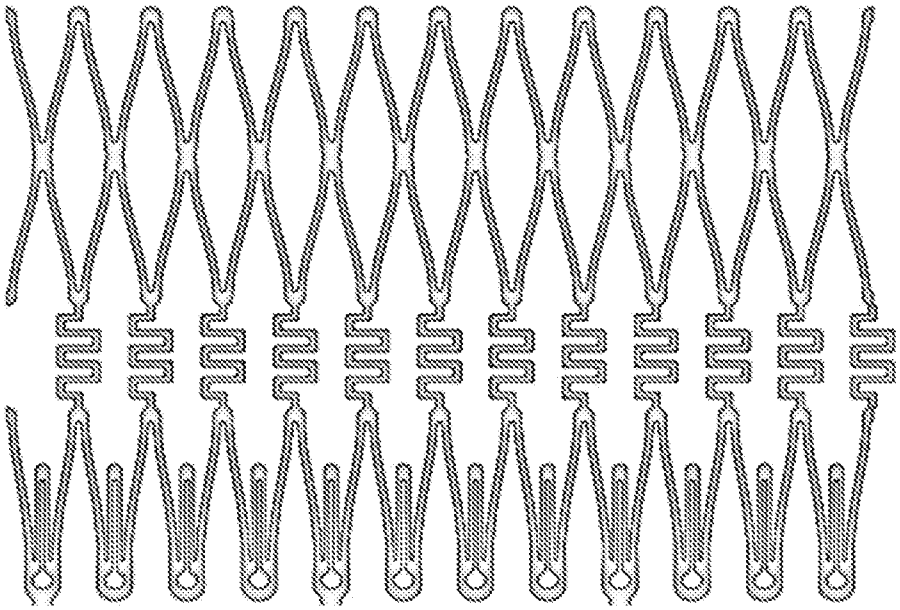

Fig.14C

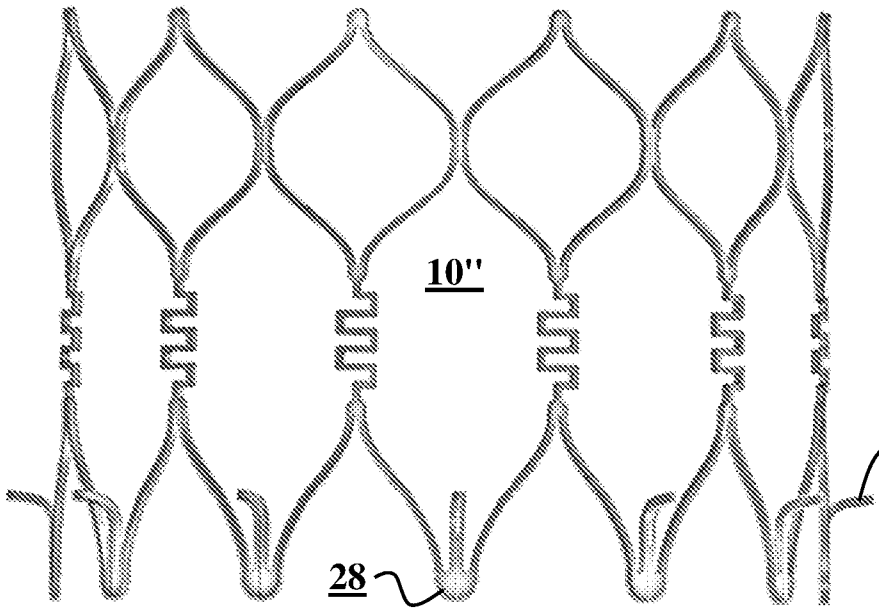

Fig.15

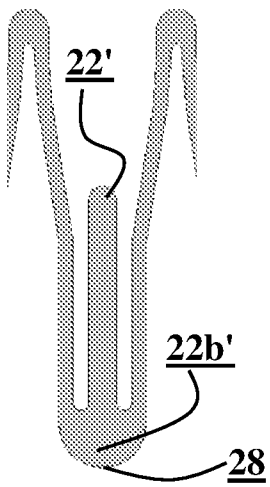

Fig.16A

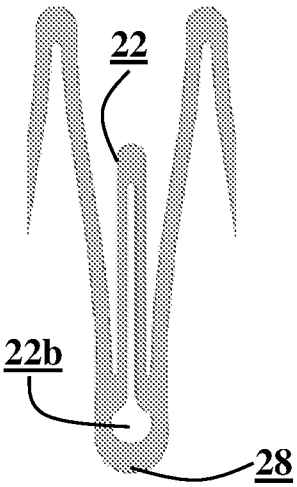

Fig.16B

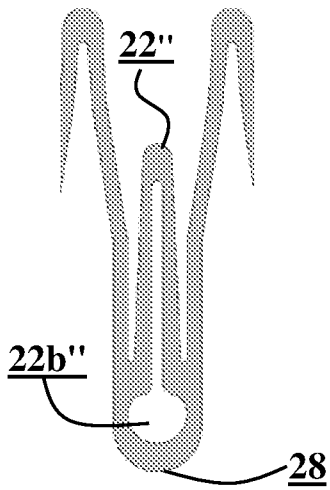

Fig.16C

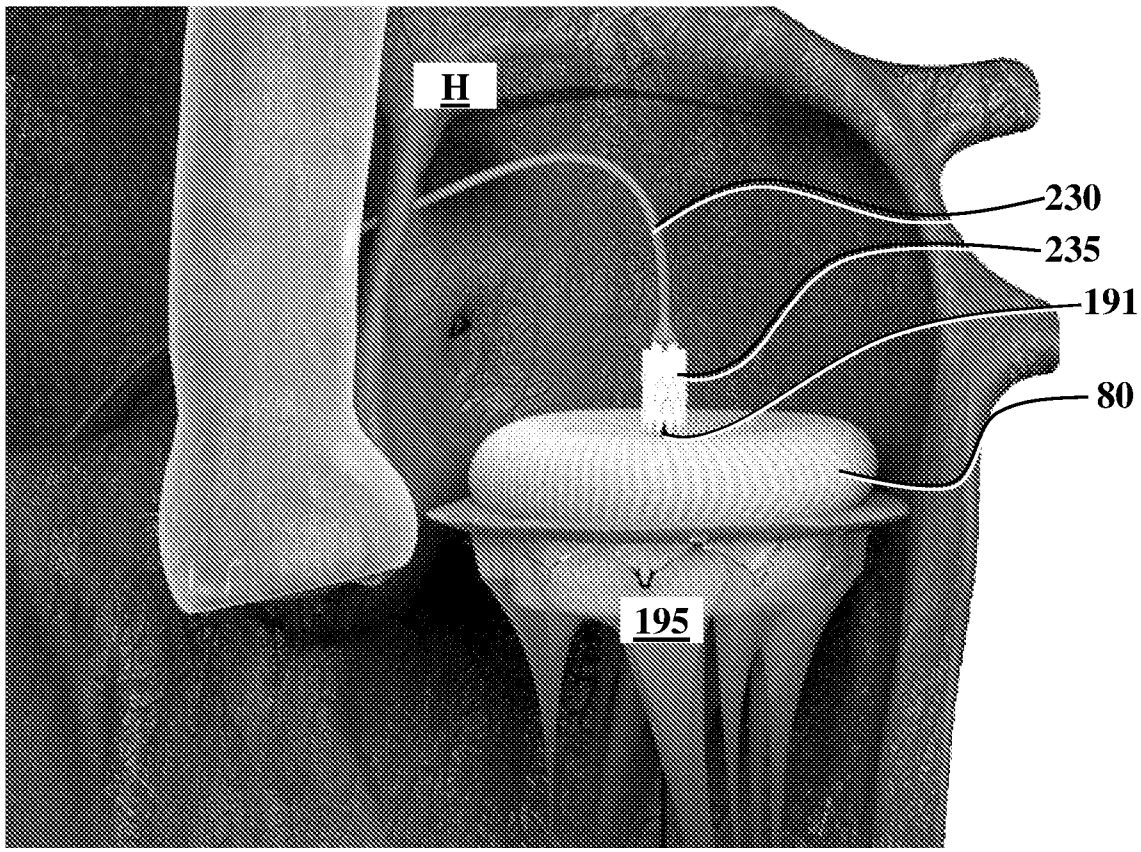

Fig.17A

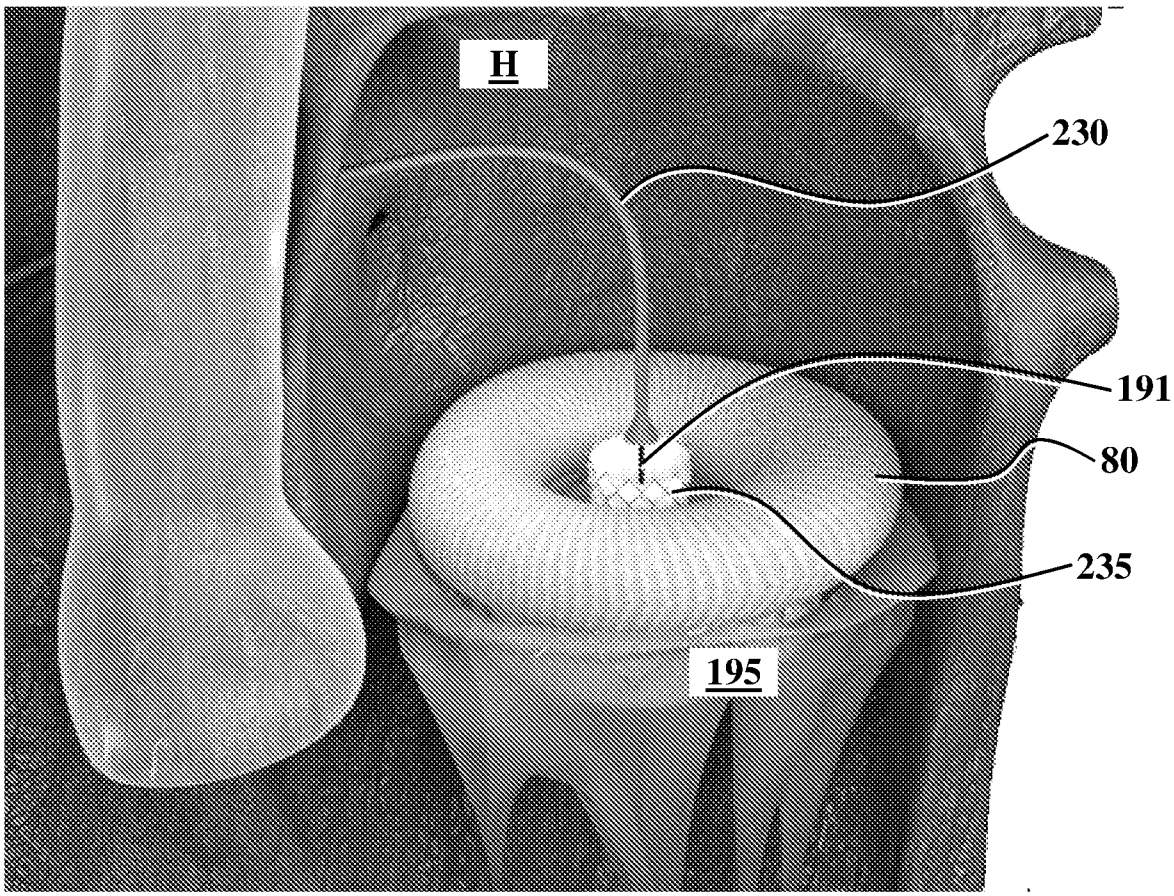

Fig.17B

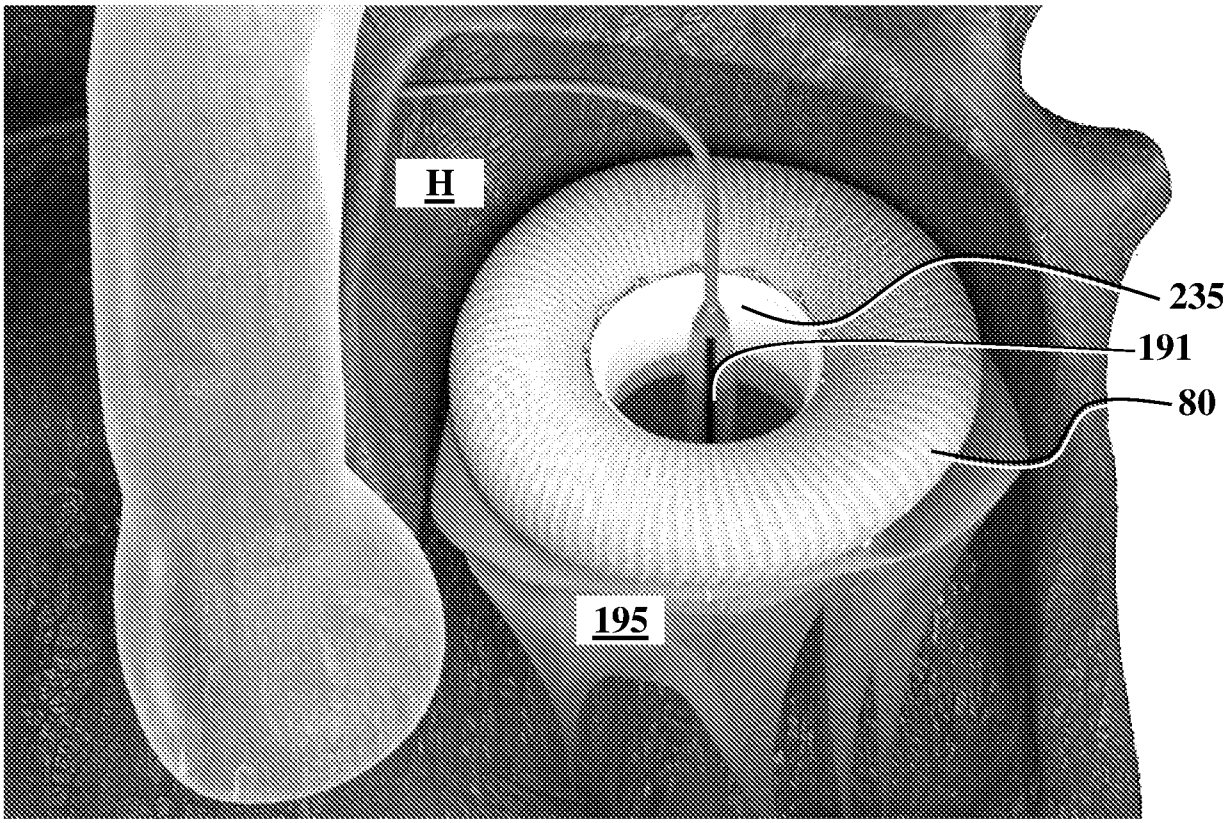

Fig.17C

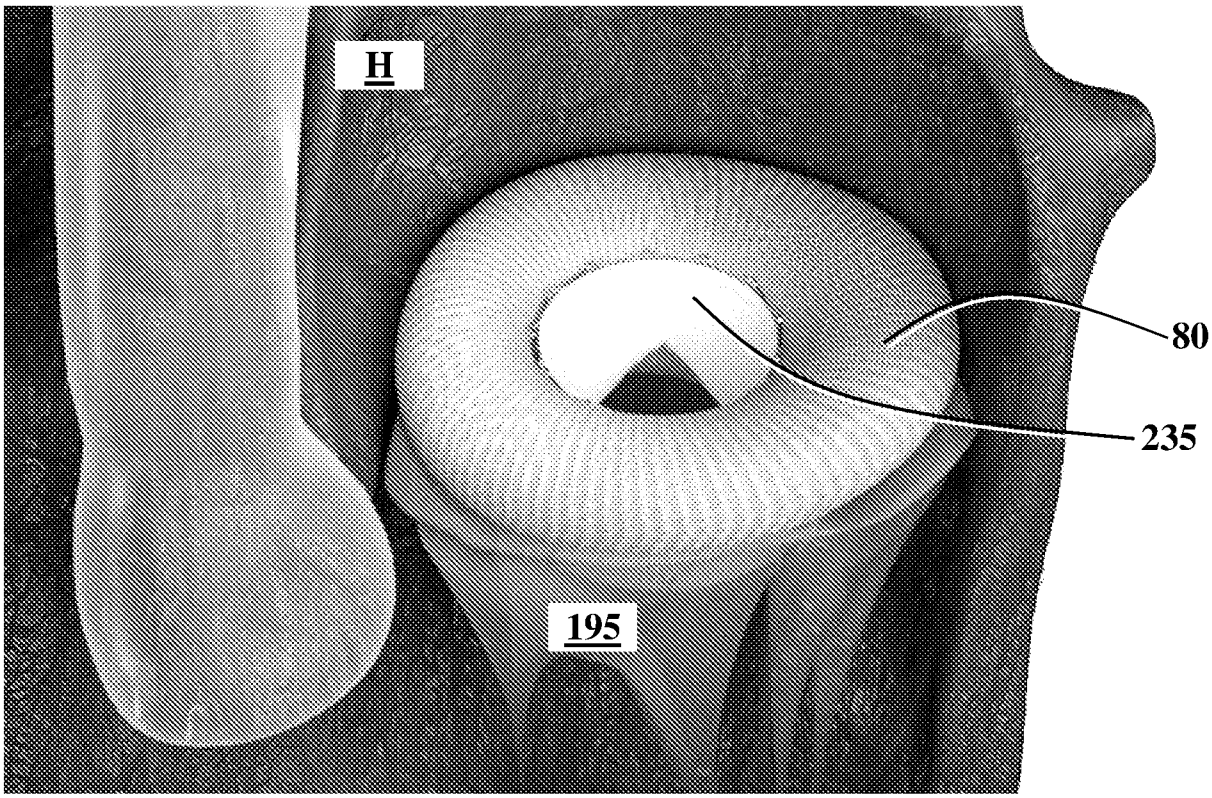

Fig.17D

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 600073-RY	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/IL2024/050637	International filing date *(day/month/year)* 28 June 2024 (28-06-2024)	(Earliest) Priority Date *(day/month/year)* 28 June 2023 (28-06-2023)
Applicant SYMBIOSIS C.M. LTD		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 3b
      [X] as suggested by the applicant
      [ ] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2024/050637

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 48-50
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 48-50 are considered a method for treatment of the human or animal body by surgery (Rule 39.1(iv) PCT) as they involve the insertion and implantation of an implant to an implantation site in the heart.

2. [X] Claims Nos.: 39-44
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2024/050637

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24 A61F2/848
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2022/331099 A1 (MORRISS JOHN [US] ET AL) 20 October 2022 (2022-10-20) fig. 65a, 79a-79b, 81, par. 235, 307-308, 360, 419-420	1-38, 45-47
A	EP 3 340 935 B1 (EDWARDS LIFESCIENCES CARDIAQ LLC [US]) 29 January 2020 (2020-01-29) fig. 21 and par. 116-117	1,31,45

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 November 2024	14/11/2024

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Porta, Marcello

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IL2024/050637

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2022331099 A1	20-10-2022	US 2019321171 A1	24-10-2019
		US 2022110747 A1	14-04-2022
		US 2022218472 A1	14-07-2022
		US 2022218473 A1	14-07-2022
		US 2022218474 A1	14-07-2022
		US 2022331099 A1	20-10-2022
		US 2022346948 A1	03-11-2022
EP 3340935 B1	29-01-2020	EP 3340935 A1	04-07-2018
		EP 3692950 A1	12-08-2020
		EP 4032504 A1	27-07-2022
		EP 4074286 A1	19-10-2022
		ES 2977863 T3	02-09-2024
		ES 2984191 T3	29-10-2024
		US 2017056166 A1	02-03-2017
		US 2019069997 A1	07-03-2019
		US 2020375731 A1	03-12-2020
		US 2024277471 A1	22-08-2024
		WO 2017035487 A1	02-03-2017

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 48-50

Claims 48-50 are considered a method for treatment of the human or animal body by surgery (Rule 39.1(iv) PCT) as they involve the insertion and implantation of an implant to an implantation site in the heart.

Continuation of Box II.2

Claims Nos.: 39-44

In reply to a clarification request about which claims had to be search, the applicant did not provide any feedback. Therefore only claims 1-38 and 45-47 were searched.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.3), should the problems which led to the Article 17(2) PCT declaration be overcome.