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(71) Applicant: **TRICARES SAS** [FR/FR]; 27, avenue de l'Opéra, 75001 Paris (FR).

(72) Inventors: **RAHMIG, Georg**; Kopernikusallee 64, 75175 Pforzheim (DE). **STRAUBINGER, Helmut**; Am Vogelacker 10A, 85609 Aschheim (DE).

(74) Agent: **HELBIG, Christian**; WAGNER + HELBIG Patentanwälte, Pfarrstr. 14, 80538 München (DE).

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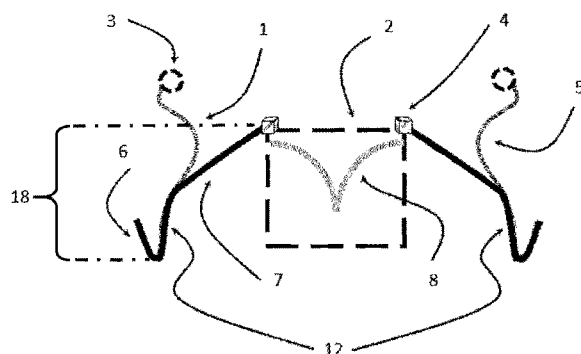


Fig. 1a

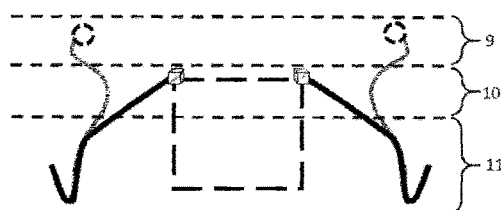


Fig. 1b

(57) Abstract: The present invention relates to a novel stent and a replacement heart valve prosthesis as well as a method for implanting same.



Three Part Stent Second Generation

The present invention relates to a novel stent and a replacement heart valve prosthesis as well as a method for implanting said prosthesis.

In the last decades minimally invasive techniques and catheter-based implantation techniques have advanced and are now feasible in many medical fields.

In a number of medical fields it is now possible to treat patients by catheter-based techniques allowing for the treatment of such patients who could otherwise not be adequately taken care of due to their physical condition and the risks connected with surgery. Such catheter-based techniques apply to delivery systems, e.g. a catheter and/or introducer sheath, for implanting the medical device to a desired target site via different access routes into a patient's body.

In particular, in recent years the treatment of heart valve diseases and deficiencies has become more and more successful. Examples are trans-apical, trans-jugular and trans-femoral procedures for heart valve replacement therapies, e.g. aortic or mitral heart valve treatments.

In many cases a stent-based prosthesis with a tissue based replacement valve is used and implanted to replace the native heart valve using a catheter delivery system.

The replacement heart valve prosthesis has to be crimped and loaded onto the catheter. The correct positioning of a replacement heart valve prosthesis, durability and good compliance with the target site and the biology of the target site are important aspects of such a prosthesis.

Hence there exists a need for a replacement heart valve prosthesis which can be correctly positioned, exhibits good durability features and has as little impact on or interference with the target site as possible and which remains long term correctly positioned. In addition, a replacement heart valve prosthesis should exhibit good sealing characteristics to avoid e.g. paravalvular leakage.

In particular in soft endogenous tissue like the mitral or tricuspid heart valve, it is difficult to properly position a replacement heart valve prosthesis and provide sufficient fixation properties as well as to avoid unnecessary interference with the endogenous valve environment.

More particularly, it is a problem to durably position the replacement heart valve, e.g. in tricuspid or mitral replacement heart valve technology wherein the diameter of the valve is large and the annulus and atrial and ventricular tissue surrounding the heart valve is either sensitive or anatomically challenging for precise positioning and fixation.

Accordingly, it is one object of the current disclosure to provide a replacement heart valve prosthesis with sufficient positioning and fixation features or/and exhibiting reduced interference characteristics at the target site, or at least to provide a prosthesis wherein the disadvantages of the prior art are essentially avoided or which show reduced disadvantages vis-à-vis the prior art.

Brief Summary of the Disclosure

In one aspect the disclosure relates to a stent or replacement heart valve prosthesis exhibiting advantageous positioning characteristics, or/and good durability characteristics or/and reduced interference characteristics.

In another aspect the disclosure relates to a stent or replacement heart valve prosthesis characterized by an inner stent combined with an outer stent wherein fixation means are connected to or form part of the inner stent.

In another aspect the disclosure relates to a replacement heart valve prosthesis comprising an inner stent and an outer stent wherein fixation means are connected to or form part of the inner stent, and at least one sealing means connected to the inner and/or outer stent and a valve connected to the inner stent.

In another aspect the disclosure relates to method for implantation or positioning a replacement heart valve prosthesis in a native tricuspid or mitral heart valve wherein the prosthesis is delivered by a catheter-based delivery system to the target site.

In another aspect the disclosure relates to a method of replacement of a malfunctioning endogenous heart valve or the implantation of a replacement heart valve prosthesis in a person experiencing impaired heart valve function.

Brief Description of the Drawings

Various embodiments of the disclosure are exemplified by the Figures wherein:

Fig. 1a illustrates a two-part stent comprising inner and outer stent (2, 1) wherein the inner stent (2) is connected by connecting means (4) with fixation means comprising connecting arms (7), connecting arches (12) and anchoring loops (6).

Fig. 1b illustrates areas 9, 10, 11 of a replacement heart valve prosthesis according to the disclosure.

Fig. 2a, 2b, 2c depict a replacement heart valve prosthesis according to the disclosure from different angles.

Fig. 3a, 3b, 3c depict an outer stent (1) according to the disclosure from different angles.

Fig. 4a to 7 show different embodiments of fixation means (18) according to the disclosure.

Fig. 8a, 8b, 8c show different embodiments of radial force wires (17) according to the disclosure.

Fig. 9 illustrates the different areas (9), (10), (11) of a replacement heart valve prosthesis according to the disclosure implanted into a native tricuspid heart valve.

Fig. 10 to 13 show a replacement heart valve prosthesis according to the disclosure loaded onto a catheter delivery system into a delivery capsule.

Fig. 14 to 16 is a sequence illustrating the deployment of a replacement heart valve prosthesis according to the disclosure at a target site in a patient heart (tricuspid).

Fig. 17 to 19 are examples of sealing means (24, 24a, 24b, 24c) in a replacement heart valve prosthesis according to the disclosure.

Detailed Description

In the following certain terms of the disclosure will be defined. Otherwise technical terms in the context of the disclosure shall be understood as by the applicable skilled person.

The term "prosthesis" or "medical device" or "implant" in the sense of the disclosure is to be understood as any medical device that can be delivered in a minimally invasive fashion or by way of a catheter based procedure. The terms can be used interchangeably. A prosthesis in the sense of the disclosure can be e.g. a stent or stent-based prosthesis or stent-based replacement heart valve prosthesis like an aortic replacement heart valve, a mitral replacement heart valve or a tricuspid replacement heart valve.

The term "catheter" or "delivery device" in the sense of the disclosure is to be understood as the device used to deploy a prosthesis in a patient at a determined site, e.g. to replace a heart valve like a native aortic heart valve, mitral heart valve or tricuspid heart valve.

A "mesh stent" or "braided mesh stent" or "braided stent" in the sense of the disclosure is a stent composed of wires in contrast to e.g. a laser cut nitinol tube.

A "cut stent" or "laser cut stent" in the sense of the disclosure is a stent which is laser cut from e.g. a nitinol tube.

A "stent area" or "stent areas" in the sense of the disclosure is a defined area of the outer stent, mesh stent or the replacement heart valve prosthesis and in particular it is a longitudinal section or an outer section defined as proximal, middle or distal area or atrial, annular or ventricular.

A "proximal area", "middle area", "distal area" in the sense of the disclosure denotes areas of the stent or prosthesis in relation to the operator performing implantation by use of a catheter wherein proximal is close to the operator and distal is away from the operator. "Middle area" denotes in a stent or prosthesis in the sense of the disclosure is the area between the distal and proximal area. The "proximal area" can also be denoted inflow end or inflow area and the "distal area" can also be denoted outflow end or outflow area with regards to the natural blood flow in situ, i.e. in vivo, in an individual (person or patient); proximal can also be denoted atrial, middle can be denoted annular and distal can be denoted ventricular.

An "annulus area" or "annular area" in the sense of the disclosure is either the respective area of an endogenous heart valve or it defines the respective area in the replacement heart valve or stent which is to be positioned at the implantation site and it meant to align with the endogenous annulus.

A "sub-annular area" in the sense of the disclosure is the area of the prosthesis which is in distal direction (or in inflow direction or in ventricular direction) of the annulus of the endogenous heart valve. The prosthesis may cover the "sub-annular area" with the U or V groove area and the distal area.

A "groove" in the sense of the disclosure describes an area of the stent or of the prosthesis exhibiting a smaller diameter than other areas and wherein distally and proximally of said groove other areas of the stent or prosthesis having a larger diameter are in neighborhood to said groove; said groove can have a V or U shape or combinations thereof or any other bended and useful

geometries or it can be characterized by just a smaller diameter as compared to the atrial and ventricular stent areas.

A "multi-part stent" in the sense of the disclosure can refer to a "two-part stent" or a "three-part stent" wherein the inner stent is connected to a fixation means or both form an integral part and an outer stent is connected with said former parts by way of useful means. The connecting means of the inner stent and fixation means can be positioned at the atrial end or area of the inner stent. The fixation means can consist of or comprise at least two connecting means, at least two connecting arches and a respective number of anchoring loops wherein the anchoring loops can advantageously be positioned essentially in the sub-annulus area or essentially in the ventricle and thus help to preventing or limiting longitudinal movement in outflow direction of the stent or prosthesis.

A "target site" in the sense of the disclosure is the location or place where the replacement heart valve prosthesis is to be implanted and where a dysfunction or malfunction shall be treated, e.g. at the annulus of a tricuspid or mitral heart valve.

A "connection" of the stents in the sense of the disclosure is the way of fixation of two stents to each other by way of suturing, by way of a clipping or clicking mechanism or any other useful manner or connecting means to attach the stents or stent and fixation means to each other.

A "connection means" or "connecting means" in the sense of the disclosure is a mechanical or physical connection of two parts of a stent or laser cut stent. The connecting means can be by e.g. welding, gluing or any other known procedure or process or means. A connecting means can also be an attachment or clipping means which exhibits a special design and geometry for releasable or non-releasable connection.

"Fixation means" or "anchoring means" in the sense of the disclosure is a component connected with the inner stent and providing essentially for anchoring the prosthesis at the target site, optionally in cooperation with additional means. In a particular aspect a fixation means is composed of or comprises an anchoring loop, an anchoring arm, a connecting arch and an inner stent anchor, preferably a connecting means connects the inner stent anchor of the fixation means with the inner stent.

An "anchoring loop" in the sense of the disclosure is a part of a stent useful in fixation of a stent or prosthesis and which aids in avoiding movement of the stent or prosthesis at the target site. In general an anchoring loop in the sense of the disclosure is a means useful for an improved fixation of a stent or prosthesis wherein a loop is fixed to or connected with or forms part of or is an integral part of the inner stent. The "loop" or "loops" in the sense of the disclosure can have different shapes like round, square etc. and are located in a defined area in a defined pattern. A "loop" in the sense of the disclosure will exhibit a defined angle with regard to the inner stent surface and it may be designed that it may stretch out straight or flip over when the stent or prosthesis is retrieved into the catheter after an initial and possibly partial deployment.

An "angle structure" or "angle" in the sense of the disclosure is an angle between two accessory lines drawn at a certain area or stent layer in order to define a certain geometry of said stent part or arch or layer with regard to other stent structures like the inner stent.

A "radial force" in the sense of the disclosure is the force exhibited by a stent or prosthesis in radial outward direction, more particularly the force exhibited by the outer stent of the prosthesis which may be a mesh or a laser cut stent, e.g. a nitinol stent. The radial force depends on the particular mesh or cut stent design and relates to the material density, e.g. the density of wires per square area in a mesh stent, or the number of cells and size of said cells

circumferentially in a certain laser cut stent level or area, e.g. the proximal/atrial, middle/annular or distal/ventricular area. The radial force in a replacement heart valve prosthesis according to the disclosure will be chosen for the outer stent or the combination of the inner and outer stent and fixation means in a magnitude to provide for good contact with the surrounding tissue and to support the fixation functionality of the stent or prosthesis and optionally also as little as possible in order to avoid an interference with the endogenous environment and biology of the target site. Thus it will be chosen in a magnitude in order to avoid interference with the implantation site and endogenous tissue and function. The radial force may be supported for its fixation function by other means, e.g. loops for fixation.

The "target area" in the sense of the disclosure is the three-dimensional space surrounding or being within the native organ like a native heart valve which can be e.g. a tricuspid or mitral heart valve.

An "atraumatic design" of the loops in the sense of the disclosure is wherein the loops or other means or parts of a stent or a prosthesis are designed to avoid any or essentially any damage of the surrounding tissue or tissue in contact with said parts or at least parts manufactured in a manner to minimize damaging or/and injuring the tissue which they contact.

"Compliance" of the stent or replacement heart valve prosthesis, e.g. comprising an inner laser cut stent within an outer mesh stent, or a laser cut inner stent within a laser cut outer stent, in the sense of the disclosure relates to a positive interference with the target tissue. "Compliance" relates to a design which exhibits good geometry adaptation of the stent or prosthesis to the implantation site and wherein the stent or prosthesis exhibits advantageous fixation characteristics, good functionality as concerns valve function and at the same a minimal interference with the endogenous heart structures and heart function.

In one aspect of the disclosure, a problem underlying the application is solved by a multiple part stent or prosthesis wherein fixation means for anchoring the stent or prosthesis are directly connected with an inner stent and wherein an outer stent is essentially touching or aligned with the surrounding endogenous tissue of the target site upon implantation.

In one aspect of the disclosure, a problem underlying the application is solved by a three part stent or prosthesis wherein the outer stent is connected with fixation means and the fixation means are connected with the inner stent while the essential fixation (anchoring) functionality at the target site is performed by the fixation means and the essential sealing functionality is performed by the outer stent and the sealing means connected therewith.

Hence in one aspect the invention provides for advantageous anchoring characteristics and/or sealing characteristics by way of connecting the anchoring means with the inner stent. It could surprisingly be found that the connection of the anchoring means to the inner stent provides for an advantageous radial force in relation to the anchoring of the stent or prosthesis at the target site. Another aspect is the advantageous force distribution due to the connection of the anchoring means with the inner stent. Another aspect is the advantage of a connection of the anchoring means only at one end of the inner stent which may lead to a positive radial force for anchoring and at the same time a decoupling of the tissue movement during heart beating. Another aspect is the advantage that the anchoring means is less coupled to the outer stent and/or that the inner and outer stents are solely coupled by a partial connection of the outer stent with the anchoring means. This may support an uncoupling of the inner and outer stent and less impact of the tissue movements during heart beating to the inner stent. The positive anchoring and force distribution may also be achieved by the particular radial design of the fixation means and their connection arches. In one aspect the connection of the connecting arches with the outer stent is advantageous because the two parts are only

connected to each other in a defined and restricted area and optionally by the braid or cells of the outer stent being interwoven with the connecting arches at defined areas and not over the entire circumferential area of the outer stent. Also the fact that the inner and outer stent are not sutured together and are only connected at a restricted area supports uncoupling of the inner stent and supports an advantageous functionality of the valve placed within the inner stent. Thus an advantageous decoupling of the anchoring function and sealing function can be achieved.

In another advantageous aspect the stent and prosthesis according to the disclosure provides for a sealing by way of the outer stent and the related sealing materials attached thereto which serves the primary purpose of sealing and avoiding paravalvular leakage. The special design of the prosthesis advantageously decouples the outer stent from the basic anchoring functionality provided by the anchoring means and which is essentially decoupled from the outer stent. Thus the outer stent serves essentially for sealing and the sealing functionality is decoupled from the anchoring functionality in turn may result in an improved sealing characteristics by a better alignment of the outer sealing stent because it serves less or essentially not an anchoring function.

The advantageous sealing characteristics of the outer stent and advantageous alignment with the surrounding tissue of the target site may be further achieved not only by the decoupling but also by the use of a braided outer stent or relatively small dimensions of the cells of the laser cut outer stent which advantageously has a reduced stiffness as compared to known laser cut stents.

A more specific description of an embodiment according to the disclosure is a stent comprising an inner stent (2) and an outer stent (1) wherein the inner stent (2) comprises or is connected with at least one fixation means (18).

The number of fixation means (18) is chosen according to the other design features of the stent and also the replacement heart valve prosthesis. The inner stent (2) comprises or can be connected with 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 36 or more fixation means (18).

A more specific description of aspects of the disclosure is a replacement heart valve prosthesis, a method of implanting such a prosthesis and a method of positioning such a prosthesis.

In particular another aspect the problem underlying the application is solved by a replacement heart valve prosthesis comprising an inner stent and an outer stent as describe above and at least one sealing means in the inner and/or outer stent and a valve connected to the inner stent, wherein the valve has optionally 2 or 3 leaflets.

In another aspect the problem underlying the application is solved by a method for implanting a replacement heart valve prosthesis as describe above using a catheter based delivery system.

In another aspect the problem underlying the application is solved by a method for positioning a replacement heart valve prosthesis in a native tricuspid or mitral heart valve wherein the prosthesis is delivered by a catheter based delivery system to the target site (e.g. the native mitral or tricuspid annulus) wherein the target site is the annulus, the prosthesis get released from the delivery system into the right or left heart chamber, wherein area 11 including the anchoring loops (6) is essentially in the ventricle, area 10 is essentially in the area of the annulus and section 9 is essentially in the atrium positioned.

In particular, one solution according to the disclosure is in further detail a stent as disclosed herein wherein the at least one fixation means (18) is composed of or comprises an anchoring loop (6), an anchoring arm (7), a

connecting arch (12) and an inner stent anchor (13), preferably a connecting means (4) connects the inner stent anchor (13) of the fixation means (18) with the inner stent (2).

A stent according to the disclosure can have various design which achieve the object. In one embodiment it is a stent wherein the inner stent (2) or/and outer stent (1) can be composed of multiple parts, or wherein the inner stent (2) or/and outer stent (1), and optionally the fixation means (18), are one integral part, e.g. laser cut from one nitinol tube, or are connected to each other.

In one embodiment the stent according to the disclosure is a stent wherein the fixation means (18) and the inner stent (2) are connected to each other by way of connecting means (4) at the atrial end or atrial area.

In a stent according to the disclosure the inner stent (2) exhibits a relatively high stiffness and the outer stent (1) exhibits a relatively low stiffness and has a relatively high flexibility in order to adapt and align with the target endogenous tissue. Thus it has been shown to be advantageous if the outer stent (1) has a higher flexibility compared to the inner stent (2). Thus the inner stent (2) has a higher stiffness as compared to the outer stent (1). Accordingly the skilled person will appreciate that he will chose appropriate materials which materials may be stainless steel, nitinol, plastics, composite materials or other known materials. In one embodiment according to the disclosure the inner stent (2) is a laser cut stent and the outer stent (1) is a laser cut stent or a braided stent, and wherein the inner stent (2) and/or outer laser cut stent (1) comprises 6 to 48 cells circumferentially and 1 to 108 cells longitudinally or the outer braided stent (1) comprises or is composed of 6 to 72 wire meshes circumferentially and 1 to 180 wire meshes longitudinally.

A stent according to the disclosure in one embodiment is composed of or comprises various structural and functional parts which may be made from various parts which are connected with each other with appropriate means. In a stent according to the disclosure the inner stent (2) and outer stent (1) are directly connected to each other by one or more sutures, a connecting mechanism, welding, riveting or/and sleeves, or the inner stent (2) and outer stent (1) are connected to each other by way of the connecting means (4).

Usually the inner stent (2) and the outer stent (1) are not directly connected but are linked by way of the fixation means (18). A stent according to the disclosure in one embodiment is a stent wherein at least one fixation means (18) is pushed or pulled through at least one cell of the outer stent (1), or at least one fixation means (18) is interwoven with the outer stent (1), or/and connected with sutures, one or more connecting means (4), by welding, riveting or/and one or more sleeves.

The stents according to the disclosure will be connected as it is useful in view of the entire design and functionality. A stent according to the disclosure in one embodiment is a stent wherein the inner stent (2) and outer stent (1) are connected to each other in the atrial area or at the atrial end.

In a stent according to the disclosure the fixation means (18) can be connected or positioned in the ventricular area or at the ventricular end or in the atrial area or at the atrial end of the inner stent (2).

It has been shown to be useful if the stent comprises means for an easier loading onto a catheter. In a stent according to the disclosure the outer stent (1) can comprise at least two loading loops (3) or/and a groove, e.g. a V or U groove (5).

Stent according to the disclosure can be defined in three sections, e.g. an atrial area (9), an annulus area (10) and a ventricular area (11).

The dimensions of the stent will be adapted to each other and the dimensions of the target area and space. In a stent according to the disclosure in one embodiment can have dimensions wherein the atrial area (9) has a diameter of 20 to 90 mm and a length of 2 to 30 mm, the annulus area (10) has a diameter of 10 to 80 mm and a length of 2 to 20 mm and the ventricular area (11) has a diameter of 20 to 90 mm and a length of 5 to 40 mm.

A stent according to the disclosure can be characterized in that the outer stent is connected with the fixation means (18) and the fixation means (18) is connected or forms a part of the inner stent. It can be advantageous if the area (12b) of the fixation means (18) is interwoven with the outer stent (1).

The skilled person will appreciate that the materials and the design and thickness or density of the materials of the stent will influence the overall prosthesis characteristics. In an embodiment wherein a wire braided stent is used as the outer stent (1), it can consist of or comprise from 1 to 108 wires.

The number of fixation means (18) can vary. In one embodiment of a stent according to the disclosure the number of connecting arms (7) and/or connecting arch (12) of the fixation means (18) is from 2 to 36.

The various dimensions of a stent according to the disclosure will be chosen as is useful and the anchoring loops (6) can exhibit an angle to the longitudinal axis of the stent of 0° to 45°, or/and have a length of 3 mm to 20 mm, or/and have a radius of 0.5 to 5mm.

In a stent according to the disclosure in one embodiment the stent may comprise an additional radial force wire (17), optionally increasing the radial force of the stent of at least 10% as compared to a stent without the radial force wire.

In a stent according to the disclosure the anchoring loop (6) can exhibit the following dimension (14), (15), (16) wherein the angle of (14) equals from 0° to 80°, (15) is 3 mm to 20 mm and (16) is 0,5 mm to 5 mm.

In addition to the features as described above the stent according to the disclosure can further comprise at least one radial force wire (17), or two, three or four radial force wires (17).

The anchoring loops support the fixation at the target site. In one embodiment a stent according to the disclosure comprises 1 to 54 anchoring loops (6).

The method as described above can be further characterized in that it relates to a method for implanting a replacement heart valve prosthesis using a catheter-based implantation and delivery system.

The catheter will be introduced as is appropriate with regards to the target native heart valve and the catheter system can be introduced trans-femoral, trans-atrial, trans-jugular, or trans-apical.

In another detail the disclosure relates to a method for positioning a replacement heart valve prosthesis in a native tricuspid or mitral heart valve wherein the prosthesis is delivered by a catheter based delivery system to the target site (e.g. the native mitral or tricuspid annulus), the prosthesis is released from the delivery system into the right or left heart chamber, wherein area 11 including the anchoring loops (6) is positioned essentially in the ventricle, area 10 is positioned essentially in the area of the annulus, and area 9 is positioned essentially in the atrium.

In said method the fixation means (18) are positioned with their anchoring loops (6) in the sub-annular area or/and ventricular area.

The prosthesis as disclosed herein can also be retrieved in case of sub-optimal positioning or other problems during the implantation procedure.

Examples

The following examples serve to illustrate various embodiments of the disclosure. They are not meant to be interpreted as restrictive in any way.

In Fig. 1a a two-part stent according to the disclosure is described comprising inner and outer stent (2, 1) wherein the inner stent (2) is connected by connecting means (4) with fixation means (18) comprising connecting arms (7), connecting arches (12) and anchoring loops (6). The connecting means (4) may exhibit a special design useful in medical devices and useful for the purpose and environment, e.g. it can be a clip mechanism or type of a screw. The connection can also be achieved by a welding process or other useful techniques to combine two parts known in the art. Inside the inner stent (2) the valve leaflets (8) are schematically indicated. The position of the valve leaflets (8) – two or three – may be adapted to the particular replacement valve type, e.g. tricuspid or mitral. Also the position within the inner stent (2) will vary depending on the replacement valve type and the particular size of the replacement valve type. Thus the valve leaflets (8) can be positioned e.g. closer to the connection of fixation means (18) and connecting means (4) that means closer to the upper part of the inner stent (2)–. It may be aligned with the annulus of the target site or further towards to the lower part of the inner stent (2) . In this embodiment according to the disclosure at the end areas of the outer stent (1) schematically loading loops (3) are shown. A prosthesis according to the disclosure may contain at least two, or three loading loops (3) but also e.g. five, seven, or nine or more. The advantage of two, three or five loading loops (3) is that in this way less space is needed when loaded onto the catheter system which advantageously reduced the overall diameter of the catheter system for delivery. Nevertheless with three loading loops a uniform pull can be achieved when loading the prosthesis onto the catheter. It may be useful to use more than

three or five or seven, eight, nine or more loading loops (3) when using a very soft outer stent (1) in order to guarantee a uniform force is applied to the prosthesis during the loading procedure. The inner stent (2) is e.g. cut from a nitinol tube and exhibits a uniform design of cells. The cell design can also vary and the density of the cell can be chosen with a variation in order to vary the stiffness of the inner stent (2). As depicted here it has a uniform diameter over its length and it will maintain essentially its diameter during heart beat at the target site. The advantage is thus that the function of the valve leaflets (8) in this way will be comparable to a native valve and the valve leaflets will coapt in an advantageous manner. The angle between the connecting arm (7) and the connecting arch (12) may vary depending on the overall size of the prosthesis and the radial force that shall be achieved. Each of the connecting arm (7) and the connecting arch (12) can have an essentially straight design or each of them can be bent. The two parts or sections (distal (12) and proximal (7)) of the fixation means (18) can also form one arch with no angle and the parts or sections can form one slightly bended arch over the whole length. The anchoring loop (6) will have a dimension which is useful in the context of the overall design and with regards to the target site. The anchoring loop (6) can reverse in its direction with regards to the connecting arch (12) or it can protrude in the same direction and in addition contain at its very end a tip which is rounded in order to prevent damages in the target tissue. The anchoring loop (6) can be designed to be essentially parallel to the connecting arch (12) or form a certain angle with the connecting arch (12) of e.g. 10 ° to 45 °. The outer stent (1) will have a design that is useful for an optimized alignment with the target site and in order to align as good as possible with the target endogenous tissue. It may exhibit a groove, e.g. a U or V groove. Said groove will align with the annulus area and support a correct positioning and it will in addition be useful for fixation of the prosthesis at the target site. The groove will be positioned in relation to the other parts of the prosthesis, i.e. fixation means (18) and inner stent (2), in order to achieve an advantageous positioning at the target site and to avoid interference with a correct

functioning of the replacement heart valve prosthesis. It will also serve to support a good compliance of the prosthesis with the heart and the overall heart function.

Fig. 1b shall illustrate an example of a replacement heart valve prosthesis according to the disclosure and its various areas, i.e. areas (9), (10), (11). Area (9) is the atrium area, area (10) is the annulus area and area (11) is the ventricular area. The fixation means (18 – the reference number is not shown) can extend over the distal end of the inner stent and also the outer stent can extend over the distal end of the inner stent. It will be appreciated that the longitudinal dimensions of the fixation means and the outer stent will be fine tuned depending on the particular size requirements of the target site.

In Fig. 2a one can see outer stent (1) and inner stent (2) wherein the fixation means are connected with the inner stent (2) by way of 12 connecting means (4). The number of connecting means (4) can vary e.g. from 4 to 20. A fixation means has two connecting arms (7) wherein the two connecting arms (7) are essentially parallel and wherein the connecting arches (12) are spaced apart and which at their ends form an anchoring loop (6) which bends backward and in the opposite direction. Fixation means (18) are superimposed wherein the connecting arches (12) cross over each other. The inner stent (2) has two rows of cells but the number of rows can vary from 2 to 20.

In Fig. 2b which is a side view of the replacement heart valve prosthesis one can see the groove (5) useful for an advantageous alignment of the prosthesis with its target site. Fixation loops (6) will align with the ventricular endogenous tissue.

In Fig. 2c a top view is depicted and the orientation and spacing of the connecting means (4) is visible as well as the outward protrusion of the

fixation loops (6). The outer stent (1) is connected via the fixation means (18) composed of connecting arms (7) and connecting arches (12) and fixation loops (6) with the inner stent (2). The outer stent (1) is not directly connected with inner stent (2). The outer stent serves for an advantageous alignment of the prosthesis with the target endogenous tissue and to mechanically isolate the outer stent (1) from the inner stent (2) supported by the fixation means (18). Thus advantageously the functionality of the replacement heart valve connected with the inner stent (2) is essentially not impaired during the heart contractions and movement of the endogenous tissue.

The Fig. 3a, 3b, 3c are variations of an outer stent (1) according to the disclosure viewed from different angles. The loading loops (3) have essentially an angle of 90 ° to the longitudinal direction of the prosthesis. Said loading loops (3) will align within the catheter during the loading procedure and tilt sideways in order to be stored during the loading onto the catheter.

Fig. 4a to 7 show different embodiments and view directions of fixation means (18) according to the disclosure wherein the special design and orientation of the connecting arms (7), connecting arches (12) and anchoring loops (6) are shown. In particular in Fig. 4c the parallel orientation of the connecting arms (7) is obvious. Such a parallel orientation supports a certain stiffness in said area whereby the loops of the connecting arches (12) are useful for an advantageous alignment of said area with the target endogenous tissue. The orientation of the fixation loops (6) in the counter-direction is useful for a fixation in the target endogenous tissue.

Fig. 4 a – c: shows another variation of the embodiments according to the disclosure. In order to increase the radial force in the ventricular area several connecting means (18) can be chosen in the stent design; one can e.g. chose 2 – 35 connecting means (18) which it is possible to adapt the radial force as

desired by variation of the number of connecting means (18), e.g. 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35. In this manner the radial force may be fine tuned as the need will be and in connection with the other features of the stent requirements. Thus the radial force can be easily varied over a range depending on the number of connecting means (18).

Fig. 5 a – c: shows another variation of the embodiments according to the disclosure. IT is possible to use solely one connecting means (18) if the radial force of the outer stent (1) shall not be increased significantly in the ventricular area, however the number of anchoring loops (6) and connecting arms (7) shall not be reduced significantly. One can e.g. the angle of the mesh design reduce close to the anchoring loops (6); in this manner one can obtain a design wherein one connecting means (18) without crossing in this area.

In Fig. 5c the connecting arches (12) do not cross each other in contrast to the embodiment depicted in Fig. 4c.

In Fig. 6 the fixation means (18) consisting of connecting arm (7), connecting arch (12) and anchoring loop (6) is shown and a special design of the connecting arm (7a) forming an inner stent anchor (13) serving for connection with the inner stent by way of connecting means (4). The connecting arm or arms (7) can be designed as one, two or more parallel struts or they can be twisted which will increase the stability or stiffness.

The anchoring loop (6) can vary in its design in various aspects as is shown in Fig. 7. One may e.g. introduce variations in the angle of the anchoring loop (14), the radius of the anchoring loop (16) and length of the anchoring loop (15). An angle of the anchoring loop (14) of 80° to 10° in relation to the connecting arch (12) can be advantageous for exhibiting a positive radial force in the area where the anchoring arch (6) will contact the native tissue

and to supporting an improved fixation. An angle (6) of 15° to 25° can be advantageous. A variation of the length of the anchoring loop (6) of 5 to 15mm and/or a radius (16) of 1 to 4 mm can also be advantageous.

Fig. 8a, 8b, 8c show different embodiments of a radial force wire (17) according to the disclosure. A radial force wire (17) may be added in order to fine tune the radial force in a certain area of the prosthesis. Advantageously the radial force wire (17) is attached to the outer stent (1) in area (10) or (11) for an improved fixation of the prosthesis at the target site.

Fig. 9 illustrates the different areas (9), (10), (11) of a replacement heart valve prosthesis according to the disclosure implanted into a native tricuspid heart valve. The different areas (9), (10), (11) can be chosen to exhibit a certain length to each other for an advantageous design of the replacement heart valve prosthesis. Advantageous ratios of these areas or lengths are e.g. atrial area (9) has a diameter of 15 to 95 mm and a length of 1 to 35 mm, the annulus area (10) has a diameter of 8 to 85 mm and a length of 2 to 25 mm and the ventricular area (11) has a diameter of 18 to 95 mm and a length of 5 to 45 mm. The ratio of area (9) and/or area (11) to area (10) is 2:1 to 4:1. The ratio of the diameter of inner stent (2) to outer stent (1) can be chosen to be 1:1.4 to 1:3.5.

A loading procedure for a replacement heart valve prosthesis according to the disclosure is illustrated in Fig. 10 to 13 wherein the anchoring loops (6) can be folded and in said manner they can be loaded onto the catheter (Fig. 10, 11). Or alternatively the anchoring loops (6) can be stretched and unfolded in order to reduce the diameter of catheter and prosthesis (Fig. 12, 13). In both cases the prosthesis is loaded onto a catheter delivery system into a delivery capsule. The prosthesis can be fully covered and only partially covered by the outer catheter sheath. In Fig. 10 one can see that the anchoring loops (6) are pressed inwardly and covered by delivery system outer shaft (21). Delivery system tip (23) is pulled back by delivery system

inner shaft (20) (Fig. 10, 11). In Fig. 12 and 13 it is shown that the anchoring loops (6) are folded and stretched longitudinally and delivery system tip (23) is pulled back by delivery system inner shaft (20).

Fig. 14 to 16 is a sequence illustrating the deployment of a replacement heart valve prosthesis according to the disclosure at a target site in a patient heart (e.g. tricuspid). Fig. 14 shows alignment of the replacement heart valve prosthesis (still within the catheter capsule) with its areas (9), (10), (11) in the atrial, annulus and ventricular area of the native valve/heart and thus aligns correctly for an advantageous functionality. In Fig. 15 the catheter tip is pushed distally (seen from the operator of the catheter) and the prosthesis partly is released from the catheter wherein the fixation means (18) and inner stent (2) is visible in the ventricular area of the heart. In a next step illustrated in Fig. 16 the prosthesis is entirely released but still in connection with the catheter via retrievability connection (22). Thus the prosthesis can still be repositioned and retrieved by the catheter in case of complications. In Fig. 16 the prosthesis has correctly aligned with the target site and the native tricuspid valve area so that a correct functioning is achieved. Such an alignment is supported by grooves (5) which direct the groove to the annulus and thus form part of the alignment function of the prosthesis according to the disclosure. The fixation means (18) does not only support fixation and a secured positioning but may also be useful to push back the native valve leaflets radially. After complete release and detachment of the retrievability connection (22) the catheter is pulled back and taken out of the patient's body and all further necessary actions are taken to finalize the procedure.

Fig. 17 to 19 are examples of sealing means (24, 24a, 24b, 24c) in a replacement heart valve prosthesis according to the disclosure. The sealing means can be combined depending on the particular prosthesis design and possible combination are e.g. atrial sealing (24a) and ventricular sealing (24b) (Fig. 17), solely ventricular sealing (24b) (Fig. 18), or a combination of

annulus sealing (24c) and ventricular sealing (24b) (Fig. 19).

Reference Number List

- 1 – outer stent (wire braided or laser cut)
- 2 – inner stent (laser cut)
- 3 – loading loops
- 4 – connecting means
- 5 – V or U groove
- 6 – anchoring loop
- 7 – connecting arm
- 7a – twisted connecting arm
- 8 – valve leaflet
- 9 – atrial (proximal) area
- 10 – annulus (middle) area
- 11 – ventricular (distal) area
- 12 – connecting arch
- 12a – atrial (proximal) connecting arch
- 12b – ventricular (distal) connecting arch
- 13 – inner stent anchor
- 14 – angle of anchoring loop
- 15 – length of anchoring loop
- 16 – radius of anchoring loop
- 17 – radial force wire
- 18 – fixation means
- 19 – stentholder
- 20 – delivery system inner shaft
- 21 – delivery system outer shaft
- 22 – retrievability connection
- 23 – delivery system tip
- 24 – sealing means
- 24a – atrial sealing
- 24b – ventricular sealing
- 24c – annular sealing

Claims

1. A stent comprising an inner stent (2) and an outer stent (1) wherein the inner stent (2) comprises or is connected with at least one fixation means (18), preferably the inner stent (2) comprises or is connected with 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 36 or more fixation means (18).
2. Stent according to claim 1, wherein the at least one fixation means (18) is composed of or comprises an anchoring loop (6), an anchoring arm (7), a connecting arch (12) and an inner stent anchor (13), preferably a connecting means (4) connects the inner stent anchor (13) of the fixation means (18) with the inner stent (2).
3. Stent according to claim 1 or 2 wherein the inner stent (2) or/and outer stent (1) can be composed of multiple parts, or wherein the inner stent (2) or/and outer stent (1), and optionally the fixation means (18), are one integral part, e.g. laser cut from one nitinol tube, or are connected to each other.
4. Stent according to claim 1, 2 or 3 wherein the fixation means (18) and the inner stent (2) are connected to each other by way of connecting means (4) at the atrial end or atrial area.
5. Stent according to claim 1, 2, 3, or 4 wherein the inner stent (2) is a laser cut stent and the outer stent (1) is a laser cut stent or a braided stent, and wherein the inner stent (2) and/or outer laser cut stent (1) comprises 6 to 48 cells circumferentially and 1 to 108 cells

longitudinally or the outer braided stent (1) comprises or is composed of 6 to 72 wire meshes circumferentially and 1 to 180 wire meshes longitudinally.

6. Stent according to any of the preceding claims wherein the inner stent (2) and outer stent (1) is directly connected to each other by one or more sutures, a connecting mechanism, welding, riveting or/and sleeves, or the inner stent (2) and outer stent (1) is connected to each other by way of the connecting means (4).
7. Stent according to any of the preceding claims wherein at least one fixation means (18) is pushed or pulled through at least one cell or a mesh of the outer stent (1), or at least one fixation means (18) is interwoven with the outer stent (1), or/and connected with sutures, one or more connecting means (4), by welding, riveting or/and one or more sleeves.
8. Stent according to any of the preceding claims wherein the inner stent (2) and outer stent (1) is connected to each other in the atrial area or at the atrial end.
9. Stent according to any of the preceding claims wherein the fixation means (18) is connected or positioned in the ventricular area or at the ventricular end or in the atrial area or at the atrial end of the inner stent (2).
10. Stent according to any of the preceding claims wherein the outer stent (1) comprises at least two loading loops (3) or/and a groove, e.g. a V or U groove (5).

11. Stent according to any of the preceding claims wherein the stent can be defined in three sections, e.g. an atrial area (9), an annulus area (10) and a ventricular area (11).
12. Stent according to claim 11 wherein the atrial area (9) has a diameter of 20 to 90 mm and a length of 2 to 30 mm, the annulus area (10) has a diameter of 10 to 80 mm and a length of 2 to 20 mm and the ventricular area (11) has a diameter of 20 to 90 mm and a length of 5 to 40 mm.
13. Stent according to claim 11 or 12 wherein the area (12b) of the fixation means (18) is interwoven with the outer stent (1).
14. Stent according to any of the preceding claims wherein the wire braided outer stent (1) consists of or comprises from 1 to 108 wires.
15. Stent according to any of the preceding claims wherein the number of connecting arms (7) and/or connecting arch (12) of the fixation means (18) is from 2 to 36.
16. Stent according to any of the preceding claims wherein the anchoring loops (6) exhibit an angle to the longitudinal axis of the stent of 0° to 45°, or/and have a length of 3 mm to 20 mm, or/and have a radius of 0.5 to 5mm.
17. Stent according to any of the preceding claims wherein the stent comprises an additional radial force wire (17), optionally increasing the radial force of the stent of at least 10 % as compared to a stent without the radial force wire.
18. Stent according to any of the preceding claims wherein the anchoring loop (6) exhibits the following dimension (14), (15), (16) wherein the

angle of (14) equals 0° bis 80°, (15) is 3 mm to 20 mm and (16) is 0,5 mm bis 5 mm.

19. Stent according to any of the preceding claims further comprising at least one radial force wire (17).
20. Stent according to any of the preceding claims wherein the stent comprises 1 to 54 anchoring loops (6).
21. A replacement heart valve prosthesis comprising a stent according to any of claims 1 to 20 and wherein the inner stent (2) and/or outer stent (1) comprise at least one sealing means (24a, 24b, 24c) and a valve connected to the inner stent (2), wherein the valve has optionally 2 or 3 valve leaflets (8).
22. A method for implanting a replacement heart valve prosthesis according to claim 21 using a catheter based implantation and delivery system.
23. Method according to claim 22 wherein the catheter system is introduced trans-femoral, trans-atrial, trans-jugular, or trans-apical.
24. A method for positioning a replacement heart valve prosthesis in a native tricuspid or mitral heart valve wherein the prosthesis is delivered by a catheter based delivery system to the target site (e.g. the native mitral or tricuspid annulus), the prosthesis is released from the delivery system into the right or left heart chamber, wherein area 11 including the anchoring loops (6) is positioned essentially in the ventricle, area 10 is positioned essentially in the area of the annulus, and area 9 is positioned essentially in the atrium.

25. Method according to claim 24 wherein the fixation means (18) are positioned with their anchoring loops (6) in the sub-annular area or/and ventricular area.

Figures

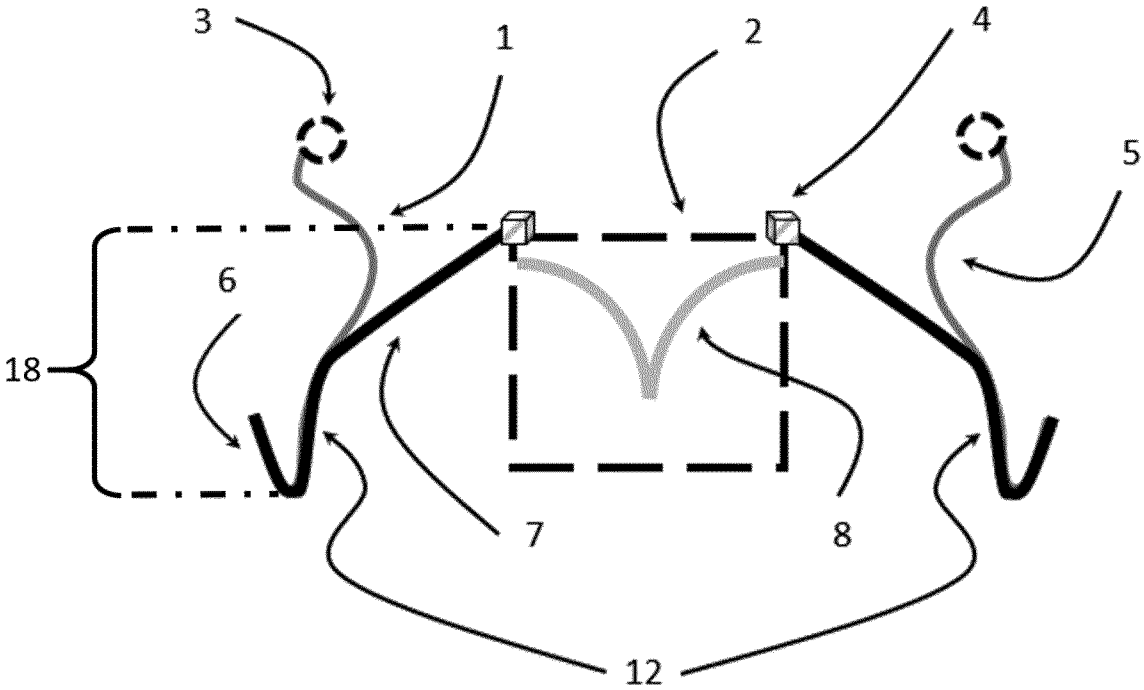


Fig. 1a

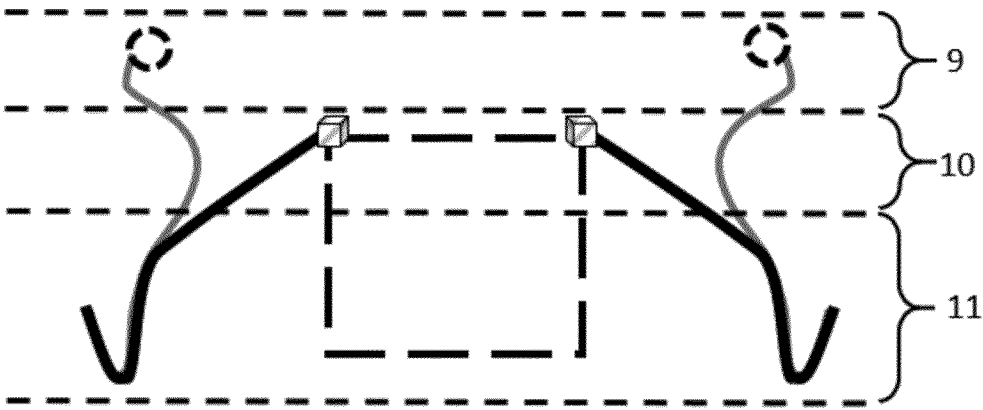


Fig. 1b

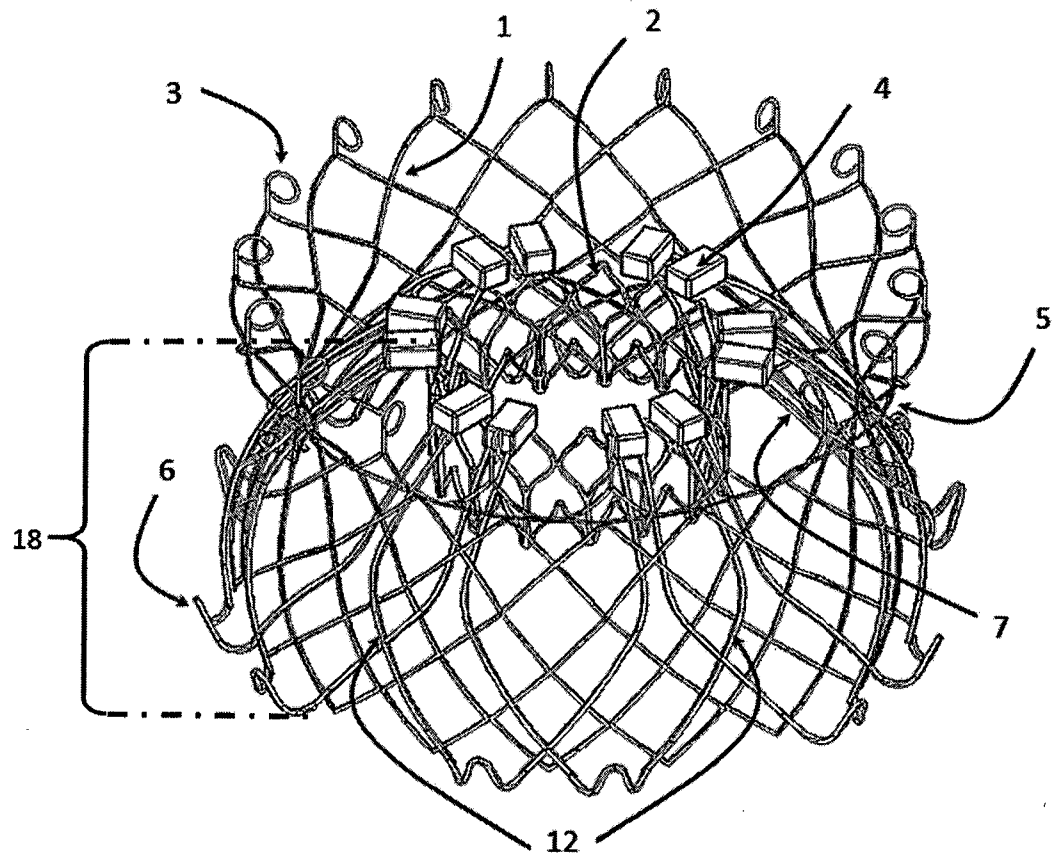


Fig. 2a

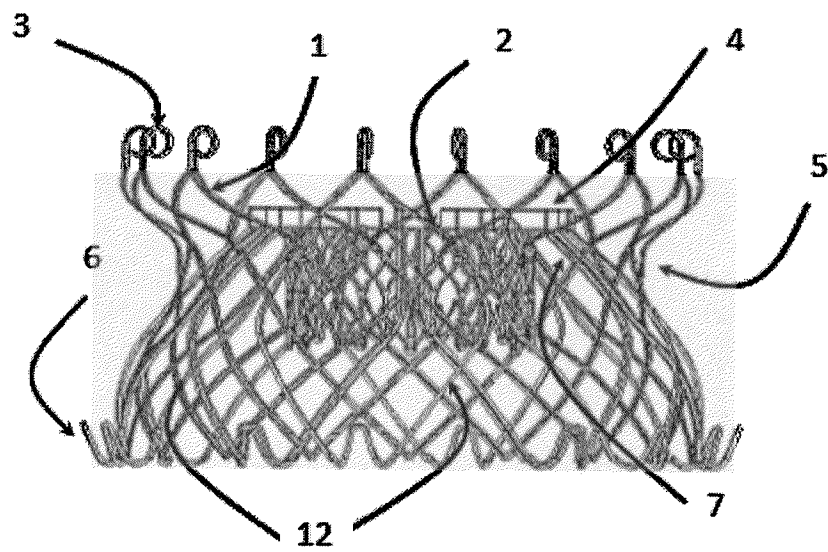


Fig. 2b

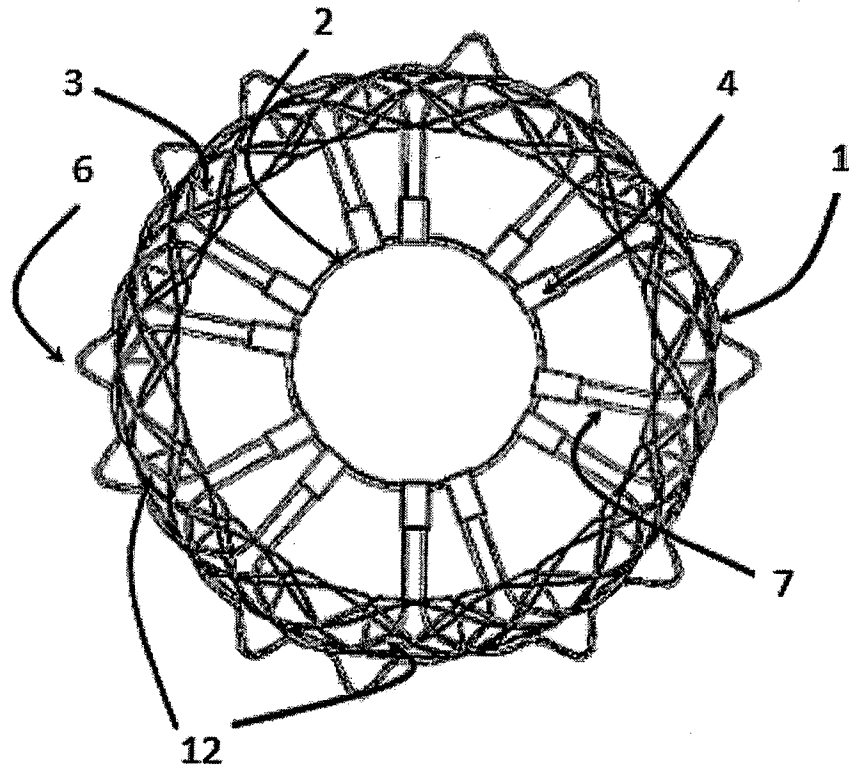


Fig. 2c

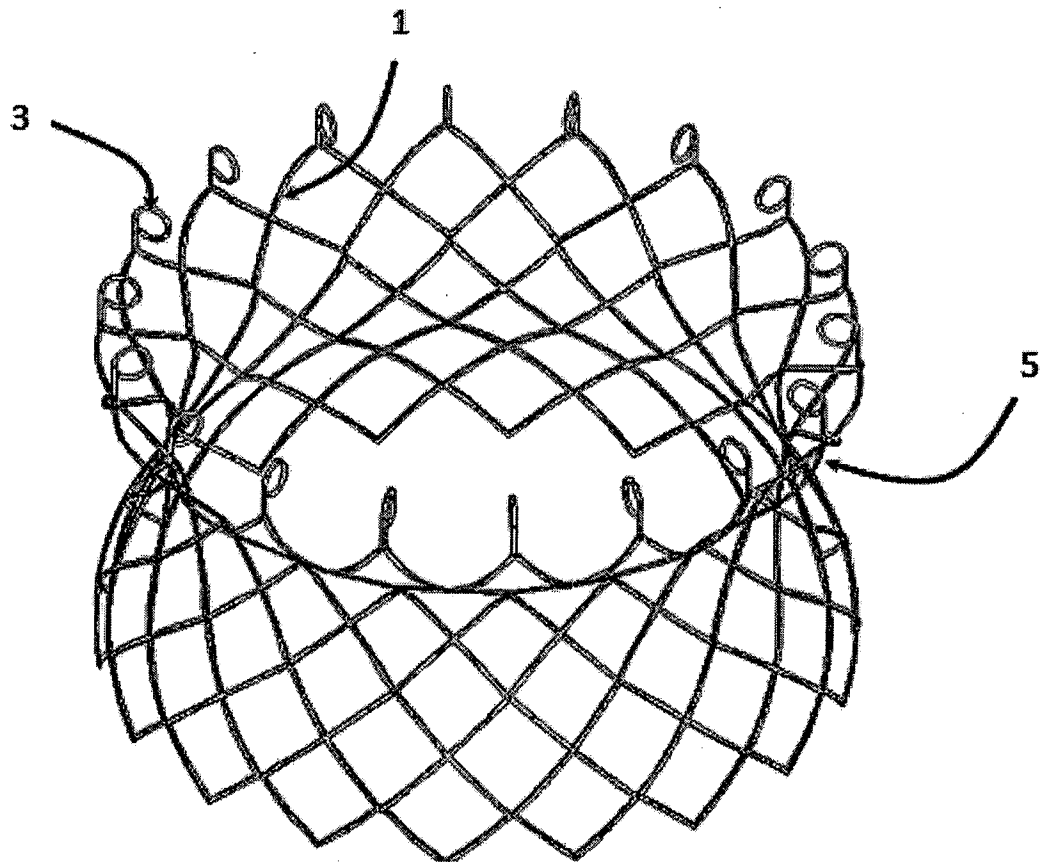


Fig. 3a

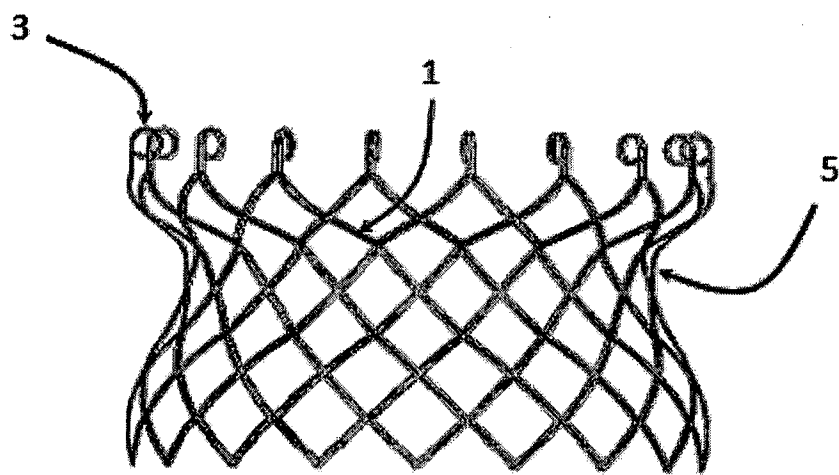


Fig. 3b

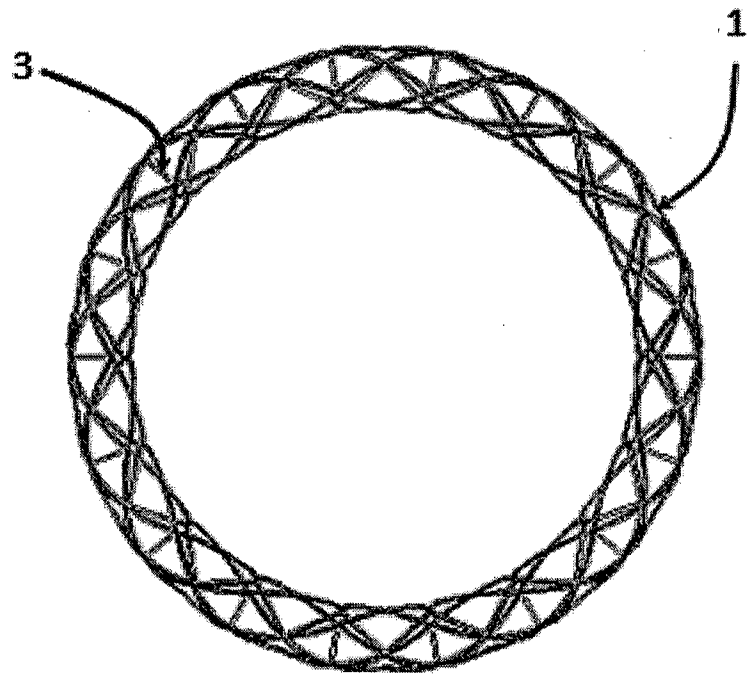


Fig. 3c

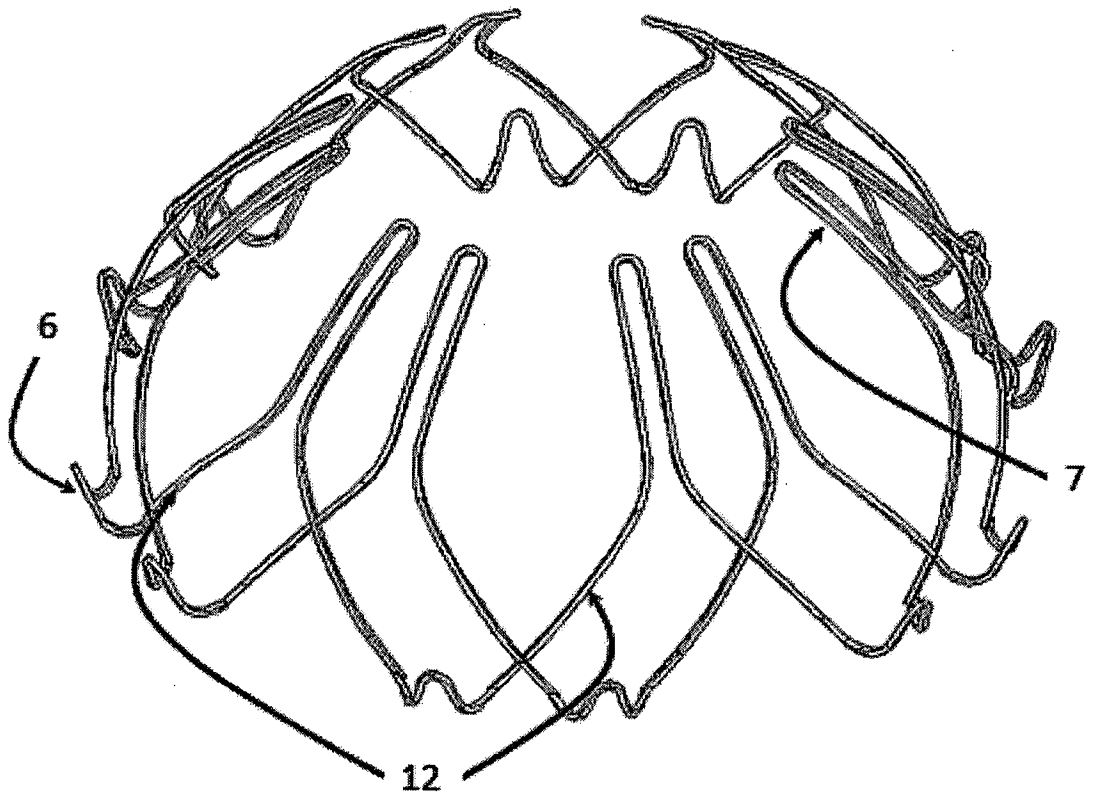


Fig. 4a

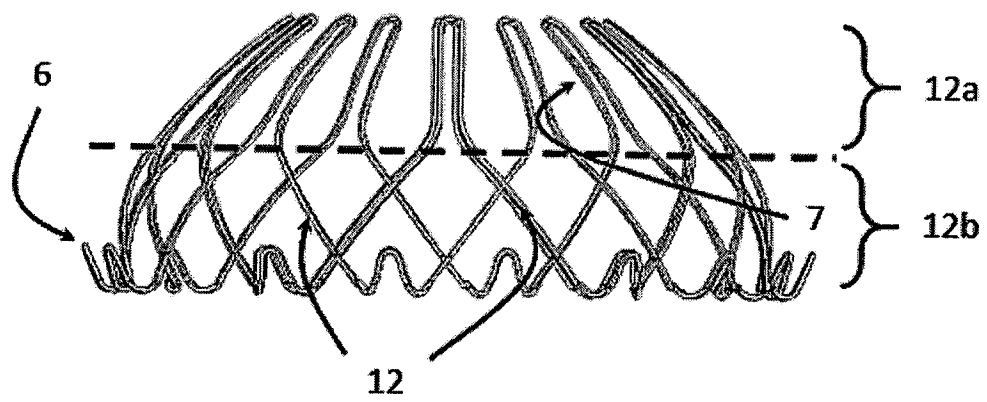


Fig. 4b

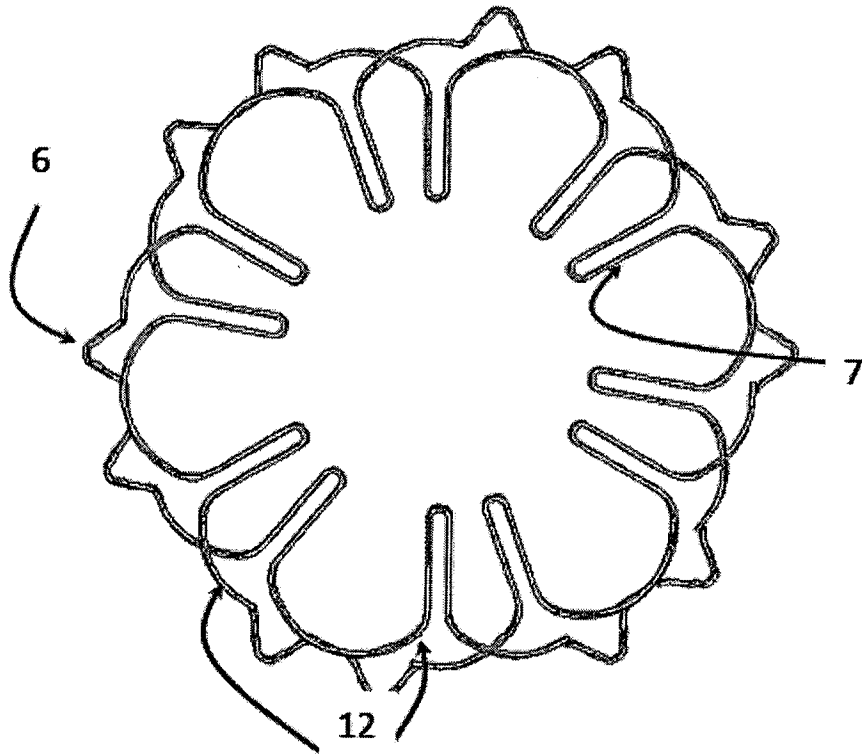


Fig. 4c

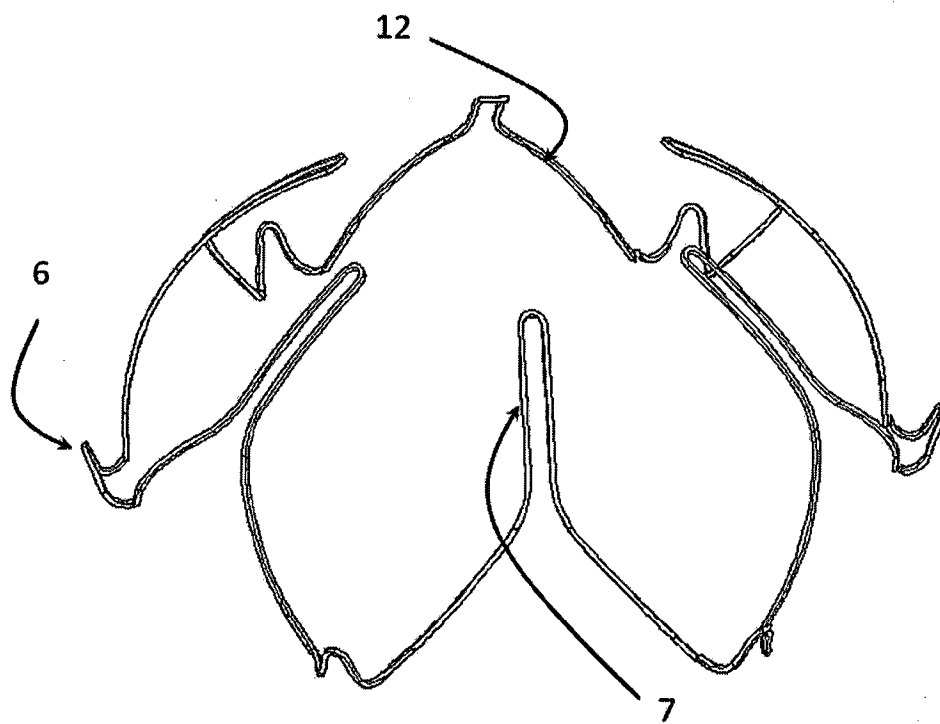


Fig. 5a

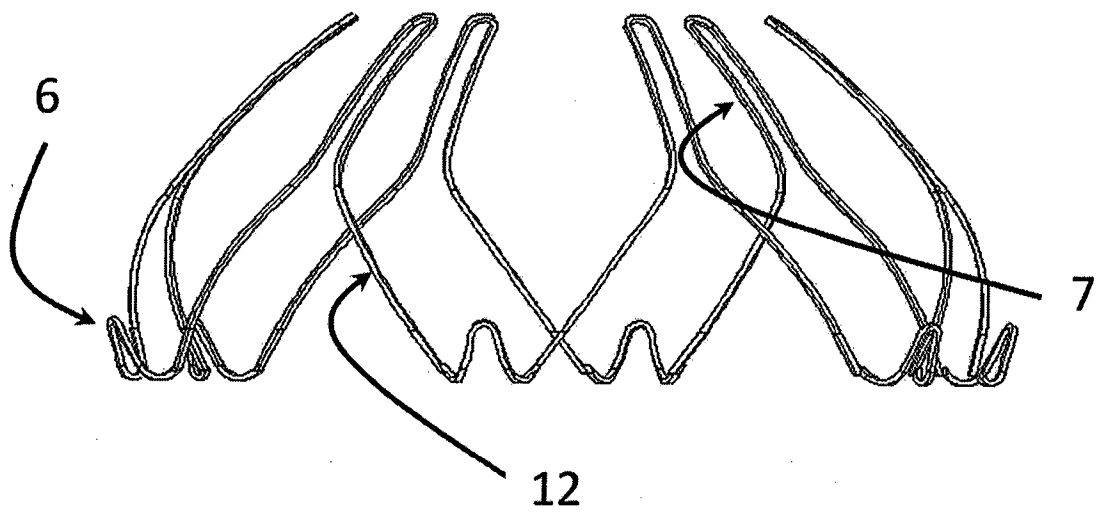


Fig. 5b

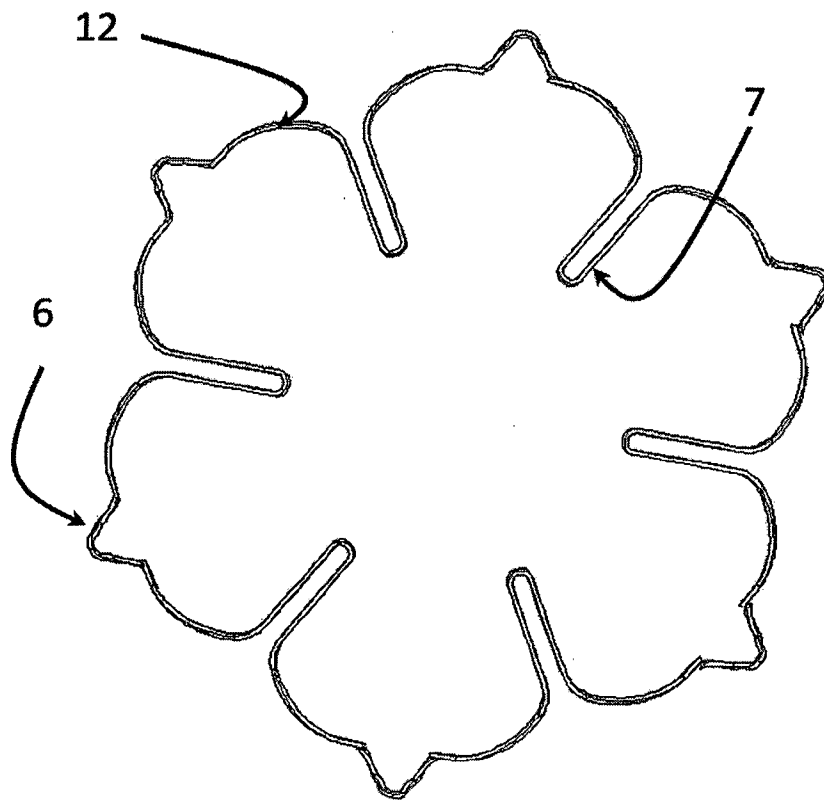


Fig. 5c

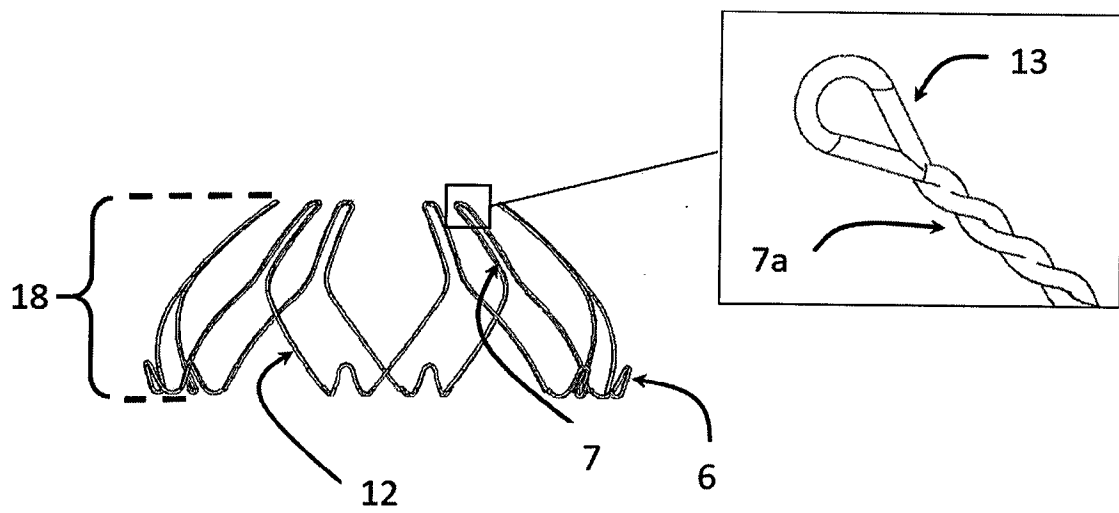


Fig. 6

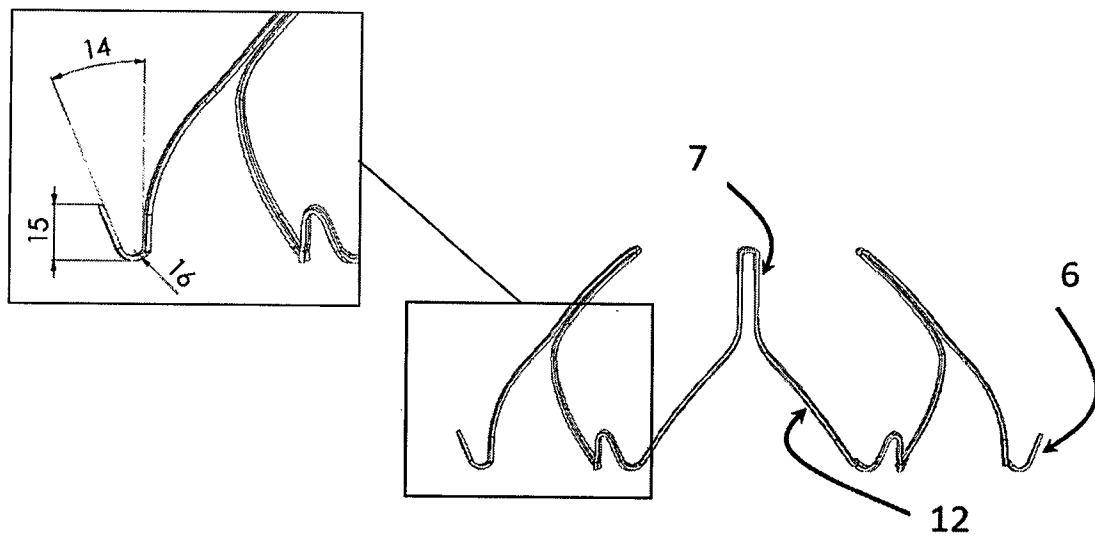


Fig. 7

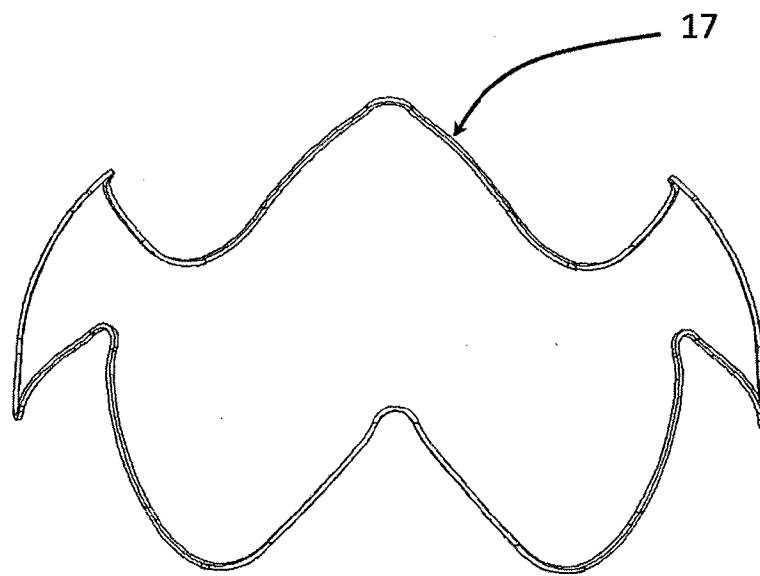


Fig. 8a

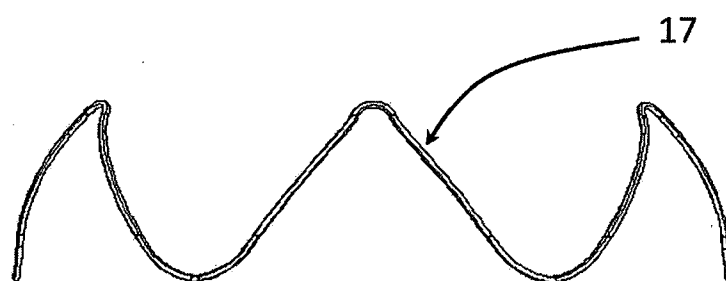


Fig. 8b

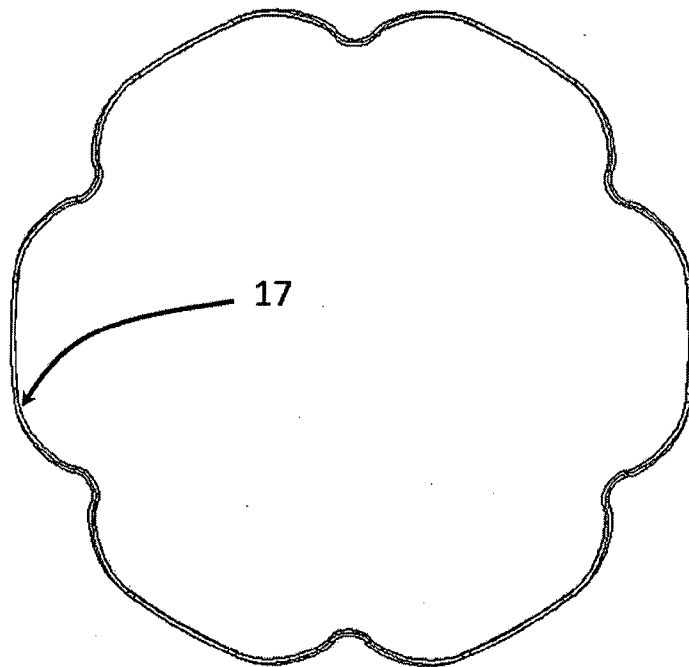


Fig. 8c

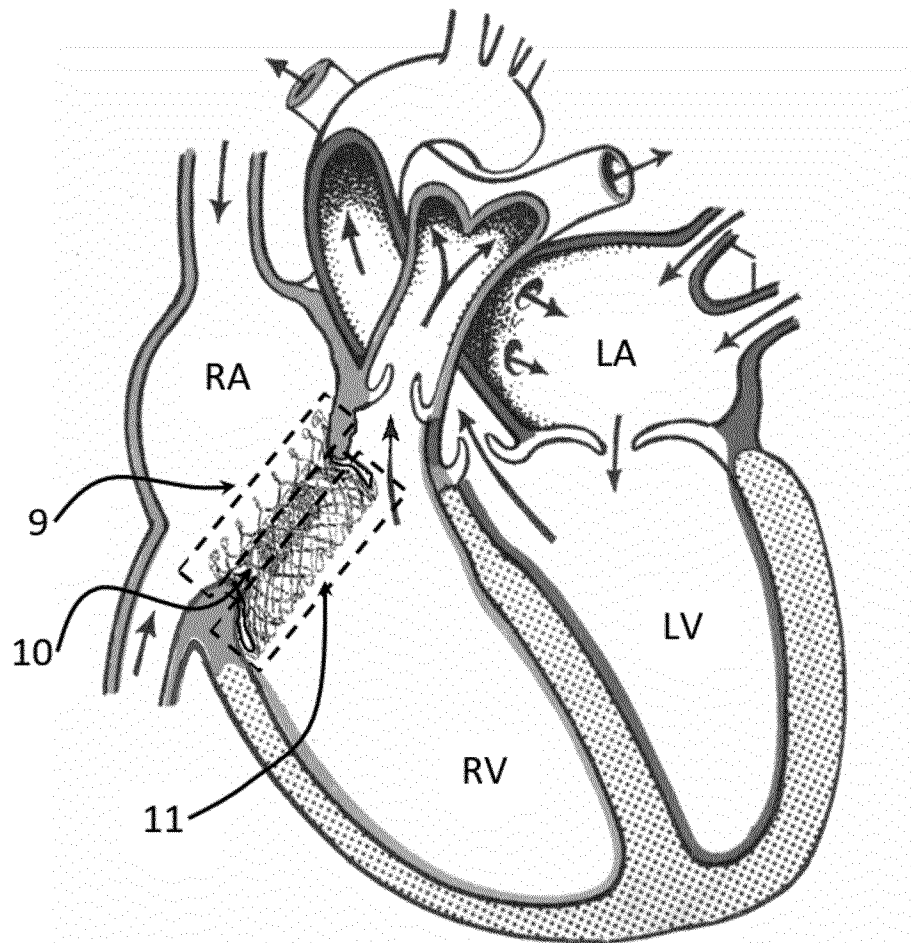


Fig. 9

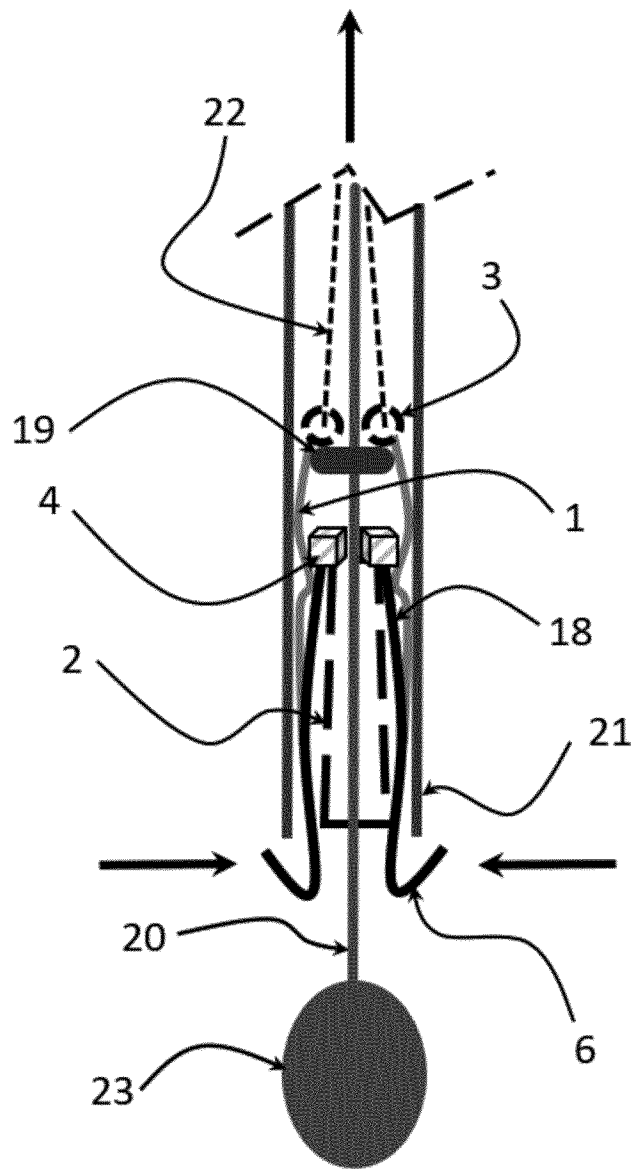


Fig. 10

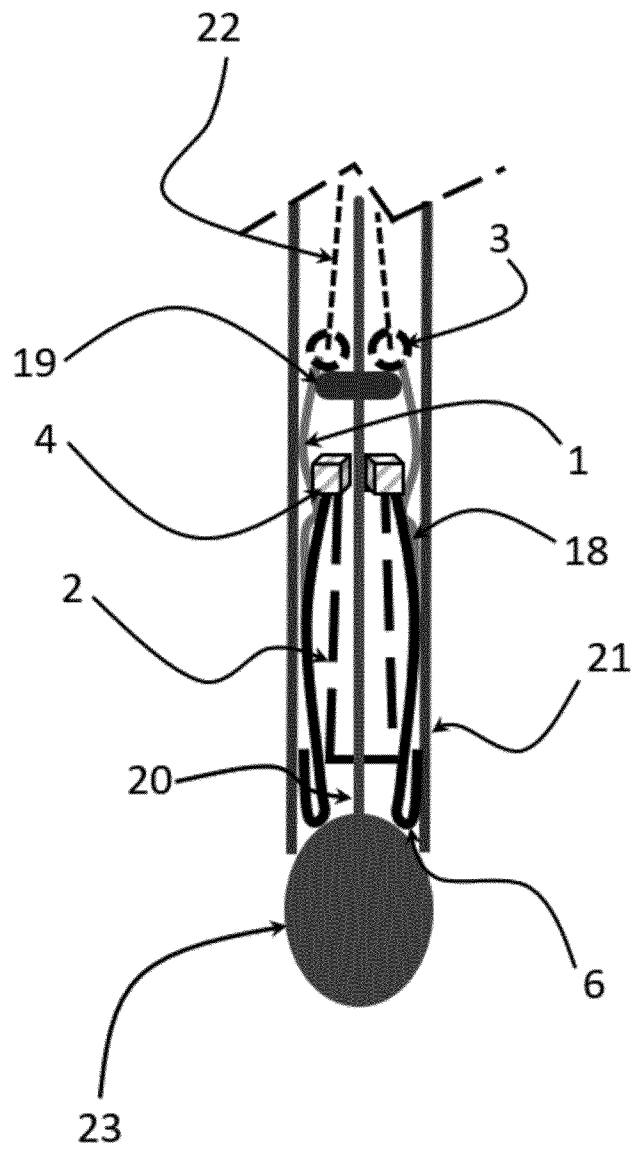


Fig. 11

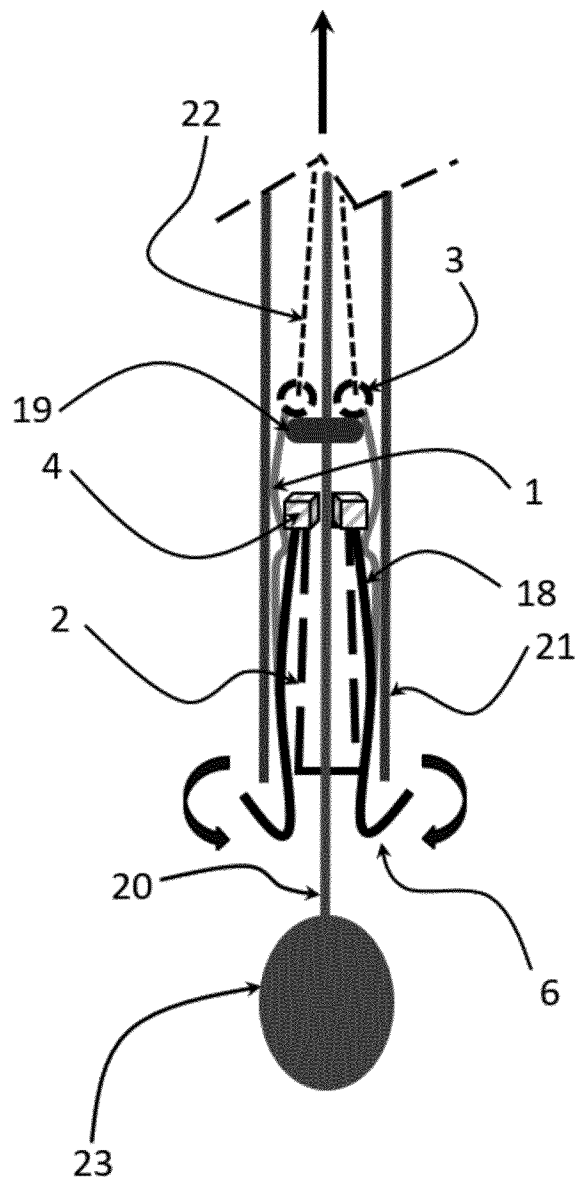


Fig. 12

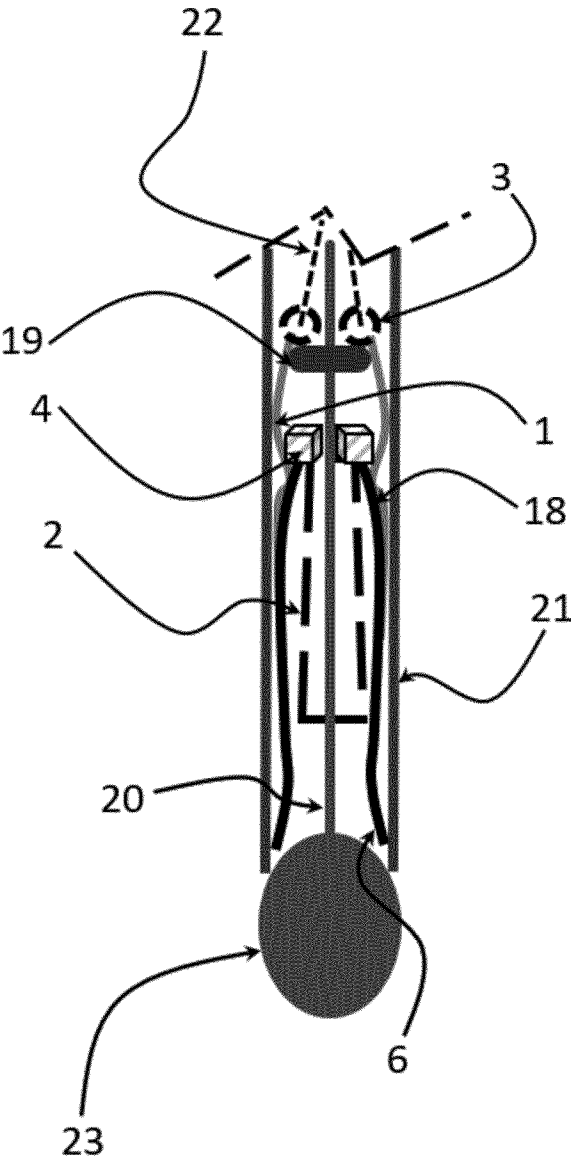


Fig. 13

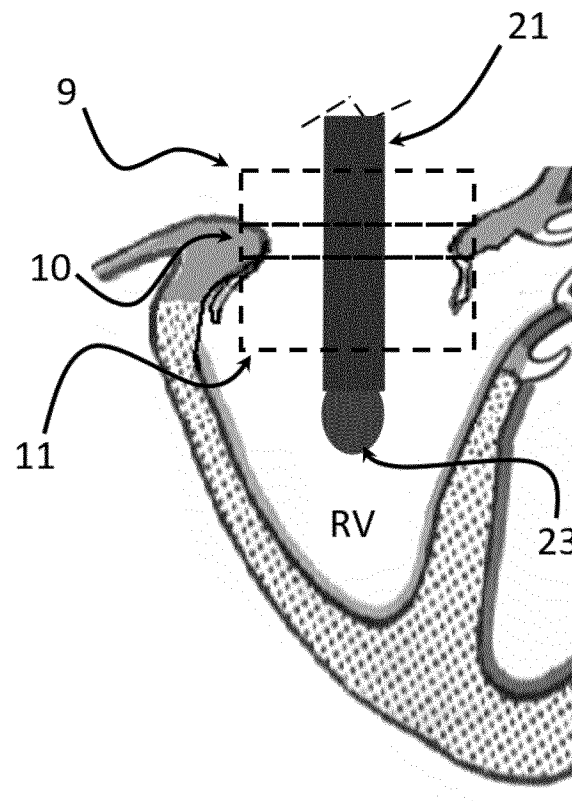


Fig. 14

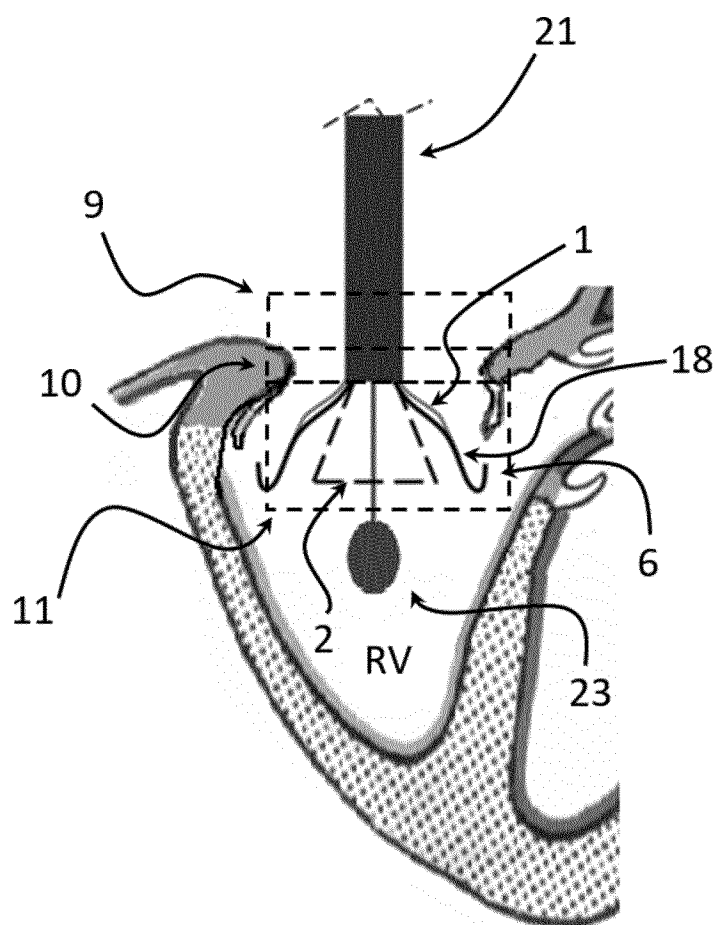


Fig. 15

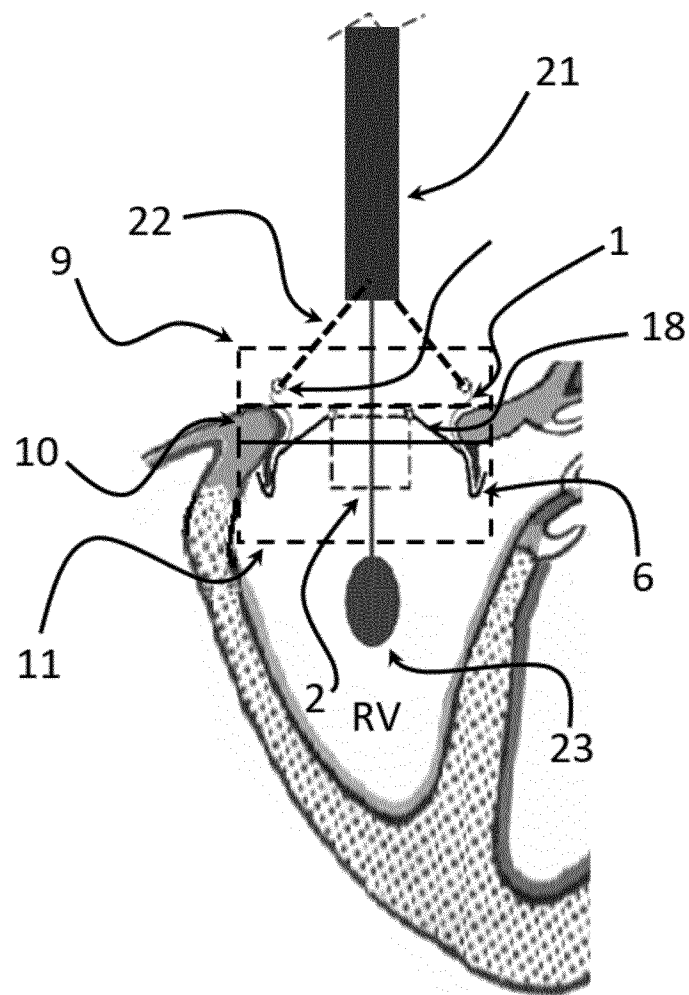


Fig. 16

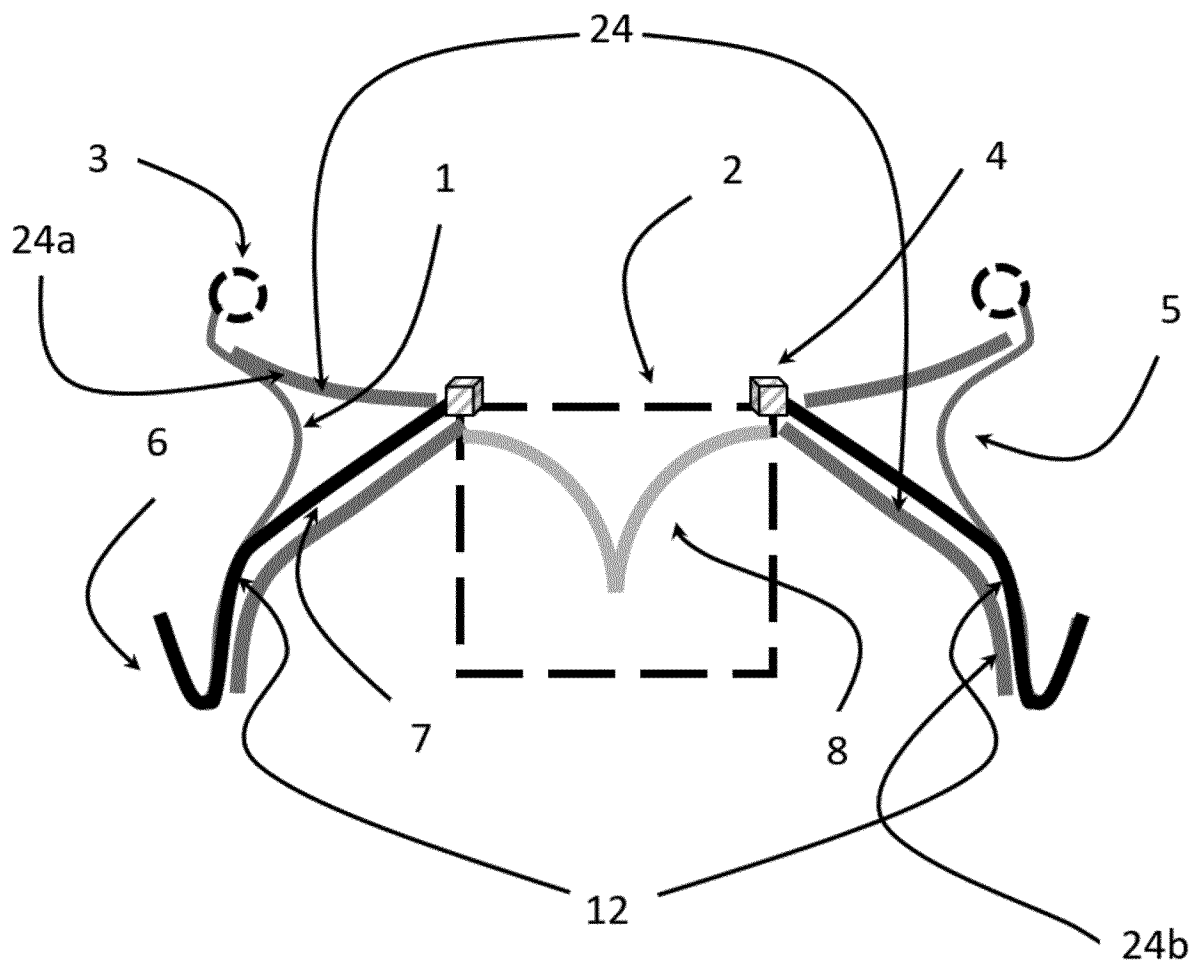


Fig. 17

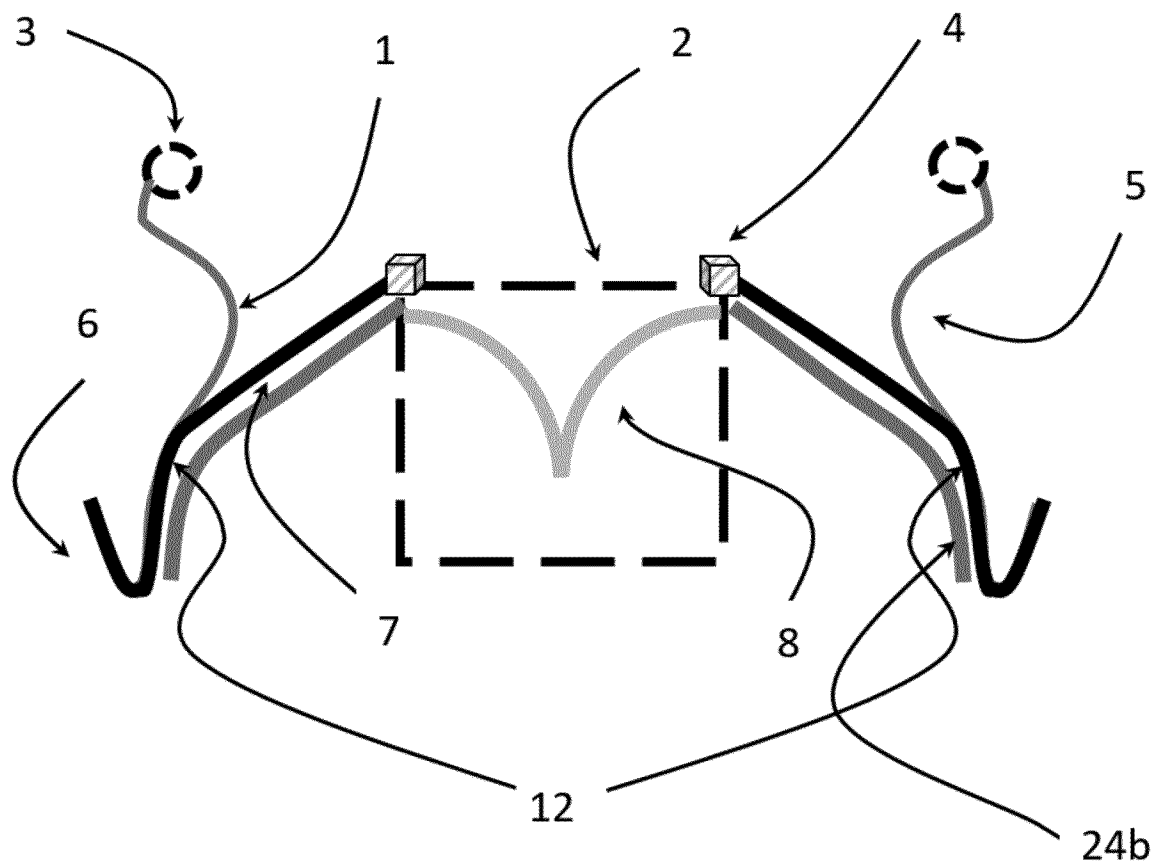


Fig. 18

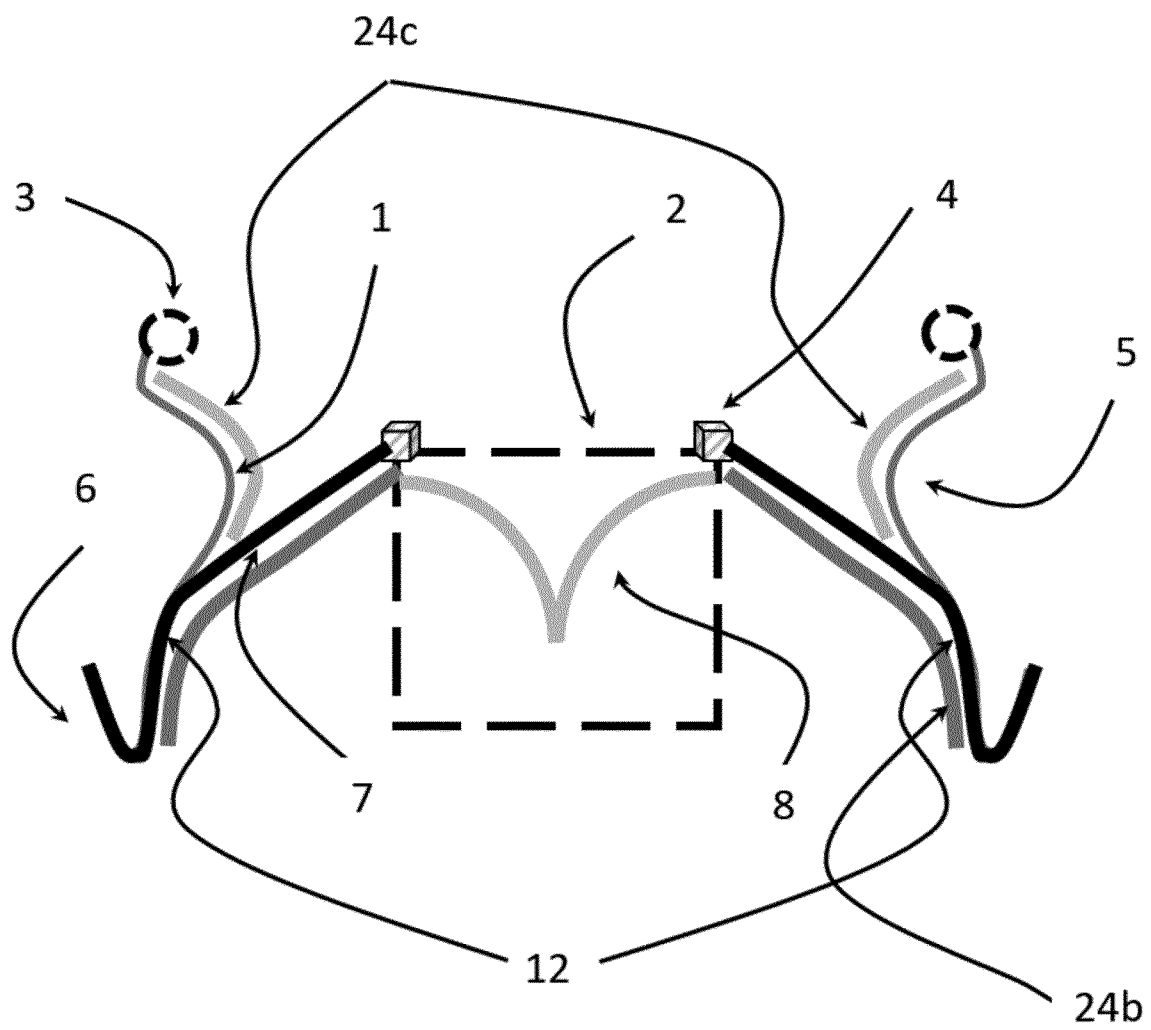


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/051955

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/24 A61F2/852 A61F2/95
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 2018/338832 A1 (GANESAN K; IYER R; MORTIER T J; SCHNEIDER L T; SCHWEICH C J) 29 November 2018 (2018-11-29)	1-16,18, 20,21
Y	paragraph [0041] - paragraph [0061]; figures 3, 12, 14 paragraph [0104]	17,19
X	----- EP 3 202 371 A1 (TRICARES [FR]) 9 August 2017 (2017-08-09) paragraph [0078] - paragraph [0085]; figure 2 paragraph [0114] - paragraph [0135]; figures 7A-C ----- -/-	1-16,18, 20,21



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

18 March 2020

Date of mailing of the international search report

26/03/2020

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Varone, Anna

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2020/051955

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. ☒ Claims Nos.: 22-25
because they relate to subject matter not required to be searched by this Authority, namely:
The methods according to claims 22-25 are considered a method for treatment of the human or animal body by surgery (Rule 39.1(iv) PCT) as it involves the insertion and implantation of an implant to an implantation site in the heart.
2. ☐ Claims Nos.:
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:
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/EP2020/051955

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/055629 A1 (OBA TRAVIS ZENYO [US] ET AL) 1 March 2018 (2018-03-01) paragraph [0113] - paragraph [0114]; figure 11d paragraph [0135] paragraph [0445] - paragraph [0453]; figure 18 -----	1-16, 18, 20, 21
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