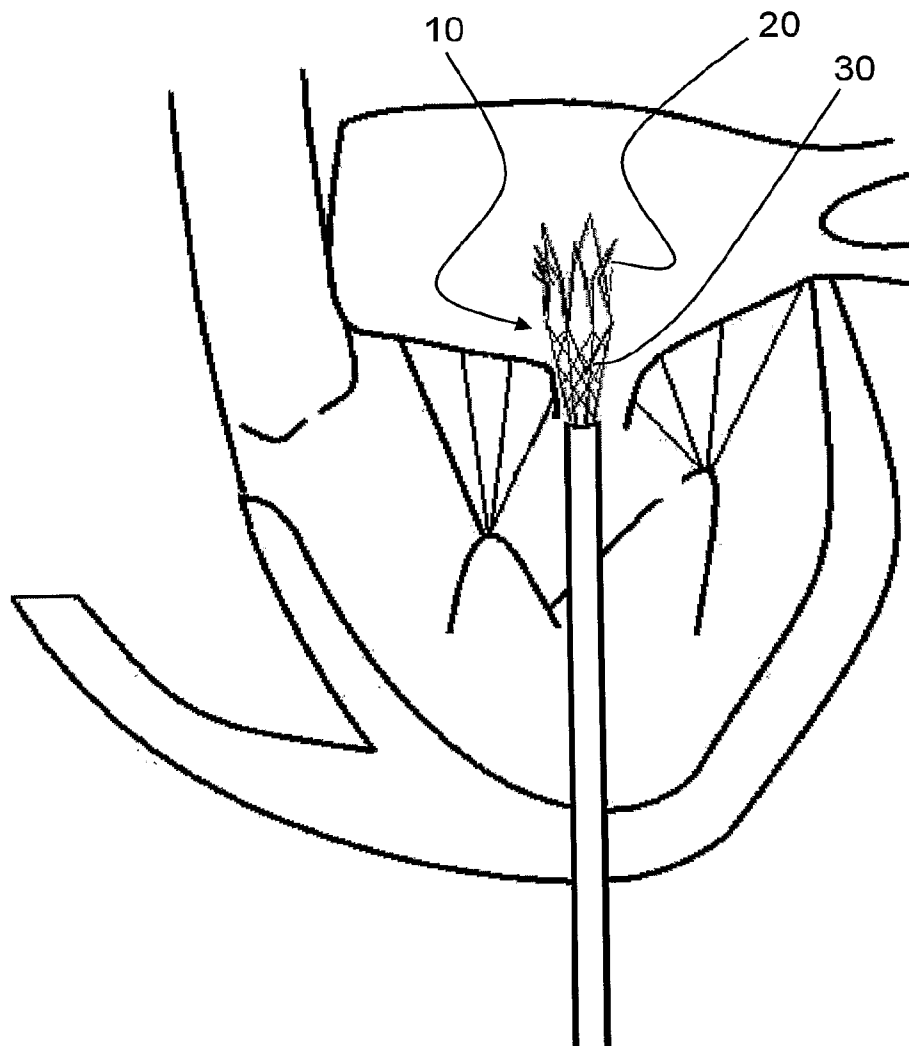




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(19) **United States**(12) **Patent Application Publication**
Lutter et al.(10) **Pub. No.: US 2012/0035703 A1**(43) **Pub. Date: Feb. 9, 2012**(54) **TRUNCATED CONICAL HEART VALVE
STENT WITH ANCHORING THREADS AND
METHODS OF USE**(30) **Foreign Application Priority Data**Sep. 13, 2007 (DE) 10 2007 043 830.5
Sep. 10, 2008 (DE) PCT/DE08/01515(75) Inventors: **Georg Lutter, Kiel (DE); Lucian
Lozonschi, Madison, WI (US)****Publication Classification**(51) **Int. Cl.**
A61F 2/84 (2006.01)
A61F 2/82 (2006.01)(73) Assignee: **Tendyne Medical, Inc.**(52) **U.S. Cl.** **623/1.11; 623/1.26**(21) Appl. No.: **13/275,751**(57) **ABSTRACT**(22) Filed: **Oct. 18, 2011****Related U.S. Application Data**(63) Continuation of application No. 12/677,958, filed on
Sep. 9, 2010.

A heart valve stent and methods of use thereof, such stent having a heart valve implant and several proximally disposed tissue anchors, also comprising a plurality of anchoring threads, each with a proximate end fastened to the stent or valve and a distal end attached to tissue within a heart chamber to provide tension between the heart chamber tissue and the stent.



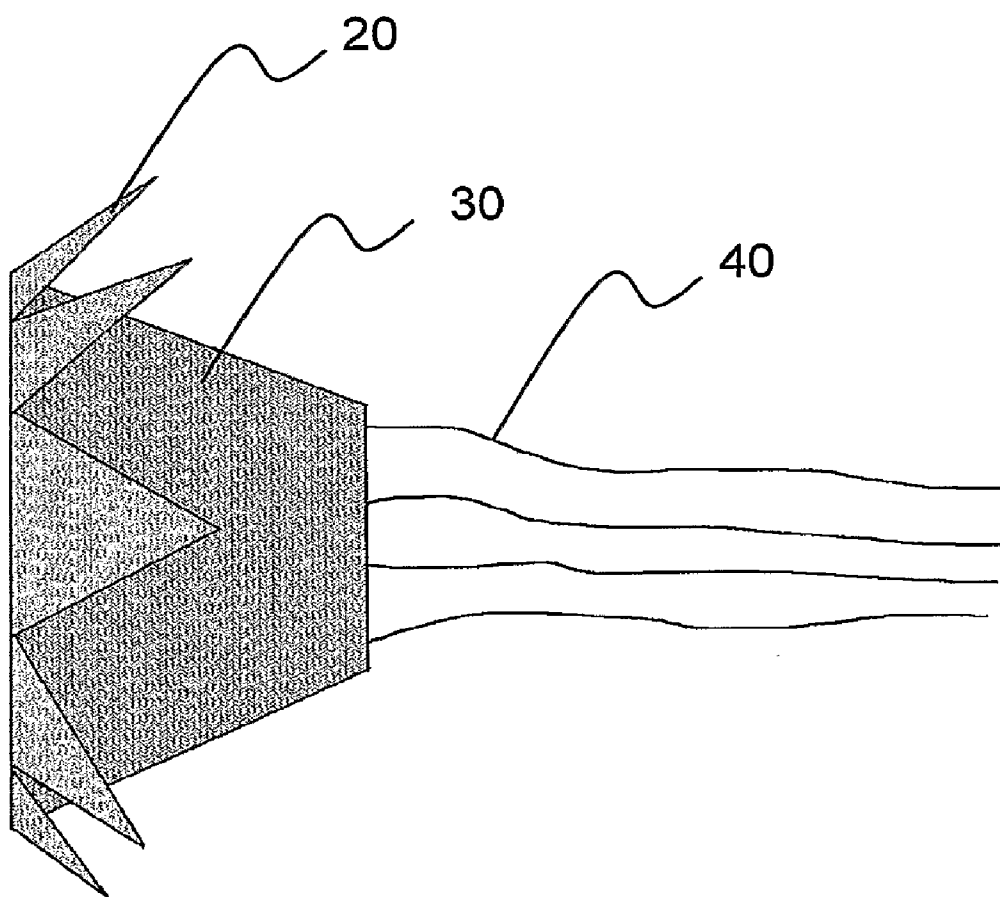


FIG. 1

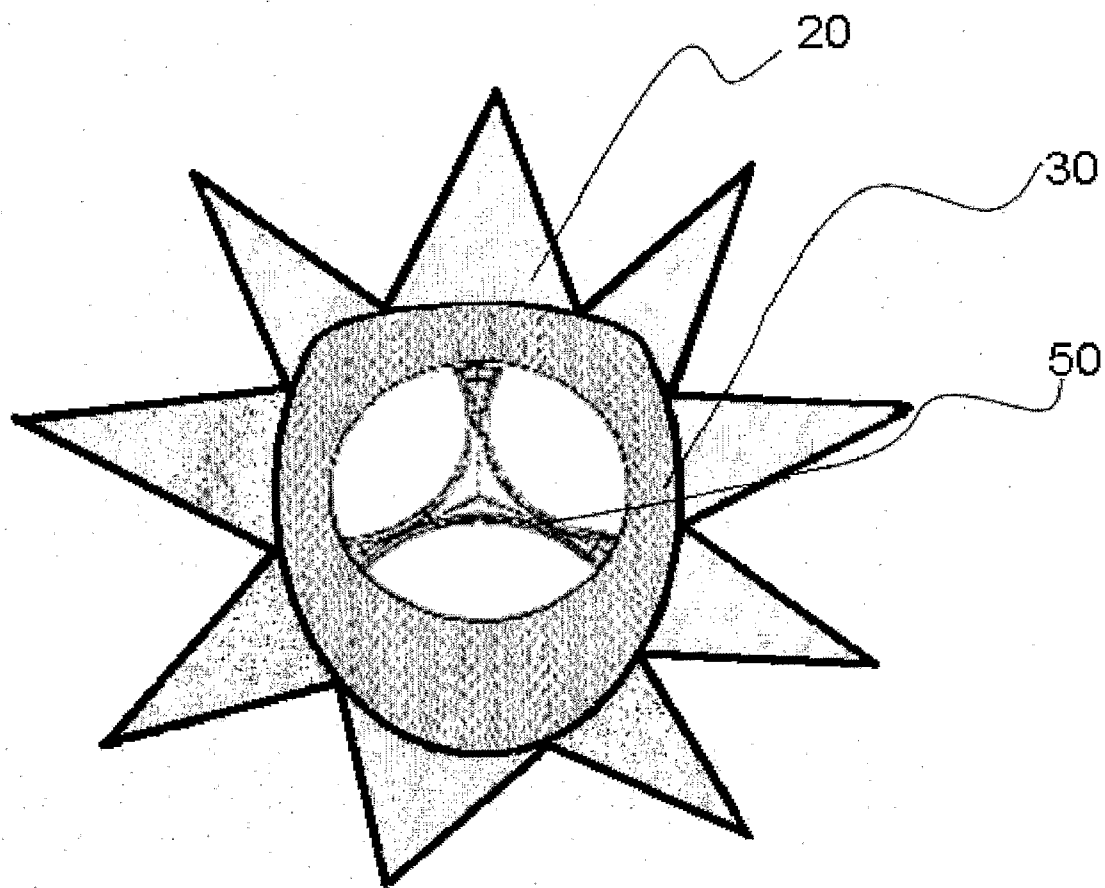


FIG. 2

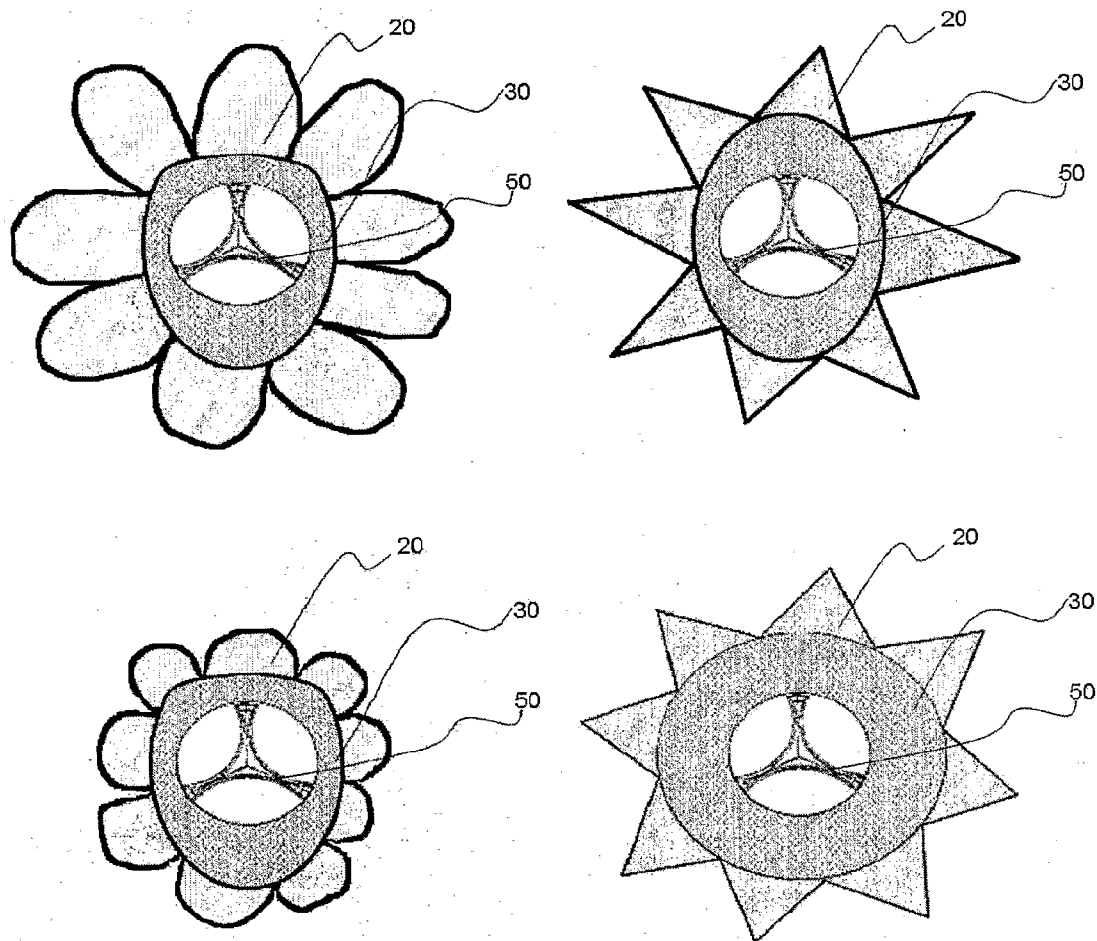


FIG. 3

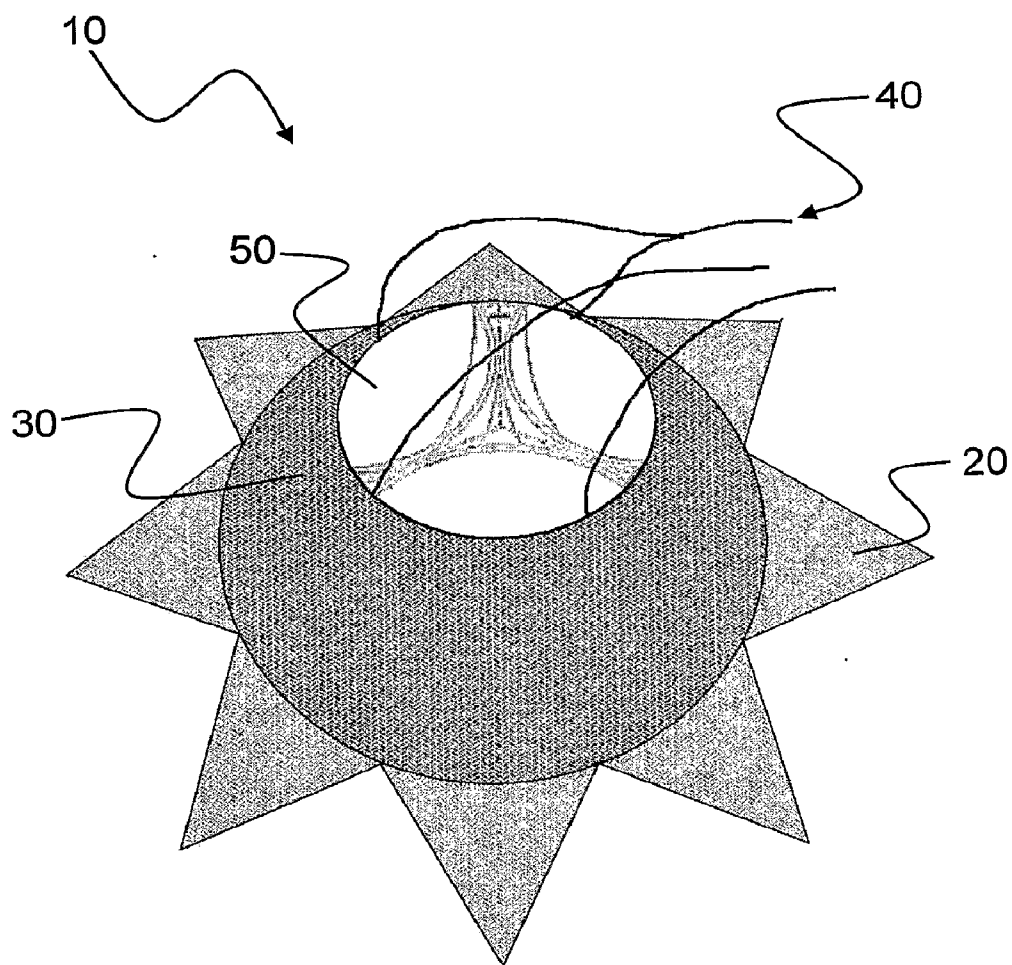


FIG. 4

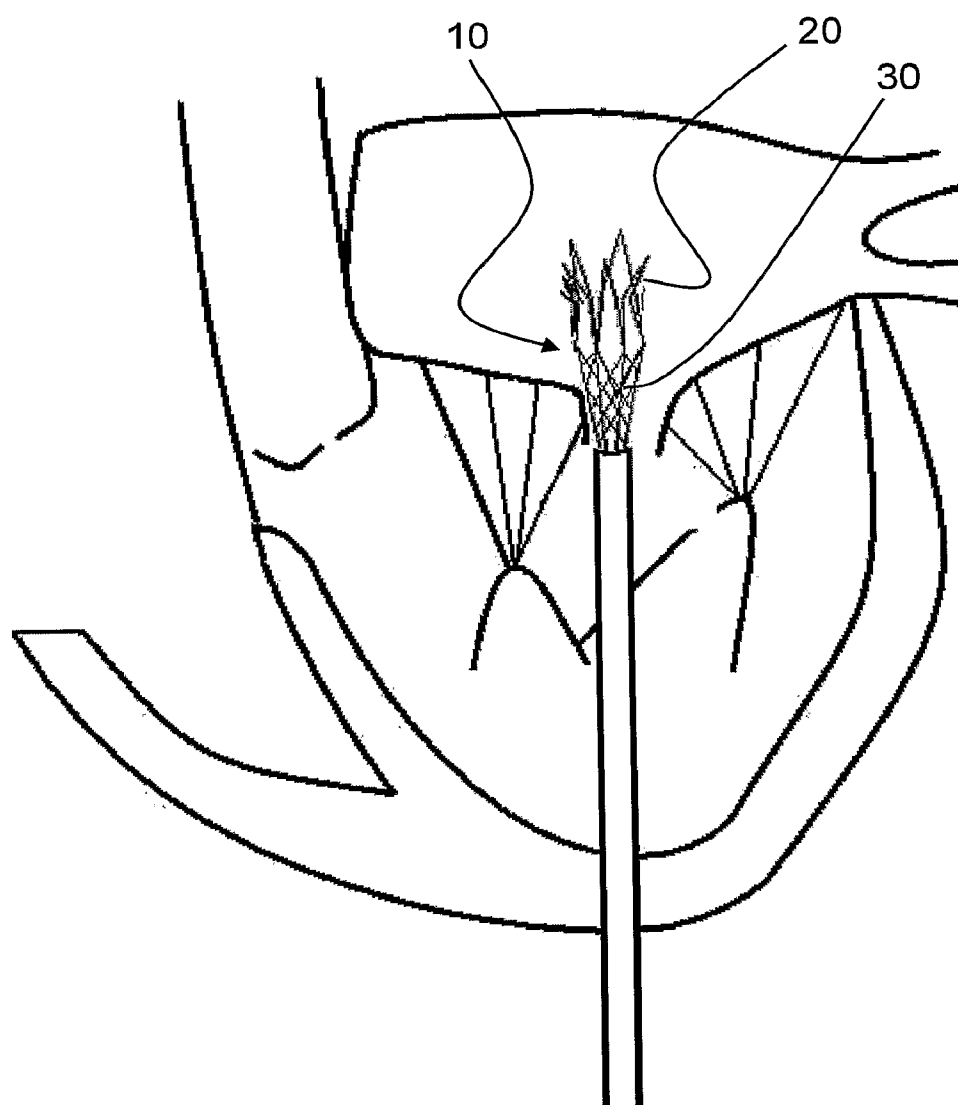


FIG. 5

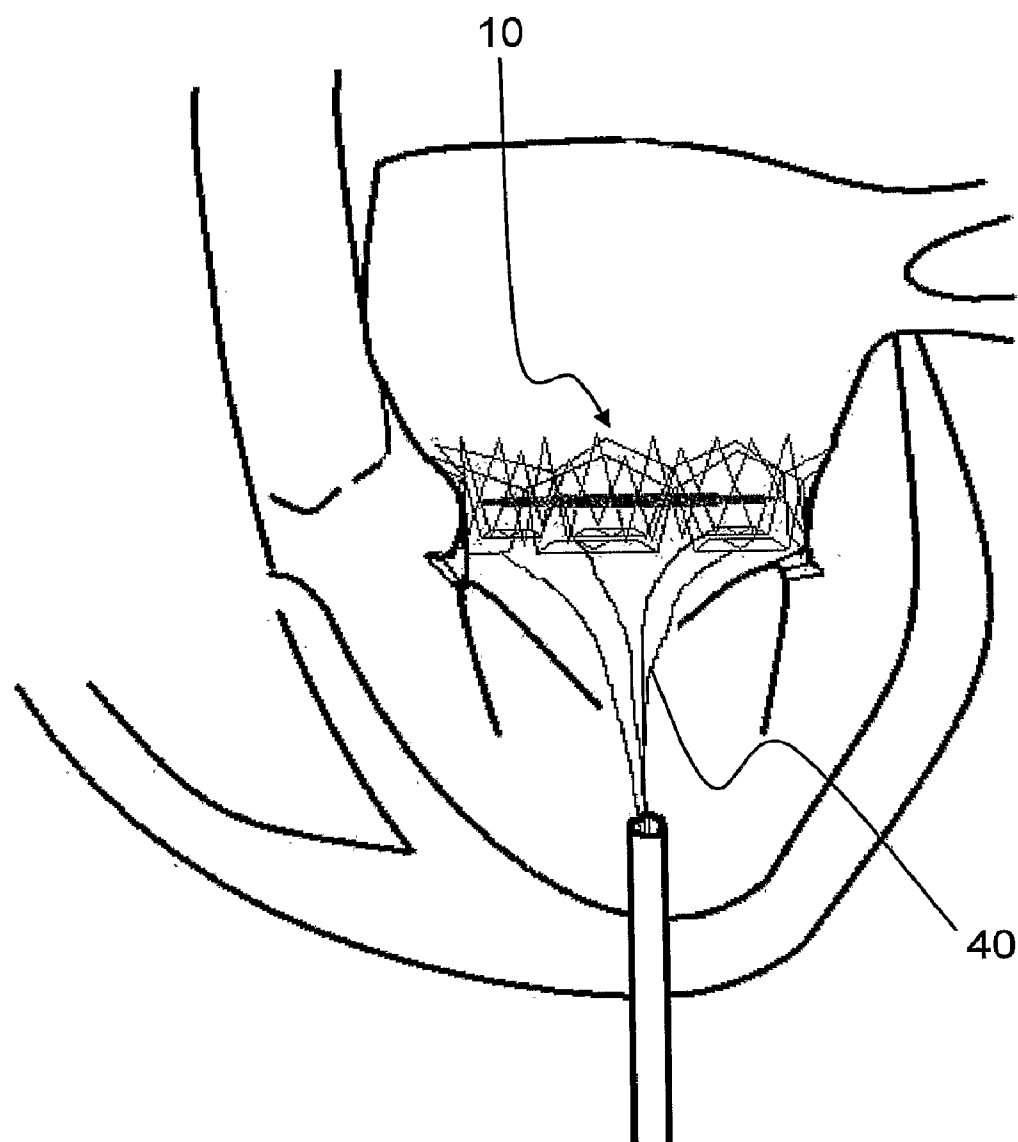


FIG. 6

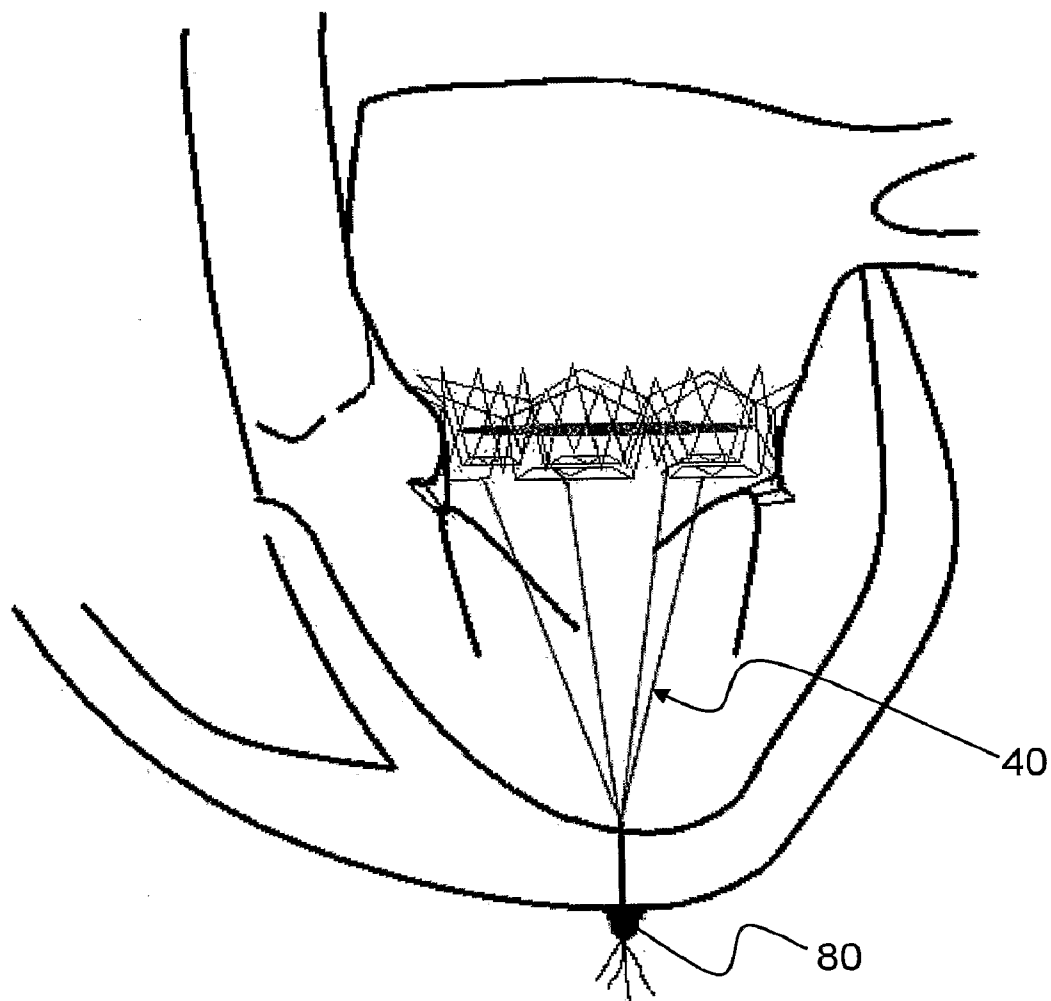


FIG. 7

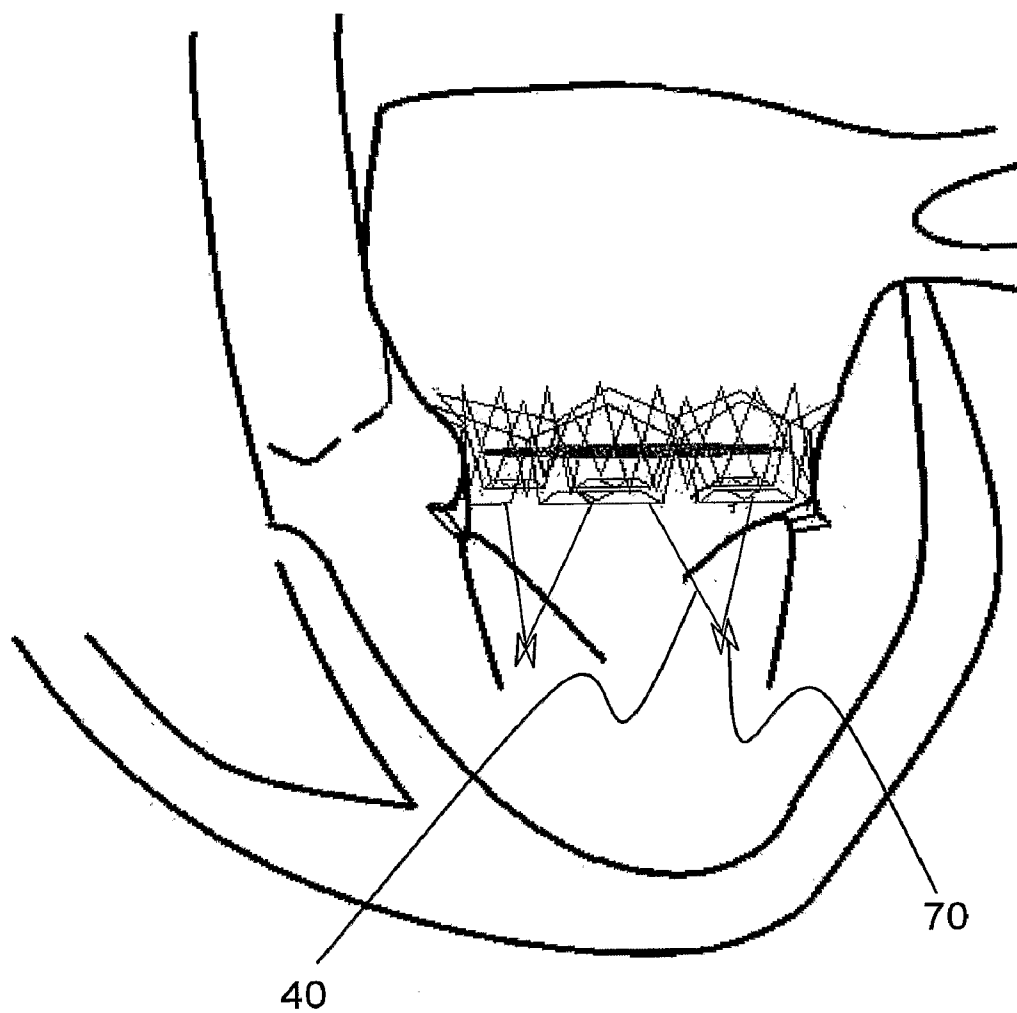


FIG. 8

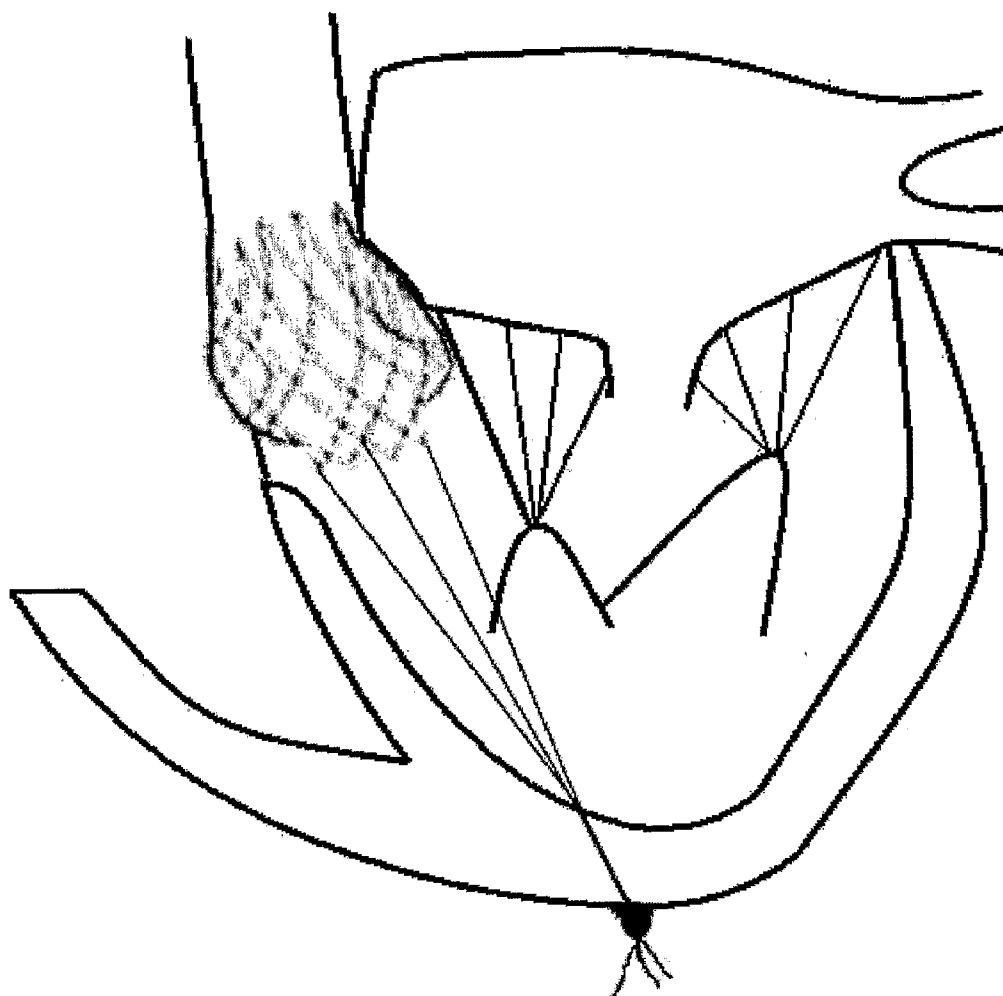


FIG. 9

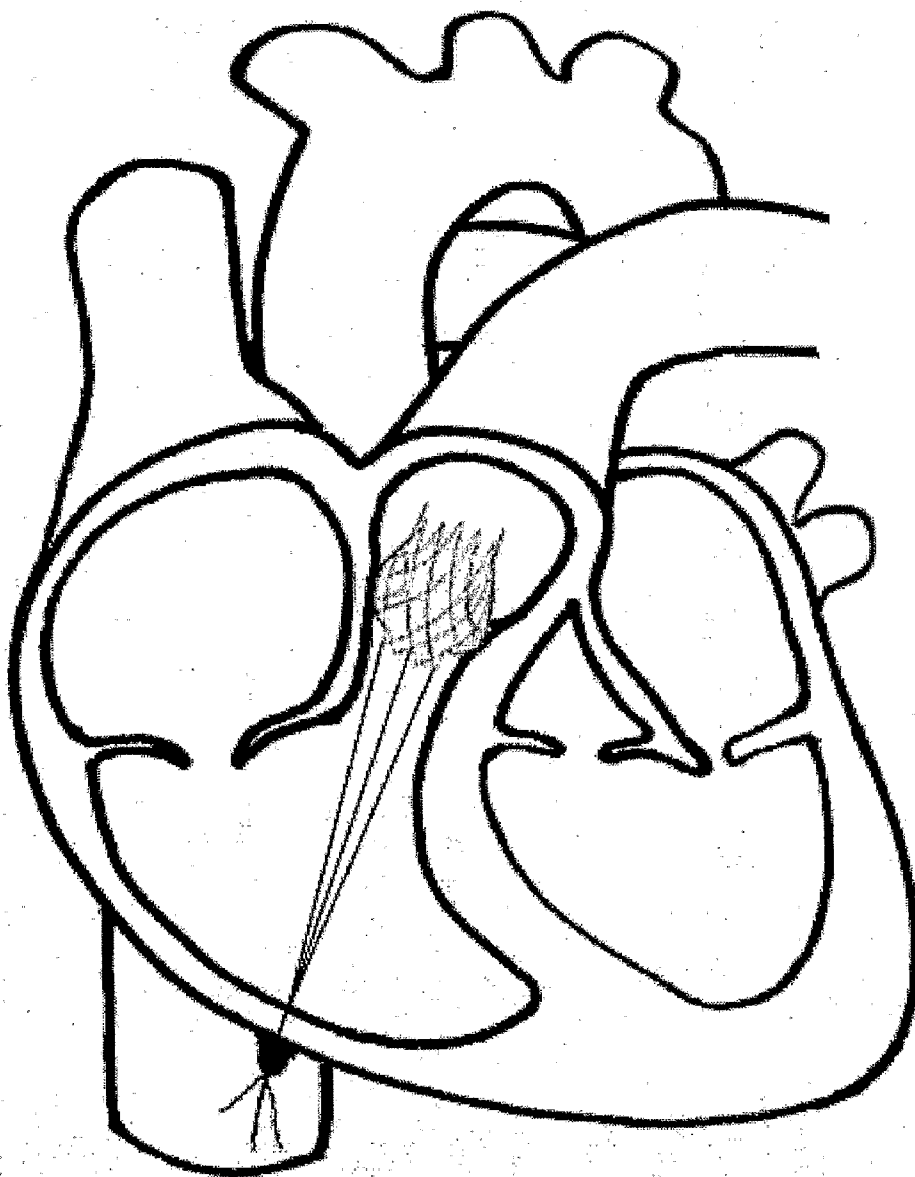


FIG. 10

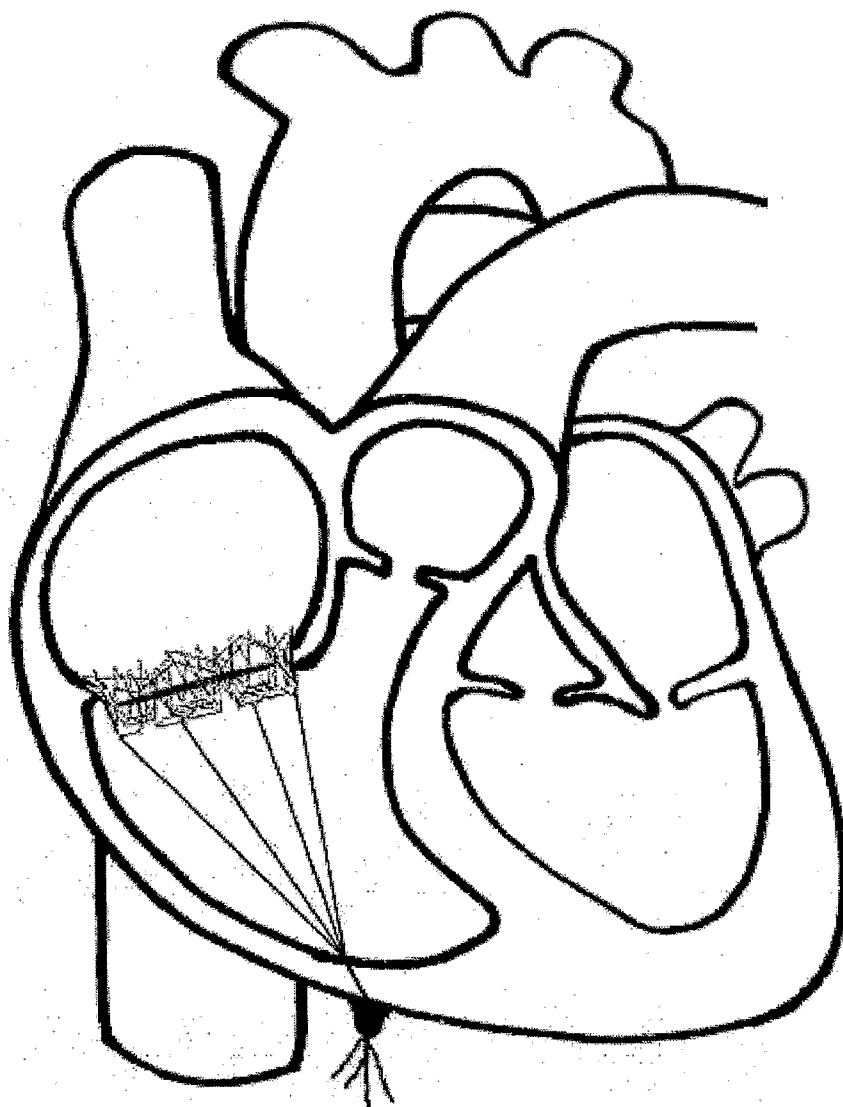


FIG. 11

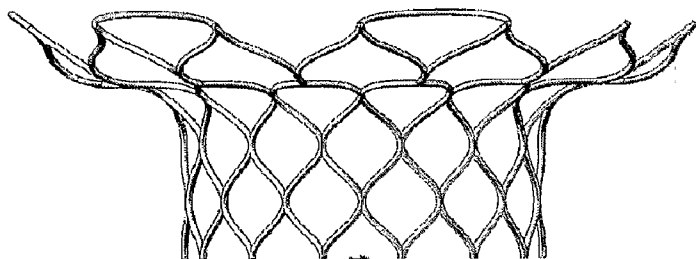


FIG. 12

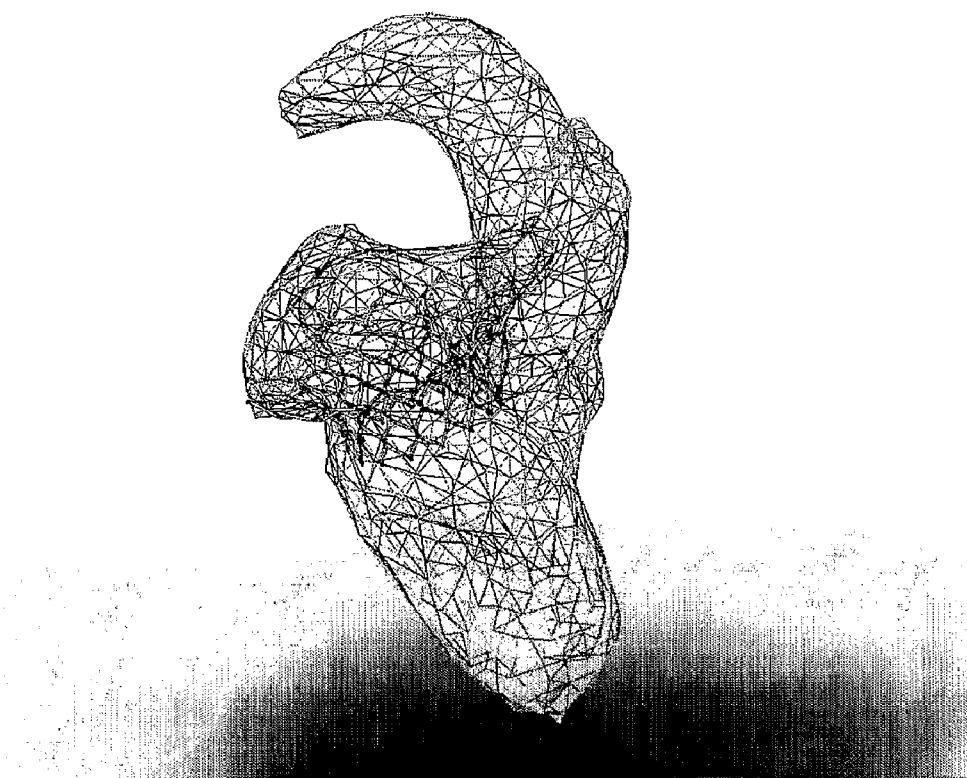


FIG. 13

TRUNCATED CONICAL HEART VALVE STENT WITH ANCHORING THREADS AND METHODS OF USE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the right of priority pursuant to 35 USC §120 to Ser. No. 12/677,958, filed Sep. 9, 2010, pursuant to 35 USC §199(a) to PCT/DE2008/001515, filed Sep. 10, 2008, and to parent German application no. 10 2007 043 830.5, filed Sep. 13, 2007, each of which is incorporated herein by reference in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] No federal government funds were used in researching or developing this invention.

BACKGROUND

Field of Invention

[0003] The invention refers to a valve stent with a section equipped to receive a heart valve implant and several of proximally disposed anchoring elements.

[0004] Such heart valve stents are known in various forms for the replacement dysplastic and degenerated heart valves. Thereby, the surgical implantation of heart valve prostheses is regularly accomplished in the cardioplegic heart. The old, functionally degenerated heart valve is resected and the new, implantable heart valve is sewed in.

[0005] However, when the mitral valve is affected, one tries, as far as possible, to maintain the old valve in spite of its malfunctioning so that the entire dynamic mitral valve apparatus is not disturbed. The reason for this is that, for instance, the chordae tendineae, which are attached to the mitral valve are very important for ventricular function. Therefore, they should preferably not be removed from the old mitral valve.

[0006] Ideally, the mitral valve (in case the old valve cannot be reconstructed) will be pushed aside as far as possible to make room for a new valve. Space does not play such an important role as compared to the aortic annulus which can be more easily stenosed (i.e., during displacement of the old aortic valve for sole percutaneous implantation).

[0007] The chordae tendineae of the mitral valve shall be, if possible, structurally maintained to preserve the ventricular geometry and hence of the left ventricle or achieve optimal function of the left chamber as far as possible. Therefore, a best possible function of the left chamber is obtained and achieved. Of significant relevance is that the anterior mitral valve leaflet is not pushed aside into the free space toward the left ventricle, but rather that it is attached to the mitral annulus so that a press forward of the anterior leaflet into the left ventricular outflow tract (LVOT) is avoided ("sam" phenomenon: systolic anterior movement). This is extremely important, because otherwise a left heart decompensation (massive dysfunction of the left ventricle) could rapidly occur.

[0008] Surgically the old mitral valve is attached to the old annulus so that there is a free flow of blood through the valve and both adjacent heart chambers. After pushing aside (attachment of the valve onto the annulus) the heart valve prosthesis is surgically implanted into the annulus.

[0009] This extensive method mandatorily takes place with the help of a heart- and lung-machine. For high risk patients

it is usually not used and minimally invasive and percutaneous methods to perform the implantation of a heart valve are sought.

[0010] In this context, the German patent DE 195 46 692 C2 and the corresponding EP 1 469 797 B1 is known. This patent describes a self-expanding heart valve prosthesis for the implantation into a human body using a catheter system with a heart valve and a foldable, valve-connected and expanding stent. Such a self-expanding heart valve prosthesis can be directed through the femoral artery with the help of a catheter based system to the area of cardiac implantation. After the stent reaches the area of implantation, it can be successively unfolded. Along its long axis, the stent is composed of several, at angles to each other, self-expanding segments that are unfolded gradually. After expansion, the heart valve prosthesis can be anchored with the support of hooks at least in the respective blood vessel close to the heart.

[0011] Another apparatus for the fixation and anchorage of heart valve prostheses is described in the German Patent 100 10 074 A1 which fundamentally consists of wire-like elements attached together. Different brackets are hereby used to secure anchorage and brace a heart valve.

[0012] Even with the known solutions there is still the danger that a heart valve will be incorrectly implanted due to wrong positioning and deficient angular adjustment of the heart valve prosthesis.

[0013] Improved positioning and angular alignment for the aortic valve can be reached by the stent described in the European Patent EP 1 469 797 B1 which consists of supportive holders which can be inserted into the aortic pouches and create a defined distance to the aortic valve. Beyond this, the possibility exists to halt a failed implantation of a heart valve prosthesis and to push the valved stent ("a valve integrated into a stent") back into the catheter delivery system (more precisely the "cartridge"). Thereby, it is possible that the stent can again slide out when good positioning for the valved stent has been reached. Thus, the valved stent can be taken in and out until the optimal positioning has been achieved ("sliding technique").

[0014] A much larger problem for the optimal positioning of the new heart valve in the stent (alternatively valved stent) still exists in the following: in most cases the old, native valve will not be eliminated by the above-described technique of implantation.

[0015] This leads to the fact that the new valve which will be pressed into (partly squashed into) the old, deformed valve will be transformed into the original form. The reason for this is that the location of implantation for the valved stent is affected by the morphology, the shape and consistency of the old native valve (for instance by sclerosis or calcification of the native valve).

[0016] Therefore, the old annulus of the valve with the corresponding changed valves determines to what extent and where the native valve will unfold and whether its form can develop. Hence, for the optimal function of the valve and maintenance of the atrial and ventricular function not only the anchorage/positioning is important, but also the fitting of the valve stent into the neo-annulus (old valve annulus with old valve shapes it) and with it the pushing back of the old valve.

[0017] Based on the fact that there are known problems of the valved stents, the challenge of this intervention is to produce a heart valved stent, especially a mitral valved stent,

for minimally-invasive transplantation, which preferably facilitates the natural functioning of the heart.

[0018] Referring to the invention, this problem will be solved with the heart valved stent and its features from claim 1. The subclaims provide advantageous designs for setting up the intervention.

[0019] The basic idea of the invention is to produce a heart valve stent which establishes the anatomic requirements for the natural exertion of the function—like a healthy heart. In the process, the invention-related heart valve stent with its self-expanding, foldable embodiment establishes a minimally-invasive operation which assures an exact positioning and secure fixation of the valve stent. Thereby, a tension between the mitral valve and ventricle similar to the natural tension of the chordae tendineae is generated, and at the same time it will be provided that the valve parts of the old mitral valve (especially the anterior mitral valve leaflet) will not disturb the flow rate of the blood.

[0020] Therefore, it is intended that the valve stent, according to the invention, is catheter-inserted into one of the heart chambers or into the adjacent large vessels of the heart, then unfolded in one of the heart chambers, whereupon its anchoring elements are fixed in the tissue. Finally, the stent is fixed at its opposed, subvalvular wall of the heart chamber under development of a tension between the wall of the heart chamber and the proximal, supra-annular, fixed anchoring elements with anchoring sutures (hereafter referred to as neo-chordae).

[0021] The fixation of the anchoring sutures in the distal wall of the heart chamber exhibits a thrust bearing to the proximal anchoring elements which will be established by a joint or another element acting as a thrust bearing. This counter bearing can be preferentially designed also as an adjusting element for the length of the sutures.

[0022] Advantages of the heart valve stents which according to the invention are the exact and easy fixation of the heart valve stent and improved contractility of the heart in minimally invasive operations in comparison with customary valve stents.

[0023] Preferentially, the axially, relatively to the longitudinal axis, arranged anchoring sutures are fixed according to the invention (the valve stent) with one end to the annulus of the heart valve implant, so that after development of a tension between the stent and the wall of the ventricle, the positioning and the angular arrangement of the valve can be directly impacted. The anchoring sutures can also be fixed at the distal part of the circumference of the valve stent. The connection between the anchoring sutures and the stent has to be conducted so that a tension which should run fundamentally in an axial direction relative to the long axis of the stent and is formed between the proximal anchoring elements and the distal counter bearing.

[0024] According to another preferential design of the invention, the anchoring sutures (neo-chordae) have elements to adjust the length of the anchoring sutures so that through the length of the anchoring sutures a certain tension between the heart valve stent and the heart wall can be regulated.

[0025] Thereby, an adjusting element, for example, for the individual length of sutures or for all sutures together can be allowed for. The adjusting element for the length of sutures is preferably designed small and can, for instance, be constructed in such a manner that this element shortens the suture to the desired length by rolling up the excess thread.

[0026] The construction of the elastic anchoring sutures along the axis are also preferred so that they are able to react

to heart contractions without having too many sutures that might negatively affect the heart function. Here the suture length should be selected so that the elasticity is not sacrificed due to the tension between the anchoring elements and the heart wall.

[0027] After adjusting the counter bearing of the adjusting element to the length of sutures, a notably beneficial design is made so that also a re-adjustment of the tension between the anchoring elements and the counter bearing, i.e. a re-tensioning of the anchoring sutures is possible without opening the heart.

[0028] Especially favored is the structure of the mitral valve stent which is fundamentally oval or u-shaped in the plane of the mitral valve annulus so that no pressure to the LVOT (left ventricular outflow tract) and/or aortic annulus is exerted. Therewith damage to the heart's function is stopped (Ma L, Tozzi P, Huber C H, Taub S, Gerelle G, von Segesser L K. Double-crowned valved stents for off-pump mitral valve replacement. *Eur J Cardiothorac Surg.* 2005 August; 28(2): 194-8; discussion 198-9.). Additionally, the subvalvular apparatus also completely retains its natural anatomy and is not compromised (Boudjemline Y, Agnoletti G, Bonnet D, Behr L, Borenstein N, Sidi D, Bonhoeffer P. Steps toward the percutaneous replacement of atrioventricular valves, an experimental study. *J Am Coll Cardiol.* 2005 Jul. 19; 46(2) i360-5).

[0029] This valve stent has for the natural mitral valve apparatus a completely adapted, exceedingly nestled form so that this conically tapered (cranial-caudal axis) not entirely circular (oval-like in the transversal axis) valve stent is able to attach to and abut to the natural form of the mitral valve. In the area of the anterior mitral valve annulus, the valve stent is flat and exerts almost no pressure on and does not constrict the LVOT. In the area of the posterior mitral valve annulus, it is oval and replicates a form like the posterior annulus. This valve stent forms a thin, restricted along the length (cranial-caudal) structure which in its form aligns completely to the mitral valve and thus in the area of the natural mitral valve annulus looks like a negative impression of it. In fact, the valve stent contacts the old mitral valve and the annulus, but leaves their anatomy completely unchanged.

[0030] In the following the invention will be closely elucidated by means of the attached figures representing the particularly preferred execution examples. It shows:

[0031] FIG. 1 a favored execution example of the valve stent according to the invention in a schematic lateral view;

[0032] FIG. 2 the demonstrated execution example in FIG. 1 with top view from above;

[0033] FIG. 3 top view on several especially preferred valve stents according to the invention;

[0034] FIG. 4 a top view from an execution example from below;

[0035] FIG. 5 a schematic view which explains the minimally-invasive transplantation of the mitral valve stent according to the invention in a first phase of insertion of the mitral valve stent into the location of transplantation;

[0036] FIG. 6 a schematic view for the demonstration of the minimally-invasive transplantation of the mitral valve stents according to the invention in a second phase after positioning of the mitral valve;

[0037] FIG. 7 a schematic view for demonstration of the minimally invasive transplantation of the mitral valve stent after completion of the fixation of the anchoring sutures outside of the apex of the ventricular heart wall;

[0038] FIG. 8 a schematic view of an alternative, intra-cardiac fixation of the anchoring sutures in the area of papillary muscles;

[0039] FIG. 9 a schematic view of a heart valve stent which is fixed in the aortic annulus according to the invention;

[0040] FIG. 10 a schematic view of a heart valve stent which is fixed in the pulmonary position according to the invention;

[0041] FIG. 11 a schematic view of a heart valve stent which is fixed in the tricuspid position according to the invention;

[0042] FIG. 12 an especially preferred execution example of the valve stent (according to the invention) in a schematic lateral view without heart valve and anchoring sutures; and

[0043] FIG. 13 a schematic dorsal, intra-cardiac view of a heart valve stent which is fixed in the mitral position according to the invention.

[0044] FIGS. 1 to 11 indicate the stent according to the invention for the implantation and fixation of heart valve prostheses in different views to show the configuration of the stents and the spatial relations of individual parts of the stent to each other in an unfolded (FIGS. 1-4 and 6-11) and in a folded condition (FIG. 5).

[0045] FIG. 1 shows a foldable mitral valve stent 10 according to the invention in a perspective lateral view. The stent 10 exhibits mainly three parts: proximally (supravalvularly) on stent 10 there are several serrated, arched anchoring (FIG. 3) elements circularly arranged which are able to anchor supravalvularly (respectively atrially) the valve stent 10 in an implanted condition. The preferable stent body 30 flattened to the LVOT is distally adjoined and is conical and in cross section ovally shaped (compare FIG. 2).

[0046] The stent body 30 forms a basket- or trapezoid-like figure which nestles to the mitral valve annulus and extends in the direction of the left ventricle. This stent 10 is held in the atrium due to its conically-tapered form and due to the atrial anchoring elements 20. A bi- or tri-leaflet valve 50 can be integrated into the stent body 30.

[0047] At the distal part of the stent body 30 (to the direction of the left ventricle) there are anchoring sutures 40 which are distally equipped to the stent body 30 for the anchorage of the entire stent 10. These anchoring sutures 40 provide for an anchorage in the opposed wall of the ventricle or for instance in the area of the papillary muscles 30 (proximal, medial or distal part of the papillary muscle); compare FIGS. 7 and 8. With the help of an adjusting element to regulate the length of sutures 70, these anchoring sutures 40 can be positioned and adjusted to the optimal length so that the heart valved stent 10 can be fixed and anchored.

[0048] FIG. 2 indicates the stent 10 in a top view. Thereby, it can be distinguished that stent 10 forms a neo-annulus, alternatively a stent body 30 in which the heart valve prosthesis 50 can be implanted and in which it can be fixed. Furthermore, it can be recognized that the invention-like stent 10 can be shaped asymmetrically in relation to several supravalvular (atrial) stent brackets 20.

[0049] This can be identified by the fact that the stent body 30 is oval-like and flattened on one side as seen in this figure, so it (the stent body 30) can be installed with its flattened side towards the direction of the LVOT. This flattening has the consequence that no pressure on this side towards the LVOT and towards the aortic valve can be exerted from the self-expanding stent in case the stent 10 is used, i.e. in the mitral

position. Further favored embodiments of the stent 10 are indicated in FIG. 3 according to the invention.

[0050] FIG. 4 demonstrates the invention-pertaining stent 10 from a bottom view. From this it is obvious that the diameter of the atrial part to the ventricular part of the stent body 30 becomes smaller so that this looks like a truncated cone from the lateral view (compare FIG. 1). The anchoring elements 20 as well as the stent body 30 can be upholstered with cloth (i.e. synthetics, pericardium, PTFE or Goretex, etc.) to achieve better sealing between the heart valve prosthesis 50, stent body 30 and the surrounding heart structure. This sealing membrane is tapered/alternatively upholstered between the heart valve prosthesis 50, the stent body 30 or onto the atrial stent struts 20 to achieve optimal sealing of the valve between both heart chambers.

[0051] In FIGS. 5 to 7 and 8, the retrograde trans-apical implantation of the valved stent is described. The retrograde trans-aortic as well as the antegrade trans-atrial approach can stent above the old mitral annulus is shown in FIG. 5. A slow unfolding (preferred self-expanding) of the atrial anchoring elements 20 can be started after successful orientation with support of labeling at the valve stent 10 (not shown). The positioning in the left atrium should be done in that way that the flattened side of the stent body 5 is turned towards the direction of the LVOT (aortic valve). The stent will be further expanded.

[0052] FIG. 6 indicates the expanded valve stent 10 in the left-atrio-ventricular in-flow tract. Anchoring sutures 40 are adjusted in or outside the wall of the heart and later—as shown in FIG. 7—they will be fixed with the support of the thrust bearing 80 which is favorably designed as an adjusting element for the length of sutures. During the adjustments for the length of the anchoring sutures 40, visualization of the mitral valve apparatus (i.e. Echo, CT, NMR) is carried out so as to optimally pull the annulus of the new stent 10 toward the ventricular wall, paravalvular leakage no longer exists, the stent 10 can be fixed in a good manner, and the mitral valve annulus and—apparatus support advantageously the left ventricular function.

[0053] Alternatively to FIG. 7, the anchoring sutures 40 can also be fixed at the papillary muscles (see FIG. 8) so that these sutures 40 represent the neo chordae and take 20 over the function of the functionless chordae tendineae. The fixation of the anchoring sutures 40 at the wall of the heart in each case result from a thrust bearing 80 which can be developed as a knot or also as an independent element. It is also possible that the ventricular anchoring sutures 40 are not only affixed to the stent body 30, but also at the integrated valve itself. The caudal anchoring sutures 40 can also be fixed at any other point of the ventricle.

[0054] FIG. 7 shows the accomplished positioning and fixation of the stent 10. After the length and location of the single anchoring sutures 40 has been determined, these anchoring sutures 40 will be fixed with the suture-length adjusting elements 70, for instance, in the left ventricular wall. The suture-length adjusting element 70 is used for the optimal calibration of the length and position of the valve stent 10 and therefore for the valve prosthesis 50. Different sutures 40 can exhibit different length and fixing positions in the ventricle.

[0055] FIGS. 9 to 11 demonstrate additional examples for the application of the valve stent 10 according to the invention, whereas the stent 10 is readjusted to the particular

anatomy (for the aortic- and pulmonary valve position a rather circular form (compare FIG. 3) and for the tricuspid position a rather oval form).

[0056] FIG. 12 shows an especially preferred designed execution example of the valve stent pertaining to the invention in a schematic lateral view which is shown without heart valve and anchoring sutures for a better clearness. For clarification in FIG. 12 of the positioning of the valve stent in situ, FIG. 13 demonstrates a schematic, dorsal, intra-cardiac view of a fixed heart valved stent in the mitral position according to the invention. Note the good alignment of the valved stent with the left atrial environment. Distances between the left atrial wall/mitral annulus and the valved stent are avoided. Heart valve and anchoring sutures for the ventricular apex have been omitted for simplification.

We claim:

1. A heart valve stent, shaped as a truncated cone, comprising: a foldable, self-expanding stent body section equipped with a heart valve implant; a plurality of tissue anchors attached to a proximal end of the stent body section in a radial pattern; and a plurality of anchoring threads, each such thread having a proximal end attached to the stent and a distal end anchored to the tissue of the heart chamber via a tissue anchor.

2. The heart valve stent of claim 1, further comprising at least one suture-length regulatory element for adjusting the length of at least one of the plurality of anchoring threads.

3. The heart valve stent of claim 1, further comprising a plurality of serrated, arched or triangular atrial anchoring elements radiating outward from the upper rim of the stent body section.

4. The heart valve stent of claim 1, further comprising wherein the heart valve implant is integrated within in the lumen of the stent body section near or at the proximal end of the stent body section.

5. The heart valve stent of claim 1, further comprising wherein at least one of the plurality of anchoring elements is made from a shape memory alloy.

6. The heart valve stent of claim 4, wherein the plurality of anchoring threads are attached around the annulus of integrated valve implant directly.

7. The heart valve stent of claim 1, wherein the plurality of anchoring threads are of varying lengths for multiple positions of tissue affixation within the ventricle.

8. The heart valve stent of claim 1, wherein distal ends of the plurality of anchoring threads are attached to, without limitation, tissue from one or more of the following areas: the chamber wall, the papillary muscles, the chordae tendineae, or the ventricular apex.

9. The heart valve stent of claim 8, wherein the distal ends of all anchoring threads perforate the heart apex and attach to a pledget or button resting on the outside of the apex pericardium.

10. A heart valve stent, shaped as a truncated cone, comprising: a foldable, self-expanding stent body section with a

heart valve implant; a plurality of serrated, arched or triangular atrial anchoring elements attached to a proximal end of the stent body section in a radial pattern; said heart valve implant integrated within the lumen of the stent body section, at or near the proximal end of the stent body section; a plurality of anchoring threads made of material with elastic properties, each such thread having a proximal end attached to the stent and a distal end anchored to the tissue the heart chamber via a tissue anchor made of a shape memory alloy; at least one suture-length regulatory element for adjusting the length of at least one of the plurality of anchoring threads; and wherein the distal ends of the plurality of anchoring threads are attached to, without limitation, tissue from one or more of the following areas: the chamber wall, the papillary muscles, the chordae tendineae, and the apex.

11. A method of delivering the heart valve stent of claim 1 via catheter insertion into one of the heart chambers, either by percutaneous or intravenous delivery, wherein the stent is folded within the catheter for delivery and then unfolded in a heart chamber, whereupon the tissue anchors radiating from the proximate end of the stent body section are fixed into supra-ventricular tissue.

12. The method claim 11, further comprising affixing the proximal ends of the plurality of anchoring threads either at intervals around the distal rim of the valve stent or at similar intervals around the annulus of the inserted valve, while anchoring the distal end of each thread to tissue inside the heart chamber via a tissue anchoring element.

13. The method of claim 12, further comprising wherein the distal ends of the threads are anchored to the tissue of one or more of the areas within the group comprising the ventricular apex, the chordae tendineae, the papillary muscles, and the chamber wall.

14. The method of claim 13, further comprising wherein the distal ends of all anchoring threads perforate the heart apex and attach to a pledget or button resting on the outside of the apex pericardium

15. The method of claim 13, further comprising wherein the lengths of the anchoring threads are adjusted by one or more adjusting elements after implantation to provide a degree of tension between the threads and the tissue anchors radiating from the proximal end of the stent body section that is similar to the tension provided a natural valve by the chordae tendineae.

16. The method of claim 14, further comprising wherein the adjusting element(s) remain in place after delivery of the stent, allowing for future re-adjustment of the tension of one or more anchoring threads without opening the heart.

* * * * *