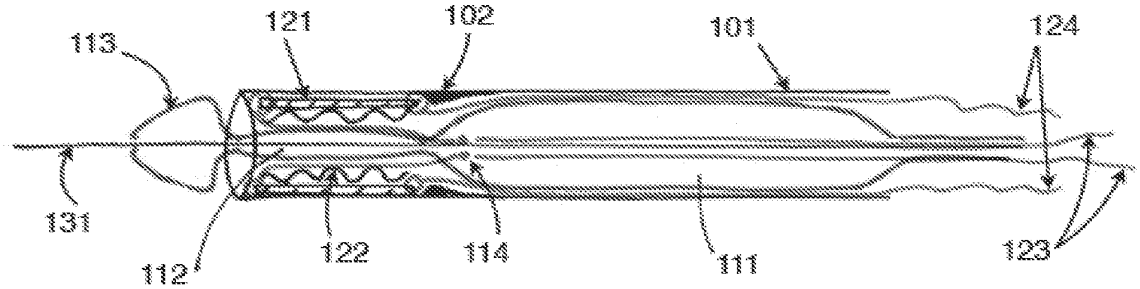
FIG. 4A



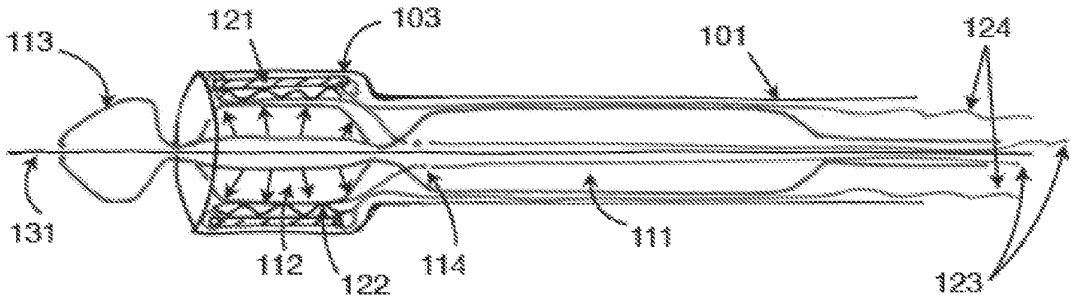


FIG. 4B

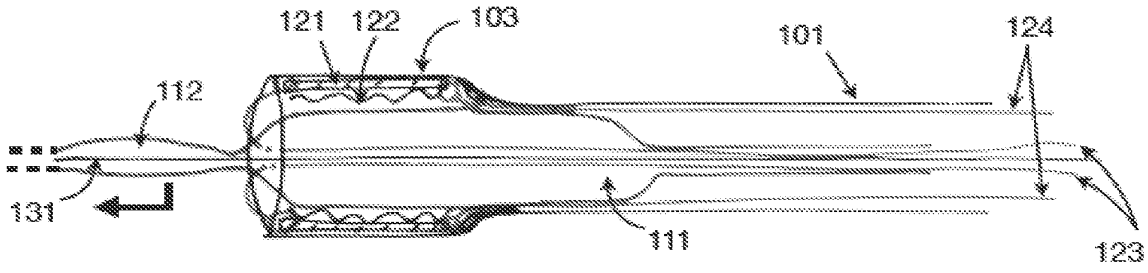
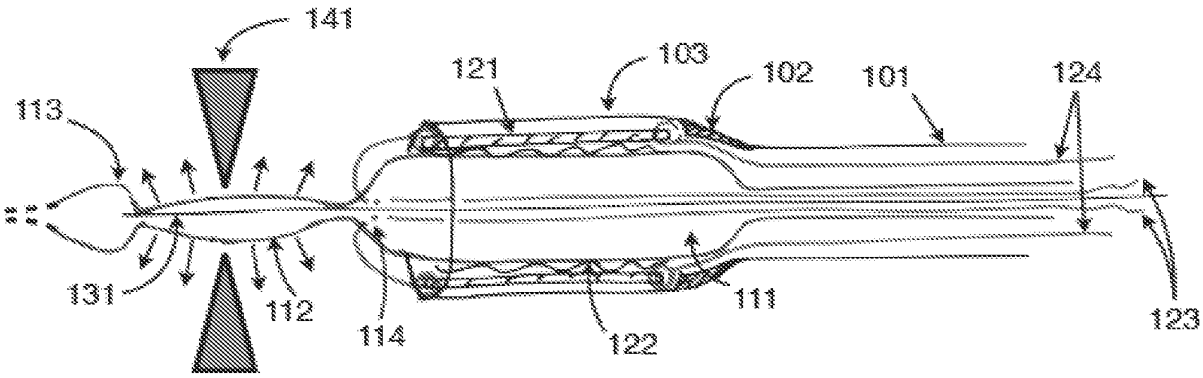


FIG. 4C

FIG. 4D



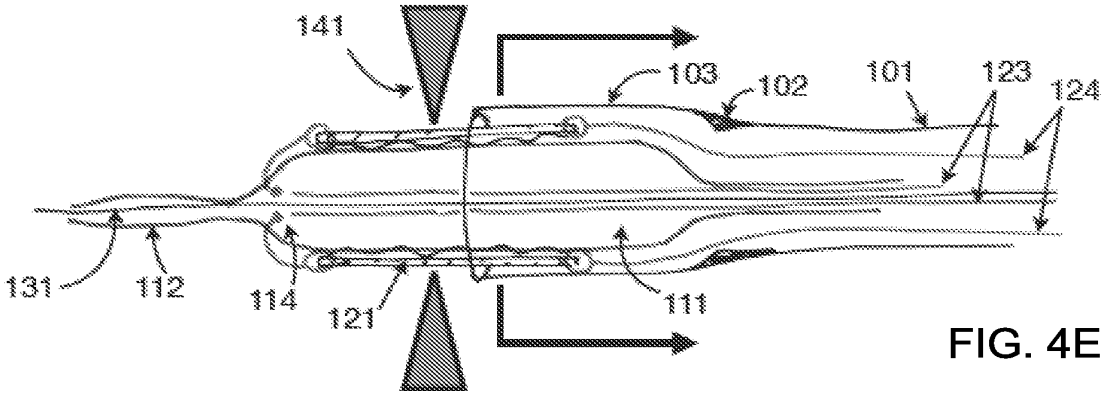


FIG. 4E

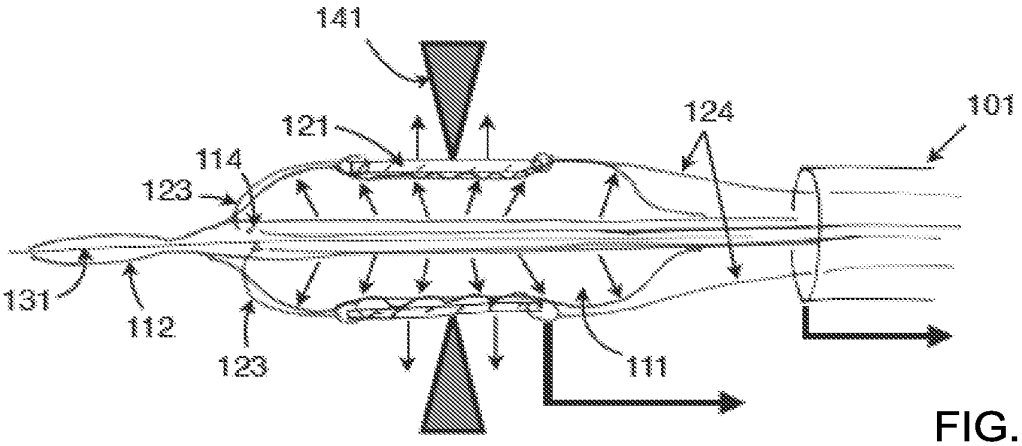


FIG. 4F

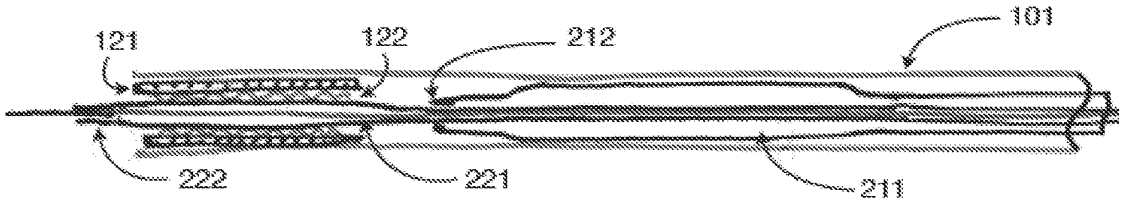


FIG. 5A

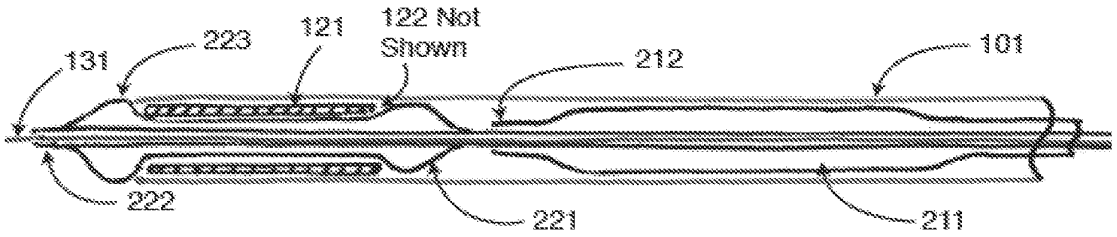


FIG. 5B

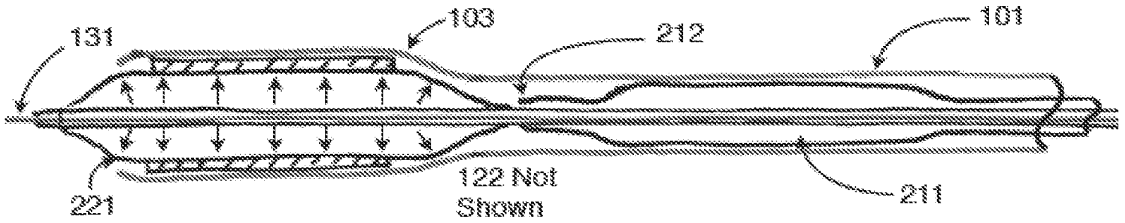


FIG. 5C

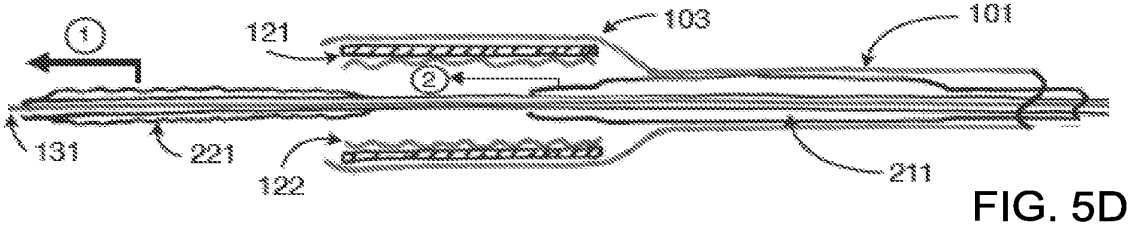


FIG. 5D

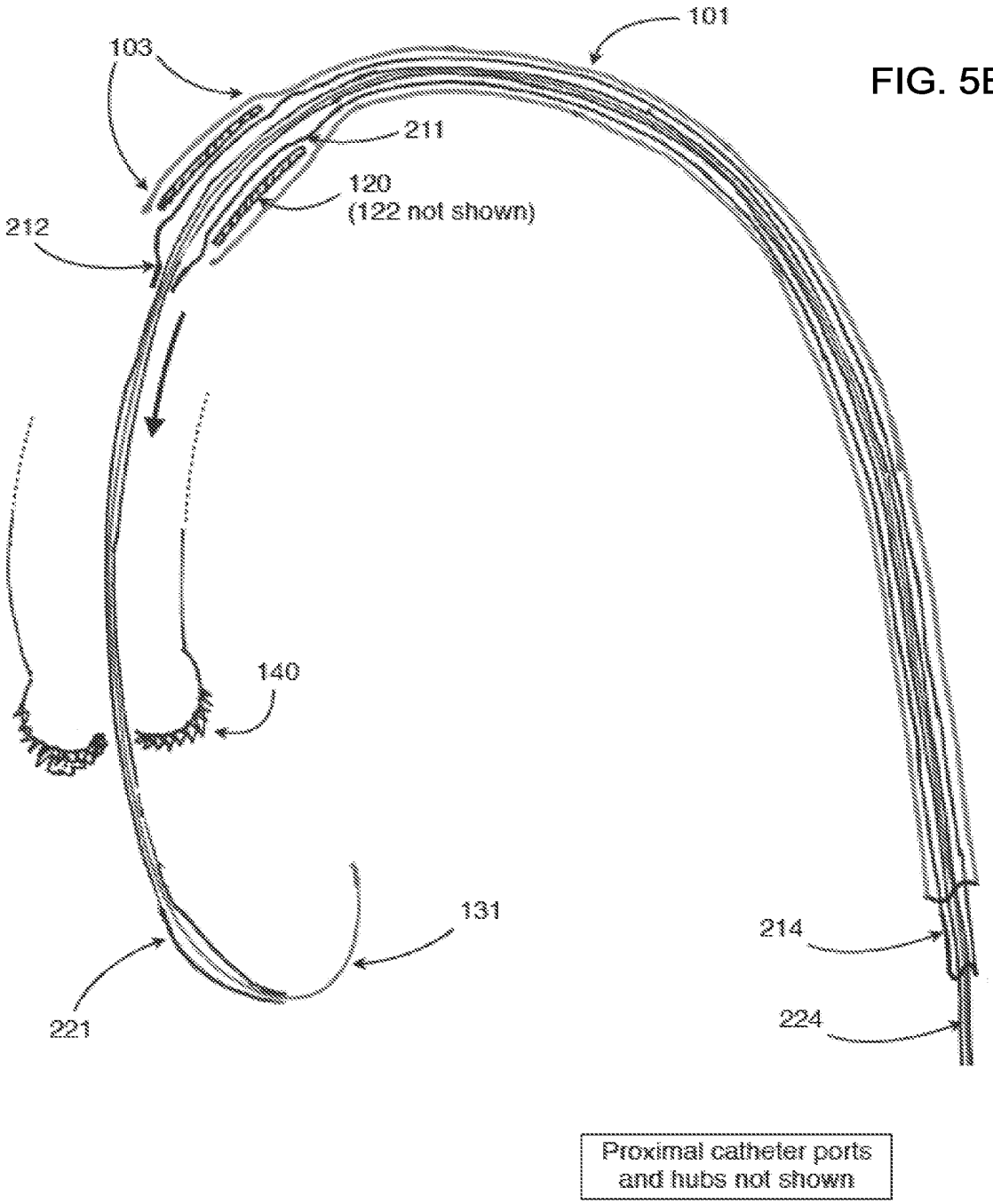
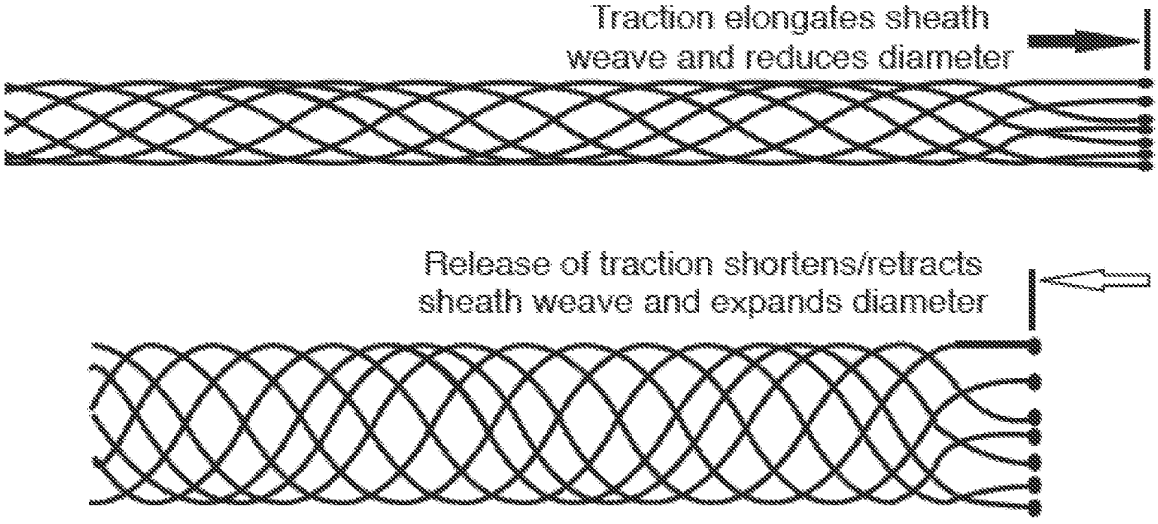

101
103
211
120
(122 not shown)
212
140
131
221
214
224
Proximal catheter ports
and hubs not shown

FIG. 5E

FIG. 6A



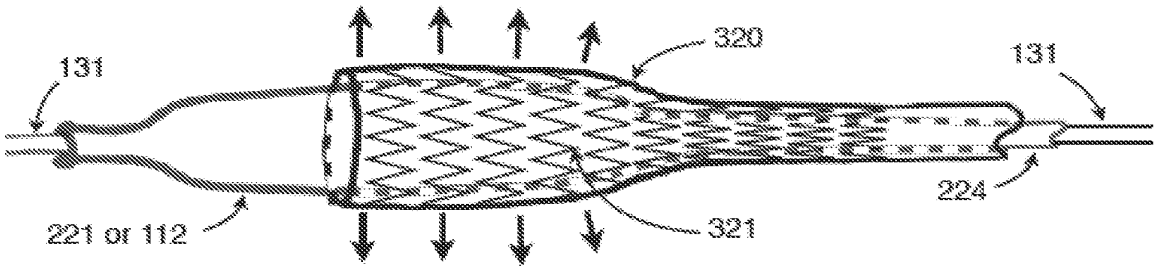


FIG. 6B

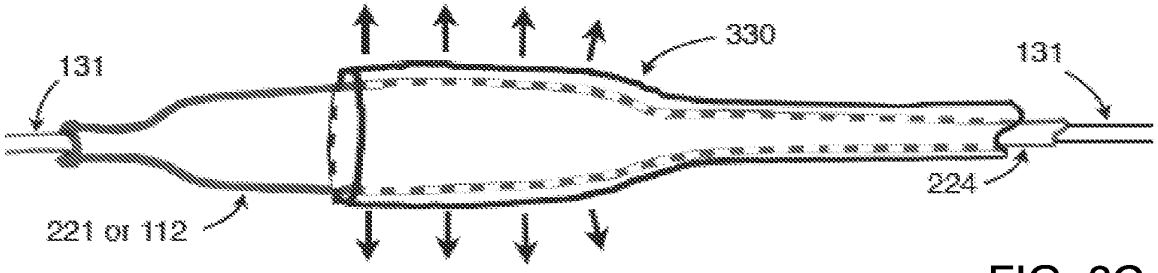
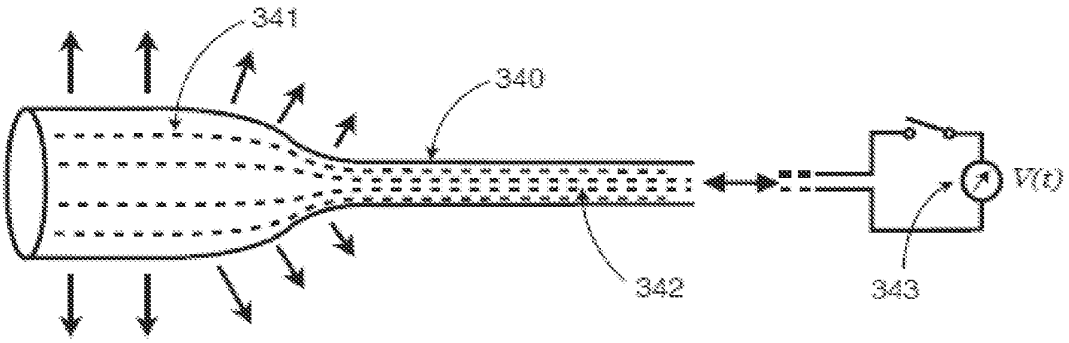


FIG. 6C

FIG. 6D



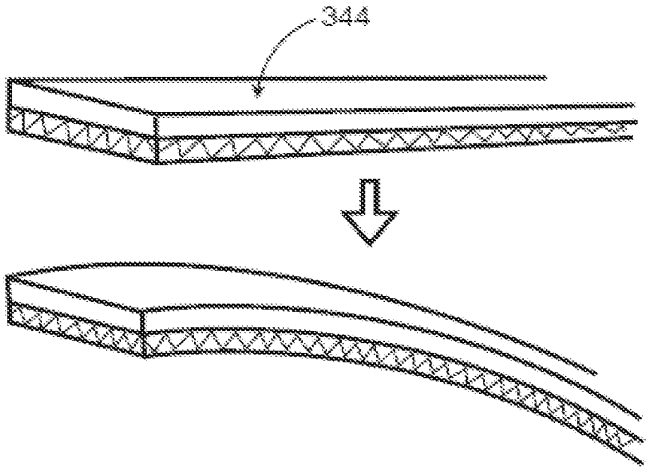


FIG. 6E

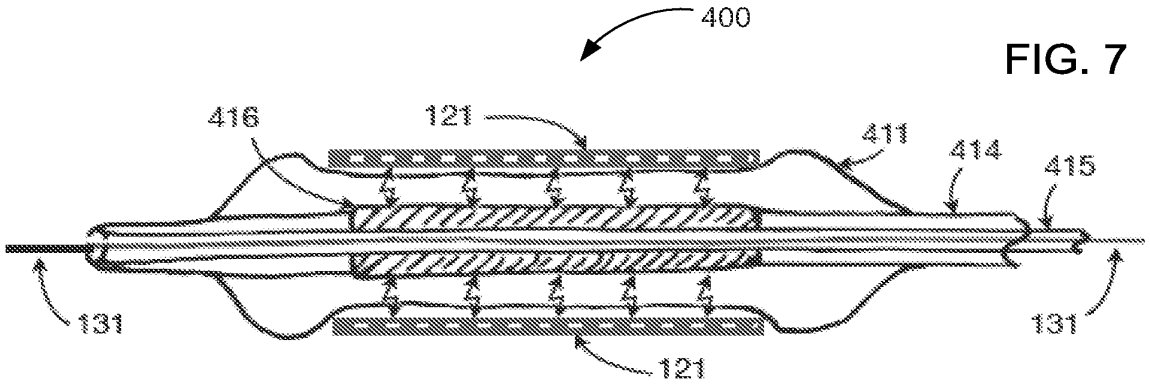


FIG. 7

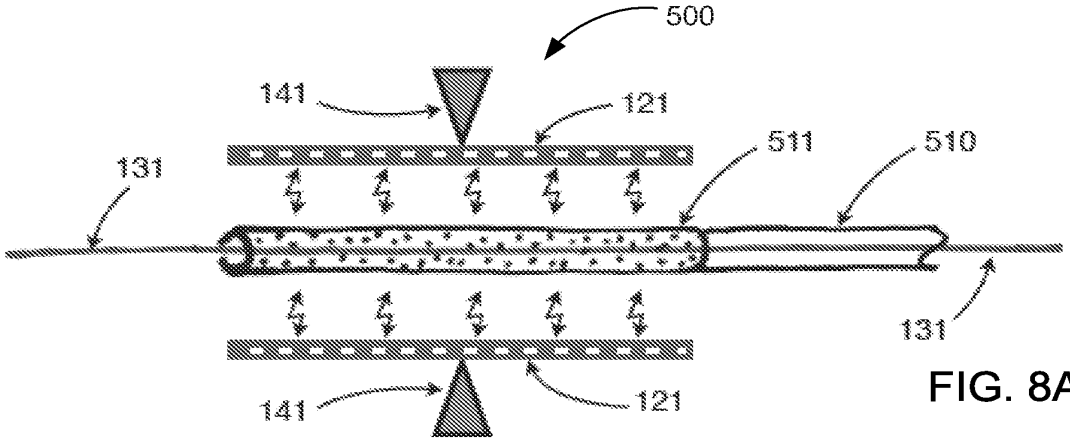


FIG. 8A

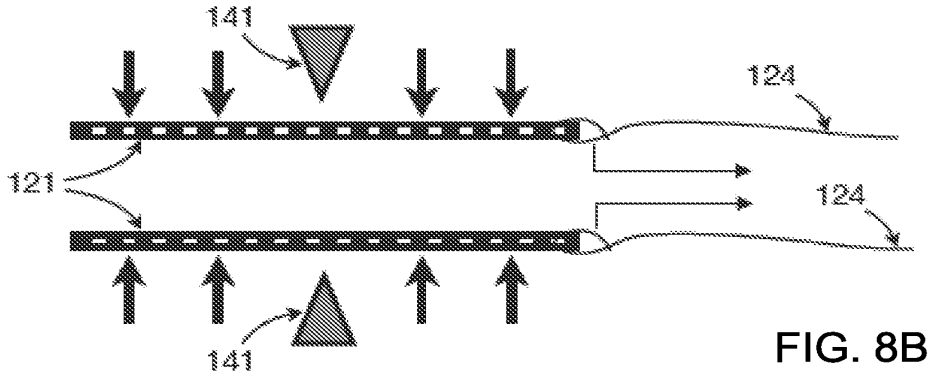


FIG. 8B

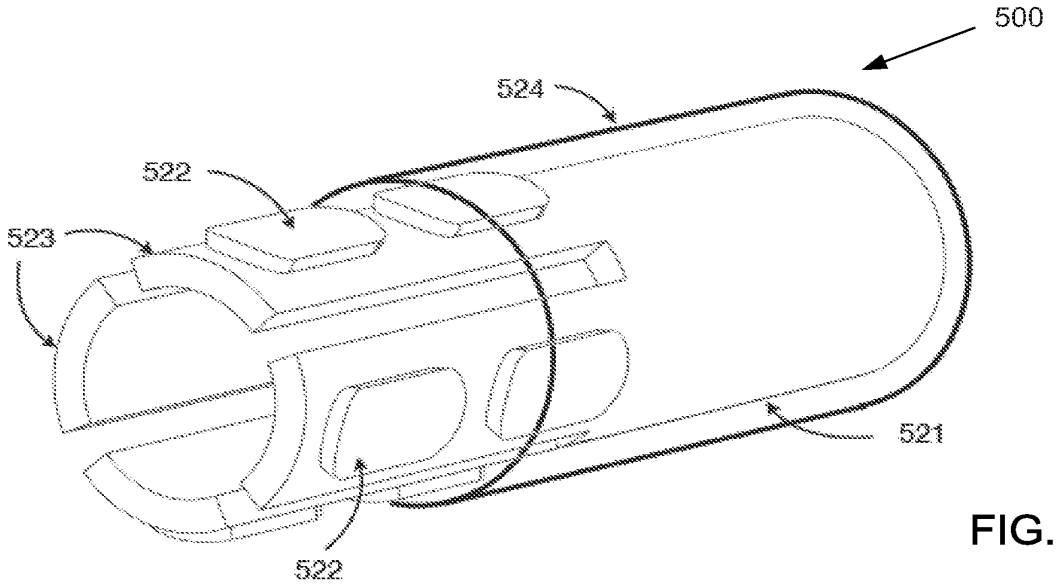

500
524
522
523
521
522

FIG. 8C

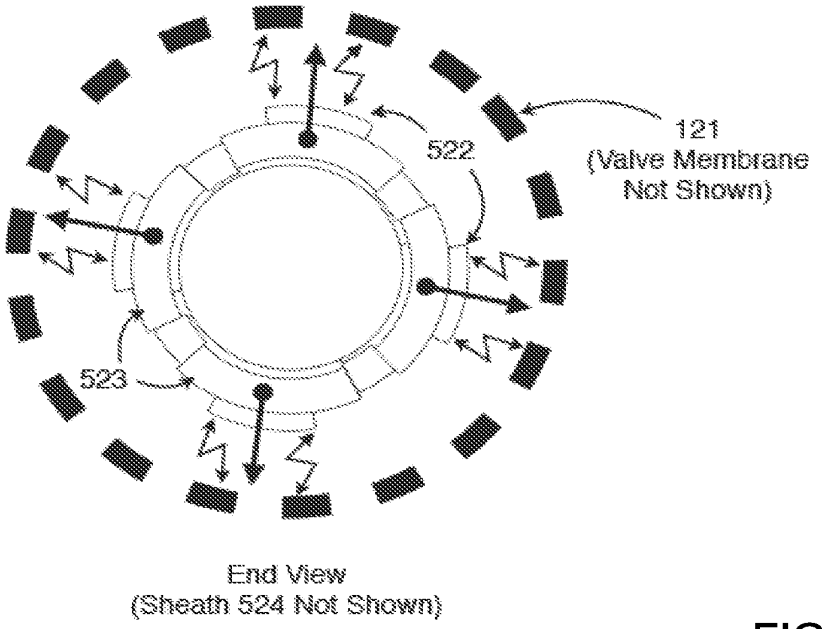

121
(Valve Membrane
Not Shown)
522
523
End View
(Sheath 524 Not Shown)

FIG. 8D

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[Continued on next page]

(54) **Title**: PERCUTANEOUSLY DELIVERABLE HEART OR BLOOD VESSEL VALVE WITH FRAME HAVING ABLUMINALLY SITUATED TISSUE MEMBRANE

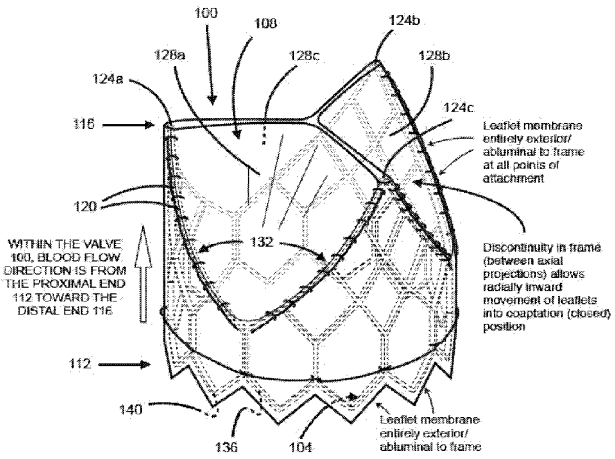

Figure 1A

(57) **Abstract**: A prosthetic valve implantable by catheter without surgery includes a frame with an abluminal surface extending between a proximal end of the frame and a distal end of the frame, and a single layer of a biocompatible membrane material mounted to the abluminal surface of the frame. The single layer of biocompatible membrane is located such that an interior surface of the membrane sheet extends between the proximal end of the frame and the distal end of the frame, and resides radially exterior the abluminal surface of the frame. In at least one embodiment, the disposition of membrane sheet at all points of attachment is entirely exterior/ab luminal to the frame, such that no part of the abluminal surface of the membrane sheet contacts the frame.

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PERCUTANEOUSLY DELIVERABLE HEART OR BLOOD VESSEL VALVE WITH FRAME HAVING ABLUMINALLY SITUATED TISSUE MEMBRANE

FIELD

The present invention relates to the field of medical devices, and more particularly, to a percutaneously deliverable heart valve and to a percutaneously deliverable blood vessel valve.

BACKGROUND

Heart valve disease is a common degenerative condition that compromises physiologic function and causes limiting symptoms and threat to life in millions of patients all over the world. There are various underlying causes, but malfunction of heart valves is ultimately expressed as insufficient conduction of blood through the plane of the valve due to narrowing of the anatomic pathway (stenosis), or as incompetent closure that allows blood to return back through the valve again, thereby reducing the effective forward conduction of blood through the valve (insufficiency or regurgitation). These hemodynamic states lead to 1) deficiency of cardiac output and 2) adverse loads on the pumping chambers of the heart, both of which in turn lead to functional compromise of the patient and often premature death unless effectively corrected.

Definitive corrective treatment of heart valve disease is conventionally performed by open-chest surgical techniques, wherein the valve is manipulated, repaired, or replaced with a prosthetic valve under direct vision. Heart valve surgery is performed in hundreds of thousands of cases yearly world-wide, but carries a high burden of cost, morbidity, and mortality, especially in susceptible patients who may be elderly or otherwise physiologically compromised by collateral disease. Further, the costs and resource requirements of the surgical enterprise restrict the availability of heart valve replacement to many more patients all over the world.

In pursuit of alternatives to heart valve surgery, over the last ten years a number of development programs have brought percutaneous, trans-catheter implantation of prosthetic heart valves into commercial use in the European Union (EU) and into pivotal clinical trials in the United States of America. Initial clinical experience in the EU was directed toward patients who had critical aortic valve stenosis, but were deemed to be at unacceptably high risk for open-heart surgical valve replacement. In several thousand such cases, utilizing both balloon-expandable and self-expanding designs in two separate programs, percutaneous heart valve replacement (PHVR) was shown to be feasible and possibly competitive with surgery in selected patients with 12-18 month mortality rates of about 25%. Grube E., et al., *Progress and Current Status of Percutaneous Aortic Valve Replacement: Results of Three Device Generations of the CoreValve Revalving System*, Circ. Cardiovasc Intervent. 2008;1:167-175.

Typically, the current percutaneous heart valve (PHV) designs, including the commercialized Medtronic CoreValve and the Edwards Lifesciences Sapien valves, comprise a biological membrane forming the operating leaflets of the valve, mounted within the interior of a metal frame, that is then collapsed onto a delivery catheter or balloon, and then constrained within an outer sheath. After an initial dilation of the diseased valve with a large balloon, this assembly is then advanced to the plane of the valve and deployed by self-expansion or by balloon expansion.

PHV designs are confronted by several central challenges. More particularly, the functioning valve leaflets are typically constructed of flexible and compressible tissue membrane valve members attached by sutures to a surrounding stent frame that together must be durable, yet of sufficiently low mass to allow for passage in collapsed form into the patient's body through an anatomic pathway—a peripheral artery, for example—of limited diameter, leading to the implantation site within the central circulation system. This condition favors simple, yet robust design geometries.

Secondly, the PHV in its implanted operating configuration must emulate both the opening mechanics and the closing mechanics of the native heart valve—two differing geometries and mechanical forms afforded by the native anatomy of the aortic valve, for example, but with the limitation that the PHV must effectively embody both within its physical and operational envelope without the benefit of the grossly different anatomical forms native to the aortic valve.

As a practical matter, the measures of effective function are simple—the pressure gradient during forward passage of blood across the valve must be as low as possible, typically 5 - 10 mmHg or less. While achieving this, the "success" of operation in the closed configuration, wherein the leaflets are pressed together along lines of apposition by the pressure of the blood pumped beyond the valve, would also appear to be simply measured by the amount of retrograde blood passage back into the pumping chamber—the "regurgitation" or "leakage."

However, since this closed phase of valve function is the phase in which the principal force loads are applied to the valve membrane leaflets, and since the manner in which the design of the valve distributes these forces determines the durability of the valve, the real measure of the valve's closing function is best understood by how well the design minimizes and distributes the force loads on the valve leaflets. To date, this problem has not been sufficiently addressed.

In the field of blood vessel diseases certain conditions may be advantageously treated by insertion of valves into an affected patient's blood vessels. Currently no such valve devices are available, though investigation of this approach has suggested potential clinical utility for blood vessel valves, and in particular for valves to be inserted into the vein system for particular

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conditions. In the first example, insufficiency of the inlet (atrioventricular) tricuspid valve to the right ventricle of the heart results in regurgitation of blood back into the right atrium, which, serving to receive blood flow returning in the veins from the entire body, then results in turn in suffusion and swelling (edema) of all the organs, most notably in the abdomen and extremities, insufficient forward conduction of blood flow from the right ventricle into the lungs causing compromise of pulmonary function, and ultimately pump failure of the right heart. Collectively these conditions are termed right heart failure, a condition that leads to incapacity and possibly to death if progressive and uncorrected. Often, the remedy is surgical repair or replacement of the tricuspid valve, but results are uncertain, damage to the right ventricle being often irreversible, and progressive heart failure may supervene despite technically successful valve surgery.

In a yet a further example, insufficiency of vein function due to the incompetence or destruction of intrinsic valves within the vein system leads to acute then chronic swelling of the veins and their dependent lymphatics and tissues. This condition can affect the deep veins of the body, commonly the lower extremities or pelvis, or the superficial veins of the lower extremities in particular, leading to progressive expansion of the veins and further valvular incompetence, a condition known as varicose veins. Millions of people worldwide suffer from these conditions and enormous funds are expended on procedures to destroy or remove these dilated incompetent veins. It has long been hoped that some form of implantable valve for the vein system could alleviate these conditions.

Several references of interest have been reviewed in preparation of the present disclosure. The applicants do not admit that the any one or more of the following references constitute citable prior art.

U.S. Patent No. 7,758,632 to Hojeibane discloses a valve construct wherein all embodiments include stent portions that act as proximal and distal anchors that are interconnected by connecting members, and further include a "cantilever valve strut" that acts as a biasing arm to "facilitate the opening and closing of the membrane assembly." Such structures may disrupt the flow channel and potentially interfere with membrane integrity when crimping the valve to mount it on an expandable balloon. In addition, at the point of engagement of the tissue against the connecting members, there is relatively intense focal stress along the straight connecting member – especially at the free edge of the leaflet. Hojeibane further utilizes flaps 403 and cusps 404 that may be independent components attached to the tubular membrane to form the membrane assembly 102. Accordingly, Hojeibane does not appear to use a flat sheet of membrane.

U.S. Patent No. 7,025,780 to Gabbay discloses two separate uses of a device referred to as a "stent." The first use is that of the stent in a surgical valve wherein it is a supportive structure to give shape and mechanical support to the tissue leaflets formed upon it. This device in Gabbay is like a surgical tissue valve. As shown in Figs. 5 and 6 of Gabbay, the stent is disposed outside of at least an inner tissue leaflet layer. In the second use, as shown in Figs. 1 and 2 of Gabbay, a tissue valve of some type is disposed within an outer frame of the vascular stent type. In this case, the tissue layer is not disposed upon the abluminal surface of the outer stent frame. The reader is directed to column 1, lines 61-63 of Gabbay that state "The prosthesis includes a valve apparatus located within a stent apparatus to form a stented valve." Gabbay further references only a "valve apparatus comprising an animal pulmonic heart valve." Accordingly, Gabbay fails to disclose a valve formed of flat tissue membrane wherein the tissue membrane is attached to the abluminal surface of a frame.

U.S. Patent Application Publication No. 2006/0190074 to Hill is directed to venous valves, and as such, the structural embodiments shown in Hill do not appear robust enough for application as prosthetic heart valves, such as in the aortic valve position. The valve material is referred to as a "cover" comprising a matrix and "integrated flexible support members 124" — essentially a reinforcing layer applied to the matrix. While tissue sources of "extracellular membrane" are cited as possible sources for the matrix, the use of a single layer tissue membrane for the leaflets is not disclosed in Hill.

With further reference to U.S. Patent Application Publication No. 2006/0190074, Hill also does not describe how the cover material is attached to the frame to achieve a sufficiently robust construct for utilization as a prosthetic heart valve. That is, while Hill generally discusses attachment of the cover to the frame at Paragraph [0072] using a variety of possible fasteners, none are shown and described relative to the frame. Of particular relevance is that while Hill mentions coupling the cover 108 to the frame 102 at connection regions 132 and 134, there is no mention of coupling the cover 108 to the arcuate portions of the frame members 126 that lead to the connection regions 132 and 134.

Accordingly, there is a need to address the shortcomings discussed above.

SUMMARY

It is to be understood that the present invention includes a variety of different versions or embodiments, and this Summary is not meant to be limiting or all-inclusive. This Summary provides some general descriptions of some of the embodiments, but may also include some more specific descriptions of other embodiments.

As noted above, the real measure of the valve's closing function is best understood by how well the design minimizes and distributes the force loads on the valve leaflets. This

condition favors design geometries in which closing apposition of the leaflet surfaces is achieved with a minimum of traction force on the valve attachment points to the frame. To this end the inventive valve achieves this and other operational advantages by situating the operating tissue membrane to the exterior/abluminal surface of the valve frame rather than the interior/luminal space of the frame and by distributing the operating force loads of the valve along the curved edges forming the distal (downstream to flow direction) end of the frame. No other known percutaneously implantable or even surgical valve bioprosthesis utilizes this configuration with the tissue membrane mounted entirely upon the abluminal aspect of the device frame which carries the closed valve force loads along the distal formed edge of the frame corresponding to the lines of attachment of the leaflet membrane.

Accordingly, in at least one embodiment, an implantable prosthetic valve is provided that includes a frame and tissue membrane. Advantageously, the tissue membrane resides to the exterior of the frame along an axial length of the frame in the flow direction of the implantable prosthetic valve when implanted. That is, the membrane sheet resides entirely exterior or abluminal to the frame when the valve is in the fully open condition and at least at all attachment points when the valve is partly or completely closed. The attachment points may comprise a plurality of sutures that are used to attach the membrane sheet to the frame at a variety of locations, such as at one or more intersections of the frame.

The descriptions of the inventive valve are focused for the purpose of technical specification upon the replacement heart valve application, but will apply as well to the blood vessel valve device. By way of example, in addition to use of the valves described herein to replace heart valves, methods and devices described herein also provide for transcatheter implantation of a valve into the inferior vena cava (the principal conduit vein from the lower body inserting into the right heart) to act as an upstream substitute in part for the tricuspid valve. Such a valve device would be advantageously designed to be low in mass with large effective orifice. The inventive valve device is proposed as suitable to this purpose. Alternatively, the condition of right heart failure may be treated in part by interposing valves into the vein system farther upstream in the venous return flow, such as in the subclavian or principal iliac veins.

Accordingly, in at least one embodiment, an implantable prosthetic valve is provided for controlling, at least in part, a flow of blood, comprising:

a frame having an abluminal frame surface, a proximal end, and a distal end, wherein the proximal end is situated at an inlet end of the frame relative to the flow of blood when implanted, and wherein the distal end is situated at an outlet end of the frame relative to the flow of blood when implanted, the frame having a tubular flow path through its interior; and

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a tissue membrane attached to the frame, the tissue membrane having an interior surface and an exterior surface;

wherein the interior surface of the tissue membrane is situated exterior the abluminal frame surface of the frame between the proximal end and distal end of the frame, when the valve is in the fully open position, the interior surface of the tissue membrane intersecting the tubular flow path of the frame when the tissue membrane is located in a closed position.

A percutaneous, trans-catheter prosthetic valve for implantation in a patient is provided, comprising:

a frame including an abluminal surface extending between a proximal end of the frame and a distal end of the frame, wherein the frame is collapsible and expandable and adapted for trans-catheter delivery; and

a biocompatible tissue material mounted to the abluminal surface of the frame to form a plurality of valve leaflets, wherein an entire interior surface of the biocompatible tissue material between the proximal end of the frame and the distal end of the frame resides radially exterior to the abluminal surface of the frame:

(a) at all points of attachment; and

(b) when the plurality of valve leaflets are in an operationally fully open position.

In at least one embodiment the frame comprises a metal alloy substantially configured as tubular stent member. In at least one embodiment a proximal portion of the frame includes a ring. In at least one embodiment a proximal portion of the frame comprises a circumferential zig-zag of wire. In at least one embodiment a proximal portion of the frame includes a lattice. In at least one embodiment the lattice is circumferentially continuous. In at least one embodiment the lattice is circumferentially discontinuous. In at least one embodiment a distal end of the frame includes two or more areas of axial continuity with the proximal end, wherein the two or more areas of axial continuity comprise axially oriented projections. In at least one embodiment the frame further comprises a distally positioned stabilization framework comprising at least one of circumferential or radial continuity with the axially oriented projections. In at least one embodiment the frame includes two or more regions of circumferential discontinuity through which operating leaflets of the biocompatible tissue material move radially inward and outward in closing and opening operation, respectively. In at least one embodiment the biocompatible tissue material between the proximal end of the frame and the distal end of the frame resides substantially adjacent the abluminal surface of the frame. In at least one embodiment the biocompatible tissue material does not contact a luminal surface of the frame. In at least one embodiment an exterior surface of the biocompatible tissue material does not contact a luminal surface of the frame.

In accordance with at least one embodiment, the frame can be a closed cell lattice type construct of circumferentially corrugated/sinusoidal/zig-zag rings. In accordance with at least one embodiment, the frame can be a wire loop with axial loops forming a support for each commissure. In at least one embodiment, the frame includes a proximal portion, wherein at least some of the abluminal surface of the proximal portion includes a tissue sheet attached thereto.

In at least one embodiment, a prosthetic valve for implantation in a patient is provided, comprising:

a frame including an abluminal surface extending between a proximal edge of the frame and a distal edge of the frame, the distal edge undulating axially to define at least two areas of circumferential discontinuity in the frame, wherein the frame is collapsible and expandable and adapted for trans-catheter delivery; and

a single layer of a biocompatible membrane material mounted to the abluminal surface of the frame to form leaflet portions, wherein the leaflet portions are collocated with the at least two areas of circumferential discontinuity in the frame.

In at least one embodiment the leaflet portions are attached to the frame at least along curved frame members formed by the distal edge of the frame and corresponding to the radially outward boundaries of the leaflet cusps.

In at least one embodiment, no portion of the biocompatible membrane material is mounted to an interior surface of the frame. In at least one embodiment, the frame comprises a metal alloy substantially configured as tubular stent member. In at least one embodiment, a proximal portion of the frame includes a lattice to which the biocompatible membrane material is circumferentially mounted entirely upon the abluminal aspect of the tubular stent member. In at least one embodiment, at least some proximal portion of the frame does not include biocompatible membrane material mounted to its luminal or abluminal surfaces. In at least one embodiment, the biocompatible membrane material extends between the proximal edge and the distal edge of the frame. In at least one embodiment, a distal portion of the frame further includes a distally extending stabilizing framework comprising a plurality of axially oriented support members that each extend from a distally extending frame projection situated adjacent the at least two areas of circumferential discontinuity in the frame. In at least one embodiment, the prosthetic valve further comprises a plurality of radial support members interconnecting the axially oriented support members. In at least one embodiment, the prosthetic valve further comprises a wire guide, wherein the wire guide is coaxially aligned with an axis of the valve, and wherein the wire guide is configured to allow for a coaxial passage of a guide wire such that coaxial alignment of the distally extending stabilizing framework may be facilitated during valve

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deployment. In at least one embodiment, the wire guide comprises at least one of a ring and a tube.

A method of preparing a percutaneous, trans-catheter prosthetic valve is also provided, the method comprising mounting a single layer of a biocompatible tissue material to an abluminal surface of a trans-catheter deliverable frame such that an interior surface of the biocompatible tissue material between a proximal end of the trans-catheter deliverable frame and a distal end of the trans-catheter deliverable frame resides radially exterior to and substantially adjacent the abluminal surface of the trans-catheter deliverable frame. In at least one embodiment the method further comprises compressing and crimping the trans-catheter deliverable frame, with the biocompatible tissue material mounted thereto, upon a delivery catheter. In at least one embodiment the method further comprises implanting the trans-catheter deliverable frame with the biocompatible tissue material mounted thereto into a patient. In at least one embodiment the trans-catheter deliverable frame comprises a stent. In at least one embodiment the method further comprises mounting the trans-catheter deliverable frame and the biocompatible tissue material mounted thereto on a mandrel.

In accordance with at least one embodiment, a method of constructing a prosthetic valve is provided, the method, comprising attaching a biocompatible membrane material to a collapsible and expandable frame to form a trans-catheter deliverable prosthetic valve, wherein an entire interior surface of the biocompatible membrane material is located exterior of the abluminal surface of the collapsible and expandable frame when leaflet portions of the biocompatible membrane material are in the valve's operationally open position. In at least one embodiment, the method further comprises associating the biocompatible prosthetic valve with a catheter.

In at least one embodiment, a prosthetic trans-catheter deliverable valve is provided that does not include one or more biasing members within the inner flow channel of the valve. That is, with the exception of the membrane during closure of the valve (when the flow cycle is not antegrade from proximal to distal through the valve), the inner flow channel is devoid of flow channel obstructions.

In at least one embodiment, a prosthetic trans-catheter valve includes a flat membrane sheet interconnected to a frame. In at least one embodiment, a flat membrane sheet is interconnected to the abluminal surface of a frame using a plurality of sutures, wherein at least some of the sutures are applied in a buttonhole suture pattern.

Various components are referred to herein as "operably associated." As used herein, "operably associated" refers to components that are linked together in operable fashion, and

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encompasses embodiments in which components are linked directly, as well as embodiments in which additional components are placed between the two linked components.

As used herein, "at least one," "one or more," and "and/or" are open-ended expressions that are both conjunctive and disjunctive in operation. For example, each of the expressions "at least one of A, B and C," "at least one of A, B, or C," "one or more of A, B, and C," "one or more of A, B, or C" and "A, B, and/or C" means A alone, B alone, C alone, A and B together, A and C together, B and C together, or A, B and C together.

As used herein, "sometime" means at some indefinite or indeterminate point of time. So for example, as used herein, "sometime after" means following, whether immediately following or at some indefinite or indeterminate point of time following the prior act.

Various embodiments of the present inventions are set forth in the attached figures and in the Detailed Description as provided herein and as embodied by the claims. It should be understood, however, that this Summary does not contain all of the aspects and embodiments of the one or more present inventions, is not meant to be limiting or restrictive in any manner, and that the invention(s) as disclosed herein is/are understood by those of ordinary skill in the art to encompass obvious improvements and modifications thereto.

Additional advantages of the present invention will become readily apparent from the following discussion, particularly when taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify the above and other advantages of various embodiments and features of the one or more present inventions, a more particular description of the one or more present inventions is rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It should be appreciated that these drawings depict only typical embodiments of the one or more present inventions and are therefore not to be considered limiting in scope. The one or more present inventions are described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Fig. 1A is a side perspective view of an embodiment of a percutaneously deliverable valve with the valve membrane illustrated in a closed position;

Fig. 1B is a side elevation view of the frame suited to balloon expansion shown in Fig. 1A;

Fig. 1C is a top plan view of the frame shown in Fig. 1B;

Fig. 1D is a side perspective view of the frame shown in Fig. 1B;

Fig. 1E is a bottom perspective view of the frame shown in Fig. 1B;

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Fig. 1F is a side elevation view of the frame shown in Fig. 1B, wherein the cylindrical frame is depicted in an "unrolled" or flat projection to illustrate the geometry of the frame members;

Fig. 1G is a side elevation view of another embodiment of a frame suited to self-expansion, wherein the cylindrical frame is depicted in an "unrolled" or flat projection to illustrate the geometry of the frame members;

Fig. 1H is a side elevation view of the frame shown in Fig. 1G;

Fig. 1I is a top plan view of the frame shown in Fig. 1H;

Fig. 1J is a side perspective view of the frame shown in Fig. 1H;

Fig. 1K is a bottom perspective view of the frame shown in Fig. 1H;

Fig. 1L is a side perspective view of an embodiment of a membrane sheet and its attachment to a frame in accordance with at least one embodiment described herein;

Fig. 2 is a simplified distal end view of an embodiment of a frame illustrating relative locations of the distal ends of two distally positioned frame projections located approximately 180 degrees apart;

Fig. 3 is a simplified distal end view of an embodiment of a frame illustrating relative locations of the distal ends of four distally positioned frame projections located approximately 90 degrees apart;

Fig. 4 is a perspective view of an embodiment of a schematic of a frame having optional stabilization framework with circumferential supports;

Fig. 5 is a perspective view of an embodiment of a schematic of a frame having optional stabilization framework with radial supports;

Fig. 6 is a flow chart of a method of constructing an embodiment of a prosthetic heart valve as described herein;

Fig. 7 is flow chart of a method of deploying an embodiment of a prosthetic heart valve as described herein; and

Fig. 8 is a schematic of a heart showing an embodiment of a heart valve as described herein implanted within a heart.

The drawings are not necessarily to scale.

DETAILED DESCRIPTION

Embodiments of the one or more inventions described herein include one or more devices, assemblies and/or methods related to prosthetic heart valves and to prosthetic blood vessel valves. A prosthetic heart valve in accordance with at least one embodiment described herein can be surgically implanted, such as by percutaneous, trans-catheter delivery, to the implantation site within the patient. One or more embodiments of the prosthetic heart valves

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described herein have application for at least aortic and pulmonary valve positions, including for structural defects and diseased valves. Other embodiments have application to the vascular system and in particular to the vein system. When reduced in scale they have particular application to the branch veins of the body and the extremities. The descriptions for these devices are effectively provided in the descriptions and specifications provided for the inventive percutaneously implantable heart valve device.

In at least one embodiment, biocompatible material is mounted to a frame to form an implantable prosthetic heart valve, and then at a later time, the implantable prosthetic heart valve is implanted within a patient, such as by way of a percutaneous, trans-catheter delivery mechanism. The percutaneously implantable heart valve is suitable for implantation into a native (orthotopic or ectopic) valve seat of a patient. Once implanted, the prosthetic heart valve serves to regulate the flow of blood associated with the patient's heart by allowing forward blood flow and substantially preventing backflow or valvular regurgitation.

Referring now to Fig. 1A, and in accordance with at least one embodiment, an implantable prosthetic heart valve 100 is shown that includes a frame 104 and a single layer membrane sheet 108, such as a biocompatible tissue membrane sheet. All or substantially all of the membrane sheet 108 is located on the exterior or abluminal side of the frame 104 between the proximal end 112 and the distal end 116 of the frame 104 when the valve leaflets are in the operationally fully open position and in any case at all points of attachment. The implantable prosthetic heart valve 100 includes a proximal (upstream) portion/margin of membrane sheet 108 that is circumferentially attached to and residing entirely upon the abluminal surface of the frame 104. In at least one embodiment, the membrane sheet 108 is connected to the frame 104 by a plurality of sutures 120. In at least one embodiment, the plurality of sutures comprise curved lines of attachment, axially concave to the distal end 116 of the frame, along the frame members at the frame's distal edge interconnecting the distally extending frame projections 124a-c. It is to be understood that alternate ways of attaching the membrane sheet 108 to the frame 104 may be used, such as staples, an adhesive, an anchoring ring, one or more bands, clips or combinations of the foregoing.

By whatever technique of attachment, the lines of attachment by which the arcuate proximal basal margin of each leaflet is anchored to the arcuate distal edge of the frame act to distribute the force loads acting on the leaflets along these lines while in the operationally closed position. The securement of the leaflets in this manner is advantageous in a high-pressure application such as the aortic valve position. Moreover, these lines of attachment also act to seal the proximal basal margin of each cusp to the frame and are critical in the case of aortic valve implantation, because some portion of these arcuate cusp margins are likely to be disposed

"above" (downstream) of the aortic valve annulus and without anatomic luminal contact to the outer aspect of the valve at this level. As such, those portions that are disposed in the "suprannular" position after implantation can be subject to high pressure blood being injected between the leaflet layer and the frame which can in turn lead to acute and chronic compromise of valve function. The specific form of leaflet attachment provided in the inventive valve addresses this problem that arises as a consequence of the abluminal/exterior position of the leaflet membrane in relation to the frame.

In at least one embodiment, the plurality of sutures 120 attaching the leaflet membrane to the distal arcuate portions of the distal edge of the frame comprise, for each arcuate segment 144, a continuous series of "buttonhole"-technique sutures 120 wherein the segments of suture interconnecting the knots are disposed to the outer/abluminal surface of the membrane. This suture configuration advantageously imposes a small biasing effect upon the leaflet towards the operationally closed position.

With regard to particular material types that may be used to form the membrane sheet, in at least one embodiment the membrane sheet 108 forming the cusp or leaflet portions includes a one-piece, single layer sheet of biocompatible membrane, such as fixed mammalian pericardium tissue or synthetic biocompatible material such as ePTFE. In at least one embodiment, the membrane sheet is made from a tissue preparation process that yields a leaflet material of suitable strength and durability for use in a prosthetic trans-catheter deliverable heart valve. The content of WO 2011/109450A2 published on September 9, 2011, is incorporated herein by reference. Although not preferred, one or more embodiments may alternatively comprise a plurality of sections of membrane sheet connected to form a contiguous sheet.

In at least one embodiment, the membrane sheet is a single layer of a substantially homogenous material. In at least one embodiment, the membrane sheet is an unlaminated single layer of material. In at least one embodiment, the membrane sheet is a single layer of material that does not include any reinforcement, such as reinforcing fibers. In at least one embodiment, the membrane sheet is a single layer of treated pericardium tissue. In at least one embodiment, the membrane sheet is a single layer of a synthetic film.

The frame 104 may include a balloon expandable material. Alternatively, the frame 104 may include one or more of a self expanding alloy such as nitinol, stainless steel, cobalt chromium, bioabsorbable metal, and non-elastic bioabsorbable plastic, such as polylactides, polyglycolides, their co-polymers, or polydioxanones. As further seen in Figs. 1A-1F, in at least one embodiment the geometry of the frame 104 at the distal end 116 may include three distally extending frame projections 124a, 124b and 124c. This configuration is described for exemplary purposes. Accordingly, alternate configurations may be used, including collapsible

and expandable percutaneously deliverable frames that include two, four, five or any multiple number of distally extending frame projections, provided the configuration in combination with the abluminally situated single layer membrane sheet 108 accommodates inward closure of the membrane sheet 108 sufficiently to facilitate operational closure of the valve after being implanted. Thus, those skilled in the art will appreciate that configurations shown and described herein are for purposes of enablement, and therefore, alternate configurations from those shown are encompassed by the claims. Consistent with the foregoing, the distally extending frame projections 124a-c are spaced apart around the circumference of the frame 104 as appropriate to facilitate closure of the membrane sheet 108 when the flow cycle is not antegrade from proximal to distal through the valve.

Referring still to Figs. 1A-1F, in at least one embodiment, the frame 104 has three distally positioned inverted "v" members also referred to herein as distally extending frame projections 124a-c located at substantially equal angular distances apart from each other at the distal end 116 of the frame 104. Alternatively, each of these distally extending frame projections may take other forms such as a single projecting beam or an extending loop formed of a continuous loop of wire. Accordingly, in at least one embodiment, each inverted "v" member or distally extending frame projection 124a-c is about 120 degrees (at the point or apex of the inverted "v" members) away on either side from the other two inverted "v" members at the distal end 116 of the frame 104. In at least one embodiment, the inverted "v" members serve as attachment locations for the membrane sheet 108. In at least one embodiment, the "v" members are integral parts of a generally arcuate configuration of frame members spanning the distal frame edge between the distally extending frame projections 124a-c such that each arcuate span forms: 1) the radially outermost margin of a leaflet cusp; and 2) the line of attachment of each leaflet membrane to the distal edge of the frame. In at least one embodiment, the proximal end 112 of the frame 104 includes a continuous framework, although minor axially oriented recessions 136 in the framework are situated between the proximal-most portions 140 of the frame 104.

With further reference to Figs. 1B-1F, in at least one embodiment, the struts 126 forming the inverted "v" members are located between approximately 40 to 90 degrees apart, and more preferably, at between approximately 50 to 70 degrees apart. By way of example and not limitation, as shown in the example depicted in Fig. 1F, the struts 126 forming distally extending frame projection 124a are about 50 degrees apart. The angular values provided herein are given for purposes of enablement and for exemplary purposes, and are not intended to be limiting. Other values are possible, and such other values are within the scope of the one or more present inventions.

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Referring again to Fig. 1A, cusp or leaflet portions 128a, 128b, and 128c reside between the spaced apart distally extending frame projections 124a-c. More particularly, circumferential discontinuities 132 in the frame 104 substantially correspond to the location of leaflet portions 128a-c in the membrane sheet 108. That is, since the membrane sheet 108 is situated exterior of the frame 104, including at the frame projections 124a-c, the absence of framework, internal struts or other types of support for a portion of the distally located membrane sheet 108 allows the abluminally positioned membrane sheet 108 to occupy an area within the flow path of the valve 100 when the flow cycle is not antegrade from proximal to distal through the valve. Therefore, when flow conditions are not antegrade, the leaflet portions 128a-c operate to close the valve 100 because of the absence of framework circumferentially between the distally extending frame projections 124a-c allows the leaflet portions 128a-c of the membrane sheet 108 to close radially inward.

Referring again to Fig. 1A, in the closed position, the leaflet portions 128a-c reside within the interior flow channel or lumen of the valve 100. Accordingly, the valve 100 includes a biocompatible membrane with a distal (downstream) portion/margin that is attached to the abluminal/exterior aspect of the frame 104 at at least two or more points (at or near the apices of the distally extending frame projections 124a-c) corresponding to two or more valve leaflet commissures, wherein the free edge of the membrane sheet 108 between the points of attachment constitutes the free edge of the valve leaflets or leaflet portions 128a-c that are free to move radially inward into a closed position contacting the other leaflet or leaflets, and radially outward into an open position.

In at least one embodiment, when the leaflets 128a-c are in their open position, the membrane sheet 108 at the distal end 116 resides entirely to the radial exterior of the frame 104 including at the distally extending frame projections 124a-c. Accordingly, when flow conditions are antegrade, the leaflets 128a-c extend radially outward from the lumen of valve 100.

In at least one embodiment, the membrane sheet 108, including the material constituting the operating leaflets portions 128a-c, is exterior/abluminal to the frame 104 and may be continuous from the leaflet portions 128a-c to the proximal end 112 of the frame 108. Alternatively, the membrane sheet 108 does not have to extend abluminally along the entire axial length of the frame 104 from the distal end 116 to the proximal end 112. More particularly, with limited proximal coverage, the membrane sheet 108 may only cover a portion of the abluminal surface of the frame 104 and reside at the distal end 116 and extend axially along the abluminal surface sufficiently to provide leaflet portions 128a-c such that there is enough membrane sheet 108 to cover the discontinuities in the frame 104 and thus function as leaflet portions 128a-c by moving radially inward and outward through the frame discontinuities

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132. For such a configuration the membrane sheet 108 needs to extend proximally from the distal end 116 a sufficient proximal distance so as to provide a sufficient seal against leakage/regurgitation through the frame 104. Simply stated, the membrane sheet 108 needs to extend axially only a limited distance axially in the proximal direction, that being to slightly beyond the annular intersection or the valve seat formed between the abluminal surface of the membrane sheet 108 situated against the native tissue. Therefore, the proximal extent of the membrane tissue 108 beyond the intersection of the valve 100 against the native tissue may vary.

In at least one embodiment, the membrane sheet 108 may wrap around the proximal edge 136 of the frame 104 so as to make a continuous inner/luminal layer within the proximal end 112 of the frame 104. In contrast, leaving a portion of the proximal end 112 uncovered by the membrane sheet 108 permits the frame to provide additional structure. By way of example, the proximal end 112 can incorporate other structural elements including flared or hooked frame projections for effective securement of the implanted valve. Such configurations have applicability to providing advantageous structure for certain valve implantation sites, such as the mitral valve.

In at least one embodiment, the membrane sheet 108 may wrap around the proximal edge of the frame 104 so as to make a continuous inner/luminal layer within the proximal end 112 of the frame 104. That is, the valve 100 does not require the membrane sheet 108 to extend proximally to the proximal edge 136 of the frame 108, however, the membrane sheet 108 may extend proximally including to the proximal end 112, and indeed, the membrane sheet 108 may wrap around the proximal edge 136 to the luminal side of the frame 104.

With reference to Fig. 1F, a side elevation view of the cylindrical frame 104 is depicted in "unrolled" flat projection to illustrate the geometry of the frame members. The structural differences of the frame 104 at the proximal end 112 and distal end 116 are readily apparent, with the areas of circumferential discontinuities 132 observable between the distally extending frame projections 124a-c. Each circumferential discontinuity 132 includes a pair of generally arcuate side portions 144 that, in at least one embodiment, include a concave (in relation to the distal end of the frame) shape relative to the circumferential discontinuity 132. These arcuate spanning side portions 144 form: 1) lines of attachment of the leaflet membrane to the frame; and 2) the proximal/radially outermost margin of the leaflet cusp, along which are borne the forces exerted upon the closed leaflets. While the leaflets are attached to the arcuate side portions 144 as by suturing, the mobile leaflet portions and the cuff portion of the membrane are preferably continuous, formed of a single sheet of biocompatible membrane disposed around and upon the abluminal aspect of the frame. As noted above, to attach the single layer

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membrane sheet 108 to the arcuate side portions 144, sutures may be applied using a continuous series of "buttonhole"-technique sutures 120 wherein the segments of suture interconnecting the knots are disposed to the outer/abluminal surface of the membrane. This suture configuration advantageously imposes a small biasing effect upon the leaflet towards the operationally closed position.

Referring now to Figs. 1G-1K, an alternative embodiment comprising a frame 104′ suited to self-expansion is shown is shown. When comparing frame 104 to frame 104′, differences in the frame structure are apparent. However, both frames 104 and 104′ have circumferential discontinuities 132 that substantially correspond to the location of leaflet portions 128a-c in the membrane sheet 108. Again, since the membrane sheet 108 is situated exterior of the frame 104′, including at the frame projections 124a-c, the absence of framework, internal struts or other types of support for a portion of the distally located membrane sheet 108 allows the abluminally positioned membrane sheet 108 to occupy an area within the flow path of the valve 100 when the flow cycle is not antegrade from proximal to distal through the valve. Similar to frame 104, the location of the circumferential discontinuities 132 in frame 104′ allow the leaflet portions 128a-c operate to close the valve 100 because of the absence of framework circumferentially between the distally extending frame projections 124a-c in frame 104′ allows the leaflet portions 128a-c of the membrane sheet 108 to close radially inward. Also similar to frame 104, each circumferential discontinuity 132 includes a pair of generally arcuate side portions 144 that, in at least one embodiment, include a concave (in relation to the distal end of the frame) shape relative to the circumferential discontinuity 132. These arcuate spanning side portions 144 form: 1) lines of attachment of the leaflet membrane to the frame; and 2) the proximal/radially outermost margin of the leaflet cusp, along which are born the forces exerted upon the closed leaflets.

As noted above, although the embodiment shown in Fig. 1A illustrates a frame 104 including three distally extending frame projections 124a-c, an alternative number of distally extending frame projections may be used, thereby yielding an implantable prosthetic heart valve with fewer or greater than three cusps. By way of example, and with reference now to Fig. 2, for a frame having two distally extending frame projections 124 that are positioned at substantially diametrically opposite sides of the frame's circumference, then two cusps would be provided. Similarly, and with reference now to Fig. 3, for a frame having four distally extending frame projections 124 that are positioned with substantially 90 degrees of separation from one another around the frame's circumference, then four cusps would be provided.

Referring now to Fig. 1L, a frame 104 is shown relative to a single layer membrane sheet 108. The illustrated single layer membrane sheet 108 includes substantially straight edges.

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However, in at least one embodiment, the distal free edge of each membrane leaflet portion has a non-linear shape. Preferentially when the leaflet free edge is not linear, it is cut in the shape of a parabola with central axis of curvature aligned to the center of the free edge of the leaflet. This effectively extends the coaptation margin and area of the leaflet free edge for a given leaflet radius, reduces the pressure on the contacting leaflet areas when the valve is closed and improves the effectiveness of orifice sealing in closure. Accordingly, free edge shapes for the leaflets are cut from the corresponding edge of the flat sheet membrane before wrapping and mounting of the membrane upon the frame.

Alternatively, in at least one embodiment, the circumference of the membrane exceeds the outer circumference of the frame. The membrane is then gathered in folds or pleats and attached at the proximal (inlet) end of the frame so as to reduce the effective circumference of the membrane at the proximal end of the frame to equal that of the frame at this level. While the proximal end of the encircling membrane sheet is then directly apposed to the abluminal aspect of the frame for secure attachment, the leaflet free edge of the membrane at the distal (outlet) end of the valve remains at the original larger circumference. This has the effect of increasing the length of each leaflet free edge and the area of each leaflet for a given radius of frame, and is useful to improve valve function, especially for large valve diameters. It will be understood that various curved and polygonal membrane shapes may be used to achieve various three dimensional leaflet shapes in a similar manner. Accordingly, in at least one embodiment, a prosthetic trans-catheter deliverable valve is provided that includes a membrane sheet formed into a tubular shape, wherein a circumference of the tubular shape is greater than a circumference of a radially adjacent portion of the frame. In at least one embodiment, a circumference of the tubular shape is between about 5 to 25% greater than a circumference of a radially adjacent portion of the frame. More preferably, a circumference of the tubular shape is between about 7 to 20% greater than a circumference of a radially adjacent portion of the frame. More preferably yet, a circumference of the tubular shape is between about 10 to 15% greater than a circumference of a radially adjacent portion of the frame. The difference in the circumference of the membrane sheet as compared to the radially adjacent portion of the frame provides leaflet portions that extend within the lumen along lines of apposition with improved sealing characteristics relative to a membrane sheet having a circumference that is substantially the same as the circumference of a radially adjacent portion of the frame.

Referring now to Fig. 4, and in accordance with a separate embodiment, the frame 104 may optionally include a distally extending stabilizing framework 400 that includes axially oriented support members 404 extending from the distally extending frame projections 124a-c. In at least one embodiment, a distally-positioned circumferential ring, or alternatively, a

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circumferentially segmented lattice 408 interconnects the axially oriented support members 404. The stabilization framework is located distally of the membrane sheet 108 that is attached to the frame 104.

Referring now to Fig. 5, and in accordance with yet a separate embodiment, an alternative to the stabilization framework of Fig. 4 is shown. More particularly, similar to the distally extending stabilizing framework 400, distally extending stabilizing framework 500 includes a plurality of axially oriented support members 404 that extend from the distally extending frame projections 124a-c; however, a plurality of radial support members 504 are used to interconnect the axially oriented support members 404, thereby providing additional stability to the distal end 116 of the frame 104. In addition, at the central point of intersection of the radial support members, a small ring or short tube coaxially aligned with the central axis of the valve and frame may be provided in order to allow for the coaxial passage of a guide wire such that coaxial alignment of the distal support framework may be facilitated during valve deployment.

With reference now to Fig. 6, and in accordance with at least one embodiment, a method 600 of constructing a prosthetic heart valve or a prosthetic vascular valve is provided. At 604, the method includes attaching a biocompatible membrane material to a frame to form a prosthetic heart valve, wherein an entire interior surface of the biocompatible membrane material is located exterior of the abluminal surface of the frame when leaflet portions of the biocompatible membrane material are in the operationally open position. As described above, a number of different ways of attaching the membrane sheet to the frame may be used, such as by suturing the membrane sheet to the exterior of the frame. At 608, the method includes associating the biocompatible prosthetic heart valve or prosthetic vascular valve with a catheter. The 604 step of associating may be preformed at a different location than the step 608 of attaching.

Referring now to Fig. 7, a flow chart illustrating the general procedure associated with implantation of the percutaneously deliverable heart valve 100 is provided. However, those skilled in the art will understand that with appropriate modification (e.g., changing the vascular entry location) the methodology also has application to a percutaneously deliverable blood vessel valve.

At 704, catheter access is gained to the patient's femoral artery and a guidewire is placed through the plane of the diseased valve that is targeted to receive the implant. Thereafter, the percutaneously deliverable heart valve 100 is removed from its packaging. If the valve was not mounted upon or otherwise associated with a delivery catheter at manufacture, then the valve is cleaned and rinsed and radially compressed upon the delivery catheter and constrained within a

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covering sheath coaxial to the delivery catheter. The prosthetic heart valve assembly, including its lumens, is preferably flushed and prepared in the usual fashion for standard balloons and catheters that do not contain a biocompatible tissue. At 708, the carrier catheter or balloon catheter is then coaxially mounted and advanced over the guidewire, such as under fluoroscopic vision initially to the level of the great vessel where it can be inspected under fluoroscopy. At 712, and after the nominal position and configuration is confirmed, the delivery system is advanced through the plane of the diseased valve under fluoroscopy, and the covering sheath is withdrawn, either at this point or during the advance prior to it, thus exposing the mounted implantable prosthetic heart valve 100 in place. At 716, in the case of a balloon expandable frame, the balloon is then inflated, deploying the percutaneously deliverable heart valve 100 in the plane of the valve. The deployed prosthetic heart valve 100 is shown in Fig. 8, wherein the percutaneously deliverable heart valve 100 serves to properly control the flow blood.

One or more of the embodiments of the percutaneously deliverable heart valve described herein may be implanted into the patient using a balloon-expandable frame or a self-expanding frame. Expandable frames are generally conveyed to the site of the target valve on balloon catheters. For insertion, the expandable frame is positioned in a compressed configuration along the delivery device, for example crimped onto the balloon of a balloon catheter that is part of the delivery device intended for coaxial mounting on a guidewire. After the expandable frame is positioned across the plane of the valve, the expandable frame is expanded by the delivery device. For a self-expanding frame, commonly a sheath is retracted, allowing expansion of the self-expanding frame.

In at least one embodiment, the frame comprises a metal alloy frame possessing a high strain design tolerance that is compressible to a relatively small diameter. By providing a device with a low profile, the implantable prosthetic heart valve allows standard retrograde arterial aortic delivery via femoral artery insertion, without surgical cutdown or general anesthesia.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

The one or more present inventions, in various embodiments, include components, methods, processes, systems and/or apparatus substantially as depicted and described herein, including various embodiments, subcombinations, and subsets thereof. Those of skill in the art

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will understand how to make and use the present invention after understanding the present disclosure.

The present invention, in various embodiments, includes providing devices and processes in the absence of items not depicted and/or described herein or in various embodiments hereof, including in the absence of such items as may have been used in previous devices or processes (e.g., for improving performance, achieving ease and/or reducing cost of implementation).

The foregoing discussion of the invention has been presented for purposes of illustration and description. The foregoing is not intended to limit the invention to the form or forms disclosed herein. In the foregoing Detailed Description for example, various features of the invention are grouped together in one or more embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the following claims are hereby incorporated into this Detailed Description, with each claim standing on its own as a separate preferred embodiment of the invention.

Moreover, though the description of the invention has included description of one or more embodiments and certain variations and modifications, other variations and modifications are within the scope of the invention (e.g., as may be within the skill and knowledge of those in the art, after understanding the present disclosure). It is intended to obtain rights which include alternative embodiments to the extent permitted, including alternate, interchangeable and/or equivalent structures, functions, ranges or acts to those claimed, whether or not such alternate, interchangeable and/or equivalent structures, functions, ranges or acts are disclosed herein, and without intending to publicly dedicate any patentable subject matter.

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CLAIMS

What is claimed is:

1. A percutaneous, trans-catheter prosthetic valve for implantation in a patient, comprising:

a frame including an abluminal surface extending between a proximal end of the frame and a distal end of the frame, wherein the frame is collapsible and expandable and adapted for trans-catheter delivery; and

a biocompatible tissue material mounted to the abluminal surface of the frame to form a plurality of valve leaflets, wherein an entire interior surface of the biocompatible tissue material between the proximal end of the frame and the distal end of the frame resides radially exterior to the abluminal surface of the frame:

(a) at all points of attachment; and

(b) when the plurality of valve leaflets are in an operationally fully open position.

2. The percutaneous, trans-catheter prosthetic valve of Claim 1, wherein the frame comprises a metal alloy substantially configured as tubular stent member.

3. The percutaneous, trans-catheter prosthetic valve of Claim 2, wherein a proximal portion of the frame includes a ring.

4. The percutaneous, trans-catheter prosthetic valve of Claim 2, wherein a proximal portion of the frame comprises a circumferential zig-zag of wire.

5. The percutaneous, trans-catheter prosthetic valve of Claim 2, wherein a proximal portion of the frame includes a lattice.

6. The percutaneous, trans-catheter prosthetic valve of Claim 5, wherein the lattice is circumferentially continuous.

7. The percutaneous, trans-catheter prosthetic valve of Claim 5, wherein the lattice is circumferentially discontinuous.

8. The percutaneous, trans-catheter prosthetic valve of Claim 1, wherein a distal end of the frame includes two or more areas of axial continuity with the proximal end, and wherein the two or more areas of axial continuity comprise axially oriented projections.

9. The percutaneous, trans-catheter prosthetic valve of Claim 8, further comprising a distally positioned stabilization framework comprising at least one of circumferential or radial continuity with the axially oriented projections.

10. The percutaneous, trans-catheter prosthetic valve of Claim 8, wherein the frame includes two or more regions of circumferential discontinuity through which the plurality of valve leaflets of the biocompatible tissue material move radially inward and outward in closing and opening operation, respectively.

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11. The percutaneous, trans-catheter prosthetic valve of Claim 1, wherein the biocompatible tissue material between the proximal end of the frame and the distal end of the frame resides substantially adjacent the abluminal surface of the frame.

12. The percutaneous, trans-catheter prosthetic valve of Claim 1, wherein the biocompatible tissue material does not contact a luminal surface of the frame.

13. The percutaneous, trans-catheter prosthetic valve of Claim 1, wherein an exterior surface of the biocompatible tissue material does not contact a luminal surface of the frame.

14. A prosthetic valve for implantation in a patient, comprising:

a frame including an abluminal surface extending between a proximal edge of the frame and a distal edge of the frame, the distal edge undulating axially to define at least two areas of circumferential discontinuity in the frame, wherein the frame is collapsible and expandable and adapted for trans-catheter delivery; and

a single layer of a biocompatible membrane material mounted to the abluminal surface of the frame to form leaflet portions, wherein the leaflet portions are collocated with the at least two areas of circumferential discontinuity in the frame.

15. The prosthetic valve of Claim 14, wherein no portion of the biocompatible membrane material is mounted to an interior surface of the frame.

16. The prosthetic valve of Claim 14, wherein the frame comprises a metal alloy substantially configured as tubular stent member.

17. The prosthetic valve of Claim 16, wherein a proximal portion of the frame includes a lattice to which the biocompatible membrane material is circumferentially mounted entirely upon the abluminal surface of the tubular stent member.

18. The prosthetic valve of Claim 17, wherein the lattice is circumferentially continuous.

19. The prosthetic valve of Claim 17, wherein the lattice is circumferentially discontinuous.

20. The prosthetic valve of Claim 14, wherein a proximal portion of the frame comprises a circumferential zig-zag of wire.

21. The prosthetic valve of Claim 14, wherein the biocompatible membrane material extends between the proximal edge and the distal edge of the frame.

22. The prosthetic valve of Claim 14, wherein at least some proximal portion of the frame does not include biocompatible membrane material mounted to its luminal or abluminal surfaces.

23. The prosthetic valve of Claim 14, wherein a distal portion of the frame further includes a distally extending stabilizing framework comprising a plurality of axially oriented

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support members that each extend from a distally extending frame projection situated adjacent the at least two areas of circumferential discontinuity in the frame.

24. The prosthetic valve of Claim 23, further comprising a plurality of radial support members interconnecting the plurality of axially oriented support members.

25. The prosthetic valve of Claim 24, further comprising a wire guide, wherein the wire guide is coaxially aligned with an axis of the prosthetic valve, and wherein the wire guide is configured to allow for a coaxial passage of a guide wire such that coaxial alignment of the distally extending stabilizing framework may be facilitated during valve deployment.

26. The prosthetic valve of Claim 25, wherein the wire guide comprises at least one of a ring and a tube.

27. The prosthetic valve of Claim 14, wherein a circumference of the biocompatible membrane material is between about 5 to 25% greater than a circumference of a radially adjacent portion of the frame.

28. A method of preparing a percutaneous, trans-catheter prosthetic valve, comprising:

mounting a single layer of a biocompatible tissue material to an abluminal surface of a trans-catheter deliverable frame such that an interior surface of the biocompatible tissue material between a proximal end of the trans-catheter deliverable frame and a distal end of the trans-catheter deliverable frame resides radially exterior to and substantially adjacent the abluminal surface of the trans-catheter deliverable frame at all points of attachment and in entirety when a plurality of leaflets of the biocompatible tissue material are in a fully open position.

29. The method of preparing a percutaneous, trans-catheter prosthetic valve of Claim 28, further comprising compressing and crimping the trans-catheter deliverable frame, with the biocompatible tissue material mounted thereto, upon a delivery catheter.

30. The method of preparing a percutaneous, trans-catheter prosthetic valve of Claim 29, further comprising implanting the trans-catheter deliverable frame with the biocompatible tissue material mounted thereto into a patient.

31. The method of preparing a percutaneous, trans-catheter prosthetic valve of Claim 28, wherein the trans-catheter deliverable frame comprises a stent.

32. The method of preparing a percutaneous, trans-catheter prosthetic valve of Claim 28, further comprising mounting the trans-catheter deliverable frame and the biocompatible tissue material mounted thereto on a mandrel.

33. A method, comprising:

attaching a biocompatible membrane material to a collapsible and expandable frame to form a trans-catheter deliverable prosthetic valve, wherein an entire interior surface of the

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biocompatible membrane material is located exterior of an abluminal surface of the collapsible and expandable frame when leaflet portions of the biocompatible membrane material are in a fully open position.

34. The method of Claim 33, wherein the attaching includes suturing the biocompatible membrane material to a distal edge of the collapsible and expandable frame that undulates in an axial direction around the collapsible and expandable frame.

35. The method of Claim 33, further comprising associating the trans-catheter deliverable prosthetic valve with a catheter.

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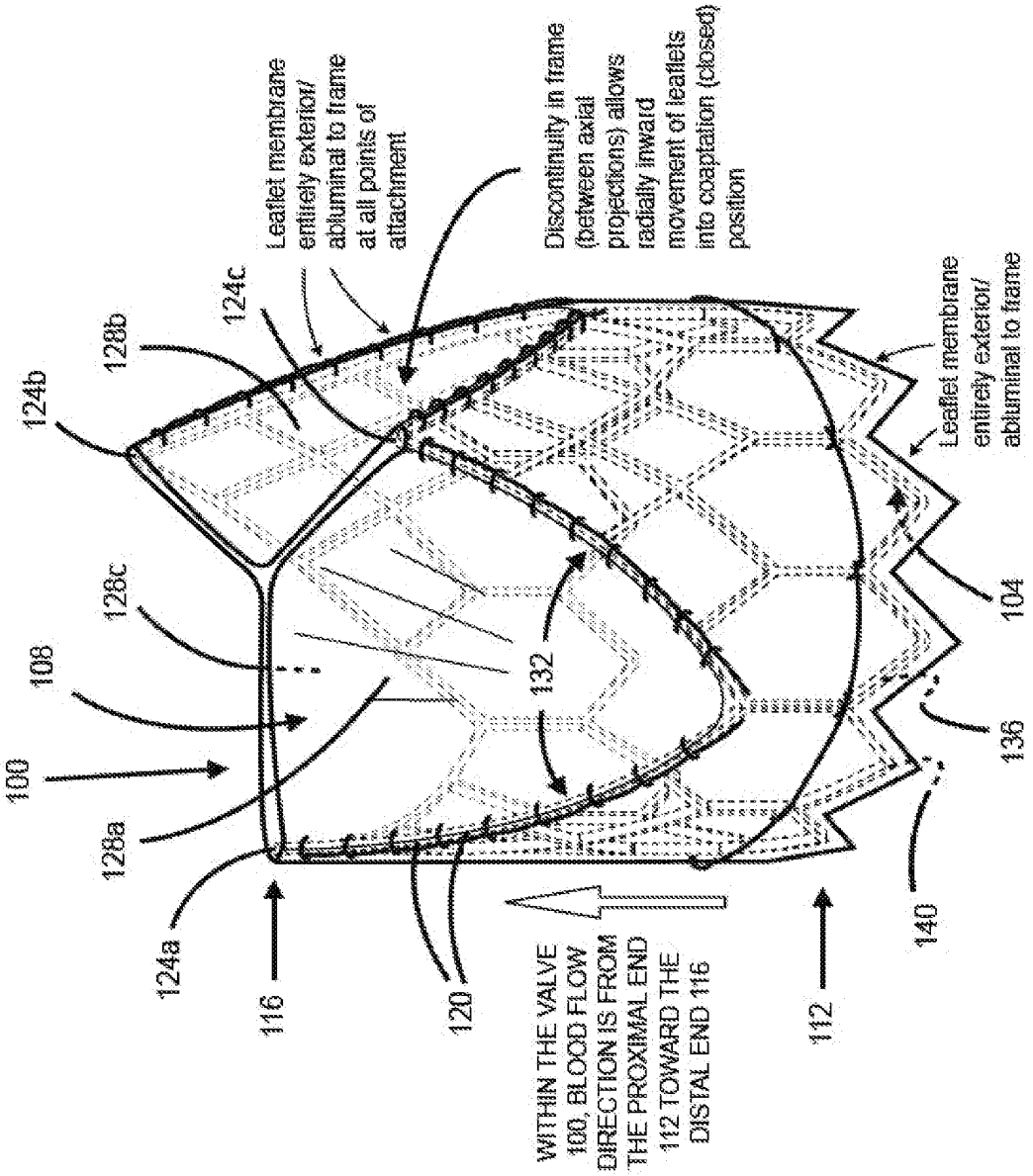

100
108
128a
128b
128c
124a
124b
124c
116
120
132
112
140
136
104
Leaflet membrane entirely exterior/ abluminal to frame at all points of attachment
Discontinuity in frame (between axial projections) allows radially inward movement of leaflets into coaptation (closed) position
Leaflet membrane entirely exterior/ abluminal to frame
WITHIN THE VALVE 100, BLOOD FLOW DIRECTION IS FROM THE PROXIMAL END 112 TOWARD THE DISTAL END 116

Figure 1A

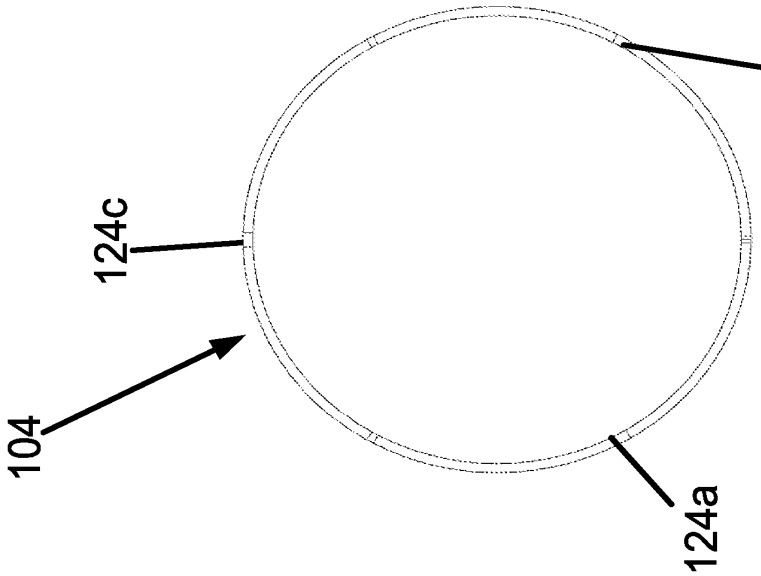


FIG. 1C

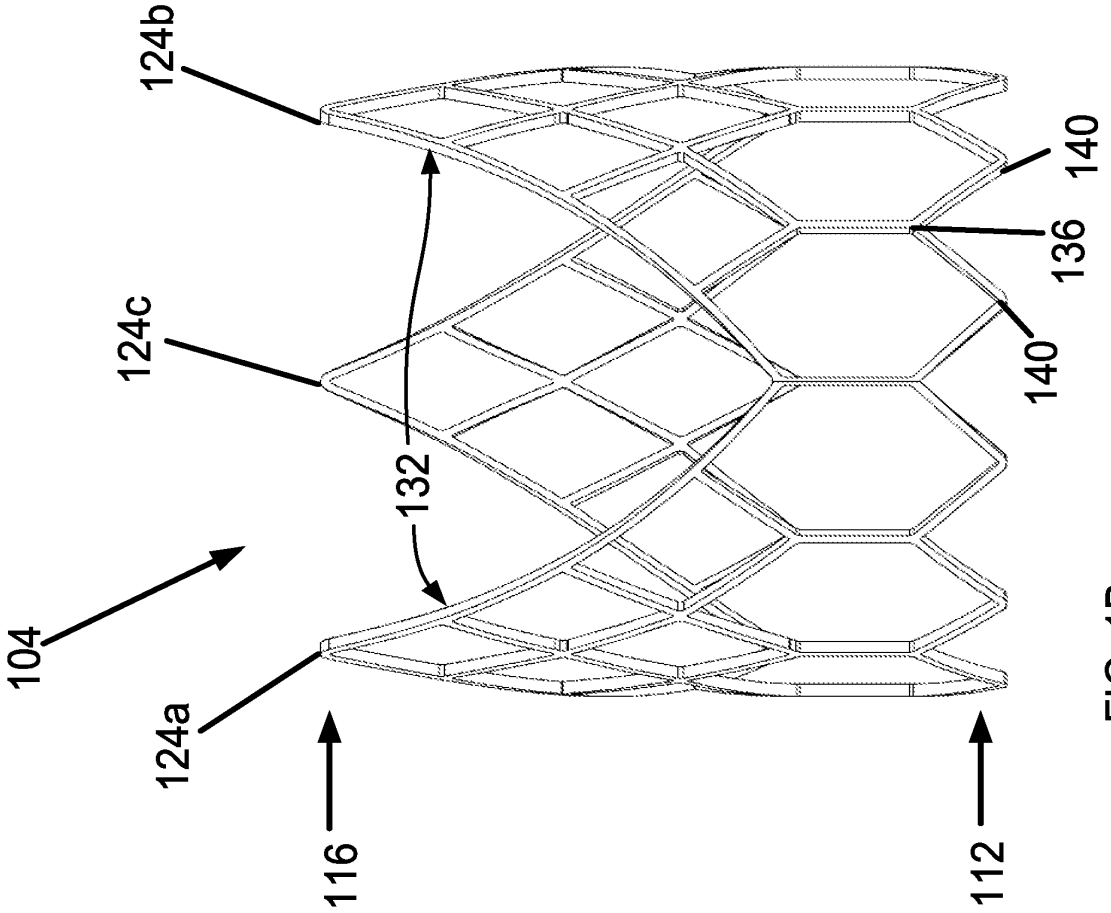
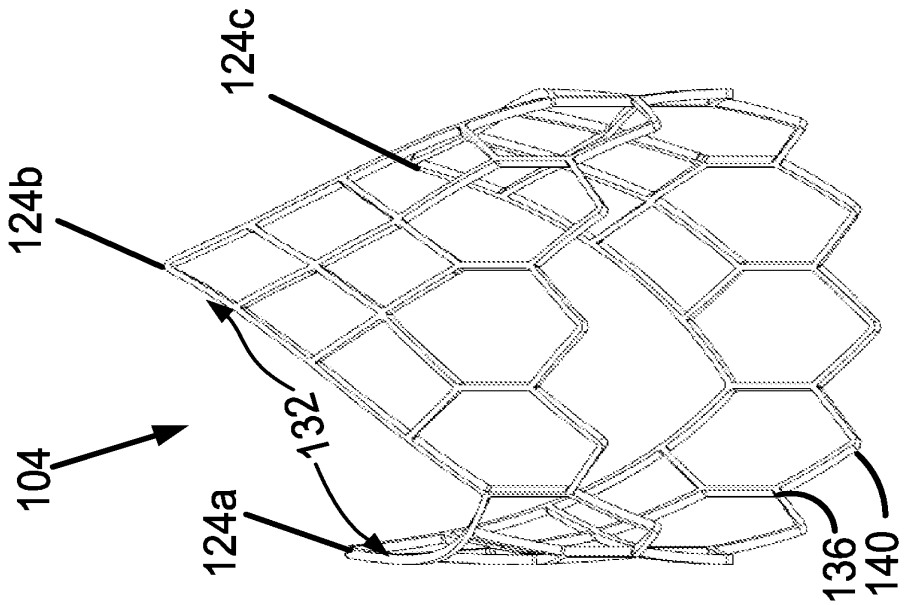


FIG. 1B

FIG. 1E


124c
124b
104
132
124a
136
140

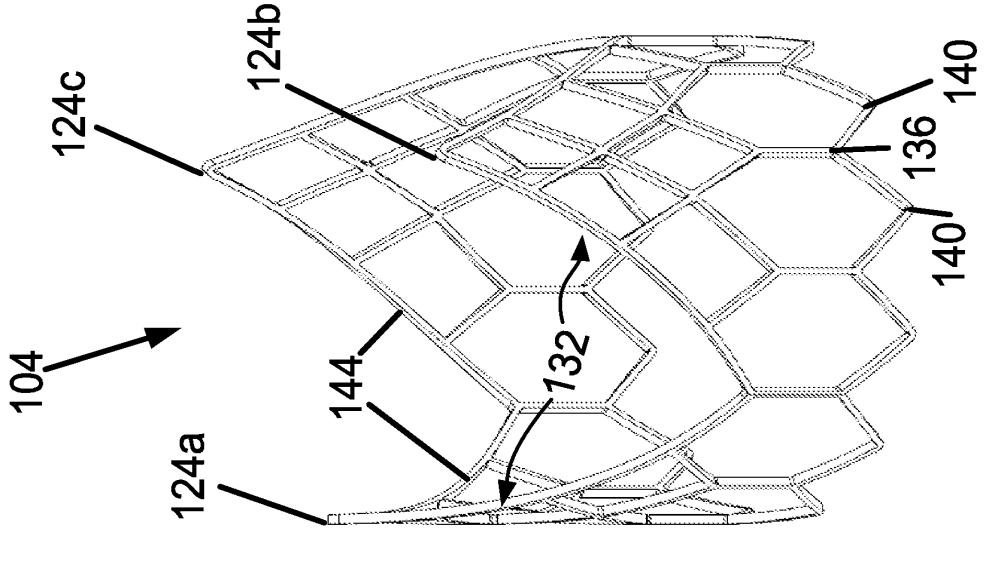

124c
124b
140
136
140
104
144
132
124a

FIG. 1D

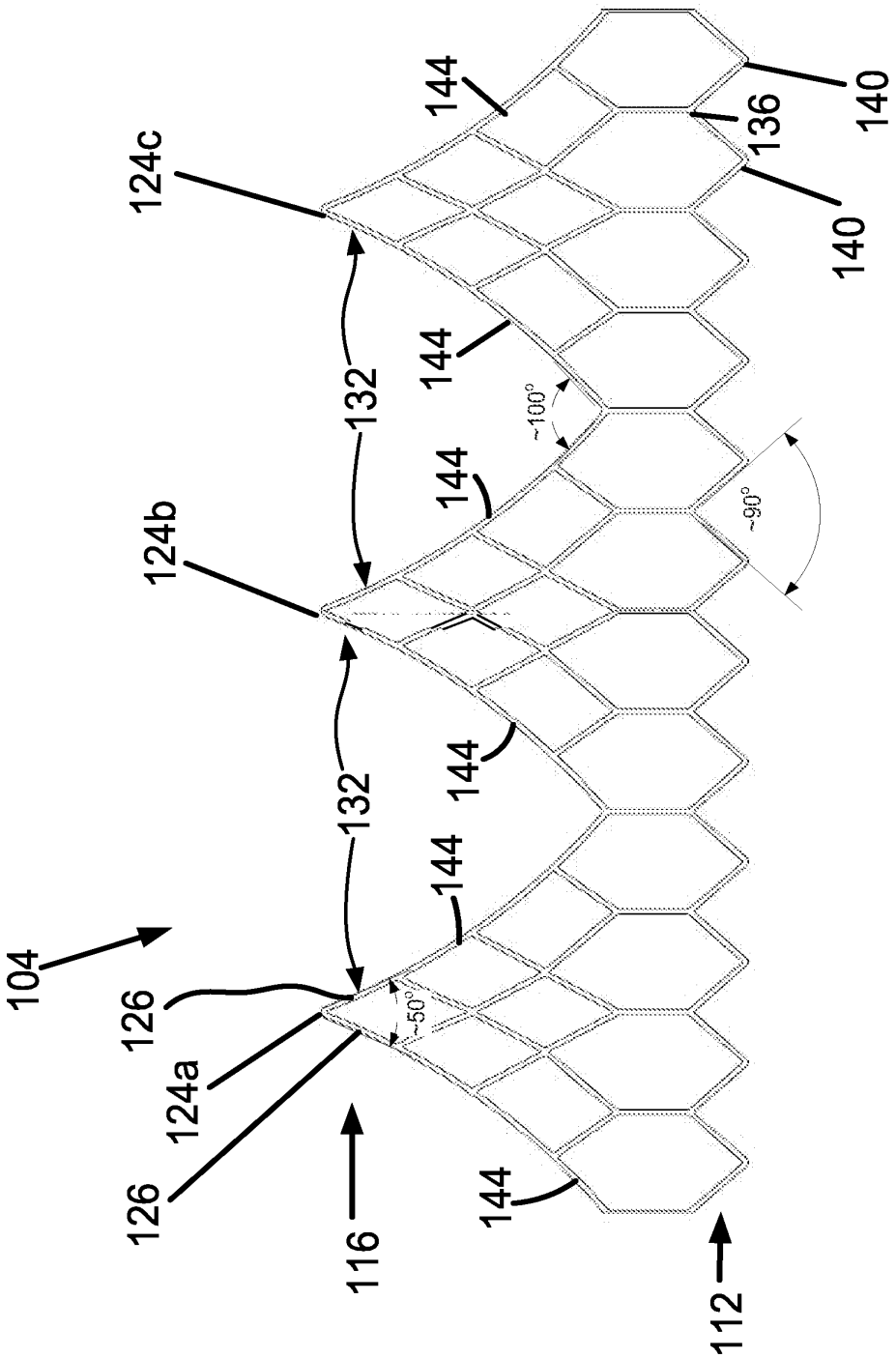

104
126
124a
126
116
112
124b
124c
132
132
144
144
144
144
144
144
140
140
136
~50°
~100°
~90°

FIG. 1F

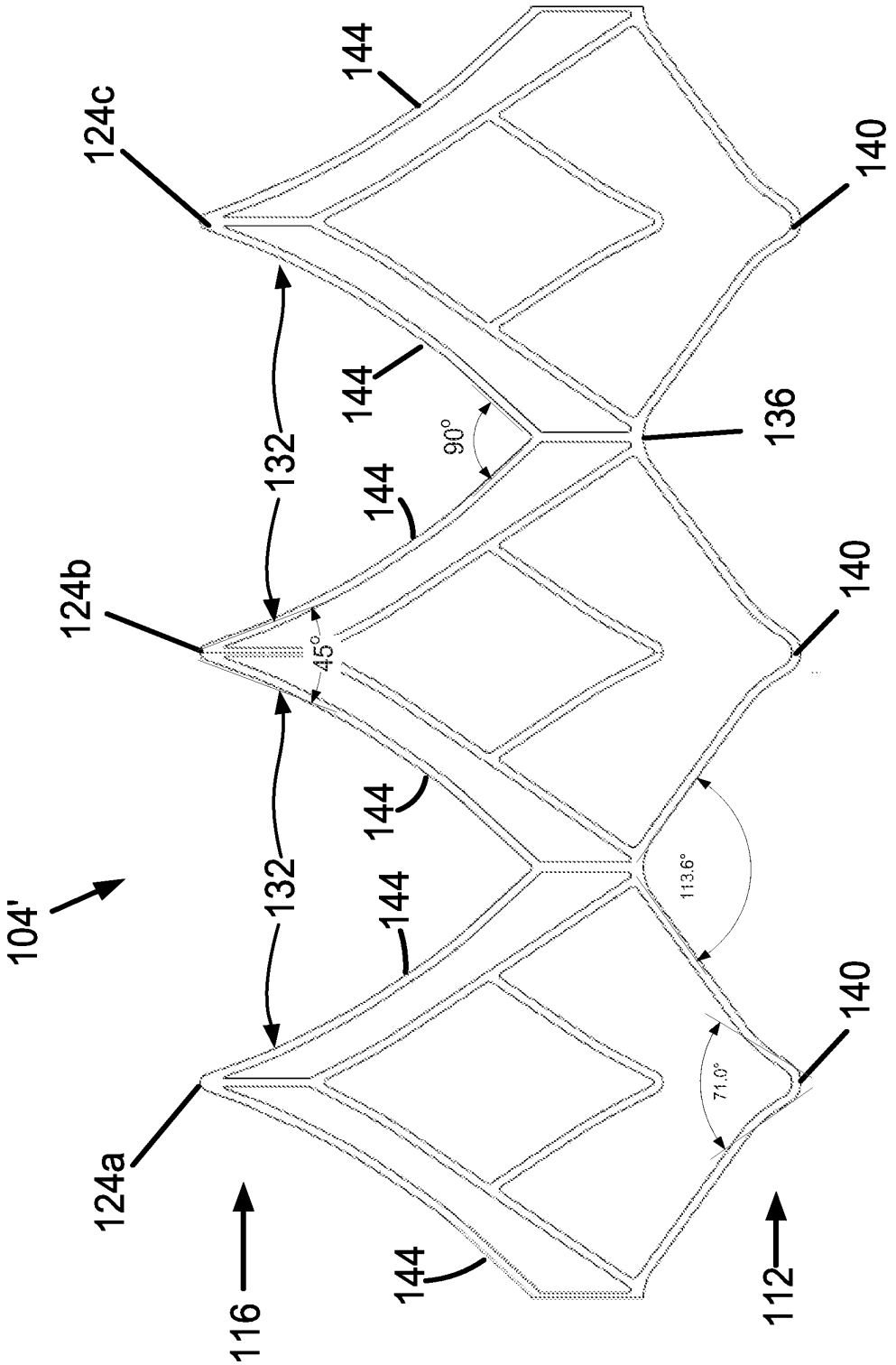

104'
116
112
124a
124b
124c
132
132
144
144
144
144
144
144
136
140
140
140
90°
45°
113.6°
71.0°

FIG. 1G

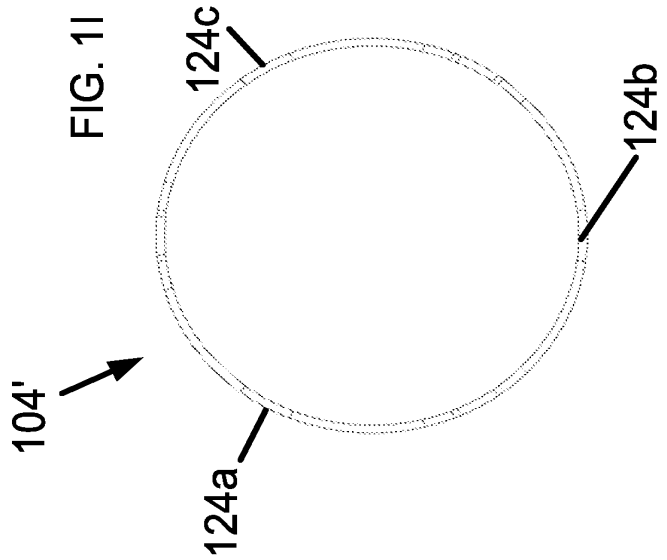

124c
124b
104'
124a

FIG. 1I

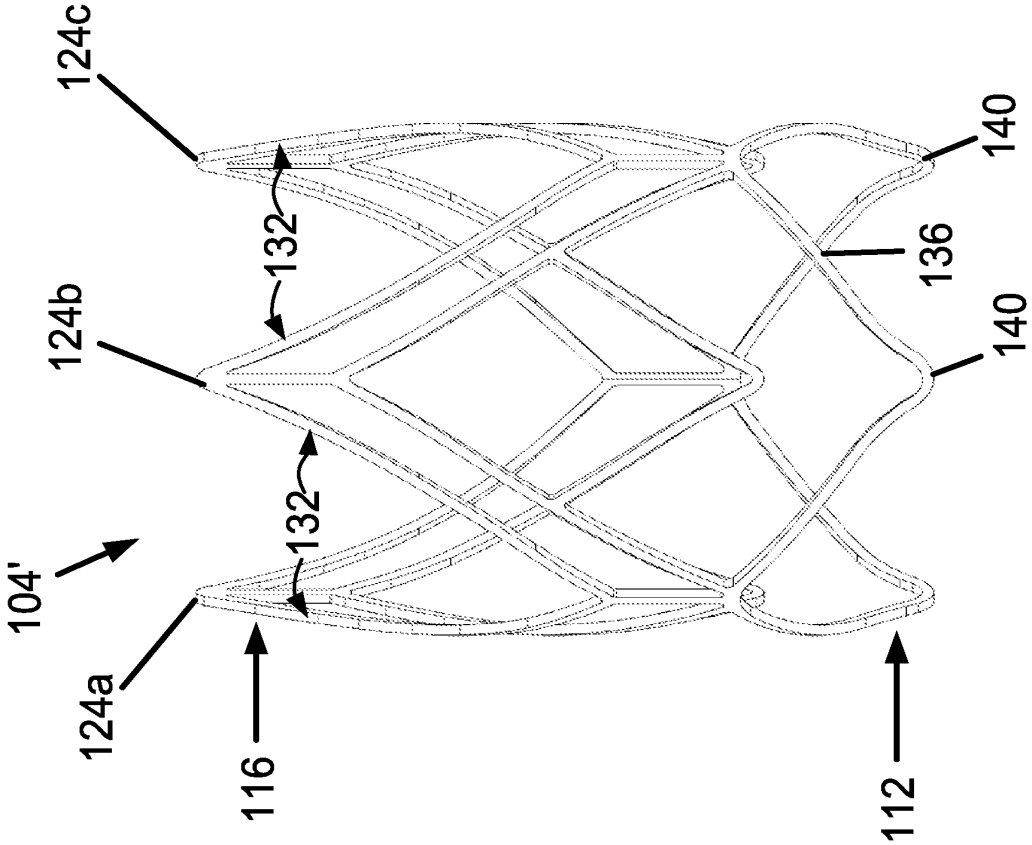

124c
140
132
136
124b
140
132
104'
124a
116
112

FIG. 1H

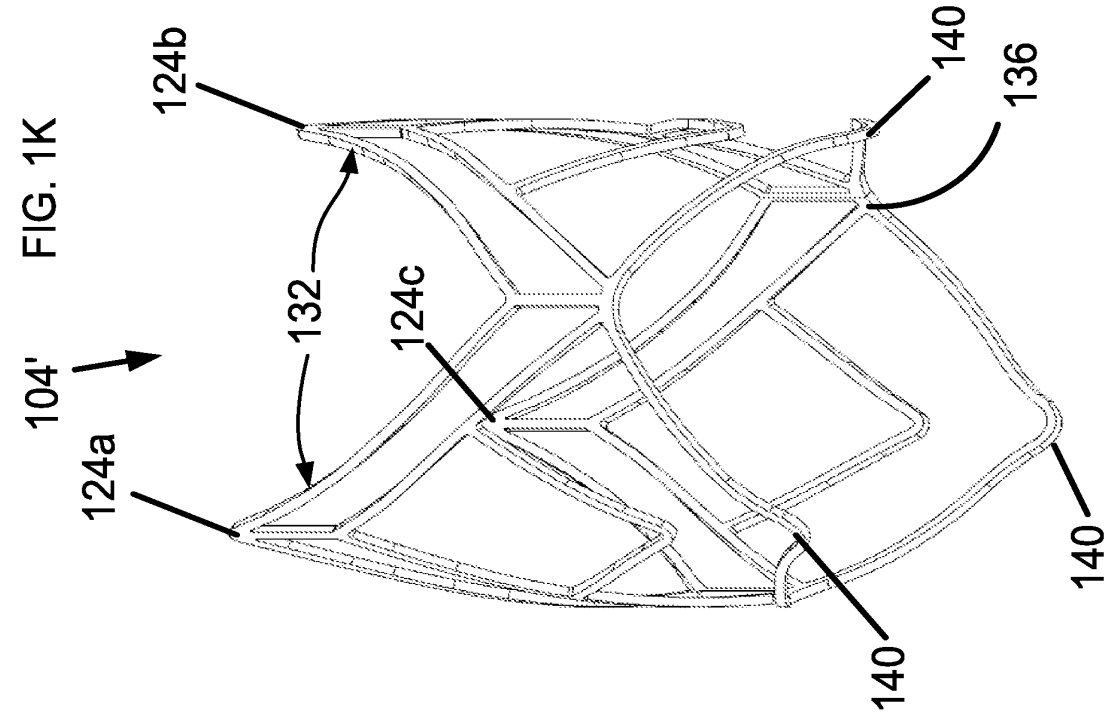

124b
140
136
104'
132
124c
124a
140
140

FIG. 1K

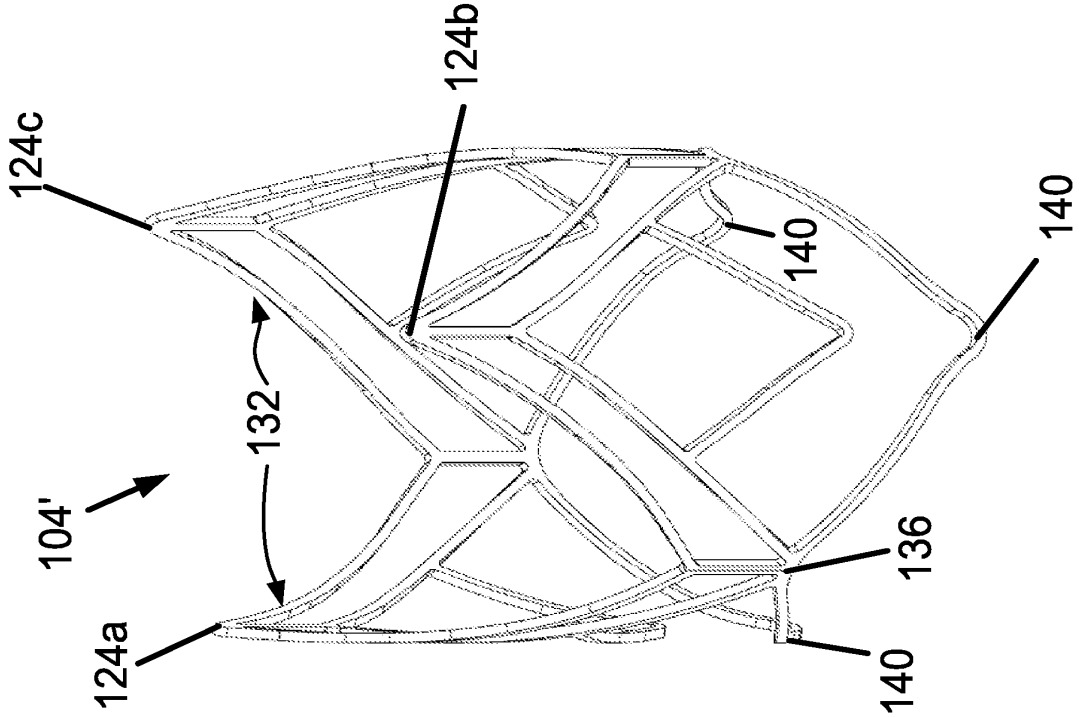

124c
124b
140
140
104'
132
136
124a
140

FIG. 1J

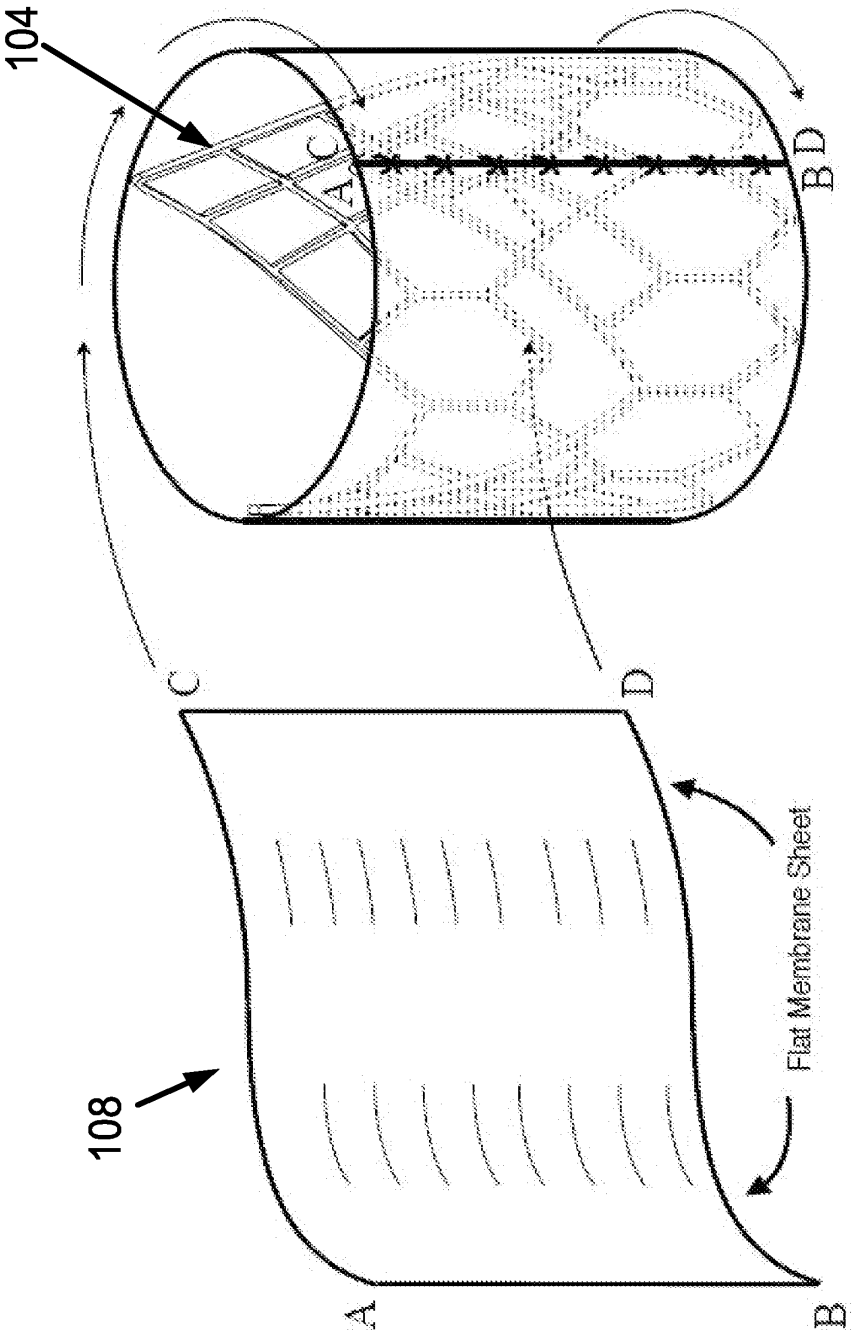

104
108
A
B
C
D
Flat Membrane Sheet
Flat membrane sheet is wrapped around outside/abluminal aspect of cylindrical frame and is secured in closed form by attaching membrane free edges A-B to C-D as by suturing. Membrane is subsequently attached to underlying frame.

FIG. 1L

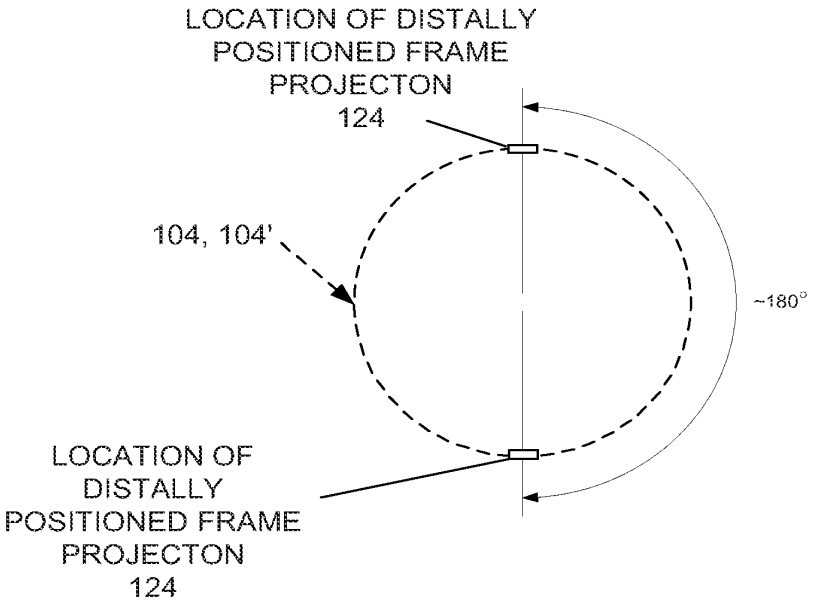

LOCATION OF DISTALLY POSITIONED FRAME PROJECTON 124
104, 104'
~180°
LOCATION OF DISTALLY POSITIONED FRAME PROJECTON 124

Fig. 2

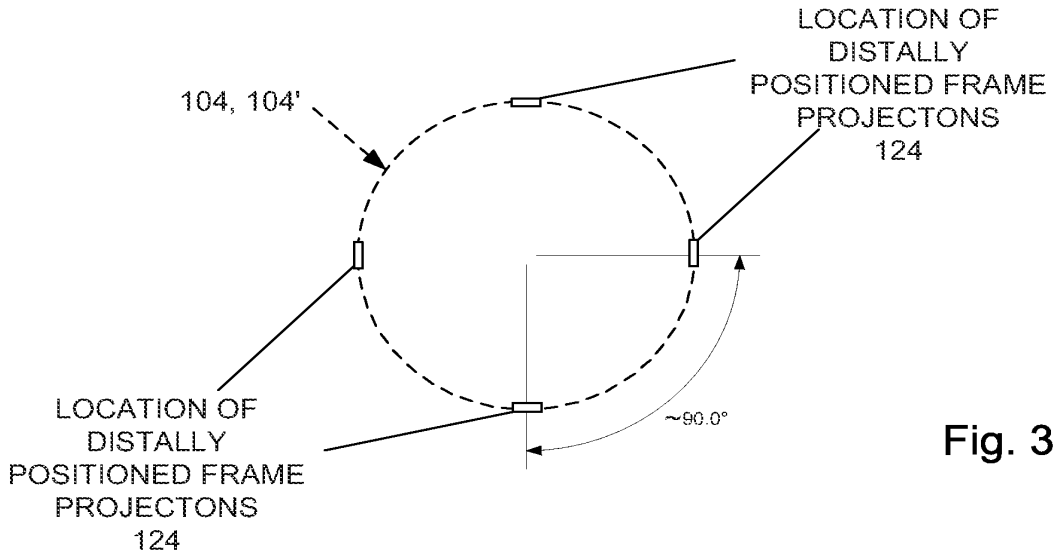

LOCATION OF DISTALLY POSITIONED FRAME PROJECTONS 124
104, 104'
~90.0°
LOCATION OF DISTALLY POSITIONED FRAME PROJECTONS 124

Fig. 3

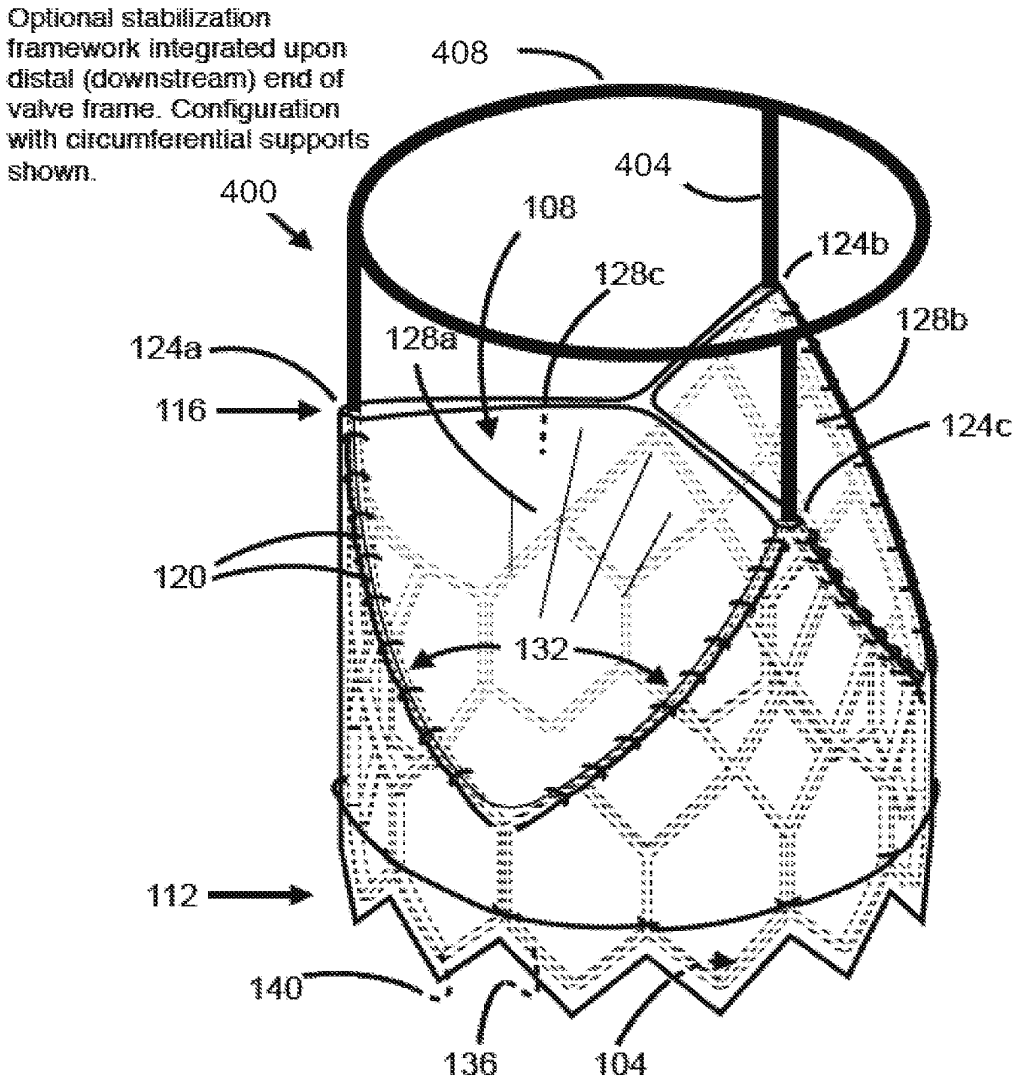

Optional stabilization framework integrated upon distal (downstream) end of valve frame. Configuration with circumferential supports shown.
408
404
400
108
124b
128c
128b
124a
128a
116
124c
120
132
112
140
136
104

Fig. 4

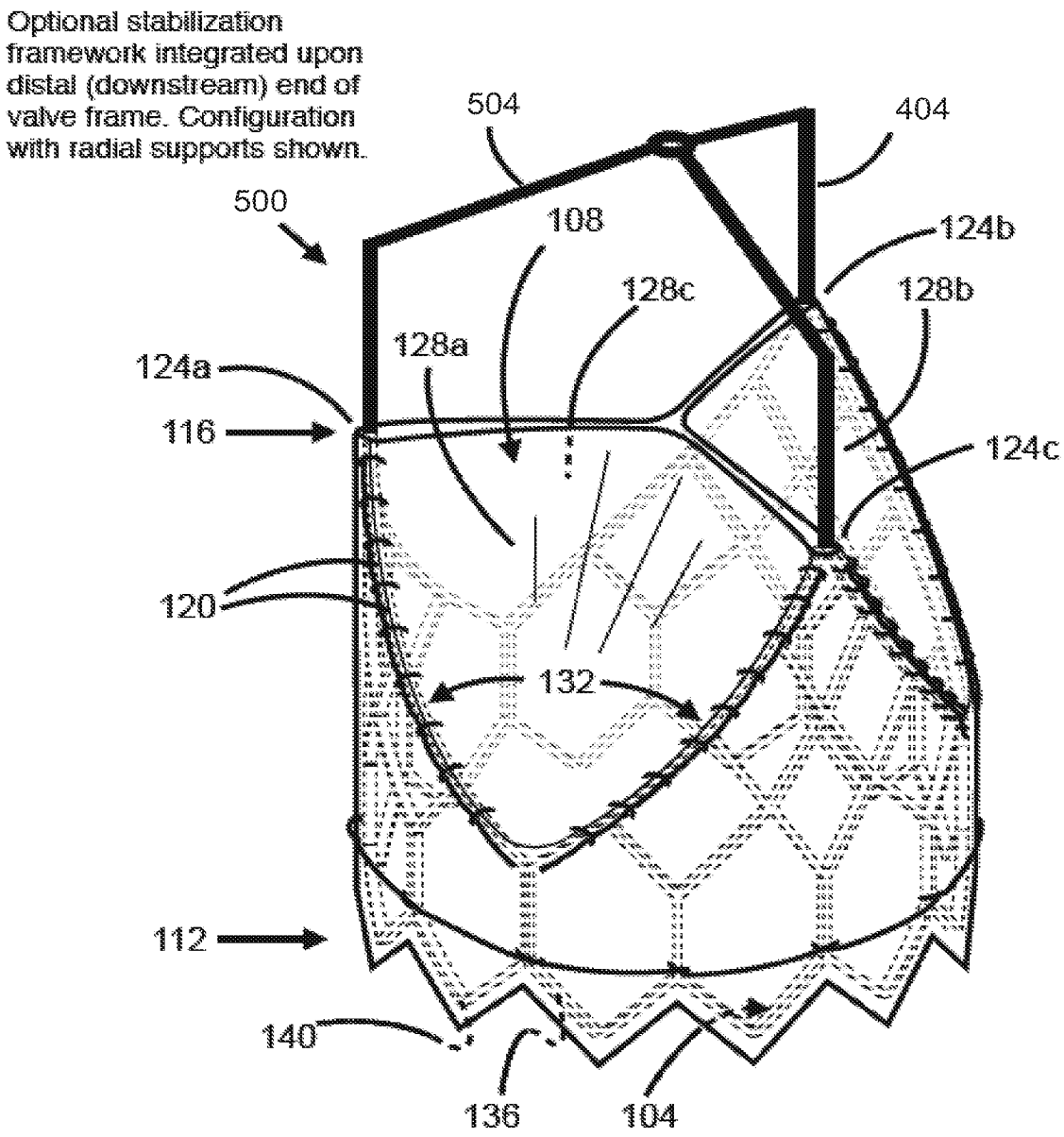

Optional stabilization framework integrated upon distal (downstream) end of valve frame. Configuration with radial supports shown.
504
404
500
108
124b
128c
128b
128a
124a
116
124c
120
132
112
140
136
104

Fig. 5

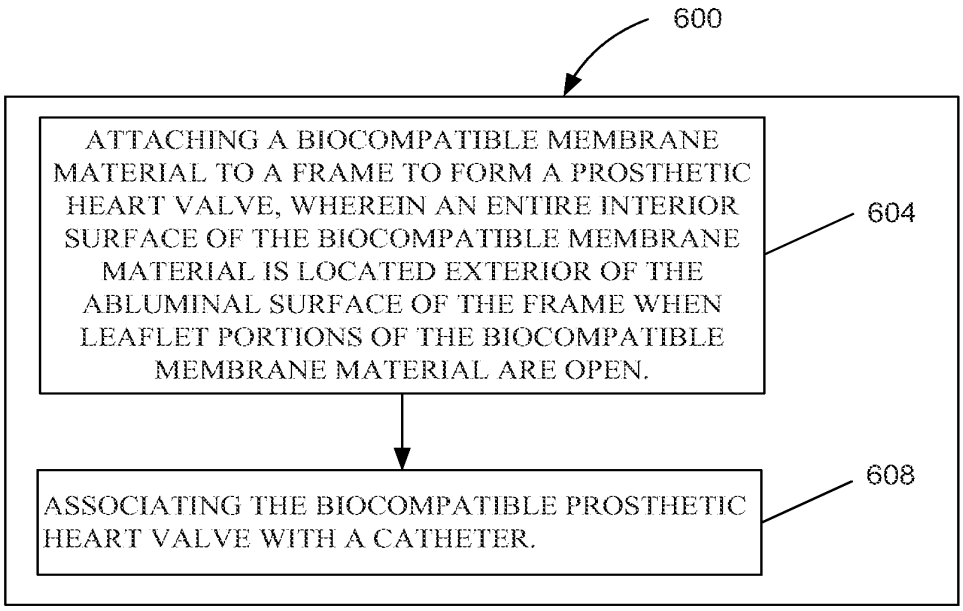

600
ATTACHING A BIOCOMPATIBLE MEMBRANE MATERIAL TO A FRAME TO FORM A PROSTHETIC HEART VALVE, WHEREIN AN ENTIRE INTERIOR SURFACE OF THE BIOCOMPATIBLE MEMBRANE MATERIAL IS LOCATED EXTERIOR OF THE ABLUMINAL SURFACE OF THE FRAME WHEN LEAFLET PORTIONS OF THE BIOCOMPATIBLE MEMBRANE MATERIAL ARE OPEN.
604
ASSOCIATING THE BIOCOMPATIBLE PROSTHETIC HEART VALVE WITH A CATHETER.
608

FIG. 6

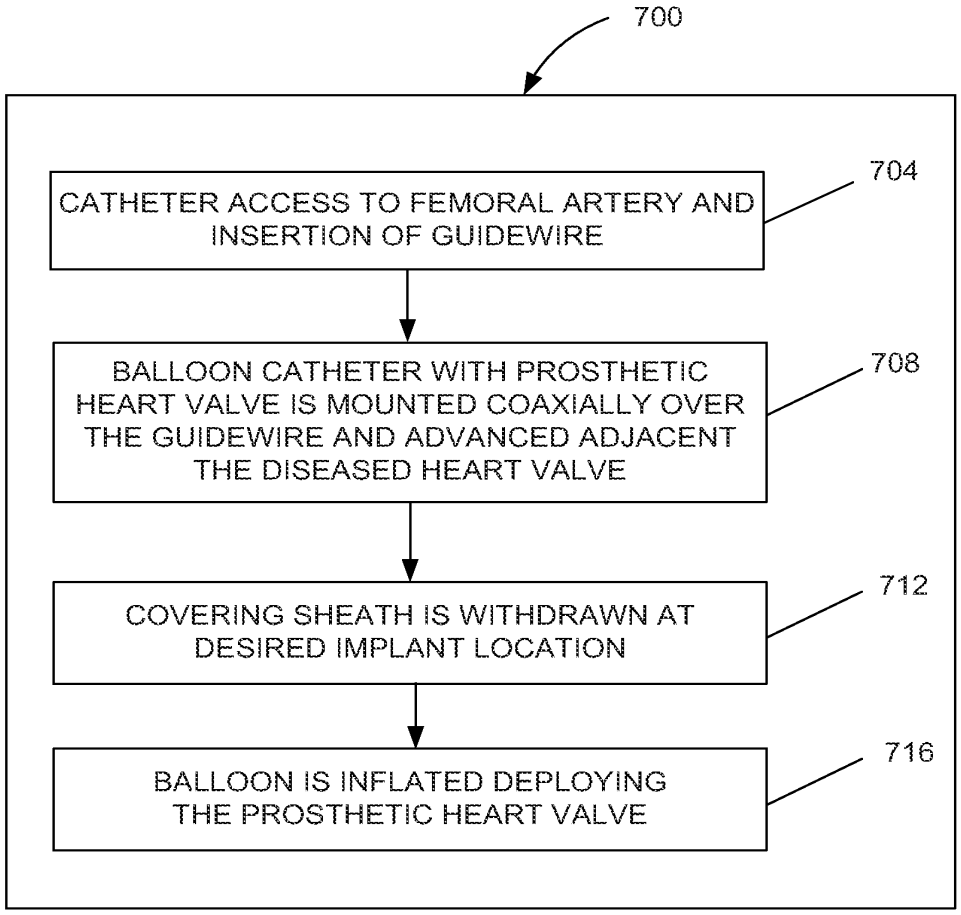

700
CATHETER ACCESS TO FEMORAL ARTERY AND INSERTION OF GUIDEWIRE
704
BALLOON CATHETER WITH PROSTHETIC HEART VALVE IS MOUNTED COAXIALLY OVER THE GUIDEWIRE AND ADVANCED ADJACENT THE DISEASED HEART VALVE
708
COVERING SHEATH IS WITHDRAWN AT DESIRED IMPLANT LOCATION
712
BALLOON IS INFLATED DEPLOYING THE PROSTHETIC HEART VALVE
716

FIG.7

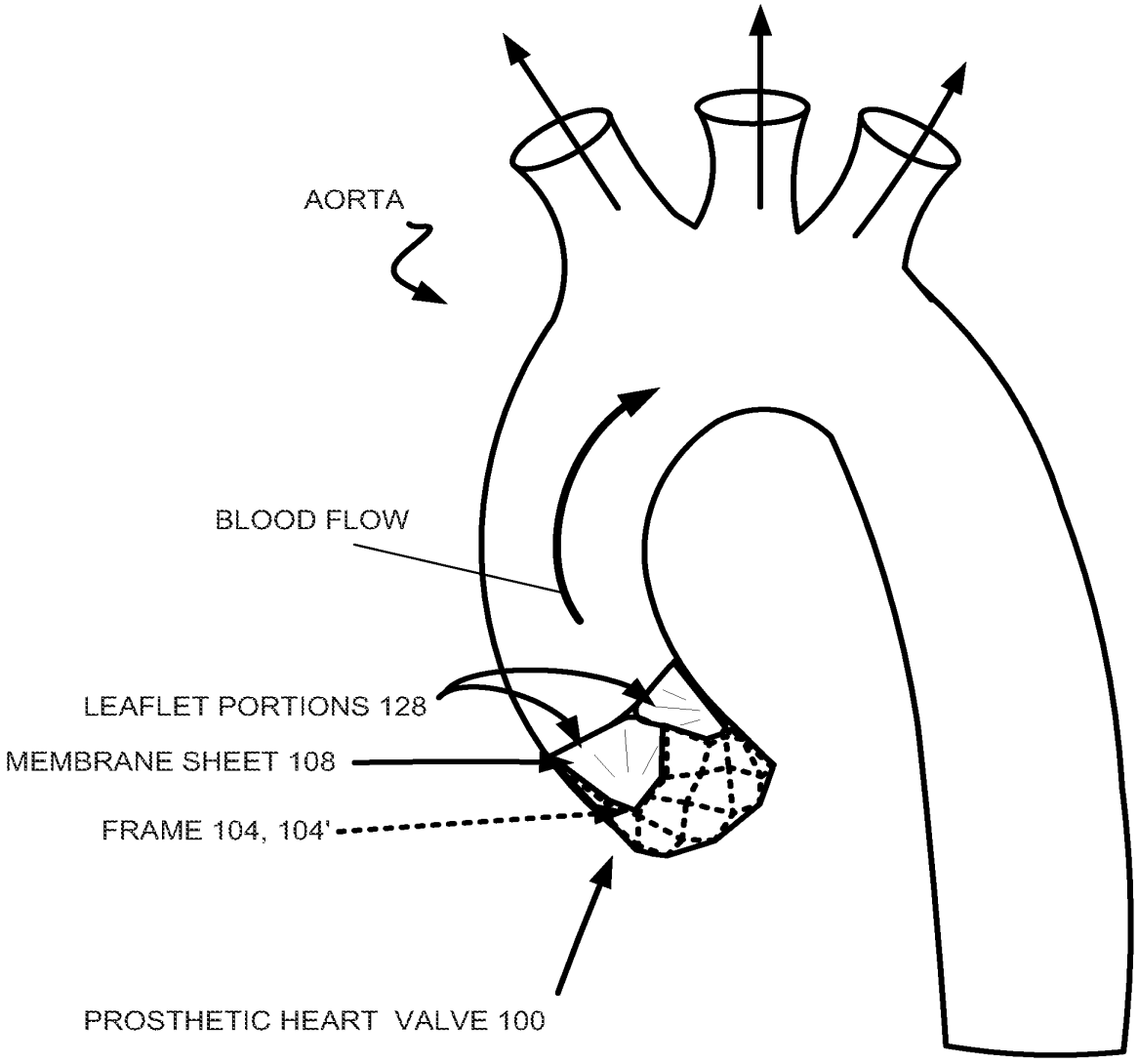

AORTA
BLOOD FLOW
LEAFLET PORTIONS 128
MEMBRANE SHEET 108
FRAME 104, 104'
PROSTHETIC HEART VALVE 100

FIG. 8

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

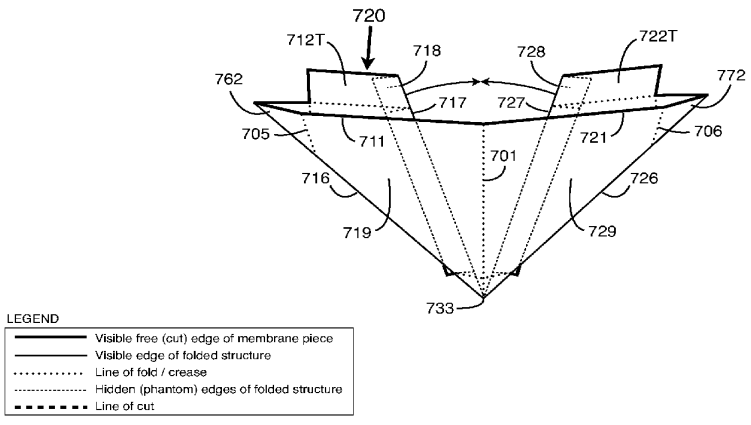
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) **Title**: PERCUTANEOUSLY DELIVERABLE HEART VALVE INCLUDING FOLDED MEMBRANE CUSPS WITH INTEGRAL LEAFLETS

Figure 7D



(57) **Abstract**: A transcatheter, percutaneously implantable, prosthetic heart valve is provided that comprises a lattice frame and two or more integrated cusp and leaflet folded structures attached to the lattice frame. The two or more integrated cusp and leaflet folded structures each comprise a flat sheet of biocompatible membrane that is folded to include a substantially conical shape according to a flat folding pattern. The substantially conical shape is further formed by joining apposing sides of the substantially conical shape along a seam. The two or more integrated cusp and leaflet folded structures are each attached along their respective seams to the lattice frame in a direction substantially parallel to an axis of the lattice frame. Embodiments of valves described herein have application within the entire vascular system.

WO 2012/082952 A2

PERCUTANEOUSLY DELIVERABLE HEART VALVE INCLUDING FOLDED MEMBRANE CUSPS WITH INTEGRAL LEAFLETS

FIELD

The present invention relates to the field of medical devices, and more particularly, to percutaneously deliverable heart valves.

BACKGROUND

The native heart valves, and in particular, the aortic valve, has a complex geometry that endows both ideal opening and closing geometries through an anatomic joining of a tubular inflow structure of the left ventricular outflow tract and an expansion of the valve sinuses above the hinging point of the valve leaflets defined by the aortic valve annular ring, part of the fibrous "skeleton" of the heart.

For the purposes of discussion and definition in the ensuing descriptions, the "upper", downstream outlet structure of the native aortic valve above its hinging point contains three valve "cusps" of a generally spherical contour with central mobile portions termed "leaflets" that are induced by fluid pressure gradients to meet centrally to close and to move radially outward to open in valve operation. The cusps are further continuous with downstream curved tissue walls meeting the tubular great vessel, the aorta, at the "sino-tubular junction". Each cusp and its upper, downstream extension above the level of leaflet closure ("coaptation") are a continuous structure of a generally spherical contour and together define the envelope of the "sinus of Valsalva. Typically, surgical prosthetic valves are implanted by excision of the diseased native valve leaflets at the level of the annular ring, and suturing of the prosthetic valve at this point, thus replacing only the opening geometry of the valve and leaving the outer structures of the cusps and the sinuses of Valsalva, the anatomy that confers proper closing geometry, generally intact.

Surgical valve prostheses are generally constructed as analogs to this central portion of the native valve geometry involved in the opening phase of the valve cycle. This approach to modeling the replacement valve prosthesis is enabled by the nature of the surgical technique: the replacement valve is sutured into the valve seat under direct vision. In contrast, a percutaneous stent-mounted heart valve ("PHV") is typically a construct in which the operating valve membrane leaflets are mounted and confined within the tubular envelope of a collapsible frame for effective transvascular delivery.

Further, in order to preclude valve regurgitation, the base of each leaflet must lie in exact apposition to the valve seat to form a seal, a condition that is difficult to satisfy without implantation under direct vision. Even then, since the diseased native valve would not be removed and its axial geometry is often distorted, it may not be possible to seat a PHV exactly

under any circumstances. Thus, a cylindrical cuff layer, interior or exterior to the frame, is usually employed that acts as a seal and provides some latitude in the positioning and alignment of the PHV along the axis of flow, allowing for reliable and effective PHV implantation and minimizing the risk of significant valve regurgitation. Finally, the diseased native valve leaflets, when pushed outward by the deployed PHV frame, may themselves form a barrier separating the sinuses of Valsalva from the leaflets of the PHV, then disrupting the native closing geometry of the valve so that the sinuses are no longer continuous with the pressurized space above the PHV leaflets.

These issues illustrate some of the challenges to the formation of a PHV; that is, how to confine operating leaflets within a partially sealed tubular structure while preserving ideal opening and closing valve behavior without the benefit of the natural mechanism of the sinuses of Valsalva in a single valve and leaflet geometry, such as the separate and distinct upper and lower geometries of the native valve. As such, there is a need for additional devices, systems and/or methods that address one or more of the problems or shortcomings noted above.

SUMMARY

It is to be understood that the present invention includes a variety of different versions or embodiments, and this Summary is not meant to be limiting or all-inclusive. This Summary provides some general descriptions of some of the embodiments, but may also include some more specific descriptions of other embodiments.

Two goals of at least some embodiments of the present inventions are: (1) to maximize effective orifice area and minimize opening pressure gradients through geometry that mimics the natural form of inflow into the valve — the tubular outflow tract of the heart pumping chamber; and (2) to minimize the inward tension on the leaflet commissures in the closed position through geometry that mimics the natural effect of the sinuses of Valsalva - an effect that prevents downward displacement of the leaflet free edges under closing pressure, thus distributing force along the lines of leaflet apposition rather than focusing it at the points of leaflet attachment to the frame.

The first of these goals dictates that the inflow to the valve, similar to that of the natural aortic valve, encounters then outwardly displaces the most central portion of the leaflets first, with opening moving progressively outward along the surface of the leaflets. The second suggests that the cross-sectional profile of the valve sinus/cusp formed in its central portion by the free edge of the leaflets, like that of the natural aortic valve, should be approximately elliptical, and that the cross-sectional diameter of each cusp should progressively decrease below the plane of leaflet apposition, like that of the natural valve cusps. One or more embodiments of the one or more present inventions answer the configuration ideals with a robust balance of

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functional geometries for valve opening and closing.

The spherical geometry of the native aortic valve leaflets is difficult to replicate in a transcatheter valve. First, while this shape is functionally robust in vivo, even if reproduced in some form it is not suited to efficient radial compression typically required for collapse into a small diameter delivery catheter used in transcatheter valve delivery systems, and discontinuities would develop in the leaflet surface that would resolve into irregular folds with at least some circumferential component, thereby threatening the restitution of the geometry on reopening at deployment. Second, tissue bioprosthetic valve leaflets, if not actually constituted of the animal valve itself, are typically constructed of flat sheet tissue membrane from which rendering of cusps with leaflets of a spherical contour would be difficult if not impossible without the use of traction force on the material, or extensive cutting and suturing of the leaflet cusp portion — an impractical approach, and a threat to the material integrity of the thin tissue membrane.

At least one embodiment of the one or more present inventions answers these challenges by employing conical rather than spherical cusp geometry, thereby reproducing some benefits of the latter with near-elliptical leaflet cross-section that progressively decreases moving proximal to the plane of leaflet apposition while being readily conformed on outward radial compression in the valve opening phase into a substantially flat folded construct against the interior tubular walls of the containing frame. This favorable resolution of the conical geometry in opening phase expresses the opening efficiency of this valve design with a large effective orifice area and low transvalvular energy losses. In the closed position, the free edges of the separate leaflets of the conical cusps meet in apposition, each cone acting as an independent valve; pressure load-bearing is enhanced by the material continuity of the cone structure with the inner apposing wall and outer wall of each cone being part of a single continuous membrane structure. Further, the conical cusps are particularly suited for compression and containment within a collapsible frame for transcatheter delivery.

In at least one embodiment, a transcatheter, percutaneously implantable, bioprosthetic heart valve having a lattice frame comprising a substantially tubular alloy metal mesh, and two or more valve cusps with leaflets mounted to the lattice frame, is provided. Further, the cusps include a flat sheet of processed mammalian tissue membrane that is folded into a substantially conical shape according to a flat folding pattern, the substantially conical shape is further formed by joining opposing sides of the substantially conical shape along a seam that is oriented along a longitudinal axis of the substantially conical shape. In at least one embodiment, the two or more cusps are attached along their seams (which may or may not include the apexes of the cusps), such as, by way of example and not limitation, along the axial centerline of the outer circumference of the cone, to an interior portion of the lattice frame along an axial flow direction

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of the valve and are further attached along the distal, downstream, edge of the substantially conical shape along at least an outer half of the substantially conical shape's edge. When the membrane valve leaflet is attached to the frame, its principal line of securement along the axial centerline of the outer circumference of the cone is attached at a non-commissural seam or edge, effecting a coaxial (to the flow axis) line of attachment at an area of the structure that advantageously bears load, thereby relieving the commissural attachment of loads associated with the securement of the cusp structures to the frame. As such, the leaflet commissure attachments, thus located at points where the leaflet membrane is continuous and uncut, advantageously need only bear the centripetal loads associated with the radially inward movement and operation of the free edges of the leaflets.

In at least one embodiment, a transcatheter, percutaneously implantable, bioprosthetic heart valve is provided wherein two distal, downstream, vertices of the flattened cusp and leaflet structure are folded over in a radially outward direction and fixed to the frame such that the vertex folds of neighboring leaflets are adjacent and define an extent of leaflet apposition at the points corresponding to leaflet commissures.

In at least one embodiment, a transcatheter, percutaneously implantable, bioprosthetic heart valve is provided wherein a vertex forming a proximal, upstream, apex of the substantially conical shape is folded over in a radially outward direction and affixed to an inner portion of the frame.

In at least one embodiment, a transcatheter, percutaneously implantable, bioprosthetic heart valve is provided wherein the flat folding pattern is polygonal and includes extending portions that, when the leaflet is mounted, extend circumferentially outward from an axial line of attachment of the leaflet to the frame so as to form, when joined and attached to corresponding extending portions of neighboring leaflets, an integral, inner, luminal, circumferentially partial or complete sealing cuff.

In at least one embodiment, a transcatheter, percutaneously implantable, bioprosthetic heart valve is provided wherein a separate tubular sealing cuff of tissue membrane is attached to an outer, abluminal surface of the frame to form a sealing cuff. In at least one embodiment, the membrane sheet is a single layer of a substantially homogenous material. In at least one embodiment, the membrane sheet is an unlaminated single layer of material. In at least one embodiment, the membrane sheet is a single layer of material that does not include any reinforcement, such as reinforcing fibers. In at least one embodiment, the membrane sheet is a single layer of treated pericardium tissue. In at least one embodiment, the membrane sheet is a single layer of a synthetic film.

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Therefore, in accordance with at least one embodiment, a transcatheter, percutaneously implantable, prosthetic heart valve is provided, comprising:

a lattice frame; and

two or more integrated cusp and leaflet folded structures attached to the lattice frame, the two or more integrated cusp and leaflet folded structures each comprising a flat sheet of biocompatible membrane that is folded to include a mobile leaflet layer and a cusp wall layer, wherein the cusp wall layer located radially outside of the mobile leaflet layer, and wherein the cusp wall layer is further formed by joining apposing sides of the cusp wall layer along a seam. In accordance with at least one embodiment, the two or more integrated cusp and leaflet folded structures are each attached along their respective seams to the lattice frame. In accordance with at least one embodiment, the seams are oriented in a direction substantially parallel to an axis of the lattice frame. In accordance with at least one embodiment, the flat sheet of biocompatible membrane forming at least one integrated cusp and leaflet folded structure of the two or more integrated cusp and leaflet folded structures comprises two or more pieces of biocompatible membrane material.

In accordance with at least one embodiment, a transcatheter, percutaneously implantable, prosthetic heart valve is provided, comprising:

a lattice frame; and

two or more integrated cusp and leaflet folded structures attached to the lattice frame, the two or more integrated cusp and leaflet folded structures each comprising a flat sheet of a biocompatible membrane that is folded to include a valve cusp according to a flat folding pattern, wherein the valve cusp is further formed by joining apposing sides of the valve cusp along a seam, and wherein the two or more integrated cusp and leaflet folded structures are each attached along their respective seams to the lattice frame in a direction substantially parallel to an axis of the lattice frame. In accordance with at least one embodiment, two distal, downstream, vertices of the integrated cusp and leaflet folded structure are folded over as vertex folds in a radially outward direction and fixed to the lattice frame such that the vertex folds of circumferentially adjacent leaflets are adjacent and define a degree of leaflet apposition at the points corresponding to leaflet commissures. In accordance with at least one embodiment, the two distal, downstream, vertices are fixed to the lattice frame by attachment not along an alignment with the vertex folds. In accordance with at least one embodiment, a vertex forming a proximal, upstream, tip of the substantially conical shape is folded over in a radially outward direction and attached to an inner portion of the lattice frame. In accordance with at least one embodiment, the flat folding pattern is polygonal and includes extending portions that, when the cusp is mounted, extend circumferentially outward from an axial line of attachment of the cusp

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to the frame so as to form, when joined and attached to corresponding extending portions of neighboring cusps, an integral, inner, luminal, circumferentially complete sealing cuff. In accordance with at least one embodiment, the flat folding pattern is polygonal and includes extending portions that, when the two or more cusps are mounted, extend circumferentially outward from an axial line of attachment of the cusp to the lattice frame so as to form a circumferentially incomplete sealing cuff portion associated with each cusp. In accordance with at least one embodiment, a separate tubular sealing cuff of biocompatible membrane is attached to an outer, abluminal surface of the lattice frame to form a sealing cuff. In accordance with at least one embodiment, the lattice frame is collapsible and expandable and comprises a metal alloy substantially configured as tubular stent member. In accordance with at least one embodiment, the biocompatible membrane comprises processed mammalian pericardium tissue. In accordance with at least one embodiment, the biocompatible membrane does not comprise a treated tissue. In accordance with at least one embodiment, the biocompatible membrane comprises a synthetic material. In accordance with at least one embodiment, the seams of the two or more integrated cusp and leaflet folded structures are each oriented along an axis of flow of the valve. In accordance with at least one embodiment, the two or more integrated cusp and leaflet folded structures are each further attached to a circumferential portion of the lattice frame along at least a portion of their distal downstream edges. In accordance with at least one embodiment, the two or more integrated cusp and leaflet folded structures are attached to the lattice frame at least at a non-commissural seam aligned with an axial flow direction of the valve.

In accordance with at least one embodiment, a transcatheter, percutaneously implantable, prosthetic heart valve is provided, comprising:

a lattice frame; and

two or more integrated cusp and leaflet structures attached to the lattice frame, the two or more integrated cusp and leaflet structures each comprising a flat sheet of biocompatible membrane that is folded to include a mobile leaflet layer and a cusp wall layer, wherein with the mobile leaflet layer in a closed position a transverse cross-sectional area of a cusp-sinus space decreases monotonically from a distal end to a proximal end of the mobile leaflet layer. In accordance with at least one embodiment, the cusp wall layer is located radially outside of the mobile leaflet layer. In accordance with at least one embodiment, the cusp wall layer is further formed by joining apposing sides of the cusp wall layer along a seam. In accordance with at least one embodiment, the mobile leaflet layer in the closed position a transverse cross-sectional length of the mobile leaflet layer decreases monotonically from a distal end to a proximal end of the mobile leaflet layer. In accordance with at least one embodiment, the mobile leaflet layer and

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the cusp wall layer of each integrated cusp and leaflet structure are a single continuous piece of biocompatible membrane.

At least one invention of the one or more present inventions is a novel integrated cusp and leaflet structure that has application for a variety uses, including implantable valves other than prosthetic heart valves. Accordingly, in at least one embodiment, and in subcombination, an integrated cusp and leaflet structure for attachment to a lattice frame to form a valve configured for implantation in a vascular system of a patient is provided, the integrated cusp and leaflet structure comprising:

a flat sheet of biocompatible membrane that is folded to include a mobile leaflet layer and a cusp wall layer, wherein the cusp wall layer is divided along a seam, and wherein the mobile leaflet layer is continuous and apposes the cusp wall layer when the integrated cusp and leaflet structure is pressed substantially flat. In accordance with at least one embodiment, the mobile leaflet layer and the cusp wall layer of the integrated cusp and leaflet structure are a single continuous piece of biocompatible membrane. In accordance with at least one embodiment, the biocompatible membrane comprises a synthetic material. In accordance with at least one embodiment, the integrated cusp and leaflet structure further comprises at least one commissure tab. In accordance with at least one embodiment, the at least one commissure tab is configured for engaging a slot within a member of the lattice frame.

One or more embodiments of the one or more present inventions are also directed to methods for forming the inventive valves described herein, as well as its component elements. Accordingly, a method of forming an integrated cusp and leaflet folded structure for use in an implantable valve having an axial flow direction is provided, comprising: folding a flat sheet of biocompatible membrane to form an integrated cusp and leaflet folded structure according to a flat folding pattern, wherein said folding includes making two diagonal folds in the flat sheet of biocompatible membrane, the two diagonal folds separating a mobile leaflet layer from a cusp wall layer of the integrated cusp and leaflet folded structure. In accordance with at least one embodiment, the two diagonal folds are angled at between about 10 to 80 degrees from the axial flow direction. In accordance with at least one embodiment, the method further comprises forming first and second cusp wall folds, wherein the cusp wall layer is further formed by joining apposing membrane portions adjacent the first and second cusp wall folds along a seam that is oriented substantially parallel with the axial flow direction.

In addition to the foregoing, in accordance with at least one embodiment, a method of forming a transcatheter, percutaneously implantable, prosthetic heart valve is provided, comprising: folding a plurality of integrated cusp and leaflet folded structures, each integrated cusp and leaflet folded structure of the plurality of integrated cusp and leaflet folded structures

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comprising a flat sheet of biocompatible membrane that is folded to form a cusp according to a flat folding pattern, wherein the cusp is further formed by joining apposing sides of the cusp along a seam; and attaching each integrated cusp and leaflet folded structure of the plurality of integrated cusp and leaflet folded structures to a lattice frame, wherein the two or more integrated cusp and leaflet folded structures are each attached along their respective seams to the lattice frame in a direction substantially parallel to an axis of the lattice frame.

Various components are referred to herein as "operably associated." As used herein, "operably associated" refers to components that are linked together in operable fashion, and encompasses embodiments in which components are linked directly, as well as embodiments in which additional components are placed between the two linked components.

As used herein, "at least one," "one or more," and "and/or" are open-ended expressions that are both conjunctive and disjunctive in operation. For example, each of the expressions "at least one of A, B and C," "at least one of A, B, or C," "one or more of A, B, and C," "one or more of A, B, or C" and "A, B, and/or C" means A alone, B alone, C alone, A and B together, A and C together, B and C together, or A, B and C together.

Various embodiments of the present inventions are set forth in the attached figures and in the Detailed Description as provided herein and as embodied by the claims. It should be understood, however, that this Summary does not contain all of the aspects and embodiments of the one or more present inventions, is not meant to be limiting or restrictive in any manner, and that the invention(s) as disclosed herein is/are understood by those of ordinary skill in the art to encompass obvious improvements and modifications thereto.

Additional advantages of the present invention will become readily apparent from the following discussion, particularly when taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify the above and other advantages and features of the one or more present inventions, a more particular description of the one or more present inventions is rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It should be appreciated that these drawings depict only typical embodiments of the one or more present inventions and are therefore not to be considered limiting of its scope. The one or more present inventions are described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Fig. 1A is a plan view of a flat sheet membrane template for the formation of an integrated cusp and leaflet folded structure in accordance with at least one embodiment of the one or more present inventions;

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Fig. 1B is an oblique axial top (distal) perspective view directed downward (proximal) and radially outward of a folded membrane sheet after execution of the template foldings illustrated in Fig. 1A, thereby yielding a completed integrated cusp and leaflet folded structure;

Fig. 1C is a side perspective view directed radially outward of the inner aspect of an initially folded version of the integrated cusp and leaflet template shown in Fig. 1A;

Fig. 1D is an oblique axial top (distal) perspective view directed downward (proximal) and radially outward of a further partially folded version of the integrated cusp and leaflet folded structure shown in Fig. 1C;

Fig. 1E is an another oblique axial top (distal) perspective view directed downward (proximal) and radially outward of a further partially folded version of the integrated cusp and leaflet folded structure shown in Fig. 1D;

Fig. 1F is a modified version of the integrated cusp and leaflet folded structure shown in Fig. 1E;

Fig. 1G is same structure and view shown in Fig. 1E, along with a top (distal) cross-section schematic view of the distal end of a three-leaflet valve in a closed operating position;

Fig. 2 is a plan view of another flat sheet membrane template for the formation of an integrated cusp and leaflet folded structure in accordance with at least one embodiment of the one or more present inventions;

Fig. 3 is a plan view of yet another flat sheet membrane template for the formation of an integrated cusp and leaflet folded structure in accordance with at least one embodiment of the one or more present inventions;

Fig. 4 is a plan view of still yet another flat sheet membrane template for the formation of an integrated cusp and leaflet folded structure in accordance with at least one embodiment of the one or more present inventions;

Fig. 5A is a plan view of another flat sheet membrane template for the formation of an integrated cusp and leaflet folded structure in accordance with at least one embodiment of the one or more present inventions;

Fig. 5B is an oblique axial top (distal) perspective view directed downward (proximal) and radially outward of a partially folded version of an integrated cusp and leaflet folded structure prepared in accordance with the template shown in Fig. 5A;

Fig. 5C is an oblique axial top (distal) perspective view directed downward (proximal) and radially outward of a further partially folded version of the integrated cusp and leaflet folded structure shown in Fig. 5B;

Fig. 5D is plan view of the inner (luminal) aspect of a completely folded version of the structure of Fig. 5C, thereby yielding a completed integrated cusp and leaflet folded structure

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prepared in accordance with the template shown in Fig. 5A (with the exception of unfolded commissure tabs);

Fig. 5E shows a detail perspective view of a folded commissure tab;

Fig. 5F shows a perspective view of the outer (abluminal) aspect of the device shown in Fig. 5D;

Fig. 6 is a plan view of yet another flat sheet membrane template for the formation of an integrated cusp and leaflet folded structure in accordance with at least one embodiment of the one or more present inventions;

Fig. 7A is a plan view of still yet another flat sheet membrane template for the formation of an integrated cusp and leaflet folded structure in accordance with at least one embodiment of the one or more present inventions;

Fig. 7B is an oblique axial top (distal) perspective view directed downward (proximal) and radially outward of a partially folded version of an integrated cusp and leaflet folded structure prepared in accordance with the template shown in Fig. 7A;

Fig. 7C is an oblique axial top (distal) perspective view directed downward (proximal) and radially outward of a further partially folded version of the integrated cusp and leaflet folded structure shown in Fig. 7B;

Fig. 7D is an oblique axial top (distal) perspective view directed downward (proximal) and radially outward of yet a further partially folded version of the integrated cusp and leaflet folded structure shown in Fig. 7C;

Fig. 7E shows a shallow oblique top perspective view of the outer (abluminal) aspect of the partially folded cusp and leaflet structure of Fig. 7D;

Fig. 7F is a plan view of the inner (luminal) aspect of a completely folded version of the structure of Fig. 7D yielding an integrated cusp and leaflet folded structure prepared in accordance with the template shown in Fig. 7A (excepting that the commissure tabs and apex are not yet folded outward);

Fig. 7G is a side perspective view of the outer (abluminal) aspect of the structure of Fig. 7F showing a completely folded version of an integrated cusp and leaflet folded structure prepared in accordance with the template shown in Fig. 7A (excepting that the commissure tabs and apex are not yet folded outward);

Fig. 7H is a plan view of the inner (luminal) aspect of a completely folded version of an integrated cusp and leaflet folded structure prepared in accordance with the template shown in Fig. 7A;

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Fig. 7I is a plan view of the outer (abluminal) aspect of a completely folded version of an integrated cusp and leaflet folded structure prepared in accordance with the template shown in Fig. 7A;

Fig. 7J is an oblique top (distal) perspective view of a completely folded version of an integrated cusp and leaflet folded structure prepared in accordance with the template shown in Fig. 7A;

Fig. 7K is a top perspective view directed downward (proximal) into the cusp space of an integrated cusp and leaflet folded structure prepared in accordance with the template shown in Fig. 7A;

Fig. 8A is an oblique top (distal) perspective view of an embodiment of a lattice frame for mounting three of the single-piece folded integrated cusp and leaflet structures as described herein;

Fig. 8B is a side elevation view of the lattice frame shown in Fig. 8A;

Fig. 8C is a side elevation view of the lattice frame of Fig. 8A with a superimposed plan view of the radially outer aspect of the completely folded integrated cusp and leaflet structure of Fig. 7I;

Fig. 8D is an oblique axial (top/distal) perspective view of an assembled three-leaflet valve in accordance with at least one embodiment;

Figs. 9A and 9B are two different oblique axial (top/distal) perspective views of another embodiment of a lattice frame for mounting three of the single-piece folded integrated cusp and leaflet structures that include commissure tabs;

Fig. 9C is a side perspective view of the lattice frame shown in Figs. 9A and 9B with a superimposed plan view of the outer aspect of the completely folded integrated cusp and leaflet structure of Fig. 7I;

Fig. 9D is a side view of the lattice frame shown in Figs. 9A and 9B with superimposed views of the outer aspect of two circumferentially adjacent completely folded integrated cusp and leaflet structures; and

Fig. 9E is an oblique axial (top/distal) perspective view of an assembled three-leaflet valve comprising the lattice frame shown in Figs. 9A and 9B and three identical folded integrated cusp and leaflet structures.

The drawings are not necessarily to scale.

DETAILED DESCRIPTION

One or more embodiments of the one or more inventions described herein include an implantable prosthetic heart valve having a frame and two or more cusp and leaflet structures mounted to the frame. The frame preferably comprises a lattice of substantially tubular alloy

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metal mesh. The cusp and leaflet structures include a membrane operable to open and close, thereby providing a functioning valve when mounted within a frame. In at least one embodiment, the membrane preferably comprises a flat sheet of processed mammalian tissue membrane that is folded into a substantially conical shape according to a flat folding pattern.

In the ensuing descriptions and referenced figures it will be seen that, when applied to a dry sheet membrane, the folding initially results in a cusp shape of an inverted pyramid with a rhomboid base. On relaxation of the folds as occurs naturally with a flexible and pliable membrane, especially when the membrane is hydrated, the cusp shape becomes substantially conical in shape and will be described as such in the ensuing descriptions as it more closely represents the embodiment of the cusp in operation of the valve.

Formation of a valve construct as described herein provides a percutaneously deliverable heart valve with a relatively small diameter for transcatheter placement. That is, the substantially conical shape associated with the flat folding patterns used to form leaflets as described herein allow for construction of a valve that can be compressed prior to introduction to a catheter to an advantageously small diameter, thereby facilitating transcatheter percutaneous delivery of the valve within a patient. The substantially conical shape is further formed by joining two axially oriented sides of the substantially conical shape along a seam that is oriented along a longitudinal axis of the substantially conical shape. The two or more integrated cusp and leaflet structures are affixed to an interior portion of the lattice frame along an axial flow direction of the valve and are further affixed along the distal, downstream, edge of the substantially conical shape along at least an outer half of the substantially conical shape's edge.

One or more of the various embodiments described herein have a number of different features and characteristics as compared to other commercially available prosthetic heart valves. For example, at least one embodiment of a transcatheter, percutaneously implantable, prosthetic heart valve described below comprises a flat polygonal sheet membrane having more than four sides and which forms an integrated cusp and leaflet structure.

In addition, at least one embodiment of a transcatheter, percutaneously implantable, prosthetic heart valve described below comprises integrated cusp and leaflet structures that are attached to a lattice frame at the circumferential perimeter locations corresponding to the commissures. At such locations, the length of the seam that forms the common line of attachment of the cusp and integral leaflet to the frame is less than one-half to two-thirds of the axial length of the membrane portion of the valve.

In at least one embodiment of a transcatheter, percutaneously implantable, prosthetic heart valve, when the valve is in the open position, the mobile leaflet layer apposes or is geometrically free to appose its full outward surface completely to the immediately radially

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located outward structure, such as at least one of the cusp wall layer or interior surface of the lattice frame. In at least one embodiment, in the closed position the transverse cross-sectional length of the mobile leaflet layer and the cross-sectional area of the cusp/sinus space decreases monotonically from the distal end to proximal end of the membrane portion of the valve. (That is, generally the property of a cone as well as an inverted pyramid.)

In at least one embodiment, the mobile leaflet layer and the immediately outward structure for the full axial length of the leaflet (cusp wall layer, frame, or other) are a single continuous piece of material.

In at least one embodiment, at the base of each cusp (that is, at the most proximal extent of the leaflet), the circumferential extent of attachment of the membrane to the frame is less than the circumferential extent of attachment of the membrane to the frame at the distal end of the cusp. In addition, at the base of each cusp, the circumferential extent of transverse (that is, on a line or on the plane of a circumferential single-plane curve of folding that is generally perpendicular to the flow axis of the valve) folding of the membrane to the frame is less than the circumferential extent of transverse folding at the distal end of the cusp.

At least one embodiment, a prosthetic valve described herein comprises an integrated cusp and leaflet structure wherein the apposing sides of the cusp are joined at one or more axially oriented seams. In at least one embodiment, all folds and seams are located on line segments.

At least one embodiment of the one or more present inventions does not include frame elements, such as support members, spanning the interior of the valve luminal to support one or more portions of the membrane sheet. Moreover, at least one embodiment of the one or more present inventions does not include any hardware shaping form inward of or attached to any portion of the mobile leaflet portion of the membrane.

In addition, at least one embodiment of the one or more present inventions does not utilize attachment of the leaflet layer to the frame along the substantially complete circumferential distance separating the commissures at any point below (more proximal than) the commissure tabs.

At least one embodiment of the one or more present inventions does not include a transverse fold or reflection of the leaflet layer along the substantially complete circumferential distance separating the commissures at any point below (more proximal than) the commissure tabs.

Nomenclature

For all embodiments presented herein it is to be understood that a "membrane" includes suitable materials for forming the cusps and leaflets. Accordingly, with regard to particular

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material types that may be used to form the membrane sheet, in at least one embodiment the membrane sheet forming the cusp or leaflet portions includes a one-piece, single layer sheet of biocompatible membrane, such as fixed mammalian pericardium tissue or synthetic biocompatible material, such as ePTFE. In at least one embodiment, the membrane sheet is made from a tissue preparation process that yields a leaflet material of suitable strength and durability for use in a prosthetic transcatheter deliverable heart valve. The content of WO 2011/109450A2 published on September 9, 2011, is incorporated herein by reference. Although the membrane sheet is preferably a single piece of material, a membrane sheet formed of a plurality of pieces of material may be used, such as two to fifty or more pieces of material that are connected.

As used herein "proximal" means situated near or closer to the upstream or flow inlet end of the valve, and "distal" means situated near or closer to the downstream or flow outlet end of the valve. This convention is further applied in the description of the various folded structure elements (membrane sections, edge segments and fold lines) that are termed "proximal" or "distal" if the final position or orientation of said element within the completed folded structure satisfies the above definitions. Likewise, one of said elements is termed, "axial", "transverse" or "circumferential" to describe its position and orientation in the completed valve.

As used herein, a "cusp" means that structural portion of a valve related to a single leaflet that encompasses a space closed toward the lower (proximal) direction and open to the upper (distal) direction, formed by the joined and/or continuous structures of the mobile leaflet portion on the radially inner side and the cusp wall portion on the radially outer side. The "cusp" in the present invention is that structure described as having a substantially conical shape.

As used herein, the "mobile leaflet layer" or "leaflet" means that radially inward portion of the cusp that moves during operation of the valve. For example, when the valve is closing the mobile leaflet layer moves radially inward toward the central axis of the valve lumen. When the valve is opening, the mobile leaflet layer moves radially outward and away from the central axis of the valve lumen.

As used herein, the "cusp wall layer" means a portion of the cusp that resides radially outward of the mobile leaflet layer. In some embodiments, a portion of the cusp wall layer moves during operation of the valve. In other embodiments, the cusp wall layer remains substantially immobile during operation of the valve.

As used herein, the "cuff wall layer" means a portion of the folded membrane structure that resides radially outward of both the cusp wall layer and the mobile leaflet layer, and where present, is radially closest to the frame of the three layers comprising the mobile leaflet layer, the cusp wall layer, and the cuff wall layer. The cuff wall layer remains substantially immobile

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during operation of the valve.

A "frame" as used herein means a substantially tubular member that holds a plurality of cusps and/or leaflets. By way of example, the frame may be a wire lattice or a lattice cut from a single tubular piece of metal alloy, that is both collapsible and expandable.

A "valve" as used herein means a frame with a plurality of cusps and/or leaflets attached thereto. In the present invention each of said leaflets is an integral part of a folded membrane cusp structure. If a frame is used that is a metal lattice that is both collapsible and expandable, such a construct may be delivered through a catheter percutaneously to a target site within a patient, such as the aortic valve.

As used herein, "cone" or "conical" means resembling a cone or portion thereof at some point in the practical use of the structure.

As used herein "substantially conical" means resembling a cone or a portion thereof at some point in the practical use of the structure with the specific property that the transverse (that is, on a plane of section generally perpendicular to the axis of flow of the valve) cross-sectional perimeter or area of said structure in the operationally closed position decreases monotonically moving from the level of the leaflet apposition to the proximal end of the valve.

As used herein, "two or more leaflets," "two or more valve leaflets," "a plurality of leaflets" or a similar term means two, three, four, or more valve leaflets. Accordingly, "a valve with two or more leaflets" includes a valve with two leaflets, a valve with three leaflets, a valve with four leaflets, and a valve with more than four leaflets.

As used herein, a "folding" means the partition of a flat sheet section of material along a sharp line of folding or crease into subsections each lying on separate planes, but without interruption of material continuity.

As used herein, a "complete folding" means folding (as above) wherein the angular change of the planar axis at the line of folding is approximately 180 degrees, such that the subsections lie on approximately parallel planes and the subsections are in approximate overlying contact with each other at least at some point.

As used herein, a "cuff" means that portion of a valve structure that lies radially outward of the cusp wall portion that in some part circumferentially encompasses at least a portion of the cusp structure and acts to limit flow that may pass retrograde around the cusp.

As used herein, "commissure" means the site of union or junction between adjacent cusps and/or leaflets, and by extension, collectively those portions of the adjacent integrated cusp and leaflet structures that are coincident at the union or junction in the completed valve structure.

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As used herein, an "integrated cusp and leaflet folded structure" means a membrane folded in accordance with one of the patterns described herein.

Folded Valve Integrated Cusp and Leaflet - Folding Pattern No. 1

Referring generally to Figs. 1A-7K, each cusp embodiment of an integrated cusp and leaflet structure described herein is a substantially flattened cone collapsed along an axis substantially perpendicular to its longitudinal axis. In one or more embodiments, the integrated cusp and leaflet structure, when being formed from a piece of membrane, is readily realized by folding a flat sheet of membrane from a closed polygon pattern. The pattern folding results in apposing seam lines aligned along their axial length. These are joined to close the cusp in the general shape of a cone with the joined seam forming the "spine" along which the cusp meets the inner aspect of the tubular frame. It can be seen that, when formed of a dry sheet membrane, the pattern results initially in a cusp shape that is an inverted pyramid with a rhomboid base that, with a flexible, pliable membrane, is congruent to a substantially conical shape. On relaxation of the folds in practical use a substantially conical cusp is realized wherein the inner mobile operating portions of the leaflet are continuous with the outer portion that forms the integral wall of the cusp sinus or pocket.

Referring now to Fig. 1A, a plan view of a rectangular flat sheet membrane template 100 is shown for the formation of a single-piece folded valve integrated cusp and leaflet. The plan view is shown with a view of that leaflet surface that faces radially inward once folded and mounted within a frame. Reference is also made to Fig. 1G, wherein a schematic of a valve in distal axial view is shown, and wherein three cusps with integral leaflets are shown within the frame that collectively form the valve. As described and illustrated in the present application, alternate polygons and other closed shapes may be employed with alternate folding patterns to generate alternate shapes and functional features of the valve cusp and leaflet, and complete valve.

Referring again to Fig. 1A, and in accordance with at least one embodiment of the one or more present inventions, dotted lines 101, 116, 117, 126 and 127 represent the position of folds or creases applied to a piece of membrane to form a leaflet structure 130. More particularly, folding at lines 116, 126 and 101 is initiated inward (with convexity of the surface disposed radially inward toward the central axis of the valve lumen) while folds 117 and 127 are folded initially outward (with convexity of surface disposed radially outward away from the central axis of the valve lumen). Since folding causes re-orientation of the various sections of the sheet template in relation to each other and to the valve geometry, final orientation of the fold lines within the structure on mounting and operation of the leaflets will not necessarily retain the same orientations as on initiation of the folds. The "inward" and "outward" conventions by this

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definition will be followed throughout the descriptions of the various folded geometries presented herein.

Referring again to Fig. 1A, a line of division by cutting is indicated at 102. Cutting at 102 results in opposing edges 115 and 125 that will be separated by folding. The other free edges of the structure are labeled as their position and orientation changes through the folding steps. Fold 101 defines the central axis of symmetry of the leaflet pattern, with the concave side of fold 101 facing radially outward toward the frame and away from the central axis of the valve lumen. Fold 101 assists in the maintenance of axial symmetry of the folded construct, but is not necessary to leaflet function and is not retained in the final operational form of the valve. (See Fig. 7A.)

Referring now to Fig. 1B, an oblique axial top (distal) perspective view of a substantially completed folded leaflet structure 130 is shown. (Three completed folded cusp and leaflet structures 130 are typically mounted to a frame to form an operating heart valve.)

The view of Fig. 1B is directed downward (proximally) and radially outward, with such view illustrating a substantially completed folded leaflet and cusp structure 130 that depicts the reoriented segments and sections of Fig. 1A after execution of the template foldings. Segments 111 and 121 form the left and right halves of the distal free edge of the mobile operating portion of the leaflet. Inward folding at 116 and 126 forms a second layer of membrane outward of the first, with segments 112 and 122 forming the distal free margin of the outer wall of the integrated cusp. In radially flatted form of the integrated cusp and leaflet structure (that is, approximating the open operating position of the leaflet), the segment 111 will appose to 112, and 121 will appose to 122.

The left cusp wall section 161 is bounded by folds 116 and 117 and edge segment 112. The right cusp wall section 171 is bounded by folds 126 and 127 and edge segment 122.

The left cuff wall section 118 is bounded by fold 117 and edge segments 113, 114 and 115. The right cuff wall section 128 is bounded by fold 127 and edge segments 123, 124 and 125. Inward folding at 117 and 127 cause these cuff wall sections 118 and 128 to position outward of the cusp wall sections 161 and 171, respectively. In radially flatted form of the completed folded structure (again, approximating the open operating position of the leaflet), the edge segment 113 will appose to 112, and edge segment 123 will appose to 122.

Folded Valve Folding Sequence

Referring now to Figs. 1C and 1D, oblique axial top (distal) perspective views of a partially completed folded leaflet and cusp are shown. The views provided by Figs. 1C and 1D are directed downward (proximally) and radially outward, with such views depicting the reoriented segments and sections of Fig. 1A after partial execution of the template foldings.

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Fig. 1C shows a perspective view of the inner aspect of the template 100 after initiation of the foldings and cutting at 102 resulting in left and right cuff wall sections 118 and 128, respectively. The cut free edges 115 and 125 are separated along with the left and right cuff wall sections 118 and 128 by outward folding at 117 and 127, respectively. Completed folding at 117 and 127 results in the cuff wall sections 118 and 128, respectively. Distally situated (with respect to the blood flow direction) edge segments 113 and 123 of the cuff wall sections 118 and 128, as well as proximally situated edge segments 115 and 125 of the cuff wall sections 118 and 128, are positioned transverse, and in at least one embodiment, substantially perpendicular, to the central axis of the valve.

Fig. 1D shows the cusp and leaflet structure 120 with the folds 116, 126, 117 and 127 at an intermediate stage of completion. Triangular left and right mobile leaflet sections 119 and 129 respectively are bounded by folds 101 and 116 and free edge segment 111 on the left, and folds 101 and 126 and free edge segment 121 on the right. Folds 117 and 127 are then brought into apposition on the outward aspect of the integrated cusp and leaflet along a seam line 132 where the folds will be joined and attached to a frame to close the shape of the single-piece continuous conical integrated cusp and leaflet.

Referring now to Figs. 1E and 1F, oblique axial top (distal) perspective views of a substantially completed folded cusp and leaflet are shown. The views provided by Figs. 1E and 1F are directed downward (proximally) and radially outward, with such views depicting the reoriented segments and sections of Fig. 1A after execution of the template foldings.

Fig. 1E shows the cusp and leaflet folding substantially completed forming the structure 130 with the seam 132 formed by the apposition of folds 117 and 127, thus forming a generally conical cusp and sinus space 131. The triangular corners formed at the distal ends of folds 116 and 126 are apposed to and attached to the cuff wall sections 118 and 128, respectively. Between adjacent cusp and leaflet structures in a multi-leaflet valve, the folded corners form the junction joining the adjacent free edges (121 of leaflet A to 111 of leaflet B, for example) of the mobile leaflet portions. When further attached to the circumferential valve frame, these corners tether the free edges of the mobile leaflet portions to the circumferential inner boundary of the generally cylindrical valve frame, thus forming valve leaflet commissures at each similar join.

Referring now to Fig. 1F, a structure similar to that of Fig. 1E is depicted, but with the cuff wall sections 118B and 128B reduced in circumferential extent from that of leaflet structure 130 shown in Fig. 1E. More particularly, depending on the clinical application of the valve, a fully circumferential cuff wall may be unnecessary, and a valve with a limited cuff wall with less tissue membrane mass may offer functional advantages. Alternatively, an additional piece

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of membrane may be placed circumferentially around the outer abluminal surface of the valve frame to act as a sealing cuff to form a barrier against valvular regurgitation.

Referring again to Fig. 1E, the apex 133 (proximal tip) of the conical cusp and leaflet forms the lower (proximal) end of the seam 132. In at least one embodiment, the apex 133 is also attached to the circumferential boundary of the valve and valve frame.

Referring now to Fig. 1G, for ease of reference the structure of Fig. 1E is again shown in Fig. 1G at the top of the page, along with a top (distal) cross-section view of the distal end of a three-leaflet valve in the closed operating position. The three cusps with leaflets are shown residing within a lattice frame in order to indicate the configuration of elements between the folded integrated cusp and leaflet structure 130 and its disposition within a three-leaflet frame-mounted valve. Suture attachments are omitted for clarity.

For each folded integrated cusp and leaflet structure, the outer axial seam 132 is aligned with one or more frame members 141 in a manner to permit the attachment of the folds 117 to 127, and to the coincident frame member by the same attachment, for example, by a single knot or line of suture. Advantageously for this purpose, the frame may preferentially contain axially oriented members that align to the seam 132 for part or all of the full axial extent of the valve. Further, said axially oriented members may advantageously contain holes or notches for securing and tying suture.

In Fig. 1G at point A, an illustrated loop symbolizing a suture knot is shown to demonstrate that a single knot may advantageously pass through or engage the frame member and the six layers; that is, the mobile leaflet section, the cusp wall section, and the cuff wall section of each adjoining cusp and leaflet structure that are coincident at this site of the commissure.

Referring still to Fig. 1G, it can be seen that the folded integrated cusp and leaflet structure, when mounted within the lattice frame and placed in the closed operating position, manifests the following configurations: (1) the left leaflet free edge segment 111 is in each case apposed to the right leaflet free edge segment 121 of the adjacent leaflet; (2) the portions of the leaflets just proximal to the free edges, thus, are also apposed to form the contact seal that enables effective closing operation, thereby preventing valvular regurgitation; and (3) the distal edges 112 and 122 of the cusp wall sections are apposed to the distal edges of the cuff wall sections 113 and 123, respectively.

Folded Valve Pattern Variation No. 2

Referring now to Fig. 2, and in accordance with at least one embodiment, a plan view of a flat sheet membrane template 200 that is polygonal rather than rectangular is shown. Template 200 contains folds 201, 216, 226, 217 and 227 that correspond to folds 101, 116, 126, 117 and

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127, respectively, and are disposed in like manner in folding execution, as are the segments enumerated. The folding pattern is designed to form a longer cone of the same diameter, which achieves a more distally disposed central point of valve leaflet coaptation, the mechanics of which are more tolerant of pressure loads. The pattern dimensions may be altered to suit the particular clinical application of the valve. The template examples disclosed herein are for enablement purposes and shall not be interpreted as limiting the scope of the claims. The example is shown for a cusp cone wall disposed at about a 60 degree angle to the horizontal (short axis) of the generally cylindrical valve geometry, whereas that angle for the rectangular pattern of Figs. 1A-1G was about 45 degrees.

Folded Valve Pattern Variation No. 3

Referring now to Fig. 3, and in accordance with at least one embodiment, a plan view of template 300 is shown for a flat sheet membrane that contains the pattern 200 of Fig. 2 with added sections that extend the distal contour of the structure when completed in folding. More particularly, the free edge of the mobile leaflet section is extended distally with a section having a polygonal or curved free edge in order to increase the contacting area of leaflet apposition in valve closing operation. Additionally, the distal contour of the cusp wall sections and cuff wall sections 318 and 328 are extended by "tab" sections 318T and 328T, respectively. These added "tab" extensions allow for increased area by which to mount the outer wall of the cusp and leaflet assembly to the frame and for elevating the cuff wall "above" (more distal to) the plane of leaflet apposition, thereby also increasing the effective volume of the cusp in closing operation. These "tab" extensions, being distally disposed after completion of folding and initial mounting within the lattice frame, or a distal portion of them may optionally be folded radially outward along 312-313 and 322-323, for example, to wrap around the distal edge of the frame such that the "tab" extension areas 318T and 328T lie on the outer, abluminal aspect of the frame where, when attached to the frame, they potentially increase the strength of the cusp attachment.

Referring still to Fig. 3, template 300 contains folds 301, 316, 326, 317 and 327 that correspond to folds 101, 116, 126, 117 and 127, respectively, and are disposed in like manner in folding execution, as are the edge segments similarly enumerated. In addition to the tab features discussed in the preceding paragraph, as with template 200, template 300 is designed to form a longer cone of the same diameter, which achieves a more distally disposed central point of valve leaflet coaptation. Again, the pattern dimensions may be altered to suit the particular clinical application of the valve. The example is shown for a cusp cone wall disposed at about a 60 degree angle to the horizontal (short axis) of the generally cylindrical valve geometry.

Folded Valve Pattern Variation No. 4

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Referring now to Fig. 4, and in accordance with at least one embodiment, a plan view of pattern 400 is shown for a flat sheet membrane similar to pattern 300, except that the extension "tab" sections 412T and 422T are distal extensions of the cusp wall sections only. This limitation reduces the double layer of membrane extension at the distal end of the completely folded integrated cusp and leaflet structure to a single layer, thereby reducing the mass of membrane in the heart valve which might otherwise disadvantageously limit the efficiency of collapsing and compressing the valve for use in the percutaneous/transcatheter delivery application.

In addition, at the lower (proximal) apex 433 of the cusp cone pattern the lower (proximal) extent of the cuff wall sections 418 and 428 is limited so as to "expose" the apex of the cone in the pattern. This feature allows, on the completely folded integrated cusp and leaflet structure, the transverse, radially outward folding of the tip of the cone-shaped cusp at line 403 between points U and V. (See figures 7.) The folding of the apex reduces the overall axial length of the cusp and leaflet structure, allowing for increased cusp/sinus volume for a given valve diameter and frame length.

The template 400 contains folds 401, 416, 426, 417 and 427 that correspond to folds 101, 116, 126, 117 and 127, respectively, and are disposed in like manner in folding execution, as are the edge segments similarly enumerated. Similar to templates 200 and 300 described above, template 400 dimensions may be altered to suit the particular clinical application of the valve. The example is shown for a cusp cone wall disposed at about a 60 degree angle to the horizontal (short axis) of the generally cylindrical valve geometry.

Folded Valve Pattern Variation No. 5

Referring now to Figs. 5A-5F, yet another embodiment of a template pattern is illustrated. Referring specifically now to Fig. 5A, a plan view of template 500 is shown for a flat sheet membrane. The template 500 contains folds 501, 516, 526, 517 and 527 that correspond to folds 101, 116, 126, 117 and 127, respectively, and are disposed in like manner in folding execution, as are the edge segments similarly enumerated.

Template 500 illustrates a flat sheet membrane that is basically rectangular and is similar to the upper (distal) portion of template 100 of Figs. 1A-1G, except that (a) the distal extension areas 512T and 522T are added at the left and right margins of the template 500, and (b) the lower quadrants forming the cuff wall sections of the template 100 are truncated in template 500 to narrow cuff wall sections 518 and 528, the extent of which is defined by the length of cut 502. These limited interior cuff sections are still used for frame attachment along the central seam 532 of the cusp and leaflet cone, and the distal extension sections 512T and 522T are still used for attachment of the outer cusp wall to the distal edge of the frame.

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Referring still to Figs. 5A-5F, corner folds 505 and 506 are now described. For template 500, after folds 516 and 526 are executed by complete folding, segments 512 and 522 are apposed and aligned to segments 511 and 521, respectively, and overlapping layers (mobile leaflet layer and cusp wall layer) form triangular corner sections at 562 and 572. Radially outward folding of these corner sections at 505 and 506 define the axial extent of the leaflet commissures such that joining the corner sections of adjacent leaflet structures along corner folds 505 and 506 causes the leaflet apposition to be at least the length of 505 in axial extent at the radial margin of the leaflet. (See Fig. 9E that illustrates an embodiment of a valve comprising a frame 920 with a plurality of integral cusp and leaflet structures 730 attached to the frame, wherein the structures 730 include corner sections 762 and 772 corresponding to the corner sections 562 and 572 of template 500.) Additionally, these double-layer triangular corner sections 562 and 572 are used for attachment of the commissures to the frame. The stent frame may optionally contain a slot at this point of attachment through which this triangular "tab" section may be inserted and attached on the abluminal surface of the frame. (Again, see Fig. 9E.)

With specific reference now to Fig. 5B, a perspective view of the inner aspect (that is, a view directed radially outward) of an initially folded structure 510 folded according to template 500 is shown. The central folding along 501 is initiated after cut 502 is executed as shown. Foldings along 501, 516, and 526 are depicted as initiated radially inward (out of the page) and foldings along 517 and 527 are depicted as initiated radially outward (into the page).

Figure 5C shows a steeply oblique perspective view of the folded integrated cusp and leaflet 520 at an intermediate stage of completion of the foldings. The view is directed from the central axis outward and obliquely downward into the cusp space showing the formation of the outer wall of the structure, that is, the cusp wall layer of the subject cusp. Folding along 517 and 527 acts to position the extension sections 518 and 528 outward of the cusp wall sections 561 and 571, respectively. Completion of folding then will position folds 517 and 527 in an axially aligned orientation in apposition to each other along their length. Folding along 516 and 526 acts to position the cusp wall sections 561 and 571 outward of the mobile leaflet sections 519 and 529, respectively. Completion of folding, which radially collapses the folded flattened structure, positions the cusp wall sections 561 and 571 in apposition to the mobile leaflet sections 519 and 529, respectively. In the final folded configuration the structure embodies the integrated cusp and leaflet in the open operating position.

In addition, completed folding at 516 and 526 also forms triangular two-layer sections, 562 and 572, respectively, that are designated as "commissure tabs". These commissure tabs are bounded by the corner folds 505 and 506, folds 516 and 526, and the free edges 511 and 521 of

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the mobile leaflet sections 519 and 529, respectively. With further reference to Figs. 5D and 5E, these commissure tabs will be folded at 505 and 506 so as to position both layers of the tabs outward of the cusp wall sections 561 and 571, respectively, with the folds 505 and 506 oriented parallel to the central axis of the valve. With regard to a multi-leaflet valve, when the cusp and leaflet structure is mounted within the frame, this folded commissure tab is aligned along fold 505 in apposition to fold 506 of an adjacent complementary commissure tab of an adjacent integrated cusp and leaflet structure. Thus mounted, the commissure tabs join the mobile leaflet layers and the cusp wall layers of adjacent folded cusp and leaflet structures along a line coincident to both 505 and 506 that forms a common seam for attachment, such as by suturing of the commissure tabs to each other and to the frame forming the circumferential margin of the membrane portion of the folded cusp and leaflet structure.

Fig. 5D shows a plan view of the inner (luminal) aspect of the folded integrated cusp and leaflet structure 530 of template pattern 500. Structure 530 is depicted in a completed state of folding, excepting that the commissure tabs 562 and 572 are not yet folded outward along fold lines 505 and 506, respectively. The radially flattened form shown gives the general configuration and orientation of the membrane segments and sections for the open operating position of the valve cusp and leaflet.

Still referring to Fig. 5D, at the uppermost (distal) portion of the cusp wall layer, the extension tabs 512T and 522T are projected above (or distal to) the lines 512 and 522 (shown in figures 5A and 5B), respectively, that lie in apposition and alignment to the free edges 511 and 521, respectively, of the mobile leaflet layer. A portion or all of these tabs 512T and 522T may be optionally folded outward along 512 and 522, respectively, around the distal edge of the frame to lie upon the outer (abluminal) surface of the frame where they may be attached to both the frame and to the cusp wall sections (where the cusp wall sections are apposed to the inner surface of the frame) through the interstices of the frame. This optional configuration provides for increased strength of attachment for bearing downward (proximally directed) operational loads associated with the valve closing.

Completing the folding associated with template pattern 500 places folds 517 and 527 into axial alignment. Once in axial alignment, apposing folds 517 and 527 are joined along their axial length to form the seam 532 that closes the generally conical cusp structure with the extension sections 518 and 528 situated outward of the cusp wall sections 561 and 571, respectively. The cusp wall sections 561 and 571 are thus disposed outward of the mobile leaflet sections 519 and 529, respectively, with the cusp wall sections axially and circumferentially apposed to the inner surfaces of the generally cylindrical frame. Advantageously, for each valve cusp and leaflet to be mounted within, the frame may contain an

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element or elements that are axially oriented and span a significant portion of the axial length of the frame, so as to align with the seam 532 for attachment, such as by suturing to the frame.

Referring now to Fig. 5E, a partial detail perspective view is shown of the commissure tab 572 configuration of the completely folded integrated cusp and leaflet structure 530, indicating radially outward folding of the commissure tab 572 along fold line 506.

With reference now to Fig. 5F, a perspective view is shown of the outer (abluminal) aspect of the completely folded cusp and leaflet structure 530 (except that the triangular commissure tabs are not yet folded) of template 500 in substantially flattened form. This view is complementary to Fig. 5D that shows the inner aspect of the same structure 530. The central seam 532 is seen on the outer face of the cusp wall sections 561 and 571 and is depicted for purposes of illustration as partly separated with the extension sections 518 and 528 incompletely flattened and folds 517 and 527 in close, but not in the complete apposition and alignment that will form the final seam line 532 for attachment to the axially oriented frame members. The slight separation depicted between folds 517 and 527 exposes the centerpoint of the mobile leaflet free edge where the mobile leaflet free edge segments 511 and 521 meet as depicted behind the cusp wall sections 561 and 571, respectively, in this view.

Folded Valve Pattern Variation No. 6

In accordance with at least one embodiment, Fig. 6 shows a plan view of another template 600 that is similar to template 500 except that the cusp cone wall angle α exceeds the 45 degrees of the generally rectangular template 500, and that the mobile leaflet sections are extended by a polygonal or curved extension section 604 of the free edge.

The change in cusp cone wall angle α also results in changes in the angle relating the lower (proximal) margins of the template and fold lines 617 and 627 to the center line of the template in order that when folding is completely executed, the fold lines 617 and 627 and the seam between them will be parallel to the central axis of the assembled valve. Likewise, the further geometry of the cusp cone wall angle will result in fold lines (optional) 613 and 623 and the long axes of extension tabs 612T and 622T being parallel to the transverse axis of the assembled valve.

The template 600 contains folds 601, 616, 626, 617, 627, optional folds 612 and 622, corner folds 605 and 606, and cut line 602 that correspond to folds 501, 516, 526, 517, 527, optional folds 512 and 522, corner folds 505 and 506, and cut line 502, respectively, of template pattern 500 and are disposed in like manner in folding execution, as are the template sections and edge segments similarly enumerated.

Folded Valve Pattern Variation No. 7

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Referring now to Figs. 7A-7F, still yet another embodiment of a template pattern is illustrated. Referring specifically now to Fig. 7A, a plan view of another template 700 is shown that is similar to template 600, but with a section of the lower (proximal) midline portion of the template cut away so as to expose the apex 733 of the triangular sections that, when folded, will form the apex of the cone-shaped cusp. Effectively, the midline portions of the extension sections 718 and 728 are removed in relation to template 600 to an extent determined by the desired length of the line segment U-V, which in turn determines the extent to which the apex of the cone-shaped cusp may be truncated by folding at U-V.

After the cusp and leaflet cone is formed by folding, the apex is folded radially outward at line U-V (703) to truncate the cone to reduce the overall length of the cusp and leaflet structure, allowing for increased cusp/sinus volume for a given valve diameter and frame length.

The template 700 contains folds 701, 716, 726, 717, 727, optional folds 712 and 722, and corner folds 705 and 706, that correspond to folds 601, 616, 626, 617, 627, optional folds 612 and 622, and corner folds 605 and 606, respectively, of template 600 and are disposed in like manner in folding execution, as are the template sections and edge segments similarly enumerated.

Fig. 7B shows a perspective view of the inner (luminal) aspect of the initially folded cusp and leaflet structure 710 of template 700 after initiation of the principal folds 716, 726, 717, 727 and 701. Inward folding along 701 assists in aligning the left and right sections of the structure, but is not necessary to the formation of the integrated cusp and leaflet folded structure or to the operation of the valve. The disposition of the folds that converge at the apex 733 of the cusp can be appreciated as later forming an overlapping two-layer triangular apex as the cusp wall sections 761 and 771 are folded outward along lines 716 and 726, respectively, so as to position the cusp wall sections 761 and 771 outward of, and in apposition to, the mobile leaflet sections 719 and 729, respectively.

Fig. 7C shows a steeply oblique perspective view of the folded integrated cusp and leaflet 720 at an intermediate stage of completion of the foldings. The view is directed from the central axis outward and obliquely downward into the cusp space showing the formation of the outer wall of the structure. Folding along 717 and 727 acts to position the extension sections 718 and 728 outward of the cusp wall sections 761 and 771, respectively. Completion of folding then will position folds 717 and 727 in an axially aligned orientation in apposition to each other along their length. Folding along 716 and 726 acts to position the cusp wall sections 761 and 771 outward of the mobile leaflet sections 719 and 729, respectively. Completion of folding, which radially collapses the folded flattened structure, positions the cusp wall sections 761 and 771 in apposition to the mobile leaflet sections 719 and 729, respectively. In the final folded

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configuration, the structure embodies the integrated cusp and leaflet in the open operating position.

With reference to Fig. 7D, completed folding at 716 and 726 also forms triangular two-layer sections, 762 and 772, respectively, that are designated as "commissure tabs." These commissure tabs are bounded by the corner folds 705 and 706, folds 716 and 726, and the free edges 711 and 721 of the mobile leaflet sections 719 and 729, respectively. With further reference to Figs. 7D and 7E, these commissure tabs will be folded at 705 and 706 so as to position both layers of the tabs outward of the cusp wall sections 761 and 771, respectively, with the folds 705 and 706 oriented parallel to the central axis of the valve. When the integrated cusp and leaflet structure is mounted within the frame, this folded commissure tab is aligned along fold 705 in apposition to fold 706 of an adjacent complementary commissure tab of an adjacent integrated cusp and leaflet structure of a multi-leaflet valve. Thus mounted, the commissure tabs join the mobile leaflet layers and the cusp wall layers of adjacent folded cusp and leaflet structures along a line coincident to both 705 and 706 that forms a common seam for attachment, such as by suturing of the commissure tabs to each other and to the frame forming the circumferential margin of the membrane portion of the folded cusp and leaflet strucutre.

Fig. 7D shows a perspective view of the inner (luminal) aspect of the partially folded integrated cusp and valve structure 720 of template 700. Integrated cusp and leaflet structure 720 is depicted in nearly completed state of folding, except that the commissure tabs 762 and 772, as well as the cusp apex 733 are not yet folded outward along fold lines 705, 706 and 703, respectively, and that the axial seam 732 is not yet formed by the apposition of the folds 717 and 727.

At the uppermost (distal) portion of the cusp wall layer, the extension tabs 712T and 722T are projected above (or distal to) the lines 712 and 722 (shown in Figs. 7A and 7B). All or a portion of these tabs 712T and 722T may be optionally folded outward along 712 and 722, respectively, around the distal edge of the frame to lie upon the outer (abluminal) surface of the frame where they may be attached to both the frame and to the cusp wall sections (apposed to the inner surface of the frame) through the interstices of the frame. This optional configuration provides for increased strength of attachment for bearing downward (proximally directed) operational loads associated with the valve closing.

Completing the folding associated with template pattern 700 places folds 717 and 727 into axial alignment. Once in axial alignment, apposing folds 717 and 727 are joined along their axial length to form the seam 732 that closes the generally conical cusp structure with the extension sections 718 and 728 situated outward of the cusp wall sections 761 and 771, respectively. The cusp wall sections 761 and 771 then are disposed outward of the mobile

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leaflet sections 719 and 729, respectively, with the cusp wall sections axially and circumferentially apposed to the inner surfaces of the generally cylindrical frame. Advantageously, for each integrated cusp and folded leaflet structure to be mounted within, the frame may contain an element or elements that are axially oriented and span a significant portion of the axial length of the frame, so as to align with the seam 732 for attachment as by suturing to the frame.

Fig. 7E shows a shallow oblique top perspective view of the outer (abluminal) aspect of the partially folded cusp and leaflet structure 720 of template 700 (except that the triangular commissure tabs 762 and 772 and apex 733 are not yet folded and that the axial seam 732 is not yet joined). This view is complementary to Fig. 7D that shows the inner aspect of the same structure 720. The central seam 732 will be formed on the outer face of the cusp wall sections 761 and 771 as folds 717 and 727 are brought together into apposition along the midline, with the extension sections 718 and 728 thus also aligned. The outward (abluminal) face of the mobile leaflet sections 719 and 729 are shown between the yet separated folds 717 and 727 before closure of the generally conical cusp along the outer seam 732.

Fig. 7F shows a plan view of the inner (luminal) aspect of the folded integrated cusp and leaflet structure 720 of template pattern 700. Structure 720 is depicted in a completed state of folding, excepting that the commissure tabs 762 and 772 are not yet folded outward along fold lines 705 and 706, respectively. In addition, the apex 733 is not folded outward. The radially flattened form shown gives the general configuration and orientation of the membrane line segments and areal sections for the open operating position of the valve cusp and leaflet.

At the uppermost (distal) portion of the cusp wall layer, the extension tabs 712T and 722T are projected above (distal to) the lines 712 and 722 (shown in Figs. 7A, 7B and 7G), respectively, below (proximal to) which the cusp wall sections 761 and 771 lie in radial apposition to the mobile leaflet sections 719 and 729, respectively, of the mobile leaflet layer. These tabs 712T and 722T may be optionally folded outward along 712 and 722, respectively, around the distal edge of the frame to lie upon the outer (abluminal) surface of the frame where they may be attached to both the frame and to the cusp wall sections (apposed to the inner surface of the frame) through the interstices of the frame. This optional configuration provides for increased strength of attachment for bearing downward (proximally directed) loads of valve closing.

Folding of the template positions folds 717 and 727 into axial alignment, joined along their axial length to form the seam that closes the generally conical cusp structure with the extension sections 718 and 728 reflected outward of the cusp wall sections 761 and 771, respectively. The cusp wall sections 761 and 771 then are disposed outward of the mobile leaflet

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sections 719 and 729, respectively, with the cusp wall sections 761 and 771 axially and circumferentially apposed to the inner surfaces of the generally cylindrical frame. Advantageously, for each valve cusp and leaflet folded structure to be mounted within, the frame may contain an element or elements that are axially oriented and span a significant portion of the axial length of the frame, so as to align with the seam 732 for attachment as by suturing to the frame.

Fig. 7G shows a perspective view of the outer (abluminal) aspect of the completely folded cusp and leaflet structure 720 (except that the triangular commissure tabs 762 and 772 and apex 733 are not yet folded) of template 700, in nearly flattened form. This view is complementary to Fig. 7F that shows the inner aspect of the same structure 720. The central seam 732 is seen on the outer face of the cusp wall sections 761 and 771 and is depicted for purposes of illustration as minimally separated with the extension sections 718 and 728 incompletely flattened and folds 717 and 727 in effectively complete apposition and alignment that forms the final seam line 732 for attachment to the axially oriented frame members. The slight separation depicted between folds 717 and 727 exposes the centerpoint between the mobile leaflet free edge segments 711 and 721 depicted behind the cusp wall sections 761 and 771, respectively, in this view.

Fig. 7H shows a plan view of the inner aspect of the completely folded integrated cusp and leaflet structure 730 of template 700. This view is substantially that of Fig. 7F except that the triangular commissure tabs 762 and 772 are folded radially outward of the cusp wall sections 761 and 771 along corner folds 705 and 706, respectively. Additionally, the apex (most proximal) portion of the cone-shaped cusp is folded radially outward along the fold line 703 (between points U and V) to the position radially outward of the joined extension sections 718 and 728 such that the apex point 733 then lies upon the seam line 732.

Fig. 7I shows a plan view of the radially outer aspect of the completely folded integrated cusp and leaflet structure 730 of template 700. The outwardly folded position of the triangular commissure tabs 762 and 772 can be seen so that they lie in apposition to the outer surface of the cusp wall sections 761 and 771, respectively. While they may attached in this position to the underlying cusp wall layer and to the frame, alternatively, the commissure tabs 762 and 772 may be positioned to point radially outward (out of the page in this view) to pass through a slot or space in the frame to be secured and attached to the outer (abluminal) surface of the frame.

Additionally, the apex (most proximal) portion of the cone-shaped cusp is folded radially outward along the fold line 703 (between points U and V) to the position radially outward of the joined extension sections 718 and 728 such that the apex point 733 then lies upon the seam line 732.

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The apex portion of the cone-shaped cusp thus configured is to be attached in this position as by suturing and may be similarly attached into this position in the act of attaching or suturing this portion of the folded cusp and leaflet structure to the frame.

Fig. 7J shows an oblique top perspective view of the completely folded and formed cusp and leaflet structure 730 with the view directed radially outward and downward (proximal). The cusp and leaflet structure is shown with the free edge of the mobile leaflet layer in the inward central position corresponding to the substantially closed operating position of the valve leaflet.

The commissure tabs 762 and 772 are depicted in radially aligned positions directed outward as would be required for passing them through slots or spaces in a suitably designed frame.

Fig. 7K shows a top perspective view of the single-piece completely folded and formed cusp and leaflet structure 730 with the view directed downward (proximal) into the cusp space. The cusp and leaflet structure is shown with the free edge of the mobile leaflet layer sections 719 and 729 in the intermediate inward position corresponding to the partially closed operating position of the valve leaflet.

The membrane structure is depicted with the free edges in a relaxed state corresponding to the typical behavior of tissue membranes when hydrated as when implanted in the body.

The commissure tabs 762 and 772 are depicted in radially aligned positions directed outward as would be required for passing them through slots or spaces in a suitably designed frame.

Metal Lattice Frame

Fig. 8A is an oblique top perspective view of a metal lattice frame 910 for mounting three of the single-piece folded integrated cusp and leaflet structures of the ensuing description in order to form a three-leaflet valve. The frame comprises a plurality of strut members 911 and three axially oriented mounting bars 912 each with holes and/or slots for passing suture and/or portions of the folded membrane structure. Each mounting bar 912 is to align with and attach to the axial outer seam of one single-piece completely folded and formed cusp and leaflet structure 730. The diameter D of the open frame, e.g., 19 – 35 mm naturally defines the deployed and operating diameter of the valve assembly after implantation in the body. The strut members 911 are of specific length and orientation to permit radial collapse and compression of the frame to a small diameter, e.g., 3-7 mm. The mounting bars 912 are near to equally spaced around the circumferential course of the frame and the length L of the arc from the center of the mounting bar 912 to the center of the closest mounting bar 912 is approximately equal to (pi x D)/3. Thus defined, L also defines the transverse circumferential distance between folds 705 and 706 , approximating the circumferential extent of the portions of the joined cusp wall sections 761 and

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771 extending between 705 and 706 of the folded cusp and leaflet structure of appropriate size when mounted within the frame 910.

Fig. 8B shows a side perspective view of the frame 910 with the view centered on the axial mounting bar 912. The axial bars are shown with holes and/or slots for passing suture and/or portions of the folded membrane structure to enable secure mounting of the folded cusp and leaflet structure within the frame.

Fig. 8C shows a side view of the frame of Fig. 8B with a superimposed plan view of the radially outer aspect of the completely folded integrated cusp and leaflet structure as depicted in Fig. 7I. The cusp wall seam 732 is aligned upon the inner surface of the mounting bar of the frame and attached by sutures in this example. (Example suture locations are shown in Figs. 8C, 9C and 9D shown with an "x"; however, it is to be understood that the locations shown are exemplary and not limiting.) As those skilled in the art will appreciate, means other than sutures for attaching folded integrated cusp and leaflet structure to the frame can be used.

The commissure tabs 762 and 772 are folded flat against the outer surface of the cusp wall layer along corner folds 705 and 706 for mounting entirely within the frame 910. Each fold 705 then forms an axially oriented seam along its length with the complementary fold 706 of the adjacent folded cusp and leaflet structure 730. (Adjacent complementary commissure tabs omitted for clarity.) Said seam is closed and attached by suture, for example, while also attaching to the radially overlying strut member 911 of the frame 910, and thereby affixes the distal margins of the cusp wall sections 761 and 771 and the mobile leaflet sections (obverse of this view) to the frame 910. The other suture points depicted attach only the cusp wall layer 761+771 to the overlying frame strut members 911. At no point within the interior operating volume of the valve is the mobile leaflet layer 719+729 penetrated by suture. This uninterrupted continuity of the operating leaflet material afforded by the folded design of the integrated cusp and leaflet structure endows the valve and its leaflets with strength, durability and resistance to stress damage at suture holes.

Fig. 8D shows an oblique axial (top/distal) perspective view of the assembled three-leaflet valve comprising the frame 910 and three identical folded integrated cusp and leaflet structures 730A, 730B and 730C attached within the frame with the view centered on an axial mounting bar 912A. The suture attachments are omitted for clarity. The cusp and leaflet structure 730A nearest in view is seen within the frame 910, with the outer aspect of the seam 732A, cuff wall extension sections 718A and 728A, and cusp wall sections 761A and 771A viewed through the interspaces of the frame 910. The seam 732A is aligned to the overlying axial mounting bar 912A to which it is attached along its length. The inner (luminal) aspect of the seams 732B and 732C and the cusp wall sections 761B, 771B, 761C and 771C of the other

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two folded cusp and leaflet structures 730B and 730C, respectively are seen on the far side of the view. The adjoined folded edges of the membrane portions of the commissure tabs 772B and 762C are shown in the far view in position opposite to the axial mounting bar 912A in the near view. The radially outward surface of the mobile leaflet sections 719A and 729A of the folded cusp and leaflet structure 730A is shown in the near view. The distal free edges of all three mobile leaflets are shown in the centrally apposed (coapted) position corresponding to the closed operating position of the valve. Fig. 8D also shows in that aspect interior to the cusps, folds 726B of cusp and leaflet structure 730B and 716C of cusp and leaflet structure 730C as they form the lower (proximal) boundary of the valve cusps.

Slotted Lattice Frame

Fig. 9A shows an oblique axial (top/distal) perspective view of a frame 920 of a design to receive the commissure tabs 762 and 772 through slots 924 in slotted members 923 in order that the tabs are secured and attached to the outer (abluminal) aspect of the frame. This approach to mounting and attaching the commissure tabs enables the loading forces on the leaflet commissures during valve operation to be advantageously distributed upon the frame slotted members 923 along their length rather than upon suture that directly tethers the leaflets, thus greatly reducing the risk of tearing of the material at points of suture penetration. The frame further comprises axial mounting bars 922 for mounting the central seams 732 joining the cusp wall sections 761 and 771 along folds 717 and 727. The frame further comprises a plurality of strut members 921 that otherwise form the metal lattice of the frame.

Each mounting bar 922 is to align with and attach to the axial outer seam of one single-piece completely folded and formed cusp and leaflet structure 730. The inner diameter D of the open frame, e.g., 19 – 35 mm naturally defines the deployed and operating diameter of the valve assembly after implantation in the body. The strut members 921 are of specific length and orientation to permit radial collapse and compression of the frame to a small diameter, e.g., 3-7 mm. The mounting bars 922 are near to equally spaced around the inner circumferential course of the frame. The length L of the arc along the inner circumference of the frame from the center of the mounting bar 922 to the center of the closest mounting bar 922 is approximately equal to (pi x D)/3. Thus defined, L also defines the transverse circumferential distance between folds 705 and 706 , approximating the circumferential extent of the portions of the joined cusp wall sections 761 and 771 extending between 705 and 706 of the folded cusp and leaflet structure of appropriate size when mounted within the frame 920.

The axial mounting bars 922 optionally contain holes and/or slots to facilitate suture attachment of the folded integrated cusp and leaflet structures 730. The frame is depicted in Figs. 9A-9E as having axial mounting bars 922 each with a hole near the proximal end to

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facilitate suture attachment of the apical (most proximal) portion of the folded cusp and leaflet structure.

Fig. 9B shows the metal lattice frame of Fig. 9A in the same perspective, but with the view centered on the slotted frame member 923.

Fig. 9C shows a side perspective view of the frame 920 centered on the axial mounting bar 922 with a superimposed plan view of the outer aspect of the completely folded integrated cusp and leaflet structure 730 (of Fig. 7I) as mounted within the frame 920 to demonstrate the relationships between the two. An example suture pattern for attachment is shown. The cusp wall seam 732 is aligned upon the inner surface of the mounting bar 922 of the frame 920 and attached by sutures in this example.

The commissure tabs 762 and 772 are to be understood as having been passed through the frame slots 924 from within the central space of the frame to the outer (abluminal) side and folded along 705 and 706, respectively onto the outer surface of the cusp and leaflet structure where they are attached along their common length both to the frame members 923 and, through the interspaces of the frame 920, to the radially underlying outer aspect of the cusp wall sections 761 and 771, respectively. The adjacent cusp and leaflet structures of the three-leaflet valve are not shown for clarity. The joining of adjacent commissure tabs at the slotted members 923 is demonstrated in Fig. 9D.

At the apical (most proximal) extent of the completely folded integrated cusp and leaflet structure 730, the apical portion folded radially outward along fold 703 is attached to the lower (most proximal) end of the axial mounting bar 922. When present, a hole near the end of the axial mounting bar 922 facilitates suture attachment at this point.

Fig. 9D shows a side perspective view of the frame 920 centered on the slotted frame member 923AB with a superimposed perspective view of the outer aspect of two circumferentially adjacent completely folded integrated cusp and leaflet structures 730A and 730B (of Fig. 7I) to demonstrate their relationships as mounted within the frame 920. An example suture pattern for attachment is shown. Suture attachment of the commissure folds 705 and 706 at the level of the slot is notably absent. Rather, attachment of the bodies of the commissure tabs 762A and 772B to the outer aspect of the frame at points removed from the free edges and folds of the material avoids suture penetration along the lines of traction in the slot and enhances the resistance of the structure to tearing at such suture attachments. The cusp wall seams 732A and 732B are aligned upon the inner surface of the mounting bars 922A and 922B, respectively of the frame 920 and attached by sutures in this example.

The commissure tabs 762A and 772B are to be understood as having been passed through the frame slot 924 from within the central space of the frame to the outer (abluminal)

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side and folded along 705A and 706B, respectively onto the outer surface of the cusp and leaflet structure where they are attached along their common length both to the frame member 923AB and, through the interspaces of the frame 920, to the radially underlying outer aspect of the cusp wall sections 761A and 771B, respectively.

Fig. 9E shows an oblique axial (top/distal) perspective view of the assembled three-leaflet valve comprising the frame 920 and three identical folded integrated cusp and leaflet structures 730A, 730B and 730C attached principally within the central space of the frame, but with the commissure tabs passed in complementary adjacent left-right pairs, 762A-772B, 762B-772C and 762C-772A, through the slots 924AB, 924BC and 924CA, of slotted frame members 923AB, 923BC, and 923CA, respectively. The view is centered on slotted member 923AB. The suture attachments are omitted for clarity.

The cusp and leaflet structure 730C farthest in view is seen within the frame 920, with the inner aspect of the seam 732C and cusp wall sections 761C and 771C in the far view. The cuff wall extension sections 718C and 728C are depicted as folded onto the outer aspect of the cusp wall sections 761C and 771C, respectively, but within the central space of the frame 920 and apposed to the inner surface of the frame. The inner (luminal) aspect of the seam 732C is shown aligned to the outwardly overlying axial mounting bar 922C to which it is attached along its length. The outer (abluminal) aspect of the top (most distal) portions of the seams 732A and 732B and the cusp wall sections 761A and 771B, of the other two folded cusp and leaflet structures 730A and 730B are also shown through the interspaces of the frame on either side of the near view.

The commissure tabs 762A and 772B, aligned and apposed along folds 705A and 706B, respectively are shown centered in the near view in position opposite to the axial mounting bar 922C and cusp wall seam 732C in the far view. The key mounting configuration of the valve commissures to the slotted frame members is here demonstrated. The triangular commissure tabs are formed as a result of the folding of the membrane template along folds 716 and 726, and are comprised of overlapping layers of the cusp wall section and the mobile leaflet section. Thus, with passage of the commissure tabs from within the interior space of the frame through the frame slots, both the cusp wall layer and the mobile leaflet layer are carried together to the outer aspect of the frame where they are attached. In addition, the interior aspect of the commissure folds 706A of cusp and leaflet structure 730A and 705B of cusp and leaflet structure 730B are shown where they mark the segment at which the commissure tabs 772A and 762B are passed through the frame slots 924CA and 924BC of slotted members 923CA and 923BC, respectively, and are tethered thereto.

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The radially outward surface of the mobile leaflet sections 719A, 729A of the folded cusp and leaflet structure 730A and sections 719B, 729B of the folded cusp and leaflet structure 730B are shown on the left and right sides, respectively of the near view. (These labels omitted for clarity.)

The distal free edges of all three mobile leaflets are shown in the centrally apposed (coapted) position corresponding to the closed operating position of the valve. Fig. 9E also shows in that aspect interior to the cusps, a portion of folds 726A of cusp and leaflet structure 730A and 716B of cusp and leaflet structure 730B as they form the lower (proximal) boundary of the valve cusps.

The template examples disclosed herein are provided for enablement purposes and shall not be interpreted as limiting the scope of the claims. For example, angular values shown and/or described herein are not to be interpreted as limiting the scope of a claim unless included in a given claim.

As those skilled in the art will appreciate, circumference length varies with the diameter circumscribed therein. Accordingly, refinements in the valve manufacturing process may address adjusting the length of the leaflet free edge to be slightly less than the edge length of the cusp wall, i.e., less than the circumferential arc length between the commissures. This adjustment depends upon the dimensions of a given valve in production, as well as the dimensions of the given valve's component elements.

In still other embodiments of the one or more present inventions, the percutaneously deliverable heart valve may include various other configurations by using different variations of the polygon pattern, so as to include, for example, an inner sealing cuff for the valve that is continuous and integral with the leaflet structure itself. In yet other embodiments, the percutaneously deliverable heart valve may include different configurations by adjusting the pattern and folding technique, such as the angle of the cone and its surface area, or the extent of apposition between the leaflets may also be specified.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

The one or more present inventions, in various embodiments, include components, methods, processes, systems and/or apparatus substantially as depicted and described herein, including various embodiments, subcombinations, and subsets thereof. Those of skill in the art

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will understand how to make and use the present invention after understanding the present disclosure.

The present invention, in various embodiments, includes providing devices and processes in the absence of items not depicted and/or described herein or in various embodiments hereof, including in the absence of such items as may have been used in previous devices or processes (e.g., for improving performance, achieving ease and/or reducing cost of implementation).

The foregoing discussion of the invention has been presented for purposes of illustration and description. The foregoing is not intended to limit the invention to the form or forms disclosed herein. In the foregoing Detailed Description for example, various features of the invention are grouped together in one or more embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the following claims are hereby incorporated into this Detailed Description, with each claim standing on its own as a separate preferred embodiment of the invention.

Moreover, though the description of the invention has included description of one or more embodiments and certain variations and modifications, other variations and modifications are within the scope of the invention (e.g., as may be within the skill and knowledge of those in the art, after understanding the present disclosure). It is intended to obtain rights which include alternative embodiments to the extent permitted, including alternate, interchangeable and/or equivalent structures, functions, ranges or steps to those claimed, whether or not such alternate, interchangeable and/or equivalent structures, functions, ranges or steps are disclosed herein, and without intending to publicly dedicate any patentable subject matter.

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CLAIMS

What is claimed is:

1. A transcatheter, percutaneously implantable, prosthetic heart valve, comprising:

a lattice frame; and

two or more integrated cusp and leaflet folded structures attached to the lattice frame, the two or more integrated cusp and leaflet folded structures each comprising a flat sheet of biocompatible membrane that is folded to include a mobile leaflet layer and a cusp wall layer, wherein the cusp wall layer located radially outside of the mobile leaflet layer, and wherein the cusp wall layer is further formed by joining apposing sides of the cusp wall layer along a seam.

2. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 1, wherein the two or more integrated cusp and leaflet folded structures are each attached along their respective seams to the lattice frame.

3. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 2, wherein the seams are oriented in a direction substantially parallel to an axis of the lattice frame.

4. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 1, wherein the flat sheet of biocompatible membrane forming at least one integrated cusp and leaflet folded structure of the two or more integrated cusp and leaflet folded structures comprises two or more pieces of biocompatible membrane material.

5. A transcatheter, percutaneously implantable, prosthetic heart valve, comprising:

a lattice frame; and

two or more integrated cusp and leaflet folded structures attached to the lattice frame, the two or more integrated cusp and leaflet folded structures each comprising a flat sheet of a biocompatible membrane that is folded to include a valve cusp according to a flat folding pattern, wherein the valve cusp is further formed by joining apposing sides of the valve cusp along a seam, and wherein the two or more integrated cusp and leaflet folded structures are each attached along their respective cusp seams to the lattice frame in a direction substantially parallel to an axis of the lattice frame.

6. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein two distal, downstream, vertices of each of the two or more integrated cusp and leaflet folded structures are folded over as vertex folds in a radially outward direction and fixed to the lattice frame such that the vertex folds of circumferentially adjacent leaflets are adjacent and define a degree of leaflet apposition at points corresponding to leaflet commissures.

7. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 6, wherein the two distal, downstream, vertices are fixed to the lattice frame by attachment not along an alignment with the vertex folds.

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8. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein a vertex forming a proximal, upstream, tip of the valve cusp is folded over in a radially outward direction and attached to an inner portion of the lattice frame.

9. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the flat folding pattern is polygonal and includes extending portions that, when the cusp is mounted, extend circumferentially outward from an axial line of attachment of the cusp to the lattice frame so as to form, when joined and attached to corresponding extending portions of neighboring cusps, an integral, inner, luminal, circumferentially complete sealing cuff.

10. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the flat folding pattern is polygonal and includes extending portions that, when the two or more integrated cusp and leaflet folded structures are mounted, extend circumferentially outward from an axial line of attachment of the cusp to the lattice frame so as to form a circumferentially incomplete sealing cuff portion associated with each cusp.

11. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein a separate tubular cuff of biocompatible membrane is attached to an outer, abluminal surface of the lattice frame to form a sealing cuff.

12. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the lattice frame is collapsible and expandable and comprises a metal alloy substantially configured as tubular stent member.

13. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the biocompatible membrane comprises processed mammalian pericardium tissue.

14. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the biocompatible membrane does not comprise a treated tissue.

15. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the biocompatible membrane comprises a synthetic material.

16. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the cusp seams of the two or more integrated cusp and leaflet folded structures are each oriented along an axis of flow of the valve.

17. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the two or more integrated cusp and leaflet folded structures are each further attached to a circumferential portion of the lattice frame along at least a portion of their distal downstream edges.

18. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 5, wherein the two or more integrated cusp and leaflet folded structures are attached to the lattice frame at least at a non-commissural seam aligned with an axial flow direction of the valve.

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19. A transcatheter, percutaneously implantable, prosthetic heart valve, comprising:

a lattice frame; and

two or more integrated cusp and leaflet structures attached to the lattice frame, the two or more integrated cusp and leaflet structures each comprising a flat sheet of biocompatible membrane that is folded to include a mobile leaflet layer and a cusp wall layer, wherein with the mobile leaflet layer in a position corresponding to a closed operating configuration of the valve a transverse cross-sectional area of a cusp-sinus space decreases monotonically from a distal end to a proximal end of the mobile leaflet layer.

20. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 19, wherein the cusp wall layer is located radially outside of the mobile leaflet layer.

21. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 19, wherein the cusp wall layer is further formed by joining apposing sides of the cusp wall layer along a seam.

22. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 19, wherein with the mobile leaflet layer in a position corresponding to a closed operating configuration of the valve a transverse cross-sectional length of the mobile leaflet layer decreases monotonically from a distal end to a proximal end of the mobile leaflet layer.

23. The transcatheter, percutaneously implantable, prosthetic heart valve of Claim 19, wherein the mobile leaflet layer and the cusp wall layer of each integrated cusp and leaflet structure are a single continuous piece of biocompatible membrane.

24. In subcombination, an integrated cusp and leaflet structure for attachment to a lattice frame to form a valve configured for implantation in a vascular system of a patient, the integrated cusp and leaflet structure comprising:

a flat sheet of a biocompatible membrane that is folded to include a mobile leaflet layer and a cusp wall layer, wherein the cusp wall layer is divided along a seam, and wherein the mobile leaflet layer is continuous and apposes the cusp wall layer when the integrated cusp and leaflet structure is pressed substantially flat.

25. The subcombination of Claim 24, wherein the mobile leaflet layer and the cusp wall layer of the integrated cusp and leaflet structure are a single continuous piece of biocompatible membrane.

26. The subcombination of Claim 24, wherein the biocompatible membrane comprises processed mammalian pericardium tissue.

27. The subcombination of Claim 24, wherein the biocompatible membrane does not comprise a treated tissue.

28. The subcombination of Claim 24, wherein the biocompatible membrane

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comprises a synthetic material.

29. The subcombination of Claim 24, wherein the integrated cusp and leaflet structure further comprises at least one commissure tab.

30. The subcombination of Claim 29, wherein the at least one commissure tab is configured for engaging a slot within a member of the lattice frame.

31. A method of forming an integrated cusp and leaflet folded structure for use in an implantable valve having an axial flow direction, comprising:

folding a flat sheet of biocompatible membrane to form an integrated cusp and leaflet folded structure according to a flat folding pattern, wherein said folding includes making two diagonal folds in the flat sheet of biocompatible membrane, the two diagonal folds separating a mobile leaflet layer from a cusp wall layer of the integrated cusp and leaflet folded structure.

32. The method of forming the integrated cusp and leaflet folded structure of Claim 31, wherein said two diagonal folds are angled at between 10 to 80 degrees from the axial flow direction.

33. The method of forming an integrated cusp and leaflet folded structure of Claim 31, further comprising forming first and second cusp wall folds, wherein the cusp wall layer is further formed by joining apposing membrane portions adjacent the first and second cusp wall folds along a seam that is oriented substantially parallel with the axial flow direction.

34. A method of forming a transcatheter, percutaneously implantable, prosthetic heart valve, comprising:

folding a plurality of integrated cusp and leaflet folded structures, each integrated cusp and leaflet folded structure of the plurality of integrated cusp and leaflet folded structures comprising a flat sheet of biocompatible membrane that is folded to form a cusp according to a flat folding pattern, wherein the cusp is further formed by joining apposing sides of the cusp along a seam; and

attaching each integrated cusp and leaflet folded structure of the plurality of integrated cusp and leaflet folded structures to a lattice frame, wherein the two or more integrated cusp and leaflet folded structures are each attached along their respective seams to the lattice frame in a direction substantially parallel to an axis of the lattice frame.

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Figure 1A

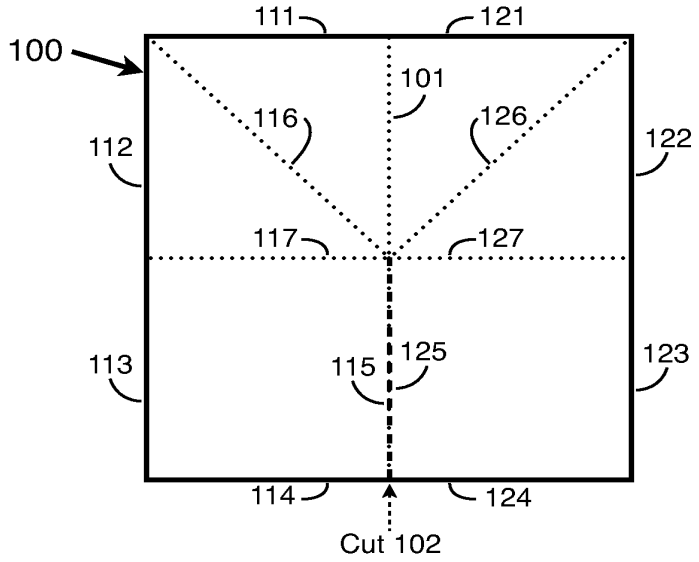
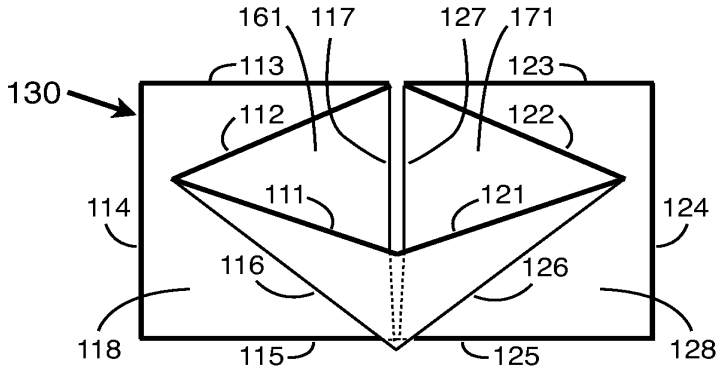


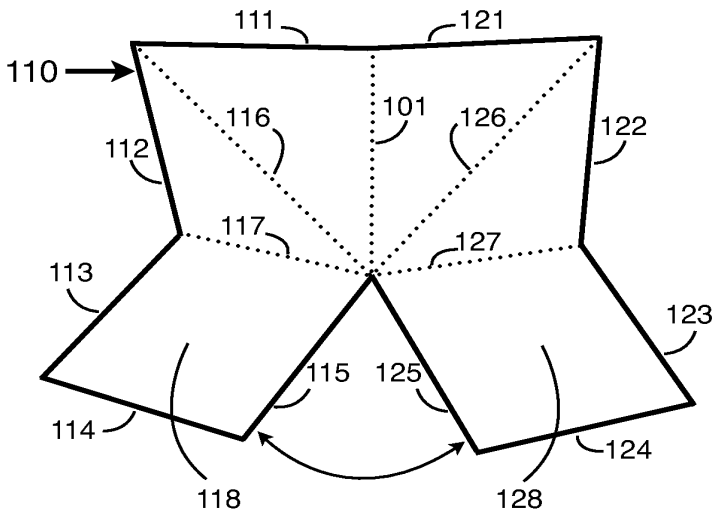
Figure 1B



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
·····	Line of fold / crease
- - - - -	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

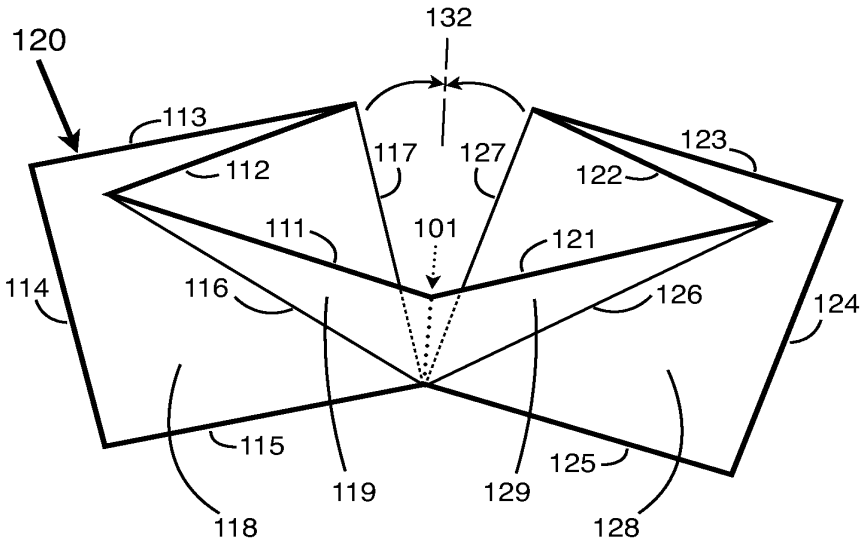
Figure 1C



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - - - -	Line of cut

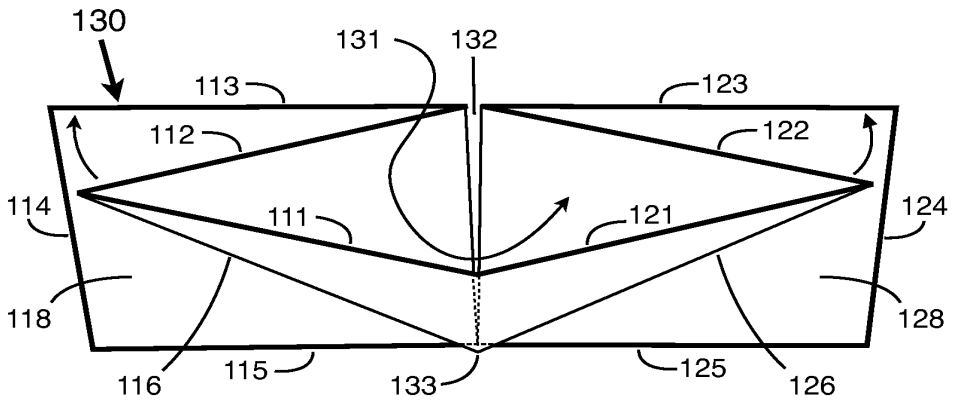
Figure 1D



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

Figure 1E



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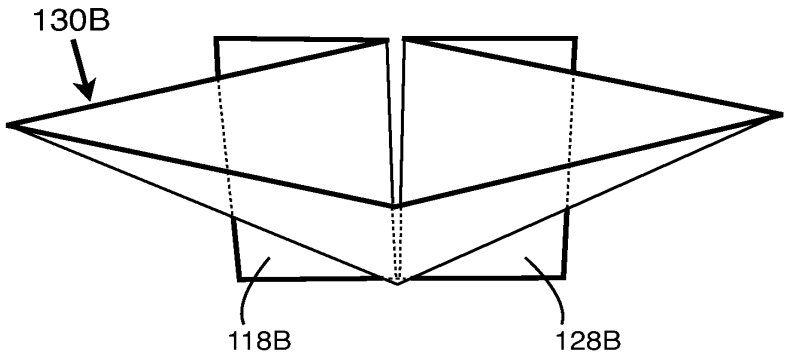


LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
- - - - -	Hidden (phantom) edges of folded structure
- - - - - - -	Line of cut

Figure 1G

Suture attachments omitted for clarity.

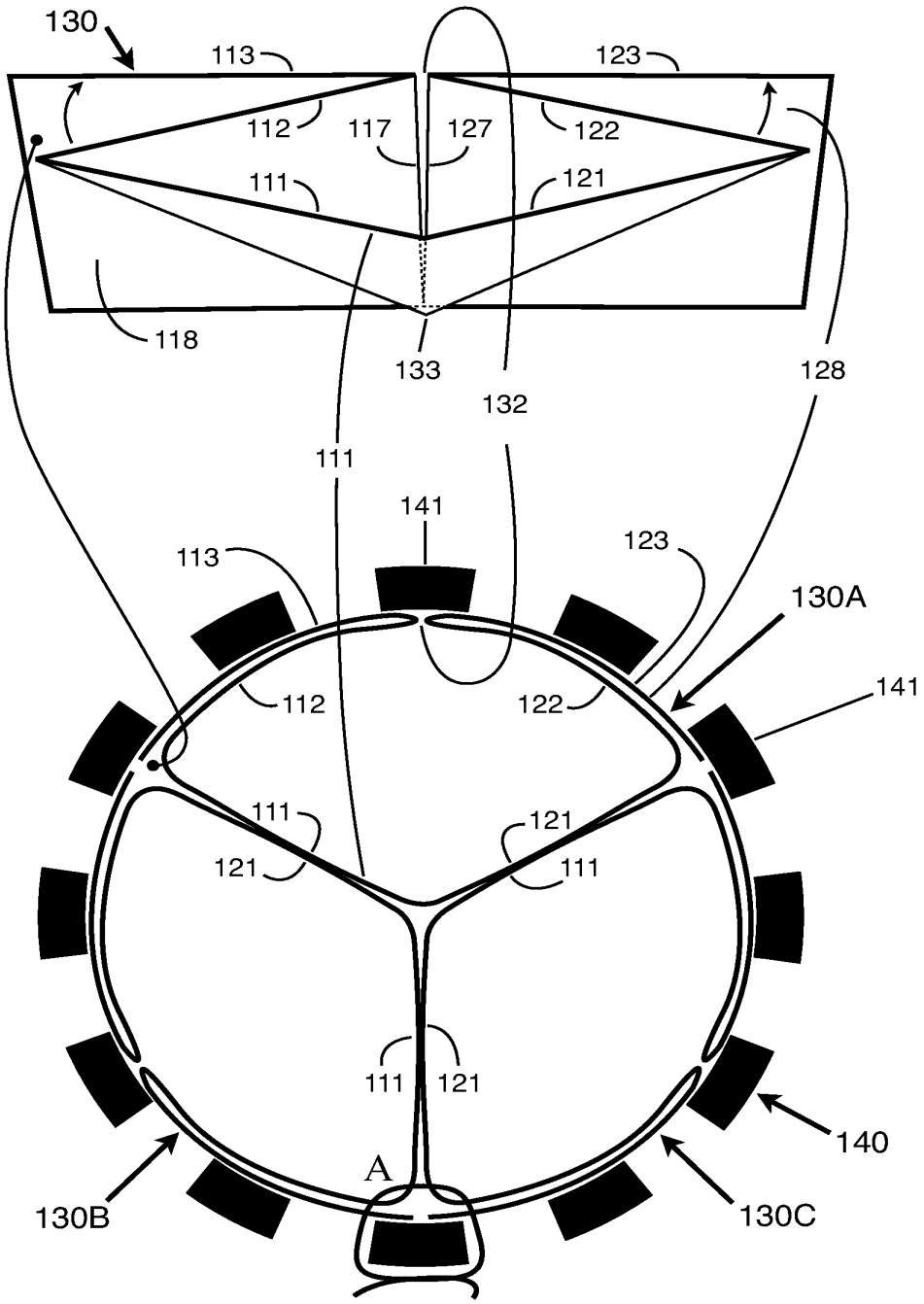
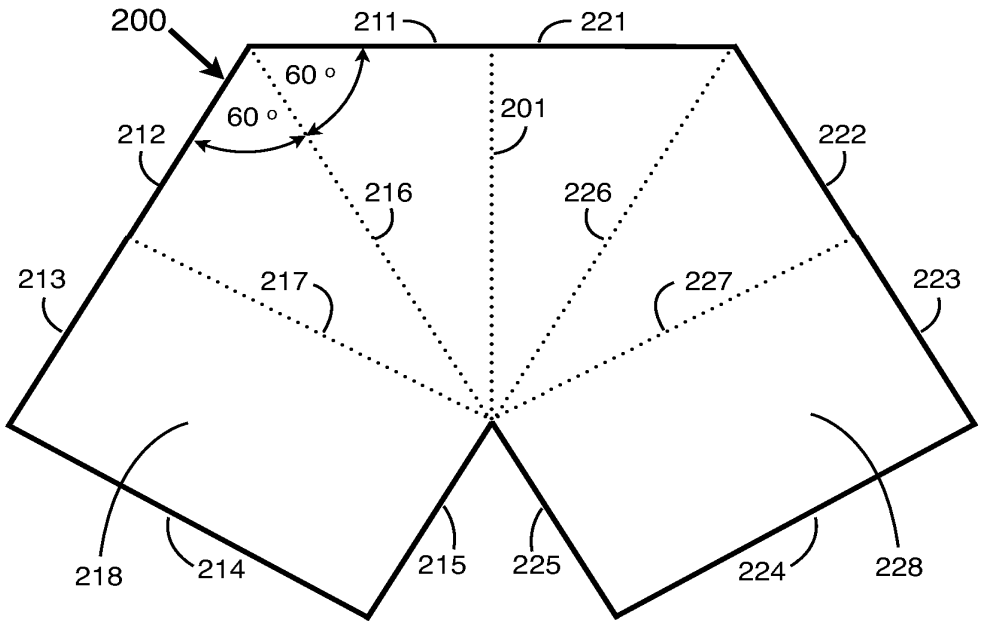


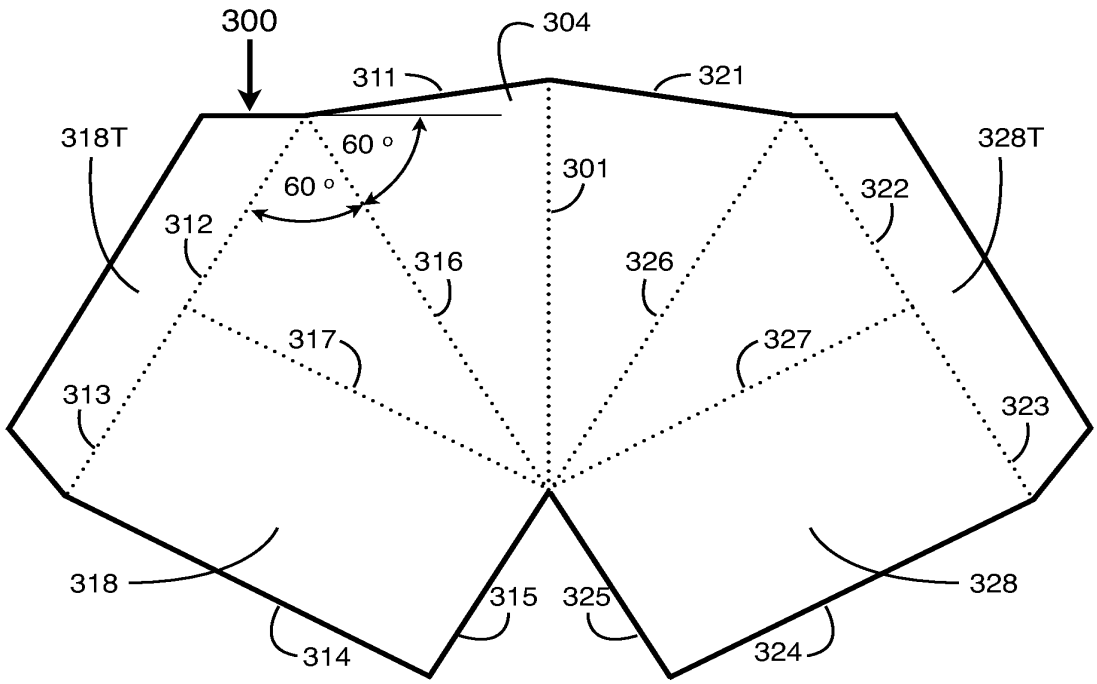
Figure 2



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

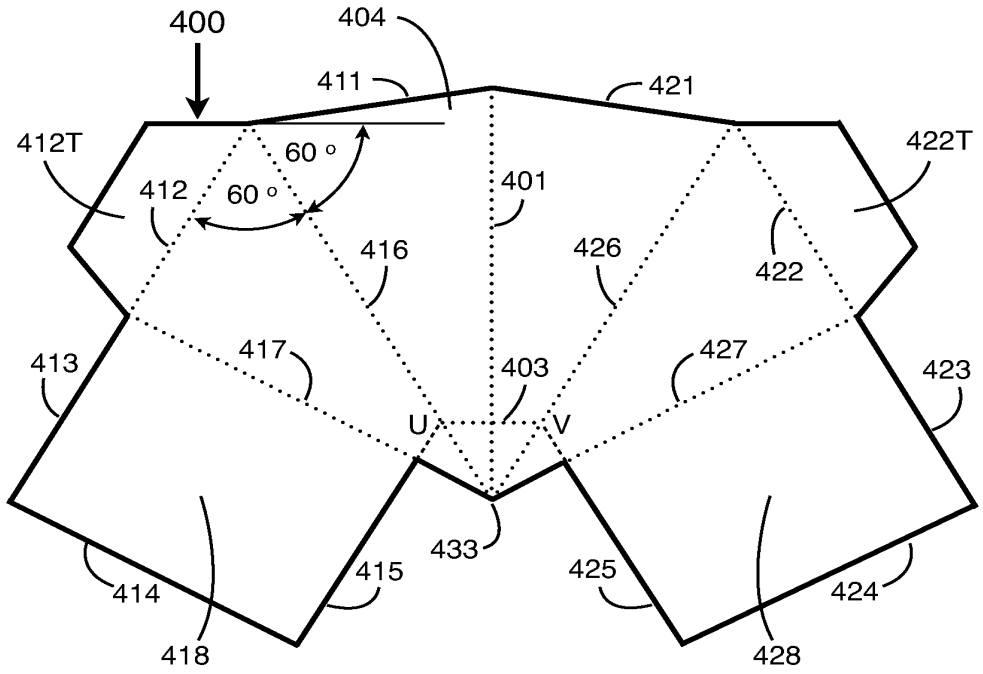
Figure 3



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
·····	Line of fold / crease
- - - - -	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

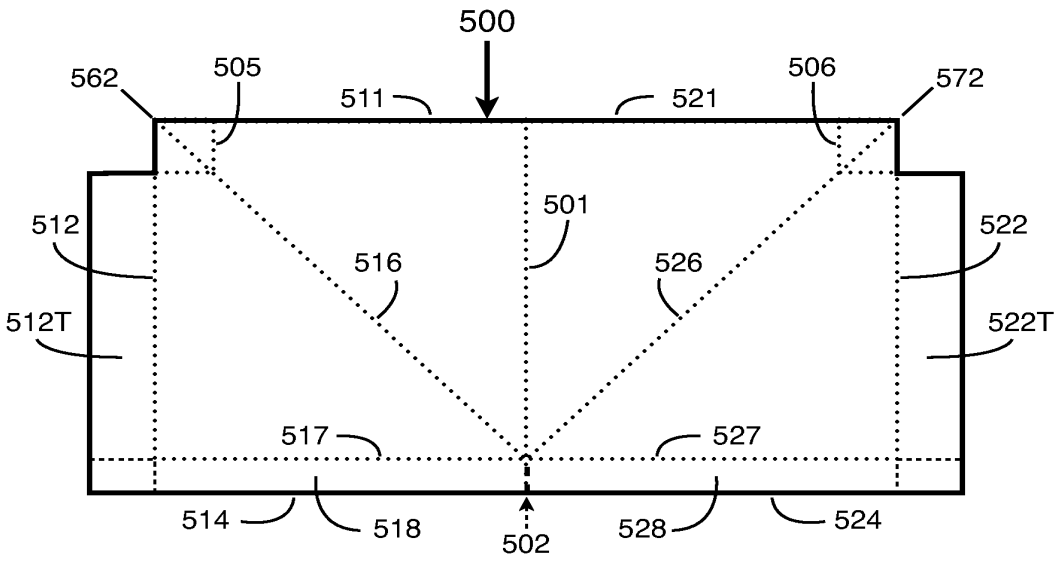
Figure 4



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

Figure 5A



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

Figure 5B

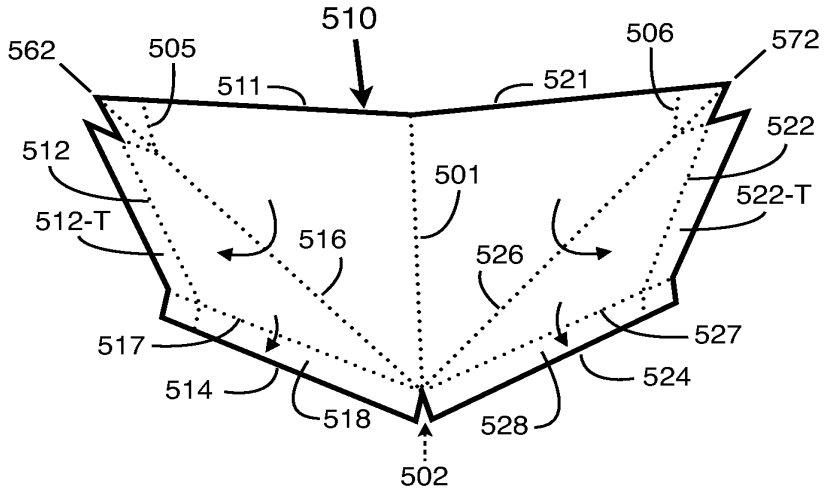
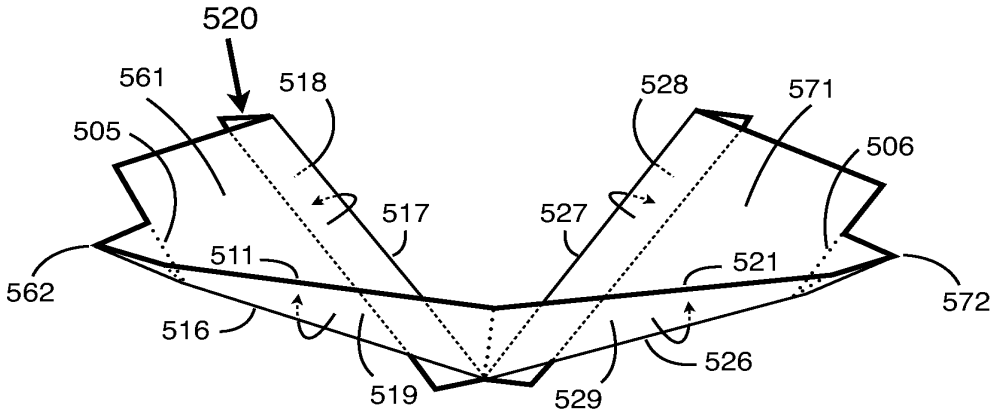


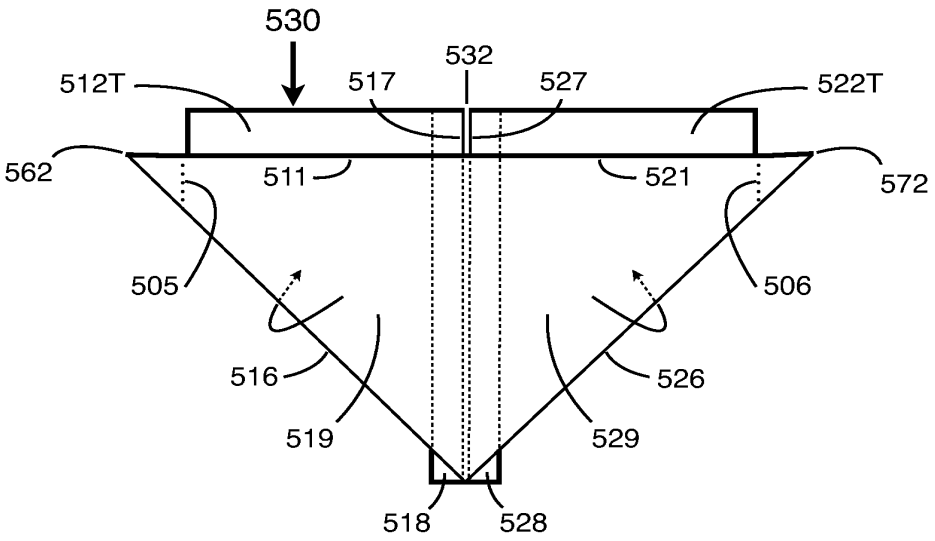
Figure 5C



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
·····	Line of fold / crease
- - - - -	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

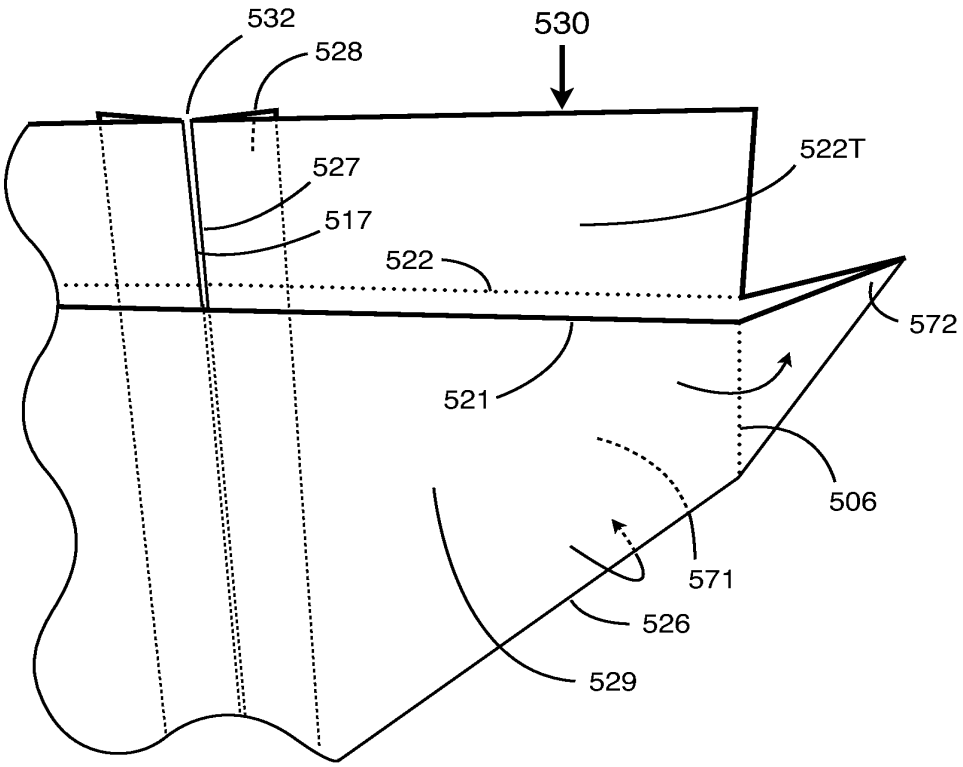
Figure 5D



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - - - -	Line of cut

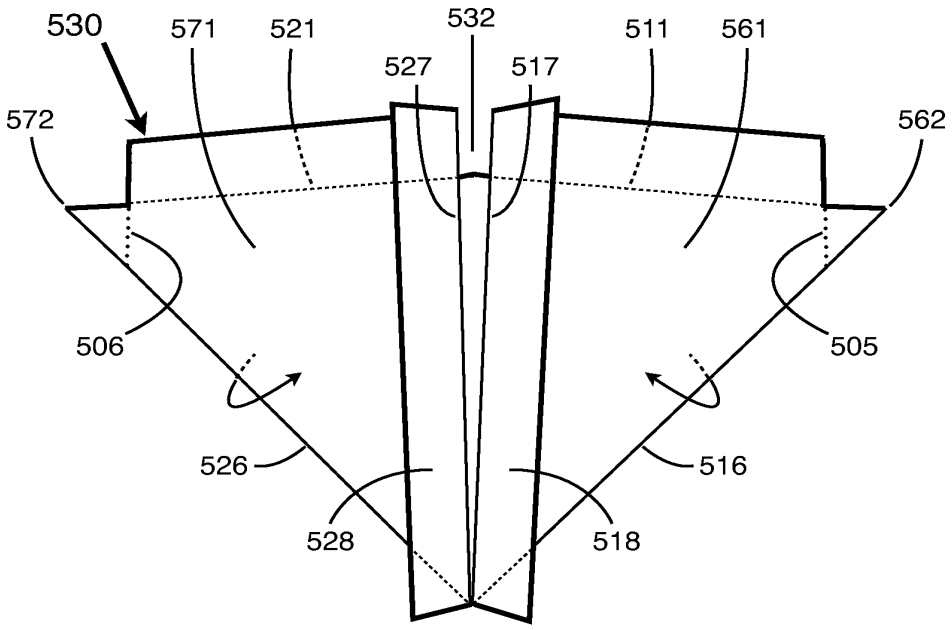
Figure 5E



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
·····	Line of fold / crease
- - - - -	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

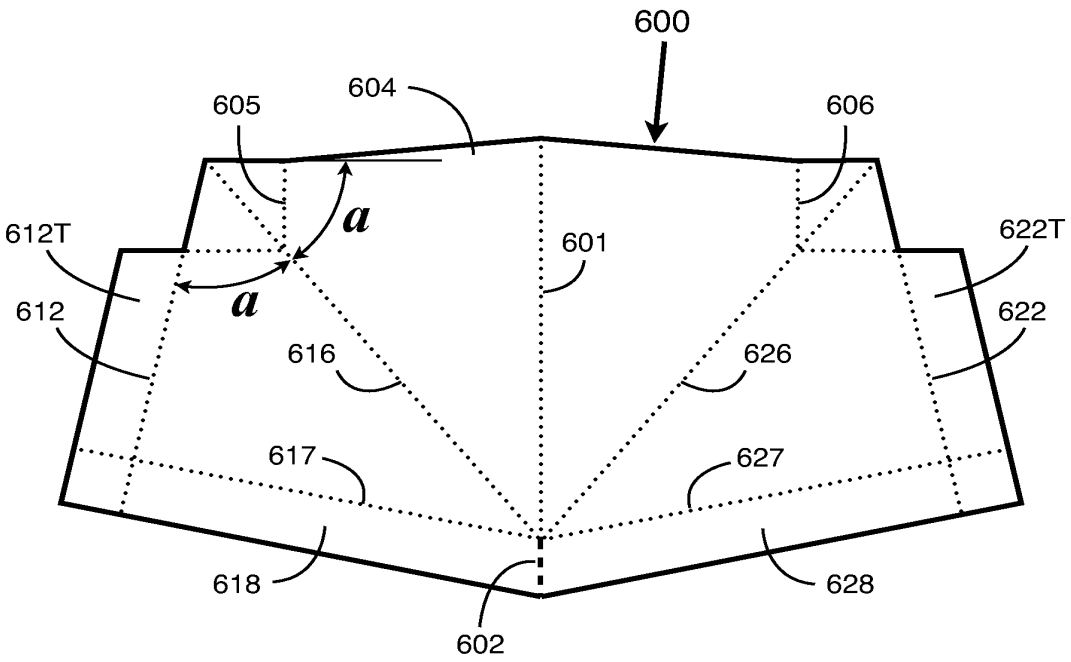
Figure 5F



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - - - -	Line of cut

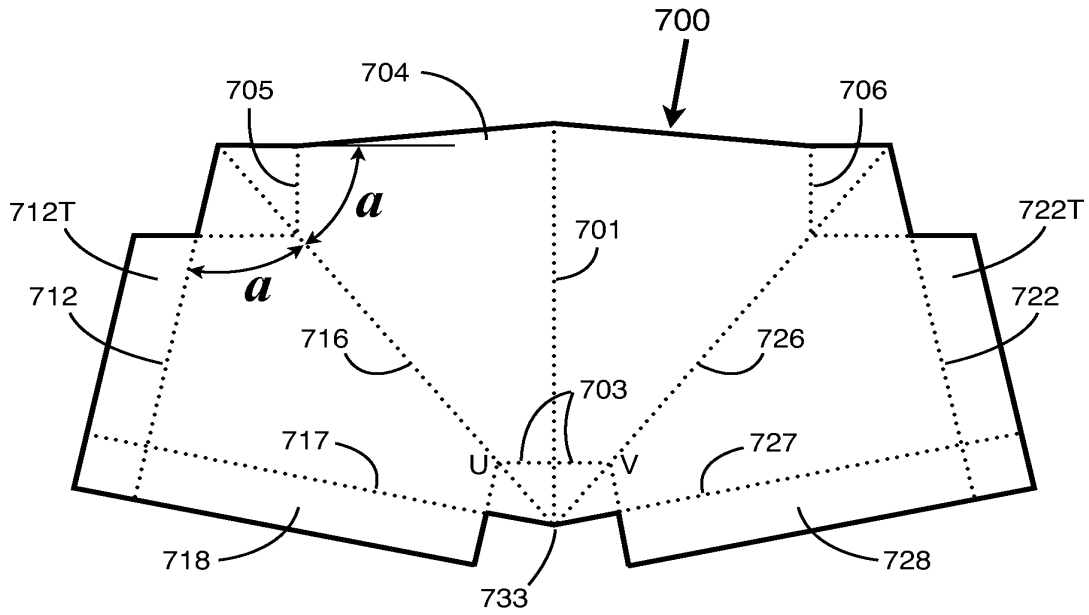
Figure 6



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
·····	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

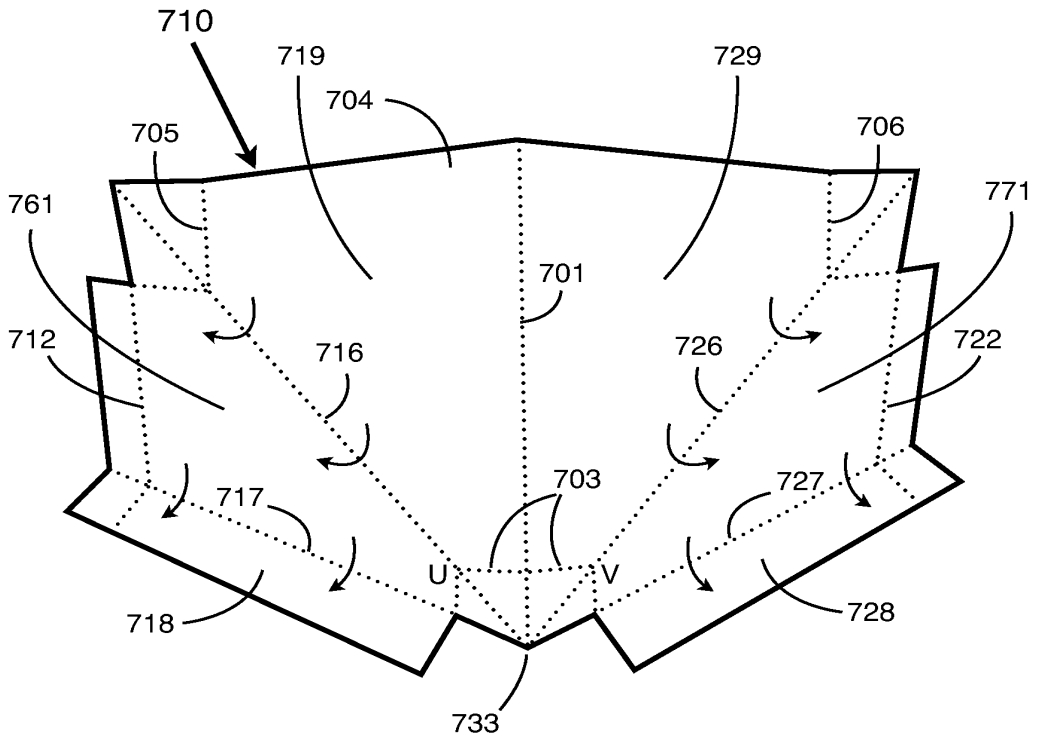
Figure 7A



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - - - -	Line of cut

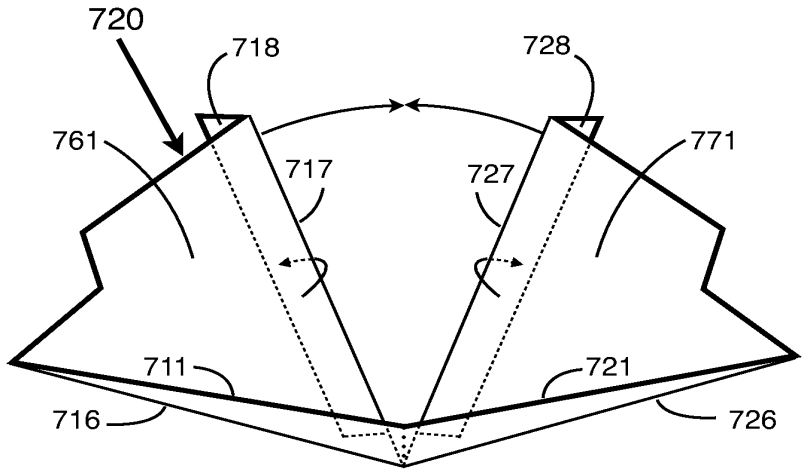
Figure 7B



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
·····	Line of fold / crease
- - - - -	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

Figure 7C



LEGEND

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———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - - -	Line of cut

Figure 7D

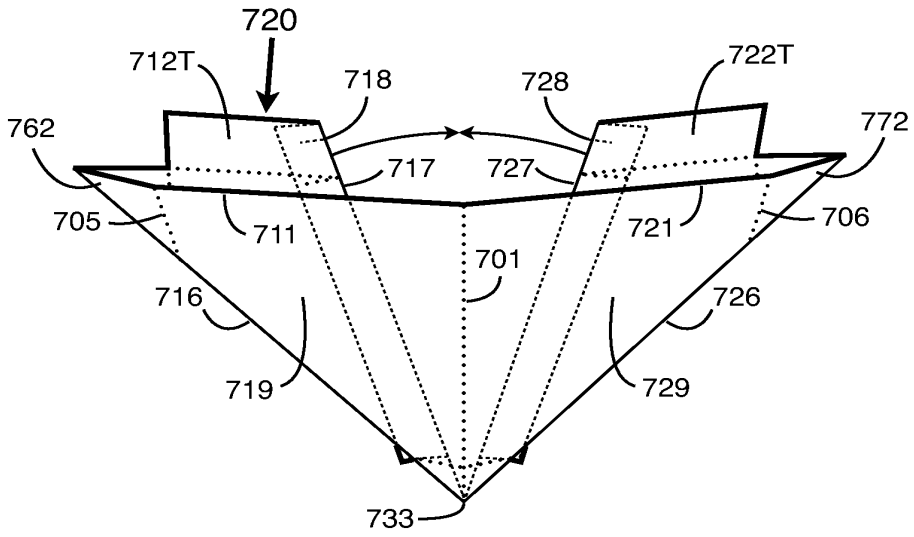
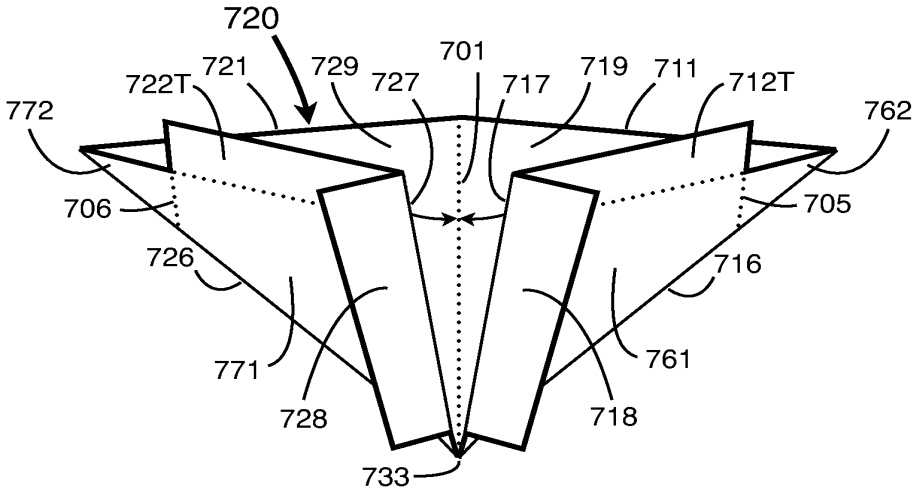


Figure 7E



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
·····	Line of fold / crease
- - - - -	Hidden (phantom) edges of folded structure
- - - - -	Line of cut

Figure 7F

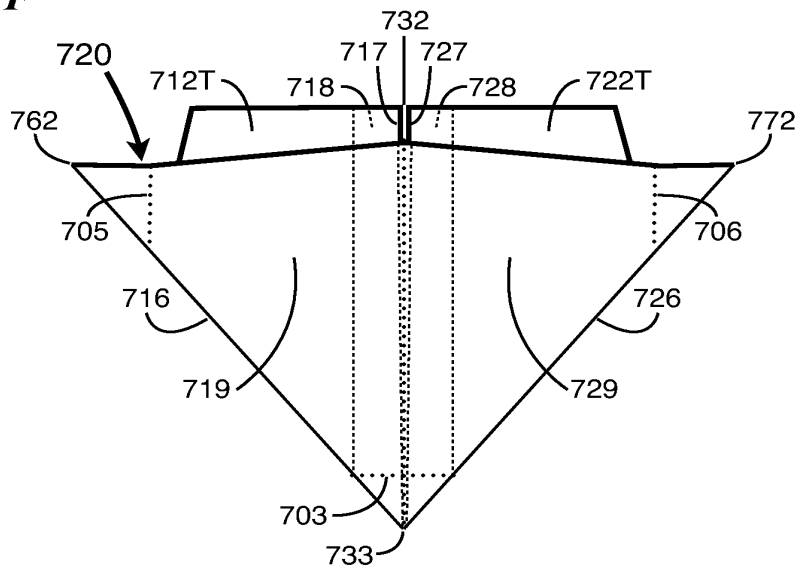


Figure 7G

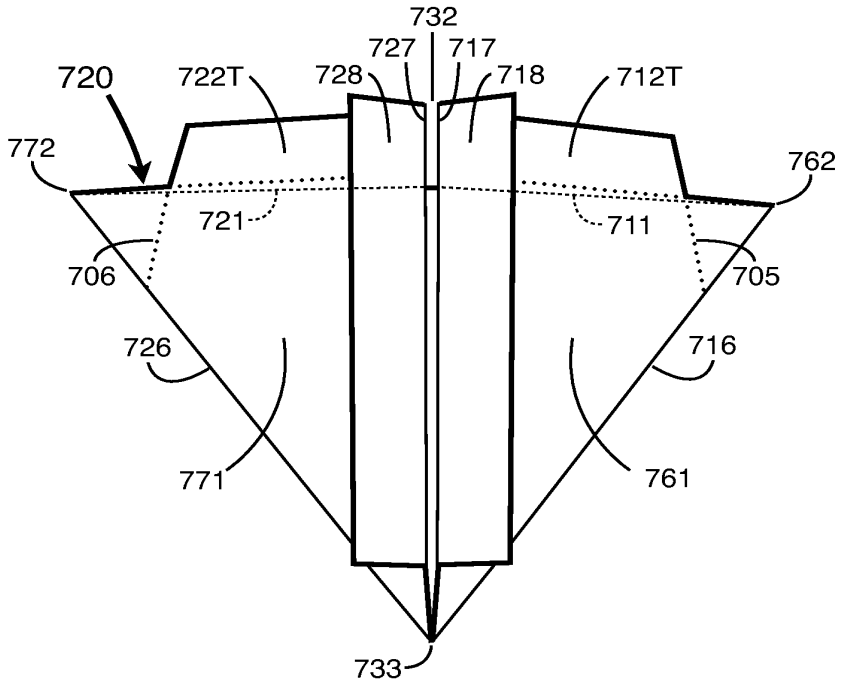


Figure 7H

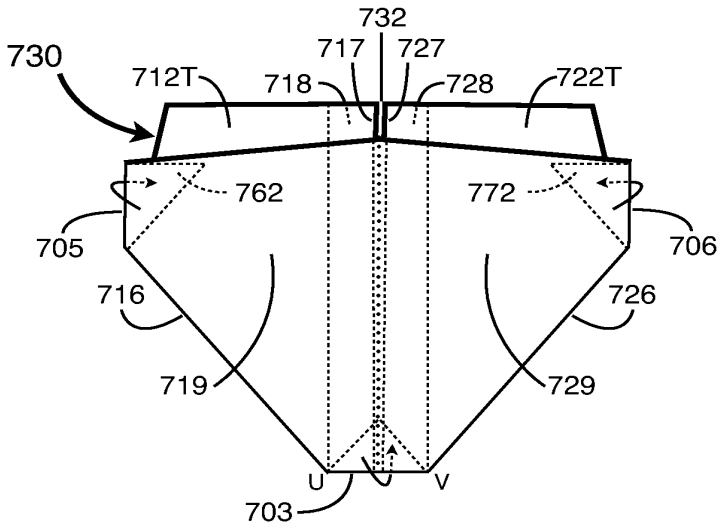


Figure 7I

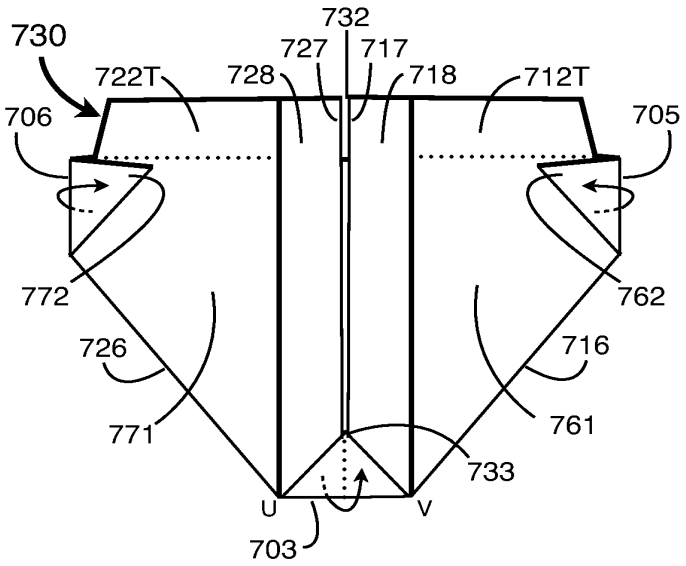
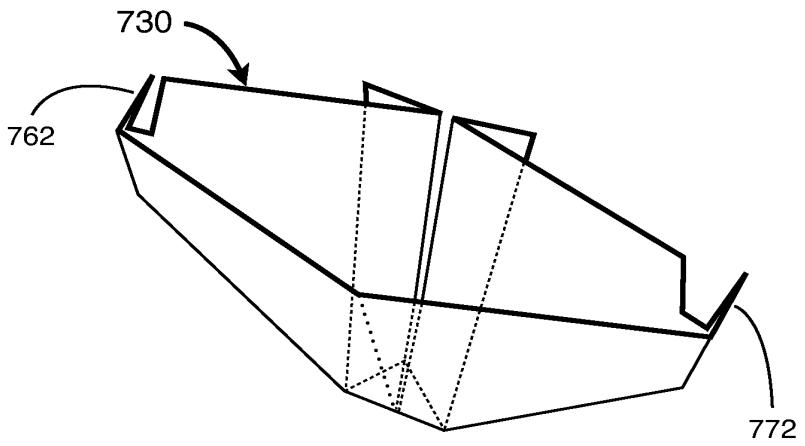


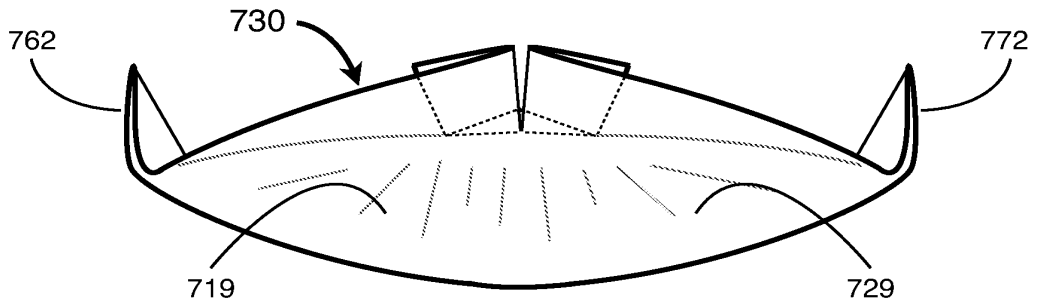
Figure 7J



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - - -	Line of cut

Figure 7K



LEGEND

———	Visible free (cut) edge of membrane piece
———	Visible edge of folded structure
.....	Line of fold / crease
-----	Hidden (phantom) edges of folded structure
- - - - - -	Line of cut

Figure 8A

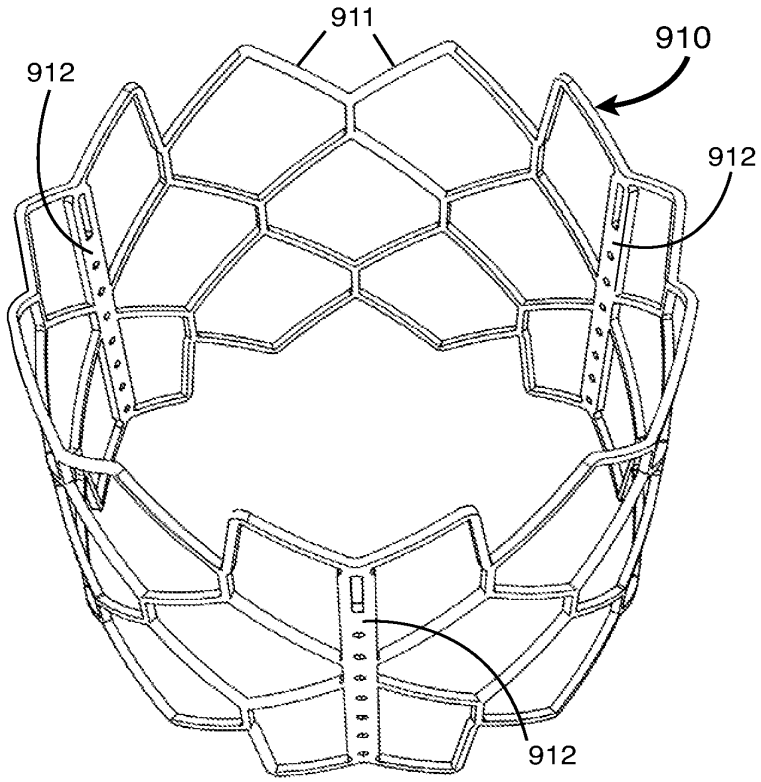


Figure 8B

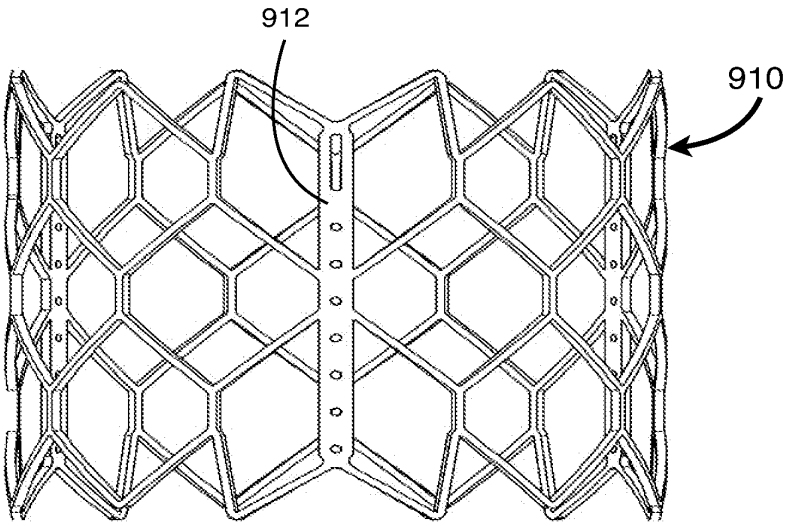


Figure 8C

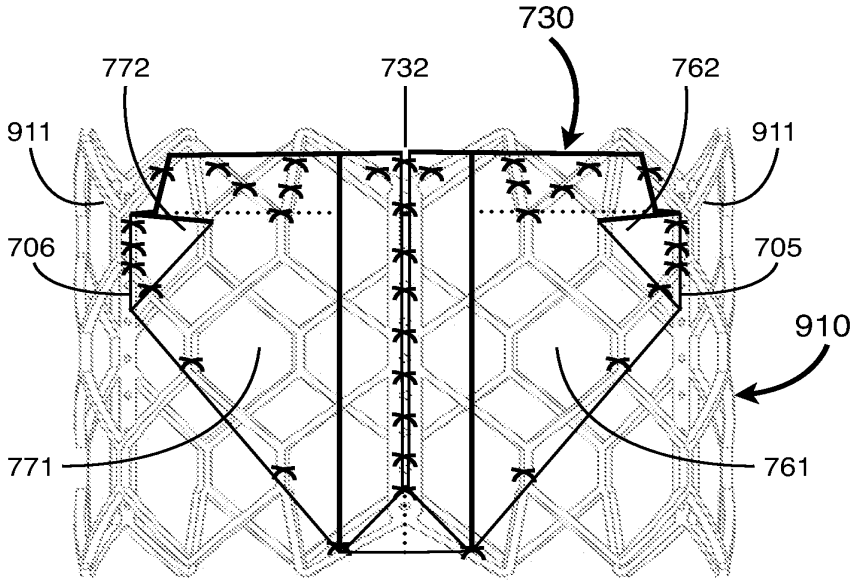
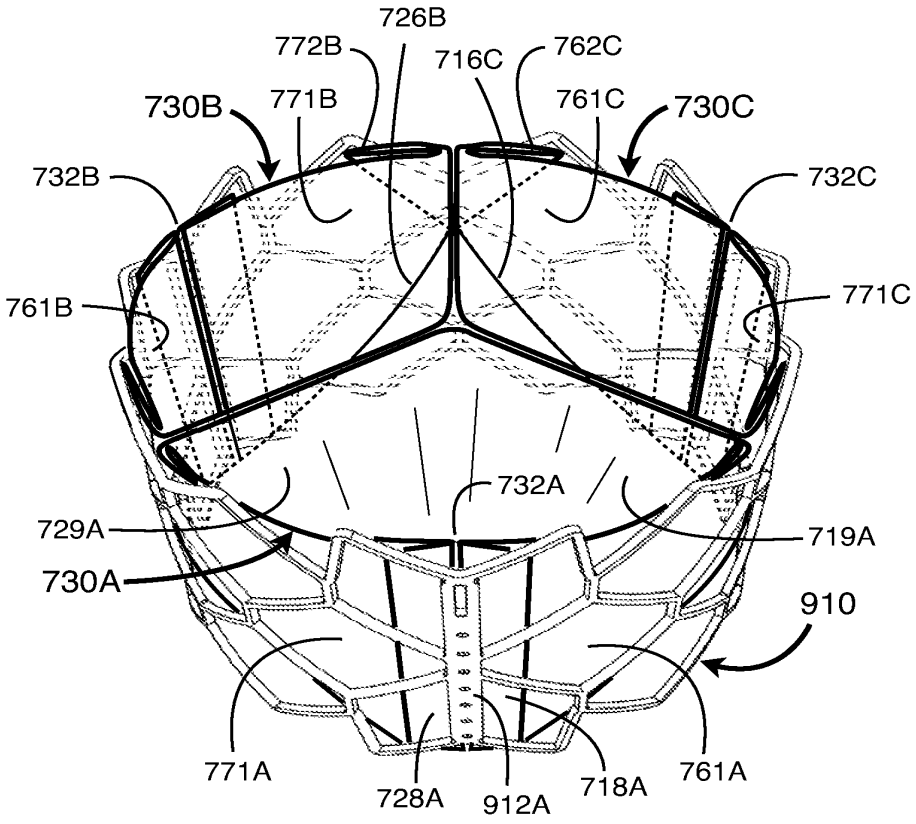


Figure 8D



Suture attachments omitted for clarity

Figure 9A

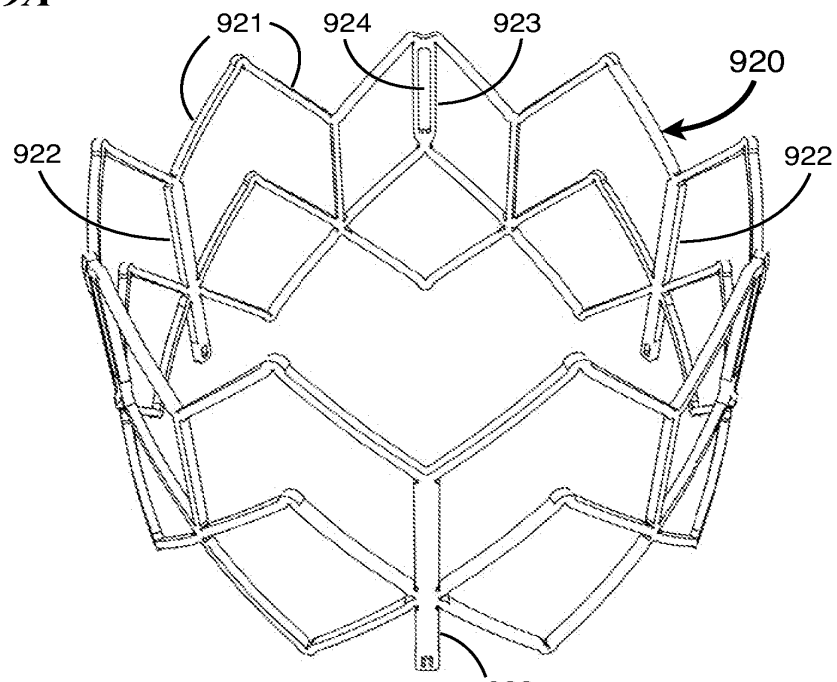


Figure 9B

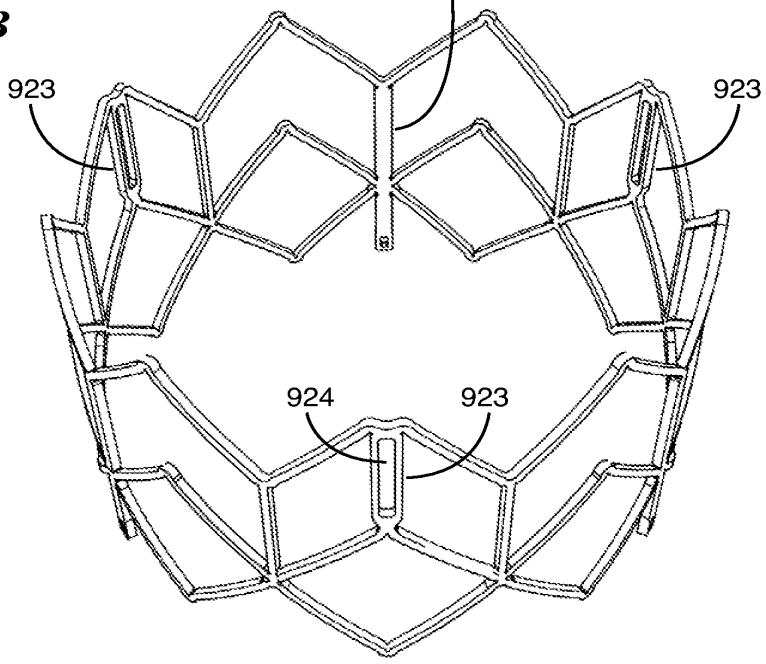


Figure 9C

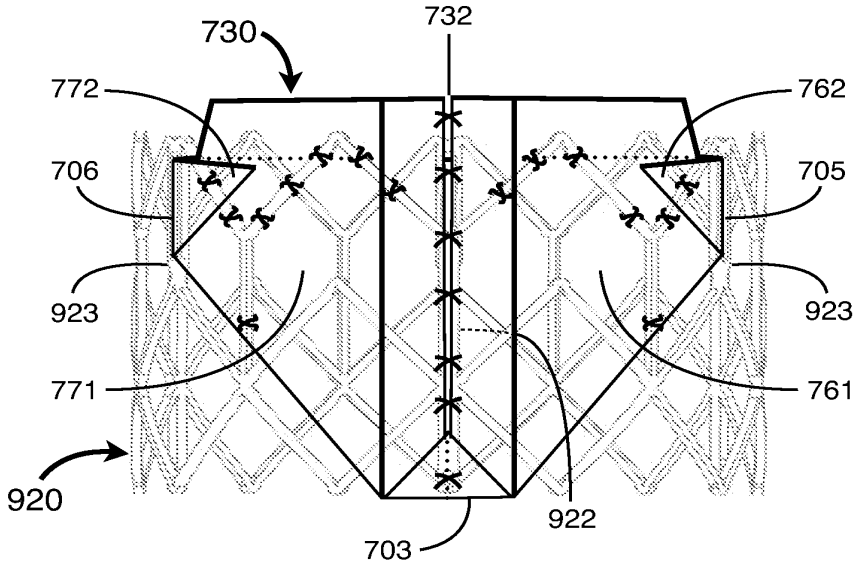


Figure 9D

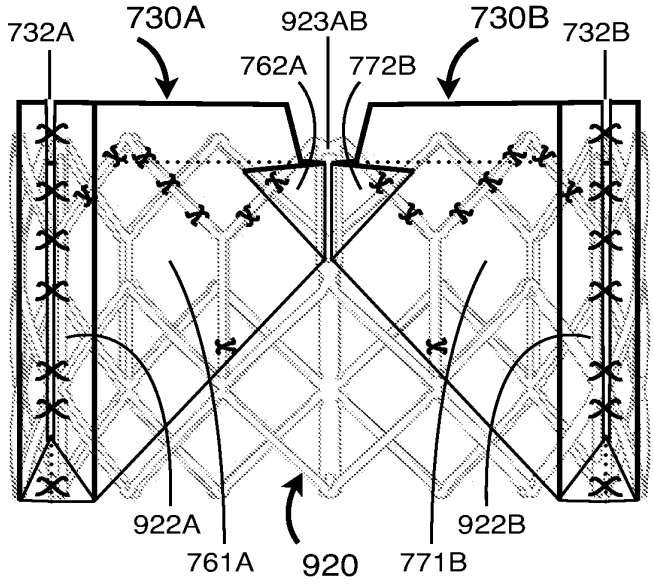
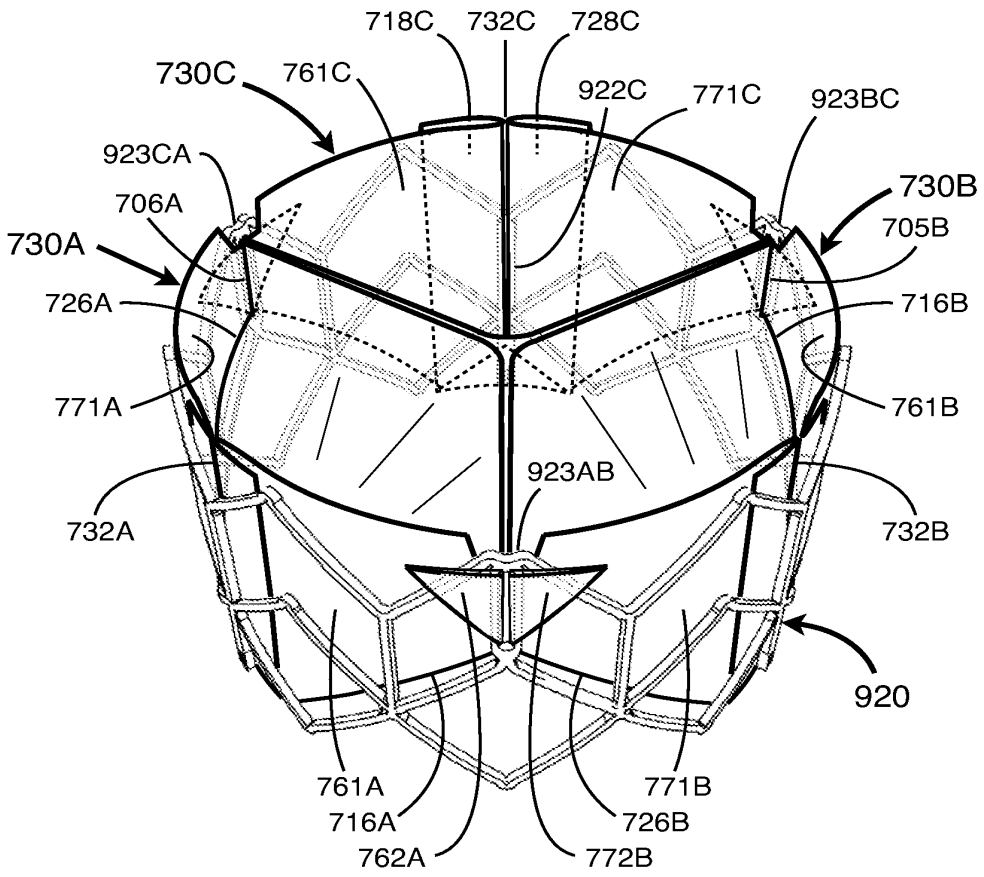


Figure 9E



Suture attachments omitted for clarity

Electronic Acknowledgement Receipt

EFS ID:	16893403
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
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Application Type:	Utility under 35 USC 111(a)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	EP1441672_Edwards_Lifesciences.pdf	1130476 3388da550c805722d00e61baa470bca30de257e7	no	74

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2	Foreign Reference	EP1603493_Edwards_Lifesciences.pdf	375942 0d0efb1c62a0bd6c25a014f52a8558fa64fa05d2	no	23
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3	Foreign Reference	EP1621162_Edwards_Lifesicences.pdf	612871 3b6432fabecfd57d7dd4a50ecd50937690ef6c78	no	36
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4	Foreign Reference	EP2000115_Edwards_Lifesciences_w_correction-page.pdf	622121 127b738e7cd7d1de0a44a53d8a540e0f0dd6e1be	no	37
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5	Foreign Reference	EP2055266_Edwards_Lifesciences.pdf	1686518 c8b3f6b2771b04d561a5c26ab4b174f22e34235c	no	75
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42	Non Patent Literature	Breuer_Application_Tissue-Engineering_Principles.PDF	1193973 cb22dd9c8f73c41c122ec7c49fe1e12cfeaab050	no	12
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43	Non Patent Literature	Cale_Hufnagel_Revisited.PDF	3204563 4b79cad74f4771c697148674880657c1296a49b3	no	5
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55	Non Patent Literature	Grube_Progress_and_Current_status_Percutaneous_Aortic_Valve_Replacement_ABSTRACT.PDF	90858 217a8fdb260fb0b95019ae4179bd5a0e6023239b	no	2
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56	Non Patent Literature	Hanlon_Pre-Use_Intraoperative_Testing_ABSTRACT.PDF	96608 7d912b4dc4c1908df4d156a6d88e641eb3801170	no	1
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58	Non Patent Literature	Hasenkam_Model_for_Acute_Haemodynamic_Studies.PDF	11581444 5710f116831550356684cebee377e71b9681b1b9	no	8
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60	Non Patent Literature	Hufnagel_Basic_Concepts_ARTICLE.PDF	4573630 e3ca35f5c89cd7c672a4124e96ffb3f6b0ef3f34	no	16
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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	16893738
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	23-SEP-2013
Filing Date:	13-NOV-2012
Time Stamp:	16:24:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	HUFNAGEL_In_The_Beginning_Surgical_Correction.PDF	2912346 f930646f4f11f982b64d1b7c802bd2fd28c280c5	no	2
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2	Non Patent Literature	HUFNAGEL_Late_Follow-up_ARTICLE.PDF	2603453 ec63db0d8c53130e6491c126a313f65853ee3579	no	10
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10	Non Patent Literature	Liao_Two-dimensional_mechanical.PDF	216352 b348140fc6c53d8cbab7f78df6753ef311e72ba9	no	3
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34	Non Patent Literature	Sellaro_Effects_of_Collagen_Fiber_Medium_term_Fatigue.PDF	1073715 cd287a8777b23026c4a7be5a5777467a974dc692	no	12
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Warnings:					
Information:					
54	Non Patent Literature	10100_US_10-887688_Declaration_of_Inventors_2008-02-28.pdf	3870953 657ad588a4b50407c16834948af838827e65db3b	no	85
Warnings:					
Information:					
55	Non Patent Literature	10100_US_10-887688_Declaration_of_Inventors_2008-12-15.pdf	1899083 359d55c2c06023369ab2c36187e7f03b2a9d5982	no	46
Warnings:					
Information:					

56	Non Patent Literature	10100_US_10-887688_Examiner_Interview_Summary_2010-07-26.pdf	187781 3287a1e03afacd01db7c7c1bfd60e9db8223977f	no	4
Warnings:					
Information:					
57	Non Patent Literature	10100_US_10-887688_Office_Action_2012-02-16.pdf	385115 edd156e8dd690f32a2d5eaf862602e7b5972d9c2	no	10
Warnings:					
Information:					
58	Non Patent Literature	10110_US_12-228192_Office_Action_2010-09-29.pdf	303920 70c49a9433dd0acbff8507779bf833421e8acdb1	no	9
Warnings:					
Information:					
59	Non Patent Literature	10110_US_12-228192_Examiner_Interview_Summary_2011-04-05.pdf	161803 8cd2ca6493510b177d8cfa48b7db348f7fb1ef65	no	3
Warnings:					
Information:					
60	Non Patent Literature	10110_US_12-228192_Final_Office_Action_2011-07-14.pdf	12085622 48467f8222486a3724a21d8328047ae8fd63e4b7	no	14
Warnings:					
Information:					
		Total Files Size (in bytes):	149108888		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/675,665

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	14 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/675,665		David Paniagua	109978.10101

CONFIRMATION NO. 1995

29880
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

WITHDRAWAL NOTICE

OC000000063948807

Date Mailed: 09/26/2013

Letter Regarding a New Notice and/or the Status of the Application

If a new notice or Filing Receipt is enclosed, applicant may disregard the previous notice mailed on 07/19/2013. The time period for reply runs from the mail date of the new notice. Within the time period for reply, applicant is required to file a reply in compliance with the requirements set forth in the new notice to avoid abandonment of the application.

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If the reply is not filed electronically via EFS-Web, the reply must be accompanied by a copy of the new notice.

If the Office previously granted a petition to withdraw the holding of abandonment or a petition to revive under 37 CFR 1.137, the status of the application has been returned to pending status.

/ktesfaye/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/675,665	11/13/2012	3738	800	109978.10101	14	3

CONFIRMATION NO. 1995

UPDATED FILING RECEIPT

29880
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

OC000000063948880

Date Mailed: 09/26/2013

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

David Paniagua, Houston, TX;
R. David Fish, Houston, TX;
Eduardo Induni, Alajuela, COSTA RICA;
Carlos Meija, Houston, TX;
Fransisco Lopez-Jimenez, Rochester, MN;

Applicant(s)

COLIBRI HEART VALVE LLC, Broomfield, CO

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 10/887,688 07/10/2004 PAT 8308797 *
which is a CIP of 10/037,266 01/04/2002 ABN
(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 12/05/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/675,665**

Projected Publication Date: 01/02/2014

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

Preliminary Class

623

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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NOT GRANTED

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PTO/AIA/80 (07-12)
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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

■ Practitioners associated with Customer Number: 29880

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

■ The address associated with Customer Number: 29880

OR

☐	Firm or Individual Name		
	Address		
	City	State	Zip
	Country		
	Telephone	Email	

Assignee Name and Address: Colibri Heart Valve LLC
2150 W. 6th Ave., Suite M
Broomfield, Colorado 80020

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be Filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record
The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	Joseph B. Horn	Date	1-17-2013
Name	Joseph B. Horn	Telephone	303 460 8667
Title	President and CEO for Colibri Heart Valve LLC		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/96 (08-12)
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U.S. Patent and Trademark Office;U.S. DEPARTMENT OF COMMERCE
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Colibri Heart Valve LLC

Application No./Patent No.: 13/675,665 Filed/Issue Date: November 13, 2012

Titled: Percutaneously Implantable Replacement Heart Valve Device and Method of Making Same

Colibri Heart Valve LLC, a limited liability company

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Inventors Paniagua, Induni, Mejia and Lopez To: Endoluminal Technology Research, LLC

   The document was recorded in the United States Patent and Trademark Office at
   Reel 031280, Frame 0839, or for which a copy thereof is attached.

2. From: Endoluminal Technology Research, LLC To: Endoluminal Technology LLC

   The document was recorded in the United States Patent and Trademark Office at
   Reel 031280, Frame 0877, or for which a copy thereof is attached.

This collection of information is required by37 CFR3.73(b). The information is required toobtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentialityis governed by35 U.S.C. 122and 37 CFR1.11 and1.14. Thiscollection is estimated to take 12 minutes to complete, including gathering, preparing, and submittingthe completed application form to the USPTO.Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent tothe Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.**SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/96 (08-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: Inventor R. David Fish To: Endoluminal Technology LLC

The document was recorded in the United States Patent and Trademark Office at
Reel 031280, Frame 0917, or for which a copy thereof is attached.

4. From: Endoluminal Technology LLC To: Vela Biosystems LLC

The document was recorded in the United States Patent and Trademark Office at
Reel 031280, Frame 0930, or for which a copy thereof is attached.

5. From: Vela Biosystems LLC To: R. David Fish and David Paniagua

The document was recorded in the United States Patent and Trademark Office at
Reel 031280, Frame 0942, or for which a copy thereof is attached.

6. From: R. David Fish and David Paniagua To: Colibri Heart Valve LLC

The document was recorded in the United States Patent and Trademark Office at
Reel 031280, Frame 0946, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/ Mark L. Yaskanin /	2013-09-30
Signature	Date
Mark L. Yaskanin	Reg. No. 45,246
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that yoube given certain informationin connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, pleasebe advised that: (1) the general authority forthe collection of thisinformation is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and(3) the principal purpose forwhich the information isused by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent applicationor patent. If you do not furnish the requested information,the U.S. Patent and Trademark Office may not be able to process and/or examineyour submission,which may result in termination of proceedings or abandonment of the applicationor expiration of the patent.

The informationprovided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the informationin order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an InternationalApplication filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, arecord may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from thissystem of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	16998851
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	30-SEP-2013
Filing Date:	13-NOV-2012
Time Stamp:	17:57:40
Application Type:	Utility under 35 USC 111(a)

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	Colibri_10101_POA.pdf	71715 67933793860a8b56e380f0c1746c90bece5e0bd5	no	1

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2	Assignee showing of ownership per 37 CFR 3.73.	Colibri_10101_3-73_Statement.pdf	124747 22c8dc939435f1b387101875fdaa05b03ef4f3bb	no	3

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/675,665	11/13/2012	David Paniagua	109978.10101

CONFIRMATION NO. 1995

29880
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

POA ACCEPTANCE LETTER

OC000000064151977

Date Mailed: 10/04/2013

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/30/2013.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/ttkim/

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LAWRENCEVILLE, NJ 08648

PUBLICATION NOTICE

OC000000065858703

Title:PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

Publication No.US-2014-0005766-A1
Publication Date:01/02/2014

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The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. Miller
Attorney Docket Number	109978.10101

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4011947		1977-03-15	Sawyer	
	2	4657133		1987-04-14	Komatsu et al.	
	3	4743231		1988-05-10	Kay et al.	
	4	6124523		2000-09-26	Banas et al.	
	5	6245102		2001-06-12	Jayaraman	
	6	6540782		2003-04-01	Snyders	
	7	6821297		2004-11-23	Snyders	
	8	6830584		2004-12-14	Seguin	

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	Attorney Docket Number	109978.10101

	9	7018406		2006-03-28	Seguin et al.	
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	4	20040158321		2004-08-12	Reuter et al.	
	5	20040230285		2004-11-18	Gifford, III et al.	
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	7	20070104395		2007-05-10	Kinigakis et al.	
	8	20070203575		2007-08-30	Forster et al.	
	9	20070276461		2007-11-29	Andreas et al.	
	10	20090005857		2009-01-01	Ischinger	
	11	20090054969		2009-02-26	Salahieh	
	12	20100241069		2010-09-23	Hatten	
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	14	20130304201		2013-11-14	Navia et al.	
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	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. Miller
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	1	2004/082527	WO		2004-09-30	Edwards Lifesciences Corp.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	MENDELSON, Karen et al., "Heart Valve Tissue Engineering: Concepts, Approaches, Progress, and Challenges" Ann Biomed Eng, 2006 Dec; 34(12); pp. 1799-1819; published online 2006 October 12 doi:10.1007/s/10439-006-9163-z	☐
	2	SCHMIDT, Dorthe et al., "Tissue engineering of heart valves using decellularized xenogeneic of polymeric starter matrices" Philos Trans R Soc Lond B Bio Sci., Aug 29, 2007, 362(1484); 1505-1512; published online June 22, 2007, doi: 10.1098/rstb.2007.2131	☐
	3	WERNER, S. et al., "Testing the Hydrodynamic properties of heart valve prostheses with a new test apparatus", Biomed Tech (Berl) 1994 Sep; 30(9); pp. 204-210 (Abstract only)	☐
	4	Office Action issued in U.S. Application No. 14/136,516, dated March 10, 2014 (109978.10102)	☐
	5	Notice of Allowance issued in U.S. Application No. 14/136,516, dated March 31, 2014 (109978.10102)	☐
	6	Cross-reference is made to U.S. Application No. 14/253,650 filed on April 15, 2014, and its associated Preliminary Amendment (109978.10104)	☐
	7	Cross-reference is made to U.S. Application No. 14/253,656 filed on April 15, 2014, and its associated Preliminary Amendment (109978.10113)	☐
	8	Cross-reference is made to U.S. Application No. 14/268,184 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10114)	☐

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	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

	9	Cross-reference is made to U.S. Application No. 14/268,190 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10115)	☐
	10	Cross-reference is made to U.S. Application No. 14/284,049 filed on May 21, 2014, and its associated Preliminary Amendment (109978.10116)	☐
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	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-05-23
Name/Print	Mark L. Yaskanin	Registration Number	45246

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(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
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(10) International Publication Number
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(71) Applicant *(for all designated States except US)*: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92614 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **IOBBI, Mario, M.** [US/US]; 187 Amherst Aisle, Irvine, CA 92612 (US).

(74) Agents: **JAMES, John, Christopher** et al.; One Edwards Way, Irvine, CA 92614 (US).

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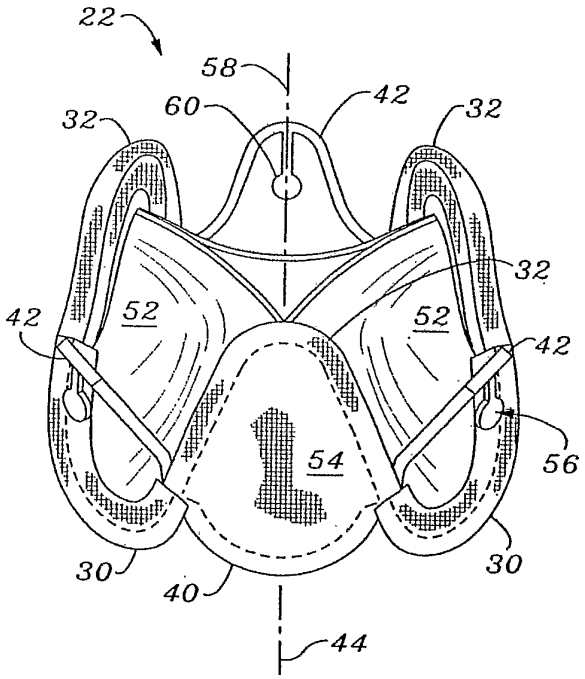
(54) Title: MINIMALLY-INVASIVE HEART VALVE WITH CUSP POSITIONERS



(57) Abstract: A prosthetic heart valve having an internal support frame with a continuous, undulating leaflet frame defined therein. The leaflet frame has three cusp regions positioned at an inflow end intermediate three commissure regions positioned at an outflow end thereof. The leaflet frame may be cloth covered and flexible leaflets attached thereto form occluding surfaces of the valve. The support frame further includes three cusp positioners rigidly fixed with respect to the leaflet frame and located at the outflow end of the support frame intermediate each pair of adjacent commissure regions. The valve is desirably compressible so as to be delivered in a minimally invasive manner through a catheter to the site of implantation. Upon expulsion from catheter, the valve expands into contact with the surrounding native valve annulus and is anchored in place without the use of sutures. In the aortic valve position, the cusp positioners angle outward into contact with the sinus cavities, and compress the native leaflets if they are not excised, or the aortic wall if they are. The support frame may be formed from a flat sheet of Nitinol that is bent into a threedimensional configuration and heat set. A holder having spring-like arms connected to inflow projections of the valve may be used to deliver, reposition and re-collapse the valve, if necessary.

WO 2004/082527 A2

MINIMALLY-INVASIVE HEART VALVE WITH CUSP POSITIONERS

Field of the Invention

[0001] The present invention relates generally to medical implants, and more particularly to minimally-invasive or collapsible/expandable heart valves and methods of delivering and implanting such valves.

Background of the Invention

[0002] Prosthetic heart valves are used to replace damaged or diseased heart valves. In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. Prosthetic heart valves can be used to replace any of these naturally occurring valves, although repair or replacement of the aortic or mitral valves is most common because they reside in the left side of the heart where pressures are the greatest.

[0003] Where replacement of a heart valve is indicated, the dysfunctional valve is typically cut out and replaced with either a mechanical valve, or a tissue or bioprosthetic-type valve. Bioprosthetic-type valves are often preferred over mechanical valves because they typically do not require long-term treatment with anticoagulants. The most common bioprosthetic-type valves are constructed with whole porcine (pig) valves, or with separate leaflets cut from bovine (cow) pericardium.

[0004] Although so-called stentless valves, comprising a section of xenograft (e.g., porcine) aorta and valve, are available, the most widely used valves include some form of artificial leaflet support. One such support is an elastic "support frame," sometimes called a "wireform" or "stent," which has a

plurality (typically three) of large radius U-shaped cusps supporting the cusp region of the leaflets of the bioprosthetic tissue (i.e., either a whole valve or three separate leaflets). The free ends of each two adjacent cusps converge somewhat asymptotically to form upstanding commissures that terminate in U-shaped tips, each being curved in the opposite direction as the cusps, and having a relatively smaller radius. The support frame typically describes a conical tube with the commissure tips at the small diameter end. This provides an undulating reference shape to which a fixed edge of each leaflet attaches (via components such as fabric and sutures) much like the natural fibrous skeleton in the aortic annulus. Therefore, the alternating cusps and commissures mimic the natural contour of leaflet attachment. Importantly, the wireform provides continuous support for each leaflet along the cusp region so as to better simulate the natural support structure.

[0005] The support frame is typically a non-ferromagnetic metal such as ELGILOY (a Co-Cr alloy) that possesses substantial elasticity. A common method of forming metallic support frames is to bend a wire into a flat (two-dimensional) undulating pattern of the alternating cusps and commissures, and then roll the flat pattern into a tube using a cylindrical roller. The free ends of the resulting three-dimensional shape, typically in the asymptotic region of the cusps, are then fastened together using a tubular splice that is plastically crimped around the ends. See Figs. 3 and 4 of U.S. Patent No. 6,296,662 for a support frame that is crimped together at a cusp midpoint.

[0006] Some valves include polymeric "support frames" rather than metallic, for various reasons. For example, U.S. Patent No. 5,895,420 discloses a plastic support frame that degrades in the body over time. Despite some favorable attributes of polymeric support frames, for example the ability to mold the complex support frame shape, conventional metallic support frames are generally preferred for their elastic properties, and have a proven track record in highly successfully heart valves. For example, the CARPENTIER-EDWARDS

Porcine Heart Valve and PERIMOUNT Pericardial Heart Valve available from Edwards Lifesciences LLC both have ELGILOY support frames and have together enjoyed the leading worldwide market position since 1976.

[0007] A conventional heart valve replacement surgery involves accessing the heart in the patient's thoracic cavity through a longitudinal incision in the chest. For example, a median sternotomy requires cutting through the sternum and forcing the two opposing halves of the rib cage to be spread apart, allowing access to the thoracic cavity and heart within. The patient is then placed on cardiopulmonary bypass which involves stopping the heart to permit access to the internal chambers. Such open heart surgery is particularly invasive and involves a lengthy and difficult recovery period.

[0008] Some attempts have been made to enable less traumatic delivery and implantation of prosthetic heart valves. For instance, U.S. Patent No. 4,056,854 to Boretos discloses a radially collapsible heart valve secured to a circular spring stent that can be compressed for delivery and expanded for securing in a valve position. Also, U.S. Patent No. 4,994,077 to Dobbin describes a disk-shaped heart valve that is connected to a radially collapsible stent for minimally invasive implantation.

[0009] Recently, a great amount of research has been done to reduce the trauma and risk associated with conventional open heart valve replacement surgery. In particular, the field of minimally invasive surgery (MIS) has exploded since the early to mid-1990s, with devices now being available to enable valve replacements without opening the chest cavity. MIS heart valve replacement surgery still typically requires bypass, but the excision of the native valve and implantation of the prosthetic valve are accomplished via elongated tubes or cannulas, with the help of endoscopes and other such visualization techniques.

[0010] Some examples of more recent MIS heart valves are shown in U.S. Patent No. 5,411,552 to Anderson, et al., U.S. Patent No. 5,980,570 to

Simpson, U.S. Patent No. 5,984,959 to Robertson, et al., U.S. Patent No. 6,425,916 to Garrison, et al., and PCT Publication No. WO 99/334142 to Vesely.

[0011] Although these and other such devices provide various ways for collapsing, delivering, and then expanding a "heart valve" per se, none of them disclose much structural detail of the valve itself. For instance, the publication to Vesely shows a tissue leaflet structure of the prior art in Fig. 1, and an expandable inner frame of the invention having stent posts in Figs. 3A-3C. The leaflets are "mounted to the stent posts 22 in a manner similar to that shown in Fig. 1." Likewise, Anderson describes mounting a porcine valve inside of an expandable stent "by means of a suitable number of sutures to form the cardiac valve prosthesis 9 shown in Fig. 2." Such general disclosures stop short of explaining how to construct a valve in a manner that maximizes long-term efficacy. In particular, the particular means of attaching the leaflets to the MIS stent is critical to ensure the integrity and durability of the valve once implanted. All of the prior art MIS valves are inadequate in this regard. Furthermore, use of conventional support stents or wireforms is difficult in MIS valves because of the need to compress the valve into a relatively small diameter delivery package, which creates material challenges.

[0012] Some MIS valves of the prior art are intended to be used without removing the natural valve leaflets. Sometimes the natural leaflets are heavily calcified, and their removal entails some risk of plaque particles being released into the bloodstream. Therefore, some of the MIS valves are designed to expand outward within the annulus and native leaflets, and compress the leaflets against the annulus. The relatively uneven surface of the calcified annulus and leaflets creates sizing problems and may complicate the delivery and placement steps. Prior art MIS valves are essentially tubular stents embellished with a native xenograft valve. The implant methodology is simply the conventional balloon expansion technique or pushing a self-expanding version from the end

of a catheter. Minimal control over the placement of the valve is provided or contemplated.

[0013] Despite some advances in MIS valve design, there remains a need for an MIS valve that is durable and which has a more flexible delivery and implantation methodology.

Summary of the Invention

[0014] The present invention provides improved prosthetic heart valves that can be implanted in a minimally-invasive manner, but which also has aspects that make it useful for conventional surgeries. The valves and implant tools and methods described herein provide a highly adaptive and simple to use endovascular delivery option for cardiac surgeons or cardiologists because of features that facilitate implantation. The valve is designed to be expelled from a delivery tube in an implant area and then expanded and/or positioned to contact the surrounding tissue without additional anchoring structures. Further, the valve and implant tools permit repositioning and even recollapse of the valve if needed.

[0015] In accordance with a first aspect of the invention, a prosthetic heart valve support frame comprises a leaflet frame and three cusp positioners. The leaflet frame has a continuous, undulating shape that mimics the natural fibrous structure of an aortic valve. The leaflet frame has three cusp regions alternating with and intermediate three commissure regions, the three cusp regions being positioned at an inflow end of the support frame and circumferentially about a flow axis defined within the support frame. The three commissure regions are positioned at an outflow end of the support frame and circumferentially about the flow axis. The three cusp positioners are rigidly fixed with respect to the leaflet frame and are disposed circumferentially about the flow axis. Each cusp positioner is located at the outflow end of the support frame and intermediate two of the commissure regions of the leaflet frame.

[0016] The leaflet frame and the cusp positioners may be formed integrally as a single piece. Desirably, the support frame is formed by a process comprising providing a two-dimensional blank of the support frame, and forming the two-dimensional blank into the three-dimensional heart valve support frame. The leaflet frame and the cusp positioners may be made of Nitinol, preferably with a martensitic transition temperature of less than about 5° C and an austenitic transition temperature of more than about 20° C.

[0017] Each cusp positioner of the heart valve support frame desirably has a U-shape with an apex of the U-shape pointing toward the outflow end of the support frame and two legs of the U-shape pointing toward the inflow end. Each of the two legs of each U-shaped cusp positioner may be rigidly fixed to the continuous leaflet frame at a location approximately midway between a cusp region and a commissure region thereof. An anti-migration member such as an elongated section terminating in an enlarged and rounded head can be rigidly fixed to each cusp positioner to project therefrom. The cusp positioners may flare outwardly from the rest of the support frame to better contact surrounding tissue.

[0018] The support frame further may include three cusp connectors rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis. Each cusp connector is located at the inflow end of the support frame and intermediate two of the cusp regions of the leaflet frame. Each cusp connector desirably has a U-shape with an apex of the U-shape pointing toward the inflow end of the support frame and two legs of the U-shape pointing toward the outflow end. In a preferred embodiment, the leaflet frame, cusp positioners, and cusp connectors are formed integrally as a single piece, and the three cusp positioners and three cusp connectors define a continuous, undulating shape that generally mimics the shape of the leaflet frame but is rotated 60° about the flow axis therefrom.

[0019] Another aspect of the invention is a collapsible prosthetic heart valve that has a collapsible leaflet frame, three separate, flexible leaflets attached to the leaflet frame, and three cusp positioners rigidly fixed with respect to the leaflet frame. The leaflet frame has three cusp regions intermediate three commissure regions, the three cusp regions being positioned at an inflow end of the leaflet frame and circumferentially about a flow axis defined within the support frame. The three commissure regions are positioned at an outflow end of the leaflet frame and circumferentially about the flow axis. Each flexible leaflet has an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween. The leaflets attach around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions. The three cusp positioners are rigidly fixed with respect to the leaflet frame and are disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the leaflet frame and intermediate two of the commissure regions of the leaflet frame.

[0020] The heart valve may incorporate the aforementioned features of the support frame, for example a leaflet frame with a continuous, undulating shape that mimics the natural fibrous structure of an aortic valve, cusp connectors, and anti-migration members on each cusp positoiner. Desirably, an inflow periphery of the heart valve is defined along alternating and rigidly fixed cusp regions and cusp connectors. The inflow periphery may have an external fabric covering, and the heart valve may further includes a fabric panel defining an exterior surface of the heart valve between each pair of cusp positioner and cusp connector. Preferably, the leaflet frame has a fabric covering along substantially its entire length, the fabric covering defining a flange, and wherein the arcuate cusp edges of the flexible leaflets attach to the fabric covering flange. The fabric covering flange may project generally outward from the leaflet frame such that the cusp edges of the flexible leaflets extend radially

outward past and underneath the leaflet frame to be sewn to the fabric covering flange. Each flexible leaflet may have a pair of tabs extending on either side of its free edge, wherein two tabs of adjacent flexible leaflets meet and pass together to the outside of the adjacent commissure region of the leaflet frame and are attached thereto using sutures through the tabs.

[0021] In accordance with a still further aspect of the invention, a collapsible prosthetic heart valve comprises:

a continuous, collapsible leaflet frame having three U-shaped cusp regions intermediate three U-shaped commissure regions, the three cusp regions being positioned at an inflow end of the leaflet frame and circumferentially about a flow axis defined within the leaflet frame, the three commissure regions being positioned at an outflow end of the leaflet frame and circumferentially about the flow axis;

a cloth covering extending around the leaflet frame; and

three separate, flexible leaflets attached to the leaflet frame, each leaflet having an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween, the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions, the commissure edges of each leaflet further including a tab, wherein the tabs of two adjacent leaflets extend through the U-shape commissure region, diverge on the outside of commissure region, and are attached to the leaflet frame on the outside of the commissure region.

[0022] The present invention also encompasses a method of implanting a prosthetic aortic heart valve with a first step of providing a collapsible prosthetic heart valve having a collapsible leaflet frame defined by three cusp regions on an inflow end of the valve intermediate three commissure regions on an outflow end of the valve. The valve includes three cusp positioners on the

outflow end and intermediate the three commissure regions. The method includes collapsing the prosthetic heart valve within a delivery tube, advancing the prosthetic heart valve within the delivery tube to an aortic annulus, expelling the prosthetic heart valve from the delivery tube by relative movement therebetween, expanding the prosthetic heart valve, and positioning the prosthetic heart valve such that the cusp positioners contact the two coronary and one non-coronary sinuses of the ascending aorta without blocking the coronary ostia.

[0023] The method preferably includes the step of connecting a holder having flexible members to the commissure regions of the prosthetic heart valve and utilizing the flexible members to perform the step of positioning the prosthetic heart valve. Flexible members of the holder may also be connected to the cusp positioners and utilized to perform the step of positioning the prosthetic heart valve, or to rotate the prosthetic heart valve during the step of positioning. Advantageously, the flexible members may be used to re-collapse the prosthetic heart valve after the step of expanding. The prosthetic heart valve is desirably expanded in a location that is inferior to a final implant position such that the cusp positioners contact the surrounding aortic annulus, and the step of positioning comprises displacing the valve in a superior direction to a final implant position. The cusp positioners may be flared outward to define a circle about a flow axis of the valve greater than a circle about the flow axis defined by the three commissure regions, such that the step of displacing the valve in a superior direction causes the outwardly flared cusp positioners to be channeled into perspective coronary sinuses.

[0024] In accordance with a preferred method, the collapsible leaflet frame is formed of a shape memory alloy having a martensitic transition temperature less than room temperature and an austenitic transition temperature less than body temperature, and the step of collapsing is done with the material of the leaflet frame at a temperature less than its martensitic transition

temperature. For example, the step of collapsing may be done in conjunction with immersing the prosthetic heart valve in an ice bath to reduce the temperature of the material of leaflet frame to below its martensitic transition temperature. In another aspect, the collapsible leaflet frame may be formed of a shape memory alloy having a memory condition in its expanded state, and wherein the step of expanding the prosthetic heart valve comprises both permitting self-expansion of the valve to an intermediate diameter and then using a physical expander to increase the diameter of the valve to the memory condition of the leaflet frame.

[0025] A further method of implanting a collapsible prosthetic heart valve provided by the present invention comprises first providing a self-expanding valve comprised of a material displaying hysteresis in the elastic or superelastic region. The valve is permitted to self-expand to a first diameter, and then the valve is assisted with a physical expander such as a balloon to further expand to a second diameter.

[0026] The prosthetic heart valve may includes a collapsible leaflet frame formed of a shape memory alloy having a martensitic transition temperature less than room temperature and an austenitic transition temperature less than body temperature, and the method may further include a step of collapsing the valve with the material of the leaflet frame at a temperature less than its martensitic transition temperature. Fir example, the step of collapsing may be done in conjunction with immersing the prosthetic heart valve in an ice bath to reduce the temperature of the material of leaflet frame to below its martensitic transition temperature.

[0027] The prosthetic heart valve may have a collapsible leaflet frame defined by three cusp regions on an inflow end of the valve intermediate three commissure regions on an outflow end of the valve, and three cusp positioners on the outflow end and intermediate the three commissure regions. In this case, the method may further include:

collapsing the prosthetic heart valve within a delivery tube;

advancing the prosthetic heart valve within the delivery tube to an aortic annulus;

expelling the prosthetic heart valve from the delivery tube by relative movement therebetween;

expanding the prosthetic heart valve by the steps of permitting self-expansion and assisting further expansion; and

positioning the prosthetic heart valve such that the cusp positioners contact the two coronary and one non-coronary sinuses of the ascending aorta without blocking the coronary ostia.

Brief Description of the Drawings

[0028] Fig. 1 is a partial view of a patient's heart generally vertically section through the left ventricle and associated heart valves, and illustrating the implantation approach of a catheter-based prosthetic valve of the present invention;

[0029] Fig. 2A is a vertical sectional view through an aortic annulus and an exemplary prosthetic heart valve of the present invention implanted therein;

[0030] Fig. 2B is a top plan view of the implanted prosthetic heart valve of Fig. 2A;

[0031] Figs. 3A-3C are perspective, top plan, and bottom plan views, respectively, of the prosthetic heart valve of Fig. 2A;

[0032] Fig. 4 is a plan view of a prosthetic heart valve support frame of the present invention in a two-dimensional blank form prior to conversion to three-dimensional final form;

[0033] Fig. 5 is a perspective view of the prosthetic heart valve support frame of Fig. 4 in its three-dimensional final form with a leaflet frame and cusp positioners;

[0034] Figs. 5A and 5B are views of a portion of the three-dimensional heart valve support frame of Fig. 5 showing alternative cusp positioner configurations;

[0035] Fig. 6A is an elevational view of a partially assembled prosthetic heart valve as in Figs. 3A-3C;

[0036] Fig. 6B is an elevational view of the prosthetic heart valve of Fig. 6A fully assembled;

[0037] Fig. 7 is a plan view of an exemplary leaflet used in the prosthetic heart valves of the present invention;

[0038] Fig. 8 is a partial sectional view of a commissure region of the exemplary prosthetic heart valve taken along line 8-8 of Fig. 3B;

[0039] Fig. 9 is a sectional view through a portion of the support frame of the exemplary prosthetic heart valve, taken along line 9-9 of Fig. 8;

[0040] Fig. 10 is a sectional view through a commissure tip region of the exemplary prosthetic heart valve, taken along line 10-10 of Fig. 8;

[0041] Fig. 11 is a schematic perspective view of a prosthetic heart valve support frame of the present invention being loaded into a delivery catheter;

[0042] Fig. 12 is a perspective view of the support frame after having been loaded into a delivery catheter;

[0043] Figs. 13A-13B are perspective and elevational views of an exemplary compressible/expandable heart valve holder attached to a prosthetic heart valve of the present invention;

[0044] Fig. 14 is a perspective view of the expulsion of an assembled prosthetic heart valve and holder as in Figs. 13A and 13B from the distal end of a delivery catheter;

[0045] Fig. 15 is a bottom plan view of an exemplary compressible/expandable heart valve holder of the present invention;

[0046] Fig. 16 is a plan view of a multi-armed flexible portion of the holder of Fig. 15; and

[0047] Figs. 17A-17B are two views of a rigid portion of the holder of Fig. 15.

Description of the Preferred Embodiments

[0048] The present invention provides an improved minimally invasive (MIS) valve support frame, MIS valve, and methods of construction and delivery as described herein and shown in the accompanying drawings.

[0049] The invention pertains primarily to flexible leaflet heart valves and internal support frames, which are also referred to in the art as stents or wireforms. As mentioned above, the flexible leaflets can be formed from biological (e.g., bovine pericardium) or synthetic material. In this context, a "support frame" for a flexible leaflet heart valve provides the primary internal structural support for the leaflets, and substantially mimics the natural fibrous skeleton of the respective valve annulus. More specifically, each of the leaflets has an outer edge that is coupled to a portion of the support frame such that its inner edge is free to move within the orifice area of the valve, thus providing the opening and closing surfaces thereof. A biological xenograft valve can be used to provide the flexible leaflets in the valves of the present invention, though the internal support frame is particularly suited to receive individual leaflets.

[0050] The leaflet frames of the present invention have a continuous, undulating shape with three arcuate or U-shaped cusp regions on the inflow end separated by three upstanding and generally axially-oriented arcuate or U-shaped commissure regions on the outflow end. Around the circumference of the leaflet frame, the shape has an alternating structure of cusp-commissure-cusp-commissure-cusp-commissure, and generally describes a conical surface of revolution with the three commissures on the outflow end of the valve being closer together than the three cusps. Some support frames may alternatively describe a tubular surface of revolution about an axis. The cusp regions and

commissure regions are evenly distributed about a flow axis through the support frame, and therefore the three cusp regions are 120° apart from each other, and each of the three commissure regions is 120° apart from the next and 60° from the adjacent cusp regions.

[0051] The term "continuous" to describe the heart valve leaflet frame means that a single continuous and closed-shape line (i.e., loop) can be drawn following the sequential cusp and commissure regions, and "undulating" refers to the serpentine or alternating sinusoidal character of the line. More generally, a continuous, undulating heart valve leaflet frame approximates the shape of the natural fibrous tissue around the aortic valve annulus so as to mimic that natural support structure for optimum functionality of the prosthetic leaflets.

[0052] The present invention primarily pertains to prosthetic heart valves suitable for minimally invasive delivery and implantation. Such minimally invasive valves are capable of being compressed or collapsed into a small profile and delivered through a catheter or cannula (a tube) to the site of implantation for remote expansion and anchoring thereto. It should be understood, however, that certain aspects of the invention described herein are beneficial for prosthetic heart valves in general, and thus not all of the claims should be construed to require a minimally invasive valve.

[0053] Fig. 1 depicts a portion of a heart of a patient with the left ventricle LV, aortic valve AV, mitral valve MV, and ascending aorta AA shown in section. A delivery catheter or tube 20 is seen in position just prior to complete expulsion and expansion of a prosthetic heart valve 22 from a distal end thereof for implant at the aortic valve AV annulus. The aortic valve AV leaflets L may first be excised prior to implant of the valve 22, or more preferably the leaflets L remain in place and are expanded outward and compressed against the lumen of the aortic valve AV annulus upon expansion of the valve. The distal end of the delivery tube 20 may optionally be stabilized by a balloon 24 (shown in phantom) inflated against the lumen of the ascending

aorta AA, or through other means. The delivery tube 20 is preferably inserted in the vasculature of the patient using a larger diameter introducer 26 through a peripheral vessel such as the femoral artery or femoral vein. Alternatively, the peripheral vessel may be the internal jugular vein, the subclavian artery, the axillary artery, the abdominal aorta, the descending aorta, or any other suitable blood vessel. The introducer 26 may be inserted by surgical cut down or percutaneously using the Seldinger technique.

[0054] Figs. 2A and 2B illustrate the prosthetic heart valve 22 implanted at the aortic valve AV annulus. The heart valve 22 includes three cusps 30 on an inflow end (one of which is not visible) and three commissures 32 on an outflow end. The direction of blood flow BF is indicated with an arrow in the ascending aorta AA. The natural leaflets are desirably compressed against the lumen of the aortic valve annulus by the prosthetic heart valve 22, as seen in Fig. 2B. The valve 22 is oriented about a flow axis such that the commissures 32 are generally aligned with the native commissures C, while the cusps (not shown but intermediate the commissures 32) are generally aligned with the natural cusps/leaflets L. The heart valve 22 contacts the lumen wall of the aortic valve AV annulus and desirably retains its position due to friction therebetween. In this regard, the heart valve 22 expands from its delivery configuration shown in Fig. 1 to the expanded configuration in Figs. 2A and 2B.

[0055] The valve 32 contacts the lumen wall around the entire periphery of the inflow end thereof and in certain areas adjacent to the inflow periphery, as will be explained below. The inflow periphery is defined by the lower ends of the cusps 30 as well as by the lower ends of three cusps connectors 40 that extend between and fill the gaps between the cusps 30. Additionally, the heart valve 22 includes three cusp positioners 42, two of which are visible in Fig. 2A, that are rigidly fixed with respect to an internal valve support frame and are each located generally at the outflow end of the valve intermediate two of the commissures 32. With reference to Fig. 2B, the cusp positioners 42 are evenly

distributed about a central flow axis 44, and when implanted align with the native leaflets L. The cusp positioners 42 preferably extend radially farther outward than the commissures 32 and compress the leaflets L against the natural sinus cavities formed just above the aortic valve AV annulus. Coronary ostia CO open from two of the three sinus cavities, as seen in Fig. 2A, and the cusp positioners 42 are sized and placed by the operator to avoid occluding flow through the coronary ostia CO. The advantageous structure and function of these cusp positioners 42 will be more fully explained below.

[0056] With reference now to Figs. 3A-3C, the exemplary prosthetic heart valve 22 will be more fully described. The shape of an internal support frame 50 seen in Fig. 5 generally governs the shape of the valve 22. As mentioned, the valve 22 includes the aforementioned cusps 30 and commissures 32 evenly distributed about a flow axis 44. The cusps 30 and cusp connectors 40 define a scalloped inflow periphery of the valve 22, while the outflow periphery is defined by the three commissures 32 and the three cusp positioners 42. The entire internal support frame 50 except for the cusp positioners 42 is covered over with one or more layers of material, the exterior layer of which is typically a fabric as shown (but not numbered). The use of a fabric such as polyethylene terephthalate provides a matrix into which surrounding tissue can grow to help anchor the valve in place.

[0057] Three flexible leaflets 52 mount to the valve 22 in a trifoil configuration with free edges 53 thereof arranged to meet or coapt in the middle of the valve and provide one-way occlusion. An outer edge of each leaflet 52 attaches to the valve 22 between two of the commissures 32 and around one of the cusps 30. An exemplary structural attachment of the leaflets 52 to the internal support frame 50 will be described below.

[0058] As mentioned, each cusp connector 40 extends between two of the cusps 30. A panel of fabric or other material 54 covers an area between the inflow or lower edge of each cusp connector 40 and the corresponding

commissures 32. Some of this panel of fabric 54 desirably contacts the lumen wall of the aortic valve AV annulus to help prevent leakage around the valve.

[0059] The exemplary cusp positioners 42 each have an inverted U-shape with an apex pointed toward the outflow end of the valve 22 and two legs extending generally toward the inflow end and connecting with the remainder of the valve. The term "U-shape" is intended to cover all configurations that have two legs and an apex therebetween. Other figurative descriptions such as V-shaped, bell-shaped, sinusoidal, arcuate, or the like are therefore encompassed by the term "U-shape". It is contemplated, however, that the cusp positioners 42 could assume other forms, such as a generally linear, cantilevered arm extending upward from the midpoint of each cusp 30. In whatever form, the cusp positioners 42 provide the valve 22 with three points of contact with the surrounding tissue that is midway between the three commissures 32 so as to help stabilize and anchor the valve in its implant position. Moreover, the cusp positioners 42 desirably perform the function of compressing the native leaflets L outward against the sinus cavities, at least in those procedures where the leaflets L are not excised.

[0060] The leaflets L in a diseased valve may be less than flexible, and indeed may be highly calcified. It is often considered preferable to avoid removing the leaflets L so as to avoid disturbing the calcification or other stenotic material that has built up around the leaflets. Therefore, the present invention desirably provides structure to compress the native leaflets L outward against the aortic wall sinus cavities and hold the leaflets in that position so as to avoid flapping and potentially interfering with blood flow through the prosthetic valve. The inverted U-shape of the cusp positioners 42 is believed to provide effective structure to both anchor the valve in the aortic valve AV annulus and also control, or corral, if you will, the obsolete native leaflets L. At the same time, the cusp positioners 42 are relatively minimal in total area so as to avoid unduly interfering with back flow of blood on the outflow side of each of the

leaflets 52, or to the coronary ostia CO. Therefore, the cusp positioners 42 are desirably defined by relatively thin members, as shown, as opposed to walls or panels, or the like. Multiple cusp positioners 42 per valve cusp 30 are conceivable, though the total solid volume taken up by the cusp positioners should be kept to a minimum so as to minimize the risk of occluding the coronary ostia CO.

[0061] The axial height of the cusp positioners 42 relative to the commissures 32 is seen best in Fig. 2A (and in Fig. 6B). Preferably, the commissures 32 are slightly taller than the cusp positioners 42, although such an arrangement is not considered mandatory. The main consideration in the size of the cusp positioners 42 is to avoid occluding the coronary ostia CO. Therefore, as seen in Fig. 2A, the cusp positioners 42 contact the surrounding aortic valve AV lumen wall just below the coronary ostia CO. Of course, the anatomy of each patient differs slightly from the next, and the precise position of the coronary ostia CO cannot be predicted with absolute certainty. Furthermore, the final location of the cusp positioners 42 is dependent on the skill of the cardiac surgeon or cardiologist. In the ideal situation, however, the cusp positioners 42 are positioned just below and aligned circumferentially with the coronary ostia CO as seen in Figs. 2A and 2B.

[0062] Figs. 2B and 3B-3C illustrate the relative outward radial position of the cusp positioners 42 with respect to the commissures 32 therebetween, and with respect to the cusp connectors 40. As seen in the isolated view of the heart valve support frame 50 in Fig. 5, the cusp positioners 42 are angled or flared outward from the remainder of the support frame. This outward flaring helps ensure good contact between the apex of the cusp positioners 42 and the surrounding walls of the aortic valve AV sinus cavities. In this regard, the outer configuration of the heart valve 22 is designed to maximize contact with the aortic valve AV lumen wall both in the annulus and for a short distance into each sinus cavity. This extensive surface contact between the prosthetic valve

22 and the surrounding tissue may obviate the need for sutures, staples, sharp barbs or other such anchoring structure, although such structure could be used in conjunction with the valve. The valve 22 is merely expelled from the end of the delivery tube 20 (Fig. 1), expanded with or without assistance of a balloon, and held in place by frictional contact between the inflow periphery against the annulus, and between the cusp positioners 42 and the sinus cavities (or intervening native leaflets).

[0063] Each cusp positioner 42 further includes at least one anti-migration member 56 rigidly fixed thereto and designed to help anchor the support frame 50 to the surrounding tissue. In the illustrated embodiment, the anti-migration members 56 each preferably includes an elongated section 58 terminating in an enlarged and rounded head 60, the configuration thus somewhat resembling a spoon. The anti-migration member 56 desirably projects out of the plane defined by the associated cusp positioner 42, and may extend generally axially in the inflow direction from the apex thereof, as seen in Fig. 3A. When the valve 22 is implanted, the anti-migration members 56 are designed to contact and become somewhat entrapped in the native leaflets. Therefore, the anti-migration members 56 act as a rounded barb of sorts to maintain the valve 22 in its implant position. The members 56 also may help prevent flapping of the native leaflets in the swirling blood flow. Numerous other configurations are contemplated, the general idea being that the anti-migration member 56 enhances the ability of the associated cusp positioner 42 to anchor to the surrounding tissue. In this regard, the term "anti-migration member" is meant to include any structure that enhances such anchoring, including both blunt and sharp structures (i.e., barbs).

[0064] Various procedures and apparatuses for converting a two-dimensional blank such as shown in Fig. 4 to the three-dimensional form of Fig. 5 are described in more detail in co-pending U.S. Patent Application Serial No. 10/251,651, filed September 20, 2002, and entitled continuous heart valve

support frame and method of manufacture. In short, the process involves bending the two-dimensional blank 70 around a cylindrical or conical mandrel and altering the material so as to retain its three-dimensional shape. For example, various nickel-titanium alloys (Nitinol) may be easily bent around a mandrel and then set into that shape using heat treatments.

[0065] In an exemplary embodiment of the present invention, the internal support frame 50 of the valve 22 is made of a material that is highly flexible so as to permit maximum relative movement between the valve cusps and commissures, and in some cases to permit constriction into a small profile diameter for minimally invasive delivery to an implantation site. At the same time the support frame must possess a minimum amount of stiffness to provide the desired support to the leaflets. Therefore, there is a balance obtained between the requisite flexibility and stiffness.

[0066] The material for the internal support frame is desirably "elastic," which means that it has the capacity to rebound from imposed strain. Various NITINOL alloys are especially suitable for making the internal support frame of the present invention as in certain circumstances they are considered to be "superelastic." Other materials that may be used include ELGILOY, titanium, stainless-steel, even polymers, and similar expedients. These latter materials do not display superelasticity but are still elastic. Other materials may fit within this definition but they must be suitable for long-term implantation in the body.

[0067] The term "superelastic" (sometimes "pseudoelastic") refers to that property of some materials to undergo extreme strains (up to 8%) without reaching their failure stress limit. Some so-called shape memory alloys (SMAs) are known to display a superelastic phenomena or rubber-like behavior in which a strain attained beyond the elastic limit of the SMA material during loading is recovered during unloading. This superelastic phenomenon occurs when load is applied to an austenitic SMA article which first deforms elastically up to the yield point of the SMA material (sometimes referred to as the critical stress).

Upon the further imposition of load, the SMA material begins to transform into stress-induced martensite or "SIM." This transformation takes place at essentially constant stress, up to the point where the SMA material is completely transformed into martensite. When the stress is removed, the SMA material will revert back into austenite and the article will return to its original, pre-programmed programmed or memorized shape.

[0068] The support frame 50 is desirably constructed of a material that exhibits hysteresis in the elastic and/or superelastic region. "Hysteresis" indicates that when the material is strained beyond the "memory condition" (defined as unconstrained geometry) it produces a stress-strain curve that is different and higher than the stress-strain curve produced as the material attempts to return to its memory condition. An example of a material that exhibits such a hysteresis is NITINOL. The presence of this hysteresis implies that it requires a greater force to displace the material form its memory condition than the material exerts as it recovers to its memory condition.

[0069] When using NITINOL the shape set is done at a particular temperature for a period of time designed to ensure certain properties in the material. Namely, the martensitic transition temperature is desirably less than room temperature and the austenitic transition temperature is desirably less than body temperature. For instance, the temperature below which the material is in martensitic form is around 0-5° C, while the temperature above which the material is in austenitic form is around 20-25° C. When the material is shape set in this way, the heart valve 22 can be cooled, such as in an ice bath, just prior to implant to change the crystalline structure of the support frame 50 to martensite and create high flexibility so as to enable compaction thereof into a small diameter delivery profile. After implant and expansion, the temperature rises from body heat above the austenitic transition temperature and thus the support frame 50 possesses the desired degree of stiffness to properly support the leaflets.

[0070] The support frame 50 (and blank 70) includes a leaflet frame 72 defined by three cusp regions 74 intermediate three commissure regions 76. In Fig. 4 the leaflet frame 72 in the blank 70 exhibits a three-leaf clover shape, while in Fig. 5 the leaflet frame 72 has a continuous, undulating shape as described above. A second three-leaf clover shape can be seen in Fig. 4 formed by the three cusp connectors 40 and three cusp positioners 42. When bent into the three-dimensional configuration of Fig. 5, two continuous, undulating shapes can be seen oriented 60° with respect to one another about the central flow axis. Each cusp connector 40 includes an apex 80 and a pair of legs 82 that rigidly attach to the leaflet frame 72 at junction points 84. Likewise, each cusp positioner 42 includes an apex 90 and a pair of legs 92 that rigidly attach to the leaflet frame 72 at junction points 94. In the preferred and illustrated embodiment, the junction points 84 and 94 are coincident.

[0071] Figs. 5A and 5B show alternative cusp positioner configurations for the three-dimensional heart valve support frame 50 of Fig. 5. As mentioned above, the anti-migration members facilitate anchoring of the support frame 50 to the surrounding anatomy, and prevent axial and rotational movement of the valve 22. The anti-migration members 56 shown in Fig. 5 project generally axially in the inflow direction from the apex 90 of each cusp positioner 42. In Fig. 5A, a second anti-migration member 57 projects generally axially in the outflow direction from the apex 90 of each cusp positioner 42. In Fig. 5B, there are multiple anti-migration members 56 extending generally axially in the inflow direction. Various combinations, placements and orientations of these examples are contemplated, and the examples should not be considered limiting.

[0072] Fig. 6A shows the valve 22 almost completely assembled, but without the aforementioned cloth covers 54 that are seen in the fully assembled valve of Fig. 6B. The covers 54 help prevent leakage of blood around the implanted valve 22, and specifically in the areas between the each pair of cusps 30.

[0073] Fig. 7 illustrates an exemplary leaflet 52 in plan view. The free edge 50 is shown as linear, but may also be arcuate, angled, trapezoidal, or other configuration. Each leaflet includes a pair of opposed generally rectangular tabs 100 at either end of the free edge 53. An arcuate cusp edge 102 extends between the tabs 100 and opposite the free edge 53. The tabs 100 and arcuate cusp edge 102 are secured to the valve 22, and specifically along the contours of the leaflet frame 72 seen in Fig. 5.

[0074] Fig. 8 is an enlarged cutaway view of one of the commissures 32 of the valve 22 taken along line 8-8 of Fig. 3B and showing the internal construction thereof. The commissure region 76 of the leaflet frame 72 tapers down in the outflow direction to a closed tip 104. Attachment flanges 106 are formed adjacent the tip 104 and desirably include a plurality of assembly holes 108 sized to permit passage of sutures therethrough. The adjacent leaflets 52 come together in the commissure regions 76 and the tabs 100 thereof are folded away from each other on the exterior of the flanges 106.

[0075] As seen in Fig. 9, the cusp edge 102 of each leaflet 52 attaches with sutures 110 to a cloth flange 112 of a tubular fabric cover 114 around the leaflet frame 72. This configuration causes tensile forces imparted by the leaflets 52 to be transferred as much as possible to the frame 72 rather than being primarily borne by the attachment sutures 110.

[0076] Fig. 10 shows the attachment structure at the commissure tip 104, and specifically illustrates sutures 120 passing through the fabric cover 114, through the assembly holes 108, and through the folded leaflet tabs 100. A second suture 122 passes through the cloth flange 112, the leaflet tab 100, and cloth covers 54 (also shown in Fig. 6B). Because each of the leaflets 52 includes the tab 100 that extends to the outside of the leaflet frame 72, high forces that are seen with closing of the valve are less likely to pull the sutures 120 through the tabs. That is, the construction shown in Fig. 10 causes tensile

forces imparted by the leaflets 52 to be transferred as much as possible from the sutures 120, 122 to the frame 72, thus helping to prevent tearing of the flexible leaflets and rendering the valve 22 more durable.

[0077] Figs. 11 and 12 schematically illustrate a technique for loading a prosthetic heart valve of the present invention into a delivery tube. For the sake of clarity, only the support frame 50 is shown being loaded into the delivery tube 20. A plurality of sutures or other such flexible members or filaments 130 are shown looped through each of the commissure regions 76 of the support frame 50. These filaments 130 extend into the distal end of the delivery tube 20 and through its lumen to a proximal end (not shown) where they are connected to a tensioning device. In actual use, the filaments 130 would be threaded through the commissures 32 of the valve 22, avoiding the flexible leaflets. A loading adapter 132 couples to the distal end of the delivery tube 20. The adapter 132 includes an inner funnel-shaped opening 134. Tension on the filaments 130 pulls the commissures 32 of the valve into the funnel-shaped opening 134 which gradually compresses the valve into a diameter smaller than the lumen of the delivery tube 20. Once the valve 22 is positioned fully within the delivery tube 20, as seen in Fig. 12, the filaments 130 and adapter 132 are removed.

[0078] Figs. 13-17 illustrate a minimally invasive holder for use with the prosthetic heart valves of the present invention. Figs. 13A and 13B show the holder 150 attach to the heart valve 22 as described above. The holder 150 includes a multi-armed flexible portion 152 and a rigid portion 154 (seen in Figs. 17A-17B). The flexible portion 152 includes a plurality, at least three, but preferably six flexible members or arms 156 extending outward from a central circular disk 158. Each of the arms 156 terminates in a rounded end having an attachment aperture 160. The arms 156 are distributed evenly about the

circumference of the circular disk 158, and are arrayed to attach to each of the commissures 32 and cusp positioners 42 of the valve 22. Releasable sutures 162 or other such attachment structure are used for this purpose.

[0079] Fig. 14 shows the assembled holder 150 and valve 22 emerging from the distal end of a delivery tube 20. Prior to this stage, the flexible members or arms 156 are oriented generally axially within the tube 20 with the valve 22 also collapsed and having its outflow prongs coupled to the distal ends of the arms 156. The arms 156 of the holder 150 are sufficiently flexible to be compressed into the small profile required for delivery through the delivery tube 20. In this regard, the flexible portion 152 is desirably made of Nitinol. A handle 170 which may be flexible or rigid attaches to the holder 150 for manipulation thereof. Displacing the handle 170 in a distal direction with respect to the tube 20 therefore expels the valve/holder combination and the resiliency of the valve 22 and holder arms 156 causes them to spring outward. It should be understood that other designs of the holder 150 may be utilized, such as replacing the spring-like arms 156 with rigid members that are hinged and spring-biased.

[0080] Figs. 15-17 illustrate specifics of the exemplary flexible portion 152 and rigid portion 154. In a relaxed configuration, the flexible portion 152 is planar, and may be cut from a sheet of Nitinol. The rigid portion 154 includes a proximal face 180 that is sized approximately the same as the circular disk 158, and small enough to fit within the delivery tube 20. A central threaded bore 182 opens to the proximal face 180 for receiving the handle 170. Fig. 15 illustrates a number of sutures 162 threaded through the holder 150 and used to couple the holder to the six outflow prongs of the prosthetic heart valve 22. Desirably, these sutures 162 are anchored with respect to the holder and each one passes over a cutting guide in the holder such that the suture may be severed along its midpoint resulting in two free ends that can be pulled free of the valve.

[0081] The holder 150 is sufficiently flexible to be compressed into a

small profile and passed through the delivery tube 20. At the same time, the flexible portion 152 and multiple flexible arms 156 have a sufficient degree of torsional strength to permit the operator to rotate the valve 22 during the implant procedure. Furthermore, the arms 156 are shaped to contact the distal mouth of the delivery tube 20 when the assembly is pulled toward the tube which, due to their radial stiffness, causes the arms to bend back toward their axial orientation within the tube. Since the distal ends of the arms are coupled to at least three of the outflow prongs of the prosthetic heart valve 22, the valve constricts accordingly. Constriction of the valve 22 after having been fully expelled from the end of the delivery tube and expanded permits repositioning of the valve 22. That is, the cusp positioners 42 are designed to contact the sinuses cavities or aortic wall after the valve 22 expands, and the retraction/constriction option afforded by the holder 150 may be necessary to disengage the cusp positioners from the surrounding tissue to reposition or re-orient the valve. Furthermore, the valve 22 can be completely collapsed and retracted back into the delivery tube to permit removal in case the surgeon or cardiologist deems the valve unsuitable for whatever reason.

Method of Use

[0082] Prior to implant, the cardiac surgeon or cardiologist measures the aortic valve AV annulus using appropriate sizers, minimally invasive or not as the case may be, a number of which are available and which will not be further described herein. The correctly sized valve is then selected and compressed into the delivery catheter or tube 20, such as with the use of the loading adapter 132 having the inner funnel-shaped opening 134 as seen in Fig. 11. To facilitate this loading step, the inner support frame 50 of the valve 20 must be able to withstand high stresses without failure. One method is to form the support frame 50 from a material that has superelastic properties, for instance a Nitinol that has a martensitic transition temperature of less than about 5° C can be immersed in an ice bath to change its crystalline structure to

martensite, which is a superelastic phase. Once loaded into the delivery tube 20, the support frame 50 will not revert back to its original shape upon a temperature rise and thus does not exert undue outward force on the tube. The heart valve 22 may be loaded around an inflation balloon, but for the sake of a small profile the balloon is used after expulsion of the valve from the tube at the implantation site.

[0083] With reference again to Fig. 1, the delivery tube 20 is seen in position just prior to complete expulsion and expansion of the prosthetic heart valve 22 from a distal end thereof for implant at the aortic valve AV annulus. The distal end of the delivery tube 20 may optionally be stabilized by a balloon 24 (shown in phantom) inflated against the lumen of the ascending aorta AA, or through other means. The delivery tube 20 is preferably inserted in the vasculature of the patient using a larger diameter introducer 26 through a peripheral vessel such as the femoral artery or femoral vein. Alternatively, the peripheral vessel may be the internal jugular vein, the subclavian artery, the axillary artery, the abdominal aorta, the descending aorta, or any other suitable blood vessel. The introducer 26 may be inserted by surgical cut down or percutaneously using the Seldinger technique.

[0084] The prosthetic heart valve 22 is expelled from the delivery tube 20 by relative movement therebetween - i.e., by pushing the valve from the tube or by retracting the tube from around the valve. The valve 22 desirably self-expands into contact with the surrounding lumen wall, but may also be assisted with an inflation balloon or other such physical expander.

[0085] With reference to Figs. 2A and 2B, the cusps positioners 42 help guide the prosthetic heart valve 22 into position in the aortic valve AV annulus. As mentioned above, the cusp positioners 42 desirably flare outward from the rest of the valve structure and are thus configured to contact the sinuses of the aortic valve AV while the cusps 30 are sized to fit within the annulus. In accordance with one method of implantation, the surgeon or cardiologist expels the heart valve 22 below (i.e., toward the left ventricle) its optimum implant position, and then axially displaces the valve upward into the desired position.

Stated another way, the heart valve 22 is expanded in a location that is inferior to a final implant position such that the cusp positioners 42 contact the surrounding aortic annulus, and the valve is then repositioned by displacing the valve in a superior direction to a final implant position. As the valve 22 ascends, the cusp positioners 42 spring outward into the three valve sinuses and help rotationally orient the valve. That is, the sinuses channel the cusp positioners 42 and correct any rotational misalignment. Finally, the valve 22 is implanted with the cusp positioners 42 in the sinus cavities (preferably below the coronary ostia CO) and the cusps 30 and cusp connectors 40 forming a scalloped yet continuous contact wall against the aortic valve AV annulus or root.

[0086] As mentioned, a physical expander (e.g., balloon) may be used to radially outwardly expand the valve 22 (including the internal support frame 50) beyond its self-expanded diameter so that it is firmly anchored in place. A prosthetic valve possessing hysteresis that is held in a reduced (first or constrained) diameter will exert an outward radial force that is less than the force at which it will resist an inward radial force. Therefore, if deployed in-situ, the device is not expected to exert enough force on the vessel wall to expand to the desired diameter. However, if the expansion is assisted by means of a balloon or other physical expander, the hysteresis of the material will allow it to better maintain its diameter once that diameter is achieved. This is unlike a self-expanding device that relies solely on the outward radial force of the device to achieve its desired diameter. It is also unlike balloon expanded devices that rely on a balloon to plastically deform the device into the desired diameter. Although it is conceivable that a balloon or other physical expander could be used in a self-expanding device made of a material that does not display a hysteresis, the benefits would not be as great.

[0087] It will be appreciated that the invention has been described hereabove with reference to certain examples or preferred embodiments as shown in the drawings. Various additions, deletions, changes and alterations may be made to the above-described embodiments and examples, and it is intended that all such additions, deletions, changes and alterations be included within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A prosthetic heart valve support frame, comprising:

a continuous, undulating valve leaflet frame that mimics the natural fibrous structure of an aortic valve, the leaflet frame having three cusp regions alternating with and intermediate three commissure regions, the three cusp regions being positioned at an inflow end of the support frame and circumferentially about a flow axis defined within the support frame, the three commissure regions being positioned at an outflow end of the support frame and circumferentially about the flow axis; and

three cusp positioners rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the support frame and intermediate two of the commissure regions of the leaflet frame.

2. The heart valve support frame of claim 1, wherein the leaflet frame and the cusp positioners are formed integrally as a single piece.

3. The heart valve support frame of claim 2, wherein the support frame is formed by a process comprising:

providing a two-dimensional blank of the support frame; and

forming the two-dimensional blank into the three-dimensional heart valve support frame.

4. The heart valve support frame of claim 1, wherein the leaflet frame and the cusp positioners are made of Nitinol.

5. The heart valve support frame of claim 1, wherein the Nitinol has a martensitic transition temperature of less than about 5° C and an austenitic transition temperature of more than about 20° C.

6. The heart valve support frame of claim 1, wherein each cusp positioner has a U-shape with an apex of the U-shape pointing toward the outflow end of the support frame and two legs of the U-shape pointing toward the inflow end.

7. The heart valve support frame of claim 6, wherein each of the two legs of each U-shaped cusp positioner is rigidly fixed to the continuous leaflet frame at a location approximately midway between a cusp region and a commissure region thereof.

8. The heart valve support frame of claim 6, further including an anti-migration member rigidly fixed to each cusp positioner and projecting therefrom.

9. The heart valve support frame of claim 8, wherein each anti-migration member comprises an elongated section terminating in an enlarged and rounded head.

10. The heart valve support frame of claim 1, wherein the support frame further includes three cusp connectors rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp connector being located at the inflow end of the support frame and intermediate two of the cusp regions of the leaflet frame.

11. The heart valve support frame of claim 10, wherein each cusp connector has a U-shape with an apex of the U-shape pointing toward the inflow end of the support frame and two legs of the U-shape pointing toward the outflow end.

12. The heart valve support frame of claim 10, wherein the leaflet frame, cusp positioners, and cusp connectors are formed integrally as a single piece, and wherein the three cusp positioners and three cusp connectors define a continuous, undulating shape that generally mimics the shape of the leaflet frame but is rotated 60° about the flow axis therefrom.

13. The heart valve support frame of claim 1, wherein the cusp positioners flare outwardly from the rest of the support frame.

14. A collapsible prosthetic heart valve, comprising:

a collapsible leaflet frame having three cusp regions intermediate three commissure regions, the three cusp regions being positioned at an inflow end of the leaflet frame and circumferentially about a flow axis defined within the support frame, the three commissure regions being positioned at an outflow end of the leaflet frame and circumferentially about the flow axis;

three separate, flexible leaflets attached to the leaflet frame, each leaflet having an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween, the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions; and

three cusp positioners rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the leaflet frame and intermediate two of the commissure regions of the leaflet frame.

15. The heart valve of claim 14, wherein each cusp positioner has a U-shape with an apex of the U-shape pointing toward the outflow end of the leaflet frame and two legs of the U-shape pointing toward the inflow end.

16. The heart valve of claim 15, wherein each of the two legs of each U-shaped cusp positioner is rigidly fixed to the continuous leaflet frame at a location approximately midway between a cusp region and a commissure region thereof.

17. The heart valve of claim 15, further including an anti-migration member rigidly fixed to each cusp positioner and projecting therefrom.

18. The heart valve of claim 14, wherein the heart valve further includes three cusp connectors rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp connector being located at the inflow end of the leaflet frame and intermediate two of the cusp regions of the leaflet frame.

19. The heart valve of claim 18, wherein each cusp connector has a U-shape with an apex of the U-shape pointing toward the inflow end of the leaflet frame and two legs of the U-shape pointing toward the outflow end.

20. The heart valve of claim 19, wherein the leaflet frame, cusp positioners, and cusp connectors are formed integrally as a single piece, and

wherein the three cusp positioners and three cusp connectors define a continuous, undulating shape that generally mimics the shape of the leaflet frame but is rotated 60° about the flow axis therefrom.

21. The heart valve of claim 18, wherein an inflow periphery of the heart valve is defined along the alternating and rigidly fixed cusp regions and cusp connectors.

22. The heart valve of claim 21, wherein the inflow periphery has an external fabric covering, and wherein the heart valve further includes a fabric panel defining an exterior surface of the heart valve between each pair of cusp positioner and cusp connector.

23. The heart valve of claim 14, wherein the leaflet frame has a fabric covering along substantially its entire length, the fabric covering defining a flange, wherein the arcuate cusp edges of the flexible leaflets attach to the fabric covering flange.

24. The heart valve of claim 23, wherein the fabric covering flange projects generally outward from the leaflet frame and the cusp edges of the flexible leaflets extend radially outward past and underneath the leaflet frame and are sewn to the fabric covering flange.

25. The heart valve of claim 14, wherein each flexible leaflet has a pair of tabs extending on either side of its free edge, wherein two tabs of adjacent flexible leaflets meet and pass together to the outside of the adjacent commissure region of the leaflet frame and are attached thereto using sutures through the tabs.

26. A collapsible prosthetic heart valve, comprising:

a continuous, collapsible leaflet frame having three U-shaped cusp regions intermediate three U-shaped commissure regions, the three cusp regions being positioned at an inflow end of the leaflet frame and circumferentially about a flow axis defined within the leaflet frame, the three commissure regions being positioned at an outflow end of the leaflet frame and circumferentially about the flow axis;

a cloth covering extending around the leaflet frame; and

three separate, flexible leaflets attached to the leaflet frame, each leaflet having an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween, the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions, the commissure edges of each leaflet further including a tab, wherein the tabs of two adjacent leaflets extend through the U-shape commissure region, diverge on the outside of commissure region, and are attached to the leaflet frame on the outside of the commissure region.

27. The prosthetic heart valve of claim 26, further comprising three cusp positioners rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the support frame and intermediate two of the commissure regions of the leaflet frame, each cusp positioner having a U-shape with an apex of the U-shape pointing toward the outflow end of the leaflet frame and two legs of the U-shape pointing toward the inflow end.

28. The heart valve of claim 26, wherein the heart valve further includes three cusp connectors rigidly fixed with respect to the leaflet frame and

disposed circumferentially about the flow axis, each cusp connector being located at the inflow end of the leaflet frame and intermediate two of the cusp regions of the leaflet frame.

29. The heart valve of claim 28, wherein an inflow periphery of the heart valve is defined along the alternating and rigidly fixed cusp regions and cusp connectors.

30. The heart valve of claim 26, wherein the leaflet frame has a fabric covering along substantially its entire length, the fabric covering defining a flange, wherein the arcuate cusp edges of the flexible leaflets attach to the fabric covering flange.

31. The heart valve of claim 30, wherein the fabric covering flange projects generally outward from the leaflet frame and the cusp edges of the flexible leaflets extend radially outward past and underneath the leaflet frame and are sewn to the fabric covering flange.

32. A method of implanting a prosthetic aortic heart valve, comprising:

providing a collapsible prosthetic heart valve having a collapsible leaflet frame defined by three cusp regions on an inflow end of the valve intermediate three commissure regions on an outflow end of the valve, the valve further including three cusp positioners on the outflow end and intermediate the three commissure regions;

collapsing the prosthetic heart valve within a delivery tube;

advancing the prosthetic heart valve within the delivery tube to an aortic annulus;

expelling the prosthetic heart valve from the delivery tube by relative movement therebetween;

expanding the prosthetic heart valve; and

positioning the prosthetic heart valve such that the cusp positioners contact the two coronary and one non-coronary sinuses of the ascending aorta without blocking the coronary ostia.

33. The method of claim 32, further including:

connecting a holder having flexible members to the commissure regions of the prosthetic heart valve and utilizing the flexible members to perform the step of positioning the prosthetic heart valve.

34. The method of claim 33, further including:

connecting flexible members of the holder to the cusp positioners and utilizing the flexible members to perform the step of positioning the prosthetic heart valve.

35. The method of claim 33, further including utilizing the flexible members to rotate the prosthetic heart valve during the step of positioning.

36. The method of claim 33, further including utilizing the flexible members to re-collapse the prosthetic heart valve after the step of expanding.

37. The method of claim 32, wherein the prosthetic heart valve is expanded in a location that is inferior to a final implant position such that the cusp positioners contact the surrounding aortic annulus, and the step of positioning comprises displacing the valve in a superior direction to a final implant position.

38. The method of claim 37, wherein the cusp positioners are flared outward to define a circle about a flow axis of the valve greater than a circle about the flow axis defined by the three commissure regions, and wherein the step of displacing the valve in a superior direction causes the outwardly flared cusp positioners to be channeled into perspective coronary sinuses.

39. The method of claim 32, wherein the collapsible leaflet frame is formed of a shape memory alloy having an austenitic transition temperature less than body temperature, and wherein the step of collapsing is done with the material of the leaflet frame at a temperature at or below its martensitic transition temperature.

40. The method of claim 39, wherein the step of collapsing is done in conjunction with immersing the prosthetic heart valve in an ice bath to reduce the temperature of the material of leaflet frame to less than or equal to its martensitic transition temperature.

41. The method of claim 32, wherein the collapsible leaflet frame is formed of a shape memory alloy having a memory condition in its expanded state, and wherein the step of expanding the prosthetic heart valve comprises both permitting self-expansion of the valve to an intermediate diameter and then using a physical expander to increase the diameter of the valve to the memory condition of the leaflet frame.

42. A method of implanting a collapsible prosthetic heart valve, comprising:

providing a self-expanding valve comprised of a material displaying hysteresis in the elastic or superelastic region;

permitting the valve to self-expand to a first diameter; and

assisting the valve with a physical expander to further expand to a second diameter.

43. The method of claim 42, wherein the prosthetic heart valve includes a collapsible leaflet frame formed of a shape memory alloy having an austenitic transition temperature less than body temperature, and further including a step of collapsing the valve with the material of the leaflet frame at a temperature at or below its martensitic transition temperature.

44. The method of claim 43, wherein the step of collapsing is done in conjunction with immersing the prosthetic heart valve in an ice bath to reduce the temperature of the material of leaflet frame to less than or equal to its martensitic transition temperature.

45. The method of claim 42, wherein the physical expander is a balloon.

46. The method of claim 42, wherein the prosthetic heart valve has a collapsible leaflet frame defined by three cusp regions on an inflow end of the valve intermediate three commissure regions on an outflow end of the valve, the valve further including three cusp positioners on the outflow end and intermediate the three commissure regions, the method further including:

collapsing the prosthetic heart valve within a delivery tube;

advancing the prosthetic heart valve within the delivery tube to an aortic annulus;

expelling the prosthetic heart valve from the delivery tube by relative movement therebetween;

expanding the prosthetic heart valve by the steps of permitting self-expansion and assisting further expansion; and

positioning the prosthetic heart valve such that the cusp positioners contact the two coronary and one non-coronary sinuses of the ascending aorta without blocking the coronary ostia.

47. The method of claim 46, further including:

connecting a holder having flexible members to the commissure regions of the prosthetic heart valve and utilizing the flexible members to perform the step of positioning the prosthetic heart valve.

48. The method of claim 47, further including:

connecting flexible members of the holder to the cusp positioners and utilizing the flexible members to perform the step of positioning the prosthetic heart valve.

49. The method of claim 47, further including utilizing the flexible members to rotate the prosthetic heart valve during the step of positioning.

50. The method of claim 47, further including utilizing the flexible members to re-collapse the prosthetic heart valve after the step of expanding.

Fig. 1

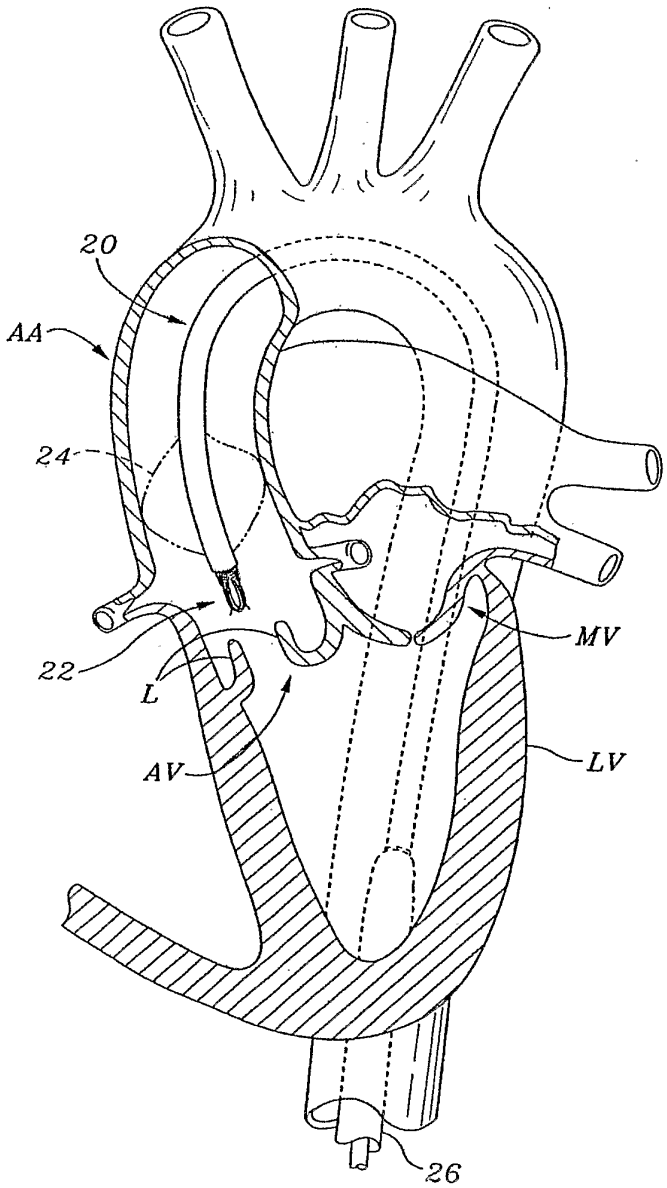


Fig. 2B

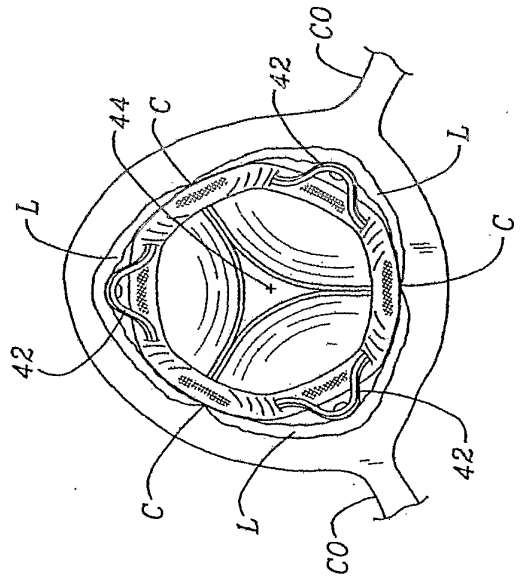


Fig. 2A

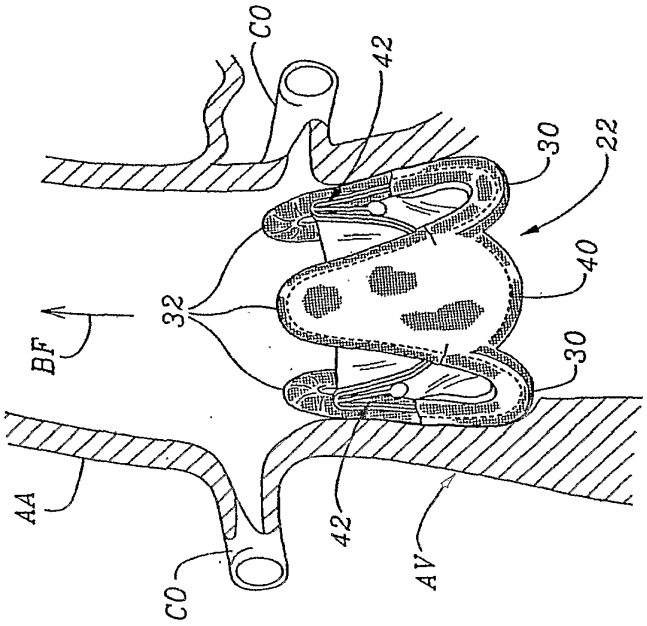


Fig. 3A

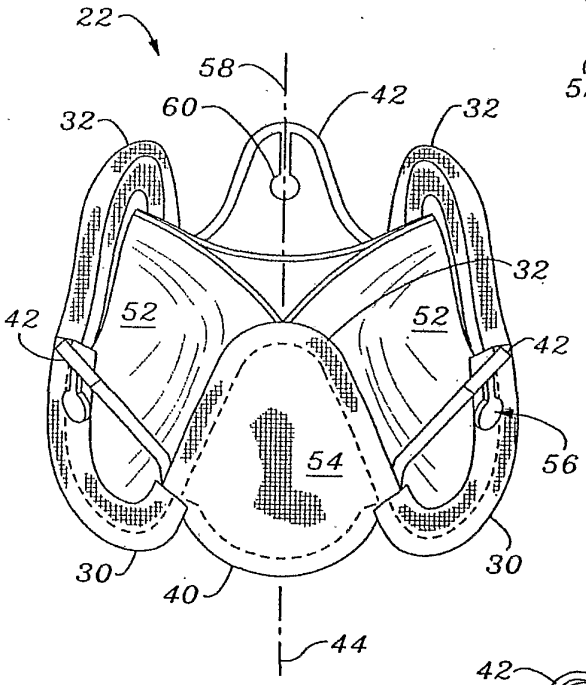


Fig. 3B

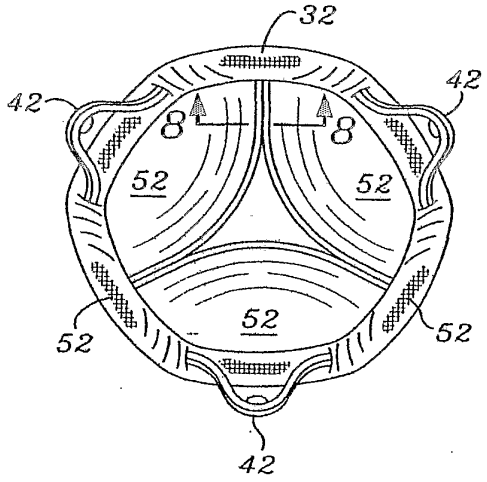


Fig. 3C

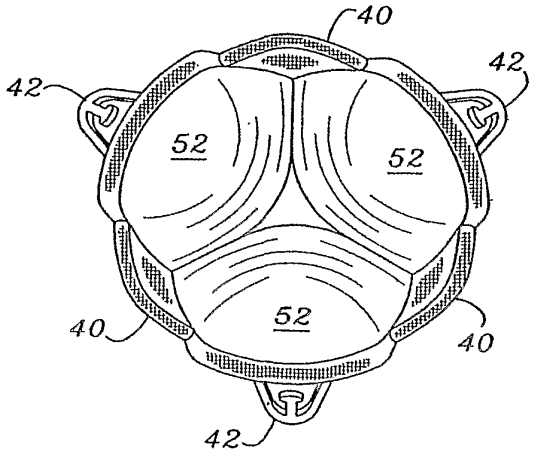


Fig. 4

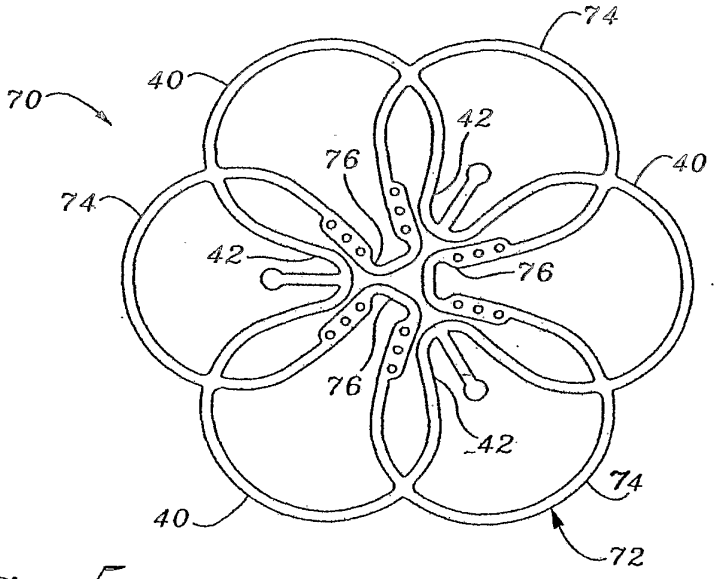
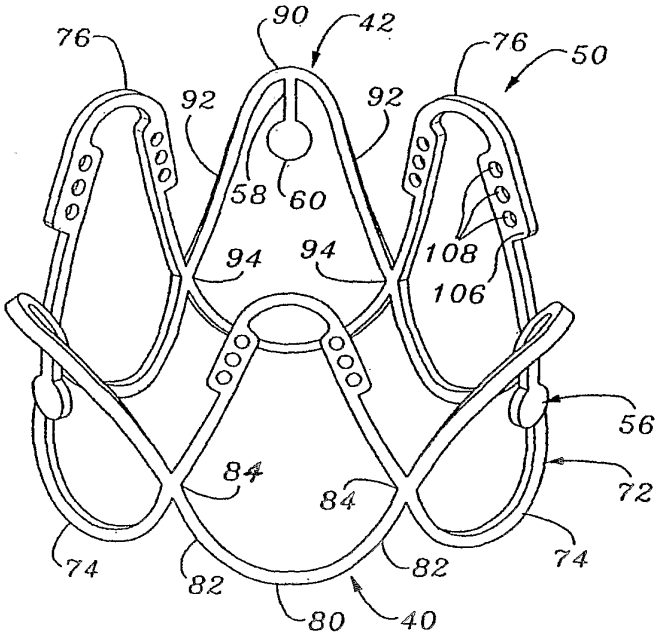


Fig. 5



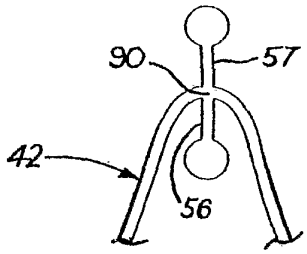


Fig. 5A

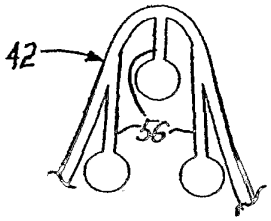


Fig. 5B

Fig. 6A

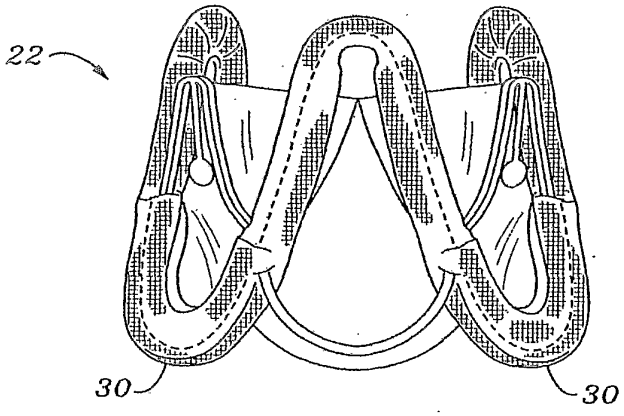


Fig. 6B

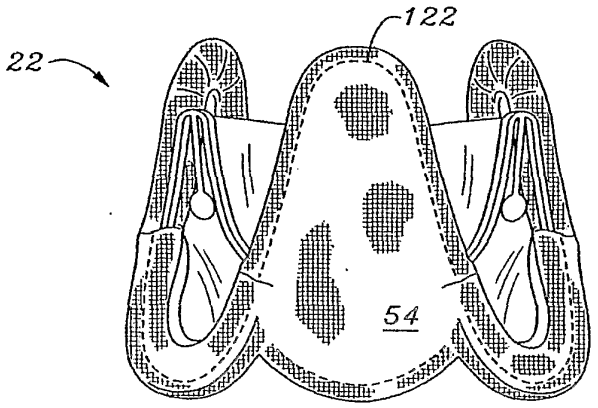


Fig. 7

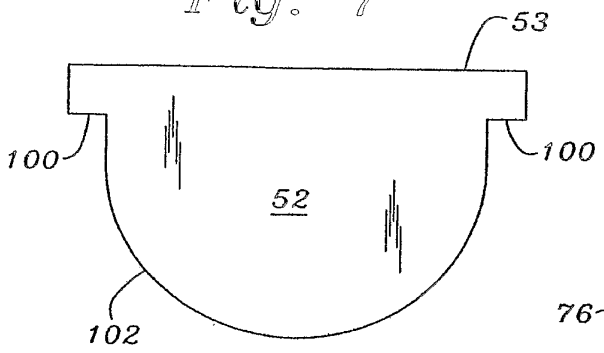


Fig. 8

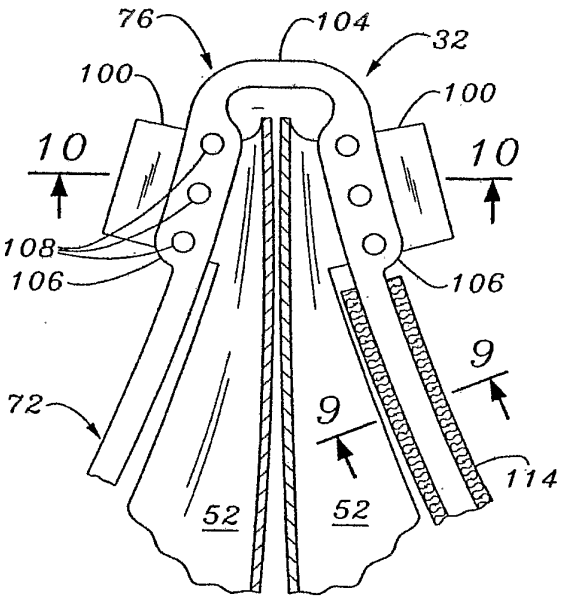


Fig. 9

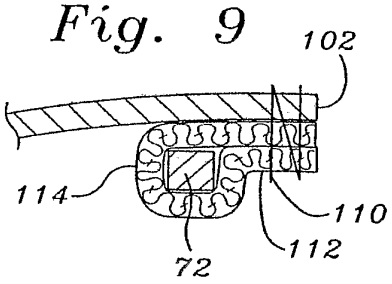


Fig. 10

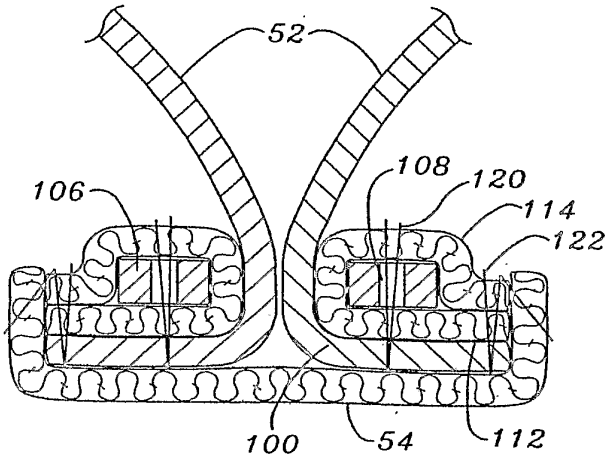


Fig. 11

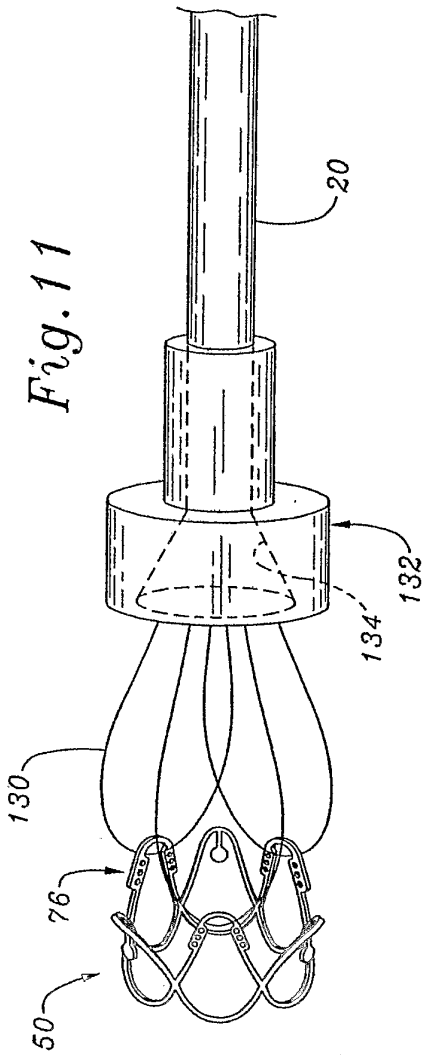


Fig. 12

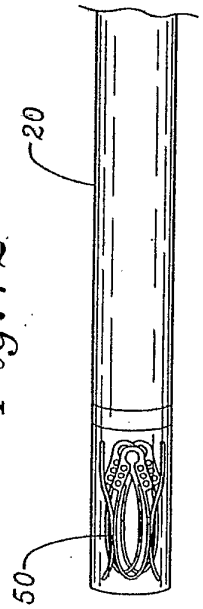


Fig. 13B

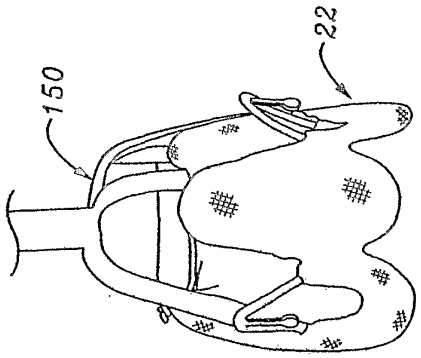


Fig. 14

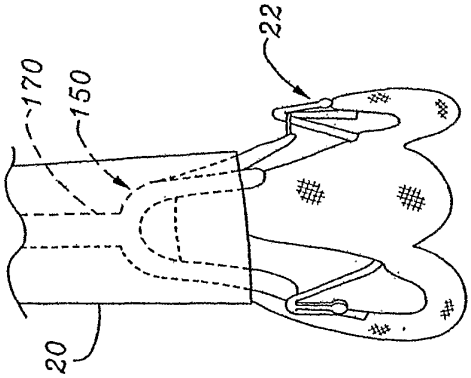


Fig. 13A

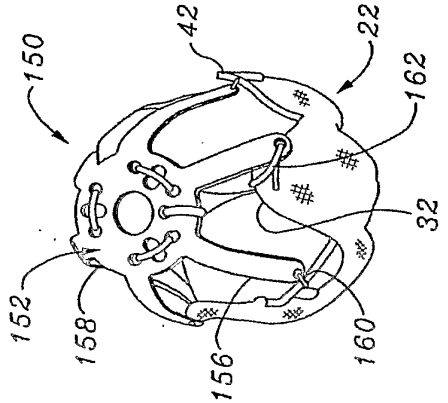


Fig. 16

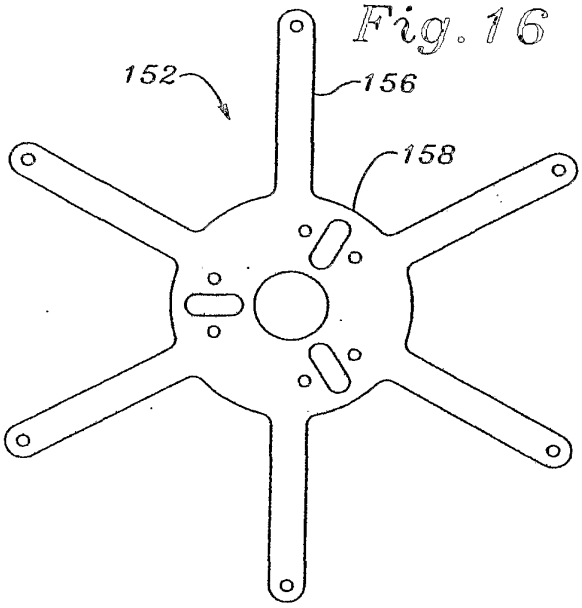


Fig. 17A

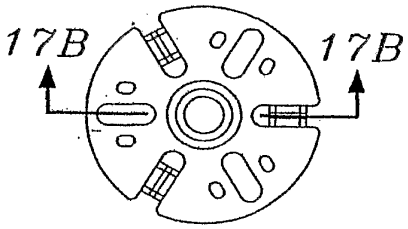


Fig. 17B

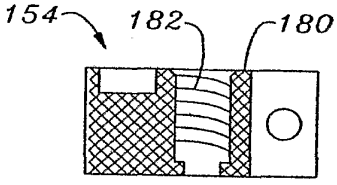
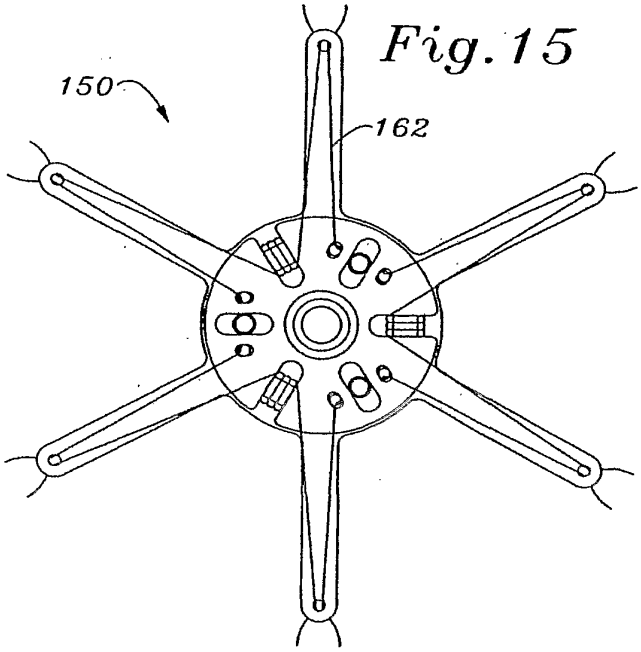


Fig. 15



Electronic Acknowledgement Receipt

EFS ID:	19117331
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	23-MAY-2014
Filing Date:	13-NOV-2012
Time Stamp:	15:21:58
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

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1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_Supp_IDS.pdf	555811 4893405e02b32cabcd0822b16649846863dc6c0c	no	7

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2	Foreign Reference	WO-2004-082527.pdf	2197853 f4d0d8ee205f8293529b296c1314228fb54751a7	no	49
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(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

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	2	20030027332		2003-02-06	Lafrance et al.	
	3	20070061008		2007-03-15	Salahieh et al.	
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	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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	1	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐
	2	Office Action issued June 9, 2014, in U.S. Application No. 14/253,650 (109978.10104)	☐
	3	Office Action issued July 8, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-08-29
Name/Print	Mark L. Yaskanin	Registration Number	45246

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EFS ID:	20002661
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	29-AUG-2014
Filing Date:	13-NOV-2012
Time Stamp:	11:15:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_Supp_IDS_2014-08-29.PDF	636455 695c0e0eda75c335307eea3b57112c831ad4dd3f	no	4

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2	Non Patent Literature	Hilbert_Biomechanics.PDF	411710 b4851a8736a6654787e31c40da105c179fcf1302	no	4
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6676698		2004-01-13	McGuckin, Jr.	
	2	6733525		2004-05-11	Yang et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action issued September 11, 2014, in U.S. Application No. 14/268,190 (File: 109978.10115)	☐
	2	Office Action issued September 3, 2014, in U.S. Application No. 14/284,049 (File: 109978.10116)	☐
	3	Office Action issued September 12, 2014, in U.S. Application No. 14/268,184 (File: 109978.10114)	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-09-17
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	20168703
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	17-SEP-2014
Filing Date:	13-NOV-2012
Time Stamp:	17:13:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_Supp_IDS_2014-09-17.PDF	656908 70904b1db64e65b714152b4ef6eb6413e6148a39	no	4
Warnings:					
Information:					

2	Non Patent Literature	10114_US_14-264184_Office_Action_2014-09-12.PDF	459730 b11ce91ce36a866c33d03b2a7d3360d4ff025cfc	no	12
Warnings:					
Information:					
3	Non Patent Literature	10115_US_14-268190_Office_Action_2014-09-11.PDF	789645 6113f5cb5892a4df0d3c7c1a6375cda9a03c1a5d	no	19
Warnings:					
Information:					
4	Non Patent Literature	10116_US_14-284049_Office_Action_2014-09-03.PDF	416178 b343786491136eddbbad5222e392024a2a80ebde	no	11
Warnings:					
Information:					
		Total Files Size (in bytes):	2322461		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6530952		2003-03-11	Vesely	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

	1	Final Office Action issued September 25, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-09-26
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Acknowledgement Receipt

EFS ID:	20253380
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	26-SEP-2014
Filing Date:	13-NOV-2012
Time Stamp:	11:46:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_Supp_IDS_2014-09-26.PDF	655948 454f135446ce10b03d9b616520175a5739c25bfc	no	4

Warnings:	
Information:	

2	Non Patent Literature	10113_US_14-253656_Final_Office_Action_2014-09-25.PDF	538987 cb00303b193a23cd9bb73177ceeba6167d2b91a4	no	14
Warnings:					
Information:					
			Total Files Size (in bytes):	1194935	

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New Applications Under 35 U.S.C. 111
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5484444		1996-01-16	Braunschweiler et al.	
	2	5645559		1997-07-08	Hachtman et al.	
	3	5683451		1997-11-04	Lenker et al.	
	4	5876448		1999-03-02	Thompson et al.	
	5	6350278		2002-02-26	Lenker et al.	
	6	6682537		2004-01-27	Ouriel et al.	
	7	6896690		2005-05-24	Lambrecht et al.	
	8	7556646		2009-07-07	Yang et al.	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
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U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Notice of Allowance issued October 7, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Application Number	13675665
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	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-10-07
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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Electronic Acknowledgement Receipt

EFS ID:	20354976
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	07-OCT-2014
Filing Date:	13-NOV-2012
Time Stamp:	18:16:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	10113_US_14-253656_Notice_of_Allowance_2014-10-07.PDF	240537 a0f5ed8b9f3c8355dca4c8e4728a4283e7b525c3	no	6

Warnings:	
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2	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_Supp_IDS_2014-10-07.PDF	638497 1ac643590fbccc5cad59236bf1f2ede02c4edfa7	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	879034	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

	1	Final Office Action issued November 7, 2014, in U.S. Application No. 14/253,650 (File: 109978.10104)	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-11-14
Name/Print	Mark L. Yaskanin	Registration Number	45246

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Electronic Acknowledgement Receipt

EFS ID:	20702019
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	14-NOV-2014
Filing Date:	13-NOV-2012
Time Stamp:	15:11:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_SUPP_IDS.PDF	658994 8b7aed36a6cae4629fe6953afb19a303024cbc4c	no	4

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Information:	

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2	Non Patent Literature	10104_US_14-253650_Final_OA_2014-11-07.PDF	574779 000a68c112ec41bd8dc3f1f478f9cd121ce592d3	no	14

Warnings:

Information:

Total Files Size (in bytes):	1233773

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New Applications Under 35 U.S.C. 111
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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

	1	Cross-reference is made to U.S. Application No. 14/502,453 filed on September 30, 2014, and its associated Preliminary Amendment (109978.10106)	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	3738
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	Attorney Docket Number	109978.10101

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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-11-20
Name/Print	Mark L. Yaskanin	Registration Number	45246

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Electronic Acknowledgement Receipt

EFS ID:	20752745
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
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Attorney Docket Number:	109978.10101
Receipt Date:	20-NOV-2014
Filing Date:	13-NOV-2012
Time Stamp:	13:28:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_SUPP_IDS_2014-11-20.PDF	680683 b5069a20d3aa2397a3b21fb103f034bbc5020d59	no	4

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2	Non Patent Literature	10106_US_14-502453_Preliminary_Amendment.PDF	138042 d392693ca35db7c7c7b2f546ead31db8e20a94d8	no	10
Warnings:					
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3	Non Patent Literature	10106_US_14-502453_2nd_Prelim_Amendment_2014-11-19.PDF	119965 2a3ff524e287df719fa75fdd883fb94f44d0285f	no	5
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PTO/SB/08a (01-10)
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(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

U.S.PATENTS Remove

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

	1	Office Action issued December 5, 2014 in U.S. Application No. 14/502,453 (109978.10106)	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-01-13
Name/Print	Mark L. Yaskanin	Registration Number	45246

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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EFS ID:	21193525
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	13-JAN-2015
Filing Date:	13-NOV-2012
Time Stamp:	12:46:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_SUPP_IDS_2015-01-13.PDF	719179 ea80c35f84bd650571756df189ca63923f16f3de	no	4

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2	Other Reference-Patent/App/Search documents	10106_Office_Action_2014-12-05.PDF	351762 6e1db64863fa3fa5dd0c8373907e9b3d1a0223cc	no	9

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5554184		1996-09-10	Machiraju	

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	1	20020052651		2002-05-02	Myers et al.	
	2	20030209835		2003-11-13	Chun et al.	

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	1	9-501594	JP		1997-02-18		Equivalent to WO/1995/005207	☐
	2	2001-500761	JP		2001-01-23		Equivalent to WO/1998/011935	☐

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	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

	3	2005-103321	JP		2005-04-21		Equivalent to EP0696447	☐
	4	2009/149462	WO		2009-12-10	Edwards Lifesciences Corporation		☐

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	1	Declaration Under 37 CFR 1.131 as filed in U.S. Patent Application No. 10/887,688 on December 15, 2008, by co-inventors of that application. (Best available copy)	☐
	2	Final Office Action issued May 8, 2015 in U.S. Application No. 14/502,453 (109978.10106)	☐

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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-06-11
Name/Print	Mark L. Yaskanin	Registration Number	45246

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/00	A2	**(11) International Publication Number:** WO 95/05207 **(43) International Publication Date:** 23 February 1995 (23.02.95)

(21) International Application Number: PCT/US94/09399

(22) International Filing Date: 18 August 1994 (18.08.94)

(30) Priority Data:
08/109,131 19 August 1993 (19.08.93) US

(71) Applicant: ENDOVASCULAR TECHNOLOGIES, INC. [US/US]; 1360 O'Brien Drive, Menlo Park, CA 94025 (US).

(72) Inventors: QUIACHON, Dinah, B.; 1872 Luby Drive, San Jose, CA 95133 (US). STERMAN, Wesley, D.; 2121 Sacramento Street #604, San Francisco, CA 94109 (US). WILLIAMS, Ronald, G.; 1313 Sherman Avenue, Menlo Park, CA 94025 (US). DILLOW, David, C.; 22851 Longdown Road, Cupertino, CA 95041 (US). BAKER, Steve, G.; 743 San Ramon, Sunnyvale, CA 94086 (US).

(74) Agent: THOMPSON, Clifton, W.; Fulwider, Patton, Lee & Utecht, 10th floor, 10877 Wilshire Boulevard, Los Angeles, CA 90024 (US).

(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: DUAL VALVE REINFORCED SHEATH AND METHOD

(57) Abstract

A large-diameter expandable sheath for use in introducing a catheter or other medical instrument into a vessel in the body of a patient. The expandable sheath comprises an elongate sheath tube formed of a flexible material which has proximal and distal extremities and a passage extending therethrough of a maximum predetermined diameter. The distal extremity of the elongate sheath tube is folded longitudinally to a smaller folded diameter. The sheath tube may be self-expanding or may be reinforced with a self-expanding wire or expandable stents. A backflow adapter is secured to the proximal extremity of the elongate sheath tube. The backflow adapter has a central opening therein in registration with the passage in the sheath tube. A normally closed primary valve is disposed in the central opening of the backflow adapter and is movable to an open position. A normally open secondary valve, movable to a closed position, may be configured in the backflow adapter proximal the sheath tube and distal the primary valve. The primary and secondary valves when open permit a catheter or other medical instrument to be inserted into the sheath, and when closed form a hemostatic seal about the catheter. A sheath introducer is provided for guiding the distal end of the sheath tube into a vessel and is configured to be positioned within the backflow adapter.

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TITLE

DUAL VALVE REINFORCED SHEATH AND METHOD

This application is a continuation-in-part of application Ser. No. 07/807,089 filed on Dec. 13, 1991, which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

This invention relates to an expandable sheath and more particularly to a dual valve, reinforced, large-diameter expandable sheath and method of use.

Expandable access catheter assemblies have heretofore been provided to facilitate the placement and removal of diagnostic and therapeutic catheters through the vascular system. Such catheter assemblies included a flexible variable-diameter catheter body, a diameter control stylet and a flexible Y-hub. The flexible Y-hub incorporates an adjustable hemostasis valve and a side port in one branch and a diameter control stylet guide wire in another branch. A flexible variable diameter catheter body is secured to the flexible Y-hub and can be expanded between a collapsed position and an expanded position by the stylet guide wire. Several deficiencies have been found in such a device. For example, the adjustable hemostasis valve is incapable of accepting large catheters. The flexible variable-diameter catheter body is objectionable in that it has a tendency to reduce in diameter and hold onto large-diameter catheters when it is attempted to place the same through the catheter body. In addition, the tip of the stylet guide wire catches a large-diameter catheter which causes elongation of the catheter body and reduction in its diameter to grab and prevent further advancement of the large-diameter catheter. There is therefore a need for a new and improved large-diameter expandable sheath which will overcome these deficiencies.

SUMMARY OF THE INVENTION

The present invention comprises a sheath assembly for use in introducing a catheter or other medical instrument into a corporeal vessel. The sheath assembly includes an elongate

sheath tube formed of a flexible material having proximal and distal extremities and having a passage extending therethrough. The distal extremity of the sheath tube may have a reinforcing means for causing radial expansion of the distal extremity of the sheath tube to an expanded diameter.

The sheath assembly further includes a backflow adapter having a body with a central opening in fluid communication with the sheath tube. The backflow adapter includes a normally closed primary valve and may include a normally open secondary valve. When the primary and secondary valves are open they permit a medical instrument to be inserted into said sheath tube and when closed form a hemostatic seal about the instrument. The sheath assembly may further include a sheath introducer capable of being disposed in the passage of said sheath tube.

The primary valve is disposed proximal the secondary valve. The primary valve has a cylindrical member formed of a flexible material having a proximal end and a distal end configured with a bore therein in fluid communication with the passage of the sheath tube. The primary valve also has a ring gear secured to one end of the cylindrical member, a rack for driving the ring gear to cause relative rotation between the ends of the cylindrical member to cause the cylindrical member to be twisted to close the bore extending through the cylindrical member, and biasing means for urging the rack into a position wherein the cylindrical member is rotated to a closed position.

The secondary valve is secured to the proximal extremity of the sheath tube, and has a cylindrical member formed of a flexible material having a proximal end and a distal end configured with a bore therein in registration with the passage of the sheath tube. The secondary valve includes rotating means for engaging the cylindrical member for causing relative rotation between the ends of the cylindrical member to cause the cylindrical member to be twisted to close the bore extending through the cylindrical member.

In general, it is an object of the present invention to provide an expandable sheath which can be utilized with

large-diameter catheters and method for using the same. Another object of the invention is to provide a sheath of the above character which is folded longitudinally to a small diameter and which can be expanded greatly when a large-diameter catheter is to be passed through it. Another object of the invention is to provide a sheath of the above character which is provided with a backflow adapter which includes a tubular diaphragm that can be moved into an hourglass or iris-like configuration to create a fluid-tight barrier around any tubular device such as a large-diameter catheter passed through the backflow adapter and the tubular diaphragm. Another object of the invention is to provide a sheath of the above character in which a dilator can be utilized for expanding the sheath. Another object of the invention is to provide a sheath of the above character in which the backflow adaptor can be readily controlled.

Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side elevational view of a large-diameter expandable sheath assembly incorporating the present invention and in which a sheath introducer is disposed in the sheath tube.

FIG. 2 is an enlarged side elevational view of the sheath introducer shown in the large-diameter expandable sheath assembly of FIG. 1.

FIG. 3 is an enlarged detail view partially in cross-section of the distal extremity of the sheath introducer shown in FIG. 2.

FIG. 4 is a cross-sectional view taken along the line 4-4 of FIG. 1.

FIG. 5 is a partial side elevational view of an alternative embodiment of an expandable sheath tube incorporating the present invention.

FIG. 6 is a cross-sectional view taken along the line 6-6

of FIG. 5.

FIG. 7 is a cross-sectional view similar to FIG. 4 showing the sheath of FIGS. 5 and 6.

FIG. 8 is an enlarged side elevational view partially in cross-section of the proximal extremity of the large expandable sheath of the sheath assembly shown in FIG. 1 and particularly showing the backflow adapter.

FIG. 9 is an end elevational view looking along the line 9-9 of FIG. 8 with certain portions being shown in cross-section and with the valve carried by the backflow adapter being in a normally closed position.

FIG. 10 is a view similar to FIG. 9, but showing the valve in an open position.

FIG. 11 is a side elevational view partially in cross section opposite the side shown in FIG. 8 of the proximal extremity of the expandable sheath.

FIG. 12 is a bottom plan view looking along the line 12-12 of FIG. 11.

FIG. 13 is a top plan view looking along the line 13-13 of FIG. 11.

FIG. 14 is a side elevational view of the valve or diaphragm utilized in the backflow adapter shown in FIGS. 9 and 10.

FIG. 15 is an alternative embodiment of a valve or diaphragm for use in the backflow adapter shown in FIGS. 9 and 10.

FIG. 16 is still another embodiment of a valve or diaphragm for use in the backflow adapter show in FIGS. 9 and 10.

FIG. 17 is a view similar to FIG. 9 but showing an alternative rack and pinion arrangement for the backflow adapter.

FIG. 18 is a cross-sectional view showing another embodiment of a rack for the closing and opening of the valve in the backflow adapter.

FIG. 19 is a cross-sectional view taken along the line 19-19 of FIG. 18.

FIG. 20 is a side elevational view of an alternative embodiment of the sheath assembly incorporating the present

invention and in which a sheath introducer is disposed in the sheath tube.

FIG. 21 is an enlarged elevational view partially in cross-section of the proximal extremity of the sheath assembly shown in FIG. 20 and particularly showing the back-flow adapter.

FIG. 22 is a partial side elevational view of an alternative embodiment of an expandable sheath tube incorporating the present invention.

FIG. 23 is a cross-sectional view taken along the line 23-23 of FIG. 22.

FIG. 24 is an end elevational view looking along the line 24-24 of FIG. 21 with certain portions being shown in cross-section and with the primary valve being in a normally closed position.

FIG. 25 is a side elevational view partly in cross-section of the primary valve shown in FIG. 24 in an open position and held by a keeper.

FIG. 26 is an enlarged detailed view partially in cross-section of an alternate embodiment of the distal extremity of the sheath tube and the sheath introducer, showing the radiopaque marker band on the introducer and a radiopaque marker on the sheath tube.

FIG. 27 is a partial side elevational view in cross-section of an alternate embodiment of an expandable sheath tube incorporating a self-expanding reinforcement means.

FIG. 28 is a partial side elevational view of an alternate embodiment of an expandable sheath tube incorporating a helical coil.

FIG. 29 is a partial side elevational view in cross-section of an alternate embodiment of an expandable sheath tube incorporating a helical coil embedded between an inner sheath tube and an outer sheath tube.

FIG. 30 is a partial side elevational view in cross-section of an alternate embodiment of an expandable sheath tube incorporating stents and a balloon for expanding the stents.

FIG. 31 is a partial side elevational view of an alternate embodiment of an expandable sheath tube incorporating U-shaped

expandable wires.

FIG. 32 is a partial side elevational view of an alternate embodiment of an expandable sheath tube incorporating a wire having a circular distal end.

FIG. 33 is a partial side elevational view of an alternate embodiment of an expandable sheath tube incorporating an expandable wire including two half-circles at the distal end of the sheath tube.

FIG. 34 is a partial side elevational view of an alternate embodiment of an expandable sheath tube incorporating expandable wires forming a "W" pattern at the distal end of the sheath tube.

FIG. 35 is a side elevational view of a sheath assembly inserted into a vessel, wherein an introducer capsule is being removed from the sheath tube.

FIG. 36 is a side elevational view of a sheath assembly inserted in a vessel wherein a removable capsule is being used to withdraw the sheath tube from the vessel.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In general, the large-diameter expandable sheath is used for introduction of a catheter into the body of a patient. It comprises an elongate sheath tube formed of a flexible material and having proximal and distal extremities and having passage therein of a predetermined maximum diameter. The distal extremity of the elongate sheath tube is folded longitudinally into a smaller diameter. A backflow adapter is secured to the proximal extremity of the elongate sheath tube. The backflow adapter has a central opening therein in registration with the passage in the sheath tube. Valve means is disposed in the central opening in the backflow adapter and is movable between open and closed positions. The valve means when in an open position permits a catheter to be introduced into the sheath and when closed forms a liquid-tight seal about the catheter extending therethrough.

More particularly as shown in FIG. 1 of the drawings, the large-diameter expandable sheath 11 consists of an elongate sheath tube 12 having proximal and distal extremities 13 and 14

and having a flow passage 16 having a maximum diameter extending therethrough. The expandable sheath 11 can have a suitable length as, for example, fifteen to thirty-five centimeters and preferably approximately eighteen centimeters with a maximum outside diameter of one centimeter. The elongate sheath tube is formed of a flexible material having a wall thickness of 0.001 to 0.020 inches (0.0254-0.51 millimeters) and preferably about 0.005 inches (0.127 millimeters) and can be formed of a suitable plastic material such as "TEFLON" (a fluorinated ethylene propylene). An alternate material is "TEFZEL" (ethylene tetrafluoroethylene). The selected material should have physical characteristics which will not be compromised by radiation sterilization.

As shown in FIG. 4, the distal extremity of the sheath tube is pleated or folded longitudinally to provide wraps or folds 17 for a distance of approximately ten centimeters from the distal end to provide a distal extremity of reduced diameter as, for example, a reduction of the outside diameter from 3/8 to 3/16 of an inch (9.52-4.76 millimeters) or approximately one-half the original size. The folding or pleating of the sheath tube 12 in this manner serves two purposes. The first purpose is to reduce the sheath diameter to facilitate introduction of the sheath and to make it less traumatic for the vessel into which it is introduced. The second reason is that with a small-diameter, thin-wall tube, as represented by the elongate sheath tube 12, there is less likelihood of kinking occurring than in a large-diameter, thin-wall tube. The distal extremity of the sheath tube 12, when folded longitudinally in this manner, serves to provide kink resistance in the distal extremity 14 while still being relatively flexible.

If it is desired to further decrease the likelihood of kinking in the large-diameter, thin-wall tube which forms the sheath tube 12, another embodiment of the sheath tube can be provided of the type shown in FIGS. 5, 6 and 7. The sheath tube 18 shown in those figures is provided with a plurality of circumferentially spaced apart flexible elongate elements 19 which are embedded in the wall of the tube 18 and extend

longitudinally along the length thereof as shown in FIG. 5. The proximal extremities are offset or staggered as shown in FIG. 5 with alternate elements 19 being shorter. This offset relationship provides a gradation in stiffness in the proximal extremity of the sheath tube 18. The elongate elements 19 can be in the form of stainless steel wires having a diameter ranging from 0.005 to 0.015 inches (0.127-0.381 millimeters) and preferably a diameter of approximately 0.010 inches (0.254 millimeters). As can be seen from FIG. 6, the sheath tube 18 can bulge outwardly around the elongate elements 19 while being relatively thin between the elongate elements to retain the flexibility of the tube 18. As also can be seen from FIG. 6, the elongate elements 19 are spaced apart in the three groups to facilitate the formation of six folds 20 as shown in FIG. 7. Thus, by way of example, each set of elongate elements can have the elongate elements spaced approximately 35° apart with each set being spaced approximately 85° apart. Spacing of the elongate elements 19 in this manner facilitates the formation of the folds shown in FIG. 7. The elongate elements 19 also provide additional rigidity longitudinally of the tube 18 so as to inhibit accordioning of the tube 18 during removal of the introducer as hereinafter described.

As shown in FIG. 22, sheath tube 12 may be provided with a sheath marker 180 located at the distal end 14 of the sheath tube. The sheath marker is formed of a radiopaque alloy, for example platinum-tungsten or platinum-iridium. The sheath marker is molded inside the distal extremity of the sheath tube to enable the physician to locate the sheath tip during the operative procedure. A laminating patch is created from a tab of sheath material located at the distal tip of the sheath. This tab is folded back over and fused to the sheath tip to laminate the radio opaque marker on the inside tip of the sheath tube. Thus, the marker resides between two laminated layers of the sheath tube. As shown in FIG. 23, the distal end of the sheath tube may be folded into four bifolds 181 to form a square-like configuration, wherein the sheath marker is embedded within one of the sides 182 of the folded square.

A backflow adapter 21 is secured to the proximal extremity

of the elongate sheath tube 12. The backflow adapter 21 consists of a housing or body 22 which is formed of a suitable material, for example, a plastic such as polycarbonate. The housing 22 is provided with a central bore 23 extending therethrough in axial alignment with the passage 16 of the sheath tube 12. A cylindrical sheath tube adapter 26 is disposed in the bore 23 and is provided with an annular recess 27 which receives an inwardly-extending flange 28 provided on the proximal extremity 13 of the sheath tube 12 (see FIG. 8). A tubular insert 29 formed of the same material as the sheath tube 12 but of a greater wall thickness, as for example twice the wall thickness of the sheath tube 12, is secured within an annular recess 30 in the sheath tube adapter 26 by suitable means such as an adhesive. The insert 29 serves as a reinforcement and serves to prevent collapse of the proximal extremities 13 of the sheath tube 12 when the expandable sheath 11 is used. The sheath tube adapter 26 is fixed within a first cylindrical collar 31 seated within the bore 23 and is held in place by solvent bonding the cylindrical collar 31 into the housing or body 22 to prevent longitudinal and/or rotational movement of the first collar 31 relative to the housing or body 22. A second collar 34 is also seated in the bore 23 and is rotatable therein. An annular ring gear 36 having teeth 36 thereon is also rotatably mounted in the bore 23 as hereinafter described.

A cylindrical or tubular valve member or diaphragm 40 is disposed between the first and second collars 31 and 34, and is provided with a bore or flow passage 41 extending therethrough. The valve member 40 is provided with inwardly extending annular lips or flanges 42 and 43 provided on opposite extremities of the same (see FIGS. 8 and 14). The flange 43 is seated in an annular recess 46 in the sheath tube adapter 26 and is retained therein by the first collar 31. The flange 42 is seated in an annular recess 47 provided in a retaining ring 48 and retained therein by the second collar 34. An annular protrusion 49 is formed integral with the retaining ring 48 and engages one side of the toothed ring gear 37 which is secured to the retaining ring 48 by suitable means such as an adhesive. Similarly, the

retaining ring 48 functionally engages the second collar 34 and causes the second collar 34 to rotate therewith.

The diaphragm or valve member 40 can have a suitable size as, for example, a length of 0.3 to 0.45 inches (7.62-11.43 millimeters) and preferably a length of approximately 0.3 inches (7.62 millimeters), and an inside diameter of 0.35 to 0.5 inches (8.89-12.7 millimeters), and preferably an inside diameter of 0.375 inches (9.52 millimeters), with a wall thickness ranging from 0.005 to 0.015 inches (0.127-0.381 millimeters), and preferably a wall thickness of 0.007 inches (0.178 millimeters). The annular lips 42 and 43 can extend inwardly for a distance of 0.032 inches (0.813 millimeters) from the outer wall surface and have a length of approximately 0.050 inches (1.27 millimeters). The diaphragm or valve member 40 can be formed of a suitable material, such as a silicone elastomer, as, for example, Dow "SILASTIC" 97-4720. It can have a Shore A hardness ranging from 20-80 and preferably a Shore hardness of 40A. Alternatively, a low durometer, tear-resistant rubber-like latex material can be utilized.

Other diaphragm or valve members such as shown in FIGS. 15 and 16 can be utilized which have the same physical conformation. In the embodiment shown in FIG. 15, small diener polyester fibers 52 are bonded to the exterior surface of the diaphragm 51 with a silicone adhesive so that the fibers 52 extend circumferentially around the outside surface of the diaphragm 51. Such fibers serve to impede radial and longitudinal distention of the diaphragm or valve member 51. The diaphragm or valve member 56 shown in FIG. 16 is provided with a cylindrical wall 57 which increases in thickness in a direction towards the distal extremity of the diaphragm. This helps the diaphragm to withstand the pressures applied to the diaphragm during use, which may cause the diaphragm to distend and leak.

Means is provided for causing relative rotation between the sheath tube adapter 26 and the retaining ring 48 for opening and closing the bore or flow passage 41 by twisting of the cylindrical valve member or diaphragm 40. This is accomplished by fixing the first collar 31 and the sheath tube

adapter 26 within the housing or body 22 by suitable means such as solvent bonding and causing rotation of the retaining ring 48 by the use of a rack 61. The rack 61 consists of a rod 62 formed of a suitable material such as stainless steel which extends through a hole 63 (see FIG. 11) in the housing or body 22 in a direction which is tangential of the bore 23. The rod 62 is disposed immediately adjacent a flange 64 formed in the body 22 against which the ring gear 36 rotates. The hole 63 opens into the bore 23 so that rack teeth 64 provided on the one side of the rod 62 engage the toothed ring gear 36 whereby upon reciprocatory movement of the rack 61, the ring gear 36 is rotated through an angle ranging from 180° to 360°, and preferably an angle of at least 270°.

An actuator 66 formed of a suitable material such as plastic is mounted on the upper extremity of the rod 62 and is secured thereto by suitable means such as an Allen-head screw 67 set into the rod 62, as shown in FIG. 13. The actuator 66 is generally rectangular in plan and is provided with an upstanding lip 68 so that it conforms to the conformation of the index finger of the hand which is to be utilized for actuating the rack 61. The actuator 66 is provided with a reinforcing rib 69 along one edge of the same. A similar actuator member 71 is provided on the body 22 underlying the actuator 66 and is also provided with a downwardly extending lip 72. The actuator member 71 is secured to the body 22 by suitable means such as an adhesive. The member 71 also has a rectangular configuration in plan and is sized so that it is adapted to be engaged by the thumb of the hand, as shown in FIG. 12. Thus, one hand can be utilized for operating the backflow adapter 21 by the index finger of the hand grasping the actuator 66 and the thumb of the same hand grasping the member 71.

A stabilization and guide rod 76 extends through a tangential bore 77 (see FIG. 11) provided in the body 22 which is spaced apart from the bore 63 and extends in a direction which is parallel thereto. The rod 76 is formed of a material such as stainless steel and is provided with a collar 78 which extends through the reinforcing rib 69 of the actuator 66 and

is secured therein by suitable means such as an Allen-head screw 79.

In an alternative embodiment of the normally closed primary valve if shown in FIGS. 24 and 25, the actuator 66 is turned 90° so that guide or stabilizer rod 76 is positioned on the opposite side of the proximal valve housing 22 to the rack 62. A ring gear 161 is configured into a gear hub 160 which causes rotation of proximal diaphragm retaining ring 158. The distal end of the primary diaphragm 40 is secured to the distal retaining ring 159 which is fixed relative to the proximal valve housing and is positioned proximal a distal retaining hub 162. The primary diaphragm is opened by depressing the actuator which causes the rack to move the ring gear and rotate the gear hub and proximal retaining ring. In addition, a cover 170 is added to the bottom of the body to encase the bottom portions of the rack and stabilizer rod. Also, a "C"-shaped keeper 171 can be used to maintain the actuator in the compressed or open valve position by placing one end over the actuator and the other end over bottom of the cover.

Referring to FIG. 11, means is provided for yieldably returning the rack 61 into a position so that the valve member or diaphragm 40 is in a normally closed position and consists of a coil spring 81 coaxially mounted on the rod 62 and having one end engaging the actuator 66 and having the other end engaging a seat 82 provided in the body 22. Means is provided for preventing the spring 81 from urging the rod 62 out of the bore 63 and consists of a lump 83 of solder or a braising material provided on the rod 62 adjacent the lower extremity of the rack teeth 64. Thus, it can be seen by the hand engaging the backflow adapter 21 using the index finger to engage the actuator 66 and the thumb to engage the actuator member 71, the rack 61 can be reciprocated back and forth to open and close a bore 86 extending through the retaining ring 48 and the sheath tube adapter 26 by forming an hourglass or iris-like closure as shown in FIG. 9 in which the radially extending lines 87 shown represents the folding over of the elastomeric material of the valve member or diaphragm 40. The collar 78 provided on the stabilization rod 76 serves to stop further travel up the rack

when the collar 78 engage a seat 88 provided in the body 22. In this position, the spring 81 is almost completely compressed as shown in FIG. 10. Following the release of the actuator 66, the spring 81 returns the rack 62 to its home position and causes the valve member or diaphragm 40 to be completely closed as shown in FIG. 9.

The ring gear 36 can be formed of a suitable material such as stainless steel and can have any suitable number of teeth. Alternatively, the ring gear can be formed of a suitable plastic such as nylon. The other portions of the backflow adapter 21 as, for example, the body 22, the first collar 31, the second collar 34, the retaining ring 48 can be formed of a suitable plastic such as polycarbonate. The metal parts such as the rod 62, the stabilization rod 76 and the spring 81 can be formed of a suitable material such as stainless steel.

As shown in FIGS. 1 and 8, means is provided for introducing liquid as, for example, a radiopaque liquid, into the bore 86 and consists of a tube 91 formed of a suitable material such as plastic extending through the first collar 31 and through the sheath tube adapter 26 so that it is in communication with the bore 86. Flexible tubing 92 is connected to the tube 91 and has a stopcock 93 of a conventional type mounted thereon which is provided with a Luer-type fitting 94. The stopcock 93 is provided with a knob 96 which can be utilized for moving the stopcock 93 between open and closed positions.

As shown in FIGS. 20-21, an alternate embodiment of the sheath assembly 11 includes a normally open secondary valve assembly 150 located adjacent the primary valve housing 22 of the backflow adapter 21. The secondary valve assembly contains a secondary diagram 151 which operates substantially the same as the primary diaphragm 40 and is actuated by a thumb wheel 152. The secondary diaphragm is made of silicone and is constructed substantially the same as the primary diaphragm. The secondary diaphragm is configured to have a suitable length, diameter and wall thickness to be compatible with the primary diaphragm. Similarly, each of the materials used in the secondary valve assembly for constructing and mounting the secondary diaphragm are substantially the same as the materials

previously described for the backflow adapter assembly.

The primary valve assembly is configured similar to that described above in conjunction with FIGS. 24 and 25. Secondary valve housing 155 is provided with a central bore 165 which is in fluid communication with the central bore 23 of the primary valve housing 22 and the passage 16 of the sheath tube 12. Likewise, secondary diaphragm or valve member 151 is provided with a flow passage extending therethrough. Thus, an instrument such as the sheath introducer 101 may be passed through the primary diaphragm when the secondary diaphragm is closed, thereby preventing blood flow through the proximal end of the large-diameter expandable sheath assembly 11. Also, orifice 163 in the valve housing and orifice 164 in the sheath tube adapter 26 are provided to accept tube 91 connected to the flexible tubing 92 of a introducer sideport assembly (not shown).

As shown in FIG. 21, the secondary valve assembly 150 comprises a secondary valve housing 155 which contains secondary diaphragm 151 and thumb wheel 152. The proximal end of the secondary diaphragm is secured to the thumb wheel by proximal retaining ring 156. The distal end of the secondary diaphragm is fixed relative to the secondary valve housing by distal retaining ring 157. Rotation of the diaphragm is achieved by rotating the thumb wheel so as to cause motion to only the proximal end of the secondary diaphragm. A rotational stop (not shown) is positioned on the thumb wheel to prevent excess rotation of the secondary diaphragm. The rotational stop may be comprised of two 1/32 of an inch (0.79 millimeters) dowel pins located on the thumb wheel and the secondary valve housing which are configured to engage each other to limit the rotation of the thumb wheel. Additionally, a silicone o-ring 153 positioned proximate the thumb wheel in the primary diaphragm distal retaining hub 162 allows rotation of the thumb wheel while preventing fluid from leaking from the backflow adapter housing.

A sheath introducer 101 is provided as a part of the assembly shown in FIG. 1 and as shown in FIG. 2 consists of an elongate tubular member 102 formed in three sections 103, 104

and 106 of different diameters. The elongate tubular member 102 can be formed of a suitable plastic material such as "PEBAX" which is formed of polyether Block Amides which is loaded with approximately 10% barium sulfate to make the same visible under X-rays. Section 103 can have a diameter ranging from 0.15 to 0.3 inches (3.81-7.62 millimeters) and preferably an outside diameter of 3/16 of an inch (4.75 millimeters). The section 104 can have a suitable diameter as, for example, 0.08 to 0.15 inches (2.03-3.81 millimeters) and preferably a diameter of 1/8 of an inch (3.17 millimeters). The section 106 can have a diameter ranging from 0.06 to 0.12 inches (1.52-3.05 millimeters) and preferably a diameter of 0.08 inches (2.03 millimeters). The distal extremities of the sections 103 and 104 are provided with tapers 107 and 108, respectively, so as to provide a tapered transition from one diameter to another. A Luer-type fitting 111 is mounted on the proximal extremity of the tubular section 103. A bore or lumen 112 (see FIG. 4) of a suitable size as, for example, one capable of passing a 0.038 inches (0.97 millimeters) guidewire, is provided in the section 106 as well as in the sections 104 and 103 extending the length of the tubular member 102.

As shown in FIG. 3, a tube 116 is mounted on the distal extremity 106 of the sheath introducer 101 and is formed of a suitable material such as silicone and is retained thereon in a suitable matter by the use of polyethylene shrink tubing 117. A cylindrical enlargement or annular bump 121 is provided on the tubular section 106 adjacent the distal extremity of the shrink tubing 117 and serves to prevent the sleeve 116 and the shrink tubing 117 from accidentally slipping off of the distal extremity of the tubular section 106.

When the sheath introducer 101 is disposed in the expandable sheath 11, as shown in FIG. 1, the proximal extremity of the silicone sleeve 116 is disposed over the distal extremity of the sheath tube 12 and serves to prevent the sharp edges of the folded sheath tube 12 from causing trauma to the interior wall of a vessel when it is introduced into the vessel when the sheath is introduced as hereinafter described. A vent hole 123 is provided in the sheath

introducer 101 which is in communication with the passage 112 proximal of the silicone sleeve 116, as shown in FIG. 3. The vent hole 123 can be utilized for flushing the elongate sheath tube 12 through the side port fitting 94 prior to use of the expandable sheath in a surgical procedure.

As shown in FIG. 26, a radiopaque marker band 185 may be positioned proximal to distal end of the sheath introducer 101. The marker band is made of a radiopaque alloy, platinum-tungsten or platinum-iridium. The marker band is positioned just proximal the retaining bump 121 over the elongate tubular member 102 and within silicone sleeve 116 and polyethylene shrink tubing 117. The platinum alloy band is held in place by both the silicone sleeve and the polyethylene shrink tubing. As appropriate, the marker band may be positioned elsewhere along the length of the sheath introducer, such as within the most distal tubular section 106.

Operation and use of the expandable sheath 11 in conjunction with the sheath introducer 101 may now be briefly described as follows. Let it be assumed that the patient has been prepared in a conventional manner and that it is desired to enter a peripheral vessel such as an artery or a vein of the patient. The desired vessel is exposed and a longitudinal or transverse incision made into that vessel. A guidewire of a suitable size is then selected as, for example, a guidewire having a diameter of 0.038 inches (0.97 millimeters). The guidewire (not shown) is introduced into the vessel and then the expandable sheath assembly 11 shown in FIG. 1 is placed over the guidewire by placing the proximal extremity of the guidewire into the lumen 112 provided in the elongate tubular member 102 and advanced through the Luer fitting 111. The rounded tip and the small diameter of the section 106 of the tubular member 102 facilitate advancement of the sheath introducer 101 into the vessel without traumatizing the vessel. The small-diameter tip section 106 is followed by the elongate sheath tube 12 which has been collapsed as hereinbefore described about the tubular section 106 until the sheath tube 12 has been introduced to the proper depth in the vessel. As soon as the sheath tube 12 has been positioned in the vessel,

the sheath introducer 101 is advanced relative to the elongate sheath tube 12 by using one hand to hold the backflow adapter 21 which is connected to the sheath tube 12 and the other hand to push the sheath introducer 101 so that the proximal extremity of the silicone sleeve 116 moves off of the distal extremity of the sheath tube 12 to expose the same.

As soon as this has been accomplished, the sheath introducer 101 is pushed forward so that section 103 enters the collapsed section of the sheath tube 12 to commence opening of the same. The sheath introducer 101 is then removed through the backflow adapter 21. The sheath introducer can be removed by grasping the backflow adapter 21 by the fingers of the hand as hereinafter described to at least partially open the same to permit removal of the sheath introducer and dilator 101 while minimizing the flow of blood from the sheath tube 12. The backflow adapter can then be released. The sheath 11 and its backflow adapter is now in its normally closed state to provide a hemostatic seal closing the flow passage 86.

The physician conducting the procedure then selects the desired catheter or other device which is desired to be introduced through the expandable sheath 11. Such a device should have a diameter of 8.5 millimeters or less or which is at least slightly less than the diameter of the bore 86. The physician grasps the actuator members 66 and 71 and presses the same to operate the rack 61 to open the diaphragm or valve member 40 permitting the physician to insert the device as, for example, the catheter through the expandable sheath 11. As soon as the catheter has been advanced as far as desired, the physician releases the pressure on the actuator members 66 and 71 permitting the diaphragm 40 to close around the device as, for example, the catheter inserted through to form a hemostatic seal about the catheter. If it is desired to reposition the catheter, it is merely necessary to push or pull the catheter and it will slide freely through the diaphragm. When it is desired to remove the catheter, the catheter need only be pulled out of the sheath 101 and the diaphragm will seal closed forming a hemostatic seal.

A silicone coating may be applied to the pleated sheath

tube 12. Coating may be applied to the inner and outer surfaces prior to attachment to the backflow adapter 21. The silicone coating on the inside diameter of the sheath tube reduces the amount of force required to advance catheters and the like through the sheath tube. Additionally, the silicone coating on the outside of the sheath tube may reduce the amount of force required to advance the expandable sheath 11 into a vessel. A suitable silicone coating material is "HYDRO-SIL-D 1.0" available from TUA systems of Sarasota, Florida. Additionally, a silicone lubricant may be applied to the ring gear 36 on the primary valve assembly and the adjacent to bearing surfaces.

The method for introducing a medical instrument into the body of a patient using the dual valve expandable sheath assembly 11 shown in FIGS. 21-26 involves opening the valves to minimize blood flow through the sheath assembly 11. First, the sheath introducer 101 is placed within the sheath assembly such that the distal end 14 of the sheath tube 12 resides in the introducer sleeve 116, as shown in FIG. 26. This step may be performed as part of the manufacturing process. After the patient is prepared for the procedure, the sheath tube and the sheath introducer are intraluminally inserted into the patient, usually through a cutdown in a vessel such as a femoral artery. The distal end 106 of the sheath introducer is then inserted into the vessel until the distal end of the sheath tube is within the vessel. The sheath introducer is then advanced into the vessel relative to the sheath tube, allowing the distal end of the sheath tube to expand. In addition, the sheath introducer may be further advanced into the sheath assembly to dilate the distal end of the sheath tube.

Next, the sheath introducer 101 is removed from the sheath assembly 11. As the distal end 106 of the sheath introducer is removed from the sheath tube 12, the secondary valve 151 is closed to form a substantially fluid tight seal between the passage 16 in the sheath tube and the secondary valve assembly 150. After the secondary diaphragm 151 is closed, the primary diaphragm 40 may be opened to fully remove the sheath introducer. Then the distal end of a catheter or other medical

instrument may be inserted through the primary valve. The primary diaphragm is then closed to form a substantially fluid tight seal around the medical instrument. Next, the secondary diaphragm is opened to allow the distal end of the medical instrument to be inserted through the secondary valve assembly, through the passage in the sheath tube and into the vessel of the patient. After the procedure has been completed, the medical instrument and the sheath assembly can be removed from the vessel and the incision which has been made in the vessel for permitting passage of the sheath assembly can be sutured.

It can be seen from the foregoing that there has been provided an expandable sheath 11 which can be made in various sizes to accommodate large-diameter devices while still providing the desired hemostatic seal. The expandable sheath can be readily inserted and removed. The sheath introducer 101 facilitates this introduction. It is provided with a distal extremity 106 which is small in diameter to permit the sheath tube 12 to be wrapped about the same as hereinbefore described. The sheath introducer 101 is provided with sections 103 and 104 of larger diameters to provide additional rigidity to the sheath introducer 101 to facilitate pushing of the sheath introducer when introducing the expandable sheath 11 into the vessel of the patient.

An alternative mechanism for actuating the diaphragm 40 is shown in FIG. 17 and consists of a pinion 131 which engages the ring gear 36 and is disposed in a cylindrical recess 132 provided in the body 22. The pinion 131 is mounted on a shaft 133. Another gear 134 is mounted on the shaft 133 and has a smaller diameter than the diameter of the pinion 131 and engages the rack teeth 64 provided on the rod 62. By providing such a gear arrangement, it can be seen that it is possible to provide a shorter rack to achieve the same degree of ring gear rotation for opening and closing of the diaphragm 40.

As can be seen in FIGS. 18 and 19, there is shown another embodiment of a mechanism for actuating the diaphragm 40. As shown therein it consists of a flexible rack 141 that is comprised of a flexible member 142 which is provided with rack teeth 143 on one side of the same which are adaptable to engage

the ring gear 36. The member 142 extends through a semi-circular slot 144 provided in the body so that it extends through the body and around the ring gear 36. An actuator 146 is provided formed integral with the rack 141 for operating the rack 141 with the fingers of the hand. In this construction the rack is substantially contained within the body 22.

As shown in FIGS. 27-36, the expandable sheath 11 may include a reinforced sheath tube 200. The reinforced sheath tube is similar to the elongate sheath tube 12 and similarly has proximal and distal extremities 201 and 202. A flow passage 203 is provided having a maximum diameter extending therethrough. One suitable material for the reinforced sheath is in an expanded PTFE (polytetrafluoroethylene). Such materials may be obtained from Impra of Temp, Arizona and W. L. Gore of Flagstaff, Arizona. An example of a suitable size for a sheath tube for use with large catheter systems would include an outer diameter of approximately 0.345 inches (8.76 millimeters) with a wall thickness of 0.005 inches (0.127 millimeters) and having a length of about twenty centimeters.

The reinforced sheath tube 200 could be supported by stents, coiled wire, coiled plastic or similar means. As shown in FIG. 27, a series of self-expanding supports 210 may be placed within the sheath tube for radial expansion. Similarly, as shown in FIG. 28, a coil 211 may be attached to the outside of the sheath tube to allow for self-expansion. Alternatively, the coil support may be embedded within an inner sheath tube 212 and outer sheath tube 213, as shown in FIG. 29. The coil or expansion system may be made of a 0.012 inches (0.3 millimeters) nitinol or similar alloy wire. As shown in FIG. 30, the reinforced sheath may include balloon expandable stents 214 which may be expanded by a balloon 215 and catheter 216 or similar means.

Alternatively, the sheath tube 200 may be made of a dacron graft 217 supported by longitudinally positioned nitinol wires 218 as shown in FIGS. 31-34. As shown in FIG. 31, the reinforcement wires may be run as tightly parallel U-shaped expansion means. Likewise, a single wire forming a circle at the distal end 202 of the sheath tube may be used. Similarly,

two wires forming half-circles at the distal end may be used to reinforce and expand the sheath as shown in FIG. 33. Alternatively, the wires may form a "W" shape at the distal end of the sheath tube to provide radial expansion, as shown in FIG. 34.

As shown in FIG. 35, the large-diameter expandable sheath assembly 11 includes an introducer capsule 220. The reinforced sheath tube 200 is packed into the introducer capsule for deployment. The introducer capsule has a significantly less inner diameter than the outer diameter of the expanded sheath tube. The introducer capsule is configured such that it will peel away from the proximal end 201 of the reinforced sheath tube as the introducer capsule is withdrawn from the distal end 202 of the sheath tube. As the sheath introducer capsule is withdrawn, the reinforced sheath tube expands radially within the vessel.

As shown in FIG. 36, a removal capsule 225 may be fitted around the proximal 201 end of the reinforced sheath tube 200 to collapse the expanded sheath tube after the sheath tube has been deployed in a vessel. The removal capsule is configured with a lengthwise slit so it may be fitted over the proximal end of the secondary valve without having to fit over the backflow adapter 21. The removal capsule outer diameter is less than the outer diameter of the expanded sheath tube so as to radial collapse the sheath tube to a smaller diameter state. Once the reinforced sheath tube is collapsed, the removal capsule and sheath tube are then removed from the vessel. This retrieval reduces potential vessel trauma from removing a large diameter sheath.

While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. For example, references to materials of construction and specific dimensions are also not intended to be limiting in any manner and other materials and dimensions could be substituted and remain within the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

CLAIMS

What is claimed is:

1. A sheath assembly comprising:

an elongate sheath tube formed of a flexible material having proximal and distal extremities and having a passage extending therethrough;

a first valve secured to the proximal extremity of said sheath tube and movable between open and closed positions, said first valve having a central opening therein in registration with the passage in said sheath tube; and

a second valve disposed proximal said first valve and movable between open and closed positions, said second valve having a central opening therein in registration with the central opening in said first valve and with the passage in said sheath tube,

wherein said first valve and said second valve when open permit a medical instrument to be inserted into said sheath tube and when closed form a hemostatic seal about the instrument.

2. The sheath assembly of claim 1, wherein said first valve comprises:

a first cylindrical member formed of a flexible material having a proximal end and a distal end configured with a bore therein in registration with the passage of said sheath tube; and

first rotating means for engaging the cylindrical member for causing relative rotation between the ends of the cylindrical member to cause the cylindrical member to be twisted to close the bore extending through the cylindrical member.

3. The sheath assembly of claim 2, wherein said second valve comprises:

a second cylindrical member formed of a flexible material having a proximal end and a distal end configured with a bore therein in registration with the bore of said first cylindrical member; and

second rotating means for engaging the second cylindrical member for causing relative rotation between the ends of the second cylindrical member to cause the second cylindrical member to be twisted to close the bore extending through the second cylindrical member.

4. The sheath assembly of claim 3, wherein the second rotating means of said second valve includes a ring gear secured to one end of the second cylindrical member, and a rack for driving the ring gear to cause rotation of the second cylindrical member.

5. The sheath assembly of claim 4, wherein the second rotating means of said second valve further comprises biasing means for urging the rack into a position wherein the second cylindrical member is rotated to a normally closed position.

6. The sheath assembly of claim 5, wherein the second rotating means of said second valve further comprises an actuator carried by the rack and configured to be engaged by the fingers of a human hand for moving the rack against the force of the biasing means to move the second valve to an open position.

7. The sheath assembly of claim 6, wherein the second rotating means of said second valve further comprises a stabilizer rod slidably mounted parallel to the rack and secured to the actuator.

8. The sheath assembly of claim 1, wherein said sheath tube includes reinforcing means for causing radial expansion of said sheath tube.

9. The sheath assembly of claim 8, wherein said reinforcing means includes a self-expanding wire.

10. The sheath assembly of claim 1, wherein the distal extremity of said sheath tube is provided with a radiopaque

marker.

11. The sheath assembly of claim 1, wherein said sheath tube is provided with a lubricating coating.

12. The sheath assembly of claim 2, wherein the first rotating means of said first valve is provided with a lubricating coating.

13. The sheath assembly of claim 3, wherein the second rotating means of said second valve is provided with a lubricating coating.

14. The sheath assembly of claim 1, wherein the distal extremity of said sheath tube is folded longitudinally to a smaller folded diameter.

15. The sheath assembly of claim 14, further comprising a sheath introducer capable of being disposed in the passage of said sheath tube, said sheath introducer having a distal extremity extending beyond the proximal extremity of said sheath tube and dilation means positioned at the distal extremity of the sheath introducer for unfolding the sheath tube.

16. The sheath assembly of claim 15, wherein the distal extremity of said sheath introducer is provided with a radiopaque marker.

17. A sheath assembly for use in introducing a catheter into a corporeal vessel, the sheath assembly comprising:

an elongate sheath tube formed of a flexible material having proximal and distal extremities and having a passage extending therethrough, the distal extremity of said sheath tube having a reinforcing means for causing radial expansion of the distal extremity of said sheath tube to an expanded diameter;

a first valve secured to the proximal extremity of said

sheath tube, said first valve having a first cylindrical member formed of a flexible material having a proximal end and a distal end configured with a bore therein in registration with the passage of said sheath tube, and having first rotating means for engaging the cylindrical member for causing relative rotation between the ends of the cylindrical member to cause the cylindrical member to be twisted to close the bore extending through the cylindrical member; and

a second valve disposed proximal said first valve, said second valve having a second cylindrical member formed of a flexible material having a proximal end and a distal end configured with a bore therein in registration with the bore of said first cylindrical member, a ring gear secured to one end of the second cylindrical member, a rack for driving the ring gear to cause relative rotation between the ends of the second cylindrical member to cause the second cylindrical member to be twisted to close the bore extending through the second cylindrical member, and biasing means for urging the rack into a position wherein the second cylindrical member is rotated to a closed position.

18. The sheath assembly of claim 17, wherein said reinforcing means includes a self-expanding wire.

19. The sheath assembly of claim 18, wherein the self-expanding wire of said reinforcing means is configured to transverse the length of said sheath tube and to form a sinusoidal shape along the perimeter of the distal extremity of said sheath tube.

20. The sheath assembly of claim 17, further comprising a sheath introducer disposed around said sheath tube, said sheath introducer having a distal extremity which has a diameter less than the expanded diameter of said sheath tube.

21. The sheath assembly of claim 18, wherein the distal extremity of said sheath tube is provided with a radiopaque marker, and the distal extremity of said sheath introducer is

provided with a radiopaque marker.

22. A backflow adapter having a body with a central opening in fluid communication with a sheath tube, the backflow adapter comprising:

a first diaphragm disposed in the central opening of said backflow adapter, said first diaphragm having a first end and a second end and being movable between open and closed positions;

first retaining means for engaging said first diaphragm for causing relative rotation between the ends of said first diaphragm;

a second diaphragm disposed in the central opening of said backflow adapter and adjacent the second end of said first diaphragm, said second diaphragm having a first end and a second end and being movable between open and closed positions; and

second retaining means for engaging said second diaphragm for causing relative rotation between the ends of said second diaphragm.

23. The backflow adapter of claim 22, wherein said second retaining means includes a gear secured to the second diaphragm and a rack for driving the gear to cause rotation of the second diaphragm.

24. The sheath assembly of claim 23, wherein the second retaining means further comprises biasing means for urging the rack into a position wherein the second diaphragm is rotated to a closed position.

25. The sheath assembly of claim 24, wherein the second retaining means further comprises an actuator carried by the rack for moving the rack against the force of the biasing means to move the second diaphragm to an open position.

26. The sheath assembly of claim 25, wherein the second retaining means further comprises a stabilizer rod slidably

mounted parallel to the rack and secured to the actuator.

27. The backflow adapter of claim 22, further comprising a sheath tube adapter secured to the body of said backflow adaptor and secured to a sheath tube so as to prevent rotation of said sheath tube adapter when either said first diaphragm or said second diaphragm are rotated within the body of said backflow adapter.

28. An expandable sheath for use in introducing a medical instrument into a body, the sheath comprising:

an elongate sheath tube having proximal and distal ends having an annular passage therethrough, said elongate sheath tube having a wall of substantially uniform thickness and being formed of a flexible material; and

reinforcing means for causing radial expansion of said sheath tube.

29. The expandable sheath of claim 28, wherein said reinforcing means includes a self-expanding wire.

30. The expandable sheath of claim 29, wherein the self-expanding wire of said reinforcing means is sinusoidal in configuration.

31. The expandable sheath of claim 29, wherein the self-expanding wire of said reinforcing means is helical in configuration.

32. The expandable sheath of claim 29, wherein the self-expanding wire of said reinforcing means is configured to transverse the length of said sheath tube and to encircle the perimeter of the distal end of said sheath tube.

33. The expandable sheath of claim 29, wherein the self-expanding wire of said reinforcing means is configured to transverse the length of said sheath tube and to form a sinusoidal shape along the perimeter of the distal end of said

sheath tube.

34. A method for introducing a medical instrument into the body of a patient, the steps of the method comprising:

providing an expandable sheath assembly including an elongate sheath tube with proximal and distal extremities and having a passage extending therethrough, means for radially expanding the distal extremity of the sheath tube, a normally open first valve positioned proximate the proximal extremity of the sheath tube, a normally closed second valve positioned proximal the first valve, and a sheath introducer slidably mounted on at least the distal extremity of the sheath tube;

introducing the sheath tube and the sheath introducer into the body of a patient;

removing the sheath introducer from the distal extremity of the sheath tube;

expanding the distal extremity of the sheath tube;

closing the first valve to form a substantially fluid tight seal between the passage in the sheath tube and the second valve;

opening the second valve;

inserting the distal end of the medical instrument through the second valve;

closing the second valve to form a substantially fluid tight seal around the medical instrument;

opening the first valve; and

guiding the distal end of the medical instrument through the first valve, through the passage in the sheath tube and into the body of the patient.

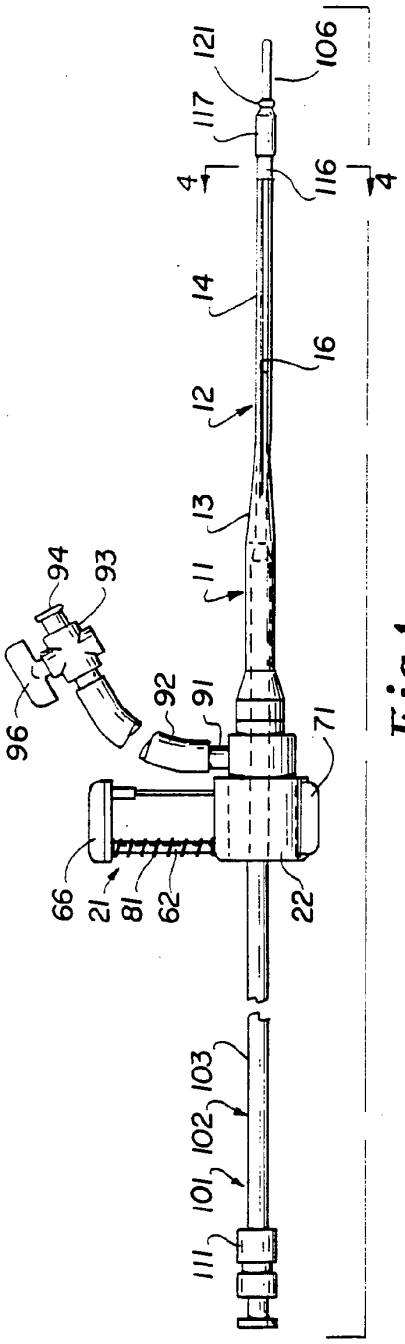


Fig.1

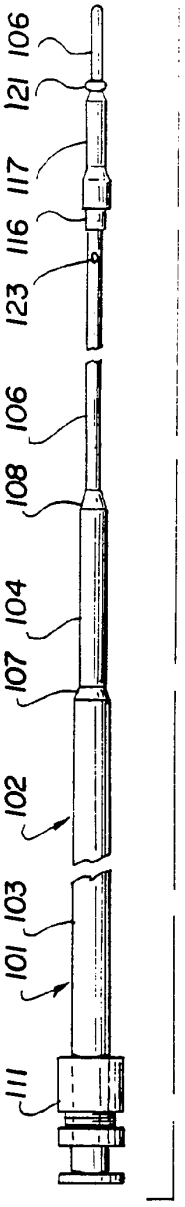


Fig.2

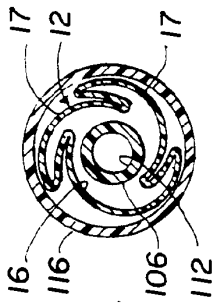


Fig.4

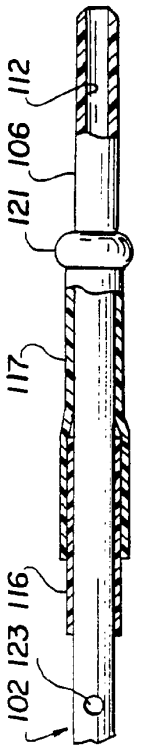


Fig.3

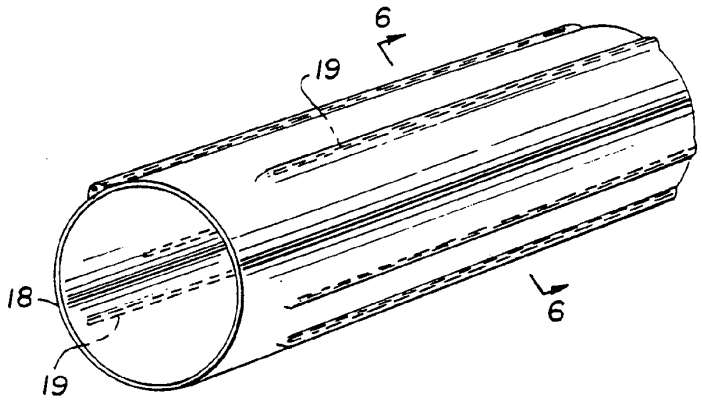


Fig.5

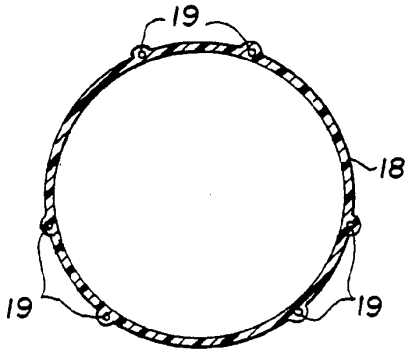


Fig.6

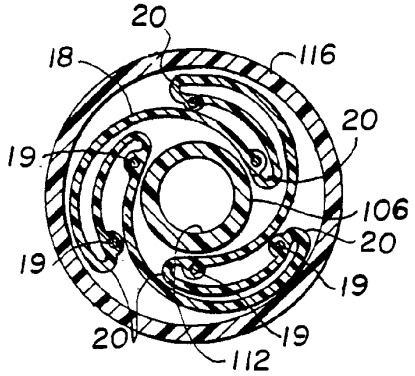


Fig.7

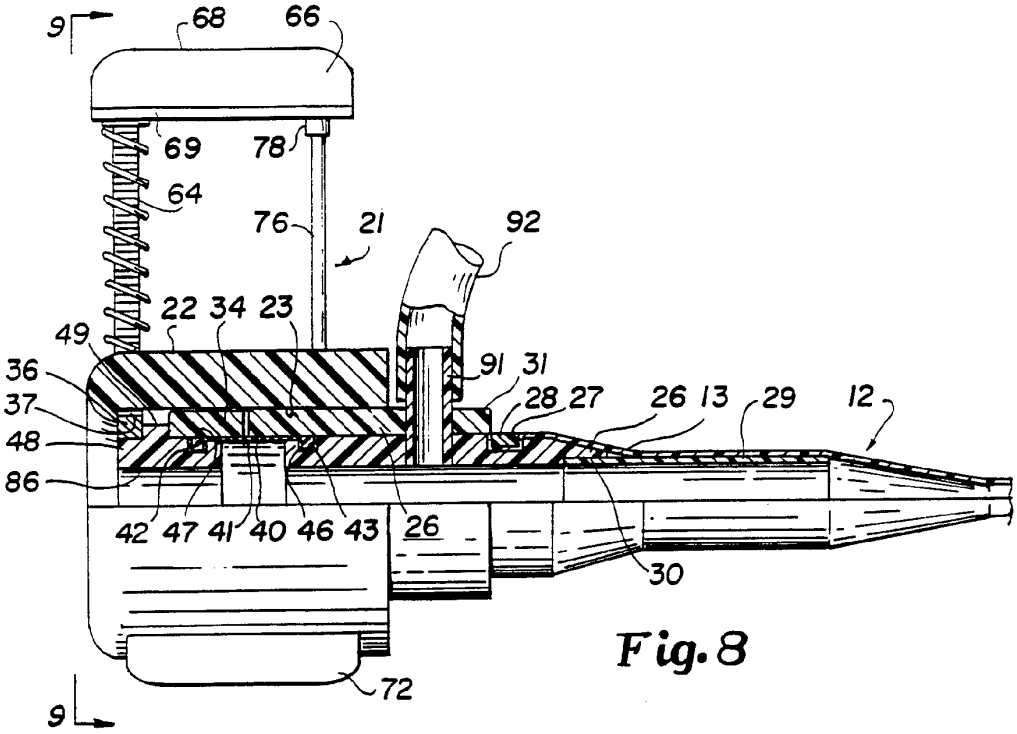


Fig. 8

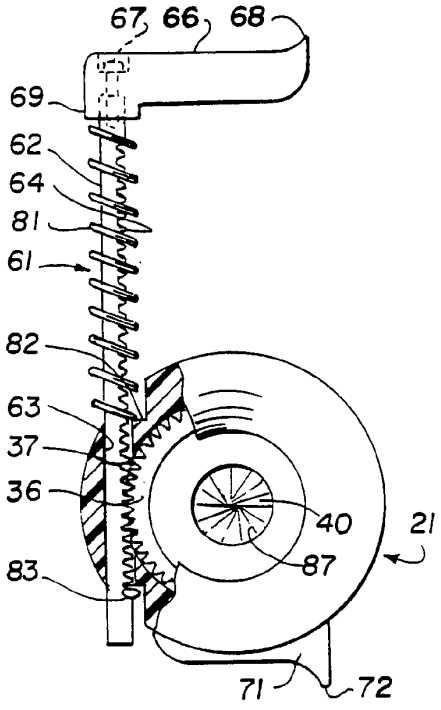


Fig. 9

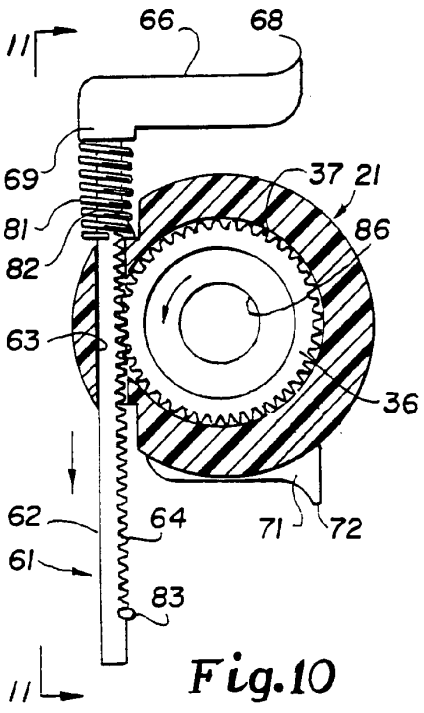


Fig. 10

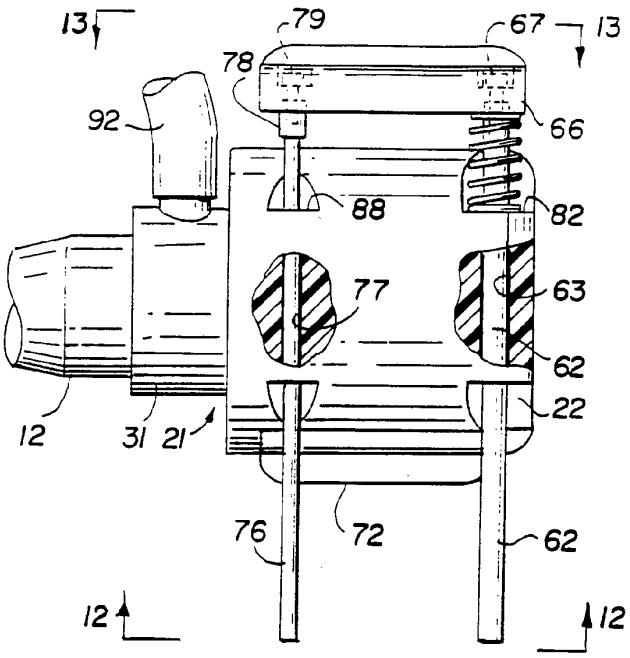


Fig.11

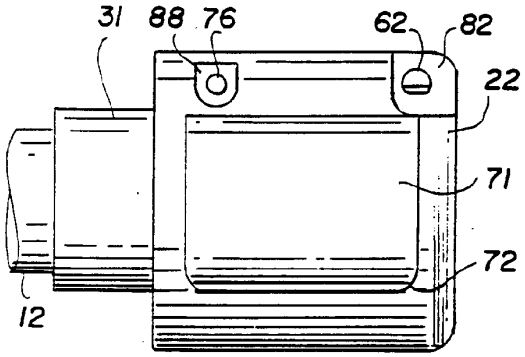


Fig.12

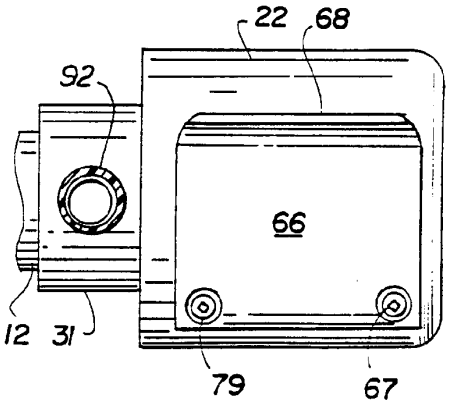


Fig.13

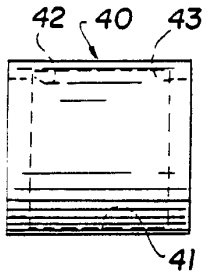


Fig.14

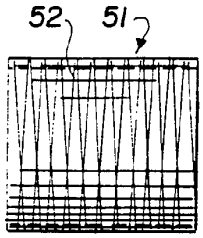


Fig.15

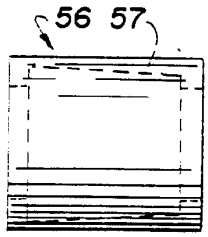


Fig.16

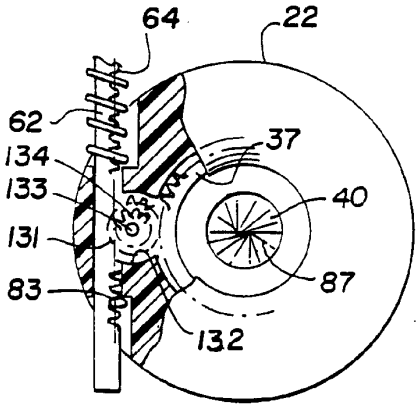


Fig.17

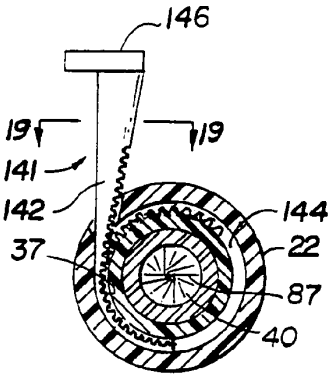


Fig.18

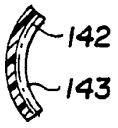
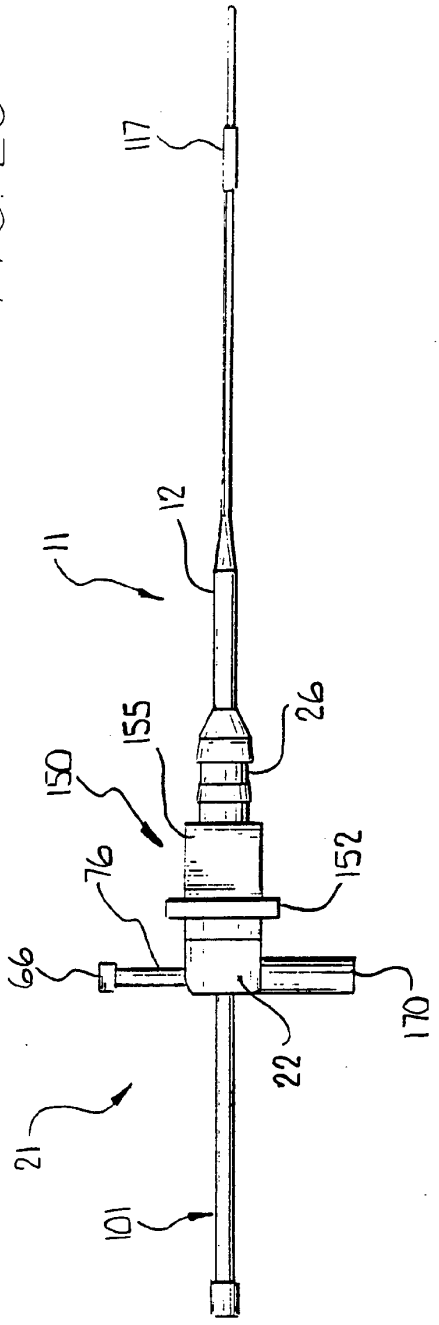


Fig.19

FIG. 20



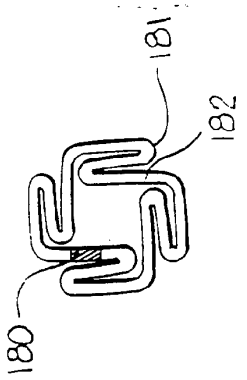


FIG. 23

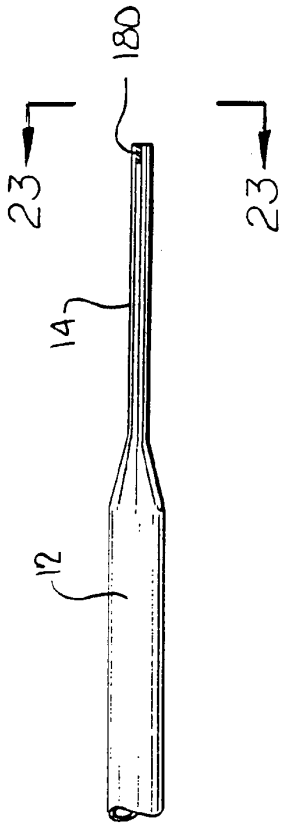


FIG. 22

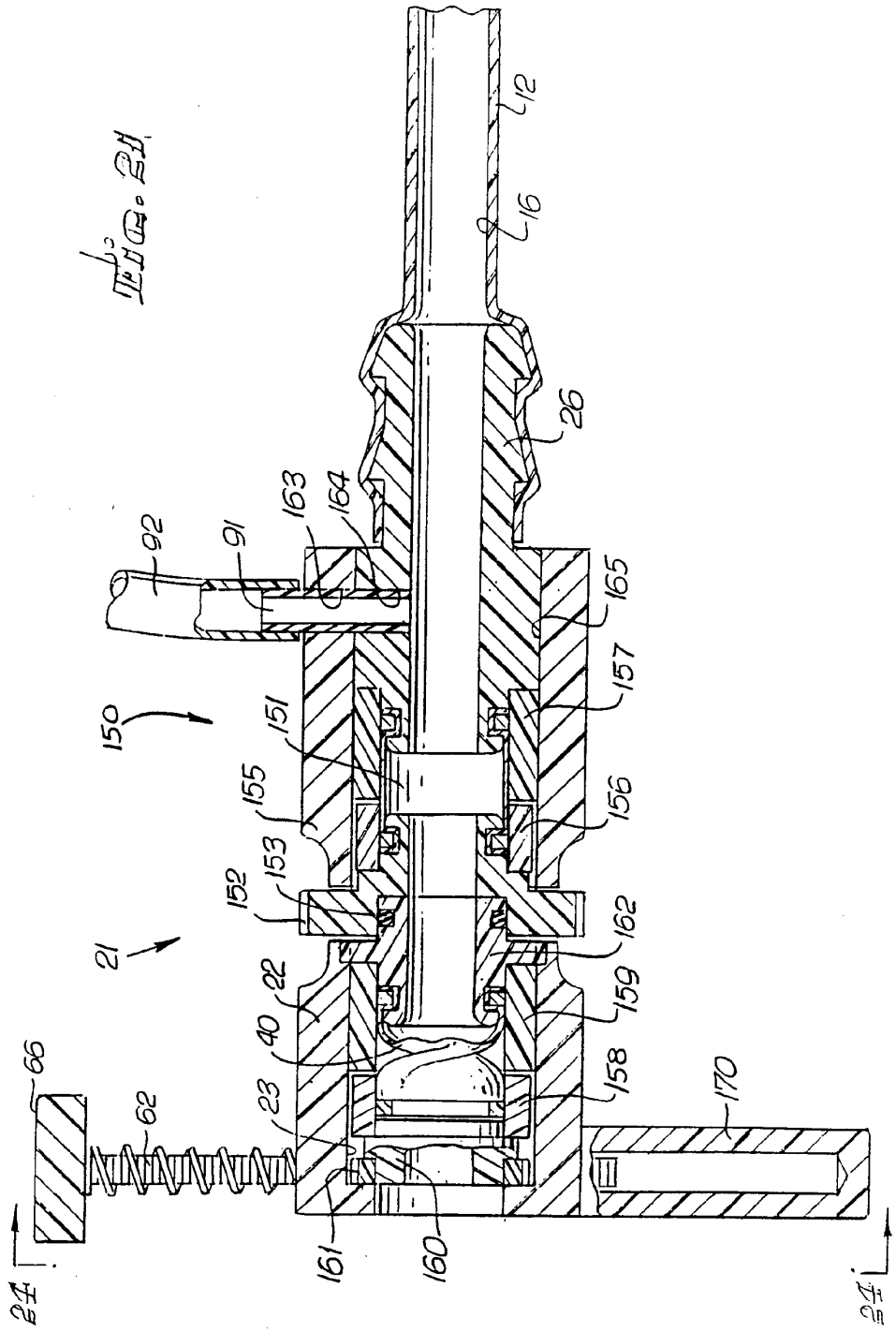


FIG. 2H
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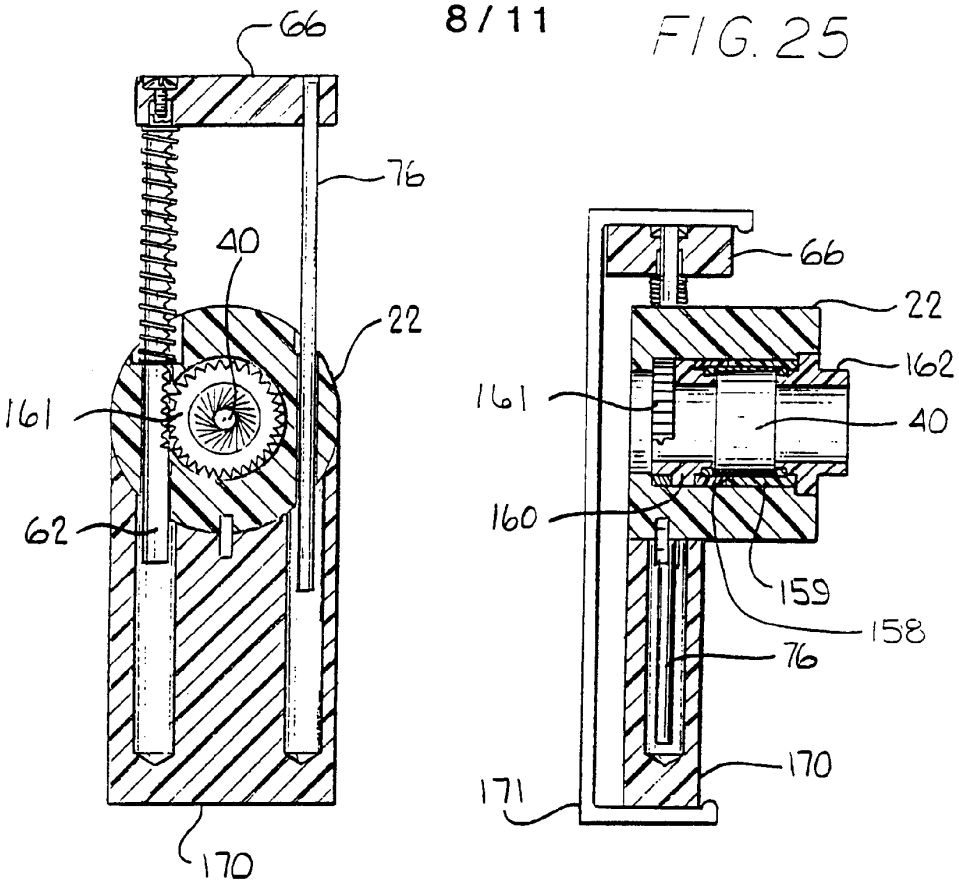
FIG.24

FIG.25



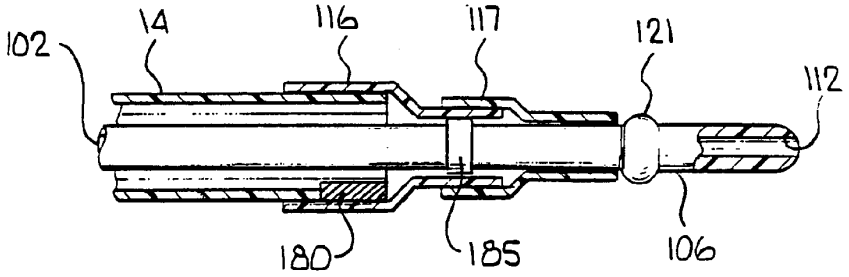


FIG.26

FIG. 27

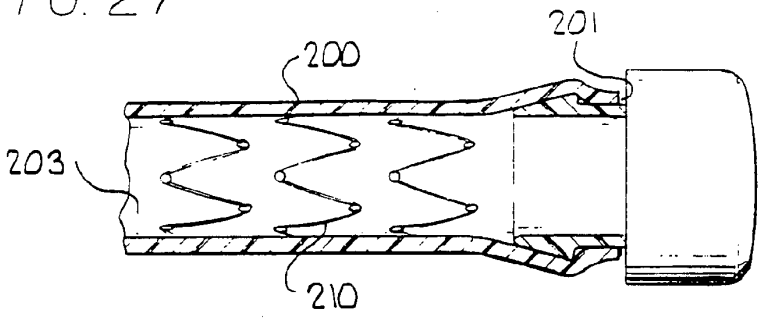


FIG. 28

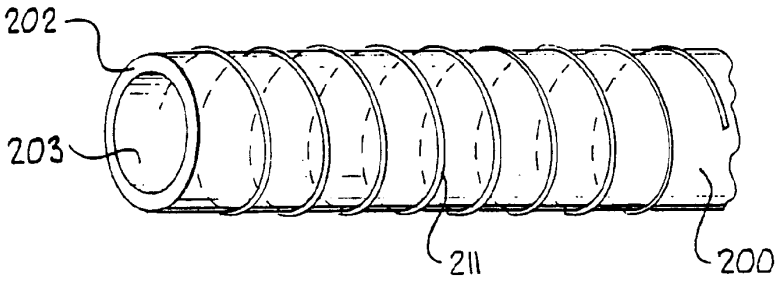


FIG. 29

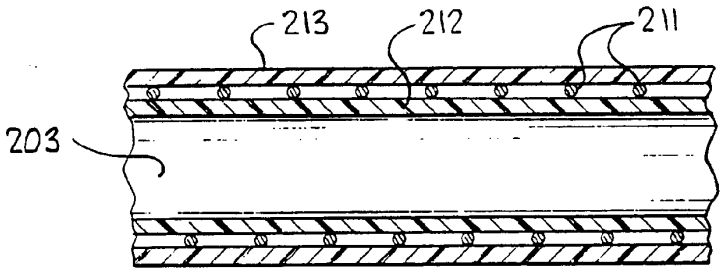


FIG. 30

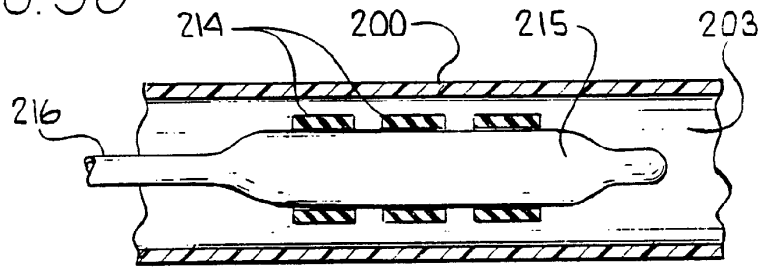


FIG. 31

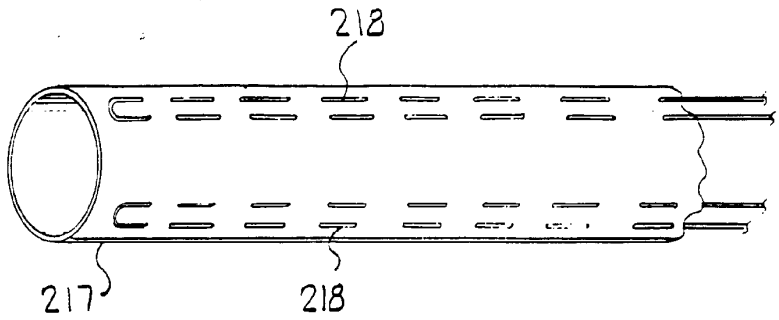


FIG. 32

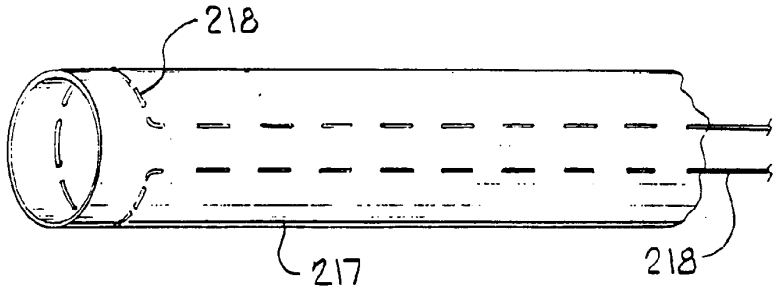


FIG. 33

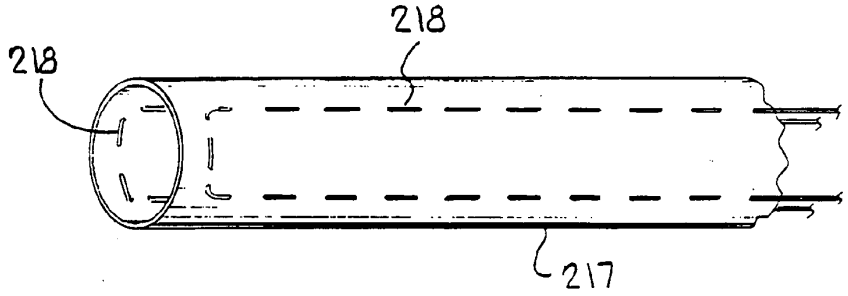
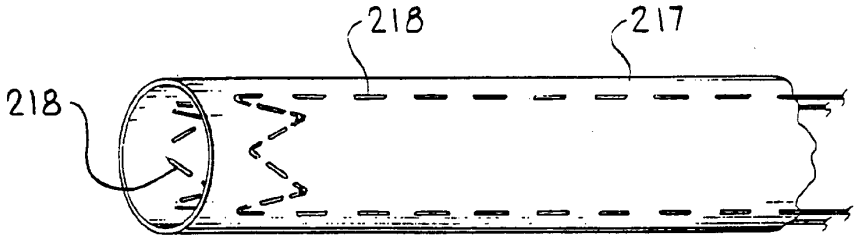


FIG. 34



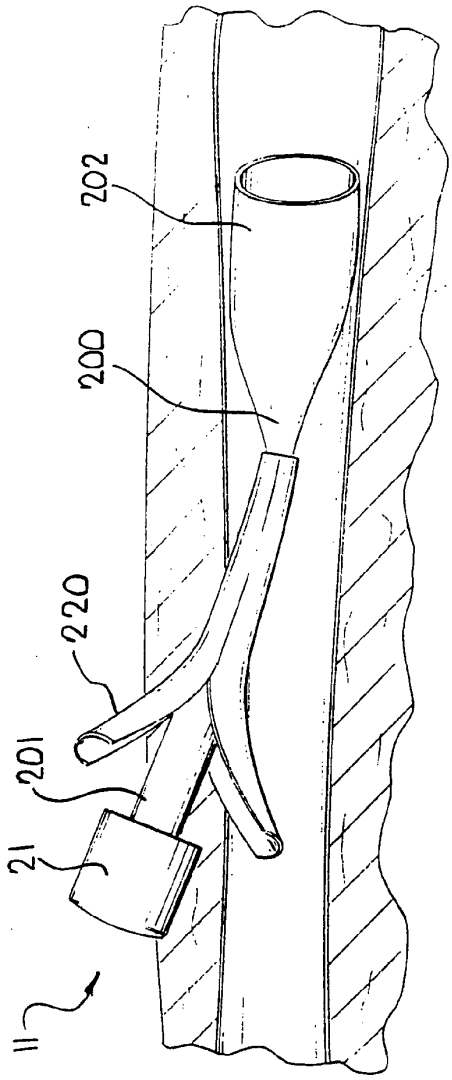


FIG. 35

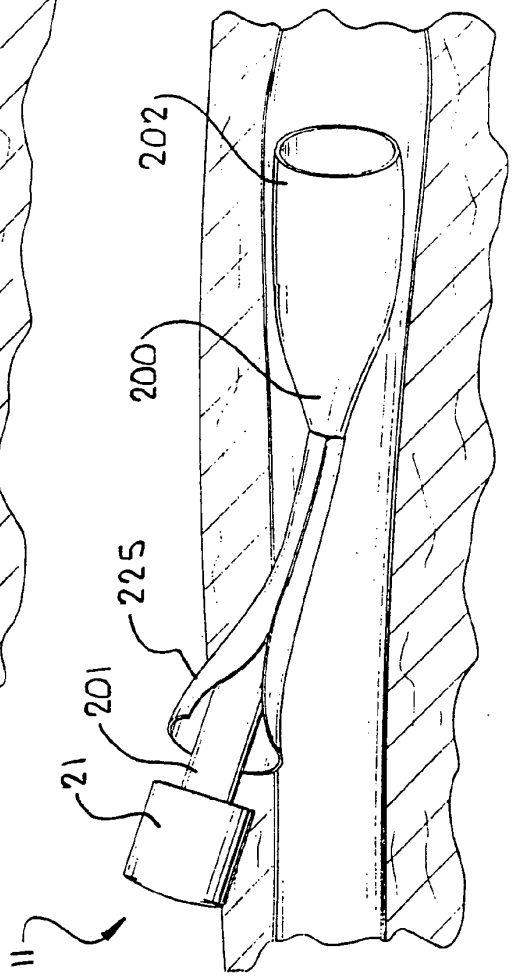


FIG. 36

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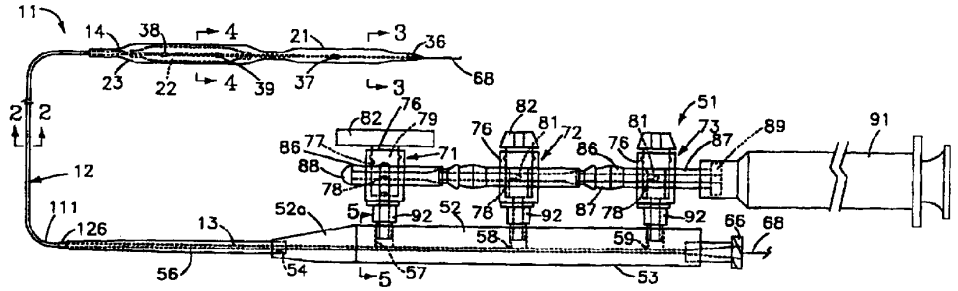

(57) Abstract

This invention is a multiple balloon catheter (11) for use in a vessel of a patient, and for use with an inflation/deflation device. A flexible elongate tubular member (12) with proximal and distal extremities (13, 14) has a distal balloon (21) mounted on the distal extremity (14) of the flexible elongate tubular member (12). Coaxial inner and outer balloons (22, 23) are mounted on the distal extremity (14) of the flexible elongate member (12) proximal of the distal balloon (21). The flexible elongate tubular member (12) has the balloon inflation lumens (17, 18, 19) therein in communication with the interiors of the distal balloon (21) and the inner and outer coaxial balloons (22, 23). A manifold is secured to the proximal extremity of the flexible elongate tubular member (12) in communication with the inflation lumens (17, 18, 19), and is adjusted to be coupled to the inflation/deflation device. Valves are carried by the inflation/deflation manifold for inflating the distal balloon in the inner and outer coaxial balloons (22, 23) one at a time, or in unison without removal of the inflation/deflation device from the manifold.

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MULTIPLE BALLOON STENT DELIVERY CATHETER AND METHOD

This invention relates to a multiple balloon stent delivery catheter and method for deploying the same in vessels of humans.

Heretofore stents have been delivered into vessels in the human body as for example arterial vessels in the heart. In delivering a stent to a lesion in such an arterial vessel, it has been the practice to first cross the lesion with a guide wire followed by a dilatation balloon catheter after which the dilatation balloon is inflated to dilate the lesion. The balloon is then deflated and the balloon catheter removed along with the guide wire. Thereafter, another guide wire is advanced through the stenosis. A stent delivery catheter is then advanced over this guide wire until the stent is disposed within the stenosis. Thereafter, the balloon of the stent delivery catheter is inflated to expand the stent into engagement with the stenosis after which the balloon is deflated and the balloon stent delivery catheter is withdrawn. Often a high pressure balloon is then advanced into the stent and inflated to more snugly secure the stent against the arterial wall. Thereafter, the high pressure balloon is deflated and the high pressure balloon catheter and

the guide wire are removed from the vessel. It has been found that such a procedure is time consuming and in addition requires the use of many different devices which require many insertions into the patient and removals of such devices from the patient. There is therefore need for a new and improved medical device for delivering stents and a method which overcomes these difficulties.

In general, it is an object of the present invention to provide a multiple balloon stent delivery catheter and method which makes it possible to deliver a stent to a desired location with a minimum number of devices inserted into and removed from the patient.

Another object of the invention is to provide a multiple balloon stent delivery catheter which can perform multiple functions.

Another object of the invention is to provide a multiple balloon stent delivery catheter in which a manifold is provided making it possible to inflate the multiple balloons one at a time or in unison without removing the catheter from the patient.

Another object of the invention is to provide a multiple balloon stent delivery catheter of the above character which makes it possible to attain different diameters for dilations of stenoses.

Another object of the invention is to provide a multiple balloon stent delivery catheter in which multiple diameter sized balloons are provided on a single catheter eliminating the need for catheter exchanges.

Another object of the invention is to provide a multiple balloon stent delivery catheter having tapered balloons.

Another object of the invention is to provide a multiple balloon stent delivery catheter of the above character in which various balloon profiles can be provided.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

FIGURE 1 is a side-elevational view of a multiple balloon catheter and a manifold for use with the same.

FIGURE 2 is an enlarged cross-sectional view taken along the line 2-2 of Figure 1.

FIGURE 3 is an enlarged cross-sectional view taken along the line 3-3 of Figure 1.

FIGURE 4 is an enlarged cross-sectional view taken along the line 4-4 of Figure 1.

FIGURE 5 is an enlarged cross-sectional view taken along the line 5-5 of Figure 1.

FIGURE 6 is an enlarged partial view in section of the coaxial balloons shown in Figure 1.

FIGURE 7 is a side-elevational view of a multiple balloon stent delivery catheter and manifold for use with the same.

FIGURE 8 is an enlarged cross-sectional view taken along the line 7-7 of Figure 7.

FIGURE 9 is a cross sectional view similar to that shown in Figure 7 but showing the outer balloon inflated to place the stent.

FIGURES 10, 11, 12, and 13 are side-elevational views of additional embodiments of multiple balloon catheters incorporating the present invention.

In general, the multiple balloon catheter is for use in the vessel of a patient with an inflation/deflation device. It is comprised of a flexible elongate tubular member having proximal and distal extremities. A distal balloon is mounted on the distal extremity of the flexible elongate tubular member. Coaxial inner and outer balloons are mounted on the distal extremity of the flexible elongate member proximal of the distal balloon. The flexible elongate tubular member has balloon inflation lumens therein in communication with the interiors of the distal balloon and the inner and outer coaxial balloons. An inflation manifold is secured to the proximal extremity of the flexible elongate tubular member and is in communication with the inflation lumens and is adapted to be connected to the inflation/deflation device. Valve means is carried by the inflation/deflation manifold for inflating the distal balloon in the inner and outer coaxial balloons one at a time or in unison without removal of the inflation/deflation device.

More in particular as shown in Figures 1 through 5 of the drawings, the multiple balloon catheter 11 consists of a flexible elongate tubular member 12 having proximal and distal extremities 13 and 14 serving as a shaft for the multiple balloon catheter 11. The

flexible elongate tubular member 12 is formed of a suitable lubricous plastic such as Nylon or a copolymer of Nylon such as Pebax or other high lubricous materials such as polyethylene. Nylon 11 has been found to be a particularly suitable material. Other Nylons such as Nylon 12 or Nylon 66 can be utilized. The diameter of the shaft can be of a suitable size such as 3-French corresponding to 0.039" of the outside diameter. The shaft 12 has a suitable length ranging from 130 to 175 centimeters and typically approximately 150 centimeters when used for angioplasty. The flexible elongate tubular member or shaft 12 is typically an extrusion and is provided with a plurality of extruded lumens therein. Thus, as shown in Figure 2 the shaft 12 is provided with a guide wire lumen 16 which is sized to receive a conventional guide wire 68, as for example one having a diameter of .014", and thus is provided with a diameter of 0.017". The shaft is also provided with three balloon inflation lumens, 17, 18 and 19 in which lumen 17 and 18 are generally crescent- shaped and lumen 19 is generally circular in cross section. A plurality of inflatable balloons is provided on the distal extremity 14 of the flexible elongate tubular member 12. Thus, as shown in Figure 1, there is provided a distal balloon 21, an inner balloon 22 which is proximal of the distal balloon 21, and an outer balloon 23 which is coaxial with the inner balloon 22. The balloons 21, 22 and 23 are formed of a non-compliant or low-compliant high pressure material which is capable of withstanding pressures in the range of 18 to 20 atmospheres. Such high strength balloon materials typically incorporate materials such as Nylon 12 or Nylon 11. The distal balloon 21 can have a diameter ranging from 1.5 to 3 millimeters and typically approximately 2 millimeters. The inner balloon 22 can have a diameter ranging from 2.0 to 4.0 millimeters and typically 2.5 or 3

millimeters, whereas the outer balloon 23 can have a diameter ranging from 2.5 to 5 millimeters and typically 3 millimeters to 3.5 millimeters. The balloons can have a wall thickness ranging from 0.0005" to 0.0015" and preferably a thickness of approximately 0.00075". The balloons 21, 22 and 23 can have a suitable working length, as for example the distal balloon 21 can have a working length of 20 millimeters, the inner balloon 22 a working length of 20 millimeters and the outer balloon 23 a working length of 22 millimeters. It should be appreciated that the balloons, if desired, can have increased or decreased lengths as desired. The balloons 21, 22 and 23 are bonded in appropriate locations on the distal extremity 14 of the flexible elongate tubular member 12 in a suitable conventional manner as for example by the use of an adhesive, heat bonding or solvent bonding to form fluid tight seals so that the balloons can be inflated. Thus as shown in Figures 3 and 4, an adhesive 26 has been provided for securing the extremities of the balloons 21, 22 and 23 to the distal extremity 14 of the flexible elongate member 12. Thus, as shown in partial view in Figure 6, an adhesive 26 is utilized for making these bonds. The flexible elongate extremity 14 is also provided with holes of ports establishing communication with the balloon inflation lumens and the interior of the associated balloons. Thus there is provided an opening or port 31 establishing communication between the interior of the distal balloon 21 and lumen 19. Similarly, there is provided an opening or port 32 establishing communication between the lumen 17 and the interior of the inner balloon 22. A port 33 establishes communication between the lumen 18 and the interior of the outer balloon 23. A soft atraumatic tip 36 is provided on the distal extremity 14 and is secured thereto by suitable means such as adhesive (not shown).

The tip can be formed of a soft plastic material as for example Pebax.

Radiopaque markers are provided on the distal extremity 14 of the flexible elongate tubular member 12 to aid in locating the positions of the balloons 21, 22 and 23 during use and consist of a radiopaque marker 37 mounted on the flexible elongate tubular member 12 equidistant between the ends of the distal balloon 21. A pair of markers 38 and 39 is also provided on the distal extremity of the flexible elongate tubular member 12 proximal of the marker 37 and spaced apart near the opposite ends of the inner balloon 22. The radiopaque markers can be formed of a suitable radiopaque material such as gold or platinum. By placing two radiopaque markers in the inner balloon 22 and a single radiopaque marker on the distal balloon 21, it is easy to differentiate the distal balloon 21 from the proximal coaxial balloons 22 and 23.

A manifold assembly 51 is secured to the proximal extremity 13 of the flexible elongate tubular member 12 which can be utilized for inflating and deflating the balloons individually without having to disconnect and reconnect an inflation/deflation device 91. The manifold assembly 51 consists of an elongate cylindrical body 52 formed of a suitable material such as polycarbonate plastic which is provided with a flat 53 so that the manifold assembly 51 will remain in an upright position when resting on a flat surface. The body 52 is provided with a tapered or cone-shaped distal extremity 52a which has a bore 54 therein which has the proximal extremity 13 of the flexible elongate tubular member 12 sealed therein and bonded therein by suitable means such as an adhesive (not shown). A strain relief sleeve 56 is provided on the proximal extremity 13. The manifold body 52 is provided with

spaced-apart balloon inflation chambers, namely a distal balloon chamber 57, an inner balloon chamber 58 and an outer balloon chamber 59. The inner balloon chamber 58 is disposed proximally of the distal balloon chamber 57 and the outer balloon chamber 59 is disposed proximally of the inner balloon chamber 58. The body 52 is provided with a plurality of longitudinally extending bores. Thus, as shown in Figure 5, there is provided a guide wire bore 61 in alignment with the guide wire lumen 16 in the flexible elongate tubular member 12. Similarly, there are provided balloon inflation bores 62, 63 and 64 in communication with balloon inflation lumens 17, 18 and 19 respectively. The chambers 57, 58 and 59 are in communication, respectively, with the bores 64, 63 and 62.

A Luer fitting 66 is mounted on the body 52 and is in communication with the guide wire bore 61 to provide a guide wire port which, as shown, has a guide wire 68 disposed therein. The guide wire 68 is of a conventional type such as an 0.014" diameter guide wire. A Tuohy-Borst adapter (not shown) typically is carried by the Luer fitting 66 to prevent blood from seeping around the guide wire while the catheter 11 is in use.

The manifold assembly 51 includes means for supplying an inflation fluid to the chambers 57, 58 and 59 and consists of valve assemblies 71, 72 and 73 connected, respectively, to the chambers 57, 58 and 59. Each of the valve assemblies 71, 72 and 73 consist of a cylindrical valve body 76 having a bore 77 therein and another bore 78 extending transversely therethrough. A stem 79 is rotatably mounted in the bore 77 and has a bore 81 extending transversely therethrough and adapted to be moved into and out of registration with the bore 78 in the valve body 76. A handle 82 is

provided on the stem 79. Each valve body 76 is connected to adjacent valve body 76. Thus as shown each valve body 76 is provided with a male fitting 86 and a female fitting 87 in communication with the transverse bore 78 in the valve body 76. As shown in Figure 1, the male fitting 86 on one valve body 76 mates with the female fitting 87 of the adjacent valve body 76 so that a fluid communication channel is established between the valve assemblies 71, 72 and 73. The most distal male fitting 86 is truncated and is plugged with a plug 88. A Luer fitting 89 is provided on the most proximal female fitting 87 and has mounted thereon a conventional ENDOFLATER™ or syringe 91. Each valve assembly 71, 72 and 73 also includes a coupling 92 which couples the bore 77 into the respective chambers 57, 58 and 59.

With such a manifold assembly, balloons 21, 22 and 23 can be inflated and deflated individually or can be inflated simultaneously as desired merely by operation of the valve assemblies 71, 72 and 73 in an appropriate manner as hereinafter described. Thus, for example, if it is desired to inflate only the distal balloon 21, all of the valve assemblies 71, 72 and 73 are turned to the closed position. The valve assembly 71 is then rotated by 90° to turn it to an open position as shown in Figure 1, after which an inflation/deflation device 91 is operated to introduce an inflation fluid chamber 57 and then into the bore 64 and into the lumen 19 for inflating the distal balloon 21. The balloon 21 can also then be deflated. If that is not desired, the valve assembly 71 can be turned another 90° to close it to prevent deflation of the balloon 21 or, alternatively, to deflate the balloon 21 and hold it uninflated, after which the catheter 11 can be moved as hereinafter described and the next balloon, as for example inner balloon 22 can be inflated by rotating

the valve 72 to the open position. Thereafter in a similar manner, the outer balloon 73 can be inflated.

Also incorporating the present invention is a multiple balloon stent delivery catheter 101 which is shown in Figure 7. This multiple balloon stent delivery catheter 101 is very similar to the multiple balloon catheter 11 hereinbefore described. It consists of a flexible elongate tubular member 12 having proximal and distal extremities 13 and 14 with a distal balloon 21 and inner and outer balloons 22 and 23. A balloon expandable stent 102 is frictionally mounted on the coaxial inner and outer balloons 22 and 23. As shown in Figure 8, the balloons 22 and 23 are not inflated and the balloon expandable stent 102 is frictionally secured to the outer balloon 23 sufficiently tightly so that a force in excess of approximately one-half pound is required to remove the stent 102 from the outer balloon 23. Such a frictional force is desirable in order to prevent inadvertent displacement of the stent 102 from the outer balloon 23 during deployment. The balloon stent 102 can be of any conventional type and can be formed of a suitable material such as stainless steel or a nickel titanium alloy. A stent of desired length can be provided. Also if desired, stents can be provided in tandem on the outer balloon 23.

As shown, the stent 102 is positioned relative to the radiopaque markers 38 and 39 so that the positioning of the stent can be precisely ascertained during deployment as hereinafter described.

Means is provided for covering the stent 102 until it has been deployed and consists of a sheath 106 and can be formed of a very thin molded plastic having a lubricous outer surface such as one made of Teflon. The sheath 106 can have a single wall thickness ranging

from 0.001" to 0.005" and preferably a wall thickness of approximately 0.0015". The sheath 106 should have a wall thickness which will resist elongation while being withdrawn as hereinafter described. The sheath 106 has a distal extremity 107 which extends slightly beyond the distal extremity of the balloon expandable stent 102, as for example a distance of approximately 1 millimeter. The sheath 106 then extends proximally over the flexible elongate tubular member shaft 12 to the proximal extremity 13 thereof. The proximal extremity 108 of the sheath 106 is secured to a cylindrical fitting 111 forming a part of a hemostasis valve assembly 112. The hemostasis valve assembly 112 includes an internally threaded cap 116 which is threadedly mounted on the cylindrical fitting 111 and engages an O-ring 117 to form a liquid-tight seal between the fitting 111 and the proximal extremity 13 of the flexible elongate member 12. A Luer-type fitting 121 in the form of a side arm is secured to the fitting 111 and provides a port 122 for introducing a flushing saline liquid which can pass into the annular space 123 between the exterior of the flexible elongate tubular member or shaft 12 over the outer balloon 23 within the sheath 106 and exiting out the distal extremity 107 of the sheath 106 to be utilized for a purpose hereinafter described.

A marker 126 visible to the human eye formed of a suitable material such as a paint or a colored tape is provided on the proximal extremity 13 of the flexible elongate tubular member 12 proximal of the hemostasis valve assembly 112. The spacing between the proximal extremity of the hemostasis valve assembly 112 and the marker 126 should be a distance at least equal to or slightly greater than the length of the stent 102 so that when the threaded cap 116 is loosened, the fitting 111 can be retracted to pull with it the sheath 106.

When the threaded cap 106 is adjacent to or overlies the marker 126, the sheath 106 will have cleared the stent 102 to permit placement of the stent 102 as hereinafter described.

A manifold assembly 51 is provided which is substantially identical to the manifold assembly 51 hereinbefore described.

Operation and use of the multiple balloon catheter 11 may now be briefly described as follows. Let it be assumed that it is desired to perform a balloon angioplasty procedure to enlarge an opening in a stenosis in an arterial vessel of the heart of a human patient. The femoral artery of the patient is accessed in a conventional manner by advancing the guide wire 68 until it extends through the stenosis. Thereafter, the multiple balloon catheter 11 is inserted into the femoral artery utilizing the guide wire 68 as a guide to advance the distal extremity 14 of the flexible elongate tubular member 12 so that the distal balloon 21 is disposed within the stenosis. As soon as this has been accomplished by observation of the marker 37 under fluoroscopy, the distal balloon 21 can be inflated by rotating the valve 71 to an open position and then introducing a suitable inflation medium such as a contrast medium to inflate the balloon to its maximum diameter and to cause a flow passage of increased size to be created in the stenosis. After this has been accomplished, the distal balloon 21 is deflated by removing the inflation medium using the inflation/deflation device or syringe 91. After this larger opening has been formed in the stenosis by the distal balloon 21, the distal extremity 14 of the flexible elongate tubular member 12 is then further advanced into the stenosis until the coaxial inner and outer balloons 22 and 23 are positioned within the

stenosis. This again can be visualized by observing the positioning of the markers 38 and 39 under fluoroscopy. The valve assembly 71 is then turned to a closed position and the valve assembly 72 is turned to an open position and an inflation medium is introduced into the inner balloon 22 which moves the outer uninflated balloon 23 into engagement with the stenosis to cause a larger size opening to be formed in the stenosis. If a still larger size opening is desired in the stenosis, the valve 73 can be turned to an open position and the outer balloon 23 can be inflated with a contrast medium or other suitable fluid. After a suitable dilation of the stenosis has occurred, the outer and inner balloons 23 and 22 can be deflated by withdrawing the inflation medium. The multiple balloon catheter 11 and the guide wire 68 can be removed from the femoral artery and the femoral artery closed surgically in a conventional manner. From the foregoing, it can be seen that all three of the balloons 21, 22 and 23 can be inflated individually or, alternatively, can be inflated in unison if desired without removal of the inflation/deflation device 91. This is made possible by use of the manifold assembly 51.

Operation and use of the multiple balloon stent delivery catheter 101 may now be briefly described as follows. Assuming that the multiple balloon stent delivery catheter 101 has been assembled as shown in Figure 7 with the stent 102 in place and with the sheath 106 overlying the same, let it be assumed that it is desired to treat a stenosis occurring in an arterial vessel of the heart of the human patient. This vessel typically is accessed through the femoral artery of the patient. A guide wire 68 is introduced into the femoral artery in a conventional manner and is advanced until its distal extremity has passed through

the stenosis. Thereafter, the multiple balloon stent delivery catheter 101 is advanced over the guide wire 68 until the small distal balloon 21 has been advanced into registration with the stenosis by observation of the marker 37. As soon as this has been accomplished, the valve 71 is opened and an inflation medium is introduced through the manifold 51 with the valves 72 and 73 in closed positions to inflate the distal balloon 21 to increase the size of the flow passage through the stenosis. After this has been accomplished, the distal balloon 21 is deflated. The distal extremity 14 of the multiple balloon stent delivery catheter 101 is advanced until the coaxial inner and outer balloons 22 and 23 are disposed within the stenosis by observation of the spaced apart markers 38 and 39. When this has occurred, the stent 102 is also positioned within the stenosis as well as the distal extremity 107 of the sheath 106.

After these desired procedures have been accomplished, the position of the stent 102 is again verified. If it is desired to change the position of the stent 102, the distal extremity 14 of the multiple balloon stent delivery catheter 101 can be changed after which the distal balloon 21 can be again inflated in the vessel to serve as an anchor for the distal extremity 14 of the flexible elongate tubular member 12. Thereafter, the sheath 106 can be removed from over the stent 102 by retracting proximally the hemostatic valve assembly 112 after loosening the threaded cap 116 and pulling it proximally until the cap 116 is in registration with the marker 126 to assure that the sheath has cleared the stent 102.

As soon as this has been accomplished, the inner balloon 22 can be inflated by opening the valve assembly 72 and leaving the valve assembly 73 closed

and supplying an inflation medium to the inner balloon 22 to expand the stent 102 radially and outwardly to increase the size of the opening or flow passage through the stenosis. If it is desired to further increase the size of the opening in the stenosis, the outer balloon 23 can then be inflated by opening of the valve 73 and supplying additional inflation medium to the manifold assembly 51 to inflate the outer balloon 23 and to carry with it and expand the stent 102 to further increase the size of the opening through the stenosis. As soon as it has been established that the stent 102 has been fully expanded to the desired diameter and embedded in the vessel wall, the balloons 21, 22 and 23 can be deflated by withdrawing inflation medium from the same. The entire multiple balloon stent delivery catheter 101 along with the guide wire 68 can then be removed from the femoral artery and the femoral artery closed surgically in a conventional manner.

It should be appreciated that in connection with the multiple balloon catheter 11 and the multiple balloon stent delivery catheter 101, that the distal balloon 21 can have any appropriate size. For example, it can be a small size balloon as hereinbefore described or, if desired, it can be a larger size balloon substantially the same size as the outer balloon 23.

It also should be appreciated that in place of one distal balloon 21, a plurality of distal balloons can be provided which are disposed in tandem, as for example as shown in Figure 11 in which another distal balloon 21a proximal of the other distal balloon 21 has been provided in the multiple balloon catheter 136. An additional marker 37a has been provided in the balloon 21a.

Another multiple balloon catheter 141 incorporating the present invention is shown in Figure 12 in which a stepped outer coaxial balloon 23a is provided having a distal extremity of lesser diameter than the proximal extremity of the balloon 23a. The proximal and distal portions of the balloon 23a can be of various lengths as desired.

In connection with the foregoing embodiments it also should be appreciated that the balloons provided on the multiple balloon catheters 11 and 101 can have various configurations. Thus, for example, as shown in Figure 13, the outer balloon 23b can be in the form of a tapered balloon having a taper which gradually decreases in a distal direction.

The balloon catheters 11 and 101 are high pressure substantially non-distensible balloons which can be distended at highly controlled and predictable rates. The balloons can be of various sizes ranging from 1 to 8 millimeters in diameter and 10 to 40 millimeters in length. The balloons can have various profiles, as for example straight, tapered, center or ends bulging portions. The catheters can be formed for over-the-wire use or can be provided with a fixed guide wire. The distal balloon can be utilized for maintaining an anatomical position for the catheter while other functions are being performed with the catheter, as for example deployment of a stent as hereinbefore described.

Various methods can be performed utilizing the multiple balloon catheter hereinbefore described. First it should be appreciated that the multiple balloon catheter can be utilized for delivering a stent without having a sheath covering the stent when that is desired as for example for purposes of economy. The method of

the present invention can be utilized with a multiple balloon stent delivery catheter which has an outer coaxial balloon which is a stepped balloon having proximal and distal portions with the distal portion having a diameter less than the diameter of the proximal portion. The stent can be mounted on the distal portion of smaller diameter. When this is the case, the sheath can be withdrawn to uncover the stent while still covering the proximal portion of the outer coaxial balloon. Thereafter, the outer coaxial balloon can be inflated to cause expansion of the uncovered distal portion to cause deployment of the stent. Alternatively, the stent can be mounted on the proximal portion of larger diameter and covered by the sheath. The distal portion of smaller diameter can then be advanced into the stenosis and can be utilized for predilating the stenosis. The outer coaxial balloon can then be delated and the catheter advanced so that the proximal portion of larger diameter with the stent thereon can be moved into the stenosis through the larger flow passage formed in inflation of the distal portion. Thereafter, the sheath can be withdrawn and the proximal portion of the distal balloon can be inflated to deploy the stent. The method can be utilized in a similar manner with the tapered outer coaxial balloon with the stent being carried by the tapered outer balloon and being advanced into the stenosis. The sheath can be withdrawn to uncover the stent after which the balloon can be inflated to deploy the stent.

Although the stent delivery catheter of the present invention has been described for delivering a single stent at a time, it should be appreciated that a plurality of shorter segmented stents all mounted on a balloon and, if necessary, on a longer balloon and then

deployed as hereinbefore described to treat longer lesions or a plurality of lesions in a vessel.

Although the present multiple balloon catheter has been described principally as a stent delivery catheter, it should be appreciated that it also can be utilized for dilating one or more stenoses in a vessel. This can be readily accomplished by deploying the catheter into the vessel as hereinbefore described and then advancing the distal balloon into a stenosis and dilating that stenosis to increase the size of the flow passage therethrough. The distal balloon can be then deflated and the catheter advanced to advance the coaxial outer and inner balloons into registration with the stenosis after which at least one of the inner and outer balloons can be inflated to increase the size of the flow passage in the stenosis. Alternatively, the inner coaxial balloon can be inflated followed by inflation of the outer coaxial balloon when a larger size flow passage is desired through the stenosis. It should be appreciated that if there are additional stenoses in the same vessel, the multiple balloons can be further advanced into the vessel to perform the same dilating procedure with additional stenoses in the vessel.

Although the catheters 11 and 101 have been described principally in connection with angioplasty procedures involving stenoses in vessels of the heart, it should be appreciated that the teaching herein is equally applicable to procedures in carotid arteries and other vessels in the human body.

CLAIMS:

1. A multiple balloon catheter for use in a vessel of a patient and for use with an inflation/deflation device comprising a flexible elongate tubular member having proximal and distal extremities, a distal balloon mounted on the distal extremity of the flexible elongate tubular member, coaxial inner and outer balloons mounted on the distal extremity of the flexible elongate member proximal of the distal balloon, said flexible elongate tubular member having balloon inflation lumens therein in communication with the interiors of the distal balloon and the inner and outer coaxial balloons and a manifold secured to the proximal extremity of the flexible elongate tubular member in communication with the inflation lumens and adjusted to be coupled to the inflation/deflation device and valve means carried by the inflation/deflation manifold for inflating the distal balloon in the inner and outer coaxial balloons one at a time or in unison without removal of the inflation/deflation device from the manifold

2. A catheter as in Claim 1 further comprising an expandable stent carried by the outer balloon, a protective sheath overlying the stent extending from the stent to the proximal extremity of the flexible elongate tubular member and means secured to the sheath for removing the sheath proximally to clear the stent.

3. A catheter as in Claim 2 wherein said means for removing the stent includes means for introducing a fluid into the annular space between the sheath and the flexible elongate tubular member.

4. A catheter as in Claim 2 wherein said means for removing the sheath includes a hemostasis valve assembly, said hemostasis valve assembly including a port for introducing a fluid into the annular space between the sheath and the flexible elongate tubular member.

5. A catheter as in Claim 1 wherein said inflation manifold further comprises ganged valve assemblies movable between open and closed positions.

6. A catheter as in Claim 4 further comprising a marker carried by the proximal extremity of the flexible elongate tubular member and spaced a predetermined distance from the hemostasis valve assembly when the sheath overlies the stent to provide a gauge visible to the human eye to designate the distance the hemostasis valve assembly must be retracted to uncover the stent.

7. A catheter as in Claim 1 wherein said outer balloon has a tapered configuration.

8. A catheter as in Claim 1 wherein said outer balloon has a stepped configuration.

9. A catheter as in Claim 1 further including an additional distal balloon proximal of the distal balloon and distal of the coaxial inner and outer balloons.

10. A catheter as in Claim 1 further comprising a stent carried by the coaxial inner and outer balloons.

11. A multiple balloon stent delivery catheter comprising a flexible elongate tubular member having

proximal and distal extremities, a distal balloon mounted on the distal extremity of the flexible elongate tubular member, coaxial inner and outer balloons mounted on the distal extremity of the flexible elongate member proximal of the distal balloon, the flexible elongate tubular member being formed with balloon inflation lumens in communication with the interiors of the distal balloon and the inner and outer balloons, a stent carried by the outer balloon, a sheath overlying the stent and extending proximally of the stent to the proximal extremity of the flexible elongate tubular member and an attachment secured to the proximal extremity of the sheath for facilitating withdrawing the sheath to uncover the stent.

12. A catheter as in Claim 11 further comprising a first radiopaque marker carried by the distal extremity of the flexible elongate member and being disposed substantially equidistant from the ends of the distal balloon, second and third radiopaque markers carried by the distal extremity of the flexible elongate tubular member spaced apart within the confines of the inner balloon whereby the position of the inner balloon can be distinguished from that of the position of the distal balloon.

13. A catheter as in Claim 11 further comprising a marker visible to the human eye carried by the proximal extremity of the flexible elongate tubular member and providing a visual indication of the distance the sheath must be retracted in order to uncover the stent.

14. A method for deploying a stent into a vessel having a blood flow lumen therein and having stenosis in the vessel at least partially occluding blood flow

in the vessel by the use of a multiple balloon stent delivery catheter having a distal extremity and a proximal extremity with a distal balloon mounted on the distal extremity and coaxial inner and outer balloons mounted on the distal extremity proximal of the distal extremity a stent carried by the outer balloon comprising advancing the distal extremity of the catheter until the distal balloon is advanced into the stenosis, inflating the distal balloon to increase the size of the flow passage in the stenosis, deflating the distal balloon, advancing the distal extremity of the catheter until the stent is disposed in the stenosis, inflating the distal balloon in the vessel to anchor the distal extremity of the catheter in the vessel, inflating at least one of the inner and outer coaxial balloons to expand the stent to embed the stent in the wall of the vessel, deflating the distal balloon and at least one of the inner and outer coaxial balloons and removing the catheter from the vessel.

15. A method as in Claim 14 by the use of a sheath covering the stent and extending to the proximal extremity of the flexible elongate tubular member and including the step of withdrawing the sheath to uncover the stent prior to inflating at least one of the inner and outer coaxial balloons.

16. A method as in Claim 15 further comprising the step of inflating the outer balloon after the inner balloon has been inflated to further expand the stent to further embed the stent in the vessel and thereafter deflating the outer balloon and the inner balloon and the distal balloon and removing the catheter from the vessel.

17. A method as in Claim 14 further comprising the steps of prior to inflation of the inner balloon or the outer balloon of utilizing the annular space between the sheath and the flexible elongate tubular member for flushing the stent.

18. A method as in Claim 14 for use with a guide wire and further comprising advancing the guide wire through the stenosis and thereafter advancing the catheter over the guide wire into the stenosis.

19. A method as in claim 14 wherein the multiple balloon stent delivery catheter has an outer coaxial balloon which is a stepped balloon having proximal and distal portions with the distal portion having a diameter less than the diameter of the proximal portion and further comprising the step of mounting the stent on the distal portion of smaller diameter and only withdrawing the sheath to uncover the stent while still covering the proximal portion of the outer coaxial balloon and thereafter inflating the outer coaxial balloon to inflate the uncovered distal portion.

20. A method as in Claim 14 wherein the multiple balloon stent delivery catheter has an outer coaxial balloon which is a stepped balloon having proximal and distal portions with the distal portion having a diameter less than the diameter of the proximal portion and further comprising the step of mounting the stent on the proximal portion of the larger diameter of the stepped balloon and further comprising the step of predilating the stenosis with the distal portion of the stepped balloon while the stent is covered by the sheath, thereafter deflating the stepped balloon, advancing the catheter so that the stent is disposed in the stenosis, retracting the sheath to expose the stent and inflating the outer coaxial stepped balloon to deploy the stent.

21. A method as in Claim 14 wherein the multiple balloon stent delivery catheter has an outer coaxial balloon which is tapered and having proximal and distal portions with the distal portion having a smaller diameter than the diameter of the proximal portion, and further comprising the step of mounting the stent on the tapered balloon.

22. A method as in Claim 14 wherein the stent is a plurality of stents carried by the outer balloon and further comprising the step of placing the plurality of stents on the outer balloon at the same time.

23. A method for performing angioplasty in a vessel having a blood flow lumen therein and having at least one stenosis in the vessel at least partially occluding blood flow in the vessel by the use of a multiple balloon delivery catheter having a distal extremity and a proximal extremity with a distal balloon mounted on the distal extremity and coaxial inner and outer balloons mounted on the distal extremity proximal of the distal balloon comprising advancing the distal extremity of the catheter until the distal balloon is advanced into the stenosis, inflating the distal balloon to increase the size of the flow passage in the stenosis, deflating the distal balloon, advancing the distal extremity of the catheter until the inner and outer coaxial balloon are disposed in the stenosis, inflating at least one of the inner and outer coaxial balloons to further increase the size of the flow passage in the stenosis, deflating the distal balloon and the at least one of the inner and outer coaxial balloons and removing the catheter from the vessel.

24. A method as in Claim 23 further including the step of first inflating the inner coaxial balloon and thereafter inflating the outer balloon to further increase the size of the flow passage through the stenosis.

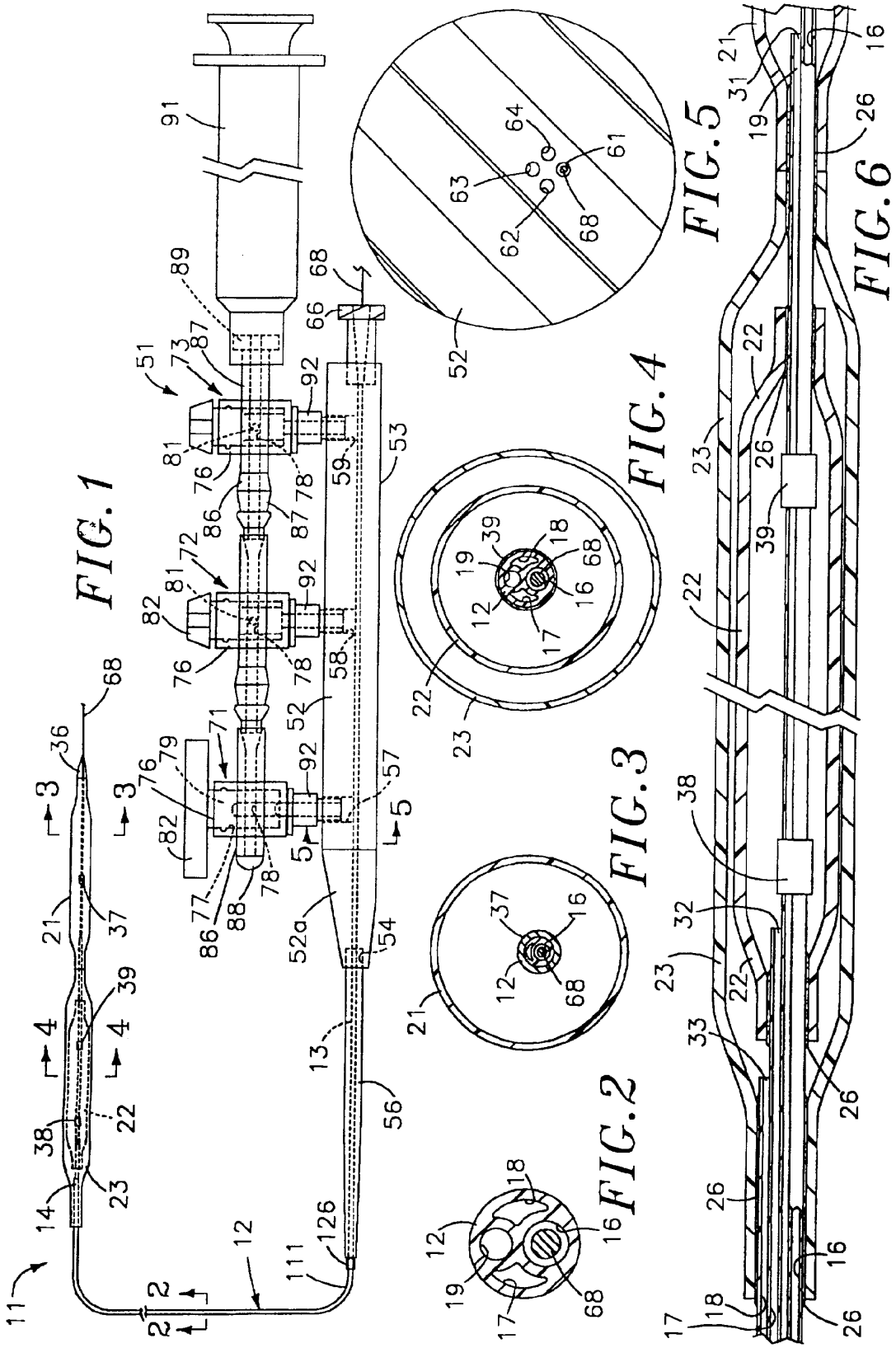

FIG. 1

FIG. 2

FIG. 3

FIG. 4

FIG. 5

FIG. 6

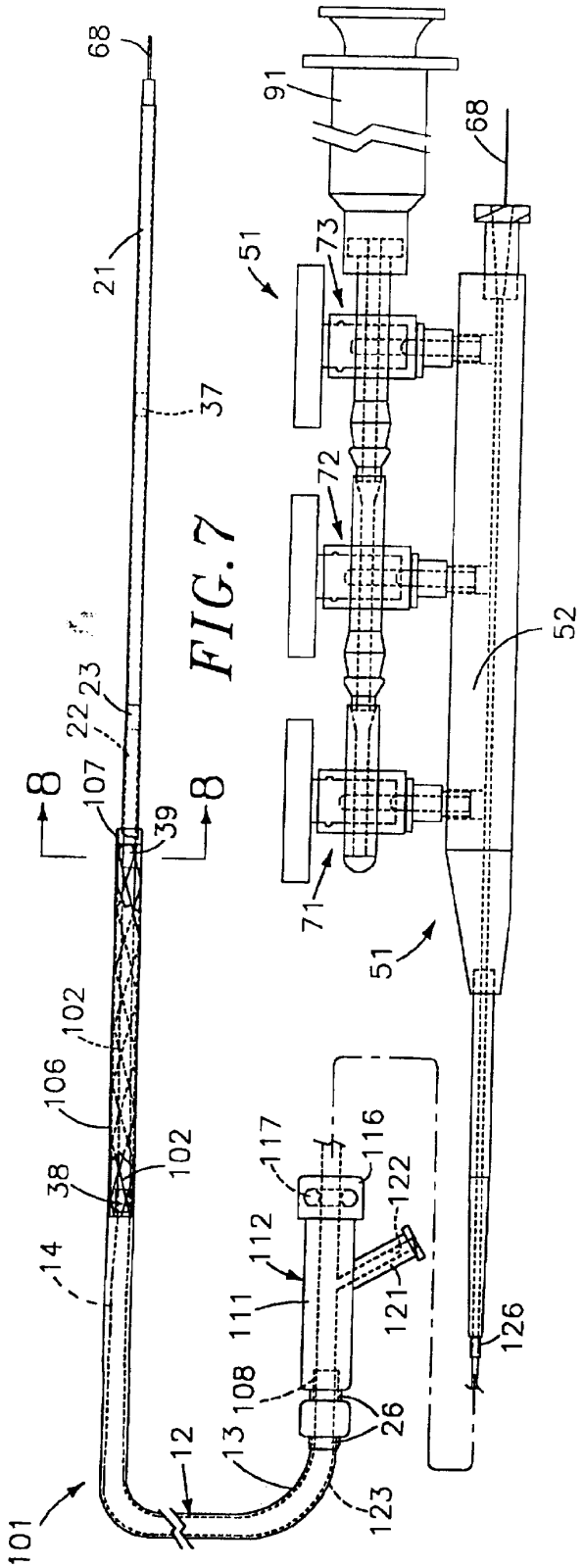

FIG. 7

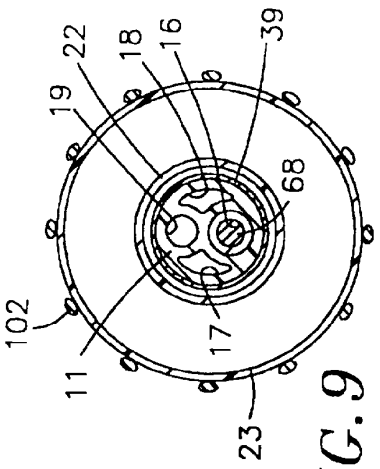

FIG. 9

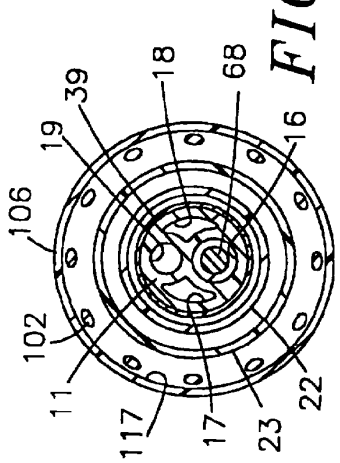

FIG. 8

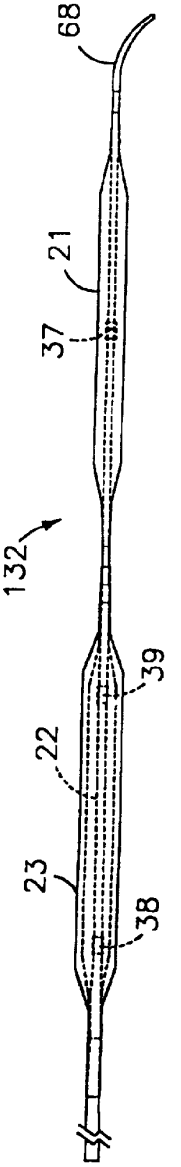

FIG. 10

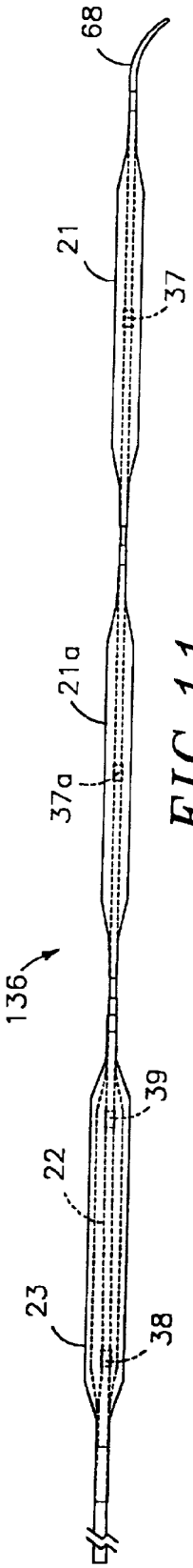

FIG. 11

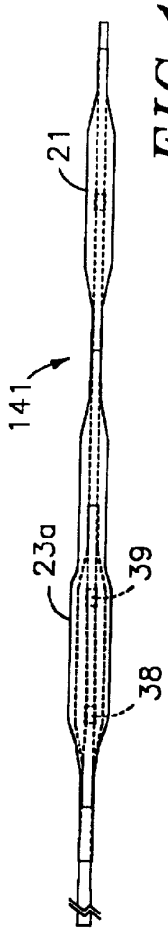

FIG. 12

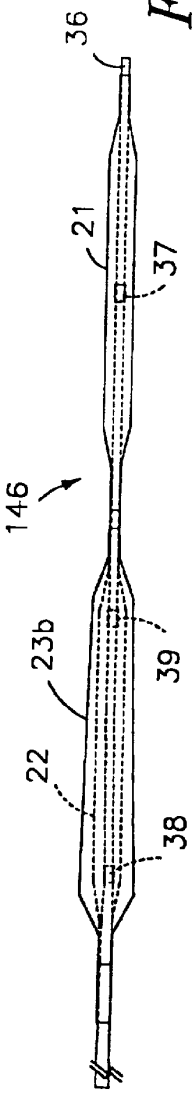

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/16326

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :606/194, 198

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)

U.S. : 606/194, 198

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

NONE

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

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,456,694 A (MARIN et al) 10 October 1995, entire document.	1-24
A, P	US 5,632,760 A (SHEIBAN et al) 27 May 1997, entire document.	1-24

☐ 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 document published on or after the international filing date

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 OCTOBER 1997	28 NOV 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer KEVIN TRUONG Telephone No. (703) 308-3767

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(54) Apparatus for deployment release of intraluminal prostheses

Vorrichtung zum Positionieren einer intraluminalen Prothese

Dispositif pour la mise an place d'une prothèse intraluminale

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99113204.4 / 0 943 302

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EP-A- 0 536 610
EP-A- 0 596 145
EP-A- 0 657 147
WO-A-93/17636
US-A- 4 793 348
US-A- 5 078 720

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EP 0 696 447 B1

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates generally to a delivery catheter for the endoluminal placement of resilient tubular prostheses, such as grafts, stents, stent-grafts, and other structures. More particularly, the present invention relates to a delivery catheter for the initial placing and optional repositioning of such intraluminal tubular protheses in body lumens, including blood vessels, for the treatment of abdominal and other aneurysms.

[0002] Vascular aneurysms are the result of abnormal dilation of a blood vessel, usually resulting from disease and/or genetic predisposition which can weaken the arterial wall and allow it to expand. While aneurysms can occur in any blood vessel, most occur in the aorta and peripheral arteries, with the majority of aortic aneurysms occurring in the abdominal aorta, usually beginning below the renal arteries and often extending distally into one or both of the iliac arteries.

[0003] Aortic aneurysms are most commonly treated in open surgical procedures where the diseased vessel segment is bypassed and repaired with an artificial vascular graft. While considered to be an effective surgical technique, particularly considering the alternative of a usually fatal ruptured abdominal aortic aneurysm, conventional vascular graft surgery suffers from a number of disadvantages. The surgical procedure is complex and requires experienced surgeons and well equipped surgical facilities. Even with the best surgeons and equipment, however, patients being treated frequently are elderly and weakened from cardiovascular and other diseases, reducing the number of eligible patients. Even for eligible patients prior to rupture, conventional aneurysm repair has a relatively high mortality rate, usually from 3% to 10%. Morbidity related to the conventional surgery includes myocardial infarction, renal failure, impotence, paralysis, and other conditions. Additionally, even with successful surgery, recovery takes several weeks, and often requires a lengthy hospital stay.

[0004] In order to overcome some or all of these drawbacks, endovascular graft placement for the treatment of aneurysms has been proposed. Although very promising, many of the proposed methods and apparatus suffer from other problems. In particular, delivery and placement of the endovascular graft within the vasculature can be problematic. Proper positioning and sizing of the endovascular graft is critical to the successful treatment of an aneurysm. With many endovascular graft structures and their associated delivery catheters, it is difficult or impossible to retract a partially released graft structure. Thus, improper initial placement of a vascular graft can sometimes require open surgical procedures for correction. Additionally, proper sizing of the graft can require maintenance of a large inventory of graft delivery catheters, where each catheter carries a graft having a different length and/or expansible diameter.

[0005] Furthermore, grafts are often resilient, biased to expand and anchor the graft within the body lumen. These resiliently expanding grafts are tightly compressed within the catheter and impose significant forces against the surrounding catheter bodies, often leading to excess friction between the graft and the catheter wall. These forces complicate the loading of the graft into the catheter, as well as the accurate release of grafts and stents in body lumens. Moreover, the catheters must maneuver the graft within the vascular system. Thus, the catheters are required to have flexible, elongate bodies which are particularly susceptible to the expanding graft, often resulting in invagination of the graft in the soft material of the catheter wall.

[0006] For these reasons, it would be desirable to provide an improved apparatus for endovascular placement of intraluminal protheses, including grafts, stents, and stent-grafts, for treating aneurysms and other conditions.

[0007] It would be particularly desirable to provide delivery catheters for the placement of endoluminal tubular prostheses which would facilitate the controlled release of resilient tubular prostheses. It would be particularly desirable to provide delivery catheters for the placement of endoluminal and other tubular prostheses which permit the repositioning and/or retrieval of partially released prostheses. It would be further desirable if such delivery catheters were able to contain the protheses firmly within the catheter until the final release of the prostheses into the blood vessel. It would also be particularly desirable to provide delivery catheters which reduce the frictional forces created by the resilient expansion against the catheter during loading and release of the prostheses.

2. Description of the Background Art

[0008] Vascular grafts and devices for their endoluminal placement are described in U.S. Patent Nos. 5,282,824; 5,242,399; 5,219,355; 5,211,658; 5,201,757; 5,192,297; 5,190,058; 5,158,548; 5,147,370; 5,104,399; 5,092,877; 5,078,726; 5,019,085; 4,990,151; 4,950,227; 4,913,141; 4,886,062; 4,820,298; 4,787,899; 4,617,932; 4,562,596; 4,577,631; and 4,140,126; and European Patent Publications 539,237; 533,511; 518,839; 518,704; 508 473; 505,686; 466 518; and 461 791. Catheters for placing vascular stents are described in U.S. Patent Nos. 5,192,297; 5,092,877; 5,089,005; 5,037,427; 4,969,890; and 4,886,062. Catheters carding a graft structure in a tube or capsule are described in U.S. Patent Nos. 5,275,622; 5,104,399; and 4,787,899; and EP466518. EP-A-364 420 describes a delivery catheter according to the preamble of inde-

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pendent claim 1.

SUMMARY OF THE INVENTION

[0009] The present invention provides a delivery catheter as defined in independent claim 1. Prefered embodiments are further specified in the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010]

Fig. 1 is a side view of a vascular graft which is exemplary of the type of radially compressible tubular prosthesis which may be placed using the delivery catheter of the present invention.

Figs. 2-18; Figs 19A-D; Figs 24A-C illustrate the use of a delivery catheter in placement of a radially compressible tubular prosthesis in a body lumen.

Figs. 20A and 20B;

Figs. 21A and 21B;

Figs. 22A and 22B; and

Figs. 23A and 23B illustrate embodiments of the retaining structure of the delivery catheter according to the invention.

Fig. 25 is a perspective view of another embodiment of a delivery catheter of the present invention, with a portion of the distal end broken away to disclose a prosthesis therein.

Figs. 26A and 26B illustrate the loading of a graft into the delivery catheter of Fig. 25.

Figs. 27A-27C illustrate the use of the delivery catheter of Fig. 25 in placement of a radially compressible tubular prosthesis in a body lumen.

Fig. 28 illustrates a preferred method of use of the delivery catheter of Fig. 25, in which tapered nosecone is withdrawn independently of the runners.

Fig. 29A is an exploded cross-sectional view of the delivery catheter of Fig. 25.

Fig. 29B is a cross-section of an alternative shaft structure and cover having increased flexibility.

Fig. 30 illustrates a housing at the proximal end of the delivery catheter of Fig. 25 which provides a mechanical advantage for withdrawing the cover.

Fig. 31 illustrates a delivery catheter cover having a rounded, atraumatic distal end with a split tip.

Fig. 32 illustrates a delivery catheter cover having runners imbedded within the distal end.

Figs. 33A and 33B are alternative cross-sectional views of a delivery catheter cover.

Fig. 34 illustrates a brace which restrains the prosthesis at a target location during deployment.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0011] The present invention provides a delivery catheter as defined in claim 1 for the endoluminal placement of intraluminal tubular prostheses, particularly grafts, stents, and stent-grafts. The tubular prostheses will be radially compressible, and the apparatus of the present invention will maintain the prostheses under compression in a narrow-diameter configuration while they are being introduced to the body lumen, typically during surgical cutdown or percutaneous introduction procedures. Placement of the tubular prosthesis is effected by releasing the prosthesis at a target location in the lumen. Thus, it is necessary that the prosthesis be sufficiently resilient and conformable to expand against the interior wall of the body lumen. It will be appreciated, however, that the prosthesis may be formed at least partly from malleable components which permit it to be subsequently further expanded, typically by inflation of a balloon within the lumen of the prosthesis.

[0012] The present invention will find greatest use in the percutaneous placement of endovascular prostheses for the treatment of diseases of the vasculature, particularly aneurysms, stenoses, and the like. Suitable prosthesis structures which may be deployed by the delivery catheter of the present invention are described in copending application Serial No. 08/255,681. One exemplary graft structure 10 is illustrated in Fig. 1. Prosthesis 10 comprises a perforate tubular frame 12 which includes a plurality of independent (non-connected) band members 14 separated from each other by small gaps 16. The tubular frame 12 is covered by an inner liner 18 and an outer liner 20, where the inner and outer liners together encase or sandwich the otherwise free-floating band members 14 therebetween. In order to secure the band members 14 in place, and secure the liners to the perforate tubular frame 12, the inner and outer liners are joined together along circumferential lines 22, preferably aligned with the gaps 16 between adjacent band members 14. The liners may be joined together by stitching, heat welding, ultrasonic welding, or the like. In the exemplary embodiment, the liners 18 and 20 are formed from polymeric sheet material and are joined together by ultrasonic welding. The band members 14 at each end of the graft 10 will have to be further secured to the liners 18 and 20. For example, they could be stitched, welded, or otherwise joined to the liners to hold them in place. The graft 10 will typically have a length in the range from about 50 mm to 500 mm, preferably from 80 mm to 200 mm, with a relaxed diameter in the range from about 4 mm to 45 mm, preferably being in the range from 5 mm to 25 mm. Such graft structures will be particularly suitable for treating vascular aneurysms.

[0013] In connection with the present invention, it has been discovered that the placement of resilient tubular prostheses imposes serious demands on delivery and imaging systems, as well as on the attending medical personnel. Prostheses are highly compressed within delivery catheters to allow maneuvering within the vascular system. The compressive forces have been found to lead to excessive friction during deployment from the delivery catheters of the prior art. Additionally, visuali-

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zation of compressed prostheses within the catheter is problematic, particularly when a branched prosthesis must be placed in a branching body lumen in a specific orientation.

[0014] The delivery catheters facilitate deployment of resilient prostheses by reducing friction at the prosthesis/catheter interface, avoiding any increase in the stiffness of the delivery system where it is not needed. It has been discovered that compressed prostheses are largely rigid, which reduces any penalty in flexibility imposed by including hard, friction-reducing runners around the prosthesis.

[0015] Referring now to Fig. 2, a delivery catheter 30 comprises a sheath 32 and a shaft or inner catheter body 34. The sheath 32 has a central lumen 36 extending from a distal end 38 to a proximal handle 40. The shaft 34 is slidably received within the central lumen 36 and has a distal end 42 and a proximal handle 44. The delivery catheter 30 receives a radially compressible tubular prosthesis P within the annular space between the outer surface of the shaft 34 and the inner surface of the lumen through sheath 32. For convenience, the prosthesis is illustrated as a radially compressed helical coil which expands by unwinding and axial shortening. The delivery catheters, however, can be used with virtually any radially compressible prosthesis, as described above.

[0016] The delivery catheter of Fig. 2 relies on maintaining the radial compression of prosthesis P by direct pressure from the sheath 32. As will be discussed in detail below in connection with Figs. 19-24, prosthesis compression may also be provided by a retaining structure which comprises a cover, spaced-apart anchors, or other equivalent structure which maintains the radial compression regardless of the position of the sheath. Using such embodiments, the prosthesis may be uncovered and located prior to release and radial expansion.

[0017] In the embodiment of Fig. 2, the prosthesis P is anchored by a plurality of penetrating stay members 50 which are circumferentially spaced-apart over the exterior of the shaft 34. The stays 50 will be spaced proximally from the distal end 42 of the shaft 34 by a distance which corresponds generally to that of the tubular prosthesis P which is to be maintained on the delivery catheter 30. The penetrating stays 50 will extend radially outward by a distance sufficient to engage the interior surface of the lumen 36 of the sheath 32. In that way, the penetrating stays 50 will be able to anchor the proximal end of the tubular prothesis P when it is held within the catheter. In particular, the prosthesis P will remain anchored as the sheath 32 is drawn proximally over the shaft 34, as illustrated in Figs. 3-5.

[0018] When initially placed in a body lumen L, the sheath 32 covers substantially the entire length of the prosthesis P with the penetrating stays 50 engaging the proximal portion of the prosthesis P, as illustrated in Fig. 3. The sheath 32 may then be retracted proximally, partially releasing the prosthesis P, as illustrated in Fig. 4. The proximal portion of the prosthesis P, however, remains anchored by the penetrating stays 50 so long as the sheath 32 remains positioned over the stays. Once the sheath 32 is withdrawn to the proximal side of the stays 50, as illustrated in Fig. 5, the prosthesis P will be fully released. Prior to such full release, however, the prosthesis P may be recaptured by advancing the sheath 32 in the distal direction relative to the shaft 32.

[0019] Referring now to Fig. 6, the catheter 30 may optionally be provided with a journal sleeve 60 near its proximal end. The journal sleeve 60 is preferably mechanically coupled to the shaft 34 by pins 62 which extend through slots 64 in the sheath 32. The journal sleeve 60 can be anchored within an introducer sleeve or other access device (not illustrated) which is used to provide percutaneous access to the body lumen being treated. After initial positioning of the catheter 30 so that the prosthesis P is located at the target location within the lumen, it is desirable to firmly anchor the catheter 30 within the introducer sheath. Journal sleeve 60 permits anchoring of the shaft 34 (which carries the prosthesis P) while allowing the sheath 34 to remain freely translatable relative to both the journal sleeve 60 and the catheter shaft 34.

[0020] The dimensions and materials of construction of the catheter 30 may vary widely, depending on the intended usage. For vascular applications, the catheter 30 will typically have a length in the range from about 50 cm to 250 cm, preferably from 100 cm to 200 cm, and a diameter in the length from about 3 mm to 8 mm, preferably from 4 mm to 6 mm. These dimensions generally refer to the exterior dimensions of the sheath 32. It will be appreciated that the catheter shaft 34 will have a smaller diameter, typically in the range from 1 mm to 5 mm, preferably from about 1.5 mm to 3 mm, allowing a sufficient annular space therebetween to receive the prosthesis P. The catheter shaft will also have a length which is greater than that of the sheath, usually by a distance sufficient to accommodate the length of the prosthesis which is being delivered, typically from 5 cm to 25 cm, preferably from 7.5 cm to 15 cm. The catheters will generally be constructed of natural or synthetic polymers, such as silicone rubber, natural rubber, polyvinylchloride, polyurethanes, polyesters, polyethylenes, polytetrafluoro-ethylenes (PTFE), and the like. Optionally, the catheter sheath and shaft may be formed as composites having a reinforcement layer incorporated within a polymeric body in order to enhance strength, flexibility, and toughness. Suitable reinforcement layers include wire mesh layers, braided layers, and the like. The tubular members of the present invention may be formed by extrusion, with the tubular diameter modified by heat expansion and/or shrinkage using conventional techniques. Particular techniques for forming vascular and other catheters suitable for use in the present invention are well described in the patent and medical literature.

[0021] Referring now to Figs. 7 and 8, a catheter 70

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having a sheath 72 with a deployable flared end will be described. Catheter 70 comprises the sheath 72, a shaft 74, and a prosthesis-containment sheath 76. A prosthesis P is contained between the sheath 72 and the shaft 74, generally as described above in connection with delivery catheter 30. The sheath 72, however, differs from that of sheath 32 in that sheath 72 has an outwardly flared distal end 78, as best seen in Fig. 8. The distal end 78 is a resilient structure, typically formed from the material of the sheath 72 itself and optionally having a plurality of elastic reinforcement elements imbedded therein to maintain the desired flared configuration, and may be radially collapsed by the containment sleeve 76, as illustrated in Fig. 7. The flared distal end of the sheath 72 is advantageous since it facilitates the release and recapture of the prosthesis P.

[0022] The flared distal end 78 of catheter 70 will usually have a fully expanded diameter d at the distal tip 79 in the range from 10 mm to 30 mm, preferably from 15 mm to 25 mm. The distal tip of diameter d will usually be greater than the diameter of the proximal portions of the sheath 72 by a factor from 2 to 8, preferably being from 2.5 to 5. The flare will extend over an axial length ℓ in the range from 3 mm to 30 mm, preferably from 5 mm to 20 mm. These flare dimensions will generally be applicable to all embodiments of the present invention where the prosthesis-containment sheath has a flared distal end.

[0023] Referring now to Figs. 9 and 10, a catheter 80 having an alternate mechanism for deploying a flared distal tip on a prosthesis-containing sheath structure 82 will be described. Catheter 80 comprises the sheath 82 having an annular lumen 84 extending from its proximal end 86 to its distal end 88. The annular lumen 84 is connected to an inflation port 90 on a proximal housing 92. A shaft 94 extends through the central lumen of the sheath 82 and carries a prosthesis P near it distal end.

[0024] The distal end of the sheath 82 is formed so that, upon inflation with a non-compressible fluid medium, typically saline or other biocompatible liquid, it assumes the outwardly flared configuration shown in Fig. 10. The structure is sufficiently elastic, however, so that removal of the inflation medium will permit the sheath 82 to resume its non-flared configuration, as illustrated in Fig. 9. Flaring of the distal end of sheath 82 facilitates both release and recapture of the prosthesis P, as with the embodiment of Figs. 7 and 8.

[0025] Conveniently, distal end 88 of sheath structure 82 comprises an outer layer 91 secured to an inner layer 92 at their respective distal ends. Both layers 91 and 92 will be composed of a flexible, non-distendable material, such as polyethylene terephthalate (PET), or other reinforced material, such as an elastomeric or non-elastomeric material reinforced with a non-distendable mesh. The outer layer will be shorter than the inner layer so that when the annular lumen 84 is inflated, the distal end will flare as shown in Fig. 10.

[0026] Alternative mechanisms for providing a deployable flare at the distal end of a prosthesis-containment sheath are illustrated in Figs. 11 and 12. The sheath 100 in Fig. 11 has a distal end 102 including a plurality of axially aligned, circumferentially spaced-apart heat memory alloy members 104. The heat memory alloys are selected to have a temperature transition where they assume a straight, non-flared configuration at low temperatures, as illustrated in full line in Fig. 11. At body temperature, however, the members 104 assume an outwardly flared configuration, as illustrated in broken line. Suitable alloy materials include nickel-titanium alloys which may be heat treated to provide the proper shapes and transition temperature.

[0027] Sheath 110 illustrated in Fig. 12 has a resilient, flared structure formed at its distal end 112. The flared distal end 112 is contained in an end cap 114 which may be distally advanced (as illustrated in broken line) by shaft 116 to release the flared end structure, as shown in broken line.

[0028] An alternative structure for facilitating the release and recapture of a prosthesis from a delivery catheter is illustrated in Figs. 13-15. A catheter 118 is provided with a sheath 120, shaft 122, and penetrating stays 124, generally as described above in connection with Figs. 2-5.

[0029] The catheter 118 further includes an eversible membrane 126 which is attached at a first end 128 to the shaft 122, and at a second end 130 to the inner surface of the lumen of sheath 120. The membrane 126 will be formed from a flexible, preferably lubricous and non-compliant material, such as PET, nylon, polytetrafluoroethylene (PTFE), any of which may be wire- or braid-reinforced, or the like. The prosthesis P will remain anchored on the shaft 122 by penetrating stays 124 as the sheath 120 is partially withdrawn (Fig. 14). The membrane 126 folds back over itself (everts) as the sheath 120 is retracted so that there are always two layers of the membrane between the distal end of the sheath and the prosthesis P. The double-layer structure of the membrane provides a high degree of lubricity during the release and optional recapture of the prosthesis P. Complete release of the prosthesis P is illustrated in Fig. 15.

[0030] Referring now to Fig. 16, an alternative prosthesis anchoring mechanism for a delivery catheter 150 is illustrated. The delivery catheter 150 includes a shaft 152 having a pair of axially spaced-apart stays 154 and 156. A pull wire 158 extends through a lumen 160 of shaft 152 and through protrusions on each of the stays 154 and 156. A guide wire GW is received through the shaft 152 in order to permit vascular introduction by conventional techniques. The radially compressible prosthesis P (such as graft 10) is placed over the distal end of the shaft extension 162, generally being aligned between the stays 154 and 156. The pull wire 158 is then advanced through the stays 154 and 156 so that it passes through each end of the prosthesis P to maintain the prosthesis P in place until the pull wire is withdrawn. While the pull wire 158 remains in place, a prosthesis-

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containment sheath 164 may be axially advanced over the graft to radially compress the graft into its desired low profile diameter. The sheath 164 includes a flared (i.e., outwardly tapered) distal end 166 to facilitate advancing the sheath over the prosthesis P, in particular so that the prosthesis P may be recaptured when it is partially deployed. The outward flare may be permanently fixed in the body of the sheath, but will preferably be selectively deployable between the flared and non-flared configuration, using any of the mechanisms described above.

[0031] Referring now to Fig. 17 and 18, a prosthesis cartridge 200 comprises a sheath extension 202 having a distal end 204 and a proximal end 206. A prosthesis P is contained within the sheath extension 202 and is mounted over a shaft extension 208. Typically, the prosthesis P will be anchored on the shaft extension 208 using penetrating stays (not shown) as described in connection with previous embodiments. The prosthesis cartridge 200 is releasably connectable to a delivery catheter 221 including a sheath 220 (or other elongate member) and shaft 222. The proximal end of the cartridge sheath 202 is configured to couple to the distal end of the catheter sheath 220. Similarly, the proximal end of the shaft extension 208 is configured to selectively couple to the distal end of the shaft 222. In this way, a user can select the diameter, length, and other characteristics of the prosthesis P which are desired to be employed in a procedure. The prosthesis, which is part of cartridge 200 (and preferably packaged in a separate, sterile pouch or other container) may then be attached to the distal end of the delivery catheter (which is separately packaged in a sterile pouch or other container) having the necessary sheath and shaft connections. The catheter sheath 220 could alternatively comprise other, non-tubular structures (elongate members). It is necessary only that the elongate member be able to connect to the sheath extension 202 to be proximally retracted over the prothesis P (and optionally distally advanced) to effect release and recapture of the prosthesis as described above.

[0032] Referring now to Figs. 19A-19D, yet another embodiment of a delivery catheter 250 will be described. Delivery catheter 250 includes flexible shaft 252 having a central lumen for receiving a guide wire GW. A sheath 254 is slidably mounted over the shaft 252, generally as described for previous embodiments. The catheter 250 differs from previous embodiments, however, in the nature of the retaining structure which is used for holding prosthesis P in place on the flexible shaft 252. The retaining structure comprises a distal anchor 256, which is conveniently in the form of a cap or other receptacle which can receive a distal end of the prosthesis therein. A proximal anchor 258 is mounted at the distal end of a sliding tube 260. As shown in Fig. 19A, when the catheter 250 is introduced to blood vessel BV the prosthesis P will be maintained in its collapsed configuration by the anchors 256 and 258, and sheath 254 will cover the prothesis and anchor structures.

[0033] After introduction, as illustrated in Fig. 19B, the sheath 254 may be withdrawn proximally to expose the prosthesis P. The prosthesis P, however, remains radially compressed by the anchors 256 and 258, even after the sheath 254 has been fully withdrawn, as illustrated in Fig. 19C. The prosthesis P may be fully released by moving the anchors 256 and 218 axially apart in order to free the compressed ends of the prosthesis, as illustrated in Fig. 19D. Prior to release, however, the exposed prostheses can be carefully positioned without interference from the sheath 254. It is a particular advantage that such partial release is achieved while still being able to readily recapture the prosthesis by readvancing the sheath 254.

[0034] Referring now to Figs. 20A and 20B, an embodiment of a delivery catheter constructed in accordance with the principles of the present invention is illustrated. The retaining structure 280 will fully cover and compress the prostheses P, and will usually be maintained within an outer sheath (not shown) equivalent to the delivery catheter sheaths illustrated previously. The retaining structure 280 will maintain radial compression of the prosthesis P within the sheath, regardless of whether the sheath covers the prosthesis. Thus, the sheath of the associated delivery catheter may be proximally retracted prior to release of the prostheses P.

[0035] The retaining structure 280 comprises a helically wound ribbon, which may optionally be formed as a helically scored or perforated cylinder. The retaining structure 280 is mounted on flexible shaft 284, typically with a distal portion of the helical ribbon attached directly or indirectly to the shaft. A pull cord 286 is attached to a proximal end of the helical ribbon, and the ribbon may be withdrawn from over the prostheses P by pulling proximally on the pull cord, as illustrated in Fig. 20b.

[0036] Yet another embodiment of the retaining structure is illustrated in Figs. 21A and 21B. Retaining structure 300 comprises a cylinder 302 having a helical wire 304 disposed over its surface. The wire 304, when pulled from the cylinder 302, separates adjacent sections of the cylinder so that they break apart, as illustrated in Fig. 21B. Thus, by attaching a first pull cord 306 to a proximal end of the wire 304, the wire can be withdrawn by pulling proximally. The resulting ribbon-like section of the cylinder may then be withdrawn by pulling on a second pull cord 308, also as shown in Fig. 21B. The prostheses P is thus released from the catheter.

[0037] Yet another embodiment of a retaining structure is illustrated in Figs. 22A and 22B structure 320 is a cylinder 322 having a single axial break line 324 formed along one side thereof. It will be appreciated that more than one axial break line may be provided. Only one is illustrated, however, for convenience. A slide structure 326 secured to the cylinder 322 at a distal end of the break line 324. A pull cord 328 is attached to the slide structure 326. Optionally, multiple pull cords could be used. The slide structure 326 may be drawn proxi-

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mally in order to open the breakline 324 in the manner of a zipper, as illustrated in Fig. 22B. In this way, the prostheses P can be released.

[0038] Yet another embodiment of the retaining structure 340 is illustrated in Figs. 23A and 23B. The retaining structure 340 comprises a plurality of individual resilient axial members 342 which are captured at their distal ends and an anchor 344. The axial elements 342 are permanently mounted in a ring structure 346 at the distal end of catheter body 348. The anchor 344 is secured at the distal end of a flexible shaft 350. The axial elements 342 are spring-loaded so that when the anchor 344 is moved distally by advancing the shaft 350, as illustrated in Fig. 23b, the individual elements will spring radially apart at the distal end. In this way, prosthesis P can be released from the retaining structure 340.

[0039] Referring now to Figs. 24A-24C, another embodiment of a retaining structure not falling under the scope of the claims will be described. The retaining structure 360 is a thin-walled tube 362 which is weakened along a circumferential (or helical) line 364, typically in the form of a score, perforation, or the like. Flexible shaft 366 secured to a distal end cap 368. By axially advancing the shaft 366, the end cap 368 and the attached portion of cylinder 362 between the score line 364 and the end cap will be pulled away from the remainder of the cylinder 362. In this way, the prostheses P can be released. The prostheses is first partially released, as shown in Fig. 24B. After the cylinder segments are fully spaced-apart, the prostheses is fully released, as shown in Fig. 24C.

[0040] Referring now to Fig. 25, a delivery catheter 430 constructed in accordance with the principles of the present invention comprises a tubular cover 432 and a shaft or inner catheter body 434. Cover 432 has a central lumen 36 extending from a proximal end 438 to a distal end 440. Shaft 434 is slidably received within central lumen 436 and extends proximally of the proximal end of cover 432.

[0041] A plurality of runners 442 extend distally from the distal end of shaft 434. Runners 442 line a portion of the inner surface of lumen 436, and slide within the lumen with the shaft. Shaft 434 also has a lumen, in which a core shaft 444 is slidably disposed. Core shaft 444 has a guidewire lumen 446. Guidewire lumen 446 optionally receives an intravascular ultrasound (IVUS) imaging transducer to provide imaging prior to, during, and after deployment of the prosthesis. Nosecone 448 is fixed to the distal end of core shaft 444, and can therefore move independently of runners 442.

[0042] Graft 10 is radially compressed and restrained within the plurality of runners 442. In turn, cover 432 prevents runners 442 from expanding outward. Runners 442 are formed from a hard material, and distribute the expansion load of prosthesis 10 over the inner surface of central lumen 436. Advantageously, the prosthesis does not invaginate in the lumen surface, and is thus able to slide relative to the cover in response to a moderate distal force. In the embodiment of Fig. 25, the deploying force is applied proximally against a slider 450 attached to distal end 438 of cover 430, while holding a lure fitting 452 at the distal end of shaft 434. An additional lure adaptor 454 at the distal end of core shaft 444 allows the core shaft to be releasably secured to the shaft 434.

[0043] Referring now to Figs. 26A and 26B, loading of graft 10 into the distal end 440 of cover 432 is facilitated by use of runners 442. As seen in Fig. 26A, extending shaft 434 distally allows runners 442 to flex outward. Graft 10 may be inserted between the outward flexed runners and compressed by withdrawing runners 442 and shaft 434 into the distal end 440 of cover 432. Nosecone 448 and core shaft 444 are shown attached to shaft 434 during loading. Alternatively, nosecone 448 may be attached to core shaft 444 after the loading of prosthesis 10. Prosthesis 10 is preferably formed of a heat memory alloy such as Nitinol™. To maintain graft 10 in a compressed state, the loading process may be done in a cold environment, such as that provided by a cold spray, liquid nitrogen, freon, an air vortex, or the like.

[0044] Referring now to Figs. 27A through 28, placement of graft 10 within a body lumen 460 begins by positioning catheter 430 at a target location. As illustrated in Fig. 27B, graft 10 is allowed to expand by retracting cover 432, proximally relative to shaft 434 and core shaft 444. As cover 432 is retracted, runners 442 maintain their axial position, sliding over the inner surface of cover 432. Once the graft 10 has fully expanded within body lumen 60, it is axially anchored by expansion against the lumen wall between the runners. Runners 442 may then be retracted proximally with shaft 434 and nosecone 448. The hard surface of runner 442 allows shaft 434 to be retracted smoothly, with little possibility of dragging graft 10 from the target position. The graft cover may also help to reduce friction during deployment. The possibility of dragging the prosthesis is further reduced by retracting nosecone 448 having a tapered proximal end 464 independently from shaft 434, as illustrated in Fig. 28. Finally, it will be recognized that the runners may also be used to help recapture a partially-deployed prosthesis.

[0045] Referring now to Fig. 29A, the elements of the present graft delivery catheter will be described. Cover 432 must be strong enough to withstand the expansion force of graft 10 but must also be flexible to allow intravascular atraumatic maneuvering. Cover 432 is optionally formed of a high strength thermoplastic elastomer such as Hytrel™. Alternatively, cover 432 may be formed of a braided reinforced polymer tubing or a linear reinforced tubing, preferably having fibers of a polyamide such as Kevlar™, Spectra™, or the like, embedded to improve tensile strength without reducing flexibility. Preferably, the cover includes a radiopaque contrast medium, e.g., a B_4SO_4 compound, to allow imaging of the placement of catheter 30 within a body lumen using

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fluoroscopy. Shaft 434 is preferably formed from PEEK, nylon, or the like, to provide column strength. Runners 442 are formed from a high strength biocompatible alloy such as Nitinol™, stainless steel, or a stainless steel alloy. Runners 442 are bonded to shaft 434, preferably being laminated between inner and outer layers of nylon, a thermoplastic elastomer such as Pebax™, or the like. Core shaft 444 is also preferably formed of PEEK. Nosecone 448 may be formed of stainless steel and bonded to the distal end of core shaft 444, or may alternatively be molded of a radiopaque plastic comprising Pebax™, nylon, Hytrel™, or the like. In any case, nosecone 448 preferably includes a radiopaque element, thereby giving an indication of the location of the distal end of graft 10 during fluoroscopically guided prostheses placement. In certain embodiments, core shaft 444 further supports marker ring 466, comprising platinum, barium, or the like, to provide a sharp radiographic contrast. Optionally, distal force imparting structure 467 is bonded to the core shaft to slide the compressed prosthesis distally over the runners.

[0046] Referring now to Fig. 29B, a helical shaft 435 provides high column strength with flexibility. Helical shaft 435 is formed from a tightly wound, high strength metal, preferably comprising stainless steel. Helical shaft 435 is easily welded to runners 442, where similar metals are used for both. Alternatively, runners 442 are laminated to helical shaft 435 with inner and/or outer layers of nylon, Pebax™, or the like. A composite cover 433 comprising polymer reinforced tubing having braided or linear Kevlar™, Spectra™, or the like, further enhances flexibility of the delivery catheter of the present invention.

[0047] The delivery catheters of the present invention significantly reduce the force required to deploy a prosthesis within a body lumen. Nonetheless, the force required to withdraw cover 432 remains substantial. For this reason, the present invention further provides a housing 470 to be attached to the distal end of shaft 434, as illustrated in Fig. 30. Rotation of handle 472 moves follower 474 along a linear screw. Slider 450 at the proximal end of cover 432 is driven axially by the movement of the follower. Cover 432 is withdrawn during deployment of the prosthesis by articulating handle 472 so as to drive slider 450 toward lure fitting 452 at the proximal end of shaft 434. The force required to withdraw the cover is typically on the order of 1 to 10 lbs., requiring only a modest mechanical advantage. However, a mechanical advantage ratio in the range from 5 to 50, as measured from the linear travel at the outside edge of handle 472 to the linear motion of follower 474, provides a highly controlled deployment. Clearly, a wide variety of mechanical linkages are available to provide such a mechanical advantage. It is particularly advantageous to provide a mechanism which allows manipulation with a single hand, as this leaves the alternate hand free to manipulate the cover relative to an introducer sheath. It will be noted that housing 470 allows independent manipulation of core shaft 444 using second lure fitting 454, as described above regarding Fig. 28.

[0048] Referring now to Fig. 31, an alternative cover 480 provides an atraumatic distal end 482 with a reduced nosecone diameter, or, alternatively, no nosecone at the distal end of core shaft 444. Atraumatic cover 480 includes a series of splits 484 to allow the distal tip of atraumatic cover 480 to open during deployment of prosthesis 10.

[0049] Referring now to Fig. 32, a further alternative cover 490, having runners 492 embedded within the central lumen, will also reduce the friction between the prosthesis and the cover during prosthesis placement. Furthermore, such a structure eliminates any danger of injury to the walls of a body lumen during placement by a distal movement of the exposed runners. Moreover, similar safety advantages could be obtained using the delivery catheter of Fig. 25 by retaining runners 442 within cover 432 during deployment of prosthesis 10. An alternative structure must be provided to apply a distal force against the prosthesis, such as distal force imparting structure 467 shown in Fig. 29A.

[0050] Referring now to Figs. 33A and 33B, alternative cross sections 494 and 496 for a delivery catheter tubular cover or shaft will provide additional column strength without a corresponding increase in stiffness. Slots 495 are also suitable for receiving the runners, thus forming the runner/shaft laminated bond. Indents 497 may receive the free distal portion of the runners to prevent rotation of the prosthesis relative to the cover during manipulation of the shaft. Alternatively, a smooth cover lumen facilitates such rotation by allowing the runners to slidingly rotate against the cover lumen surface.

[0051] Referring now to Fig. 34, a brace 590 optionally restrains the prosthesis at the target location while withdrawing cover 432. Brace 590 attaches to introducer sheath 580 with a locking collar 592. Bar 594 extends proximally from locking collar 592, and is slidably received by tabs 596 protruding from housing 470. Once the prosthesis is positioned at the target location, a set screw 598 is tightened to fix the distance between the proximal end of delivery catheter 430 and the introduction sheath 580. Rotating handle 472 thus withdraws cover 430 proximally through introduction sheath 580 without distally advancing shaft 434. This minimizes the danger of advancing the exposed runners into the lumen wall during deployment, and thus allows deployment by a single surgeon. The compressive load on bar 594 is reduced by friction reducer tube 570.

[0052] A wide variety of compression bearing structures could be used in place of bar 590. A telescoping tube with single or multiple overlapping sections having set screws would eliminate the protruding proximal end of the rod. Such a telescoping tube may optionally surround catheter 430 between the introducer sheath and housing. Alternatively, a flexible tube having good column stiffness disposed over the delivery catheter also prevents axial movement of the prosthesis, and avoids

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the long, rigid, and potentially cumbersome bar structure. Such a flexible tube preferably comprises a tightly wound coil analogous to flexible shaft 435 shown in Fig. 29B. Although a fixed length tube may be used, telescoping flexible overlapped tubes, usually having a locking device such as set screws, compressive clamps, or the like, are preferred.

[0053] The brace of the present invention may advantageously be used with alternative proximal housings having a wide variety of mechanisms for translating the cover relative to the shaft, including electric motors, foot operated linkages, and the like.

[0054] Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity and understanding, certain changes and modifications will be obvious to those of skill in the art. For example, the present cover and/or runners may be attached to the elongate shaft as a cartridge, preferably preloaded with a prosthesis. Thus, the scope of the present invention is limited only by the appended claims.

Claims

1. A delivery catheter for positioning radially compressible prostheses (P), comprising an elongate flexible shaft (350, 444) having a proximal end and a distal end, a retaining structure (280, 300, 320, 340) near the distal end of the shaft (350, 444) which releasably holds the axial position of the prosthesis (P) on the shaft (350, 444), and a sheath (254, 434) slidably received over the shaft (350, 444) to cover the prosthesis (P) while the prosthesis (P) is held on the shaft (350, 444) by the retaining structure (280, 300, 320, 340) which comprises means (282, 302, 322, 342, 442) for circumferentially supporting the prosthesis (P) within the sheath (254, 434), **characterized** in that the retaining structure (280, 300, 320, 340) is adapted to extend from a proximal end of the prosthesis (P) to the distal end of the prosthesis (P) so that said means (282, 302, 322, 342, 442) for circumferentially supporting the prosthesis (P) supports the prosthesis (P) over its full length.

2. The catheter of claim 1, characterized in that the supporting means comprises a plurality of axial elements (342, 442) attached to the shaft (350).

3. The catheter of claim 2, characterized in that the elements (342, 442) are flexible radially outwardly to release the prosthesis (P).

4. The catheter of claim 3, characterized in that the elements (442) are runners having proximal ends being affixed together.

5. The catheter of claim 4, characterized in that the proximal ends of the runners (442) are affixed to the sheath (434).

6. The catheter of claim 5, characterized in that the supporting means comprises a cover (432) releasably disposed over the elements (442).

7. The catheter of claim 1, characterized in that the supporting means comprises a cover (282, 302, 322) releasably disposed over the prosthesis (P).

8. The catheter of anyone of the claims 1 to 7, characterized in that the retaining structure (280, 300, 320, 340) extends between the prosthesis (P) and the surrounding sheath (254, 434).

9. The catheter of anyone of the claims 1 to 8, characterized in that the sheath (254, 434) comprises a flexible polymer material and the retaining structure (280, 300, 320, 340) a material which is harder than that of the sheath (254, 434).

10. The catheter of anyone of the claims 1 to 9, characterized in that a deployable outwardly flarable distal end and means for reconfiguring the distal end of the sheath (254, 434) between a non-flared and a flared configuration are provided.

11. The catheter of anyone of the claims 1 to 10, characterized in that a shaft extension (208) coupling at the distal end of the shaft (222) and a sheath extension (202) coupling at the distal end of the sheath (220) are provided, the prosthesis (P) being radially compressed over the shaft extension (208) and within the sheath extension (202).

Patentansprüche

1. Einführkatheter zum Positionieren radial komprimierbarer Prothesen (P), mit einem langen, flexiblen Schaft (350, 444), der ein proximales Ende und ein distales Ende besitzt, einer Haltestruktur (280, 300, 320, 340) in der Nähe des distalen Endes des Schafts (350, 444), die die axiale Position der Prothese (P) am Schaft (350, 444) lösbar hält, und einer Hülse (254, 434), die über dem Schaft (350, 444) gleitend aufgenommen ist, um die Prothese (P) zu bedecken, während die Prothese (P) auf dem Schaft (350, 444) durch die Haltestruktur (280, 300, 320, 340) gehalten wird, die eine Einrichtung (282, 302, 322, 342, 442) umfaßt, um die Prothese (P) in der Hülse (254, 434) in Umfangsrichtugn zu unterstützen, **dadurch gekennzeichnet**, daß die Haltestruktur (280, 300, 320, 340) so beschaffen ist, daß sie sich von einem proximalen Ende der Prothese (P) zum distalen Ende der Prothese (P) erstreckt,

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so daß die Einrichtung (282, 302, 322, 342, 442) zum Stützen der Prothese (P) in Umfangsrichtung die Prothese (P) auf ihrer gesamten Länge stützt.

2. Katheter nach Anspruch 1, dadurch gekennzeichnet, daß die Stützeinrichtung mehrere axiale Elemente (342, 442) umfaßt, die am Schaft (350) befestigt sind.

3. Katheter nach Anspruch 2, dadurch gekennzeichnet, daß die Elemente (342, 442) radial auswärts flexibel sind, um die Prothese (P) freizugeben.

4. Katheter nach Anspruch 3, dadurch gekennzeichnet, daß die Elemente (442) Kufen sind, deren proximale Enden aneinander befestigt sind.

5. Katheter nach Anspruch 4, dadurch gekennzeichnet, daß die proximalen Enden der Kufen (442) an der Hülse (434) befestigt sind.

6. Katheter nach Anspruch 5, dadurch gekennzeichnet, daß die Stützeinrichtung eine Abdeckung (432) aufweist, die über den Elementen (442) lösbar angeordnet ist.

7. Katheter nach Anspruch 1, dadurch gekennzeichnet, daß die Stützeinrichtung eine Abdeckung (282, 302, 322) umfaßt, die über der Prothese (P) lösbar angeordnet ist.

8. Katheter nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß sich die Haltestruktur (280, 300, 320, 340) zwischen der Prothese (P) und der umgebenden Hülse (254, 434) erstreckt.

9. Katheter nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß die Hülse (254, 434) ein flexibles Polymermaterial umfaßt und die Haltestruktur (280, 300, 320, 340) ein Material, das härter als dasjenige der Hülse (254, 434) ist, umfaßt.

10. Katheter nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß ein nach außen entfaltbares, bauschbares distales Ende und eine Einrichtung zum Umkonfigurieren des distalen Endes der Hülse (254, 434) zwischen einer nicht gebauschten und einer gebauschten Konfiguration vorgesehen sind.

11. Katheter nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, daß eine Schaftverlängerung (208), die mit dem distalen Ende des Schafts (222) gekoppelt ist, und eine Hülsenverlängerung (202), die mit dem distalen Ende der Hülse (220) gekoppelt ist, vorgesehen sind, wobei die Prothese (P) über der Schaftverlängerung (208) und in der Hülsenverlängerung (202) radial komprimiert ist.

Revendications

1. Cathéter d'introduction destiné à positionner radialement des prothèses pouvant être compressées (P), comprenant une tige flexible allongée (350, 444) présentant une extrémité proximale et une extrémité distale, une structure de retenue (280, 300, 320, 340) à proximité de l'extrémité distale de la tige (350, 444) qui maintient de manière amovible la position axiale de la prothèse (P) sur la tige (350, 444), et une gaine (254, 434) reçue de manière à pouvoir coulisser sur la tige (350, 444) afin de recouvrir la prothèse (P) lorsque la prothèse (P) est maintenue sur la tige (350, 444) par la structure de retenue (280, 300, 320, 340) qui comprend des moyens (282, 302, 322, 342, 442) destinés à supporter circonférentiellement la prothèse (P) à l'intérieur de la gaine (254, 434), caractérisé en ce que la structure de retenue (280, 300 320, 340) est conçue de manière à s'étendre depuis une extrémité proximale de la prothèse (P) vers l'extrémité distale de la prothèse (P) de telle sorte que lesdits moyens (282, 302, 322, 342, 442) destinés à supporter circonférentiellement la prothèse (P) supportent la prothèse (P) sur la totalité de sa longueur.

2. Cathéter selon la revendication 1, caractérisé en ce que les moyens support comprennent une pluralité d'éléments axiaux (342, 442) fixés sur la tige (350).

3. Cathéter selon la revendication 2, caractérisé en ce que les éléments (342, 442) sont flexibles radialement vers l'extérieur afin de relâcher la prothèse (P).

4. 'Cathéter selon la revendication 3, caractérisé en ce que les éléments (442) sont des broches dont les extrémités proximales sont fixées ensemble.

5. Cathéter selon la revendication 4, caractérisé en ce que les extrémités proximales des broches (442) sont fixées sur la gaine (434).

6. Cathéter selon la revendication 5, caractérisé en ce que les moyens support comprennent un couvercle (432) disposé de manière amovible au-dessus des éléments (442).

7. Cathéter selon la revendication 1, caractérisé en ce que les moyens support comprennent un couvercle (282, 302, 322) disposé de manière amovible audessus de la prothèse (P).

8. Cathéter selon l'une quelconque des revendications 1 à 7, caractérisé en ce que la structure de retenue (280, 300, 320, 340) s'étend entre la prothèse (P) et la gaine enveloppe (254, 434).

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9. Cathéter selon l'une quelconque des revendications 1 à 8, caractérisé en ce que la gaine (254, 434) est constituée en un matériau polymère souple et la structure de retenue (280, 300, 320, 340) en un matériau qui est plus dur que celui de la gaine (254, 434).

10. Cathéter selon l'une quelconque des revendications 1 à 9, caractérisé en ce qu'une extrémité distale déployable pouvant s'évaser vers l'extérieur et des moyens destinés à modifier la configuration de l'extrémité distale de la gaine (254, 434), entre une configuration non évasée et évasée, sont prévus.

11. Cathéter selon l'une quelconque des revendications 1 à 10, caractérisé en ce qu'une extension de tige (208) pouvant être couplée à l'extrémité distale de la tige (222) et une extension de gaine (202) pouvant être couplée à l'extrémité distale de la gaine (220) sont prévues, la prothèse (P) étant comprimée radialement au-dessus de l'extension de tige (208) et à l'intérieur de l'extension de gaine (202).

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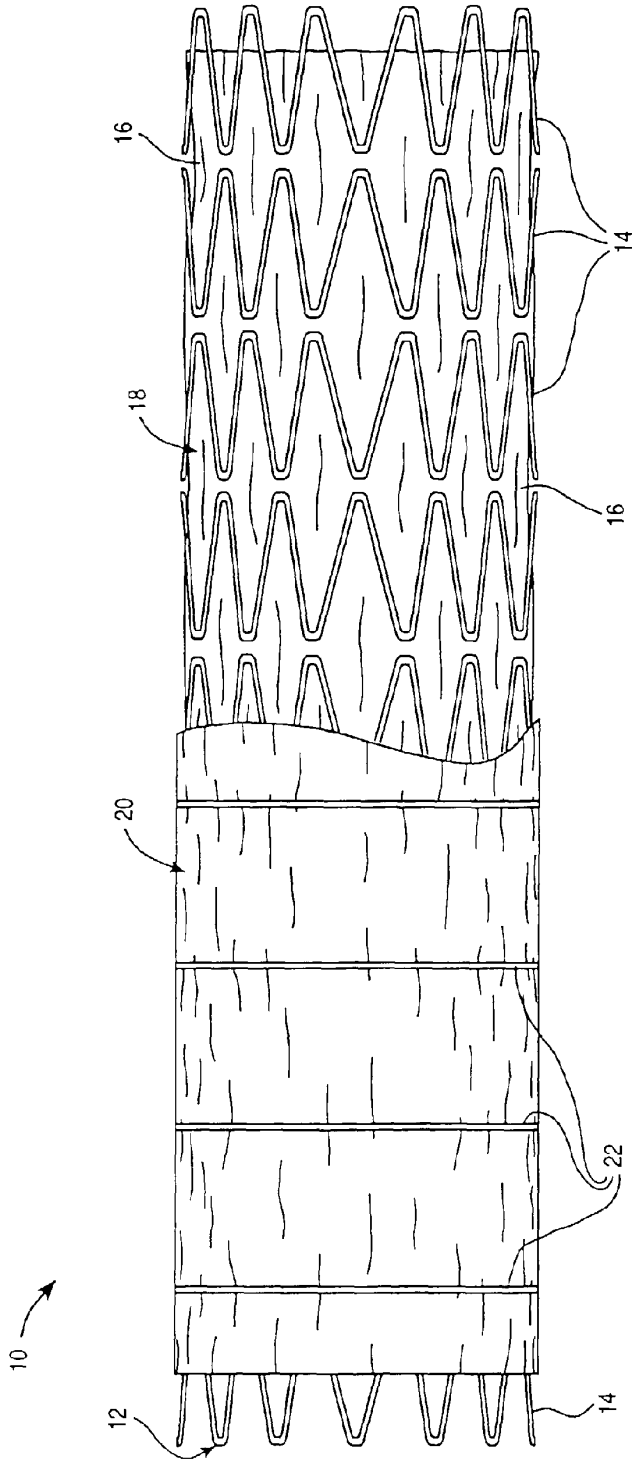

FIG. 1

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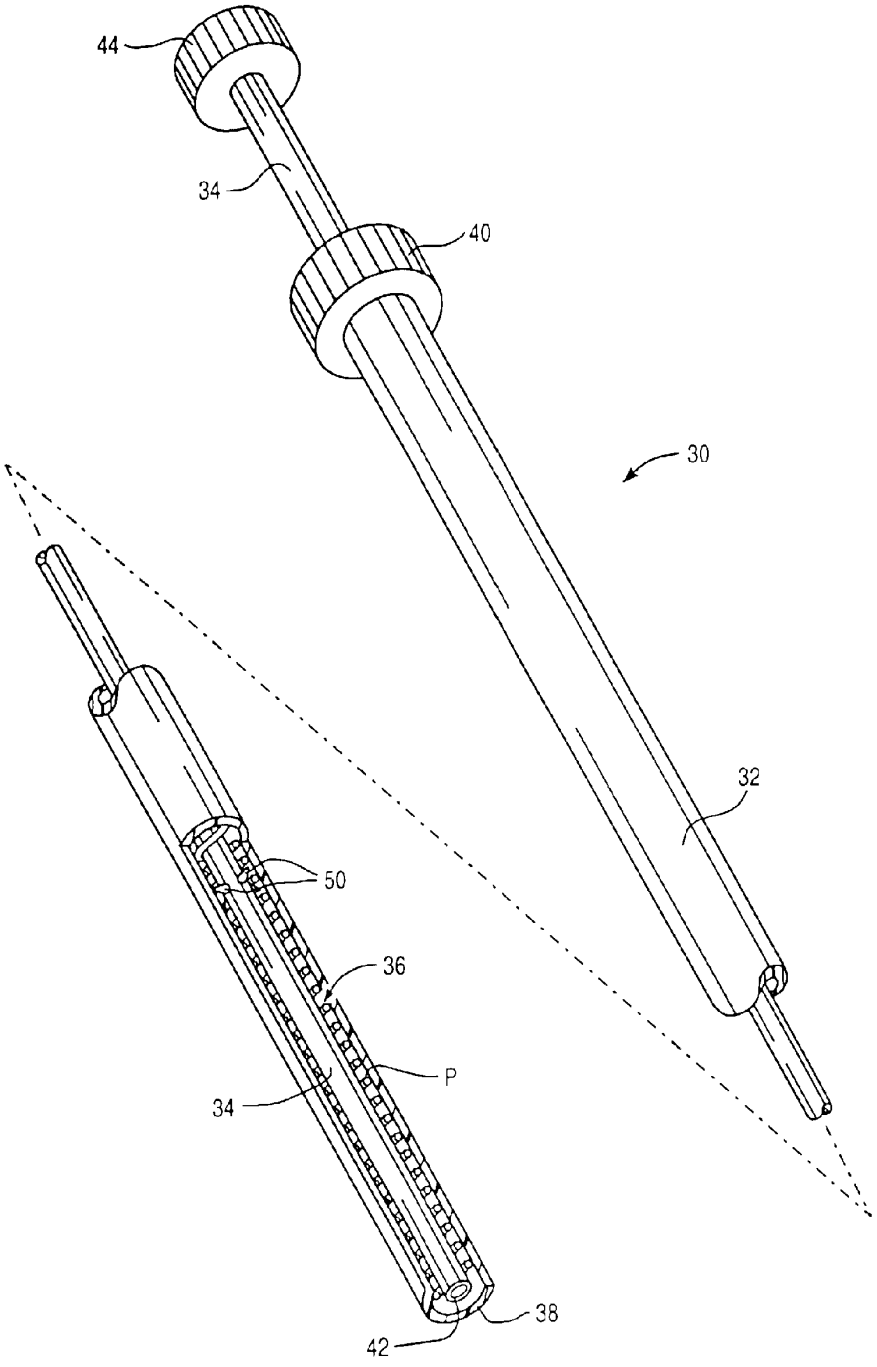

FIG. 2

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1935 of 2319

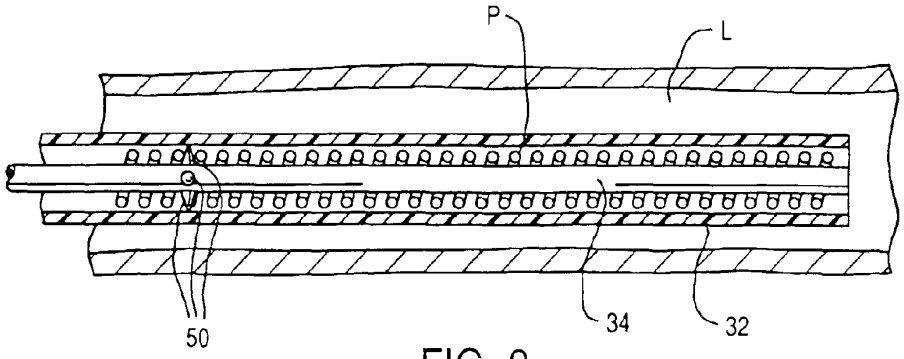

FIG. 3

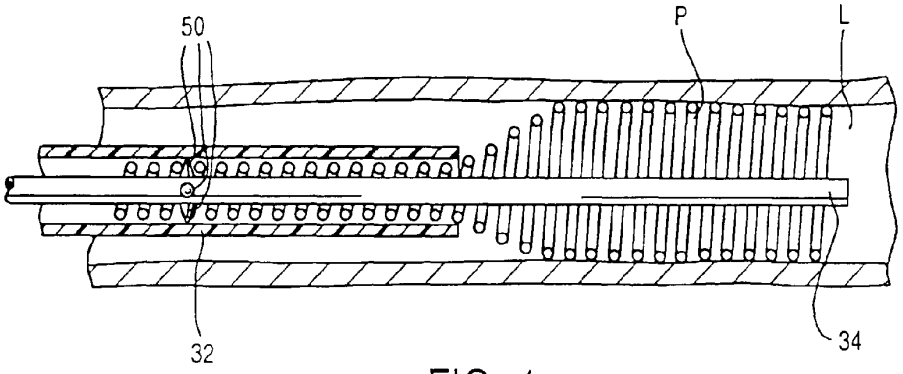

FIG. 4

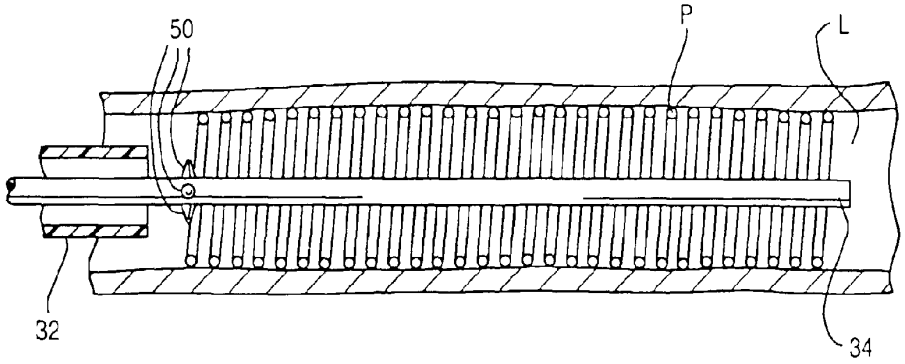

FIG. 5

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1936 of 2319

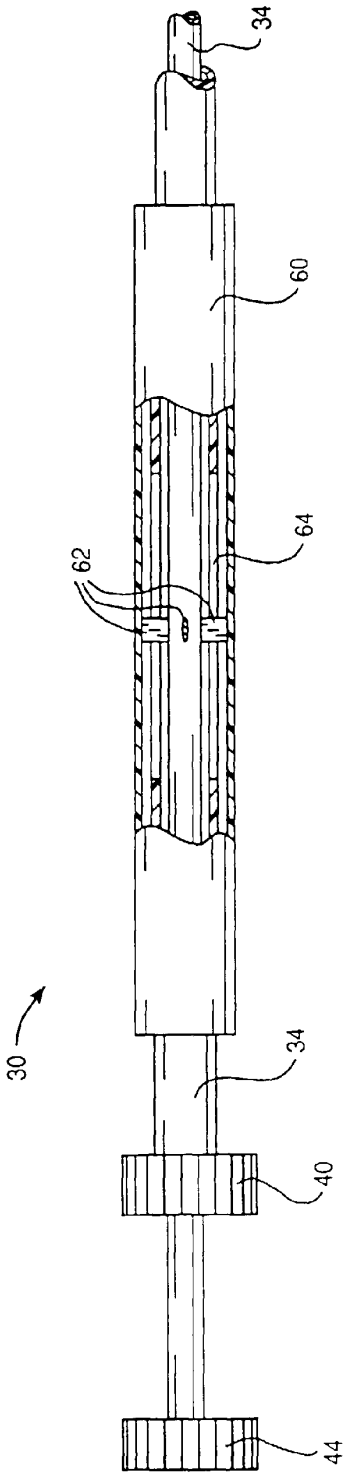

FIG. 6

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1937 of 2319

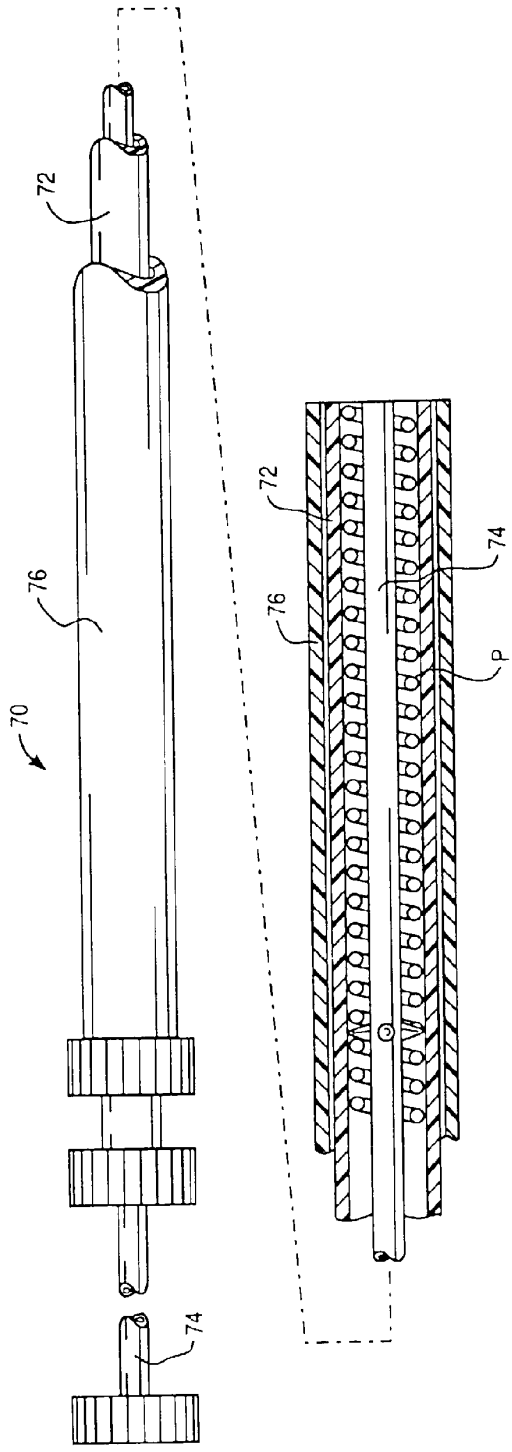

FIG. 7

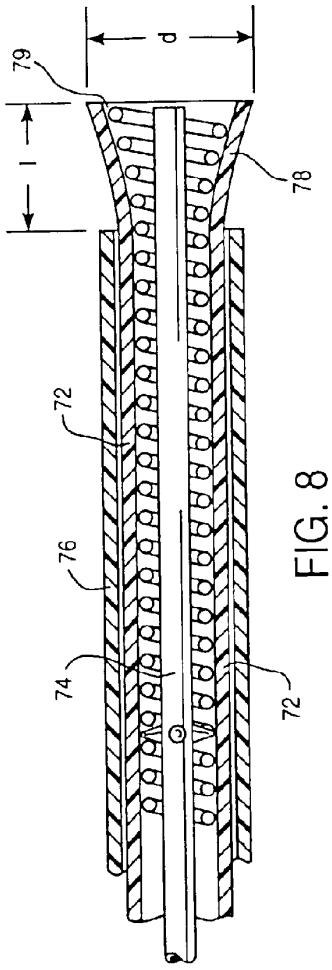

FIG. 8

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1938 of 2319

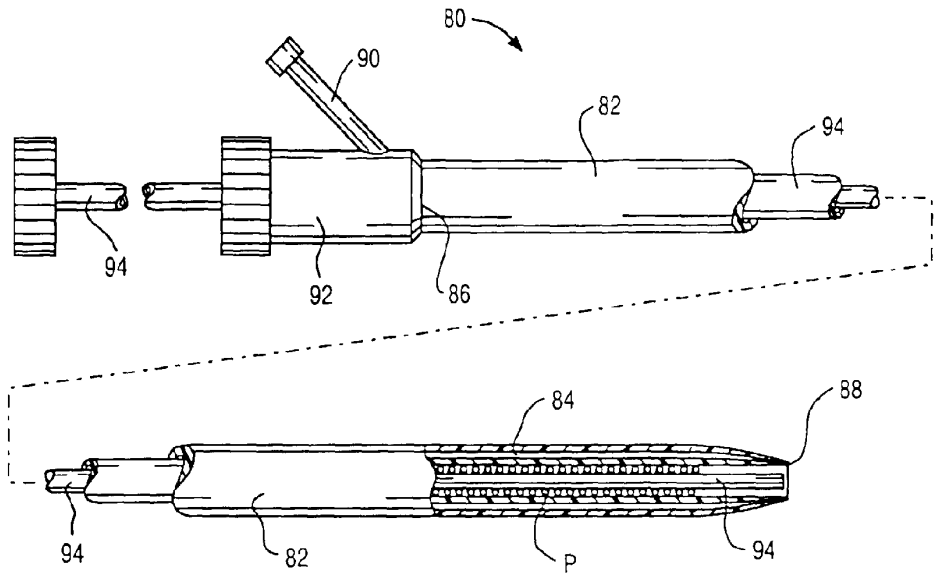

FIG. 9

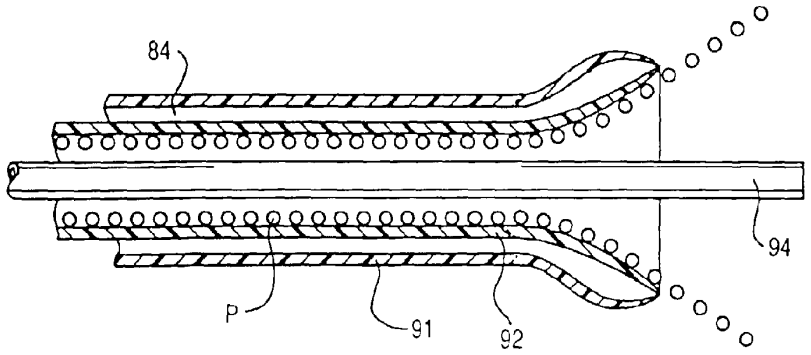

FIG. 10

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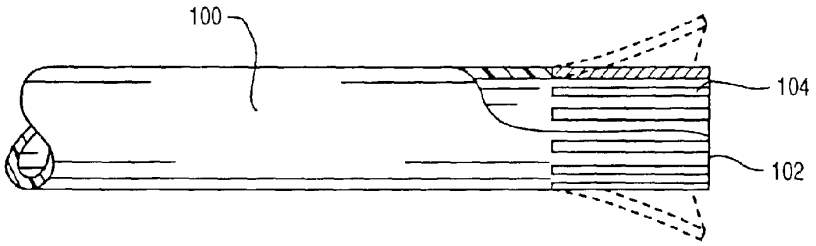

FIG. 11

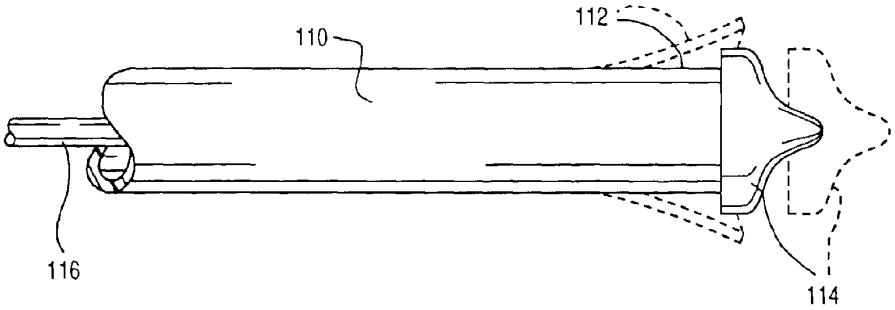

FIG. 12

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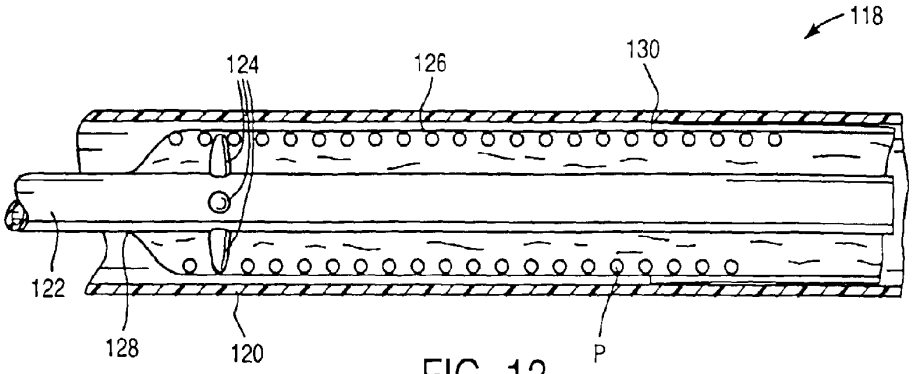

FIG. 13

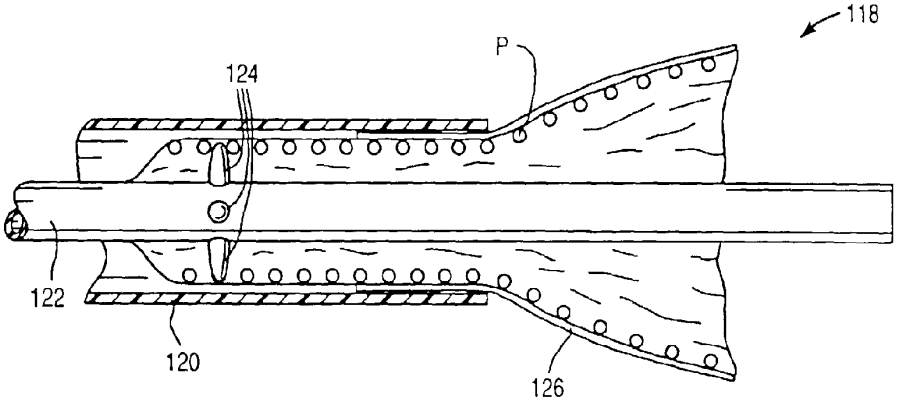

FIG. 14

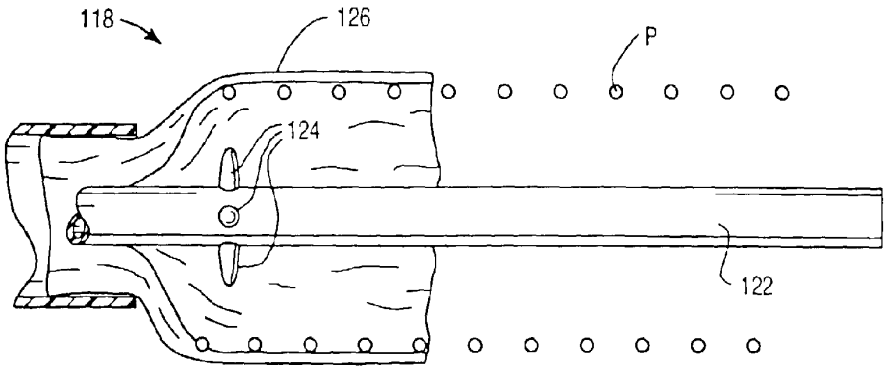

FIG. 15

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1941 of 2319

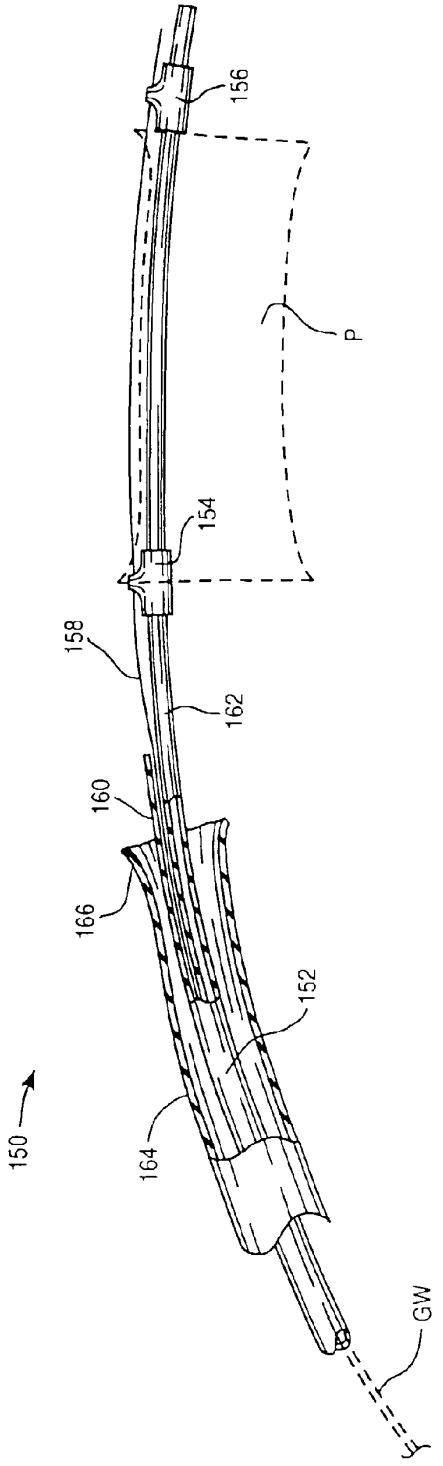

FIG. 16

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1942 of 2319

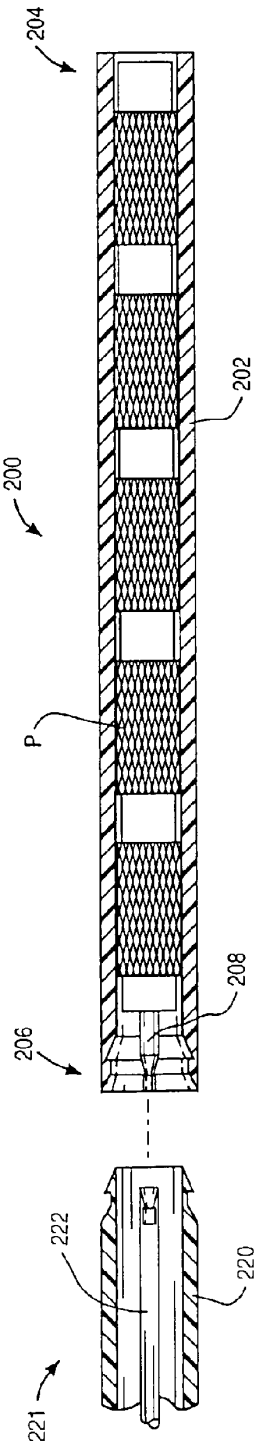

FIG. 17

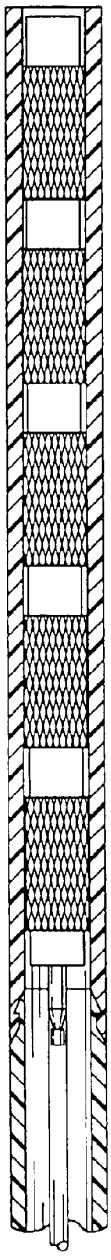

FIG. 18

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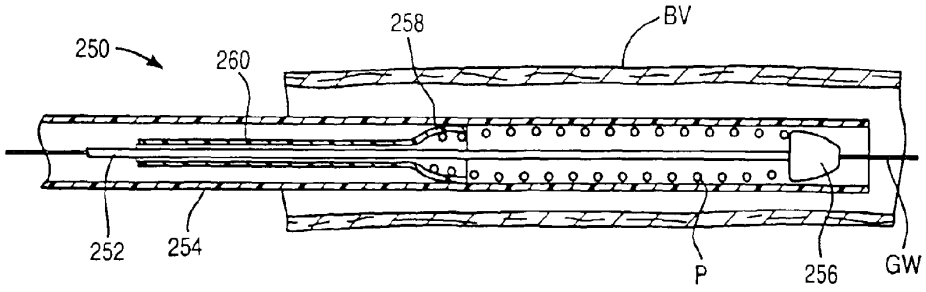

FIG. 19A

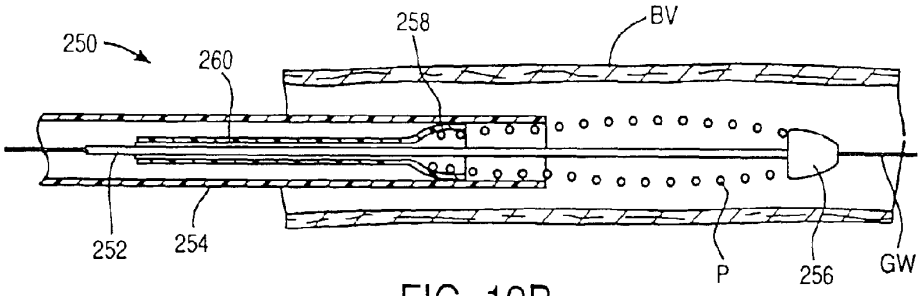

FIG. 19B

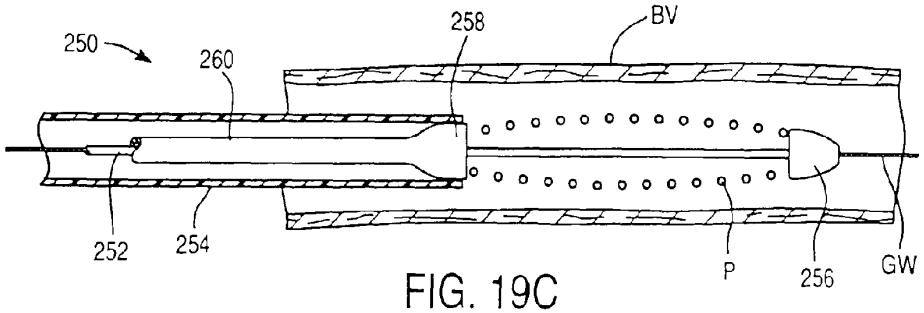

FIG. 19C

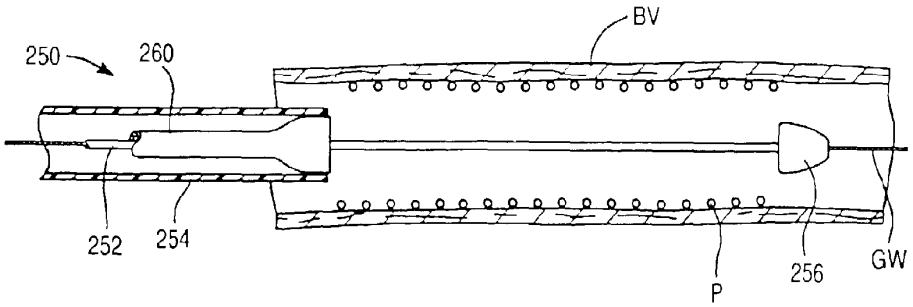

FIG. 19D

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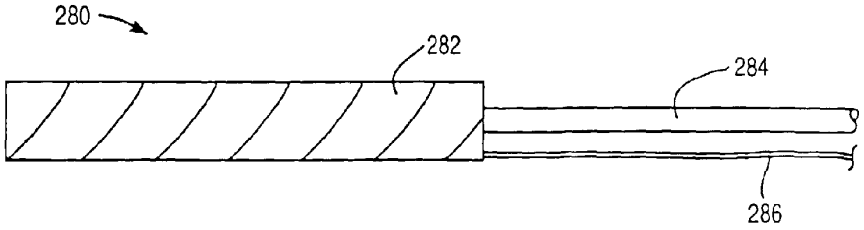

FIG. 20A

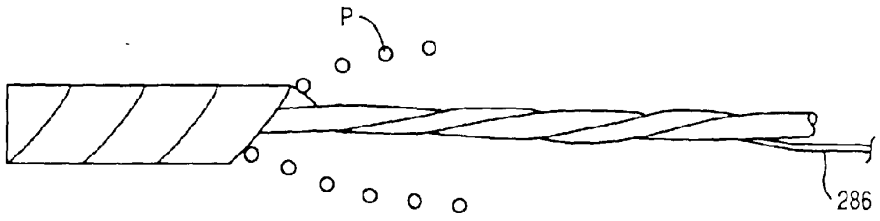

FIG. 20B

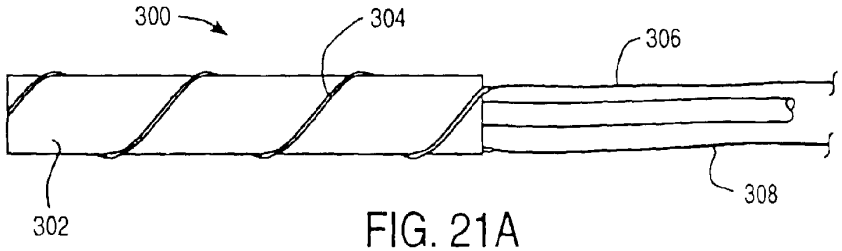

FIG. 21A

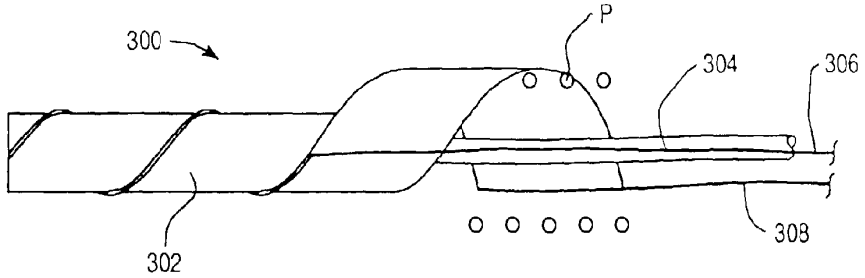

FIG. 21B

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1945 of 2319

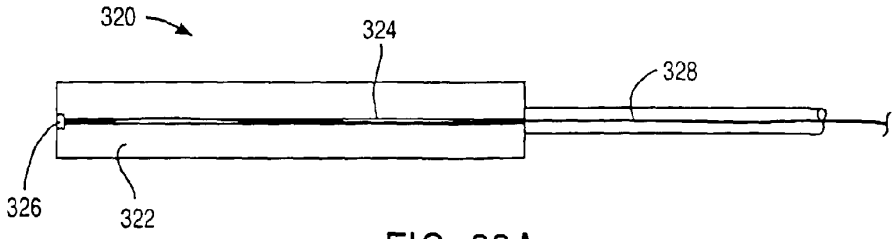

FIG. 22A

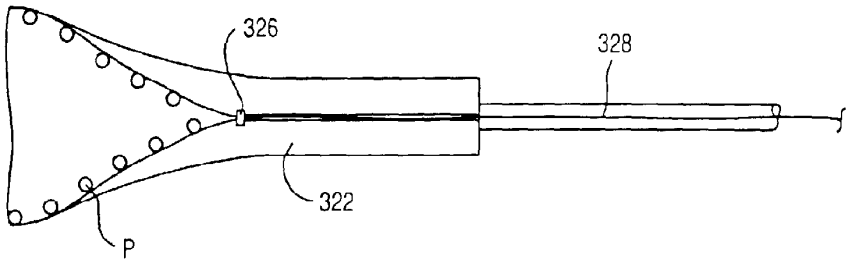

FIG. 22B

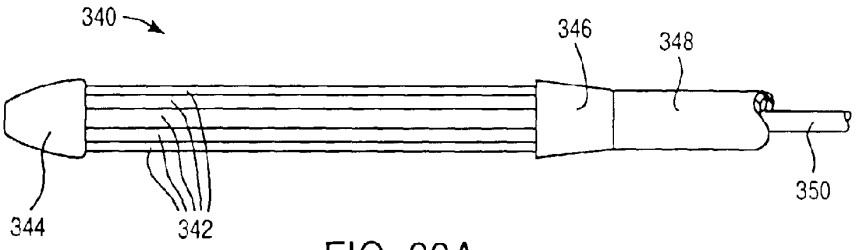

FIG. 23A

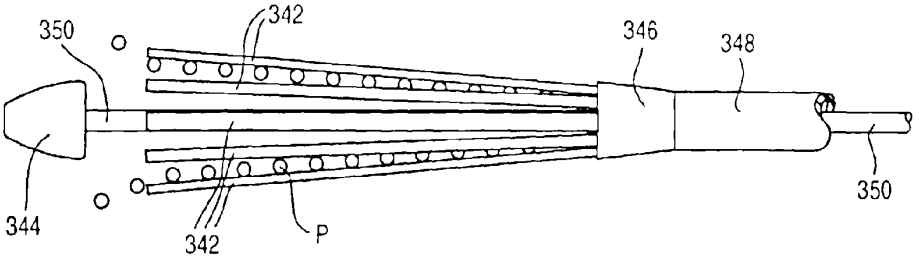

FIG. 23B

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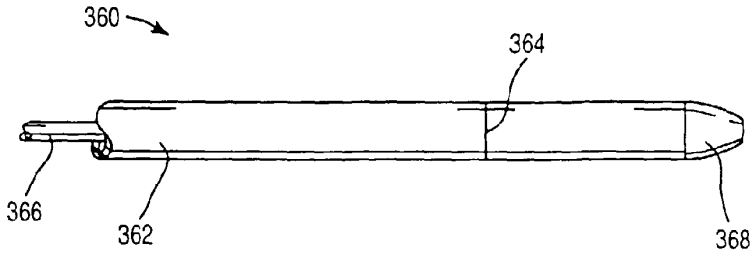

FIG. 24A

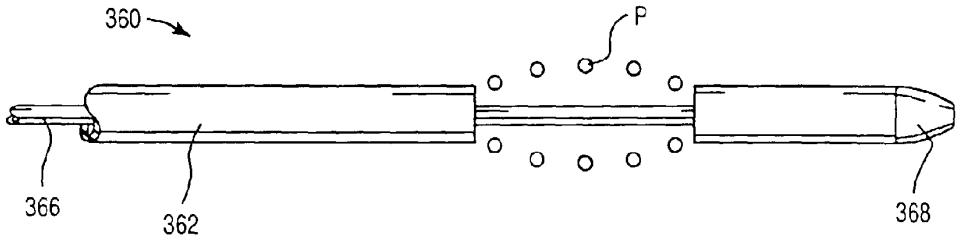

FIG. 24B

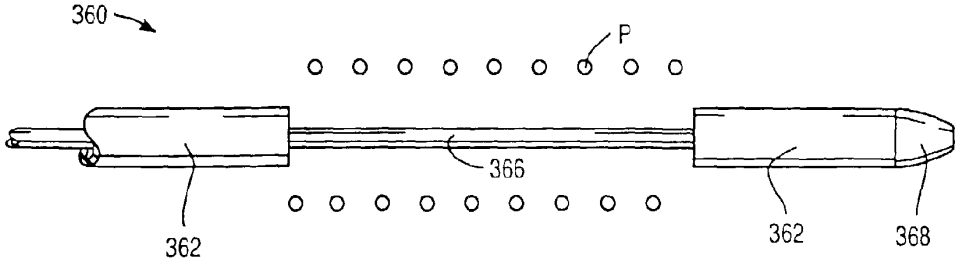

FIG. 24C

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1947 of 2319

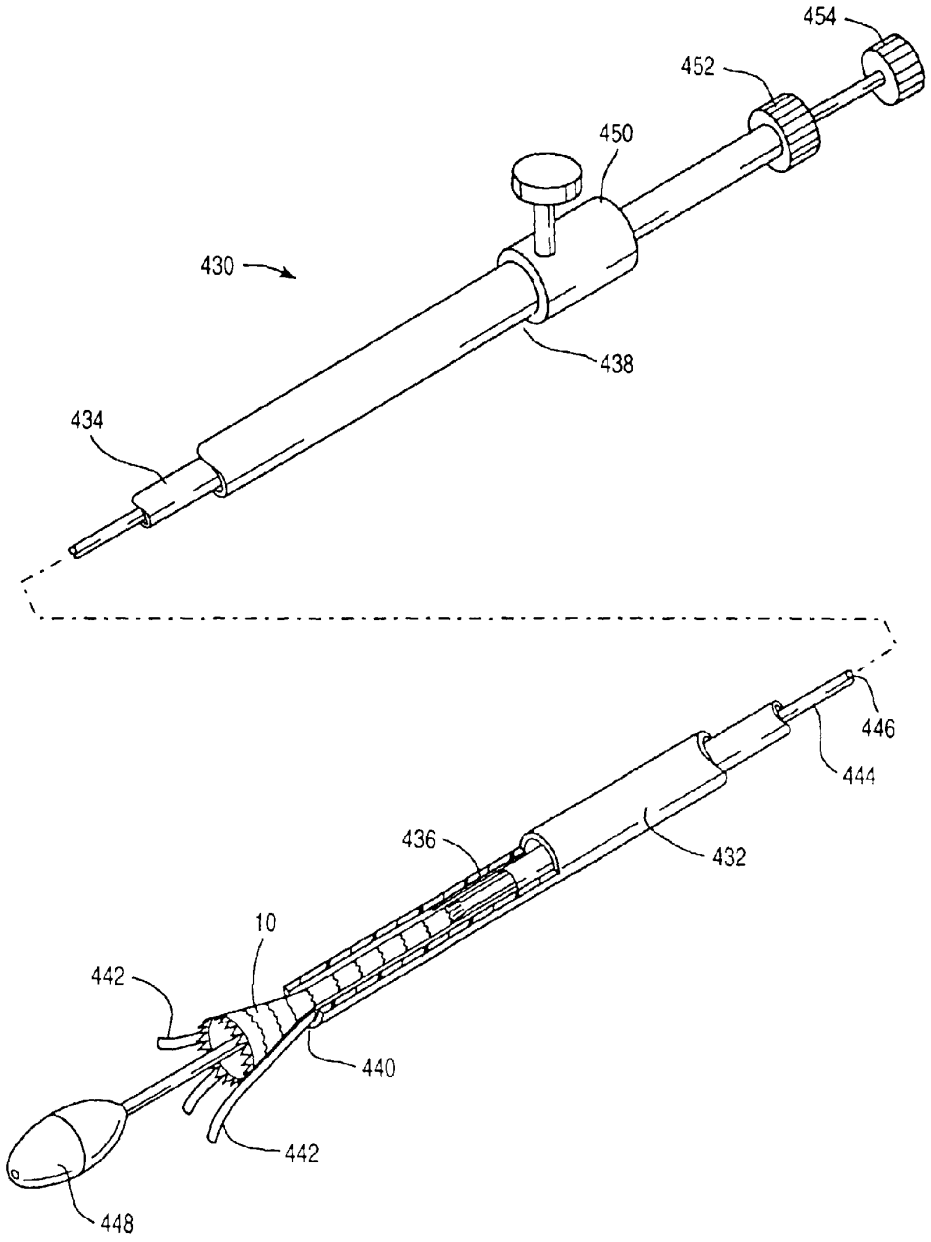

FIG. 25

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1948 of 2319

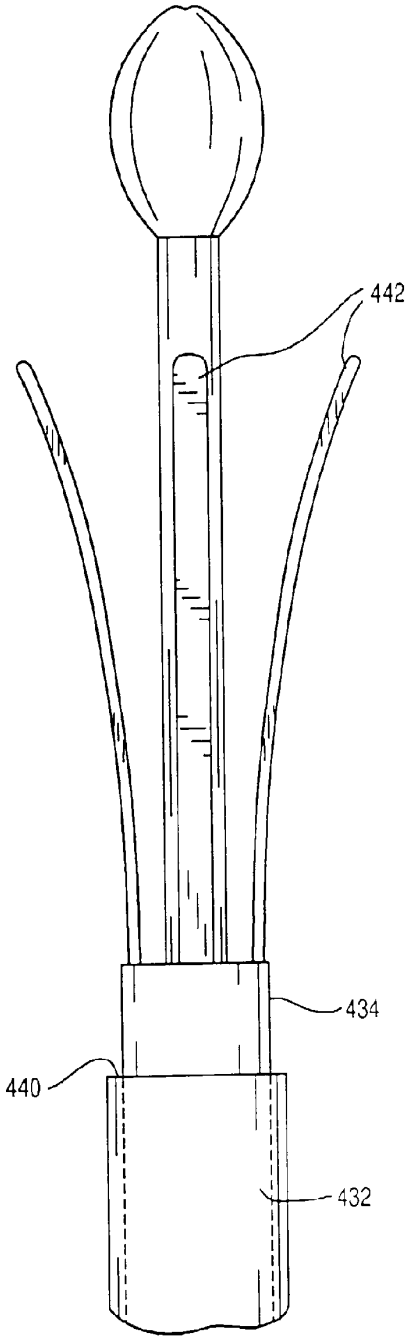

FIG. 26A

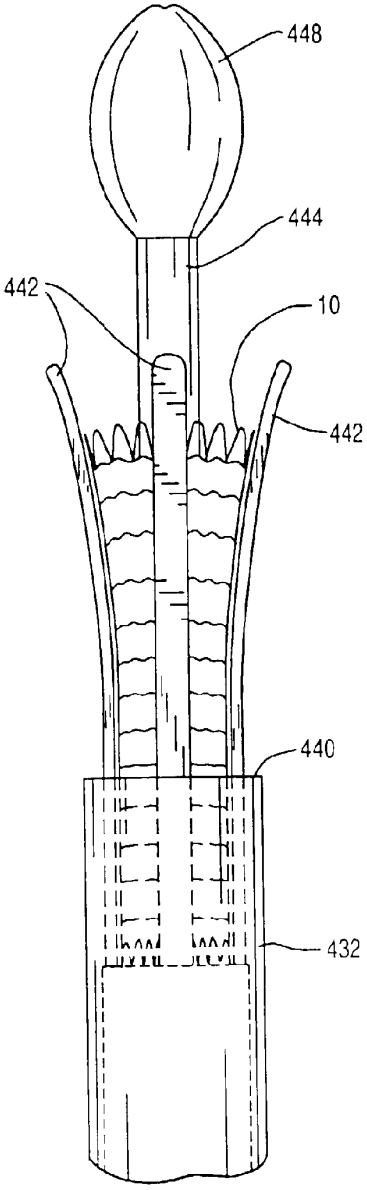

FIG. 26B

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 1949 of 2319

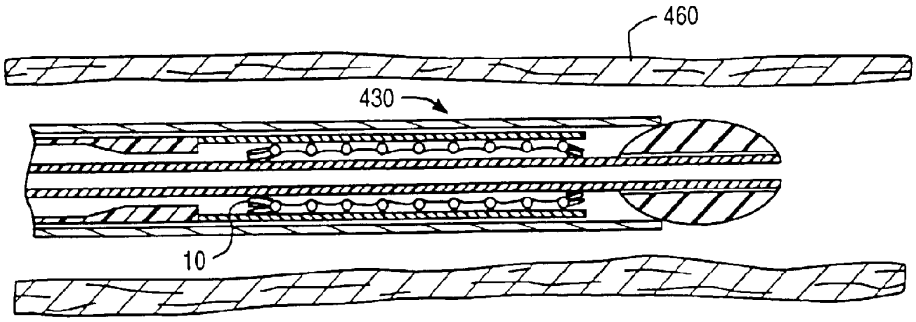

FIG. 27A

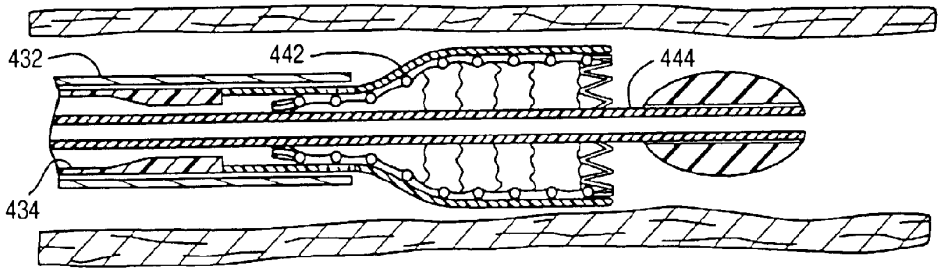

FIG. 27B

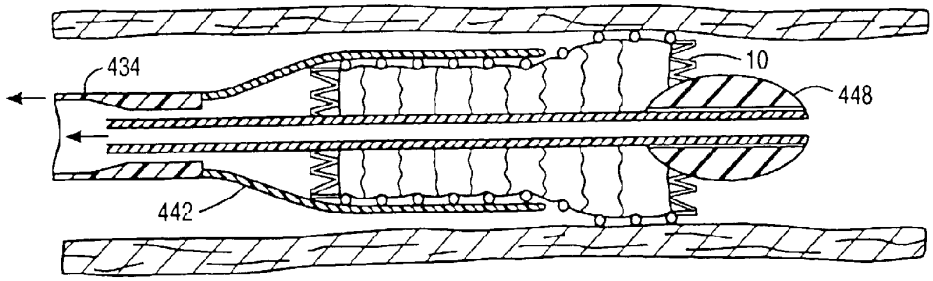

FIG. 27C

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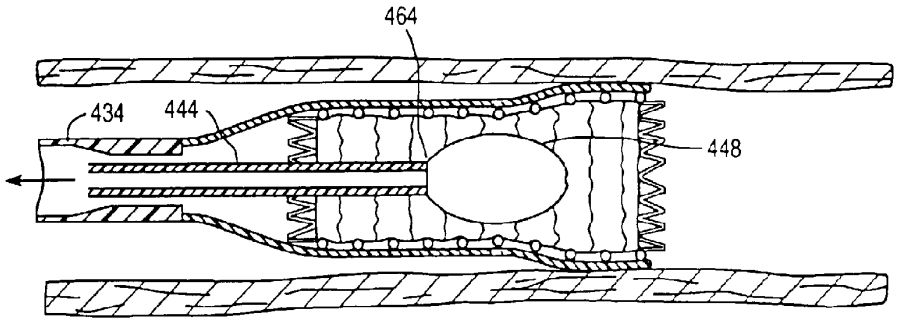

FIG. 28

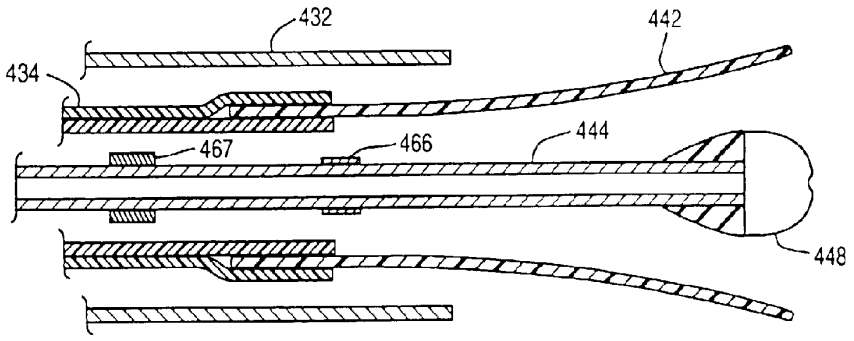

FIG. 29A

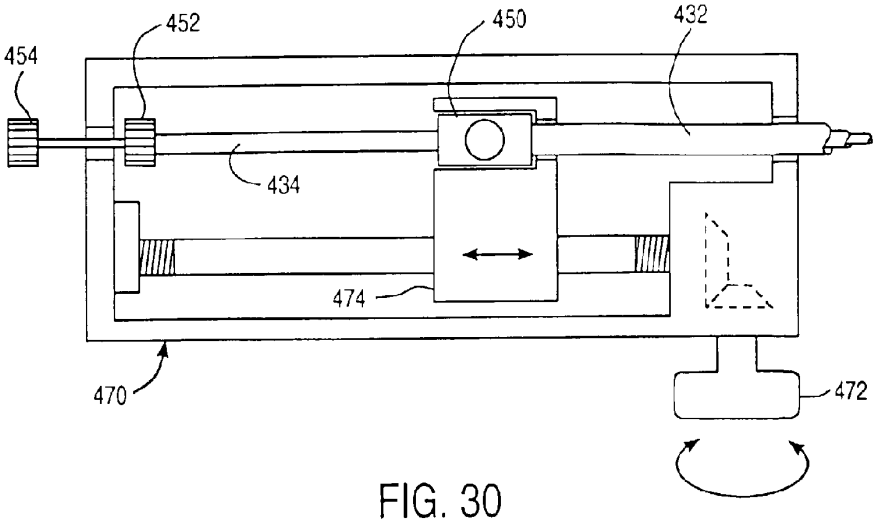

FIG. 30

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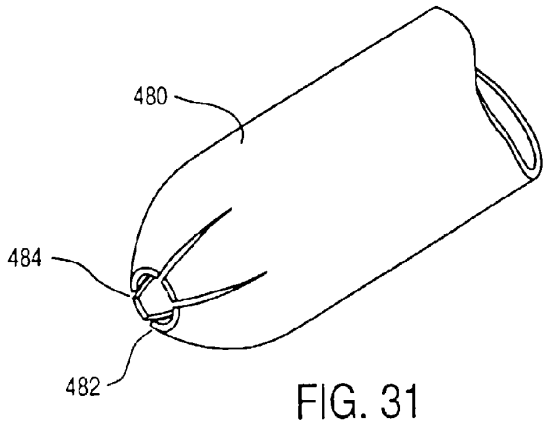

FIG. 31

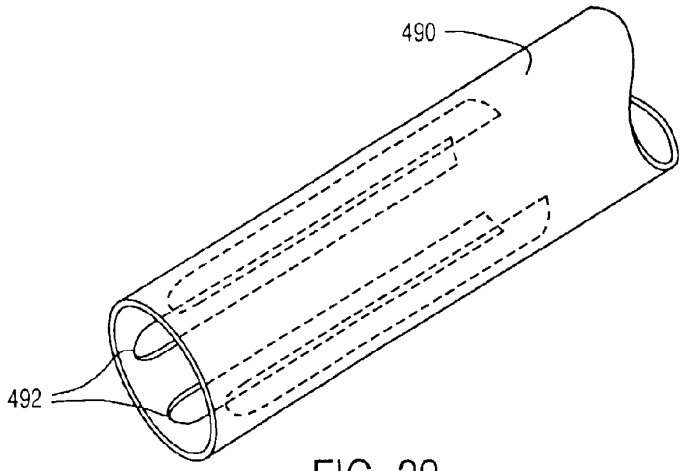

FIG. 32

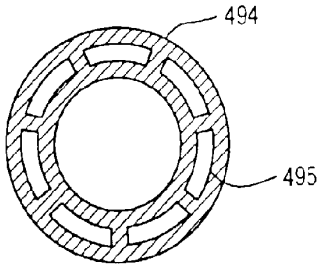

FIG. 33A

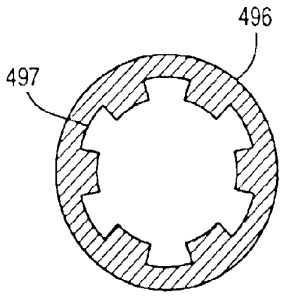

FIG. 33B

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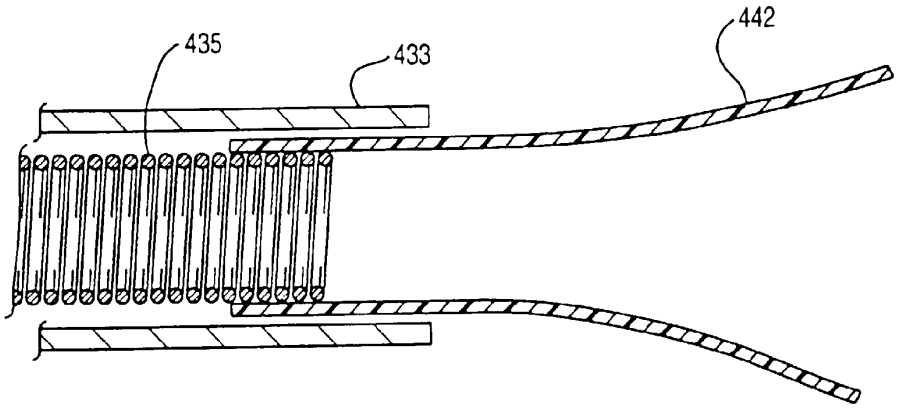

FIG. 29B

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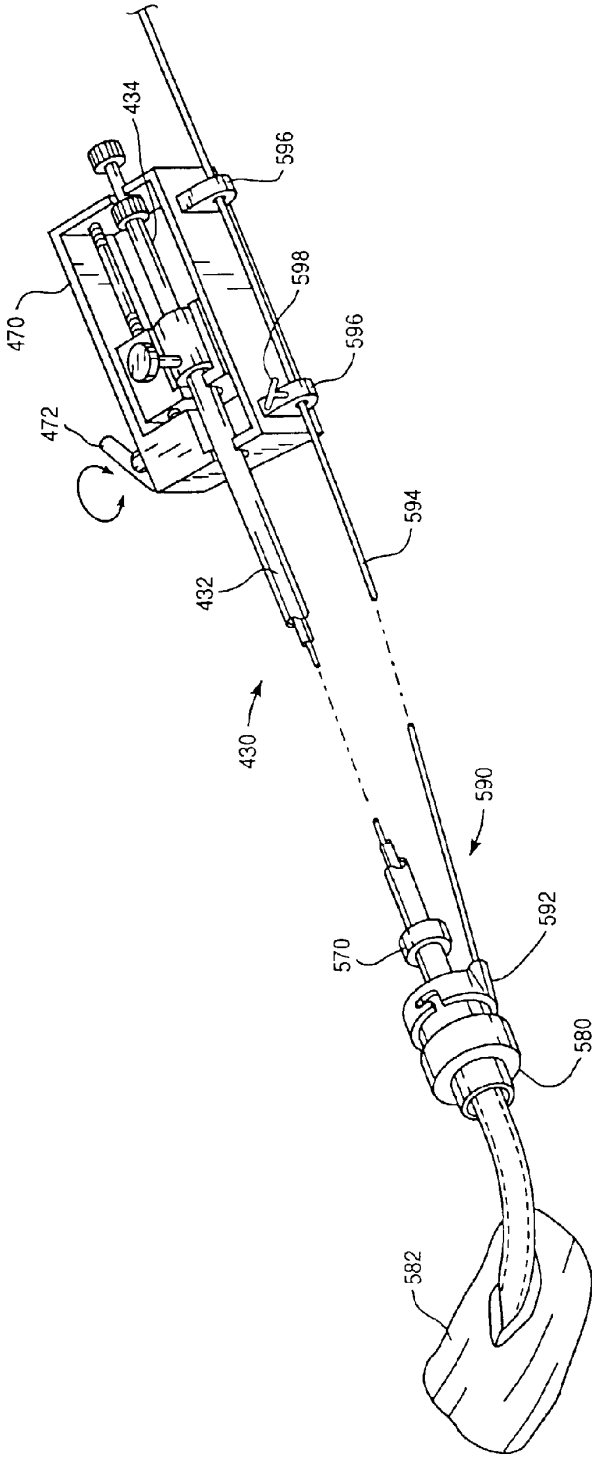

FIG. 34

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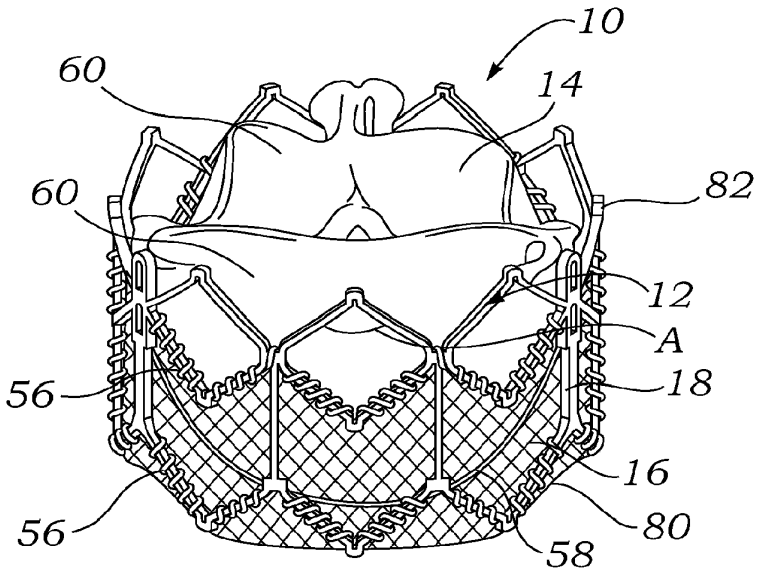
[Continued on next page]

(54) Title: LOW PROFILE TRANSCATHETER HEART VALVE

Fig. 1



(57) Abstract: An implantable prosthetic valve, according to one embodiment, comprises a frame, a leaflet structure, and a skirt member. The frame can have a plurality of axial struts interconnected by a plurality of circumferential struts. The leaflet structure comprises a plurality of leaflets (e.g., three leaflets arrange to form a tricuspid valve). The leaflet structure has a scalloped lower edge portion secured to the frame. The skirt member can be disposed between the leaflet structure and the frame.

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LOW PROFILE TRANSCATHETER HEART VALVE

FIELD

[001] The present disclosure relates to implantable devices and, more particularly, to valve prosthetics for implantation into body ducts, such as native heart valve annuluses.

DESCRIPTION OF THE RELATED ART

[002] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require replacement of the native valve with an artificial valve. There are a number of known artificial valves and a number of known methods of implanting these artificial valves in humans.

[003] Various surgical techniques may be used to repair a diseased or damaged valve. In a valve replacement operation, the damaged leaflets are excised and the annulus sculpted to receive a replacement valve. Due to aortic stenosis and other heart valve diseases, thousands of patients undergo surgery each year wherein the defective native heart valve is replaced by a prosthetic valve, either bioprosthetic or mechanical. Another less drastic method for treating defective valves is through repair or reconstruction, which is typically used on minimally calcified valves. The problem with surgical therapy is the significant insult it imposes on these chronically ill patients with high morbidity and mortality rates associated with surgical repair.

[004] When the valve is replaced, surgical implantation of the prosthetic valve typically requires an open-chest surgery during which the heart is stopped and patient placed on cardiopulmonary bypass (a so-called "heart-lung machine"). In one common surgical procedure, the diseased native valve leaflets are excised and a prosthetic valve is sutured to the surrounding tissue at the valve annulus. Because of the trauma associated with the procedure and the attendant duration of extracorporeal blood circulation, some patients do not

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survive the surgical procedure or die shortly thereafter. It is well known that the risk to the patient increases with the amount of time required on extracorporeal circulation. Due to these risks, a substantial number of patients with defective valves are deemed inoperable because their condition is too frail to withstand the procedure. By some estimates, more than 50% of the subjects suffering from aortic stenosis who are older than 80 years cannot be operated on for aortic valve replacement.

[005] Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For instance, U.S. Patent Nos. 5,411,522 and 6,730,118, which are incorporated herein by reference, describe collapsible transcatheter heart valves that can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent.

[006] An important design parameter of a transcatheter heart valve is the diameter of the folded or crimped profile. The diameter of the crimped profile is important because it directly influences the physician's ability to advance the valve through the femoral artery or vein. More particularly, a smaller profile allows for treatment of a wider population of patients, with enhanced safety.

SUMMARY

[007] The present disclosure is directed toward new and non-obvious methods and apparatuses relating to prosthetic valves, such as heart valves.

[008] In one representative embodiment, an implantable prosthetic valve comprises a radially collapsible and expandable frame, or stent, and a leaflet structure comprising a plurality of leaflets. The leaflet structure has a scalloped lower edge portion that is positioned inside of and secured to the frame. The valve can further include an annular skirt member, which can be disposed

between the frame and the leaflet structure such that the scalloped lower edge portion can be attached to an inner surface of the skirt member. Each leaflet can have an upper edge, a curved lower edge and two side flaps extending between respective ends of the upper edge and the lower edge, wherein each side flap is secured to an adjacent side flap of another leaflet to form commissures of the leaflet structure. Each commissure can be attached to one of the commissure attachment posts, and a reinforcing bar can be positioned against each side flap for reinforcing the attachments between the commissures and the commissure attachment posts.

[009] The frame can comprise a plurality of angularly spaced, axial struts that are interconnected by a plurality of rows of circumferential struts. Each row of circumferential struts desirably includes struts arranged in a zig-zag or saw-tooth pattern extending around the circumference of the frame.

[010] In certain embodiments, at least one row, and preferably all rows, of circumferential struts include pairs of circumferential struts extending between two axial struts. Each strut of the pair has one end connected to a respective axial strut and another end interconnected to an adjacent end of the other strut of the same pair by a crown portion such that a gap exists between the adjacent ends of the struts. The angle between the struts of each pair desirably is between about 90 and 110 degrees, with about 100 degrees being a specific example. The frame desirably is made of a nickel-cobalt based alloy, such as a nickel cobalt chromium molybdenum alloy (e.g., MP35N™).

[011] In another representative embodiment, an implantable prosthetic valve comprises a radially collapsible and expandable annular frame and a leaflet structure supported by the frame. The frame can comprise a plurality of interconnected struts defining a plurality of open cells in the frame. The valve further includes an annular cover member disposed on and covering the cells of at least a portion of the frame. The cover member desirably comprises an elastomer, such as silicon, that can expand and stretch when the valve is expanded from a crimped state to an expanded state.

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[012] The cover member may be a thin sleeve of silicon that surrounds at least a portion of the frame. Alternatively, the cover member may be formed by dipping at least a portion of the frame in silicon or another suitable elastomer in liquefied form.

[013] In another representative embodiment, a method is disclosed for crimping an implantable prosthetic valve having a frame and leaflets supported by the frame. The method comprises placing the valve in the crimping aperture of a crimping device such that a compressible material is disposed between the crimping jaws of the crimping device and the frame of the valve. Pressure is applied against the compressible material and the valve with the crimping jaws to radially crimp the valve to a smaller profile and compress the compressible material against the valve such that the compressible material extends into open cells of the frame and pushes the leaflets away from the inside of the frame.

[014] The foregoing and other features and advantages of the invention will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[015] FIG. 1 is a perspective view of a representative embodiment of a prosthetic heart valve.

[016] FIG. 2 is another perspective view of the prosthetic valve of FIG. 1.

[017] FIG. 3 is another perspective view of the prosthetic valve of FIG. 1.

[018] FIG. 4 is an enlarged view of a section of the valve shown in FIG. 3.

[019] FIG. 5 is a bottom perspective view of the prosthetic valve of FIG. 1 showing the inside of the valve.

[020] FIG. 6 is a top plan view of the prosthetic valve of FIG. 1.

[021] FIG. 6A is an enlarged partial top view of the valve of FIG. 1 illustrating the positioning of the reinforcing bars with respect to the commissure attachment posts of the frame.

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[022] FIG. 7 is a perspective view of the frame of the prosthetic valve of FIG. 1.

[023] FIG. 8 is a perspective view of an alternative embodiment of a frame that can be used in the prosthetic valve of FIG. 1.

[024] FIG. 9 is a flattened view of 120-degree segment of the frame shown in FIG. 7.

[025] FIG. 10 is a flattened view of 120-degree segment of the frame shown in FIG. 8.

[026] FIG. 11 is a front view of a reinforcing bar that can be used to reinforce the connection of the valve leaflets to a frame in a prosthetic valve such as shown in FIG. 1.

[027] FIG. 12 is a perspective view of the reinforcing bar of FIG. 11 and a PET sleeve that can be used to cover the bar.

[028] FIG. 13 is a flattened view of a leaflet of the valve shown in FIG. 1.

[029] FIG. 14 is a flattened view of the opposite side of the leaflet showing a reinforcing strip secured adjacent the bottom edge of the leaflet.

[030] FIG. 15 is a top plan view of the leaflet structure of the valve of FIG. 1 prior to attachment to the frame.

[031] FIG. 16 is a flattened view of the skirt used in the valve shown in FIG. 1.

[032] FIG. 18 is a bottom perspective view of the leaflet structure connected to the skirt so as to form a leaflet assembly.

[033] FIG. 19 is a side view of a balloon catheter and a prosthetic valve crimped onto the balloon of the balloon catheter.

[034] FIG. 20 is a front view of a crimping device showing a prosthetic valve positioned in the crimping aperture of the crimping device with a protective sleeve disposed between the valve and the crimping jaws.

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[035] FIG. 21 is a front view of the crimping device shown after the crimping jaws are forced inwardly to compress the valve and the protective sleeve.

[036] FIG. 22 is a side view of the valve and protective sleeve after removal from the crimping device.

[037] FIG. 23 is a side view of a prosthetic valve that has been crimped onto a balloon of a balloon catheter without a protective sleeve.

[038] FIG. 24 is a side view of a prosthetic valve that has been crimped onto a balloon of a balloon catheter using a protective sleeve in the manner shown in FIGS. 20-21.

[039] FIG. 25 is a side view of a frame for a prosthetic valve having a silicon skirt, or sleeve, disposed on the outside of the frame.

[040] FIG. 26 is a side view of a frame for a prosthetic valve having a silicon encapsulating layer covering the inside and outside of the frame.

[041] FIG. 27 is a perspective view of a prosthetic valve comprising a frame having a silicon encapsulating layer.

[042] FIG. 28 is a perspective view of the valve of FIG. 27 after it has been crimped to a smaller diameter.

[043] FIG. 29 is a side view of the valve of FIG. 27 after it has been expanded by a balloon catheter.

[044] FIGS. 30A-30C are graphs illustrating the results of respective uniaxial tests performed on respective silicon test strips.

[045] FIGS. 31A-31F are graphs illustrating the results of respective uniaxial tests performed on respective silicon test strips having deliberately introduced tears.

DETAILED DESCRIPTION

[046] FIGS. 1 and 2 illustrate an implantable prosthetic valve 10, according to one embodiment. Valve 10 in the illustrated embodiment generally comprises a frame, or stent, 12, a leaflet structure 14 supported by the frame, and a skirt 16

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secured to the outer surface of the leaflet structure. Valve 10 typically is implanted in the annulus of the native aortic valve but also can be adapted to be implanted in other native valves of the heart or in various other ducts or orifices of the body. Valve 10 has a "lower" end 80 and an "upper" end 82. In the context of the present application, the terms "lower" and "upper" are used interchangeably with the terms "inflow" and "outflow", respectively. Thus, for example, the lower end 80 of the valve is its inflow end and the upper end 82 of the valve is its outflow end.

[047] Valve 10 and frame 12 are configured to be radially collapsible to a collapsed or crimped state for introduction into the body on a delivery catheter and radially expandable to an expanded state for implanting the valve at a desired location in the body (e.g., the native aortic valve). Frame 12 can be made of a plastically-expandable material that permits crimping of the valve to a smaller profile for delivery and expansion of the valve using an expansion device such as the balloon of a balloon catheter. Exemplary plastically-expandable materials that can be used to form the frame are described below. Alternatively, valve 10 can be a so-called self-expanding valve wherein the frame is made of a self-expanding material such as Nitinol. A self-expanding valve can be crimped to a smaller profile and held in the crimped state with a restraining device such as a sheath covering the valve. When the valve is positioned at or near the target site, the restraining device is removed to allow the valve to self-expand to its expanded, functional size.

[048] Referring also to FIG. 7 (which shows the frame alone for purposes of illustration), frame 12 is an annular, stent-like structure having a plurality of angularly spaced, vertically extending, commissure attachment posts, or struts, 18. Posts 18 can be interconnected via a lower row 36a of circumferentially extending struts 20 and first and second rows upper rows 36b, 36c, respectively, of circumferentially extending struts 22 and 24, respectively. The struts in each row desirably are arranged in a zig-zag or generally saw-tooth like pattern extending in the direction of the circumference of the frame as shown. Adjacent struts in the same row can be interconnected to one another as shown in FIGS. 1

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and 5 to form an angle A, which desirably is between about 90 and 110 degrees, with about 100 degrees being a specific example. The selection of angle A between approximately 90 and 110 degrees optimizes the radial strength of frame 12 when expanded yet still permits the frame 12 to be evenly crimped and then expanded in the manner described below.

[049] In the illustrated embodiment, pairs of adjacent circumferential struts in the same row are connected to each other by a respective, generally U-shaped crown structure, or crown portion, 26. Crown structures 26 each include a horizontal portion extending between and connecting the adjacent ends of the struts such that a gap 28 is defined between the adjacent ends and the crown structure connects the adjacent ends at a location offset from the strut's natural point of intersection. Crown structures 26 significantly reduce residual strains on the frame 12 at the location of struts 20, 22, 24 during crimping and expanding of the frame 20 in the manner described below. Each pair of struts 22 connected at a common crown structure 26 forms a cell with an adjacent pair of struts 24 in the row above. Each cell can be connected to an adjacent cell at a node 32. Each node 32 can be interconnected with the lower row of struts by a respective vertical (axial) strut 30 that is connected to and extends between a respective node 32 and a location on the lower row of struts 20 where two struts are connected at their ends opposite crown structures 26.

[050] In certain embodiments, lower struts 20 have a greater thickness or diameter than upper struts 22, 24. In one implementation, for example, lower struts 20 have a thickness T (FIG. 9) of about 0.42 mm and upper struts 22, 24 have a thickness T of about 0.38 mm. Because there is only one row of lower struts 20 and two rows of upper struts 22, 24 in the illustrated configuration, enlargement of lower struts 20 with respect to upper struts 22, 24 enhances the radial strength of the frame at the lower area of the frame and allows for more uniform expansion of the frame.

[051] FIG. 9 shows a flattened view of a 120-degree segment of frame 12 shown in FIG. 7, the segment comprising a portion of the frame extending

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between two posts 18. As shown, the frame segment has three columns 34 and three rows 36a, 36b, 36c of struts per segment. Each column 34 is defined by the adjoining pairs of struts 20, 22, 24 extending between two axially extending struts 18, 30. Frame 12 desirably is comprised of three 120-degree segments, with each segment being bounded by two posts 18. Accordingly, frame 12 in the illustrated embodiment includes 9 total columns per frame.

[052] The number of columns and rows desirably is minimized to reduce the overall crimp profile of the valve, as further discussed below. The arrangement of FIGS. 7 and 9 typically is used for valves that are less than about 29 mm in diameter, and are most suitable for valves that are about 20-26 mm in diameter. In working examples of valves comprising frame 12, a 20-mm valve can be crimped to a diameter of about 17 Fr, a 23-mm valve can be crimped to a diameter of about 18 Fr and a 26-mm valve can be crimped to a diameter of about 19 Fr. For valves that are about 29 mm and larger in diameter, it may be desirable to add another row and column of struts.

[053] For example, FIGS. 8 and 10 show an alternative frame 40 that is similar to frame 12 except that frame 40 has four rows of struts (a lowermost, first row 52a of struts 42, a second row 52b of struts 44, a third row 52c of struts 46, and an uppermost row 52d of struts 48) instead of three rows of struts, as well as four columns 50 of struts for each 120-degree frame segment instead of three columns of struts. FIG. 10 shows a flattened view of a 120-degree segment of frame 40 shown in FIG. 8. Frame 40 in the illustrated embodiment includes three such 120-degree segments, providing 12 total columns 50 of struts for the frame.

[054] Struts 46 of the third row desirably are facing in the opposite direction of the struts 48 of the fourth row (i.e., the apexes or crown portions are facing in the opposite direction), to help avoid buckling of the vertical posts of the frame during crimping and expansion of the valve. Struts 44 of the second row can be arranged so as to be facing in the same direction as the struts 42 of the first row as shown (i.e., the apexes or crown portions are facing in the same direction).

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Alternatively, struts 44 of the second row can be facing in the opposing direction from struts 42 of the first row so as to form square cells, like the cells formed by the struts 46, 48 of the third and fourth rows, respectively. Frame 40 can also include axially extending struts 54 connected to and extending between the ends of each strut 42, 44, 46, 48 aligned in a column 50 that are not connected to a post 18. As noted above, frame 40 is most suitable for valves 29 mm and larger in diameter (when expanded to its functional size). In a working example of a valve incorporating frame 40, a 29-mm valve can be crimped to a diameter of about 21 Fr.

[055] Suitable plastically-expandable materials that can be used to form the frame include, without limitation, stainless steel, a nickel based alloy (e.g., a nickel-cobalt-chromium alloy), polymers, or combinations thereof. In particular embodiments, frame 20 is made of a nickel-cobalt-chromium-molybdenum alloy, such as MP35N™ (tradename of SPS Technologies), which is equivalent to UNS R30035 (covered by ASTM F562-02). MP35N™/UNS R30035 comprises 35% nickel, 35% cobalt, 20% chromium, and 10% molybdenum, by weight. It has been found that the use of MP35N to form frame 20 provides superior structural results over stainless steel. In particular, when MP35N is used as the frame material, less material is needed to achieve the same or better performance in radial and crush force resistance, fatigue resistances, and corrosion resistance. Moreover, since less material is required, the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly for percutaneous delivery to the treatment location in the body.

[056] Referring again to FIG. 1, skirt 16 can be formed, for example, of polyethylene terephthalate (PET) ribbon. The thickness of the skirt can vary, but is desirably less than 6 mil, and desirably less than 4 mil, and even more desirably about 2 mil. Skirt 16 can be secured to the inside of frame 12 via Lenzing sutures 56, as shown in FIG. 1. Leaflet structure 14 can be attached to the skirt via a thin PET reinforcing strip 68 (or sleeve), discussed below, which enables a secure suturing and protects the pericardial tissue of the leaflet structure from tears. Leaflet structure 14 can be sandwiched between skirt 16

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and the thin PET strip 68 as shown. Suture 58, which secures the PET strip and the leaflet structure 14 to skirt 16 can be any suitable suture, such as an Ethibond suture. Suture 58 desirably tracks the curvature of the bottom edge of leaflet structure 14, as described in more detail below. Leaflet structure 14 can be formed of bovine pericardial tissue, biocompatible synthetic materials, or various other suitable natural or synthetic materials as known in the art and described in U.S. Patent No. 6,730,118, which is incorporated by reference herein.

[057] Leaflet structure 14 can comprise three leaflets 60, which can be arranged to collapse in a tricuspid arrangement, as best shown in FIGS. 2 and 6. The lower edge of leaflet structure 14 desirably has an undulating, curved scalloped shape (suture line 58 shown in FIG. 1 tracks the scalloped shape of the leaflet structure). By forming the leaflets with this scalloped geometry, stresses on the leaflets are reduced, which in turn improves durability of the valve. Moreover, by virtue of the scalloped shape, folds and ripples at the belly of each leaflet (the central region of each leaflet), which can cause early calcification in those areas, can be eliminated or at least minimized. The scalloped geometry also reduces the amount of tissue material used to form leaflet structure, thereby allowing a smaller, more even crimped profile at the inflow end of the valve.

[058] Leaflets 60 can be secured to one another at their adjacent sides to form commissures 84 of the leaflet structure (the edges where the leaflets come together). Leaflet structure 14 can be secured to frame 12 using suitable techniques and mechanisms. For example, as best shown in FIG. 6, commissures 84 of the leaflet structure desirably are aligned with the support posts 18 and secured thereto using sutures. The point of attachment of the leaflets to the posts 18 can be reinforced with bars 62 (FIG. 11), which desirably are made of a relatively rigid material (compared to the leaflets), such as stainless steel.

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[059] FIG. 13 shows a single leaflet 60, which has a curved lower edge 64 and two flaps 66 extending between the upper edge and curved lower edge of the leaflet. The curved lower edge 64 forms a single scallop. When secured to two other leaflets to form leaflet structure 14, the curved lower edges of the leaflets collectively form the scalloped shaped lower edge portion of the leaflet structure (as best shown in FIG. 18). As further shown in FIG. 13, two reinforcing bars 62 can be secured to the leaflet adjacent to flaps 66 (e.g., using sutures). The flaps can then be folded over bars 62 and secured in the folded position using sutures. If desired, as shown in FIG. 12, each bar 62 can be placed in a protective sleeve 68 (e.g., a PET sleeve) before being secured to a leaflet.

[060] As shown in FIG. 14, the lower curved edge 64 of the leaflet can be reinforced for later securement to the skirt 16, such as by securing a reinforcing strip 68 along the curved lower edge between flaps 66 on the side of the leaflet opposite bars 62. Three such leaflets 60 can be prepared in the same manner and then connected to each other at their flaps 66 in a tricuspid arrangement to form leaflet structure 14, as shown in FIG. 15. The reinforcing strips 68 on the leaflets collectively define a ribbon or sleeve that extends along the lower edge portion of the inside surface of the leaflet structure.

[061] As noted above, leaflet structure 14 can be secured to frame 12 with skirt 16. Skirt 16 desirably comprises a tough, tear resistant material such as PET, although various other synthetic or natural materials can be used. Skirt 16 can be much thinner than traditional skirts. In one embodiment, for example, skirt 16 is a PET skirt having a thickness of about 0.07 mm at its edges and about 0.06 mm at its center. The thinner skirt can provide for better crimping performances while still providing good perivalvular sealing.

[062] FIG. 16 shows a flattened view of the skirt before the opposite ends are secured to each other to form the annular shape shown in FIG. 17. As shown, the upper edge of skirt 16 desirably has an undulated shape that generally follows the shape of the second row of struts 22 of the frame. In this manner,

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the upper edge of skirt 16 can be tightly secured to struts 22 with sutures 56 (as best shown in FIG. 1). Skirt 16 can also be formed with slits 70 to facilitate attachment of the skirt to the frame. Slits 70 are aligned with crown structures 26 of struts 22 when the skirt is secured to the frame. Slits 70 are dimensioned so as to allow an upper edge portion of skirt to be partially wrapped around struts 22 and reduce stresses in the skirt during the attachment procedure. For example, in the illustrated embodiment, skirt 16 is placed on the inside of frame 12 and an upper edge portion of the skirt is wrapped around the upper surfaces of struts 22 and secured in place with sutures 56. Wrapping the upper edge portion of the skirt around struts 22 in this manner provides for a stronger and more durable attachment of the skirt to the frame. Although not shown, the lower edge of the skirt can be shaped to conform generally to the contour of the lowermost row of struts 22 to improve the flow of blood past the inflow end of the valve.

[063] As further shown in FIG. 17, various suture lines can be added to the skirt to facilitate attachment of the skirt to the leaflet structure and to the frame. For example, a scalloped shaped suture line 72 can be used as a guide to suture the lower edge of the leaflet structure at the proper location against the inner surface of the skirt using suture 59 (as best shown in FIG. 5). Another scalloped shaped suture line 74 (FIG. 17) can be use as a guide to suture the leaflet structure to the skirt using sutures 58 (FIG. 1). Reinforcing strips 68 secured to the lower edge of the leaflets reinforces the leaflets along suture line 58 and protects against tearing of the leaflets. FIG. 18 shows a leaflet assembly comprised of skirt 16 and leaflet structure 14 secured to the skirt. The leaflet assembly can then be secured to frame 12 in the manner described below. In alternative embodiments, the skirt, without the leaflet structure, can be connected to the frame first, and then the leaflet structure can be connected to the skirt.

[064] FIG. 6 shows a top view of the valve assembly attached to frame 12. Leaflets 60 are shown in a generally closed position. As shown, the commissures of the leaflets are aligned with posts 18 of the frame. The leaflets

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can be secured to the frame using sutures extending through flaps 66 of the leaflets, openings 76 in bars 62, and openings 78 in posts 18, effectively securing flaps 66 to posts 18. As noted above, bars 62 reinforce the flaps at the area of connection with posts and protect against tearing of the leaflets.

[065] As shown in FIG. 6A, bars 62 desirably are aligned perpendicular and as straight as possible with respect to posts 18 of the frame, such that bars 62 and post 18 at each commissure form a "T" shape. The width of bars 62 and the attachment of the commissures via the bars provides a clearance between the deflectable portions of the leaflets 60 (the portions not secured by sutures to the frame) and the frame, while the edge radius (thickness) of bars 62 serves as a flex hinge for the leaflets 60 during valve opening and closing, thereby increasing the space between the leaflets and the frame. By increasing the space between the moving portions of the leaflets and frame and by having the leaflets flex against an edge radius of bars 62, contact between the moving portions of the leaflets (especially the outflow edges of the leaflets) and the frame can be avoided during working cycles, which in turn improves the durability of the valve assembly. This configuration also enhances perfusion through the coronary sinuses.

[066] FIG. 19 depicts a side view of a valve 10 crimped on a balloon delivery catheter 100. The valve is crimped onto balloon 110 of balloon catheter 100. It is desirable to protect leaflet structure 14 of the valve from damage during crimping to ensure durability of the leaflet structure and at the same time, it is desirable to reduce as much as possible the crimped profile size of the valve. During the crimping procedure the tissue of the leaflet structure (e.g., bovine pericardial tissue or other suitable tissue) is pressed against against the inner surface of the metal frame and portions of the tissue can protrude into the open cells of the frame between the struts and can be pinched due to the scissor-like motion of the struts of the frame. If the valve is severely crimped to achieve a small crimping size, this scissor-like motion can result in cuts and rupture of the tissue leaflets.

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[067] Skirt 16, described above, can protect against damage to the leaflet structure during crimping to a certain degree. However, the skirt's main purpose is structural and it does not in certain embodiments cover the entire frame. Therefore, in such embodiments, the skirt may not fully protect the leaflet structure during crimping and as such, the frame can still cause damage to the leaflet structure.

[068] FIGS. 20 and 21 show an embodiment of a crimping apparatus for atraumatic crimping of a valve onto a balloon in a manner that further protects against damage to the leaflets. The crimping apparatus (also referred to as a crimper), indicated generally at 200, has an aperture 202 sized to receive a valve in an expanded state. FIG. 20 shows aperture 202 in a fully open or dilated state with a valve 10 positioned inside aperture 202. Crimping apparatus 200 has a plurality of crimper jaws 206 (12 in the illustrated embodiment) which are configured to move radially inwardly to radially compress (crimp) the valve to a smaller profile around the balloon of a balloon catheter.

[069] A deformable material is positioned between the outside of the frame and the crimping jaws 206. In the illustrated embodiment, the deformable material comprises a protective sleeve, or covering, 204 that is placed around the valve so that it covers the outer surface of the frame of the valve and prevents the hard surface of the crimping jaws from directly contacting the frame of the valve. The sleeve 204 desirably is sized to fully cover the outer surface of the frame. Sleeve 204 desirably is made of a soft, flexible and compressible material. The sleeve can be formed from generally available materials, including, but not limited to, natural or synthetic sponge (e.g., polyurethane sponge), a foamed material made of a suitable polymer such as polyurethane or polyethylene, or any of various suitable elastomeric materials, such as polyurethane, silicon, polyolefins or a variety of hydrogels, to name a few.

[070] The sleeve is desirably stored in a wet environment (e.g., immersed in saline) prior to use. After placing sleeve 204 around the valve, the valve and

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the sleeve are placed into crimping apparatus 200 as shown in FIG. 20. Balloon 110 of a balloon catheter can then be positioned within the leaflets 60 of the valve (FIG. 21). FIG. 21 shows crimper jaws 206 surrounding sleeve 204, which in turn surrounds frame 12 and leaflet structure 14 of valve 10. Balloon 110 typically is placed at the center of the valve so that the valve can be evenly expanded during implantation of the valve within the body.

[071] As seen in FIG. 21, during crimping, the sponge-like material of protective sleeve 204 protrudes into the open cells of frame 12 and occupies this space, thereby preventing leaflet structure 14 from entering this space and being pinched or otherwise damaged. After crimping is completed, the valve with the protective sleeve is removed from the crimping apparatus. Sleeve 204 can then be gently peeled away from the frame. Because the protective sleeve presses the leaflet structure inwardly and away from the frame during crimping, the valve can be crimped to a small profile without damaging the leaflet structure.

[072] FIGS. 23 and 24 illustrate an advantage that can be gained by using protective sleeve 204. FIG. 23 shows a prosthetic valve that was crimped without using the protective sleeve. Dotted line 300 identifies an area of the valve where leaflet structure 302 has been pressed between struts of a frame 304, which can damage the leaflet structure as discussed above.

[073] In contrast, FIG. 24 shows a prosthetic valve that was crimped using protective sleeve 204. In this example, leaflet structure 302 was pressed inwardly and away from the inside of frame 304 and, therefore, the leaflet structure was not pinched or squeezed between the struts of the frame.

[074] Accordingly, since the leaflet structure is pushed away from the frame when the protective sleeve is used, the leaflet structure is less likely to be pinched or cut during the crimping process. Also, when using a protective sleeve, a very ordered structure of balloon-leaflets-frame (from inward to outward) can be achieved. When no such protective sleeve is utilized, some portion of the balloon, leaflets, and frame are much more likely to overlap after

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the crimping procedure and the resulting structure is less predictable and uniform.

[075] In addition to the foam or sponge-type protective sleeve described above, other types of sleeves or protective layers of deformable material can be used to protect the leaflets against damage during crimping of a valve. In one implementation, for example, a layer (e.g., rectangular slices) of deformable material (e.g., sponge, rubber, silicon, polyurethane, etc.) can be disposed on each crimping jaw 206 so as to form a sleeve around the valve upon crimping. Alternatively, deformable packets filled with a flowable, deformable material, such as a gel or gas, can be disposed on each crimping jaw for contacting the valve upon crimping. In addition, the deformable material (e.g., sleeve 204) can be covered with a thin PET cloth, among many other fabric materials or other suitable materials, to prevent particles of the deformable materials from migrating to the valve during crimping.

[076] The skirt of a prosthetic valve serves several functions. In particular embodiments, for example, the skirt functions to seal and prevent (or decrease) perivalvular leakage, to anchor the leaflet structure to the frame, and to protect the leaflets against damage caused by contact with the frame during crimping and during working cycles of the valve. The skirt used with the prosthetic valve discussed above has been described as being a fabric, such as a PET cloth. PET or other fabrics are substantially non-elastic (i.e., substantially non-stretchable and non-compressible). As such, the skirt in certain implementations limits the smallest achievable crimping diameter of the valve and can wrinkle after expansion from the crimped diameter.

[077] In alternative embodiments, such as discussed below, a prosthetic valve can be provided with a skirt that is made of a stretchable and/or compressible material, such as silicon. Due to the compressibility of such a skirt, the valve can be crimped to a relatively smaller diameter as compared to a valve having a non-compressible skirt. Furthermore, such a skirt can recover its original,

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smooth surfaces with little or no wrinkling after expansion from the crimped state.

[078] FIG. 25 shows an embodiment of a frame 12 that has an elastic "over-tube" skirt or sleeve 340 that extends completely around and covers at least a portion of the outside of the frame. In particular embodiments, skirt 340 is made of silicon, which can undergo large deformations while maintaining its elasticity. Such a silicon skirt can be a thin sleeve that covers a portion of frame 12 from the outside. In the illustrated embodiment, the height of the skirt is less than the overall height of frame 12, however, the skirt can vary in height and need not be the height shown in FIG. 25. For example, the height of the skirt can be the same as or greater than that of the frame so as to completely cover the outside of the frame. In an alternative embodiment, the skirt 340 can be mounted to the inside of the frame using, for example, sutures or an adhesive. When mounted inside of the frame, the skirt can protect the leaflets from abrasion against the inside of the frame. Other materials that can be used to form the skirt or sleeve include, but are not limited to, PTFE, ePTFE, polyurethane, polyolefins, hydrogels, biological materials (e.g., pericardium or biological polymers such as collagen, gelatin, or hyaluronic acid derivatives) or combinations thereof.

[079] In another embodiment, the entire frame or a portion thereof can be dipped in liquefied material (e.g., liquid silicon or any of the materials described above for forming the sleeve 340 that can be liquefied for dip coating the frame) in order to encapsulate the entire frame (or at least that portion that is dipped) in silicon. FIG. 26 is a side view of a frame 12 that has been dipped in silicon to form a continuous cylindrical silicon covering 342 encapsulating the struts of the frame and filling the spaces between the struts. FIG. 26 shows the covering 342 before it is trimmed to remove excess material extending beyond the ends of the frame. Although less desirable, the frame can be dipped such that the silicon encapsulates the struts of the frame but does not fill the open spaces between the struts of the frame.

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[080] FIG. 27 shows an embodiment of a prosthetic valve 400 comprising a frame 402 and a leaflet structure 404 mounted to the inside of the frame (e.g., using sutures as shown). Frame 402 has a skirt in the form of silicon covering 406 that is formed, for example, by dipping the frame into liquid silicon. FIG. 27 shows valve 400 in its expanded state. In FIG. 28, valve 400 has been crimped to a smaller profile. During crimping, coating 406, which extends across and fills the open cells between the struts of the frame, is effective to push leaflet structure 404 inward and away from the frame, thereby protecting the leaflet structure from pinching or tearing. FIG. 29 shows valve 400 after being expanded by a balloon of a balloon catheter.

[081] In order to test the durability and stretch resistance of the silicon used, several uniaxial tests were conducted. In particular, silicon strips of about 5x50 mm (with a thickness of about 0.85 mm) were tested in a uniaxial tester. FIGS. 30A-30C show graphs of the results of the uniaxial testing of silicon strips. In addition, tears were deliberately introduced into silicon strips at a middle of the strips and at the edge of the strips while the strips were stretched on a uniaxial tester. The tears were introduced by making holes in the silicon strips with a needle. FIGS. 31A-31F show graphs of the results of the uniaxial testing of silicon strips with deliberately introduced tears.

[082] It was found that ultimate tensile stretch for a thin layer of silicon was over 500% and that samples that had tears that were deliberately introduced continued to show notable strength. Accordingly, the elasticity of silicon permits silicon dipped frames to be crimped to very low profiles and expanded back out to larger profiles without significant damage to the silicon layer. In addition, the silicon material can increase friction between the frame and the native annulus where the prosthetic valve is implanted, resulting in better anchoring and preventing/reducing perivalvular leaks.

[083] A silicon skirt can be mounted on a frame by various means, including by using a mandrel. Also, it may be desirable to use a silicon skirt in combination with a cloth or fabric skirt. For example, it may be desirable to

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place a silicon skirt on the outside of a cloth or fabric skirt that is surrounding at least a portion of a frame.

[084] Alternatively or additionally, a silicon skirt could also be placed on the inside of the frame and attached to the frame so that it offers the leaflets improved protecting during working cycles. Alternatively, instead of silicon, the skirt can be made of an auxetic and/or swelling material, such as synthetic or natural hydrogels. An auxetic material is one that expands laterally while stretched longitudinally, which means that this material has a negative Poisson ration. If the frame is covered with an auxetic material it can expand radially while being stretched circumferentially when the valve is expanded from its crimped state. Such expansion can improve the fit of the valve at the native valve annulus, thereby preventing or reducing perivalvular leakage.

[085] In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims. We therefore claim as our invention all that comes within the scope and spirit of these claims.

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We claim:

1. An implantable prosthetic valve comprising:

a radially collapsible and expandable annular frame, the frame having a plurality of angularly spaced commissure attachment posts;

an annular skirt member positioned inside of and secured to the frame; and

a leaflet structure comprising a plurality of leaflets, the leaflet structure having a scalloped lower edge portion secured to an inner surface of the skirt member, each leaflet having an upper edge, a curved lower edge and two side flaps extending between respective ends of the upper edge and the lower edge, wherein each side flap is secured to an adjacent side flap of another leaflet to form commissures of the leaflet structure, each commissure being attached to one of the commissure attachment posts; and

a reinforcing bar positioned against each side flap for reinforcing the attachments between the commissures and the commissure attachment posts.

2. The prosthetic valve of claim 1, wherein the commissures are attached to the commissure attachment posts with sutures extending through the side flaps, the reinforcing bars and the commissure attachment posts.

3. The prosthetic valve of claim 1, further comprising an elastomeric sleeve disposed on the outside of the frame.

4. The prosthetic valve of claim 1, further comprising an annular elastomeric layer encapsulating at least a portion of the frame.

5. The valve of claim 1, wherein the frame comprises a plurality of axial struts and a plurality of rows of circumferential struts extending between and interconnecting the axial struts.

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6. The valve of claim 5, wherein at least one row of circumferential struts includes pairs of circumferential struts extending between two axial struts, the struts of each pair having adjacent ends interconnected by a generally U-shaped crown portion defining a gap between the adjacent ends.

7. The valve of claim 6, wherein an angle between each pair of struts is between about 90 and 110 degrees.

8. The valve of claim 1, wherein the frame comprises a nickel cobalt chromium alloy.

9. The valve of claim 4, wherein the nickel cobalt chromium alloy comprises MP35N.

10. The valve of claim 1, wherein the leaflets are connected to each other at adjacent sides to form commissures of the leaflet structure, each leaflet having a curved lower edge portion comprising a scallop extending between two commissures, the curved lower edge portions of the leaflets collectively defining the scalloped lower edge portion of the leaflet structure.

11. The valve of claim 10, further comprising an annular skirt secured to the inside of the frame.

12. The valve of claim 11, wherein the lower edge portion of the leaflet structure is secured to the inside of the skirt and the commissures are secured to respective axial struts of the frame.

13. The valve of claim 12, further comprising a reinforcing strip, separate from the skirt, that is secured to an inner surface of the lower edge portion of the leaflet structure.

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14. The valve of claim 5, wherein the rows of circumferential struts includes at least a first row of circumferential struts adjacent the inflow end of the valve and a second row of circumferential struts adjacent the outflow end of the valve, wherein the struts of the first row are thicker than the struts of the second row.

15. An implantable prosthetic valve comprising:

a radially collapsible and expandable annular frame, the frame comprising a plurality of interconnected struts defining a plurality of open cells in the frame;

a leaflet structure supported by the frame and comprising a plurality of leaflets; and

an annular cover member disposed on and covering the cells of at least a portion of the frame, the cover member being made of silicon.

16. The valve of claim 15, wherein the cover member comprises a sleeve.

17. The valve of claim 15, wherein the sleeve is disposed on the outside of the frame.

18. The valve of claim 15, wherein the cover member is an encapsulating layer encapsulating said at least a portion of the frame and filling the cells of said at least a portion of the frame.

19. The valve of claim 15, wherein the leaflets are connected to each other at adjacent sides to form commissures of the leaflet structure, each leaflet having a curved lower edge portion comprising a scallop extending between two commissures, the curved lower edge portions of the leaflets collectively defining a scalloped lower edge portion of the leaflet structure that is positioned inside and secured to the frame.

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Fig. 1

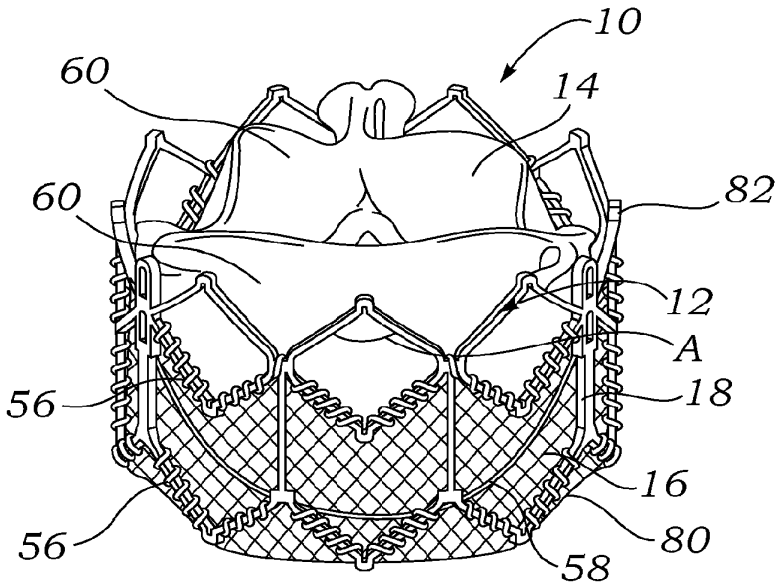

Fig. 2

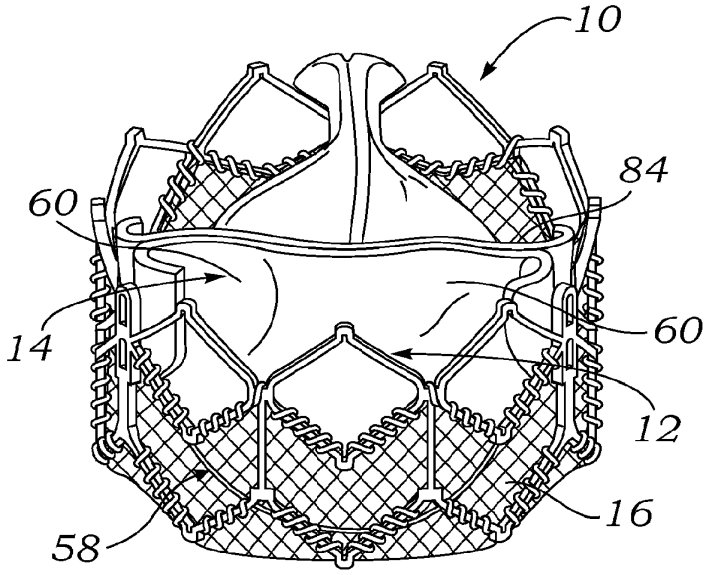

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Fig. 3

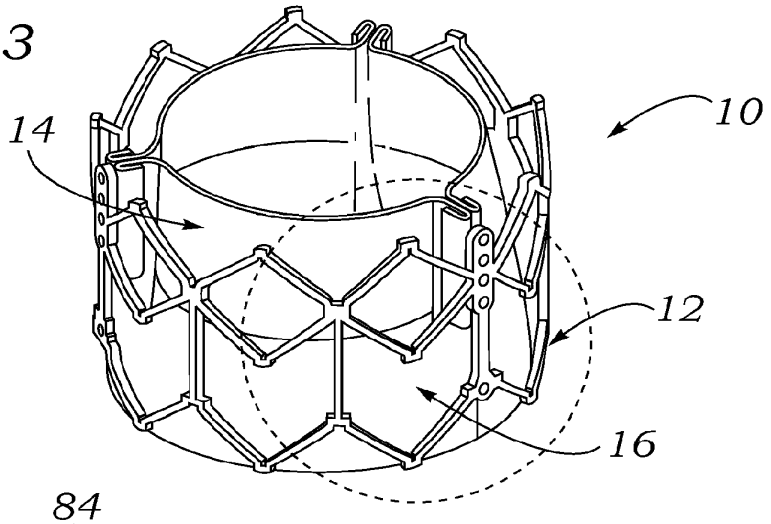

Fig. 4

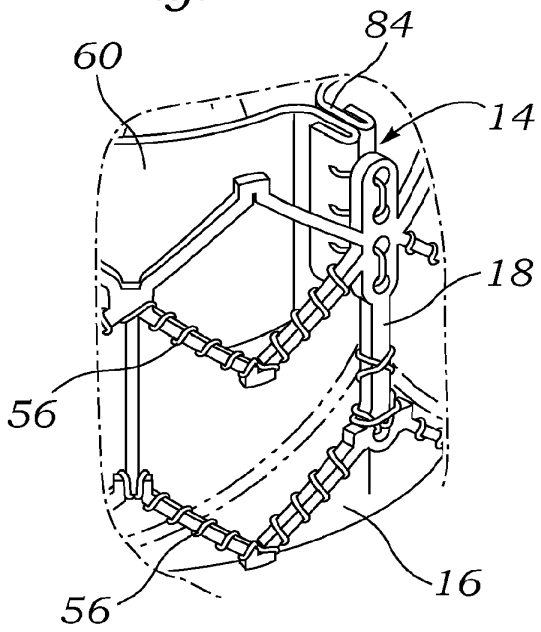

Fig. 5

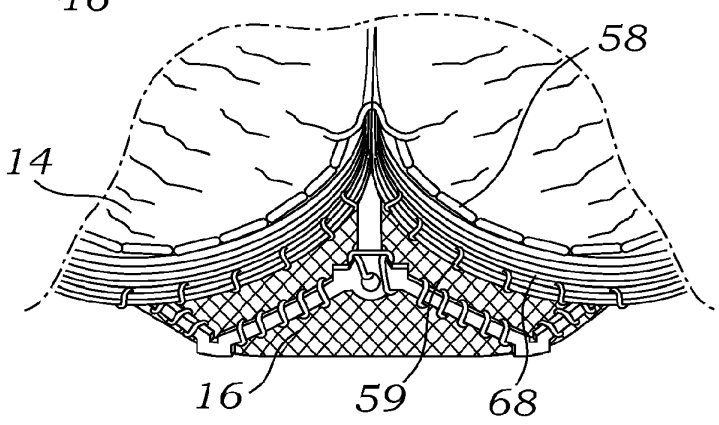

Fig. 6

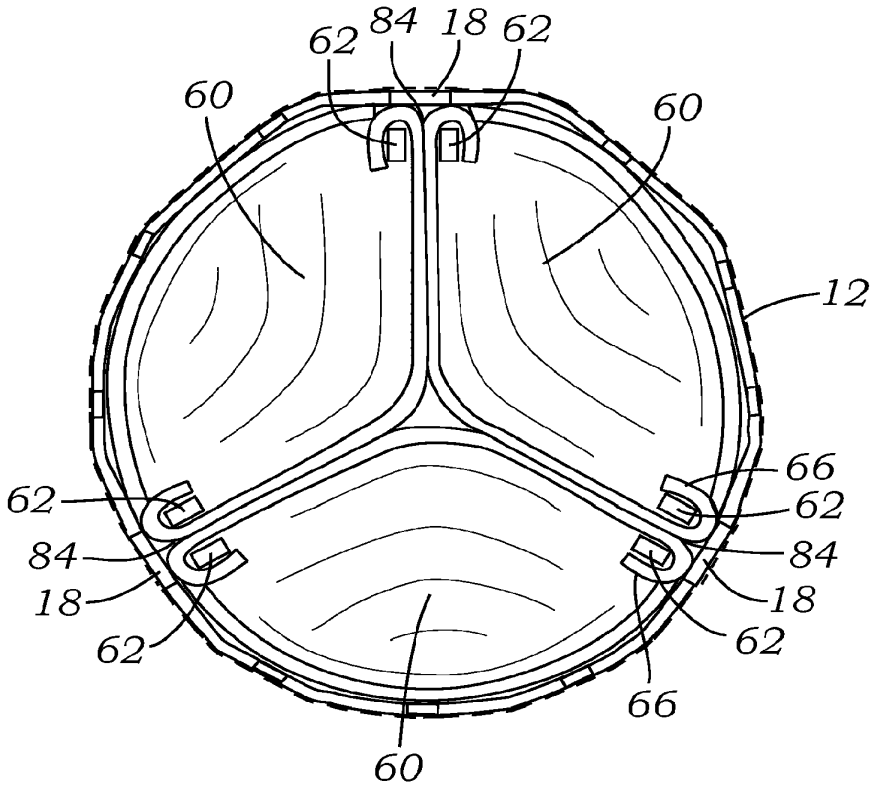

Fig. 7

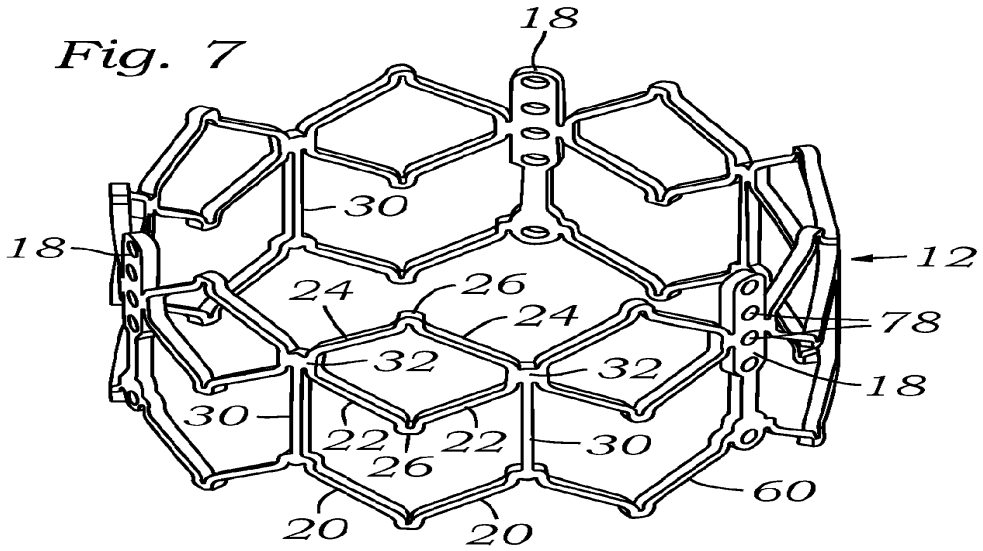

Fig. 8

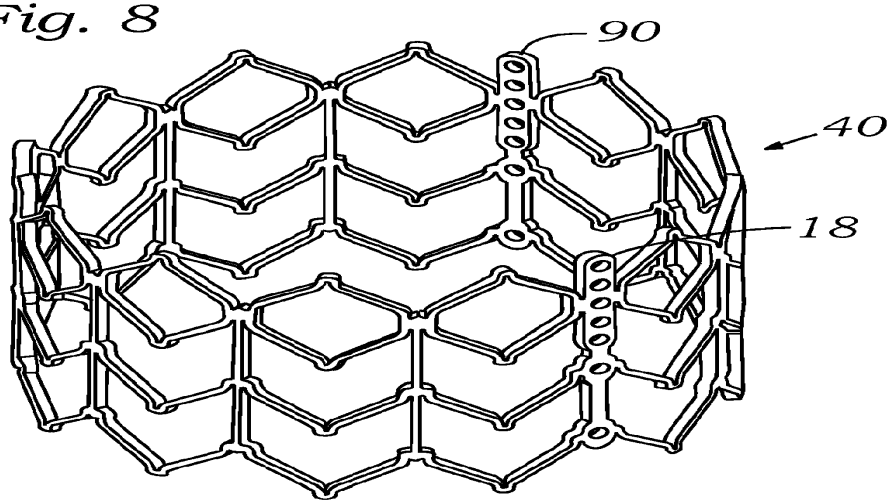

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Fig. 9

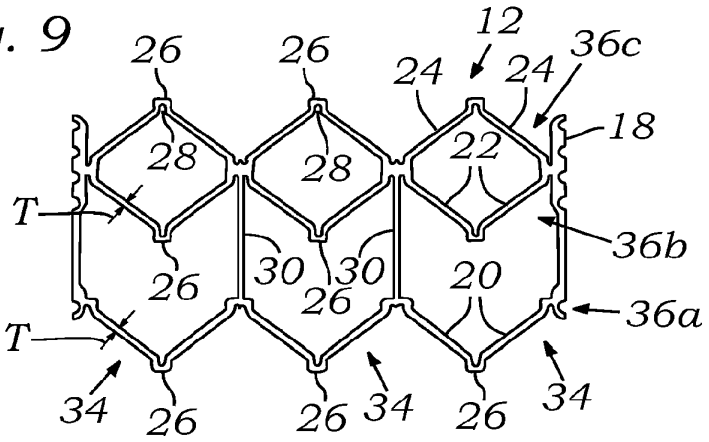

Fig. 10

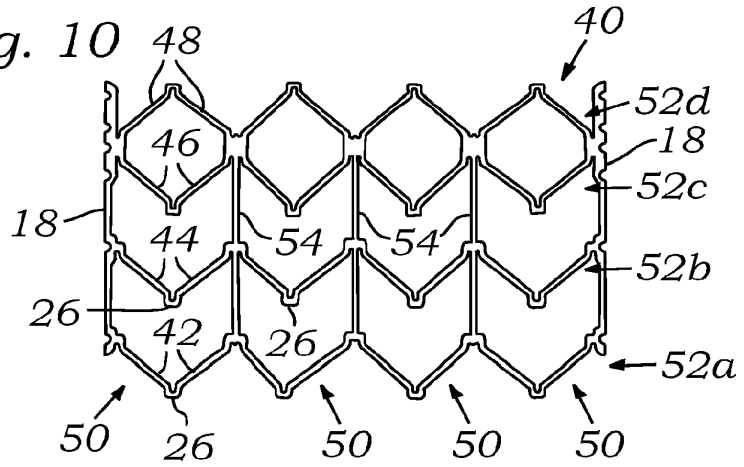

Fig. 11

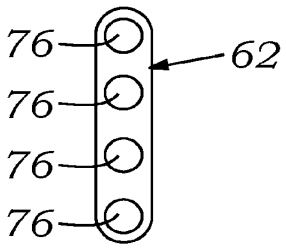

Fig. 12

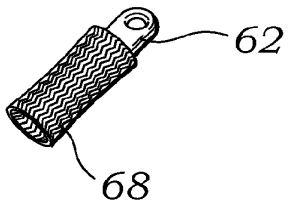

Fig. 13

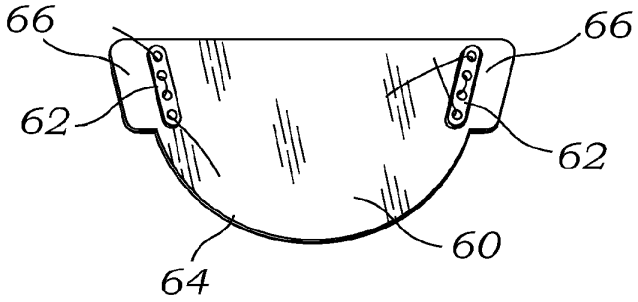

Fig. 14

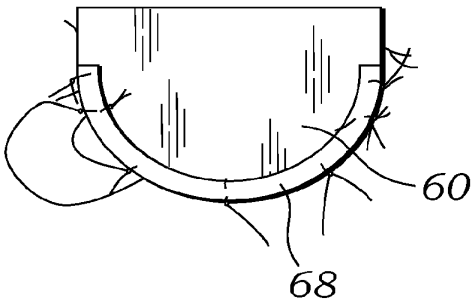

Fig. 15

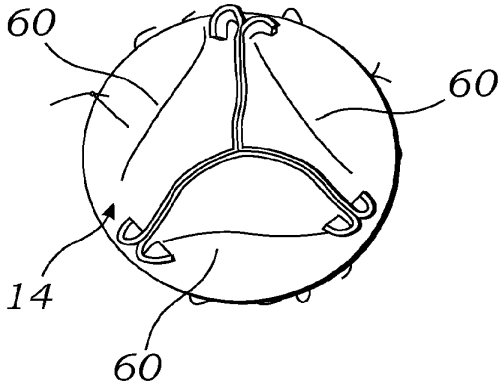

Fig. 6A

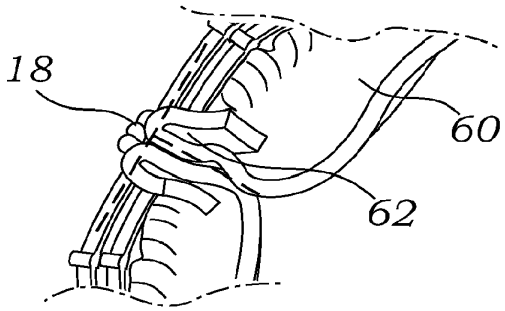

Fig. 16

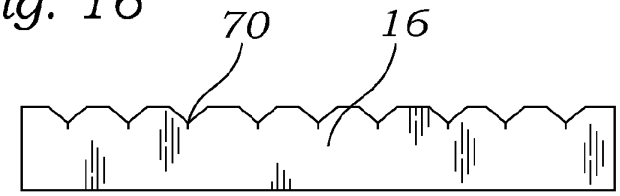

Fig. 17

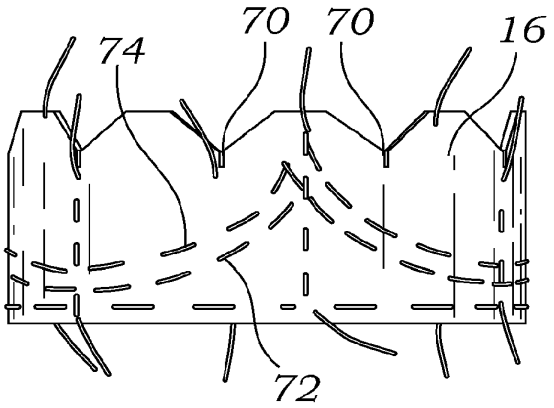

Fig. 18

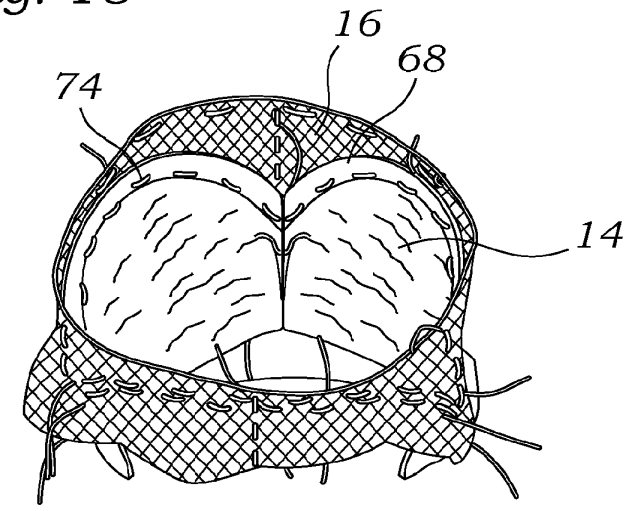

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Fig. 19

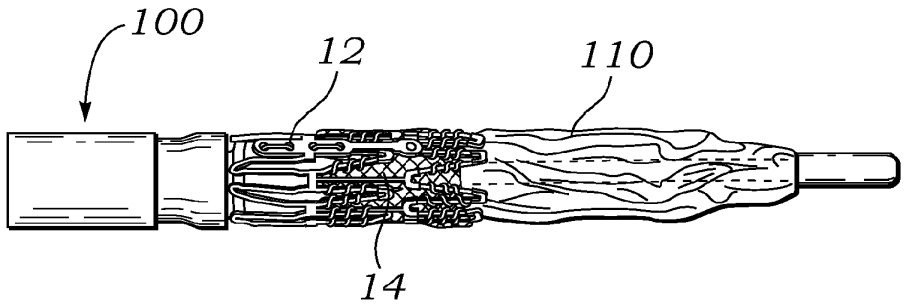

Fig. 20

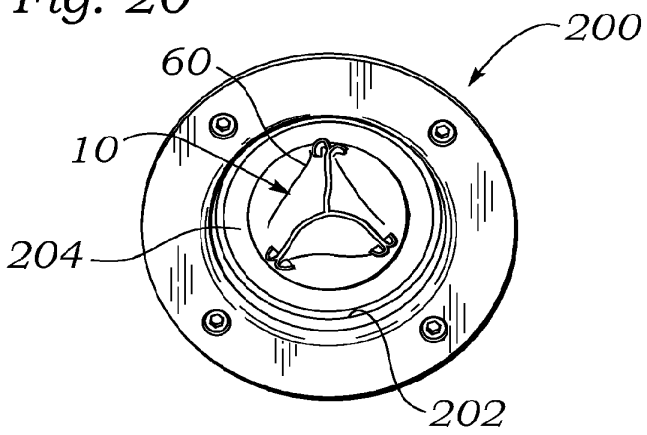

Fig. 21

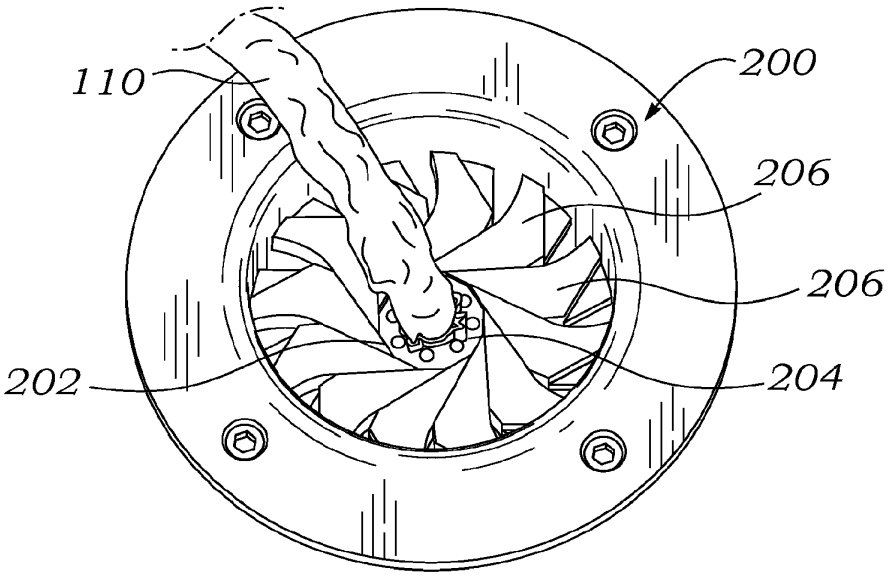

Fig. 22

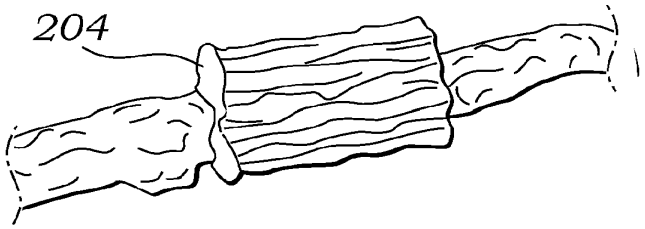

Fig. 23

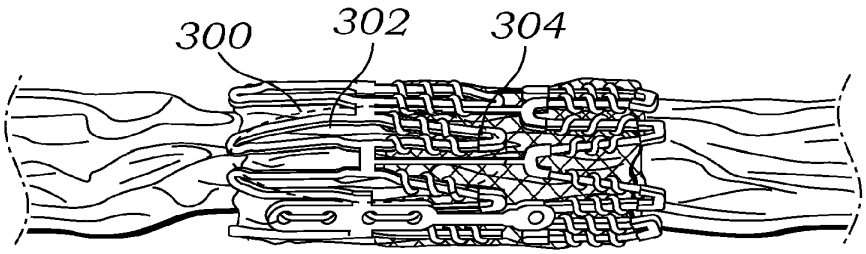

Fig. 24

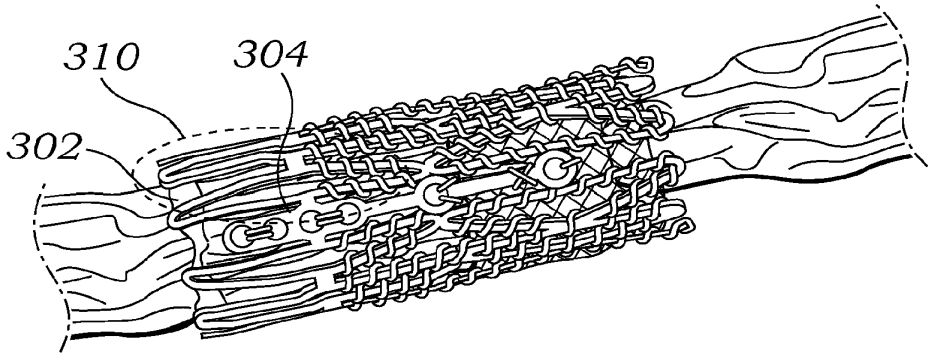

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Fig. 25

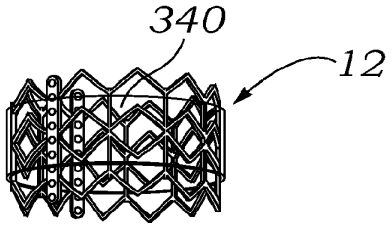

Fig. 26

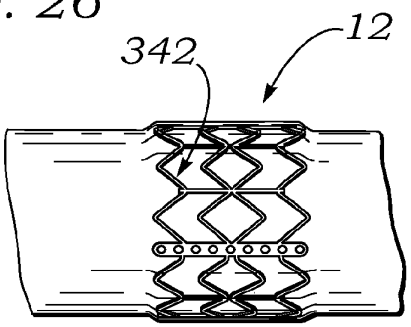

Fig. 27

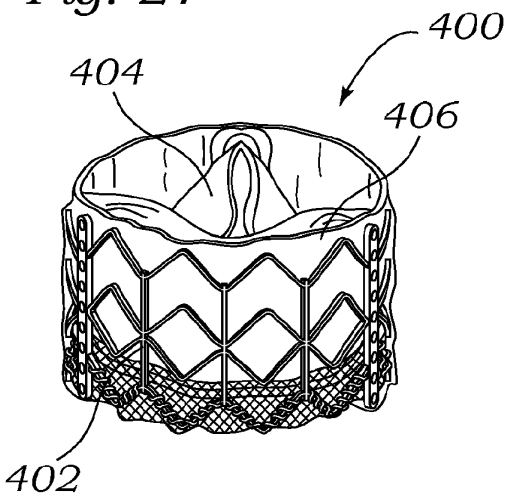

Fig. 28

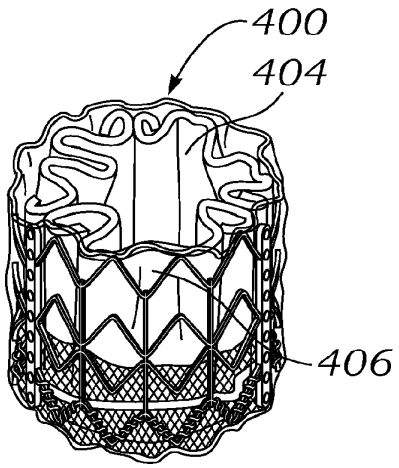

Fig. 29

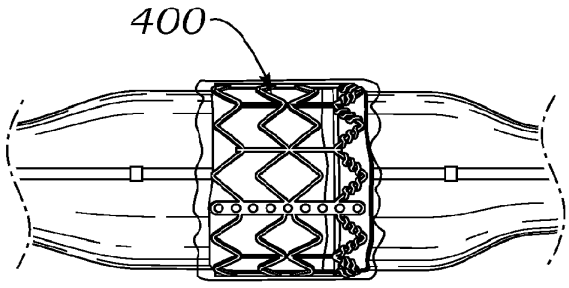

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Fig. 30A

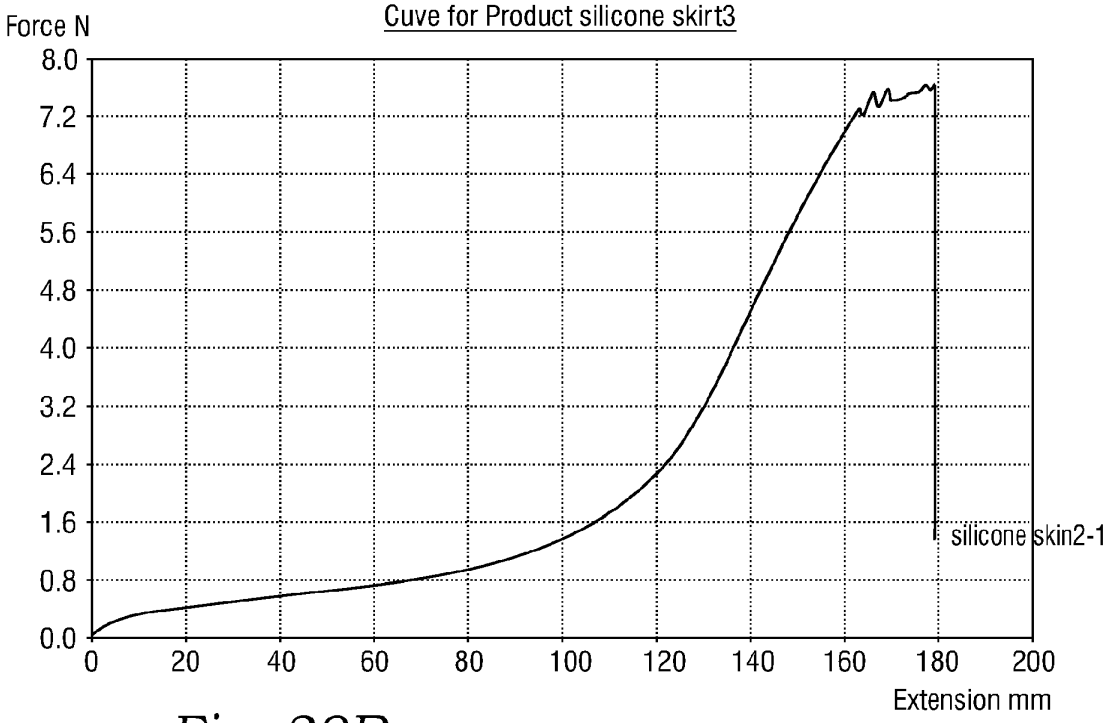

Fig. 30B

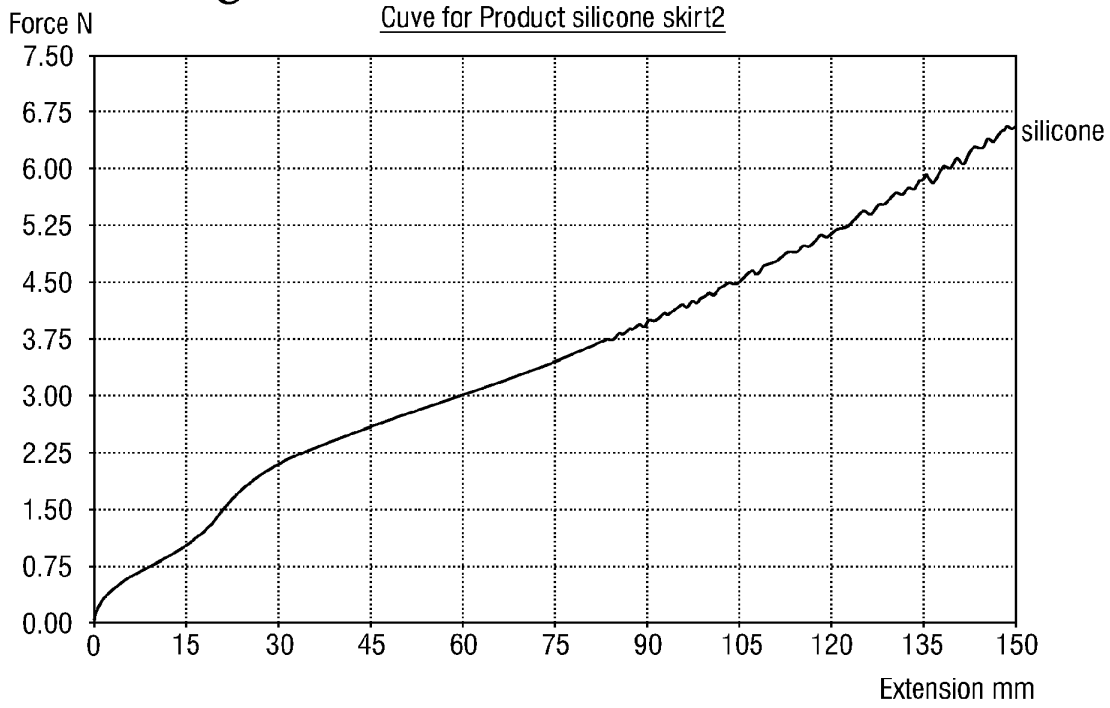

Fig. 30C

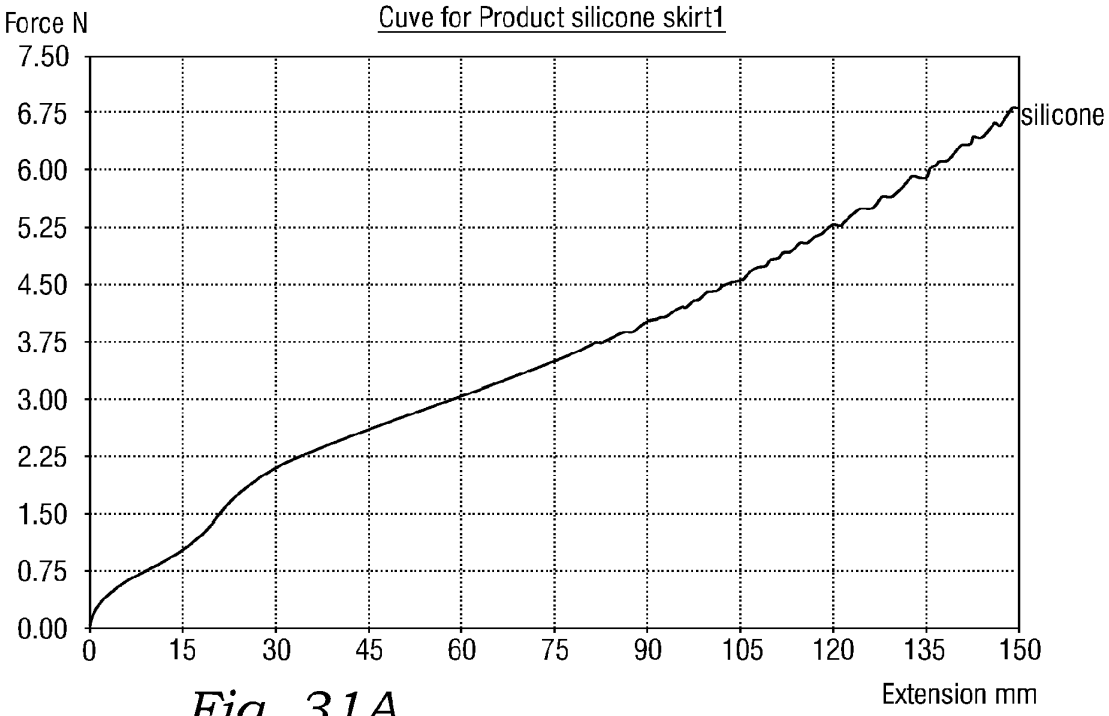

Fig. 31A

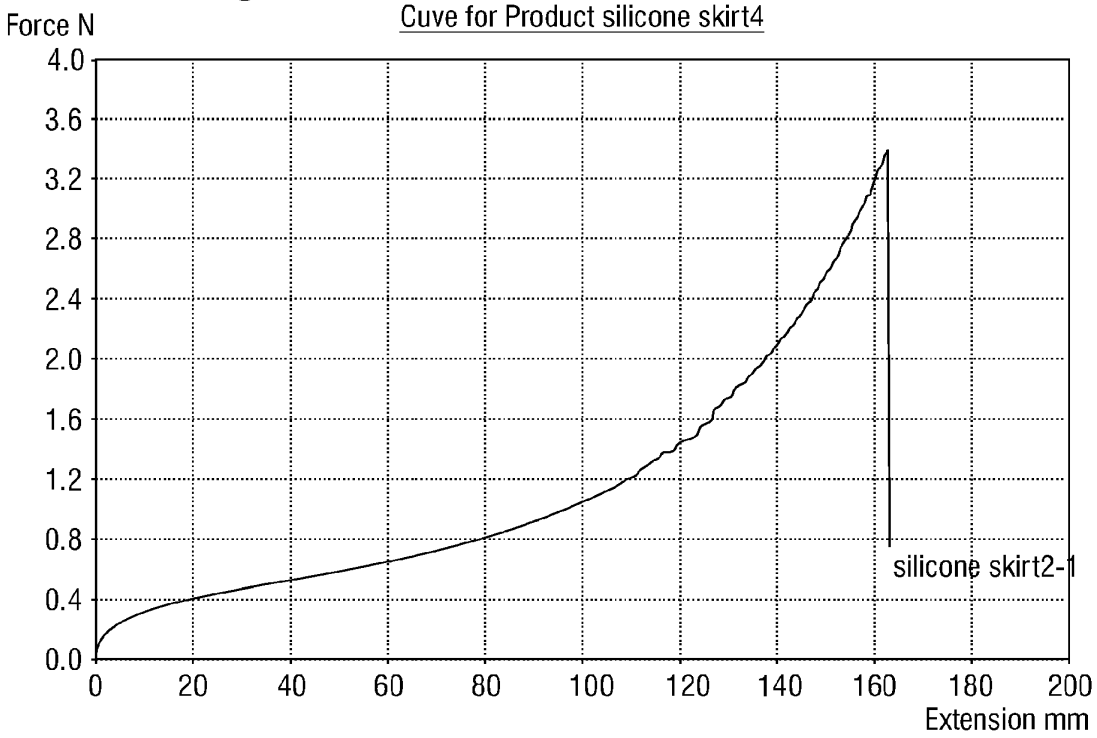

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Fig. 31B

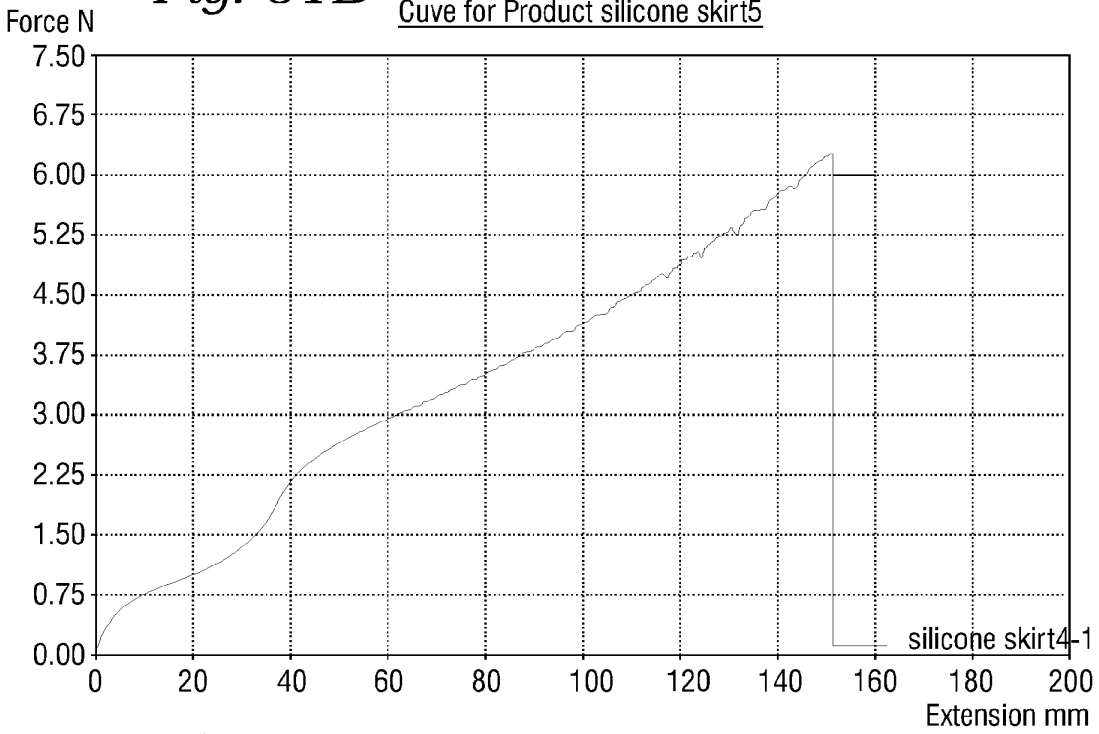

Fig. 31C

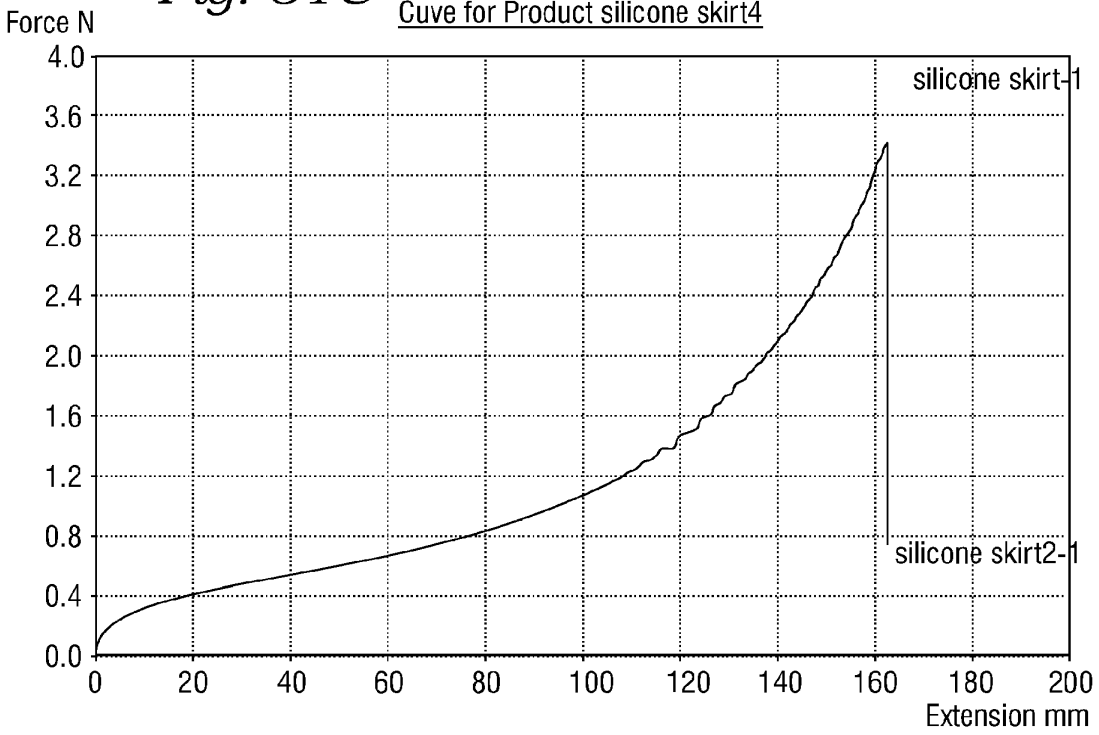

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Fig. 31D

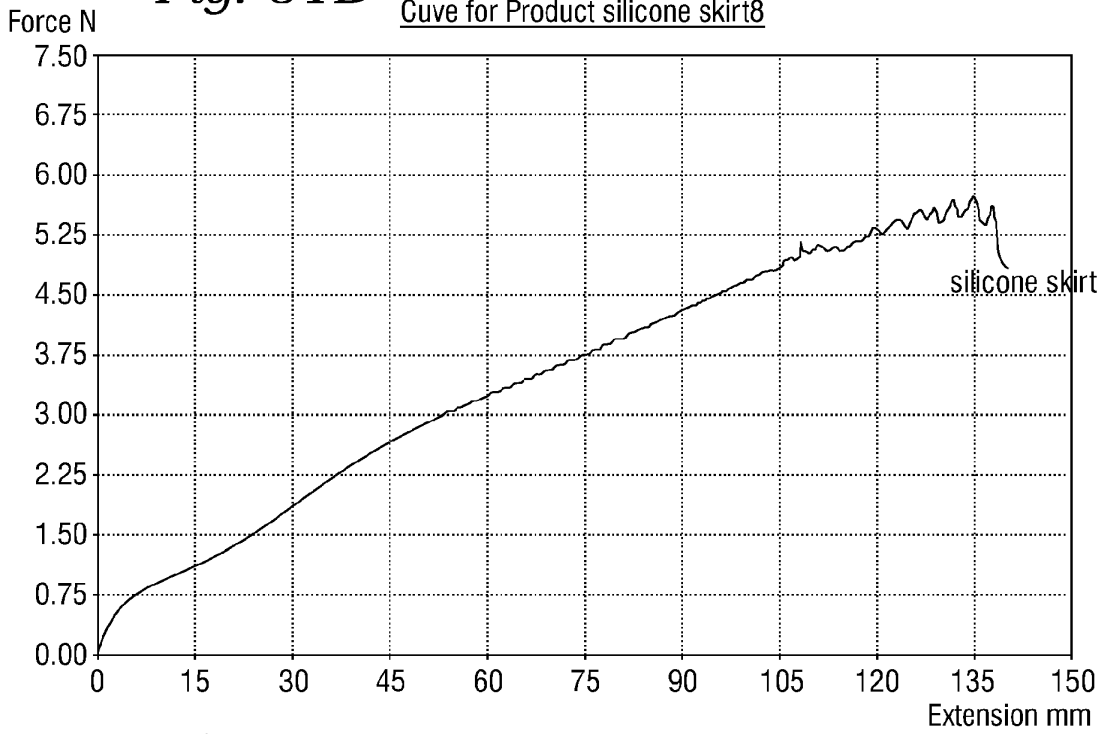


Fig. 31E

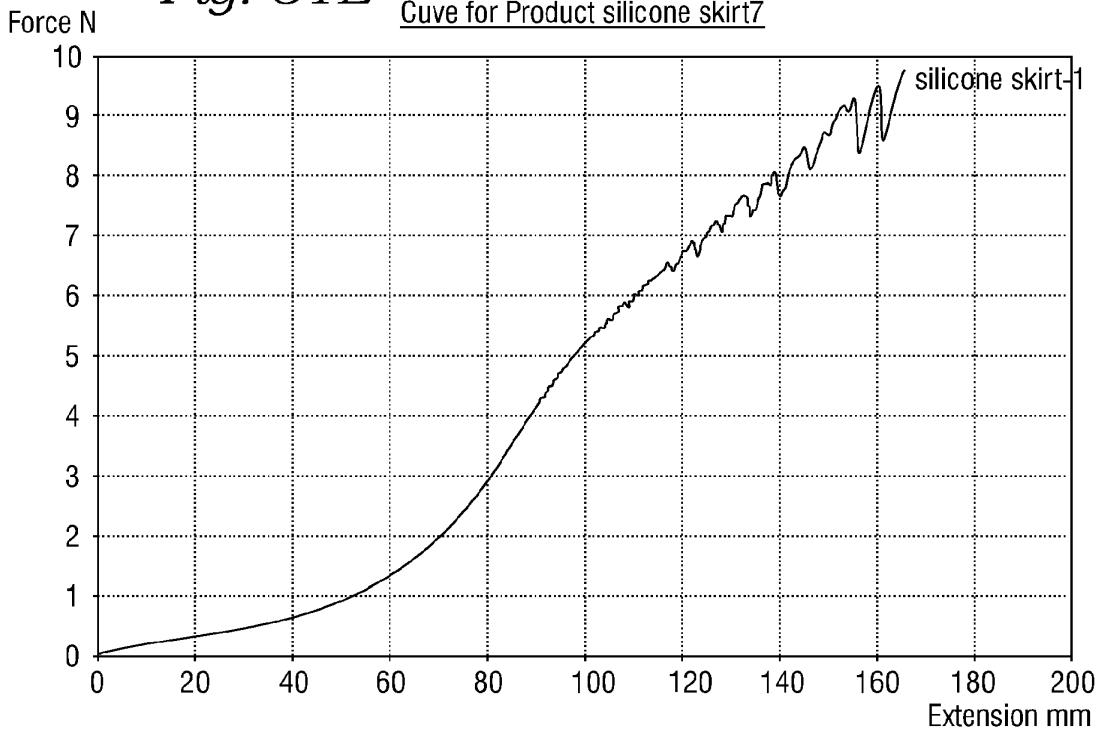
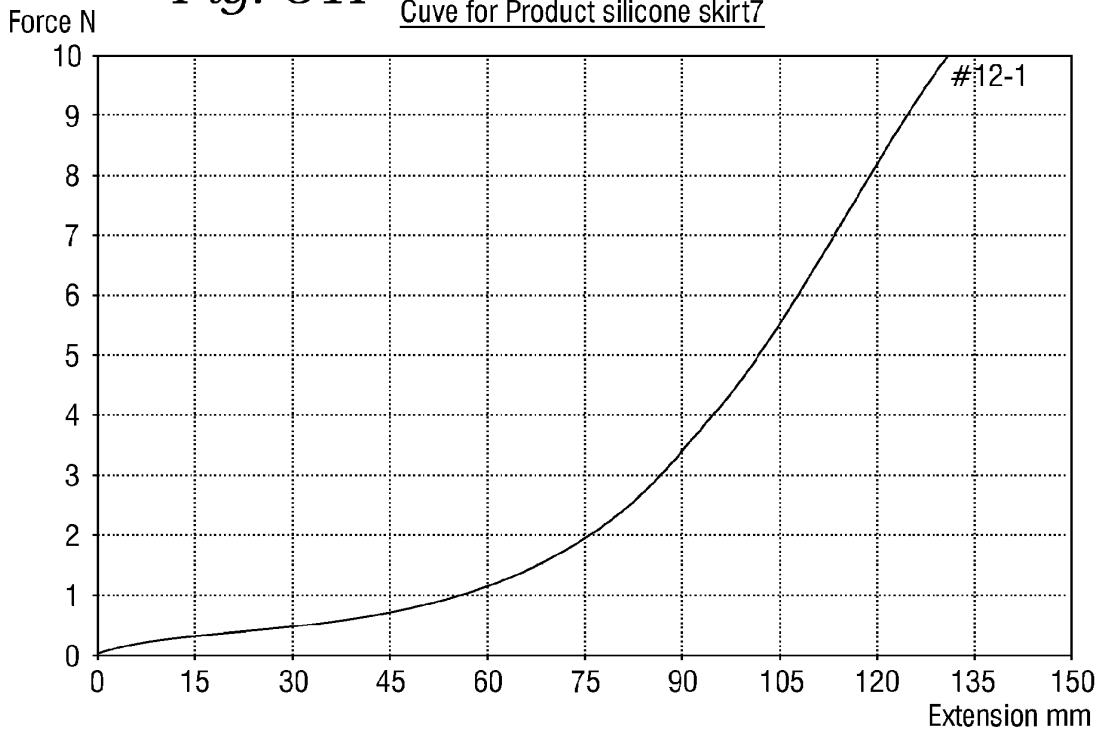


Fig. 31F



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Electronic Acknowledgement Receipt

EFS ID:	22601705
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	11-JUN-2015
Filing Date:	13-NOV-2012
Time Stamp:	13:27:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_Supp_IDS_2015-06-11.PDF	630914 cb7e1b14285a606c19e0412f70eb4b4518ef661e	no	4

Warnings:	
Information:	

2	Foreign Reference	WO-1995-005207.PDF	1830719 8d8439b132e183e99b8eda6fd6531f7684b0a3a4	no	41
Warnings:					
Information:					
3	Foreign Reference	WO-1998-011935.PDF	1276360 d4659ecbc9a09de2a741cfbbcb9be6362273c67d	no	31
Warnings:					
Information:					
4	Foreign Reference	EP0696447.PDF	1289143 204e7402d972b324e6b9aa99c82edefdae4bfc93	no	32
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5	Non Patent Literature	10-887688_Declaration_Under_37_CFR_1-131_filed_2008-12-15.pdf	1898770 dae08c3d864259a8b50f8695c6028c16cdf48fba	no	46
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6	Non Patent Literature	10106_US_14-502453_Final_Office_Action_2015-05-08.PDF	358607 844085e2edd2b6b6f5b143d67cd866c8be0b4695	no	9
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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	11/13/2012	David Paniagua	109978.10101	1995

29880 7590 07/06/2015

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
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LAWRENCEVILLE, NJ 08648

EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
07/06/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No. 13/675,665	Applicant(s) PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/11/2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-10,27-29 and 33* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-10,27-29 and 33* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 27-29, and 33 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 1 recites the limitations "the inner cavity" and “said artificial valve’s outer surface” in lines 3 and 4 respectively. There is insufficient antecedent basis for these limitations in the claim. Claims 2-10 depend upon claim 1 and inherit all issues with the claim.

Also in claim 1, line 3 recites “and disposed within the inner cavity of said stent member affixed at one or more points". It is unclear 1) what exactly is disposed in the inner cavity, and 2) what is affixed. The clause seems to be a plurality of fragments that does not appear to be grammatically clear. The claim lacks a colon after the preamble and seems to missing dividing commas or semicolons within the claim.

Claim 1 lines 5-7 recites, “cusps or leaflets formed by folding of a sheet of said biocompatible tissue material without affixing of separate cusps or leaflets or cutting slits into

said material to form said cusps or leaflets." This is unclear as to 1) what the separate cusps are not affixed to, 2) “or leaflets" in an incomplete fragment, 3) if cutting slits is intended to be an option or if it is supposed to mean without cutting slits, 4) is "to form said cusps or leaflets” different/in addition to “cusps or leaflets formed by” or intended to refer to the same forming process.

Claim 6 recites the limitation "the patient" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 is indefinite as the biocompatible tissue material is required to be synthetic. Tissue and synthetic appear to be alternatives to one another and thus in direct conflict with one another. Claim 8 depends upon claim 7 and inherits all issues associated with the claim.

Claim 8 appears to be a Markush style claim, however is missing an “and” following “metal alloy”.

Claim 27 recites the limitations "the inner cavity", “said artificial valve’s outer surface”, “said sheet”, and “said cusps” in lines 3, 4, 7, and 7 respectively. There is insufficient antecedent basis for these limitations in the claim. Claims 28-29 depend upon claim 27 and inherit all issues with the claim.

Also in claim 27, line 3 recites “and disposed within the inner cavity of said stent member affixed at one or more points". It is unclear 1) what exactly is disposed in the inner cavity, and 2) what is affixed. The clause seems to be a plurality of fragments that does not appear to be grammatically clear. The claim lacks a colon after the preamble and seems to missing dividing commas or semicolons within the claim.

Claim 27 lines 5-7 recites, “a leaflet or cusp portion formed by folding of a first sheet portion of said biocompatible tissue material without affixing of separate cusps or leaflets or cutting slits into said sheet to form said cusps or leaflets." This is unclear as to 1) what the separate cusps are not affixed to, 2) “or leaflets" in an incomplete fragment, 3) if cutting slits is intended to be an option or if it is supposed to mean without cutting slits, 4) is "to form said cusps or leaflets” different than “a leaflet or cusp portion formed by” or intended to refer to the same forming process (one is singular and other is plural, and the separate cusps or leaflets of line 6 are not affixed thus not present to form by cutting slits).

Claim 29 recites the limitation "the form" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant may consider changing "suturing is in the form of double continuous sutures” to recite --suturing comprises double continuous sutures--.

Claim 33 recites the limitations "the inner cavity", “said artificial valve’s outer surface”, “said sheet”, and “said cusps” in lines 3, 4, 7, and 7 respectively. There is insufficient antecedent basis for these limitations in the claim.

Also in claim 33, line 3 recites “and disposed within the inner cavity of said stent member affixed at one or more points". It is unclear 1) what exactly is disposed in the inner cavity, and 2) what is affixed. The clause seems to be a plurality of fragments that does not appear to be grammatically clear. The claim lacks a colon after the preamble and seems to missing dividing commas or semicolons within the claim.

Claim 33 lines 5-7 recites, “a leaflet or cusp portion formed by folding of a first sheet portion of said biocompatible tissue material without affixing of separate cusps or leaflets or cutting slits into said sheet to form said cusps or leaflets." This is unclear as to 1) what the

separate cusps are not affixed to, 2) “or leaflets" in an incomplete fragment, 3) if cutting slits is intended to be an option or if it is supposed to mean without cutting slits, 4) is "to form said cusps or leaflets” different than “a leaflet or cusp portion formed by” or intended to refer to the same forming process.

Here is an example of a modified claim 1 that would seemingly clear up any 112 2nd indefiniteness (emphasis added):

> A percutaneously implantable replacement heart valve device comprising**:**
>
> an expandable stent member **having an inner cavity;** and
>
> a flexible, compressible artificial valve **having leaflets**;
>
> the artificial valve disposed within the inner cavity of the stent member, **and an outer surface** of the artificial valve being affixed **to** said stent member at one or more points,
>
> said leaflets formed by folding a sheet of biocompatible tissue material without affixing separate leaflets **together and without** cutting slits into said material.

Product-by-Process

It is noted that claims 1, 27, and 33 each contain a product by process limitation wherein the leaflets or cusps (or leaflet/cusp portion) is *formed by* folding a sheet portion without affixing separate cusps or cutting slits to form cusps/leaflets. Because these are product claims, patentable weight has been given to the end product structure, and not the method of manufacture/forming. See MPEP 2113.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 7-8, 10, 27-28, and 33 are rejected under pre-AIA 35 U.S.C. 102e as being anticipated by Cribier (US 6,908,481 B2). Referring to claims 1, 33, Cribier discloses a percutaneously implantable replacement heart valve device (13; fig.4, 6b for example; col.1, lines 15-19) comprising an expandable stent (10; expands from compressed state in fig.4a to expanded state in fig.4b; col.10, lines 49-51) and a flexible, compressible artificial valve (14 or 14+19) made of biocompatible tissue material (col.10, lines 52-58) and disposed within the inner cavity of the stent (see fig.4, 6b, 6d) affixed at one or more points on the valves outer surface to the stent (at point 18, see fig.6b; col.11, lines 34-36), the valve (14 or 14+19) having cusps or leaflets (cusp/leaflet portion, 16) formed by folding a sheet of the material (synthetic or

pericardium, col.14 line 61-col.15 line 9; folds/pleats made so material will collapse along these folds/pleats, col.15, lines 36-52; col.5, lines 7-11) without affixing separate cusps or leaflets.

Referring to claims 2, 7-8, and 10, Cribier discloses the stent member (10) to be made of stainless steel (col.5, lines 55-57), the valve (14) comprising a biological material (pericardium) or a synthetic material such as PTFE (Teflon, col.5, lines 20-27), the stent (10) is balloon catheter expandable (col.9, lines 11-13; fig.12-13).

Referring to claims 27-28, Cribier further discloses the leaflet or cusp (16) formed by folding a first sheet portion (folds/pleats in 14; col.15, lines 36-53; col.4, lines 51-52; col.5, lines 7-11), and an outer tubular cuff (19) formed by folding a second sheet portion (see fig.6d for example; fold at bottom of stent), the first (14) and second (19) sheet portions affixed together (see fig.6d; col.13, lines 57-65), such as by continuous suturing (sewing, col.13, lines 57-65, continuous suture, col.13, lines 33-35).

Claims 1 and 9 are rejected under pre-AIA 35 U.S.C. 102e as being anticipated by Spenser et al. (US 6,893,460 B2). Spenser discloses a percutaneously implantable replacement heart valve device (fig.23e) comprising an expandable stent (380; col.16, lines 11-20) and a flexible, compressible artificial valve (370/371; fig.23b) made of biocompatible tissue material (may be pericardium patch, col.15, lines 51-54) and disposed within the inner cavity of the stent (fig.23e) affixed at one or more points on the valves outer surface to the stent (fig.23e, suture lines), the valve (370/371) having cusps or leaflets (378) formed by folding a sheet of the material (fold 370/371 from a sheet into a tube, and fold at suture lines 373; col.15, lines 44-46,

57-61) without affixing separate cusps or leaflets (see figs.23a-23e). Spenser discloses the stent (380) to be self-expandable (shape memory, col.8, lines 24-34).

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-5 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Cribier (US 6,908,481 B2) in view of Dewanjee (US 4,553,974). Cribier discloses the tissue material to be pericardium for example, and is silent to the specific source of pericardium, however discloses such materials are common in cardiac surgery (col.5, lines 20-30; col.15, lines 6-9). Dewanjee teaches in the same field of tissues useful as prostheses such as heart valve leaflets (col.1, lines 8-11; col.3, lines 50-55), specific sources of pericardium to include calf pericardium (juvenile) and porcine pericardium (col.3, lines 50-55; col.10, lines 53-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Cribier's implant having pericardium tissue generically, with Dewanjee's teaching of known specific types of pericardium (bovine calf and porcine) for valve leaflet applications, as such is shown to be an obvious known material in the art.

Claim 6 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Cribier (US 6,908,481 B2) in view of Cox (US 2002/0032482 A1). Cribier discloses the tissue material to be pericardium for example, and is silent to the specific source of pericardium, however

discloses such materials are common in cardiac surgery (col.5, lines 20-30; col.15, lines 6-9). Cox teaches in the same field of tissues useful as prostheses such as heart valve leaflets that may or may not be stented (P0105, P0115, P0116), specific materials being autologous flat sheet pericardium as a known type of pericardium for valve leaflet use as it provides more biocompatibility than foreign tissues sources (P0072, P0122, P0125). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Cribier's implant having pericardium tissue generically, with Cox's teaching of specifically autologous pericardium as a known pericardium for valve leaflet applications, as such is shown to be an obvious known material in the art that provides increased biocompatibility.

Claim 29 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Cribier (US 6,908,481 B2) in view of Deac (US 5,344,442). Cribier discloses the replacement heart valve substantially as claimed (see above), comprising two sheet portions sutured together by continuous suture lines (sewing, col.13, lines 57-65, continuous suture, col.13, lines 33-35), however is silent to mention if they are single or double. Deac teaches in the same field of heart valve prostheses, use of double continuous sutures to affix two tissue sheets together (col.5, lines 36-60; col.6, lines 45-55) as a known suturing technique for sewing tissue membrane material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Deac's taught double continuous suturing technique with Cribier's implant having membranes sutured, so as to use Deac's specific suturing as such is taught to be known mode for suturing tissue in the field of heart valve prostheses.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cheryl Miller whose telephone number is 571-272-4755. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M./
Examiner, Art Unit 3738
/THOMAS J SWEET/
Supervisory Patent Examiner, Art Unit 3738

Notice of References Cited	Application/Control No. 13/675,665	Applicant(s)/Patent Under Reexamination PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,908,481 B2	06-2005	Cribier, Alain	623/2.11
*	B	US-6,893,460 B2	05-2005	Spenser et al.	623/2.14
*	C	US-2002/0032482 A1	03-2002	Cox, James L.	623/2.16
*	D	US-4,553,974	11-1985	Dewanjee, Mrinal K.	8/94.11
*	E	US-5,344,442	09-1994	Deac, Radu	623/2.12
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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Receipt date: 11/20/2014	Application Number	13675665	13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-11-13	
	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10101	

	1	Cross-reference is made to U.S. Application No. 14/502,453 filed on September 30, 2014, and its associated Preliminary Amendment (109978.10106)	☐

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	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10101	

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☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-11-20
Name/Print	Mark L. Yaskanin	Registration Number	45246

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/Cheryl Miller/ 06/27/2015

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	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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	3	20070061008		2007-03-15	Salahieh et al.	
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Receipt date: 08/29/2014	Application Number	13675665 13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
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	1	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐
	2	Office Action issued June 9, 2014, in U.S. Application No. 14/253,650 (109978.10104)	☐
	3	Office Action issued July 8, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐
	4	Office Action issued August 15, 2014, in U.S. Application No. 14/284,063 (File: 109978.10117)	☐

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	Examiner Name	Cheryl L. MILLER	
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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-08-29
Name/Print	Mark L. Yaskanin	Registration Number	45246

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Receipt date: 09/17/2014

13675665 - GAU: 3738

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

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	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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	1	Office Action issued September 11, 2014, in U.S. Application No. 14/268,190 (File: 109978.10115)	☐
	2	Office Action issued September 3, 2014, in U.S. Application No. 14/284,049 (File: 109978.10116)	☐
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-09-17
Name/Print	Mark L. Yaskanin	Registration Number	45246

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	Examiner Name	not assigned
	Attorney Docket Number	109978.10101

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	1	20020095994		2002-07-25	Vesely et al.	
	2	20020123789		2002-09-05	Francis et al.	
	3	20020128708		2002-09-21	Northrup et al.	
	4	20030078659		2003-04-24	Yang	
	5	20030102000		2003-06-05	Stevens et al.	

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	6	20030130727		2003-07-10	Drasler et al.	
	7	20030130729		2003-07-10	Paniagua et al.	
	8	20030130731		2003-07-10	Vidlund et al.	
	9	20030153974		2003-08-14	Spenser et al.	
	10	20030187362		2003-10-02	Murphy et al.	
	11	20030195620		2003-10-16	Huynh et al.	
	12	20030204023		2003-10-30	Koob et al.	
	13	20030212460		2003-11-13	Darois et al.	
	14	20030212462		2003-11-13	Gryska et al.	
	15	20030217415		2003-11-27	Crouch et al.	
	16	20040024452		2004-02-05	Kruse et al.	

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	17	20040055608		2004-03-25	Stevens et al.	
	18	20040059418		2004-03-25	McKay et al.	
	19	20040098092		2004-05-20	Butaric et al.	
	20	20040193261		2004-09-30	Berreklouw	
	21	20040243153		2004-12-02	Liddicoat et al.	
	22	20040243229		2004-12-02	Vidlund et al.	
	23	20050004668		2005-01-06	Aklog et al.	
	24	20050027369		2005-02-03	Eldridge et al.	
	25	20050043819		2005-02-24	Schmidt et al.	
	26	20050096673		2005-05-05	Stack et al.	
	27	20050113910		2005-05-26	Paniagua et al.	

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	28	20050137681		2005-06-23	Shoemaker et al.	
	29	20050137682		2005-06-23	Justino	
	30	20050142163		2005-06-30	Hunter et al.	
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	39	20050175657		2005-08-11	Hunter et al.	
	40	20050187618		2005-08-25	Gabbay	
	41	20050191248		2005-09-01	Hunter et al.	
	42	20050228494		2005-10-13	Marquez	
	43	20050246035		2005-11-03	Wolfinbarger, Jr. et al.	
	44	20050247320		2005-11-10	Stack et al.	
	45	20050267529		2005-12-01	Crockett et al.	
	46	20060004439		2006-01-05	Spenser et al.	
	47	20060004443		2006-01-05	Liddicoat et al.	
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	50	20060041306		2006-02-23	Vidlund et al.	
	51	20060074486		2006-04-06	Liddicoat et al.	
	52	20060089708		2006-04-27	Osse et al.	
	53	20060111733		2006-05-25	Shriver	
	54	20060129225		2006-06-15	Kopia et al.	
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	56	20060140916		2006-06-29	Siani-Rose et al.	
	57	20060173475		2006-08-03	Lafontaine et al.	
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	59	20060190074		2006-08-24	Hill et al.	
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	61	20060195010		2006-08-31	Arnal et al.	
	62	20060195183		2006-08-31	Navia et al.	
	63	20060206203		2006-09-14	Yang et al.	
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	65	20060240063		2006-10-26	Hunter et al.	
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	72	20060292125		2006-12-28	Kellar et al.	
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	74	20070043431		2007-02-22	Melsheimer	
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	83	20070250154		2007-10-25	Greenberg et al.	
	84	20070263226		2007-11-15	Kurtz et al.	
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	94	20080102439		2008-05-01	Tian et al.	
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	105	20090030511		2009-01-29	Paniagua et al.	
	106	20090043383		2009-02-12	McGregor et al.	
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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Name/Print	Mark L. Yaskanin	Registration Number	45246

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	1	1441672	EP		2011-09-14	Edwards Lifesciences PVT, Inc.		☐

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☐ See attached certification statement.

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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-09-26
Name/Print	Mark L. Yaskanin	Registration Number	45246

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/Cheryl Miller/ 06/27/2015

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5484444		1996-01-16	Braunschweiler et al.	
	2	5645559		1997-07-08	Hachtman et al.	
	3	5683451		1997-11-04	Lenker et al.	
	4	5876448		1999-03-02	Thompson et al.	
	5	6350278		2002-02-26	Lenker et al.	
	6	6682537		2004-01-27	Ouriel et al.	
	7	6896690		2005-05-24	Lambrecht et al.	
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Receipt date: 10/07/2014	Application Number	13675665	13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-11-13	
(Not for submission under 37 CFR 1.99)	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10101	

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	1	Notice of Allowance issued October 7, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐

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Examiner Signature	/Cheryl Miller/	Date Considered	06/27/2015

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Receipt date: 10/07/2014	Application Number	13675665	13675665 - GAU: 3738
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	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-10-07
Name/Print	Mark L. Yaskanin	Registration Number	45246

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/Cheryl Miller/ 06/27/2015

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	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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Receipt date: 11/14/2014	Application Number	13675665 13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
(Not for submission under 37 CFR 1.99)	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

	1	Final Office Action issued November 7, 2014, in U.S. Application No. 14/253,650 (File: 109978.10104)	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-11-13	
	First Named Inventor	David Paniagua	
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/Cheryl Miller/ 06/27/2015

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. Miller
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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4011947		1977-03-15	Sawyer	
	2	4657133		1987-04-14	Komatsu et al.	
	3	4743231		1988-05-10	Kay et al.	
	4	6124523		2000-09-26	Banas et al.	
	5	6245102		2001-06-12	Jayaraman	
	6	6540782		2003-04-01	Snyders	
	7	6821297		2004-11-23	Snyders	
	8	6830584		2004-12-14	Seguin	

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Receipt date: 05/23/2014	Application Number	13675665	13675665 - GAU: 3738
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	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. Miller	
	Attorney Docket Number	109978.10101	

	9	7018406		2006-03-28	Seguin et al.	
	10	8512401		2013-08-20	Murray et al.	
	11	8512403		2013-08-20	Navia et al.	

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	1	20020151970		2002-10-17	Garrison et al.	
	2	20030149477		2003-08-07	Gabbay	
	3	20040039442		2004-02-26	St. Goar	
	4	20040158321		2004-08-12	Reuter et al.	
	5	20040230285		2004-11-18	Gifford, III et al.	
	6	20050241981		2005-11-03	Gupta et al.	

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	7	20070104395		2007-05-10	Kinigakis et al.	
	8	20070203575		2007-08-30	Forster et al.	
	9	20070276461		2007-11-29	Andreas et al.	
	10	20090005857		2009-01-01	Ischinger	
	11	20090054969		2009-02-26	Salahieh	
	12	20100241069		2010-09-23	Hatten	
	13	20110240511		2011-10-06	Bolton et al.	
	14	20130304201		2013-11-14	Navia et al.	
	15	20140039613		2014-02-06	Navia et al.	

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	Attorney Docket Number	109978.10101

	1	2004/082527	WO		2004-09-30	Edwards Lifesciences Corp.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	MENDELSON, Karen et al., "Heart Valve Tissue Engineering: Concepts, Approaches, Progress, and Challenges" Ann Biomed Eng, 2006 Dec; 34(12); pp. 1799-1819; published online 2006 October 12 doi:10.1007/s/10439-006-9163-z	☐
	2	SCHMIDT, Dorthe et al., "Tissue engineering of heart valves using decellularized xenogeneic of polymeric starter matrices" Philos Trans R Soc Lond B Bio Sci., Aug 29, 2007, 362(1484); 1505-1512; published online June 22, 2007, doi: 10.1098/rstb.2007.2131	☐
	3	WERNER, S. et al., "Testing the Hydrodynamic properties of heart valve prostheses with a new test apparatus", Biomed Tech (Berl) 1994 Sep; 30(9); pp. 204-210 (Abstract only)	☐
	4	Office Action issued in U.S. Application No. 14/136,516, dated March 10, 2014 (109978.10102)	☐
	5	Notice of Allowance issued in U.S. Application No. 14/136,516, dated March 31, 2014 (109978.10102)	☐
	6	Cross-reference is made to U.S. Application No. 14/253,650 filed on April 15, 2014, and its associated Preliminary Amendment (109978.10104)	☐
	7	Cross-reference is made to U.S. Application No. 14/253,656 filed on April 15, 2014, and its associated Preliminary Amendment (109978.10113)	☐
	8	Cross-reference is made to U.S. Application No. 14/268,184 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10114)	☐

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Receipt date: 05/23/2014	Application Number	13675665 13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
(Not for submission under 37 CFR 1.99)	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

	9	Cross-reference is made to U.S. Application No. 14/268,190 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10115)	☐
	10	Cross-reference is made to U.S. Application No. 14/284,049 filed on May 21, 2014, and its associated Preliminary Amendment (109978.10116)	☐
	11	Cross-reference is made to U.S. Application No. 14/284,063 filed on May 21, 2014, and its associated Preliminary Amendment (109978.10117)	☐

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Examiner Signature	/Cheryl Miller/	Date Considered	06/27/2015

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Receipt date: 05/23/2014	Application Number	13675665	13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-11-13	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. Miller	
	Attorney Docket Number	109978.10101	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2014-05-23
Name/Print	Mark L. Yaskanin	Registration Number	45246

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The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

/Cheryl Miller/ 06/27/2015

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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Receipt date: 01/13/2015	Application Number	13675665 13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
(Not for submission under 37 CFR 1.99)	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

	1	Office Action issued December 5, 2014 in U.S. Application No. 14/502,453 (109978.10106)	☐

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EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	06/27/2015

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Receipt date: 01/13/2015	Application Number	13675665	13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-11-13	
	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10101	

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Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-01-13
Name/Print	Mark L. Yaskanin	Registration Number	45246

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/Cheryl Miller/ 06/27/2015

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13675665	PANIAGUA ET AL.
	Examiner	Art Unit
	CHERYL MILLER	3738

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East text search, review parent application files	6/27/2015	cm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/C.M./ Examiner.Art Unit 3738	

EAST Search History

EAST Search History (Prior Art)

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L8	263	6 and @ad<"20040710"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:48
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L11	162	9 and (resilient or "self-expandable" or "self-expanding" or "self-expands") and (sheet or patch)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:50
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L13	126	623/2.$2.ccls. and ((autologous or autograft) with pericardi$2)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 23:07
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S21	416	S20 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
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S25	199	S23 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S26	85	S24 not S25	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S27	364	S23 and (pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:59
S28	85	S27 not S24	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
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S39	2	"20100268332".pn. or "20100217371".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 21:30
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S43	1	bessler.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:06
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5554184		1996-09-10	Machiraju	
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	1	20020052651		2002-05-02	Myers et al.	
	2	20030209835		2003-11-13	Chun et al.	
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	9-501594	JP		1997-02-18		Equivalent to WO/1995/005207	☐
	2	2001-500761	JP		2001-01-23		Equivalent to WO/1998/011935	☐

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Receipt date: 06/11/2015	Application Number	13675665	13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-11-13	
(**Not for submission under 37 CFR 1.99)**	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10101	

	3	2005-103321	JP		2005-04-21		Equivalent to EP0696447	☐
	4	2009/149462	WO		2009-12-10	Edwards Lifesciences Corporation		☐

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	1	Declaration Under 37 CFR 1.131 as filed in U.S. Patent Application No. 10/887,688 on December 15, 2008, by co-inventors of that application. (Best available copy)	☐
	2	Final Office Action issued May 8, 2015 in U.S. Application No. 14/502,453 (109978.10106)	☐

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Examiner Signature	/Cheryl Miller/	Date Considered	06/27/2015

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Receipt date: 06/11/2015	Application Number	13675665	13675665 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-11-13	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10101	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-06-11
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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/Cheryl Miller/ 06/27/2015

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. Miller
Attorney Docket Number	109978.10101

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4275469		1981-06-30	Gabbay	
	2	5558875		1996-09-24	Wang	
	3	7214344		2007-01-14	Carpentier et al.	

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	2	20020146393		2002-10-10	Bell et al.	
	3	20030118560		2003-06-25	Kelly et al.	

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	Application Number	13675665
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	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

	4	20060212111		2006-09-21	Case et al.		

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	1	Office Action issued July 6, 2015, in U.S. Application No. 13/367,252 (109978.10111)	☐
	2	Notice of Allowance issued August 14, 2015, in U.S. Application No. 13/367,252 (109978.10111)	☐

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2015-09-10
Name/Print	Mark L. Yaskanin	Registration Number	45246

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Electronic Acknowledgement Receipt

EFS ID:	23450275
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	10-SEP-2015
Filing Date:	13-NOV-2012
Time Stamp:	11:18:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_SUPP_IDS.PDF	1124144 d60be5aa63c4f633f3f49a02fde586cdff8990b9	no	4

Warnings:

Information:

2	Non Patent Literature	10111_US_13-367252_Office_Action_2015-07-06.PDF	383589 2c373b764fa1342e0bf2e006e4d71b8c29fd8c51	no	10
Warnings:					
Information:					
3	Non Patent Literature	10111_US_13-367252_Notice-of_Allowance_2015-08-14.PDF	309772 77609b22cc76e8db995167747e488a38c13926a2	no	6
Warnings:					
Information:					
		Total Files Size (in bytes):	1817505		

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	)	Group Art Unit: 3738
	)	
David Panigua et al.	)	Confirmation No. 1995
	)	
Application No.: 13/675,665	)	Examiner: Cheryl L. Miller
	)	
Filed: November 13, 2012	)	AMENDMENT AND RESPONSE
	)	
Atty. File No.: 109978.10101	)	**Filed Electronically**
	)	
Entitled: PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Madam:

In response to the July 6, 2015 Office Action (the "Office Action"), please amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Applicants concurrently submit a three-month request for extension of time with the requisite small entity fee. Please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. **(Currently Amended)** A percutaneously implantable replacement heart valve device for implantation in a patient, comprising:

an expandable stent member having an inner channel, the expandable stent member collapsible and configured for percutaneous delivery; and

a valve means ~~a flexible, compressible artificial valve~~ made of biocompatible tissue material and attached to the expandable stent member, the valve means including an outer cuff layer and two to four individual leaflets, wherein each of the two to four individual leaflets is rectangular in shape in side elevation view, wherein a crease is located between the two to four individual leaflets and the outer cuff layer at a base of the two to four individual leaflets, and wherein after implantation in the patient, the valve means resides as a single element entirely within the inner channel of the expandable stent member, wherein only the two to four individual leaflets reside radially inward from the outer cuff layer, and wherein the valve means is formed without ~~and disposed within the inner cavity of said stent member affixed at one or more points on said artificial valve's outer surface to said stent member, said artificial valve having cusps or leaflets formed by folding of a sheet of said biocompatible tissue material without affixing of separate cusps or leaflets or~~ cutting slits into said biocompatible tissue material to form said ~~cusps or~~ leaflets.

2. **(Original)** The percutaneously implantable replacement heart valve device of claim 1, wherein said expandable stent member is made of a metal or alloy of metals selected from the group consisting of nickel-titanium alloy, titanium and stainless steel.

3. **(Canceled)**

4. **(Currently Amended)** The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said ~~artificial~~ valve means comprises porcine pericardium tissue.

5. **(Canceled)**

6. **(Currently Amended)** The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said ~~artificial~~ valve means comprises autologous tissue obtained from the patient into whom said replacement heart valve device will be implanted.

7.-8. **(Canceled)**

9. **(Currently Amended)** The percutaneously implantable heart valve device of claim 1, wherein said expandable stent member is self-expanding when implanted.

10. **(Currently Amended)** The percutaneously implantable heart valve device of claim 1, wherein said expandable stent member is balloon catheter expandable when implanted.

11.-33. **(Cancelled)**

REMARKS/ARGUMENTS

The present Amendment and Response comprises Applicant's reply to the Examiner's July 6, 2015 Office Action. Claims 3, 5, 7-8 and 11-33 are cancelled. Claims 1, 4, 6, 9 and 10 are amended. No new claims have been added. Accordingly, Claims 1, 2, 4, 6, 9 and 10 are now pending in view of the above amendments.

Applicants believe that no new matter has been added with regard to the claim amendments provided herein. Applicants do not donate or disclaim any claims or subject matter with the claim amendments made herein, and the Applicants expressly reserve the right to prosecute the original claims, prior version of claims or any unclaimed subject matter in one or more future filed continuing applications. Applicants do not acquiesce to any of the rejections set forth in the Office Action.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited reference and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, the Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding. Also, Applicants' arguments related to each cited reference are not an admission that the cited references are, in fact, prior art.

I. Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected Claims 1-10, 27-29 and 33 under 35 U.S.C. § 112, Second Paragraph for indefiniteness on the grounds that they do not distinctly claim the subject matter of the invention. In response, Claim 1 has been amended to delete the wording "the inner cavity of said stent member affixed at one or more points on said artificial valve's outer surface." In addition, the Applicants have amended "said artificial valve having cusps or leaflets formed by folding of a sheet of said biocompatible tissue material without affixing of separate cusps or leaflets or cutting slits into said material to form said cusps or leaflets" to read "wherein the valve means is formed without cutting slits into said biocompatible tissue material to form said leaflets." Applicants believe that the changes to Claim 1 address the 35 U.S.C. § 112, Second Paragraph, rejections and request the Examiner to withdraw the indefinite rejections of Claim 1.

With regard to Claim 6, "a patient" is now recited in the preamble of Claim 1, and therefore, there is now antecedent basis for "the patient" in Claim 6. Accordingly, the Examiner is requested to withdraw the 35 U.S.C. § 112, Second Paragraph, rejection of Claim 6.

Claims 7, 8, 27 and 33 are cancelled. Therefore the 35 U.S.C. § 112, Second Paragraph, rejections of these claims are now moot.

Based on the amendments the claims, the Examiner is requested to withdraw the 35 U.S.C. § 112, Second Paragraph, rejections of the pending claims.

II. Prior Art Rejections

A. Rejections Under 35 U.S.C. § 102(e)

The Examiner rejected Claims 1-2, 7-8, 10, 27-28 and 33 under pre-AIA 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,908,481 to Cribier ("Cribier").

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 2128 of 2319

Because the Examiner has asserted Cribier under 35 U.S.C. § 102(e), Applicants do not admit that Cribier is in fact prior art to the claimed invention but reserve the right to swear behind Cribier if necessary to remove it as a reference. In the Office Action, the Examiner asserted that the present invention is unpatentable over Cribier.

It is well recognized that claims are anticipated if, and only if, each and every element, as set forth in the claim is found in a single prior art reference. Vertegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as a complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). See MPEP § 2131. To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 U.S.P.Q. 344 (C.C.P.A. 1978). Additionally, the elements of the reference must be arranged as required by the claim. In re Bond, 15 U.S.P.Q. 2d 1566 (Fed. Cir. 1999). Applicant respectfully submits that the cited reference does not teach all the materials elements and do not arrange the elements as required by the rejected claim, as amended.

Independent Claim 1 has been amended to read as follows:

> 1. A percutaneously implantable replacement heart valve device for implantation in a patient, comprising:
>
> an expandable stent member having an inner channel, the expandable stent member collapsible and configured for percutaneous delivery; and
>
> a valve means made of biocompatible tissue material and attached to the expandable stent member, the valve means including an outer cuff layer and two to four individual leaflets, wherein each of the two to four individual leaflets is rectangular in shape in side elevation view, wherein a crease is located between the two to four individual leaflets and the outer cuff layer at a base of the two to four individual leaflets, and wherein after implantation in the patient, the valve means resides as a single element entirely within the inner channel of the expandable stent member, wherein only the two to four individual leaflets reside radially inward from the

outer cuff layer, and wherein the valve means is formed without cutting slits into said biocompatible tissue material to form said leaflets.

Applicants believe that support for all amendments to the claims in this reply reside within U.S. Pat. App. No. 10/037,266 filed on January 4, 2002, including at least Figures 1-3B, as well as the associated portions of the specification. Applicants further note to the Examiner's attention that Claim 1, as amended, includes some limitations recited in Claim 1 of Applicants' granted U.S. Pat. No. 8,790,398.

In view of the amendments made to Claim 1, at the least, Cribier fails to disclose the limitations that the valve means resides as a single element entirely within the inner channel of the expandable stent member, as well as having two to four individual leaflets that are rectangular in shape in side elevation view. Other limitations may also distinguishable. Figs. 11a-11e of Cribier are provided below (it is noted that Cribier includes other figures):

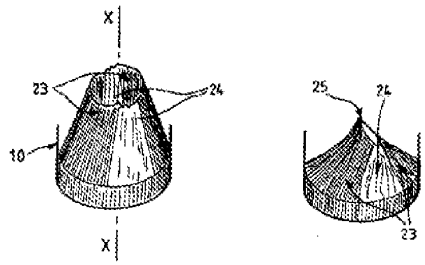


FIG_11a

FIG_11b

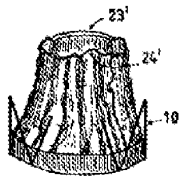


FIG_11c

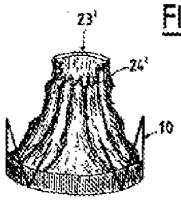


FIG_11d

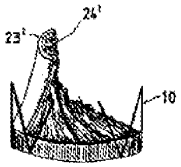
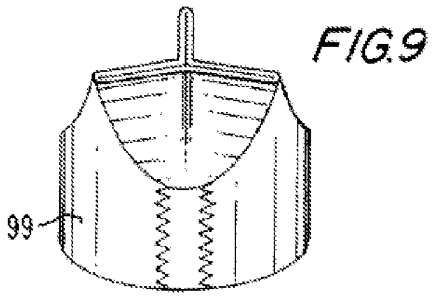


FIG_11e

The valve means of Cribier appears to extend beyond the frame 10 and does not include two to four individual leaflets that are rectangular in shape in side elevation view. Based on the foregoing, the Examiner is requested to withdraw the pre-AIA 35 U.S.C. § 102(e) rejection of amended Claim 1 based on Cribier.

The Examiner rejected Claims 1 and 9 under pre-AIA 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,893,460 to Spenser ("Spenser"). Because the Examiner has asserted Spenser under 35 U.S.C. § 102(e), Applicants do not admit that Spenser is in fact prior art to the claimed invention, but reserve the right to swear behind Spenser if necessary to remove it as a reference. In the Office Action, the Examiner asserted that the present invention is unpatentable over Spenser.

At the least, Spenser fails to disclose the limitations that the two to four individual leaflets that are rectangular in shape in side elevation view (other limitations may also distinguishable). More particularly, the valve means of Spenser appears to include arcuate-shaped leaflet portions, such as those shown in Fig. 9 below (it is noted that Spenser includes other figures):



Based on the foregoing, the Examiner is requested to withdraw the pre-AIA 35 U.S.C. § 102(e) rejection of amended Claim 1 based on Spenser.

B. Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 3-5 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Cribier in view of U.S. Patent No. 4,553,974 to Dewanjee ("Dewanjee"); Claim 6 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Cribier in view of U.S. Patent Application Publication No. 2002/0032482 to Cox ("Cox"); and Claim 29 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Cribier in view of U.S. Patent No. 5,344,442 to Deac ("Deac").

If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). See MPEP §2143.03. Based on the cited references, Claim 1 appears to be nonobvious under 35 U.S.C. §103. Accordingly, the Examiner is requested to withdraw the 35 U.S.C. §103 rejections of previously rejected, but still pending Claims 3, 5 and 6 that depend from Claim 1.

CONCLUSION

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds a remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Respectfully submitted,

FOX ROTHSCHILD LLP

/ Mark L. Yaskanin /

Mark L. Yaskanin
Registration No. 45,246
Customer No. 29880
Phone: (303) 446.3852
Facsimile: (303) 292.1300

Dated: January 6, 2016

Electronic Patent Application Fee Transmittal					
Application Number:	13675665				
Filing Date:	13-Nov-2012				
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME				
First Named Inventor/Applicant Name:	David Paniagua				
Filer:	Mark Lauren Yaskanin/Carol Donahue				
Attorney Docket Number:	109978.10101				
Filed as Small Entity					
Filing Fees for Utility under 35 USC 111(a)					
Description		**Fee Code**	**Quantity**	**Amount**	**Sub-Total in USD($)**
Basic Filing:					
Pages:					
Claims:					
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					
Post-Allowance-and-Post-Issuance:					
Extension-of-Time:					

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	2253	1	700	700
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
		Total in USD ($)		**790**

Electronic Acknowledgement Receipt	
EFS ID:	24547159
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Mark Lauren Yaskanin/Carol Donahue
Filer Authorized By:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10101
Receipt Date:	06-JAN-2016
Filing Date:	13-NOV-2012
Time Stamp:	18:01:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$790
RAM confirmation Number	5050
Deposit Account	501943
Authorized User	YASKANIN, MARK L.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 CFR 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)	

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Charge any Additional Fees required under 37 CFR 1.21 (Miscellaneous fees and charges)

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Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10101_SUPP_IDS.PDF	1070992 14dece3c9799b87bcf317062fc4b5b4fd142ebd8	no	4
Warnings:					
Information:					
3	Foreign Reference	WO-2010-141847.PDF	1544183 f87e43199ce67e82339efeb48d086d50ce429253	no	30
Warnings:					
Information:					
4	Non Patent Literature	NPL_Sacks_Orthotropic-Mechanical-Properties.PDF	1342139 5a8c5d283cc2913d281d59c05ef0008ce8858944	no	11
Warnings:					
Information:					
5	Non Patent Literature	10110_US_12-229192_Notice-of-Allowance_2011-09-22.PDF	196253 d25ac9ebd4c20c489d8480f1c7c1ec0dfc99fb32	no	4
Warnings:					
Information:					
6		10101_OA_Response_2016-01-06.PDF	202590 218ef324ebef7ba69be23945e3efbdff17ea8843	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
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7	Fee Worksheet (SB06)	fee-info.pdf	32961 19427d8cd97aa626ac4f4629f703eb850535d723	no	2
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 109978.10101
Application Number 13/675,665	Filed 2012-11-13
For Percutaneously Implantable Replacement Heart Valve Device and Method of Making Same	
Art Unit 3738	Examiner Cheryl L. Miller

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

		Fee	Small Entity Fee	Micro Entity Fee	
☐	One month (37 CFR 1.17(a)(1))	$200	$100	$50	$
☐	Two months (37 CFR 1.17(a)(2))	$600	$300	$150	$
☑	Three months (37 CFR 1.17(a)(3))	$1,400	$700	$350	$ 700
☐	Four months (37 CFR 1.17(a)(4))	$2,200	$1,100	$550	$
☐	Five months (37 CFR 1.17(a)(5))	$3,000	$1,500	$750	$

☑ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-1943.

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I am the

☐ applicant.

☑ attorney or agent of record. Registration number 45246.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/ Mark L. Yaskanin /	2016-01-06
Signature	Date
Mark L. Yaskanin	303-446-3852
Typed or printed name	Telephone Number

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☐ * Total of _____ forms are submitted.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

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	1	2010/141847	WO		2010-12-09	ATS Medical, Inc.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

	1	SACKS, Michael S. et al., "Orthotropic Mechanical Properties of Chemically Treated Bovine Pericardium" Annals of Biomedical Engineering, 1998, vol. 26, pp. 892-902 (10254 OA, 12/03/15)	
	2	Notice of Allowance issued September 22, 2011, in U.S. Application No. 12/228,192 (109978.10110)	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/ Mark L. Yaskanin /	Date (YYYY-MM-DD)	2016-01-06
Name/Print	Mark L. Yaskanin	Registration Number	45246

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(74) Agent: **WRIGLEY, Barbara A.**; OPPENHEIMER WOLFF & DONNELLY LLP, Plaza VII, Suite 3300, 45 South Seventh Street, Minneapolis, MN 55402-1609 (US).

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

— *of inventorship (Rule 4.17(iv))*

[Continued on next page]

(54) **Title**: FLEXIBLE COMMISSURE STRUCTURE FOR ATTACHING VALVE BIOPROSTHESIS

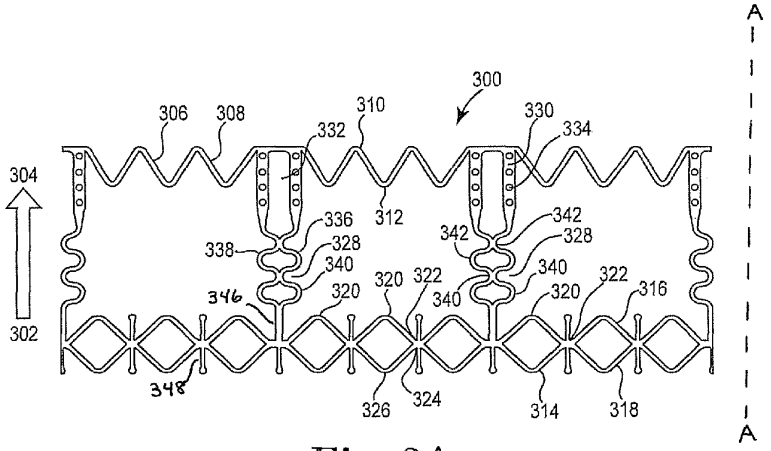

Fig. 3A

(57) **Abstract**: A cylindrical anchoring structure for supporting a tissue heart valve is disclosed. The cylindrical anchoring structure defines a central longitudinal axis and includes an inflow ring having at least one sinusoidal-shaped wire with a plurality of peaks and troughs and an outflow ring having at least one sinusoidal-shaped wire with a plurality of peaks and troughs. A flexible commissure post having a longitudinal axis connects the inflow ring and the outflow ring. The flexible commissure post has a bending flexibility along a plane defined by a surface containing all straight lines connecting any point on the central longitudinal axis of the cylindrical anchoring structure and any point on the longitudinal axis of the flexible commissure post.

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Published:

— *with international search report (Art. 21(3))*

FLEXIBLE COMMISSURE STRUCTURE FOR ATTACHING VALVE BIOPROSTHESIS

BACKGROUND OF THE INVENTION

Field of the Invention.

[0001] The present invention relates to bioprosthetic heart valve replacement systems. More particularly, the present invention relates to a bioprosthetic heart valve supported by a tubular, expandable anchoring structure having commissure posts of improved bending flexibility.

Description of the Related Art.

[0002] Prosthetic heart valves may be used to replace diseased natural heart valves in human patients. Minimally invasive bioprosthetic heart valves typically include a proximal end or inflow ring and a distal end or outflow ring. At least two, but typically three, support structures extend from and connect the inflow ring to the outflow ring. These support structures are commonly referred to as commissure posts. In conventional devices these posts are rigid to provide support to the heart valve, but are also somewhat longitudinally flexible to allow them to be manipulated during implantation. The commissure posts define the juncture between adjacent tissue or synthetic leaflets otherwise secured thereto.

[0003] The body of the heart valve typically includes a plurality of multiple leaflets of valve tissue joined by seams with each seam formed by the junction of two leaflets. The inlet comprises an inflow annulus, preferably with either a scalloped or straight edge. The inflow ring may further optionally include a reinforcement structure, such as fabric, that can be stitched to it. Both the inflow and outflow rings are typically formed with an undulating or sinusoidal configuration, which are connected by the rigid commissure posts. The anchoring structure for a minimally invasive heart valve is typically made from a wire frame of metal that exhibits a high modulus of elasticity and that is biocompatible, such as Nitinol, as such materials exhibiting superior radial compressibility allow the

anchoring structure to self-expand upon the release of the radially compressive forces. Optional, integrally formed commissural tabs attach the tissue segments to the commissural posts of the stent. Alternatively, the tissue heart valve may simply be attached to the commissural posts along the seam line or at a portion of the outflow end. During delivery and deployment, the stented heart valve resides in a radially-compressed or folded configuration in a delivery tool or catheter.

[0004] One problem associated with the delivery and deployment of a conventional stented bioprosthetic heart valves with rigid commissural posts is that binding, overlapping or interference can occur between adjacent heart valve segments. For example, the stented heart valve is typically placed in a delivery mechanism. As the delivery mechanism is threaded through the vasculature it bends as it follows the artery. In addition, upon deployment the delivery system containing the stented heart valve may curve slightly. In both of these cases, the inside radius of the bend causes wire segments of the anchoring structure to move toward each other causing overlapping. Moreover, on the outside radius of the bend, the wire segments may move away from each other, leaving large gaps that prevent the inflow ring from effectively seating the valve in the annulus. This can lead to improper annulus support, trauma, flow disturbance, kinking, paravalvular leakage, and interference with coronary ostia.

[0005] Still a further problem associated with minimally invasive bioprosthetic heart valves is the failure of the commissure posts to accommodate a curved aortic profile. This in turn leads to leaking, improper support of the annulus and potential trauma to the aortic wall.

[0006] Yet another problem is that the rigid commissure posts in conventional designs fail to allow the inflow and outflow rings to fully radially expand leading to leaking and improper seating of the valve in the annulus.

[0007] The present invention is directed to solving, or at least reducing, some or all of the aforementioned problems.

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 2148 of 2319

SUMMARY OF THE INVENTION

[0008] The present invention advantageously provides a stented heart valve that includes a commissure structure which has a bending flexibility that is greater than those of conventional structures and avoids the problems associated with conventional stented bioprosthetic valves and also exhibits improved overall flexibility.

[0009] An exemplary embodiment of the invention provides a stented bioprosthetic heart valve that includes a plurality of commissural posts formed from a single wire having a sinusoidal wave pattern cut along a longitudinal axis thereof.

[0010] Another exemplary embodiment of the invention provides a minimally invasive bioprosthetic heart valve that includes a plurality of commissural posts formed from multiple wires each having a sinusoidal wave pattern cut along a longitudinal axis thereof.

[0011] Yet another exemplary embodiment of the invention provides a stented bioprosthetic heart valve that includes commissural posts formed by a single or double wire each including a generally sinusoidal wave pattern cut along a longitudinal length thereof wherein the bending flexibility of the commissure post increases as the frequency of the generally sinusoidal wave increases.

[0012] In yet another exemplary embodiment of the invention, a stented bioprosthetic heart valve includes commissural posts formed by a single or double wire each including a generally sinusoidal wave pattern cut along a longitudinal length thereof wherein the bending flexibility of the commissure post increases as the amplitude or wave height of the generally sinusoidal waves increases.

[0013] In yet another exemplary embodiment of the invention, a stented bioprosthetic heart valve includes commissural posts formed by a single or double wire each including a generally sinusoidal wave pattern cut along a longitudinal

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length thereof wherein the bending flexibility of the commissure post increases as the frequency and amplitude of the generally sinusoidal waves increases.

[0014] In yet another exemplary embodiment of the invention, a stented bioprosthetic heart valve includes commissural posts formed by a single or double wire each including a generally sinusoidal wave pattern cut along a longitudinal length thereof wherein the bending flexibility of the commissure post increases as the wavelength, or peak to peak distance, decreases.

[0015] In yet another exemplary embodiment of the invention, the flexible commissure posts have a bending flexibility along a plane defined by a surface containing all straight lines connecting any point on the central longitudinal axis of the cylindrical anchoring structure and any point on the longitudinal axis of the flexible commisure posts.

[0016] In yet another exemplary embodiment of the invention, a stented bioprosthetic heart valve includes commissural posts that are especially designed for replacement of aortic and pulmonary valves.

[0017] In another exemplary embodiment of the invention a valve assembly is provided, comprising a valve and anchoring structure with flexible commissure posts, in which the valve comprises a body having a proximal end and a distal end, an inlet at the proximal end, and an outlet at the distal end. The inlet comprises an inflow annulus, preferably with either a scalloped or straight edge. The outlet comprises a plurality of tabs that are supported by the commissural posts anchoring structure at the outlet end. In exemplary embodiments of the invention, the plurality of tabs is spaced evenly around the circumference of the valve.

[0018] It should be noted that for the purposes of this invention, the phrase "generally sinusoidal" is intended to include waves characterized by sine and cosine functions as well as waves which are not rigorously characterized by those functions, but nevertheless resemble such waves. In a more general way, such waves include those which are characterized as having one or more peaks and

troughs. As an example, a wave whose peaks and troughs are U-shaped or bulbous is intended to be included. Also intended to be included, without limiting the definition, are waves which are more triangular in shape such as a saw-tooth wave or waves whose peaks and troughs are rectangular.

[0019] The flexible commissure post in accordance with the invention ensures complete or full radial expansion and deployment of the inflow and outflow rings thus providing for precise placement of the heart valve and a more open path for blood flow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 shows an exemplary valve during normal operation. FIG. 1A shows the valve in the open position during peak flow. FIG. 1B shows the valve in closed position to prevent backflow of the fluid across the valve.

[0021] FIG. 2 is an exemplary bioprosthetic tissue valve for use with the present invention.

[0022] FIG. 3A depicts an exemplary embodiment of a tubular anchoring device including flexible commissure posts in accordance with one aspect of the present invention cut along line A-A and laid flat.

[0023] FIG. 3B depicts a variation of the tubular anchoring device with flexible commissure posts illustrated in FIG. 3A.

[0024] FIG. 4A depicts a further embodiment of one aspect of a tubular anchoring device with flexible commissure posts in accordance with the present invention cut along line B-B and laid flat.

[0025] FIG. 4B depicts a variation of the tubular anchoring device with flexible commissure posts illustrated in FIG. 4A.

[0026] FIG. 5A depicts an exemplary embodiment of the bioprosthetic heart valve of FIG. 2 supported by the tubular anchoring structure with flexible commisure posts of the present invention.

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[0027] FIG. 5B is a top view of the cylindrical anchoring structure showing the longitudinal axis L' through the center of the cylindrical anchoring structure.

[0028] FIG. 6 depicts the exemplary bioprosthetic heart valve supported by the tubular anchoring structure with flexible commisure posts of the present invention positioned within an aorta.

DETAILED DESCRIPTION OF THE INVENTION

[0029] While this invention may be embodied in many different forms, there are described in detail herein various embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

[0030] When referring to the terms "peak" and "trough" as they relate to the commissure posts these terms are defined with respect to the left and right sides of the figures, respectively. As seen in the figures, each of the commissure posts has a paddle end and a proximal/straight end. With regard to the commissure posts, peaks are the first and subsequent sinusoidal wave commencing at the inflow end and are concave relative to the right side of the respective figure and convex relative to the left side of the respective figure. Troughs as they pertain to the commissure post, on the other hand, are convex relative to the right side of the figure and concave relative to the left side of the figure. As may be appreciated by those of ordinary skill in the art, the commissure post may have a sinusoidal wave formed from one wire, as depicted in FIGS. 4A and 4B or may have sinusoidal waves formed from multiple wires, as depicted in FIGS. 3A and 3B.

[0031] In addition given constant wave amplitude, as the frequency of the sinusoidal waves increases, the bending flexibility of the commissure posts increases. Further, given constant wave frequency, as the amplitude of the waves increases the bending flexibility of the commissure posts increases. Moreover, increasing wave amplitude and wave frequency result in an increase in commissure post bending flexibility. In addition, as the peak to peak distance,

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or wavelength, between each wave decreases, the bending flexibility of the commissure post increases.

[0032] As seen in the figures, the tubular or generally cylindrical anchoring structure includes an inflow end with an inflow ring and an outflow end with an outflow ring. With respect to the inflow and outflow rings peaks are concave relative to the proximal end of the anchoring structure and convex relative to the distal end of the anchoring structure. Troughs, on the other hand, are convex relative to the proximal end of the anchoring structure and concave relative to the distal end of the anchoring structure.

[0033] In addition, by "flexible" commissure posts and enhanced or greater "flexibility" we mean the bending capacity or bending flexibility of the commissure posts of the stented heart valve in or along a plane defined by the surface containing all the straight lines that connect any point on the longitudinal axis running through the center of the cylindrical anchoring structure (as seen in FIG. 5B) and any point on the longitudinal axis of the commissure post (as seen in FIG. 5A). The bending flexibility of the commissure posts in accordance with the invention is 10% or more than conventional rigid posts, which tend to flex only along the longitudinal axis of the post.

[0034] Turning now to the figures, the invention relates to valve replacement systems including a tubular anchoring structure that has flexible commissure posts. As illustrated in FIG. 1, a valve (1) comprises a distal or outflow end (2), leaflets (3) and a proximal or inflow end (4). A typical valve functions similar to a collapsible tube in that it opens widely during systole or in response to muscular contraction, to enable unobstructed forward flow across the valvular orifice (FIG. 1A). In contrast, at the end of systole or contraction, as illustrated in FIG. 1B, as forward flow decelerates, the walls of the tube are forced centrally between the sites of attachment to the vessel wall and the valve closes completely.

[0035] One embodiment of a bioprosthetic valve 5 for use with the system of the present invention is illustrated in FIG. 2 and is comprised of a body having a

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proximal end or inflow portion 6 and a distal end or outflow portion 7. The body is comprised of multiple leaflets of valve tissue joined by seams 8, wherein each seam is formed by a junction of two leaflets. An optional commissural tab region 9, which may be integrally formed from adjacent leaflets, extends from each seam at the distal end of the valve body. The proximal end 6 has a peripheral edge that can be scalloped or straight. The proximal end or inflow 6 of the valve can further comprise an optional reinforcement structure 10 that can be stitched to it. In preferred embodiments of the invention, the inflow edge of the valve is scalloped. The novel design for a bioprosthetic heart valve system supported by a tubular, expandable anchoring structure having commissure posts of improved bending flexibility is not limited, however, to the specific valve illustrated in FIG. 2.

[0036] Turning now to FIG. 3A one exemplary embodiment of a tubular, expandable anchoring structure 300 including commissure posts of improved bending flexibility is shown. Blood inflow is depicted at 302 and outflow is depicted at 304. The anchoring structure is generally cylindrical in shape but for purposes of illustration is depicted as being cut along line A-A and laid flat. The anchoring structure 300 includes an outflow ring 306 having a single sinusoidal-shaped wire 308 including peaks 310 and troughs 312. Anchoring structure 300 also includes inflow ring 314 having two sinusoidal-shaped wires designated as distal inflow wire ring 316 and proximal inflow wire ring 318. Distal inflow wire ring 316 includes peaks 320 and troughs 322. Proximal inflow wire ring 318 includes peaks 324 and troughs 326. As can be seen from FIG. 3A the troughs 322 of distal inflow wire ring 316 are joined to the peaks 324 of proximal inflow wire ring 318. Those of ordinary skill in the art will appreciate that although two inflow wires forming inflow ring 314 are depicted, a single wire, triple wires or any other configuration may also be used. At the outflow end, flexible commissure posts 328 include paddle portion 330 that couples the commissure posts 328 to the outflow ring 306. Paddle portion 330 with axial slot 332 extends along the longitudinal axis of commissure post 330. Suturing holes 334 are positioned on the outer periphery of paddle 330 and are used to suture a bioprosthetic heart valve, such as shown in FIG. 2, to the anchoring structure 300.

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Commissure post 328 includes first and second commissure post wires 336, 338 each with peaks 340 and troughs 342 that converge to a single wire 346 at the inflow end that couples the flexible commisure posts to the inflow ring 314. As can be seen from FIG. 3A the first commissure post wire 336 is joined at trough 342 to a peak 340 of the second commissure wire 338. The number of commissure posts 328 in this embodiment can range from two to four, depending on the number of leaflets present in the valve sinus. Thus, in one embodiment the anchoring structure comprises three support posts for a three-leaflet valve with a sinus that features three natural commissural posts. The commissure posts 328 of the anchoring structure 300 are configured to coincide with the natural commissural points of the sinus. The inflow ring 314 optionally includes finger-like elements 348 positioned between distal and proximal inflow wires and extend in an axial direction therefrom. Finger-like elements 348 are designed to lend additional support to fabric that may cover inflow rim 314 to anchor the fabric and permit tissue ingrowth. In addition, although only two waves are shown those of ordinary skill in the art will appreciate that the number of waves may be varied to achieve the desired bending flexibility.

[0037] FIG. 3B depicts a variation of the tubular, expandable anchoring structure 300 including commissure posts of improved bending flexibility of FIG. 3A. In FIG. 3B paddle portion 330 has been eliminated and a single wire 346' extends from the commissure post which couples the commissure post directly to the outflow ring. Single wire 346' may contain suturing holes to attach the tissue heart valve to the commisure posts. The anchoring structure 300 includes an outflow ring 306 having a single sinusoidal-shaped wire 308 including peaks 310 and troughs 312. Anchoring structure 300 also includes inflow ring 314 having two sinusoidal-shaped wires designated as distal inflow wire ring 316 and proximal inflow wire ring 318. Distal inflow wire ring 316 includes peaks 320 and troughs 322. Proximal inflow wire ring 318 includes peaks 324 and troughs 326. As can be seen from FIG. 3B the troughs 322 of distal inflow wire ring 316 are joined to the peaks 324 of proximal inflow wire ring 318. Those of ordinary skill in the art will appreciate that although two inflow wires forming inflow ring 314 are depicted, a single wire, triple wires or any other configuration may also be

used. Commissure post 328 includes first and second commissure post wires 336, 338 each with peaks 340 and troughs 342. As can be seen from FIG. 3B the first commissure post wire 336 is joined at trough 342 to a peak 340 of the second commissure wire 338. The number of commissure posts 328 in this embodiment can range from two to four, depending on the number of leaflets present in the valve sinus. Thus, in one embodiment the anchoring structure comprises three support posts for a three-leaflet valve with a sinus that features three natural commissural posts. The commissure posts 328 of the anchoring structure 300 are configured to coincide with the natural commissural points of the sinus. In addition, while multiple waves are depicted the actual number of waves may vary depending on the desired bending flexibility.

[0038] Turning now to FIG. 4A another exemplary embodiment of a tubular, expandable anchoring structure 400 including commissure posts of improved bending flexibility is shown. Blood inflow is depicted at 402 and outflow is depicted at 404. The anchoring structure 400 includes an outflow ring 406 having a single sinusoidal-shaped wire 408 including peaks 410 and troughs 412. Anchoring structure 400 also includes inflow ring 414 having first and second sinusoidal-shaped wires designated as distal inflow wire ring 416 and proximal inflow wire ring 418. Distal inflow wire ring 416 includes peaks 420 and troughs 422. Proximal inflow wire ring 418 includes peaks 424 and troughs 426. As can be seen from FIG. 4A the troughs 422 of distal inflow wire ring 416 are joined to the peaks 424 of proximal inflow wire ring 418. One of ordinary skill in the art will appreciate that although two inflow wires forming inflow ring 414 are depicted, a single wire, triple wires or any other configuration may also be used. Flexible commissure posts 428 include paddle portion 430 with axial slot 432 at the outflow end and extending along the longitudinal axis of commissure post 430. Suturing holes 434 are positioned on the outer periphery of paddle 430 and are used to suture a bioprosthetic heart valve, such as shown in FIG. 2, to the anchoring structure 400. Commissure post 428 includes a single sinusoidal wave like wire 436 with peaks 440 and troughs 442 which couples to the inflow ring 414 by single wire 446. The number of commissure posts 428 in this embodiment

can range from two to four, depending on the number of leaflets present in the valve sinus. Thus, in one embodiment the anchoring structure comprises three support posts for a three-leaflet valve with a sinus that features three natural commissural posts. The commissure posts 428 of the anchoring structure 400 are configured to coincide with the natural commissural posts of the sinus. In addition, although only two waves are shown those of ordinary skill in the art will appreciate that the number of waves may be varied to achieve the desired bending flexibility.

[0039] FIG. 4B depicts a variation of the tubular, expandable anchoring structure 400 including commissure posts of improved bending flexibility of FIG. 4A. In FIG. 4B paddle portion 430 has been eliminated and a single wire 446' extends from the commissure post which couples the commissure post directly to the outflow ring. Single wire 346' may contain suturing holes to attach the tissue heart valve to the commisure posts. The anchoring structure 400 includes an outflow ring 406 having a single sinusoidal-shaped wire 408 including peaks 410 and troughs 412. Anchoring structure 400 also includes inflow ring 414 having two sinusoidal-shaped wires designated as distal inflow wire ring 416 and proximal inflow wire ring 418. Distal inflow wire ring 416 includes peaks 420 and troughs 422. Proximal inflow wire ring 418 includes peaks 424 and troughs 426. As can be seen from FIG. 4B the troughs 422 of distal inflow wire ring 416 are joined to the peaks 424 of proximal inflow wire ring 418. Those of ordinary skill in the art will appreciate that although two inflow wires forming inflow ring 414 are depicted, a single wire, triple wires or any other configuration may also be used. Commissure post 428 includes a single commissure post wire 436 each with peaks 440 and troughs 442. The number of commissure posts 428 in this embodiment can range from two to four, depending on the number of leaflets present in the valve sinus. Thus, in one embodiment the anchoring structure comprises three support posts for a three-leaflet valve with a sinus that features three natural commissural posts. The commissure posts 428 of the anchoring structure 400 are configured to coincide with the natural commissural points of the

sinus. In addition, while multiple waves are depicted the actual number of waves may vary depending on the desired bending flexibility.

[0040] FIG. 5 shows an exemplary bioprosthetic valve system including the exemplary anchoring structure with flexible commissure posts depicted in FIGS. 4A. Those of ordinary skill in the art will appreciate that the anchoring structure of FIG. 3A, 3B or 4B may also be used.

[0041] The anchoring structure 500 is adapted to support a valve such as that illustrated in FIG. 2. As seen in FIG. 5A, the anchoring structure 500 has a generally tubular or cylindrical configuration within which a bioprosthetic heart valve 5 is secured. The valve 5 is secured at its proximal (inflow) annulus by attachment to the inflow ring 514 of the anchoring structure 500 and at its distal end via the optional commissural tabs 9 that are threaded through the axially extending slots 532 of the paddle portion 530. Paddle portion 530 couples the flexible commissure posts 528 to the outflow ring 506 of the anchoring structure 500, whereas the proximal end of the commissure posts 528 are coupled to the inflow ring 514 of the anchoring structure 500 by single wire connector 546.

[0042] In FIG. 5A the outflow ring 506 of the anchoring structure 500 is depicted as comprising a single sinusoidal-shaped wire that extends between commisure posts 528 generally at or above the axially extending slots 532 that reside therein. The single wire of the outflow ring 506 is configured in an undulating or sinusoidal pattern forming peaks 510 and troughs 512. Anchoring structure 500 also includes inflow ring 514 having first and second sinusoidal-shaped wires designated as distal inflow wire ring 516 and proximal inflow wire ring 518. Distal inflow wire ring 516 includes peaks 520 and troughs 522. Proximal inflow wire ring 518 includes peaks 524 and troughs 526. As can be seen from FIG. 5A the troughs 522 of distal inflow wire ring 516 are joined to the peaks 524 of proximal inflow wire ring 518. This arrangement allows the distal inflow wire ring and proximal inflow wire ring to move together when the valve is in its radially compressed state prior to delivery thus preventing possible damage to the bioprosthetic heart valve.

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[0043] Flexible commissure posts 528 include paddle portion 530 with axial slot 532 extending along the longitudinal axis (L) of commissure post 528. Suturing holes 534 are positioned on the outer periphery of paddle 530 and are used to suture a bioprosthetic heart valve, such as shown in FIG. 2, to the anchoring structure 500. Paddle portion 530 of commissure post 528 connects commissure post 528 to the single wire of inflow ring 506 at trough 512. The single wire connector 546 couples commissure post 528 to the inflow ring 514. Single wire connector 546 is designed to stabilize the anchoring structure and to prevent distortion of the valve during compression and expansion. The single wire connector 546 extends longitudinally in the axial direction of the cylindrical anchoring structure 500. Those of ordinary skill in the art will appreciate that both the inflow ring 514 and outflow ring 506 can be comprised of any number of wires without deviating from the spirit of the present invention.

[0044] Both the inflow 514 and outflow 506 rings of the anchoring structure 500 are formed with an sinusoidal wave configuration, although the inflow ring 514 may have a longer wavelength (circumferential dimension from peak to peak) and a lesser wave height (axial dimension from peak to peak) than the outflow ring 506. The wavelengths and wave heights of the inflow 514 and outflow 506 rings are selected to ensure uniform compression and expansion of the anchoring structure without distortion. The wavelength of the inflow rim 514 is further selected to support the geometry of the scalloped inflow annulus of a preferred valve of the present invention. Notably, as shown in FIG. 5, the sinusoidal wave pattern that forms the distal and proximal wires 516, 518 of inflow ring 514 is configured such that the single wire connector 546 is connected to the point at which peaks 524 and troughs 522 meet. Similarly, the undulating or sinusoidal wave pattern that forms the outflow ring 506 of the anchoring structure 500 is configured such that the paddle portion 530 of the commissure posts 528 is connected to the trough 512 of the single wire outflow ring 506. Locating the paddle portion of the commissure post 528 at the troughs 512 of the outflow ring 506 will prevent the longitudinal extension of outflow ring in the direction of the valve secured within the lumen of the anchoring structure upon compression of

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the valve assembly, thereby eliminating any contact between valve and anchoring structure. Thus, compression of the valve and anchoring structure 500 does not lead to distortion of or injury to the tissue valve.

[0045] FIG. 5 further shows that the commissure posts 528 include sinusoidal-shaped waves cut thereinto. An important function of the commissure posts 528 is the stabilization of the valve in general, and in particular the prevention of any longitudinal extension at points of valve attachment to preclude valve stretching or distortion upon compression of the device. Another important function of the sinusoidal-shaped commissure posts is to provide for axial and bending decoupling of the inflow and outflow rings to ensure complete circumferential expansion and deployment of the inflow and outflow rings during placement thus providing a more open path for blood flow to the coronary ostia and through the coronary artery. As will be appreciated by those of skill in the art, the wavelengths, frequency and amplitude of the waves of the commissure posts in accordance with the present invention are selected to ensure uniform compression and expansion of the anchoring structure without distortion upon deployment and to ensure that the inflow ring expands to its full circumferential profile to allow for proper seating within the annulus.

[0046] The number of support posts 528 in this preferred embodiment can range from two to four, depending on the number of commissural posts present in the valve sinus. Thus, in a preferred embodiment, the anchoring structure comprises three support posts for a three-leaflet valve with a sinus that features three natural commissural posts. The support posts 528 of the anchoring structure 500 are configured to coincide with the natural commissural posts of the sinus.

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[0047] As can be seen from FIG. 5, inflow ring 514 may be covered with a cloth or fabric material 550. The fabric 550 may comprise any suitable material including, but not limited to, woven polyester, polyester velour, polyethylene terepthalate, polytetrafluoroethylene (PTFE), or other biocompatible material. Fabric 550 permits for tissue ingrowth over time to firmly position the minimally invasive bioprosthetic valve system in the annulus.

[0048] FIG. 5B depicts the longitudinal axis (L') running through the center of the cylindrical anchoring structure, which in turn defines the plane of commissural post bending flexibility as hereinbefore noted.

[0049] FIG. 6 shows a bioprosthetic valve system including the exemplary anchoring structure with flexible commissure posts of FIG. 4A fully seated within an aorta after deployment. Those of ordinary skill in the art will appreciate that the anchoring structure of FIG. 3A, 3B or 4B and variations thereof may also be used. In the exemplary embodiment discussed above, a crimping tool may be used to crimp the exemplary heart valve supported by the anchoring structure with flexible commissure posts. The crimped valve is loaded into a delivery device, known to those of ordinary skill in the art, which is then used to deliver the crimped stented heart valve to an aortic annulus. The crimped stented heart valve may be delivered surgically or transapically. In surgical placement, the patient may be put on bypass and the aorta at least partially transected. The surgeon then positions the delivery device within the aortic annulus 630, radially compressing the native leaflets 632 as the crimped heart valve expands, such that the exposed inflow end 602 is substantially aligned with the inflow annulus of the native valve. As will be appreciated by those of ordinary skill in the art, warm bodily fluids may cause the exposed portion of the stented heart valve 600, i.e. the inflow end 602, to start to expand to the "remembered" shape as further illustrated in FIG. 6. Alternatively or in addition, the surgeon may apply a warm solution to the implantation site to promote re-expansion of the stented heart valve 600, such as a warm saline solution.

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[0050] As the stented heart valve 600 starts to expand the delivery device 630 may be retracted to expose an additional length of the inflow end 602 of the stented heart valve 600 until the stented heart valve 600 completely expands in the aortic annulus 630 where it friction fits and seals into place. The bending flexibility of the commissure posts ensures that binding, overlapping and/or interference between adjacent segments of the anchoring structure with heart valve is minimized and/or eliminated. In addition, the enhanced bending flexibility of the commissure posts ensures that the heart valve is properly seated in the aortic annulus.

[0051] Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

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CLAIMS

We claim:

1. A structure for supporting a bioprosthetic heart valve comprising:
a cylindrical anchoring structure defining a central longitudinal axis, the cylindrical anchoring structure comprising:
an inflow ring including at least one sinusoidal-shaped wire having a plurality of peaks and troughs;
an outflow ring including at least one sinusoidal-shaped wire having a plurality of peaks and troughs; and
at least one flexible commissure post having a longitudinal axis, the flexible commissure post connecting the inflow ring and the outflow ring,
wherein the flexible commissure post has a bending flexibility along a plane defined by a surface containing all straight lines connecting any point on the central longitudinal axis of the cylindrical anchoring structure and any point on the longitudinal axis of the flexible commisure post.

2. The anchoring structure of claim 1 wherein the at least one flexible commissure post includes a paddle portion operably connected to the outflow ring, the paddle portion including an axial slot extending along the longitudinal axis thereof.

3. The anchoring structure of claims 1 or 2 wherein the at least one flexible commissure post includes a single wire having at least one peak and one trough.

4. The anchoring structure of claim 3 wherein the single wire has a plurality of peaks and troughs forming a plurality of generally sinusoidal waves.

5. The anchoring structure of claim 4 wherein the frequency of the sinusoidal waves varies along the longitudinal axis of the flexible commissure post.

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6. The anchoring structure of claim 4 wherein the wavelength of the sinusoidal waves varies along the longitudinal axis of the flexible commissure post.

7. The anchoring structure of claim 4 wherein the wavelength of the sinusoidal waves is substantially constant along the longitudinal axis of the flexible commissure post.

8. The anchoring structure of claim 4 wherein the bending flexibility of the flexible commissure post increases as the frequency of the sinusoidal waves increases.

9. The anchoring structure of claim 4 wherein the bending flexibility of the flexible commissure post increases as the wave height of the sinusoidal waves increases.

10. The anchoring structure of claim 4 wherein the bending flexibility of the flexible commissure post increases as the peak-to-peak distance between adjacent waves decreases.

11. The anchoring structure of claim 3 wherein the inflow ring includes a first sinusoidal-shaped wire and a second sinusoidal-shaped wire, the first and second sinusoidal-shape wires each having a plurality of peaks and troughs.

12. The anchoring structure of claim 11 wherein the peaks of the first sinusoidal-shaped wire are joined to the troughs of the second sinusoidal-shaped wire.

13. The anchoring structure of claim 12 wherein the at least one flexible commissure post includes a vertical connection member, the vertical connection member joined to the inflow ring at the intersection between one of the peaks of the first sinusoidal-shaped wire and one of the troughs of the second sinusoidal-shaped wire.

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14. The anchoring structure of claims 1 or 2 wherein the at least one flexible commissure post includes first and second wires, each of the wires including at least one peak and one trough.

15. The anchoring structure of claim 14 wherein the at least one peak of the first wire abuts the at least one trough of the second wire.

16. The anchoring structure of claim 15 wherein the first and second wires each include a plurality of peaks and troughs forming a plurality of generally sinusoidal waves.

17. The anchoring structure of claim 16 wherein the bending flexibility of the flexible commissure post increases as the frequency of the sinusoidal waves of the first and second wires increases.

18. The anchoring structure of claim 16 wherein the bending flexibility of the flexible commissure post increases as the wave height of the sinusoidal waves of the first and second wires increases.

19. The anchoring structure of claim 16 wherein the bending flexibility of the flexible commissure post increases as the peak-to-peak distance between adjacent waves of the first and second wires decreases.

20. The anchoring structure of claims 1 or 2 wherein the bending flexibility of the commissure post is greater than 10% of a rigid or semi-rigid commissure post.

21. The anchoring structure of claim 2 wherein the paddle portion of the at least one flexible commissure post is connected to one of the troughs of the outflow ring.

22. The anchoring structure of claim 2 wherein the paddle portion of the at least one flexible commissure post is connected to one of the peaks of the outflow ring.

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23. The anchoring structure of claim 2 further comprising a bioprosthetic heart valve disposed within the cylindrical anchoring structure, the bioprosthetic heart valve including a plurality of leaflets defining a valve body having an inflow end and an outflow end.

24. The anchoring structure of claim 23 wherein adjacent leaflets are joined together by a seam at the junction of the leaflets, and wherein a commissural tab extends from each of the seams near the outflow end of the valve body.

25. The anchoring structure of claim 24 wherein the cylindrical anchoring structure includes a plurality of flexible commissure posts, and wherein the bioprosthetic heart valve is secured to the cylindrical anchoring structure by threading the commissural tabs through the axial slots in the paddle portions of the flexible commissure posts.

26. The anchoring structure of claim 25 wherein the commissural tabs are formed integral with the leaflets.

27. The anchoring structure of claim 25 further comprising at least one suture hole formed in each of the paddle portions for suturing the commissural tabs to the paddle portions.

28. The anchoring structure of claim 25 further comprising a biocompatible cloth covering positioned around at least a portion of the inflow ring.

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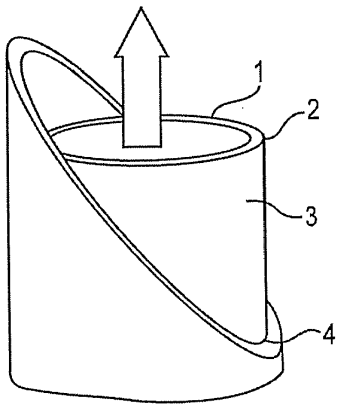

Fig. 1A

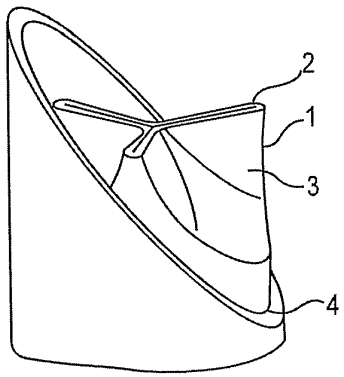

Fig. 1B

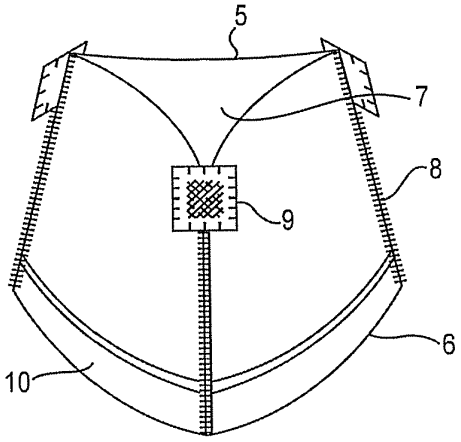

Fig. 2

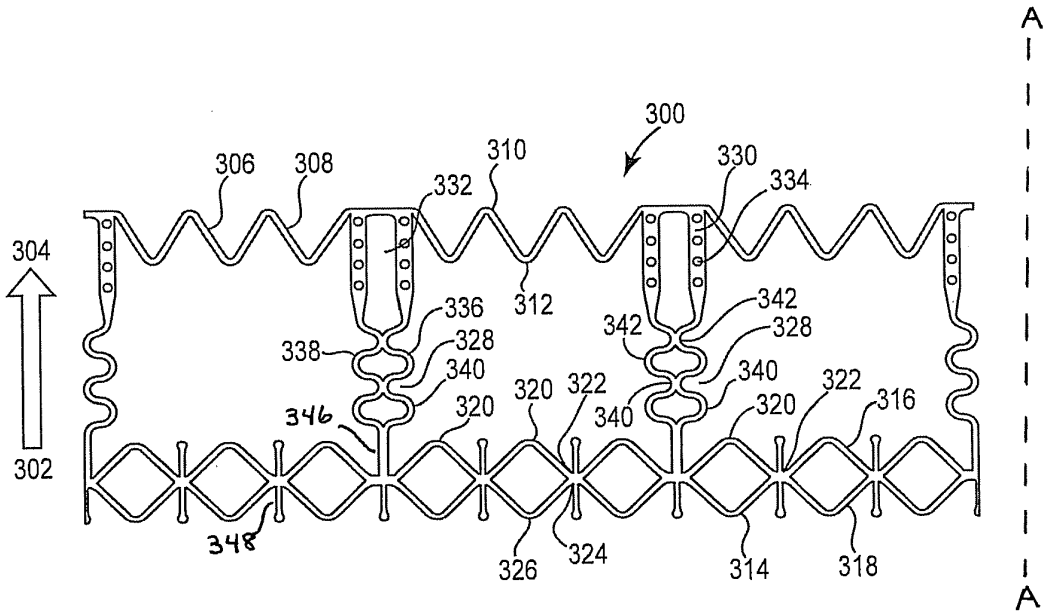
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Fig. 3A

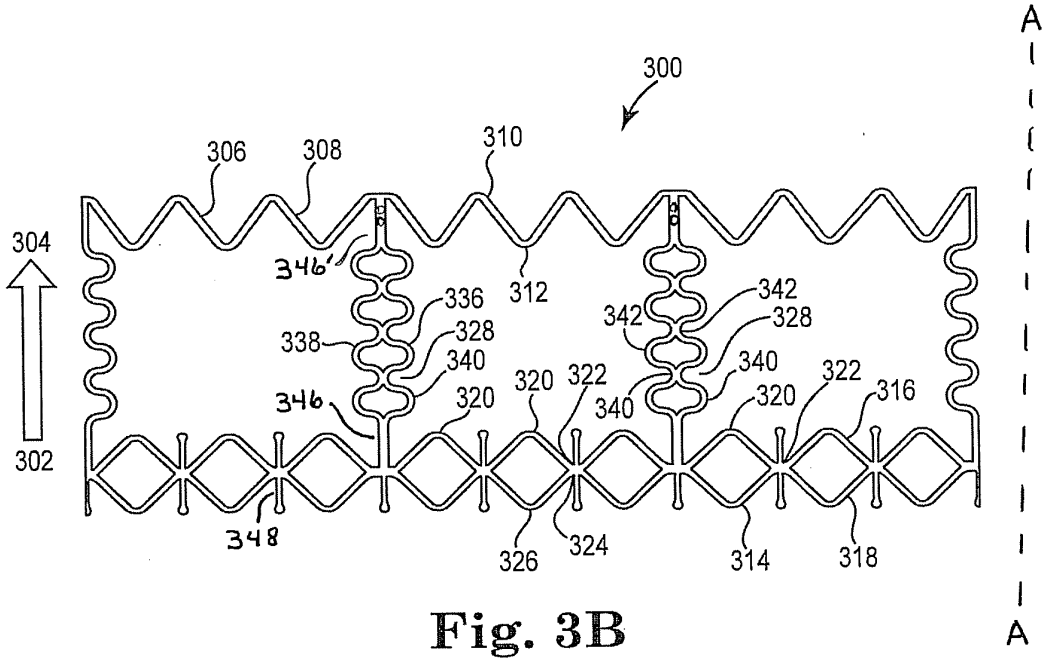
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Fig. 3B

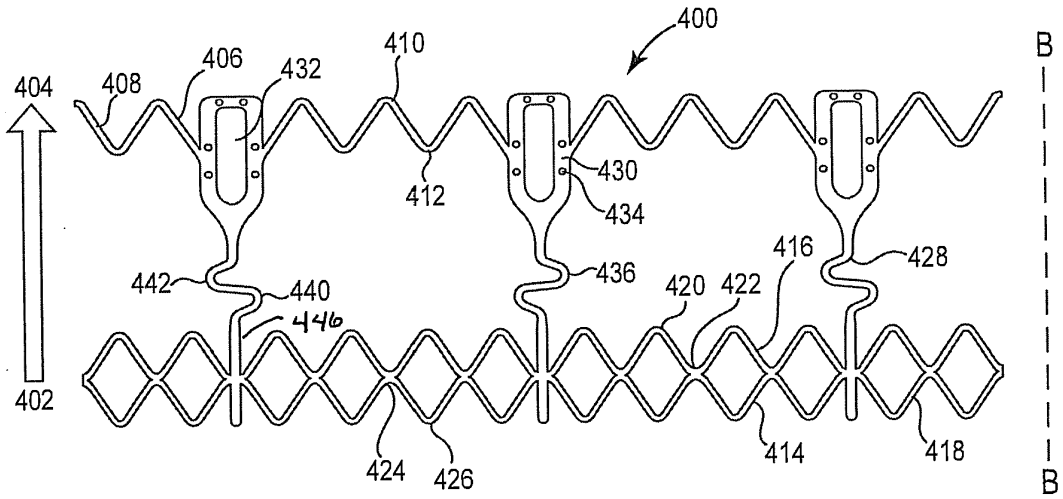
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Fig. 4A

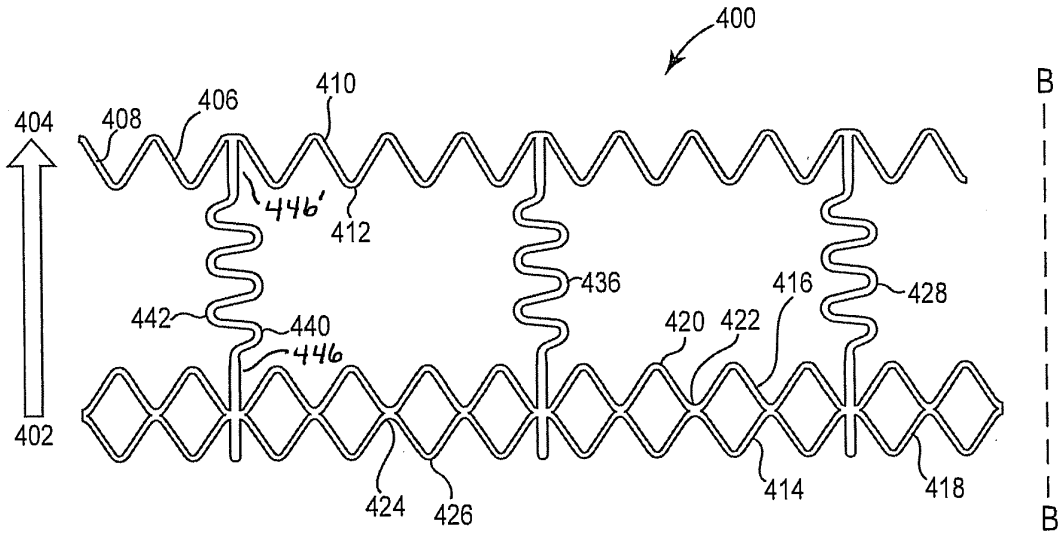
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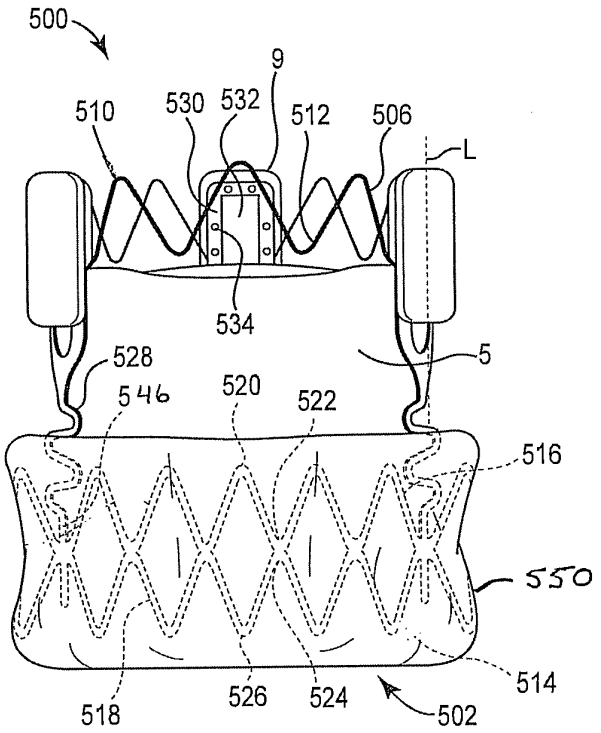
Fig. 4B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502

Fig. 5A

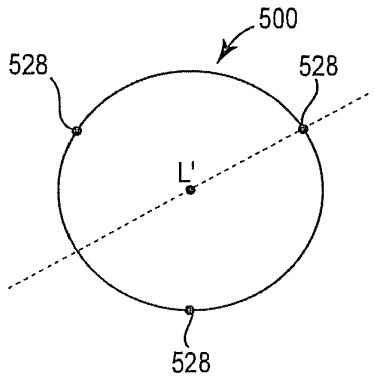
500
528
528
L'
528

Fig. 5B

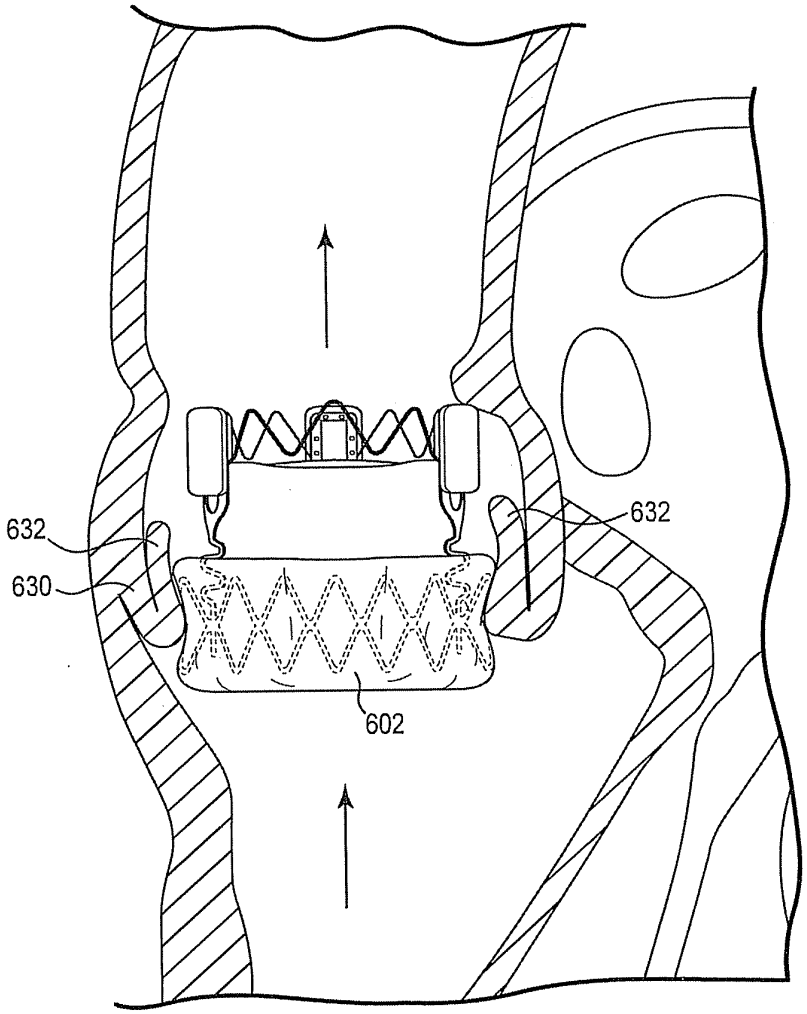

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/037445

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/24 (2010.01)
USPC - 623/2.38
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)
IPC(8) - A61F 2/24 (2010.01)
USPC - 623/2.11, 2.18, 2.38; 600/587

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)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/045338 A1 (BRAIDO) 09 April 2009 (09.04.2009) entire document	1, 3-12, 14-20
--		----------
Y		2, 13, 21-28
Y	US 2005/0075584 A1 (CALI) 07 April 2005 (07.04.2005) entire document	2, 13, 21-28
A	US 2006/0178740 A1 (STACCHINO et al) 10 August 2006 (10.08.2006) entire document	1-28

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 July 2010	10 AUG 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/675,665	Filing Date 11/13/2012	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	195
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	195

APPLICATION AS AMENDED – PART II

AMENDMENT 01/06/2016

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 6	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/GLORIA J. TRAMMELL/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	11/13/2012	David Paniagua	109978.10101	1995

29880 7590 04/22/2016

FOX ROTHSCHILD LLP
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LAWRENCEVILLE, NJ 08648

EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
04/22/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No. 13/675,665	Applicant(s) PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/6/2016*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1,2,4,6,9 and 10* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2,4,6, 9 and 10* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Response to Arguments

Applicant's arguments with respect to claims 1-2, 4, 6, and 9-10 have been considered but are moot because the amendment has necessitated new grounds for rejection (see below).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope

of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/forms/. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-2 and 4 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,308,797 B2. Although the claims at issue are not identical, they are not patentably distinct from each other because the application claims are merely broader than the patent claims.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 4 of U.S. Patent No. 8,790,398 B2. Although the claims at issue are not identical, they are not patentably distinct from each other because the application claim is merely broader than the patent claim.

Claim Rejections - 35 USC § 112

> The following is a quotation of 35 U.S.C. 112(b):
> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
>
> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4, 6, and 9-10 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 1, lines 8-9 recites "wherein a crease is located between the two to four individual leaflets and the outer cuff layer at a base of the two to four individual leaflets". This statement is somewhat unclear since the crease is claimed to be located in two different locations (*between* the leaflets and the cuff; and also *at* the base of the leaflets-thus on the leaflets). It is unclear how the crease could possibly be located *at* the base (thus part of the leaflets), while also being located *between* the leaflets and cuff. These two locations are contradictory. It seems applicant may have intended to describe the crease between bases of the leaflets and the outer cuff layer. Applicant may consider either removing the language "at a base of the two to four individual leaflets" from the claim; or alternately, changing "between the two to four individual leaflets" to recite --between bases of the two to four individual leaflets--. Claims 2, 4, 6, and 9-10 depend upon claim 1 and inherit all issues associated with the claim.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wittens (US 2011/0004295 A1) discloses a tube shaped valve with stent; Schreck

(US 2002/0198594 A1) discloses stent with attached tube valve; Jayaraman (US 5,855,597) discloses a stent with attached patches as valve leaflets; and Gabbay (US 4,491,986) discloses a stent with tube valve. Also worth noting, Garrison et al. (US 2002/0151970 A1, previously cited in IDS) stent valve of figures 32-38 is similar however seems to lack a crease between leaflets and cuff and Cox (US 2002/0032482 A1, previously cited) discloses a similar valve with optional stent (P0115-P0116), however lacking details of the stent structure and whether it is expandable and configured for percutaneous delivery and the valve further appears to lack a defined crease.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cheryl Miller whose telephone number is 571-272-4755. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M./
Examiner, Art Unit 3738
/THOMAS J SWEET/
Supervisory Patent Examiner, Art Unit 3738

Notice of References Cited	Application/Control No. 13/675,665	Applicant(s)/Patent Under Reexamination PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-8,308,797 B2	11-2012	Paniagua; David	A61F2/2412	623/2.14
*	B	US-8,790,398 B2	07-2014	Paniagua; David	A61F2/2412	623/1.24
*	C	US-2011/0004295 A1	01-2011	Wittens; Cornelis Hendrikus Anna	A61F2/2418	623/1.24
*	D	US-2002/0198594 A1	12-2002	Schreck, Stefan	A61F2/2418	623/2.11
*	E	US-5,855,597 A	01-1999	Jayaraman; Swaminathan	A61F2/2412	623/1.16
*	F	US-4,491,986 A	01-1985	Gabbay; Shlomo	A61F2/2418	623/2.18
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1973	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
S2	410	S1 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
S3	430	S1 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S4	674	S2 S3	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S5	8	"09/973,609"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:17
S6	275	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN. OR ("5397351").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:42
S7	11	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
S8	9	("3626518" | "3691567" | "3868956" | "3911502" | "4030142" | "4503569" | "4759758" | "4994077").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
S9	2	("4038703" | "4106129").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:45
S10	0	"a61f2002.""3601".cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/03 14:01
S11	0	a61f2002/3601.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/03 14:01
S12	4	"4759758".pn. or "5935163".pn. or "5861028".pn. or "5855602".pn.	US-PGPUB; USPAT;	OR	ON	2014/11/02 15:29

			USOCR			
S13	4	S12 and pericardium	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 15:29
S14	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S15	416	S14 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S16	430	S14 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S17	680	S15 S16	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S18	199	S17 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:26
S19	1	"6579307".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:34
S20	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S21	416	S20 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S22	430	S20 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S23	680	S21 S22	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S24	279	S23 and (valve with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S25	199	S23 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S26	85	S24 not S25	US-PGPUB;	OR	ON	2014/11/02 20:44

			USPAT; USOCR			
S27	364	S23 and (pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:59
S28	85	S27 not S24	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
S29	80	S28 not S25	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
S30	1	"6676698".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:32
S31	1	"6652578".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 10:38
S32	1	"7556646".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 13:32
S33	1	"6733525".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 14:12
S34	1	bessler.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 13:59
S35	2	"6197143".pn. or "20030060875".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:53
S36	2	"20020052651".pn. or "5554184".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:55
S37	1	"20030209835".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:57
S38	19	"10/037,266"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 21:10
S39	2	"20100268332".pn. or "20100217371".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 21:30
S40	1	"8308797".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 23:11

S41	5	"10/037,266"	USPAT; USOCR	OR	ON	2015/06/26 23:32
S42	43	bessler.in. and valve	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:05
S43	1	bessler.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:06
S44	38	myers.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:07
S45	30	cox.in. and 623/2.$2.ccls. and tube	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:09
S46	2	"4470157".pn. or "5163955".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:14
S47	1	"5411552".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:32
S48	1	"6908481".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 15:34
S49	139	("20010010017" | "20010023372" | "20010049558" | "20020005073" | "20020028243" | "20020029783" | "20020037940" | "20020042621" | "20020091441" | "20020095167" | "3014024" | "3029819" | "3105492" | "3320972" | "3409914" | "3548417" | "3562820" | "3588920" | "3671979" | "3709175" | "3878565" | "3945052" | "3966401" | "3983581" | "3986828" | "4035849" | "4055861" | "4056854" | "4060081" | "4082507" | "4084268" | "4106129" | "4164045" | "4172295" | "4218782" | "4222126" | "4233493" | "4265694" | "4291420" | "4340977" | "4350492" | "4364127" | "4388735" | "4423525" | "4441216" | "4456589" | "4473423" | "4477930" | "4490859" | "4517687" | "4545082" | "4597762" | "4600533" | "4631052" | "4666442" | "4728328" | "4759758" | "4759759" | "4798611" | "4801299" | "4870966" | "4883458" | "4892539" | "4966604" | "4976733" | "4979939" | "5006104" | "5007896" | "5011488" | "5026366" | "5032128" | "5047041" | "5047050" | "5052771" | "5061277" | "5080660" | "5139515" | "5163955" | "5171273" | "5226889" | "5261878" | "5282847" | "5326370" | "5326371" | "5332402" | "5336616" | "5360443" | "5374539"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:46

		"5376110" | "5383927" | "5411552" | "5413601" | "5449384" | "5476506" | "5480424" | "5489297" | "5500015" | "5509930" | "5522879" | "5522881" | "5545215" | "5549664" | "5549666" | "5571170" | "5571173" | "5571174" | "5578071" | "5578072" | "5582168" | "5591229" | "5634928" | "5653749" | "5713953" | "5728152" | "5733299" | "5741333" | "5746775" | "5769780" | "5782914" | "5787887" | "5840081" | "5855601" | "5861028" | "5862806" | "5895420" | "5931969" | "5957949" | "5961539" | "5961549" | "5972030" | "5976179").PN.				
S50	169	("6004328" | "6004330" | "6010531" | "6029671" | "6045576" | "6053938" | "6091984" | "6102944" | "6117169" | "6125852" | "6126686" | "6129756" | "6162245" | "6168614" | "6168619" | "6171335" | "6174327" | "6186999" | "6197143" | "6214055" | "6221091" | "6231602" | "6254629" | "6254630" | "6254636" | "6264691" | "6269819" | "6270526" | "6277397" | "6277555" | "6287335" | "6293970" | "6312462" | "6312474" | "6334873" | "6342069" | "6350282" | "6352554" | "6352708" | "6358275" | "6358284" | "6371980" | "6376244" | "6378221" | "6383171" | "6391333" | "6409755" | "6418339" | "6425916" | "6432712" | "6440167" | "6458153" | "6461382" | "6468313" | "6471723" | "6482227" | "6482228" | "6482240" | "6491719" | "6494909" | "6503272" | "6534004" | "6553681" | "6558418" | "6565960" | "6569200" | "6582458" | "6582462" | "6582464" | "6599524" | "6610088" | "6624890" | "6626938" | "6652577" | "6652578" | "6666886" | "6682559" | "6685739" | "6696074" | "6702826" | "6719788" | "6719789" | "6736823" | "6764510" | "6773456" | "6773457" | "6790229" | "6792979" | "6802319" | "6802806" | "6821530" | "6893460" | "6908481" | "6913608" | "6916338" | "6942694" | "6951571" | "6961123" | "6977231" | "6986735" | "7004925" | "7008763" | "7011688" | "7018404" | "7022348" | "7025780" | "7037333" | "7039446" | "7041132" | "7053051" | "7060092" | "7070616" | "7077862" | "7084082" | "7138226" | "7153324" | "7160322" | "7164145" | "7166570" | "7189259" | "7213601" | "7214242" | "7232461" | "7261732" | "7289211" | "7309461" | "7311730" | "7318998" | "7329279" | "7331993" | "7354702" | "7381218" | "7381219" | "7399315" | "7427291" | "7431725" | "7468073" | "7473237" | "7481838" | "7503929" | "7510571" | "7510575" | "7524330" | "7566343" | "7585321" | "7604661" | "7618446" |	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:47

		"7622276" | "7628805" | "7648676" | "7670368" | "7708775" | "7758632" | "7780722" | "7789909" | "7846203" | "7846204" | "7871431" | "7892281" | "7914576" | "7967833" | "7981151" | "8002825" | "8007992" | "8057540" | "8080054" | "8105375" | "RE40404" | "RE42395").PN.				
S51	148	("20020095994" | "20020123789" | "20020128708" | "20030078659" | "20030102000" | "20030130727" | "20030130729" | "20030130731" | "20030153974" | "20030187362" | "20030195620" | "20030204023" | "20030212460" | "20030212462" | "20030217415" | "20040024452" | "20040055608" | "20040059418" | "20040098092" | "20040193261" | "20040243153" | "20040243229" | "20050004668" | "20050027369" | "20050043819" | "20050096673" | "20050113910" | "20050137681" | "20050137682" | "20050142163" | "20050147562" | "20050147599" | "20050147643" | "20050148512" | "20050158274" | "20050159811" | "20050169958" | "20050169959" | "20050175657" | "20050187618" | "20050191248" | "20050228494" | "20050246035" | "20050247320" | "20050267529" | "20060004439" | "20060004443" | "20060020336" | "20060025800" | "20060041306" | "20060074486" | "20060089708" | "20060111733" | "20060129225" | "20060134079" | "20060140916" | "20060173475" | "20060178740" | "20060190074" | "20060193885" | "20060195010" | "20060195183" | "20060206203" | "20060229701" | "20060240063" | "20060240064" | "20060259134" | "20060259135" | "20060259137" | "20060265056" | "20060287571" | "20060292125" | "20070010857" | "20070043431" | "20070050014" | "20070050022" | "20070056346" | "20070060932" | "20070100426" | "20070128174" | "20070173861" | "20070213813" | "20070250154" | "20070263226" | "20070276432" | "20080004686" | "20080009667" | "20080009940" | "20080029105" | "20080039871" | "20080039926" | "20080058798" | "20080082113" | "20080102439" | "20080133004" | "20080147182" | "20080154356" | "20080177381" | "20080183280" | "20080183283" | "20080190989" | "20080195200" | "20080199843" | "20080200977" | "20090030511" | "20090043383" | "20090062907" | "20090112309" | "20090132032" | "20090157175" | "20090164005" | "20090187241"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:48

		"20090248149" | "20090254175" | "20090281609" | "20100030259" | "20100036479" | "20100036484" | "20100048987" | "20100049312" | "20100131054" | "20100161036" | "20100185277" | "20100217382" | "20100234878" | "20100249918" | "20100256749" | "20100256751" | "20100312333" | "20110004299" | "20110015728" | "20110040375" | "20110087322" | "20110137409" | "20110146361" | "20110153009" | "20110166636" | "20110178597" | "20110218619" | "20110224607" | "20110300625" | "20110301700" | "20120078343" | "20120078356" | "20120095551" | "20120158128" | "20120185038" | "20120310041").PN.				
S52	26	("20020151970" | "20030149477" | "20040039442" | "20040158321" | "20040230285" | "20050241981" | "20070104395" | "20070203575" | "20070276461" | "20090005857" | "20090054969" | "20100241069" | "20110240511" | "20130304201" | "20140039613" | "4011947" | "4657133" | "4743231" | "6124523" | "6245102" | "6540782" | "6821297" | "6830584" | "7018406" | "8512401" | "8512403").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:48
S53	4	("20020032481" | "20030027332" | "20070061008" | "20100043197").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:49
S54	2	("6676698" | "6733525").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:49
S55	1	("6530952").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:49
S56	8	("5484444" | "5645559" | "5683451" | "5876448" | "6350278" | "6682537" | "6896690" | "7556646").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:49
S57	3	("20020052651" | "20030209835" | "5554184").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:50
S58	500	S49 or S50 or S51 or S52 or S53 or S54 or S55 or S56 or S57	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:51
S59	222	S58 and @rlad<"20040710"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:51
S60	321	S58 and @ad<"20040710"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:51

S61	389	S59 S60	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:51
S62	1	"4056854".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 20:01
S63	381	623/2.1$1.ccls. and (sheet with (tissue or pericardi$2))	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:28
S64	92	S63 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:30
S65	46	S63 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:30
S66	117	S64 S65	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:30
S67	1762	623/2.$2.ccls. and pericardi$2 and (stent or frame)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:46
S68	1011	623/2.$2.ccls. and ((calf or juvenile or porcine or animal or mammal) with pericardi$2) and (stent or frame)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:47
S69	317	S68 and @rlad<"20040710"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:48
S70	263	S68 and @ad<"20040710"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:48
S71	458	S69 S70	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:48
S72	240	S71 and (resilient or "self-expandable" or "self-expanding" or "self-expands")	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:49
S73	162	S71 and (resilient or "self-expandable" or "self-expanding" or "self-expands") and (sheet or patch)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:50
S74	97	623/2.$2.ccls. and (autologous with pericardi$2)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 23:07
S75	126	623/2.$2.ccls. and ((autologous or autograft) with pericardi$2)	US-PGPUB; USPAT;	OR	ON	2015/06/27 23:07

			USOCR			
S76	37	S75 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 23:07
S77	39	S75 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 23:08
S78	57	S76 S77	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 23:08
S79	129	("3989701" | "4261342" | "4790844" | "4960424").PN. OR ("5344442").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/06/27 23:18
S80	1	"6908481".pn.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/06/28 00:06
S81	1	"20020032482".pn.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/06/28 00:12
S82	1	"6893460".pn.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/06/28 00:23
S83	21	623/2.$2.ccls. and (double with continuous with sutur$4)	US-PGPUB; USPAT; USOCR	OR	OFF	2015/06/28 00:52
S84	3728	a61f2/2412.cpc. or a61f2/2415.cpc. or a61f2/2418.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/11 14:52
S85	625	S84 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/11 14:53
S86	454	S84 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/11 14:53
S87	891	S85 S86	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/11 14:53
S88	52	(US-20100114299-$ or US-20060167543-$ or US-20060142848-$ or US-20050065594-$ or US-20040193253-$ or US-20030040792-$ or US-20020151970-$ or US-20110137409-$ or US-20030078652-$ or US-20020052651-$ or US-20020032482-$ or US-20020198594-$ or US-20030023303-$ or US-20040186565-$ or US-20050075725-$ or US-20060004442-$ or US-20090118826-$).did. or (US-7947072-$ or US-6733525-$ or US-6730121-$ or US-	US-PGPUB; USPAT	OR	OFF	2016/04/12 13:07

		6425916-$ or US-6299637-$ or US-6027525-$ or US-5957949-$ or US-5855601-$ or US-5607465-$ or US-5449384-$ or US-5163953-$ or US-4601718-$ or US-4759758-$ or US-7547322-$ or US-5895420-$ or US-5713953-$ or US-5509930-$ or US-5489297-$ or US-4340977-$ or US-5358518-$ or US-4343048-$ or US-4491986-$ or US-8308797-$ or US-8790398-$ or US-4470157-$ or US-4056854-$).did. or (US-4297749-$ or US-5545215-$ or US-6553681-$ or US-6682559-$ or US-6736846-$ or US-8613763-$ or US-5344442-$ or US-6358277-$ or US-4790844-$).did.				
S89	52	(US-20100114299-$ or US-20060167543-$ or US-20060142848-$ or US-20050065594-$ or US-20040193253-$ or US-20030040792-$ or US-20020151970-$ or US-20110137409-$ or US-20030078652-$ or US-20020052651-$ or US-20020032482-$ or US-20020198594-$ or US-20030023303-$ or US-20040186565-$ or US-20050075725-$ or US-20060004442-$ or US-20090118826-$).did. or (US-7947072-$ or US-6733525-$ or US-6730121-$ or US-6425916-$ or US-6299637-$ or US-6027525-$ or US-5957949-$ or US-5855601-$ or US-5607465-$ or US-5449384-$ or US-5163953-$ or US-4601718-$ or US-4759758-$ or US-7547322-$ or US-5895420-$ or US-5713953-$ or US-5509930-$ or US-5489297-$ or US-4340977-$ or US-5358518-$ or US-4343048-$ or US-4491986-$ or US-8308797-$ or US-8790398-$ or US-4470157-$ or US-4056854-$).did. or (US-4297749-$ or US-5545215-$ or US-6553681-$ or US-6682559-$ or US-6736846-$ or US-8613763-$ or US-5344442-$ or US-6358277-$ or US-4790844-$).did.	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 13:07
S90	29	paniagua.in. and valve	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 15:39
S91	9	paniagua.in. and valve	USPAT; USOCR	OR	ON	2016/04/12 15:39
S92	3733	a61f2/2412.cpc. or a61f2/2415.cpc. or a61f2/2418.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S93	625	S92 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S94	454	S92 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S95	891	S93 S94	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S96	299	S95 and pericardi$3	USPAT; USOCR	OR	ON	2016/04/12 16:00
S97	498	S95 and pericardi$3	US-	OR	ON	2016/04/12

			PGPUB; USPAT; USOCR			16:00
S98	344	S95 and pericardi$3 and (expand$4 or collaps$4)	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:01
S99	286	S95 and pericardi$3 and (expand$4 or collaps$4) and (cuff or crease or fold$4 or invert$3 or evert$3)	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:02
S100	425	S95 and (pericardi$3 or tube) and (expand$4 or collaps$4) and (cuff or crease or fold$4 or invert$3 or evert$3)	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:02
S101	57	(US-20100114299-$ or US-20060167543-$ or US-20060142848-$ or US-20050065594-$ or US-20040193253-$ or US-20030040792-$ or US-20020151970-$ or US-20110137409-$ or US-20030078652-$ or US-20020052651-$ or US-20020032482-$ or US-20020198594-$ or US-20030023303-$ or US-20040186565-$ or US-20050075725-$ or US-20060004442-$ or US-20090118826-$).did. or (US-7947072-$ or US-6733525-$ or US-6730121-$ or US-6425916-$ or US-6299637-$ or US-6027525-$ or US-5957949-$ or US-5855601-$ or US-5607465-$ or US-5449384-$ or US-5163953-$ or US-4601718-$ or US-4759758-$ or US-7547322-$ or US-5895420-$ or US-5713953-$ or US-5509930-$ or US-5489297-$ or US-4340977-$ or US-5358518-$ or US-4343048-$ or US-4491986-$ or US-8308797-$ or US-8790398-$ or US-4470157-$ or US-4056854-$).did. or (US-4297749-$ or US-5545215-$ or US-6553681-$ or US-6682559-$ or US-6736846-$ or US-8613763-$ or US-5344442-$ or US-6358277-$ or US-4790844-$ or US-8109995-$ or US-8361144-$ or US-8900294-$ or US-9125739-$ or US-9186248-$).did.	US-PGPUB; USPAT	OR	OFF	2016/04/12 16:03
S102	400	S100 not S101	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:03
S103	1	"6579307".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:19
S104	8	("20080131522").PN. or ("20020119437" | "20020146393" | "20030118560" | "20060212111" | "4275469" | "5558875" | "7214344").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:36
S105	1	"20020032482".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/15 15:35
S106	1	"8308797".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/15 19:36

S107	23	"10/037,266"	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/15 19:39
S108	4	"10/037,266" and crease	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/15 19:44

4/16/2016 7:11:02 PM
C:\Users\cmiller2\Documents\EAST\Workspaces\13675665.wsp

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. Miller
Attorney Docket Number	109978.10101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20080131522		2008-06-05	Liu et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2010/141847	WO		2010-12-09	ATS Medical, Inc.		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2012-11-13
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. Miller
	Attorney Docket Number	109978.10101

	1	SACKS, Michael S. et al., "Orthotropic Mechanical Properties of Chemically Treated Bovine Pericardium" Annals of Biomedical Engineering, 1998, vol. 26, pp. 892-902 (10254 OA, 12/03/15)	
	2	Notice of Allowance issued September 22, 2011, in U.S. Application No. 12/228,192 (109978.10110)	

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Examiner Signature	/Cheryl Miller/	Date Considered	04/16/2016

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Attorney Docket Number	109978.10101

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4275469		1981-06-30	Gabbay	
	2	5558875		1996-09-24	Wang	
	3	7214344		2007-01-14	Carpentier et al.	

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	1	20020119437		2002-08-29	Grooms et al.	
	2	20020146393		2002-10-10	Bell et al.	
	3	20030118560		2003-06-25	Kelly et al.	

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Receipt date: 09/10/2015

13675665 - GAU: 3738

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. Miller
Attorney Docket Number	109978.10101

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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	4	20060212111		2006-09-21	Case et al.		

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	1	Office Action issued July 6, 2015, in U.S. Application No. 13/367,252 (109978.10111)	☐
	2	Notice of Allowance issued August 14, 2015, in U.S. Application No. 13/367,252 (109978.10111)	☐

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Examiner Signature	/Cheryl Miller/	Date Considered	04/16/2016

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13675665	PANIAGUA ET AL.
	Examiner	Art Unit
	CHERYL MILLER	3738

CPC- SEARCHED		
Symbol	Date	Examiner
A61f2/2418, 2412, 2415	4/12/2016	cm

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East text search, review parent application files	6/27/2015	cm
Inventor name search	4/12/2016	cm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/C.M./ Examiner.Art Unit 3738	

PTO/SB/08a (03-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5080670		1992-01-14	Imamura	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030138945		2003-07-24	McAllister	
	2	20060155366		2006-07-13	LaDuca et al.	
	3	20060229716		2006-10-12	Mitrev	
	4	20090054976		2009-02-26	Tuval et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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	1	Office Action issued April 8, 2016 in U.S. Application No. 14/502,453 (File: 109978.10106)	

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Examiner Signature		Date Considered	

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	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gunjan Agarwal/	Date (YYYY-MM-DD)	2016-07-19
Name/Print	Gunjan Agarwal	Registration Number	69661

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	13675665
Filing Date:	13-Nov-2012
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Filer:	Gunjan Agarwal/Carol Donahue
Attorney Docket Number:	109978.10101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for Continued Examination	2801	1	600	600
		Total in USD ($)		**600**

Electronic Acknowledgement Receipt	
EFS ID:	26389875
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Gunjan Agarwal/Carol Donahue
Filer Authorized By:	Gunjan Agarwal
Attorney Docket Number:	109978.10101
Receipt Date:	19-JUL-2016
Filing Date:	13-NOV-2012
Time Stamp:	14:34:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$600
RAM confirmation Number	072016INTEFSW14345700
Deposit Account	5690
Authorized User	Carol Donahue
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	10101_RCE.PDF	1379945 748d060eae0a6baf846064308d033030ef3546c0	no	3
Warnings:					
Information:					
2		10101_OAResponse.pdf	21592 c659dcab93616d94b4c403ca0202b9eaf2f35b70	yes	6
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Response After Final Action		1	1	
	Claims		2	3	
	Applicant Arguments/Remarks Made in an Amendment		4	6	
Warnings:					
Information:					
3	Transmittal Letter	10101_IDS_Transmittal.pdf	26921 c52f5607a3e19bc2cfb2e16b756af259aca9204a	no	5
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	10101_Supp_IDS.PDF	1085941 36b2b67242c4a1ad21a1af5a654f484de2f17d72	no	4
Warnings:					
Information:					
5	Non Patent Literature	10106_US_14-502453_Office_Action_2016-04-08.PDF	222548 9c49a591349215df65d5063a0f430331049af1f9	no	6

Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30982 27afb385cf87328d18b0a8e755ec946649c2f420	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2767929		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
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Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	13675665	Filing Date	2012-11-13	Docket Number (if applicable)	109978.10101	Art Unit	3738
First Named Inventor	David Paniagua			Examiner Name	Cheryl L. Miller		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, to any international application that does not comply with the requirements of 35 U.S.C. 371, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV.

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 501943

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

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Signature of Registered U.S. Patent Practitioner			
Signature	/Gunjan Agarwal/	Date (YYYY-MM-DD)	2016-07-19
Name	Gunjan Agarwal	Registration Number	69661

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Attorney Docket No. 109978.10101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	:	
	:	
David Paniagua et al.	:	Confirmation No.: 1995
	:	
Application No.: 13/675,665	:	Group Art Unit: 3738
	:	
Filed: November 13, 2012	:	Examiner: Cheryl L. Miller

Title: PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

AMENDMENT AND RESPONSE TO OFFICE ACTION, REQUEST FOR CONTINUED EXAMINATION AND REQUEST FOR EXAMINER INTERVIEW

This Amendment And Response To Final Office Action, Request for Continued Examination And Request For Examiner Interview is in reply to the Final Office Action issued on April 22, 2016 in the application captioned above. The following remarks are respectfully submitted.

AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior versions, and listings, of the claims in the application.

1. (Currently Amended) A percutaneously implantable replacement heart valve device for implantation in a patient, comprising:

an expandable stent member having an inner channel, the expandable stent member collapsible and configured for percutaneous delivery; and

a valve means made of biocompatible tissue material and attached to the expandable stent member, the valve means including an outer cuff layer and two to four individual leaflets, wherein each of the two to four individual leaflets is rectangular in shape in side elevation view, wherein a crease is located between a base of the two to four individual leaflets and the outer cuff layer ~~at a base of the two to four individual leaflets~~, and wherein after implantation in the patient, the valve means resides as a single element entirely within the inner channel of the expandable stent member, wherein only the two to four individual leaflets reside radially inward from the outer cuff layer, and wherein the valve means is formed without cutting slits into said biocompatible tissue material to form said leaflets.

2. (Original) The percutaneously implantable replacement heart valve device of claim 1, wherein said expandable stent member is made of a metal or alloy of metals selected from the group consisting of nickel-titanium alloy, titanium and stainless steel.

3. (Canceled)

4. (Previously Presented) The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said valve means comprises porcine pericardium tissue.

5. (Canceled)

6. (Previously Presented) The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said valve means comprises autologous tissue obtained from the patient into whom said replacement heart valve device will be implanted.

7.-8. (Canceled)

9. (Previously Presented) The percutaneously implantable heart valve device of claim 1, wherein said expandable stent member is self-expanding when implanted.

10. (Previously Presented) The percutaneously implantable heart valve device of claim 1, wherein said expandable stent member is balloon catheter expandable when implanted.

11.-33. (Cancelled)

REMARKS

In the Office Action, the Office rejected claims 1, 2, 4, 6, 9 and 10. More specifically:

- The Office rejected claims 1-2 and 4 under nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,308,797;
- The Office rejected claim 1 under nonstatutory double patenting as being unpatentable over claim 4 of U.S. Patent No. 8,790,398; and
- The Office rejected claims 1-2, 4, 6 and 9-10 under 35 U.S.C. §112 pre-AIA, second paragraph, as failing to point out and distinctly claim the subject matter regarded as the invention.

Claim 1 has been amended. Support for these amendments can be found in at least paragraphs [0046] and FIGS. 3A and 3B of the published application. Upon entry of these amendments and remarks, claims 1, 2, 4, 6, 9 and 10 will remain pending. For the reasons set forth below, Applicant asks the Office to withdraw the rejections associated with the claims.

Rejections Under Double Patenting

The Office rejected claims 1-2 and 4 under nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,308,797; and claim 1 under nonstatutory double patenting as being unpatentable over claim 4 of U.S. Patent No. 8,790,398.

Applicant does not necessarily agree with the Office's assertions, and hereby respectfully reserves the right to refute and contest any and all contentions made by the Office in issuing these rejections. Nevertheless, Applicant notes that there has not yet been any indication of allowable subject matter in the present application, and accordingly applicants respectfully request that the Office hold these rejections in abeyance until allowable subject matter is

indicated. At that time applicants will consider the possibility of filing, solely in order to advance prosecution, one or more Terminal Disclaimers under 37 CFR 1.321(c).

Rejections Under 35 U.S.C. §112 pre-AIA, second paragraph

On page 4 of the Office Action, the Office rejected claims 1, 2, 4, 6, 9 and 10 under 35 U.S.C. §112 pre-AIA, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter of the invention. Specifically, the Office asserted that it is unclear how the crease could be located at the base of the leaflets while also being located between the leaflets and the cuff.

Without conceding the merits of the rejection, and solely to advance prosecution, Applicant has amended claim 1 to recite "wherein a crease is located between a base of the two to four individual leaflets and the outer cuff layer."

Accordingly, Applicant respectfully requests that the Office withdraw the §112, second paragraph, rejections associated with claims 1-2, 4, 6 and 9-10.

CONCLUSION AND REQUEST FOR INTERVIEW

For the reasons discussed above, Applicant respectfully asks the Examiner to reconsider and withdraw all outstanding rejections.

If the next Office Action will not result in allowance of the claims, Applicant requests an interview to discuss any remaining issues. Applicant invites the Examiner to contact the undersigned attorney to schedule a convenient time.

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment, or credit any overpayment, to Deposit Account No. 50-1943.

Respectfully submitted,

FOX ROTHSCHILD LLP

/Gunjan Agarwal/
Gunjan Agarwal
Registration No. 69,661

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Date: July 19 2016

Docket No.: 109978.10101
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
David Paniagua et al.

Application No.: 13/675,665 Confirmation No.: 1995

Filed: November 13, 2012 Art Unit: 3738

For: Percutaneously Implantable Replacement Heart Valve Device and Method of Making Same Examiner: C. L. Miller

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- [ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- [x] B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- [ ] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))

☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ ii. Payment in the amount of the fee set forth in 1. 17(p), presently believed to be $180, is enclosed.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(p) payment in the amount of $180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

[x] A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated August 5, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the U.S. Patent(s) and/or U.S. Patent Application Publication(s) on PTO/SB/08 is/are not being submitted.

[ ] B. Document(s) _____is (are) deemed substantially cumulative to document(s) _____ , and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[ ] C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

<<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

[ ] 3. Cite Nos. _____ are not in the English language. In accordance with 1.98(c), Applicant states:

[ ] An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application , or English-language abstract (or claim) is enclosed.

[ ] The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).

[ ] A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]

[ ] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

[ ] A concise explanation of document(s) _____ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).

☐ 5. Other information being provided for the examiner's consideration follows:

6. Related Patents and Patent Applications. The Examiner is hereby advised of the existence of the patents, patent applications, and/or other proceedings before the Patent Office listed below which: (1) share at least some common disclosure with the instant application, (2) serve as the basis of priority for the instant application, and/or (3) otherwise may relate to the instant application or one or more of the other matters listed below. For completeness, the instant application is also included in the list.

It is respectfully requested that the Examiner review each matter listed below and its associated prosecution history (e.g., Office Actions, Responses to Office Actions, Interview Summaries, Notice of Allowances, and so forth) as part of evaluating the instant application. The prosecution history for each matter listed below should be readily available to the Examiner through the Patent Office's internal systems. Since these materials are already easily accessible to the Examiner, a hard copy has not been provided. However, at the Examiner's request, Applicant will provide a hard copy of any matter listed below including its prosecution history (or one or more individual documents from the prosecution history). Applicant believes that this is an efficient and effective way to allow the Examiner to consider the applicability of the matters listed below to the instant application.

The attached form PTO/SB/08b includes a reference to the information listed below concerning related patents and patent applications. Applicant requests that the Examiner initial the attached PTO/SB/08b form next to this reference to indicate that the Examiner has considered this information as part of evaluating the instant application. By initialing the form in this manner, the Examiner expressly acknowledges that he/she has considered each matter listed below, as well as all of the documents included in its prosecution history, as part of examining the instant application.

Application Serial No.	**Filing Date**	**Title of Invention**

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated

for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-1943, under Order No. 109978.10101.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-1943, under Order No. 109978.10101 from which the undersigned is authorized to draw.

Dated: July 19, 2016

Respectfully submitted,

By/Gunjan Agarwal/
Gunjan Agarwal
Registration No.: 69,661
FOX ROTHSCHILD LLP
997 Lenox Drive, Building 3
Lawrenceville, New Jersey 08648-2311
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Attorneys/Agents For Applicant

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/675,665	Filing Date 11/13/2012	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	07/19/2016	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 6	Minus	** 20	= 0	X $40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0	X $210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/STELLA LITTLE/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	26389875
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Gunjan Agarwal/Carol Donahue
Filer Authorized By:	Gunjan Agarwal
Attorney Docket Number:	109978.10101
Receipt Date:	19-JUL-2016
Filing Date:	13-NOV-2012
Time Stamp:	14:34:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$600
RAM confirmation Number	072016INTEFSW14345700
Deposit Account	501943
Authorized User	Carol Donahue
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	10101_RCE.PDF	1379945 748d060eae0a6baf846064308d033030ef3546c0	no	3
Warnings:					
Information:					
2		10101_OAResponse.pdf	21592 c659dcab93616d94b4c403ca0202b9eaf2f35b70	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	6

Warnings:					
Information:					
3	Transmittal Letter	10101_IDS_Transmittal.pdf	26921 c52f5607a3e19bc2cfb2e16b756af259aca9204a	no	5
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	10101_Supp_IDS.PDF	1085941 36b2b67242c4a1ad21a1af5a654f484de2f17d72	no	4
Warnings:					
Information:					
5	Non Patent Literature	10106_US_14-502453_Office_Action_2016-04-08.PDF	222548 9c49a591349215df65d5063a0f430331049af1f9	no	6

Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30982 27afb385cf87328d18b0a8e755ec946649c2f420	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2767929		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	11/13/2012	David Paniagua	109978.10101	1995

29880 7590 07/29/2016

FOX ROTHSCHILD LLP
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997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
07/29/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No. 13/675,665	Applicant(s) PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/19/2016*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1,2,4,6,9 and 10* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2 and 4* is/are rejected.

8)☒ Claim(s) *6,9 and 10* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 19, 2016 has been entered.

Response to Arguments

Applicant's amendment filed July 19, 2016 has overcome the previous 112 2nd rejections.

The previous double patenting rejections have been maintained herein, because a terminal disclaimer was not filed with applicant's response.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d

1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/forms/. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-2 and 4 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,308,797 B2, cited previously. Although the claims at issue are not identical, they are not patentably distinct from each other because the application claims are merely broader than the patent claims.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 4 of U.S. Patent No. 8,790,398 B2, cited previously. Although the claims at issue are not identical, they are not patentably distinct from each other because the application claim is merely broader than the patent claim.

Allowable Subject Matter

Claims 6, 9, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dzemeshkevich et al. (US 4,692,164) discloses a two layer tissue valve with resilient frame; Schwartz et al. (US 2002/0099439 A1) discloses a frame with a plurality of cusps therein (fig.25-27); Obermiller et al. (US 2004/0049262 A1) discloses a stent with valve pockets; and McGuckin et al. (US 2002/0055772 A1) discloses a stent with valve therein (fig.42-44).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cheryl Miller whose telephone number is 571-272-4755. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M./
Examiner, Art Unit 3738
/THOMAS J SWEET/

Supervisory Patent Examiner, Art Unit 3738

Notice of References Cited	Application/Control No. 13/675,665	Applicant(s)/Patent Under Reexamination PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-4,692,164 A	09-1987	Dzemeshkevich; Sergei L.	A61F2/2412	623/2.14
*	B	US-2002/0099439 A1	07-2002	Schwartz, Robert S.	A61F2/2412	623/1.24
*	C	US-2004/0049262 A1	03-2004	Obermiller, Joseph F.	A61F2/2418	623/1.15
*	D	US-2002/0055772 A1	05-2002	McGuckin, James F. JR.	A61B17/12036	623/1.24
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5080670		1992-01-14	Imamura	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030138945		2003-07-24	McAllister	
	2	20060155366		2006-07-13	LaDuca et al.	
	3	20060229716		2006-10-12	Mitrev	
	4	20090054976		2009-02-26	Tuval et al.	

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.L.M/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Office Action issued April 8, 2016 in U.S. Application No. 14/502,453 (File: 109978.10106)	

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EXAMINER SIGNATURE

Examiner Signature	/CHERYL L MILLER/	Date Considered	07/23/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gunjan Agarwal/	Date (YYYY-MM-DD)	2016-07-19
Name/Print	Gunjan Agarwal	Registration Number	69661

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

/CHERYL L MILLER/ 07/23/2016

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13675665	PANIAGUA ET AL.
	Examiner	Art Unit
	CHERYL MILLER	3738

CPC- SEARCHED		
Symbol	Date	Examiner
A61f2/2418, 2412, 2415	4/12/2016	cm
update	7/22/2016	cm

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East text search, review parent application files	6/27/2015	cm
Inventor name search	4/12/2016	cm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/C.M./ Examiner.Art Unit 3738	

EAST Search History

EAST Search History (Prior Art)

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L7	2	L6 and @pd>"20160401"	US-PGPUB; USPAT; USOCR	OR	ON	2016/07/23 00:15
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S4	674	S2 S3	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S5	8	"09/973,609"	US-PGPUB; USPAT;	OR	ON	2014/06/02 11:17

			USOCR			
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S14	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
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S25	199	S23 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
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S32	1	"7556646".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 13:32
S33	1	"6733525".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 14:12
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S38	19	"10/037,266"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 21:10
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S44	38	myers.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:07
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S72	240	S71 and (resilient or "self-expandable" or "self-expanding" or "self-expands")	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:49
S73	162	S71 and (resilient or "self-expandable" or "self-expanding" or "self-expands") and (sheet or patch)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:50
S74	97	623/2.$2.ccls. and (autologous with pericardi$2)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 23:07
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S83	21	623/2.$2.ccls. and (double with continuous with sutur$4)	US-PGPUB; USPAT;	OR	OFF	2015/06/28 00:52

			USOCR			
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S85	625	S84 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/11 14:53
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		$ or US-6358277-$ or US-4790844-$).did.				
S90	29	paniagua.in. and valve	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 15:39
S91	9	paniagua.in. and valve	USPAT; USOCR	OR	ON	2016/04/12 15:39
S92	3733	a61f2/2412.cpc. or a61f2/2415.cpc. or a61f2/2418.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S93	625	S92 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S94	454	S92 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S95	891	S93 S94	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S96	299	S95 and pericardi$3	USPAT; USOCR	OR	ON	2016/04/12 16:00
S97	498	S95 and pericardi$3	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:00
S98	344	S95 and pericardi$3 and (expand$4 or collaps$4)	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:01
S99	286	S95 and pericardi$3 and (expand$4 or collaps$4) and (cuff or crease or fold$4 or invert$3 or evert$3)	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:02
S100	425	S95 and (pericardi$3 or tube) and (expand$4 or collaps$4) and (cuff or crease or fold$4 or invert$3 or evert$3)	US-PGPUB; USPAT; USOCR	OR	ON	2016/04/12 16:02
S101	57	(US-20100114299-$ or US-20060167543-$ or US-20060142848-$ or US-20050065594-$ or US-20040193253-$ or US-20030040792-$ or US-20020151970-$ or US-20110137409-$ or US-20030078652-$ or US-20020052651-$ or US-20020032482-$ or US-20020198594-$ or US-20030023303-$ or US-20040186565-$ or US-20050075725-$ or US-20060004442-$ or US-20090118826-$).did. or (US-7947072-$ or US-6733525-$ or US-6730121-$ or US-6425916-$ or US-6299637-$ or US-6027525-$ or US-5957949-$ or US-5855601-$ or US-5607465-$ or US-5449384-$ or US-5163953-$ or US-4601718-$ or US-4759758-$ or US-7547322-$ or US-5895420-$ or US-5713953-$ or US-5509930-$ or US-5489297-$ or US-4340977-$ or US-5358518-$ or US-4343048-$ or US-4491986-$ or US-8308797-$ or US-8790398-$ or US-4470157-$ or US-4056854-	US-PGPUB; USPAT	OR	OFF	2016/04/12 16:03

		$).did. or (US-4297749-$ or US-5545215-$ or US-6553681-$ or US-6682559-$ or US-6736846-$ or US-8613763-$ or US-5344442-$ or US-6358277-$ or US-4790844-$ or US-8109995-$ or US-8361144-$ or US-8900294-$ or US-9125739-$ or US-9186248-$).did.				
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Attorney Docket No. 109978.10101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	:	
	:	
David Paniagua et al.	:	Confirmation No.: 1995
	:	
Application No.: 13/675,665	:	Group Art Unit: 3738
	:	
Filed: November 13, 2012	:	Examiner: Cheryl L. Miller

Title: PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

AMENDMENT AND RESPONSE TO OFFICE ACTION AND REQUEST FOR EXAMINER INTERVIEW

This Amendment And Response To Office Action And Request For Examiner Interview is in reply to the Office Action issued on July 29, 2016 in the application captioned above. The following remarks are respectfully submitted.

AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior versions, and listings, of the claims in the application.

1. (Previously Presented) A percutaneously implantable replacement heart valve device for implantation in a patient, comprising:

an expandable stent member having an inner channel, the expandable stent member collapsible and configured for percutaneous delivery; and

a valve means made of biocompatible tissue material and attached to the expandable stent member, the valve means including an outer cuff layer and two to four individual leaflets, wherein each of the two to four individual leaflets is rectangular in shape in side elevation view, wherein a crease is located between a base of the two to four individual leaflets and the outer cuff layer, and wherein after implantation in the patient, the valve means resides as a single element entirely within the inner channel of the expandable stent member, wherein only the two to four individual leaflets reside radially inward from the outer cuff layer, and wherein the valve means is formed without cutting slits into said biocompatible tissue material to form said leaflets.

2. (Original) The percutaneously implantable replacement heart valve device of claim 1, wherein said expandable stent member is made of a metal or alloy of metals selected from the group consisting of nickel-titanium alloy, titanium and stainless steel.

3. (Canceled)

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4. (Previously Presented) The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said valve means comprises porcine pericardium tissue.

5. (Canceled)

6. (Previously Presented) The percutaneously implantable replacement heart valve device of claim 1, wherein said biocompatible tissue material of said valve means comprises autologous tissue obtained from the patient into whom said replacement heart valve device will be implanted.

7.-8. (Canceled)

9. (Previously Presented) The percutaneously implantable heart valve device of claim 1, wherein said expandable stent member is self-expanding when implanted.

10. (Previously Presented) The percutaneously implantable heart valve device of claim 1, wherein said expandable stent member is balloon catheter expandable when implanted.

11.-33. (Cancelled)

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REMARKS

In the Office Action, the Office rejected claims 1, 2, and 4 and objected to claims 6, 9 and 10. More specifically:

- The Office rejected claims 1, 2 and 4 under nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,308,797;
- The Office rejected claim 1 under nonstatutory double patenting as being unpatentable over claim 4 of U.S. Patent No. 8,790,398; and
- The Office objected claims 6, 9 and 10 as being dependent upon a rejected based claim, but would be allowable if rewritten in independent form including all of the limitations of the baes claim and any intervening claims.

No claims have been amended. For the reasons set forth below, Applicant asks the Office to withdraw the rejections associated with the claims.

Rejections Under Double Patenting

The Office rejected claims 1-2 and 4 under nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 8,308,797; and claim 1 under nonstatutory double patenting as being unpatentable over claim 4 of U.S. Patent No. 8,790,398.

While Applicant does not necessarily agree with the Office's assertions, in order to progress this application to allowance, Applicant submits the requested Terminal Disclaimers Accordingly, Applicant respectfully requests that the Office withdraw the double patenting rejections associated with claims 1, 2 and 4.

Objections to Claims 6, 9 and 10

Applicant asserts that with the submission of the Terminal Disclaimers for claims 1, 2 and 4, claims 6, 9 and 10 are no longer dependent upon rejected claims.

Accordingly, Applicant respectfully requests that the Office withdraw the objections associated with claims 6, 9 and 10.

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 2256 of 2319

CONCLUSION AND REQUEST FOR INTERVIEW

For the reasons discussed above, Applicant respectfully asks the Examiner to reconsider and withdraw all outstanding rejections.

If the next Office Action will not result in allowance of the claims, Applicant requests an interview to discuss any remaining issues. Applicant invites the Examiner to contact the undersigned attorney to schedule a convenient time.

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment, or credit any overpayment, to Deposit Account No. 50-1943.

Respectfully submitted,

FOX ROTHSCHILD LLP

/Gunjan Agarwal/
Gunjan Agarwal
Registration No. 69,661

Fox Rothschild LLP
Princeton Pike Corporate Center
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Telephone: 412-391-2414
Facsimile: 609-896-1469
Date: October 26, 2016

PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 109978.10101

In re Application of: David Panigua

Application No.: 13/675,665

Filed: 2012-11-13

For: PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

The applicant, COLIBRI HEART VALVE LLC, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 8790398 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 69661

/Gunjan Agarwal/ — Signature
10/26/2016 — Date

Gunjan Agarwal — Typed or printed name

Patent Attorney of Record — Title
412-391-2414 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 109978.10101

In re Application of: David Panigua

Application No.: 13/675,665

Filed: 2012-11-13

For: PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

The applicant, COLIBRI HEART VALVE LLC, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 8308797 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 69661

/Gunjan Agarwal/ — Signature
10/26/2016 — Date

Gunjan Agarwal — Typed or printed name

Patent Attorney of Record — Title
412-391-2414 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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Electronic Patent Application Fee Transmittal	
Application Number:	13675665
Filing Date:	13-Nov-2012
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Filer:	Gunjan Agarwal/Carol Donahue
Attorney Docket Number:	109978.10101
Filed as Small Entity	
Filing Fees for Utility under 35 USC 111(a)	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	2814	2	160	320
		Total in USD ($)		**320**

Electronic Acknowledgement Receipt	
EFS ID:	27331858
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Gunjan Agarwal/Carol Donahue
Filer Authorized By:	Gunjan Agarwal
Attorney Docket Number:	109978.10101
Receipt Date:	26-OCT-2016
Filing Date:	13-NOV-2012
Time Stamp:	16:46:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$320
RAM confirmation Number	102716INTEFSW16472700
Deposit Account	501943
Authorized User	Carol Donahue
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10101_Response.pdf	34663 47f912c6c4c2294bfe1c7285d021dedb020e0ffa	yes	6
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	3	
	Applicant Arguments/Remarks Made in an Amendment		4	6	
Warnings:					
Information:					
2	Terminal Disclaimer Filed	10101_Terminal_Disclaimer_Pat_8790398.PDF	167727 845383ec99dcc0c84789dd1bf940a0d2242fe454	no	2
Warnings:					
Information:					
3	Terminal Disclaimer Filed	10101_Terminal_Disclaimer_Pat_8308797.PDF	167594 643b02bd65295e4e40cc3ae5ca8f76fecfb64a45	no	2
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30765 4e5e15e2dff2cfb94ff645cd610b5adea82788fd	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	400749		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
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Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	13/675,665	PANIAGUA ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 26 October, 2016	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

/CRYSTAL QUEEN/

Technology Center: PLRC

Telephone: _____

2 TD'S APPROVED.

U.S. Patent and Trademark Office

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/675,665	Filing Date 11/13/2012	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 10/26/2016

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 6	Minus	** 20	= 0	X $40 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $210 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/DORIAN EVANS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6166184		2000-12-26	Hendriks et al.	
	2	7632309		2009-12-15	Brendzel et al.	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20010007956		2001-07-12	Letac et al.	

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Notice of Allowance issued September 19, 2016 in U.S. Application No. 14/502,453 (File: 109978.10106)	
	2	Office Action issued October 7, 2016, in U.S. Application No. 14/829,349 (File: 109978.10120)	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gunjan Agarwal/	Date (YYYY-MM-DD)	2016-11-15
Name/Print	Gunjan Agarwal	Registration Number	69661

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	13675665
Filing Date:	13-Nov-2012
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Filer:	Gunjan Agarwal/Carol Donahue
Attorney Docket Number:	109978.10101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	90	90
		Total in USD ($)		**90**

Electronic Acknowledgement Receipt

EFS ID:	27519553
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Gunjan Agarwal/Carol Donahue
Filer Authorized By:	Gunjan Agarwal
Attorney Docket Number:	109978.10101
Receipt Date:	15-NOV-2016
Filing Date:	13-NOV-2012
Time Stamp:	16:28:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$90
RAM confirmation Number	111616INTEFSW16301500
Deposit Account	501943
Authorized User	Carol Donahue
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	10101_IDS_Transmittal.pdf	40640 2736a559b3191af3f8a5f3733af8cfa778d088e3	no	5
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10101_IDS.pdf	1081320 9399b636d24c280924d540b1c4bb8dfccff332db	no	4
Warnings:					
Information:					
3	Non Patent Literature	10106_US_14-502453_Notice-of-Allowance_2016-09-19.pdf	658913 42bbcd18b5f0341a2b4d66b27d98a66db3c0e927	no	8
Warnings:					
Information:					
4	Non Patent Literature	10120_US_14-829349_Office-Action_2016-10-07.pdf	563355 f728706ed8b23bfdf3cce0d1b88df2cdd7409038	no	9
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30754 27eb4ba695bf808429ac81601ae6512d29b69a2d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2374982		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: 109978.10101
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
David Paniagua et al.

Application No.: 13/675,665 — Confirmation No.: 1995

Filed: November 13, 2012 — Art Unit: 3738

For: Percutaneously Implantable Replacement Heart Valve Device and Method of Making Same — Examiner: C. L. Miller

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- [ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- [ ] B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- [X] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))

☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☒ ii. Payment in the amount of the fee set forth in 1. 17(p), presently believed to be $180, is enclosed.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(p) payment in the amount of $180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

[x] A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated August 5, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the U.S. Patent(s) and/or U.S. Patent Application Publication(s) on PTO/SB/08 is/are not being submitted.

[ ] B. Document(s) _____is (are) deemed substantially cumulative to document(s) _____ , and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[ ] C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

<<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

[ ] 3. Cite Nos. _____ are not in the English language. In accordance with 1.98(c), Applicant states:

[ ] An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application , or English-language abstract (or claim) is enclosed.

[ ] The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).

[ ] A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]

[ ] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

[ ] A concise explanation of document(s) _____ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).

☐ 5. Other information being provided for the examiner's consideration follows:

6. Related Patents and Patent Applications. The Examiner is hereby advised of the existence of the patents, patent applications, and/or other proceedings before the Patent Office listed below which: (1) share at least some common disclosure with the instant application, (2) serve as the basis of priority for the instant application, and/or (3) otherwise may relate to the instant application or one or more of the other matters listed below. For completeness, the instant application is also included in the list.

It is respectfully requested that the Examiner review each matter listed below and its associated prosecution history (e.g., Office Actions, Responses to Office Actions, Interview Summaries, Notice of Allowances, and so forth) as part of evaluating the instant application. The prosecution history for each matter listed below should be readily available to the Examiner through the Patent Office's internal systems. Since these materials are already easily accessible to the Examiner, a hard copy has not been provided. However, at the Examiner's request, Applicant will provide a hard copy of any matter listed below including its prosecution history (or one or more individual documents from the prosecution history). Applicant believes that this is an efficient and effective way to allow the Examiner to consider the applicability of the matters listed below to the instant application.

The attached form PTO/SB/08b includes a reference to the information listed below concerning related patents and patent applications. Applicant requests that the Examiner initial the attached PTO/SB/08b form next to this reference to indicate that the Examiner has considered this information as part of evaluating the instant application. By initialing the form in this manner, the Examiner expressly acknowledges that he/she has considered each matter listed below, as well as all of the documents included in its prosecution history, as part of examining the instant application.

Application Serial No.	Filing Date	Title of Invention

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated

for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

Please charge our Credit Card in the amount of $90.00 covering the fee set forth in 37 C.F.R. § 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-1943, under Order No. 109978.10101.

Dated: November 15, 2016

Respectfully submitted,

By/Gunjan Agarwal/
Gunjan Agarwal
Registration No.: 69,661
FOX ROTHSCHILD LLP
997 Lenox Drive, Building 3
Lawrenceville, New Jersey 08648-2311
(412) 391-2414
(609) 896-1469 (Fax)
Attorneys/Agents For Applicant

ACTIVE\42951221

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

29880 7590 11/18/2016

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/18/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	11/13/2012	David Paniagua	109978.10101	1995

TITLE OF INVENTION: PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	02/21/2017

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 02/11)

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

29880 7590 11/18/2016
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	11/13/2012	David Paniagua	109978.10101	1995

TITLE OF INVENTION: PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	02/21/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
MILLER, CHERYL L	3738	623-001200

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 2284 of 2319

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	11/13/2012	David Paniagua	109978.10101	1995

29880 7590 11/18/2016

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/18/2016

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 13/675,665	Applicant(s) PANIAGUA ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the response with terminal disclaimers filed 10/26/2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1,2,4,6,9 and 10*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/C. M./	/THOMAS J SWEET/
Examiner, Art Unit 3738	Supervisory Patent Examiner, Art Unit 3738

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	4024	a61f2/2412.cpc. or a61f2/2418.cpc. or a61f2/2475.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2016/11/03 16:16
L2	605	L1 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/11/03 16:16
L3	415	L1 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2016/11/03 16:16
L4	850	2 3	US-PGPUB; USPAT; USOCR	OR	ON	2016/11/03 16:16
L5	4	L4 and @pd>"20160701"	US-PGPUB; USPAT; USOCR	OR	ON	2016/11/03 16:17
S1	1973	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
S2	410	S1 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
S3	430	S1 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S4	674	S2 S3	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
S5	8	"09/973,609"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:17
S6	275	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN. OR ("5397351").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:42
S7	11	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN.	US-PGPUB; USPAT;	OR	OFF	2014/06/02 11:43

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S9	2	("4038703" | "4106129").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:45
S10	0	"a61f2002.""3601".cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/03 14:01
S11	0	a61f2002/3601.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/03 14:01
S12	4	"4759758".pn. or "5935163".pn. or "5861028".pn. or "5855602".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 15:29
S13	4	S12 and pericardium	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 15:29
S14	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S15	416	S14 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S16	430	S14 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S17	680	S15 S16	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:25
S18	199	S17 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:26
S19	1	"6579307".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 16:34
S20	2098	623/1.24.ccls. or 623/1.26.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
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			USPAT; USOCR			
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S23	680	S21 S22	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S24	279	S23 and (valve with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S25	199	S23 and (leaflets with pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S26	85	S24 not S25	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:44
S27	364	S23 and (pericardi$3)	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 20:59
S28	85	S27 not S24	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
S29	80	S28 not S25	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:00
S30	1	"6676698".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/02 21:32
S31	1	"6652578".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 10:38
S32	1	"7556646".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 13:32
S33	1	"6733525".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 14:12
S34	1	bessler.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 13:59
S35	2	"6197143".pn. or "20030060875".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:53

S36	2	"20020052651".pn. or "5554184".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:55
S37	1	"20030209835".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 15:57
S38	19	"10/037,266"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 21:10
S39	2	"20100268332".pn. or "20100217371".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 21:30
S40	1	"8308797".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/26 23:11
S41	5	"10/037,266"	USPAT; USOCR	OR	ON	2015/06/26 23:32
S42	43	bessler.in. and valve	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:05
S43	1	bessler.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:06
S44	38	myers.in. and 623/2.$2.ccls.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:07
S45	30	cox.in. and 623/2.$2.ccls. and tube	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:09
S46	2	"4470157".pn. or "5163955".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:14
S47	1	"5411552".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 14:32
S48	1	"6908481".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 15:34
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Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 2292 of 2319

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S61	389	S59 S60	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 19:51
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S70	263	S68 and @ad<"20040710"	US-PGPUB; USPAT;	OR	ON	2015/06/27 22:48

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S73	162	S71 and (resilient or "self-expandable" or "self-expanding" or "self-expands") and (sheet or patch)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 22:50
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S75	126	623/2.$2.ccls. and ((autologous or autograft) with pericardi$2)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/27 23:07
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S91	9	paniagua.in. and valve	USPAT;	OR	ON	2016/04/12

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S96	299	S95 and pericardi$3	USPAT; USOCR	OR	ON	2016/04/12 16:00
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Edwards Lifesciences Corporation, et al. Exhibit 1017, p. 2300 of 2319

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13675665	PANIAGUA ET AL.
	Examiner	Art Unit
	CHERYL MILLER	3738

CPC- SEARCHED		
Symbol	Date	Examiner
A61f2/2418, 2412, 2415	4/12/2016	cm
update	7/22/2016	cm
A61f2/2412, 2418, 2475	11/3/2016	cm

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East text search, review parent application files	6/27/2015	cm
Inventor name search	4/12/2016	cm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
Claim text search		11/3/2016	cm

/C.M./ Examiner.Art Unit 3738	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13675665	PANIAGUA ET AL.
	Examiner	**Art Unit**
	CHERYL MILLER	3738

CPC							
Symbol						**Type**	**Version**
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A61F		2002	/	9534		A	2013-01-01
A61F		2	/	2439		A	2013-01-01
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A61F		2230	/	0078		A	2013-01-01
A61F		2210	/	0076		A	2013-01-01
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A61F		2	/	2436		I	2013-01-01
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A61F		2220	/	0008		A	2013-01-01
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/C.M./ Examiner.Art Unit 3738	11/03/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	6	
/THOMAS J SWEET/ Supervisory Patent Examiner.Art Unit 3738	11/14/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13675665	PANIAGUA ET AL.
	Examiner	**Art Unit**
	CHERYL MILLER	3738

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CPC Combination Sets					
Symbol			**Type**	**Set**	**Ranking**	**Version**
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/C.M./ Examiner.Art Unit 3738 (Assistant Examiner)	11/03/2016 (Date)	**Total Claims Allowed:** 6	
/THOMAS J SWEET/ Supervisory Patent Examiner.Art Unit 3738 (Primary Examiner)	11/14/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 5

U.S. Patent and Trademark Office

Part of Paper No. 20161103

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	13675665	PANIAGUA ET AL.
	Examiner	**Art Unit**
	CHERYL MILLER	3738

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
		A	6	1	F	2 / 24 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

/C.M./ Examiner.Art Unit 3738 (Assistant Examiner)	11/03/2016 (Date)	**Total Claims Allowed:** 6	
/THOMAS J SWEET/ Supervisory Patent Examiner.Art Unit 3738 (Primary Examiner)	11/14/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 5

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13675665	PANIAGUA ET AL.
	Examiner	**Art Unit**
	CHERYL MILLER	3738

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

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	16		32												

/C.M./ Examiner.Art Unit 3738	11/03/2016	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	6	
/THOMAS J SWEET/ Supervisory Patent Examiner.Art Unit 3738	11/14/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 1995

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/675,665	11/13/2012 RULE	623	3738	109978.10101

APPLICANTS

COLIBRI HEART VALVE LLC, Broomfield, CO;

INVENTORS

David Paniagua, Houston, TX;
R. David Fish, Houston, TX;
Eduardo Induni, Alajuela, COSTA RICA;
Carlos Meija, Houston, TX;
Fransisco Lopez-Jimenez, Rochester, MN;

**** CONTINUING DATA ***************************

This application is a CON of 10/887,688 07/10/2004 PAT 8308797 *
which is a CIP of 10/037,266 01/04/2002 ABN
(*)Data provided by applicant is not consistent with PTO records.

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
12/05/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /CHERYL L MILLER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		TX	12	~~14~~ 6	~~3~~ 1

ADDRESS

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648
UNITED STATES

TITLE

PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
800	No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	11/13/2012	David Paniagua	109978.10101	1995

29880 7590 12/07/2016

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
12/07/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Corrected Notice of Allowability	**Application No.** 13/675,665	**Applicant(s)** PANIAGUA ET AL.	
	Examiner CHERYL MILLER	**Art Unit** 3738	**AIA (First Inventor to File) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the IDS filed 11/15/2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1,2,4,6,9 and 10*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/CHRISTIAN SEVILLA/ Primary Examiner, Art Unit 3775	/C. M./ Examiner, Art Unit 3738

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6166184		2000-12-26	Hendriks et al.	
	2	7632309		2009-12-15	Brendzel et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20010007956		2001-07-12	Letac et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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/CHERYL L MILLER/ 12/01/2016

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.L.M/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Notice of Allowance issued September 19, 2016 in U.S. Application No. 14/502,453 (File: 109978.10106)	
	2	Office Action issued October 7, 2016, in U.S. Application No. 14/829,349 (File: 109978.10120)	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/CHERYL L MILLER/	Date Considered	12/01/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.L.M/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13675665
	Filing Date	2012-11-13
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10101

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Gunjan Agarwal/	Date (YYYY-MM-DD)	2016-11-15
Name/Print	Gunjan Agarwal	Registration Number	69661

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

/CHERYL L MILLER/ 12/01/2016

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.L.M/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

12/01/2016

/CHERYL L MILLER/

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.L.M/

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

29880 7590 11/18/2016
FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	11/13/2012	David Paniagua	109978.10101	1995

TITLE OF INVENTION: PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	02/21/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
MILLER, CHERYL L	3738	623-001200

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 FOX ROTHSCHILD LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: COLIBRI HEART VALVE LLC
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Broomfield, Colorado

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-1943 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Gunjan Agarwal/ Date 16 February 2017
Typed or printed name Gunjan Agarwal Registration No. 69661

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	13675665
Filing Date:	13-Nov-2012
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Filer:	Gunjan Agarwal/Carol Donahue
Attorney Docket Number:	109978.10101

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	480	480

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**480**

Electronic Acknowledgement Receipt	
EFS ID:	28377435
Application Number:	13675665
International Application Number:	
Confirmation Number:	1995
Title of Invention:	PERCUTANEOUSLY IMPLANTABLE REPLACEMENT HEART VALVE DEVICE AND METHOD OF MAKING SAME
First Named Inventor/Applicant Name:	David Paniagua
Customer Number:	29880
Filer:	Gunjan Agarwal/Carol Donahue
Filer Authorized By:	Gunjan Agarwal
Attorney Docket Number:	109978.10101
Receipt Date:	16-FEB-2017
Filing Date:	13-NOV-2012
Time Stamp:	13:54:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$480
RAM confirmation Number	021717INTEFSW13554800
Deposit Account	501943
Authorized User	Carol Donahue
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	10101_Issue_Fee_Transmittal.pdf	138336 73a0c0ee45e9ec8332746da02d90ef944f49ab84	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30898 5ce97089049aca59379346e87fc461af955e32dc	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	169234		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	13675665
Filing Date	2012-11-13
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. Miller
Attorney Docket Number	109978.10101

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4275469		1981-06-30	Gabbay	
	2	5558875		1996-09-24	Wang	
	3	7214344		05/2007 ~~2007-01-14~~	Carpentier et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

Change(s) applied to document.
/N.W.S./
12/14/2016

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020119437		2002-08-29	Grooms et al.	
	2	20020146393		2002-10-10	Bell et al.	
	3	20030118560		2003-06-25	Kelly et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/675,665	04/04/2017	9610158	109978.10101	1995

29880 7590 03/15/2017

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE
BLDG. #3
LAWRENCEVILLE, NJ 08648

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 630 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

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