d. At 248d, immersion of the tissue in 0.1 - 25% glutaraldehyde (filtered to limit oligomeric content) for between about 3 days to 5 weeks, and more preferably, for between about 3 days to 4 weeks, and more preferably yet, for between about 3 weeks to 4 weeks, at 0 to 37°C, and more preferably, 0.25% glutaraldehyde for 7 days at 4°C; or

e. At 248e, immersion in the tissue in one of the above formalin, glutaraldehyde, or oligomeric filtered glutaraldehyde solutions together with added amino acids, lysine and/or histidine, wherein the concentration of the amino acids, L-lysine or histidine, used as an additive to the fixative is in the range of about 100 - 1000 milliMolar, with a preferred value of about 684 mM.

In addition to the foregoing, combinations of the processes listed above may be performed, including: step a followed by step b; step a followed by step c; and step a followed by step d.

As those skilled in the art will appreciate, heat-shrink testing may be conducted on tissue samples to correlate the effectiveness of protein cross-linking. Here, results of heat-shrink testing performed on one or more samples of tissue prepared in accordance with at least one embodiment using formalin showed that the tissue had a shrink temperature of 90°C. This compares favorably with samples prepared using glutaraldehyde, wherein the shrink temperature was 80°C. Accordingly, formalin is a suitable variant of fixation. It is noted that formalin was generally abandoned by the field, largely because of material properties that were unfavorable and because of inadequate or unstable protein cross-linking. Such problems have been overcome through the pretreatments described herein, allowing production of tissue with strength, pliability, and durability in a relatively thin membrane. When used in a prosthetic implant, such as a heart valve, the tissue characteristics imparted by the tissue preparation process facilitate formation of a construct having a relatively low-profile, which also thereby facilitates dry packaging of the prosthetic implant. The same advantages are also achieved using the pretreatments when using a glutaraldehyde process.

Referring still to Fig. 2B, after fixation for collagen cross-linking at 248, an alcohol post-fixation treatment at 252 is preferably performed by rinsing the tissue in distilled water at 256, and then at 260 rinsing the tissue in 25% isopropyl alcohol for between about 30 minutes to 14 days or more at between about 0 to 37°C, and more preferably, for at least about 7 days at 20°C. At 264, the tissue undergoes a rinsing with distilled water.

In accordance with at least one embodiment, treatment of the tissue, including from the time of harvest to the time of implantation or grafting, does not include contact and/or exposure to a polymer to infiltrate and/or encapsulate tissue fibers of the tissue.

Referring now to Fig. 3, the drying process at 300 is performed after the tissue preparation at 200. Thus, in accordance with at least one embodiment, the tissue is dried under a load. More particularly, for the tissue drying at 304, the tissue is placed minimally stretched flat (that is, stretched just enough to eliminate visible wrinkles and bubbles) on a flat surface (e.g., a polymer or acrylic sheet) at 308, and held fixed at its edges at 312. Optionally, the joined tissue and underlying sheet are then set in a slight curve. The tension maintains the substantially flat structure of the tissue as it dries, thereby mitigating or preventing excessive shrinkage, wrinkling, and/or curling at the edges, and also making the rate of drying more uniform across the surface of the tissue because of the surface tension between the plate and the tissue. Alternatively, the tissue is dried while compressed between acrylic plates. When drying the tissue, the temperature is held at between about 4 to 37°C, and more preferably, between about 20 to 37°C (i.e., approximately room temperature to normal human body temperature), and more preferably, at about 20°C. At 314, the drying process is performed in substantially dark conditions (i.e., substantially no visible light) for between about 6 hours to 5 days, and more preferably, for about 72 hours. By way of example, the tissue is dried in dark conditions at a temperature of about 20°C for between about 6 hours to 5 days, and more preferably, for about 72 hours. As those skilled in the art will appreciate, drying the tissue while the tissue is compressed between plates requires a longer period of time.

In at least one embodiment, after drying, the tissue lots are inspected at 316, such as by stereomicroscopy, to identify and discard those with defects or discontinuities of the fiber matrix. If desired, the preferential fiber direction for each piece may be identified to determine a particular orientation, for example, to determine the free edge of the pieces that will form valve leaflets for a heart valve. Depending upon the size (i.e., the area) of the tissue being prepared and the size of tissue needed for a given implant, the tissue may be trimmed or otherwise sized in optional sizing at 320, such as by cutting the tissue into an appropriately sized and shaped sheet for implant formation and/or manipulation. Preferably, cutting of the tissue membrane is oriented so that the resulting free edge is parallel to the preferential fiber direction of the tissue membrane. Optionally, the free edge may also be cut with a parabolic or other curved profile to compensate for any attachment angles in order to increase the total contact surface between the tissue membrane and any associated frame or other structure. This approach minimizes weaknesses in the operating margins of the tissue assembly and advantageously distributes the principal loading forces of the operating implant along the long axis of the collagen fibers. As a result, the tissue is resistant to surface fracture and fraying.

As shown in Fig. 3, optional sizing at 320 is performed after the drying at 304 and inspection at 316. A rectangular shaped piece of tissue 400 is shown in Fig. 4. The tissue 400

may be manipulated for use in a variety of prosthetic implants and grafts.

As mentioned above, tissue prepared by the methods described herein has been successfully prepared by rinsing with 25% isopropyl alcohol for a period of 7 days, and after the further treatment steps described herein, provided an ultimate tensile strength of greater than 25 MegaPascals. Here, the combination of tissue pliability and tensile strength is sought for purposes of producing a material having property characteristics suitable for being physically manipulated to form prosthetic implants, such as a tissue leaflet assembly for a heart valve or a ligament, while providing a tissue material that will operate properly once implanted. These techniques are intended to conserve and preserve collagen fibers, minimize damage to the tissue and improve tissue characteristics. The preparation and fixation techniques produce tissue membrane material that may be rendered and used at lesser thicknesses than typically rendered in the prior art. Thinner membranes are more pliable, but with conventional tissue preparation techniques the tensile strength of the tissue is sacrificed. Advantageously, the preparation techniques described herein have produced membranes that have as much as three times the tensile strength of a commercial product of the prior art. This achieved strength is thus desirable for providing a tissue assembly having a low profile with appropriate durability, even in a substantially dry state. More particularly, the tissue possesses a relatively high tensile strength. By way of example and not limitation, testing has shown that embodiments of tissue prepared as described herein provide a tissue having a tensile strength of approximately three times the tensile strength of current pericardial valve tissue, such as on the order of approximately 25 MegaPascals, thereby providing about 2,000 times the physiologic load strength for valve tissue. Moreover, testing of an embodiment of an implantable prosthetic heart valve made with tissue prepared as described herein and under a static load of greater than approximately 250 mmHg showed less than approximately 14% leakage, wherein such results are generally considered superior to surgical tissue valve prostheses.

With reference to Fig. 5, stress-strain curve results for five different tissue samples prepared in accordance with an embodiment are shown. For the testing results shown, the yield stress or ultimate tensile strength was obtained by attaching strips of tissue fixed at the ends in a linear force tester and increasing the length by 0.3 mm/sec while recording resultant force (tension) until the material ruptured or separated entirely; these measurements were then used to calculate the stress-strain curves depicted in Fig. 5. As illustrated in the graph, the yield stress or ultimate tensile strength of the various tissue samples varied from about 30 to about 50 MegaPascals. More particularly, for each curve shown in Fig. 5, the testing procedures were the same. That is, each of the curves shown pertain to separate pieces of tissue that were subjected to the same test. The results show a minimum ultimate tensile strength of 30 MegaPascals, with

a range up to 50 MegaPascals. Accordingly, the illustrated test results demonstrate consistency of the ultimate tensile strength results for the tissue treatment process.

It is to be understood that the tissue generated from one or more of the tissue preparation procedures described herein may be used for a variety of devices or uses, and that use in a prosthetic heart valve is but one possible application for utilizing the tissue. For example, the tissue may be used in a shunt, or as graft material for repair or modification of one or more human organs, including the heart and its blood vessels. By way of further example, the tissue may be used as a pericardial membrane patch for repair of congenital heart defects. The tissue also has application as a prosthetic tissue in tendon and ligament replacement, and as a tissue product for wound management. Moreover, for use in a prosthetic heart valve, the tissue may be configured in a variety of ways and attached to a frame in a variety of ways. In addition, a plurality of separate tissue pieces may each be connected together, such as by suturing, to form a larger composite of treated tissue material. Thereafter, whether the prosthetic implant or graft is made of a folded tissue assembly or a plurality of separate tissue pieces, the resulting prosthetic implant or graft may then be further manipulated for treatment of a patient.

In at least one embodiment, tissue generated from one or more of the tissue preparation procedures described herein may be used to form a prosthetic implant that includes a stent, frame, bone screw or other fastening or anchoring mechanism. In yet other embodiments, tissue generated from one or more of the tissue preparation procedures described herein may be used to form a prosthetic implant or graph that does not include a stent, frame, bone screw or other fastening or anchoring mechanism. Tissue generated from one or more of the tissue preparation procedures described herein may be may be packaged for delivery in a substantially dry, partially hydrated or hydrated ("wet") state. For example, a prosthetic implant utilizing a prepared tissue described herein may be packaged for delivery as a hydrated prosthetic implant. Accordingly, while a portion of the tissue preparation process may include drying the tissue so that it may be manipulated more easily, the tissue may then be hydrated at a later point in time prior to implantation, and it may be maintained in a hydrated condition up to and including packaging, delivery and implantation into a patient. Hydration of the tissue membrane portion occurs rapidly and begins with simple preparatory flushing of the tissue. Those skilled in the art will appreciate that one or more embodiments described herein provide a tissue 400 suitable for implanting in a human, wherein the implantable tissue may be allowed to dry prior to implanting and effectively rehydrated at the time of implanting, such as by flushing of the tissue at the time of implanting using saline or water.

All embodiments described herein are described for use in human patients. However, all embodiments described herein have application for use in veterinary medicine, such as equine

medicine.

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 apparatuses substantially as depicted and described herein, including various embodiments, subcombinations, and subsets thereof. Those of skill in the art 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 descriptions 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.

CLAIMS

What is claimed is:

1. A prepared tissue for medical use, comprising:

a section of treated tissue harvested from a mammalian organism, the section of treated tissue including an ultimate tensile strength of greater than about 15 MegaPascals.

2. The prepared tissue of Claim 1, wherein the section of treated tissue has a thickness of between about 50 to 500 micrometers.

3. The prepared tissue of Claim 1, wherein the section of treated tissue comprises a water content of less than about 60% by weight of the section of treated tissue.

4. The prepared tissue of Claim 1, wherein the section of treated tissue comprises a water content of less than about 50% by weight of the section of treated tissue.

5. The prepared tissue of Claim 1, wherein the section of treated tissue comprises a water content of less than about 40% by weight of the section of treated tissue.

6. The prepared tissue of Claim 1, wherein the section of treated tissue is attached to a frame ex vivo for at least one of: (a) surgical use; or (b) percutaneous implantation.

7. The prepared tissue of Claim 1, wherein the section of treated tissue does not include a matrix that has been exposed to a polymer infiltrate.

8. The prepared tissue of Claim 1, wherein the section of treated tissue is unbraided and uncompounded.

9. The prepared tissue of Claim 1, wherein the section of treated tissue comprises an ultimate tensile strength of greater than about 25 MegaPascals.

10. The prepared tissue of Claim 9, wherein the section of treated tissue is unbraided and uncompounded.

11. The prepared tissue of Claim 1, wherein the section of treated tissue has been exposed to isopropyl alcohol before contacting the section of treated tissue with either glutaraldehyde or formalin.

12. The prepared tissue of Claim 1, wherein the section of treated tissue has been exposed to a solution containing formalin after pretreatment with isopropyl alcohol.

13. The prepared tissue of Claim 1, wherein the section of treated tissue has been exposed to a solution containing glutaraldehyde after pretreatment with isopropyl alcohol.

14. The prepared tissue of Claim 1, wherein the section of treated tissue comprises a pericardium tissue.

15. A prepared tissue for medical use with a patient, comprising:

a section of tissue harvested from a mammalian organism, wherein the section of tissue is prepared ex vivo for future grafting or implantation in the patient, the section of tissue

including a thickness of about 50 to 500 micrometers and an ultimate tensile strength of greater than about 25 MegaPascals.

16. The prepared tissue of Claim 15, wherein the section of tissue is unbraided and uncompounded.

17. The prepared tissue of Claim 15, wherein the section of tissue comprises a water content of less than about 40% by weight of the section of tissue.

18. The prepared tissue of Claim 15, wherein the section of tissue is attached to a frame ex vivo for at least one of: (a) surgical use; or (b) percutaneous implantation in the patient.

19. The prepared tissue of Claim 15, wherein the section of tissue does not include a matrix that has been exposed to a polymer infiltrate.

20. The prepared tissue of Claim 15, wherein the section of tissue comprises a treated pericardium tissue.

21. A method of preparing a tissue for medical use, comprising:

providing a section of tissue harvested from a mammalian organism; and

causing osmotic shocking of the section of tissue by performing multiple rinses of the section of tissue with distilled water.

22. The method of Claim 21, further comprising hydrating the section of tissue during a plurality of time intervals using distilled water.

23. The method of Claim 22, further comprising not using saline for causing at least one of the osmotic shocking and the hydrating of the section of tissue.

24. The method of Claim 21, further comprising pretreating the section of tissue with glycerol before contacting the section of tissue with one or more of isopropyl alcohol, glutaraldehyde and formalin.

25. The method of Claim 24, further comprising contacting the section of tissue with a solution containing formalin after pretreating the section of tissue with glycerol.

26. The method of Claim 24, further comprising contacting the section of tissue with a solution containing glutaraldehyde after pretreating the section of tissue with glycerol.

27. The method of Claim 21, further comprising pretreating the section of tissue with isopropyl alcohol before contacting the section of tissue with either glutaraldehyde or formalin.

28. The method of Claim 27, further comprising contacting the section of tissue with a solution containing formalin after pretreating the section of tissue with isopropyl alcohol.

29. The method of Claim 27, further comprising contacting the section of tissue with a solution containing glutaraldehyde after pretreating the section of tissue with isopropyl alcohol.

30. The method of Claim 21, further comprising exposing the section of tissue to light energy for a period of time, the period of time extending until there is no further visible separation of lipid droplets from an exposed surface of the section of tissue.

31. The method of Claim 30, wherein the light energy is at least equivalent to exposing the section of tissue to a 50 watt incandescent light source with a flat radiant face situated at a distance of about 10 centimeters from the exposed surface for about 15 minutes.

32. The method of Claim 21, wherein the section of tissue comprises a treated pericardium tissue.

33. A method of preparing a section of tissue for medical use, comprising:

(a) cleaning and decellularizing the section of tissue by performing multiple rinses of the section of tissue with distilled water;

(b) rinsing the section of tissue with isopropyl alcohol for a first period of time of not less than about 7 days; and

(c) contacting the section of tissue with one of

(i) a formalin solution, or

(ii) a glutaraldehyde solution

for a second period of time of not less than about 6 days;

wherein step (b) occurs sometime after step (a), and wherein step (c) occurs sometime after step (b).

34. The method of Claim 33, wherein for step (c):

if the formalin solution is used, then the formalin solution comprises a concentration of about 1 - 37.5% formalin; and

if the glutaraldehyde solution is used, then the glutaraldehyde solution comprises a concentration of about 0.1 - 25% glutaraldehyde.

35. The method of Claim 33, further comprising exposing the section of tissue to light energy for an exposure duration, the exposure duration extending until there is no further visible separation of lipid droplets from an exposed surface of the section of tissue.

36. The method of Claim 35, wherein the light energy is at least equivalent to exposing the section of tissue to a 50 watt incandescent light source with a flat radiant face situated at a distance of about 10 centimeters from the exposed surface for about 15 minutes.

37. The method of Claim 33, further comprising:

(d) rinsing the section of tissue with distilled water and isopropyl alcohol for a post-fixation period of time of not less than about 7 days;

wherein step (d) occurs sometime after step (c).

38. The method of Claim 33, wherein the section of tissue comprises an ultimate tensile strength of greater than about 25 MegaPascals.

39. The method of Claim 33, wherein the section of tissue comprises a treated pericardium tissue.

40. A method of preparing a section of tissue for medical use, comprising:

(a) contacting the section of tissue with distilled water;

(b) contacting the section of tissue with isopropyl alcohol for a pre-fixation period of time of not less than about 3 days; and

(c) contacting the section of tissue with one of

(i) a formalin solution, or

(ii) a glutaraldehyde solution

for a fixation period of time of not less than about 3 days; and

(d) contacting the section of tissue with isopropyl alcohol for a post-fixation period of time of not less than about 3 days;

wherein step (b) occurs sometime after step (a), wherein step (c) occurs sometime after step (b), and wherein step (d) occurs sometime after step (c).

41. The method of Claim 40, wherein for step (c):

if the formalin solution is used, then the formalin solution comprises a concentration of about 1 - 37.5% formalin; and

if the glutaraldehyde solution is used, then the glutaraldehyde solution comprises a concentration of about 0.1 - 25% glutaraldehyde.

42. The method of Claim 40, wherein for step (c):

if the formalin solution is used, then the formalin solution comprises a concentration of about 8-12% formalin; and

if the glutaraldehyde solution is used, then the glutaraldehyde solution comprises a concentration of about 0.1-0.5% glutaraldehyde.

43. The method of Claim 40, wherein the section of tissue comprises a treated pericardium tissue.

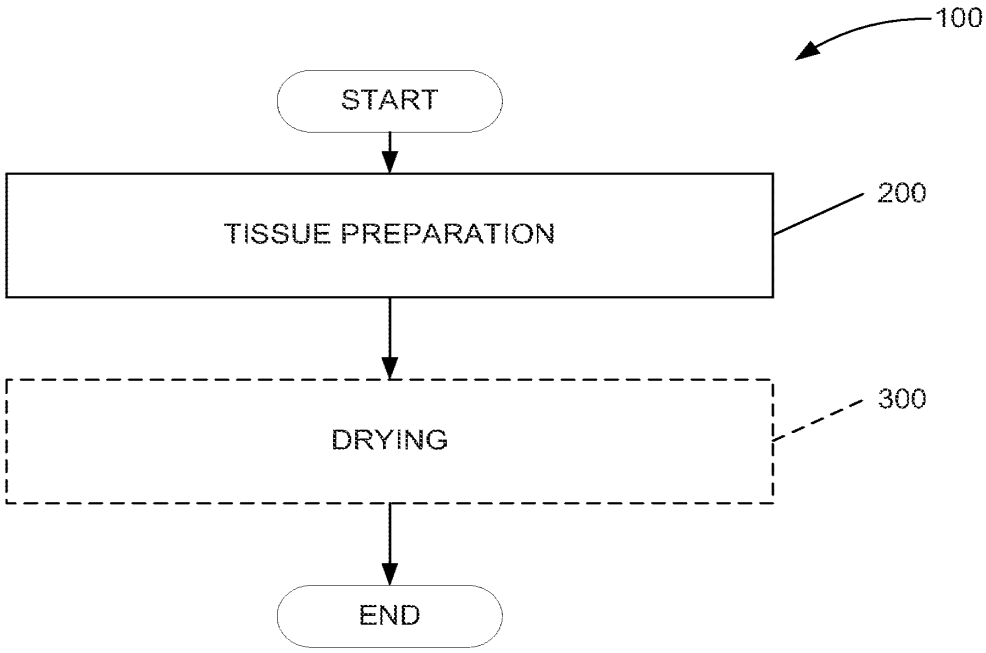


FIG. 1

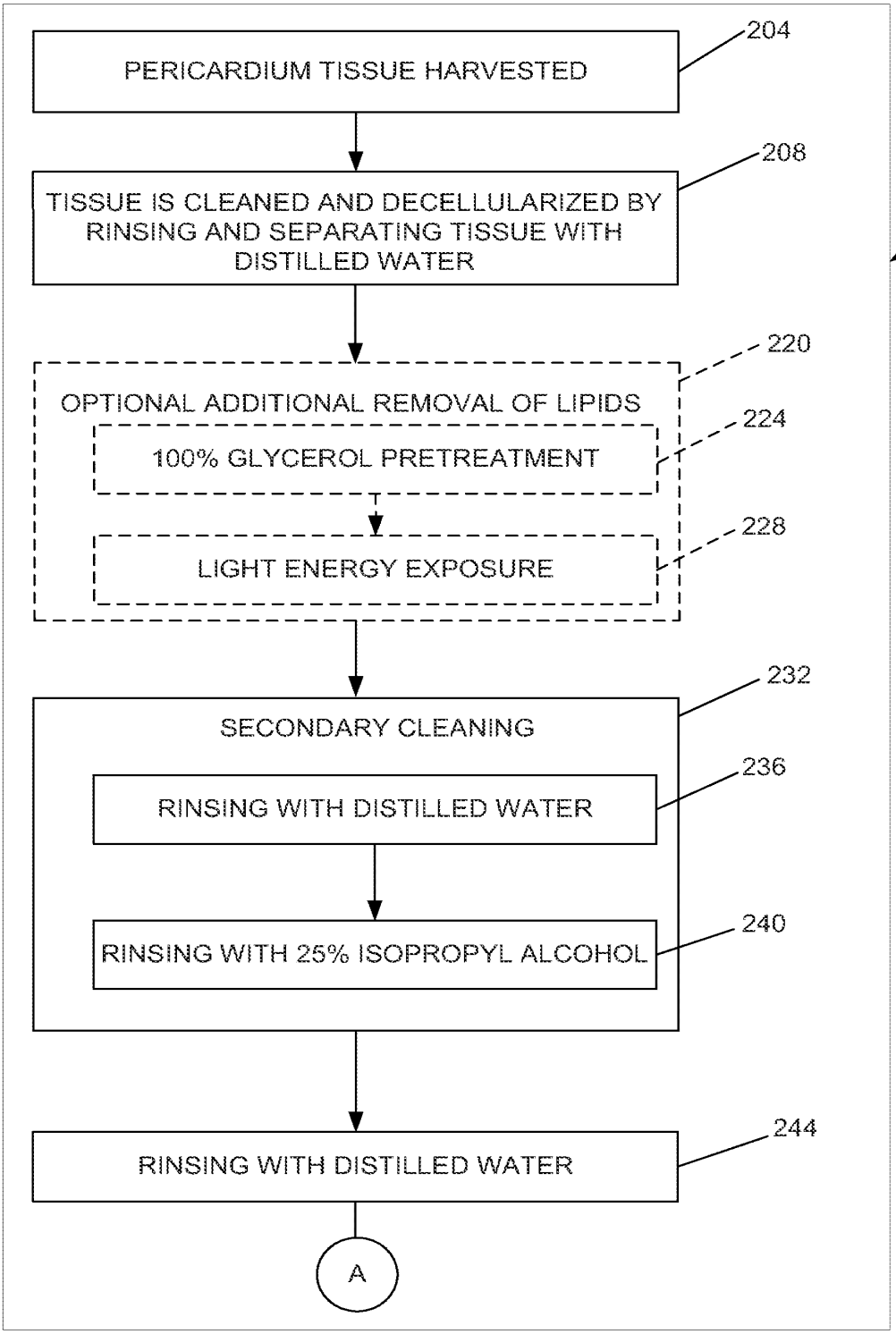

PERICARDIUM TISSUE HARVESTED
204
TISSUE IS CLEANED AND DECELLULARIZED BY RINSING AND SEPARATING TISSUE WITH DISTILLED WATER
208
200
OPTIONAL ADDITIONAL REMOVAL OF LIPIDS
220
100% GLYCEROL PRETREATMENT
224
LIGHT ENERGY EXPOSURE
228
SECONDARY CLEANING
232
RINSING WITH DISTILLED WATER
236
RINSING WITH 25% ISOPROPYL ALCOHOL
240
RINSING WITH DISTILLED WATER
244
A

FIG. 2A

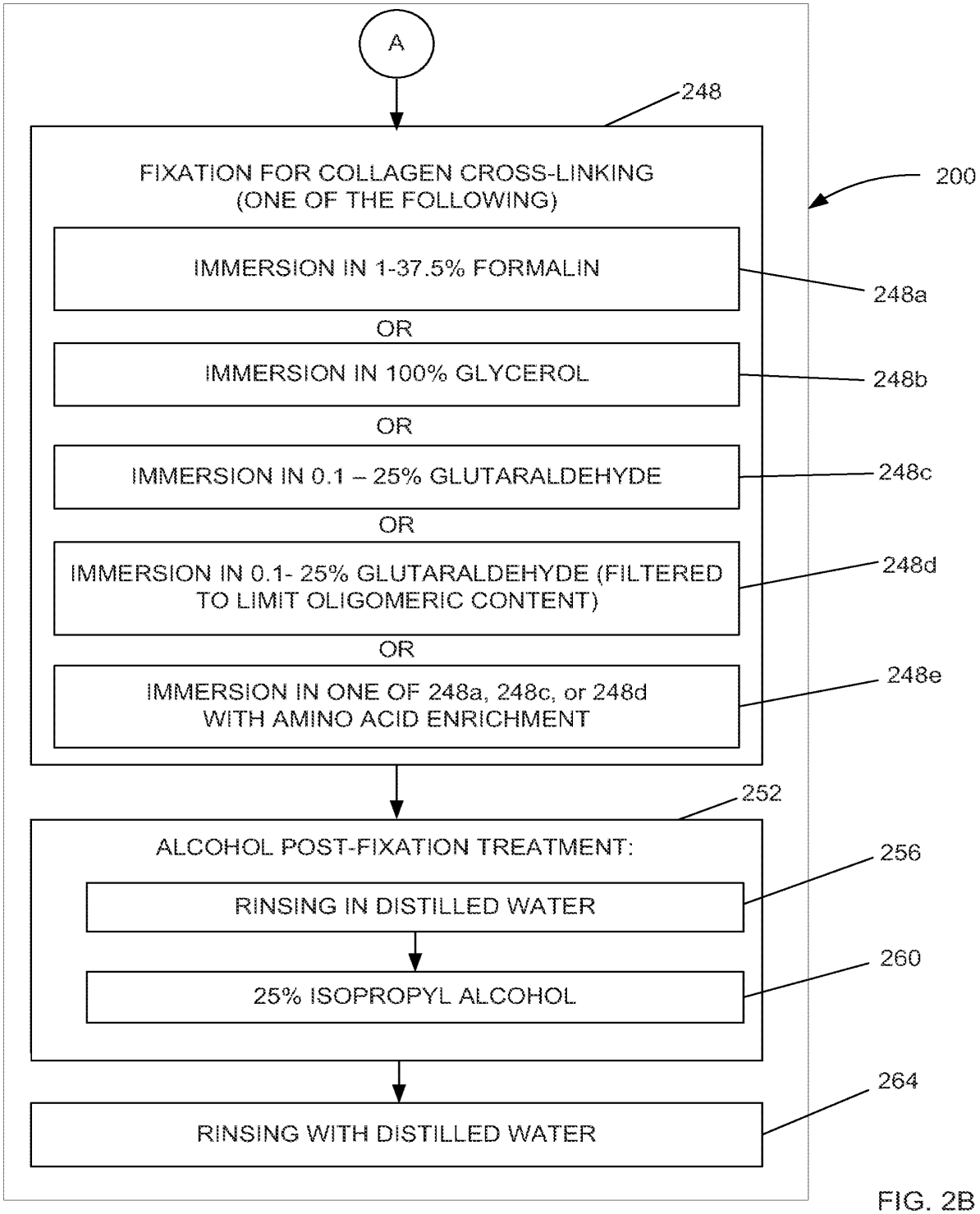

A
248
FIXATION FOR COLLAGEN CROSS-LINKING
(ONE OF THE FOLLOWING)
200
IMMERSION IN 1-37.5% FORMALIN
248a
OR
IMMERSION IN 100% GLYCEROL
248b
OR
IMMERSION IN 0.1 – 25% GLUTARALDEHYDE
248c
OR
IMMERSION IN 0.1- 25% GLUTARALDEHYDE (FILTERED TO LIMIT OLIGOMERIC CONTENT)
248d
OR
IMMERSION IN ONE OF 248a, 248c, or 248d WITH AMINO ACID ENRICHMENT
248e
252
ALCOHOL POST-FIXATION TREATMENT:
256
RINSING IN DISTILLED WATER
260
25% ISOPROPYL ALCOHOL
264
RINSING WITH DISTILLED WATER

FIG. 2B

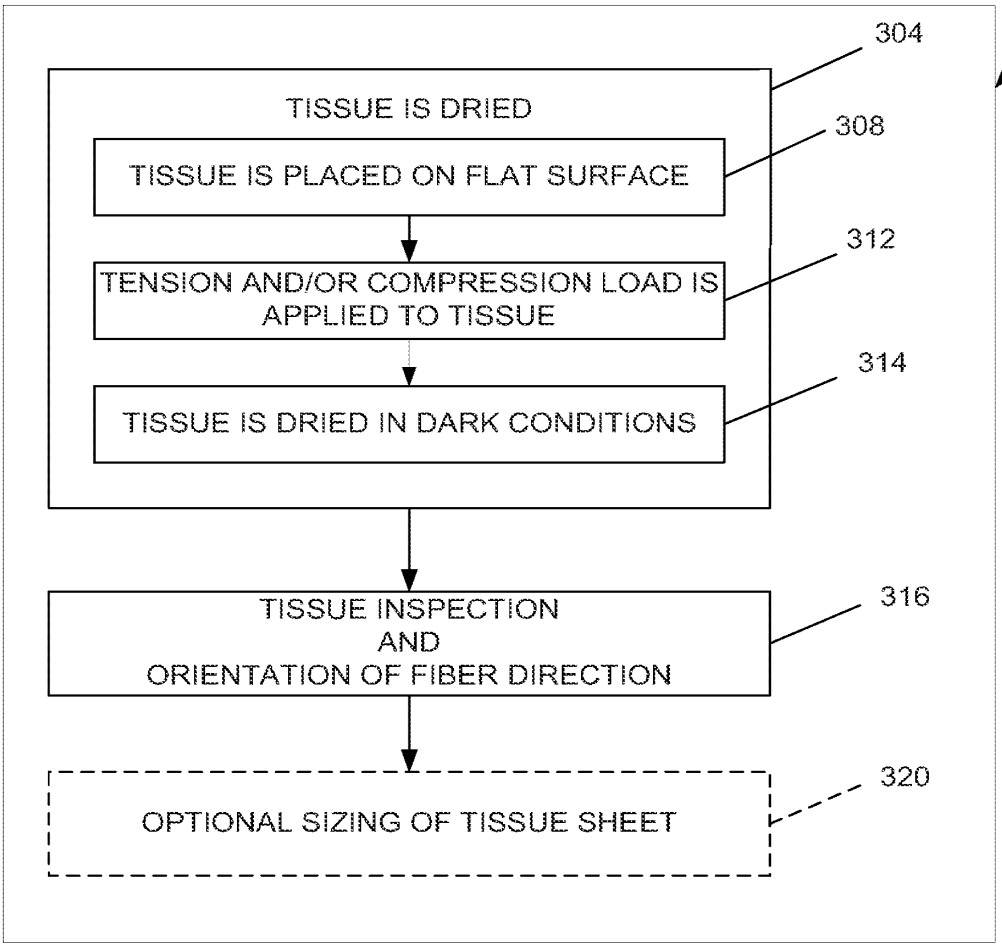

300
304
TISSUE IS DRIED
308
TISSUE IS PLACED ON FLAT SURFACE
312
TENSION AND/OR COMPRESSION LOAD IS APPLIED TO TISSUE
314
TISSUE IS DRIED IN DARK CONDITIONS
316
TISSUE INSPECTION AND ORIENTATION OF FIBER DIRECTION
320
OPTIONAL SIZING OF TISSUE SHEET

FIG. 3

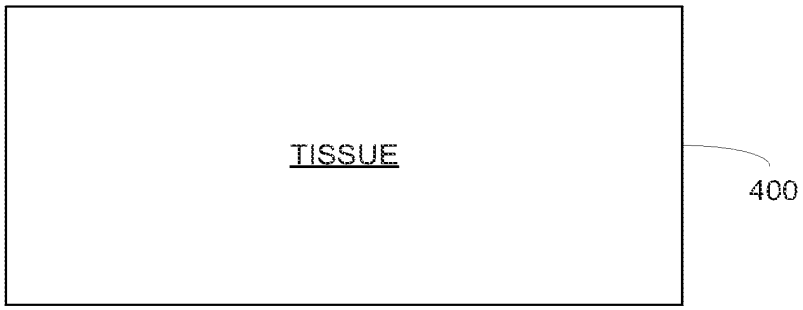
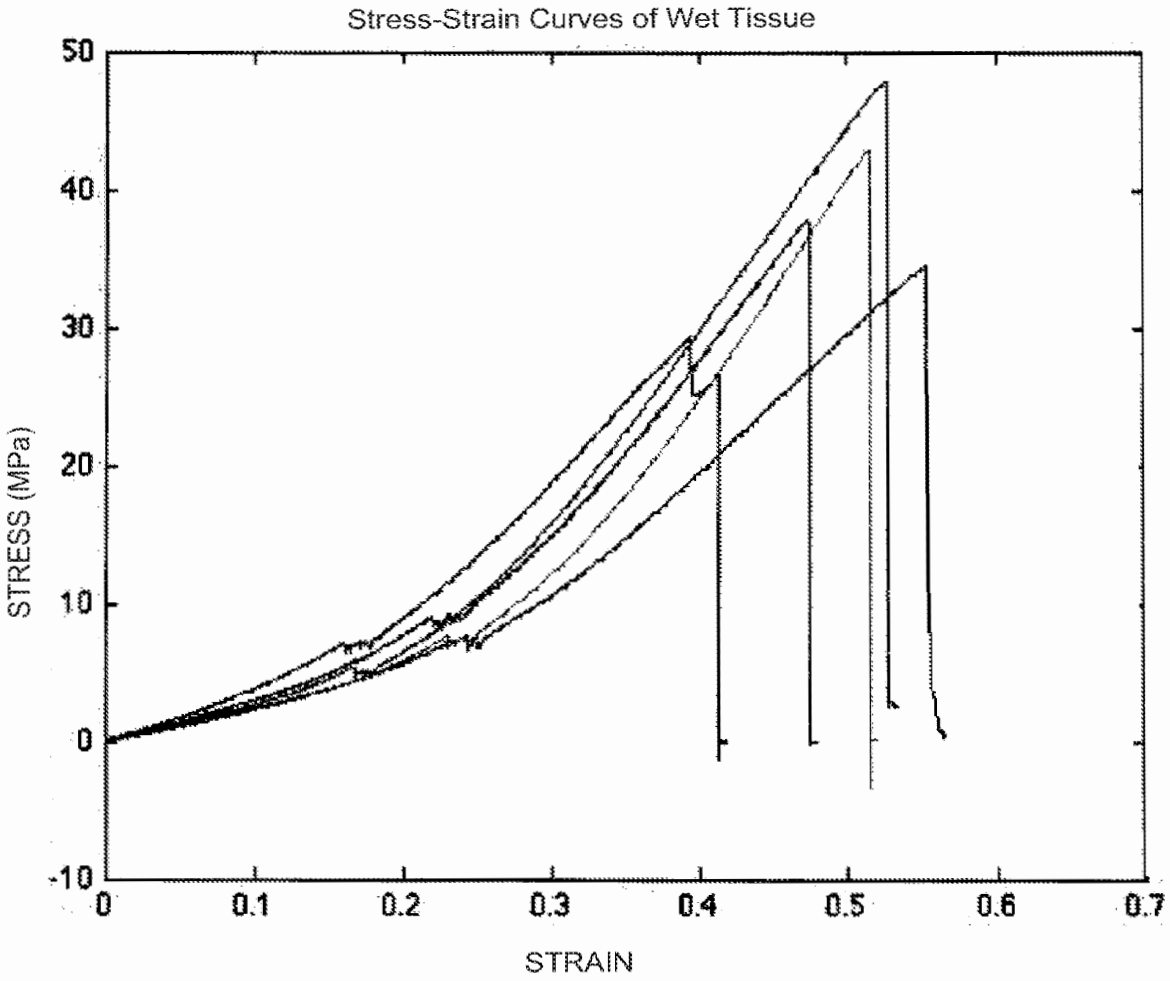

TISSUE
400

FIG.4



Stress-strain curves in wet or hydrated state of five samples. Each curve corresponds to a separate sample.

FIG. 5

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 September 2011 (09.09.2011)

PCT

(10) International Publication Number
WO 2011/109450 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2011/026763

(22) International Filing Date:
1 March 2011 (01.03.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/309,109	1 March 2010 (01.03.2010)	US
13/038,361	1 March 2011 (01.03.2011)	US

(71) Applicant *(for all designated States except US)*: **COLIBRI HEART VALVE LLC** [US/US]; 2150 W. 6th Ave, Suite M, Broomfield, CO 80020 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **FISH, R., David** [US/US]; 6349 Vanderbilt Street, Houston, TX 77005 (US). **PANIAGUA, David** [CR/US]; 3813 Drummond Street, Houston, TX 77025 (US).

(74) Agent: **YASKANIN, Mark, L.**; Holme Roberts & Owen LLP, 1700 Lincoln Street, Suite 4100, Denver, CO 80203 (US).

(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, RO, RS, RU, 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, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,

[Continued on next page]

(54) Title: PERCUTANEOUSLY DELIVERABLE HEART VALVE AND METHODS ASSOCIATED THEREWITH

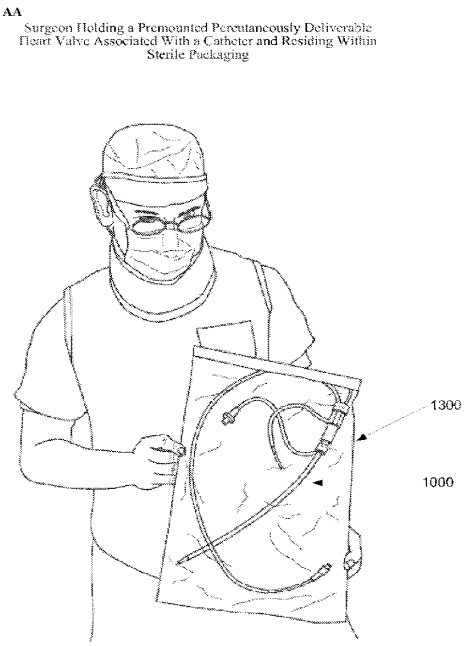


FIG.13

(57) Abstract: A prosthetic heart valve implantable by catheter without surgery includes a substantially "dry" membrane or tissue material. In at least one embodiment, the tissue is folded in a dry state to form a tissue leaflet assembly that is then attached to a frame to form an implantable prosthetic heart valve. Alternatively, one or more tissue leaflets are operatively associated with a frame to form an implantable prosthetic heart valve. The implantable prosthetic heart valve is subsequently pre-mounted on an integrated catheter delivery system. The catheter delivery system that includes the implantable prosthetic heart valve is then packaged and transported while the tissue remains dry. The implantable prosthetic heart valve, while remaining substantially dry, can then be implanted into the receiving patient.

WO 2011/109450 A2

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))*

PERCUTANEOUSLY DELIVERABLE HEART VALVE AND METHODS ASSOCIATED THEREWITH

FIELD

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

The application of PHVR thus far has been challenged by the technical difficulties of the implantation sequence—especially in the aortic valve position. The technique for available devices is limited by the large caliber of the devices and their delivery catheters; often, if it can be done at all in some smaller arteries, open surgical exposure and management of the femoral artery is required to insert the 18 – 24 French (6 – 8 mm diameter) systems, and their bulkiness inside the central arteries can threaten the safety of the delivery sequence. Further, access site bleeding complications form a significant part of the adverse events of the procedures.

Typically, the current PHV designs comprise a biological membrane forming the operating leaflets of the valve, attached within 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.

The effective caliber of the valve delivery system is determined by the total bulk of each coaxially mounted component. The bulk of the PHV itself is determined by the diameter of the frame and by the thickness, stiffness, and particular arrangement of the inner membrane forming the operating leaflets of the valve. The characteristic thickness of current PHV membranes is thus a limiting factor in the ultimate delivery profile of the PHV. Such characteristic membrane thickness is, in turn, a result of the methods by which it is processed and ultimately delivered for use. Typically, glutaraldehyde fixation (for protein cross-linking) of animal tissue is employed to produce suitable biological membranes for incorporation. Requirements for strength and durability have determined the most useful ranges for tissue thickness and cross-linking while typically imposing countervailing stiffness and brittleness. Subsequent hydration in suitable solutions improves these characteristics, but the hydrated membrane by this means also gains thickness.

One of the evident requirements for a PHV design is that the valve functions with a high degree of competence immediately on deployment, since the patient's hemodynamic survival depends on it. To this end, in part, like surgical valve prostheses, current PHV designs are completed, transported, and delivered for use in a hydrated state in a jar of solution. In use, commercially available surgical and percutaneously implanted bioprosthetic heart valves are rinsed and prepared before use in a "wet" state. More particularly, commercially available prosthetic heart valves are rinsed, crimped, and mounted in the catheterization lab. Accordingly, problems with current commercially available prosthetic heart valves include the time, cost and variability associated with the necessity to rinse, crimp, and mount the valve in the catheterization lab. That is, current mounting of prosthetic heart valves in the catheterization lab imposes one or more of delay, cost, technical burdens and possible errors. Avoiding one or

more of these problems would be advantageous. In addition, current "wet" valve designs impose additional profile on the collapsed valve. The hydrated membrane, while having desirable and necessary flexibility for reliable operation immediately on deployment, also imposes a large part of the thickness of the assembled and mounted valve that compromises its deliverability.

Expanding on some of the problems described above, the use of current PHVs in the catheter lab requires a number of preparatory acts that are potentially troublesome and can prolong the delivery sequence during a critical phase of the procedure. Since PHVs are delivered for use "wet" in a preservative solution, they have to be treated prior to insertion with a series of cleansing and hydrating solutions. Once this is completed, the PHVs have to be mounted on their delivery catheters. Special crimping and mounting tools are needed in the case of the balloon-expandable Edwards Sapien valve, for example. 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.

In at least one embodiment, a substantially "dry" membrane PHV system is provided wherein a tissue material is prepared and folded in a dry state to form a tissue leaflet assembly. Thereafter, the tissue leaflet assembly is attached to a frame to form an implantable prosthetic heart valve that is subsequently pre-mounted in an integrated catheter delivery system. The catheter delivery system that includes the prosthetic heart valve is then packaged and transported while the tissue leaflet assembly remains substantially dry. The prosthetic heart valve is available for use directly out of its package envelope. Accordingly, it can be inserted into the body without need of hydration, crimping or mounting tools, or other preparatory acts. That is, the tissue forming the tissue leaflet assembly of the prosthetic heart valve can be treated and dried, then while remaining dry, folded into a tissue leaflet assembly. Thereafter, the tissue leaflet assembly is at least partially rehydrated and then attached within a frame, such as a stent, to form an implantable prosthetic heart valve. The tissue leaflet assembly of the prosthetic heart valve is then allowed to dry. The prosthetic heart valve can thereafter be subsequently packaged, delivered, and shipped while the tissue leaflet assembly of the prosthetic heart valve remains in a dry condition. The prosthetic heart valve can then be implanted into the receiving patient. Accordingly, the PHV system simplifies arterial insertion, and, as the dry condition also confers lower bulk and profile, procedural manipulation and associated complications may be

reduced if not eliminated. In addition, one or more embodiments of the present invention widen the candidacy of patients with smaller arteries for the PHV procedure. As an added advantage, at least one embodiment of the present invention allows the implantation to take place under shorten elapsed times at the most critical phase of the procedure.

In at least one embodiment, a membrane PHV system is provided wherein a tissue material is prepared and folded in a dry state to form a tissue leaflet assembly, and further wherein the tissue leaflet assembly is thereafter at least partially hydrated and attached to a frame that is subsequently pre-mounted in an integrated catheter delivery system.

In at least one embodiment, a membrane PHV system is provided wherein a tissue material is prepared and folded in a dry state to form a tissue leaflet assembly, and further wherein the tissue leaflet assembly is at least partially hydrated and attached to a frame to form the prosthetic heart valve. Thereafter, the prosthetic heart valve is allowed to dry and subsequently pre-mounted in an integrated catheter delivery system after which the tissue leaflet assembly of the prosthetic heart valve remains dry, and wherein the system is then associated with a package for shipment while the tissue leaflet assembly remains dry.

In at least one embodiment, a membrane PHV system is provided wherein a tissue material is prepared and then folded in a dry state to form a tissue leaflet assembly, and further wherein the tissue leaflet assembly is at least partially hydrated and attached to a frame to form the prosthetic heart valve. Thereafter, the prosthetic heart valve is allowed to dry and subsequently pre-mounted in an integrated catheter delivery system after which the tissue leaflet assembly of the prosthetic heart valve is then at least partially hydrated and associated with a package for shipment.

In at least one embodiment, an article adapted for trans-catheter delivery into a patient is provided, comprising: a prosthetic heart valve further comprising a treated tissue attached to a frame, wherein the treated tissue comprises a thickness of about 50 to 500 micrometers and an ultimate tensile strength of greater than about 15 MegaPascals when at a water content of less than about 50% by weight of the section of treated tissue. Here it is noted that the tensile strength of the treated tissue described herein is higher than the tensile strength of other known prepared tissues, whether hydrated or dry. In at least one embodiment, the water content of the treated tissue is less than about 40% by weight of the treated tissue. In at least one embodiment, the ultimate tensile strength is greater than about 20 MegaPascals. In at least one embodiment, the treated tissue does not include a matrix that has been exposed to a polymer infiltrate. In at least one embodiment the treated tissue comprises a treated pericardium tissue.

In at least one embodiment, the method further comprises exposing the section of tissue to light energy for an exposure duration, the exposure duration extending until there is no further

visible separation of lipid droplets from an exposed surface of the section of tissue. In at least one embodiment, the light energy is at least equivalent to exposing the section of tissue to a 25-100 watt light source, and more preferably, a 50 watt incandescent light source with a flat radiant face situated at a distance of about 10 centimeters from the exposed surface for about 15 minutes. In at least one embodiment, the method further comprises: (d) rinsing the section of tissue with distilled water and isopropyl alcohol for a post-fixation period of time of not less than about 7 days; wherein step (d) occurs after step (c).

In at least one embodiment, an article adapted for implantation in a patient is provided, comprising: a prosthetic heart valve further comprising a treated tissue attached to a frame, wherein the treated tissue comprises a water content of less than about 60% by weight of the treated tissue. In at least one embodiment, the treated tissue comprises a section of pericardium tissue having an ultimate tensile strength of greater than about 12 MegaPascals. In at least one embodiment, the section of treated tissue comprises a thickness of between about 50 to 300 micrometers. In at least one embodiment, the water content of the treated tissue is less than about 40% by weight of the treated tissue.

As used herein, the term "dry" (or "substantially dry") when referring to the state of the tissue that forms the heart valve of the percutaneous heart valve means a moisture content less than the water moisture content of the tissue when the tissue is allowed to fully rehydrate in the body of a patient. Typically, pericardium tissue treated in accordance with one or more embodiments described herein is about 70% by weight water when fully hydrated. Drying to a constitution of less than 40% by weight of water usefully alters the handling properties for purposes of folding and sewing the tissue. As those skilled in the art will appreciate, the moisture content of the tissue may vary when dry. For example, the moisture content of the tissue when being folded and dry may be different than the moisture content of the tissue when dry and being shipped in a premounted state within a catheter delivery system.

Advantageously, at least one embodiment of the one or more present inventions is directed to a prosthetic heart valve that is mounted onto a valve delivery system and stored in a sterile package. Accordingly, in at least one embodiment, an assembly is provided, comprising:

a prosthetic heart valve including:

a frame; and

a tissue leaflet assembly attached to the frame;

a percutaneously insertable valve delivery mechanism, wherein the prosthetic heart valve is releasably mounted onto the percutaneously insertable valve delivery mechanism; and

sterile packaging containing the prosthetic heart valve releasably mounted onto the percutaneously insertable valve delivery mechanism.

In at least one embodiment, the percutaneously insertable valve delivery mechanism comprises a balloon catheter. In at least one embodiment, the balloon catheter is a 12 to 14 French balloon catheter. In at least one embodiment, the balloon catheter is less than about 12 French. In at least one embodiment, the balloon catheter is between about 5 to 12 French. In at least one embodiment, the percutaneously insertable valve delivery mechanism comprises a mandrel. In at least one embodiment, tissue forming the tissue leaflet assembly within the sterile packaging is at least one of hydrated and not substantially dry. In at least one embodiment, tissue forming the tissue leaflet assembly within the sterile packaging is substantially dry. In at least one embodiment, the frame comprises a stent. In at least one embodiment, tissue forming the tissue leaflet assembly comprises treated pericardium tissue.

At least one embodiment of the one or more present inventions includes a prosthetic heart valve for implantation in a patient. Accordingly, a pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve ready for implantation in a patient is provided, comprising:

a frame; and,

a tissue leaflet assembly attached to the frame, the tissue leaflet assembly comprising a substantially dry tissue.

In at least one embodiment, the substantially dry tissue comprises treated pericardium tissue. In at least one embodiment, the frame and tissue leaflet assembly attached thereto are operably associated with a 12 to 14 French balloon catheter. In at least one embodiment, the frame and tissue leaflet assembly attached thereto are operably associated with a balloon catheter having a size of less than about 12 French. In at least one embodiment, the frame and tissue leaflet assembly attached thereto are operably associated with a balloon catheter having a size of between about 5 to 12 French. In at least one embodiment, the substantially dry tissue comprises a water moisture content of less than about 40% by weight of the substantially dry tissue.

In at least another embodiment, an assembly for use with a patient is provided, comprising:

a sealed sterile package containing a delivery system for percutaneously deploying a heart valve in the patient, the heart valve including:

a frame releasably mounted on the delivery system within the sealed sterile package; and

a tissue leaflet assembly attached to the frame.

In at least one embodiment, the tissue leaflet assembly comprises pericardium tissue.

In at least one embodiment, a method is provided, comprising:

partially compressing and mounting a prosthetic heart valve upon a delivery catheter, the

prosthetic heart valve comprising a tissue;

allowing the tissue to at least partially dry;

further compressing and mounting the prosthetic heart valve upon the delivery catheter; and

sterilizing and packaging the prosthetic heart valve and delivery catheter.

In at least one embodiment, the method further comprises transporting the sterilized and packaged prosthetic heart valve and delivery catheter. In at least one embodiment, the tissue comprises treated pericardium tissue. In at least one embodiment, prior to partially compressing and mounting the prosthetic heart valve upon the delivery catheter, the tissue is at least one of (a) not substantially dry, and (b) at least partially hydrated.

For the various embodiments described herein, the prosthetic heart valve, including the tissue leaflet assembly, comprises membrane tissue other than pericardium tissue.

In at least one embodiment, a method is provided, comprising:

attaching pericardium tissue to a frame;

partially compressing and mounting the frame, with the tissue attached thereto, upon a delivery catheter;

allowing the tissue to at least partially dry;

further compressing and mounting the frame, with the tissue attached thereto, upon the delivery catheter; and

sterilizing and packaging the frame and delivery catheter, with the tissue attached thereto.

In at least one embodiment, prior to partially compressing and mounting the frame, the tissue is at least one of (a) not substantially dry, and (b) at least partially hydrated. In at least one embodiment, the method further comprises transporting the sterilized and packaged frame, with the tissue attached thereto, mounted upon the delivery catheter, to a surgical or medical procedure facility. In at least one embodiment, prior to attaching the tissue to the frame the tissue is folded to form a tissue leaflet assembly. In at least one embodiment, the tissue leaflet assembly comprises at least one cuff and at least one pleat.

In at least one embodiment, a method of preparing a percutaneous, trans-catheter prosthetic heart valve is provided, the method comprising:

providing a membrane tissue from an organism;

treating the membrane tissue with at least one chemical to produce a treated membrane tissue;

drying the treated membrane tissue until it is a substantially dry tissue;

attaching the substantially dry tissue in a frame;

rehydrating the substantially dry tissue that is attached within the frame to form a rehydrated tissue;

collapsing the frame with the rehydrated tissue attached thereto; and

drying the rehydrated tissue within the collapsed frame until it is a substantially dry tissue.

In at least one embodiment the method further comprises compressing and mounting the frame, with the substantially dry tissue attached thereto, upon a delivery catheter. In at least one embodiment the method further comprises sterilizing and packaging the frame, with the substantially dry tissue attached thereto, mounted upon the delivery catheter. In at least one embodiment, the treating comprises sterilizing the frame with the substantially dry tissue attached thereto with exposure to at least one of ethylene oxide, a proton beam, and gamma radiation. In at least one embodiment, the method further comprises shipping the sterilized and packaged frame with the substantially dry tissue attached thereto, mounted upon the delivery catheter, to a surgery or medical procedure facility. In at least one embodiment, prior to the attaching step the dry tissue is not folded to provide a cuff and/or a pleat. In at least one embodiment, prior to the attaching step the dry tissue is folded to form a tissue leaflet assembly. In at least one embodiment, the tissue leaflet assembly comprises at least one cuff and at least one pleat.

In at least one embodiment, the method of preparing a percutaneous, trans-catheter prosthetic heart valve further comprises implanting the frame with the substantially dry tissue attached thereto into a patient. In at least one embodiment, the frame comprises a stent. In at least one embodiment, the method further comprises mounting the frame and the tissue leaflet assembly attached thereto upon a 12 to 14 French balloon catheter. In at least one embodiment, the method further comprises mounting the frame and the tissue leaflet assembly attached thereto upon a balloon catheter having a size of less than about 12 French. In at least one embodiment, the method further comprises mounting the frame and the tissue leaflet assembly attached thereto upon a balloon catheter having a size of between about 5 to 12 French. In at least one embodiment, the method further comprises mounting the frame and the tissue leaflet assembly attached thereto on a mandrel. In at least one embodiment, the method of preparing a percutaneous, trans-catheter prosthetic heart valve further comprises immersion of the membrane tissue in buffered or unbuffered 1-37.5% formalin for between about 3 days to 3 weeks. In at least one embodiment, the method of preparing a percutaneous, trans-catheter prosthetic heart valve further comprises immersion of the membrane tissue in buffered or unbuffered 1-37.5% formalin for between about 3 days to 5 weeks. In at least one embodiment the treating comprises immersion of the membrane tissue in 100% glycerol for greater than 3

weeks. In at least one embodiment the treating comprises immersion of the membrane tissue in 0.1 - 25% glutaraldehyde for between about 3 days to 3 weeks. In at least one embodiment the treating comprises immersion of the membrane tissue in 0.1 - 25% glutaraldehyde for between about 3 days to 5 weeks. In at least one embodiment the treating comprises immersion of the membrane tissue in oligomeric filtered 0.1 - 25% glutaraldehyde for between about 3 days to 3 weeks. In at least one embodiment the treating comprises immersion of the membrane tissue in oligomeric filtered 0.1 - 25% glutaraldehyde for between about 3 days to 5 weeks. In at least one embodiment the treating comprises immersion of the membrane tissue in the aforementioned formalin, glutaraldehyde, or oligomeric filtered glutaraldehyde solutions with the added free amino acids lysine and/or histidine. In at least one embodiment the treating does not include contact and/or exposure to a polymer to infiltrate and/or encapsulate tissue fibers of the tissue.

In at least one embodiment, a method of preparing a percutaneous, trans-catheter prosthetic heart valve is provided, the method comprising:

providing a section of tissue harvested from a mammalian organism; and

causing osmotic shocking of the section of tissue by performing multiple rinses of the section of tissue with distilled water. In at least one embodiment, the method further comprises hydrating the section of tissue during a plurality of time intervals using distilled water. In at least one embodiment the section tissue comprises pericardium tissue. In at least one embodiment, the method further comprises not using saline for causing at least one of the osmotic shocking and the hydrating of the tissue. In at least one embodiment, the method further comprises pretreating the section of tissue with glycerol before contacting the section of tissue with one or more of isopropyl alcohol, glutaraldehyde and formalin. In at least one embodiment, the method further comprises contacting the section of tissue with a solution containing formalin after pretreating the section of tissue with glycerol. In at least one embodiment, the method further comprises contacting the section of tissue with a solution containing glutaraldehyde after pretreating the section of tissue with glycerol. In at least one embodiment, the method further comprises pretreating the section of tissue with isopropyl alcohol before contacting the section of tissue with either glutaraldehyde and formalin. In at least one embodiment, the method further comprises contacting the section of tissue with a solution containing formalin after pretreating the section of tissue with isopropyl alcohol. In at least one embodiment, the method further comprises contacting the section of tissue with a solution containing glutaraldehyde after pretreating the section of tissue with isopropyl alcohol. In at least one embodiment, the method further comprises exposing the section of tissue to light energy for a period time, the period of time extending until there is no further visible separation

of lipid droplets from an exposed surface of the section of tissue. In at least one embodiment, the light energy is at least equivalent to exposing the section of tissue to a 50 watt incandescent light source with a flat radiant face situated at a distance of about 10 centimeters from the exposed surface for about 15 minutes.

With regard to delivery characteristics, another significant advantage of an implantable prosthetic heart valve using a relatively thin tissue component described herein is that the implantable prosthetic heart valve offers a relatively low packing volume as compared to commercially available prosthetic heart valves. As a result, the implantable prosthetic heart valve provides a relatively low catheter delivery profile, thereby enabling implantation in patients possessing relatively small diameter vascular systems.

In accordance with one or more embodiments, a dry tissue membrane has substantially less mass than a wet membrane. By way of example, a substantially dry pericardium tissue prepared by one or more of the present embodiments has approximately 30% of the mass of a wet pericardium tissue, and marked reduction in profile and packing volume, thereby achieving a relatively low profile and making it suitable for implantation in greater number of patients, especially those having small diameter vascular systems. In addition, a dry prosthetic heart valve does not require storage and transport in preservative. A dry prosthetic heart valve can be mounted on a delivery catheter at its location of manufacture, which allows for pre-packaging of an integrated delivery system. Together with a relatively low profile, embodiments of the prosthetic heart valves thereby offer reliability and convenience because the implantable prosthetic heart valve is pre-mounted upon a delivery catheter and forms part of a pre-packaged delivery system. In addition, a dry prosthetic heart valve does not require rinsing, rehydration, or mounting upon a delivery catheter in a catheterization lab. Therefore, a dry prosthetic heart valve can be inserted directly from package into the body at a critical time during the procedure. Advantageously, this avoids procedure time, manipulation, and errors of mounting, crimping, and orienting catheters and sheaths. Once at the surgical facility/location, the dry prosthetic heart valve is inserted and delivered by balloon catheter expansion in the plane of the diseased valve in the standard way and the dry prosthetic heart valve begins to function immediately, even in its dry state or not fully rehydrated state (because some rehydration will occur upon flushing of the catheter with the prosthetic heart valve residing therein), with rehydration of the tissue membrane subsequently completing naturally in the body.

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.

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 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 is 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 is described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Fig. 1 is a flow chart of a method associated with at least of one embodiment of the present invention;

Figs. 2A-2B are a flow chart illustrating elements of the tissue preparation;

Fig. 3 is a flow chart illustrating elements of the drying and sizing;

Fig. 4 is a flow chart illustrating elements of the valve construction with attachment of tissue membrane leaflets to a frame;

Fig. 5 is a flow chart illustrating elements of the mounting of the valve into a delivery system;

Fig. 6 is a flow chart illustrating elements of the ensheathing, sterilization, and packaging;

Fig. 7 is a flow chart illustrating elements of the delivery of the valve into a patient;

Fig. 8A is a view of a one-piece section of tissue prior to being folded;

Fig. 8B is a view of two (of three) separate pieces of tissue after folding (detailed below);

Fig. 8C is a view of the two pieces of tissue shown in Fig. 8B after being sutured together at the pleat formed after folding (detailed below);

Fig. 8D is a view of a tissue blank with the line of primary fold shown using a dashed line;

Fig. 8E is a perspective view of the tissue blank being folded along the primary fold line;

Fig. 8F is a 2-part figure showing the pleats fold lines and pleats after folding;

Fig. 8G is a detail perspective view of a single pleat shown in Fig. 8F;

Fig. 8H is a perspective schematic view of a folded and seamed tissue leaflet assembly;

Fig. 8I is a perspective schematic view of a frame;

Fig. 8J is a perspective schematic view of the frame of Fig. 8I with the tissue leaflet assembly of Fig. 8H attached thereto;

Fig. 8K is side elevation schematic view of the device shown in Fig. 8J;

Fig. 8L is an end schematic view of the frame and tissue leaflet assembly attached thereto;

Fig. 9 is a graph that shows actual stress-strain test results for five tissue samples prepared in accordance with at least one embodiment;

Fig. 10 is a schematic of a portion of a catheter with a percutaneously deliverable heart valve mounted thereto;

Fig. 11A is a photo of an implantable prosthetic heart valve, including a tissue leaflet assembly attached within a frame, wherein the tissue is situated in a partially open orientation;

Fig. 11B is a drawing of an implantable prosthetic heart valve, including a tissue leaflet assembly attached within a frame, wherein the tissue is situated in a closed orientation;

Fig. 11C is a side cutaway view of an implantable prosthetic heart valve, including a tissue leaflet assembly attached within a frame, wherein the tissue is situated in a closed orientation;

Fig. 11D is another side cutaway view of an implantable prosthetic heart valve, including a tissue leaflet assembly attached within a frame, wherein the tissue is situated in a closed orientation;

Fig. 12 is a photo of valve tissue after testing through 30,000,000 cycles of pumping used to model human heart conditions, wherein the photo shows a smooth uniform surface;

Fig. 13 is a drawing of a surgeon holding a premounted percutaneously deliverable heart valve associated with a catheter and residing within sterile packaging;

Fig. 14 is a schematic of a simplified cutaway view of a human heart, including heart valves that may be targeted for receiving an embodiment of an implantable prosthetic heart valve;

Fig. 15 is a schematic of a human aorta receiving a catheter with an implantable prosthetic heart valve mounted thereto; and

Fig. 16 is a schematic of a human aorta with the implanted prosthetic heart valve implanted at the site of the original diseased aortic valve.

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 a prosthetic heart valve. 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 described herein have application for at least aortic and pulmonary valve positions, including for structural defects and diseased valves.

In at least one embodiment, biocompatible material is attached within 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. 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. 1, a flow chart illustrates at least one embodiment of a prosthetic heart valve preparation and delivery method 100. The prosthetic heart valve preparation and delivery method 100 generally includes a plurality of procedures to include tissue preparation at 200, drying at 300, tissue leaflet assembly construction and attachment to frame at 400 to form an implantable prosthetic heart valve, mounting of the prosthetic heart valve (that is, the frame with the tissue leaflet assembly) into a delivery system at 500, ensheathing, sterilizing and packaging the delivery system including the prosthetic heart valve at 600, and finally, delivering the prosthetic heart valve into the patient at 700. Further detail of the prosthetic heart valve preparation and delivery method 100 is provided below.

At least one or more embodiments described herein include a relatively thin tissue component. By way of example and not limitation, in at least one embodiment the tissue has a thickness of approximately 50 - 150 μm, and further possesses characteristics of pliability and resistance to calcification after implantation. The relatively thin nature of the tissue used in the implantable prosthetic heart valve assists with biocompatibility. In addition, the relatively thin

tissue component thereby provides for a relatively low mass. As a result, an implantable prosthetic heart valve using the tissue can accelerate to a relatively high heart rate in beats per minute with competent function.

Tissue suitable for use in the one or more prosthetic heart valves and/or one or more assemblies described herein is relatively thin and can generally be considered to be a membrane. Those skilled in the art will appreciate that both natural and synthetic types of materials may be used to form a leaflet assembly of a prosthetic heart valves. Accordingly, it is to be understood that although treated pericardium tissue is described as a suitable material for use in the leaflet assembly of a prosthetic heart valve of one or more embodiments described herein, material other than xenograft tissue membrane can be used, and indeed, xenograft tissue membrane other than pericardium tissue can be used. More specifically, synthetic materials may include, but are not limited to, PTFE, PET, Dacron, and nylon. In addition, other than pericardium tissue, xenograft tissue membrane may include, but is not limited to, membrane material from the intestine, lung and brain. Suitable material may also comprise allograft material, that is, material from human sources. The listing of possible materials is for exemplary purposes and shall not be considered limiting.

With reference now to Fig. 2A, the process associated with preparation of a biocompatible tissue consistent with the above-noted characteristics is described. In at least one embodiment, pericardium tissue, such as porcine or bovine pericardium tissue, is harvested at 204 and then processed to serve as the biocompatible tissue for association with a frame, such as by attaching within a frame. Accordingly, subsequent to the harvesting at 204, the pericardium tissue is cleaned and decellularized at 208. More particularly, in at least one embodiment the tissue is initially cleaned with distilled water using gentle rubbing and hydrodynamic pressure at 208 in order to remove adherent non-pericardial and non-collagenous tissue. In at least one embodiment, the hydrodynamic pressure at 208 is provided by spraying the tissue with a relatively weak stream of liquid to remove at least some of the non-collagenous material associated with the tissue. The rinsing at 208 is to achieve effective decellularization of the pericardium tissue through osmotic shock. Typically, the thickness of the tissue in the cleaned condition varies from about 50 to 500 micrometers, depending on the source of raw tissue. Cleaning preferably continues until there is no visible adherent non-pericardial or non-collagenous tissue.

With continued reference to Fig. 2A, after the tissue has been cleaned and decellularized at 208, the tissue then undergoes optional additional removal of lipids at 220 to further treat the tissue for preventing immunologic response and calcification. More particularly, the tissue first optionally undergoes a 100% glycerol pretreatment at 224 while being positioned on a flat

surface (e.g., an acrylic plate), after which the tissue becomes nearly transparent.

At 228, the tissue optionally undergoes a "thermophotonic" process. In at least one embodiment, the tissue is optionally exposed to light energy for additional removal of lipids and for initial cross-linking of the collagen. By way of example and not limitation, in at least one embodiment a 25-100 watt incandescent light source, and more preferably, a 50 watt incandescent light source with a flat radiant face is employed at a distance of about 10 centimeters from the tissue surface, typically requiring 15 minutes of exposure before further visible separation of lipid droplets from the tissue stops.

Still referring to Fig. 2A, the tissue is then cleaned again in secondary cleaning at 232. More particularly, at 236 the tissue is again rinsed with distilled water. Thereafter, at 240 the tissue is rinsed with 25% isopropyl alcohol for periods of several hours to several days and weeks, depending on the desired tissue properties of pliability and tensile strength. By way of example and not limitation, tissue has been successfully prepared by rinsing with 25% isopropyl alcohol for a period of 7 days, and after further treatment steps described herein, provided an ultimate tensile strength of greater than 25 MegaPascals. Here, the combination of tissue pliability and tensile strength is sought for purposes of producing a material having property characteristics suitable for being physically manipulated to form a tissue leaflet assembly or other configuration appropriate for attaching with a frame, while providing a tissue material that will operate properly once implanted. These techniques are intended to conserve and preserve collagen fibers, minimizing damage to the tissue and improving tissue characteristics. The preparation and fixation techniques produce tissue membrane material that may be rendered and used at lesser thickness than typically rendered in the prior art. Thinner membranes are more pliable, but with conventional preparation techniques the tensile strength of the tissue is sacrificed. Advantageously, the preparation techniques described herein have produced membranes that have as much as three times the tensile strength of a commercial product of the prior art. This achieved strength is thus enabling for providing a tissue leaflet assembly having a low profile with appropriate durability, even in a substantially dry state. More particularly, the tissue possesses a relatively high tensile strength. By way of example and not limitation, testing has shown that embodiments of tissue prepared as described herein provide a tissue with a tensile strength of approximately three times the tensile strength of current pericardial valve tissue, such as on the order of approximately 25 MegaPascals, thereby providing about 2000 times the physiologic load strength for valve tissue. Moreover, testing of an embodiment of an implantable prosthetic heart valve made with tissue prepared as described herein and under a static load of greater than approximately 250 mmHg showed less than approximately 14% leakage, wherein such results are generally considered superior to surgical tissue valve

prostheses.

In at least one embodiment where isopropyl alcohol is described as a rinsing agent, ethanol may be used in its place as an alternative, although resulting tissue properties may vary.

With reference to Fig. 9, stress-strain curve results for five different tissue samples prepared in accordance with an embodiment are shown. For the testing results shown, the yield stress or ultimate tensile strength was obtained by mounting strips of tissue fixed at the ends in a linear force tester and increasing the length by 0.3 mm/sec while recording resultant force (tension) until the material ruptured or separated entirely; these measurements were then used to calculate the stress-strain curves depicted in Fig. 9. As illustrated in the graph, the yield stress or ultimate tensile strength of the various tissue samples varied from about 30 to about 50 MegaPascals. More particularly, for each curve shown in Fig. 9, the testing procedures were the same. That is, each of the curves shown pertain to separate pieces of tissue that were subjected to the same test. The results show a minimum ultimate tensile strength of 30 MegaPascals, with a range up to 50 MegaPascals. Accordingly, the illustrated test results demonstrate consistency of the ultimate tensile strength results for the tissue treatment process.

With reference back to Fig. 2A, the tissue is rinsed with distilled water at 244 as a final cleaning step and for rehydration.

Referring now to Fig. 2B, following the rinse with distilled water at 244, treatment of the tissue continues. More particularly, fixation for collagen cross-linking at 248 is achieved by performing at least one of the following:

a. At 248a, immersion of the tissue in 1-37.5% formalin, ideally a buffered solution, for between about 3 days to 5 weeks, and more preferably, for between about 3 days to 4 weeks, and more preferably yet, for between about 3 weeks to 4 weeks, at a temperature of between about 4 to 37°C, and more preferably, 10% formalin for 6 days at 20°C; or

b. At 248b, immersion of the tissue in 100% glycerol for up to 6 weeks at between 4 to 37°C, and more preferably, immersion of the tissue in 100% glycerol for about 3 weeks at 20°C; or

c. At 248c, immersion of the tissue in 0.1 - 25% glutaraldehyde for between about 3 days to 5 weeks, and more preferably, for between about 3 days to 4 weeks, and more preferably yet, for between about 3 weeks to 4 weeks, at 0 to 37°C, and more preferably, immersion of the tissue in 0.25% glutaraldehyde for 7 days at 4°C; or

d. At 248d, immersion of the tissue in 0.1 - 25% glutaraldehyde (filtered to limit oligomeric content) for between about 3 days to 5 weeks, and more preferably, for between about 3 days to 4 weeks, and more preferably yet, for between about 3 weeks to 4 weeks, at 0 to 37°C, and more preferably, 0.25% glutaraldehyde for 7 days at 4°C; or

e. At 248e, immersion in the tissue in one of the above formalin, glutaraldehyde, or oligomeric filtered glutaraldehyde solutions together with added amino acids, lysine and/or histidine, wherein the concentration of the amino acids, L-lysine or histidine, used as an additive to the fixative is in the range of about 100 - 1000 milliMolar, with a preferred value of about 684 mM.

In addition to the foregoing, combinations of the processes listed above may be performed, including: step a followed by step b; step a followed by step c; and step a followed by step d.

As those skilled in the art will appreciate, heat-shrink testing may be conducted on tissue samples to correlate the effectiveness of protein cross-linking. Here, results of heat-shrink testing performed on one or more samples of tissue prepared in accordance with at least one embodiment using formalin showed that the tissue had a shrink temperature of 90°C. This compares favorably with samples prepared using glutaraldehyde, wherein the shrink temperature was 80°C. Accordingly, formalin is a suitable variant of fixation. It is noted that formalin was generally abandoned by the field, largely because of material properties that were unfavorable and because of inadequate or unstable protein cross-linking. Such problems have been overcome through the pretreatments described herein, allowing production of tissue with strength, pliability, and durability in a relatively thin membrane. When used in a percutaneous deliverable heart valve (also referred to herein as "prosthetic heart valve"), the tissue characteristics imparted by the tissue preparation process facilitate formation of a construct having a relatively low-profile, which also thereby facilitates dry packaging of the prosthetic heart valve. The same advantages are also achieved using the pretreatments when using a glutaraldehyde process.

Referring still to Fig. 2B, after fixation for collagen cross-linking at 248, an alcohol post-fixation treatment at 252 is preferably performed by rinsing the tissue in distilled water at 256, and then at 260 rinsing the tissue in 25% isopropyl alcohol for between about 30 minutes to 14 days or more at between about 0 to 37°C, and more preferably, for at least about 7 days at 20°C. At 264, the tissue undergoes a rinsing with distilled water.

In accordance with at least one embodiment, treatment of the tissue, including from the time of harvest to the time of implantation or grafting, does not include contact and/or exposure to a polymer to infiltrate and/or encapsulate tissue fibers of the tissue.

Referring now to Figs. 1 and 3, the drying process at 300 is performed after the tissue preparation at 200. Thus, in accordance with at least one embodiment, the tissue is dried under a load. More particularly, for the tissue drying at 304, the tissue is placed minimally stretched flat (that is, stretched just enough to eliminate visible wrinkles and bubbles) on a flat surface (e.g., a polymer or acrylic sheet) at 308, and held fixed at its edges at 312. Optionally, the joined tissue

and underlying sheet are then set in a slight curve. The tension maintains the substantially flat structure of the tissue as it dries, thereby mitigating or preventing excessive shrinkage, wrinkling, and/or curling at the edges, and also making the rate of drying more uniform across the surface of the tissue because of the surface tension between the plate and the tissue. Alternatively, the tissue is dried while compressed between acrylic plates. When drying the tissue, the temperature is held at between about 4 to 37°C, and more preferably, between about 20 to 37°C (i.e., approximately room temperature to normal human body temperature), and more preferably, at about 20°C. At 314, the drying process is performed in substantially dark conditions (i.e., substantially no visible light) for between about 6 hours to 5 days, and more preferably, for about 72 hours. By way of example, the tissue is dried in dark conditions at a temperature of about 20°C for between about 6 hours to 5 days, and more preferably, for about 72 hours. As those skilled in the art will appreciate, drying the tissue while the tissue is compressed between plates requires a longer period of time.

In at least one embodiment, after drying, the tissue lots are inspected at 316, such as by stereomicroscopy, to identify and discard those with defects or discontinuities of the fiber matrix. In addition, the preferential fiber direction for each piece is identified to determine the necessary orientation of the free edge of the pieces that will form the valve leaflets. Depending upon the size (i.e., the area) of the tissue being prepared and the size of tissue needed for a given valve, the tissue may be trimmed or otherwise sized in optional sizing at 320, such as by cutting the tissue into an appropriately sized and shaped sheet for valve formation. Preferably, cutting of the tissue membrane is oriented so that the resulting free edge of the leaflet is parallel to the preferential fiber direction of the tissue membrane. Optionally, the free edge of the leaflets may also be cut with a parabolic or other curved profile to compensate for the downward angle from the commissural leaflet attachment point to the central coaptation point and to increase the total contact surface between the coapting leaflets. This approach minimizes focal weaknesses in the operating margins of the leaflet assembly and advantageously distributes the principal loading forces of the operating valve along the long axis of the collagen fibers. As a result, the tissue is resistant to surface fracture and fraying. As shown in Fig. 3, optional sizing at 320 is performed after the drying at 304 and inspection at 316.

With reference now to Fig. 4, an embodiment associated with forming a tissue leaflet assembly and attachment to a frame to form a prosthetic heart valve at 400 is further described. It is to be understood that the tissue generated from one or more of the tissue preparation procedures described herein may be used for a variety of devices or uses, and that use in a prosthetic heart valve is but one possible application for utilizing the tissue. For example, the tissue may be used in a shunt, or as graft material for repair or modification of one or more

human organs, including the heart and its blood vessels. By way of further example, the tissue may be used as a pericardial membrane patch for repair of congenital heart defects. The tissue also has application as a prosthetic tissue in tendon and ligament replacement, and as a tissue product for wound management. Moreover, for use in a prosthetic heart valve, the tissue may be configured in a variety of ways and attached to a frame in a variety of ways. By way of example and not limitation, in at least one embodiment, the prepared tissue is formed into a tissue leaflet assembly at 404 by folding the tissue at 408, preferably while the tissue is in a dry state, to form at least a portion of the tissue leaflet assembly. Here, those skilled in the art will appreciate that a completed tissue leaflet assembly may be formed of a single monolithic piece of tissue 800, such as that shown in Fig. 8A, or alternatively, as shown in Figs. 8B and 8C, it may be formed of a plurality of tissue pieces 802 that are operatively connected, such as by gluing or sewing the tissue pieces together along seams 804. As seen in Fig. 8C, the seams 804 are preferably situated at overlapping portions of pleats 832 of the plurality of tissue pieces 802.

As those skilled in the art will further appreciate, a single monolithic piece of tissue 800 or a plurality of tissue pieces 802 may be used to form a prosthetic heart valve, wherein the tissue leaflet assembly is not a folded construct. By way of example and not limitation, a plurality of separate tissue pieces may each be attached to a frame (such as by suturing) to form a prosthetic heart valve. Thereafter, whether the prosthetic heart valve is made of a folded tissue leaflet assembly or a plurality of separate tissue pieces attached to a frame, the resulting prosthetic heart valve may then be further manipulated for delivery as a dry prosthetic heart valve.

In an alternative embodiment, tissue generated from one or more of the tissue preparation procedures described herein may be used to form a prosthetic heart valve that includes a frame, and that may be implanted by a "trans-apical" approach in which the prosthetic heart valve is surgically inserted through the chest wall and the apex of the heart.

In yet another alternative embodiment, tissue generated from one or more of the tissue preparation procedures described herein may be used to form a prosthetic heart valve that does not include a frame, and is not delivered via a catheter, but rather, is implanted via a surgical opening through the patient's chest. In such a case, the prosthetic heart valve may be packaged for delivery as a dry prosthetic heart valve.

In still yet another alternative embodiment, tissue generated from one or more of the tissue preparation procedures described herein may be used to form a prosthetic heart valve that includes a frame, but that is not delivered via a catheter, but rather, is implanted via a surgical opening through the patient's chest. In such a case, the prosthetic heart valve may be packaged for delivery as a dry prosthetic heart valve.

As a further alternative to the embodiments described herein, tissue may be implanted in a "wet" or hydrated state. For example, a prosthetic heart valve utilizing a prepared tissue described herein may be packaged for delivery as a hydrated prosthetic heart valve. Accordingly, while a portion of the tissue preparation process may include drying the tissue so that it may be manipulated more easily, the tissue may then be hydrated at a later point in time prior to implantation, and it may be maintained in a hydrated condition up to and including packaging, delivery and implantation into a patient. Advantages associated with using a folded tissue leaflet assembly include that a folded structure allows a relatively thin membrane to be used by avoiding suture lines in loaded, dynamically active surfaces. Accordingly, a sutureless leaflet assembly preserves long-term integrity. However, it is to be understood that a prosthetic heart valve that does not include a folded tissue leaflet assembly is encompassed by one or more embodiments described herein.

With reference now to Figs. 8D-8L, and in accordance with at least one embodiment, for a prosthetic heart valve that includes a tissue leaflet assembly formed of a folded tissue membrane, the folding sequence for the tissue is shown for configuring the tissue into a completed tissue leaflet assembly. More particularly, a tissue blank 808 is shown in Fig. 8D, wherein the tissue blank 808 is a single monolithic piece of tissue 800. Depending upon the size requirements for a given tissue leaflet assembly, a line of primary fold or fold line 812 (shown as a dashed line) is visualized for the tissue blank 808. As shown in Fig. 8D, the primary fold 814 is achieved along the fold line 812 by folding the bottom edge 816 of the tissue blank 808 toward the top edge 820, but leaving a cuff portion 824 along the upper portion 828 of the tissue blank 808. Here, it is noted that the direction of top and bottom are relative to each other and are used as a convenience for describing the folding sequence, wherein such directions correspond to the orientation of the page illustrating the drawings. Advantageously, the folding geometry of Figs. 8D-8L forms cuffs 824 that are continuous with the leaflets, thereby reducing the risk of aortic insufficiency or leakage.

With reference now to Fig. 8F, after folding the tissue blank 808 along fold line 812 to form primary fold 814, pleats are formed by folding the tissue along its length. For the embodiment shown in Fig. 8F, three pleats 832a, 832b, and 832c are shown. Fig 8G illustrates a detail drawing of a single pleat 832 representative of one of pleats 832a-c. In Fig. 8G, the inner leaflet layer free edge 836 is shown, as is the valve sinus 840 and the commissure folds 844.

Referring again to Fig. 4 as well as Fig. 8H, at 412 the folded tissue is seamed to form a folded tissue leaflet assembly. More particularly, Fig. 8H shows a schematic perspective drawing of tissue leaflet assembly 848, wherein the pleated tissue construct shown in the bottom half of Fig. 8F is seamed, such as along seam 850, to form a substantially tubular construct. At

416, the folded tissue leaflet assembly 848 is maintained dry or is partially hydrated prior to mounting the tissue leaflet assembly in a frame. At 420, the tissue leaflet assembly 848 is then attached within a frame, such as frame 852 shown in Fig. 8I. The tissue leaflet assembly 848 attached within a frame 852 forms an implantable prosthetic heart valve 860, such as that shown in the schematic perspective drawing of Fig. 8J, side elevation view Fig. 8K, as well as that shown in the photo of Fig. 11A, and drawing of Fig. 11B. Fig. 8K illustrates possible suture points 864 where the tissue leaflet assembly 848 can be sutured to the frame 852. That is, the tissue leaflet assembly 848 may be attached within the frame 852, such as by suturing the outer layer of the tissue leaflet assembly 848 to the frame. In the foregoing sentence, and as used herein, it is noted that the term "attached" means that the tissue leaflet assembly 848 is secured to the frame 852, although the inner leaflet layer free edges 836 are able to readily move during operation of the prosthetic heart valve 860.

Referring now to Fig. 11C, a cutaway side elevation view of a prosthetic heart valve 860 that includes a frame 852 with a tissue leaflet assembly 848 attached therein is shown. The tissue membrane leaflet assembly 848 is disposed coaxially within the frame 852. As shown in Fig. 11C, the valve 860 is illustrated in the closed position with the leaflet free edges 836 in at least partial contact with each other. An arc 1112 of the leaflet free edges 836 (out of plane of the cutaway view) is continuous with pleats 832 at the radial edge of the tissue leaflet assembly 848, and may be seen in the alternate view shown in Fig. 8L. The tissue membrane leaflet assembly 848 is attached to the frame 852 along the axially oriented membrane pleats 832, as illustrated again in Fig. 8L. The extended cuff layer is attached circumferentially at the distal edge 1104 of the frame 852. By way of example and not limitation, continuous suture attachment 1108 may be used to attach the extended cuff layer to the distal edge 1104.

Referring now to Fig. 11D, an embodiment is shown wherein the cuff layer is not extended distally to the distal edge 1104 of the frame 852. As shown in Fig. 11D, the distal edge of the cuff layer is attached circumferentially to an inner aspect of the frame 852, such as along those possible suture points 864 illustrated in Fig. 8K. As a result, a distal portion 1116 of the frame 852 does not include any portion of the tissue leaflet assembly 848, such as the cuff layer. However, with the valve 860 in the closed position the leaflet free edges 836 still at least partially contact each other.

With reference now to Fig. 8L, an end view of the prosthetic heart valve is shown. As depicted in Fig. 8L, the pleats 832 are used as the portion of the tissue leaflet assembly 848 to attach to the frame 852. As can be seen in Fig. 8L, the outer cuff layer is attached to the frame members of frame 852. When the prosthetic heart valve 860 is closed, the cusps 868 formed by the inner leaflet layer are generally situated as depicted in Fig. 8L. Fig. 12 is a photo of the

tissue leaflets of a prosthetic heart valve after 30,000,000 cycles of testing to model performance if associated with a human heart. In testing, the prosthetic heart valve 860 has demonstrated a natural opening gradient of approximately 5 mmHg.

It will be appreciated by one of ordinary skill in the art that the tissue leaflet assembly 848 described and shown herein is but one possible construct for forming a flow control mechanism that can be attached to a frame to regulate the flow of blood in a patient's vascular system upon deployment. That is, the illustrated tissue leaflet assembly 848 is provided by way of example and not limitation, and in no way should be interpreted to limit the geometries of membrane leaflet assemblies that can be used to regulate fluid flow. Accordingly, other leaflet configurations and constructs are considered encompassed by claims directed to or otherwise including premounted percutaneously deliverable valves.

As those skilled in the art will appreciate, the frame 852 may be a stent or a structure having similarities to a stent. The frame 852 essentially serves as a holding mechanism for the tissue leaflet assembly 848 that can then be inserted percutaneously into a patient, wherein the frame 852 serves as a way to anchor the folded tissue leaflet assembly 848 to a vascular portion (e.g., *in situ* arterial tissue) of the patient. Thus, at 424 the tissue leaflet assembly 848 is inserted into a frame 852. More particularly, at 424a the frame 852 may comprise a balloon-expandable frame, or alternatively, at 424b a self-expanding frame may be used. After the tissue leaflet assembly is inserted into the frame, at 428 the folded tissue leaflet assembly 848 is attached to the frame 852, such as by suturing the tissue leaflet assembly 848 to the frame 852 to form an implantable prosthetic heart valve 860, such as that shown in Fig. 8L. In at least one embodiment, after attaching the tissue leaflet assembly 848 within the frame 852 and connecting the tissue leaflet assembly 848 to the frame 852 to form an implantable prosthetic heart valve 860, at 432 the prosthetic heart valve 860 is fully hydrated for inspection and testing. Thereafter, the fully constructed implantable prosthetic heart valve 860 may be dried and maintained in a substantially dry condition. Accordingly, as those skilled in the art will appreciate, one or more embodiments described herein provide a tissue 800 suitable for implanting in a human, wherein the implantable tissue may be allowed to dry prior to implanting, or it may be hydrated prior to implanting. In addition, the tissue 800 is suitable for use in forming a tissue leaflet assembly 848 for use in a prosthetic heart valve, including an implantable prosthetic heart valve 860 that can be implanted with its tissue leaflet assembly in a dry state, or with its tissue leaflet assembly in a partially or fully hydrated state.

One or more of the embodiments of the tissue leaflet assemblies 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 860 allows standard retrograde arterial aortic delivery via femoral artery insertion, without surgical cutdown or general anesthesia. This is achieved by providing the prosthetic heart valve on a premounted delivery system with the tissue leaflet assembly or tissue membrane construct in a substantially dry condition.

In accordance with one or more embodiments, a dry tissue membrane has substantially less mass than a wet membrane. By way of example, a substantially dry pericardium tissue prepared by one or more of the present embodiments has approximately 30% of the mass of a wet pericardium tissue, and marked reduction in profile and packing volume, thereby achieving a relatively low profile and making it suitable for implantation in greater number of patients, especially those having small diameter vascular systems. In addition, a dry prosthetic heart valve does not require storage and transport in preservative. A dry prosthetic heart valve can be mounted on a delivery catheter at its location of manufacture, which allows for pre-packaging of an integrated delivery system. In the foregoing sentence, it is noted that the term "mounted" means that the prosthetic heart valve 860 is temporarily associated with the delivery catheter. Together with a relatively low profile, embodiments of the prosthetic heart valve thereby offer reliability and convenience because the implantable prosthetic heart valve 860 is pre-mounted upon its delivery catheter and forms part of a pre-packaged delivery system. In addition, a dry prosthetic heart valve does not require rinsing, rehydration, or mounting in a catheterization lab. Therefore, a dry prosthetic heart valve can be inserted directly from package into the patient's body at a critical time during the procedure. Advantageously, this avoids procedure time, manipulation, and errors of mounting, crimping, and orienting catheters and sheaths. Once at the surgical facility/location, the dry prosthetic heart valve is inserted and delivered by balloon catheter expansion in the plane of the target valve in the standard way and the dry prosthetic heart valve begins to function immediately, even without specific steps to rehydrate the tissue membrane portion of the heart valve from its dry state, with hydration of the tissue membrane subsequently occurring rapidly and naturally in the body. More particularly, hydration of the tissue membrane portion occurs rapidly and begins with simple preparatory flushing of catheter

lumens with saline. Thereafter, hydration continues with device insertion and dwelling into the central blood vessels, and completes naturally after deployment in the patient's body.

The low profile of the implantable prosthetic valve is particularly advantageous for patient's having relatively small diameter vascular systems. Table 1 provides aortic and pulmonary valve prosthesis sizing.

Table 1: Aortic and Pulmonary Valve Prosthesis Sizing

Aorta/Pulmonary Valve Diameter	**Collapsed Implantable Prosthetic Heart Valve Size (French)**	**Collapsed Implantable Prosthetic Heart Valve Diameter**
19 - 21 mm	12 French	4.0 mm
22 - 26 mm	14 French	4.7 mm
27 - 30 mm	16 French	5.3 mm

For most human patients, the femoral artery has a diameter of between about 5-8 mm. Accordingly, it is apparent that embodiments of the collapsed implantable prosthetic heart valves 860 described herein offer a low profile that enables a larger group of patients to qualify for receiving an implantable prosthetic heart valve 860. As a result of the sizing advantages offered by one or more embodiments of implantable prosthetic heart valves 860 described herein, virtually no candidate patients would be excluded from treatment with an implantable prosthetic heart valve 860 without open heart surgery and without general anesthesia on the basis of inadequate femoral blood vessel access caliber. In addition, one or more embodiments of the implantable prosthetic heart valve 860 described herein feature a scalable construct, wherein the implantable prosthetic heart valves 860 can be produced to accommodate target valve diameters ranging between 6 - 35 mm, and wherein the implantable prosthetic heart valves 860 offer consistent function using fundamentally a single design.

Referring now to Fig. 5, the mounting of the implantable prosthetic heart valve 860 into a delivery system at 500 is further described. More particularly, at 504 an implantable prosthetic heart valve 860 (also referred to herein as a percutaneously deliverable heart valve) is collapsed. The initial phase of collapsing the percutaneously deliverable heart valve is executed with the tissue membrane in a hydrated condition. That is, since the percutaneously deliverable heart valve 860 includes the frame 852 with the tissue leaflet assembly 848 attached within the frame 852, the percutaneously deliverable heart valve 860 is collapsed down as an integral unit. If a balloon-expandable frame is used, then an axial puller may be utilized to collapse down the frame 852 of the percutaneously deliverable heart valve 860 without the application of force directly to the sides of the frame 852. This procedure offers the advantage of preserving the cell structure of the frame 852 while also maintaining the orientation of the leaflets of the tissue leaflet assembly 848 as the percutaneously deliverable heart valve 860 is compressed. The

proper orientation and disposition of the leaflets is facilitated by the hydrated state of the leaflets. This assists in preventing tissue prolapse or bulging of the tissue 800 or 802 through the frame 852. In addition, this technique reduces recompression strain on the metal frame 852 (e.g., a stent) that can tend to compromise fatigue life of the frame 852. This technique also tends to promote the circumferentially uniform collapsing of cells in the frame 852, thereby mitigating bunching of the tissue that forms the tissue leaflet assembly 848 of the percutaneously deliverable heart valve 860. For a self-expanding frame, the sides are forced to collapse by providing a radial compression force to the frame and may be assisted by axial traction force.

With further reference to Fig. 5, the percutaneously deliverable heart valve 860 (i.e., the frame 852 with the tissue leaflet assembly 848 attached thereto) is collapsed in an initially hydrated state. At 508 the delivery mandrel or balloon is inserted into a delivery sheath, and the mounting segment is then extended out the end of the sheath. Thereafter, at 512 the sheath and frame are coaxially mounted and then compressed with initial crimping onto the mounting segment with the tissue leaflet assembly 848 still in a hydrated state. At 516, the tissue leaflet assembly 848 of the percutaneously deliverable heart valve 860 is then allowed to dry, which further reduces the volume and profile of the tissue membrane leaflets, permitting further compression by radial force. Accordingly, in the final compression step, the percutaneously deliverable heart valve 860 is then further crimped with a circumferential crimping tool at 520 to finally mount the compressed valve/frame onto the delivery mandrel or balloon catheter.

Referring now to Fig. 6, the ensheathing, sterilization and packaging at 600 is described. More particularly, once the percutaneously deliverable heart valve 860 is coaxially mounted and crimped on a delivery mandrel or balloon catheter as described above and shown in Fig. 5, the assembly is then inserted at 604 into a distal end of a delivery sheath, such as by "backloading" the assembly into position with a distal end of the percutaneously deliverable heart valve 860 contained within the delivery sheath proximate the end of the sheath. Reference here is made to Fig. 10 that schematically illustrates catheter 1000 with an implantable prosthetic heart valve 860 mounted thereto.

With further reference to Fig. 6, at 608 the percutaneously deliverable heart valve 860 and delivery catheters are sterilized, such as by using by one or more of ethylene oxide, proton beam, or gamma radiation. At 612, the assembly is then optionally packaged in a sterile package. Additional elements are optionally shipped with the assembly, wherein, by way of example, such elements may include any necessary delivery tools and documentation. In at least one embodiment, the package may optionally contain a device to control the water vapor content

within the sealed volume of the package. Fig. 13 depicts a surgeon holding a sterile package 1300 containing a premounted percutaneously implantable prosthetic heart valve.

Referring now to Fig. 7, a flow chart illustrating the general procedure associated with implantation of the percutaneously deliverable heart valve 860 is provided. More particularly, 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. Fig. 14 is a schematic of a simplified cutaway view of a human heart, including heart valves that may be targeted for receiving an embodiment of an implantable prosthetic heart valve. Fig. 15 illustrates the aorta with the guidewire placed through the diseased aortic valve. At 708, the percutaneously deliverable heart valve 860 in the form of a prepackaged assembled dry prosthetic heart valve is removed from the sterile packaging. The dry prosthetic heart valve assembly, including its lumens, are preferably flushed and prepared in the usual fashion for standard balloons and catheters that do not contain a biocompatible tissue. Advantageously, implantation of the dry prosthetic heart valve assembly can be conducted without specific maneuvers for rehydration of the tissue leaflet assembly 848 of the percutaneously deliverable heart valve 860. Some rehydration of the tissue leaflets may occur as a consequence of the routine flushing of the catheter lumens in preparation for use as with any other catheters. Additionally, implantation of the dry prosthetic heart valve assembly can proceed without additional cleaning steps, such as by having to use alcohol or water rinsing solutions. In addition, further mounting of the dry tissue leaflet assembly 848 that resides in the frame 852 of the percutaneously deliverable heart valve 860 is not needed, thereby obviating the need for another mounting step. Accordingly, the percutaneously deliverable heart valve 860 can essentially be implanted percutaneously in its dry state. At 712, 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 716, 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 860 in place. At 720, in the case of a balloon expandable frame, and assuming the delivery approach involving the pre-mounting of the percutaneously deliverable heart valve 860 on the expansion balloon, the balloon is then inflated, deploying the percutaneously deliverable heart valve 860 in the plane of the valve. At 724, the leaflets of the percutaneously deliverable heart valve 860 operate immediately. The deployed prosthetic heart valve 860 is shown in Fig. 16, wherein the tissue leaflet assembly 848 serves to properly control the flow blood.

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 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.

CLAIMS

What is claimed is:

1. An assembly, comprising:

a prosthetic heart valve including:

a frame; and

a tissue leaflet assembly attached to the frame;

a percutaneously insertable valve delivery mechanism, wherein the prosthetic heart valve is releasably mounted onto the percutaneously insertable valve delivery mechanism; and

sterile packaging containing the prosthetic heart valve releasably mounted onto the percutaneously insertable valve delivery mechanism.

2. The assembly of Claim 1, wherein the percutaneously insertable valve delivery mechanism comprises a balloon catheter.

3. The assembly of Claim 2, wherein the balloon catheter is a 12 to 14 French balloon catheter.

4. The assembly of Claim 2, wherein the balloon catheter is less than about 12 French.

5. The assembly of Claim 2, wherein the balloon catheter is between about 5 to 12 French.

6. The assembly of Claim 1, wherein the percutaneously insertable valve delivery mechanism comprises a mandrel.

7. The assembly of Claim 1, wherein tissue forming the tissue leaflet assembly within the sterile packaging is at least one of hydrated and not substantially dry.

8. The assembly of Claim 1, wherein tissue forming the tissue leaflet assembly within the sterile packaging is substantially dry.

9. The assembly of Claim 1, wherein the frame comprises a stent.

10. The assembly of Claim 1, wherein tissue forming the tissue leaflet assembly comprises treated pericardium tissue.

11. A pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve ready for implantation in a patient, comprising:

a frame; and

a tissue leaflet assembly attached to the frame, the tissue leaflet assembly comprising a substantially dry tissue.

12. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the substantially dry tissue comprises treated pericardium tissue.

13. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the substantially dry tissue comprises a water moisture content of less than about 40% by weight of the substantially dry tissue.

14. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the frame and the tissue leaflet assembly attached thereto are operably associated with a 12 to 14 French balloon catheter.

15. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the frame and the tissue leaflet assembly attached thereto are operably associated with a balloon catheter having a size of less than about 12 French.

16. The pre-packaged percutaneous, trans-catheter deliverable prosthetic heart valve of Claim 11, wherein the frame and the tissue leaflet assembly attached thereto are operably associated with a balloon catheter having a size of between about 5 to 12 French.

17. An assembly for use with a patient, comprising:

a sealed sterile package containing a delivery system for percutaneously deploying a heart valve in the patient, the heart valve including:

a frame releasably mounted on the delivery system within the sealed sterile package; and

a tissue leaflet assembly attached to the frame.

18. The assembly of Claim 17, wherein the tissue leaflet assembly comprises a treated pericardium tissue.

19. The assembly of Claim 17, wherein the delivery system includes a percutaneously insertable balloon catheter.

20. The assembly of Claim 19, wherein the balloon catheter is a 12 to 14 French balloon catheter.

21. The assembly of Claim 19, wherein the balloon catheter is less than about 12 French.

22. The assembly of Claim 19, wherein the balloon catheter is between about 5 to 12 French.

23. The assembly of Claim 17, wherein the delivery system includes a percutaneously insertable mandrel.

24. The assembly of Claim 17, wherein the tissue leaflet assembly within the sealed sterile package is at least one of partially hydrated and not substantially dry.

25. The assembly of Claim 17, wherein the tissue leaflet assembly within the sealed sterile package is substantially dry.

26. The assembly of Claim 17, wherein the frame comprises a stent.

27. An article adapted for implantation in a patient, comprising:

a prosthetic heart valve further comprising a treated tissue attached to a frame, wherein the treated tissue comprises a water content of less than about 60% by weight of the treated tissue.

28. The article of Claim 27, wherein the treated tissue comprises a section of treated pericardium tissue having an ultimate tensile strength of greater than about 12 MegaPascals.

29. The article of Claim 28, wherein the section of pericardium tissue comprises a thickness of between about 50 to 300 micrometers.

30. The article of Claim 27, wherein the water content of the treated tissue is less than about 40% by weight of the treated tissue.

31. An article adapted for trans-catheter delivery into a patient, comprising:

a prosthetic heart valve further comprising a treated tissue attached to a frame, wherein the treated tissue comprises a thickness of about 50 to 500 micrometers and an ultimate tensile strength of greater than about 15 MegaPascals when at a water content of less than about 50% by weight of the treated tissue.

32. The article of Claim 31, wherein the treated tissue comprises a treated pericardium tissue.

33. The article of Claim 31, wherein the water content of the treated tissue is less than about 40% by weight of the treated tissue.

34. The article of Claim 31, wherein the ultimate tensile strength is greater than about 20 MegaPascals.

35. The article of Claim 31, wherein the treated tissue does not include a matrix that has been exposed to a polymer infiltrate.

36. A method, comprising:

partially compressing and mounting a prosthetic heart valve upon a delivery catheter, the prosthetic heart valve comprising a tissue;

allowing the tissue to at least partially dry;

further compressing and mounting the prosthetic heart valve upon the delivery catheter; and

sterilizing and packaging the prosthetic heart valve and delivery catheter.

37. The method of Claim 36, further comprising transporting the sterilized and packaged prosthetic heart valve and delivery catheter.

38. The method of Claim 36, wherein the tissue comprises a treated pericardium tissue.

39. The method of Claim 36, wherein prior to partially compressing and mounting the prosthetic heart valve upon the delivery catheter, the tissue is at least one of (a) not substantially dry, and (b) at least partially hydrated.

40. A method, comprising:

attaching a tissue to a frame;

partially compressing and mounting the frame, with the tissue attached thereto, upon a delivery catheter;

allowing the tissue to at least partially dry;

further compressing and mounting the frame, with the tissue attached thereto, upon the delivery catheter; and

sterilizing and packaging the frame and delivery catheter, with the tissue attached thereto.

41. The method of Claim 40, wherein prior to partially compressing and mounting the frame, the tissue is at least one of (a) not substantially dry, and (b) at least partially hydrated.

42. The method of Claim 40, further comprising transporting the sterilized and packaged frame, with the tissue attached thereto, mounted upon the delivery catheter, to a surgical or medical procedure facility.

43. The method of Claim 40, wherein prior to attaching the tissue to the frame the tissue is folded to form a tissue leaflet assembly.

44. The method of Claim 43, wherein the tissue leaflet assembly comprises at least one cuff and at least one pleat.

45. The method of Claim 40, wherein the tissue comprises a treated pericardium tissue.

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

providing a membrane tissue from an organism;

treating the membrane tissue with at least one chemical to produce a treated membrane tissue;

drying the treated membrane tissue until it is a substantially dry tissue;

attaching the substantially dry tissue to a frame;

rehydrating the substantially dry tissue that is attached to the frame to form a rehydrated tissue;

collapsing the frame with the rehydrated tissue attached thereto; and

drying the rehydrated tissue attached to the collapsed frame until it is a substantially dry tissue.

47. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, further comprising compressing and mounting the frame, with the tissue attached thereto, upon a delivery catheter.

48. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 47, further comprising sterilizing and packaging the frame, with the substantially dry tissue attached thereto, mounted upon the delivery catheter.

49. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 48, further comprising at least one of transporting and shipping the sterilized and packaged frame with the substantially dry tissue attached thereto, mounted upon the delivery catheter, to a surgical or medical procedure facility.

50. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 49, further comprising implanting the frame with the substantially dry tissue attached thereto into a patient.

51. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein the frame comprises a stent.

52. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein prior to the attaching step the dry tissue is not folded with a cuff and a pleat.

53. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein prior to the attaching step the dry tissue is folded to form a tissue leaflet assembly.

54. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, wherein the tissue leaflet assembly comprises at least one cuff and at least one pleat.

55. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a 12 to 14 French balloon catheter.

56. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a balloon catheter having a size of less than about 12 French.

57. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, further comprising mounting the frame and the tissue leaflet assembly attached thereto upon a balloon catheter having a size of between about 5 to 12 French.

58. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 53, further comprising mounting the frame and the tissue leaflet assembly attached thereto on a mandrel.

59. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, further comprising sterilizing the frame with the substantially dry tissue attached thereto with exposure to at least one of ethylene oxide, a proton beam, and gamma radiation.

60. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1 – 37.5% formalin solution for between about 3 days to 3 weeks.

61. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1 – 37.5% formalin solution for between about 3 days to 5 weeks.

62. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1 - 37.5% formalin solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

63. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a buffered or unbuffered 1 - 37.5% formalin solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

64. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in 100% glycerol for greater than about 3 weeks.

65. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a 0.1 - 25% glutaraldehyde solution for between about 3 days to 3 weeks.

66. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a 0.1 - 25% glutaraldehyde solution for between about 3 days to 5 weeks.

67. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a 0.1 - 25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

68. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in a 0.1 - 25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

69. The met ous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1 - 25% glutaraldehyde solution for between about 3 days to 3 weeks.

70. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1 - 25% glutaraldehyde solution for between about 3 days to 5 weeks.

71. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1 - 25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 3 weeks.

72. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein said treating comprises immersion of the membrane tissue in an oligomeric filtered 0.1 - 25% glutaraldehyde solution containing at least one of free amino acids (a) lysine and (b) histidine, for between about 3 days to 5 weeks.

73. The method of preparing a percutaneous, trans-catheter prosthetic heart valve of Claim 46, wherein the membrane tissue comprises a treated pericardium tissue.

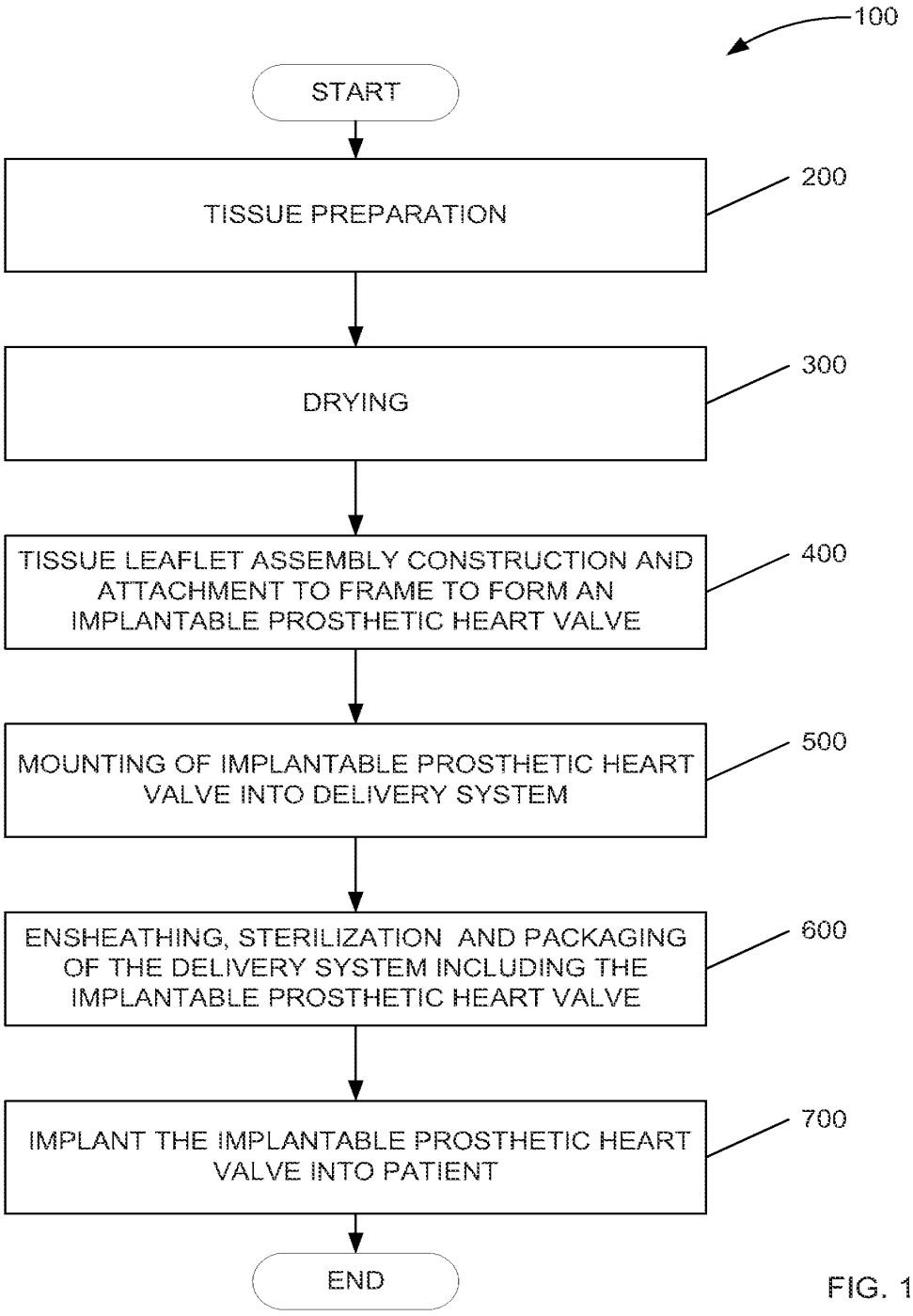


FIG. 1

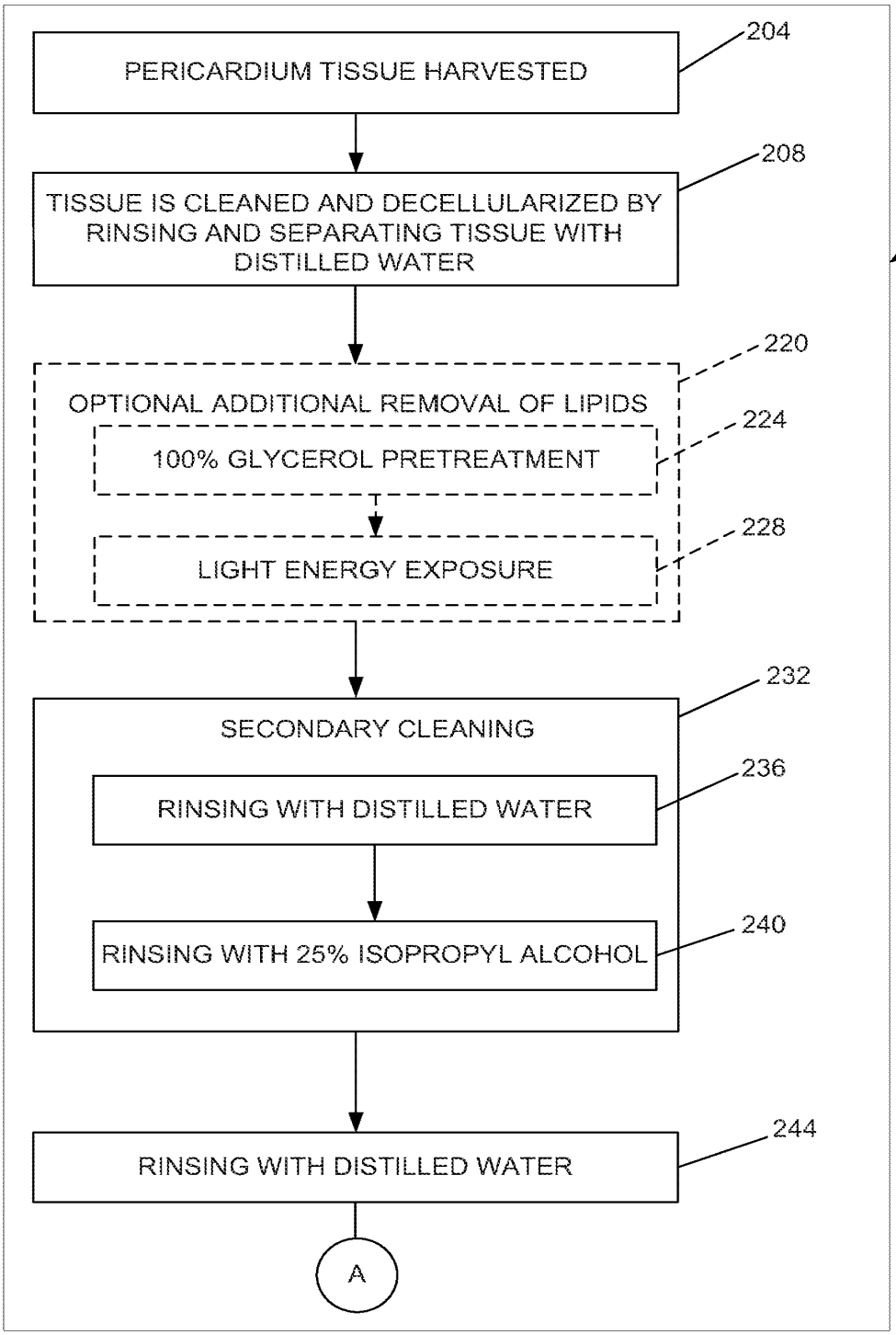


FIG. 2A

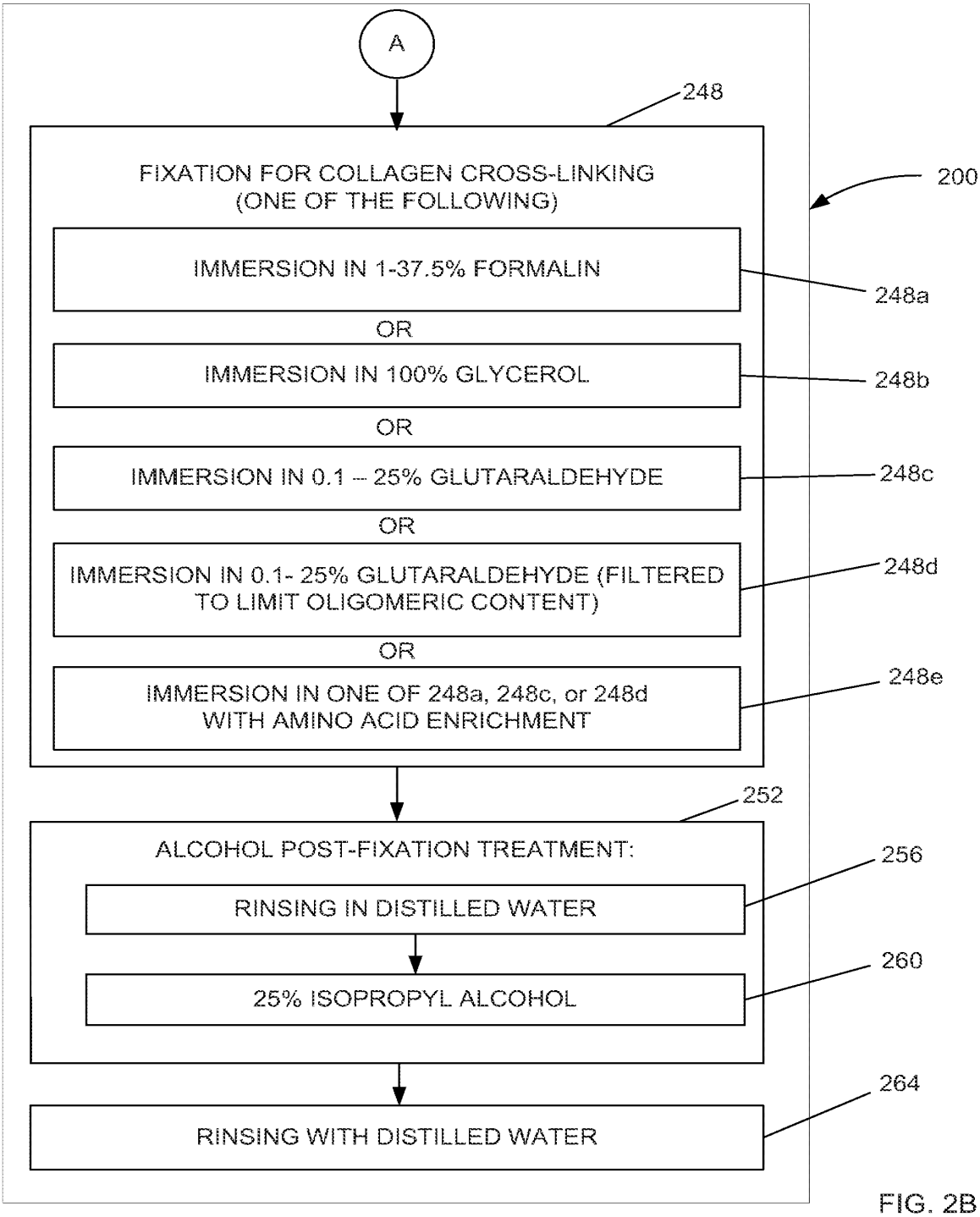


FIG. 2B

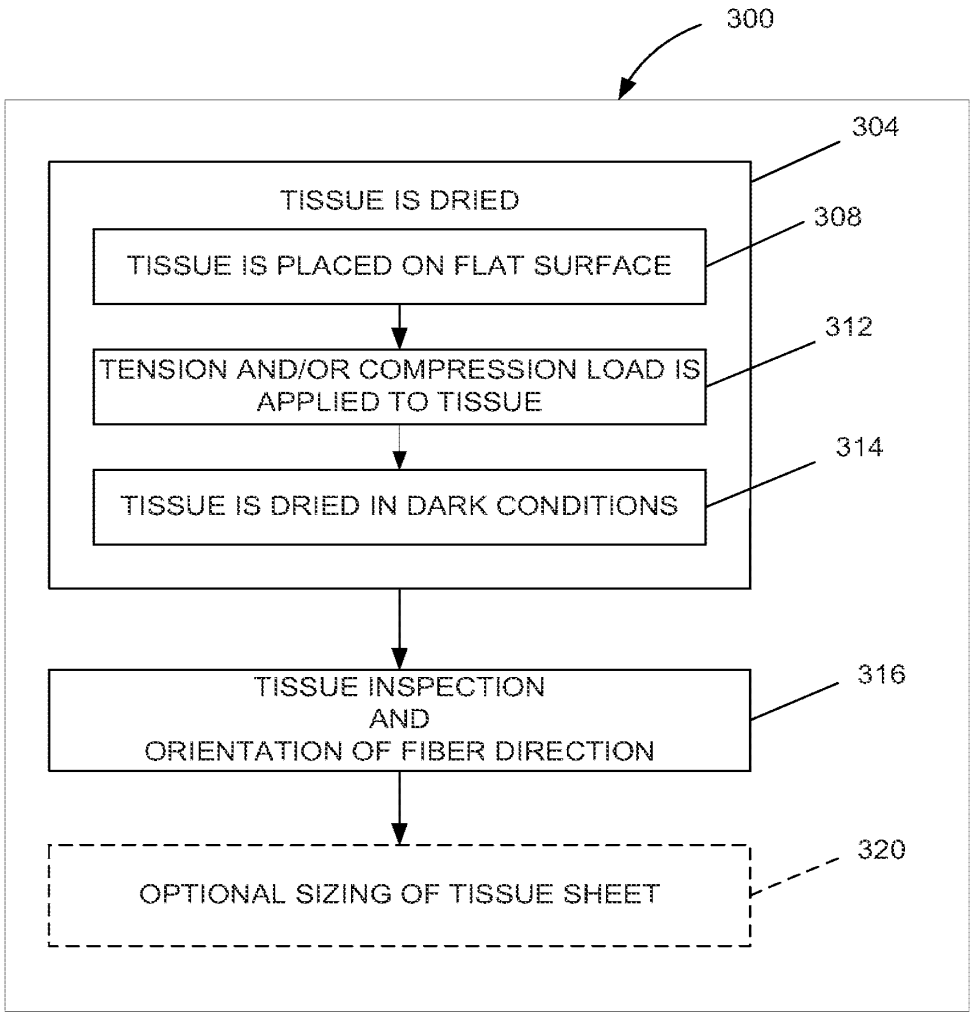


FIG. 3

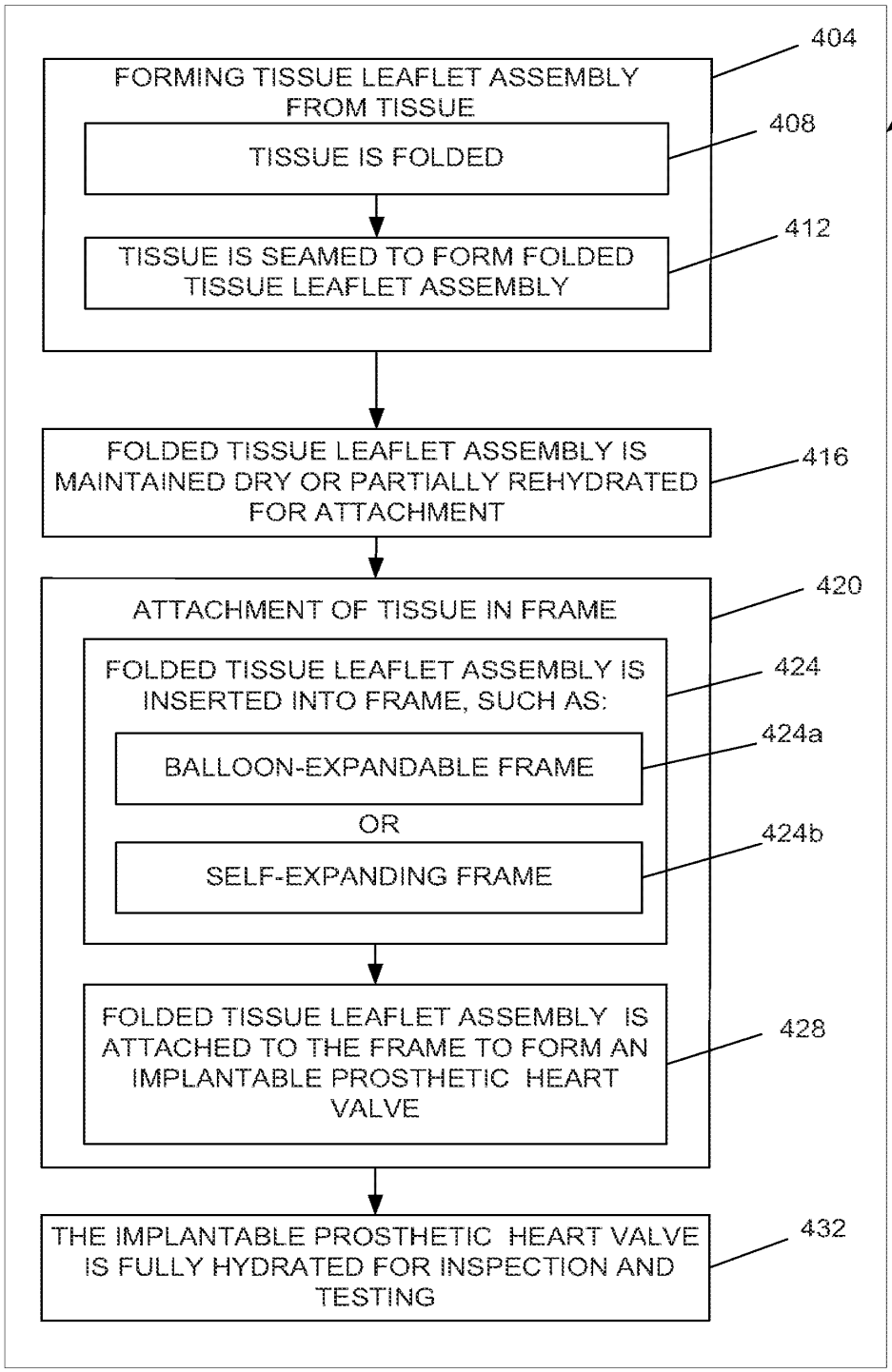


FIG. 4

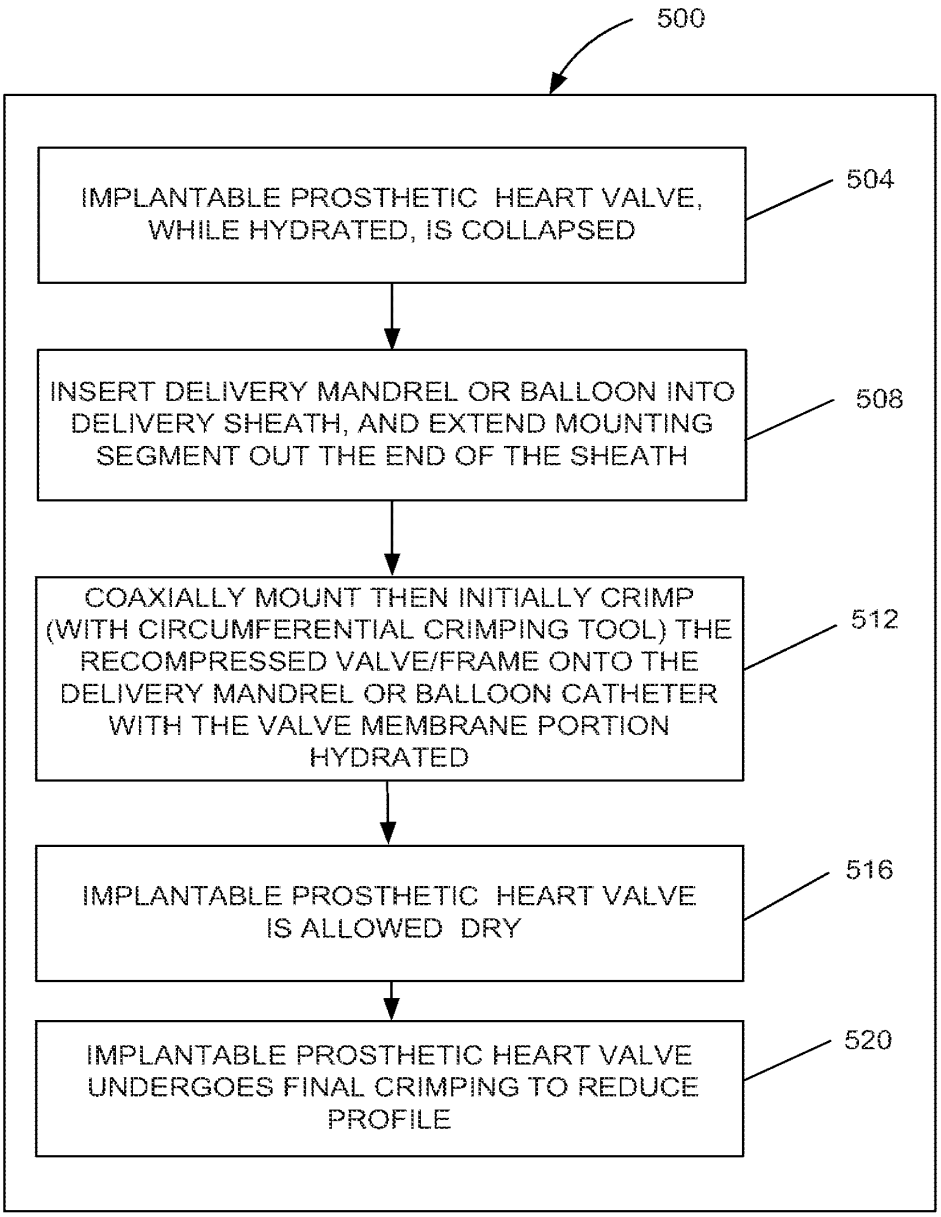


FIG. 5

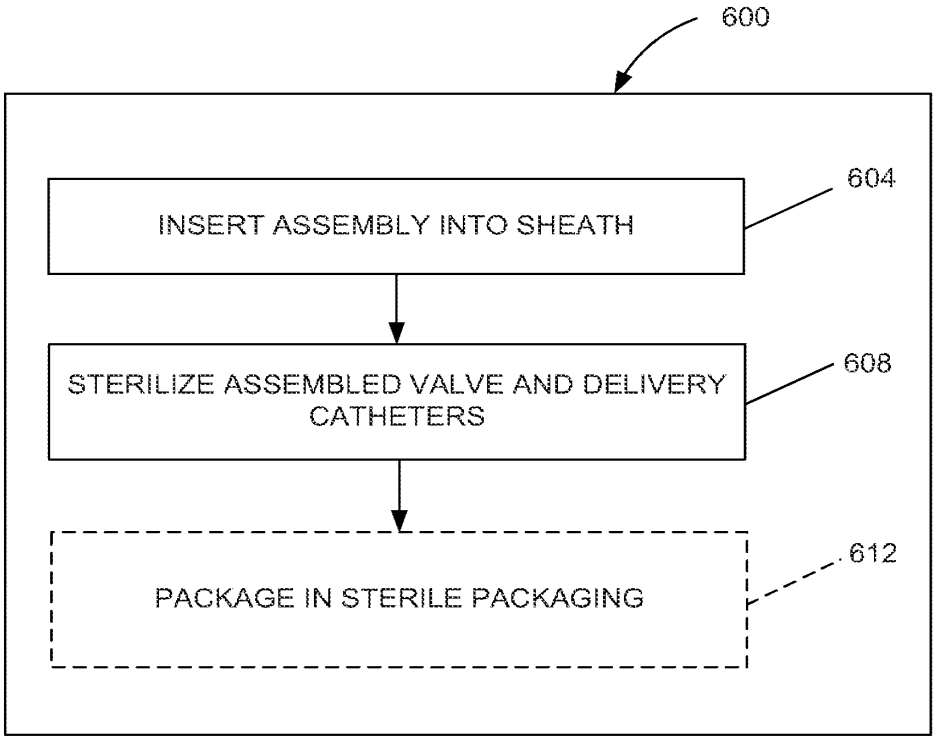


FIG. 6

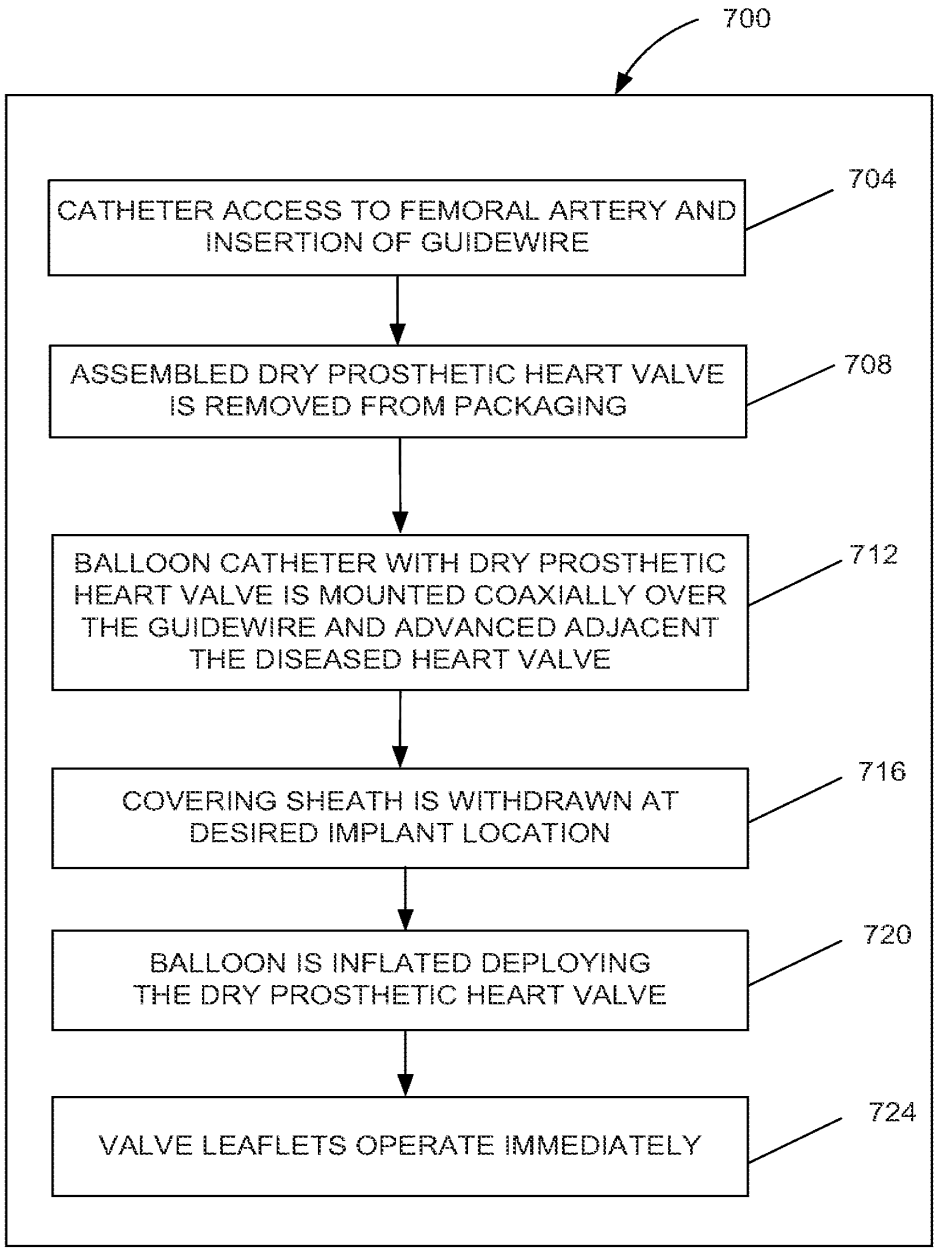


FIG.7

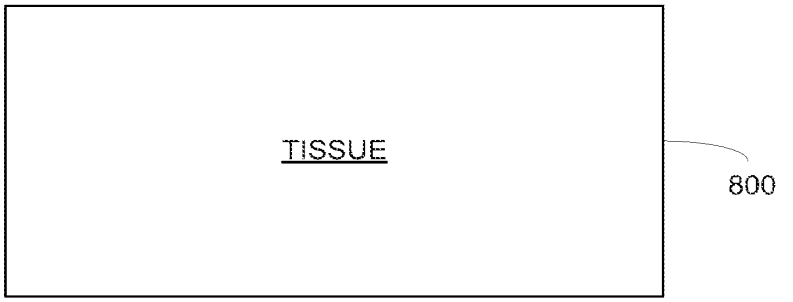


FIG.8A

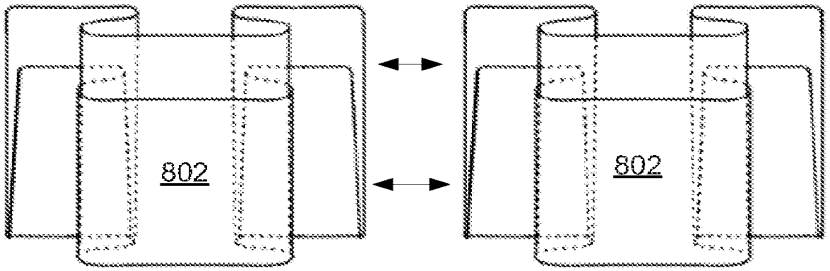


FIG.8B

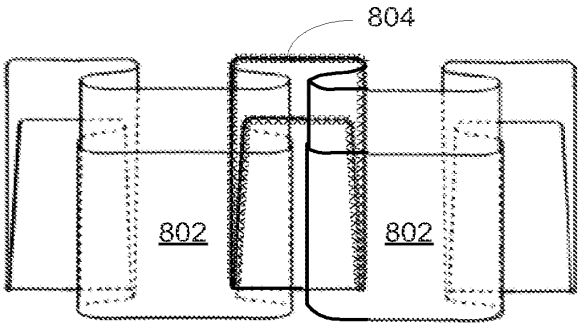


FIG.8C

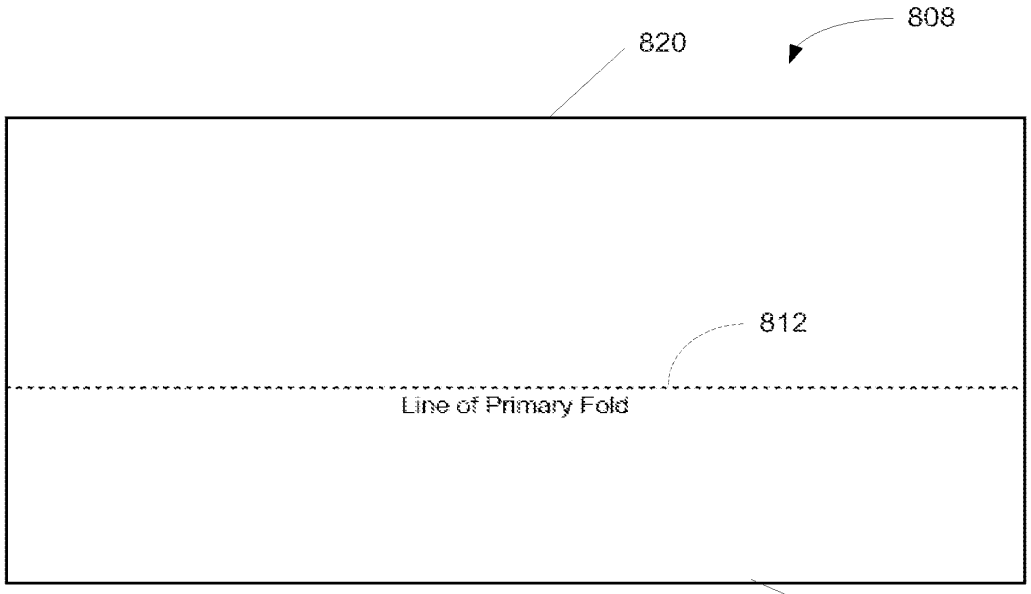

808
820
812
Line of Primary Fold
816

FIG.8D

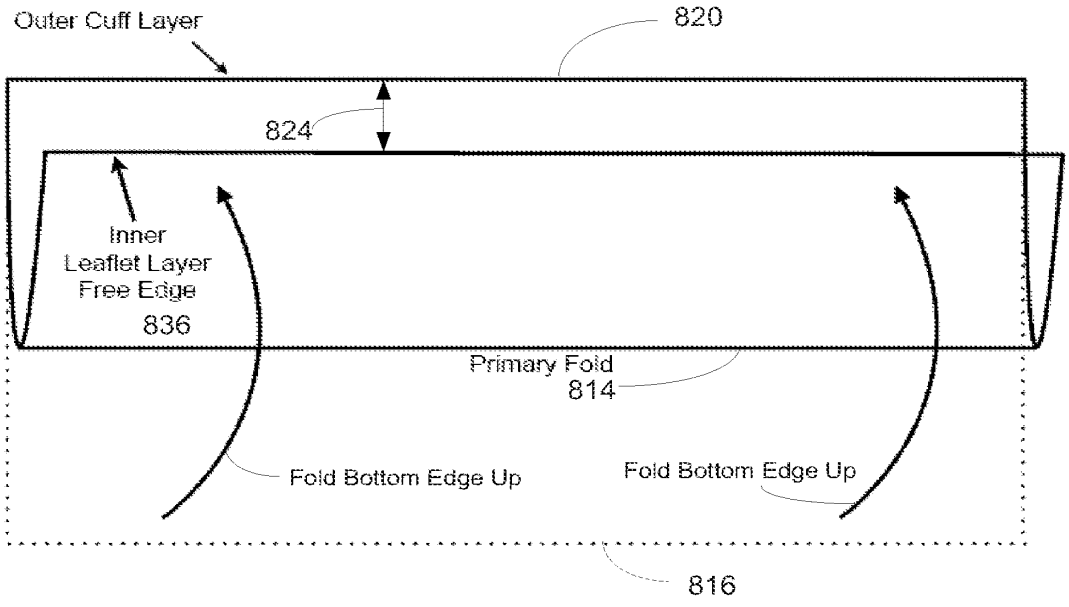

Outer Cuff Layer
820
824
Inner
Leaflet Layer
Free Edge
836
Primary Fold
814
Fold Bottom Edge Up
Fold Bottom Edge Up
816

FIG.8E

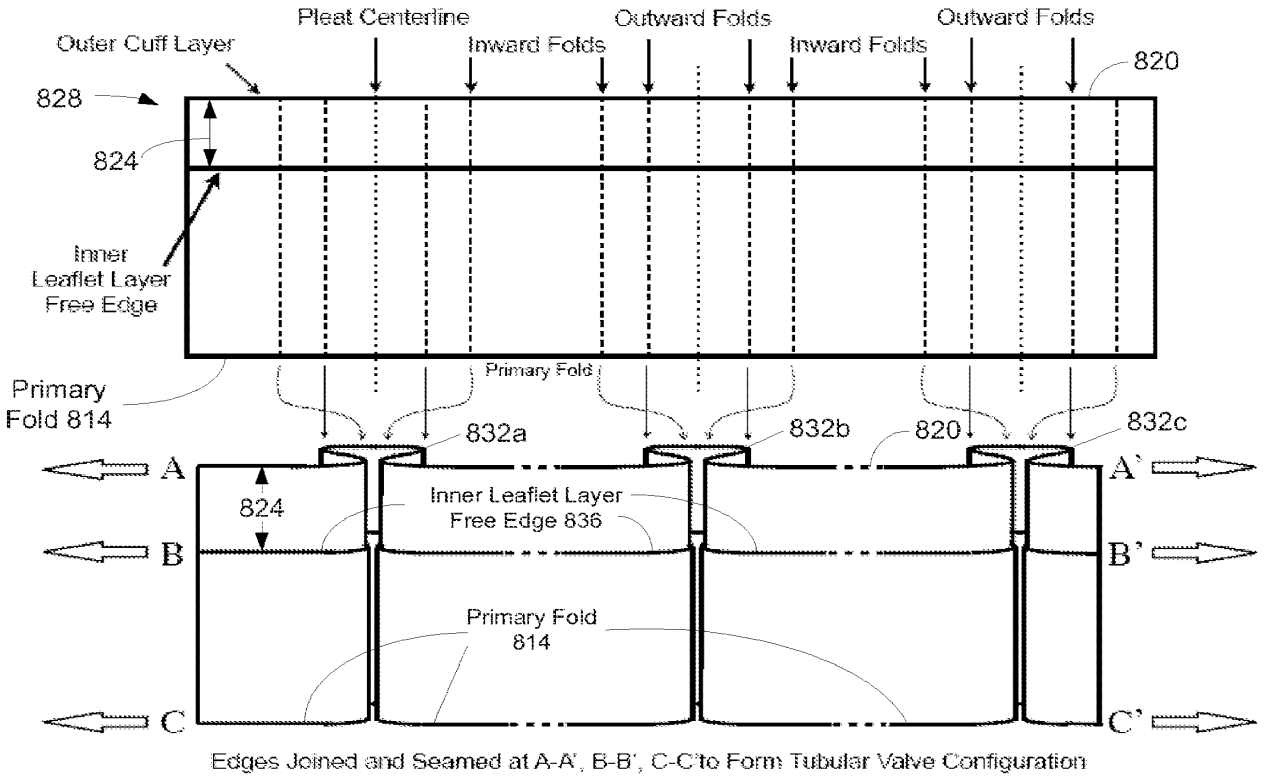

Pleat Centerline
Outward Folds
Outward Folds
Outer Cuff Layer
Inward Folds
Inward Folds
820
828
824
Inner
Leaflet Layer
Free Edge
Primary Fold
Primary
Fold 814
832a
832b
820
832c
A
A'
824
Inner Leaflet Layer
Free Edge 836
B
B'
Primary Fold
814
C
C'
Edges Joined and Seamed at A-A', B-B', C-C'to Form Tubular Valve Configuration

FIG.8F

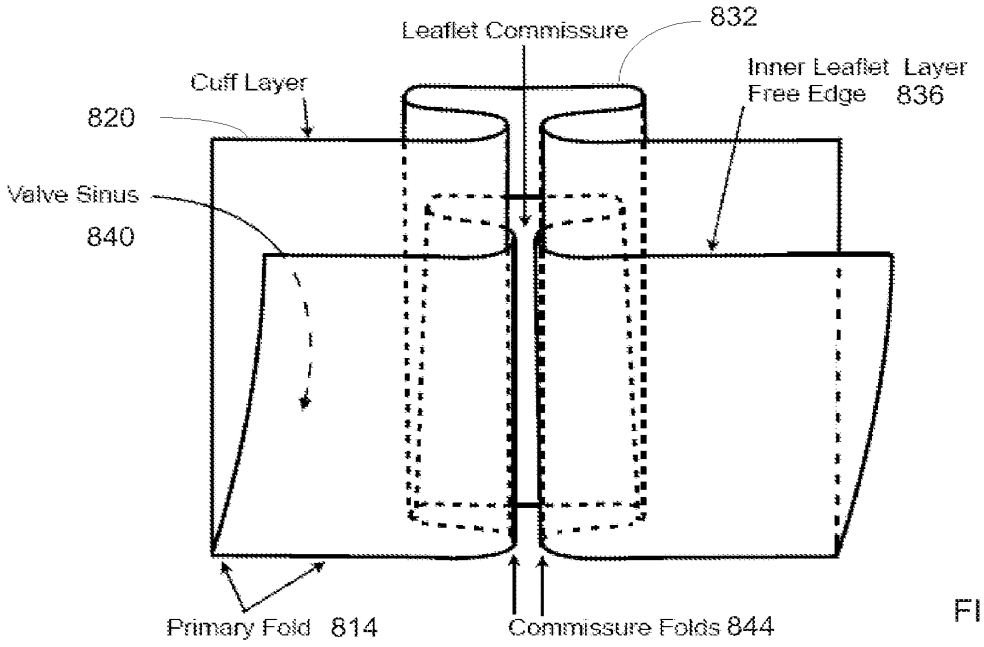


FIG.8G

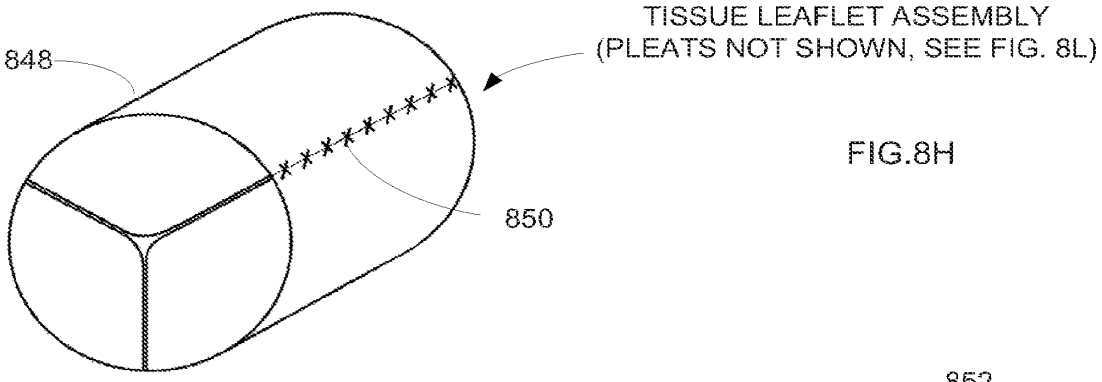


FIG.8H

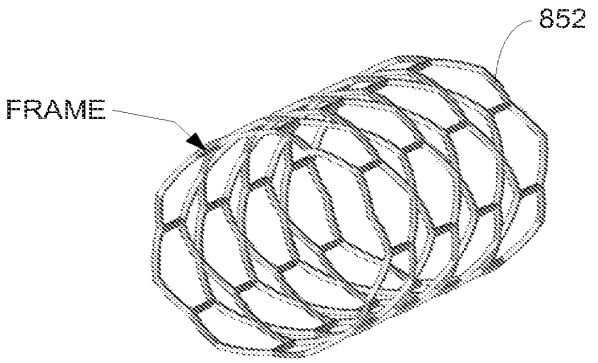


FIG.8I

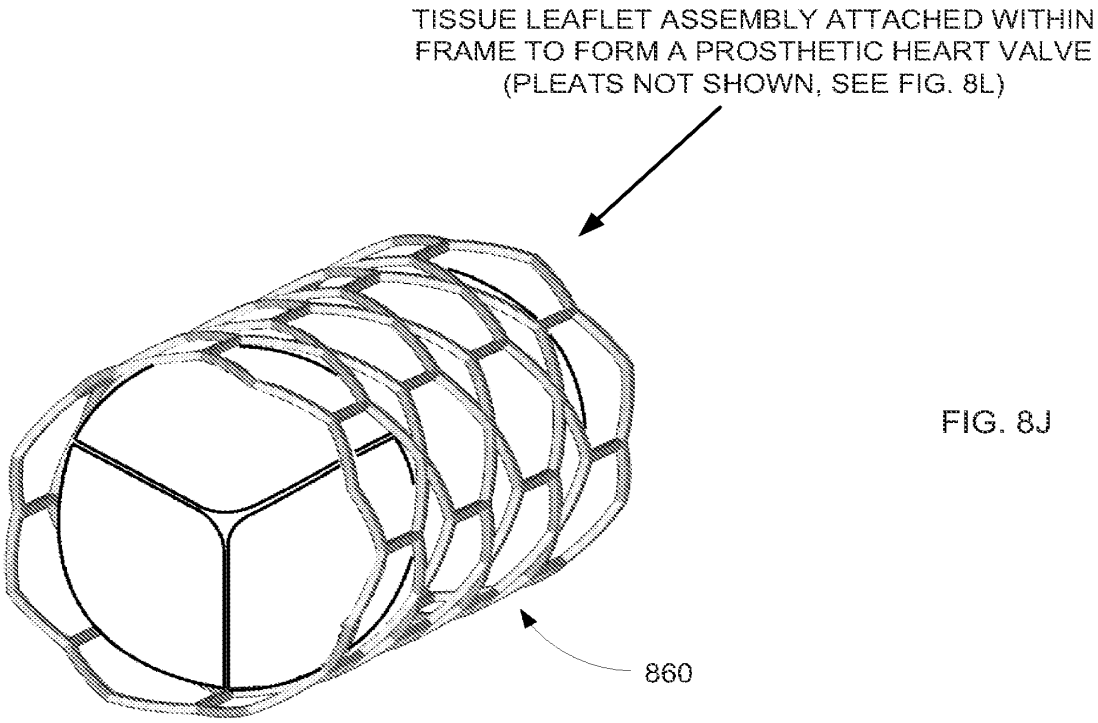


FIG. 8J

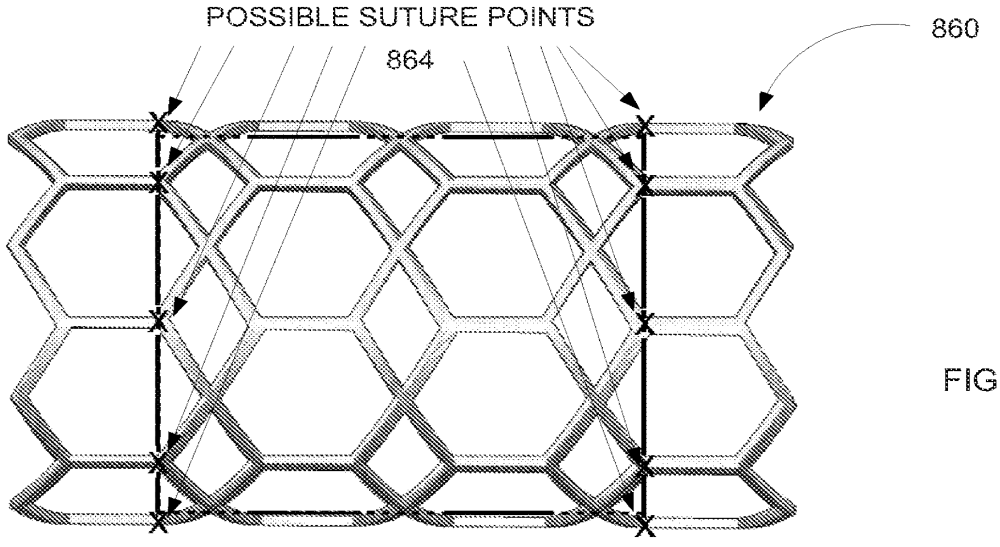


FIG. 8K

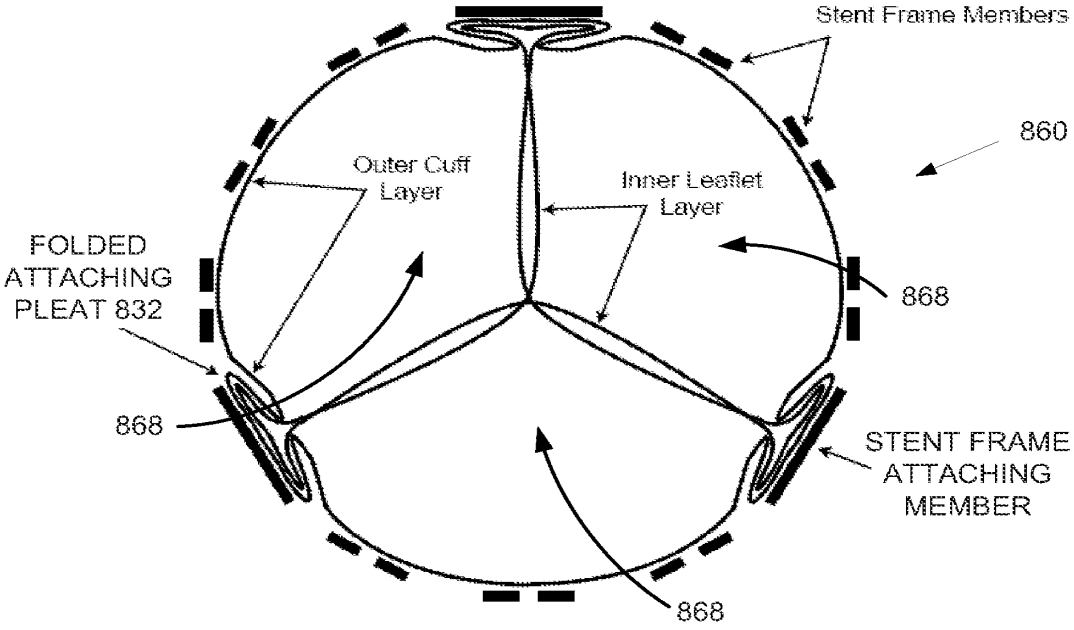
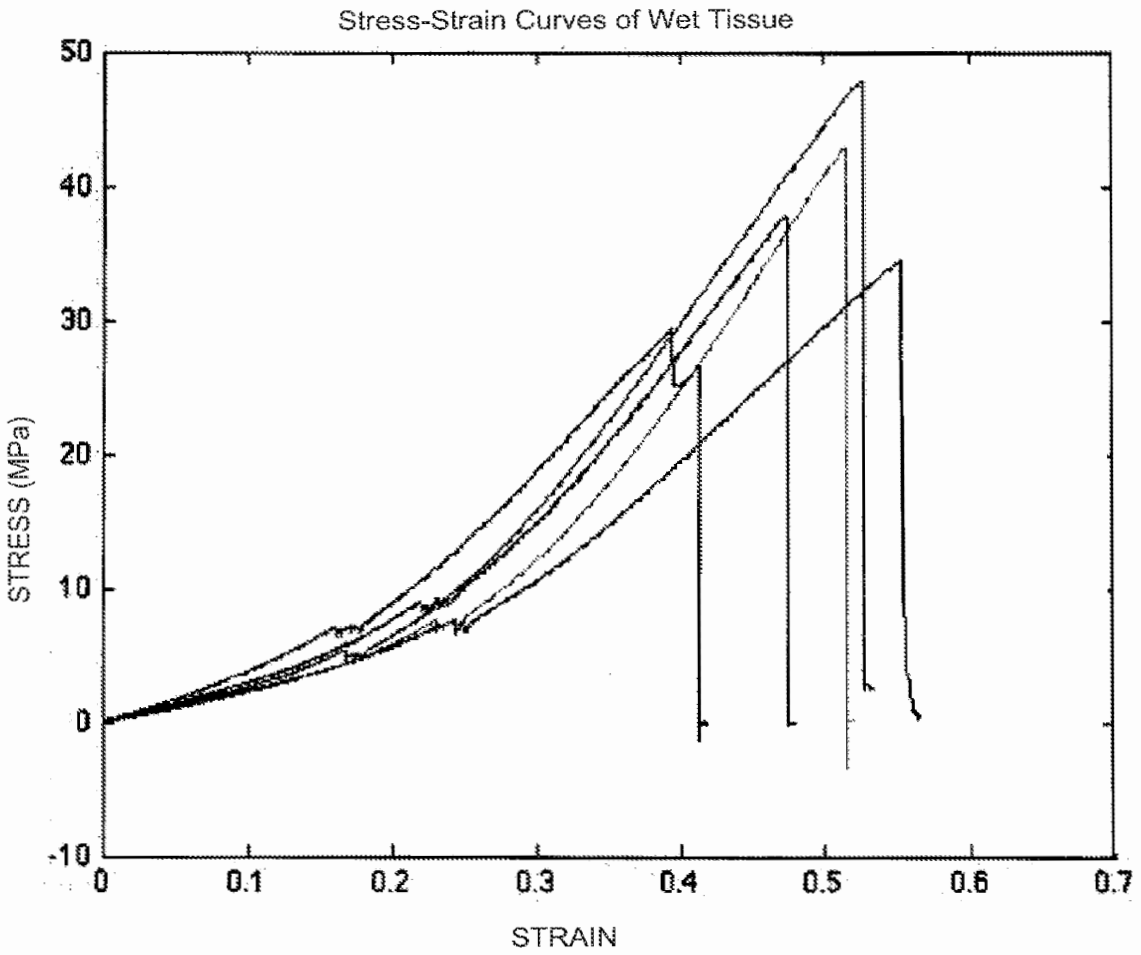


FIG.8L



Stress-strain curves in wet or hydrated state of five samples. Each curve corresponds to a separate sample.

FIG. 9

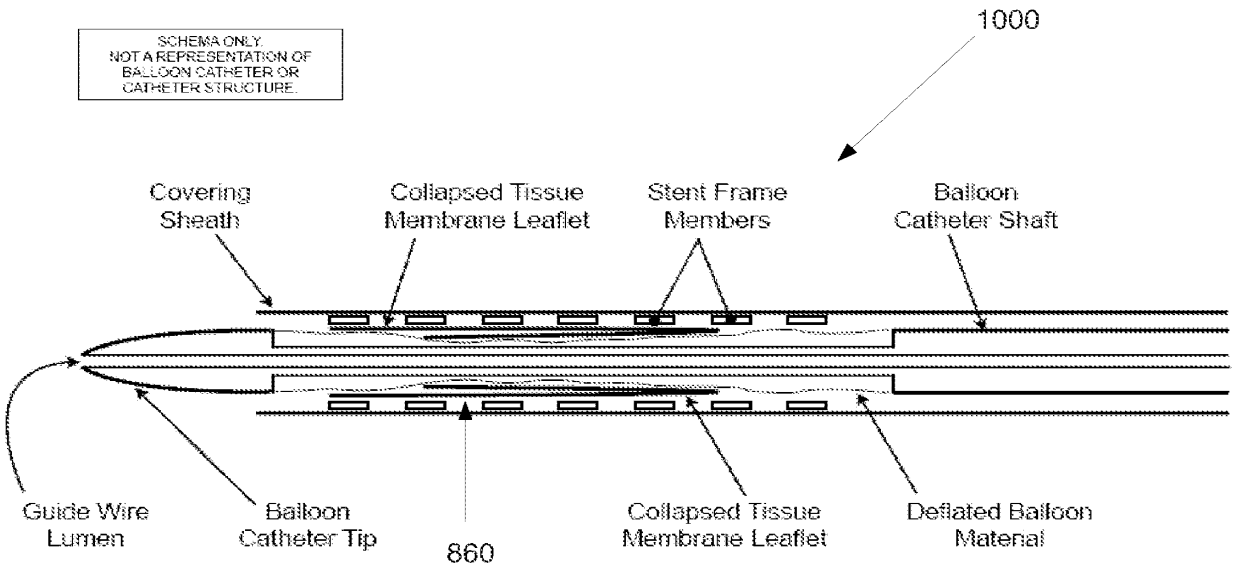


FIG.10

Photo of Tissue Leaflet Assembly Attached in Frame to Form Implantable Prosthetic Heart Valve

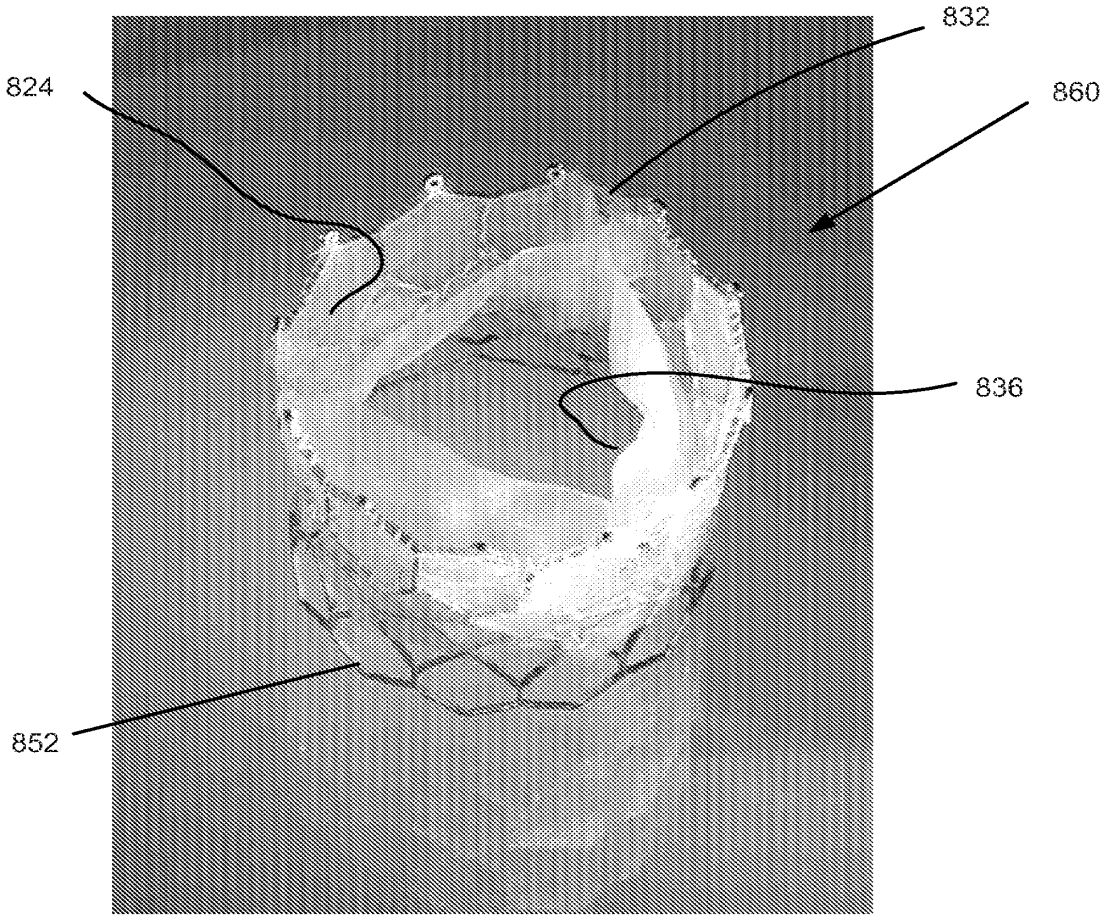


FIG.11A

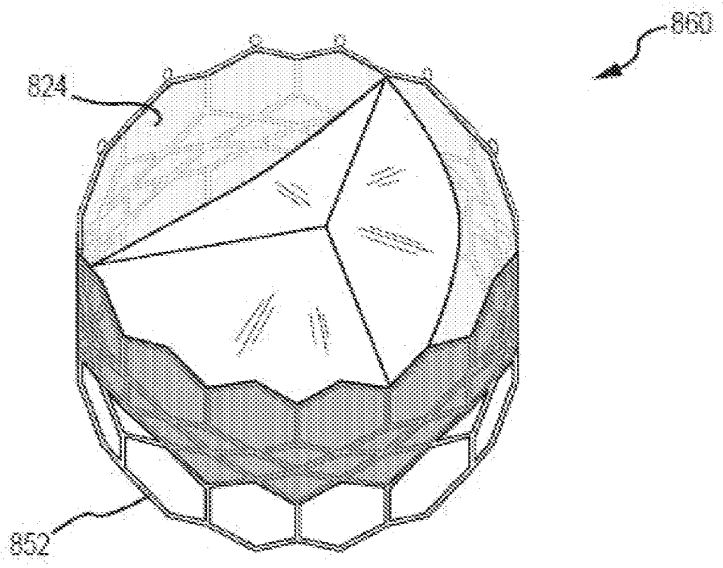


FIG. 11B

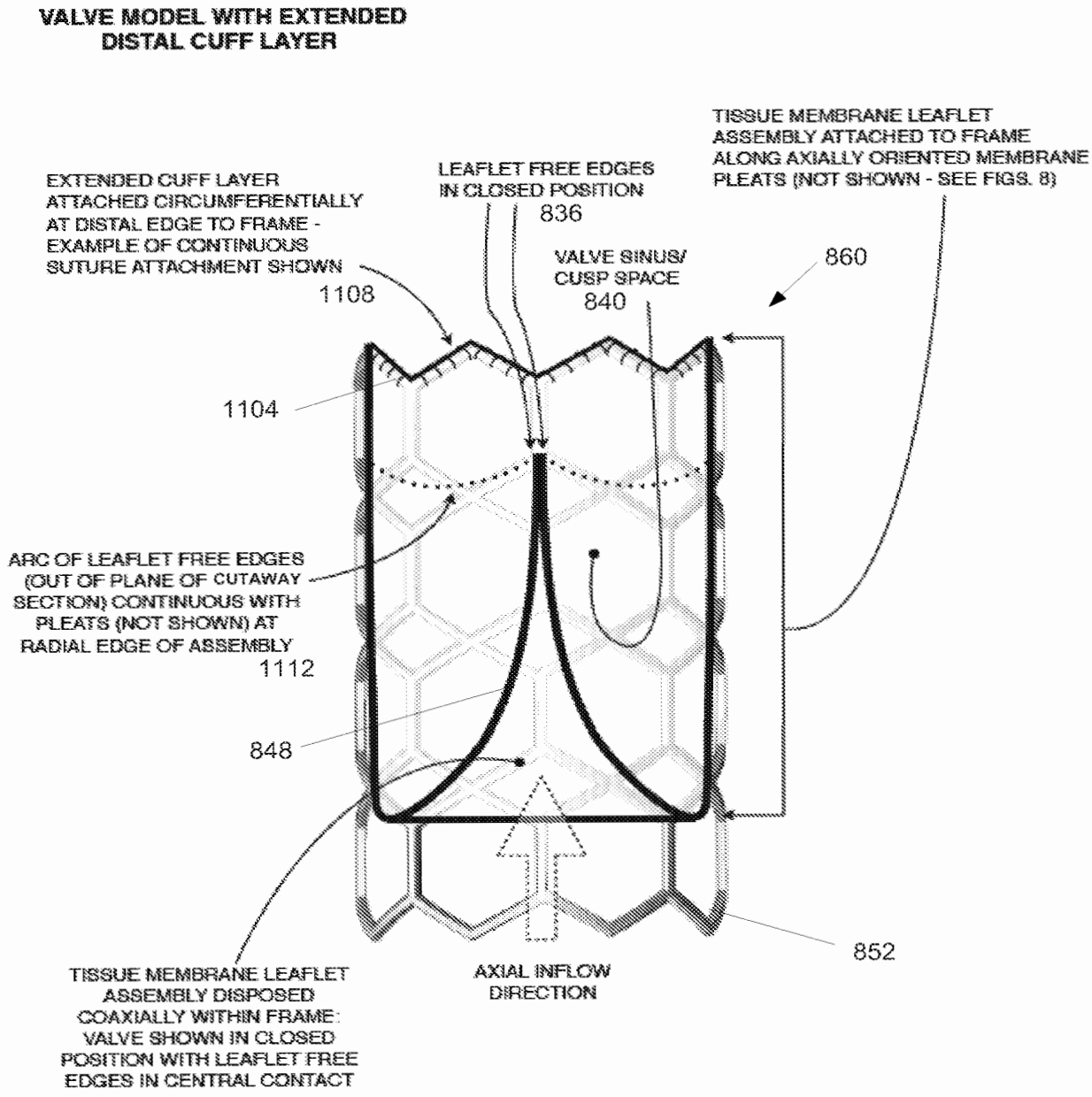


FIG. 11C

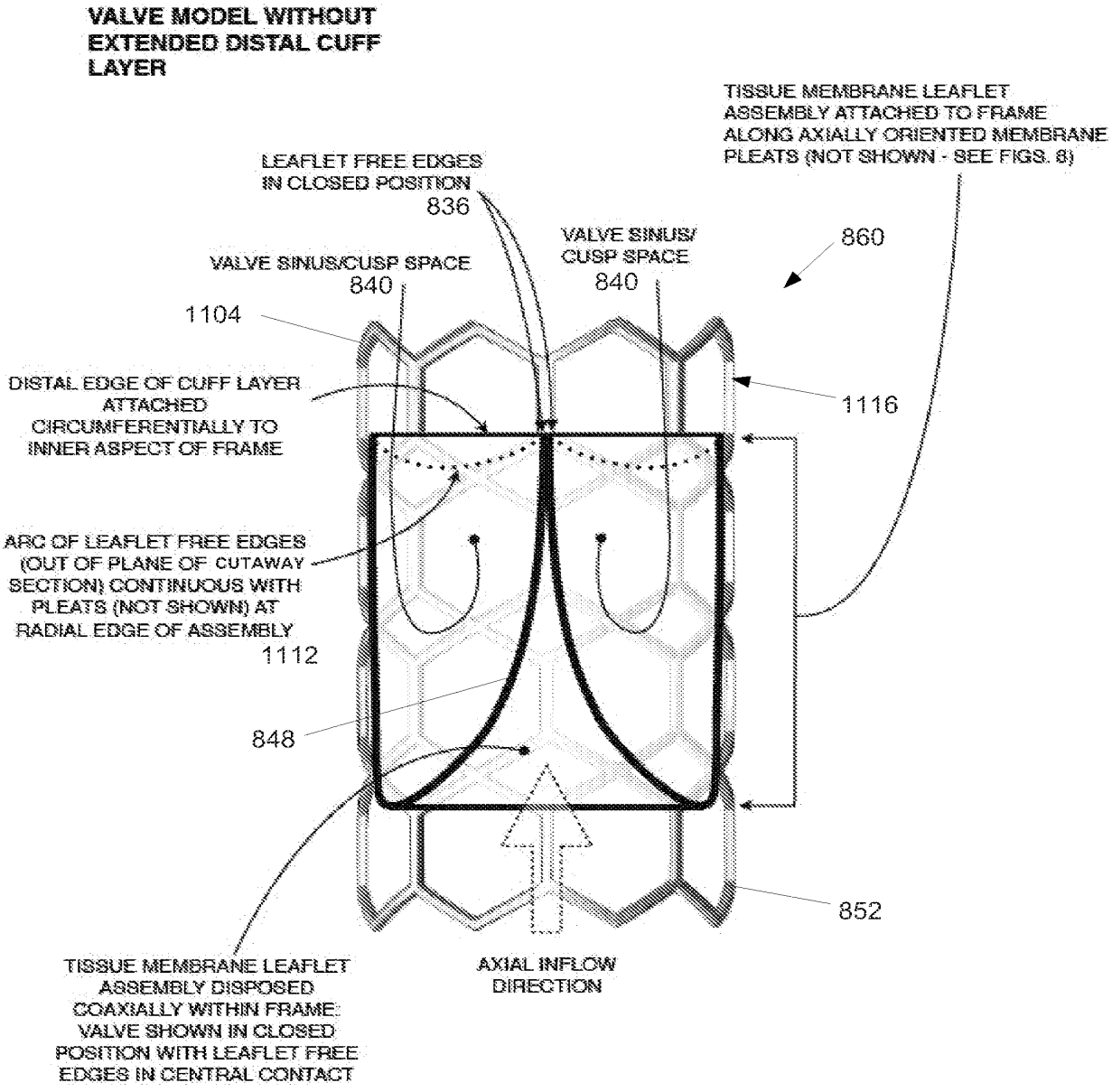


FIG. 11D

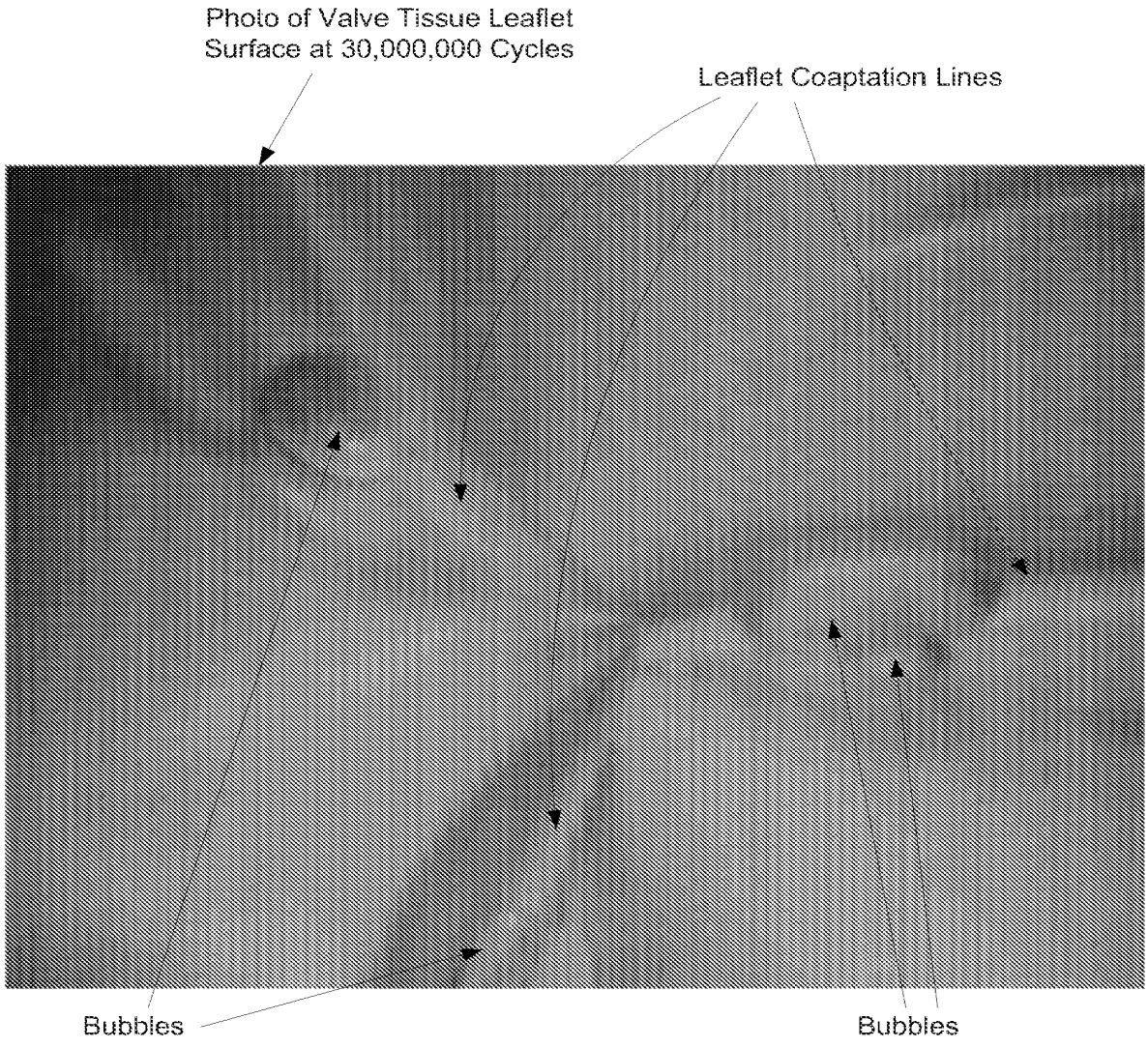


FIG.12

Surgeon Holding a Premounted Percutaneously Deliverable Heart Valve Associated With a Catheter and Residing Within Sterile Packaging

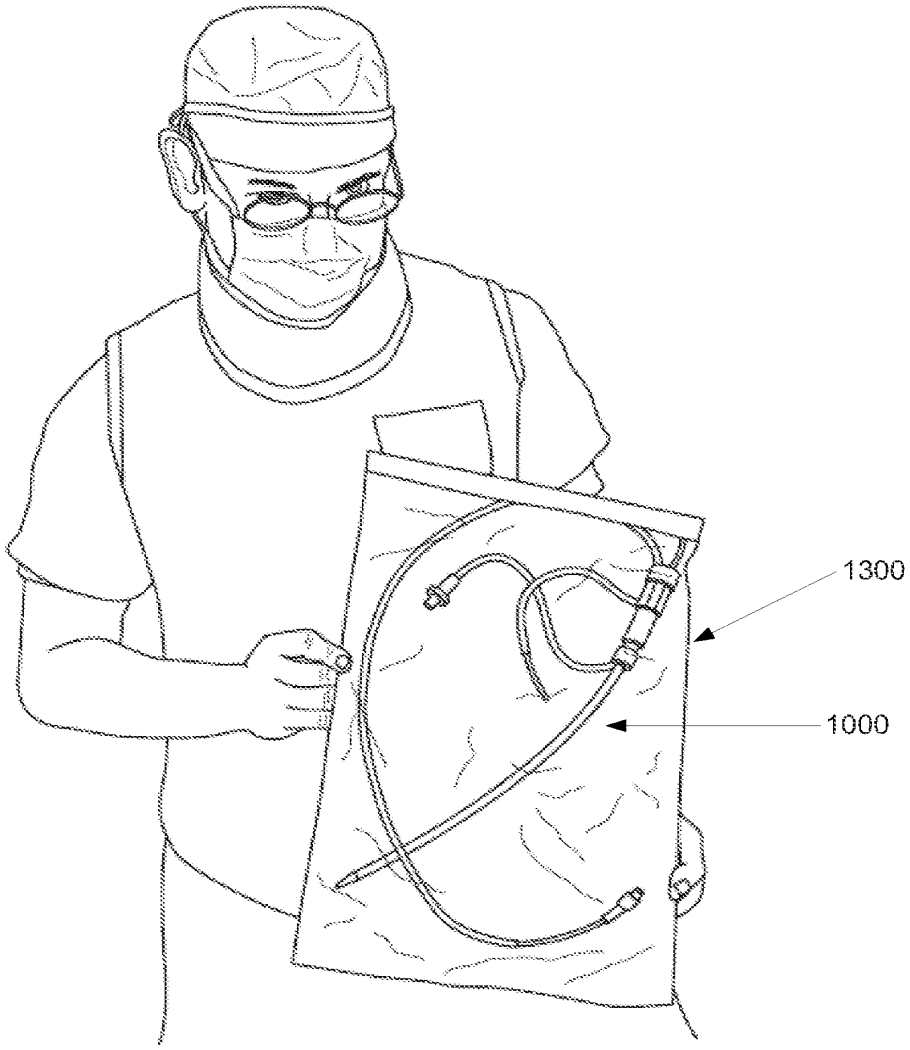


FIG.13

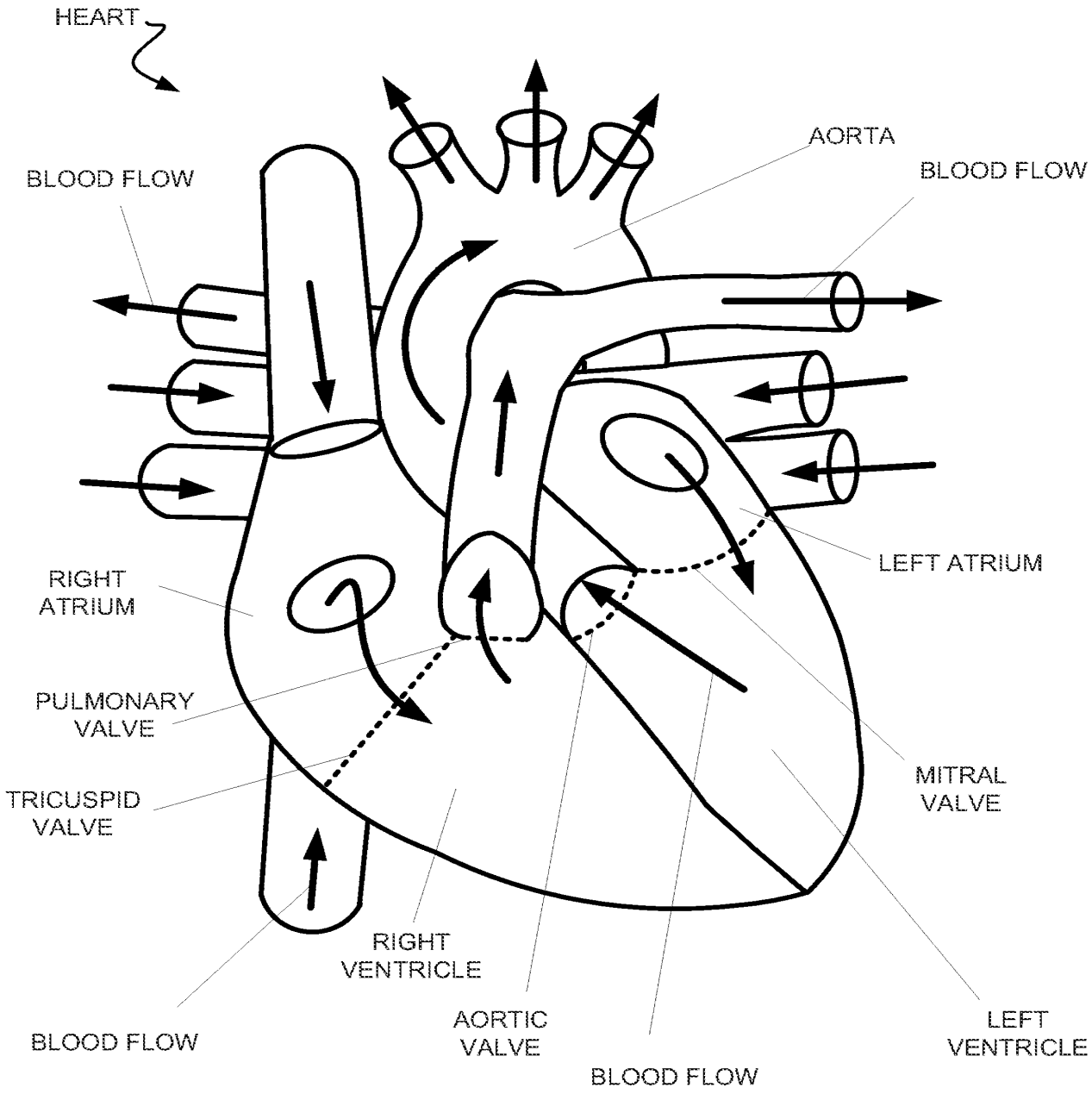


FIG.14

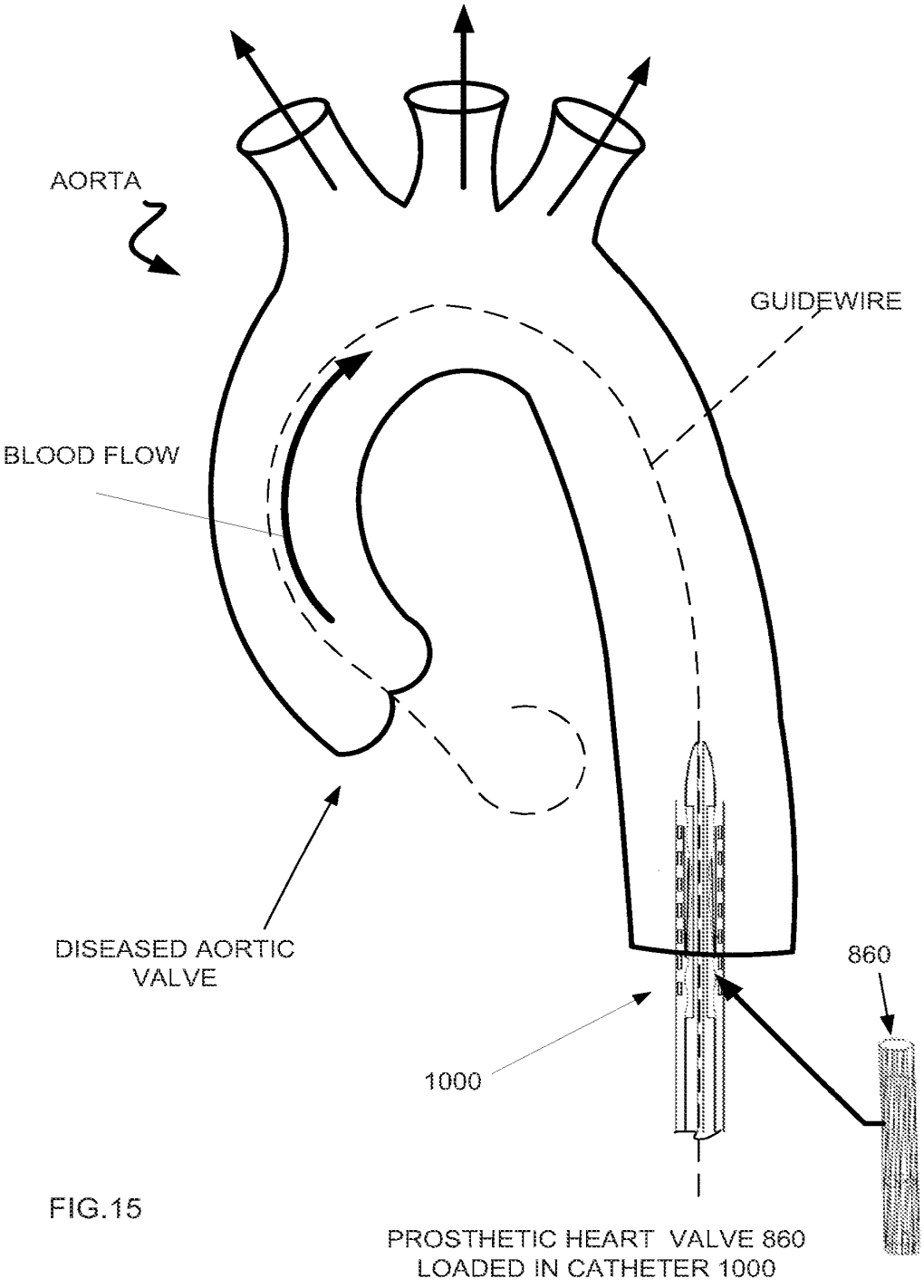


FIG.15

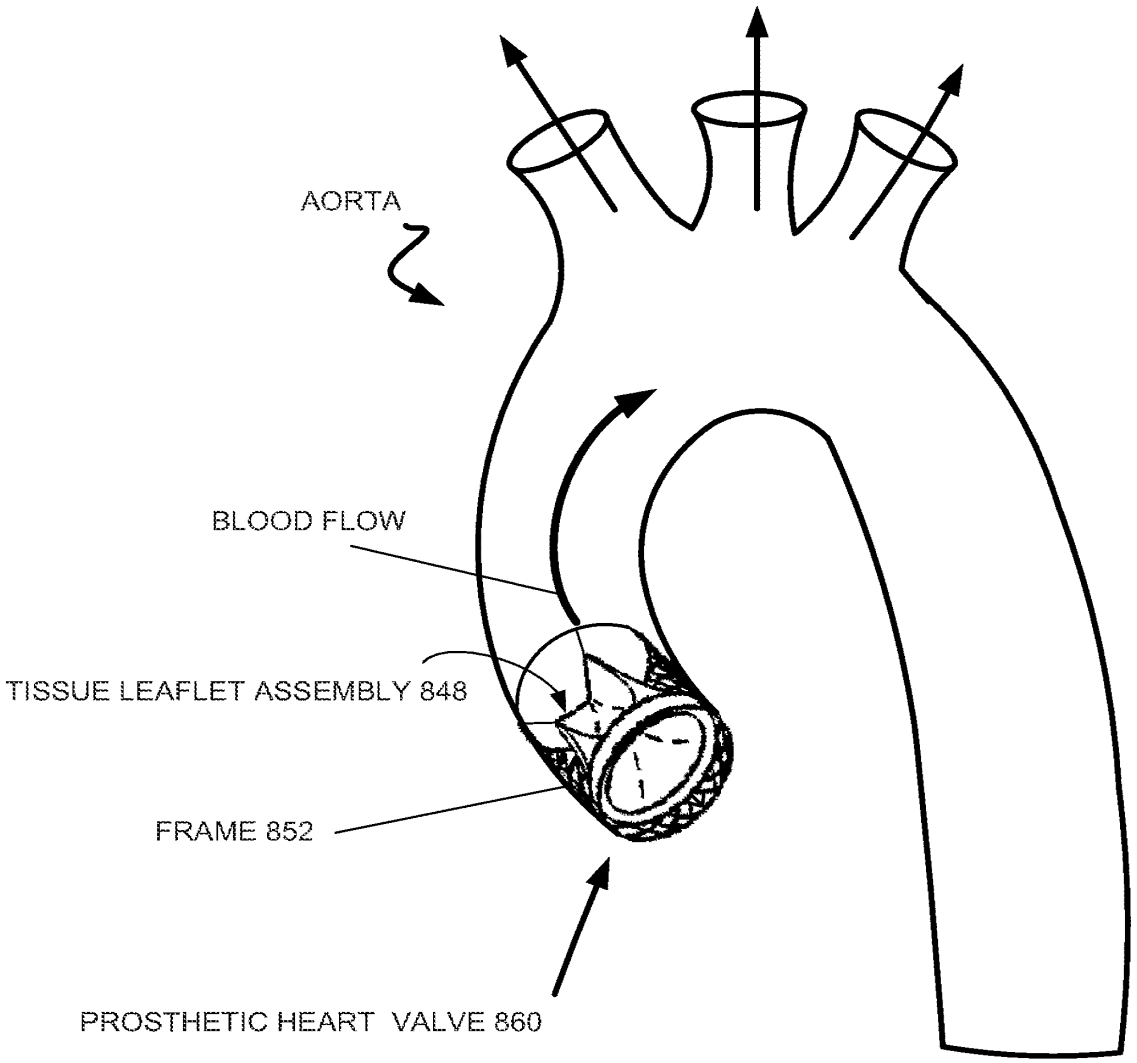


FIG. 16

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 January 2012 (12.01.2012)

PCT

(10) International Publication Number
WO 2012/006124 A2

(51) International Patent Classification:
A61M 25/10 (2006.01) *A61M 25/06* (2006.01)
A61M 25/01 (2006.01) *A61M 29/02* (2006.01)
A61M 25/088 (2006.01)

(21) International Application Number:
PCT/US2011/042252

(22) International Filing Date:
28 June 2011 (28.06.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/359,242 28 June 2010 (28.06.2010) US

(71) Applicant *(for all designated States except US)*: **VELA BIOSYSTEMS LLC** [US/US]; 2150 W. 6th Ave, Suite M., Broomfield, CO 80020 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **FISH, David, R.** [US/US]; 6349 Vanderbilt Street, Houston, TX 77005 (US).

(74) Agent: **YASKANIN, Mark, L.**; Holme Roberts & Owen LLP, 1700 Lincoln Street, Suite 4100, Denver, CO 80202 (US).

(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, RO, RS, RU, 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, 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**: METHOD AND APPARATUS FOR THE ENDOLUMINAL DELIVERY OF INTRAVASCULAR DEVICES

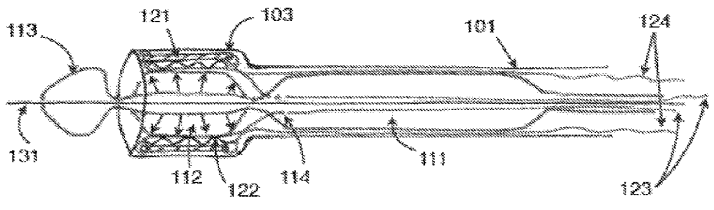


FIG. 4B

(57) **Abstract**: A dual-balloon delivery catheter system includes a carrier segment that is a lead/carrier balloon or mandrel at a distal portion of a catheter. The carrier segment is sequentially arrayed with a more proximally positioned delivery segment, wherein the delivery segment is a delivery balloon or mandrel. The first carrier segment expands the stent-valve a sufficient amount to receive the delivery segment after the carrier segment is moved away from the sent-valve. The delivery segment is then positioned at the target site and the stent-valve is then deployed.

WO 2012/006124 A2

METHOD AND APPARATUS FOR THE ENDOLUMINAL DELIVERY OF INTRAVASCULAR DEVICES

FIELD

Embodiments of the one or more present inventions relate to surgical methods and apparatus in general, and more particularly to surgical methods and apparatus for the endoluminal delivery of intravascular devices to a site within the body.

For the purposes of illustration but not limitation, embodiments of the one or more present inventions will hereinafter be discussed in the context of delivering a percutaneous heart valve to a valve seat located within the heart; however, it should be appreciated that at least one embodiment of the one or more present inventions is also applicable to other endoluminal delivery applications.

BACKGROUND

Percutaneous aortic valves, such as those available from Edwards Lifesciences LLC (Irvine, CA) under the tradename SAPIEN® typically utilize an expandable frame having valve leaflets attached thereto. This expandable frame essentially comprises a stent, with the valve leaflets (preferably in the form of tissue membrane) attached to a portion thereof. For this reason, these percutaneous aortic valves are commonly referred to as "stent-valves". Typically, the percutaneous aortic stent-valve is compressed down upon a deflated balloon catheter, the combined assembly is then inserted into the femoral artery through a covering sheath, and then the combined assembly is delivered endoluminally through the iliac artery and aorta to the valve seat. At the valve seat, the balloon is used to expand the stent so that the stent-valve is set at the valve seat, then the balloon is deflated, and finally the balloon catheter is withdrawn, whereupon the leaflets of the stent-valve act in place of the natural leaflets of the diseased aortic valve.

Percutaneous heart valves of the sort described above currently show great promise, particularly for elderly and/or otherwise infirm patients who cannot tolerate the trauma of conventional open heart valve replacement procedures.

Unfortunately, current percutaneous heart valve systems require the use of relatively large delivery/deployment apparatus. More particularly, since the internal balloon must be capable of expanding the stent portion of the stent-valve to the full size of the natural valve seat, and since the deflated size of a balloon having this full-expansion capability is relatively large, and since the stent-valve must be disposed circumferentially outboard of the balloon, the overall size of the delivery/deployment apparatus is necessarily large. By way of example but not limitation, the Edwards SAPIEN® delivery/deployment apparatus is typically approximately 7 to 8 mm in diameter.

Clinically, this can present a significant problem for the surgeon, since the preferred access to the vascular system of the patient is via the femoral artery, with subsequent delivery to the aortic valve seat via the iliac artery and aorta. However, the femoral artery is typically only about 5 to 8 mm in diameter, and this 5-8 mm range is for the general population as a whole - elderly female patients, who are expected to make up a substantial percentage of the candidate population for percutaneous aortic valve replacement, are on the smaller end of this range (e.g., perhaps 5-6 mm in diameter). Thus, it can be difficult or even impossible to pass the 7-8 mm (diameter) SAPIEN® device through the 5-6 mm (diameter) femoral artery of an elderly female patient, particularly where the femoral artery is tortuous, stenotic and/or occluded. Surgical incision has sometimes been required in order to gain access to a higher level of the ilio-femoral artery (e.g., within the pelvis) that is large enough to accommodate the stent-valve assembly. However, this approach is generally more invasive, and often leads to complications such as substantial bleeding and artery obstruction.

Referring now to Fig. 1, a schematic side view of a catheter-deliverable device, or stent-valve, known in the prior art is shown. The stent-valve may have an expanded diameter of approximately 25 mm. However, the stent-valve can be compressed to approximately 4 mm in diameter. As shown in Fig. 2, to achieve expansion of the stent-valve, it may be mounted on a typical prior art large-diameter delivery balloon catheter that is inflatable to a diameter of 25 mm. However, the combined diameter of the stent-valve mounted on to the large-diameter delivery balloon catheter is perhaps 18 Fr or 6 mm, which is too large to insert into some patient's femoral artery.

For the foregoing reasons, there is a substantial need for a new and improved method and apparatus for the endoluminal delivery of intravascular devices to a site within the body.

SUMMARY

It is to be understood that embodiments of the one or more present inventions include 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.

When first considered, a solution associated with the difficulty of placing a stent-valve in a relatively small femoral artery appears to be use of a small delivery device. Accordingly, a small-diameter delivery balloon initially appears to address the problem. However, and with reference now to Fig. 3, if a small diameter delivery balloon catheter is used, then while the stent-valve can be compressed to a relatively small diameter, the small-diameter delivery balloon is incapable of fully expanding the stent-valve to 25 mm; that is, a small diameter

delivery balloon may only be capable of expanding the stent-valve to approximately 10 mm in diameter, for example.

At least one embodiment of the one or more present inventions addresses the aforementioned problems associated with the prior art by providing a novel method and apparatus for the endoluminal delivery of intravascular devices to a site within the body, at least one embodiment of the one or more present inventions takes advantage of the principle of dividing the volume of the stent-valve delivery apparatus into smaller diameter parts for separate insertion into the vascular system of a patient (e.g., into a relatively small diameter access vessel such as the femoral artery) and then re-assembling those parts within another portion of the vascular system of the patient (e.g., in a larger diameter vessel such as the aorta) which can accommodate the full size of the assembled components. By dividing the balloon expansion task into two serially-deployed balloons, activated in a staged fashion, the stent-valve can be delivered with a smaller profile, yet full stent-valve expansion at the valve seat can be ensured. Accordingly, novel devices and methods are proposed that involve transfer of a deliverable device, such as a stent-valve, after insertion into the body from its "carrier segment" to another "delivery segment" which may reside on the same or separate catheters, and deployment of the stent-valve from that "delivery segment" that is capable of expansion to suitable diameter for the stent-valve.

In at least one embodiment of the one or more present inventions, the stent-valve can be pre-mounted within a packaged pre-assembled delivery system for ready transport and clinical use.

In a first preferred form of the one or more present inventions, the first "carrier" balloon and second "delivery" balloon are mounted on separate inserter elements for independent delivery to the larger blood vessel, such as the aorta, where the second "delivery" balloon is united with the then-partially-expanded stent-valve – in this form, each balloon is independently advanced to the aorta via its own inserter element.

In a second preferred form of the one or more present inventions, the first and second balloons are serially disposed on a single inserter element, with the first "carrier" balloon being mounted to the inserter element distal to (or, optionally, more proximal to) the second "delivery" balloon – in this form, a single inserter element is used to sequentially position the first "carrier" balloon and second "delivery" balloon relative to the stent-valve.

In a third preferred form of the one or more present inventions, the first "carrier" balloon and second "delivery" balloon are mounted on separate inserter elements, but these inserter elements are arranged in a co-axial fashion so as to permit a telescoping action between the two inserter elements (and hence a telescoping action between the first "carrier" balloon and the

second "delivery" balloon). In this form, the first "carrier" balloon shaft, being coaxially mounted upon a leading guide wire, can act as something of a firmer guidewire for the second "delivery" balloon.

In addition to the foregoing, after initial expansion of the stent-valve via the first "carrier" balloon, the first "carrier" balloon catheter can be removed and replaced by a shaped catheter element in order to provide guidance and assistance in traversing the central arteries and crossing the plane of (and, optionally, preparing) the native valve seat. This shaped catheter element can be disposed on an inserter element distal to the second "delivery" balloon or to the first carrier balloon, if desired.

If desired, the first "carrier" balloon can alternatively be another expandable device, e.g., the first "carrier" balloon (which constitutes the mounting segment for the stent-valve) can be an expandable mandrel. Alternatively, the stent-valve may be initially mounted on a non-expanding element, that is, simply a low-profile mandrel or other segment of the delivery catheter.

It should be appreciated that while at least one embodiment of the one or more present inventions has sometimes been discussed in the context of delivering a stent-valve to the aortic valve seat, it may also be used to deliver other valves to other valve seats, and/or for delivering other intravascular devices to other sites within the body.

It should also be appreciated that while at least one embodiment of the one or more present inventions is sometimes discussed in the context of advancing the stent-valve through the arterial system of the body, it may also be used to advance the stent-valve through the venous system of the body, or to endoluminally advance a device through some other luminal system of the body.

In at least one embodiment of the one or more present inventions, the covering sheath (through which the various components are advanced into the blood vessel) can be flexible and expandable so as to allow initial expansion of the stent-valve, and the exchange of the first "carrier" balloon and the second "delivery" balloon within the covering sheath, so that the apparatus is continuously protected.

It will be seen that at least one embodiment of the one or more present inventions provides a novel method and apparatus for the endoluminal delivery of an intravascular device to a site within the body.

Accordingly, at least one embodiment described herein is directed to a stent-valve and delivery system that is inserted separately into the femoral artery, then assembled inside the aorta, and thereafter advanced for deployment at the valve plane. This means that the limiting size of the artery (or vein, for the pulmonary valve) access diameter is determined by the largest

single piece of the system - effectively the stent/valve itself. When the stent/valve is compressed without the balloon catheter, it is possible to deliver a valve into the circulation in as small as 14 French sheath rather than an 18 to 24 French, as has previously been achieved.

In at least one embodiment, an in-line dual-balloon delivery catheter system includes a carrier segment that is a lead/carrier balloon or mandrel at the distal portion of a catheter with the carrier segment arrayed in-line on a catheter shaft with a more proximally positioned delivery segment together at the distal portion of the catheter shaft. In essence, since the first "carrier" balloon only needs to expand the stent-valve a sufficient amount to receive the deflated second "delivery" balloon, the first "carrier" balloon can be quite small in its deflated condition. Moreover, the stent-valve, unrestricted by the traditional need for mounting on a single, relatively large deployment balloon, can be compressed to its minimum structural diameter for mounting on the relatively small first "carrier" balloon. As a result, the combined assembly (i.e., of carrier balloon catheter and stent-valve) can be much smaller in diameter than previous delivery devices at the time of accessing the vascular system of the patient. At the same time, by thereafter uniting the stent-valve with the second, larger "delivery" balloon, sufficient stent expansion can be provided to ensure secure valve seating.

In at least one embodiment, a woven wire "stent" with or without sheath investment is provided wherein its length is coupled to diameter. Nitinol or another alloy wire is formed in an expanded sheath shape and compressed by traction on trailing wire ends. At the point of the procedure requiring distal sheath expansion, the traction is released to allow expansion to a mechanically biased open position. Alternatively, traction wires may be attached to a distal end of the wire weave within the sheath and a traction force, there applied, causes simultaneous expansion and shortening of the distal end of the sheath, thereby advantageously releasing the underlying mounted stent-valve and exposing it for deployment.

In at least one embodiment a mechanism is provided for retaining a stent-valve frame on a delivery balloon by magnetic or electromagnetic means. The frame is preferably constituted of or contains ferrous metal elements. By such means, a stent-valve can be securely advanced through the vascular system without need for a covering sheath, thereby simplifying the delivery procedure and the system. The stent-valve is retained on the balloon segment by magnetic force.

In at least one embodiment, a device that utilizes magnetic force to deploy and, if desired, later retrieve a stent-valve is provided, the device using a magnetic force set at a level to permit ready balloon expansion of a stent-valve at a plane of the diseased native valve. As the frame of the stent-valve is pushed away from the magnet, retention force weakens, thereby allowing unimpeded final device expansion. A stronger magnet/electromagnet mounted on a separate catheter can be used to retrieve or reposition the stent-valve. In addition, a strong

magnet mounted on a retrieval catheter can be used to retract the stent-valve frame from the native valve seat.

For the purposes of illustration but not limitation, embodiments of the one or more present inventions are hereinafter discussed in the context of delivering a prosthetic stent-valve to the aortic valve seat; however, it should be appreciated that at least one embodiment of the one or more present inventions is also applicable to other endoluminal delivery applications.

Accordingly, in at least one embodiment, a system for providing endoluminal delivery of a deliverable device through vasculature of a patient to a delivery site within the patient is provided, the system comprising:

an outer delivery sheath including a distal section, wherein at least a portion of the outer delivery sheath is sized for insertion into the vasculature of the patient;

a carrier segment located at a distal portion of a catheter shaft, the carrier segment having an outer surface sized to temporarily hold the deliverable device in the distal section of the outer delivery sheath, wherein at least a portion of the catheter shaft is located within and coaxial to the outer delivery sheath; and

a delivery segment located coaxial to the outer delivery sheath, the delivery segment having an outer surface sized to radially fit within the deliverable device after detaching the deliverable device from the carrier segment when the deliverable device resides within the distal section of the outer delivery sheath, wherein the delivery segment is configured to deploy the deliverable device at the delivery site.

In addition to the foregoing, in at least one embodiment at least a portion of the distal section of the outer delivery sheath is expandable. In at least one embodiment, the at least a portion of the distal section of the outer delivery sheath comprises one or more electrically activated elements. In at least one embodiment, the at least a portion of the distal section of the outer delivery sheath comprises one or more piezo-ceramic elements. In at least one embodiment, the at least a portion of the distal section of the outer delivery sheath comprises a passively expandable material that is expandable upon application of an outward radial force applied by at least one of the carrier segment and the delivery segment. In at least one embodiment, the at least a portion of the distal section of the outer delivery sheath expands upon application of a tensile force to the at least a portion of the distal section.

In at least one embodiment, the distal section includes at least one of an internal projection and a narrowed area extending radially inward from an interior surface of the distal section.

In at least one embodiment, a portion of an internal surface of the outer delivery sheath further comprises a guide for retaining at least a portion of a longitudinally extending element

configured to selectively manipulate at least a part of the outer delivery sheath or a structure coaxial to the outer delivery sheath. In at least one embodiment, a portion of an internal surface of the outer delivery sheath further comprises a guide, the guide comprising at least one of:

(a) a lumen; and

(b) a grommet;

wherein the guide retains at least one control line for selective retention of the deliverable device.

In at least one embodiment, the carrier segment and the delivery segment are both situated upon the catheter shaft. In at least one embodiment, the carrier segment is situated upon the catheter shaft, and wherein the delivery segment is associated with a delivery segment shaft that is coaxial to the catheter shaft and axially moveable relative to the catheter shaft. In at least one embodiment, the carrier segment is an expandable balloon having an expanded diameter smaller than an expanded diameter for the delivery segment. In at least one embodiment, the delivery segment is an expandable balloon having an expanded diameter larger than an expanded diameter for the carrier segment. In at least one embodiment, at least one of the carrier segment and the delivery segment is a mandrel. In at least one embodiment, the mandrel is expandable by mechanical or electromechanical means. In at least one embodiment, the mandrel is not expandable.

In at least one embodiment, the delivery segment is located axially proximal to the carrier segment. In at least one embodiment, the delivery segment is located axially distal to the carrier segment.

In at least one embodiment, one or both of the carrier segment and the delivery segment include at least one magnet or electromagnet to aid manipulation of the deliverable device.

In at least one embodiment an assembly for intravascular delivery of a deliverable device to a delivery site within a patient is provided, comprising:

a first catheter including a first catheter shaft;

a carrier segment situated along the first catheter shaft, the carrier segment configured to receive the deliverable device prior to inserting the first catheter within the patient; and

a delivery segment sequentially positioned in an axial orientation relative to the carrier segment, wherein the delivery segment is configured to engage the deliverable device within the patient while the deliverable device is coaxial to at least a portion of the first catheter, and wherein the delivery segment is configured to thereafter deploy the deliverable device at the delivery site.

[0037] In at least one embodiment, the delivery segment is also situated along the first catheter. In at least one embodiment, the delivery segment is situated along a second catheter, the second catheter comprising a coaxial lumen through which passes the first catheter. In at least one embodiment, at least one of the first catheter and the second catheter comprise a curved distal portion.

One or more embodiments of the one or more present inventions also pertain to methods of delivering a device, such as a stent-valve, within a patient. Accordingly, in at least one embodiment, a method of delivering a deliverable device through vasculature of a patient to a target site within the patient is provided, comprising:

mounting the deliverable device on a selectively expandable carrier segment located along a catheter shaft, wherein at least a portion of the catheter shaft is located within and coaxial to an outer delivery sheath;

inserting the outer delivery sheath and catheter shaft into the patient;

moving the outer delivery sheath within the patient to position the selectively expandable carrier segment and the deliverable device near the target site;

partially expanding the deliverable device using the selectively expandable carrier segment while the deliverable device remains at least partially within the outer delivery sheath;

positioning a delivery segment radially within the deliverable device and partially expanding the delivery segment to facilitate engagement of the delivery segment with the deliverable device;

moving the delivery segment and deliverable device to the target site; and

deploying the deliverable device at the target site by further expanding the delivery segment.

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 at least one embodiment of the one or more present inventions 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. 1 is a schematic side view of a catheter-deliverable device frame (or stent-valve) known in the prior art;

Fig. 2 is a schematic side view of a typical prior art large-diameter delivery balloon catheter in a deflated state;

Fig. 3 is a schematic side view of a small-diameter delivery balloon catheter in a deflated state;

Fig. 4A is a side view of an in-line dual balloon delivery system in accordance with at least one embodiment of the one or more present inventions;

Fig. 4B is a side view of the system shown in Fig. 4A, wherein the carrier balloon is dilated to partially expand a stent-valve to accommodate the larger delivery balloon (catheter inflation ports, lumens, wire lumens not shown for clarity);

Fig. 4C is a side view of the system shown in Fig. 4B, wherein the deflated carrier balloon is advanced out of the partially expanded valve device as the delivery balloon is advanced into the stent-valve to "capture" or "dock" with the stent-valve;

Fig. 4D is a side view of the system shown in Fig. 4C, wherein the carrier balloon is optionally inflated to facilitate crossing the plane of the diseased heart valve with the delivery system, and wherein the delivery balloon is positioned astride the stent-valve to capture and subsequently deploy the stent-valve;

Fig. 4E is a side view of the system shown in Fig. 4D, wherein after the stent-valve is positioned in the plane of the heart valve, the sheath is withdrawn to expose the stent-valve in place at the heart valve seat and to allow for deployment if the stent-valve by expansion;

Fig. 4F is a side view of the system shown in Fig. 4E, wherein with the stent-valve is positioned at the valve seat and the sheath withdrawn, and wherein the delivery balloon then expanded to deploy the stent-valve;

Fig. 5A is a side view of a catheter delivery system in accordance with another embodiment of the one or more present inventions, wherein a carrier balloon shaft passes through a central coaxial lumen of a delivery balloon (wherein the wall of central lumen is omitted for clarity);

Fig. 5B is a side view of the system shown in Fig. 5A, wherein partial inflation of the leading carrier balloon may be used as a "nose cone" to facilitate insertion of the delivery catheter into a patient's artery;

Fig. 5C is a side view of the system shown in Fig. 5B, wherein full inflation of the leading carrier balloon partially expands the stent-valve within an expandable sheath segment;

Fig. 5D is a side view of the system shown in Fig. 5C, wherein at "(1)" the leading carrier balloon is deflated and advanced out of the stent-valve, and wherein at "(2)" the delivery balloon is advanced into position within stent-valve to "dock" with or "capture" the stent-valve;

Fig. 5E is a side view of the system shown in Fig. 5D, wherein the leading carrier balloon and guidewire are first advanced into the left ventricle (in the case of implantation in the native aortic valve seat), and wherein the leading carrier balloon shaft then acts as a guide rail for delivery of the balloon catheter;

Fig. 6A is a side view of an embodiment of a sheath, wherein traction elongates the sheath weave and reduces its diameter, and wherein release of the traction shortens/retracts the sheath weave and expands its diameter;

Fig. 6B is a side view of an embodiment of a cut shape memory alloy stent (nitinol) within a sheath wall investment that expands as a contained balloon and/or stent-valve (omitted for clarity) is expanded therein and self-contracts as the balloon is deflated;

Fig. 6C is a side view of an embodiment of a plastic material sheath that passively expands;

Fig. 6D is a side view of an embodiment of electrically actuated piezo-ceramic (p-c) elements sealed within an elastic sheath wall, wherein each p-c element is connected by a conductor pair to a voltage controlled power source, wherein a switch engages a power source, and wherein p-c elements expand the sheath when electrically energized;

Fig. 6E is a perspective view of an embodiment of actuator elements that utilize differential alloy laminates, wherein an application of current induces bend in the actuator;

Fig. 7 is a side view of an embodiment of a device for retaining a stent-valve on a delivery balloon by magnetic or electromagnetic means (for Figs. 7-8B, conductors and a power source for electromagnet are not shown; the valve membrane or other valve mechanism is not shown; the balloon inflation lumen and optional control lines/harness are omitted for clarity);

Fig. 8A is a side view of an embodiment of a retrieval catheter device that utilizes magnetic force to retrieve a stent-valve;

Fig. 8B is a side view of a stent-valve wherein the stent-valve is contracted by magnetic force and thereafter can be retracted from the native valve seat by optional control lines or a harness;

Fig. 8C is a side perspective view of an embodiment of a multipolar magnetic retrieval catheter system; and

Fig. 8D is an end view of the system shown in Fig. 8C positioned radially within a stent-valve.

For the figures presented herein, balloons in a collapsed state are depicted as partially expanded to emphasize the difference in sizes. In addition, balloon catheter wire lumen and inflation lumens are omitted for clarity.

The drawings are not necessarily to scale.

DETAILED DESCRIPTION

Overview

In general, at least one embodiment of the one or more present inventions uses a serial approach for delivering and deploying the percutaneous aortic valve at the valve seat. This serial approach allows various components of the combined assembly (i.e., the various components of the balloon catheter and the stent-valve) to be separately introduced into the vascular system of the patient, each with its own minimized profile, so as to facilitate a low-profile endoluminal delivery of the system components into the large central blood vessels (e.g. the aorta) where, in a preferred sequence, these components are co-axially re-assembled prior to advancement to the target valve seat. As a result, at least one embodiment of the one or more present inventions facilitates femoral artery access to the aortic valve seat, even with patients having small femoral artery diameters (e.g., elderly female patients). In other words, since the various components of the system are not fully assembled at the time of insertion into the vascular system of the patient, and are only fully assembled at some point subsequent to insertion (e.g., within a larger diameter blood vessel upstream (farther inward) of the insertion site), a relatively large access vessel is no longer necessary - thereby making percutaneous heart

valve therapy available for a larger patient population and with a lower risk of access site and blood vessel complications. By way of example but not limitation, where the intravascular device comprises an aortic stent-valve, the various components of the system can be easily introduced into a relatively narrow femoral artery and thereafter assembled in a larger upstream (farther inward) vessel (e.g., in the relatively wide aorta) before being advanced to and seated at the native aortic valve seat.

More particularly, at least one embodiment of the one or more present inventions preferably utilizes two separate balloons for a staged deployment of the stent-valve: a first, smaller-diameter "carrier" balloon for initial stent expansion (e.g., for preliminarily expanding the stent while the stent-valve is disposed in the descending aorta), and a second, larger-diameter "delivery" balloon for ultimate stent seating at the native valve seat. In one preferred form of at least one embodiment of the one or more present inventions, the stent-valve is mounted on the deflated first, smaller-diameter "carrier" balloon, then this relatively small assembly is introduced (within a covering sheath) into the relatively small femoral artery, advanced through the femoral artery, up through the iliac artery, and then into the relatively large descending aorta. The first, smaller-diameter "carrier" balloon is then inflated so as to expand the stent-valve to an intermediate diameter configuration that is large enough in diameter to receive the deflated second, larger-diameter "delivery" balloon. The first "carrier" balloon is then deflated, the first "carrier" balloon is withdrawn and replaced by the deflated second "delivery" balloon which, by partial inflation or other means, captures the stent-valve, and the assembly is then advanced up the descending aorta, ascending aorta, etc. to the native valve seat. The second "delivery" balloon is then inflated so as to set the stent-valve at the valve seat. Finally, the second "delivery" balloon is deflated and withdrawn from the surgical site.

In-line Dual-Balloon Catheter Delivery System

With reference now to Figs. 4A-4F, a stent-valve 120 may be advanced upon a first, smaller-diameter "carrier" balloon to the aorta and initially deployed (using the first, smaller-diameter "carrier" balloon) to an intermediate size, followed by co-axial exchange for the second, larger-diameter "delivery" balloon for advancement to the valve seat, and then further expansion of the stent-valve 120 at the valve seat. Alternatively, the stent-valve 120 may be advanced upon the carrier balloon all the way to the target valve seat and initially deployed before coaxial exchange for the delivery balloon and subsequent final expansion.

Referring now to Fig. 4A, an integrated system is shown in the form of an in-line dual-balloon delivery catheter system 100 that features an in-line dual-balloon catheter configuration. The configuration shown in Fig. 4A illustrates the in-line dual-balloon delivery catheter system 100 as it is being translated through the patient's body toward the target valve seat, such as the

aortic valve. For the in-line dual-balloon delivery catheter system 100 described herein, the carrier segment 112 is a lead/carrier balloon or mandrel at the distal portion of a catheter with the carrier segment 112 arrayed in-line on a catheter shaft with a more proximally positioned delivery segment 111 together at the distal portion of the catheter shaft. Alternatively, the delivery segment may be positioned distal to the carrier segment. The carrier segment 112 and delivery segment 111 are, for the case of the balloon-expandable stent-valve 120 example in this discussion, expandable balloons, for example, but may also be mandrels or expandable mandrels.

Here, it is noted that, in at least one embodiment (including both the in-line dual-balloon delivery catheter system 100 and the telescoping delivery system 200), a delivery segment comprising a delivery mandrel can be non-expanding. By way of example and not limitation, the means by which the delivery segment retains the stent-valve may vary. For example, in addition to friction, the delivery segment may retain the stent-valve by use of magnetic force. For such an assembly, if the stent-valve (or other deliverable device) is self-expanding or actuated to expansion and retained on the delivery segment for release by some other means (electronic, heat, e.g.), then the delivery mandrel can be non-expanding.

For the configuration shown in Fig. 4A, an outer delivery sheath 101 having, for example, a lengthwise body 104 that is 14 French inside diameter, is coaxially situated over a guidewire 131, for example, a 0.035 inch diameter wire, whereupon the integrated pair of expandable balloons reside. It is noted that all sizes and material types presented herein are exemplary and are not intended to be limiting, nor should they be interpreted as limiting, unless otherwise claimed. Although not required, an optional nose cone 113 may be positioned distally of the carrier segment 112 to assist with insertion of the catheter into the artery and subsequent traverse through it. In the embodiment wherein the delivery segment is disposed distal to the carrier segment, said nose cone is positioned immediately distal to the delivery segment and approximated to the tip of the sheath. The carrier segment 112 is used to hold the stent-valve 120 in place within the outer delivery sheath 101 and provide initial expansion of the stent-valve 120. Thereafter, the delivery segment 111 is used to provide final expansion of the stent-valve 120 for deployment of the stent-valve 120 at the valve seat.

The in-line dual-balloon delivery catheter system 100 is assembled external to the body by passing the delivery catheter with its linearly arrayed carrier segment 112 and delivery segment 111 within the central coaxial lumen of the delivery sheath 101 such that the carrier segment 112 of the catheter extends and is fully exposed beyond the distal terminal opening of the delivery sheath 101. The catheter-deliverable device, such as the stent-valve 120 in this example, is then coaxially mounted upon the carrier segment 112 by collapsing and compressing

it onto the carrier segment 112 such that friction between the two retains the device 120 upon the carrier segment 112. The carrier segment 112 with the catheter-deliverable device (stent-valve 120) mounted upon it is then retracted back (proximally) into the distal portion of the delivery sheath 101 so that the device is completely covered within the sheath 101. In some cases the tip of the carrier segment 112 may be extended beyond the end of the sheath. In such a case, partial expansion of the leading tip 113 of the carrier segment 112 (balloon or expandable mandrel) may be used to form the tapered "nose cone" as noted above, to facilitate advancement or insertion of the delivery system into the blood vessel. Alternatively, the carrier segment may be fabricated with a soft plastic tapered tip for this purpose.

In the example of retrograde (in relation to blood flow) passage of the delivery system carrying the catheter-deliverable device, initial guidance for passage of the delivery system is established by advancement of the guidewire 131 across the heart valve seat 141 into the upstream anatomic chamber, such as the left ventricle, there acting as a guiding rail for the coaxial advancement of the delivery system catheters. Then, at a point external to the body, by inserting the guide wire 131 into the distal tip of the carrier segment 112 of the delivery catheter, the assembled in-line dual-balloon delivery catheter system 100 with sheath 101 is then advanced into the body coaxially over the guidewire 131 to a position proximate to but short of the target anatomic site--in this case, the diseased heart valve seat 141.

Referring now to Fig. 4B, when in the aorta, the leading carrier segment 112 is expanded as by balloon inflation, thus partially expanding the catheter-deliverable device (stent-valve 120) within the expandable distal segment 103 of the delivery sheath 101. That is, the carrier segment 112 is used to pre-dilate the stent-valve 120 so that the diameter of the stent-valve 120 is sufficient to accept the delivery segment 111 when the delivery segment 111 is at least partially deflated or not fully expanded. The outer delivery sheath may include an expandable and flexible distal segment to accommodate the partially expanded stent-valve 120 and hold the partially expanded stent-valve 120 in place. The carrier segment 112 is then contracted as by balloon deflation and advanced by advancing the delivery catheter out of the catheter-deliverable device (stent-valve 120) that is retained within the expanded distal segment 103 of the sheath 101. Optional shallow flanges 102 on the internal surface of the sheath 101 immediately proximal and/or distal to the mounted position of the device 120 can be used to assist in retention of the device during movement relating to the exchange of the carrier segment 112 for the delivery segment 111 with the advance of the delivery catheter. Alternatively, retention or control lines 123, 124 of wire or suture material may be attached to the device 120, as on the frame 121 of the stent-valve 120. Other forms of retaining force may be advantageously

applied, such as by incorporating magnetic or electromagnetic elements within the delivery catheter shaft or within the sheath wall.

Referring now to Fig. 4C, as the delivery catheter 110 is thus advanced, the delivery segment 111 integrated thereupon thus is also advanced within the sheath 101 to a position astride the catheter-deliverable device (stent-valve 120) within the delivery sheath 101, with the tip of the delivery catheter extended beyond the tip of the delivery sheath 101. More particularly, the delivery segment 111 is advanced axially to a position radially interior to the stent-valve 120. The delivery segment 111 is then partially expanded to contact the stent-valve 120.

Referring to Fig. 4D, with the delivery segment 111 positioned within the stent-valve 120, in at least one embodiment the carrier segment 112 is positioned at the valve seat and may be further expanded to facilitate advancement of the stent-valve 120 within the plane of the aortic valve. That is, if deemed desirable by the surgeon, the carrier segment 112 is temporarily expanded and then contracted or deflated within the plane of the valve seat to facilitate subsequent axial advancement of the delivery segment 111 that carries the stent-valve 120.

With the projected tip of the delivery segment, and beyond that the carrier segment leading, the delivery catheter, catheter-deliverable device (stent-valve 120), and delivery sheath 101 are advanced together as a unit across the target anatomic plane (native heart valve seat 141, for example) to a position astride the target plane deemed suitable for deployment of the catheter-deliverable device (stent-valve 120). In the embodiment wherein the carrier segment is disposed proximal to the delivery segment this advancement occurs with the tip of the delivery segment leading the catheter assembly, and the carrier segment further proximal within the sheath. Referring now to Fig. 4E, after the delivery segment 111 is positioned in the plane of the target valve seat, the outer delivery sheath of the delivery system is withdrawn (as shown by the arrows in Fig. 4E) to expose the stent-valve 120; however, the stent-valve 120 remains undeployed because it continues to remain attached to the delivery segment 111. That is, the delivery sheath 101 is coaxially retracted with the delivery catheter held in place so as to expose the catheter-deliverable device (stent-valve 120) retained upon the delivery segment 111 at the site of deployment. The catheter-deliverable device (stent-valve 120) is then deployed by expansion of the delivery segment 111, such as by balloon inflation. Accordingly, and referring now to Fig. 4F, after the stent-valve 120 is exposed at the plane of the aortic valve, the delivery segment 111 is expanded to deploy the stent-valve 120. With full expansion and deployment of the catheter-deliverable device (stent-valve 120) the device is retained within the target anatomic plane (native heart valve seat 141). The delivery segment 111 is then contracted as by balloon deflation, function of the deployed device is confirmed, and the delivery catheter, delivery

sheath 101, and guidewire 131 are retracted from the anatomic target area and removed from the body to complete the procedure.

In at least one embodiment, optional retention/control lines 123, 124 are released from valve frame 121 after successful deployment of stent-valve 120 is confirmed. Then balloon catheter 110 and guidewire 131 are removed from the valve seat 141 and withdrawn into sheath 101 for removal from the body.

In at least one embodiment, the carrier segment 112 is located axially proximal to the delivery segment 111. For such a configuration, the delivery segment 111 is advanced outside the sheath 101 and leads the assembly until the point the exchange is made. Then after the stent-valve 120 is partially expanded by the carrier segment 112, the delivery segment 111 is pulled back into the sheath 101 where the stent-valve 120 is retained, and the delivery segment 111 then captures the stent-valve 120. In this case, the tip of the delivery segment 111 at the tip of the sheath 101 will lead the further advance while the carrier segment 112 is sequestered more proximally in the sheath 101.

Telescoping Catheter Delivery System

Referring now to Figs. 5A-5E, in an alternative embodiment, a telescoping delivery system 200 for a stent-valve 120 is provided wherein a delivery balloon catheter 210 is co-axially situated or "threaded" over a carrier balloon catheter shaft 224 associated with a carrier segment 221. Accordingly, the carrier segment 221 can be advanced axially independent of the axial position of the delivery balloon 211. As a result, the carrier segment shaft 224 acts as a guide rail for the delivery balloon catheter 210 and the stent-valve 120 that is then radially positioned exterior to the delivery balloon 211. Step-by-step illustrations are provided in the drawings and are described in the following paragraphs.

Referring now to Fig. 5A, an outer delivery sheath 101 having, for example, a proximal shaft body with a 14 French inside diameter, is coaxially situated over a guidewire 131, whereupon a carrier segment shaft 224 and a delivery balloon shaft 214 are also co-axially situated. For the embodiment of the telescoping delivery system 200 described, the carrier segment 221 is a carrier balloon or mandrel at a distal portion of a carrier catheter 220 that is passed within the central lumen of a larger delivery catheter 210 that has a delivery segment 211 at its distal portion. By way of example and not limitation, the carrier segment shaft has a 0.035 inch outer diameter and is connected to the carrier segment 221 that is expandable to between 5-10 mm in diameter. The delivery segment 211 is, for the case of the balloon-expandable stent-valve 120 example, an expandable delivery balloon, for example. Accordingly, the delivery balloon may have an outside diameter of, for example, approximately 12-14 French when

uninflated, and, in separate embodiments, is located axially either proximal or distal to the carrier segment 221.

The system is assembled external to the body by passing the carrier catheter 220 within the central coaxial lumen of the larger delivery catheter 210 such that the carrier segment 221 extends and is fully exposed beyond the tip 212 of the delivery catheter. These two catheters thus joined are then passed together through the delivery sheath 101 such that the carrier segment 221 of the carrier catheter 220 again extends and is fully exposed beyond the tip of the delivery sheath 101. The catheter-deliverable device, such as the stent-valve 120 in this example, is then coaxially mounted upon the carrier segment 221 by collapsing and compressing it onto the carrier segment 221 such that friction between the two retains the device 120 upon the carrier segment 221. The carrier segment 221 with the catheter-deliverable device (stent-valve 120) mounted upon it is then retracted back (proximally) into the delivery sheath 101 so that the device is completely covered within the sheath 101.

Referring now to Fig. 5B, the lead carrier segment balloon 221 optionally may be partially expanded to hold the stent-valve 120 within the outer delivery sheath 101. In addition, in some cases the tip 222 of the carrier catheter and carrier segment 221 may be extended beyond the end of the sheath 101. In such a case, partial expansion of the leading tip 223 of the carrier segment 221 (balloon or expandable mandrel) may be used to form a tapered "nose cone" to facilitate advancement or insertion of the delivery system into the blood vessel. Alternatively, and as previously noted for the in-line dual-balloon delivery catheter system 100, the carrier catheter 220 for the telescoping delivery system 200 may be fabricated with a soft plastic tapered tip for this purpose.

In the example of retrograde (in relation to blood flow) passage of the delivery system carrying the catheter-deliverable device, initial guidance for passage of the delivery system is established by advancement of the guidewire 131 across the heart valve seat 141 into the upstream anatomic chamber, such as the left ventricle, there acting as a guiding rail for the coaxial advancement of the delivery system catheters. Then, at a point external to the body, by inserting the guide wire 131 into the distal tip of the carrier catheter 220, the assembled delivery catheter system 200 with carrier catheter 220, delivery catheter 210 and sheath 101 is then advanced into the body coaxially over the guidewire 131 to a position proximate to but short of the target anatomic site--in this case, the diseased heart valve seat 141.

Referring now to Fig. 5C, in at least one embodiment, when in the aorta the carrier segment 221 is further expanded to effect expansion of the stent-valve 120 within the outer delivery sheath so that the delivery balloon can be advanced axially and positioned radially to the interior of the stent-valve 120. That is, when in the aorta, the leading carrier segment 221 is

expanded, such as by balloon inflation, thus partially expanding the catheter-deliverable device (stent-valve 120) within the expandable distal segment 103 of the delivery sheath 101. In at least one embodiment, the outer delivery sheath 101 includes an expandable, flexible distal segment 103 that allows partial expansion of the stent-valve 120 within the outer delivery sheath, such as to a sufficient diameter to receive the unexpanded delivery balloon 211. Although the distal segment of the outer delivery sheath may be expandable, the outer delivery sheath shaft 104 located axially proximal to the carrier segment 221 preferably remains relatively small in diameter, that is, at its original unexpanded diameter, such as having a 14 French inside diameter at the entry point of the body and blood vessel.

With reference now to Fig. 5D, after partial expansion of the stent-valve 120 within the distal portion 103 of the outer delivery sheath 101, the carrier segment 221 is contracted as by balloon deflation and is then advanced axially beyond the outer delivery sheath 101 and out of the catheter-deliverable device (stent-valve 120) leaving it retained within the expanded distal segment 103 of the sheath 101.

The delivery segment balloon 211 is then axially advanced to a position radially to the interior of the stent-valve 120. With the delivery segment 211 of the delivery catheter 210 then coaxially advanced over the shaft 224 of the carrier catheter to a position astride the catheter-deliverable device (stent-valve 120) within the delivery sheath 101, the delivery segment balloon 211 is then partially expanded to dock or capture the stent-valve 120.

Referring now to Fig. 5E, the leading carrier segment balloon 221 of the carrier catheter 220 is then advanced across the target anatomic plane (native heart valve seat 141) coaxially following the guide wire 131 there in place, where it then provides additional mechanical guidance and support for the further coaxial advancement of the larger delivery catheter 210 upon the shaft 224 of the carrier catheter 220. Alternatively, the carrier catheter 220 may be coaxially withdrawn from the system and the body leaving the guide wire in place , then a shaped catheter (one with specifically designed terminal curves, such as "pig tail" or Amplatz type curves commonly found on angiographic catheters, to facilitate its being properly situated relative to the anatomy) may then be advanced over the guide wire to the upstream anatomic chamber, its shaft then substituting for the shaft 224 of the carrier catheter. Accordingly, Fig. 5E illustrates the guidewire 131 and carrier segment 221 as having passed the aortic valve such that the guidewire and carrier segment reside within the patient's left ventricle. Axial advancement of the carrier segment 221 and the carrier catheter shaft 224 can be done independent of the location of the delivery balloon 211. Thereafter, the delivery segment balloon 211 and the delivery catheter shaft 214 are axially advanced co-axially over the carrier catheter shaft 224 that acts as a guide rail for the delivery segment balloon 211. More

particularly, with the projected tip 212 of the delivery catheter 211 leading beyond the tip of the sheath, the delivery segment 211, catheter-deliverable device (stent-valve 120), and delivery sheath 101 are advanced together as a unit across the target anatomic plane (native heart valve seat 141, for example) to a position astride the target plane deemed suitable for deployment of the catheter-deliverable device (stent-valve 120).

Once positioned at the plane of the valve seat of the patient's aortic valve, the delivery sheath 101 is coaxially retracted with the delivery catheter held in place so as to expose the catheter-deliverable device (stent-valve 120) retained upon the delivery segment 211 at the site of deployment. Thereafter, the final delivery balloon is expanded to deploy the stent-valve 120.

With full expansion and deployment of the catheter-deliverable device (stent-valve 120) the device is retained within the target anatomic plane (native heart valve seat 141). The delivery segment 211 is then contracted as by balloon deflation, function of the deployed device is confirmed, and the delivery catheter, carrier catheter, delivery sheath 101, and guide wire 131 are retracted from the anatomic target area and removed from the body to complete the procedure.

Expandable Outer Delivery Sheath

As described herein, at least one embodiment of the endoluminal delivery system includes an outer delivery sheath that further comprises a distal segment that is expandable. Several different ways of providing an expandable distal segment are described in the following paragraphs.

Referring now to Fig. 6A, the distal segment of the outer delivery sheath 310 may comprise a woven alloy wire portion 311. By way of example and not limitation, the distal segment may be similar in design to the IDEV TECHNOLOGIES SUPERA® stent that includes woven nitinol wire. Alternatively, in at least one embodiment, the woven wire portion 311 may further comprise a flexible plastic investment; that is, a configuration wherein the woven wire portion resides within a flexible plastic matrix forming a tubular portion of the outer delivery sheath. In typical operation, the wire weave is formed in expanded configuration and elongated by longitudinal traction force on the wire elements with resulting contraction of the tubular form to a decreased diameter. Thereafter, the release of traction force effects self-expansion of the weave. In at least one embodiment, a distal portion of the distal segment of the outer delivery sheath 310 may be widened by using control lines to pull on control ends of the woven wire portion of the distal segment.

Referring now to Fig. 6B, in an alternative embodiment, the distal segment of the outer delivery sheath 320 includes a cut nitinol stent 321 residing within the sheath investment. More particularly, the distal segment of the outer delivery sheath includes a nitinol stent 321

embedded within the distal segment, wherein the nitinol stent 321 provides shape-memory functionality for the distal segment. As a result, when the balloon catheter is inflated within the distal segment with the stent-valve 120 mounted on it, the distal segment expands to accommodate the inflated balloon catheter and stent-valve. Thereafter, when the balloon catheter is pushed out of the outer delivery sheath 320, the distal segment then retracts because of the shape-memory functionality associated with the nitinol stent 321 residing with the distal segment.

Referring now to Fig. 6C, in at least one embodiment the distal segment of the outer delivery sheath 330 comprises an elastic material that can passively expand and optionally retract. That is, when a balloon catheter is expanded within the distal segment, the elastic material accommodates the expansion. Thereafter, with deflation of the balloon catheter the elastic material forming the distal segment retracts. Alternatively, the sheath material, such as PTFE (polytetrafluoroethylene) may expand but not contract. In such case, the thin-walled sheath material folds inward along longitudinal lines when retracted through a proximally disposed entry sheath or the vascular entry point itself, permitting ready removal from the body, even in a persistently expanded condition.

Referring now to Fig. 6D, in an alternative embodiment, the distal segment of the outer delivery sheath 340 includes a plurality of electrically actuated piezo-ceramic elements 341. Electrical wiring or conductors 342 extend to the proximal end of the outer delivery sheath 340 to facilitate application of an electrical current to the piezo-ceramic elements 341. When desired, the surgeon closes a circuit to engage a power source 343 and apply the electrical current to the piezo-ceramic elements 341 via the electrical wiring or conductors 342. Upon being energized, the piezo-ceramic elements 341 expand the distal segment of the outer delivery sheath 340. Contraction of the distal segment is achieved by terminating the electrical current to the piezo-ceramic elements 341. Further reference here is made to U.S. Patent No. 5,415,633, the content of which is incorporated by reference in its entirety.

Referring now to Fig. 6E, a variation of the use of electrically charged elements comprises the use of active elements featuring differential alloy sandwiches or laminates 344 that bend when a current is applied. The bending of the active elements causes the distal segment to expand. As with the piezo-ceramic elements 341 described above, contraction of the distal segment is achieved by terminating the application of electrical current to the differential alloy sandwiches or laminates 344.

In another alternative embodiment, a magnetic or electromagnetic force is used to retain a stent-valve 120 on a delivery segment balloon for advancement to the target valve plane and subsequent deployment. More particularly, and with reference now to Fig. 7, an alternative

endoluminal magnetic delivery system 400 is shown that utilizes a magnetic or electromagnetic force to maintain the position of the stent-valve 120 on the delivery segment balloon 411, wherein the delivery segment balloon 411 is located at or near the distal portion of a delivery catheter shaft 414. The magnet or electromagnet 416 are preferably incorporated into the balloon catheter shaft 414 co-axial to and axially centered along the delivery segment balloon 411 so as to align with the axial position of the mounted stent-valve. As one of skill in the art will appreciate, the stent-valve 120 must incorporate a material susceptible to magnetism in a sufficient quantity and distribution to facilitate attraction of the stent-valve 120 to the magnet or electromagnet 416 incorporated into the balloon catheter shaft 414. A guidewire 131 serves to guide the co-axially situated delivery balloon catheter 410. The delivery balloon may be partially expanded to: (a) provide a nose cone for facilitating insertion of the delivery system into, and traverse through the patient's blood vessel; and/or (b) to provide further frictional force for securing the stent-valve 120. Since the stent-valve 120 is held in place by a magnetic or electromagnetic force as well as any further frictional force due to partial expansion of the delivery balloon, the stent-valve 120 can be securely advanced through the patient's vascular system without need of an outer delivery sheath, thereby simplifying and reducing the profile of the delivery system. Once the target valve plane is reached, the delivery balloon 411 is expanded, thereby overcoming the magnetic or electromagnetic force (of course, an electromagnetic force may be terminated by stopping current to the electromagnet), to deploy the stent-valve 120 at the plane of the diseased native valve. Similarly, the magnet of the magnetic delivery catheter 410 may be incorporated into the delivery segment balloons of the in-line dual balloon system 100 and/or the telescoping catheter delivery system 200 in a similar manner to facilitate capture and retention of the stent-valve upon the delivery segment balloon in its traverse through the anatomic structures.

In addition to endoluminal delivery of a stent-valve 120, at least one embodiment of the one or more present inventions is directed to a retrieval and/or repositioning system 500 that can be used to remove a deployed stent-valve 120 from a patient, or otherwise reposition the stent-valve 120 within the patient. With reference now to Figs. 8A and 8B, an embodiment of a retrieval and/or repositioning system 500 is shown. The retrieval and/or repositioning system comprises a retrieval catheter 510 on a distal portion of which is integrated a magnet 511, and more preferably, an electromagnet of sufficient strength to at least partially collapse and secure a previously deployed stent-valve 120. With reference to Fig. 8B, the partially collapsed valve is then either withdrawn (that is, retrieved from the patient), for example as by traction on optional control lines 124 as shown, or repositioned and then redeployed.

Referring now to Figs. 8C and 8D, in a separate embodiment, a multipolar magnetic retrieval catheter system 520 is provided in which multiple magnetic elements 522 are circumferentially arrayed and disposed at a distal portion of a retrieval catheter 521 in a manner that allows the radially outward movement of the magnets 522, and the portions of the underlying catheter elements 523 to which they are attached, into contact with the radially interior surface of the deployed stent-valve 120. In at least one embodiment, the underlying portions 523 of the catheter to which the magnets 522 are attached are longitudinally separate from each other so that they are free to move independently from each other as the attached magnets 522 move radially outward. In at least one embodiment, the magnets 522 are of like polarity and are initially restrained into proximity with each other by an overlying sheath mechanism. When said sheath 524 is retracted the distal catheter portions 523 with their attached magnets 522 move radially outward under repulsive magnetic force into contact with the stent-valve 120. The close proximity if not complete contact of the magnets 522 to the stent-valve frame 121 advantageously maximizes the retention force facilitating the traction force applied in the removal of the device from the valve plane. The sheath 524 may be re-advanced over the magnetic distal portions 523 of the catheter, thus applying radially inward force on the device frame that serves to contract it and facilitate its removal under axial traction.

Shaped Catheter

The various sheath and catheter shafts described herein for the various embodiments may include a "shaped" distal portion. More particularly, a "shaped" catheter may be used to assist in crossing anatomic resistance or provide guidance for recrossing the valve plane in the event the guide wire is displaced from the ventricle. This problem occurs when the stent-valve and the delivery system are advanced around the aorta. In such a situation, the traction forces, not uncommonly, will pull the guide wire out of the ventricle. If this happens—with the delivery system already in the aorta—it requires the delivery system be removed from the patient's body and the sequence started over from the beginning. Advantageously, one or more embodiments described herein can assist with avoiding this problem. That is, a catheter can be used that includes a distal portion with one or more curved shapes, such as "pig tail" or Amplatz type curves commonly found on angiographic catheters, and including a central coaxial lumen through which is passed the guidewire. The shaped catheter is used to "steer" the guide wire across the very narrowed valve orifice. Thus, in one embodiment, a "shaped" catheter is passed within the central lumen of the delivery catheter. In such a configuration, the guide wire can be re-crossed through the valve plane more readily, and the shaped catheter—advantageously, a relatively firm catheter—can be advanced to the ventricle and left to act as an enhanced support rail for the delivery catheter.

To assist in the understanding of the present invention the following list of components and associated numbering found in the drawings is provided herein:

Number	Component
100	In-Line Dual Balloon Catheter Delivery System
101	Delivery Sheath
102	Optional Flange Of Internal Sheath
103	Expandable, Flexible Sheath Segment
104	Sheath Body
110	Dual In-Line Balloon Catheter Assembly
111	Delivery Segment Is Delivery Balloon
112	Carrier Segment Is In-Line Leading Carrier Balloon
113	Optional Nose Cone
114	Exit Of Distal Control Lines From Catheter Shaft
120	Stent-Valve Assembly
121	Valve Frame
122	Collapsed Valve Membrane
123	Optional Control Lines Attached To Distal End Of Valve Frame (Passed Within Catheter Shaft)
124	Optional Control Lines Attached To Proximal End Of Valve Frame
130	Guide Wire Assembly
131	Guide Wire
140	Native Heart Valve
141	Native Heart Valve Seat
200	Telescoping Balloon Catheter Delivery System
210	Delivery Balloon Catheter Assembly
211	Delivery Segment Is Delivery Balloon
212	Tip Of Delivery Segment Balloon
213	Partially Inflated Leading Tip Of Delivery Segment Balloon
214	Delivery Balloon Catheter Shaft
220	Carrier Balloon Catheter Assembly
221	Carrier Segment Is Leading Balloon That Coaxially Telescopes Within Central Lumen Of Delivery Segment Balloon
222	Tip Of Carrier Segment Balloon
223	Inflated Leading Tip Of Carrier Segment Balloon
224	Shaft Of Carrier Catheter

300 Expandable Sheath System
310 Woven Wire Sheath
320 Sheath With Embedded Nitinol Stent
321 Nitinol Stent
330 Flexible Plastic Sheath
340 Electronically Actuated Sheath
341 Piezo-Ceramic Elements
342 Conductors
343 Power Source
344 Alloy Laminates
400 Magnetic Balloon Catheter Delivery System
410 Magnetic Balloon Delivery Catheter
411 Delivery Balloon
412 Tip Of Magnetic Balloon Delivery Catheter
413 Partially Inflated Tip Of Delivery Balloon
414 Shaft Of Magnetic Balloon Delivery Catheter
415 Guide Wire Lumen Of Magnetic Balloon Delivery Catheter
416 Magnet Or Electromagnet
500 Magnetic Retrieval Catheter System
510 Magnetic Retrieval Catheter Assembly
511 Magnet Or Electromagnet
520 Multipolar Magnetic Retrieval Catheter Assembly
521 Multipolar Magnetic Retrieval Catheter
522 Magnets – Circumferentially Arrayed
523 Distal Mobile Catheter Elements Attaching To Magnets
524 Sheath

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

will understand how to make and use the one or more present inventions after understanding the present disclosure.

The one or more present inventions, 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 one or more present inventions has been presented for purposes of illustration and description. The foregoing is not intended to limit the one or more present inventions to the form or forms disclosed herein. In the foregoing Detailed Description for example, various features of the one or more present inventions 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 one or more present inventions 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 one or more present inventions.

Moreover, though the description of the one or more present inventions has included description of one or more embodiments and certain variations and modifications, other variations and modifications are within the scope of the one or more present inventions (e.g., as may be within the skill and knowledge of those in the art, after understanding the present disclosure). It will be understood that many changes in the details, materials, steps and arrangements of elements, which have been herein described and illustrated in order to explain the nature of the invention, may be made by those skilled in the art without departing from the scope of embodiments of the one or more present inventions. 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.

CLAIMS

What Is Claimed Is:

1. A system for providing endoluminal delivery of a deliverable device through vasculature of a patient to a delivery site within the patient, comprising:

an outer delivery sheath including a distal section, wherein at least a portion of the outer delivery sheath is sized for insertion into the vasculature of the patient;

a carrier segment located at a distal portion of a catheter shaft, the carrier segment having an outer surface sized to temporarily hold the deliverable device in the distal section of the outer delivery sheath, wherein at least a portion of the catheter shaft is located within and coaxial to the outer delivery sheath; and

a delivery segment located coaxial to the outer delivery sheath, the delivery segment having an outer surface sized to radially fit within the deliverable device after detaching the deliverable device from the carrier segment when the deliverable device resides within the distal section of the outer delivery sheath, wherein the delivery segment is configured to deploy the deliverable device at the delivery site.

2. The system of Claim 1, wherein at least a portion of the distal section of the outer delivery sheath is expandable.

3. The system of Claim 2, wherein the at least a portion of the distal section of the outer delivery sheath comprises one or more electrically activated elements.

4. The system of Claim 2, wherein the at least a portion of the distal section of the outer delivery sheath comprises one or more piezo-ceramic elements.

5. The system of Claim 2, wherein the at least a portion of the distal section of the outer delivery sheath comprises a passively expandable material that is expandable upon application of an outward radial force applied by at least one of the carrier segment and the delivery segment.

6. The system of Claim 2, wherein the at least a portion of the distal section of the outer delivery sheath expands upon application of a tensile force to the at least a portion of the distal section.

7. The system of Claim 1, wherein the distal section includes at least one of an internal projection and a narrowed area extending radially inward from an interior surface of the distal section.

8. The system of Claim 1, wherein a portion of an internal surface of the outer delivery sheath further comprises a guide for retaining at least a portion of a longitudinally extending element configured to selectively manipulate at least a part of the outer delivery sheath or a structure coaxial to the outer delivery sheath.

9. The system of Claim 1, wherein a portion of an internal surface of the outer delivery sheath further comprises a guide, the guide comprising at least one of:

(a) a lumen; and

(b) a grommet;

wherein the guide retains at least one control line for selective retention of the deliverable device.

10. The system of Claim 1, wherein the carrier segment and the delivery segment are both situated upon the catheter shaft.

11. The system of Claim 1, wherein the carrier segment is situated upon the catheter shaft, and wherein the delivery segment is associated with a delivery segment shaft that is coaxial to the catheter shaft and axially moveable relative to the catheter shaft.

12. The system of Claim 1, wherein the carrier segment is an expandable balloon having an expanded diameter smaller than an expanded diameter for the delivery segment.

13. The system of Claim 1, wherein the delivery segment is an expandable balloon having an expanded diameter larger than an expanded diameter for the carrier segment.

14. The system of Claim 1, wherein at least one of the carrier segment and the delivery segment is a mandrel.

15. The system of Claim 14, wherein the mandrel is expandable by mechanical or electromechanical means.

16. The system of Claim 14, wherein the mandrel is not expandable.

17. The system of Claim 1, wherein the delivery segment is located axially proximal to the carrier segment.

18. The system of Claim 1, wherein the delivery segment is located axially distal to the carrier segment.

19. The system of Claim 1, wherein the delivery segment includes a magnet to aid in capture and retention of the deliverable device on the delivery segment.

20. An assembly for intravascular delivery of a deliverable device to a delivery site within a patient, comprising:

a first catheter including a first catheter shaft;

a carrier segment situated along the first catheter shaft, the carrier segment configured to receive the deliverable device prior to inserting the first catheter within the patient; and

a delivery segment sequentially positioned in an axial orientation relative to the carrier segment, wherein the delivery segment is configured to engage the deliverable device within the patient while the deliverable device is coaxial to at least a portion of

the first catheter, and wherein the delivery segment is configured to thereafter deploy the deliverable device at the delivery site.

21. The assembly of Claim 20, wherein the delivery segment is also situated along the first catheter.

22. The assembly of Claim 20, wherein the delivery segment is situated along a second catheter, the second catheter comprising a coaxial lumen through which passes the first catheter.

23. The assembly of Claim 22, wherein at least one of the first catheter and the second catheter comprise a curved distal portion.

24. The assembly of Claim 20, wherein the carrier segment is an expandable balloon.

25. The assembly of Claim 20, wherein the carrier segment is a mandrel.

26. The assembly of Claim 25, wherein the mandrel is expandable by mechanical or electromechanical means.

27. The assembly of Claim 25, wherein the mandrel is non-expandable.

28. The assembly of Claim 20, wherein the delivery segment is an expandable balloon.

29. The assembly of Claim 20, wherein the delivery segment is a mandrel.

30. The assembly of Claim 29, wherein the mandrel is expandable by mechanical or electromechanical means.

31. The assembly of Claim 29, wherein the mandrel is non-expandable.

32. The assembly of Claim 20, wherein the delivery segment includes a magnet to aid in capture and retention of the deliverable device on the delivery segment.

33. The assembly of Claim 20, wherein the delivery segment includes an electromagnet to aid in capture and retention of the deliverable device on the delivery segment.

34. A method of delivering a deliverable device through vasculature of a patient to a target site within the patient, comprising:

mounting the deliverable device on a selectively expandable carrier segment located along a catheter shaft, wherein at least a portion of the catheter shaft is located within and coaxial to an outer delivery sheath;

inserting the outer delivery sheath and catheter shaft into the patient;

moving the outer delivery sheath within the patient to position the selectively expandable carrier segment and the deliverable device near the target site;

partially expanding the deliverable device using the selectively expandable carrier segment while the deliverable device remains at least partially within the outer delivery sheath;

positioning a delivery segment radially within the deliverable device and partially expanding the delivery segment to facilitate engagement of the delivery segment with the deliverable device;

moving the delivery segment and deliverable device to the target site; and

deploying the deliverable device at the target site by further expanding the delivery segment.

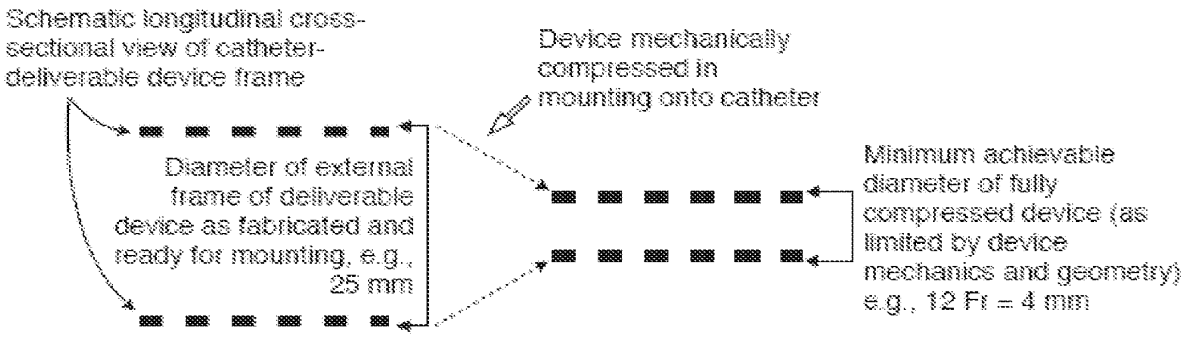


FIG. 1
(PRIOR ART)

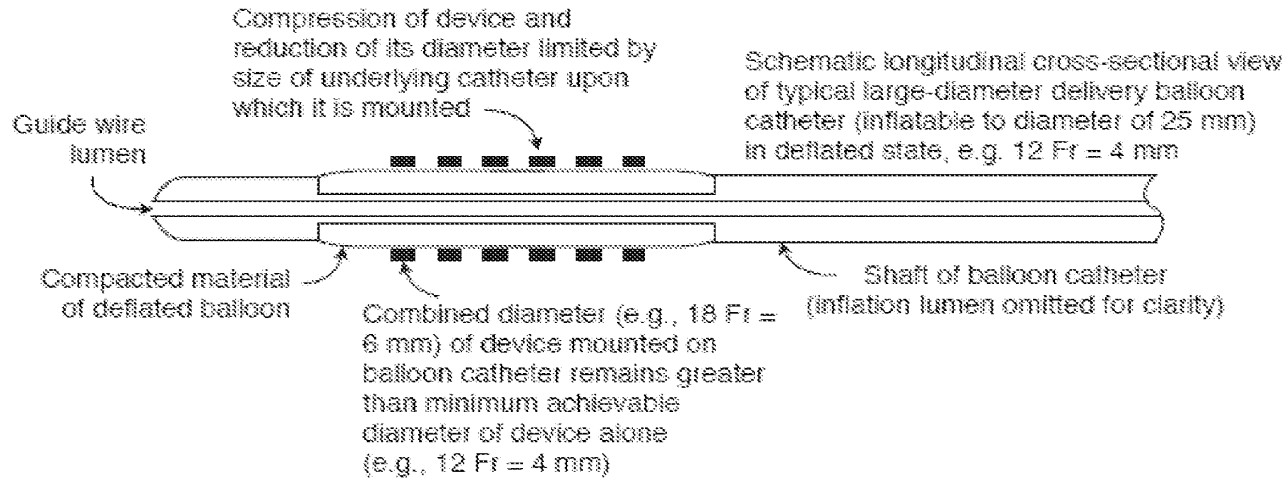


FIG. 2
(PRIOR ART)

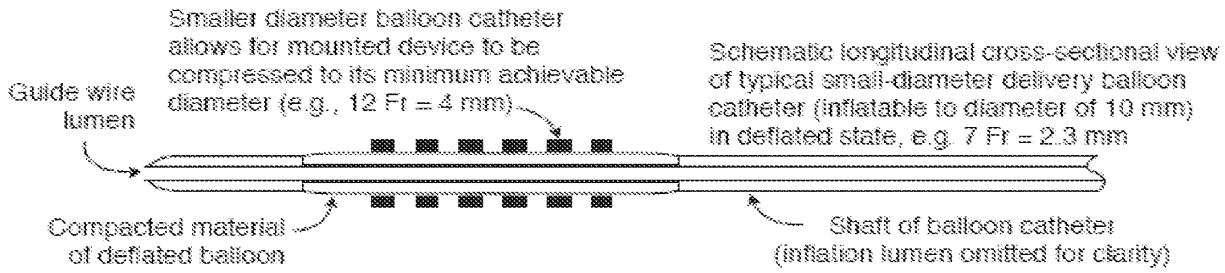
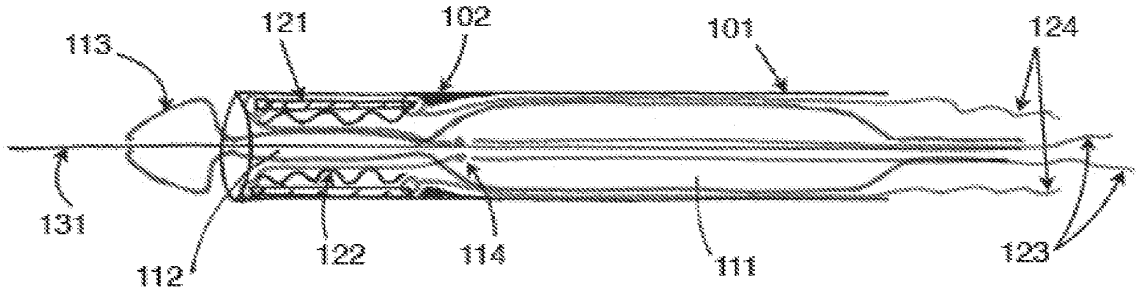

Smaller diameter balloon catheter allows for mounted device to be compressed to its minimum achievable diameter (e.g., 12 Fr = 4 mm)
Guide wire lumen
Schematic longitudinal cross-sectional view of typical small-diameter delivery balloon catheter (inflatable to diameter of 10 mm) in deflated state, e.g. 7 Fr = 2.3 mm
Compacted material of deflated balloon
Shaft of balloon catheter (inflation lumen omitted for clarity)

FIG. 3

FIG. 4A



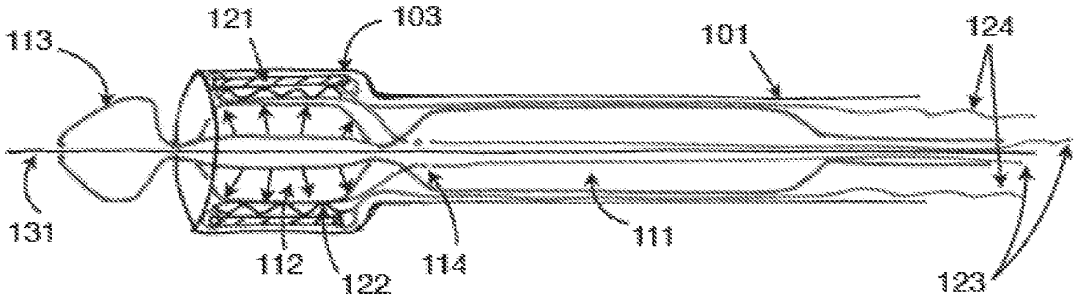


FIG. 4B

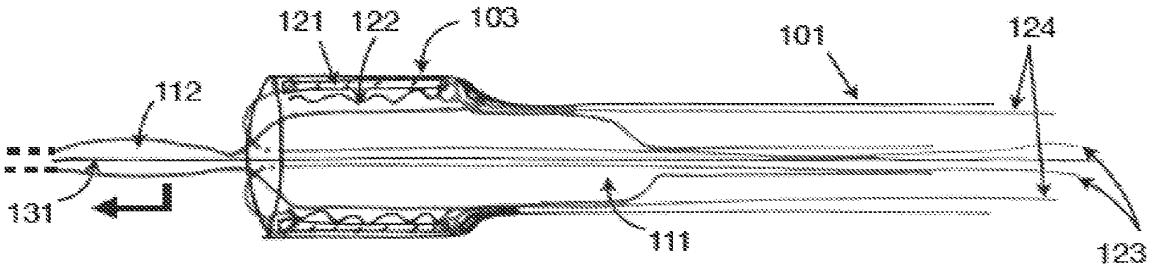
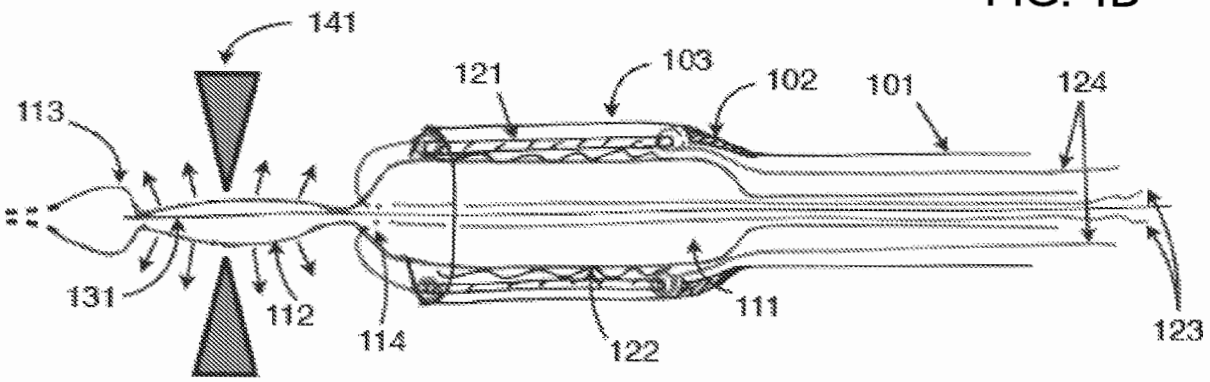


FIG. 4C

FIG. 4D



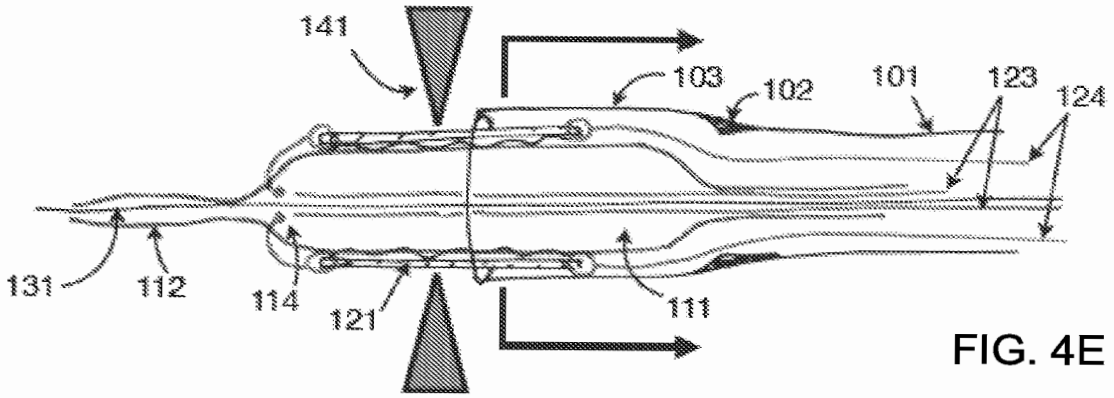


FIG. 4E

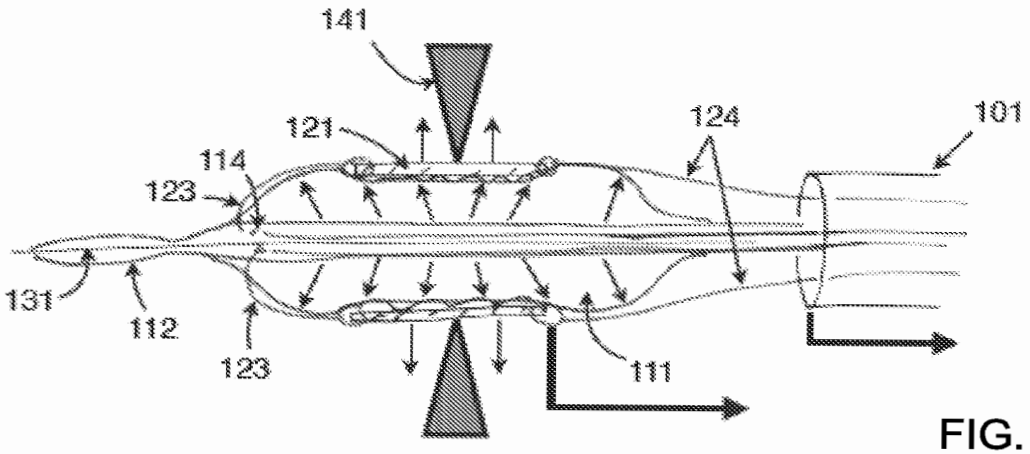


FIG. 4F

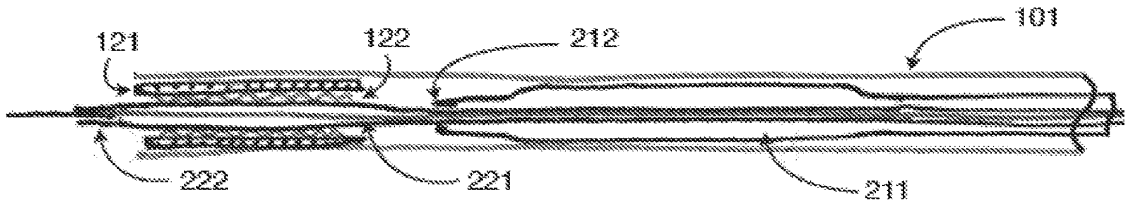


FIG. 5A

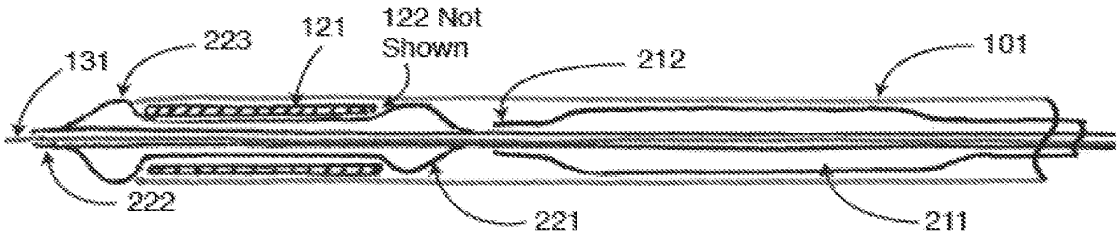


FIG. 5B

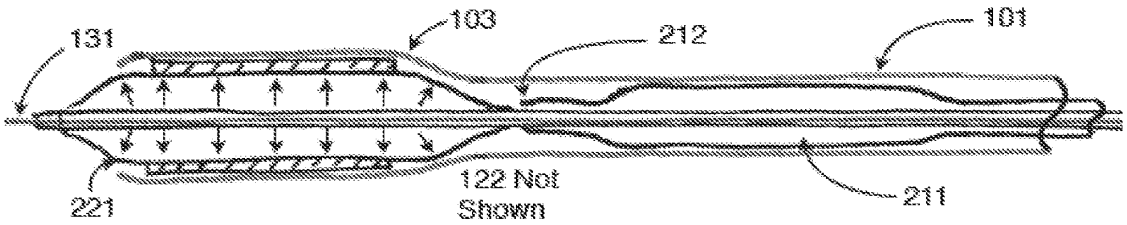


FIG. 5C

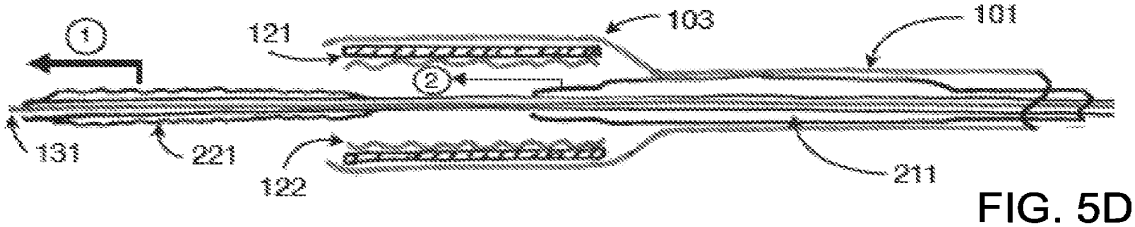


FIG. 5D

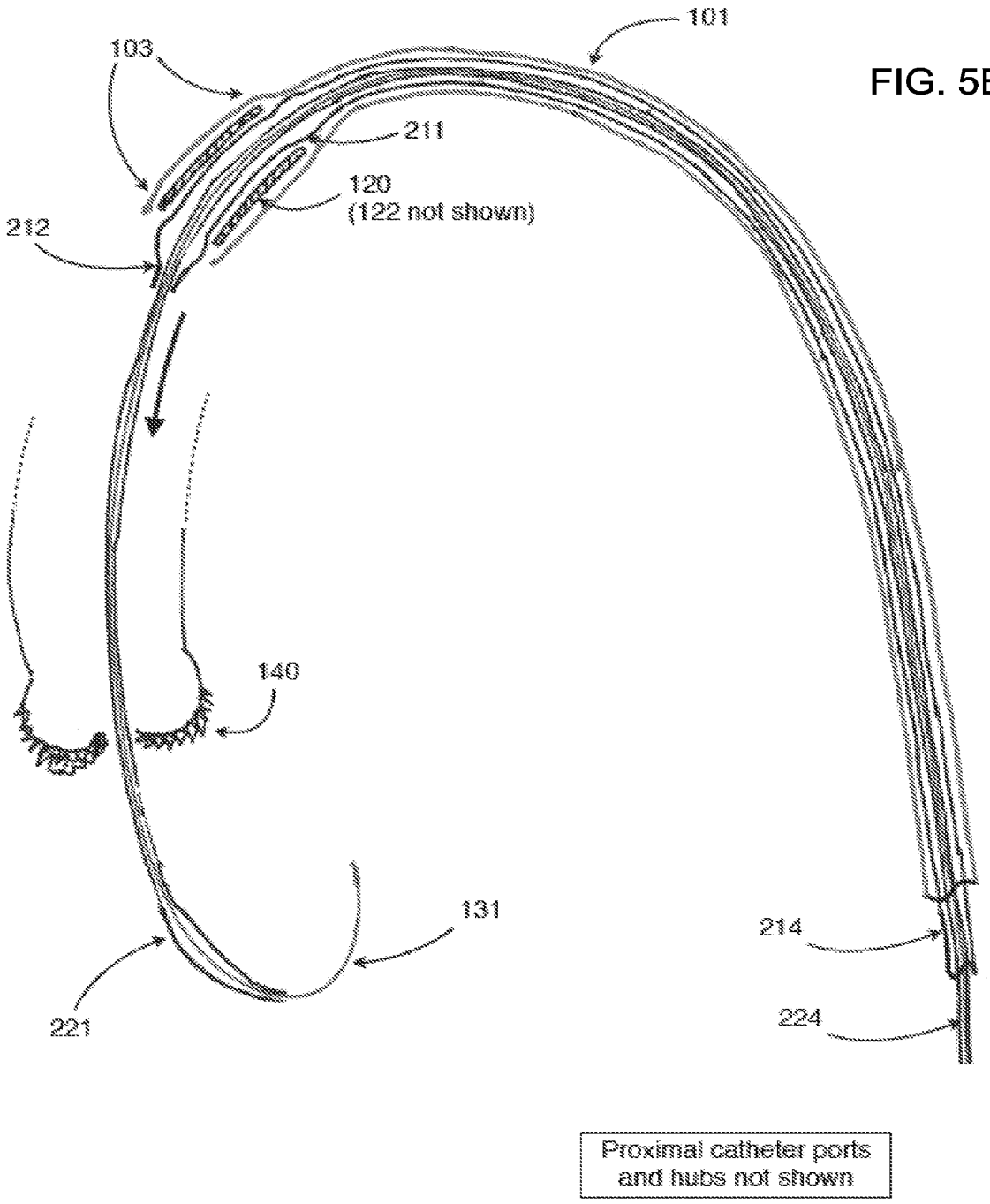
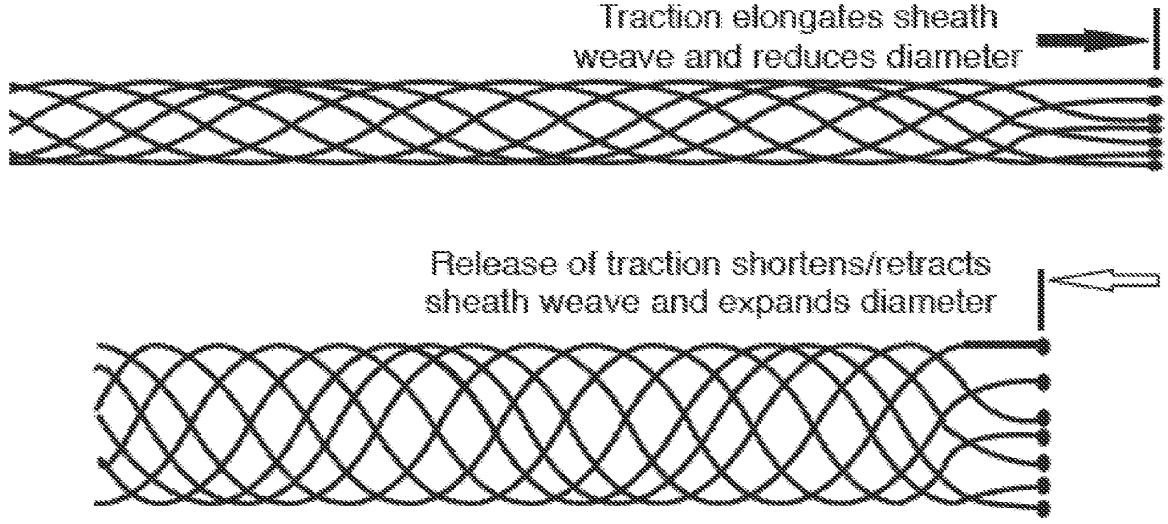

101
103
211
120
(122 not shown)
212
140
131
214
224
221
Proximal catheter ports
and hubs not shown

FIG. 5E

FIG. 6A



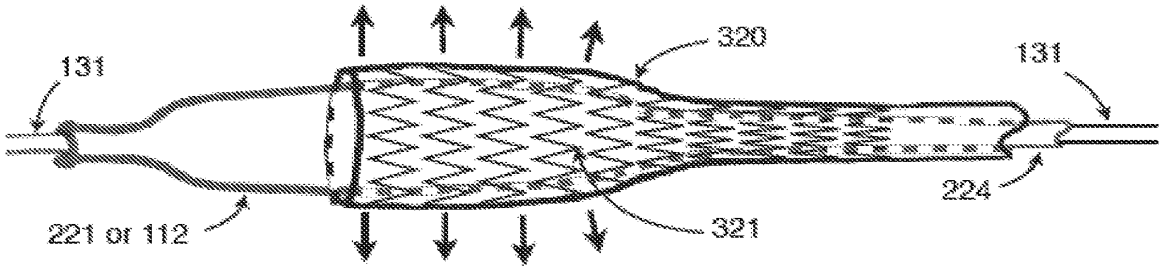


FIG. 6B

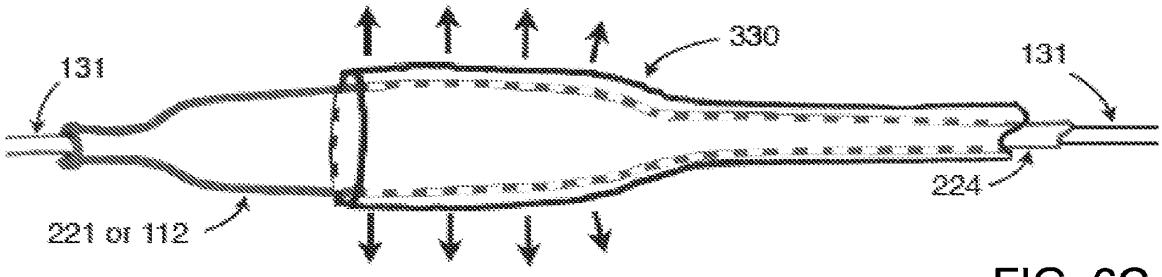
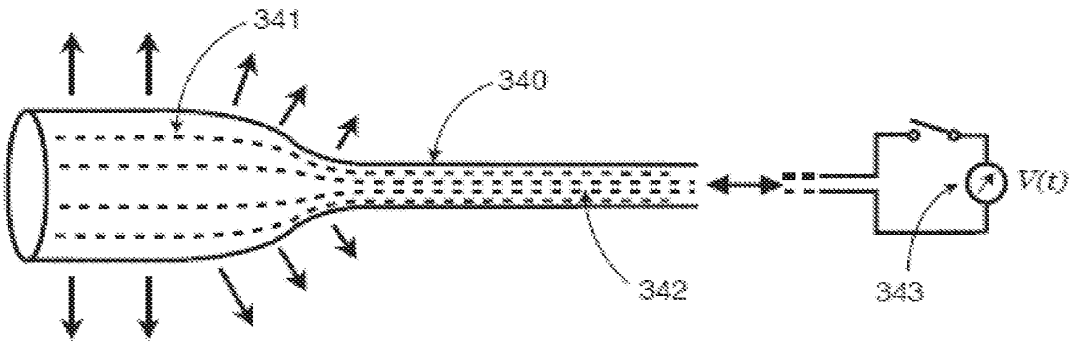


FIG. 6C

FIG. 6D



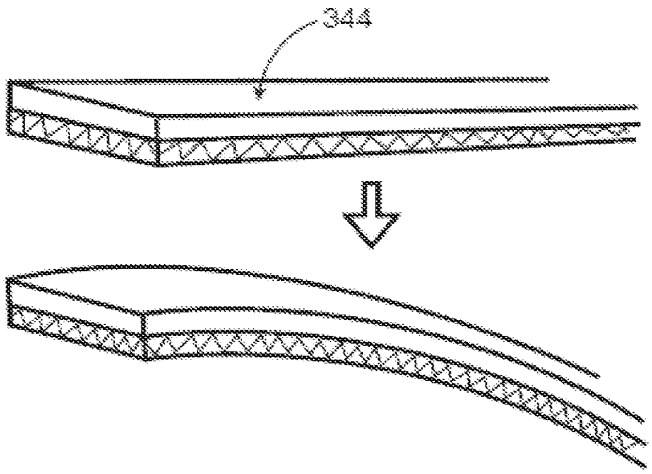


FIG. 6E

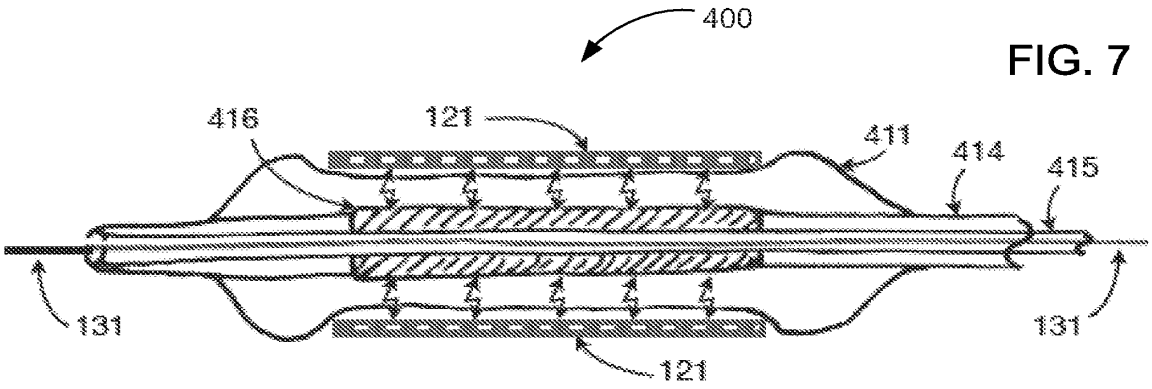


FIG. 7

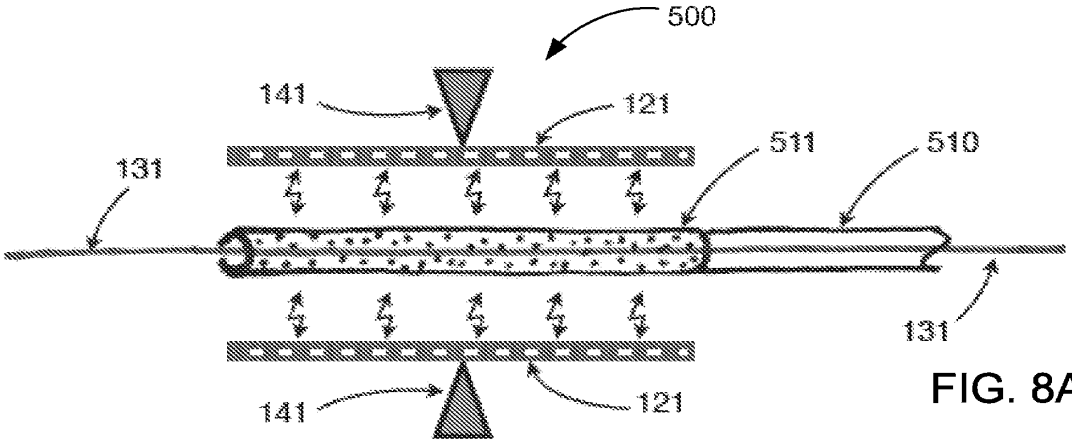


FIG. 8A

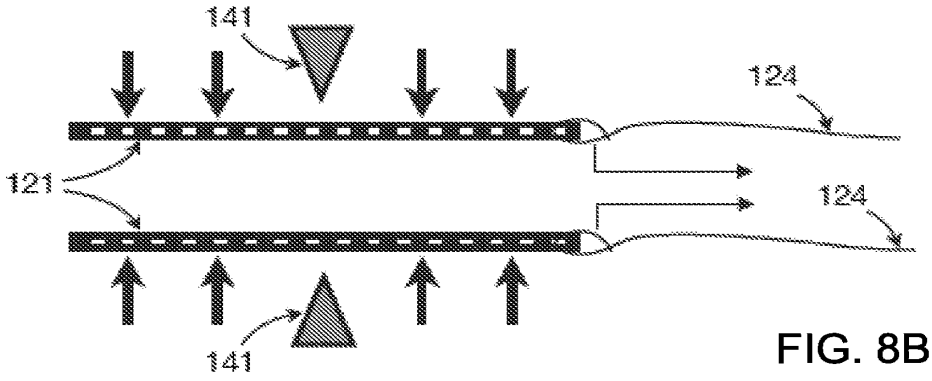


FIG. 8B

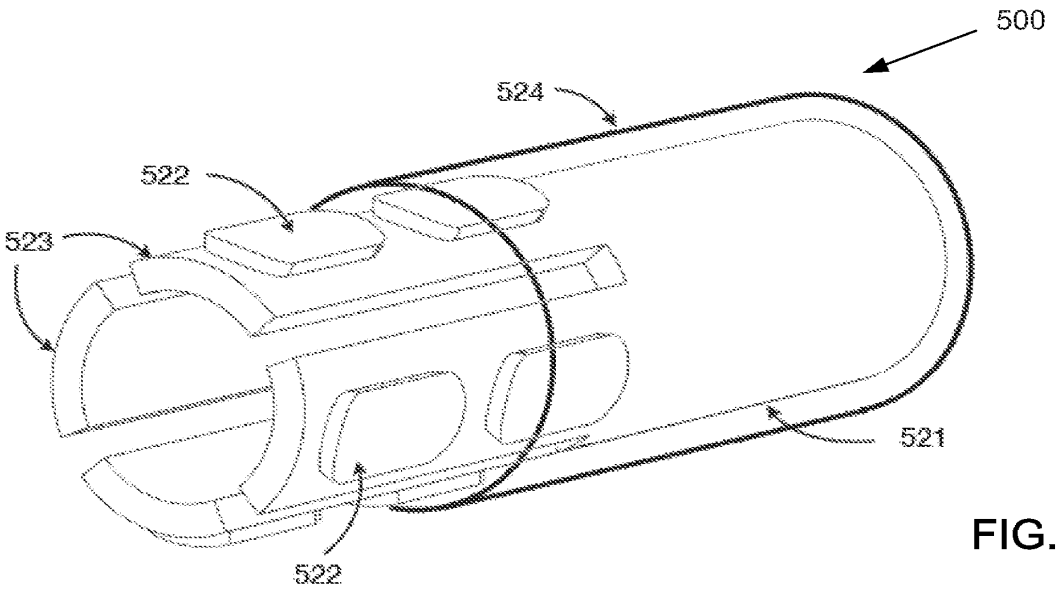

500
524
522
523
521
522

FIG. 8C

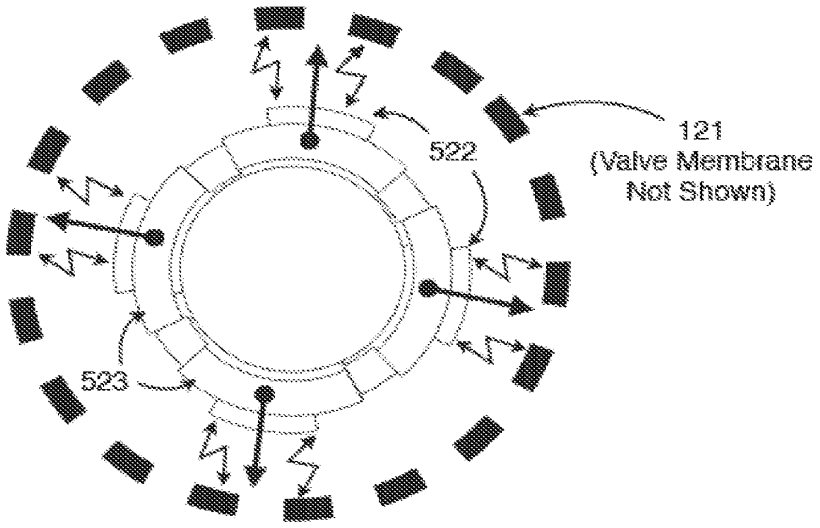

121
(Valve Membrane
Not Shown)
522
523
End View
(Sheath 524 Not Shown)

FIG. 8D

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 March 2012 (29.03.2012)

PCT

(10) International Publication Number
WO 2012/040643 A2

(51) International Patent Classification:
A61F 2/24 (2006.01) *A61F 2/82* (2006.01)
A61F 2/04 (2006.01) *A61L 27/04* (2006.01)
A61L 27/28 (2006.01) *A61M 25/01* (2006.01)

(21) International Application Number:
PCT/US2011/053120

(22) International Filing Date:
23 September 2011 (23.09.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/385,867 23 September 2010 (23.09.2010) US
13/243,980 23 September 2011 (23.09.2011) US

(71) Applicant *(for all designated States except US)*: **COLIBRI HEART VALVE LLC** [US/US]; 2150 W. 6th Ave, Suite M, Broomfield, CO 80020 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **FISH, R., David** [US/US]; 6349 Vanderbilt Street, Houston, TX 77005 (US). **PANIAGUA, David** [CR/US]; 3813 Drummond Street, Houston, TX 77025 (US). **INDUNI, Eduardo** [CR/CR]; Resi Alajuela H7, Alajuela, 906-4050 (CR).

(74) Agent: **YASKANIN, Mark**; Holme Roberts & Owen LLP, 1700 Lincoln Street, Suite 4100, Denver, CO 80203 (US).

(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, 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).

[Continued on next page]

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

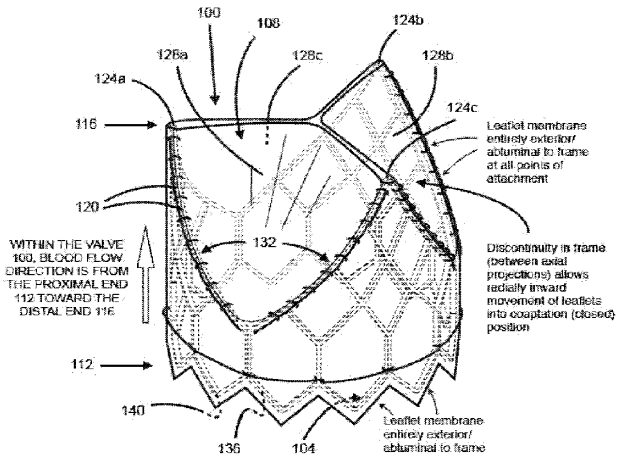


Figure 1A

(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.

WO 2012/040643 A2

Published:

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

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

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

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

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

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;

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

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.

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

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

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.

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

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

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

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.

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.

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

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

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.

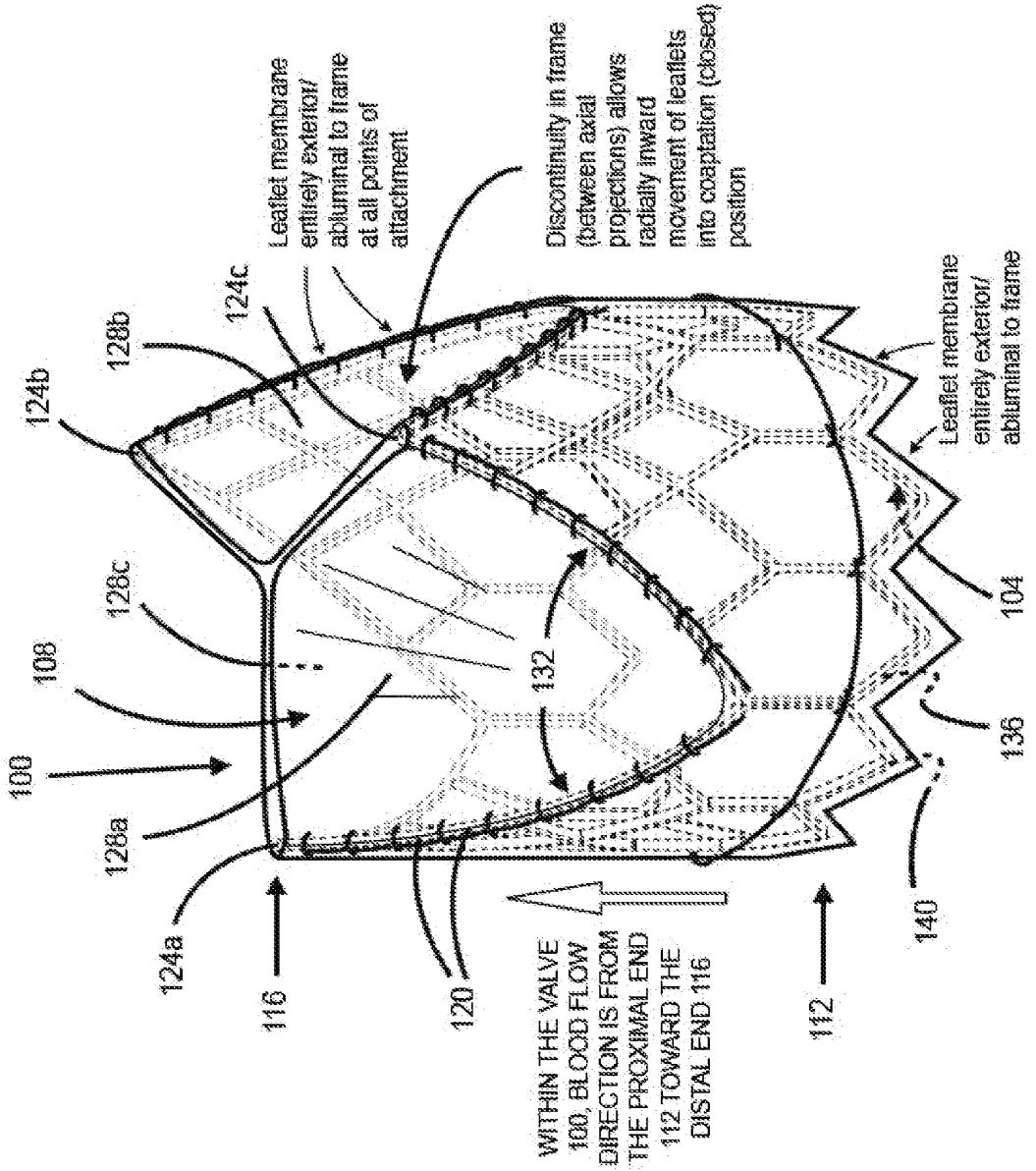

Leaflet membrane entirely exterior/ abluminal to frame at all points of attachment
Discontinuity in frame (between axial projections) allows radially inward movement of leaflets into coaptation (closed) position
Leaflet membrane entirely exterior/ abluminal to frame
124c
128b
124b
128c
108
100
128a
124a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

Figure 1A

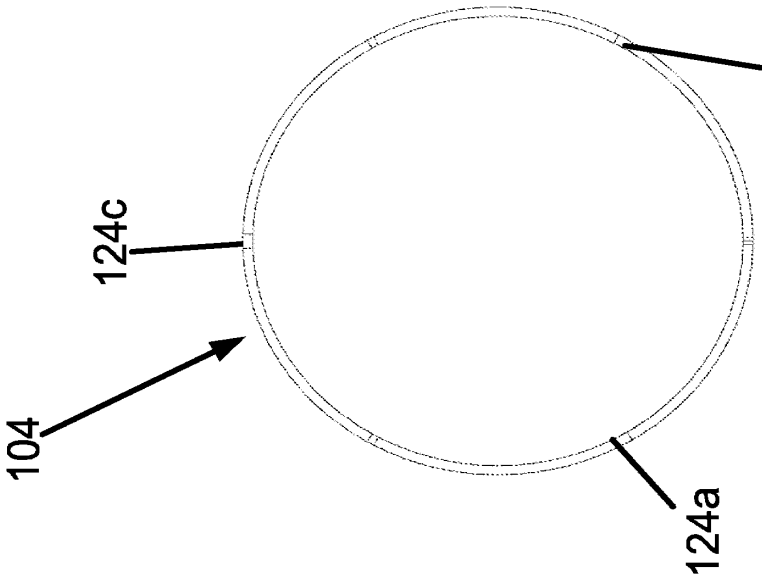


FIG. 1C

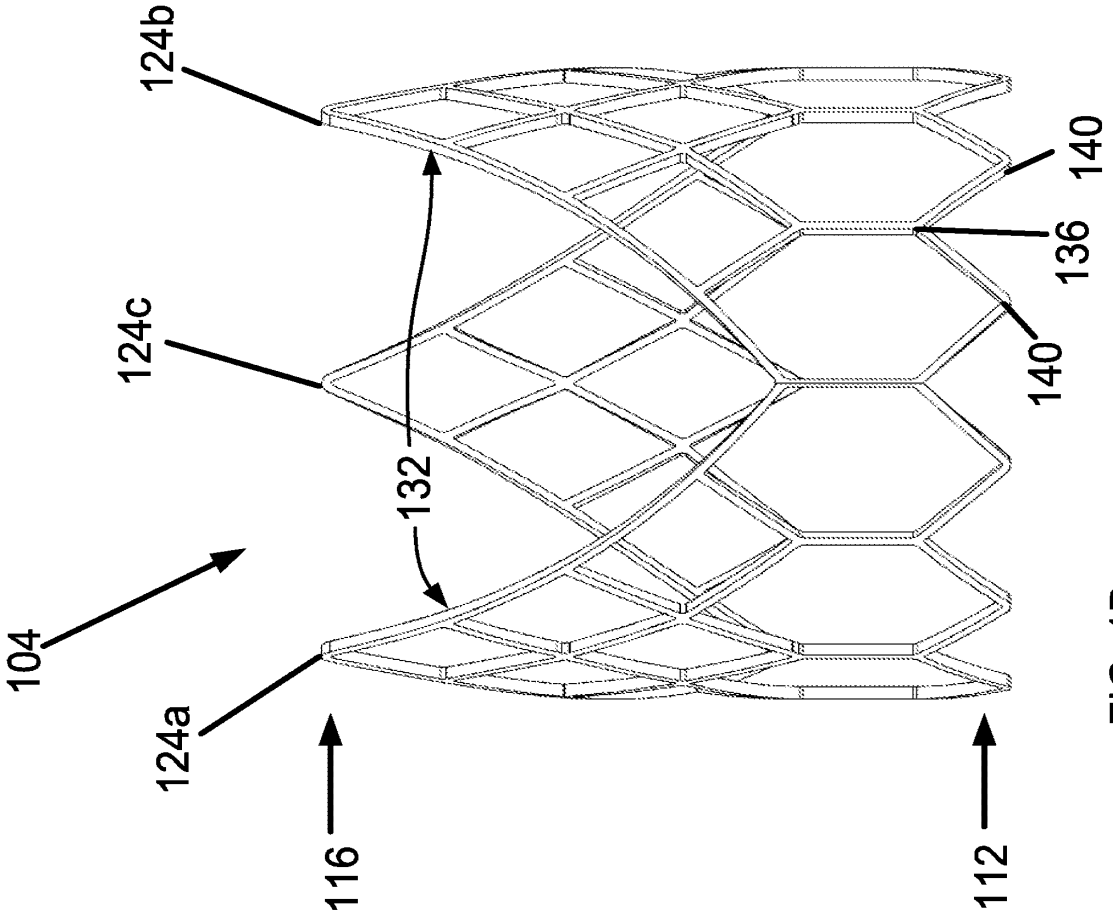
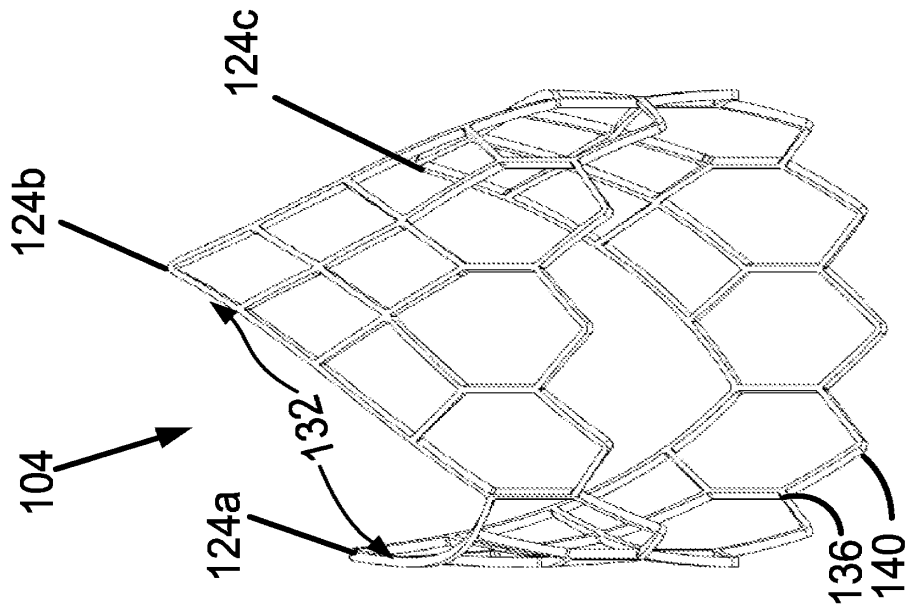


FIG. 1B

FIG. 1E


124c
124b
104
132
124a
136
140

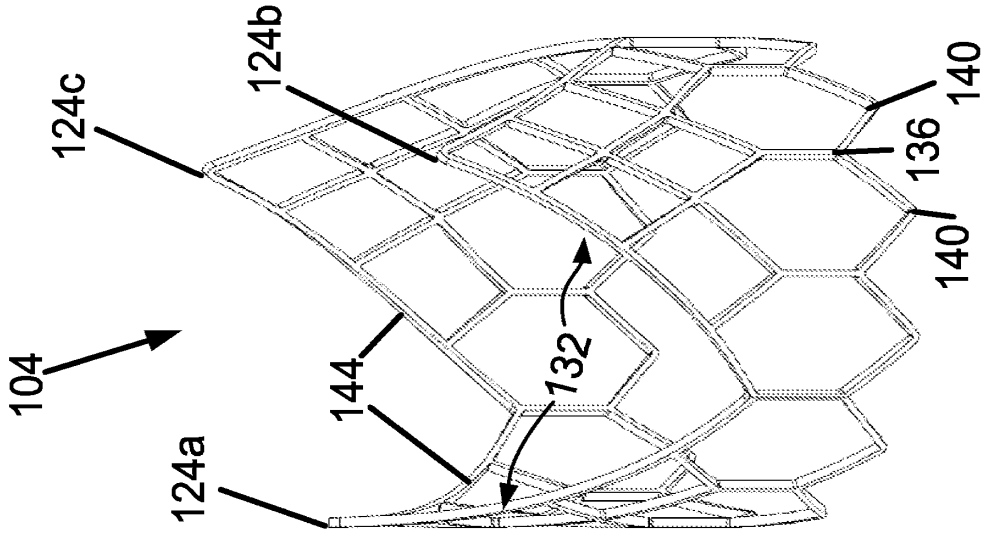

124c
124b
140
136
140
104
144
132
124a

FIG. 1D

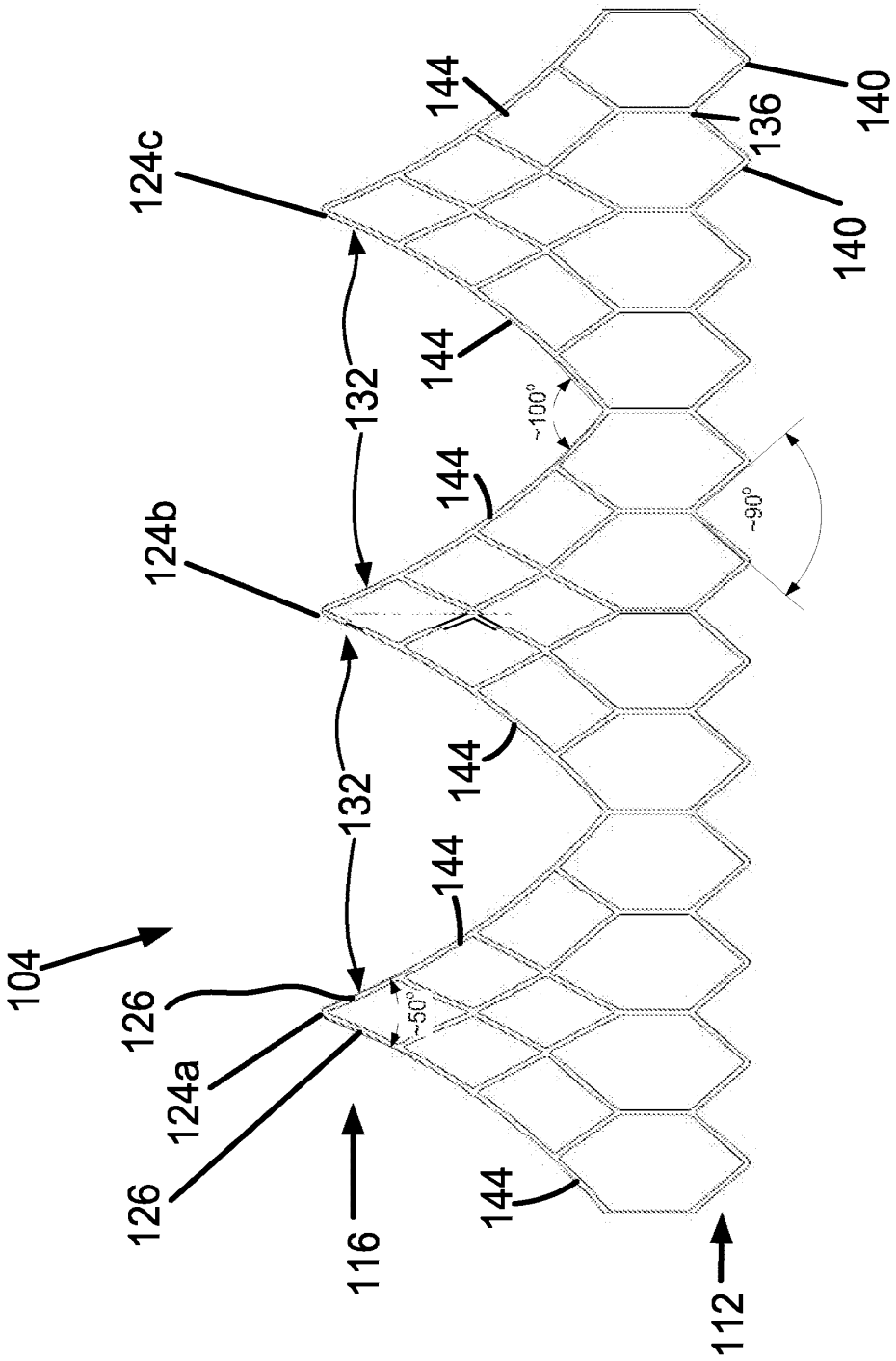

104
126
124a
126
116
112
124b
124c
132
132
144
144
144
144
144
144
140
140
136
~50°
~100°
~90°

FIG. 1F

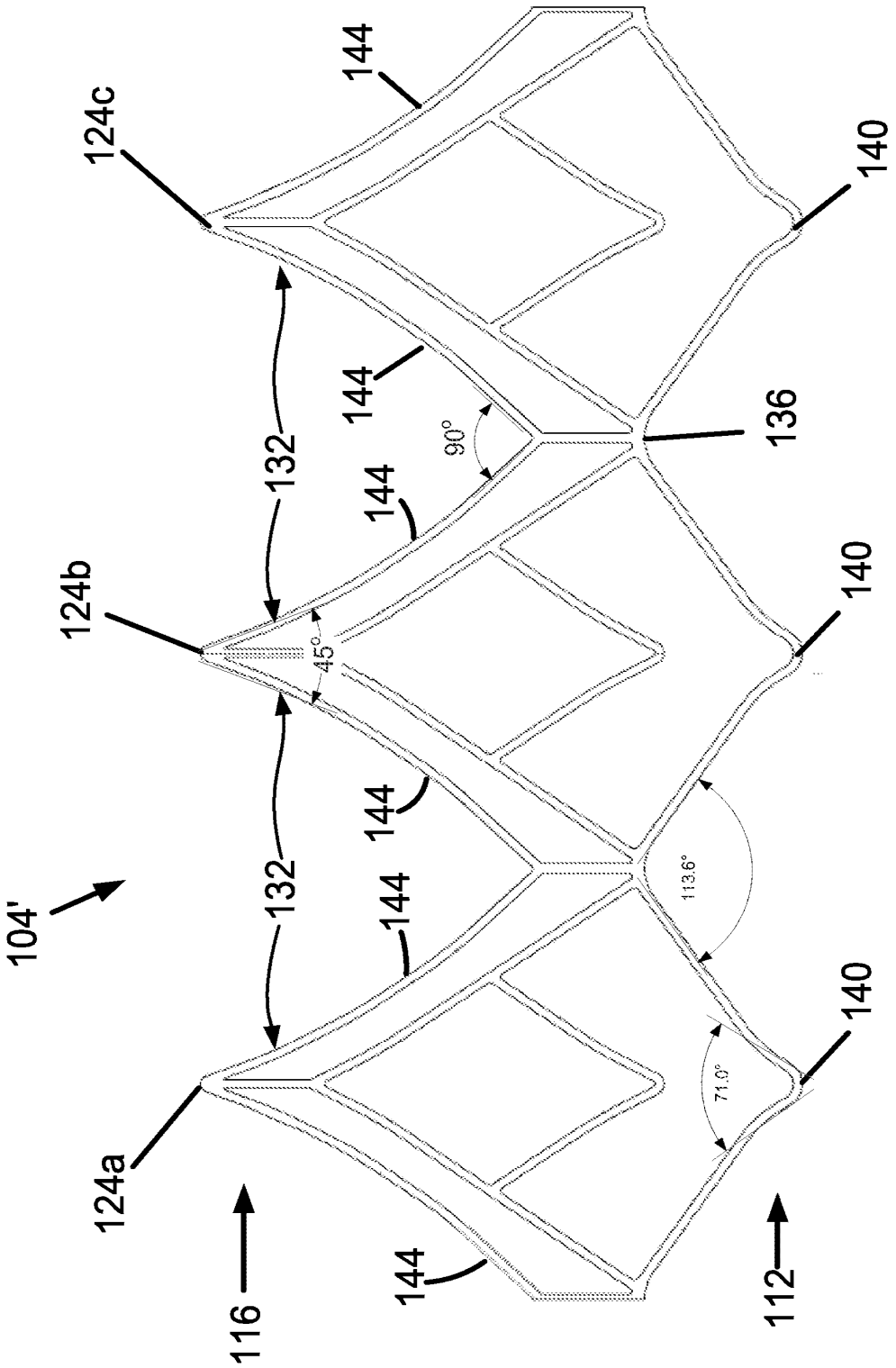

104'
116
112
124a
124b
124c
132
132
144
144
144
144
144
144
136
140
140
140
90°
45°
113.6°
71.0°

FIG. 1G

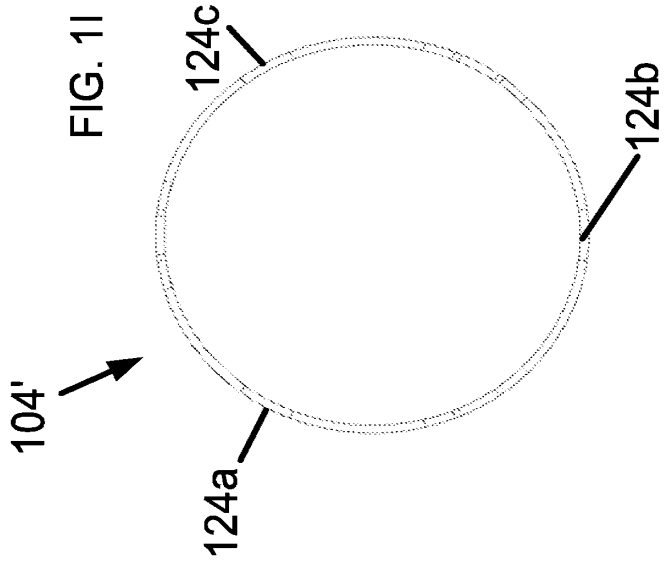

124c
124b
104'
124a

FIG. 1I

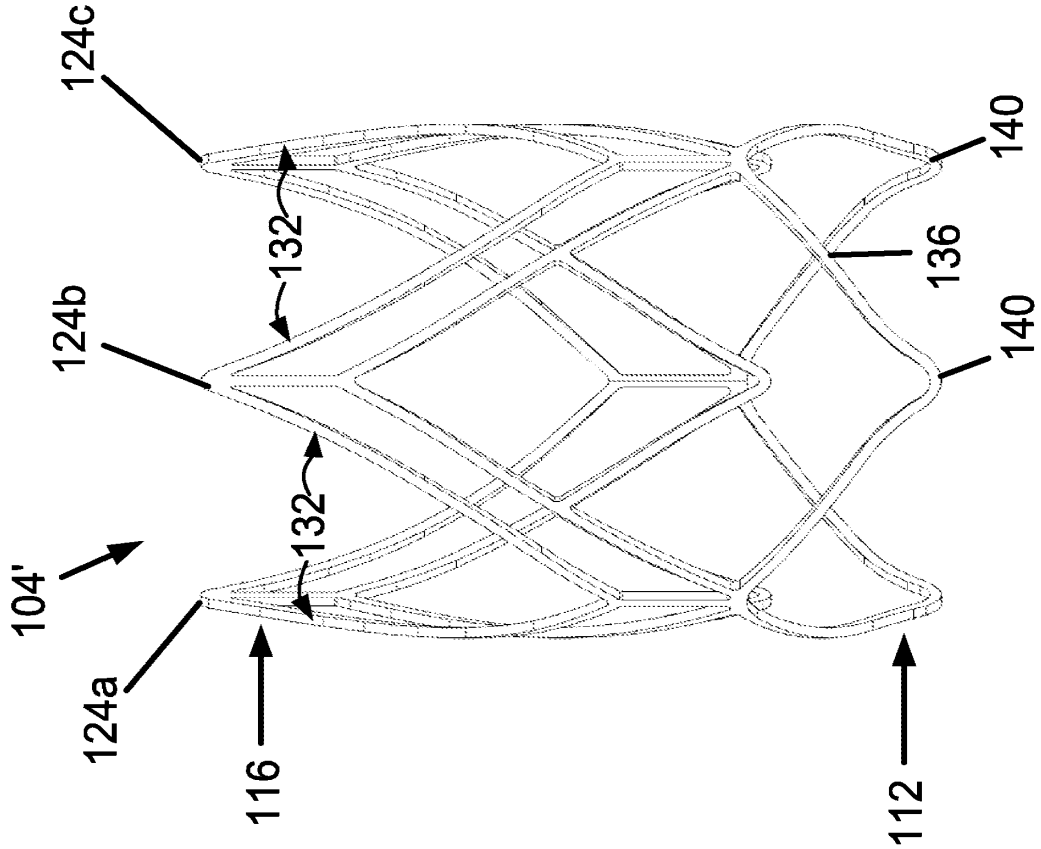

124c
132
140
136
124b
140
132
104'
124a
116
112

FIG. 1H

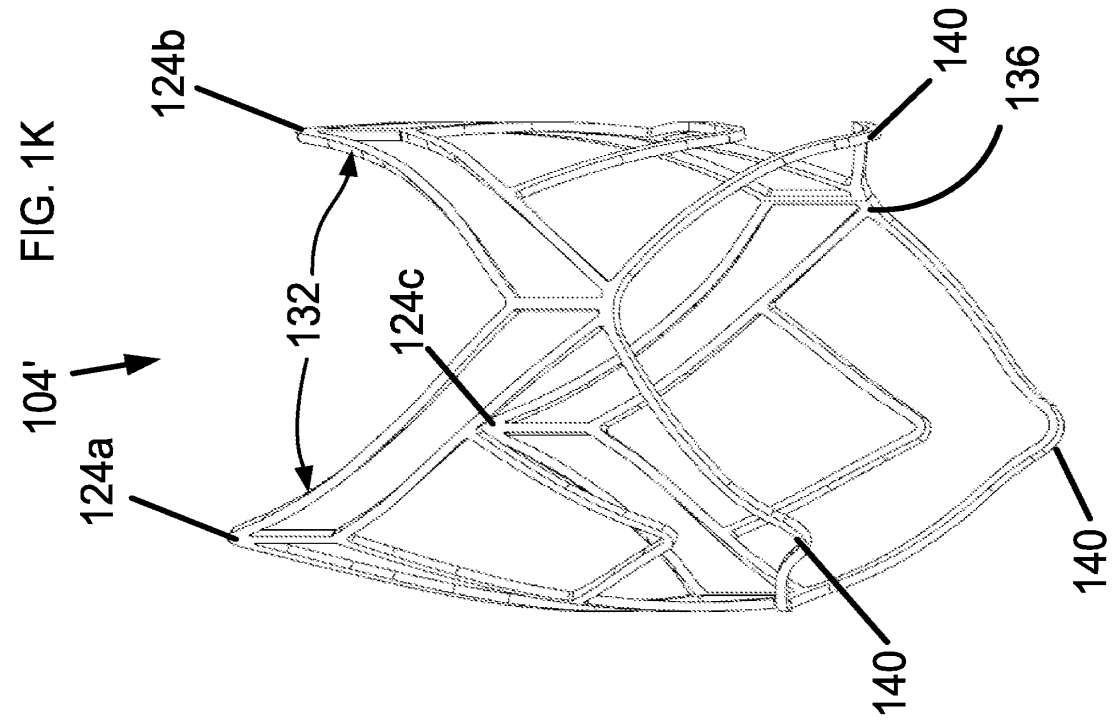

124b
140
136
132
124c
104'
124a
140
140

FIG. 1K

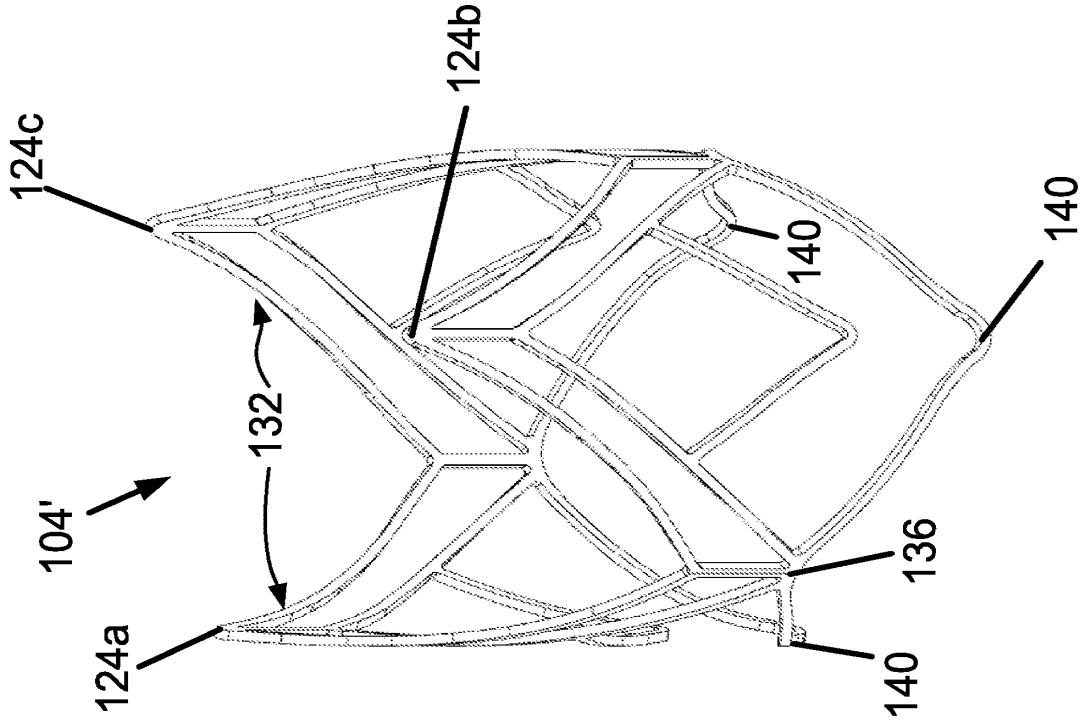

124c
124b
140
140
132
104'
136
124a
140

FIG. 1J

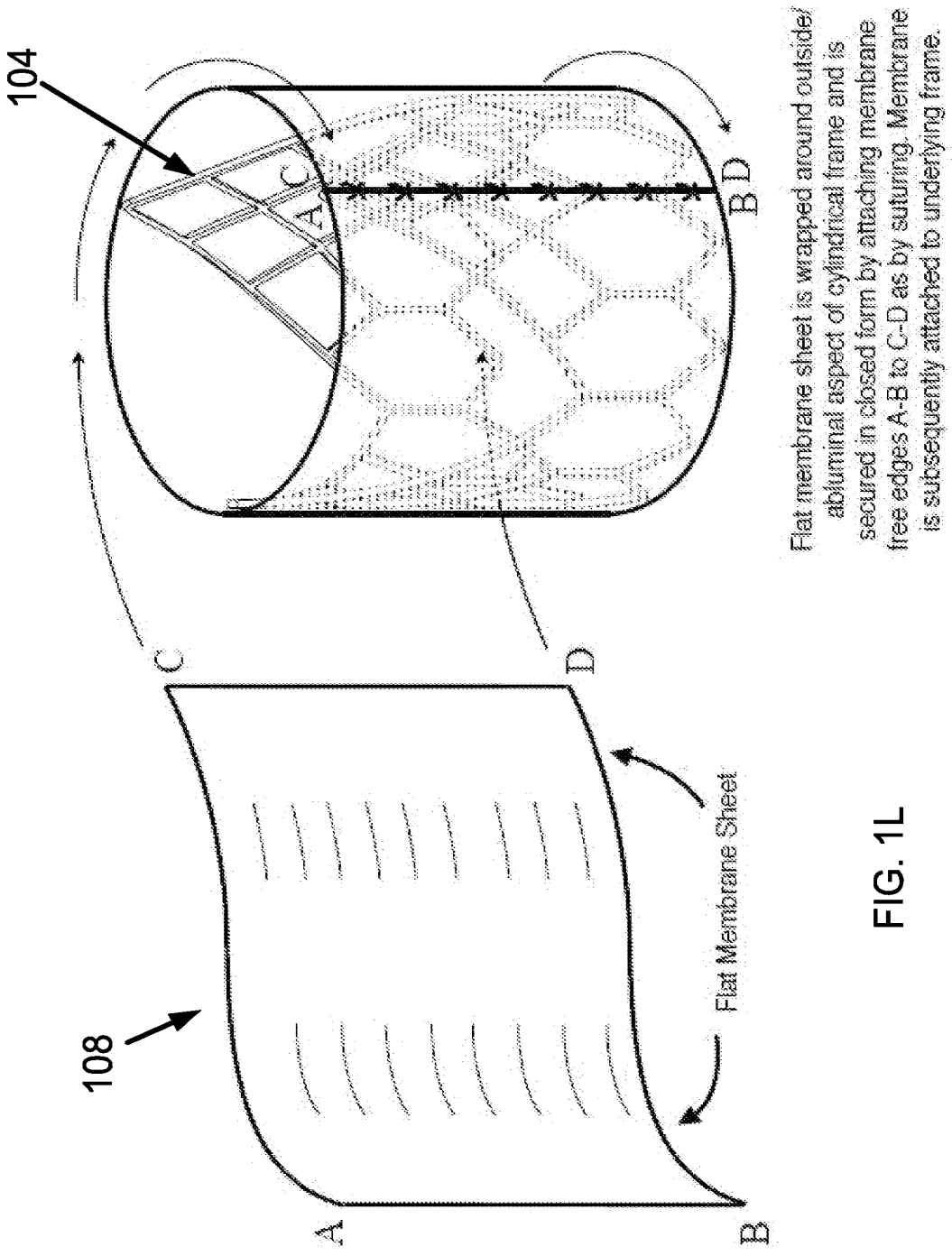

104
108
A
B
C
D
Flat Membrane Sheet
Flat membrane sheet is wrapped around outside/abluminal aspect of cylindrical frame and is secured in closed form by attaching membrane free edges A-B to C-D as by suturing. Membrane is subsequently attached to underlying frame.

FIG. 1L

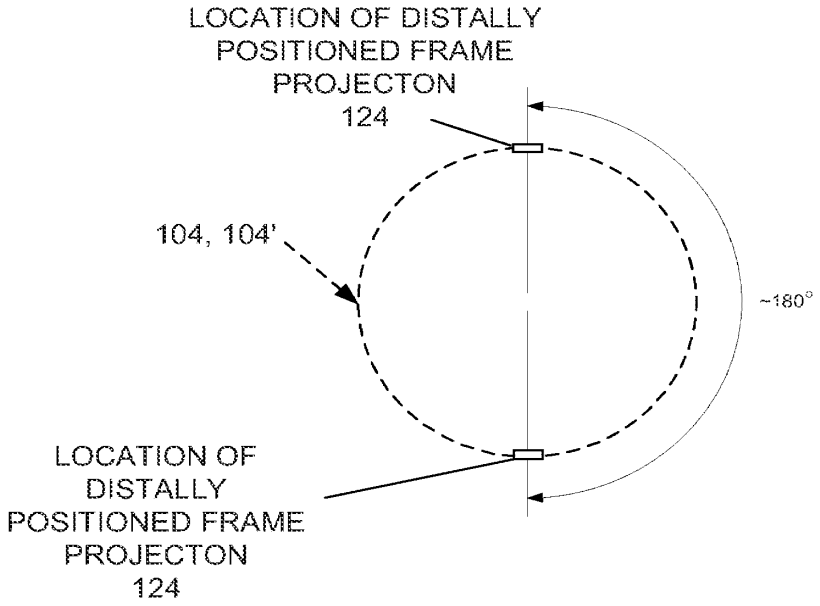

LOCATION OF DISTALLY POSITIONED FRAME PROJECTON 124
104, 104'
~180°
LOCATION OF DISTALLY POSITIONED FRAME PROJECTON 124

Fig. 2

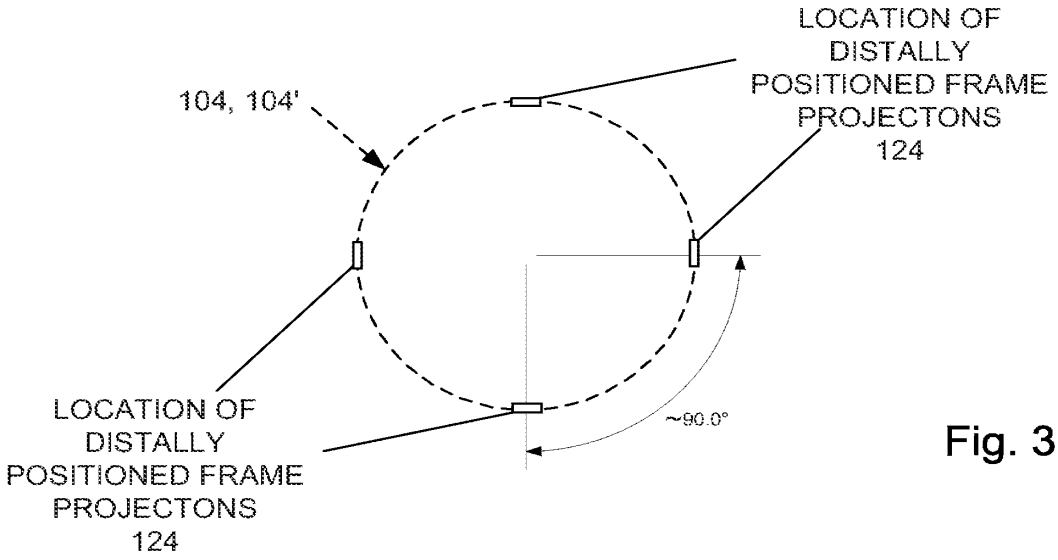

LOCATION OF DISTALLY POSITIONED FRAME PROJECTONS 124
104, 104'
~90.0°
LOCATION OF DISTALLY POSITIONED FRAME PROJECTONS 124

Fig. 3

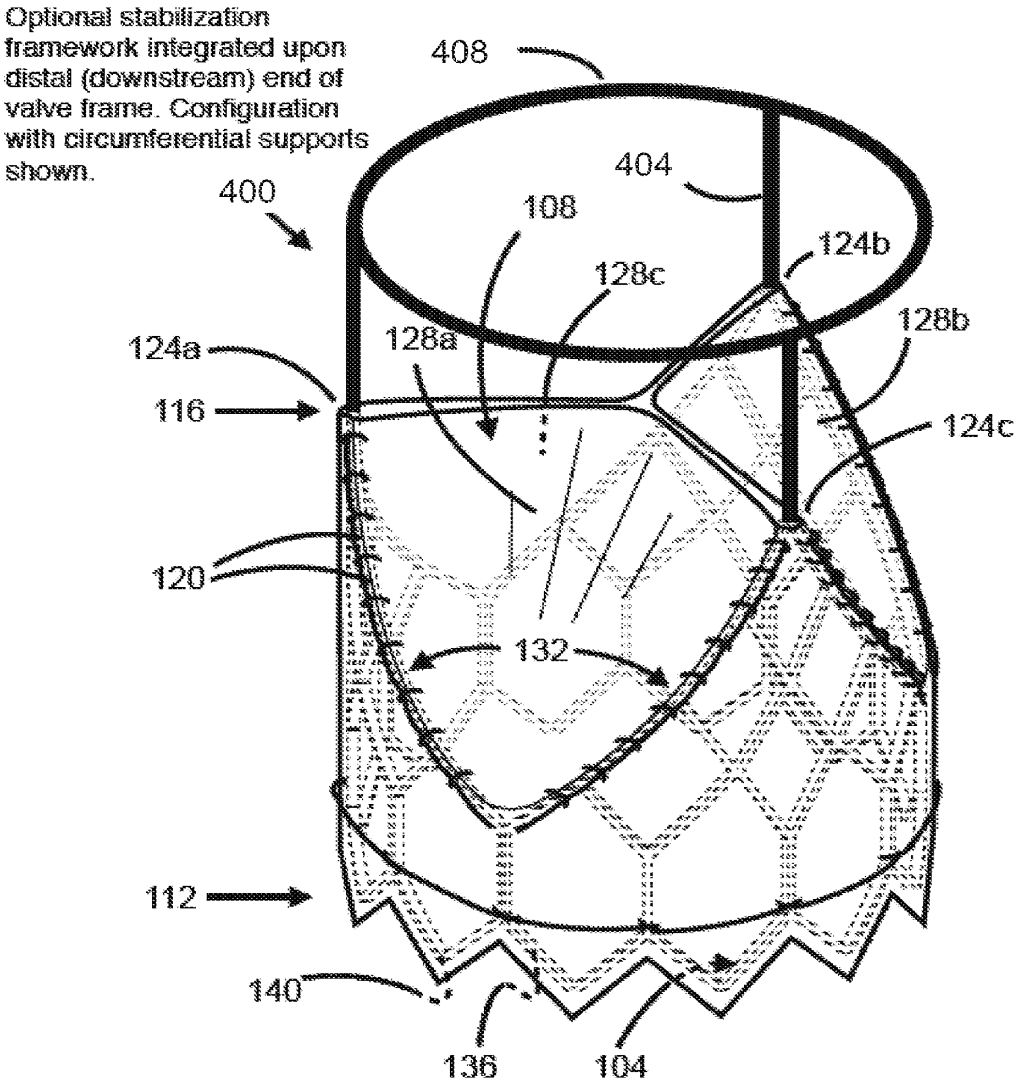

Optional stabilization framework integrated upon distal (downstream) end of valve frame. Configuration with circumferential supports shown.
408
404
400
108
124b
128c
128b
124a
128a
116
124c
120
132
112
140
136
104

Fig. 4

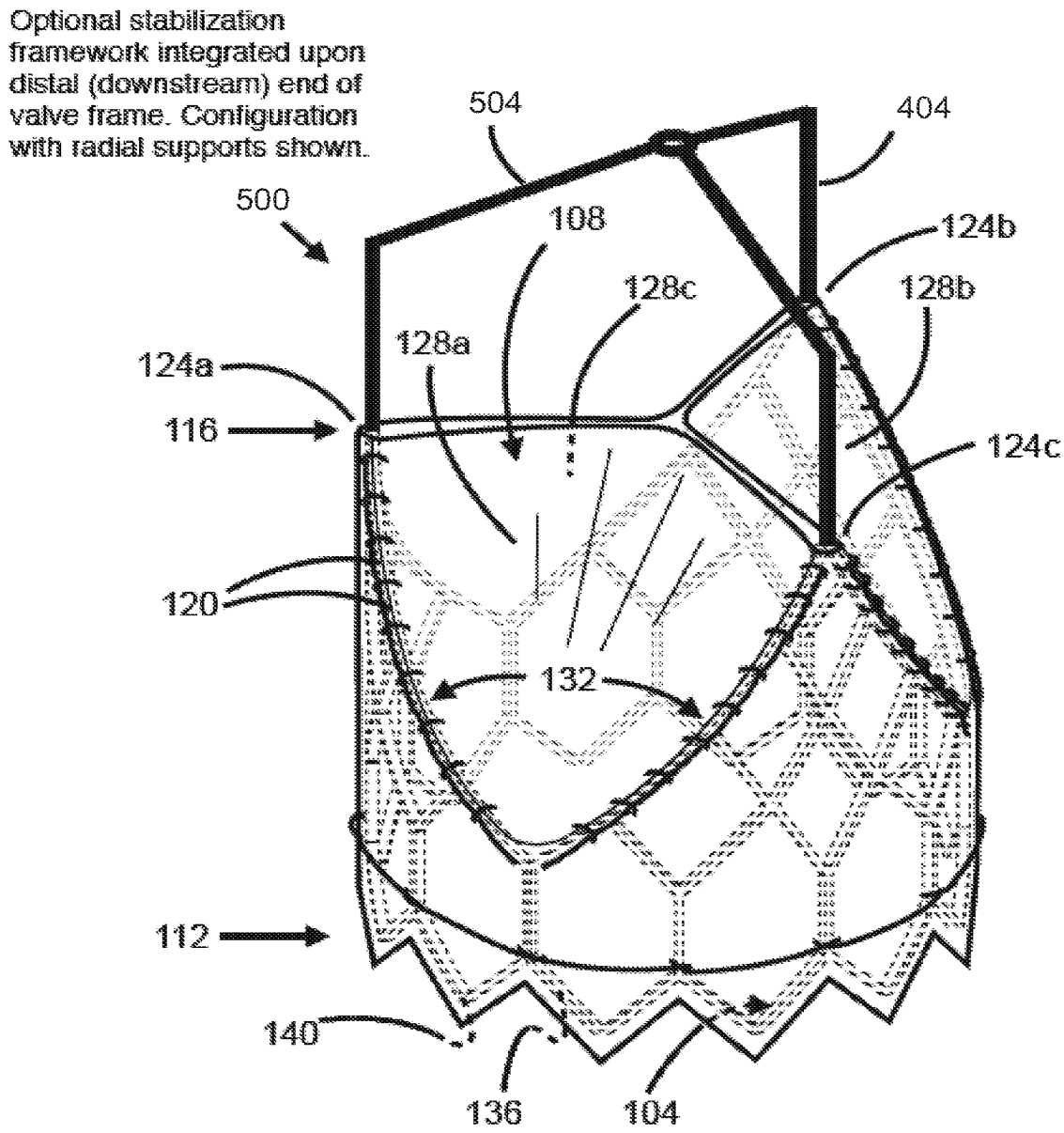

Optional stabilization framework integrated upon distal (downstream) end of valve frame. Configuration with radial supports shown.
504
404
500
108
124b
128c
128b
128a
124a
116
124c
120
132
112
140
136
104

Fig. 5

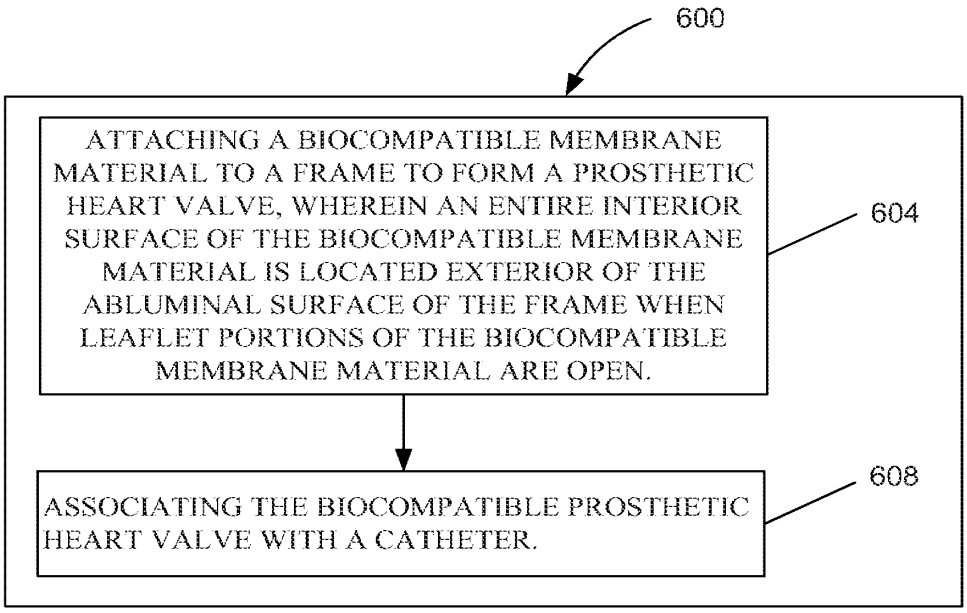

600
ATTACHING A BIOCOMPATIBLE MEMBRANE MATERIAL TO A FRAME TO FORM A PROSTHETIC HEART VALVE, WHEREIN AN ENTIRE INTERIOR SURFACE OF THE BIOCOMPATIBLE MEMBRANE MATERIAL IS LOCATED EXTERIOR OF THE ABLUMINAL SURFACE OF THE FRAME WHEN LEAFLET PORTIONS OF THE BIOCOMPATIBLE MEMBRANE MATERIAL ARE OPEN.
604
ASSOCIATING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

FIG. 6

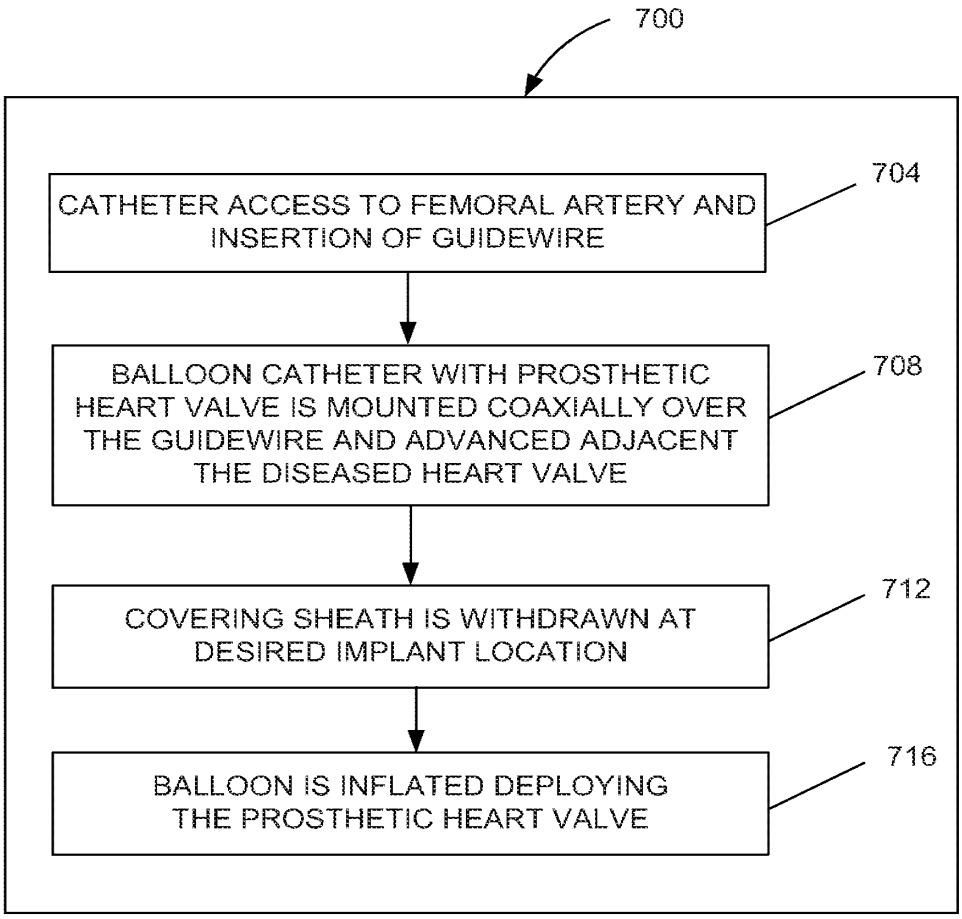

700
CATHETER ACCESS TO FEMORAL ARTERY AND INSERTION OF GUIDEWIRE
704
BALLOON CATHETER WITH PROSTHETIC HEART VALVE IS MOUNTED COAXIALLY OVER THE GUIDEWIRE AND ADVANCED ADJACENT THE DISEASED HEART VALVE
708
COVERING SHEATH IS WITHDRAWN AT DESIRED IMPLANT LOCATION
712
BALLOON IS INFLATED DEPLOYING THE PROSTHETIC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

FIG.7

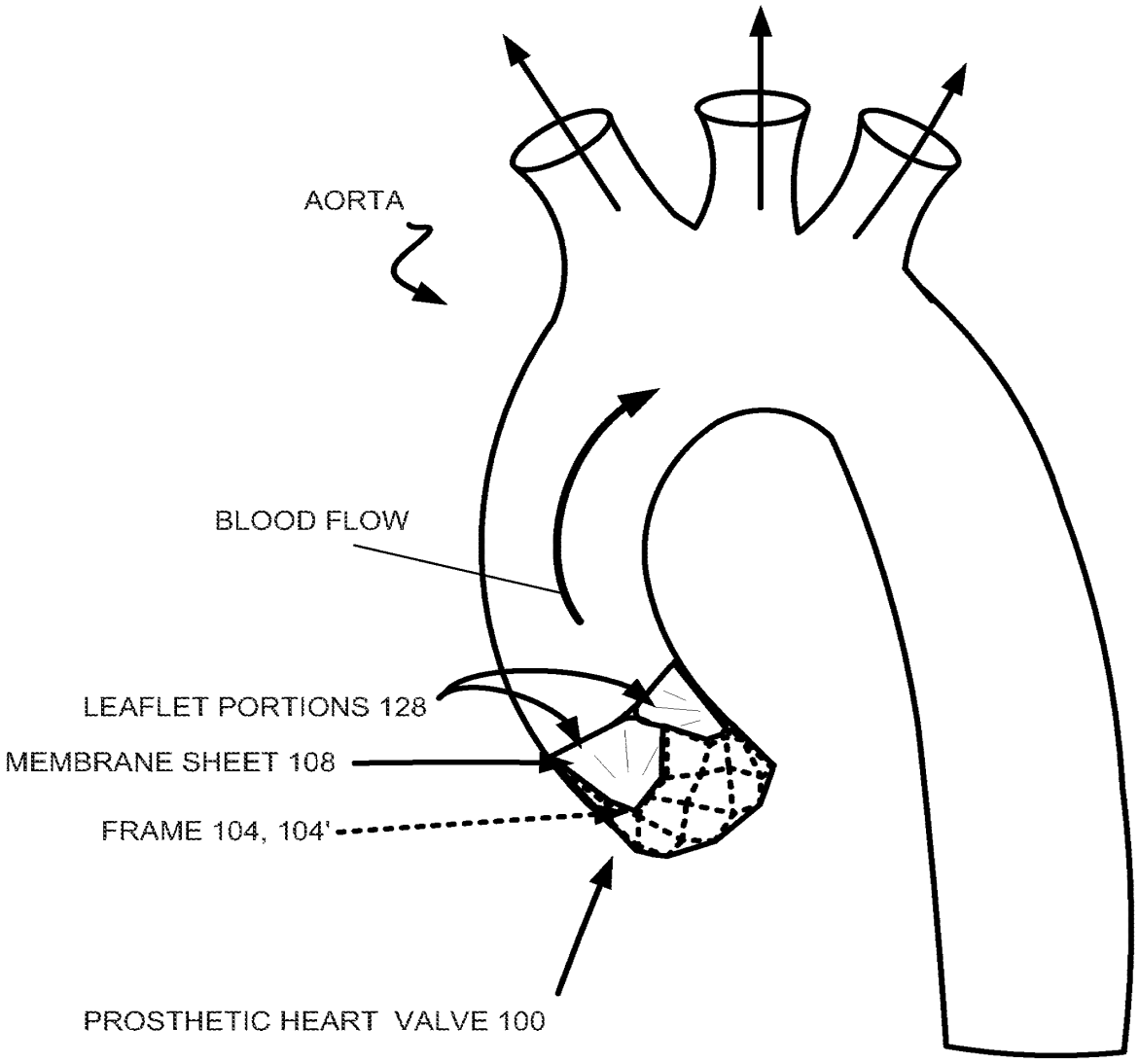

AORTA
BLOOD FLOW
LEAFLET PORTIONS 128
MEMBRANE SHEET 108
FRAME 104, 104'
PROSTHETIC HEART VALVE 100

FIG. 8

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 June 2012 (21.06.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/082952 A2

(51) International Patent Classification:
A61F 2/24 (2006.01) *A61F 2/82* (2006.01)
A61M 39/22 (2006.01) *A61M 25/00* (2006.01)

(21) International Application Number:
PCT/US2011/064989

(22) International Filing Date:
14 December 2011 (14.12.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/423,051 14 December 2010 (14.12.2010) US
13/326,196 14 December 2011 (14.12.2011) US

(71) Applicant *(for all designated States except US)*: **COLIBRI HEART VALVE LLC** [US/US]; 2150 W. 6th Ave., Suite M, Broomfield, CO 80020 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **FISH, David, R.** [US/US]; 6349 Vanderbilt Street, Houston, TX 77005 (US). **INDUNI, Eduardo** [CR/CR]; Resi Aljuela H7, Alajuela, 906 4050 (CR). **PANIAGUA, David** [CR/US]; 3813 Drummond Street, Houston, TX 77025 (US).

(74) Agent: **YASKANIN, Mark, L.**; Bryan Cave LLP, 1700 Lincoln Street, Suite 4100, Denver, CO 80203 (US).

(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.

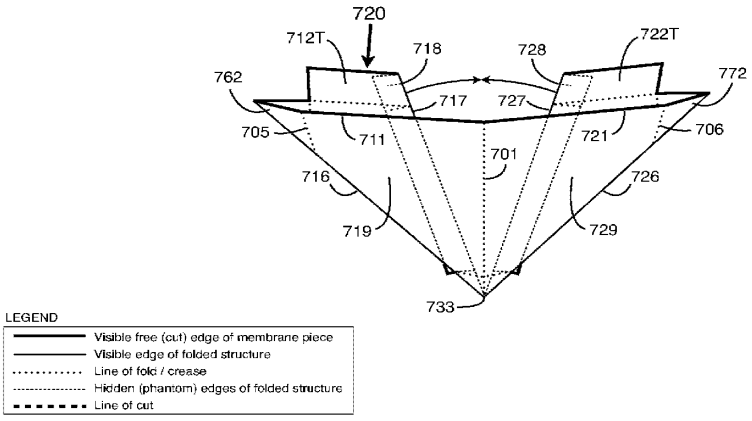
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, 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

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

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.

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

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

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

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;

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

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;

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

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

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

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

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.

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

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.

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

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

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

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.

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

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

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

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

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

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

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.

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

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

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

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)

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.

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

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.

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.

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.

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

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.

Figure 1A

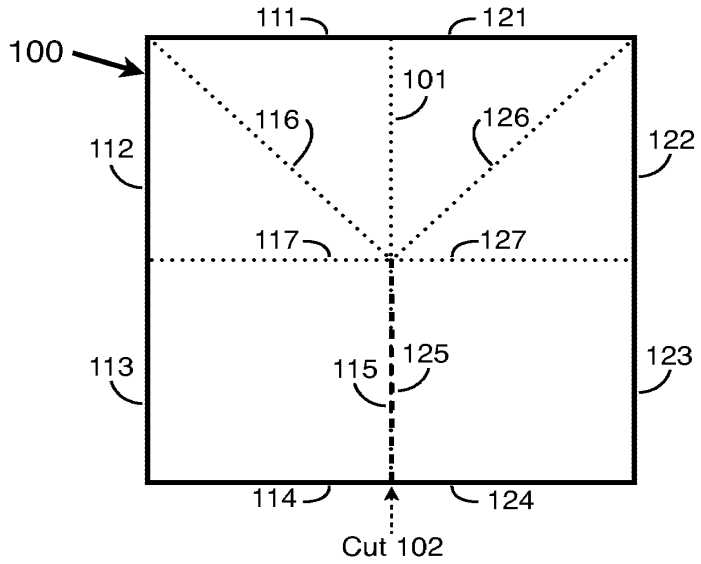
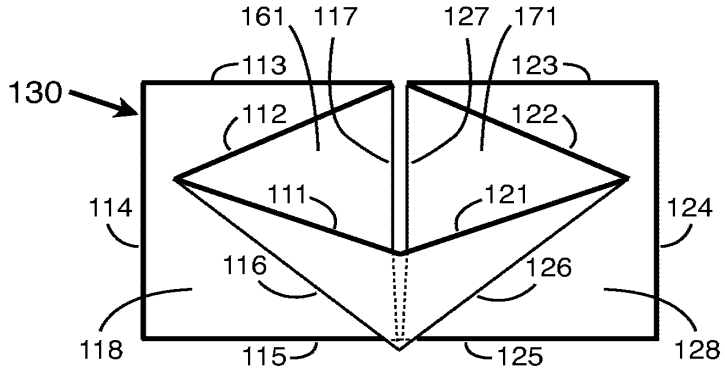


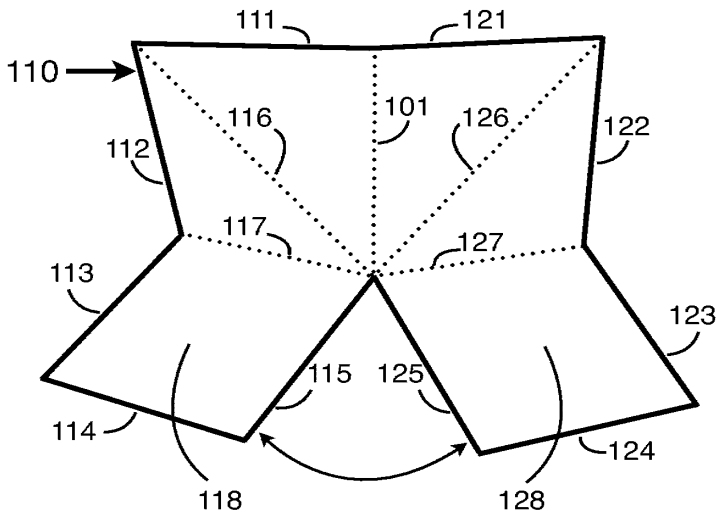
Figure 1B



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

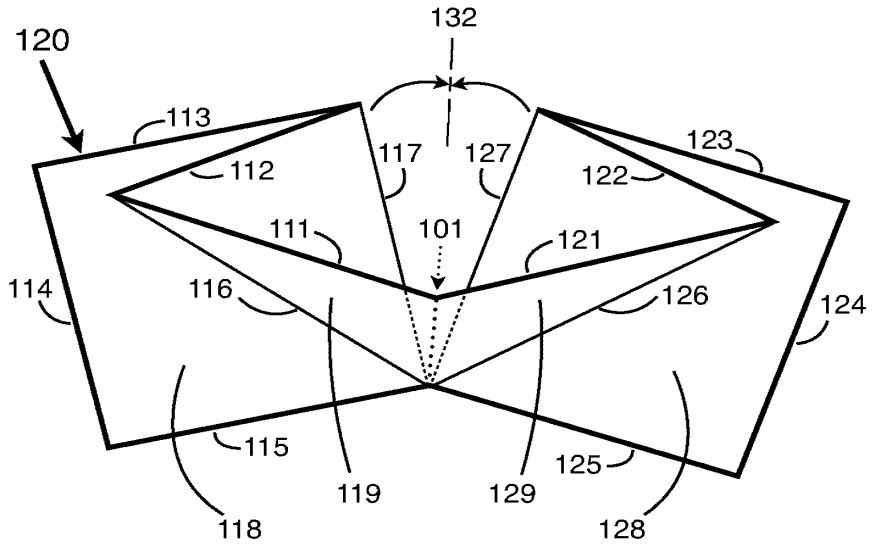
Figure 1C



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

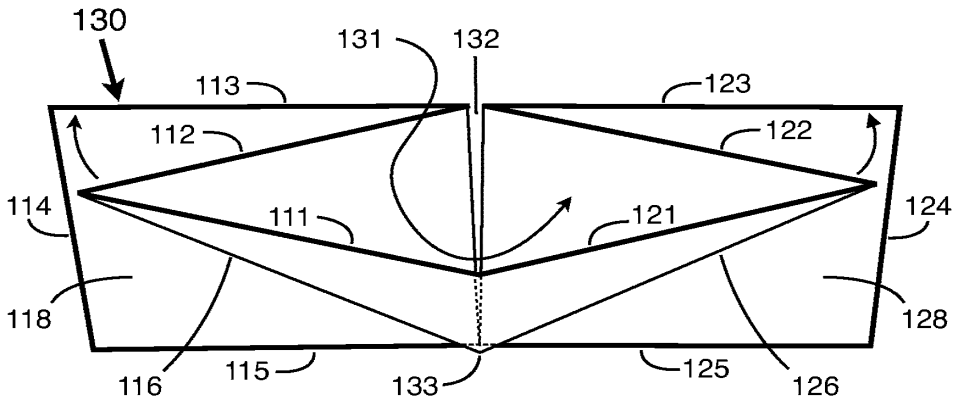
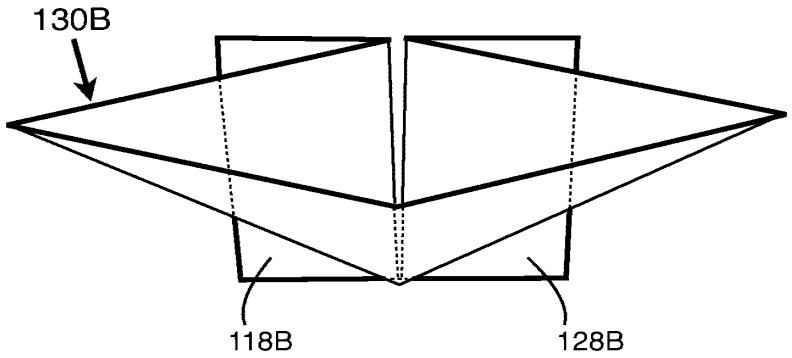


Figure 1F



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.

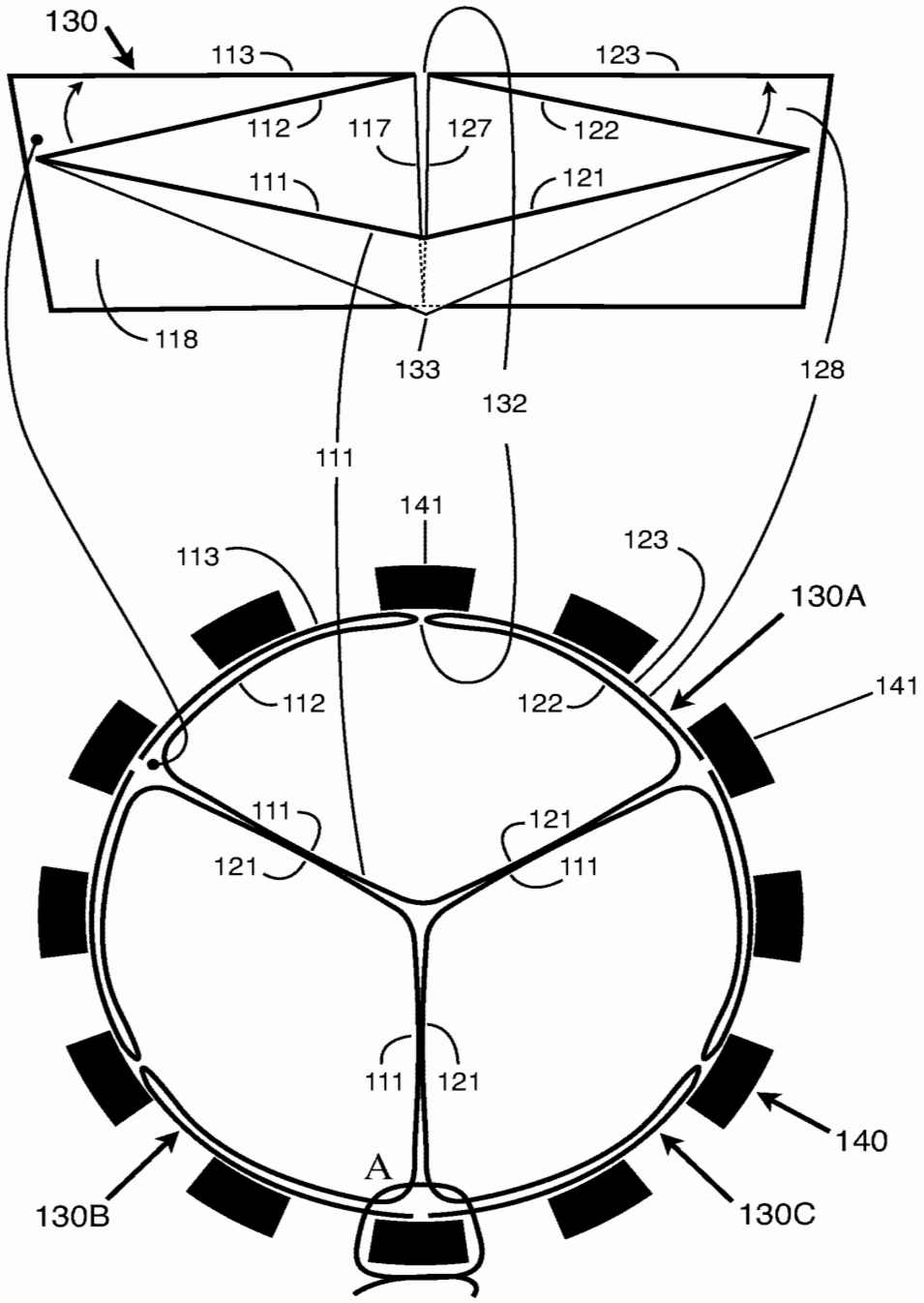
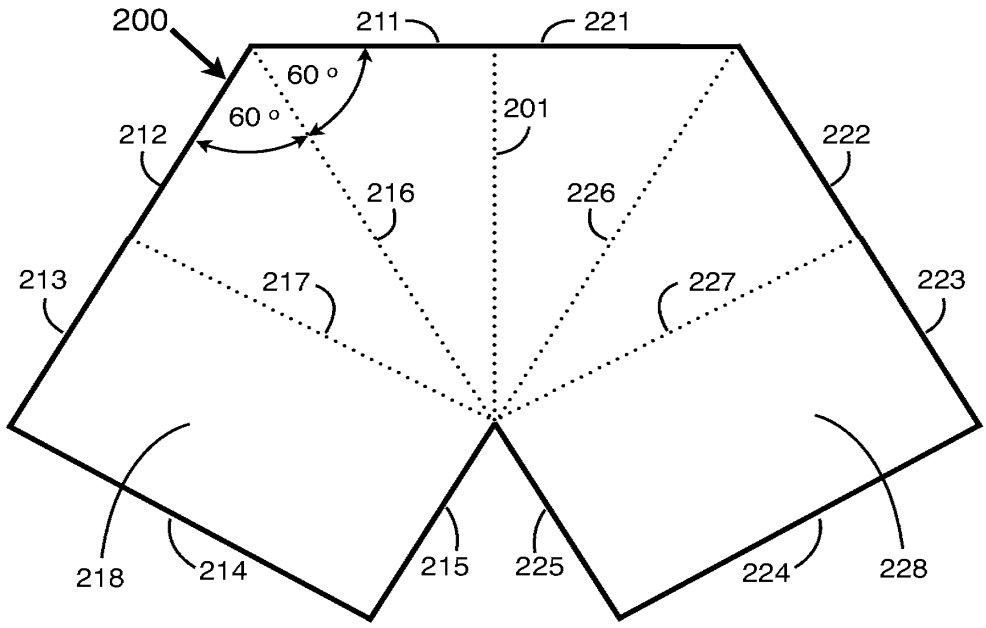


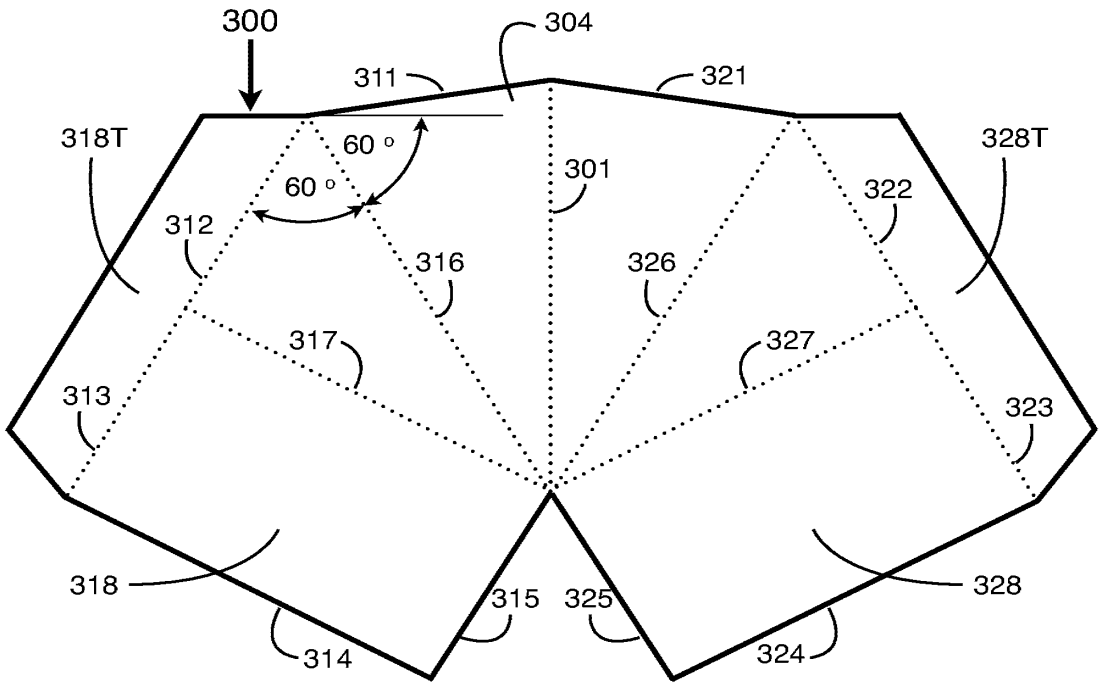
Figure 2



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

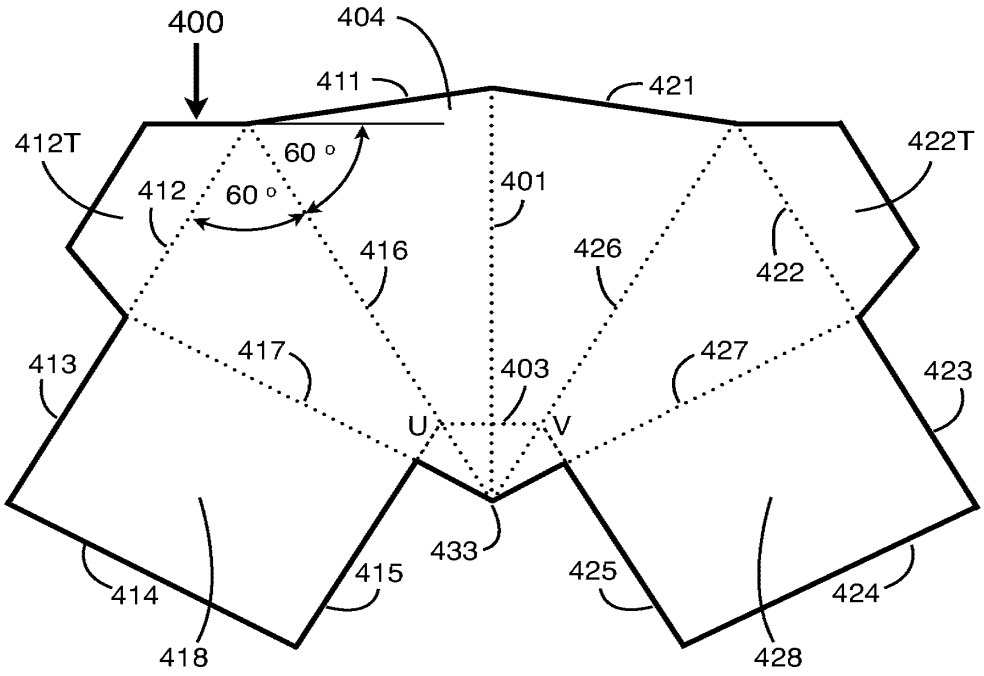
Figure 3



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

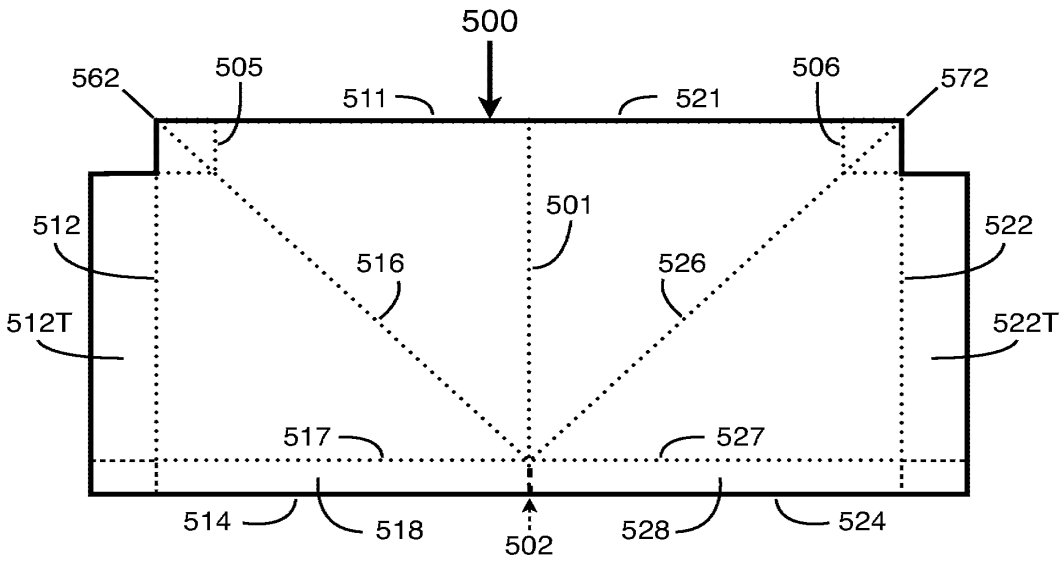
Figure 4



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

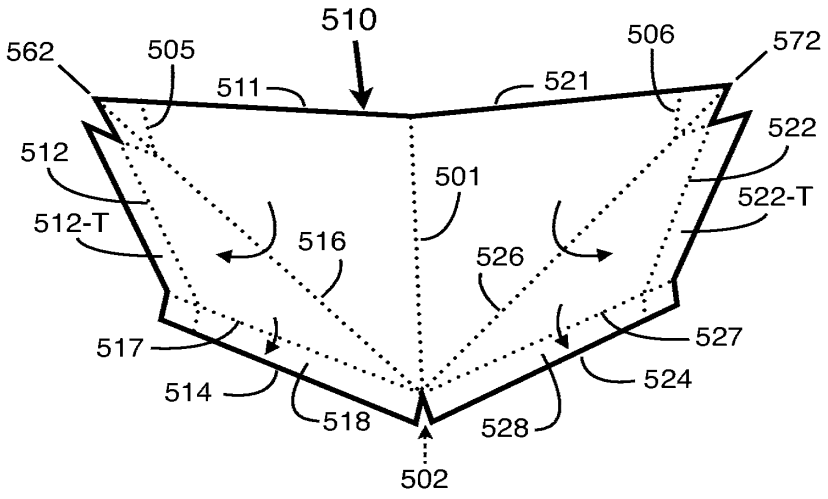
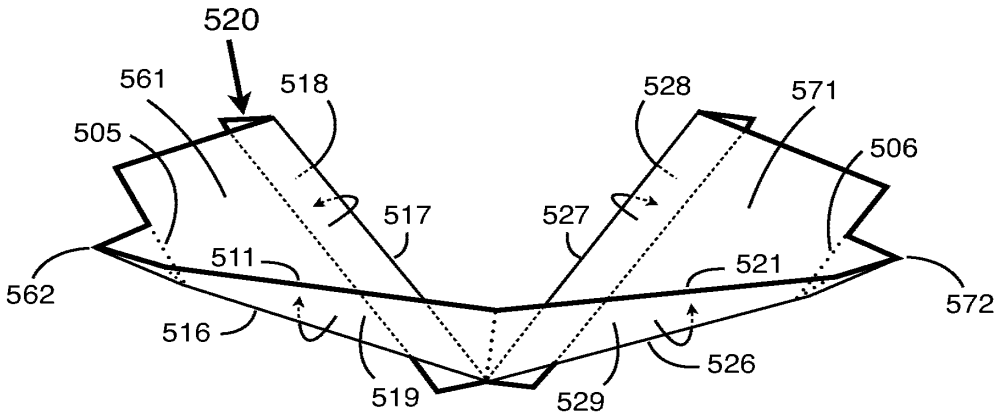


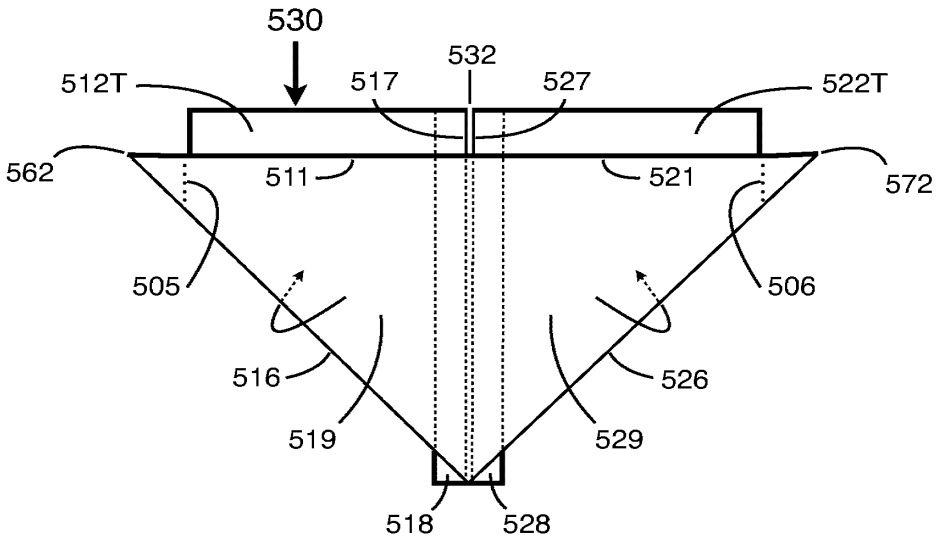
Figure 5C



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

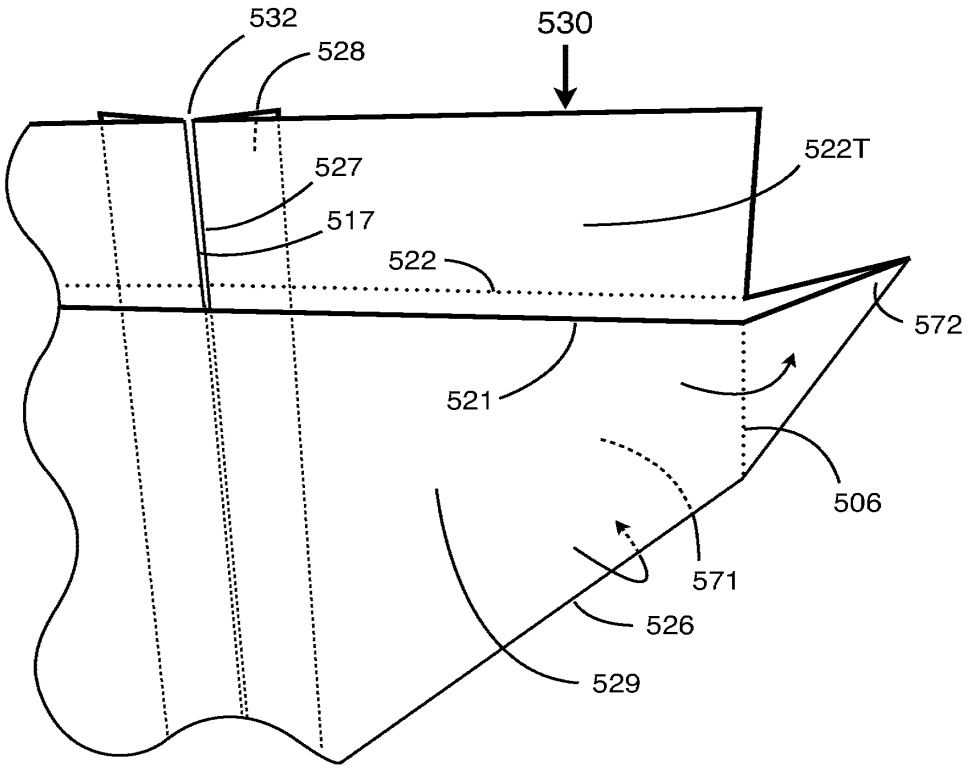
Figure 5D



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

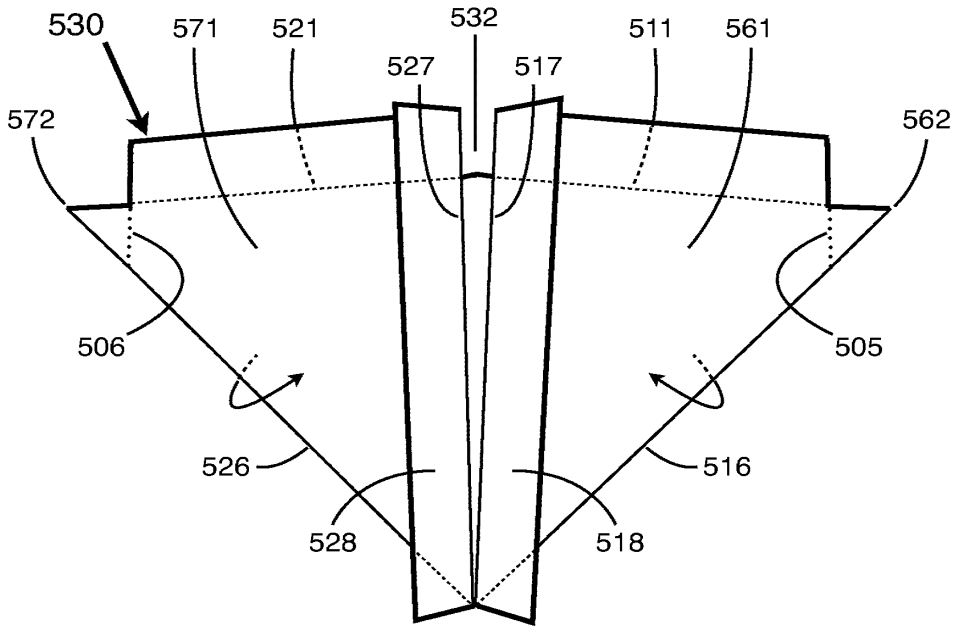
Figure 5E



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

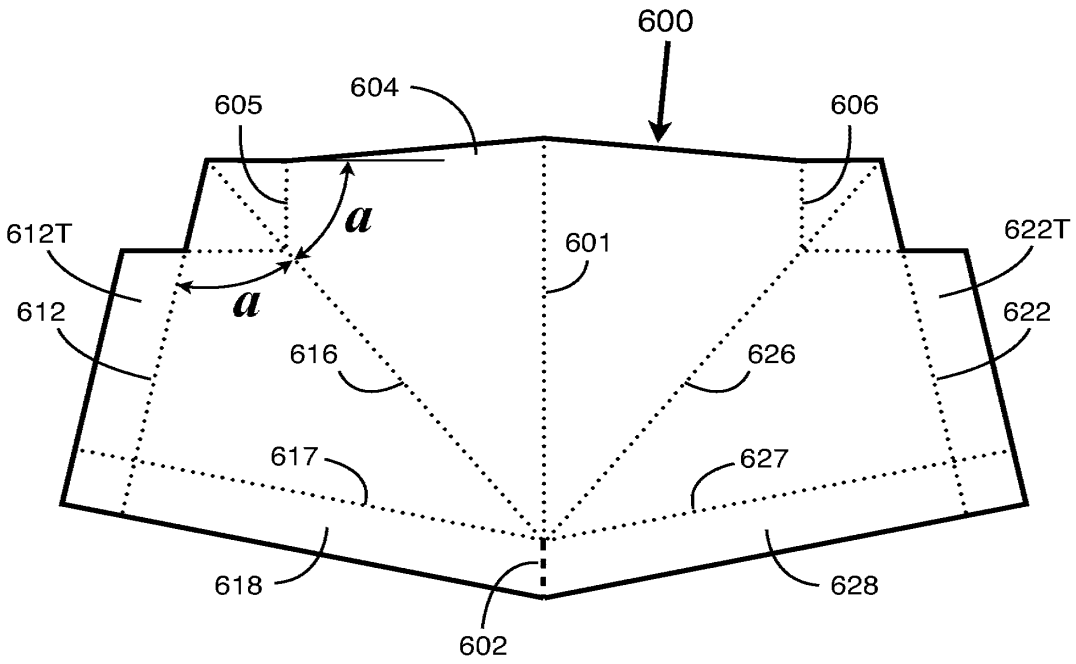
Figure 5F



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

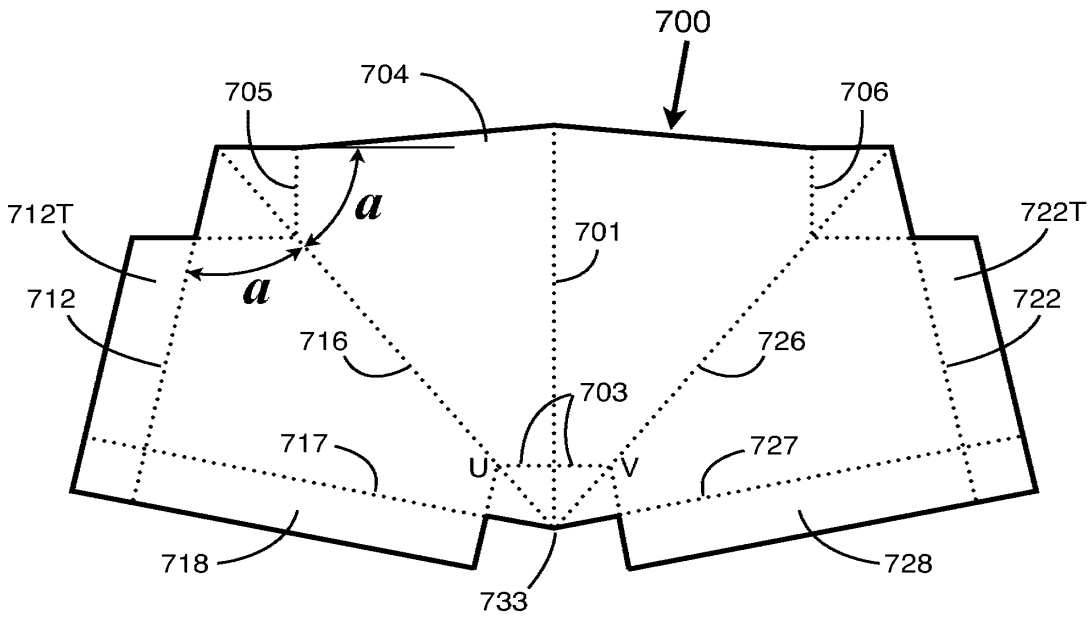
Figure 6



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

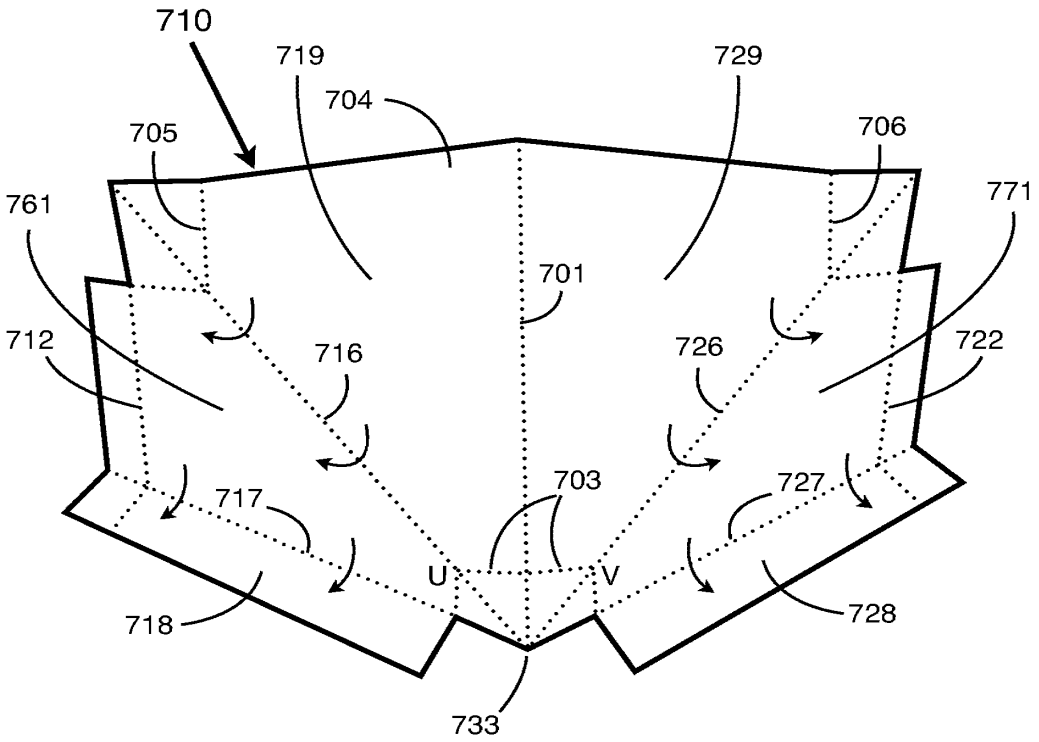
Figure 7A



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

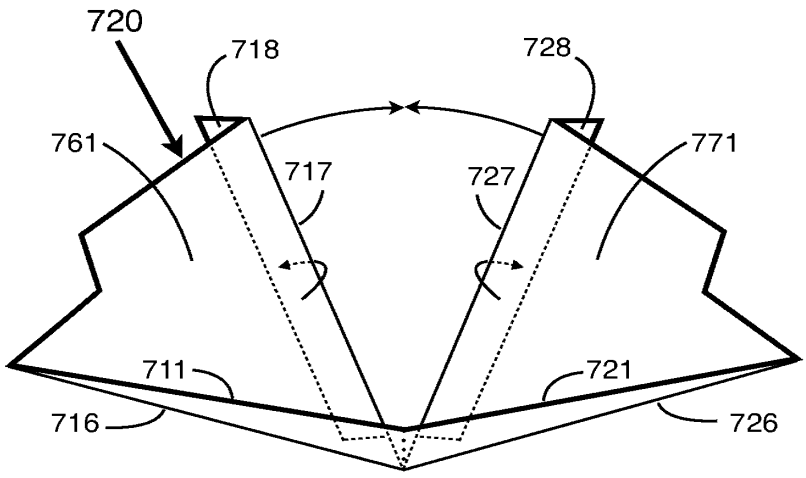
Figure 7B



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

———	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 7D

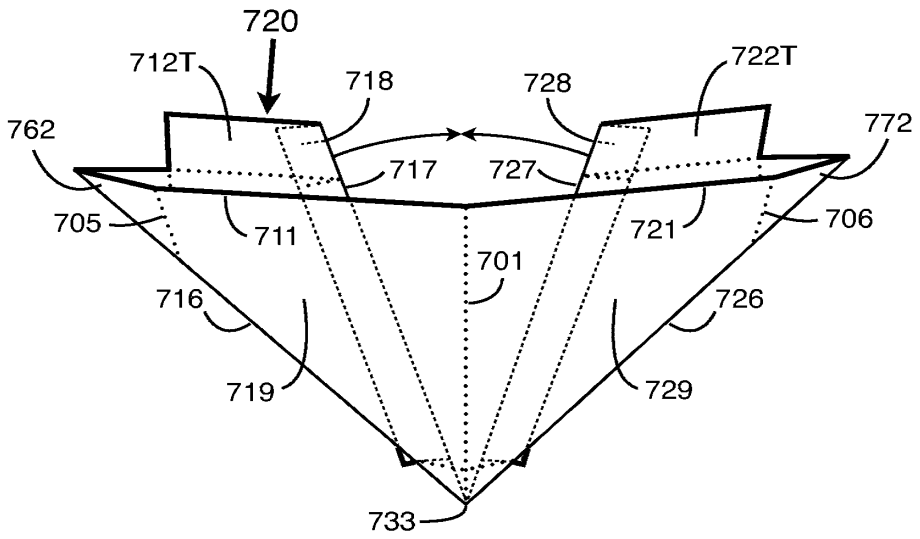
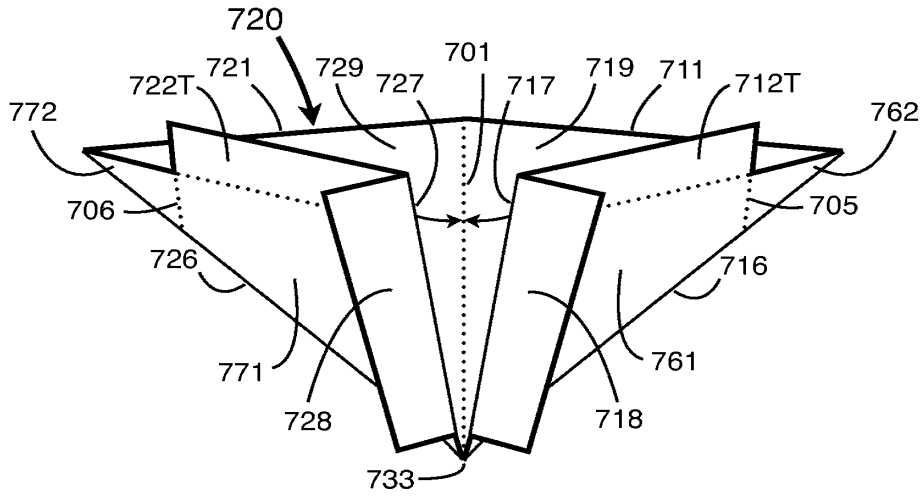


Figure 7E



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

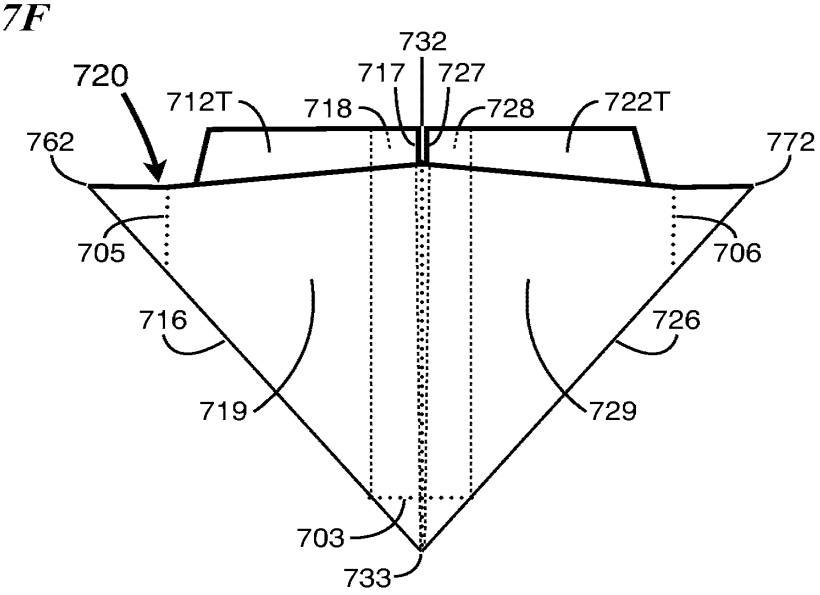


Figure 7G

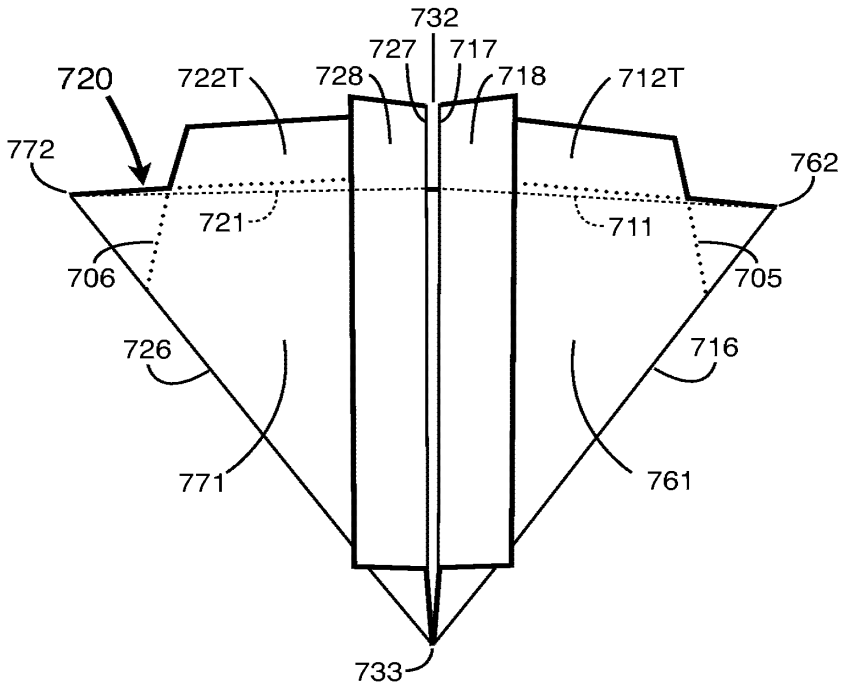


Figure 7H

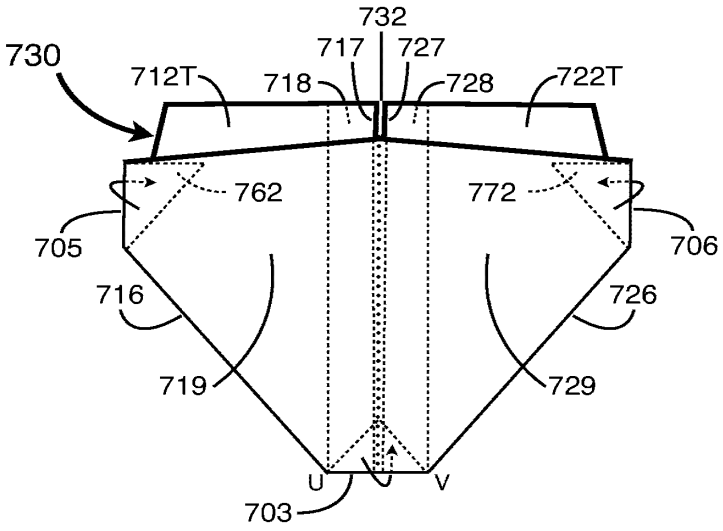


Figure 7I

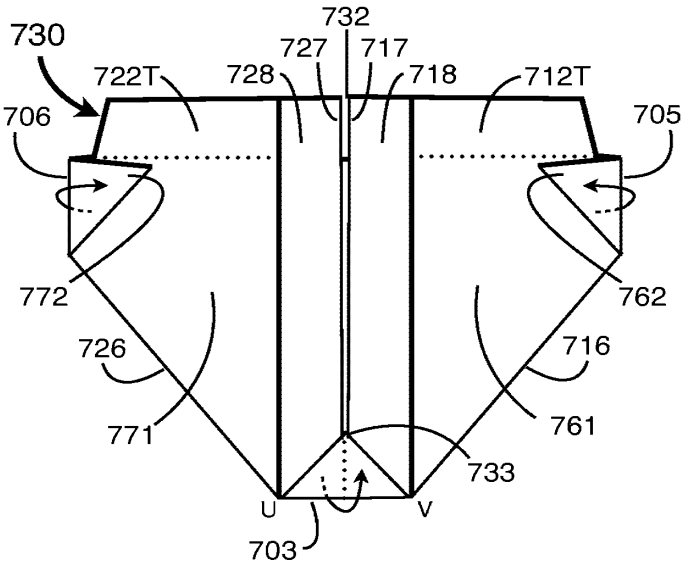
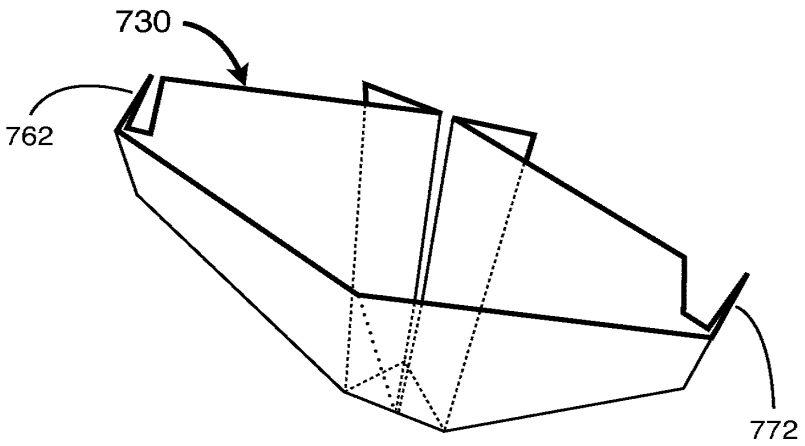


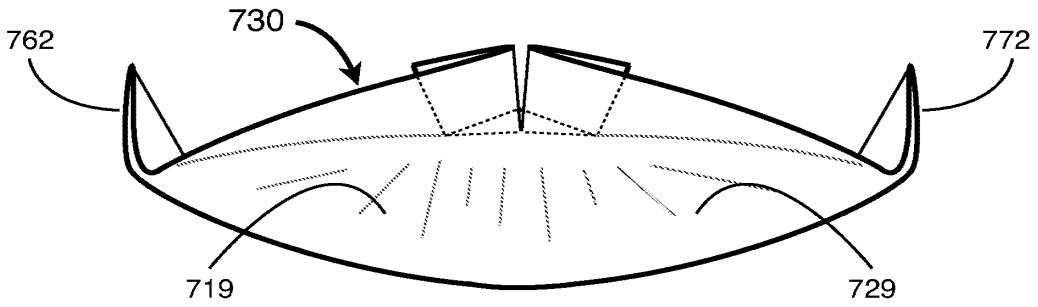
Figure 7J



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

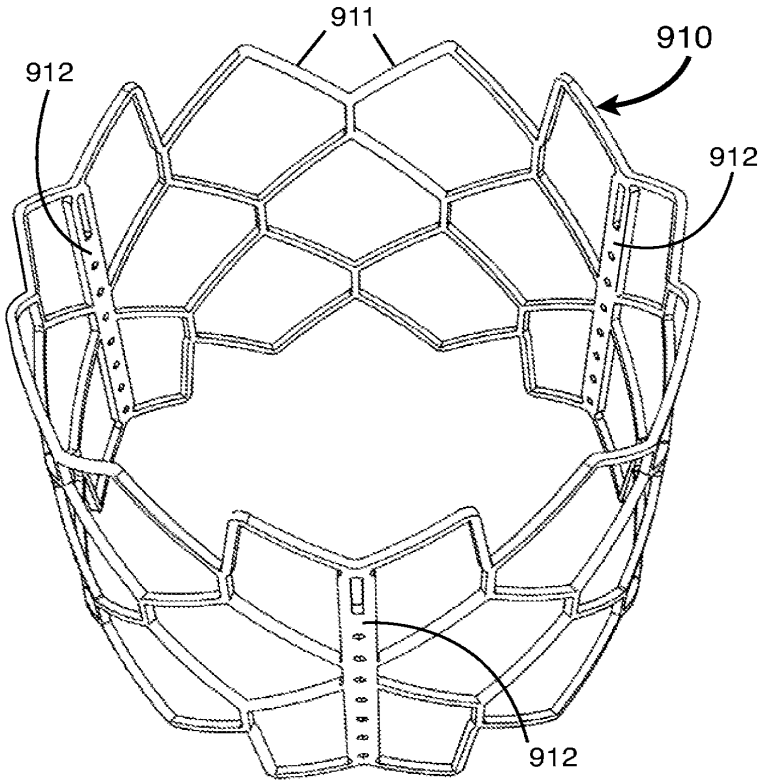


Figure 8B

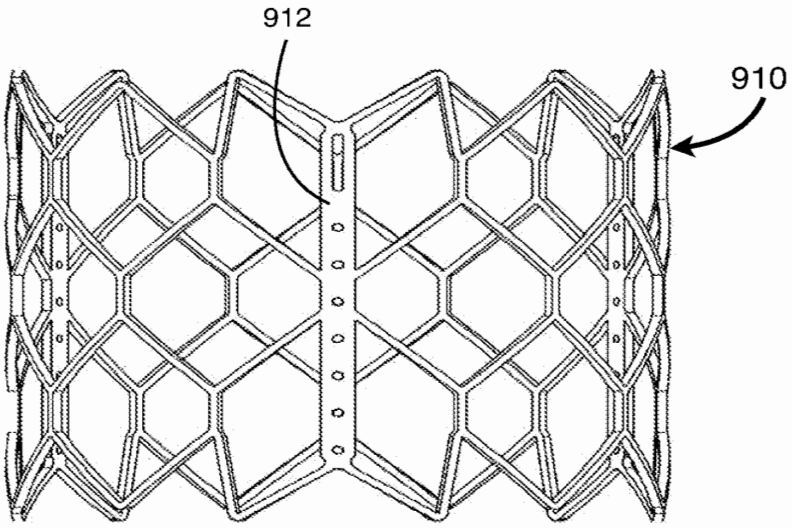


Figure 8C

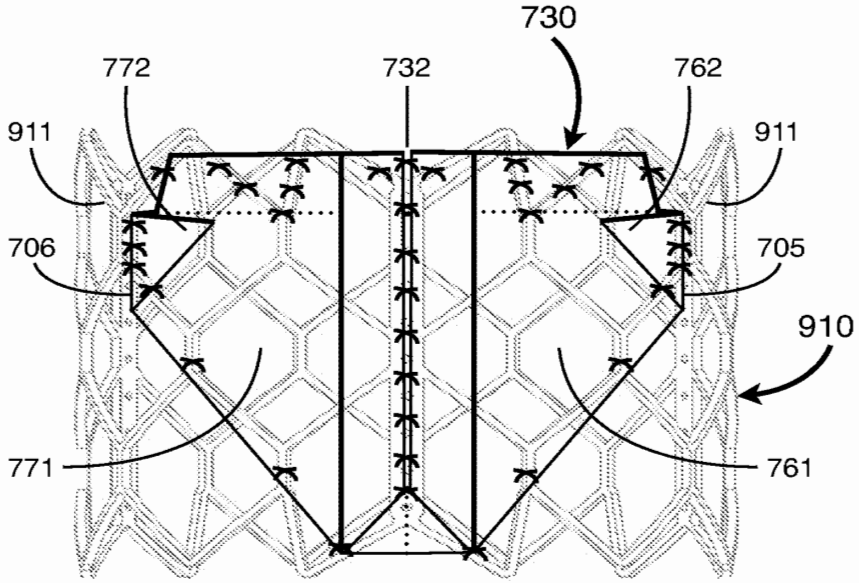
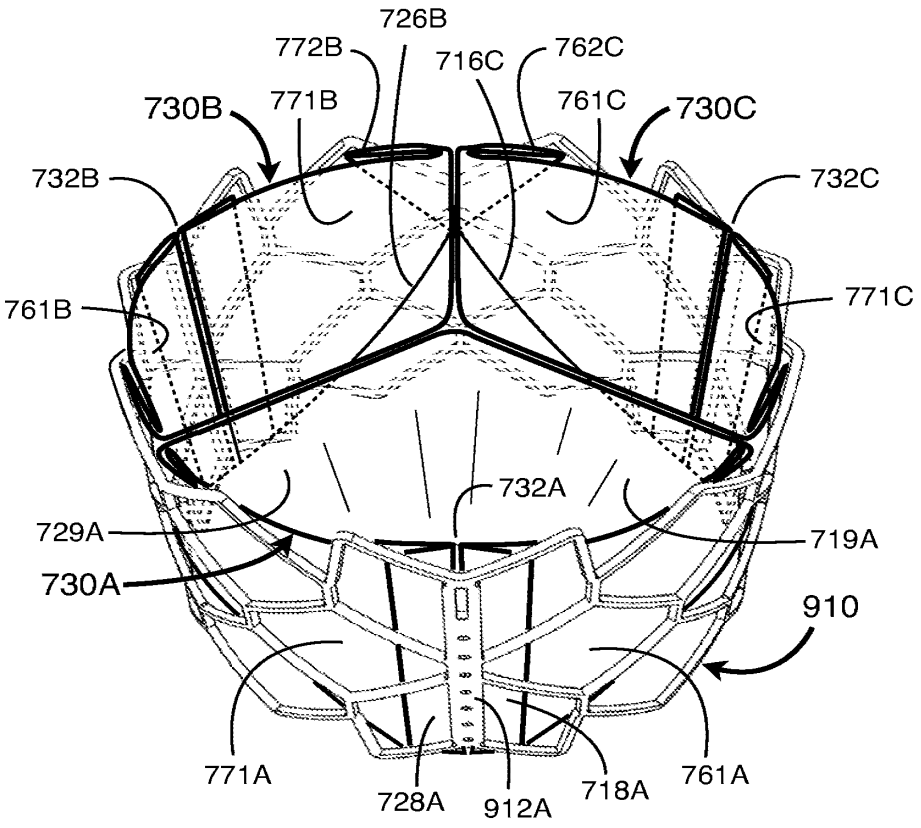


Figure 8D



Suture attachments omitted for clarity

Figure 9A

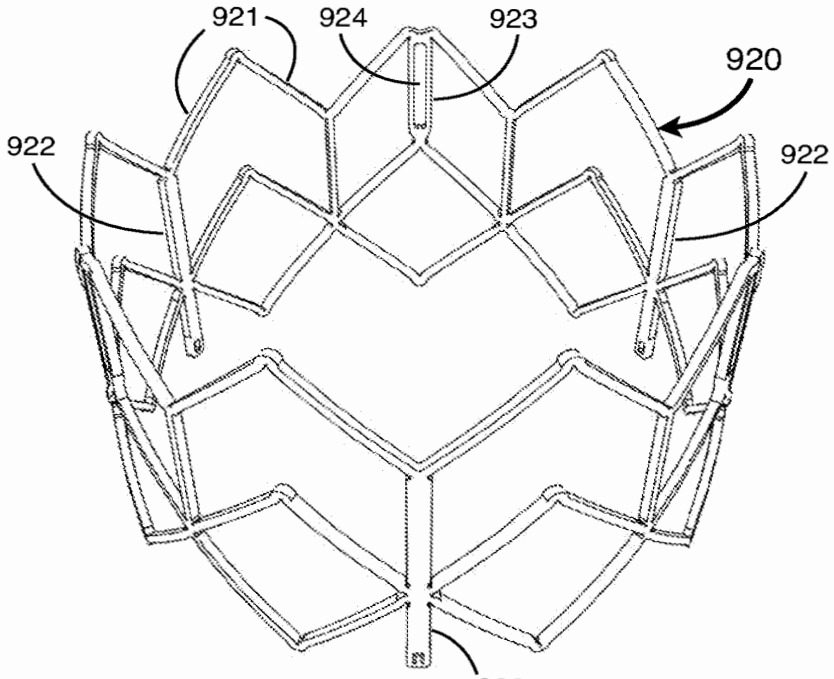


Figure 9B

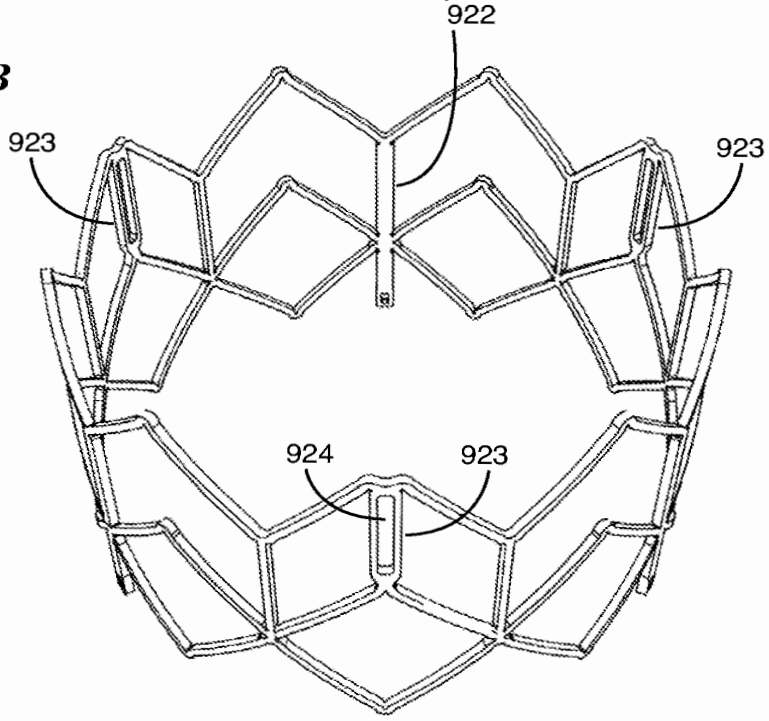


Figure 9C

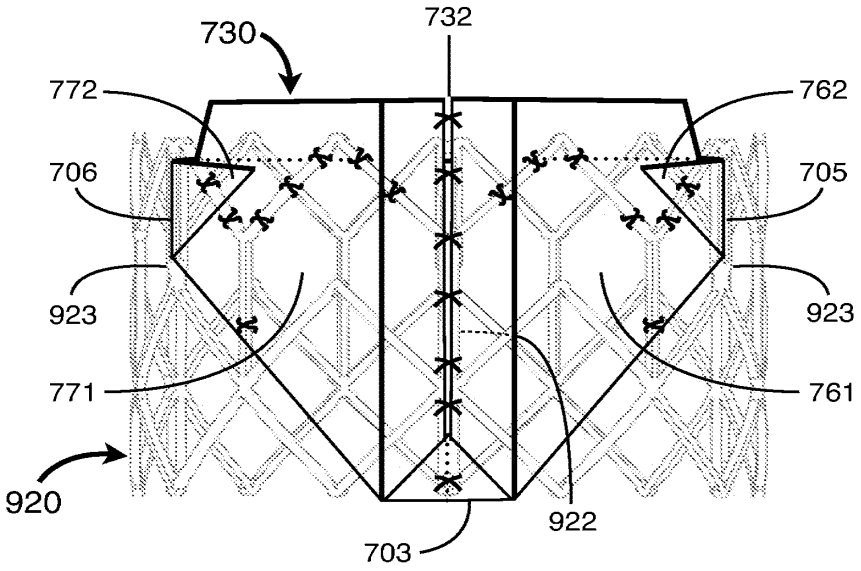


Figure 9D

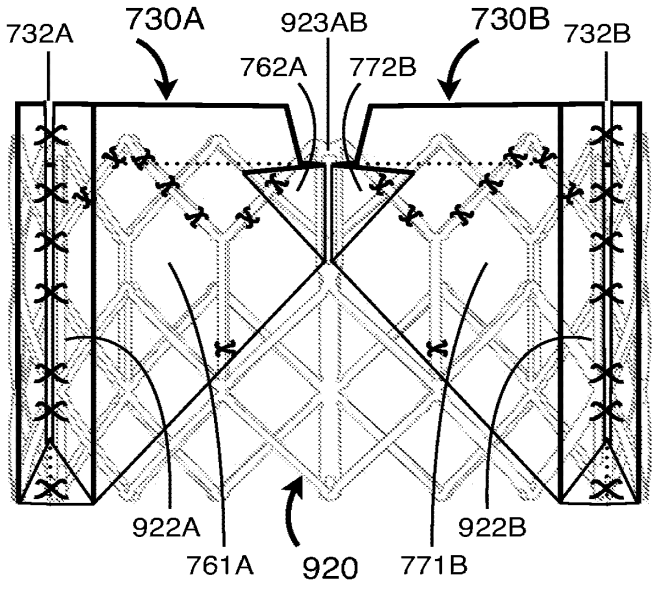
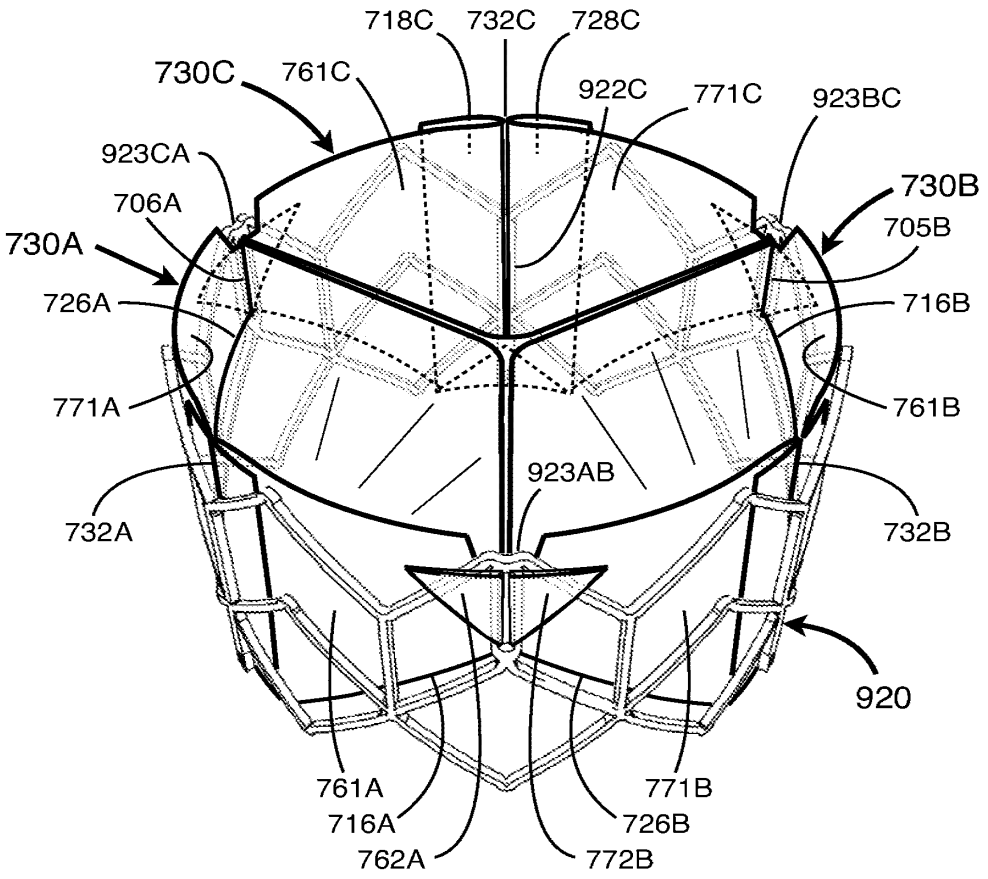


Figure 9E



Suture attachments omitted for clarity

Electronic Acknowledgement Receipt

EFS ID:	19117938
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	23-MAY-2014
Filing Date:	15-APR-2014
Time Stamp:	16:50:22
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_10104_IDS_1.pdf	607953 7711e5d5efb8453e643b756fd2b2f6983ff04ea8	no	31

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_IDS_2.pdf	592244 6876a05bbf87dc2bf9ea43a178692bfef915e2b8	no	27
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_IDS_3.pdf	562498 2958641a58a03645d59925d5b4e2f7dde437a965	no	8
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
4	Non Patent Literature	10113_US-14253656_Preliminary_Amendment.PDF	174477 29b4371419a40b1f2da7be8323b2621346c356fd	no	16
Warnings:					
Information:					
5	Non Patent Literature	10114_US-14268184_Preliminary_Amendment.PDF	177016 a87df354bd33e4092be4c598b659a19a873b3734	no	17
Warnings:					
Information:					
6	Non Patent Literature	10115_US-14268190_Preliminary_Amendment.PDF	175787 95f70cf8f129b740a3037e4089f63a07acd2922e	no	17
Warnings:					
Information:					
7	Non Patent Literature	10116_US-14284049_Preliminary_Amendment.PDF	172221 ecebba8c1a9be8121a83dbd907fc6bc6b91ef0a8	no	14
Warnings:					
Information:					
8	Non Patent Literature	10117_US-14284063_Preliminary_Amendment.PDF	172431 869f1797f56edb0b5a6b917f23daf966999373cb	no	14
Warnings:					
Information:					
9	Foreign Reference	EP1441672_Edwards_Lifesciences.pdf	1130476 3388da550c805722d00e61baa470bca30de257e7	no	74
Warnings:					
Information:					

10	Foreign Reference	EP1603493_Edwards_Lifesciences.pdf	375942 0d0efb1c62a0bd6c25a014f52a8558fa64fa05d2	no	23
Warnings:					
Information:					
11	Foreign Reference	EP1621162_Edwards_Lifesicences.pdf	612871 3b6432fabecfd57d7dd4a50ecd50937690ef6c78	no	36
Warnings:					
Information:					
12	Foreign Reference	EP2000115_Edwards_Lifesciences_w_correction-page.pdf	622121 127b738e7cd7d1de0a44a53d8a540e0f0dd6e1be	no	37
Warnings:					
Information:					
13	Foreign Reference	EP2055266_Edwards_Lifesciences.pdf	1686518 c8b3f6b2771b04d561a5c26ab4b174f22e34235c	no	75
Warnings:					
Information:					
14	Foreign Reference	EP2260796_Edwards_Lifesciences.pdf	687874 ce7fa6bf070455444f6e74da4ef60b7a3f674aa4	no	36
Warnings:					
Information:					
15	Foreign Reference	RU-235561C.PDF	87094 aaf3f4b729f5a0d6bc9244c77c4d16ae3f216a38	no	1
Warnings:					
Information:					
16	Foreign Reference	WO-1991-017720.PDF	857121 f24db653dcc46adde9c9d39603bd72c0b3a78fb6	no	21
Warnings:					
Information:					
17	Foreign Reference	WO-1992-017118.PDF	2805645 638de26e8e8896033e8afee7df03039263f619e5	no	76
Warnings:					
Information:					
18	Foreign Reference	WO-1998-029057.pdf	2664467 be466b93ef409a5976928ffaaf669c0dd4ba1fec	no	67
Warnings:					
Information:					

19	Foreign Reference	WO-1999-030646.PDF	765730 7605d4bc1bb0d3c74771cf2d87ab444d229758a2	no	23
Warnings:					
Information:					
20	Foreign Reference	WO-2000-012164.pdf	739646 bf23c238b4f8efe9fb4fc1de68266ebe35dae28b	no	18
Warnings:					
Information:					
21	Foreign Reference	WO-2001-002031.PDF	1210923 38fcd5acbaf2e93b980fb1fb5c3f5f361bbaf550	no	28
Warnings:					
Information:					
22	Foreign Reference	WO-2003-047468.pdf	4575234 f44b1886047fe62acc40595be0ee2c8259bce3d7	no	115
Warnings:					
Information:					
23	Foreign Reference	WO-2003-092554.PDF	7059641 d19d0f8fcc5d99e66df1c159377c5cbf2e5387c4	no	64
Warnings:					
Information:					
24	Foreign Reference	WO-2004-026124.pdf	2030970 c3068eb99a9104b919114ec7836f5912c8edf32f	no	65
Warnings:					
Information:					
25	Foreign Reference	WO-2004-082527.pdf	2197853 f4d0d8ee205f8293529b296c1314228fb54751a7	no	49
Warnings:					
Information:					
26	Foreign Reference	WO-2006-095342.PDF	5286175 b69d3d54f504055a484b36409b27e280d9e93ce5	no	73
Warnings:					
Information:					
27	Foreign Reference	WO-2007-138572.PDF	2881341 61a6766d1d18ad5e70fbf27b421bb8dd29f9cf18	no	71
Warnings:					
Information:					

28	Foreign Reference	WO-2008-063537.pdf	746540 1dc74f37508aef50fee43062ac86a18f900fc528	no	23
Warnings:					
Information:					
29	Foreign Reference	WO-2008-106531.pdf	1730961 a5bd15dd7ba5b8e6c40c41e516370bd97fc2b4be	no	26
Warnings:					
Information:					
30	Foreign Reference	WO-2009-156471.PDF	1102714 34029217aa67c5b5a444eccd48a981219de58ab4	no	29
Warnings:					
Information:					
31	Foreign Reference	WO-2009-052188.PDF	1888039 9b53b000fcc1721e38d9a19c633caba20d12fe11	no	37
Warnings:					
Information:					
32	Foreign Reference	WO-2010-024801.pdf	3565559 19f208ef9f9c40f51e4cb509c0d73ef28d2b2d3f	no	88
Warnings:					
Information:					
33	Foreign Reference	WO-2010-027363.pdf	4228355 d87dd6be9d572612dcce9be2fcc5d2e4b3691b57	no	84
Warnings:					
Information:					
34	Foreign Reference	WO-2010-080594.pdf	2492471 73aba383d4f39b2f770c94ab9b34ef3abd7451a4	no	58
Warnings:					
Information:					
35	Foreign Reference	WO-2010-117541.pdf	1341907 b9793f46e8e9cc0b18f28621cd0a29be3bc642bb	no	28
Warnings:					
Information:					
36	Foreign Reference	WO-2011-109433.PDF	1332406 7d3b4acf33d8fafbaf81ce324f95775805264 68a	no	24
Warnings:					
Information:					

37	Foreign Reference	WO-2011-109450.PDF	3458144 49cb567520f19f7be95fe5acd0e8ad5314900200	no	61
Warnings:					
Information:					
38	Foreign Reference	WO-2012-006124.PDF	2412038 222cb6e8e002d8b9722257271f752482b6d4a883	no	40
Warnings:					
Information:					
39	Foreign Reference	WO-2012-040643.pdf	2150457 801967121722e8ee194b0f64e73bce4451ccf882	no	40
Warnings:					
Information:					
40	Foreign Reference	WO-2012-082952.pdf	3197416 94066c07d105032afc59b55f485ba481853e2d35	no	68
Warnings:					
Information:					
41	Non Patent Literature	Angelini_Affidavit.PDF	89997 1882a66e67c83bdbeaf11b57b173118d0d549524	no	3
Warnings:					
Information:					
42	Non Patent Literature	Lamas_Affidavit.PDF	105865 eab4bde34d7db0bebc5894c11a4bf83e93e91f5a	no	3
Warnings:					
Information:					
43	Non Patent Literature	Andersen_Transluminal_Implantation_ARTICLE.PDF	2432965 358b67d469862dfe6f7b8a375fdcb76c2785ce67	no	5
Warnings:					
Information:					
44	Non Patent Literature	Artificial_Heart_Valve_Wikipedia.PDF	609769 2c28588b338338ed5b4893ca9c5c2ea92af67e07	no	7
Warnings:					
Information:					
45	Non Patent Literature	Bonhoeffer_Percutaneous_insertion.PDF	582627 f8893183c6fb6cf60158ce59c83e421daa33902f	no	6
Warnings:					
Information:					

46	Non Patent Literature	Bonhoeffer_Percutaneous_replacement.PDF	370353 facea19512aa7b20dfc92c9d14af6c27cce8d69a	no	3
Warnings:					
Information:					
47	Non Patent Literature	Bonhoeffer_Transcatheter_Implantation.PDF	585441 7fa67d034d657eb9462f6d95cd254cc84972e966	no	5
Warnings:					
Information:					
48	Non Patent Literature	Boudjemline_Pulmonary_Valve_Replacement.PDF	755441 ac1b0ae12450bd7078b99f9f5c5a6891494dd799	no	8
Warnings:					
Information:					
49	Non Patent Literature	Braga-Vilela_Extracellular_Matrix_ARTICLE.PDF	790354 5cf2f84f8906ecbf3fb2baa7479ab5a7fdca4bcd	no	11
Warnings:					
Information:					
50	Non Patent Literature	Breuer_Application_Tissue-Engineering_Principles.PDF	1193973 cb22dd9c8f73c41c122ec7c49fe1e12cfeaab050	no	12
Warnings:					
Information:					
51	Non Patent Literature	Cale_Hufnagel_Revisited.PDF	3204563 4b79cad74f4771c697148674880657c1296a49b3	no	5
Warnings:					
Information:					
52	Non Patent Literature	Cerralaza_comparision_of_the_hydrodynamical_behaviour.PDF	2421201 c02074e95f1beadf976dbea2e3e316926aac6549	no	10
Warnings:					
Information:					
53	Non Patent Literature	Chew_Simulation_of_damage_in_porcine_PHV.pdf	51589 286cb3b52a03caf5af8260c5caaacbb38445f7f3	no	1
Warnings:					
Information:					
54	Non Patent Literature	Christie_on_Stress_Reduction.pdf	257727 b323a72ccd8f4a2ddb13527cfe1ed5a6222d3f21	no	2
Warnings:					
Information:					

55	Non Patent Literature	Collagen_Wikipedia.PDF	811919 49bafebe6fd07bdc8d88f58f67b8e43d92a0447d	no	10
Warnings:					
Information:					
56	Non Patent Literature	Collins_Evolution_of_artificial_heart.PDF	597234 1b2acdd6677ccd15d758e0dbd359078be06ad1d2	no	3
Warnings:					
Information:					
57	Non Patent Literature	Corden_Influence_of_Open_Leaflet_Geometry.PDF	3120701 d5ee06d8ea93a23065e895465fa8f846a58b2deb	no	15
Warnings:					
Information:					
58	Non Patent Literature	Cribier_Percutaneous_Transcatheter_Implantation.PDF	428986 131e0ba37e5b5dfd6ab94d459e6c217b69ede34d	no	4
Warnings:					
Information:					
59	Non Patent Literature	Edwards_Lifesciences_Receives_FDA_Approval.PDF	96124 b4c2bf9173bcd824e026504c765b7bd31f95f112	no	2
Warnings:					
Information:					
60	Non Patent Literature	Fish_Percutaneous_Heart_Valve_Replacement_Enthusiasm_Tempered.PDF	375136 d5049196713f8e9963b35ce8d9863ae8cd62b8e4	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	89441241		

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.

Electronic Acknowledgement Receipt

EFS ID:	19118844
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	23-MAY-2014
Filing Date:	15-APR-2014
Time Stamp:	16:52:18
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	Fishbein_Cardiac_pathology.PDF	778550 2aaf2fb31ef72da6417306a2f4f1eaa2494e48cb	no	6

Warnings:

Information:

2	Non Patent Literature	Gloeckner_Mechanical_eval_Multilayered_ARTICLE.PDF	323951 d4a3564e8c6577cb31ee10cc2c37e740120cdb65	no	9
Warnings:					
Information:					
3	Non Patent Literature	Grube_Progress_and_Current_status_Percutaneous_Aortic_Valve_Replacement_ABSTRACT.PDF	90858 217a8fdb260fb0b95019ae4179bd5a0e6023239b	no	2
Warnings:					
Information:					
4	Non Patent Literature	Hanlon_Pre-Use_Intraoperative_Testing_ABSTRACT.PDF	96608 7d912b4dc4c1908df4d156a6d88e641eb3801170	no	1
Warnings:					
Information:					
5	Non Patent Literature	Bech-Hanssen_Aortic-Prosthetic_Valve_Design.PDF	825607 f50878d0bb17d73a36edc953945aab857129bd22	no	12
Warnings:					
Information:					
6	Non Patent Literature	Hasenkam_Model_for_Acute_Haemodynamic_Studies.PDF	11581444 5710f116831550356684cebee377e71b9681b1b9	no	8
Warnings:					
Information:					
7	Non Patent Literature	Hiester_Optimal_Bovine_ARTICLE.PDF	2032169 2047e897090c4aa801abf2a1ca3943831df73411	no	7
Warnings:					
Information:					
8	Non Patent Literature	Hufnagel_Basic_Concepts_ARTICLE.PDF	4573630 e3ca35f5c89cd7c672a4124e96ffb3f6b0ef3f34	no	16
Warnings:					
Information:					
9	Non Patent Literature	HUFNAGEL_In_The_Beginning_Surgical_Correction.PDF	2912346 f930646f4f11f982b64d1b7c802bd2fd28c280c5	no	2
Warnings:					
Information:					
10	Non Patent Literature	HUFNAGEL_Late_Follow-up_ARTICLE.PDF	2603453 ec63db0d8c53130e6491c126a313f65853ee3579	no	10
Warnings:					
Information:					

11	Non Patent Literature	HUFNAGEL_Surgical_Correction_ARTICLE.PDF	13046267 3b9e3c15930877d2e2732e02c0c88b8ce4d40ce7	no	11
Warnings:					
Information:					
12	Non Patent Literature	Hufnagel_Vessels_and_Valves.PDF	1988054 ad47ed6f9b9d4b844cd80820b663cdf7b823be74	no	15
Warnings:					
Information:					
13	Non Patent Literature	Introduction_to_Stereomicroscopy.PDF	1264551 c5090da82548abcf3be66d126936b55eddc2214d	no	14
Warnings:					
Information:					
14	Non Patent Literature	IOPatch_Tutoplact_Description.PDF	148782 3770718a1f2231e34d7d789f8ef34ab3dd88fd8a	no	2
Warnings:					
Information:					
15	Non Patent Literature	Knudsen_catheter-implanted.PDF	8219060 ca8b200b129c12a44cb5460a5851c542bd241a47	no	10
Warnings:					
Information:					
16	Non Patent Literature	Lax_Estimation_of_Ejection_Fraction.PDF	465199 3dc7e34ea659168378c5229ac44957bc9c21e4de	no	8
Warnings:					
Information:					
17	Non Patent Literature	Liao_Molecular_Orientation_ARTICLE.PDF	654708 ea622a62d87b5faf1dc5e5b2a3fe09df2145079d	no	10
Warnings:					
Information:					
18	Non Patent Literature	Liao_Two-dimensional_mechanical.PDF	216352 b348140fc6c53d8cbab7f78df6753ef311e72ba9	no	3
Warnings:					
Information:					
19	Non Patent Literature	Yu_New_Polyurethane_Valves.PDF	8941586 758c058c11671afd5929b70f47c8ac9e63171415	no	7
Warnings:					
Information:					

20	Non Patent Literature	Mendelson_Heart_Valve_Tissue_Engineering.pdf	500094 7b302205e83f4aa72d9f617442f4ec8f2fc09433	no	21
Warnings:					
Information:					
21	Non Patent Literature	Mirnajafi_The_Effects_of_Collagen_Fiber_ARTICLE.PDF	356222 d09d6fc75240a18c54c294f815e2b7a8e449b7eb	no	10
Warnings:					
Information:					
22	Non Patent Literature	Mirzaie_A_New_Storage_Solution.PDF	4664571 b75369b4cce58ddfc464a681473750f5c4c6f596	no	8
Warnings:					
Information:					
23	Non Patent Literature	Moazami_Transluminal_Aortic_Valve.PDF	388780 eceb0d75974b1f7ceacdc3f4d0ffdf05dba5cc75	no	5
Warnings:					
Information:					
24	Non Patent Literature	Nienaber_Nonsurgical_Reconstruction.PDF	159419 278d7a3bcdec3d53b2a1531c31e3a2cc5e3b0eae	no	7
Warnings:					
Information:					
25	Non Patent Literature	Noorlander_Quantitative_Method.PDF	685471 0113df2fae6c4bef20a4ca0d41a9b935af4fa7e1	no	6
Warnings:					
Information:					
26	Non Patent Literature	Nunn_Structural_Failure.PDF	455905 fae81b3dbe91e1def2e6254d7bd477cf1501051d	no	9
Warnings:					
Information:					
27	Non Patent Literature	Optical_Microscope_Wilipedia.PDF	753293 dbf282ac3626a46bd9134797fa7c10d14dbf2edb	no	9
Warnings:					
Information:					
28	Non Patent Literature	Orthogonality_Wikipedia.PDF	303738 5e60b7beef40f21b1cbb6d5d57897ac69576ad80	no	5
Warnings:					
Information:					

29	Non Patent Literature	Paniagua_Percutaneous_Heart_Valve_Chronic_In_Vitro_Testing_Model.PDF	207888 0d707e39d7d5b43a6349b4ca066f8b70d65a9139	no	3
Warnings:					
Information:					
30	Non Patent Literature	Paniagua_First_Human_Case.PDF	672008 9789a295ded2878c0c7302016ae722bb1a7314f9	no	6
Warnings:					
Information:					
31	Non Patent Literature	Paniagua_Percutaneous_Implantation_Amer_Heart_Assoc_2009.PDF	73221 bf2806f21f232a3294912a45ad33701789b288d8	no	2
Warnings:					
Information:					
32	Non Patent Literature	Pathak_Treatment_of_Bioprosthetic_Heart.PDF	209469 902ff931f93e7ab58ac7cdc437497d0053399e008	no	5
Warnings:					
Information:					
33	Non Patent Literature	Pavenik_Development_and_Init_Experimental.PDF	488049 1ea2e4de27d43722ad1c6ee6e28497943ac9e59a	no	4
Warnings:					
Information:					
34	Non Patent Literature	Pick_blog.PDF	310856 86a845a7f2080703f7c385eaaa5486b773205637	no	4
Warnings:					
Information:					
35	Non Patent Literature	Pohl_In_Vitro_Testing.PDF	7954857 602e8becafcece58fe6f018a62f44a81872aa787	no	10
Warnings:					
Information:					
36	Non Patent Literature	Purinya_Biomechanical_and_Structural_Properties_ARTICLE.PDF	9033310 34aac3a58f859b89ab2505a0489222a61754299d	no	13
Warnings:					
Information:					
37	Non Patent Literature	Sacks_Bioprosthetic_Heart_Valve.PDF	99008 570883ddb36988959b09d02258ed0ab7f3800d5c	no	2
Warnings:					
Information:					

38	Non Patent Literature	Sacks_Collagen_Fiber_Architecture_Bovine_ARTICLE.PDF	3761051 d5119914f47d53a9c348585767778a44e30e20548	no	6
Warnings:					
Information:					
39	Non Patent Literature	Sacks_Small_Angle_Light_Scattering_ARTICLE.PDF	3345039 9495edf3aa353514978a28f514f45a073d734f7d	no	12
Warnings:					
Information:					
40	Non Patent Literature	Sacks_Experimentally-Derived_Fiber_Orientation.PDF	215108 4a1341505cd9ca7fc67a01b8f0ce670140a61ccd	no	8
Warnings:					
Information:					
41	Non Patent Literature	Sacks_Quantification_of_FIber_Architecture.PDF	471676 b05631f1bd34303fd453c8a24ec6a296c8fd4cef	no	10
Warnings:					
Information:					
42	Non Patent Literature	Samouillan_Comparison_of_Chemical_Treatments.PDF	664621 8d558e2571de81927599cae4fc48dccb952c6598	no	9
Warnings:					
Information:					
43	Non Patent Literature	Schmidt_Tissue_Engineering.PDF	385883 2fdcb92358f8beb310184ce9f2ac341789697617	no	8
Warnings:					
Information:					
44	Non Patent Literature	Schoen_Tissue_heart_valves.PDF	2069247 d9a1b496e3eb0d61558e84906fc402190a9158e1	no	27
Warnings:					
Information:					
45	Non Patent Literature	Sellaro_Effects_of_Collagen_Fiber_Medium_term_Fatigue.PDF	1073715 cd287a8777b23026c4a7be5a5777467a974dc692	no	12
Warnings:					
Information:					
46	Non Patent Literature	Sellaro_Effects_of_Collagen_Fiber.PDF	4016322 1b0154df51d6b35c01174b4e32a1c80a2ce71ce6	no	93
Warnings:					
Information:					

47	Non Patent Literature	Shandas_Method_for_Determining.PDF	618161 a9868be0708de5efc8515492c3281a8649ba164d	no	8
Warnings:					
Information:					
48	Non Patent Literature	Shen_Effect_of_Ethanol_and_Ether.PDF	121067 d574ba13fcd303eea8cbba5d95977defdacb2c3c	no	4
Warnings:					
Information:					
49	Non Patent Literature	Shen_Protein_adsorption.PDF	242606 2b5fa6df708fe69b690844cc07eb391e74b66a91	no	4
Warnings:					
Information:					
50	Non Patent Literature	Simionescu_Mapping_Glutaraldehyde-treated_ARTICLE.PDF	12862309 46f0ddd8d9e9a9dcf7c4c0d5534d96a246963cb4	no	8
Warnings:					
Information:					
51	Non Patent Literature	Sun_Response_of_heterograft.PDF	378209 0ee8524826d07372cd39b222a4becefefdc5b28a	no	12
Warnings:					
Information:					
52	Non Patent Literature	Topol_Textbook_of_Interventional_Cardiology.PDF	4225303 511d60021cec8bae1413a3eaca66792d91c043bc	no	40
Warnings:					
Information:					
53	Non Patent Literature	Vyavahare_Mechanics_of_Bioprosthetic.PDF	603983 d9140785f6c37c4ebc0c6c67ddddc5b833f9dce5	no	7
Warnings:					
Information:					
54	Non Patent Literature	Vyavahare_Prevention_of_Glutaraldehyde-Fixed.PDF	1056189 68ce64403862d585c863880446 0a3994147fe882	no	6
Warnings:					
Information:					
55	Non Patent Literature	Werner_testing_the_hydrodynamic_properties.PDF	95402 aa85009f41fa024ab5edffa0cfe1bbb34674d77c	no	1
Warnings:					
Information:					

56	Non Patent Literature	Wiegner_Mechanical_and_structural_Correlates.PDF	2297229 96e7a6cc92ff1c1b3608d71dbf41f07420727836	no	9
Warnings:					
Information:					
57	Non Patent Literature	Yasui_Determination_Collagen_Fiber_Orientation.PDF	725024 3eab612e51d5d59166ecb0dd25c2475a7750b877	no	7
Warnings:					
Information:					
58	Non Patent Literature	Zioupos_Anisotropic_Elasticity.PDF	15680386 f08432932351a38c9e402937644f10ff8ac832cc	no	9
Warnings:					
Information:					
59	Non Patent Literature	Zioupos_Mechanical_Optical_Anisotropy_ARTICLE.PDF	1726194 bffabe81bf8ec916e9e9564a18b972c126949fd8	no	7
Warnings:					
Information:					
60	Non Patent Literature	10102_US-14136516_Office_Action_2014-03-10.PDF	793847 3b87faee238a76cecaa885d3b3b5119f9bc9bf54	no	13
Warnings:					
Information:					
		Total Files Size (in bytes):	145507905		

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.

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.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 06/09/2014

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
06/09/2014	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. 14/253,650	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 *4/15/2014*.

☐ 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) *34-38* 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) *34-38* 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 *4/15/2014* 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 *5/23/2014, 5/23/2014, 5/23/2014*.

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 34-38 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 34 line 4 and 14 recite "a prosthetic heart valve" and "the prosthetic heart valve" respectively. This is unclear as the preamble requires "A percutaneous bioprosthetic heart valve", thus it is unclear if the "prosthetic heart valve" is intended to refer to the percutaneous bioprosthetic heart valve, or intended to be a different, additional heart valve thereto. Claims 35-38 depend upon claim 34 and inherit all issues with the claim. It is suggested to change "a prosthetic heart valve" to --the bioprosthetic heart valve--.

Claim 34, last line recites "a collapsed configuration". It is unclear if this is intending to refer to the collapsed configuration of line 15, or to be a different, additional collapsed configuration. It is suggested to change "a collapsed configuration" in line 16 to --the collapsed configuration--.

Claim 34, line 7, "its" is indefinite as this is unclear what "its" is referring to.

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 34 and 38 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Garrison et al. (US 6,425,916 B1). Garrison discloses a percutaneous bioprosthetic heart valve and delivery and implantation system (see figures 31-38) configured for percutaneous use (see fig.31, 38; other delivery methods may also be used, col.11, lines 10-12; for example fig.3-6) comprising: a stent member (111+26d+8d; see fig.38) having an inner channel (central lumen), the stent member (8d+26d+111) being collapsible (seen in fig.31, 36, 37) and expandable (seen in fig.32, 33, 38) and configured for percutaneous delivery (see fig.31; col.11, lines 10-12; figs.3-6), the stent member (111+26d+8d) including a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration (seen in fig.38), a valve means (6d) residing entirely within the inner channel (see fig.38) of the stent member (111+26d+8d), the valve means (6d) including an outer cuff layer (bottom portion of 6d, behind 111, seen in fig.38) and two to four individual leaflets (upper portion of 6d, see fig.38); and a catheter comprising a pusher member (4D) and moveable sheath (116), both the pusher member (4d or 64) and sheath (116 or 10) having a lumen (see fig.31, 37, 2, 3), wherein the pusher member (64

or 4D) is disposed in the sheath lumen, and the prosthetic heart valve (fig.38) is collapsed onto the pusher member (4D or 64; see fig.37, 3) to reside in a collapsed configuration on the pusher member and is restrained in a collapsed configuration by the sheath (116 or 10). Garrison discloses the pusher member (4d or 64) to include a controlled release mechanism (balloon 112 or 52) that can be activated (via inflation).

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 34-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Gabbay (US 2002/0032481 A1) in view of Garrison (US 6,425,916 B1). Referring to claim 34, Gabbay discloses a percutaneous bioprosthetic heart valve and delivery and implantation system (figs.1-4, 9a-9b) configured for percutaneous use (may be closed chest procedure, P0066, P0069, P0071, P0107, through blood vessel) comprising: a stent member (14) having an inner channel (central lumen), the stent member (14) being collapsible (fig.9a, 9b) and expandable (fig.2, 11) and configured for percutaneous delivery (closed chest procedure, through blood vessel, P0066, P0069, P0071, P0107), the stent member (14) including a tubular structure away from its central portion that flares at both ends (30, 32) in a trumpet-like configuration (see fig.2; P0043), a valve means (12) residing entirely within the inner channel of the stent member (seen in fig.2), the valve means (12) including an outer cuff layer (20) and two to four individual leaflets (22, 24, 26); and a catheter comprising a pusher member (210 or 716) and moveable sheath (208 or 704),

both the pusher member and sheath having a lumen (see fig.9a, 9b, 21; P0105, P0108), wherein the pusher member (210 or 716) is disposed in the sheath lumen (fig.9a, 9b, 21), the prosthetic heart valve restrained in a collapsed configuration by the sheath (fig.9a, 9b, 20). Gabbay discloses the valve and delivery system substantially as claimed, however does not disclose the valve to be collapsed onto the pusher member (210 or 716), to reside in a collapsed configuration on the pusher member (Gabbay's pusher member 210 or 716 is a plunger member with lumen, ending proximally to the valve, which pushes out the valve from behind). Garrison teaches in the same field of prosthetic heart valves and delivery systems therefore (see fig.21 for example), an alternate pusher member (78b) for a self-expanding stent valve (6a) used in catheter delivery systems (fig.21), the alternate pusher member (78a) having a hollow tube (distal end of 78a) extending distally of the plunger (80b and 83b), to which a prosthetic valve is collapsed onto (see fig.21), this aids in assembly, and also allows use of guidewire for positioning (col.8, lines 24-34; col.9, lines 10-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Gabbay's disclosed prosthetic valve and delivery system, with Garrison's teaching of alternate pusher member (78a), in order to provide Gabbay's system with easier loading and positioning.

Gabbay discloses the stent member (14) to be self-expanding and comprising nitinol (P0045). Gabbay discloses the stent member (14) to include two circles of barbs (38, 40; P0048, fig.1b, 3) on an outer surface of the stent member (14). Gabbay as modified by Garrison's pusher (78b) discloses the pusher member to include a controlled release mechanism (80/80b) that can be activated (by being pushed axially).

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. 14/253,650	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-6,425,916 B1	07-2002	Garrison et al.	623/2.11
*	B	US-2002/0032481 A1	03-2002	Gabbay, Shlomo	623/2.11
	C	US-			
	D	US-			
	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	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
L1	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
L2	410	1 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:02
L3	430	1 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
L4	674	2 3	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:03
L5	8	"09/973,609"	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/02 11:17
L6	275	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN. OR ("5397351").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:42
L7	11	("3130419" | "3143742" | "3571815" | "3574865" | "3626518" | "3911502" | "4580568" | "4648383").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
L8	9	("3626518" | "3691567" | "3868956" | "3911502" | "4030142" | "4503569" | "4759758" | "4994077").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:43
L9	2	("4038703" | "4106129").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/02 11:45

6/2/2014 11:51:56 AM
C:\Users\cmiller2\Documents\EAST\Workspaces\14253650.wsp

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

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	RE40404		2008-06-24	Schmitt et al.	
	2	RE42395		2011-05-24	Wright et al.	
	3	3014024		1961-12-19	Lieberman et al.	
	4	3029819		1962-04-17	Edward	
	5	3105492		1963-10-01	Jeckel	
	6	3320972		1967-05-23	High et al.	
	7	3409914		1968-11-12	Jones	
	8	3548417		1970-12-22	Kischer et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	9	3562820		1971-02-16	Braun	
	10	3588920		1971-06-29	Wesolowski	
	11	3671979		1972-06-27	Moulopoulos	
	12	3709175		1973-01-09	Edwards et al.	
	13	3878565		1975-04-22	Sauvage	
	14	3966401		1976-06-29	Hancock et al.	
	15	3945052		1976-03-23	Liebig	
	16	3983581		1976-10-05	Angell et al.	
	17	3986828		1976-10-19	Hoffman, Jr. et al.	
	18	4011947		1977-03-15	Sawyer	
	19	4035849		1977-07-19	Angell et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	20	4055861		1977-11-01	Carpentier et al.	
	21	4056854		1977-11-08	Boretos et al.	
	22	4060081		1977-11-29	Yannas et al.	
	23	4082507		1978-04-04	Sawyer	
	24	4084268		1978-04-18	Ionescu et al.	
	25	4106129		1978-08-15	Carpentier et al.	
	26	4164045		1979-08-14	Bokros et al.	
	27	4172295		1979-10-30	Batten	
	28	4218782		1980-08-26	Rygg	
	29	4222126		1970-09-16	Boretos et al.	
	30	4233493		1980-11-11	Nath et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	31	4265694		1981-05-05	Boretos et al.	
	32	4291420		1981-09-29	Reul	
	33	4340977		1982-07-27	Bownlee et al.	
	34	4350492		1982-09-21	Wright et al.	
	35	4364127		1982-12-21	Pierce et al.	
	36	4388735		1983-06-21	Ionescu et al.	
	37	4423525		1984-01-03	Vallana et al.	
	38	4441216		1984-04-10	Ionescu et al.	
	39	4456589		1984-06-26	Holman et al.	
	40	4473423		1984-09-25	Kolff	
	41	4477930		1984-10-23	Totten et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	42	4490859		1985-01-01	Black et al.	
	43	4517687		1985-05-21	Liebig et al.	
	44	4545082		1985-10-08	Hood	
	45	4597762		1986-07-01	Walter et al.	
	46	4600533		1986-07-15	Chu	
	47	4631052		1986-12-23	Kensey	
	48	4657133		1987-04-14	Komatsu et al.	
	49	4666442		1987-05-19	Arru et al.	
	50	4728328		1998-03-01	Hughes et al.	
	51	4743231		1988-05-10	Kay et al.	
	52	4759758		1988-07-26	Gabbay	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	53	4759759		1988-07-26	Walker et al.	
	54	4798611		1989-01-17	Freeman, Jr.	
	55	4801299		1989-01-31	Brendel et al.	
	56	4870966		1989-10-03	Dellon et al.	
	57	4883458		1989-11-28	Shiber	
	58	4892539		1990-01-09	Koch	
	59	4966604		1990-10-30	Reiss	
	60	4976733		1990-12-11	Giradot	
	61	4979939		1990-12-25	Shiber	
	62	5006104		1991-04-09	Smith et al.	
	63	5007896		1991-04-16	Shiber	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	64	5011488		1991-04-30	Ginsburg	
	65	5026366		1991-06-25	Leckrone	
	66	5032128		1991-07-16	Alonso	
	67	5047041		1991-09-10	Samuels	
	68	5047050		1991-09-10	Arpesani	
	69	5061277		1991-10-29	Carpentier et al.	
	70	5080660		1992-01-14	Buelna	
	71	5052771		1991-10-01	Williams et al.	
	72	5139515		1992-08-18	Robicsek	
	73	5163955		1992-11-17	Love et al.	
	74	5171273		1992-12-15	Silver et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	75	5226889		1993-07-13	Sheiban	
	76	5261878		1993-11-16	Galindo	
	77	5282847		1994-02-01	Trescony et al.	
	78	5326370		1994-07-05	Love et al.	
	79	5326371		1994-07-05	Love et al.	
	80	5332402		1994-07-26	Teitelbaum	
	81	5336616		1994-08-09	Livesey et al.	
	82	5360443		1994-11-01	Barone et al.	
	83	5374539		1994-12-20	Nimni et al.	
	84	5376110		1994-12-27	Tu et al.	
	85	5383927		1995-01-24	De Goiceochea et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	86	5411552		1995-05-02	Andersen et al.	
	87	5413601		1995-05-09	Keshelava	
	88	5449384		1995-09-12	Johnson	
	89	5476506		1995-12-19	Lunn	
	90	5480424		1996-01-02	Cox	
	91	5489297		1996-02-06	Duran	
	92	5500015		1996-03-19	Deac	
	93	5509930		1996-04-23	Love	
	94	5522879		1995-06-04	Scopelianos	
	95	5522881		1996-06-04	Lentz	
	96	5545215		1996-08-13	Duran	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	97	5549664		1996-08-27	Hirata et al.	
	98	5549666		1996-08-27	Hata et al.	
	99	5571170		1996-11-05	Palmaz et al.	
	100	5571173		1996-11-05	Parodi	
	101	5571174		1996-11-05	Love et al.	
	102	5578071		1996-11-26	Parodi	
	103	5578072		1996-11-26	Barone et al.	
	104	5582168		1996-12-10	Samuels et al.	
	105	5591229		1997-01-07	Parodi	
	106	5634928		1997-06-03	Fischell et al.	
	107	5653749		1997-08-05	Love et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	108	5713953		1998-02-03	Vallana et al.	
	109	5728152		1998-03-17	Mirsch, II et al.	
	110	5733299		1998-03-21	Sheiban et al.	
	111	5741333		1998-04-21	Frid	
	112	5746775		1998-05-05	Levy et al.	
	113	5769780		1998-06-23	Hata et al.	
	114	5782914		1998-07-21	Schankereli	
	115	5787887		1998-08-04	Klingenbeck-Regn	
	116	5840081		1998-11-24	Anderson et al.	
	117	5855601		1999-01-05	Bessler et al.	
	118	5861028		1999-01-19	Angell	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	119	5862806		1999-01-26	Cheung	
	120	5895420		1999-04-20	Mirsch, II et al.	
	121	5931969		1999-08-03	Carpentier et al.	
	122	5957949		1999-09-28	Leonhardt et al.	
	123	5961539		1999-10-05	Northup et al.	
	124	5961549		1999-10-05	Nguyen et al.	
	125	5972030		1999-10-26	Garrison et al.	
	126	5976179		1999-11-02	Inoue	
	127	6004328		1999-12-21	Solar	
	128	6004330		1999-12-21	Middleman et al.	
	129	6010531		2000-01-04	Donlon et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	130	6029671		2000-02-29	Stevens et al.	
	131	6045576		2000-04-04	Starr et al.	
	132	6053938		2000-04-25	Goldmann et al.	
	133	6091984		2000-07-18	Perelman et al.	
	134	6102944		2000-08-15	Huynh et al.	
	135	6117169		2000-09-12	Moe	
	136	6124523		2000-09-26	Banas et al.	
	137	6125852		2000-10-03	Stevens et al.	
	138	6126686		2000-10-03	Badylak et al.	
	139	6129756		2000-10-10	Kugler	
	140	6162245		2000-12-19	Jayaraman	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	141	6168614		2001-01-02	Andersen et al.	
	142	6168619		2001-01-02	Dinh et al.	
	143	6171335		2001-01-09	Wheatley et al.	
	144	6174327		2001-01-16	Mertens et al.	
	145	6186999		2001-02-13	Chen	
	146	6197143		2001-03-06	Bodnar	
	147	6214055		2001-04-10	Simionescu et al.	
	148	6221091		2001-04-24	Khosravi	
	149	6231602		2001-05-15	Carpentier et al.	
	150	6245102		2001-06-12	Jayaraman	
	151	6254629		2001-07-03	Inoue	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	152	6254630		2001-07-03	Inoue	
	153	6254636		2001-07-03	Peredo	
	154	6264691		2001-07-24	Gabbay	
	155	6269819		2001-08-07	Oz et al.	
	156	6270526		2001-08-07	Cox	
	157	6277397		2001-08-21	Shimizu	
	158	6277555		2001-08-21	Duran et al.	
	159	6287335		2001-09-11	Drasler et al.	
	160	6293970		2001-09-25	Wolfinbarger, Jr. et al.	
	161	6312462		2001-11-06	McDermott et al.	
	162	6312474		2001-11-06	Francis et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	163	6334873		2002-01-01	Lane et al.	
	164	6342069		2002-01-29	Deac et al.	
	165	6350282		2002-02-26	Eberhardt	
	166	6352554		2002-03-05	De Paulis	
	167	6352708		2002-03-05	Duran et al.	
	168	6358275		2002-03-19	McIlroy et al.	
	169	6358284		2002-03-19	Fearnot et al.	
	170	6371980		2002-04-16	Rudakov et al.	
	171	6376244		2002-04-23	Atala et al.	
	172	6378221		2002-04-30	Ekholm, Jr. et al.	
	173	6383171		2002-05-07	Gifford et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	174	6391333		2002-05-21	Li et al.	
	175	6409755		2002-06-25	Vrba	
	176	6418339		2002-07-09	Essenpreis et al.	
	177	6425916		2002-07-30	Garrison et al.	
	178	6432712		2002-08-13	Wolfinbarger, Jr. et al.	
	179	6440167		2002-08-27	Shimizu	
	180	6458153		2002-10-01	Bailey et al.	
	181	6461382		2002-10-08	Cao	
	182	6468313		2002-10-22	Claeson et al.	
	183	6471723		2002-10-29	Ashworth et al.	
	184	6482227		2002-11-19	Solovay	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	185	6482228		2002-11-19	Norred	
	186	6482240		2002-11-19	Echmayer et al.	
	187	6491719		2002-12-10	Fogarty et al.	
	188	6494909		2002-12-17	Greenhalgh	
	189	6503272		2003-01-07	Duerig et al.	
	190	6534004		2003-03-18	Chen et al.	
	191	6540782		2003-04-01	Snyders	
	192	6558418		2003-05-06	Carpentier et al.	
	193	6569200		2003-05-27	Wolfinbarger Jr. et al.	
	194	6565960		2003-05-20	Koob et al.	
	195	6582458		2003-06-24	White et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	196	6582462		2003-06-24	Andersen et al.	
	197	6582464		2003-06-24	Gabbay	
	198	6599524		2003-07-29	Li et al.	
	199	6624890		2003-09-23	Backman et al.	
	200	6626938		2003-09-30	Butaric et al.	
	201	6652577		2003-11-25	Gianotti	
	202	6652578		2003-11-25	Bailey et al.	
	203	6553681		2003-04-29	Ekholm, Jr. et al.	
	204	6610088		2003-08-26	Gabbay	
	205	6666886		2003-12-23	Tranquillo et al.	
	206	6682559		2001-01-27	Myers et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	207	6685739		2004-02-03	Dimatteo et al.	
	208	6696074		2004-02-24	Dia et al.	
	209	6719788		2004-04-13	Cox	
	210	6719789		2004-04-13	Cox	
	211	6702826		2004-03-09	Liddicoat et al.	
	212	6736823		2004-05-18	Darios et al.	
	213	6764510		2004-07-20	Vidlund et al.	
	214	6773456		2004-08-10	Gordon et al.	
	215	6773457		2004-08-10	Ivancev	
	216	6790229		2004-09-14	Berreklouw	
	217	6792979		2004-09-21	Konya et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	218	6802319		2004-10-12	Stevens et al.	
	219	6802806		2004-10-12	McCarthy et al.	
	220	6821297		2004-11-23	Snyders	
	221	6821530		2004-11-23	Koob et al.	
	222	6830584		2004-12-14	Seguin	
	223	6893460		2005-05-17	Spenser et al.	
	224	6908481		2005-06-21	Cribier	
	225	6913608		2005-07-02	Liddicoat et al.	
	226	6916338		2005-07-12	Speziali	
	227	6942694		2005-09-13	Liddicoat et al.	
	228	6951571		2005-10-04	Srivastava	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	229	6961123		2005-11-01	Wang et al.	
	230	6977231		2005-12-20	Matsuda	
	231	6986735		2006-01-17	Abraham et al.	
	232	7004925		2006-02-28	Navia et al.	
	233	7008763		2006-03-07	Cheung	
	234	7011688		2006-03-14	Gryska et al.	
	235	7018404		2006-03-28	Holmberg et al.	
	236	7018406		2006-03-28	Seguin et al.	
	237	7022348		2006-04-04	Ketharananthan	
	238	7025780		2006-04-11	Gabbay	
	239	7037333		2006-05-02	Myers et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	240	7039446		2006-05-02	Ruchti et al.	
	241	7041132		2006-05-09	Quijano et al	
	242	7053051		2006-05-30	Hendriks et al	
	243	7060092		2006-06-13	Kuribayashi et al.	
	244	7070616		2006-07-04	Majercak et al.	
	245	7077862		2006-07-18	Vidlund et al.	
	246	7084082		2006-08-01	Shimizu	
	247	7138226		2006-11-21	Vincek et al.	
	248	7153324		2006-12-26	Case et al.	
	249	7160322		2007-01-09	Gabbay	
	250	7164145		2007-01-16	Shakespeare	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	251	7166570		2007-01-23	Hunter et al.	
	252	7189259		2007-03-13	Simionescu et al.	
	253	7213601		2007-05-08	Stevens et al.	
	254	7214242		2007-05-08	Abraham et al.	
	255	7232461		2007-06-19	Ramer	
	256	7261732		2007-08-28	Justino	
	257	7289211		2007-10-30	Walsh, Jr. et al.	
	258	7309461		2007-12-18	Kujawski et al.	
	259	7311730		2007-12-25	Gabbay	
	260	7318998		2008-01-15	Goldstein et al.	
	261	7331993		2008-02-19	White	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	262	7329279		2008-02-12	Haug et al.	
	263	7354702		2008-04-08	Dai et al.	
	264	7381218		2008-06-03	Schreck	
	265	7381219		2008-06-03	Salahieh et al.	
	266	7399315		2008-07-15	Iobbi	
	267	7427291		2008-09-23	Liddicoat et al.	
	268	7431725		2008-10-07	Stack et al.	
	269	7468073		2008-12-23	Johnson et al.	
	270	7473237		2009-01-06	Navia et al.	
	271	7481838		2009-01-27	Carpentier et al.	
	272	7503929		2009-03-17	Johnson et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	273	7510571		2009-03-31	Spiridigliozzi et al.	
	274	7510575		2009-03-31	Spenser et al.	
	275	7524330		2009-04-28	Berreklouw	
	276	7566343		2009-07-28	Jenson et al.	
	277	7585321		2009-09-08	Cribier	
	278	7604661		2009-10-20	Pavcnik et al.	
	279	7618446		2009-11-17	Andersen et al.	
	280	7622276		2009-11-24	Cunanan et al.	
	281	7628805		2009-12-08	Spenser et al.	
	282	7648676		2010-01-19	Mills et al.	
	283	7670368		2010-03-02	Hill et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	284	7708775		2010-05-04	Rowe et al.	
	285	7758632		2010-07-20	Hojeibane et al.	
	286	7780722		2010-08-24	Thielen et al.	
	287	7789909		2010-09-07	Andersen et al.	
	288	7846203		2010-12-07	Cribier	
	289	7846204		2010-12-07	Letac et al.	
	290	7871431		2011-01-18	Gurm et al.	
	291	7892281		2011-02-22	Seguin et al.	
	292	7914576		2011-03-29	Navia et al.	
	293	7967833		2011-06-28	Sterman et al.	
	294	7981151		2011-07-19	Rowe	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	295	8002825		2011-08-23	Letac et al.	
	296	8007992		2011-08-30	Tian et al.	
	297	8057540		2011-11-15	Letac et al.	
	298	8080054		2011-12-20	Rowe	
	299	8105375		2012-01-31	Navia et al.	
	300	8512401		2013-08-20	Murray et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
(Not for submission under 37 CFR 1.99)	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	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	Cross-reference is made to U.S. Application No. 14/253,656 filed on April 15, 2014, and its associated Preliminary Amendment (109978.10113)	☐
	2	Cross-reference is made to U.S. Application No. 14/268,184 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10114)	☐
	3	Cross-reference is made to U.S. Application No. 14/268,190 filed on May 2, 2014, and its associated Preliminary Amendment (109978.10115)	☐
	4	Cross-reference is made to U.S. Application No. 14/284,049 filed on May 21, 2014, and its associated Preliminary Amendment (109978.10116)	☐
	5	Cross-reference is made to U.S. Application No. 14/284,063 filed on May 21, 2014, and its associated Preliminary Amendment (109978.10117)	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	06/02/2014

*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. /CM/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	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
623	1.24, 1.26, 2.12-2.19	6/2/2014	cm

SEARCH NOTES		
Search Notes	Date	Examiner

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/C.M./ Examiner.Art Unit 3738	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

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	8512403		2013-08-20	Navia et al.	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add

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	20010010017		2001-07-26	Cribier et al.	
	2	20010049558		2001-12-06	Liddicoat et al.	
	3	20010023372		2001-09-20	Chen et al.	
	4	20020005073		2002-01-17	Tompkins et al.	
	5	20020028243		2002-03-07	Masters	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	6	20020029783		2002-03-14	Stevens et al.	
	7	20020037940		2002-03-28	Koob et al.	
	8	20020042621		2002-04-11	Liddicoat et al.	
	9	20020091441		2002-07-11	Guzik	
	10	20020095167		2002-07-18	Liddicoat et al.	
	11	20020095994		2002-07-25	Vesley et al.	
	12	20020123789		2002-09-05	Francis et al.	
	13	20020128708		2002-09-12	Northrup et al.	
	14	20020151970		2002-10-17	Garrison et al.	
	15	20030078659		2003-04-24	Yang	
	16	20030102000		2003-06-05	Stevens et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	17	20030130727		2003-07-10	Drasler et al.	
	18	20030130729		2003-07-10	Paniagua et al.	
	19	20030130731		2003-07-10	Vidlund et al.	
	20	20030149477		2003-08-07	Gabbay	
	21	20030153974		2003-08-14	Spenser et al.	
	22	20030187362		2003-10-02	Murphy et al.	
	23	20030195620		2003-10-16	Huynh et al.	
	24	20030204023		2003-10-30	Koob et al.	
	25	20030212460		2003-11-13	Darios et al.	
	26	20030212462		2003-11-13	Gryska et al.	
	27	20030217415		2003-11-27	Crouch et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	28	20040024452		2004-02-05	Kruse et al.	
	29	20040039442		2004-02-26	St. Goar	
	30	20040055608		2004-03-25	Stevens et al.	
	31	20040059418		2004-03-25	McKay et al.	
	32	20040098092		2004-05-20	Butaric et al.	
	33	20040158321		2004-08-12	Reuter et al.	
	34	20040193261		2004-09-30	Berreklouw	
	35	20040230285		2004-11-18	Gifford, III et al.	
	36	20040243153		2004-12-02	Liddicoat et al.	
	37	20040243229		2004-12-02	Vidlund et al.	
	38	20050004668		2005-01-06	Aklog et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	39	20050027369		2005-02-03	Eldridge et al.	
	40	20050043819		2005-02-24	Schimdt et al.	
	41	20050096673		2005-05-05	Stack et al.	
	42	20050113910		2005-05-26	Paniagua et al.	
	43	20050137681		2005-06-23	Shoemaker et al.	
	44	20050137682		2005-06-23	Justino	
	45	20050142163		2005-06-30	Hunter et al.	
	46	20050147562		2005-07-07	Hunter et al.	
	47	20050147599		2005-07-07	Hunter et al.	
	48	20050147643		2005-07-07	Hunter et al.	
	49	20050148512		2005-07-07	Hunter et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	50	20050158274		2005-07-21	Hunter et al.	
	51	20050159811		2005-07-21	Lane	
	52	20050169958		2005-08-04	Hunter et al.	
	53	20050169959		2005-08-04	Hunter et al.	
	54	20050175657		2005-08-11	Hunter et al.	
	55	20050187618		2005-08-25	Gabbay	
	56	20050191248		2005-09-01	Hunter et al.	
	57	20050228494		2005-10-13	Marquez	
	58	20050241981		2005-11-03	Gupta et al.	
	59	20050246035		2005-11-03	Wolfinbarger et al.	
	60	20050247320		2005-11-10	Stack et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	61	20050267529		2005-12-01	Crockett et al.	
	62	20060004439		2006-01-05	Spenser et al.	
	63	20060004443		2006-01-05	Liddicoat et al.	
	64	20060020336		2006-01-26	Liddicoat	
	65	20060025800		2006-02-02	Suresh	
	66	20060041306		2006-02-23	Vidlund	
	67	20060074486		2006-04-06	Liddicoat et al.	
	68	20060089708		2006-04-27	Osse et al.	
	69	20060111733		2006-05-25	Shriver	
	70	20060129225		2006-06-15	Kopia et al.	
	71	20060134079		2006-06-22	Sih et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	72	20060140916		2006-06-29	Siani-Rose et al.	
	73	20060173475		2006-08-03	Lafontaine et al.	
	74	20060178740		2006-08-10	Stacchino et al.	
	75	20060190074		2006-08-24	Hill et al.	
	76	20060193885		2006-08-31	Neethling et al.	
	77	20060195010		2006-08-31	Arnal et al.	
	78	20060195183		2006-08-31	Navia et al.	
	79	20060206203		2006-09-14	Yang et al.	
	80	20060229701		2006-10-12	Gurm et al.	
	81	20060240063		2006-10-26	Hunter et al.	
	82	20060240064		2006-10-26	Hunter et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	83	20060259134		2006-11-16	Schwammenthal et al.	
	84	20060259135		2006-11-16	Navia et al.	
	85	20060259137		2006-11-16	Artof et al.	
	86	20060265056		2006-11-23	Nguyen et al.	
	87	20060287571		2006-12-21	Gozzi et al.	
	88	20060292125		2006-12-28	Kellar et al.	
	89	20070010857		2007-01-11	Sugimoto et al.	
	90	20070043431		2007-02-22	Melsheimer	
	91	20070050014		2007-03-01	Johnson	
	92	20070050022		2007-03-01	Vidlund et al.	
	93	20070056346		2007-03-15	Spenser et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	94	20070060932		2007-03-15	Stack et al.	
	95	20070100426		2007-05-03	Rudakov et al.	
	96	20070104395		2007-05-10	Kinigakis et al.	
	97	20070128174		2007-06-07	Kleinsek et al.	
	98	20070173861		2007-07-26	Strommer et al.	
	99	20070203575		2007-08-30	Forster et al.	
	100	20070213813		2007-09-13	Von Segessler et al.	
	101	20070250154		2007-10-25	Greenberg et al.	
	102	20070263226		2007-11-15	Kurtz et al.	
	103	20070276432		2007-11-29	Stack et al.	
	104	20070276461		2007-11-29	Andreas et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	105	20080004686		2008-01-03	Hunt et al.	
	106	20080009667		2008-01-10	Longhini et al.	
	107	20080009940		2008-01-10	Cribier	
	108	20080029105		2008-02-07	Stevens et al.	
	109	20080039871		2008-02-14	Wallace et al.	
	110	20080039926		2008-02-14	Majercak et al.	
	111	20080058798		2008-03-06	Wallace et al.	
	112	20080082113		2008-04-03	Bishop et al.	
	113	20080102439		2008-05-01	Tian et al.	
	114	20080133004		2008-06-05	White	
	115	20080147182		2008-06-19	Righini et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	116	20080154356		2008-06-26	Obermiller et al.	
	117	20080177381		2008-07-24	Navia et al.	
	118	20080183280		2008-07-31	Agnew et al.	
	119	20080183283		2008-07-31	Downing	
	120	20080195200		2008-08-14	Vidlund et al.	
	121	20080190989		2008-08-14	Crews et al.	
	122	20080199843		2008-08-21	Haverich et al.	
	123	20080200977		2008-08-21	Paul et al.	
	124	20090005857		2009-01-01	Ischinger	
	125	20090030511		2009-01-29	Paniagua et al.	
	126	20090043383		2009-02-12	McGregor et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	127	20090054969		2009-02-26	Salahieh	
	128	20090062907		2009-03-05	Quijano et al.	
	129	20090112309		2009-04-30	Jaramillo et al.	
	130	20090132032		2009-09-15	Cribier	
	131	20090157175		2009-06-18	Benichou	
	132	20090164005		2009-06-25	Dove et al.	
	133	20090187241		2009-07-23	Melsheimer	
	134	20090248149		2009-10-01	Gabbay	
	135	20090254175		2009-10-08	Quijano et al.	
	136	20090281609		2009-11-12	Benichou et al.	
	137	20090030511		2009-01-29	Paniagua et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	138	20100030259		2010-02-04	Pavcnik et al.	
	139	20100036479		2010-02-11	Hill et al.	
	140	20100036484		2010-02-11	Hariton et al.	
	141	20100048987		2010-02-25	Khairkhahan	
	142	20100049312		2010-02-25	Edoga et al.	
	143	20100131054		2010-05-27	Tuval et al.	
	144	20100161036		2010-06-24	Pintor et al.	
	145	20100185277		2010-07-22	Braido et al.	
	146	20100217382		2010-08-26	Chau et al.	
	147	20100234878		2010-09-16	Hruska	
	148	20100241069		2010-09-23	Hatten	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	149	20100249918		2010-09-30	Zhang	
	150	20100256749		2010-10-07	Tran et al.	
	151	20100256751		2010-10-07	Rowe et al.	
	152	20100312333		2010-12-09	Navia et al.	
	153	20110015728		2011-01-20	Jimenez et al.	
	154	20110040375		2011-02-17	Letac et al.	
	155	20110004299		2011-01-06	Navia et al.	
	156	20110087322		2011-04-14	Letac et al.	
	157	20110137409		2011-06-09	Yang et al.	
	158	20110146361		2011-06-23	Davidson et al.	
	159	20110153009		2011-06-23	Navia et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	160	20110166636		2011-07-07	Rowe	
	161	20110178597		2011-07-21	Navia et al.	
	162	20110218619		2011-09-08	Benichou et al.	
	163	20110224607		2011-09-15	Vogelbaum et al.	
	164	20110240511		2011-10-06	Bolton et al.	
	165	20110300625		2011-12-08	Paniagua et al.	
	166	20110301700		2011-12-08	Fish et al.	
	167	20120078343		2012-03-29	Fish	
	168	20120078356		2012-03-29	Fish et al.	
	169	20120095551		2012-04-19	Navia et al.	
	170	20120158128		2012-06-21	Gautam et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	171	20120185038		2012-07-19	Fish et al.	
	172	20120310041		2012-12-06	Paniagua et al.	
	173	20130304201		2013-11-14	Navia et al.	
	174	20140039613		2013-02-06	Navia et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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	1441672	EP		2011-09-14	Edwards Lifesciences PVT, Inc.		☐
	2	1603493	EP		2005-12-14	Edwards Lifesciences Corp.		☐
	3	1621162	EP		2012-05-30	Edwards Lifesciences PVT, Inc.		☐
	4	2000115	EP		2011-05-04	Edwards Lifesciences PVT, Inc.		☐
	5	2055266	EP		2012-02-15	Edwards Lifesciences PVT, Inc.		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	6	2260796	EP		2013-02-20	Edwards Lifesciences PVT, Inc.		☐
	7	2355361C	RU		2009-05-20	Zhuravleva Irina Jur Evn		☐
	8	1991/017720	WO		1991-11-28	Andersen et al.		☐
	9	1992/017118	WO		1992-10-15	Shturman Cardiology Systems, Inc.		☐
	10	1998/029057	WO		1998-07-09	Cordis Corporation		☐
	11	1999/30646	WO		1999-06-24	St. Jude Medical, Inc.		☐
	12	2000/012164	WO		2000-03-09	The Cleveland Clinic Foundation		☐
	13	2001/002031	WO		2001-01-11	Biomedical Design, Inc.		☐
	14	2003/047468	WO		2003-06-12	Percutaneous Valve Technologies		☐
	15	2003/092554	WO		2003-11-13	The General Hospital Corporation		☐
	16	2004/026124	WO		2004-04-01	The Cleveland Clinic Foundation		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	17	2004/082527	WO		2004-09-30	Edwards Lifesciences Corp.		☐
	18	2006/095342	WO		2006-09-14	Technion Research & Development Foundation Ltd.		☐
	19	2007/138572	WO		2007-12-06	Mor Research Applications Ltd.		☐
	20	2008/063537	WO		2008-08-14	St. Jude Medical, Inc.		☐
	21	2008/106531	WO		2008-09-04	Edwards Lifesciences Corp.		☐
	22	2009/156471	WO		2009-12-30	Iberhospitex, S.A.		☐
	23	2009/052188	WO		2009-04-23	Edwards Lifesciences Corp.		☐
	24	2010/024801	WO		2010-03-04	Cardiokinetix, Inc.		☐
	25	2010/027363	WO		2010-03-11	Merlin MD PTE Ltd.		☐
	26	2010/080594	WO		2010-07-15	Edwards Lifesciences Corp.		☐
	27	2010/117541	WO		2010-10-14	Medtronic Vascular Inc.		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	28	2011/109433	WO		2011-03-11	Paniagua et al.		☐
	29	2011/109450	WO		2011-09-09	Colibri Heart Valve LLC		☐
	30	2012/006124	WO		2012-01-12	Fish		☐
	31	2012/040643	WO		2012-03-29	Fish et al.		☐
	32	2012/082952	WO		2012-06-21	Fish et al.		☐

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	Affidavit of Dr. Paolo Angelini, M.D., signed August 25, 2009	☐
	2	Affidavit of Dr. Gervasio A. Lamas, M.D., signed September 3, 2009	☐
	3	ANDERSEN, H.R. et al., "Transluminal implantation of artificial heart valve" European Heart Journal, 1992, 13, pp. 704-708	☐
	4	"Artificial heart valve" http://en.wikipedia.org/Artificial_heart_valve, printed May 13, 2009	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	5	BONHOEFFER, Philipp M.D. et al., "Percutaneous Insertion of the Pulmonary Valve" J of the Amer College of Cardiology, Vol 39, No 10, Elsevier Science, Inc. 2002, pp 1664-1669, London, UK, and Paris, FR	☐
	6	BONHOEFFER, Philipp et al., "Percutaeous replacement of pulmonary valve in a right-centricle to pulmonary-artery prosthetic conduit with valve dysfunction" Early Report, The Lacet, Vol 356, October 21, 2000, pp. 1403-1405	☐
	7	BONHOEFFER, Philipp et al., "Transcatherter Implantation of a Bovine Valve in Pulmonary Position: A Lamb Study" Circulation J. of the Amer Heart Assoc, 2000; 102; pp. 813-816	☐
	8	BOUDJEMLINE, Younes et al., "Percutaneous pulmonary valve replacement in a large right ventricular outflow tract: An experimental study" J. Am. Coll. Cardiol. 2004; 43; pp. 1082-1087	☐
	9	BRAGA-VILELA, A. et al., "Extracellular Matrix of Porcine Pericardium; Biochemistry and Collagen Architecture" J. Membr Biol., 2008	☐
	10	BREUER, Christopher K. M.D. et al., "Application of Tissue-Engineering Principles toward the Development of a Semilunar Heart Valve Substitute" Tissue Engineering, Vol 10, No. 11/12, 2004, pp. 1725-1736	☐
	11	CALE, A.R. et al., "Revisited: a descending thorasic aortic valve to treat prosthetic valve insufficiency" Ann Thorac Surg, May 1993, 55(5), pp. 1218-2	☐
	12	CERROLAZA, M et al., "A comparison of the hydrodynamical behaviour of three heart aortic prostheses by numerical methods"	☐
	13	CHEW, G.G. et al., Abstract for "Simulation of Damage in a Porcine Prosthetic Heart Valve" J. Med. Eng. Technol., 1999 Sep-Oct; 23(5): 178-89 (Abstract only)	☐
	14	CHRISTIE G.W. et al., Abstract for "On Stress Reduction in Bioprosthetic Heart Valve Leaflets by the Use of a Flexible Stent" J. Card Surg, 1991 Dec; 6(4) pp. 476-81 (Abstract only)	☐
	15	"Collagen" http://en.wikipedia.org/wiki/Collagen, printed May 13, 2009	☐

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	16	COLLINS, J. J., Jr, "The Evolution of artificial heart valve" N. Engl J Med, 1991 Feb 28; Vol. 324(9), pp. 624-626	☐
	17	CORDEN, J. et al., "The influence of open leaflet geometry on the haemodynamic flow characteristics of polyrethane trileaflet artificial heart valve" PubMed medline query, page 1 of 1	☐
	18	CRIBIER, Alain et al., "Percutaneious Transcatheter Implantation of an Aoritc Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description" Circulation J of the Amer Heart Assoc, originally published online Nov 25, 2002	☐
	19	Edwards Lifesciences Receives FDA Approval for New Heart Valve, http:www.medicalnewstoday.com/articles/149588.php, May 11, 2009	☐
	20	FISH, R. David, "Percutaneous Heart Valve Replacement: Enthusiasm Tempered" Circulation J of the Amer Heart Assoc, 2004; Vol. 110; pp. 1876-1878	☐
	21	FISHBEIN, M.C. et al., "Cardiac pathology after aortic valve replacement using Hufnagel trileaflet prostheses: study of 20 necropsy patients" Ann Heart J., April 1975, 89(4), pp. 443-448	☐
	22	GLOECKNER, D. Claire et al., "Mechanical Evaluation and Design of a Multilayered Collagenous Repair Biomaterial" J. of Biomedical Materials Research Part A, Vol. 52 Iss 2, PP 365-373, Published online Aug. 15, 2000, Wiley Periodicals, Inc.	☐
	23	GRUBE, 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 (Abstract only)	☐
	24	HANLON, JG et al., "Pre-use intraoperative testing of autologous tissue for valvular surgery: a proof of concept study" J. Heart Valve Dis, Nov 1999; 8(6); pp. 614-23	☐
	25	BECH-HANSSEN, Odd, M.D. et al., "Aortic Prosthetic Valve Desing and Size: Relation to Doppler Echocardiographic Finding and Pressure Recovery --- An In Vitro Study" J. Am Soc Echocardiography 2000; Vol. 13, pp. 39-50	☐
	26	HASENKAM, J.M. et al., "A model for acute haemodynamic studies in the ascending aorta in pigs" Cardiovasc Res, July 1988, 22(7), pp. 464-71	☐

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	27	HIESTER,E.D. et al., "Optimal bovine pericardial tissue selection sites. I. Fiber architecture and tissue thickness measurements." J. Biomed Mater Res, 1998, Feb, 01; 39(2), pp. 207-14	☐
	28	HUFNAGEL, Charles A., M.D., "Basic Concepts in the Development of Cardiovascular Prosthes" The American Journal of Surgery, Vol 137, March 1979	☐
	29	HUFNAGEL, Charles.A., MD et al., "In the beginning. Surgical Correction of Aortic Insufficiency" 1954; Ann Thorac Surg 1989 May; 47(3), pp. 475-476	☐
	30	HUFNAGEL, Charles.A., MD et al., "Late follow-up of ball-valve prostheses in the descending thoracic aortia", J. Throrac Cardiovasc Surg, December 1976, 72(6), pp. 900-909	☐
	31	HUFNAGEL, Charles.A., MD et al., "Surgical Correction of Aortic Insufficiency" Surgery Vol 35, May, 1954 No. 5	☐
	32	HUFNAGEL, Charles A., "Vessels and Valves", Sec. 1: Development of Cardiac Surgery, Chap 7, pp. 43-55	☐
	33	Introduction to Stereomicroscopy, http://www.microscopyu.com/articles/stereomicroscopy/stereointro.html, Copyright 2000-2012, printed on March 15, 2012	☐
	34	IOPATCH(R) Tutoplast(R) Processed Pericardium Directions for Use; http://www.iopinc.com/ surgeons_and_medical_professionals/iopatch/directions.asp, printed on June 2, 2009	☐
	35	KNUDSEN, LL et al., "Catheter-implanted prosthetic heart valves. Transluminal catheter implantation of a new expandable artificial heart valve in the descending thoracic aorta in isolated vessels and closed chest pigs" Int J. Artif Organs, May 1993, 16(5); pp. 253-62	☐
	36	LAX, Jorge A., M.D., et al. "Estimation of the Ejection Fraction in Patients with Myocardial Infarction Obtained from the Combined Index of Systolic and Diastolic Left Ventricular Function: A New Method" J of the American Soc of Echocardiography, Vol 13, No. 2	☐
	37	LIAO, Jun et al., "Molecular orientation of collagen in intact planar connective tissues under biaxial stretch" Acta Biomateriala, Vol. 1, Iss. 1, January 2005, pp 45-54	☐

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
(Not for submission under 37 CFR 1.99)	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	38	LIAO, K X et al., "Two-dimensional mechanical and ultrastructural correlates of bovine pericardium for prosthetic valves" ASAIO Trans, June 1, 1991, 37(3); pp. 341-51	☐
	39	LS, Yu et al., "New Polyurethane valves in new soft artificial heart" ASAIO Trans 1989 Jul-Sep; 35(3), pp. 301-304	☐
	40	MENDELSON, Karen et al., "Heart Valve Tissue Engineering: Concepts, Approaches, Progress, and Challenges" Ann Biomed Eng, 2006 Dec; 34(12); 1799-1819; published online 2006 October 12 doi:10.1007/s/10439-006-9163-z	☐
	41	MIRNAJAFI, A. et al. "The effects of collagen fiber orientation of the flexural properties of pericardial heterograft biomaterials" Biomaterials, 2005 Mar; 26(7): pp. 795-804	☐
	42	MIRZAIE, M. et al., "A new storage solution for porcine aortic valves" Ann Thorac Cardiovasc Surg. 2007 Apr;13(2), pp. 102-109	☐
	43	MOAZAMI, N. et al., "Transluminal aortic valve placement. A feasibility study with a newly designed collapsible aortic valve" ASAIO J, Sept-Oct 1996, 42(5), pp. 381-385	☐
	44	NIENABER C., M.D. et al., "Nonsurgical Reconstruction of Thoracic Aortic Dissection By Stent-Graft Placement" N. Eng. J. Med, May 20, 1999, Col. 340, No. 20	☐
	45	NOORLANDER, Maril L. et al., "A Quantitative Method to Determine the Orientation of Collagen Fibers in the Dermis" The J. of Histochemistry & Cytochemistry, Vol 50(11): 2002, pp. 1469-1474	☐
	46	NUNN, D.B., "Structural Failure of Dacron Arterial Grafts" Seminars in Vascular Surgery, Col 12, No. 1 (March), 1999, pp. 88-91	☐
	47	Optical Microscope, Wikipedia, http://en.wikipedia.org/wiki/Stereomiscroscope, May 13, 2009	☐
	48	Orthogonality, http://en.wikipedia.org/wiki/Orthogonal, May 13, 2009	☐

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	49	PANIAGUA, DAVID, ET AL., Percutaneous Heart Valve In the Chronic In Vitro Testing Model, Circulation, 2002, pp. 51-52, Vol. 106, American Heart Association, US.	☐
	50	PANIAGUA, DAVID ET AL., First Human Case of Retrograde Transcatheter Implantation of an Aortic Valve Prosthesis, Texas Heart Institute Journal, 2005, pp. 91-96, Vol. 32, US.	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	06/02/2014

*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. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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]

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	1	PANIAGUA, DAVID et al., Abstract 4622: "Percutaneous Implantation of a Low Profile, Dry Membrane, Heart Valve in an Integrated Delivery System in the Aortic and Pulmonary Positions: One-month Animal Results," Circulation, American Heart Association, Inc., 2009; Vol. 120: pp. 982	☐
	2	PATHAK, CP et al., "Treatment of bioprosthetic heart valve tissue with long chain alcohol solution to lower calcification potential" J Biomed Mater Res A. 2004 Apr 1;69(1), pp. 140-144	☐
	3	PAVENIK, Susan, M.D., PhD et al., "Development and Initial Experimental Evaluation of a Prosthetic Aortic Valve for Transcatherter Placement" Cardivascular Radiology, April 1992, pp. 151-154	☐
	4	PICK, Adam, "True or False: An Edwards Lifesciences' Tissue Valve Replacement Requires 1,800 Hand-Sewn Stitches" http://heart-valve-surgery.com/heart-surgery-blog/2008/02/26. printed August 13, 2010	☐
	5	POHL, M. et al., "In vitro testing of artificial heart valves; comparison between Newtonian and non-Newtonian fluids" Artif Argns, Jan 1996; 20(1); pp. 37-46	☐
	6	PURINYA, B. et al., "Biomechanical and Structural Properties of the Explanted Bioprosthetic Valve Leaflets" J. of Biomechanis, Vol 27, Iss 1, Jan 1994 Pages 1-11 Elsevier Science Ltd, 1993.	☐
	7	SACKS, M S et al., "Bioprosthetic heart valve heterograft biomaterials: structure, mechanical behavior and computational simulation" Expert Rev Med Devices, 2006 Nov; 3(6): pp. 817-34 (Abstract only)	☐
	8	SACKS, M S et al., "Collagen fiber architecture of bovine pericardium" ASAIO J, July 1, 1994, 40(3), pp. 632-637	☐
	9	SACKS, M S et al., "A small angle light scattering device for planar connective tissue miscrostructural analysis" Ann Biomed Eng, July 1, 1997, 254(4), pp. 678-89	☐
	10	SACKS, Michael S, "Incorporation of experimentally-derived fiber orientation into a structural constitutive model for planar collagenous tissues" J. Biomech Eng, April 1, 2003, 125(2), pp. 280-7	☐
	11	SACKS, Michael S. et al., "Quantification of the fiber architecture and biaxial mechanical behavior of porcine intestinal submucosa" J of Biomedical Research, Vol 46, Iss 1, July 1999, pp 1-10	☐

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
(Not for submission under 37 CFR 1.99)	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	12	SAMOUILLAN, V. et al., " Comparison of chemical treatments on the chain dynamics and thermal stability of bovine pericardium collagen" J Biomed Mater Res A. 2003 Feb 1;64(2), pp. 330-338	☐
	13	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	☐
	14	SCHOEN, Frederick J., "Tissue heart valves: Current challenges and future research perspectives" J of Biomedical Materials Research, Vol 47, Iss 4, December 15, 1999, pp. 439-465	☐
	15	SELLARO, Tiffany L., "Effects of Collagen Orientation on the Medium-Term Fatigue Response of Heart Valve Biomaterials" 2003, (published thesis) pp. 40-45	☐
	16	SELLARO, Tiffany L. et al., "Effects of Collagen Fiber Orientation on the Response of Biologically Derived Soft Tissue Biomaterials to Cyclic Loading" J. Biomed Mater Res A 2007, Jan 01; 80(1): 194-205); published online Oct. 13, 2006 by Wiley InterScience	☐
	17	SHANDAS, Robin PhD et al., "A Method for Determining the Reference Effective Flow Areas for Mechanical Heart Valve Prostheses" Circulation April 25, 2000	☐
	18	SHEN, Ming et al., "Effect of ethanol and ether in the prevention of calcification of bioprostheses" Ann Thorac Surg. 2001 May;71(5 Suppl), pp. 413-416	☐
	19	SHEN, Ming et al., "Protein adsorption in glutaraldehyde-preserved bovine pericardium and porcine valve tissues" The Annals of Thoracic Surgery, 2001; 71, pp. 409	☐
	20	SIMIONESCU, D et al., "Mapping of glutaraldehyde-treated bovine pericardium and tissue selection for bioprosthetic heart valve" J. Biomed Mater Res, 1993, June 01:27(6), pp. 697-704	☐
	21	SUN, Wei et al., "Response of heterograft heart valve biomaterials to moderate cyclic loading" J Biomed Mater Res A, June 2004, 69(4), pp. 658-69	☐
	22	TOPOL, Eric J., "Textbook of Interventional Cardiology", 1990, Chs. 43-44, pp. 831-867	☐

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	23	VYAVAHARE, Narendra et al., "Mechanisms of bioprosthetic heart valve failure: Fatigue causes collagen denaturation and glycosaminoglysan loss" J of Biomedical Research, Vol 446, Iss 1, July 1999, pp 44-50	☐
	24	VYAVAHARE, NR et al., "Prevention of Glutaraldehyde-Fixed Bioprosthetic Heart Valve Calcification by Alcohol Pretreatment: Further Mechanistic Studies" J Heart Valve Dis. 2000 Jul;9(4), pp. 561-6	☐
	25	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)	☐
	26	WIEGNER, A W et al., "Mechanical and structural correlates of canine pericardium" Circ Res, Sept 1, 1981m 49(3), pp. 807-14	☐
	27	YASUI, Takeshi et al., "Determination of collagen fiber orientation in human tissue by use of polarization measurement of molecular second-harmonic-generation light", Applied Optics, Vol 42, No 14, May 10, 2004, pp. 2861-2867	☐
	28	ZIOUPOS, P. et al., "Anisotropic Elasticity and Strength of Glutaraldehyde Fixed Bovine Pericardium for Use in Pericardial Bioprosthetic Valves" J. Biomed Mater Res., 1994 Jan, 28(1), pp. 49-57	☐
	29	ZIOUPOS, P. et al., "Mechanical and Optical anisotrophy of bovine pericardium" Med Biol Eng Comput, 1992 Jan; 30 (1); pp. 76-82	☐
	30	Office Action issued in U.S. Application No. 14/136,516, dated March 10, 2014 (109978.10102)	☐
	31	Notice of Allowance issued in U.S. Application No. 14/136,516, dated March 31, 2014 (109978.10102)	☐
	32	Office Action issued in U.S. Application 10/887,688, dated November 28, 2007 (54813-10100)	☐
	33	Final Office Action issued in U.S. Application 10/887,688, dated July 15, 2008 (54813-10100)	☐

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	34	Office Action issued in U.S. Application 10/887,688, dated March 16, 2009 (54813-10100)	☐
	35	Examiner Interview Summary issued in U.S. Application 10/887,688, dated June 12, 2009 (54813-10100)	☐
	36	Final Office Action issued in U.S. Application 10/887,688, dated March 2, 2010 (54813-10100)	☐
	37	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed September 14, 2009 (54813-10100)	☐
	38	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed February 28, 2008 (54813-10100)	☐
	39	Supplemental Declaration Under 37 CFR 1.131 by inventors filed in U.S. Application 10/887,688, filed December 15, 2008 (54813-10100)	☐
	40	Examiner Interview Summary issued in U.S. Application 10/887,688, dated July 26, 2010 (54813-10100)	☐
	41	Office Action issued in U.S. Application 10/887,688, dated February 16, 2012 (54813-10100)	☐
	42	Office Action issued September 29, 2010, issued in U.S. Application 12/228,192 (54813-10110)	☐
	43	Examiner Interview Summary, dated 04/05/2011 in U.S. Application No. 12/228,192 (54813-10110)	☐
	44	Final Office Action issued July 14, 2011, in U.S. Application No. 12/228,192 (54813-10110)	☐

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

	45	Office Action issued in U.S. Application 10/037,266, dated May 8, 2003	☐
	46	Final Office Action issued in U.S. Application 10/037,266, dated March 9, 2004	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	06/02/2014

*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. /CM/

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

■ United States application or PCT international application number 14/253,650 filed on 2014-04-15.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: R. David FISH Date (Optional): _____

Signature: RDFish

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

■ United States application or PCT international application number 14/253,650 filed on 2014-04-15.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: David PANIAGUA Date (Optional) :

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

Electronic Acknowledgement Receipt

EFS ID:	19431497
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	27-JUN-2014
Filing Date:	15-APR-2014
Time Stamp:	10:43:01
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	Oath or Declaration filed	Colibri_10104_Fish_Declaration.PDF	342756 1528ee711c85b4924129699d7e6ae385978886e9	no	1

Warnings:

Information:

2	Oath or Declaration filed	Colibri_10104_Paniagua_Declaration.PDF	333387 2ec4bb12665cd234c519287fb96bf7a4c0eb161f	no	1

Warnings:	
Information:	
Total Files Size (in bytes):	676143

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
David PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	AMENDMENT AND RESPONSE
Atty. File No.: 109978.10104	**Filed Electronically**
Entitled: PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM (as amended)	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Certificate of EFS-Web Transmission
I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on July 24, 2014.
Typed or printed name of person signing this certificate: Mark L. Yaskanin
Signature: / Mark L. Yaskanin /
Registration Number: 45,246

Dear Sir:

In response to the June 9, 2014 Office Action (the "Office Action"), please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 5 of this paper.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

AMENDMENTS TO THE SPECIFICATION

Please amend the Title as follows:

PERCUTANEOUS ~~BIOPROSTHETIC~~ REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1-33. (Cancelled)

34. (Currently Amended) ~~A percutaneous bioprosthetic heart valve and a delivery and implantation system configured for percutaneous use where a bioprosthetic heart valve is indicated,~~ An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:

a prosthetic heart valve including:

a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration; and

a valve means residing entirely within the inner channel of the stent member, the valve means including ~~an outer cuff layer and~~ two to four individual leaflets made of fixed pericardial tissue, wherein the valve means is attached to a proximal and wider part of the stent member;

a ~~catheter~~ delivery system including a pusher member and a moveable sheath, [[both]] the pusher member including a guidewire lumen ~~and the moveable sheath each including a lumen~~, wherein the pusher member is disposed within [[the]] a lumen of the moveable sheath, and wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed

configuration on the pusher member and is restrained in [[a]] the collapsed configuration by the moveable sheath.

35. (Currently Amended) The ~~percutaneous bioprosthetic heart valve and the delivery and implantation system~~ assembly of Claim 34, wherein the stent member is self-expanding.

36. (Currently Amended) The ~~percutaneous bioprosthetic heart valve and the delivery and implantation system~~ assembly of Claim 35, wherein the stent member comprises nitinol.

37. (Currently Amended) The ~~percutaneous bioprosthetic heart valve and the delivery and implantation system~~ assembly of Claim 34, wherein the stent member includes two circles of barbs on an outer surface of the stent member.

38. (Currently Amended) The ~~percutaneous bioprosthetic heart valve and the delivery and implantation system~~ assembly of Claim 34, wherein the pusher member includes a controlled release mechanism that can be activated.

REMARKS/ARGUMENTS

The present Amendment and Response comprises Applicants' reply to the Examiner's June 9, 2014 Office Action. No claims are cancelled. Claims 34-38 are amended. No new claims have been added. Accordingly, Claims 34-38 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, previously pending claims, or any unclaimed subject matter in one or more future filed continuing applications.

Applicants have amended the "stent member" limitation to further recite that the stent member is "configured for transluminal percutaneous delivery." The Applicants have also amended the title. Support for these amendments can be found in Paragraph [0057] of U.S. Pat. App. Pub. No. 2003/0130729 (filed January 4, 2002) from which the present application claims priority.

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. Rejection Under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), Second Paragraph

The Examiner rejected Claims 34-38 under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), Second Paragraph for indefiniteness on the grounds that the claims fail to particularly point out and distinctly claims the subject matter of the invention.

The Applicants have amended the preamble of Claim 34. Applicants believe that the amended preamble addresses any indefiniteness issue previously asserted by the Examiner.

The Applicants have also adopted the Examiner's suggestion for addressing the last line of Claim 34 (changing "a collapsed configuration" to "the collapsed configuration.") Applicant notes with appreciation the Examiner's suggestion.

Based on the foregoing, the Examiner is respectfully requested to withdraw the 35 U.S.C. § 112 rejections.

II. Prior Art Rejections

A. Rejection Under 35 U.S.C. § 102(e)

The Examiner rejected Claims 34 and 38, under pre-AIA 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,425,916 to Garrison et al. ("Garrison"). The Applicants have addressed Garrison in the present reply, however, if necessary, the Applicants reserve the right to "swear behind" Garrison if the Applicants choose to do so at a later time.

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).

Applicants have amended independent Claim 34 to now read as follows:

> An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:
> a prosthetic heart valve including:
> a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration; and
> a valve means residing entirely within the inner channel of the stent member, the valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means is attached to a proximal and wider part of the stent member;
> a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, and wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath.

As amended, Claim 34 now recites "a valve means residing entirely within the inner channel of the stent member, the valve means including two to four individual leaflets made of fixed pericardial tissue." Support for this amended claim wording can be found at least in Paragraphs [0048]-[0053] of U.S. Pat. App. Pub. No. 2003/0130729 (filed January 4, 2002) from which the present application claims priority.

Turning now to Garrison, while Garrison mentions synthetic materials (Garrison, col. 5, ll. 50-60), the only written description of a "tissue" material of Garrison is found at col. 5, ll. 42-48, wherein Garrison states:

> The posts 32 support a valve portion 38 which performs the functions of the patient's malfunctioning native valve. Referring to FIGS. 10 and 11, the valve portion 38 is preferably a stentless tissue valve such as a tri-leaflet 39 stentless porcine valve. The valve portion 38 has a base 41 which is secured to the support structure 26 with sutures (not shown).

Thus, review of Garrison reveals that Garrison uses "a trileaflet 39 stentless porcine valve." That is, Garrison does not disclose *"two to four individual leaflets made of fixed pericardial tissue,"* as claimed in amended Claim 34. Accordingly, Garrison fails to anticipate the amended wording of Claim 34.

As amended, Claim 34 further recites that "the valve means is attached to a proximal and wider part of the stent member." Support for this amended claim wording can be found in the last sentence of Paragraph [0052] of U.S. Pat. App. Pub. No. 2003/0130729 (filed January 4, 2002) from which the present application claims priority. Such structure is not disclosed in the cited references, including Garrison. More particularly, at least one embodiment of Garrison does not attach commissures to the frame as is evidenced by the inverted valve structure shown in Figures 35 and 38.

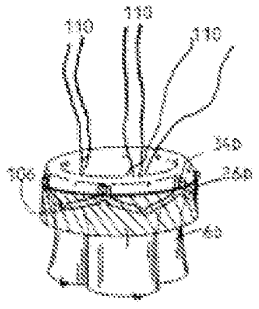


FIG. 35

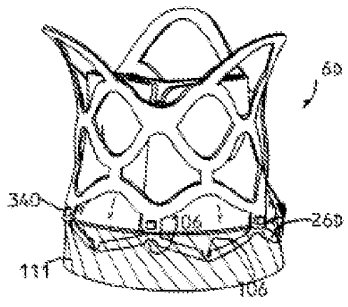


FIG. 38

With regard to Garrison, the valve 6D is attached to a circumferential ring 111 around the support structure 26D. (Garrison, col.10, ll. 51-62.) This is at the distal end of the construct. Accordingly, Garrison does not disclose that "the valve means is attached to a proximal and wider part of the stent member" as recited in amended Claim 34. Moreover, by the inverted structure shown, which is the only method that Garrison discloses as the union of Garrison's various elements, the valve displacer and valve are joined outside the patient's body *prior to* advancing as a system. Indeed, Garrison states that "[t]he valve 6D is coupled to a valve displacer 8D prior to introduction into the patient." (Garrison, col. 10, ll. 40-42.) Thus, when connected together for insertion, the valve is *inverted* as shown above. This is the only method that Garrison discloses and describes when the components are together *before* implantation. Accordingly, Garrison cannot disclose that the "prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath," wherein "the valve means is attached to a proximal and wider part of the stent member," as claimed in amended Claim 34, if the proximal end of the valve 6D is never attached to any structure other than the sutures 110 that are removed after inverting the valve 6D. "The catheter 4D is then removed and the sutures 110 are pulled to invert the valve 6D as shown in FIG. 33. An end of each suture 110 is then pulled to remove the sutures 110." (Garrison, col. 11, ll. 29-32.)

With regard to the Garrison embodiment shown in Fig. 10, the valve portion 38 is connected to a support structure 26.

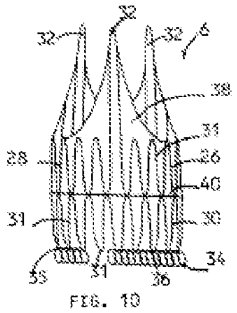


FIG. 10

However, the support structure 26 is not a "stent member" that "includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration," as claimed in Claim 34. If one considers the valve displacer 8 shown in Fig. 9 of Garrison, then the support structure 26 is attached to the valve displacer 8 along its distal end using protrusions 34.

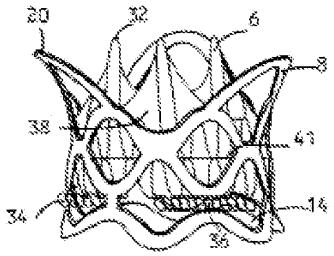


FIG. 9

However, Garrison discloses that the valve displacer 8 and support structure 26 are separate components that are only combined in the body following the valve displacer deployment. Moreover, the support structure 26 contains a porcine valve per Garrison, but the support structure 26, not the valve, is attached to the *distal* end of the valve displacer 8.

MPEP §2131 clearly states that to anticipate a claim, the reference must teach every element of the claim. In addition, The United States Court of Appeals for the Federal Circuit has held "that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus,

cannot anticipate under 35 U.S.C. § 102." Net Moneyin, Inc., v. Verisign, Inc., 2008 U.S. App. LEXIS 21827 (CAFC 2008).

For the foregoing reasons, Garrison does not disclose the claim limitations as recited in amended Claim 34 presented herein. Accordingly, the Examiner is respectfully requested to withdraw the 35 U.S.C. § 102(e) rejection of Claim 34, as well as its dependent Claim 38.

B. Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 34-38 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0032481 to Gabbay ("Gabbay") in view of Garrison. The Applicants have addressed Gabbay in the present reply, however, if necessary, the Applicants reserve the right to "swear behind" Gabbay if the Applicants choose to do so at a later time.

The U.S. Supreme Court, in KSR Int'l. Co. v. Teleflex Inc., 82 USPQ 2d 1385, 1391 (2007), reiterated the standard for determining obviousness under 35 U.S.C. § 103 as being the factual inquiries set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham, the Court stated that obviousness is determined by first determining the scope and content of the prior art, then ascertaining the differences between the invention, as claimed, and the prior art, and then resolving the level of ordinary skill in the prior art. Against this background, the obviousness or non-obviousness of the claimed subject matter is determined.

To establish a prima facie case of obviousness under 35 U.S.C. §103(a), the Examiner must clearly articulate the reason(s) why the claimed invention would have been obvious (i.e., the analysis supporting the rejection must be made explicit). See MPEP § 2142. "Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some

articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See MPEP § 2142 and In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006); see also KSR Int'l Co., 82 USPQ 2d at 1396. To support a § 103(a) rejection, the Examiner must demonstrate that a person of ordinary skill in the art would have had reason to attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. See Noelle v. Lederman, 355 F.3d 1343, 1351–52 (Fed. Cir. 2004); Brown & Williamson Tobacco Co. v. Philip Morris, Inc., 229 F.3d 1120, 1121 (Fed. Cir. 2000); see also KSR Int'l Co., 82 USPQ2d at 1391.

Referring now to Gabbay, as noted above, amended Claim 34 now recites "the valve means is attached to a proximal and wider part of the stent member." However, Gabbay discloses that the valve is attached to a portion of the sent that is spaced apart from both ends of the frame. Figure 2 of Gabbay is shown below.

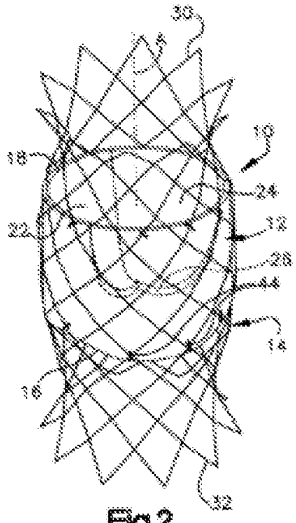


Fig.2

When referring to Fig. 2, Gabbay states that the "[t]he valve 12 may be affixed relative to the stent portion 14, such as by one or more sutures 44. The sutures 44 may be located at the inflow

and outflow ends 16 and 18 of the valve 12 to connect the valve to the stent 14 to inhibit axial movement of the valve relative to the stent." (Gabbay, ¶ [0049].) Accordingly, Gabbay does not disclose that "the valve means is attached to a proximal and wider part of the stent member," as now recited in amended Claim 34. In addition, based on the discussion above pertaining to Garrison, either alone or in combination with Garrison, Gabbay does not disclose the foregoing recited claim limitation.

In addition to the foregoing, Claim 34 further recites the following:

> a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, and wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath.

As stated by the Examiner on page 5 of the Office Action, "Gabbay does not disclose the valve to be collapsed onto the pusher member (210 or 716), to reside in a collapsed configuration on the pusher member." The Examiner then goes on to modify Gabbay with Garrison, stating, in part, that Garrison provides "an alternate pusher member (78a) having a hollow tube (distal end of 78a) extending distally of the plunger (80a and 83b), to which a prosthetic valve is collapsed onto," and that Garrison "allows use of guidewire for positioning." While it is true that Garrison discloses a guidewire, the problem is that Gabbay does not include a "pusher member including a guidewire lumen," as recited in amended Claim 34, and the structure of Gabbay is not consistent with being altered as suggested by the Examiner. More particularly, Gabbay does not use a guidewire and will not work with a guidewire because Gabbay uses a trigger mechanism 206 associated with a plunger mechanism 210. Figure 9A of Gabbay is provided below:

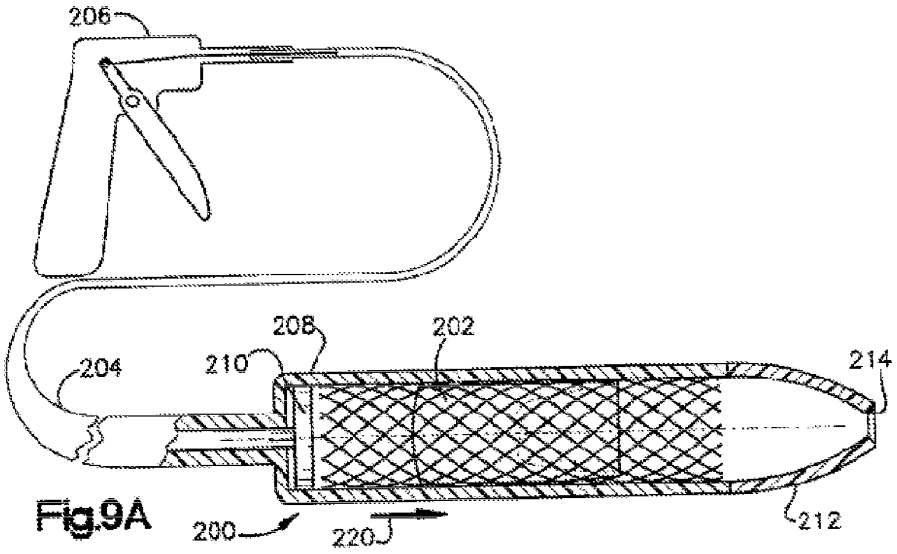


Fig.9A

Gabbay states that "[a] plunger mechanism 210 is located at a proximal end of the enclosure 208 for urging the prosthesis 202 generally axially from the enclosure 208." (Gabbay, ¶ [0064].) Therefore, to combine Garrison with Gabbay as suggested by the Examiner causes a change in the principle of operation of the Gabbay device, because the entire trigger mechanism 206 and plunger mechanism 210 (that is, Gabbay's delivery structure) would no longer operate to deliver the valve if a guidewire exists instead of the plunger linkage. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." MPEP § 2143.02; citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Moreover, as cited on page 10 in Appeal 2011-001382 (*Ex Parte* Mueller et al., App. No. 10/348,306) by the PTAB, "[i]f references taken in combination would produce a 'seemingly inoperative device,' such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness." McGinley v. Franklin Sports, Inc., 262 F3d. 1339, 1354 (Fed. Cir. 2001).

Based on the foregoing, Gabbay alone or in combination with Garrison fails to render amended Claim 34 obvious. Accordingly, the Examiner is respectfully requested to withdraw the 35 U.S.C. §103 rejection of amended independent Claim 34.

With regard to dependent Claims 35-38, 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. Accordingly, the Examiner is requested to withdraw the rejection of dependent Claims 35-38.

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.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

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: July 24, 2014

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20030027332		2003-02-06	Lafrance et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐

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	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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)	2014-07-24
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.

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:	19673567
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Customer Number:	29880
Filer:	Mark Lauren Yaskanin
Filer Authorized By:	
Attorney Docket Number:	109978.10104
Receipt Date:	24-JUL-2014
Filing Date:	15-APR-2014
Time Stamp:	14:52:14
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		Reply_to_6-9-14_OA.pdf	236614 42180b0d39864074c36785d4cf3b74170ec33590	yes	15

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	2
	Claims	3	4
	Applicant Arguments/Remarks Made in an Amendment	5	15

Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	Supp_IDS_10104.pdf	630724 be130094667577377fd6303be3b442d728ad59e46	no	4
Warnings:					
Information:					
3	Non Patent Literature	Hilbert_Biomechanics.PDF	411755 338e7fb710e2ac5a3c67a5af9783502ab656af57	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	1279093		

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/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 14/253,650	Filing Date 04/15/2014	☐ 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	07/24/2014	(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))	* 5	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
/CAROL BARNES/

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
14/253,650	04/15/2014	David PANIAGUA	109978.10104

CONFIRMATION NO. 5427

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

PUBLICATION NOTICE

OC000000070187790

Title:PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

Publication No.US-2014-0228944-A1
Publication Date:08/14/2014

NOTICE OF PUBLICATION OF APPLICATION

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.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20030027332		2003-02-06	Lafrance et al.	
	2	20070061008		2007-03-15	Salahieh et al.	
	3	20100043197		2010-02-25	Abbate et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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	Office Action issued July 8, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐
	2	Office Action issued August 15, 2014, in U.S. Application No. 14/284,063 (File: 109978.10117)	☐
	3	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐

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	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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)	2014-08-21
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.

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:	19930554
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	21-AUG-2014
Filing Date:	15-APR-2014
Time Stamp:	16:10:08
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_10104_Supp_IDS.PDF	643473 5b32c557b249c6507a6252947d92fb0bd8460fbd	no	4
Warnings:					
Information:					

2	Non Patent Literature	10113_US_14-253656_Office_Action_2014-07-08.PDF	437014 37dc712effb927478d8a4a3f745f32f2fabbfcb2	no	11
Warnings:					
Information:					
3	Non Patent Literature	10117_US_14-284063_Office_Action_2014-08-15.PDF	405746 767cb51c75a56970fcae19c2c2d9362f0c07ac12	no	10
Warnings:					
Information:					
4	Non Patent Literature	Hilbert_Biomechanics.PDF	411710 b4851a8736a6654787e31c40da105c179fcf1302	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	1897943	

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 (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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)	☐

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	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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)	2014-09-12
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.

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:	20123129
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	12-SEP-2014
Filing Date:	15-APR-2014
Time Stamp:	13:40:40
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_10104_Supp_IDS_2014-09-12.PDF	649155 3e7a857f9eb78a275667c3e5b40e0f3a4cac0ea4	no	4

Warnings:	
Information:	

2	Non Patent Literature	10115_US_14-268190_Office_Action_2014-09-11.PDF	789645 6113f5cb5892a4df0d3c7c1a6375cda9a03c1a5d	no	19
Warnings:					
Information:					
3	Non Patent Literature	10116_US_14-284049_Office_Action_2014-09-03.PDF	416178 b343786491136eddbbad5222e392024a2a80ebde	no	11
Warnings:					
Information:					
4	Non Patent Literature	10114_US_14-264184_Office_Action_2014-09-12.PDF	459730 b11ce91ce36a866c33d03b2a7d3360d4ff025cfc	no	12
Warnings:					
Information:					
		Total Files Size (in bytes):	2314708		

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 (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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	6530952		2003-03-11	Vesely	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	Final Office Action issued September 25, 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	

*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	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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)	2014-09-26
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.**

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 Acknowledgement Receipt

EFS ID:	20252523
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	26-SEP-2014
Filing Date:	15-APR-2014
Time Stamp:	10:56:56
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_Final_Office_Action_2014-09-25.PDF	538987 cb00303b193a23cd9bb73177ceeba6167d2b91a4	no	14
Warnings:					
Information:					

2	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2014-09-26.PDF	626847 61082b383f5b6d924ba6b9532246b90838e132ba	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	1165834	

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 (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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	

*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	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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)	2014-10-07
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.

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:	20354902
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	07-OCT-2014
Filing Date:	15-APR-2014
Time Stamp:	18:10:58
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_10104_Supp_IDS_2014-10-07.PDF	648570 5d6497751aa0165bda4e56aa23ed53b099d30a12	no	4

Warnings:	
Information:	

2	Non Patent Literature	10113_US_14-253656_Notice_of_Allowance_2014-10-07.PDF	240537 a0f5ed8b9f3c8355dca4c8e4728a4283e7b525c3	no	6
Warnings:					
Information:					
			Total Files Size (in bytes):	889107	

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
David PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	
Atty. File No.: 109978.10104	SUPPLEMENTAL AMENDMENT
	Filed Electronically
Entitled: PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM (as amended)	**Certificate of EFS-Web Transmission** I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 16 October 2014. Typed or printed name of person signing this certificate: Carol Donahue Signature: / Carol Donahue /

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Applicants submit the enclosed claim amendments for the Examiner's consideration.

Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Applicants believe no fees are due for this submission. However, 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:

1-33. (Cancelled)

34. (Currently Amended) An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:

a prosthetic heart valve including:

a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from [[its]] a central portion that flares at both ends in a trumpet-like configuration; and

a valve means residing entirely within the inner channel of the stent member, the valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means is attached to a proximal ~~and wider part~~ portion of the stent member;

a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, [[and]] wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath, and wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath.

35. (Previously Presented) The assembly of Claim 34, wherein the stent member is self-expanding.

36. (Previously Presented) The assembly of Claim 35, wherein the stent member comprises nitinol.

37. (Previously Presented) The assembly of Claim 34, wherein the stent member includes two circles of barbs on an outer surface of the stent member.

38. (Previously Presented) The assembly of Claim 34, wherein the pusher member includes a controlled release mechanism that can be activated.

REMARKS/ARGUMENTS

The present filing is a Supplemental Amendment to Applicants' reply dated July 24, 2014 to the USPTO Office Action dated June 9, 2014. An Examiner's Interview (discussed below) was conducted on October 14, 2014, and this Supplemental Amendment has been prepared to place the application in a condition for allowance. No claims are cancelled. Claim 34 is amended, with support for the amendments found in Fig. 8 of the present application. No new claims have been added. Accordingly, Claims 34-38 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, previously pending claims, or any unclaimed subject matter in one or more future filed continuing applications.

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. Examiner's Interview

Applicants' Attorney and Applicants express their sincere appreciation to Examiner Cheryl L. Miller for conducting a telephone interview with the undersigned Applicants' Attorney and Joseph B. Horn (CEO and President of Colibri Heart Valve LLC (the assignee of the present application)) on October 14, 2014. Applicants will provide a reply upon receiving the Examiner's Interview Summary.

Again, the Applicants and the Applicants' Attorney thank the Examiner for participating in the Examiner's Interview.

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.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

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: October 16, 2014

Electronic Acknowledgement Receipt

EFS ID:	20433382
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	16-OCT-2014
Filing Date:	15-APR-2014
Time Stamp:	14:24:45
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		Colibri_10104_Supplemental_Amendment_2014-10-16.PDF	130990 00caee70f0fd5c021339f6212a993066305405e5	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Supplemental Response or Supplemental Amendment	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	5
Warnings:			
Information:			
	Total Files Size (in bytes):	130990	

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/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 14/253,650	Filing Date 04/15/2014	☐ 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	10/16/2014	(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))	* 5	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
/TERRY MALLOY/

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.

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.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 10/24/2014

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
10/24/2014	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

Applicant-Initiated Interview Summary	**Application No.** 14/253,650	**Applicant(s)** PANIAGUA ET AL.	
	Examiner CHERYL MILLER	**Art Unit** 3738	

All participants (applicant, applicant's representative, PTO personnel):

(1) *CHERYL MILLER (Examiner)*. (3)*Joe Horn (Assignee)*.

(2) *Mark Yaskanin (Reg. No.45,246)*. (4)_____.

Date of Interview: *14 October 2014*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☒112 ☒102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *34*.

Identification of prior art discussed: *Gabbay (US 2002/0032481 A1) and Garrison (6,425,916 B1)* .

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

See Continuation Sheet.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CHERYL MILLER/ Examiner, Art Unit 3738	/THOMAS J SWEET/ Supervisory Patent Examiner, Art Unit 3738

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The official amendment filed July 24, 2014 was discussed. The amendment appears to overcome the previous indefinite issues. Although it was suggested by examiner to remove "its" from the claim to make more clear what "its" refers to. The limitation of the valve means attached to a proximal and wider part of the stent member was discussed. Examiner noted that Gabbay's valve of figure 2 for example, although centered on the stent member, is attached to the proximal portion at one suture line and the distal portion at another suture line, and thus, claiming the positioning of the valve more proximally than distally, or the valve itself, as a whole, is positioned closer to the proximal end of the stent member than the distal end, may be needed to overcome such interpretations discussed above. Such language would appear to be more close to that recited in the specification as well, thus would avoid any new matter issues, as the examiner had concern for lack of support of the valve attached to the wider portion, as this detail does not appear to be shown in the drawings. Also, the proximal part of the stent member has no reference point, thus any end of a stent member in the prior art may be considered a proximal end. Applicant may consider defining where the proximal end is, possibly by the inflow/outflow of leaflets or blood flow, or alternately, by the prosthetic valve's orientation/positioning on the pusher member (which end is where on the pusher). Applicant plans to file a supplemental amendment in next week or so, which the examiner has agreed to have entered and will conduct a new search and consideration at that point in time.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	REPLY TO APPLICANT-INITIATED INTERVIEW SUMMARY
Atty. File No.: 109978.10104	**Filed Electronically**
Entitled: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Certificate of EFS-Web Transmission
I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 31 October 2014.
Typed or printed name of person signing this certificate:
Carol Donahue
Signature: /Carol Donahue/

Dear Sir:

Applicants submit the following reply to the October 24, 2014 Applicant-Initiated Interview Summary. The participants in the Interview were Examiner, Cheryl Miller, Joseph Horn (for the Assignee), and Applicants' undersigned counsel. Applicants' Attorney expresses his sincere appreciation to the Examiner for conducting the telephone interview on October 14, 2014.

An Interview Summary was prepared by the Examiner and mailed on October 24, 2014. The Applicants' Attorney is in agreement with the Examiner's Summary as set forth in the Interview Summary, regarding the claim and prior art discussed. While there was not a resolution reached regarding the exact wording needed for claim amendments, the Examiner offered guidance to the Applicants possible amendments to put the claims in condition for allowance. Applicants filed claim amendments on October 16, 2014 in a Supplement Amendment. In the Supplemental Amendment, the Applicants endeavored to provide claim

wording supported by the application that would place the application in a condition for allowance.

Notwithstanding the Applicants' amendments set forth in the Supplemental Amendment, which Applicants believes places the application in a condition for allowance, the Applicants' Attorney nonetheless invites the Examiner to contact Applicants' Attorney directly by phone at (303) 446-3852 if an Examiner's Amendment is needed to place the application in a condition for allowance.

Applicant believes no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

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: 31 October 2014

Electronic Acknowledgement Receipt

EFS ID:	20577188
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	31-OCT-2014
Filing Date:	15-APR-2014
Time Stamp:	15:25:17
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	Applicant summary of interview with examiner	Colibri_10104_Reply_to_Interview_Summary.PDF	87454 025eae7243aea2f1b98e9dd46b47566dbac1b48d	no	2
Warnings:					
Information:					

Total Files Size (in bytes):	87454

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.

OK TO ENTER: /CM/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
David PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	
Atty. File No.: 109978.10104	SUPPLEMENTAL AMENDMENT
	Filed Electronically
Entitled: PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM (as amended)	**Certificate of EFS-Web Transmission** I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 16 October 2014. Typed or printed name of person signing this certificate: Carol Donahue Signature: / Carol Donahue /

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Applicants submit the enclosed claim amendments for the Examiner's consideration.

Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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					
If you wish to add additional U.S. Patent citation information please click the Add button.						Add

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	20030027332		2003-02-06	Lafrance et al.	
If you wish to add additional U.S. Published Application citation information please click the Add button.						Add

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							☐
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]

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 07/24/2014	Application Number	14253650 14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
(Not for submission under 37 CFR 1.99)	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	11/03/2014

*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. /CM/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	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
623	1.24, 1.26, 2.12-2.19	6/2/2014	cm
update		11/1/2014	cm

SEARCH NOTES		
Search Notes	Date	Examiner
East text search	11/2/2014	cm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/C.M./ Examiner.Art Unit 3738	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20030027332		2003-02-06	Lafrance et al.	
	2	20070061008		2007-03-15	Salahieh et al.	
	3	20100043197		2010-02-25	Abbate et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 08/21/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

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	Office Action issued July 8, 2014, in U.S. Application No. 14/253,656 (File: 109978.10113)	☐
	2	Office Action issued August 15, 2014, in U.S. Application No. 14/284,063 (File: 109978.10117)	☐
	3	HILBERT et al., "Biomechanics: Allograft Heart Valves," Cardiac Reconstructions with Allograft Tissues, Springer, New York (2005), pp. 210-212	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	11/03/2014

*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. /CM/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"7556646".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 13:32
L2	1	"6733525".pn.	US-PGPUB; USPAT; USOCR	OR	ON	2014/11/03 14:12
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;	OR	ON	2014/06/03 14:01

			USOCR			
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
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;	OR	ON	2014/11/02 20:44

			USPAT; USOCR			
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

11/3/2014 2:17:15 PM
C:\Users\cmiller2\Documents\EAST\Workspaces\14253650.wsp

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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.	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 10/07/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
(**Not for submission under 37 CFR 1.99)**	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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	/Cheryl Miller/	Date Considered	11/03/2014

*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. /CM/

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.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 11/07/2014

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
11/07/2014	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. 14/253,650	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 *10/16/2014 and 7/24/2014*.

☐ 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) *34-38* 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) *34-38* 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 *10/7/2014, 9/26/2014, 9/12/2014, 8/21/2014, 7/24/2014*.

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.

Supplemental Amendment

The supplemental amendment filed October 16, 2014 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 34-38 have been considered but are moot because the arguments do not apply to any of the specific combination of references being used in the current rejection.

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 34-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 6,652,578 B2) in view of Cribier (US 6,908,481 B2). Bailey discloses an assembly to treat a native heart valve, the assembly comprising: a prosthetic heart valve (figs.7-12) including a stent member (12) having an inner channel, the stent member (12) collapsible, expandable, and configured for transluminal percutaneous delivery (fig.20a-20i; col.63-67), wherein the stent member (12) includes a tubular structure away from a central portion that flares at both ends (42, 44) in a trumpet-like configuration (see fig.12a and 12b, wherein flanges 42 and 44 appear to be more trumpet shaped when placed in the body and surrounding the annulus, as

opposed to the perpendicular shape in fig.7) and a valve means (11b+28) residing entirely within the inner channel of the stent member (see fig.10), the valve means including two to four individual leaflets (26) of tissue (biologically derived membranes col.8, lines 47-49; col.9, lines 20-25; col.5, lines 53-60), the valve means (11b+28) attached to a proximal portion of the stent member (as the valve means is attached along the majority of the inner surface of stent, 11b is coplanar with stent length and leaflets 26 are attached to stent at seams 29 which extend from a proximal portion to a distal portion, thus the valve is attached to *both* a proximal portion and a distal portion of the stent member, which includes attachment at the proximal portion and thus meets the claim limitation); a delivery system (fig.19) including a pusher member (222) and a moveable sheath (217), the pusher member (222) including a guidewire lumen (see fig.19), the pusher member (222) disposed within a lumen (216) of the moveable sheath (217), wherein the prosthetic valve (40; fig.7-11) is collapsed onto the pusher member (222) to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath (217; see fig.19; wherein valve 10 is shown, however applies also to valve 40; col.14, lines 63-67), and wherein a distal end of the prosthetic valve is located at a distal end of the moveable sheath (see fig.19; col.14, lines 63-67; Baileys valve is attached to both proximal and distal portions of the stent member; thus, either end of the stent member may be considered the proximal end, and the opposite end would be the distal end, both of which are located at the distal end of the moveable sheath). Bailey discloses the assembly substantially as claimed, having leaflets (26) of biological tissue (biologically derived membranes col.8, lines 47-49), however is silent to mention what type of tissue specifically. Cribier teaches in the same field of prosthetic heart valves, use of fixed pericardial tissue (col.5, lines 20-30) for the leaflets that are

attached to an expandable stent in a similar manner as Bailey (see fig.6a-6c and col.5, lines 30-46 of Cribier compared to figs.10 of Bailey), fixed pericardial tissue taught by Cribier to be an example of a biologically derived membrane material used for leaflets attached to expandable stent structures (col.5, lines 20-30; col.15, lines 5-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Baileys assembly with Cribier's alternate choice of material for leaflets, as such would be an obvious alternate material choice known in the art.

Bailey discloses the stent member to be self-expanding and comprising nitinol (col.5, lines 44-53; col.8, lines 13-17). Bailey discloses two circles of barbs on the stent member (pointed ends of triangles in flanges 42 and 44 may be considered barbs as the project and anchor to tissue). Bailey discloses the pusher member (222) to include a control release mechanism (220 and 218; function to hold valve in place longitudinally on pusher while sheath is withdrawn slowly, to control deployment by longitudinal restraint).

In the alternative to the above rejection, claims 34-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 6,652,578 B2) in view of Cribier (US 6,908,481 B2). Bailey discloses an assembly to treat a native heart valve, the assembly comprising: a prosthetic heart valve (figs.7-12 or figs.1-6) including a stent member (12) having an inner channel, the stent member (12) collapsible, expandable, and configured for transluminal percutaneous delivery (fig.20a-20i; col.63-67), wherein the stent member (12) includes a tubular structure away from a central portion that flares at both ends (42, 44 fig.10,12 or alternately 22, 18 fig.4, 6) and a valve means (11b+28) residing entirely within the inner channel of the stent

member (see fig.10 and 4), the valve means including two to four individual leaflets (26) of tissue (biologically derived membranes col.8, lines 47-49; col.9, lines 20-25; col.5, lines 53-60), the valve means (11b+28) attached to a proximal portion of the stent member (as the valve means is attached along the entire inner surface of stent, 11b is coplanar with stent and leaflets 26 are attached to stent at seams 29 which extend from a proximal portion to a distal portion, thus the valve is attached to both a proximal portion and a distal portion of the stent member, which includes attachment at the proximal portion and thus meets the claim limitation; in the embodiment of fig.4, the leaflets are positioned closer to the bottom of the stent member, which is disclosed to be the proximal portion); a delivery system (fig.19) including a pusher member (222) and a moveable sheath (217), the pusher member (222) including a guidewire lumen (see fig.19), the pusher member (222) disposed within a lumen (216) of the moveable sheath (217), wherein the prosthetic valve (40; fig.7-11) is collapsed onto the pusher member (222) to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath (217; see fig.19; wherein valve 10 is shown, however applies also to valve 40; col.14, lines 63-67), and wherein a distal end of the prosthetic valve is located at a distal end of the moveable sheath (see fig.19; col.14, lines 63-67; Baileys valve is attached to both proximal and distal portions of the stent member; thus, either end of the stent member may be considered the proximal end, and the opposite end would be the distal end, both of which are located at the distal end of the moveable sheath). Bailey discloses the assembly substantially as claimed, having leaflets (26) of biological tissue (biologically derived membranes col.8, lines 47-49), however is silent to mention what type of tissue specifically. Bailey also shows two ends flared (18 and 20 in fig.4 and 42 and 44 in fig.10), and discloses these may be at an acute, right,

or perpendicular angle (col.5 line 64-col.6 line 4), however does not recite that the flared ends are specifically "trumpet" shaped. Cribier teaches in the same field of prosthetic heart valves, use of fixed pericardial tissue (col.5, lines 20-30) for the leaflets that are attached to an expandable stent in a similar manner as Bailey (see fig.6a-6c and col.5, lines 30-46 of Cribier compared to figs.10 of Bailey), fixed pericardial tissue taught by Cribier to be an example of a biologically derived membrane material used for leaflets attached to expandable stent structures (col.5, lines 20-30; col.15, lines 5-9) and Cribier also teaches a stent (10) with flared ends (12) similar to Bailey (see Cribier fig.3a, 3b), for the same purpose of anchoring against the native valve annulus (col.8, lines 62-67; col.9, lines 21-29), however more of a trumpet shaped flare (concave, col.5, lines 64-67; fig.3a, 3b). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Baileys assembly with Cribier's alternate choice of material for Baileys leaflets, as such would be an obvious alternate material choice known in the art and with Cribier's alternate trumpet shaped flares, as such is an obvious alternate flare shape that serves the same purpose as Baileys flared ends (anchoring above and below the native valve annulus).

Bailey discloses the stent member to be self-expanding and comprising nitinol (col.5, lines 44-53; col.8, lines 13-17). Bailey discloses two circles of barbs on the stent member (pointed ends of triangles in flanges 42 and 44 may be considered barbs as the project and anchor to tissue). Bailey discloses the pusher member (222) to include a control release mechanism (220 and 218; function to hold valve in place longitudinally on pusher while sheath is withdrawn slowly, to control deployment by longitudinal restraint).

Claims 34 and 38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Garrison et al. (US 6,425,916 B1, cited previously) in view of Cribier (US 6,908,481 B2) and Gabbay (US 2002/0032481 A1, cited previously). Garrison discloses an assembly to treat a native heart valve in a patient comprising: a prosthetic heart valve (figs.31-38) including configured for percutaneous use (see fig.31, 38; other delivery methods may also be used, col.11, lines 10-12; for example fig.3-6) comprising: a stent member (111+26d+8d; see fig.38) having an inner channel (central lumen), the stent member (8d+26d+111) being collapsible (seen in fig.31, 36, 37) and expandable (seen in fig.32, 33, 38) and configured for percutaneous delivery (see fig.31; other delivery methods may be used, col.11, lines 10-12; figs.3-6), the stent member (111+26d+8d) including a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration (seen in fig.38), a valve means (6d) residing entirely within the inner channel (see fig.38; valve does reside entirely within inner channel in the implanted state; noting that the claims do not require valve to reside entirely within the inner channel of the stent member when the prosthetic heart valve is collapsed on the pusher member *and* when the prosthetic heart valve is in the released from the delivery system; such a claim limitation would seemingly overcome this rejection) of the stent member (111+26d+8d), the valve means (6d) including two to four individual leaflets (upper portion of 6d, see fig.38) of biological tissue material (membrane material that is preserved/fixed prior to implantation as seen in fig.34; col.11, lines 4-5, thus assumingly tissue, however not specific as to what type); the valve attached to one end of the stent member (bottom, inflow end, see fig.36, 37) and a delivery system including a pusher member (4D) and moveable sheath (116), both the pusher member (4d or 64) and sheath (116 or 10) having a lumen (see fig.31, 37, 2, 3), wherein the pusher member

(64 or 4D) is disposed in the sheath lumen, and the prosthetic heart valve (fig.38) is collapsed onto the pusher member (4D or 64; see fig.37, 3) to reside in a collapsed configuration on the pusher member and is restrained in a collapsed configuration by the sheath (116 or 10), a distal end of the valve is located at the distal end of the sheath (both proximal and distal ends of the prosthetic valve are positioned in the distal end of the sheath). Garrison discloses the assembly substantially as claimed, however does not disclose 1) pericardium to be the specific type of fixed tissue used for leaflets and 2) the valve attached to the proximal end of the stent when in the distal end of the sheath (Garrison discloses that when the prosthetic valve is in the distal end of the sheath, it is positioned/oriented such that the attachment of the stent to the valve is at the distal end instead of the proximal end). Cribier teaches in the same field of prosthetic heart valves, use of fixed pericardial tissue (col.5, lines 20-30) for the leaflets that are attached to an expandable stent (fig.6a-6c and col.5, lines 30-46 of Cribier), fixed pericardial tissue taught by Cribier to be an example of a biologically derived membrane material used for leaflets attached to expandable stent structures (col.5, lines 20-30; col.15, lines 5-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Garrison's assembly of figs.31-38 with Cribier's alternate choice of material (pericardium) for Garrisons leaflets, as such would be an obvious alternate material choice known in the art. Further, Gabbay teaches in the same field of expandable prosthetic heart valves and percutaneous delivery systems therefor, positioning a prosthetic heart valve such that the outflow end is closer to the distal end of the sheath than the inflow end (seen in figure 11) or alternately, positioning such that the inflow end of the valve is closer to the distal end of sheath than the outflow end (seen in figure 19, 22) and that such are obvious alternative positions of the heart valve within

the sheath, depending on which valve in the heart is being replaced and the direction in which the delivery system is inserted (P0071, P0106). It would have been obvious to one having ordinary skill in the art at the time the invention was made also combine Garrison's assembly with Gabbay's teaching of alternate orientation of the prosthesis within the sheath, as such is shown by Gabbay to be an obvious alternate positioning providing for different delivery routes and positioning at different valves within the heart.

Garrison discloses the pusher member (4d or 64) to include a controlled release mechanism (balloon 112 or 52) that can be activated (via inflation).

Claims 34-38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 6,733,525 B2) in view of Yang et al. (US 7,556,646 B2) and further in view of Gabbay (US 2002/0032481 A1, cited previously). Yang 525' discloses an assembly to treat a native heart valve in a patient comprising: a prosthetic heart valve (fig.21a-21c embodiment) including configured for percutaneous use (compressible, see fig.21b; col.4, lines 5-17; col.6, lines 23-40) comprising: a stent member (602) having an inner channel (central lumen seen in fig.21b, 21c), the stent member (602) being collapsible (seen in fig.21b) and expandable (seen in fig.21c) and configured for percutaneous delivery (col.16, lines 7-11; col.4, lines 5-17), the stent member (602) including a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration (seen in fig.21a; flared out outflow **and** overlapped sides at inflow, col.16, liners 10-11), a valve means (626) residing entirely within the inner channel (fig.21a-21c, fig.2a, 2b) of the stent member (602), the valve means (626) including two to four individual leaflets (626) of fixed pericardium (col.1, lines 22-40; col.6, lines 14-16); the valve

attached to one end of the stent member (inflow end, see fig.21a-21c) and a delivery system comprising a moveable outer sheath and pusher (col.16, lines 43-59; col.12, lines 41-50), however does not disclose specific details of the delivery system. Yang 646' teaches in the same field of delivery of Yang 525 type of prosthetic heart valves. Yang 646' teaches the delivery system particulars to include an outer moveable sheath (disclosed percutaneous catheter tube; col.5 line 65-col.6 line 2) and a pusher member (end of 24, at 26 in fig.1 for example) having a lumen for a guidewire (28) and the prosthetic heart valve (30) is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member (fig.1) and is restrained in a collapsed configuration by the sheath (col.5 lines 65-col.6 line 2), a distal end of the valve (30) is located at the distal end of the sheath (both proximal and distal ends of the prosthetic valve are positioned in the distal end of the sheath). Further, Gabbay teaches in the same field of expandable prosthetic heart valves and percutaneous delivery systems therefor, positioning a prosthetic heart valve such that the outflow end is closer to the distal end of the sheath than the inflow end (seen in figure 11) or alternately, positioning such that the inflow end of the valve is closer to the distal end of sheath than the outflow end (seen in figure 19, 22) and that such are obvious alternative positions of the heart valve within the sheath, depending on which valve in the heart is being replaced and the direction in which the delivery system is inserted (P0071, P0106). It would have been obvious to one having ordinary skill in the art at the time the invention was made also combine Yang525's prosthetic heart valve with Yang 646's teaching of a delivery system for heart valves of Yang 525', also with Gabbay's teaching of alternate orientations of a heart valve on the distal ends of delivery systems, in order to provide Yang

525's prosthetic valve with a delivery system that may be introduced through various routes and to various valves within the heart.

Yang 525' discloses the stent (602) to be self-expandable and to comprise nitinol (col.6, lines 5-14; col.6, lines 23-34; col.8, lines 35-38; col.14, lines 30-43) and two circles of barbs (fig.11e for example, col.15, lines 45-53). Yang 525' (as modified by Yang 646 delivery system and Gabbay's orientation on a delivery system) discloses the pusher member (24/26 of Yang 646') to include a controlled release mechanism (balloon or pivoting arms) that can be activated (via inflation or turning gears).

Conclusion

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. 14/253,650	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-6,652,578 B2	11-2003	Bailey et al.	623/1.24
*	B	US-6,908,481 B2	06-2005	Cribier, Alain	623/2.11
*	C	US-6,733,525 B2	05-2004	Yang et al.	623/2.18
*	D	US-7,556,646 B2	07-2009	Yang et al.	623/2.11
	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	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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 09/12/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

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)	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	11/03/2014

*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. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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	6530952		2003-03-11	Vesely	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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							☐

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]

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 09/26/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

	1	Final Office Action issued September 25, 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	/Cheryl Miller/	Date Considered	11/03/2014

*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. /CM/

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	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.

[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	14253650
	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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)	2014-11-20
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.

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:	20752868
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	20-NOV-2014
Filing Date:	15-APR-2014
Time Stamp:	13:34:29
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	10106_US_14-502453_Preliminary_Amendment.PDF	138042 d392693ca35db7c7c7b2f546ead31db8e20a94d8	no	10

Warnings:

Information:

2	Non Patent Literature	10106_US_14-502453_2nd_Prelim_Amendment_2014-11-19.PDF	119965 2a3ff524e287df719fa75fdd883fb94f44d0285f	no	5
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2014-11-20.PDF	703510 73bf8281af7e7c03b2d19117991bbb1782cc82de	no	4
Warnings:					
Information:					

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

Total Files Size (in bytes):	961517

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 (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20030209835		2003-11-13	Chun et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	1	Office Action issued December 5, 2014 in U.S. Application No. 14/502,453 (109978.10106)	☐
	2	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)	☐

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	14253650
	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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)	2015-05-07
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.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 3738
David PANIAGUA et al.	Confirmation No. 5427
Application No.: 14/253,650	Examiner: Cheryl L. MILLER
Filed: April 15, 2014	AMENDMENT AND RESPONSE
Atty. File No.: 109978.10104	**Filed Electronically**
Entitled: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Certificate of EFS-Web Transmission
I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 07 May 2015 .
Typed or printed name of person signing this certificate:
Carol Donahue
Signature: / Carol Donahue /

Dear Sir:

In response to the November 7, 2014 Final Office Action (the "Office Action"), please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.

A Request for Continued Examination and a 3-month extension are submitted herewith along with the associated fees. Applicants believe no additional fees are due for this submission. However, 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:

1-33. (Cancelled)

34. (Currently Amended) An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:

a prosthetic heart valve including:

a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and

a valve means ~~residing entirely within the inner channel of the stent member, the valve means~~ including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means and all fixed pericardial tissue reside entirely within the inner channel of the stent member, wherein the valve means is attached closer to a proximal and wider part ~~portion~~ of the stent member;

a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath, [[and]] wherein a distal end of the prosthetic heart valve is

located at a distal end of the moveable sheath, and wherein the valve means resides entirely within the inner channel of the stent member when the stent member is collapsed onto the pusher member and further resides entirely within the inner channel of the stent member when the stent member is unrestrained from the moveable sheath upon deployment in the patient.

35. (Previously Presented) The assembly of Claim 34, wherein the stent member is self-expanding.

36. (Previously Presented) The assembly of Claim 35, wherein the stent member comprises nitinol.

37. (Previously Presented) The assembly of Claim 34, wherein the stent member includes two circles of barbs on an outer surface of the stent member.

38. (Previously Presented) The assembly of Claim 34, wherein the pusher member includes a controlled release mechanism that can be activated.

REMARKS/ARGUMENTS

The present Amendment and Response comprises Applicant's reply to the Examiner's November 7, 2014 Final Office Action. No claims have been cancelled. Claim 34 has been amended. No new claims have been added. Accordingly, Claims 34-38 remain pending in view of the above amendments.

Claim 34 has been amended to recite, in part: "wherein the valve means and all fixed pericardial tissue reside entirely within the inner channel of the stent member." In addition, Claim 34 has been further amended to recite "wherein the valve means resides entirely within the inner channel of the stent member when the stent member is collapsed onto the pusher member and further resides entirely within the inner channel of the stent member when the stent member is unrestrained from the moveable sheath upon deployment in the patient." Support for the foregoing amendments can be found, in part, in the Abstract, as well as in Figures 5 and 6 of the present application. Claim 34 has also been amended to recite "the valve means is attached closer to a proximal and wider part of the stent member." Support for this claim amendment can be found in the last sentence of Paragraph [0052] of Patent Application Publication No. 2003/0130729, which corresponds to U.S. Patent Application No. 10/037,266 from which priority is claimed. Accordingly, Applicants believe that no new matter has been added with regard to the claim amendments provided herein and that support for all claimed subject matter can be found in U.S. Patent Application No. 10/037,266 filed on January 4, 2002.

Applicants do not donate or disclaim any claims or subject matter with the claim amendments made herein, nor do the Applicants acquiesce to any rejections. The Applicants

expressly reserve the right to prosecute the original claims, previously pending claims, or any unclaimed subject matter in one or more future filed continuing applications.

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. Prior Art Rejections

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 34-38 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,652,578 to Bailey et al. ("Bailey") in view of U.S. Patent No. 6,908,481 to Cribier ("Cribier"); rejected Claims 34-38 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,425,916 to Garrison et al. ("Garrison") in view of Cribier and U.S. Patent Application Publication No. 2002/0032481 to Gabbay ("Gabbay"); and rejected Claims 34-38 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,733,525 to Yang et al. ("Yang '525") in view of U.S. Patent No. 7,556,646 to Yang et al., ("Yang '646") and further in view of Gabbay.

The U.S. Supreme Court, in KSR Int'l. Co. v. Teleflex Inc., 82 USPQ 2d 1385, 1391 (2007), reiterated the standard for determining obviousness under 35 U.S.C. § 103 as being the factual inquiries set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham, the Court stated that obviousness is determined by first determining the scope and content of the prior art, then ascertaining the differences between the invention, as claimed, and the prior art, and then resolving the level of ordinary skill in the prior art. Against this background, the obviousness or non-obviousness of the claimed subject matter is determined. When making any obviousness rejection, the Examiner must first acquire a thorough understanding of the claimed invention by reading the specification and claims to understand what the Applicant is claiming as his or her invention. MPEP § 904.

To establish a prima facie case of obviousness under 35 U.S.C. §103(a), the Examiner must clearly articulate the reason(s) why the claimed invention would have been obvious (i.e., the analysis supporting the rejection must be made explicit). See MPEP § 2142. "Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See MPEP § 2142 and In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006); see also KSR Int'l Co., 82 USPQ 2d at 1396. To support a § 103(a) rejection, the Examiner must demonstrate that a person of ordinary skill in the art would have had reason to attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. See Noelle v. Lederman, 355 F.3d 1343, 1351–52 (Fed. Cir. 2004); Brown & Williamson Tobacco Co. v. Philip Morris, Inc., 229 F.3d 1120, 1121 (Fed. Cir. 2000); see also KSR Int'l Co., 82 USPQ2d at 1391.

The following sections address the various 35 U.S.C. § 103(a) rejections.

35 U.S.C. § 103(a) Rejections As Being Unpatentable Over Bailey In View Of Cribier

Claims 34-38 were rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Bailey in view of Cribier.

The Applicants have amended Claim 34 to recite, in part:

> a valve means including two to four individual leaflets made of fixed pericardial tissue, *wherein the valve means and all fixed pericardial tissue reside entirely within the inner channel of the stent member, wherein the valve means is attached closer to a proximal and wider part of the stent member*;

Bailey fails to disclose at least the limitations shown above in italics. More particularly, Bailey discloses that the tissue is located on an abluminal side of the frame. This is shown in Figures 4, 10 and 16 of Bailey, as reproduced below:

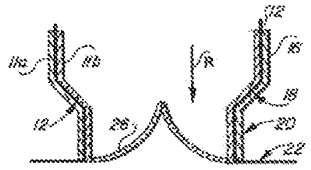


Fig. 4

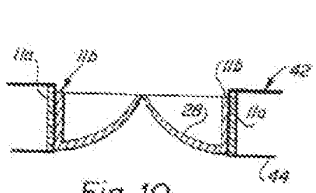


Fig. 10

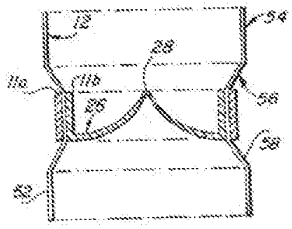


Fig. 16

In addition, Bailey states "[i]t should be appreciated, that **the graft member 11 should cover at least a portion of the ablumenal surface of the stent body member 12** in order to exclude the anatomic valves. . . ." (Bailey, col. 9, ll. 59-62.) (Emphasis added.) Accordingly, Bailey teaches away from a configuration where tissue is limited to the interior of the stent member, as recited in amended Claim 34, which states "*wherein the valve means and all fixed pericardial tissue reside entirely within the inner channel of the stent member.*"

In addition to the foregoing, the Applicants assert that Bailey does not enable a device that does not include the valve arms or blood flow regulator struts. There is no question that Bailey insists on the valve regulator arms being present. Reference here is made to Figs. 3, 9 and 15 of Bailey shown below. Each of the embodiments described in Bailey uses valve leaflets 26 that are biased using valve arms 24.

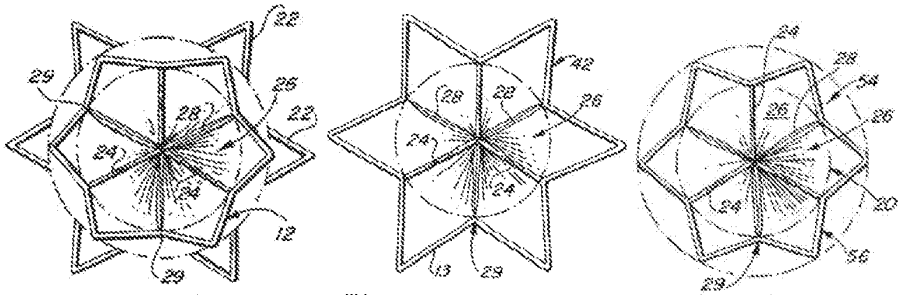


Fig. 3 Fig. 9 Fig. 15

In addition, the specification of Bailey states: "The stent body member is shaped to include the following stent sections: ... **and at least one valve arm or blood flow regulator struts"** (Bailey, col. 5, ll. 51-54)(emphasis added); "[f]low regulation in the inventive stent valve prosthesis is provided by the combination of the prosthetic valve leaflets **and the valve arms** and is biased closed..." (Bailey, col. 6,11. 10-12)(emphasis added); and **"[c]ertain elements are common to each of the preferred embodiments of the invention, specifically, each embodiment includes ... at least one biasing arm []** [that] projects from the stent body member and into the central annular opening of the stent body member." (Bailey, col. 7, ll. 58-67.) (Emphasis added.) Accordingly, Bailey requires use of at least one biasing arm within the inner channel of the stent body member.

Applicants further direct the Examiner's attention to Bailey, wherein when discussing the struts, Bailey states:

> The struts of the stent are encapsulated by the outer graft-membrane. **The valve regulator-struts** are encapsulated by the inner leaflet-membrane **and serve to bias the valve to the closed position**. The regulator-struts also prevent inversion or prolapse of the otherwise unsupported leaflet-membrane during increased supra-valvular pressure.

(Bailey, col. 6, ll. 23-26.) (Emphases added.) Here, it is clear that Bailey recognized the necessity to provide some type of mechanism to prevent prolapse of the leaflet membrane when closing. However, if the valve arms or blood flow regulator struts "serve to bias the valve to the closed position," then such biasing force must be overcome by the heart when attempting to pump blood through the valve. Accordingly, the valve arms or blood flow regulator struts of Bailey not only cause resistance to blood flow, but they add a level of complexity associated with interconnecting the leaflet-membrane to the valve arms or blood flow regulator struts, as well as crimping and deploying the valve.

Bailey also makes it clear that the valve arms or blood flow regulator struts are part of the stent member. More particularly, Bailey states:

> Valve arms or regulator struts 24 **are coupled or formed integral with the stent body member 12** and are positioned adjacent the junction point between intermediate annular section 20 and the proximal anchor flange 22 of the stent body member 12.

(Bailey, col. 9, ll. 25-29.) (Emphasis added.) Bailey does not enable its tissue assembly to operate properly as a valve *without* the valve arms or blood flow regulator struts. Accordingly, while Bailey discloses a construct that uses a plurality of valve arms or flow regulator struts 24, Bailey provides information insufficient to enable one of ordinary skill in the art to practice the invention without undue experimentation *if* the

valve arms or regulator struts are *not* present. In the present application, valve arms or regulator struts are not used, and therefore, Bailey does not disclose or enable a device that lacks these structures.

In addition to the foregoing, Cribier has been cited by the Examiner as disclosing fixed pericardial tissue for the leaflets. However, Cribier is only deployed using a balloon catheter (contrary to the limitations recited in current independent Claim 34) and more importantly, requires the valvular structure to include strengthening struts 14a, pleats 22 or other reinforcing feature. Cribier states:

> The **valvular tissue forms a continuous surface and is provided with guiding means formed or incorporated within, creating stiffened zones** which induce the valvular structure to follow a patterned movement from its open position to its closed state and vice-versa, **providing therefore a structure sufficiently rigid to prevent diversion**, in particular into the left ventricle and thus preventing any regurgitation of blood into the left ventricle in case of aortic implantation.

(Cribier, col. 3, l. 67 to col. 4, l. 8.) (Emphasis added.) Accordingly, there is no disclosure in Cribier of fixed pericardial tissue (as recited in Claim 34 herein) without the use of the reinforcing features taught by Cribier. Indeed, Cribier further states "[t]hese reinforcing pleats and/or struts, rectilinear or inclined, have the advantage to impart a reproducible movement and, accordingly, **to avoid the valvular structure from closing to a nonstructurized collapse on the frame base**." (Cribier, col. 15, ll. 49-52.) (Emphasis added.) The use of fixed pericardial tissue from Cribier without reinforcing structure is not enabled.

Based on the foregoing, the Examiner is requested to withdraw the 35 U.S.C. § 103(a) rejections of Claims 34-38 as being unpatentable over Bailey in view of Cribier.

35 U.S.C. § 103(a) Rejection As Being Unpatentable Over Garrison In View Of Cribier And Gabbay

Claims 34-38 were rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Garrison in view of Cribier and Gabbay.

As suggested by the Examiner on page 7 of the Office Action dated November 7, 2014, the Applicants have amended the wording of Claim 34 to now recite, in part:

> wherein the valve means resides entirely within the inner channel of the stent member when the stent member is collapsed onto the pusher member and further resides entirely within the inner channel of the stent member when the stent member is unrestrained from the moveable sheath upon deployment in the patient.

Garrison clearly fails to disclose the above recited limitations. Indeed, Garrison does not attach commissures to the frame as is evidenced by the inverted valve structure shown in Figures 35 and 38.

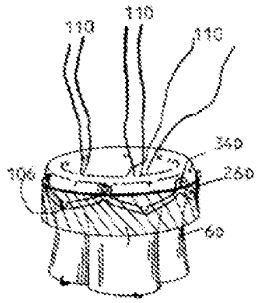


FIG. 35

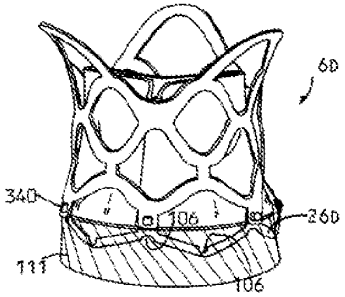


FIG. 38

With regard to Garrison, the valve 6D is attached to a circumferential ring 111 around the support structure 26D. (Garrison, col.10, ll. 51-62.) This is at the distal end of the construct. Accordingly, Garrison also does not disclose that "the valve means is attached closer to a proximal and wider part of the stent" as recited in amended Claim 34.

Moreover, by the inverted structure shown, which is the only method that Garrison discloses as the union of Garrison's various elements, the valve displacer and valve are joined outside the patient's body *prior to* advancing as a system. Indeed, Garrison states that "[t]he valve 6D is coupled to a valve displacer 8D prior to introduction into the patient." (Garrison, col. 10, ll. 40-42.) Thus, when connected together for insertion, the valve is *inverted* as shown above. This is the only method that Garrison discloses and describes when the components are together *before* implantation. Accordingly, Garrison cannot disclose that the "prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath," wherein "the valve means is attached closer to a proximal and wider part of the stent," as claimed in amended Claim 34, if the proximal end of the valve 6D is never attached to any structure other than the sutures 110 that are removed after inverting the valve 6D. "The catheter 4D is then removed and the sutures 110 are pulled to invert the valve 6D as shown in FIG. 33. An end of each suture 110 is then pulled to remove the sutures 110." (Garrison, col. 11, ll. 29-32.)

With regard to the Garrison embodiment shown in Fig. 10, the valve portion 38 is connected to a support structure 26.

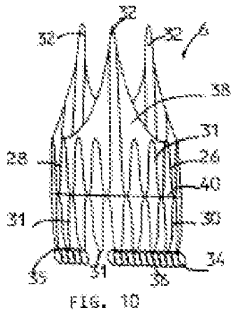


FIG. 10

However, the support structure 26 is not a "stent member" that "includes a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration," as claimed in Claim 34. If one considers the valve displacer 8 shown in Fig. 9 of Garrison, then the support structure 26 is attached to the valve displacer 8 along its distal end using protrusions 34.

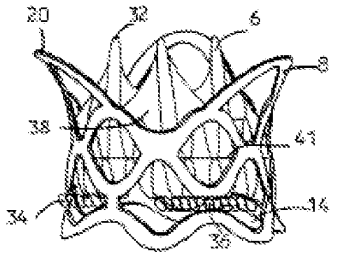


FIG. 9

However, Garrison discloses that the valve displacer 8 and support structure 26 are separate components that are only combined in the body following the valve displacer deployment. Moreover, the support structure 26 contains a porcine valve per Garrison, but the support structure 26, not the valve, is attached to the *distal* end of the valve displacer 8.

In addition to the foregoing, the Applicants reference their remarks above regarding the tissue disclosed in Cribier. Again, there is no disclosure in Cribier of fixed pericardial tissue (as recited in Claim 34 herein) without the use of the reinforcing features taught by Cribier. Moreover, the reinforcing features of Cribier would be required if the tissue is going to be combined with Garrison, because Garrison discloses the inverted leaflet configuration for deployment without attaching the proximal portion of the leaflets to the frame. Thus, Cribier does not facilitate a working embodiment when combined with Garrison.

Based on the foregoing, the Examiner is requested to withdraw the 35 U.S.C. § 103(a) rejection of Claims 34-38 as being unpatentable over Garrison in view of Cribier and Gabbay.

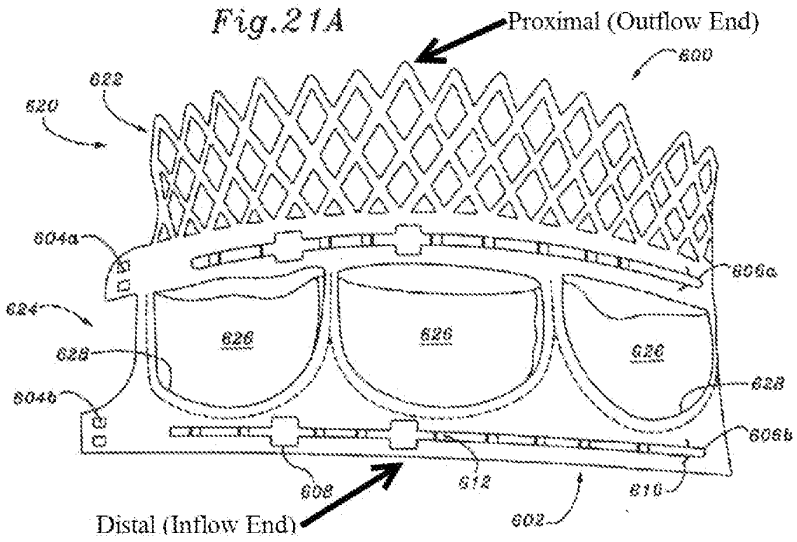
35 U.S.C. § 103(a) Rejection As Being Unpatentable Over Yang '525 In View Of Yang '646 And Further In View Of Gabbay

Claims 34-38 were rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Yang '525 in view of Yang '646 and further in view of Gabbay.

In the Office Action, the Examiner has stated that Yang '525 discloses "a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration (seen in fig.21A; flared out outflow **and** overlapped sides at inflow, col. 16, line[]s 10-11)." (Office Action, pg. 7.) (Emphasis in original.) Yang '525 states: "FIG. 21B illustrates the stent 602 by itself in a partial state of unrolling, while FIG. 21C shows the stent fully unrolled. Note the flared configuration of the mesh 622 on the outflow section 620 and the overlapped sides of the stent." There is no disclosure within Yang '525 that the stent member is flared "at both ends in a trumpet-like configuration," as recited in Claim 34 herein. Moreover, even within Yang '646, the specification states "in the aortic position, **an outflow portion** of the valve may extend upward into and even flare out and contact the aorta to better stabilize the commissure regions of the valve." (Yang '646, col. 6, ll. 7-9.) Therefore, even Yang '646 only supports that the outflow end of the frame is flared. Moreover, the text of Yang '646 quoted above identifies not only what part of the valve is flared but why; that is, to "contact the aorta to better stabilize the commissure regions of the valve." Id.

Accordingly, although the text states of Yang '525 states that there are "overlapped sides of the stent," this is associated with the rolled configuration of the stent, whereas Claim 34 recites "a central portion that flares at both ends in a trumpet-like configuration." Accordingly, Yang '525 and Yang '646 fail to disclose this limitation.

In addition to the foregoing, Yang '525 fails to disclose the limitation "wherein the valve means is attached closer to a proximal and wider part of the stent member," as currently recited in independent Claim 34. Indeed, Yang '525 discloses the opposite. That is, Yang '525 discloses that the valve is attached closer to the inflow end. See Figure 21A of Yang '525 reproduced below (with Applicants' annotations as to the inflow and outflow ends):



Turning now to the delivery system, the Examiner stated on page 10 of the Office Action that Yang '525 "does not disclose specific details of the delivery system." The Applicants agree with this assessment. However, the Applicants respectfully disagree with the Examiner's assertions concerning the delivery system allegedly disclosed in Yang '646. More particularly, the Examiner has stated that Yang '646 discloses "a pusher member (end of 24, at 26 in fig. 1 for example)." (Office Action, pg. 10, l. 6.) Upon Review, Yang '646 identifies structure 24 as the catheter shaft. (Yang '646, col. 6, l. 33.) The Examiner further states in the Office Action that "the prosthetic heart valve (30) is collapsed onto the pusher member to reside in a collapsed

configuration on the pusher member (fig. 1)." (Office Action, pg. 10, ll. 7-8.) However, as can be seen in Fig. 1 of Yang '646, the catheter shaft 24 *terminates* proximal (to the right in Fig. 1) of the valve 30. Fig. 1 of Yang '646 is reproduced below.

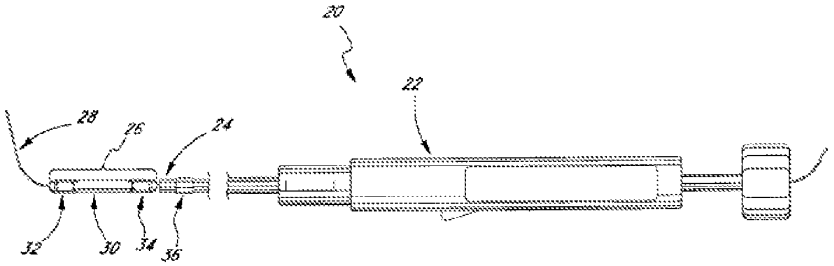


FIG.1

Accordingly, the expandable heart valve 30 cannot be collapsed onto the catheter shaft 24 because the catheter shaft carries stabilization balloon 36 and the catheter shaft 24 terminates proximally of the valve 30. Indeed, Yang '646 states "[t]he system may further include a stabilization balloon 36 provided on the catheter shaft 24 just proximal of the deployment mechanism 26." (Yang '646, col. 6, ll. 39-41.)

Assuming, *arguendo*, that the Examiner is asserting that deployment mechanism 26 is a "pusher member" corresponding to structure claimed by the Applicants, the Applicants respectfully note that Yang '646 discloses structure different than a pusher member. More particularly, when referring to Fig. 1, Yang '646 states that "[t]he expandable heart valve 30 is seen **held in a contracted configuration between a distal collet body 32 and a proximal collet body 34** of the deployment mechanism 26." (Yang '646, col. 6, ll. 36-39.) (Emphasis added.) It is clear from Yang '646 that the deployment mechanism 26 is a mechanical device for both *holding* and *causing the expansion* of the valve 30. Indeed, the description of Fig. 3A states "FIG. 3A is a longitudinal sectional view through a portion of the **distal end of the delivery and deployment system of FIG. 1 illustrating part of a mechanism for controlling the expansion**

of a heart valve, which is shown in its contracted configuration." (Yang '646, col. 4, ll. 47-51.) (Emphasis added.)

Applicants further reference Fig. 7A. Yang '646 states that "FIGS. 7A-7F are perspective views showing a number of steps in the delivery and deployment of an expandable heart valve using the system of FIG. 4." (Yang '646, col. 5, ll. 1-3.) Fig. 7A is reproduced below.

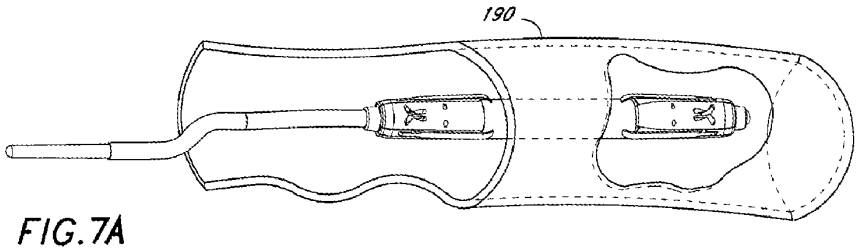


FIG. 7A

When viewing Fig. 7A, it can be seen that the deployment mechanism resides within vessel 190 *without* use of a sheath to restrain the valve. This is contrary to the limitation of Claim 34 of the present application, which recites, in part, that "the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath." Accordingly, neither the embodiment shown in Fig. 1 nor the embodiment shown in Figs. 4 and 7A of Yang '646 use a moveable sheath to restrain the prosthetic heart valve in a collapsed configuration.

Based on the foregoing, the Examiner is requested to withdraw the 35 U.S.C. § 103(a) rejection of Claims 34-38 as being unpatentable over Yang '525 in view of Yang '646 and further in view of Gabbay.

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.

A Request for Continued Examination and a 3-month extension are submitted herewith along with the associated fees. Applicants believe no additional fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

Respectfully submitted,

FOX ROTHSCHILD LLP

/ Mark L. Yaskanin /

Mark L. Yaskanin, Esq.
Registration No. 45,246
Customer No. 29880
Phone: (303) 446.3852
Facsimile: (303) 292.1300

Dated: May 7, 2015

Electronic Patent Application Fee Transmittal

Application Number:	14253650
Filing Date:	15-Apr-2014
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Filer:	Mark Lauren Yaskanin
Attorney Docket Number:	109978.10104

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 $0 paid	2253	1	700	700
Miscellaneous:				
Request for Continued Examination	2801	1	600	600
		Total in USD ($)		**1300**

Electronic Acknowledgement Receipt	
EFS ID:	22281169
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	07-MAY-2015
Filing Date:	15-APR-2014
Time Stamp:	18:11:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1300
RAM confirmation Number	4275
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 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 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	Extension of Time	Colibri_10104_Extension_2015-05-07.PDF	154424 0a121865ee9d08f32b2061d4f0685039e5cd568d	no	2
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	Colibri_10104_RCE_2015-05-07.PDF	116796 184a29617eed6cfadb3355c4de191a65c0ec7c70	no	1
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	Colibri_10104_Supp_IDS_2015-05-07.PDF	744536 433399b3c0c1ebff850dad3448be57723b5ec0df	no	4
Warnings:					
Information:					
4	Non Patent Literature	10100_US_10-887688_Declaration_of_Inventors_2008-12-15.pdf	1899083 359d55c2c06023369ab2c36187e7f03b2a9d5982	no	46
Warnings:					
Information:					
5	Non Patent Literature	10106_Office_Action_App_14-502453_2014-12-05.PDF	355935 7619eb689048f7c7147d8b4d3ca70dab4e83dd23	no	9
Warnings:					
Information:					
6		Colibri_10104_Final_OA_Reply_2015-05-07.PDF	921118 3a8d23275d9651414604c0f788e0d0979f4bcc05	yes	18

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	18	
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	32535 5fd928f93693f04067ca0824fa3a334f8ec1bf6f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	4224427		

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/AIA/22 (03-13)
Approved for use through 7/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 109978.10104
Application Number 14/253,650	Filed 2014-04-15
For Percutaneously Bioprosthetic Heart Valve and a Delivery and Implantation System	
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.

☑ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 45,246.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/ Mark L. Yaskanin /	7 May 2015
Signature	Date
Mark L. Yaskanin	303.446.3852
Typed or printed name	Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

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.

PTO/SB/30 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	14/253,650
Filing Date	2015-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. 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).

   a. ☐ 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.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☑ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☑ Other Request for Extension of Time

2. Miscellaneous

   a. ☐ 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)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-1943.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☑ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/ Mark L. Yaskanin /	Date	7 May 2015
Name (Print/Type)	Mark L. Yaskanin	Registration No.	45,246

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature			
Name (Print/Type)		Date	

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/253,650	Filing Date 04/15/2014	☐ 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	05/07/2015	(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))	* 5	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
/Ruby Johnson/

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.

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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	5554184		1996-09-10	Machiraju	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20020052651		2002-05-02	Myers et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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	9-501594	JP		1997-02-18		Equivalent to WO/1995/005207	☐
	2	2001-500761	JP		2001-01-23		Equivalent to WO/1998/011935	☐
	3	2005-103321	JP		2005-04-21		Equivalent to EP0696447	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

	4	2009/149462	WO		2009-12-10	Edwards Lifesciences Corporation		☐

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	Final Office Action issued May 8, 2015 in U.S. Application No. 14/502,453 (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.

[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	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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.**

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.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

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.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**GB**	United Kingdom	**MR**	Mauritania
AU	Australia	**GE**	Georgia	**MW**	Malawi
BB	Barbados	**GN**	Guinea	**NE**	Niger
BE	Belgium	**GR**	Greece	**NL**	Netherlands
BF	Burkina Faso	**HU**	Hungary	**NO**	Norway
BG	Bulgaria	**IE**	Ireland	**NZ**	New Zealand
BJ	Benin	**IT**	Italy	**PL**	Poland
BR	Brazil	**JP**	Japan	**PT**	Portugal
BY	Belarus	**KE**	Kenya	**RO**	Romania
CA	Canada	**KG**	Kyrgystan	**RU**	Russian Federation
CF	Central African Republic	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CG	Congo			**SE**	Sweden
CH	Switzerland	**KR**	Republic of Korea	**SI**	Slovenia
CI	Côte d'Ivoire	**KZ**	Kazakhstan	**SK**	Slovakia
CM	Cameroon	**LI**	Liechtenstein	**SN**	Senegal
CN	China	**LK**	Sri Lanka	**TD**	Chad
CS	Czechoslovakia	**LU**	Luxembourg	**TG**	Togo
CZ	Czech Republic	**LV**	Latvia	**TJ**	Tajikistan
DE	Germany	**MC**	Monaco	**TT**	Trinidad and Tobago
DK	Denmark	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**US**	United States of America
FI	Finland	**ML**	Mali	**UZ**	Uzbekistan
FR	France	**MN**	Mongolia	**VN**	Viet Nam
GA	Gabon				

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.

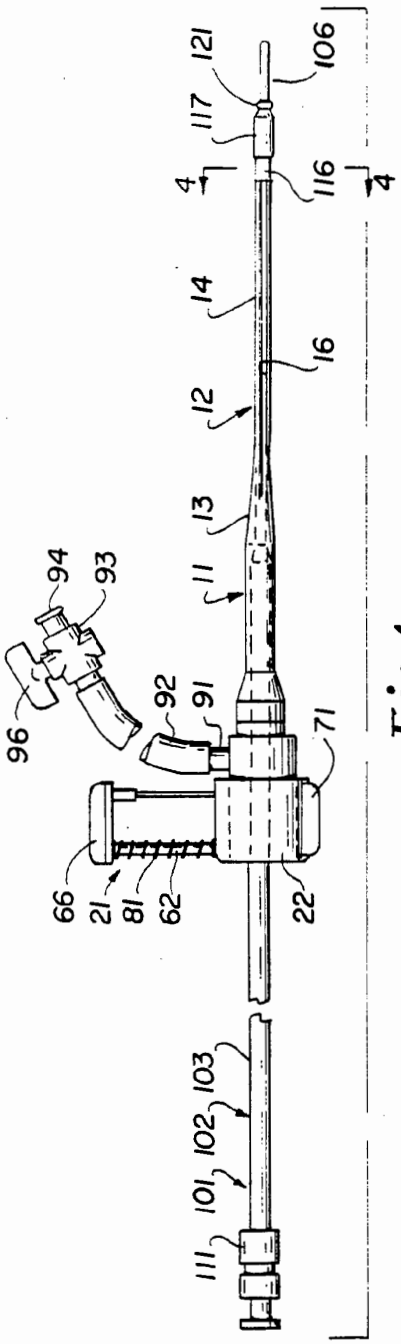


Fig.1

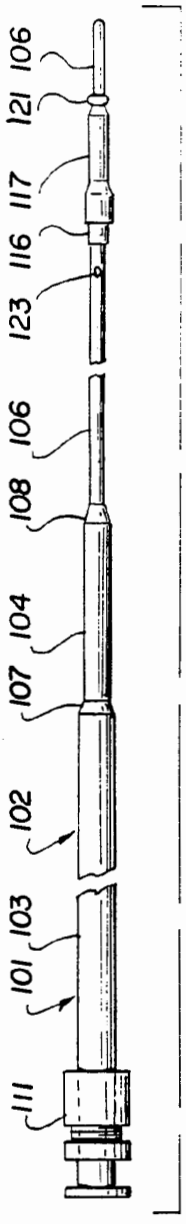


Fig.2

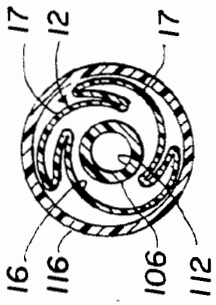


Fig.4

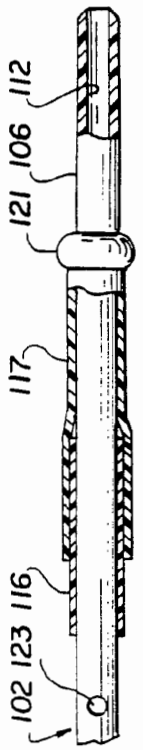


Fig.3

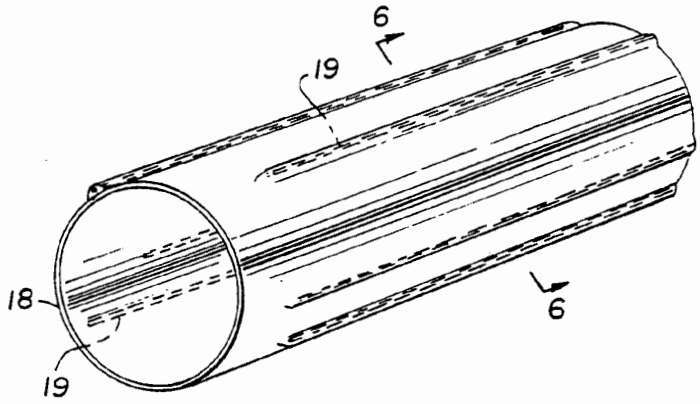


Fig.5

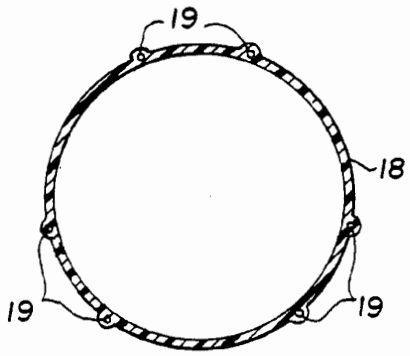


Fig.6

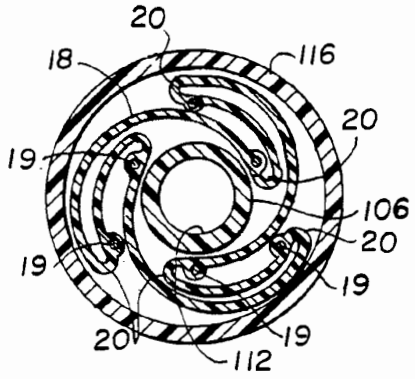


Fig.7

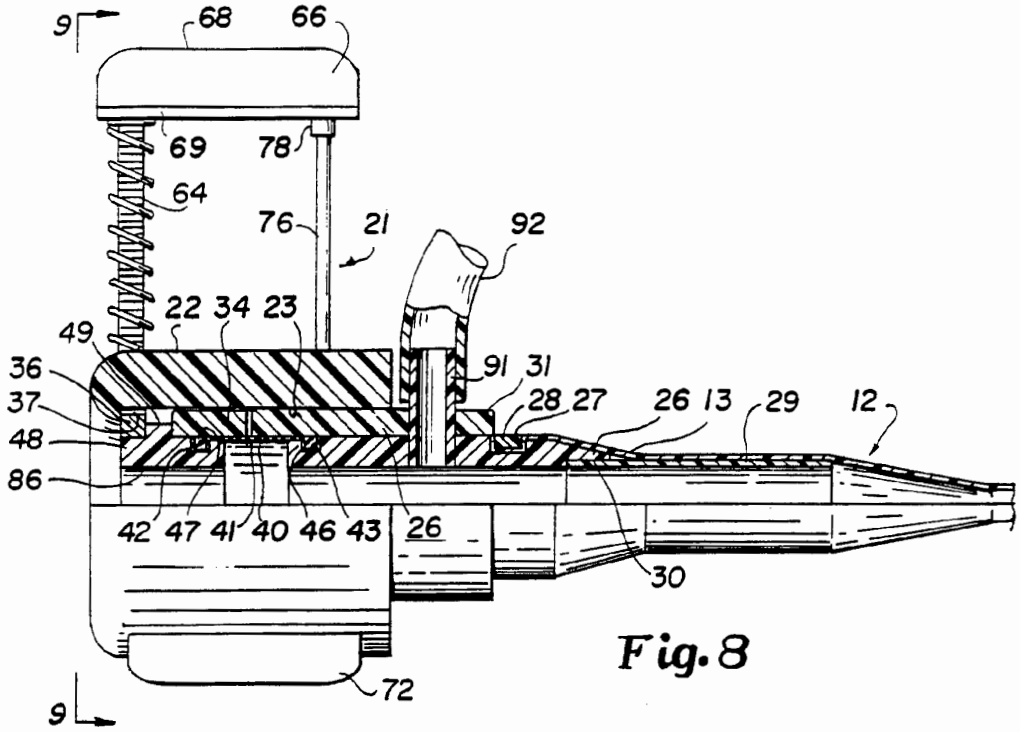


Fig. 8

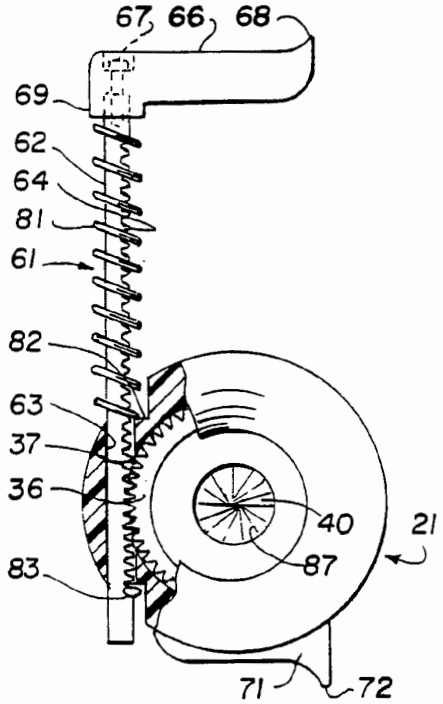


Fig. 9

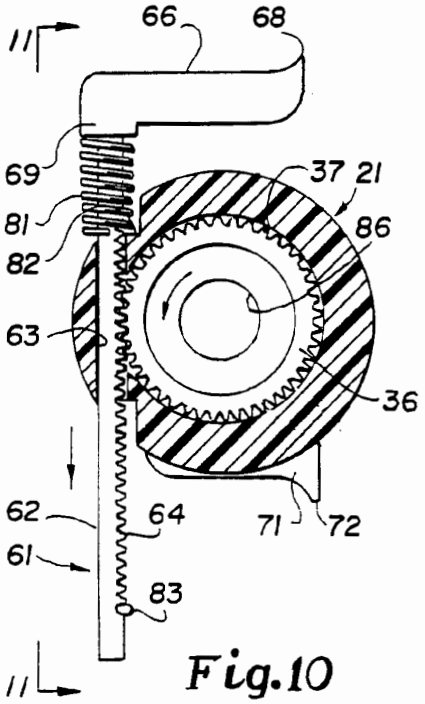


Fig. 10

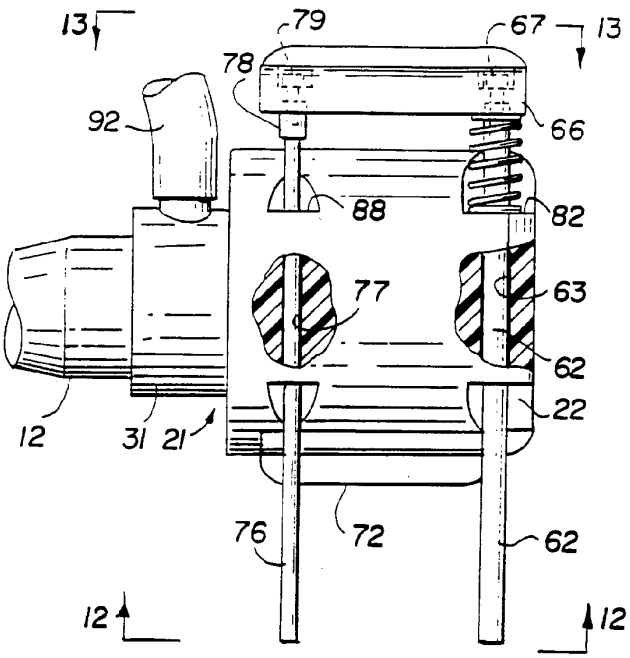


Fig.11

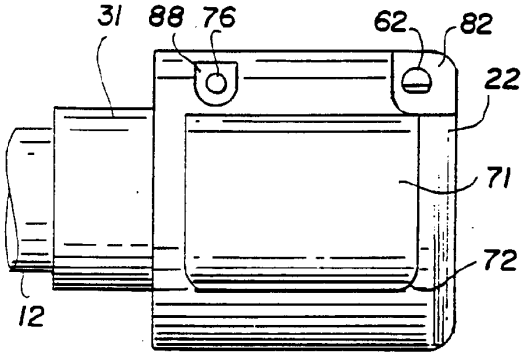


Fig.12

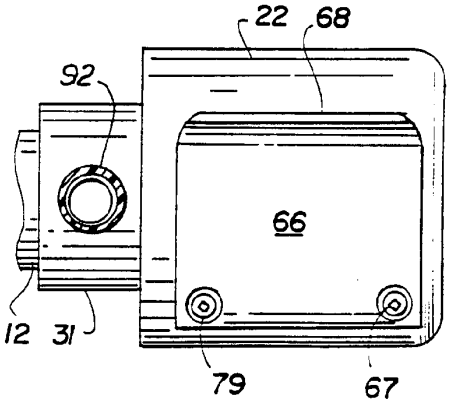


Fig.13

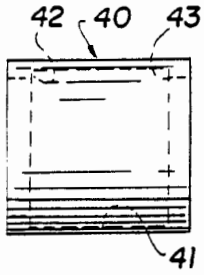


Fig.14

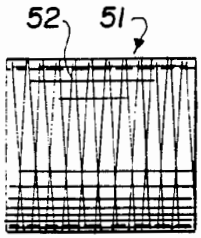


Fig.15

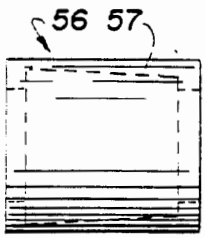


Fig.16

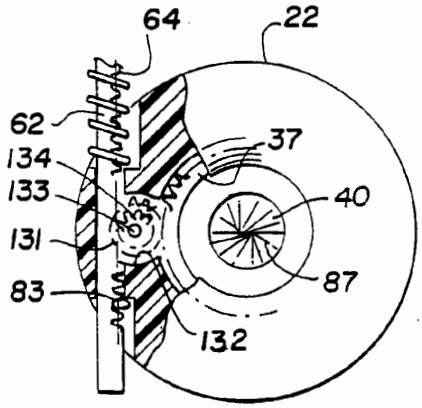


Fig.17

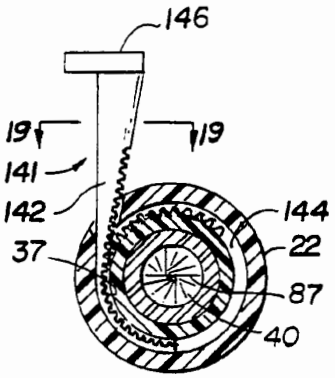
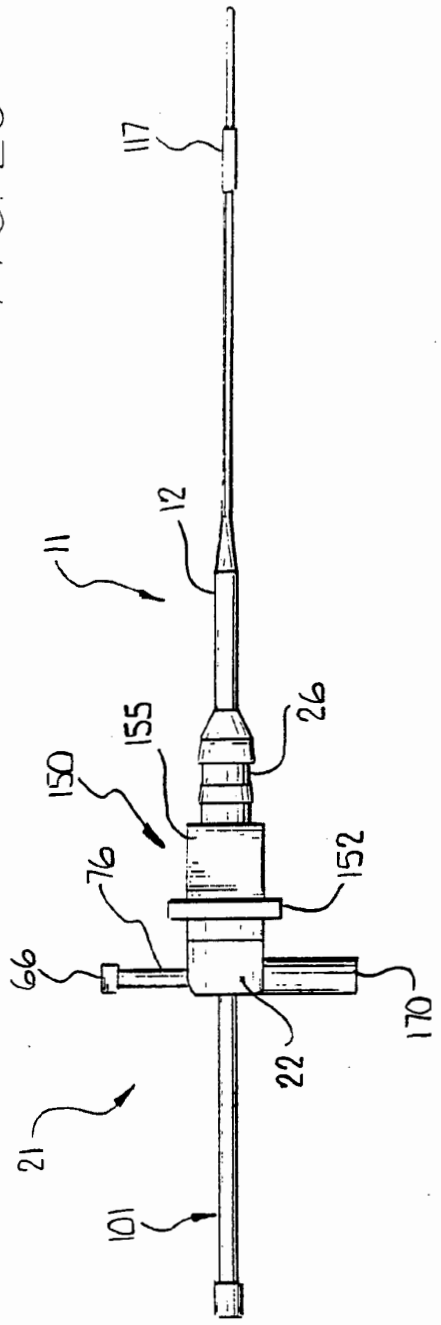


Fig.18

Fig.19

FIG. 20



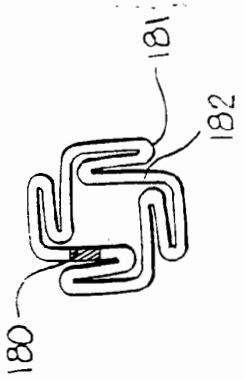


FIG. 23

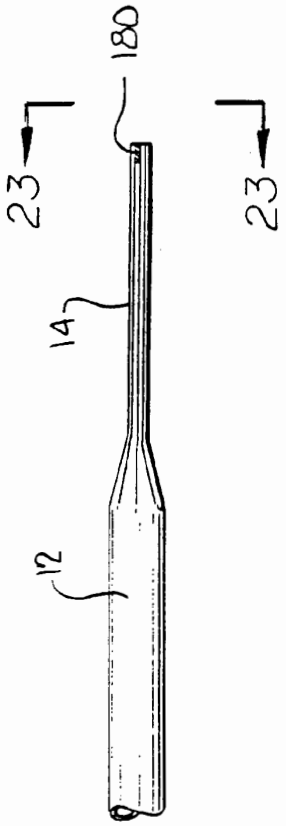


FIG. 22

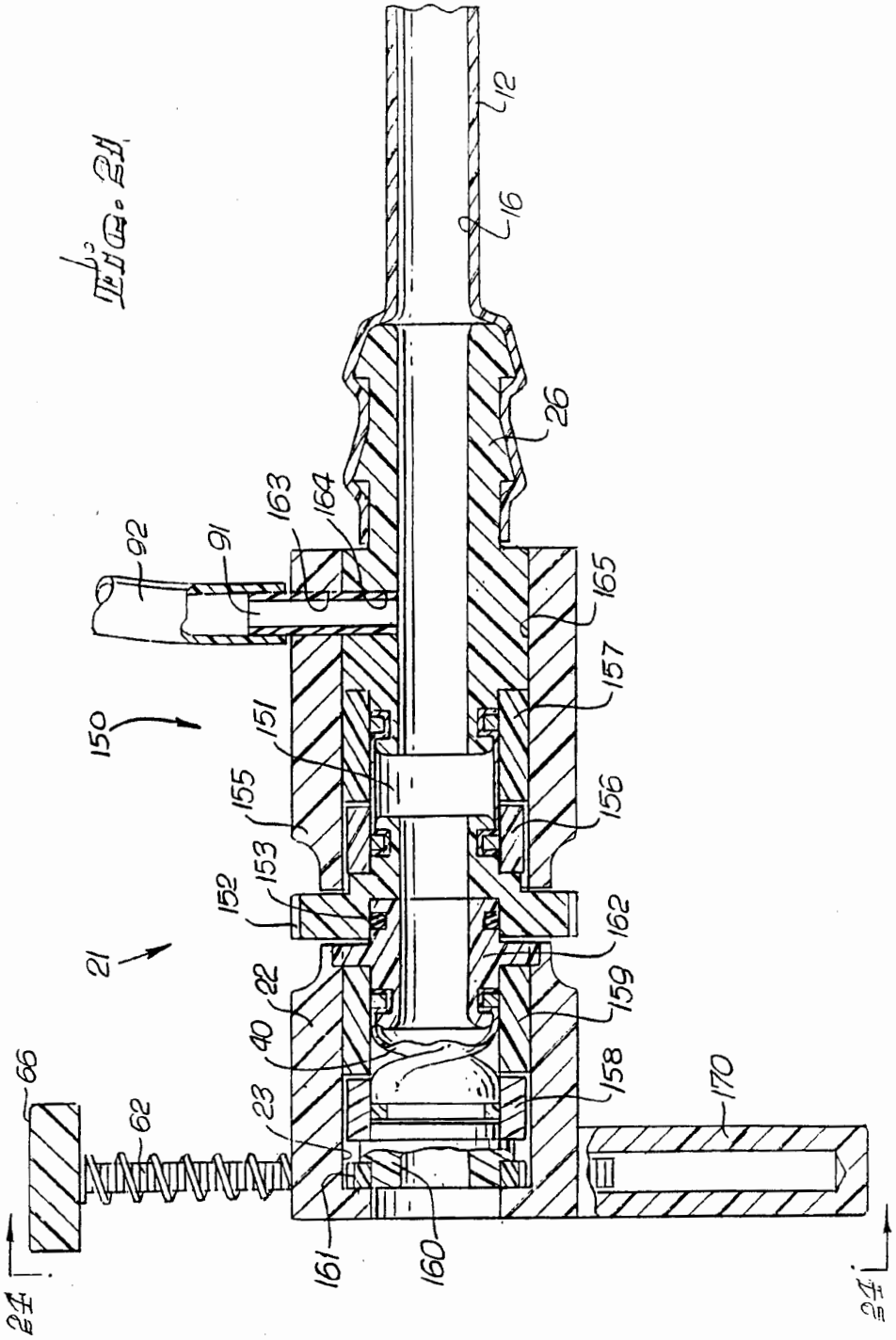


FIG. 2H
12
16
26
163
164
92
91
165
157
150
151
155
156
153
152
162
21
22
159
40
158
170
66
62
23
161
160
24
24

FIG.24

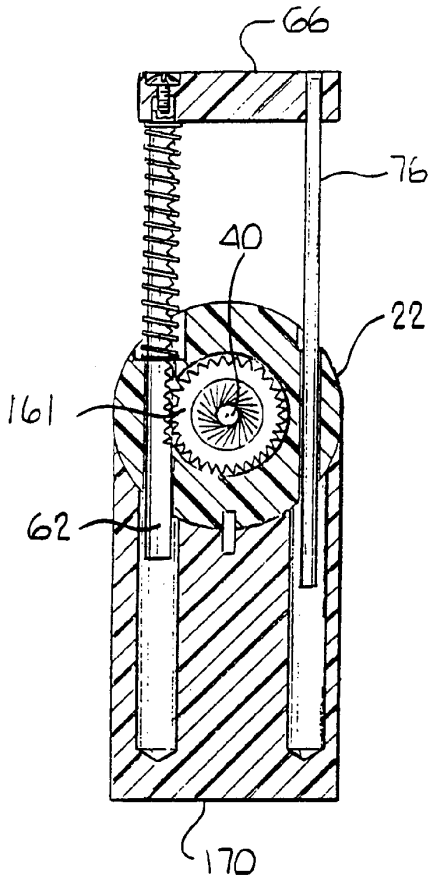
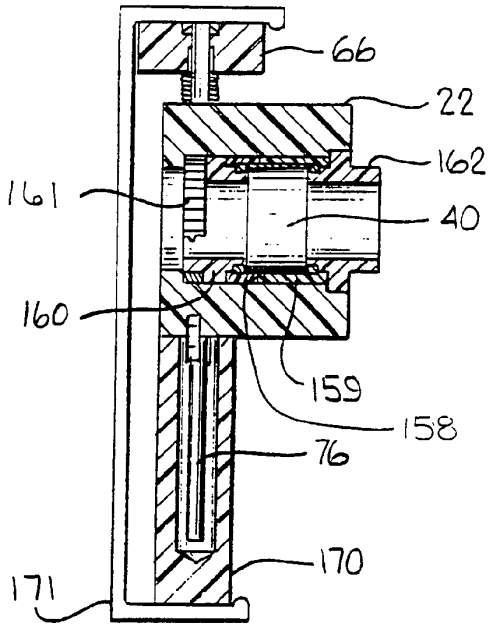


FIG. 25



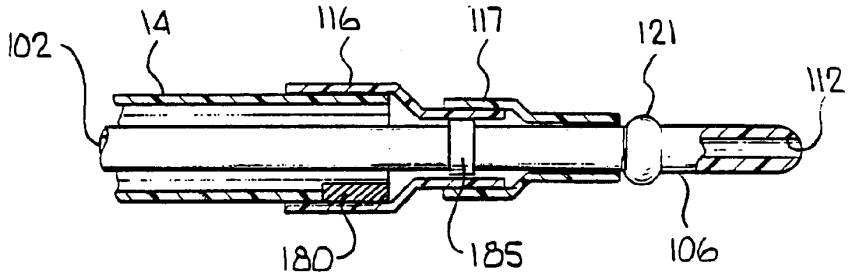


FIG. 26

FIG. 27

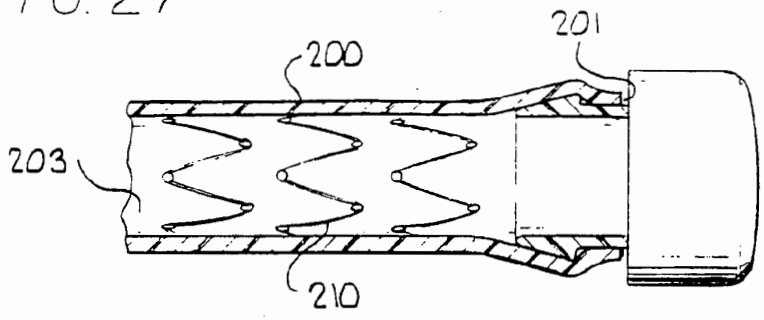


FIG. 28

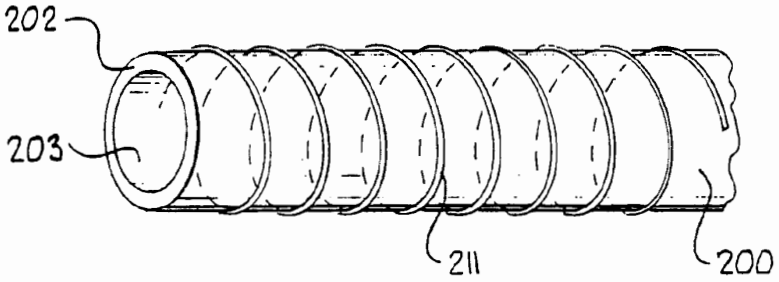


FIG. 29

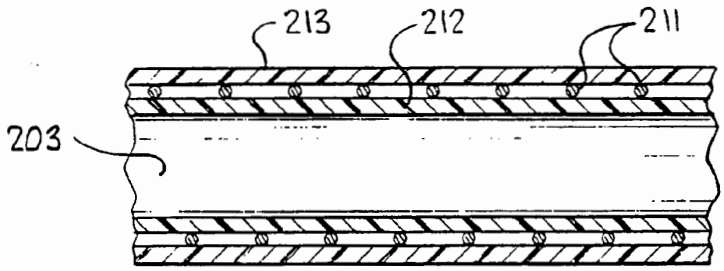


FIG. 30

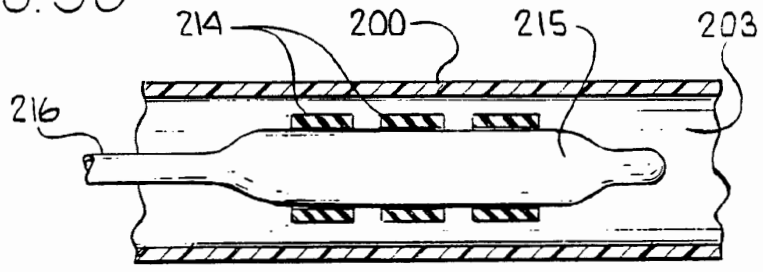


FIG. 31

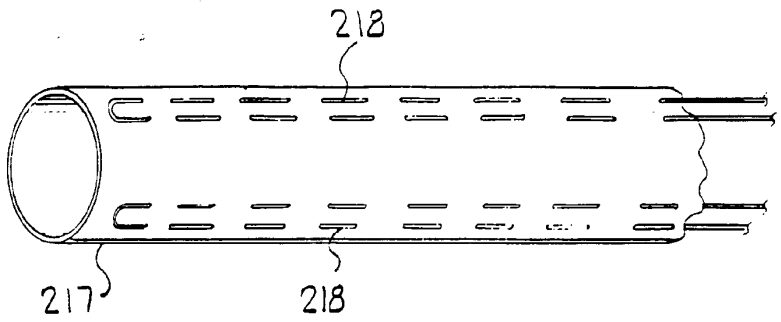


FIG. 32

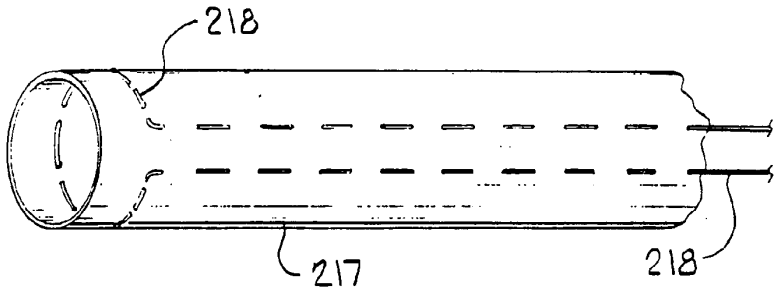


FIG. 33

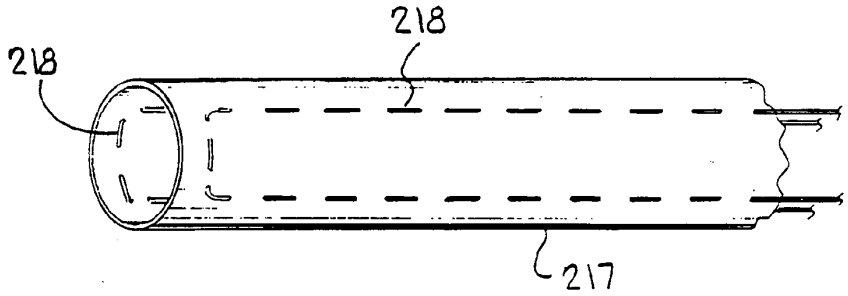
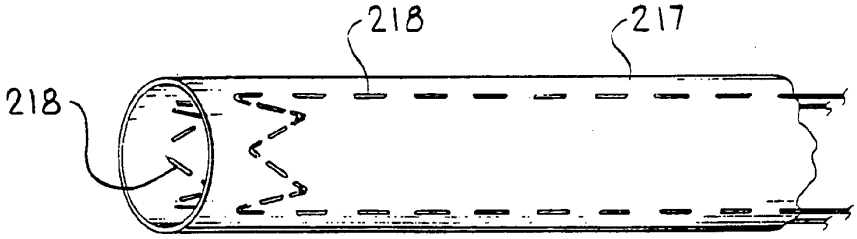


FIG. 34



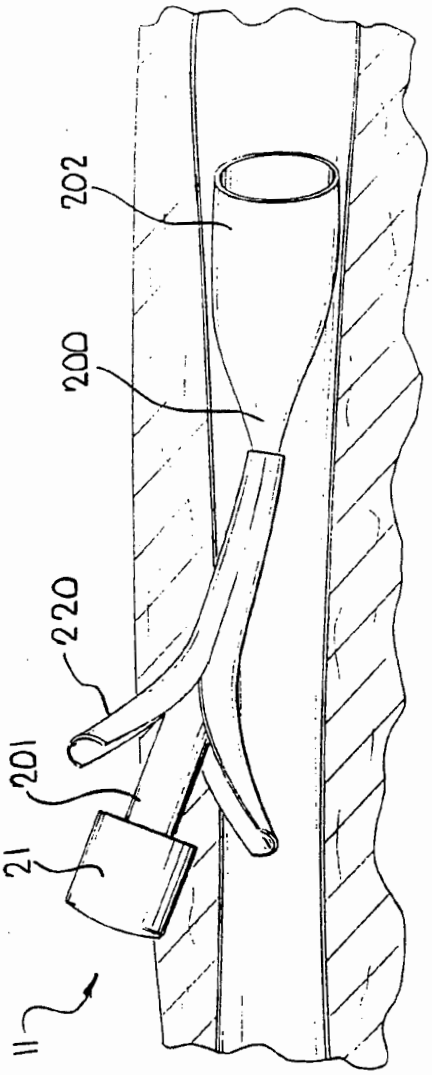


FIG. 35

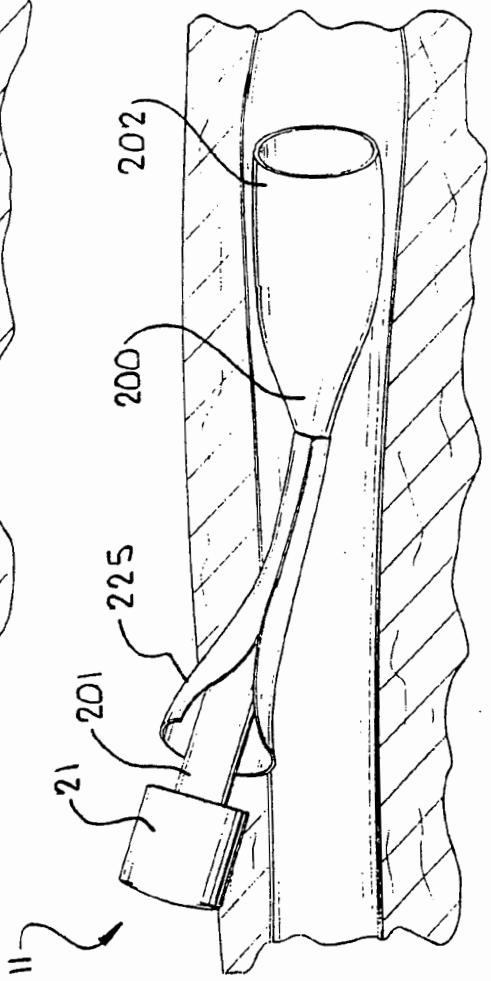


FIG. 36

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 29/00	A1	(11) International Publication Number: WO 98/11935
		(43) International Publication Date: 26 March 1998 (26.03.98)

(21) International Application Number: PCT/US97/16326

(22) International Filing Date: 15 September 1997 (15.09.97)

(30) Priority Data:
08/717,299 20 September 1996 (20.09.96) US

(71) Applicant: INTELLA INTERVENTIONAL SYSTEMS [US/US]; 870 Hermosa Drive, Sunnyvale, CA 94086 (US).

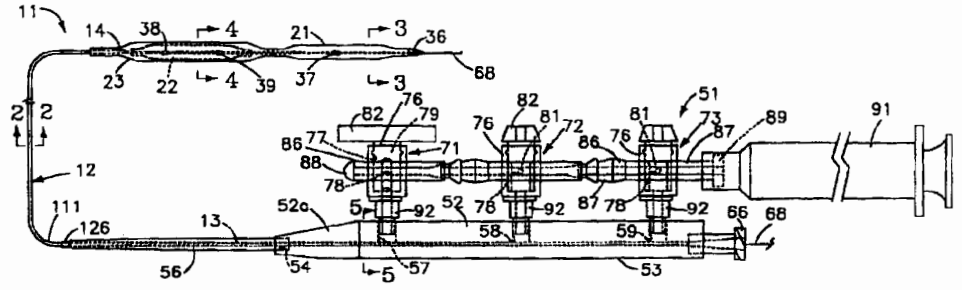
(72) Inventors: HEDGE, Anant, V.; 36105 Touluse Street, Newark, CA 94560 (US). GANDHI, Deepak, R.; 911 Bowen Avenue, San Jose, CA 95123 (US). BOURNE, Thomas; Apartment 96, 2650 California Street, Mountain View, CA 94040 (US). KERMODE, James, R.; 1080 Kildare Avenue, Sunnyvale, CA 94087 (US).

(74) Agent: HOHBACH, Harold, C.; Flehr, Hohbach, Test, Albritton & Herbert LLP, 4 Embarcadero Center, Suite 3400, San Francisco, CA 94111-4187 (US).

(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: MULTIPLE BALLOON STENT DELIVERY CATHETER AND METHOD



(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.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

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.

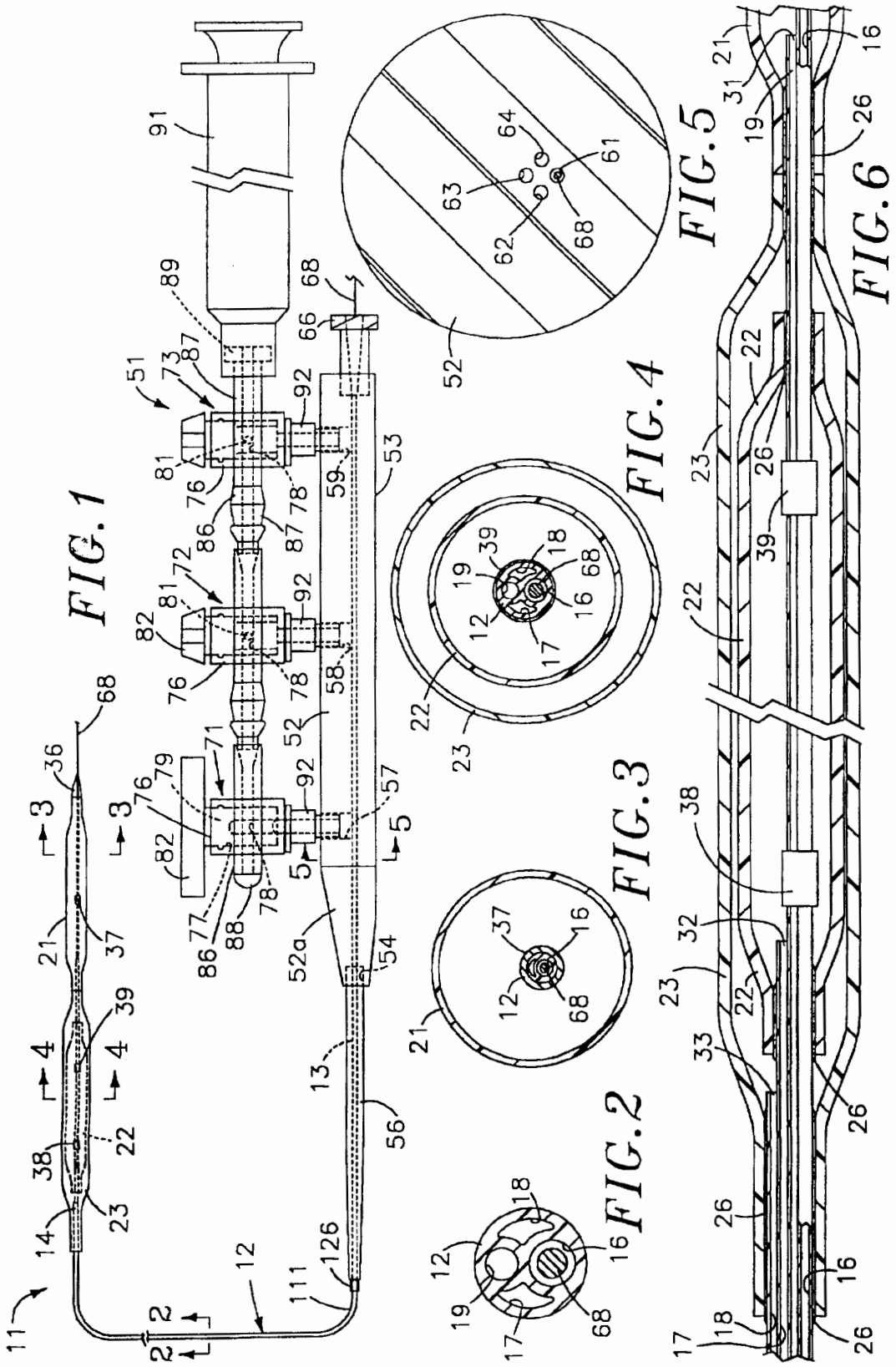


FIG. 1

FIG. 2

FIG. 3

FIG. 4

FIG. 5

FIG. 6

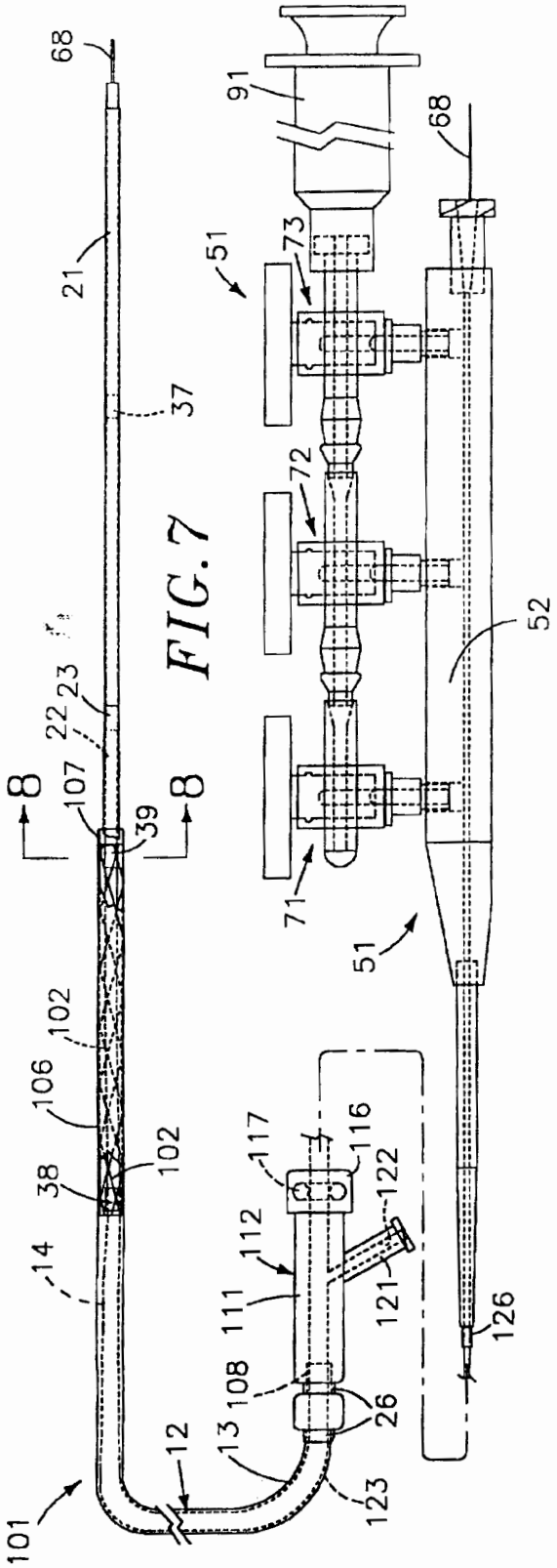


FIG. 7

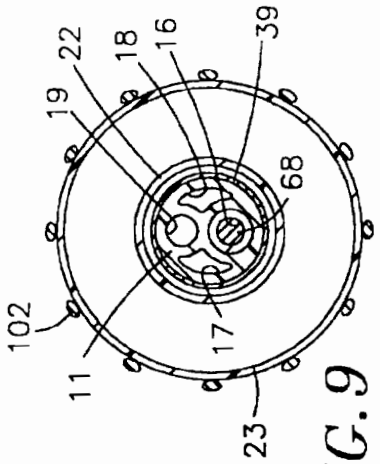


FIG. 9

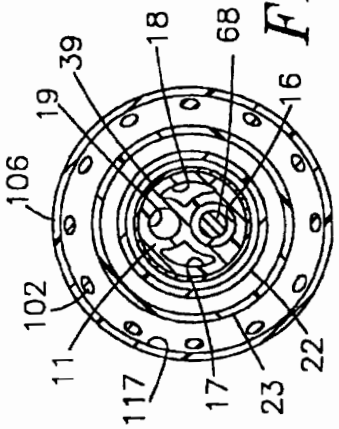


FIG. 8

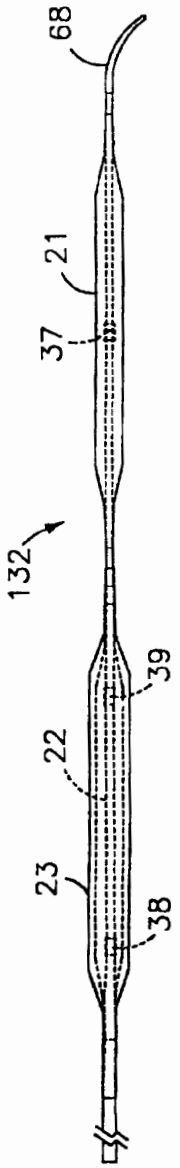


FIG. 10

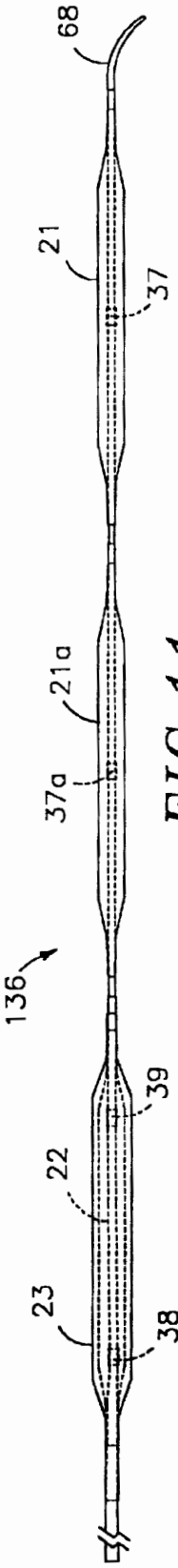


FIG. 11

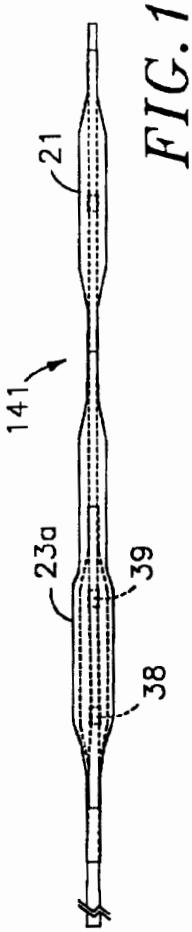


FIG. 12

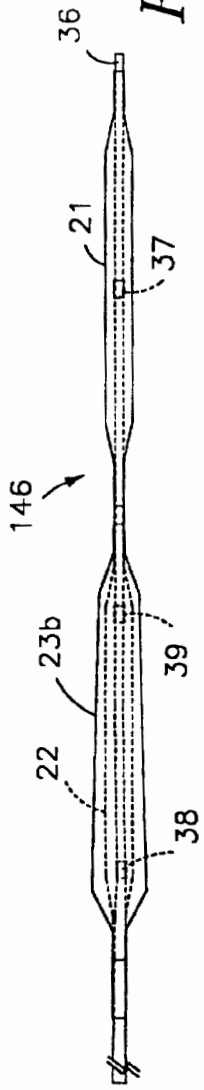


FIG. 13

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:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 30 OCTOBER 1997	Date of mailing of the international search report 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

Form PCT/ISA/210 (second sheet)(July 1992)*

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 696 447 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
19.01.2000 Bulletin 2000/03

(51) Int Cl.7: **A61F 2/06**

(21) Application number: **95112564.0**

(22) Date of filing: **10.08.1995**

(54) Apparatus for deployment release of intraluminal prostheses

Vorrichtung zum Positionieren einer intraluminalen Prothese

Dispositif pour la mise an place d'une prothèse intraluminale

(84) Designated Contracting States:
DE FR

(30) Priority: **12.08.1994 US 290021**
07.06.1995 US 475200

(43) Date of publication of application:
14.02.1996 Bulletin 1996/07

(60) Divisional application: **99113203.6 / 0 948 946**
99113204.4 / 0 943 302

(73) Proprietor: **CARDIOVASCULAR CONCEPTS, INC.**
Portola Valley, CA 94028 (US)

(72) Inventors:
- **Lenker, Jay A.**
  Los Altos Hills California 94024 (US)
- **Evans, Michael A.**
  Palo Alto California 94301 (US)
- **Kim, Steven W.**
  Sunnyvale California 94086 (US)
- **Glynn, Brian**
  Sunnyvale California 94086 (US)
- **Watanabe, Gwendolyn A.**
  166 Mountain View California 94043 (US)
- **Freislinger, Kirsten**
  Palo Alto California 94301 (US)
- **Ryan, Timothy J.**
  Los Gatos California 95032 (US)
- **Zarins, Christopher K.**
  Portola Valley California 94028 (US)
- **Murphy, Richard O.**
  Mountain View California 94043 (US)

(74) Representative: **Sparing - Röhl - Henseler**
Patentanwälte
Postfach 14 04 43
40074 Düsseldorf (DE)

(56) References cited:
EP-A- 0 274 846
EP-A- 0 364 420
EP-A- 0 461 791
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

Printed by Jouve, 75001 PARIS (FR)

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-

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-

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

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-

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-

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

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

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,

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 enffaltbares, 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).

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).

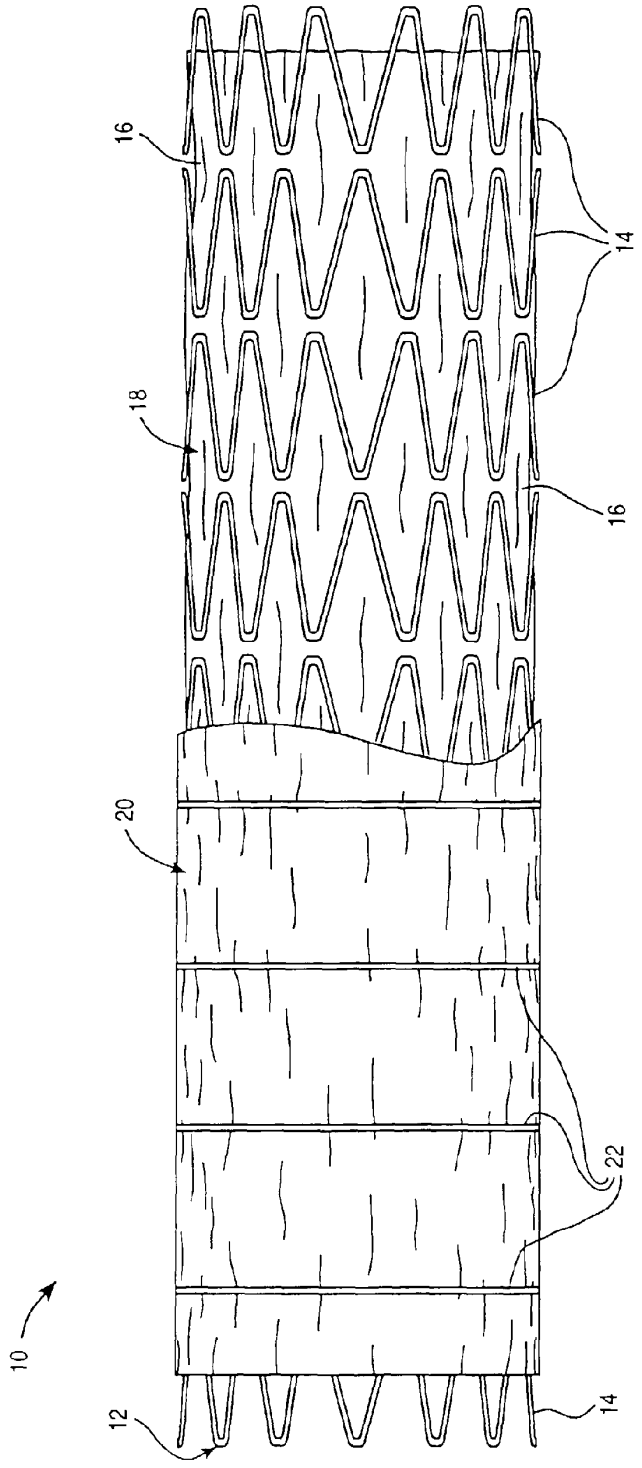


FIG. 1

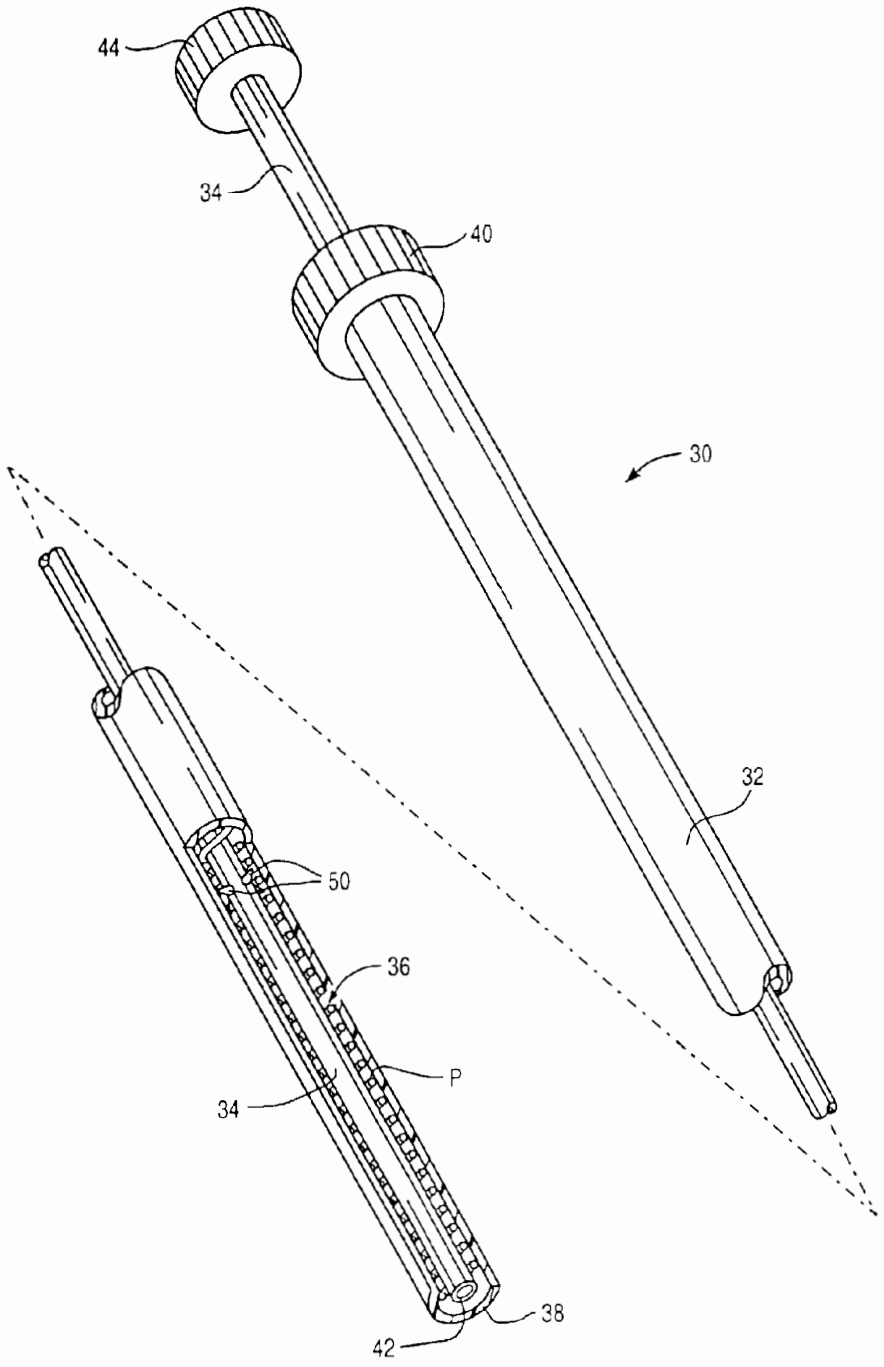


FIG. 2

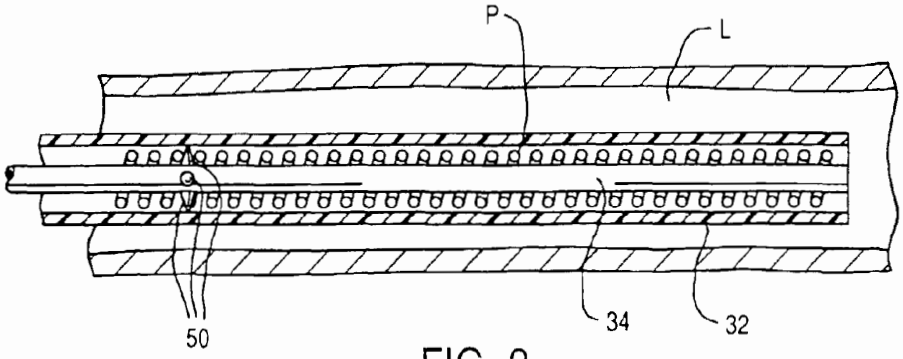


FIG. 3

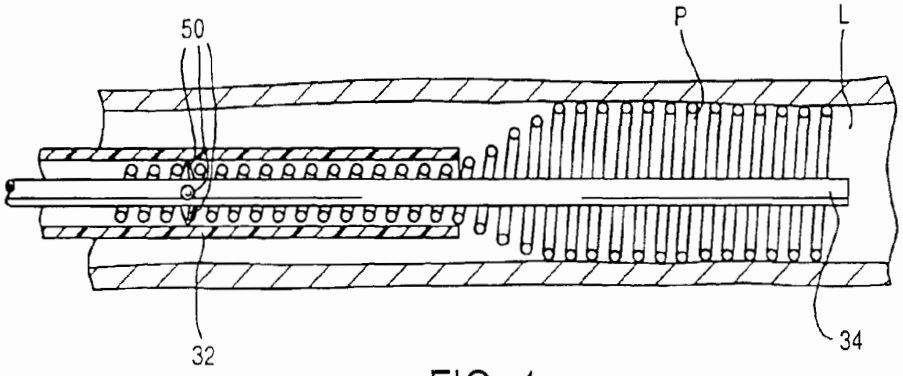


FIG. 4

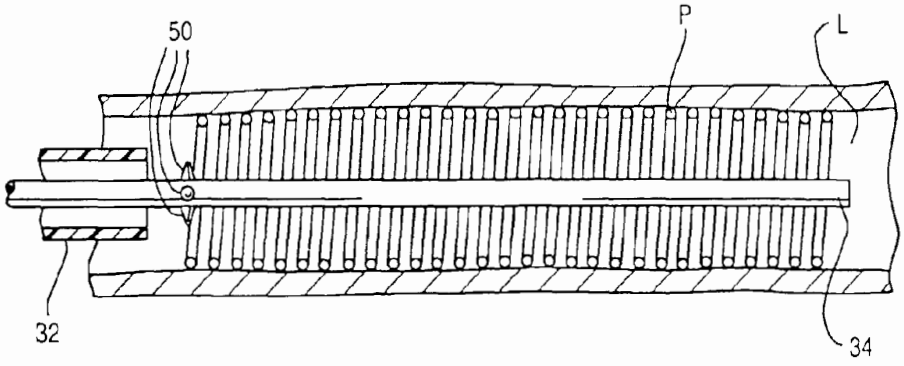


FIG. 5

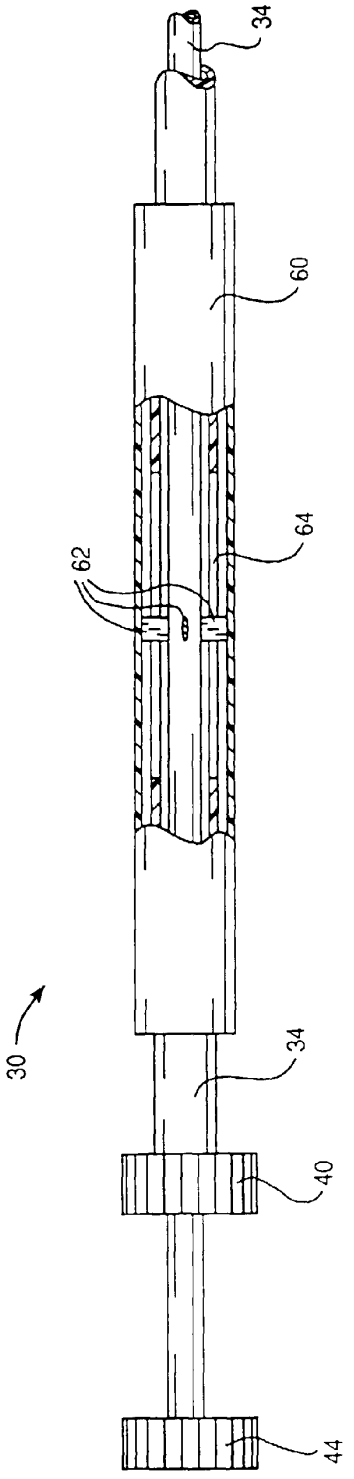


FIG. 6

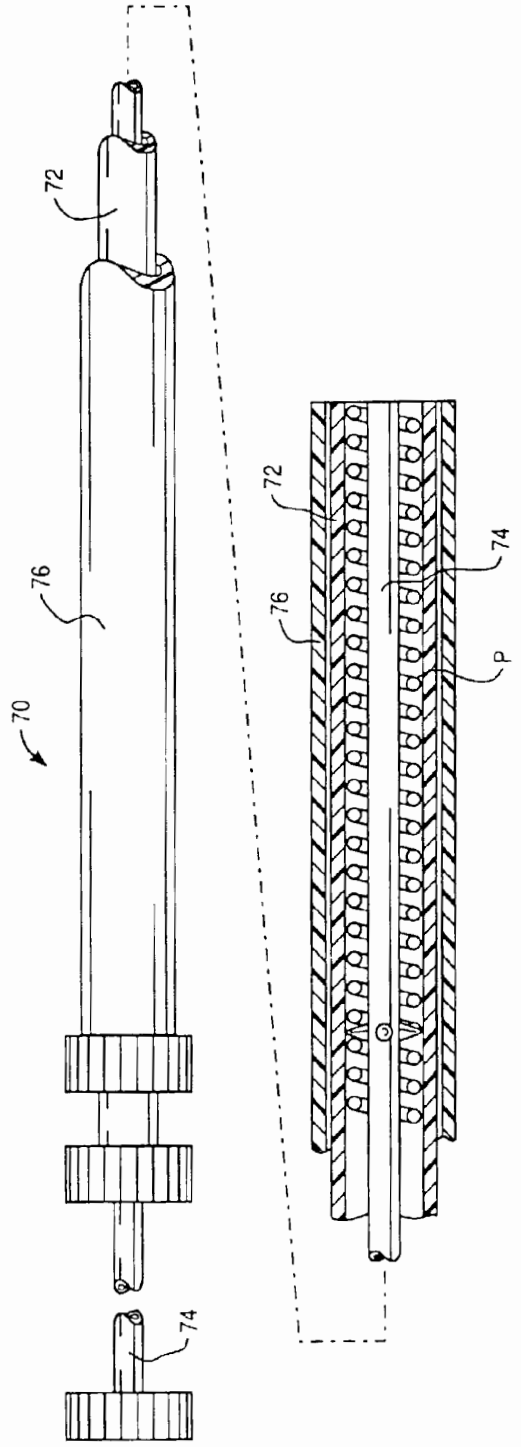


FIG. 7

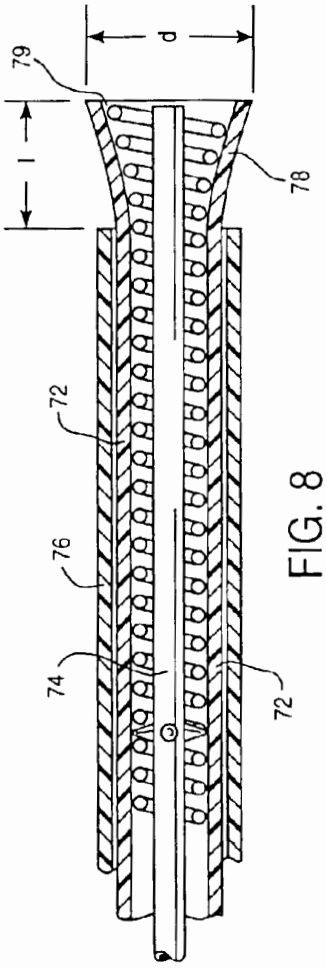


FIG. 8

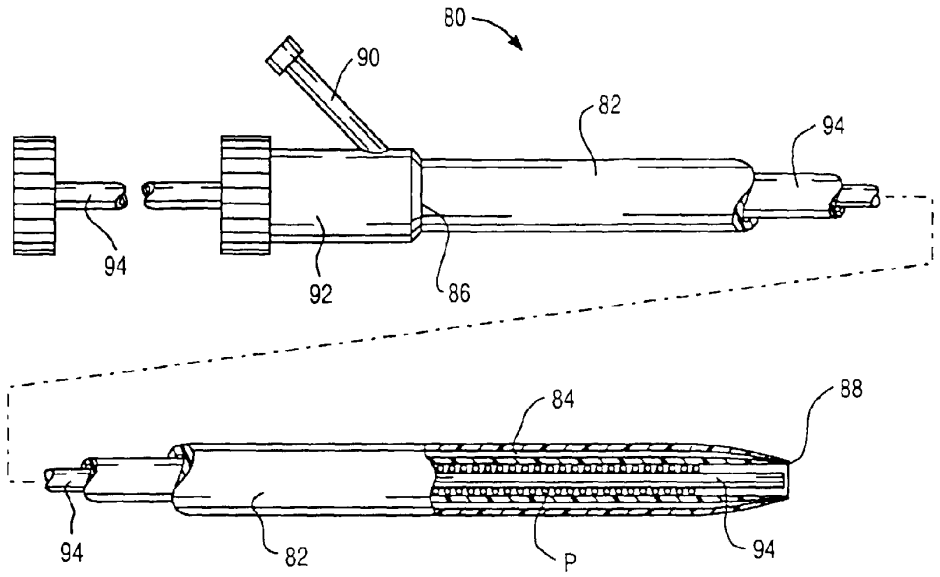


FIG. 9

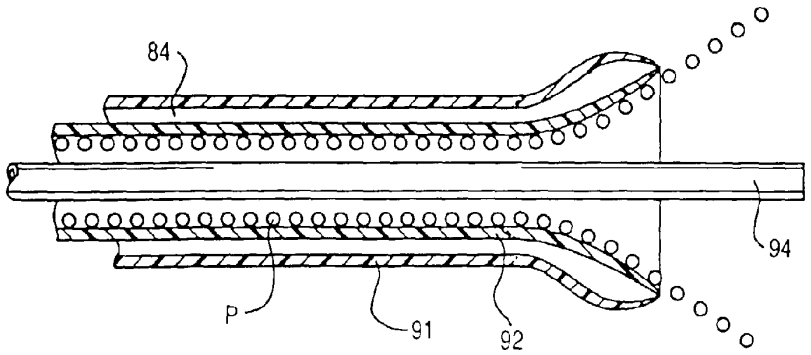


FIG. 10

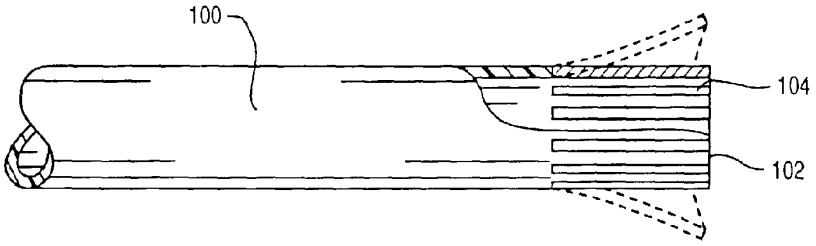


FIG. 11

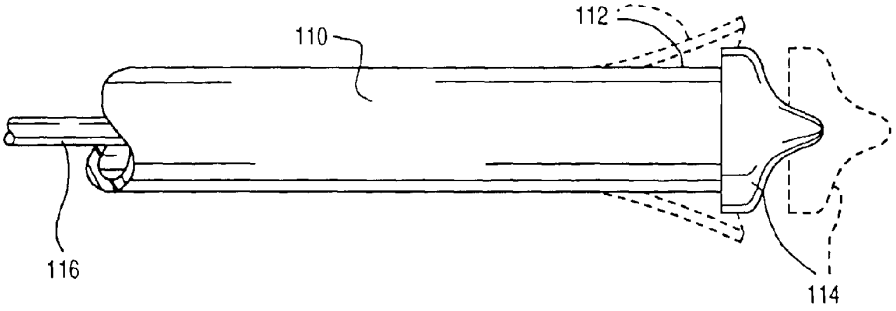


FIG. 12

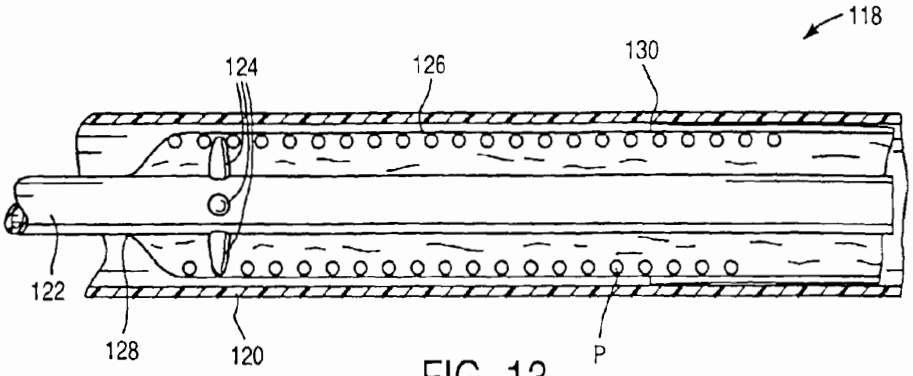


FIG. 13

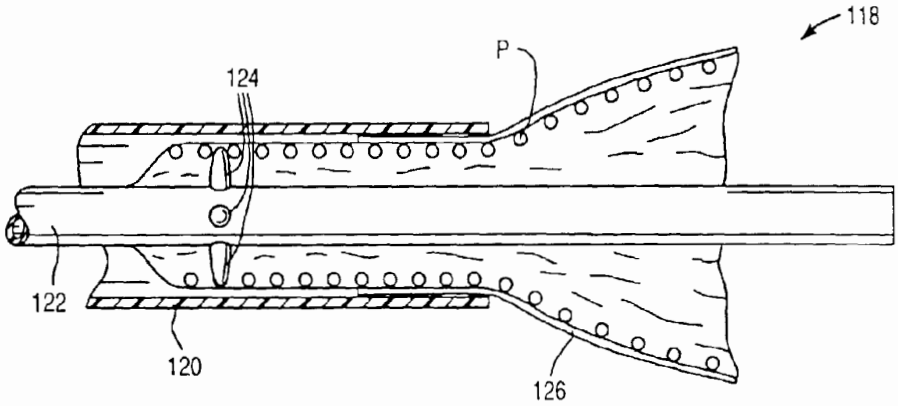


FIG. 14

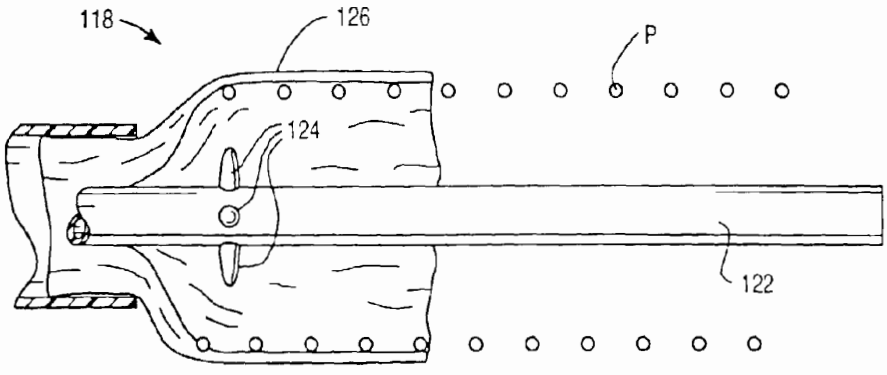


FIG. 15

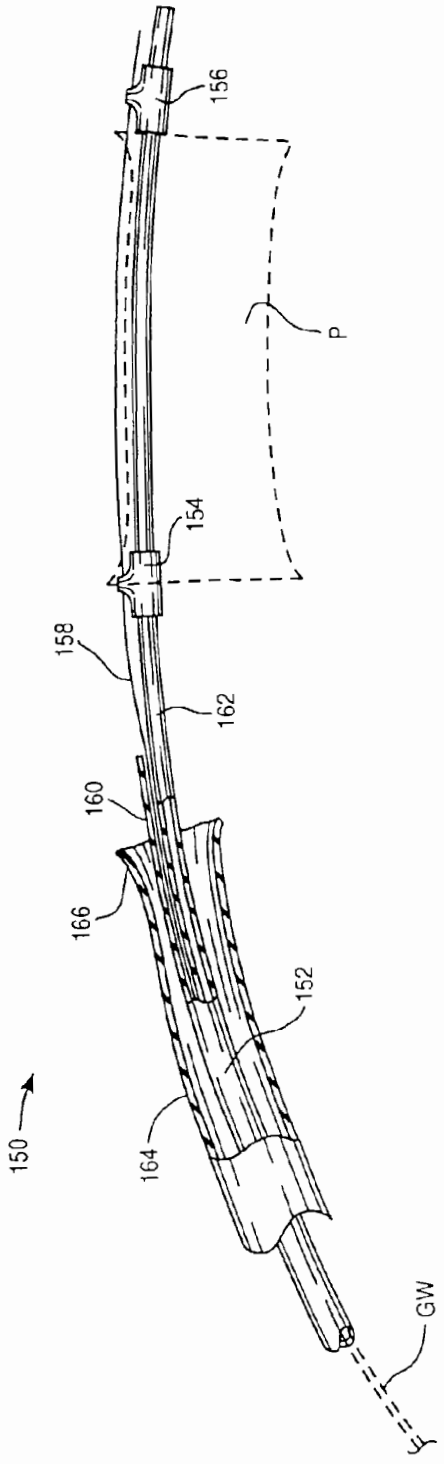


FIG. 16

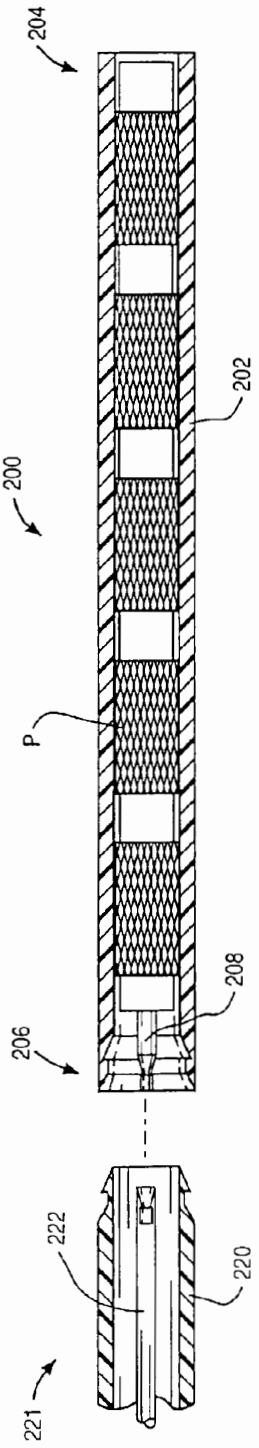


FIG. 17

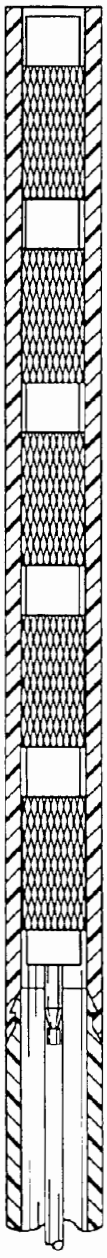


FIG. 18

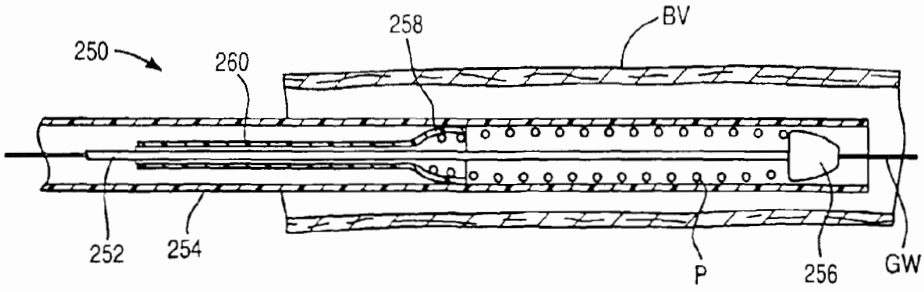


FIG. 19A

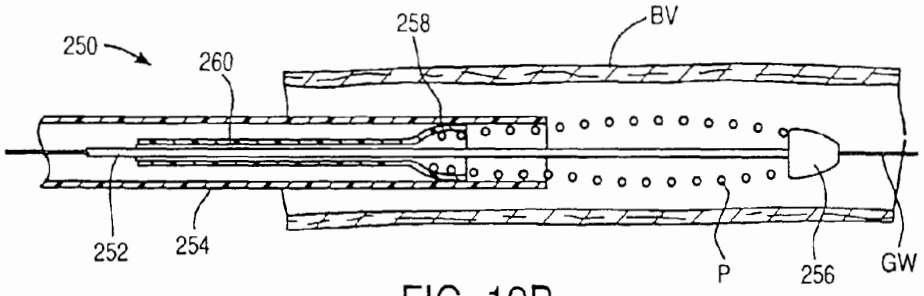


FIG. 19B

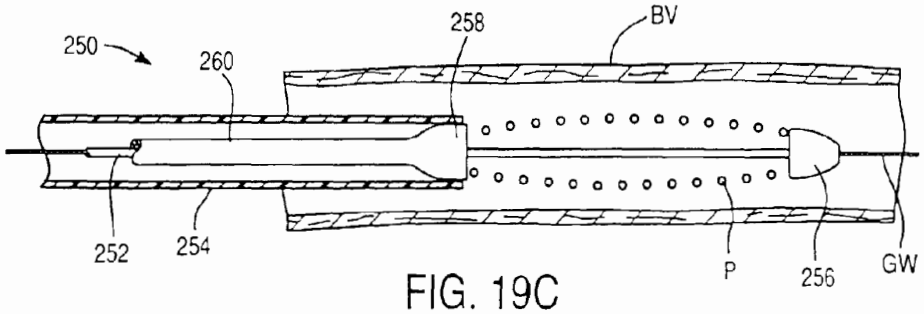


FIG. 19C

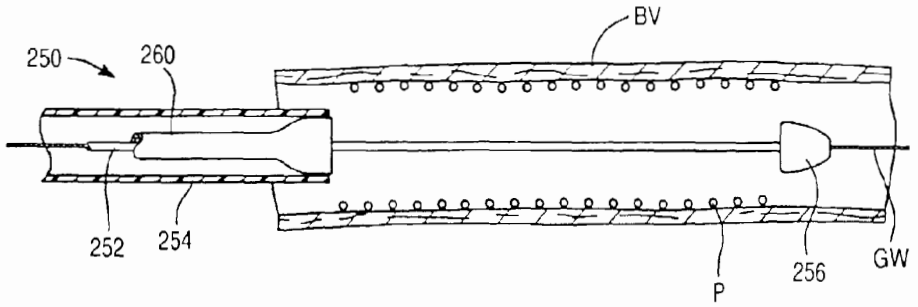


FIG. 19D

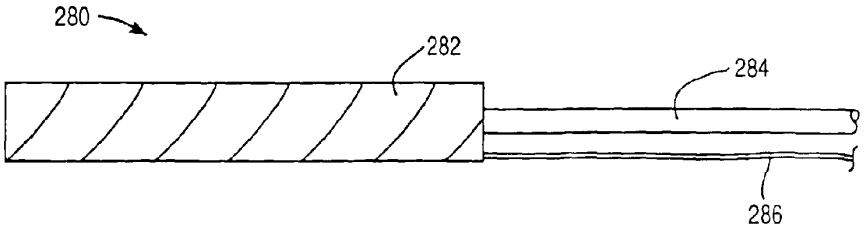


FIG. 20A

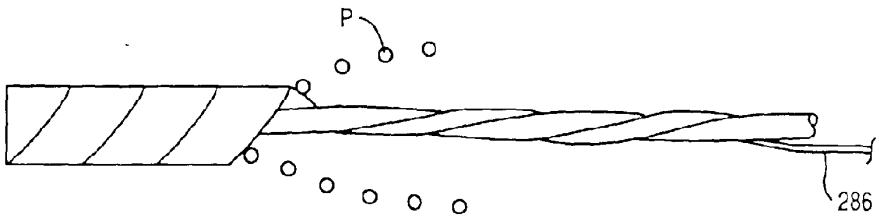


FIG. 20B

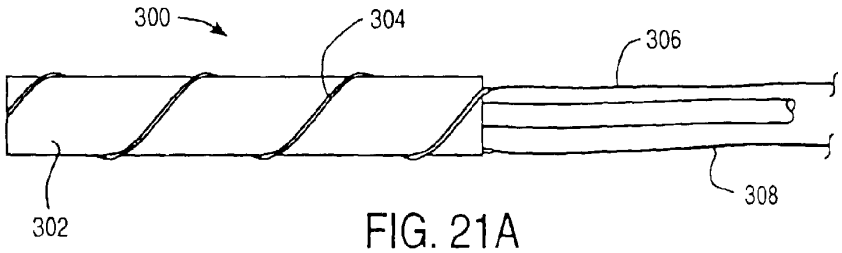


FIG. 21A

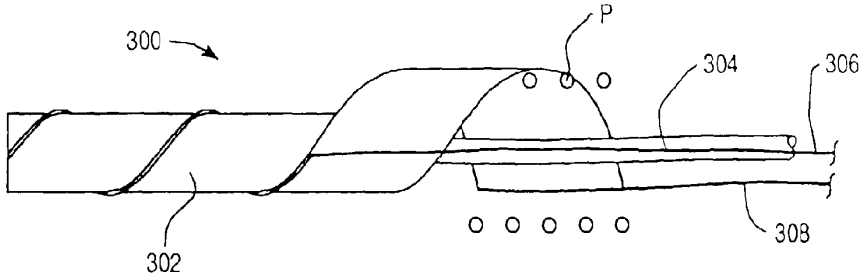


FIG. 21B

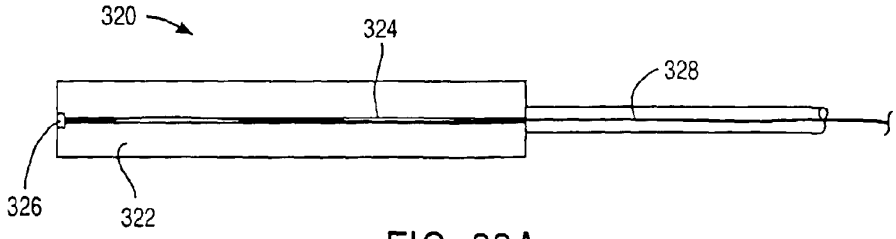


FIG. 22A

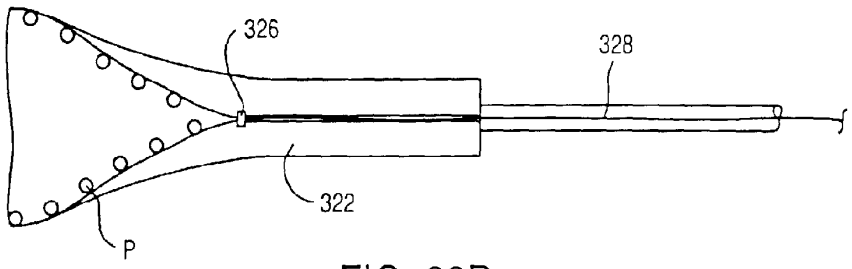


FIG. 22B

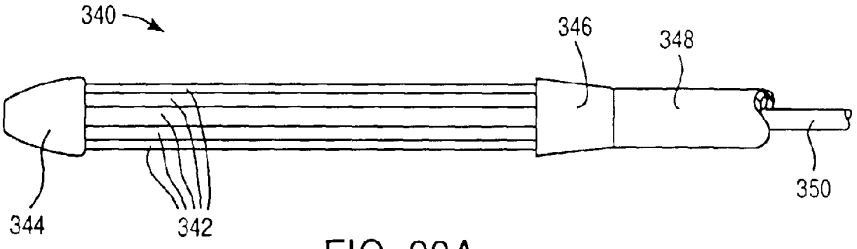


FIG. 23A

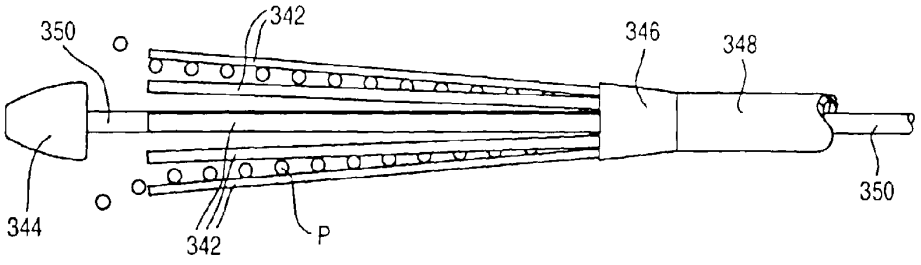


FIG. 23B

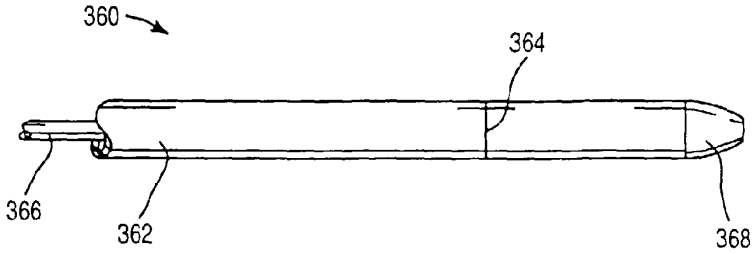


FIG. 24A

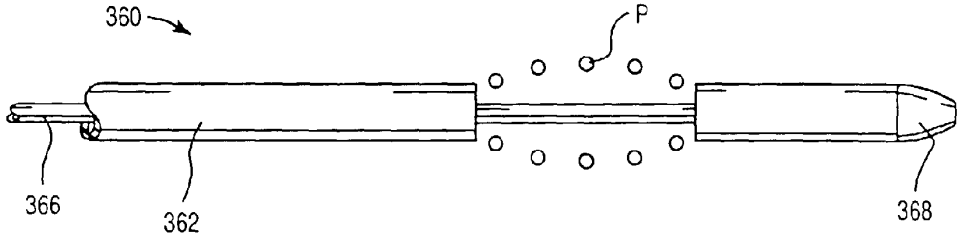


FIG. 24B

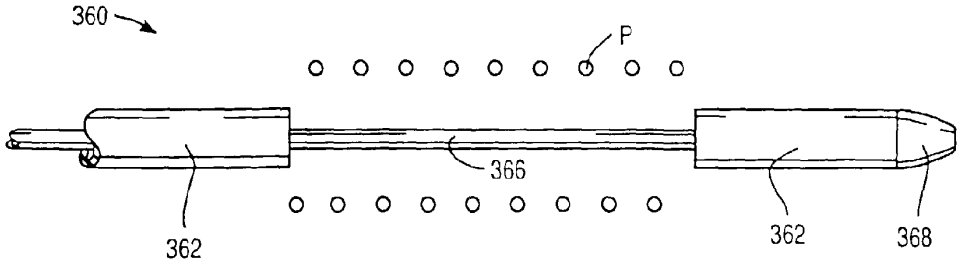


FIG. 24C

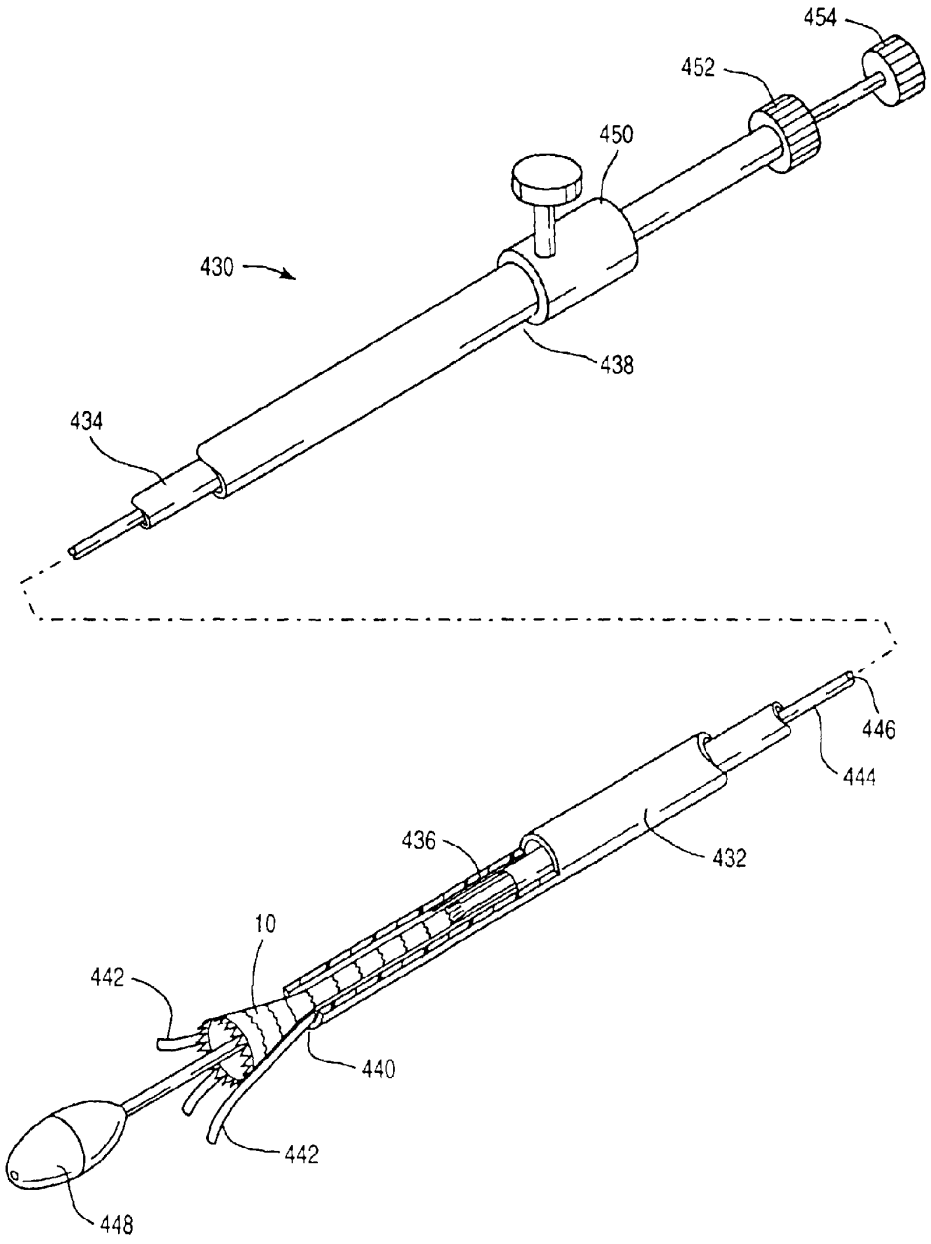


FIG. 25

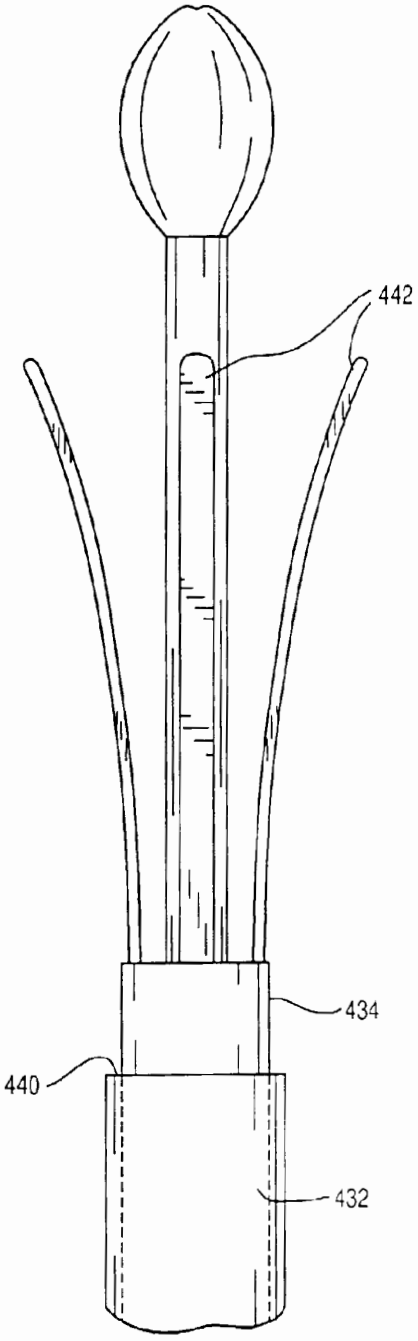


FIG. 26A

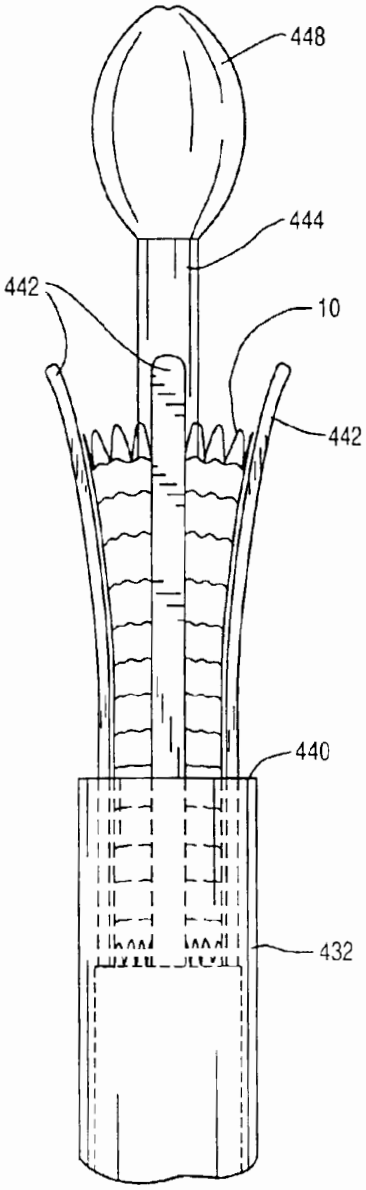


FIG. 26B

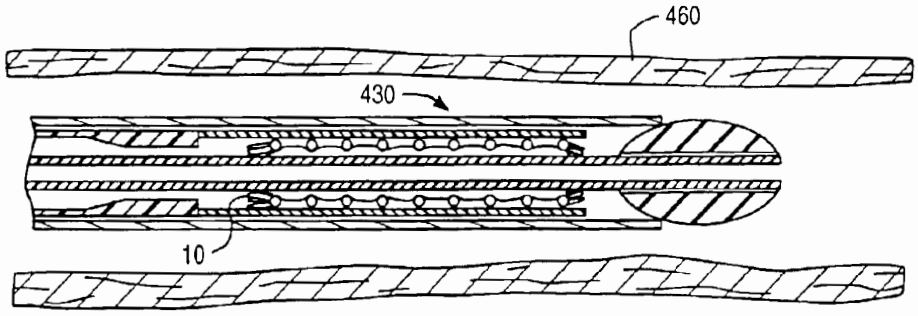


FIG. 27A

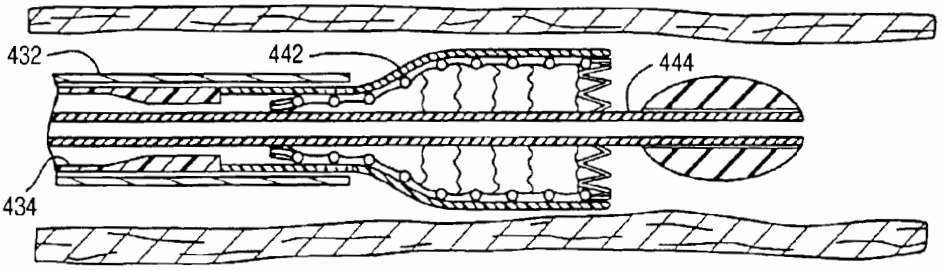


FIG. 27B

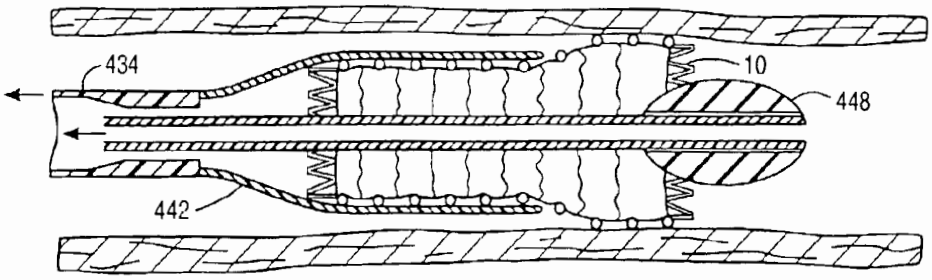


FIG. 27C

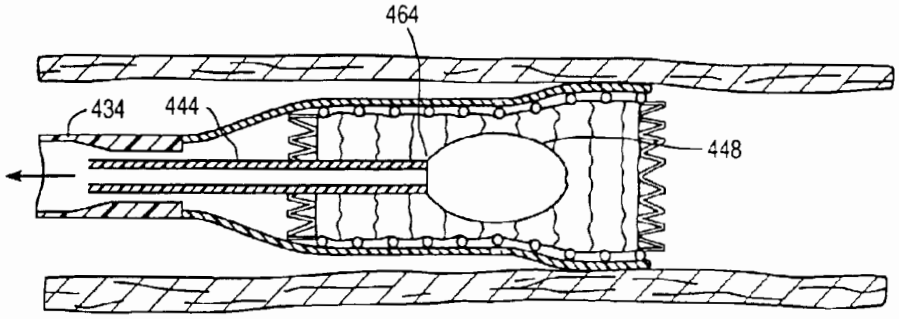


FIG. 28

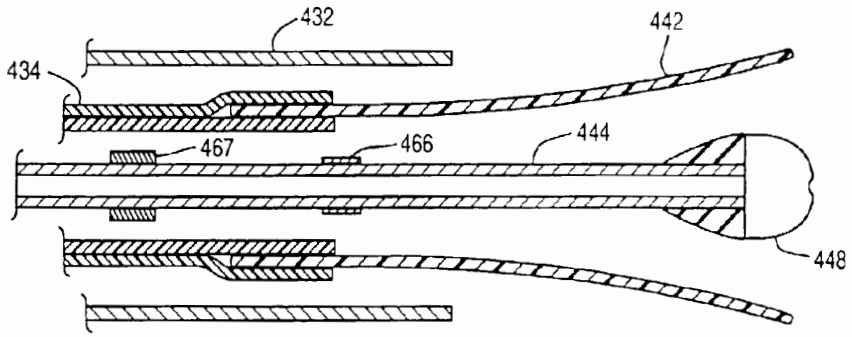


FIG. 29A

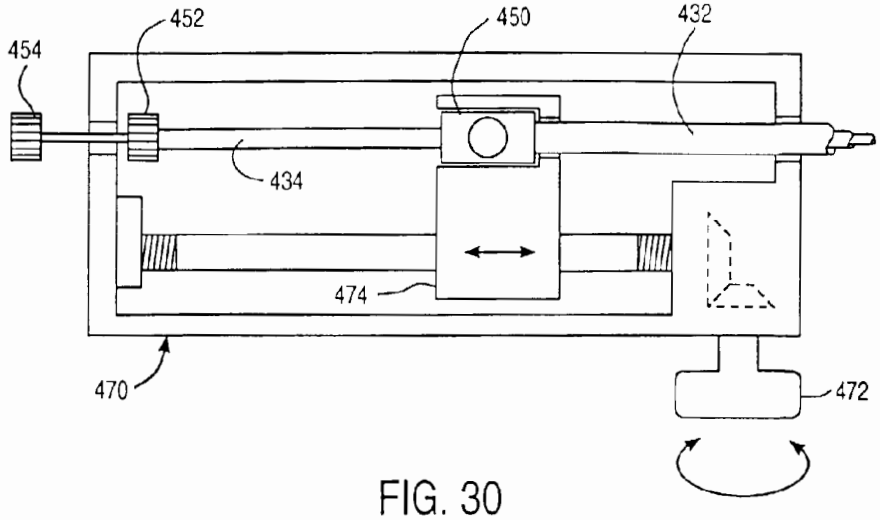


FIG. 30

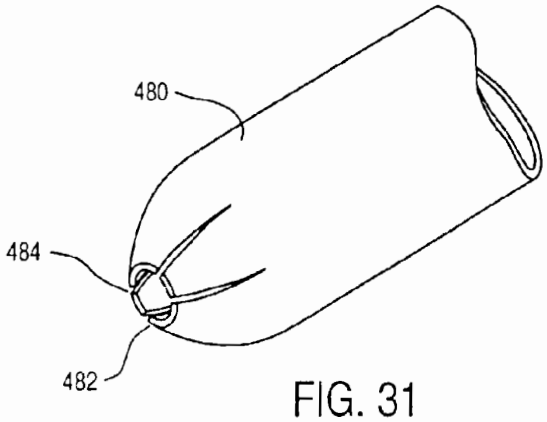


FIG. 31

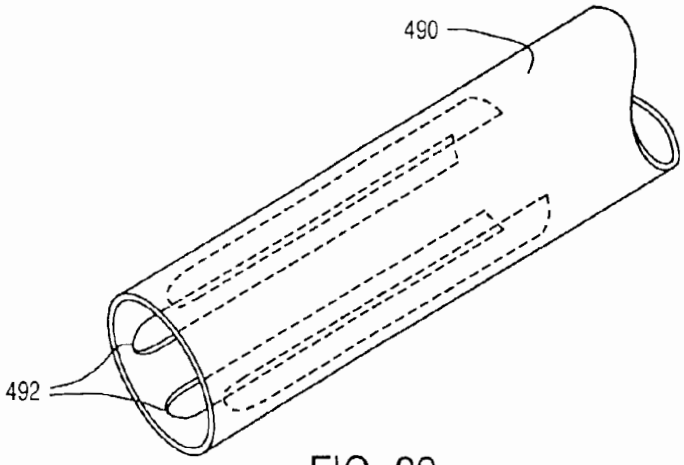


FIG. 32

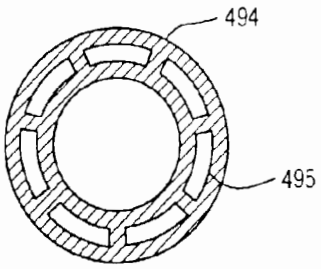


FIG. 33A

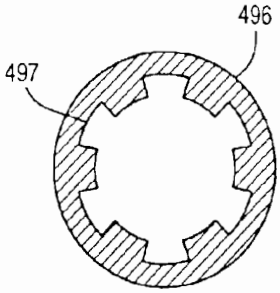


FIG. 33B

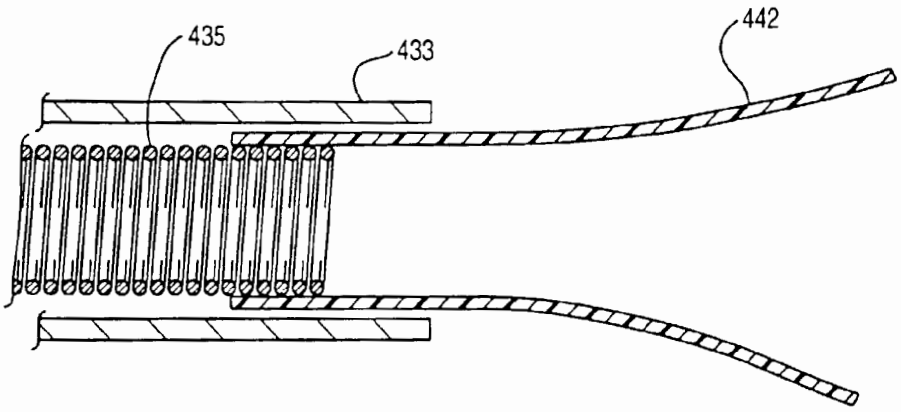


FIG. 29B

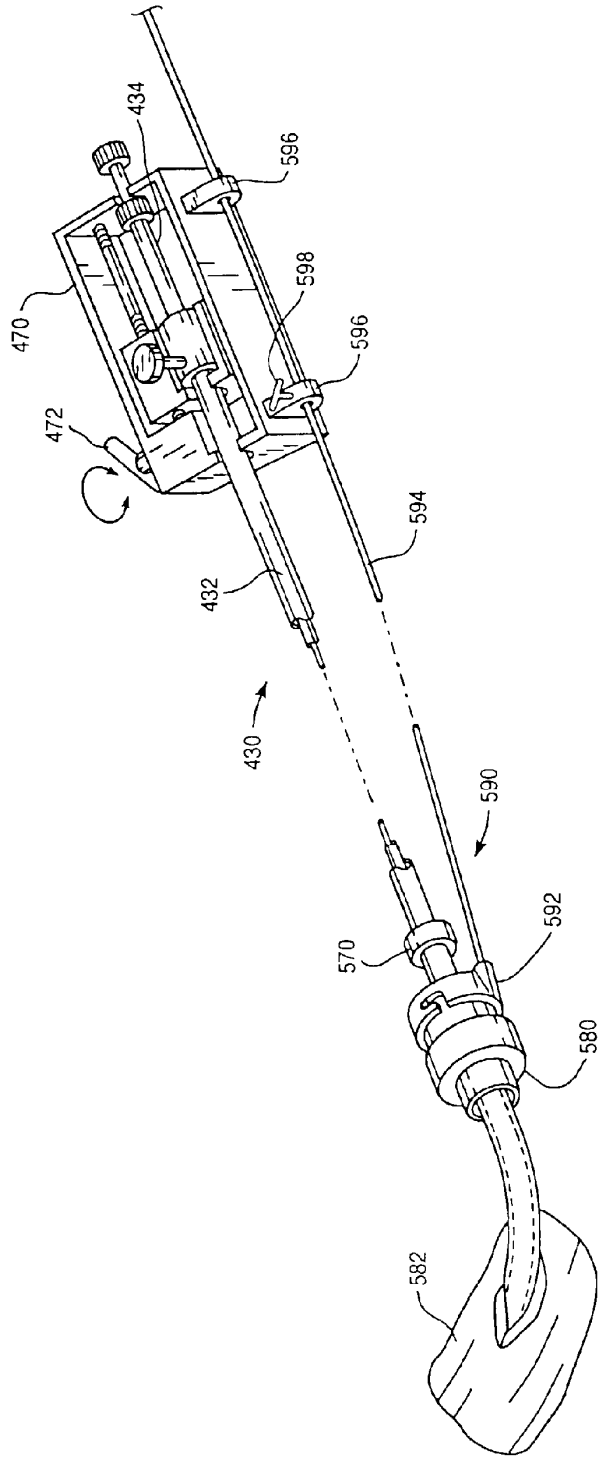


FIG. 34

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 December 2009 (10.12.2009)

PCT

(10) International Publication Number
WO 2009/149462 A2

(51) International Patent Classification:
A61F 2/24 (2006.01)

(21) International Application Number:
PCT/US2009/046646

(22) International Filing Date:
8 June 2009 (08.06.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/059,656 6 June 2008 (06.06.2008) US

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

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HARITON, Ilia** [IL/IL]; 36-C Haatzmaut St., Zichron-Yaacov (IL). **BENICHOU, Netanel** [IL/IL]; D.N. Hof-Carmel, 30808 (IL). **NITZAN, Yaacov** [IL/IL]; Haaliya Hashniya St. 42/1, Herzeliya (IL). **FELSEN, Bellla** [IL/IL]; 26 Hazvi St, 34555 Haifa (IL). **NGUYEN-THIEN-NH, Diana** [US/US]; One Edwards Way, Irvine, CA 92614 (US). **KHANNA, Rajesh** [US/US]; One Edwards Way, Irvine, CA 92614 (US). **NGUYEN, Son** [US/US]; One Edwards Way, Irvine, CA 92614 (US). **LEVI, Tamir** [IL/IL]; Moshav Ein HaEmek (IL). **PELLED, Itai** [US/US]; One Edwards Way, Irvine, CA 92614 (US).

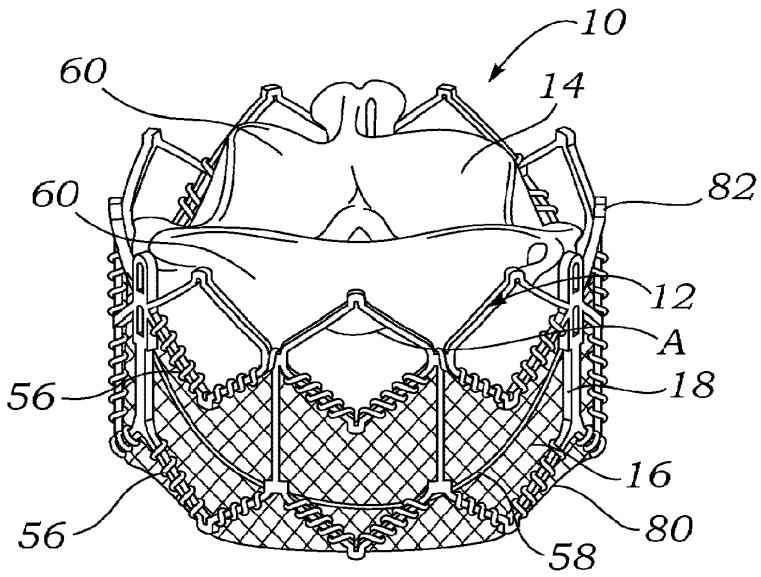
(74) Agents: **HAUSER, David, L.** et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (US).

(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, RO, RS, RU, SC, SD,

[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.

WO 2009/149462 A2

SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, 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))*

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

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.

[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.

[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.

[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

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

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

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).

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

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.

[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,

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

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.

[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

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

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,

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.

[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

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.

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.

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.

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.

Fig. 1

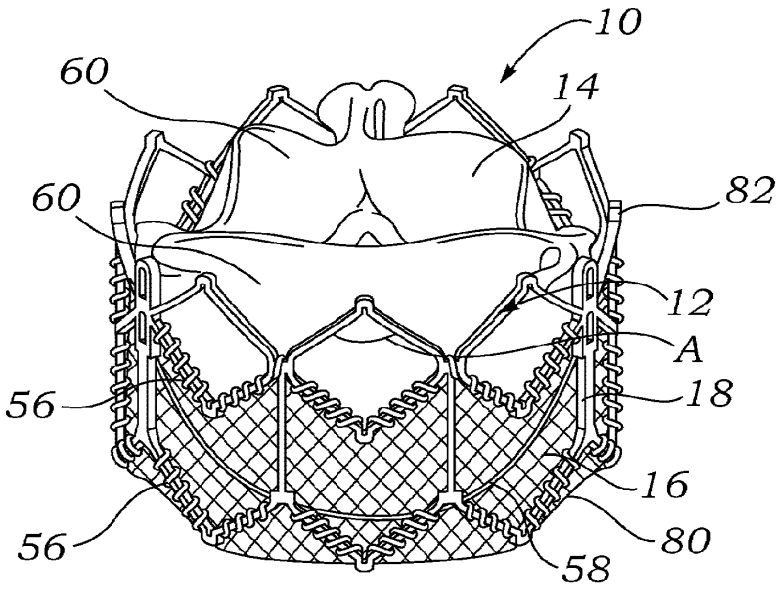


Fig. 2

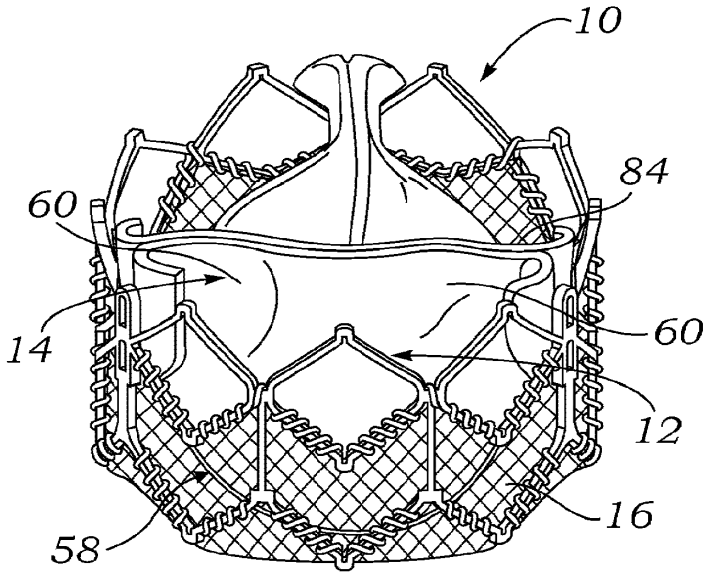


Fig. 3

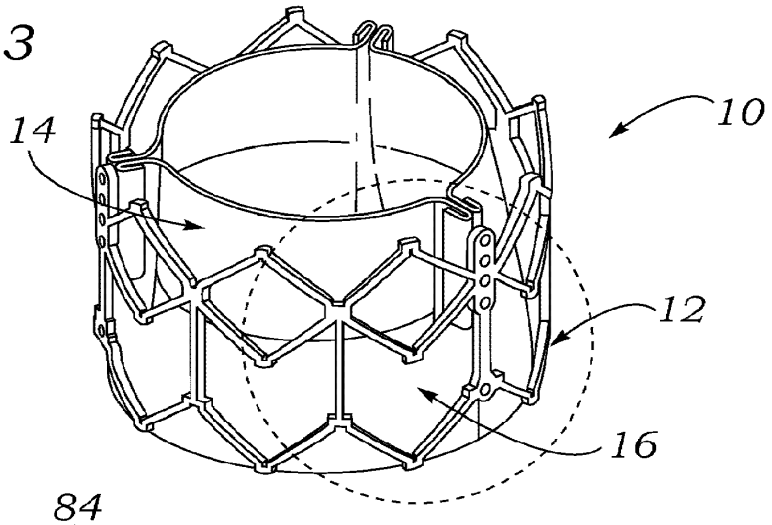


Fig. 4

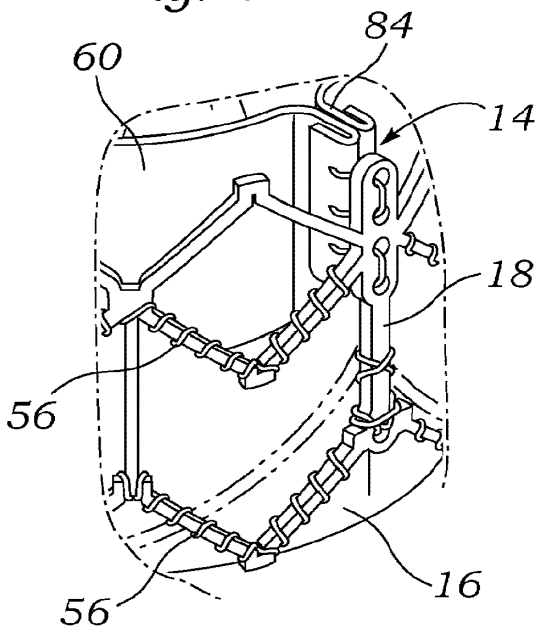


Fig. 5

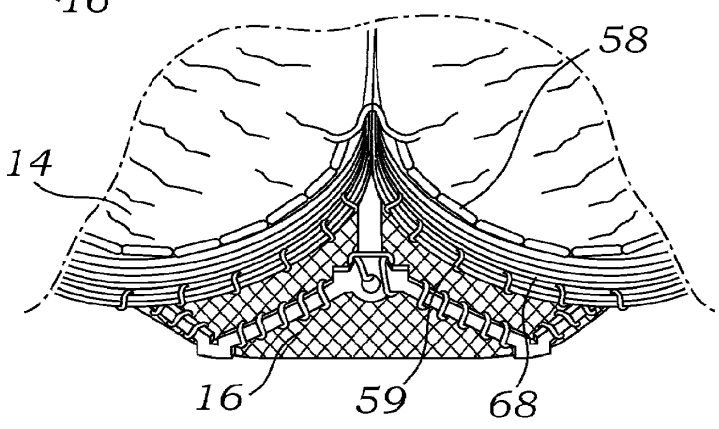


Fig. 6

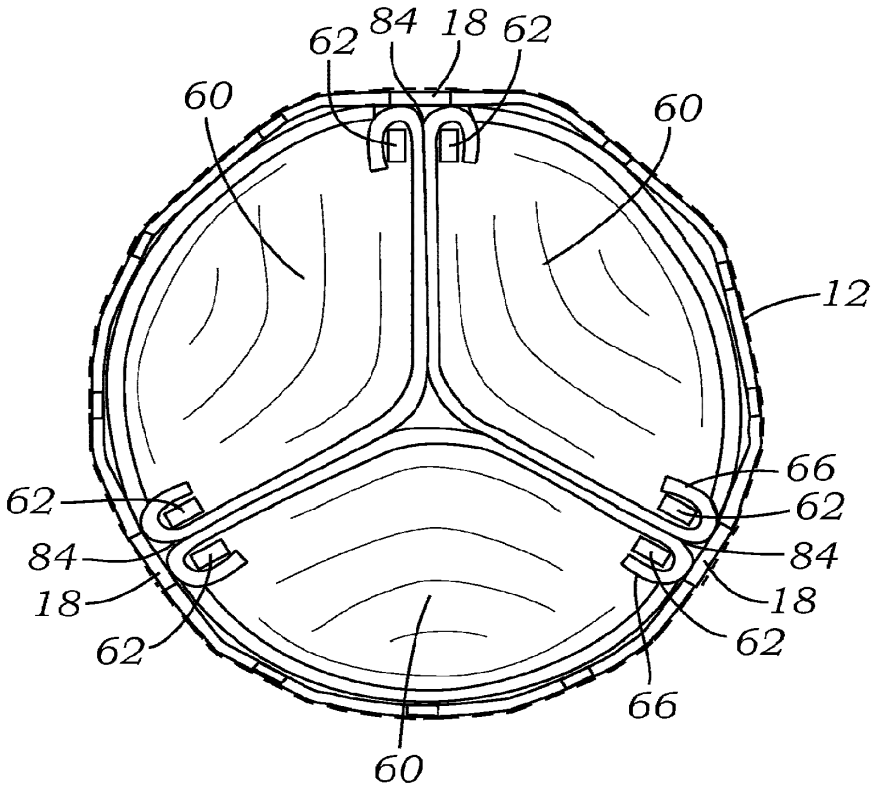


Fig. 7

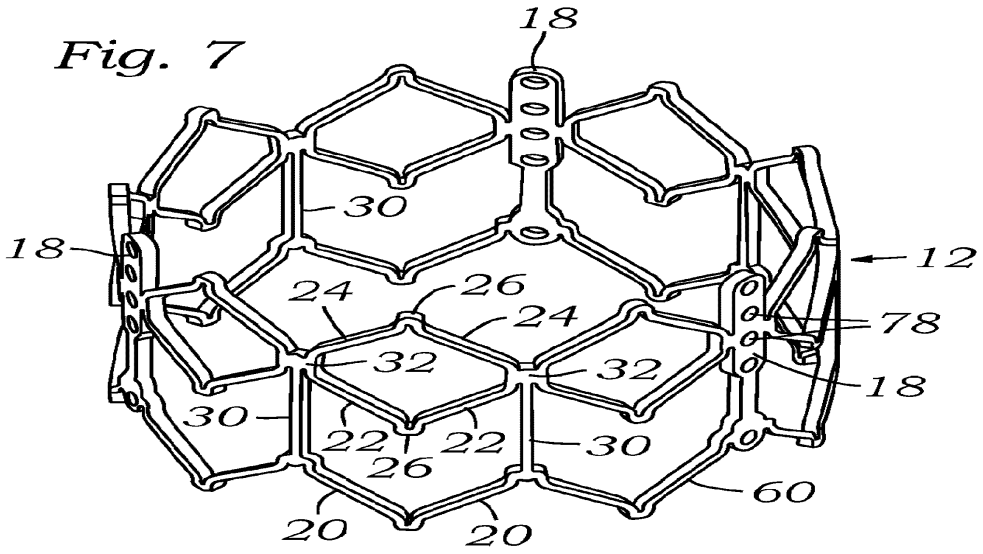


Fig. 8

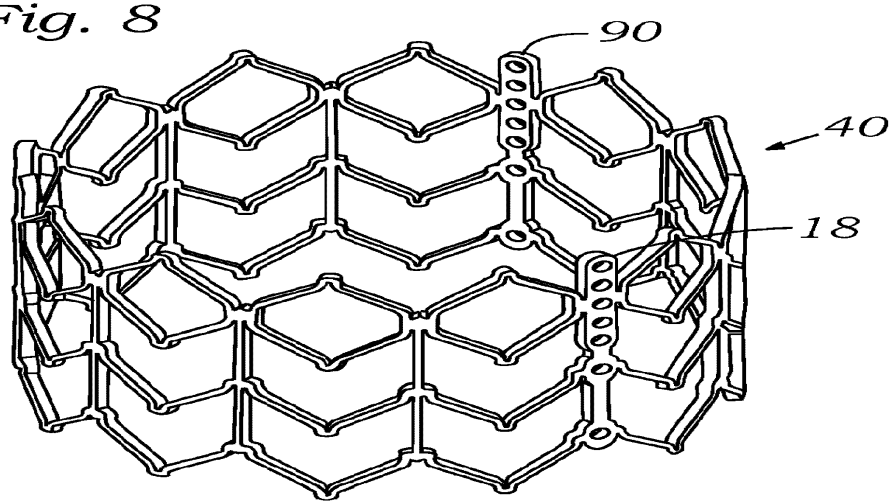


Fig. 9

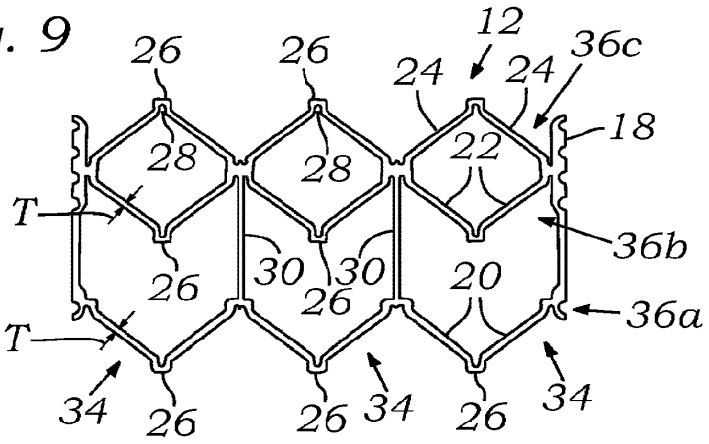


Fig. 10

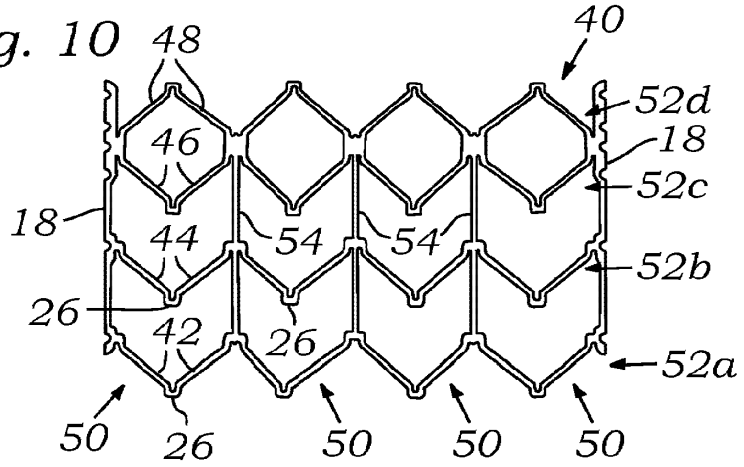


Fig. 11

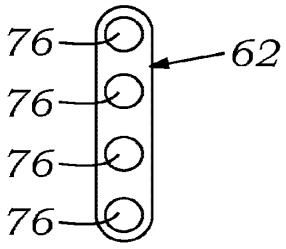


Fig. 12

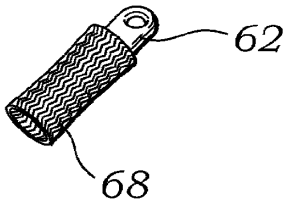


Fig. 13

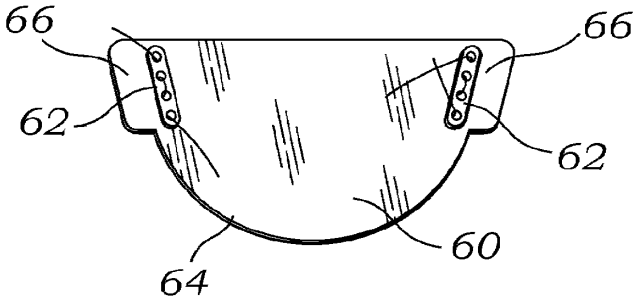


Fig. 14

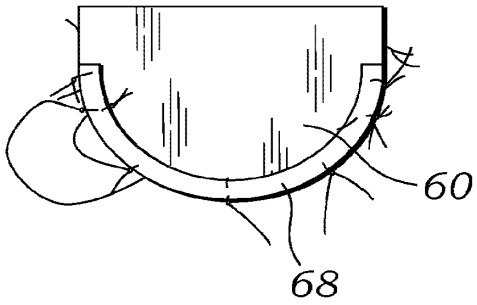


Fig. 15

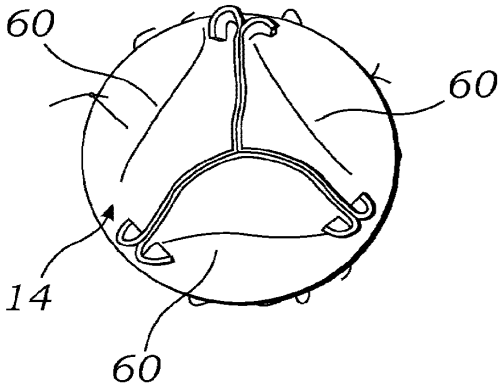


Fig. 6A

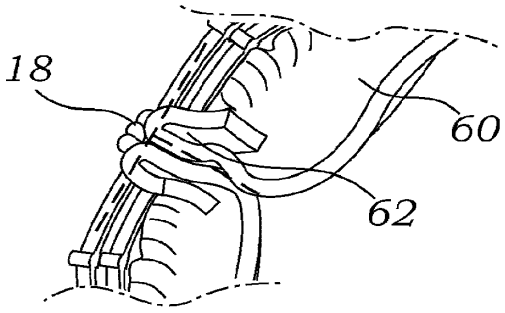


Fig. 16

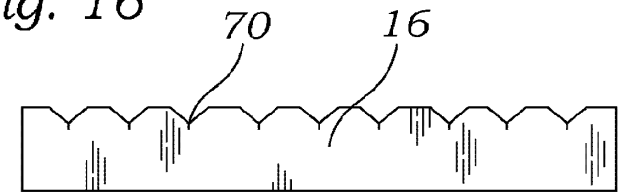


Fig. 17

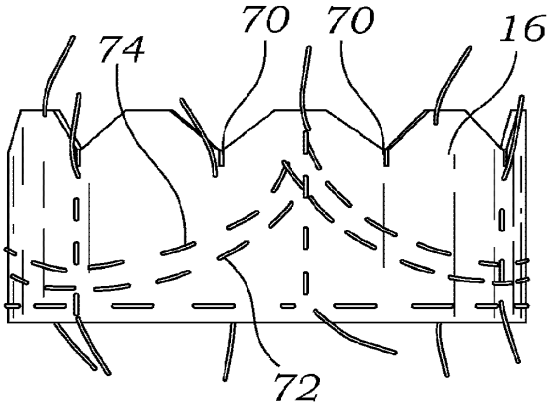


Fig. 18

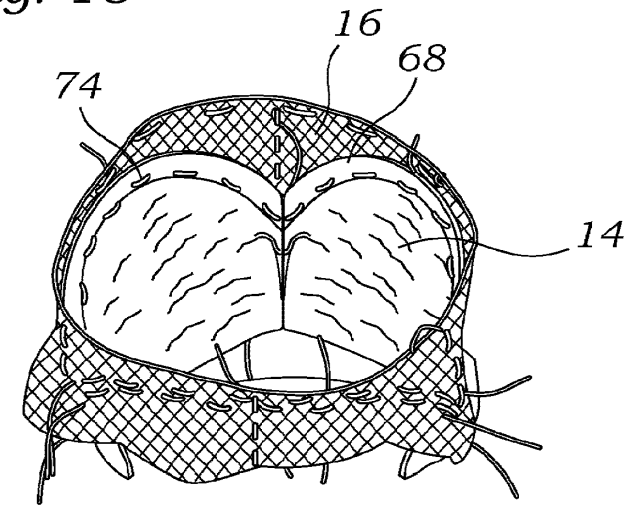


Fig. 19

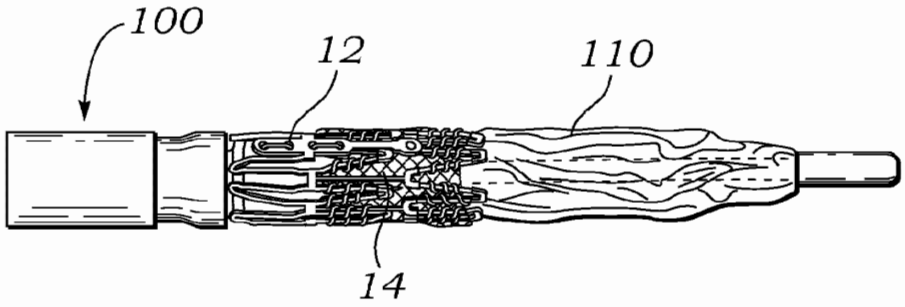


Fig. 20

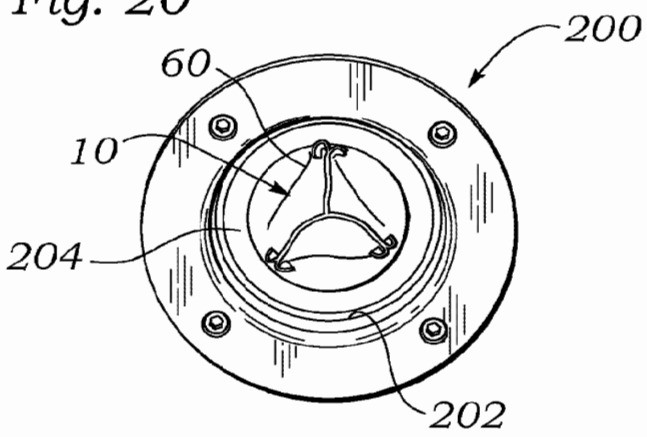


Fig. 21

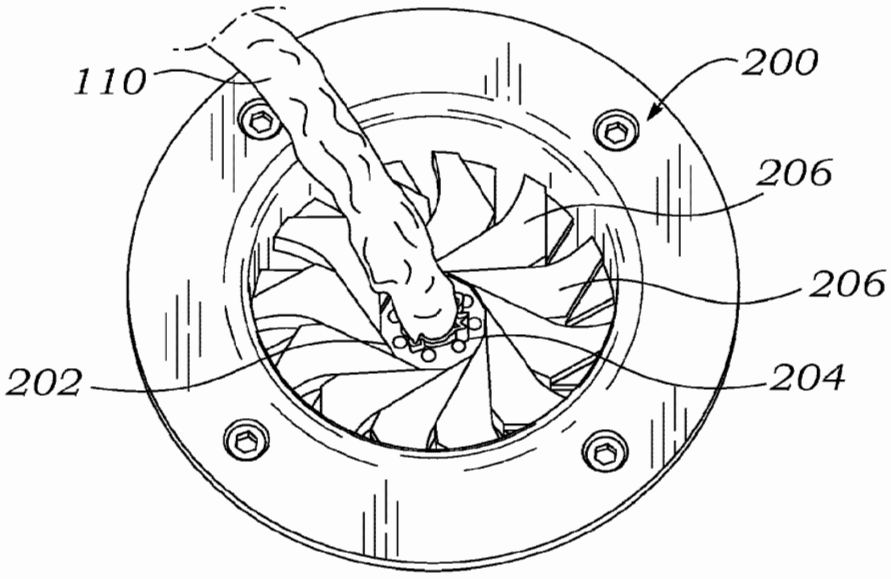


Fig. 22

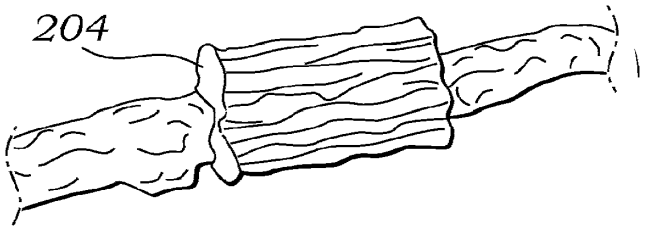


Fig. 23

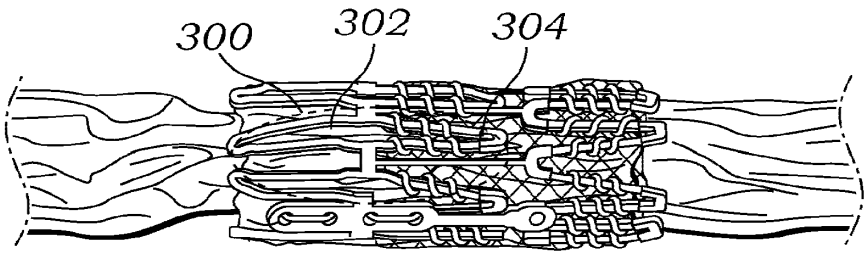


Fig. 24

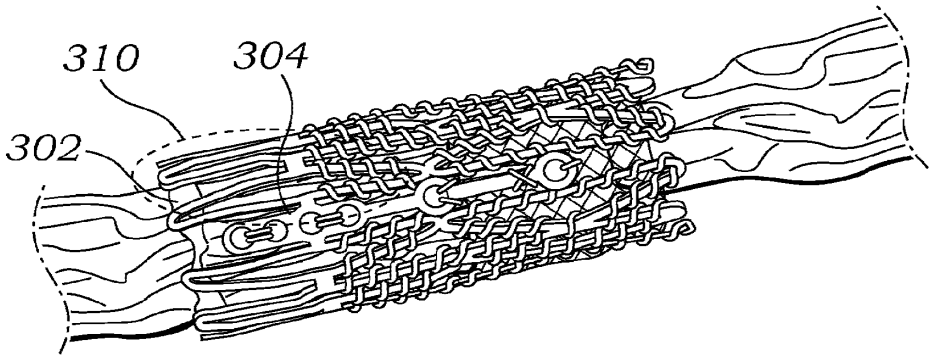


Fig. 25

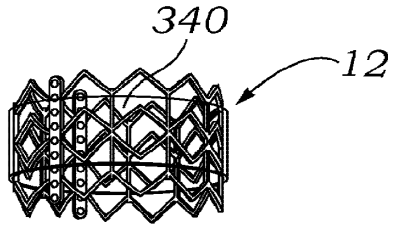


Fig. 26

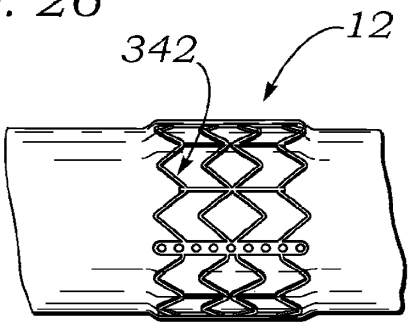


Fig. 27

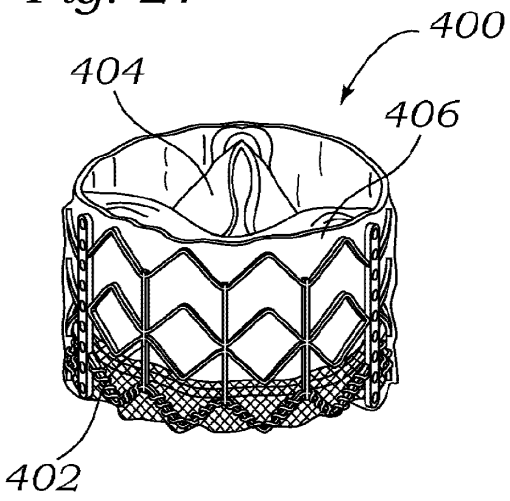


Fig. 28

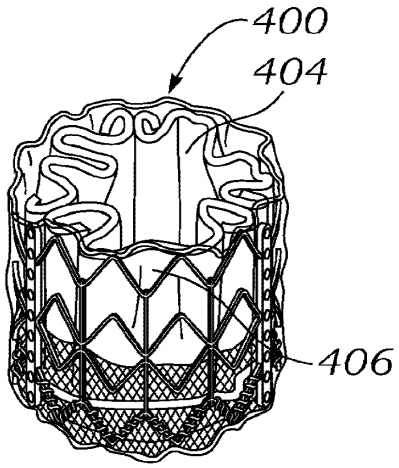


Fig. 29

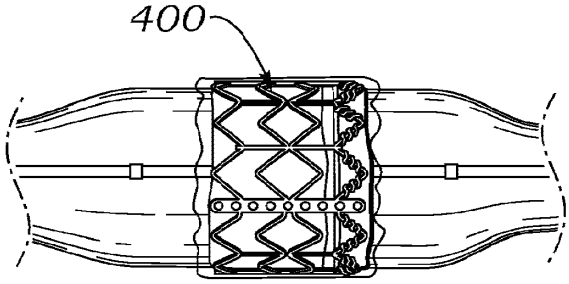


Fig. 30A

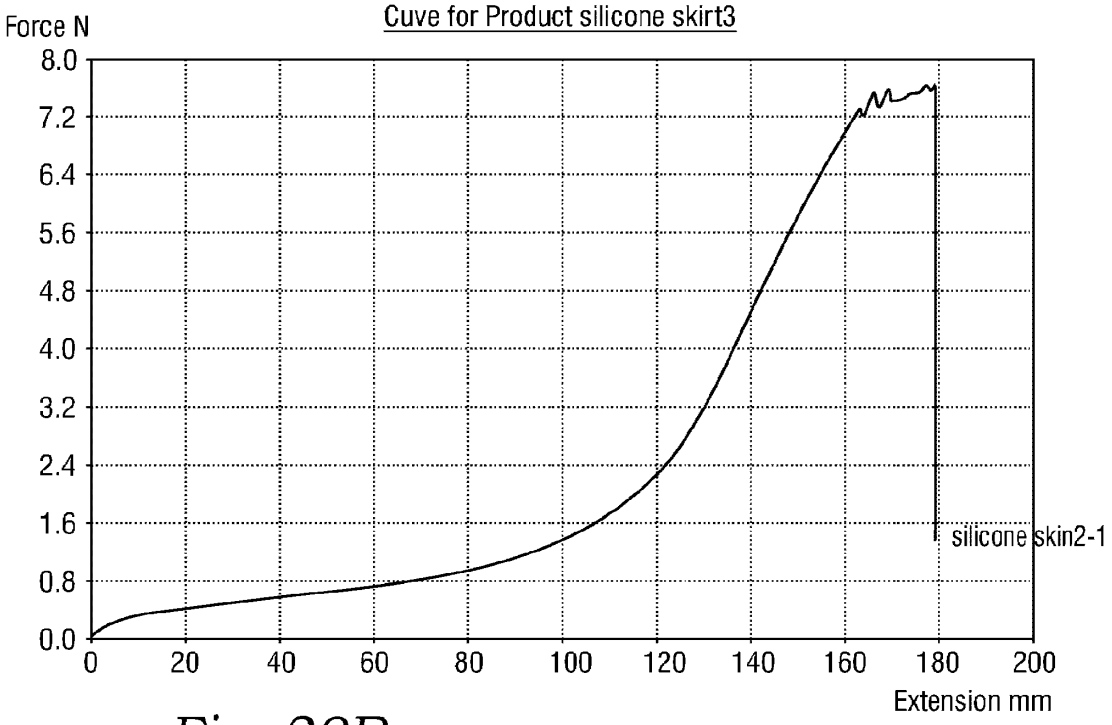


Fig. 30B

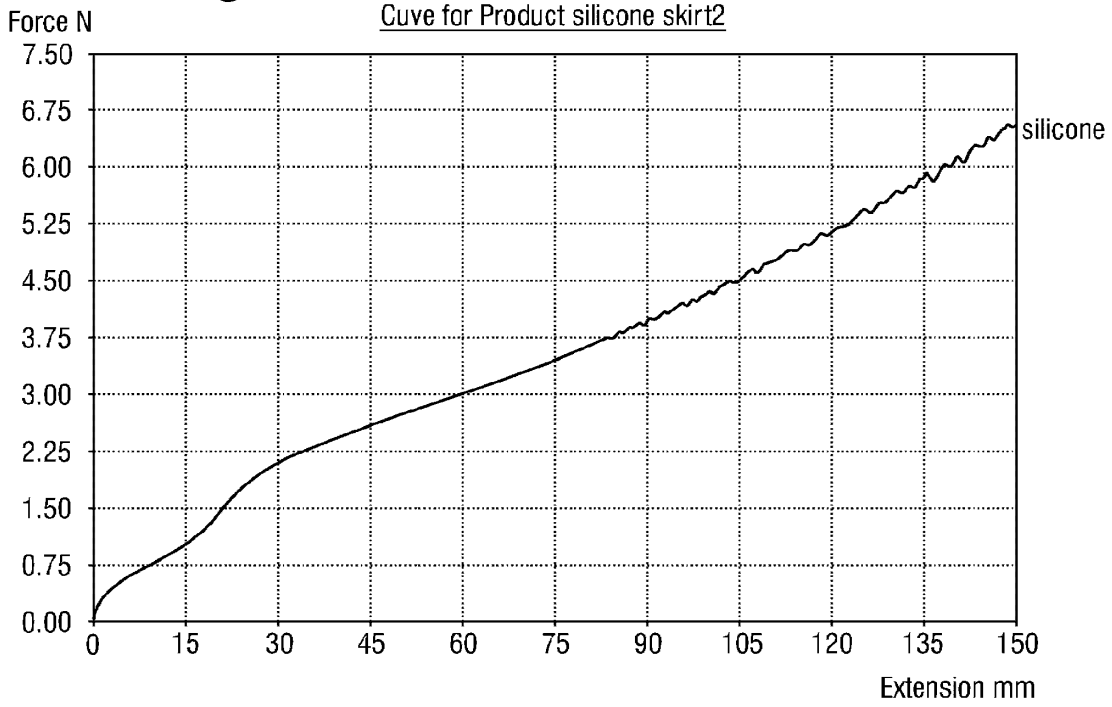


Fig. 30C

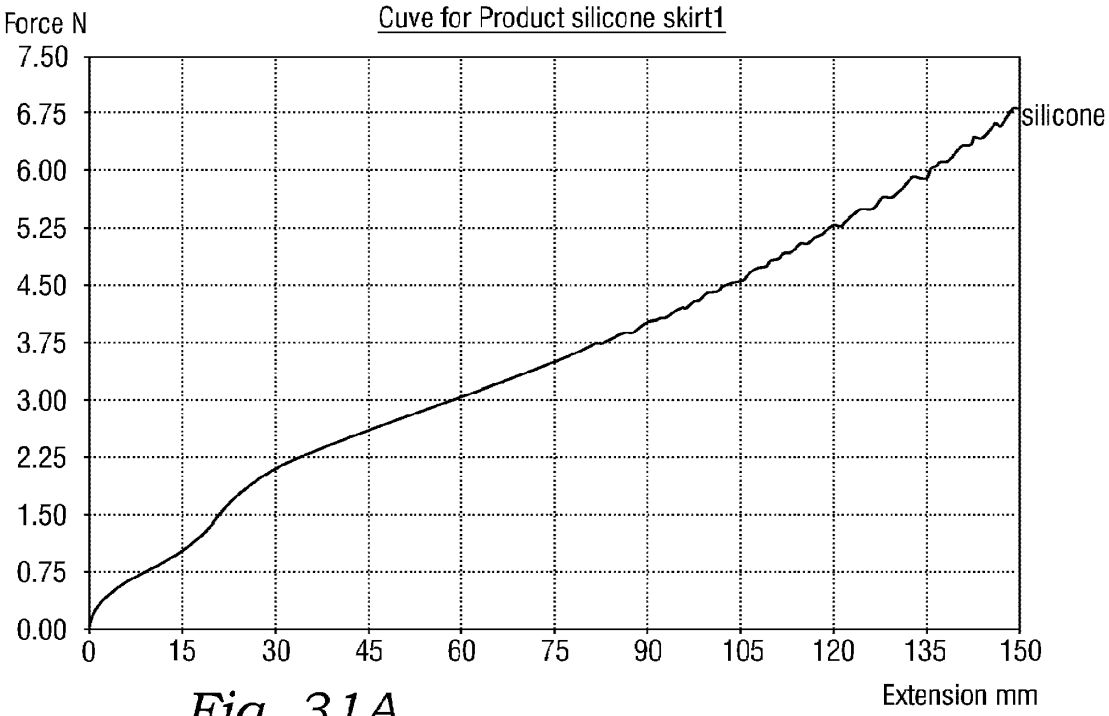


Fig. 31A

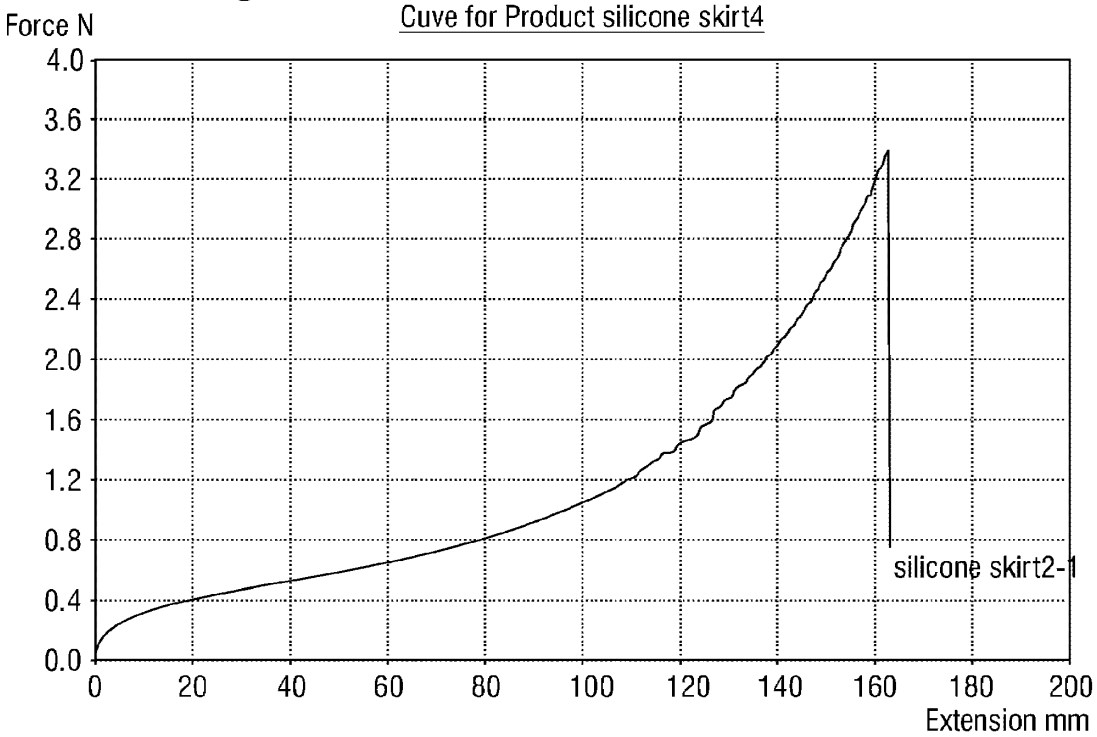


Fig. 31B

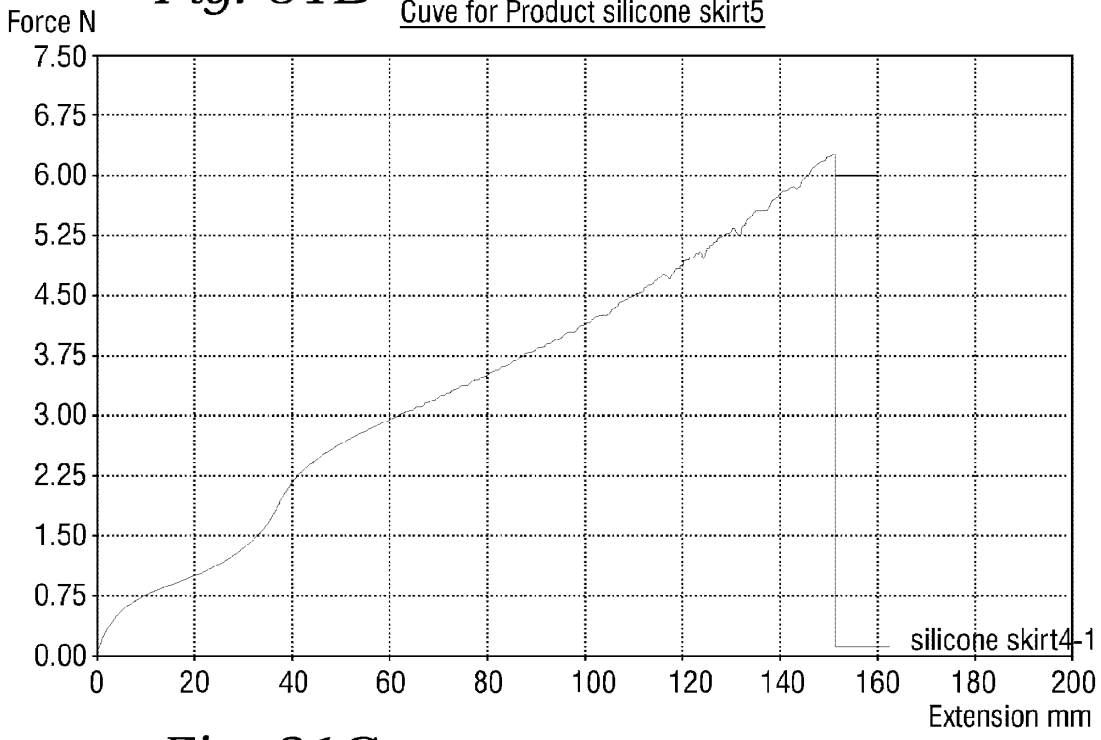


Fig. 31C

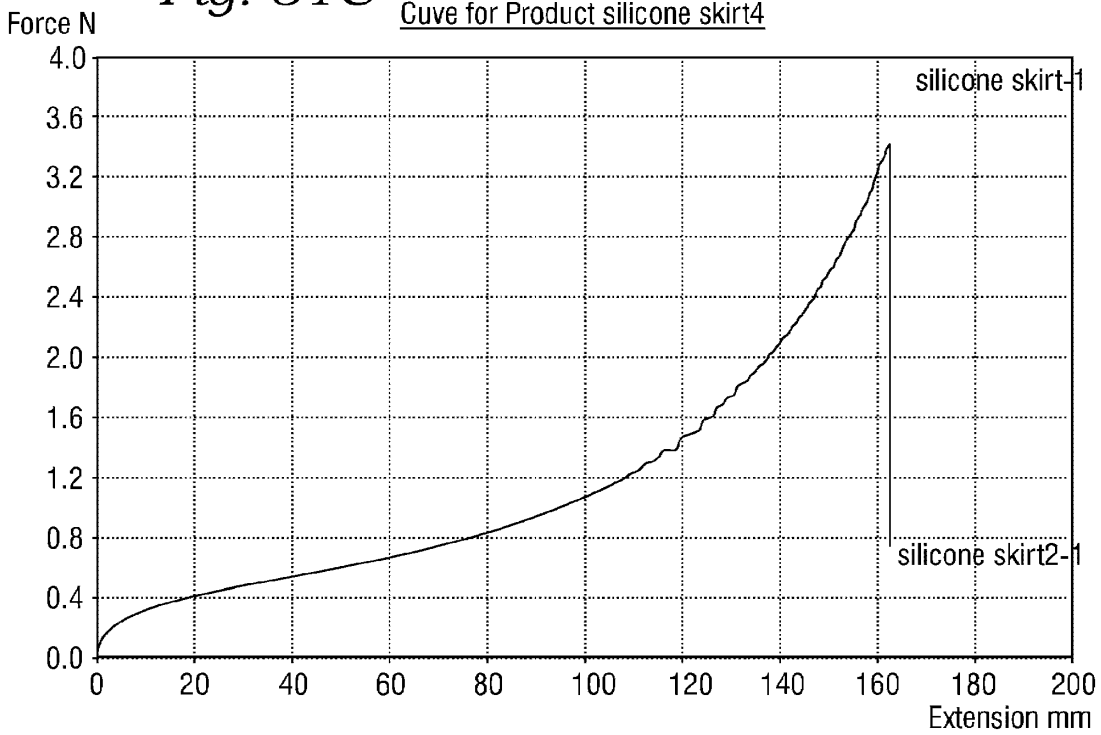


Fig. 31D

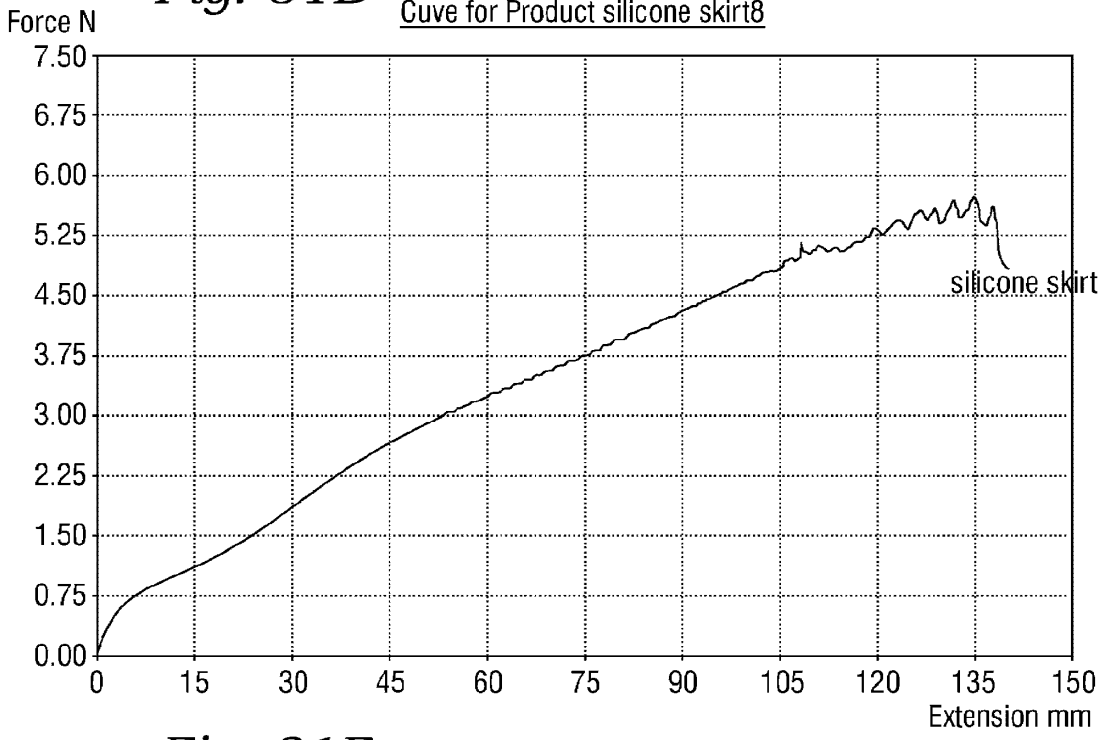


Fig. 31E

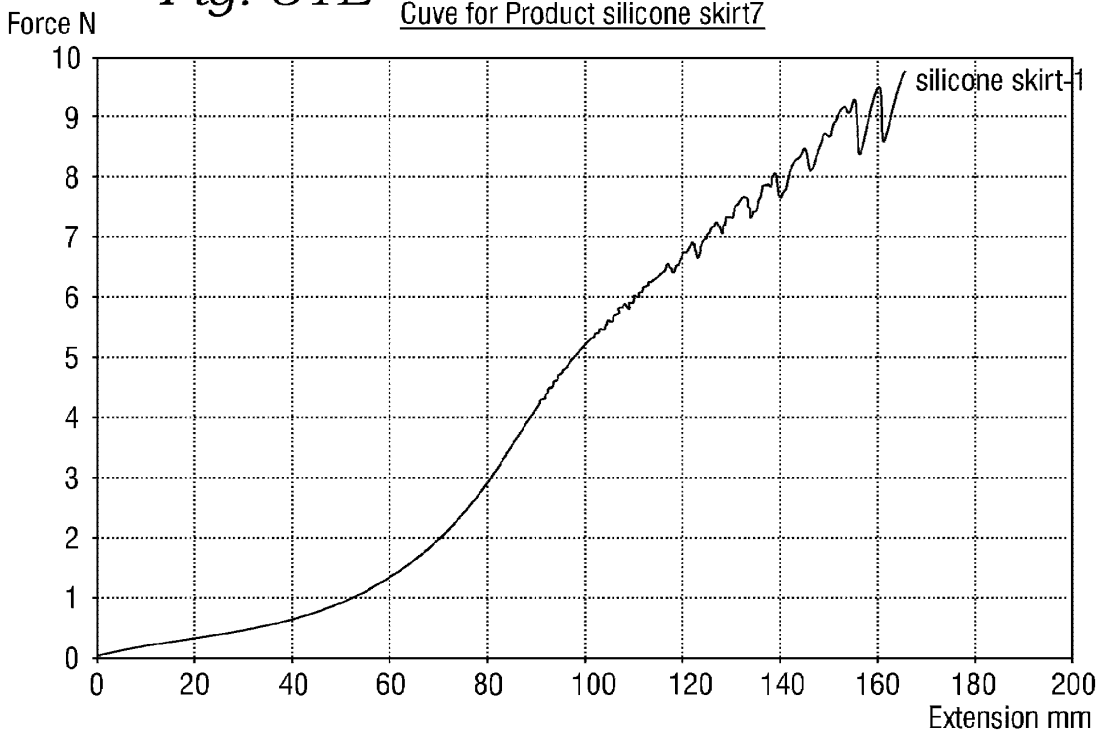
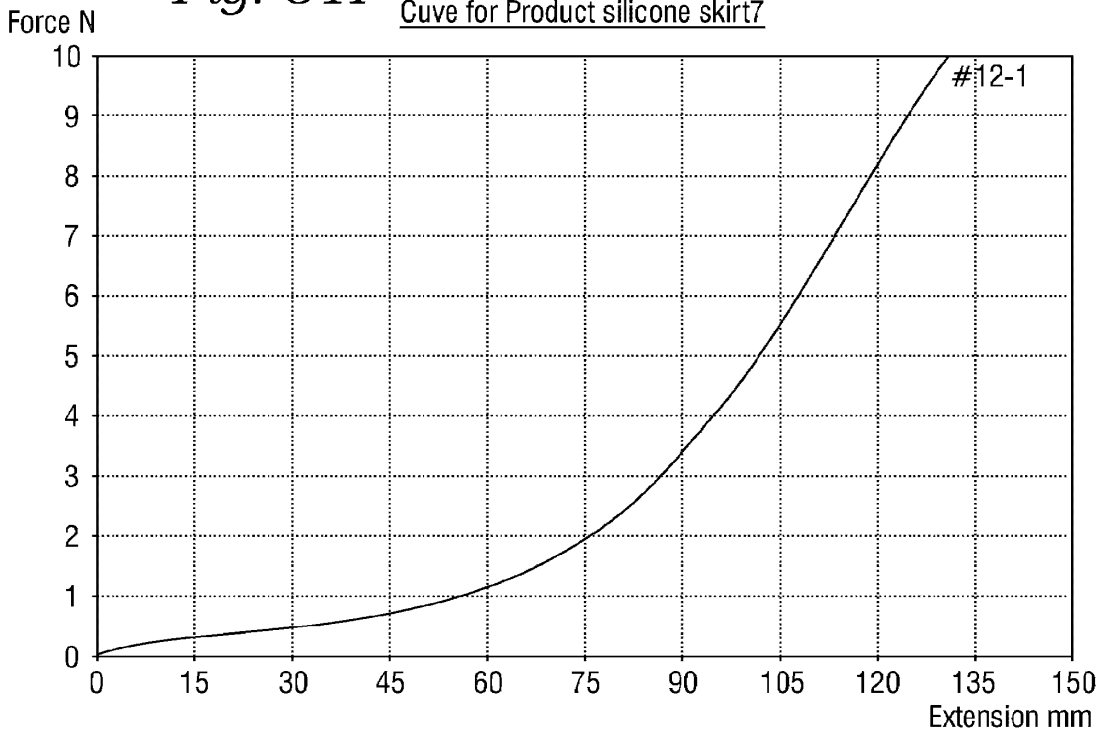


Fig. 31F


Cuve for Product silicone skirt7
Force N
10
9
8
7
6
5
4
3
2
1
0
#12-1
0
15
30
45
60
75
90
105
120
135
150
Extension mm

Electronic Acknowledgement Receipt

EFS ID:	22603655
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	11-JUN-2015
Filing Date:	15-APR-2014
Time Stamp:	14:47:59
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_10104_Supp_IDS_2015-06-11.PDF	650688 6232b4feacc017f9fc2a0a3556537d15dd044807	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
Warnings:					
Information:					
5	Foreign Reference	WO-2009-149462.PDF	1394005 4d484e54c510d8718b3cce46f5897bbedccd6466	no	40
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
6	Non Patent Literature	10106_US_14-502453_Final_Office_Action_2015-05-08.PDF	358607 844085e2edd2b6b6f5b143d67cd866c8be0b4695	no	9
Warnings:					
Information:					
		Total Files Size (in bytes):	6799522		

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.

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 07/16/2015

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: 07/16/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

TITLE OF INVENTION: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

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	10/16/2015

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 07/16/2015
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.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

TITLE OF INVENTION: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

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	10/16/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
MILLER, CHERYL L	3738	623-001260

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

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.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 07/16/2015

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: 07/16/2015

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.

PTOL-85 (Rev. 02/11)

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. 14/253,650	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 *5/7/2015*.
   ☐ 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 *34-38*. 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

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Yaskanin (Reg. No. 45,246) on July 1, 2015. The amendment was agreed upon in order to overcome potential indefiniteness as well as more clearly overcome the previous Bailey rejection, and place the application in condition for allowance.

The application has been amended as follows:

Claim 1, lines 10-12 have been amended as such:

pericardial tissue, wherein the valve means ~~and all fixed pericardial tissue~~ resides entirely within the inner channel of the stent member, ~~wherein the valve means is attached closer to a proximal and wider part of the stent member~~ and wherein no reinforcing members reside within the inner channel of the stent member;

Claim 1, lines 19-21 have been amended as such:

within the inner channel of the stent member ~~when the stent member is collapsed onto the pusher~~

~~member and further resides entirely within the inner channel of the stent member when the stent~~

~~member is unrestrained from the moveable sheath~~ in said collapsed configuration and is configured

to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.

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

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. 5427

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/253,650	04/15/2014 RULE	623	3738	109978.10104

APPLICANTS

Colibri Heart Valve LLC, Broomfield, CO;

INVENTORS

David PANIAGUA, Houston, TX;
R. David FISH, Houston, TX;

**** CONTINUING DATA ***************************

This application is a CON of 13/675,665 11/13/2012
which is a CON of 10/887,688 07/10/2004 PAT 8308797
which is a CIP of 10/037,266 01/04/2002 ABN

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/01/2014

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☐ No	/CHERYL L MILLER/ Examiner's Signature	☐ Initials	TX	12	5	1

ADDRESS

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

TITLE

PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

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

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	2463	A61F2/2412.cpc. or A61F2/2436.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09
S40	264	A61F2/2412.cpc. and A61F2/2436.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09

S41	46	S40 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09
S42	11	S40 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09
S43	54	S41 S42	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:09
S44	1424	S39 and pericardi$3	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:11
S45	261	S44 and @rlad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12
S46	180	S44 and @ad<"20020104"	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12
S47	361	S45 S46	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12
S48	348	S47 not S43	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12
S49	172	S48 and (taper$4 or flar$3 or conical)	US-PGPUB; USPAT; USOCR	OR	ON	2015/06/30 13:12

6/30/2015 3:01:08 PM
C:\Users\cmiller2\Documents\EAST\Workspaces\14253650.wsp

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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	5554184		1996-09-10	Machiraju	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20020052651		2002-05-02	Myers et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

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	9-501594	JP		1997-02-18		Equivalent to WO/1995/005207	☐
	2	2001-500761	JP		2001-01-23		Equivalent to WO/1998/011935	☐
	3	2005-103321	JP		2005-04-21		Equivalent to EP0696447	☐

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 06/11/2015	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
(**Not for submission under 37 CFR 1.99)**	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

	4	2009/149462	WO		2009-12-10	Edwards Lifesciences Corporation		☐

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	Final Office Action issued May 8, 2015 in U.S. Application No. 14/502,453 (109978.10106)	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	06/30/2015

*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. /CM/

Receipt date: 06/11/2015	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David PANIAGUA	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

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.

/Cheryl Miller/ 06/30/2015

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David Paniagua
	Art Unit	3738
	Examiner Name	Cheryl L. MILLER
	Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20030209835		2003-11-13	Chun et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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]

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/07/2015	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

	1	Office Action issued December 5, 2014 in U.S. Application No. 14/502,453 (109978.10106)	☐
	2	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)	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	06/30/2015

*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. /CM/

Receipt date: 05/07/2015	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

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)	2015-05-07
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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

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.

/Cheryl Miller/ 06/30/2015

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David Paniagua
Art Unit	3738
Examiner Name	Cheryl L. MILLER
Attorney Docket Number	109978.10104

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					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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							☐

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]

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 11/20/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2014-04-15	
	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

	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	/Cheryl Miller/	Date Considered	06/30/2015

*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. /CM/

Receipt date: 11/20/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-04-15	
	First Named Inventor	David Paniagua	
	Art Unit	3738	
	Examiner Name	Cheryl L. MILLER	
	Attorney Docket Number	109978.10104	

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)	2014-11-20
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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

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.

/Cheryl Miller/ 06/30/2015

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	PANIAGUA ET AL.
	Examiner	Art Unit
	CHERYL MILLER	3738

CPC- SEARCHED		
Symbol	Date	Examiner
A61F2/2412, 2436	6/30/2015	cm

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	1.24, 1.26, 2.12-2.19	6/2/2014	cm
update		11/1/2014	cm

SEARCH NOTES		
Search Notes	Date	Examiner
East text search	11/2/2014	cm
East text search	6/30/2015	cm

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61F2	2412	6/30/2015	cm

/C.M./ Examiner.Art Unit 3738	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

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	8512403		2013-08-20	Navia et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	20010010017		2001-07-26	Cribier et al.	
	2	20010049558		2001-12-06	Liddicoat et al.	
	3	20010023372		2001-09-20	Chen et al.	
	4	20020005073		2002-01-17	Tompkins et al.	
	5	20020028243		2002-03-07	Masters	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	6	20020029783		2002-03-14	Stevens et al.	
	7	20020037940		2002-03-28	Koob et al.	
	8	20020042621		2002-04-11	Liddicoat et al.	
	9	20020091441		2002-07-11	Guzik	
	10	20020095167		2002-07-18	Liddicoat et al.	
	11	20020095994		2002-07-25	Vesley et al.	
	12	20020123789		2002-09-05	Francis et al.	
	13	20020128708		2002-09-12	Northrup et al.	
	14	20020151970		2002-10-17	Garrison et al.	
	15	20030078659		2003-04-24	Yang	
	16	20030102000		2003-06-05	Stevens et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	17	20030130727		2003-07-10	Drasler et al.	
	18	20030130729		2003-07-10	Paniagua et al.	
	19	20030130731		2003-07-10	Vidlund et al.	
	20	20030149477		2003-08-07	Gabbay	
	21	20030153974		2003-08-14	Spenser et al.	
	22	20030187362		2003-10-02	Murphy et al.	
	23	20030195620		2003-10-16	Huynh et al.	
	24	20030204023		2003-10-30	Koob et al.	
	25	20030212460		2003-11-13	Darios et al.	
	26	20030212462		2003-11-13	Gryska et al.	
	27	20030217415		2003-11-27	Crouch et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	28	20040024452		2004-02-05	Kruse et al.	
	29	20040039442		2004-02-26	St. Goar	
	30	20040055608		2004-03-25	Stevens et al.	
	31	20040059418		2004-03-25	McKay et al.	
	32	20040098092		2004-05-20	Butaric et al.	
	33	20040158321		2004-08-12	Reuter et al.	
	34	20040193261		2004-09-30	Berreklouw	
	35	20040230285		2004-11-18	Gifford, III et al.	
	36	20040243153		2004-12-02	Liddicoat et al.	
	37	20040243229		2004-12-02	Vidlund et al.	
	38	20050004668		2005-01-06	Aklog et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	39	20050027369		2005-02-03	Eldridge et al.	
	40	20050043819		2005-02-24	Schimdt et al.	
	41	20050096673		2005-05-05	Stack et al.	
	42	20050113910		2005-05-26	Paniagua et al.	
	43	20050137681		2005-06-23	Shoemaker et al.	
	44	20050137682		2005-06-23	Justino	
	45	20050142163		2005-06-30	Hunter et al.	
	46	20050147562		2005-07-07	Hunter et al.	
	47	20050147599		2005-07-07	Hunter et al.	
	48	20050147643		2005-07-07	Hunter et al.	
	49	20050148512		2005-07-07	Hunter et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	50	20050158274		2005-07-21	Hunter et al.	
	51	20050159811		2005-07-21	Lane	
	52	20050169958		2005-08-04	Hunter et al.	
	53	20050169959		2005-08-04	Hunter et al.	
	54	20050175657		2005-08-11	Hunter et al.	
	55	20050187618		2005-08-25	Gabbay	
	56	20050191248		2005-09-01	Hunter et al.	
	57	20050228494		2005-10-13	Marquez	
	58	20050241981		2005-11-03	Gupta et al.	
	59	20050246035		2005-11-03	Wolfinbarger et al.	
	60	20050247320		2005-11-10	Stack et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	61	20050267529		2005-12-01	Crockett et al.	
	62	20060004439		2006-01-05	Spenser et al.	
	63	20060004443		2006-01-05	Liddicoat et al.	
	64	20060020336		2006-01-26	Liddicoat	
	65	20060025800		2006-02-02	Suresh	
	66	20060041306		2006-02-23	Vidlund	
	67	20060074486		2006-04-06	Liddicoat et al.	
	68	20060089708		2006-04-27	Osse et al.	
	69	20060111733		2006-05-25	Shriver	
	70	20060129225		2006-06-15	Kopia et al.	
	71	20060134079		2006-06-22	Sih et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	72	20060140916		2006-06-29	Siani-Rose et al.	
	73	20060173475		2006-08-03	Lafontaine et al.	
	74	20060178740		2006-08-10	Stacchino et al.	
	75	20060190074		2006-08-24	Hill et al.	
	76	20060193885		2006-08-31	Neethling et al.	
	77	20060195010		2006-08-31	Arnal et al.	
	78	20060195183		2006-08-31	Navia et al.	
	79	20060206203		2006-09-14	Yang et al.	
	80	20060229701		2006-10-12	Gurm et al.	
	81	20060240063		2006-10-26	Hunter et al.	
	82	20060240064		2006-10-26	Hunter et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	83	20060259134		2006-11-16	Schwammenthal et al.	
	84	20060259135		2006-11-16	Navia et al.	
	85	20060259137		2006-11-16	Artof et al.	
	86	20060265056		2006-11-23	Nguyen et al.	
	87	20060287571		2006-12-21	Gozzi et al.	
	88	20060292125		2006-12-28	Kellar et al.	
	89	20070010857		2007-01-11	Sugimoto et al.	
	90	20070043431		2007-02-22	Melsheimer	
	91	20070050014		2007-03-01	Johnson	
	92	20070050022		2007-03-01	Vidlund et al.	
	93	20070056346		2007-03-15	Spenser et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	94	20070060932		2007-03-15	Stack et al.	
	95	20070100426		2007-05-03	Rudakov et al.	
	96	20070104395		2007-05-10	Kinigakis et al.	
	97	20070128174		2007-06-07	Kleinsek et al.	
	98	20070173861		2007-07-26	Strommer et al.	
	99	20070203575		2007-08-30	Forster et al.	
	100	20070213813		2007-09-13	Von Segessler et al.	
	101	20070250154		2007-10-25	Greenberg et al.	
	102	20070263226		2007-11-15	Kurtz et al.	
	103	20070276432		2007-11-29	Stack et al.	
	104	20070276461		2007-11-29	Andreas et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	105	20080004686		2008-01-03	Hunt et al.	
	106	20080009667		2008-01-10	Longhini et al.	
	107	20080009940		2008-01-10	Cribier	
	108	20080029105		2008-02-07	Stevens et al.	
	109	20080039871		2008-02-14	Wallace et al.	
	110	20080039926		2008-02-14	Majercak et al.	
	111	20080058798		2008-03-06	Wallace et al.	
	112	20080082113		2008-04-03	Bishop et al.	
	113	20080102439		2008-05-01	Tian et al.	
	114	20080133004		2008-06-05	White	
	115	20080147182		2008-06-19	Righini et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	116	20080154356		2008-06-26	Obermiller et al.	
	117	20080177381		2008-07-24	Navia et al.	
	118	20080183280		2008-07-31	Agnew et al.	
	119	20080183283		2008-07-31	Downing	
	120	20080195200		2008-08-14	Vidlund et al.	
	121	20080190989		2008-08-14	Crews et al.	
	122	20080199843		2008-08-21	Haverich et al.	
	123	20080200977		2008-08-21	Paul et al.	
	124	20090005857		2009-01-01	Ischinger	
	125	20090030511		2009-01-29	Paniagua et al.	
	126	20090043383		2009-02-12	McGregor et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	127	20090054969		2009-02-26	Salahieh	
	128	20090062907		2009-03-05	Quijano et al.	
	129	20090112309		2009-04-30	Jaramillo et al.	
	130	20090132032		2009-09-15	Cribier	
	131	20090157175		2009-06-18	Benichou	
	132	20090164005		2009-06-25	Dove et al.	
	133	20090187241		2009-07-23	Melsheimer	
	134	20090248149		2009-10-01	Gabbay	
	135	20090254175		2009-10-08	Quijano et al.	
	136	20090281609		2009-11-12	Benichou et al.	
	137	20090030511		2009-01-29	Paniagua et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

	138	20100030259		2010-02-04	Pavcnik et al.	
	139	20100036479		2010-02-11	Hill et al.	
	140	20100036484		2010-02-11	Hariton et al.	
	141	20100048987		2010-02-25	Khairkhahan	
	142	20100049312		2010-02-25	Edoga et al.	
	143	20100131054		2010-05-27	Tuval et al.	
	144	20100161036		2010-06-24	Pintor et al.	
	145	20100185277		2010-07-22	Braido et al.	
	146	20100217382		2010-08-26	Chau et al.	
	147	20100234878		2010-09-16	Hruska	
	148	20100241069		2010-09-23	Hatten	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	149	20100249918		2010-09-30	Zhang	
	150	20100256749		2010-10-07	Tran et al.	
	151	20100256751		2010-10-07	Rowe et al.	
	152	20100312333		2010-12-09	Navia et al.	
	153	20110015728		2011-01-20	Jimenez et al.	
	154	20110040375		2011-02-17	Letac et al.	
	155	20110004299		2011-01-06	Navia et al.	
	156	20110087322		2011-04-14	Letac et al.	
	157	20110137409		2011-06-09	Yang et al.	
	158	20110146361		2011-06-23	Davidson et al.	
	159	20110153009		2011-06-23	Navia et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	160	20110166636		2011-07-07	Rowe	
	161	20110178597		2011-07-21	Navia et al.	
	162	20110218619		2011-09-08	Benichou et al.	
	163	20110224607		2011-09-15	Vogelbaum et al.	
	164	20110240511		2011-10-06	Bolton et al.	
	165	20110300625		2011-12-08	Paniagua et al.	
	166	20110301700		2011-12-08	Fish et al.	
	167	20120078343		2012-03-29	Fish	
	168	20120078356		2012-03-29	Fish et al.	
	169	20120095551		2012-04-19	Navia et al.	
	170	20120158128		2012-06-21	Gautam et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	171	20120185038		2012-07-19	Fish et al.	
	172	20120310041		2012-12-06	Paniagua et al.	
	173	20130304201		2013-11-14	Navia et al.	
	174	20140039613		2013-02-06	Navia et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

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	1441672	EP		2011-09-14	Edwards Lifesciences PVT, Inc.		☐
	2	1603493	EP		2005-12-14	Edwards Lifesciences Corp.		☐
	3	1621162	EP		2012-05-30	Edwards Lifesciences PVT, Inc.		☐
	4	2000115	EP		2011-05-04	Edwards Lifesciences PVT, Inc.		☐
	5	2055266	EP		2012-02-15	Edwards Lifesciences PVT, Inc.		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	6	2260796	EP		2013-02-20	Edwards Lifesciences PVT, Inc.		☐
	7	2355361C	RU		2009-05-20	Zhuravleva Irina Jur Evn		☐
	8	1991/017720	WO		1991-11-28	Andersen et al.		☐
	9	1992/017118	WO		1992-10-15	Shturman Cardiology Systems, Inc.		☐
	10	1998/029057	WO		1998-07-09	Cordis Corporation		☐
	11	1999/30646	WO		1999-06-24	St. Jude Medical, Inc.		☐
	12	2000/012164	WO		2000-03-09	The Cleveland Clinic Foundation		☐
	13	2001/002031	WO		2001-01-11	Biomedical Design, Inc.		☐
	14	2003/047468	WO		2003-06-12	Percutaneous Valve Technologies		☐
	15	2003/092554	WO		2003-11-13	The General Hospital Corporation		☐
	16	2004/026124	WO		2004-04-01	The Cleveland Clinic Foundation		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	17	2004/082527	WO		2004-09-30	Edwards Lifesciences Corp.		☐
	18	2006/095342	WO		2006-09-14	Technion Research & Development Foundation Ltd.		☐
	19	2007/138572	WO		2007-12-06	Mor Research Applications Ltd.		☐
	20	2008/063537	WO		2008-08-14	St. Jude Medical, Inc.		☐
	21	2008/106531	WO		2008-09-04	Edwards Lifesciences Corp.		☐
	22	2009/156471	WO		2009-12-30	Iberhospitex, S.A.		☐
	23	2009/052188	WO		2009-04-23	Edwards Lifesciences Corp.		☐
	24	2010/024801	WO		2010-03-04	Cardiokinetix, Inc.		☐
	25	2010/027363	WO		2010-03-11	Merlin MD PTE Ltd.		☐
	26	2010/080594	WO		2010-07-15	Edwards Lifesciences Corp.		☐
	27	2010/117541	WO		2010-10-14	Medtronic Vascular Inc.		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	28	2011/109433	WO		2011-03-11	Paniagua et al.		☐
	29	2011/109450	WO		2011-09-09	Colibri Heart Valve LLC		☐
	30	2012/006124	WO		2012-01-12	Fish		☐
	31	2012/040643	WO		2012-03-29	Fish et al.		☐
	32	2012/082952	WO		2012-06-21	Fish et al.		☐

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	Affidavit of Dr. Paolo Angelini, M.D., signed August 25, 2009	☐
	2	Affidavit of Dr. Gervasio A. Lamas, M.D., signed September 3, 2009	☐
	3	ANDERSEN, H.R. et al., "Transluminal implantation of artificial heart valve" European Heart Journal, 1992, 13, pp. 704-708	☐
	4	"Artificial heart valve" http://en.wikipedia.org/Artificial_heart_valve, printed May 13, 2009	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	5	BONHOEFFER, Philipp M.D. et al., "Percutaneous Insertion of the Pulmonary Valve" J of the Amer College of Cardiology, Vol 39, No 10, Elsevier Science, Inc. 2002, pp 1664-1669, London, UK, and Paris, FR	☐
	6	BONHOEFFER, Philipp et al., "Percutaeous replacement of pulmonary valve in a right-centricle to pulmonary-artery prosthetic conduit with valve dysfunction" Early Report, The Lacet, Vol 356, October 21, 2000, pp. 1403-1405	☐
	7	BONHOEFFER, Philipp et al., "Transcatherter Implantation of a Bovine Valve in Pulmonary Position: A Lamb Study" Circulation J. of the Amer Heart Assoc, 2000; 102; pp. 813-816	☐
	8	BOUDJEMLINE, Younes et al., "Percutaneous pulmonary valve replacement in a large right ventricular outflow tract: An experimental study" J. Am. Coll. Cardiol. 2004; 43; pp. 1082-1087	☐
	9	BRAGA-VILELA, A. et al., "Extracellular Matrix of Porcine Pericardium; Biochemistry and Collagen Architecture" J. Membr Biol., 2008	☐
	10	BREUER, Christopher K. M.D. et al., "Application of Tissue-Engineering Principles toward the Development of a Semilunar Heart Valve Substitute" Tissue Engineering, Vol 10, No. 11/12, 2004, pp. 1725-1736	☐
	11	CALE, A.R. et al., "Revisited: a descending thorasic aortic valve to treat prosthetic valve insufficiency" Ann Thorac Surg, May 1993, 55(5), pp. 1218-2	☐
	12	CERROLAZA, M et al., "A comparison of the hydrodynamical behaviour of three heart aortic prostheses by numerical methods" no date provided /cm/	☐
	13	CHEW, G.G. et al., Abstract for "Simulation of Damage in a Porcine Prosthetic Heart Valve" J. Med. Eng. Technol., 1999 Sep-Oct; 23(5): 178-89 (Abstract only)	☐
	14	CHRISTIE G.W. et al., Abstract for "On Stress Reduction in Bioprosthetic Heart Valve Leaflets by the Use of a Flexible Stent" J. Card Surg, 1991 Dec; 6(4) pp. 476-81 (Abstract only)	☐
	15	"Collagen" http://en.wikipedia.org/wiki/Collagen, printed May 13, 2009 ~~ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/~~	☐

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	16	COLLINS, J. J., Jr, "The Evolution of artificial heart valve" N. Engl J Med, 1991 Feb 28; Vol. 324(9), pp. 624-626	☐
	17	CORDEN, J. et al., "The influence of open leaflet geometry on the haemodynamic flow characteristics of polyrethane trileaflet artificial heart valve" PubMed medline query, page 1 of 1 no date provided /cm/	☐
	18	CRIBIER, Alain et al., "Percutaneious Transcatheter Implantation of an Aoritc Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description" Circulation J of the Amer Heart Assoc, originally published online Nov 25, 2002	☐
	19	Edwards Lifesciences Receives FDA Approval for New Heart Valve, http:www.medicalnewstoday.com/articles/149588.php, May 11, 2009	☐
	20	FISH, R. David, "Percutaneous Heart Valve Replacement: Enthusiasm Tempered" Circulation J of the Amer Heart Assoc, 2004; Vol. 110; pp. 1876-1878	☐
	21	FISHBEIN, M.C. et al., "Cardiac pathology after aortic valve replacement using Hufnagel trileaflet prostheses: study of 20 necropsy patients" Ann Heart J., April 1975, 89(4), pp. 443-448	☐
	22	GLOECKNER, D. Claire et al., "Mechanical Evaluation and Design of a Multilayered Collagenous Repair Biomaterial" J. of Biomedical Materials Research Part A, Vol. 52 Iss 2, PP 365-373, Published online Aug. 15, 2000, Wiley Periodicals, Inc.	☐
	23	GRUBE, 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 (Abstract only)	☐
	24	HANLON, JG et al., "Pre-use intraoperative testing of autologous tissue for valvular surgery: a proof of concept study" J. Heart Valve Dis, Nov 1999; 8(6); pp. 614-23	☐
	25	BECH-HANSSEN, Odd, M.D. et al., "Aortic Prosthetic Valve Desing and Size: Relation to Doppler Echocardiographic Finding and Pressure Recovery --- An In Vitro Study" J. Am Soc Echocardiography 2000; Vol. 13, pp. 39-50	☐
	26	HASENKAM, J.M. et al., "A model for acute haemodynamic studies in the ascending aorta in pigs" Cardiovasc Res, July 1988, 22(7), pp. 464-71 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/	☐

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	27	HIESTER,E.D. et al., "Optimal bovine pericardial tissue selection sites. I. Fiber architecture and tissue thickness measurements." J. Biomed Mater Res, 1998, Feb, 01; 39(2), pp. 207-14	☐
	28	HUFNAGEL, Charles A., M.D., "Basic Concepts in the Development of Cardiovascular Prosthes" The American Journal of Surgery, Vol 137, March 1979	☐
	29	HUFNAGEL, Charles.A., MD et al., "In the beginning. Surgical Correction of Aortic Insufficiency" 1954; Ann Thorac Surg 1989 May; 47(3), pp. 475-476	☐
	30	HUFNAGEL, Charles.A., MD et al., "Late follow-up of ball-valve prostheses in the descending thoracic aortia", J. Throrac Cardiovasc Surg, December 1976, 72(6), pp. 900-909	☐
	31	HUFNAGEL, Charles.A., MD et al., "Surgical Correction of Aortic Insufficiency" Surgery Vol 35, May, 1954 No. 5	☐
	32	HUFNAGEL, Charles A., "Vessels and Valves", Sec. 1: Development of Cardiac Surgery, Chap 7, pp. 43-55 no date provided /cm/	☐
	33	Introduction to Stereomicroscopy, http://www.microscopyu.com/articles/stereomicroscopy/stereointro.html, Copyright 2000-2012, printed on March 15, 2012	☐
	34	IOPATCH(R) Tutoplast(R) Processed Pericardium Directions for Use; http://www.iopinc.com/ surgeons_and_medical_professionals/iopatch/directions.asp, printed on June 2, 2009	☐
	35	KNUDSEN, LL et al., "Catheter-implanted prosthetic heart valves. Transluminal catheter implantation of a new expandable artificial heart valve in the descending thoracic aorta in isolated vessels and closed chest pigs" Int J. Artif Organs, May 1993, 16(5); pp. 253-62	☐
	36	LAX, Jorge A., M.D., et al. "Estimation of the Ejection Fraction in Patients with Myocardial Infarction Obtained from the Combined Index of Systolic and Diastolic Left Ventricular Function: A New Method" J of the American Soc of Echocardiography, Vol 13, No. 2 no date provided /cm/	☐
	37	LIAO, Jun et al., "Molecular orientation of collagen in intact planar connective tissues under biaxial stretch" Acta Biomateriala, Vol. 1, Iss. 1, January 2005, pp 45-54	☐

~~ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/~~

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	38	LIAO, K X et al., "Two-dimensional mechanical and ultrastructural correlates of bovine pericardium for prosthetic valves" ASAIO Trans, June 1, 1991, 37(3); pp. 341-51	☐
	39	LS, Yu et al., "New Polyurethane valves in new soft artificial heart" ASAIO Trans 1989 Jul-Sep; 35(3), pp. 301-304	☐
	40	MENDELSON, Karen et al., "Heart Valve Tissue Engineering: Concepts, Approaches, Progress, and Challenges" Ann Biomed Eng, 2006 Dec; 34(12); 1799-1819; published online 2006 October 12 doi:10.1007/s/10439-006-9163-z	☐
	41	MIRNAJAFI, A. et al. "The effects of collagen fiber orientation of the flexural properties of pericardial heterograft biomaterials" Biomaterials, 2005 Mar; 26(7): pp. 795-804	☐
	42	MIRZAIE, M. et al., "A new storage solution for porcine aortic valves" Ann Thorac Cardiovasc Surg. 2007 Apr;13(2), pp. 102-109	☐
	43	MOAZAMI, N. et al., "Transluminal aortic valve placement. A feasibility study with a newly designed collapsible aortic valve" ASAIO J, Sept-Oct 1996, 42(5), pp. 381-385	☐
	44	NIENABER C., M.D. et al., "Nonsurgical Reconstruction of Thoracic Aortic Dissection By Stent-Graft Placement" N. Eng. J. Med, May 20, 1999, Col. 340, No. 20	☐
	45	NOORLANDER, Maril L. et al., "A Quantitative Method to Determine the Orientation of Collagen Fibers in the Dermis" The J. of Histochemistry & Cytochemistry, Vol 50(11): 2002, pp. 1469-1474	☐
	46	NUNN, D.B., "Structural Failure of Dacron Arterial Grafts" Seminars in Vascular Surgery, Col 12, No. 1 (March), 1999, pp. 88-91	☐
	47	Optical Microscope, Wikipedia, http://en.wikipedia.org/wiki/Stereomiscroscope, May 13, 2009	☐
	48	Orthogonality, http://en.wikipedia.org/wiki/Orthogonal, May 13, 2009	☐

~~ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/~~

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	49	PANIAGUA, DAVID, ET AL., Percutaneous Heart Valve In the Chronic In Vitro Testing Model, Circulation, 2002, pp. 51-52, Vol. 106, American Heart Association, US.	☐
	50	PANIAGUA, DAVID ET AL., First Human Case of Retrograde Transcatheter Implantation of an Aortic Valve Prosthesis, Texas Heart Institute Journal, 2005, pp. 91-96, Vol. 32, US.	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Cheryl Miller/	Date Considered	07/13/2015

*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. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14253650
Filing Date	2014-04-15
First Named Inventor	David PANIAGUA
Art Unit	3738
Examiner Name	Not assigned yet
Attorney Docket Number	109978.10104

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)	2014-05-23
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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

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.

/Cheryl Miller/ 07/13/2015

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	PANIAGUA ET AL.
	Examiner	**Art Unit**
	CHERYL MILLER	3738

CPC						
Symbol					**Type**	**Version**
A61F		2	/	2412	F	2013-01-01
A61F		2002	/	9534	A	2013-01-01
A61F		2	/	2439	A	2013-01-01
Y10T		29	/	49412	A	2015-01-15
A61F		2230	/	0078	A	2013-01-01
A61F		2	/	2415	I	2013-01-01
A61F		2	/	2418	I	2013-01-01
A61F		2	/	2436	I	2013-01-01
Y10S		623	/	917	A	2013-01-01
A61F		2	/	24	I	2013-01-01
A61F		2	/	2475	I	2013-01-01
A61F		2250	/	0039	A	2013-01-01
A61B		8	/	12	I	2013-01-01
A61F		2	/	2433	I	2013-01-01
A61F		2	/	2427	I	2013-01-01
A61F		2220	/	0008	A	2013-01-01
A61F		2220	/	0016	A	2013-01-01
A61F		2220	/	0075	A	2013-01-01
A61F		2210	/	0014	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/C.M./ Examiner.Art Unit 3738	06/30/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	5	
/THOMAS J SWEET/ Supervisory Patent Examiner.Art Unit 3738	07/07/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	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)	06/30/2015 (Date)	**Total Claims Allowed:** 5	
/THOMAS J SWEET/ Supervisory Patent Examiner.Art Unit 3738 (Primary Examiner)	07/07/2015 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 8

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14253650	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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17		33										
	2		18	1	34										
	3		19	2	35										
	4		20	3	36										
	5		21	4	37										
	6		22	5	38										
	7		23												
	8		24												
	9		25												
	10		26												
	11		27												
	12		28												
	13		29												
	14		30												
	15		31												
	16		32												

/C.M./ Examiner.Art Unit 3738	06/30/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	5	
/THOMAS J SWEET/ Supervisory Patent Examiner.Art Unit 3738	07/07/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

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.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

29880 7590 07/28/2015

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
07/28/2015	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

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	14/253,650	PANIAGUA ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

All participants (applicant, applicant's representative, PTO personnel):

(1) *CHERYL MILLER (Examiner)*. (3)_____.

(2) *Mark Yaskanin (Reg.No.45,246)*. (4)_____.

Date of Interview: *16 July 2015*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1/34*.

Identification of prior art discussed: *n/a*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Attorney for Applicant contacted Examiner to bring to attention a typographic error in the examiners amendment in notice of allowance dated July 16, 2015. The examiners amendment makes changes to "claim 1". This is a typographical error, and the examiners amendment should have referenced independent claim 34. It is noted that the examiners amendment to claim 1 is intended to refer to claim 34, which has been renumbered as claim 1 upon issue.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CHERYL MILLER/ Examiner, Art Unit 3738	/THOMAS J SWEET/ Supervisory Patent Examiner, Art Unit 3738

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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
14/253,650	04/15/2014	3738	800	109978.10104	5	1

CONFIRMATION NO. 5427

CORRECTED FILING RECEIPT

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

OC000000078320723

Date Mailed: 07/28/2015

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;

Applicant(s)

Colibri Heart Valve LLC, Broomfield, CO;

Assignment For Published Patent Application

Colibri Heart Valve LLC, Broomfield, CO

Power of Attorney: The patent practitioners associated with Customer Number 29880

Domestic Priority data as claimed by applicant

This application is a CON of 13/675,665 11/13/2012
which is a CON of 10/887,688 07/10/2004 PAT 8308797
which is a CIP of 10/037,266 01/04/2002 ABN

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: 05/01/2014
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/253,650**

Projected Publication Date: Not Applicable

Non-Publication Request: No

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

PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

Preliminary Class

623

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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 07/16/2015
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.
14/253,650	04/15/2014	David PANIAGUA	109978.10104	5427

TITLE OF INVENTION: PERCUTANEOUS BIOPROSTHETIC HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM

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	10/16/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
MILLER, CHERYL L	3738	623-001260

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 /Mark L. Yaskanin/ Date 29 July 2015
Typed or printed name Mark L. Yaskanin Registration No. 45,246

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:	14253650
Filing Date:	15-Apr-2014
Title of Invention:	PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
First Named Inventor/Applicant Name:	David PANIAGUA
Filer:	Mark Lauren Yaskanin/Carol Donahue
Attorney Docket Number:	109978.10104

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:	23057469
Application Number:	14253650
International Application Number:	
Confirmation Number:	5427
Title of Invention:	PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM
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:	109978.10104
Receipt Date:	29-JUL-2015
Filing Date:	15-APR-2014
Time Stamp:	14:14:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$480
RAM confirmation Number	371
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 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 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	Applicant summary of interview with examiner	Colibri_10104_Statement_Re_Interview_Summary_2015-07-29.PDF	94490 0eaeb412c27dffd8efbc380d089dd074d6ed9f40	no	2
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	Colibri_10104_Issue_Fee_Transmittal_2015-07-29.PDF	87492 3a7a74d001a82e25751912834785dd61a4437baf	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30569 6344efc6750064c9c577d657f5b194fc99297743	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	212551		

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:		)	Group Art Unit: 3738
	PANIAGUA et al.	)	Examiner: Cheryl L. MILLER
Application No.:	14/253,650	)	Confirmation No.: 5427
Filed:	April 15, 2014	)	**STATEMENT OF THE SUBSTANCE OF EXAMINER'S INTERVIEW**
Atty. File No.:	109978.10104	)	
For: PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM		)	**(FILED ELECTRONICALLY)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Certificate of EFS-Web Transmission
I hereby certify that this correspondence is being electronically transmitted to the U.S. Patent & Trademark Office by the EFS-Web system on 29 July 2015.
Typed or printed name of person signing this certificate: Carol Donahue
Signature: /Carol Donahue/

Dear Madam:

Applicants' Attorney confirms that Applicants' Attorney called Examiner Cheryl Miller on July 16, 2015 to notify the Examiner that the Examiner's Amendment in the matter of U.S. Pat. App. No. 14/253,650 contained a typographic error as described in the Applicant-Initiated Interview Summary. Applicants' Attorney agrees with the content of the interview of July 16, 2015 as set forth and described in the Applicant-Initiated Interview Summary dated July 28, 2015.

Applicants believe no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 50-1943.

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: July 29, 2015

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
(Not for submission under 37 CFR 1.99)	First Named Inventor	David PANIAGUA	
Change(s) applied to document,	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

/J.E.B./
7/30/2015

	20	4055861		1977-11-01	Carpentier et al.	
	21	4056854		1977-11-08	Boretos et al.	
	22	4060081		1977-11-29	Yannas et al.	
	23	4082507		1978-04-04	Sawyer	
	24	4084268		1978-04-18	Ionescu et al.	
	25	4106129		1978-08-15	Carpentier et al.	
	26	4164045		1979-08-14	Bokros et al.	
	27	4172295		1979-10-30	Batten	
	28	4218782		1980-08-26	Rygg	
	29	4222126		~~1978-09-16~~	Boretos et al.	September 16, 1980
	30	4233493		1980-11-11	Nath et al.	

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
(Not for submission under 37 CFR 1.99)	First Named Inventor	David PANIAGUA	
Change(s) applied to document,	Art Unit	3738	
	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

/J.E.B./
7/30/2015

	86	5411552		1995-05-02	Andersen et al.	
	87	5413601		1995-05-09	Keshelava	
	88	5449384		1995-09-12	Johnson	
	89	5476506		1995-12-19	Lunn	
	90	5480424		1996-01-02	Cox	
	91	5489297		1996-02-06	Duran	
	92	5500015		1996-03-19	Deac	
	93	5509930		1996-04-23	Love	
	94	5522879		~~1995-06-04~~	Scopelianos	June 4, 1996
	95	5522881		1996-06-04	Lentz	
	96	5545215		1996-08-13	Duran	

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014	Application Number	14253650	14253650 - GAU: 3738
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-04-15	
(Not for submission under 37 CFR 1.99)	First Named Inventor	David PANIAGUA	
Change(s) applied	Art Unit	3738	
to document,	Examiner Name	Not assigned yet	
	Attorney Docket Number	109978.10104	

/J.E.B./
7/30/2015

	196	6582462		2003-06-24	Andersen et al.	
	197	6582464		2003-06-24	Gabbay	
	198	6599524		2003-07-29	Li et al.	
	199	6624890		2003-09-23	Backman et al.	
	200	6626938		2003-09-30	Butaric et al.	
	201	6652577		2003-11-25	Gianotti	
	202	6652578		2003-11-25	Bailey et al.	
	203	6553681		2003-04-29	Ekholm, Jr. et al.	
	204	6610088		2003-08-26	Gabbay	
	205	6666886		2003-12-23	Tranquillo et al.	
	206	6682559		~~2001-01-27~~	Myers et al.	January 27, 2004

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CM/

Receipt date: 05/23/2014

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14253650
	Filing Date	2014-04-15
	First Named Inventor	David PANIAGUA
	Art Unit	3738
	Examiner Name	Not assigned yet
	Attorney Docket Number	109978.10104

	127	20090054969		2009-02-26	Salahieh	
Change(s) applied to document, /J.E.B./ 7/31/2015	128	20090062907		2009-03-05	Quijano et al.	
	129	20090112309		2009-04-30	Jaramillo et al.	
	130	20090132032		~~2009-05-15~~	Cribier	May 21, 2009
	131	20090157175		2009-06-18	Benichou	
	132	20090164005		2009-06-25	Dove et al.	
	133	20090187241		2009-07-23	Melsheimer	
	134	20090248149		2009-10-01	Gabbay	
	135	20090254175		2009-10-08	Quijano et al.	
	136	20090281609		2009-11-12	Benichou et al.	
	137	20090030511		2009-01-29	Paniagua 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
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/253,650	09/08/2015	9125739	109978.10104	5427

29880 7590 08/19/2015

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 0 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.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

David PANIAGUA, Houston, TX;
Colibri Heart Valve LLC, Broomfield, CO;
R. David FISH, Houston, TX;

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Central District of California, Southern Division on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	12/5/2019	Central District of California, Southern Division

PLAINTIFF	DEFENDANT
Colibri Heart Valve LLC	Medtronic CoreValve LLC; and Medtronic plc

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	9,125,739	9/9/2015	Colibri Heart Valve LLC
2	8,900,294	12/2/2014	Colibri Heart Valve LLC
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Central District of California, Southern Division on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	12/5/2019	Central District of California, Southern Division

PLAINTIFF	DEFENDANT
Colibri Heart Valve LLC	Medtronic CoreValve LLC; and Medtronic plc

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	9,125,739	9/9/2015	Colibri Heart Valve LLC
2	8,900,294	12/2/2014	Colibri Heart Valve LLC
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy