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Paper 35
Date: August 25, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,
Petitioners,

v.

AORTIC INNOVATIONS, LLC,
Patent Owner.

IPR2022-00556
Patent 10,987,236 B1

Before JOHN G. NEW, JASON W. MELVIN, and RYAN H. FLAX,
Administrative Patent Judges.

NEW, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Petitioners Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively "Petitioner") have failed to establish by a preponderance of the evidence that challenged claims 1–4 of Patent Owner Aortic Innovations, LLC's ("Patent Owner") U.S. Patent No. 10,987,236 B1 (Ex. 1001, "'236 patent") is unpatentable.

A. Procedural History

On February 7, 2022, Petitioner filed its Petition (Paper 1, "Petition" or "Pet.") seeking *inter partes* review of claims 1–4 of the '236 patent. Patent Owner timely filed a Preliminary Response. Paper 8 ("Prelim. Resp."). On September 8, 2022, and pursuant to 35 U.S.C. § 314, we instituted *inter partes* review of challenged claims 1–4 of the '236 patent (Paper 10, "Institution Decision" or "Dec.").

After institution of trial, Patent Owner filed a Response (Paper 18, "PO Resp."), to which Petitioner filed a Reply (Paper 22, "Pet. Reply"), and Patent Owner, in turn, filed a Sur-Reply (Paper 27, "PO Sur-Reply").

Oral argument was held on June 16, 2023. A transcript of the oral argument is included in the record. Paper 34 ("Hearing Tr.").

B. Related Proceedings

Petitioner identifies as related matters *Edwards Lifesciences Corp. v. Aortic Innovations LLC*, PR2021-01527, challenging claims of US 10,792,172 B2 (the "'172 patent") (Final Written Decision entered March 10, 2023) and *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584, challenging claims of US 10,857,011 B2 (the "'011 patent") (Final Written Decision entered March 28, 2023). Pet. 108–109. Petitioner also identifies *Edwards Lifesciences Corp. v. Aortic Innovations LLC*, IPR2022-00193 challenging claims of US 10,881,538 B1 (the "'538 patent") (Final Written Decision entered April 24, 2023) and *Edwards Lifesciences Corp. v. Aortic Innovations LLC*, IPR2022-00034 concerning US 10,966,846 B2 (the "'846 patent") (Final Written Decision entered March 24, 2023). *Id.* at 109. The '236 patent is part of the same patent family, and shares a specification with, the '172, '011, '538, and '846 patents. *Id.*

Petitioner has appealed the Decision entered in IPR2022-00034 to the U.S. Court of Appeals for the Federal Circuit. *See* IPR2022-00034, Paper 51. Patent Owner has appealed the Decision entered in IPR2022-00193 to the same venue. *See* IPR2022-00193, Paper 15. Both appeals remain pending.

Petitioner and Patent Owner identify *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, No. 1-21-CV-01377 (D. Del., Sept. 28, 2021), where Patent Owner asserts, *inter alia*, the '236 patent against Petitioner, as

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an additional related matter. *See, e.g.*, Pet. 109; *see also* Ex. 1050 (complaint).

C. Real Parties-in-Interest

Petitioner identifies Edwards Lifesciences Corp. and Edwards Lifesciences LLC, as the real parties-in-interest. Pet. 108. Patent Owner identifies Aortic Innovations, LLC as the real party-in-interest. Paper 3 at 1. There is no dispute over the real parties-in-interest in this proceeding

D. The Instituted Grounds of Unpatentability

Petitioner contends that challenged claims 1–4 of the '236 patent are unpatentable based upon the following grounds, all of which have been instituted in this proceeding:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–4	103[1]	Cribier,[2] Walther[3]

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '236 patent have an effective filing date prior to the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103 throughout this Decision.

[2] A. Cribier et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien® Heart Valve Using the Transfemoral Approach*, 34(5) HERZ 347–56 (2009) ("Cribier") Ex. 1012.

[3] T. Walther et al., *Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of the SAPIEN + cloth trans-catheter heart*

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Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
2	1–4	103	Spenser,[4] Walther
3	1–4	103	Spenser, Spenser II[5]
4	1–4	102(e)	Levi[6]
5	1–4	103	Levi
6	1–4	103	Levi, Walther
7	1–4	103	Levi, Spenser II

Petitioner relies on the Declaration of Nigel Buller, M.D. (Ex. 1003). Patent Owner relies on the Declaration of Stephen J.D. Brecker, M.D. (Ex. 2002). We have reviewed the credentials of Petitioners' declarant, Dr. Buller, and Patent Owner's declarant, Dr. Brecker, and consider both to be qualified to provide the opinions for which their testimony has been submitted.

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valve in the Carpentier-Edwards Perimount valves, 40 EUR. J. CARDIO-THORACIC SURGERY 1120–26 (2011) ("Walther") Ex. 1007.

[4] Spenser et al. (US 7,510,575 B2, March 31, 2009) ("Spenser") Ex. 1010.

[5] Spenser et al. (WO 2006/005015 A2, January 12, 2006) ("Spenser II") Ex. 1011.

[6] Levi et al. (US 9,393,110 B2, July 19, 2016) ("Levi") Ex. 1008.

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E. The '236 patent

The '236 patent is entitled "Transcatheter Aortic Valve Repair Having Improved Paravalvular Seal." Ex. 1001, code (54). The '236 patent issued from Appl. Ser. No. 17/131,869, which claims priority through a series of continuation and divisional applications to Appl. No. 13/706,896, filed on December 6, 2012. *Id.* at codes (21), (60). The '236 patent also claims priority to Provisional Appl. No. 61/723,446, filed on November 7, 2012, and Provisional Appl. No. 61/567,458, filed on December 6, 2011. *Id.* at code (60).[7]

The '236 patent discloses an endograft device, including a transcatheter heart valve, used for endovascular repair of ascending aortic aneurysms. Ex. 1001, col. 2, ll. 51–52. Specifically, the Specification discloses that "[t]he endograft device also includes a valve element that is secured to the balloon-expandable frame at the proximal end of the second prosthetic component." *Id.* at col. 2, ll. 65–67. According to the

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[7] According to Petitioner, "[d]uring prosecution, Patent Owner stated that the application's 'effective filing date … is believed to be based on Provisional Patent Application No. 61/723,446, filed on November 7, 2012.'" Pet. 26 (quoting Ex. 1049, 274). Petitioner asserts that "the '236 patent is not entitled to a priority date of December 6, 2011 because the '458 provisional does not adequately support or enable the '236 patent's claims." *Id.* Because all the asserted references bear a publication or filing date that antedates the earlier priority date of the '458 provisional, we need not address whether the '236 patent claims are entitled to claim priority to the '458 provisional.

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Specification, none of the devices in clinical use for endovascular repair of ascending aortic aneurysms "have been designed with the purpose of endovascular repair of multiple types of ascending aortic aneurysms." *Id.* at col. 2, ll. 35–37.

> The Specification describes a need for a device
>
> that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions. A device is also needed that would allow for treatment of different coronary anatomical variations among the patient population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

Id. at col. 2, ll. 38–46.

Figure 11 of the '236 patent is reproduced below:

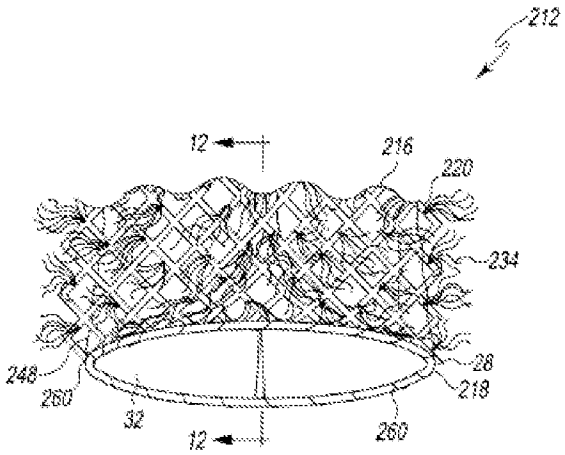

Fig. 11

Figure 11 of the '236 patent is a perspective view of a proximal end of a prosthetic component 212.

Component 212 includes a dual-frame structure with a circular inner frame 218 secured to circular outer frame 216 *via* a plurality of stitches 260. *Id.* at Fig. 11, col. 14, ll. 6–9.

Figure 13 of the '236 patent depicts a different view of the relevant portion of the invention and is reproduced below.

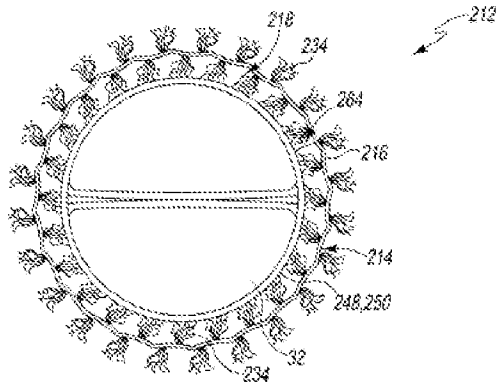

Fig. 13

Figure 13 of the '236 patent depicts a plan view of the prosthetic device 212

As illustrated in Figure 13, the device with circular dual frame component 214 includes an outer frame 216 secured to a balloon-expandable inner frame 218. *Id.* at Fig. 13, col. 14, ll. 6–8.

As also shown in Figures 11 and 13, the inner frame 218 houses the prosthetic valve 32. Ex. 1001, Fig. 13, col. 13, ll. 42. Collagen fibers 234 extend outwardly and inwardly from outer frame 216. *See id.* at Fig. 13, col. 12, ll. 43, 46–48. Outer frame 216 is a grid with diagonally oriented members as compared to those at the proximal end of the device. *See* Fig. 11. Figures 11 and 13 further illustrate fibers 234 extending outwardly from proximal section 220 and inwardly into the passageway formed by the

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stent. *Id.* at Figs. 11, 13, col. 14, ll. 30–33. According to the Specification, these collagen fibers 234 "aid in preventing paravalvular leaks and migration of the proximal component 212 within the aortic walls." *Id.* at col. 12, ll. 44–45.

The Specification further describes "[b]alloon-expandable frame 218 . . . as a balloon-expandable tubular stent 244." Ex. 1001, col. 13, ll. 41–43. "[S]tent 244 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration." *Id.* at col. 13, ll. 46–48. "When the inner frame 218 is unexpanded, the outer surface 248 of the stent 244 is spaced apart from the fibers 234 attached to the outer frame 216." *Id.* at Fig. 13, col. 14, ll. 13–16 When inner frame 218 is expanded, outer surface 248 of stent 244 engages fibers 234 through covering material 250, thereby closing gap 264 so that fibers 234 and covering material 250 create a seal between inner frame 218 and outer frame 216. *Id.* at Fig. 13, col. 14, ll. 19–32.

F. Representative Claim

Challenged claim 1 is the sole independent claim of the '236 patent, and is representative of the claims on appeal. Claim 1 recites:

> 1. A transcatheter aortic valve assembly comprising: an outer frame formed from a metallic material;
>
> an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the

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prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

wherein the outer frame is secured to the inner graft covering by stitching;

a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst,

wherein the first portion of fibers extend radially outwardly of the outer frame,

wherein the first portion of fibers is non-metallic; and a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst

wherein the second portion of fibers is non-metallic,

wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,

wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,

wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable to the radially expanded orientation and,

wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

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Ex. 1001, cols. 21–22, ll. 14–19.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art in November 2012 would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. Pet. 28. Petitioner asserts that such a skilled artisan would, where necessary, work with a medical device engineer to experiment with or manufacture a prosthetic heart valve. *Id.* at 28–29 (citing Ex. 1003 ¶ 45).

Patent Owner does not expressly challenge Petitioner's definition. Because Petitioner's definition is commensurate with the level of skill reflected by the '236 patent and the prior art, we adopt Petitioner's characterization of a person of ordinary skill in the art as being an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. Such a person would, when necessary, work with a medical device engineer to experiment with, or manufacture, a prosthetic heart valve. *See, e.g.*, Exs. 1006, 1010, 1030, 1033; *see also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

B. Claim construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2020). Under that standard, claim terms "are generally

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given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Petitioner argues that no claim terms require additional construction beyond the *Phillips* standard enunciated above. Pet. 23 (citing 37 C.F.R. § 42.100(b); *Phillips*, 415 F.3d 1312–13). Patent Owner does not dispute Petitioner's assertion and we consequently apply the claim terms according to their plain and ordinary meaning, as would have been understood by a person of ordinary skill in the art at the time of the invention, without further construction. If any claim language requires interpretation to analyze patentability based on the parties' positions and evidence, we discuss such interpretation in our patentability analysis below.

C. Principles of law

1. Burden of Proof

"In an [*inter partes* review], the petitioner has the burden from the

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onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). Therefore, in an *inter partes* review, the burden of proof is on the Petitioner to show that the challenged claims are unpatentable; that burden never shifts to the patentee. *See* 35 U.S.C. § 316(e); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) (citing *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015)).

2. Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373 (Fed. Cir. 2003) (quoting *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987)). It is well settled that "a reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (quoting *In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962)).

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3. Obviousness

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter 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. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In determining obviousness when all elements of a claim are found in multiple pieces of prior art, "the factfinder must further consider the factual questions of whether a person of ordinary skill in the art would be motivated to combine those references, and whether in making that combination, a person of ordinary skill would have had a reasonable expectation of success." *Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1380 (Fed. Cir. 2015); *see also WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999) ("When an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references."). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988); *see also In re Magnum Oil Tools*, 829 F.3d at 1381 (finding a party that petitions the

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Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so").

An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see In re Translogic Tech, Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). In *KSR*, the Supreme Court also stated that an invention may be found obvious if trying a course of conduct would have been obvious to a person of ordinary skill in the art:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. at 421. "*KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless 'the improvement is more than the predictable use of prior art elements according to their established functions.'" *In re Kubin*, 561 F.3d 1351, 1359–60 (Fed. Cir. 2009) (citing *KSR*, 550 U.S. at 417).

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We analyze the asserted challenges to patentability in accordance with the above-stated principles.

D. Grounds 1–7: "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame"

Challenged independent claim 1, from which each of claims 2–7 depends, expressly recites "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." Ex. 1001, col. 2, ll. 8–10. Petitioner argues that Spenser II, Walther, or Levi teaches this limitation of claim 1. *See* Pet. 47–49, 74–76, 97–99. Because we find this issue to be dispositive of this *inter partes* review, we focus our analysis upon this limitation.

1. Overview of Spenser II (Ex. 1011)

Spenser II is a PCT Publication that published on Jan. 12, 2006. Ex. 1011, codes (10), (43). On its face, therefore, Spenser II qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

Spenser II is directed to "the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses." Ex. 1011 ¶ 1. Spenser II teaches that prosthetic valves may be implanted "either through open heart surgery or by use of newer percutaneous methods," but with both methods paravalvular leaks are a known side effect." *Id.* ¶ 11. Spenser II further notes that "[p]ercutaneous introduction of medical devices is a preferred surgical procedure" and "considered safer and less invasive." *Id.*

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¶ 12.

Figure 22 of Spenser II is reproduced below:

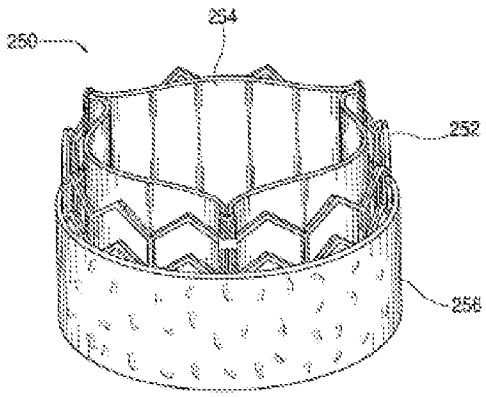

FIG. 22

Figure 22 of Spenser II is a perspective view of an embodiment of the prosthetic valve

Spenser II's Figure 22 shows an embodiment including a layer of compressible material, such as a cloth material, along an exterior surface of a stented valve. Ex. 1011 ¶ 85. Specifically, Figure 22 illustrates stented valve 250 including a circular stent structure 252 surrounding a valvular structure 254. *Id.* at Fig. 22, ¶ 144. "[S]tent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration." *Id.* at ¶ 144. The device further includes circular layer of compressible material 256 surrounding the outside of stent structure 252. *Id.* at Fig. 22, ¶ 145. "The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve," and may be formed of PET. *Id.* "[T]he compressible material 256 may resemble a

cloth or fabric having small fibers extending from the surface of the material." *Id.* This "compressible material expands after deployment at a treatment site" and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." *Id.* "In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm." *Id.*

2. Overview of Walther (Ex. 1007)

Walther is an article published in the European Journal of Cardio-thoracic Surgery, with a copyright date of 2011. Ex. 1007, 1120. Petitioner contends that Walther was published online on April 3, 2011, and qualifies as prior art under pre-AIA 35 U.S.C. § 102(b). Pet. 22. Patent Owner argues that Petitioner has failed to demonstrate that Walther is available as prior art. Prelim. Resp. 86–88.[8]

Walther is directed to a method of deploying a trans-catheter valve in a previously implanted degenerative bioprosthetic valve. Ex. 1007, 1120. Specifically, Walther describes implanting an Edwards SAPIEN transcatheter heart valve ("THV") cloth valve, "which is identical to the

[8] For purposes of this Decision, we need not resolve whether Walther qualifies as prior art because, for the reasons explained below, we are not persuaded that Walther discloses the dispositive limitation identified above.

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SAPIEN model, but has an added outer cloth for implantation into a degenerative bovine pericardium, Carpentier-Edwards Perimount (CEP) bioprosthetic valve." *Id.* Walther discloses that:

> The CEP surgical valves are made with a base that is more rigid than other valves. When a SAPIEN™ valve is expanded in the CEP valve, the rigid base does not easily conform to the profile of the expanded stent frame, which leaves gaps between the two valves, resulting in higher paravalvular leak. The addition of an outer cloth to the SAPIEN™ cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better 'fit' within surgical Perimount valves.

Id. Additionally, Walther discloses that the outer cloth "reduce[s] paravalvular leak," "increase[s] 'fit' within EW surgical Perimount valves [a benchtop valve]," and "promote[s] tissue ingrowth, which further decreases paravalvular leakage." *Id.*

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Figure 1 of Walther is reproduced below:

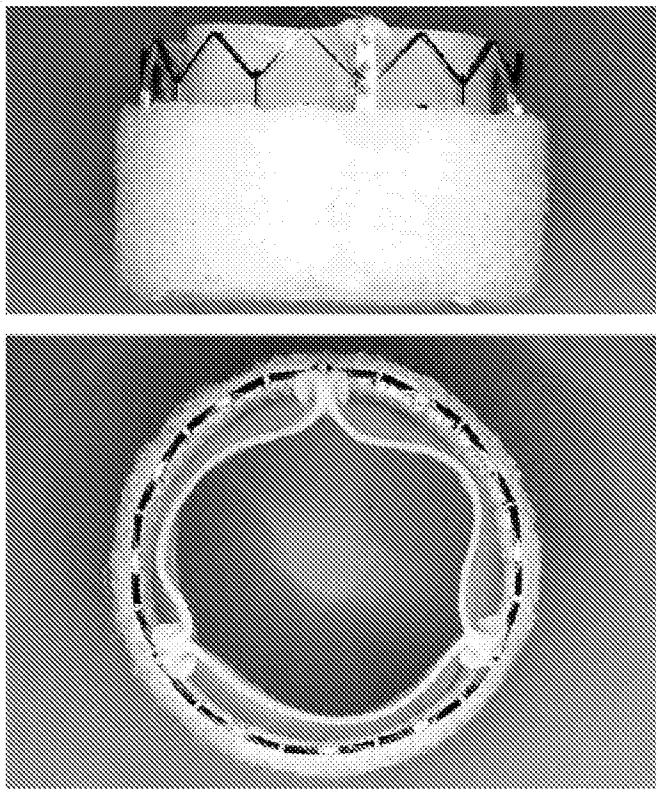


Fig. 1. Cloth valve.

Figure 1 of Walther depicts lateral (top) and longitudinal (bottom) views of the SAPIEN THV

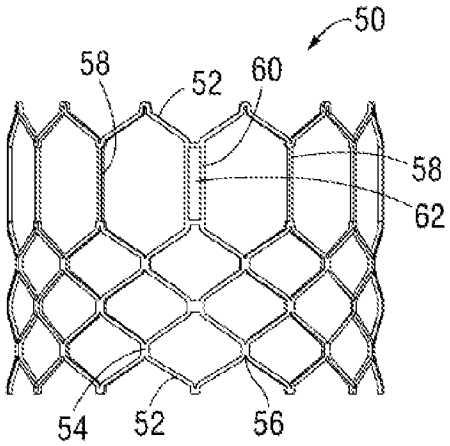
Figure 1 of Walther provides two photographic views (side view and top-down view) of the SAPIEN THV with a cloth encircling the lower two thirds of the valve. *Id.* at Fig. 1, 1121. Walther describes deploying the SAPIEN valves inside "various CEP valves" via the 33F Ascendra system. *Id.* at 1121.

3. Overview of Levi (Ex. 1008)

Levi is a U.S. patent that issued on July 19, 2016, from an application filed on October 5, 2011. Ex. 1008, codes (10), (22), (45). Thus, on its face, Levi qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

Levi is directed to a prosthetic heart valve. Ex. 1008, col. 1, ll. 16–18. Figure 11 of Levi is reproduced below:

FIG. 11



Levi's Figure 11 depicts a frame for use in a prosthetic heart valve

Specifically, Figure 11 illustrates frame 50 that:

> comprises multiple rows of circumferentially extending, angled struts **52** that are connected to each other at nodes, or connecting portions, **54** and **56**. The uppermost row of struts **52** are connected to an adjacent row of struts by a plurality of axially extending struts **58** and commissure window frame portions **60**. Each commissure frame portion **60** defines a slot, or commissure window, **62** for mounting a respective commissure of the valvular structure.

Id. at cols. 8–9, ll. 61–3.

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Figure 2 of Levi is reproduced below:

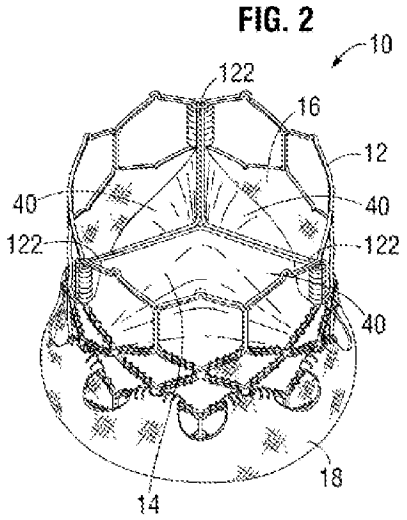

Figure 2 of Levi depicts an exemplary embodiment of a prosthetic heart valve

Figure 2 depicts a prosthetic heart valve 10 including valvular structure 16, surrounded by circular stent or frame 12. *Id.* at Fig. 2, col. 5, ll. 52–58. The bottom portion of frame 12 is covered by inner skirt 16 on the inside of frame 12 and outer skirt 18 on the outside of frame 12. *See id.* at Fig. 2, col. 5, ll. 52–58, col. 9, ll. 24–25, col. 13, ll. 49–50. Valvular structure 16 includes "three leaflets 40, collectively forming a leaflet structure, which can be arranged to collapse in a tricuspid arrangement." *Id.* at Fig. 2, col. 5, ll. 59–61. "[L]eaflets 40 are secured to one another at their adjacent sides to form commissures 122 of the leaflet structures." *Id.* at col. 11, ll. 35–37.

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Figure 20 of Levi is reproduced below:

FIG. 20

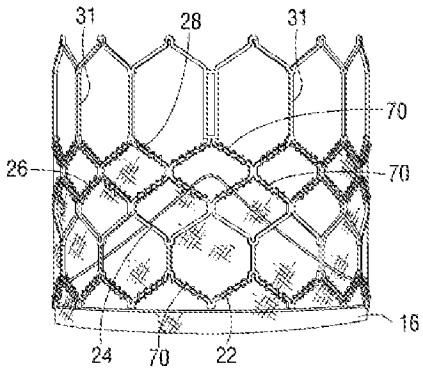

Figure 20 of Levi depicts the assembly of the inner skirt and frame of a prosthetic heart valve

Figure 20 depicts a valve with skirt 16 arranged on frame 12. *Id.* at Fig. 20, col. 10, ll. 5–17. Specifically, frame 12 includes struts 22, 24, 26, and 28. *Id.* at Fig. 20, col. 7, ll. 16–21. "[S]econd, third, and fourth rows of structures 24, 26, and 28 define two intermediate rows of cells defining openings 38. The fourth and fifth rows of struts 28 and 32, along with frame portions 30 and 31, define an upper row of cells defining openings 40." *Id.* at Fig. 20, col. 7, ll. 19–23. "[T]he upper edge of skirt 16 can be tightly secured to structures 28 with sutures 70." *Id.* at Fig. 20, col. 10, ll. 16–18. "[S]kirt 16 can also be secured to the first, second, and third rows of struts 22, 24, and 26, respectively, with sutures 70." *Id.* at col. 10, ll. 28–30.

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Figure 42 of Levi is reproduced below:

FIG. 42

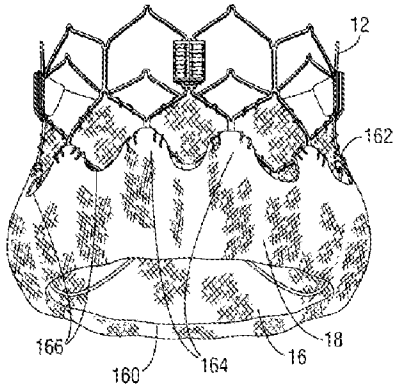

Figure 42 of Levi depicts aspects of an exemplary embodiment of a prosthetic heart valve

Figure 42 illustrates portions of the valve assembly including an outer skirt 18 with projections 164 that are sutured to the outer side of frame 12. *Id.* at Fig. 42, col. 13, ll. 54–61. Skirt 18 includes lower edge 160 that can be sutured to the lower edge of inner skirt 16 at the inflow end of the valve. *Id.* Outer skirt 12 includes excess material between the lower and upper edges. *Id.* at Figs. 2, 43, col. 13, ll. 62–66. Levi discloses that when

> valve **10** is deployed within the body the excess material of the outer skirt **18** can fill in gaps **5** between the frame **12** and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus. The outer skirt **18** therefore cooperates with the inner skirt **16** to avoid perivalvular leakage after implantation of the valve **10**.

Id. at col. 14, ll. 4–9.

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4. Analysis

a. Challenged claim 1

In our Final Written Decision in IPR2022-00034 (the "'034 IPR"), we addressed the issue of whether Petitioner had shown, by a preponderance of the evidence, that the limitation of challenged claim 1 reciting "wherein the outer seal is free of an outer graft covering between the fibers and the outer frame" was obvious over Walther, Spenser II, or Levi. In the '034 IPR, Petitioner relied upon these references as teaching this limitation, as it also does in the present *inter partes* review. *See* Pet. 47–49, 74–76, 97–99; IPR2022-00034, Paper 2 at 30, 53–54, 58, 85. In our Final Written Decision in that proceeding, we held that Petitioner had failed to meet its burden of showing that the limitation was anticipated or obvious over the references cited by Petitioner. *See* IPR2022-00034, Paper 50 at 39–51.

In the present *inter partes* review, we are presented with an essentially identical limitation of claim 1 of the '236 patent: "[W]herein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." The slight differences in the language of the respective limitation of claim 6 of the '846 patent in the '034 IPR and challenged claim 1 of the '236 patent do not significantly alter our reasoning. For context, claim 6 of the '846 patent requires that the "outer seal" is free of an external graft covering, whereas challenged claim 1 of the '236 patent more broadly requires that "the valve assembly" is free of an outer graft covering. The differences in the language of the two claims is insignificant, because both claims prohibit an external graft covering

between the "fibers and the outer frame." In the '236 patent, the fibers attached to the outer frame form a "sealing interface against the annulus and native valve leaflets of the patient," whereas in the '846 patent the "outer seal" is "formed of outwardly extending fibers positioned externally to the outer frame."

Similarly, there is little doubt that the "first portion of fibers" recited in claim 1 of the '236 patent corresponds to the "outwardly extending fibers" recited in claim 6 of the '846 patent. The fibers in independent claim 1 of the '236 patent are described as "extend[ing] radially outwardly of the outer frame" whereas in claim 6 of the '846 patent the fibers are described as "outwardly extending" and "positioned externally to the outer frame." The fibers of both claims are depicted in Figures 11 and 13 of the identical Specifications of both the '846 patent and the '236 patent (reproduced below) as "fibers 234 extend[ing] outwardly from the proximal section 220" of the prosthetic valve:

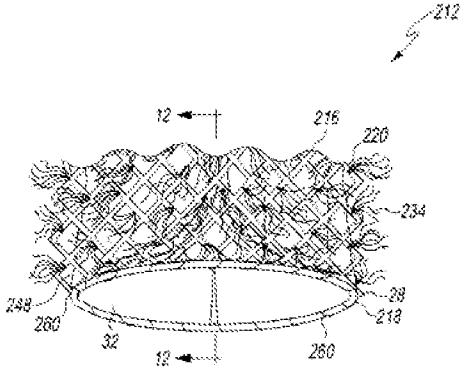

Fig. 11

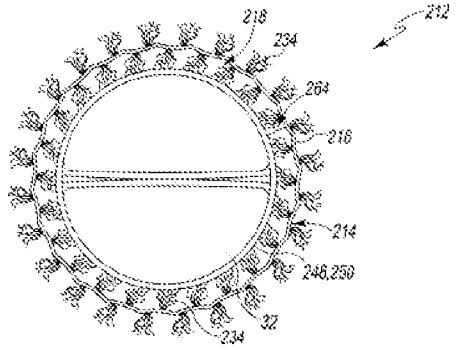

Fig. 13

Figures 11 and 13 of the '236 patent depict, respectively, perspective and plan views of the prosthetic device 212

Consequently, we discern no significant or patentable difference between these two limitations of claim 6 of the '846 patent and here-challenged claim 1 of the '236 patent.

Petitioner's arguments with respect to both of these limitations in the '034 IPR and in the present *inter partes* review are essentially the same. Briefly, Petitioner argues that that Spenser II teaches that compressible material 256 "is disposed along an outer surface of the stent structure 252" and is, therefore, attached to the frame. Pet. 75 (citing Ex. 1011 ¶ 145, Fig. 22; Ex. 1003 ¶ 192). According to Petitioner, Spenser II's compressible material is also "free of an outer graft covering between the fibers and the outer frame," because Spenser II never depicts or mentions an "outer graft covering" between the compressible material and frame. *Id.* at 75–76 (citing Ex. 1003 ¶ 205).

Petitioner also notes that Spenser, cited in combination with Spenser II in Ground 3, similarly does not depict or otherwise mention an "outer graft covering" on the exterior of frame 575. Pet. 76 (citing Ex. 1010, Fig. 44a). Petitioner reasons that, if Spenser II's compressible material were added to Figure 44a's frame, there would be no "outer graft covering" between the compressible material's fibers and the frame. *Id.* (citing Ex. 1003 ¶ 205).

With respect to Walther, Petitioner argues that Walther discloses that the outer cloth, which is stitched to the valve's perimeter, was the only modification made to SAPIEN. Pet. 47 (citing Ex. 1007, 1120). Petitioner

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contends that Walther does not state that the outer cloth includes a "graft covering" and the cloth does not include any visible graft covering.

Pointing to Figure 1 of Walther, Petitioner contends that Walther's outer cloth is also "free of an outer graft covering between the fibers and the outer frame." Pet. 47–48 (citing Ex. 1007, Fig. 1; Ex. 1003 ¶¶ 120, 140). Petitioner argues that Walther's fibers directly contact the frame without any visible intervening graft covering and Walther never mentions an "outer graft covering." *Id.* (citing Ex. 1007, Fig. 1; Ex. 1003 ¶ 120).

With respect to Levi, Petitioner argues that the reference teaches that Levi's valve is also free of an "outer graft covering" between the fibers of the outer skirt and the outer frame. Pet. 97 (citing Ex. 1003 ¶ 265). Petitioner asserts that Levi teaches that the outer skirt is sutured directly to the outer frame and the inner skirt. *Id.* at 97–98 (citing Ex. 1008, col. 13, ll. 58–61). Consequently, argues Petitioner, Levi does not include any "outer graft covering" on the exterior of the outer frame of the prosthetic heart valve. *Id.* at 98 (citing Ex. 1008, Fig. 20; Ex. 1003 ¶¶ 270–271).

Petitioner also argues that a person of ordinary skill in the art would have understood that if Levi's outer skirt is replaced with Walther's outer cloth, or Spenser II's compressible material, there would be no "outer graft covering" between the radially extending fibers of the outer cloth/compressible material (i.e., the first portion) and the outer frame, because Levi does not include any "outer graft covering" on the exterior of the outer frame. Pet. 98–99 (citing Ex. 1003 ¶ 266).

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In our Final Written Decision in the '034 IPR, we explained why we concluded that Petitioner had failed to meet its burden of proving, by a preponderance of the evidence, that any of the cited prior art references (*see supra* Section I.D) relied upon by Petitioner anticipate or render obvious the limitation of challenged claim 1 reciting "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." *See* IPR2022-00034, Paper 50 at 39–52. We adopt the same reasoning here.

As an initial matter, there is little disagreement between the parties and their experts that PET can be a graft covering. However, the disputed limitation requires something more. Specifically, it requires that "the outer seal is free of an outer graft covering between the fibers and the outer frame."

We are not persuaded that Petitioner has demonstrated, by a preponderance of the evidence of record, that Levi, Spenser II, or Walther, upon which Petitioner relies, teaches or suggests the incorporated limitation of claim 1 reciting "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." In our analysis, we must first determine what is meant by the claim term "outer graft covering."

As the plain language of the claim term suggests, an "outer graft covering" must cover some, or all, of the metallic outer frame of the prosthetic heart valve. Consequently, and according to the plain and ordinary meaning, we understand an "outer graft covering" to be a structure,

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such as a cloth, fabric or other material, that covers all, or part of, the metallic outer frame. Importantly, because an outer graft covering must cover the external surface of the outer frame, and specifically "between the first portion of fibers and the outer frame," we understand this claim term to mean that the cover must extend over (i.e., "cover") not only the struts and members of the metallic outer frame, but must also cover the open spaces, or interstices, in the spaces between those struts and members.

Consequently, the ordinary and customary meaning of the limitation "free of an outer graft covering between the fibers and the outer frame" is that there can be no such outer graft covering present anywhere between the outwardly extending fibers and the metallic outer frame.

The Specification of the '236 patent further reinforces of the ordinary meaning of an "outer graft covering," as claimed. Figure 11 of the '236 patent is reproduced again below:

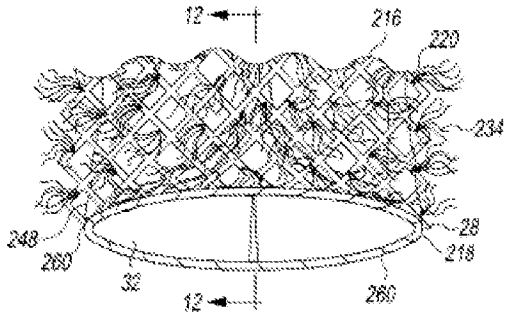

Fig. 11

Figure 11 of the '236 patent is a perspective view of a proximal end of a prosthetic component 212

Figure 11 depicts the outer seal, consisting of outwardly (i.e., radially) extending fibers 234 positioned externally to the outer frame 216, the fibers being directly attached at their proximal termini to the outer frame 216. No structure or material is depicted as covering the spaces between the struts and members of the frame or as being between the fibers and the frame. Figure 9 of the '236 patent, a segment of which is reproduced below, depicts a similar arrangement:

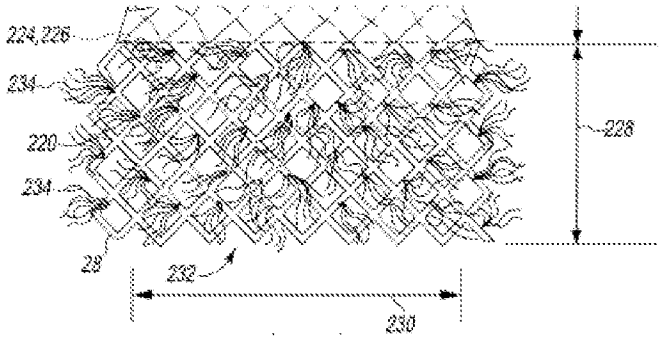

Figure 9 (detail) of the '236 patent depicts a lateral view of the claimed invention (*see* Ex. 1001, Fig. 19)

Figure 13 of the '236 patent, reproduced again below, depicts a similar situation from a view through the longitudinal axis of the prosthetic heart valve:

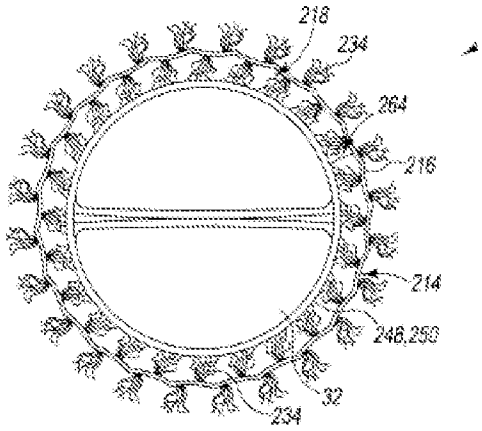

Fig. 13

Figure 13 of the '236 patent depicts a plan view of the prosthetic device 212

The Specification further discloses, with respect to the outwardly extending fibers, that:

> In some embodiments, a plurality of fibers *may be attached to the third section of the self-expanding frame* [i.e., the outer frame surrounding the heart valve]. When the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame may be engaged with the plurality of fibers.

Ex. 1001, col. 3, ll. 26–30 (emphasis added). The Specification elaborates that:

> In the illustrative embodiment, collagen fibers **234** are attached to the proximal section **220** to aid in preventing paravalvular leaks and migration of the proximal component **212** within the aortic walls. The fibers **234** extend outwardly from the proximal section **220** and inwardly into the passageway **232**.

Id. at col. 12, ll. 43–48.

The '236 patent Specification further discloses that:

> [T]he proximal section **360** of the self-expanding frame **350** [i.e., the portion surrounding the prosthetic valve, *see, e.g.*, col. 4, ll. 44–49] is formed in an open-cell stent configuration, and each of the sections **62**, **64** is formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections **360**, **62**, **64** may be formed in a single configuration, including the open-cell stent configuration, mesh-like stent configuration, or Z-stent configuration. The sections **60**, **62**, **64** may also be formed as a single monolithic component.
>
> *[T]he outer surface **314** of the proximal section **360** of the frame **350** is uncovered such that fluid is permitted to pass through the openings **318***. The outer surface **316** of the sections **62**, **64** are covered with low profile polyester, ePTFE, or other nonporous covering material **84** such that fluid is prevented from passing through the surface **320**.

Ex. 1001, col. 16, ll. 50–65 (emphasis added).

Given these disclosures of the '236 patent Specification, as well as the ordinary and customary meaning of the claim language (as would be understood by the ordinarily skilled artisan), as we explained above, an "outer graft covering" is a material or structure that covers at least a portion of the outer surface of the prosthetic heart valve, such that both the struts and members of the metallic outer frame, as well as the interstices between those struts and members, is covered by the outer graft covering.

Furthermore, our understanding of this claim limitation is consistent with that argued by Patent Owner's expert. As Dr. Brecker explained:

> The fibers in the patent's figures are sparsely distributed. See Figs. 8–9, 11–16, 20–22. Moreover, as is particularly clear in Figure 13 (but also present elsewhere), there are gaps and spaces between the fibers that extend to the frame. These gaps and spaces were, I believe, counterintuitive because a POSITA would

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> have, at the time, favored a solid, non-porous, graft material to address PVL—like the ones seen in Walther, Spenser II, and Levi. *See also* Ex. 1003 [Buller-Decl.] ¶¶153 (POSITA "would have understood that the openings between the fibers must be small … to form an effective sealing interface … If the openings were too wide, blood may disadvantageously leak through the openings."), 156. That a sparse distribution of fibers with significant gaps and spaces would be porous, at least until compressed within the body would form a seal is an unexpected result.

Ex. 2103 ¶ 160.

Bearing this claim term construction in mind, we deal with each prior art reference in turn.

i. Levi

In our Decision to Institute, we preliminarily determined that the PET "outer skirt" of Levi constitutes an "outer graft covering." Dec. 47 (citing IPR2022-00034, Paper 14 at 27). As we stated in that Decision, with reference to the '034 IPR:

> Similarly, Petitioner provides no persuasive evidence that Levi discloses the limitation of disclaimed independent claim 1 (from which challenged claim 6 depends) reciting "wherein the outer seal is free of an outer graft covering between the fibers and the outer frame." We agree with Patent Owner that, having argued that "Levi teaches that the outer skirt is sutured directly to the outer frame and the inner skirt" and "Levi does not include any 'outer graft covering' on the exterior of the outer frame," Petitioner has failed to recognize that Levi's outer skirt is an "outer graft covering."

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Id. at 51–52 (quoting IPR2022-00034, Paper 14 at 27). We concluded, for these same reasons, that the outer skirt of Levi corresponded to the "outer graft covering" of challenged claim 1. *Id.* This was particularly so because we also concluded in that Decision that the outer skirt of Levi does not meet the requirements of an outwardly extending fibers that form a first sealing interface. *Id.* at 51. Specifically, we concluded that:

> We agree with Patent Owner that nothing in Levi suggests that the "woven PET fabric" used to form the outer skirt expressly or inherently meets this requirement. We are not persuaded by Petitioner's contention that the laser-cut woven PET disclosed for use in Levi's outer skirt would necessarily exhibit the type of "hairiness" described for PET yarn used in other textile applications.

Id. at 51 (quoting IPR2022-00034, Paper 14 at 26 (citations omitted)).

Petitioner does not contest these conclusions in its Reply to Patent Owner's Response, or otherwise provide any additional argument or evidence to demonstrate that the outer skirt of Levi does not constitute the outer graft covering prohibited by challenged claim 1. Consequently, our initial determinations stand.

Furthermore, our understanding of an outer graft covering as a material or structure that covers at least a portion of the outer surface of the prosthetic heart valve, such that both the struts and members of the metallic outer frame, as well as the interstices between those struts and members, is covered by the outer graft covering, reinforces our prior conclusion that the outer skirt of Levi constitutes an outer graft covering that is prohibited by challenged claim 1. We consequently conclude that Petitioner has not met

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its burden with respect to demonstrating, by a preponderance of the evidence, that Levi teaches or suggests the limitation reciting "wherein the outer seal is free of an outer graft covering between the fibers and the outer frame."

ii. Spenser II

Spenser II teaches:

> In accordance with yet another preferred embodiment, a stented valve is provided wherein a compressible material, such as a clot[h] or fabric, extends around an exterior portion of the stent. The compressible material may be formed of polyethylene terephthalate (PET) and is configured to expand into the gaps.

Ex. 1011 ¶ 55. More specifically, Spenser II teaches that:

> To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252. The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve. In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm. *In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.* In various embodiments, the fibers may be straight, curved or hook-shaped. The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage.

Id. at ¶ 145 (emphasis added).

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Figure 22 of Spenser II, reproduced below, depicts an embodiment corresponding to these descriptions:

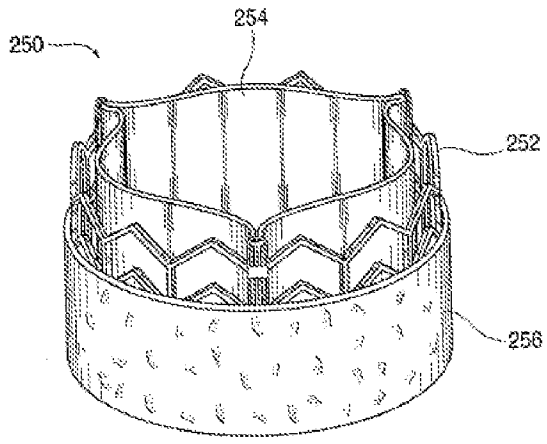

FIG. 22

Spenser II thus teaches a "a compressible material, such as a clot[h] or fabric, extending around the exterior portion" of the valve, as depicted in Figure 22, and may be "in the form of a sleeve." Ex. 1011 ¶¶ 55, 145. This cloth or material can be made of PET, and we find that a person of ordinary skill in the art would understand that a cloth or fabric can comprise woven fibers, as in the woven outer skirt of Levi. Ex. 1011 ¶ 145; Ex. 1008, col. 13, ll. 50–54; *see also* Ex. 1003 ¶ 118 (Petitioner's expert citing Merriam-Webster, *Cloth*, *available at*: https://www.merriam-webster.com/dictionary/cloth) (last visited August 8, 2023) (defining "cloth" as "a pliable material made usually by weaving, felting, or knitting natural or synthetic fibers and filaments")).

Both the description and Figure 22 of Spenser II show a cloth covering the proximal outer surface of the metallic outer frame of the

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prosthetic heart valve, including the spaces between the struts and members of the frame. Furthermore, the reference discloses that any fibers extending outwardly from the cloth arise from the surface of the cloth, and are not attached directly to the frame, as depicted in Figure 11 of the '236 patent Specification. Thus, even were such fibers made of the same material as the cloth, which is not clear from the reference's disclosure, the cloth would be between the surface-residing fibers and the metallic outer frame.

We conclude that a person of ordinary skill in the art would have recognized that the sleeve-like cloth or fabric of Spenser II corresponds to an outer graft covering between its fibers and its outer frame, and such a covering would be between Spenser II's surface fibers and its metallic outer frame. Such an outer graft cover is prohibited by the language of challenged claim 1, even if it and associated extending fibers are of the same material.

Petitioner argues that Spenser II does not "disclose or suggest any 'outer graft covering' between the outwardly extending fibers of the outward-facing surface of the compressible material (i.e., first portion) and the stent." Pet. 75–76. We agree that Spenser II does not use the term "outer graft covering." Nevertheless, we find that the Spenser II, including Figure 22, discloses that the cloth or fabric is disposed along the outer surface of the prosthetic heart valve, including over the spaces between the struts and members of the metallic outer frame. We conclude that this structural arrangement would be understood by a skilled artisan as describing that the cloth or fabric constituted an outer cover for the graft (i.e., the prosthetic valve). *See Phillips*, 415 F.3d at 1312–13.

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We therefore conclude, for the reasons we have explained, that Petitioner has failed to demonstrate, by a preponderance of the evidence, that Spenser II teaches or suggests "wherein the outer seal is free of an outer graft covering between the fibers and the outer frame."

iii. Walther

Walther teaches benchtop evaluation of the "*in vitro* hydrodynamic performance of the Edwards SAPIEN + cloth trans-catheter heart valve (THV) implanted within the Carpentier-Edwards Perimount (CEP) valve" as a testbed for evaluating prosthetic-valve-in-prosthetic-valve replacement techniques. Ex. 1007, Abstr.

Walther teaches that "[t]he current valve-in-valve study is focused on the use of an Edwards SAPIEN™ trans-catheter heart valve (THV) cloth valve (see Fig. 1), which is identical to the SAPIEN model, but has an added outer cloth." Ex. 1007, 1120. Walther further teaches that:

> The addition of an outer cloth to the SAPIEN™ cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better 'fit' within surgical Perimount valves.
>
> *Why is the outer cloth required?*
>
> - reduce paravalvular leak;
> - increase 'fit' within EW surgical Perimount valves; and
> - promote tissue ingrowth, which further decreases paravalvular leakage.

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Id. Walther states that the outer cloth layer consisted of "[a]n added poly(ethylene terephthalate) (PET) cloth … stitched onto the perimeter of each SAPIEN valve." *Id.* at 1121.

Walther depicts the SAPIEN-plus-cloth valve in both transverse and longitudinal views in Figure 1, which is reproduced again below:

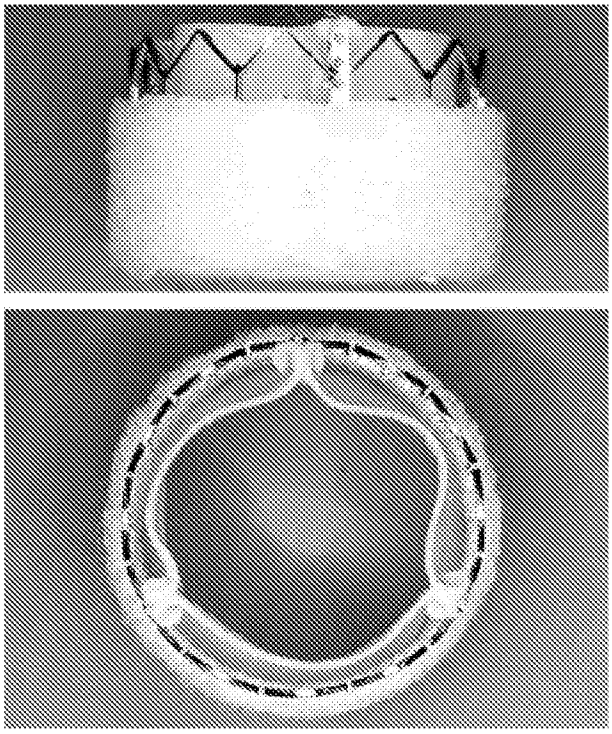

Figure 1 of Walther depicts lateral (top) and longitudinal (bottom) views of the prosthetic SAPIEN-plus-cloth valve

Walther provides no additional details concerning the structure of the SAPIEN-plus-cloth prosthetic valve.

Our reasoning with respect to Walther parallels our reasoning with respect to Spenser II. Walther teaches an outer cloth that circumferentially covers the entire proximal outer surface of the SAPIEN prosthetic valve. *See* Ex. 1007, Fig. 1. Other variants of Walther, such as Petitioner's

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SAPIEN 3 and the SAPIEN 3 Ultra TAVRs, also have a cloth cover extending circumferentially over the proximal outer surface, including over the open spaces between the struts and members of the outer frame of the prosthetic valve, and directly adjacent to the outer frame. *See, e.g.*, Ex. 2026, 7, 8. Furthermore, at least a portion of the outer cloth cover must be positioned between the outer frame of the valve and its outwardly extending fibers in a manner prohibited by the language of challenged claim 1 (much as we explained above regarding Spenser II).

We find that a person of ordinary skill in the art would understand that the outer cloth disclosed by Walther (as well as Petitioner's SAPIEN 3 and SAPIEN 3 Ultra variants of the SAPIEN valve disclosed by Walther) is qualitatively different from the examples of the claimed feature of "free of an outer graft covering between the fibers and the outer frame" described in the '236 patent showing the fibers attached directly to, and extending directly from, the struts and members of the outer frame, but leaving the struts and members of the outer frame uncovered. *See, e.g.*, Ex. 1001, col. 16, ll. 50–65, Figs. 9, 11, 13. We conclude that a skilled artisan would have found that the outer cloth of Walther would constitute an "outer graft covering" under our claim construction and that, as plainly shown in the photographs above, this covering resides between the surface fibers and the metal stent portion of the device, and therefore does not satisfy challenged claim 1's limitations.

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iv. Conclusion

For the reasons we have explained above, we conclude that Petitioner has failed to demonstrate, by a preponderance of the evidence, that the asserted grounds anticipate or render obvious challenged claim 1 of the '236 patent.

b. Challenged claims 2–4

Challenged claims 2–4 depend from independent claim 1 and, consequently, incorporate by reference all of the limitations of claim 1, including "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame." *See Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1357 (Fed. Cir. 2007) (holding that a "claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers" (quoting 35 U.S.C § 112, ¶ 4 (2000))).

Because we conclude that Petitioner has failed to meet its burden of showing, by a preponderance of the evidence, that the cited prior art anticipates or teaches this limitation, we arrive at the same conclusion for challenged claims 2–4.

III. CONCLUSION

For the reasons we have set forth above, and after having analyzed the entirety of the record and assigning appropriate weight to the cited supporting evidence, we determine that Petitioner has failed to establish, by

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a preponderance of the evidence, that challenged claims 1–4 of the '236 patent are unpatentable.

IV. ORDER

Accordingly, it is

ORDERED that Petitioner has failed to show by a preponderance of the evidence that claims 1–4 of the '236 patent are unpatentable;

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–4	103	Cribier, Walther		1–4
1–4	103	Spenser, Walther		1–4
1–4	103	Spenser, Spenser II		1–4
1–4	102(e)	Levi		1–4
1–4	103	Levi		1–4
1–4	103	Levi, Walther		1–4
1–4	103	Levi, Spenser II		1–4
Overall Outcome				1–4

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION, and
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

AORTIC INNOVATIONS, LLC,
Patent Owner.

IPR2022-00556
Patent 10,987,236 B2

Before JOHN G. NEW, JASON W. MELVIN, and RYAN H. FLAX,
Administrative Patent Judges.

NEW, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Petitioner Edwards Lifesciences Corporation, And Edwards Lifesciences LLC ("Petitioner") has filed a Petition (Paper 1, "Pet.") seeking *inter partes* review of claims 1–4 (all claims) of US Patent 10,987,236 B2 (Ex. 1001, the "'236 patent"). Patent Owner Aortic Innovations, LLC ("Patent Owner") timely filed a Preliminary Response. Paper 8 ("Prelim. Resp.").

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless … the information presented in the petition … and any response … shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition and the Preliminary Response, and the evidence of record, we determine that the evidence presented demonstrates a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of the challenged claims of the '236 patent.

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies Edwards Lifesciences Corp. and Edwards Lifesciences LLC, as the real parties-in-interest. Pet. 111. Patent Owner identifies Aortic Innovations, LLC as the real party-in-interest. Paper 4, 1.

B. Related Matters

Petitioner represents that it has filed a Petition for *inter partes* review of U.S. Patent No. 10,792,172 (the "'172 patent") in *Edwards Lifesciences*

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Corp. v. Aortic Innovations, LLC, IPR2021-01527 (Filed Sept. 10, 2021). Pet. 108. Petitioner states that it has also filed a Petition for *inter partes* review of U.S. Patent No. 10,857,011 ("the '011 patent") in *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2021-01584 (Filed Sept. 28, 2021). *Id.* at 108–109. Petitioner has additionally filed a Petition for *inter partes* review of U.S. Patent No. 10,966,846 (the "'846 patent"). *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-00034 (Filed Oct. 11, 2021). *Id.* at 109. Petitioner has also filed a Petition for *inter partes* review of U.S. Patent No. 10,881,538 (the "'538 patent"), *Edwards Lifesciences Corp. v. Aortic Innovations*, LLC, IPR2022-00193 (Filed Nov. 11, 2021). *Id.* Petitioner has also filed a Petition for *inter partes* review of U.S. Patent No. 11,129,735 (the "'735 patent"), *Edwards Lifesciences Corp. v. Aortic Innovations, LLC*, IPR2022-0549 (Filed February 4, 2022). *Id.* Petitioner asserts that the '236 patent is part of the same patent family and shares a common specification with the '172, '011, '846, '538, and '735 patents. *Id.*

Further, Petitioner and Patent Owner both identify *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, Case No. 1-21-CV-01377 (D. Del., filed Sept. 28, 2021), in which Patent Owner alleges infringement of the '735 patent, '538 patent, the '846 patent, and '236 patents by Petitioner. Pet. 109; Paper 3, 1.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–4 of the '236 patent are unpatentable, based upon the following grounds:

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Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–4	103	Cribier[1], Walther[2]
2	1–4	103	Spenser[3], Walther
3	1–4	103	Spenser, Spenser II[4]
4	1–4	102(e)	Levi[5]
5	1–4	103	Levi
6	1–4	103	Levi, Walther
7	1–4	103	Levi, Spenser II

Petitioner also relies upon, *inter alia*, the Declarations of Dr. Nigel P. Buller (the "Buller Declaration," Ex. 1003) and Sylvia D. Hall-Ellis (the "Hall-Ellis Declaration," Ex. 1059). Patent Owner relies upon, *inter alia*, the Declarations of Dr. Stephen J.D. Brecker (the "Brecker Declaration," Ex. 2002).

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[1] A. Cribier et al., *Technique of Transcatheter Aortic Valve Implantation with the Edwards-Sapien® Heart Valve Using the Transfemoral Approach*, 34 HERZ 347–56 (2009) ("Cribier") Ex. 1012.

[2] T. Walther et al., *Trans-Catheter Valve-in-Valve Implantation: in vitro Hydrodynamic Performance of the SAPIEN + Cloth Trans-Catheter Heart Valve in the Carpentier-Edwards Perimount Valves*, 40 EUR. JOUR. CARDIO-THORACIC SURG. 1120–26 (2011) ("Walther") Ex. 1007.

[3] Spenser et al. (US 7,510,575 B2, March 31, 2009) ("Spenser") Ex. 1010.

[4] Spenser et al. (WO 2006/005015 A2, January 12, 2006) ("Spenser II") Ex. 1011.

[5] Levi et al. (US 9,393,110 B2, July 19, 2016) ("Levi") Ex. 1008.

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D. The '236 Patent

The '236 patent is titled "Transcatheter Aortic Valve Repair Having Improved Paravalvular Seal." Ex. 1001, code (54). The '236 patent issued from Appl. No. 17/131,869 (the "'869 application"), which claims priority through a series of continuation and divisional applications to Appl. No. 13/706,896, filed on December 6, 2012. *Id.* at codes (21), (60). The '236 patent also claims priority to Provisional Appl. No. 61/723,446, filed on Nov. 7, 2012, and Provisional Appl. No. 61/567,458, filed on Dec. 6, 2011. *Id.* at code (60).[6]

The '236 patent discloses an endograft device, including a transcatheter heart valve, used for endovascular repair of ascending aortic aneurysms. Ex. 1001, col. 2, ll. 51–52. Specifically, the Specification discloses that "[t]he endograft device also includes a valve element that is secured to the balloon-expandable frame at the proximal end of the second prosthetic component." *Id.* at col. 2, ll. 65–67. According to the

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[6] According to Petitioner, "[d]uring prosecution of U.S. Patent No. 10,792,172 (the "'172 patent), a parent to the '236 patent, Patent Owner stated that the application's 'effective filing date . . . is believed to be based on Provisional Patent Application No. 61/723,446, filed on November 7, 2012.'" Pet. 26 (quoting Ex. 1049, 274).

Petitioner argues that "the '236 patent is not entitled to a priority date of December 6, 2011 because the '458 provisional does not adequately support or enable the '236 patent's claims." Pet. 21 (citing *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). Petitioner contends that "Patent Owner first added the disclosure of outwardly extending fibers in the November 2012 provisional." Pet. 26 (citing Ex. 1006 ¶ 24). Because all the asserted references bear a publication or filing date that antedates the earlier priority date of the'458 provisional, we need not address at this stage whether the '172 patent claims are entitled to claim priority to the '458 provisional.

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Specification, none of the devices in clinical use for endovascular repair of ascending aortic aneurysms "have been designed with the purpose of endovascular repair of multiple types of ascending aortic aneurysms." *Id.* at col. 2, ll. 35–37. The Specification describes a need for a device:

> [T]hat can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions. A device is also needed that would allow for treatment of different coronary anatomical variations among the patient population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

Id. at col. 2, ll. 37–46.

Figure 11 of the '236 patent is reproduced below.

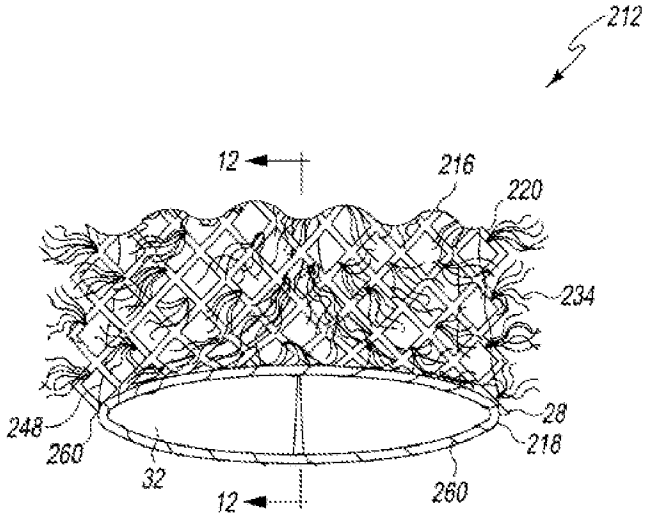

Fig. 11

Figure 11 of the '236 patent is a perspective view a proximal end of the proximal prosthetic component

As shown above, component 212 includes a dual-frame structure with circular inner frame 218 secured to circular outer frame 216 via a plurality of stitches 260. *Id.* at Fig. 11, col. 14, ll. 6–9.

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Figure 13 of the '236 patent depicts a different view of the relevant portion of the same embodiment as Figure 11 and is reproduced below.

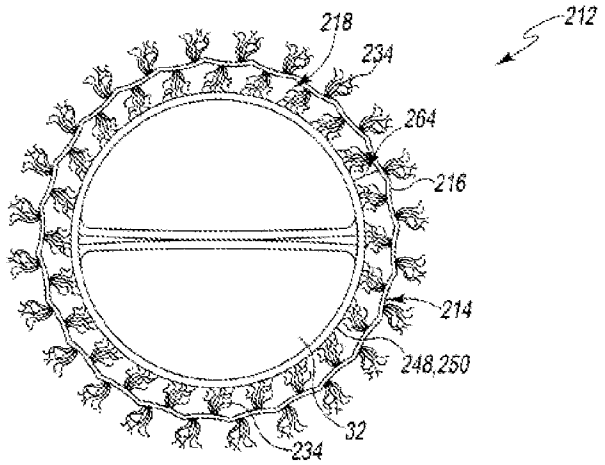

Fig. 13

Figure 13 of the '236 patent is a plan view of the proximal prosthetic component showing the inner frame in an unexpanded position

As shown above, the device with circular dual frame component 214 includes outer frame 216 secured to balloon-expandable inner frame 218. *Id.* at Fig. 13, 14, ll. 6–8.

As also shown in Figures 11 and 13, inner frame 218 houses prosthetic valve 32. *Id.* at Figs. 11, 13, col. 13, ll. 42. Collagen fibers 234 extend outwardly and inwardly from outer frame 216. *See id.* at Fig. 13, col. 12, ll. 43, 46–48. Outer frame 216 is a grid with diagonally oriented members as compared to those at the proximal end of the device. *See* Fig. 11. Figures 11 and 13 further illustrate fibers 234 extending outwardly from proximal section 220 and inwardly into the passageway formed by the stent. *Id.* at Figs. 11, 13, col. 14, ll. 30–33. According to the Specification, these collagen fibers 234 "aid in preventing paravalvular leaks and migration of

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the proximal component 212 within the aortic walls." *Id.* at col. 12, ll. 43–45.

The Specification further describes "[b]alloon-expandable frame 218 … as a balloon-expandable tubular stent 244." *Id.* at col. 13, ll. 41–43. "[S]tent 244 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration." *Id.* at col. 13, ll. 46–48. "When the inner frame 218 is unexpanded, the outer surface 248 of the stent 244 is spaced apart from the fibers 234 attached to the outer frame 216." *Id.* at Fig. 13, col. 14, ll. 13–16. When inner frame 218 is expanded, outer surface 248 of stent 244 engages fibers 234 through covering material 250, thereby closing gap 264 so that fibers 234 and covering material 250 create a seal between inner frame 218 and outer frame 216. *Id.* at Fig. 13, col. 14, ll. 19–32.

E. The Challenged Claims

Claims 1–4 are the challenged claims in this proceeding. *See* Section II.D. above. Claim 1, the sole independent claim, recites:

> 1. A transcatheter aortic valve assembly comprising:
>
> an outer frame formed from a metallic material;
>
> an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,
>
> wherein the outer frame is secured to the inner graft covering by stitching;

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a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst,

wherein the first portion of fibers extend radially outwardly of the outer frame,

wherein the first portion of fibers is non-metallic;

and a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst

wherein the second portion of fibers is non-metallic,

wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,

wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,

wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable to the radially expanded orientation and,

wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

Id. at cols. 21–22, ll. 14–19.

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F. Prosecution History of the '236 Patent

The '236 patent matured from U.S. Appl. Ser. No. 17/131,869, which was filed on December 23, 2020, with original claims 1–10. Ex. 1001, codes (21), (22); Ex. 1002, 253–355. The applicant filed a Preliminary Amendment on January 26, 2021, replacing the original claims with new claims 11–14. *Id.* at 235–36.

On February 11, 2021 and March 17, 2021, Patent Owner submitted terminal disclaimers to obviate a double patenting rejection over prior U.S. Patents 10,792,172 B2, 10,857,011 B2, 10,881,538 B1, and 10,888,441 B1. Ex. 1002, 205-207.

The Examiner issued a Notice of Allowance for claims 11 and 14–16, as claims 1–4 on March 24, 2021. Ex. 2002, 7–9. In the Reasons for Allowance, the Examiner stated that:

> [T]he prior art of record does not disclose or render obvious a first portion of fibers positioned radially outwardly of the outer frame and a second portion of fibers carried by the outer frame wherein the first portion of fibers and second portion of fibers are in overlapping radial alignment; the valve assembly being free from an outer graft covering between the first portion of fibers and the outer frame in combination with the other recited features.

Id. at 8.

III. ANALYSIS

A. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2020). Under that standard, claim terms "are generally

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given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing Phillips, 415 F.3d at 1312–17). Extrinsic evidence may also be considered, but is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Neither Petitioner nor Patent Owner proposes a construction for any claim terms apart from their plain and customary meaning. Pet. 29; *see generally* Prelim. Resp. Nor do we perceive, at this stage of the proceeding, a need to construe any claim terms of the '236 patent for purposes of determining whether to institute trial. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 295, 803 (Fed. Cir. 1999) (holding that "only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy"); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

B. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. Pet. 28. Petitioner contends that this

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skilled artisan would, where necessary, work as a member of a team in combination with a medical device engineer to experiment with or manufacture a prosthetic heart valve. *Id.* at 28–29 (citing Ex. 1003 ¶ 45). Patent Owner does not argue otherwise or propose an alternative definition. *See generally* Prelim. Resp.

At this stage of the proceeding and for purposes of our analysis in this Decision, we adopt Petitioner's definition because we find that that definition is consistent with the level of skill in the art, as reflected by the prior art. *See, e.g.*, Exs. 1007–1012; *see also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. Grounds 1 and 2: Obviousness over Cribier or Spenser and Walther

In each of the related cases IPR2021-01527, IPR2021-01584, IPR2022-00034, IPR2022-00193 (*see supra* Section II.B), each of the independent claims of the challenged patents recites some or all of the same, or substantially the same, limitations of claim 1 of the '236 patent reciting:

> 1. an outer frame formed from a metallic material;
>
> 2. an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

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3. wherein the outer frame is secured to the inner graft covering by stitching;

4. a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst,

5. wherein the first portion of fibers extend radially outwardly of the outer frame,

6. wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,

7. wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,

8. wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

9. wherein the valve assembly is balloon expandable to the radially expanded orientation

See IPR2021-01527, Ex. 1001 col. 21, ll. 7–23 (reciting limitations 1, 2, 3, 4, 5), cols. 21–22, ll. 48–15 (reciting limitations 1, 2, 3, 4, 5); IPR2021-01584, Ex. 1001 col. 21, ll. 4–30 (reciting limitations 1, 2, 3, 4, 5, 9), col. 22, ll. 12–44 (reciting limitations 1, 2, 3, 4, 5, 6, 9); IPR2022-00034, Ex. 1001 cols. 21–22, ll. 15–6 (reciting limitations 1, 2, 3, 4, 5, 6, 7, 8, 9); IPR2021-00193 cols. 21, ll. 14–55 (reciting limitations 1, 2, 3, 4, 5, 6, 8, 9), col. 22, ll. 15–55 (reciting limitations 1, 2, 3, 4, 5, 6, 8, 9).

In each of these related cases, we instituted *inter partes* review, finding that Petitioner had demonstrated a reasonable likelihood that at least

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one of the challenged claims reciting these same, or substantially the same, limitations of claim 1 of the '236 patent, are obvious over at least one of the proposed Grounds, which rely upon the same combinations of references cited in the present Petition's Grounds 1–7. *See, e.g.*, IPR2022-00034 Paper 14 at 4, 61 (Grounds 1 and 3–8 same as the present Petition Grounds 1–7); IPR2022-00193 Paper 15 at 4, 67 (Grounds 1–6 same as present Grounds 1–6). For these reasons and for consistency, our reasons for granting institution in these related cases is relevant here and we incorporate by reference herein our reasoning and conclusions from our Decisions to Institute in the related cases with respect to limitations 1–9 above of Claim 1 of the '236 patent. *See, e.g.*, IPR2022-00034 Paper 14 at 13–27; 31–43, 51–55, Paper 22 at 6–10; IPR2022-00193 Paper 15 at 18–33, 37–50, 59–66, Paper 21 at 8–11, 15–18.

Challenged claim 1 of the '236 patent additionally recites:

> a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst
>
> wherein the second portion of fibers is non-metallic,
>
> wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,
>
> …
>
> wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,
>
> …
>
> wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface

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Claim 1 also requires that the first and second portions of the fibers are non-metallic. Ex. 1001 col. 21, l. 31, col. 22, l. 2.

These limitations are not present in the claims of the challenged patents of the related *inter partes* reviews listed above. Therefore, the issue of whether Petitioner has demonstrated a reasonable likelihood of success of prevailing at trial here with respect to these specific limitations is dispositive of our Decision to Institute in the present case. Indeed, these additional limitations are the only ones Patent Owner disputes in the present proceeding in its Preliminary Response. *See generally* Prelim. Resp. We address these limitations, Petitioner's related contentions, and Patent Owner's arguments below.

1. Claim 1: first and second portion of radially positioned fibers forming a first and second sealing interface in overlapping radial alignment to form the respective first sealing interface and second sealing interface

a. Introduction

Claim 1 is the sole independent claim of the '236 patent. Claim 1 recites, *inter alia*, the following limitations:

> a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst,
>
> wherein the first portion of fibers extend radially outwardly of the outer frame,
>
> …
>
> and a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the

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> outer frame when the second portion of fibers is compressed thereagainst

Ex. 1001 col. 21, ll. 25–35. Petitioner argues that each of Walther, Spenser II, and Levi, teaches these limitations. *See* Pet. 36–47, 63–74, 88–97. We begin our analysis with Walther.

b. Overview of Walther (Ex. 1007)

Walther is an article published in the European Journal of Cardio-thoracic Surgery that bears a copyright date of 2011. Ex. 1007, 1120. Petitioner contends that Walther was published online on April 3, 2011, and qualifies as prior art under pre-AIA 35 U.S.C. § 102(b). Pet. 22.

Walther is directed to a method of deploying a trans-catheter valve in a previously implanted degenerative bioprosthetic valve. Ex. 1007, 1120. Specifically, Walther describes implanting an Edwards SAPIEN THV cloth valve, "which is identical to the SAPIEN model, but has an added outer cloth for implantation into a degenerative bovine pericardium, Carpentier-Edwards Perimount (CEP) bioprosthetic valve." *Id.* Walther discloses that:

> The CEP surgical valves are made with a base that is more rigid than other valves. When a SAPIEN™ valve is expanded in the CEP valve, the rigid base does not easily conform to the profile of the expanded stent frame, which leaves gaps between the two valves, resulting in higher paravalvular leak. The addition of an outer cloth to the SAPIEN™ cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves and improve resistance to migration with better 'fit' within surgical Perimount valves.

Id. Additionally, Walther discloses that the outer cloth "reduce[s] paravalvular leak," "increase[s] 'fit' within EW Perimount valves [a

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benchtop valve]," and "promote[s] tissue ingrowth, which further decreases paravalvular leakage." *Id.*

Figure 1 of Walther is reproduced below:

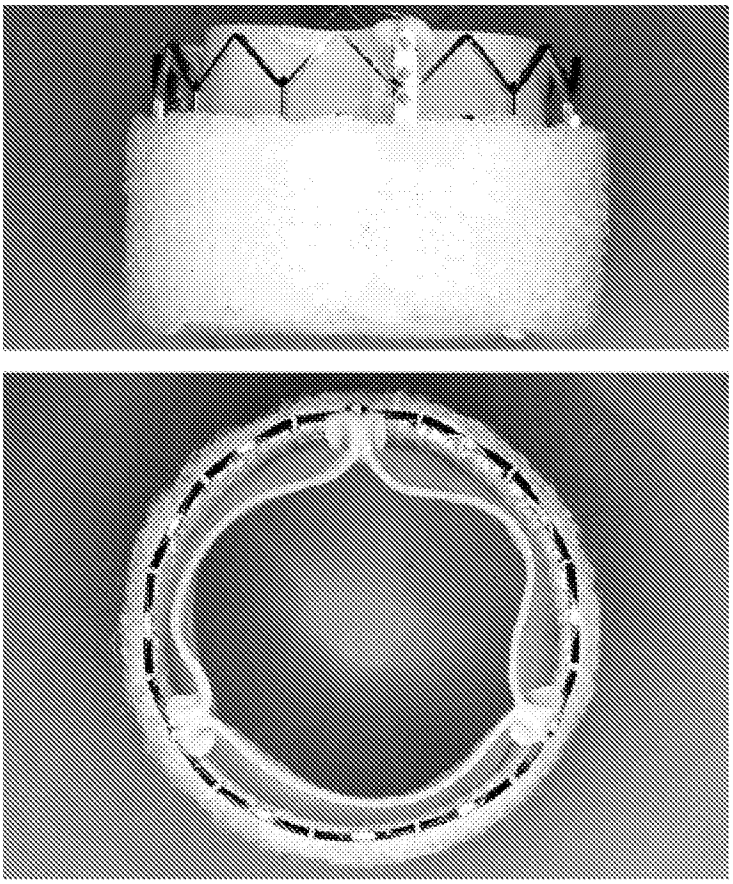

Fig. 1. Cloth valve.

Figure 1 of Walther depicts two views of the SAPIEN THV

Figure 1 of Walther provides two photographic views (side view at top and top-down view at bottom) of the SAPIEN THV with a cloth encircling approximately the lower two thirds of the valve. *Id.* at Fig. 1, 1121. Walther describes deploying the SAPIEN valves inside "various CEP valves" *via* the 33 F Ascendra catheter system. *Id.* at 1121.

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c. Petitioner's contentions with respect to Walther

i. "a first portion of [non-metallic] fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets"

Petitioner argues that Walther teaches that its outer PET cloth is positioned radially outwardly of the outer frame, and is formed of nonmetallic, PET (i.e., non-metallic) fibers that extend radially outwardly of the outer frame.[7] Pet. 36–37 (citing Ex. 1007, 1121, Fig. 1; Ex. 1003 ¶ 115). Petitioner contends that Walther's outer fibers are configured to form a sealing interface against the cardiac annulus and native valve leaflets when compressed against them. *Id.* at 37 (citing Ex. 1003 ¶¶ 118–120). Petitioner's witness, Dr. Buller, explains that Walther describes implanting the cloth-covered SAPIEN within a surgical valve, and that the fibrous outer cloth "is designed to reduce paravalvular leak by creating a seal between the two valves" by compressing the radially extending fibers against the surgical valve's annulus and leaflets. *Id.* (citing Ex. 1003 ¶¶ 1120–1121; Ex. 1007 Fig. 2).

Petitioner asserts that a person of ordinary skill in the art would have understood that expanding Walther's cloth-covered SAPIEN within a native aortic valve would form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed against it. Pet. 38 (citing Ex. 1003 ¶ 118). Petitioner points to Cribier, which, Petitioner contends, teaches that the SAPIEN THV presses against the aortic valve's annulus and native leaflets upon implantation. *Id.*

[7] We understand PET to refer to polyethylene terephthalate.

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Specifically, Petitioner argues that Cribier teaches states that the SAPIEN valve is "advanced to the native aortic valve[,] … positioned across the aortic annulus, and delivered by balloon inflation[.]" *Id.* at 39 (citing Ex. 1012, 347). According to Petitioner, Cribier instructs that "before deployment, one third to half of the stented prosthesis needs to rest above the annulus and the remainder in the LVOT [left ventricular outflow tract] in order to minimize perivalvular leaks and avoid coronary occlusion." *Id.* (citing Ex. 1012, 353).

Petitioner reasons that the '236 patent identifies the annulus as the point where the leaflets begin and that when expanded in this location, SAPIEN presses against and displaces the patient's native aortic leaflets. *Id.* (Ex. 1001 col. 1, ll. 58–60, Fig. 2; Ex. 1003 ¶ 119; *see also* Ex. 1047, 74 (describing SAPIEN as "crush[ing] the leaflets of the native valve against the wall.")). Petitioner contends that expanding Walther's cloth-covered SAPIEN in a native aortic valve would press Walther's fibers against the patient's annulus and native leaflets to form a sealing interface. *Id.* at 41 (Ex. 1003 ¶ 121). According to Petitioner, if one-third to one-half of Walther's cloth-covered SAPIEN THV rested above the annulus and the remainder in the LVOT, the central fibers would press against the annulus and the fibers "above the annulus" would press against the leaflets. *Id.* (citing Ex. 1003 ¶ 121; Ex. 1047, 74).

Petitioner contends that a skilled artisan would have found it obvious to deploy the valve within a patient's native valve so that the outer cloth forms a sealing interface with the annulus and native leaflets, and would have been motivated to apply Walther's outer cloth covering to reduce paravalvular leakage ("PVL"), a problem well known in the contemporaneous art. Pet. 42 (citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S.

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398, 416 (2007); Ex. 1003 ¶¶ 122, 124). Petitioner argues that a person of skill in the art would also have had a reasonable expectation of success in deploying the cloth-covered SAPIEN in a patient's native aortic valve based upon Walther's teaching of a successful balloon deployment of the cloth-covered SAPIEN that "demonstrated excellent hydrodynamic performance" and that an in-patient procedure "is feasible." *Id.* (citing Ex. 1007, 1125; Ex. 1003 ¶ 125).

ii. a second portion of [non-metallic] fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame

With respect to this limitation of independent claim 1, Petitioner argues that Walther's outer cloth also includes inwardly facing fibers on the inward-facing surface of the cloth that form a sealing interface against the outer frame. Pet. 43 (citing Ex. 1007, Fig. 1; Ex. 1003 ¶ 132). Petitioner points to a portion of Walther's Figure 1, which is reproduced, as annotated by Petitioner, below:

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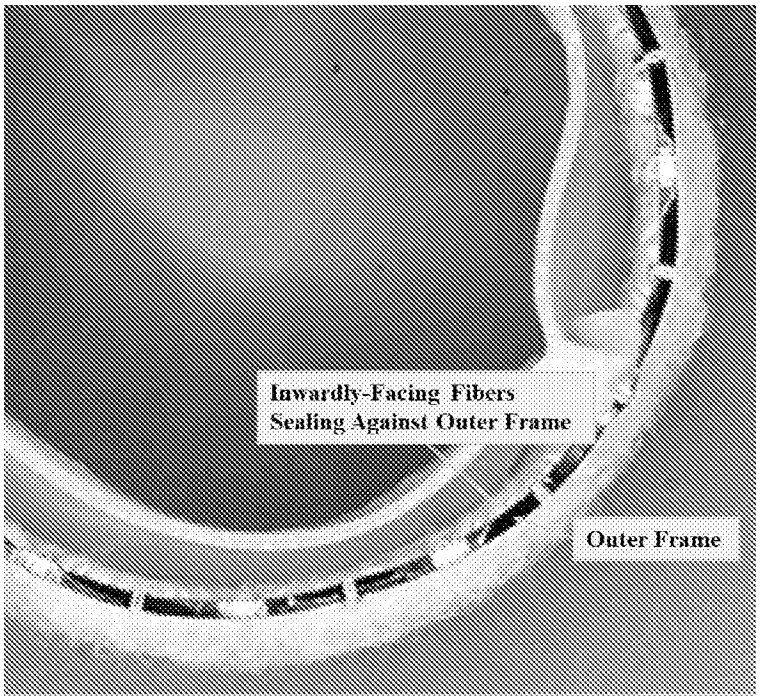

Figure 1 of Walter (annotated by Petitioner) depicts a magnified plan view of a portion of Walther's cloth-covered SAPIEN THV

Petitioner asserts that Figure 1 depicts some of the inwardly facing fibers pressing through the open cells of the outer frame and extending radially inwardly of the outer frame, and annotates the figure with two text boxes labeling these features. Pet. 44 (citing Ex. 1007, Fig. 1; Ex. 1003 ¶ 132). According to Petitioner, the inwardly facing fibers that do not pass through the open cells of the outer frame instead press against and form a sealing interface with the outer frame. Id. (citing Ex. 1003 ¶ 132). These fibers, Petitioner argues, are the "second portion of fibers" recited by claim 1. *Id.*

Petitioner notes that Walther teaches that the outer cloth is "stitched onto the perimeter of each SAPIEN valve," and carried by the outer frame, and that the inwardly facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded.

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Pet. 45 (citing Ex. 1007, 1121, Fig. 1; Ex. 1003 ¶¶ 133–134). Petitioner reasons that these inwardly facing fibers must form a sealing interface with the frame in the expanded state, because Walther discloses that the cloth prevents PVL, which could not happen if blood could leak between the cloth and expanded frame. *Id.* (citing Ex. 1003 ¶ 134).

iii. "wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment"

Petitioner asserts further that Walther's first and second portion of fibers are interwoven and part of a single PET cloth and, therefore, are in overlapping radial alignment. Pet. 46. Petitioner also notes, as discussed above, that Walther's cloth-covered SAPIEN is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal against them. *Id.* at 47.

iv. "wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface"

Petitioner argues that Walther's cloth-covered SAPIEN is configured, upon expansion of the valve, to (1) compress the first portion of fibers against the annulus and leaflets to form a first sealing interface upon expansion of the valve, and (2) compress the second portion of fibers against the frame to form a second sealing interface, as argued above. Pet. 50.

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d. Patent Owner's Preliminary Response

Patent Owner argues that Petitioner fails to clearly identify "a second portion of fibers," that is "configured to form a second sealing interface" or that is in "overlapping radial alignment" with the claimed "first portion of fibers." Prelim. Resp. 31. Specifically, Patent Owner contends that Petitioner's reliance upon Walther's Figure 1 to allege disclosure of a "second portion of fibers" is misplaced. *Id.* at 32–33 (citing Pet. 43–45). Patent Owner argues that it is unclear what is shown in that Figure, and that it is possible that the Petitioner is pointing to the white fabric on the inside of the black "outer frame," which is, Patent Owner asserts, the inner PET cuff that the Petition identifies as the claimed "polymeric graft covering," i.e., the inner frame of claim 1, as depicted in Figure 1 of Cribier. *Id.* (citing Pet. 34). As such, Patent Owner contends it presumptively cannot also satisfy the separate "second portion of fibers" limitation, because there is a "strong" and "clear implication" that when two structures are separately named in a claim "the named entities are not one and the same structure." *Id.* at 34. (citing *HTC Corp. v. Cellular Commc'ns Equip.*, LLC, 701 F. App'x 978, 982 (Fed. Cir. 2017); *Becton, Dickinson & Co. v. Tyco Healthcare Grp.*, LP, 616 F.3d 1249, 1254 (Fed. Cir. 2010)).

Furthermore, argues Patent Owner, the arrow added by Petitioner to Walther's Figure 1 appears to point to the sutures that secure the inner graft covering to the frame, which, Patent Owner contends, are different from the more visible stitches that secure the outer graft covering to the frame. Prelim. Resp. 35. (citing Pet. 44). Patent Owner asserts that these are the same stitches that the Petitioner asserts satisfy the limitation, "the outer frame is secured to the inner graft covering by stitching." Prelim. Resp. 35.

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Patent Owner repeats that there is a strong implication that the same structure cannot satisfy two different claim limitations. *Id.*

Patent Owner disputes Petitioner's contention that "[a]s shown [in Petitioner's annotated Figure 1 of Walther], some of the inwardly facing fibers are pressed through the open cells of the outer frame and extend radially inwardly of the outer frame." Prelim. Resp. 35–36 (quoting Pet. 44). Patent Owner asserts that this is not shown, and that Petitioner does not explain how the fibers could push through the open cells of the outer frame given the presence of the inner frame. *Id.* at 36. Patent Owner points to the Declaration of its expert, Dr. Brecker, who states that:

> The image is very blurry and difficult to discern. To the extent this blurry image shows any fibers that appear on the inside of the frame, the fibers may just as well be stray fibers from the stitching on top of the fame or may emanate from the outer surface of the PET cloth and wrapped over the top of the outer frame when the cloth was cut.

Id. (quoting Ex. 2002 ¶ 45). Patent Owner contends that any such "stray fibers" cannot constitute "a second sealing interface against the outer frame when the second portion of fibers is compressed [against it]" give the '236 patent's disclosure that "the fibers *234* and the covering material *250* create a seal between the inner frame *218* and the other frame *216*." *Id.* at 37 (quoting Ex. 1001, col. 14, ll. 31–32).

Patent Owner further contends that the testimony of Petitioner's witness, Dr. Buller, with respect to this issue is conclusory, and thus insufficient to establish a disclosure. Prelim. Resp. 37 (citing Ex. 1003 ¶ 132; also citing 37 C.F.R. §42.65(a); *Ericsson Inc. v. Intellectual Ventures I, LLC*, 890 F.3d 1336, 1346 (Fed. Cir. 2018)). Furthermore, Patent

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Owner's witness, Dr. Brecker, directly disputes Dr. Buller's conclusion. *Id.* (citing Ex. 2002 ¶¶ 46–49).

Patent Owner also argues that Petitioner fails to prove that Walther's alleged "second" portion of fibers are in "overlapping radial alignment" with the "first portion of fibers" as required by the claims. Prelim. Resp. 40. Patent Owner notes that the Petition states that, "Walther's first and second portion of fibers are interwoven and part of a single PET cloth, as illustrated in Figure 1 below, and, therefore, are in overlapping radial alignment." *Id.* (quoting Pet. 46). Patent Owner repeats its previous observation that only a few stray fibers of indeterminate origin are visible in Walther's Figure 1, which, therefore does not show that "the first portion of fibers and the second portion of fibers are in overlapping radial alignment." *Id.* at 40–41.

e. Analysis

We find that Petitioner has demonstrated a reasonable likelihood of prevailing at trial with respect to these limitations, and that Patent Owner's arguments, as developed at this stage of the proceeding, are insufficient to overcome that likelihood. Nevertheless, we acknowledge that a degree of uncertainty remains, and we expect this issue to be further developed at trial.

Figure 13 of the '236 patent depicts the "first portion of fibers positioned radially outwardly of the outer frame" and the "second portion of fibers carried by the outer frame," as recited by claim 1. Figure 13 is reproduced below:

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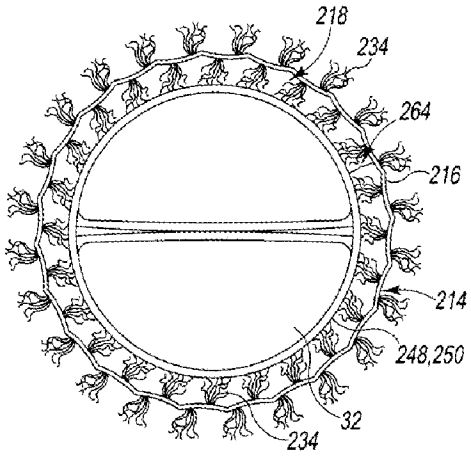

FIG. 13 of the '236 patent is a plan view of the proximal prosthetic component showing the inner frame in an unexpanded position

The collagen fibers 234 of Figure 13 constitute the first portion of fibers positioned radially outwardly of the outer frame (*see also* Figure 14) and the second portion of the fibers carried by the outer frame that are recited in claim 1. Petitioner argues that the outer cloth taught by Walther contains the first portion of fibers positioned radially outward of the outer frame, and that these fibers form a first sealing interface against the cardiac annulus and native leaflets when the prosthetic valve is positioned and expanded in place at the cardiac-aortic junction. On the present record, we agree with Petitioner that a person of ordinary skill in the art would understand that Walther teaches this limitation.

This issue of whether Walther teaches the remaining limitations in question turns on the nature of the "outer cloth" taught by Walther that is added to the SAPIEN valve. *See* Ex. 1007, 1120, 1121. Walther minimally describes the nature of this added outer cloth, stating only that it comprises a "poly(ethylene terephthalate) (PET) cloth … stitched onto the perimeter of each SAPIEN valve." *Id.* at 1121.

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Figure 1 of Walther, as magnified and annotated by Petitioner is again reproduced below:

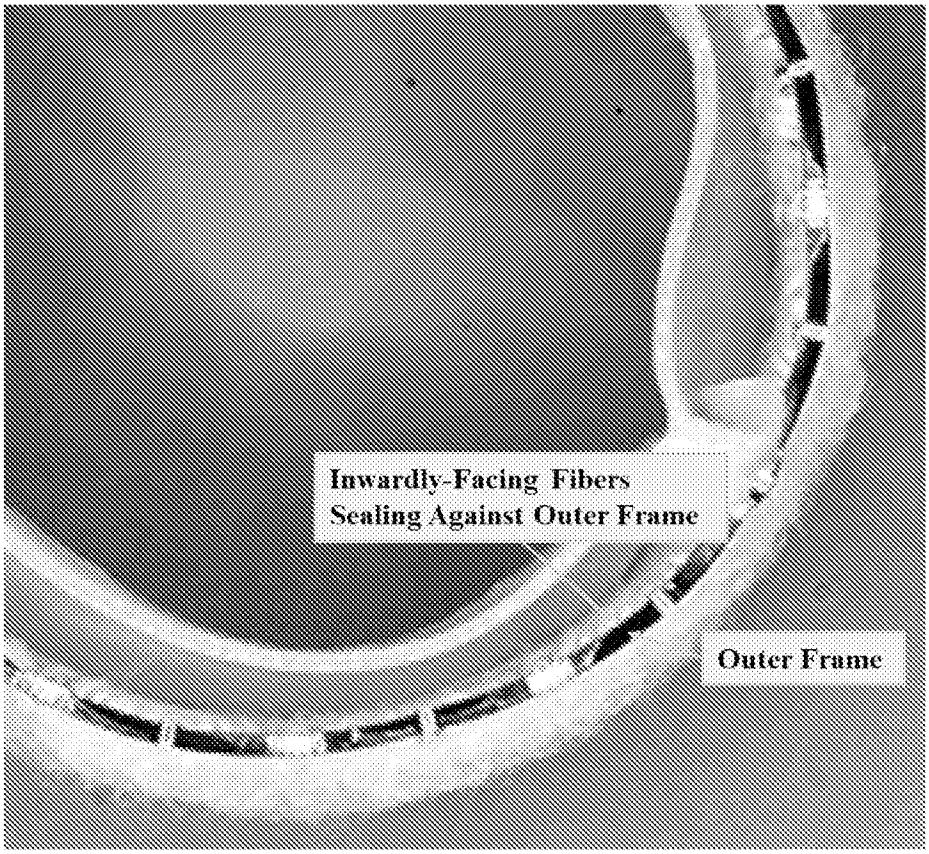

Figure 1 of Walther (annotated by Petitioner) depicts a magnified plan view of a portion of Walther's cloth-covered SAPIEN THV

Petitioner argues that "the inwardly-facing fibers press[] through the open cells of the outer frame and extending radially inwardly of the outer frame" and that these "inwardly-facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded." Pet. 44–45. We interpret Petitioner's argument to mean that, either due to the elastic nature of the PET cloth or, when expanded *in situ* into the annulus of the aortic valve, the resulting inward force of the pressure exerted on the outer cloth of the valve by the annulus and native leaflets of

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the aortic valve would force some of the fibers of the outer cloth inwards through the interstices of the metallic outer frame against the inner frame, thus forming a second portion of inward facing fibers, and forming a second sealing interface between the inner and outer frames. In any event, the figure from Walther above appears to show fibers on the inside and on the outside of the metallic frame.

This analysis depends at least in part upon the nature of Walther's outer cloth. A close inspection of Walther's Figure 1 could lead an individual to conclude that the outer cloth comprises an outer fibrous layer and a solid woven "backing layer" that forms the inner surface of the cloth. This could be interpreted as being the brighter white line forming the inner surface of the outer cloth. Such a backing layer would prevent any of the outer fibers from penetrating inwardly through the interstices of the outer frame and also from forming a second sealing interface between inner and outer frames. Dr. Brecker opines that such a backing layer indeed exists:

> If we magnify Walther's Figure 1, then we can identify what appears to be the dense PET layer (highlighted in yellow in the second image) sandwiched beneath a fibrous finish and the black metal frame.

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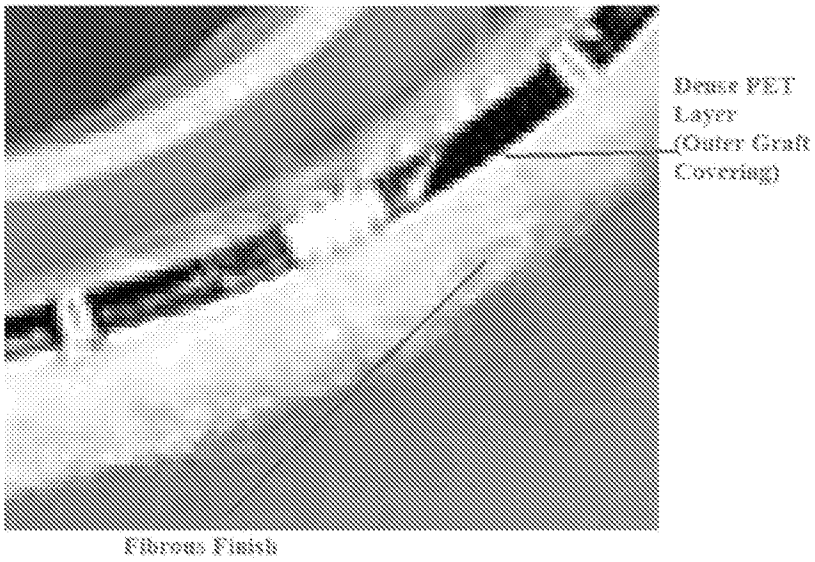

Second image of Dr. Brecker's annotated, magnified Figure 1 of Walther

> I note that Dr. Buller acknowledges that graft material can be made of polyesters, which include PET and repeatedly relies on a dense PET layer/cloth/skirt as the claimed "inner graft covering." Ex. 1003 [Buller-Decl.] ¶¶ 60, 109, 174, 232. … I also understand that Dr. Buller relies on the fibrous finish for the claimed "first portion of fibers positioned radially outwardly of the outer frame." *Id.*, ¶¶115-117.

Ex. 2002 ¶ 37.

By contrast, Petitioner's expert, Dr. Buller, discerns no such dense backing layer/cloth/skirt, stating that:

> Expansion of Walther's cloth-covered SAPIEN within a patient's native aortic valve would similarly compress the outwardly extending fibers of the outward-facing surface of the cloth (i.e., first portion) against the patient's annulus and native leaflets to form a first sealing interface and the inwardly extending fibers of the inward-facing surface of the cloth (i.e., second portion) against SAPIEN's outer frame to form a second sealing interface.

Ex. 1003 ¶ 147.

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What we are left with, at this stage of the proceeding, is the parties' two declarants squinting at a magnified, pixelated image from Walther's Figure 1 and, without significant additional evidence of record, opining as to what it is that they think they see in Walther's outer cloth. As we have mentioned, Walther itself offers us minimal help with respect to the issue of the nature of its outer cloth. No other relevant evidence of record with respect to how a skilled artisan would understand the cloth actually used in Walther has been presented in the record at this stage.

Furthermore, if the outer cloth of Walther contains both outward facing (a first portion of fibers) and an inward facing portion of fibers unconstrained by a dense backing layer of woven PET (the second portion), then the inward and outward facing fibers would be "in overlapping radial alignment," as required by claim 1.

We expect that both parties will further develop this issue at trial. Nevertheless, at this stage of the proceeding, we conclude that Petitioner has presented a plausible interpretation of Walther, which, if supported by the trial record, would demonstrate that Walther teaches the limitations of claim 1 reciting:

> a first portion of fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst,
>
> wherein the first portion of fibers extend radially outwardly of the outer frame,
>
> wherein the first portion of fibers is non-metallic;
>
> and a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst

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wherein the second portion of fibers is non-metallic,

wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment.

We conclude that Petitioner has, therefore, demonstrated a reasonable likelihood of prevailing at trial upon this issue.

2. Claim 1: "wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame"

a. Petitioner's contentions with respect to Walther

Pointing again to Figure 1 of Walther, Petitioner argues that Walther teaches that the outer cloth, which is stitched to the valve's perimeter, was the only modification made to SAPIEN. Pet. 47 (citing Ex. 1007, 1120). Petitioner notes that Walther does not state that the outer cloth includes a "graft covering" and contends that the cloth does not include any visible graft covering. *Id.* (citing Ex. 1012, Fig. 1; Ex. 1003 ¶ 140). Petitioner therefore asserts that a person of ordinary skill in the art would have understood that Walther's cloth-covered SAPIEN is free of an outer graft covering between the first portion of fibers and the outer frame. *Id.* at 49 (Ex. 1003 ¶ 140).

b. Patent Owner's Preliminary Response

Patent Owner responds that Petitioner and its witness, Dr. Buller, confirm that PET fabric or cloth are used to make graft coverings, and that Petitioner relies on PET fabrics to meet the "inner graft covering" limitation. Prelim. Resp. 15. According to Patent Owner, Petitioner acknowledges that PET fabric can be a graft covering. *Id.* Furthermore, argues Patent Owner, the Board has found, in a related proceeding, and after evaluating arguments

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very similar to those made in this proceeding, that Levi's woven PET outer skirt is an "outer graft covering." *Id.* (citing Ex. 2043, 27); *compare* Ex. 2047 85–86, *with* Pet. 97–98.

Patent Owner contends that, just as Levi's woven PET is an "outer graft covering," so too is Walther's outer PET cloth. Prelim. Resp. 21 (citing Ex. 2046, 7–10). According to Patent Owner, Walther teaches that "outer cloth" is "[a]n added poly(ethylene terephthalate) (PET) cloth … stitched onto the perimeter of each SAPIEN valve." *Id.* (citing Ex. 1007, 1120, 1121). Petitioner notes that, for Grounds 1, 2, and 6, Petitioner relies on Walther's outer PET cloth as carrying the "first portion of fibers." *Id.* (citing Pet. 36–37, 63–64, 90–91).

Petitioner contends that Walther does not need to explicitly state that the outer cloth includes a "graft covering" because the outer cloth is made of PET, which Petitioner's own expert testifies is a "graft material." Pet. 22 (citing Ex. 1003 ¶ 60 (further citing Ex. 1035, col. 5, ll. 53–59). Patent Owner asserts that PET is also the same material its witness testifies is a "polymeric graft covering." *Id.* (citing Ex. 1003 ¶ 109).

Patent Owner disputes Petitioner's assertion that the cloth does not include any visible graft covering. Prelim Resp. 22. Patent Owner contends that the distinction between the '236's figures (free of an outer graft covering) and Figure 1 of Walther (including an outer graft covering) is readily apparent. *Id.* (citing Ex. 1001 Fig. 11; Ex. 1007, Fig. 1). Patent Owner points to Dr. Brecker's opinion that Walther's outer cloth includes a dense layer of PET that acts as the "outer graft covering" and is located between the frame and the alleged "first portion of fibers":

> If we magnify Walther's Figure 1, then we can identify what appears to be the dense PET layer (highlighted in yellow in the

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> second image) sandwiched beneath a fibrous finish and the black metal frame. Ex. 1007 Fig 1. (excerpted, magnified, annotated) (yellow highlighting added). I note that Dr. Buller acknowledges that graft material can be made of polyesters, which include PET and repeatedly relies on a dense PET layer/cloth/skirt as the claimed "inner graft covering." Ex. 1003 ¶¶ 60, 109, 174, 232. This is consistent with my understanding that conventional densely woven PET cloth constitutes a "graft covering." I also understand that Dr. Buller relies on the fibrous finish for the claimed "first portion of fibers positioned radially outwardly of the outer frame." *Id.*, ¶¶115-117. Accordingly, a POSITA would understand that the dense PET layer underneath the outer PET cloth's fibrous finish would be an "outer graft covering between the first portion of the fibers and the outer frame."

Prelim. Resp. 23–25 (quoting Ex. 2002 ¶ 37; *see* second image of Dr. Brecker's annotated, magnified Figure 1 of Walther, reproduced above).

Patent Owner asserts that there is therefore no support for Petitioner's assertion that a person of ordinary skill in the art would have understood that Walther's cloth-covered SAPIEN is "free of an outer graft covering between the first portion of fibers and the outer frame." Prelim. Resp. 25 (quoting Pet. 49). Rather, argues Patent Owner, a skilled artisan would have understood that Walther's outer PET cloth is an "outer graft covering," and that, as shown in Figure 1 of Walther, this PET cloth is located "between the first portion of fibers and the outer frame" as precluded by the claims. *Id.*

c. Analysis

Our analysis with respect to this limitation mirrors our previous analysis with respect to the first and second portions of, respectively, inward and radially outward facing fibers, overlapping and aligned radially, and forming first and second sealing interfaces. To put the matter succinctly, the issue turns on the nature of Walther's outer cloth. If the outer cloth

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possesses a woven PET "backing layer" on the inner surface of the outer cloth, interposed between the fibrous portion of the outer cloth and the metallic outer frame, such a woven layer of PET could reasonably be interpreted as constituting an "outer graft covering." If, on the other hand, there is no such layer, and the outer cloth of Walther is simply a mass of PET fibers without a woven "backing layer" of, e.g., PET cloth, then there would be no outer graft covering, and the fibrous outer PET cloth of Walther would, as we have explained above, constitute the first and second portions of fibers recited in claim 1. It is difficult to tell solely from the magnified and pixelated Figure 1 of Walther whether skilled artisans would understand such a layer to actually exist and, the experts' testimony notwithstanding, there is not sufficient evidence of record to determine whether there is a layer constituting the "outer graft covering" that is excluded by claim 1. However, the figure appears to show fibers on the outside and on the inside of Walther's metallic scaffold.

We repeat that this is an issue that we expect the parties to develop at trial. At this stage of the proceedings, however, we conclude that Petitioner has made a plausible and reasonable, if not conclusive, showing that it would likely prevail at trial in demonstrating that this negative limitation would have been obvious over Walther.

3. Conclusion

Incorporating our reasoning with respect to the remaining limitations from our Decisions to Institute in the previous, related *inter partes* reviews (*see, e.g.*, IPR2021-01584, Paper 15; IPR2021-00193, Papers 14, 22) we conclude that, for the purposes of this Decision, on this record Petitioner has established a reasonable likelihood of prevailing at trial in showing that

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claim 1 is obvious over the combination of at least Cribier and Walther (Ground 1) and Spenser and Walther (Ground 2). We address the remaining grounds of the Petition below in a more limited manner to provide additional guidance for the parties during trial. We have considered and also address below in Section III.F Patent Owner's arguments concerning objective indicia of nonobviousness.

4. Dependent claims 2–4

Claim 2 depends from independent claim 1 and recites: "wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame." Ex. 1001 col. 22, ll. 20–25. Petitioner contends that Cribier shows that SAPIEN's inner PET fabric cuff (i.e., inner graft covering) extends to the proximal inflow end of SAPIEN's outer frame. Pet. 51 (citing Ex. 1012, 348, Fig. 1; Ex. 1003 ¶ 149). We agree with Petitioner that this is a reasonable interpretation of the teachings of Cribier and we find that there is a reasonable likelihood of Petitioner prevailing at trial with respect to this claim. Patent Owner does not expressly contest this claim at this stage of the proceeding.

Claim 3 depends from claim 1 and recites "wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers." Ex. 1001 col. 22, ll. 26–29. Similarly, claim 4 also depends from claim 1 and recites "wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers,

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wherein the opening extends to the outer frame." Ex. 1001 col. 22, ll. 30–35.

Petitioner argues that Walther's cloth-covered SAPIEN includes radially extending first portion of fibers. Pet. 54. Petitioner contends that a person of ordinary skill in the art would have understood that small openings inherently exist between the radially extending fibers that are formed by spacing between the adjacent fibers. *Id.* (citing Ex. 1007, Fig. 1; Ex. 1003 ¶ 152). According to Petitioner, Figure 1 of Walther shows that the fibers of the outer cloth are dense enough to prevent blood from flowing through the fibers, but still loose enough to create small gaps. *Id.* (citing Ex. 1003 ¶ 153). Petitioner argues that these small gaps define a plurality of "opening[s] extending through a thickness" of the radially extending fibers, as recited in claim 3. *Id.* Patent Owner does not expressly contest claim 3 or 4 at this stage of the proceeding.

We agree with Petitioner that this is a reasonable interpretation of the teachings of Walther and we find that there is a reasonable likelihood of Petitioner prevailing at trial with respect to these claims. Again, Patent Owner has not yet addressed these claims. *See generally* Prelim. Resp.

D. Ground 3: Spenser and Spenser II

1. Claim 1: first and section portion of radially positioned fibers forming a first and second sealing interface in overlapping radial alignment to form the respective first sealing interface and second sealing interface

a. Introduction

Petitioner relies upon Spenser as teaching a heart valve assembly similar to the SAPIEN prosthetic valve, but which lacks radially extending

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fibers forming the sealing interfaces. Pet. 56. For the reasons explained in Section III.C above, we agree with Petitioner that it has demonstrated a reasonable likelihood of prevailing in showing that Spenser teaches these limitations. As with its reliance upon Walther in Grounds 1 and 2, under Ground 3 Petitioner relies upon Spenser II as teaching the limitations of claim 1 reciting:

> a second portion of fibers carried by the outer frame that is configured to form a second sealing interface against the outer frame when the second portion of fibers is compressed thereagainst
>
> wherein the second portion of fibers is non-metallic,
>
> wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,
>
> …
>
> wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame,
>
> …
>
> wherein expansion of the valve assembly is configured to compress the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

We thus turn to the question of whether Petitioner has demonstrated a reasonable likelihood of prevailing at trial in proving that these limitations are obvious over Spenser II.

b. Overview of Spenser II (Ex. 1011)

Spenser II is a PCT Publication that published on Jan. 12, 2006. Ex. 1011, codes (10), (43). Spenser II facially qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

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Spenser II is directed to "the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses." Ex. 1011 ¶ 1. Spenser II discloses that prosthetic valves may be implanted "either through open heart surgery or by use of newer percutaneous methods," but with "both methods paravalvular leaks are a known side effect." *Id.* ¶ 11. Spenser II further notes that "[p]ercutaneous introduction of medical devices is a preferred surgical procedure" and "considered safer and less invasive." *Id.* ¶ 12.

Figure 22 of Spenser II is reproduced below:

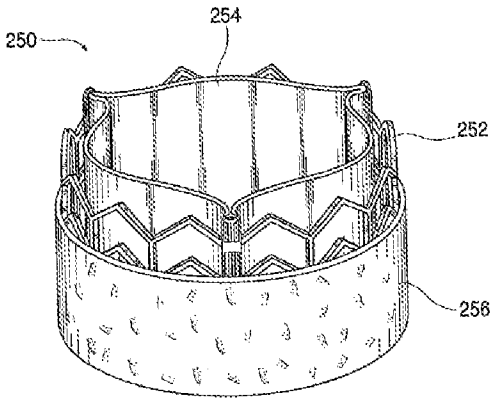

FIG. 22

Figure 22 illustrates a valve device, in accordance with a preferred embodiment

Spenser II's Figure 22 embodiment, as shown above, includes a layer of compressible material, such as a cloth material, along an exterior surface of a stented valve. *Id.* ¶ 85.

Specifically, Figure 22 illustrates stented (artificial) valve 250 including circular stent structure 252 surrounding valvular structure 254. *Id.* at Fig. 22, ¶ 144. "[S]tent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in

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the open configuration." *Id.* ¶ 144. The device further includes circular layer of compressible material 256 surrounding the outside of stent structure 252. *Id.* at Fig. 22, ¶ 145. "The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve," and may be formed of PET. *Id.* "[T]he compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material." *Id.* This "compressible material expands after deployment at a treatment site" and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." *Id.* "In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm." *Id.*

c. Petitioner's contentions with respect to Walther

i. "a first portion of [non-metallic] fibers positioned radially outwardly of the outer frame that is configured to form a first sealing interface against the annulus and native valve leaflets"

Petitioner argues that Spenser II teaches that "[t]o reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252." Pet. 67 (citing Ex. 1011 ¶ 145, Fig. 22). Petitioner also notes that Spenser II teaches that the compressible material "may resemble a cloth or fabric having small fibers extending from the surface of the material." *Id.* Petitioner asserts that the fibers extending outwardly from the compressible material are the "first portion of fibers" required by claim 1. *Id.* (citing Ex. 1003 ¶ 187). Petitioner also notes that, in a preferred embodiment, Spenser II teaches that the compressible material

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is formed of nonmetallic PET fibers. *Id.* at 68 (Ex. 1011 ¶ 145; Ex. 1003 ¶ 187).

Petitioner contends that Spenser II's compressible material expands upon implantation in the patient's heart valve and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." Pet. 68 (citing Ex. 1011 ¶ 145). Petitioner argues that the compressible material is "configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers is compressed thereagainst," as required by claim 1. *Id.* (citing Ex. 1003 ¶ 188). Petitioner contends that a person of ordinary skill in the art would have been motivated to adopt Spenser II's compressible material to reduce PVL, which was a known problem of THV implantation. *Id.*

ii. Second portion of fibers

Petitioner argues that, in addition to an outward facing surface, the compressible material of Spenser II possesses an inward-facing surface also formed of non-metallic fibers. Pet. 72 (citing Ex. 1011 ¶ 145, Fig. 22; Ex. 1003 ¶ 195). According to Petitioner, the inward-facing fibers are the "second portion of fibers" required by claim 1. Petitioner points to Spenser II's Figure 22 as showing that the inwardly facing fibers are compressed against the outer frame and form a sealing interface with the frame when the frame is expanded. *Id.* (citing Ex. 1003 ¶ 195).

iii. First and second portions of fibers in overlapping radial alignment

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Petitioner also argues that Spenser II teaches that its compressible material "may resemble a [PET] cloth or fabric having small fibers extending from the surface of the material." Pet. 73 (citing Ex. 1011 ¶ 145). According to Petitioner, a skilled artisan would understand that such a PET cloth or fabric would include fibers on both its outward-facing surface (a first portion) and on its inward-facing surface (a second portion). *Id.* Petitioner asserts that, because the two portions of fibers are part of a single PET cloth disposed along the exterior of the outer frame, a person of ordinary skill in the art would understand that the two portions of fibers, located on opposite surfaces of the compressible material, are in overlapping radial alignment. *Id.*

iv. Compress fibers to form a sealing interface

Petitioner contends that Spenser II's compressible material, in combination with the valve of Spenser's Figure 44a, is configured, upon expansion of the valve, to: (1) compress the first portion of fibers against the annulus and leaflets to form a first sealing interface upon expansion of the valve, and (2) compress the second portion of fibers against the frame to form a second sealing interface. Pet. 78.

v. Free of an outer graft covering

Petitioner asserts that Spenser II teaches that its compressible material, "may resemble a cloth or fabric having small fibers extending from the surface of the material" that is "disposed along an outer surface" of the stent. Pet. 75 (citing Ex. 1011 ¶ 145). Petitioner asserts that Spenser II does not disclose or suggest any "outer graft covering" between the outwardly

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extending fibers of the outward-facing surface of the compressible material (i.e., first portion) and the stent. *Id.* at 75–76 (citing Ex. 1003 ¶ 205). Petitioner concludes that a skilled artisan would have understood that there is therefore no "outer graft covering" between the fibers of the compressible material and the outer frame. *Id.*

d. Patent Owner's Preliminary Response

i. a first portion of inward facing fibers and a second portion of outward facing fibers

Patent Owner responds that there is no evidence that Spenser II's compressible material sleeve has "a second portion of fibers … configure[d] to form a second sealing interface" and that is "in overlapping radial alignment" with the "first portion of fibers." Prelim. Resp. 41. Patent Owner contends that Spenser II's Figure 22 shows only the outer surface of compressible material sleeve 256. *Id.* at 42. According to Patent Owner, no "inwardly-facing fibers" are visible in Figure 22, nor are they otherwise mentioned by Spenser II. *Id.* Patent Owner argues that, because Petitioner does not rely upon any actual disclosure in Spenser II, its argument necessarily lies in inherency but, constitutes mere conjecture. *Id.*

Patent Owner acknowledges that Spenser II indicates that the compressible material "may resemble a cloth or fabric having small fibers extending from the surface of the material." Prelim. Resp. 43 (citing Ex. 1011 ¶ 145). Patent Owner notes that, in Figure 22 these fibers are depicted as the curved lines on the outer surface of element 256, but no other fibers are visible or described. *Id.* Nor, Patent Owner asserts, were any such fibers mentioned by Petitioner during the prosecution of the Spenser II application. *Id.* at 43–44. Patent Owner therefore contends that Petitioner

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has failed to meet its burden of showing that the inward facing fibers are necessarily present.

Similarly, argues Patent Owner, because the "second portion of fibers" in Spenser II are not visible, Petitioner's argument that "the first portion of fibers and the second portion of fibers are in overlapping radial alignment," is based upon what a POSITA would allegedly understand about a PET cloth or fabric. Prelim. Resp. 46 (citing Pet. 73). Patent Owner contends that Petitioner cannot, however, demonstrate that such fibers are "necessarily" present at all, and therefore also cannot show that the fibers are in overlapping radial alignment with the first portion of fibers. *Id.*

ii. Free of an outer graft covering

Patent Owner next argues that Spenser II's compressible material sleeve is an "outer graft covering between the first portion of fibers and the outer frame" that is expressly precluded from claim 1. Prelim. Resp. 26. Patent Owner notes that Spenser II's Figure 22 was discussed at length in prosecution where the Applicant argued, and the Examiner agreed, that Spenser II did not disclose or render obvious the "free of an outer graft covering" limitation. *Id.* (citing Ex. 1002, 196) ("Spenser [II] appears to include an outer graft covering between the fibers and the outer frame"), *see also id.* at 8 ("The following is an examiner's statement of reasons for allowance: the prior art of record does not disclose or render obvious … the valve assembly being free from an outer graft covering between the first portion of fibers and the outer frame")).

Patent Owner contends that Petitioner's argument that the "free of an outer graft covering" limitation is contrary to Spenser II's express teaching. Prelim. Resp. 27 (quoting Pet. 75–76). Patent Owner points out that

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Petitioner and its witness, Dr. Buller, explicitly rely on a PET fabric cuff as forming an "inner graft covering." *Id.* (citing Pet. 34, 60). Patent Owner notes that Petitioner and its expert do not explain why Spenser II's compressible material sleeve made of PET is not also a graft covering. *Id.* Patent Owner points to the following explanation by its witness, Dr. Brecker:

> Similar to Walther, a POSITA would understand Spenser II's compressible material sleeve as illustrated to be a PET cloth with fibers on top of the denser PET layer. See Ex. 1011 [Spenser II] ¶ 145 ("the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material."). This dense PET layer forms an "outer graft covering." It is located between the alleged "first portion of fibers," located on the outer surface of the PET sleeve, and the outer frame. Thus, Spenser II is not "free of an outer graft covering between the first portion of fibers and the outer frame." Ex. 1011 [Spenser II] Fig. 22 (annotated in red). It is also notable that Dr. Buller, in his declaration in IPR2022-00034, repeatedly stated that "Spenser II does not disclose any additional 'outer graft covering' between the fibrous fabric of the compressible material and the stent frame." Ex. 2042 [IPR2022-00034 Buller-Decl.] ¶¶ 92, 193. Dr. Buller does not state that Spenser II's sleeve is not itself an "outer graft covering.

Id. at 28–29 (citing Ex. 2002 ¶ 40 (figure omitted)). Patent Owner concludes that, because Spenser II's PET sleeve is itself "an outer graft covering between the first portion of the fibers and the outer frame," it does not meet the requirement of claim 1 that "the valve assembly is free of" such an "outer graft covering." *Id.* at 29.

e. Analysis

Based upon the evidence of record at this stage of the proceeding, we have questions whether Petitioner is reasonably likely to prevail at trial in

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showing that Spenser II teaches a second portion of inward facing fibers forming a second sealing interface. Further, on this record, whether the compressible material of Spenser II constitutes an outer graft covering or not is similarly not susceptible of easy resolution.

With respect to these issues, Spenser II teaches:

> In accordance with yet another preferred embodiment, a stented valve is provided wherein a compressible material, such as a clot[h] or fabric, extends around an exterior portion of the stent. The compressible material may be formed of polyethylene terephthalate (PET) and is configured to expand into the gaps. Furthermore, fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage. In one variation, a tissue growth factor may be disposed on the material to encourage tissue growth between the material and the surrounding tissue.

Ex. 1011 ¶ 55. Spenser II further teaches that:

> To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252. The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve. In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm. In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped. The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of

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> tissue into the material, thereby further sealing the gaps. Any suitable tissue growth factor may be used. In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

Id. ¶ 145.

The "cloth" or "fabric" of compressible material 256 of Spenser II thus may have "small fibers extending from the surface of the material." Spenser II does not expressly state that such fibers extend only from the *outer* surface of the material, it merely states that the fibers extend from the "surface," and a person of ordinary skill in the art could reasonably conclude that the fibers of the material extend from both inner and outer surfaces of the cloth or fabric material. As such, these fibers could be reasonably interpreted as corresponding to the claimed first and second portions of inward and outward facing fibers, respectively.

On the other hand, Spenser II also teaches that, in certain configurations, "the compressible material 256 may resemble a cloth or fabric," and may be formed of PET. Ex. 1011 ¶¶ 55, 145. PET is a polymeric material that, as the evidence of record shows, may constitute a fabric-like weave (*see, e.g.*, Ex. 2019[8] Fig. 1A; *see also* Ex. 2020[9], 23–24,

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[8] B. A. Meslmani, *Development of thrombus-resistant and cell compatible crimped polyethylene terephthalate cardiovascular grafts using surface co-immobilized heparin and collagen*, 43 MATERIALS SCI. AND ENG'G C 538–46 (2014) ("Meslmani") Ex. 2019.

[9] A. Rodrigues et al., *Mechanical Behavior of PET Fibers and Textiles for Stent-Grafts Using Video Extensometry and Image Analysis*, 30 SCI. AND TECH. OF MATERIALS 23–33 (2018) ("Rodrigues") Ex. 2020.

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Fig. 8; Ex. 2021[10], Fig. 1.18A) or may be fibrous or "hairy" in appearance, as depicted in Walther (*see* Ex. 1007, Figs 1, 2; *see also* Ex. 1028[11], 124 (stating that PET yarn can exhibit "hairiness"), or possibly some combination thereof, as suggested by Dr. Brecker. *See* Ex. 2002 ¶ 37. Indeed, Spenser II directly suggests the latter ("hairiness") when it discloses that the compressible material may "resemble a cloth or fabric having small fibers extending from the surface of the material."

As we have explained, such extending fibers could reasonably be interpreted by a skilled artisan as constituting the first and second portions of inward and outward facing fibers recited in claim 1. However, the "cloth or fabric" from which the fibers extend could also be reasonably interpreted as constituting the "outer graft covering between the first portion of fibers and the outer frame" that is precluded by claim 1. We have previously found, in a related *inter partes* review, that the densely woven outer PET skirt of Levi constitutes an outer graft covering. *See* IPR2022-00034 Paper 14, at 27. Spenser II's description of a fabric or cloth compressible material suggests a similar outer graft covering. We expect that the parties will wish to develop this argument further at trial.

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[10] S. De Bock, A (BIO)MECHANICAL ANALYSIS OF STENT GRAFTS FOR THE TREATMENT OF ABDOMINAL AORTIC ANEURYSMS, Doctoral Dissertation, Faculteit Ingenieurswetenschappen en Architectuur, Universiteit Ghent (Academic Year 2013-2014) ("De Bock") Ex. 2021.

[11] G.K. Tyagi, *Yarn Structure and Properties From Different Spinning Techniques*, 119–154, *in* C.A. Lawrence, ed., ADVANCES IN YARN SPINNING TECHNOLOGY (2010) ("Tyagi") Ex. 1028.

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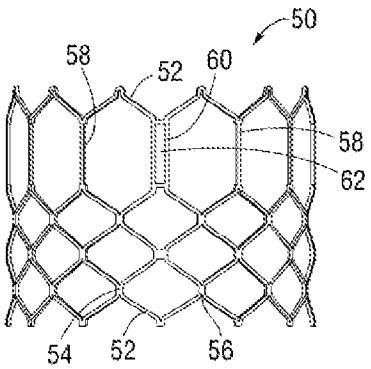
E. Grounds 4–7: Anticipation by (Ground 4), or Obviousness (Ground 5) over Levi, and over Levi and Walther (Ground 6) or Levi and Spenser II (Ground 7)

1. Overview of Levi (Ex. 1008)

Levi is a U.S. Patent that issued on July 19, 2016, from an application filed on October 5, 2011. Ex. 1008, codes (10), (22), (45). Thus, on its face, Levi qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

Levi is directed to a prosthetic heart valve. Ex. 1008, col. 1, ll. 16–18. Figure 11 of Levi is reproduced below:

FIG. 11



Levi's Figure 11 depicts a frame for use in a prosthetic heart valve.

Specifically, Figure 11 illustrates frame 50, which:

> comprises multiple rows of circumferentially extending, angled struts **52** that are connected to each other at nodes, or connecting portions, **54** and **56**. The uppermost row of struts 52 are connected to an adjacent row of struts by a plurality of axially extending struts **58** and commissure window frame portions 60. Each commissure frame portion 60 defines a slot, or commissure window, **62** for mounting a respective commissure of the valvular structure.

Id. at cols. 8–9, ll. 61–3.

Figure 2 of Levi is reproduced below:

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FIG. 2

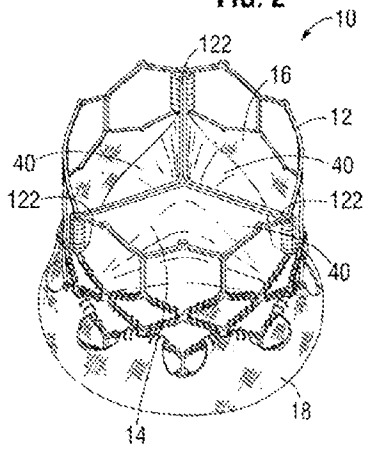

Figure 2 of Levi depicts an exemplary embodiment of a prosthetic heart valve

Figure 2 depicts a prosthetic heart valve 10 including valvular structure 16, surrounded by circular stent or frame 12. *Id.* at Fig. 2, col. 5, ll. 52–58. The bottom portion of frame 12 is covered by inner skirt 16 on the inside of frame 12 and outer skirt 18 on the outside of frame 12. *See id.* at Fig. 2, col. 5, ll. 52–58, col. 9, ll. 24–25, col. 13, ll. 49–50. Valvular structure 16 includes "three leaflets 40, collectively forming a leaflet structure, which can be arranged to collapse in a tricuspid arrangement." *Id.* at Fig. 2, col. 5, ll. 59–61. "[L]eaflets 40 are secured to one another at their adjacent sides to form commissures 122 of the leaflet structures." *Id.* at col. 11, ll. 35–37.

Figure 20 of Levi is reproduced below:

FIG. 20

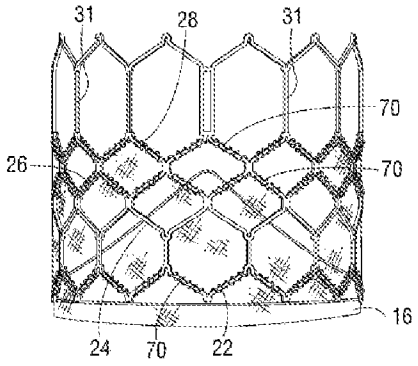

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Figure 20 of Levi depicts the assembly of the inner skirt and frame of a prosthetic heart valve

Figure 20 depicts a valve with skirt 16 arranged on frame 12. *Id.* at Fig. 20, col. 10, ll. 5–17. Specifically, frame 12 includes struts 22, 24, 26, and 28. *Id.* at Fig. 20, col. 7, ll. 16–21. "[S]econd, third, and fourth rows of structures 24, 26, and 28 define two intermediate rows of cells defining openings 38. The fourth and fifth rows of struts 28 and 32, along with frame portions 30 and 31, define an upper row of cells defining openings 40." *Id.* at Fig. 20, col. 7, ll. 19–23. "[T]he upper edge of skirt 16 can be tightly secured to structures 28 with sutures 70." *Id.* at Fig. 20, col. 10, ll. 16–18. "[S]kirt 16 can also be secured to the first, second, and third rows of struts 22, 24, and 26, respectively, with sutures 70." *Id.* at col. 10, ll. 28–30.

Figure 42 of Levi is reproduced below:

FIG. 20

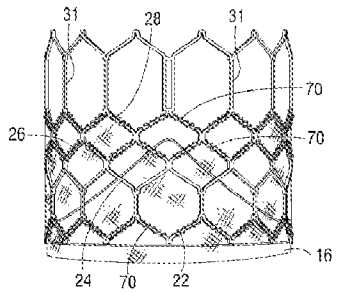

Figure 42 of Levi depicts aspects of an exemplary embodiment of a prosthetic heart valve

Figure 42 illustrates portions of the valve assembly including an outer skirt 18 with projections 164 that are sutured to the outer side of frame 12. *Id.* at Fig. 42, col. 13, ll. 54–61. Skirt 18 includes lower edge 160 that can be sutured to the lower edge of inner skirt 16 at the inflow end of the valve. *Id.* Outer skirt 12 includes excess material between the lower and upper edges. *Id.* at Figs. 2, 43, col. 13, ll. 62–66. Levi discloses that when

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> valve **10** is deployed within the body the excess material of the outer skirt **18** can fill in gaps **5** between the frame **12** and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus. The outer skirt **18** therefore cooperates with the inner skirt **16** to avoid perivalvular leakage after implantation of the valve **10**.

Id. at col. 14, ll. 4–9.

2. Analysis

In our Decision to Institute in related IPR2022-00034, we found that Petitioner was unlikely to prevail at trial in demonstrating that: (1) the woven fabric of Levi possessed *outwardly extending fibers* that form a first sealing interface, and (2) that the outer skirt of Levi was an "outer graft covering" which precluded by the present claim 1. *See., e.g.*, IPR2022-00034, Paper 14 at 13–27; *see also* Prelim. Resp. 14. Specifically, with respect to (1), we found that:

> We understand the requirement for "outwardly extending," in accordance with its plain and customary meaning, to mean that the tips of the fibers must extend in a generally outward direction from the frame as shown, for example, in Figures 8, 9, 11–14, and 20 of the '846 patent. We agree with Patent Owner that nothing in Levi suggests that the "woven PET fabric" used to form the outer skirt expressly or inherently meets this requirement. We are not persuaded by Petitioner's contention that the laser-cut woven PET disclosed for use in Levi's outer skirt would necessarily exhibit the type of "hairiness" described for PET yarn used in other textile applications.

IPR2022-00034, Paper 14 at 26 (citations omitted). With respect to (2) we found that:

> Similarly, Petitioner provides no persuasive evidence that Levi discloses the limitation of disclaimed independent claim 1 (from which challenged claim 6 depends) reciting "wherein the outer

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> seal is free of an outer graft covering between the fibers and the outer frame." We agree with Patent Owner that, having argued that "Levi teaches that the outer skirt is sutured directly to the outer frame and the inner skirt" and "Levi does not include any 'outer graft covering' on the exterior of the outer frame," Petitioner has failed to recognize that Levi's outer skirt is an "outer graft covering."

Id. at 27. We incorporate here that same reasoning from those Decisions and similarly conclude that, for those same reasons, Petitioner is unlikely to prevail at trial upon Grounds 4 and 5.

With respect to Ground 6 (obviousness over Levi and Walther), Petitioner argues that it would have been obvious to replace Levi's outer skirt, with the outer cloth covering of Walther or the compressible material of Spenser II. Pet. 90–91, 95–99. We have explained above our reasoning as to why we conclude that Petitioner has established a reasonable likelihood of success at trial, at least with respect to the Walther-based Grounds 1 and 2, of demonstrating that Walther teaches the limitations of claim 1 reciting the first and second portions of non-metallic fibers forming first and second sealing interfaces and positioned in overlapping radial alignment and does not teach or suggest an outer graft covering. We have also explained our similar reasoning with respect to Spenser II in Petitioner's Ground 3. We find that this reasoning applies equally to Grounds 6 and 7, and we conclude that Petitioner has demonstrated a reasonable likelihood of success in demonstrating that at least claim 1 is obvious over the combinations of Walther or Spenser II and Levi. We expect that the parties will continue to develop their arguments with respect to these Grounds at trial.

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F. Objective Indicia of Nonobviousness

Patent Owner also argues that evidence of objective indicia strongly supports a finding of nonobviousness (and, thus, denial of institution). Prelim. Resp. 2. Patent Owner argues that its claimed invention meets a "long-felt need to reduce PVL while maintaining a small valve profile." *Id.* at 6 (quoting Ex. 1002, 185).

Patent Owner explains that paraventricular leakage ("PVL") around implanted transcatheter aortic valve replacements was a major cause of mortality and rehospitalization. Prelim. Resp. 3 (citing, *e.g.*, Ex. 1002, 183, 185). A competing problem was designing a prosthetic valve that is small enough in its crimped state to permit endovascular delivery. *Id.*

Patent Owner relates that, by 2012, a blood impermeable, dense "outer seal" was employed in the art to reduce paravalvular leakage. Prelim. Resp. 4 (citing Ex. 1002, 186). According to Patent Owner, these outer seals often were composed of a blood impermeable graft material made of a woven fabric such as PET. *Id.* (citing Ex. 1035, col. 5, ll. 53-59). Patent Owner argues that those of skill in the art also recognized, however, that such outer seals formed of a dense woven PET "tend[ed] to deform the struts of the frame and prevents uniform crimping." *Id.* Ex. 1002, 183. The resulting structures were also too large and bulky in the crimped position and could not be delivered endovascularly. *Id.* Patent Owner points to Walther, for example, as teaching a thick, bulky, outer cloth. *Id.*

Patent Owner contends the claimed invention provides a solution to these problems through a combination of features found in the claimed inventions. Prelim. Resp. 6 (citing Ex. 1002, 195). Patent Owner provides four reasons why its invention met this long-felt need. *Id.*

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First, argues Patent Owner, the claimed invention greatly reduced the crimped profile of the device by not using a graft material and requiring that "the valve assembly" be "free of an outer graft covering between the first portion of fibers and the outer frame." Prelim. Resp. 6–7 (citing Ex. 1001, claim 1). Patent Owner states that, by omitting the impermeable outer seal of the prior art, this not only reduced the crimped profile by removing bulky material, but also prevented deformation of the struts of the frame and allowed for more uniform crimping. *Id.* at 7.

Second, Patent Owner contends, to create adequate sealing to prevent PVL in the absence of an outer graft covering, the claimed invention provides two sets of fibers that create two separate "sealing interfaces … when those fibers are compressed." *Id.*

The third reason Patent Owner advances is that, for the "first portion of fibers" to adequately "form a first sealing interface against the annulus and native valve leaflets of the patient," the claimed inventions require the fibers to "extend radially outwardly of the outer frame." *Id.* at 11.

Finally, argues Patent Owner, a fourth limitation of the invention requires that "the first portion of fibers and the second portion of fibers are in overlapping radial alignment" as shown, e.g., in Figures 13 and 14 of the '236 patent. Aligning these fibers aligns the seals and thus prevents blood leakage after the fibers have been compressed. *Id.*

Patent Owner therefore contends that this collection of limitations, addresses a long-felt need by allowing for a TAVR with a narrow profile that can be endovascularly delivered while still limiting PVL. *Id.* at 11–12.

Objective evidence that an invention satisfied a long-felt and unmet need that existed before the patent's filing date supports that an invention is non-obvious. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324,

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1332 (Fed. Cir. 2009). We find that, at this stage of the proceeding, Patent Owner has not provided sufficient *objective* evidence to show the existence of a "long-felt, unmet need alleviated by the patent." *Id.*

Virtually all of Patent Owner's arguments with respect to its meeting a long-felt unmet need derive support from arguments made by Patent Owner (the then-Applicant) during the prosecution of the '236 patent, arguments which are necessarily, of their very nature, self-serving. Patent Owner points to little objective evidence that its invention was recognized as having met a long-felt need, rather, its arguments were directed to showing only that a putative need existed and had not yet been met. Patent Owner presents no evidence that its valve met a need that had not been previously met by the prior art (i.e., by the art upon which Grounds 1–6 are based, particularly Walther and Spenser II.

Patent Owner may develop this argument and evidence further at trial, but for the purpose of this Decision, we find that a lack of sufficient, persuasive objective evidence supporting that the invention met a long-felt need that outweighs Petitioner's assertions and the present evidentiary record showing obviousness.

G. Discretionary Denial under 35 U.S.C. § 325(d)

Finally, Patent Owner urges us to exercise our discretion under § 325(d) to deny institution because the same or substantially the same prior art or arguments were previously presented to the Office. Prelim. Resp. 70–81. Petitioner takes a contrary position, arguing that the Board should not deny institution under 35 U.S.C. § 325(d). Pet. 104–1088. We address the parties' arguments below.

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1. Legal standard

Under § 325(d), we have discretion to deny a petition that presents the same or substantially the same prior art or arguments as previously presented to the Office. *See* 35 U.S.C. § 325(d). In evaluating whether the factual predicate under § 325(d) is met, we consider a number of non-exclusive factors, as set forth in our decision in *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential) ("the *Becton, Dickinson* factors"):

(a) the similarities and material differences between the asserted art and the prior art involved during examination;

(b) the cumulative nature of the asserted art and the prior art evaluated during examination;

(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

(d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson, IPR2017-01586, Paper 8 at 17–18.

In performing an analysis under § 325(d):

> [T]he Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented

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> to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.... If, after review of [*Becton, Dickinson*] factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner has demonstrated a material error by the Office.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential). Consequently, we first turn to an analysis of *Becton, Dickinson* factors (a), (b), and (d) under this framework to determine whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.

2. Part One of the *Advanced Bionics* Analysis

Patent Owner argues that Levi and Spenser II were before, and were considered by, the Examiner during prosecution. Prelim Resp. 71–72. Patent Owner acknowledges that Spenser, Walther, and Cribier were not specifically before the Examiner, but argues that the portions of those references relied upon by Petitioner are "substantially similar" to the considered portions of Levi and Spenser II. *Id.* at 74.

As noted by Patent Owner, in the related IPRs, the Board found that Spenser, Walther, and Cribier are substantially similar to Levi and Spenser II. Prelim. Resp. 74; *see* IPR2021-01527, Paper 15 at 24; IPR2022-00034, Paper 14 at 58; *see also* IPR2021-01584, Paper 15 at 26 (holding that a different Cribier reference, Walther, and Spenser were substantially similar to Levi and Spenser II). We incorporate the reasoning from those Decisions

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herein, finding that Spenser, Walther, and Cribier are substantially similar to Levi and Spenser II.

We next turn to examine whether the Examiner materially erred in his consideration of the references.

3. Part Two of the *Advanced Bionics* Analysis

Petitioner notes that Walther was not before the Examiner during prosecution of the '869 application. Petitioner argues that the Examiner erred in failing to consider whether any reference (or combination of references) that were before the Examiner disclosed Walther's combination of a prosthetic heart valve having: (1) a fibrous outer seal stitched to the exterior of a balloon-expandable stent frame and (2) an "inner graft covering" stitched to the interior of the stent frame. Pet. 104.

Original claim 11, which became independent claim 1, was added by amendment to the '869 application on January 26, 2021. Claim 11 recited "wherein the valve assembly is free of a polymeric outer graft covering that covers an exterior surface of the outer frame." Ex. 1002, 235–236. In a claim chart accompanying the claim when added, Patent Owner (the then-Applicant) explained this limitation as follows:

> The inclusion of an embodiment that includes an outer graft covering, and an embodiment without an outer graft covering provides support for the negative limitations disclosed herein. The specification even states "It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials," implying that alternate sealing materials, such as a non porous graft covering may or may not be provided.

Id. at 240.

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In remarks to the Examiner on February 16, 2021, Patent Owner discussed both Levi and Spenser II. In prosecution, Patent Owner stated:

> Thus, as these studies show, PVL is a long-felt problem and a method of addressing them has been needed.... However, a robust outer seal system on a TAVR presents problems with expansion forces, foreshortening, underexpansion, and crossing of the aorta. The claimed invention addresses these problems.
>
> ...
>
> There were multiple TAVRs available in 2012 at the effective filing date of this application, however, none of TA VRs known to Applicant taught a fiber outer seal.
>
> ....
>
> [Levi] appears to teach an inner and outer seal in FIG. 42. [Spenser II] appears to teach a thick band with fibers emanating therefrom in FIG. 22, however, there is no graft forming the inner frame, thus the inner sealing is missing.
>
> ....
>
> The combination of a balloon expandable transcatheter stent valve with an outer seal with outwardly extending fibers, along with the other limitations found in the claims, presented an improvement over the prior art, with particular reference to the unexpected results of products covered by claims in prosecution of the '137 Application (Now USPN 10,792,172). Applicant submits that it was not obvious to combine the seal found in the references submitted with the information disclosure statement with the TAVR technology of record to seal against the native leaflets of the patient with a fiber outer seal.

Ex. 1002, 185–194.

Patent Owner concluded during prosecution that:

> Additionally, placing outer seal bands as disclosed by Spencer, Cribier and Levi, creates significant technical limitations in the functionality of the TAVR device during loading of the device into a sheath and deployment of the devices *in vivo*. These disclosures show balloon- expandable stent frames. A balloon-expandable frame has a dynamic length, where in an undeployed crimped state, the frame is taller and gradually shortens as the frame is ballooned and expanded to be placed in its final *in vivo*

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> position. Applicant submits that the density of this outer seal band (Spen[s]er [II], Cribier, and Levi) restricts the necessary foreshortening of the stent frame during deployment in vivo and can cause PVL, migration, under-deployment and malfunction of the valve leaflets.

Ex. 1002, 195. Patent Owner thus argued that the outer graft coverings of Spenser II and Levi were disadvantageous for mechanical reasons in a balloon-expandable THV, but did not consider whether the "compressible material" of Spenser II *itself* comprised the first and second portions of fibers forming the first and second interfaces in overlapping radial alignment.

In a Non-Final Office Action, issued on February 26, 2021, the Examiner rejected Patent Owner's original claims 11–14 as unpatentable under 35 U.S.C. § 103 as being obvious over the combination of Nguyen et al. (WO 2006/124649), Greenhalgh (US 2002/0052649) and Braido et al. (US 2011/0098802).[12] Ex. 1002, 104. The Examiner found that Nguyen teaches an aortic valve assembly comprising a radially-expandable outer frame and inner frame corresponding to Patent Owner's claimed invention. *Id.* The Examiner also found that Nguyen did not teach first and second portions of fibers forming first and second sealing interfaces aligned radially and overlapping. *Id.* at 104-105.

The Examiner found that Greenhalgh teaches a stent graft with a "sealing material" (22) positioned outside of a stent graft area (frame/stent 20) (Fig. 1). Ex. 1002, 105. The Examiner found that Greenhalgh thus

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[12] The Examiner also rejected the claims as unpatentable over 35 U.S.C. §§ 101 and 112(b) as being indefinite. Exs. 1002, 1003. These rejections were subsequently overcome by Patent Owner, and we do not consider them here.

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discloses a first portion of fibers positioned radially outwardly of the outer frame that forms a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers are compressed against it, in which the first portion of fibers extend radially outwardly of the outer frame, and a second portion of fibers carried by the outer frame forming a second sealing interface against the outer frame when the second portion of fibers are compressed against it. *Id.* The Examiner concluded that it would have been obvious to a person of ordinary skill in the art modify Nguyen to include radially extending fibers, as taught by Greenhalgh, to further improve the seal of the device once implanted and prevent leakage. *Id.*

The Examiner also found that Braido teaches a heart valve assembly in the same field of endeavor that comprises an outer graft covering that covers an exterior surface of an outer frame, in which the outer graft covering is distinct from the inner graft covering. Ex. 1002, 105. The Examiner concluded that it would have been obvious to a skilled artisan to combine the teachings of Braido with those of Nguyen and Greenhalgh to comprise an outer covering, that covers an exterior surface of an outer frame, as taught by Braido, to further improve the seal of the device once implanted and prevent leakage. *Id.*

Patent Owner responded to the Examiner's rejection by amending independent claim 11 (which, as noted, became the present claim 1) as follows "wherein the valve assembly is free of ~~a polymeric~~ an outer graft covering between the first portion of fibers and the outer frame ~~that covers an exterior surface of the outer frame~~. Ex. 1002, 94 (strikethroughs indicate deletions, underlining indicates additions). Patent Owner argued that:

> Nguyen, however, is not modifiable to add the stent graft of Greenhaulgh and achieve acceptable performance. As the name

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> "stent graft" implies, Greenhaulgh includes a graft material, which is what the fibers extend from.
>
> *[0024] Stent graft 10 comprises a thin, flexible, biocompatible substrate 18, preferably tubular and having stents 20 located at either end Stents 20 are spring-like supports which hold the graft open and allow the ends to be sealingly attached to the wall 16 of the artery to either side of aneurysm 12.*
>
> Independent claim 11, however, requires that the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame. Thus, Greenhalgh, teaches away from the claimed invention. Similarly, Braido teaches the presence of an outer graft covering and also teaches away from the claimed invention.

Id.

The Examiner subsequently allowed the claims, stating in a Notice of Allowance, issued on March 24, 2021, that:

> [T]he prior art of record does not disclose or render obvious a first portion of fibers positioned radially outwardly of the outer frame and a second portion of fibers carried by the outer frame wherein the first portion of fibers and second portion of fibers are in overlapping radial alignment; the valve assembly being free from an outer graft covering between the first portion of fibers and the outer frame in combination with the other recited features.

Ex. 1002, 8.

We agree with Petitioner and conclude that the Examiner erred in the examination of the '869 application. Specifically, we do not find that the Examiner considered the question of whether the compressible material of Spenser II itself constituted the first and second portion of fibers forming first and second sealing interfaces, and was *not*, in fact, an outer graft covering. Rather, the compressible material of Spenser II (the "thick band")

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was argued by Patent Owner as constituting an outer graft covering, an argument accepted by the Examiner.

We have explained above why we find that this is a central question posed by the Petition before us, and one the Examiner failed to adequately consider. In view of this error by the Examiner, we decline to exercise our discretion to deny institution under 35 U.S.C. § 325(d).

IV. CONCLUSION

For the forgoing reasons, Petitioner has demonstrated a reasonable likelihood that at least one challenged claim of the '236 patent would have been obvious over the prior art of record. Accordingly, we institute an *inter partes* review of all challenged claims of the '236 patent, based on all of the grounds identified in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, *inter partes* review is instituted on all claims and all Grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review of the '236 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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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 District of Delaware on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	9/28/2021	District of Delaware

PLAINTIFF	DEFENDANT
AORTIC INNOVATIONS LLC	EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES (U.S.) INC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	10,881,538	1/5/2021	Aortic Innovations, LLC
2	10,966,846	4/6/2021	Aortic Innovations LLC
3	10,987,236	4/27/2021	Aortic Innovations LLC
4	11,129,735	9/28/2021	Aortic Innovations LLC
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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/131,869	12/23/2020	Ali Shahriari	426/2/20 UTIL

CONFIRMATION NO. 1293

175373
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PUBLICATION NOTICE

OC00000124906728

Title:TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Publication No.US-2021-0106445-A1
Publication Date:04/15/2021

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 Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, 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 https://portal.uspto.gov/pair/PublicPair. 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.

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/131,869	04/27/2021	10987236	426/2/20 UTIL	1293

175373 7590 04/07/2021

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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):

Ali Shahriari, Boca Raton, FL;
Aortic Innovations, LLC, Hilsboro Beach, FL

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Document Description: Issue Fee Payment (PTO-85B)

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
17131869	23-Dec-2020	Ali Shahriari	426/2/20 UTIL	1293

TITLE OF INVENTION :

TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Small	Utility under 35 USC 111(a)	3774	001200	TIFFANY SHIPMON

Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
$600	$0	$600	24-Jun-2021	$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
175373 Aortic Innovations, LLC 4917 Waters Edge Drive, Suite 275 Raleigh NC 27606 UNITED STATES 919-348-2194 usptomail@nkpatentlaw.com	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☐ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status

Change in Entity Status

○ Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.
Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.

◉ 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.

Doc Code: IFEE PTOL/85B-EFS

Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:

☒ Issue Fee

☐ I authorize USPTO to apply my previously paid issue fee to the current fees due

☐ Publication Fee

☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____

☐ Advance Order - # of copies _____

☒ If **in addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number 506191 . The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed

NOTE: If no name is listed, no name will be printed
For printing on the patent front page, list to be displayed as entered

1. NK Patent Law
2.
3.

5.Assignee Name(s) and Residence Data To Be Printed

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.

Name	City	State	Country	Category
Aortic Innovations, LLC	Hillsboro Beach	FLORIDA	united states	other

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Justin R. Nifong/	**Date**	03-24-2021
Name	Justin Robert Nifong	**Registration Number**	59389

Electronic Patent Application Fee Transmittal

Application Number:	17131869
Filing Date:	23-Dec-2020
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/20 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPL ISSUE FEE	2501	1	600	600
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**600**

Electronic Acknowledgement Receipt

EFS ID:	42264206
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	24-MAR-2021
Filing Date:	23-DEC-2020
Time Stamp:	06:55:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$600
RAM confirmation Number	E20213N755101283
Deposit Account	506191
Authorized User	Justin Nifong

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	46099 62e2b3c31e1e946f6d1d7d0d1ee5c473662e1b18	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32313 1258cc0fe95ddbaf880d249579f449e0cbefbfad	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	78412		

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

New Applications Under 35 U.S.C. 111

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

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

175373 7590 03/24/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	
ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 03/24/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/131,869	12/23/2020	Ali Shahriari	426/2/20 UTIL	1293

TITLE OF INVENTION: TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	06/24/2021

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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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)

175373 7590 03/24/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/131,869	12/23/2020	Ali Shahriari	426/2/20 UTIL	1293

TITLE OF INVENTION: TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	06/24/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
SHIPMON, TIFFANY P	3774	623-001200

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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.
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.
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. _____

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 119
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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.
17/131,869	12/23/2020	Ali Shahriari	426/2/20 UTIL	1293

175373 7590 03/24/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	
ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 03/24/2021

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 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. 17/131,869	Applicant(s) Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	Art Unit 3774	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the amendment filed February 28,2021.
   ☐ 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 11 and 14-16 . 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 _____.

/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Terminal Disclaimer

2. The terminal disclaimer filed on March 17, 2021 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **10,881,538; 10,888,441 and 10,857,011** has been reviewed and is accepted. The terminal disclaimer has been recorded.

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance: the prior art of record does not disclose or render obvious a first portion of fibers positioned radially outwardly of the outer frame and a second portion of fibers carried by the outer frame wherein the first portion of fibers and second portion of fibers are in overlapping radial alignment; the valve assembly being free from an outer graft covering between the first portion of fibers and the outer frame in combination with the other recited features.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY P SHIPMON whose telephone number is (571)270-1448. The examiner can normally be reached on MONDAY-FRIDAY.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Dieterle can be reached on 571-270-7872. 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 https://ppair-my.uspto.gov/pair/PrivatePair. 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.

/TIFFANY P SHIPMON/
Examiner, Art Unit 3774

/Jennifer Dieterle/
Supervisory Patent Examiner, Art Unit 3774

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/131,869	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

CPC						
Symbol					**Type**	**Version**
A61F	/	2	/	856	F	2013-01-01
A61F	/	2	/	2418	I	2013-01-01
A61F	/	2	/	82	I	2013-01-01
A61F	/	2	/	962	I	2013-01-01
A61F	/	2	/	07	I	2013-01-01
A61F	/	2002	/	061	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	04 March 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	4	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	18 March 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	13

U.S. Patent and Trademark Office — Part of Paper No.: 20210302

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 125
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/131,869	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61F	/	2	/	856	
	/		/		

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774 (Assistant Examiner)	04 March 2021 (Date)	**Total Claims Allowed:** 4	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774 (Primary Examiner)	18 March 2021 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 13

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/131,869	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	11														
2	14														
3	15														
4	16														

/TIFFANY P SHIPMON/ Examiner, Art Unit 3774	04 March 2021	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	4	
/Jennifer Dieterle/ Supervisory Patent Examiner, Art Unit 3774	18 March 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	13

U.S. Patent and Trademark Office

Part of Paper No.: 20210302

Aortic Innovations, LLC, Exhibit 2131
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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/131,869	Shahriari, Ali
	Examiner	**Art Unit**
	TIFFANY P SHIPMON	3774

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F 2/856,07,2418,82,962, 2002/061	02/13/2021	T.S.

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
EAST Search History	02/13/2021	T.S.
Updated EAST Search	03/02/2021	T.S.

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
A61F	2/856	03/02/2021	T.S.

	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S8	59	a61f2/2412	US-PGPUB; USPAT;	OR	OFF	2014/06/28 23:31

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S137	24,545	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S138	15,139	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S139	16,719	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S140	3,555	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S141	11,168	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S142	1,881	(S136 S137 S138 S139 S140 S141) and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:02
S143	1	("9044311").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/13 20:21
S144	25	(US-10034784-$ | US-10065824-$ | US-16788806-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:45

		3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.				
S145	0	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:46
S146	0	"16788806"	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:47
S147	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/11 20:50
S148	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 10:30
S149	5	"20080132993"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 11:39
S150	14	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S151	1	"16788806"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S152	15	(US-10478320-$ | US-16788806-$ | US-20050010277-$ | US-20080082159-$ | US-20090264993-$ | US-3226814-$ | US-3402751-$ | US-3408731-$ | US-3574284-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:46
S153	13	(US-16788806-$ | US-20040230287-$ | US-20080275548-$ | US-20110257731-$	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/04/13 14:46

		| US-20120158121-$ | US-3125764-$ | US-3314328-$ | US-3668892-$).DID.	FPRS; EPO; JPO; DERWENT			
S154	0	(AI-20040230287-$ | AI-20080275548-$ | AI-20110257731-$ | AI-20120158121-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:47
S155	3,758	623/1.12	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S156	51	S155 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S157	7,650	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S158	5,220	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S159	4,196	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S160	2,120	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S161	1,463	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S162	11,262	S157 S158 S159 S160 S161	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:44
S163	282	S162 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:44
S164	1	"20040256759"	US-PGPUB; USPAT	OR	OFF	2020/06/06 15:28
S165	119	(US-10028848-$ | US-10034784-$ | US-10065824-$ | US-10321985-$ | US-16808137-$ | US-18153473-$ | US-19857887-$ | US-2858390-$ | US-20010044650-$ | US-20020082684-$ | US-20020177890-$ | US-20030040771-$	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:05

| US-20040210304-$ | US-20040249399-$ | US-20050043790-$ | US-20050197687-$ | US-20060149351-$ | US-20060155366-$ | US-20070067014-$ | US-20070095283-$ | US-20070168013-$ | US-20070203559-$ | US-20070219613-$ | US-20070250146-$ | US-20070276464-$ | US-20080132993-$ | US-20080132999-$ | US-20080262592-$ | US-20080275548-$ | US-20090036977-$ | US-20090099644-$ | US-20090099650-$ | US-20090125098-$ | US-20090171456-$ | US-20090198315-$ | US-20090312834-$ | US-20100042202-$ | US-20100049313-$ | US-20100087907-$ | US-20100094409-$ | US-20110257731-$ | US-20120046726-$ | US-20120089218-$ | US-20130013050-$ | US-20130144373-$ | US-20140046428-$ | US-20140172064-$ | US-20140316513-$ | US-20140336749-$ | US-20160022450-$ | US-20160270935-$ | US-20170209254-$ | US-2787925-$ | US-3002816-$ | US-3002826-$ | US-3005270-$ | US-3016877-$ | US-3021408-$ | US-3025694-$ | US-3034007-$ | US-3095343-$ | US-3102417-$ | US-3114001-$ | US-3157174-$ | US-3179931-$ | US-3206438-$ | US-3220613-$ | US-3220899-$ | US-3226710-$ | US-3258117-$ | US-3269739-$ | US-3289282-$ | US-3314324-$ | US-3358140-$ | US-3393021-$ | US-3393136-$ | US-3394119-$ | US-3397355-$ | US-3398701-$ | US-3414635-$ | US-3419788-$ | US-3425584-$ | US-3452070-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3561102-$ | US-3562673-$ | US-3582462-$ | US-3603156-$ | US-3617234-$ | US-3623067-$ | US-3629739-$ | US-3652198-$ | US-3715317-$ | US-3715337-$ | US-3721676-$ | US-3757263-$ | US-3833341-$ | US-3864808-$ | US-3911490-$ | US-3940040-$ | US-3943427-$ | US-3976179-$ | US-5004346-$ | US-5061275-$ | US-5254632-$ | US-5334868-$ | US-5464721-$ | US-5609627-$ | US-5716393-$ | US-5718159-$ | US-

		5752829-$ | US-5773457-$ | US-5814752-$ | US-5918925-$ | US-5957974-$ | US-7018404-$ | US-7771467-$ | US-7799072-$ | US-7914569-$ | US-D187180-$).DID.				
S166	15	(DE-10065824-$ | DN-102014805-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20020177890-$ | AI-20030040771-$ | AI-20040210304-$ | AI-20040249399-$ | NO-2004089249-$ | AI-20050043790-$ | AI-20050197687-$ | NO-2005087117-$ | AI-20060149351-$ | AI-20060155366-$ | NO-2006127412-$ | AI-20070067014-$ | AI-20070095283-$ | AI-20070168013-$ | AI-20070203559-$ | AI-20070219613-$ | AI-20070250146-$ | AI-20070276464-$ | AI-20080132993-$ | AI-20080132999-$ | AI-20080262592-$ | AI-20080275548-$ | AI-20090036977-$ | AI-20090099644-$ | AI-20090099650-$ | AI-20090125098-$ | AI-20090171456-$ | AI-20090198315-$ | AI-20090312834-$ | AI-20100042202-$ | AI-20100049313-$ | NO-2010006627-$ | AI-20100087907-$ | AI-20100094409-$ | NO-2010031060-$ | NO-2010105195-$ | AI-20110257731-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | AI-20120046726-$ | AI-20120089218-$ | NO-2012147675-$ | AI-20130013050-$ | AI-20130144373-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2013086132-$ | AI-20140046428-$ | AI-20140172064-$ | AI-20140316513-$ | AI-20140336749-$ | NO-2014072501-$ | AI-20160022450-$ | AI-20160270935-$ | AI-20170209254-$ | EP-2787925-$ | BI-3482228-$ | BI-3582462-$ | BI-5254632-$ | BI-5334868-$ | JS-2012068165-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:05
S167	34	(US-16808137-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:07
S168	1	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$	US-PGPUB; USPAT;	OR	OFF	2020/06/06 16:07

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S169	6	((frame with (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:53
S170	7	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 17:50
S171	1	("9370419").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:30
S172	627	("20010039450" | "20020013571" | "20020026216" | "20020082630" | "20020107565" | "20020123802" | "20020151970" | "20020183835" | "20020183838" | "20020188348" | "20020198594" | "20030023303" | "20030050694" | "20030078652" | "20030130729" | "20030153943" | "20030163194" | "20030167071" | "20030171806" | "20030199975" | "20030229394" | "20030229395" | "20030233142" | "20030236568" | "20030236569" | "20040002719" | "20040003819" | "20040010305" | "20040015230" | "20040015232" | "20040015233" | "20040019374" | "20040019377" | "20040019378" | "20040024447" | "20040024451" | "20040024452" | "20040030321" | "20040030381" | "20040030382" | "20040030405" | "20040034380" | "20040034411" | "20040039436" | "20040039442" | "20040039443" | "20040044350" | "20040044365" | "20040044403" | "20040049207" | "20040049211" | "20040049266" | "20040059351" | "20040059411" | "20040059412" | "20040060161" | "20040073301" | "20040073302" | "20040078072" | "20040078074" | "20040082910" | "20040082923" | "20040082991" | "20040087975" | "20040088045" | "20040088046" | "20040092858" | "20040093060" | "20040093070" | "20040093080" | "20040097979" | "20040098098" |	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:31

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S176	1,905	S175 and (seal$4)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/07 10:04
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S183	5,229	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S184	4,210	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S185	2,127	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S186	1,467	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S187	11,297	S182 S183 S184 S185 S186	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S188	2,885	S181 and S187	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/17 09:59
S189	1	("7799072").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/17 10:48
S190	4	"16736879"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 13:27
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S195	10	(CN-102014805-$ | NO-2005087117-$ | NO-2006127412-$ | NO-2010006627-$ | NO-2010031060-$ | NO-2010105195-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | EP-2787925-$ | JS-2012068165-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:37
S196	50	(US-10034784-$ | US-10065824-$ | US-16736879-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:41
S197	8	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:41
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S210	2,147	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S211	1,470	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S212	11,433	S207 S208 S209 S210 S211	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S215	56	2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
S216	0	wo2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
S217	0	(2006/124649).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 09:23

S218	0	(2006/0124649).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 09:24
S219	5	("2006124649").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/07/29 09:24
S220	1	"16808137"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:55
S221	4	"20090125098"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:29
S222	7	"20030040771"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:30
S223	1,779	(cuff with (fiber barb))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 11:58
S224	270	("20020036220" | "20030023303" | "20030050694" | "20030130726" | "20040049262" | "20040093075" | "20040102837" | "20040111111" | "20040210304" | "20040260389" | "20050096726" | "20050137682" | "20050137695" | "20050137697" | "20050203605" | "20050256566" | "20060008497" | "20060020327" | "20060025857" | "20060036308" | "20060074484" | "20060122692" | "20060149360" | "20060161249" | "20060173532" | "20060178740" | "20060206202" | "20060241744" | "20060241745" | "20060259120" | "20060259136" | "20060259137" | "20060265056" | "20060276813" | "20060276874" | "20070010876" |	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:03

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"20080125853" | "20080140189" |
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S225	1	(spense.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S226	573	(spence.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S227	10	(US-20070288087-$ | US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:17

S228	16	(US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-7175652-$ | US-7470284-$ | US-7740656-$ | US-7972370-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S229	34	(US-16910189-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S230	5	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$ | WO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130090729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:20
S231	7,889	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S232	5,349	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S233	4,324	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S234	2,182	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S235	1,479	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S236	11,602	S231 S232 S233 S234 S235	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53

S237	22	S236 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:54
S238	1,634	S236 and ((fibers))	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:55
S239	1,688	S236 and ((fibers))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S240	332	S236 and ((fibers)) and (frame and graft)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S245	4	(US-10716662-$ | US-16910189-$ | US-20090143855-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:02
S246	3	(wO-2001049213-$ | wO-2004032987-$ | AI-20090143855-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:04
S247	361	"4164046"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:09
S248	1	("4164046").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:09
S249	1	("20070142907").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:11
S256	85	(shahriari near ali).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 14:07
S257	51	"2006124649"	US-PGPUB; USPAT;	OR	OFF	2020/11/06 15:17

			USOCR; FPRS; EPO; JPO; DERWENT			
S258	0	("2006124649").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 15:17
S259	25	"12882605"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:02
S260	0	"12882605.app"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S261	0	"12882605".app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S262	0	("12882605").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S263	0	("2006018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S264	1	("20060018514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 16:03
S265	7	"20060018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S266	30	"2006018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S267	16	(US-10716662-$ | US-17024060-$ | US-20070288087-$ | US-20090143855-$ |	US-PGPUB; USPAT;	OR	OFF	2020/11/06 19:25

		US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$ | US-3992608-$).DID.	USOCR; FPRS; EPO; JPO; DERWENT			
S268	0	("(NO-2001049213-$\|NO-2004032987-$|AI-20070288087-$\|AI-20090143855-$|AI-20100217382-$\|AI-20100249916-$|NO-2011069048-$\|AI-20120123529-$|AI-20200197199-$\|VA-223131450-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 19:25
S269	0	(WO-2001049213-$ | NO-2004032987-$ | AI-20070288087-$ | AI-20090143855-$ | AI-20100217382-$ | AI-20100249916-$ | NO-2011069048-$ | AI-20120123529-$ | AI-20200197199-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 19:26
S272	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:22
S273	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:23
S274	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:24
S275	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:25
S276	5,725	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S277	26,012	A61F2/07.CPC.	US-PGPUB; USPAT;	OR	OFF	2021/01/16 10:26

			USOCR; FPRS; EPO; JPO; DERWENT			
S278	17,240	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S279	17,642	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S280	3,934	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S281	5,886	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S282	7,416	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S283	11,668	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S284	18,724	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S285	5,565	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/01/16 10:27

			FPRS; EPO; JPO; DERWENT			
S286	4,782	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S287	535	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S288	12,232	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S289	1,710	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S290	11,758	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S291	15,314	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S292	32,596	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S293	9,253	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:28

			JPO; DERWENT			
S294	17,878	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S295	3,437	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S296	3,130	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S297	14,644	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S298	1,594	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S299	3,931	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S300	2,511	(S272 S273 S274 S275 S276 S277 S278 S279 S280 S281 S282 S283 S284 S285 S286 S287 S288 S289 S290 S291 S292 S293 S294 S295 S296 S297 S298 S299) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:31
S301	1,676	S300 and (seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:33

			JPO; DERWENT			
S302	48	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/01/16 11:48
S303	13	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/01/16 11:49
S304	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:20
S305	2	(US-20120123529-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:21
S306	4	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:34
S307	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:35
S309	8	(US-10792172-$ | US-20020052649-$ | US-3333075-$ | US-3370418-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:46
S310	3	(("9333075") or ("7921678") or ("9370418")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:48
S311	15	(US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:48

S312	0	("(us-20130304196-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:49
S313	2	(us-20130304196-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:49
S315	1	("20120123529").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:50
S317	0	(AI-20020052649-$ | AI-20060276813-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:51
S318	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:52
S319	2	(US-20110009948-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:54
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Bibliographic Data

Application No: 17/131,869

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged: /TIFFANY P SHIPMON/ Examiner's Signature | Initials

Title: TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/23/2020	623	3774	426/2/20 UTIL
RULE			

APPLICANTS

Aortic Innovations, LLC, Hilsboro Beach, FL, UNITED STATES

INVENTORS

Ali Shahriari, Boca Raton, FL, UNITED STATES

CONTINUING DATA

This application is a CON of 17060557 10/01/2020 PAT 10888441

17060557 is a CON of 16910189 06/24/2020 PAT 10857011

16910189 is a CON of 16808137 03/03/2020 PAT 10792172

16808137 is a CON of 16736879 01/08/2020 PAT 10842655

16736879 is a CON of 16042286 07/23/2018 PAT 10555823

16042286 is a CON of 14614628 02/05/2015 PAT 10028848

14614628 is a CON of 14569306 12/12/2014 PAT 9339399

14569306 is a DIV of 13706896 12/06/2012 PAT 8940040

13706896 has PRO of 61723446 11/07/2012

13706896 has PRO of 61567458 12/06/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

01/07/2021

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

Aortic Innovations, LLC

4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
UNITED STATES

FILING FEE RECEIVED

$3,000

Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	17131869
Filing Date	23-Dec-2020
First Named Inventor	Ali Shahriari
Attorney Docket Number	426/2/20 UTIL
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Aortic Innovations, LLC	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

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as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○	I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

- ◉ Small Entity
- ○ Micro Entity
- ○ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

- ◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

  Registration Number 59389

- ○ A sole inventor
- ○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application
- ○ A joint inventor; all of whom are signing this request

Signature	/Justin R. Nifong/
Name	Justin R. Nifong

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	17131869
Filing Date:	23-Dec-2020
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/20 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 17131869

Filing Date: 23-Dec-2020

Applicant/Patent under Reexamination: Shahriari

Electronic Terminal Disclaimer filed on March 17, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	42209195
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	17-MAR-2021
Filing Date:	23-DEC-2020
Time Stamp:	16:33:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$170
RAM confirmation Number	E20213GG33100429
Deposit Account	506191
Authorized User	Justin Nifong

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33429 53e436c414741a0e850cc394298754b636cc8f4f	no	2
Warnings:					
Information:					
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Warnings:					
Information:					
		Total Files Size (in bytes):	63920		

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.

Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	17131869
Filing Date	23-Dec-2020
First Named Inventor	Ali Shahriari
Attorney Docket Number	426/2/20 UTIL
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Aortic Innovations, LLC	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

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as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

- (●) Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.
- ( ) I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

- (●) Small Entity
- ( ) Micro Entity
- ( ) Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

- (●) An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

  Registration Number 59389

- ( ) A sole inventor
- ( ) A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application
- ( ) A joint inventor; all of whom are signing this request

Signature	/Justin R. Nifong/
Name	Justin R. Nifong

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	17131869
Filing Date:	23-Dec-2020
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/20 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 17131869

Filing Date: 23-Dec-2020

Applicant/Patent under Reexamination: Shahriari

Electronic Terminal Disclaimer filed on March 17, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	42207599
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	17-MAR-2021
Filing Date:	23-DEC-2020
Time Stamp:	15:20:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$170
RAM confirmation Number	E20213GF20003925
Deposit Account	506191
Authorized User	Justin Nifong

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33492 5164f8517a7e5ecf91dec4da5a1924322597 2d70	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30492 310ba31b754803c5a8eeee0970a455249de 05389	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	63984		

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.

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/131,869	Confirmation No.:	1293
Applicant	:	Aortic Innovations, LLC		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	December 23, 2020		
TC/A.U.	:	3774		
Examiner	:	Shipmon, Tiffany		
Docket No.	:	426/2/20 UTIL		
Customer No.	:	175373		

Title of Invention: TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Response to Office Action

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

Remarks begin on page 4 of this paper.

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Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

Claims 1-10 (Canceled)

11. (Currently Amended) A transcatheter aortic valve assembly comprising:

an outer frame formed from a metallic material;

an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

wherein the outer frame is secured to the inner graft covering by stitching;

a first portion of fibers positioned radially outwardly of the outer frame that ~~forms~~ is configured to form a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers ~~are~~ is compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame,

wherein the first portion of fibers is non-metallic; and

a second portion of fibers carried by the outer frame that ~~forms~~ is configured to form a second sealing interface against the outer frame when the second portion of fibers ~~are~~ is compressed thereagainst,

wherein the second portion of fibers is non-metallic,

wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,

wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,

wherein the valve assembly is free of ~~a polymeric~~ an outer graft covering between the first portion of fibers and the outer frame ~~that covers an exterior surface of the outer frame~~,

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wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable to the radially expanded orientation and,

wherein expansion of the valve assembly is configured to compress ~~compresses~~ the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

12. (Canceled)

13. (Canceled)

14. (Currently Amended) The valve assembly according to claim 11, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering and through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame.

15. (New) The valve assembly of claim 11, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers.

16. (New) The valve assembly of claim 11, wherein the second portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the outer frame.

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REMARKS

This is in response to the Office Action mailed February 26, 2021.

35 USC 101 REJECTIONS

Claims 11-14 stand rejected under 35 USC 101. Applicant has amended the claims to recite that the valve is "configured to be positioned in a patient so that….." as requested by the examiner. Applicant thus submits that appropriate correction has been provided.

35 USC 112 REJECTIONS

Claims 11-14 stand rejected under 35 USC 112 as being indefinite. Specifically, applicant had recited that the limitation "wherein the valve assembly is free of a polymeric outer graft covering that covers an exterior surface of the outer frame." The Office Action indicates that the outer graft covering does not seem to be positively claimed. The Examiner interpreted this limitation to mean *that an outer graft covering covers the exterior surface of the outer frame, but is not engaged with the valve*. This is not the interpretation that Applicant had intended. Applicant has amended the claims to clarify the presence of this negative limitation. Indeed, the feature is not positively recited in the claims and is instead claimed as a negative limitation.

Applicant notes that the claims recite a so-called negative limitation: *"wherein the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame."* MPEP 2173 is controlling on the use of support for negative limitations:

> *Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under* ***35 U.S.C. 112****, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to*

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establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Additionally, the Federal Circuit has clarified the standards for negative limitations as well. The Federal Circuit has held that a negative limitation has written description support when the specification "describes a reason to exclude the relevant limitation." *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012). That standard is easily satisfied with the disclosure. Such written description support need not rise to the level of disclaimer. In fact, it is possible for the patentee to support both the inclusion and exclusion of the same material. The specification discloses multiple embodiments of a heart valve, and some of the embodiments show a design with an outer graft covering, and some of the other embodiments show a design that is free of an outer graft covering. The inclusion of an embodiment that includes an outer graft covering, and an embodiment without an outer graft covering provides support for the negative limitations disclosed herein. The specification even states "It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials," implying that alternate sealing materials, such as a non porous graft covering may or may not be provided.

35 USC 103 REJECTIONS

Claims 11-14 stand rejected under 35 USC 103 as being unpatentable over Nguyen in view of Greenhalgh and further in view of Braido.

Nguyen discloses a self-expanding heart valve, conventionally known in the industry as CoreValve by Medtronic.

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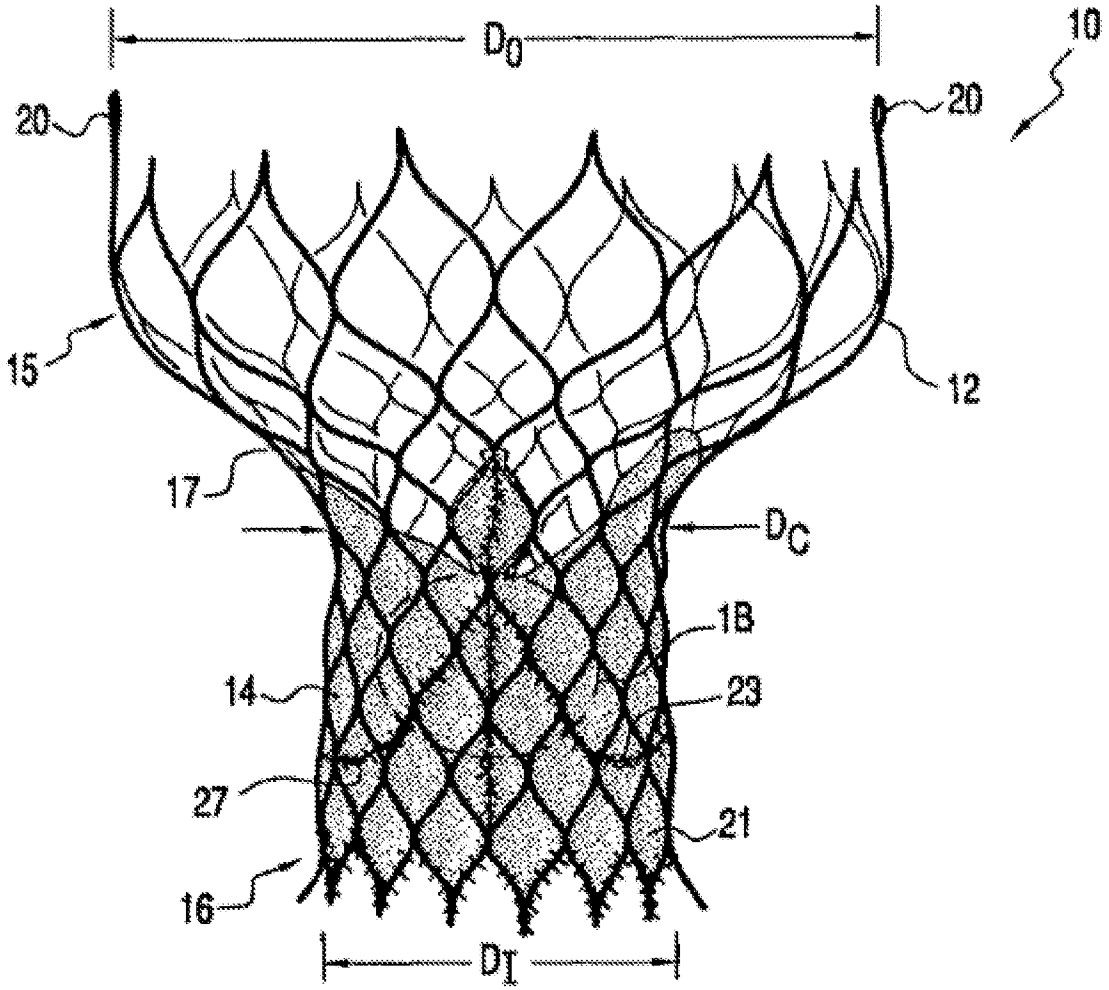

An inner skirt is shown as 21 that is internal to the frame 12. Future embodiments of the CoreValve product have included an outer skirt, such as CoreValve Evolut Pro, a commercially available TAVR.

Greenhalgh teaches an aneurysm treatment stent graft 10 that has loop fibers (FIG. 4) or other meandering fibers (FIG. 5) extending from a stent graft covering 18.

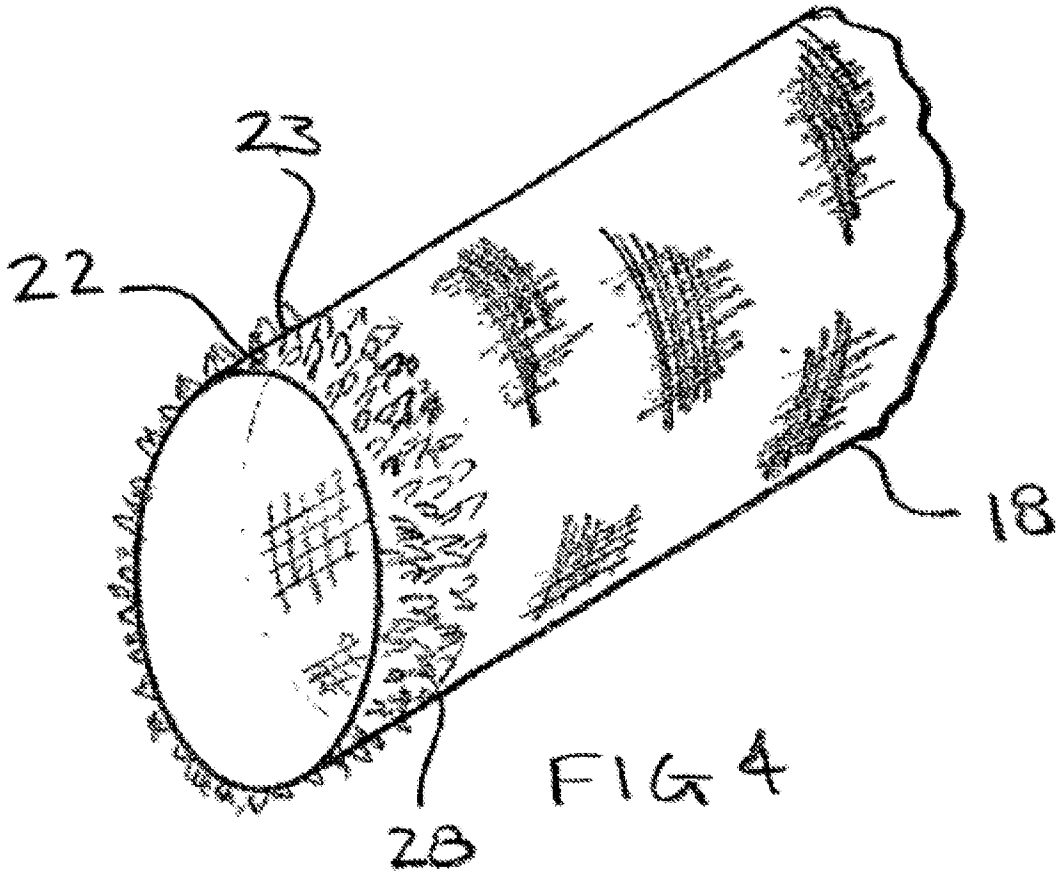

FIG 4

Braido teaches a TAVR assembly that includes an outer cuff 285.

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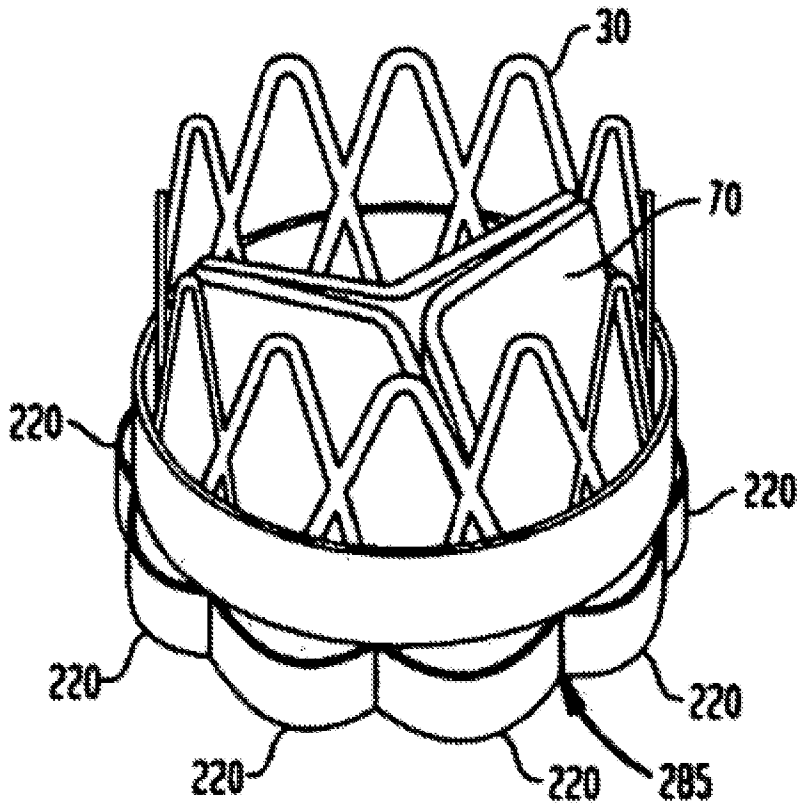
FIG. 10



CLAIM 11

Claim 11 has been amended to recite:

A transcatheter aortic valve assembly comprising:
an outer frame formed from a metallic material;
an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,
wherein the outer frame is secured to the inner graft covering by stitching;
a first portion of fibers positioned radially outwardly of the outer frame that ~~forms~~ <u>is configured to form</u> a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers ~~are~~ <u>is</u> compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame,

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wherein the first portion of fibers is non-metallic; and

a second portion of fibers carried by the outer frame that ~~forms~~ is configured to form a second sealing interface against the outer frame when the second portion of fibers ~~are~~ is compressed thereagainst,

wherein the second portion of fibers is non-metallic,

wherein the first portion of fibers and the second portion of fibers are in overlapping radial alignment,

wherein the transcatheter aortic valve is configured to be positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,

wherein the valve assembly is free of ~~a polymeric~~ an outer graft covering between the first portion of fibers and the outer frame ~~that covers an exterior surface of the outer frame~~,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable to the radially expanded orientation and,

wherein expansion of the valve assembly is configured to compress ~~compresses~~ the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

The combination of Nguyen, Greenhalgh, and Braido does not arrive at the claimed invention. The claims are directed towards an improved transcatheter aortic valve replacement (TAVR) that address paravalvular leaks (PVL). Namely, by having an inner frame that is a graft covering around the heart valve, sealing aspects are provided to the valve against the metallic outer frame. This helps to provide a seal around an inner facing surface of the metallic frame, as well as to protect at least portions of the valve leaflets from contact with the metal frame. The outer seal provides sealing between the outer frame and the patient's anatomical wall, while avoiding problems associated with conventional TAVR devices that will be discussed further herein.

US Patent Publication No. 20120123529 ("Levi") well describes this problem of crimp profile with respect to the inner skirt:

> *[0066] Known fabric skirts comprise a weave of warp and weft fibers that extend perpendicular to each other and with one set of fibers extending perpendicularly to the upper and lower edges of the skirt. When the metal frame, to which the fabric skirt is secured, is radially compressed, the overall axial length of the frame increases. Unfortunately, a fabric skirt, which inherently has limited elasticity, cannot elongate along with the frame and therefore tends to deform the struts of the frame and prevents uniform crimping.*

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While this was in reference to the inner skirt, the same concerns are presented with an outer skirt where conformability to the native annulus is even more pronounced. Thus, it should be evident that a balloon expandable outer frame (which is thus subject to higher compressive forces) having an outer graft covering of sufficient height, along with an inner graft covering, presented significant engineering design challenges. Designing an outer seal that would effectively seal and limit PVL for a balloon expandable frame is thus desirable, yet not have problems associated with inelasticity of a graft as described in Levi.

Nguyen, however, is not modifiable to add the stent graft of Greenhaulgh and achieve acceptable performance. As the name "stent graft" implies, Greenhaulgh includes a graft material, which is what the fibers extend from.

> *[0024] Stent graft **10** comprises a thin, flexible, biocompatible substrate **18**, preferably tubular and having stents **20** located at either end. Stents **20** are spring-like supports which hold the graft open and allow the ends to be sealingly attached to the wall **16** of the artery to either side of aneurysm **12**.*

Independent claim 11, however, requires that the valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame. Thus, Greenhalgh, teaches away from the claimed invention. Similarly, Braido teaches the presence of an outer graft covering and also teaches away from the claimed invention.

The improvement associated with the claimed invention is the generally loosely constructed outer seal. This outer seal has an increased surface area, which advantageously allows for increased area for blood thrombosis and tissue ingrowth, both of which will address PVL. This allows for the claimed TAVR to have a radially compressed orientation that doesn't create "bunching" of the outer seal, which then impacts overall cross-profile size, while allowing for an expanded orientation that has an increased overall surface area that doesn't have foreshortening issues associated with conventional TAVRs. In other words, the claimed invention allows for an outer seal that can stretch in the axial direction and the radial direction upon radial compression and expansion during deployment, while not causing permanent deformation of the wire frame due to significant crimping force.

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NEW CLAIMS 15 AND 16

New claims 15 and 16 are similar. Claim 15, as an example, recites:

The valve assembly of claim 11, wherein the first portion of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers.

This is well illustrated, in, for example, FIG. 13 of the application as filed:

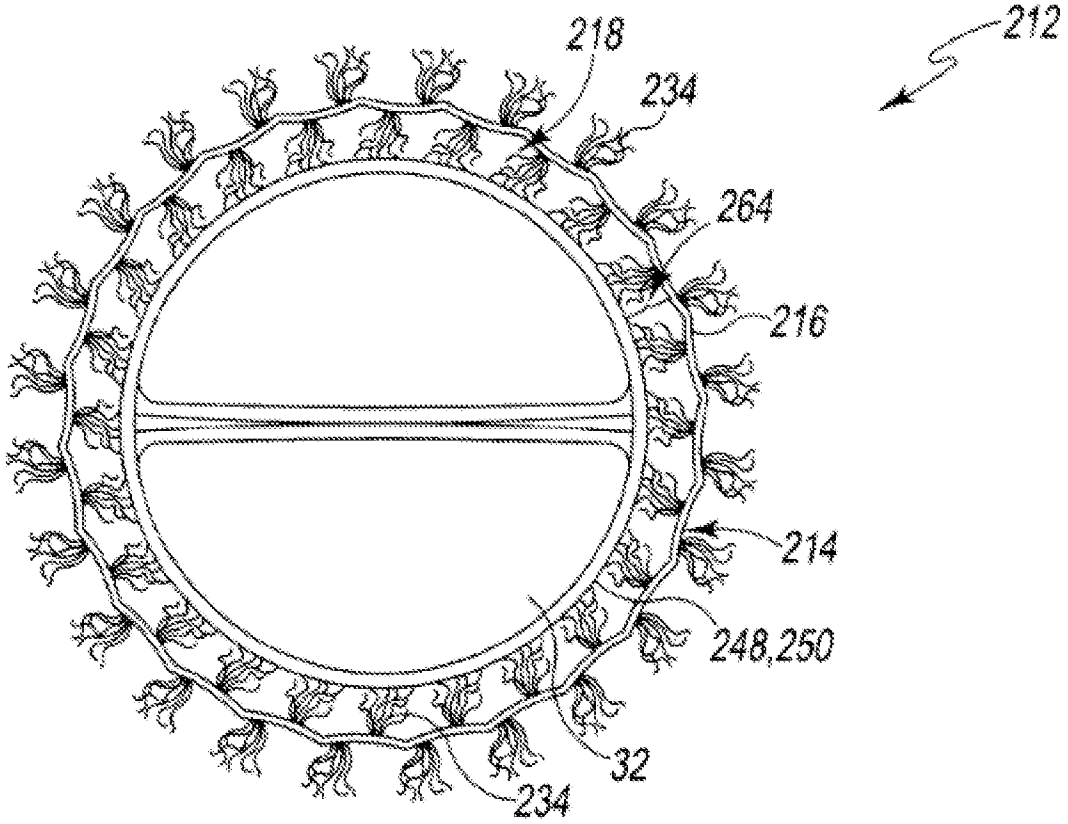

Fig. 13

This advantageously allows a portion of the seal that will allow for tissue ingrowth, while also providing pliability of the seal so that the foreshortening and force issues described in Levi are not as pronounced. Applicant submits that this is patentable over the references of record. Greenhalgh does, however, also teach forming openings within the stent graft seal for creating an opportunity for tissue ingrowth. From Greenhalgh:

> *[0030] As shown in FIG. 3, for substrates 18 comprising elastic, non-woven, continuous membranes formed of polymers such as expanded polytetrafluoroethylene and polyurethane, regions 22 of higher permeability are preferably formed by creating or enlarging pores 26 in narrow bands around the graft. The pores may be formed by mechanically piercing the membrane, etching with chemicals or ablating with a laser.*
>
> *[0031] ..... By including regions 22 of ePTFE comprising pores 26 having relatively greater size than the remaining portion of the graft, areas are created in the graft which will promote the ingrowth of living animal tissue to attach and seal the vessel to the graft via a biological attachment.....*

So Greenhalgh is aimed at providing for openings in the seal as well, however, Greenhalgh accomplishes this through a very different process compared with spacing apart fibers as claimed. Applicant submits that claims 15 and 16 are thus patentable over the prior art of record.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: February 28, 2021

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 206
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Electronic Acknowledgement Receipt

EFS ID:	42044975
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	28-FEB-2021
Filing Date:	23-DEC-2020
Time Stamp:	09:16:34
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		426-2-20UTIL-rsp-to-OA-2-26.pdf	634145 d6a7a52d94a86df1f3ca6218c571aedfc7aeb83f	yes	12

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	12
Warnings:			
Information:			
	Total Files Size (in bytes):	634145	

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New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/131,869	12/23/2020	Ali Shahriari	426/2/20 UTIL	1293

175373 7590 02/26/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	
SHIPMON, TIFFANY P	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
02/26/2021	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):

usptomail@nkpatentlaw.com

Office Action Summary	Application No. 17/131,869	Applicant(s) Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	Art Unit 3774	AIA (FITF) 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 26 January 2021.

☐ 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) 11-14 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) 11-14 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 23 December 2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Terminal Disclaimer

2. The terminal disclaimer filed on February 11, 2021 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **17/096253,17007373,17006793,16941117,10888441,10881538,10857011,10792172** has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 11-14 are rejected under 35 U.S.C. 101 because Section 33(a) of the America Invents Act reads as follows:

> Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

Claims 11 is rejected under 35 U.S.C. 101 and section 33(a) of the America Invents Act as being directed to or encompassing a human organism. See also *Animals - Patentability*, 1077 *Off. Gaz. Pat. Office* 24 (April 21, 1987) (indicating that human organisms are excluded from the scope of patentable subject matter under 35 U.S.C. 101). Claim 11 line 15 recites "….overlapping radial alignment with native valve leaflets of the aorta to seal" which claims part of the human body. This claim can be amended to recite "wherein the transcatheter aortic valve is configured to be positioned in a patient so

that…" overlap in radial alignment with native lave leaflets of the aorta to seal" in order to overcome this rejection.

Claim Rejections - 35 USC § 112

5. 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.

6. Claims 11-14 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 applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

7. Referring to claim 11 applicant recites the limitation "wherein the valve assembly is free of a polymeric outer graft covering that covers an exterior surface of the claim".

8. The outer graft covering does not seem to be positively recited in the claim. It is unclear what the applicant is fully intending to claim with this feature and as such should be clarified.

9. Examiner has interpreted this limitation to mean that an outer graft covering, covers the exterior surface of the outer frame, but is not engaged with the valve. However, appropriate clarification is required.

10. Claim 12 recites the limitation "the outer graft covering" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

11. 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, 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.

12. Claims 11-14 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (WO 2006/124649) in view of Greenhalgh (US 2002/0052649) and further in view of Braido et al. (US 2011/0098802).

13. Referring to claims 11-12, Nguyen et al. a transcatheter aortic valve assembly comprising: an outer frame(12) formed from a metallic material(page 12 lines 6-9) ; an inner frame(skirt, 21) that engages a prosthetic heart valve(14) having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve(see Figs. 5-6) and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve(Fig. 1A), wherein the outer frame is secured to the inner graft covering by stitching(page 12, lines 1-6); wherein the valve assembly has a radially compressed orientation and a radially expanded orientation(page 6 lines 7-10).

14. Nguyen et al. lacks a detailed description of a first portion of fibers positioned radially outwardly of the outer frame that forms a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers are compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame; and a second portion of fibers carried by the outer frame that forms a second sealing interface against the outer frame when the second portion of fibers are compressed thereagainst, wherein the first portion of fibers and the second portion of fibers radially overlap, wherein the transcatheter aortic valve is positioned in a patient so that the first sealing

interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst, wherein expansion compresses the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

15. Greenhalgh discloses a stent graft with a sealing material (22) positioned outside of a stent graft area (frame/stent 20) (Fig. 1). Greenhalgh discloses of a first portion of fibers positioned radially outwardly of the outer frame that forms a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers are compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame (See Figs. 4-5, radially extending fibers, 23/28) ; and a second portion of fibers carried by the outer frame (See Figs. 4-5, radially extending fibers, 23/28; see annotation below) that forms a second sealing interface against the outer frame when the second portion of fibers are compressed thereagainst. Additionally, Greenhalgh discloses the fibers along the surface of the graft where the first and second fibers can be arranged to create the textured surface area(paragraph 33)

16. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Nguyen et al. to include radially extending fibers as taught in Greenhalgh in order to further improve the seal of the device once implanted and prevent leakage.

17. Nguyen et al. as modified by Greenhalgh teaches a valve assembly with an inner frame and outer frame with a first and second sealing surface that are formed from fibers positioned radially outwardly of the outer frame. Therefore, the examiner interprets the limitation of "wherein the transcatheter aortic valve is positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst and wherein expansion compresses the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface"(the fibers expand with the valve assembly) as a recitation of intended use. Therefore the modified device is fully capable of performing the function.

18. Modified Nguyen et al. lacks a detailed description of wherein the valve assembly is free of a polymeric outer graft covering that covers an exterior surface of the outer frame, wherein the outer graft covering that the valve assembly is free of is distinct from the inner graft covering and the valve assembly is balloon expandable to the radially expanded orientation.

19. Braido et al. teaches a heart valve assembly in the same field of endeavor that comprises an outer graft covering (285) that covers an exterior surface of an outer frame, wherein the outer graft covering that the valve assembly is free of is distinct from the inner graft covering (See Figs. 17 and 18) and wherein the valve assembly is balloon expandable to the radially expanded orientation (paragraph 64). It would have been obvious to a person of ordinary skill in the art at the time of the invention to further modify the valve assembly of Nguyen et al. to be balloon expandable and comprise an outer covering, that covers an exterior surface of an outer frame as taught in Braido et al. in order to in order to further improve the seal of the device once implanted and prevent leakage. Additionally, it only requires routine skill in the art to use a self-expanding valve assembly or a balloon expandable assembly in order to deliver and implant the valve in the desired locations.

20. Referring to claim 14, Nguyen et al. discloses wherein the inner graft covering extends to the proximal inflow end of the outer frame (Fig. 1A), wherein, stitching (23) extending between the inner graft covering through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame.

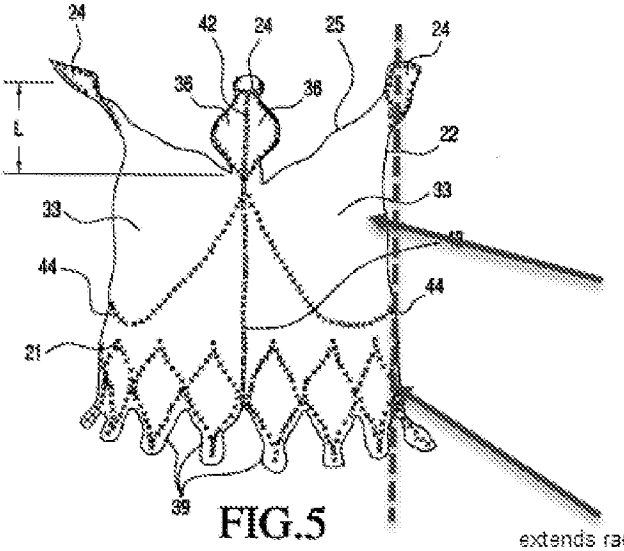

FIG.5

outer frame

extends radially outwardly of the prosthetic heart valve

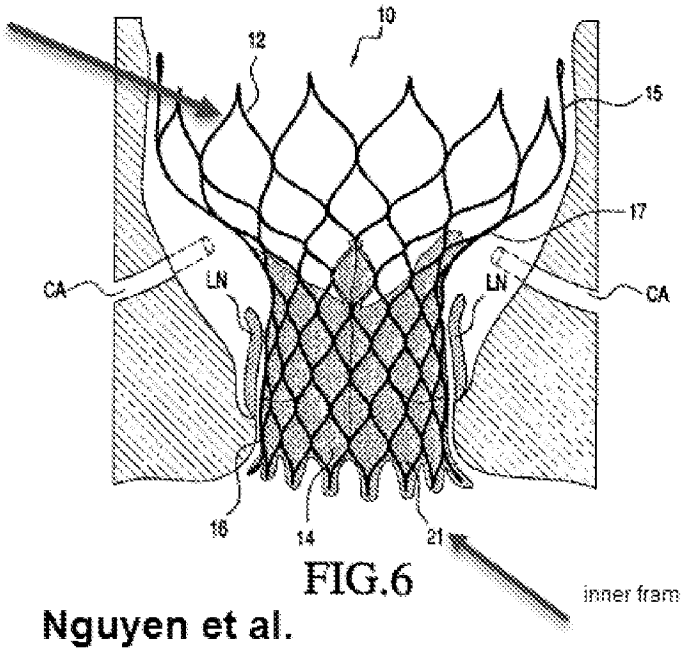

FIG.6

Nguyen et al.

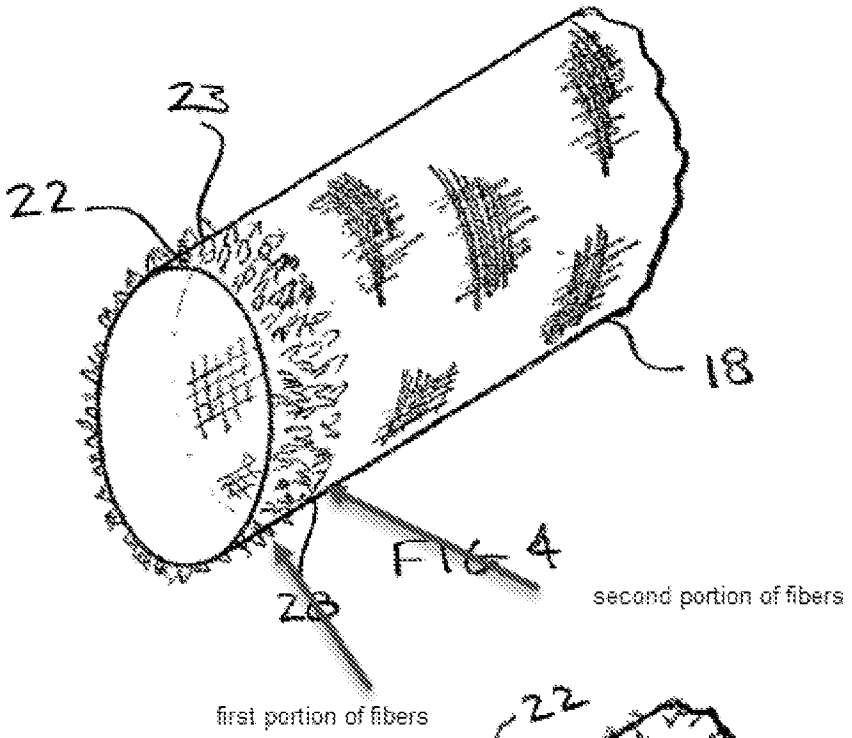

FIG 4

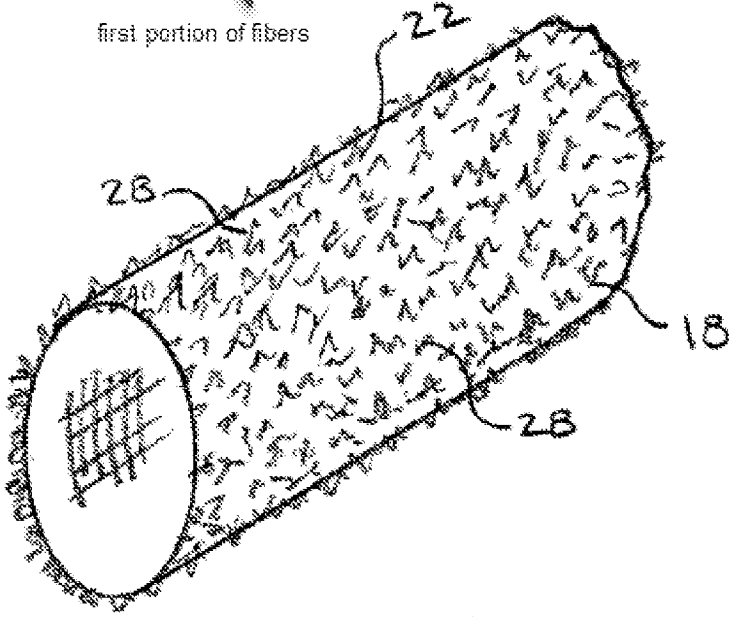

FIG 5

Greenhalgh

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY P SHIPMON whose telephone number is (571)270-1448. The examiner can normally be reached on MONDAY-FRIDAY.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Dieterle can be reached on 571-270-7872. 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 https://ppair-my.uspto.gov/pair/PrivatePair. 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.

/TIFFANY P SHIPMON/
Examiner, Art Unit 3774

/Jennifer Dieterle/
Supervisory Patent Examiner, Art Unit 3774
2/23/21

Notice of References Cited	Application/Control No. 17/131,869	Applicant(s)/Patent Under Reexamination Shahriari, Ali	
	Examiner TIFFANY P SHIPMON	Art Unit 3774	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20020052649-A1	05-2002	Greenhalgh, E. Skott	A61F2/0063	623/1.35
*	B	US-20110098802-A1	04-2011	Braido; Peter N.	A61F2/2442	623/1.26
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

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	N	WO-2006124649-A2	11-2006	WO	MICHIELS ROBRECHT	A61F2/2418
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/131,869	Shahriari, Ali
	Examiner	Art Unit
	TIFFANY P SHIPMON	3774

CPC - Searched*		
Symbol	Date	Examiner
A61F 2/856,07,2418,82,962, 2002/061	02/13/2021	T.S.

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST Search History	02/13/2021	T.S.

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

	/TIFFANY P SHIPMON/ Examiner, Art Unit 3774

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 220
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S11	11	a61f2/2475	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2014/06/28 23:31
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			EPO; JPO; DERWENT			
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S73	9,150	S68 S69 S70 S71 S72	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/02/05 09:58
S74	6,389	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S75	4,396	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04

S76	3,436	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S77	1,760	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S78	1,352	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S79	9,503	S74 S75 S76 S77 S78	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S80	9,503	S74 S75 S76 S77 S78 S79	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/04/15 09:04
S81	4,461	S80 and (artery arteries)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:06
S82	1,118	S80 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/15 09:09
S83	6,421	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S84	4,413	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S85	3,462	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S86	1,773	a61f2/2433.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/04/29 11:05

			EPO; JPO; DERWENT			
S87	1,354	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S88	9,549	S83 S84 S85 S86 S87	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S89	9,549	S83 S84 S85 S86 S87 S88	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/04/29 11:05
S90	1,126	S89 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/04/29 11:05
S91	1	("20090254172").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/05/14 15:40
S92	9	("20060155366" | "20100049313" | "6258117").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:09
S93	2	("20080262592").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
S94	6	("20070168013" | "20140172064" | "20140316513").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10
S95	6	("20020177890" | "5976179").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:10

S96	3	"20140316513"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:19
S97	2	"20070168013"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:20
S98	4	"20140172065"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:21
S99	6	"20100049313"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:26
S100	2	"20060155366"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:29
S101	6,666	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S102	4,593	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S103	3,601	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S104	1,864	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S105	1,380	a61f2/2475.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/07/21 10:35

			EPO; JPO; DERWENT			
S106	9,898	S101 S102 S103 S104 S105	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S107	9,898	S101 S102 S103 S104 S105 S106	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/07/21 10:35
S108	1,179	S107 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 10:35
S109	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 11:44
S110	4	"14614628"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/07/21 12:36
S111	7,098	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S112	4,889	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S113	3,856	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S114	1,965	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S115	1,422	a61f2/2475.cpc.	US-PGPUB; USPAT;	OR	OFF	2019/12/08 16:15

			EPO; JPO; DERWENT			
S116	10,508	S111 S112 S113 S114 S115	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S117	10,508	S111 S112 S113 S114 S115 S116	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2019/12/08 16:15
S118	1,256	S117 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2019/12/08 16:15
S120	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S121	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S122	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S123	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S124	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S125	10,919	S120 S121 S122 S123 S124	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45
S126	10,919	S120 S121 S122 S123 S124 S125	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 11:45

S127	1,305	S126 and (artery arteries) and (aortic near arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2020/03/13 11:45
S128	7,401	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S129	5,076	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S130	4,040	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S131	2,043	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S132	1,443	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S133	10,919	S128 S129 S130 S131 S132	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S134	10,919	S128 S129 S130 S131 S132 S133	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:54
S135	966	S134 and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 14:56
S136	5,500	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01

S137	24,545	A61F2/07.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S138	15,139	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S139	16,719	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S140	3,555	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S141	11,168	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:01
S142	1,881	(S136 S137 S138 S139 S140 S141) and (stent and artery and seal$4 and arch)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/03/13 19:02
S143	1	("9044311").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/13 20:21
S144	25	(US-10034784-$ | US-10065824-$ | US-16788806-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:45

		3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.				
S145	0	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:46
S146	0	"16788806"	US-PGPUB; USPAT	OR	OFF	2020/03/13 21:47
S147	1	("20080132993").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/04/11 20:50
S148	4	"20070067014"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 10:30
S149	5	"20080132993"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 11:39
S150	14	"13706896"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S151	1	"16788806"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 12:11
S152	15	(US-10478320-$ | US-16788806-$ | US-20050010277-$ | US-20080082159-$ | US-20090264993-$ | US-3226814-$ | US-3402751-$ | US-3408731-$ | US-3574284-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:46
S153	13	(US-16788806-$ | US-20040230287-$ | US-20080275548-$ | US-20110257731-$	US-PGPUB; USPAT; USOCR;	OR	OFF	2020/04/13 14:46

		| US-20120158121-$ | US-3125764-$ | US-3314328-$ | US-3668892-$).DID.	FPRS; EPO; JPO; DERWENT			
S154	0	(AI-20040230287-$ | AI-20080275548-$ | AI-20110257731-$ | AI-20120158121-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/04/13 14:47
S155	3,758	623/1.12	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S156	51	S155 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:43
S157	7,650	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S158	5,220	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S159	4,196	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S160	2,120	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S161	1,463	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:43
S162	11,262	S157 S158 S159 S160 S161	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/06/06 14:44
S163	282	S162 and ((fibers with collagen))	US-PGPUB; USPAT	OR	OFF	2020/06/06 14:44
S164	1	"20040256759"	US-PGPUB; USPAT	OR	OFF	2020/06/06 15:28
S165	119	(US-10028848-$ | US-10034784-$ | US-10065824-$ | US-10321985-$ | US-16808137-$ | US-18153473-$ | US-19857887-$ | US-2858390-$ | US-20010044650-$ | US-20020082684-$ | US-20020177890-$ | US-20030040771-$	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:05

| US-20040210304-$ | US-20040249399-$ | US-20050043790-$ | US-20050197687-$ | US-20060149351-$ | US-20060155366-$ | US-20070067014-$ | US-20070095283-$ | US-20070168013-$ | US-20070203559-$ | US-20070219613-$ | US-20070250146-$ | US-20070276464-$ | US-20080132993-$ | US-20080132999-$ | US-20080262592-$ | US-20080275548-$ | US-20090036977-$ | US-20090099644-$ | US-20090099650-$ | US-20090125098-$ | US-20090171456-$ | US-20090198315-$ | US-20090312834-$ | US-20100042202-$ | US-20100049313-$ | US-20100087907-$ | US-20100094409-$ | US-20110257731-$ | US-20120046726-$ | US-20120089218-$ | US-20130013050-$ | US-20130144373-$ | US-20140046428-$ | US-20140172064-$ | US-20140316513-$ | US-20140336749-$ | US-20160022450-$ | US-20160270935-$ | US-20170209254-$ | US-2787925-$ | US-3002816-$ | US-3002826-$ | US-3005270-$ | US-3016877-$ | US-3021408-$ | US-3025694-$ | US-3034007-$ | US-3095343-$ | US-3102417-$ | US-3114001-$ | US-3157174-$ | US-3179931-$ | US-3206438-$ | US-3220613-$ | US-3220899-$ | US-3226710-$ | US-3258117-$ | US-3269739-$ | US-3289282-$ | US-3314324-$ | US-3358140-$ | US-3393021-$ | US-3393136-$ | US-3394119-$ | US-3397355-$ | US-3398701-$ | US-3414635-$ | US-3419788-$ | US-3425584-$ | US-3452070-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3561102-$ | US-3562673-$ | US-3582462-$ | US-3603156-$ | US-3617234-$ | US-3623067-$ | US-3629739-$ | US-3652198-$ | US-3715317-$ | US-3715337-$ | US-3721676-$ | US-3757263-$ | US-3833341-$ | US-3864808-$ | US-3911490-$ | US-3940040-$ | US-3943427-$ | US-3976179-$ | US-5004346-$ | US-5061275-$ | US-5254632-$ | US-5334868-$ | US-5464721-$ | US-5609627-$ | US-5716393-$ | US-5718159-$ | US-

		5752829-$ | US-5773457-$ | US-5814752-$ | US-5918925-$ | US-5957974-$ | US-7018404-$ | US-7771467-$ | US-7799072-$ | US-7914569-$ | US-D187180-$).DID.				
S166	15	(DE-10065824-$ | DN-102014805-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20020177890-$ | AI-20030040771-$ | AI-20040210304-$ | AI-20040249399-$ | NO-2004089249-$ | AI-20050043790-$ | AI-20050197687-$ | NO-2005087117-$ | AI-20060149351-$ | AI-20060155366-$ | NO-2006127412-$ | AI-20070067014-$ | AI-20070095283-$ | AI-20070168013-$ | AI-20070203559-$ | AI-20070219613-$ | AI-20070250146-$ | AI-20070276464-$ | AI-20080132993-$ | AI-20080132999-$ | AI-20080262592-$ | AI-20080275548-$ | AI-20090036977-$ | AI-20090099644-$ | AI-20090099650-$ | AI-20090125098-$ | AI-20090171456-$ | AI-20090198315-$ | AI-20090312834-$ | AI-20100042202-$ | AI-20100049313-$ | NO-2010006627-$ | AI-20100087907-$ | AI-20100094409-$ | NO-2010031060-$ | NO-2010105195-$ | AI-20110257731-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | AI-20120046726-$ | AI-20120089218-$ | NO-2012147675-$ | AI-20130013050-$ | AI-20130144373-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2013086132-$ | AI-20140046428-$ | AI-20140172064-$ | AI-20140316513-$ | AI-20140336749-$ | NO-2014072501-$ | AI-20160022450-$ | AI-20160270935-$ | AI-20170209254-$ | EP-2787925-$ | BI-3482228-$ | BI-3582462-$ | BI-5254632-$ | BI-5334868-$ | JS-2012068165-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:05
S167	34	(US-16808137-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; DERWENT	OR	OFF	2020/06/06 16:07
S168	1	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$	US-PGPUB; USPAT;	OR	OFF	2020/06/06 16:07

		| NO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130090729-$ | VA-223131450-$).DID.	USOCR; FPRS; EPO; DERWENT			
S169	6	((frame with (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 16:53
S170	7	((frame same (inner and outer) same seal$4) same graft) and (heart with valve)	US-PGPUB; USPAT	OR	OFF	2020/06/06 17:50
S171	1	("9370419").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:30
S172	627	("20010039450" | "20020013571" | "20020026216" | "20020082630" | "20020107565" | "20020123802" | "20020151970" | "20020183835" | "20020183838" | "20020188348" | "20020198594" | "20030023303" | "20030050694" | "20030078652" | "20030130729" | "20030153943" | "20030163194" | "20030167071" | "20030171806" | "20030199975" | "20030229394" | "20030229395" | "20030233142" | "20030236568" | "20030236569" | "20040002719" | "20040003819" | "20040010305" | "20040015230" | "20040015232" | "20040015233" | "20040019374" | "20040019377" | "20040019378" | "20040024447" | "20040024451" | "20040024452" | "20040030321" | "20040030381" | "20040030382" | "20040030405" | "20040034380" | "20040034411" | "20040039436" | "20040039442" | "20040039443" | "20040044350" | "20040044365" | "20040044403" | "20040049207" | "20040049211" | "20040049266" | "20040059351" | "20040059411" | "20040059412" | "20040060161" | "20040073301" | "20040073302" | "20040078072" | "20040078074" | "20040082910" | "20040082923" | "20040082991" | "20040087975" | "20040088045" | "20040088046" | "20040092858" | "20040093060" | "20040093070" | "20040093080" | "20040097979" | "20040098098" |	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/06 19:31

"20040098112" | "20040102839" |
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"20040106976" | "20040106990" |
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"20040117009" | "20040122448" |
"20040122512" | "20040122513" |
"20040122514" | "20040122515" |
"20040122516" | "20040127979" |
"20040127980" | "20040127981" |
"20040127982" | "20040133220" |
"20040133267").PN. OR ("20040133273"
| "20040138742" | "20040138743" |
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S195	10	(CN-102014805-$ | NO-2005087117-$ | NO-2006127412-$ | NO-2010006627-$ | NO-2010031060-$ | NO-2010105195-$ | NO-2011035154-$ | JP-2011502628-$ | JP-2011507658-$ | EP-2787925-$ | JS-2012068165-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:37
S196	50	(US-10034784-$ | US-10065824-$ | US-16736879-$ | US-19857887-$ | US-20010044650-$ | US-20020082684-$ | US-20040249399-$ | US-20070219613-$ | US-20090036977-$ | US-20090099650-$ | US-20100087907-$ | US-20130013050-$ | US-3002816-$ | US-3025694-$ | US-3220613-$ | US-3289282-$ | US-3482228-$ | US-3506622-$ | US-3545549-$ | US-3562673-$ | US-3652198-$ | US-3715337-$ | US-3757263-$ | US-5464721-$ | US-5609627-$ | US-5773457-$ | US-5814752-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:41
S197	8	(DE-10065824-$ | DE-19857887-$ | AI-20010044650-$ | AI-20020082684-$ | AI-20040249399-$ | AI-20070219613-$ | AI-20090036977-$ | AI-20090099650-$ | AI-20100087907-$ | AI-20130013050-$ | NO-2013040663-$ | NO-2013059596-$ | NO-2014072501-$ | BI-3482228-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/06/17 14:41
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S208	5,285	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S209	4,260	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
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S211	1,470	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S212	11,433	S207 S208 S209 S210 S211	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/07/20 11:59
S215	56	2006/124649	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/07/29 09:23
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S226	573	(spence.in.) and valve	US-PGPUB; USPAT; USOCR	OR	OFF	2020/07/29 12:22
S227	10	(US-20070288087-$ | US-20100217382-$ | US-20100249916-$ | US-20120123529-$ | US-20200197199-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:17

S228	16	(US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-7175652-$ | US-7470284-$ | US-7740656-$ | US-7972370-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S229	34	(US-16910189-$ | US-20020052649-$ | US-20040243221-$ | US-20040256759-$ | US-20070179591-$ | US-20070213815-$ | US-20070219620-$ | US-20080021547-$ | US-20090105805-$ | US-20100204781-$ | US-20120123529-$ | US-20120296418-$ | US-20130090729-$ | US-3370418-$ | US-5663667-$ | US-5665117-$ | US-5824037-$ | US-20130144373-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:19
S230	5	(AI-20020052649-$ | AI-20040243221-$ | AI-20040256759-$ | JP-2005124959-$ | WO-2006005015-$ | AI-20070179591-$ | AI-20070213815-$ | AI-20070219620-$ | AI-20080021547-$ | AI-20090105805-$ | AI-20100204781-$ | AI-20120123529-$ | AI-20120296418-$ | AI-20130090729-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/04 10:20
S231	7,889	a61f2/2418.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S232	5,349	a61f2/2412.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S233	4,324	a61f2/2436.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S234	2,182	a61f2/2433.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S235	1,479	a61f2/2475.cpc.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53
S236	11,602	S231 S232 S233 S234 S235	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:53

S237	22	S236 and ((fibers with collagen) same migration)	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:54
S238	1,634	S236 and ((fibers))	US-PGPUB; USPAT	OR	OFF	2020/08/28 15:55
S239	1,688	S236 and ((fibers))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S240	332	S236 and ((fibers)) and (frame and graft)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/08/28 15:55
S245	4	(US-10716662-$ | US-16910189-$ | US-20090143855-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:02
S246	3	(wO-2001049213-$ | wO-2004032987-$ | AI-20090143855-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:04
S247	361	"4164046"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/09/27 23:09
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S249	1	("20070142907").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/09/27 23:11
S256	85	(shahriari near ali).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 14:07
S257	51	"2006124649"	US-PGPUB; USPAT;	OR	OFF	2020/11/06 15:17

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S259	25	"12882605"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:02
S260	0	"12882605.app"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
S261	0	"12882605".app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:03
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S265	7	"20060018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S266	30	"2006018514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 16:04
S267	16	(US-10716662-$ | US-17024060-$ | US-20070288087-$ | US-20090143855-$ |	US-PGPUB; USPAT;	OR	OFF	2020/11/06 19:25

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S268	0	("(NO-2001049213-$\|NO-2004032987-$|AI-20070288087-$\|AI-20090143855-$|AI-20100217382-$\|AI-20100249916-$|NO-2011069048-$\|AI-20120123529-$|AI-20200197199-$\|VA-223131450-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/06 19:25
S269	0	(WO-2001049213-$ | NO-2004032987-$ | AI-20070288087-$ | AI-20090143855-$ | AI-20100217382-$ | AI-20100249916-$ | NO-2011069048-$ | AI-20120123529-$ | AI-20200197199-$ | VA-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2020/11/06 19:26
S272	14	(US-10792172-$ | US-17096253-$ | US-20040082989-$ | US-20040256759-$ | US-20120123529-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:22
S273	9	(US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | US-20120123529-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:23
S274	23	(US-10792172-$ | US-17096253-$ | US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3333075-$ | US-3370418-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:24
S275	21	(US-20020052649-$ | US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | WO-2006005015-$ | WO-2006124649-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | WO-3829057-$ | WO-223131450-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:25
S276	5,725	A61F2/856.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S277	26,012	A61F2/07.CPC.	US-PGPUB; USPAT;	OR	OFF	2021/01/16 10:26

			USOCR; FPRS; EPO; JPO; DERWENT			
S278	17,240	A61F2/2418.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S279	17,642	A61F2/82.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:26
S280	3,934	A61F2/962.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S281	5,886	A61F2/24.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S282	7,416	A61F2/86.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S283	11,668	A61F2/89.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S284	18,724	A61F2/90.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S285	5,565	A61F2002/061.CPC.	US-PGPUB; USPAT; USOCR;	OR	OFF	2021/01/16 10:27

			FPRS; EPO; JPO; DERWENT			
S286	4,782	A61F2002/067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S287	535	A61F2210/00.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:27
S288	12,232	A61F2210/0014.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S289	1,710	A61F2210/0057.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S290	11,758	A61F2220/0008.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S291	15,314	A61F2220/0016.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S292	32,596	A61F2220/0025.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S293	9,253	A61F2220/0058.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:28

			JPO; DERWENT			
S294	17,878	A61F2220/0075.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:28
S295	3,437	A61F2230/001.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S296	3,130	A61F2230/0034.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S297	14,644	A61F2230/0067.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S298	1,594	A61F2250/0048.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S299	3,931	A61F2250/0069.CPC.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:29
S300	2,511	(S272 S273 S274 S275 S276 S277 S278 S279 S280 S281 S282 S283 S284 S285 S286 S287 S288 S289 S290 S291 S292 S293 S294 S295 S296 S297 S298 S299) and (heart adj3 valve) and (fiber$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/16 10:31
S301	1,676	S300 and (seal$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/01/16 10:33

			JPO; DERWENT			
S302	48	((("SHAHRIARI") near3 ("Ali"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2021/01/16 11:48
S303	13	((("AORTIC") near3 ("INNOVATIONS") near3 ("LLC"))).AS,AANM.	USPAT	OR	OFF	2021/01/16 11:49
S304	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:20
S305	2	(US-20120123529-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 17:21
S306	4	"16910189"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:34
S307	2	"17060557"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/01/26 18:35
S309	8	(US-10792172-$ | US-20020052649-$ | US-3333075-$ | US-3370418-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:46
S310	3	(("9333075") or ("7921678") or ("9370418")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:48
S311	15	(US-20030153974-$ | US-20040082989-$ | US-20040256759-$ | US-20110098802-$ | US-20120123529-$ | US-20130304196-$ | US-3829057-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:48

S312	0	("(us-20130304196-$).DID.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:49
S313	2	(us-20130304196-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:49
S315	1	("20120123529").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/02/11 17:50
S317	0	(AI-20020052649-$ | AI-20060276813-$ | AI-20080077236-$ | AI-20080188929-$ | AI-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:51
S318	10	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:52
S319	2	(US-20110009948-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:54
S320	5	"20060005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S321	96	"2006005015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/11 17:55
S322	5	"15876053"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:11

S323	2	("2018/0206982").URPN.	USPAT	OR	OFF	2021/02/13 09:12
S324	0	"20010049555"	USPAT	OR	OFF	2021/02/13 09:14
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S326	3	"20070233228"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
S327	3	"20120296418"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:16
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S329	4	("20130190862" | "20160317305").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:26
S330	4	("20070233228" | "20120296418").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27
S331	835	("20020173842" | "20030100939" | "20040186563" | "20050203617" | "20070162102" | "20080183271" | "20100204781" | "20130274873" | "20140200661" | "20150073546" | "4222126" | "4733665" | "4759758" | "4777951" | "5026366" | "5032128" | "5332402" | "5411055" | "5558644" | "5571175" | "5609626" | "6231602" | "6425916" | "6440764" | "6689123" | "6893460" | "6936067" | "7655034" | "7993394" | "8652203" | "20030212454" | "20050075728" | "20070112422" | "20100168844" | "20100198347" | "4829990" | "5397351" | "5545214" | "5549665" | "5584803" | "5855602" | "6027525" | "6132473" | "6168614" | "6221091" | "6302906" | "6350277" | "6454799" | "6605112" | "6908481" | "7510575" | "7563280" | "20070233228" | "20020138135" | "20050203614" | "20050234546" | "20060149350" | "20070260305" | "3714671" | "4297749" | "4441216" | "4692164" | "4762128" | "4883458" | "4994077" | "5007896" | "5163953" | "5360444" | "5411552" | "5591185" | "5639274" | "5665115" | "5716417" | "5749890" | "5756476" | "5855601" | "6171335" | "6245102" | "6299637" | "6488704" | "6569196" | "6769161" | "7393360" | "7585321" | "7959672" | "8167932" | "8747463" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 09:27

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S334	0	"17131869"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:12
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S336	13	S328 and (outer$4 with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 11:49
S337	27	S328 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:00
S338	36,075	l11and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14

S339	27	S331 and ((outer$4 exter$4 outsid$$)with (graft))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:14
S340	13	(US-10258464-$ | US-20110218619-$ | US-20110319991-$ | US-3339377-$ | US-3408214-$ | US-3532868-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:56
S341	12	(US-20020052649-$ | US-20060276813-$ | US-20080077236-$ | US-20080188929-$ | US-20080319521-$ | US-3333075-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 12:57
S342	4	"20110098802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2021/02/13 15:10

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17131869
Filing Date	2020-12-23
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/20 UTIL

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	1	20180311037	A1	2018-11-01	Morriss	43A

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Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	02/22/2021

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Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-02-16
Name/Print	Justin R. Nifong	Registration Number	59389

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Attorney Docket Number	426/2/20 UTIL

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	1	10258464		2019-04-16	Delaloye et al.	
	2	8408214		2013-04-02	Spenser	
	3	9339377		2016-05-17	Quadri et al.	
	4	9532868		2017-01-03	Braido	

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	1	20110218619	A1	2011-09-08	Benichou et al.	
	2	20110319991	A1	2011-12-29	Hariton et al.	

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	3	20120123529	A1	2012-05-17	Levi et al.	

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	1	PATSPADE Search Report, dated 1/21/2021, Pgs. 1-53, USA	

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Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-01-26
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	1	10792172		2020-10-06	Shahriari	
	2	7381219		2008-06-03	Salahieh et al.	
	3	7921678		2011-04-12	Norris et al.	FIG. 4
	4	9333075		2016-05-10	Biadillah et al.	
	5	9370418		2016-06-21	Pintor et al.	FIG. 20

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	1	20020052649	A1	2002-05-02	Greenhalgh	FIG. 5

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	2	20040082989	A1	2004-04-29	Cook William A. et al.	
	3	20040256759	A1	2004-12-23	Hartley	FIG. 4
	4	20120123529	A1	2012-05-17	Levi et al.	FIG. 1
	5	20110098802	A1	2011-04-28	Braido	
	6	20030153974	A1	2003-08-14	Spenser	
	7	20130304196	A1	2013-11-14	Kelly	[0031]

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	1	2006005015	WO		2012-05-17	Spenser	FIG. 21-22	
	2	9829057	WO		2012-05-17	Cribier	FIG. 6D	
	3	2006124649	WO		2006-11-23	Nguyen		

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	1	BOBO, Donald E., Edwards Lifesciences Surgical Heart Valve Therapy, 12/9/2011 presumed publication, slide 13	
	2	BULLER, Nigel, Declaration in IPR IPR2017-01293, 10/11/2016	

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

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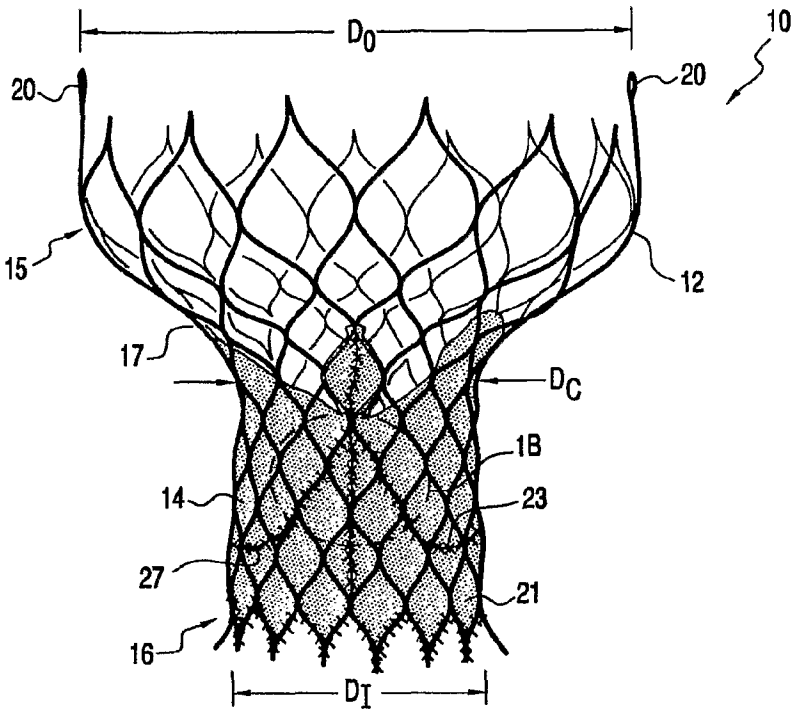
(54) Title: HEART VALVE PROTHESIS AND METHODS OF MANUFACTURE AND USE



(57) Abstract: A heart valve prosthesis is provided having a self-expanding multi-level frame that supports a valve body comprising a skirt and plurality of coapting leaflets. The frame transitions between a contracted delivery configuration that enables percutaneous transluminal delivery, and an expanded deployed configuration having an asymmetric hourglass shape. The valve body skirt and leaflets are constructed so that the center of coaptation may be selected to reduce horizontal forces applied to the commissures of the valve, and to efficiently distribute and transmit forces along the leaflets and to the frame. Alternatively, the valve body may be used as a surgically implantable replacement valve prosthesis.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

HEART VALVE PROSTHESIS AND METHODS OF MANUFACTURE AND USE

Field Of The Invention

The present invention relates to replacement valves for improving the cardiac function of a patient suffering from cardiac valve dysfunction, such as aortic valve regurgitation or aortic stenosis. More particularly, the present invention relates to heart valve prostheses that provide improved durability and are particularly well-suited for percutaneous delivery.

Background Of The Invention

Heart valve replacement has become a routine surgical procedure for patients suffering from valve regurgitation or stenotic calcification of the leaflets. While certain procedures may be performed using minimally-invasive techniques (so-called "keyhole" techniques), the vast majority of valve replacements entail full sternotomy and placing the patient on cardiopulmonary bypass. Traditional open surgery inflicts significant patient trauma and discomfort, requires extensive recuperation times, and may result in life-threatening complications.

To address these concerns, within the last decade efforts have been made to perform cardiac valve replacements using minimally-invasive techniques. In

these methods, laparoscopic instruments are employed to make small openings through the patient's ribs to provide access to the heart. While considerable effort has been devoted to such techniques, widespread acceptance has been limited by the clinician's ability to access only certain regions of the heart using laparoscopic instruments.

Still other efforts have been focused on percutaneous transluminal delivery of replacement cardiac valves to solve the problems presented by traditional open surgery and minimally-invasive surgical methods. In such methods, a valve prosthesis is compacted for delivery in a catheter and then advanced, for example, through an opening in the femoral artery and through the descending aorta to the heart, where the prosthesis then is deployed in the aortic valve annulus. Although transluminal techniques have attained widespread acceptance with respect to delivery of stents to restore vessel patency, only mixed results have been obtained with respect to percutaneous delivery of relatively more complicated valve prostheses.

One such example of a previously-known heart valve prosthesis is described in U.S. Patent No. 6,454,799 to Schreck. The prosthesis described in that patent comprises a fabric-based heart valve disposed within a plastically deformable wire-mesh base, and is delivered via expansion of a balloon catheter. One drawback with balloon catheter delivery of the prosthetic valve is that the valve leaflets may be damaged when compressed between the balloon and the base during deployment. In addition, because balloon expandable structures tend to experience some recoil following

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balloon deflation, perivalvular leaks may develop around the circumference of the valve prosthesis.

Accordingly it would be desirable to provide a percutaneously-deliverable valve prosthesis that reduces the risk of leaflet damage during deployment of the prosthesis. It further would be desirable to provide a valve prosthesis that reduces the risk of perivalvular leaks resulting from recoil of the prosthesis following deployment.

U.S. Patent No. 6,027,525 to Suh, et al. describes a valve prosthesis comprising a series of self-expanding units affixed to a polymeric cover and having a valve disposed therein. Such devices are not suitable for cardiac valve replacement because of the limited ability to compact the valve disposed within the prosthesis. Moreover, such valve prostheses would be particularly undesirable for treating aortic valve defects, because the polymeric cover would obscure the ostia of the coronary arteries, both disrupting blood flow to the coronary arteries and preventing subsequent catheterization of those arteries. Accordingly, it would be desirable to provide a valve prosthesis that is self-expanding, yet permits the valve to be compacted to a greater degree than previously-known designs.

U.S. Patent No. 6,682,559 to Myers, et al. also describes a valve prosthesis having an essentially tubular design. One drawback of such configurations is that relatively large horizontal forces arise along the coaptation edges of the leaflets and are transmitted to the commissural points. These forces may adversely affect the durability of the leaflets and lead to valve failure. In view of this, it would be desirable to provide a valve wherein the center of coaptation of the

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leaflets may be selected so as to reduce horizontal forces applied to coaptation edges of the leaflets and commissural points, thereby improving durability of the valve. In addition, it would be desirable to provide a valve design that more uniformly distributes horizontal forces over the coaptation edges of the leaflets, rather than concentrating those forces at the commissural points.

In an effort to more nearly recreate the force distribution along the leaflets of natural tissue valves, some previously-known valve designs include circular base portions having longitudinal projections that function as anchors for the commissural points, such as described in U.S. Patent No. 5,855,601 to Bessler, et al. and U.S. Patent No. 6,582,462 to Andersen, et al.

While the valve prostheses of Bessler and Andersen may be readily collapsed for delivery, those designs are susceptible to problems once deployed. For example, the longitudinal projections of such prostheses may not provide sufficient rigidity to withstand compressive forces applied during normal movements of the heart. Deformation of the commissural anchors may result in varied forces being imposed on the commissures and leaflets, in turn adversely impacting functioning of the leaflets. In addition, because the exteriors of the foregoing valve prostheses are substantially cylindrical, the prostheses are less likely to adequately conform to, and become anchored within the valve annulus anatomy during deployment. As a result, cyclic loading of the valve may result in some slippage or migration of the anchor relative to the patient's anatomy.

In view of the foregoing, it would be desirable to provide a valve that is capable of conforming to a

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patient's anatomy while providing a uniform degree of rigidity and protection for critical valve components.

It also would be desirable to provide a valve prosthesis having portions that are capable of deforming circumferentially to adapt to the shape of the pre-existing valve annulus, but which is not susceptible to deformation or migration due to normal movement of the heart.

It further would be desirable to provide a valve prosthesis having a multi-level component that is anatomically shaped when deployed, thereby enhancing anchoring of the valve and reducing the risk of migration and perivalvular leaks.

It still further would be desirable to provide a valve prosthesis wherein the valve body is configured to facilitate fabrication, and to assume a reduced delivery profile compared to previously known designs without damaging the functional components of the valve body.

Summary Of The Invention

In view of the foregoing, it is an object of the present invention to provide a valve prosthesis that overcomes the drawbacks of previously-known designs, and which may be implanted using open surgical, minimally invasive, or percutaneous implantation techniques.

It is yet another object of the present invention to provide a percutaneously-deliverable valve prosthesis that exhibits a markedly reduced delivery profile over known designs.

It is also an object of the present invention to provide a percutaneously-deliverable valve prosthesis that reduces the risk of damage to the leaflets or other

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functional components of the valve body during delivery and deployment of the prosthesis.

It is a further object of this invention to provide a valve prosthesis that reduces the risk of perivalvular leaks resulting from elastic recoil of the prosthesis following deployment.

It is another object of the present invention to provide a valve prosthesis that is self-expanding and permits ready access to adjoining anatomical structures, such as the coronary arteries.

It is a still further object of the present invention to provide a valve in which the center of coaptation of the leaflets may be selected so as to reduce horizontal forces applied to coaptation edges of the leaflets and commissural points, thereby improving durability of the valve.

In addition, it is an object of this invention to provide a valve design that more uniformly distributes forces over the coaptation edges of the leaflets, rather than concentrating those forces at the commissural points.

It is yet another object of this invention to provide a valve that is anatomically shaped, provides a uniform high degree of rigidity and protection for critical valve components, and which is less susceptible to deformation arising from normal movement of the heart.

It is an object of the present invention to provide a valve prosthesis having portions that are capable of deforming circumferentially to adapt to the shape of the pre-existing valve annulus, but which is not susceptible to deformation or migration due to normal movement of the heart.

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It is also an object of this invention to provide a valve prosthesis having a multi-level component that is anatomically shaped when deployed, thereby enhancing anchoring of the valve and reducing the risk of migration and perivalvular leaks.

It is a further object of the present invention to provide a valve prosthesis wherein a valve is disposed within a rigid portion of a multilevel frame, so that valve area and function are not impaired, but inflow and/or outflow portions of the multilevel frame are capable of conforming to patient anatomy anomalies.

It is a further object of the present invention to provide a valve prosthesis that facilitates alignment of the heart valve prosthesis with the direction of blood flow.

These and other objects of the present invention are accomplished by providing a heart valve prosthesis wherein a self-expanding multi-level frame supports a valve body comprising a skirt and plurality of coapting leaflets. The frame has a contracted delivery configuration, in which the prosthesis may be stored within a catheter for percutaneous delivery, and an expanded deployed configuration having an asymmetric hourglass shape.

In a first preferred embodiment, the valve body skirt and leaflets are constructed of porcine, bovine, equine or other mammalian tissue, such as pericardial tissue, and are sewn, welded, molded or glued together so as to efficiently distribute forces along the leaflets and to the frame. In a particularly preferred embodiment, the skirt comprises three sections of mammalian tissue that are joined along adjacent edges, so

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that the tissue folds easily to a collapsed delivery profile without bunching.

Alternatively, the skirt of the valve body may comprise a synthetic or polymetric material, such as Dacron, expanded polytetrafluoroethylene ("ePTFE"), or other suitable synthetic graft material. The valve body leaflets may be constructed of porcine, bovine, equine or other mammalian tissue, such as pericardial tissue, and are sewn, welded, molded or glued to the skirt so as to efficiently distribute forces along the leaflets and to the frame. The use of synthetic or polymeric materials for the valve skirt in conjunction with mammalian tissue leaflets may offer distinct advantages. In particular, the synthetic material may provide the same structural properties as the mammalian tissue but at reduced thickness, thereby enabling the valve body to be collapsed to a smaller delivery profile. Alternatively, the leaflets also may comprise a synthetic or polymeric material.

In accordance with the principles of the present invention, the frame comprises multiple levels, including a proximal conical inflow section, a constriction region and a flared distal outflow section. Each of the inflow and outflow sections is capable of deforming to a non-circular cross-section to conform to the patient's anatomy, while the constriction region is configured to retain a circular cross-section that preserves proper functioning of the valve body.

The frame comprises a plurality of cells having a pattern that varies along the length of the frame to provide a high degree of anchoring and alignment of the valve prosthesis. The cell pattern further is selected to provide a uniform diameter where the commissural

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joints of the leaflets are attached to the frame, while permitting the inflow and outflow regions to expand to conform to the patient's anatomy. In this manner, optimal functioning of the valve body may be obtained even though the frame may be deployed in anatomies having a range of sizes. In addition, the frame resists deformation caused by movement of the heart and enables a functional portion of the valve body to be disposed supra-annularly to the native valve, with a portion of the valve prosthesis extending into the native valve annulus.

In one embodiment suitable for aortic valve replacement, the valve body comprises a skirt coupled to three leaflets. The components may be formed of animal pericardial tissue or synthetic material, and are sewn, glued, welded or molded together. The lateral ends of the leaflets include enlarged regions that are folded to both form the commissural joints and fasten the commissural joints to the frame. The skirt and leaflets further are configured so that the joints align with contours of the cell pattern of the frame.

In a preferred embodiment, the commissural joints are affixed to the frame at locations above the area of coaptation, to provide a selectable center of coaptation of the leaflets. This design provides a more efficient delivery configuration because the commissures are not compressed against the leaflets when the valve prosthesis is reduced to the contracted delivery configuration. Additionally, by lengthening the distance to the commissures, the design mimics the functioning of natural tissue valves by distributing forces along the coaptation edges and reducing horizontal forces transmitted to the commissural joints.

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In alternative embodiments, the valve body of the present invention may include a sewing ring in lieu of the frame to facilitate surgical implantation, and may employ as few as two and as many as four leaflets.

Methods of making and using the valve prostheses of the present invention are also provided.

Brief Description Of The Drawings

The above and other objects and advantages of the present invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts throughout, and in which:

FIGS. 1A, 1B and 1C are, respectively, side and top end views of an exemplary valve prosthesis of the present invention in the expanded deployed configuration and an enlarged region of the frame of the valve prosthesis;

FIG. 2 is a side view of the frame of the valve prosthesis of FIGS. 1 in a contracted delivery configuration;

FIGS. 3A and 3B are, respectively, plan views of a leaflet and the skirt employed in the valve body of the present invention;

FIGS. 4A, 4B, 4C, and 4D are, respectively, a perspective view of a leaflet with its enlarged regions folded, a plan view of an embodiment of the valve body of the present invention in which the leaflets are fastened to the skirt, a perspective view of an alternative embodiment of a skirt, and a perspective view of another alternative embodiment of a skirt;

FIG. 5 is a side view of the valve body of FIG. 4B fully assembled; and

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FIG. 6 is a side view depicting the valve prosthesis of the present invention deployed atop a patient's aortic valve.

Detailed Description Of The Invention

The present invention is directed to a heart valve prosthesis having a self-expanding frame that supports a valve body. In a preferred embodiment, the frame has a tri-level asymmetric hourglass shape with a conical proximal section, an enlarged distal section and a constriction region having a predefined curvature when the frame is deployed. In the context of the present application, the proximal section constitutes the "inflow" portion of the valve prosthesis and is disposed in the aortic annulus of the patient's left ventricle, while the distal section constitutes the "outflow" portion of the valve prosthesis and is positioned in the patient's ascending aorta.

In a preferred embodiment the valve body comprises three leaflets that are fastened together at enlarged lateral end regions to form commissural joints, with the unattached edges forming the coaptation edges of the valve. The leaflets are fastened to a skirt, which is in turn affixed to the frame. The enlarged lateral end regions of the leaflets permit the material to be folded over to enhance durability of the valve and reduce stress concentration points that could lead to fatigue or tearing of the leaflets. The commissural joints are mounted above the plane of the coaptation edges of the valve body to minimize the contracted delivery profile of the valve prosthesis, while the configuration of the edges permits uniform stress distribution along the coaptation edges.

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Referring to FIGS. 1, an exemplary embodiment of a valve prosthesis constructed in accordance with the principles of the present invention is described. Valve prosthesis 10 comprises expandable frame 12 having valve body 14 affixed to its interior surface, e.g., by sutures. Frame 12 preferably comprises a self-expanding structure formed by laser cutting or etching a metal alloy tube comprising, for example, stainless steel or a shape memory material such as nickel titanium. The frame has an expanded deployed configuration that is impressed upon the metal alloy tube using techniques that are per se known in the art. Valve body 14 preferably comprises individual leaflets assembled to a skirt. All of the components of valve body 14, i.e., the skirt and leaflets, may be formed of a natural or man-made material. Alternatively, the leaflets may be formed from a natural material, such as porcine, equine or bovine pericardium, while the skirt comprises a synthetic or polymeric material, such as Dacron, ePTFE, or similar material.

Frame 12 preferably includes multiple levels, including outflow section 15, inflow section 16 and constriction region 17. As depicted in the enlarged view of FIG. 1B, the frame comprises a plurality of cells having sizes that vary along the length of the prosthesis. As indicated by dotted lines **a**, **b** and **c**, each cell comprises two zig-zag structures having unequal-length struts, wherein the vertices of the zig-zags are coupled together. For example, zig-zag 18 has length $\mathbf{z}_1$ whereas zig-zag 19 has greater length $\mathbf{z}_2$. This cell design permits each level of cells between the proximal and distal ends of the frame to be tailored to meet specific design requirements, such as,

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compressibility, expansion characteristics, radial strength and so as to define a suitable contour for attachment of the valve body.

The cell pattern of frame 12 also enables the frame to expand to the tri-level asymmetric hourglass shape depicted in FIG. 1A, having conical inflow section, enlarged outflow section and fixed diameter constricted region. Each section of frame 12 has a substantially circular cross-section in the expanded deployed configuration, but in addition the cell patterns of the inflow and outflow sections permit those sections to adapt to the specific anatomy of the patient, thereby reducing the risk of migration and reducing the risk of perivalvular leaks. The cell patterns employed in the constriction region are selected to provide a uniform circular cross-section area for the constriction region when deployed, and a pre-determined radius of curvature for the transition between the constriction region and outflow section of the frame. In particular, the convex-concave shape of frame 12 within the constriction region ensures that the frame is held away from the opposing sinus wall in the ascending aorta, thus ensuring adequate blood flow to the coronary arteries and facilitating catheter access to the coronary arteries.

Enlarged outflow section has nominal deployed diameter D_O, inflow section has nominal deployed diameter D_I, and constriction region has deployed substantially fixed diameter D_C. The conical shape of the inflow region and smooth transitions between adjacent sections of frame 12 are expected to be particularly advantageous in directing blood flow through the valve body with little or no turbulence, as compared to step changes in

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diameter observed for surgically implanted replacement valves.

The above-described cell pattern permits each of the inflow and outflow sections of frame 12 to expand to a diameter within a range of deployed diameters, while retaining constriction region 17 at a substantially constant diameter. Thus, for example, outflow diameter D_o may range from 30 to 55 mm, while inflow diameter D_I may vary from 19 to 34 mm. Illustratively, frame 12 may be manufactured in four sizes having a range of diameters D_o, D_I and D_c as set forth in Table 1 below:

Table 1

	Size A	Size B	Size C	Size D
D_o	40 mm	50 mm	40 mm	50 mm
D_c	22 mm	22 mm	24 mm	24 mm
D_I	26 mm	26 mm	29 mm	29 mm

Advantageously, these four frame sizes are expected to cover a wide range of patient anatomies, while requiring construction of only two sizes of valve bodies (22 and 24 mm). Compared to previously-known commercially available surgical valves, which vary from approximately 17 mm to 31 mm in one millimeter increments, it is expected that the above four sizes of valve prosthesis of the present invention could be used for more than 75% of the patient population, thus greatly reducing the costs associated with manufacturing and inventorying large numbers of parts.

When configured as a replacement for an aortic valve, inflow section 16 extends into and anchors within the aortic annulus of a patient's left ventricle and

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outflow section 15 is positioned in the patient's ascending aorta. Importantly, the configuration of outflow section 15 is expected to provide optimal alignment of the valve body with the direction of blood flow. In addition, the cell pattern of outflow section 15 also serves to anchor the outflow section in the patient's ascending aorta to prevent lateral movement or migration of frame 12. As depicted in FIG. 1C, the use of relatively larger cells in the outflow section of frame 12, combined with the convex-concave shape of constriction region 17, ensures that the frame does not obstruct blood flow to the patient's coronary arteries when deployed and allows for catheter access to the coronary arteries. Frame 12 also may include eyelets 20 for use in loading the heart valve prosthesis 10 into a delivery catheter.

Still referring to FIGS. 1, valve body 14 includes skirt 21 affixed to frame 12, and leaflets 22. Leaflets 22 are attached along their bases to skirt 21, for example, using sutures 23 or a suitable biocompatible adhesive. Adjoining pairs of leaflets are attached to one another at their lateral ends to form commissures 24, with free edges 25 of the leaflets forming coaptation edges that meet in area of coaptation 26.

As depicted in FIG. 1A, the curve formed at joint 27 between the base of each leaflet 22 and skirt 21 follows the contour of the cell pattern of frame 12, so that most of the length of joint 27 is directly supported by frame 12, thereby transmitting forces applied to the valve body directly to the frame. As further depicted in FIG. 1C, commissures 24 are configured to span a cell of frame 12, so that force is evenly distributed within the commissures and to frame 12.

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Referring to FIG. 2, valve prosthesis 10 is shown in the contracted delivery configuration. In this state, valve prosthesis may be loaded into a catheter for percutaneous transluminal delivery via a femoral artery and the descending aorta to a patient's aortic valve. In accordance with one aspect of the present invention, commissures 24 are disposed longitudinally offset from coaptation edges 25 of the valve body, thereby permitting a smaller delivery profile than achievable with previously-known replacement valves. In addition, because frame 12 self-expands upon being released from the delivery catheter, there is no need to use a balloon catheter during placement of valve prosthesis 10, thereby avoiding the potential for inflicting compressive injury to the valve leaflets during inflation of the balloon.

Referring now to FIGS. 3A and 3B, skirt 21 and leaflet 22 of a preferred aortic valve embodiment of the present invention are described. In one preferred embodiment, skirt 21 and leaflet 22 are cut from a sheet of animal pericardial tissue, such as porcine pericardial tissue, either manually or using a die or laser cutting system. The pericardial tissue may be processed in accordance with tissue processing techniques that are per se known in the art for forming and treating tissue valve material. In a preferred embodiment, skirt 21 and leaflets 22 have a thickness of between 0.008" and 0.016", and more preferably between 0.012" and 0.014".

In an alternative preferred embodiment, leaflets 22 are formed from animal pericardial tissue as described above, while skirt 21 is cut from a sheet of synthetic or polymer material, such as Dacron, ePTFE, or other similar material as known in the art. In this case, skirt 21 has a thickness of between 0.004" and

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0.012", and more preferably between 0.006" and 0.008", and may thus be compressed to a substantially smaller delivery profile. Alternatively, skirt 21 and leaflets 22 may be constructed of a synthetic or polymeric material.

Leaflet 22 includes enlarged lateral ends 30 and 31 disposed at either end of free edge 32, and body 33. Free edge 32 forms coaptation edge 25 of the finished valve body 14, while lateral ends 30 and 31 are folded and joined to adjacent leaflets to form commissures 24. In accordance with one aspect of the present invention, free edges 32 assume the form of catenaries when the valve body is affixed to frame 12, thereby providing uniform loading along the length of the coaptation edge in a manner similar to a suspension bridge. Body 33 is joined to skirt 21 as described below. Lateral ends 30 and 31 illustratively are shown in FIG. 3A as having fold lines **d**, **e** and **f**, to define flaps 34, 35 and 36.

In the embodiment of FIG. 3B, skirt 21 includes panels 21a, 21b and 21c, each panel having scalloped area 37, reinforcing tab 38, and end tab 39. Scalloped area 37 or each panel 21a, 21b and 21c is joined to a body 33 of a respective leaflet 22. Reinforcing tabs 38 illustratively include fold lines **g**, **h** and **i**, between panels 21a-21b and 21b-21c, except for reinforcing tabs 40 and 41 at the lateral ends of the panels 21a and 21c, which have only one fold apiece. As described below, reinforcing tabs 40 and 41 are joined to one another, e.g., by sutures or gluing, so that skirt 21 forms a frustum of a cone. In one preferred embodiment, panels 21a, 21b and 21c are cut conjoined from a single piece of animal pericardium, as depicted in FIG. 3B.

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End tabs 39 are folded over the ends of the proximal-most row of cells of frame 12 to secure skirt 21 to the frame and seal against perivalvular bypass flows (see FIG. 1A). Because end tabs 39 are directly supported by the last zig-zag row of cells of frame 12, there is no opportunity for an unsupported edge of the skirt to flap or otherwise extend into the flow path along the inflow edge of skirt 21. Thus, the design of the valve prosthesis not only ensures that there are no flaps to disrupt flow or serve as sites for thrombus formation, but also reduces the risk that hemodynamic flow against such flaps could cause frame 12 to migrate.

It has been observed that when panels 21a-21c are cut conjoined from a single piece of animal pericardium, the skirt has a tendency to bunch-up or "accordion" when the valve body is collapsed to its reduced delivery configuration. However, applicants have discovered that if panels 21a-21c are severed along fold lines **h** in FIG. 3B, or individually cut from a piece of animal pericardium, this phenomenon is not observed, and the skirt can be collapsed to a substantially smaller profile. In particular, whereas a tissue-based skirt comprising conjoined panels 21a-21c, as shown in FIG. 3B, fits within a 21 French delivery catheter, forming skirt 21 of individual panels 21a-21c enables the device to fit within an 18 French catheter, resulting in a reduction in the delivery profile of about twenty-five percent (25%).

As a still further alternative, skirt 21 may be formed of a synthetic or polymeric material, such as Dacron, ePTFE, or similar material selected for its properties and biocompatibility. As opposed to leaflets 22, which provide a mechanical function through movement, skirt 21 functions primarily to create a seal to prevent

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perivalvular leaks. Accordingly, a thin synthetic material may be used in place of thicker mammalian tissue to serve this purpose. As a result, the device may be compacted to a reduced delivery profile by virtue of the decreased volume of the skirt. For example, use of a synthetic skirt with a valve body having tissue-based leaflets may enable the device to fit within a catheter having even less than an 18 French diameter.

Referring to FIGS. 4A and 4B, assembly of valve body 14 from the above-described embodiments of skirt 21 and leaflets 22 is described. In FIG. 4A, flap 34 first is folded along line **d**. Flap 35 is folded along line **e** so that it lies atop flap 34, forming seam 42 comprising a triple thickness of the tissue. Flap 36 then is folded along line **f**. Adjoining leaflets 22 then are fastened together along adjacent seams 42, resulting in a leaflet assembly.

Reinforcing tabs 38 are folded along lines **g**, **h** and **i** to form seams 43 comprising a double thickness of tissue, or in the case of separate panels 21a-21c, joined to form seams along tabs 38. Next, the leaflet assembly is attached to skirt 21 along the bottom edges of bodies 33 of the leaflets to form joints 44. At this stage of the assembly, prior to attaching reinforcing tab 40 to 41 and the remaining seam 42 of leaflets 22, the valve body appears as depicted in FIG. 4B. Reinforcing tabs 40 and 41 then are fastened together to form another seam 43 along skirt 21 and the remaining seam 42 between leaflets 22. Valve body 14 then is ready to be affixed to frame 12.

Referring to FIG. 4C, alternative embodiment of a synthetic skirt for a valve body of the present invention is described. Skirt 45 of FIG. 4C is formed

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from tube 47 of commercially available synthetic material, such as described above. Tube 47 is cut at one end to form scalloped areas 37, while notches are cut at the other end of the tube to form end tabs 39. Leaflets 22, which may comprise natural or synthetic material, then are assembled and attached to skirt 45 in a manner similar to that described above. Because skirt 45 is essentially cylindrical, it preferably comprises a material that is sufficiently flexible to stretch to conform to the desired shape of frame when end tabs 39 are attached to frame 12.

In FIG. 4D, another alternative embodiment of a synthetic skirt for a valve body of the present invention is described. In this case, the skirt first is cut from tube 47 into a shape shown in FIG. 4C, and then formed into a shape resembling the frustum of a cone by creating triangular pleats 48. In particular, prior to the attachment of a leaflet assembly, the apices of the scalloped areas 37 are folded upon themselves and joined, such as by sewing, bonding, welding, molding, or gluing together to form pleats 48. As illustrated in FIG. 4D, pleats 48 may be formed by seams 49, and may have a width selected to impart any desired amount of taper to the skirt 46. The leaflets then may be assembled and attached to the skirt, and the valve body attached to frame 12, as described above. Advantageously, pleats 48 provides strengthened attachment points to secure skirt 46 to frame 12.

Referring to FIG. 5, valve body 14 is shown as it would appear when affixed to frame 12, but with frame 12 omitted to better illustrate where the valve body is affixed to the frame. During the step of affixing the valve body to the frame, flaps 36 of adjacent leaflets

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are affixed, e.g., by sutures, to span a cell of the frame to support commissures 24 (compare to FIG. 1B) and end tabs 39 are folded over and affixed to the proximal-most row of cells of the frame 12 (compare to FIG. 1A). Valve body 14 also is attached to frame 12 along seams 43 formed by the reinforcing tabs. Each joint 44 is aligned with and fastened to (e.g., by sutures or glue) to a curved contour defined by the struts of the cells of frame 12, so that joint 44 is affixed to and supported by frame 12 over most of the length of the joint. As discussed above, the configuration of the cells in frame 12 may be specifically customized define a curved contour that supports joints 44 of the valve body.

When completed assembled to frame 12, valve body 14 is affixed to frame 12 along the edges of flaps 36 of the commissures, end tabs 39, leaflet seams 42, reinforcing tab seams 43 and joints 44. In this manner, forces imposed on leaflets 22, commissures 24 and joints 44 are efficiently and evenly distributed over the valve body and transferred to frame 12, thus reducing stress concentration and fatigue of the valve body components. Moreover, the use of multiple thicknesses of material along seams 42 and 43 is expected to provide a highly durable valve body that will last for many years once implanted in a patient.

In accordance with another aspect of the present invention, the center of coaptation of leaflets 22 is a distance **L** below the point at which the commissures are affixed to the frame, as shown in FIG. 5. Compared to previously-known designs, in the present invention the overall lengths of the coaptation edges are increased, while leaflets 22 coapt along a shorter

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portion of those lengths. Several advantages arise from this design:

- the leaflets require only minimal pressure to open and have a rapid closing time.
- the valve demonstrates better washing dynamics when open, i.e., less turbulence along the free edges of the leaflets.
- the valve provides a more uniform distribution of stresses along the coaptation edges of leaflets 22.
- the angle at which force is transmitted to the commissures is increased, thereby substantially reducing the horizontal forces applied to the commissures that tend to pull the commissures away from the frame.
- controlling the center of the height of coaptation allows the commissures to be located proximal of the center of coaptation, thereby reducing the contracted delivery profile of the valve prosthesis.

All of the foregoing benefits are expected to reduce non-uniform loads applied to the valve body, and substantially enhance the durability of the valve prosthesis.

As will of course be apparent to one of skill in the art of prosthetic valve design, the assembly steps described above are merely illustrative, and a different order of assembling the leaflets and skirt to form valve body 14 may be employed. In an alternative embodiment, a conventional sewing ring may be attached to valve body 14 and frame 12 may be omitted. In this case, the valve prosthesis may be implanted surgically, rather than by percutaneous transluminal delivery. In this case, commissures 24 may be attached to the ascending aorta by sutures or other means as described above.

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Referring now to FIG. 6, implantation of valve prosthesis 10 of the present invention is described and is shown having skirt 46 from FIG. 4D. As discussed above, valve prosthesis preferably comprises a self-expanding multilevel frame that may be compressed to a contracted delivery configuration, as depicted in FIG. 3, onto an inner member of a delivery catheter. The valve prosthesis and inner member may then be loaded into a delivery sheath of conventional design, e.g., having a diameter of 18-20 French or less. Due in part to the fact that commissures 24 are longitudinally offset from the coaptation edges of the leaflets, the ability to customize the cell pattern along the length of the frame, and the construction of the skirt, it is expected that valve prosthesis may be designed to achieve a significantly smaller delivery profile than previously-known percutaneously-deliverable replacement valves.

The delivery catheter and valve prosthesis are then advanced in a retrograde manner through a cut-down to the femoral artery and into the patient's descending aorta. The catheter then is advanced, under fluoroscopic guidance, over the aortic arch, through the ascending aorta and mid-way across the defective aortic valve. Once positioning of the catheter is confirmed, the sheath of the delivery catheter may be withdrawn proximally, thereby permitting the valve prosthesis to self-expand.

As the valve prosthesis expands, it traps native leaflets **LN** of the patient's defective aortic valve against the valve annulus, retaining the native valve in a permanently open state. As further illustrated in FIG. 6, outflow section 15 of the valve prosthesis expands against, and aligns the prosthesis within, the ascending aorta, while inflow section 16

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becomes anchored in the aortic annulus of the left ventricle, so that skirt 21 reduces the risk of perivalvular leaks.

As also seen in FIG. 6, the deployed configuration of constriction region 17 holds valve body 14 in a supra-annular position, away from the heart walls, thereby ensuring that the constriction region expands to the predetermined fixed diameter. This in turn ensures that the valve body does not experience any unexpected lateral loads and therefore expands to its design diameter, e.g., illustratively either 22 or 24 mm as in Table 1 above.

Because outflow section 15 of frame 12 employs relatively larger cells than the remainder of the frame, valve prosthesis 10 does not disrupt blood flow into coronary arteries **CA** when deployed, and also does not obstruct subsequent catheter access to the coronary arteries. Accordingly, a clinician may readily gain access to the coronary arteries, for example, to perform angioplasty or stenting, simply by directing the angioplasty or stent delivery system guide wire through the openings in the cell pattern of frame 12.

While preferred embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

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What Is Claimed Is:

1. A valve prosthesis comprising:

a self-expanding multi-level frame having a contracted delivery configuration and an expanded deployed configuration, the multi-level frame having in the expanded deployed configuration an enlarged outflow section with a first nominal diameter, a conical inflow section having a second nominal diameter and a constriction region having a third fixed diameter smaller than the first and second nominal diameters; and

a valve body affixed to the multi-level frame, the valve body comprising a plurality of leaflets affixed to a skirt.

2. The valve prosthesis of claim 1 wherein the multi-level frame comprises a cell pattern defined by unequal length zig-zags.

3. The valve prosthesis of claim 1 wherein the conical section has a proximal end and the conical inflow section flares outward towards the proximal end.

4. The valve prosthesis of claim 1 wherein adjoining leaflets are affixed together to form commissures and have free edges that define coaptation edges and a center of coaptation, the commissures being longitudinally offset from the center of coaptation.

5. The valve prosthesis of claim 4 wherein the commissures are affixed to the multi-level frame at a location proximal of the center of coaptation.

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6. The valve prosthesis of claim 5 wherein the multi-level frame comprises a cell pattern and the commissures include flaps that span an entire area of at least one cell of the cell pattern.

7. The valve prosthesis of claim 4 wherein the commissures and coaptation edges of the leaflets define catenaries that substantially uniformly distribute loads over the leaflets.

8. The valve prosthesis of claim 7 wherein the catenaries are configured to reduce horizontal loads applied to the commissures.

9. The valve prosthesis of claim 1 wherein the leaflets are affixed to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the multi-level frame.

10. The valve prothesis of claim 9 wherein the multi-level frame further comprises a cell pattern that defines a contour configured to support the joints.

11. The valve prosthesis of claim 4 wherein each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures.

12. The valve prosthesis of claim 1 wherein the skirt further comprises a plurality of longitudinally-oriented reinforcing tabs or pleats.

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13. The valve prosthesis of claim 12 wherein the reinforcing tabs or pleats are affixed to the multi-level frame.

14. The valve prosthesis of claim 12 wherein the skirt further comprises a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the multi-level frame.

15. The valve prosthesis of claim 1 wherein the leaflets comprise a material selected from one of: porcine, bovine, equine or other mammalian pericardial tissue, synthetic material or polymeric material.

16. The valve prosthesis of claim 1 wherein the valve body is deployed supra-annularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the multi-level frame is in the expanded deployed configuration.

17. The valve prosthesis of claim 1 wherein the multi-level frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration.

18. The valve prosthesis of claim 1 wherein the multi-level frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration.

19. The valve prosthesis of claim 1 wherein multi-level frame has proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends.

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20. The valve prosthesis of claim 1 wherein the constriction region comprises a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constriction region to the outflow section.

21. The valve prosthesis of claim 1 wherein the skirt comprises a synthetic material.

22. The valve prosthesis of claim 21 wherein the skirt has a tubular shape in an undeformed configuration.

23. The valve prosthesis of claim 22 wherein skirt is configured in conical frustum shape formed by deforming the synthetic material.

24. The valve prosthesis of claim 23 wherein the conical frustum shape is formed by creating a plurality of longitudinally-oriented pleats in the synthetic material.

25. The valve prosthesis of claim 1 wherein the skirt comprises two or more individual panels of animal pericardial material.

26. The valve prosthesis of claim 1 wherein the skirt comprises two or more conjoined panels of animal pericardial material.

27. A valve prosthesis comprising:

a valve body comprising a plurality of leaflets affixed to a skirt, adjoining leaflets affixed together to form commissures and having free edges that define coaptation edges and a center of coaptation,

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wherein the commissures are longitudinally offset from the center of coaptation and define catenaries that substantially uniformly distribute loads over the leaflets.

28. The valve prosthesis of claim 27 wherein the catenaries are configured to reduce horizontal loads applied to the commissures.

29. The valve prosthesis of claim 27 wherein each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures.

30. The valve prosthesis of claim 27 wherein the skirt further comprises a plurality of longitudinally-oriented reinforcing tabs or pleats.

31. The valve prosthesis of claim 27 wherein the leaflets comprise a material selected from one of: porcine, bovine, equine or other mammalian pericardial tissue, synthetic material or polymeric material.

32. The valve prosthesis of claim 27 wherein the valve prosthesis further comprises a self-expanding frame, the leaflets are affixed to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame.

33. The valve prothesis of claim 32 wherein the frame further comprises a cell pattern that defines a contour configured to support the joints.

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34. The valve prosthesis of claim 30 wherein the valve prosthesis further comprises a self-expanding frame and the reinforcing tabs or pleats are affixed to the frame.

35. The valve prosthesis of claim 27 further comprising a self-expanding frame having a contracted delivery configuration and an expanded deployed configuration.

36. The valve prosthesis of claim 35 wherein the frame comprises a cell pattern defined by unequal length zig-zags.

37. The valve prosthesis of claim 35 wherein the commissures are affixed to the frame at a location proximal of the center of coaptation.

38. The valve prosthesis of claim 35 wherein the frame comprises a cell pattern and the commissures include flaps that span an entire area of at least one cell of the cell pattern.

39. The valve prosthesis of claim 35 wherein the skirt further comprises a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame.

40. The valve prosthesis of claim 35 wherein the valve body is deployed supra-annularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration.

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41. The valve prosthesis of claim 35 wherein the frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration.

42. The valve prosthesis of claim 35 wherein the frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration.

43. The valve prosthesis of claim 35 wherein frame has proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends.

44. The valve prosthesis of claim 35 wherein the frame has, in the expanded deployed configuration, an enlarged outflow section with a first nominal diameter, a conical inflow section having a second nominal diameter and a constriction region having a third fixed diameter smaller than the first and second nominal diameters.

45. The valve prosthesis of claim 44 wherein the conical section has a proximal end and the conical section flares outward towards the proximal end.

46. The valve prosthesis of claim 44 wherein the constriction region comprises a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section.

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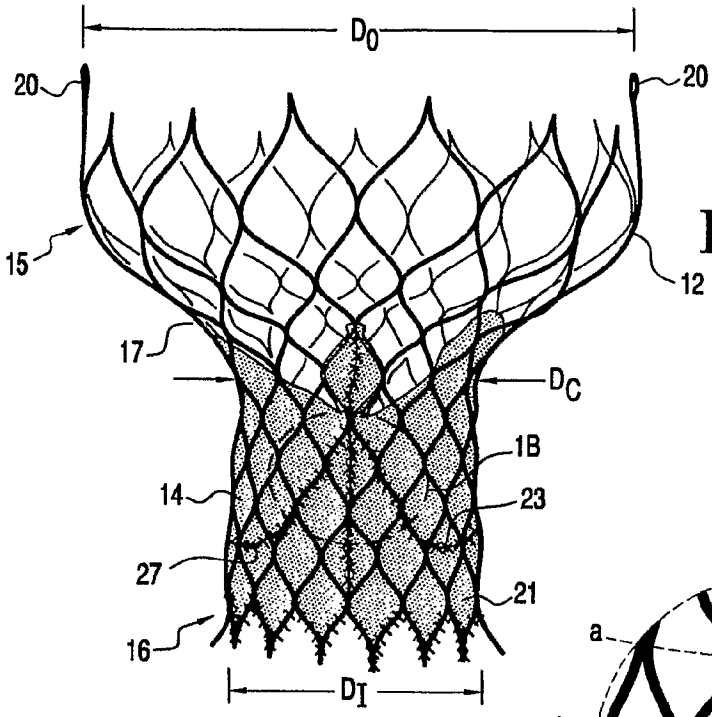

FIG.1A

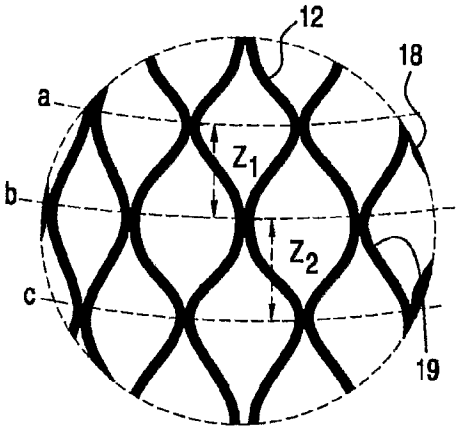

FIG.1B

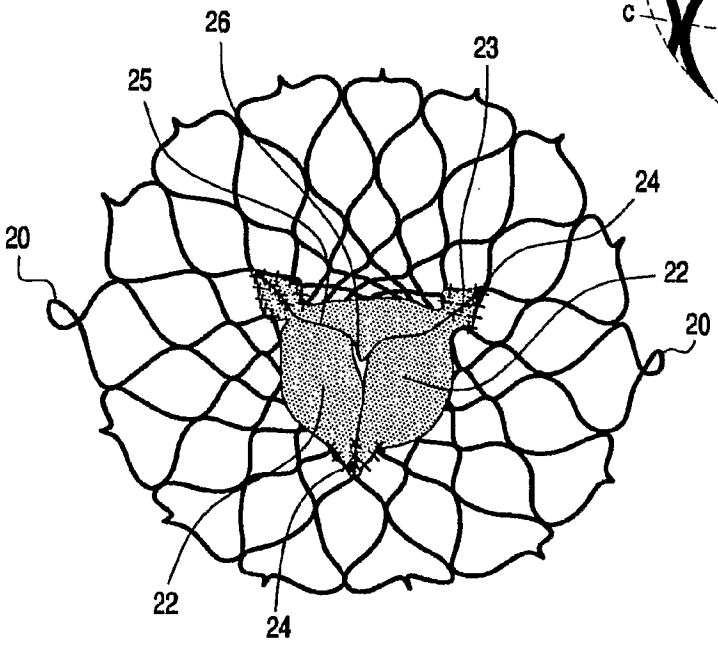

FIG.1C

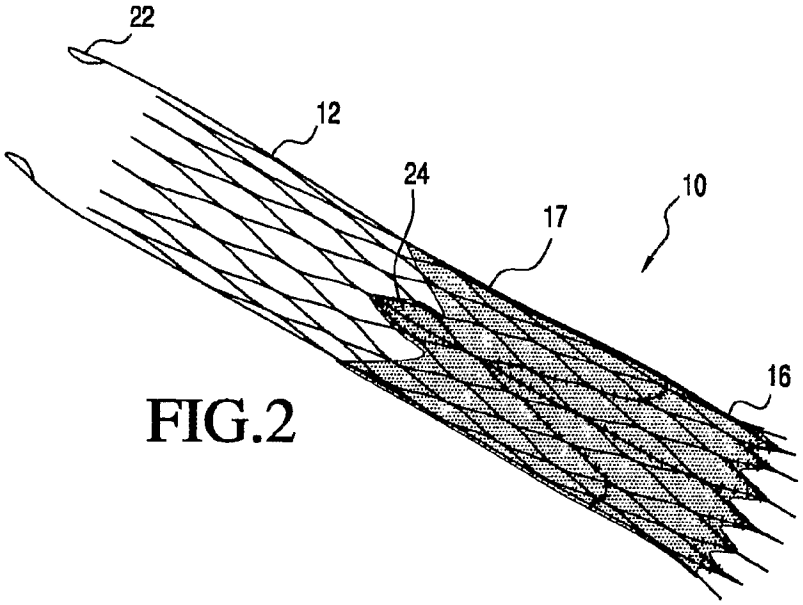

FIG.2

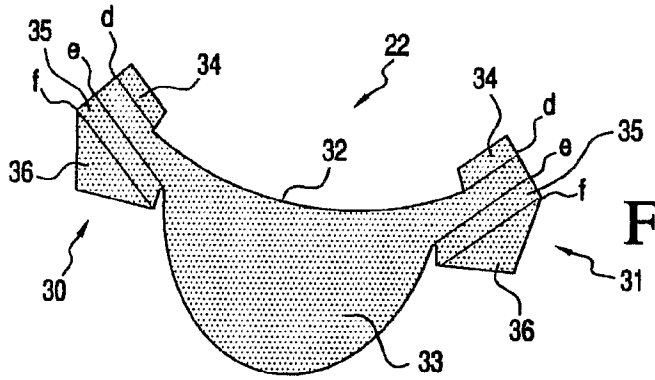

FIG.3A

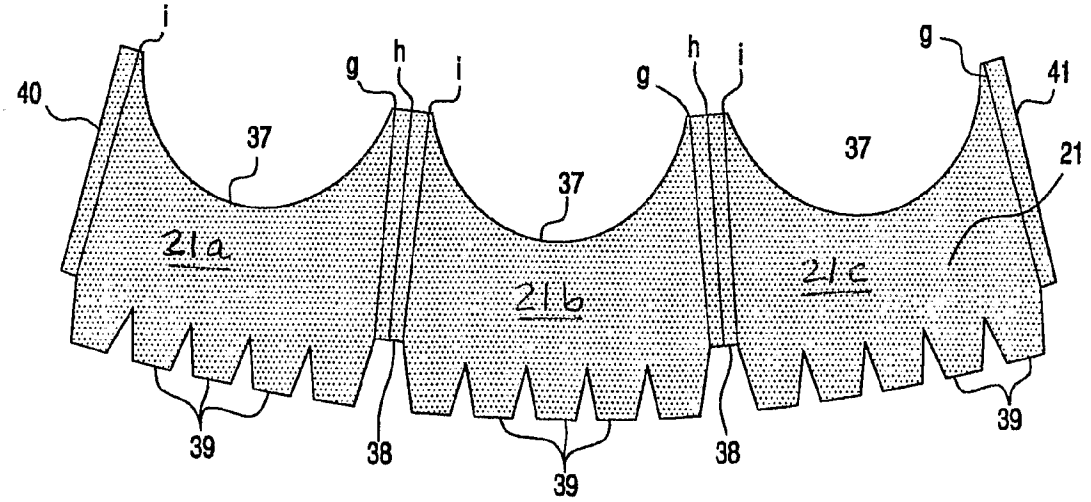

FIG.3B

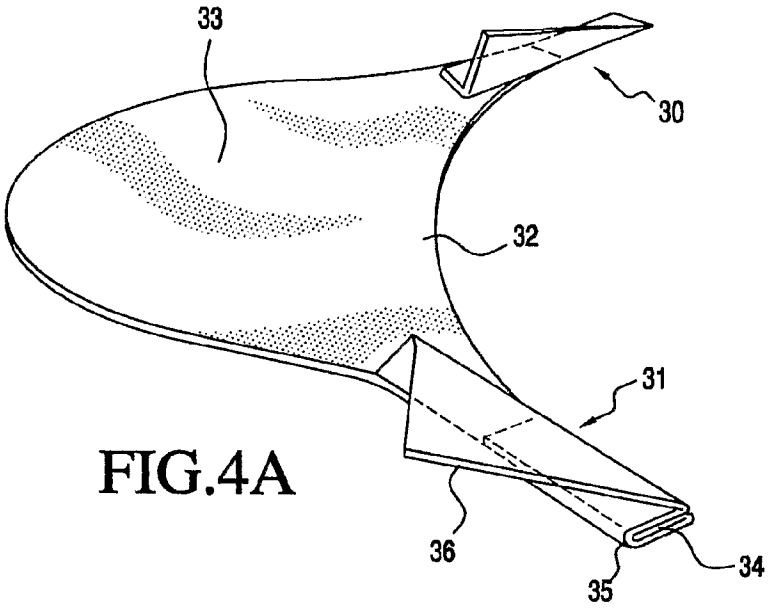
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FIG.4A

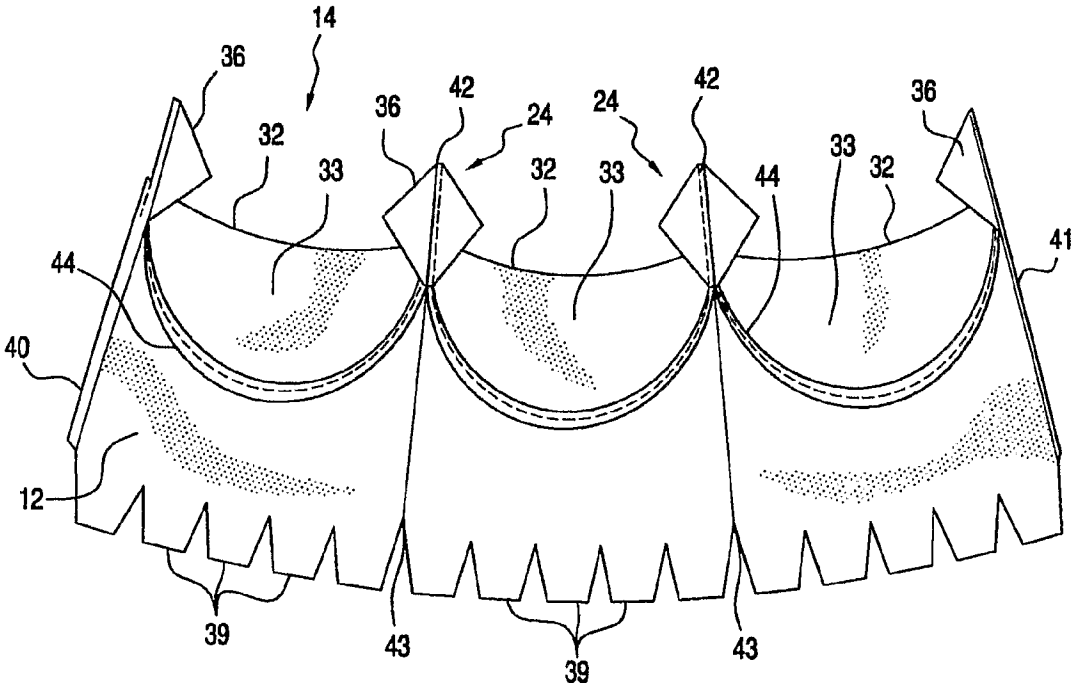
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FIG.4B

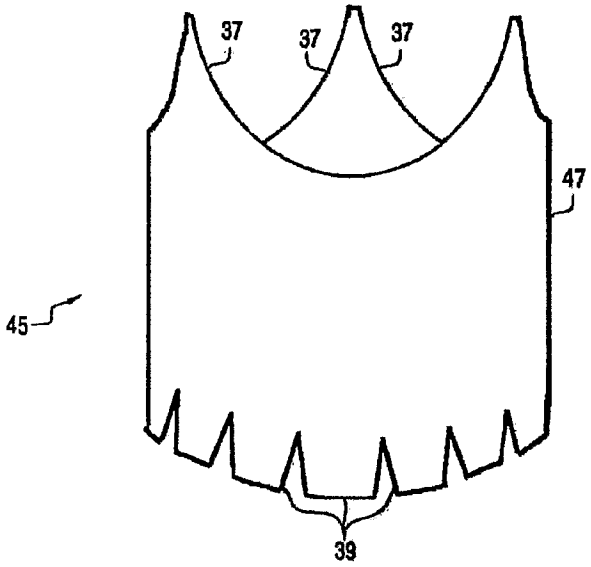

FIG.4C

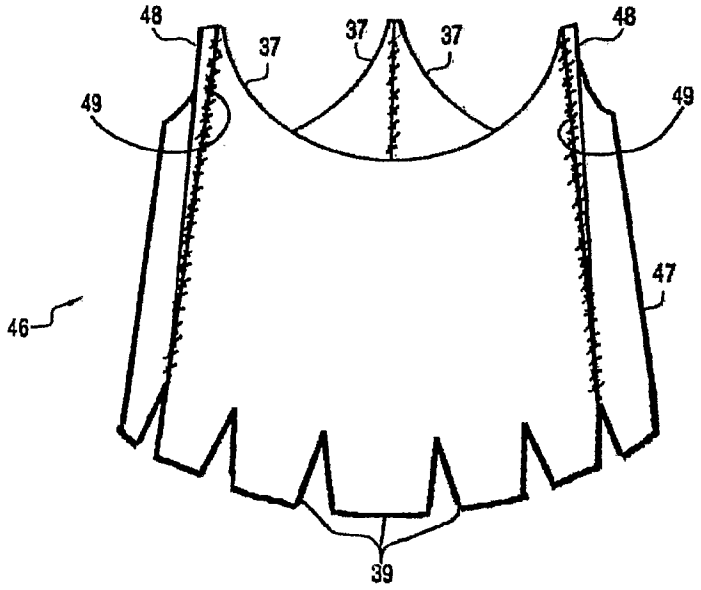

FIG.4D

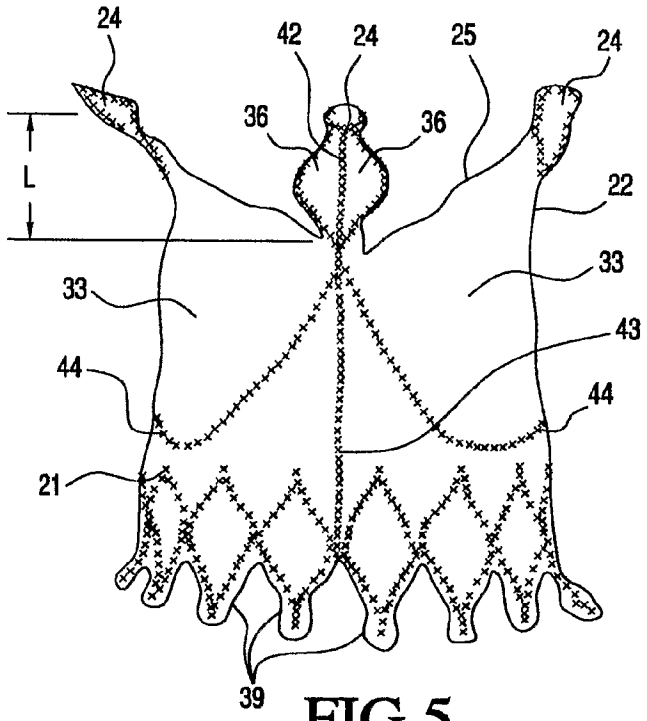
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FIG.5

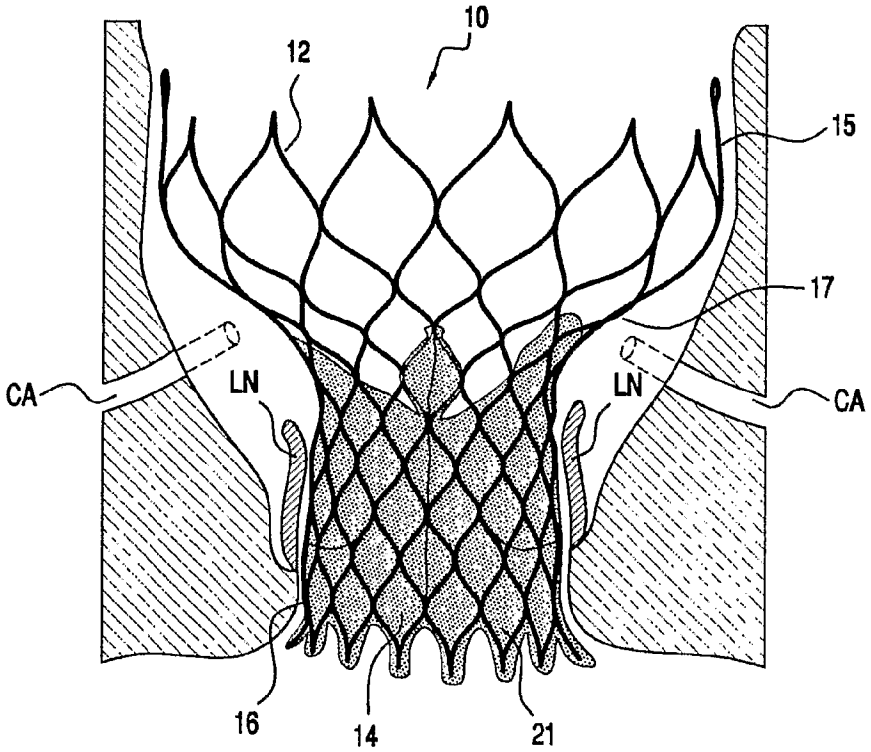
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FIG.6

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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Application Number	17131869
Filing Date	2020-12-23
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/20 UTIL

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	1	9333075		2016-05-10	Biadillah et al.	

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	2	20060276813	A1	2006-12-07	Greenberg	
	3	20080077236	A1	2008-03-27	Letac et al.	
	4	20080188929	A1	2008-08-07	Schreck	
	5	20080319521	A1	2008-12-25	Norris et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E. P. S./

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Attorney Docket Number	426/2/20 UTIL

	6	20110009948	A1	2011-01-13	Huang et al.	

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	1	2006005015	WO	No	2011-01-13	No Inventor		

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	1	MURGITROYD, Search Report dated February 2, 2021, USA	
	2	EDWARDS LIFESCIENCES 2011 ANNUAL REPORT, page 6, USA, published 2011.	
	3	AL-ATTAR, NAWWAR, Next generation surgical aortic biological prostheses : "sutureless valves", published December 21, 2011, available at https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-10/Next-Generation-Surgical-Aortic-Biological-Prostheses-Sutureless-Valves	
	4	KOCHER, Alfred, One-year outcomes of the Surgical Treatment of Aortic Stenosis Witha Next Generation Surgical Aortic Valve (TRITON) trial:A prospective multicenter study of rapid-deployment aortic valvereplacement with the EDWARDS INTUITY Valve System, January 2013, available at https://www.jtcvs.org/article/S0022-5223(12)01111-7/pdf	

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Examiner Signature	/TIFFANY P SHIPMON/	Date Considered	02/11/2021

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/20 UTIL

[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. /E. P. S./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17131869
Filing Date	2020-12-23
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/20 UTIL

CERTIFICATION STATEMENT

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See attached certification statement.

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

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

Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-02-03
Name/Print	Justin R. Nifong	Registration Number	59389

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

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Application Number	17131869
Filing Date	2020-12-23
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Art Unit	3774
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17131869
	Filing Date	2020-12-23
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	Tiffany Shipmon
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Signature	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-02-16
Name/Print	Justin R. Nifong	Registration Number	59389

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Electronic Acknowledgement Receipt

EFS ID:	41938887
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	16-FEB-2021
Filing Date:	23-DEC-2020
Time Stamp:	20:42:45
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	Information Disclosure Statement (IDS) Form (SB08)	426-2-20-ids-2-16-2021.pdf	1034306 b1285f3e0c5d6c901990b6c29f179ca74f525e64	no	4

Warnings:

Information:	
Total Files Size (in bytes):	1034306

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COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/131,869	Confirmation No.:	1293
Applicant	:	Aortic Innovations, LLC		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	Nov 12, 2020		
TC/A.U.	:	3774		
Examiner	:	Shipmon, Tiffany		
Docket No.	:	426/2/20 UTIL		
Customer No.	:	175373		

Title of Invention: DEVICE FOR ENDOVASCULAR AORTIC REPAIR

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REMARKS

Remarks begin on page 2 of this paper.

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 333
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Electronic Acknowledgement Receipt

EFS ID:	41931564
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	16-FEB-2021
Filing Date:	23-DEC-2020
Time Stamp:	13:53:50
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		426-2-20UTIL-PrelimRemarks-2-16-2021.pdf	1044325 31d5ece11e372241e71aa5bd1e32074738f3f54f	yes	17

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Claims	2	17
	Preliminary Amendment	1	1
Warnings:			
Information:			
	Total Files Size (in bytes):	1044325	

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REMARKS

The claims are directed towards an improved transcatheter aortic valve replacement (TAVR) that address paravalvular leaks (PVL). Namely, by having an inner frame that is a graft covering around the heart valve, sealing aspects are provided to the valve against the metallic outer frame. This helps to provide a seal around an inner facing surface of the metallic frame, as well as to protect at least portions of the valve leaflets from contact with the metal frame. The outer seal provides sealing between the outer frame and the patient's anatomical wall, while avoiding problems associated with conventional TAVR devices that will be discussed further herein.

PROBLEMS WITH EXISTING TAVR DEVICES

TAVR devices have competing design forces at all times. The TAVR must maximize valve leaflet size, provide sealing characteristics to reduce PVL and PVR[1], yet, must maintain a small overall crimped profile as the compressed TAVR must be delivered endovascularly through an access artery and cross the native heart valve of the patient[2], maintain appropriate asymmetric foreshortening characteristics[3], and maintain appropriate hoop stresses and forces so that undue pressure is not required to inflate the balloon for balloon expandable valves or for self-expansion for self-expanding valves, or underexpansion of the valve assembly can occur[4].

US Patent Publication No. 20120123529 ("Levi"), which is discussed further herein, well describes this problem of crimp profile with respect to the inner skirt:

> *[0066] Known fabric skirts comprise a weave of warp and weft fibers that extend perpendicular to each other and with one set of fibers extending perpendicularly to the upper and lower edges of the skirt. When the metal frame, to which the fabric skirt is secured, is radially compressed, the overall axial length of the frame increases. Unfortunately, a fabric skirt, which inherently has limited elasticity, cannot elongate along with the frame and therefore tends to deform the struts of the frame and prevents uniform crimping.*

While this was in reference to the inner skirt, the same concerns are presented with an outer skirt where conformability to the native annulus is even more pronounced. Thus, it should be evident that a balloon expandable outer frame (which is thus subject to higher compressive forces) having an outer graft covering of sufficient height, along with an inner graft covering, presented significant engineering design

[1] https://www.acc.org/latest-in-cardiology/articles/2017/02/02/08/25/transcatheter-management-of-paravalvular-leaks
[2] https://www.sciencedirect.com/science/article/pii/S2666084919304760
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6551197/
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5300953/

Aortic Innovations, LLC, Exhibit 2131
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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

challenges. Designing an outer seal that would effectively seal and limit PVL for a balloon expandable frame is thus desirable.

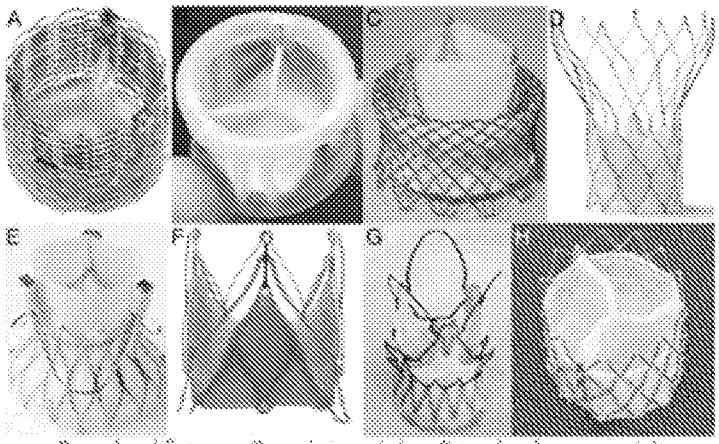
The issue with the outer seal is particularly relevant because paravalvular leaks and regurgitation are a persistent problem with TAVR. For example, a recent study found that the CoreValve prosthesis, one of the few available TAVR devices in the United States market, had moderate or severe PVR of 11.4% and 9.0% at 30 days. From the study involving 60 patients:

> *The primary efficacy endpoint was defined as the proportion of patients with less-than-mild prosthetic valve regurgitation at 30 days and amounted to 72.4%, with no patient showing evidence for moderate or severe regurgitation. Of the patients without a pacemaker at baseline, 11.8% required implantation of a permanent pacemaker within 30 days after TAVR. The mean transprosthetic gradient was low with 6.4 mm Hg as typical for a supra-annular valve design, though acknowledging that no patient requiring a 23-mm device was included. The pre-defined primary safety endpoints, all-cause mortality and disabling stroke at 30 days, amounted to 1.7% each in a patient population with a mean Society of Thoracic Surgeons score of 6.4%. Thirty-day rates of major vascular complications and life-threatening or disabling bleeding were 10.0% and 11.7%, respectively.*
>
> *The presented data are promising and support the concept to mimic surgical-like outcomes as it relates to PVR by the addition of an external seal that compensates for incomplete stent-landing zone apposition...*
>
> http://interventions.onlinejacc.org/content/jint/11/2/169.full.pdf
>
> From another study:
>
> *Moderate to severe regurgitation after TAVR confers a poor prognosis and is associated with an increased risk of all-cause mortality Even mild PVL has been shown to have a negative impact on survival. Kodali et al reported on the outcomes of patients who underwent TAVR from the randomized cohorts of the PARTNER trial and continued access registries. Data were analyzed from a total of 2,434 patients. PVL was reported as mild in 38% and moderate/severe in 9.1% of patients after TAVR. There was no difference in 30-day mortality. Instead, the adverse effect was expressed later with a significant increase in 1-year all-cause and cardiac mortality and repeat hospitalization in those with worsening PVL.*
>
> https://citoday.com/articles/2015-july-aug/managing-paravalvular-leaks-after-tavr

Thus, as these studies show, PVL is a long-felt problem and a method of addressing them has been needed. Studies show high one year mortality and rehospitalization rates of 35% and 31% may be attributed to PVL, and reducing PVL will thus reduce mortality and rehospitalization rates. According to this study, an external seal helps to address PVL and PVR. Surgical valves, as will be discussed herein, did not traditionally have significant PVL concerns because the valve leaflets were removed from the patient, and a sealing ring or similar could be stitchably engaged with the aorta in an open heart procedure. However, a robust outer seal system on a TAVR presents problems with expansion forces, foreshortening, underexpansion, and crossing of the aorta. The claimed invention addresses these problems.

A LONG-FELT NEED EXISTED TO REDUCE PVL WHILE MAINTAINING SMALL VALVE PROFILE, AND MULTIPLE ATTEMPTS TO DO SO WERE NOT LEADING TOWARDS THE CLAIMED INVENTION

There were multiple TAVRs available in 2012 at the effective filing date of this application, however, none of TAVRs known to Applicant taught a fiber outer seal. As an example, consider the following image depicting one example of the state of the art for TAVRs in 2012:



Download figure Open in new tab Download powerpoint

Figure 4
Valves Undergoing Early Evaluation

(A) Lotus (Boston Scientific Inc., Natick, Massachusetts), (B) Direct Flow (Direct Flow Medical Inc., Santa Rosa, California), (C) HLT (Bracco Inc., Princeton, New Jersey), (D) Portico (St. Jude Medical Inc., St. Paul, Minnesota), (E) Engager (Medtronic Inc., Minneapolis Minnesota), (F) JenaClip (JenaValve Inc., Munich, Germany), (G) Acurate valve (Symetis Inc., Ecublens, Switzerland), and (H) Inovare (Braile Biomedica Inc., São José do Rio Preto, Brazil) valves.

https://pubmed.ncbi.nlm.nih.gov/22749306/

In this image, there are eight (8) distinct transcatheter valves shown. Four (4) of the eight (8) appear to teach an outer seal, and several of the ones that do not teach an outer seal had later variations of their product lines that do teach an outer seal. None of them teach a fiber based outer seal. Much of the art taught an outer seal that was largely non-compliant in structure, and sealed by having an initial density or non–porosity conducive to sealing. None of the seals worked by having a group of fibers that would work to seal against PVL once the fibers were compressed from implantation.

A DISCUSSION OF SOME OF THE PRIOR ART FOLLOWS:

TRANSCATHETER VALVE TECHNOLOGY

An example of a transcutaneous valve having an inner and outer seal is shown in at least WO98/29057 ("Cribier"). See for example FIG. 6D that shows a cover extending from an inner surface to an outer surface of the stent frame.

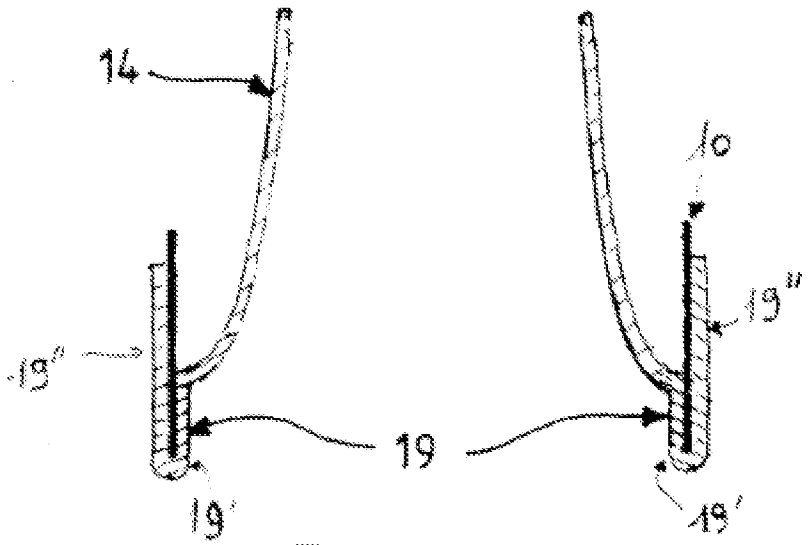
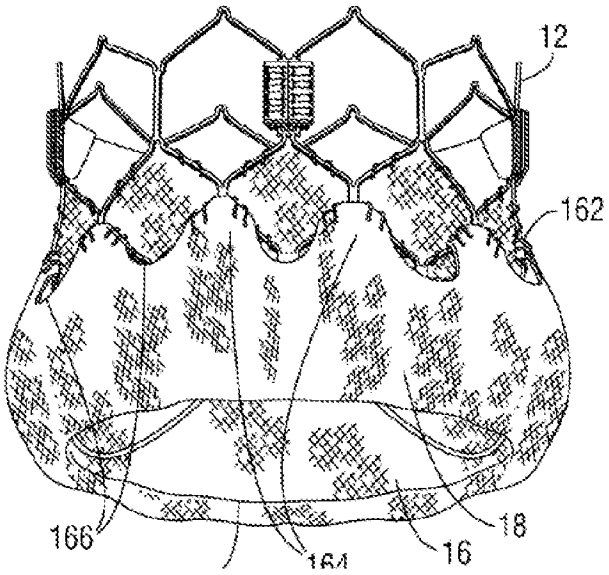


FIG_6d

Similarly, US Patent Publication No. 20120123529 ("Levi") appears to teach an inner and outer seal in FIG. 42.

FIG. 42



WO2006/005015 ("Spenser") appears to teach a thick band with fibers emanating therefrom in FIG. 22, however, there is no graft forming the inner frame, thus the inner sealing is missing. FIG. 22 is reproduced below:

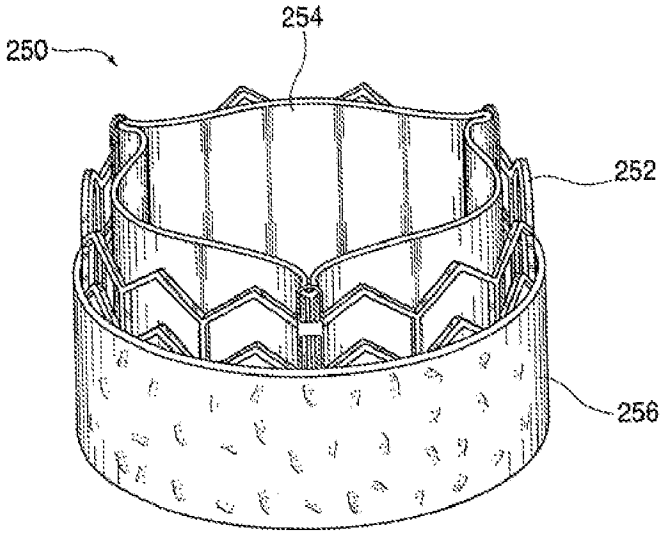


FIG. 22

US Patent No. 7381219 ("Salaheih") teaches a repositionable TAVR with sacs filled by hydrogel or similar on an exterior of the TAVR for sealing the TAVR:

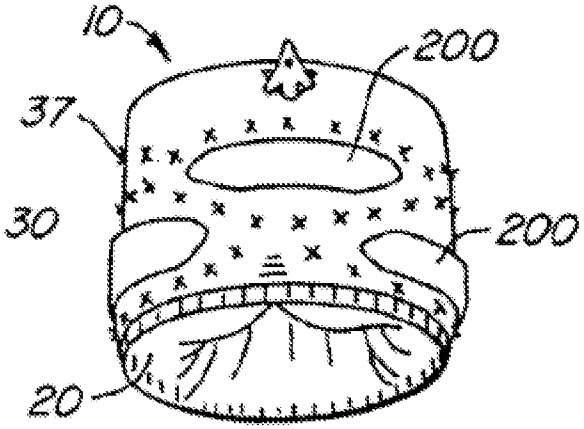


FIG. 15A

US Patent No. 9333075 ("Delaloye") teaches a TAVR with an outer seal at a proximal end.

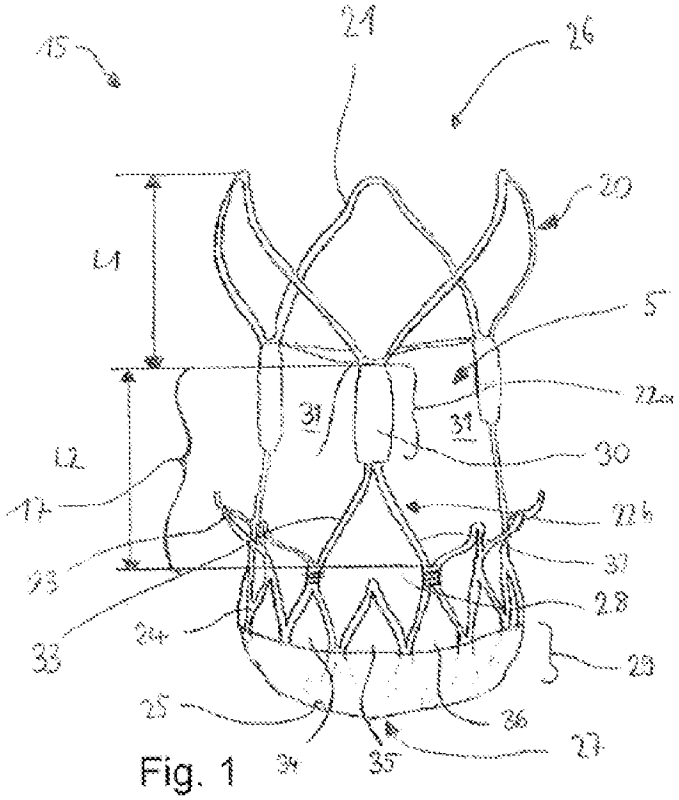


Fig. 1

US Patent No. 10,016,271 ("Morriss") teaches a Transcatheter Mitral Valve with an outer seal that includes barbs or fibers 170 that are "rigid and shape enough to penetrate tissue."

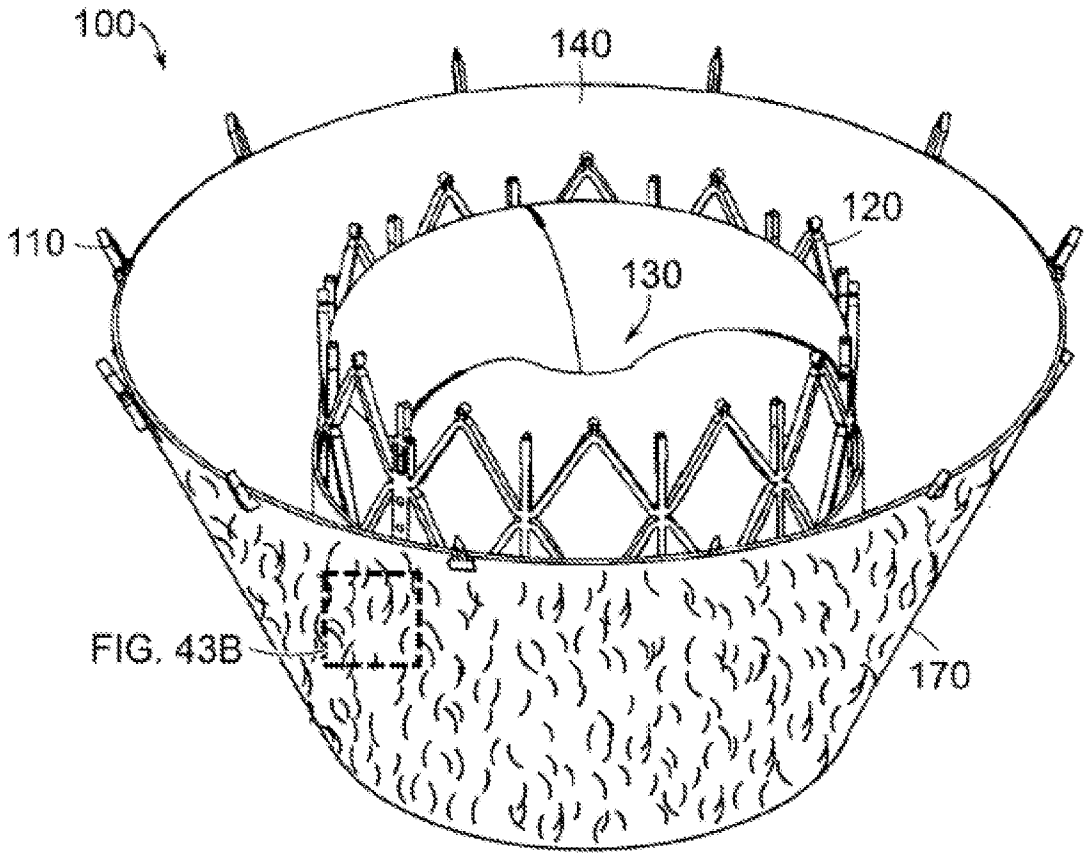


FIG. 43A

The barbs 274 extend from a base 140 as taught in Morriss.

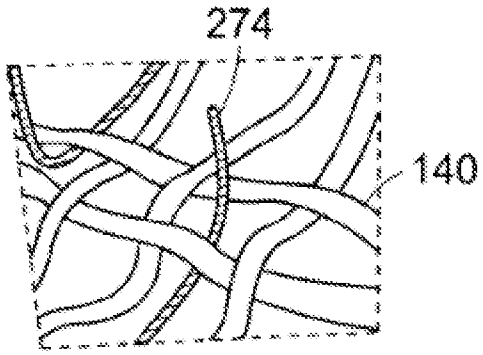


FIG. 43B

This teaching in Morriss is thus cumulative of many references discussed herein, with particular reference to FIG. 5D of Spenser.

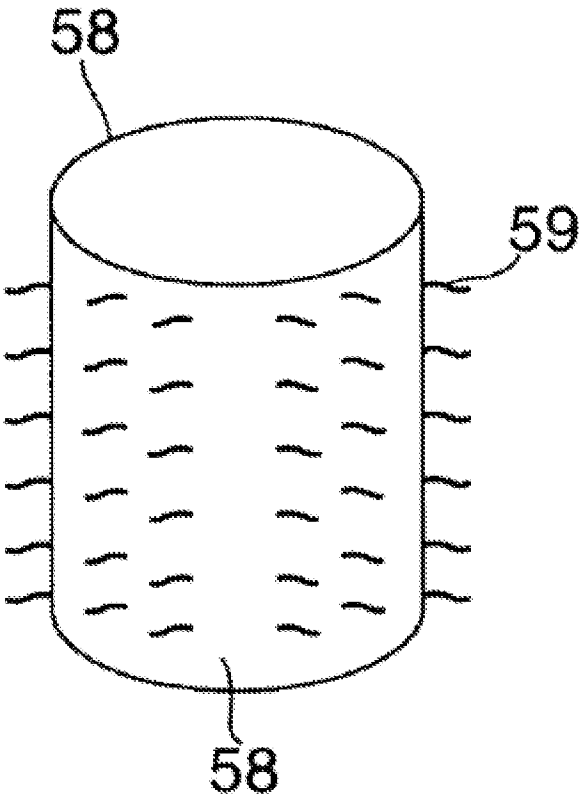


FIG. 5d

STENT GRAFT TECHNOLOGY

Various stent grafts have also been developed that include one or more seals. US Patent Publication No. 2004/0256759 ("Hartley") teaches a velour band at a distal end of the stent graft.

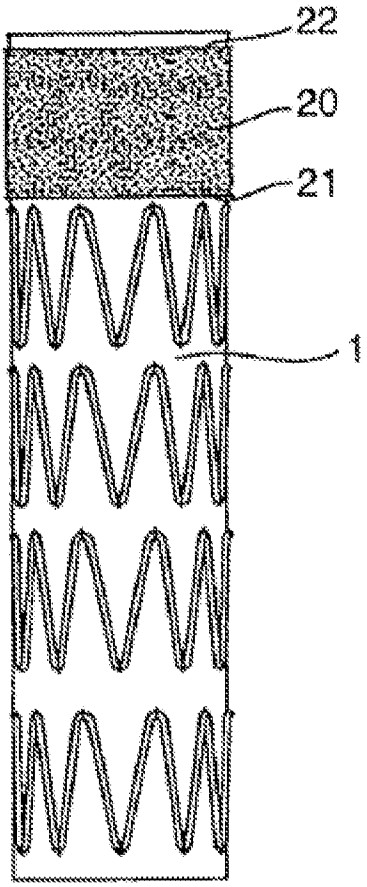


Fig 2

Similarly, US Patent No. 7,921,678 ("Norris") teaches a stent graft with loops of outwardly extending material.

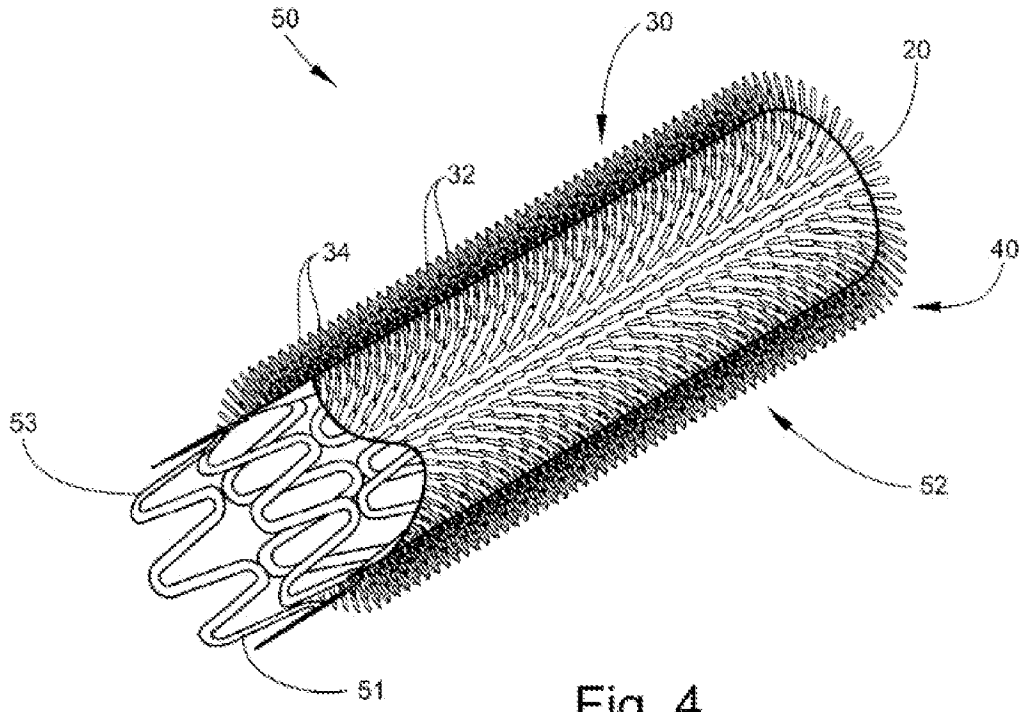


Fig. 4

US Patent Publication No. 2004/0082989 ("Cook") teaches a cuff portion with a frayed portion 22:

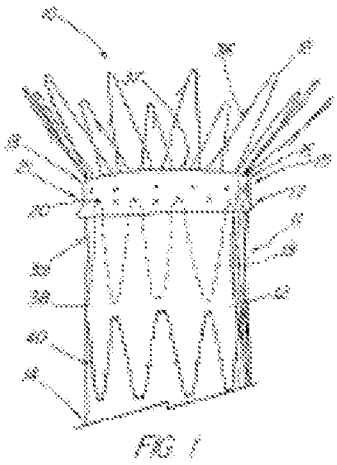


FIG. 1

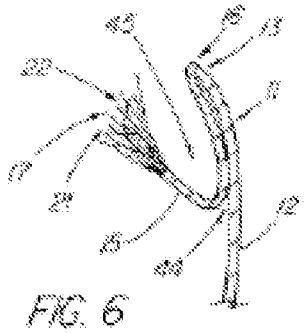


FIG. 6

US Patent Publication No. US 2002/0052649 ("Greenhalgh") teaches a stent graft with fibers emanating therefrom:

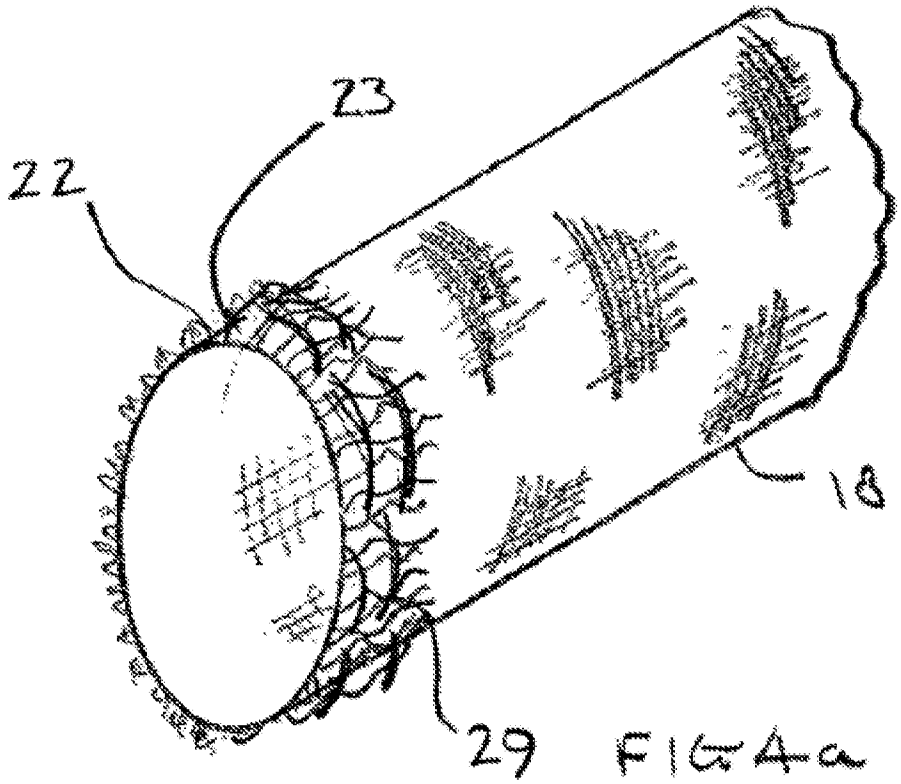


FIG 4a

SURGICAL VALVES

The non-patent literature of Intuity does appear to teach an external seal that includes fibers. Intuity appears to show a surgical valve from 2011 that has a plush outer seal similar to the valve shown in US Patent No. 9,370,418, which has been discussed in prosecution of Application No. 16/808,137 in front of Examiner Shipmon and that is related to this pending application.

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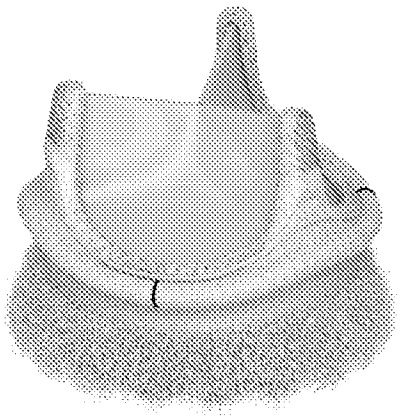

This surgical valve would appear to teach a seal that seals below the leaflets, and not against native valve leaflets of the patient. In fact, typically the native leaflets are surgically removed during surgical heart valve replacement. Additionally, because a surgical valve does not have the access issues associated with transcatheter valves, the increased overall profile of a surgical valve such as Intuity is not as problematic.

IMPROVEMENTS ASSOCIATED WITH CLAIMED INVENTION

The combination of a balloon expandable transcatheter stent valve with an outer seal with outwardly extending fibers, along with the other limitations found in the claims, presented an improvement over the prior art, with particular reference to the unexpected results of products covered by claims in prosecution of the '137 Application (Now USPN 10,792,172). Applicant submits that it was not obvious to combine the seal found in the references submitted with the information disclosure statement with the TAVR technology of record to seal against the native leaflets of the patient with a fiber outer seal. The reasons for this are discussed herein.

The native annulus of a patient is relatively small in diameter, and with a diseased aorta suffering from stenosis, the diameter limitations become even more pronounced. At the position where the native leaflets extending into the ascending aorta, sizing a valve is difficult, and crossing the valve without pre-dilation has proven challenging. Placing a seal on an inner surface of the outer frame, along with a seal on an outer surface of the outer frame thus undesirably increases the overall valve profile. Additionally, the compressed assembly must fit within a sheath or catheter for delivery into the patient through an access artery and cross the aortic valve. For this reason, much of the prior art where an inner and outer seal is disclosed, teaches a relatively thin graft material for both the inner seal and outer seal. (See, for example, Cribier and Levi discussed herein). When there was an outer seal, the seal also often had a

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relatively short height so that the sealing aspects would be below the native leaflets or extending into crevices created by the native leaflets, but not radially overlapping with the leaflets at a most narrow spot of the ascending aorta (see again Cribier, and Levi with the billowing outer graft). On devices that had an outer seal of more sufficient thickness, the device often did not have an inner seal (see, for example, Spenser); this was likely due to increased valve profile, and increased hoop forces that made expansion of the compressed valve more difficult and susceptible to underexpansion, or undesirable valve crimp profile.

The Intuity valve is of such high crossing profile that it is implanted without a sheath and through a conventional surgical approach after the native valve leaflets have been surgically removed to create space. The Intuity valve is stitched to the annulus to create a seal.

Additionally, placing outer seal bands as disclosed by Spencer, Cribier and Levi, creates significant technical limitations in the functionality of the TAVR device during loading of the device into a sheath and deployment of the devices *in vivo*. These disclosures show balloon- expandable stent frames. A balloon- expandable frame has a dynamic length, where in an undeployed crimped state, the frame is taller and gradually shortens as the frame is ballooned and expanded to be placed in its final *in vivo* position. Applicant submits that the density of this outer seal band (Spencer, Cribier, and Levi) restricts the necessary foreshortening of the stent frame during deployment *in vivo* and can cause PVL, migration, under-deployment and malfunction of the valve leaflets. Thus when the Levi valve was created, significant laxity was designed and allowed in the short outer seal to accommodate the foreshortening of the stent frame. Due to these sizing issues, despite the availability of an outer seal having outwardly extending fibers in the stent graft, heart valves, and other stent materials, a TAVR with an inner seal and an outer seal where the outer seal included outwardly extending fibers from a graft covering, along with other limitations found in the claims, was not developed.

Applicant thus submits that the claimed invention represents an improvement over the prior art of record in reducing PVL, while maintaining a sufficiently small enough profile to be implanted endovascularly without concerns associated of foreshortening and under-deployment typically expected of a device having an inner and outer seal where the outer seal has significant dimensionality.

The fibers increase the surface area of the outer seal, which encourages tissue ingrowth to reduce PVL and increase thrombosis. This also increases the stability of the TAVR in the aorta so that the TAVR does not migrate within the aorta. These advantages are provided in a TAVR that still maintains good compressibility while reducing the overall crimp profile of the TAVR as compared to a modified TAVR with a large thickness outer seal.

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Applicant thus submits that the invention claimed herein is patentable over the prior art of record.

THE CLAIMED IMPROVEMENT OF A SEALING MATERIAL INCLUDING A PLURALITY OF OUTWARDLY EXTENDING FIBERS IS NOT OBVIOUS OVER THE PRIOR ART OF RECORD BECAUSE THE VALVE PROFILE WOULD BE UNSATISFACTORILY INCREASED IF ONE WERE TO COMBINE THE OUTER SEAL OF SPENSER AND TAVR VALVES HAVING AN INNER SEAL

As discussed, maintaining a small overall valve profile is crucial for valve performance and deployability. However, the seal of Spenser appears to be relatively thick in construction, including a graft covering or sleeve with fibers extending from the sleeve. Foreshortening of the Spenser seal would likely be more problematic as well given the construction and would not only significantly increase the crossing profile, but also restrict the expansion of the balloon-expanding frame and result in underdeployment and valve malfunction. Spenser discloses a seal having a thickness of up to 5 mm, which would increase overall valve profile by up to 10 mm. Valve designs are typically in the 20 to 30 mm diameter range, and thus a 10 mm increase in diameter size, in addition to adding an inner graft covering as claimed, would be undesirable. Furthermore, addition of a seal of such significant thickness would increase the inflation pressures required of the balloon assembly, where rupture of the balloon has already proven problematic.

Furthermore, Spenser already teaches a method of addressing PVL, namely, seal 256. ("To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252.) [0145]. When the prior art already teaches a solution to the problem, then one of ordinary skill would not look to further modify the prior art by adding an inner seal, to address the problem that the prior art has already addressed. Additionally, the Spenser device, as modified to meet the claimed invention, may have problems associated with crimp profile, and Spenser appears to include an outer graft covering between the fibers and the outer frame, which is a claimed negative limitation. Finally, Spenser is not modifiable to be free of an outer graft covering, as such modification would have no structure for the fibers to attach to since the fibers emanate from compressible material 256.

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ONE WOULD NOT LOOK TO STENT GRAFT SEALS TO MODIFY A TAVR SUCH AS LEVI, CRIBIER, OR SPENSER

Some of the stent graft references disclose outwardly extending fibers. One of ordinary skill would not look to stent graft technology because the stent grafts require a much greater seal area for treating aneurysms or dissections. See for example, Hartley and Norris. The stent grafts are self-expanding with a larger profile and reduced hoop stress. The structure of stent grafts is such that they may not be able to resist the recoil forces of the stenosed aortic valve, leading to underdeployment of the stent graft. Stent grafts due to the design of their stent skeleton do not significantly foreshorten and thus a less compliant sheet of velour or base band with fibers will not restrict the expansion of the stent graft in its intended use location, namely healthy aortic necks of aneurysms; this is due to the rings of stents that are spaced-apart, as compared to the open cell, interconnected structure of the claimed invention.

For successful use of a stent graft, the proximal section of the stent graft should be placed in relatively healthy aortic segments. The use of stent grafts in heavily calcified aortic sections has generally been undesirable and the crossing profile does not pose the similar challenges seen in treatment of aortic valve stenosis, thus less compliant thicker bands may be used externally on the stent grafts used for treatment of aneurysms or dissection.

TAVRs have a different frame design as compared to stent grafts where the TAVR has an interconnected frame structure. The structure of the TAVR is such that it can resist the recoil forces of the stenosed aortic valve and foreshortening is a function of the deployed state of the valve after balloon expansion. Thus the requirements for external seals are much different than those for stent grafts. Due to the fact that a stent graft will not further carry an internal component such as prosthetic leaflets like a TAVR, and the profile considerations of a stent graft are not as pronounced as a TAVR.

Additionally, and importantly, the stent graft technology generally appears to teach a graft covering on the outside of the metal stent frame, and the fibers extend from the graft covering. The claimed invention recites that the outer seal is free of an outer graft covering.

External seal bands such as those disclosed by Spencer will significantly add to the profile of the TAVR and prevent smooth crossing of the stenosed aortic valve, thus an inner seal is not likely designed for the Spenser valve as it will add further to the crossing profile. Similarly, a band of velour or dense band additional fibers as disclosed by Hartley would not likely be used together with the Spencer or Cribier valve because it will restrict the expansion and the foreshortening of the TAVR during balloon expansion and result in underdeployment of the TAVR resulting in PVL, migration and valve malfunction.

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Finally, TAVRs have much more limited axial length for proper placement relative to the coronaries to avoid inadvertent covering of the coronaries. The claimed invention allows significant expansion of the TAVR without restricting the valve opening or stent foreshortening in addition to allowing for a lower profile of the TAVR making it possible to use an inner graft frame that further reduces leaks and protects the prosthetic valve leaflets from hitting the metallic frame.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: February 16, 2021

/Justin R. Nifong/
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PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/131,869	Filing Date 12/23/2020	☐ 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 $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ 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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	02/16/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 4	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LAVINIA D JOHNSON/
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The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/25 PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION AND TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	17131869
Filing Date	23-Dec-2020
First Named Inventor	Ali Shahriari
Attorney Docket Number	426/2/20 UTIL
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Aortic Innovations, LLC	100 %

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

17096253 filed on 11/12/2020

17007373 filed on 08/31/2020

17006793 filed on 08/29/2020

16941117 filed on 07/28/2020

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

10888441

10881538

10857011

10792172

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
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◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicants claims the following fee status:

◉ Small Entity

○ Micro Entity

○ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

- (●) An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

  Registration Number 59389

- ( ) A sole inventor
- ( ) A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application
- ( ) A joint inventor; all of whom are signing this request

Signature	/Justin R. Nifong/
Name	Justin R. Nifong

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	17131869
Filing Date:	23-Dec-2020
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/20 UTIL

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**170**

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Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 17131869

Filing Date: 23-Dec-2020

Applicant/Patent under Reexamination: Shahriari

Electronic Terminal Disclaimer filed on February 11, 2021

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EFS ID:	41906364
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
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Filer:	Justin Robert Nifong
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Attorney Docket Number:	426/2/20 UTIL
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(Not for submission under 37 CFR 1.99)

Application Number	17131869
Filing Date	2020-12-23
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	Tiffany Shipmon
Attorney Docket Number	426/2/20 UTIL

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	4	20080188929	A1	2008-08-07	Schreck	
	5	20080319521	A1	2008-12-25	Norris et al.	

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	Application Number	17131869
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	Examiner Name	Tiffany Shipmon
	Attorney Docket Number	426/2/20 UTIL

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	1	MURGITROYD, Search Report dated February 2, 2021, USA	
	2	EDWARDS LIFESCIENCES 2011 ANNUAL REPORT, page 6, USA, published 2011.	
	3	AL-ATTAR, NAWWAR, Next generation surgical aortic biological prostheses : "sutureless valves", published December 21, 2011, available at https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-10/Next-Generation-Surgical-Aortic-Biological-Prostheses-Sutureless-Valves	
	4	KOCHER, Alfred, One-year outcomes of the Surgical Treatment of Aortic Stenosis Witha Next Generation Surgical Aortic Valve (TRITON) trial:A prospective multicenter study of rapid-deployment aortic valvereplacement with the EDWARDS INTUITY Valve System, January 2013, available at https://www.jtcvs.org/article/S0022-5223(12)01111-7/pdf	

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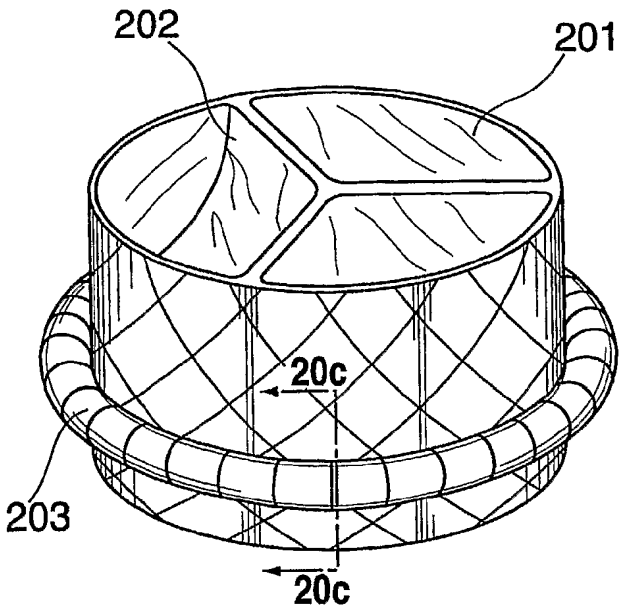
(54) Title: PARAVALVULAR LEAK DETECTION, SEALING AND PREVENTION



(57) Abstract: The present invention provides a series of new percutaneous concepts of paravalvular repairs including identifying the leak location, several repair techniques and finally built-in means for leak prevention, built on percutaneous valves. A catheter-delivered device locates cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

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PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

FIELD OF THE INVENTION

[0001] The present invention relates to implantable devices. More particularly it relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses.

BACKGROUND OF THE INVENTION

[0002] Cardiac valve implantation is well known in the art. Less well addressed is how to detect possible leaks between the valve and surrounding blood vessel, how to seal such leaks, or how to design the valve such that it automatically seals the leaks.

[0003] Machiraju in U.S. Patent No 5,554,184, entitled "HEART VALVE ", describes a heart valve and a technique for effecting valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or a bovine or porcine pericardial or other synthetic sheet material equivalent thereof, preferably in a configuration which substantially restores the original anatomy of the heart, including chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and the two far ends are sutured together to yield a bileaflet valve having appended chordae and tabs.

[0004] Machiraju does not address leaks that can occur around the implanted valve.

[0005] Schreck in U.S. Patent No. 6,454,799, entitled, "MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE", describes expandable heart valves for minimally invasive valve replacement surgeries. In a first embodiment, an expandable pre-assembled heart valve includes a plastically-expandable annular base having a plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided, with the prosthetic section being connected to the commissure posts and defining leaflets therebetween, and the fabric section being attached to the annular base. In a second embodiment, an expandable heart valve includes an annular tissue-engaging base and a subassembly having an elastic wireform and a plurality of leaflets connected thereto. The annular base and subassembly are separately stored and connected just prior to delivery to the host annulus. Preferably the leaflet subassembly is stored in its relaxed configuration to avoid deformation of the leaflets. The expandable heart valves may be implanted using a balloon catheter. Preferably the leaflets of the heart valves are secured to the commissure regions of the expandable stents using a clamping arrangement to reduce stress.

[0006] Schreck also does not address leaks that can occur around the implanted valve.

[0007] Amplatz in U.S. Patent No. 6,638,257, entitled, "INTRAVASCULAR FLOW RESTRICTOR," describes an intravascular flow restrictor that comprises a braided tubular structure designed to be

placed in the main pulmonary artery for limiting blood pressure in the lungs. The braided structure is designed to be collapsed for placement in a delivery catheter, but when it is ejected from the delivery catheter, it assumes a substantially larger diameter disk shaped device having one or more longitudinal channels or passways therethrough.

[0008] Amplatz also does not address leaks that can occur around the implanted valve. In addition, Amplatz's braided structures are of a shape and size not appropriate for paravalvular leak detection and sealing. Their geometry is designed for the conditions of the transceptal hole and not appropriate for valve leakage.

[0009] Spenser et al. in U.S. Patent Application No. 20030153974, entitled "IMPLANTABLE PROSTHETIC VALVE", describe a prosthesis device suitable for implantation in body ducts. The device comprises a support stent bring comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through a body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent bring provided with a plurality of longitudinally rigid support beams of fixed length, and (2) a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet. When flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly to provide blockage to the reverse flow.

[0010] Spenser et al. also do not address leaks that can occur around the implanted valve.

[0011] With regard to the general topic of prosthetic valves, implantation is currently done either through open heart surgery or by use of newer percutaneous methods, some of which are described in the patents mentioned above. With both methods paravalvular leaks are a known side effect. One way to approach the leak problem is to identify the leak location and repair it. Another approach is to equip the prosthesis with means to prevent the leak ("self-sealing" prosthesis). Both these approaches are encompassed by the present invention.

[0012] Percutaneous introduction of medical devices is a preferred surgical procedure for it involves making only a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation. In contrast, surgical placement involves a large chest surgical incision and requires general anesthesia, to expose a large portion of a patient's thoracic region. Percutaneous introduction is therefore considered safer and less invasive.

[0013] Percutaneous introduction of a leak detection and repair device or of a self-sealing valve resembles other known interventional cardiologic procedures. The percutaneous deployment procedure and device has an impact on several parameters of the product design, some of which are explained hereinafter.

[0014] In summary, the present invention provides new concepts of percutaneous paravalvular repair, including means for identifying the leak location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.

SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, a catheter-delivered device is provided for locating cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The device comprises at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

[0016] Furthermore, in accordance with another preferred embodiment of the present invention, a spacing element is provided to maintain the wires adjacent to the wall of the body vessel.

[0017] There is thus also provided in accordance with a preferred embodiment of the present invention, a catheter-delivered stent for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The stent, which is delivered via a guidewire to the cavity and held in place in the cavity by friction, comprises a support structure and an impermeable membrane, the membrane preventing the passage of fluids through the stent, thereby sealing the cavity.

[0018] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is balloon-expandable and the membrane comprises a tab spring-hinged to the inside of the stent lumen and sized to occlude the lumen when closed. The tab is

held open by the stent balloon during insertion and springs closed when the balloon is removed after the stent is expanded.

[0019] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is self-expandable, wherein the membrane is a material covering at least one end of the stent.

[0020] Furthermore, in accordance with another preferred embodiment of the present invention, the stent is comprised of shape memory material.

[0021] Furthermore, in accordance with another preferred embodiment of the present invention, the material is nitinol.

[0022] Furthermore, in accordance with another preferred embodiment of the present invention, the stent is covered on its external walls with hooks comprised of shape memory material and which extend, upon insertion of the stent, into adjacent body vessel walls.

[0023] Furthermore, in accordance with another preferred embodiment of the present invention, the distal end of the stent-delivery catheter is substantially perpendicular to the wall of the vessel at a point inside the cavity and the stent guidewire terminates in an anchoring mechanism that is inserted through the catheter and into the vessel wall, anchoring itself in the vessel wall and providing greater anchorage for the stent.

[0024] Furthermore, in accordance with another preferred embodiment of the present invention, the anchoring mechanism is a hook comprised of shape memory material that is compressed for catheter

delivery into the vessel wall, whereupon the hook extends out, anchoring the guidewire into the vessel wall.

[0025] Furthermore, in accordance with another preferred embodiment of the present invention, the anchoring mechanism is a threaded point that is threaded into the vessel wall anchoring the guidewire into the vessel wall.

[0026] Also provided in accordance with a preferred embodiment of the present invention, is a device for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The device comprises a first guidewire threaded through the cavity, a second guidewire slidably coupled to the first guidewire and inserted such that the slidable coupling is moved to a desired point in the cavity, a first catheter inserted over the first guidewire to the point in the cavity, a second catheter inserted over the second guidewire to the desired point in the cavity, a first component of a two-component biological adhesive inserted through the first catheter to the desired point, a second component of the two-component adhesive inserted through the second catheter to the desired point, the two components thereby mixing to form a plug that seals the cavity.

[0027] Furthermore, in accordance with another preferred embodiment of the present invention, the device is adapted to apply an adhesive with more than two components.

[0028] Furthermore, in accordance with another preferred embodiment of the present invention, instead of two guidewires and two catheters, a single catheter and guidewire are used for delivery, with the

catheter comprising two lumens, each lumen providing delivery for one of the two-component adhesive components, and the catheter terminates in a mixer that forces the components to mix when they exit the catheter in the cavity, thereby creating the plug that seals the cavity.

[0029] Furthermore, in accordance with another preferred embodiment of the present invention, instead of two-component adhesive components being delivered via the catheters, a radiation-cured adhesive is delivered via one of the catheters and a radiation source is delivered via the other catheter, wherein the radiation source is applied to the adhesive to create the plug in the cavity.

[0030] Also provided in accordance with a preferred embodiment of the present invention is a catheter-delivered assembly for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The assembly is delivered via guidewire to the cavity and comprises two sealing stents connected by a suture, the suture running back up the catheter, the sealing stents comprising a stent structure and sealing membrane. One stent of the assembly is inserted underneath the cavity and the other stent is inserted inside the cavity, the membranes preventing the passage of fluids through the stent, thereby sealing the cavity and each stent helping anchor the other in place.

[0031] There is thus also provided in accordance with a preferred embodiment of the present invention, a prosthetic valve with integrated sealing ring attached to the outside wall, the ring having a circumference greater than that of the valve and elastically conforming to seal cavities

between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0032] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a balloon.

[0033] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of spring-wire tabs mounted adjacent to one another around the circumference of the valve and covered with an impermeable membrane. The tabs are folded against the body of the valve during catheter delivery, and, upon egress from the catheter, the tabs spring out to form the sealing ring.

[0034] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, and further comprises a balloon under the tabs. The tabs are folded down on the deflated balloon during catheter delivery, and, upon egress from the catheter, the balloon is inflated, thereby opening the tabs to form the sealing ring.

[0035] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, each tab spring-hinged to the valve. The tabs are folded against the body of the valve during catheter delivery, and, upon egress from the catheter, the tabs spring out to form the sealing ring.

[0036] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

[0037] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

[0038] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing ring comprises modified struts of the stent, the modification comprising geometrical constraints that, upon expansion of the stent, cause the struts to bend out from the stent body, thereby creating the sealing ring.

[0039] There is thus also provided in accordance with a preferred embodiment of the present invention, a prosthetic valve with integrated sealing means, the sealing means comprising sutures attached around the perimeter of the valve and extending back out of the body. Patches can be pushed down the sutures and attached to the point where the suture is attached to the valve, thereby sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0040] There is thus also provided in accordance with a preferred embodiment of the present invention, a catheter-delivered prosthetic valve with integrated sealing means, the sealing means comprising an elastic stent that is first deployed and inside which the valve is deployed. The elastic stent seals any cavity existing between the valve and the wall of

the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0041] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for locating cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0042] inserting a balloon mounted on a flexible wire next to the valve,

[0043] wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

[0044] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0045] inserting an impermeable stent into the cavity,

[0046] whereby the stent seals the cavity.

[0047] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0048] inserting a first guidewire into the cavity;

[0049] running a loop attached to a second guidewire over the first guidewire to a point inside the cavity;

[0050] injecting one component of a two-component adhesive through a catheter over the first guidewire to the cavity; and

[0051] injecting the second component of the two-component adhesive through a catheter over the second guidewire to the cavity,

[0052] wherein the components combine to create an adhesive plug that seals the cavity.

[0053] Furthermore, in accordance with another preferred embodiment of the present invention, instead of the first adhesive component, a radiation-cured adhesive is injected and instead of the second adhesive component a radiation source is applied, thereby creating the adhesive plug.

[0054] Furthermore, in accordance with another preferred embodiment of the present invention, only one guidewire is used and the two components are inserted via separate lumens within a single catheter over the guidewire.

[0055] In accordance with yet another preferred embodiment, a stented valve is provided wherein a compressible material, such as a clot or fabric, extends around an exterior portion of the stent. The compressible material may be formed of polyethylene terephthalate (PET) and is configured to expand into the gaps. Furthermore, fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage. In one variation, a tissue growth factor

may be disposed on the material to encourage tissue growth between the material and the surrounding tissue.

[0056] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for providing integrated sealing capability in an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0057] providing an expandable elastic ring around the outside of the valve; and

[0058] expanding the ring,

[0059] wherein the ring seals any cavities.

[0060] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0061] inserting a sealing stent at the distal end of the cavity; and

[0062] inserting a second sealing stent attached to the first stent into the cavity.

BRIEF DESCRIPTION OF THE FIGURES

[0063] To better understand the present invention and appreciate its practical applications, the following Figures are provided and referenced hereafter. It should be noted that the Figures are given as

examples only and in no way limit the scope of the invention as defined in the appended claims. Like components are denoted by like reference numerals.

[0064] Figure 1 illustrates an implanted valve with a cavity creating a paravalvular leak and a device, in accordance with a preferred embodiment of the present invention, comprising a soft guidewire with an inflatable balloon and designed to identify the exact location of the paravalvular leak.

[0065] Figures 2a and 2b depict a plurality of balloons on soft guidewires, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

[0066] Figure 3 illustrates a plurality of balloons on soft guidewires and kept along the perimeter of the blood vessel by a ring, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

[0067] Figures 4a to 4c depict the process, in accordance with another preferred embodiment of the present invention, of inserting a sealing stent over a guidewire to close a paravalvular leak.

[0068] Figures 5a to 5d depict several types of sealing stents, in accordance with another preferred embodiment of the present invention.

[0069] Figures 6a to 6d illustrate blocking a paravalvular leak with a sealing device, in accordance with another preferred embodiment of the present invention, assisted by anchors, which attach the device to the aortic wall (or annulus).

[0070] Figure 7 illustrates an anchoring apparatus, in accordance with another preferred embodiment of the present invention, for achieving sealing as shown in Figure 6, in this case by use of a screw, which is embedded into to the aortic wall (or annulus).

[0071] Figures 8a and 8b depict a leak repair done, in accordance with another preferred embodiment of the present invention, using a two-component biological glue.

[0072] Figures 9a to 9c depict a leak repair done, in accordance with another preferred embodiment of the present invention, using an ultra-violet light-cured biological glue.

[0073] Figure 10 illustrates a catheter, in accordance with another preferred embodiment of the present invention, that inserts a two-component biological glue into a balloon in order to block a paravalvular leak.

[0074] Figures 11a to 11f illustrate a device and procedure, in accordance with another preferred embodiment of the present invention, for blocking a paravalvular leak using two connected sealing stents.

[0075] Figures 12 depicts a valve, in accordance with another preferred embodiment of the present invention, with a built-in inflatable portion allowing to fill gaps between the valve stent and the aortic wall in order to prevent paravalvular leaks.

[0076] Figures 13a to 13d illustrate a valve, in accordance with another preferred embodiment of the present invention, having a flexible and self-expanding portion for blocking possible leaks around the stent.

[0077] Figures 14a to 14c illustrate a valve, in accordance with another preferred embodiment of the present invention, having a having a flexible and self-expanding portion for blocking possible leaks around the stent..

[0078] Figures 15a to 15c illustrate a valve, in accordance with another preferred embodiment of the present invention, having a plurality of flexible and expanding segments on its proximal side for blocking possible leaks around the stent.

[0079] Figures 16a and 16b illustrate a valve device, in accordance with another preferred embodiment of the present invention, comprising an additional portion for blocking possible leaks around the stent.

[0080] Figures 17a to 17e illustrate a valve device, in accordance with another preferred embodiment of the present invention, where the stent is adapted such that when expanded, a portion of the stent is forced to protrude radially, thereby blocking possible leaks.

[0081] Figures 18a to 18e illustrate a valve, in accordance with another preferred embodiment of the present invention, constructed with additional sutures attached to the proximal side, allowing attachment of extra pieces of pericardium or artificial fabric for blocking paravalvular leaks.

[0082] Figures 19a to 19d depict a procedure, in accordance with another preferred embodiment of the present invention, the procedure comprising two stages: first, insertion of a stent that includes an outer sealing layer; and second, insertion of a prosthetic valve through the stent.

[0083] Figures 20a to 20g illustrate a valve, in accordance with another preferred embodiment of the present invention, having a sealing element made of a flexible and expandable material for blocking leaks around the stent.

[0084] Figure 21 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein the sealing element is attached to the valve in a sealing line for providing an improved crimped profile.

[0085] Figure 22 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.

DETAILED DESCRIPTION OF THE INVENTION

[0086] The present invention provides methods and apparatuses for substantially reducing or effectively eliminating the deleterious effects of paravalvular leaks in prosthetic valves. More specifically, it enables locating, sealing, and preventing paravalvular leaks using both dedicated and integrated (with the valve) means.

[0087] While the present invention is particularly suited for prosthetic heart valve leaks, such as a prosthetic aortic valve, it can also be applied to other leakage problems such as in other blood vessels, a septum, or other body lumens. Similarly, while the prosthetic valve described herein is a tricuspid valve, it could be another type of valve as well.

[0088] A main aspect of the present invention is the introduction of several novel designs and methods for locating paravalvular leaks in prosthetic valves.

[0089] Another main aspect of the present invention are several novel designs for sealing paravalvular leaks detected in prosthetic valves.

[0090] Another main aspect of the present invention are several novel designs for modifying percutaneous prosthetic valves to automatically seal paravalvular leaks when the valve is implanted.

[0091] Another main aspect of the present invention is a novel design that automatically seals paravalvular leaks when the valve is implanted without requiring valve modification.

[0092] Another main aspect of the present invention is the disclosure of several novel designs for modifying percutaneous prosthetic valves to enable sealing of paravalvular leaks after the valve is implanted.

[0093] For locating paravalvular leaks, the present invention provides several designs comprising catheter-delivered balloons mounted on flexible guidewires. The balloons are delivered to a point near the valve. When regurgitation (leaking) occurs during diastole, the balloons are drawn into the leak-producing cavities occurring between the valve and the wall of the blood vessel, thereby providing a means to deliver means for sealing the leak.

[0094] For sealing paravalvular leaks, the present invention provides several designs including sealing stents, and multi-component and radiation-cured adhesive compounds.

[0095] Sealing stents are crimped stents that are delivered to the leak location, expanded, and anchored in place. The stents are designed to block flow, thereby sealing the leak. Several innovations are provided for these operations.

[0096] Delivery of the sealing stent is via a guidewire that is anchored in the wall of the blood vessel at the leak location. The anchoring means can be a hook, for example a multi-headed hook composed of a shape memory alloy, such as nickel titanium (also known as nitinol), which is crimped at low temperature for delivery. The anchoring means expands back to its original shape due to the higher temperature of the blood vessel wall at its deployment point, thereby anchoring itself into the blood vessel wall.

[0097] Another anchoring means is for the guidewire to be terminated in a screw, which can be threaded into the blood vessel wall.

[0098] Once delivered to the leak location via the guidewire, the sealed stent is expanded. This can be done by another agent, such as a balloon, or by making the stent self-expanding. In the case of balloon inflation, the stent is crimped around the deflated balloon prior to insertion in the delivery catheter. Upon delivery the balloon is inflated, thereby expanding the stent, and then the balloons can be deflated and withdrawn. In the case of the self-expanding stent, the stent is preferably built from a shape memory alloy, such as nickel titanium (also known as nitinol), which can be crimped at low temperature for delivery, expanding back to its original shape due to the higher body temperature at the deployment site. Alternatively the self-expanding stent can be a metallic stent comprised of a physiologically acceptable metal such as stainless

steel or an alloy such as nitinol, which is compressed or wound on a delivery, catheter or device. When the stent is released from the delivery catheter or device, it expands.

[0099] The sealing stent is held in place by friction. Additional holding force can be obtained by adding hooks around the perimeter of the stent, such as self-expanding hooks made of shape memory alloy.

[00100] The expanded stent includes an internal element that seals the stent's own lumen, preventing flow through the stent and thereby sealing the cavity causing the leak. Examples of internal sealing elements include a spring-hinged flap inside the stent lumen that opens upon stent expansion or, in the case of the self-expanding stent, a membrane covering one or both openings of the stent.

[00101] In some cases, it may be preferred to use two sealing stents. In this embodiment, the two stents are connected in series by a suture. The delivery catheter is extended through the top of the cavity and out the bottom of the cavity to deploy one of the sealing stents and then, together with the stents' guide wire, retracted. This pulls the deployed stent back until it catches in the bottom of the cavity. The catheter is further retracted, and the second stent is deployed into the cavity. The catheter is further retracted and the second stent is pulled back, catching it (from the bottom) in the top of the cavity.

[00102] An alternative sealing element to the sealing stent is a biological adhesive compound that can be delivered to the cavity via catheterization. In such a case, two catheters are brought to the leak location. The catheters are used in one of the following ways: to deliver two adhesive components that, when mixed, harden to form an adhesive

sealing plug, or to deliver a radiation-cured adhesive and the cure source, for example an ultra-violet light source, to produce an adhesive sealing plug.

[00103] In both sealing element designs there is a need to bring the distal catheter ends in close proximity to one another, for proper mixing or curing, at the leak point. This is accomplished as follows: a first catheter is used to insert the leak detector guidewire mentioned above. A second guidewire is fitted with a loop, and the loop is run over the first guidewire until it reaches the leak location. The respective cathethers are then slid over their guidewires to meet at the leak location, thereby providing egress for applying the bi-component adhesive or radiation-cured adhesive.

[00104] Another delivery design for a bi-component adhesive utilizes a single catheter run over the leak detection guidewire. The catheter has three lumens: one to track the guidewire and one for each adhesive component. A mixing means at the distal end of the catheter mixes the components at the leak location to form the sealing plug.

[00105] In other embodiments of the present invention, leak sealing means are integrated into the valve as an impermeable ring that, when the valve is implanted, adaptively seals any gaps between the valve and the surrounding lumen.

[00106] In one embodiment of such a self-sealing valve, the ring is deflated for delivery and then inflated for sealing.

[00107] In another self-sealing valve embodiment, the ring is a sponge-like material that is compressed for delivery and then expands for sealing.

[00108] In another self-sealing valve embodiment, the ring comprises a set of flaps that are closed for delivery and are opened either by balloon inflation, by the geometry of their connection to the valve, or by spring-action.

[00109] In another self-sealing valve embodiment, the ring comprises a set of self-expanding tubes.

[00110] In another self-sealing valve embodiment, the ring comprises struts of the valve's stent that are geometrically constrained to bend and enlarge their final diameter in respect to the main stent geometry when expanded from the crimped form

[00111] In another embodiment where sealing means are built into the valve, a set of filament pairs are attached around the valve and feed back to the delivery catheter ingress. When a paravalvular leak is detected, impermeable patches of a material such as pericardium are threaded onto the local filament pair and pushed down to the leak location where they are tied off in place.

[00112] In another embodiment of the present invention, a sealing stent is first inserted into the lumen, and then the valve is inserted inside the sealing stent.

[00113] The aforementioned embodiments as well as other embodiments, manufacturing methods, different designs and different types of devices are discussed with reference to the drawings. Note that

the drawings are only given for the purpose of understanding the present invention and presenting some preferred embodiments of the present invention. The drawings are not meant to limit the scope of the present invention as defined in the appended claims.

[00114] Figure 1 illustrates a simple leak detector 27 in accordance with a preferred embodiment of the present invention. Leak detector 27 detects a leak between general tricuspid implantable prosthesis valve 20 and the aortic annulus 22. Leak detector 27 will typically be used together with leak sealing devices, like those described later in this specification.

[00115] A cavity 24 exists between the perimeter of valve 20 and aortic annulus 22. The cavity could have any number of causes, including calcification or other irregularities in the aortic annulus 22 that prevent proper sealing between the valve 20 and the annulus 22. The cavity will cause regurgitation (leaking) during diastole, characterized by blood flowing 25 from the aorta into the left ventricle. Leak detector 27, is delivered through catheter 21 to a position above valve 20. Leak detector 27 comprises a soft guide wire 28 on which is mounted inflatable balloon 29, which is inflated after leak detector 27 has been passed through catheter 21. Guidewire 28 is soft enough that during diastole inflated balloon 29 is drawn into the regurgitation flow and lodges in cavity 24 in between valve 20 and annulus 22.

[00116] Figures 2a and 2b depict a multiple leak detector 228 that is similar to leak detector 27 of Figure 1 but which comprises a plurality of soft guidewires 31 rather than just the single guidewire 28 of detector 27. On each guidewire 31 is mounted a balloon 35. Figure 2b is a top view showing valve 20 during diastole. Two cavities 24 cause a flow of blood,

which pulls the balloon 35 closest to each cavity 24 into that cavity while remaining balloons 35 stay stationary. At this point, cavity 24 locations can be determined and marked and the cavities repaired.

[00117] Figure 3 illustrates an annular-configured leak detector 229, which incorporates an adaptation that can be used to force wire(s) 40 of leak detector 27 or multiple-leak detector 228 (implementation shown) to remain close to aortic wall 45 rather than being allowed to drift to the center of the aorta. The advantage of this adaptation is that, in the case of detectors 27 and 228, if there is a central leak in valve 20, a balloon near the center of the aorta might be drawn into the central leak instead of to the paravalvular cavity, thereby indicating a false paravalvular leak. Spacing ring 40 is a compressible wire ring that pops open after catheter 21 delivery. Guidewire(s) 42 are distributively attached to the external edge of ring 40 and are thereby held by the ring against the aortic wall 45.

[00118] Figures 4a to 4c depict an implantable valve 49 deployed in the native aortic valve position, creating a cavity 24, which causes paravalvular regurgitation (leak) during diastole. In Figure 4a, guidewire 46, which can be a leak detection device like those shown in Figures 1, 2, and 3, is inserted through cavity 24. Balloon 33 is deflated. In Figure 4b, a balloon-expandable sealing stent (stent with an impermeable membrane that prevents the passage of fluids through the stent), is catheter-deployed over guidewire 46. Balloon 33 is inflated, causing balloon-expandable sealing stent 47 to be expanded, thereby sealing cavity 24 and stopping the paravalvular leak. Figure 4c shows a similar leak repair with the difference that a self-expanding sealing stent 48 is used, and therefore balloon inflation is not required. The sealing stents 47 and 48 are anchored by friction between themselves and the surrounding aortic

annulus. Means for providing stronger anchoring for sealing stents are described later in this specification.

[00119] Figures 5a and 5b illustrate an embodiment of a balloon-expandable sealing stent (such as that used in Figure 4b) in accordance with another preferred embodiment of the present invention. The outer part 51 of the stent is made of a material that can be reshaped by plastic deformation. Sealing element 52, comprising an impermeable membrane, is connected to the inside wall of outer part 51 by spring hinge 53. The balloon-expandable sealing stent 47 is crimped on balloon 55. Once balloon 55 has reached cavity 24, the balloon is inflated, thereby expanding the sealing stent (Figure 5a). Balloon 33 is then deflated, whereupon (Figure 5b) sealing element 52 is forced by spring 53 to close and seal the lumen of the stent.

[00120] Figures 5c and 5d show a self-expanding sealing stent (such as that used in Figure 4c) in accordance with another preferred embodiment of the present invention. One way to implement the self-expanding sealing stent is to build stent framework 56 from a shape memory material such as nitinol 56 and cover it with a layer of impermeable material 58. The self-expanding sealing stent is catheter-delivered to the cavity, whereupon the stent opens, its shape adjusting to the shape of the cavity and its impermeable covering 58 sealing the cavity, to prevent the paravalvular regurgitation. To anchor the self-expanding sealing stent in place, hooks 59 can be included on framework 56. Hooks 59 are attached to framework 56 and extend through sealing material 58 and into the wall of the aortic annulus. The hooks are self-extending. One way to implement them is to make them from a shape memory material such as nitinol.

[00121] Figures 6a to 6d illustrate a technique for anchoring a sealing stent 66 (such as balloon-expandable sealing stent 47 or self-expanding sealing stent 48) into an open cavity 24, which is situated between aortic annulus 63 and prosthetic valve 20, and which creates paravalvular regurgitation. In Figure 6a, a guidewire 61 is led through cavity 24 by balloon 29 (this can be done with a device such as those disclosed in Figures 1 to 3). Guiding catheter 603 is fed over the guidewire, and the guidewire is removed. In Figure 6b an additional wire, anchoring wire 67, which terminates in anchoring apparatus 65, is inserted through catheter 63 to the anchoring location in cavity 24. Anchor 65 is a hook with one or more hook heads that can be compressed for delivery and will spring back to their original position when the delivery compression is removed (in other words, when the device emerges from the delivery catheter). Anchor 65 could be composed of flexible metal or a shape memory compound. Anchor 65 penetrates the aortic annulus at an approximately perpendicular angle due to the angled tip of guiding catheter 603. Figure 6c shows sealing stent 66 inserted via anchoring wire 67 and expanded to seal the cavity by one of the methods described in Figure 4 or 5. In the case shown in Figure 6c, a self expandable sealing stent as described in Figure 4 is shown. This method enables improved anchoring forces in comparison to friction alone, which is the sole anchoring for the embodiments shown Figures 4 and 5. Figure 6d shows the final step of the procedure, where the wire is detached from the anchor at detaching point 68.

[00122] Figure 7 depicts an apparatus that is similar to that illustrated in Figure 6, only here anchor 65 is implemented as a screw tip 69. The anchoring is accomplished by rotating anchoring wire 67, thereby threading tip 69 into aortic annulus 22.

[00123] Figures 8a to 8d demonstrate an apparatus for repairing a paravalvular leak by means of biological bi-component adhesive material (such as an epoxy resin), the components of which are in liquid form and turn to solid when mixed, in accordance with another preferred embodiment of the present invention. The leak is caused by an open cavity between valve 20 and annulus 22. A leak detector, such as those shown in Figures 1 to 3, is used to run guidewire 83 through cavity 24. A second guidewire 84 with a slide element 85 is slid over the first guide wire 83. Slide element 85 enables second guidewire 84 to slide over first guidewire 28 and can be a ring at the end of second wire 84. In Figure 8b, when slide element 85 and first guidewire 83 reach a point approximately midway through cavity 24, catheters 86 and 87 are slid over guidewires 28 and 84, respectively, until the catheters meet at meeting point 75.

[00124] In Figure 8c one of the components of a biological bi-component adhesive material is injected via catheter 86, and the other component is injected via catheter 87. The liquid adhesive components meet at the catheter outlets at meeting point 75, mixing to create the adhesive blocking element 89, which repairs the paravalvular leak by closing cavity 24. Figure 8d depicts a top view of the final result of the repaired cavity showing that adhesive blocking element has been formed to seal cavity 24 between valve 20 and annulus 22.

[00125] Figure 9 illustrates another apparatus for blocking a leak by means of biological adhesive in accordance with another preferred embodiment of the present invention. Again, two guidewires meet at meeting point 75, and catheters, in this case 91 and 93, are fed over the guidewires to meeting point 75. However, in this case the blocking adhesive material comprises one liquid component that is solidified by the

presence of ultra-violet light or another radiation cure. The liquid adhesive material is inserted into cavity 24 at catheter meeting point 75 via catheter 91. Active wave 96 shining through light probe catheter 93 hardens the material, creating sealing block 95, which closes the leak caused by cavity 24.

[00126] Figures 10a to 10e illustrate another apparatus for repairing a paravalvular leak using a bi-component adhesive material in accordance with another preferred embodiment of the present invention. Figure 10a shows a multiple-lumen catheter 100 that can be slid over guidewire 99 to the desired location, inside cavity 24 between aorta 82 and prosthetic valve 81. Figure 10b is a cross-section of the catheter 100's multiple-lumen shaft. Lumens 102 and 103 provide means of approach for the separate components of the adhesive. Lumen 104 provides means for catheter to be fed over guidewire 28. Figure 10c shows a bi-component adhesive infusion chamber 100 in the form of a double syringe connected to the end of catheter 100 that is proximal to the medical operator. Figure 10d illustrates a mixing element 105 located at the distal end of catheter 100 (its location can be seen in Figure 10a). Mixing element 105 serves to mix the two adhesive components as they emerge from distal end of catheter 100 after being forced out of chamber 101, thereby ensuring that they will solidify and cure inside cavity 24. Figure 10e shows the adhesive components after they have been infused by chamber 101 via multiple-lumen catheter 100 and mixing element 105 into cavity 24 to form a plug. The cured adhesive fills the cavity and blocks the leak. Also shown in Figure 10e is an optional flexible mesh bag 106, which receives and holds the adhesive mix. The bag prevents possible migration of adhesive material during insertion and prevents the adhesive from passing through stent struts 108 in cases where such valve designs are present.

[00127] Figures 11a to 11f illustrate an apparatus for repairing a paravalvular leak in accordance with another preferred embodiment of the present invention. Two self-expanding sealing stents 110 are connected by suture 112 and pushed into insertion catheter 111 (Figure 11b). At this stage, insertion into the catheter has reduced the stents' diameter, enabling them to enter a cavity 24 between a prosthetic valve and surrounding blood vessel. Figures 11c and 11d depict an implanted valve 115 where two large calcifications 116 create cavity 117, which causes regurgitation and must be repaired. (The calcification is just one example of a condition that creates a cavity that must be repaired. The cavity could equally have been caused by other factors, the cause is not determinant for the embodiment.) Figure 11e depicts insertion catheter 111 inserted over guidewire 28 to a point where the distal (delivery) end of the catheter has passed through the bottom of cavity 117. A first sealing stent 110 is deployed below the bottom of cavity 117. Catheter 111 is withdrawn and suture 112 is partially retracted, pulling the first sealing stent 110 into the bottom of the cavity, where it lodges. With reference to Figure 11f, insertion catheter 111 is withdrawn until its distal end is near the top of cavity 24, whereupon a second sealing stent 110 is deployed. Suture 112 is further retracted, pulling the second stent into the top of the cavity, where it lodges. The final step of the procedure is to disconnect the proximal part of the suture at point 119.

[00128] Figure 12 depicts a valve adapted to seal paravalvular leaks in accordance with a preferred embodiment of the present invention. Valve 121 is held in holder stent 124 with sealing element 120 attached circumferentially around stent 124's outer surface. When valve 121 is implanted, sealing element 120 is expanded to seal any peripheral paravalvular leaks. Several means can be used to implement expansion of

sealing element 120. In the implementation shown in Figure 12, sealing element 120 is inflated by operator application of syringe 123, and it constitutes a balloon-like portion, made of a pliant physiologically acceptable polymeric material such as polyurethane. The inflation media can be saline solution, the patient's blood, or another physiologically acceptable fluid.

[00129] Alternatively, the sealing portion can be made of a material that, on contact with a fluid, soaks up the fluid and swells up. Once inserted into the body, the sealing portion comes into contact with the blood, causing it to swell and seal the cavity.

[00130] Figures 13a to 13d depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Figure 13a depicts an implantable valve 124. Stent 125 has a sealing component 126 connected to its inlet. Sealing component 126 is comprised of a plurality of flaps 127 and expands to a larger diameter than the principal diameter of the stent 125, creating an extra sealing line to prevent paravalvular leaks. Figure 13b depicts a top view of valve 124. Sealing component 126 comprises a plurality of flaps 127 that, independent of one another, are connected to the valve stent 125. Each flap 127 is made of spring wire 131, which, after the valve is deployed, causes flap 127 to extend out. Flaps 127 are covered with impermeable sealing material 128. Flaps 127 are arranged such that they are substantially perpendicular to the longitudinal axis of stent 124 and overlap one another, ensuring a full seal.

[00131] Figure 13c shows stent-mounted valve 124 in its crimped configuration. Introducing sheath tube 130 holds stent 125 and sealing

component 126 crimped on balloon 129. After deployment, flaps 127 of sealing component 126 open to their final diameter.

[00132] Figure 13d shows a cross-section of a self-expanding sealing flap 127. Stent strut 133 is attached to spring wire ring 131 by mechanical attachment means 134, which can be a rivet, a screw, etc. Spring wire ring 131 can be folded into introducing sheath tube 130 shown in Figure 13c and, when released from tube 130, springs back to its shape as shown in Figure 13d.

[00133] Figure 14 illustrates a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. This design includes balloon-inflatable stent 140 (containing a prosthetic valve) and balloon-inflated sealing ring 145, which is similar to sealing component 126 of Figure 13, only here balloon-inflatable wire 145 is used instead of spring wire ring 131. Stent 140 is inflated using a double balloon. First balloon section 142 inflates stent 140 to the desired diameter, and then second balloon section 143 inflates sealing flaps 145 perpendicular to stent 140, creating a larger diameter and thus sealing any cavities around the stent.

[00134] Figures 15a and 15b depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. In this embodiment the sealing ring comprises flexible sealing elements 150. Each sealing element 150 is independently spring-actuated. When the valve is crimped, sealing elements 150 fold, enabling valve to be reduced to a small diameter for insertion. When valve is expanded to its final diameter, sealing elements 150 open to a larger diameter 154 to seal cavities around the valve, preventing

paravalvular leaks. Since each sealing element 150 is independent, sealing elements adjacent to native valve tissue 152 remain closed. These closed elements provide a further benefit of adding compressive forces that improve the anchoring of the valve.

[00135] Figures 16a to 16c depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Here the sealing ring 165 comprises at least one of a plurality of flexible, self-expanding sealing elements 165 connected to the outer surface of stent 160. Similar to the embodiment shown in Figure 15, when stent 160 is pressed against the native tissue, sealing element 165 will stay compressed against the wall. But where there is a gap between stent 160 and the surrounding tissue, sealing element 165 will expand and block any possible leak. With reference to Figure 16b, sealing element 165 is made of self-expanding mesh 166 covered with PET (polyethylene terephthalate) mesh 167 or other impermeable material.

[00136] Figures 17a to 17e depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention, wherein the sealing component is built into a ring 172 of the stent struts. In the figure the ring of struts 172 is located at the stent's inlet; however, the ring of struts can equally be implemented at another point along the stent. The modified struts 173 comprising ring of struts 172 are designed so that they are geometrically constrained such that, upon expansion of the stent from crimped state (Figure 17a) to expanded state (Figure 17b), ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.

[00137] Figures 17c and 17d show front and side views of the geometrical restriction in modified strut 173 that causes the displacement of point 175, creating enlarged diameter 169. Figure 17c shows modified strut 173 before stent expansion and in line with the rest of the stent wall. Figure 17d shows modified strut 173 after stent expansion, which has caused modified strut 173 to rise up and out, creating the sealing ring. Figure 17e details the operation of the geometric restriction: when stent 170 is crimped, the strut legs are relatively close to each other 176, making strut height relatively large 177. After expansion, the strut legs are spaced further apart 176a, leading to displacement of point 175, and lessening of strut height 177a. The result of the movement of point 175 is shown in Figures 17c, 17d, and 17e. When the stent is crimped, as shown in Figure 17c and the left side of Figure 17e, point 175 is low. When the stent is expanded, as shown in the right side of Figure 17e, point 175 moves up, pulling the stent to the shape shown in 17d .

[00138] Figures 18a to 18e depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. In Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being advanced toward the stenotic aortic valve 175. At least one of a plurality of sutures 181 are connected to valve 180 at inlet end 187. The sutures spread back along the balloon's shaft 183 and continue back along the deployment path and out of the patient's body as shown in Figure 18b.

[00139] Inflating balloon 183, as shown in Figure 18c, anchors valve 185 in annulus 179 with sutures 181 arranged around it. In cases where paravalvular cavities 178 are present, it is possible to repair them assisted by sutures 181. Figure 18d shows a patch 189 made of

pericardium (or other suitable patch material) inserted on sutures 181 and pushed to the leaking cavity by means of a pushing catheter 190. After the patch is in place, a knot or clip 191 is used to secure it, thereby repairing the leak (18e).

[00140] Figures 19a to19d depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. First elastic sealing stent 195 is inserted in the desired location. Then, valve 196 is inserted into sealing stent 195. Figure 19a shows inserting catheter 191 with sealing stent 195 and valve 196 mounted on it. Sealing stent 195 and valve 196 can be either balloon inflated as shown in this figure, or self-expanding which would then require an introducing sheath.

[00141] Figure 19b shows the two stents placed in the native aortic valve. Sealing stent 195 compensates for irregular shapes, while the stented valve 196, which is mounted inside sealing stent 195, can be absolutely round. Sealing stent 195 is able to avoid leaks caused by cavities or irregularities caused by pieces of calcification as described earlier in this patent. The sealing component of sealing stent 195 can be self-expandable hydrophilic sponge 197 (Figure 19c) or other suitable material. Sealing stent 195 can include hooks 198 that open when the stent is inserted, improving the anchoring of the stent in the annulus as well as improving sealing around the stent by blocking blood (Figure 19d).

[00142] Figure 20a depicts a stented valve 201 having a valvular structure 202 along an interior region and a mechanism along an exterior region for sealing paravalvular leaks in accordance with yet another

preferred embodiment. In this embodiment, a flexible sealing element 203 provides a sealing ring. The sealing element 203 may be formed of any material suitable for implantation in the human body, such as, for example, a sponge material. When the stented valve 201 is crimped to a smaller diameter, sealing element 203 is also crimped, thereby enabling valve to be easily advanced to a treatment site. For purposes of illustration, figure 20f illustrates sealing element 203 before crimping, while Figure 20g illustrates sealing element in a crimped condition. When the valve is expanded to its final diameter, sealing element 203 expands to its original size diameter by internal spring forces and/or by absorbing blood. Expansion of the sealing element seals cavities around the valve and thereby prevents paravalvular leaks. In addition to the mechanical effect of blocking cavities, blood protein preferably adheres to the sealing element, thereby causing coagulation for further leak prevention. Figures 20c and 20d provide cross-sectional views of preferred sealing elements. A tubular form 203a shown in figure 20c is configured to be crimped to a smaller size than a rod form 203b shown in figure 20d. Figure 20e illustrates the sealing element with additional fibers 206, which increase the active surface, thus increasing the effect of protein adhesion and enhancing coagulation and sealing. Figure 20e also illustrates a suture 207 as one preferred means for attachment to the valve body. Figure 20b is a perspective view illustrating another preferred embodiment of a valve 210 having a sealing mechanism. In this variation, two sealing elements 204, 205 are provided along an exterior region.

[00143] Figure 21 depicts yet another stented valve 220 adapted to seal paravalvular leaks. In this embodiment, a sealing element 223, which is preferably made of the same materials described above with

respect to figures 20a through 20g, is attached to the stent in a non-linear sealing line. In preferred configurations, the line can be adjacent to the connection of a valvular structure 222 to the stent or according to the lines of the stent structure. In one feature, an improved crimped profile may be achieved using the illustrated attachment line.

[00144] Figure 22 depicts yet another stented valve 250 configured to reduce or prevent paravalvular leaks. The stented valve generally comprises an expandable stent structure 252 which supports a valvular structure 254. The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration.

[00145] To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252. The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve. In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm. In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped. The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage

coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps. Any suitable tissue growth factor may be used. In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

[00146] In yet another embodiment, a biocompatible hydrogel may be applied to the outside surface of a prosthetic valve. After deployment, the hydrogel absorbs fluids from the blood and expands to the fill the gaps between the valve and surrounding tissue (e.g., host annulus). In preferred methods, the hydrogel may be applied to the surface of the stented valve before deployment or may be applied after deployment.

[00138] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

CLAIMS

1. A catheter-delivered device for locating cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

2. The device of Claim 1 further comprising a spacing element to maintain the wires adjacent to the wall of the body vessel.

3. A catheter-delivered stent for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the stent delivered via guide wire to the cavity, held in place in the cavity by friction, and comprising a support structure and an impermeable membrane, the membrane preventing the passage of fluids through the stent, thereby sealing the cavity.

4. The device of Claim 3, wherein the sealing stent is balloon-expandable type and the membrane comprises a tab spring-hinged to the inside of the stent lumen and sized to occlude the lumen when closed, the tab being held open by the stent balloon during insertion and springing closed when the balloon is removed after the stent is expanded.

5. The device of Claim 3, wherein the sealing stent is self-expandable, wherein the membrane is a material covering at least one end of the stent.

6. The device of Claim 5, wherein the stent is comprised of shape memory material.

7. The device of Claim 6, wherein the material is nitinol.

8. The device of Claim 5 further covered on its external walls with hooks comprised of shape memory material and which extend, upon insertion of the stent, into adjacent body vessel walls.

9. The device of Claim 3, wherein the distal end of the stent-delivery catheter is substantially perpendicular to the wall of the vessel at a point inside the cavity and the stent guidewire terminates in an anchoring mechanism that is inserted through the catheter and into the vessel wall, anchoring itself in the vessel wall and providing greater anchorage for the stent.

10. The device of Claim 9, wherein the anchoring mechanism is a hook comprised of shape memory material that is compressed for catheter delivery into the vessel wall whereupon the hook extends out, anchoring the guide wire into the vessel wall.

11. The device of Claim 10, wherein the anchoring mechanism is a threaded point that is threaded into the vessel wall anchoring the guide wire into the vessel wall.

12. A device for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising a first guidewire threaded through the cavity, a second guidewire slidably coupled to the first wire and inserted such that the slidable coupling is moved to a point in the cavity, a first catheter inserted over the first guidewire to the point in the cavity, a second catheter inserted over the second guidewire to the point in the cavity, a first component of a two-component biological adhesive inserted through the first catheter to the point, a second component of the two-component adhesive inserted through the second catheter to the point, and the two components thereby mixing to form a plug that seals the cavity.

13. The device of Claim 12 adapted to apply an adhesive with more than two components.

14. The device of Claim 12, wherein, instead of two guidewires and two catheters, a single catheter and guidewire are used for delivery, with the catheter comprising two lumens, each lumen providing delivery for one of the two-component adhesive components, the catheter terminating in a mixer that forces the components to mix when the exit the catheter in the cavity, thereby creating the plug that seals the cavity.

15. The device of Claim 12, wherein, instead of two-component adhesive components being delivered via the catheters, a radiation-cured adhesive is delivered via one of the catheters and a radiation source is delivered via the other catheter, wherein the radiation source is applied to the adhesive to create the plug in the cavity.

16. A catheter-delivered assembly for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the assembly delivered via guidewire to the cavity and comprising two sealing stents connected by a suture, the suture running back up the catheter, the sealing stents comprising a stent structure and sealing membrane, one stent of the assembly inserted underneath the cavity and the other stent inserted inside the cavity, the membranes preventing the passage of fluids through the stent, thereby sealing the cavity and each stent helping anchor the other in place.

17. A prosthetic valve with integrated sealing ring attached to the outside wall, the ring having a circumference greater than that of the valve and elastically conforming to seal cavities between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

18. The device of Claim 17, wherein the ring comprises a balloon.

19. The device of Claim 17, wherein the ring comprises a plurality of spring-wire tabs mounted adjacent to one another around the circumference of the valve and covered with an impermeable membrane and wherein the tabs are folded against the body of the valve during catheter delivery and where, upon egress from the catheter, the tabs spring out to form the sealing ring.

20. The device of Claim 17, wherein the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, and further comprising a balloon under

the tabs and wherein the tabs are folded down on the deflated balloon during catheter delivery and wherein, upon egress from the catheter, the balloon is inflated, thereby opening the tabs to form the sealing ring.

21. The device of Claim 17, wherein the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, each tab spring-hinged to the valve and wherein the tabs are folded against the body of the valve during catheter delivery and wherein, upon egress from the catheter, the tabs spring out to form the sealing ring.

22. The device of Claim 17, wherein the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

23. The device of Claim 17, wherein the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

24. The device of Claim 17, wherein the sealing ring comprises modified struts of the stent, the modification comprising geometrical constraints that, upon expansion of the stent, cause the struts to bend out from the stent body, thereby creating the sealing ring.

25. A prosthetic valve with integrated sealing means, the sealing means comprising sutures attached around the perimeter of the valve and extending back out of the body and wherein patches can be pushed down the sutures and attached to the point where the suture is

attached to the valve, thereby sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

26. A catheter-delivered prosthetic valve with integrated sealing means, the sealing means comprising an elastic stent that is first deployed and inside which the valve is deployed, the elastic stent sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

27. A prosthetic valve for implantation in a body channel, comprising:

a substantially cylindrical stent structure configured for radial expansion;

a valvular structure providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

a layer of compressible material disposed along an outer surface of the stent structure, the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel.

28. The prosthetic valve of claim 27, wherein the compressible material is formed of polyethylene terephthalate.

29. The prosthetic valve of claim 28, further comprising a tissue growth factor disposed along the compressible material and

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

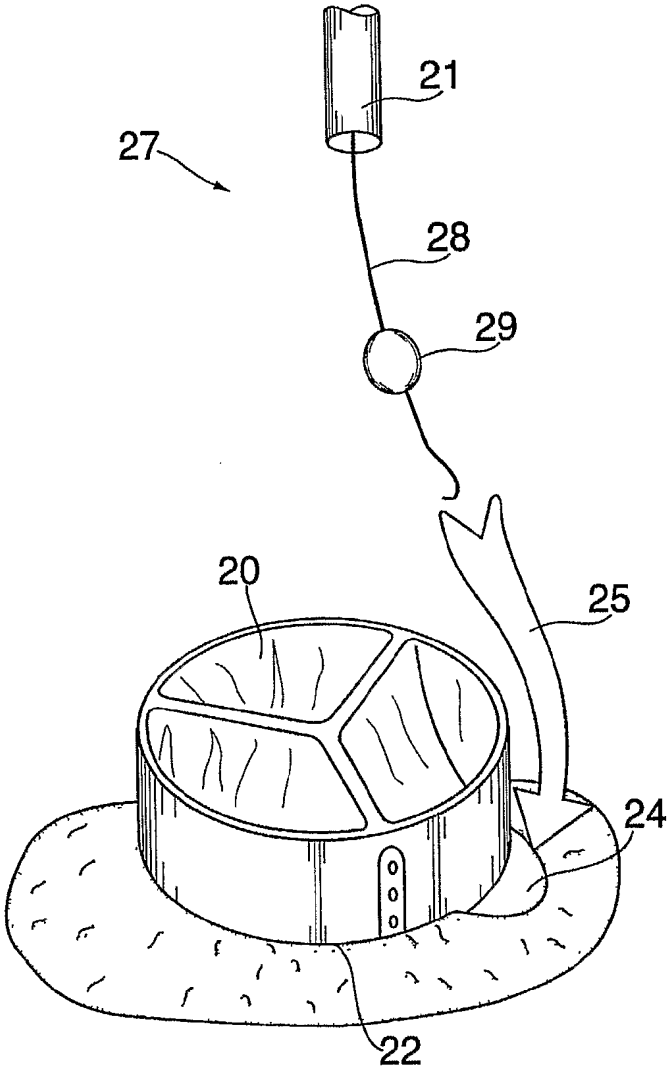

FIG. 1

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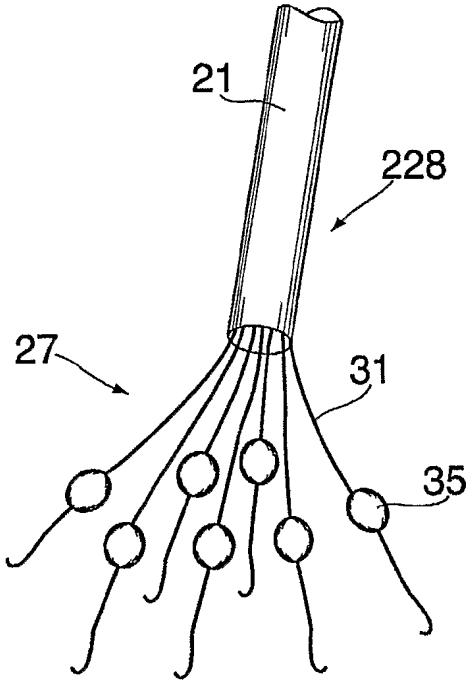

FIG. 2a

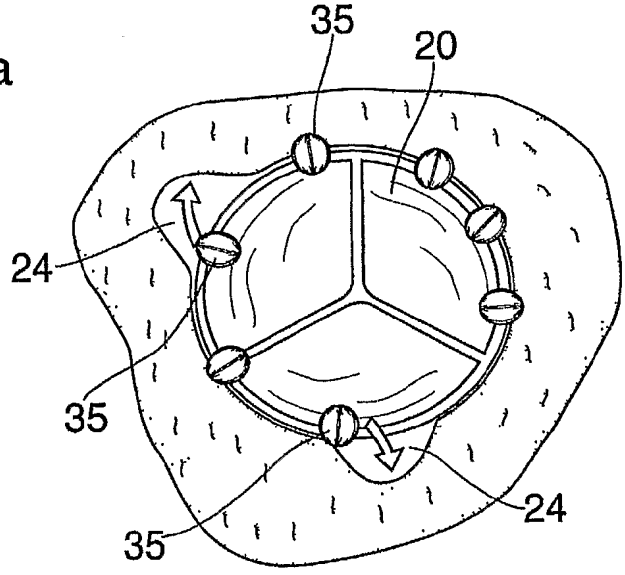

FIG. 2b

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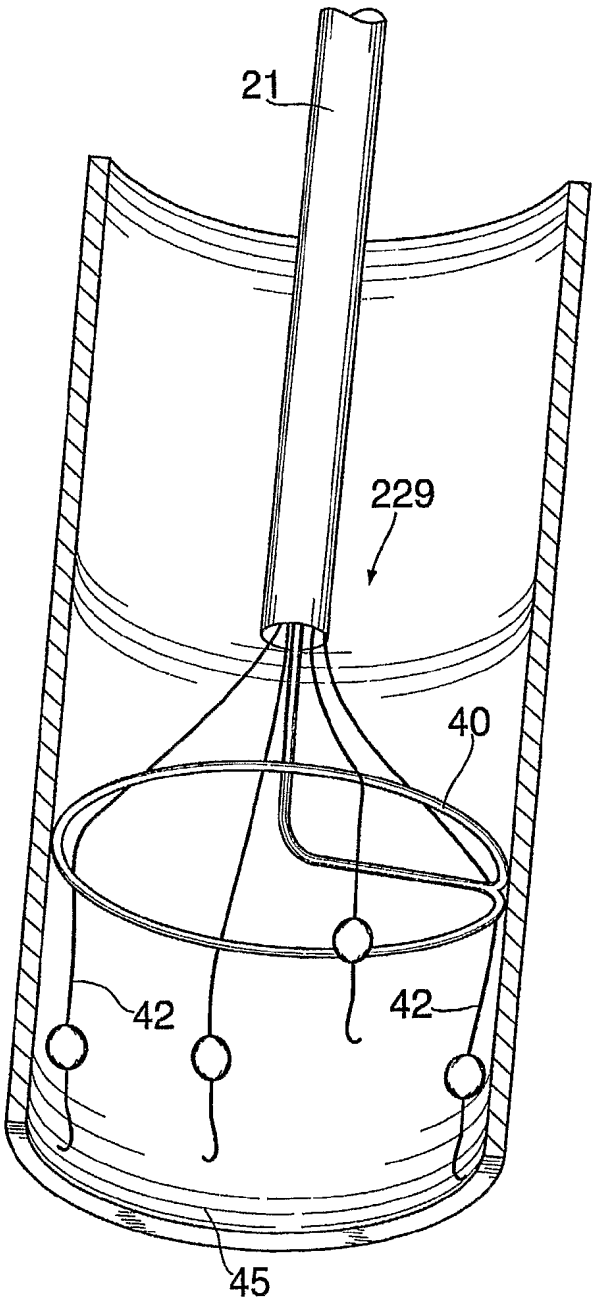

FIG. 3

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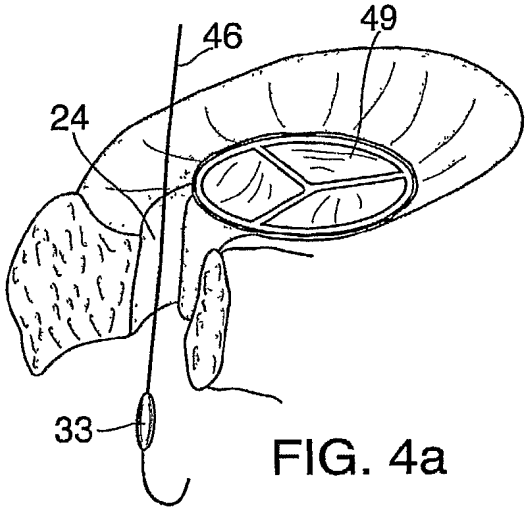

FIG. 4a

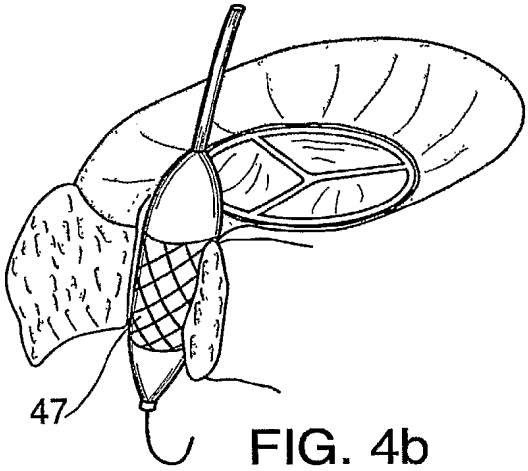

FIG. 4b

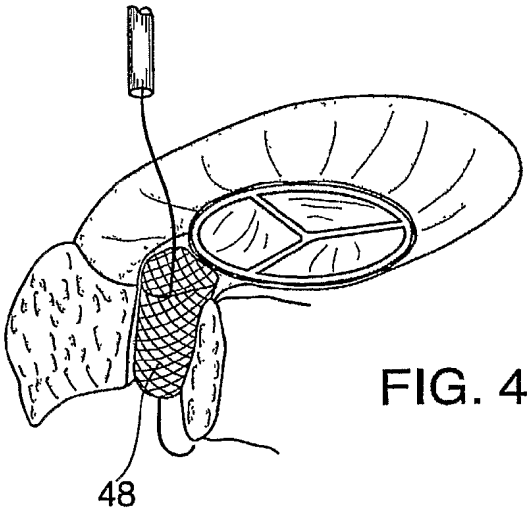

FIG. 4c

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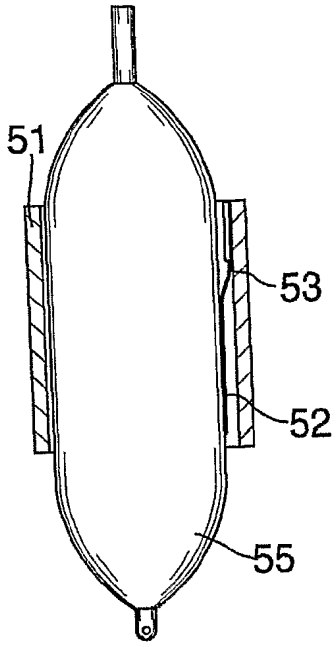

FIG. 5a

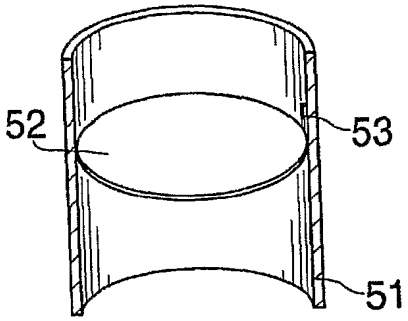

FIG. 5b

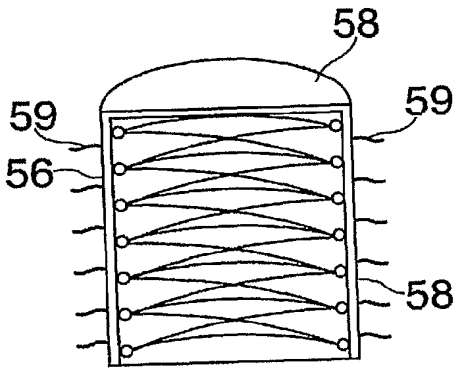

FIG. 5c

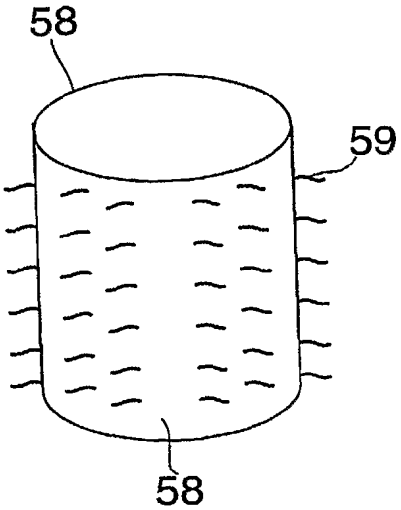

FIG. 5d

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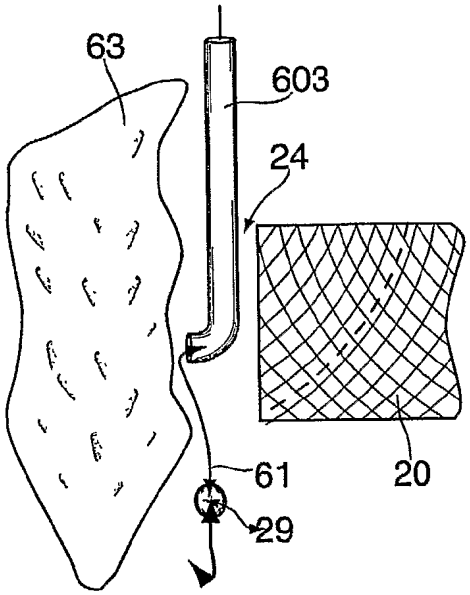

FIG. 6a

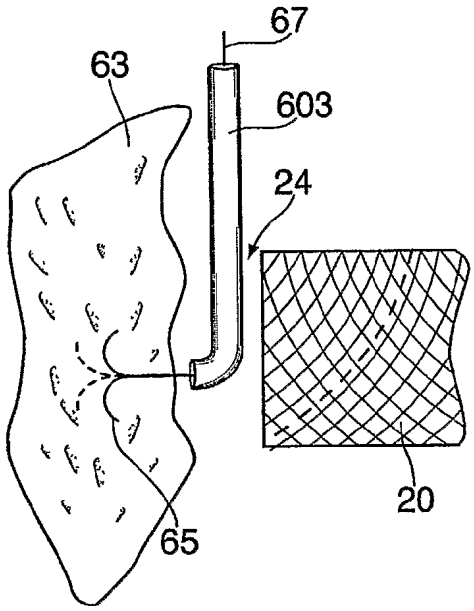

FIG. 6b

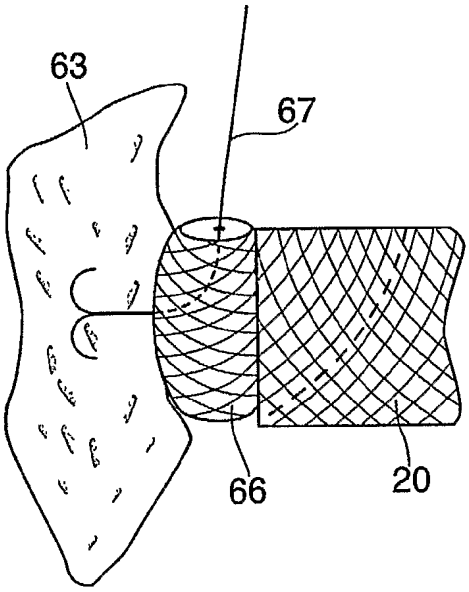

FIG. 6c

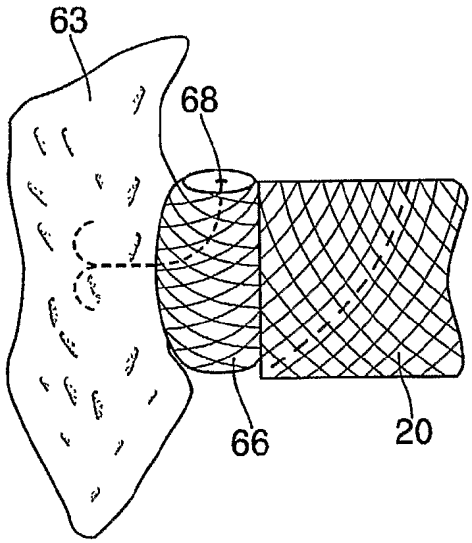

FIG. 6d

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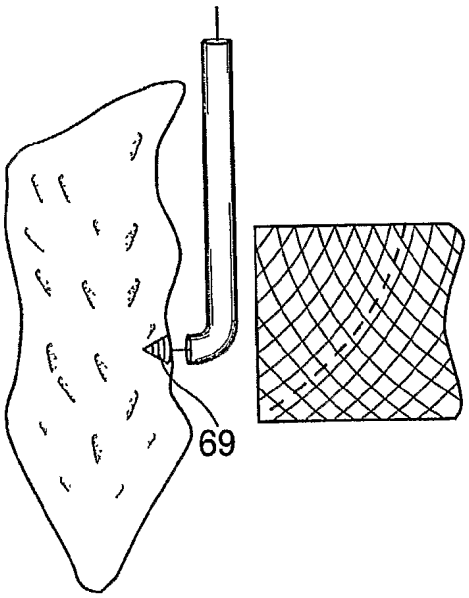

FIG. 7

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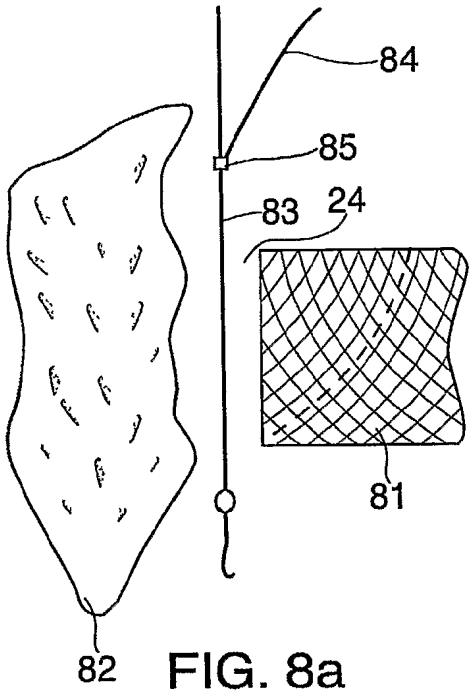

FIG. 8a

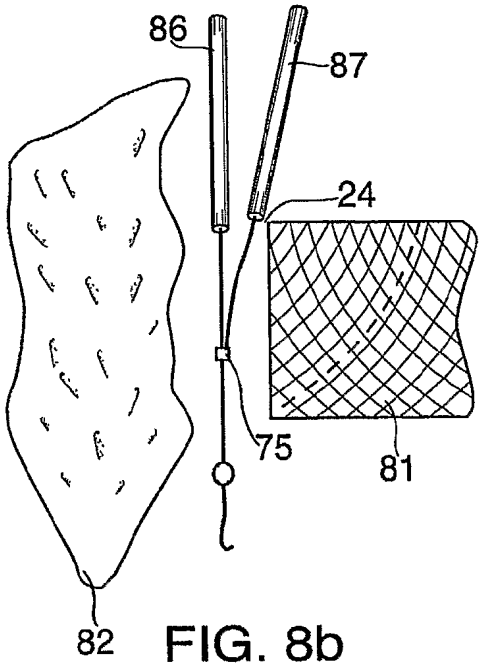

FIG. 8b

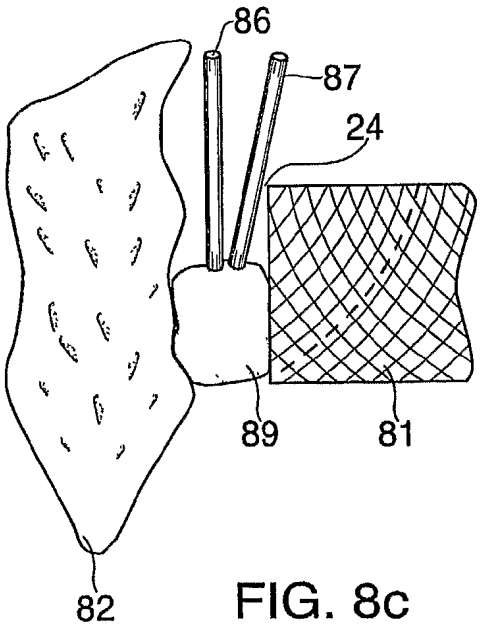

FIG. 8c

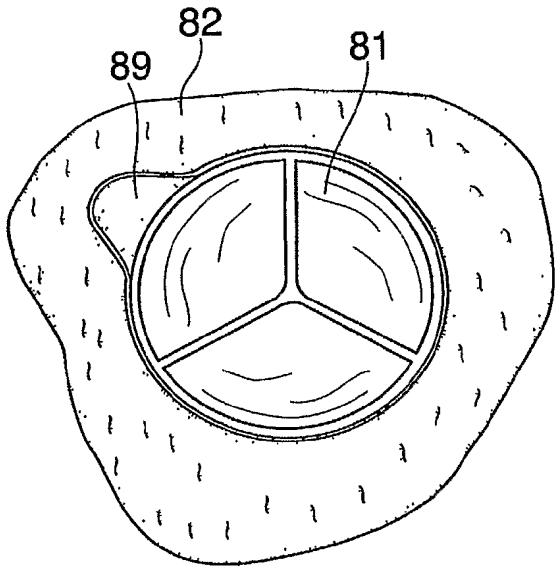

FIG. 8d

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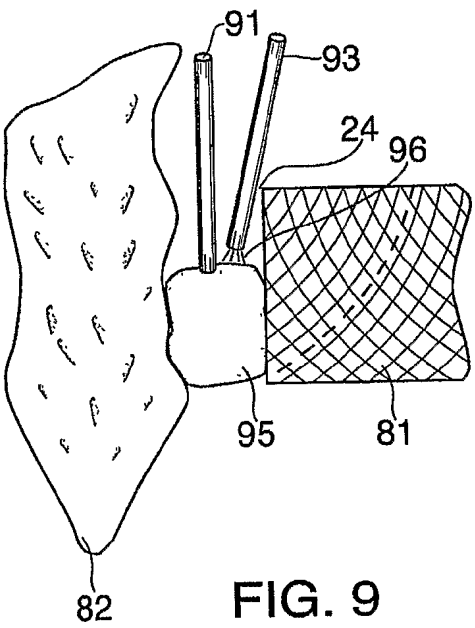

FIG. 9

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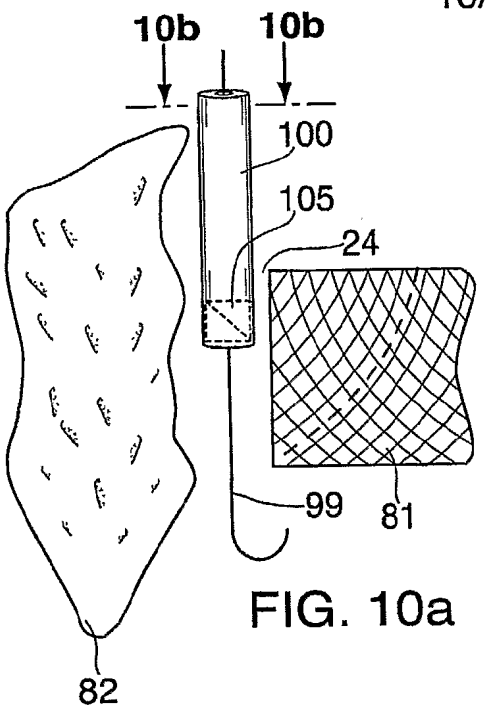

FIG. 10a

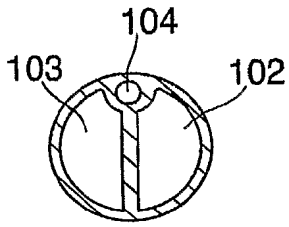

FIG. 10b

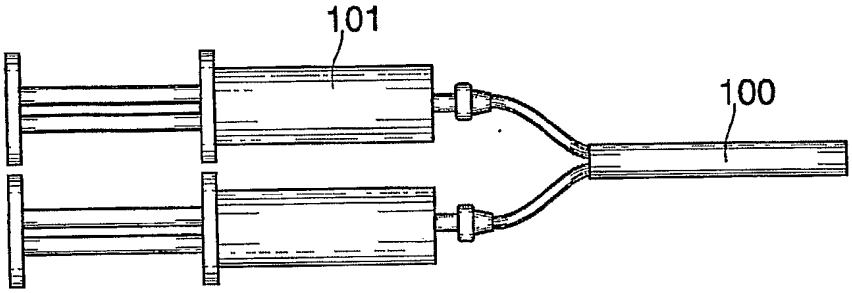

FIG. 10c

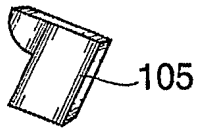

FIG. 10d

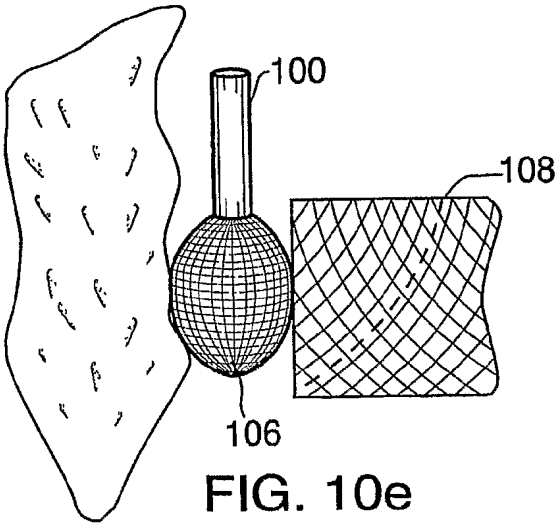

FIG. 10e

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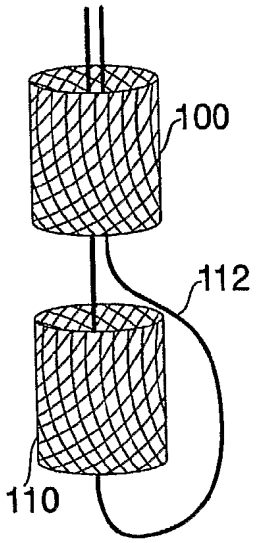

FIG. 11a

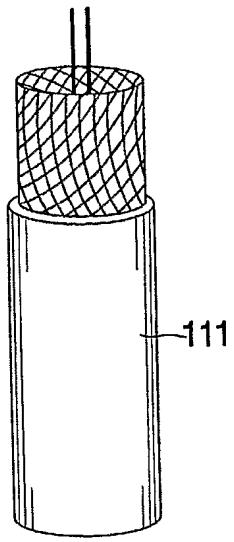

FIG. 11b

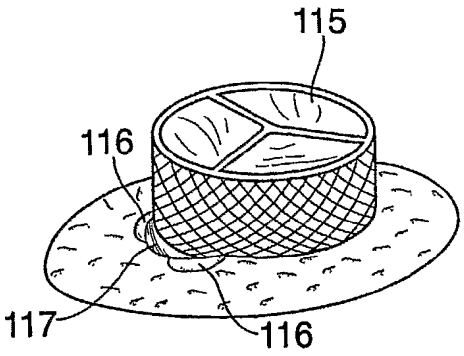

FIG. 11c

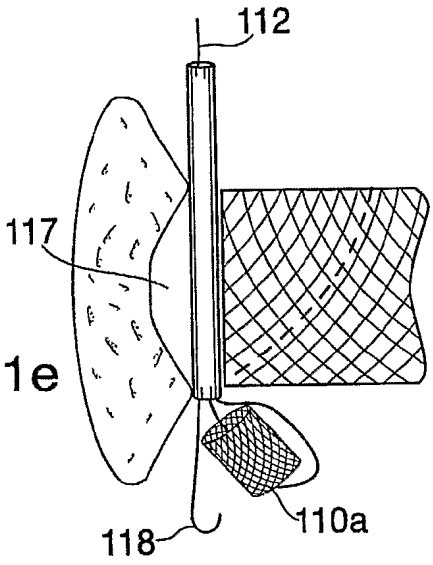

FIG. 11e

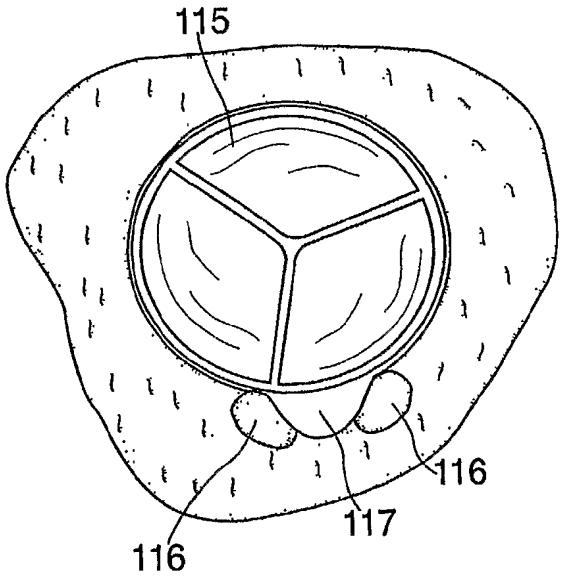

FIG. 11d

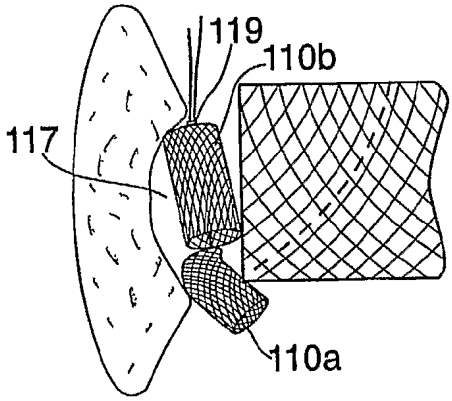

FIG. 11f

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Page 2131 - 421
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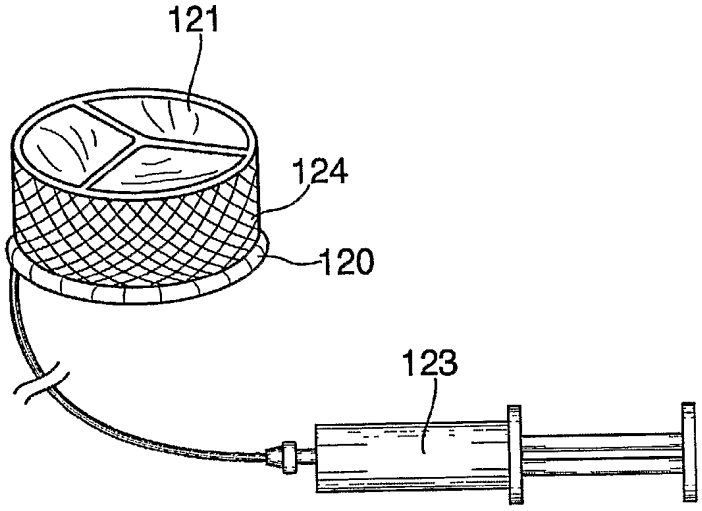

FIG. 12

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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

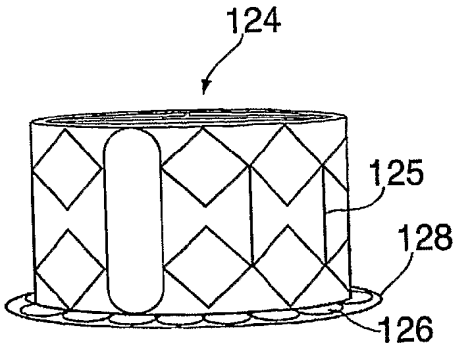

FIG. 13a

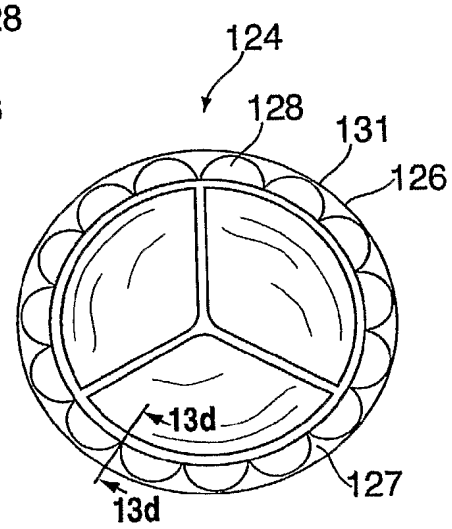

FIG. 13b

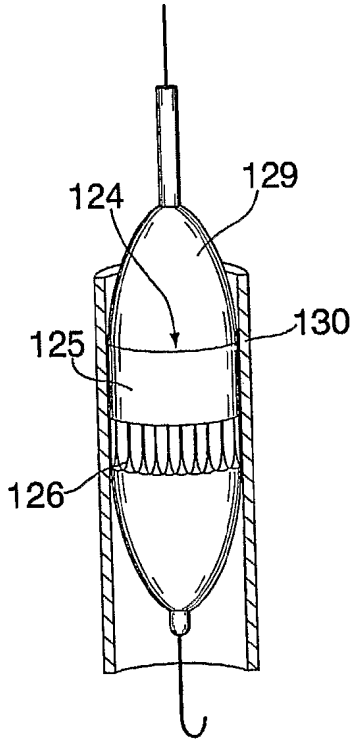

FIG. 13c

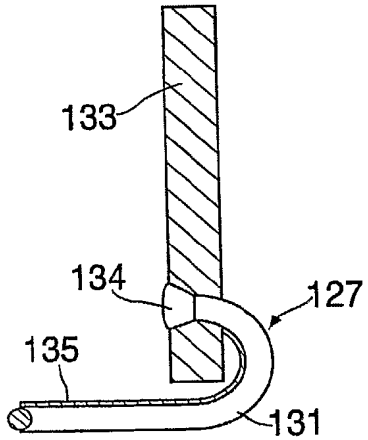

FIG. 13d

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 423
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

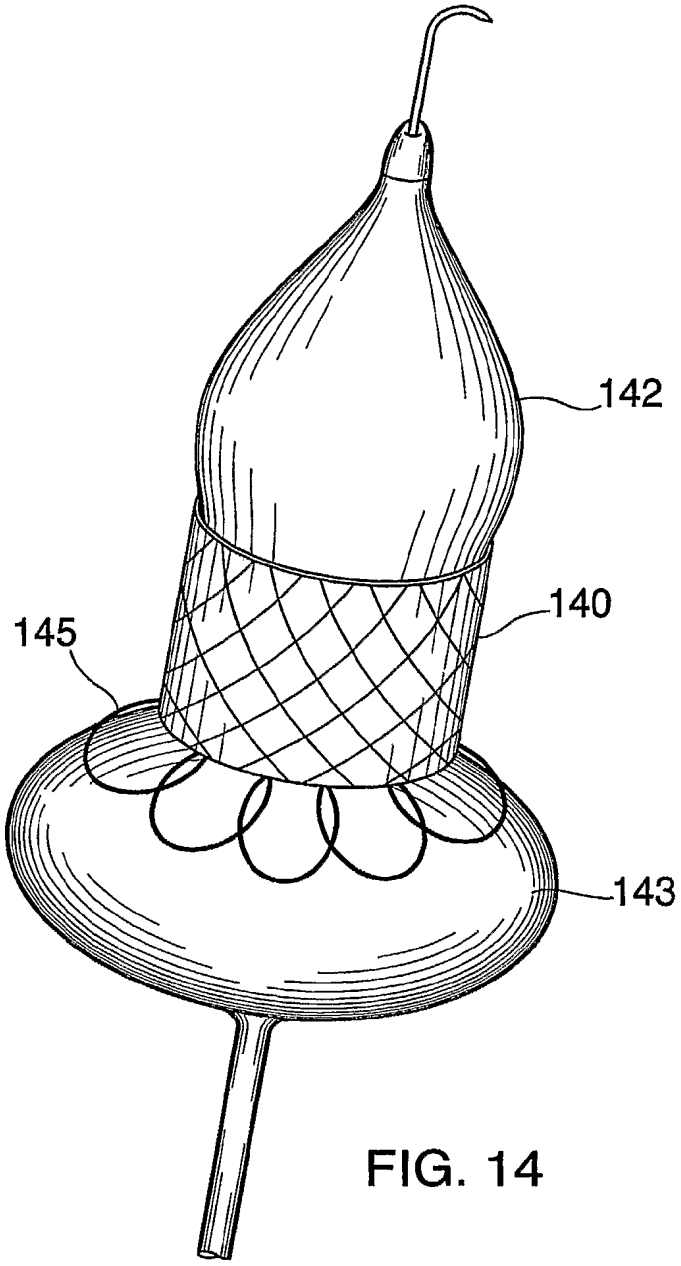

FIG. 14

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 424
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

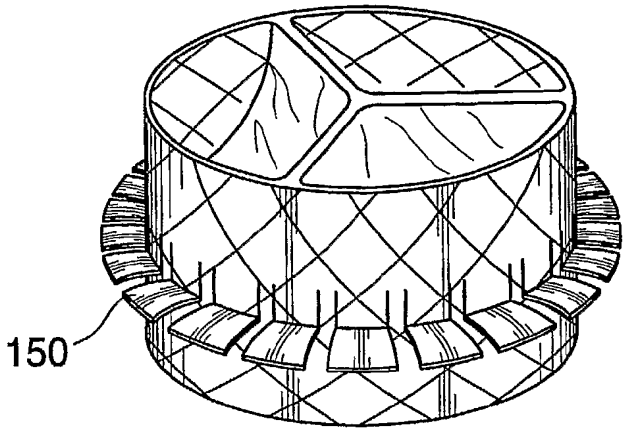

FIG. 15a

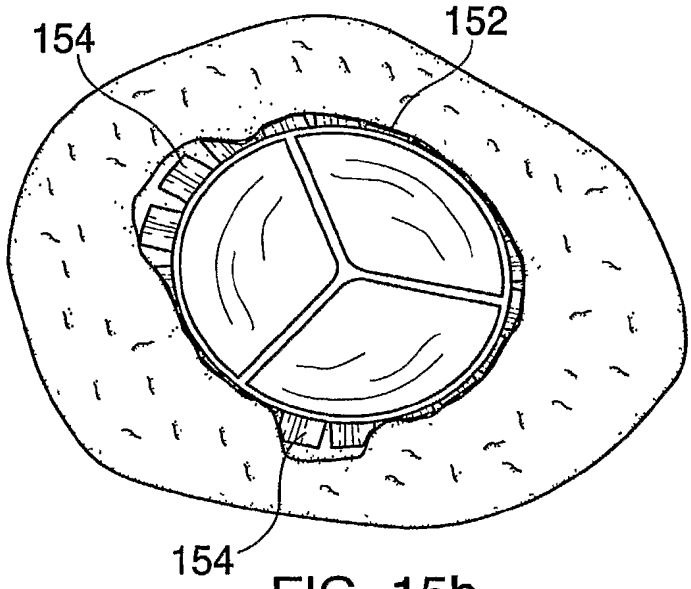

FIG. 15b

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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

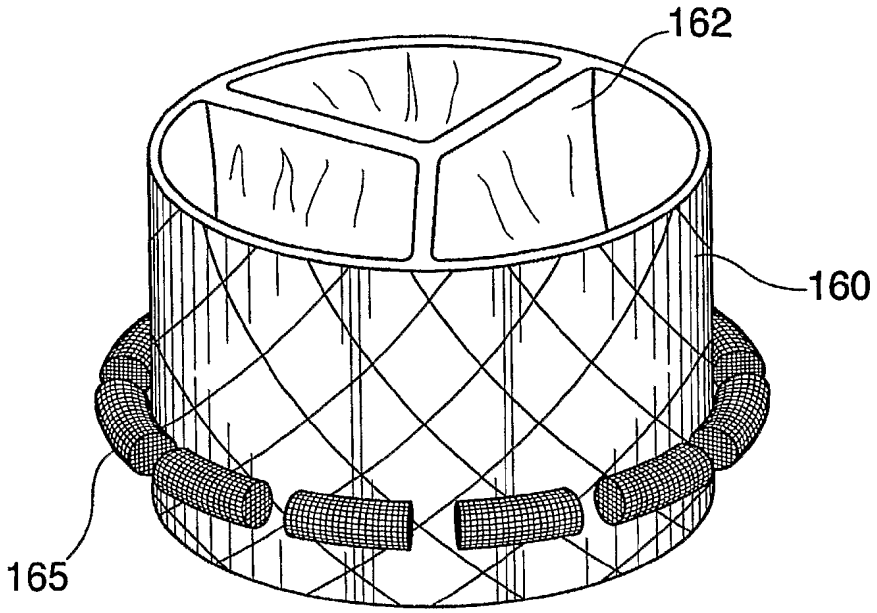

FIG. 16a

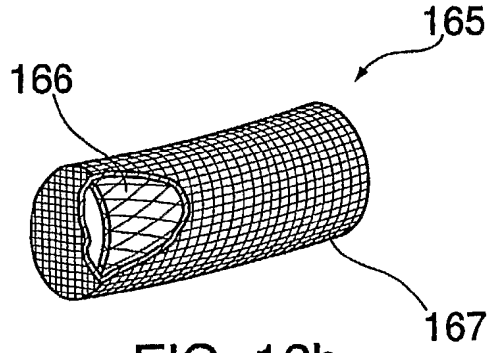

FIG. 16b

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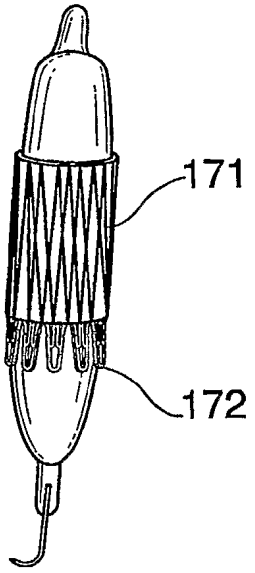

FIG. 17a

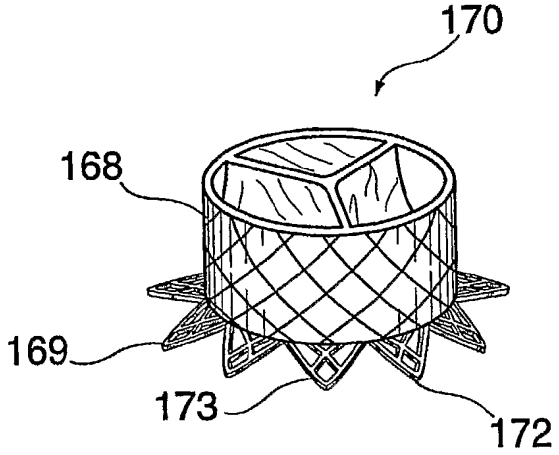

FIG. 17b

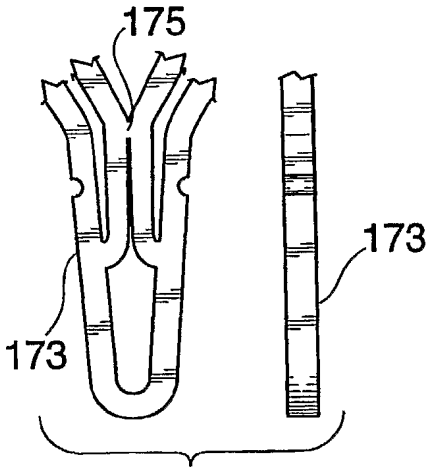

FIG. 17c

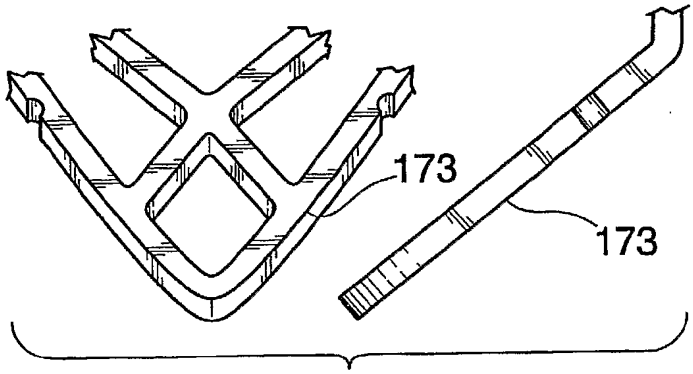

FIG. 17d

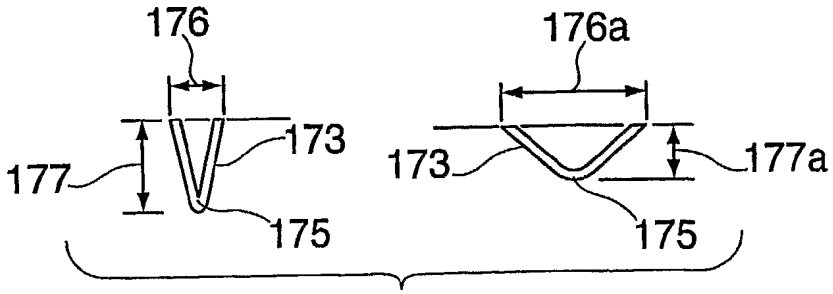

FIG. 17e

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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

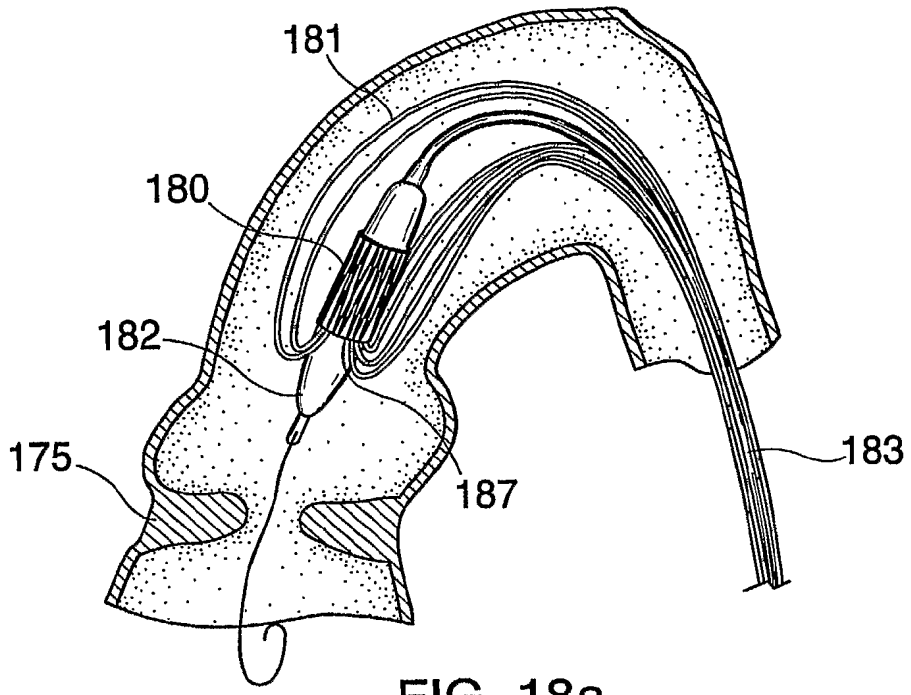

FIG. 18a

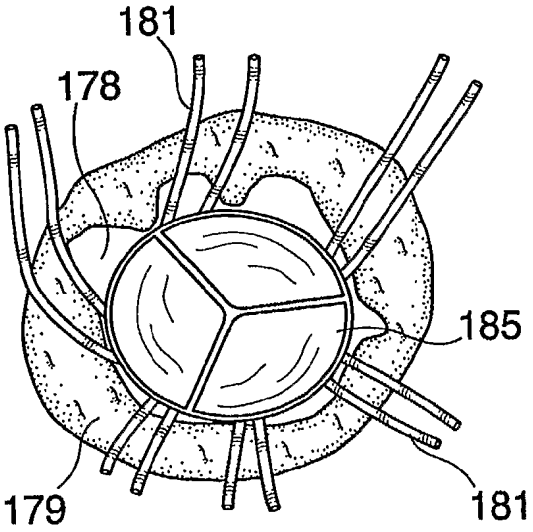

FIG. 18c

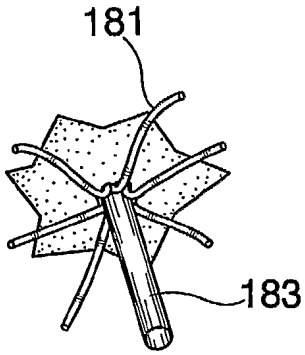

FIG. 18b

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Page 2131 - 428
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

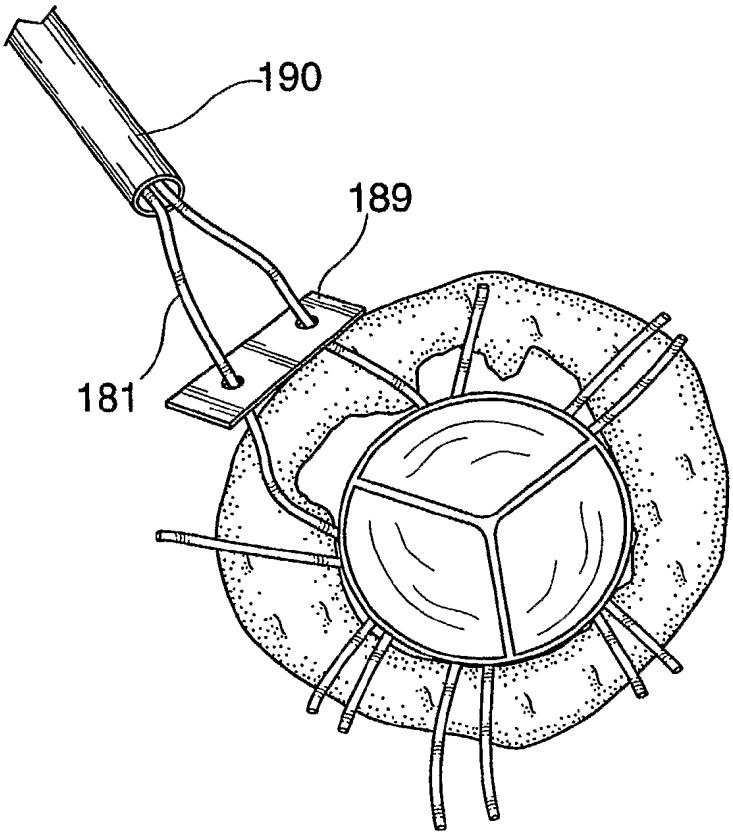

FIG. 18d

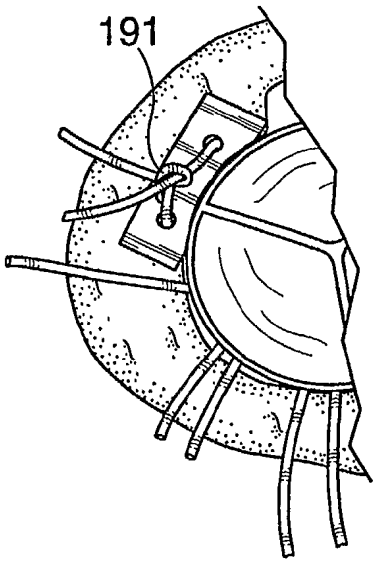

FIG. 18e

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Page 2131 - 429
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

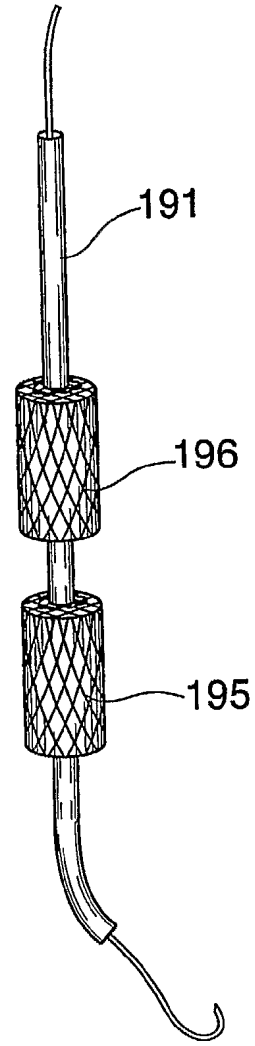

FIG. 19a

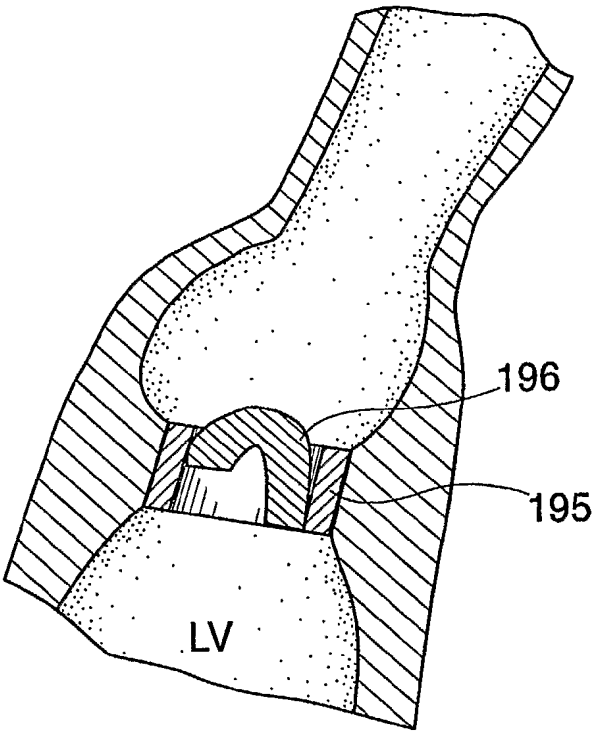

FIG. 19b

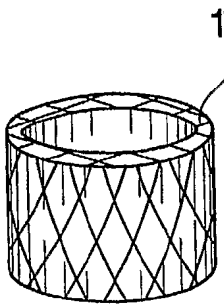

FIG. 19c

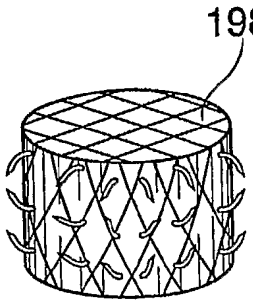

FIG. 19d

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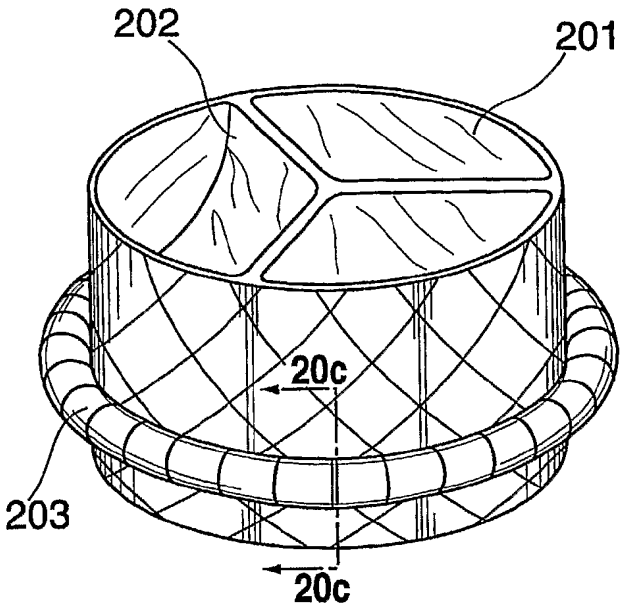

FIG. 20a

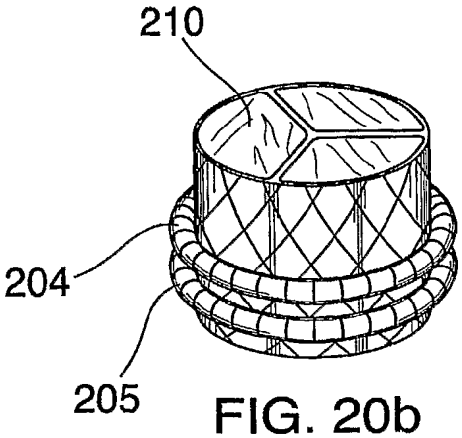

FIG. 20b

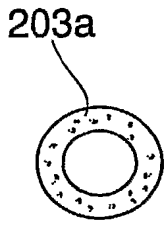

FIG. 20c

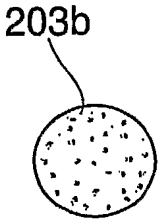

FIG. 20d

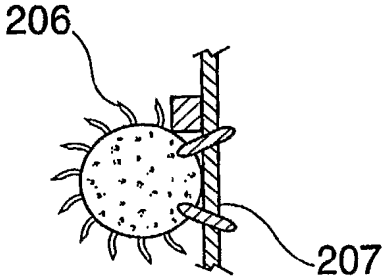

FIG. 20e

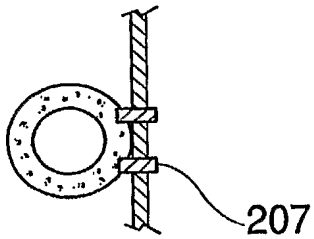

FIG. 20f

FIG. 20g

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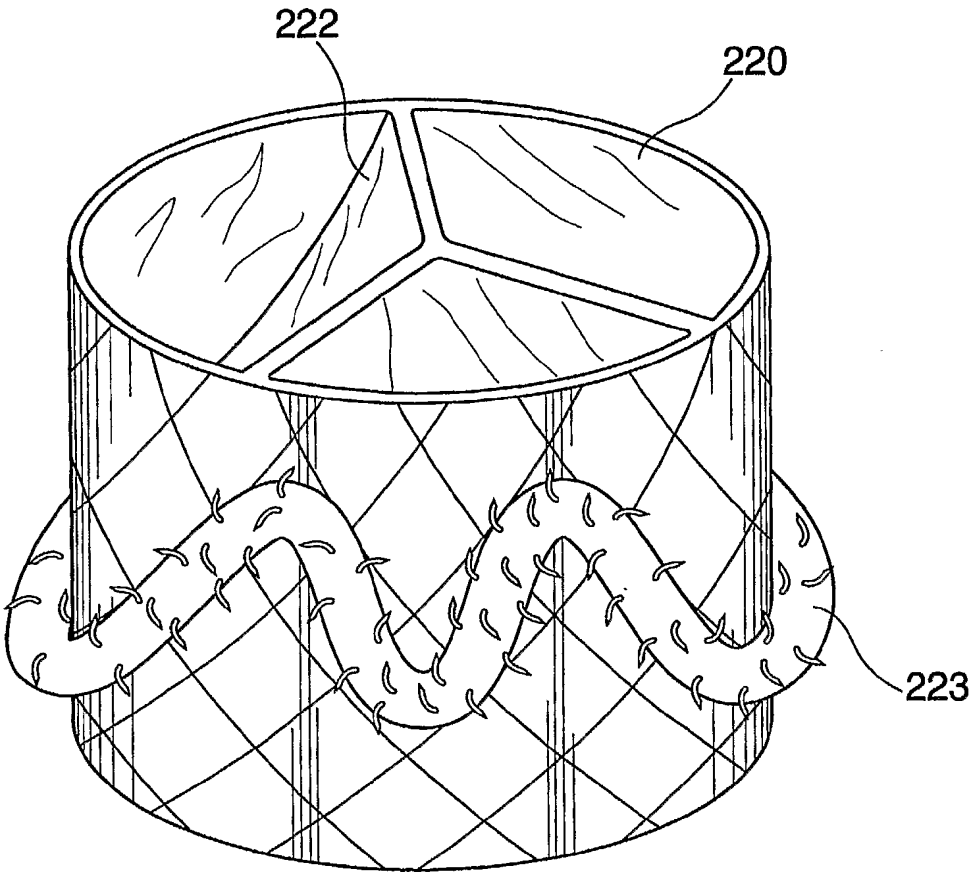

FIG. 21

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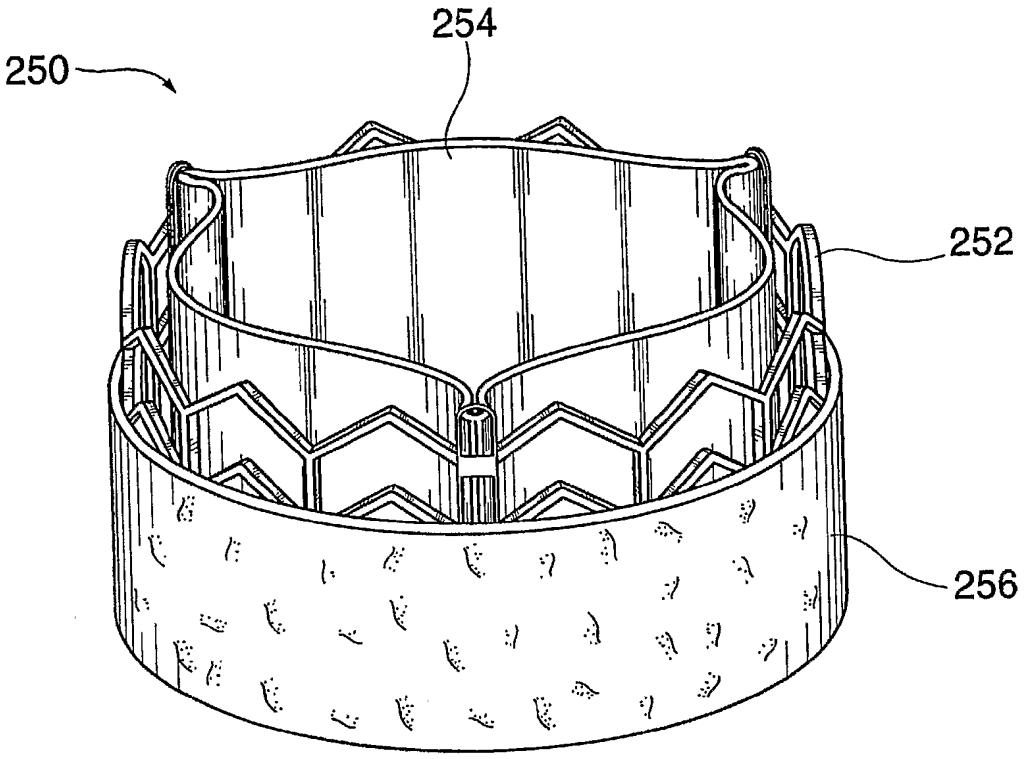

FIG. 22

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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Electronic Acknowledgement Receipt

EFS ID:	41819952
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	03-FEB-2021
Filing Date:	23-DEC-2020
Time Stamp:	07:21:45
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	Information Disclosure Statement (IDS) Form (SB08)	426-2-20-ids-2-3-2021.pdf	1034941 54f0e74778bdd2238c94176cf6070fb749a87ebc	no	5

Warnings:

Information:					
2	Non Patent Literature	426-2-19-npl-webpage.pdf	487553 851bc819011464427e1fbe8820810c934ee7ada7	no	7
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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					
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3	Non Patent Literature	NYSE_EW_2011-printed.pdf	434312 fd4bc0a832297239a54b1086e3c96655c8c43e55	no	28
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5	Non Patent Literature	WO2006005015A2.pdf	2565626 7873fb5b3a110a392da0b767b647876782accd67	no	68
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6	Non Patent Literature	PIIS0022522312011117.pdf	170371 4bf21f40320ac3925dcd1fe2497f02cdbc6a51fa	no	7
Warnings:					
Information:					
		Total Files Size (in bytes):	6311692		

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.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/131,869	12/23/2020	Ali Shahriari	426/2/20 UTIL

CONFIRMATION NO. 1293

175373
Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

POA ACCEPTANCE LETTER

OC000000122959505

Date Mailed: 02/01/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/26/2021.

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

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/sibrahim/

COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	17/131,869	Confirmation No.:	1293
Applicant	:	Aortic Innovations, LLC		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	Nov 12, 2020		
TC/A.U.	:	3774		
Examiner	:	Shipmon, Tiffany		
Docket No.	:	426/2/20 UTIL		
Customer No.	:	175373		

Title of Invention: DEVICE FOR ENDOVASCULAR AORTIC REPAIR

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

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

Remarks begin on page 4 of this paper.

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Electronic Acknowledgement Receipt

EFS ID:	41752189
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	26-JAN-2021
Filing Date:	23-DEC-2020
Time Stamp:	19:43:55
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		426-2-20UTIL-PrelimAmend.pdf	549431 71cd1945c7d95ef47fbc654e0ca266870379 7a6d	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	9
Warnings:			
Information:			
	Total Files Size (in bytes):	549431	

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New Applications Under 35 U.S.C. 111

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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.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

Claims 1-10 (Canceled)

11. (New) A transcatheter aortic valve assembly comprising:

an outer frame formed from a metallic material;

an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

wherein the outer frame is secured to the inner graft covering by stitching;

a first portion of fibers positioned radially outwardly of the outer frame that forms a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers are compressed thereagainst, wherein the first portion of fibers extend radially outwardly of the outer frame; and

a second portion of fibers carried by the outer frame that forms a second sealing interface against the outer frame when the second portion of fibers are compressed thereagainst,

wherein the transcatheter aortic valve is positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,

wherein the valve assembly is free of a polymeric outer graft covering that covers an exterior surface of the outer frame,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable to the radially expanded orientation and,

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wherein expansion compresses the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.

12. (New) The valve assembly according to claim 11, wherein the outer graft covering that the valve assembly is free of is distinct from the inner graft covering.

13. (New) The valve assembly according to claim 11, wherein the first portion of fibers and the second portion of fibers radially overlap.

14. (New) The valve assembly according to claim 11, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering through the outer frame secures the inner graft covering to the proximal inflow end of the outer frame.

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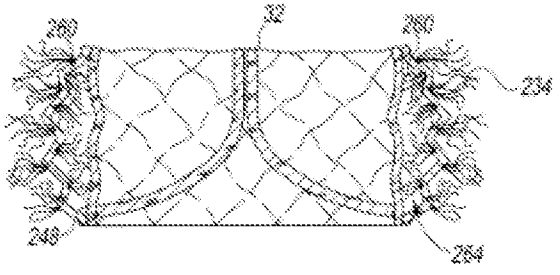
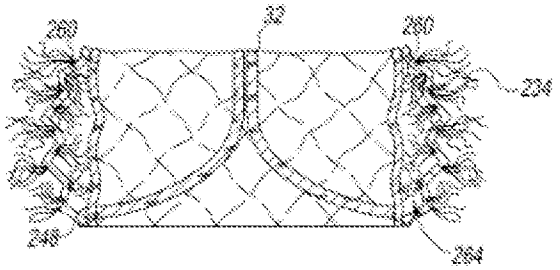
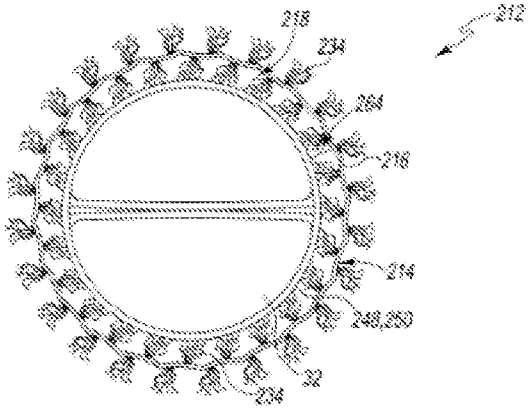
REMARKS

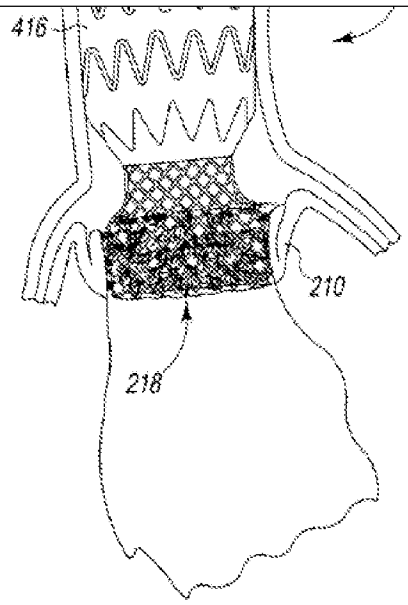
Applicant submits new claims herewith for consideration.

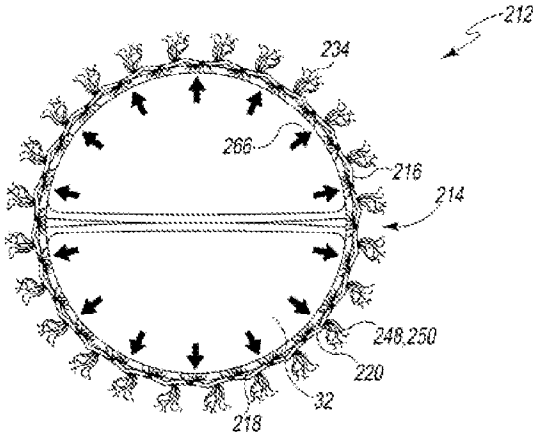
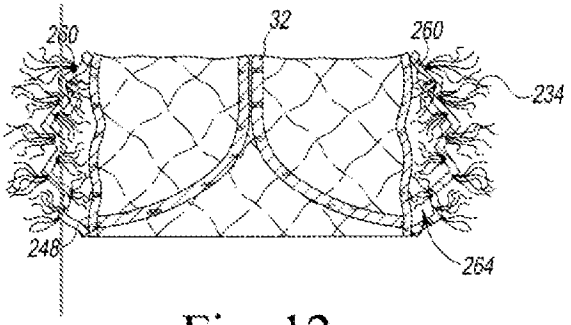
A claims chart showing one or more exemplary support mapping is provided herewith for consideration by the Examiner.

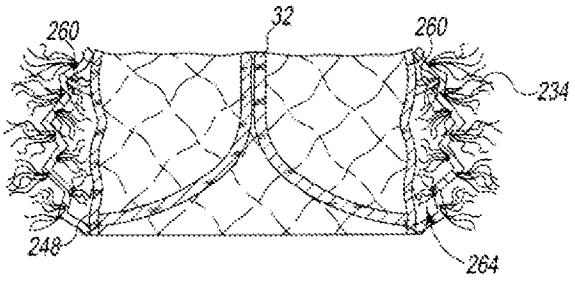
Claims	
11.(New) A transcatheter aortic valve assembly comprising:	
an outer frame formed from a metallic material;	[0110] The dual-frame **414** includes a self-expanding outer frame **416** and a balloon-expandable inner frame **218** that is secured to the self-expanding outer frame **416** and houses the valve **32**. Referring now to FIG. 9, the self-expanding outer frame **416** has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the outer frame **416** may be formed from a polymeric material. The outer frame **416** includes an elongated proximal section **220**, an inwardly tapered section **422**, an outwardly tapered middle section **62**, and an elongated distal section **64**.
an inner frame that engages a prosthetic heart valve having prosthetic leaflets,	The leaflets of the valve are illustrated as 32 and the inner frame 218.  Fig. 12
wherein the inner frame includes a cylindrically extending polymeric inner graft covering extending at least partially radially	[0089] In the illustrative embodiment, the outer surface **248** of the stent **244** is covered with low-profile polyester, ePTFE, or other

outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,	nonporous covering material **250** that prevents fluid from passing through the outer surface **248**. However, it should be appreciated that the stent **244** may be covered with standard polyester, ePTFE or other nonporous materials.
wherein the outer frame is secured to the inner graft covering by stitching;	[0091] Referring now to FIG. 11, the inner frame **218** of the dual-frame component **214** is secured to the outer frame **216** via a plurality of stitches **260**. It should be appreciated that in other embodiments soldering, welding or other fasteners may be used to secure the inner frame **218** to the outer frame **216**. As shown in FIGS. 11-14, the inner frame **218** and the valve component **32** are positioned in the passageway **232** defined in the self-expanding frame **216**. When the inner frame **218** is unexpanded, the outer surface **248** of the stent **244** is spaced apart from the fibers **234** attached to the outer frame **216**. In the illustrative embodiment, a gap **264** is defined therebetween, and the gap **264** has a magnitude of about 2 mm to about 3 mm.
a first portion of fibers positioned radially outwardly of the outer frame that forms a first sealing interface against the annulus and native valve leaflets of the patient when the first portion of fibers are compressed thereagainst,	See first portion of fibers in FIG. 12 and FIG. 20. [0113] In the illustrative embodiment, collagen fibers **234** are attached to the proximal section **220** to aid in preventing paravalvular leaks and migration of the valve component **412** within the aortic walls. The fibers **234** extend outwardly from the proximal section **220** and inwardly into the passageway **232**. It should be appreciated that in other embodiments the outer frame **216** may be covered with hydrogel or other sealing materials. In other embodiments, a plurality of barbs or hooks may be attached to the proximal section **220**. The hooks may be configured to further engage the tissue of the aorta and inhibit or prevent migration of the device **10**.

	See first portion of fibers outwardly of the frame in FIG. 20.
wherein the first portion of fibers extend radially outwardly of the outer frame; and	As illustrated, the first portion of fibers extend radially outwardly of the outer frame.  Fig. 12
a second portion of fibers carried by the outer frame that forms a second sealing interface against the outer frame when the second portion of fibers are compressed thereagainst,	 Fig. 13 The second portion of fibers is carried by the outer frame and forms a second sealing interface against the outer frame.
wherein the transcatheter aortic valve is positioned in a patient so that the first sealing interface is in overlapping radial alignment with native valve leaflets of the aorta to seal thereagainst,	See FIG. 22

	 Fig. 22
wherein the valve assembly is free of a polymeric outer graft covering that covers an exterior surface of the outer frame,	The inclusion of an embodiment that includes an outer graft covering, and an embodiment without an outer graft covering provides support for the negative limitations disclosed herein. The specification even states "It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials," implying that alternate sealing materials, such as a non porous graft covering may or may not be provided.
wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,	[0118] As described above, the outer frame **416** of the dual-frame **414** is secured to a balloon-expandable inner frame **218**, which is positioned in the passageway **232** and houses the valve **32**. As described above, the balloon-expandable frame **218** is expandable during implantation from an unexpanded diameter **450** to the expanded diameter (not shown).
wherein the valve assembly is balloon expandable to the radially expanded orientation and,	[0118] As described above, the outer frame **416** of the dual-frame **414** is secured to a balloon-expandable inner frame **218**, which is positioned in the passageway **232** and houses the valve **32**. As described above, the balloon-

	expandable frame **218** is expandable during implantation from an unexpanded diameter **450** to the expanded diameter (not shown).
wherein expansion compresses the first portion of fibers and the second portion of fibers to form the respective first sealing interface and second sealing interface.	See FIG. 14  Fig. 14
12. (New) The valve assembly according to claim 11, wherein the outer graft covering that the valve assembly is free of is distinct from the inner graft covering.	As illustrated, the outer graft covering is distinct from the inner graft covering. The specification discloses an inner and outer graft in some embodiments, and then an inner graft and radially extending fibers in other embodiments.
13. (New) The valve assembly according to claim 11, wherein the first portion of fibers and the second portion of fibers radially overlap.	See added line to FIG. 12 (Applicant added):  Fig. 12
14. (New) The valve assembly according to claim 11, wherein the inner graft covering extends to the proximal inflow end of the outer frame, wherein, stitching extending between the inner graft covering through the outer frame secures the inner graft covering to	This is well illustrated in FIG. 12.

the proximal inflow end of the outer frame.	 Fig. 12

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: January 26, 2021

/Justin R. Nifong/
Justin R. Nifong
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POWER OF ATTORNEY FOR PATENT APPLICATIONS

Under 37 CFR § 3.73(b) and/or (c), Aortic Innovations, LLC, hereby certifies that it is the Assignee of the entire right, title, and interest in and to the patent applications listed below. Each of the patent applications listed below is assigned to Aortic Innovations, LLC. As required by 37 CFR § 3.73(b)(1)(i) and/or (c)(1)(i), the documentary evidence of the chain of title from the original owner to the Assignee was submitted for recordation pursuant to 37 § CFR 3.11 as shown in the Reel/Frame numbers listed below.

Title	Serial No.	Filing Date	Assignment	Date
Transcathetor Arotic Valve for Endovascular Aortic Repair	61/723,446	11/7/2012	029574/0731	1/7/2013
Transcathetor Aortic Valve for Endovascular Aortic Repair	61/567,458	12/6/2011	029005/0233	9/19/2012
Branched Aortic Graft and Method of Using the Same	61/777,918	3/12/2013	030346/0253	5/3/2013
Device for Endovascular Aortic Repair and Method of Using the Same	13/706,896	12/6/2012	032145/0696	2/5/2014
Device for Endovascular Aortic Repair and Method of Using the Same	US2012/068165	12/6/2012	029574/0887	1/7/2013
Transcatheral Mitral Valve and Delivery System	61/780,242	3/13/2013	030346/0233	5/3/2013
Device for Transcatheter Mitral Valve Repair and Replacement	61/817,118	4/29/2013	032145/0696	2/5/2014

The undersigned, acting as the Assignee, hereby revokes all prior powers of attorney, if applicable, and appoints the practitioners associated with the customer number 175373 as my/our attorney(s) or agent(s) to prosecute the patent(s) and/or patent application(s) and transact all business in the United States Patent and Trademark Office connected therewith.

By: Ali Shahriari Date: 1/15/2021

Ali Shahriari, Owner

Aortic Innovations, LLC

Electronic Acknowledgement Receipt

EFS ID:	41747259
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Donna Donovan
Filer Authorized By:	Justin Robert Nifong
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	26-JAN-2021
Filing Date:	23-DEC-2020
Time Stamp:	14:51:23
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	Power of Attorney	426-2-20UTIL-20210126-Executed-POA.pdf	71865 2016341971af10f09563d4f8548d8e44050cc9ac	no	1

Warnings:

Information:	
Total Files Size (in bytes):	71865

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
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/131,869	Filing Date 12/23/2020	☐ 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 $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ 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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/26/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 4	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/SHARON M WEST/
*** 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.	

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 (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17131869
Filing Date	2020-12-23
First Named Inventor	Ali Shahriari
Art Unit	3774
Examiner Name	-
Attorney Docket Number	426/2/20 UTIL

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	10258464		2019-04-16	Delaloye et al.	
	2	8408214		2013-04-02	Spenser	
	3	9339377		2016-05-17	Quadri et al.	
	4	9532868		2017-01-03	Braido	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20110218619	A1	2011-09-08	Benichou et al.	
	2	20110319991	A1	2011-12-29	Hariton et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17131869
	Filing Date	2020-12-23
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	-
	Attorney Docket Number	426/2/20 UTIL

	3	20120123529	A1	2012-05-17	Levi et al.			

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

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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	PATSPADE Search Report, dated 1/21/2021, Pgs. 1-53, USA	

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	17131869
	Filing Date	2020-12-23
	First Named Inventor	Ali Shahriari
	Art Unit	3774
	Examiner Name	-
	Attorney Docket Number	426/2/20 UTIL

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	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-01-26
Name/Print	Justin R. Nifong	Registration Number	59389

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.

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EFS ID:	41742062
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong/Donna Donovan
Filer Authorized By:	Justin Robert Nifong
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	26-JAN-2021
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Time Stamp:	10:07:20
Application Type:	Utility under 35 USC 111(a)

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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)	426-2-20UTIL-20210126-IDS.pdf	1034487 a267e9f68f4ad211236e7b49923532628f02f3ac	no	4

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(Not for submission under 37 CFR 1.99)

Application Number	17131869
Filing Date	2020-12-23
First Named Inventor	Shahriari, Ali
Art Unit	3774
Examiner Name	Shipmon, Tiffany
Attorney Docket Number	426/2/20 UTIL

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	2	7381219		2008-06-03	Salahieh et al.	
	3	7921678		2011-04-12	Norris et al.	FIG. 4
	4	9333075		2016-05-10	Biadillah et al.	
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	1	20020052649	A1	2002-05-02	Greenhalgh	FIG. 5

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	Application Number	17131869
	Filing Date	2020-12-23
	First Named Inventor	Shahriari, Ali
	Art Unit	3774
	Examiner Name	Shipmon, Tiffany
	Attorney Docket Number	426/2/20 UTIL

	2	20040082989	A1	2004-04-29	Cook William A. et al.	
	3	20040256759	A1	2004-12-23	Hartley	FIG. 4
	4	20120123529	A1	2012-05-17	Levi et al.	FIG. 1
	5	20110098802	A1	2011-04-28	Braido	
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	2	9829057	WO		2012-05-17	Cribier	FIG. 6D	
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	1	BOBO, Donald E., Edwards Lifesciences Surgical Heart Valve Therapy, 12/9/2011 presumed publication, slide 13	
	2	BULLER, Nigel, Declaration in IPR IPR2017-01293, 10/11/2016	

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	Application Number	17131869
	Filing Date	2020-12-23
	First Named Inventor	Shahriari, Ali
	Art Unit	3774
	Examiner Name	Shipmon, Tiffany
	Attorney Docket Number	426/2/20 UTIL

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See attached certification statement.

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

☒ A certification statement is not submitted herewith.

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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	/Justin R. Nifong/	Date (YYYY-MM-DD)	2021-01-22
Name/Print	Justin R. Nifong	Registration Number	59389

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EFS ID:	41713305
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
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Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	22-JAN-2021
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Application Type:	Utility under 35 USC 111(a)

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2	Non Patent Literature	426-2-19-ids-npl-printed.pdf	9001459 e4493c050276448220371b891bda8bd5dec85b49	no	307
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(51) International Patent Classification 6 : **A61F 2/24**	**A1**	**(11) International Publication Number:** **WO 98/29057** **(43) International Publication Date:** 9 July 1998 (09.07.98)

(21) International Application Number: PCT/EP97/07337

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96402929.2 31 December 1996 (31.12.96) EP
(34) Countries for which the regional or international application was filed: GB et al.

(71) Applicant *(for all designated States except US)*: CORDIS CORPORATION [US/US]; 40 Technology Drive, Warren, NJ 07059 (US).

(72) Inventors; and
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(74) Agents: GUTMAN, Ernest et al.; Ernest Gutman – Yves Plasseraud S.A., 3, rue Chauveau–Lagarde, F–75008 Paris (FR).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

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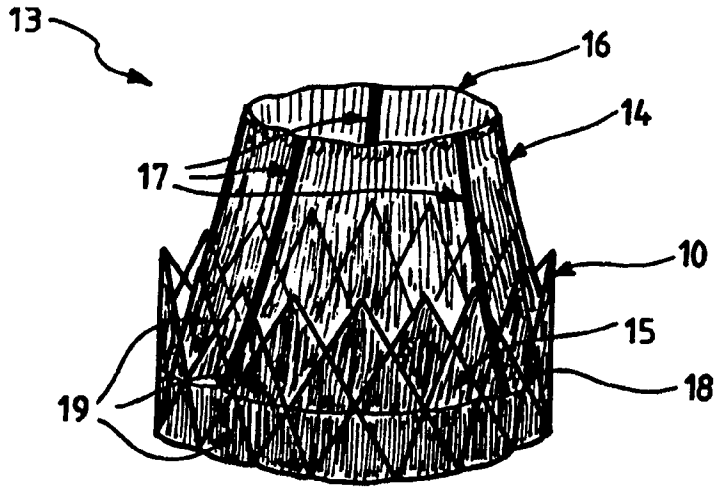
(54) Title: VALVE PROSTHESIS FOR IMPLANTATION IN BODY CHANNELS

(57) Abstract



The present invention is aimed to provide a valve prothesis (IV) especially used in case of aortic stenosis, which structure is capable of resisting the powerful recoil force and to stand the forceful balloon inflation performed to deploy the valve and to embed it in the aortic annulus. A valve prothesis (13) for implantation in a body channel according to the invention comprises a collapsible valvular structure (14) and an expandable frame (10, 10') on which said valvular structure (14) is mounted. The valvular structure (14) is composed of a valvular tissue compatible with the human body and blood, the valvular tissue being sufficiently supple and resistant to allow said valvular structure (14) to be deformed from a closed state to an opened state. Said valvular tissue forms a continuous surface and is provided with guiding means (17) formed or incorporated within, said guiding means creating stiffened zones which induce said valvular structure (14) to follow a patterned movement in its expansion to its opened state and in its turning back to its closed state. The valvular structure can be extended to an internal cover (19) which is fastened to the lower end (15) of the valvular structure to prevent from regurgitation.

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VALVE PROSTHESIS FOR IMPLANTATION IN BODY CHANNELS

The present invention relates to a valve prosthesis for implantation in body channels, more particularly but not only to, cardiac valve prosthesis to be implanted by a transcutaneous catheterization technique.

The valve prosthesis can be also applied to other body channels provided with native valves, such as veins or in organs (liver, intestine, urethra,...).

The present invention also relates to a method for implanting a valve prosthesis, such as the valve according to the present invention.

Implantable valves, which will be indifferently designated hereafter as "IV", "valve prosthesis" or "prosthetic valve", permits the reparation of a valvular defect by a less invasive technique in place of the usual surgical valve implantation which, in the case of valvular heart diseases, requires thoracotomy and extracorporeal circulation. A particular use for the IV concerns patients who cannot be operated on because of an associated disease or because of very old age or also patients who could be operated on but only at a very high risk.

Although the IV of the present invention and the process for implanting said IV can be used in various heart valve diseases, the following description will first concern the aortic orifice in aortic stenosis, more particularly in its degenerative form in elderly patients.

Aortic stenosis is a disease of the aortic valve in the left ventricle of the heart. The aortic valvular orifice is normally capable of opening during systole up to 4 to 6 cm^2, therefore allowing free ejection of the ventricular blood volume into the aorta. This aortic valvular orifice can become tightly stenosed, and therefore the blood cannot anymore be freely ejected from the left ventricle. In fact, only a reduced amount of blood can be ejected by the left ventricle which has to markedly increase the intra-cavitary pressure

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Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 468
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

to force the stenosed aortic orifice. In such aortic diseases, the patients can have syncope, chest pain, and mainly difficulty in breathing. The evolution of such a disease is disastrous when symptoms of cardiac failure appear, since 50 % of the patients die in the year following the first symptoms of the disease.

The only commonly available treatment is the replacement of the stenosed aortic valve by a prosthetic valve via surgery: this treatment moreover providing excellent results. If surgery is impossible to perform, i.e., if the patient is deemed inoperable or operable only at a too high surgical risk, an alternative possibility is to dilate the valve with a balloon catheter to enlarge the aortic orifice. Unfortunately, a good result is obtained only in about half of the cases and there is a high restenosis rate, i.e., about 80% after one year.

Aortic stenosis is a very common disease in people above seventy years old and occurs more and more frequently as the subject gets older. As evidenced, the present tendency of the general evolution of the population is becoming older and older. Also, it can be evaluated, as a crude estimation, that about 30 to 50% of the subjects who are older than 80 years and have a tight aortic stenosis, either cannot be operated on for aortic valve replacement with a reasonable surgical risk or even cannot be considered at all for surgery.

It can be estimated that, about 30 to 40 persons out of a million per year, could benefit from an implantable aortic valve positioned by a catheterization technique. Until now, the implantation of a valve prosthesis for the treatment of aortic stenosis is considered unrealistic to perform since it is deemed difficult to superpose another valve such an implantable valve on the distorted stenosed native valve without excising the latter.

From 1985, the technique of aortic valvuloplasty with a balloon catheter has been introduced for the treatment of subjects in whom surgery cannot be performed at all or which could be performed only with a

prohibitive surgical risk. Despite the considerable deformation of the stenosed aortic valve, commonly with marked calcification, it is often possible to enlarge significantly the aortic orifice by balloon inflation, a procedure which is considered as low risk.

However, this technique has been abandoned by most physicians because of the very high restenosis rate which occurs in about 80% of the patients within 10 to 12 months. Indeed, immediately after deflation of the balloon, a strong recoil phenomenon often produces a loss of half or even two thirds of the opening area obtained by the inflated balloon. For instance, inflation of a 20 mm diameter balloon in a stenosed aortic orifice of 0.5 cm^2 area gives, when forcefully and fully inflated, an opening area equal to the cross sectionnal area of the maximally inflated balloon, i.e., about 3 cm^2. However, measurements performed a few minutes after deflation and removal of the balloon have only an area around 1 cm^2 to 1.2 cm^2. This is due to the considerable recoil of the fibrous tissue of the diseased valve. The drawback in this procedure has also been clearly shown on fresh post mortem specimens.

However, it is important to note that whereas the natural normal aortic valve is able to open with an orifice of about 5 to 6 cm^2 and to accommodate a blood flow of more that 15 l/min. during heavy exercise for instance, an opening area of about 1.5 to 2 cm^2 can accept a 6 to 8 l/min blood flow without a significant pressure gradient. Such a flow corresponds to the cardiac output of the elderly subject with limited physical activity.

Therefore, an IV would not have to produce a large opening of the aortic orifice since an opening about 2 cm^2 would be sufficient in most subjects, in particular in elderly subjects, whose cardiac output probably does not reach more than 6 to 8 l/min. during normal physical activity. For instance, the surgically implanted mechanical valves have an opening area which is far from the natural valve opening that ranges from 2 to 2.5 cm^2,

mainly because of the room taken by the large circular structure supporting the valvular part of the device.

The prior art describes examples of cardiac valves prosthesis that are aimed at being implanted without surgical intervention by way of catheterization. For instance, US patent n° 5,411,552 describes a collapsible valve able to be introduced in the body in a compressed presentation and expanded in the right position by balloon inflation.

Such valves, with a semi-lunar leaflet design, tend to imitate the natural valve. However, this type of design is inherently fragile, and such structures are not strong enough to be used in the case of aortic stenosis because of the strong recoil that will distort this weak structure and because they would not be able to resist the balloon inflation performed to position the implantable valve. Furthermore, this valvular structure is attached to a metallic frame of thin wires that will not be able to be tightly secured against the valve annulus. The metallic frame of this implantable valve is made of thin wires like in stents, which are implanted in vessels after balloon dilatation. Such a light stent structure is too weak to allow the implantable valve to be forcefully embedded into the aortic annulus. Moreover, there is a high risk of massive regurgitation (during the diastolic phase) through the spaces between the frame wires which is another prohibitive risk that would make this implantable valve impossible to use in clinical practice.

Furthermore, an important point in view of the development of the IV is that it is possible to maximally inflate a balloon placed inside the compressed implantable valve to expand it and insert it in the stenosed aortic valve up to about 20 to 23 mm in diameter. At the time of maximum balloon inflation, the balloon is absolutely stiff and cylindrical without any waist. At that moment, the implantable valve is squeezed and crushed between the strong aortic annulus and the rigid balloon with the risk of

causing irreversible damage to the valvular structure of the implantable valve.

SUMMARY OF THE INVENTION

The invention is aimed to overcome these drawbacks and to implant an IV which will remain reliable for years.

A particular aim of the present invention is to provide an IV, especially aimed at being used in case of aortic stenosis, which structure is capable of resisting the powerful recoil force and to stand the forceful balloon inflation performed to deploy the IV and to embed it in the aortic annulus.

Another aim of the present invention is to provide an efficient prosthesis valve which can be implanted by a catheterization technique, in particular in a stenosed aortic orifice, taking advantage of the strong structure made of the distorted stenosed valve and of the large opening area produced by preliminary balloon inflation, performed as an initial step of the procedure.

A further aim of the present invention is to provide an implantable valve which would not produce any risk of fluid regurgitation.

A further aim of the present invention is to provide a valve prosthesis implantation technique using a two-balloon catheter and a two-frame device.

These aims are achieved according to the present invention which provides a valve prosthesis of the type mentioned in the introductory part and wherein said valve prosthesis comprises a collapsible continuous structure with guiding means providing stiffness and a frame to which said structure is fastened, said frame being strong enough to resist the recoil phenomenon of the fibrous tissue of the diseased valve.

The IV, which is strongly embedded, enables the implantable valve to be maintained in the right position without any risk of further displacement, which would be a catastrophic event.

More precisely, this valvular structure comprises a valvular tissue compatible with the human body and blood, which is supple and resistant to allow said valvular structure to pass from a closed state to an open state to allow a body fluid, more particularly the blood, exerting pressure on said valvular structure, to flow. 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.

Moreover, the guided structure of the IV of the invention allows the tissue of this structure to open and close with the same patterned movement while occupying as little space as possible in the closed state of the valve. Therefore, owing to these guiding means, the valvular structure withstands the unceasing movements under blood pressure changes during the heart beats.

More preferably, the valvular structure has a substantially truncated hyperboloïdal shape in its expanded position, with a larger base and a growing closer neck, ending in a smaller extremity forming the upper part of the valvular structure. The valvular structure has a curvature at its surface that is concave towards the aortic wall. Such a shape produces a strong and efficient structure in view of the systolo-diastolic movement of the valvular tissue. Such a valvular structure with its simple and regular shape also lowers the risk of being damaged by forceful balloon inflation at the time of IV deployment.

A trunco-hyperboloïdal shape with a small diameter at the upper extremity facilitates the closure of the valve at the beginning of diastole in initiating the starting of the reverse movement of the valvular tissue towards its base. Another advantage of this truncated hyperboloïdal shape is that

the upper extremity of the valvular structure, because of its smaller diameter, remains at a distance from the coronary ostia during systole as well as during diastole, thus offering an additional security to ensure not to impede at all the passage of blood from the aorta to the coronary ostia.

As another advantageous embodiment of the invention, the guiding means of the valvular structure are inclined strips from the base to the upper extremity of the valvular structure with regard to the central axis of the valvular structure. This inclination initiates and imparts a general helicoidal movement of the valvular structure around said central axis at the time of closure or opening of said structure, such a movement enabling to help initiate and finalize the closure of the valvular structure. In particular, this movement improves the collapse of the valvular structure towards its base at the time of diastole and during the reversal of flow at the very beginning of diastole. During diastole, the valvular structure thus falls down, folding on itself and collapses on its base, therefore closing the aortic orifice. The strips can be pleats, strenghthening struts or thickened zones.

In other embodiments, said guiding means are rectilinear strips from the base to the upper extremity of the valvular structure. In this case, the guiding means can comprise pleats, struts or thickened zones. In a particular embodiment, the stiffened zones then created can be advantageously two main portions, trapezoidal in shape, formed symmetrically one to each other with regard to the central axis of the valvular structure, and two less rigid portions separating said two main portions to lead to a tight closeness in shape of a closed slot at the time of closure of the upper extremities of the main portions of the valvular structure. The thickened zones can be extended up to form the stiffened zones.

More particularly, each of said main slightly rigid portions occupy approximately one third of the circumference of the valvular structure when this latter is in its open position. The slightly rigid portions maintain the

valvular structure closed during diastole by firmly applying themselves on each other. The closure of the valvular structure at the time of diastole thus does not have any tendency to collapse too much towards the aortic annulus.

Preferably, the guiding means are a number of pleats formed within the tissue by folding, or formed by recesses or grooves made in the tissue. The shape of the pleats is adapted to achieve a global shape of the desired type for said position.

Alternatively, the guiding means are made of strengthening struts, preferably at least three, incorporated in the tissue in combination or not with said pleats.

The guiding means and, in particular, the strengthening struts, help to prevent the valvular tissue from collapsing back too much and to reverse inside the left ventricle through the base of the frame, preventing the risk of blood regurgitation.

In a preferred prosthetic valve of the invention, said valvular tissue is made of synthetic biocompatible material such as Teflon® or Dacron®, polyethylene, polyamide, or made of biological material such as pericardium, porcine leaflets and the like. These materials are commonly used in cardiac surgery and are quite resistant, particularly to folding movements due to the inceasing systolo-diastolic movements of the valvular tissue and particularly at the junction with the frame of the implantable valve.

The valvular structure is fastened along a substantial portion of an expandable frame, by sewing, by molding or by gluing to exhibit a tightness sufficiently hermetical to prevent any regurgitation of said body fluid between the frame and the valvular structure.

Preferably, an internal cover is coupled or is integral to the valvular structure and placed between said valvular structure and the internal wall of the frame to prevent any passage of the body fluid through said frame.

Therefore, there is no regurgitation of blood as it would be the case if there were any space between the valvular structure fastened on the frame and the zone of application of the frame on the aortic annulus. The internal cover makes a sort of "sleeve" at least below the fastening of the valvular structure covering the internal surface of the frame and thus prevents any regurgitation of blood through the frame.

In the present invention, the frame is a substantially cylindrical structure capable of maintaining said body channel open in its expanded state and supporting said collapsible valvular structure.

In a preferred embodiment of the invention, the frame is made of a material which is distinguishable from biological tissue to be easily visible by non invasive imaging techniques.

Preferably, said frame is a stainless metal structure or a foldable plastic material, made of intercrossing, preferably with rounded and smooth linear bars. This frame is strong enough to resist the recoil phenomenon of the fibrous tissue of the diseased valve. The size of the bars and their number are determined to give both the maximal rigidity when said frame is expanded and the smallest volume when the frame is compressed.

More preferably, the frame has projecting curved extremities and presents a concave shape. This is aimed at reinforcing the embedding and the locking of the implantable valve in the distorted aortic orifice.

In a preferred embodiment of the present invention, the IV is made in two parts, a first reinforced frame coupled with a second frame which is made of thinner bars than said first frame and which is embedded inside the second frame. This second frame to which the valvular structure is fastened as described above, is preferably less bulky than the first frame to occupy as little space as possible and to be easily expanded using low pressure balloon inflation.

The present invention also relates to a double balloon catheter to separately position the first frame in the dilated stenosed aortic valve and

place the second frame that comprises the valvular structure. This catheter comprises two balloons fixed on a catheter shaft and separated by few centimeters.

The first balloon is of the type sufficiently strong to avoid bursting even at a very high pressure inflation and is aimed at carrying, in its deflated state, a strong frame aimed at scaffolding the previously dilated stenosed aortic valve. The second balloon is aimed at carrying the second frame with the valvular structure.

An advantage of this double balloon catheter is that each balloon has an external diameter which is smaller than known balloons since each element to be expanded is smaller.

Moreover, such a double balloon catheter allows to enlarge the choice for making an efficient valvular structure enabling to overcome the following two contradictory conditions:

1) having a soft and mobile valvular structure capable of opening and closing freely in the blood stream, without risk of being damaged by balloon inflation; and

2) needing a very strong structure able to resist the recoil force of the stenosed valve and capable of resisting, without any damage, a strong pressure inflation of the expanding balloon.

Furthermore, the shaft of said double balloon catheter comprises two lumens for successive and separate inflation of each balloon. Of note, an additional lumen capable of allowing a rapid inflation takes additional room in the shaft.

The invention also relates to a method of using a two-balloon catheter with a first frame and second frame to which a valve prosthesis of the type previously described is fastened.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained and other advantages and features will appear with reference to the accompanying schematical drawings wherein :

- Figures 1a, 1b and 1c illustrate, in section views, respectively, the normal aortic valve in systole, in diastole and a stenosed aortic valve;

- Figures 2a and 2b illustrate two examples of a metallic frame which are combined to a valvular structure according to the present invention;

- Figures 3a and 3b illustrate a frame according to the invention in its expanded position with an opening out of the extremities, respectively, with a cylindrical and a concave shape;

- Figures 4a and b illustrate an IV of the invention respectively in its compressed position and in its expanded position in an open position as in systole;

- Figures 5a and 5b illustrate respectively an IV of the invention in its closed position and a sectional view according to the central axis of such a valvular structure which is closed as in diastole;

- Figures 6a to 6d illustrate a sectional view according to the central axis of an IV according to the present invention and showing the internal cover and the external cover of the valvular structure overlapping partially or non overlapping the frame bars;

- Figure 7 illustrates the frontal zig-zag fastening line of the valvular tissue on the frame;

- Figures 8a and 8b illustrate, respectively, a perspective view of a valvular structure and an internal cover made all of one piece and a perspective view of the corresponding frame into which they will be inserted and fastened;

- Figures 9a and 9b illustrate inclined strengthening struts, an example of a valvular structure according to the invention, respectively in the open position and in the closed position;

- Figures 10a and 10b illustrate an example of a valvular structure comprising pleats, respectively in the open and in the closed position;

- Figures 11a and 11b illustrate a valvular structure comprising two trapezoïdal slightly rigid portions, respectively in the open and in the closed position;

- Figures 11c to 11e illustrate a valvular structure comprising a rectangular stiffened zone, respectively in the open, intermediate and closed position;

- Figures 12a and 12b illustrate, respectively, a perspective and cross sectional views of an implantable valve in its compressed presentation squeezed on a balloon catheter;

- Figures 13a to 13l illustrate views of the successive procedure steps for the IV implantation in a stenosed aortic orifice;

- Figure 14 illustrate an implantable valve made in two parts in its compressed presentation squeezed on a two-balloon catheter with a reinforced frame on a first balloon and with the implantable valve on the second balloon; and

- Figures 15a to 15f illustrate the successive steps of the implantation of the implantation valve in two parts with a two-balloon catheter;

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the diastole and systole illustrations of section views of Figures 1a and 1b, the arrows A indicates the general direction of the blood flow. The semi-lunar leaflets 1 and 2 of a native aortic valve (with only two out of three shown here) are thin, supple and move easily from the completely open position (systole) to the closed position (diastole). The leaflets originate from an aortic annulus 2a.

The leaflets 1' and 2' of a stenosed valve as illustrated in Figure 1c, are thickened, distorted, calcified and more or less fused, leaving only a small hole or a narrow slit 3, which makes the ejection of blood from the left

ventricle cavity 4 into the aorta 5 difficult and limited. Figures 1a to 1c show also the coronary artery ostium 6a and 6b and Figure 1a shows, in particular, the mitral valve 7 of the left ventricle cavity 4.

An implantable valve according to the invention essentially comprises a supple valvular structure supported by a strong frame. The positioning of the implantable valve is an important point since the expanded frame has to be positioned exactly at the level of the native valvular leaflets 1, 2 of the native valve, the structures of which are pushed aside by the inflated balloon.

Ideally, the implantable valve is positioned with the fastening line of the valvular structure on the frame exactly on the remains of the crushed stenosed valve to prevent any regurgitation of blood. In practice, it is difficult to position the implantable valve within less than 2 or 3 mm. However, any risk of regurgitation of blood is eliminated with the presence of an internal cover, as will be described below.

The upper limit of the frame should be placed below the opening of the coronary arteries, i.e., the coronary ostia 6, or at their level so that the frame does not impede free blood flow in the coronary arteries. This point is a delicate part of positioning an IV since the distance between the superior limit of the leaflets of the natural valve and the coronary ostia 6 is only about 5 to 6 mm. However, the ostia are located in the Valsalva sinus 8 which constitutes a hollow that are located a little out of the way. This helps to prevent from impeding the coronary blood flow by the IV.

At the time of implantation, the operator evaluates the exact positioning of the coronary ostia by looking at the image produced by a sus-valvular angiogram with contrast injection performed before the implantation procedure. This image will be fixed in the same projection on a satellite TV screen and will permit the evaluation of the level of the origin of the right and left coronary arteries. Possibly, in case the ostia are not clearly seen by sus-valvular angiography, a thin guide wire, as those used

in coronary angioplasty, is positioned in each of the coronary arteries to serve as a marker of the coronary ostia.

The lower part of the frame of the IV preferably extends by 2 or 3 mm inside the left ventricle 4, below the aortic annulus 2a. However, this part of the frame should not reach the insertion of the septal leaflet of the mitral valve 7, so that it does not interfere with its movements, particularly during diastole.

Figures 2a and 2b show respectively an example of a cylindrical frame 10 comprising intercrossing linear bars 11, with two intersections I by bar 11, the bars 11 being soldered or provided from a folded wire to constitute the frame, with for instance a 20 mm, 15 mm or 12 mm height, and an example with only one intersection of bars 11. Preferably, such a frame is expandable from a size of about 4 to 5 millimeters to a size of about 20 to 25 mm in diameter, or even to about 30-35 mm (or more) in particular cases, for instance for the mitral valve. Moreover, said frame, in its fully expanded state, has a height of approximately between 10 and 15 mm and in its fully compressed frame, a height of approximately 20 mm. The number and the size of the bars are adapted to be sufficiently strong and rigid when the frame is fully open in the aortic orifice to resist the strong recoil force exerted by the distorted stenosed aortic orifice after deflation of the balloon used in the catheterization technique which has been previously maximally inflated to enlarge the stenosed valve orifice;

The frame may have several configurations according to the number of bars 11 and intersections. This number, as well as the size and the strength of the bars 11, are calculated taking into account all the requirements described, i.e., a small size in its compressed form, its capacity to be enlarged up to at least 20 mm in diameter and being strong when positioned in the aortic orifice to be able to be forcefully embedded in the remains of the diseased aortic valve and to resist the recoil force of the

aortic annulus. The diameter of the bars is choosen, for instance, in the range of 0.1-0.6 mm.

A frame particularly advantageous presents, when deployed in its expanded state, an opening out 12 at both extremities as shown in Figures 3a and 3b, the frame having a linear profile (Figure 3a) or a concave shape profile (Figure 3b). This is aimed at reinforcing the embedding of the IV in the aortic orifice. However, the free extremities of the openings 12 are rounded and very smooth to avoid any traumatism of the aorta or of the myocardium.

The structure of a preferred frame used in the present invention both maintains the aortic orifice fully open once dilated and produces a support for the valvular structure. The frame is also foldable. When folded by compression, the diameter of said frame is about 4 to 5 millimeters, in view of its transcutaneous introduction in the femoral artery through an arterial sheath of 14 to 16 F (F means French, a unit usually used in cardiology field) i.e., about 4.5 to 5.1 mm. Also, as described below, when positioned in the aortic orifice, the frame is able to expand under the force of an inflated balloon up to a size of 20 to 23 mm in diameter.

The frame is preferably a metallic frame, preferably made of steel. It constitutes a frame with a grate type design able to support the valvular structure and to behave as a strong scaffold for the open stenosed aortic orifice.

When the frame is fully expanded, its intercrossing bars push against the remains of the native stenosed valve that has been crushed aside against the aortic annulus by the inflated balloon. This produces a penetration and embeds the bars within the remains of the stenosed valve, in particular owing to a concave profile of the frame provided with an opening out, as illustrated in Figure 3b. This embedding of the frame on the aortic annulus, or more precisely on the remains of the crushed distorted

aortic valve, will be determinant for the strong fixation of the IV in the right position, without any risk of displacement.

Moreover, the fact that the valve leaflets in degenerative aortic stenosis are grossly distorted and calcified, sometimes leaving only a small hole or a small slit in the middle of the orifice, has to be considered an advantage for the implantation of the valve and for its stable positioning without risk of later mobilization. The fibrous and calcified structure of the distorted valve provides a strong base for the frame of the IV and the powerful recoil phenomenon that results from elasticity of the tissues contribute to the fixation of the metallic frame.

The height of the fully expanded frame of the illustrated frames 10 is preferably between 10 and 15 mm. Indeed, since the passage from the compressed state to the expanded state results in a shortening of the metallic structure, the structure in its compressed form is a little longer, i.e., preferably about 20 mm length. This does not constitute a drawback for its transcutaneous introduction and its positioning in the aortic orifice.

As mentioned above, the frame is strong enough to be able to oppose the powerful recoil force of the distended valve and of the aortic annulus 2a. Preferably it does not possess any flexible properties. When the frame has reached its maximal expanded shape under the push of a forcefully inflated balloon, it remains substantially without any decrease in size and without any change of shape. The size of the bars that are the basic elements of the frame is calculated in such a way to provide a substantial rigidity when the frame is fully expanded. The size of the bars and their number are calculated to give both maximal rigidity when expanded and the smallest volume when the metallic frame is its compressed position.

At the time of making the IV, the frame is expanded by dilatation to its broadest dimension, i.e., between 20 mm and 25 mm in diameter, so as to be able to fasten the valvular structure on the inside side of its surface.

This fastening is performed using the techniques in current use for the making of products such as other prosthetic heart valves or multipolars catheters etc. Afterwards, it is compressed in its minimal size, i.e., 4 or 5 mm, in diameter in view of its introduction in the femoral artery. At time of the IV positioning, the frame is expanded again by balloon inflation to its maximal size in the aortic orifice.

If the frame is built in an expanded position, it will be compressed, after fastening the valvular structure, by exerting a circular force on its periphery and/or on its total height until obtaining the smallest compressed position. If the frame is built in its compressed position, it will be first dilated, for instance, by inflation of a balloon and then compressed again as described above.

To help localizing the IV, the frame being the only visible component of the valve, the shaft of the balloon catheter on which will be mounted the IV before introduction in the body (see below) possesses preferentially metallic reference marks easily seen on fluoroscopy. One mark will be at level of the upper border of the frame and the other at the level of the lower border. The IV, when mounted on the catheter shaft and crimpled on it, is exactly positioned taking into account these reference marks on the shaft.

Accordingly, the frame is visible during fluoroscopy when introduced in the patient's body. When the frame is positioned at the level of the aortic annulus, the upper border of the frame is placed below the coronary ostia. Furthermore, the implanting process during which the balloon inflation completely obstructs the aortic orifice, as seen below, is performed within a very short time, i.e., around 10 to 15 seconds. This also explains why the frame is clearly and easily seen, without spending time to localize it. More particularly, its upper and lower borders are clearly delineated.

Figures 4a and 4b show an example of a preferred IV 13 of the present invention, respectively in its compressed position, in view of its introduction and positioning in the aortic orifice, and in its expanded and opened (systole) position. Figures 5a and 5b show the expanded position of this example closed in diastole, respectively in perspective and in a crossed section view along the central axis X'X of the valve prosthesis.

The valvular structure 14 is compressed inside the frame 10 when this is in its compressed position (Figure 4a), i.e., it fits into a 4 to 5 mm diameter space. On the other hand, the valvular structure can expand (Figure 4b) and follow the frame expansion produced by the inflated balloon. It will have to be able to reach the size of the inside of the fully deployed frame.

The illustrated IV 13 is made of a combination of two main parts:

1) the expandible but substantially rigid structure made of the frame 10, a metallic frame in the example; and

2) a soft and mobile tissue constituting the valvular structure 14 exhibiting a continuous surface truncated between a base 15 and an upper extremity 16; the tissue is fastened to the bars 11 of the frame at its base 16 and is able to open in systole and to close in diastole at its extremity 16, as the blood flows in a pulsatile way from the left ventricle towards the aorta.

The tissue has rectilinear struts 17 incorporated in it in plane including the central axis X'X, in order to strengthen it, in particular, in its closed state with a minimal occupation of the space, and to induce a patterned movement between its open and closed state. Other examples of strengthening struts are described below. They are formed from thicker zones of the tissue or from strips of stiffening material incorporated in the tissue; they can also beglued or soldered on the valvular tissue.

These strengthening struts help to prevent the valvular tissue from collapsing back too much and to evert inside the left ventricle through the

base of the frame. These reinforcements of the valvular tissue help maintain the folded tissue above the level of the orifice during diastole, prevent too much folding back and risk of inversion of the valvular structure inside the left ventricle. By also preventing too much folding, a decrease of the risk of thrombi formation can also be expected by reducing the number of folds.

The truncated shape forming a continuous surface enables to obtain a strong structure and is more efficient for the systolo-diastolic movements of the valvular tissue during heart beats. The truncoïdal shape facilitates the closure of the valve structure at the beginning of diastole in facilitating the start of the reverse movement of the valvular tissue towards its base at the time of diastole, i.e., at the time of flow reversal at the very beginning of diastole. During diastole, the valvular structure 14 thus falls down, folding on itself, thereby collapsing on its base, and therefore closing the aortic orifice. In fact, the valvular structure has preferably, as illustrated, an hyperboloid shape, with a curvature on its surface concave towards the aortic wall that will contribute to initiating its closure.

Moreover, the basis of the truncated hyperboloïd is fixed on the lower part of a frame and the smallest extremity of the truncated hyperboloïd is free in the blood stream, during the respected closing and opening phasis.

An important advantage of this hyperboloïdal shape is that the upper extremity 16 of the valvular structure 14 can remain at a distance from the coronary ostia during systole as well as during diastole, because of its smaller diameter, thus offering an additional security to make certain that the passage of blood from aorta to the coronary ostia is not impeded.

The base 15 of the truncated tissue is attached on the frame 10 along a line of coupling 18 disposed between the inferior fourth and the third fourth of the frame in the example. The upper extremity 16, with the smaller diameter, overpasses the upper part of the frame by a few

millimeters; 6 to 8 mm, for instance. This gives the valvular structure a total height of about 12 to 15 mm.

The upper extremity 16 of the truncated tissue, i.e., the smaller diameter of the hyperboloïdal structure 14, is about 17 to 18 mm in diameter (producing a 2.3 to 2.5 cm^2 area opening) for a 20 mm diameter base of the truncated structure, or 19 to 20 mm in diameter (producing a 2.8 or a 3 cm^2 area opening) for a 23 mm diameter base. An opening area around 2 cm^2 or slightly above, gives satisfactory results, particularly in elderly patients who would not reasonably need to exert high cardiac output.

For instance, in the present example, the line of fastening of the base of the truncated tissue on the frame will have to expand from a 12.5 mm perimeter (for a 4 mm external diameter of the compressed IV) to a 63 mm perimeter (for a 20 mm external diameter of the expanded IV), or to a 72 mm perimeter (for a 23 mm external diameter, in case a 23 mm balloon is used).

Another advantage of this truncated continuous shape is that it is stronger and has less risk of being destroyed or distorted by the forceful balloon inflation at the time of IV deployment. Also, if the truncated hyperboloïdal shape is marked, for instance, with a 16 or 17 mm diameter of the upper extremity as compared to a 20 mm diameter of the base (or 18 to 20 mm for 23 mm), the smaller upper part is compliant during balloon inflation in order to enable the balloon to expand cylindrically to its maximal 20 mm diameter (or 23 mm). This is made possible by using a material with some elastic or compliant properties.

The valvular structure of the invention, as shown in the illustrated example, includes advantageously a third part, i.e., the internal cover 19 to be fixed on the internal wall of the frame 10. This internal cover prevents any passage of blood through the spaces between the bars 11 of the frame in case the implantable valve would be positioned with the fastening line of

the valvular structure on the frame not exactly on the remains of the dilated aortic valve, i.e., either above or below. It also strengthens the fastening of the valvular structure 14 to the frame 10.

In the different sectional views of the different examples of IV according to the invention, as illustrated at Figures 6a to 6c, the internal cover 19 covers the totality of the internal side of the frame 10 (Figure 6a), only the lower part of the frame 10 (figure 6b), or it can additionally cover partially 3 to 5 mm as shown in the passage of blood from aorta to the coronary ostia Figure 6c, the upper part defined above the coupling line 18 of the valvular structure.

For instance, such an extension of the internal cover 19 above the fastening line 18 of the valvular structure will give another security to avoid any risk of regurgitation through the spaces between the bars 11 in case the IV would be positioned too low with respect to the border of the native aortic valve.

The internal cover can also be molded to the valvular structure or casted to it which therefore constitutes an integral structure. The valvular structure and the internal cover are therefore strongly locked together with minimum risk of detachment of the valvular structure which is unceasingly in motion during systole and diastole. In that case, only the internal cover has to be fastened on the internal surface of the frame which renders the making of the IV easier and makes the complete device stronger and more resistant. In particular, the junction of the mobile part of the valvular structure and the fixed part being molded as one piece is stronger and capable to face the inceasing movements during the systolo-diastolic displacements without any risk of detachment.

The presence of the internal cover makes an additional layer of plastic material that occupies the inside of the frame and increases the final size of the IV. Therefore, in the case in which the internal cover is limited to the inferior part of the frame (that is, below the fastening line of the valvular

structure), it does not occupy any additional space inside the frame. Here also, it is more convenient and safer to make the valvular structure and this limited internal cover in one piece.

In other aspects, to prevent any regurgitation of blood from the aorta towards the left ventricle during diastole, the base of the valvular structure is preferably positioned exactly at the level of the aortic annulus against the remains of distorted stenosed valve pushed apart by the inflated balloon. Therefore, there is no possibility of blood passage through the spaces between the metallic frame bars 11 below the attachment of the valvular structure.

However, to avoid any risk of leaks, the part of the frame below the fastening of the valvular structure (about 3 to 5 mm) is preferably covered by an internal cover which is preferably made with the same tissue as the valvular structure. Thus, there would be no regurgitation of blood which is a possibility when there is any space between the valvular structure fastened on the metallic frame and the line of application of the frame on the aortic annulus. The internal cover makes a sort of "sleeve" below the fastening of the valvular structure on the internal surface of the frame, covering the spaces between the frame bars of the frame at this level, thus preventing any regurgitation of blood through these spaces.

The internal cover can also have another function, i.e., it can be used to fasten the valvular structure inside the frame, as described below.

At Figure 6d, the internal cover 19 is extended at its lower end 19' to an external cover 19" which is rolled up to be applied on the external wall of the stent 10. The internal and external cover are molded, glued or soldered to the bars of the stent 10.

The coupling process of the valvular structure on the frame is of importance since it has to be very strong without any risk of detachment of the valvular structure from the frame during millions of heart beats with pulsatile blood flow alternatively opening and closing the valvular structure.

The valvular structure of the invention folds toa very small size inside the frame in the compressed position of the valve and is expandable up to 20 to 23 mm diameter. Also, the valvular structure can resist the strong force exerted by the maximally inflated balloon that will powerfully squeeze it against the bars of the frame or against the internal cover, this one being squeezed directly against the bars of the frame. The junction zone is also particularly subjected to very strong pressure exerted by the inflated balloon. Furthermore, this junction zone must not tear or break off during expansion of the balloon. At this time, each part of the junction zone is squeezed against the bars but nonetheless follows the expansion of the frame.

As shown in Figure 7, the junction zone is, for example, a fastening line 20 which follows the design of a "zig-zag" line drawn by the intercrossing bars 11 of the frame on the internal cover 19.

The fastening of the valvular structure to the frame can be made by sewing the internal and/or the external cover to the bars. To prevent any leakage of blood, stitches are preferably numerous and very close to each other, either as separated stitches or as a continuous suture line. Also, the stitches are made directly around the bars 11. Furthermore, since the valvular structure is expanded together with the metallic frame, the stitches, if made as a continuous suture line, are also able to expand at the same time.

The fastening process can also be made by molding the base of the valvular structure on the frame. At this level, the bars 11 are imbedded in the coupling line of the valvular structure 14. This mold way also concerns the internal cover 19, when it goes below the coupling line 14 on the frame over few millimeters, for example, 2 to 4 mm. As mentioned above, this is intended in order to prevent any regurgitation of blood just below the lower part of the valvular structure 14 in case the frame 10 would not be exactly positioned on the aortic annulus but at few millimeters away.

The fastening process can further be made by gluing or soldering the valvular structure on the bars with sufficiently powerful biocompatible glues. The same remark can be made concerning the internal cover of the frame below the coupling line of the valvular structure.

Also, this allows the coupling line to follow the frame changes from the compressed position to its expanded one.

The valvular structure can also be fastened on the internal cover previously fixed at the total length of the internal surface of the metallic frame. The internal cover constitutes therefore a surface on which any type of valvular structure be more easily sewed, molded or glued. Because it is a structure with a large surface and is not involved in the movements of the valvular tissue during systole and diastole, the internal cover is more easily fastened to the internal surface of the frame.

In the particular embodiment shown in Figure 8, the internal cover 19 is fastened, after introduction (indicated by the arrow B), at the upper and lower extremities of the frame 10 on the upper and lower zig-zag lines of the intercrossing bars 11. In fact, the fastening of the internal cover 19 on the zig-zag lines made by the intercrossing bars 11 of the frame allows an easier passage of blood from the aorta above the IV towards the coronary ostia. Indeed, the blood can find more space to flow into the coronary ostia by passing through the lowest point of each triangular space made by two intercrossing bars 11, as indicated by the arrows A1 (see also Figure 1b).

The fastening of the internal cover 19 on the extremities can be reinforced by various points of attachment on various parts of the internal surface of the frame 10. The internal cover 27 can be fastened by sewing, molding or gluing the bars 11 onto the frame.

Fastening the valvular tissue (and the cover tissue below) on the inside of the frame, requires work on the frame in its expanded position to have access to the inside of this cylindric frame. In a preferred embodiment

the frame is expanded a first time for fastening the valvular tissue on its bars, then compressed back to a smaller size to be able to be introduced via arterial introducer and finally expanded again by the balloon inflation.

Since it is aimed at being positioned in the heart after having been introduced by a catheterization technique by a transcutaneous route in a peripheral artery, mainly the femoral artery, the IV should preferably have the smallest possible external diameter. Ideally, it should be able to be introduced in the femoral artery through a 14 F (4,5 mm) size arterial introducer which is the size of the arterial introducer commonly used to perform an aortic dilatation. However, a 16 F (5,1 mm) or even a 18 F (5,7 mm) introducer would also be acceptable.

Above this size, the introduction of the IV in the femoral artery should probably be done by a surgical technique. This is still quite acceptable since the surgical procedure would be a very light procedure which could be done by a surgeon with a simple local anaesthesia. It has to be recalled that this technique is used to position big metallic frames, about 24 F in size (7.64 mm in diameter), in the abdominal aorta for the treatment of aneurysms of the abdominal aorta. In that situation, this necessitates surgical repair of the artery after withdrawal of the sheath (M. D. Dake, New Engl. J Med. 1994;331:1729-34).

Ideally, an IV should be able to last several tenths of life years without defect, like the mechanical prosthetic valves which are currently implanted by the surgeons. Nevertheless, an implantable valve that would last at least ten years without risk of deterioration would be effective for the treatment of elderly patients.

A valvular structure according to the invention is made of a supple and reinforced tissue which has a thickness to be thin enough to occupy as less as possible space in the compressed form of the valve, is pliable, and also strong enough to stand the unceasing movements under the blood pressure changes during heart beats. The valvular structure is capable of

moving from its closed position to its open position under the action of the force exerted by the movements of the blood during systole and diastole, without having any significant resistance to blood displacements.

The material used for the tissue, which exhibits the above mentioned requirements, may be Teflon® or Dacron®, which are quite resistant to folding movements, at least when they are used to repair cardiac defects such as inter-atrial or interventricular defects or when they are used to repair a valve such as the mitral valve which is subjected to high pressure changes and movements during heart beats. Also, a main point is the inceasing systolo-diastolic movements of the valvular tissue, particularly at its junction with the rigid part of the IV, and it is therefore necessary to find the most possible resistant material tissue.

As mentioned previously, the valvular structure can also possibly be made with biological tissue such as the pericardium, or with porcine leaflets, which are commonly used in bioprosthetic surgically implanted valves.

Moreover, the valvular prosthesis of the present invention does not induce any significant thrombosis phenomenon during its stay in the blood flow and is biologically neutral.

To prevent the risk of thrombus formation and of emboli caused by clots, a substance with anti-thrombic properties could be used, such as heparine, ticlopidine, phosphorylcholine, etc. either as a coating material or it can be incorporated into the material used for the implantable valve, in particular, for the valvular structure and/or for the internal cover.

The valvular structure of the invention can have several types of designs and shapes. Besides the example illustrated in Figures 4 and 5, examples of strengthened valvular structures according to the invention are shown in Figures 9 to 11, respectively in the closed (figures 9a, 10a, 11a) and in the open state (figures 9b, 10b, 11b) to form a prosthetic valve

according to the present invention. In those figures, the frame line is simplified to clarify the drawings.

To help initiate and finalize the closure of the valvular structure, four strengthening struts 14 are slightly inclined from the base to the upper part as compared to the central axis X'X of the structure, as shown in Figures 9a and 9b. Accordingly, a patterned movement of the valvular structure, during the closing and the opening phases, is initiated. This patterned movement is, in the present case, an helicoïdal-type one, as suggested in Figures 9b and 10b by the circular arrow.

Figures 10a and 10b illustrate another embodiment to help the closing of the valvular structure and which also involves an helicoïdal movement. Represented by lines 22, inclined pleats are formed in the tissue to impart such a movement. As illustrated, these lines have an inclination from the base to the upper part of the tissue 14. Pleats are formed by folding the tissue or by alternating thinner and thicker portions. The width and the number of those pleats are variable, and depend particularly on the type of material used. According to another example, these pleats 34 are combined with the above described inclined strengthening struts.

These 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.

Another shape of the valvular structure comprises two portions: one portion being flexible but with some rigidity, having a rectangular shape, occupying about one third of the circumference of the valvular structure, and the other portion being more supple, flexible and foldable occupying the rest of the circumference at its base as well as at its upper, free border. According to Figure 11c, this valve is opened, during the ejection of blood, i.e., during systol. In Figure 11d, a front view of the valve

is closed, during an intermediate diastole, and in Figure 11e the same closed valve during diastole is shown from a side view. The semi-rigid part 24' moves little during systole and during diastole. The foldable part 23' moves away from the rigid part during systole to let the blood flow through the orifice thus made. This orifice, due to the diameter of the upper part which is the same as that of the open stent, is large, generally as large as that of the open stent. At the time of diastole, due to the reverse of pressure, the foldable part moves back towards the semi-rigid part and presses on it, and thus closes the orifice and prevents any regurgitation of blood.

The advantage of such a valve design is to allow a large opening of the upper part of the valvular structure, not only to permit more blood flow at time of systole after the valve has been implanted, but also at the very time of implantation, when the balloon is maximally inflated to expand the valve to imbed it in the valvular annulus. The diameter of the upper part of the valvular structure could be the same size as the balloon, so that there would be no distension of the valvular part of the valve at the time of implantation, and therefore no risk of deterioration of the valvular structure by the inflated balloon.

The foldable part of the valve could be reinforced by strenghtening struts to prevent an eversion of the valve towards the left ventricle during diastole.

Another shape of the valvular structure, as illustrated in Figures 11a and 11b comprise four portions, alternatively a main portion 23 and a more narrow portion 24. The main and the narrow portions are facing each other. Each portion has an isosceles trapezoidal shape. The main portions 23 are flexible but with some slight rigidity and the more narrow portions 24 are compliant, more supple and foldable. In this type of design, the two slightly rigid portions 23 maintain the valvular structure closed during diastole by firmly applying on each other in their upper extremities, thus

forming a slot-like closure 25. This particular embodiment needs less foldable tissue than in the previous embodiments and the closure of the valvular structure at the time of early diastole does not have any tendency to collapse towards the aortic annulus.

Another design for the valvular structure is a combination of a cylindrical shape followed by a truncated shape.

This type of valvular structure is longer that the hyperboloïdal type, for instance, 25 or 30 mm long, therefore exceeding out of the upper part of the metallic frame, by 10 to 20 mm. The cylindrical part corresponds to the metallic frame and remains inside it. The truncated conic shape is the upper part of the valvular structure, totally exceeding out of the upper extremity of the metallic frame. An advantage of such a design is that the balloon can be inflated only in the cylindrical part of the valvular structure, therefore without risk of stretching the truncated conical part of the upper diameter which is smaller than that of the inflated balloon.

When the upper extremity of the cylindrical part has the same size as the lower extremity, there is no difference during balloon inflation in the degree of force exerted by the balloon on the lower and on the upper extremity of the valvular structure. Preferably, rectilinear reinforcing struts are used in this embodiment, to strengthen the valve structure and aid in its shutting without collapsing and inverting inside the left ventricle through the aortic annulus under the force of the diastolic pressure.

Two different processes for implanting a valve according to the present invention are shown respectively in Figures 13a to 13l with a unique balloon catheter, as illustrated in Figures 12a and 12b and in Figures 15a to 15f, with a two-balloon catheter, as illustrated in Figure 14.

The IV positioning in the aortic orifice and its expansion can be performed with the help of a unique substantially cylindrical balloon catheter 26 in the so-called unique-balloon catheterization technique.

Preparing for its introduction by transcutaneous route in the femoral artery, the IV 13 is, as illustrated in the perspective view of Figure 10a in a compressed form crimpled on the balloon catheter 26. A central sectional view of the mounted IV 13 on the complete balloon catheter 26 is shown in Figure 12b.

The shaft 27f of the balloon dilatation catheter 26 is as small as possible, i.e., a 7F (2.2 mm) or a 6 F (1.9 mm) size. The balloon 26 is mounted on the shaft 27 between two rings R. Moreover, the shaft 27 comprises a lumen 28 (Figure 12b) as large as possible for inflation of the balloon 26 with diluted contrast to allow simple and fast inflation and deflation. It has also another lumen 29 able to accept a stiff guide wire 30, for example 0.036 to 0.038 inches (0.97 mm), to help position the implantable valve with precision.

The balloon 26 has, for example, a 3 to 4 cm length in its cylindrical part and the smallest possible size when completely deflated so that it will be able to be placed inside the folded valve having an outside diameter which ranges between about 4 and 5 mm. Therefore, the folded balloon preferably has at the most a section diameter of about 2.5 to 3 mm.

The balloon is therefore made of a very thin plastic material. It is inflated with saline containing a small amount of contrast dye in such a way to remain very fluid and visible when using X-ray.

However, the balloon 26 has to be sufficiently strong to resist the high pressure that it has to withstand to be capable of expanding the folded valvular structure 14 and the compressed frame in the stenosed aortic orifice considering that, although pre-dilated, the aortic orifice still exerts a quite strong resistance to expansion because of the recoil phenomenon.

This procedure is shown in Figures 13a to 13e.

In contrast to the technique used when performing the usual aortic dilatation (without valve implantation), i.e., inflating the balloon maximally markedly above the nominal pressure, if possible, up to the bursting point

(which occurs always with a longitudinal tear, without deleterious consequence, and with the advantage of both exerting a maximal dilating force and restoring blood ejection instantaneously), the balloon inflated for expansion of an implantable valve should not burst in any case. Indeed, bursting of the balloon would involve a risk of incomplete valve expansion and wrong positioning. Therefore, the balloon should be very resistant to a very high pressure inflation. Furthermore, the balloon is inflated only up to the nominal pressure indicated by the maker and the pressure is controlled during inflation by using a manometer. Such relatively low pressure should be sufficient since prior to positioning the IV, an efficacious dilatation of the stenosed aortic valve according to the usual technique with a maximally inflated balloon for example 20 mm or 25 mm in size in such a way to soften the distorted valvular tissue and facilitate the enlargement of the opening of the valve at time of IV implantation is performed.

The implantation of the aortic valve 20 can be made in two steps, as described as follows.

The first step, as shown in Figures 13a to 13f, consists in introducing the shaft 27 and balloon catheter 26 along the guide wire previously positioned in the ventricle 4 (Figures 13a-13b). The dilatation of the stenosed aortic valve 1', 2' using a regular balloon catheter, according to the commonly performed procedure, i.e., with the guide wire 30 introduced in the ventricle 4 (Figure 13a) and with maximal inflation of the balloon 26 (Figures 13c to 13d) up to the bursting point. Dilatation is performed at least with a balloon having about 20 mm diameter, but it can be performed with a balloon having about 23 mm diameter so as to increase maximally the aortic orifice opening before implantation of the valve although the implantable valve is about 20 mm in diameter. This preliminary dilatation of the aortic orifice helps in limiting the force required to inflate the balloon used to expand the implantable valve and position it in the aortic orifice, and also in limiting the recoil of the aortic valve that

occurs immediately after balloon deflation. The balloon is deflated (Figure 13a) and pulled back on the wire guide 30 left inside the ventricle.

Owing to the marked recoil of the stenosed valve and also of the strong aortic annulus, the 20 mm diameter valve is forcefully maintained against the valvular remains at the level of the aortic annulus. Preliminary dilatation has another advantage in that it permits an easier expansion of the IV, having a lower pressure balloon inflation which helps prevent damage of the valvular structure of the IV. This also facilitates the accurate positioning of the prosthetic valve.

The second step corresponds to the implantation of the valve 13 is shown in Figures 13g to 13l. The positioning of the IV needs to be precise at a near 2 or 3 mm, since the coronary ostia 6 has to remain absolutely free of any obstruction by the valve 13 (Figures 13k and 13l). As mentioned above, this is, for example, performed with the help of the image of the sus-valvular angiogram in the same projection fixed on an adjacent TV screen. The expansion and the positioning of the valve prosthesis 13 is performed within a few seconds (15 to 20 among at most) since during the maximal balloon inflation (which has to be maintained only a very few seconds, 3, 4, 5) the aortic orifice is obstructed by the inflated balloon 31 and the cardiac output is zero (Figure 13h). As for the pre-dilatation act itself, the balloon 26 is immediately deflated within less than 5 or 6 seconds (Figure 13j) and, as soon as the deflation has clearly begun, the closing and opening states of the IV are active whereas the balloon is pulled back briskly in the aorta (Figures 13j to 13l). In case the IV is not maximally expanded by the first inflation, it is possible to replace the balloon inside the IV and to reinflate it so as to reinforce the expansion of the IV.

The IV 13 can also be used in aortic regurgitation. This concerns more often younger patients rather than those with aortic stenosis. The contraindication to surgical valve replacement is often not due to the old age of the patients, but stems mainly from particular cases where the

general status of the patient is too weak to allow surgery, or because of associated pathological conditions. Apart from the fact that there is no need for a preliminary dilatation, the procedure of the valve implantation remains approximately the same. The balloon inflation inside the IV is chosen accordingly, taking also into account the fact that it is necessary to overdilate the aortic annulus to obtain a recoil phenomenon of the annulus after balloon deflation to help maintain the IV in position without any risk of displacement.

However, the size of the expanded implantable valve is around 25 to 30 mm in diameter, or even bigger, because the aortic annulus is usually enlarged. A preliminary measurement of the annulus will have to be performed on the sus-valvular angiography and by echocardiography to determine the optimal size to choose.

The IV can be used in the mitral position, mainly in case of mitral regurgitation, but also in case of mitral stenosis. Here again, the IV 20 is only described when used only in cases of contraindication to surgical valve repair or replacement. The procedure is based on the same general principles though the route for the valve positioning is different, using the transseptal route, like the commonly performed mitral dilatation procedure in mitral stenosis. The IV size is quite larger than for the aortic localization (about 30 to 35 mm in diameter when expanded or clearly above in case of a large mitral annulus, a frequent occurrence in mitral insufficiency), to be capable of occupying the mitral area. A preliminary measurement of the mitral annulus is performed to determine the optimal implantable valve size to choose. Since the introduction of the IV is performed through a venous route, almost always through the femoral vein which is quite large and distensable, the bigger the size of the IV in its compressed position is not a drawback even if the diameter size is about 6 or 7 mm. Moreover, the problem of protection of the coronary ostia as encountered in the aortic

position does not exist here which therefore makes the procedure easier to be performed.

Finally, the IV can be used to replace the tricuspid valve in patients with a tricuspid insufficiency. This procedure is simple to perform since the positioning of the IV is made by the venous route, using the shortest way to place in the right position at the level of the tricuspid orifice practically without any danger from clot migration during the procedure. A large implantable valve is used, with a diameter of about 40 mm or even larger because the tricuspid annulus is often markedly dilated in tricuspid insufficiency. Here also, as in the mitral position, the compressed IV and the catheter used can be without inconvenience, quite larger than that for the aortic position because of the venous route used.

Furthermore, it has to be noted that the IV can be used also as a first step in the treatment of patients who have contraindication to surgery, when they are examined for the first time, but who could improve later on after correction of the initial hemodynamic failure. The IV procedure can be used as a bridge towards surgery for patients in a weak general condition which are expected to improve within the following weeks or months after the IV procedure in such a way that they can be treated by open heart surgery later on. In the same vein, the IV procedure can be used as a bridge towards surgical valve replacement or repair in patients with a profoundly altered cardiac function that can improve secondarily owing to the hemodynamic improvement resulting from the correction of the initial valvular disease by the IV implantation.

Another technique for implantation of an aortic valve by transcutaneous catheterization uses a two-balloon catheter.

An example of this technique using the two parts IV with a two-balloon catheter 40 is shown in Figure 14.

Two-balloons 26 and 26' are fixed on a unique catheter shaft 27, said balloons being separated by a few millimeters. The two balloons are

preferably short, i.e., about 2 to 2.5 cm long in their cylindrical part. The first balloon 26 to be used, carries a first frame 10 aimed at scaffolding the stenosed aortic orifice after initial dilatation. This first balloon 26 is positioned on the aorta side, above the second balloon 26' which is positioned on the left ventricle side. The second balloon 26' carries the expandable valve 13 which is of the type described above made of a second frame 10' and a valvular structure 14 attached to said frame 10'. The difference is that the second frame does not need to be as strong as the first frame and is easier to expand with low balloon pressure inflation which does not risk damaging the valvular structure 14.

This enlarges the choice for making a valvular structure without having to face two contradictory conditions:

1) having a soft and mobile valvular structure 14 capable of opening and closing freely in the blood stream without risk of being damaged by a balloon inflation; and

2) needing a reinforced frame strong enough to be capable of resisting without any damage, a strong pressure inflation of the expanding balloon.

The shaft 27 of this successive two-balloon catheter 40 comprises two lumens for successive and separate inflation of each balloon. Indeed, an additional lumen capable of allowing a fast inflation occupies space in the shaft and therefore an enlargement of the shaft is necessary. However, this enlargement of the shaft stops at the level of the first balloon 26 since, further to said first balloon, only one lumen is necessary to inflate the second balloon 26', at the level of the IV which is the biggest part of the device.

Another advantage of this two part IV with a two-balloon catheter is that each set of implantable valve and balloon has a smaller external diameter since each element to be expanded, considered separately, is

smaller than in combination. This allows obtaining more easily a final device with an external diameter 14 F.

The first balloon is sufficiently strong to avoid bursting even at a very high pressure inflation. This first balloon is mounted in the frame in its deflated position, prior to its introduction by the strong frame which is aimed to scaffold the dilated stenosed aortic valve. The size and shape of said frame is comparable to what has been described previously but said frame is calculated (in particular the material, the number and diameter of its bars are chosen by the person skilled in the art) to make sure that it will resist the recoil of the dilated valve and that it will be securely embedded in the remains of the native aortic valve.

The second balloon does not need to be as strong as the first one and, therefore, can be thinner, occupying less space and being easier to expand with a lower pressure for balloon inflation. This second balloon 26' is mounted in the valve itself which, as in the preceding description, comprises a frame to support the valvular structure and said valvular structure.

Also, the second frame 10' does not need to be as strong as the first one. This frame can be slightly shorter, 10 mm instead of 12 mm, and its bars can be thinner. This frame can have an external surface which is a bit rough to allow better fixation on the first frame when expanded. The bars may also have some hooks to fasten to the first frame.

The valvular structure is attached on said second frame and expanded by relatively low pressure in the second balloon called hereafter the IV balloon. It does not need to be as strong as in the preceding case (IV in one part and unique balloon catheter technique) and, therefore, it occupies less space and has less risk to be damaged at the time of expansion.

This technique is shown in Figures 15a to 15f.

One of the problems relevant to the IV implantation procedure as described above, with the IV in one part, is the expansion at the same time by the same balloon inflation of both the frame and the valvular structure. Indeed, the frame is a solid element and the valvular structure is a relative weak one that could be damaged when squeezed by the inflated balloon.

Therefore, the valve implantation can be performed in two immediately successive steps. The first step (Figures 15a-15b) corresponds to the expansion and the positioning of the first frame with the first balloon 26 wherein inflation is performed at a high pressure. The second step (Figures 15d-15e) corresponds to the expansion and the positioning of the valvular structure 14 inside the frame 10' using the second balloon 26'. This second step follows the first one within a few seconds because, in the time interval between the two steps, there is a total aortic regurgitation towards the left ventricle which is an hemodynamic condition that cannot be maintened for more than a few heart beats, i.e., a few seconds, without inducing a massive pulmonary edema and a drop to zero of the cardiac output.

In another embodiment, the first frame to be introduced comprises the valvular structure and the second frame being stronger than the first one to scaffold the previously deleted stenosed aortic valve.

The advantage of this two step procedure would be to allow expansion and positioning of the frame part 10' of the IV 13 using strong pressure inflation of the balloon 26' without the risk of damaging the valvular structure 14 which, for its own expansion, would need only light pressure inflation.

The method is schematically detailed in Figures 15a to 15f. A previous dilatation of the stenosed aortic valve is performed as an initial step of the procedure to prepare the distorted valve to facilitate the following steps:

1/ positioning the double balloon catheter 40 with the first balloon 26 with the frame at the level of the aortic annulus 2a, the second IV balloon 26' being inside the left ventricle beyond the aortic annulus 2a (Figure 15a);

2/ compression of the stenosed aortic valve 1', 2' with the first balloon 26 having a 20 mm, preferably with a 23 mm diameter, the balloon being inflated maximally up to the bursting point, to prepare the IV insertion (Figure 15b). Inflation lasts a few seconds (preferably 10 seconds at most) with powerful pressure being used to expand the frame and forcefully embed said frame in the remains of the dilated valve;

3/ an immediate speedy deflation of said first balloon 26 follows (Figure 15c); as soon as the balloon 26 is beginning to clearly deflate, the first frame 10 remaining attached to the stenosed valve 1', 2', the catheter 40 is withdrawn to position the IV balloon 26' inside the previously expanded frame 26 (Figure 15c in which the frame 10' is partially drawn for clarity purpose);

4/ immediately after being well positioned, the IV balloon 26' is promptly inflated, to expand the IV 13 (Figure 15c); and

5/ when the IV 13 is blocked inside the first frame 10, the IV balloon 26' is deflated (Figure 18f).

Finally, the whole device has to be withdrawn to allow hemostasis of the femoral artery puncture hole.

The total duration of the successive steps, particularly the time during which the balloons are inflated, and the time during which the frame is expanded whereas the valve has not yet been positioned and expanded, is about 20 to 30 seconds. This is feasible if the balloons are inflated and deflated within very a few seconds, 6 to 8, for instance. This is permitted if the lumen of the shaft can be sufficiently large, taking into account the inescapable small diameter size of the shaft. This can also be facilitated by a device producing instantaneously a strong inflation or deflation pressure.

CLAIMS

1. A valve prosthesis for implantation in a body channel, the prosthesis comprising a collapsible valvular structure (14), and an expandable frame (10, 10') on which said valvular structure (14) is mounted, said valvular structure (14) being composed of a valvular tissue compatible with the human body and blood, the valvular tissue being sufficiently supple and resistant to allow said valvular structure (14) to pass from a closed state to an open state to allow a body fluid exerting pressure on the valvular structure (14) to flow, wherein said valvular tissue forms a continuous surface and is provided with guiding means formed or incorporated within, said guiding means creating stiffened zones which induce said valvular structure (14) to follow a patterned movement in its expansion to said open state and closed state, providing therefore a structure sufficiently rigid to prevent eversion.

2. The prosthetic valve according to claim 1, wherein an internal cover (19) is coupled to the valvular structure (14) and placed between said valvular structure (14) and the internal wall of the structure of the frame (10) to prevent any passage of the body fluid through said structure.

3. A prosthetic valve according to claim 2, wherein the internal cover is extended in its lower end by an external cover rolled upon the external wall of the structure of the frame.

4. A prosthetic valve according to claim 2 or 3, wherein both the valvular structure (14) and the cover (19) are one piece.

5. A prosthetic valve according to claim 2 or 3, wherein the valvular structure and/or the cover are coated with or are made of an anti-thrombic substance.

6. A prosthetic valve according to claim 2, wherein the internal cover (14) covers the full length of the internal surface of the frame (10) or only a part of said internal surface.

7. A prosthetic valve according to claim 1, wherein said valvular structure (14) has a substantially truncated hyperboloïdal shape in its open state.

8. A prosthetic valve according to claim 1, wherein said guiding means comprise strips inclined from the base (15) to the upper extremity (16) of the valvular structure (14) when compared to the central symmetry axis (XX') of the valvular structure (14), the curvature of said guiding means being concave towards said upper extremity (16) to impart an helicoidal movement to the valvular structure (14) when compared to the central axis (XX') of the valvular structure (14).

9. A prosthetic valve according to claim 8, wherein said guiding means comprise inclined pleats extending from the base (15) of the valvular structure (14) to the upper extremity (16) of said valvular structure (14).

10. A prosthetic valve according to claim 8, wherein said guiding means comprise at least 3, strengthening struts (17, 21), formed from thickened zones or incorporated strips of stiffening material.

11. A prosthetic valve according to claim 7, wherein the strips are soldered or glued on the valvular tissue.

12. A prosthetic valve according to anyone of claims 1 to 7, wherein said guiding means are rectilinear (17) in plane including the central axis (X'X) from the basis (15) to the upper extremity (16) of the valvular structure (14).

13. A prosthetic valve according to claim 12, wherein said guiding means comprise pleats extending from the base (15) of the valvular structure (14) to the upper extremity (16) of said valvular structure (14).

14. A prosthetic valve according to claim 12, wherein said guiding means comprise at least 3 strengthening struts (17, 21), formed from thickened zones or incorporated strips of stiffening material.

15. A prosthetic valve according to claim 1, wherein said stiffened zones are main parts (23) of trapezoidal shape, preferably two main parts formed symmetrically with regard to the central axis (XX') of the valvular structure (14), separated by less rigid parts (24), and in that said guiding means are of a rectilinear type.

16. A prosthetic valve according to claim 15, wherein each of said main parts (23) occupies approximately one third of the circumference of the upper part of the valvular structure (14) when this latter is in its open position.

17. A prosthetic valve according to claim 15, wherein the main parts (23) are thickened zones and the other parts (24) are thinner zones.

18. A prosthetic valve according to claim 1, wherein stiffened zones are a continuous of rectangular shape, completed by a flexible and foldable part to constitute the volumbar structure.

19. A prosthetic valve according to claim 1, wherein said valvular tissue is made of synthetic biocompatible material such as polyethylene or polyamide, or made of biological material as pericardium or porcine leaflets.

20. A prosthetic valve according to claim 1, wherein said valvular structure (14) is fastened to the frame (10) by sewing, by molding, soldering or by gluing, to prevent regurgitation of said body fluid between the frame (10) and the valvular structure (14).

21. A prosthetic valve according to claim 1, wherein said frame (10) is expandable from a size on the order of 4 to 5 millimeters to a size of 20 to 35 mm in diameter.

22. A prosthetic valve according to claim 1, wherein said frame (10), in its fully expanded form, has a height of approximately between 10 and 15 mm and in its fully compressed frame, a height of approximately 20 mm.

23. A prosthetic valve according to claim 1, wherein said frame (10) is made in material which is distinguishable from biological tissue by non invasive imaging techniques.

24. A prosthetic valve according to claim 1, wherein said frame (10) is a foldable plastic or stainless metal structure made of intercrossing, linear bars, preferably rounded and smooth.

25. A prosthetic valve according to claim 23, wherein the size and the number of the bars are determined to give both the maximal rigidity when said frame (10) is in its expanded state and the smallest volume when the frame (10) is in its compressed state.

26. A prosthetic valve according to claim 1, wherein the frame (10) has a concave shape comprising projecting curved bars at the extremities (12).

27. A prosthetic valve according to claim 1, wherein a first frame (10) is coupled with another frame (10') which has bars of size substantially lower than said first frame (10) and which is embedded inside this latter, along a common shaft (27), the first frame being compressed with a first balloon catheter (26) and the second frame (26') being a part of a prosthetic valve (13) according to claim 1, each frame squeezed on each of the two balloons in order to constitute a sequential double balloon catheter (40).

28. A double balloon catheter according to claim 27, to separately position a first frame to be introduced in the previously dilated stenosed aortic valve and place a second frame that comprises the valvular structure, this catheter comprising two balloons fixed on a catheter shaft and separated by a few millimeters, the first balloon to be introduced being sufficiently strong to avoid bursting even at a very high inflation pressure and aimed at carrying, in its deflated state, a strong frame aimed at scaffolding the previously dilated stenosed aortic valve, the second balloon being aimed at carrying the second frame with the valvular structure.

29. A double balloon catheter according to claim 27, to separately position a first frame to be introduced in the previously dilated stenosed aortic valve that comprise the valvular structure and place a second frame, this catheter comprising two balloons fixed on a catheter shaft and separated by a few millimeters, the first balloon being aimed at carrying the second frame with the valvular structure, a strong frame aimed at scaffolding the previously dilated stenosed aortic valve, the second balloon to be introduced being sufficiently strong to avoid bursting even at a very high inflation pressure and aimed at carrying, in its deflated state,

30. A double balloon catheter according to claim 27, having a shaft comprising two lumens for successive and separate inflation of each balloon and an additional lumen for passage of a guide wire.

31. A method of using a two-balloon catheter with a first frame and second frame to which a valve prosthesis according to claim 1 is fastened, wherein a valve implantation is performed comprising two immediately successive steps of:

1/ expanding and positioning a first frame by inflating a first balloon (26) at a high inflation pressure,

2/ expanding and positioning a valvular structure (14) inside the frame (10') using a second balloon (26'), wherein step (2) occurs within a few seconds after step 1 and wherein a total aortic regurgitation towards the left ventricle takes place in the time interval between the two steps as an hemodynamic condition that cannot be faced for more than a few heart beats, and wherein an expansion and positioning of the frame part (10') of the IV (13) is allowed using a strong pressure inflation of the balloon (26') without risking damaging the valvular structure (14) which needs only a light pressure inflation for its own expansion

32. A method according to claim 31, wherein a previous dilatation of the stenosed aortic valve is performed as an initial step of the procedure to prepare the distorted valve to facilitate the following steps:

1/ positioning the double balloon catheter (40) with the first balloon (26) with the frame at the level of the aortic annulus (2a), the second IV balloon (26') being inside the left ventricle beyond the aortic annulus (2a);

2/ compressing the stenosed aortic valve (1', 2') with the first balloon (26), the balloon being inflated maximally up to the bursting point, to prepare the IV insertion, inflation lasting a few seconds with a powerful pressure to expand the frame and forcefully embed said frame in the remains of the dilated valve, pushing away remains of the previously dilated stenosed natural valve;

3/ deflating immediate said first balloon (26) and; the first frame (10) remaining attached to the stenosed valve (1', 2'), the catheter (40) is pulled back to position the IV balloon (26') inside the previously expanded frame (26);

4/ immediately after being well positioned, the IV balloon (26') is promptly inflated, to expand the IV 13;

5/ when the IV 13 is blocked inside the first frame (10), the IV balloon (26') is deflated.

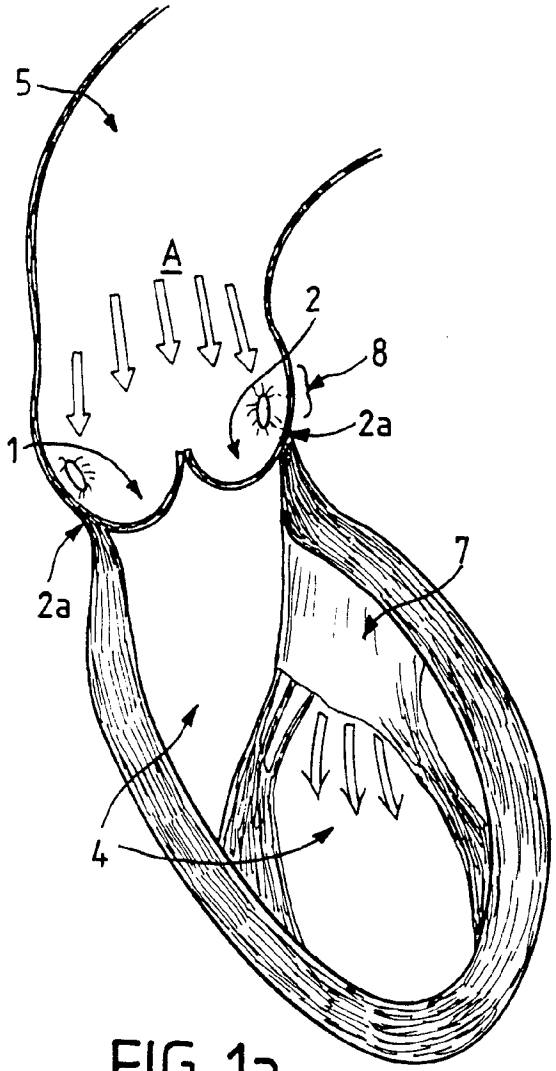


FIG_1a

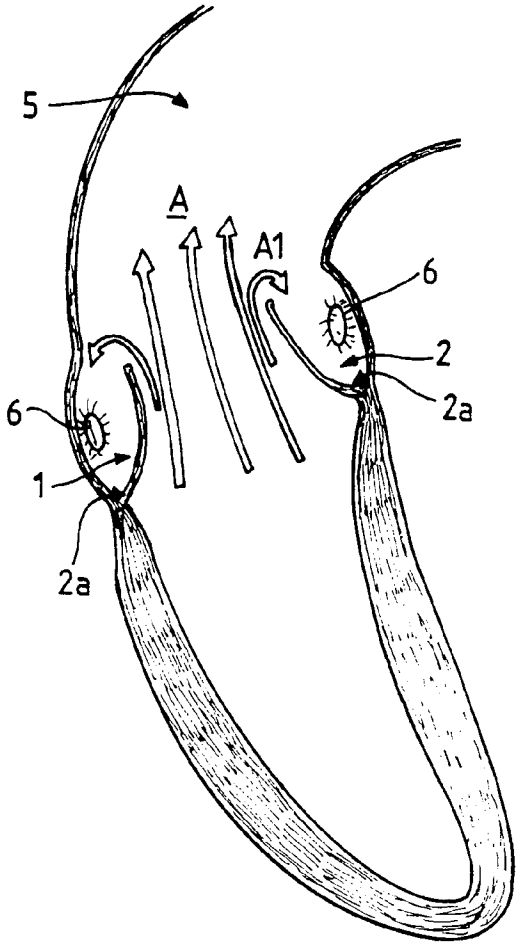


FIG_1b

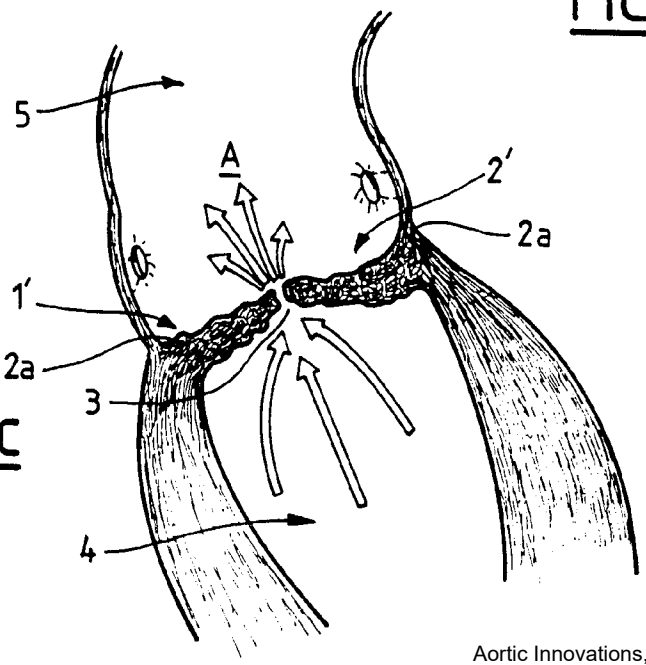


FIG_1c

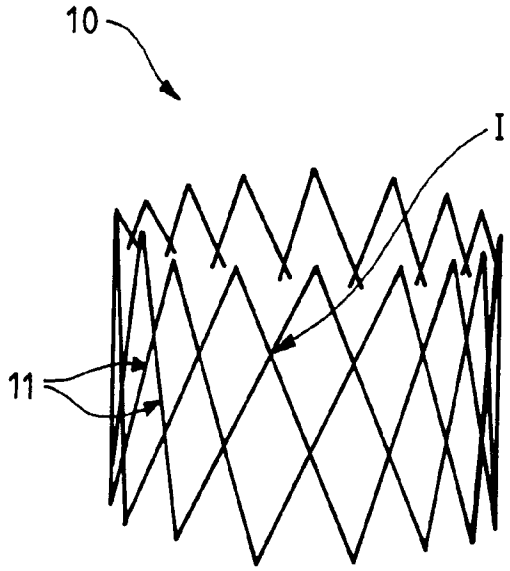


FIG_2a

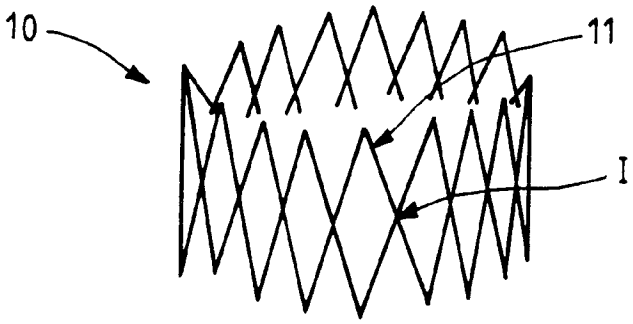


FIG_2b

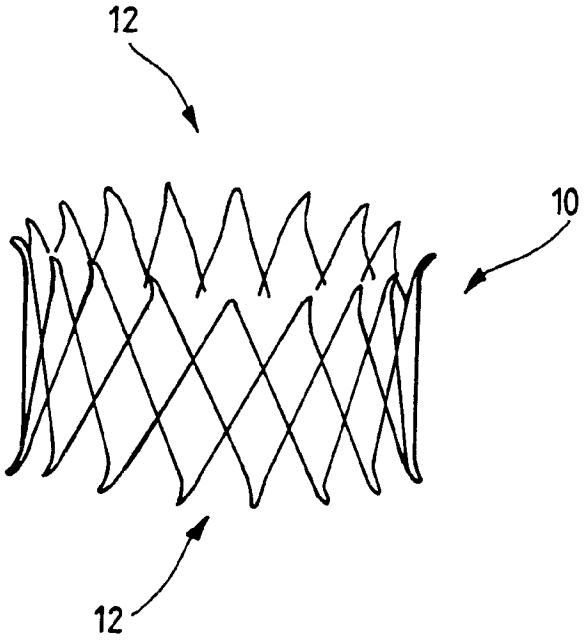


FIG_3a

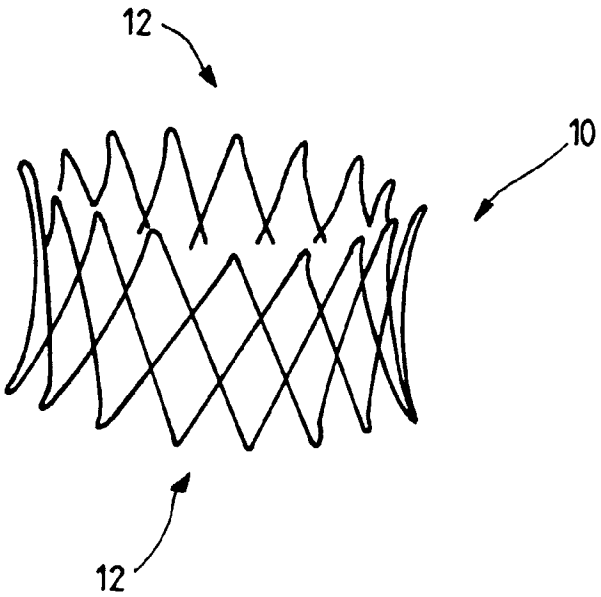


FIG_3b

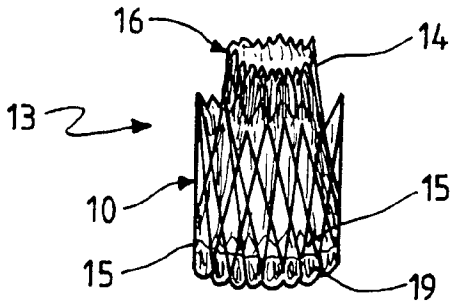


FIG_4a

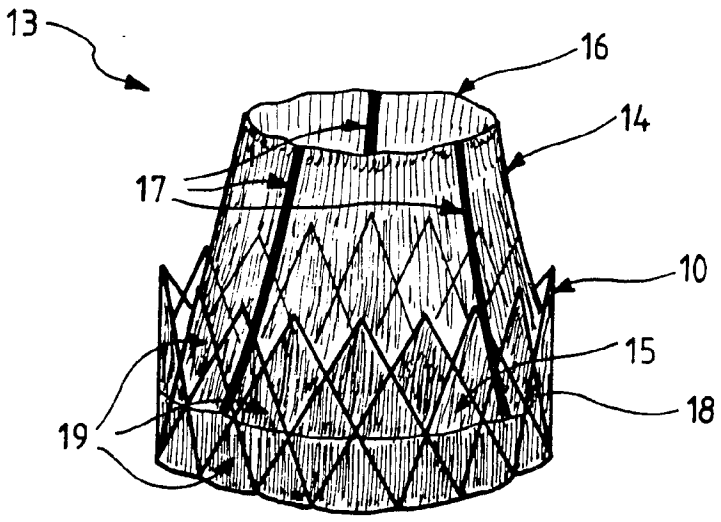


FIG_4b

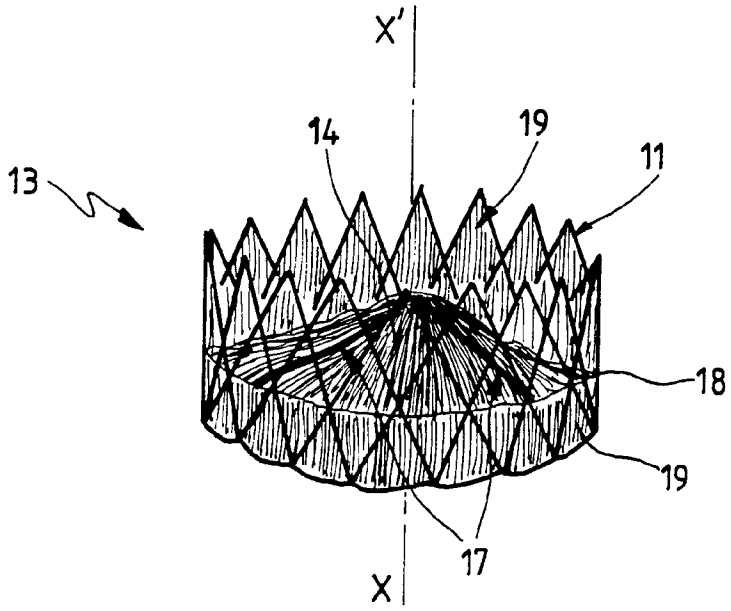


FIG_5a

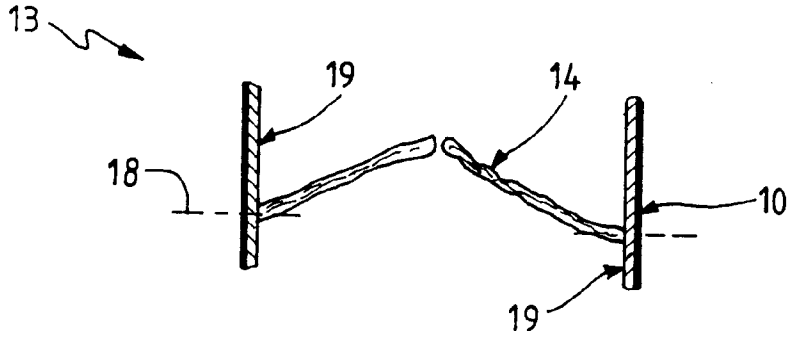


FIG_5b

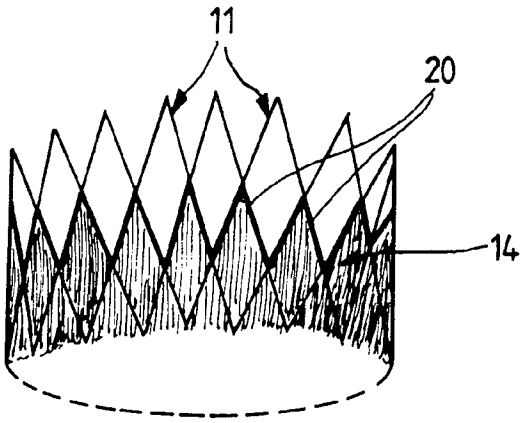


FIG_7

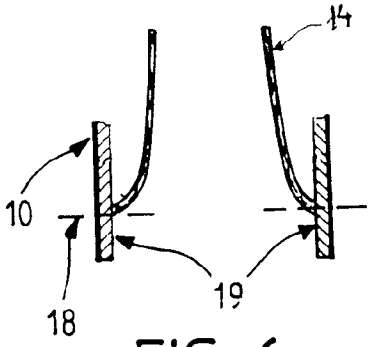


FIG_6a

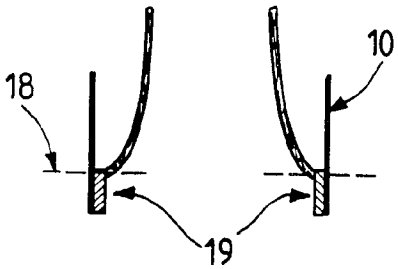


FIG_6b

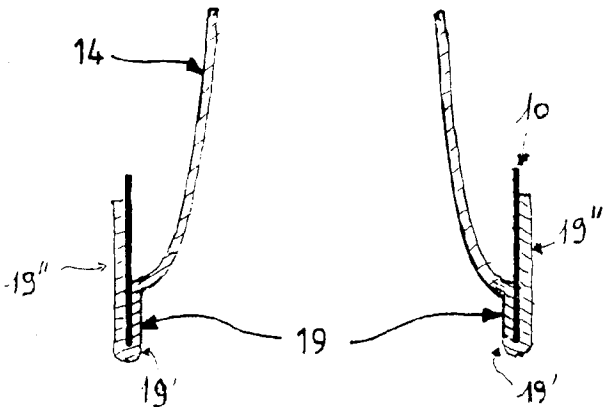


FIG_6d

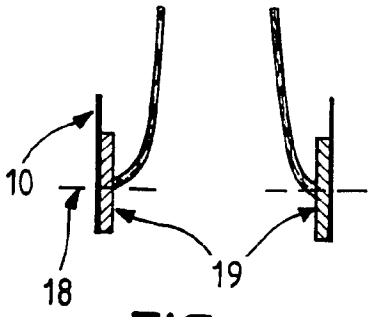


FIG_6c

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 517
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

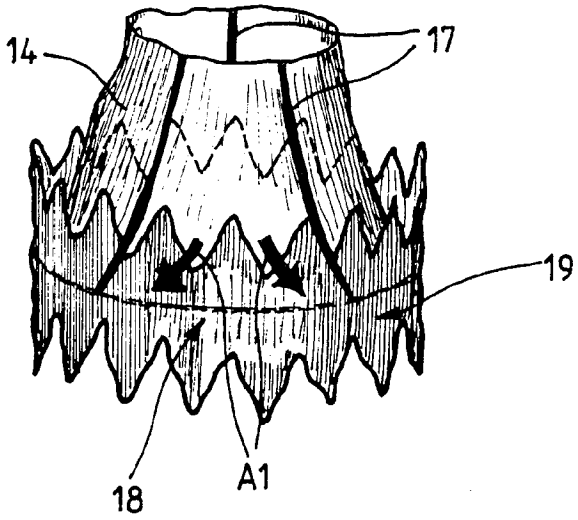


FIG_8a

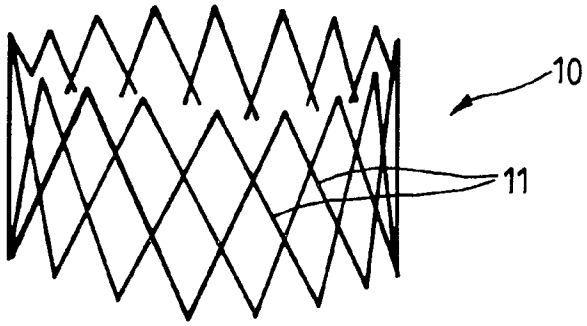


FIG_8b

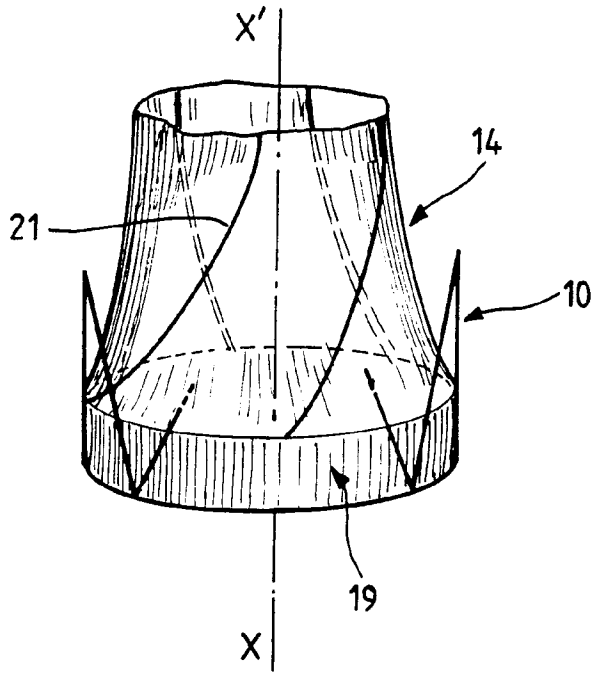


FIG_9a

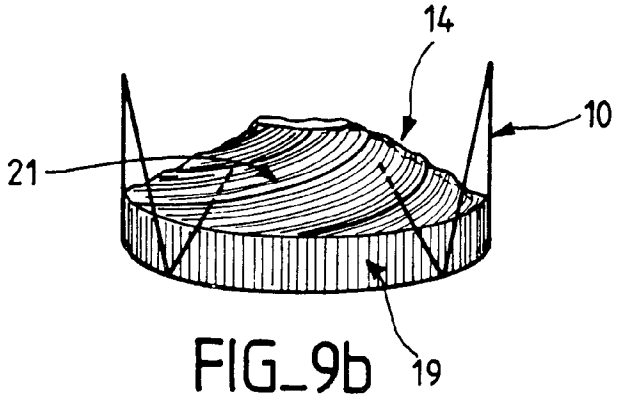


FIG_9b

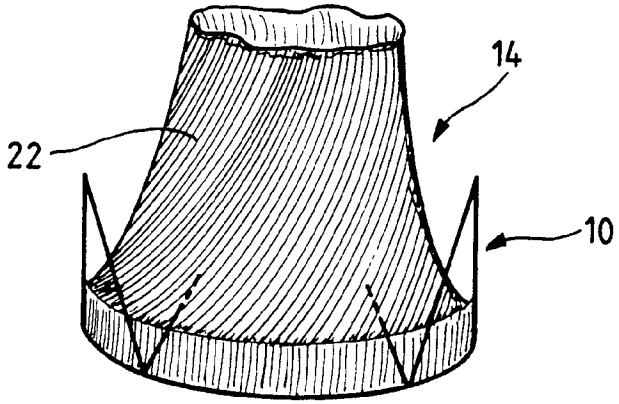


FIG_10a

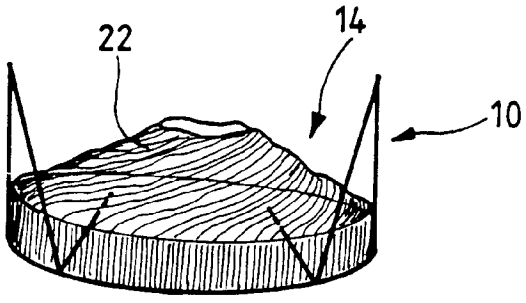


FIG_10b

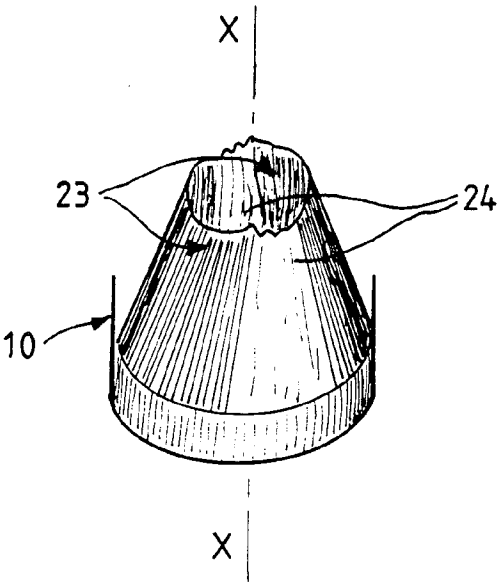


FIG_11a

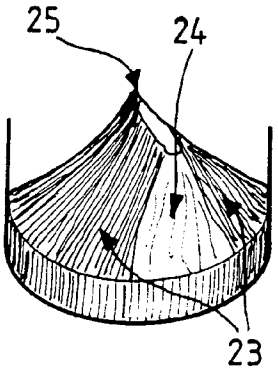


FIG_11b

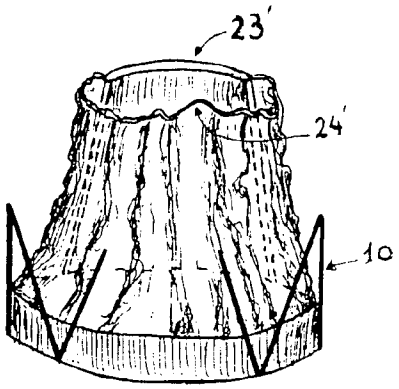


FIG_11c

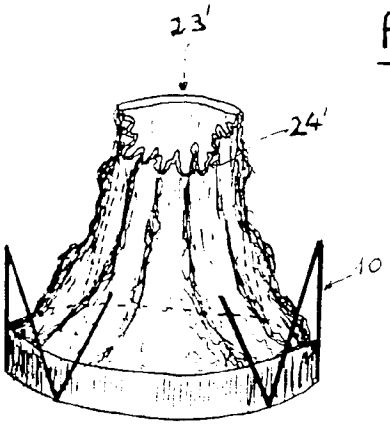


FIG_11d

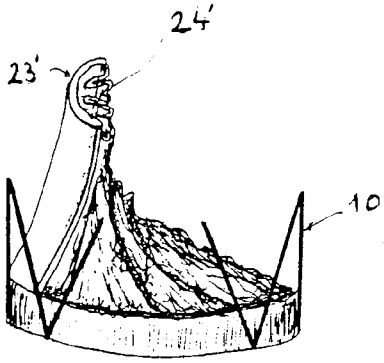


FIG_11e

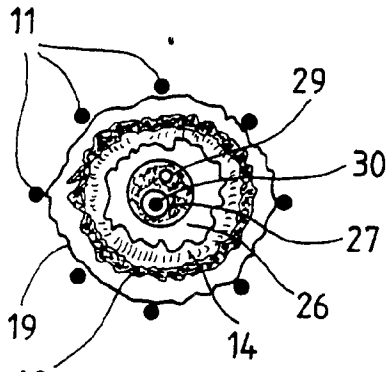


FIG_12b

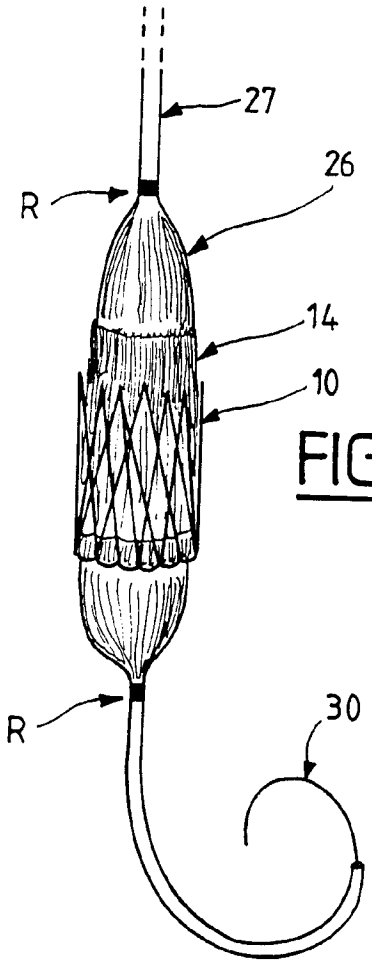


FIG_12a

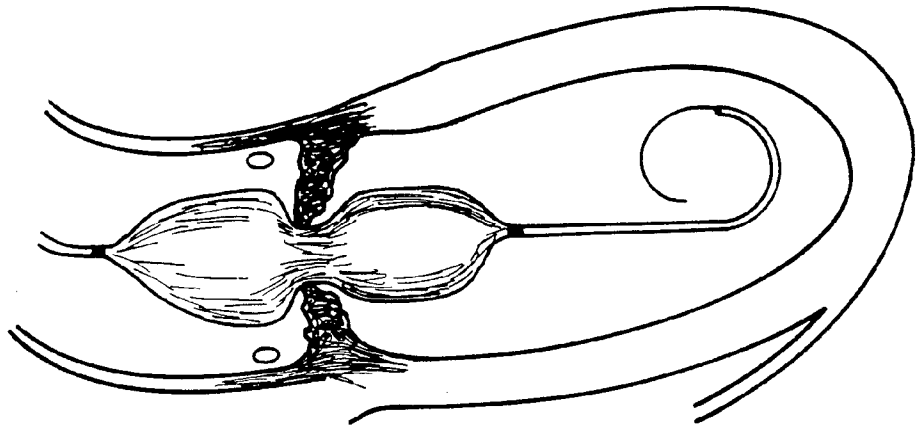


FIG_13c

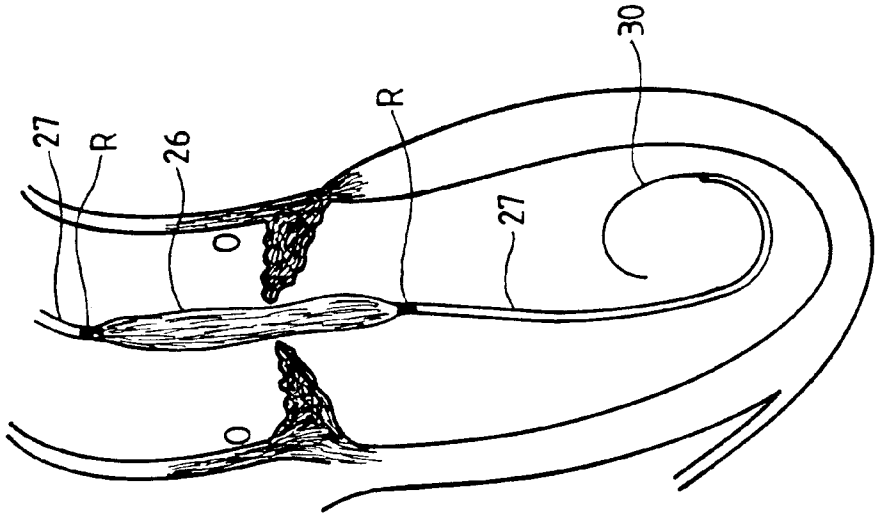


FIG_13b

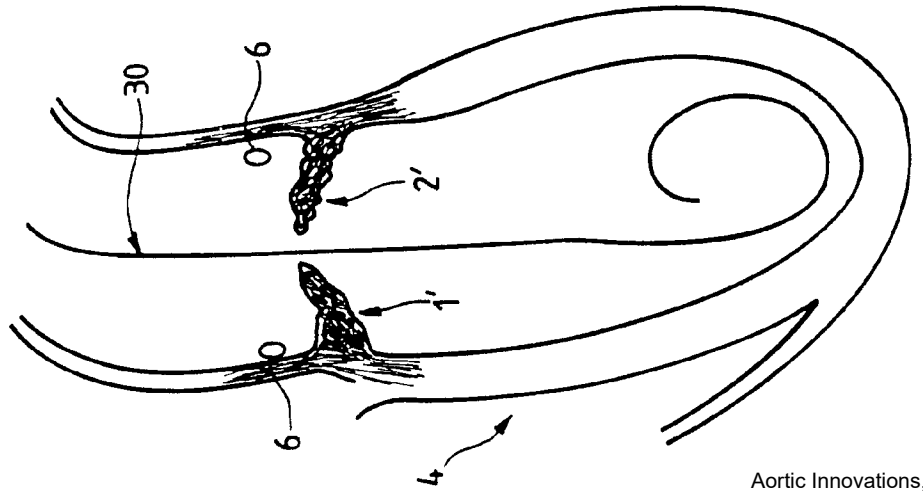


FIG_13a

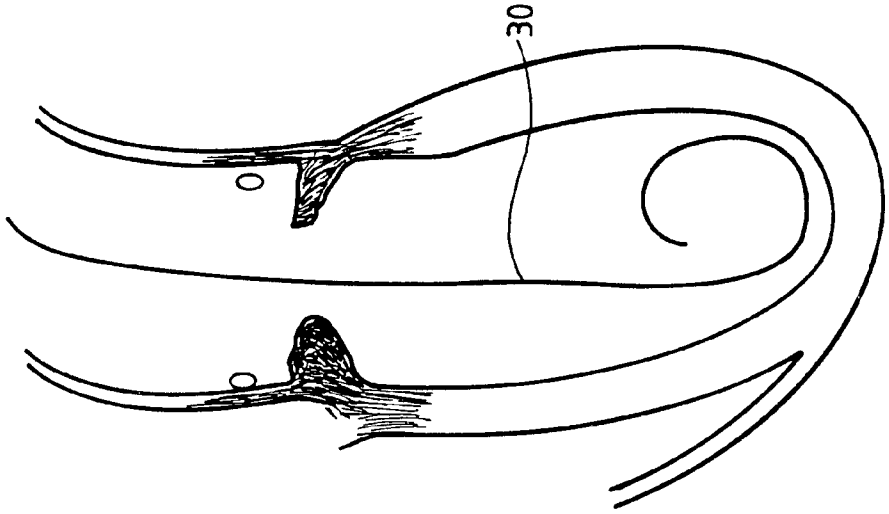


FIG_13f

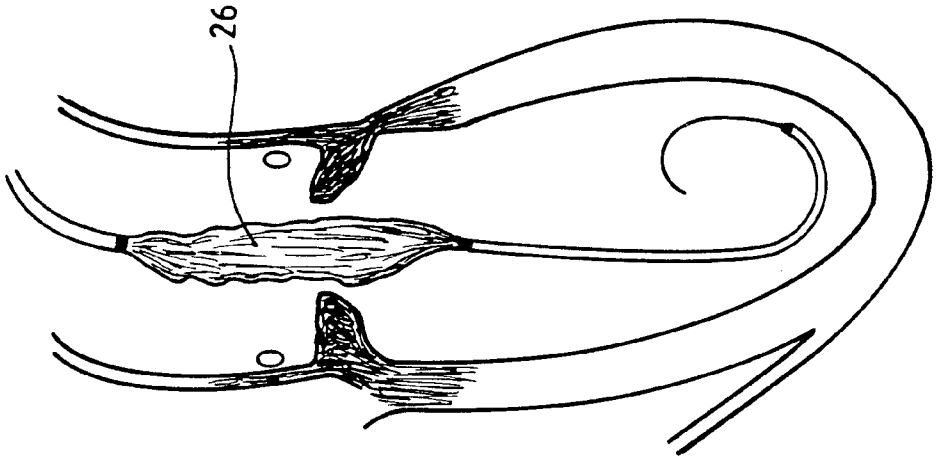


FIG_13e

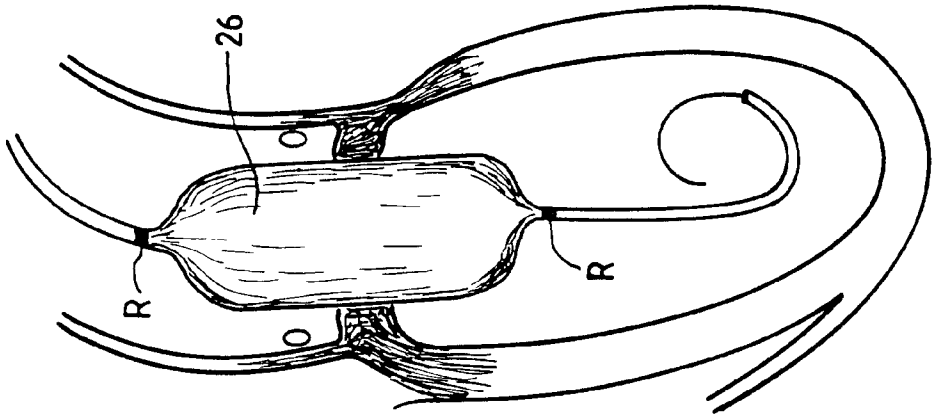


FIG_13d

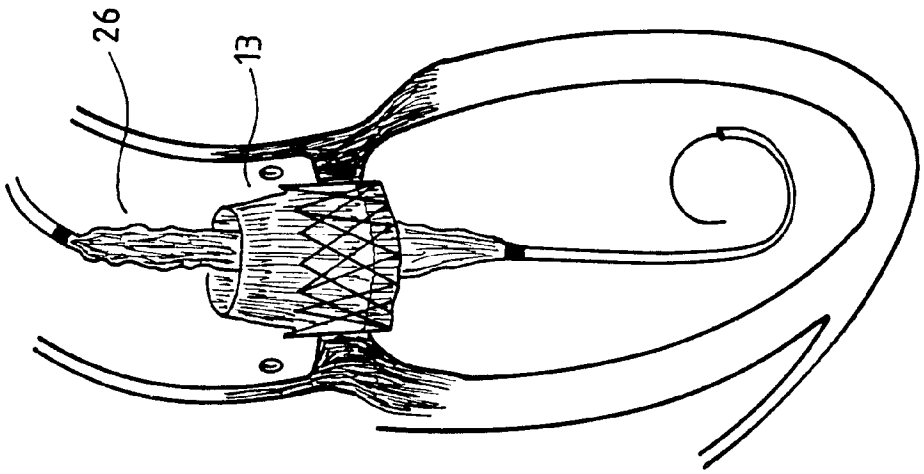


FIG_13i

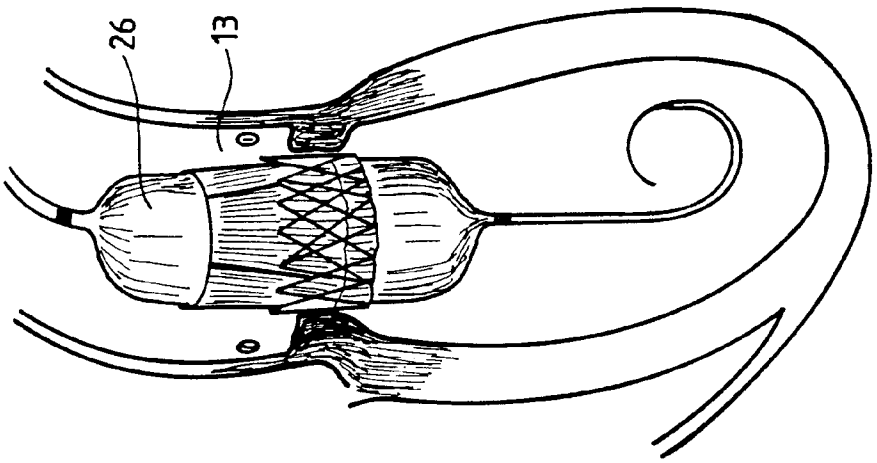


FIG_13h

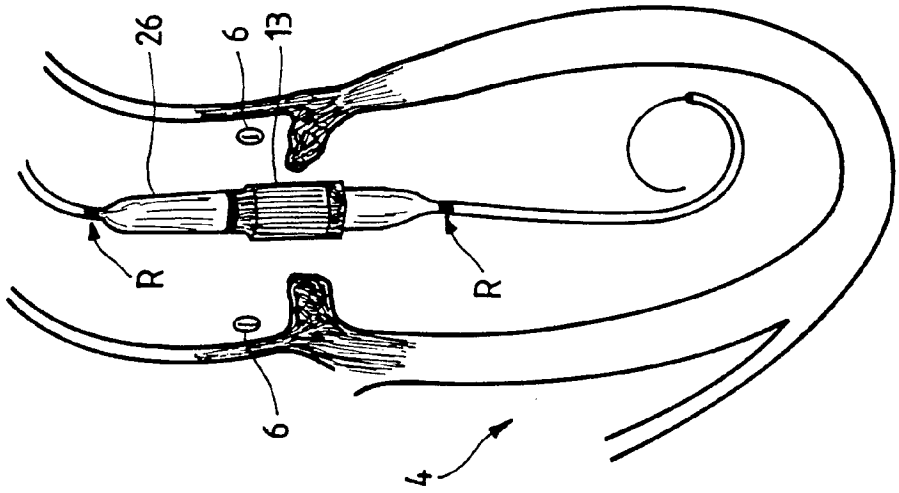


FIG_13g

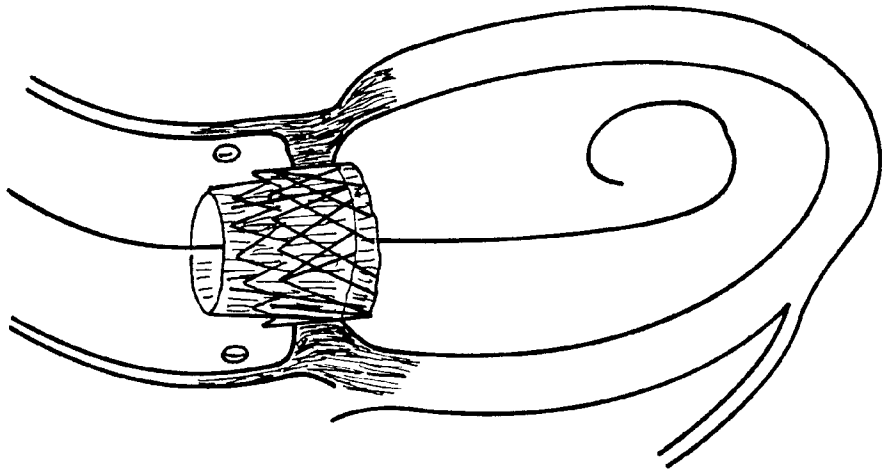


FIG_13l

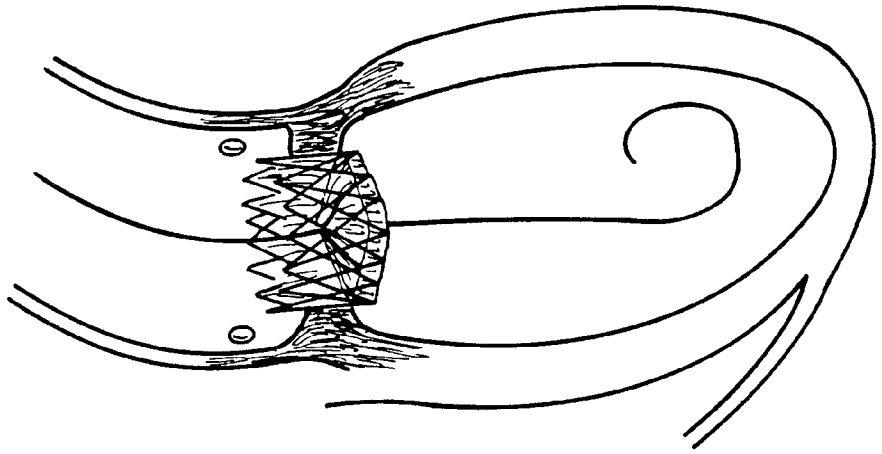


FIG_13k

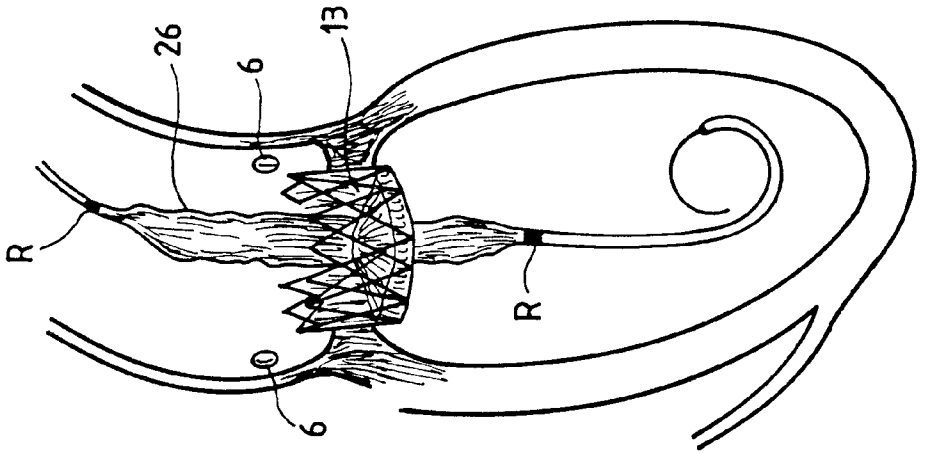
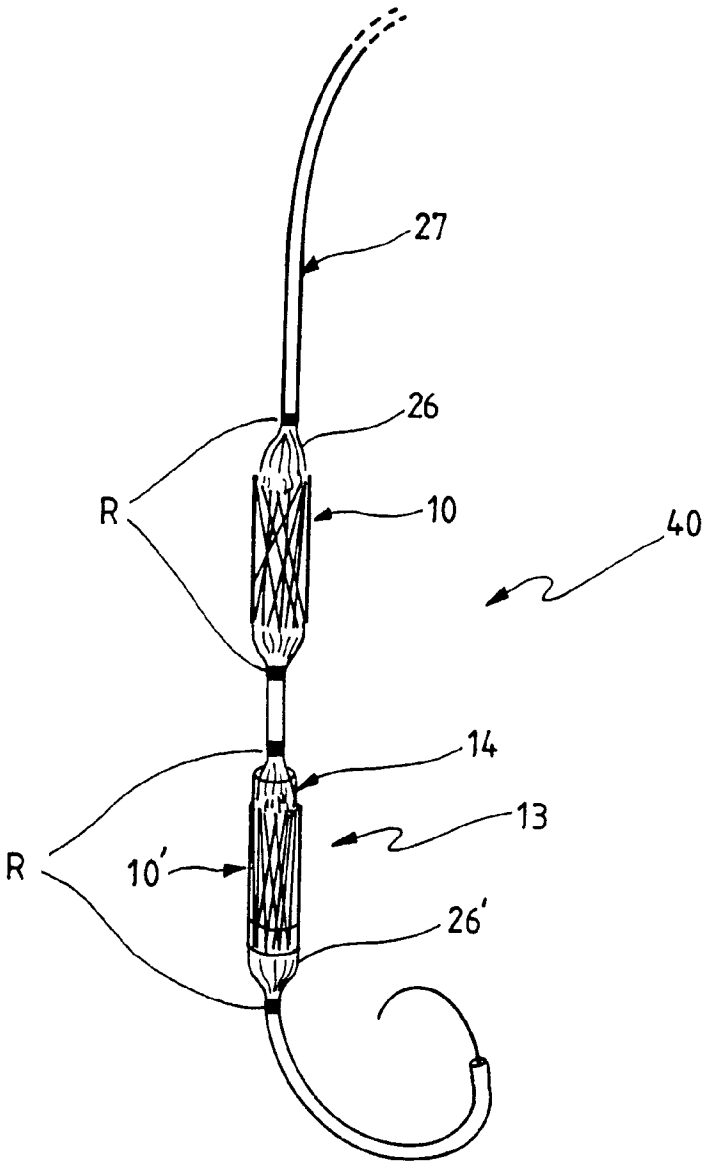


FIG_13j

FIG_14



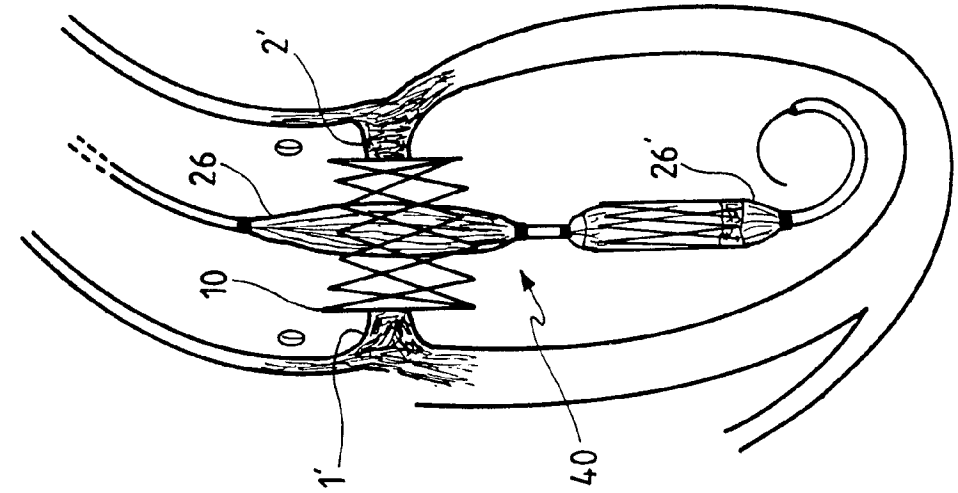


FIG_15c

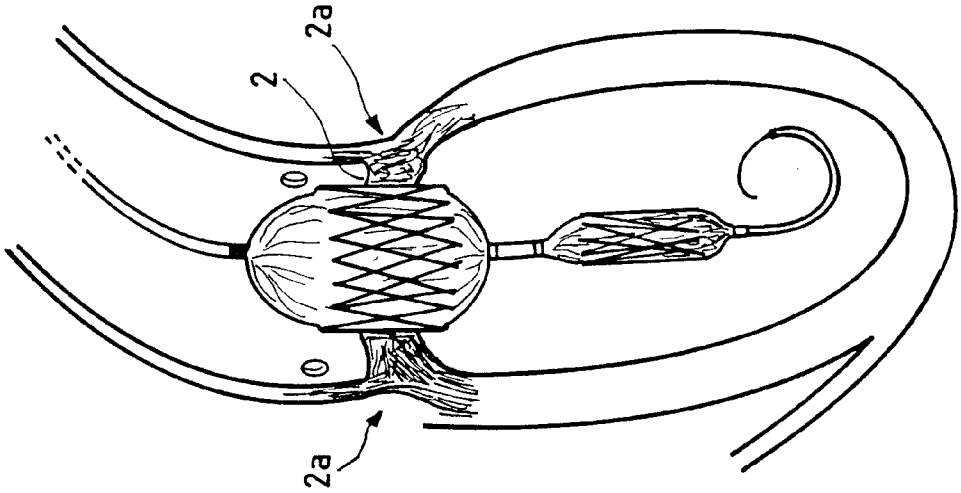


FIG_15b

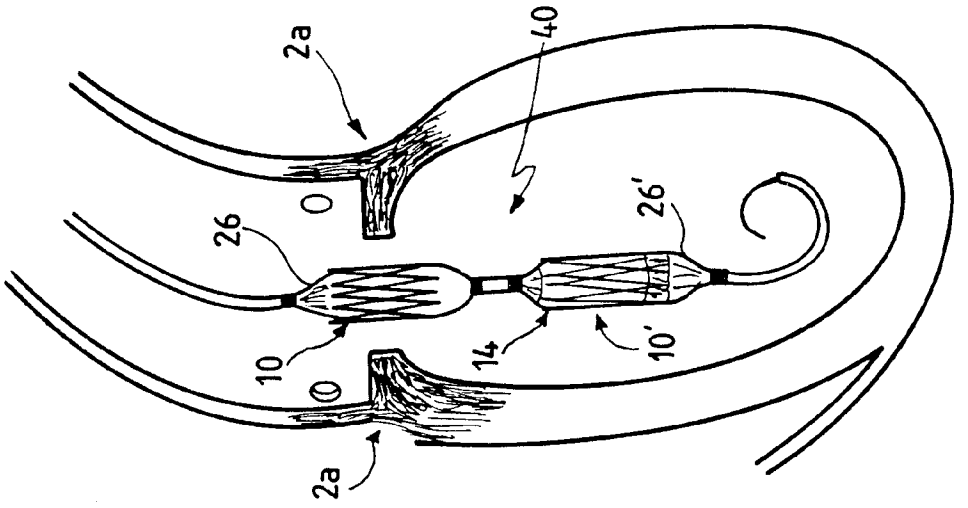


FIG_15a

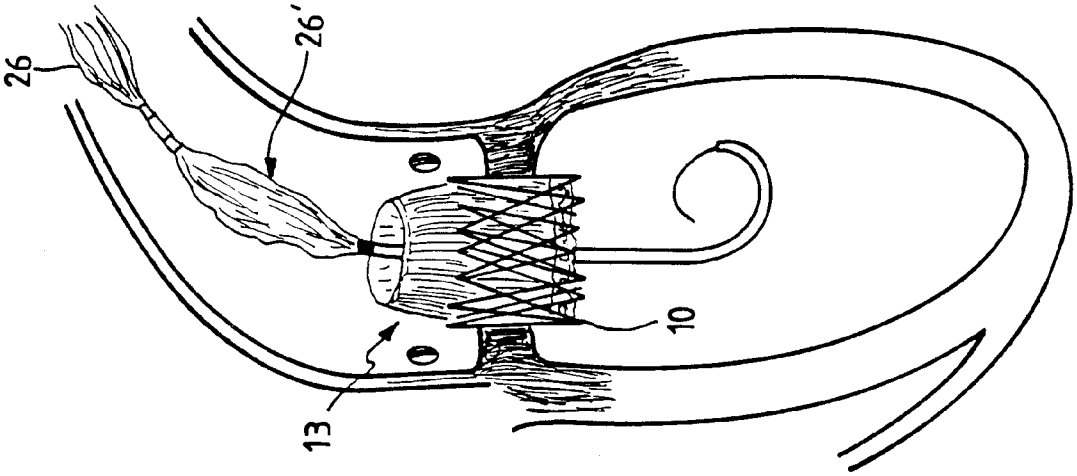


FIG_15f

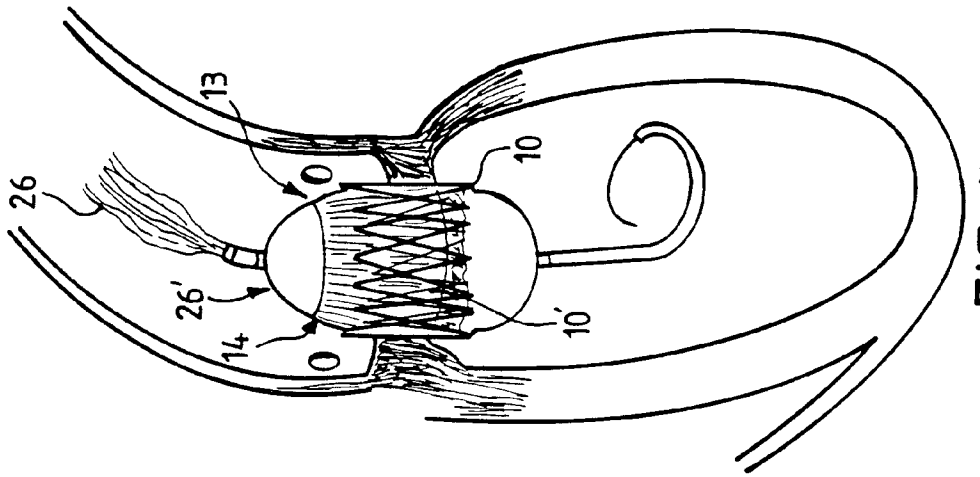


FIG_15e

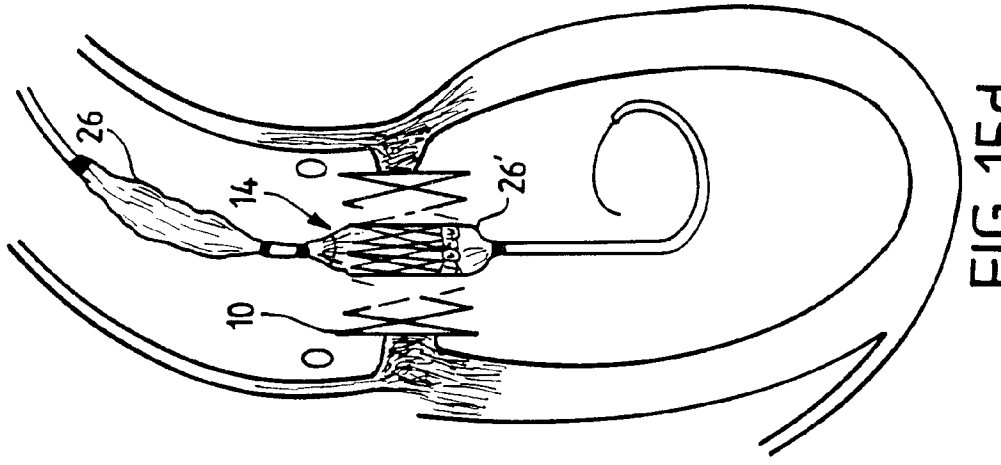


FIG_15d

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 97/07337

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/24

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 411 552 A (ANDERSEN HENNING R ET AL) 2 May 1995 cited in the application see column 5, line 9 - column 6, line 39; claims; figures	1,19,20, 23-25
A	---	7,10,12, 14,21
A	WO 93 01768 A (STEVENS JOHN H) 4 February 1993 -----	1,7,19, 23,24

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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

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Date of the actual completion of the international search	Date of mailing of the international search report
6 May 1998	19. 05. 98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 97/07337

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31,32
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

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

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

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

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

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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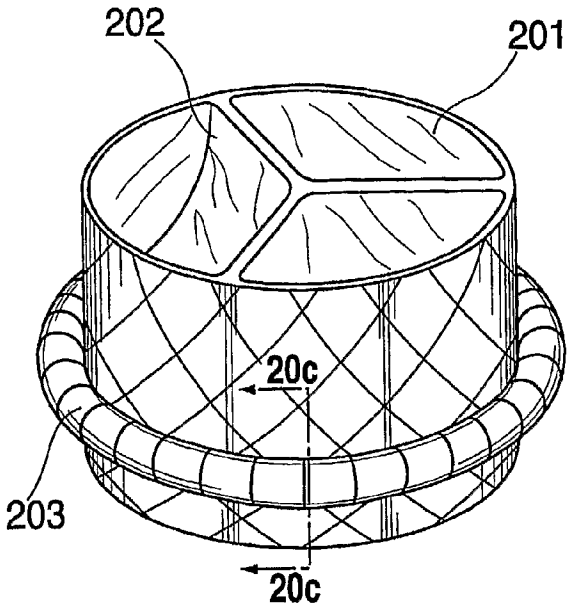
(54) Title: PARAVALVULAR LEAK DETECTION, SEALING AND PREVENTION



(57) Abstract: The present invention provides a series of new percutaneous concepts of paravalvular repairs including identifying the leak location, several repair techniques and finally built-in means for leak prevention, built on percutaneous valves. A catheter-delivered device locates cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

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PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

FIELD OF THE INVENTION

[0001] The present invention relates to implantable devices. More particularly it relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses.

BACKGROUND OF THE INVENTION

[0002] Cardiac valve implantation is well known in the art. Less well addressed is how to detect possible leaks between the valve and surrounding blood vessel, how to seal such leaks, or how to design the valve such that it automatically seals the leaks.

[0003] Machiraju in U.S. Patent No 5,554,184, entitled "HEART VALVE ", describes a heart valve and a technique for effecting valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or a bovine or porcine pericardial or other synthetic sheet material equivalent thereof, preferably in a configuration which substantially restores the original anatomy of the heart, including chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and the two far ends are sutured together to yield a bileaflet valve having appended chordae and tabs.

[0004] Machiraju does not address leaks that can occur around the implanted valve.

[0005] Schreck in U.S. Patent No. 6,454,799, entitled, "MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE", describes expandable heart valves for minimally invasive valve replacement surgeries. In a first embodiment, an expandable pre-assembled heart valve includes a plastically-expandable annular base having a plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided, with the prosthetic section being connected to the commissure posts and defining leaflets therebetween, and the fabric section being attached to the annular base. In a second embodiment, an expandable heart valve includes an annular tissue-engaging base and a subassembly having an elastic wireform and a plurality of leaflets connected thereto. The annular base and subassembly are separately stored and connected just prior to delivery to the host annulus. Preferably the leaflet subassembly is stored in its relaxed configuration to avoid deformation of the leaflets. The expandable heart valves may be implanted using a balloon catheter. Preferably the leaflets of the heart valves are secured to the commissure regions of the expandable stents using a clamping arrangement to reduce stress.

[0006] Schreck also does not address leaks that can occur around the implanted valve.

[0007] Amplatz in U.S. Patent No. 6,638,257, entitled, "INTRAVASCULAR FLOW RESTRICTOR," describes an intravascular flow restrictor that comprises a braided tubular structure designed to be

placed in the main pulmonary artery for limiting blood pressure in the lungs. The braided structure is designed to be collapsed for placement in a delivery catheter, but when it is ejected from the delivery catheter, it assumes a substantially larger diameter disk shaped device having one or more longitudinal channels or passways therethrough.

[0008] Amplatz also does not address leaks that can occur around the implanted valve. In addition, Amplatz's braided structures are of a shape and size not appropriate for paravalvular leak detection and sealing. Their geometry is designed for the conditions of the transceptal hole and not appropriate for valve leakage.

[0009] Spenser et al. in U.S. Patent Application No. 20030153974, entitled "IMPLANTABLE PROSTHETIC VALVE", describe a prosthesis device suitable for implantation in body ducts. The device comprises a support stent bring comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through a body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent bring provided with a plurality of longitudinally rigid support beams of fixed length, and (2) a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet. When flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly to provide blockage to the reverse flow.

[0010] Spenser et al. also do not address leaks that can occur around the implanted valve.

[0011] With regard to the general topic of prosthetic valves, implantation is currently done either through open heart surgery or by use of newer percutaneous methods, some of which are described in the patents mentioned above. With both methods paravalvular leaks are a known side effect. One way to approach the leak problem is to identify the leak location and repair it. Another approach is to equip the prosthesis with means to prevent the leak ("self-sealing" prosthesis). Both these approaches are encompassed by the present invention.

[0012] Percutaneous introduction of medical devices is a preferred surgical procedure for it involves making only a very small perforation in the patient's skin (usually in the groin or armpit area) under local anesthetic sedation. In contrast, surgical placement involves a large chest surgical incision and requires general anesthesia, to expose a large portion of a patient's thoracic region. Percutaneous introduction is therefore considered safer and less invasive.

[0013] Percutaneous introduction of a leak detection and repair device or of a self-sealing valve resembles other known interventional cardiologic procedures. The percutaneous deployment procedure and device has an impact on several parameters of the product design, some of which are explained hereinafter.

[0014] In summary, the present invention provides new concepts of percutaneous paravalvular repair, including means for identifying the leak location, repair techniques, and means for leak prevention that can be engineered into the prosthesis valve itself.

SUMMARY OF THE INVENTION

[0015] In accordance with a preferred embodiment of the present invention, a catheter-delivered device is provided for locating cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The device comprises at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

[0016] Furthermore, in accordance with another preferred embodiment of the present invention, a spacing element is provided to maintain the wires adjacent to the wall of the body vessel.

[0017] There is thus also provided in accordance with a preferred embodiment of the present invention, a catheter-delivered stent for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The stent, which is delivered via a guidewire to the cavity and held in place in the cavity by friction, comprises a support structure and an impermeable membrane, the membrane preventing the passage of fluids through the stent, thereby sealing the cavity.

[0018] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is balloon-expandable and the membrane comprises a tab spring-hinged to the inside of the stent lumen and sized to occlude the lumen when closed. The tab is

held open by the stent balloon during insertion and springs closed when the balloon is removed after the stent is expanded.

[0019] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing stent is self-expandable, wherein the membrane is a material covering at least one end of the stent.

[0020] Furthermore, in accordance with another preferred embodiment of the present invention, the stent is comprised of shape memory material.

[0021] Furthermore, in accordance with another preferred embodiment of the present invention, the material is nitinol.

[0022] Furthermore, in accordance with another preferred embodiment of the present invention, the stent is covered on its external walls with hooks comprised of shape memory material and which extend, upon insertion of the stent, into adjacent body vessel walls.

[0023] Furthermore, in accordance with another preferred embodiment of the present invention, the distal end of the stent-delivery catheter is substantially perpendicular to the wall of the vessel at a point inside the cavity and the stent guidewire terminates in an anchoring mechanism that is inserted through the catheter and into the vessel wall, anchoring itself in the vessel wall and providing greater anchorage for the stent.

[0024] Furthermore, in accordance with another preferred embodiment of the present invention, the anchoring mechanism is a hook comprised of shape memory material that is compressed for catheter

delivery into the vessel wall, whereupon the hook extends out, anchoring the guidewire into the vessel wall.

[0025] Furthermore, in accordance with another preferred embodiment of the present invention, the anchoring mechanism is a threaded point that is threaded into the vessel wall anchoring the guidewire into the vessel wall.

[0026] Also provided in accordance with a preferred embodiment of the present invention, is a device for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The device comprises a first guidewire threaded through the cavity, a second guidewire slidably coupled to the first guidewire and inserted such that the slidable coupling is moved to a desired point in the cavity, a first catheter inserted over the first guidewire to the point in the cavity, a second catheter inserted over the second guidewire to the desired point in the cavity, a first component of a two-component biological adhesive inserted through the first catheter to the desired point, a second component of the two-component adhesive inserted through the second catheter to the desired point, the two components thereby mixing to form a plug that seals the cavity.

[0027] Furthermore, in accordance with another preferred embodiment of the present invention, the device is adapted to apply an adhesive with more than two components.

[0028] Furthermore, in accordance with another preferred embodiment of the present invention, instead of two guidewires and two catheters, a single catheter and guidewire are used for delivery, with the

catheter comprising two lumens, each lumen providing delivery for one of the two-component adhesive components, and the catheter terminates in a mixer that forces the components to mix when they exit the catheter in the cavity, thereby creating the plug that seals the cavity.

[0029] Furthermore, in accordance with another preferred embodiment of the present invention, instead of two-component adhesive components being delivered via the catheters, a radiation-cured adhesive is delivered via one of the catheters and a radiation source is delivered via the other catheter, wherein the radiation source is applied to the adhesive to create the plug in the cavity.

[0030] Also provided in accordance with a preferred embodiment of the present invention is a catheter-delivered assembly for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The assembly is delivered via guidewire to the cavity and comprises two sealing stents connected by a suture, the suture running back up the catheter, the sealing stents comprising a stent structure and sealing membrane. One stent of the assembly is inserted underneath the cavity and the other stent is inserted inside the cavity, the membranes preventing the passage of fluids through the stent, thereby sealing the cavity and each stent helping anchor the other in place.

[0031] There is thus also provided in accordance with a preferred embodiment of the present invention, a prosthetic valve with integrated sealing ring attached to the outside wall, the ring having a circumference greater than that of the valve and elastically conforming to seal cavities

between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0032] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a balloon.

[0033] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of spring-wire tabs mounted adjacent to one another around the circumference of the valve and covered with an impermeable membrane. The tabs are folded against the body of the valve during catheter delivery, and, upon egress from the catheter, the tabs spring out to form the sealing ring.

[0034] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, and further comprises a balloon under the tabs. The tabs are folded down on the deflated balloon during catheter delivery, and, upon egress from the catheter, the balloon is inflated, thereby opening the tabs to form the sealing ring.

[0035] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, each tab spring-hinged to the valve. The tabs are folded against the body of the valve during catheter delivery, and, upon egress from the catheter, the tabs spring out to form the sealing ring.

[0036] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

[0037] Furthermore, in accordance with another preferred embodiment of the present invention, the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

[0038] Furthermore, in accordance with another preferred embodiment of the present invention, the sealing ring comprises modified struts of the stent, the modification comprising geometrical constraints that, upon expansion of the stent, cause the struts to bend out from the stent body, thereby creating the sealing ring.

[0039] There is thus also provided in accordance with a preferred embodiment of the present invention, a prosthetic valve with integrated sealing means, the sealing means comprising sutures attached around the perimeter of the valve and extending back out of the body. Patches can be pushed down the sutures and attached to the point where the suture is attached to the valve, thereby sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0040] There is thus also provided in accordance with a preferred embodiment of the present invention, a catheter-delivered prosthetic valve with integrated sealing means, the sealing means comprising an elastic stent that is first deployed and inside which the valve is deployed. The elastic stent seals any cavity existing between the valve and the wall of

the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

[0041] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for locating cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0042] inserting a balloon mounted on a flexible wire next to the valve,

[0043] wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

[0044] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0045] inserting an impermeable stent into the cavity,

[0046] whereby the stent seals the cavity.

[0047] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0048] inserting a first guidewire into the cavity;

[0049] running a loop attached to a second guidewire over the first guidewire to a point inside the cavity;

[0050] injecting one component of a two-component adhesive through a catheter over the first guidewire to the cavity; and

[0051] injecting the second component of the two-component adhesive through a catheter over the second guidewire to the cavity,

[0052] wherein the components combine to create an adhesive plug that seals the cavity.

[0053] Furthermore, in accordance with another preferred embodiment of the present invention, instead of the first adhesive component, a radiation-cured adhesive is injected and instead of the second adhesive component a radiation source is applied, thereby creating the adhesive plug.

[0054] Furthermore, in accordance with another preferred embodiment of the present invention, only one guidewire is used and the two components are inserted via separate lumens within a single catheter over the guidewire.

[0055] In accordance with yet another preferred embodiment, a stented valve is provided wherein a compressible material, such as a clot or fabric, extends around an exterior portion of the stent. The compressible material may be formed of polyethylene terephthalate (PET) and is configured to expand into the gaps. Furthermore, fibers on the material may be configured to encourage coagulation of blood to further fills the gaps and prevent leakage. In one variation, a tissue growth factor

may be disposed on the material to encourage tissue growth between the material and the surrounding tissue.

[0056] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for providing integrated sealing capability in an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0057] providing an expandable elastic ring around the outside of the valve; and

[0058] expanding the ring,

[0059] wherein the ring seals any cavities.

[0060] There is thus also provided in accordance with a preferred embodiment of the present invention, a method for sealing cavities between an implanted prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole. The method comprises:

[0061] inserting a sealing stent at the distal end of the cavity; and

[0062] inserting a second sealing stent attached to the first stent into the cavity.

BRIEF DESCRIPTION OF THE FIGURES

[0063] To better understand the present invention and appreciate its practical applications, the following Figures are provided and referenced hereafter. It should be noted that the Figures are given as

examples only and in no way limit the scope of the invention as defined in the appended claims. Like components are denoted by like reference numerals.

[0064] Figure 1 illustrates an implanted valve with a cavity creating a paravalvular leak and a device, in accordance with a preferred embodiment of the present invention, comprising a soft guidewire with an inflatable balloon and designed to identify the exact location of the paravalvular leak.

[0065] Figures 2a and 2b depict a plurality of balloons on soft guidewires, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

[0066] Figure 3 illustrates a plurality of balloons on soft guidewires and kept along the perimeter of the blood vessel by a ring, in accordance with another preferred embodiment of the present invention, designed to identify paravalvular leaks around an implanted valve.

[0067] Figures 4a to 4c depict the process, in accordance with another preferred embodiment of the present invention, of inserting a sealing stent over a guidewire to close a paravalvular leak.

[0068] Figures 5a to 5d depict several types of sealing stents, in accordance with another preferred embodiment of the present invention.

[0069] Figures 6a to 6d illustrate blocking a paravalvular leak with a sealing device, in accordance with another preferred embodiment of the present invention, assisted by anchors, which attach the device to the aortic wall (or annulus).

[0070] Figure 7 illustrates an anchoring apparatus, in accordance with another preferred embodiment of the present invention, for achieving sealing as shown in Figure 6, in this case by use of a screw, which is embedded into to the aortic wall (or annulus).

[0071] Figures 8a and 8b depict a leak repair done, in accordance with another preferred embodiment of the present invention, using a two-component biological glue.

[0072] Figures 9a to 9c depict a leak repair done, in accordance with another preferred embodiment of the present invention, using an ultra-violet light-cured biological glue.

[0073] Figure 10 illustrates a catheter, in accordance with another preferred embodiment of the present invention, that inserts a two-component biological glue into a balloon in order to block a paravalvular leak.

[0074] Figures 11a to 11f illustrate a device and procedure, in accordance with another preferred embodiment of the present invention, for blocking a paravalvular leak using two connected sealing stents.

[0075] Figures 12 depicts a valve, in accordance with another preferred embodiment of the present invention, with a built-in inflatable portion allowing to fill gaps between the valve stent and the aortic wall in order to prevent paravalvular leaks.

[0076] Figures 13a to 13d illustrate a valve, in accordance with another preferred embodiment of the present invention, having a flexible and self-expanding portion for blocking possible leaks around the stent.

[0077] Figures 14a to 14c illustrate a valve, in accordance with another preferred embodiment of the present invention, having a having a flexible and self-expanding portion for blocking possible leaks around the stent..

[0078] Figures 15a to 15c illustrate a valve, in accordance with another preferred embodiment of the present invention, having a plurality of flexible and expanding segments on its proximal side for blocking possible leaks around the stent.

[0079] Figures 16a and 16b illustrate a valve device, in accordance with another preferred embodiment of the present invention, comprising an additional portion for blocking possible leaks around the stent.

[0080] Figures 17a to 17e illustrate a valve device, in accordance with another preferred embodiment of the present invention, where the stent is adapted such that when expanded, a portion of the stent is forced to protrude radially, thereby blocking possible leaks.

[0081] Figures 18a to 18e illustrate a valve, in accordance with another preferred embodiment of the present invention, constructed with additional sutures attached to the proximal side, allowing attachment of extra pieces of pericardium or artificial fabric for blocking paravalvular leaks.

[0082] Figures 19a to 19d depict a procedure, in accordance with another preferred embodiment of the present invention, the procedure comprising two stages: first, insertion of a stent that includes an outer sealing layer; and second, insertion of a prosthetic valve through the stent.

[0083] Figures 20a to 20g illustrate a valve, in accordance with another preferred embodiment of the present invention, having a sealing element made of a flexible and expandable material for blocking leaks around the stent.

[0084] Figure 21 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein the sealing element is attached to the valve in a sealing line for providing an improved crimped profile.

[0085] Figure 22 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve.

DETAILED DESCRIPTION OF THE INVENTION

[0086] The present invention provides methods and apparatuses for substantially reducing or effectively eliminating the deleterious effects of paravalvular leaks in prosthetic valves. More specifically, it enables locating, sealing, and preventing paravalvular leaks using both dedicated and integrated (with the valve) means.

[0087] While the present invention is particularly suited for prosthetic heart valve leaks, such as a prosthetic aortic valve, it can also be applied to other leakage problems such as in other blood vessels, a septum, or other body lumens. Similarly, while the prosthetic valve described herein is a tricuspid valve, it could be another type of valve as well.

[0088] A main aspect of the present invention is the introduction of several novel designs and methods for locating paravalvular leaks in prosthetic valves.

[0089] Another main aspect of the present invention are several novel designs for sealing paravalvular leaks detected in prosthetic valves.

[0090] Another main aspect of the present invention are several novel designs for modifying percutaneous prosthetic valves to automatically seal paravalvular leaks when the valve is implanted.

[0091] Another main aspect of the present invention is a novel design that automatically seals paravalvular leaks when the valve is implanted without requiring valve modification.

[0092] Another main aspect of the present invention is the disclosure of several novel designs for modifying percutaneous prosthetic valves to enable sealing of paravalvular leaks after the valve is implanted.

[0093] For locating paravalvular leaks, the present invention provides several designs comprising catheter-delivered balloons mounted on flexible guidewires. The balloons are delivered to a point near the valve. When regurgitation (leaking) occurs during diastole, the balloons are drawn into the leak-producing cavities occurring between the valve and the wall of the blood vessel, thereby providing a means to deliver means for sealing the leak.

[0094] For sealing paravalvular leaks, the present invention provides several designs including sealing stents, and multi-component and radiation-cured adhesive compounds.

[0095] Sealing stents are crimped stents that are delivered to the leak location, expanded, and anchored in place. The stents are designed to block flow, thereby sealing the leak. Several innovations are provided for these operations.

[0096] Delivery of the sealing stent is via a guidewire that is anchored in the wall of the blood vessel at the leak location. The anchoring means can be a hook, for example a multi-headed hook composed of a shape memory alloy, such as nickel titanium (also known as nitinol), which is crimped at low temperature for delivery. The anchoring means expands back to its original shape due to the higher temperature of the blood vessel wall at its deployment point, thereby anchoring itself into the blood vessel wall.

[0097] Another anchoring means is for the guidewire to be terminated in a screw, which can be threaded into the blood vessel wall.

[0098] Once delivered to the leak location via the guidewire, the sealed stent is expanded. This can be done by another agent, such as a balloon, or by making the stent self-expanding. In the case of balloon inflation, the stent is crimped around the deflated balloon prior to insertion in the delivery catheter. Upon delivery the balloon is inflated, thereby expanding the stent, and then the balloons can be deflated and withdrawn. In the case of the self-expanding stent, the stent is preferably built from a shape memory alloy, such as nickel titanium (also known as nitinol), which can be crimped at low temperature for delivery, expanding back to its original shape due to the higher body temperature at the deployment site. Alternatively the self-expanding stent can be a metallic stent comprised of a physiologically acceptable metal such as stainless

steel or an alloy such as nitinol, which is compressed or wound on a delivery, catheter or device. When the stent is released from the delivery catheter or device, it expands.

[0099] The sealing stent is held in place by friction. Additional holding force can be obtained by adding hooks around the perimeter of the stent, such as self-expanding hooks made of shape memory alloy.

[00100] The expanded stent includes an internal element that seals the stent's own lumen, preventing flow through the stent and thereby sealing the cavity causing the leak. Examples of internal sealing elements include a spring-hinged flap inside the stent lumen that opens upon stent expansion or, in the case of the self-expanding stent, a membrane covering one or both openings of the stent.

[00101] In some cases, it may be preferred to use two sealing stents. In this embodiment, the two stents are connected in series by a suture. The delivery catheter is extended through the top of the cavity and out the bottom of the cavity to deploy one of the sealing stents and then, together with the stents' guide wire, retracted. This pulls the deployed stent back until it catches in the bottom of the cavity. The catheter is further retracted, and the second stent is deployed into the cavity. The catheter is further retracted and the second stent is pulled back, catching it (from the bottom) in the top of the cavity.

[00102] An alternative sealing element to the sealing stent is a biological adhesive compound that can be delivered to the cavity via catheterization. In such a case, two catheters are brought to the leak location. The catheters are used in one of the following ways: to deliver two adhesive components that, when mixed, harden to form an adhesive

sealing plug, or to deliver a radiation-cured adhesive and the cure source, for example an ultra-violet light source, to produce an adhesive sealing plug.

[00103] In both sealing element designs there is a need to bring the distal catheter ends in close proximity to one another, for proper mixing or curing, at the leak point. This is accomplished as follows: a first catheter is used to insert the leak detector guidewire mentioned above. A second guidewire is fitted with a loop, and the loop is run over the first guidewire until it reaches the leak location. The respective cathethers are then slid over their guidewires to meet at the leak location, thereby providing egress for applying the bi-component adhesive or radiation-cured adhesive.

[00104] Another delivery design for a bi-component adhesive utilizes a single catheter run over the leak detection guidewire. The catheter has three lumens: one to track the guidewire and one for each adhesive component. A mixing means at the distal end of the catheter mixes the components at the leak location to form the sealing plug.

[00105] In other embodiments of the present invention, leak sealing means are integrated into the valve as an impermeable ring that, when the valve is implanted, adaptively seals any gaps between the valve and the surrounding lumen.

[00106] In one embodiment of such a self-sealing valve, the ring is deflated for delivery and then inflated for sealing.

[00107] In another self-sealing valve embodiment, the ring is a sponge-like material that is compressed for delivery and then expands for sealing.

[00108] In another self-sealing valve embodiment, the ring comprises a set of flaps that are closed for delivery and are opened either by balloon inflation, by the geometry of their connection to the valve, or by spring-action.

[00109] In another self-sealing valve embodiment, the ring comprises a set of self-expanding tubes.

[00110] In another self-sealing valve embodiment, the ring comprises struts of the valve's stent that are geometrically constrained to bend and enlarge their final diameter in respect to the main stent geometry when expanded from the crimped form

[00111] In another embodiment where sealing means are built into the valve, a set of filament pairs are attached around the valve and feed back to the delivery catheter ingress. When a paravalvular leak is detected, impermeable patches of a material such as pericardium are threaded onto the local filament pair and pushed down to the leak location where they are tied off in place.

[00112] In another embodiment of the present invention, a sealing stent is first inserted into the lumen, and then the valve is inserted inside the sealing stent.

[00113] The aforementioned embodiments as well as other embodiments, manufacturing methods, different designs and different types of devices are discussed with reference to the drawings. Note that

the drawings are only given for the purpose of understanding the present invention and presenting some preferred embodiments of the present invention. The drawings are not meant to limit the scope of the present invention as defined in the appended claims.

[00114] Figure 1 illustrates a simple leak detector 27 in accordance with a preferred embodiment of the present invention. Leak detector 27 detects a leak between general tricuspid implantable prosthesis valve 20 and the aortic annulus 22. Leak detector 27 will typically be used together with leak sealing devices, like those described later in this specification.

[00115] A cavity 24 exists between the perimeter of valve 20 and aortic annulus 22. The cavity could have any number of causes, including calcification or other irregularities in the aortic annulus 22 that prevent proper sealing between the valve 20 and the annulus 22. The cavity will cause regurgitation (leaking) during diastole, characterized by blood flowing 25 from the aorta into the left ventricle. Leak detector 27, is delivered through catheter 21 to a position above valve 20. Leak detector 27 comprises a soft guide wire 28 on which is mounted inflatable balloon 29, which is inflated after leak detector 27 has been passed through catheter 21. Guidewire 28 is soft enough that during diastole inflated balloon 29 is drawn into the regurgitation flow and lodges in cavity 24 in between valve 20 and annulus 22.

[00116] Figures 2a and 2b depict a multiple leak detector 228 that is similar to leak detector 27 of Figure 1 but which comprises a plurality of soft guidewires 31 rather than just the single guidewire 28 of detector 27. On each guidewire 31 is mounted a balloon 35. Figure 2b is a top view showing valve 20 during diastole. Two cavities 24 cause a flow of blood,

which pulls the balloon 35 closest to each cavity 24 into that cavity while remaining balloons 35 stay stationary. At this point, cavity 24 locations can be determined and marked and the cavities repaired.

[00117] Figure 3 illustrates an annular-configured leak detector 229, which incorporates an adaptation that can be used to force wire(s) 40 of leak detector 27 or multiple-leak detector 228 (implementation shown) to remain close to aortic wall 45 rather than being allowed to drift to the center of the aorta. The advantage of this adaptation is that, in the case of detectors 27 and 228, if there is a central leak in valve 20, a balloon near the center of the aorta might be drawn into the central leak instead of to the paravalvular cavity, thereby indicating a false paravalvular leak. Spacing ring 40 is a compressible wire ring that pops open after catheter 21 delivery. Guidewire(s) 42 are distributively attached to the external edge of ring 40 and are thereby held by the ring against the aortic wall 45.

[00118] Figures 4a to 4c depict an implantable valve 49 deployed in the native aortic valve position, creating a cavity 24, which causes paravalvular regurgitation (leak) during diastole. In Figure 4a, guidewire 46, which can be a leak detection device like those shown in Figures 1, 2, and 3, is inserted through cavity 24. Balloon 33 is deflated. In Figure 4b, a balloon-expandable sealing stent (stent with an impermeable membrane that prevents the passage of fluids through the stent), is catheter-deployed over guidewire 46. Balloon 33 is inflated, causing balloon-expandable sealing stent 47 to be expanded, thereby sealing cavity 24 and stopping the paravalvular leak. Figure 4c shows a similar leak repair with the difference that a self-expanding sealing stent 48 is used, and therefore balloon inflation is not required. The sealing stents 47 and 48 are anchored by friction between themselves and the surrounding aortic

annulus. Means for providing stronger anchoring for sealing stents are described later in this specification.

[00119] Figures 5a and 5b illustrate an embodiment of a balloon-expandable sealing stent (such as that used in Figure 4b) in accordance with another preferred embodiment of the present invention. The outer part 51 of the stent is made of a material that can be reshaped by plastic deformation. Sealing element 52, comprising an impermeable membrane, is connected to the inside wall of outer part 51 by spring hinge 53. The balloon-expandable sealing stent 47 is crimped on balloon 55. Once balloon 55 has reached cavity 24, the balloon is inflated, thereby expanding the sealing stent (Figure 5a). Balloon 33 is then deflated, whereupon (Figure 5b) sealing element 52 is forced by spring 53 to close and seal the lumen of the stent.

[00120] Figures 5c and 5d show a self-expanding sealing stent (such as that used in Figure 4c) in accordance with another preferred embodiment of the present invention. One way to implement the self-expanding sealing stent is to build stent framework 56 from a shape memory material such as nitinol 56 and cover it with a layer of impermeable material 58. The self-expanding sealing stent is catheter-delivered to the cavity, whereupon the stent opens, its shape adjusting to the shape of the cavity and its impermeable covering 58 sealing the cavity, to prevent the paravalvular regurgitation. To anchor the self-expanding sealing stent in place, hooks 59 can be included on framework 56. Hooks 59 are attached to framework 56 and extend through sealing material 58 and into the wall of the aortic annulus. The hooks are self-extending. One way to implement them is to make them from a shape memory material such as nitinol.

[00121] Figures 6a to 6d illustrate a technique for anchoring a sealing stent 66 (such as balloon-expandable sealing stent 47 or self-expanding sealing stent 48) into an open cavity 24, which is situated between aortic annulus 63 and prosthetic valve 20, and which creates paravalvular regurgitation. In Figure 6a, a guidewire 61 is led through cavity 24 by balloon 29 (this can be done with a device such as those disclosed in Figures 1 to 3). Guiding catheter 603 is fed over the guidewire, and the guidewire is removed. In Figure 6b an additional wire, anchoring wire 67, which terminates in anchoring apparatus 65, is inserted through catheter 63 to the anchoring location in cavity 24. Anchor 65 is a hook with one or more hook heads that can be compressed for delivery and will spring back to their original position when the delivery compression is removed (in other words, when the device emerges from the delivery catheter). Anchor 65 could be composed of flexible metal or a shape memory compound. Anchor 65 penetrates the aortic annulus at an approximately perpendicular angle due to the angled tip of guiding catheter 603. Figure 6c shows sealing stent 66 inserted via anchoring wire 67 and expanded to seal the cavity by one of the methods described in Figure 4 or 5. In the case shown in Figure 6c, a self expandable sealing stent as described in Figure 4 is shown. This method enables improved anchoring forces in comparison to friction alone, which is the sole anchoring for the embodiments shown Figures 4 and 5. Figure 6d shows the final step of the procedure, where the wire is detached from the anchor at detaching point 68.

[00122] Figure 7 depicts an apparatus that is similar to that illustrated in Figure 6, only here anchor 65 is implemented as a screw tip 69. The anchoring is accomplished by rotating anchoring wire 67, thereby threading tip 69 into aortic annulus 22.

[00123] Figures 8a to 8d demonstrate an apparatus for repairing a paravalvular leak by means of biological bi-component adhesive material (such as an epoxy resin), the components of which are in liquid form and turn to solid when mixed, in accordance with another preferred embodiment of the present invention. The leak is caused by an open cavity between valve 20 and annulus 22. A leak detector, such as those shown in Figures 1 to 3, is used to run guidewire 83 through cavity 24. A second guidewire 84 with a slide element 85 is slid over the first guide wire 83. Slide element 85 enables second guidewire 84 to slide over first guidewire 28 and can be a ring at the end of second wire 84. In Figure 8b, when slide element 85 and first guidewire 83 reach a point approximately midway through cavity 24, catheters 86 and 87 are slid over guidewires 28 and 84, respectively, until the catheters meet at meeting point 75.

[00124] In Figure 8c one of the components of a biological bi-component adhesive material is injected via catheter 86, and the other component is injected via catheter 87. The liquid adhesive components meet at the catheter outlets at meeting point 75, mixing to create the adhesive blocking element 89, which repairs the paravalvular leak by closing cavity 24. Figure 8d depicts a top view of the final result of the repaired cavity showing that adhesive blocking element has been formed to seal cavity 24 between valve 20 and annulus 22.

[00125] Figure 9 illustrates another apparatus for blocking a leak by means of biological adhesive in accordance with another preferred embodiment of the present invention. Again, two guidewires meet at meeting point 75, and catheters, in this case 91 and 93, are fed over the guidewires to meeting point 75. However, in this case the blocking adhesive material comprises one liquid component that is solidified by the

presence of ultra-violet light or another radiation cure. The liquid adhesive material is inserted into cavity 24 at catheter meeting point 75 via catheter 91. Active wave 96 shining through light probe catheter 93 hardens the material, creating sealing block 95, which closes the leak caused by cavity 24.

[00126] Figures 10a to 10e illustrate another apparatus for repairing a paravalvular leak using a bi-component adhesive material in accordance with another preferred embodiment of the present invention. Figure 10a shows a multiple-lumen catheter 100 that can be slid over guidewire 99 to the desired location, inside cavity 24 between aorta 82 and prosthetic valve 81. Figure 10b is a cross-section of the catheter 100's multiple-lumen shaft. Lumens 102 and 103 provide means of approach for the separate components of the adhesive. Lumen 104 provides means for catheter to be fed over guidewire 28. Figure 10c shows a bi-component adhesive infusion chamber 100 in the form of a double syringe connected to the end of catheter 100 that is proximal to the medical operator. Figure 10d illustrates a mixing element 105 located at the distal end of catheter 100 (its location can be seen in Figure 10a). Mixing element 105 serves to mix the two adhesive components as they emerge from distal end of catheter 100 after being forced out of chamber 101, thereby ensuring that they will solidify and cure inside cavity 24. Figure 10e shows the adhesive components after they have been infused by chamber 101 via multiple-lumen catheter 100 and mixing element 105 into cavity 24 to form a plug. The cured adhesive fills the cavity and blocks the leak. Also shown in Figure 10e is an optional flexible mesh bag 106, which receives and holds the adhesive mix. The bag prevents possible migration of adhesive material during insertion and prevents the adhesive from passing through stent struts 108 in cases where such valve designs are present.

[00127] Figures 11a to 11f illustrate an apparatus for repairing a paravalvular leak in accordance with another preferred embodiment of the present invention. Two self-expanding sealing stents 110 are connected by suture 112 and pushed into insertion catheter 111 (Figure 11b). At this stage, insertion into the catheter has reduced the stents' diameter, enabling them to enter a cavity 24 between a prosthetic valve and surrounding blood vessel. Figures 11c and 11d depict an implanted valve 115 where two large calcifications 116 create cavity 117, which causes regurgitation and must be repaired. (The calcification is just one example of a condition that creates a cavity that must be repaired. The cavity could equally have been caused by other factors, the cause is not determinant for the embodiment.) Figure 11e depicts insertion catheter 111 inserted over guidewire 28 to a point where the distal (delivery) end of the catheter has passed through the bottom of cavity 117. A first sealing stent 110 is deployed below the bottom of cavity 117. Catheter 111 is withdrawn and suture 112 is partially retracted, pulling the first sealing stent 110 into the bottom of the cavity, where it lodges. With reference to Figure 11f, insertion catheter 111 is withdrawn until its distal end is near the top of cavity 24, whereupon a second sealing stent 110 is deployed. Suture 112 is further retracted, pulling the second stent into the top of the cavity, where it lodges. The final step of the procedure is to disconnect the proximal part of the suture at point 119.

[00128] Figure 12 depicts a valve adapted to seal paravalvular leaks in accordance with a preferred embodiment of the present invention. Valve 121 is held in holder stent 124 with sealing element 120 attached circumferentially around stent 124's outer surface. When valve 121 is implanted, sealing element 120 is expanded to seal any peripheral paravalvular leaks. Several means can be used to implement expansion of

sealing element 120. In the implementation shown in Figure 12, sealing element 120 is inflated by operator application of syringe 123, and it constitutes a balloon-like portion, made of a pliant physiologically acceptable polymeric material such as polyurethane. The inflation media can be saline solution, the patient's blood, or another physiologically acceptable fluid.

[00129] Alternatively, the sealing portion can be made of a material that, on contact with a fluid, soaks up the fluid and swells up. Once inserted into the body, the sealing portion comes into contact with the blood, causing it to swell and seal the cavity.

[00130] Figures 13a to 13d depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Figure 13a depicts an implantable valve 124. Stent 125 has a sealing component 126 connected to its inlet. Sealing component 126 is comprised of a plurality of flaps 127 and expands to a larger diameter than the principal diameter of the stent 125, creating an extra sealing line to prevent paravalvular leaks. Figure 13b depicts a top view of valve 124. Sealing component 126 comprises a plurality of flaps 127 that, independent of one another, are connected to the valve stent 125. Each flap 127 is made of spring wire 131, which, after the valve is deployed, causes flap 127 to extend out. Flaps 127 are covered with impermeable sealing material 128. Flaps 127 are arranged such that they are substantially perpendicular to the longitudinal axis of stent 124 and overlap one another, ensuring a full seal.

[00131] Figure 13c shows stent-mounted valve 124 in its crimped configuration. Introducing sheath tube 130 holds stent 125 and sealing

component 126 crimped on balloon 129. After deployment, flaps 127 of sealing component 126 open to their final diameter.

[00132] Figure 13d shows a cross-section of a self-expanding sealing flap 127. Stent strut 133 is attached to spring wire ring 131 by mechanical attachment means 134, which can be a rivet, a screw, etc. Spring wire ring 131 can be folded into introducing sheath tube 130 shown in Figure 13c and, when released from tube 130, springs back to its shape as shown in Figure 13d.

[00133] Figure 14 illustrates a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. This design includes balloon-inflatable stent 140 (containing a prosthetic valve) and balloon-inflated sealing ring 145, which is similar to sealing component 126 of Figure 13, only here balloon-inflatable wire 145 is used instead of spring wire ring 131. Stent 140 is inflated using a double balloon. First balloon section 142 inflates stent 140 to the desired diameter, and then second balloon section 143 inflates sealing flaps 145 perpendicular to stent 140, creating a larger diameter and thus sealing any cavities around the stent.

[00134] Figures 15a and 15b depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. In this embodiment the sealing ring comprises flexible sealing elements 150. Each sealing element 150 is independently spring-actuated. When the valve is crimped, sealing elements 150 fold, enabling valve to be reduced to a small diameter for insertion. When valve is expanded to its final diameter, sealing elements 150 open to a larger diameter 154 to seal cavities around the valve, preventing

paravalvular leaks. Since each sealing element 150 is independent, sealing elements adjacent to native valve tissue 152 remain closed. These closed elements provide a further benefit of adding compressive forces that improve the anchoring of the valve.

[00135] Figures 16a to 16c depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention. Here the sealing ring 165 comprises at least one of a plurality of flexible, self-expanding sealing elements 165 connected to the outer surface of stent 160. Similar to the embodiment shown in Figure 15, when stent 160 is pressed against the native tissue, sealing element 165 will stay compressed against the wall. But where there is a gap between stent 160 and the surrounding tissue, sealing element 165 will expand and block any possible leak. With reference to Figure 16b, sealing element 165 is made of self-expanding mesh 166 covered with PET (polyethylene terephthalate) mesh 167 or other impermeable material.

[00136] Figures 17a to 17e depict a valve adapted to seal paravalvular leaks in accordance with another preferred embodiment of the present invention, wherein the sealing component is built into a ring 172 of the stent struts. In the figure the ring of struts 172 is located at the stent's inlet; however, the ring of struts can equally be implemented at another point along the stent. The modified struts 173 comprising ring of struts 172 are designed so that they are geometrically constrained such that, upon expansion of the stent from crimped state (Figure 17a) to expanded state (Figure 17b), ring of struts 172 bend to a final diameter 169 substantially larger than the final diameter 168 of the rest of the expanded stent, thereby sealing paravalvular cavities and associate leaks.

[00137] Figures 17c and 17d show front and side views of the geometrical restriction in modified strut 173 that causes the displacement of point 175, creating enlarged diameter 169. Figure 17c shows modified strut 173 before stent expansion and in line with the rest of the stent wall. Figure 17d shows modified strut 173 after stent expansion, which has caused modified strut 173 to rise up and out, creating the sealing ring. Figure 17e details the operation of the geometric restriction: when stent 170 is crimped, the strut legs are relatively close to each other 176, making strut height relatively large 177. After expansion, the strut legs are spaced further apart 176a, leading to displacement of point 175, and lessening of strut height 177a. The result of the movement of point 175 is shown in Figures 17c, 17d, and 17e. When the stent is crimped, as shown in Figure 17c and the left side of Figure 17e, point 175 is low. When the stent is expanded, as shown in the right side of Figure 17e, point 175 moves up, pulling the stent to the shape shown in 17d .

[00138] Figures 18a to 18e depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. In Figure 18a percutaneous valve 180 crimped on balloon 182 is shown being advanced toward the stenotic aortic valve 175. At least one of a plurality of sutures 181 are connected to valve 180 at inlet end 187. The sutures spread back along the balloon's shaft 183 and continue back along the deployment path and out of the patient's body as shown in Figure 18b.

[00139] Inflating balloon 183, as shown in Figure 18c, anchors valve 185 in annulus 179 with sutures 181 arranged around it. In cases where paravalvular cavities 178 are present, it is possible to repair them assisted by sutures 181. Figure 18d shows a patch 189 made of

pericardium (or other suitable patch material) inserted on sutures 181 and pushed to the leaking cavity by means of a pushing catheter 190. After the patch is in place, a knot or clip 191 is used to secure it, thereby repairing the leak (18e).

[00140] Figures 19a to19d depict a valve adapted to include means for sealing paravalvular leaks in accordance with another preferred embodiment of the present invention. First elastic sealing stent 195 is inserted in the desired location. Then, valve 196 is inserted into sealing stent 195. Figure 19a shows inserting catheter 191 with sealing stent 195 and valve 196 mounted on it. Sealing stent 195 and valve 196 can be either balloon inflated as shown in this figure, or self-expanding which would then require an introducing sheath.

[00141] Figure 19b shows the two stents placed in the native aortic valve. Sealing stent 195 compensates for irregular shapes, while the stented valve 196, which is mounted inside sealing stent 195, can be absolutely round. Sealing stent 195 is able to avoid leaks caused by cavities or irregularities caused by pieces of calcification as described earlier in this patent. The sealing component of sealing stent 195 can be self-expandable hydrophilic sponge 197 (Figure 19c) or other suitable material. Sealing stent 195 can include hooks 198 that open when the stent is inserted, improving the anchoring of the stent in the annulus as well as improving sealing around the stent by blocking blood (Figure 19d).

[00142] Figure 20a depicts a stented valve 201 having a valvular structure 202 along an interior region and a mechanism along an exterior region for sealing paravalvular leaks in accordance with yet another

preferred embodiment. In this embodiment, a flexible sealing element 203 provides a sealing ring. The sealing element 203 may be formed of any material suitable for implantation in the human body, such as, for example, a sponge material. When the stented valve 201 is crimped to a smaller diameter, sealing element 203 is also crimped, thereby enabling valve to be easily advanced to a treatment site. For purposes of illustration, figure 20f illustrates sealing element 203 before crimping, while Figure 20g illustrates sealing element in a crimped condition. When the valve is expanded to its final diameter, sealing element 203 expands to its original size diameter by internal spring forces and/or by absorbing blood. Expansion of the sealing element seals cavities around the valve and thereby prevents paravalvular leaks. In addition to the mechanical effect of blocking cavities, blood protein preferably adheres to the sealing element, thereby causing coagulation for further leak prevention. Figures 20c and 20d provide cross-sectional views of preferred sealing elements. A tubular form 203a shown in figure 20c is configured to be crimped to a smaller size than a rod form 203b shown in figure 20d. Figure 20e illustrates the sealing element with additional fibers 206, which increase the active surface, thus increasing the effect of protein adhesion and enhancing coagulation and sealing. Figure 20e also illustrates a suture 207 as one preferred means for attachment to the valve body. Figure 20b is a perspective view illustrating another preferred embodiment of a valve 210 having a sealing mechanism. In this variation, two sealing elements 204, 205 are provided along an exterior region.

[00143] Figure 21 depicts yet another stented valve 220 adapted to seal paravalvular leaks. In this embodiment, a sealing element 223, which is preferably made of the same materials described above with

respect to figures 20a through 20g, is attached to the stent in a non-linear sealing line. In preferred configurations, the line can be adjacent to the connection of a valvular structure 222 to the stent or according to the lines of the stent structure. In one feature, an improved crimped profile may be achieved using the illustrated attachment line.

[00144] Figure 22 depicts yet another stented valve 250 configured to reduce or prevent paravalvular leaks. The stented valve generally comprises an expandable stent structure 252 which supports a valvular structure 254. The stent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration.

[00145] To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252. The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve. In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm. In certain configurations, the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material. In various embodiments, the fibers may be straight, curved or hook-shaped. The compressible material expands after deployment at a treatment site. As the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue. Accordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage. In addition, the compressible material, and especially the fibers, may be adapted to encourage

coagulation of blood to further fill the gaps and prevent leakage. In an alternative configuration, a tissue growth factor may be applied to the compressible material for promoting the growth of tissue into the material, thereby further sealing the gaps. Any suitable tissue growth factor may be used. In various preferred methods, the growth factor may be applied along the outer surface of the compressible material or the material may be soaked or dipped in the growth factor before use.

[00146] In yet another embodiment, a biocompatible hydrogel may be applied to the outside surface of a prosthetic valve. After deployment, the hydrogel absorbs fluids from the blood and expands to the fill the gaps between the valve and surrounding tissue (e.g., host annulus). In preferred methods, the hydrogel may be applied to the surface of the stented valve before deployment or may be applied after deployment.

[00138] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

CLAIMS

1. A catheter-delivered device for locating cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising at least one of a plurality of flexible wires, the wire having attached to it a balloon, wherein the balloon is pulled by the leak through the cavity and wherein the wire then serves to mark the cavity location.

2. The device of Claim 1 further comprising a spacing element to maintain the wires adjacent to the wall of the body vessel.

3. A catheter-delivered stent for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the stent delivered via guide wire to the cavity, held in place in the cavity by friction, and comprising a support structure and an impermeable membrane, the membrane preventing the passage of fluids through the stent, thereby sealing the cavity.

4. The device of Claim 3, wherein the sealing stent is balloon-expandable type and the membrane comprises a tab spring-hinged to the inside of the stent lumen and sized to occlude the lumen when closed, the tab being held open by the stent balloon during insertion and springing closed when the balloon is removed after the stent is expanded.

5. The device of Claim 3, wherein the sealing stent is self-expandable, wherein the membrane is a material covering at least one end of the stent.

6. The device of Claim 5, wherein the stent is comprised of shape memory material.

7. The device of Claim 6, wherein the material is nitinol.

8. The device of Claim 5 further covered on its external walls with hooks comprised of shape memory material and which extend, upon insertion of the stent, into adjacent body vessel walls.

9. The device of Claim 3, wherein the distal end of the stent-delivery catheter is substantially perpendicular to the wall of the vessel at a point inside the cavity and the stent guidewire terminates in an anchoring mechanism that is inserted through the catheter and into the vessel wall, anchoring itself in the vessel wall and providing greater anchorage for the stent.

10. The device of Claim 9, wherein the anchoring mechanism is a hook comprised of shape memory material that is compressed for catheter delivery into the vessel wall whereupon the hook extends out, anchoring the guide wire into the vessel wall.

11. The device of Claim 10, wherein the anchoring mechanism is a threaded point that is threaded into the vessel wall anchoring the guide wire into the vessel wall.

12. A device for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the device comprising a first guidewire threaded through the cavity, a second guidewire slidably coupled to the first wire and inserted such that the slidable coupling is moved to a point in the cavity, a first catheter inserted over the first guidewire to the point in the cavity, a second catheter inserted over the second guidewire to the point in the cavity, a first component of a two-component biological adhesive inserted through the first catheter to the point, a second component of the two-component adhesive inserted through the second catheter to the point, and the two components thereby mixing to form a plug that seals the cavity.

13. The device of Claim 12 adapted to apply an adhesive with more than two components.

14. The device of Claim 12, wherein, instead of two guidewires and two catheters, a single catheter and guidewire are used for delivery, with the catheter comprising two lumens, each lumen providing delivery for one of the two-component adhesive components, the catheter terminating in a mixer that forces the components to mix when the exit the catheter in the cavity, thereby creating the plug that seals the cavity.

15. The device of Claim 12, wherein, instead of two-component adhesive components being delivered via the catheters, a radiation-cured adhesive is delivered via one of the catheters and a radiation source is delivered via the other catheter, wherein the radiation source is applied to the adhesive to create the plug in the cavity.

16. A catheter-delivered assembly for sealing cavities occurring between a prosthetic valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole, the assembly delivered via guidewire to the cavity and comprising two sealing stents connected by a suture, the suture running back up the catheter, the sealing stents comprising a stent structure and sealing membrane, one stent of the assembly inserted underneath the cavity and the other stent inserted inside the cavity, the membranes preventing the passage of fluids through the stent, thereby sealing the cavity and each stent helping anchor the other in place.

17. A prosthetic valve with integrated sealing ring attached to the outside wall, the ring having a circumference greater than that of the valve and elastically conforming to seal cavities between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

18. The device of Claim 17, wherein the ring comprises a balloon.

19. The device of Claim 17, wherein the ring comprises a plurality of spring-wire tabs mounted adjacent to one another around the circumference of the valve and covered with an impermeable membrane and wherein the tabs are folded against the body of the valve during catheter delivery and where, upon egress from the catheter, the tabs spring out to form the sealing ring.

20. The device of Claim 17, wherein the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, and further comprising a balloon under

the tabs and wherein the tabs are folded down on the deflated balloon during catheter delivery and wherein, upon egress from the catheter, the balloon is inflated, thereby opening the tabs to form the sealing ring.

21. The device of Claim 17, wherein the ring comprises a plurality of impermeable tabs mounted adjacent to one another around the circumference of the valve, each tab spring-hinged to the valve and wherein the tabs are folded against the body of the valve during catheter delivery and wherein, upon egress from the catheter, the tabs spring out to form the sealing ring.

22. The device of Claim 17, wherein the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

23. The device of Claim 17, wherein the ring comprises at least one of a plurality of flexible, self-expanding sealing elements comprised of self-expanding mesh covered with an impermeable membrane.

24. The device of Claim 17, wherein the sealing ring comprises modified struts of the stent, the modification comprising geometrical constraints that, upon expansion of the stent, cause the struts to bend out from the stent body, thereby creating the sealing ring.

25. A prosthetic valve with integrated sealing means, the sealing means comprising sutures attached around the perimeter of the valve and extending back out of the body and wherein patches can be pushed down the sutures and attached to the point where the suture is

attached to the valve, thereby sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

26. A catheter-delivered prosthetic valve with integrated sealing means, the sealing means comprising an elastic stent that is first deployed and inside which the valve is deployed, the elastic stent sealing any cavity existing between the valve and the wall of the body vessel where the valve is implanted, the cavities producing paravalvular leaks during diastole.

27. A prosthetic valve for implantation in a body channel, comprising:

a substantially cylindrical stent structure configured for radial expansion;

a valvular structure providing a flexible conduit having an inlet and an outlet, the valvular structure being formed of a pliant material attached to the stent structure and forming three valve leaflets;

a layer of compressible material disposed along an outer surface of the stent structure, the compressible material being adapted for expansion after deployment to fill gaps between the prosthetic valve and the body channel.

28. The prosthetic valve of claim 27, wherein the compressible material is formed of polyethylene terephthalate.

29. The prosthetic valve of claim 28, further comprising a tissue growth factor disposed along the compressible material and

wherein the compressible material includes a plurality of fibers extending outward from the outer surface.

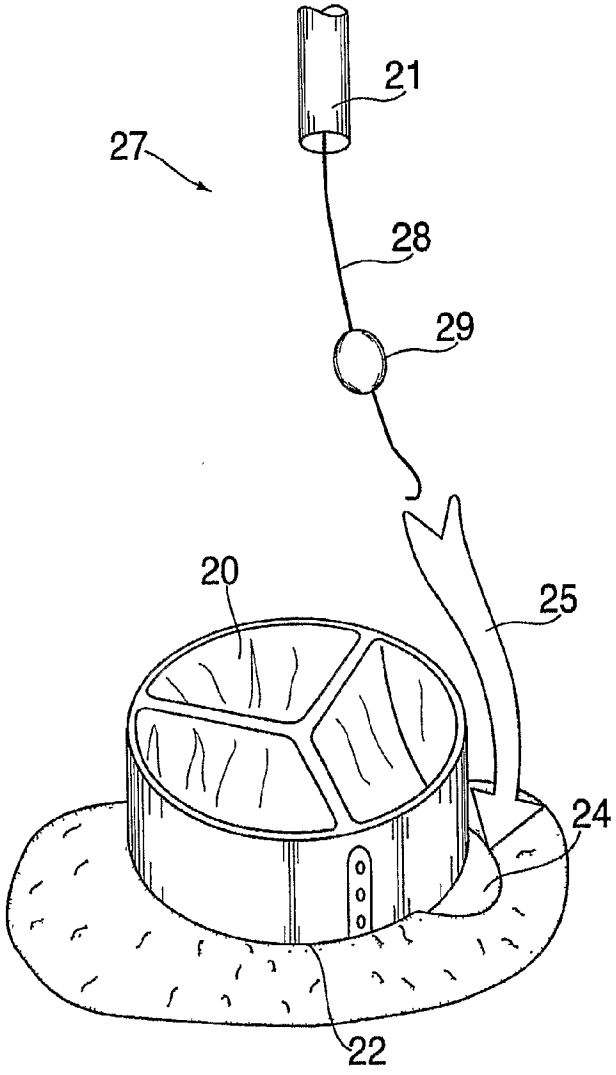

FIG. 1

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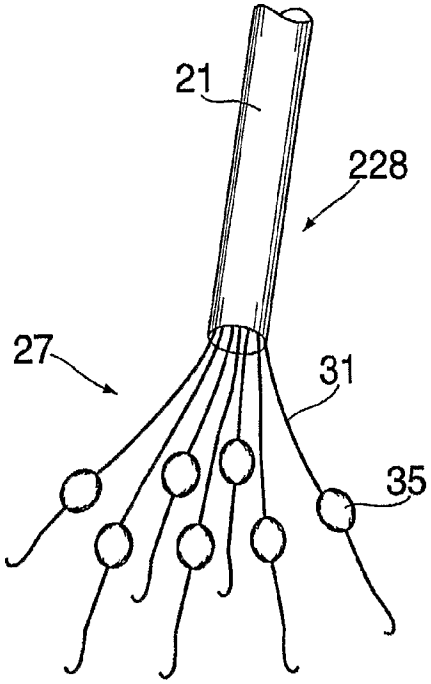

FIG. 2a

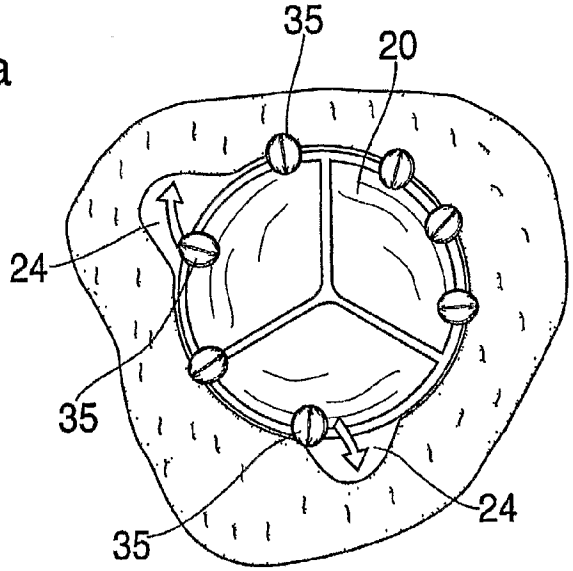

FIG. 2b

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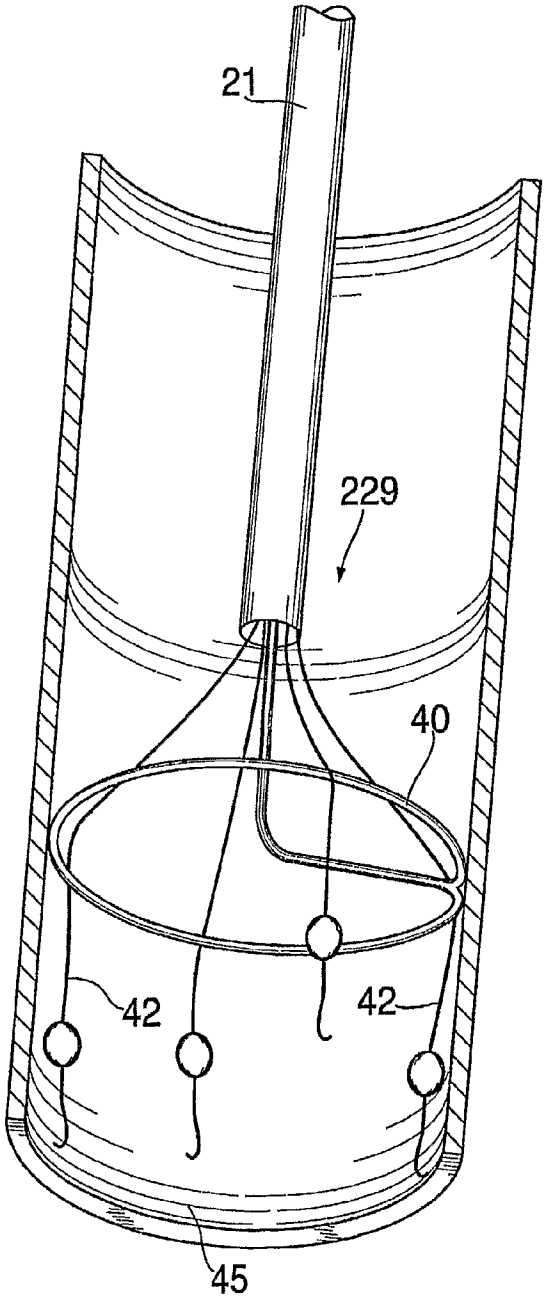

FIG. 3

Aortic Innovations, LLC, Exhibit 2131
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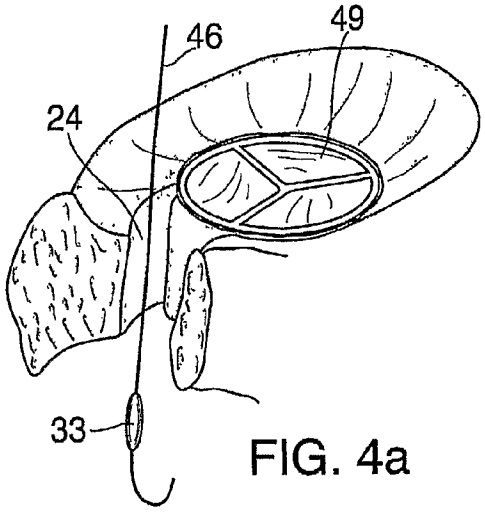

FIG. 4a

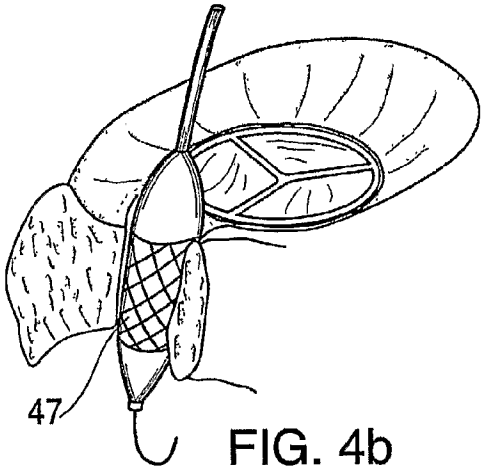

FIG. 4b

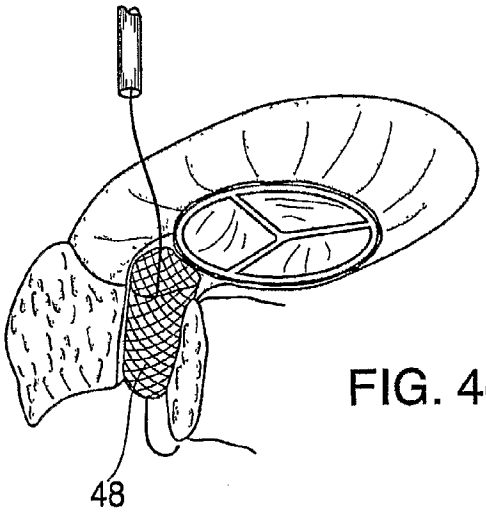

FIG. 4c

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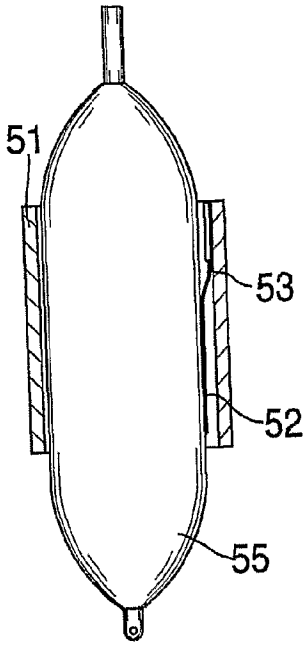

FIG. 5a

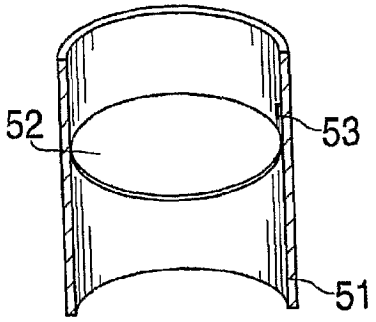

FIG. 5b

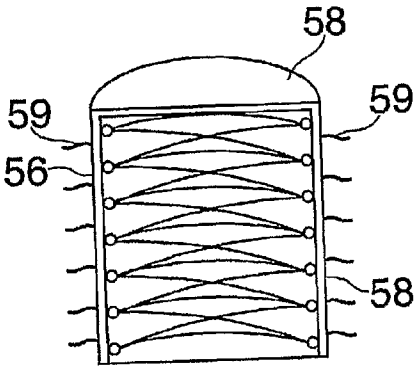

FIG. 5c

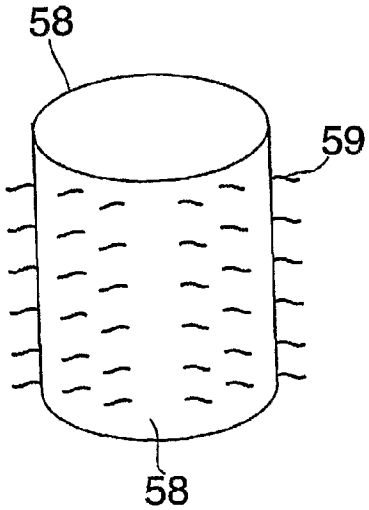

FIG. 5d

Aortic Innovations, LLC, Exhibit 2131
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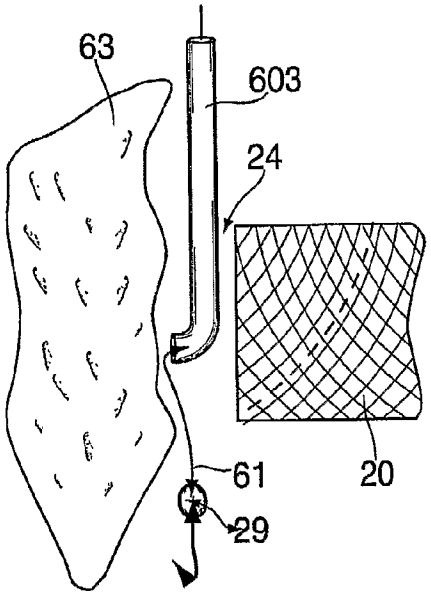

FIG. 6a

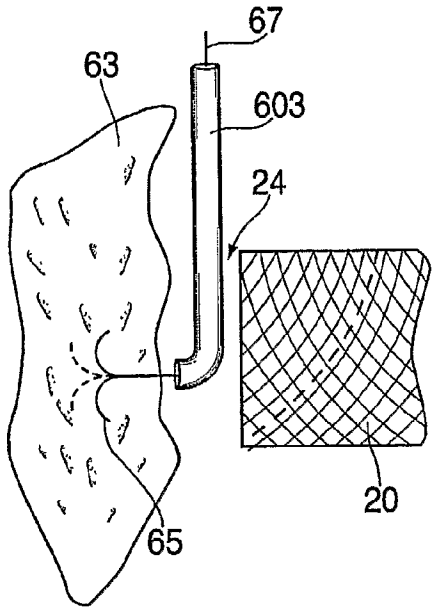

FIG. 6b

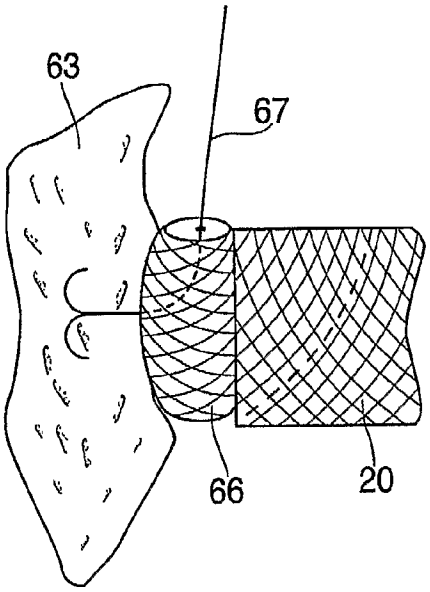

FIG. 6c

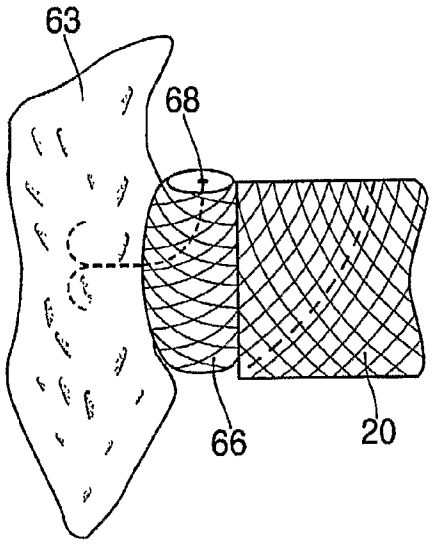

FIG. 6d

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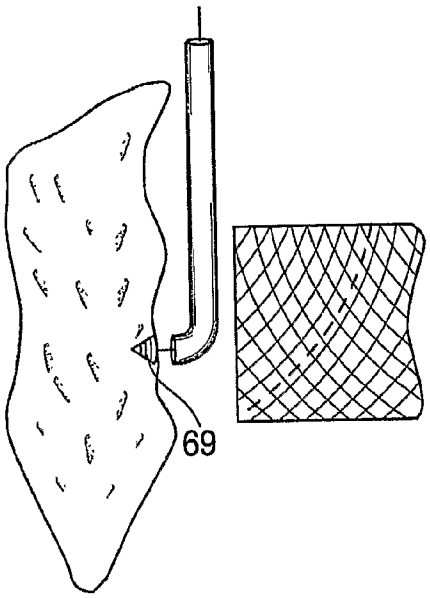

FIG. 7

Aortic Innovations, LLC, Exhibit 2131
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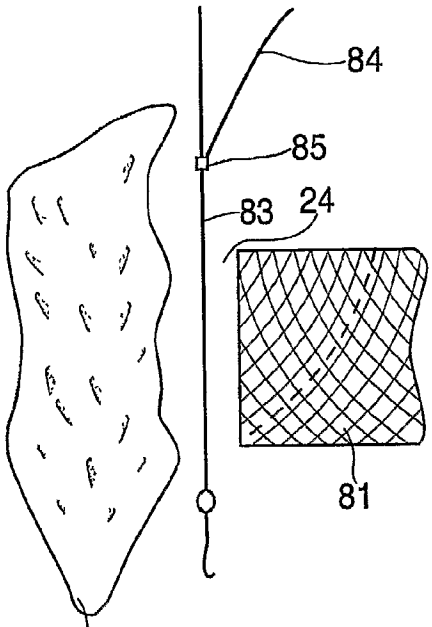

FIG. 8a

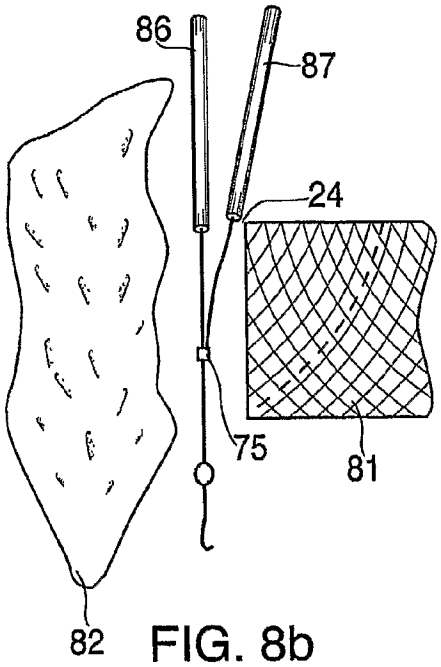

FIG. 8b

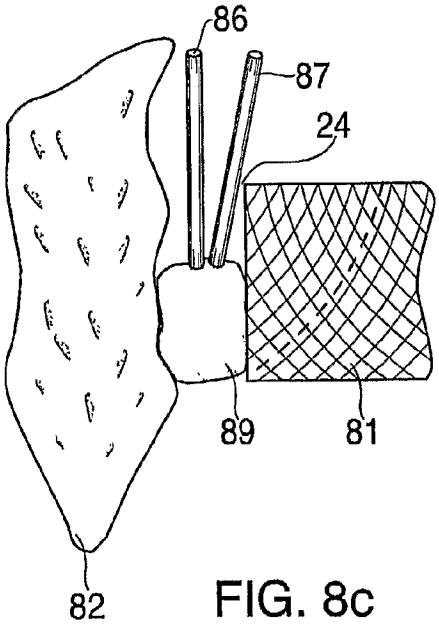

FIG. 8c

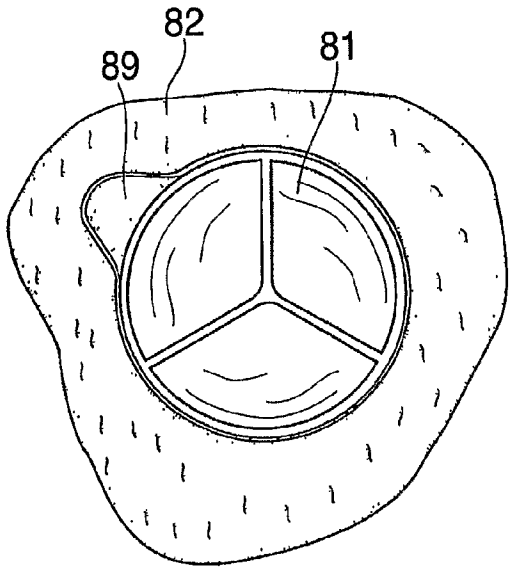

FIG. 8d

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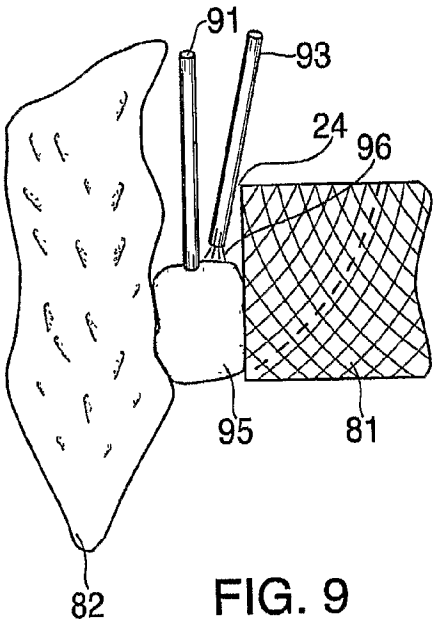

FIG. 9

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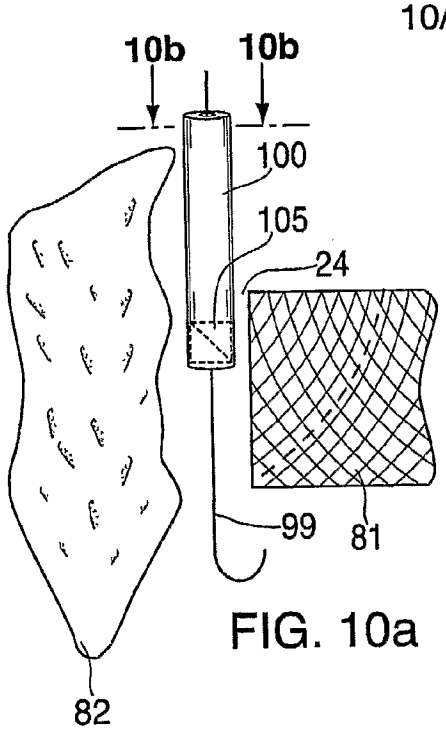

FIG. 10a

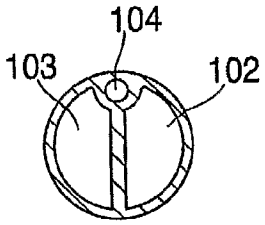

FIG. 10b

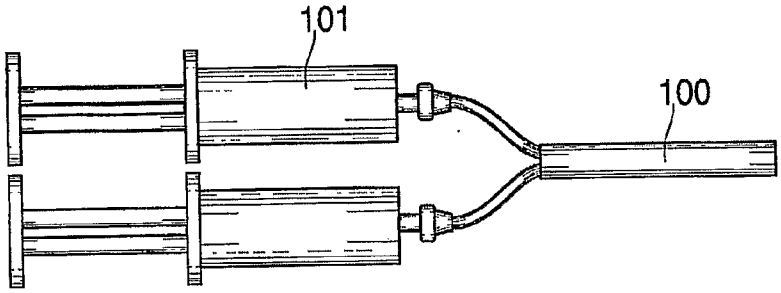

FIG. 10c

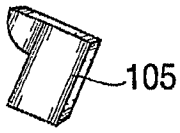

FIG. 10d

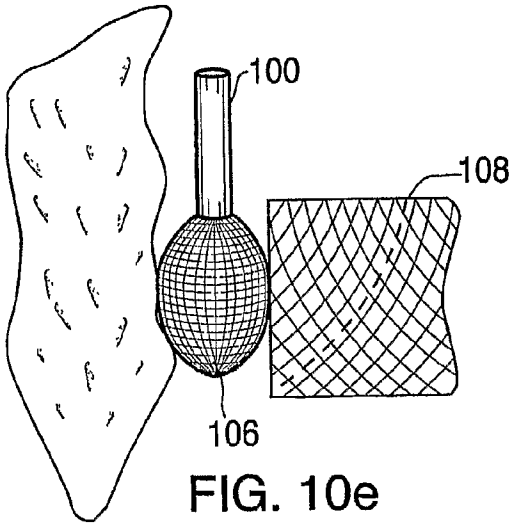

FIG. 10e

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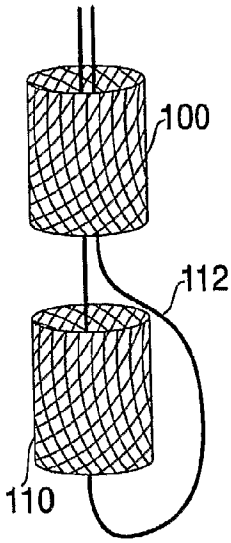

FIG. 11a

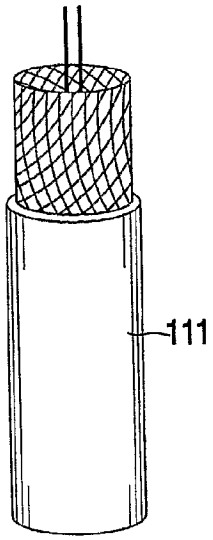

FIG. 11b

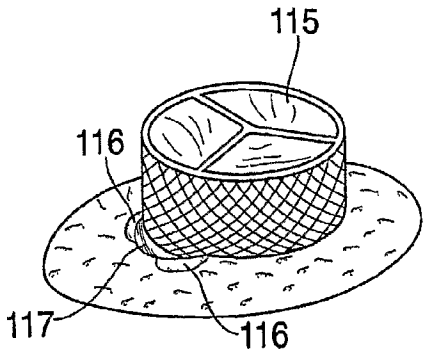

FIG. 11c

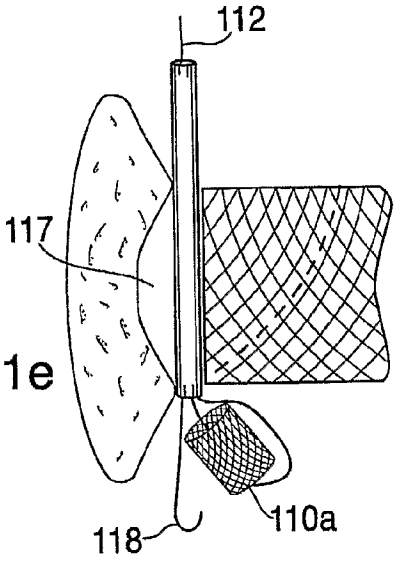

FIG. 11e

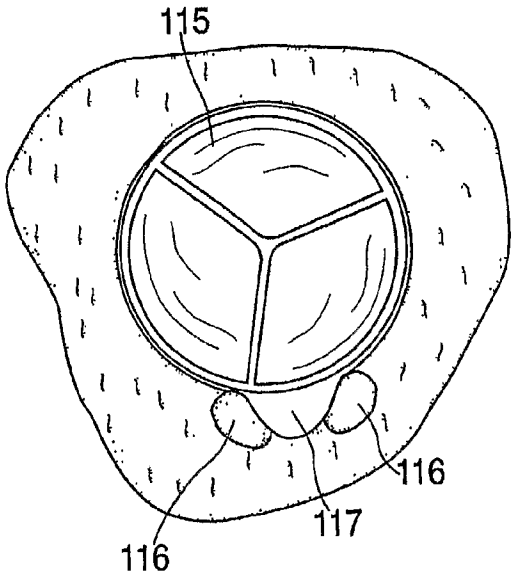

FIG. 11d

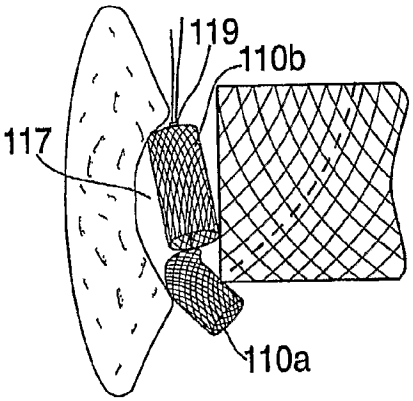

FIG. 11f

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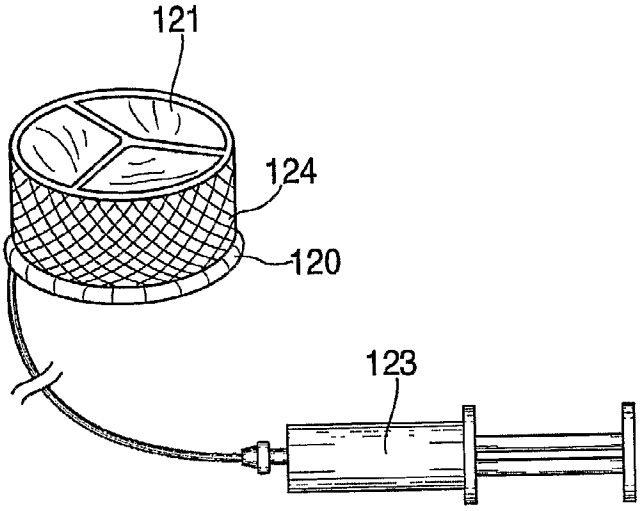

FIG. 12

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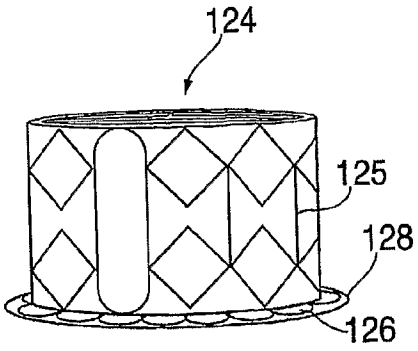

FIG. 13a

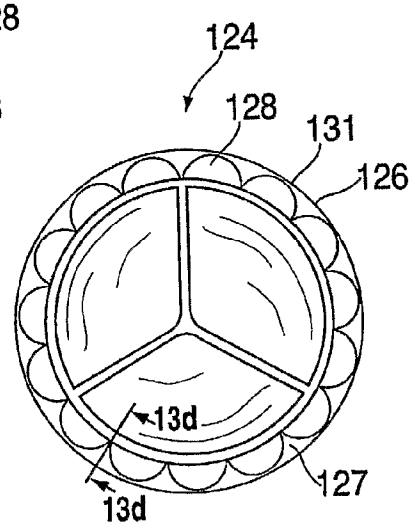

FIG. 13b

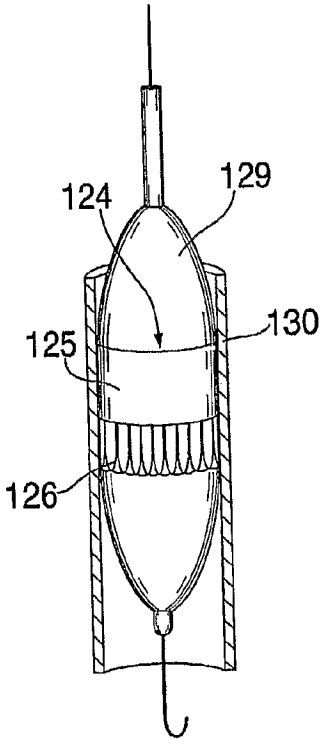

FIG. 13c

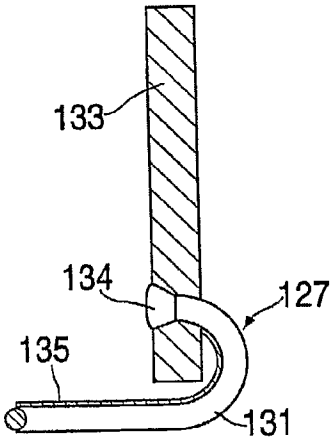

FIG. 13d

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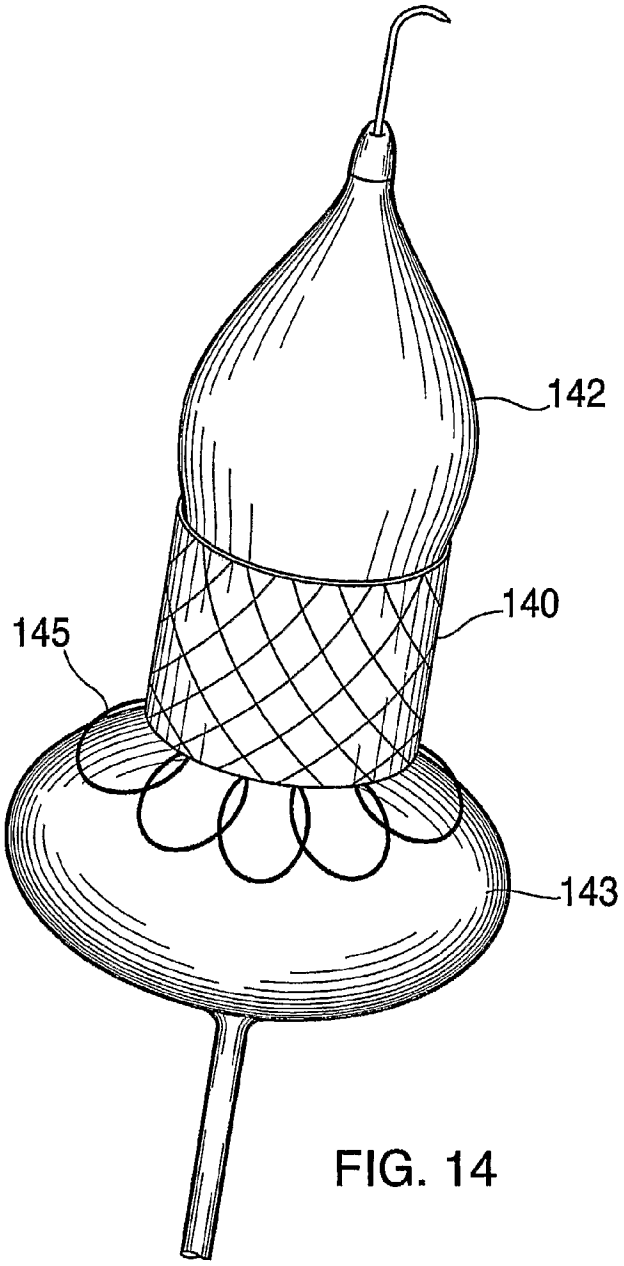

FIG. 14

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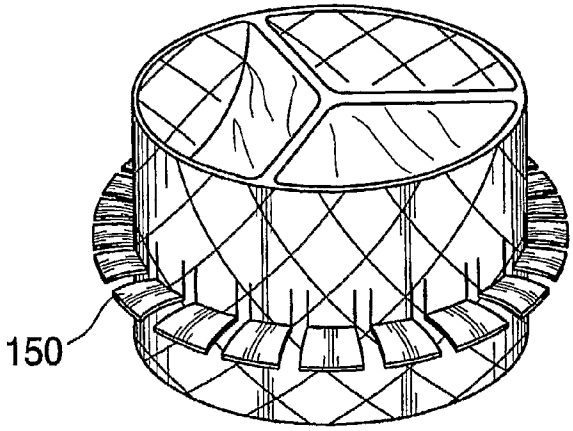

FIG. 15a

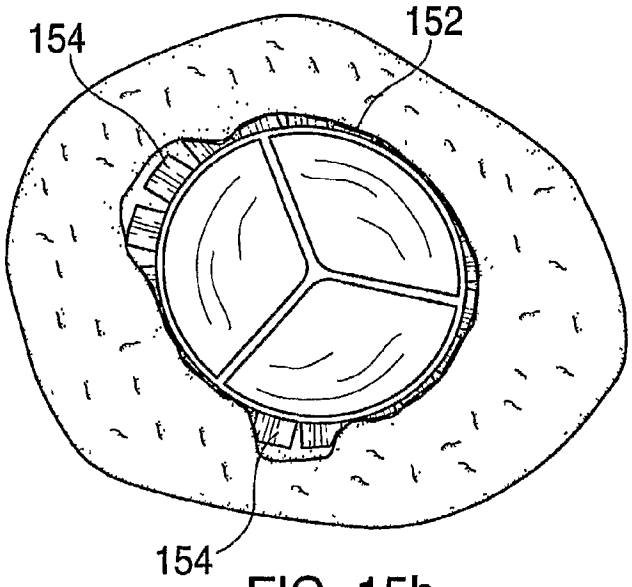

FIG. 15b

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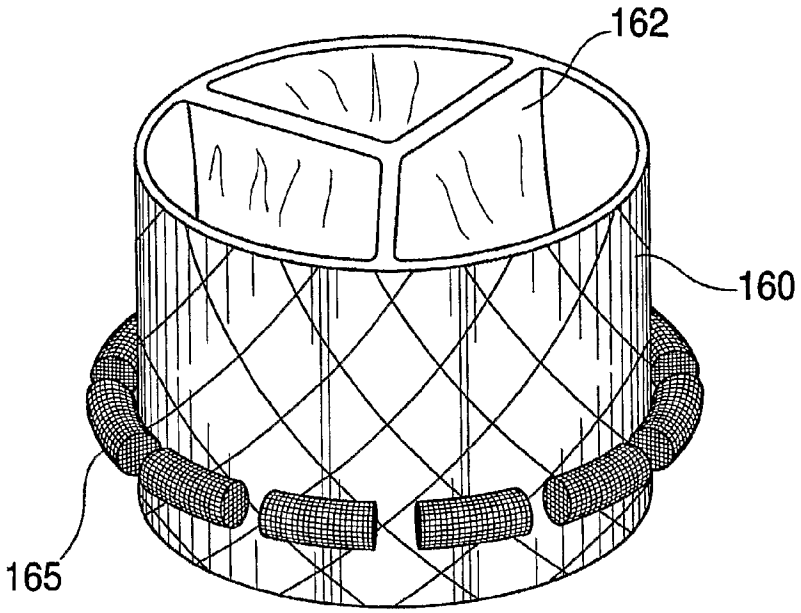

FIG. 16a

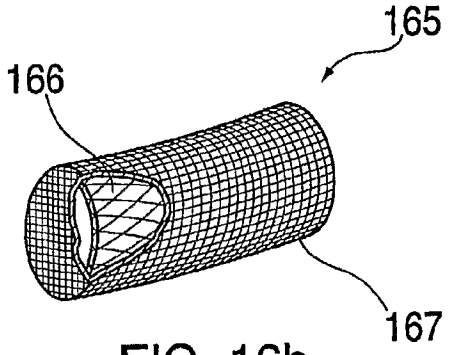

FIG. 16b

Aortic Innovations, LLC, Exhibit 2131
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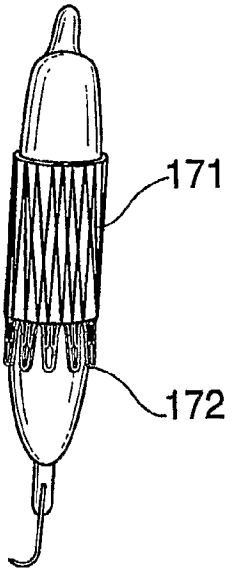

FIG. 17a

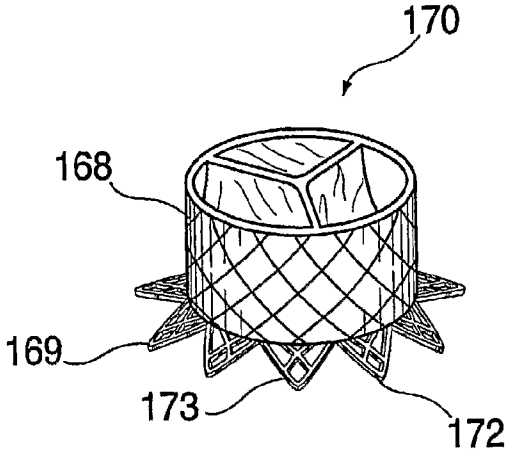

FIG. 17b

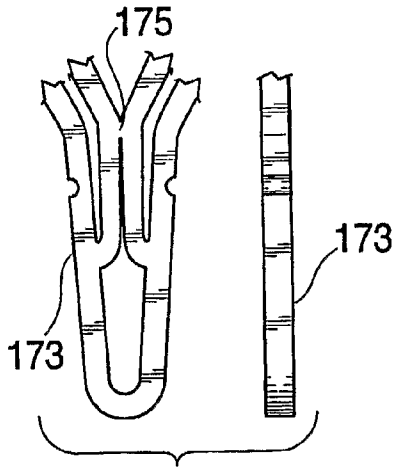

FIG. 17c

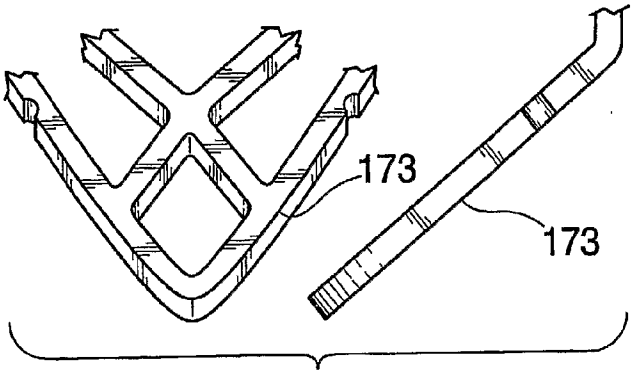

FIG. 17d

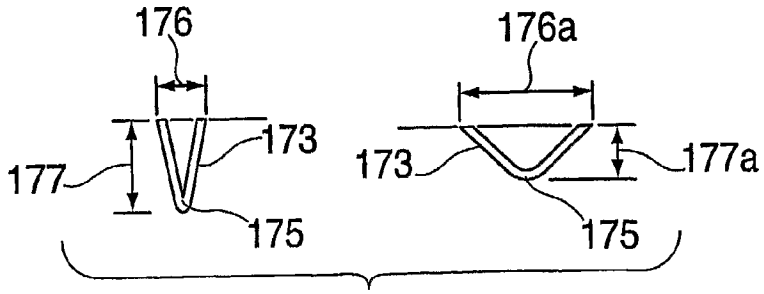

FIG. 17e

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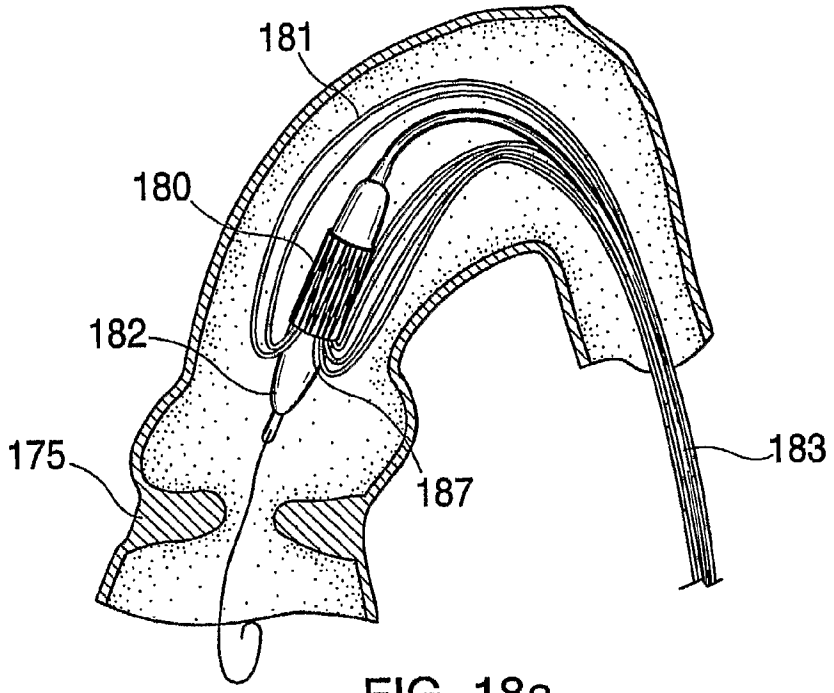

FIG. 18a

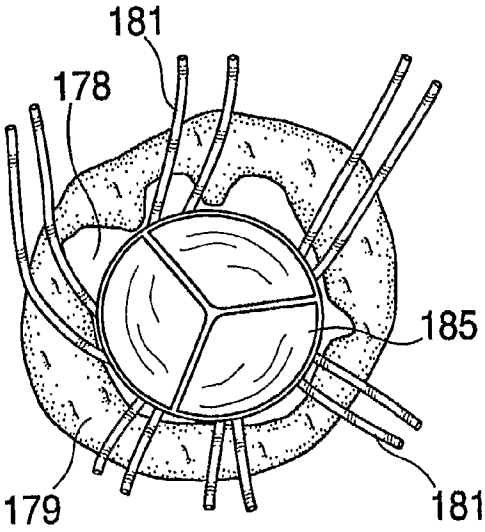

FIG. 18c

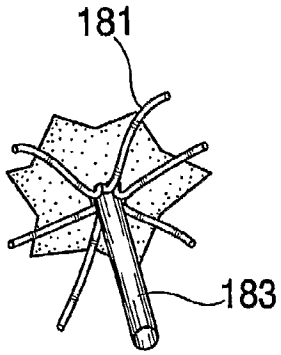

FIG. 18b

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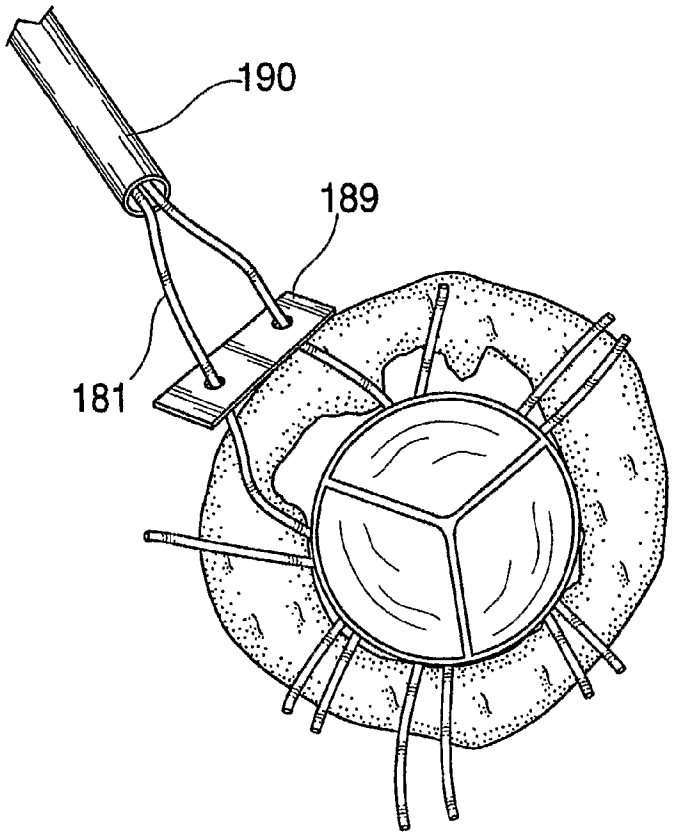

FIG. 18d

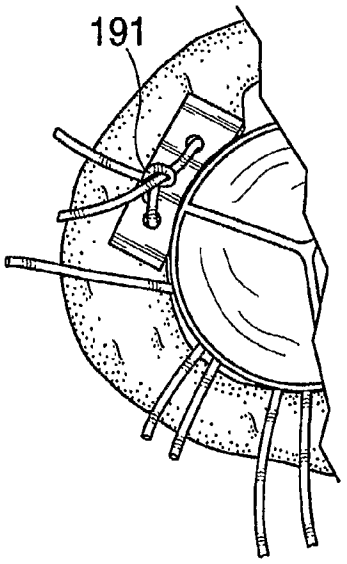

FIG. 18e

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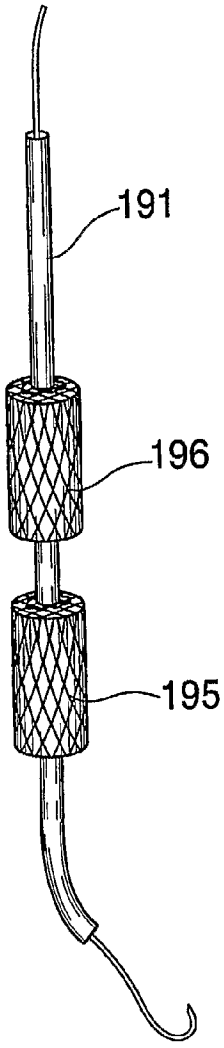

FIG. 19a

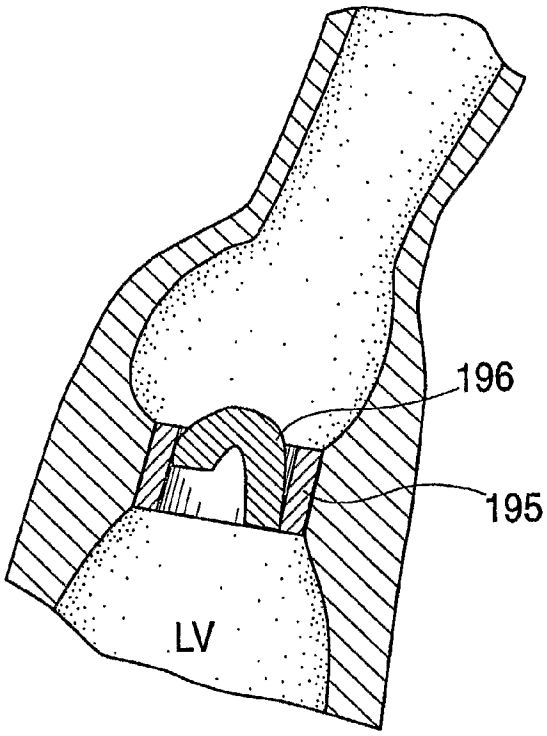

FIG. 19b

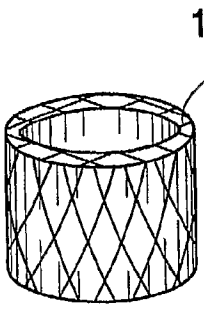

FIG. 19c

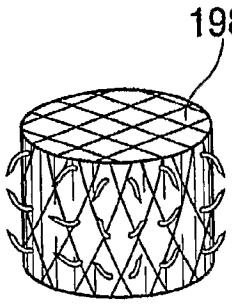

FIG. 19d

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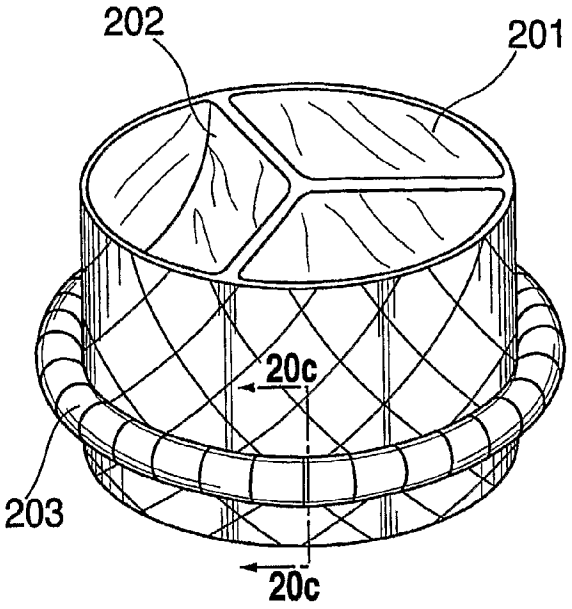

FIG. 20a

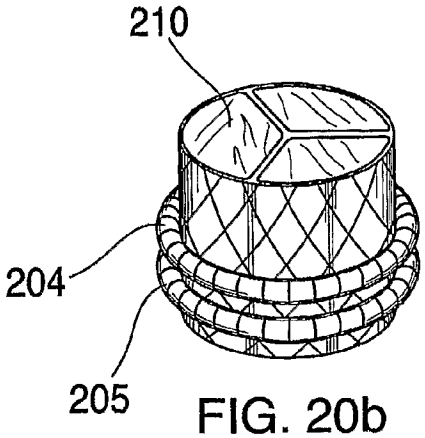

FIG. 20b

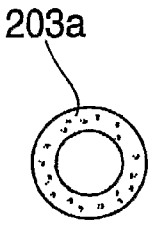

FIG. 20c

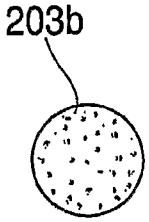

FIG. 20d

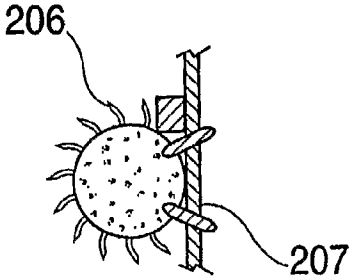

FIG. 20e

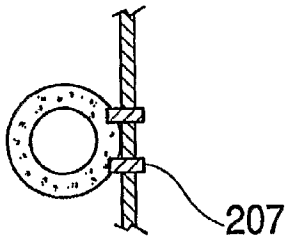

FIG. 20f

FIG. 20g

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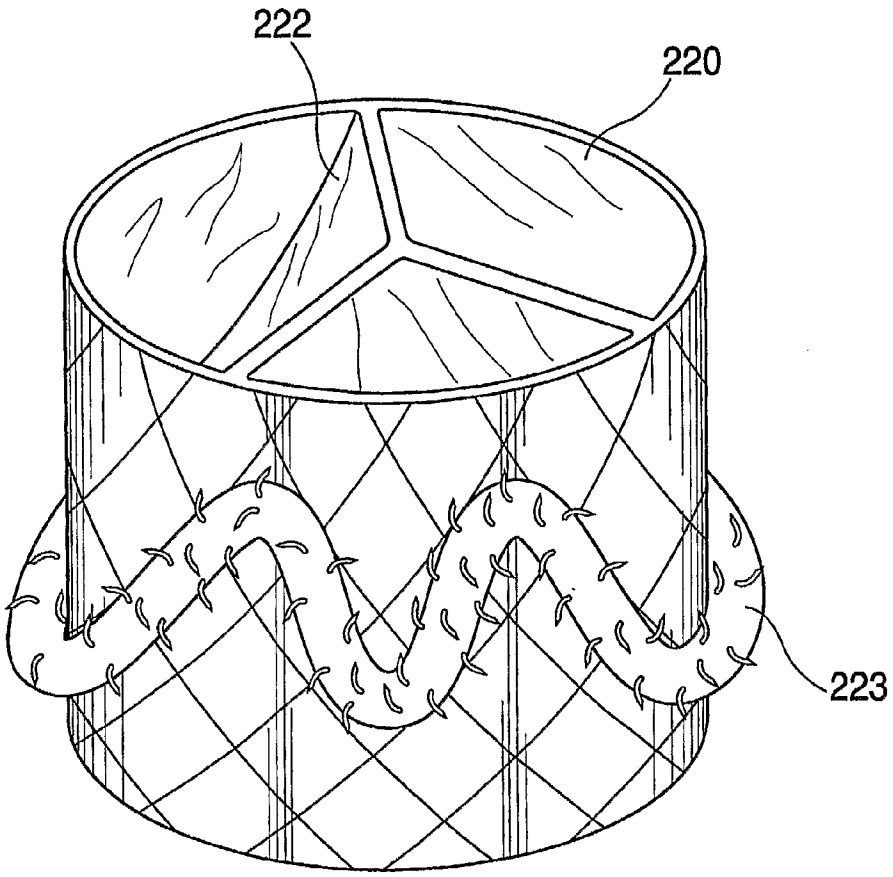

FIG. 21

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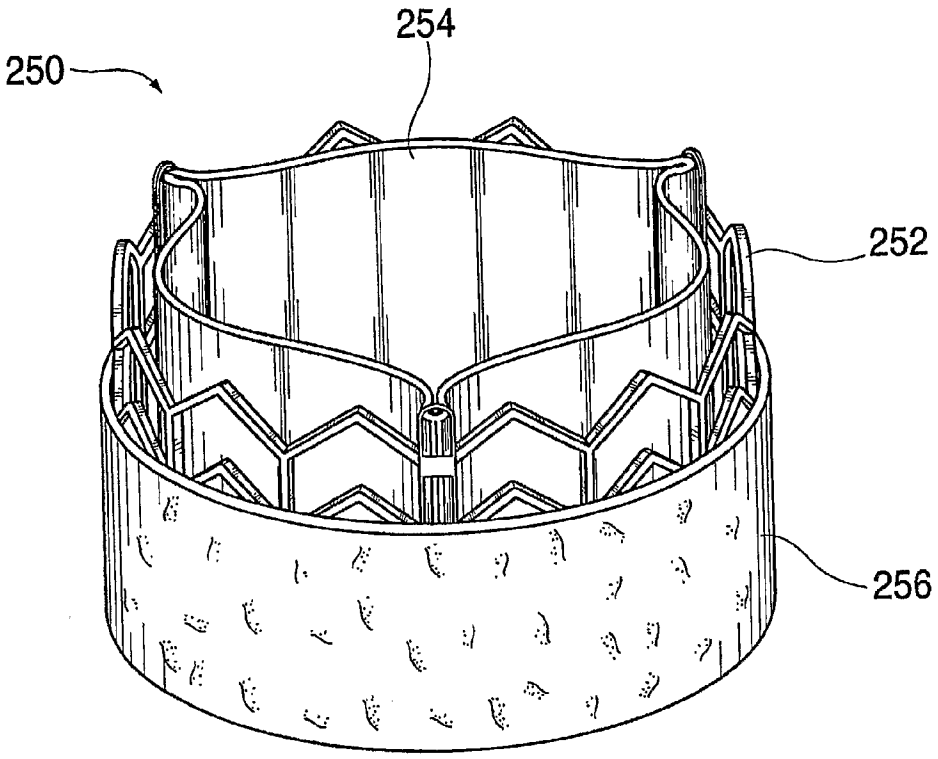

FIG. 22

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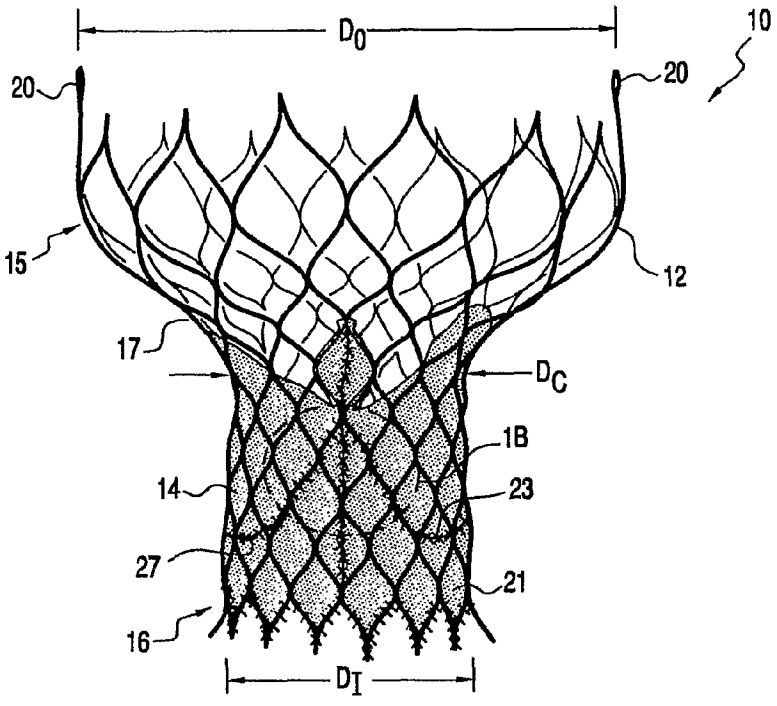
(54) Title: HEART VALVE PROTHESIS AND METHODS OF MANUFACTURE AND USE



(57) Abstract: A heart valve prosthesis is provided having a self-expanding multi-level frame that supports a valve body comprising a skirt and plurality of coapting leaflets. The frame transitions between a contracted delivery configuration that enables percutaneous transluminal delivery, and an expanded deployed configuration having an asymmetric hourglass shape. The valve body skirt and leaflets are constructed so that the center of coaptation may be selected to reduce horizontal forces applied to the commissures of the valve, and to efficiently distribute and transmit forces along the leaflets and to the frame. Alternatively, the valve body may be used as a surgically implantable replacement valve prosthesis.

WO 2006/124649 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

HEART VALVE PROSTHESIS AND METHODS OF MANUFACTURE AND USE

Field Of The Invention

The present invention relates to replacement valves for improving the cardiac function of a patient suffering from cardiac valve dysfunction, such as aortic valve regurgitation or aortic stenosis. More particularly, the present invention relates to heart valve prostheses that provide improved durability and are particularly well-suited for percutaneous delivery.

Background Of The Invention

Heart valve replacement has become a routine surgical procedure for patients suffering from valve regurgitation or stenotic calcification of the leaflets. While certain procedures may be performed using minimally-invasive techniques (so-called "keyhole" techniques), the vast majority of valve replacements entail full sternotomy and placing the patient on cardiopulmonary bypass. Traditional open surgery inflicts significant patient trauma and discomfort, requires extensive recuperation times, and may result in life-threatening complications.

To address these concerns, within the last decade efforts have been made to perform cardiac valve replacements using minimally-invasive techniques. In

these methods, laparoscopic instruments are employed to make small openings through the patient's ribs to provide access to the heart. While considerable effort has been devoted to such techniques, widespread acceptance has been limited by the clinician's ability to access only certain regions of the heart using laparoscopic instruments.

Still other efforts have been focused on percutaneous transluminal delivery of replacement cardiac valves to solve the problems presented by traditional open surgery and minimally-invasive surgical methods. In such methods, a valve prosthesis is compacted for delivery in a catheter and then advanced, for example, through an opening in the femoral artery and through the descending aorta to the heart, where the prosthesis then is deployed in the aortic valve annulus. Although transluminal techniques have attained widespread acceptance with respect to delivery of stents to restore vessel patency, only mixed results have been obtained with respect to percutaneous delivery of relatively more complicated valve prostheses.

One such example of a previously-known heart valve prosthesis is described in U.S. Patent No. 6,454,799 to Schreck. The prosthesis described in that patent comprises a fabric-based heart valve disposed within a plastically deformable wire-mesh base, and is delivered via expansion of a balloon catheter. One drawback with balloon catheter delivery of the prosthetic valve is that the valve leaflets may be damaged when compressed between the balloon and the base during deployment. In addition, because balloon expandable structures tend to experience some recoil following

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balloon deflation, perivalvular leaks may develop around the circumference of the valve prosthesis.

Accordingly it would be desirable to provide a percutaneously-deliverable valve prosthesis that reduces the risk of leaflet damage during deployment of the prosthesis. It further would be desirable to provide a valve prosthesis that reduces the risk of perivalvular leaks resulting from recoil of the prosthesis following deployment.

U.S. Patent No. 6,027,525 to Suh, et al. describes a valve prosthesis comprising a series of self-expanding units affixed to a polymeric cover and having a valve disposed therein. Such devices are not suitable for cardiac valve replacement because of the limited ability to compact the valve disposed within the prosthesis. Moreover, such valve prostheses would be particularly undesirable for treating aortic valve defects, because the polymeric cover would obscure the ostia of the coronary arteries, both disrupting blood flow to the coronary arteries and preventing subsequent catheterization of those arteries. Accordingly, it would be desirable to provide a valve prosthesis that is self-expanding, yet permits the valve to be compacted to a greater degree than previously-known designs.

U.S. Patent No. 6,682,559 to Myers, et al. also describes a valve prosthesis having an essentially tubular design. One drawback of such configurations is that relatively large horizontal forces arise along the coaptation edges of the leaflets and are transmitted to the commissural points. These forces may adversely affect the durability of the leaflets and lead to valve failure. In view of this, it would be desirable to provide a valve wherein the center of coaptation of the

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leaflets may be selected so as to reduce horizontal forces applied to coaptation edges of the leaflets and commissural points, thereby improving durability of the valve. In addition, it would be desirable to provide a valve design that more uniformly distributes horizontal forces over the coaptation edges of the leaflets, rather than concentrating those forces at the commissural points.

In an effort to more nearly recreate the force distribution along the leaflets of natural tissue valves, some previously-known valve designs include circular base portions having longitudinal projections that function as anchors for the commissural points, such as described in U.S. Patent No. 5,855,601 to Bessler, et al. and U.S. Patent No. 6,582,462 to Andersen, et al.

While the valve prostheses of Bessler and Andersen may be readily collapsed for delivery, those designs are susceptible to problems once deployed. For example, the longitudinal projections of such prostheses may not provide sufficient rigidity to withstand compressive forces applied during normal movements of the heart. Deformation of the commissural anchors may result in varied forces being imposed on the commissures and leaflets, in turn adversely impacting functioning of the leaflets. In addition, because the exteriors of the foregoing valve prostheses are substantially cylindrical, the prostheses are less likely to adequately conform to, and become anchored within the valve annulus anatomy during deployment. As a result, cyclic loading of the valve may result in some slippage or migration of the anchor relative to the patient's anatomy.

In view of the foregoing, it would be desirable to provide a valve that is capable of conforming to a

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patient's anatomy while providing a uniform degree of rigidity and protection for critical valve components.

It also would be desirable to provide a valve prosthesis having portions that are capable of deforming circumferentially to adapt to the shape of the pre-existing valve annulus, but which is not susceptible to deformation or migration due to normal movement of the heart.

It further would be desirable to provide a valve prosthesis having a multi-level component that is anatomically shaped when deployed, thereby enhancing anchoring of the valve and reducing the risk of migration and perivalvular leaks.

It still further would be desirable to provide a valve prosthesis wherein the valve body is configured to facilitate fabrication, and to assume a reduced delivery profile compared to previously known designs without damaging the functional components of the valve body.

Summary Of The Invention

In view of the foregoing, it is an object of the present invention to provide a valve prosthesis that overcomes the drawbacks of previously-known designs, and which may be implanted using open surgical, minimally invasive, or percutaneous implantation techniques.

It is yet another object of the present invention to provide a percutaneously-deliverable valve prosthesis that exhibits a markedly reduced delivery profile over known designs.

It is also an object of the present invention to provide a percutaneously-deliverable valve prosthesis that reduces the risk of damage to the leaflets or other

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functional components of the valve body during delivery and deployment of the prosthesis.

It is a further object of this invention to provide a valve prosthesis that reduces the risk of perivalvular leaks resulting from elastic recoil of the prosthesis following deployment.

It is another object of the present invention to provide a valve prosthesis that is self-expanding and permits ready access to adjoining anatomical structures, such as the coronary arteries.

It is a still further object of the present invention to provide a valve in which the center of coaptation of the leaflets may be selected so as to reduce horizontal forces applied to coaptation edges of the leaflets and commissural points, thereby improving durability of the valve.

In addition, it is an object of this invention to provide a valve design that more uniformly distributes forces over the coaptation edges of the leaflets, rather than concentrating those forces at the commissural points.

It is yet another object of this invention to provide a valve that is anatomically shaped, provides a uniform high degree of rigidity and protection for critical valve components, and which is less susceptible to deformation arising from normal movement of the heart.

It is an object of the present invention to provide a valve prosthesis having portions that are capable of deforming circumferentially to adapt to the shape of the pre-existing valve annulus, but which is not susceptible to deformation or migration due to normal movement of the heart.

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It is also an object of this invention to provide a valve prosthesis having a multi-level component that is anatomically shaped when deployed, thereby enhancing anchoring of the valve and reducing the risk of migration and perivalvular leaks.

It is a further object of the present invention to provide a valve prosthesis wherein a valve is disposed within a rigid portion of a multilevel frame, so that valve area and function are not impaired, but inflow and/or outflow portions of the multilevel frame are capable of conforming to patient anatomy anomalies.

It is a further object of the present invention to provide a valve prosthesis that facilitates alignment of the heart valve prosthesis with the direction of blood flow.

These and other objects of the present invention are accomplished by providing a heart valve prosthesis wherein a self-expanding multi-level frame supports a valve body comprising a skirt and plurality of coapting leaflets. The frame has a contracted delivery configuration, in which the prosthesis may be stored within a catheter for percutaneous delivery, and an expanded deployed configuration having an asymmetric hourglass shape.

In a first preferred embodiment, the valve body skirt and leaflets are constructed of porcine, bovine, equine or other mammalian tissue, such as pericardial tissue, and are sewn, welded, molded or glued together so as to efficiently distribute forces along the leaflets and to the frame. In a particularly preferred embodiment, the skirt comprises three sections of mammalian tissue that are joined along adjacent edges, so

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that the tissue folds easily to a collapsed delivery profile without bunching.

Alternatively, the skirt of the valve body may comprise a synthetic or polymetric material, such as Dacron, expanded polytetrafluoroethylene ("ePTFE"), or other suitable synthetic graft material. The valve body leaflets may be constructed of porcine, bovine, equine or other mammalian tissue, such as pericardial tissue, and are sewn, welded, molded or glued to the skirt so as to efficiently distribute forces along the leaflets and to the frame. The use of synthetic or polymeric materials for the valve skirt in conjunction with mammalian tissue leaflets may offer distinct advantages. In particular, the synthetic material may provide the same structural properties as the mammalian tissue but at reduced thickness, thereby enabling the valve body to be collapsed to a smaller delivery profile. Alternatively, the leaflets also may comprise a synthetic or polymeric material.

In accordance with the principles of the present invention, the frame comprises multiple levels, including a proximal conical inflow section, a constriction region and a flared distal outflow section. Each of the inflow and outflow sections is capable of deforming to a non-circular cross-section to conform to the patient's anatomy, while the constriction region is configured to retain a circular cross-section that preserves proper functioning of the valve body.

The frame comprises a plurality of cells having a pattern that varies along the length of the frame to provide a high degree of anchoring and alignment of the valve prosthesis. The cell pattern further is selected to provide a uniform diameter where the commissural

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joints of the leaflets are attached to the frame, while permitting the inflow and outflow regions to expand to conform to the patient's anatomy. In this manner, optimal functioning of the valve body may be obtained even though the frame may be deployed in anatomies having a range of sizes. In addition, the frame resists deformation caused by movement of the heart and enables a functional portion of the valve body to be disposed supra-annularly to the native valve, with a portion of the valve prosthesis extending into the native valve annulus.

In one embodiment suitable for aortic valve replacement, the valve body comprises a skirt coupled to three leaflets. The components may be formed of animal pericardial tissue or synthetic material, and are sewn, glued, welded or molded together. The lateral ends of the leaflets include enlarged regions that are folded to both form the commissural joints and fasten the commissural joints to the frame. The skirt and leaflets further are configured so that the joints align with contours of the cell pattern of the frame.

In a preferred embodiment, the commissural joints are affixed to the frame at locations above the area of coaptation, to provide a selectable center of coaptation of the leaflets. This design provides a more efficient delivery configuration because the commissures are not compressed against the leaflets when the valve prosthesis is reduced to the contracted delivery configuration. Additionally, by lengthening the distance to the commissures, the design mimics the functioning of natural tissue valves by distributing forces along the coaptation edges and reducing horizontal forces transmitted to the commissural joints.

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In alternative embodiments, the valve body of the present invention may include a sewing ring in lieu of the frame to facilitate surgical implantation, and may employ as few as two and as many as four leaflets.

Methods of making and using the valve prostheses of the present invention are also provided.

Brief Description Of The Drawings

The above and other objects and advantages of the present invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts throughout, and in which:

FIGS. 1A, 1B and 1C are, respectively, side and top end views of an exemplary valve prosthesis of the present invention in the expanded deployed configuration and an enlarged region of the frame of the valve prosthesis;

FIG. 2 is a side view of the frame of the valve prosthesis of FIGS. 1 in a contracted delivery configuration;

FIGS. 3A and 3B are, respectively, plan views of a leaflet and the skirt employed in the valve body of the present invention;

FIGS. 4A, 4B, 4C, and 4D are, respectively, a perspective view of a leaflet with its enlarged regions folded, a plan view of an embodiment of the valve body of the present invention in which the leaflets are fastened to the skirt, a perspective view of an alternative embodiment of a skirt, and a perspective view of another alternative embodiment of a skirt;

FIG. 5 is a side view of the valve body of FIG. 4B fully assembled; and

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FIG. 6 is a side view depicting the valve prosthesis of the present invention deployed atop a patient's aortic valve.

Detailed Description Of The Invention

The present invention is directed to a heart valve prosthesis having a self-expanding frame that supports a valve body. In a preferred embodiment, the frame has a tri-level asymmetric hourglass shape with a conical proximal section, an enlarged distal section and a constriction region having a predefined curvature when the frame is deployed. In the context of the present application, the proximal section constitutes the "inflow" portion of the valve prosthesis and is disposed in the aortic annulus of the patient's left ventricle, while the distal section constitutes the "outflow" portion of the valve prosthesis and is positioned in the patient's ascending aorta.

In a preferred embodiment the valve body comprises three leaflets that are fastened together at enlarged lateral end regions to form commissural joints, with the unattached edges forming the coaptation edges of the valve. The leaflets are fastened to a skirt, which is in turn affixed to the frame. The enlarged lateral end regions of the leaflets permit the material to be folded over to enhance durability of the valve and reduce stress concentration points that could lead to fatigue or tearing of the leaflets. The commissural joints are mounted above the plane of the coaptation edges of the valve body to minimize the contracted delivery profile of the valve prosthesis, while the configuration of the edges permits uniform stress distribution along the coaptation edges.

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Referring to FIGS. 1, an exemplary embodiment of a valve prosthesis constructed in accordance with the principles of the present invention is described. Valve prosthesis 10 comprises expandable frame 12 having valve body 14 affixed to its interior surface, e.g., by sutures. Frame 12 preferably comprises a self-expanding structure formed by laser cutting or etching a metal alloy tube comprising, for example, stainless steel or a shape memory material such as nickel titanium. The frame has an expanded deployed configuration that is impressed upon the metal alloy tube using techniques that are per se known in the art. Valve body 14 preferably comprises individual leaflets assembled to a skirt. All of the components of valve body 14, i.e., the skirt and leaflets, may be formed of a natural or man-made material. Alternatively, the leaflets may be formed from a natural material, such as porcine, equine or bovine pericardium, while the skirt comprises a synthetic or polymeric material, such as Dacron, ePTFE, or similar material.

Frame 12 preferably includes multiple levels, including outflow section 15, inflow section 16 and constriction region 17. As depicted in the enlarged view of FIG. 1B, the frame comprises a plurality of cells having sizes that vary along the length of the prosthesis. As indicated by dotted lines **a**, **b** and **c**, each cell comprises two zig-zag structures having unequal-length struts, wherein the vertices of the zig-zags are coupled together. For example, zig-zag 18 has length $\mathbf{z_1}$ whereas zig-zag 19 has greater length $\mathbf{z_2}$. This cell design permits each level of cells between the proximal and distal ends of the frame to be tailored to meet specific design requirements, such as,

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compressibility, expansion characteristics, radial strength and so as to define a suitable contour for attachment of the valve body.

The cell pattern of frame 12 also enables the frame to expand to the tri-level asymmetric hourglass shape depicted in FIG. 1A, having conical inflow section, enlarged outflow section and fixed diameter constricted region. Each section of frame 12 has a substantially circular cross-section in the expanded deployed configuration, but in addition the cell patterns of the inflow and outflow sections permit those sections to adapt to the specific anatomy of the patient, thereby reducing the risk of migration and reducing the risk of perivalvular leaks. The cell patterns employed in the constriction region are selected to provide a uniform circular cross-section area for the constriction region when deployed, and a pre-determined radius of curvature for the transition between the constriction region and outflow section of the frame. In particular, the convex-concave shape of frame 12 within the constriction region ensures that the frame is held away from the opposing sinus wall in the ascending aorta, thus ensuring adequate blood flow to the coronary arteries and facilitating catheter access to the coronary arteries.

Enlarged outflow section has nominal deployed diameter D_O, inflow section has nominal deployed diameter D_I, and constriction region has deployed substantially fixed diameter D_C. The conical shape of the inflow region and smooth transitions between adjacent sections of frame 12 are expected to be particularly advantageous in directing blood flow through the valve body with little or no turbulence, as compared to step changes in

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diameter observed for surgically implanted replacement valves.

The above-described cell pattern permits each of the inflow and outflow sections of frame 12 to expand to a diameter within a range of deployed diameters, while retaining constriction region 17 at a substantially constant diameter. Thus, for example, outflow diameter D_O may range from 30 to 55 mm, while inflow diameter D_I may vary from 19 to 34 mm. Illustratively, frame 12 may be manufactured in four sizes having a range of diameters D_O, D_I and D_C as set forth in Table 1 below:

Table 1

	Size A	Size B	Size C	Size D
D_O	40 mm	50 mm	40 mm	50 mm
D_C	22 mm	22 mm	24 mm	24 mm
D_I	26 mm	26 mm	29 mm	29 mm

Advantageously, these four frame sizes are expected to cover a wide range of patient anatomies, while requiring construction of only two sizes of valve bodies (22 and 24 mm). Compared to previously-known commercially available surgical valves, which vary from approximately 17 mm to 31 mm in one millimeter increments, it is expected that the above four sizes of valve prosthesis of the present invention could be used for more than 75% of the patient population, thus greatly reducing the costs associated with manufacturing and inventorying large numbers of parts.

When configured as a replacement for an aortic valve, inflow section 16 extends into and anchors within the aortic annulus of a patient's left ventricle and

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outflow section 15 is positioned in the patient's ascending aorta. Importantly, the configuration of outflow section 15 is expected to provide optimal alignment of the valve body with the direction of blood flow. In addition, the cell pattern of outflow section 15 also serves to anchor the outflow section in the patient's ascending aorta to prevent lateral movement or migration of frame 12. As depicted in FIG. 1C, the use of relatively larger cells in the outflow section of frame 12, combined with the convex-concave shape of constriction region 17, ensures that the frame does not obstruct blood flow to the patient's coronary arteries when deployed and allows for catheter access to the coronary arteries. Frame 12 also may include eyelets 20 for use in loading the heart valve prosthesis 10 into a delivery catheter.

Still referring to FIGS. 1, valve body 14 includes skirt 21 affixed to frame 12, and leaflets 22. Leaflets 22 are attached along their bases to skirt 21, for example, using sutures 23 or a suitable biocompatible adhesive. Adjoining pairs of leaflets are attached to one another at their lateral ends to form commissures 24, with free edges 25 of the leaflets forming coaptation edges that meet in area of coaptation 26.

As depicted in FIG. 1A, the curve formed at joint 27 between the base of each leaflet 22 and skirt 21 follows the contour of the cell pattern of frame 12, so that most of the length of joint 27 is directly supported by frame 12, thereby transmitting forces applied to the valve body directly to the frame. As further depicted in FIG. 1C, commissures 24 are configured to span a cell of frame 12, so that force is evenly distributed within the commissures and to frame 12.

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Referring to FIG. 2, valve prosthesis 10 is shown in the contracted delivery configuration. In this state, valve prosthesis may be loaded into a catheter for percutaneous transluminal delivery via a femoral artery and the descending aorta to a patient's aortic valve. In accordance with one aspect of the present invention, commissures 24 are disposed longitudinally offset from coaptation edges 25 of the valve body, thereby permitting a smaller delivery profile than achievable with previously-known replacement valves. In addition, because frame 12 self-expands upon being released from the delivery catheter, there is no need to use a balloon catheter during placement of valve prosthesis 10, thereby avoiding the potential for inflicting compressive injury to the valve leaflets during inflation of the balloon.

Referring now to FIGS. 3A and 3B, skirt 21 and leaflet 22 of a preferred aortic valve embodiment of the present invention are described. In one preferred embodiment, skirt 21 and leaflet 22 are cut from a sheet of animal pericardial tissue, such as porcine pericardial tissue, either manually or using a die or laser cutting system. The pericardial tissue may be processed in accordance with tissue processing techniques that are per se known in the art for forming and treating tissue valve material. In a preferred embodiment, skirt 21 and leaflets 22 have a thickness of between 0.008" and 0.016", and more preferably between 0.012" and 0.014".

In an alternative preferred embodiment, leaflets 22 are formed from animal pericardial tissue as described above, while skirt 21 is cut from a sheet of synthetic or polymer material, such as Dacron, ePTFE, or other similar material as known in the art. In this case, skirt 21 has a thickness of between 0.004" and

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0.012", and more preferably between 0.006" and 0.008", and may thus be compressed to a substantially smaller delivery profile. Alternatively, skirt 21 and leaflets 22 may be constructed of a synthetic or polymeric material.

Leaflet 22 includes enlarged lateral ends 30 and 31 disposed at either end of free edge 32, and body 33. Free edge 32 forms coaptation edge 25 of the finished valve body 14, while lateral ends 30 and 31 are folded and joined to adjacent leaflets to form commissures 24. In accordance with one aspect of the present invention, free edges 32 assume the form of catenaries when the valve body is affixed to frame 12, thereby providing uniform loading along the length of the coaptation edge in a manner similar to a suspension bridge. Body 33 is joined to skirt 21 as described below. Lateral ends 30 and 31 illustratively are shown in FIG. 3A as having fold lines **d**, **e** and **f**, to define flaps 34, 35 and 36.

In the embodiment of FIG. 3B, skirt 21 includes panels 21a, 21b and 21c, each panel having scalloped area 37, reinforcing tab 38, and end tab 39. Scalloped area 37 or each panel 21a, 21b and 21c is joined to a body 33 of a respective leaflet 22. Reinforcing tabs 38 illustratively include fold lines **g**, **h** and **i**, between panels 21a-21b and 21b-21c, except for reinforcing tabs 40 and 41 at the lateral ends of the panels 21a and 21c, which have only one fold apiece. As described below, reinforcing tabs 40 and 41 are joined to one another, e.g., by sutures or gluing, so that skirt 21 forms a frustum of a cone. In one preferred embodiment, panels 21a, 21b and 21c are cut conjoined from a single piece of animal pericardium, as depicted in FIG. 3B.

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End tabs 39 are folded over the ends of the proximal-most row of cells of frame 12 to secure skirt 21 to the frame and seal against perivalvular bypass flows (see FIG. 1A). Because end tabs 39 are directly supported by the last zig-zag row of cells of frame 12, there is no opportunity for an unsupported edge of the skirt to flap or otherwise extend into the flow path along the inflow edge of skirt 21. Thus, the design of the valve prosthesis not only ensures that there are no flaps to disrupt flow or serve as sites for thrombus formation, but also reduces the risk that hemodynamic flow against such flaps could cause frame 12 to migrate.

It has been observed that when panels 21a-21c are cut conjoined from a single piece of animal pericardium, the skirt has a tendency to bunch-up or "accordion" when the valve body is collapsed to its reduced delivery configuration. However, applicants have discovered that if panels 21a-21c are severed along fold lines **h** in FIG. 3B, or individually cut from a piece of animal pericardium, this phenomenon is not observed, and the skirt can be collapsed to a substantially smaller profile. In particular, whereas a tissue-based skirt comprising conjoined panels 21a-21c, as shown in FIG. 3B, fits within a 21 French delivery catheter, forming skirt 21 of individual panels 21a-21c enables the device to fit within an 18 French catheter, resulting in a reduction in the delivery profile of about twenty-five percent (25%).

As a still further alternative, skirt 21 may be formed of a synthetic or polymeric material, such as Dacron, ePTFE, or similar material selected for its properties and biocompatibility. As opposed to leaflets 22, which provide a mechanical function through movement, skirt 21 functions primarily to create a seal to prevent

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perivalvular leaks. Accordingly, a thin synthetic material may be used in place of thicker mammalian tissue to serve this purpose. As a result, the device may be compacted to a reduced delivery profile by virtue of the decreased volume of the skirt. For example, use of a synthetic skirt with a valve body having tissue-based leaflets may enable the device to fit within a catheter having even less than an 18 French diameter.

Referring to FIGS. 4A and 4B, assembly of valve body 14 from the above-described embodiments of skirt 21 and leaflets 22 is described. In FIG. 4A, flap 34 first is folded along line **d**. Flap 35 is folded along line **e** so that it lies atop flap 34, forming seam 42 comprising a triple thickness of the tissue. Flap 36 then is folded along line **f**. Adjoining leaflets 22 then are fastened together along adjacent seams 42, resulting in a leaflet assembly.

Reinforcing tabs 38 are folded along lines **g**, **h** and **i** to form seams 43 comprising a double thickness of tissue, or in the case of separate panels 21a-21c, joined to form seams along tabs 38. Next, the leaflet assembly is attached to skirt 21 along the bottom edges of bodies 33 of the leaflets to form joints 44. At this stage of the assembly, prior to attaching reinforcing tab 40 to 41 and the remaining seam 42 of leaflets 22, the valve body appears as depicted in FIG. 4B. Reinforcing tabs 40 and 41 then are fastened together to form another seam 43 along skirt 21 and the remaining seam 42 between leaflets 22. Valve body 14 then is ready to be affixed to frame 12.

Referring to FIG. 4C, alternative embodiment of a synthetic skirt for a valve body of the present invention is described. Skirt 45 of FIG. 4C is formed

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from tube 47 of commercially available synthetic material, such as described above. Tube 47 is cut at one end to form scalloped areas 37, while notches are cut at the other end of the tube to form end tabs 39. Leaflets 22, which may comprise natural or synthetic material, then are assembled and attached to skirt 45 in a manner similar to that described above. Because skirt 45 is essentially cylindrical, it preferably comprises a material that is sufficiently flexible to stretch to conform to the desired shape of frame when end tabs 39 are attached to frame 12.

In FIG. 4D, another alternative embodiment of a synthetic skirt for a valve body of the present invention is described. In this case, the skirt first is cut from tube 47 into a shape shown in FIG. 4C, and then formed into a shape resembling the frustum of a cone by creating triangular pleats 48. In particular, prior to the attachment of a leaflet assembly, the apices of the scalloped areas 37 are folded upon themselves and joined, such as by sewing, bonding, welding, molding, or gluing together to form pleats 48. As illustrated in FIG. 4D, pleats 48 may be formed by seams 49, and may have a width selected to impart any desired amount of taper to the skirt 46. The leaflets then may be assembled and attached to the skirt, and the valve body attached to frame 12, as described above. Advantageously, pleats 48 provides strengthened attachment points to secure skirt 46 to frame 12.

Referring to FIG. 5, valve body 14 is shown as it would appear when affixed to frame 12, but with frame 12 omitted to better illustrate where the valve body is affixed to the frame. During the step of affixing the valve body to the frame, flaps 36 of adjacent leaflets

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are affixed, e.g., by sutures, to span a cell of the frame to support commissures 24 (compare to FIG. 1B) and end tabs 39 are folded over and affixed to the proximal-most row of cells of the frame 12 (compare to FIG. 1A). Valve body 14 also is attached to frame 12 along seams 43 formed by the reinforcing tabs. Each joint 44 is aligned with and fastened to (e.g., by sutures or glue) to a curved contour defined by the struts of the cells of frame 12, so that joint 44 is affixed to and supported by frame 12 over most of the length of the joint. As discussed above, the configuration of the cells in frame 12 may be specifically customized define a curved contour that supports joints 44 of the valve body.

When completed assembled to frame 12, valve body 14 is affixed to frame 12 along the edges of flaps 36 of the commissures, end tabs 39, leaflet seams 42, reinforcing tab seams 43 and joints 44. In this manner, forces imposed on leaflets 22, commissures 24 and joints 44 are efficiently and evenly distributed over the valve body and transferred to frame 12, thus reducing stress concentration and fatigue of the valve body components. Moreover, the use of multiple thicknesses of material along seams 42 and 43 is expected to provide a highly durable valve body that will last for many years once implanted in a patient.

In accordance with another aspect of the present invention, the center of coaptation of leaflets 22 is a distance **L** below the point at which the commissures are affixed to the frame, as shown in FIG. 5. Compared to previously-known designs, in the present invention the overall lengths of the coaptation edges are increased, while leaflets 22 coapt along a shorter

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portion of those lengths. Several advantages arise from this design:

- the leaflets require only minimal pressure to open and have a rapid closing time.
- the valve demonstrates better washing dynamics when open, i.e., less turbulence along the free edges of the leaflets.
- the valve provides a more uniform distribution of stresses along the coaptation edges of leaflets 22.
- the angle at which force is transmitted to the commissures is increased, thereby substantially reducing the horizontal forces applied to the commissures that tend to pull the commissures away from the frame.
- controlling the center of the height of coaptation allows the commissures to be located proximal of the center of coaptation, thereby reducing the contracted delivery profile of the valve prosthesis.

All of the foregoing benefits are expected to reduce non-uniform loads applied to the valve body, and substantially enhance the durability of the valve prosthesis.

As will of course be apparent to one of skill in the art of prosthetic valve design, the assembly steps described above are merely illustrative, and a different order of assembling the leaflets and skirt to form valve body 14 may be employed. In an alternative embodiment, a conventional sewing ring may be attached to valve body 14 and frame 12 may be omitted. In this case, the valve prosthesis may be implanted surgically, rather than by percutaneous transluminal delivery. In this case, commissures 24 may be attached to the ascending aorta by sutures or other means as described above.

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Referring now to FIG. 6, implantation of valve prosthesis 10 of the present invention is described and is shown having skirt 46 from FIG. 4D. As discussed above, valve prosthesis preferably comprises a self-expanding multilevel frame that may be compressed to a contracted delivery configuration, as depicted in FIG. 3, onto an inner member of a delivery catheter. The valve prosthesis and inner member may then be loaded into a delivery sheath of conventional design, e.g., having a diameter of 18-20 French or less. Due in part to the fact that commissures 24 are longitudinally offset from the coaptation edges of the leaflets, the ability to customize the cell pattern along the length of the frame, and the construction of the skirt, it is expected that valve prosthesis may be designed to achieve a significantly smaller delivery profile than previously-known percutaneously-deliverable replacement valves.

The delivery catheter and valve prosthesis are then advanced in a retrograde manner through a cut-down to the femoral artery and into the patient's descending aorta. The catheter then is advanced, under fluoroscopic guidance, over the aortic arch, through the ascending aorta and mid-way across the defective aortic valve. Once positioning of the catheter is confirmed, the sheath of the delivery catheter may be withdrawn proximally, thereby permitting the valve prosthesis to self-expand.

As the valve prosthesis expands, it traps native leaflets **LN** of the patient's defective aortic valve against the valve annulus, retaining the native valve in a permanently open state. As further illustrated in FIG. 6, outflow section 15 of the valve prosthesis expands against, and aligns the prosthesis within, the ascending aorta, while inflow section 16

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becomes anchored in the aortic annulus of the left ventricle, so that skirt 21 reduces the risk of perivalvular leaks.

As also seen in FIG. 6, the deployed configuration of constriction region 17 holds valve body 14 in a supra-annular position, away from the heart walls, thereby ensuring that the constriction region expands to the predetermined fixed diameter. This in turn ensures that the valve body does not experience any unexpected lateral loads and therefore expands to its design diameter, e.g., illustratively either 22 or 24 mm as in Table 1 above.

Because outflow section 15 of frame 12 employs relatively larger cells than the remainder of the frame, valve prosthesis 10 does not disrupt blood flow into coronary arteries **CA** when deployed, and also does not obstruct subsequent catheter access to the coronary arteries. Accordingly, a clinician may readily gain access to the coronary arteries, for example, to perform angioplasty or stenting, simply by directing the angioplasty or stent delivery system guide wire through the openings in the cell pattern of frame 12.

While preferred embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

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What Is Claimed Is:

1. A valve prosthesis comprising:

a self-expanding multi-level frame having a contracted delivery configuration and an expanded deployed configuration, the multi-level frame having in the expanded deployed configuration an enlarged outflow section with a first nominal diameter, a conical inflow section having a second nominal diameter and a constriction region having a third fixed diameter smaller than the first and second nominal diameters; and

a valve body affixed to the multi-level frame, the valve body comprising a plurality of leaflets affixed to a skirt.

2. The valve prosthesis of claim 1 wherein the multi-level frame comprises a cell pattern defined by unequal length zig-zags.

3. The valve prosthesis of claim 1 wherein the conical section has a proximal end and the conical inflow section flares outward towards the proximal end.

4. The valve prosthesis of claim 1 wherein adjoining leaflets are affixed together to form commissures and have free edges that define coaptation edges and a center of coaptation, the commissures being longitudinally offset from the center of coaptation.

5. The valve prosthesis of claim 4 wherein the commissures are affixed to the multi-level frame at a location proximal of the center of coaptation.

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6. The valve prosthesis of claim 5 wherein the multi-level frame comprises a cell pattern and the commissures include flaps that span an entire area of at least one cell of the cell pattern.

7. The valve prosthesis of claim 4 wherein the commissures and coaptation edges of the leaflets define catenaries that substantially uniformly distribute loads over the leaflets.

8. The valve prosthesis of claim 7 wherein the catenaries are configured to reduce horizontal loads applied to the commissures.

9. The valve prosthesis of claim 1 wherein the leaflets are affixed to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the multi-level frame.

10. The valve prothesis of claim 9 wherein the multi-level frame further comprises a cell pattern that defines a contour configured to support the joints.

11. The valve prosthesis of claim 4 wherein each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures.

12. The valve prosthesis of claim 1 wherein the skirt further comprises a plurality of longitudinally-oriented reinforcing tabs or pleats.

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13. The valve prosthesis of claim 12 wherein the reinforcing tabs or pleats are affixed to the multi-level frame.

14. The valve prosthesis of claim 12 wherein the skirt further comprises a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the multi-level frame.

15. The valve prosthesis of claim 1 wherein the leaflets comprise a material selected from one of: porcine, bovine, equine or other mammalian pericardial tissue, synthetic material or polymeric material.

16. The valve prosthesis of claim 1 wherein the valve body is deployed supra-annularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the multi-level frame is in the expanded deployed configuration.

17. The valve prosthesis of claim 1 wherein the multi-level frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration.

18. The valve prosthesis of claim 1 wherein the multi-level frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration.

19. The valve prosthesis of claim 1 wherein multi-level frame has proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends.

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20. The valve prosthesis of claim 1 wherein the constriction region comprises a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constriction region to the outflow section.

21. The valve prosthesis of claim 1 wherein the skirt comprises a synthetic material.

22. The valve prosthesis of claim 21 wherein the skirt has a tubular shape in an undeformed configuration.

23. The valve prosthesis of claim 22 wherein skirt is configured in conical frustum shape formed by deforming the synthetic material.

24. The valve prosthesis of claim 23 wherein the conical frustum shape is formed by creating a plurality of longitudinally-oriented pleats in the synthetic material.

25. The valve prosthesis of claim 1 wherein the skirt comprises two or more individual panels of animal pericardial material.

26. The valve prosthesis of claim 1 wherein the skirt comprises two or more conjoined panels of animal pericardial material.

27. A valve prosthesis comprising:

a valve body comprising a plurality of leaflets affixed to a skirt, adjoining leaflets affixed together to form commissures and having free edges that define coaptation edges and a center of coaptation,

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wherein the commissures are longitudinally offset from the center of coaptation and define catenaries that substantially uniformly distribute loads over the leaflets.

28. The valve prosthesis of claim 27 wherein the catenaries are configured to reduce horizontal loads applied to the commissures.

29. The valve prosthesis of claim 27 wherein each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures.

30. The valve prosthesis of claim 27 wherein the skirt further comprises a plurality of longitudinally-oriented reinforcing tabs or pleats.

31. The valve prosthesis of claim 27 wherein the leaflets comprise a material selected from one of: porcine, bovine, equine or other mammalian pericardial tissue, synthetic material or polymeric material.

32. The valve prosthesis of claim 27 wherein the valve prosthesis further comprises a self-expanding frame, the leaflets are affixed to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame.

33. The valve prothesis of claim 32 wherein the frame further comprises a cell pattern that defines a contour configured to support the joints.

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34. The valve prosthesis of claim 30 wherein the valve prosthesis further comprises a self-expanding frame and the reinforcing tabs or pleats are affixed to the frame.

35. The valve prosthesis of claim 27 further comprising a self-expanding frame having a contracted delivery configuration and an expanded deployed configuration.

36. The valve prosthesis of claim 35 wherein the frame comprises a cell pattern defined by unequal length zig-zags.

37. The valve prosthesis of claim 35 wherein the commissures are affixed to the frame at a location proximal of the center of coaptation.

38. The valve prosthesis of claim 35 wherein the frame comprises a cell pattern and the commissures include flaps that span an entire area of at least one cell of the cell pattern.

39. The valve prosthesis of claim 35 wherein the skirt further comprises a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame.

40. The valve prosthesis of claim 35 wherein the valve body is deployed supra-annularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration.

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41. The valve prosthesis of claim 35 wherein the frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration.

42. The valve prosthesis of claim 35 wherein the frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration.

43. The valve prosthesis of claim 35 wherein frame has proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends.

44. The valve prosthesis of claim 35 wherein the frame has, in the expanded deployed configuration, an enlarged outflow section with a first nominal diameter, a conical inflow section having a second nominal diameter and a constriction region having a third fixed diameter smaller than the first and second nominal diameters.

45. The valve prosthesis of claim 44 wherein the conical section has a proximal end and the conical section flares outward towards the proximal end.

46. The valve prosthesis of claim 44 wherein the constriction region comprises a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section.

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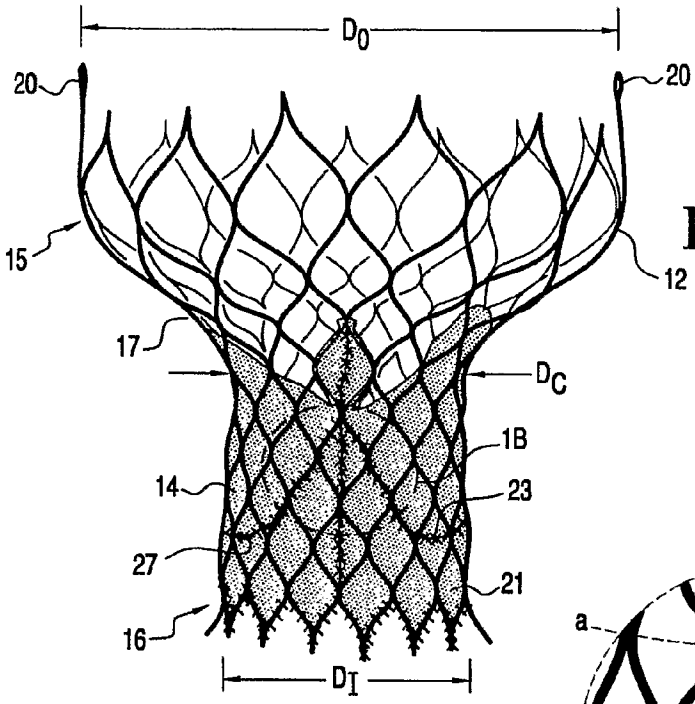

FIG.1A

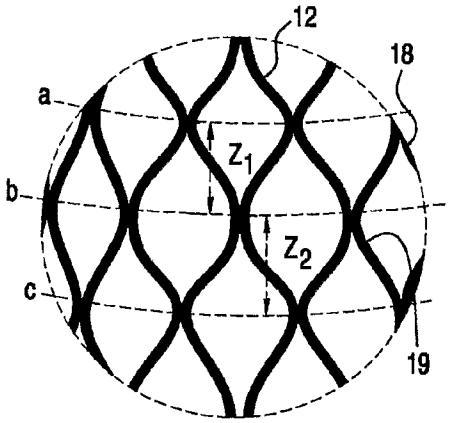

FIG.1B

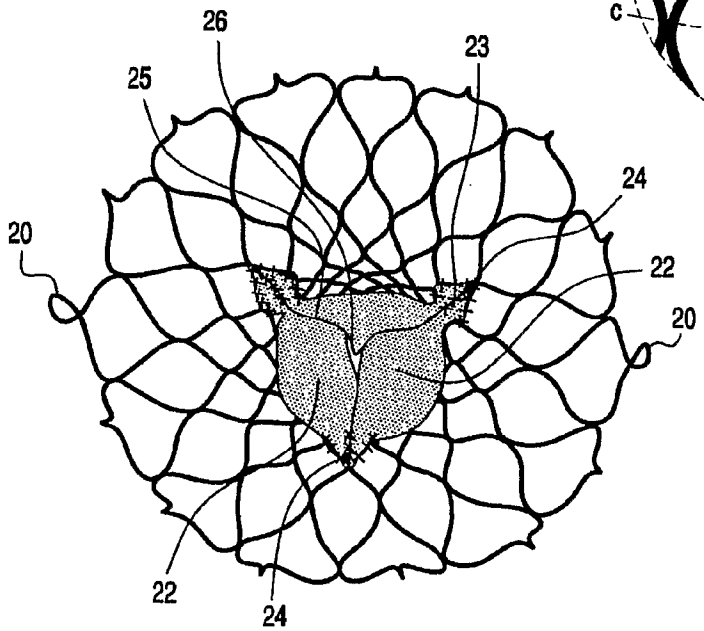

FIG.1C

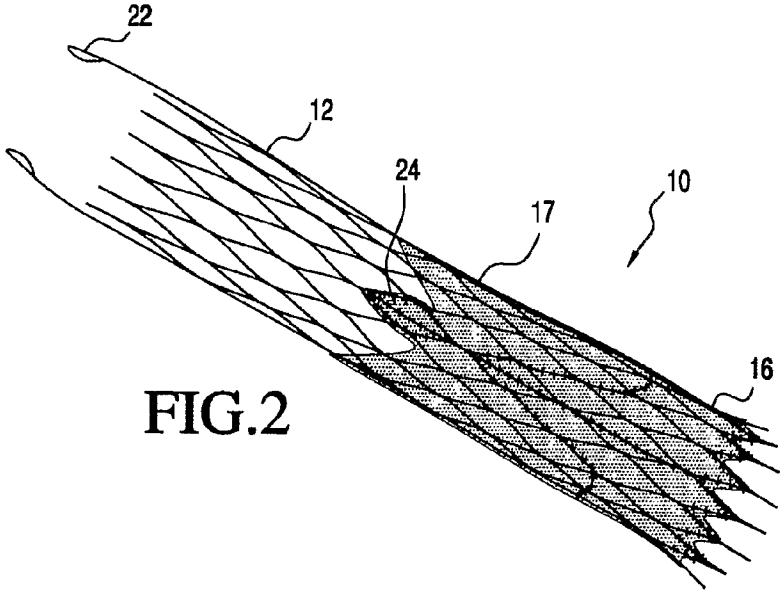

FIG.2

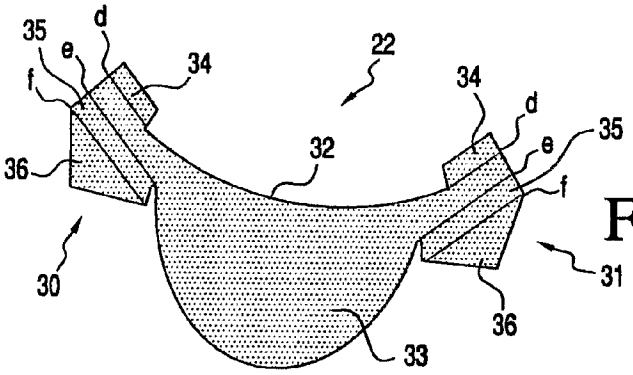

FIG.3A

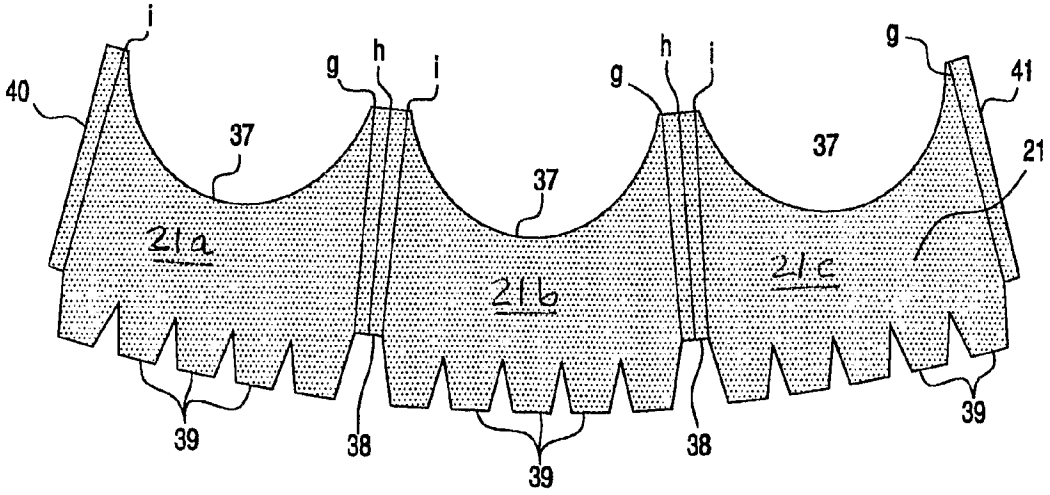

FIG.3B

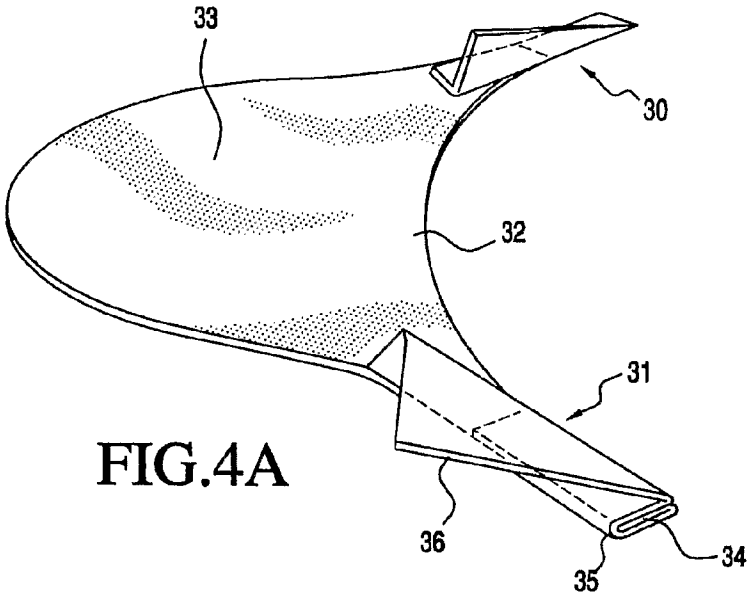
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FIG.4A

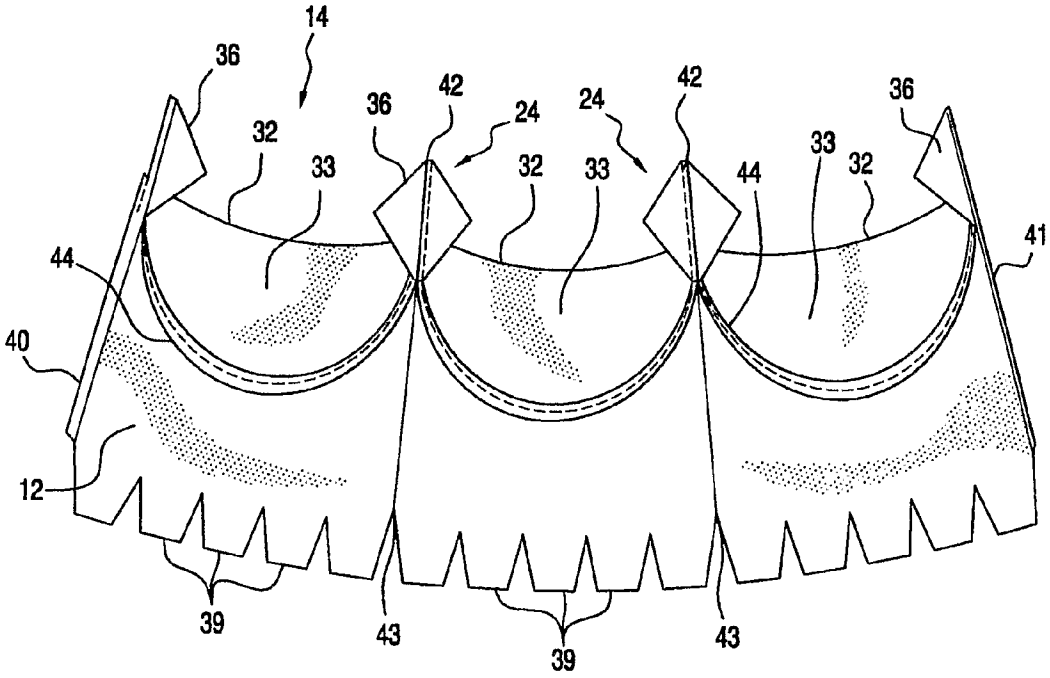
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FIG.4B

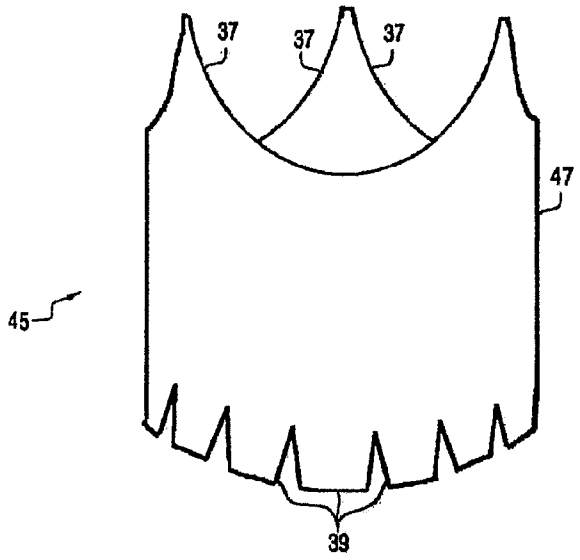

FIG.4C

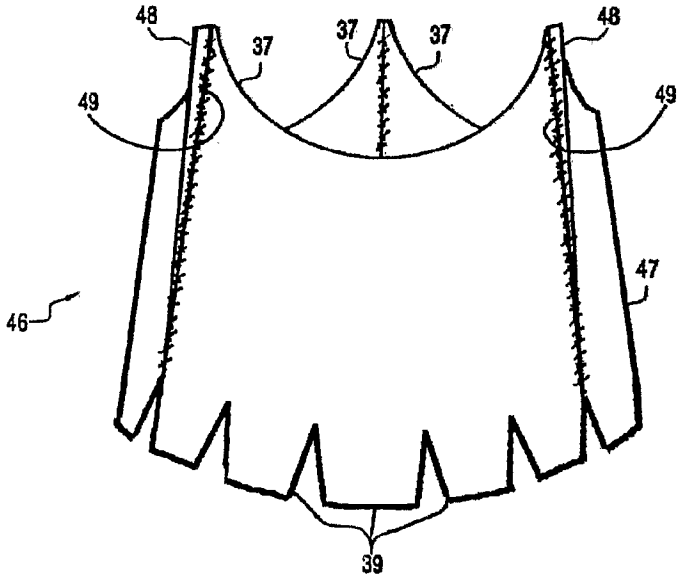

FIG.4D

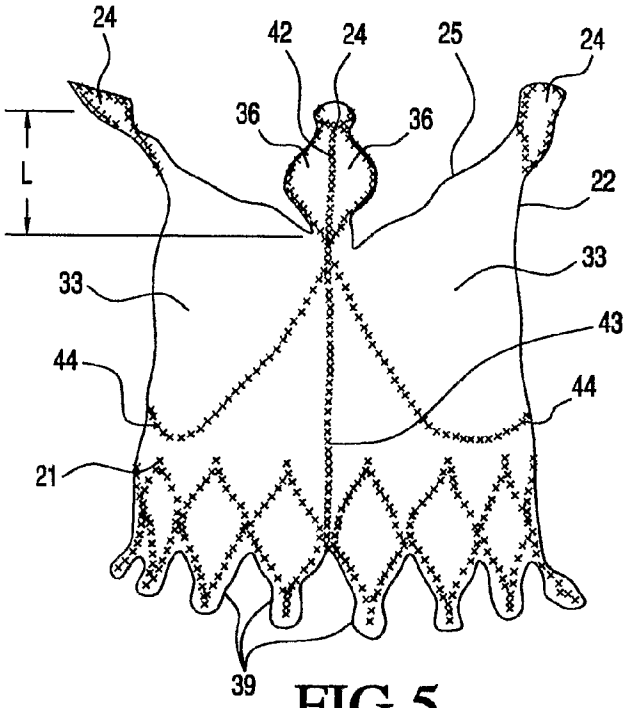
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FIG.5

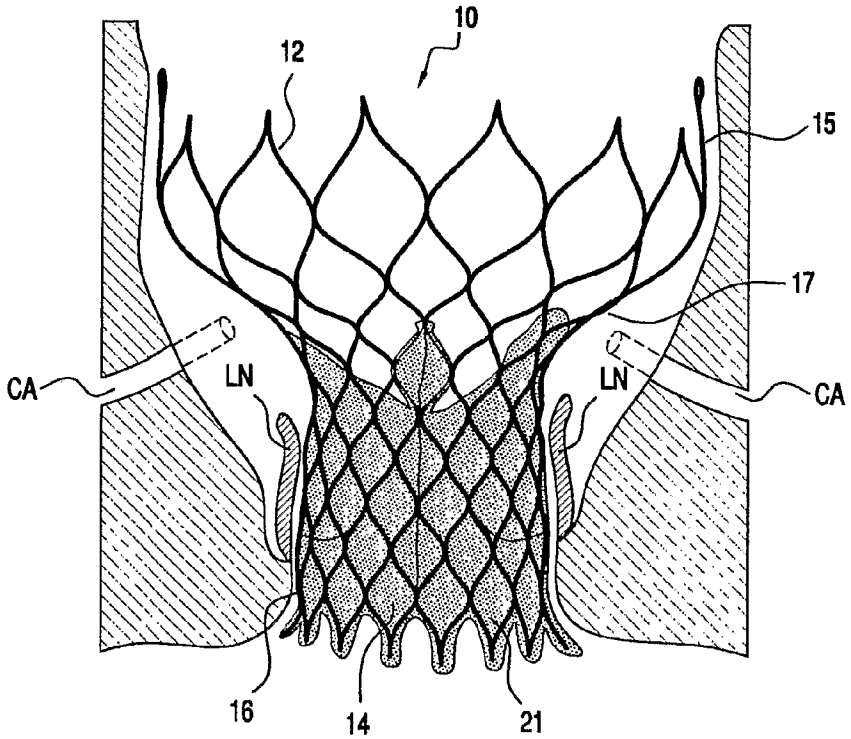
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FIG.6

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/131,869	12/23/2020	Ali Shahriari	426/2/20 UTIL	1293

175373 7590 01/15/2021

Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

EXAMINER	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
01/15/2021	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):

usptomail@nkpatentlaw.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/131,869	**Applicant(s)** Shahriari, Ali	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** No

1. THE REQUEST FILED 23 December 2020 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/131,869

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	350		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	10 minus 20 =	*	x 50 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 240 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	830		TOTAL	

APPLICATION AS AMENDED - PART II

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

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

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

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United States Patent and Trademark Office
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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
17/131,869	12/23/2020		830	426/2/20 UTIL	10	1

CONFIRMATION NO. 1293

175373
Aortic Innovations, LLC
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606

FILING RECEIPT

OC000000122327598

Date Mailed: 01/08/2021

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

Ali Shahriari, Boca Raton, FL;

Applicant(s)

Aortic Innovations, LLC, Hilsboro Beach, FL

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 17/060,557 10/01/2020 PAT 10888441
which is a CON of 16/910,189 06/24/2020 PAT 10857011
which is a CON of 16/808,137 03/03/2020 PAT 10792172
which is a CON of 16/736,879 01/08/2020 PAT 10842655
which is a CON of 16/042,286 07/23/2018 PAT 10555823
which is a CON of 14/614,628 02/05/2015 PAT 10028848
which is a CON of 14/569,306 12/12/2014 PAT 9339399
which is a DIV of 13/706,896 12/06/2012 PAT 8940040
which claims benefit of 61/723,446 11/07/2012
and claims benefit of 61/567,458 12/06/2011

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 Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 01/07/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/131,869**

Projected Publication Date: 04/15/2021

Non-Publication Request: No

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

TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

Preliminary Class

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.

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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

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).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor

community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

Aortic Innovations, LLC, Exhibit 2131
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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Ali Shahriari	Nonprovisional Application Number (if known):	
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Justin R. Nifong/	Date 2020-12-23
Name (Print/Typed) Justin R. Nifong	Practitioner Registration Number 59389

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 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.

TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

[0001] This application is a continuation of U.S. Patent Application No. 17/060,557 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on October 1, 2020, which is a continuation of U.S. Patent Application No. 16/910,189 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on June 24, 2020, which is a continuation of U.S. Patent Application No. 16/808,137 entitled "HEART VALVE REPLACEMENT DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on March 3, 2020 and issued as U.S. Patent No. 10,792,172 on October 6, 2020, which is a continuation of U.S. Patent Application No. 16/736,879 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on January 8, 2020, which is a continuation of U.S. Patent Application No. 16/042,286 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on July 23, 2018 and issued as U.S. Patent No. 10,555,823 on February 11, 2020, which is a continuation of U.S. Patent Application No. 14/614,628 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on February 5, 2015 and issued as U.S. Patent No. 10,028,848 on July 24, 2018, which is a continuation of U.S. Patent Application No. 14/569,306 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on December 12, 2014 and issued as U.S. Patent No. 9,339,399 on May 17, 2016, which is a divisional of U.S. Patent Application No. 13/706,896 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on December 6, 2012 and issued as U.S. Patent No. 8,940,040 on January 27, 2015, which claims the benefit under 35 U.S.C. § 119 to U.S. Provisional

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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

Application Serial No. 61/567,458 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on December 6, 2011. Application No. 13/706,896 also claims priority under § 119 to U.S. Provisional Application Serial No. 61/723,446 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on November 7, 2012. Each of the applications referenced herein are incorporated by reference in their entirety.

TECHNICAL FIELD

[0002] The present disclosure relates to a device and method of using same for endovascular aortic repair, including repair of aortic valve disease, aortic stenosis, ascending aortic aneurysms, aortic insufficiency, aortic regurgitation, ascending aneurysm, bicuspid valve disease, and/or Type A dissections.

BACKGROUND

[0003] The normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of Valsalva, the sinutubular junction, and the tubular portion. The challenge facing practitioners of endovascular repair of ascending aortic aneurysms is that there is a very short proximal landing zone at the level of the sinutubular junction, there is variable coronary anatomy from patient to patient, and, in many cases, there is involvement of the aortic valve with either stenosis or insufficiency. Generally speaking, and as discussed in the article SURGERY INSIGHT: THE DILATED ASCENDING AORTA — INDICATIONS FOR SURGICAL INTERVENTION, by James E. Davies and Thralf M. Sundt published in Nature Clinical Practice Cardiovascular Medicine (2007), the contents of which are incorporated herein by reference in its entirety, there are three basic types of involvement of the ascending aorta, designated as Type A,

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B, or C. These will be discussed in further detail below and are shown in FIGS. 1A-1C, which have been reproduced from the referenced article.

[0004] Type A aneurysms are most commonly found in younger patients and patients with connective tissue disorders such as Marfan syndrome. The anatomical characteristics of Type A aneurysms are dilatation of the sinuses of Valsalva with or without dilatation of the aortic annulus. The sinutubular junction is most often dilated. The valve could be normal, stenotic or insufficient. An example of a Type A aneurysm is shown in FIG. 1A.

[0005] The anatomical characteristics of Type B aneurysms are dilatation of the tubular portion. Initially the sinutubular junction may be normal or mildly dilated, however as the aneurysm grows, it stretches the sinutubular junction and may eventually lead to aortic insufficiency. The valve could be normal, stenotic or insufficient. The bulk of the aneurysm is at the level of the tubular aorta. An example of a Type B aneurysm is shown in FIG. lB.

[0006] The anatomical characteristics of Type C aneurysms are dilatation of the sinuses of Valsalva, sinutubular junction and the tubular portion of the aorta. The valve could be normal, stenotic or insufficient. Type B and C aneurysms are most commonly found in an older group of patients. An example of a Type C aneurysm is shown in FIG. 1C.

[0007] There are devices clinically used for endovascular repair of ascending aortic aneurysms. Although transcatheter valves are a clinical reality, none in clinical use have been designed with the purpose of endovascular repair of multiple types of ascending aortic aneurysms. Indeed, a device is needed that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions. A device is also needed that would allow for treatment of different coronary anatomical variations among the patient

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population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

SUMMARY

[0008] According to one aspect of the disclosure, an endograft device for endovascular repair of ascending aortic aneurysms is disclosed. The endograft device includes a first prosthetic component that has a proximal frame and a distal frame that is secured to the proximal frame and extends to a distal end of the first prosthetic component. The endograft device also includes at least one conduit that is secured to the first prosthetic component and that is positioned adjacent to the proximal frame, and a second prosthetic component that is secured to a proximal end of the first prosthetic component. The second prosthetic component includes a balloon-expandable frame extending distally from a proximal end of the second prosthetic component and a self-expanding frame that is connected to the balloon-expandable frame and extends to a distal end of the second prosthetic component. The endograft device also includes a valve element that is secured to the balloon-expandable frame at the proximal end of the second prosthetic component.

[0009] In some embodiments, the self-expanding frame may have an hourglass shape. In some embodiments, the self-expanding frame may include a first section that tapers inwardly between a proximal end and a distal end. The endograft device may also include a second section having a proximal end that is secured to the distal end of the first section. The second section may taper outwardly between the proximal end of the second section and a distal end of the second section. Additionally, in some embodiments, the proximal end of the first section may be connected to a distal end of the balloon-expandable frame.

[0010] In some embodiments, the self-expanding frame may include a third section that extends proximally from the proximal end of the first section. The third section may have a

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passageway defined therein, and the balloon-expandable frame may be positioned in the passageway of the third section of the self-expanding frame. In some embodiments, the balloon-expandable frame may be expandable between an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

[0011] In some embodiments, a plurality of fibers may be attached to the third section of the self-expanding frame. When the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame may be engaged with the plurality of fibers.

[0012] In some embodiments, the proximal frame of the first prosthetic component may have a passageway defined therein, and the distal end of the second prosthetic component may be positioned in the passageway of the first prosthetic component.

[0013] In some embodiments, the conduit may include a pair of conduits positioned on opposite sides of the first prosthetic component. Additionally, in some embodiments, the conduit may have a proximal opening that is positioned adjacent to a proximal end of the first prosthetic component.

[0014] In some embodiments, the proximal frame may include a first section secured to the distal end of the second prosthetic component, and a second section connected to the first section. The second section may taper outward between a proximal end connected to the first section and a distal end. The conduit may have a distal opening defined in the second section of the proximal frame.

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[0015] Additionally, in some embodiments, the endograft device may include a stent having a distal end positioned in the proximal opening of the at least one conduit and a proximal end configured to be positioned in a coronary artery.

[0016] In some embodiments, an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component may be covered such that fluid is prevented from passing therethrough. Additionally, an outer surface of the distal frame of the first prosthetic component may be uncovered such that is fluid permitted to pass therethrough.

[0017] According to another aspect, a transcatheter valve is disclosed. The transcatheter valve includes a frame component having a balloon-expandable frame extending distally from a proximal end of the frame component and a self-expanding frame secured to the balloon-expandable frame. The self-expanding frame includes a first section that tapers inwardly between a proximal end and a distal end, and a second section that tapers outwardly between a proximal end secured to the distal end of the first section and a distal end. A valve element is positioned in the balloon-expandable frame at the proximal end of the frame component.

[0018] In some embodiments, the frame component may be a dual-frame component. The self-expanding frame may be an outer frame of the dual-frame component and may have a passageway defined therein. The balloon-expandable frame may be an inner frame of the dual-frame component that is positioned in the passageway defined in the self-expanding frame. Additionally, the balloon-expandable frame may be expandable between an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

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[0019] In some embodiments, a plurality of fibers may be attached to the self-expanding frame. When the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame may be engaged with the plurality of fibers. Additionally, in some embodiments, an outer surface of the first section of the self-expanding frame may be uncovered such that fluid is permitted to pass therethrough and an outer surface of the second section of the self-expanding frame may be covered such that fluid is prevented from passing therethrough.

[0020] In some embodiments, the self-expanding frame may include an elongated section extending distally from the second section. The elongated section may have a length that is greater than a combined length of the first section and the second section. Additionally, in some embodiments, the self-expanding frame may be covered with at least one of a collagen and hydrogel. In some embodiments, the valve element may be one of a bicuspid valve and a tricuspid valve.

[0021] According to another aspect, a method of repairing a patient's aorta is disclosed. The method includes introducing a first prosthetic component into the patient's aorta such that a proximal frame of the first prosthetic component is positioned in the ascending aorta and a distal frame of the first prosthetic component is positioned in the aortic arch of the patient's aorta, advancing a covered stent through a conduit defined in the first prosthetic component into a coronary artery of the patient's aorta, securing a second prosthetic component to a proximal end of the first prosthetic component in the patient's aorta, and expanding a proximal section of the second prosthetic component into engagement with the aortic annulus of the patient's aorta such that a valve secured to the proximal section is positioned in the aortic annulus proximal to the coronary arteries.

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[0022] In some embodiments, expanding the proximal section of the second prosthetic component may include operating a balloon-expandable frame. Additionally, in some embodiments, expanding the proximal section of the second prosthetic component may include permitting a self-expanding frame to expand into engagement with the aortic annulus, and operating the balloon-expandable frame may include advancing an outer surface of the balloon-expandable frame into engagement with an inner surface of the self-expanding frame after the self-expanding frame is engaged with the aortic annulus.

[0023] In some embodiments, operating the balloon-expandable frame may include advancing an outer surface of the balloon-expandable frame into engagement with the aortic annulus.

[0024] In some embodiments, an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component may be covered such that fluid is prevented from passing therethrough. Additionally, an outer surface of the distal frame of the first prosthetic component may be uncovered such that is permitted to pass therethrough.

[0025] In some embodiments, introducing the first prosthetic component into the patient's aorta and advancing the covered stent through the conduit defined in the first prosthetic component into the coronary artery of the patient's aorta may be performed during a first surgical procedure. In some embodiments, securing the second prosthetic component to the proximal end of the first prosthetic component and expanding the proximal section of the second prosthetic component into engagement with the aortic annulus of the patient's aorta may be performed during a second surgical procedure different from the first surgical procedure.

[0026] In some embodiments, the method may also include introducing the second prosthetic component into the ascending aorta prior to introducing the first prosthetic component.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

[0028] FIG. 1 is an illustrative aorta;

[0029] FIG. 1A is an example of a Type A aneurysm;

[0030] FIG. 1B is an example of a Type B aneurysm;

[0031] FIG. 1C is an example of a Type C aneurysm;

[0032] FIG. 2 is partial cutaway view of an aorta with an embodiment of an endovascular prosthetic device implanted therein;

[0033] FIG. 3 is an elevation view of a proximal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0034] FIG. 4 is an elevation view of a distal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0035] FIG. 5 is a cross sectional view of the distal prosthetic component of FIG. 4 taken along the line 5-5 in FIG. 4;

[0036] FIG. 6 is a partial cutaway view of the aorta with the distal prosthetic component of FIG. 3 implanted therein;

[0037] FIG. 7 is a view similar to FIG. 6 showing stents extending from the distal prosthetic component;

[0038] FIG. 8 is an elevation view of another embodiment of a proximal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0039] FIG. 9 is an elevation view of a self-expanding outer frame of the proximal prosthetic component of FIG. 8;

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[0040] FIG. 10 is an elevation view of a balloon-expandable inner frame of the proximal prosthetic component of FIG. 8;

[0041] FIG. 11 is a perspective view a proximal end of the proximal prosthetic component of FIG. 8;

[0042] FIG. 12 is a cross-sectional elevation view of the proximal prosthetic component of FIG. 8 taken along the line 12-12 in FIG. 11;

[0043] FIG. 13 is a plan view of the proximal prosthetic component of FIG. 8 showing the inner frame in an unexpanded position;

[0044] FIG. 14 is a plan view similar to FIG. 13 showing the inner frame in an expanded position;

[0045] FIG. 15 is a partial cutaway view of the aorta with the distal prosthetic component of FIG. 4 secured to the proximal prosthetic component of FIG. 8;

[0046] FIG. 16 is a view similar to FIG. 15 showing the inner frame in an expanded position;

[0047] FIG. 17 is an embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. 3;

[0048] FIGS. 18-19 are partial cutaway views of the aorta with the transcatheter valve of FIG. 17 implanted therein;

[0049] FIG. 20 is another embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. 8; and

[0050] FIGS. 21-22 are partial cutaway views of the aorta with the transcatheter valve of FIG. 20 implanted therein.

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DETAILED DESCRIPTION OF THE DRAWINGS

[0051] While the concepts of the present disclosure are susceptible to various modifications and alternative forms, specific exemplary embodiments thereof have been illustrated by way of example in the drawings and will herein be described in detail. It should be understood, however, that there is no intent to limit the concepts of the present disclosure to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

[0052] Terms representing anatomical references, such as anterior, posterior, medial, lateral, superior, inferior, distal, proximal, etcetera, may be used throughout the specification in reference to the orthopaedic implants and surgical instruments described herein as well as in reference to the patient's natural anatomy. Such terms have well-understood meanings in both the study of anatomy and the field of orthopaedics. Use of such anatomical reference terms in the written description and claims is intended to be consistent with their well-understood meanings unless noted otherwise. For example, the term "proximal" refers to the direction that is generally closest to the heart, and the term "distal" refers to the direction that is generally furthest from the heart.

[0053] Referring to FIGS. 2-16, exemplary designs of an endovascular prosthetic device or endograft device 10 (hereinafter device 10) are shown. The device 10 is intended for the treatment of most ascending aortic aneurysms and is configured to treat any type of ascending aneurysm regardless of involvement of the aortic valve and the sinuses of Valsalva. As described in greater detail below, the device 10 permits future coronary and aortic valve interventions as well as extension of a fenestrated/ branch graft into the aortic arch. Part of the device 10 may also be modified and used as a transcatheter valve, as described in greater detail below in regard to FIGS.

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17-22. Such a valve may be introduced transfemorally or through the subclavian artery or the apex of the heart.

[0054] Referring now to FIGS. 2-7, the device 10 includes a proximal component 12 that is attached to a distal component 14. As shown in FIG. 2, the distal component 14 may be secured to the proximal component 12 when implanted into a patient's aorta 16. When implanted, the proximal component 12 is positioned in the patient's ascending aorta 18, while the distal component 14 extends distally into the arch 20 of the patient's aorta 16. The distal component 14 includes a pair of "Endo-cabrol conduits" or conduits 22, and each conduit 22 is sized to receive a catheter or stent 24 for coronary blood flow, as described in greater detail below. The device 10 is configured to treat all ascending aneurysms with or without dilated sinutubular junctions and aortic valve disease.

[0055] As shown in FIG. 3, the proximal component 12 includes a frame 26 that extends from a proximal end 28 to a distal end 30. The frame 26 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 12. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. It should be appreciated that in other embodiments the valve 32 may be tricuspid or quadracuspid. The valve 32 may be constructed from treated bovine pericardium or other suitable proven biological or synthetic material. When the proximal component 12 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the proximal component 12.

[0056] The valve 32 is housed in a balloon-expandable frame 34 of the frame 26. As shown in FIG. 3, the balloon-expandable frame 34 is embodied as a balloon-expandable stent 38 that extends distally from the proximal end 28 of the component 12 and has a length 40 of

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approximately 15 mm. In other embodiments, the stent 38 may be longer or shorter depending on, for example, the patient's anatomy. The stent 38 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 38 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface 42 of the stent 38 is covered with low-profile polyester, ePTFE, or other nonporous covering material 44 that prevents fluid from passing through the outer surface 42. However, it should be appreciated that the stent 38 may be covered with standard polyester or other nonporous materials.

[0057] As shown in FIG. 3, the stent 38 of the balloon-expandable frame 34 has a diameter 46. As described in greater detail below, the balloon-expandable frame 34 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 46. In the illustrative embodiment, the expanded diameter 46 is equal to approximately 26 mm when the frame 34 is expanded. In other embodiments, the expanded diameter may be greater than or less than 26 mm depending on, for example, the patient's anatomy. Examples of balloon-expandable stents are described in U.S. Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft" by Julio C. Palmaz and U.S. Patent No. 6,582,462 entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis" by Henning Rud Andersen et al., which are expressly incorporated herein by reference. In the illustrative embodiment, the diameter 46 is oversized relative to the diameter of the aortic annulus 210 (see FIG. 1) such that an interference fit is created between the stent 38 and the annulus 210 when the component 12 is implanted and the stent 38 is expanded, as described in greater detail below.

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[0058] The balloon-expandable frame 34 is attached to a self-expanding frame 50. In the illustrative embodiment, the distal end 52 of the balloon-expandable frame 34 is secured to the proximal end 54 of the frame 50 by stitching or sewing the frames 34, 50 together, thereby forming the frame 26 of the component 12. It should be appreciated that in other embodiments the frames 34, 50 may be secured together via welding or other fasteners. The frames 34, 50 may also be formed as a single, monolithic frame.

[0059] As shown in FIG. 3, the self-expanding frame 50 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the frame 50 may be formed from a polymeric material. The frame 50 includes an inwardly tapered proximal section 60, an outwardly tapered middle section 62, and an elongated distal section 64. The section 60 includes the proximal end 54 of the frame 50 and has a distal end 66 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 60 tapers inwardly between the ends 54, 66 from approximately 26 mm at the end 54 to approximately 22 mm at the end 66. In the illustrative embodiment, the proximal section 60 has a length 70 of approximately 10 mm. It should be appreciated that in other embodiments the dimensions of the section 60 may vary depending on, for example, the patient's anatomy.

[0060] The outwardly tapered middle section 62 of the self-expanding frame 50 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy. Among other things, the

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tapered sections 60, 62 of the proximal component 12 permit the placement of the stents 24 that extend from the distal component 14 to the coronary arteries, as described in greater detail below.

[0061] The elongated distal section 64 of the self-expanding frame 50 extends distally from the proximal end 74 to the distal end 30 of the component 12. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 25 mm and has a diameter 80 of approximately 28 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[0062] As shown in FIG. 3, the proximal section 60 of the self-expanding frame 50 is formed in an open-cell stent configuration, and the sections 62, 64 are formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 60, 62, 64 may be formed in a single configuration, including an open-cell stent configuration or Z-stent configuration. The sections 60, 62, 64 may also be formed as a single monolithic component. The outer surface 82 of the self-expanding frame 50 is covered with low profile polyester, ePTFE, or other nonporous covering material 84 such that fluid is prevented from passing through the surface 82. In that way, the entire outer surface of the component 12 is covered to prevent fluid from passing therethrough. The covering material 84 immediately distal to the balloon-expandable frame 34 is equipped with a "trap door" 86, which may be opened to permit the passage of one or more surgical instruments for embolization of possible paravalvular leaks. The entire outer surface of component 12 may be also covered with low-profile Dacron or other synthetic material. It

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should also be appreciated that all or part of the component 12 may be covered with hydrogel or other sealing material.

[0063] As described above, the device 10 also includes a distal component 14, which is secured to the distal end 30 of the proximal component 12 when the device 10 is implanted in the patient's aorta 16. Referring now to FIG. 4, the distal component 14 includes a frame 100 that extends from a proximal end 102 configured to be secured to the proximal component 12 to a distal end 104. The frame 100 has a passageway 106 defined therein, which extends through the ends 102, 104 of the component 14. The passageway 106 has a diameter 108 and is sized to receive the distal end 30 of the proximal component 12 when the device 10 is assembled.

[0064] In the illustrative embodiment, the components 12, 14 are secured together via an interference fit between the frame 100 and the distal end 30 of the proximal component 12. Specifically, the diameter 108 of the passageway 106 is less than the diameter 80 of the proximal component 12. In the illustrative embodiment, the diameter 108 is equal to approximately 26 mm. It should be appreciated that in other embodiments the components 12, 14 may be secured together via stitching or other fastening means.

[0065] As shown in FIG. 4, the component 14 includes a proximal frame 110 that is connected to an elongated distal frame 112. The proximal frame 110 and the distal frame 112 are formed from metallic materials, such as, nitinol, stainless steel, or other implant grade metallic materials. It should be appreciated that in other embodiments the frames 110, 112 may be formed from a polymeric material. The proximal frame 110 is formed in a Z-stent configuration, and the distal frame 112 is formed in an open-cell configuration. Each of the frames 110, 112 is self-expanding. In the illustrative embodiment, the distal frame 112 is secured to the distal end 114 of the proximal frame 110 by stitching or sewing the frames 110, 112 together. It should be

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appreciated that in other embodiments the frames 110, 112 may be secured together via welding or other fasteners. The frames 110, 112 may also be formed as a single, monolithic frame.

[0066] The proximal frame 110 has an outer surface 120 that is covered with low profile polyester, ePTFE, or other nonporous covering material 122. As a result, fluid is prevented from passing through the surface 120. The distal frame 112 is uncovered such that fluid is permitted to pass through the openings 124 formed therein.

[0067] As shown in FIG. 4, the proximal frame 110 includes a proximal section 126, an outwardly tapered section 128 extending distally from the proximal section 126, and an elongated distal section 130. The proximal section 126 includes the proximal end 102 of the component 14 and has a distal end 132 connected to the proximal end 134 of the outwardly tapered section 128. In the illustrative embodiment, the proximal section 126 has a length 136 of approximately 25 mm. It should be appreciated that in other embodiments the dimensions of the section 126 may vary depending on, for example, the patient's anatomy.

[0068] The tapered section 128 of the frame 110 has the proximal end 134 and a distal end 140 connected to the proximal end 142 of the elongated distal section 130. The section 128 tapers outwardly from a diameter of approximately 26 mm at the end 132 to a diameter between approximately 44 mm and 48 mm at the end 140. In the illustrative embodiment, the tapered section 128 has a length 146 of approximately 10 mm. It should be appreciated that in other embodiments the dimensions of the section 128 may vary depending on, for example, the patient's anatomy.

[0069] The elongated distal section 130 of the frame 110 extends distally from the proximal end 142 to the distal end 114 of the frame 110. In the illustrative embodiment, the section 130 has a length 150. In one particular non-limiting example, the length 150 of the elongated distal

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section 130 is approximately 20 mm. The section 130 also has a diameter 152 of between approximately 44 mm and 48 mm. In other embodiments, the dimensions of the section 130 may vary depending on, for example, the patient's anatomy.

[0070] As described above, the distal component 14 also includes a pair of conduits 22, which are connected to the proximal frame 110. Each conduit 22 has a distal end 160 secured to the tapered section 128 of the frame 110 and a proximal end 162 positioned adjacent to the proximal end 102 of the component 12. As shown in FIG. 4, the conduit 22 does not extend beyond the proximal end 102 of the component 12. Each conduit 22 has a passageway 164 that extends through the ends 160, 162 and is sized to receive a stent 24.

[0071] The passageway 164 has a proximal opening 166 defined in the end 162. The opening 166 has a diameter 168 that in the exemplary embodiment is equal to approximately 5 mm. As shown in FIG. 5, the passageway 164 has a distal opening 170 that is defined in the end 160 and the tapered section 128 of the frame 110. The distal opening 170 has a diameter 172 that is greater than the diameter 168. In the illustrative embodiment, the diameter 172 is equal to approximately 8 mm. The passageway 164 measures approximately 8 mm in diameter over a distance 174 of approximately 5 mm and tapers smoothly into the approximately 5 mm diameter 168 at a junction 176. The passageway 164 maintains the diameter 168 between the junction 176 and the proximal opening 166. In the illustrative embodiment, the passageway 164 has a length 180 of approximately 2 cm between the junction 176 and the proximal opening 166.

[0072] Each conduit 22 is wire reinforced and allows for passage of catheters or stents 24 and easier cannulation of the coronary ostia, regardless of deployment orientation. This configuration allows stenting of the coronary arteries 182 (see FIG. 1) prior to the deployment of component 12, as described in greater detail below. In the illustrative embodiment, the tapered

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section 128 permits the uncompromised passage of stents 24 into the coronary arteries 182 in such a way that the stents are not compressed between the sinutubular junction and the device 10 itself.

[0073] As shown in FIG. 4, the elongated distal frame 112 of the component 14 extends distally from the distal end 114 of the frame 110 to the distal end 104 of the component 14. In the illustrative embodiment, the frame 112 has a length 190. In one particular non-limiting example, the length 190 of the elongated frame 112 is approximately 10 cm, which is sufficient to cover the arch 20 of the aorta 18 when implanted therein. In other embodiments, the dimensions of the frame 112 may vary depending on, for example, the patient's anatomy. The distal frame 112 permits the accurate deployment of component 14 without compromising the circulation to supra-aortic branches. It also allows for cannulation of the supra-aortic branches, if placement of a fenestrated/ branch arch device is necessary.

[0074] To implant the device 10 in the patient's aorta 16, a surgeon may obtain open exposure or percutaneous access to the common femoral artery. The iliac arteries or an iliac conduit may also be used. After obtaining access and placing a stiff wire in the ascending aorta 18, the device 10 and the delivery system are prepared. In the illustrative embodiment, the delivery system is composed of a 100-105 cm hydrophilic sheath. As shown in FIG. 6, the distal component 14 is delivered first. After performing a lateral oblique thoracic aortogram, the component 14 is deployed such that the distal end 114 of the proximal frame 110 is positioned proximal to the innominate artery 200, thereby ensuring that the distal openings 170 of the conduits 22 are at 12 and 6 o'clock positions in relationship to the innominate artery 200.

[0075] Using the contralateral common femoral artery wires, standard coronary guide catheters are introduced through the distal frame 112 of the component 14 into each conduit 22. The conduits 22 may then be cannulated with the catheters prior to insertion of the stents 24.

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Alternatively, the conduits 22 may be pre-cannulated. Using the catheters, access is obtained to the right and left coronary arteries 182. The stents 24 are advanced into the passageways 164 through the distal openings 170 and out of the conduits 22 to bridge the arteries 182 and the conduits 22, as shown in FIG. 7. In that way, each artery 182 is connected to its respective conduit 22. Each stent 24 is covered and may be embodied as a balloon-expandable stent or a self-expanding stent. It should be appreciated that coronary artery bypasses may be performed to the right and left coronary systems prior to the placement of the component 14.

[0076] The proximal component 12 may be deployed after the implantation of the distal component 14. The components 12, 14 may be deployed in a single surgical procedure taking place on a single day or the component 14 may be deployed in one procedure, and the component 12 may be deployed in another, separate procedure at a later date. As shown in FIG. 1, the proximal component 12 is deployed into the position across the native aortic valve 202.

[0077] To do so, a stiff wire is passed through the aortic valve 202 into the left ventricle 204. The delivery system for the proximal component 12 is passed through the valve 202. An example of a delivery system is described in U.S. Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft" by Julio C. Palmaz, which is incorporated herein by reference. When the delivery system is in position, the proximal component 12 is released by unsheathing the system, thereby permitting expansion of the self-expanding frame 50. As described above, the self-expanding frame 50 engages the proximal end 102 of the distal component 14 to secure the components 12, 14 together and seal the distal end 30 of the component 12 within the distal component 14. As shown in FIG. 2, the proximal end 28 of the proximal component 12 is positioned in the aortic annulus, and the

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hour-glass shape of the component 12 provides a space for the native aortic valve leaflets such that the leaflets are not pressed against or over the openings of coronary arteries 182.

[0078] The balloon-expandable frame 34 may be now deployed by inflating the balloon within the delivery system. This deploys the frame 34 to the predetermined expanded diameter 46 and advances the frame 34 into engagement with the aortic annulus 210, thereby sealing the aortic annulus 210 such that fluid is permitted to pass from the left ventricle 204 only through the valve 32. As shown FIG. 1, the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182. It should be appreciated that the deployment of the component 12 may be performed during rapid ventricular pacing (RVP). In cases with aortic stenosis, the valve 32 may be dilated with balloon angioplasty prior to the introduction of the proximal component 12.

[0079] Referring now to FIGS. 8-16, another embodiment of a proximal component 212 of the device 10 is shown. Some features of the embodiment illustrated in FIGS. 8-16 are substantially similar to those described above in reference to the embodiment of FIGS. 1-7. Such features are designated in FIGS. 8-16 with the same reference numbers as those used in FIGS. 1-7. Similar to the proximal component 12 of FIGS. 1-7, the proximal component 212 may be secured to the distal component 14 when implanted into a patient's aorta 16. When implanted, the proximal component 212 is positioned in the patient's ascending aorta 18, while the distal component 14 extends distally into the arch 20 of the patient's aorta 16.

[0080] As shown in FIG. 8, the proximal component 212 includes a dual-frame 214 that extends from a proximal end 28 to a distal end 30. The frame 214 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 212. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. It should be appreciated that in other embodiments the valve 32 may be tricuspid or quadracuspid. The valve 32 may be constructed

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from treated bovine pericardium or other suitable proven biological or synthetic material. When the proximal component 212 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the proximal component 212.

[0081] The dual-frame 214 of the proximal component 212 includes a self-expanding outer frame 216 and a balloon-expandable inner frame 218 that is secured to the self-expanding outer frame 216 and houses the valve 32. Referring now to FIG. 9, the self-expanding outer frame 216 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the outer frame 216 may be formed from a polymeric material. The outer frame 216 includes an elongated proximal section 220, an inwardly tapered section 222, an outwardly tapered middle section 62, and an elongated distal section 64.

[0082] The elongated proximal section 220 of the outer frame 216 includes the proximal end 28 of the component 212 and has a distal end 224 connected to a proximal end 226 of the inwardly tapered section 222. The proximal section 220 is embodied as a tubular stent. It should be appreciated that in other embodiments the section 220 may be shaped as a prism, cone, or other geometric shape depending on the patient's anatomy.

[0083] In the illustrative embodiment, the proximal section 220 has a length 228 that is equal to approximately 15 mm. The proximal section 220 also has a diameter 230 of approximately 32 mm. It should be appreciated that in other embodiments the dimensions of the frame 216 may vary according to the anatomy of the patient. In the illustrative embodiment, the diameter 230 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the proximal section 220 and the annulus 210 when the component 212 is implanted, as

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described in greater detail below. As shown in FIG. 9, the proximal section 220 defines a passageway 232 in the outer frame 216.

[0084] In the illustrative embodiment, collagen fibers 234 are attached to the proximal section 220 to aid in preventing paravalvular leaks and migration of the proximal component 212 within the aortic walls. The fibers 234 extend outwardly from the proximal section 220 and inwardly into the passageway 232. It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials. In other embodiments, a plurality of barbs or hooks may be attached to the proximal section 220. The hooks may be configured to further engage the tissue of the aorta and inhibit or prevent migration of the device 10.

[0085] The inwardly tapered section 222 of the outer frame 216 includes the proximal end 226 and has a distal end 236 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 222 tapers inwardly between the ends 226, 236 from approximately 32 mm at the end 226 to approximately 22 mm at the end 236. In the illustrative embodiment, the inwardly tapered section 222 has a length 238 of approximately 10 mm.

[0086] The outwardly tapered middle section 62 of the self-expanding frame 216 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy.

[0087] The elongated distal section 64 of the self-expanding frame 216 extends distally from the proximal end 74 to the distal end 30 of the component 212. In the illustrative embodiment,

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the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 30 mm and has a diameter 80 of approximately 34 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[0088] As shown in FIG. 9, the proximal section 220 and the inwardly tapered section 222 of the self-expanding frame 216 are formed in an open-cell stent configuration, and the sections 62, 64 are formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 62, 64, 220, 222 may be formed in a single configuration, including an open-cell stent configuration or Z-stent configuration. The sections 62, 64, 220, 222 may also be formed as a single monolithic component. The outer surface 240 of the sections 62, 64, 222 are covered with low profile polyester, ePTFE, or other nonporous covering material 242 such that fluid is prevented from passing through the surface 240. The covering material 242 immediately distal to the proximal section 220 is equipped with a "trap door" 86, which may be opened to permit the passage of one or more surgical instruments for embolization of possible paravalvular leaks. The outer surface 240 of the sections 62, 64, 222 may be also covered with low-profile Dacron or other synthetic material. It should also be appreciated that all or part of the frame 216 may be covered with hydrogel or other sealing material.

[0089] As described above, the outer frame 216 of the dual-frame 214 is secured to a balloon-expandable inner frame 218, which is positioned in the passageway 232. As shown in FIG. 10, the frame 218 houses the valve 32. The balloon-expandable frame 218 is embodied as a balloon-expandable tubular stent 244 that has a length 246 of approximately 15 mm. In other

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embodiments, the stent 244 may be longer or shorter depending on, for example, the patient's anatomy. The stent 244 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 244 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface 248 of the stent 244 is covered with low-profile polyester, ePTFE, or other nonporous covering material 250 that prevents fluid from passing through the outer surface 248. However, it should be appreciated that the stent 244 may be covered with standard polyester, ePTFE or other nonporous materials.

[0090] As shown in FIG. 10, the stent 244 of the inner frame 218 has a diameter 252. As described in greater detail below, the balloon-expandable frame 218 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 252. In the illustrative embodiment, the expanded diameter 252 is equal to approximately 26 mm when the inner frame 218 is expanded. In other embodiments, the expanded diameter may be equal to, or greater than, the diameter 230 of the proximal section 220 of the outer frame 216. In the illustrative embodiment, the expanded diameter 252 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the proximal section 220 and the annulus 210 when the component 212 is implanted, and the inner frame 218 is expanded, as described in greater detail below.

[0091] Referring now to FIG. 11, the inner frame 218 of the dual-frame component 214 is secured to the outer frame 216 via a plurality of stitches 260. It should be appreciated that in other embodiments soldering, welding or other fasteners may be used to secure the inner frame 218 to the outer frame 216. As shown in FIGS. 11-14, the inner frame 218 and the valve component 32

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are positioned in the passageway 232 defined in the self-expanding frame 216. When the inner frame 218 is unexpanded, the outer surface 248 of the stent 244 is spaced apart from the fibers 234 attached to the outer frame 216. In the illustrative embodiment, a gap 264 is defined therebetween, and the gap 264 has a magnitude of about 2 mm to about 3 mm.

[0092] As shown in FIG. 14, the balloon-expandable inner frame 218 may be expanded in the direction indicated by arrows 266. As described above, the diameter 230 of the proximal section 220 of the outer frame 216 is oversized relative to the diameter of the aortic annulus 210. As such, when the component 212 is implanted, the proximal section 220 is reduced to the diameter of the annulus 210. Because the expanded diameter 252 of the stent 244 is greater than the diameter of the annulus, the outer surface 248 of the stent 244 engages the fibers 234 (and hence the inner surface of the proximal section 220 of the outer frame 216) through the covering material 250. In that way, the gap 264 is closed, and the fibers 234 and the covering material 250 create a seal between the inner frame 218 and the outer frame 216.

[0093] To implant an endograft device 10 that includes proximal component 212 in the patient's aorta 16, a surgeon may obtain open exposure or percutaneous access to the common femoral artery. The surgeon may then implant the distal component 14 in the manner described above in regard to FIGS. 1-7 and advance the stents 24 into position in the arteries 182. The proximal component 212 may be deployed after the implantation of the distal component 14. To do so, a stiff wire is passed through the aortic valve 202 into the left ventricle 204. The delivery system for the proximal component 212 is then passed through the valve 202.

[0094] When the delivery system is in position, the proximal component 212 is released by unsheathing the system, thereby permitting expansion of the self-expanding frame 216. The self-expanding frame 216 engages the proximal end 102 of the distal component 14 to secure the

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components 212, 14 together and seal the distal end 30 of the component 212 within the distal component 14.

[0095] When the frame 216 is unsheathed, the proximal section 220 expands into engagement with the aortic annulus 210, thereby creating an interference fit between the frame 216 and the annulus 210 and stabilizing the device 10 in place. As shown in FIG. 15, the inner frame 218 is initially unexpanded within the outer frame 216. The inner frame 218 may be deployed by expanding the balloon assembly. Expansion of the balloon-expandable inner frame 218 engages the inner frame 218 with the outer frame 216 and compresses the collagen fiber/hydrogel coated proximal section 220 of the outer frame 216 against the aortic annulus 210. As shown in FIG. 16, the combined engagement of the frames 216, 218 seals the annulus 210 and the paravalvular areas, and thus, prevents paravalvular leakage. As such, fluid is permitted to pass from the left ventricle 204 only through the valve 32 of the component 212. As shown FIGS. 15-16, the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182. It should be appreciated that the deployment of the component 212 may be performed during rapid ventricular pacing (RVP). In cases with aortic stenosis, the valve 32 may be dilated with balloon angioplasty prior to the introduction of the proximal component 212.

[0096] In each of the embodiments described above, the self-expanding frame portion of proximal components 12, 212 significantly improves the accuracy and control of the deployment of the device 10. The bicuspid configuration of the valve 32 serves three distinct purposes, including (1) by reducing the number of valve commissures to two, the profile will be reduced, (2) the valve 32 may conform better to the aortic annulus, and (3) when the annulus is asymmetrical, the incidence of aortic insufficiency may be reduced.

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[0097] Referring now to FIGS. 17-22, the proximal component 12 or the proximal component 212 may be used as a transcatheter valve with slight modification. Such a valve may be deployed via a transfemoral or trans-axillary route, as will be described in further detail below.

[0098] Referring now to FIGS. 17-19, one embodiment of a transcatheter valve component 312 is shown. Some features of the embodiment illustrated in FIGS. 17-19 are substantially similar to those described above in reference to the proximal component 12 of FIGS. 1-7. Such features are designated in FIGS. 17-19 with the same reference numbers as those used in FIGS. 1-7. Similar to the proximal component 12 of FIGS. 1-7, the transcatheter valve component 312 includes a frame 26 that extends from a proximal end 28 to a distal end 30. The frame 326 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the valve component 312. When the valve component 312 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the valve component 312.

[0099] The valve 32 is housed in a balloon-expandable frame 34 of the frame 26. As shown in FIG. 17, the balloon-expandable frame 34 is embodied as a balloon-expandable stent 38 that extends distally from the proximal end 28 of the transcatheter valve component 312 and has a length 40 of approximately 15 mm. In other embodiments, the stent 38 may be longer or shorter depending on, for example, the patient's anatomy. The stent 38 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 38 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface 42 of the stent 38 is covered with low-profile polyester, ePTFE, or other nonporous covering material 44 that prevents fluid from passing

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through the outer surface 42. However, it should be appreciated that the stent 38 may be covered with standard polyester, ePTFE or other nonporous materials.

[00100] As shown in FIG. 17, the stent 38 of the balloon-expandable frame 34 has a diameter 46. As described in greater detail below, the balloon-expandable frame 34 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 46. In the illustrative embodiment, the expanded diameter 46 is equal to approximately 26 mm when the frame 34 is expanded. In other embodiments, the expanded diameter may be greater than or less than 26 mm depending on, for example, the patient's anatomy. In the illustrative embodiment, the diameter 46 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the stent 38 and the annulus 210 when the transcatheter valve component 312 is implanted.

[00101] The balloon-expandable frame 34 is attached to a self-expanding frame 350. In the illustrative embodiment, the distal end 52 of the balloon-expandable frame 34 is secured to the proximal end 54 of the frame 350 by stitching or sewing the frames 34, 350 together, thereby forming the frame 26 of the transcatheter valve component 312. It should be appreciated that in other embodiments the frames 34, 350 may be secured together via welding or other fasteners. The frames 34, 350 may also be formed as a single, monolithic frame.

[00102] As shown in FIG. 17, the self-expanding frame 350 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the frame 350 may be formed from a polymeric material. The frame 350 includes an inwardly tapered proximal section 360, an outwardly tapered middle section 62, and an elongated distal section 64. The section 360 includes the proximal end 54 of the frame 350 and has a distal end 66 connected to the proximal end 68 of

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the outwardly tapered middle section 62. The section 360 tapers inwardly between the ends 54, 66 from approximately 26 mm at the end 54 to approximately 22 mm at the end 66. In the illustrative embodiment, the proximal section 360 has a length 70 of approximately 15 mm.

[00103] The outwardly tapered middle section 62 of the self-expanding frame 350 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy.

[00104] The elongated distal section 64 of the self-expanding frame 350 extends distally from the proximal end 74 to the distal end 30 of the valve component 312. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 30 mm and has a diameter 80 of approximately 34 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[00105] As shown in FIG. 3, the proximal section 360 of the self-expanding frame 350 is formed in an open-cell stent configuration, and each of the sections 62, 64 is formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 360, 62, 64 may be formed in a single configuration, including the open-cell stent configuration, mesh-like stent configuration, or Z-stent configuration. The sections 60, 62, 64 may also be formed as a single monolithic component.

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[00106] As shown in FIG. 17, the outer surface 314 of the proximal section 360 of the frame 350 is uncovered such that fluid is permitted to pass through the openings 318. The outer surface 316 of the sections 62, 64 are covered with low profile polyester, ePTFE, or other nonporous covering material 84 such that fluid is prevented from passing through the surface 320. The outer surface 320 of the valve component 312 may also be covered with low-profile Dacron or other synthetic material. The uncovered, open cell stent section 360 is configured to allow for coronary artery perfusion. The covered sections 62, 64 serve to stabilize the valve component 312 against the aorta 18 and provide a docking station to ascending aortic extensions or fenestrated/ branch arch grafts. The covered sections 62, 64 would also permit endograft extension of the valve component 312 for suitable type B aneurysms without dilation of the sinutubular junction.

[00107] The delivery of the transcatheter valve component 312 may begin by gaining access to the left ventricle across the native aortic valve. An ascending aortogram may be performed to locate the right and left coronary arteries. An over the wire introducer system, including a guidewire, is used to introduce the valve component 312 into the aorta 18. After the guidewire has been placed into the left ventricle 204 via the iliofemoral, subclavian, or carotid vessels, the valve component 312 may be delivered through the common femoral artery and passed across the native aortic valve 202. After performing an angiogram to delineate the location of the coronary arteries 182, the valve component 312 is released by unsheathing the delivery system, thereby permitting expansion of the self-expanding frame 350, as shown in FIGS. 18-19.

[00108] The balloon-expandable frame 34 may be now deployed by inflating the balloon within the delivery system. This deploys the frame 34 to the predetermined expanded diameter 46 and advances the frame 34 into engagement with the aortic annulus 210, thereby sealing the aortic annulus 210 such that fluid is permitted to pass from the left ventricle 204 only through the valve

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32 and the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182, as shown in FIGS. 18-19. The openings 318 of the uncovered section 360 of the valve component 312 permit blood flow to the coronary arteries 182 for promote circulation. It should be appreciated that the deployment of the valve component 312 may be performed during rapid ventricular pacing (RVP).

[00109] Referring now to FIGS. 20-22, another embodiment of a transcatheter valve component (hereinafter valve component 412) is shown. Some features of the embodiment illustrated in FIGS. 20-22 are substantially similar to those described above in reference to the proximal component 212 of FIGS. 8-16. Such features are designated in FIGS. 20-22 with the same reference numbers as those used in FIGS. 8-16. Similar to the proximal component 212 of FIGS. 8-16, the valve component 412 includes a dual-frame 414 that extends from a proximal end 28 to a distal end 30. The frame 414 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 412. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. When the valve component 412 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the valve component 412.

[00110] The dual-frame 414 includes a self-expanding outer frame 416 and a balloon-expandable inner frame 218 that is secured to the self-expanding outer frame 416 and houses the valve 32. Referring now to FIG. 9, the self-expanding outer frame 416 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the outer frame 416 may be formed from a polymeric material. The outer frame 416 includes an elongated proximal section

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220, an inwardly tapered section 422, an outwardly tapered middle section 62, and an elongated distal section 64.

[00111] The elongated proximal section 220 of the outer frame 416 includes the proximal end 28 of the component 412 and has a distal end 224 connected to a proximal end 226 of the inwardly tapered section 222. The proximal section 220 is embodied as a tubular stent. It should be appreciated that in other embodiments the section 220 may be shaped as a prism, cone, or other geometric shape depending on the patient's anatomy.

[00112] In the illustrative embodiment, the proximal section 220 has a length 228 that is equal to approximately 15 mm. The proximal section 220 also has a diameter 230 of approximately 32 mm. It should be appreciated that in other embodiments the dimensions of the frame 416 may vary according to the anatomy of the patient. In the illustrative embodiment, the diameter 230 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the proximal section 220 and the annulus 210 when the valve component 412 is implanted, as described in greater detail below. As shown in FIG. 9, the proximal section 220 defines a passageway 232 in the outer frame 416.

[00113] In the illustrative embodiment, collagen fibers 234 are attached to the proximal section 220 to aid in preventing paravalvular leaks and migration of the valve component 412 within the aortic walls. The fibers 234 extend outwardly from the proximal section 220 and inwardly into the passageway 232. It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials. In other embodiments, a plurality of barbs or hooks may be attached to the proximal section 220. The hooks may be configured to further engage the tissue of the aorta and inhibit or prevent migration of the device 10.

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[00114] The inwardly tapered section 422 of the outer frame 416 includes the proximal end 226 and a distal end 236 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 422 tapers inwardly between the ends 226, 236 from approximately 32 mm at the end 226 to approximately 22 mm at the end 236. In the illustrative embodiment, the inwardly tapered section 422 has a length 238 of approximately 10 mm.

[00115] The outwardly tapered middle section 62 of the self-expanding frame 416 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy.

[00116] The elongated distal section 64 of the self-expanding frame 416 extends distally from the proximal end 74 to the distal end 30 of the component 412. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 30 mm and has a diameter 80 of approximately 34 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[00117] As shown in FIG. 20, each of the proximal section 220 and the inwardly tapered section 422 of the self-expanding frame 416 is formed in an open-cell stent configuration, and each of the sections 62, 64 is formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 62, 64, 220, 422 may be formed in a single configuration, including the

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open-cell stent configuration, mesh-like stent configuration, or Z-stent configuration. The sections 62, 64, 220, 422 may also be formed as a single monolithic component. The outer surfaces 440 of the sections 62, 64 are covered with low profile polyester, ePTFE, or other nonporous covering material 442 such that fluid is prevented from passing through the surface 440. The outer surface 444 of the section 422 is uncovered such that fluid is permitted to pass through openings 446 defined in the surface 444. The uncovered, open cell section 422 is configured to allow for coronary artery perfusion. The covered sections 62, 64 serve to stabilize the valve component 412 against the aorta 18 and provide a docking station to ascending aortic extensions or fenestrated/ branch arch grafts.

[00118] As described above, the outer frame 416 of the dual-frame 414 is secured to a balloon-expandable inner frame 218, which is positioned in the passageway 232 and houses the valve 32. As described above, the balloon-expandable frame 218 is expandable during implantation from an unexpanded diameter 450 to the expanded diameter (not shown).

[00119] To deploy the valve component 412, a stiff wire is passed through the aortic valve 202 into the left ventricle 204. The delivery system for the valve component 412 is then passed through the valve 202. When the delivery system is in position, the valve component 412 is released by unsheathing the system, thereby permitting expansion of the self-expanding frame 416. The proximal section 220 of the frame 416 expands into engagement with the aortic annulus 210, thereby creating an interference fit between the frame 416 and the annulus 210 and stabilizing the valve component 412 in place. As shown in FIG. 21, the inner frame 218 is initially unexpanded within the outer frame 416. The inner frame 218 may be deployed by expanding the balloon assembly. Expansion of the balloon-expandable inner frame 218 engages the inner frame 218 with

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the outer frame 416 and compresses the collagen fiber/hydrogel coated proximal section 220 of the outer frame 416 against the aortic annulus 210.

[00120] As shown in FIG. 22, the combined engagement of the frames 218, 416 seals the annulus 210 and the paravalvular areas, and thus, prevents paravalvular leakage. As such, fluid is permitted to pass from the left ventricle 204 only through the valve 32 of the component 412. The openings 446 of the uncovered section 422 of the valve component 412 permit blood flow to the coronary arteries 182 for promote circulation.

[00121] It should be appreciated that the design of components 12, 14, 212 and the transcatheter valves 312, 412 has intentionally taken into account the potential failure modes and allows for correction of any such failure modes. For example, with respect to components 12, 14, 212, paravalvular leaks may be corrected. More specifically, with respect to a paravalvular leak (type Ia endoleak), leakage around the valve 32 would act as a type la endoleak. The trapdoors 86 in components 12, 312 would allow for coil embolization of the area of the leak. Two trapdoors at 180 degree location would allow access to the entire area above the aortic annulus. Since the coronary arteries 182 are protected by the conduits 22 in the distal component 14, coil embolization of this area would not compromise the coronary blood flow. Coil embolization of paravalvular leaks are already being performed clinically after heart valve surgery if there are additional leaks around the valve.

[00122] Aortic insufficiency (Al) after implantation may also be corrected. Significant Al has been documented in up to 17% of patients after transcatheter valve implantation. Except heavy annular calcification, the tricuspid morphology of the current valves and the ovoid shape of the aortic annulus can cause malcoaptation of the valve leaflets causing Al. The bicuspid valve nature

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of the designs discussed herein potentially eliminates the problem with malcoaptation and AI secondary to that.

[00123] Structural valve degeneration may also be corrected. More specifically, the bicuspid valve design allows for placement of another transcatheter valve across the first device without compromising valvular flow area.

[00124] Coronary insufficiency may also be corrected. The Cabrol endo-conduits 22 in conjunction with the tapered section 128 of component 14 ensure uninterrupted coronary blood flow. By first deploying the component 14, the surgeon will be able to work through the Cabrol conduits 22 and using standard catheters and guidewires to cannulate the right and left coronary arteries. Stents 24 are deployed from the coronary arteries into the Cabrol conduits 22. Deployment the component 12 or component 212 may be delayed until coronary blood flow is secured. The tapered design will mitigate the risk of compression of the coronary stents between the device 10 and the aortic wall.

[00125] For the transcatheter valves 312, 412, paravalvular leaks may also be corrected in that the open cell midsections 360, 422 of the valve allow the cannulation and stenting of the coronary arteries with potential coil embolization of the leak after the protection of the coronary artery if necessary.

[00126] Structural valve degeneration in the transcatheter valves 312, 412 may be corrected in that the bicuspid valve design permit for placement of another transcatheter valve across the first device without compromising valvular flow area.

[00127] The dual frame component may also take the form of other transcatheter valvular replacement devices such as, for example, prosthetic mitral and tricuspid valves. The dual frame

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component may also be used to enhance sealing zones of endovascular devices to treat abdominal and thoracic aneurysms, and in applications to treat peripheral vascular disease.

[00128] It will be appreciated that the devices and methods described herein have broad applications. The foregoing embodiments were chosen and described in order to illustrate principles of the methods and apparatuses as well as some practical applications. The preceding description enables others skilled in the art to utilize methods and apparatuses in various embodiments and with various modifications as are suited to the particular use contemplated. In accordance with the provisions of the patent statutes, the principles and modes of operation of this disclosure have been explained and illustrated in exemplary embodiments.

[00129] It is intended that the scope of the present methods and apparatuses be defined by the following claims. However, it must be understood that this disclosure may be practiced otherwise than is specifically explained and illustrated without departing from its spirit or scope. It should be understood by those skilled in the art that various alternatives to the embodiments described herein may be employed in practicing the claims without departing from the spirit and scope as defined in the following claims.

[00130] The scope of the disclosure should be determined, not with reference to the above description, but should instead be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. It is anticipated and intended that future developments will occur in the arts discussed herein, and that the disclosed systems and methods will be incorporated into such future examples. Furthermore, all terms used in the claims are intended to be given their broadest reasonable constructions and their ordinary meanings as understood by those skilled in the art unless an explicit indication to the contrary is made herein. In particular, use of the singular articles such as “a,” “the,” “said,” etc. should be read to recite one

Aortic Innovations, LLC, Exhibit 2131
Page 2131 - 685
IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

or more of the indicated elements unless a claim recites an explicit limitation to the contrary. It is intended that the following claims define the scope of the disclosure and that the method and apparatus within the scope of these claims and their equivalents be covered thereby. In sum, it should be understood that the disclosure is capable of modification and variation and is limited only by the following claims.

Aortic Innovations, LLC, Exhibit 2131
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CLAIMS

1. An endograft device for endovascular repair of ascending aortic aneurysms, comprising:

a first endograft prosthetic component comprising (i) a proximal frame, and (ii) a distal frame secured to the proximal frame and extending to a distal end of the first prosthetic component,

at least one conduit secured to the first prosthetic component and positioned adjacent to the proximal frame,

a second prosthetic component secured to a proximal end of the first prosthetic component, the second prosthetic component comprising (i) a balloon-expandable frame extending distally from a proximal end of the second prosthetic component, and (ii) a self-expanding frame connected to the balloon-expandable frame and extending to a distal end of the second prosthetic component, and

a valve element secured to the balloon-expandable frame at the proximal end of the second prosthetic component.

2. The endograft device of claim 1, wherein the self-expanding frame has an hourglass shape.

3. The endograft device of claim 2, wherein the self-expanding frame includes:

a first section that tapers inwardly between a proximal end and a distal end, and

a second section having a proximal end that is connected to the distal end of the first section, the second section tapering outwardly between the proximal end of the second section and a distal end of the second section.

4. The endograft device of claim 3, wherein the proximal end of the first section is secured to a distal end of the balloon-expandable frame.

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5. The endograft device of claim 3, wherein:

the self-expanding frame includes a third section extending proximally from the proximal end of the first section, the third section having a passageway defined therein, and

the balloon-expandable frame is positioned in the passageway of the third section of the self-expanding frame.

6. The endograft device of claim 5, wherein the balloon-expandable frame is expandable between (i) an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and (ii) an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

7. The endograft device of claim 6, wherein a plurality of fibers are attached to the third section of the self-expanding frame, and when the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame is engaged with the plurality of fibers.

8. The endograft device of claim 1, wherein the proximal frame of the first prosthetic component has a passageway defined therein, and the distal end of the second prosthetic component is positioned in the passageway of the first prosthetic component.

9. The endograft device of claim 1, wherein the at least one conduit includes a pair of conduits positioned on opposite sides of the first prosthetic component.

10. A method of implanting a heart valve in a stent component, the method comprising:

placing a heart valve in a first component;

securing the first component within a second component,

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wherein the deployment occurs endovascularly.

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ABSTRACT OF THE DISCLOSURE

A transcatheter aortic valve replacement (TAVR) device includes a paravalvular seal that includes outwardly extending fibers that create a seal with the aortic annulus when the TAVR is deployed.

Aortic Innovations, LLC, Exhibit 2131
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IPR2023-01151, Edwards Lifesciences Corp. et al v. Aortic Innovations, LLC

PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME

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 _____ filed on _____.

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: Ali SHAHRIARI Date (Optional): 12/5/12

Signature: A. Shah

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.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Justin Robert Nifong
Attorney Docket Number:	426/2/20 UTIL

Filed as Small Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2100	2100
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**3000**

Electronic Acknowledgement Receipt

EFS ID:	41473279
Application Number:	17131869
International Application Number:	
Confirmation Number:	1293
Title of Invention:	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
Filer:	Justin Robert Nifong
Filer Authorized By:	
Attorney Docket Number:	426/2/20 UTIL
Receipt Date:	23-DEC-2020
Filing Date:	
Time Stamp:	09:05:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$3000
RAM confirmation Number	E2020BM006582116
Deposit Account	506191
Authorized User	Justin Nifong

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.21 (Miscellaneous fees and charges)

37 CFR 1.20 (Post Issuance fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.16 (National application filing, search, and examination fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	WebADS.pdf	146964 6e3b440055d38913c2caba4fc83841c82fbeacaf	no	8
Warnings:					
Information:					
2	Drawings-only black and white line drawings	426-2-20UTIL-Drwgs.pdf	908849 39cf7b4c21c2388f90aae3be9d8a6b4d9f7117e2	no	19
Warnings:					
Information:					
3	TrackOne Request	426-2-20UTIL-TrackOneRequest.pdf	114453 558a019d2e150f1c1da8a77ac39779e36b454fd8	no	2
Warnings:					
Information:					
4		426-2-20UTIL-Spec-claims-abs.pdf	292805 c82ea7ef92cbd253248a2bf6f9b2976adc5b2e0d	yes	43

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	39
Claims	40	42
Abstract	43	43

Warnings:					
Information:					
5	Oath or Declaration filed	AI-dec.pdf	67230 a62c3f5d2b8351d6a4bcd8addef0916372ecbef3	no	1

Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	38392 b5b6b3e26f69ab9b2b948e62770b97038e0adeeb	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1568693	

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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/20 UTIL
	Application Number	
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Ali		Shahriari	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Boca Raton	State/Province	FL	Country of Residence i	US

Mailing Address of Inventor:

Address 1	977 Hilsboro Mile		
Address 2			
City	Hilsboro Beach	State/Province	FL
Postal Code	33062	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	175373		
Email Address	docket@nkpatentlaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL		
Attorney Docket Number	426/2/20 UTIL	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	19	Suggested Figure for Publication (if any)	20

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/20 UTIL
	Application Number	
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	175373		

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix	Remove
Registration Number					
Prefix	**Given Name**	Middle Name	**Family Name**	Suffix	Remove
Registration Number					

Additional Representative Information blocks may be generated within this form by selecting the **Add** button.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/20 UTIL
	Application Number	
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status		Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	17060557	2020-10-01

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17060557	Continuation of	16910189	2020-06-24	10857011	2020-12-08

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16910189	Continuation of	16808137	2020-03-03	10792172	2020-10-06

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16808137	Continuation of	16736879	2020-01-08	10842655	2020-11-24

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16736879	Continuation of	16042286	2018-07-23	10555823	2020-02-11

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16042286	Continuation of	14614628	2015-02-05	10028848	2018-07-24

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14614628	Continuation of	14569306	2014-12-12	9339399	2016-05-17

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/20 UTIL
	Application Number	
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14569306	Division of	13706896	2012-12-06	8940040	2015-01-27

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13706896	Claims benefit of provisional	61723446	2012-11-07

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13706896	Claims benefit of provisional	61567458	2011-12-06

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

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

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (08-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/20 UTIL
	Application Number	
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (08-15)
Approved for use through 04/30/2017. OMB 0651-0032
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/20 UTIL
	Application Number	
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◯ Assignee	◯ Legal Representative under 35 U.S.C. 117	◯ Joint Inventor
◯ Person to whom the inventor is obligated to assign.	◯ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:	

If the Applicant is an Organization check here. ☒

Organization Name	Aortic Innovations, LLC

Mailing Address Information For Applicant:

Address 1	977 Hilsboro Mile		
Address 2			
City	Hilsboro Beach	**State/Province**	FL
Country[i]	US	Postal Code	33062
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/20 UTIL
	Application Number	
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	426/2/20 UTIL
	Application Number	
Title of Invention	TRANSCATHETER AORTIC VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL	

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e. g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Justin R. Nifong/			Date (YYYY-MM-DD)	
First Name	Justin	Last Name	Nifong	Registration Number	59389

Additional Signature may be generated within this form by selecting the Add button.

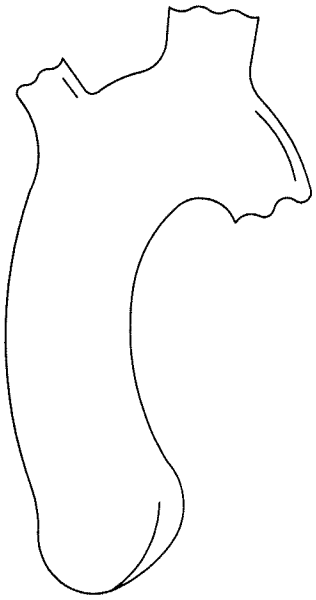

Fig. 1

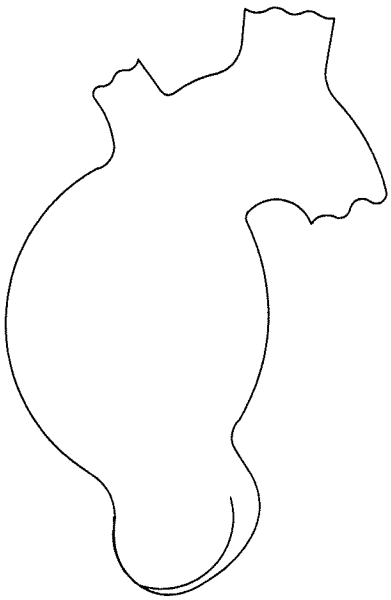

Fig. 1B

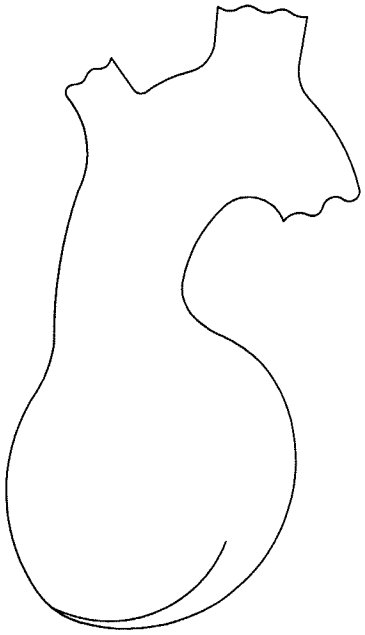

Fig. 1A

Fig. 1C

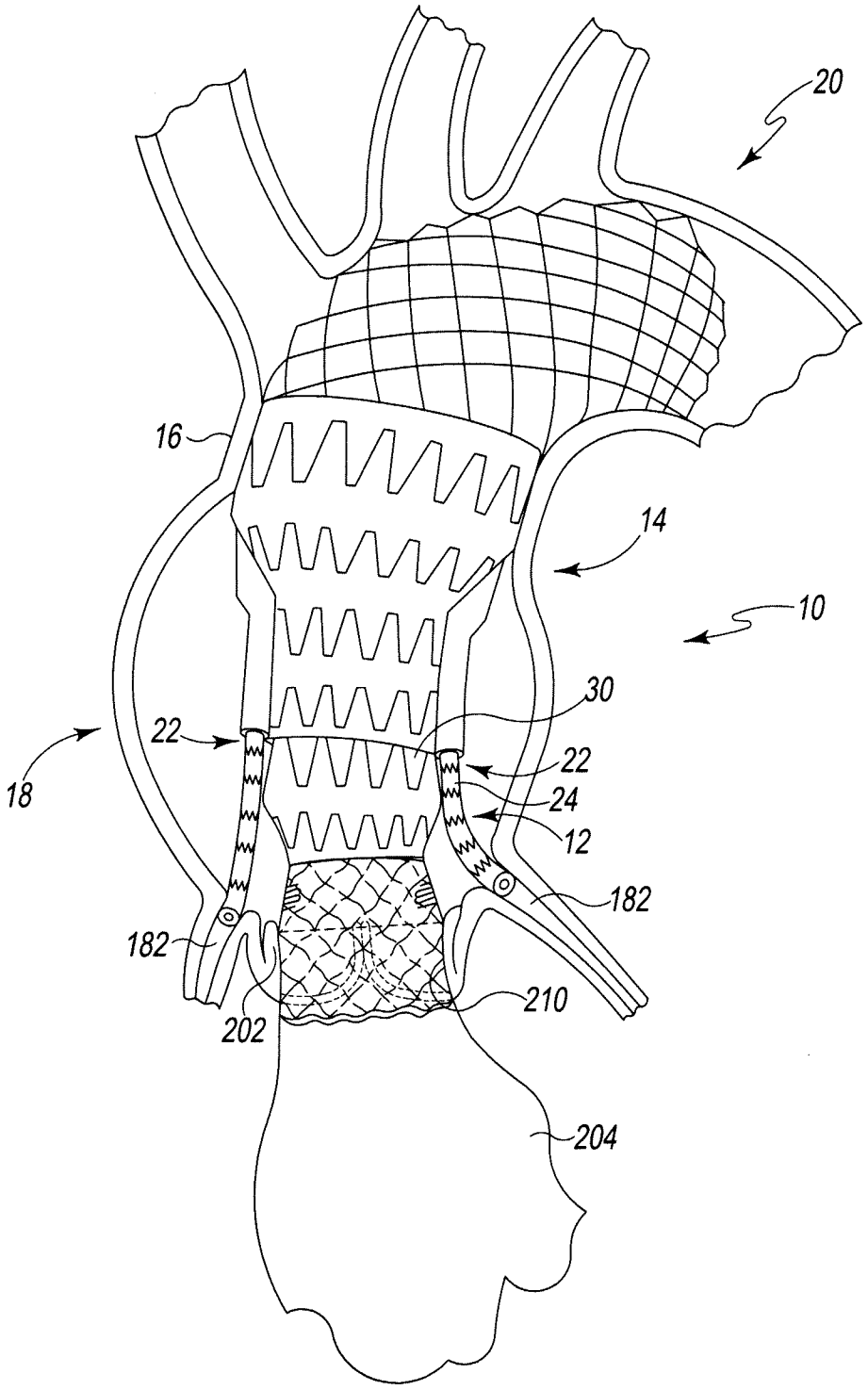

Fig. 2

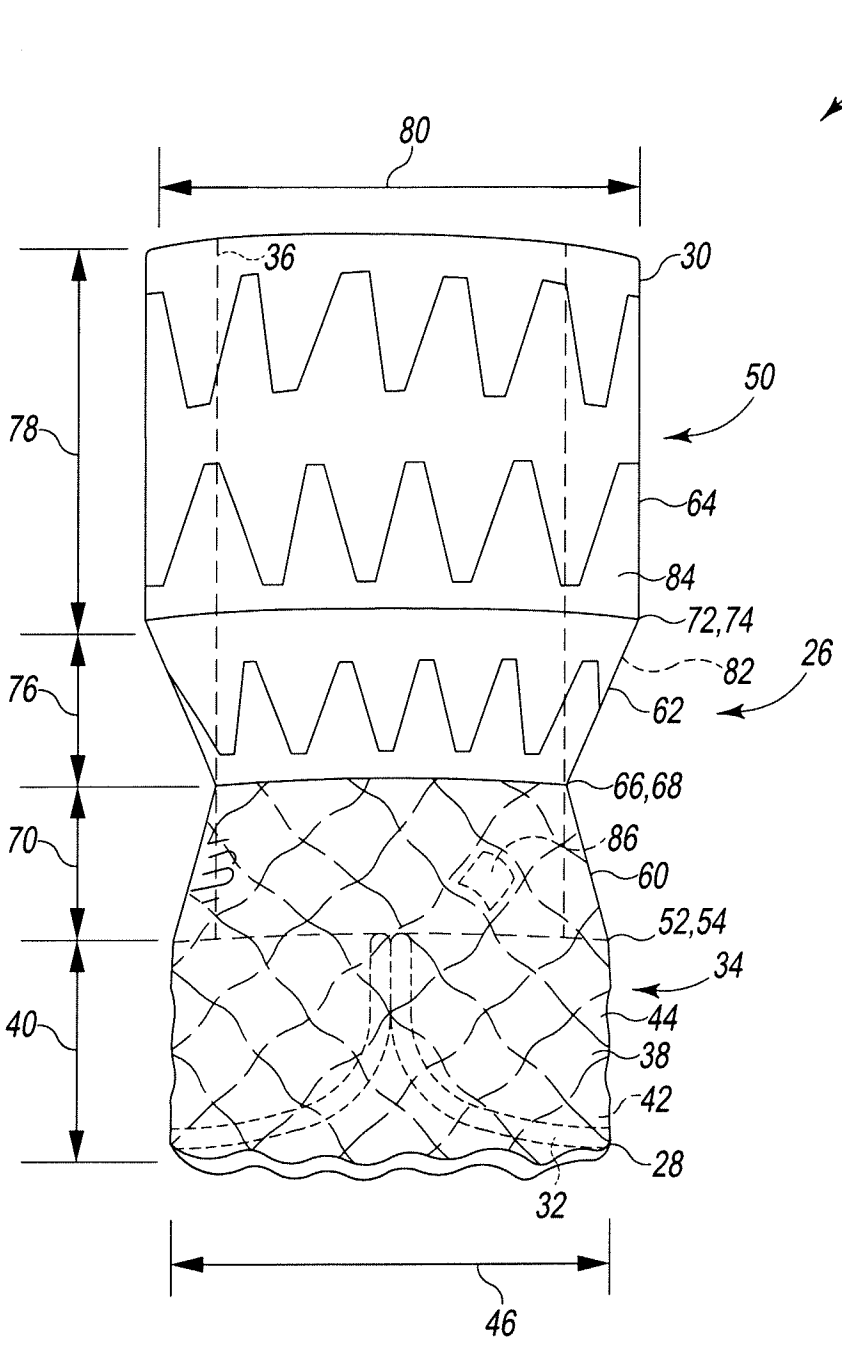
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Fig. 3

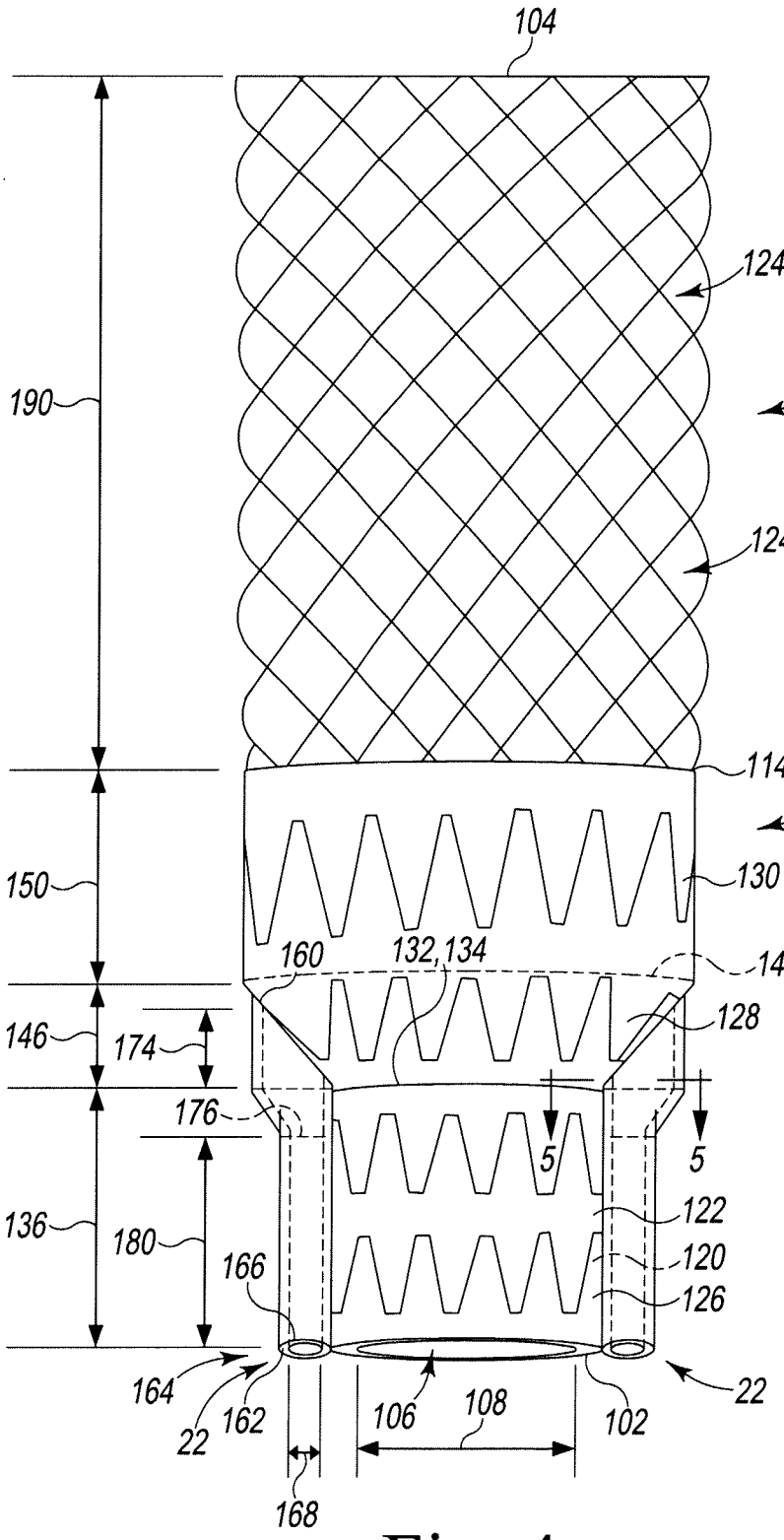
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Fig. 4

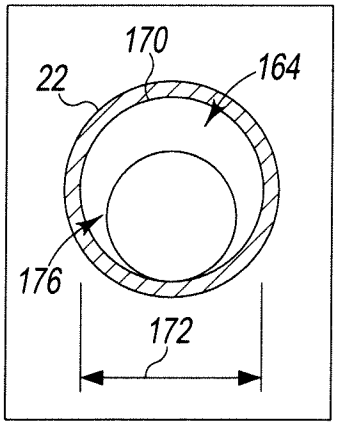
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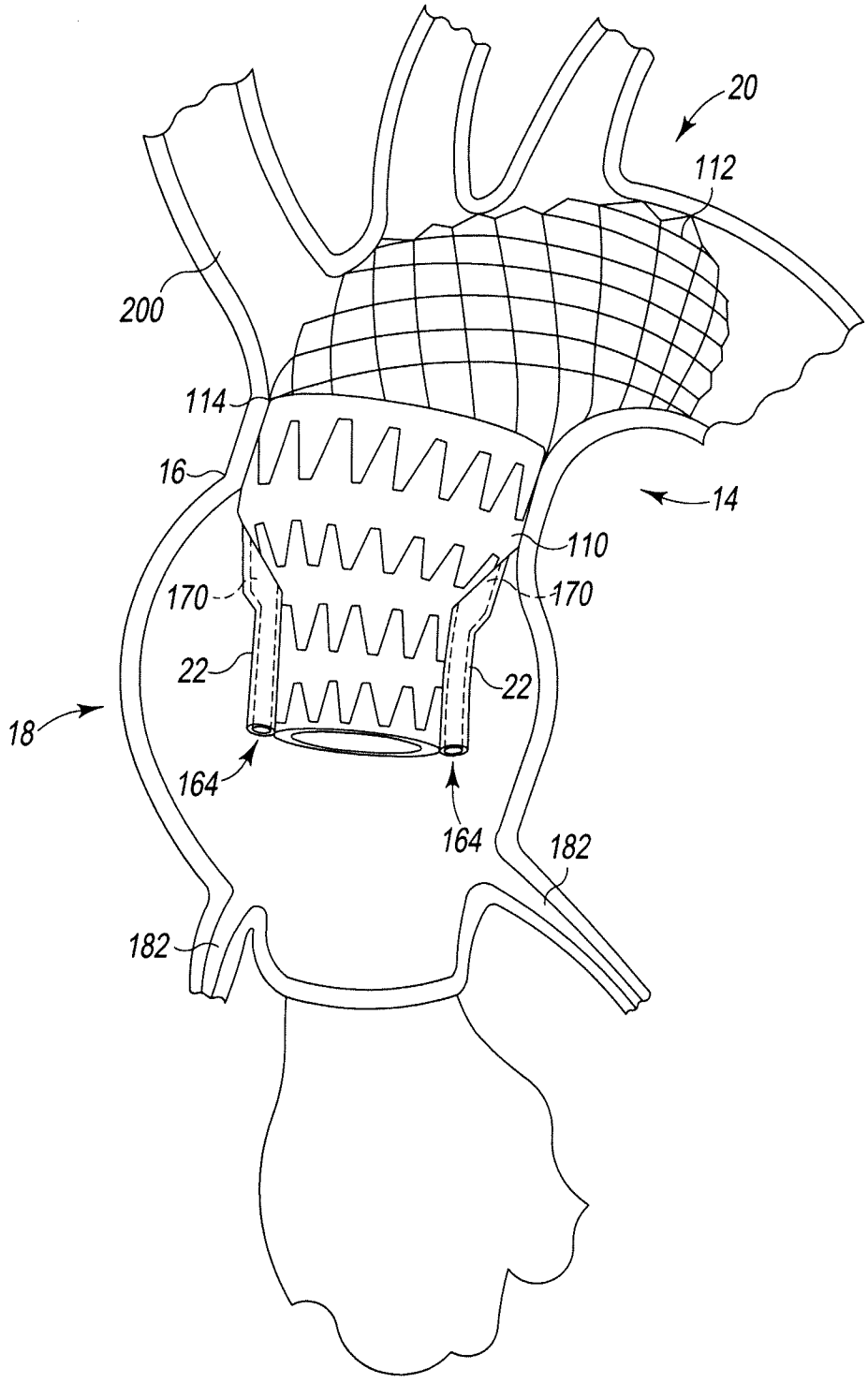
Fig. 5



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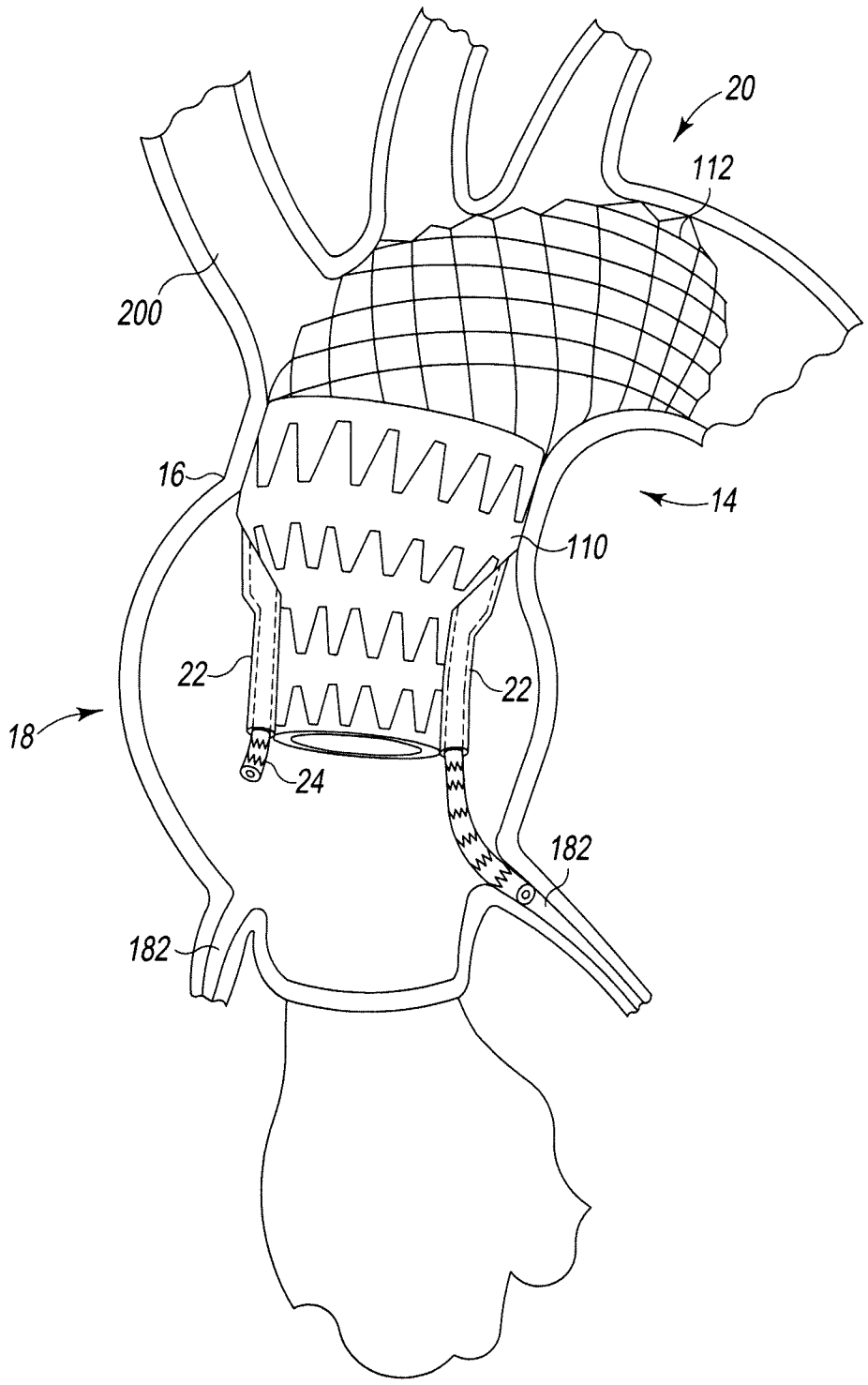

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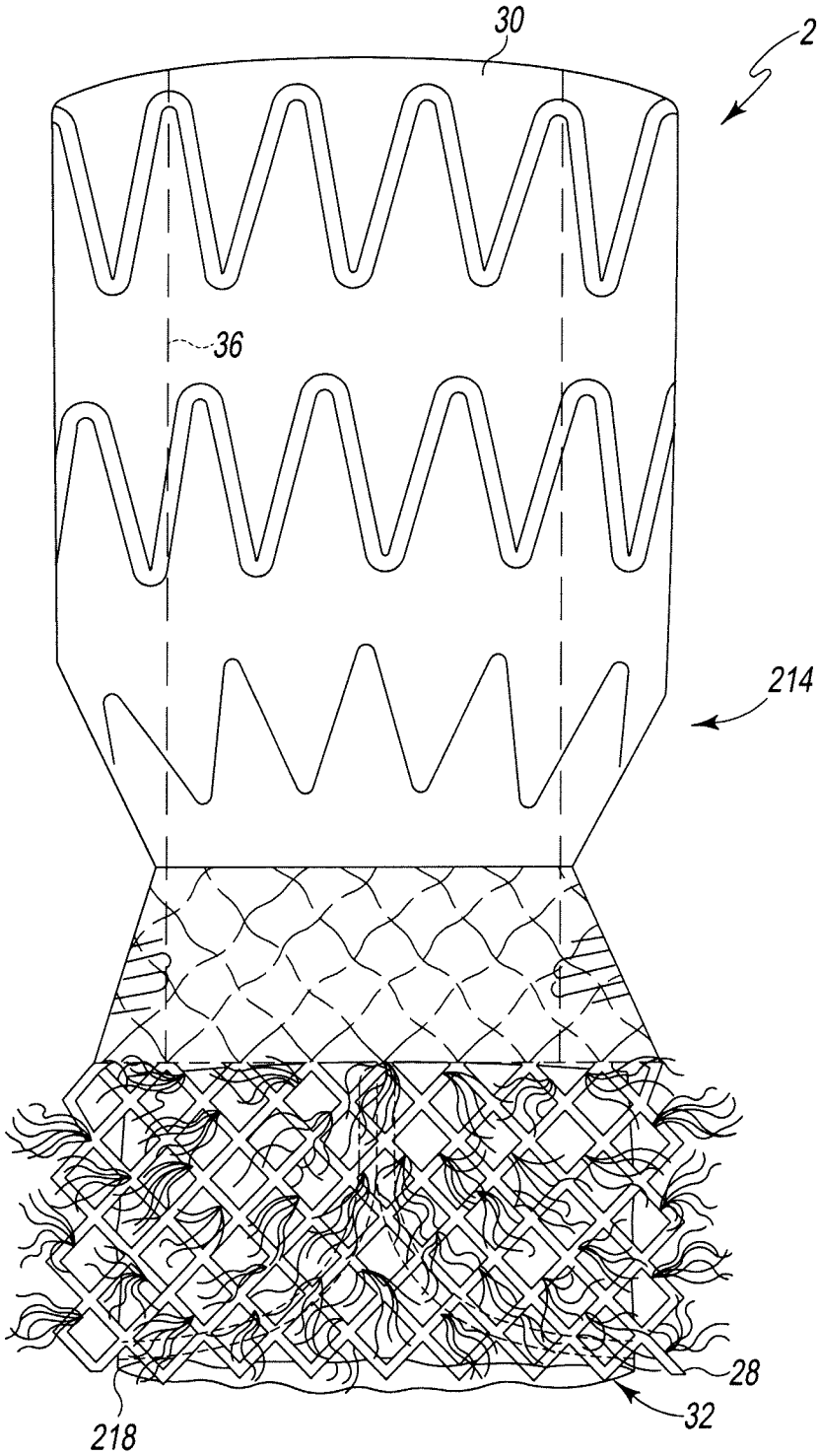

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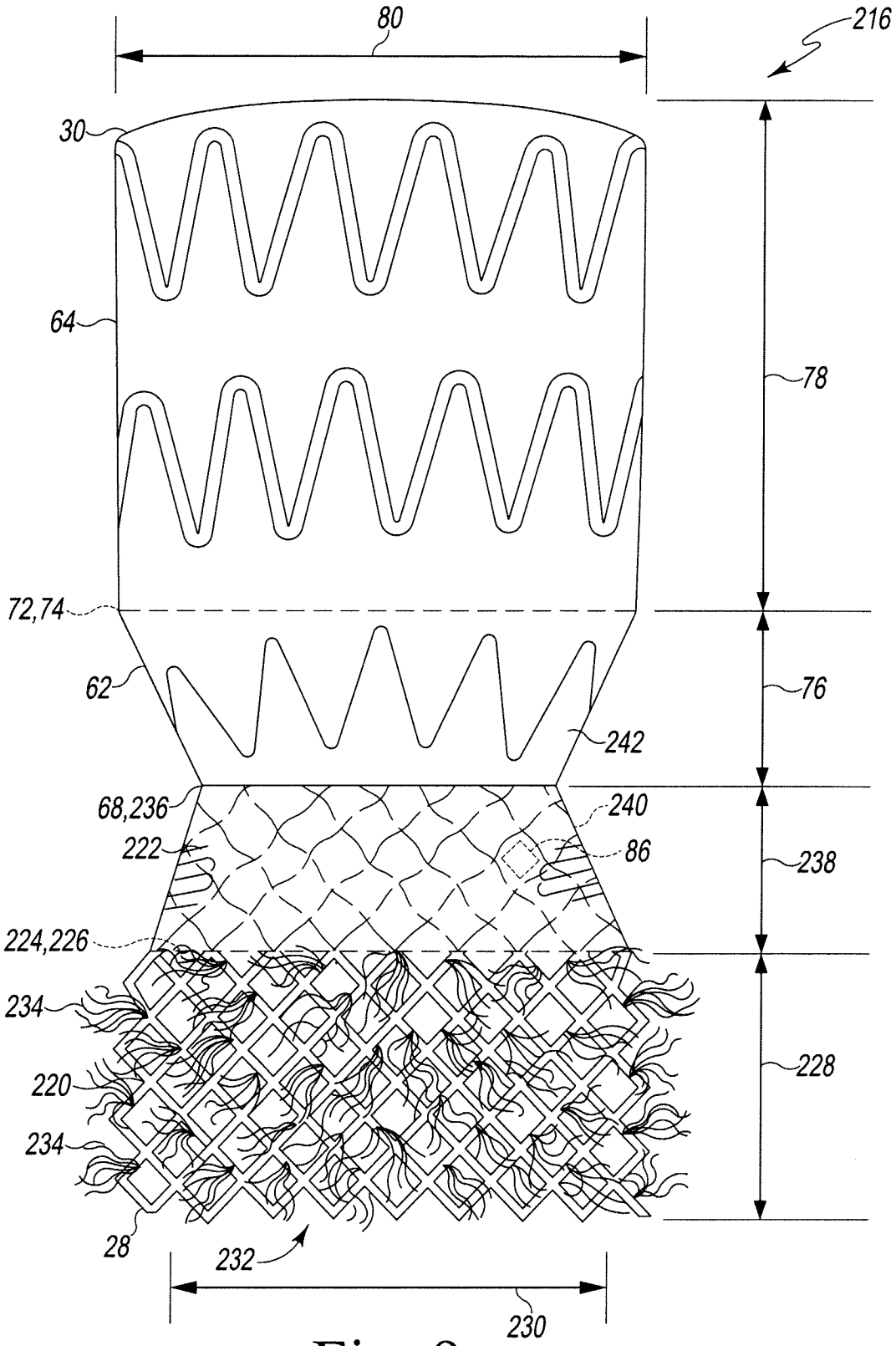
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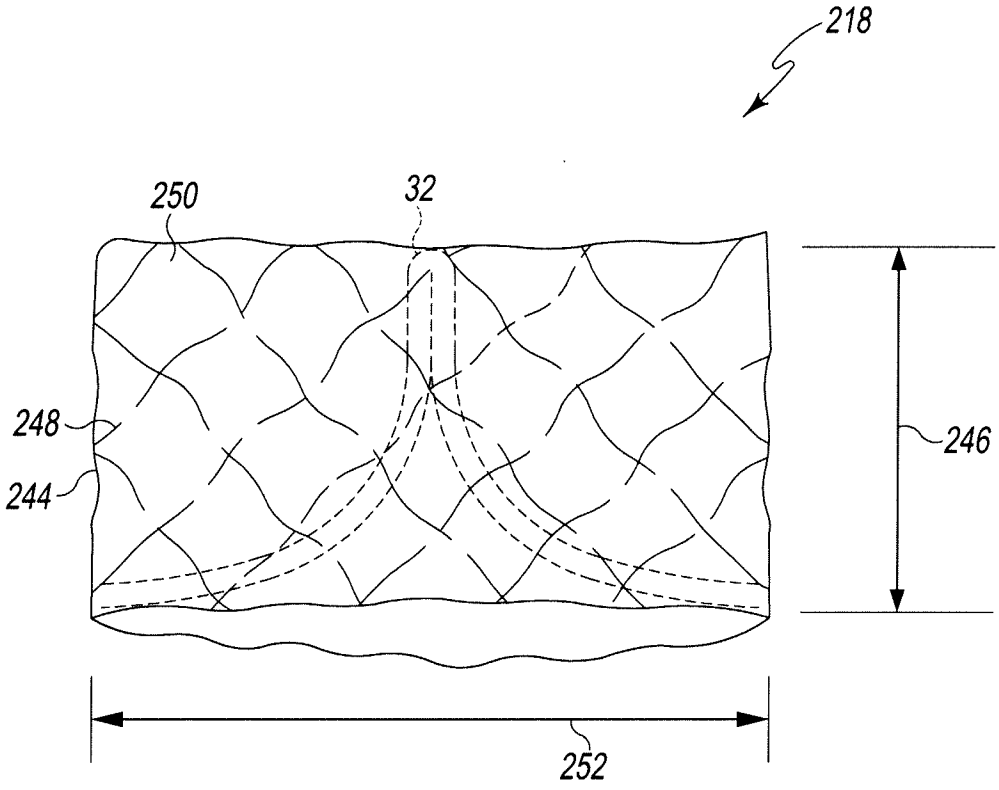
Fig. 9



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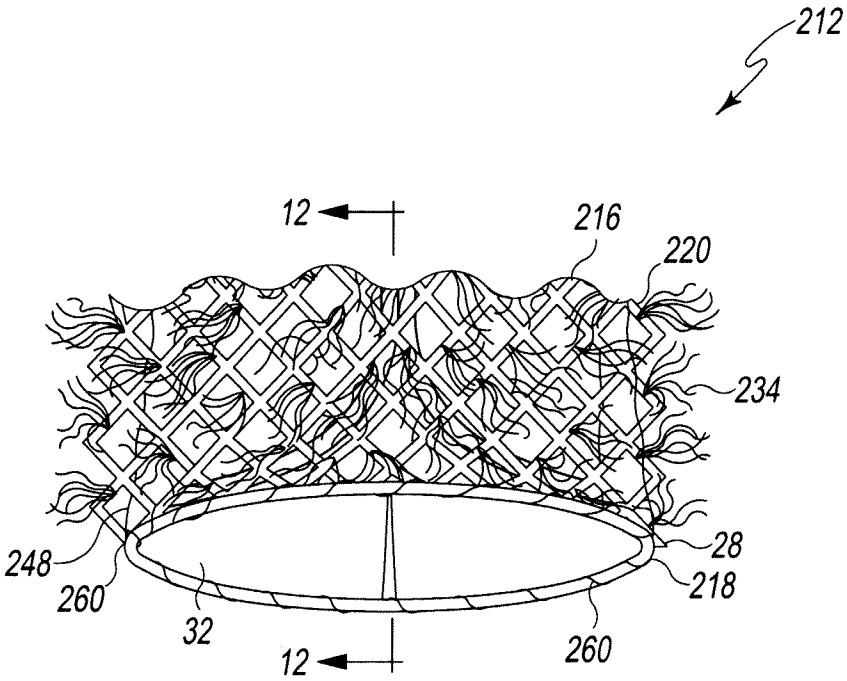

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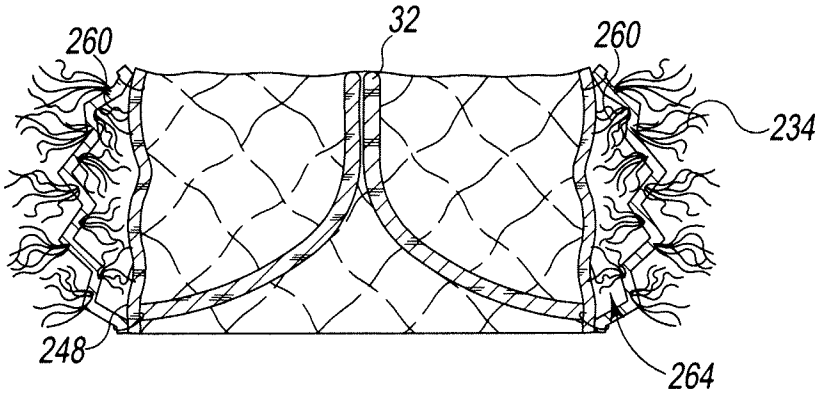

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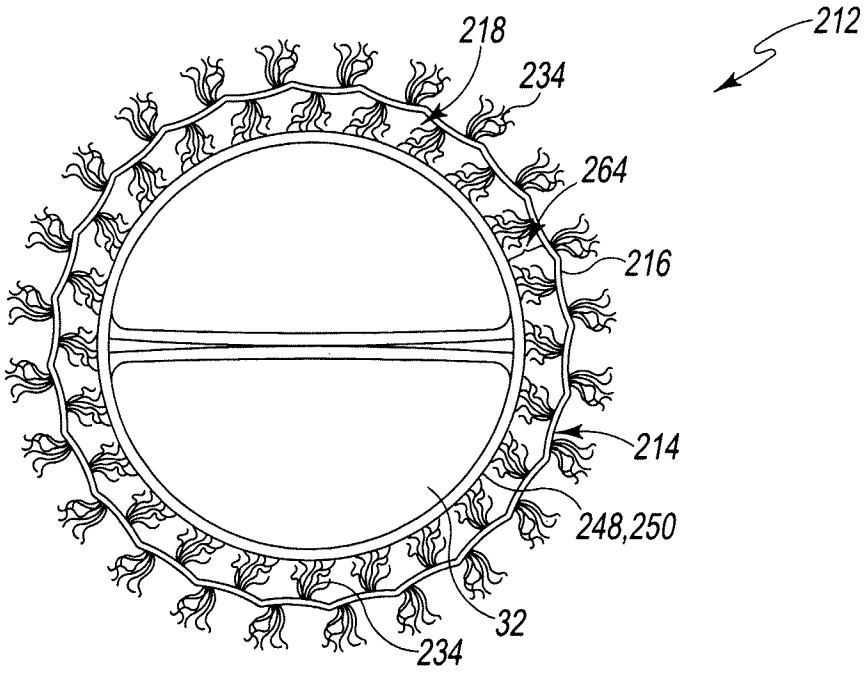
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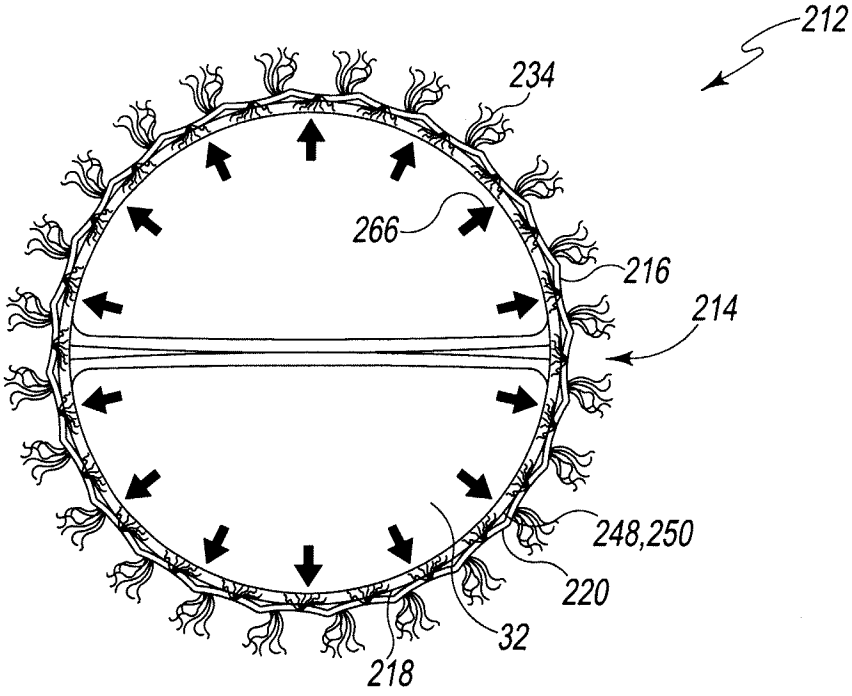
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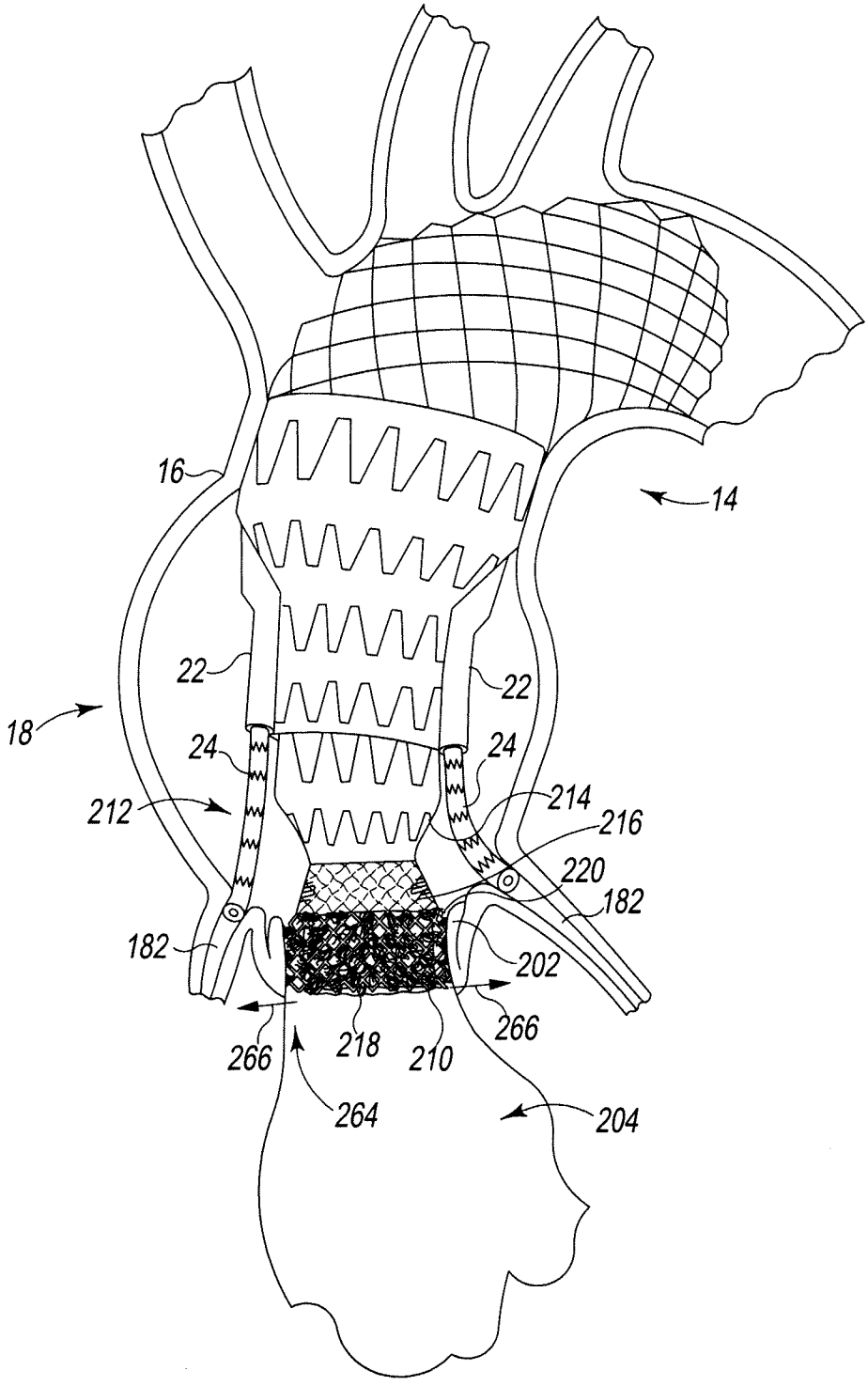
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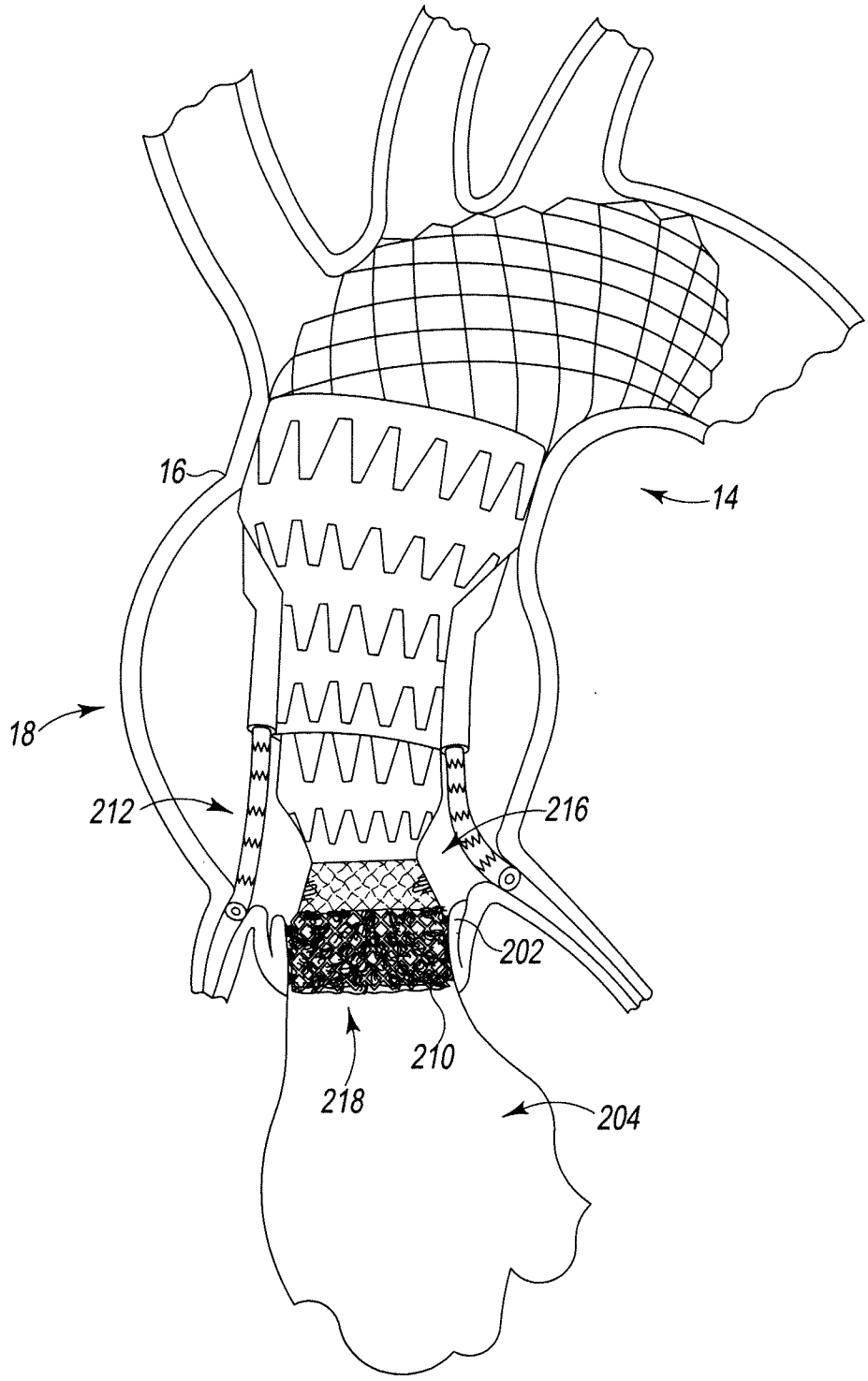
Fig. 15



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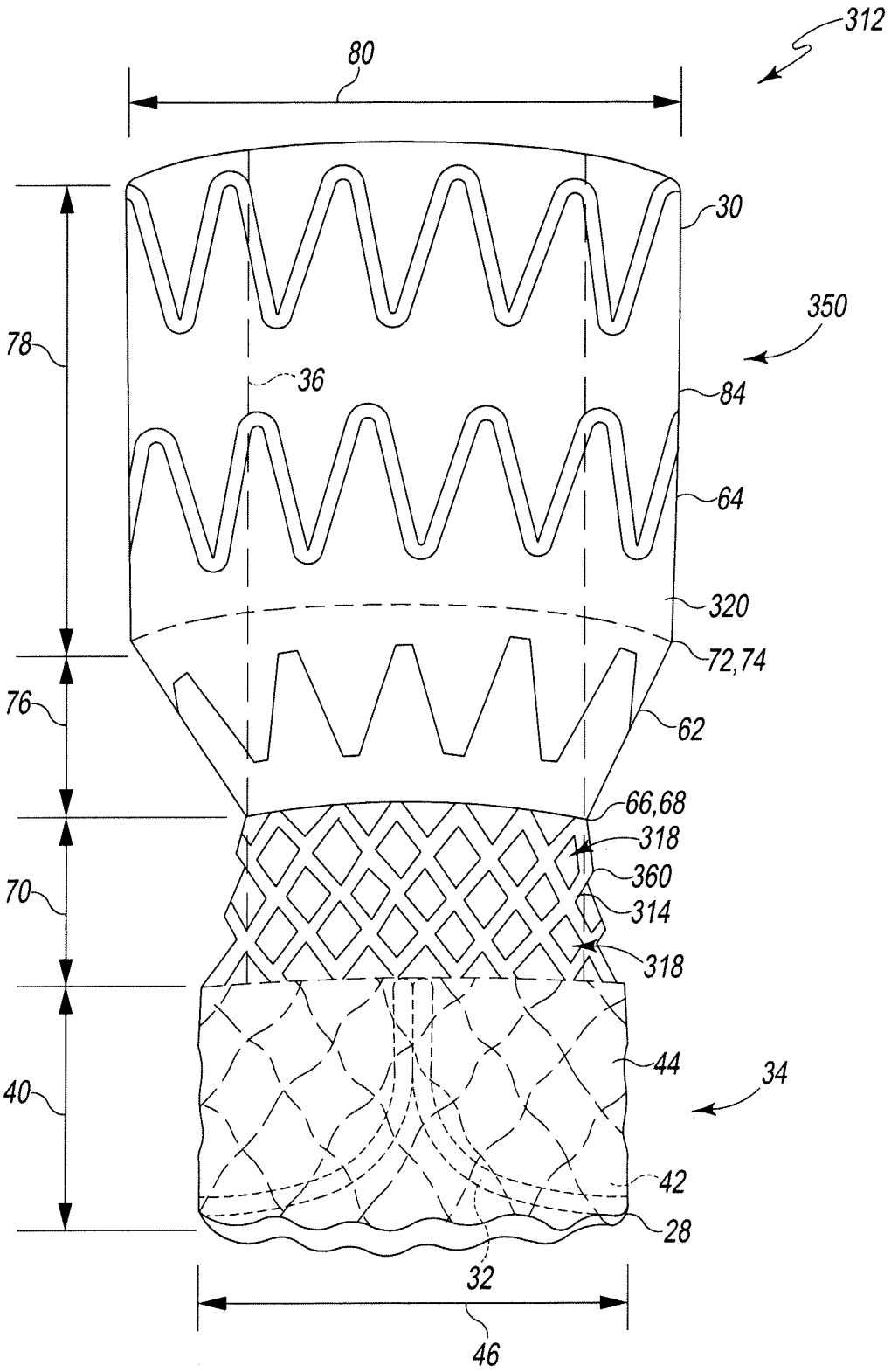
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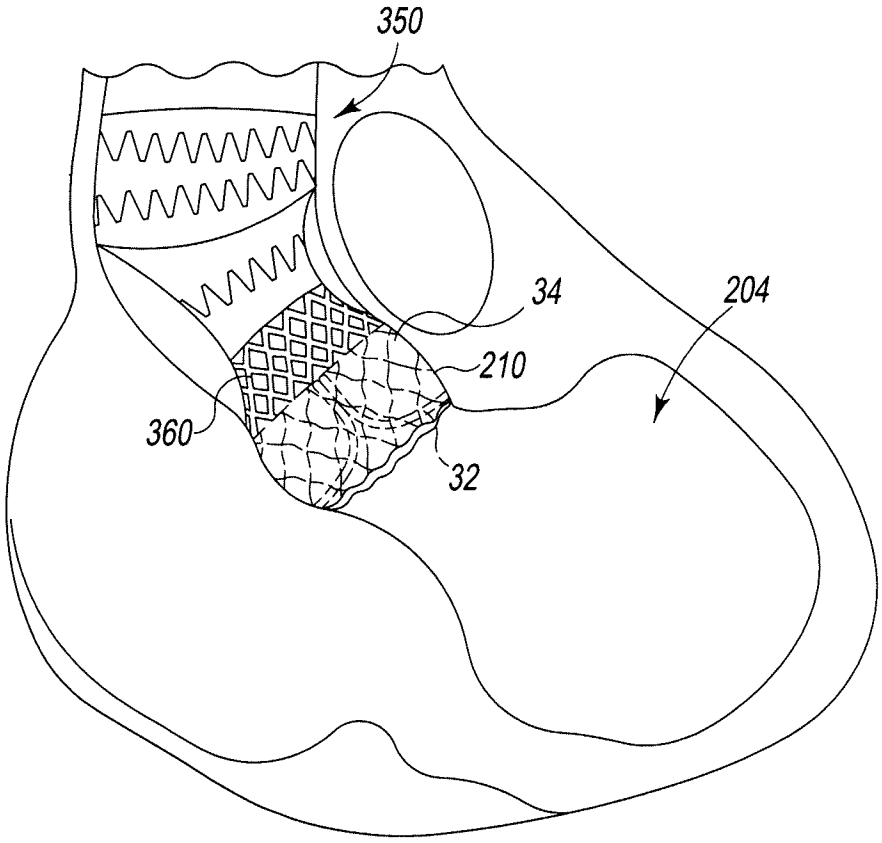
Fig. 17



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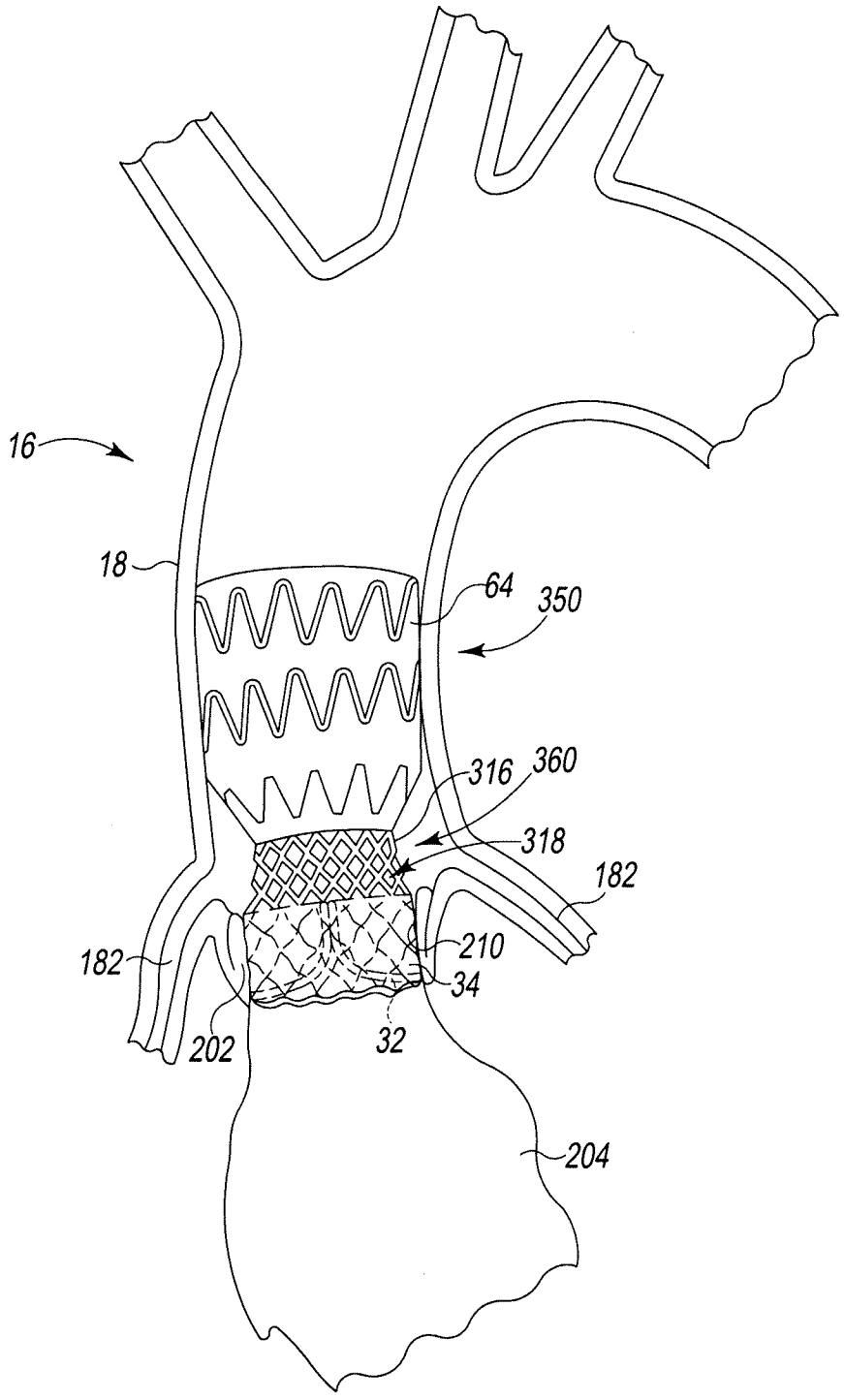

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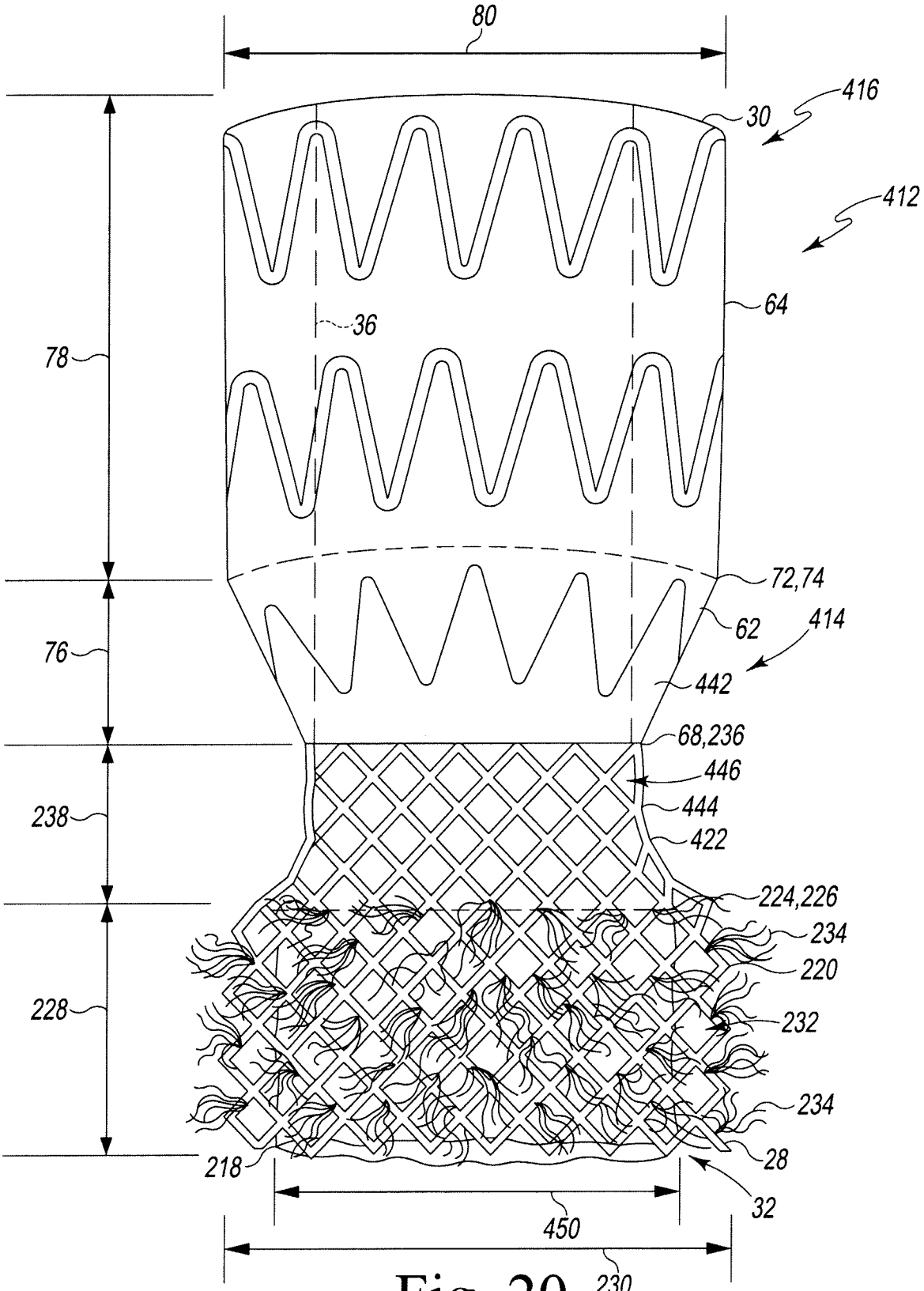
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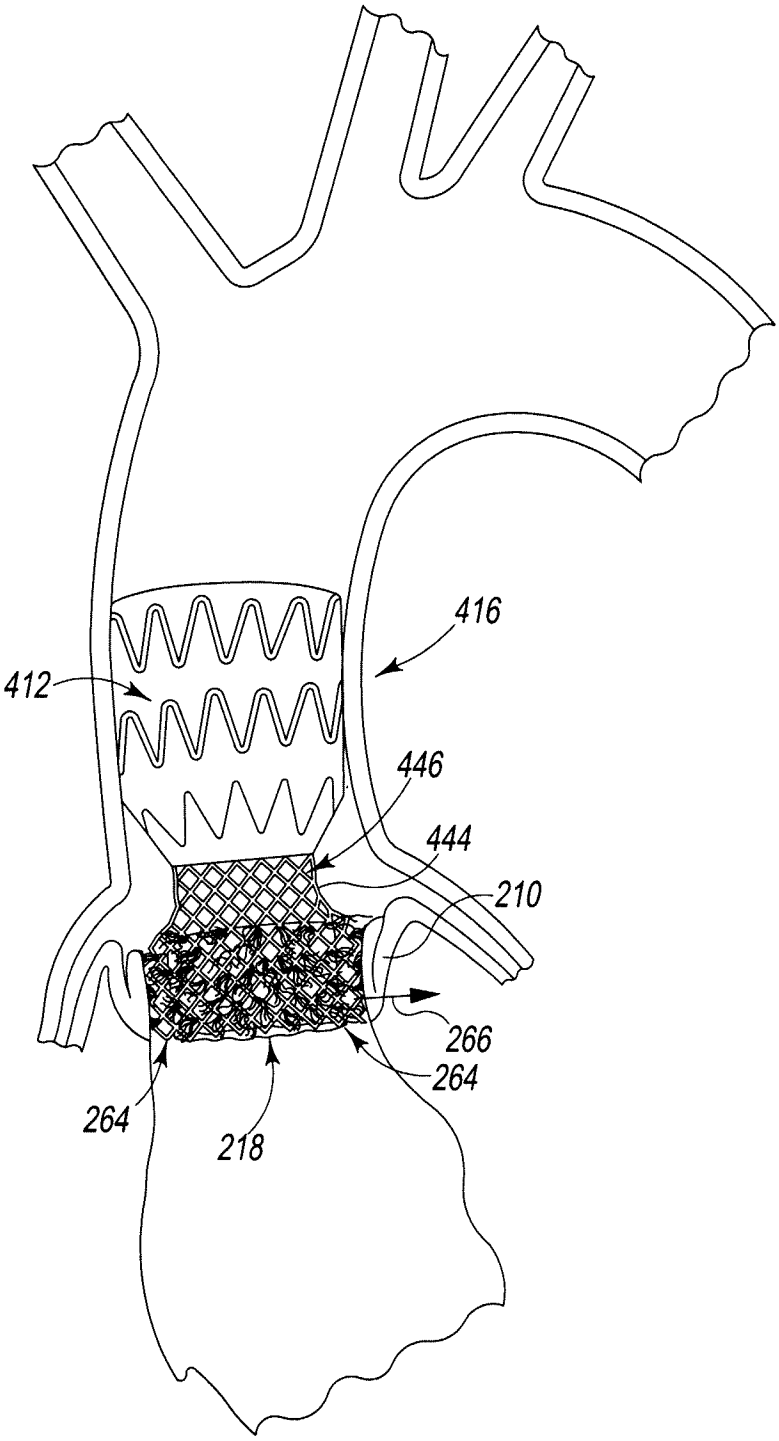
Fig. 20



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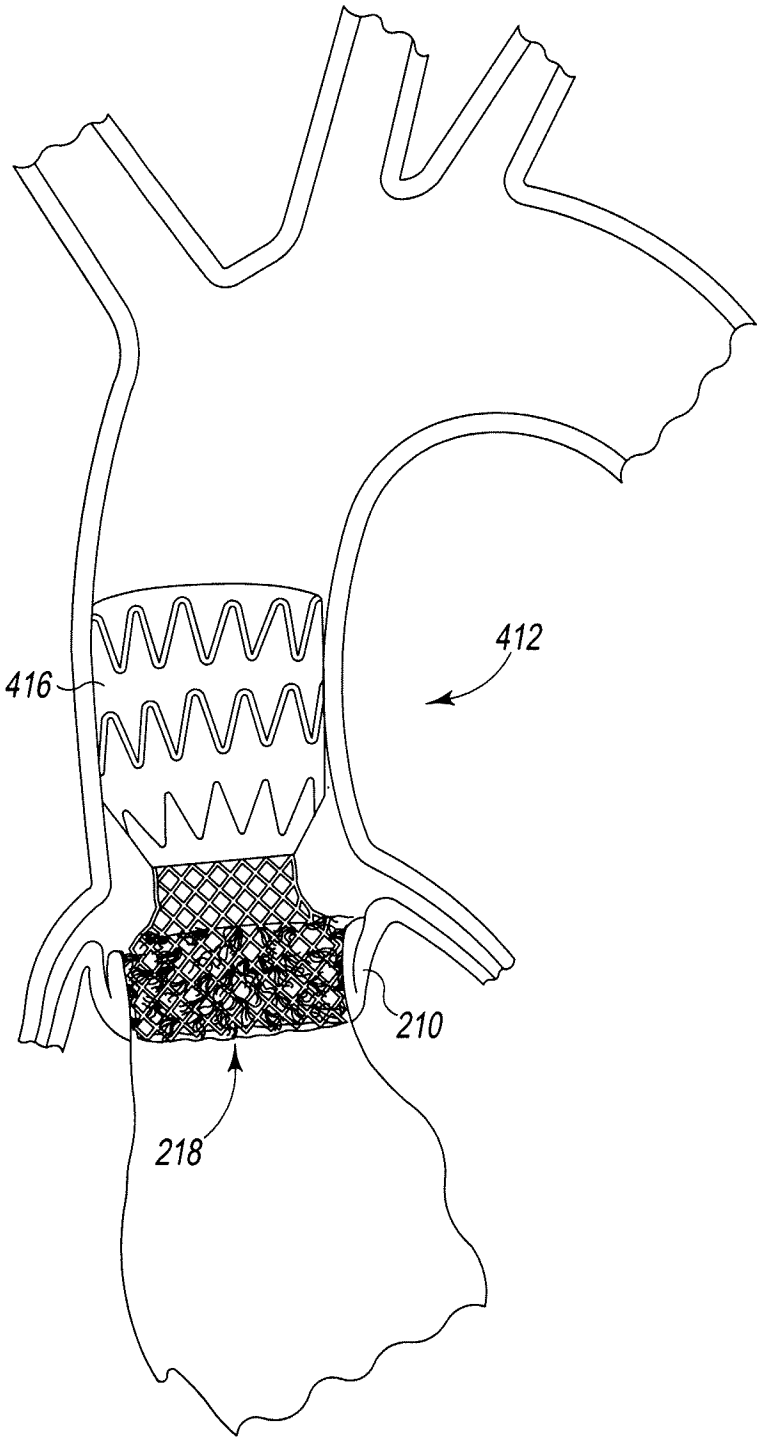

Fig. 22