object on relevancy grounds or seek AEO protections in that proceeding. Instead, Aortic seeks to take advantage of Edwards' compliance with this Court's request and improperly avoid the PTAB procedures it should have used to seek discovery of the demonstrative.

Second, because Edwards has not relied on the SAPIEN 3 Ultra demonstrative to support any of its positions in the IPRs, either as prior art or otherwise, the demonstrative is simply not relevant to any argument or issue in the IPRs. Aortic mischaracterizes the record in both the IPRs and Aortic's prosecution of the challenged patents in arguing otherwise. Aortic incorrectly asserts that "Edwards has placed the features of its valve at issue in the IPRs." Mot. at 14. Edwards has done no such thing. Edwards has not relied on SAPIEN 3 Ultra as prior art in any of the IPRs and has not made any arguments relying on the demonstrative Aortic seeks to de-designate. Indeed, even setting aside issues with priority dates, Edwards could not have relied on the SAPIEN 3 Ultra demonstrative as prior art in the IPRs because it is a physical device, not a printed publication. *See* 35 U.S.C. §311(b).

As discussed in further detail below, Aortic has relied on articles and images of SAPIEN 3 Ultra in attempts to support its arguments during prosecution of several of its patents—and did so before filing suit. *See infra* §IV.B.2. Edwards' only discussions of SAPIEN 3 Ultra in the IPRs have been in reference to Aortic's reliance on SAPIEN 3 Ultra during prosecution of the patents. Edwards is not using SAPIEN 3 Ultra "offensively" in the IPRs as Aortic incorrectly suggests. Mot. at 15. The only citation Aortic provides for this inaccurate characterization of the record proves this point. Aortic cites to a portion of Edwards' Petitioner's reply where Edwards responded to Aortic's attempts to distinguish the prior art based on the allegedly "sparsely distributed fibers" shown in the patent's figures. *See Id.* at 15 (citing D.I. 64 at 6-7 (citing Ex. 16

('846 Petitioner's Reply) at 1-8)).[1] In responding to Aortic's "sparsely distributed fibers" argument, Edwards informed the PTAB that Aortic had argued during prosecution that SAPIEN 3 Ultra "appears to be covered by the claimed invention" and relied on an image of SAPIEN 3 Ultra in making that argument. D.I. 64, Ex. 16 at 4-5. Edwards then noted that the same alleged differences between the "sparsely distributed fibers" in the patent's figures and the prior art were also present between the patent's figures and ***the image*** of SAPIEN 3 Ultra ***that Aortic relied on during prosecution***. *See id.* at 5. Aortic's ***prosecution statements***, including those relying on images of SAPIEN 3 Ultra, are relevant to the IPRs and were properly relied on by Edwards. In contrast, Edwards' physical SAPIEN 3 Ultra demonstrative is not relevant to any arguments or issues in the IPRs and has never been relied on by Edwards in those proceedings.

2. Aortic Seeks to De-designate the Demonstrative for an Improper Purpose Unrelated to this Litigation

Aortic's arguments during prosecution of its patents suggest that it is seeking the demonstrative for the improper purpose of crafting patent claims that read on Edwards' device. *See Glenmede*, 56 F.3d at 483 (factors that may be considered in evaluating whether good cause exists include "whether the information is being sought for a legitimate purpose or for an improper purpose"); *Pansy*, 23 F.3d at 787. For example, Aortic continues to obtain patents without an "inner frame" limitation after Edwards' identified that limitation as missing from its Sapien 3 Ultra valve. D.I. 11 (Edwards' Motion to Dismiss at 10-14); Lea Decl. Ex. 9 ('834 Patent at Claim 1).

Moreover, Aortic has repeatedly argued to the Patent Office that SAPIEN 3 Ultra "appears to be covered by the claimed invention" in an unpersuasive effort to take credit for Edwards'

[1] Pages 6-7 do not exist in D.I. 64. It appears Aortic intended to cite pages 3-4.

innovations and somehow show that Aortic's patents solved a need in the TAVR industry. *See* Lea Decl. Ex. 5 ('846 patent November 30, 2020 Amendment) at 19-20; Ex. 6 ('172 patent Preliminary Amendment) at 11-12; Ex. 7 ('011 patent August 18, 2020 Amendment) at 14. During prosecution of another patent, Aortic argued that SAPIEN 3 Ultra's "sealing skirt appears to be covered by the claimed invention" and relied on an unidentified ***image*** to argue that SAPIEN 3 Ultra's valve has "openings within the seal [that] provide for proper expansion of the valve." Lea Decl. Ex. 8 ('834 patent August 14, 2021 Amendment) at 27-28.

Aortic's improper prosecution motive is further evidenced by Aortic's insistence that the valve have no designation under the Stipulated Protective Order whatsoever. *See* Mot. at 6, n1. Aortic knows that even a "CONFIDENTIAL" designation under the protective order would limit its use of the demonstrative to "prosecution or defense of this action," preventing Aortic from achieving its true goal of using the demonstrative to prosecute new claims.[2] D.I. 47, §6(a). Aortic's prosecution-motive is wholly unrelated to this action and is improper. This Court should not endorse Aortic's improper attempt to take advantage of Edwards' production of the demonstrative.

C. <u>The Remaining *Pansy* Factors Support the AEO Designation</u>

Aortic has not argued, nor could it credibly argue, that accessing the demonstrative is an issue important to the public, or that the party benefiting from the sought-after order is a public

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[2] A CONFIDENTIAL designation would be insufficient to protect Edwards' highly sensitive technical information precisely because Dr. Shahriari is intimately involved in prosecution and the CONFIDENTIAL designation does not include a prosecution bar. *See* D.I. 47, §7 (only the access of AEO information subjects a recipient to a patent prosecution bar).

entity or official Unlike the actual life-saving valves sold by Edwards, Aortic cannot credibly argue that the disclosure of the demonstrative is important to public health or safety.[3] *See Crum & Crum Enterprises, Inc. v. NDC of California, L.P.*, No. CIV. 09-145 RBK, 2011 WL 886356, at *3 (D. Del. Mar. 10, 2011), at *4 (finding *Pansy* factor 4 favored nondisclosure because the parties "are not public officials or public entities, and there is no evidence that breach of the agreement will cause harm to the public"). Finally, disclosure is not necessary to promote efficiency among current or future litigants. As noted above, Aortic is in possession of the demonstrative valve that it seeks to make public and has a technical expert to consult with regarding the features of that demonstrative valve. Thus, all the *Pansy* factors support maintaining the AEO designation of the demonstrative valve.

V. CONCLUSION

For the foregoing reasons, this Court should deny Plaintiff's Motion to De-Designate Valve Demonstrative as Attorneys Eyes Only.

[3] Aortic has not sought an injunction in this case, nor reasonably could it. The public interest would strongly weigh against enjoining sales of this life-saving medical device.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Anthony D. Raucci

Brian P. Egan (#6227)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
began@morrisnichols.com
araucci@morrisnichols.com

Attorneys for Defendants

OF COUNSEL:

John B. Sganga, Jr.
Craig S. Summers
Christy G. Lea
Joshua J. Stowell
Brian C. Barnes
KNOBBE MARTENS
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404

Brian C. Horne
KNOBBE MARTENS
1925 Century Park East, Suite 600
Los Angeles, CA 90067
(310) 551-3450

Mark Vorder-Bruegge, Jr.
Matthew M. Lubozynski
WYATT, TARRANT & COMBS, LLP
6070 Poplar Avenue, Suite 300
Memphis, TN 38119
(901) 537-1000

November 14, 2022

CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 14, 2022, upon the following in the manner indicated:

Adam W. Poff, Esquire — *VIA ELECTRONIC MAIL*
Robert M. Vrana, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP
Rodney Square
1000 North King Street
Wilmington, DE 19801
Attorneys for Plaintiff

John Campbell, Esquire — *VIA ELECTRONIC MAIL*
John F. Garvish, Esquire
Joel L. Thollander, Esquire
Geoffrey L. Smith, Esquire
Caroline E. Burks, Esquire
MCKOOL SMITH, P.C.
303 Colorado, Suite 2100
Austin, TX 78701
Attorneys for Plaintiff

Alan P. Block, Esquire — *VIA ELECTRONIC MAIL*
MCKOOL SMITH, P.C.
300 South Grand Avenue, Suite 2900
Los Angeles, CA 90071
Attorneys for Plaintiff

Casey L. Shomaker, Esquire — *VIA ELECTRONIC MAIL*
MCKOOL SMITH, P.C.
300 Crescent Court, Suite 1500
Dallas, TX 75201
Attorneys for Plaintiff

/s/ Anthony D. Raucci

Anthony D. Raucci (#5948)

EXHIBIT 71

US011491033B2

(12) **United States Patent**
Shahriari

(10) **Patent No.: US 11,491,033 B2**
(45) **Date of Patent: Nov. 8, 2022**

(54) **TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL**

(71) Applicant: **Aortic Innovations, LLC**, Hillsboro Beach, FL (US)

(72) Inventor: **Ali Shahriari**, Hillsboro Beach, FL (US)

(73) Assignee: **Aortic Innovations, LLC**, Hillsboro Beach, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **17/719,160**

(22) Filed: **Apr. 12, 2022**

(65) **Prior Publication Data**

US 2022/0241097 A1 Aug. 4, 2022

Related U.S. Application Data

(60) Continuation of application No. 17/327,673, filed on May 22, 2021, now Pat. No. 11,337,834, which is a (Continued)

(51) **Int. Cl.**
A61F 2/856 (2013.01)
A61F 2/07 (2013.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/856*** (2013.01); ***A61F 2/07*** (2013.01); ***A61F 2/2418*** (2013.01); ***A61F 2/82*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 2/856; A61F 2/07; A61F 2/2418; A61F 2/82; A61F 2/962; A61F 2/24;
(Continued)

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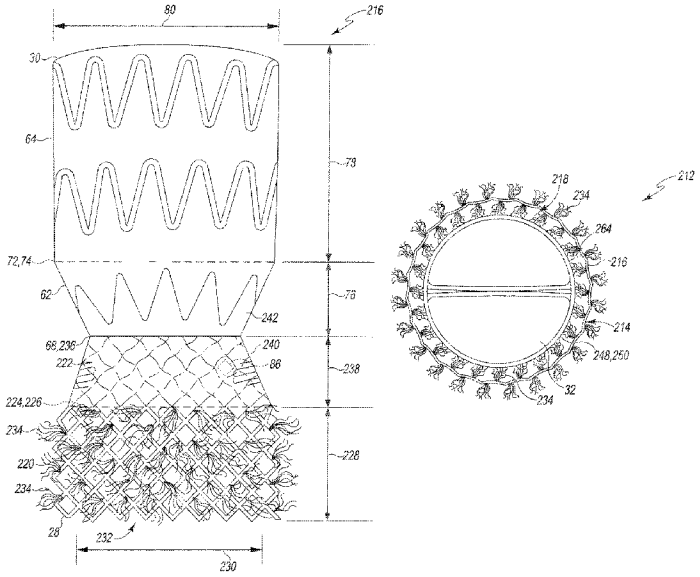
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(Continued)

Primary Examiner — Paul B Prebilic
(74) *Attorney, Agent, or Firm* — NK Patent Law

(57) **ABSTRACT**

A heart valve assembly includes an inner frame comprising a graft covering housing a prosthetic heart valve, wherein the graft covering extends around the prosthetic heart valve for providing sealing to the heart valve, an outer frame formed from a metallic material and defining a gridded configuration, and being secured to the graft covering by a plurality of stitches, and a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall to prevent paravalvular leaks. The sealing material includes a plurality of radially extending fibers that extend outwardly of the outer frame. The graft covering is made of polyester, polytetrafluoroethylene, expanded polytetrafluoroethylene, or a polymer.

6 Claims, 19 Drawing Sheets



Related U.S. Application Data

continuation of application No. 17/213,251, filed on Mar. 26, 2021, which is a continuation of application No. 17/096,253, filed on Nov. 12, 2020, now Pat. No. 10,966,846, which is a continuation of application No. 17/060,557, filed on Oct. 1, 2020, now Pat. No. 10,888,441, which is a continuation of application No. 16/910,189, filed on Jun. 24, 2020, now Pat. No. 10,857,011, which is a continuation of application No. 16/808,137, filed on Mar. 3, 2020, now Pat. No. 10,792,172, which is a continuation of application No. 16/736,879, filed on Jan. 8, 2020, now Pat. No. 10,842,655, which is a continuation of application No. 16/042,286, filed on Jul. 23, 2018, now Pat. No. 10,555,823, which is a continuation of application No. 14/614,628, filed on Feb. 5, 2015, now Pat. No. 10,028,848, which is a continuation of application No. 14/569,306, filed on Dec. 12, 2014, now Pat. No. 9,339,399, which is a division of application No. 13/706,896, filed on Dec. 6, 2012, now Pat. No. 8,940,040.

(60) Provisional application No. 61/723,446, filed on Nov. 7, 2012, provisional application No. 61/567,458, filed on Dec. 6, 2011.

(51) **Int. Cl.**

A61F 2/24	(2006.01)
A61F 2/82	(2013.01)
A61F 2/962	(2013.01)
A61F 2/06	(2013.01)
A61F 2/89	(2013.01)
A61F 2/90	(2013.01)
A61F 2/86	(2013.01)

(52) **U.S. Cl.**

CPC ***A61F 2/962*** (2013.01); *A61F 2/24* (2013.01); *A61F 2/86* (2013.01); *A61F 2/89* (2013.01); *A61F 2/90* (2013.01); *A61F 2002/061* (2013.01); *A61F 2002/067* (2013.01); *A61F 2210/00* (2013.01); *A61F 2210/0014* (2013.01); *A61F 2210/0057* (2013.01); *A61F 2220/0008* (2013.01); *A61F 2220/0016* (2013.01); *A61F 2220/0025* (2013.01); *A61F 2220/0058* (2013.01); *A61F 2220/0075* (2013.01); *A61F 2230/001* (2013.01); *A61F 2230/0034* (2013.01); *A61F 2230/0067* (2013.01); *A61F 2250/0048* (2013.01); *A61F 2250/0069* (2013.01)

(58) **Field of Classification Search**

CPC A61F 2/86; A61F 2/89; A61F 2/90; A61F 2002/061067; A61F 2210/00; A61F 2210/0014; A61F 2210/0057; A61F 220/0008; A61F 220/0016; A61F 220/0025; A61F 220/0058; A61F 220/0075; A61F 2230/001; A61F 2230/0034; A61F 2230/0067; A61F 2250/0048; A61F 2250/0069; A61F 2002/061; A61F 2002/067; A61F 2220/0008; A61F 2220/0016; A61F 2220/0025; A61F 2220/0058; A61F 2220/0075

See application file for complete search history.

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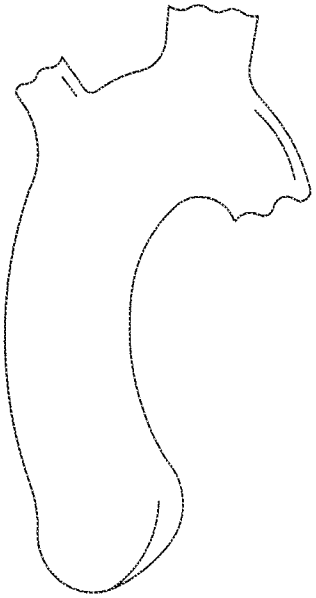


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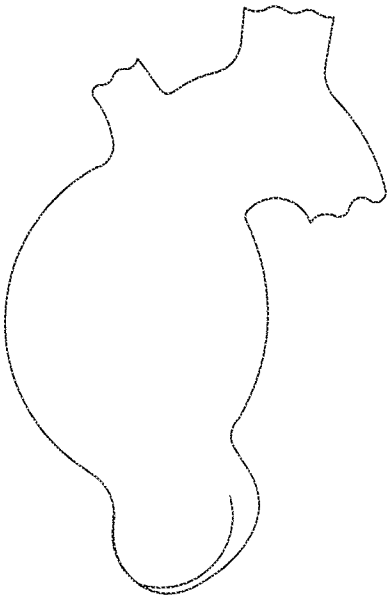


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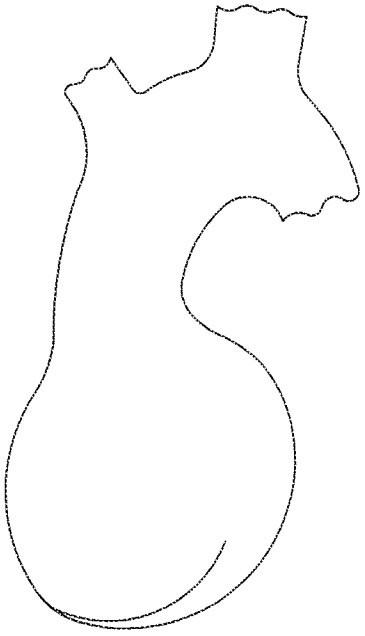


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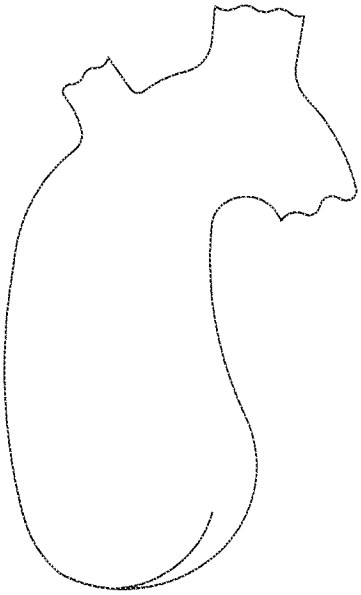


Fig. 1C

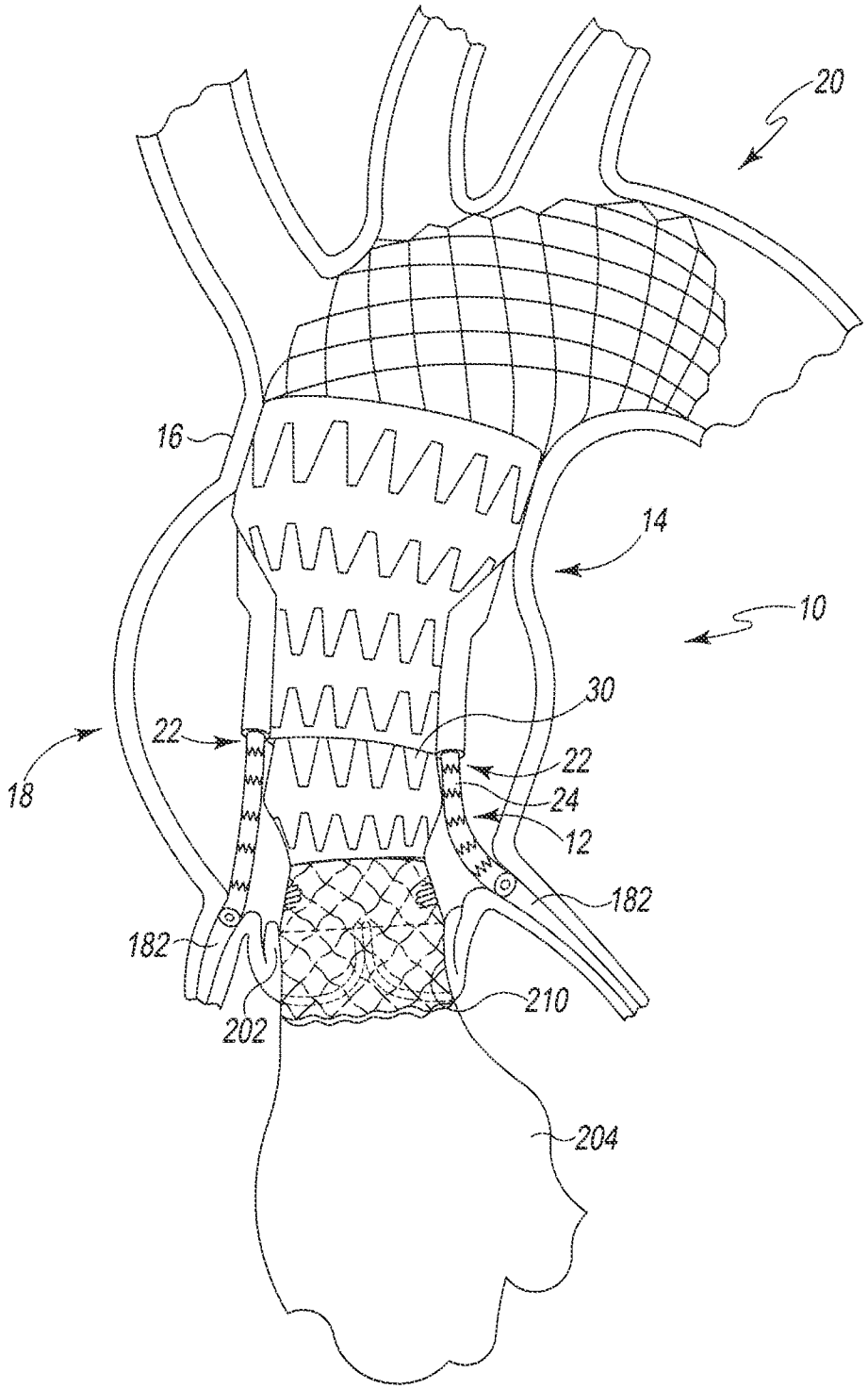


Fig. 2

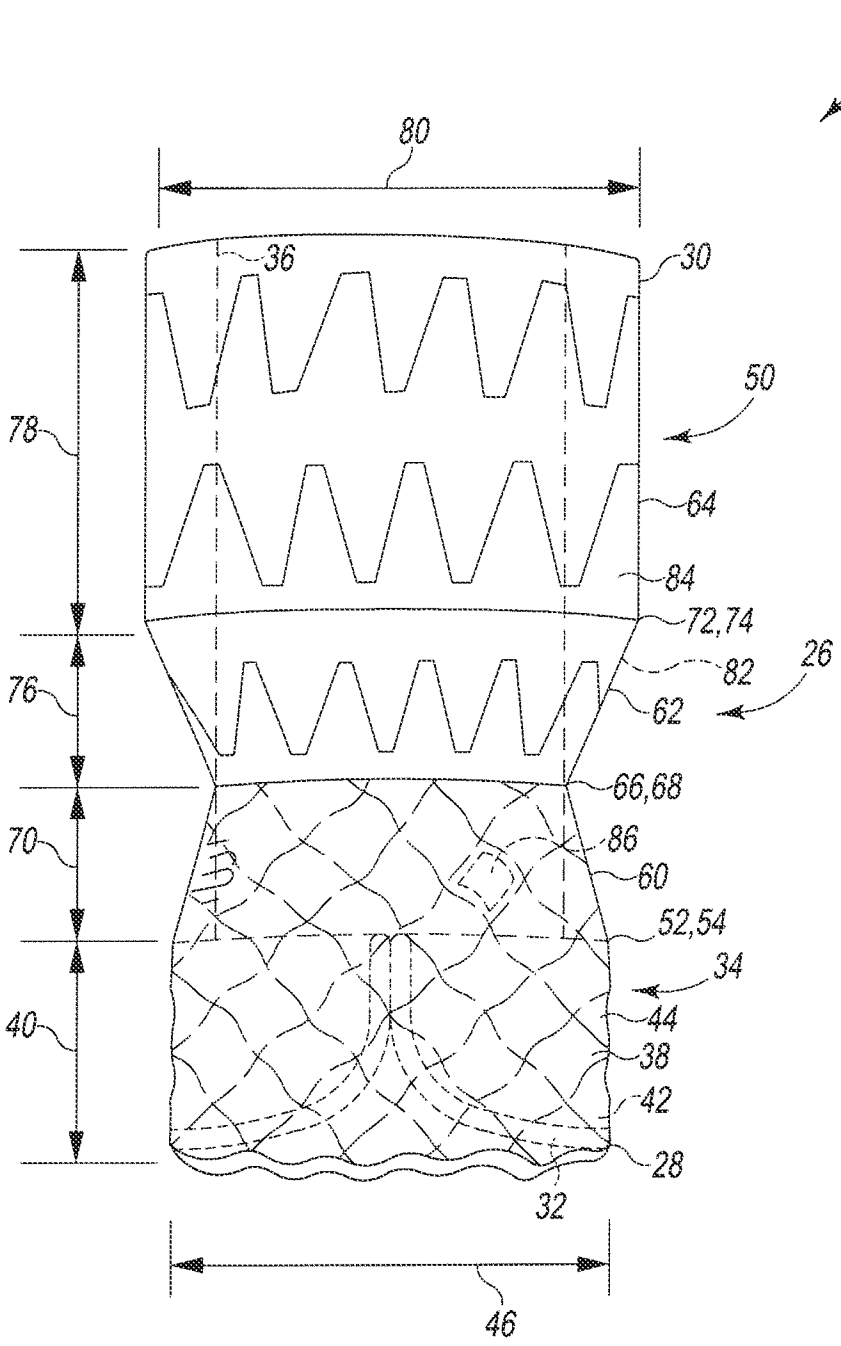

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Fig. 3

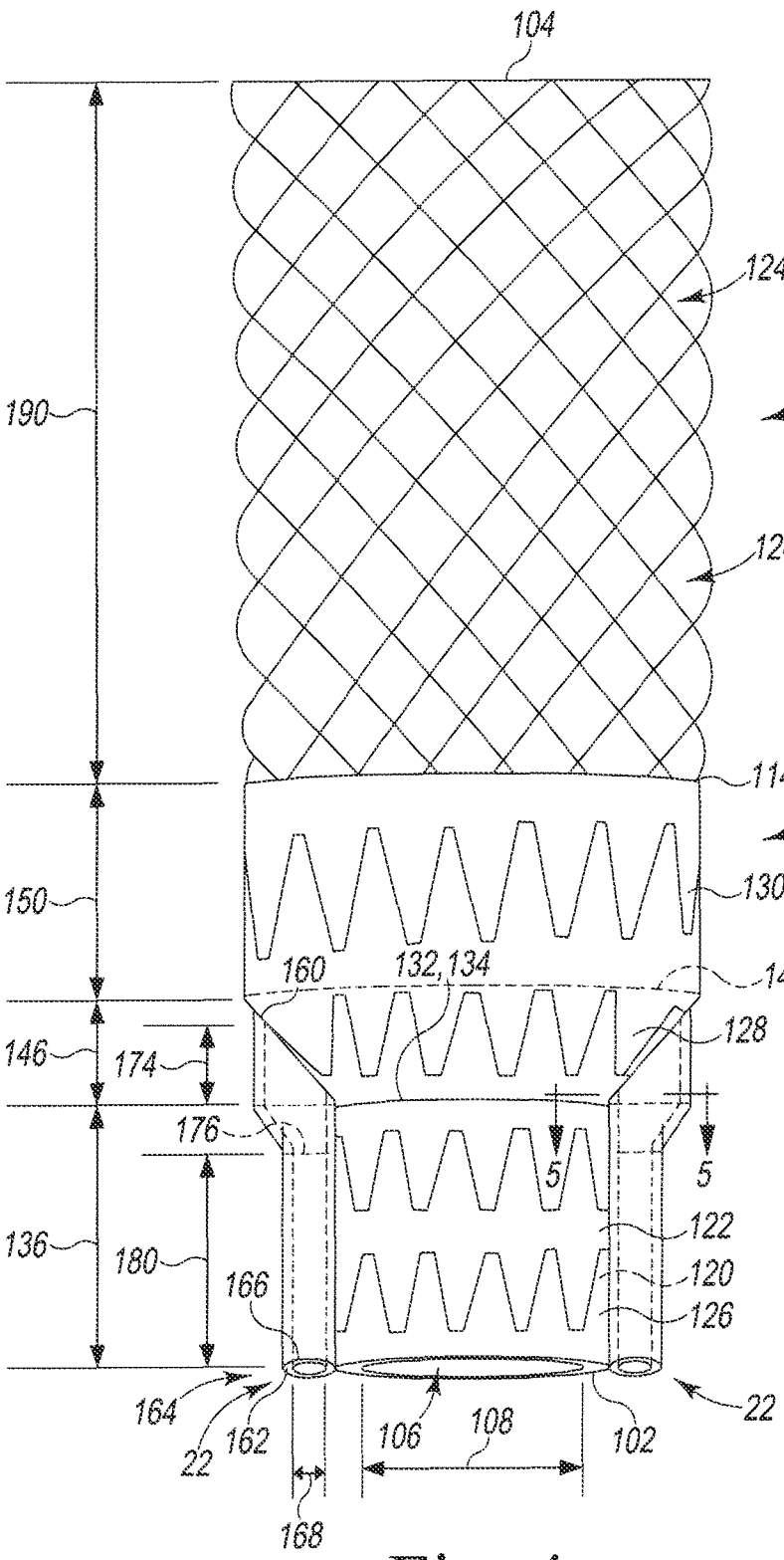

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Fig. 4

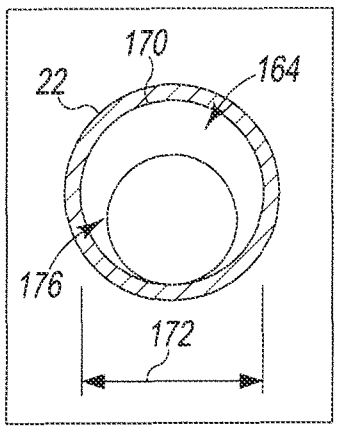

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Fig. 5

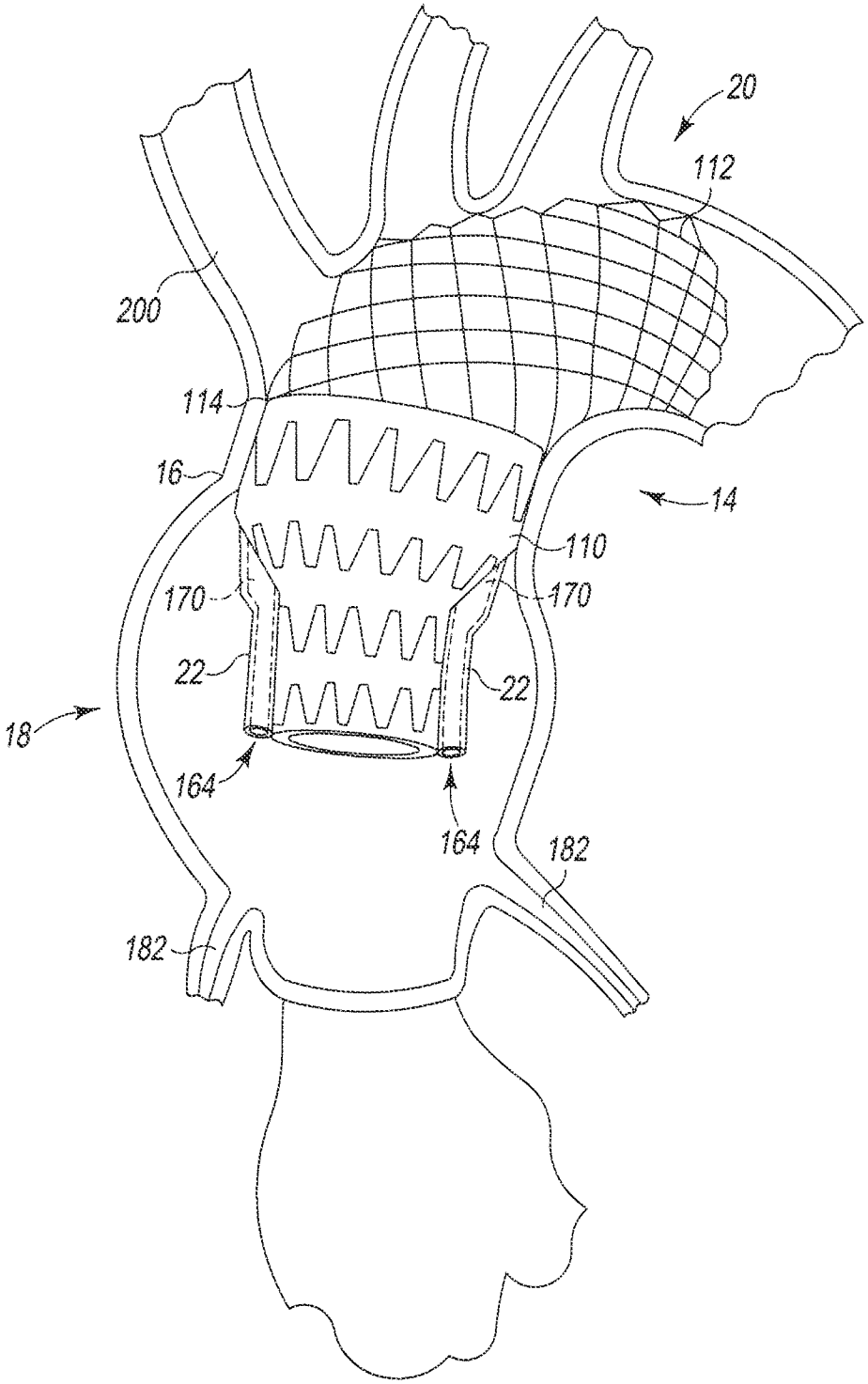


Fig. 6

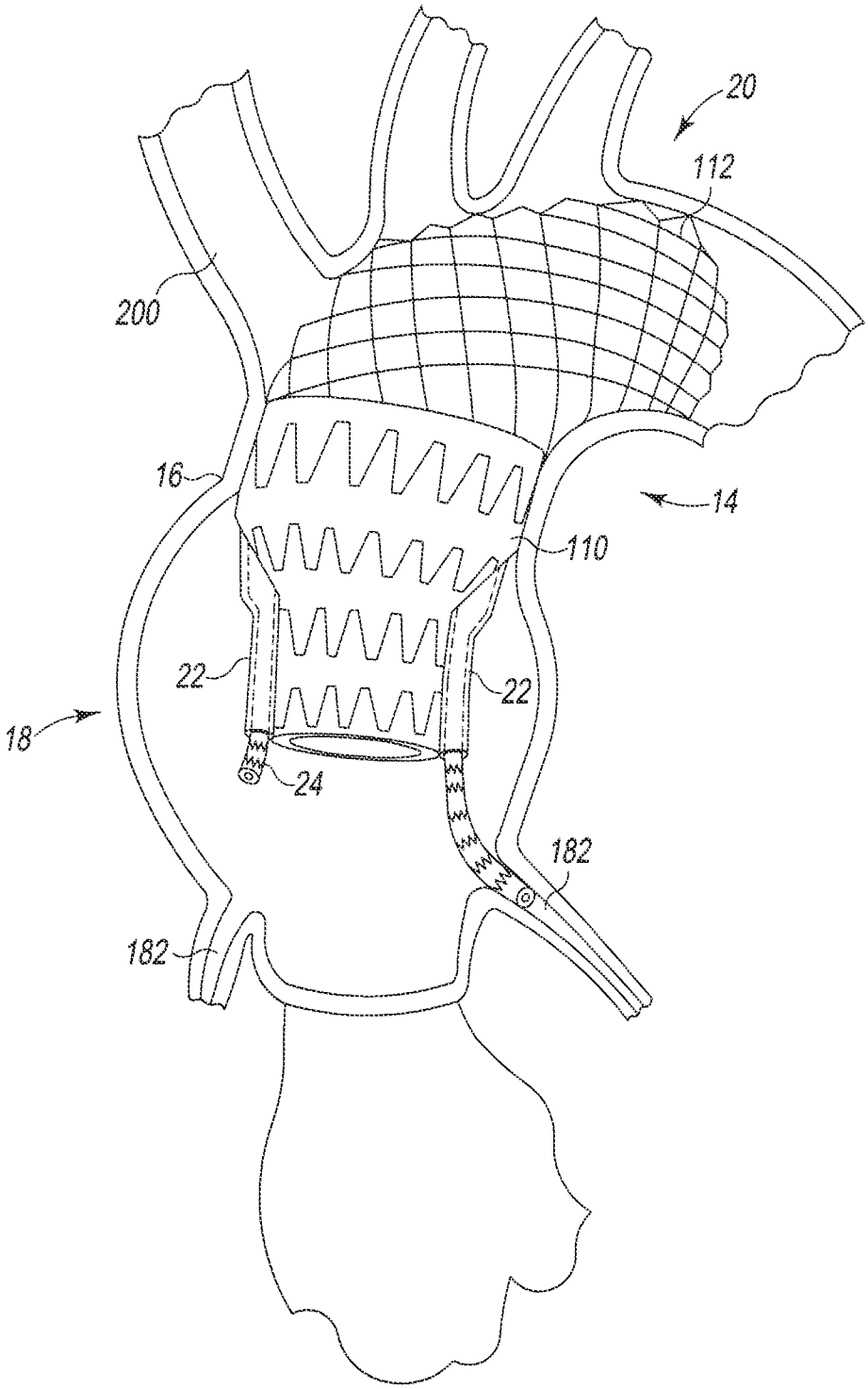


Fig. 7

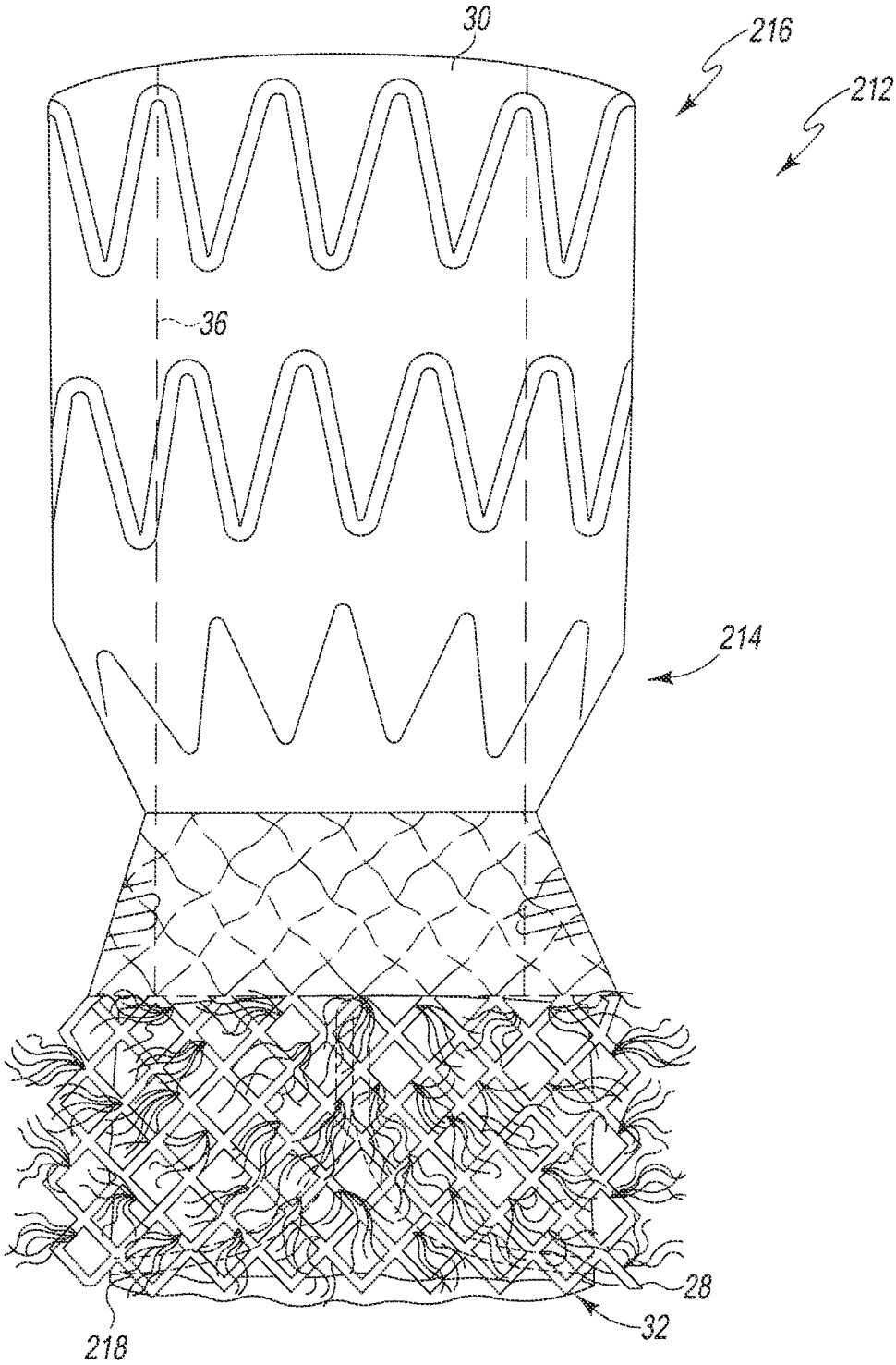


Fig. 8

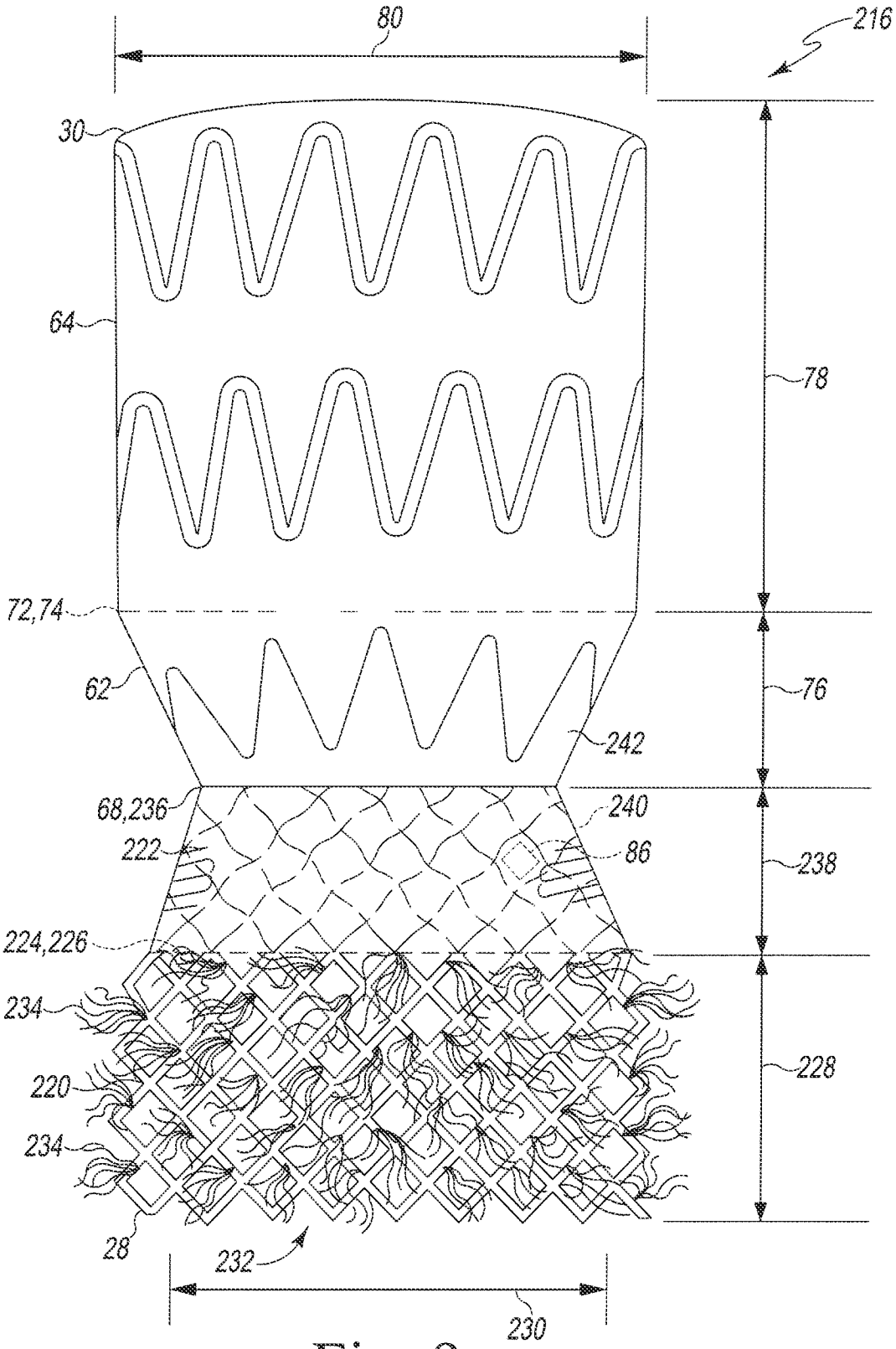

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Fig. 9

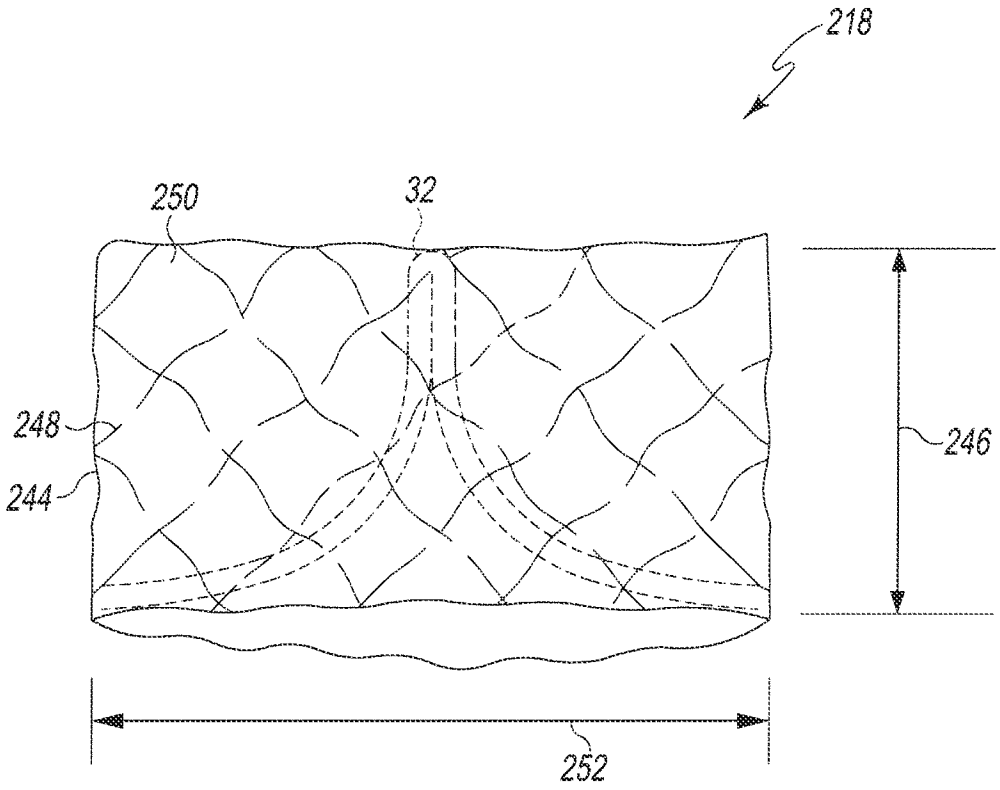


Fig. 10

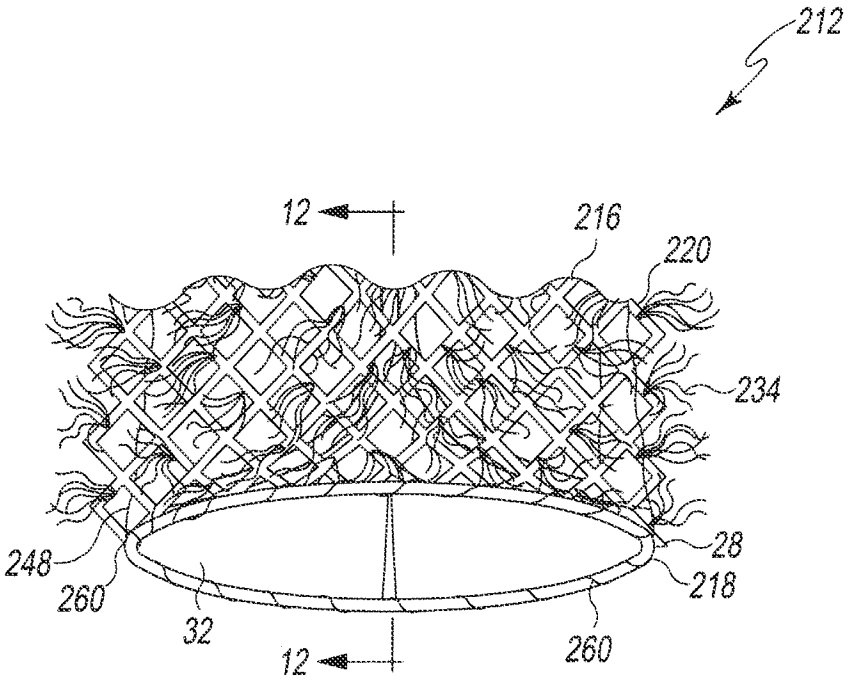


Fig. 11

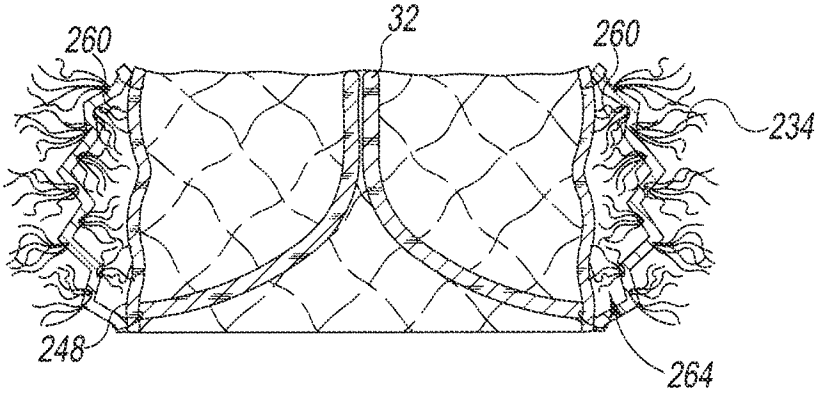


Fig. 12

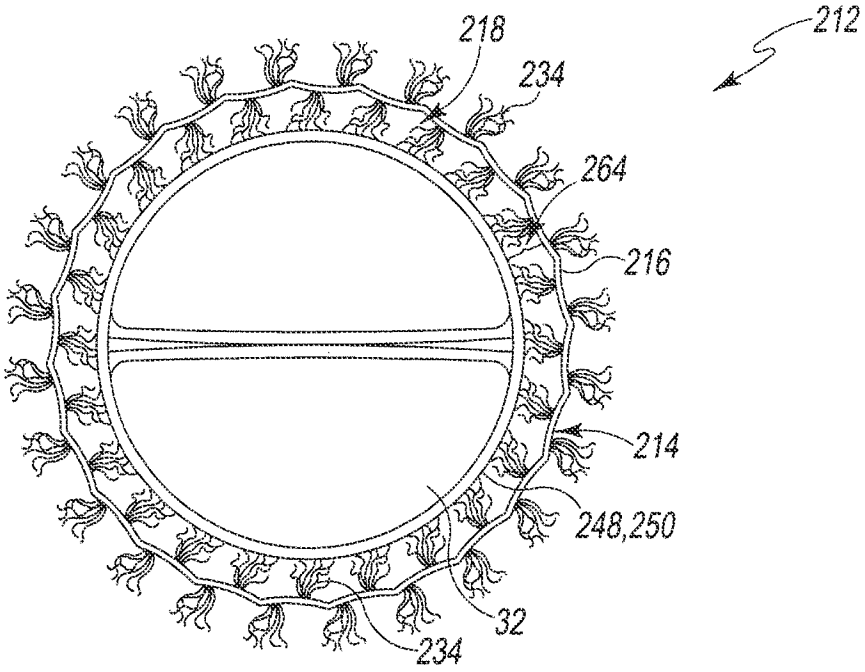

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Fig. 13

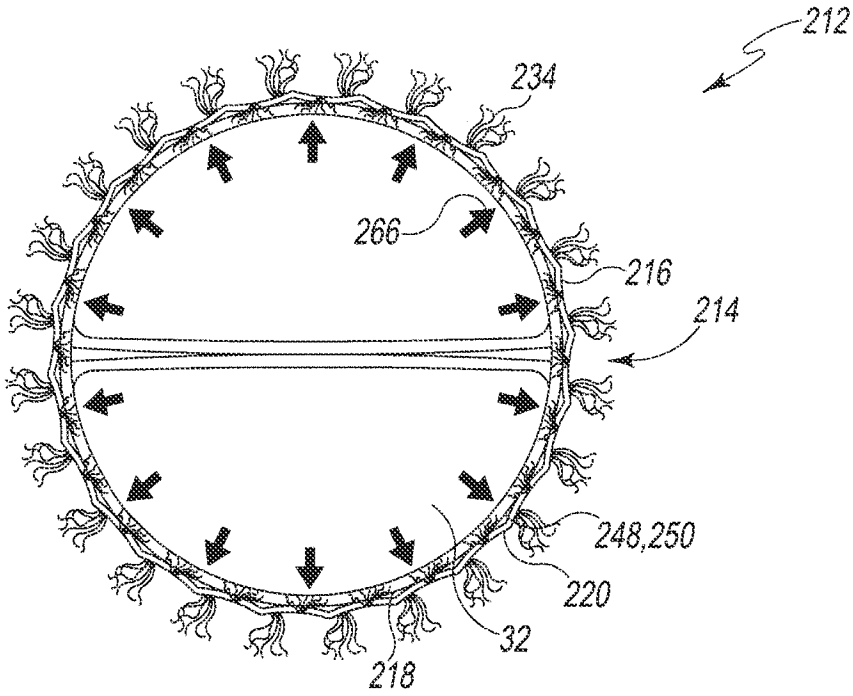

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216
214
248,250
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32
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Fig. 14

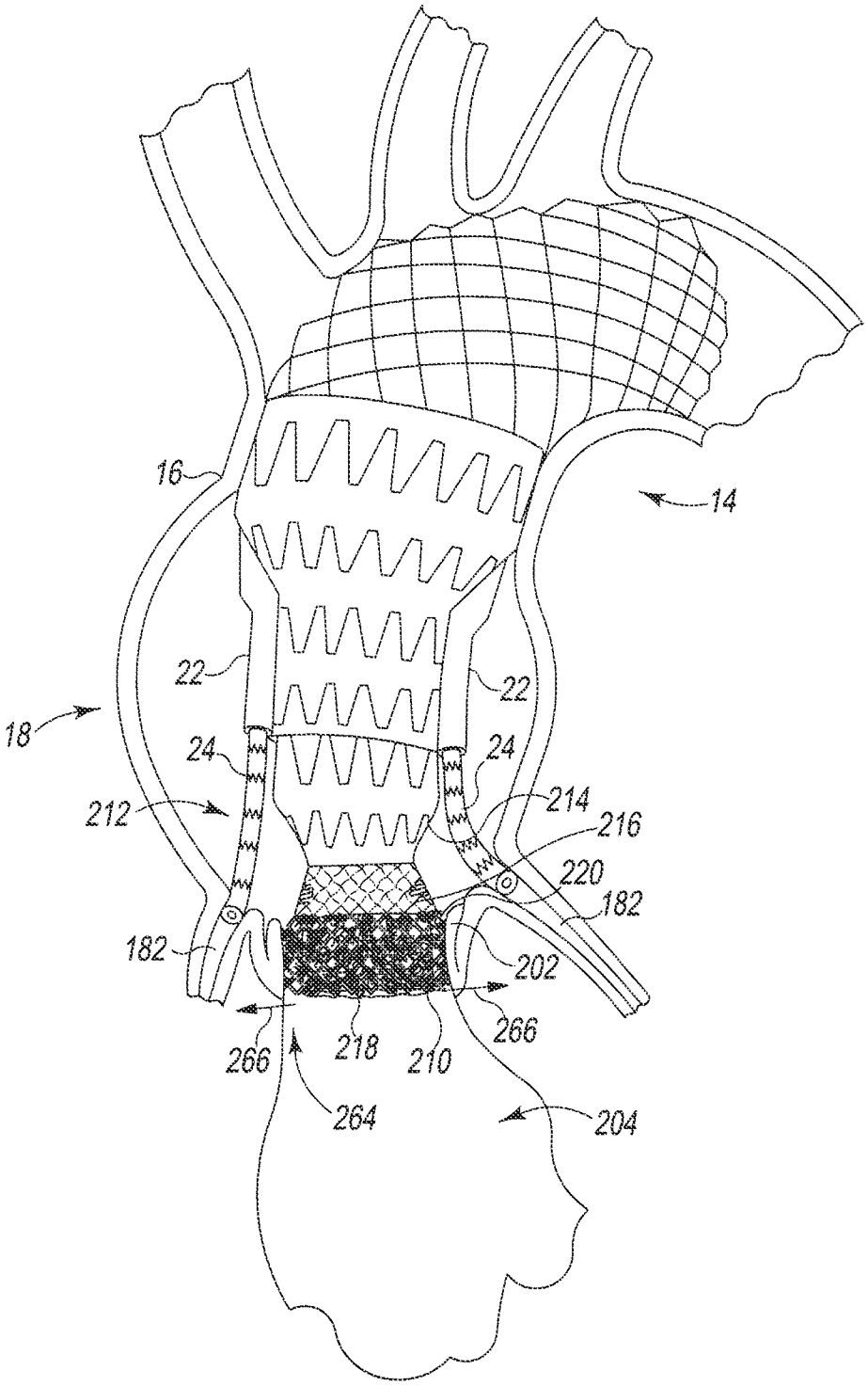

16
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266
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Fig. 15

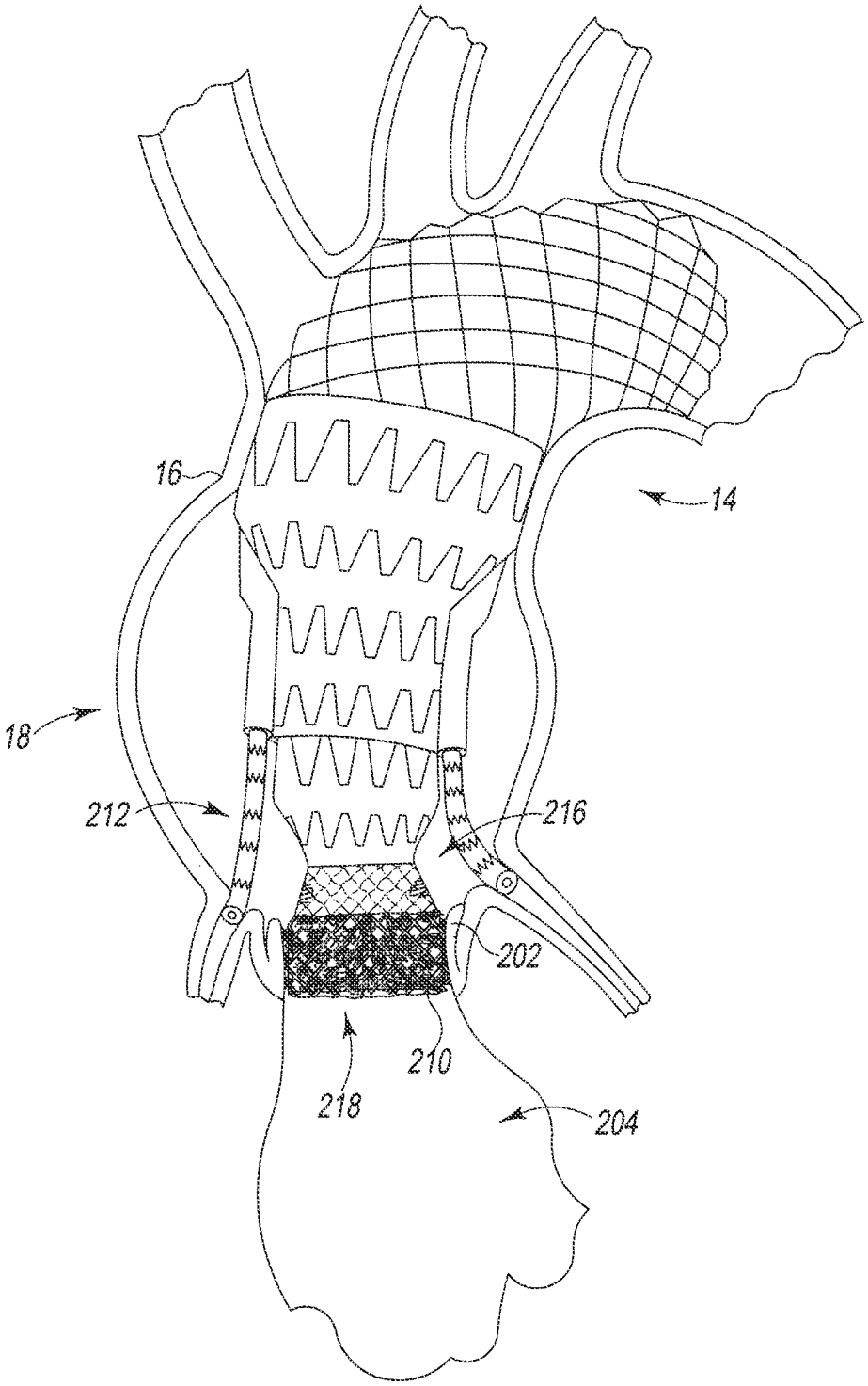


Fig. 16

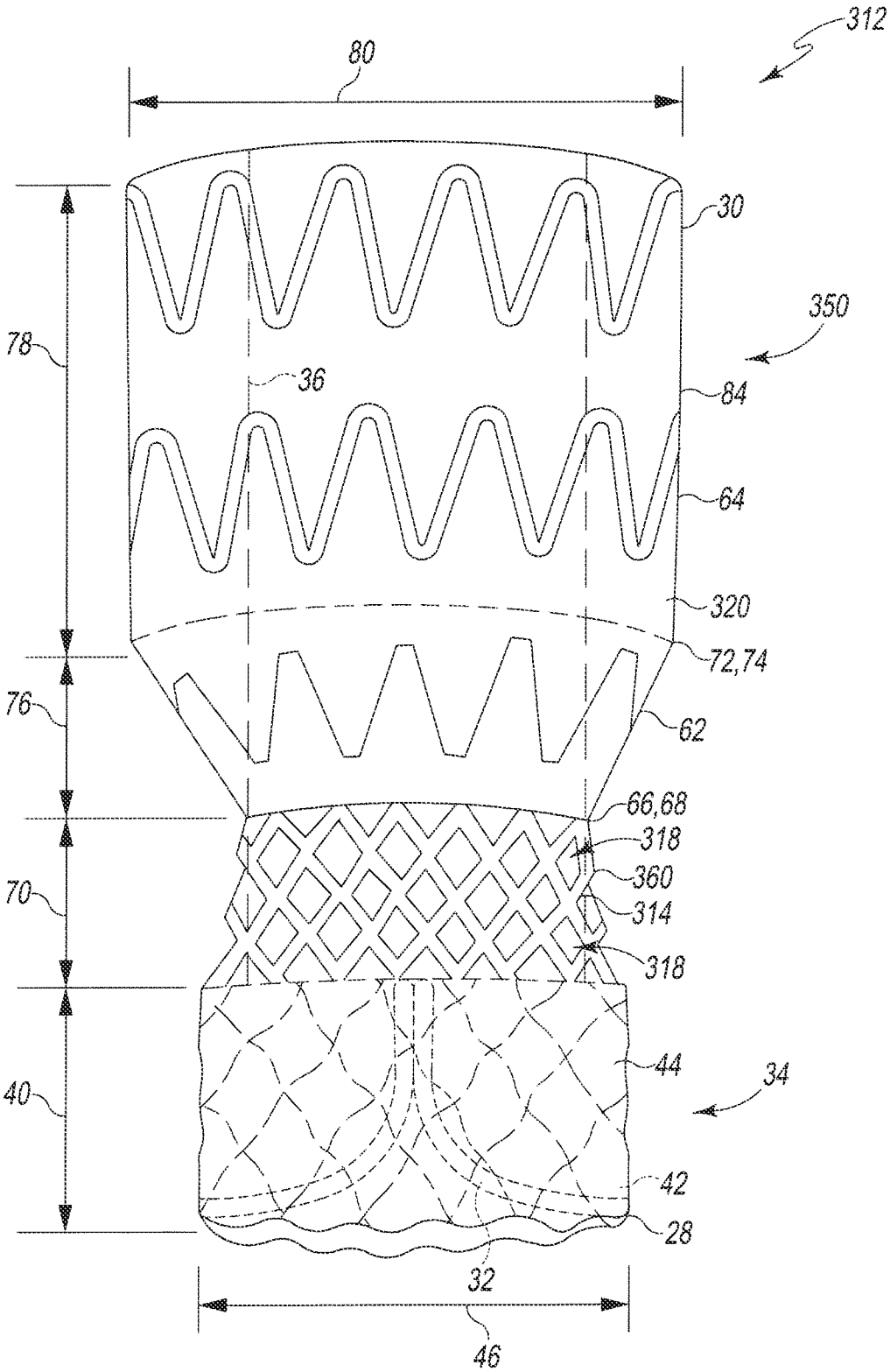

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Fig. 17

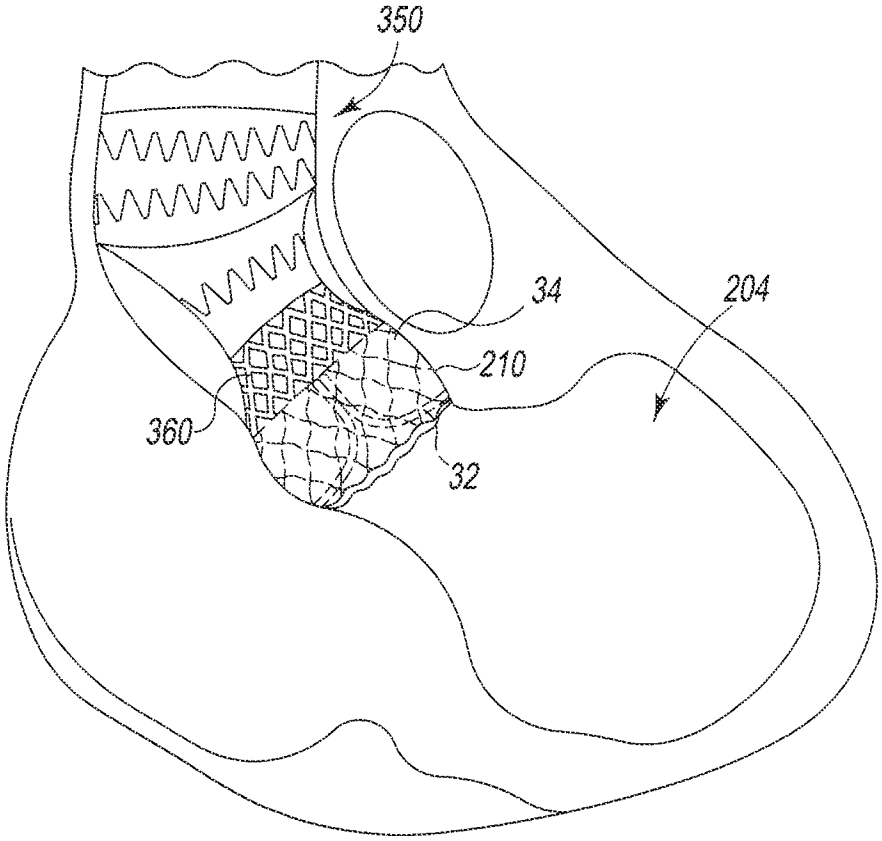


Fig. 18

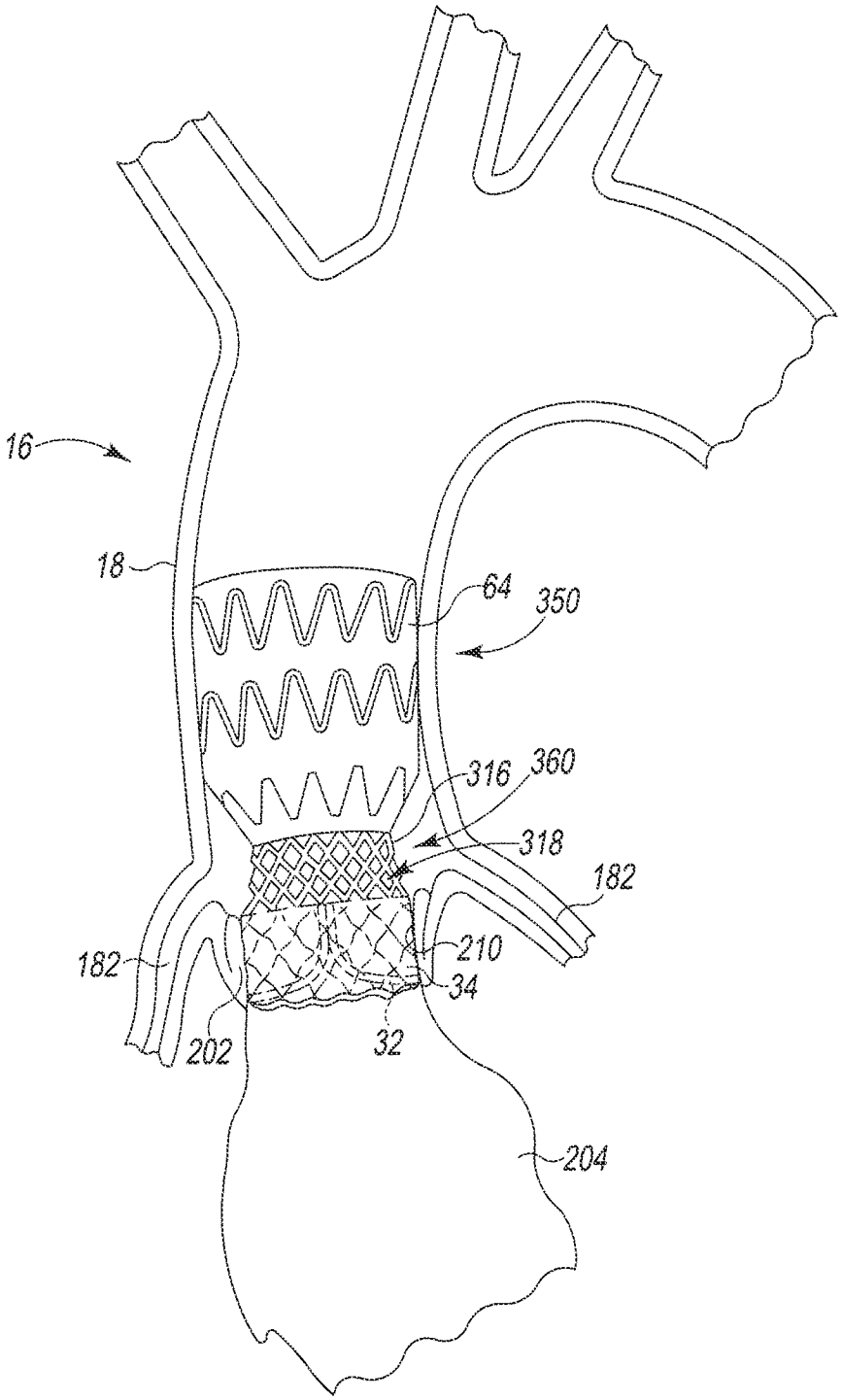


Fig. 19

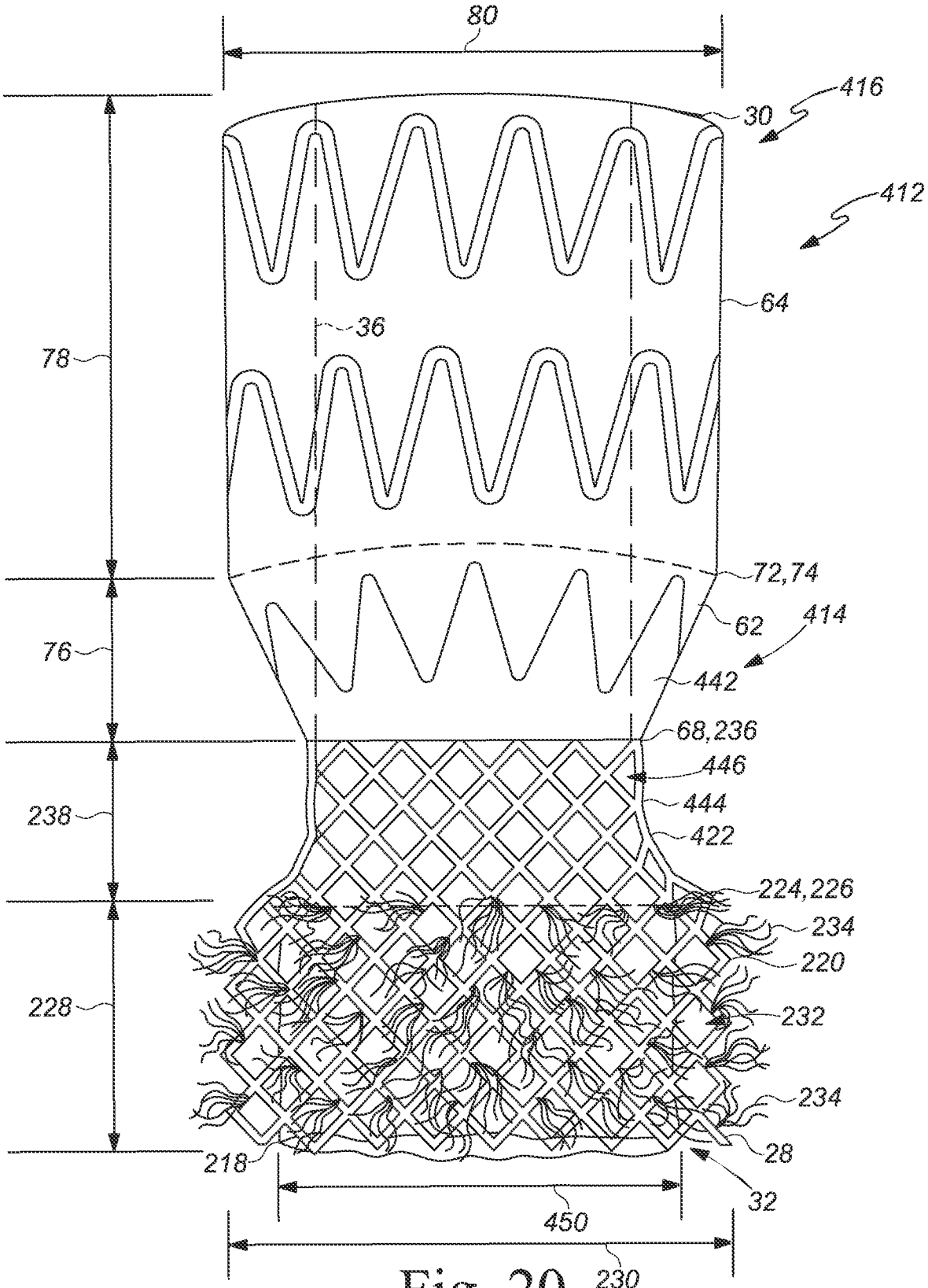

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Fig. 20

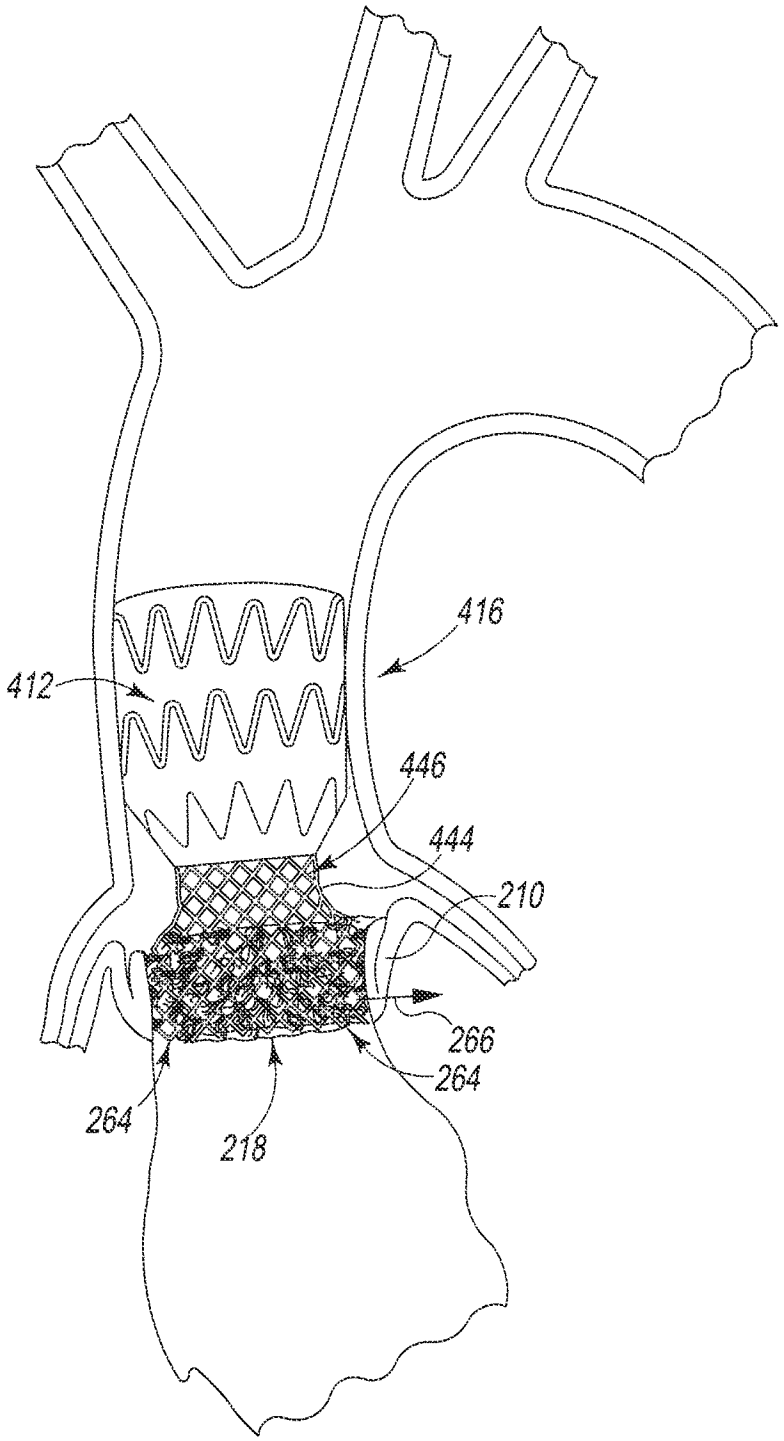


Fig. 21

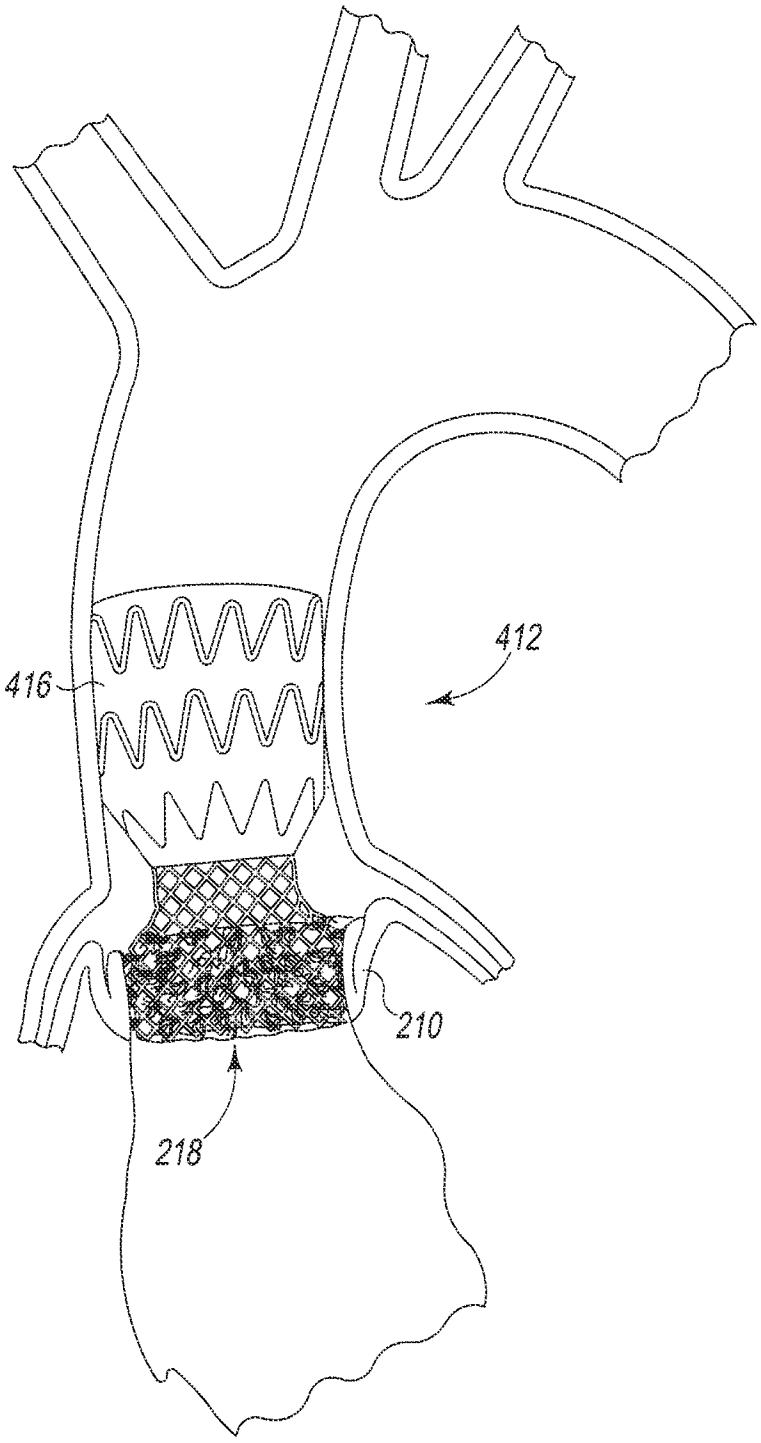


Fig. 22

TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

This application is a continuation of U.S. patent application Ser. No. 17/213,251 entitled TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL, which was filed on Mar. 26, 2021, which is a continuation of U.S. patent application Ser. No. 17/096,253 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on Nov. 12, 2020, and issued as U.S. Pat. No. 10,966,846 on Apr. 6, 2021, which is a continuation of U.S. patent application Ser. No. 17/060,557 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on Oct. 1, 2020 and issued as U.S. Pat. No. 10,888,441 on Jan. 12, 2021, which is a continuation of U.S. patent application Ser. No. 16/910,189 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jun. 24, 2020 and issued as U.S. Pat. No. 10,857,011 on Dec. 8, 2020, which is a continuation of U.S. patent application Ser. No. 16/808,137 entitled "HEART VALVE REPLACEMENT DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Mar. 3, 2020 and issued as U.S. Pat. No. 10,792,172 on Oct. 6, 2020, which is a continuation of U.S. patent application Ser. No. 16/736,879 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jan. 8, 2020 and issued as U.S. Pat. No. 10,842,655 on Nov. 24, 2020, which is a continuation of U.S. patent application Ser. No. 16/042,286 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jul. 23, 2018 and issued as U.S. Pat. No. 10,555,823 on Feb. 11, 2020, which is a continuation of U.S. patent application Ser. No. 14/614,628 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Feb. 5, 2015 and issued as U.S. Pat. No. 10,028,848 on Jul. 24, 2018, which is a continuation of U.S. patent application Ser. No. 14/569,306 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Dec. 12, 2014 and issued as U.S. Pat. No. 9,339,399 on May 17, 2016, which is a divisional of U.S. patent application Ser. No. 13/706,896 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Dec. 6, 2012 and issued as U.S. Pat. No. 8,940,040 on Jan. 27, 2015, which claims the benefit under 35 U.S.C. § 119 to U.S. Provisional Application Ser. No. 61/567,458 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on Dec. 6, 2011. application Ser. No. 13/706,896 also claims priority under § 119 to U.S. Provisional Application Ser. No. 61/723,446 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on Nov. 7, 2012. Each of the applications referenced herein are incorporated by reference in their entirety.

TECHNICAL FIELD

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

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, B, or C. These will be discussed in further detail below and are shown in FIGS. **1**A-**1**C, which have been reproduced from the referenced article.

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. **1**A.

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. **1**B.

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. **1**C.

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 population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

SUMMARY

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 adj acent 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.

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.

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 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

In some embodiments, the method may also include introducing the second prosthetic component into the ascending aorta prior to introducing the first prosthetic component.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

FIG. **1** is an illustrative aorta;

FIG. **1**A is an example of a Type A aneurysm;

FIG. **1**B is an example of a Type B aneurysm;

FIG. **1**C is an example of a Type C aneurysm;

FIG. **2** is partial cutaway view of an aorta with an embodiment of an endovascular prosthetic device implanted therein;

FIG. **3** is an elevation view of a proximal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **4** is an elevation view of a distal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **5** is a cross sectional view of the distal prosthetic component of FIG. **4** taken along the line **5-5** in FIG. **4**;

FIG. **6** is a partial cutaway view of the aorta with the distal prosthetic component of FIG. **3** implanted therein;

FIG. **7** is a view similar to FIG. **6** showing stents extending from the distal prosthetic component;

FIG. **8** is an elevation view of another embodiment of a proximal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **9** is an elevation view of a self-expanding outer frame of the proximal prosthetic component of FIG. **8**;

FIG. **10** is an elevation view of a balloon-expandable inner frame of the proximal prosthetic component of FIG. **8**;

FIG. **11** is a perspective view a proximal end of the proximal prosthetic component of FIG. **8**;

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**;

FIG. **13** is a plan view of the proximal prosthetic component of FIG. **8** showing the inner frame in an unexpanded position;

FIG. **14** is a plan view similar to FIG. **13** showing the inner frame in an expanded position;

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**;

FIG. **16** is a view similar to FIG. **15** showing the inner frame in an expanded position;

FIG. **17** is an embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. **3**;

FIGS. **18-19** are partial cutaway views of the aorta with the transcatheter valve of FIG. **17** implanted therein;

FIG. **20** is another embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. **8**; and

FIGS. **21-22** are partial cutaway views of the aorta with the transcatheter valve of FIG. **20** implanted therein.

DETAILED DESCRIPTION OF THE DRAWINGS

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.

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.

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. **17-22**. Such a valve may be introduced transfemorally or through the subclavian artery or the apex of the heart.

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.

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**.

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 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.

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. Pat. 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. Pat. 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.

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.

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.

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 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.

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**.

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 should also be appreciated that all or part of the component **12** may be covered with hydrogel or other sealing material.

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.

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.

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 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.

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.

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.

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.

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 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.

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**.

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**.

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 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.

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.

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**.

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**. 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**.

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**.

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. Pat. 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 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**.

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**.

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**.

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 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**.

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**.

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.

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 described in greater detail below. As shown in FIG. **9**, the proximal section **220** defines a passageway **232** in the outer frame **216**.

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**. As illustrated, the fibers **234** are arcuate. 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**.

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.

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.

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, 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**.

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.

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 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.

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.

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.

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**.

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**.

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 components **212**, **14** together and seal the distal end **30** of the component **212** within the distal component **14**.

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**.

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.

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.

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**.

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 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.

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.

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.

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 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.

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.

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**.

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 configu-

ration, mesh-like stent configuration, or Z-stent configuration. The sections **60**, **62**, **64** may also be formed as a single monolithic component.

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.

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**.

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** 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).

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**.

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**.

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.

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**.

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**.

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.

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.

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**.

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 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.

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).

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 the outer frame **416** and compresses the collagen fiber/hydrogel coated proximal section **220** of the outer frame **416** against the aortic annulus **210**.

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.

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 Ia 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.

Aortic insufficiency (AI) after implantation may also be corrected. Significant AI 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 AI. The bicuspid valve nature of the designs discussed herein potentially eliminates the problem with malcoaptation and AI secondary to that.

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.

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.

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.

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.

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 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.

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.

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 under-

stood 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.

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 sy stems 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 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.

The invention claimed is:

1. An endovascular prosthetic heart valve assembly having improved sealing for addressing paravalvular leakage for use in a patient, comprising:

a frame formed of a plurality of cells,

wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering about the leaflet assembly that is positioned radially inwardly of the frame and engaged with the leaflet assembly for providing sealing against paravalvular leakage; and

a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage,

wherein the sealing assembly extends over each of the at least two rows of cells,

wherein the sealing assembly lays against the frame when the prosthetic heart valve assembly is in the radially compressed orientation and the radially expanded orientation,

wherein the prosthetic heart valve assembly is sized and shaped to be endovascularly deployed through a femoral artery of the patient,

wherein the prosthetic heart valve assembly defines spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state,

wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state:

presses the sealing assembly against the native leaflets of the aorta to impart compression of the sealing assembly that compresses the plurality of fibers relative to the spacings thereby reducing the spacings; and

expands the polymer covering radially outwardly,

wherein the compression of the plurality of fibers relative to the spacings and the expansion of the polymer covering cooperatively create a paravalvular seal about the frame and the native leaflets by reducing the spaces in the sealing assembly.

2. The prosthetic heart valve assembly of claim **1**, wherein the frame is self-expanding.

3. The prosthetic heart valve assembly of claim **1**, wherein the frame defines an hour glass shape.

4. The prosthetic heart valve assembly of claim **1**, wherein the plurality of cells are a same shape.

5. The prosthetic heart valve assembly of claim **1**, wherein the frame is integrally formed.

6. The prosthetic heart valve assembly of claim **1**, wherein the plurality of fibers define fibers that extend outwardly to a tip of each respective fiber.

* * * * *

EXHIBIT 72

US011497634B2

(12) **United States Patent**
Shahriari

(10) **Patent No.: US 11,497,634 B2**
(45) **Date of Patent: *Nov. 15, 2022**

(54) **TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL**

(71) Applicant: **Aortic Innovations, LLC**, Hillsboro Beach, FL (US)

(72) Inventor: **Ali Shahriari**, Hillsboro Beach, FL (US)

(73) Assignee: **Aortic Innovations, LLC**, Hillsboro Beach, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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CPC A61F 2/856; A61F 2/07; A61F 2/2418; A61F 2/82; A61F 2/90; A61F 2210/0014
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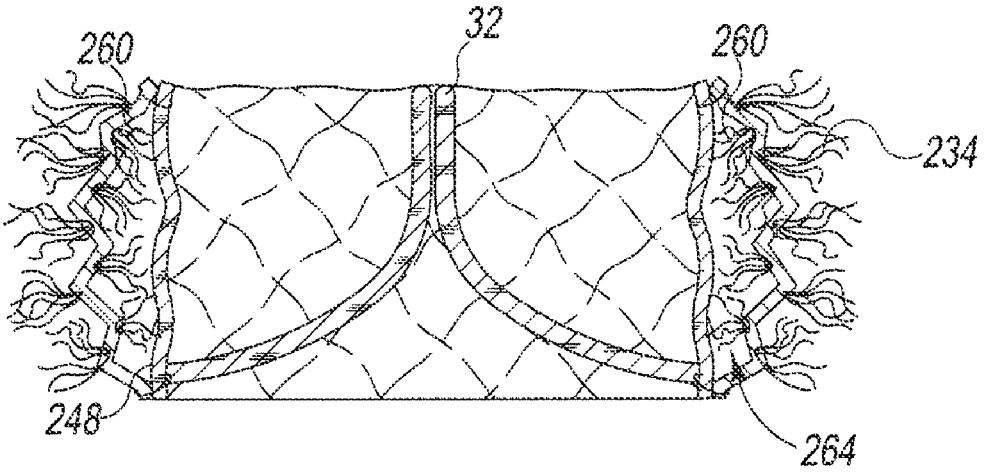
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Primary Examiner — Jennifer Dieterle
Assistant Examiner — Tiffany P Shipmon
(74) *Attorney, Agent, or Firm* — NK Patent Law

(57) **ABSTRACT**

A heart valve assembly includes an inner frame comprising a graft covering housing a prosthetic heart valve, wherein the graft covering extends around the prosthetic heart valve for providing sealing to the heart valve, an outer frame formed from a metallic material and defining a gridded configuration, and being secured to the graft covering by a plurality of stitches, and a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall to prevent paravalvular leaks. The sealing material includes a plurality of radially extending fibers that extend outwardly of the outer frame. The graft covering is made of polyester, polytetrafluoroethylene, expanded polytetrafluoroethylene, or a polymer.

10 Claims, 19 Drawing Sheets



Related U.S. Application Data

No. 17/096,253, filed on Nov. 12, 2020, now Pat. No. 10,966,846, which is a continuation of application No. 17/060,557, filed on Oct. 1, 2020, now Pat. No. 10,888,441, which is a continuation of application No. 16/910,189, filed on Jun. 24, 2020, now Pat. No. 10,857,011, which is a continuation of application No. 16/808,137, filed on Mar. 3, 2020, now Pat. No. 10,792,172, which is a continuation of application No. 16/736,879, filed on Jan. 8, 2020, now Pat. No. 10,842,655, which is a continuation of application No. 16/042,286, filed on Jul. 23, 2018, now Pat. No. 10,555,823, which is a continuation of application No. 14/614,628, filed on Feb. 5, 2015, now Pat. No. 10,028,848, which is a continuation of application No. 14/569,306, filed on Dec. 12, 2014, now Pat. No. 9,339,399, which is a division of application No. 13/706,896, filed on Dec. 6, 2012, now Pat. No. 8,940,040.

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A61F 2/962	(2013.01)
A61F 2/82	(2013.01)
A61F 2/06	(2013.01)
A61F 2/89	(2013.01)
A61F 2/90	(2013.01)
A61F 2/86	(2013.01)

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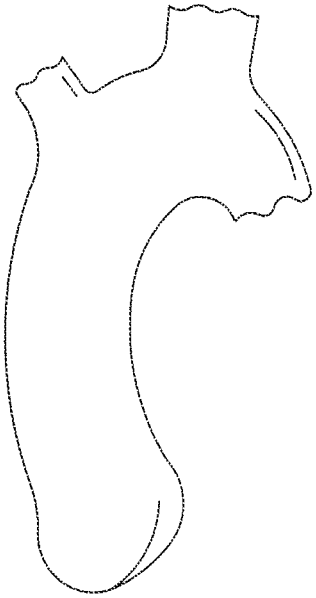


Fig. 1

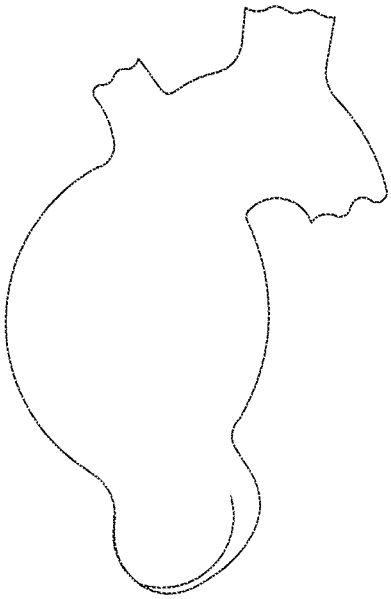


Fig. 1B

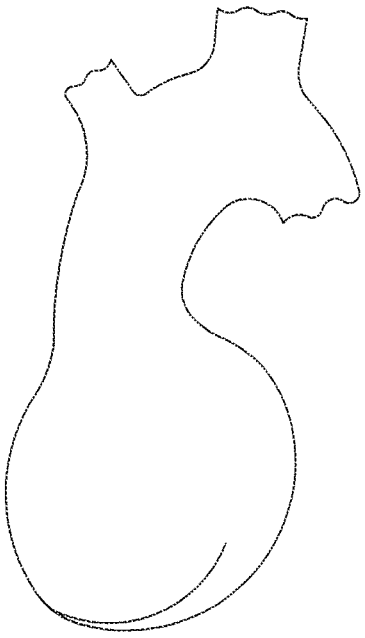


Fig. 1A

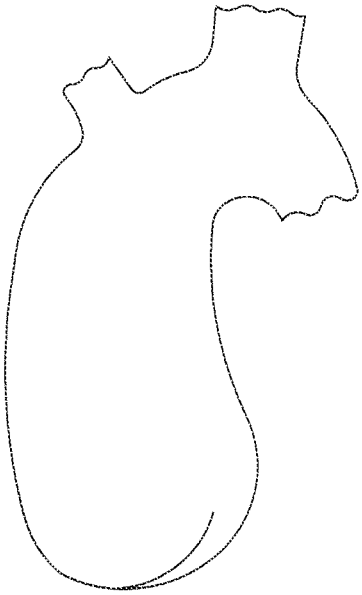


Fig. 1C

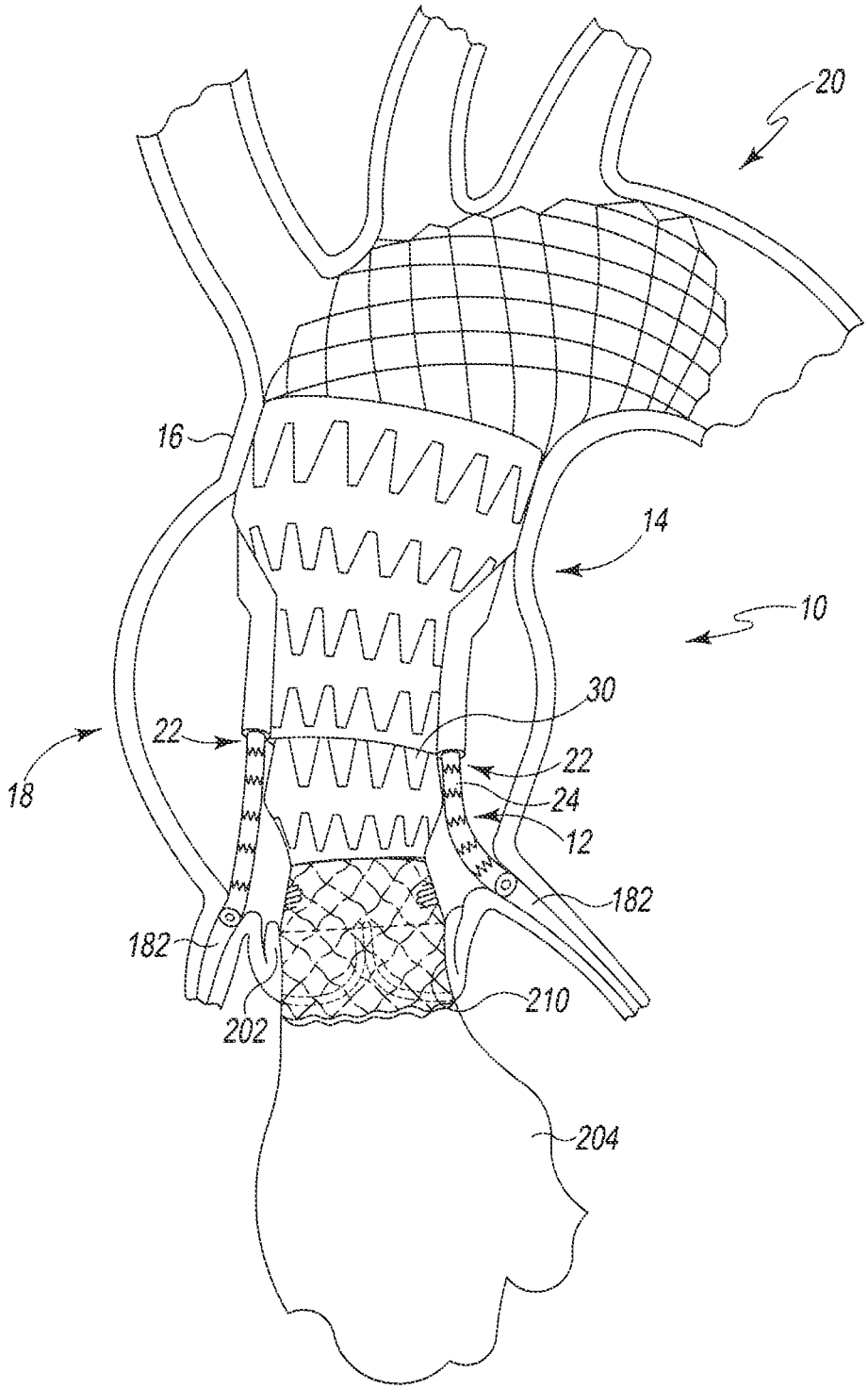


Fig. 2

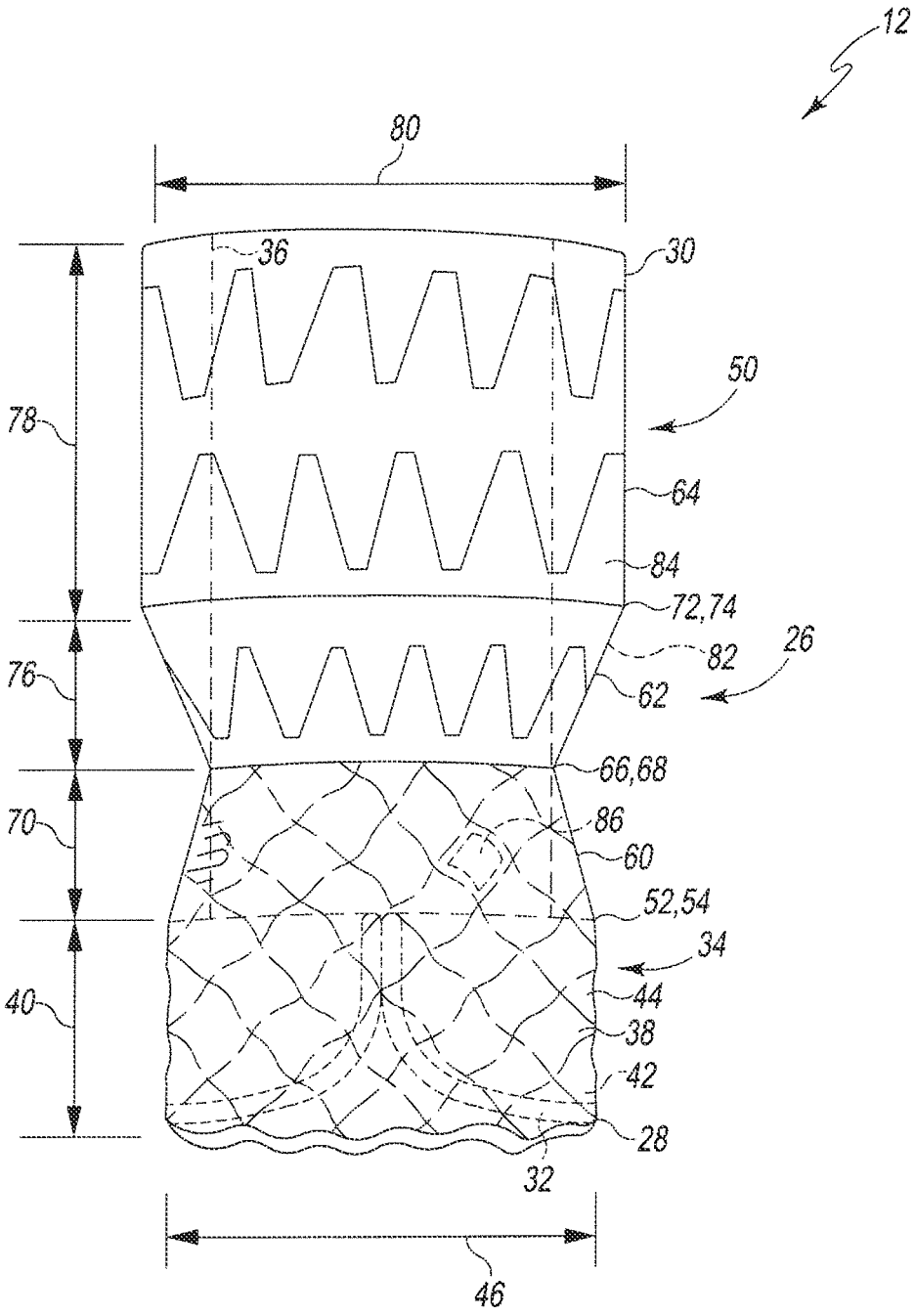

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Fig. 3

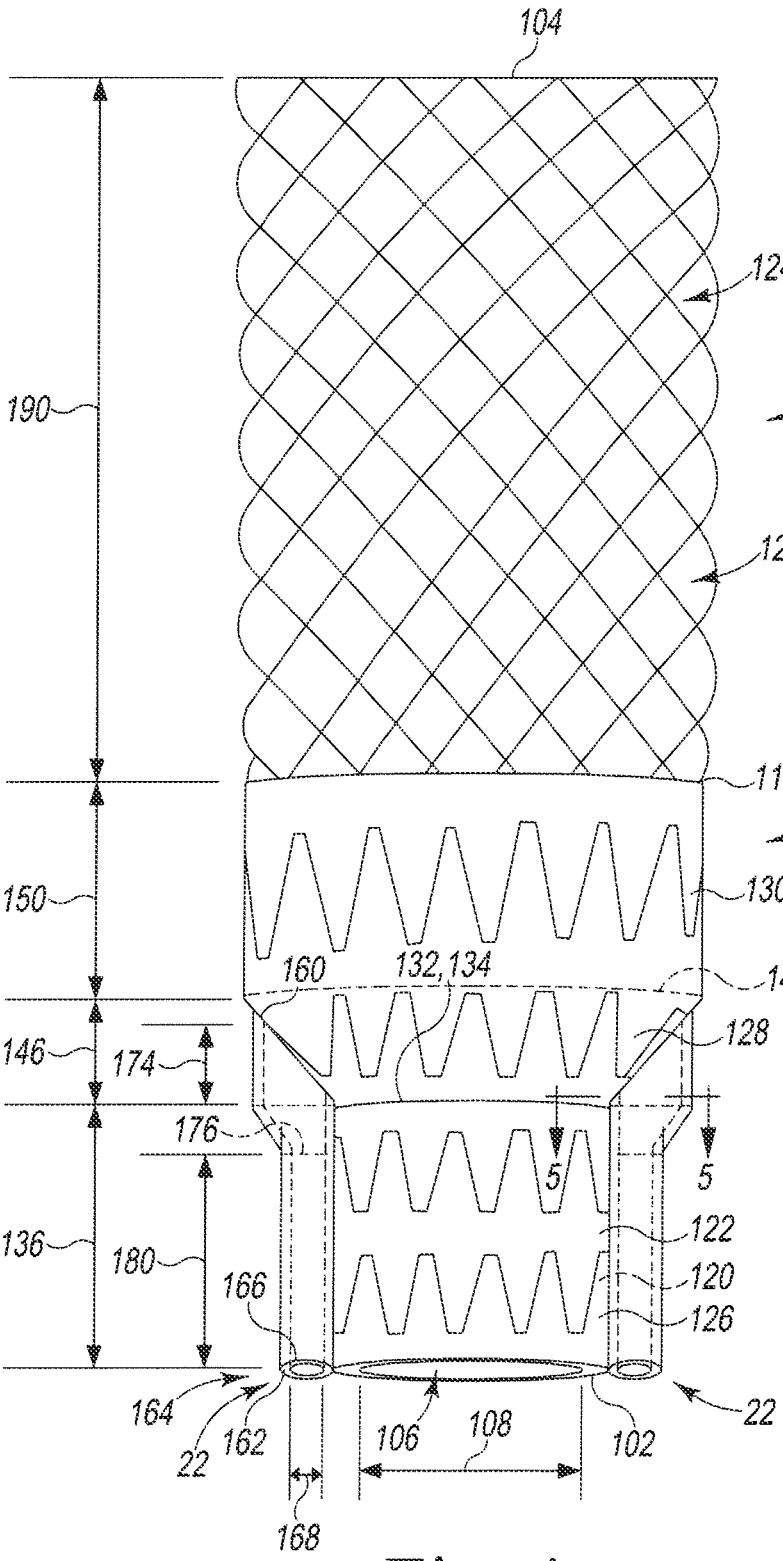

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Fig. 4

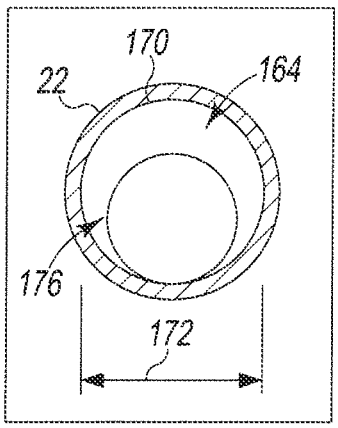

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Fig. 5

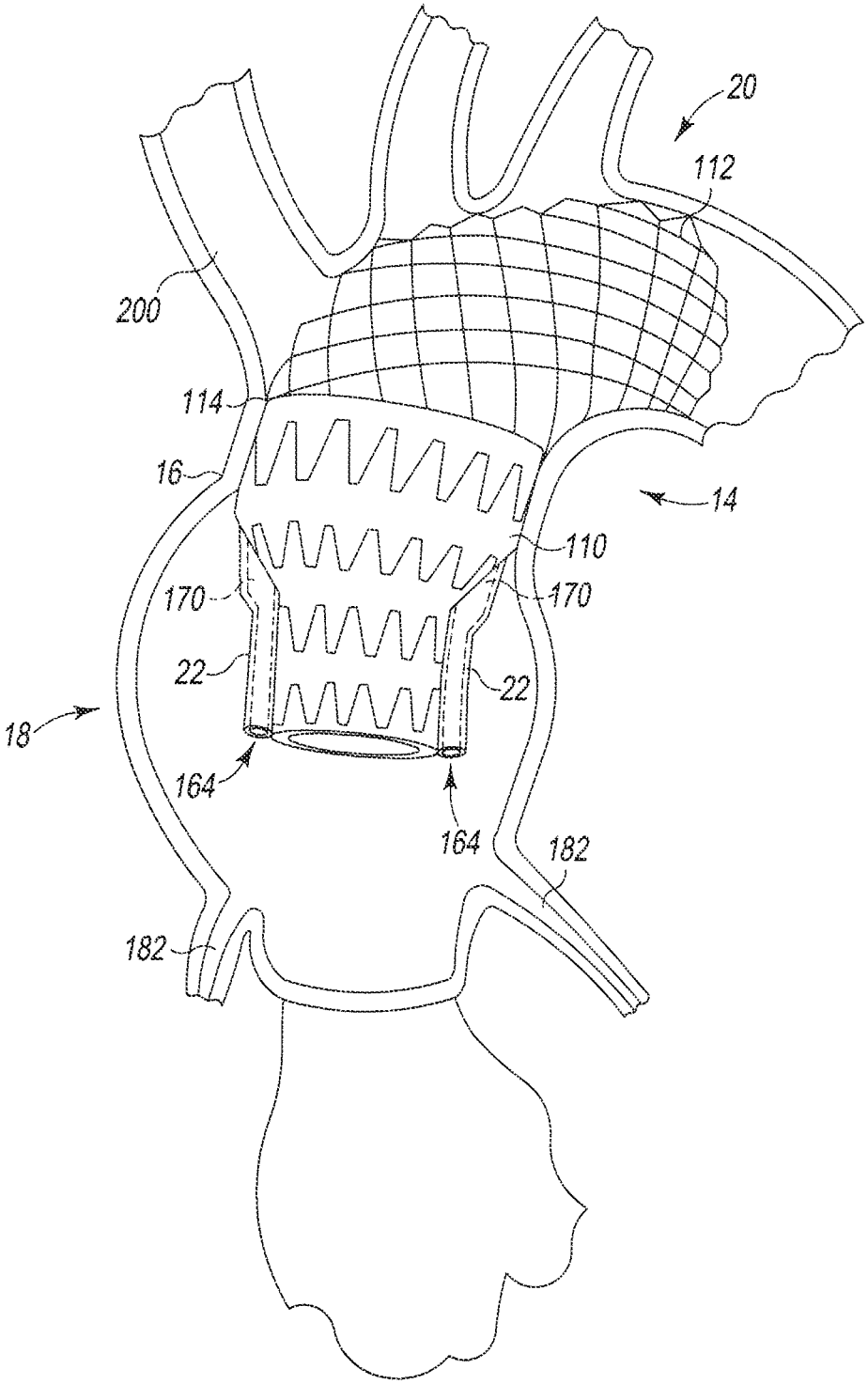


Fig. 6

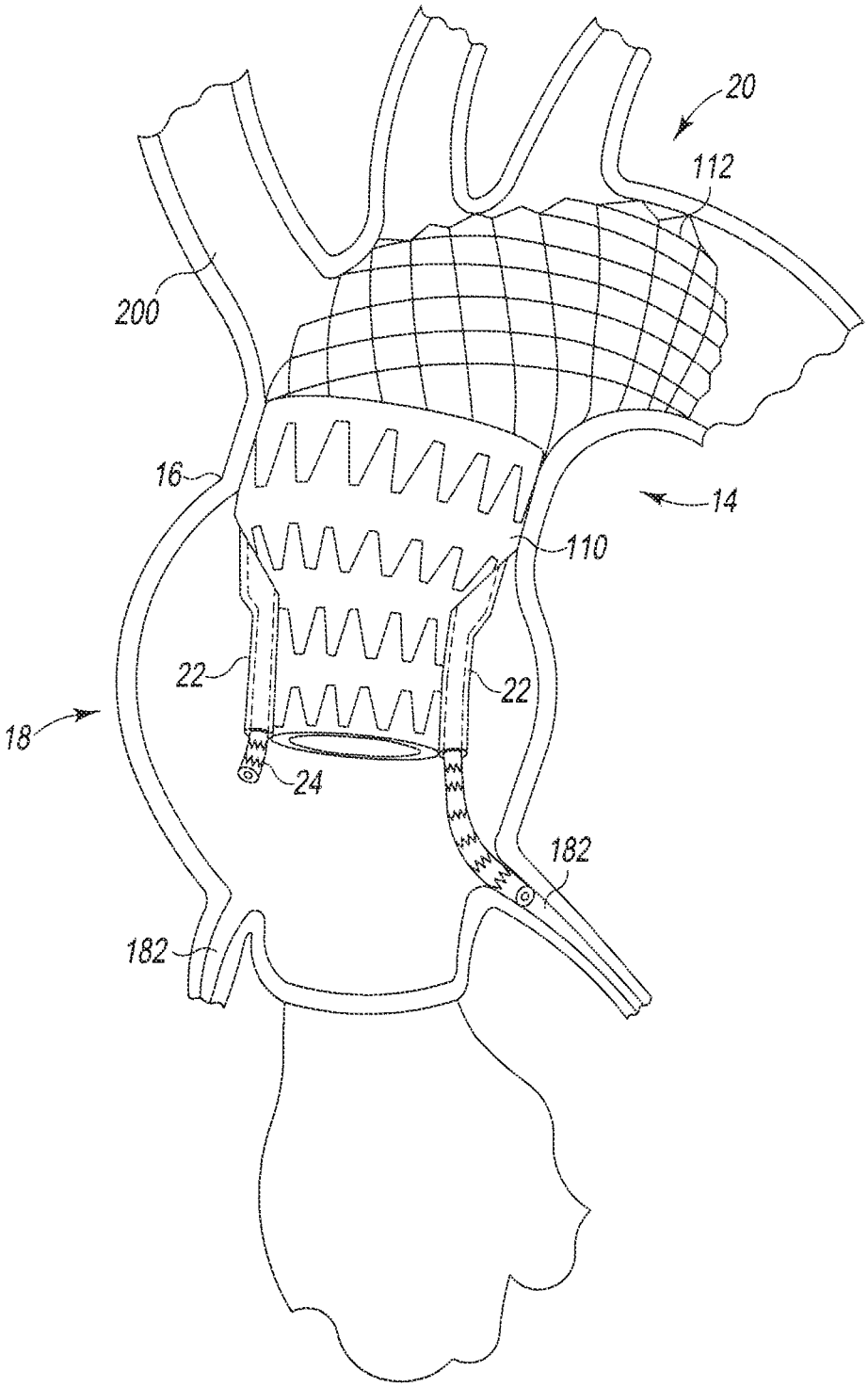


Fig. 7

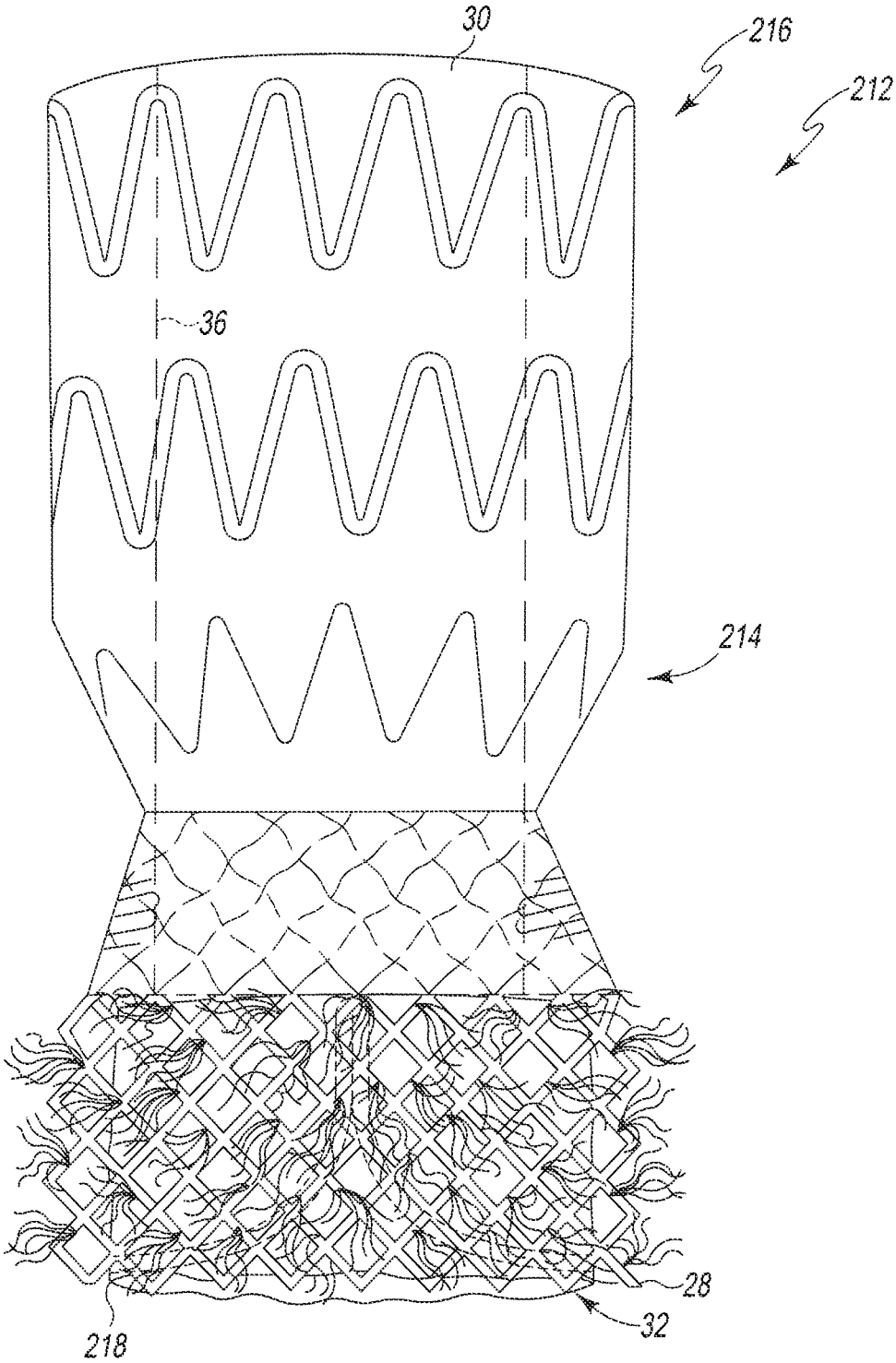


Fig. 8

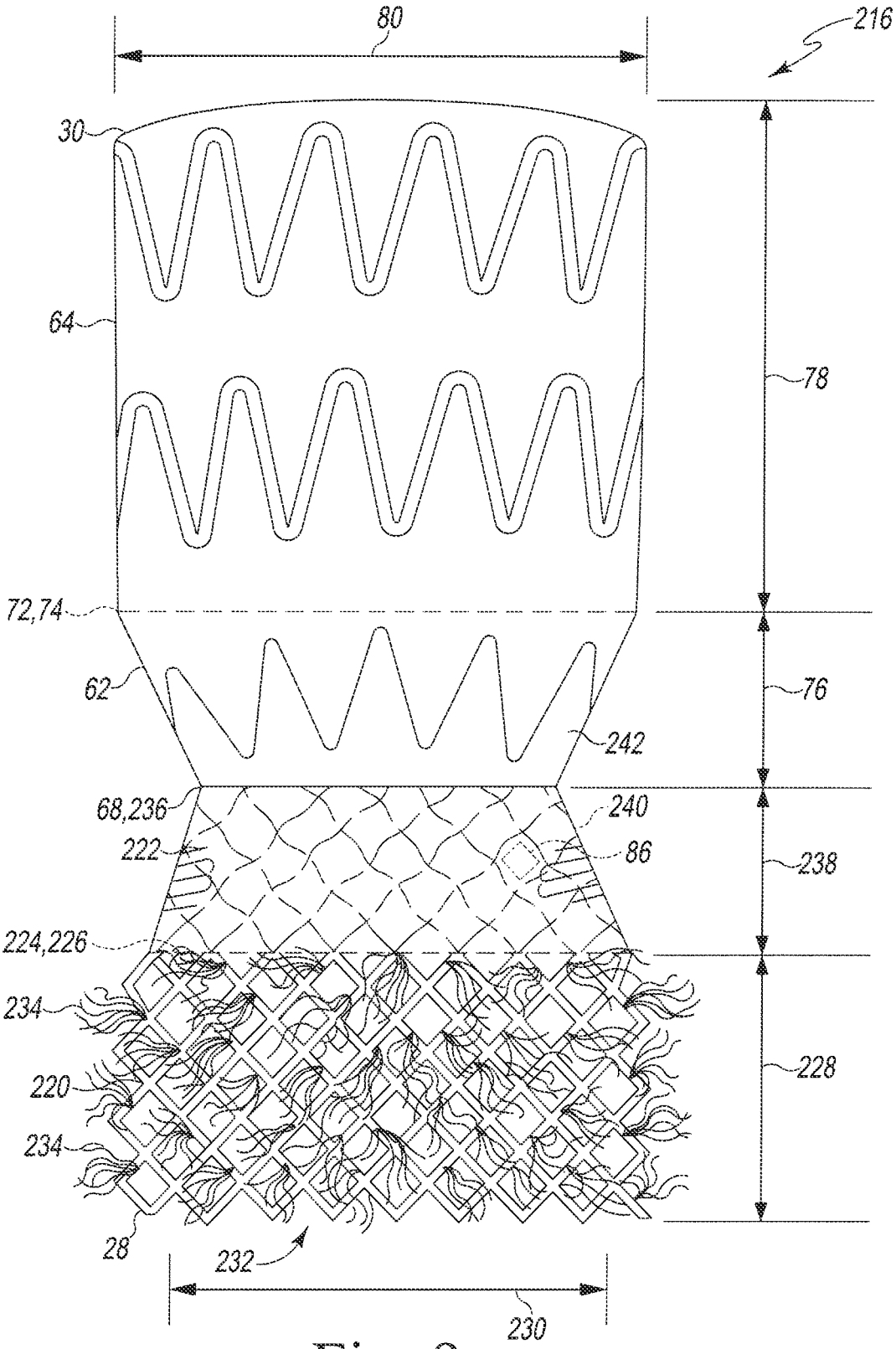

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Fig. 9

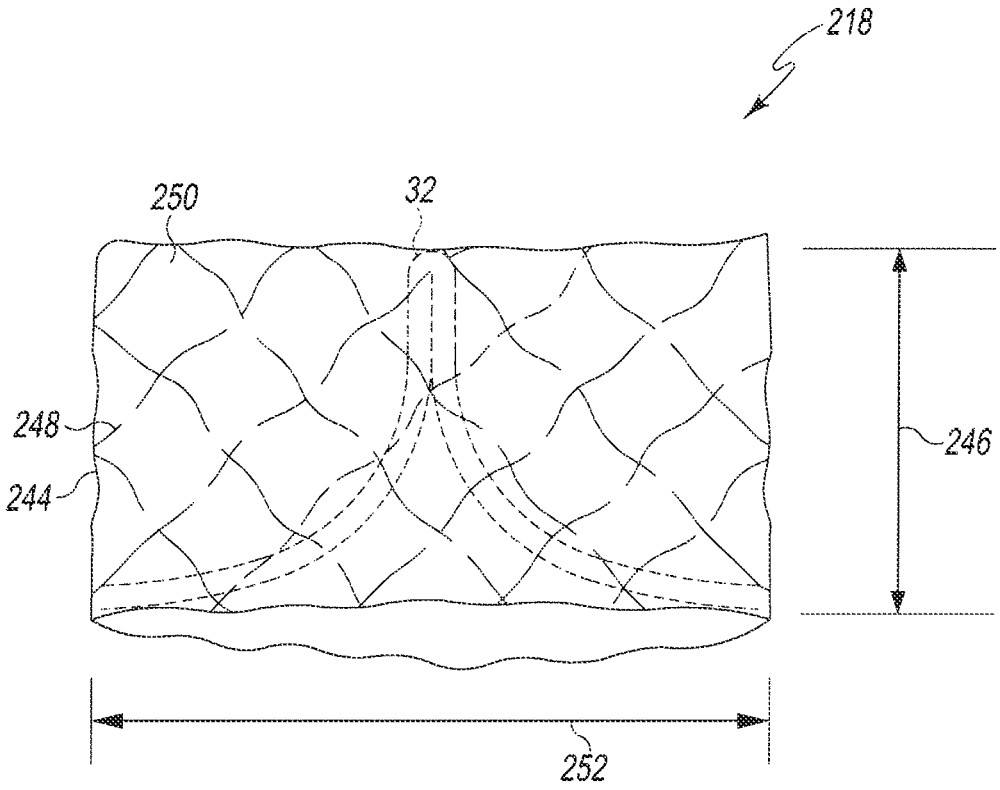


Fig. 10

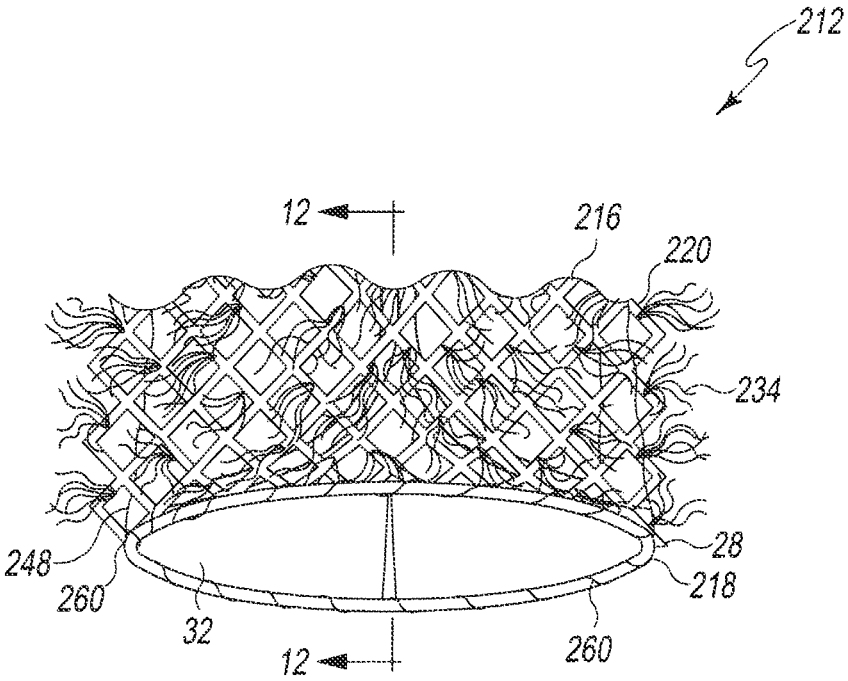


Fig. 11

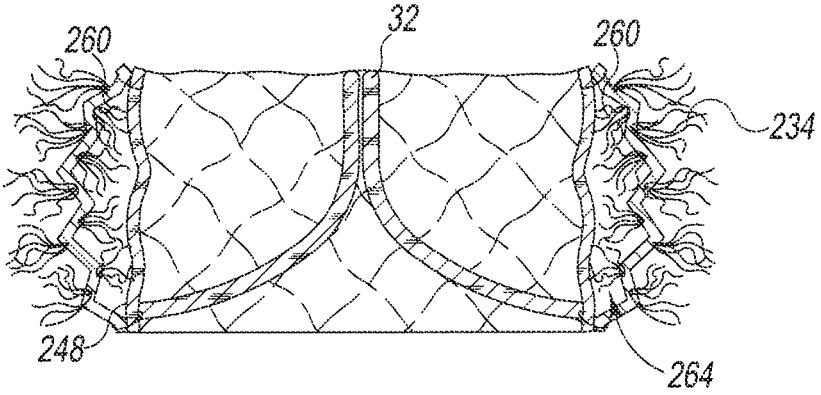


Fig. 12

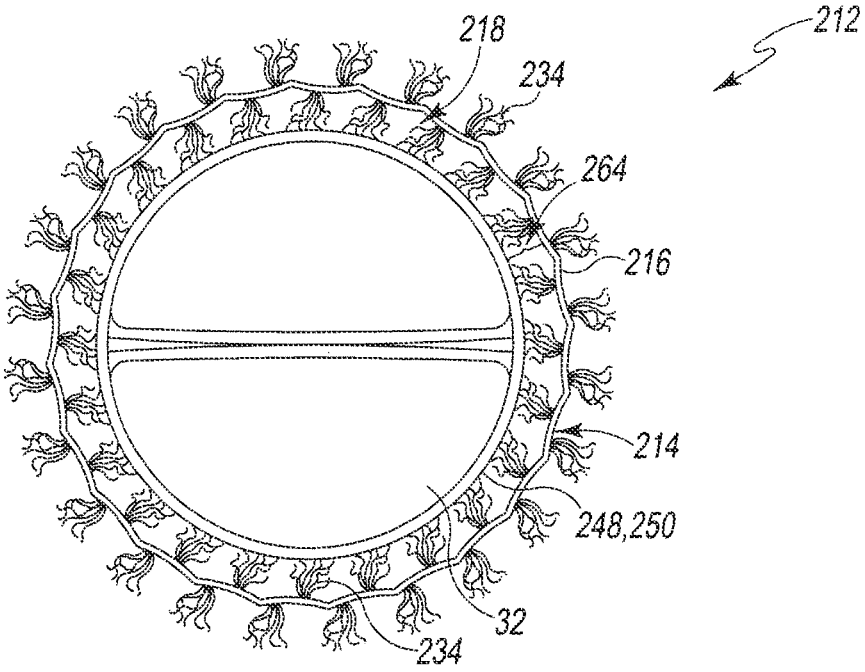

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Fig. 13

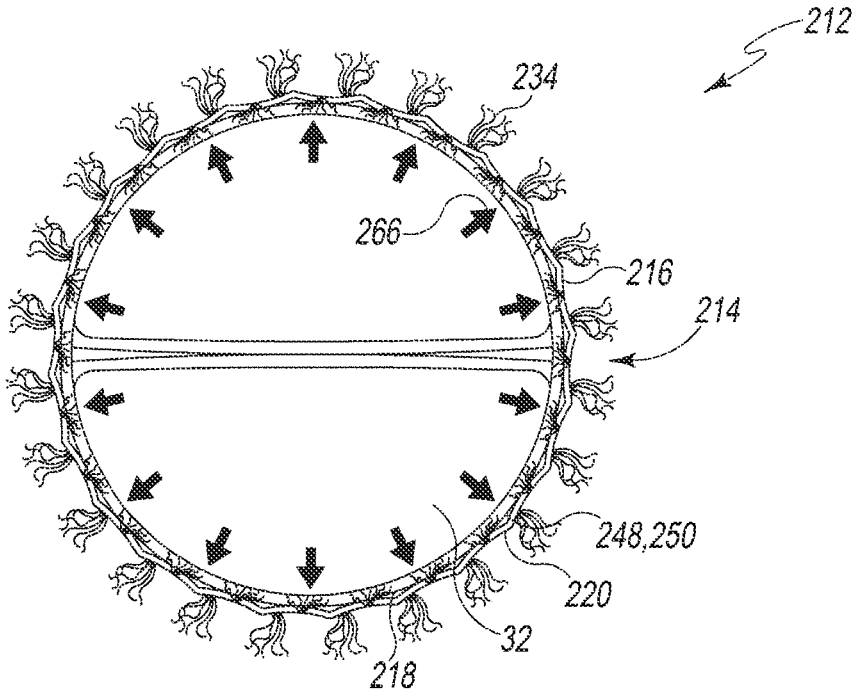

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Fig. 14

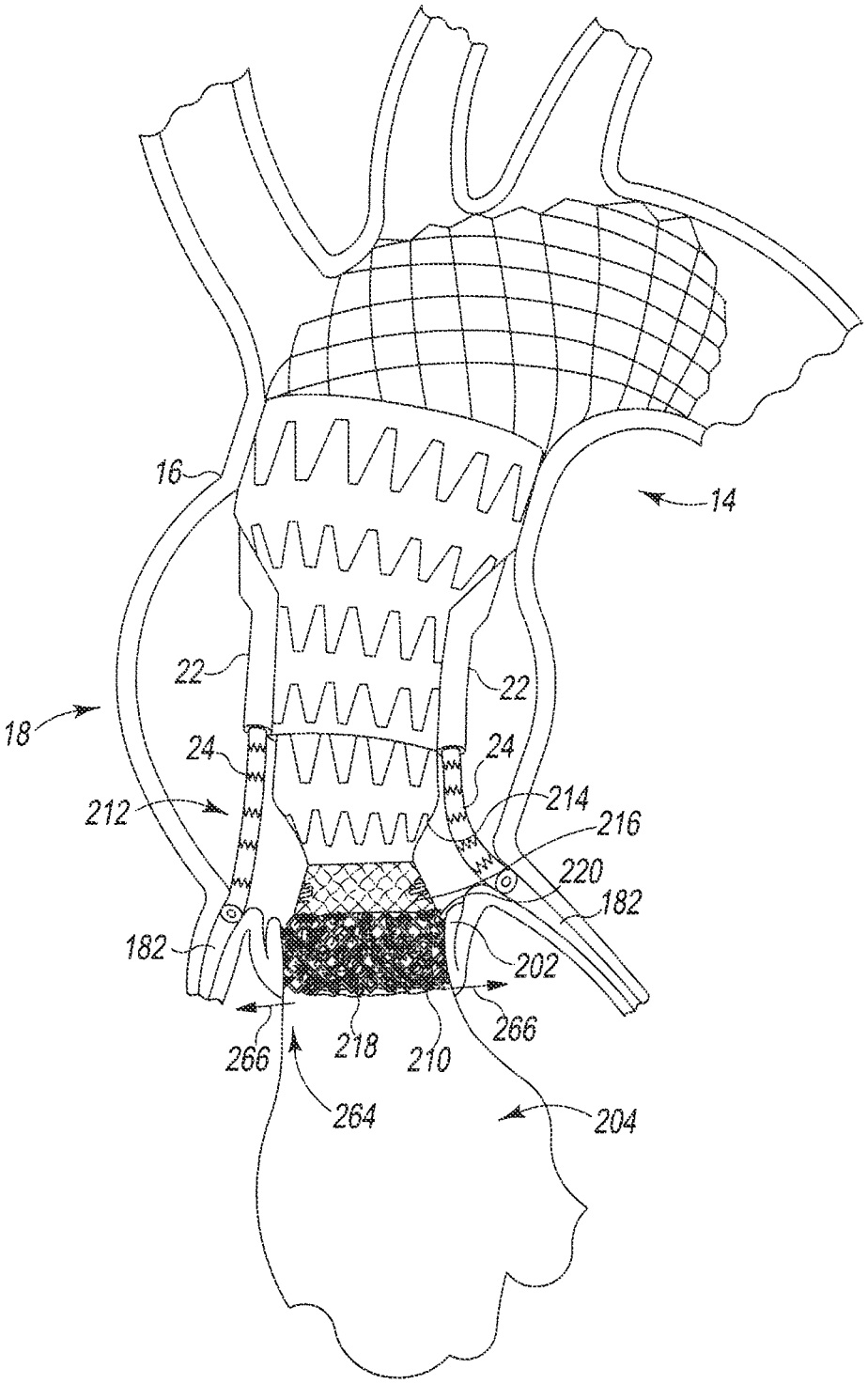

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Fig. 15

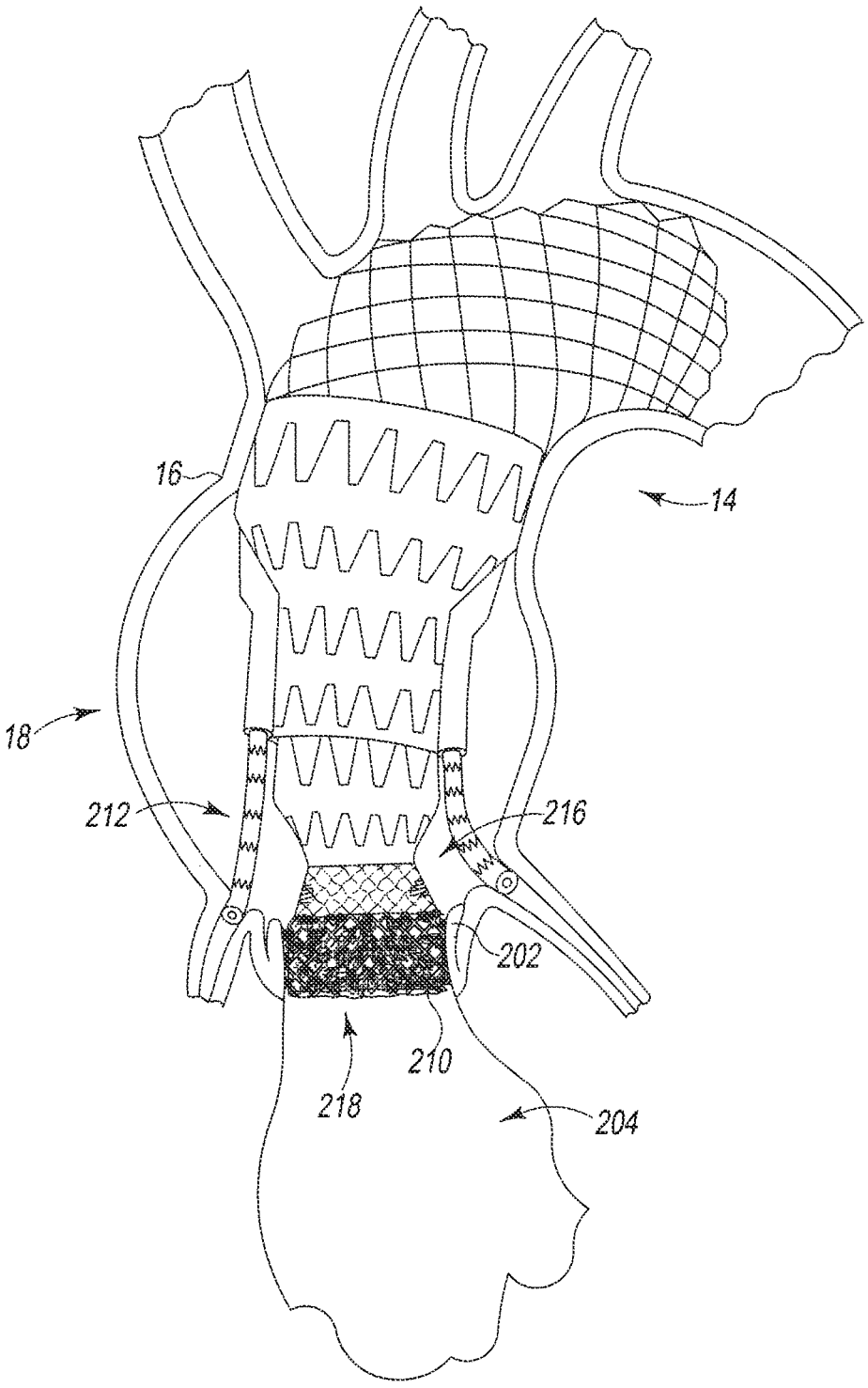


Fig. 16

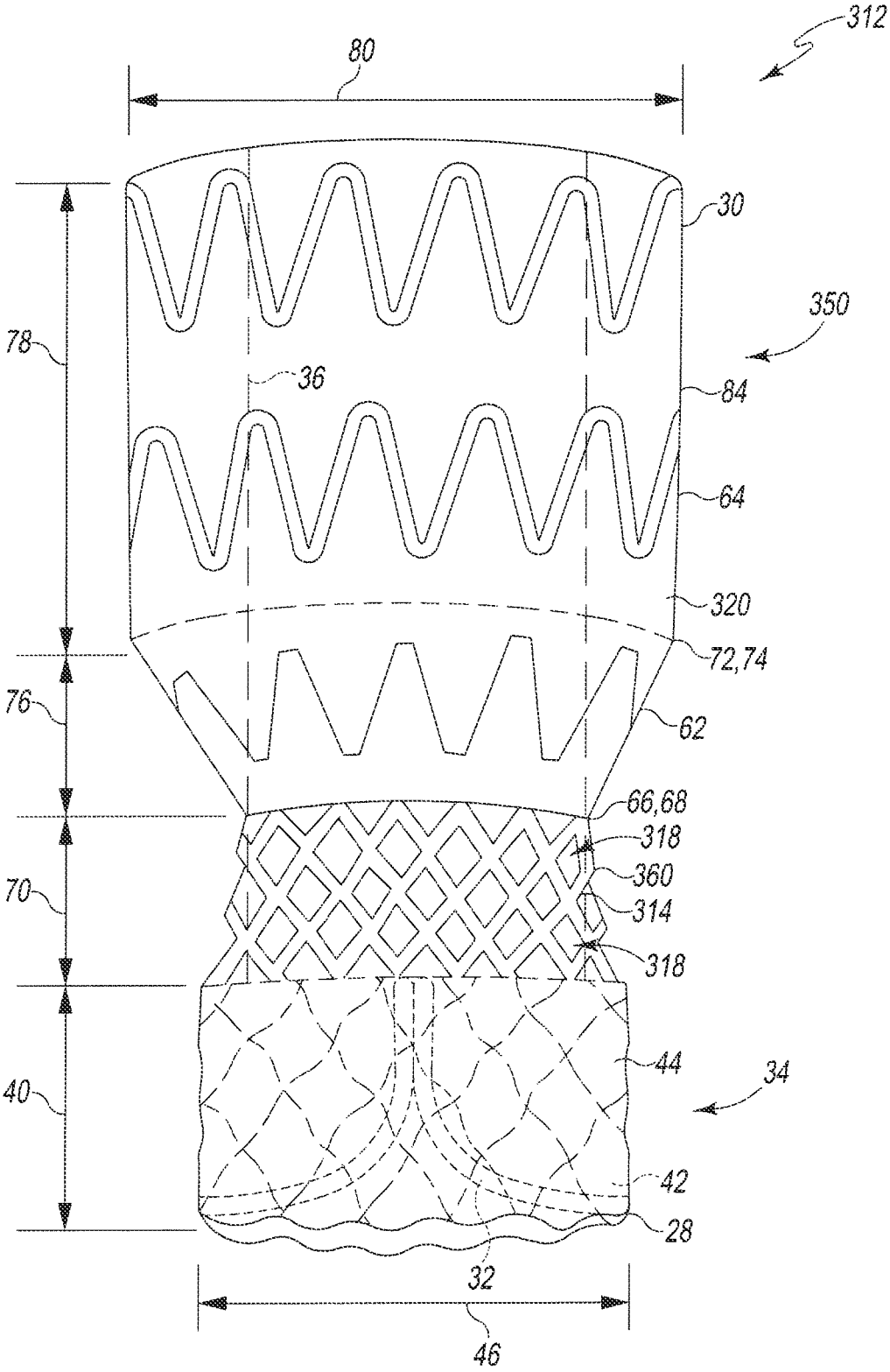

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Fig. 17

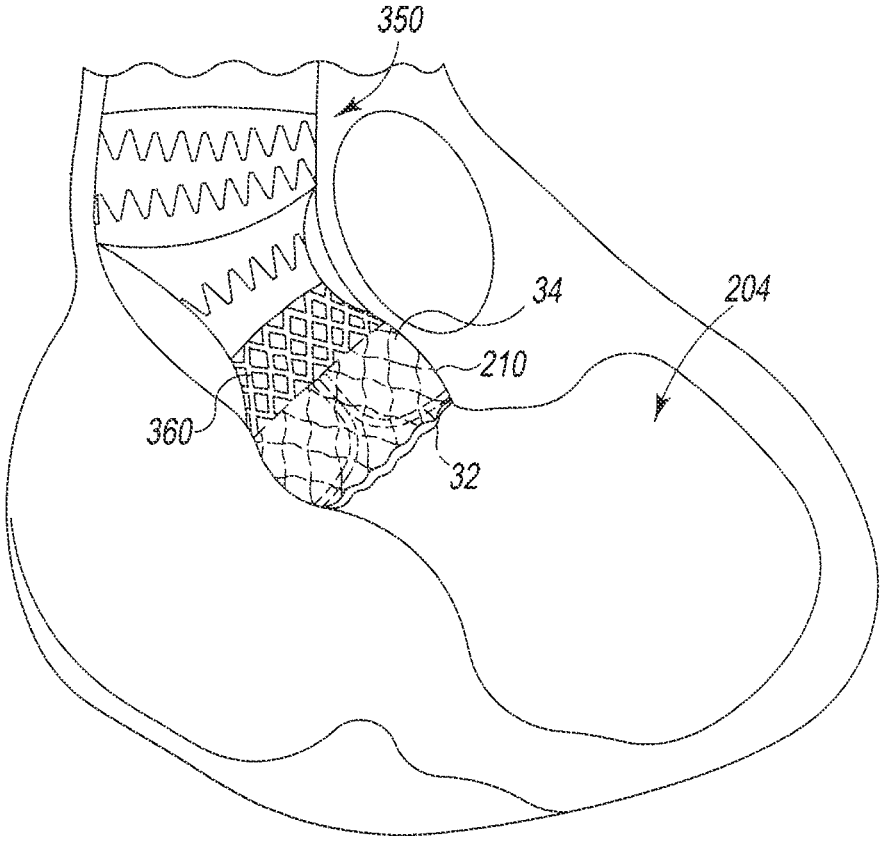


Fig. 18

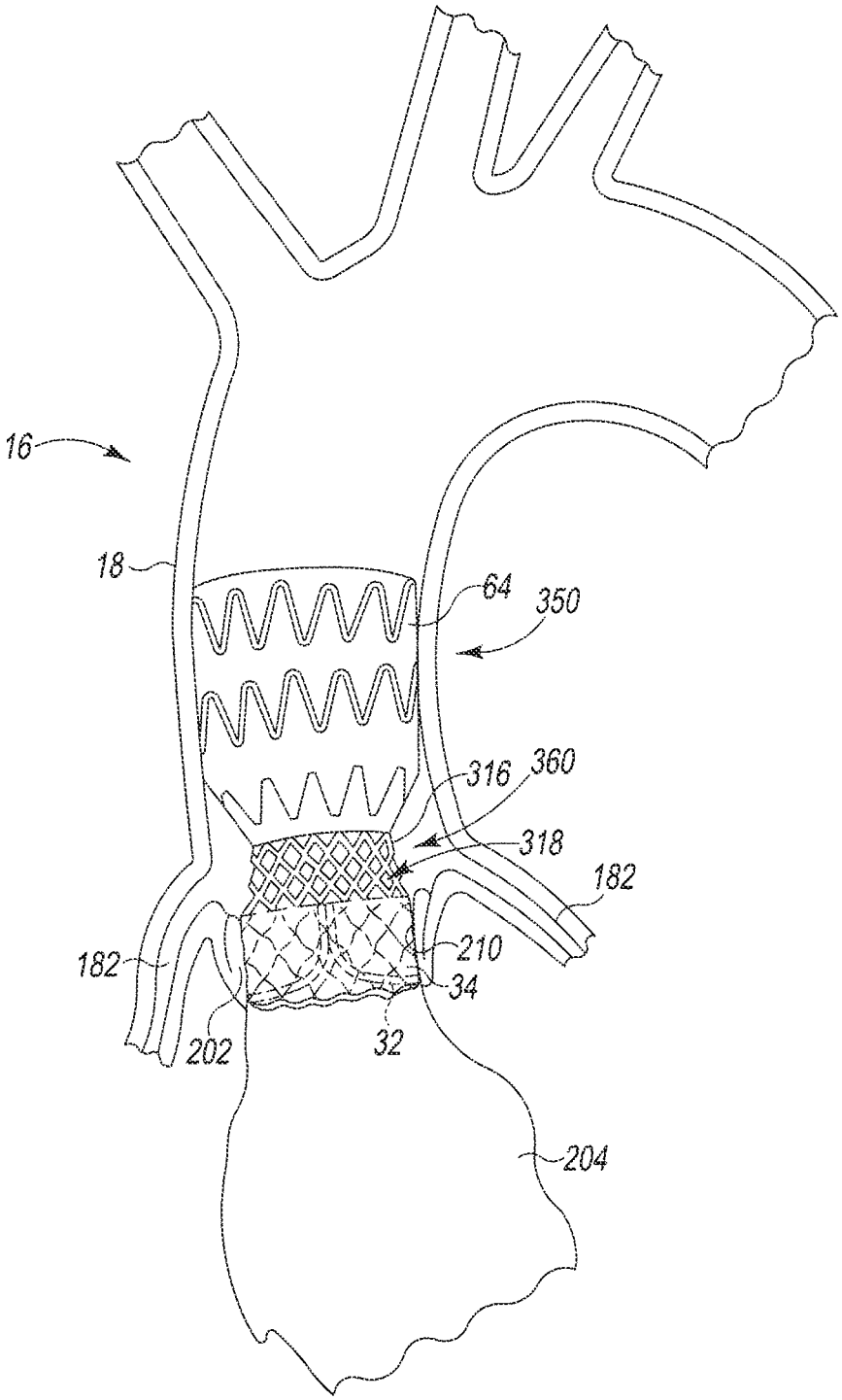


Fig. 19

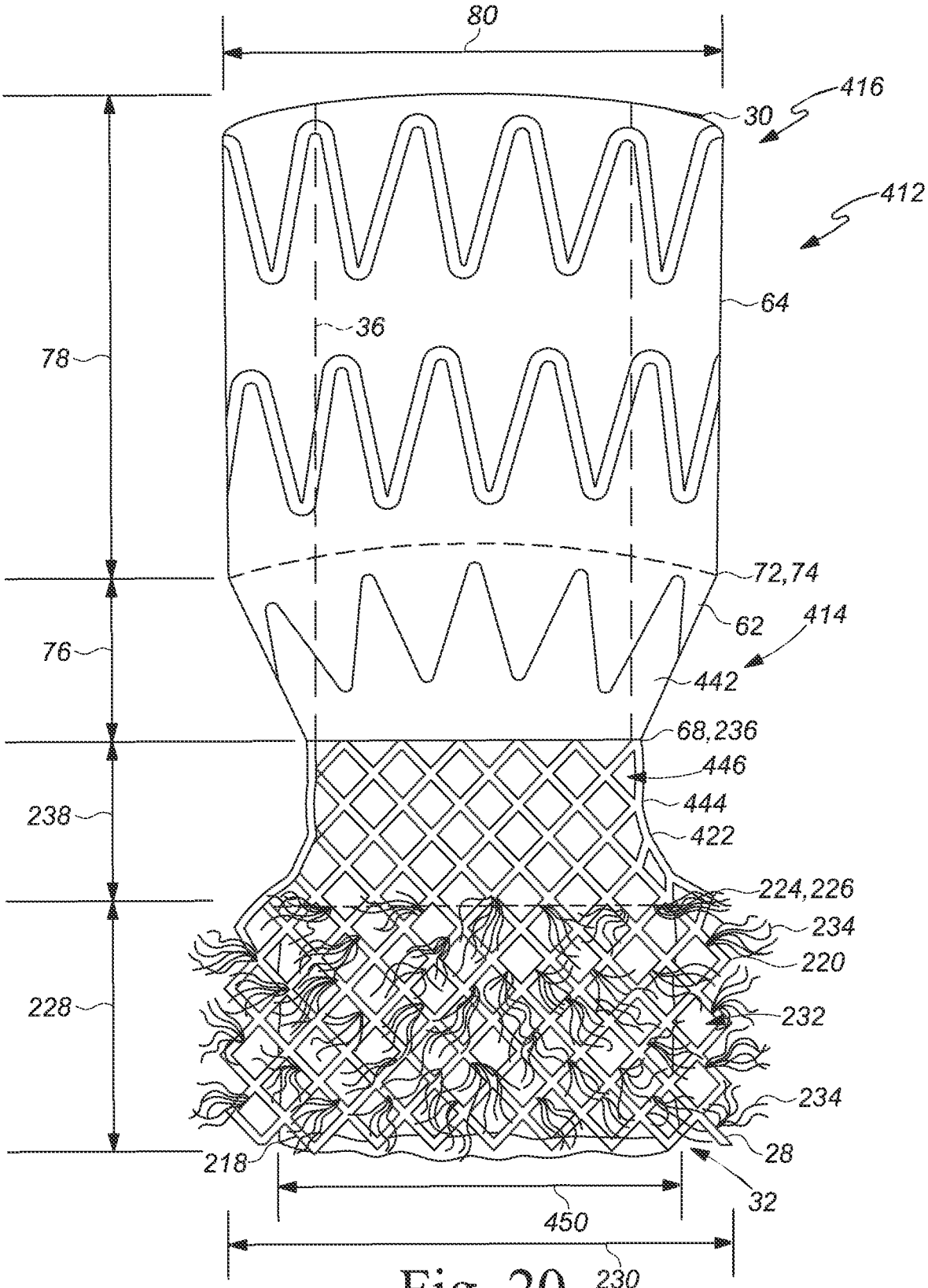

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Fig. 20

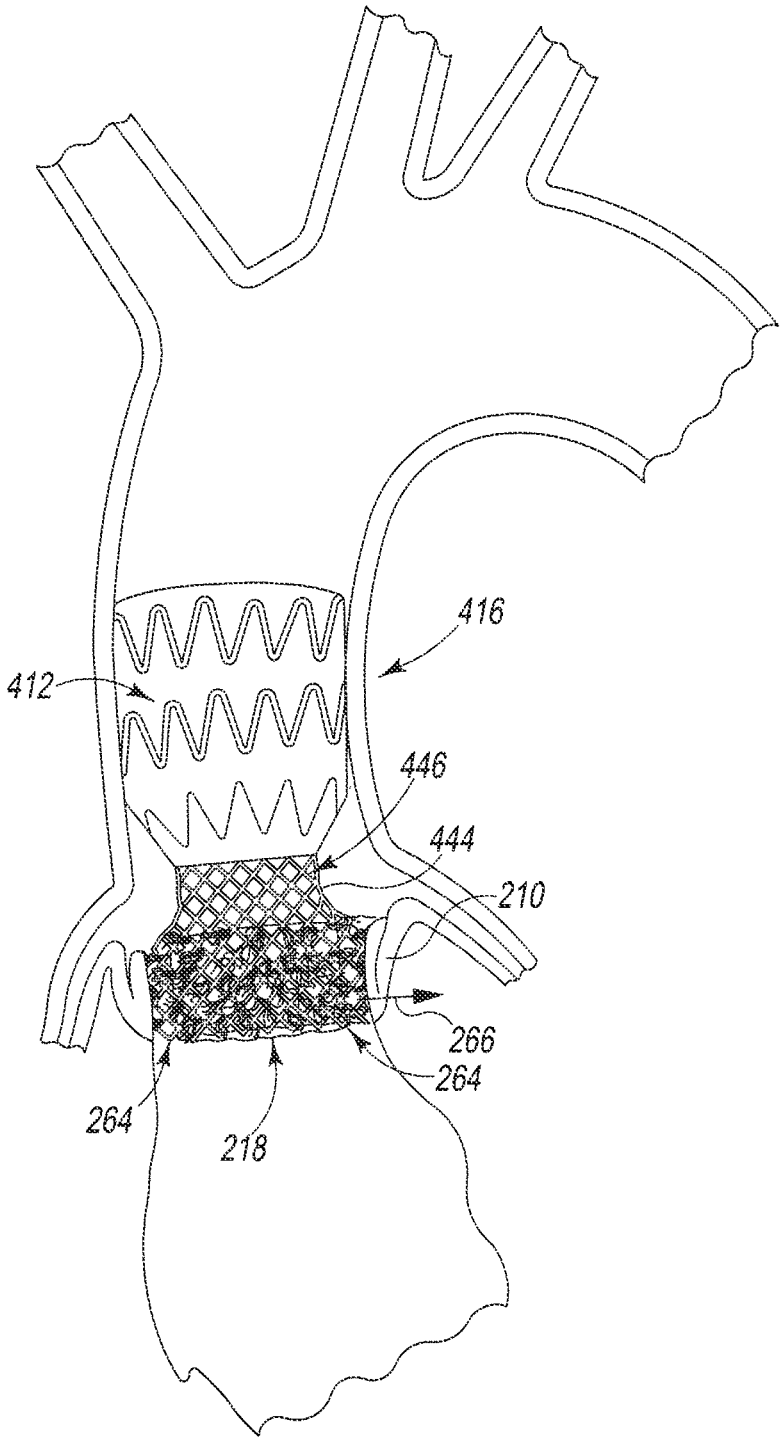


Fig. 21

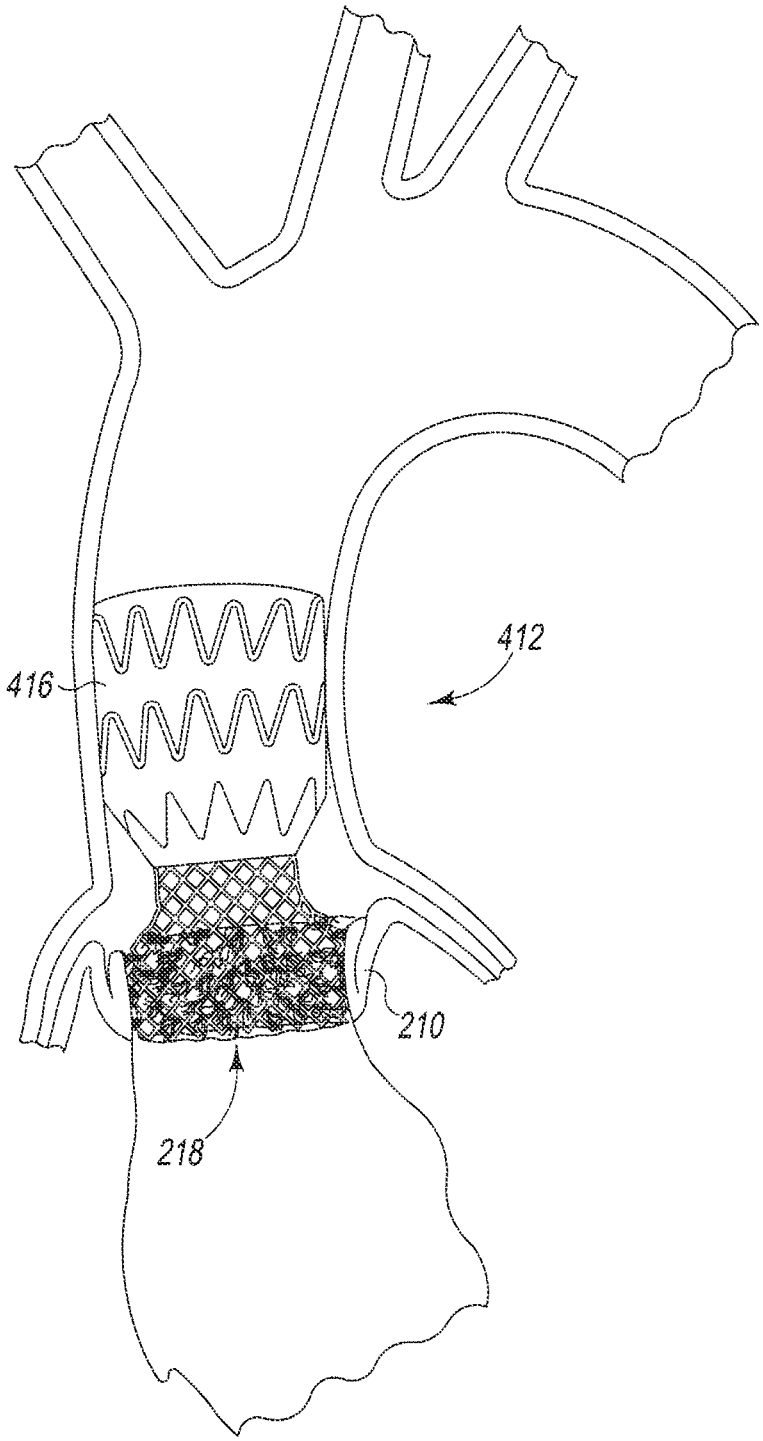


Fig. 22

TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

This application is a continuation of U.S. patent application Ser. No. 17/213,251 entitled TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL, which was filed on Mar. 26, 2021, which is a continuation of U.S. patent application Ser. No. 17/096,253 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on Nov. 12, 2020, and issued as U.S. Pat. No. 10,966,846 on Apr. 6, 2021, which is a continuation of U.S. patent application Ser. No. 17/060,557 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on Oct. 1, 2020 and issued as U.S. Pat. No. 10,888,441 on Jan. 12, 2021, which is a continuation of U.S. patent application Ser. No. 16/910,189 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jun. 24, 2020 and issued as U.S. Pat. No. 10,857,011 on Dec. 8, 2020, which is a continuation of U.S. patent application Ser. No. 16/808,137 entitled "HEART VALVE REPLACEMENT DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Mar. 3, 2020 and issued as U.S. Pat. No. 10,792,172 on Oct. 6, 2020, which is a continuation of U.S. patent application Ser. No. 16/736,879 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jan. 8, 2020 and issued as U.S. Pat. No. 10,842,655 on Nov. 24, 2020, which is a continuation of U.S. patent application Ser. No. 16/042,286 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jul. 23, 2018 and issued as U.S. Pat. No. 10,555,823 on Feb. 11, 2020, which is a continuation of U.S. patent application Ser. No. 14/614,628 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Feb. 5, 2015 and issued as U.S. Pat. No. 10,028,848 on Jul. 24, 2018, which is a continuation of U.S. patent application Ser. No. 14/569,306 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Dec. 12, 2014 and issued as U.S. Pat. No. 9,339,399 on May 17, 2016, which is a divisional of U.S. patent application Ser. No. 13/706,896 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Dec. 6, 2012 and issued as U.S. Pat. No. 8,940,040 on Jan. 27, 2015, which claims the benefit under 35 U.S.C. § 119 to U.S. Provisional Application Ser. No. 61/567,458 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on Dec. 6, 2011. Application Ser. No. 13/706,896 also claims priority under § 119 to U.S. Provisional Application Ser. No. 61/723,446 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on Nov. 7, 2012. Each of the applications referenced herein are incorporated by reference in their entirety.

TECHNICAL FIELD

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

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, B, or C. These will be discussed in further detail below and are shown in FIGS. **1**A-**1**C, which have been reproduced from the referenced article.

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. **1**A.

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. **1**B.

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. **1**C.

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 population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

SUMMARY

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.

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.

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 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

In some embodiments, the method may also include introducing the second prosthetic component into the ascending aorta prior to introducing the first prosthetic component.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

FIG. **1** is an illustrative aorta;

FIG. **1**A is an example of a Type A aneurysm;

FIG. **1**B is an example of a Type B aneurysm;

FIG. **1**C is an example of a Type C aneurysm;

FIG. **2** is partial cutaway view of an aorta with an embodiment of an endovascular prosthetic device implanted therein;

FIG. **3** is an elevation view of a proximal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **4** is an elevation view of a distal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **5** is a cross sectional view of the distal prosthetic component of FIG. **4** taken along the line **5-5** in FIG. **4**;

FIG. **6** is a partial cutaway view of the aorta with the distal prosthetic component of FIG. **3** implanted therein;

FIG. **7** is a view similar to FIG. **6** showing stents extending from the distal prosthetic component;

FIG. **8** is an elevation view of another embodiment of a proximal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **9** is an elevation view of a self-expanding outer frame of the proximal prosthetic component of FIG. **8**;

FIG. **10** is an elevation view of a balloon-expandable inner frame of the proximal prosthetic component of FIG. **8**;

FIG. **11** is a perspective view a proximal end of the proximal prosthetic component of FIG. **8**;

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**;

FIG. **13** is a plan view of the proximal prosthetic component of FIG. **8** showing the inner frame in an unexpanded position;

FIG. **14** is a plan view similar to FIG. **13** showing the inner frame in an expanded position;

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**;

FIG. **16** is a view similar to FIG. **15** showing the inner frame in an expanded position;

FIG. **17** is an embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. **3**;

FIGS. **18-19** are partial cutaway views of the aorta with the transcatheter valve of FIG. **17** implanted therein;

FIG. **20** is another embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. **8**; and

FIGS. **21-22** are partial cutaway views of the aorta with the transcatheter valve of FIG. **20** implanted therein.

DETAILED DESCRIPTION OF THE DRAWINGS

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.

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.

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. **17-22**. Such a valve may be introduced transfemorally or through the subclavian artery or the apex of the heart.

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.

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**.

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 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.

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. Pat. 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. Pat. 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.

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.

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.

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 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.

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**.

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 should also be appreciated that all or part of the component **12** may be covered with hydrogel or other sealing material.

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.

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.

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 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.

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.

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.

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.

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 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.

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**.

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**.

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 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.

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.

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**.

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**. 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**.

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**.

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. Pat. 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 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**.

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**.

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**.

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 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**.

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**.

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.

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 described in greater detail below. As shown in FIG. **9**, the proximal section **220** defines a passageway **232** in the outer frame **216**.

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**.

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.

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.

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, 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**.

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.

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 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.

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.

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.

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**.

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**.

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 components **212**, **14** together and seal the distal end **30** of the component **212** within the distal component **14**.

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**.

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.

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.

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**.

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 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.

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.

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.

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 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.

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.

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**.

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 configu-

ration, mesh-like stent configuration, or Z-stent configuration. The sections **60**, **62**, **64** may also be formed as a single monolithic component.

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.

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**.

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** 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).

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**.

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**.

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.

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**.

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**.

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.

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.

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**.

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 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.

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).

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 the outer frame **416** and compresses the collagen fiber/hydrogel coated proximal section **220** of the outer frame **416** against the aortic annulus **210**.

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.

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 1a 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.

Aortic insufficiency (AI) after implantation may also be corrected. Significant AI 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 AI. The bicuspid valve nature of the designs discussed herein potentially eliminates the problem with malcoaptation and AI secondary to that.

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.

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.

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.

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.

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 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.

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.

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 under-

stood 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.

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 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.

The invention claimed is:

1. A transcatheter aortic heart valve assembly comprising:

a graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto;

a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through a circumference of the frame, the struts adjoining each other at an inflow end of the frame to form apices, and the struts cooperatively forming an open cell configuration,

wherein the frame is secured to the graft covering,

wherein the graft covering is made of a polymer; and

a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame,

wherein the fibers are arcuate, spaced-apart, and outwardly extending,

wherein the fibers are spaced-apart to define spacings in a radially extending direction from the outermost aspect of the fibers to the outer surface of the frame such that fluid is permitted to pass therethrough when the valve assembly is in an uncompressed state,

wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an end of the most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers,

wherein the plurality of spaced-apart fibers is compressed when the heart valve assembly is pressed against native valve leaflets of the aorta to form a seal against the native valve leaflets and the frame by compression of the fibers into the radially extending spacings,

wherein the graft covering is engaged with fibers of the plurality of fibers,

wherein, in operation the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery.

2. The valve assembly of claim **1**, wherein the frame extends distally further than the prosthetic heart valve leaflets.

3. The valve assembly of claim **1**, wherein the frame is a singular, integral component.

4. The valve assembly of claim **1**, wherein the frame and the graft covering are attached by stitching at a top and bottom portion of the graft covering.

5. The valve assembly of claim **1**, wherein the valve assembly is balloon expandable.

6. The valve assembly of claim **1**, wherein the graft covering forms an inner frame for housing the prosthetic heart valve leaflets.

7. The valve assembly of claim **1**, wherein the valve assembly is configured for being received within a catheter that is delivered through the femoral artery of the patient.

8. The valve assembly of claim **1**, wherein the fibers are collagen fibers.

9. The valve assembly of claim **1**, wherein a row of cells distal to the graft covering is uncovered by the graft covering and the fibers.

10. The valve assembly of claim **1**, further including a plurality of fibers that extend radially inwardly from the frame.

* * * * *

EXHIBIT 73

US011523918B2

(12) **United States Patent**
Shahriari

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(45) **Date of Patent: *Dec. 13, 2022**

(54) **TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL**

(71) Applicant: **Aortic Innovations, LLC**, Hillsboro Beach, FL (US)

(72) Inventor: **Ali Shahriari**, Hillsboro Beach, FL (US)

(73) Assignee: **Aortic Innovations, LLC**, Hillsboro Beach, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(58) **Field of Classification Search**
CPC A61F 2/856; A61F 2/07; A61F 2/2418; A61F 2/82; A61F 2/962; A61F 2/24;
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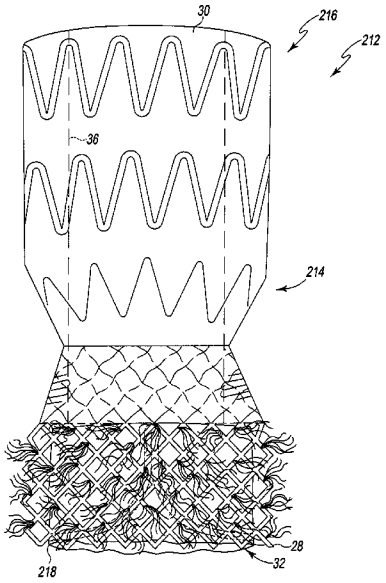
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Primary Examiner — Paul B Prebilic
(74) *Attorney, Agent, or Firm* — NK Patent Law

(57) **ABSTRACT**

A transcatheter valve assembly replacement device includes a paravalvular seal that includes outwardly extending fibers that create a seal with the annulus when the valve assembly is deployed. An inwardly extending seal is attached to an outer frame. The inwardly extending seal is engaged with prosthetic valve leaflets.

27 Claims, 19 Drawing Sheets



Related U.S. Application Data

continuation of application No. 17/060,557, filed on Oct. 1, 2020, now Pat. No. 10,888,441, which is a continuation of application No. 16/910,189, filed on Jun. 24, 2020, now Pat. No. 10,857,011, which is a continuation of application No. 16/808,137, filed on Mar. 3, 2020, now Pat. No. 10,792,172, which is a continuation of application No. 16/736,879, filed on Jan. 8, 2020, now Pat. No. 10,842,655, which is a continuation of application No. 16/042,286, filed on Jul. 23, 2018, now Pat. No. 10,555,823, which is a continuation of application No. 14/614,628, filed on Feb. 5, 2015, now Pat. No. 10,028,848, which is a continuation of application No. 14/569,306, filed on Dec. 12, 2014, now Pat. No. 9,339,399, which is a division of application No. 13/706,896, filed on Dec. 6, 2012, now Pat. No. 8,940,040.

(60) Provisional application No. 61/723,446, filed on Nov. 7, 2012, provisional application No. 61/567,458, filed on Dec. 6, 2011.

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A61F 2/24	(2006.01)
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A61F 2/86	(2013.01)
A61F 2/89	(2013.01)
A61F 2/90	(2013.01)
A61F 2/06	(2013.01)

(52) **U.S. Cl.**

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See application file for complete search history.

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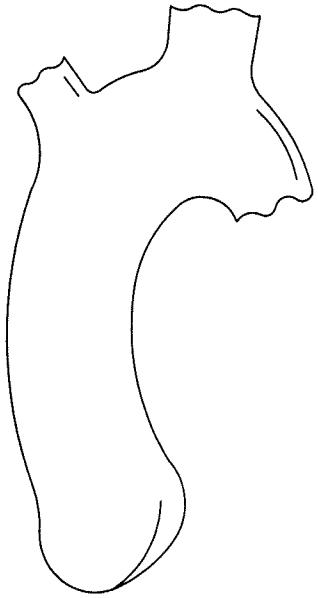


Fig. 1

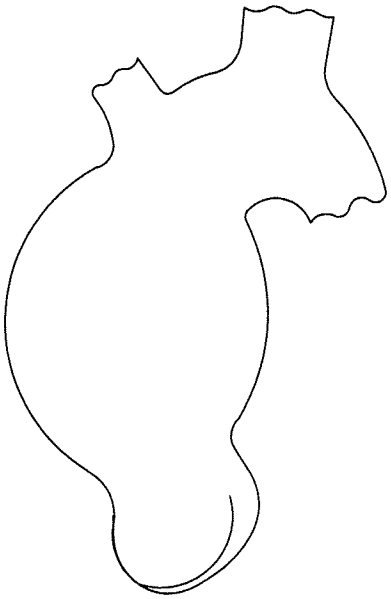


Fig. 1B

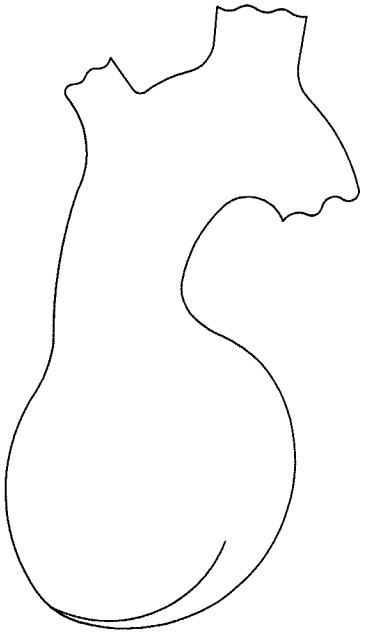


Fig. 1A

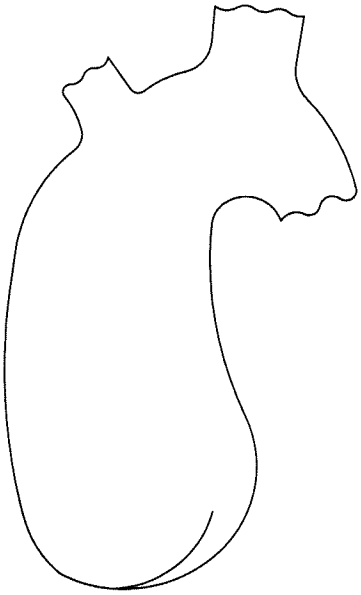


Fig. 1C

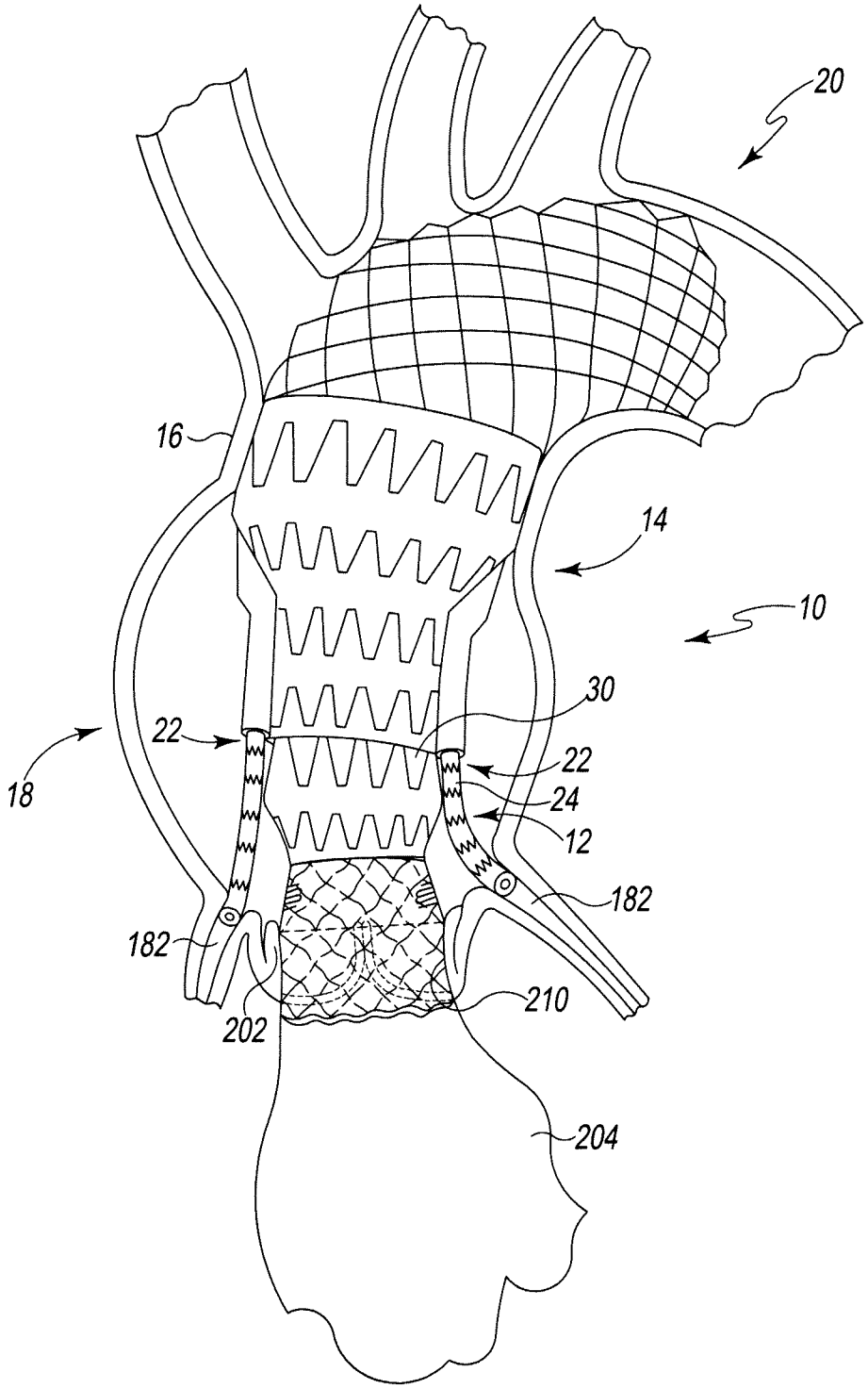


Fig. 2

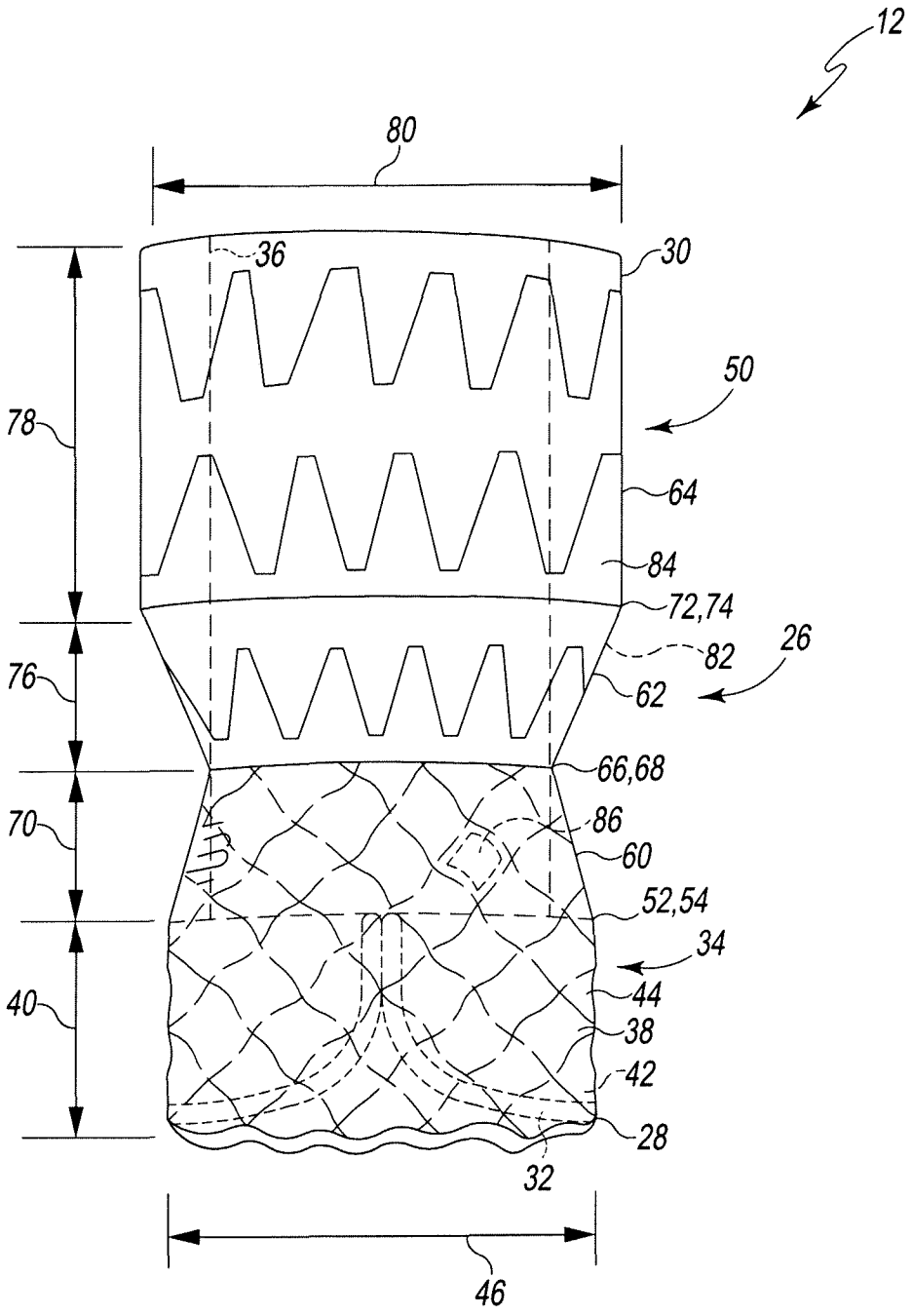

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Fig. 3

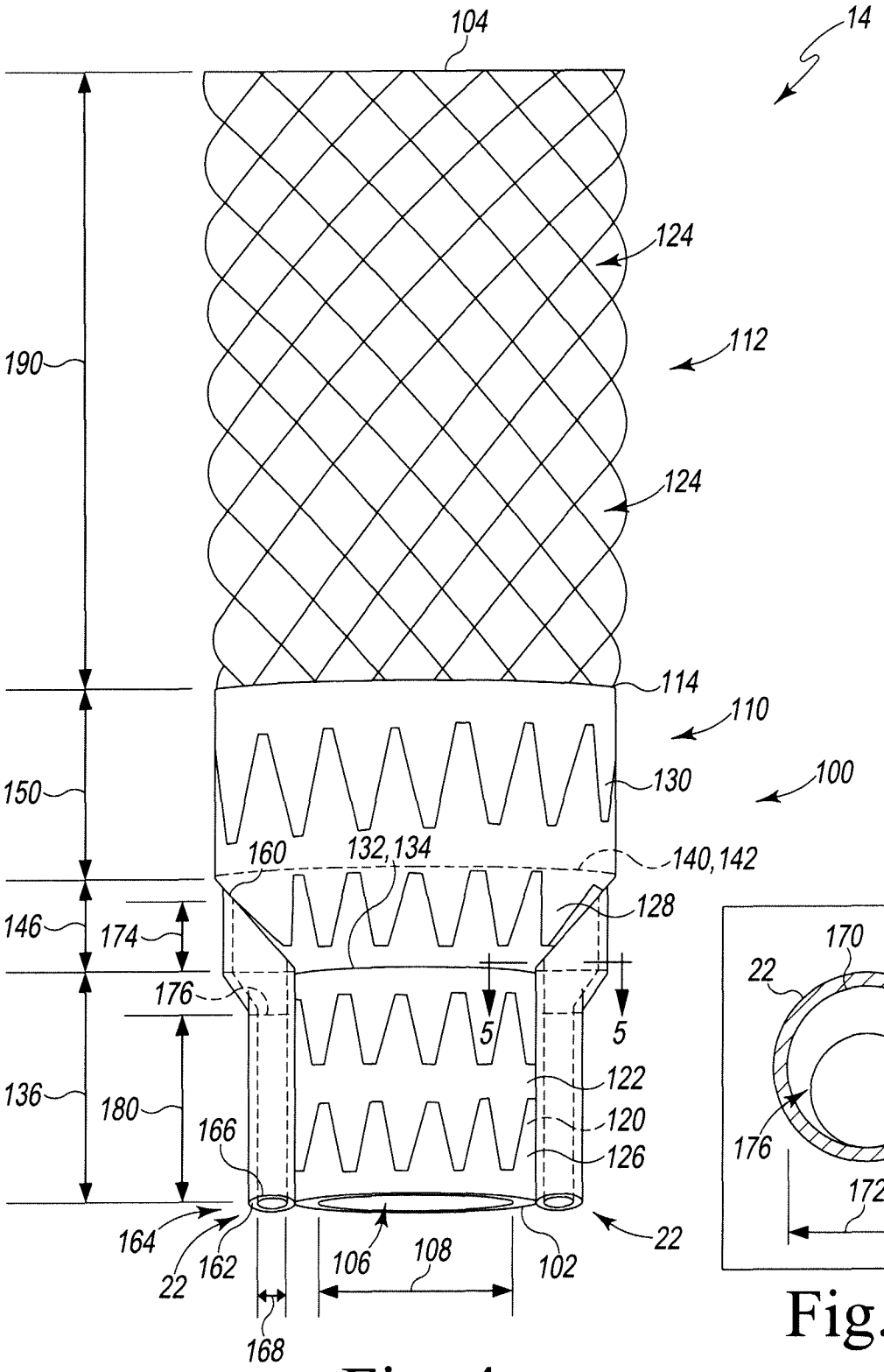

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Fig. 4

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Fig. 5

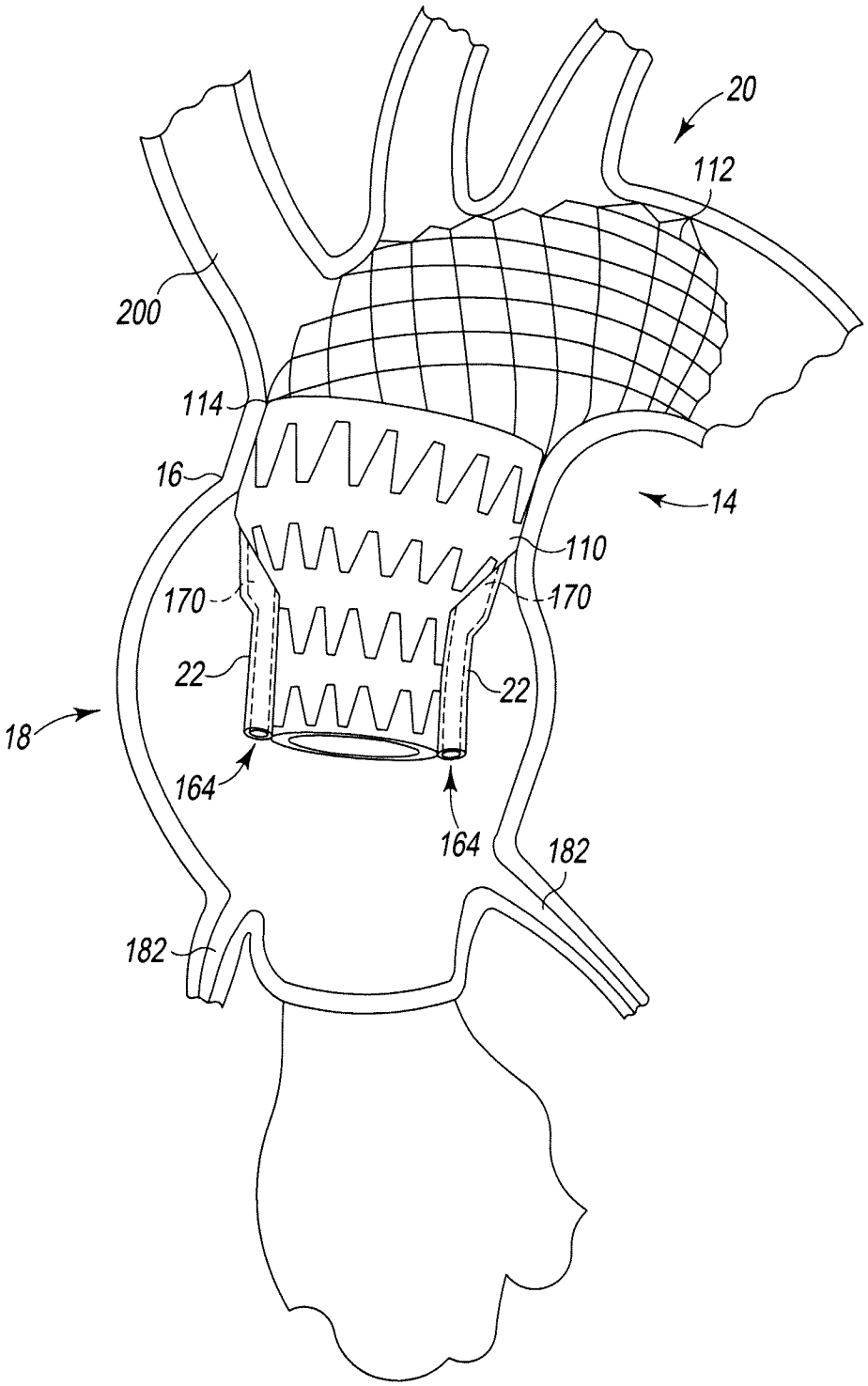


Fig. 6

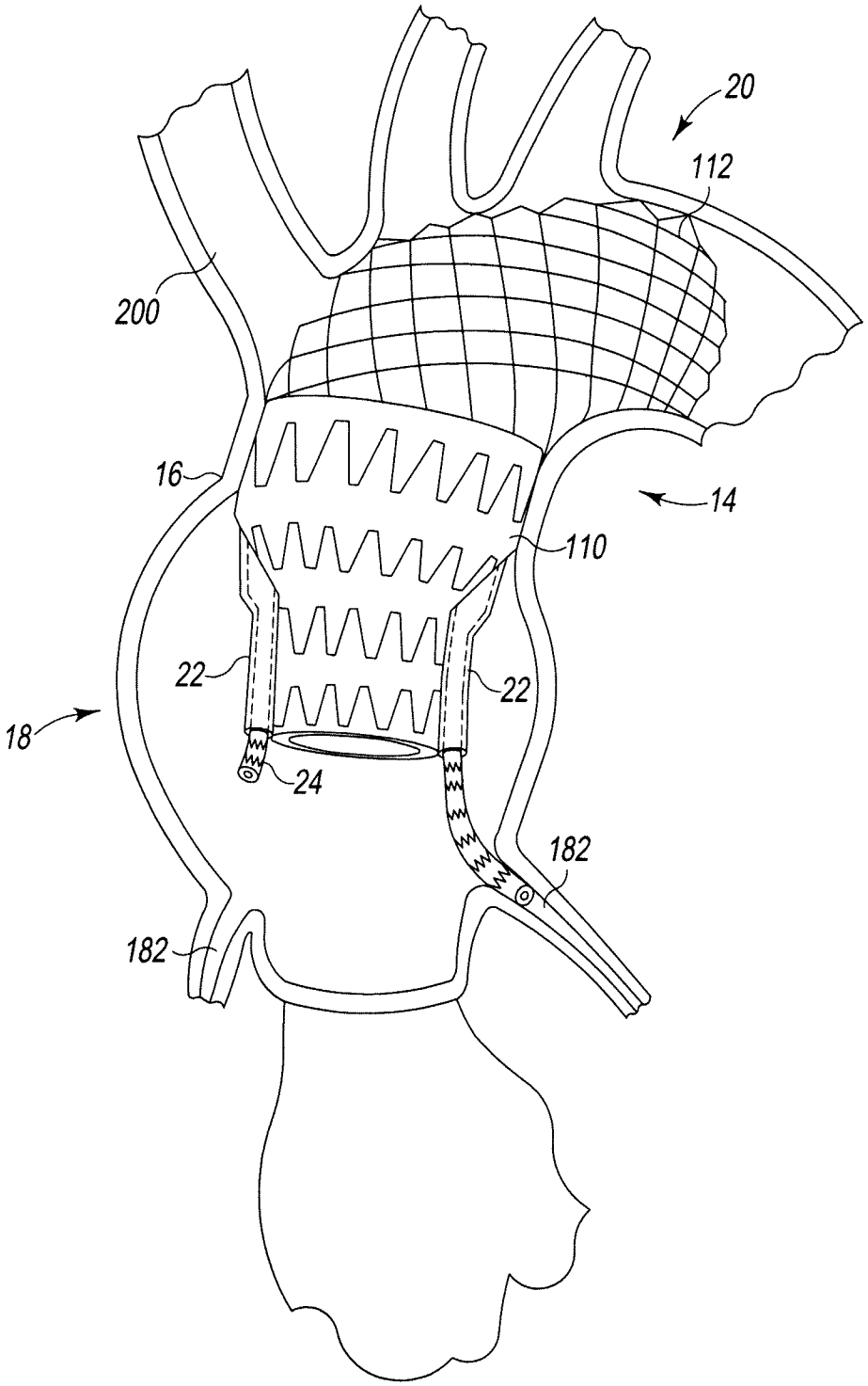


Fig. 7

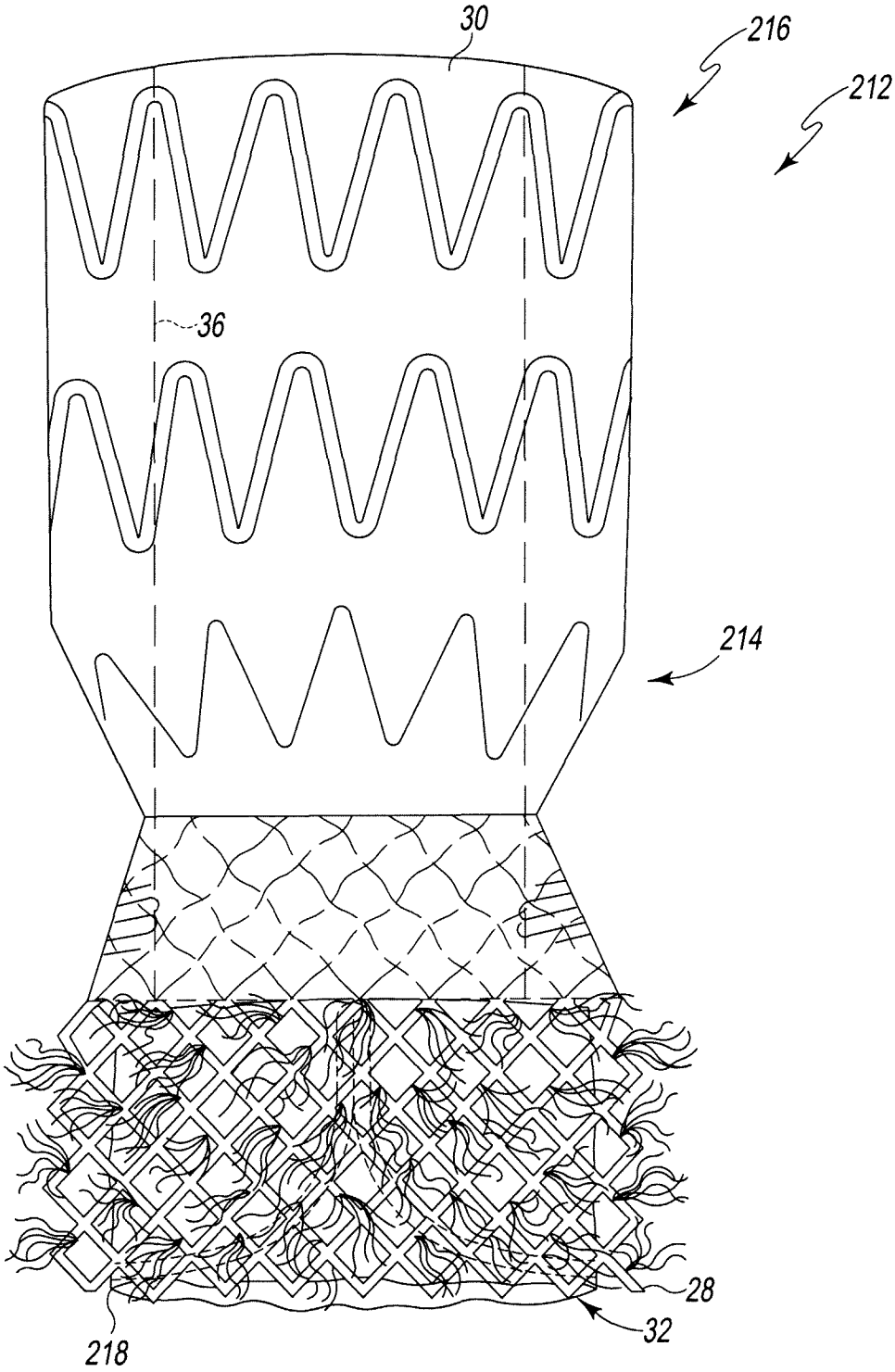


Fig. 8

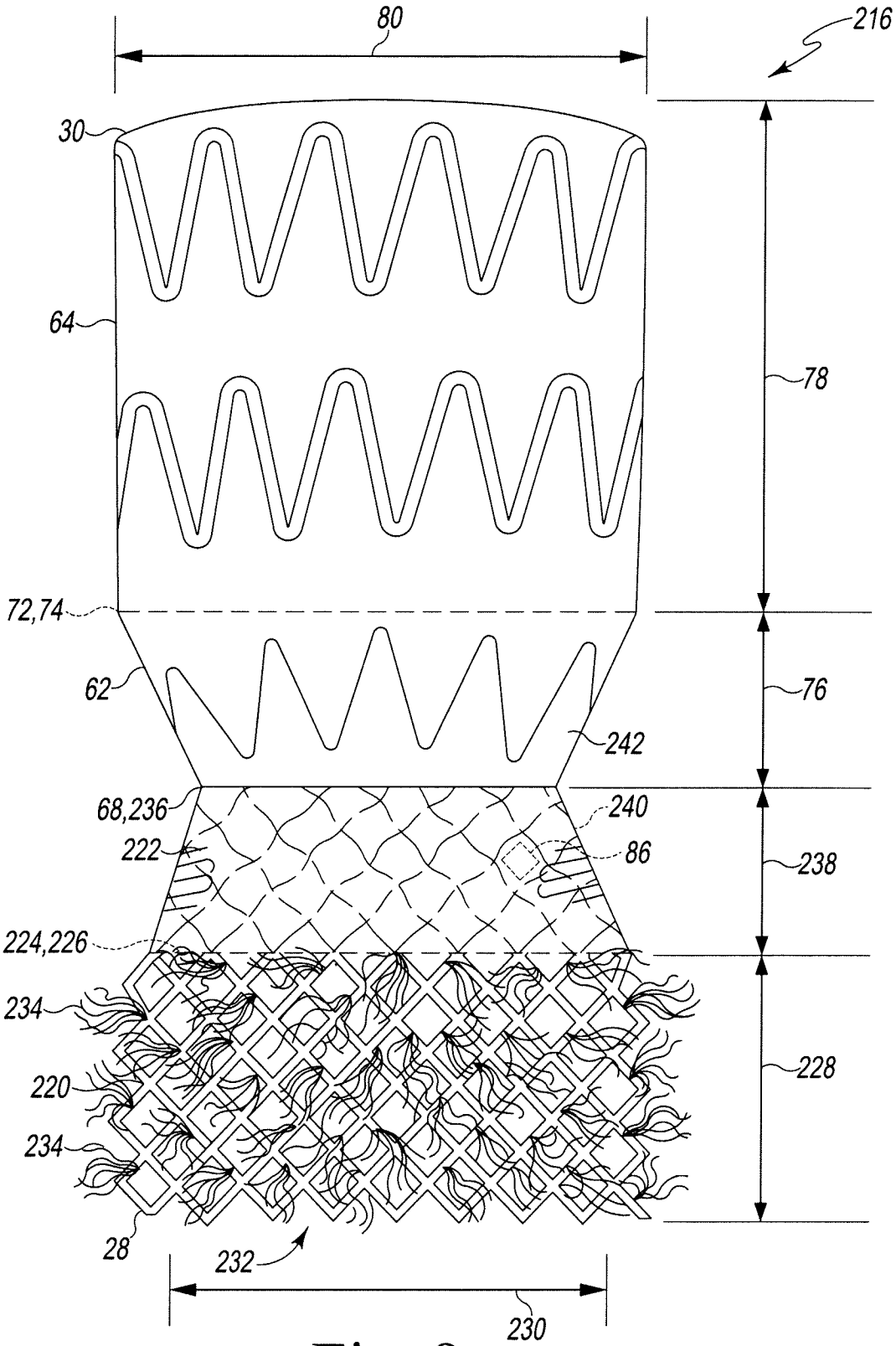

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Fig. 9

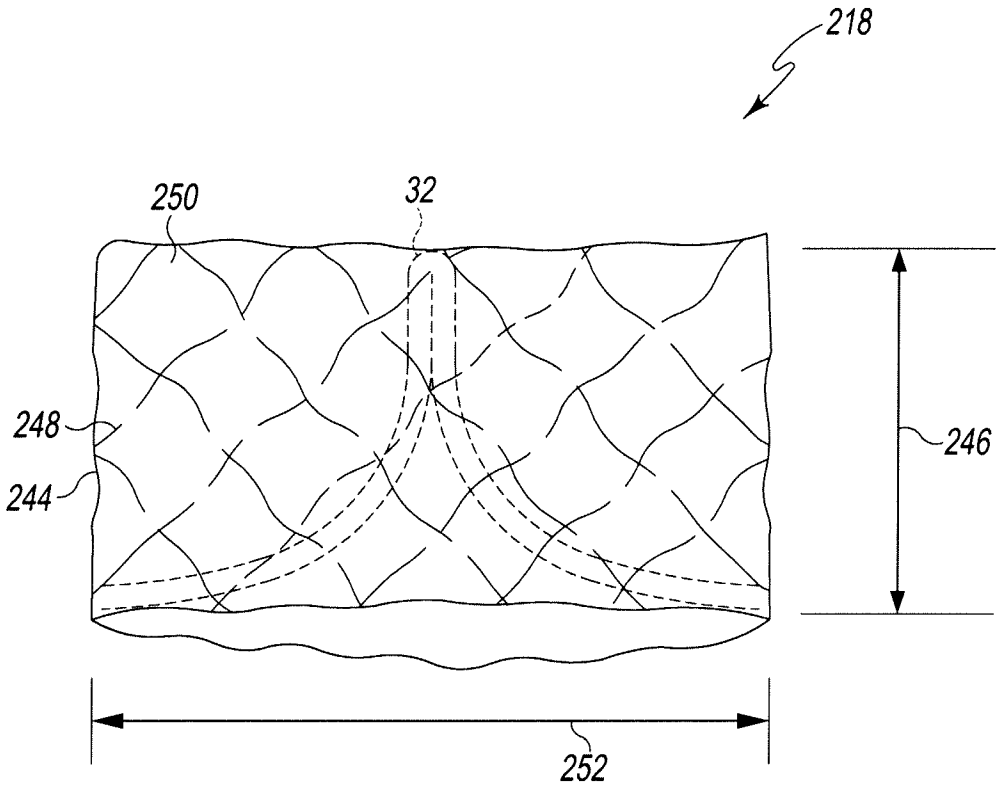


Fig. 10

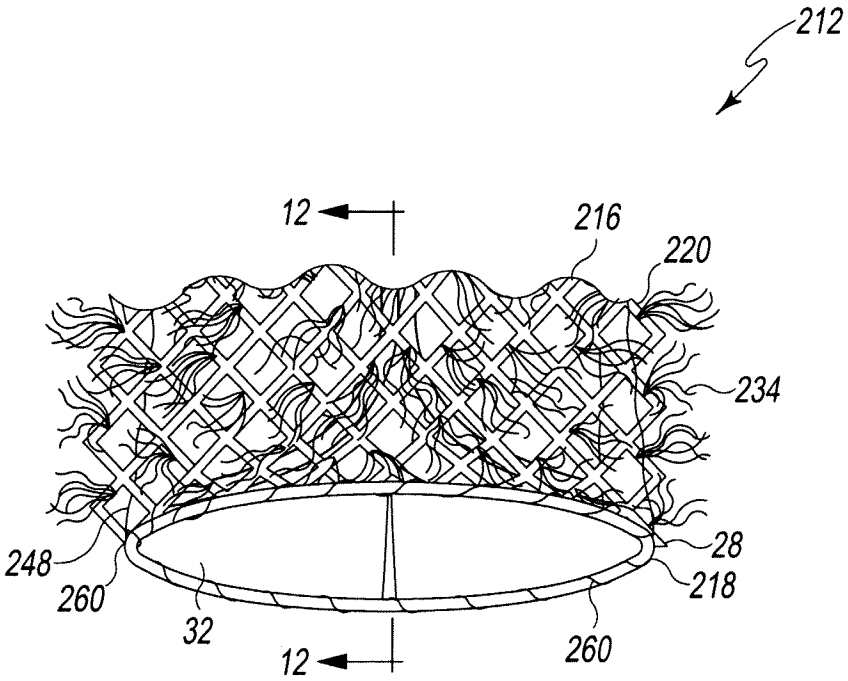


Fig. 11

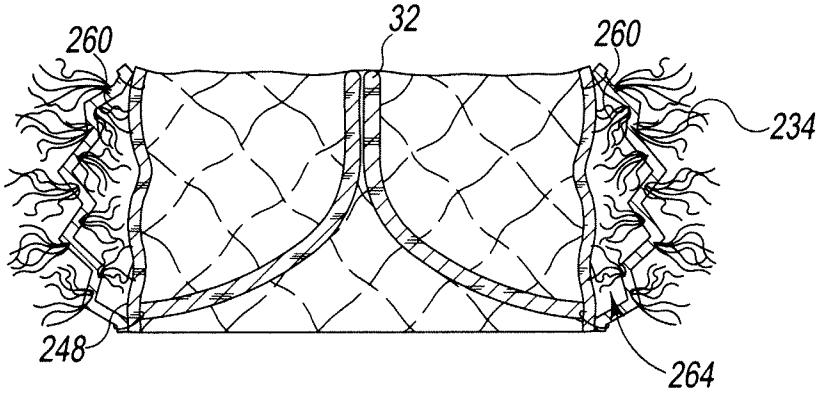


Fig. 12

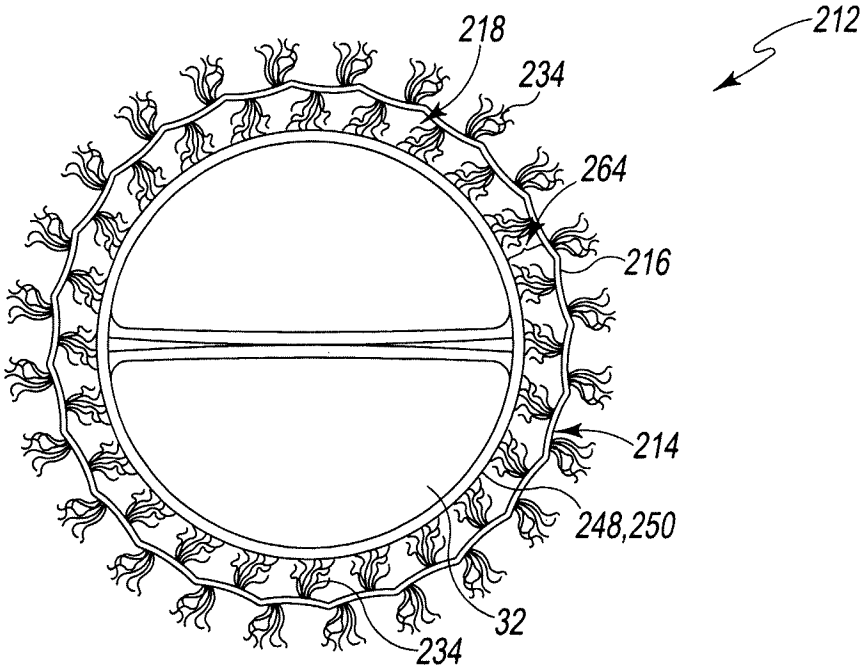

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Fig. 13

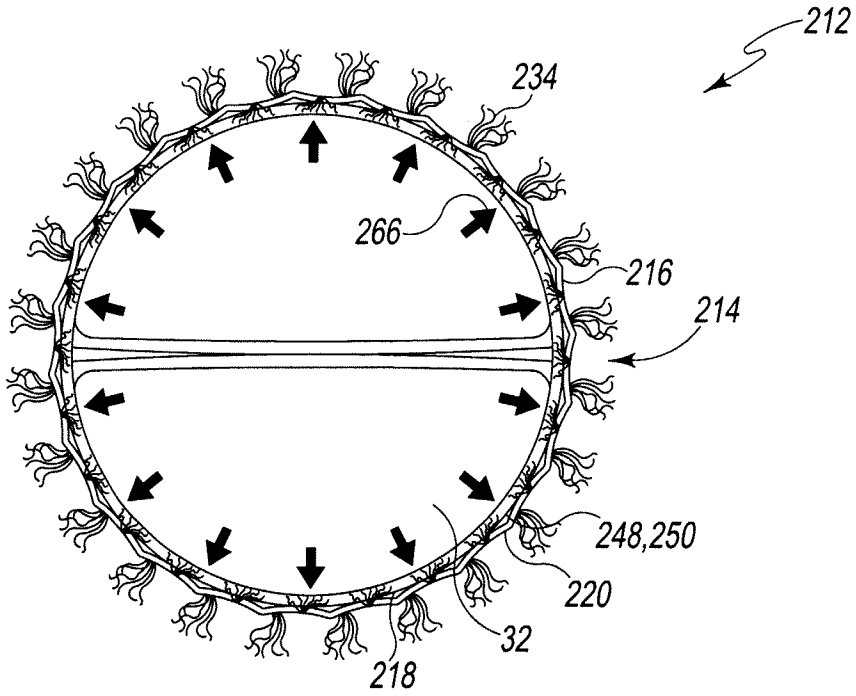

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Fig. 14

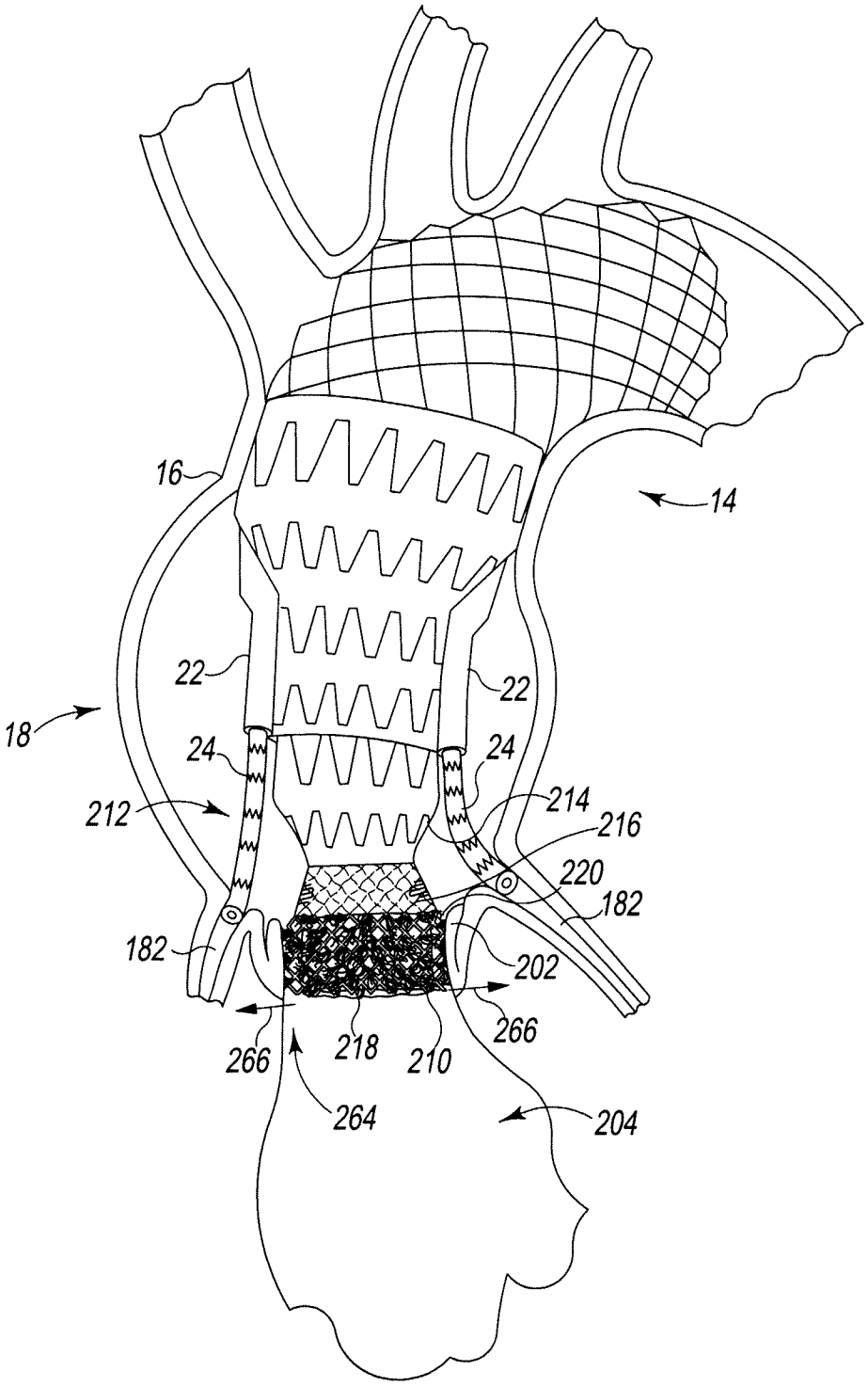

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Fig. 15

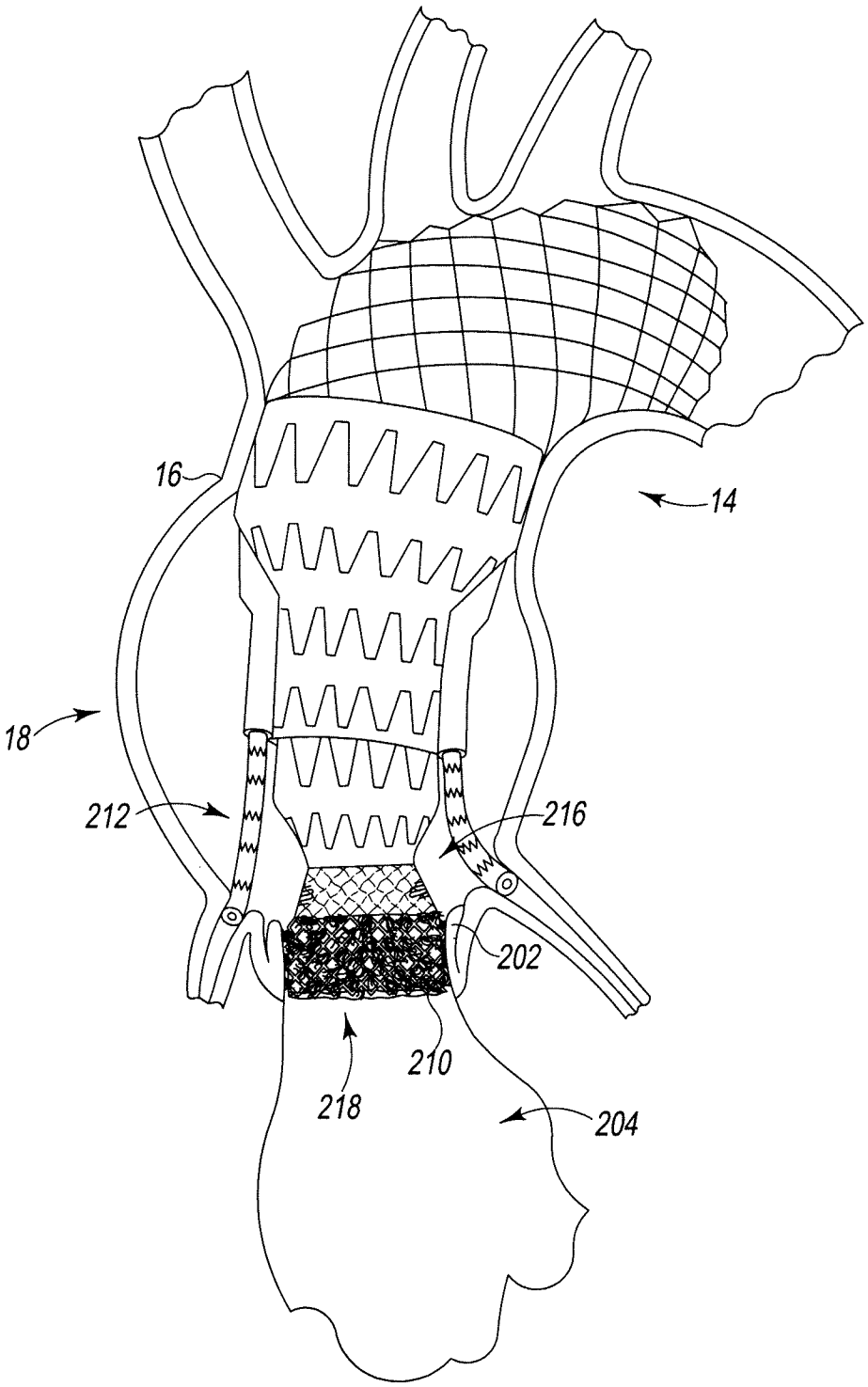


Fig. 16

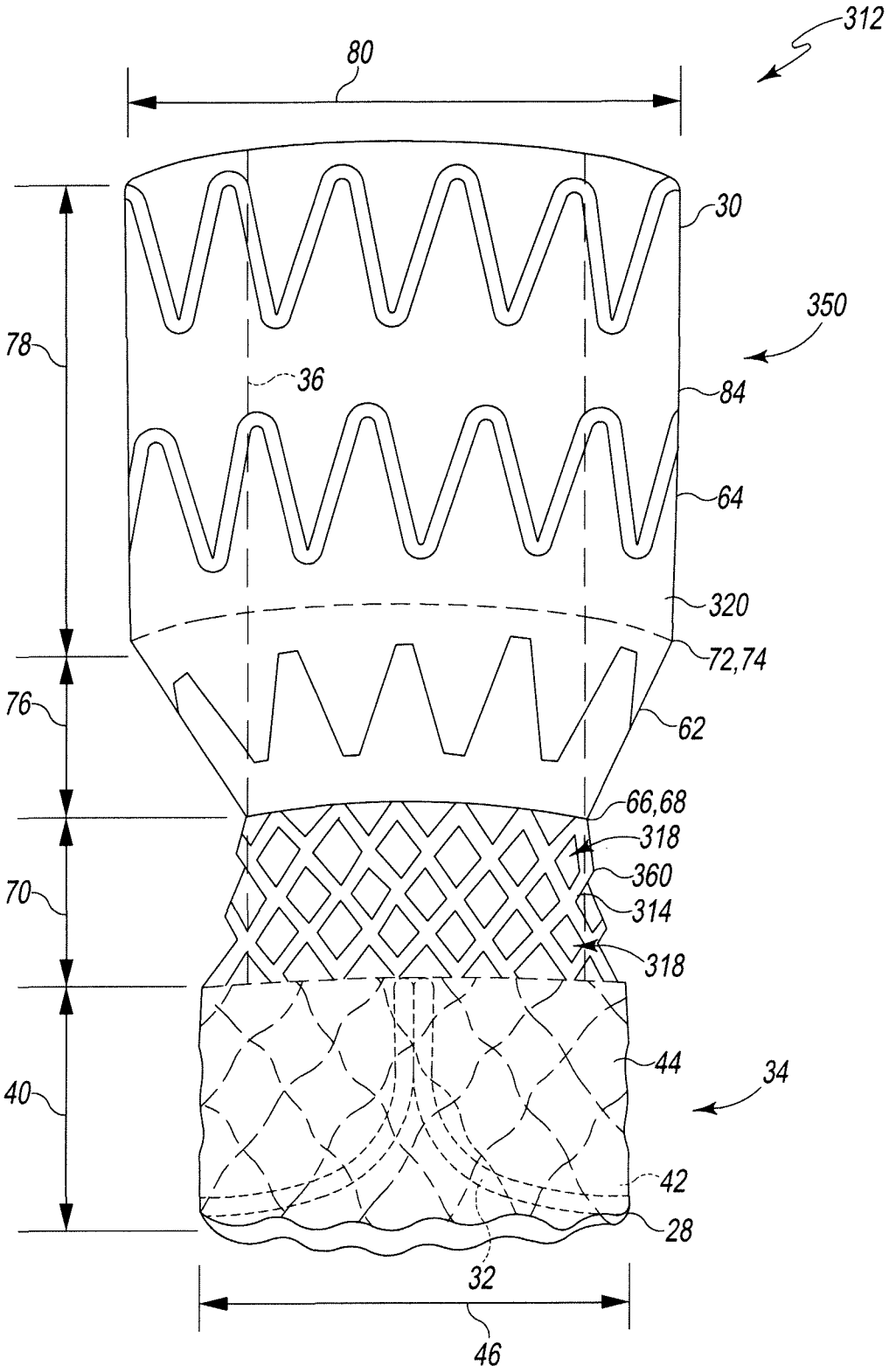

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Fig. 17

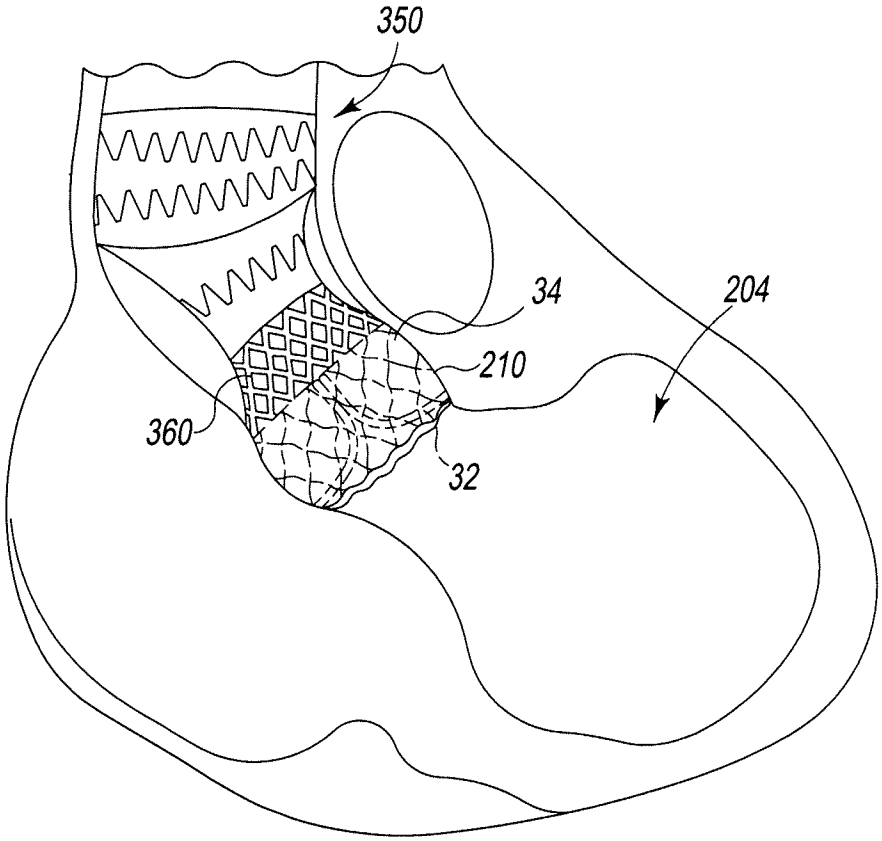


Fig. 18

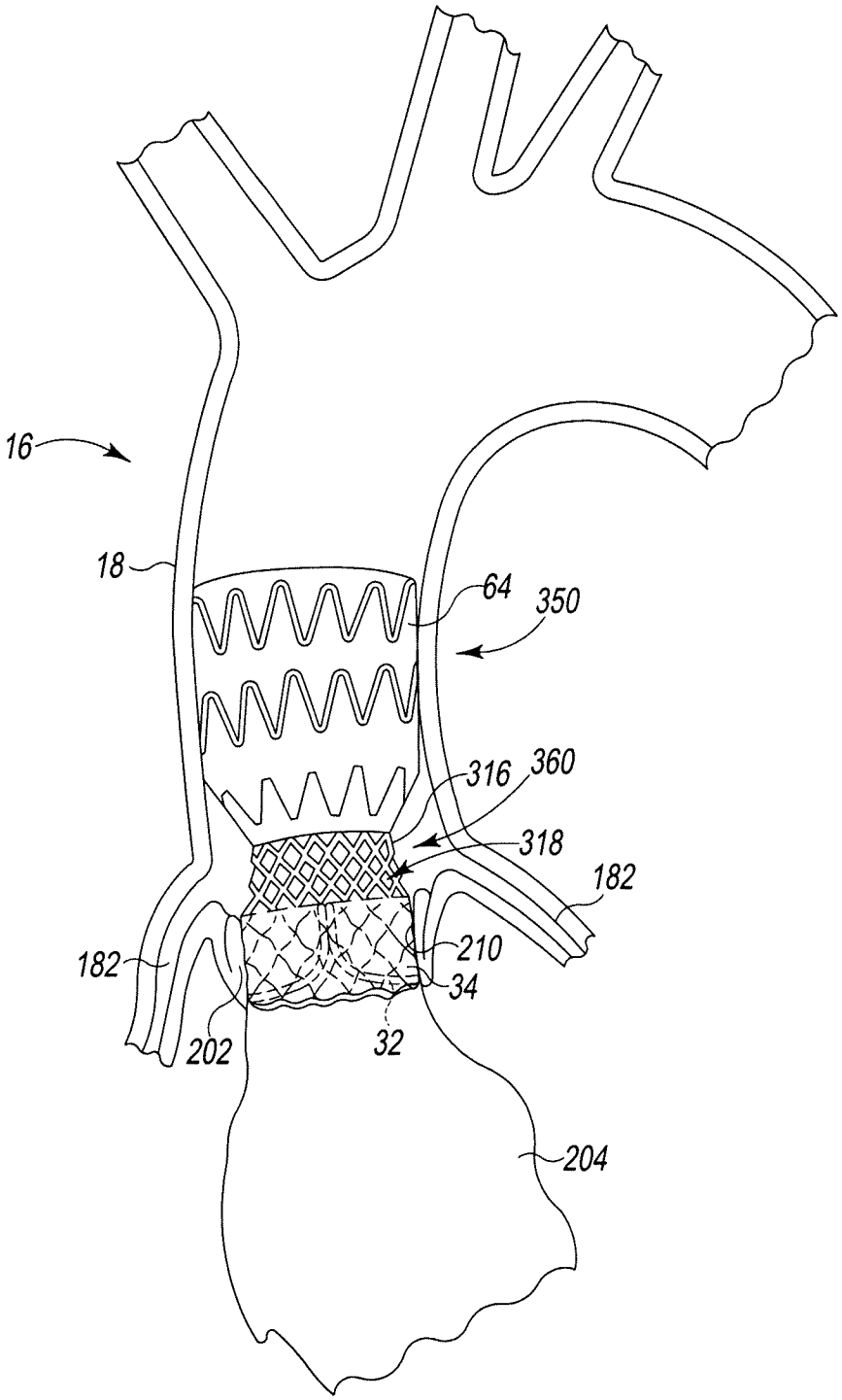


Fig. 19

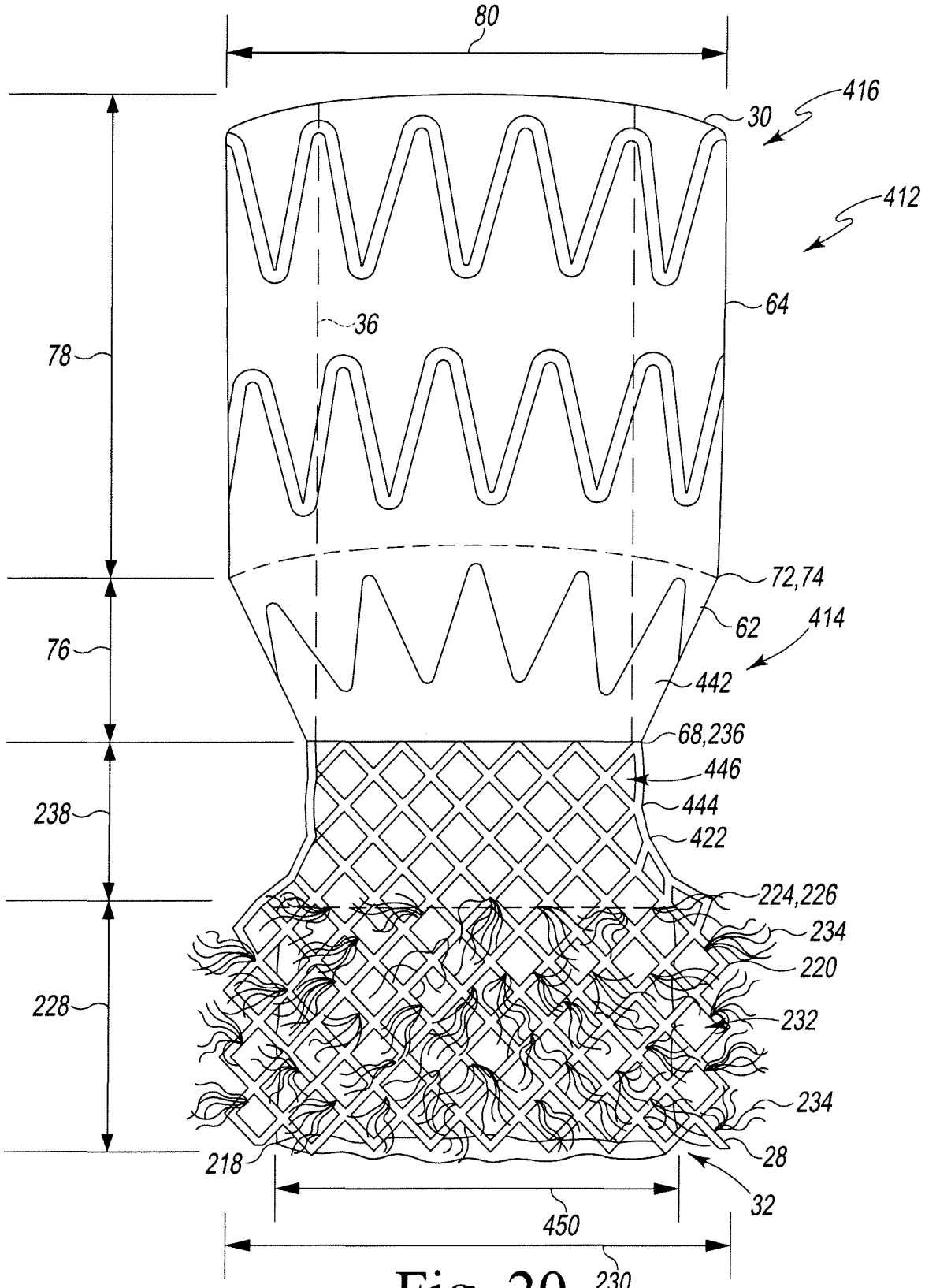

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Fig. 20

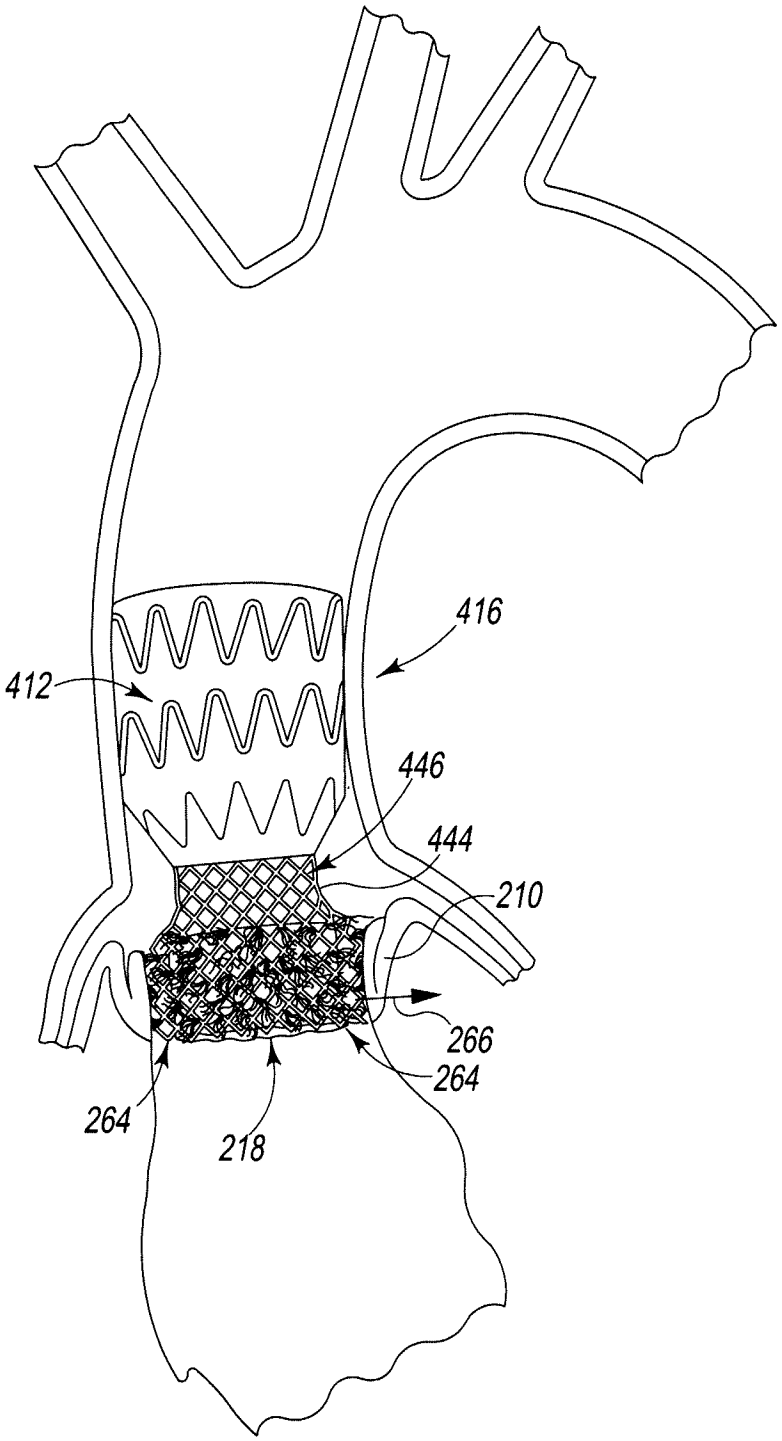


Fig. 21

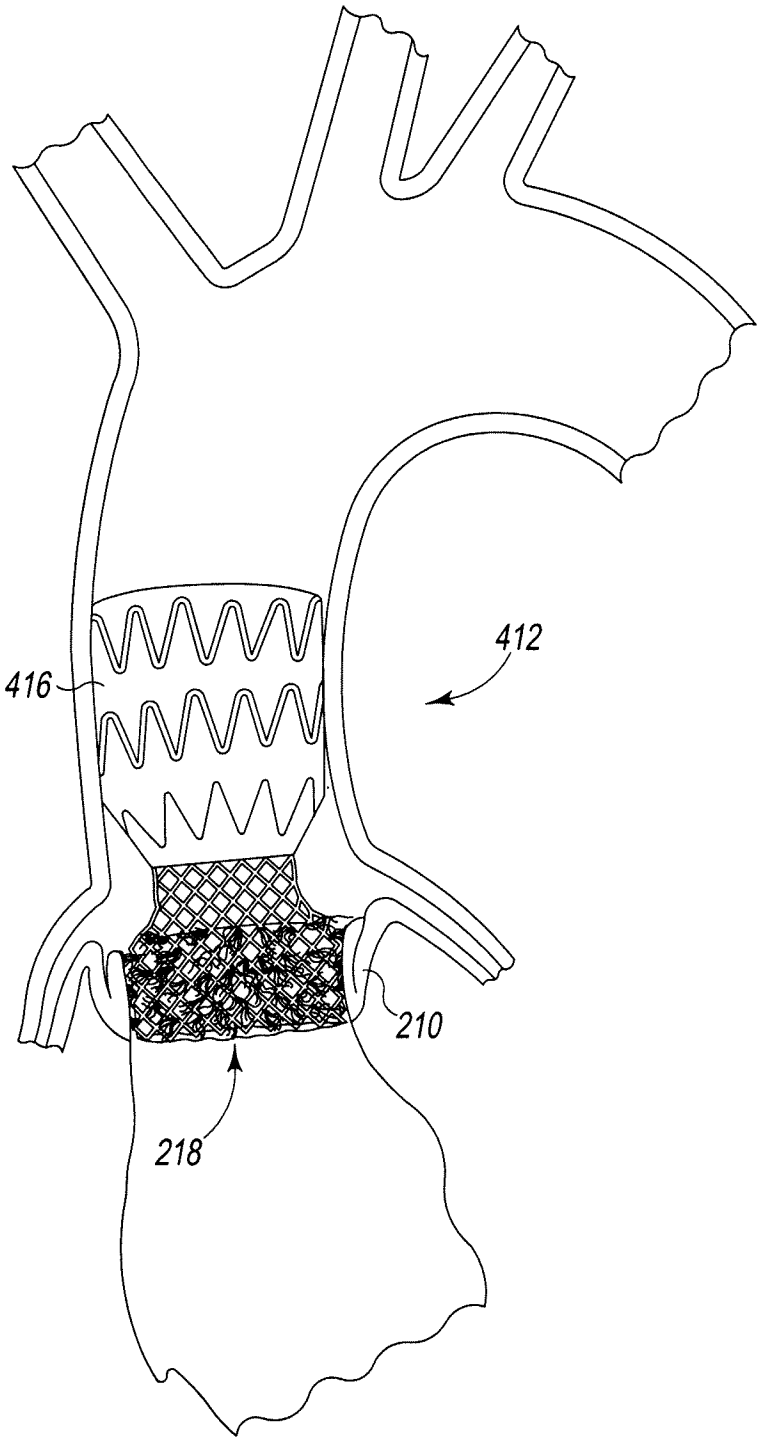


Fig. 22

TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

This application is a continuation of U.S. patent application Ser. No. 17/096,253 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on Nov. 12, 2020, which is issuing as U.S. Pat. No. 10,966,846 on Apr. 6, 2021, which is a continuation of U.S. patent application Ser. No. 17/060,557 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR", which was filed on Oct. 1, 2020 and issued as U.S. Pat. No. 10,888,441 on Jan. 12, 2021, which is a continuation of U.S. patent application Ser. No. 16/910,189 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jun. 24, 2020, which is a continuation of U.S. patent application Ser. No. 16/808,137 entitled "HEART VALVE REPLACEMENT DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Mar. 3, 2020 and issued as U.S. Pat. No. 10,792,172 on Oct. 6, 2020, which is a continuation of U.S. patent application Ser. No. 16/736,879 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jan. 8, 2020, which is a continuation of U.S. patent application Ser. No. 16/042,286 entitled "DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jul. 23, 2018 and issued as U.S. Pat. No. 10,555,823 on Feb. 11, 2020, which is a continuation of U.S. patent application Ser. No. 14/614,628 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Feb. 5, 2015 and issued as U.S. Pat. No. 10,028,848 on Jul. 24, 2018, which is a continuation of U.S. patent application Ser. No. 14/569,306 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Dec. 12, 2014 and issued as U.S. Pat. No. 9,339,399 on May 17, 2016, which is a divisional of U.S. patent application Ser. No. 13/706,896 entitled "Device for Endovascular Aortic Repair and Method of Using the Same", which was filed on Dec. 6, 2012 and issued as U.S. Pat. No. 8,940,040 on Jan. 27, 2015, which claims the benefit under 35 U.S.C. § 119 to U.S. Provisional Application Ser. No. 61/567,458 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on Dec. 6, 2011. Application Ser. No. 13/706,896 also claims priority under § 119 to U.S. Provisional Application Ser. No. 61/723,446 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair", which was filed on Nov. 7, 2012. Each of the applications referenced herein are incorporated by reference in their entirety.

TECHNICAL FIELD

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

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, B, or C. These will be discussed in further detail below and are shown in FIGS. **1**A-**1**C, which have been reproduced from the referenced article.

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. **1**A.

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. **1**B.

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. **1**C.

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 population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

SUMMARY

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.

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.

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 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

In some embodiments, the method may also include introducing the second prosthetic component into the ascending aorta prior to introducing the first prosthetic component.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

FIG. **1** is an illustrative aorta;

FIG. **1**A is an example of a Type A aneurysm;

FIG. **1**B is an example of a Type B aneurysm;

FIG. **1**C is an example of a Type C aneurysm;

FIG. **2** is partial cutaway view of an aorta with an embodiment of an endovascular prosthetic device implanted therein;

FIG. **3** is an elevation view of a proximal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **4** is an elevation view of a distal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **5** is a cross sectional view of the distal prosthetic component of FIG. **4** taken along the line **5-5** in FIG. **4**;

FIG. **6** is a partial cutaway view of the aorta with the distal prosthetic component of FIG. **3** implanted therein;

FIG. **7** is a view similar to FIG. **6** showing stents extending from the distal prosthetic component;

FIG. **8** is an elevation view of another embodiment of a proximal prosthetic component of the endovascular prosthetic device of FIG. **2**;

FIG. **9** is an elevation view of a self-expanding outer frame of the proximal prosthetic component of FIG. **8**;

FIG. **10** is an elevation view of a balloon-expandable inner frame of the proximal prosthetic component of FIG. **8**;

FIG. **11** is a perspective view a proximal end of the proximal prosthetic component of FIG. **8**;

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**;

FIG. **13** is a plan view of the proximal prosthetic component of FIG. **8** showing the inner frame in an unexpanded position;

FIG. **14** is a plan view similar to FIG. **13** showing the inner frame in an expanded position;

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**;

FIG. **16** is a view similar to FIG. **15** showing the inner frame in an expanded position;

FIG. **17** is an embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. **3**;

FIGS. **18-19** are partial cutaway views of the aorta with the transcatheter valve of FIG. **17** implanted therein;

FIG. **20** is another embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. **8**; and

FIGS. **21-22** are partial cutaway views of the aorta with the transcatheter valve of FIG. **20** implanted therein.

DETAILED DESCRIPTION OF THE DRAWINGS

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.

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.

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. **17-22**. Such a valve may be introduced transfemorally or through the subclavian artery or the apex of the heart.

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.

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**.

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 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.

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. Pat. 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. Pat. 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.

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.

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.

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 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.

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**.

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 should also be appreciated that all or part of the component **12** may be covered with hydrogel or other sealing material.

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.

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.

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 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.

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.

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.

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.

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 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.

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**.

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**.

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 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.

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.

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**.

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**. 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**.

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**.

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. Pat. 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 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**.

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**.

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**.

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 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**.

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**.

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.

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 described in greater detail below. As shown in FIG. **9**, the proximal section **220** defines a passageway **232** in the outer frame **216**.

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**. As illustrated, the fibers **234** are arcuate. 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**.

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.

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.

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, 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**.

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.

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 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.

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.

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.

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**.

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**.

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 components **212**, **14** together and seal the distal end **30** of the component **212** within the distal component **14**.

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** such that the fibers are flexible. 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**.

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.

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.

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**.

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 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.

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.

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.

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 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.

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.

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**.

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.

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 mate-

rial **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.

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**.

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** 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).

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**.

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**.

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.

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**.

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**.

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.

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.

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**.

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 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.

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). As shown, the balloon-expandable frame **218** is illustrated as a graft covering as indicated by the undulating proximal end of inner frame **218**, and the graft covering engages the prosthetic heart valve leaflets of the valve **32**.

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 the outer frame **416** and compresses the collagen fiber/hydrogel coated proximal section **220** of the outer frame **416** against the aortic annulus **210**.

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.

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 Ia 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.

Aortic insufficiency (AI) after implantation may also be corrected. Significant AI 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 AI. The bicuspid valve nature of the designs discussed herein potentially eliminates the problem with malcoaptation and AI secondary to that.

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.

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.

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.

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.

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 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.

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.

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.

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 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.

The invention claimed is:

1. An endovascularly deployed heart valve assembly comprising:

a graft covering for engaging prosthetic heart valve leaflets, wherein the graft covering engages the prosthetic heart valve leaflets for providing sealing thereto;

a frame formed from a metallic material and defining an open cell configuration and having an inflow end portion and an outflow end portion, and being secured to the graft covering; and

a sealing material positioned externally to the frame for providing sealing between the frame and a patient's anatomical wall of the aorta to prevent paravalvular leaks,

wherein the sealing material begins at the inflow end portion of the frame and extends over at least two rows of cells formed in the open cell configuration of the frame,

wherein the sealing material includes a plurality of outwardly extending fibers that extend outwardly of the frame,

wherein the fibers are arcuate,

wherein the fibers are flexible such that compression of the fibers imparts movement thereto,

wherein the fibers are in contact with the frame along a height of the sealing material,

wherein the fibers are spaced-apart to define spacings in a circumferentially extending direction and an axially extending direction along an outer surface of the frame,

wherein the spacings extend radially through a thickness of the sealing material beginning at an outermost portion of the fibers and extending to the frame,

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

wherein the sealing material is configured for being pressed against native aortic leaflets of the patient and compressing in response thereto, wherein being pressed against the native aortic leaflets forms a seal against the native valve leaflets and the frame by compression of the fibers into the spacings to reduce the spacings extending to the frame,

wherein the heart valve assembly is sized and shaped for being delivered endovascularly through a femoral artery of a patient.

2. The endovascularly deployed heart valve assembly of claim **1**, wherein the fibers are collagen fibers.

3. The endovascularly deployed heart valve assembly of claim **1**, wherein open cells formed in the open cell configuration are of a same shape.

4. The endovascularly deployed heart valve assembly of claim **1**, wherein the graft covering, prosthetic leaflets, and the sealing material are radially overlapping.

5. The endovascularly deployed heart valve assembly of claim **1**, further comprising a second plurality of fibers, the second plurality of fibers being spaced-radially inwardly of the plurality of fibers,

wherein, expansion of the graft covering closes a gap between the graft covering and the second plurality of fibers to thereby create a seal therebetween.

6. The endovascularly deployed heart valve assembly of claim **1**, wherein the fibers extend outwardly to different positions relative to a centerline run through a longitudinal of the heart valve assembly.

7. The endovascularly deployed heart valve assembly of claim **1**, wherein the graft covering extends to the inflow end portion of the frame, wherein, stitching extending between the graft covering and through the frame secures the graft covering to the inflow end portion of the frame.

8. The endovascularly deployed heart valve assembly of claim **1**, wherein an end of the most proximal apices of the frame are uncovered by sealing material and the graft covering,

wherein the end of the most proximal apices of the frame extends more proximally than a proximal end of the sealing material.

9. The endovascularly deployed heart valve assembly of claim **1**, wherein the end of the frame in which sealing material begins at the inflow end portion of the frame is configured for being radially aligned with the aortic annulus when the valve assembly is deployed.

10. An endovascular prosthetic heart valve assembly for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly;

a first plurality of fibers that extend away from the frame,

wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native aortic heart valve annulus of the patient; and

a second plurality of fibers that is positioned inwardly from the first plurality of fibers,

wherein the second plurality of fibers is in direct contact with the frame,

wherein the first plurality of fibers radially overlap the second plurality of fibers to cooperatively cover the frame,

wherein the heart valve assembly is sized and shaped for being delivered endovascularly through a femoral artery of a patient into the aorta,

wherein the prosthetic heart valve defines a spacing extending through a thickness of the first plurality of fibers that is created by a distance between fibers

thereof and through a thickness of the second plurality of fibers created by a distance between fibers thereof,

wherein, compression of the first plurality of fibers and the second plurality of fibers in response to expansion of the prosthetic heart valve compresses the first plurality of fibers and the second plurality of fibers relative to the spacing to create a seal thereabout.

11. The endovascularly deployed heart valve assembly of claim **1**, wherein the frame is self-expanding.

12. The valve assembly of claim **10**, wherein the frame is self-expanding.

13. The endovascularly deployed heart valve assembly of claim **1**, wherein the frame defines an hour glass shape.

14. The valve assembly of claim **10**, wherein the frame defines an hour glass shape.

15. The valve assembly of claim **10**, wherein the plurality of cells are a same shape.

16. The endovascularly deployed heart valve assembly of claim **1**, wherein the frame is integrally formed.

17. The valve assembly of claim **10**, wherein the frame is integrally formed.

18. The endovascularly deployed heart valve assembly of claim **1**, wherein the fibers define fibers that extend outwardly to a tip of each respective fiber.

19. The valve assembly of claim **10**, wherein the first plurality of fibers define fibers that extend outwardly to a tip of each respective fiber.

20. The endovascularly deployed heart valve assembly of claim **1**, wherein the graft covering forms an inner frame for supporting the prosthetic heart valve leaflets.

21. An endovascular prosthetic heart valve assembly for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells,

wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly;

a first layer for forming a seal upon compression,

the first layer configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native aortic heart valve annulus of the patient,

wherein the first layer comprises a plurality of fibers that extend away from the frame, wherein the plurality of fibers is compressed against the native aortic heart valve annulus of the patient; and

a second layer for forming a seal upon compression,

wherein the second layer is positioned radially inwardly from the first layer,

wherein the second layer is in direct contact with the frame,

wherein the second layer defines a spacing extending through a thickness of the second layer for passage of fluid therethrough prior to forming a seal upon compression,

wherein the heart valve assembly is sized and shaped for being delivered endovascularly through a femoral artery of a patient into the aorta,

wherein, compression of the first layer and the second layer in response to expansion of the prosthetic heart valve compresses the fibers of the first layer relative to the spacing to create a paravalvular seal.

22. The valve assembly of claim **21**, wherein the first layer and the second layer are distinct layers.

23. The valve assembly of claim **21**, wherein the frame is self-expanding.

24. The valve assembly of claim **21**, wherein the frame defines an hour glass shape.

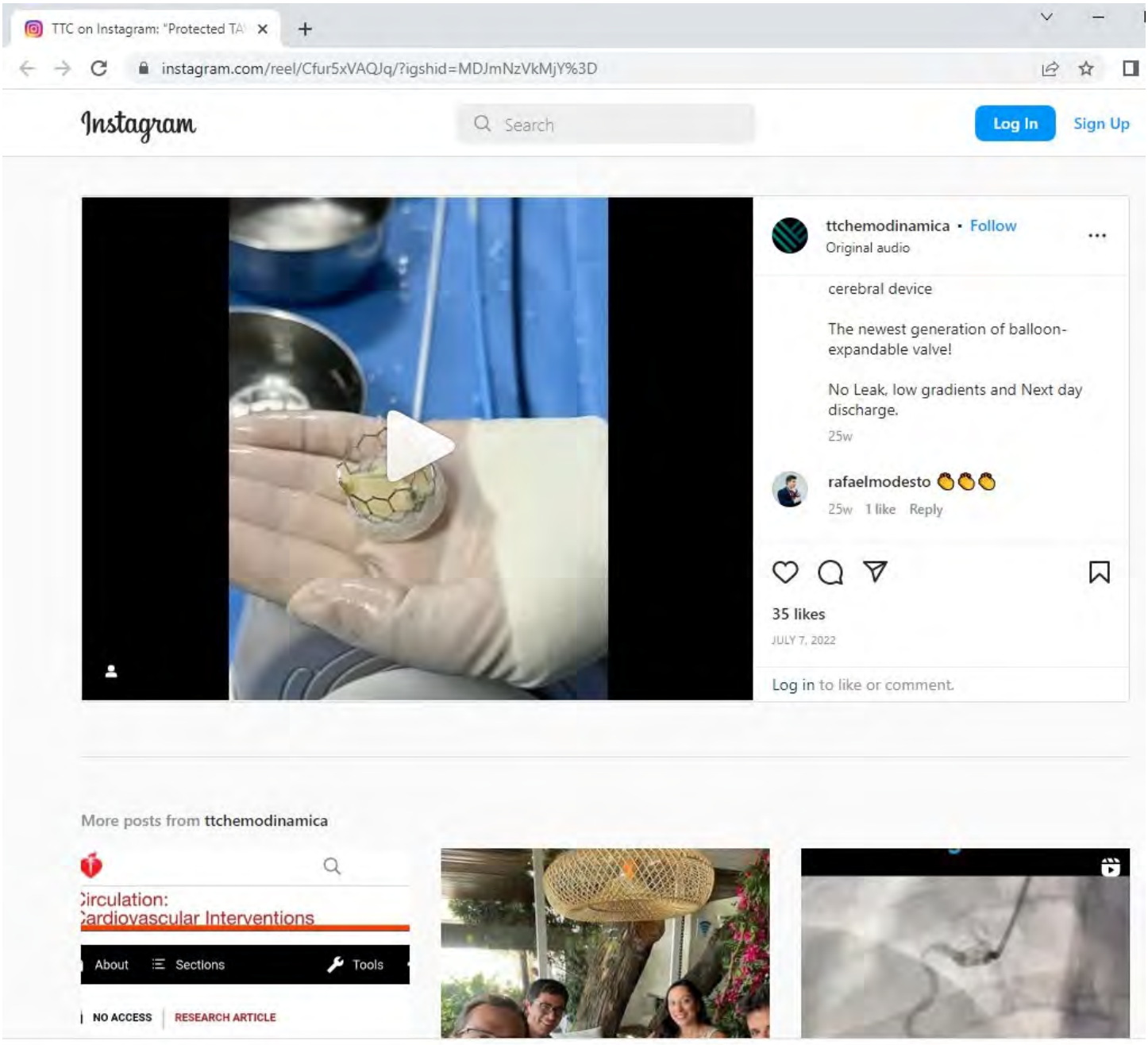
25. The valve assembly of claim **21**, wherein the plurality of cells are a same shape.

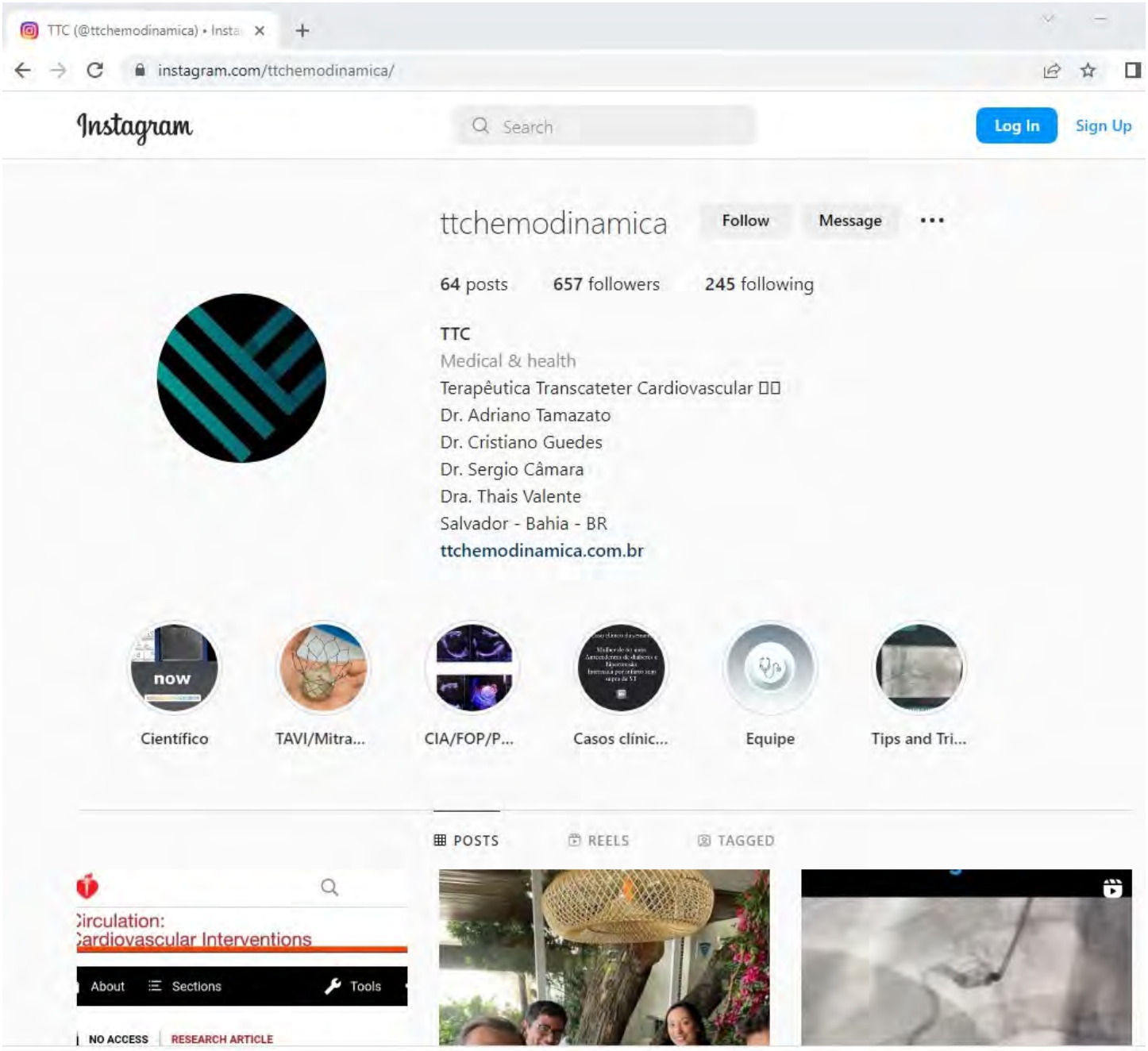
26. The valve assembly of claim **21**, wherein the frame is integrally formed.

27. The valve assembly of claim **21**, wherein the fibers of the first layer define fibers that extend outwardly to a tip of each respective fiber.

* * * * *

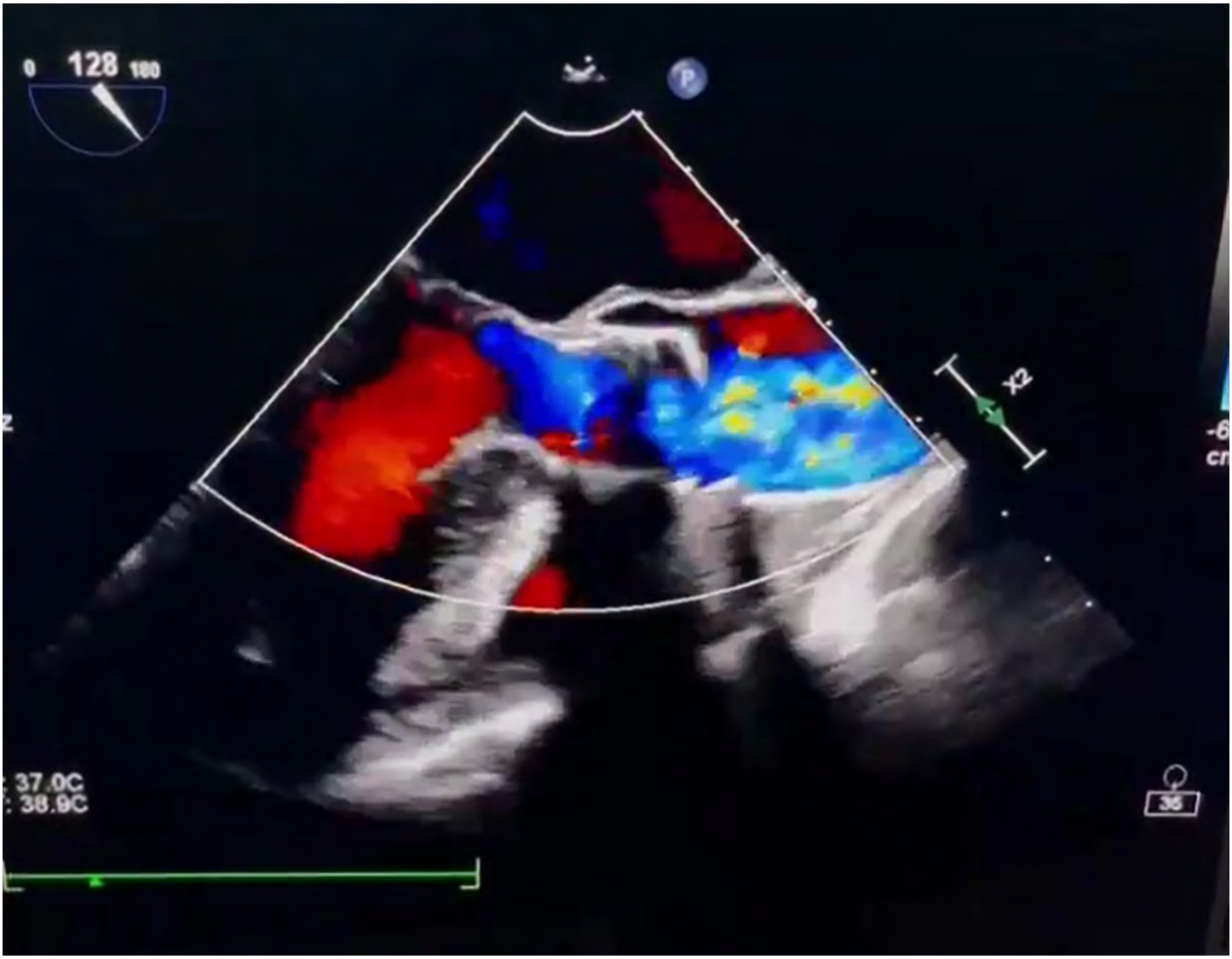
EXHIBIT 74

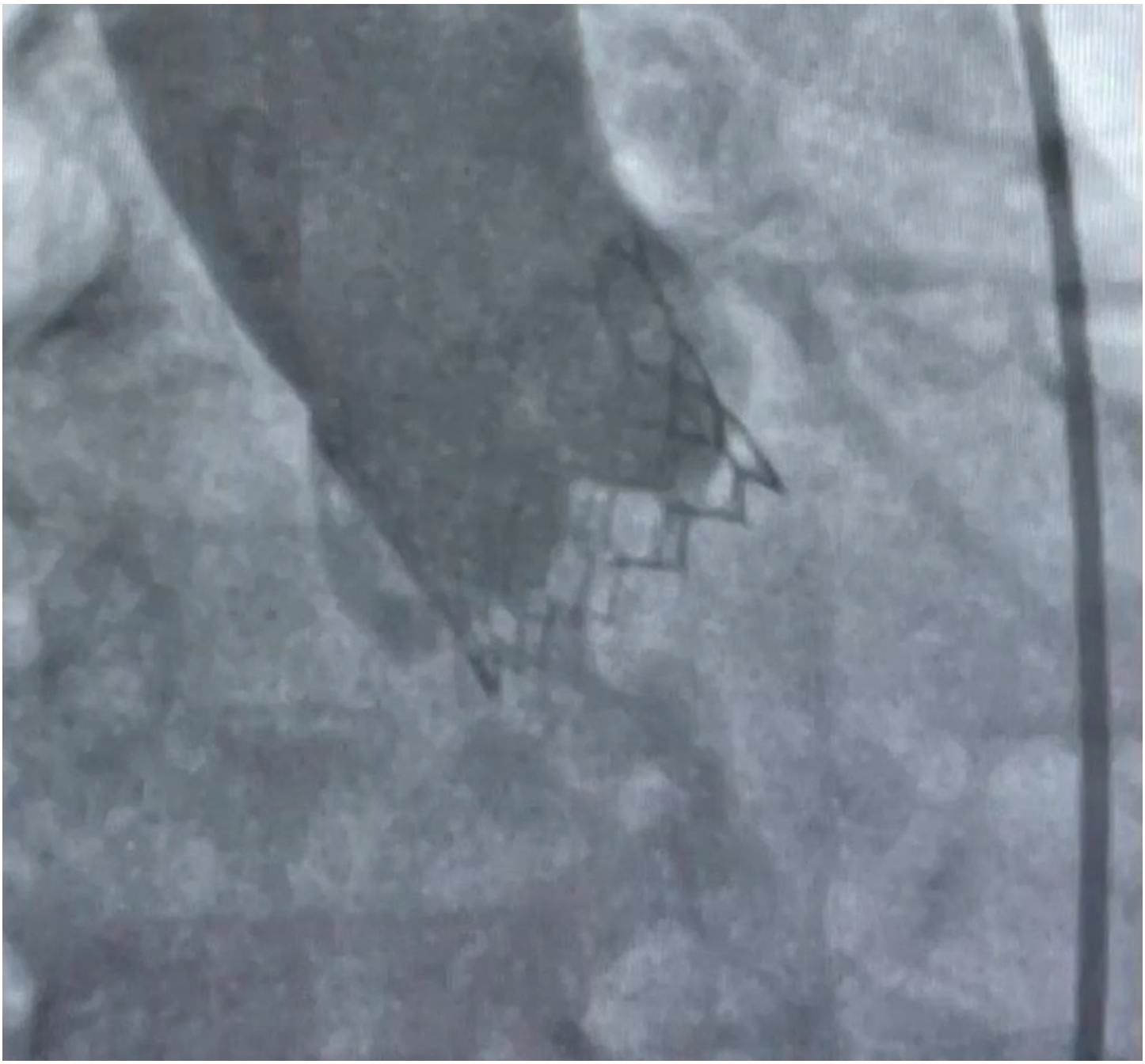

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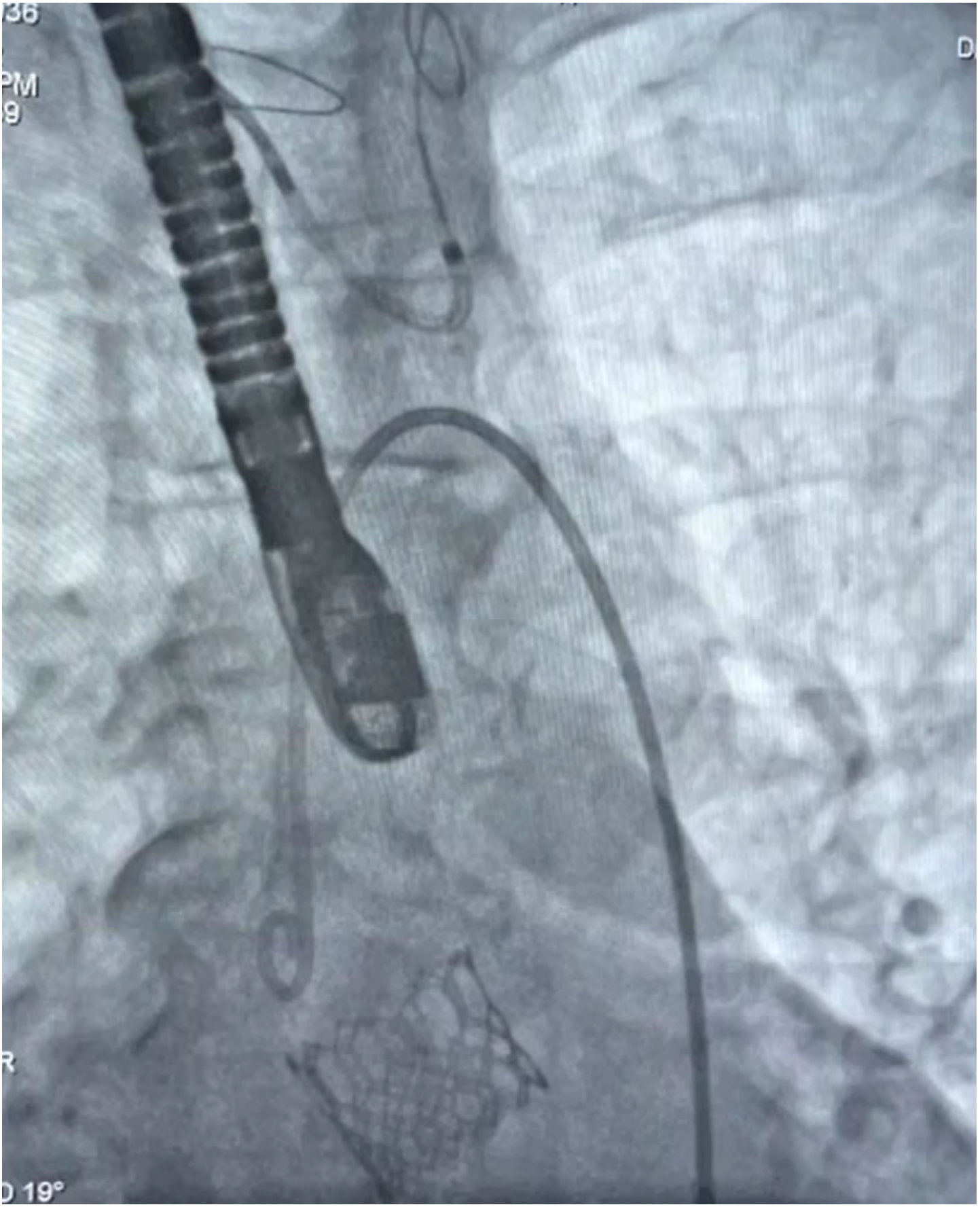


EXHIBIT 75

Geoffrey Smith

From: Geoffrey Smith
Sent: Wednesday, February 15, 2023 5:45 PM
To: John Sganga; Joshua Stowell; Craig Summers; Christy Lea; Brian Horne; Brian Barnes; Mark Vorder-Bruegge, Jr.; Matthew M. Lubozynski; Egan, Brian P.; Anthony D. Raucci, Esquire (araucci@mnat.com); Keith_Newburry@edwards.com
Cc: John B. Campbell; Aortic-MS; Poff, Adam; Vrana, Robert
Subject: Aortic Innovations' Patents
Attachments: US11337834.pdf; US11389310.pdf; US11491033.pdf; US11497634.pdf; US11523918.pdf

Dear Counsel,

As you may be aware, Aortic Innovations LLC ("Aortic") filed a complaint earlier this week against Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc. (collectively "Edwards") in Delaware (1-23-cv-00158) alleging infringement of at least one claim of U.S. Patent Nos. 11,337,834 and 11,389,310 by Edwards' SAPIEN 3 Ultra and SAPIEN 3 Ultra with Resilia leaflets. As you are aware, our Firm represents Aortic. Aortic has been awarded multiple other patents related to its transcatheter aortic valve replacement ("TAVR") technology, including U.S. Patent No. 11,491,033 ("the '033 Patent"), U.S. Patent No. 11,497,634 ("the '634 Patent"), and U.S. Patent No. 11,523,918 ("the '918 Patent"). Copies of the '033, '634, and '918 Patents are attached for your reference. Edwards' SAPIEN 3 Ultra and SAPIEN 3 Ultra with Resilia leaflets practice one or more claims of each of the '033, '634, and '918 Patents. Accordingly, Edwards may be interested in a license to these patents, particularly for the SAPIEN 3 Ultra and SAPIEN 3 Ultra with Resilia leaflets.

We look forward to hearing from you. If you have any questions, or would like to discuss further, please let us know.

Enclosures: U.S. Patent Nos. 11,337,834, 11,389,310, 11,491,033, 11,497,634, and 11,523,918

Regards,

Geoff

McKool Smith | Geoffrey Smith
Principal | Austin | (512) 692-8728

EXHIBIT 76

Not all TAVR valves are made alike.
Your valve choice matters.

Understand why your first valve choice matters

If you have severe aortic stenosis and are experiencing symptoms, you now have even more choices when it comes to which transcatheter aortic valve replacement (TAVR) valve you receive. Understanding which TAVR valve you are receiving is very important, as not all TAVR valves are created equal.

SAPIEN 3 TAVR valves, the most widely used TAVR heart valves

By choosing one of the Edwards SAPIEN transcatheter heart valves, you are getting one of the most widely used TAVR valves around the world, having been implanted in over 763,000 patients around the world.*

TAVR with the SAPIEN 3, has similar durability to that of the leading surgical valves at 5 years.[†‡1,2]

Edwards' newest valve, the SAPIEN 3 Ultra RESILIA valve is a bovine (cow) heart tissue valve that has been treated with a special Edwards technology to block calcium build-up on the valve, potentially allowing the valve to last longer.[†1]

Both the SAPIEN 3 Ultra RESILIA valve and the leading surgical valves use RESILIA tissue, known to block calcium build-up on the tissue, which could potentially allow the valve to last longer.[†1] Before today, the RESILIA tissue was only approved to be used on surgical heart valves.[†1]

The SAPIEN 3 Ultra RESILIA valve is the only TAVR valve with RESILIA tissue[†1]



The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves

*Currently, does not include the SAPIEN 3 Ultra RESILIA valve.
† RESILIA tissue has not been studied for long-term results in patients.
‡ Propensity matched analysis of intermediate risk patients using VARC3 definitions of SVD and SVD related BVF at 5 years.

Now is the time to ask for the SAPIEN 3 Ultra RESILIA valve when getting TAVR

The type of TAVR valve you receive can impact your heart and your future.

Designed like your heart

- The valves are designed to work like your native valve and begin working immediately once they are implanted.

Designed to last

- The frame of the valves is made from cobalt chromium to help with strength and durability.
- TAVR with the SAPIEN 3 has similar durability to that of the leading surgical valves at 5 years.[†‡1,2]
- An outer sealing skirt surrounds the bottom of the valve, to help stop any possible leakage around the valve.

Designed for your unique needs

- SAPIEN 3 TAVR valves come in four unique sizes to provide a better fit for each individual patient.

Designed for your future

- The SAPIEN 3 TAVR valves are designed purposely with a specific low frame height to facilitate future procedures, if needed.[§]
- The SAPIEN 3 Ultra RESILIA valve is a bovine (cow) heart tissue that has been treated with special Edwards tehnology to block calcium build-up on the valve, potentially allowing the valve to last longer.[†1]
- Up to 75% of patients who get TAVR also have coronary artery disease.[3] By getting one of the SAPIEN 3 TAVR valves, your physician may have better access to your coronaries in the future, should you need another procedure, due to its unique shape and low frame height design.

Serious risks associated with the TAVR procedure, similar to those of open heart surgery, include death, stroke, serious damage to the arteries, or serious bleeding.

Ask which TAVR valve you are getting today

Understand why your first transcatheter valve choice matters. Know the different types of valves available to you. Don't settle for just any TAVR valve. Make sure you understand your options.

Download the below fact sheet to help you better understand the SAPIEN 3 TAVR valves' clinical difference.

Download the SAPIEN 3 Ultra RESILIA TAVR Fact Sheet

Edwards SAPIEN 3 TAVR valves built on decades of success

Edwards continues to build upon its best-in-class design and technology for each of its successive valves. With each generation of Edwards valves comes better patient outcomes and clinical benefits when compared to surgical valves.[¶]



FDA Approved 2022

Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve

The Edwards SAPIEN 3 Ultra RESILIA valve builds upon the best-in-class and proven SAPIEN valve platform, while also using the tissue from the leading Edwards surgical valves.

Edwards' commitment to technology continues with the SAPIEN 3 Ultra RESILIA valve. Built using the proven SAPIEN 3 valve, the SAPIEN 3 Ultra RESILIA transcatheter heart valve is made with RESILIA tissue (previously only used on Edwards surgical valves) and designed to reduce calcium build up on the valve tissue, potentially allowing the valve to last longer.*[1]

FDA Approved 2018

Edwards SAPIEN 3 ULTRA Transcatheter Heart Valve

Built upon the proven SAPIEN platform, the Edwards SAPIEN 3 Ultra transcatheter heart valve was designed with patient's future needs in mind.

Edwards' commitment to best-in-class technology continues with the SAPIEN 3 Ultra valve. Built upon the proven SAPIEN platform, the SAPIEN 3 Ultra transcatheter heart valve was designed with patients' future needs in mind. Its low frame height and large cell design easily facilitates future coronary access if a patient requires a procedure post-TAVR. It continues to provide alternative options for patients other than open heart surgery.

FDA Approved 2015

Edwards SAPIEN 3 Transcatheter Heart Valve

Considered best in class because of its better clinical outcomes, the Edwards SAPIEN 3 transcatheter valve became available to more patients, including those who were considered low risk for open heart surgery.

The Edwards SAPIEN 3 continued to advance heart valve technology, providing additional access routes and more valve sizes to meet patients' needs. The Edwards SAPIEN 3 TAVR continued to show success in clinical data by achieving 1% death and stroke rate for those patients who are considered low-risk, which provided patients with better clinical outcomes than open heart surgery.[1]

Next page: know the clinical difference

Learn about the benefits of Edwards valves and what that means for getting back to the life you love.

> Go to the Clinical Difference Page

References

1. Flameng et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. J Thorac Cardiovasc Surg. 2015;149:340–5.

2. Pibarot 2020 (S-13919) describes 5-yr PII S3i trial outcomes similar between S3 and SAVR, based on VARC3 definition.

3. Coronary Angiography and Percutaneous Coronary Intervention after Transcatheter Aortic Valve Replacement. JACC 2018: 1360–78.

***Currently, does not include the SAPIEN 3 Ultra RESILIA valve.**

†RESILIA tissue has not been studied for long-term results in patients.

[+] Propensity matched analysis of intermediate risk patients using VARC3 definitions of SVD and SVD related BVF at 5 years.

[§] Indication for aortic THV-in-THV with demonstrated future coronary access (68/68 patients).

[¶] The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and re-hospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.

Important Risk Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications:
The Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications (Who should not use):
The Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System should not be used in patients who:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.
- Have a mitral ring that is damaged and can no longer support the valve.

Warnings:

- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are sensitive to anesthesia, contrast media, cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or plastics.
- The Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves may not last as long in younger patients, or patients with a disease that results in more calcium in their blood.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage. X-ray guidance used during the procedure may cause injury to the skin, which may be painful, damaging, and long-lasting.
- Patient's creatinine level should be measured prior to the procedure.
- Patients who have already had a valve replaced should be carefully assessed by their physician prior to receiving a new valve to ensure proper placement of the new valve.
- Injury can occur if the delivery system is not used properly.
- Transcatheter heart valve patients should talk to their physicians about the potential need for medications that thin the blood or prevent blood clots from forming. Patients who do not may be at increased risk of a stroke. Blood-thinning medication may increase the risk of bleeding in the brain (stroke).
- Transcatheter valve replacement is not recommended in previous mitral valve rings that are damaged or have become too rigid.

Precautions:
The long-term durability of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 transcatheter heart valves are not known at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart

valve is performing. Limited clinical data are available for transcatheter aortic valve replacement in patients who are born with an aortic heart valve that has only two leaflets and who are determined to be at low risk for open heart surgery. A patient's anatomical characteristics should be considered by their physicians when using the valve in this patient population. In addition, patient age should be considered as long-term durability of the valve has not been established. Patients who need a dental procedure should talk to their doctor about risk of infection and needing antibiotics. Patients should be treated post-procedure for heart infection as a precaution.

The safety and effectiveness of the transcatheter heart valves are also not known for patients who have:

- An aortic heart valve that is not calcified, contains only one leaflet, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks.
- Who have a prosthetic ring in the tricuspid position.
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities such as a blood clot, a diseased mitral valve that is calcified or leaking, or Gorlin syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors.
- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly.
- Diseased, abnormal, or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for the delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- Whose previously implanted artificial valve or ring is not securely in place or is damaged that could cause it to leak.
- Whose previously implanted valve or ring could block a blood vessel caused from the leaflet partially detaching.

Potential risks associated with the procedure include:

- Death, stroke, paralysis (loss of muscle function), permanent disability, or severe bleeding.
- Risks to the heart, including heart attack or heart failure, sudden loss of heart function, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pacemaker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis (narrowing), too much fluid around the heart, injury to the structure of the heart.
- Risks to your lungs or breathing, including difficulty breathing, fainting, dizziness, buildup of fluid in or around the lungs, weakness, or inability to exercise.
- Risks involving bleeding or your blood supply, including formation of a blood clot, high or low blood pressure, limited blood supply, a decrease in red blood cells, or abnormal lab values, bleeding in the abdominal cavity, collection of blood under the skin, serious damage to the arteries, severe bleeding in the heart or in the body that could require a transfusion or surgery.
- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection, or bleeding at incision sites, or swelling.

Additional potential risks specifically associated with the use of the heart valves include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery or emergency heart surgery and possible removal of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), valve issues not related to structure (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage) or mechanical failure of the delivery system and/or accessories.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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EXHIBIT 77

Edwards



Deliver Outcomes you Demand

As a leader in heart valves for over 60 years, Edwards Lifesciences is dedicated to providing you a destination for the latest transcatheter heart valve information, tools, resources, and innovative solutions.

Introducing SAPIEN 3 Ultra valve, now powered by RESILIA tissue

SAPIEN 3 Ultra RESILIA valve takes TAVR even further with the potential to improve valve longevity and reduce reintervention.*† Building on the benefits of the SAPIEN 3 platform, SAPIEN 3 Ultra RESILIA valve features a proprietary calcium-blocking technology, the same tissue technology used in the #1 implanted surgical valve in the US, and is the only transcather heart valve (THV) with dry tissue storage.

Learn about SAPIEN 3 Ultra RESILIA valve →



Edwards SAPIEN 3 Ultra RESILIA Valve

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

†RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model. Flameng, et al. *J Thorac Cardiovasc Surg* 2015;149:340–5.

Training and education programs

We offer training on the safe and effective use of our technology, and education programs designed to optimize procedures to better serve your patients.

Review tools →

Important Safety Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in

The resource library contains the latest data, patient guides, best practices and additional materials to help you and your Heart Team stay current and well-informed.

Get TAVR Resources →

ACC/AHA Guideline expands TAVR as a Class I recommendation

The ACC/AHA released key updates in their 2020 Guideline for Valvular Heart Disease, including recommendations for the treatment of severe symptomatic aortic stenosis and transcatheter valve repair/implantation for patients. Have these guidelines readily available for your team.

View the pocketguide →





Your first-time valve choice today affects your patients' treatment options

Important Safety Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in

tomorrow[1]

As you expand TAVR to new patient populations, protecting the lifetime management of your patients becomes the new standard.

See the data →



Edwards SAPIEN 3 Ultra TAVR



Medical information request

Edwards Lifesciences is committed to providing healthcare professionals with accurate, unbiased, and balanced evidence-based product information in order to support clinical decision-making and facilitate better patient outcomes.

Request Transcatheter Heart Valve Medical Information →

Important Safety Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in



Research and education grants

Through its educational and research grant programs, Edwards Lifesciences is committed to supporting independent programs that further clinical knowledge, scientific exchange, medical education and delivery of effective therapies for structural heart disease and critical care monitoring, and is further committed to supporting independent research in the area of valve science and hemodynamic monitoring in order to enhance scientific knowledge for the purpose of extending and enhancing human life.

Go to the Edwards Lifesciences Grant portal →

Stay connected

Be the first to receive the latest news in transcatheter heart valves, including event announcements.

Register for updates →

References: **1.** De Backer O, Landes U, Fuchs A, et al. Coronary access after TAVR-in-TAVR as evaluated by multidetector computed tomography. *JACC Cardiovasc Interv*. 2020; 13(21):2528-2538.

Important Safety Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in

COOKIE PREFERENCES

Important Safety Information

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Edwards

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EXHIBIT 78

Edwards

Living. Proof.

To you, it's giving your low-risk severe aortic stenosis patients a chance for superior* outcomes.

For him, it's setting the stage for an incredible encore.

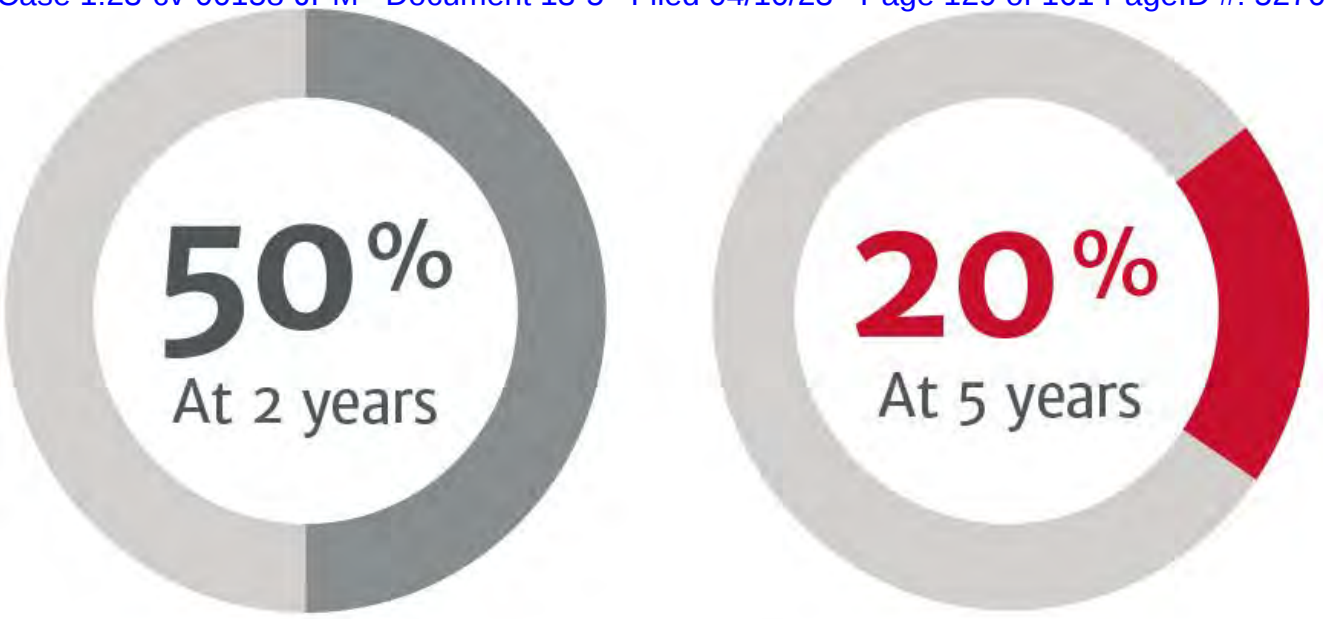


Read the recently published ACC/AHA Guideline, which highlights TAVR for a treatment of valvular heart disease.

No one knows your symptomatic severe aortic stenosis (SAS) patients like you do.

They count on your expertise to guide them. The path to the best chance at superior* outcomes for your low surgical risk patients.

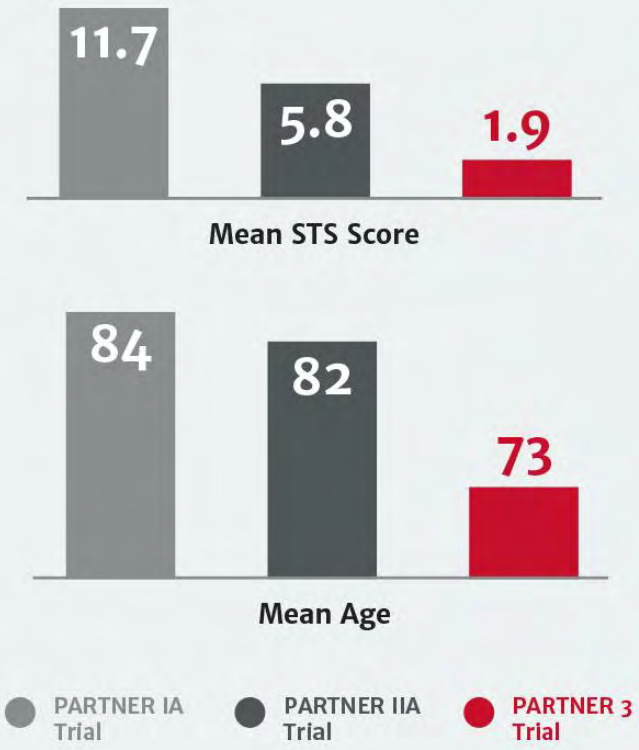
* The PARTNER 3 TRIAL, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint all-cause death, all stroke, and rehabilitation and multiple pre-specified secondary endpoints.



Patient survival rate as low as after symptoms onset[1]

Severe aortic stenosis is progressive and can quickly become life-threatening

Even when your patients don't acknowledge symptoms attributed to severe aortic stenosis, they trust you to identify the signs of severe aortic stenosis and they trust you to know when to act.[2] Delays in referral for AVR treatment cost lives.[3] A plan for aortic valve replacement as soon as symptoms occur gives SAS patients the best possible chance at survival.

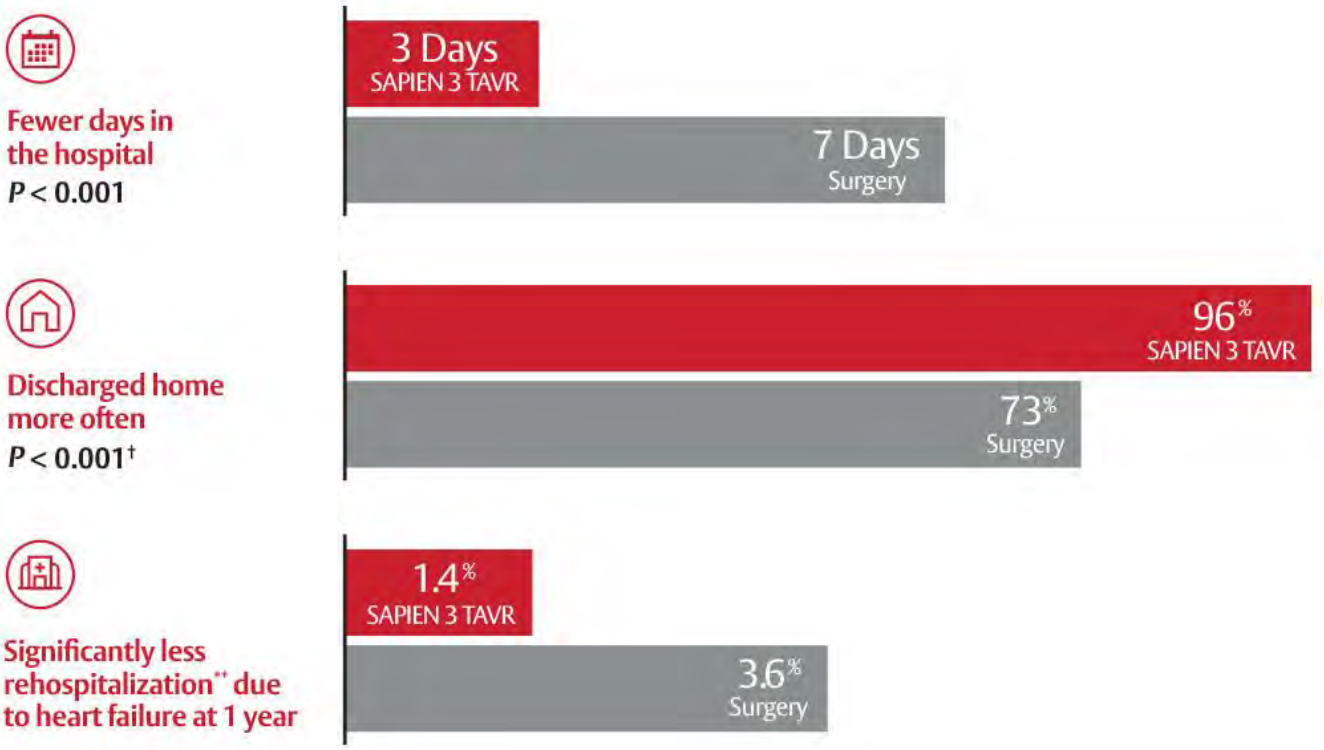




Free even your *low-risk surgical patients* from the burden of SAS with TAVR

The PARTNER 3 Trial demonstrated unprecedented clinical outcomes with SAPIEN 3 TAVR, and is now proven superior* to surgery in low-risk symptomatic SAS patients.[4] So, you can consider your low-risk patients' individual health and lifestyle needs, and guide them to a lower-risk treatment option.

* The PARTNER 3 TRIAL, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint all-cause death, all stroke, and rehabilitation and multiple pre-specified secondary endpoints.



Give your patients the chance to get back to their lives faster

SAPIEN 3 TAVR is proven superior* across outcomes that matter most to your patients.[4,5] TAVR patients recovered more rapidly than surgical patients, experiencing a better quality of life from baseline† and a greater feeling of well-being at 30 days.[6]

*The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint all-cause death, all stroke, and rehospitalization‡ and multiple pre-specified secondary endpoints.
†Excludes multiplicity adjustment.
**Rehospitalization (valve-related or procedure-related and including heart failure).



Your SAS patients trust you to guide them to the right treatment

Unlock the path to the best chance at superior* outcomes for your low surgical risk patients by guiding all your patients with valvular heart disease to a Multidisciplinary Heart Valve Team for timely treatment evaluation.

Collaborate with a Heart Team →

*The PARTNER 3 TRIAL, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint all-cause death, all stroke, and rehabilitation and multiple pre-specified secondary endpoints.

References: **1.** Otto CM. Timing of aortic valve surgery. *Heart.* 2000;84:211-18. **2.** 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease. *JACC* 2014;63(22);e57-185. **3.** Malaisrie SC, McDonald E, Kruse J, et al. Mortality while waiting for aortic valve replacement. *Ann Thorac Surg.* 2014;98:1564-71. **4.** Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019;380(18):1695-1705. **5.** Leon MB, Mack MJ. PARTNER 3: transcatheter or surgical aortic valve replacement in low risk patients with aortic stenosis. Presented at ACC 2019; March 2019; New Orleans, LA. **6.** The Partner 3 Trial Clinical Study Report; April 2019.

Important Safety Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The valves and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections, or who have significant annuloplasty ring dehiscence.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. The devices are designed, intended, and distributed for single use only. Do not resterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Incorrect sizingof the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its s ipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing prostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken or the storage solution does not completely cover the valve (SAPIEN 3 and SAPIEN 3 Ultra only), the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution (SAPIEN 3 and SAPIEN 3 Ultra only), rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Do not perform stand-alone balloon aortic valvuloplasty procedures in the INSPIRIS RESILIA aortic valve for the sizes 19-25 mm. This may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial annuloplasty ring dehiscence due to high risk of PVL. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial (incomplete) annuloplasty rings in the absence of annular calcium due to increased risk of valve embolization. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of rigid annuloplasty rings due to increased risk of PVL or THV deformation.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durab of the valve has not been established. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or

breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. If a significant increase in resistance occurs when advancing the catheter through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications. As compared to SAPIEN 3, system advancement force may be higher with the use of SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA THV in tortuous/challenging vessel anatomies. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium preventing safe transseptal access. Special care must be exercised in mitral valve replacement to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; pre-existing prosthetic ring in the tricuspid position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; access characteristics that would preclude safe placement of the Edwards sheath, such as severe obstructive calcification or severe tortuosity; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing prosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture, annuloplasty ring dehiscence); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage. For left/right axillary approach, ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery. Residual mean gradient may be higher in a "THV-in-failing prosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting prosthesis be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; thoracic bleeding; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury or brachial plexus injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve, Edwards SAPIEN 3 Ultra transcatheter heart valve, and the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

COOKIE PREFERENCES

Important Safety Information

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EXHIBIT 79

Edwards



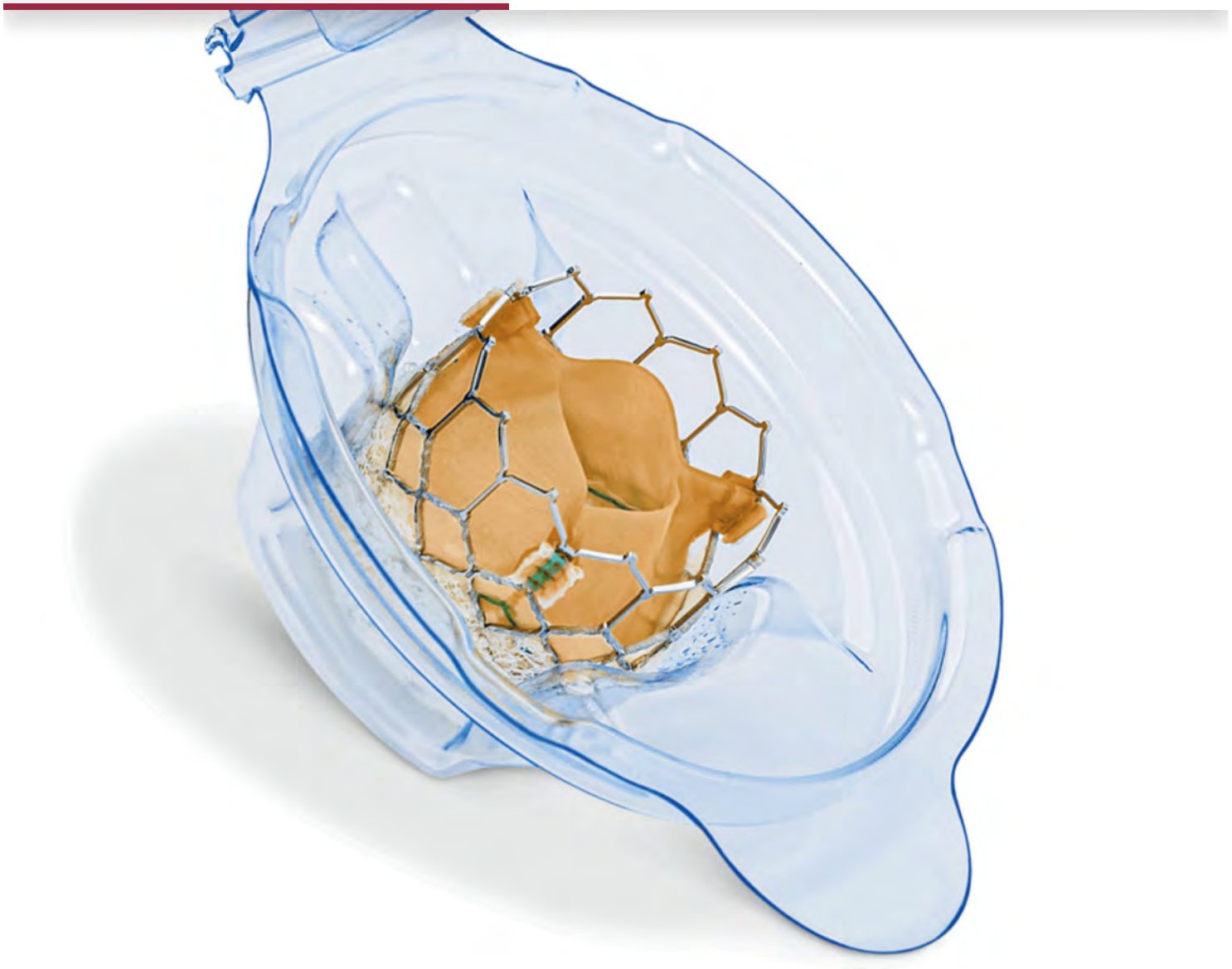
Building on the benefits of the SAPIEN 3 platform

SAPIEN 3 Ultra valve, now powered by RESILIA tissue



Important safety information

The SAPIEN 3 ULTRA RESILIA system | How it works | Clinical data

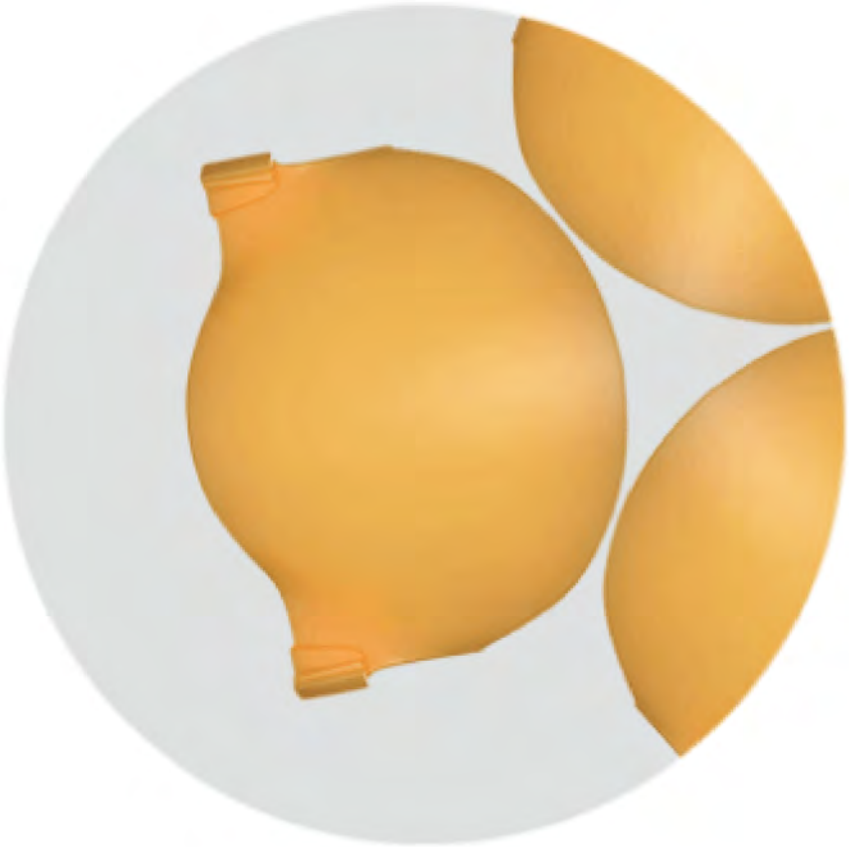




Important safety information



Advanced calcium-blocking technology*[1]



Same tissue technology used in the #1 implanted surgical valve in the US

Important safety information



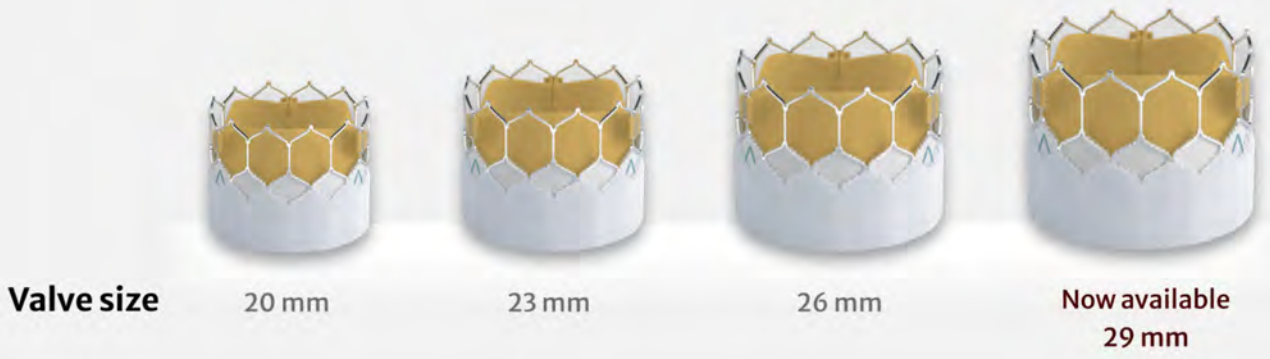
Potential to improve valve longevity and reduce reintervention*†[1]



Important safety information

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. †RESILIA tissue tested against tissue from commercially available bovine pericardial from Edwards Lifesciences in a juvenile sheep model. Flameng, et al. J Thorac Cardiovasc Surg.

The SAPIEN 3 Ultra valve outer paravalvular leak skirt now available in the 29mm valve size



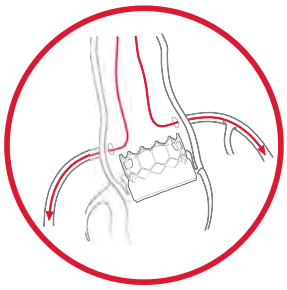
SAPIEN 3 TAVR fully addresses the vital considerations for lifetime management

Important safety information



Superior outcomes*[2]

- 1% death and disabling stroke at one year[2]
- 90.9% none/trace PVL at discharge[3]
- 6.5% new pacemaker rate at 30 days[2]



Facilitates future treatment options

- 100% successful post–TAVR coronary access rate (68/68 patients)[4]
- The only valve with a THV–in–THV indication



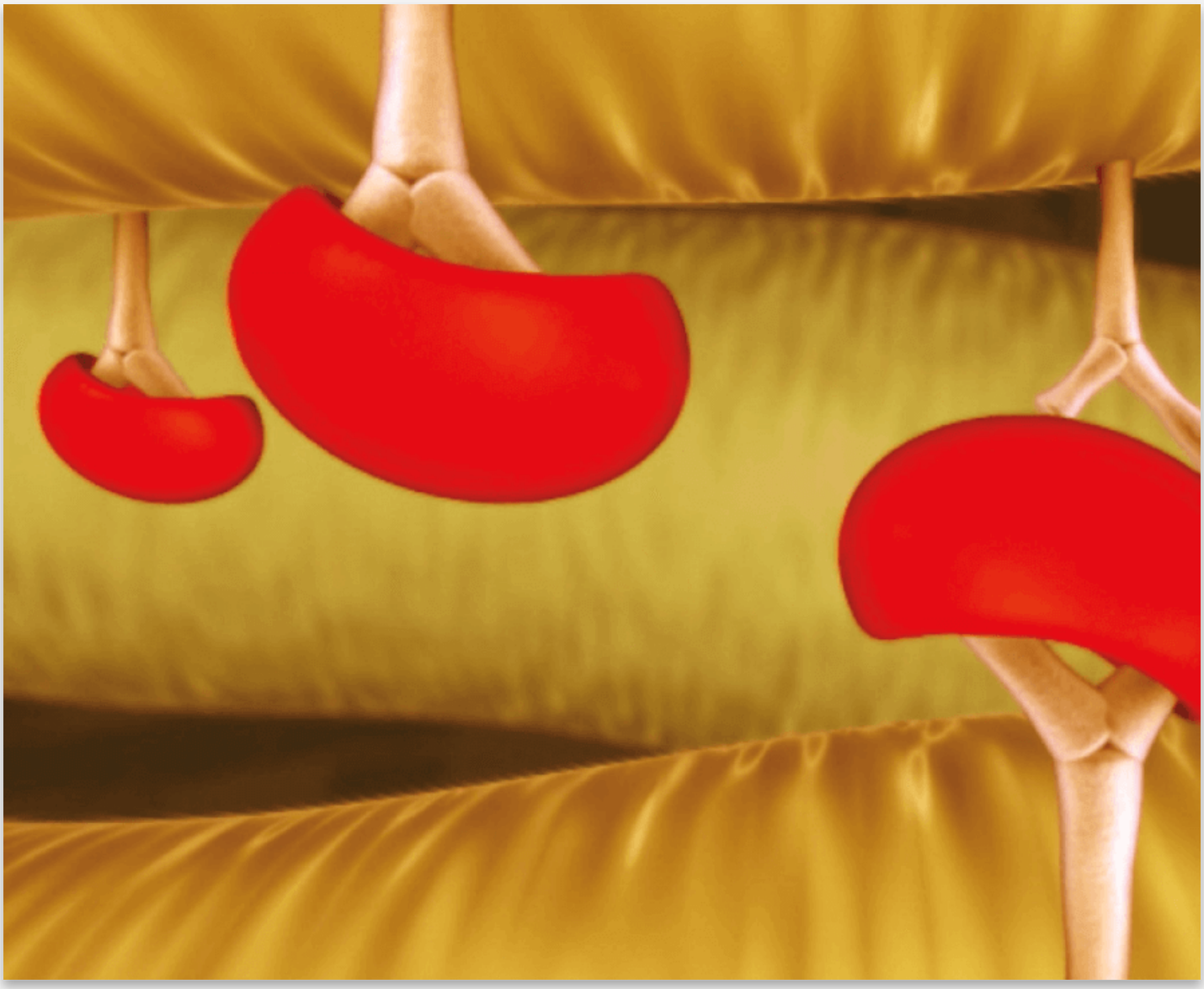
Durability that stands up to SAVR†[5]

- SAPIEN 3 valve durability proven similar to SAVR at 5 years[5]

Important safety information

Advanced calcium blocking technology*[1]

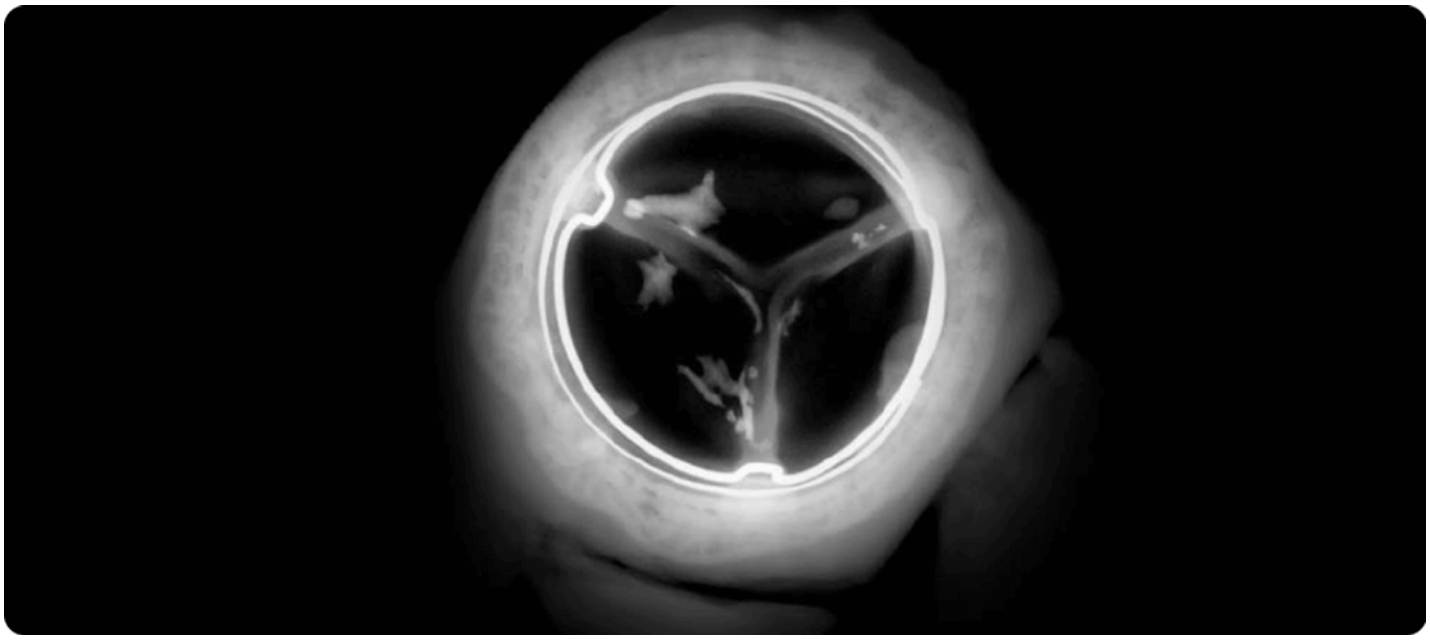
Stable-capping blocks calcium from binding to the tissue*[1]



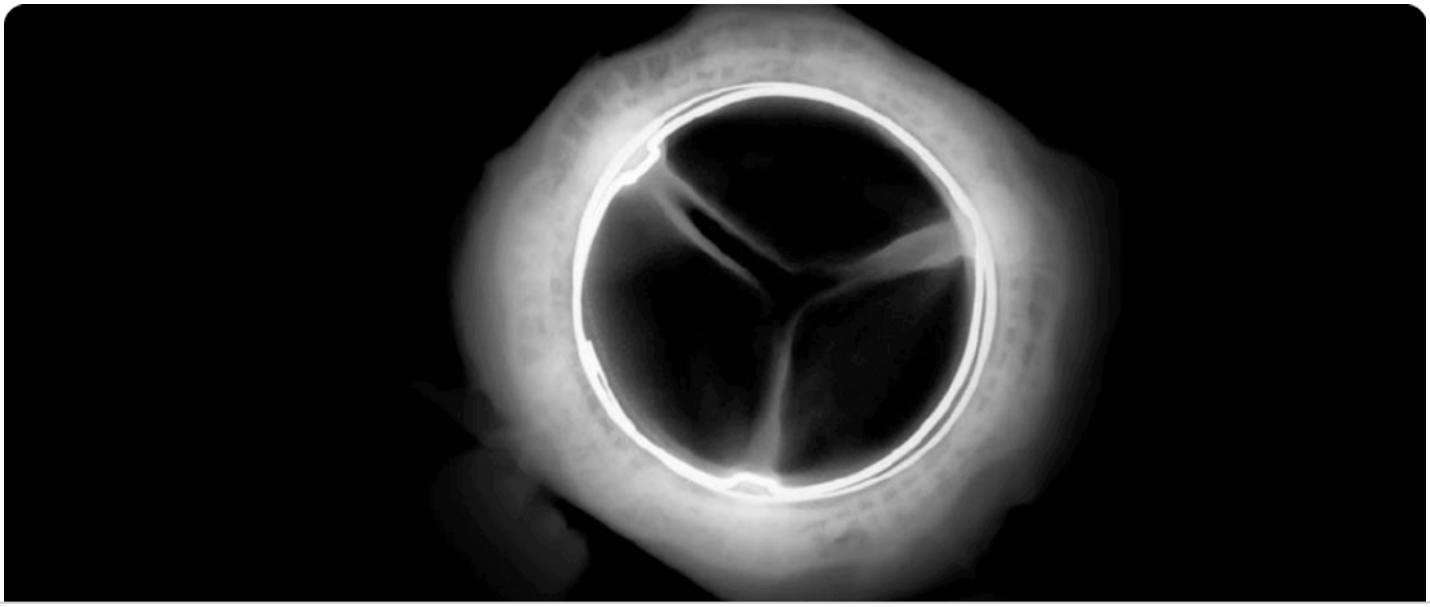
*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients

Important safety information

compared to traditional surgical valve tissue treatments*[1]

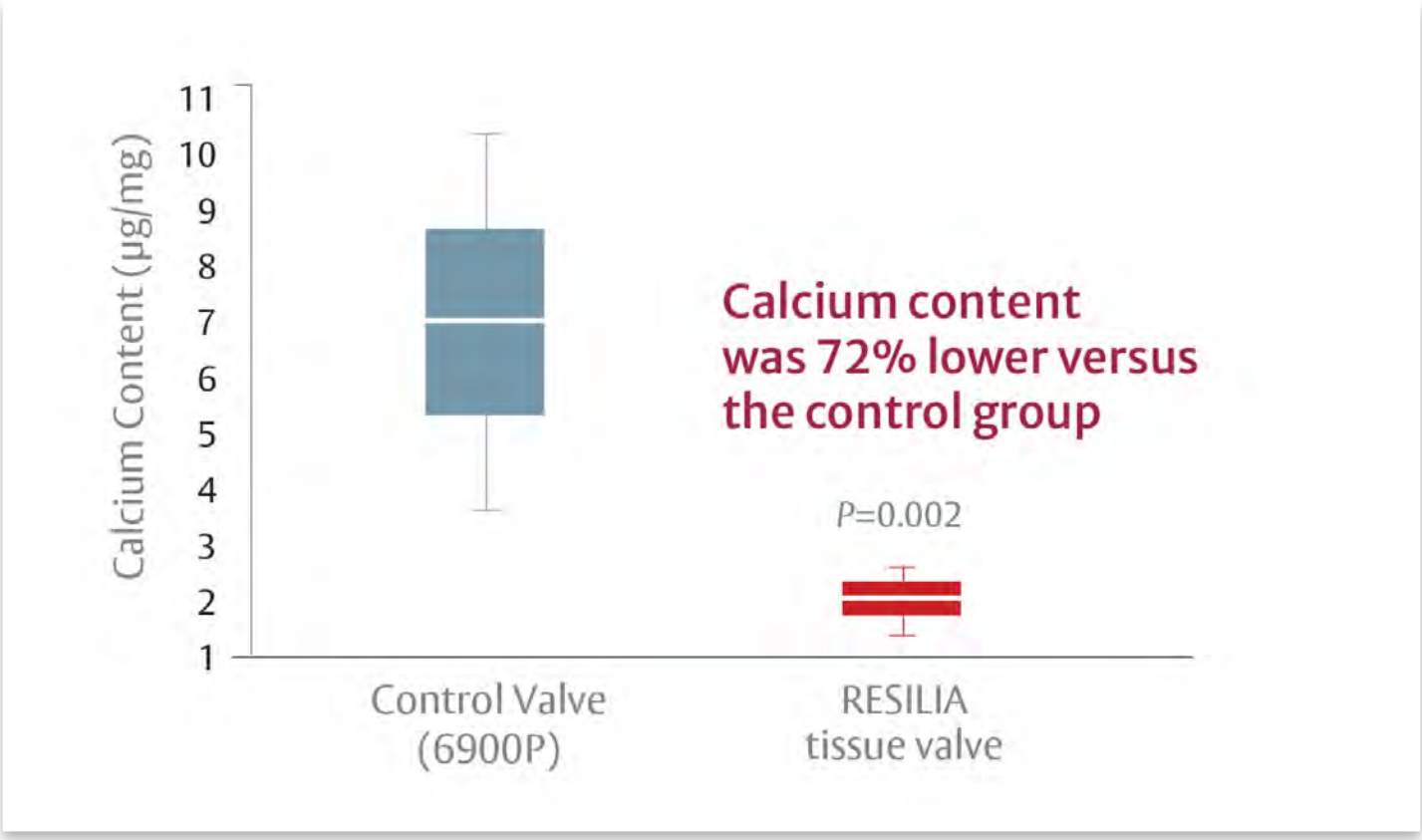


Control valve (6900P)



Important safety information

RESILIA tissue showed significant improvement in calcium-blocking properties

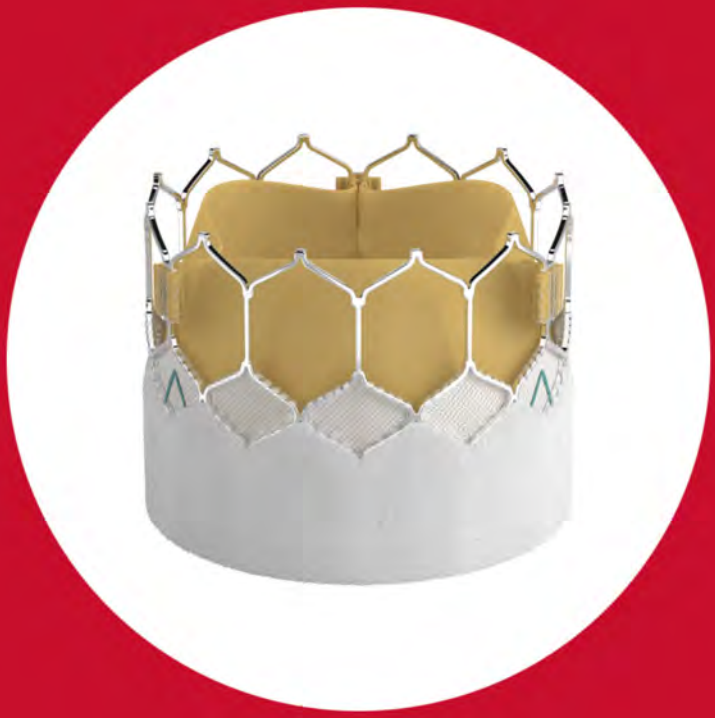


*RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model. Flameng, et al. J Thorac Cardiovasc Surg. 2015;149:340-345.

See the clinical evidence behind RESILIA tissue

Important safety information

Download now



References

1. Flameng W, et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. J Thorac Cardiovasc Surg. 2015;149:340 -5.
2. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380:1695-1705. doi:10.1056/NEJMoa1814052.
3. Nazif TM, Cahill TJ, Daniels D, et al. Real-world experience with the SAPIEN 3 ultra transcatheter heart valve: a propensity-matched analysis from the United States. Circ Cardiovasc Interv. 2021;14:e010543.

Important safety information

Important safety information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The valves and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections, or who have significant annuloplasty ring dehiscence.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing prostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the

Important safety information

delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution (SAPIEN 3 and SAPIEN 3 Ultra only), rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Do not perform stand-alone balloon aortic valvuloplasty procedures in the INSPIRIS RESILIA aortic valve for the sizes 19-25 mm. This may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial annuloplasty ring dehiscence due to high risk of PVL. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial (incomplete) annuloplasty rings in the absence of annular calcium due to increased risk of valve embolization. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of rigid annuloplasty rings due to increased risk of PVL or THV deformation.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. If a significant increase in resistance occurs when advancing the catheter through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications. As compared to SAPIEN 3, system advancement force may be higher with the use of SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA THV in tortuous/challenging vessel anatomies. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium preventing safe transseptal access. Special care must be exercised in mitral valve replacement to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; pre-existing prosthetic ring in the tricuspid position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia

Important safety information

greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; access characteristics that would preclude safe placement of the Edwards sheath, such as severe obstructive calcification or severe tortuosity; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing prosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture, annuloplasty ring dehiscence); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage. For left/right axillary approach, ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery. Residual mean gradient may be higher in a "THV-in-failing prosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting prosthesis be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; thoracic bleeding; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury or brachial plexus injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation;

Important safety information

SAPIEN 3 Ultra transcatheter heart valve, and the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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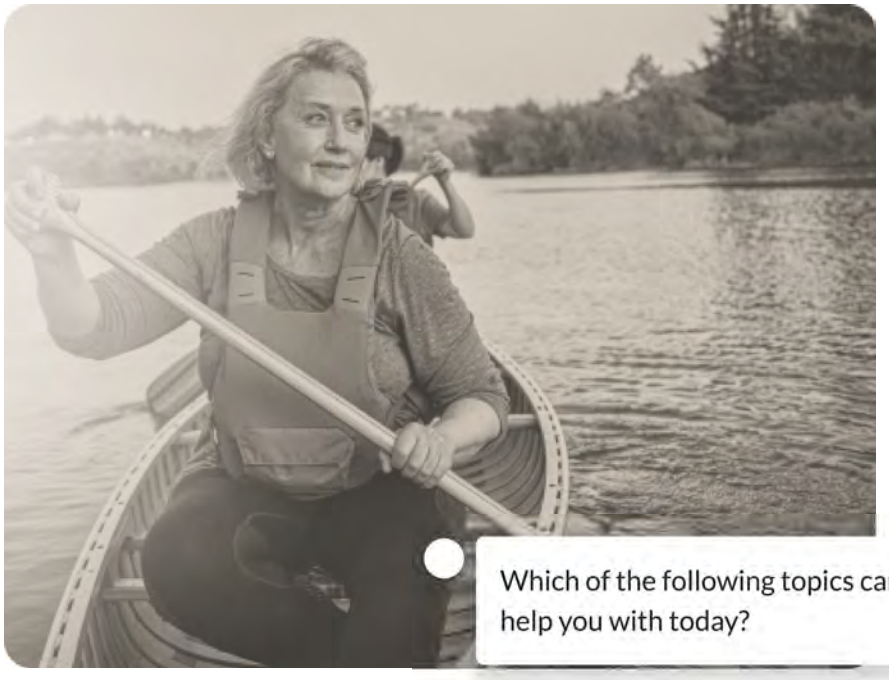
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Stop? I'm just getting started.

Transcatheter aortic valve replacement (TAVR)

Learn more



What are you waiting for?

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Get back to life with TAVR, the less invasive aortic heart valve replacement option for severe aortic stenosis

Ask your doctor for a TAVR evaluation today.

Find out if TAVR is right for you

Aortic stenosis is a progressive disease that affects up to



2.5 Million
people over the age of 75 in the United States.

Once it advances to the severe stage, the deadly disease won't wait for you to delay treatment.[1,2]

Learn what causes aortic stenosis

After the onset of symptoms, patients with severe aortic stenosis have a survival rate



as low as
50%

at 2 years, without heart valve replacement.[3]

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Learn why treatment can't wait

On average, transcatheter aortic valve replacement is a



that can treat your severe aortic stenosis, with next day discharge for most patients. This allows you to get back to your life quicker.

Learn about less invasive TAVR

Can a heart valve be replaced without open heart surgery?

Yes. In fact, TAVR should be considered for all patients suffering from severe aortic stenosis and who are experiencing symptoms. With transcatheter aortic valve replacement, you don't need to have your chest opened. This less invasive option is available to patients living with severe aortic stenosis. With TAVR, patients have a shorter recovery time and most patients return home the next day. It is time to talk to your doctor about a TAVR evaluation. Take back your future by treating your severe aortic stenosis.

Explore how TAVR works

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[Video: Watch Mario's story >]



Want more information delivered directly to you?

Get a free information kit by email or mail to learn about severe

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What you'll receive in your kit:

- Education on severe aortic stenosis and symptoms checklist once it becomes severe
- Information on TAVR as a treatment option
- Videos of patients sharing their experiences with TAVR
- Discussion guide for talking with your doctor
- List of hospitals in your area that perform TAVR

Get your free info kit

References
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2. Osnabrugge RLJ, Mylotte D, Head SJ, et al. Aortic Stenosis in the elderly: disease prevalence and number of candidates for transcatheter aortic valve replacement: a meta-analysis and modeling study. J Am Coll Cardiol. 2013;62(11):1002-1012.
3. Otto C. Timing of aortic valve surgery [Valve Disease]. Heart. 2000;84(2):211-218.

Important Risk Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications:

The Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic

ring who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications (Who should not use):

The Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System should not be used in patients who:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.
- Have a mitral ring that is damaged and can no longer support the valve.

Warnings:

The Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System should not be used in patients who:

- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are sensitive to anesthesia, contrast media, cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or plastics.
- The Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves may not last as long in younger patients, or patients with a disease that results in more calcium in their blood.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage. X-ray guidance used during the procedure may cause injury to the skin, which may be painful, damaging, and long-lasting.

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- Patients who have already had a valve replaced should be carefully assessed by their physician prior to receiving a new valve to ensure proper placement of the new valve.
- Injury can occur if the delivery system is not used properly.
- Transcatheter heart valve patients should talk to their physicians about the potential need for medications that thin the blood or prevent blood clots from forming. Patients who do not may be at increased risk of a stroke. Blood-thinning medication may increase the risk of bleeding in the brain (stroke).
- Transcatheter valve replacement is not recommended in previous mitral valve rings that are damaged or have become too rigid.

Precautions:

The long-term durability of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 transcatheter heart valves are not known at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. Limited clinical data are available for transcatheter aortic valve replacement in patients who are born with an aortic heart valve that has only two leaflets and who are determined to be at low risk for open heart surgery. A patient's anatomical characteristics should be considered by their physicians when using the valve in this patient population. In addition, patient age should be considered as long-term durability of the valve has not been established. Patients who need a dental procedure should talk to their doctor about risk of infection and needing antibiotics. Patients should be treated post-procedure for heart infection as a precaution.

The safety and effectiveness of the transcatheter heart valves are also not known for patients who have:

- An aortic heart valve that is not calcified, contains only one leaflet, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks.
- Who have a prosthetic ring in the tricuspid position.
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities

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syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors.

- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly.
- Diseased, abnormal, or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for the delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- Whose previously implanted artificial valve or ring is not securely in place or is damaged that could cause it to leak.
- Whose previously implanted valve or ring could block a blood vessel caused from the leaflet partially detaching.

Potential risks associated with the procedure include:

- Death, stroke, paralysis (loss of muscle function), permanent disability, or severe bleeding.
- Risks to the heart, including heart attack or heart failure, sudden loss of heart function, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pacemaker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis (narrowing), too much fluid around the heart, injury to the structure of the heart.
- Risks to your lungs or breathing, including difficulty breathing, fainting, dizziness, buildup of fluid in or around the lungs, weakness, or inability to exercise.
- Risks involving bleeding or your blood supply, including formation of a blood clot, high or low blood pressure, limited blood supply, a decrease in red blood cells, or abnormal lab values, bleeding in the abdominal cavity, collection of blood under the skin, serious damage to the arteries, severe bleeding in the heart or in the body that could require a transfusion or surgery.

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- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection, or bleeding at incision sites, or swelling.

Additional potential risks specifically associated with the use of the heart valves include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery or emergency heart surgery and possible removal of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), valve issues not related to structure (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage) or mechanical failure of the delivery system and/or accessories.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

Stay Informed

Stay informed about severe aortic stenosis and its treatment options, including transcatheter aortic valve replacement (TAVR).

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*Stock Advisor returns as of September 17, 2021

Mark Wilterding -- *Vice President, Investor Relations*

Thanks, Diego. Good afternoon and thank you for joining us everyone. With me on today's call are Mike Mussallem, Chairman and Chief Executive Officer; and Scott Ullem, Chief Financial Officer. Just after the close of regular trading, Edwards Lifesciences released fourth quarter 2020 financial results. During today's call, Management will discuss those results included in the press release and accompanying financial schedules and then use the remaining time for Q&A. Please note that Management will be making forward-looking statements that are based on estimates, assumptions, and projections. These statements include, but aren't limited to financial guidance and expectations for longer-term growth opportunities, regulatory approvals, clinical trials, litigation, reimbursement, competitive matters, and foreign currency fluctuations. These statements speak only as of the date when they were made and Edwards does not take -- undertake any obligation to update them after today. Additionally, the statements involve risks and uncertainties, including but not limited to those associated with the pandemic that could cause actual results to differ materially. Information concerning factors that could cause these differences and important safety information may be found in the press release our 2019 Annual Report on Form 10-K and Edwards' other SEC filings, all of which are available on the company's website at edwards.com. Finally, a quick reminder that when using the terms underlying and adjusted, Management is referring to non-GAAP financial measures, otherwise they are referring to GAAP results. Reconciliations between GAAP and non-GAAP numbers mentioned during the call are included in today's press release.

With that, I'd like to turn the call over to Mike for his comments. Mike?

Michael A. Mussallem -- *Chairman and Chief Executive Officer*

Thank you, Mark. Before we discuss fourth quarter's results and our expectations for 2021 and beyond, I want to spend a minute reflecting on 2020. Structural heart patients were severely impacted beginning in March, experiencing significant difficulties entering the system, which also had a profound impact on second quarter procedures and even though healthcare systems adapted to the challenge, the resurgence of COVID that began late in the year continues to impact structural heart patients, who need care. Despite unprecedented challenges throughout the year, I'm proud of our team's steadfast dedication to

challenges throughout the year, I'm proud of our team's steadfast dedication to our patient-focused strategy. We continue to invest in developing solutions that extend lives, improve the quality of life and offer greater value for the healthcare system. Along those lines, we celebrated some exciting milestones in 2020 that directly impacted patients. In TAVR, despite headwinds, more than 100,000 patients benefited from treatment with SAPIEN valves worldwide. In Surgical Structural Heart, we launched our KONECT aortic valved conduit and Inspiris became the leading aortic surgical valve worldwide. We've seen early positive clinical evidence across the TMTT platform, physician feedback is encouraging and patient outcomes have been distinguished. And in Critical Care, we met the increased demand for core pressure monitoring products due to the pandemic,

and we're proud that we were able to help over 1 million patients globally with our monitoring technology.

To support our innovation and growth, we continued to invest in our people and our infrastructure. During the year when job losses impacted many families across the globe, Edwards prioritized protecting our employees and we grew our team to 15,000 worldwide. We continue to make strategic R&D investments that enabled us to fuel progress and despite this unique environment and extraordinary prior year growth, underlying sales grew 1% in 2020 to $4.4 billion, which is a reflection of the life-threatening needs of the patients that Edwards serves. Looking into 2021, while we expect the pandemic to continue to impact the global healthcare system, we remain optimistic about the year ahead. As we indicated at our investor conference, we expect full year sales between $4.9 billion and $5.3 billion representing mid-teens underlying growth on a year-over-year basis. Based on our year-to-date experience, we expect Q1 sales to be slightly down sequentially, although in line with the first quarter of last year, which was largely unaffected by COVID.

Our 2021 guidance continues to assume COVID will stress the global healthcare system, it leads through the winter months with procedures ramping later in the year. This expectation assumes that vaccines are effective and widely administered by mid-year 2021 and hospitals continue to improve their ability to treat non-COVID patients, who need care for conditions such as aortic stenosis and even though we expect the COVID impact on sales at the start of the year, we are continuing to invest now in our innovations that have the tremendous opportunity to enhance patients' lives and bring significant value to the healthcare system. We recognize the uncertain impact and timeframe for recovery from this unique global challenge, but we remain confident that our patient-focused strategy of continued investment positions us well and even stronger when the world emerges from the pandemic.

Now turning to our quarterly results, consistent with our guidance at our

Now turning to our quarterly results, consistent with our guidance at our investor conference last month, fourth quarter sales of $1.2 billion were in line with the year ago period when Edwards' grew nearly 20% on an underlying basis, reflecting the strength, even during the ongoing pandemic. Full-year 2020 global sales -- global TAVR sales of 2.9 billion increased 4% on an underlying basis over the prior year. 2020 growth reflected increased sales in every region lifted by greater awareness of the benefits of TAVR therapy and increased adoption of our leading technologies. Based on the strength of the SAPIEN platform, we retained our strong leadership position while also maintaining our disciplined price strategy. In the fourth quarter, global TAVR sales were $776 million, up slightly from the year ago period. We estimate global TAVR procedure growth was

comparable with our growth and globally, average selling prices were stable. Although the rollout was somewhat impacted, SAPIEN 3 Ultra now represents more than two-thirds of our global TAVR sales and physician feedback on ease of use and improved paravalvular leak performance remains outstanding.

In the U.S., our Q4 TAVR sales were approximately level with the third quarter and declined in the mid-single digit range versus last year. We estimate overall Q4 U.S. procedures declined at a comparable rate. Recall that our U.S. TAVR sales in the year ago period increased nearly 40% driven by the strong PARTNER 3 evidence that led to a third quarter 2019 indication expansion and improved patient access under an updated TAVR NCD. We expect these factors to resume lifting treatment rates, as the pandemic subsides. Growth at smaller TAVR centers, which are providing local access to aortic stenosis patients was more than offset by declines in larger accounts, where referrals have been disrupted by the resurgence of COVID. Outside the U.S., in the fourth quarter, we estimated total TAVR procedures grew in the high single digits on a year-over-year basis and Edwards growth was comparable. Edwards' underlying TAVR growth in Europe versus the prior year was in the mid-single digit range. Growth was driven by continued strong adoption of our SAPIEN platform and was more pronounced in countries that were more severely impacted by the first wave of COVID in 2020. Outside of the U.S. and Europe, we continue to see very good TAVR adoption in the fourth quarter. Sales growth in Japan, Australia, and Korea were strong, where therapy adoption is still low. In Japan, we continue to anticipate providing SAPIEN 3 for low-risk patients prior to the end of this year. In China, which was a minor contributor to Q4 sales, we remain focused on growing our dedicated clinical support team to assist leading hospitals, as they build their TAVR programs. In addition to geographic expansion of our TAVR therapies, we remain focused on indication expansion. We talked at our recent Investor Conference about our early TAVR trial, which is focused on the treatment of asymptomatic patients. Enrollment is now two-thirds complete and we remain optimistic that the trial will be fully enrolled in 2021. Separately, we

we remain optimistic that the trial will be fully enrolled in 2021. Separately, we continue to plan to initiate an important pivotal trial for moderate aortic stenosis to determine the optimal time to treat patients, who have this progressive disease. We believe that some patients may benefit from earlier treatment, when they have moderate AS rather than risking irreversible damage as the disease progresses. We're optimistic about the potential of this trial and we anticipate FDA approval to begin enrollment this year.

In November 2020, we are pleased that the American Heart Association announced the launch of an initiative, called Target Aortic Stenosis, a quality improvement program aimed to develop optimal standards of care. The program features a learning collaborative comprised of experts and volunteers from pilot hospital locations around the nation. AHA noticed that if left untreated, the condition worsens and patients with severe aortic stenosis have a survival rate as low as 50% at two years. Aortic stenosis is also a risk factor for heart failure, a costly disease projected the cost the US Healthcare System $70 billion in 2030.

In summary, we continue to anticipate 2021 underlying TAVR sales growth in the 15% to 20% range, as we shared at our Investor Conference. We expect continuing COVID related challenges early in 2021, turning to a more normalized growth environment in the second half of the year. We remain confident in this large global opportunity will exceed $7 billion by 2024, which implies a compounded annual growth rate in the low double-digit range.

Turning to Transcatheter Mitral and Tricuspid Therapies or TMTT, we've made meaningful progress moving from early stage development to clinical use across all of our platforms with over 3,000 patients treated to-date. To transform treatment and unlock the significant long-term growth opportunity, we remain focused on three key value drivers, a portfolio of differentiated therapies, positive pivotal trial results to support approvals and adoption and favorable real-world clinical outcomes. In Europe, PASCAL leaflet repair continues to deliver excellent results. In Q4, we continued the introduction of PASCAL Ace for mitral and tricuspid patients and we're pleased with the early real world results and positive physician feedback regarding its differentiated features and narrower profile. We plan to make both PASCAL Ace and PASCAL available on a single next generation platform called the PASCAL Precision System. This new system is designed to elevate the user experience with enhanced maneuverability, navigation, and stability enabling improved procedural precision. From a clinical perspective, in this challenging near-term environment, we are experiencing a negative impact to clinical trial enrollment. However, our team and research partners are highly motivated to build on the differentiated data presented in 2020 and expand our body of clinical evidence in this exciting field. We will look

forward to presenting meaningful follow-up data across our portfolio at medical meetings later this year.

We progressed in the enrollment of our three CLASP pivotal studies. We also received approval for use of the Edwards PASCAL Precision System in these pivotal studies. The company is still expects U.S. approval of PASCAL for patients with DMR late next year. We continue to enrolling SAPIEN M3 pivotal study and Circle designed to demonstrate strong safety and efficacy for transcatheter mitral replacement and we're on track to initiate our first clinical experience with our next generation EVOQUE Mitral Replacement System. The EVOQUE tricuspid replacement study, TRISCEND continue to enroll in Q4 and we're on track to initiate the TRISCEND II randomized pivotal study based on FDA's Breakthrough pathway designation. We look forward to bringing this important treatment option to more patients that are in significant need.

Turning to recent news, we commenced CMS for ensuring mitral valve disease patients have improved access to therapy options through the updated NCD. This update, which includes coverage with Evidence Development achieves the balance of patient access with high quality outcomes. Fourth quarter global sales were $13 million, representing sequential improvement versus Q3. Full year 2020 sales were $42 million. We expect continuing COVID related challenges early in 2021, but we anticipate a ramp up through the rest of the year. We maintain our beliefs that the total TMTT sales will approximately double in 2021. We continue to estimate the global TMTT opportunity to reach $3 billion by 2025 with significant growth beyond. We remain committed to transforming the treatment of these patients and believe our portfolio strategy positions us well for ultimate leadership.

In Surgical Structural Heart, full-year 2020 global sales of $762 million decreased 10% on an underlying basis over the prior year, in line of our guidance, with our guidance of 5% to 15% decline. Fourth quarter sales of $204 million held steady with Q3 and declined 2% year-over-year on an underlying basis, which was below our previous expectation for positive growth. Over the course of the quarter, hospitals experience an influx of COVID patients limiting surgical procedures. Despite this impact, we are encouraged that the U.S. achieve positive growth in Q4, driven by adoption of our newest premium technologies. We remain very encouraged by the steady global adoption of Edwards Premium RESILIA tissue valves, including the Inspiris aortic surgical valve and the recently launched KONECT aortic valved conduit. In the fourth quarter, Inspiris valve utilization grew in all regions, and we continue to add new centers.

Sales in the U.S. are ramping for KONECT, the first preassembled ready to implant aortic tissue valve conduit for patients who require replacement of the

implant aortic tissue valve conduit for patients, who require replacement of the aortic valve, root, and the ascending aorta, which is a critical unmet patient need. We continue to focus on comprehensive physician training and robust data collection for the HARPOON Beating Heart Mitral Valve Repair System. We are seeing favorable patient outcomes with faster surgery and recovery times with this minimally invasive therapy. The U.S. pivotal trial is now under way and the first patient was treated in December. In summary, we expect full-year 2021 underlying sales growth in the high single-digit range for surgical structural heart driven by market adoption of our newest technologies. After a challenging start, we expect improving year-over-year comparisons, as we progress through the year. We are excited by our ability to provide innovative surgical treatment options for more patients and to extend our global leadership in premium Surgical Structural Heart technologies. We believe the current $1.8 billion Surgical Structural Heart opportunity will grow mid single digits through 2026.

In Critical Care, full year 2020 global sales of $725 million decreased 3% on an underlying basis versus the prior year, in line with our guidance of flat to down 5%. Fourth quarter Critical Care sales of $198 million decreased 2% on an underlying basis, driven by the decline in HemoSphere orders in the U.S., as hospitals limited their capital spending. Sales of our TruWave disposable pressure monitoring devices used in the ICU were lifted by the increased COVID hospitalizations late in the fourth quarter in both the U.S. and Europe. Demand for our products used in more intense surgeries remains strong, but were more than offset by the impact of delayed elective procedures. In summary, we expect full-year 2021 underlying sales growth in the high single-digit range for critical care. We remain excited about our pipeline of Critical Care innovations, as we continue to shift our focus to smart recovery technologies designed to help clinicians make better decisions for their patients.

Now, I'll ask Scott to provide some more detail on the company's financial results.

Scott B. Ullem -- *Corporate Vice President, Chief Financial Officer*

Hey, thanks a lot Mike. Today, I'll provide a wrap-up of 2020 including detailed results from the fourth quarter as well as provide an update on guidance for the first quarter and full year of 2021. Despite the wave of COVID that began during the fourth quarter, we are pleased that we were able to achieve our sales guidance ranges across all product lines. Sales in the fourth quarter were flat year-over-year on an underlying basis and adjusted earnings per share grew 2% to $0.50 versus the prior year. GAAP earnings per share was similar at $0.49. For the full year 2020, sales increased 1% on an underlying basis to $4.4 billion, adjusted earnings per share was flat at $1.86 and we generated over $700 million

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Premarket Approval (PMA)

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	SAPIEN 3 Ultra Transcatheter Heart Valve System
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered
Applicant	EDWARDS LIFESCIENCES, LLC. One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S099
Date Received	10/21/2019
Decision Date	01/27/2021
Product Code	NPT[24]
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track No User Fee
Supplement Reason	Location Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval for the Edwards Costa Rica manufacturing site to manufacture the SAPIEN 3 Ultra transcatheter heart valve (Model 9750TFX, sizes 20mm, 23mm, and 26mm), located at:Zona Franca La Lima, De la entrada de Pequeno Mundo 100 mts oeste y 200 mts surFinca 31 y 32Guadalupe, CartagoCosta Rica 30106

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