IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AORTIC INNOVATIONS LLC, **Plaintiff,** **v.** **EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES (U.S.) INC.,** **Defendants.**	)	**C.A. NO. 1-23--CV-00158 (JPM)** **DEMAND FOR JURY TRIAL**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Edwards v. Aortic Innovations
U.S. Patent 11,497,634
Edwards Ex. 1122

Plaintiff Aortic Innovations LLC ("Aortic" or "Plaintiff") files this Second Amended Complaint against Defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc. (collectively "Edwards" or "Defendants") and hereby alleges as follows:

NATURE OF ACTION

1. Aortic alleges that Edwards has infringed and continues to infringe at least one claim of U.S. Patent Nos. 11,337,834 ("the '834 Patent"); 11,389,310 ("the '310 Patent"); 11,491,033 ("the '033 Patent"); 11,497,634 ("the '634 Patent"); 11,523,918 ("the '918 Patent") (collectively, "Patents-in-Suit") (Exs. 1-2; 71-73).

2. Aortic was founded in 2011 to develop the ideas of Dr. Ali Shahriari to help patients with damaged aortic valves. Dr. Shahriari is a cardiothoracic surgeon based in Florida who has practiced for more than 20 years and focused on treating the toughest cardiology cases. Originally from Sweden, Dr. Shahriari received his medical degree from University of Gothenburg Faculty of Medicine and trained at the Mayo Clinic and at Yale University. During his work as a cardiothoracic surgeon, Dr. Shahriari conceived of the inventions reflected in the Patents-in-Suit for performing transcatheter aortic valve replacements ("TAVR").

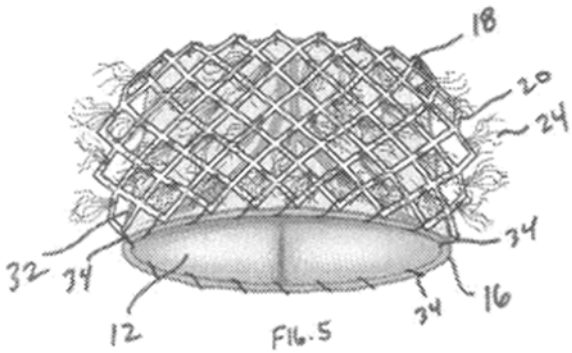
3. TAVR is a procedure where a replacement aortic heart valve is delivered by a catheter that is passed through an artery of a patient. Prior to TAVR, patients undergoing heart valve replacement would have their chest incised in an open heart procedure called Surgical Aortic Valve Repair ("SAVR"). SAVR often led to increased complications and was not deemed suitable for high risk patients who were often determined to be inoperable. The first TAVR device was approved in the United States by the Food and Drug Administration in 2011. Since that time,

TAVR has become the leading choice for aortic valve replacement compared to the SAVR approach, with the number of TAVR procedures exceeding the number of SAVR procedures for the first time in 2019. Ex. 5, *TAVR Is Now Dominant Form of Aortic Valve Replacement in the United States* (November 17, 2020), https://www.dicardiology.com/article/tavr-now-dominant-form-aortic-valve-replacement-united-states.

4. Foreseeing the promise of TAVR in his work as a cardiothoracic surgeon, Dr. Shahriari was at the forefront of TAVR technology development. By 2012, Dr. Shahriari conceived of TAVR devices that use an outer covering with fibers to promote sealing and aid in the prevention of paravalvular leaks—*e.g.*, leaks around the TAVR device. Since that time, Dr. Shahriari has worked on refining his ideas and—together with Aortic—has filed patent applications on his inventions in the United States and elsewhere. Aortic has secured numerous patents on Dr. Shahriari's revolutionary inventions in this technology space, including the Patents-in-Suit, which cover various TAVR assemblies.

5. Edwards infringes the Patents-in-Suit through the manufacture, use, sale, offer for sale, and/or import of at least all versions and sizes of Edwards' Sapien 3 Ultra. On information and belief, Edwards' Sapien 3 Ultra is a transcatheter aortic heart valve deployed using a balloon catheter where the heart valve has an outer covering with fibers to aid in the prevention of paravalvular leaks. On information and belief, Edwards has marketed and sold Sapien 3 Ultra to others in the medical industry, including hospitals, medical centers, doctors, clinicians, care providers and patients, with knowledge of Aortic's intellectual property asserted herein. As a result of such actions, Edwards infringes, contributes to the infringement of, and/or induces the infringement of each of the Patents-in-Suit.

6. The similarities between the patent applications filed by Dr. Shahriari and the Sapien 3 Ultra product sold by Edwards are striking. The following images showing drawings from Dr. Shahriari's 2012 patent application (on the left) next to the Sapien 3 Ultra product (on the right) demonstrate these similarities:





Compare Ex. 6, U.S. Prov. Pat. App. No. 61/723,446, Figure 5 with Ex. 3, Sapien 3 Ultra, Sapien 3 Ultra image, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth.

PARTIES

7. Plaintiff Aortic Innovations LLC is a company organized under the laws of the State of Florida, with a principal place of business in Hillsboro Beach, Florida.

8. On information and belief, Defendant Edwards Lifesciences Corporation is a corporation organized under the laws of the state of Delaware, with its principal place of business at 1 Edwards Way, Irvine, CA 92614. On information and belief, Edwards Lifesciences Corporation is registered with the Delaware Secretary of State to transact business in Delaware. On information and belief, Edwards Lifesciences Corporation maintains a registered agent in

Delaware, namely The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Edwards Lifesciences Corporation is the ultimate parent company of Edwards Lifesciences LLC, Edwards Lifesciences (U.S.) Inc. and other Edwards Lifesciences entities. On information and belief, Defendant Edwards Lifesciences Corporation is the registrant of the website www.newheartvalve.com.

9. On information and belief, Defendant Edwards Lifesciences LLC is a limited liability company organized under the laws of the state of Delaware, with its principal place of business at 1 Edwards Way, Irvine, CA 92614. On information and belief, Edwards Lifesciences LLC is registered with the Delaware Secretary of State to transact business in Delaware, namely The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Edwards Lifesciences LLC is a wholly-owned subsidiary of Edwards Lifesciences Corporation and/or Edwards Lifesciences (U.S.) Inc. On information and belief, Defendant Edwards Lifesciences LLC is the registrant of the websites www.edwards.com and www.tavrbyedwards.com.

10. On information and belief, Defendant Edwards Lifesciences (U.S.) Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 1 Edwards Way, Irvine, CA 92614. On information and belief, Edwards Lifesciences (U.S.) Inc. is registered with the Delaware Secretary of State to transact business in Delaware, namely The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Edwards Lifesciences (U.S.) Inc. is a wholly-owned subsidiary of Edwards Lifesciences Corporation.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over the patent infringement claims asserted in this case under 28 U.S.C. §§ 1331 and 1338.

12. This Court has personal jurisdiction over each named Edwards entity. Each named Edwards entity is incorporated in, present within, and/or has minimum contacts within the State of Delaware and this judicial district and has purposefully availed itself of the privileges of conducting business in the State of Delaware and in this judicial district. Further, Aortic's causes of action arise directly from Defendants' business contacts and other activities in the State of Delaware and in this judicial district.

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400 because Edwards has committed, and continues to commit, acts of infringement in this District and is incorporated in and has regular and established places of business in this District. On information and belief, each of the named Edwards entities maintains regular and established places of business in the District including at its affiliated hospitals in this District. Further, venue is proper because Edwards conducts substantial business in this forum, including: (i) at least a portion of the infringements alleged herein; and (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct and/or deriving substantial revenue from goods and services provided to individuals in Delaware and this District.

14. On information and belief, Edwards has employees working in the District of Delaware, including employees directly involved with, testing, sales, importation, training and operations of the Sapien 3 Ultra—an accused infringing device in this matter. On information and

belief, for example, Edwards employs clinical field, sales specialists, and/or others that work at hospitals in this District.[1]

15. Edwards also conducts business within the District of Delaware. For example, on information and belief, Edwards' employees operating within this District solicit orders for Edwards' products; demonstrate Edwards' products; maintain an inventory of Edwards' products; educate and assist physicians with TAVR procedures; and/or fill orders from their inventory of Edwards' products within this District. Ex. 4, Declaration of Y.J. Oh; Ex. 10.

16. On information and belief, Edwards also maintains regular and established places of business in the District of Delaware at its affiliated hospitals. For example, on information and belief, Edwards maintains a website[2,3] identifying and directing potential patients in need of TAVR to the affiliated hospitals in the District of Delaware—including Christiana Care Health System in Newark, DE, Bayhealth Medical Center in Dover, DE and Beebe Medical Center in Lewes, DE 19958[4]—that provide the Edwards Sapien 3 Ultra.[5] Further, Edwards maintains a consignment of Sapien 3 Ultra valves at these hospitals and others. See Ex. 4, Oh Declaration and attachments.

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[1] Ex. 8, https://www.linkedin.com/in/rich-steigerwalt-077bbb52/ (Senior Field Clinical Specialist in transcatheter aortic valves); Ex. 4, Declaration of Y.J. Oh; Ex. 10.

[2] Ex. 9, https://newheartvalve.com/find-tavr-hospital/.

[3] The website indicates that TAVR procedures are performed at identified hospitals. TAVR includes Edwards' SAPIEN 3 Transcatheter Heart Valve ("THV") System and Edwards' SAPIEN 3 Ultra and SAPIEN 3 Ultra Resilia THV Systems. *See* Exs. 9-10.

[4] Ex. 10, TAVR Information provided by Edwards for the Cristiana Care Health System in Newark, DE, Bayhealth Medical Center in Dover, DE, and Beebe Medical Center in Lewes, DE 19958.

[5] "Sapien 3 Ultra" as used herein encompasses Sapien 3 Ultra and Sapien 3 Ultra with Resilia leaflets.

17. Further, on information and belief, Edwards' employees provide onsite education and outreach and participate in TAVR procedures at Edwards affiliated hospitals in this District. These employees help select new patients for TAVR procedures, including with the Sapien 3 Ultra. Further, on information and belief, Edwards employees participate in surgical interventions involving TAVR devices, including the Sapien 3 Ultra, including at least preparing the devices prior to insertion by the doctor into the patient and controlling and maintaining a watchful eye over doctors and others performing the procedures.[6]

18. On information and belief, Edwards has created a consignment, sales, distribution, implantation, and service system comprising substantial resources within the District of Delaware. *Id*. Through its distribution channels, Edwards introduces infringing products into the stream of commerce with the knowledge, expectation, and intent that they will be sold, implanted, and used in the United States, including in the State of Delaware and in this District. *See*, Ex. 4.

19. On information and belief, acts of infringement take place in this District. As noted above, on information and belief, Edwards conducts business through several hospitals in the District of Delaware. On information and belief, Edwards consigns Sapien 3 Ultra devices to hospitals and/or medical staff located at least at the hospitals listed above. *Id.* Those devices are then sold to and inserted into patients. Each consignment, sale, implantation, use, operation, and the continued use by the patient constitutes an infringing act in the District of Delaware and elsewhere.

20. In addition, on information and belief, Edwards has previously availed itself of this District in the past 10 years by bringing and defending against numerous patent infringement

[6] Ex. 4, Declaration of Y.J. Oh.

matters—including cases involving similar subject matter to that in the instant suit—in this District as reflected in the table below:

Case Name	Case Filing Date	Edwards Party
Aortic Innovations LLC v. Edwards Lifesciences Corporation, et al., 1-21-cv-01377 (DDE)	Sept 28, 2021	Defendant
Abbott Cardiovascular Systems. Inc. et al v. Edwards Lifesciences Corporation, et al., 1-19-cv-00149 (DDE)	Jan. 28, 2019	Defendant
Boston Scientific Scimed. Inc. v. Edwards Lifesciences LLC, 1-18-cv-01535 (DDE)	Oct. 03, 2018	Defendant
Edwards Lifesciences LLC v. Boston Scientific Corp., 1-18-cv-01294 (DDE)	Aug. 22, 2018	Plaintiff
Kaldren LLC v. Edwards Lifesciences Corporation, 1-17-cv-01268 (DDE)	Sep. 05, 2017	Defendant
Boston Scientific Corporation, et al. v. Edwards Lifesciences Corporation, 1-16-cv-00275 (DDE)	Apr. 19, 2016	Defendant
Endoheart AG v. Edwards Lifesciences Corporation, 1-14-cv-01473 (DDE)	Dec. 10, 2014	Defendant
Edwards Lifesciences LLC, et al. v. Medtronic Corevalve LLC, et al., 1-12-cv-00023 (DDE)	Jan. 11, 2012	Plaintiff

This further demonstrates that jurisdiction and venue are proper and convenient for Edwards in this District.

THE AORTIC INNOVATIONS PATENTS

21. On May 24, 2022, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 11,337,834 ("the '834 Patent"), entitled "Transcatheter Valve Repair Having Improved Paravalvular Seal," to inventor Dr. Ali Shahriari. Aortic owns all rights to the '834 Patent necessary to bring this action. A true and correct copy of the '834 Patent is attached hereto as Exhibit 1 and incorporated herein by reference.

22. On July 19, 2022, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 11,389,310 ("the '310 Patent"), entitled "Device for Aortic Repair and Method of Using the Same" to inventor Dr. Ali Shahriari. Aortic owns all rights to the '846 Patent necessary to bring this action. A true and correct copy of the '310 Patent is attached hereto as Exhibit 2 and incorporated herein by reference.

23. On November 8, 2022, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 11,491,033 ("the '033 Patent"), entitled "Transcatheter Valve Repair Having Improved Paravalvular Seal" to inventor Dr. Ali Shahriari. Aortic owns all rights to the '033 Patent necessary to bring this action. A true and correct copy of the '033 Patent is attached hereto as Exhibit 71 and incorporated herein by reference.

24. On November 15, 2022, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 11,497,634 ("the '634 Patent"), entitled "Transcatheter Valve Repair Having Improved Paravalvular Seal" to inventor Dr. Ali Shahriari. Aortic owns all rights to the '634 Patent necessary to bring this action. A true and correct copy of the '634 Patent is attached hereto as Exhibit 72 and incorporated herein by reference.

25. On December 13, 2022, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 11,523,918 ("the '918 Patent"), entitled "Transcatheter Valve Repair Having Improved Paravalvular Seal" to inventor Dr. Ali Shahriari. Aortic owns all rights to the '918 Patent necessary to bring this action. A true and correct copy of the '918 Patent is attached hereto as Exhibit 73 and incorporated herein by reference.

BACKGROUND

A. DR. SHAHRIARI'S TAVR INVENTIONS

26. Dr. Shahriari is the sole inventor of the Patents-in-Suit. Dr. Shahriari conceived of novel concepts related to endovascular aortic repair starting in 2011. Specifically, Dr. Shahriari invented a transcatheter aortic valve replacement ("TAVR") device and an aneurysm treatment device in 2011 and further refined his inventions thereafter.

27. Dr. Shahriari filed patent applications on a TAVR having outwardly or radially extending fibers for treating paravalvular leaks in 2012. As Dr. Shahriari explained in his 2012 patent application, the "fibers … aid in preventing paravalvular leaks and migration of the transcatheter valve device … within the aortic walls." Ex. 6, U.S. Prov. Appl. 61/723,446 at [0024]. Dr. Shahriari's first issued patent directed towards a TAVR having outwardly extending fibers was granted in January 2015. *See* Ex. 11, U.S. Patent 8,940,040. The addition of outwardly extending fibers on an outside surface of the stent frame addressed many shortcomings of conventional TAVR devices, as discussed further below.

B. DR. SHAHRIARI'S INTERACTIONS WITH EDWARDS AND EDWARDS' KNOWLEDGE OF AORTIC'S PATENTS

28. While working on his TAVR inventions, Dr. Shahriari also worked on another device called the Ascyrus Medical Device Stent ("AMDS") on behalf of Ascyrus Medical, LLC

("Ascyrus"), a company that Dr. Shahriari had formed. The AMDS is life changing technology designed to repair type-A dissections in the aorta—*i.e.*, tears in the ascending aorta where it exits the aortic valve.

29. Based on interest and funding from investors, Dr. Shahriari focused his initial efforts on bringing the AMDS to market. After bringing the AMDS to market, Dr. Shahriari planned to return his focus to Aortic and bringing his TAVR designs to market.

30. Edwards was aware of Aortic's patent applications directed towards a TAVR design with outwardly extending fibers at least as early as November, 2014.

31. Specifically, Edwards filed U.S. Patent Application No. 14/033,075 ("the Edwards '075 Application") on September 20, 2013. Ex. 12 at 003-036. The Edwards '075 Application is directed towards a combination implant that includes a TAVR device with an additional stent for ascending aorta repair.

32. During prosecution of the Edwards '075 Application, Edwards cited WIPO Patent Publication WO2013/086132 ("the Aortic '132 Application") (Ex. 13) by Aortic Innovations in an Information Disclosure Statement filed on November 13, 2014.

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2013/086132	WO	A1	2013-06-13	Aortic Innovations Llc		☐

Ex. 12 at 001.

33. The November 14, 2014 Information Disclosure Statement was filed by Pui Tong Ho, who, on information and belief, was and is in-house Intellectual Property Counsel for Edwards.

34. The Aortic '132 Application contains virtually the same disclosure and subject matter as the Patents-in-Suit. Compare Ex. 13 to Exs. 1-2.

35. Additionally, Edwards filed U.S. Patent Application No. 15/445,651 ("the Edwards '651 Application") on February 28, 2017. Ex. 14 at 005-040. The Edwards '651 Application is a continuation of the Edwards '075 Application.

36. During prosecution of the Edwards '651 Application, Edwards cited the Aortic '132 Application in an Information Disclosure Statement filed on March 30, 2017.



Ex. 14 at 001.

37. The March 30, 2017 Information Disclosure Statement was filed by Thomas C. Richardson, who, on information and belief, was and remains in-house Intellectual Property Counsel for Edwards.

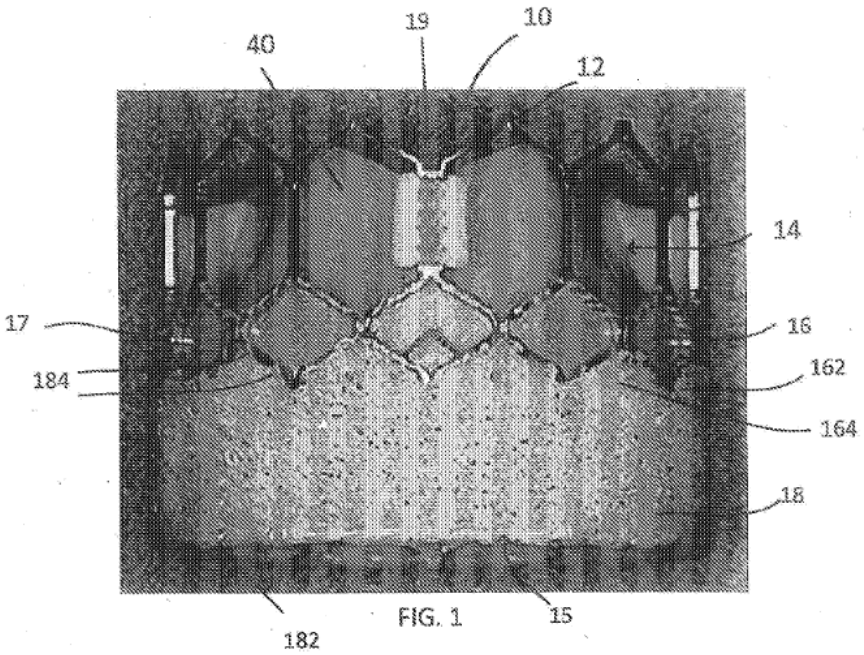
38. Not only was Edwards aware of Aortic's patent and technology as a result of its patent prosecution activities, but Edwards also learned of Dr. Shahriari's inventions directly from discussions with Dr. Shahriari. Specifically, on or around early 2017, Dr. Shahriari contacted Edwards to discuss his AMDS device. Ex. 15. Specifically, on April 19, 2017, Dr. Shahriari sent an email to Donald Bobo and Larry Wood of Edwards. *Id*. On information and belief, Donald Bobo is Corporate Vice President of Strategy and Corporate Development for Edwards and Larry Wood is Corporate Vice President of Transcatheter Aortic Valve Replacement for Edwards.

39. In the April 19, 2017 email, Dr. Shahriari, in addition to discussing his AMDS work, also told Edwards that the "IP for modular use of a transcatheter valve with an aortic graft

has been granted to us." *Id*. Edwards then arranged a conference call for May 2, 2017, to which Bernard Zovighian, Amir Blumenfeld, Jack Westhart, Mr. Wood, and Mr. Bobo were all invited. Ex. 16. On information and belief, Mr. Zovighian is now and was Corporate VP and General Manager of Transcatheter Mitral and Tricuspid Therapy of Edwards, and has been announced to assume the Chief Executive Officer position starting in May of this year, Dr. Blumenfeld is now a Senior Director of Discovery at Edwards, and Mr. Westhart is Senior Director of Corporate Development. Despite Dr. Shahriari's intent to discuss Ascyrus's inventions and the AMDS with Edwards during the conference call, Edwards, and specifically, Dr. Blumenfeld, asked for information on Aortic's inventions and the Aortic patents and expressed little to no interest in Ascyrus or the AMDS. On information and belief, based on the questions asked during the 2017 conference call, Edwards, including specifically, Dr. Blumenfeld, were aware of Aortic's patents and the inventions described therein.

40. On May 31, 2017, less than a month after the May 2, 2017 conference call between Dr. Shahriari and Edwards, Edwards filed a provisional patent application, U.S. Provisional Patent Application No. 62/513,348 ("the Edwards '348 Application"), on a TAVR design that included

outwardly extending fibers. Ex. 17. FIG. 1 of the '348 Application is representative:



Ex. 17, U.S. Provisional Patent Application No. 62/513,348, 046, Figure 1.

41. Upon information and belief, the TAVR device shown in the Edwards '348 Application, specifically with reference to FIG. 1, is an example of the Edwards Sapien 3 Ultra TAVR, a valve produced by Edwards and sold in the United States, Canada, Europe, and other countries throughout the world. Edwards did not inform Dr. Shahriari during the May 2, 2017 conference call or thereafter that it was introducing a competing TAVR device or that its soon-to-be introduced TAVR device included fibers similar to the fibers described in the Aortic Innovations patents.

42. In October 2017, Philip Nowell, then Vice President of Global Business Strategy and Commercialization of Ascyrus Medical, who was aware of Edwards' interest in Aortic's TAVR devices, sent an email to Mr. Bobo to discuss "other devices we have in development of

which you are already aware following your earlier discussions with Dr. Shahriari." Ex. 18. Mr. Nowell received no response from Edwards.

43. Likewise in 2019, Dr. Shahriari sent an email to Mr. Bobo to further follow up on the AMDS, but again, Edwards did not respond. Ex. 19. Dr. Shahriari subsequently learned of Edwards' release of the Sapien 3 Ultra with an outwardly extending fiber seal and its use of Aortic's patented inventions.

44. Edwards' infringing Sapien 3 Ultra valve incorporating Dr. Shahriari's inventions was adopted by medical professionals soon after its launch, quickly establishing a foothold in the TAVR market. As a result of Edwards' misappropriations of Dr. Shahriari's inventions, Aortic was effectively precluded from bringing its TAVR device to market and selling its TAVR business.

45. On August 31, 2018, after discussions with Dr. Shahriari, Edwards filed U.S. Patent Application No. 16/120,112 ("the Edwards '112 Application"), which claims priority through intermediate applications to the Edwards '348 Application. Upon information and belief, the Edwards '112 Application is directed to TAVR devices and currently claims, among other things, an outer sealing member that includes "a plurality of pile yarns extending outwardly from the mesh layer." Ex. 20 at 001.

46. Upon information and belief, at least claim 1, the first independent claim of the Edwards '112 Application, is similar to the disclosure in the Aortic '132 Application and its related family members. *Id*.

47. Similarly, Edwards filed U.S. Patent Application No. 16/902,373 ("the Edwards '373 Application") on June 16, 2020. Ex. 21. The Edwards '373 Application claims priority

through intermediate applications to a U.S. Provisional Patent Application No. 61/912,231 ("the Edwards '231 Application"), filed on December 5, 2013. Ex. 21 at 003.

48. The Edwards '373 Application is directed to a TAVR device and includes disclosure directed towards a "pile fabric" that forms a sealing skirt. This is illustrated in FIG. 38:

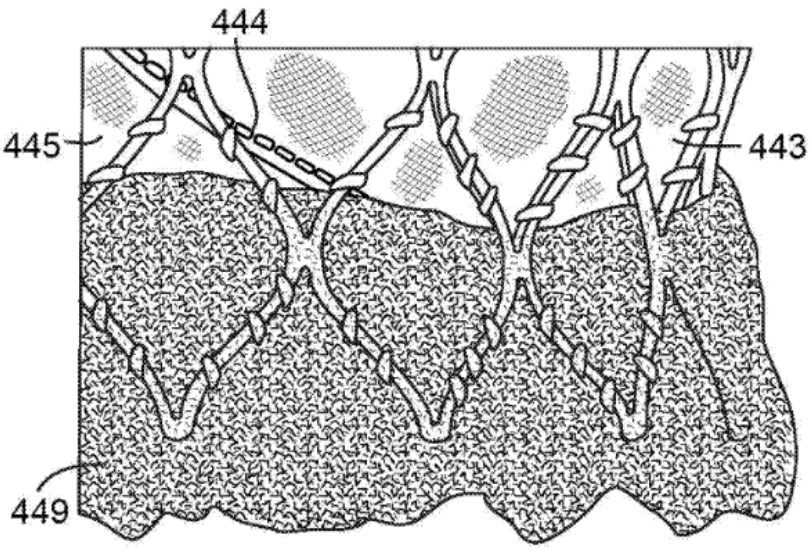


FIG. 38

Ex. 21, 071, Figure 38.

49. The Edwards '373 Application currently claims, among other things, a "collapsible and expandable sealing skirt" that comprises "a pile fabric and can contact tissue surrounding the prosthetic valve when the prosthetic valve is implanted within a native valve annulus." *Id.* at 047.

50. In addition, prior to filing suit in September 2021, Aortic contacted Edwards in a good faith effort to license the Aortic patent portfolio. Specifically, on July 19, 2021, Dr. Shahriari sent an email to Mr. Bobo and Chief IP Counsel Keith Newburry expressly informing them of Edwards' practice of certain Aortic patents in connection with the Sapien 3 Ultra (as well as Edwards' practice of Aortic's mitral valve patents in relation to Edwards' Sapien M3 valve) and

requesting the opportunity to discuss a potential license. Ex. 22. On information and belief, after receiving notice, Edwards has not ceased practicing the Aortic patents identified in Aortic's July 19, 2021 email.

51. Further, as noted above, on September 28, 2021, Aortic brought suit against Edwards in Delaware in the case styled as *Aortic Innovations LLC v. Edwards Lifesciences Corporation*, et al., 1-21-cv-01377 (DDE) ("First Action"). Therein, Aortic asserted that Edwards and its Sapien 3 Ultra infringe U.S. Patent Nos. U.S. Patent Nos. 10,881,538 ("the '538 Patent"); 10,966,846 ("the '846 Patent"); 10,987,236 ("the '236 Patent"); and 11,129,735 ("the '735 Patent). Further, on or around May 26, 2022 and January 10, 2023, Aortic served detailed infringement and supplemental infringement contentions in the First Action. On information and belief, after receiving notice, Edwards has not ceased practicing any of the Aortic patents-at-issue in the 1-21-cv-01377 (DDE) matter.

52. Edwards has admitted to knowledge of the '310, '834, '033, and '634 Patents and Aortic's accusations of infringement. For example, Edwards attached the '310, '834, '033, and '634 patents to its responsive claim construction brief. *Aortic Innovations LLC v. Edwards Lifesciences Corporation*, et al., 1-21-cv-01377 (DDE), D.I. 96, i.v. and 3. Further, regarding the '834 and other patents, Edwards has stated "Aortic continues to obtain patents without an "inner frame" limitation after Edwards' identified that limitation as missing from its Sapien 3 Ultra valve" and acknowledged that "Aortic has repeatedly argued to the Patent Office that SAPIEN 3 Ultra 'appears to be covered by the claimed invention.'" *Aortic Innovations LLC v. Edwards Lifesciences Corporation*, et al., 1-21-cv-01377 (DDE), D.I. 75 at 12-13.

53. Further, on February 15, 2023, after the filing of the original complaint in this matter alleging infringement of the ’834 and ’310 Patents by Edwards (D.I. 1), counsel for Aortic sent correspondence to Edwards and its counsel, providing express notice to Edwards regarding its infringement of Aortic’s ’834, ’310, ’033, ’634, and ’918 Patents in connection with the Sapien 3 Ultra and Sapien 3 Ultra with Resilia leaflets. Ex. 75. Aortic’s notice correspondence further included copies of each of the ’834, ’310, ’033, ’634, and ’918 Patents. *Id*. Aortic’s notice correspondence was received by Edwards as reflected by Edwards’ responsive correspondence dated February 15, 2023.

54. On information and belief, despite receiving notice and its awareness of the Patents-in-Suit and its infringement thereof, Edwards has not ceased practicing any of the Aortic Patents-in-Suit. Instead, Edwards has continued the manufacture, offer for sale, market, and sell the Sapien 3 Ultra, launched and is continuing to manufacture, offer for sale, market, and sell the Sapien 3 Ultra with Resilia leaflets and is continuing to develop and test the Sapien X4 TAVR device for marketing. Ex. 63; Exs. 76-80.

C. TAVR IMPROVEMENTS AND MARKET GROWTH

55. TAVR was not widely accepted technology in the field in 2011. The first FDA approved TAVR device was not approved until November, 2011, slightly more than a decade ago for extreme risk patients. TAVR was then approved for intermediate risk patients in 2016. Following further advancements in TAVR technology, the FDA approved TAVR for low risk patients in 2019. Ex. 23, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S085.

56. Since its original development in the early 2000's, TAVR has suffered from various shortcomings. One of the most discussed shortcomings is leakage around the replacement valve assembly. Ex. 24, S. Lerakis, MD, et al., Paravalvular Aortic Leak After Transcatheter Aortic Valve Replacement, Circulation. 2013;127:397–407 (January 22, 2013), https ://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.112.142000). This leakage is termed paravalvular leakage and/or paravalvular regurgitation (collectively "PVL"). PVL can be deadly and is considered one of the largest drawbacks associated with TAVR. Some studies report a PVL rate of around 48% in predicate TAVR devices. *Id*.

57. Despite this and other shortcomings of early TAVR devices, the advancement of TAVR has been significant, with TAVR procedures outpacing SAVR procedures for the first time in 2019. Ex. 5, TAVR Is Now Dominant Form of Aortic Valve Replacement in the United States (November 17, 2020), https://www.dicardiology.com/article/tavr-now-dominant-form-aortic-valve-replacement-united-states. On information and belief, the continued success of TAVR relative to SAVR is in large part due to the adoption of outer sealing skirts including those with radially or outwardly extending fibers, which have been found to dramatically reduce PVL.

58. Edwards has released several TAVR devices on the market. One of the first TAVR devices produced by Edwards was the Sapien XT valve. Ex. 25, Edwards Lifesciences Launching SAPIEN XT Valve In The U.S. (June 16, 2014), https://www.prnewswire.com/news-releases/edwards-lifesciences-launching-sapien-xt-valve-in-the-us-263350811.html. This valve did not have an outer seal on the TAVR. A representative image of the Sapien XT is shown below:



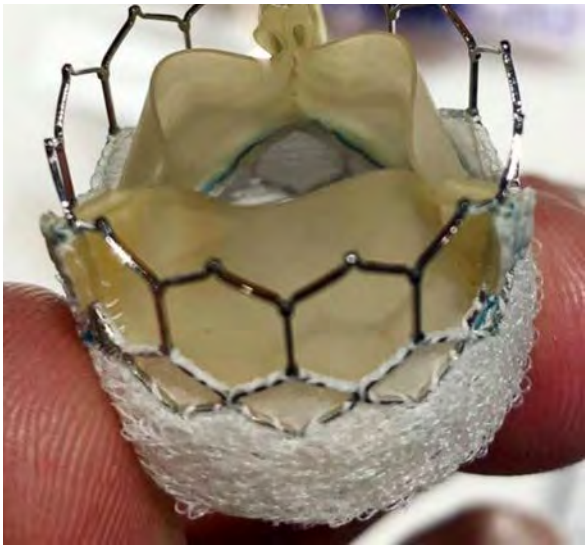
Ex. 26, https://www.edwards.com/gb/devices/heart-valves/sapien-xt-valve.

59. Edwards also introduced the Sapien 3 TAVR, which included a loosely fit outer skirt with openings that would provide minimal sealing to attempt to address PVL. On information and belief, the sealing was accomplished by the billowing of the skirt, and retrograde blood flow into the skirt. On information and belief, the Sapien 3 did not have any outwardly extending fibers on its outer skirt to provide for sealing. A representative image of the Sapien 3 is shown below:

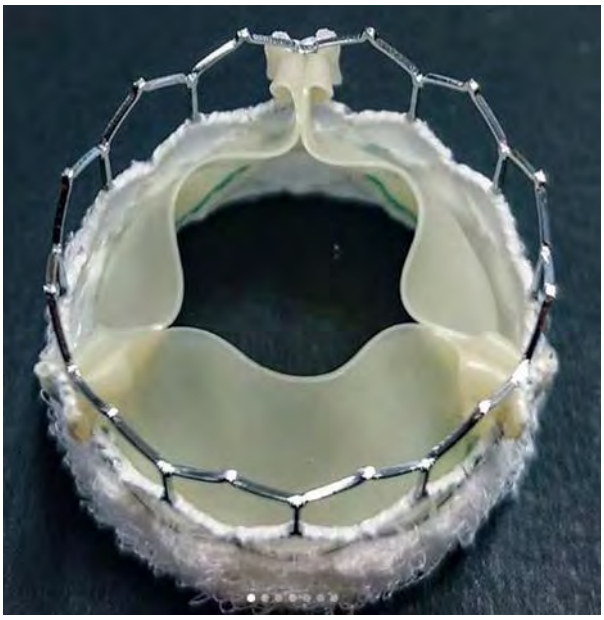


Ex. 27, https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3.

60. Edwards received FDA approval for the Sapien 3 Ultra TAVR and Sapien 3 Ultra TAVR with Resilia leaflets—which practice the inventions of the Patents-in-Suit—in December, 2018 and July 2022, respectively. Ex. 28, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S074; Ex. 52, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S141. The Sapien 3 Ultra is a TAVR that has a heightened outer skirt made of radially or outwardly extending fibers. Some representative images of the Sapien 3 Ultra are shown below:



Ex. 29, Sapien 3 Ultra image available at https://www.instagram.com/p/BysjboFBLiG/.



Ex. 30, Sapien 3 Ultra image by Calin Iulian, MD, available at https:// www.instagram.com/ p/CMwNvDgpFIQ/?igshid=1u39mbgvqtvj9.



Ex. 3, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth.

61. On information and belief, the Edwards Sapien 3 Ultra has quickly overtaken Edwards' predecessor TAVR device, the Sapien 3, and represented more than two-thirds of

Edwards' global TAVR sales by the end of 2020. Indeed, in the Edwards earnings call for the Fourth Quarter of 2020, CEO Michael Mussallem stated, "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." Ex. 31, Edwards Lifesciences Corp. (EW) Q4 2020 Earnings Call Transcript (January 27, 2021), https://www.fool.com/earnings/call-transcripts/2021/01/27/edwards-lifesciences-corp-ew-q4-2020-earnings-call/.[7] Further, in 2021 Edwards reported around $3.1 billion in sales associated with the Sapien 3 Ultra—i.e., $3.4 billion in sales for its TAVR product group, 92% of which were associated with the Sapien 3 Ultra. Ex. 53, 24-25 (Edwards' 10-K for 2021); Ex. 54, 4 (Edwards Investor Presentation).

62. On information and belief, the market cap of Edwards as measured by the New York Stock Exchange has increased from approximately 31.00 Billion USD at the time of the initial FDA approval of the Sapien 3 Ultra to as high as 78.00 Billion USD thereafter. https://ycharts.com/companies/EW/market_cap.

63. On information and belief, the rapid adoption of Sapien 3 Ultra is due in large part to the heightened outer skirt with radially or outwardly extending fibers. According to Edwards' studies, the fiber skirt of the Sapien 3 Ultra has led to a significant reduction in PVL. According to a recently released study, PVL in the predecessor Sapien 3 valve was 48%, whereas PVL was only 11.2% in Sapien 3 Ultra, representing an approximate 75% reduction in PVL. Ex. 32,

[7] Edwards Lifesciences Corporation's earnings call discussed sales included in Edwards Lifesciences Corporation's Form 10-K for the Fiscal Year Ending Dec. 31, 2020. Edwards Lifesciences Corporation's 10-Ks and Annual Reports specify that "'Edwards' and 'Edwards Lifesciences' refer to Edwards Lifesciences Corporation and its subsidiaries. Ex. 36 at 1; Ex. 55 at 1. (Edwards' 10-K for 2022). Exhibit 21.1 of Edwards 10-K's specifies that Edwards Lifesciences LLC is a subsidiary of Edwards which is included in these filings.

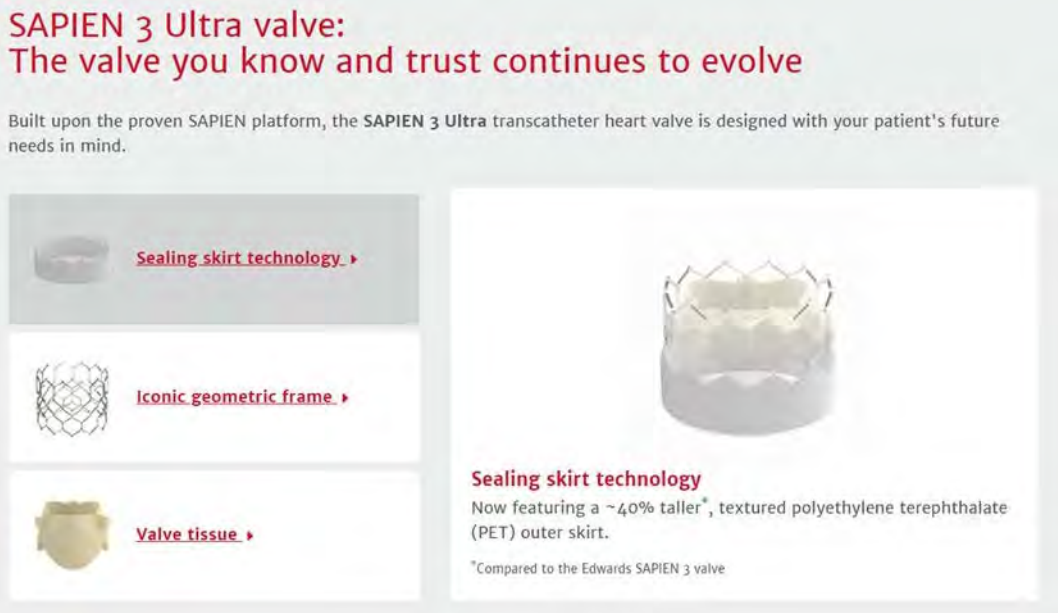
Minimizing Paravalvular Regurgitation With the Novel SAPIEN 3 Ultra TAVR Prosthesis: A Real-World Comparison Study (March 18, 2021), https: //www.frontiersin.org/articles/ 10.3389/fcvm.2021.623146/full. Indeed, as reflected in Edwards' marketing materials, the Sapien 3 Ultra outer skirt and its reduction of PVL is a highly marketed feature by Edwards.

EDWARDS'S ACCUSED PRODUCTS

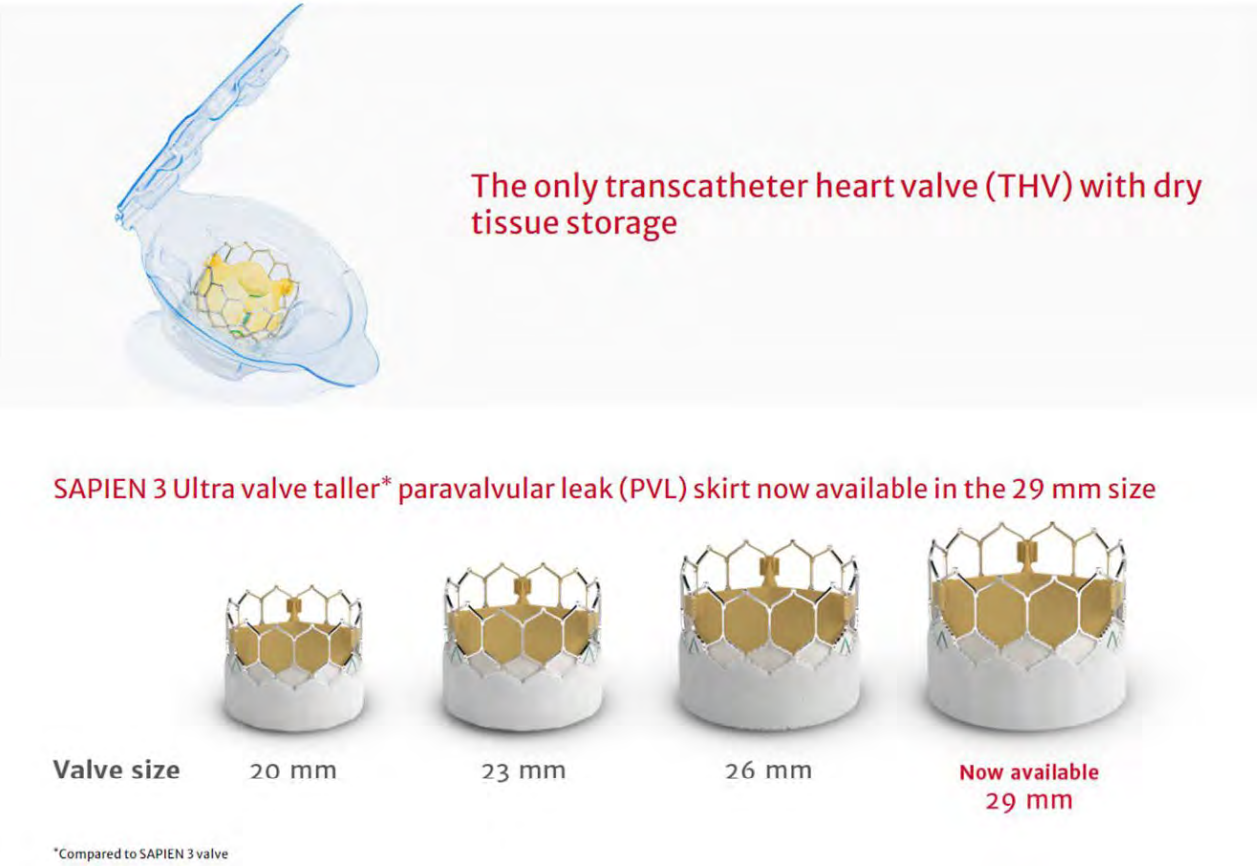
A. EDWARDS MAKES, IMPORTS, EXPORTS, USES, SELLS, AND/OR OFFERS FOR SALE PRODUCTS THAT INFRINGE THE PATENTS-IN-SUIT.

64. Edwards makes, imports, exports, uses, sells, and/or offers for sale TAVR devices that infringe at least one claim of each of the Patents-in-Suit ("Accused Products").

65. For example, on information and belief, Edwards manufactures, imports, exports, tests, uses, offers for sale, and sells a TAVR device called Sapien 3 Ultra (including, but not limited to, Sapien 3 Ultra with Resilia leaflets) and/or components thereof. An image of the Sapien 3 Ultra TAVR device and components thereof are shown below:



Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra.



Ex. 56, https://www.heartvalves.com/heart-team/devices/tavr/sapien-3-ultra-resilia.

66. On information and belief, Edwards received FDA approval for the Sapien 3 Ultra in December 2018. Ex. 28, https: //www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P140031S074.

67. On information and belief, Edwards received FDA approval for the Sapien 3 Ultra with Resilia leaflets in July 2022. Ex. 52, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S141. On information and belief, Edwards launched the Sapien 3 Ultra with Resilia leaflets in Sept. 2022. Ex. 69.

68. On information and belief, Edwards manufacturers and/or assembles Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore, Ireland and elsewhere. *See* Ex. 34, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P140031S099; Ex. 35, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S102; Ex. 57, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S151; Ex. 58, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S150; Ex. 59, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S148; Edwards Lifesciences Corporation, Annual Report (Form 10-K) (December 31, 2022), available at Ex. 55, https://d18rn0p25nwr6d.cloudfront.net/CIK-0001099800/8e36830a-715c-4dcc-be2e-70dff0f309a3.pdf (including financial information on "Edwards Lifesciences Corporation and its subsidiaries", see Footnote 7, supra).

69. On information and belief, Edwards supplies in and/or from the United States some or all of the components of the Sapien 3 Ultra in such a manner that such components will be combined outside of the United States to form the Sapien 3 Ultra. Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in Costa Rica and at other non-U.S. locations.

70. On information and belief, Edwards markets, consigns, sells, and/or provides Sapien 3 Ultra to hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States directly, and/or through sales representatives or distributors, and provides restrictions, requirements, and/or instructions on how to store, maintain, handle, deploy and/or use Sapien 3 Ultra. For example, on information and belief, Edwards implements an approval process

for hospitals receiving consignments of the Sapien 3 Ultra and requires those hospitals agree to follow and abide by Edwards' consignment and pricing agreements for the Sapien 3 Ultra TAVR. Ex. 4, Oh Declaration; Ex. 70; Ex. 67. For further example, Edwards advertises its Sapien 3 Ultra product on social media and public webpages registered to Edwards' parent corporation and provides public videos branded and/or sponsored by Edwards. *See, e.g.*, Ex. 68 (LinkedIn) and 69 (Twitter); Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra; Ex. 56, https://www.heartvalves.com/heart-team/devices/tavr/sapien-3-ultra-resilia; Ex. 37, https://www.youtube.com/watch?v=o3whx7CdM3I at 3:05; Ex. 38, https://newheartvalve.com/; Ex. 39, https://www.tavrbyedwards.com/. Edwards Lifesciences Corporation's recent SEC filings also include repeated mentions of the Sapien 3 Ultra product. *See* Edwards Lifesciences Corporation, Form 10-K (Dec. 31, 2020) at 2, 24[8], available at Ex. 36; Edwards Lifesciences Corporation Form 10-K (Dec. 31, 2019) at 2, 24, 26, available at Ex. 40, https:// www.sec.gov/ ix?doc=/Archives/edgar/data/0001099800/000109980020000005/ew10-kq42019.htm[9]; Ex. 53, Edwards Lifesciences Corporation, Form 10-K (Dec. 31, 2021), Ex. 55, Edwards Lifesciences Corporation, Form 10-K (Dec. 31, 2022). On information and belief, advertising and brochures from Edwards Lifesciences Corporation are directed towards selling products manufactured and owned by Edwards Lifesciences LLC.

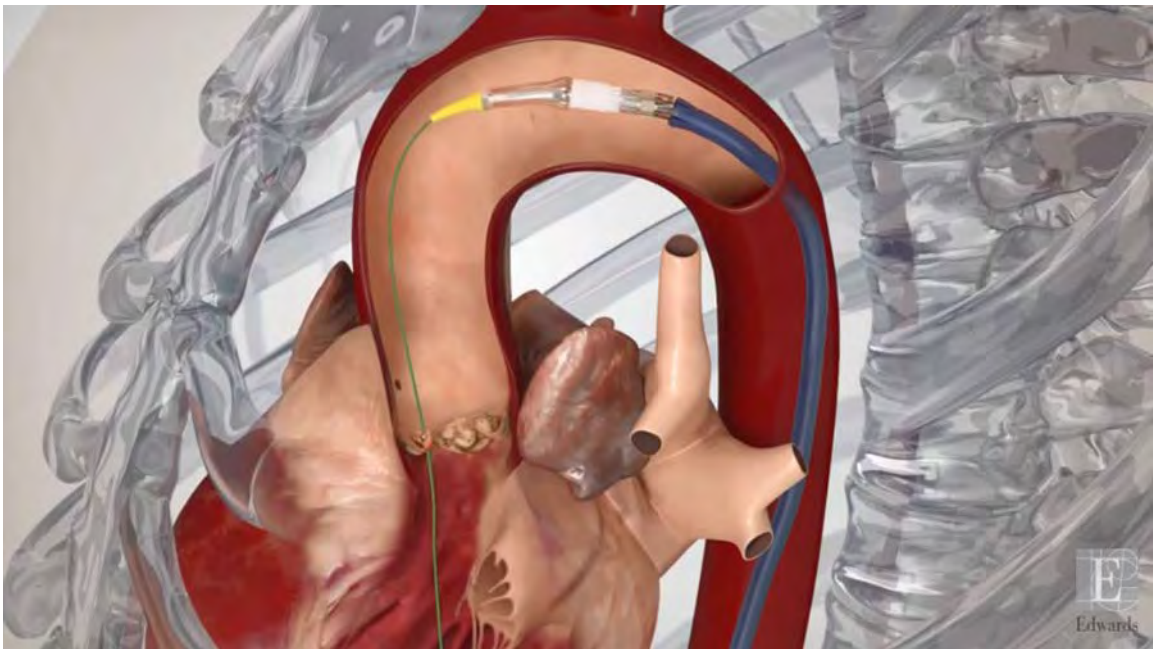
71. Edwards also regularly includes information concerning the production and sale of Sapien 3 Ultra in Edwards Lifesciences Corporation's SEC filings and presentations to Edwards' investors. *See, e.g.*, Edwards Lifesciences Corporation, Annual Report (Form 10-K)

[8] *See* Footnote 7, *supra*.
[9] *See* Footnote 7, *supra*.

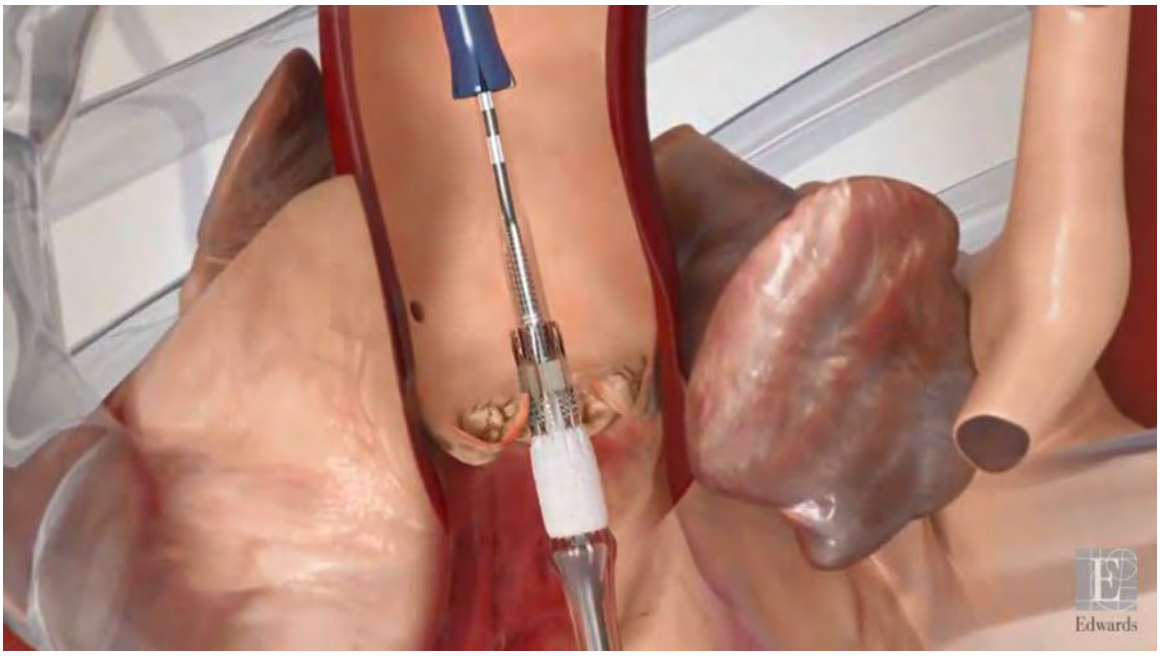
(December 31, 2022), available at Ex. 55, https://d18rn0p25nwr6d.cloudfront.net/CIK-0001099800/8e36830a-715c-4dcc-be2e-70dff0f309a3.pdf; Ex. 53, Edwards Lifesciences Corporation, Form 10-K (Dec. 31, 2021); Edwards Lifesciences Corporation Form 10-K (2020) at 2, 24, available at Ex. 36; Edwards Lifesciences Corporation Form 10-K (2019) at 2, 24, 26, available at Ex. 40; 2020 Investor Conference: Transcatheter Aortic Heart Valves (December 10, 2020), Ex. 41, https://s27.q4cdn.com/788244549/files/doc_presentations/2020_IC_Binder.pdf; Edwards Lifesciences 39th Annual J.P. Morgan Healthcare Conference (January 11, 2021), Ex. 42, https://s27.q4cdn.com/788244549/files/doc_presentations/EW-JPMorgan-2021_vFINAL.pdf; Ex. 57; Ex. 54, 4 (Edwards Investor Presentation); Ex. 60, Investor Conference Transcript 2022; Ex. 63, Investor Conference Transcript Q4 2022.[10]

72. Use of Sapien 3 Ultra is depicted in a video provided by Edwards titled "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I; *see also* Ex. 37; https://youtu.be/ekkcx97PNgw. The following images of Sapien 3 Ultra are screenshots captured from this video demonstrating endovascular transcatheter delivery of the Sapien 3 Ultra prosthetic heart valve assembly through a femoral artery of a patient. The Sapien 3 Ultra is designed, sized, shaped, configured, manufactured, and tested by Edwards to be an endovascular prosthetic heart valve endovascularly deliverable though a femoral artery of a patient.

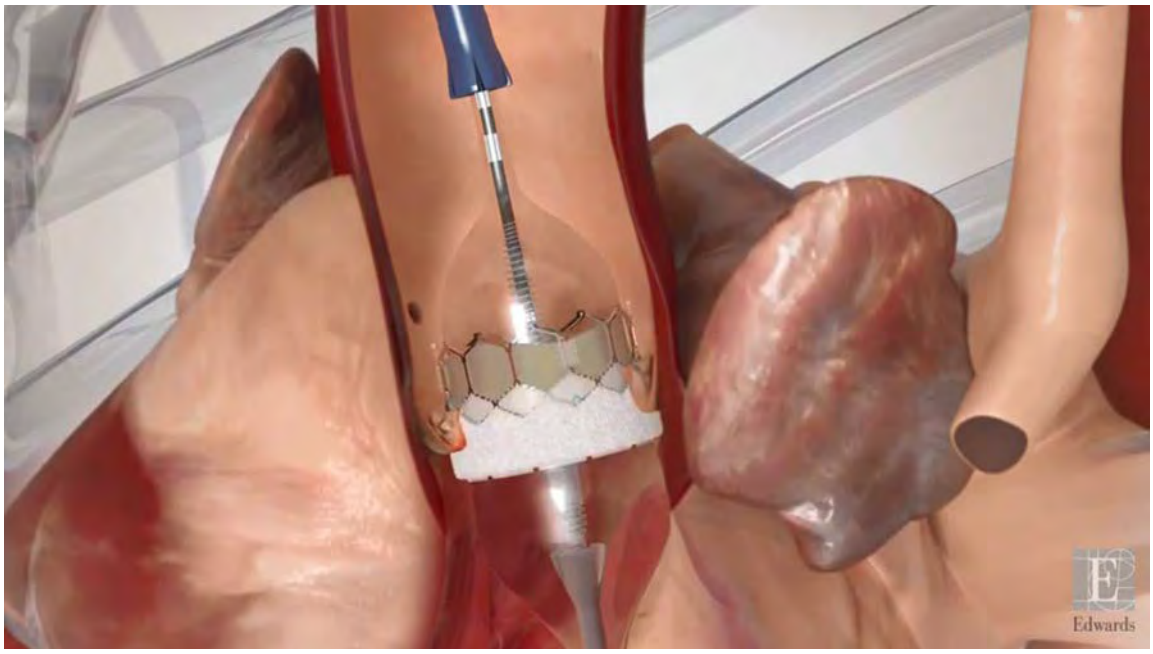
[10] *See* Footnote 7, *supra*, noting that such information includes information from Edwards Lifesciences LLC.



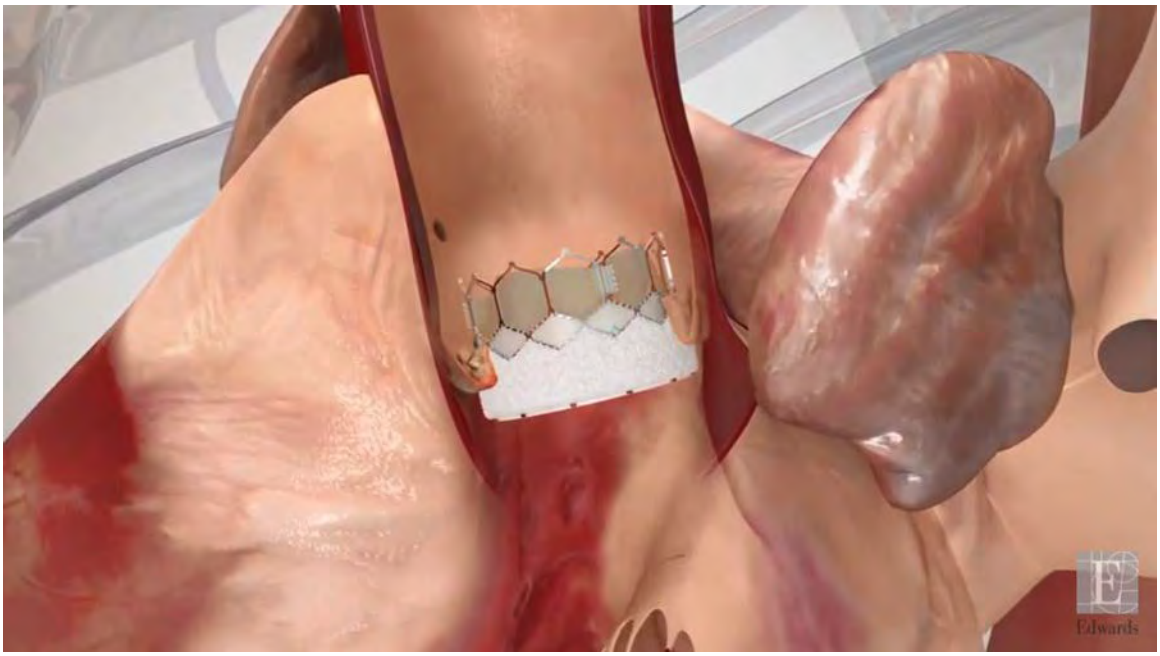
Id. at 1:08.



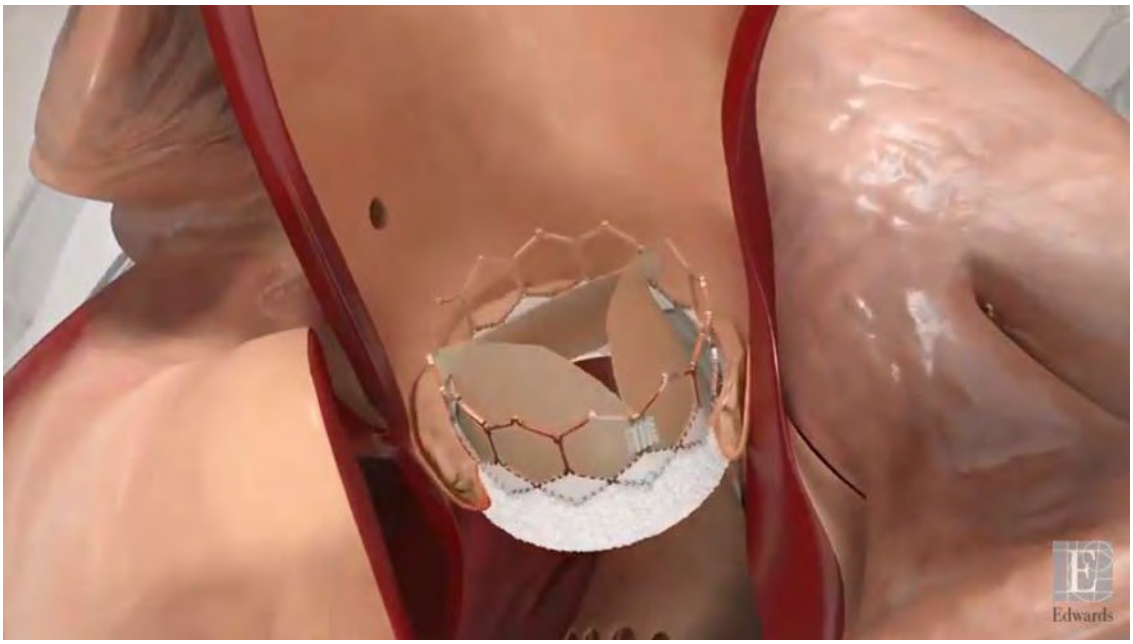
Id. at 1:13.



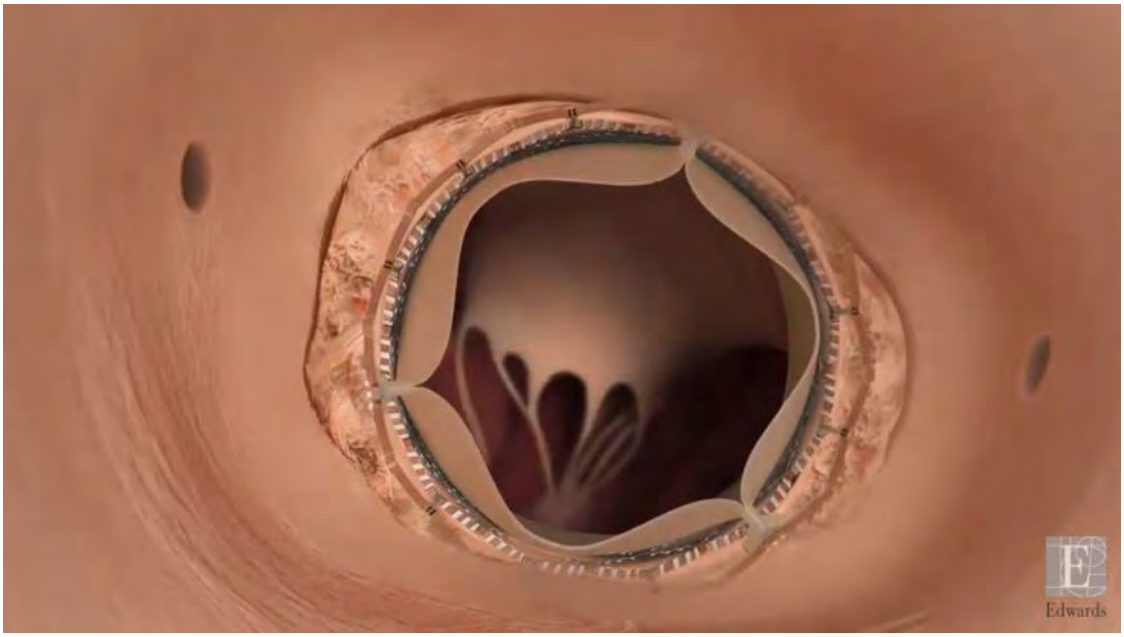
Id. at 1:25.



Id. at 1:48.

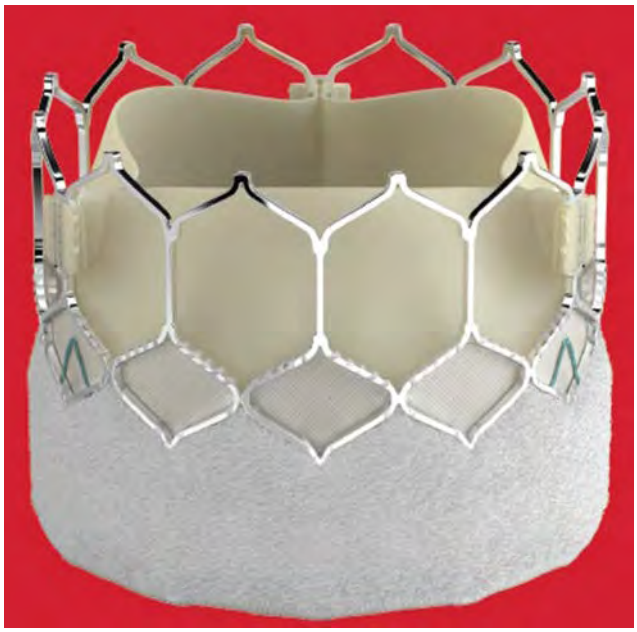


Id. at 1:54.

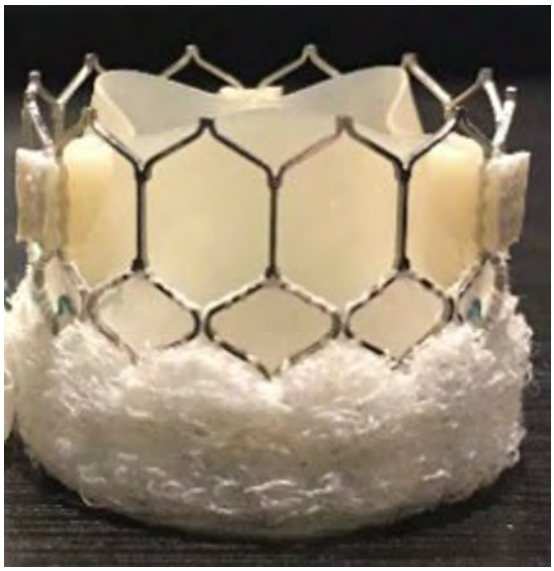


Id. at 1:59.

73. On information and belief, the Sapien 3 Ultra includes a frame made from a metallic material in an open cell configuration with an inflow end and an outflow end.



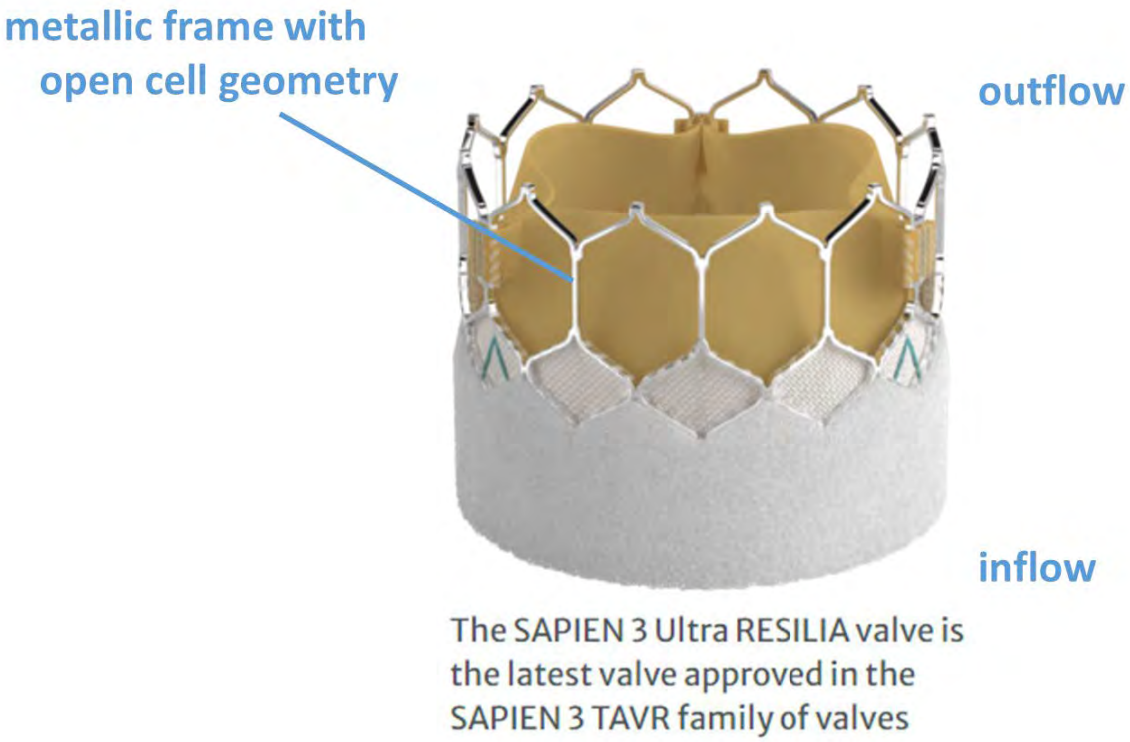
Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 1-2, Ex. 43, https://edwardseducation.com/eacts2020/documents/PP--EU-0118%20v1.0%20S3%20Ultra%20on%20Commander%20Implanter%20Brochure.pdf.



Sapien 3 Ultra image by William Suh, MD at Ex. 7, https://twitter.com/willsuh76/status/1280708440734617600/photo/1.



Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve.



Ex. 61, https://tavrbyedwards.edwards.com/why-edwards-tavr/

74. On information and belief, the Edwards Sapien 3 Ultra frame is formed from a cobalt-chromium metallic alloy designed to be "balloon-expandable" from a radially compressed orientation to a radially expanded orientation. The Sapien 3 Ultra includes a trileaflet assembly within the metallic frame

1.0 Device Description

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve (THV) System

The Edwards SAPIEN 3 Ultra Transcatheter Heart Valve system consists of the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves and delivery systems.

- **Edwards SAPIEN 3 Ultra Transcatheter Heart Valve – (Figure 1)**

The Edwards SAPIEN 3 Ultra transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) inner and outer fabric skirts. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.



9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

Valve Size	Valve Height
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm

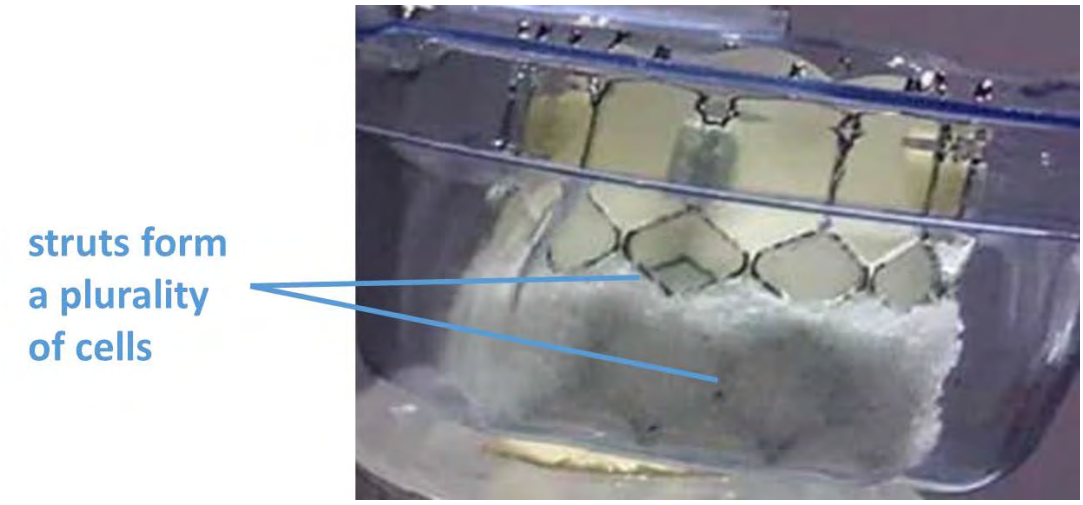
Sapien 3 Ultra Instructions for Use at 2, Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf; *see also* Sapien 3 Ultra

(PMA P140031/S085) FDA Summary of Safety and Effectiveness Data at 2-3, Ex. 45, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.

75. On information and belief, the Edwards Sapien 3 Ultra frame is formed by a plurality of struts that together form a plurality of cells in an open cell configuration with at least two rows of cells at an inflow end of the frame.



Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra.



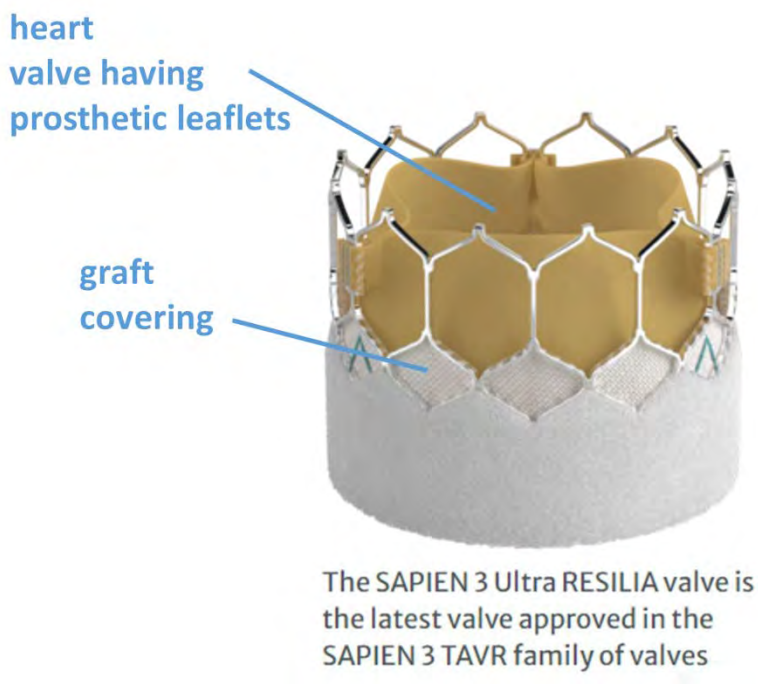
Ex. 3, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth.

76. On information and belief, the Edwards Sapien 3 Ultra frame struts adjoin each other at an inflow end to form apices.



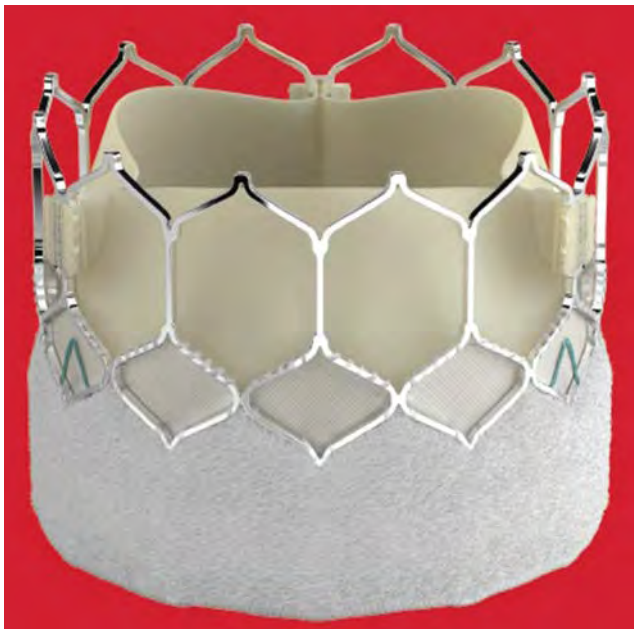
Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added).

77. On information and belief, the Edwards Sapien 3 Ultra includes a polymer graft covering, radially inward of the frame that houses and engages the prosthetic heart valve leaflets. Sapien 3 Ultra Instructions for Use at 2, Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf; *see also* Sapien 3 Ultra (PMA P140031/S085) FDA Summary of Safety and Effectiveness Data at 2-3, Ex. 45, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.



Ex. 61, https://tavrbyedwards.edwards.com/why-edwards-tavr/.

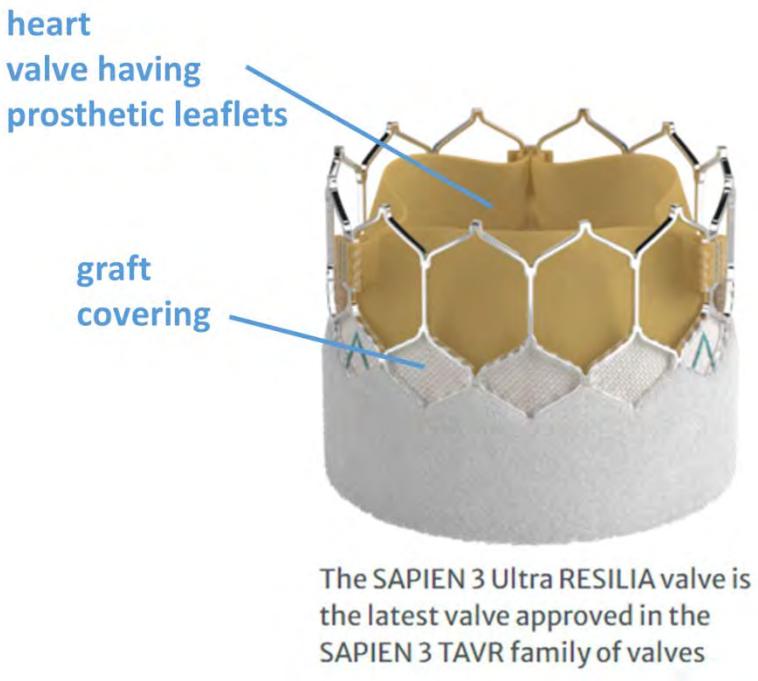
78. On information and belief, the Sapien 3 Ultra polymer graft covering is made from polyethylene terephthalate (PET) and extends around, engages, and provides sealing to the heart valve leaflets. *Id.*



Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 1-2, Ex. 46, https://edwardseducation.com/eacts2020/documents/PP--EU-0118%20v1.0%20S3%20Ultra%20on%20Commander%20Implanter%20Brochure.pdf



Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added) (showing polymer graft cover extending around and providing sealing to the valve leaflets).



Ex. 61, https://tavrbyedwards.edwards.com/why-edwards-tavr/.

79. On information and belief, the frame is secured to the polymer graft covering by a plurality of stitches.



Ex. 46, Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 2.



Ex. 29, https://www.instagram.com/p/BysjboFBLiG/ (showing stitching attaching the polymer graft covering to the frame).

80. On information and belief the polymer graft covering is attached to and engaged with the leaflet assembly to provide sealing against paravalvular leakage is and positioned radially inward of the metallic frame and radially outward of the leaflet assembly.



Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 2 (showing stitching attaching leaflet assembly to the polymer graft covering).

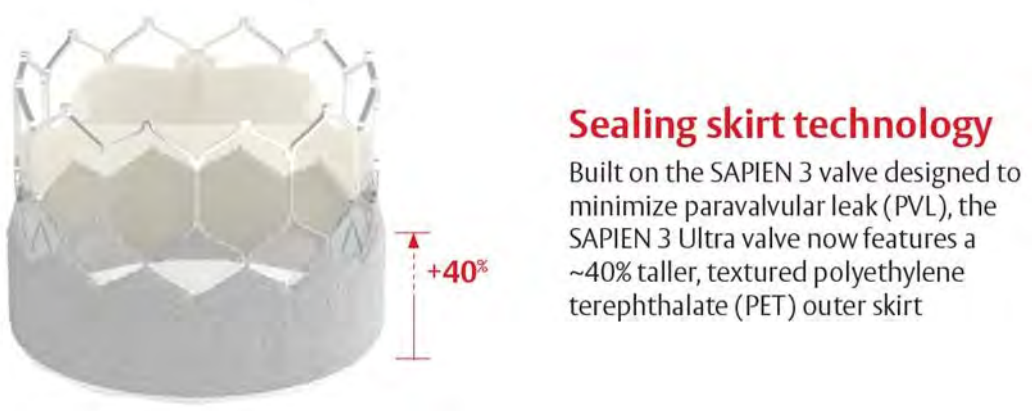


Ex. 29, https://www.instagram.com/p/BysjboFBLiG/ (showing stitching attaching leaflet assembly to the polymer graft covering).



Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added) (showing polymer graft covering positioned inward of the metallic frame and outward of the valve leaflets).

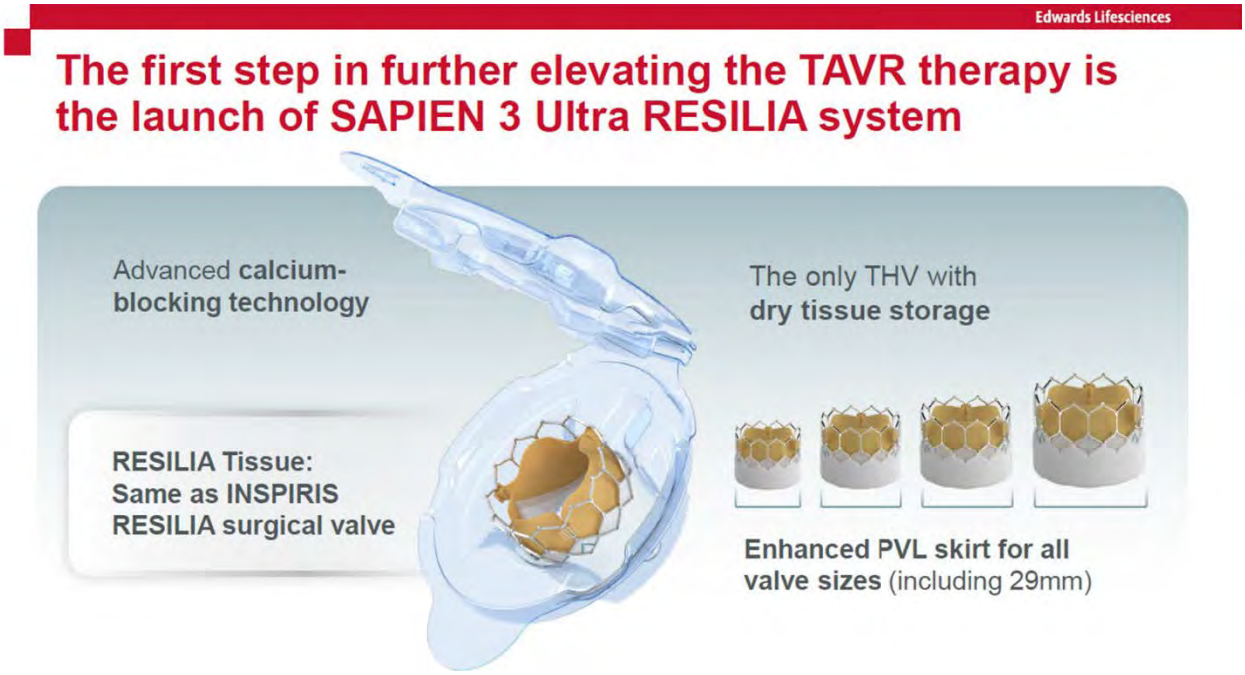
81. On information and belief, the Sapien 3 Ultra includes a sealing assembly and sealing material positioned external to the frame for providing sealing between the frame and a patient's anatomical aortic wall to prevent paravalvular leaks.



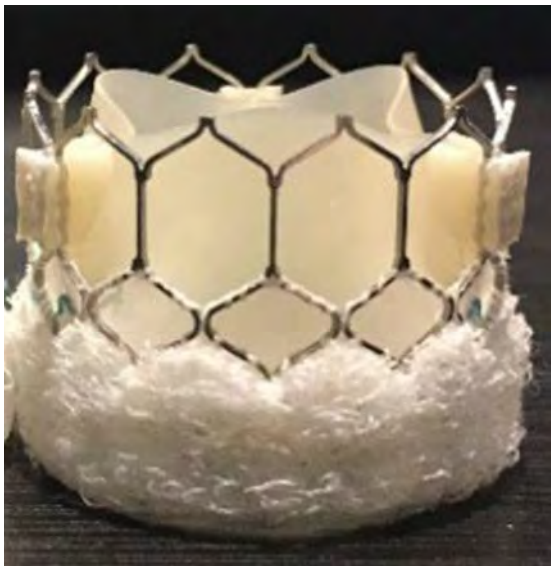
Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 2.



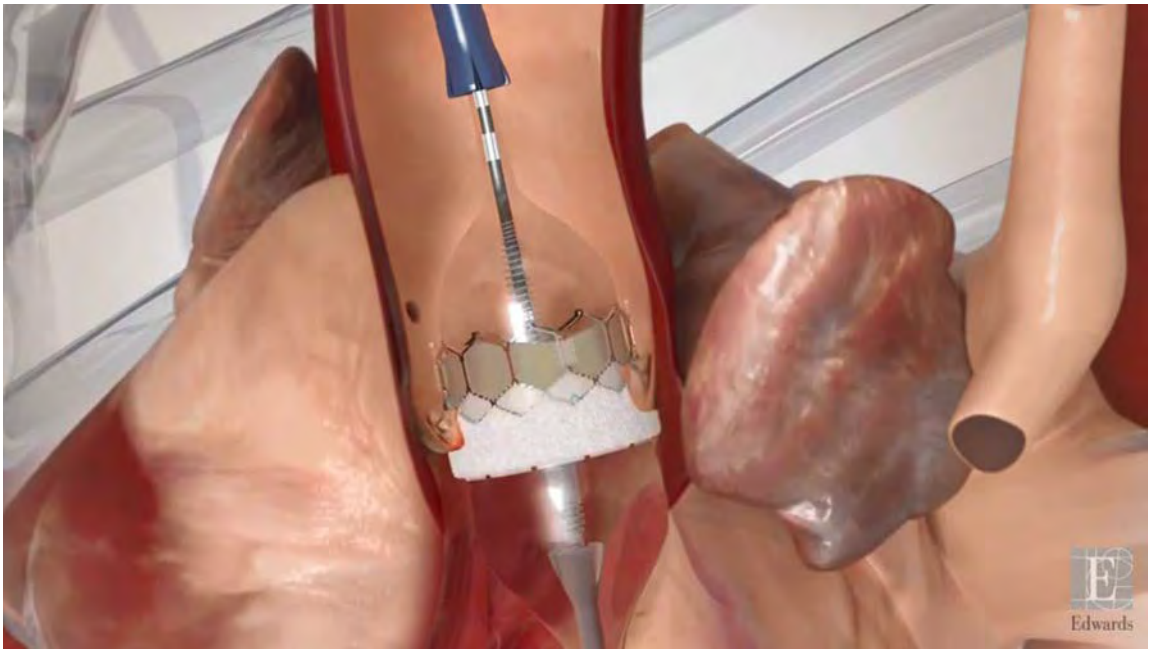
Ex. 62, https://twitter.com/RajTayalMD/status/1587518463127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg.



Ex. 63, https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/TRANSCATHETER-AORTIC-VALVE-REPLACEMENT.pdf

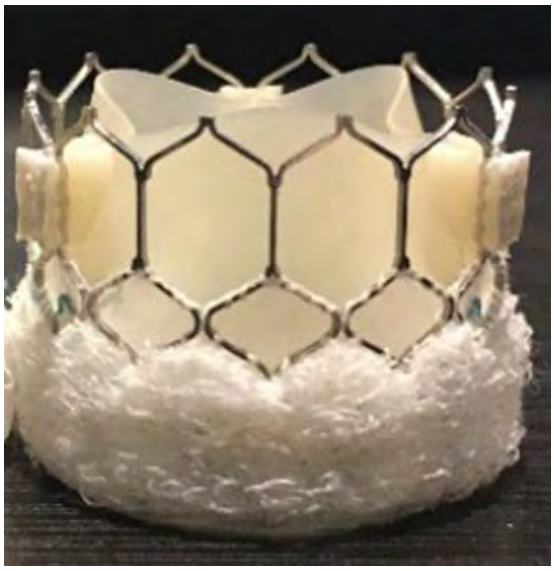


Sapien 3 Ultra image by William Suh, MD at Ex. 7, https://twitter.com/willsuh76/status/1280708440734617600/photo/1.

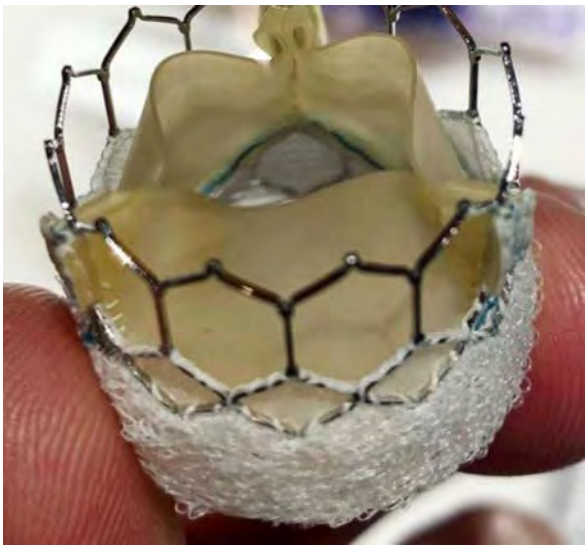


Ex.37, "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I at 1:25.

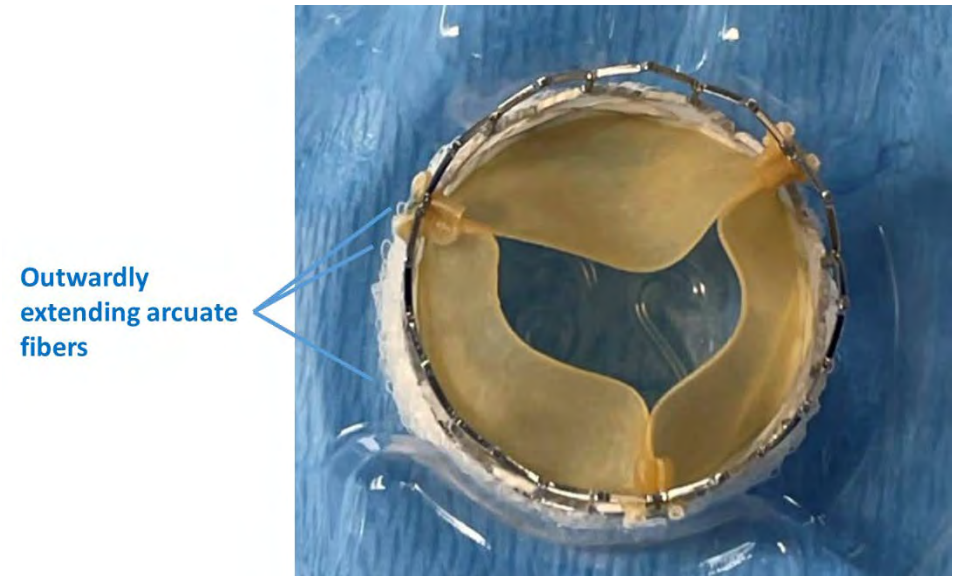
82. On information and belief, the Sapien 3 Ultra sealing material and sealing assembly include a plurality of fibers. On information and belief, the plurality of fibers include flexible, compressible, outwardly extending, spaced apart arcuate fibers that extend outwardly, away from the frame for providing sealing against paravalvular leakage. On information and belief, the sealing material is attached to and includes fibers extending over each of at least two rows of cells in the frame at the inflow end. On information and belief, fibers are engaged with the graft covering.



Sapien 3 Ultra image by William Suh, MD at Ex. 7, https://twitter.com/willsuh76/status/1280708440734617600/photo/1.



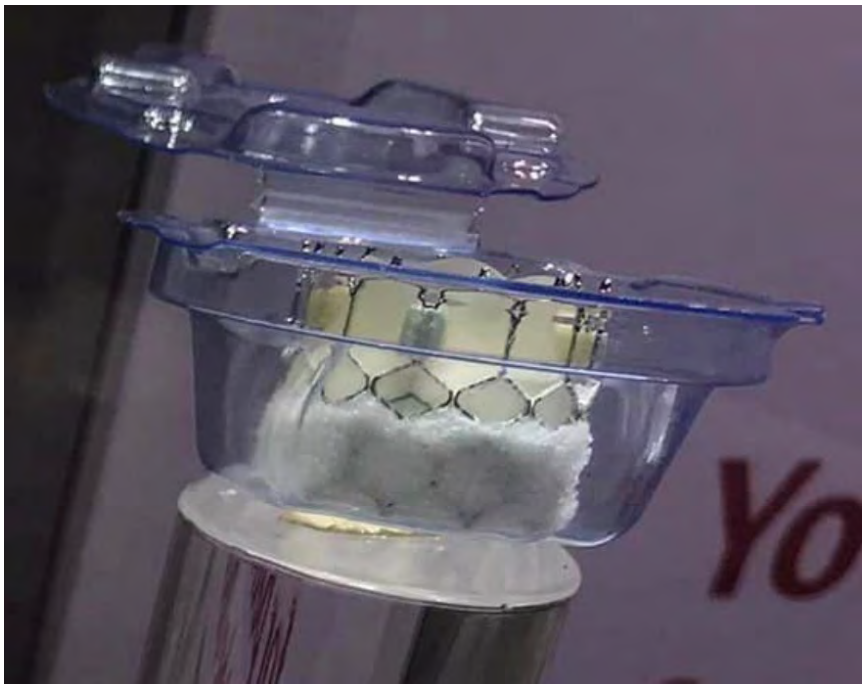
Ex. 29, https://www.instagram.com/p/BysjboFBLiG/ (showing outwardly extending fibers).



Ex. 64, https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing flexible, arcuate, spaced-apart, and outwardly extending fibers).

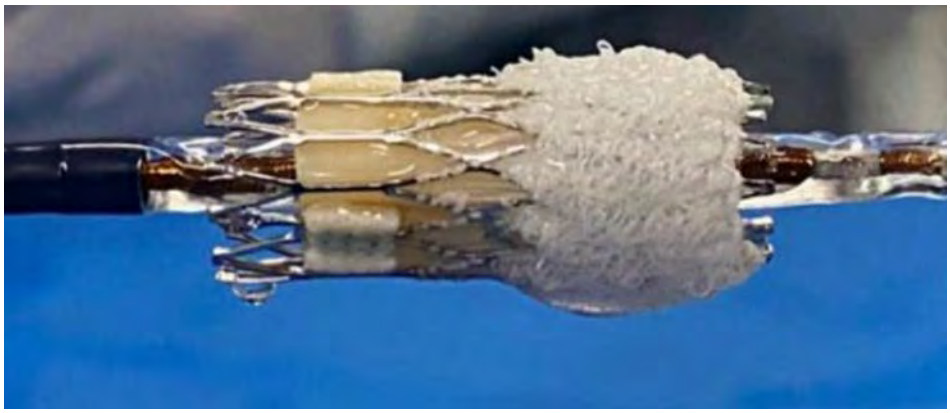


Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve.

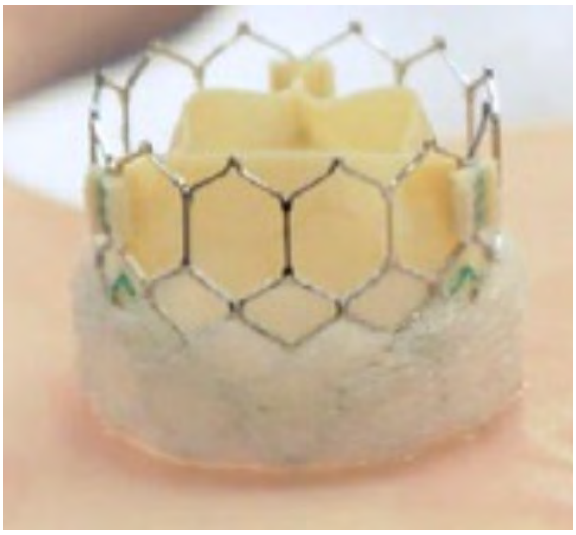


Ex. 3, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing fibers extending over at least two rows of cells).

83. On information and belief, the Sapien 3 Ultra is designed and configured such that the plurality of fibers of the sealing material contact the frame along the height of the sealing material in both the radially compressed orientation and the radially expanded orientation of the heart valve assembly. Further, on information and belief, the sealing assembly of the Sapien 3 Ultra lays against the frame when the Sapien 3 Ultra is in the radially compressed and expanded orientations.



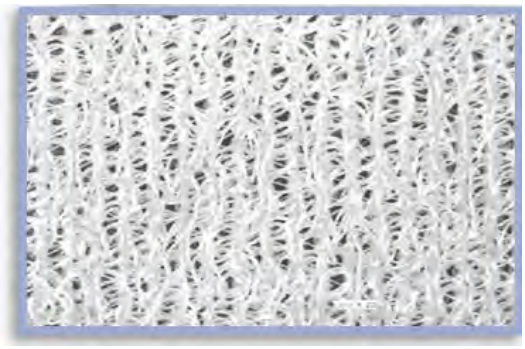
Ex. 48, https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU.



Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve.

84. On information and belief, the Sapien 3 Ultra defines spacings extending radially through a thickness of the sealing assembly and the plurality of fibers that begins at an outermost portion of the fibers and to and through the cells of the frame. Further, on information and belief, the spacings between fibers extend in a circumferential direction in an axial direction along the outer surface of the frame. On information and belief, the spacings are designed and configured

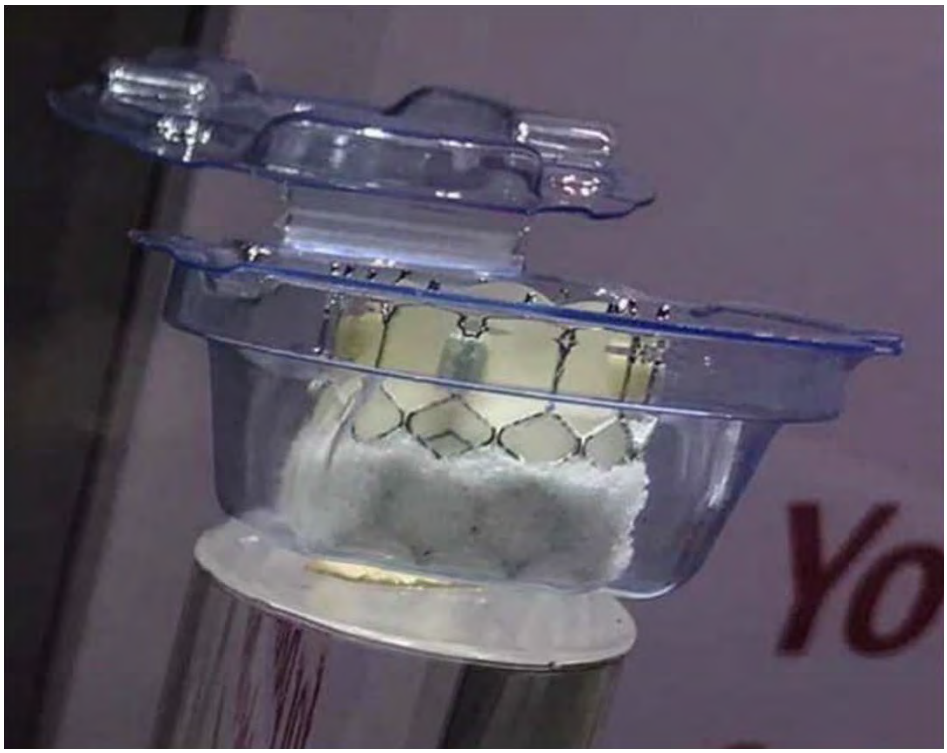
by Edwards to allow fluid to pass through when the valve assembly is in its uncompressed, undeployed state



Ex. 66, https://www.heartvalves.com/gb/edwards-sapien-3-tavi/edwards-sapien-3-ultra-valve.



Ex.66, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (showing spacings).



Ex. 3, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing spacings).



Ex. 3, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing spacings).

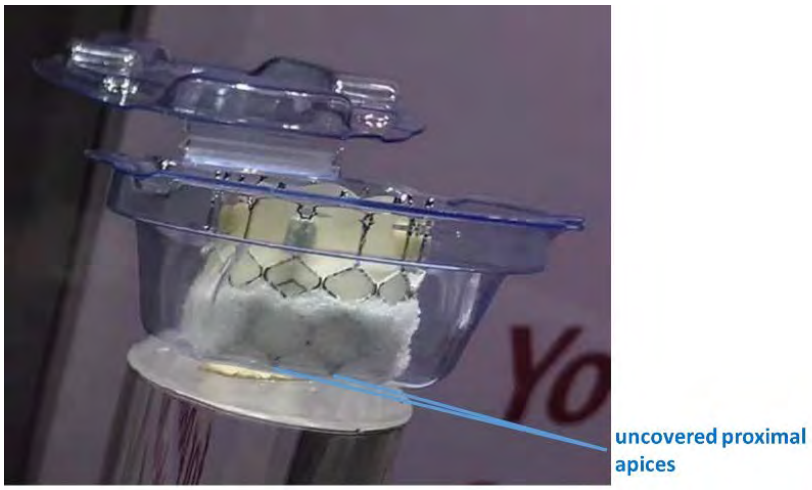


Ex. 74, Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil.

85. On information and belief, the end of the most proximal apices of the Sapien 3 Ultra frame are uncovered by the fibers and the graft covering and extend more proximally than a most proximal fiber.



Ex. 48, https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU.



Ex. 3, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth

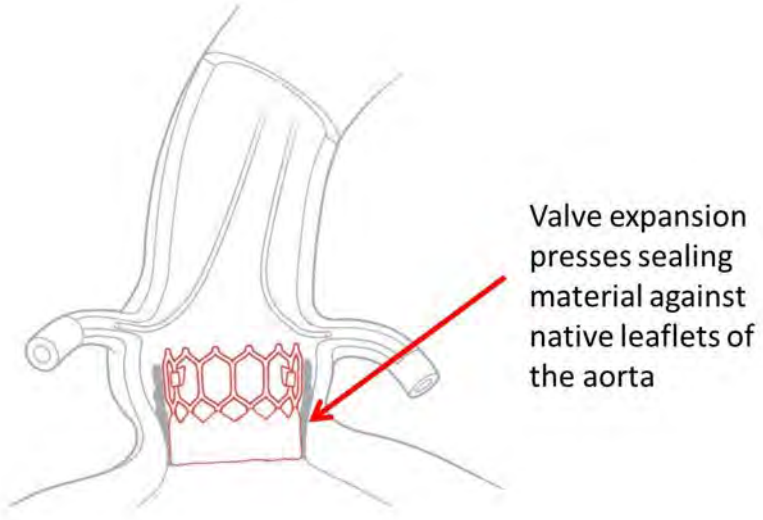
86. On information and belief, the Sapien 3 Ultra is balloon expandable with a radially compressed orientation and a radially expanded orientation.



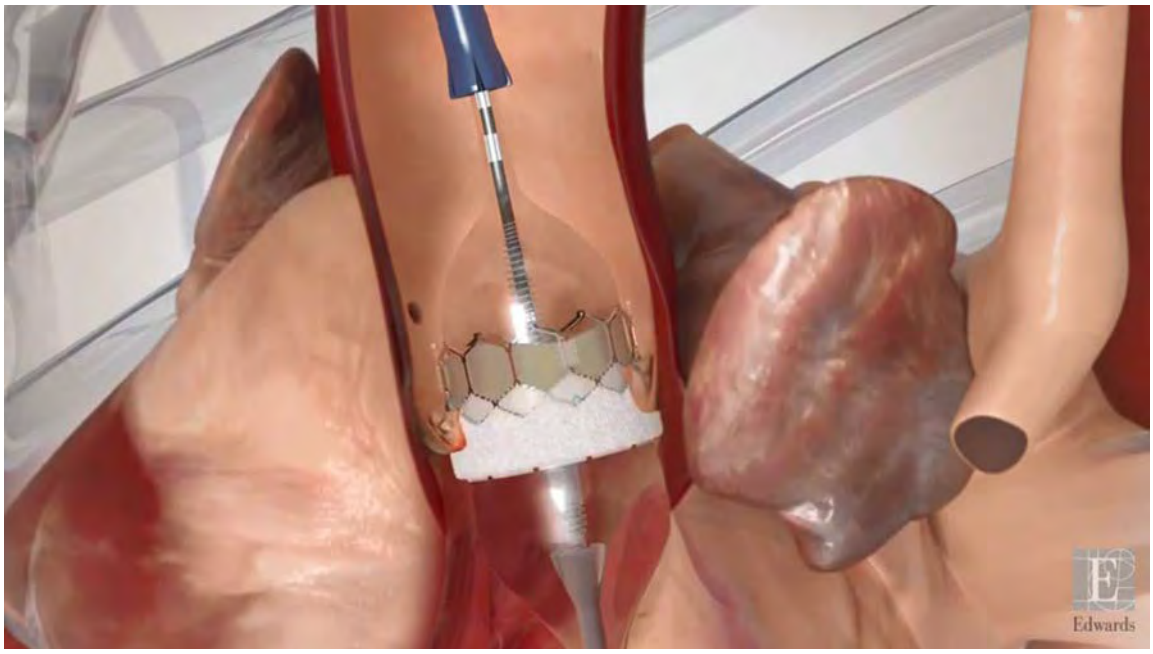
Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), Ex. 47, http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf; Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 1 (annotation added).

87. On information and belief, the Sapien 3 Ultra is designed, tested, and configured to be expandable for deployment within the native heart valve annulus of a patient from a radially

compressed orientation to a radially expanded orientation to press the sealing assembly and the radially outwardly extending fibers of the sealing material into engagement with the native leaflets of the aorta of the patient. In such a configuration, the Sapien 3 Ultra is further designed, tested, and configured to compress the plurality of fibers relative to and/or into the spacings to reduce the spacings and create a seal against the leaflets and the frame.

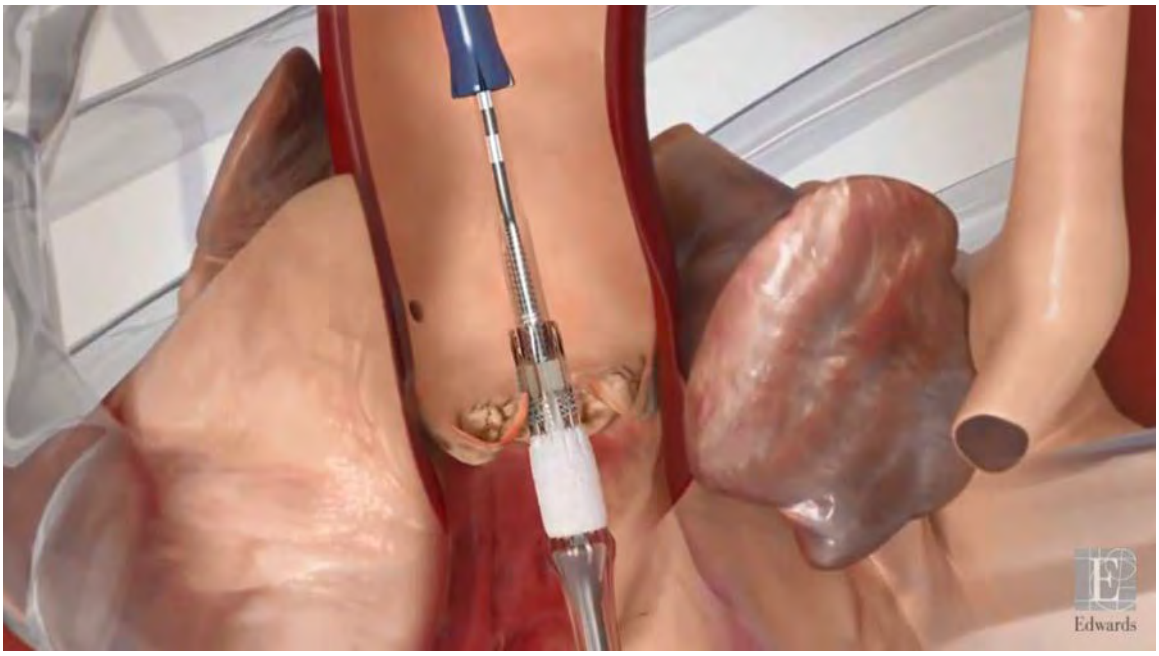


Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra Valve" at 4 (annotation added).

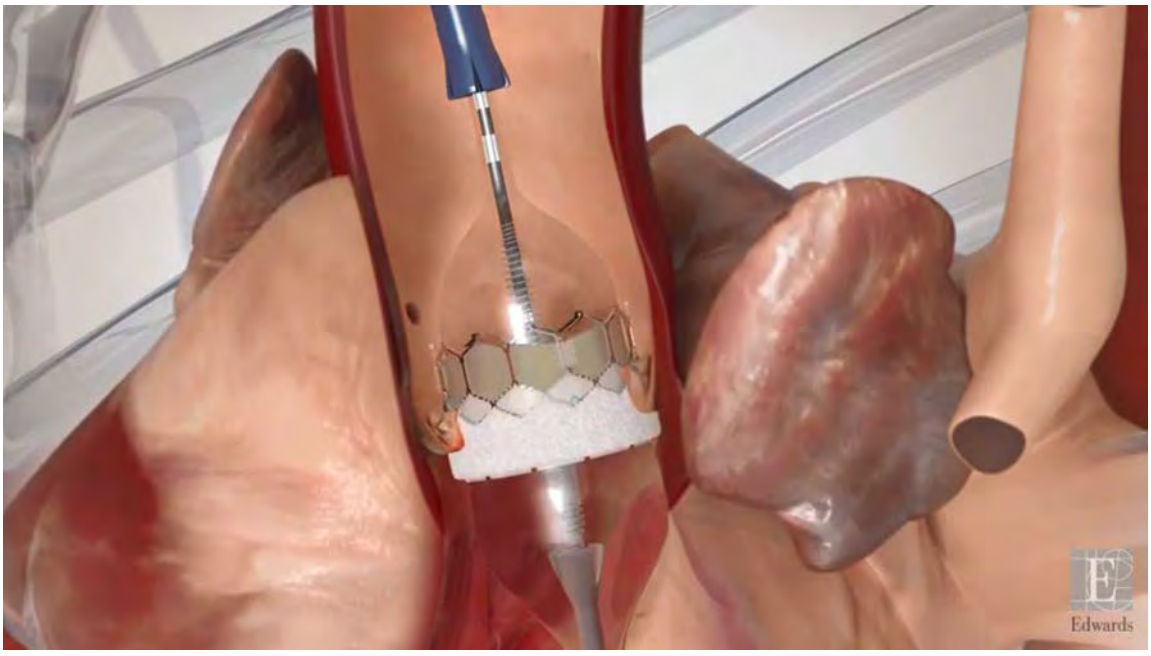


Ex.37, "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I at 1:25.

88. Further, on information and belief, in the Sapien 3 Ultra is designed and configured such that when expanded to the deployed state, the polymer covering is expandable radially outwardly.

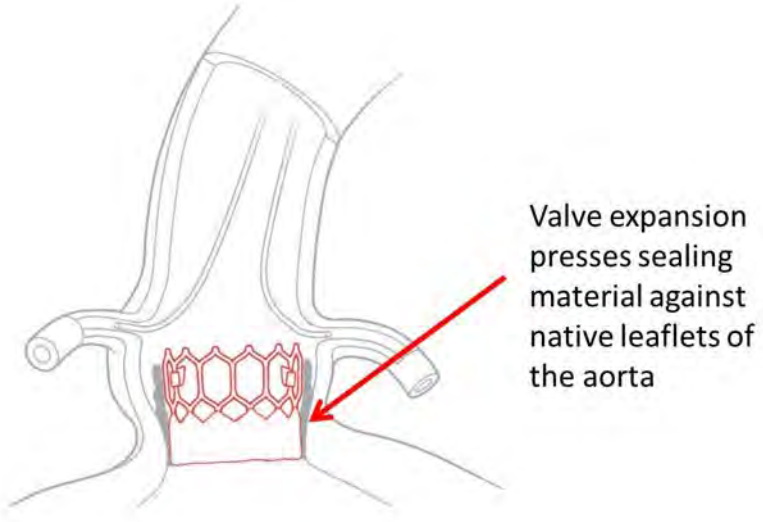


Ex. 37, "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I at 1:13.

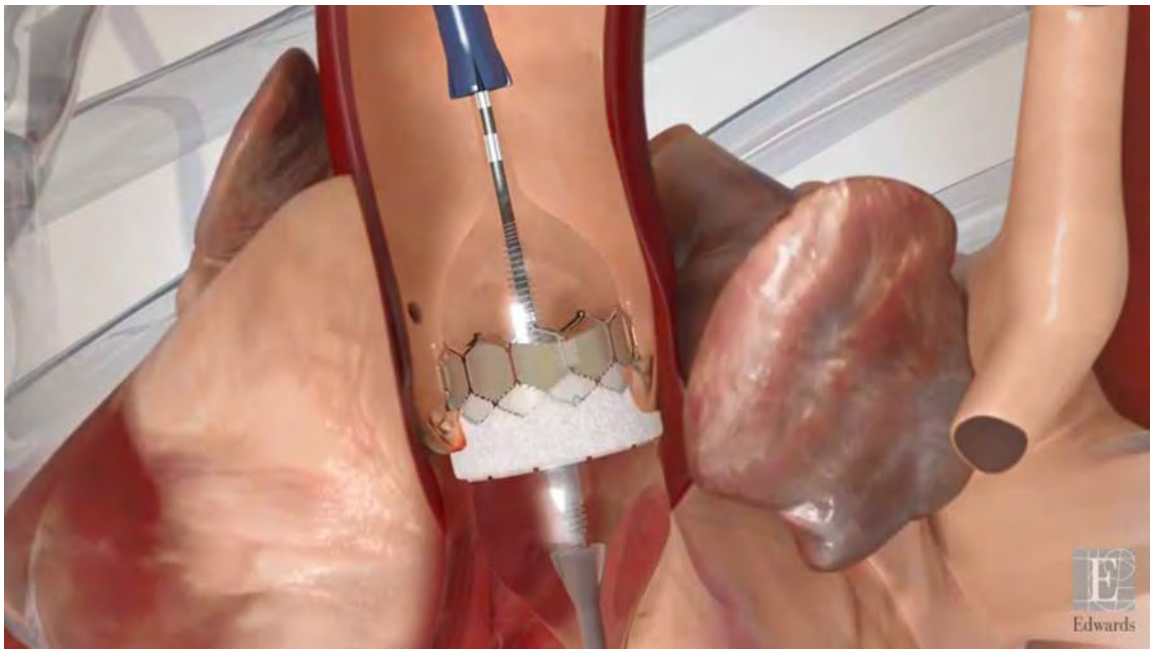


Ex. 37, "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I at 1:25.

89. Further, on information and belief, in the Sapien 3 Ultra is designed and configured such that when expanded to the deployed state, compression of the fibers relative to the spacings and expansion of the polymer covering together create a paravalvular seal about the frame and native leaflets by reducing the spaces in the sealing assembly.



Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra Valve" at 4 (annotation added).



Ex.37, "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I at 1:25.

90. On information and belief, as reflected in the Edwards' materials cited herein, the Sapien 3 Ultra is an endovascular transcatheter prosthetic heart valve designed, configured, sized, shaped, tested, and intended for endovascular deployment and delivery through a femoral artery of a patient by Edwards.

91. On information and belief, Edwards designed, intends, instructs, demonstrates, restricts, oversees, and directs and controls to hospitals, doctors and other medical professional to use the Sapien 3 Ultra in TAVR procedures whereby a doctor or other medical professional endovascularly delivers and/or deploys the Sapien 3 Ultra transcatheter aortic valve assembly via a femoral artery into the aortic valve of the patient. Ex. 37, https://www.youtube.com/watch?v=o3whx7CdM3I; Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf.

92. On information and belief, when used or tested, the Sapien 3 Ultra, and any other Edwards' products that operate in the same or substantially the same manner, either alone or in combination, directly infringe at least one claim of each of the Patents-in-Suit.

93. On information and belief, the Sapien 3 Ultra is designed and sold to be used in TAVR procedures in a specific way, as directed by the instructions for use provided with Sapien 3 Ultra and in promotion and training materials concerning Sapien 3 Ultra. *See, e.g.*, Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf. Edwards manuals and its promotion and training materials provide specific instructions and guidance for using Sapien 3 Ultra in a way that infringes at least one claim of each of the Patents-in-Suit, and they do not contemplate any non-infringing uses.

94. In addition, the Patents-in-Suit are infringed when Edwards offers for sale and sells the Sapien 3 Ultra. Edwards offers for sale and promotes the Sapien 3 Ultra, through Edwards's websites, online videos, at medical conferences and trade shows, and through its sales representatives. Further, Edwards provides marketing and other promotional materials to patients encouraging the selection of the Sapien 3 Ultra, such as through social media (Ex. 69); its www.edwards.com patient portal; https://www.edwards.com/healthcare-professionals/products-services/transcatheter-heart/transcatheter-sapien-3-ultra-resilia; https://www.heartvalves.com/heart-team/devices/tavr/sapien-3-ultra-resilia; https://www.tavrbyedwards.com/why-edwards-tavr/; https://www.newheartvalve.com; https://www.nowismytime.com; https://www.reachfortheheart.com; and https://www.justgettingstarted.com; https://youtu.be/ekkcx97PNgw.

95. On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra, including, but not limited to the Sapien 3 Ultra Resilia to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement#

96. Further, the Patents-in-Suit are directly infringed when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, marketing, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors and/or directs in whole or in part such activities and testing.

97. Edwards further commits acts of direct infringement when Edwards and physicians (or other medical professionals) as directed and controlled by Edwards, including by clinical specialists and/or other Edwards employees, use prepare, and/or deploy the Sapien 3 Ultra. When the Sapien 3 Ultra is prepared, implanted, and/or deployed by Edwards and others, such as those mentioned above, Edwards, is liable for direct infringement as actors in a joint enterprise and/or for conditioning use of the Sapien 3 Ultra and/or participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. *See, e.g.*, Ex. 4; Ex. 70; Ex. 67. Edwards is liable for these acts of direct infringement performed jointly with others in this district and elsewhere by making its products available to users, instructing users to use those products in an infringing manner, and controlling, participating in, overseeing, and/or supporting Sapien 3 Ultra procedures.

GENERAL ALLEGATIONS RELATED TO INFRINGEMENT

98. Edwards has infringed and continues to directly and indirectly infringe at least one claim of each of the Patents-in-Suit by engaging in acts constituting infringement under 35 U.S.C. § 271(a), (b), (c) and/or (f), including but not limited to one or more of making, using, selling, offering for sale, importing, exporting the Accused Products, and inducing and contributing to infringement by others, in this District and elsewhere in the United States.

99. As a result of Edwards' infringement, Aortic has suffered and will continue to suffer harm in the form of damages. Aortic is entitled to pre-suit damages for Edwards' infringement from the date of issuance of each of the Patents-in-Suit up to six years prior to the filing the suit as allowed under 35 U.S.C. §286 and to ongoing damages. To the extent applicable, the requirements of 35 U.S.C. § 287 have been met with respect to the Patents-in-Suit. Further, as a result of Edwards' misappropriations of Dr. Shahriari's inventions, Aortic was effectively precluded from bringing its TAVR device to market and selling its TAVR business.

100. Edwards and its senior employees had direct communications with Aortic and Dr. Shahriari regarding Dr. Shahriari's inventions and the Aortic patents. Edwards also had knowledge of Aortic's patents and applications, including at least the Aortic '132 Application, which was cited during prosecution of Edwards' '651 Application, and the '310, '834, '033, and '634 Patents (to which Edwards has admitted to monitoring and having knowledge of as discussed further supra.).

101. Based on Edwards' interactions with Dr. Shahriari in the 2017 timeframe and thereafter, Edwards was aware or should have been aware of Dr. Shahriari's inventions related to TAVR and the use of an outer seal comprised of extending fibers. Despite such knowledge, Edwards incorporated Dr. Shahriari's TAVR inventions in and released to market its Sapien 3

Ultra device. Edwards subsequently ignored communications from Dr. Shahriari or from others on Dr. Shahriari's behalf.

102. Further, prior to filing suit, Aortic Innovations contacted Edwards in a good faith effort to discuss Edwards' potential licensing of the Aortic patent portfolio. Specifically, on July 19, 2021, Dr. Shahriari sent an email to Mr. Bobo and Keith Newburry (Edwards' Vice President, Chief Intellectual Property Counsel) expressly informing them of Edwards' practice of Aortic's portfolio including patents related to the Patents-in-Suit in relation to the Sapien 3 Ultra (as well as Edwards' practice of Aortic's mitral valve patents in relation to the Sapien M3) and requesting the opportunity to discuss a potential license. Ex. 22. On information and belief, after receiving notice, Edwards has not ceased its practice of the Aortic patents

103. Mr. Bobo responded to Dr. Shahriari on July 20, 2021 stating: "Thanks for the email and additional details, let me get to the team and take a look and we should be able to talk once we've taken a look. I've copied my admin Greta who can help with a followup time in early August." Ex. 49.

104. Instead of offering dates for a discussion in early August as Mr. Bobo suggested in the July 20, 2021 email, Mr. Bobo's assistant, Greta Cook, emailed Dr. Shahriari on July 21, 2021 with some proposed dates between August 30, 2021 and November 6, 2021. Ex. 50.

105. Upon information and belief, Edward's proffered dates for a discussion between Dr. Shahrari and Mr. Bobo between August 30, 2021 and November 6, 2021 instead of in "early August" as originally proposed by Mr. Bobo was intended to delay discussions between the Parties.

106. Despite Edwards' apparent attempts to postpone potential licensing discussions, Dr. Shahriari, continuing to want to reach an amicable resolution with Edwards, approached Seth Damergy of UBS, an investment banker that had previously worked with Dr. Shahriari in connection with the sale of Ascyrus, to reach out to Mr. Bobo. Dr. Shahriari informed Mr. Bobo of this via an email sent on July 26, 2021 in which Dr. Shahriari wrote "Thank you both for the follow up. We have engaged Seth Damergy and the UBS team that worked with us on the sale of Ascyrus to assist here and he and his team will reach out to your assistant to help coordinate a call and discuss next steps. We look forward to our future discussions and the opportunity to work together." Ex. 51.

107. Aortic's representatives continued to correspond with Edwards, who implied that they were working towards a resolution of the dispute.

108. On September 10, 2021, Edwards filed an Inter Partes Review ("IPR") against Aortic's U.S. Patent No. 10,792,172 ("'172 Patent")—one of Aortic's patents identified in the July 19, 2021 email Dr. Shahriari sent to Edwards. *See* Ex. 22.

109. Despite the offer by Dr. Shahriari to reach an amicable resolution, Edwards did not make itself available to have a discussion with Dr. Shahriari until September 15, 2021—5 days after filing an IPR against the '172 Patent. But, instead of discussing a potential license of Dr. Sharhriari's patents in good faith, Mr. Bobo informed Dr. Shahriari that he was "insulted" by Dr. Shahriari's patents. Additionally, Mr. Westhart informed Dr. Shahriari that Edwards would seek to tie up Aortic Innovations in litigation for years.

110. On September 28, 2021, Aortic filed a patent infringement against Edwards alleging that Edwards has infringed and continues to infringe at least one claim of U.S. Patent Nos.

10,881,538 ("the '538 Patent"); 10,966,846 ("the '846 Patent"); 10,987,236 ("the '236 Patent"); and 11,129,735 ("the '735 Patent) based on its infringing acts related to the Sapien 3 Ultra TAVR device. *Aortic Innovations LLC v. Edwards Lifesciences Corporation, et al.*, 1-21-cv-01377 (DDE) at D.I. 1. On information and belief, since at least that time, Edwards has not ceased its infringing acts set forth in Aortic's Complaint in the First Action.

111. On information and belief, since at least the time of Dr. Shahriari's July 19, 2021 email and the filing of Aortic's complaint in September 28, 2021, Edwards has investigated Aortic's patents and patent applications at least in connection with the numerous IPR's filed to date by Edwards on Aortic's patents, including, IPR2021-01527 (filed on U.S. Patent No. 10, 792,172), IPR2021-01584 (filed on U.S. Patent No. 10,857,011), IPR2022-0034 (filed on U.S. Patent No. 10,966,846), IPR2022-0193 (filed on U.S. Patent No. 10,881,538), IPR2022-0549 (filed on U.S. Patent No. 11,129,735), and IPR2022-0556 (filed on U.S. Patent No. 10,987,236). Edwards has further investigated its infringement in connection with the Sapien 3 Ultra alleged to infringe certain Aortic patents in connection with the First Complaint. *See* Dkt. No. 1 and Aortic's Infringement Contentions in *Aortic Innovations LLC v. Edwards Lifesciences Corporation, et al.*, 1-21-cv-01377 (DDE); *see also* Ex. 49 (July 20, 2021 email from D. Bobo to A. Shahriari stating: "Thanks for the email and additional details, let me get to the team and take a look and we should be able to talk once we've taken a look.").

112. Further, as noted above, Edwards has admitted to knowledge of the '310, '834, '033, and '634 Patents and Aortic's accusations of infringement. For example, Edwards attached the '310, '834, '033, and '634 patents to its responsive claim construction brief in the First Action. *Aortic Innovations LLC v. Edwards Lifesciences Corporation*, et al., 1-21-cv-01377 (DDE), D.I.

96, i.v. and 3, n.1. Further, regarding the '834 and other Aortic patents, Edwards has stated "Aortic continues to obtain patents without an "inner frame" limitation after Edwards' identified that limitation as missing from its Sapien 3 Ultra valve" and acknowledged that "Aortic has repeatedly argued to the Patent Office that SAPIEN 3 Ultra 'appears to be covered by the claimed invention.'" *Aortic Innovations LLC v. Edwards Lifesciences Corporation*, et al., 1-21-cv-01377 (DDE), D.I. 75 at 12-13. On information and belief, despite receiving notice, Edwards has not ceased practicing any of the Aortic Patents-in-Suit. Instead, Edwards has continued its infringement and further launched the Sapien 3 Ultra with Resilia leaflets and is continuing to develop and test the Sapien X4 TAVR device for marketing.

113. On information and belief, based on Edwards' pre-suit and post-suit IPR filings on Aortic's patents and the currently pending lawsuit between the parties involving related patents and the Sapien 3 Ultra product, Edwards has or should have been aware of the '834, '310, '033, '634, and '918 Patents at least as of the dates of their issuance on May 24, 2022, July 19, 2022, Nov. 8, 2022, Nov. 15, 2022, and Dec. 13, 2022, respectively.

114. Further, on February 15, 2023, after the filing of the original complaint in this matter alleging infringement of the '834 and '310 Patents by Edwards (D.I. 1), counsel for Aortic sent correspondence to Edwards and its counsel, providing express notice to Edwards regarding its infringement of Aortic's '834, '310, '033, '634, and '918 Patents in connection with the Sapien 3 Ultra and Sapien 3 Ultra with Resilia leaflets. Ex. 75. Aortic's notice correspondence further included copies of each of the '834, '310, '033, '634, and '918 Patents. *Id*. Aortic's notice correspondence was received by Edwards as reflected by Edwards' responsive correspondence dated February 15, 2023. On information and belief, despite receiving notice, Edwards has not

ceased practicing any of the Aortic Patents-in-Suit despite being given adequate opportunity to do so. Instead, Edwards has continued its infringing activities despite knowledge of the Patents-in-Suit and its infringement thereof. *See, e.g.,* Exs. 76-80.

115. As demonstrated by the foregoing, Edwards' infringement of the Patents-in-Suit has been, and continues to be, without permission, consent, authorization, or license. As a result, Edwards's conduct was and continues to be willful and egregious.

COUNT I: INFRINGEMENT OF THE '834 PATENT

116. Aortic incorporates by reference the preceding paragraphs as though fully set forth herein.

117. Edwards infringes, contributes to the infringement of, and/or induces infringement of '834 Patent by making, using, selling, offering for sale, exporting from and/or importing into the United States the Accused Products and/or components that are covered by one or more claims of the '834 Patent.

118. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one or more claims of the '834 Patent. Edwards makes, uses, sells, offers for sale, imports, and/or exports in and/or from this District and elsewhere in the United States, the Accused Products and/or components thereof and thus directly infringes claims of the '834 Patent.

119. For example, Claim 18 of the '834 Patent is reproduced below:

> 18. An endovascular prosthetic heart valve for use in a patient, comprising:
>
> a frame formed of a plurality of struts that cooperate to form 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 carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly; and

a plurality of fibers that extend away from the frame,

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,

wherein the 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 heart valve annulus of the patient,

wherein the prosthetic heart valve defines a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame,

wherein, compression of the plurality of fibers in response to expansion of the prosthetic heart valve compresses the plurality of fibers relative to the spacings to create a seal thereabout,

wherein the plurality of fibers extends over each of the at least two rows of cells.

120. As a non-limiting example, on information and belief, the Sapien 3 Ultra is an endovascular prosthetic heart valve for use in a patient.

121. On information and belief, the Sapien 3 Ultra includes a frame formed of a plurality of struts that cooperate to form a plurality of cells.

122. On information and belief, the Sapien 3 Ultra plurality of cells defines at least two rows of cells at an inflow end of the frame.

123. On information and belief, the Sapien 3 Ultra frame is radially expandable from a radially compressed orientation to a radially expanded orientation.

124. On information and belief, the Sapien 3 Ultra includes a leaflet assembly within the frame.

125. On information and belief, the Sapien 3 Ultra includes a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly.

126. On information and belief, the Sapien 3 Ultra includes a plurality of fibers that extend away from the frame.

127. On information and belief, the Sapien 3 Ultra is designed and configured by Edwards to be endovascularly deployed through a femoral artery of the patient.

128. On information and belief, the Sapien 3 Ultra plurality of fibers is designed and 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 heart valve annulus of the patient.

129. On information and belief, the Sapien 3 Ultra defines a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame.

130. On information and belief, the Sapien 3 Ultra is designed and configured such that compression of the plurality of fibers in response to expansion of the prosthetic heart valve compresses the plurality of fibers relative to the spacings to create a seal thereabout.

131. On information and belief, the Sapien 3 Ultra plurality of fibers extends over each of the at least two rows of cells.

132. Further, the ’834 Patent is infringed by Edwards when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, marketing, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or

tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors and/or directs in whole or in part such activities and testing.

133. Edwards further commits acts of direct infringement when Edwards and physicians (or other medical professionals) as directed and controlled by Edwards, including by clinical specialists and/or other Edwards employees, use prepare, and/or deploy the Sapien 3 Ultra. When the Sapien 3 Ultra is prepared, implanted, and/or deployed by Edwards and others, such as those mentioned above, Edwards, is liable for direct infringement as actors in a joint enterprise and/or for conditioning use of the Sapien 3 Ultra and/or participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. *See, e.g.*, Ex. 4; Ex. 70; Ex, 67. Edwards is liable for these acts of direct infringement performed jointly with others in this district and elsewhere by making its products available to users, instructing users to use those products in an infringing manner, and controlling, participating in, overseeing, and/or supporting Sapien 3 Ultra procedures.

134. Edwards also indirectly infringes claims of the ’834 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards’s affiliated hospitals, doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the ’834 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing, product manuals, advertisements, and other information to customers and end users suggesting

they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, assist in the Sapien 3 Ultra TAVR procedures, and maintain a "watchful eye" over doctors and other medical staff before and during such procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Products as intended by Edwards to directly infringe the '834 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '834 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '834 Patent.

135. Edwards also indirectly infringes claims of the '834 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' use of the Accused Products, such that the '834 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the '834 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the '834 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '834 Patent and with intent, or willful blindness, that they cause the direct infringement of the '834 Patent.

COUNT II: INFRINGEMENT OF THE '310 PATENT

136. Aortic incorporates by reference the preceding paragraphs as though fully set forth herein.

137. Edwards infringes, contributes to the infringement of, and/or induces infringement of the '310 Patent by making, using, selling, offering for sale, exporting from and/or importing into the United States the Accused Products and/or components that are covered by one or more claims of the '310 Patent.

138. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one of more claims of the '310 Patent. Edwards makes, uses, sells, offers for sale, imports, and/or exports in and/or from this District and/or elsewhere in the United States, the Accused Products and/or components thereof and thus directly infringes claims of the '310 Patent.

139. For example, Claim 11 of the '310 Patent is reproduced below:

> 11. A transcatheter aortic heart valve assembly comprising:
>
> a graft covering engaging prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart valve leaflets for providing sealing to the prosthetic heart valve leaflets;
>
> a frame formed from a metallic material and defining an open cell configuration, 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 to prevent paravalvular leaks,
>
> wherein the sealing material is attached to the frame,
>
> wherein the sealing material defines a height that extends over at least a first two rows of cells in the frame,
>
> wherein the sealing material includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame;

> wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient,
>
> wherein the heart valve assembly has a radially compressed orientation and a radially expanded orientation,
>
> wherein expansion of the heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the outwardly extending fibers into engagement with native leaflets of the aorta of the patient,
>
> wherein the plurality of fibers is in contact with the frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation.

140. As a non-limiting example, on information and belief, the Sapien 3 Ultra is a transcatheter heart valve assembly.

141. On information and belief, the Sapien 3 Ultra includes a graft covering engaging prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart valve leaflets for providing sealing to the prosthetic heart valve leaflets.

142. On information and belief, the Sapien 3 Ultra includes a frame formed from a metallic material and defining an open cell configuration, and being secured to the graft covering.

143. On information and belief, the Sapien 3 Ultra includes a sealing material positioned externally to the frame for providing sealing between the frame and a patient's anatomical wall to prevent paravalvular leaks.

144. On information and belief, the Sapien 3 Ultra sealing material is attached to the frame.

145. On information and belief, the Sapien 3 Ultra sealing material defines a height that extends over at least a first two rows of cells in the frame.

146. On information and belief, the Sapien 3 Ultra sealing material includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame.

147. On information and belief, the Sapien 3 Ultra heart valve assembly is designed and configured to be deployed endovascularly through a femoral artery of the patient.

148. On information and belief, the Sapien 3 Ultra heart valve assembly has a radially compressed orientation and a radially expanded orientation.

149. On information and belief, the Sapien 3 Ultra is designed and configured such that expansion of heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the outwardly extending fibers into engagement with native leaflets of the aorta of the patient.

150. On information and belief, the Sapien 3 Ultra plurality of fibers are designed and configured to be in contact with the frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation.

151. Further, the ’310 Patent is infringed by Edwards when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, marketing, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors and/or directs in whole or in part such activities and testing.

152. Edwards further commits acts of direct infringement when Edwards and physicians (or other medical professionals) as directed and controlled by Edwards, including by clinical specialists and/or other Edwards employees, use, prepare, and/or deploy the Sapien 3 Ultra. When the Sapien 3 Ultra is prepared, implanted, and/or deployed by Edwards and others, such as

those mentioned above, Edwards, is liable for direct infringement as actors in a joint enterprise and/or for conditioning use of the Sapien 3 Ultra and/or participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. *See, e.g.*, Ex. 4; Ex. 70; Ex. 67. Edwards is liable for these acts of direct infringement performed jointly with others in this district and elsewhere by making its products available to users, instructing users to use those products in an infringing manner, and controlling, participating in, overseeing, and/or supporting Sapien 3 Ultra procedures.

153. Edwards also indirectly infringes claims of the '310 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards's affiliated hospitals, doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards's affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the '310 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, assist in the Sapien 3 Ultra TAVR procedures, and maintain a "watchful eye" over doctors and other medical staff before and during such procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused

Products as intended by Edwards to directly infringe the ’310 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the ’310 Patent and with the intent, or willful blindness, that the induced acts directly infringe the ’310 Patent.

154. Edwards also indirectly infringes claims of the ’310 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards’s affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ use of the Accused Products, such that the ’310 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the ’310 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the ’310 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the ’310 Patent and with intent, or willful blindness, that they cause the direct infringement of the ’310 Patent.

COUNT III: INFRINGEMENT OF THE ’033 PATENT

155. Aortic incorporates by reference the preceding paragraphs as though fully set forth herein.

156. Edwards infringes, contributes to the infringement of, and/or induces infringement of the ’033 Patent by making, using, selling, offering for sale, exporting from and/or importing

into the United States the Accused Products and/or components that are covered by one or more claims of the '033 Patent.

157. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one of more claims of the '033 Patent. Edwards makes, uses, sells, offers for sale, imports, and/or exports in and/or from this District and/or elsewhere in the United States, the Accused Products and thus directly infringes claims of the '033 Patent.

158. For example, Claim 1 of the '033 Patent is reproduced below:

> 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.

159. As a non-limiting example, on information and belief, the Sapien 3 Ultra is an endovascular prosthetic heart valve assembly having improved sealing for addressing paravalvular leakage for use in a patient.

160. On information and belief, the Sapien 3 Ultra includes 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.

161. On information and belief, the Sapien 3 Ultra includes a leaflet assembly within the frame.

162. On information and belief, the Sapien 3 Ultra includes 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.

163. On information and belief, the Sapien 3 Ultra includes 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.

164. On information and belief, the Sapien 3 Ultra sealing assembly lays against the frame when the prosthetic heart valve assembly is in the radially compressed orientation and the radially expanded orientation.

165. On information and belief, the Sapien 3 Ultra is sized and shaped to be endovascularly deployed through a femoral artery of the patient.

166. On information and belief, the Sapien 3 Ultra 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.

167. On information and belief, the Sapien 3 Ultra is designed and configured such that 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. 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.

168. Further, the ’033 Patent is infringed by Edwards when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, marketing, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or

tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors and/or directs in whole or in part such activities and testing.

169. Edwards further commits acts of direct infringement when Edwards and physicians (or other medical professionals) as directed and controlled by Edwards, including by clinical specialists and/or other Edwards employees, use, prepare, and/or deploy the Sapien 3 Ultra. When the Sapien 3 Ultra is prepared, implanted, and/or deployed by Edwards and others, such as those mentioned above, Edwards, is liable for direct infringement as actors in a joint enterprise and/or for conditioning use of the Sapien 3 Ultra and/or participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. *See, e.g.*, Ex. 4; Ex. 70; Ex. 67. Edwards is liable for these acts of direct infringement performed jointly with others in this district and elsewhere by making its products available to users, instructing users to use those products in an infringing manner, and controlling, participating in, overseeing, and/or supporting Sapien 3 Ultra procedures.

170. Edwards also indirectly infringes claims of the ’033 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards’s affiliated hospitals, doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the ’033 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing, product manuals, advertisements, and other information to customers and end users suggesting

they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, assist in the Sapien 3 Ultra TAVR procedures, and maintain a "watchful eye" over doctors and other medical staff before and during such procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Products as intended by Edwards to directly infringe the '033 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '033 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '033 Patent.

171. Edwards also indirectly infringes claims of the '033 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' use of the Accused Products, such that the '033 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the '033 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the '033 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '033 Patent and with intent, or willful blindness, that they cause the direct infringement of the '033 Patent.

COUNT IV: INFRINGEMENT OF THE '634 PATENT

172. Aortic incorporates by reference the preceding paragraphs as though fully set forth herein.

173. Edwards infringes, contributes to the infringement of, and/or induces infringement of the '634 Patent by making, using, selling, offering for sale, exporting from and/or importing into the United States the Accused Products and/or components that are covered by one or more claims of the '634 Patent.

174. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one of more claims of the '634 Patent. Edwards makes, uses, sells, offers for sale, imports, and/or exports in and/or from this District and/or elsewhere in the United States, the Accused Products and/or components thereof and thus directly infringes claims of the '634 Patent.

175. For example, Claim 1 of the '634 Patent is reproduced below:

> 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.

176. As a non-limiting example, on information and belief, the Sapien 3 Ultra is a transcatheter aortic heart valve assembly.

177. On information and belief, the Sapien 3 Ultra includes a graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto.

178. On information and belief, the Sapien 3 Ultra includes 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.

179. On information and belief, the Sapien 3 Ultra frame is secured to the graft covering.

180. On information and belief, the Sapien 3 Ultra graft covering is made of a polymer.

181. On information and belief, the Sapien 3 Ultra includes a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame.

182. On information and belief, the Sapien 3 Ultra fibers are arcuate, spaced-apart, and outwardly extending.

183. On information and belief, the Sapien 3 Ultra 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.

184. On information and belief, the Sapien 3 Ultra 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.

185. On information and belief, the Sapien 3 Ultra is designed and configured such that 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.

186. On information and belief, the Sapien 3 Ultra is designed and configured such that the graft covering is engaged with fibers of the plurality of fibers.

187. On information and belief, the Sapien 3 Ultra is defined and configured such that 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.

188. Further, the ’634 Patent is infringed by Edwards when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, marketing, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or

tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors and/or directs in whole or in part such activities and testing.

189. Edwards further commits acts of direct infringement when Edwards and physicians (or other medical professionals) as directed and controlled by Edwards, including by clinical specialists and/or other Edwards employees, use, prepare, and/or deploy the Sapien 3 Ultra. When the Sapien 3 Ultra is prepared, implanted, and/or deployed by Edwards and others, such as those mentioned above, Edwards, is liable for direct infringement as actors in a joint enterprise and/or for conditioning use of the Sapien 3 Ultra and/or participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. *See, e.g.*, Ex. 4; Ex. 70; Ex. 67. Edwards is liable for these acts of direct infringement performed jointly with others in this district and elsewhere by making its products available to users, instructing users to use those products in an infringing manner, and controlling, participating in, overseeing, and/or supporting Sapien 3 Ultra procedures.

190. Edwards also indirectly infringes claims of the ’634 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards’s affiliated hospitals, doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the ’634 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing, product manuals, advertisements, and other information to customers and end users suggesting

they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, assist in the Sapien 3 Ultra TAVR procedures, and maintain a "watchful eye" over doctors and other medical staff before and during such procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Products as intended by Edwards to directly infringe the '634 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '634 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '634 Patent.

191. Edwards also indirectly infringes claims of the '634 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' use of the Accused Products, such that the '634 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the '634 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the '634 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '634 Patent and with intent, or willful blindness, that they cause the direct infringement of the '634 Patent.

COUNT V: INFRINGEMENT OF THE '918 PATENT

192. Aortic incorporates by reference the preceding paragraphs as though fully set forth herein.

193. Edwards infringes, contributes to the infringement of, and/or induces infringement of the '918 Patent by making, using, selling, offering for sale, exporting from and/or importing into the United States the Accused Products and/or components that are covered by one or more claims of the '918 Patent.

194. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one of more claims of the '918 Patent. Edwards makes, uses, sells, offers for sale, imports, and/or exports in and/or from this District and/or elsewhere in the United States, the Accused Products and/or components thereof and thus directly infringes claims of the '918 Patent.

> 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.

195. As a non-limiting example, on information and belief, the Sapien 3 Ultra is an endovascularly deployed heart valve assembly comprising.

196. On information and belief, the Sapien 3 Ultra includes a graft covering for engaging prosthetic heart valve leaflets, wherein the graft covering engages the prosthetic heart valve leaflets for providing sealing thereto.

197. On information and belief, the Sapien 3 Ultra includes 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.

198. On information and belief, the Sapien 3 Ultra sealing material is 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.

199. On information and belief, the Sapien 3 Ultra sealing material includes a plurality of outwardly extending fibers that extend outwardly of the frame.

200. On information and belief, the Sapien 3 Ultra fibers are arcuate.

201. On information and belief, the Sapien 3 Ultra fibers are flexible such that compression of the fibers imparts movement thereto.

202. On information and belief, the Sapien 3 Ultra fibers are in contact with the frame along a height of the sealing material.

203. On information and belief, the Sapien 3 Ultra 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.

204. On information and belief, the Sapien 3 Ultra heart valve assembly has a radially compressed orientation and a radially expanded orientation.

205. On information and belief, the Sapien 3 Ultra 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.

206. On information and belief, the Sapien 3 Ultra heart valve assembly is sized and shaped for being delivered endovascularly through a femoral artery of a patient.

207. Further, the ’918 Patent is infringed by Edwards when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability,

marketing, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors and/or directs in whole or in part such activities and testing.

208. Edwards further commits acts of direct infringement when Edwards and physicians (or other medical professionals) as directed and controlled by Edwards, including by clinical specialists and/or other Edwards employees, use, prepare, and/or deploy the Sapien 3 Ultra. When the Sapien 3 Ultra is prepared, implanted, and/or deployed by Edwards and others, such as those mentioned above, Edwards, is liable for direct infringement as actors in a joint enterprise and/or for conditioning use of the Sapien 3 Ultra and/or participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. *See, e.g.*, Ex. 4; Ex. 70; Ex. 67. Edwards is liable for these acts of direct infringement performed jointly with others in this district and elsewhere by making its products available to users, instructing users to use those products in an infringing manner, and controlling, participating in, overseeing, and/or supporting Sapien 3 Ultra procedures.

209. Edwards also indirectly infringes claims of the ’918 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Edwards’s affiliated hospitals, doctors, medical professionals, distributors, customers, and end users, in this District and elsewhere in the United States. For example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe through their use and deployment of the inventions claimed in the ’918 Patent. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions for use, documentation, online technical support and videos, marketing,

product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. Also as noted above, Edwards sends its employees to hospitals to provide product and instructional materials, educate doctors on the installation and use of the Sapien 3 Ultra, help select patients for Sapien 3 Ultra TAVR, assist in the Sapien 3 Ultra TAVR procedures, and maintain a "watchful eye" over doctors and other medical staff before and during such procedures. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Products as intended by Edwards to directly infringe the '918 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or willful blindness of the '918 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '918 Patent.

210. Edwards also indirectly infringes claims of the '918 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. On information and belief, Edwards's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' use of the Accused Products, such that the '918 Patent is directly infringed. The Accused Products and/or accused components within the Accused Products are material to the invention of the '918 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Edwards to be especially made or especially adapted for use in infringement of the '918 Patent. Edwards has performed and continues to perform these affirmative acts with knowledge or

willful blindness of the '918 Patent and with intent, or willful blindness, that they cause the direct infringement of the '918 Patent.

PRAYER FOR RELIEF

WHEREFORE, Aortic respectfully requests that this Court enter judgment in its favor as follows and award Aortic the following relief:

1. a judgment in favor of Aortic that Edwards has directly and/or indirectly infringed and infringes one or more claims of each of the Patents-in-Suit;

2. a judgment that Edwards's infringement has been willful and deliberate;

3. an award of damages adequate to compensate Aortic for infringement (past and continuing) of the Patents-in-Suit by Edwards, in an amount to be proven at trial, but in no event less than a reasonable royalty, including supplemental damages post-verdict, together with pre-judgment and post-judgment interest and costs, until such time as Edwards ceases its infringing conduct;

4. a judgement declaring that Edwards' infringement has been willful and awarding enhanced damages for willful infringement;

5. a judgment declaring that this case is exceptional and awarding Aortic its costs of this action, as well as reasonable attorneys' fees as provided by 35 U.S.C. § 285;

6. pre-judgment and post-judgment interest at the maximum amount permitted by law;

7. an accounting for acts of infringement;

8. a judgment and order requiring Edwards to pay Aortic compulsory ongoing licensing fees, as determined by the Court in equity;

9. such other equitable relief which may be requested and to which Aortic is entitled; and

10. all other relief, in law or equity, to which Aortic is entitled and/or the Court deems just and proper.

Dated: April 10, 2023

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DEMAND FOR JURY TRIAL

In accordance with Rule 38(b) of the Federal Rules of Civil Procedure and Local Rule CV-38.1, Plaintiff respectfully demands a jury trial of all issues triable to a jury.

Dated: April 10, 2023

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ *Adam W. Poff*
Adam W. Poff

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on April 10, 2023, a copy of the foregoing document was served on the persons listed below in the manner indicated:

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EXHIBIT 1

US011337834B2

(12) **United States Patent**
Shahriari

(10) **Patent No.: US 11,337,834 B2**
(45) **Date of Patent: *May 24, 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.

(21) Appl. No.: **17/327,673**

(22) Filed: **May 22, 2021**

(65) **Prior Publication Data**

US 2021/0275330 A1 Sep. 9, 2021

Related U.S. Application Data

(63) Continuation of application No. 17/213,251, filed on Mar. 26, 2021, which is a continuation of application (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; A61F 2/86; A61F 2/89; A61F 2/90; A61F 2002/061; A61F 2002/067; A61F 2210/00; A61F 2210/0014; A61F 2210/0057; A61F 2220/008; A61F 2220/0016; A61F 2220/0025; A61F 2220/0058;
(Continued)

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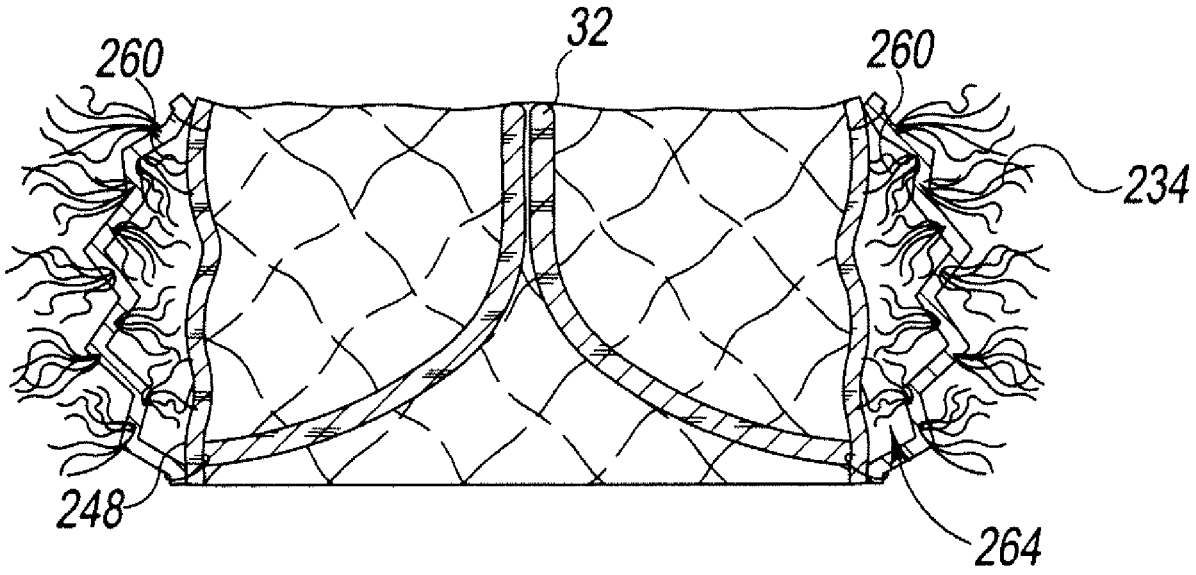
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(Continued)

Primary Examiner — Jennifer Dieterle
Assistant Examiner — Tiffany P Shipmon
(74) *Attorney, Agent, or Firm* — NK Patent Law

(57) **ABSTRACT**

A transcatheter valve assembly replacement device includes an improved paravalvular seal.

18 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 continuation 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 2/962	(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)

(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 2220/0075; A61F 2230/001; A61F 2230/0034; A61F 2230/0067; A61F 2250/0048; A61F 2250/0069

See application file for complete search history.

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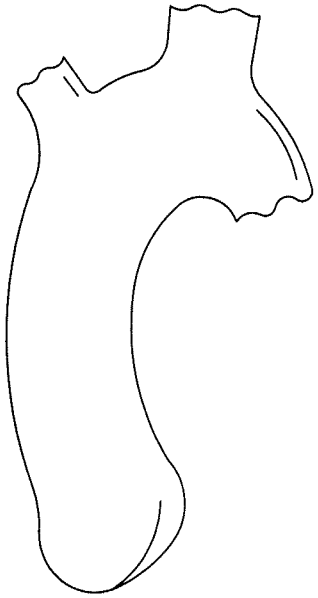


Fig. 1

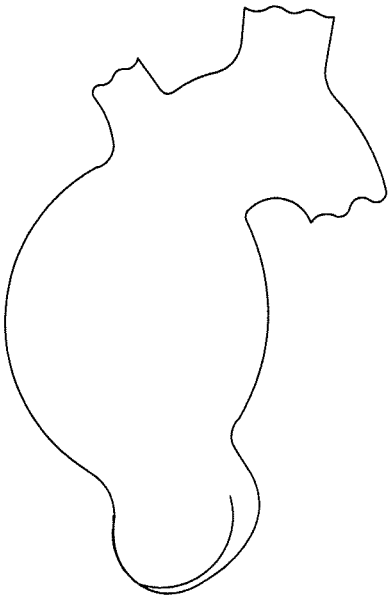


Fig. 1B

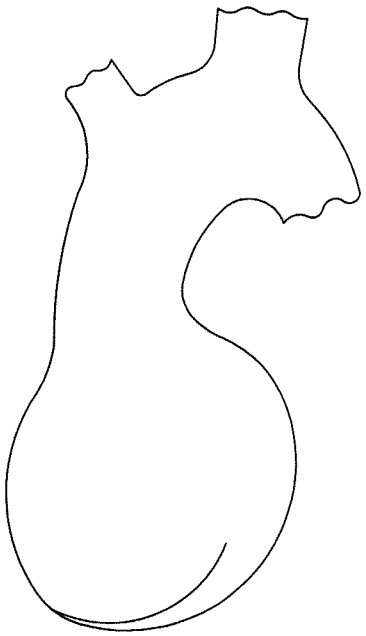


Fig. 1A



Fig. 1C

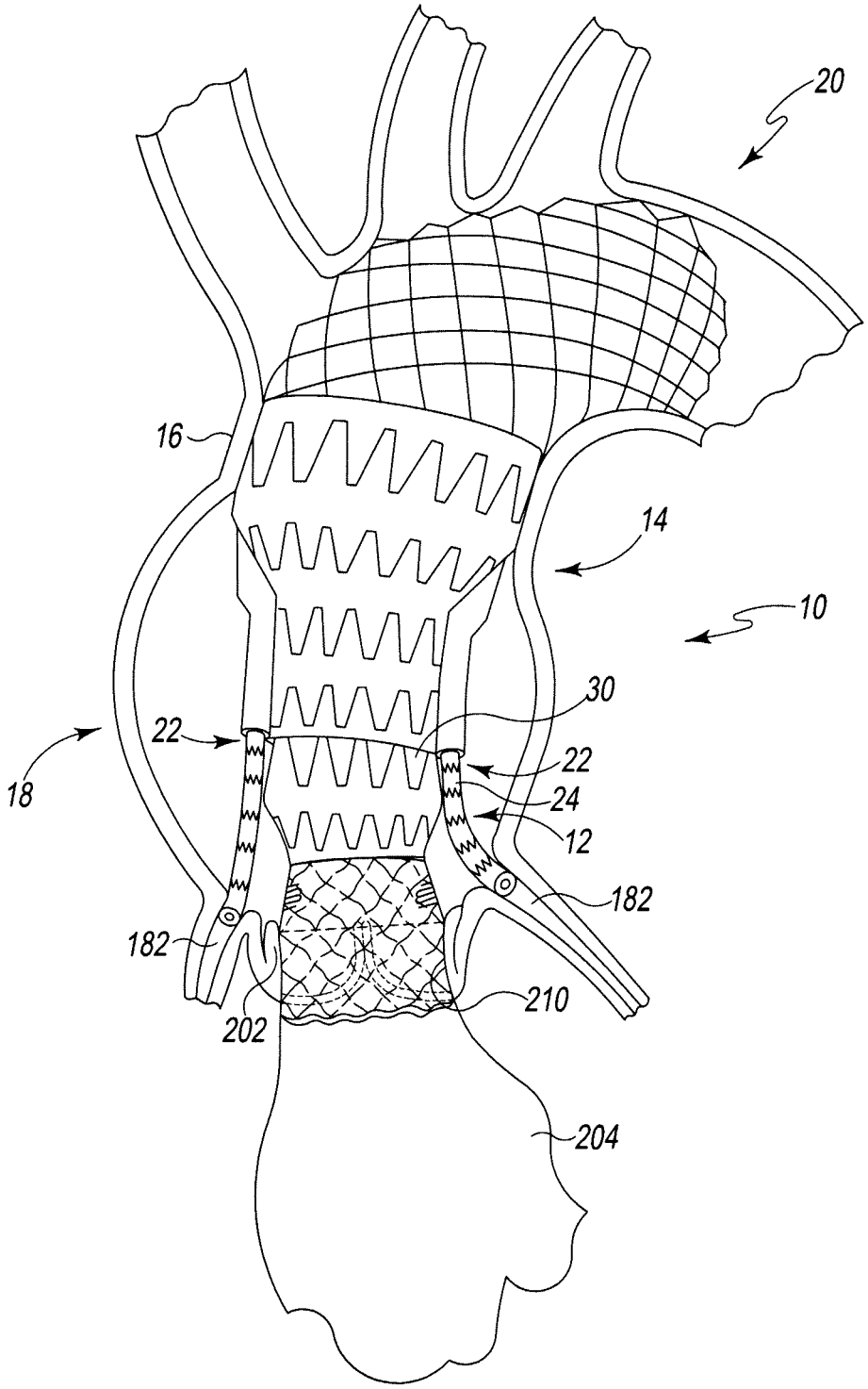


Fig. 2

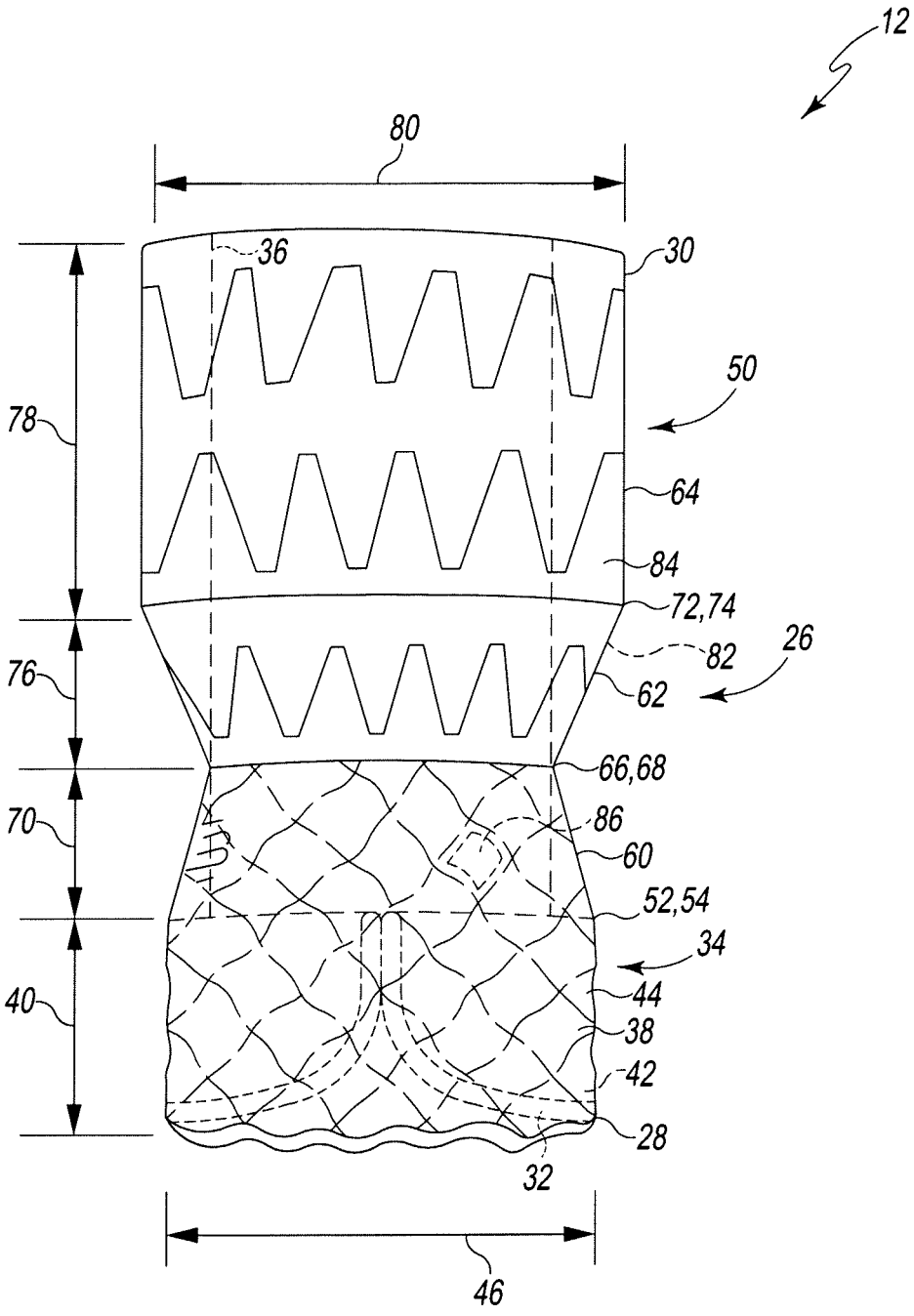

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Fig. 3

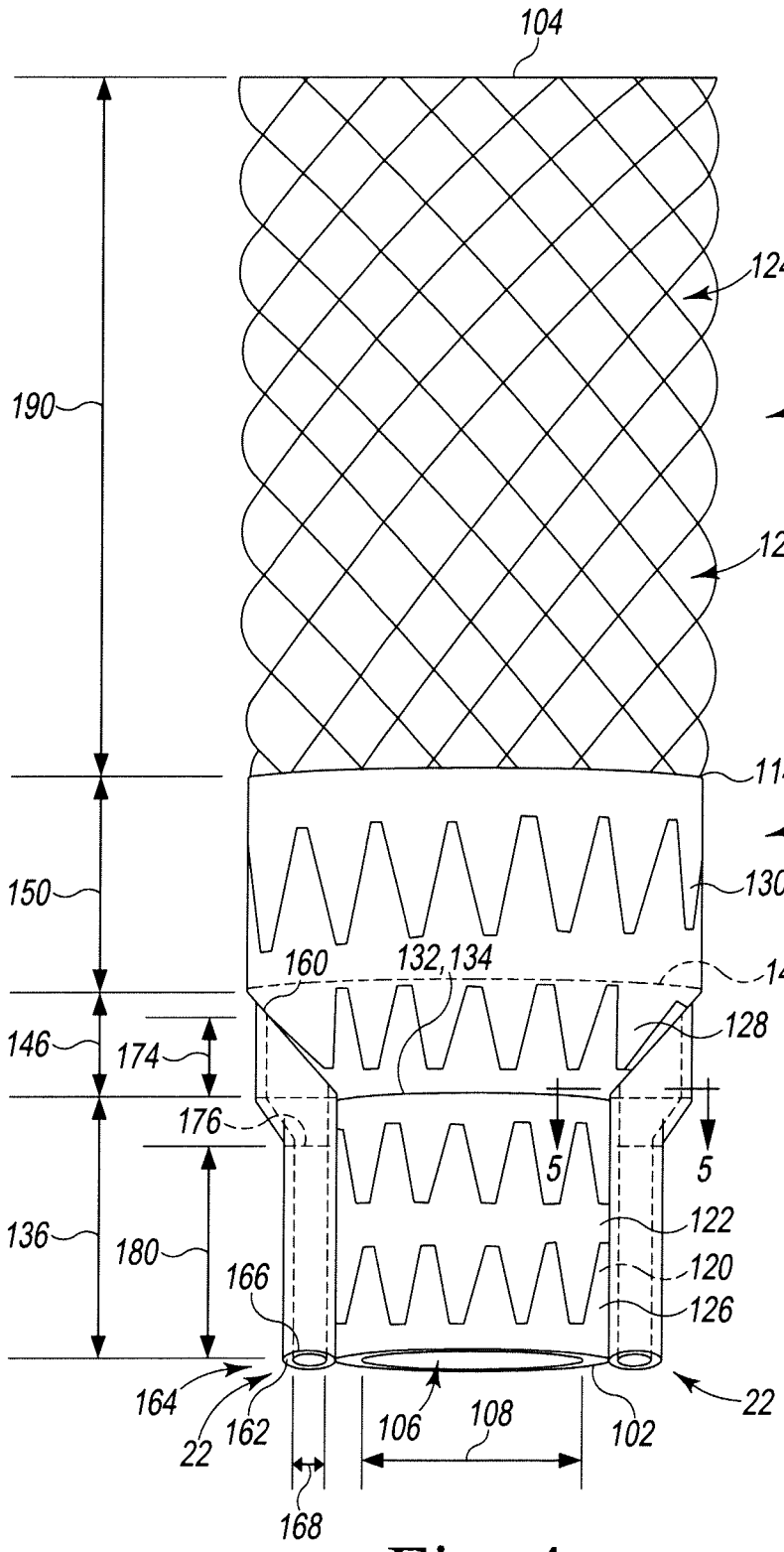

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Fig. 4

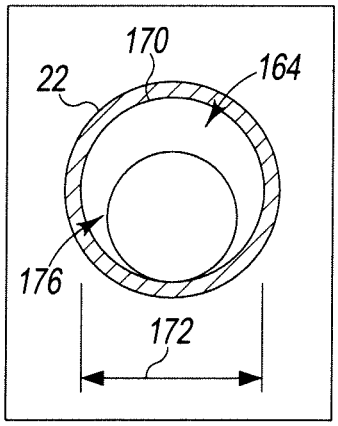

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Fig. 5

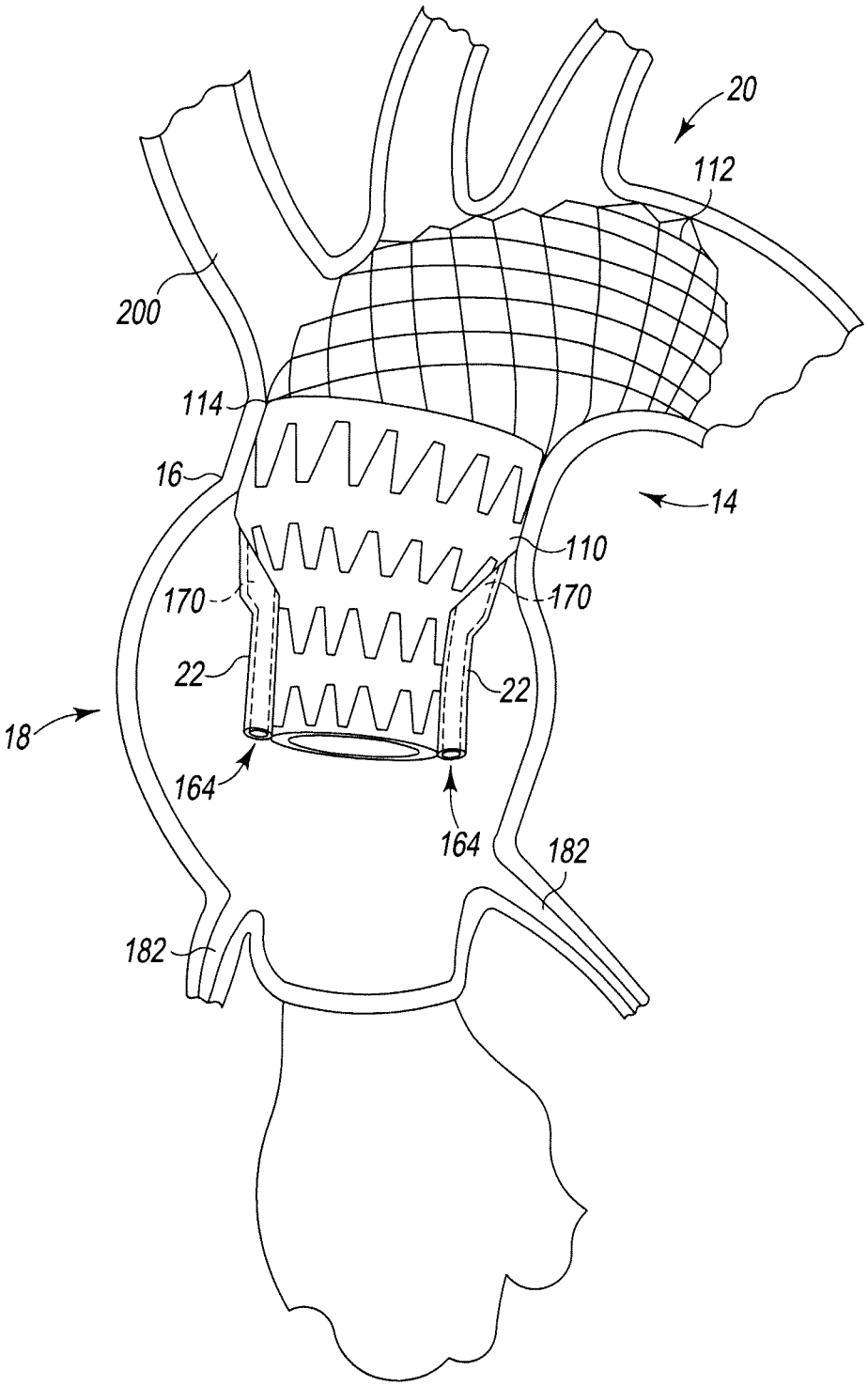


Fig. 6

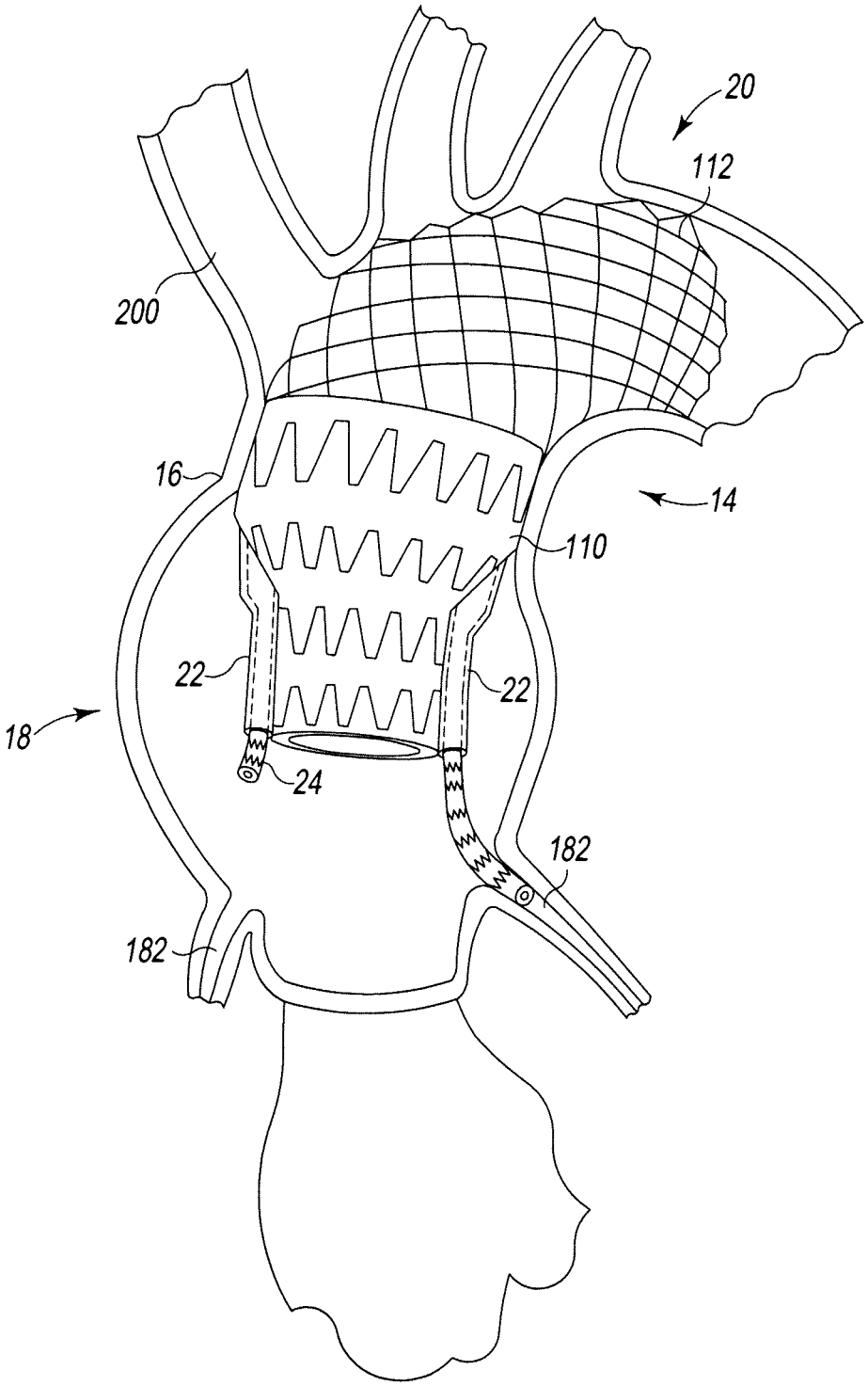


Fig. 7

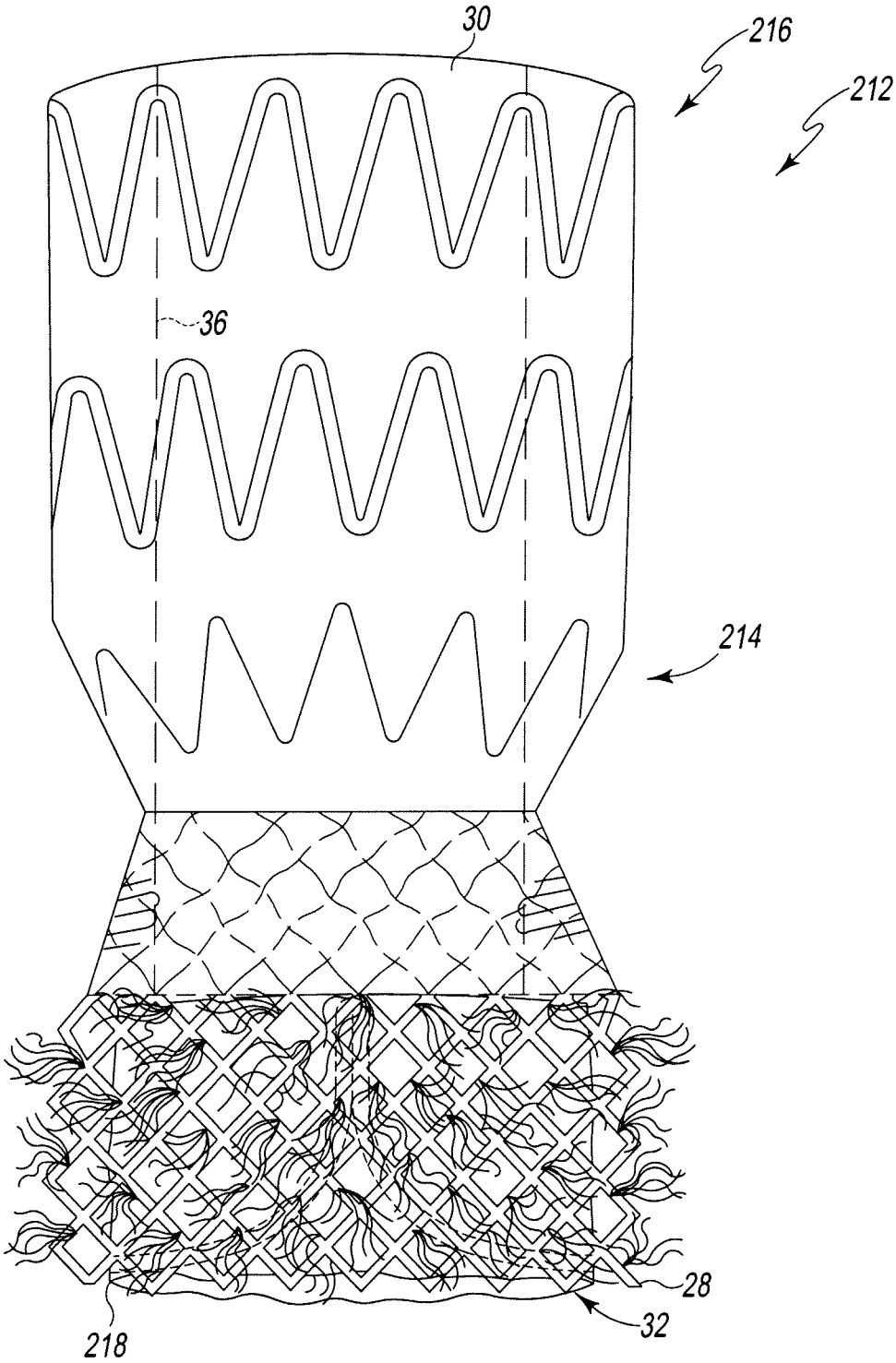


Fig. 8

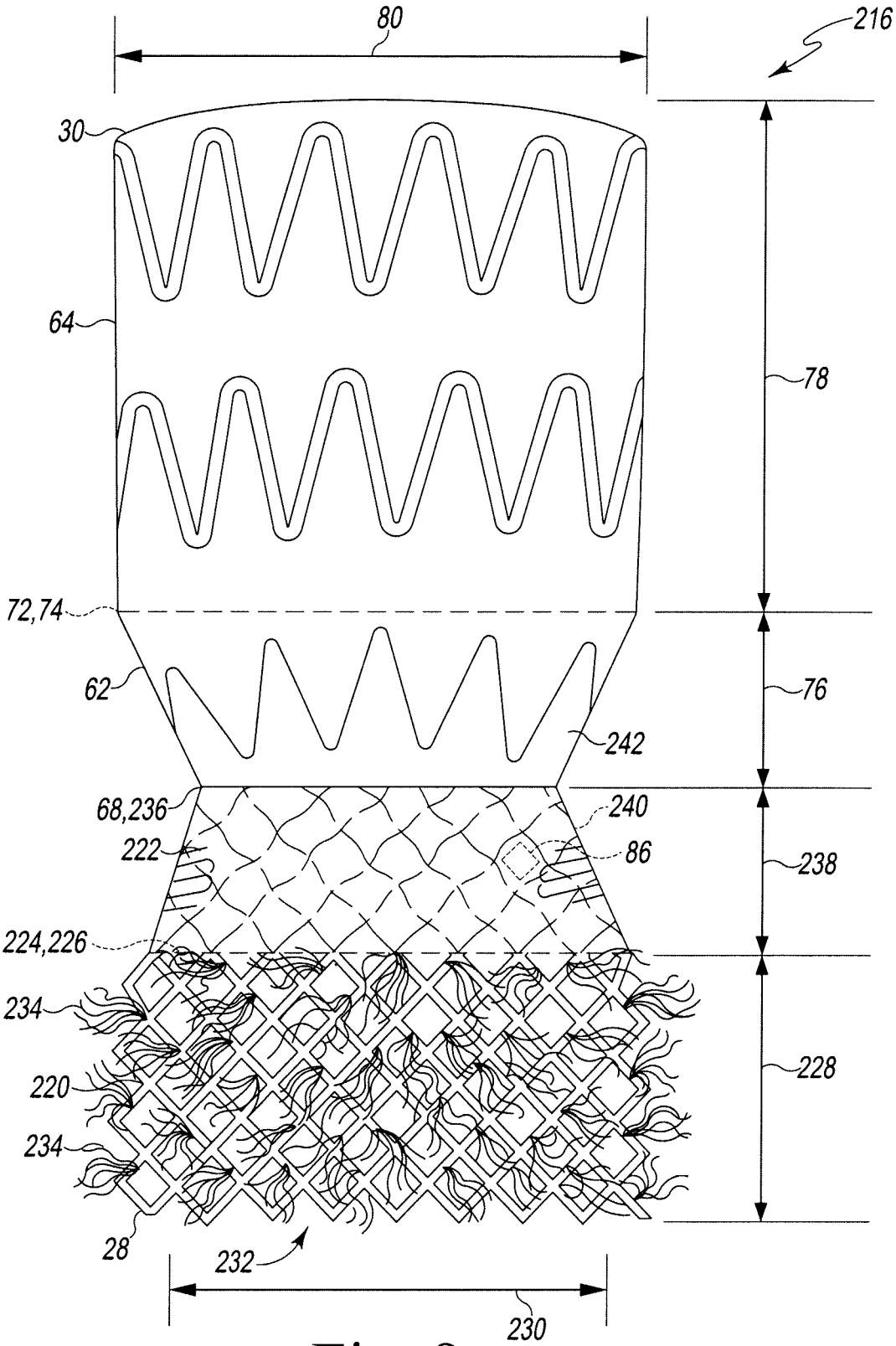

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Fig. 9

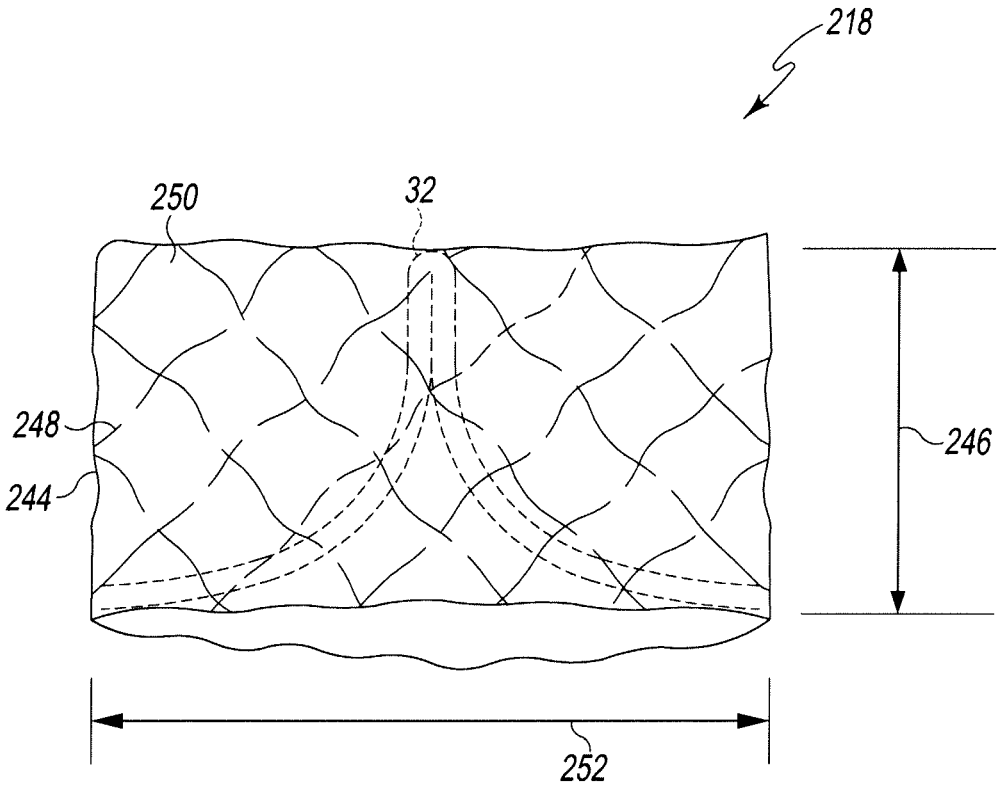


Fig. 10

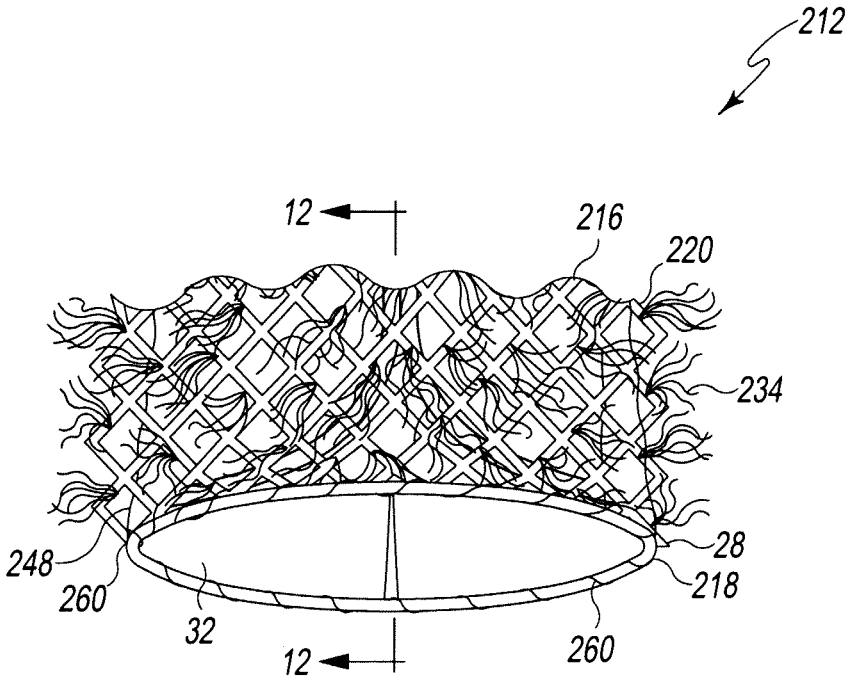


Fig. 11

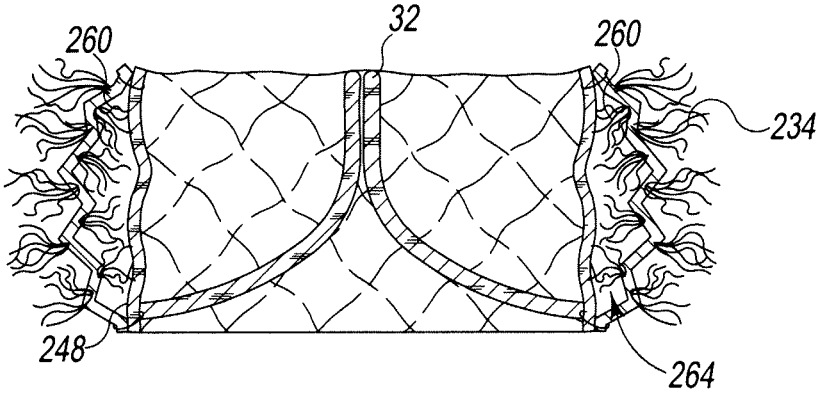


Fig. 12

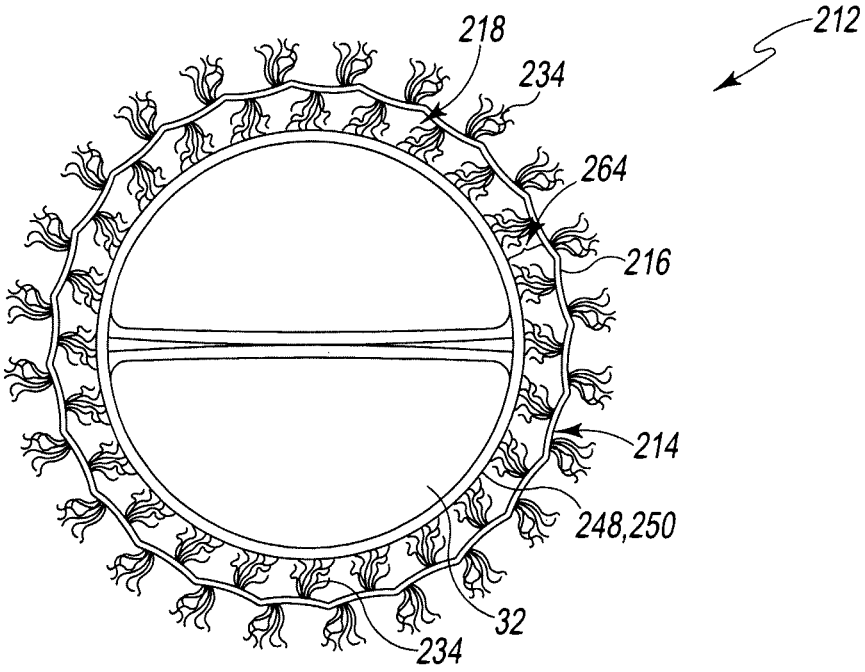

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Fig. 13

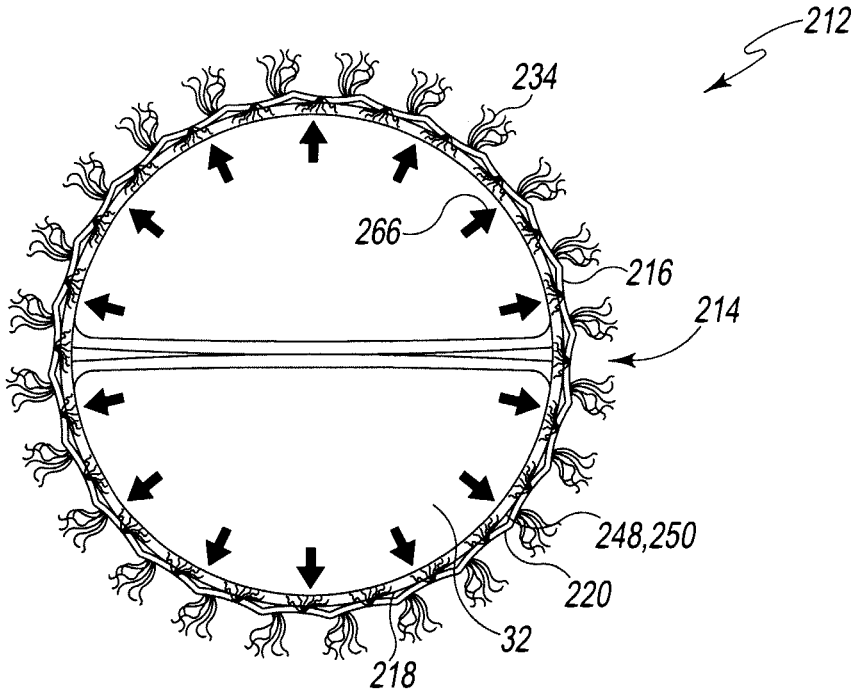

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Fig. 14

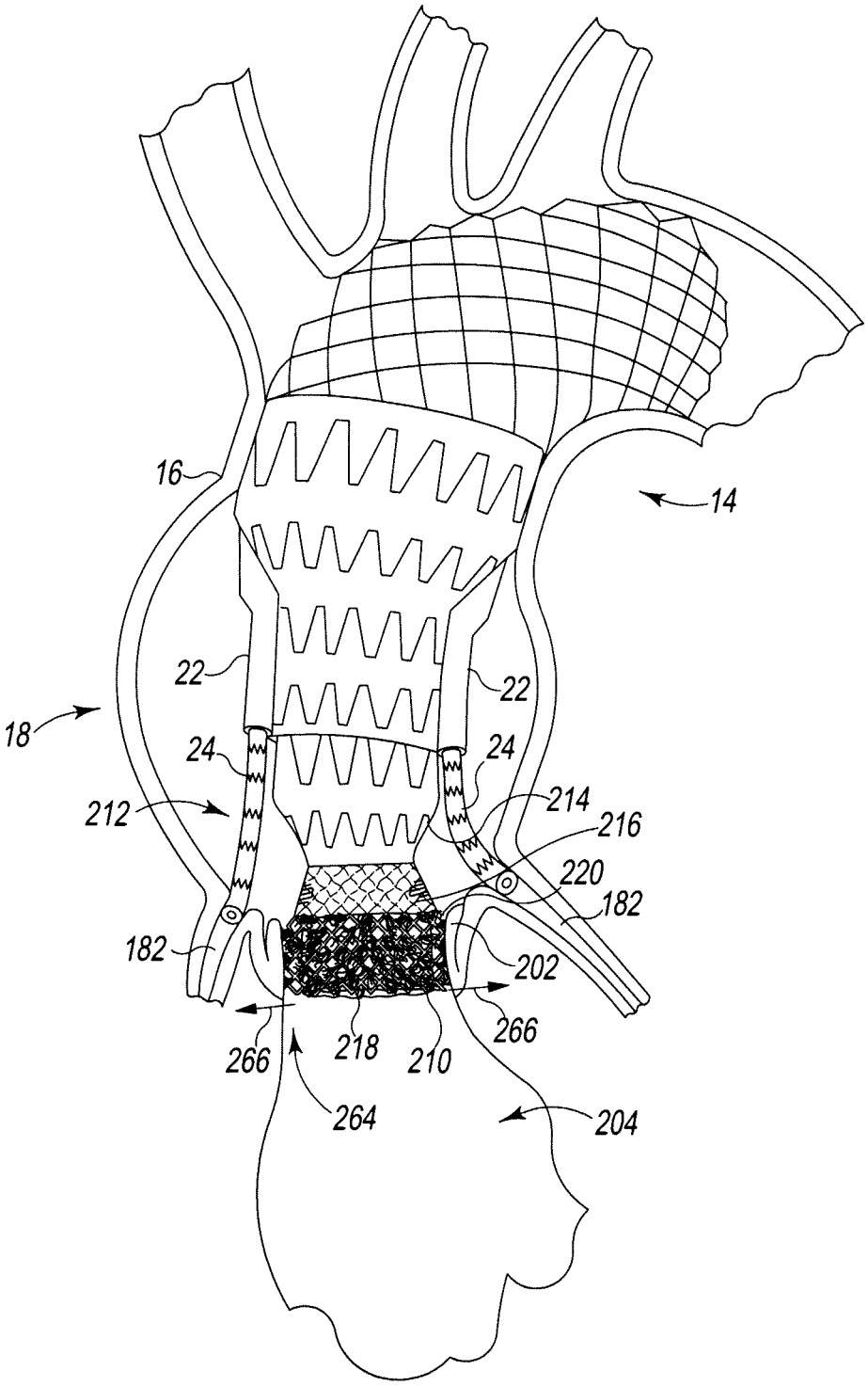

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Fig. 15

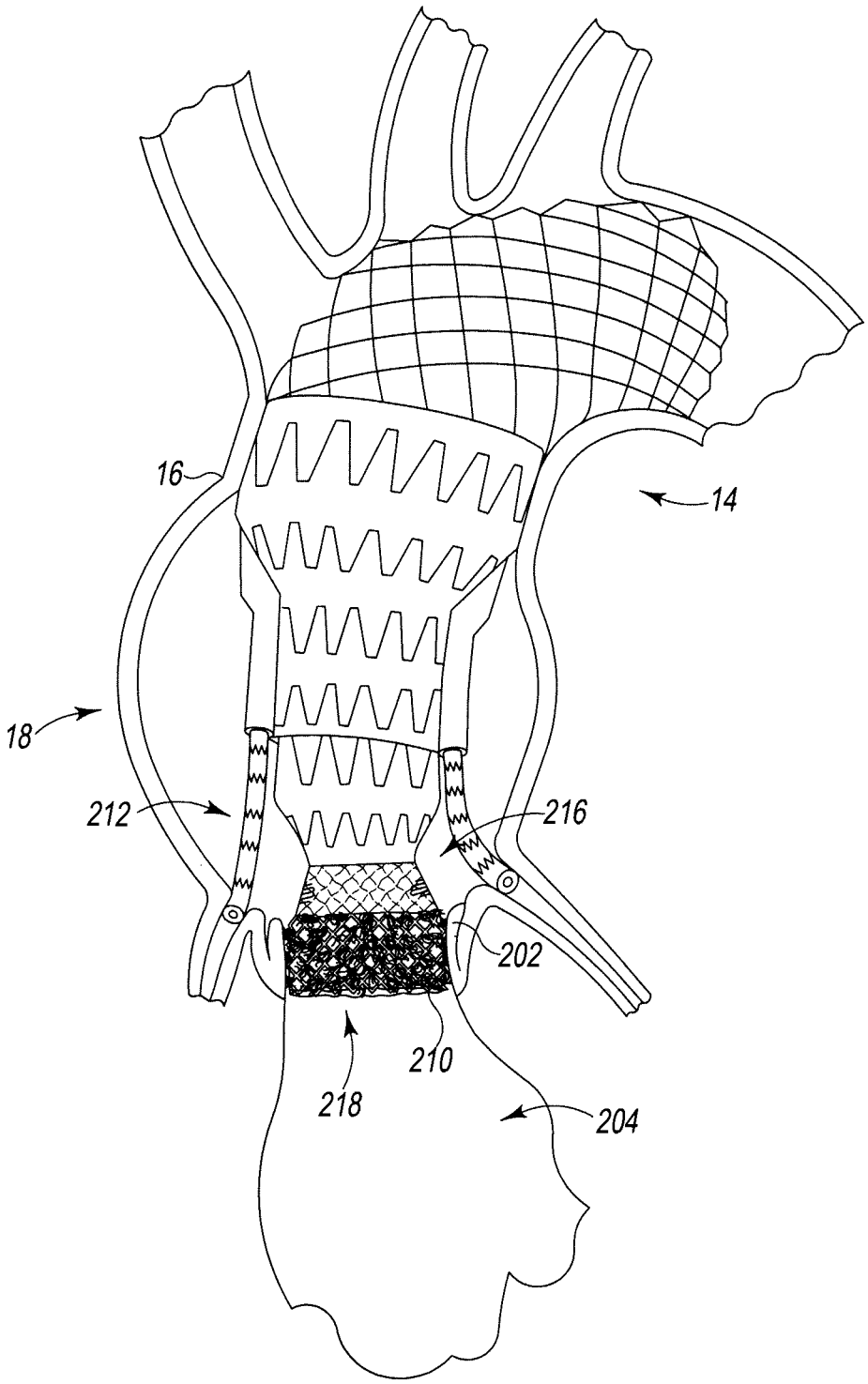


Fig. 16

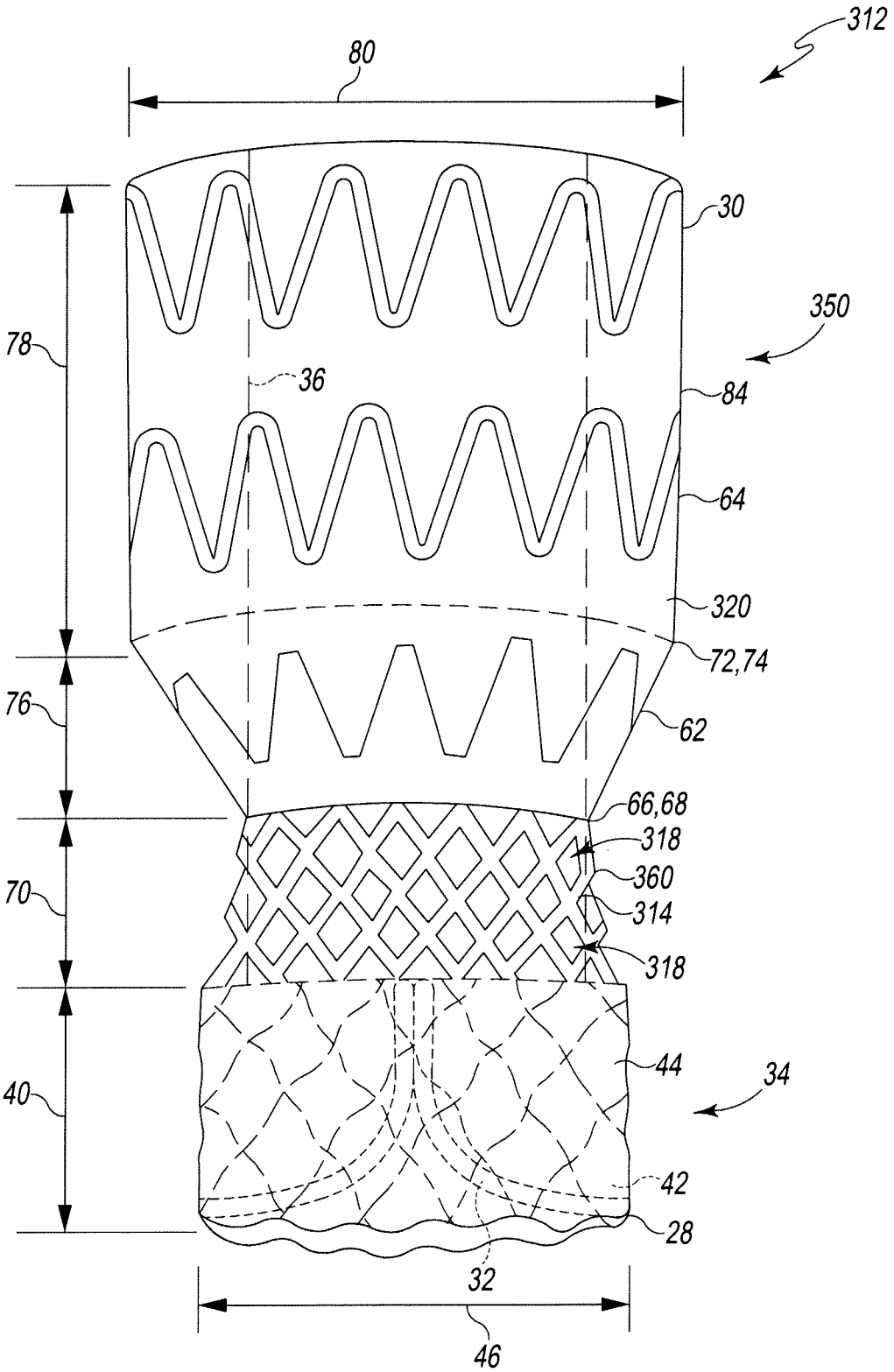

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Fig. 17

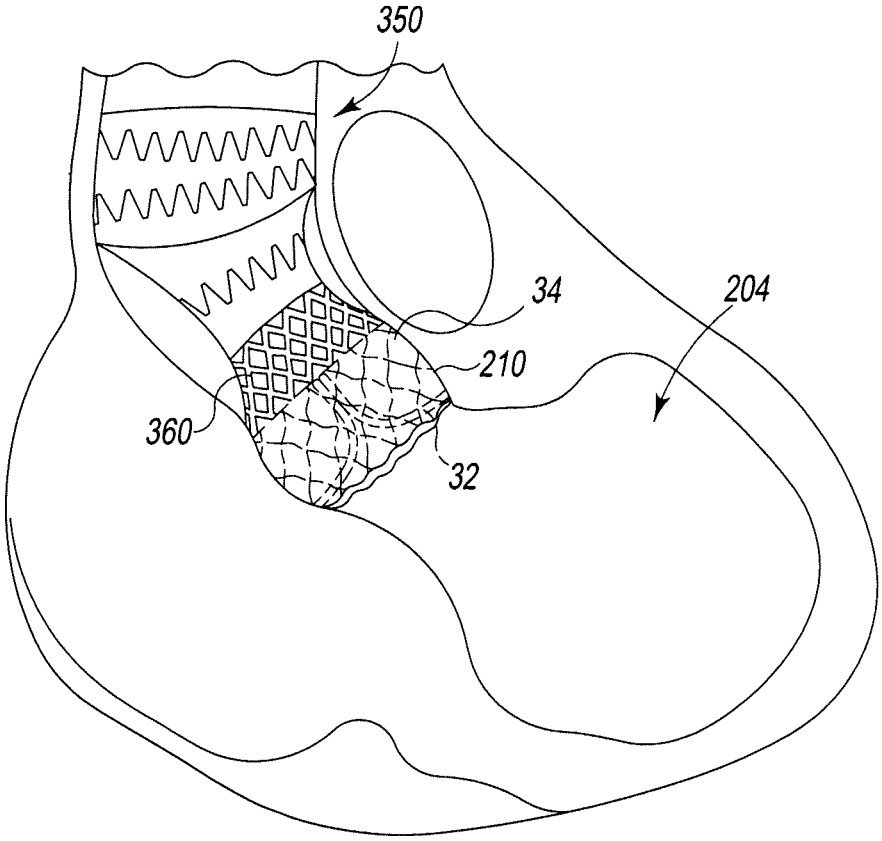


Fig. 18

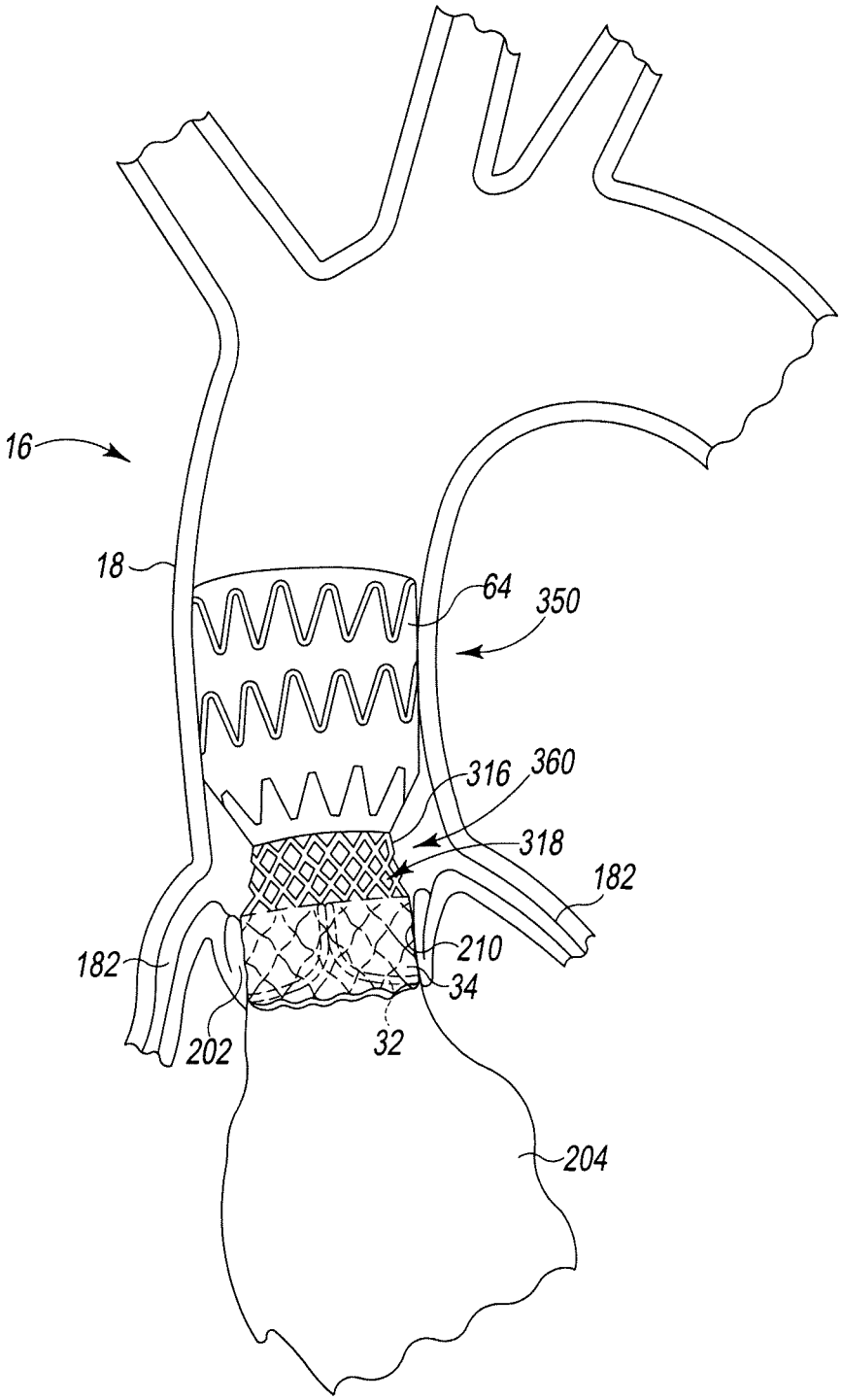


Fig. 19

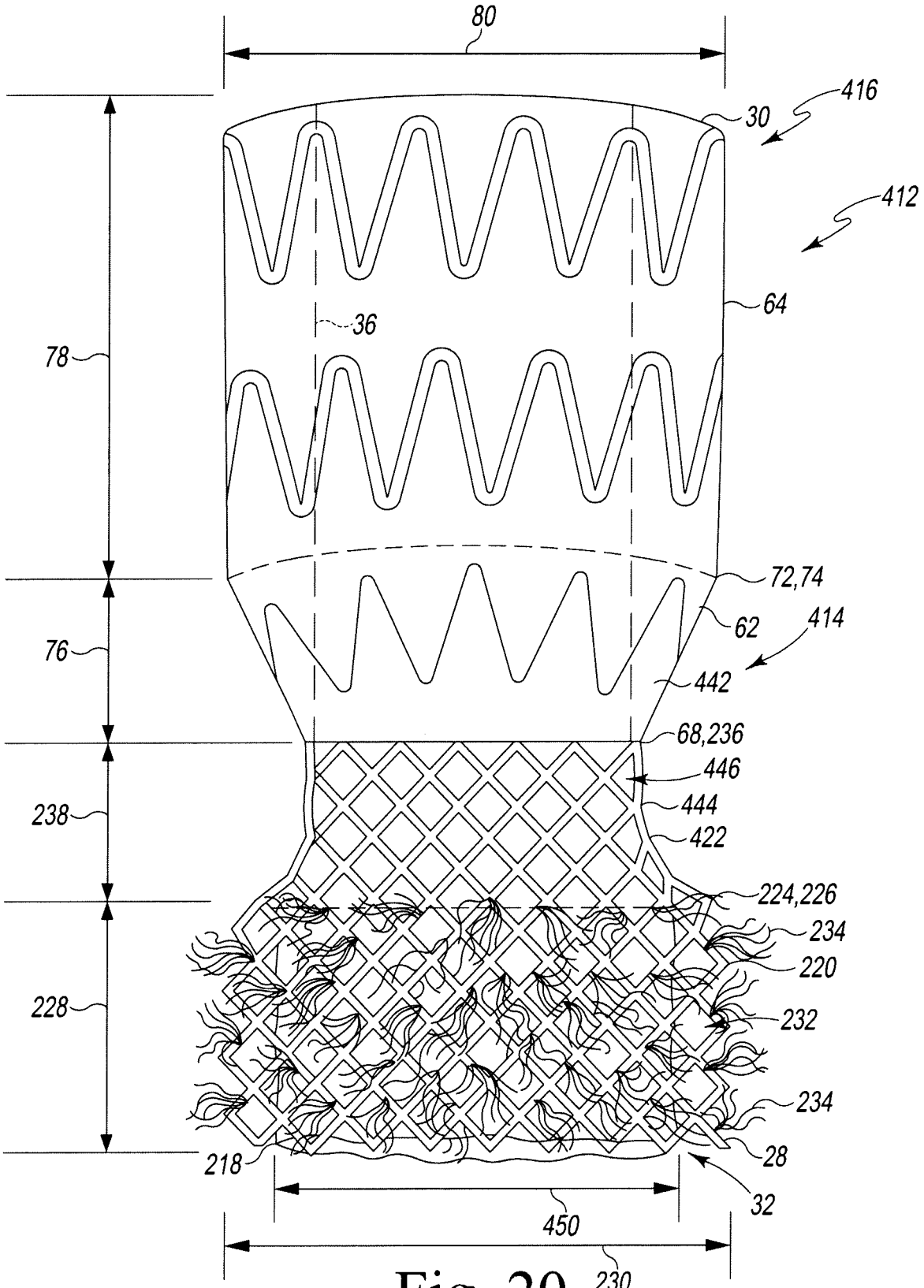

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Fig. 20

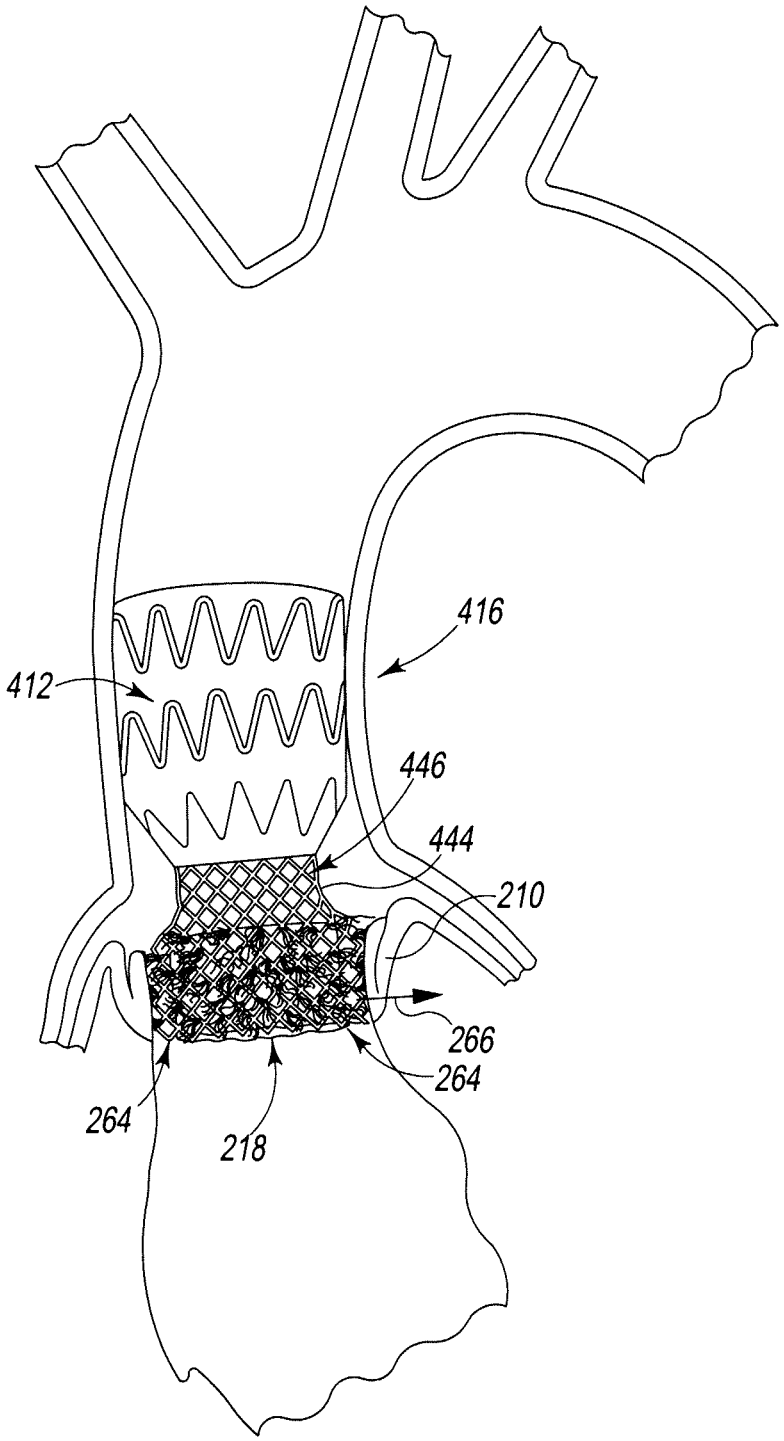


Fig. 21

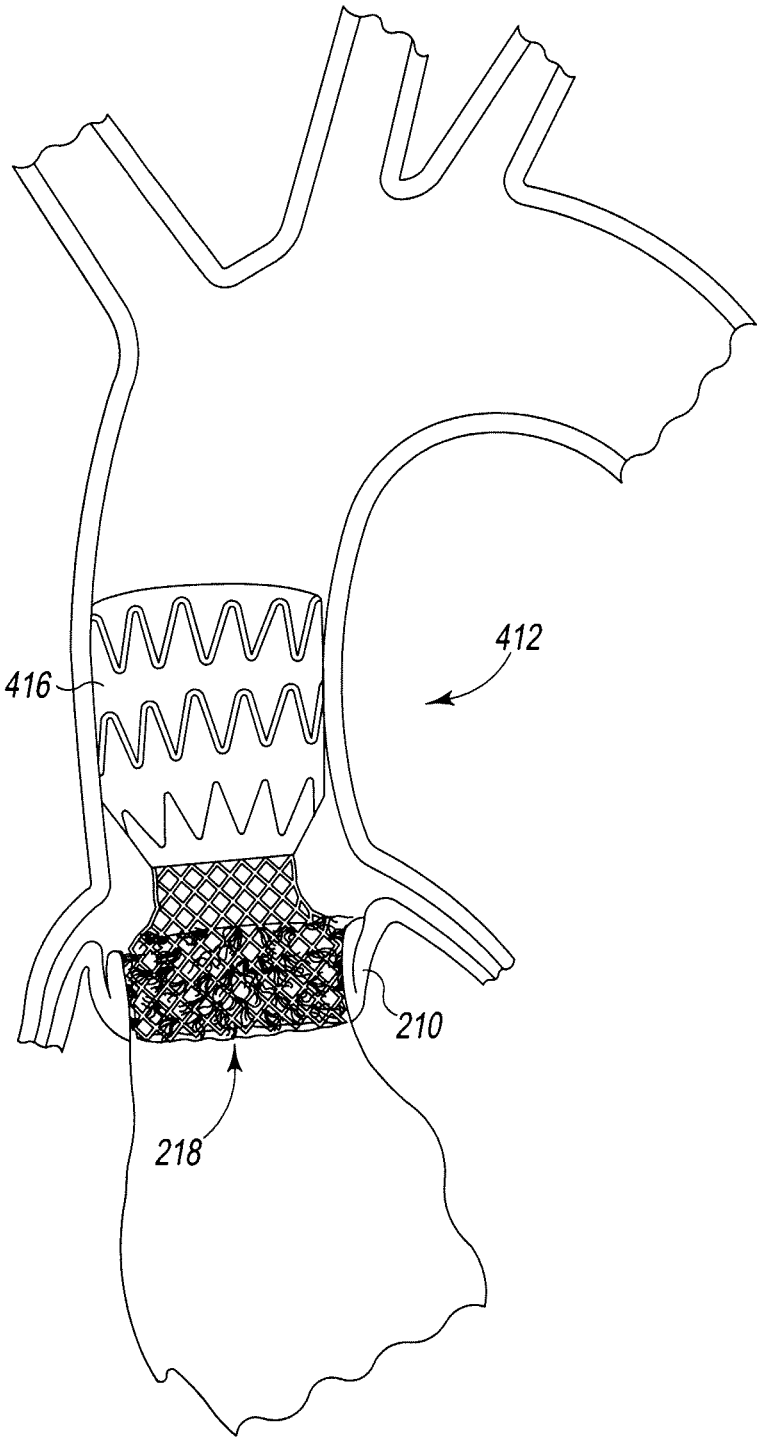


Fig. 22

TRANSCATHETER VALVE REPAIR HAVING IMPROVED PARAVALVULAR SEAL

This application is a continuation of U.S. patent application Ser. No. 17/213,251 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, 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 Serial 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 la endoleak. The trapdoors **86** in components **12**, **312** would allow for coil embolization of the area of the leak. Two trapdoors at 180 degree location would allow access to the entire area above the aortic annulus. Since the coronary arteries **182** are protected by the conduits **22** in the distal component **14**, coil embolization of this area would not compromise the coronary blood flow. Coil embolization of paravalvular leaks are already being performed clinically after heart valve surgery if there are additional leaks around the valve.

Aortic insufficiency (Al) after implantation may also be corrected. Significant Al has been documented in up to 17% of patients after transcatheter valve implantation. Except heavy annular calcification, the tricuspid morphology of the current valves and the ovoid shape of the aortic annulus can cause malcoaptation of the valve leaflets causing Al. The bicuspid valve nature of the designs discussed herein potentially eliminates the problem with malcoaptation and Al 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. An endovascular prosthetic heart valve 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, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

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

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,

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 heart valve annulus of the patient;

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

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

2. The prosthetic heart valve of claim **1**, wherein the second plurality of fibers defines a spacing extending through a thickness thereof that is created by a distance between adjacent fibers, wherein the spacing extends to the frame.

3. The prosthetic heart valve of claim **1**, wherein the polymer covering extends proximally further than a proximal end of the leaflet assembly.

4. The prosthetic heart valve of claim **1**, wherein a distance that the first plurality of fibers extends from a centerline extending longitudinally through the frame varies along a length of the centerline.

5. The prosthetic heart valve of claim **1**, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first plurality of fibers extends over each of the at least two rows of cells.

6. The prosthetic heart valve of claim **1**, wherein the first plurality of fibers and the second plurality of fibers are non-metallic.

7. The prosthetic heart valve of claim **1**, wherein the first plurality of fibers and the second plurality of fibers are collagen fibers.

8. The prosthetic heart valve of claim **1**, wherein the cells formed in the frame are gridded.

9. The prosthetic heart valve of claim **1**, wherein the prosthetic heart valve is free of a non-porous graft covering between the first plurality of fibers and the frame and the second plurality of fibers and the frame.

10. The prosthetic heart valve of claim **1**, wherein the polymer covering is stitched to the frame.

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

12. The prosthetic heart valve of claim **1**, wherein the polymer covering and the first plurality of fibers and the second plurality of fibers are distinct elements.

13. The prosthetic heart valve of claim **1**, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient.

14. The prosthetic heart valve of claim **1**, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

15. The prosthetic heart valve of claim **1**, wherein the first plurality of fibers defines a spacing that extends through a thickness thereof that is created by a distance between adjacent fibers thereof.

16. The prosthetic heart valve of claim **1**, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

17. An endovascular prosthetic heart valve 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 radially outwardly of 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 heart valve annulus of the patient; and

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

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

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,

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

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 relative to the spacing to create a seal thereabout.

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

a frame formed of a plurality of struts that cooperate to form 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 carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly; and

a plurality of fibers that extend away from the frame,

wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,

wherein the 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 heart valve annulus of the patient,

wherein the prosthetic heart valve defines a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame,

wherein, compression of the plurality of fibers in response to expansion of the prosthetic heart valve compresses the plurality of fibers relative to the spacings to create a seal thereabout,

wherein the plurality of fibers extends over each of the at least two rows of cells.

* * * * *

EXHIBIT 2

US011389310B2

(12) **United States Patent**
Shahriari

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(45) **Date of Patent: *Jul. 19, 2022**

(54) **DEVICE FOR AORTIC REPAIR AND METHOD OF USING THE SAME**

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(*) 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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(60) Continuation of application No. 16/935,261, filed on Jul. 22, 2020, which is a continuation of application (Continued)

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A61F 2/856 (2013.01)
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CPC ***A61F 2/856*** (2013.01); ***A61F 2/07*** (2013.01); ***A61F 2/2418*** (2013.01); ***A61F 2/82*** (2013.01); ***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);
(Continued)

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See application file for complete search history.

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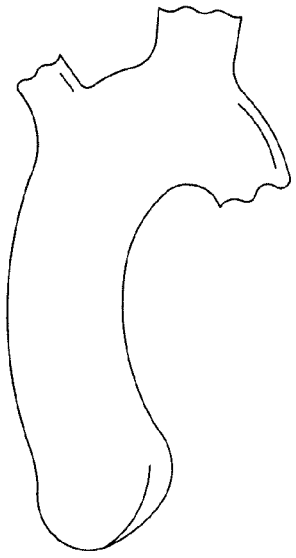
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(57) **ABSTRACT**

A transcatheter valve includes an outer seal made of outwardly extending fibers and is configured for transfemoral delivery within a patient.

15 Claims, 19 Drawing Sheets



Related U.S. Application Data

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 2/89	(2013.01)
A61F 2/90	(2013.01)
A61F 2/86	(2013.01)

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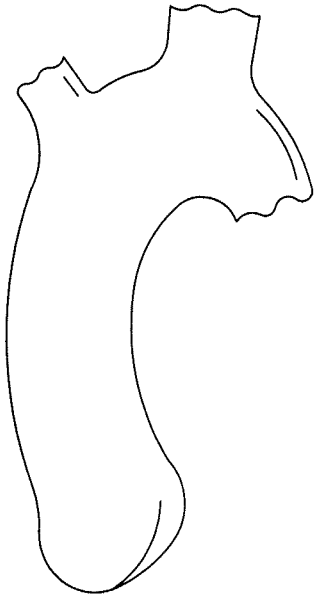


Fig. 1

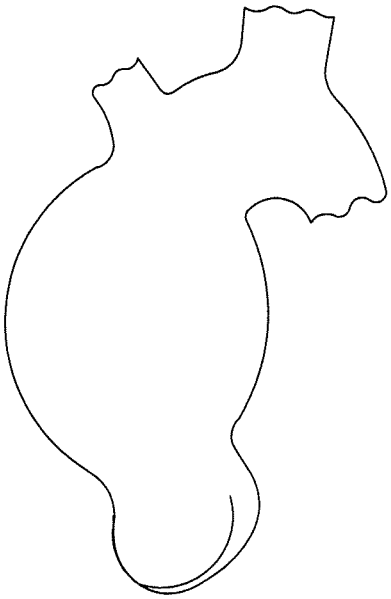


Fig. 1B

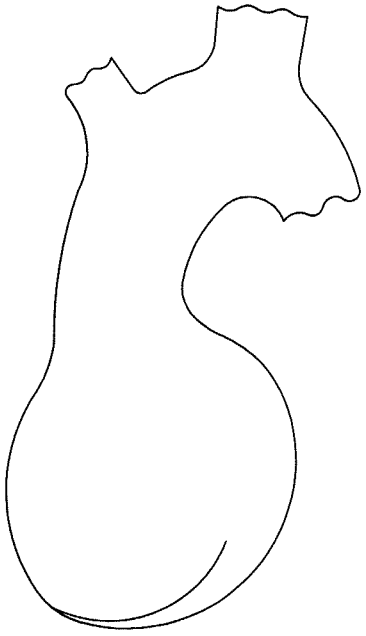


Fig. 1A



Fig. 1C

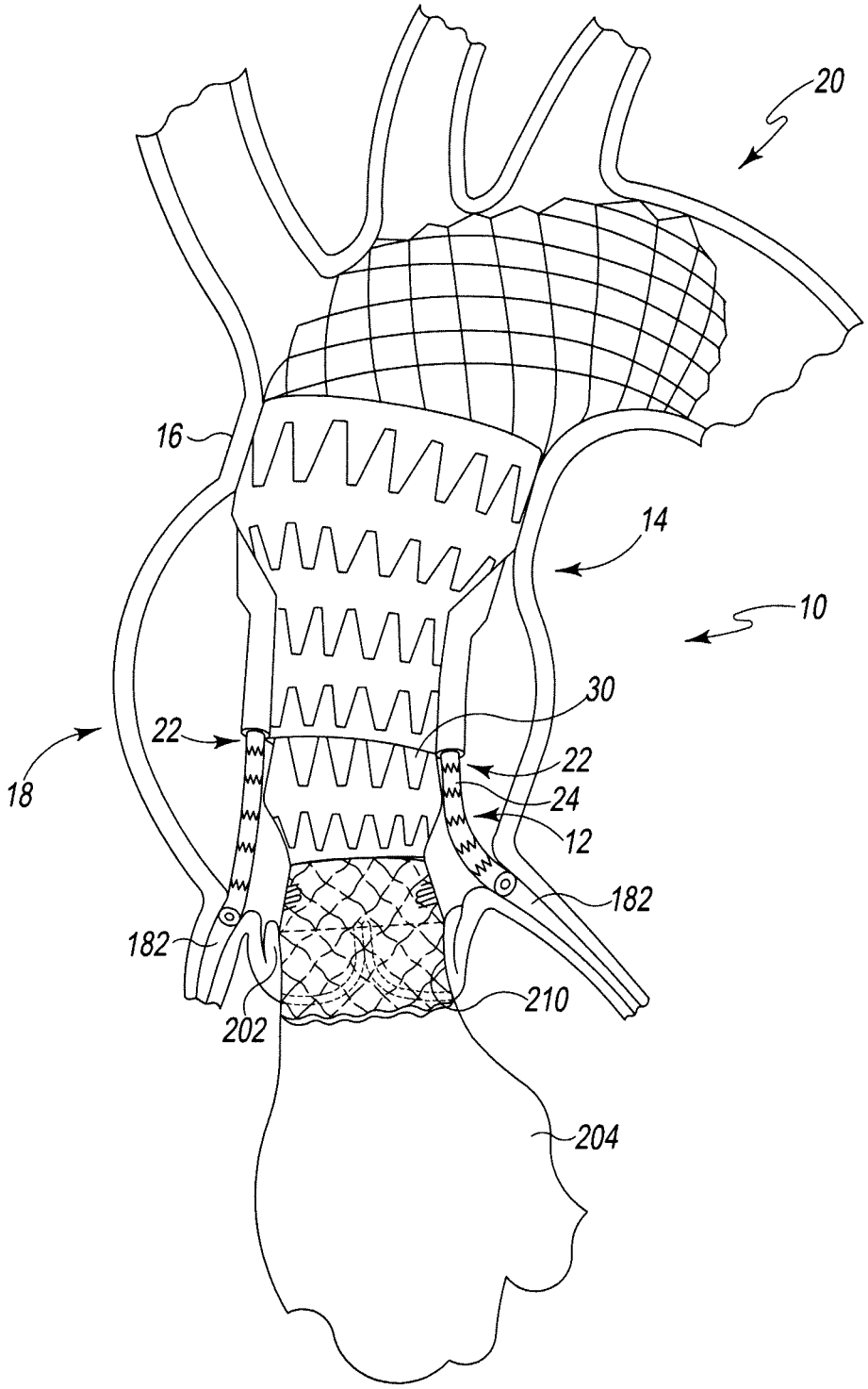


Fig. 2

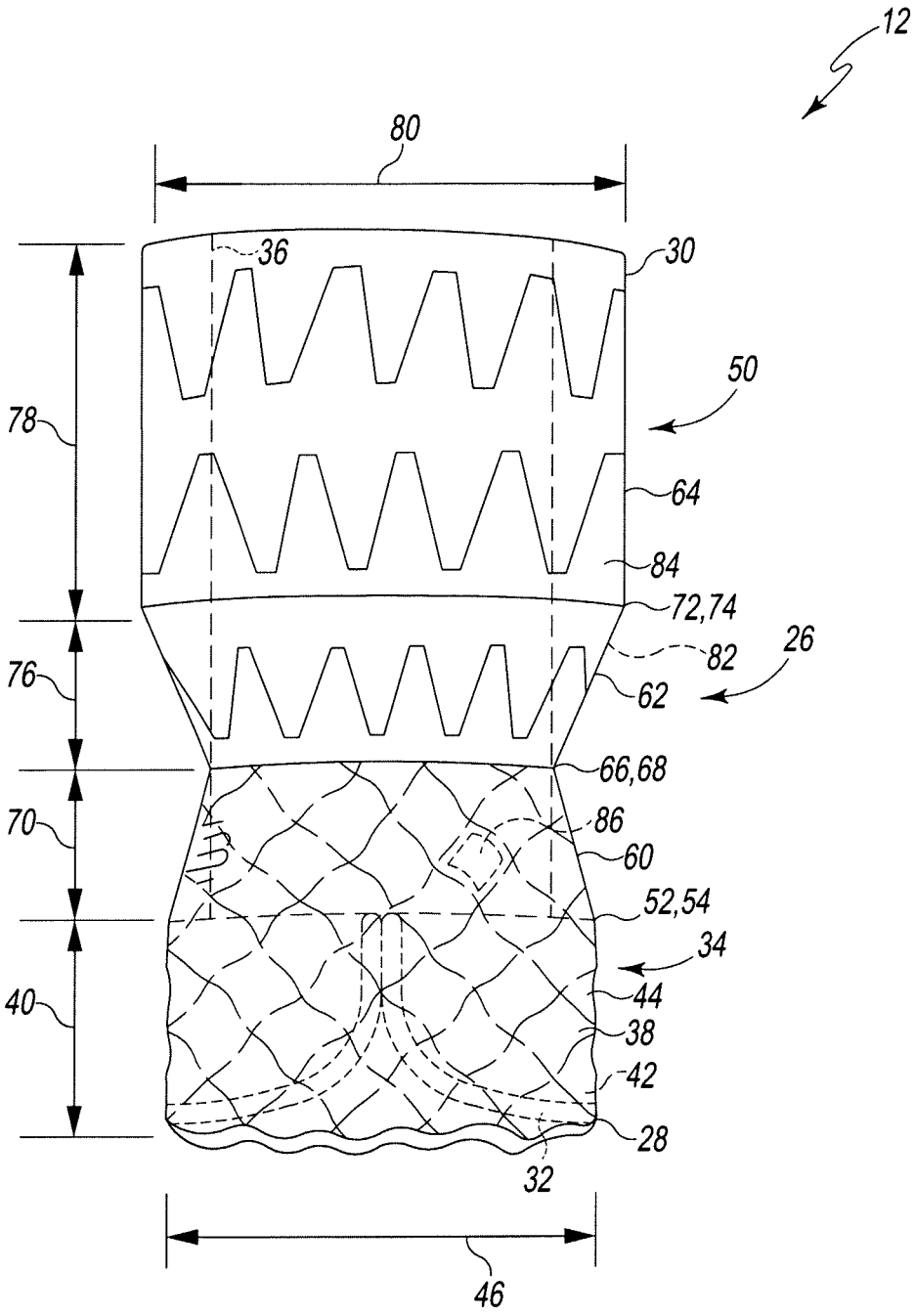

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Fig. 3

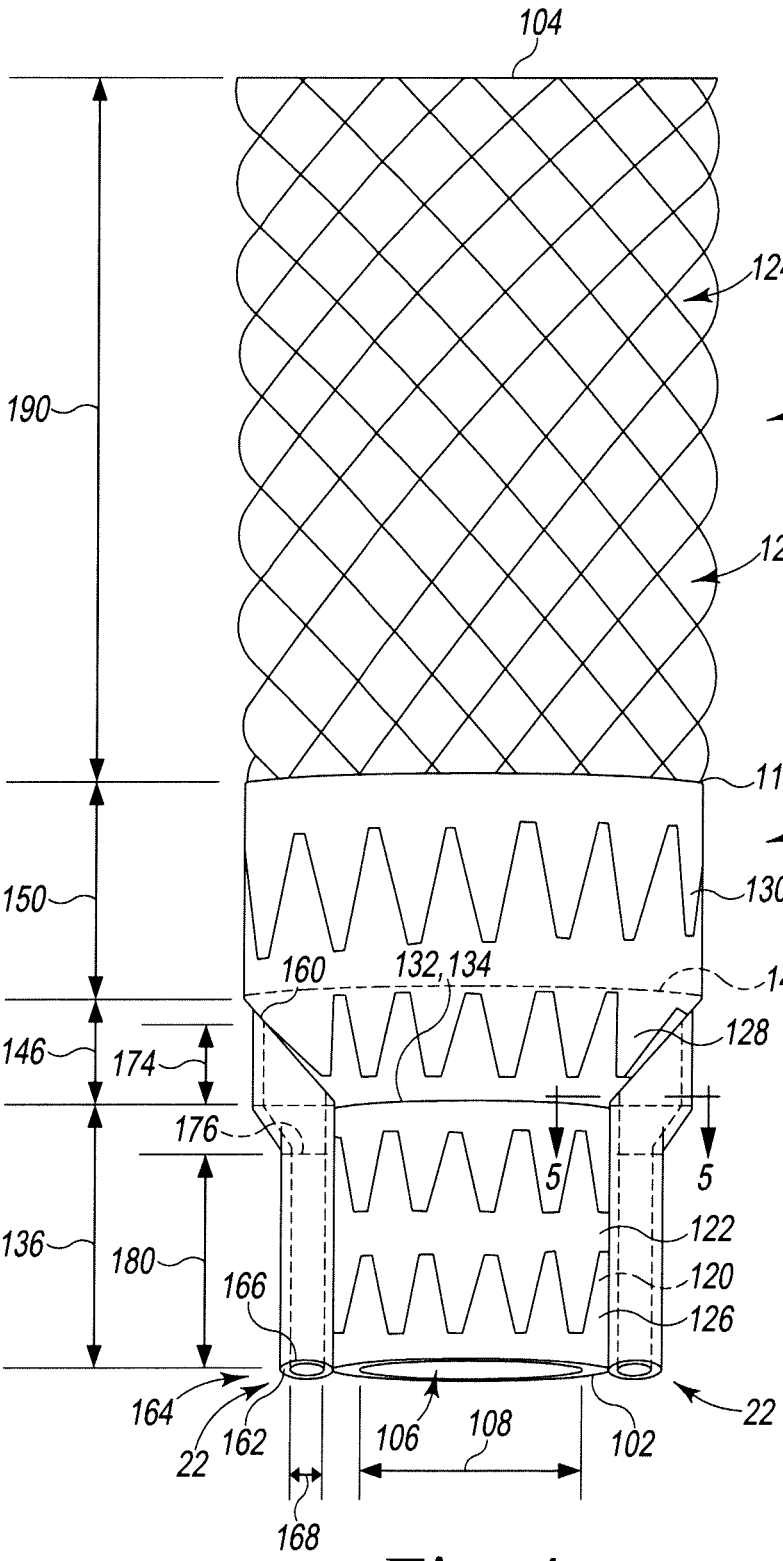

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Fig. 4

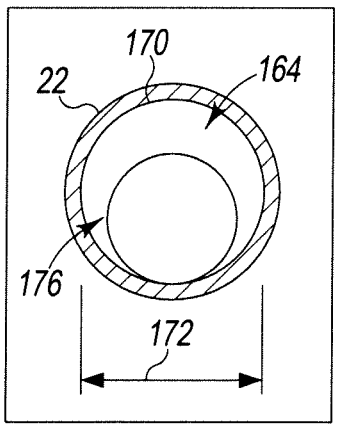

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Fig. 5

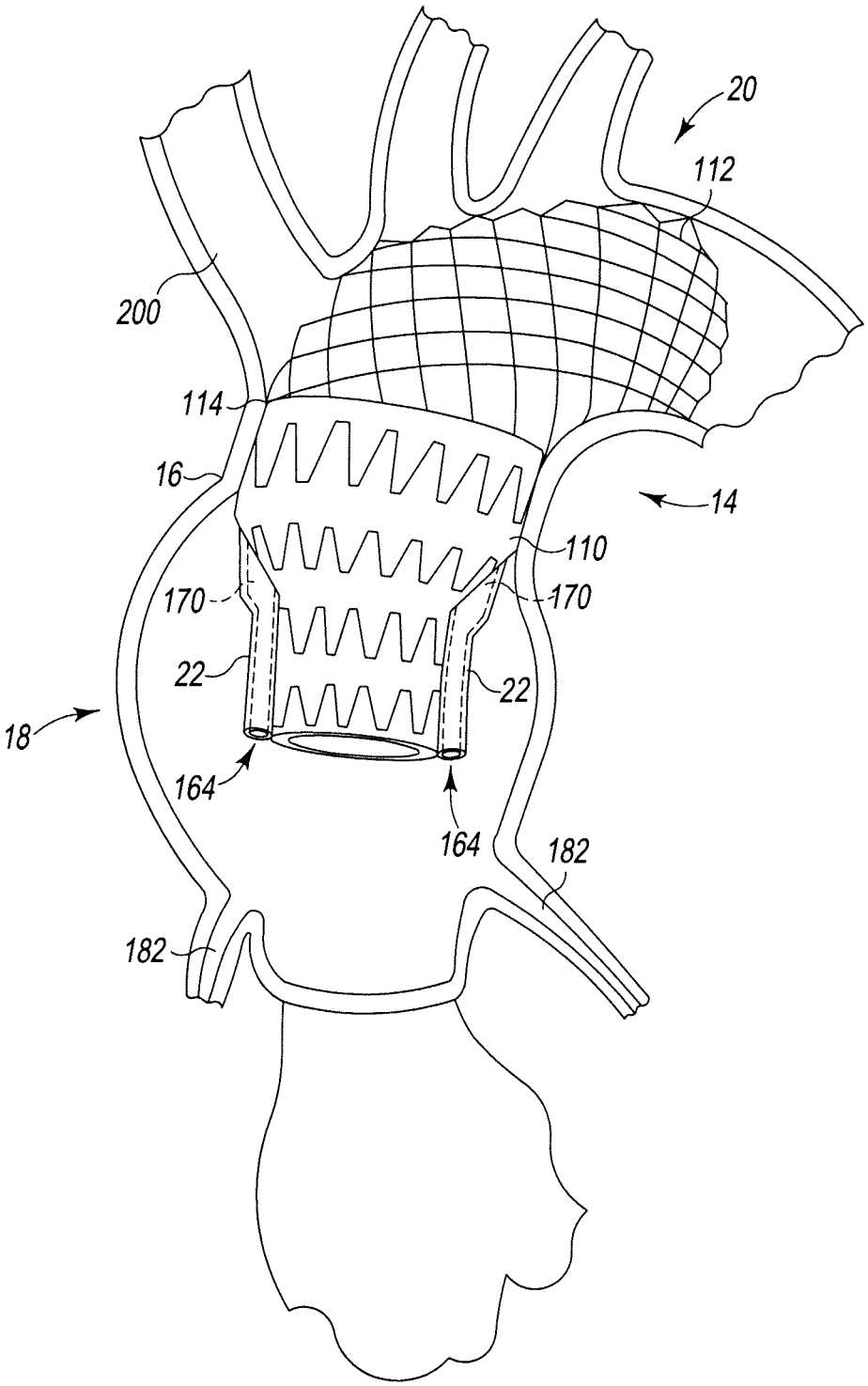


Fig. 6

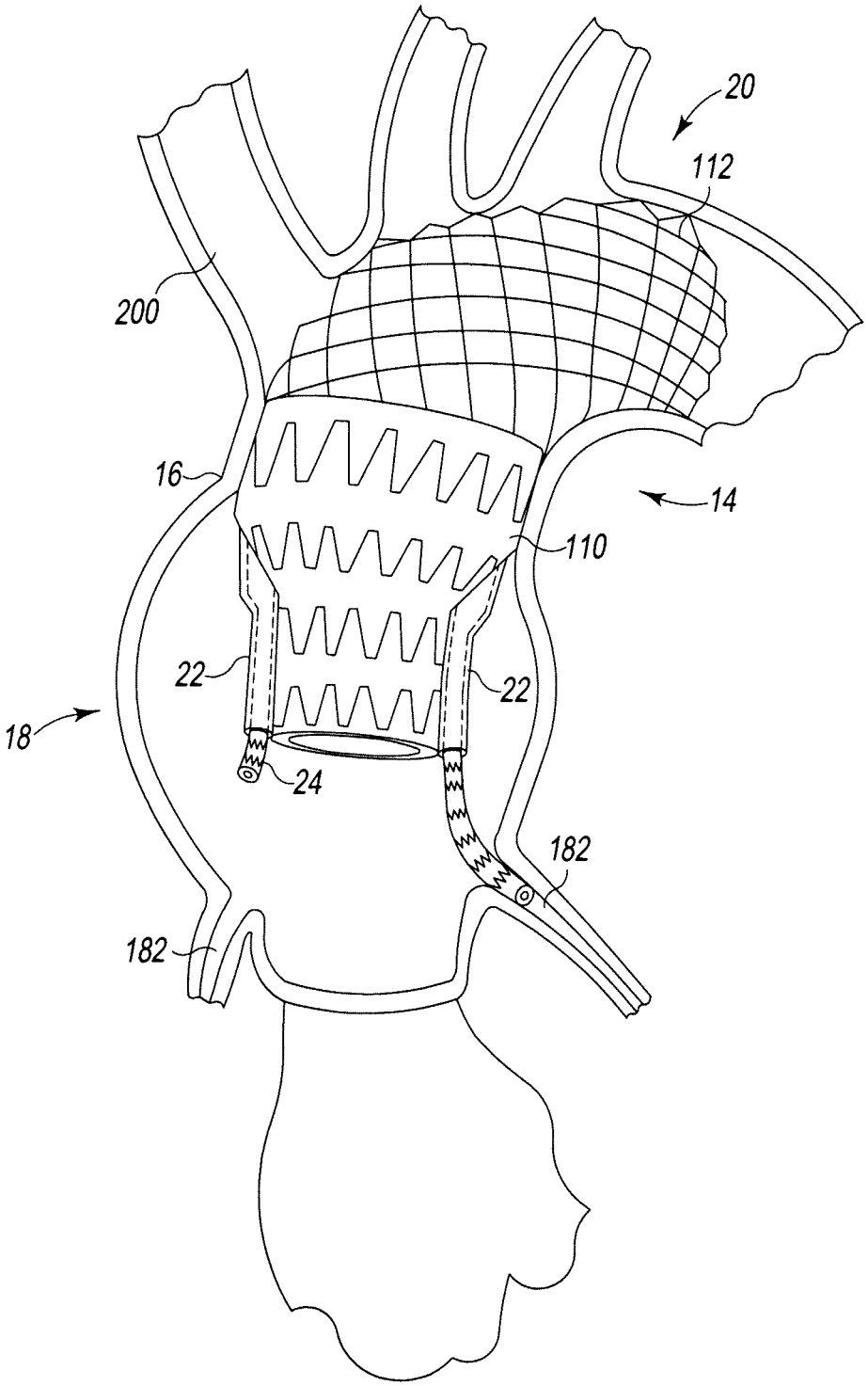


Fig. 7

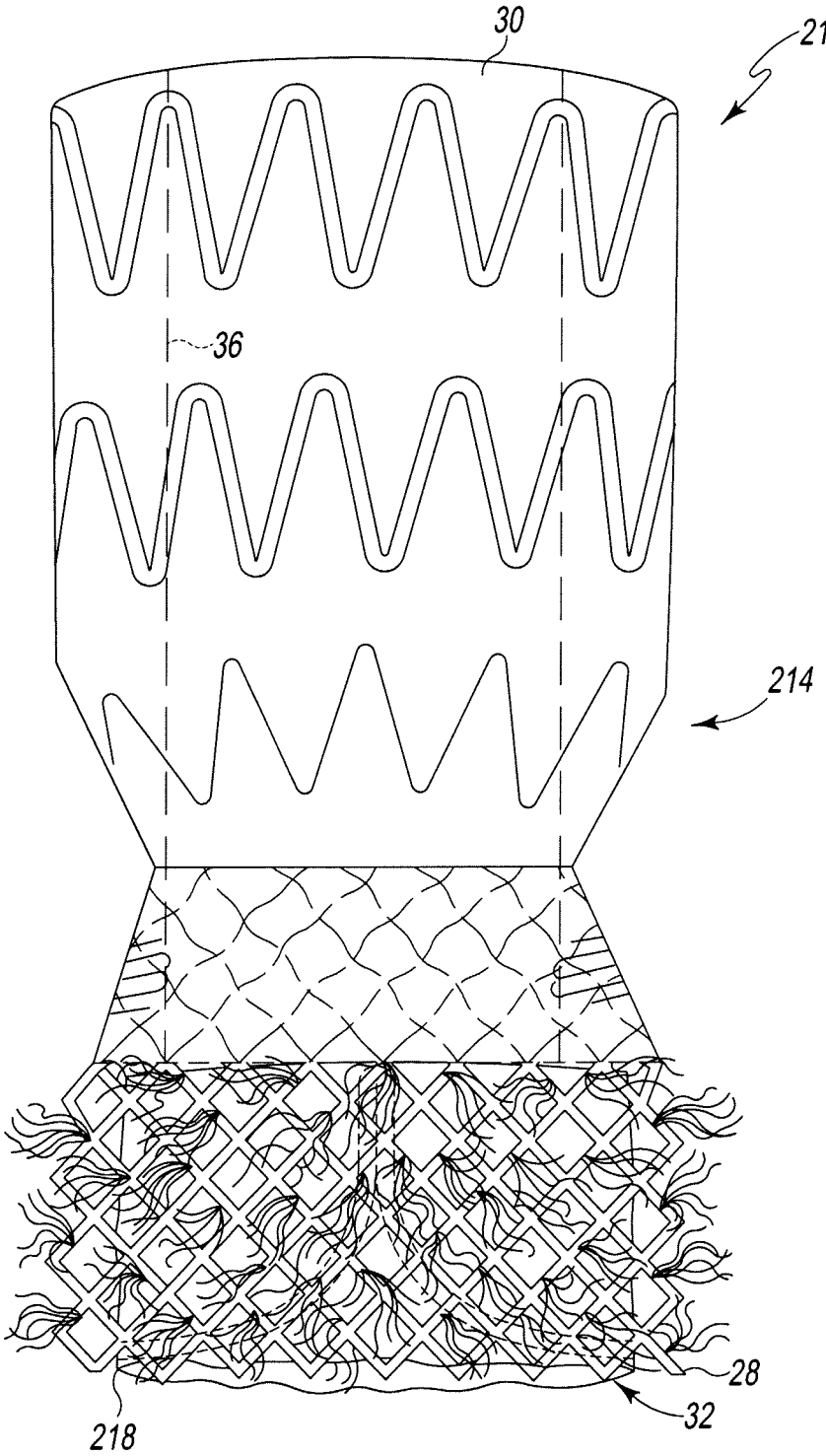


Fig. 8

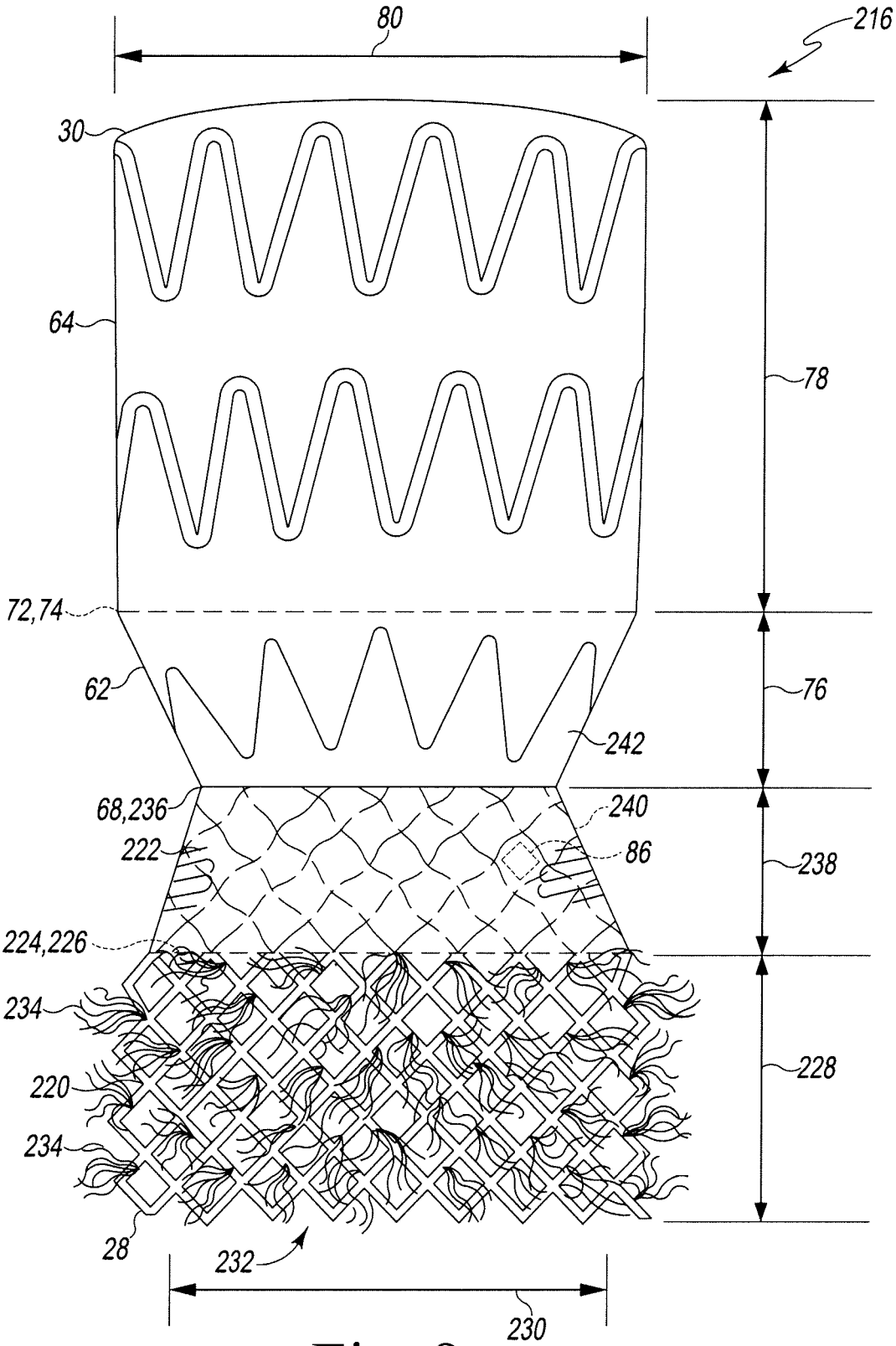

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Fig. 9

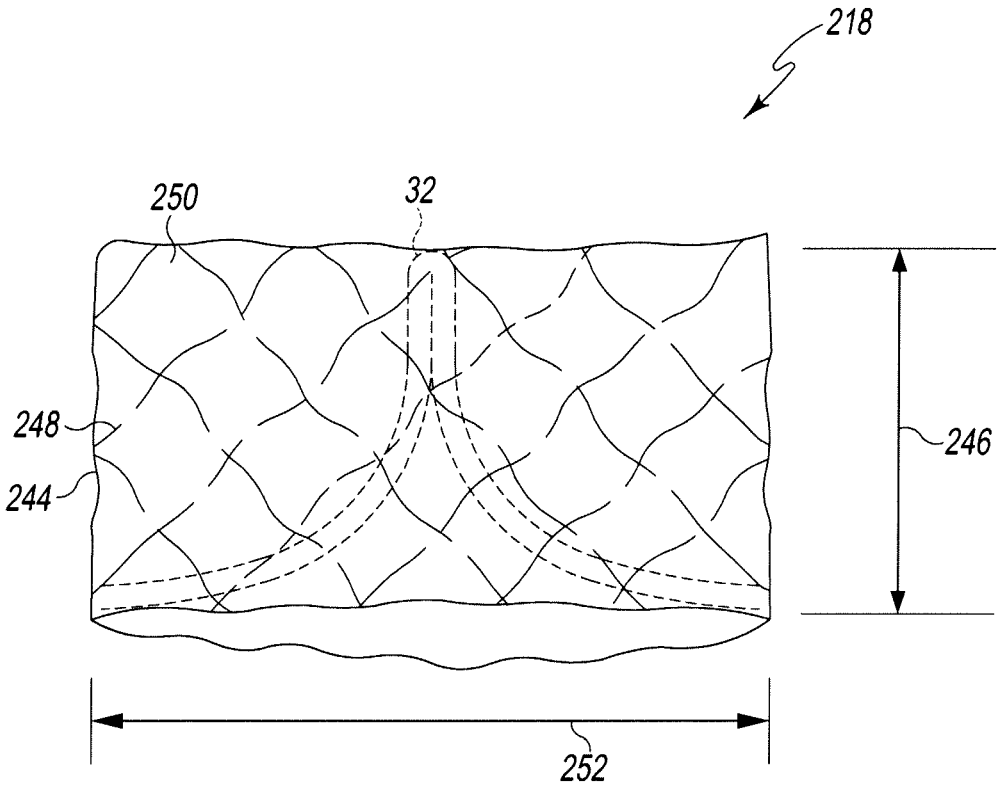


Fig. 10

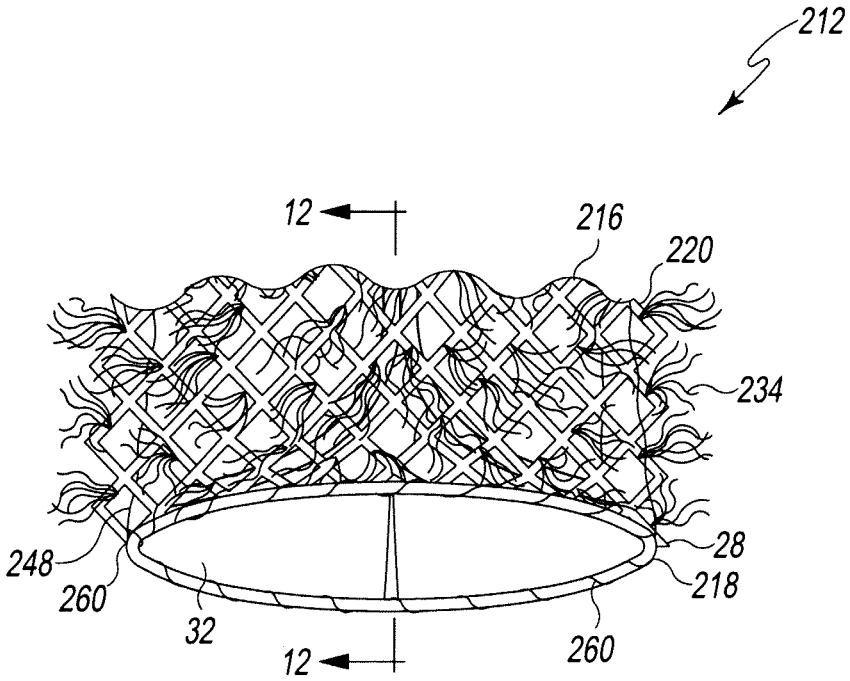


Fig. 11

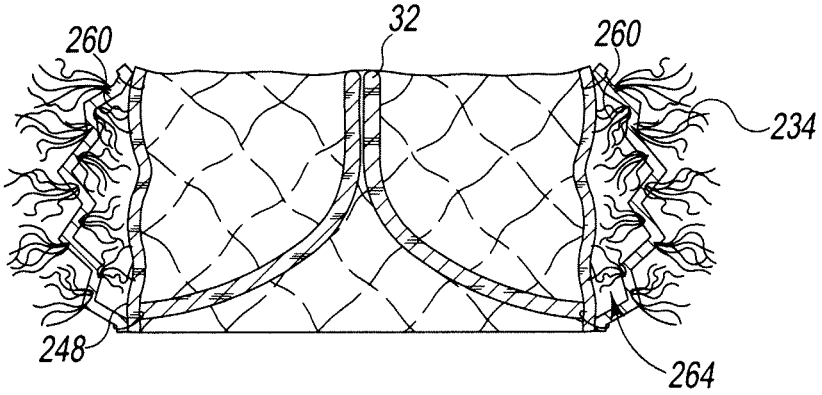


Fig. 12

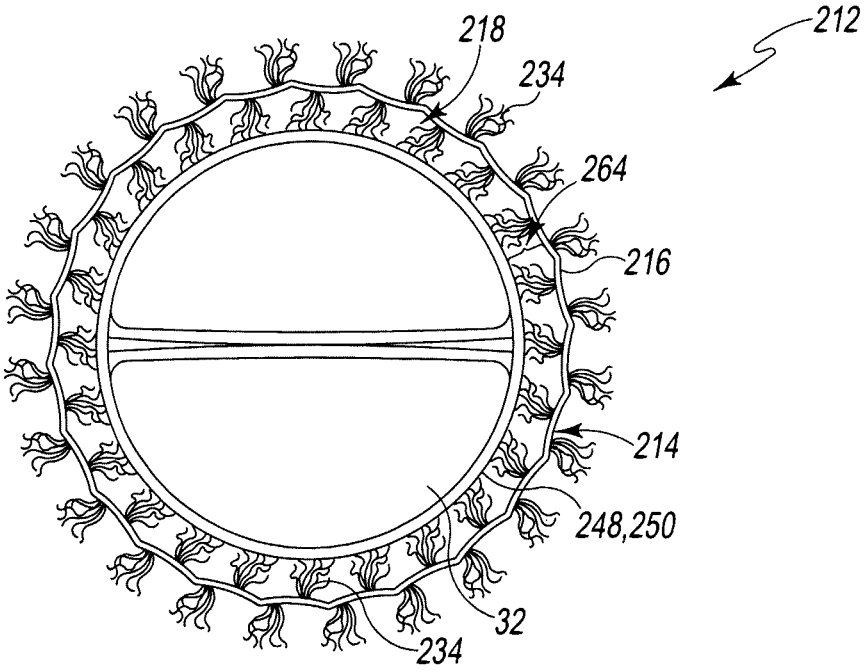

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Fig. 13

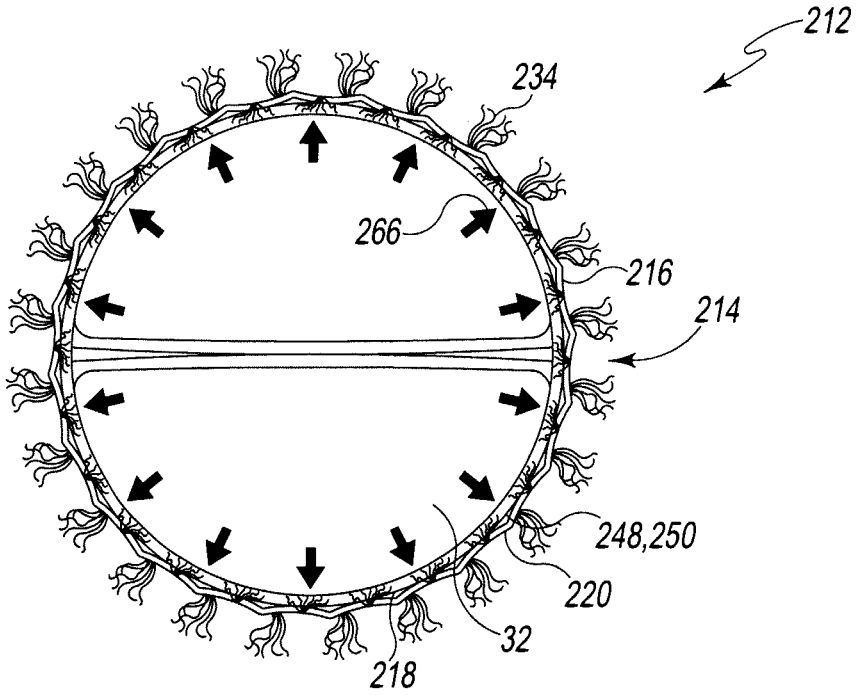

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Fig. 14

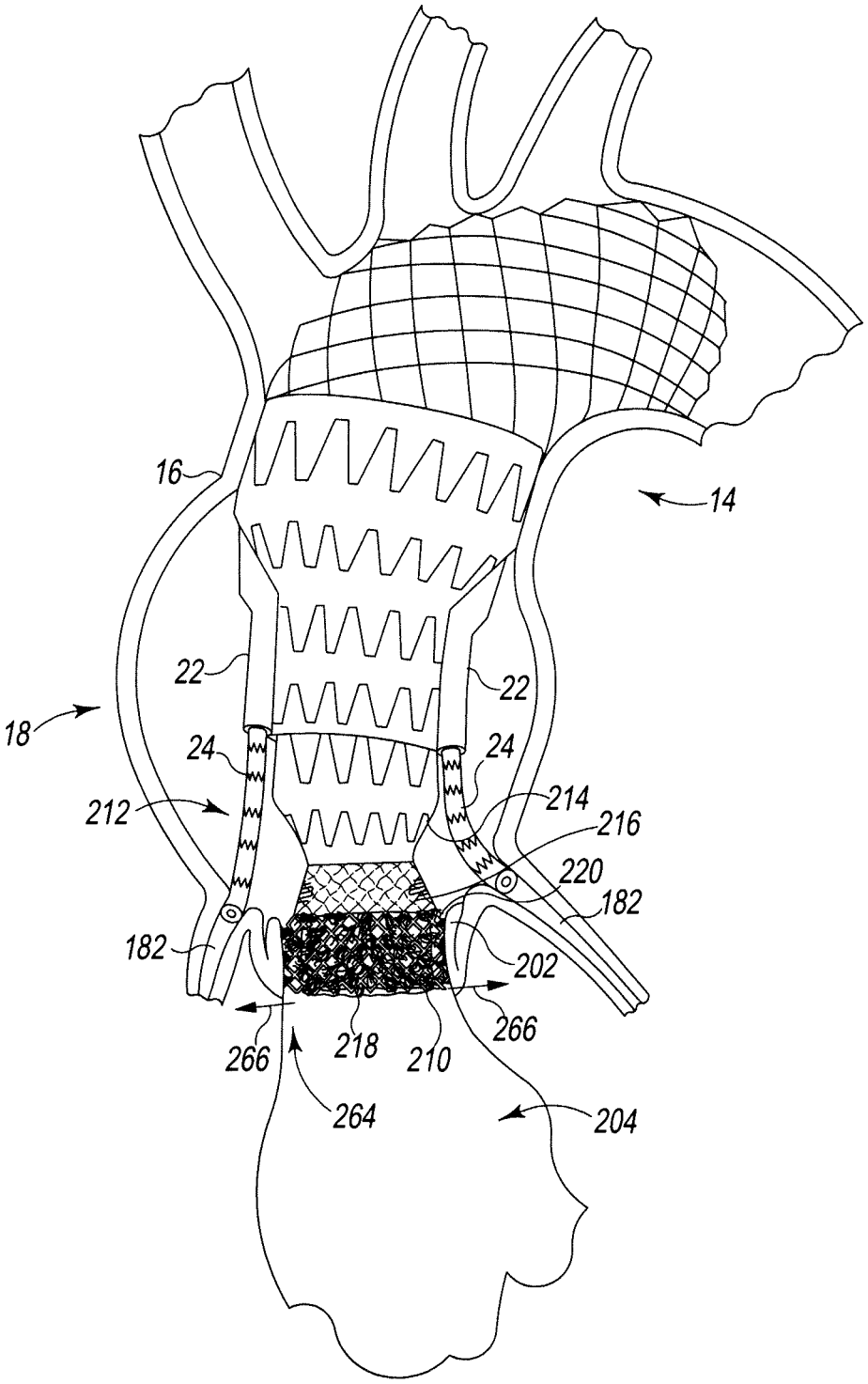

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Fig. 15

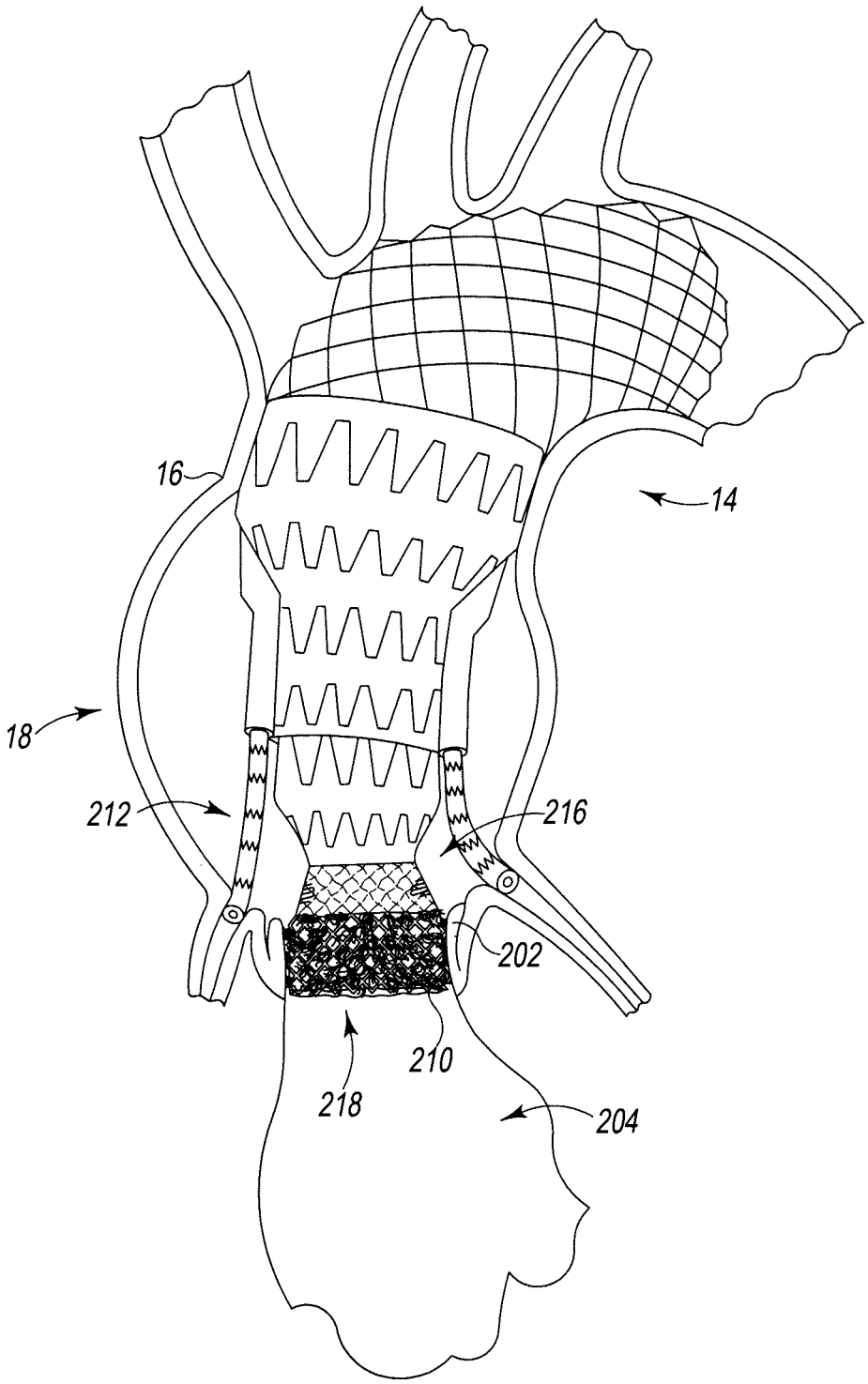


Fig. 16

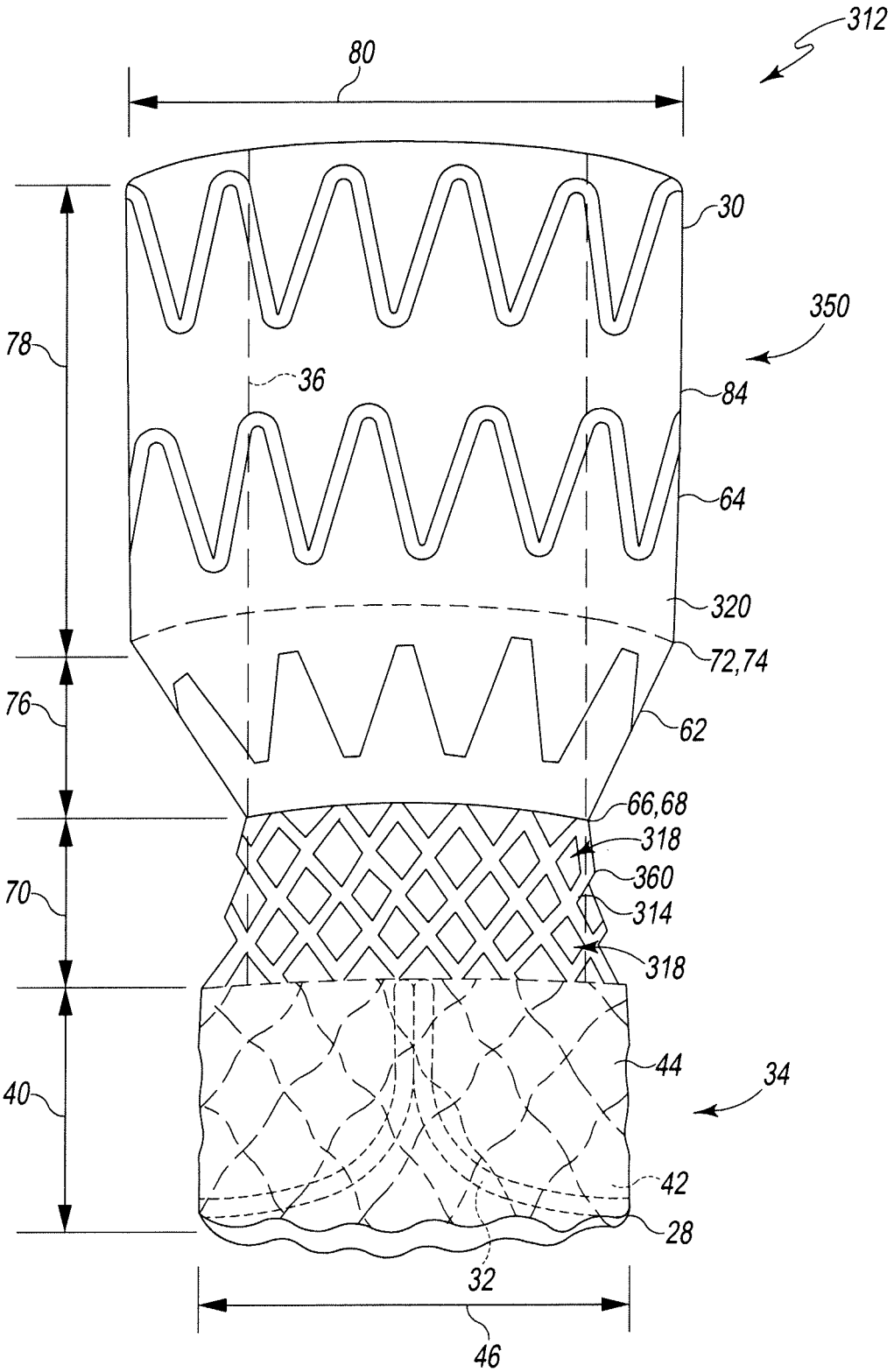

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Fig. 17

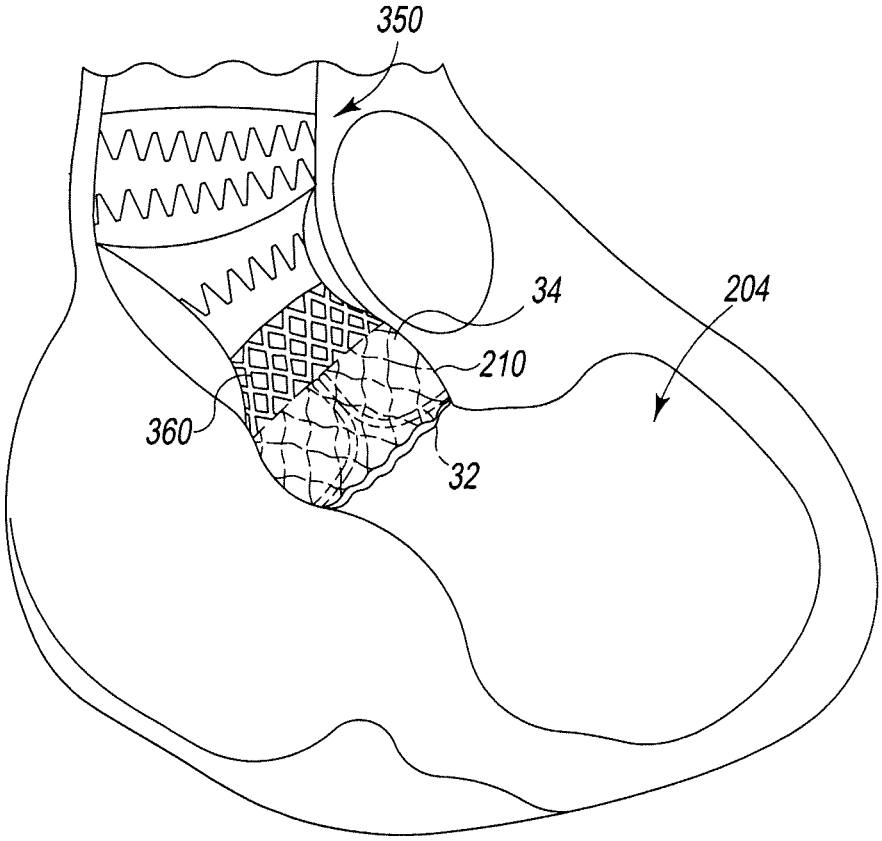


Fig. 18

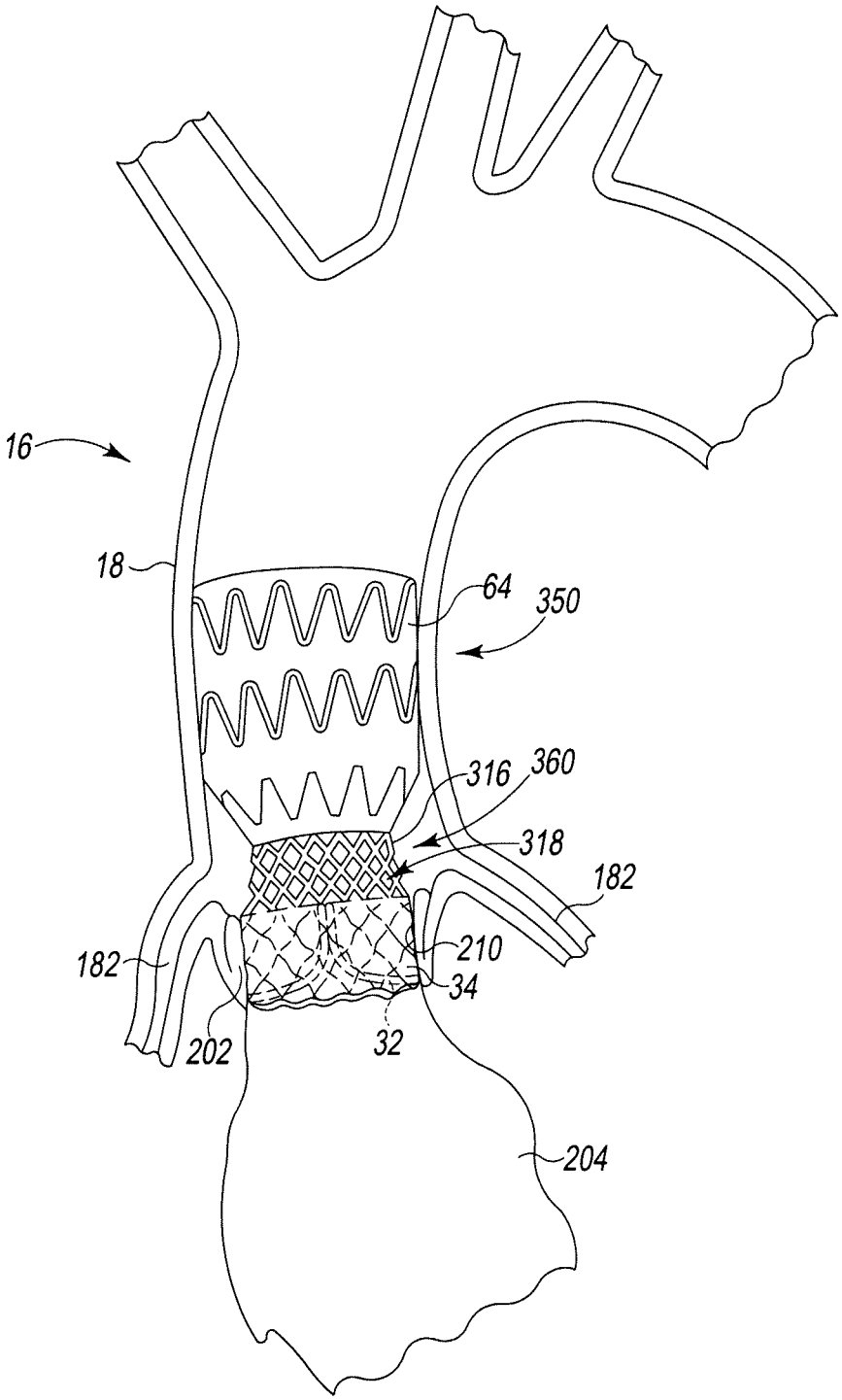


Fig. 19

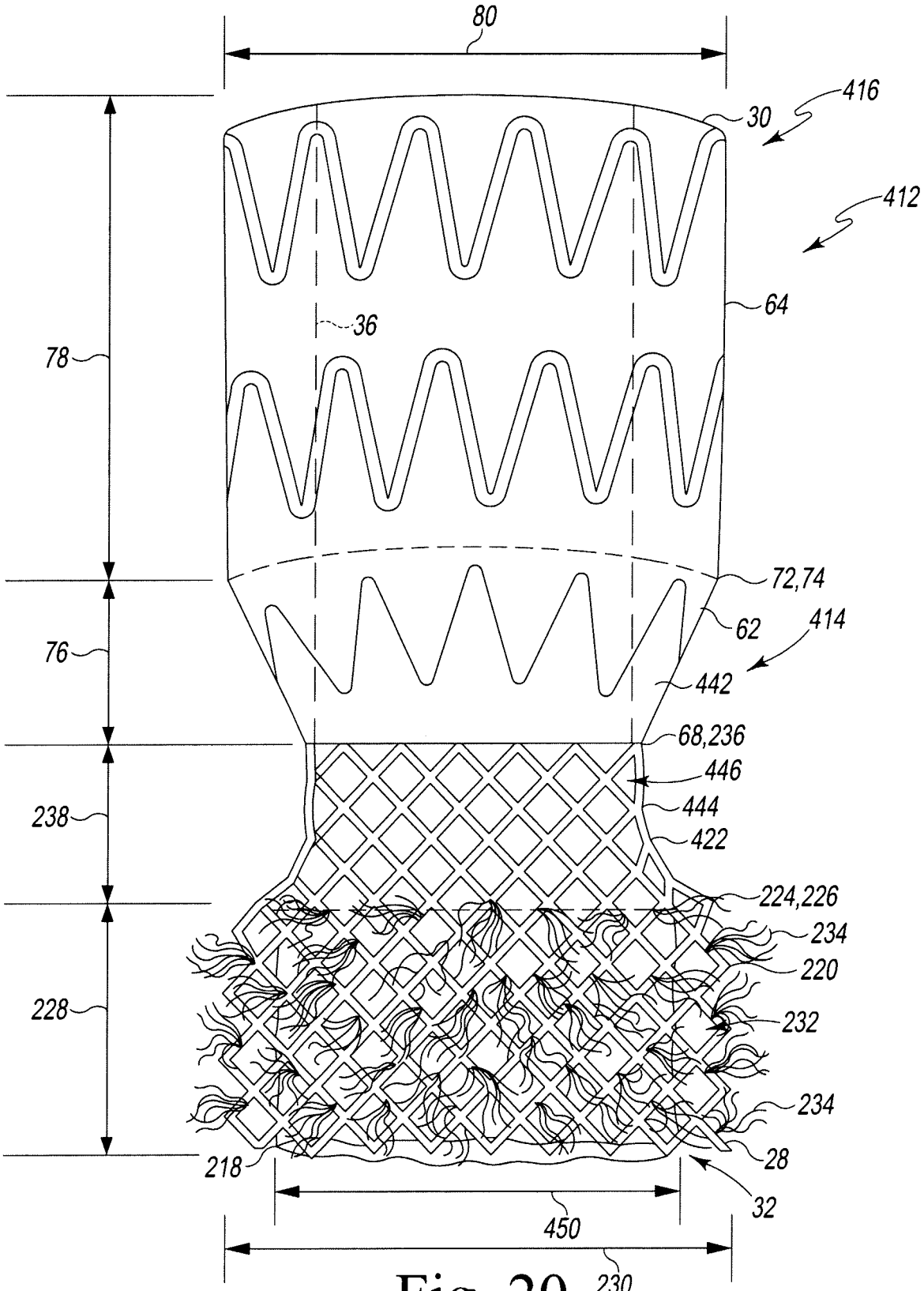

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Fig. 20

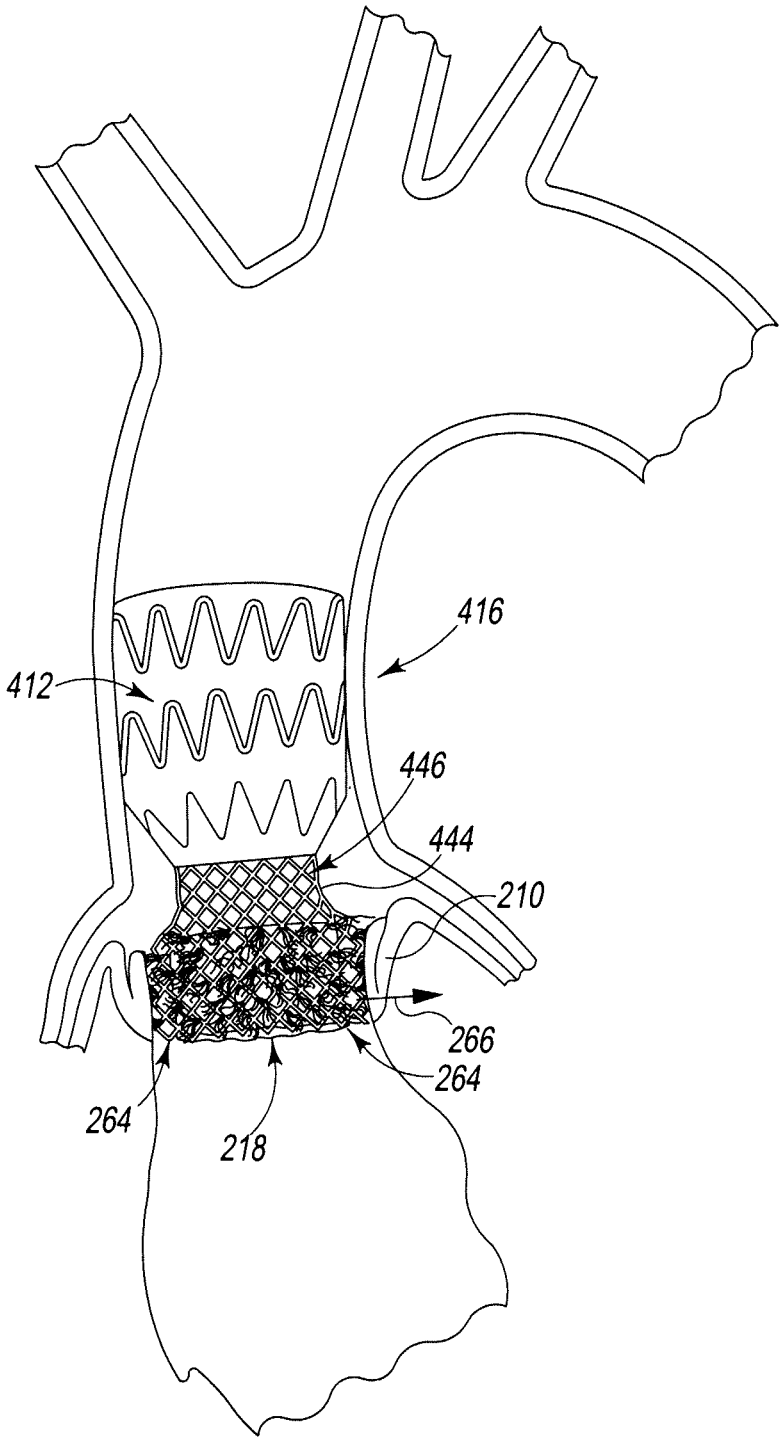


Fig. 21

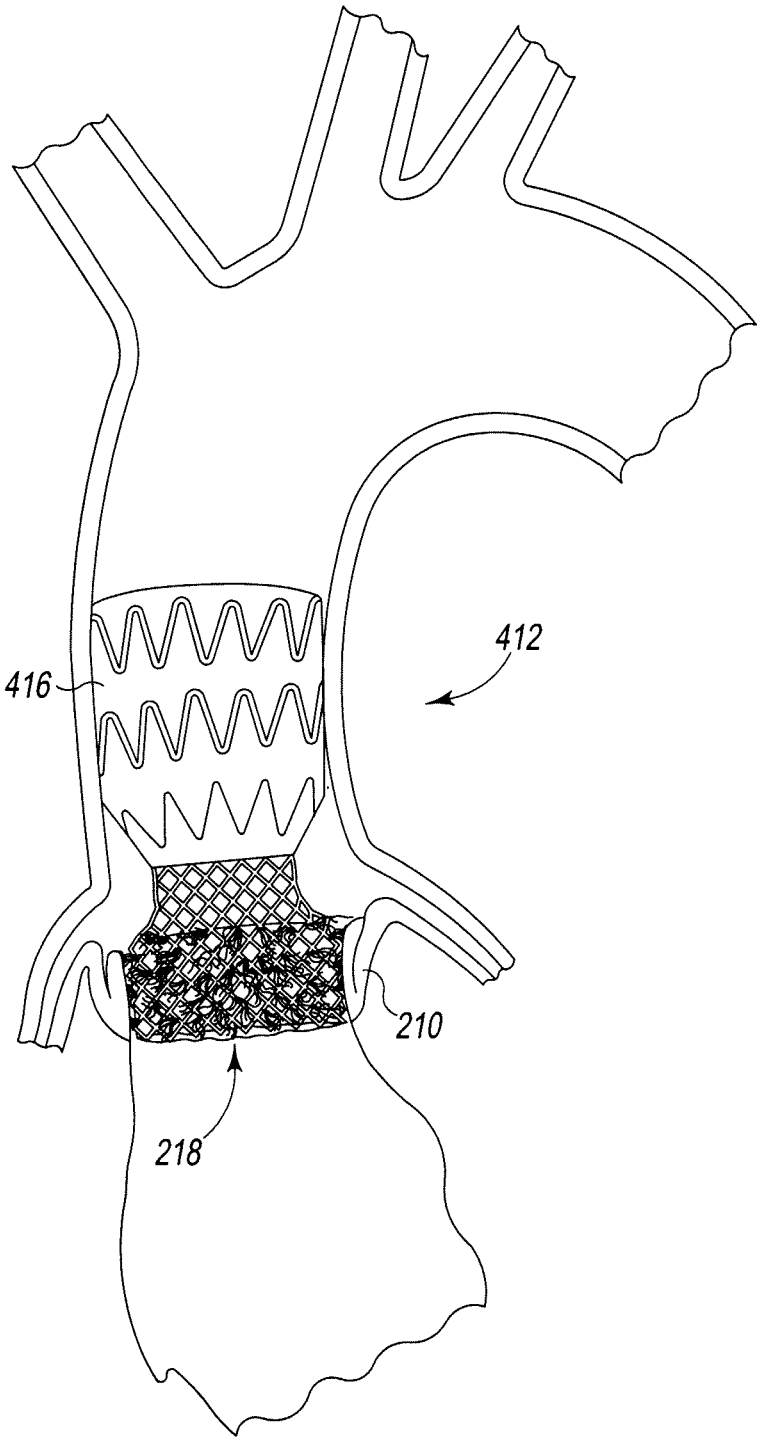


Fig. 22

DEVICE FOR AORTIC REPAIR AND METHOD OF USING THE SAME

This application is a continuation of U.S. patent application Ser. No. 16/935,261 entitled "DEVICE FOR AORTIC REPAIR AND METHOD OF USING THE SAME", which was filed on Jul. 22, 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, 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 cov-

ered 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 per-

formed 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 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 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 compo-

nent **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 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. A transcatheter heart valve assembly comprising:

a graft covering housing prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart valve leaflets for providing sealing to the heart valve leaflets;

an outer frame formed from a metallic material and defining an open cell configuration, and being secured to the graft covering; 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,

wherein the sealing material is attached to the outer frame,

wherein the sealing material defines a height that partially extends over at least a first two rows of cells in the outer frame,

wherein the sealing material includes a plurality of radially extending, arcuate fibers that extend outwardly of the outer frame;

wherein the graft covering is made of polyester, polytetrafluoroethylene, expanded polytetrafluoroethylene, or a polymer,

wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient,

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

wherein expansion of the heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the radially extending fibers into engagement with native leaflets of the aorta of the patient,

wherein the plurality of fibers is in contact with the outer frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation,

wherein the outer frame extends distally further than the prosthetic heart valve leaflets.

2. The valve assembly of claim **1**, wherein open cells of the open cell configuration are a square shape.

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

4. The valve assembly of claim **1**, wherein the radially extending fibers are collagen fibers.

5. A transcatheter heart valve assembly comprising:

a graft covering housing prosthetic heart valve leaflets, wherein the graft covering extends radially outwardly around the prosthetic heart valve leaflets and radially inwardly of an outer frame for providing sealing to the prosthetic heart valve leaflets;

wherein the outer frame is formed from a metallic material and defines an open cell configuration, and being secured to the graft covering; 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,

wherein the sealing material is attached to the outer frame,

wherein the sealing material defines a height that partially extends over at least a first two proximal circumferentially extending rows of cells in the outer frame,

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

wherein the radially extending fibers are arcuate,

wherein the graft covering extends beyond a proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame,

wherein the plurality of radially extending fibers form a circumferential surface that extends outwardly of the outer frame;

wherein the fibers radially overlap with the prosthetic heart valve leaflets,

wherein the graft covering is made of polyester, polytetrafluoroethylene, expanded polytetrafluoroethylene, or a polymer,

wherein the valve assembly is expandable during endovascular deployment,

wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient,

wherein expansion of the heart valve assembly is configured to press the sealing material against native valve leaflets of an aorta of the patient,

wherein the plurality of fibers is in contact with the at least a first two proximal circumferentially extending rows of cells along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation.

6. The valve assembly of claim **5**, further including a second portion of fibers that extend radially inwardly from the outer frame.

7. The valve assembly of claim **5**, wherein open cells of the open cell configuration are a square shape.

8. The valve assembly of claim **5**, wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve.

9. The valve assembly of claim **5**, wherein the radially extending fibers are collagen fibers.

10. The valve assembly of claim **5**, further including a second portion of fibers that extend radially inwardly from the outer frame.

11. A transcatheter aortic heart valve assembly comprising:

a graft covering engaging prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart valve leaflets for providing sealing to the prosthetic heart valve leaflets;

a frame formed from a metallic material and defining an open cell configuration, 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 to prevent paravalvular leaks,

wherein the sealing material is attached to the frame,

wherein the sealing material defines a height that extends over at least a first two rows of cells in the frame,

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

wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient,

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

wherein expansion of the heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the outwardly extending fibers into engagement with native leaflets of the aorta of the patient,

wherein the plurality of fibers is in contact with the frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation.

12. The valve assembly of claim **11**, wherein open cells of the open cell configuration are a square shape.

13. The valve assembly of claim **11**, wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve.

14. The valve assembly of claim **11**, wherein the outwardly extending fibers are collagen fibers.

15. The valve assembly of claim **11**, further including a second portion of fibers that extend radially inwardly from the frame.

* * * * *

EXHIBIT 3

Afshin SADRI likes this

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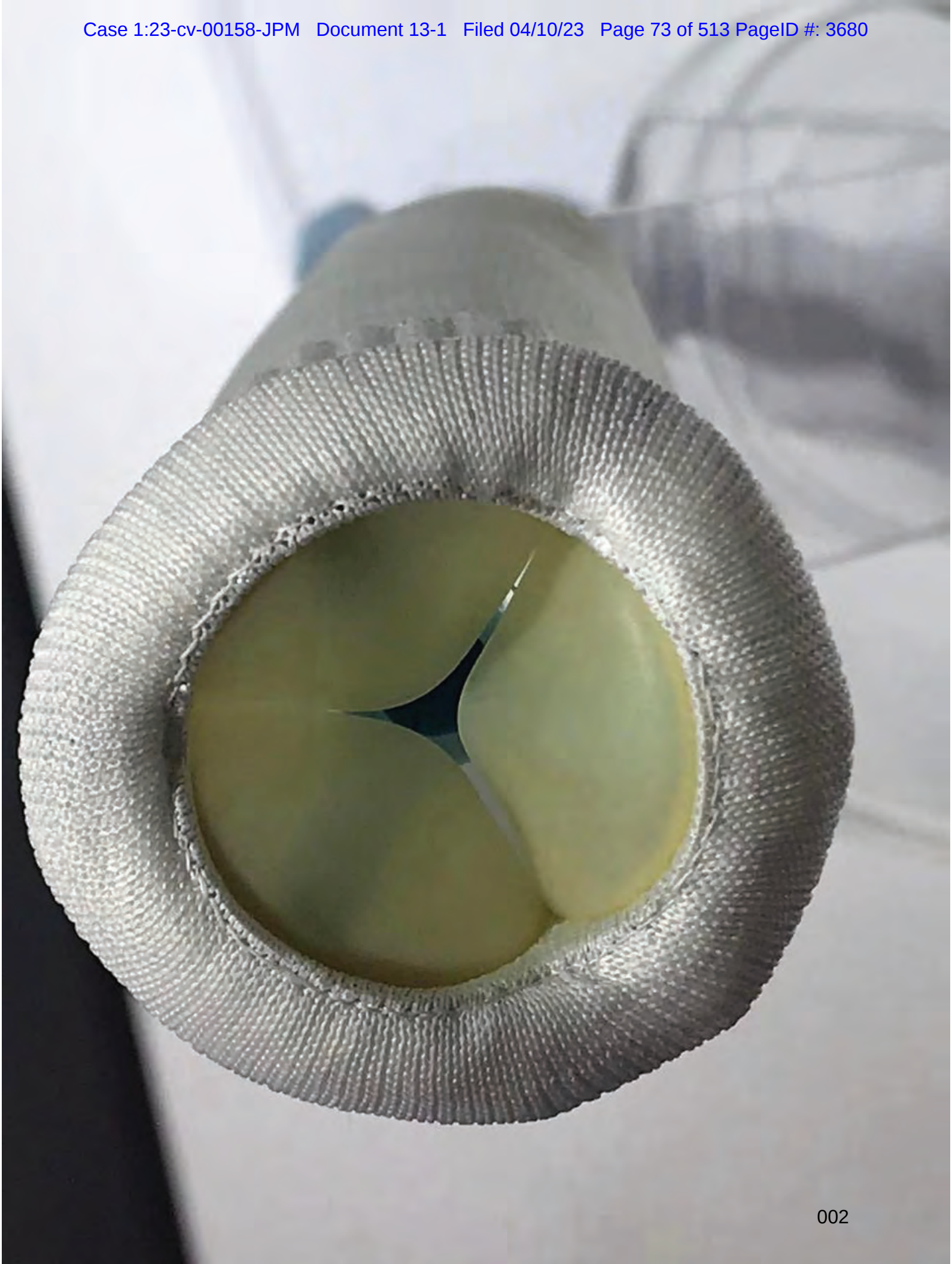
Attendees look at the Resila surgical aortic valve, which was displayed alongside it Sapien 3 TAVR valve in the Edwards Lifesciences booth at the American Heart Association 2022 meeting today. #AHA #AHA22

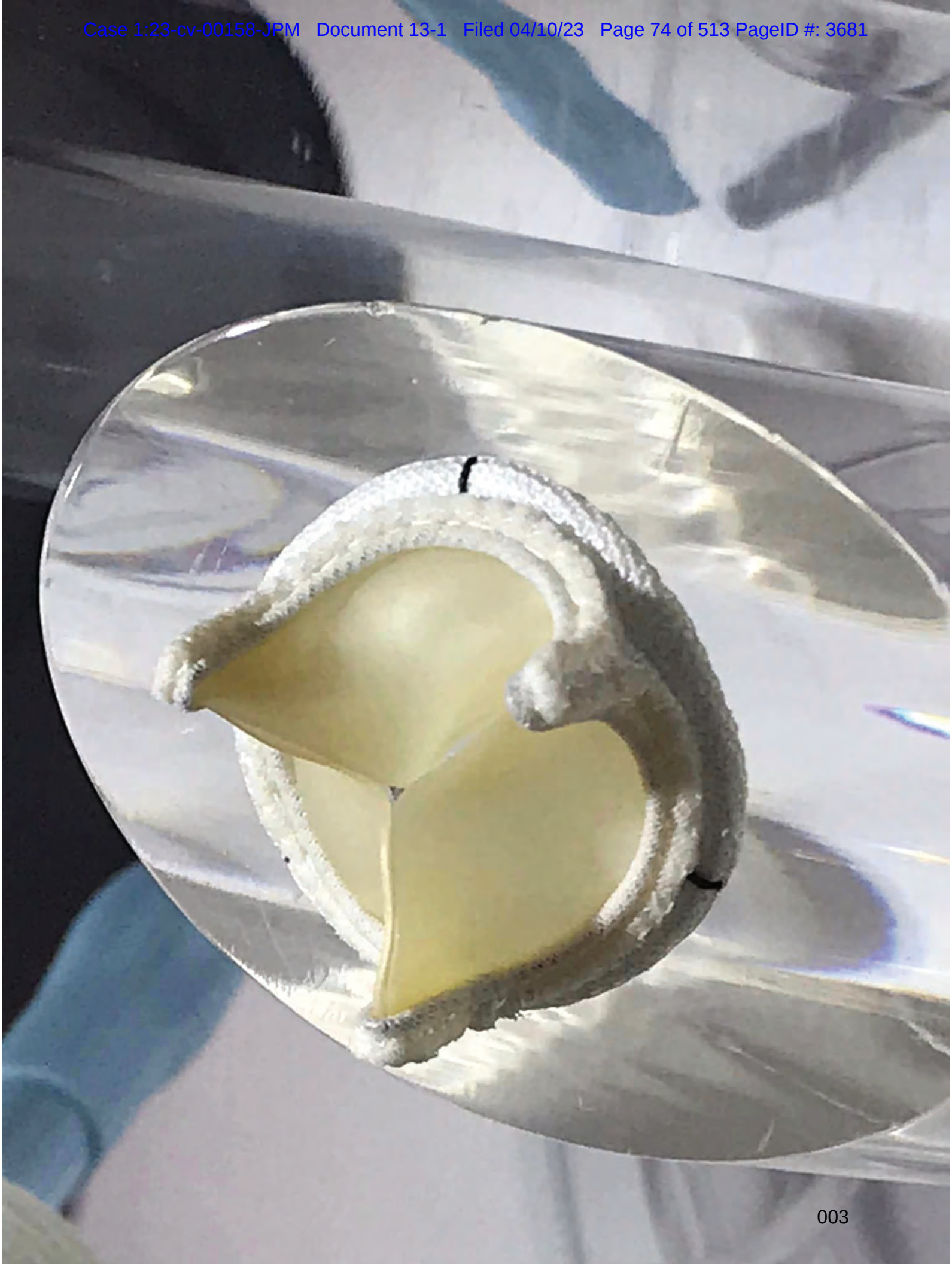


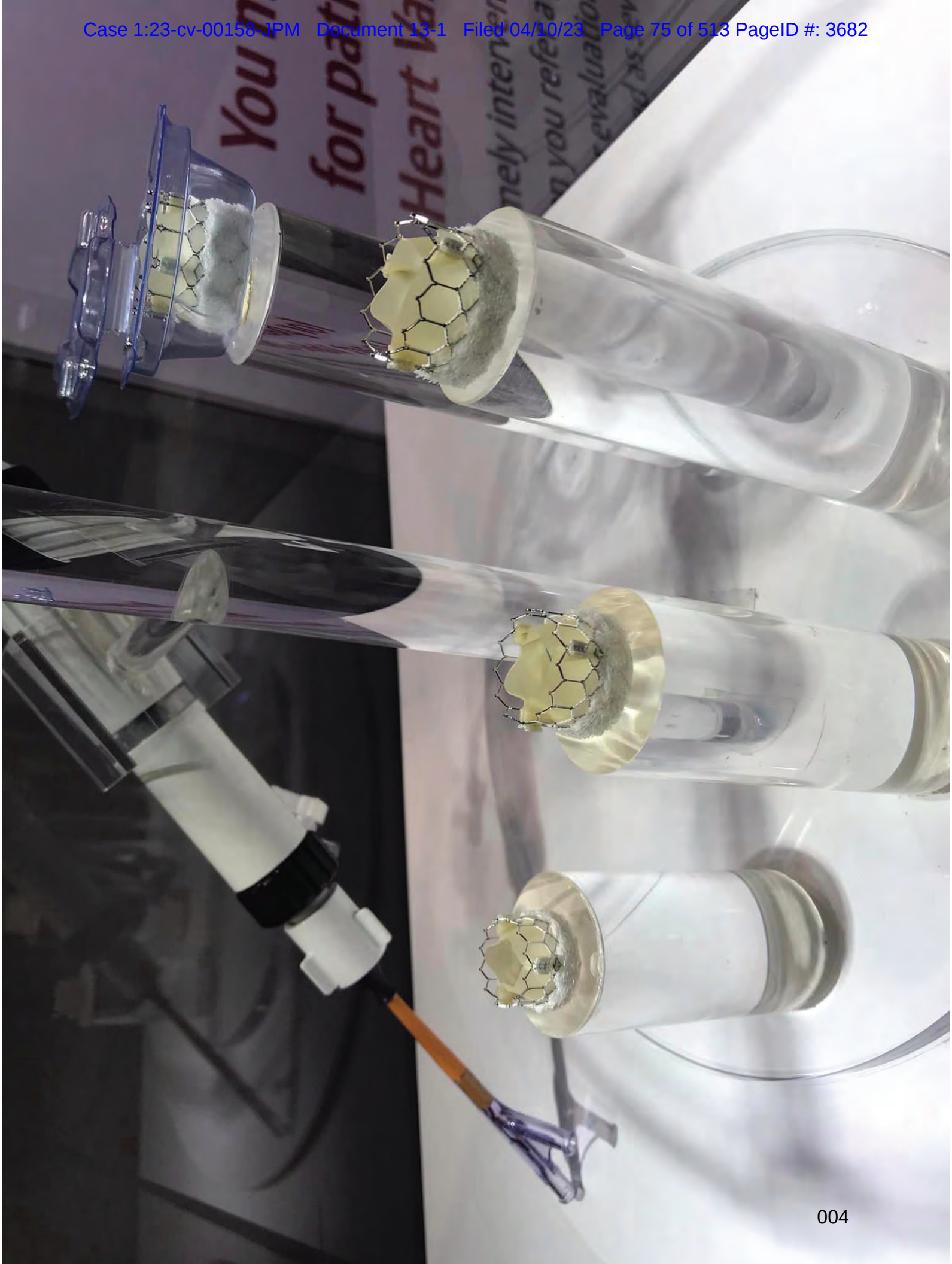
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Edwards Lifesciences
Proven performance of the PERIMOUNT valve design – a design with published clinical durability of over 20 years[2-4]







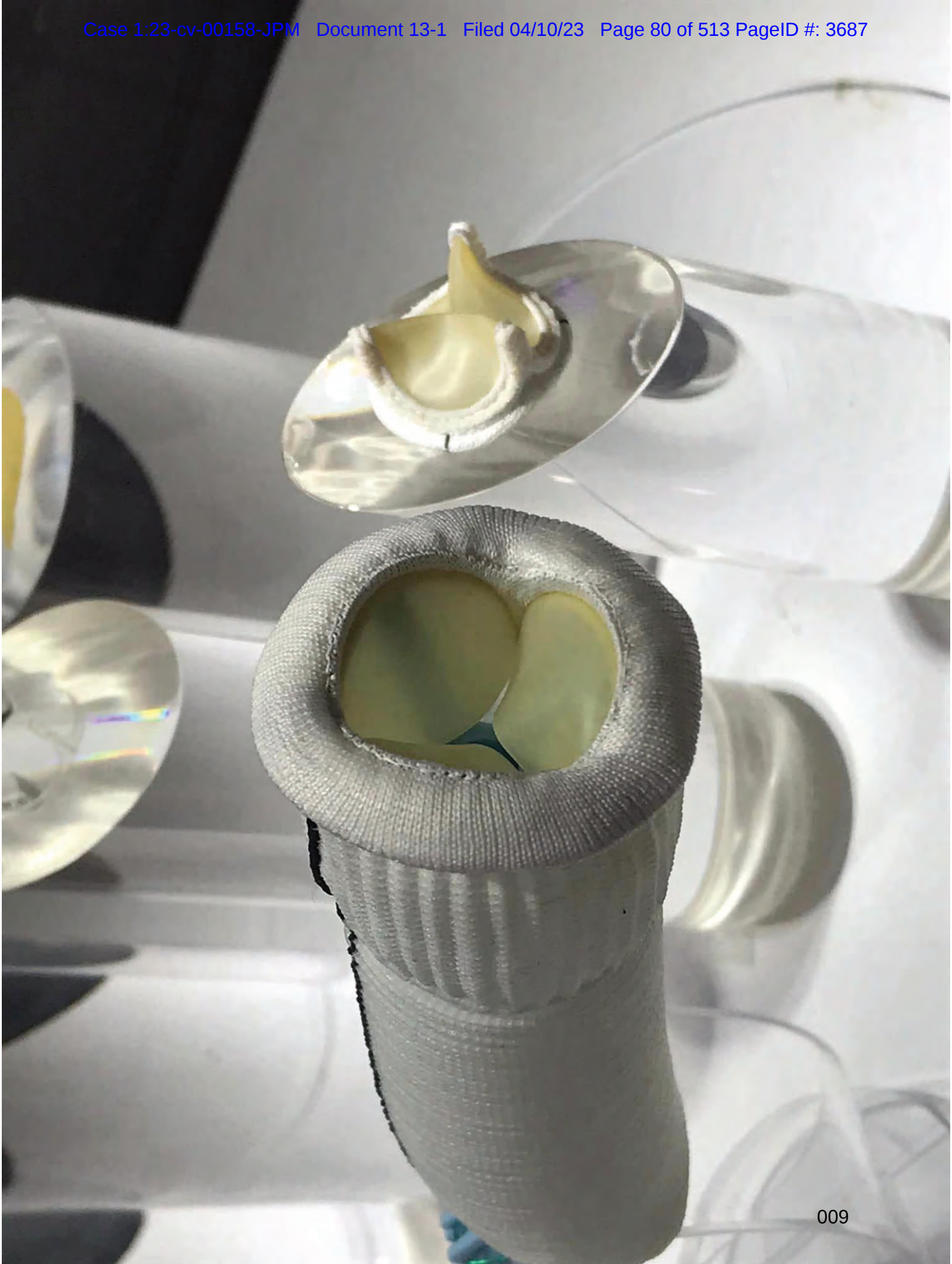


EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AORTIC INNOVATIONS LLC, Plaintiff, v. EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC and EDWARDS LIFESCIENCES (U.S.) INC., Defendants.	)	Case No. 1:21-cv-01377-JPM

DECLARATION OF YJ OH

I, YJ Oh, hereby declare as follows:

1. I am the Senior Vice President of Global and U.S. Marketing for Transcatheter Heart Valves at Edwards Lifesciences Corporation. I have personal knowledge of the matters set forth herein and, if called upon to testify, I could and would testify competently thereto.

2. At Edwards, in addition to other duties, I oversee the marketing of the SAPIEN 3 Ultra device. Edwards' SAPIEN 3 Ultra transcatheter heart valve (THV) system is a catheter-based artificial heart valve system designed to replace a diseased heart valve without open-heart surgery. In November 2018, European regulatory authorities approved the SAPIEN 3 Ultra THV system for the treatment of severe aortic stenosis (narrowing of the aortic valve) of the patients' own heart valve. In December 2018, the FDA similarly approved the SAPIEN 3 Ultra THV system. All sales are subject to the restrictions of the respective regulatory agency

I. EDWARDS' COMMERCIAL DEVICE

3. The SAPIEN 3 Ultra transcatheter heart valve (THV) system includes the prosthetic heart valve, a delivery system, a crimper, and other accessories. Edwards sells its SAPIEN 3 Ultra THV system only to approved hospitals with an Edwards' account number. Those hospitals have facilities (catheterization laboratories or operating rooms) and physicians (interventional cardiologists or sometimes cardiac surgeons) capable of implanting the valve in patients. Edwards does not sell its SAPIEN 3 Ultra THV system to physician offices, outpatient surgery centers, clinics, or non-approved hospitals.

4. Edwards always enters into a Pricing Agreement with an approved hospital before selling its SAPIEN 3 Ultra THV system to the hospital. Edwards also enters into a Consignment Agreement with approved hospitals.

5. I have attached as Exhibit 1 a true and correct copy of Edwards' Consignment Agreement. That Consignment Agreement requires hospitals to use the SAPIEN 3 Ultra THV system "only for its own internal use" (¶1) and "only for immediate use in providing care to Consignee's patients." (¶6). It also provides that purchases of Consigned Products are governed by the "terms and conditions set forth in the Pricing Agreement." (¶2).

6. I have attached as Exhibit 2 a true and correct copy of Edwards' Pricing Agreement. That Pricing Agreement requires hospitals maintain the confidentiality of Edwards' information, including the details of its products. Paragraph 9 provides: "Each party agrees that all information provided to it by the other party pursuant to this Agreement, including information concerning pricing, products and customers, is confidential and proprietary information of the disclosing party. Each party agrees not to disclose such confidential information directly or indirectly to any third party or to use such confidential information for

any purpose other than for fulfilling its obligations under this Agreement. Upon either party's request, the other party shall return all confidential information to the requesting party or destroy all such information and certify in writing as to its destruction. This provision shall survive the termination or expiration of this Agreement."

7. For approved hospitals with an Edwards' account number, Edwards provides the hospitals with an inventory of consigned kits that includes the SAPIEN 3 Ultra valve, the delivery system, and other accessories. Within the kit, the SAPIEN 3 Ultra valve is stored in a box with a tamper resistant seal and an identifying bar code. Within that sealed box, the valve is stored in a jar of glutaraldehyde with a tamper resistant seal. That jar is covered in white labels, including an identifying bar code. It is not possible to see the valve details through the labels and the glutaraldehyde.

8. When an interventional cardiologist at an approved hospital decides to implant a SAPIEN 3 Ultra valve in a patient, an Edwards' representative (such as a clinical specialist or territory manager) attends the procedure, which is typically performed in a catheterization laboratory or an operating room. The SAPIEN 3 Ultra THV system is expensive (tens of thousands of dollars) and proprietary to Edwards, so the Edwards' representative keeps a close eye on the system components. Once the seals on the box and the jar are broken, Edwards' representative records the serial number and other details, and, the hospital is charged for the valve.

9. The reason Edwards stores the SAPIEN 3 Ultra valve in glutaraldehyde is because the valve tissue consists of bovine pericardium tissue. Bovine pericardium tissue will degrade if stored in dry, open-air environments, so the valve is stored in a glutaraldehyde solution to preserve the bovine pericardium tissue. Glutaraldehyde is a hazardous chemical that is likely to

irritate the eyes and skin of a person who comes into contact with it. Therefore, Edwards advises that anyone handling the SAPIEN 3 Ultra device wear protective equipment, such as gloves, a lab coat, a face shield, and goggles.

10. Once the implanting team removes the SAPIEN 3 Ultra valve from the glutaraldehyde, they rinse it in two different bowls of saline for 1 minute each. After it is rinsed in saline, the valve is crimped onto the delivery system and must be implanted in the patient within 30 minutes of being removed from the saline.

II. EDWARDS' RESILIA VALVE

11. In September 2022, Edwards launched its SAPIEN 3 Ultra RESILIA valve following FDA approval. That valve includes bovine pericardial tissue treated with proprietary RESILIA anti-calcification technology. It is packaged in a sterile plastic container within a sealed foil pouch. Both the foil pouch and the plastic container include bar codes that identify the valve for tracking purposes. Like the original SAPIEN 3 Ultra valve, the valve with RESILIA tissue sells for tens of thousands of dollars. Edwards only sells the Sapien 3 Ultra RESILIA valve to the approved hospitals. Edwards does not sell it to physician offices, outpatient surgery centers, clinics, or non-approved hospitals. Edwards sells the Sapien 3 Ultra RESILIA valve under the same Consignment Agreement and Pricing Agreement that I referred to earlier in my declaration.

III. DEMONSTRATIVE VALVE

12. Edwards developed a demonstrative version of the SAPIEN 3 Ultra valve replacing the bovine pericardium tissue with a latex material. Because the leaflets are latex, the SAPIEN 3 Ultra demonstrative may be stored in dry, open-air environments, making it more practical for handling and inspecting the valve.

13. Edwards also assembles the demonstrative valve using a simplified procedure rather than the production procedure of the commercial valve. The valve reflects the same overall appearance and component materials (skirts, frame, sutures) as the commercial valve.

14. Edwards does not sell or distribute its SAPIEN 3 Ultra demonstrative valve to third parties or to the general public.

15. Edwards would never provide its SAPIEN 3 Ultra demonstrative valve to a competitor or any other party who is drafting patent claims on heart valves or related devices.

16. Edwards would be significantly harmed by a competitive entity or a licensing entity having access to its physical valve, whether it be the commercial valve or the demonstrative valve. Important design details can be discerned from the physical valve that cannot be identified from a mere photograph or video. Those highly sensitive design details include precisely how and where the leaflets and the skirts are attached to the valve including, how and where the leaflet connections are formed, how and where sutures are placed, and how and where the skirts and leaflets are folded. These intricate design details cannot be discerned from publicly available photographs or a video. Many of them would require disassembly of the physical valve to discern. For example, having the physical valve would allow a third party to determine the exact knitting/weaving patterns for the skirts, which are proprietary information of Edwards. These intricate design details contribute to the SAPIEN 3 Ultra valve's advantages, making it the leading THV valve on the market.

17. Edwards has invested significant resources into developing its SAPIEN 3 Ultra THV system, including its new model with RESILIA tissue, and would be harmed if competitors or other companies were to learn about product features that are not generally known. Some companies may attempt to use this information to develop copycat valves. Such actions would

harm Edwards' profits, which would harm Edwards' ability to innovate life saving devices for its patients.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on November ___, 2022 in Irvine, California.

YJ Oh

Digitally signed by YJ Oh
DN: cn=YJ Oh,
email=YJ_Oh@edwards.com
Date: 2022.11.12 09:59:43 -08'00'

YJ Oh, SVP Global & U.S. Marketing THV

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
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Rodney Square
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Wilmington, DE 19801
Attorneys for Plaintiff

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MCKOOL SMITH, P.C.
300 Crescent Court, Suite 1500
Dallas, TX 75201
Attorneys for Plaintiff

/s/ Anthony D. Raucci

Anthony D. Raucci (#5948)

EXHIBIT 1



CONSIGNMENT AGREEMENT

This Agreement is entered into as of the date this Agreement is executed by the last party to sign below, ("Effective Date"), by and between Edwards Lifesciences LLC, a Delaware limited liability company (hereinafter, "Consignor") and [Hospital Name] (hereinafter, "Consignee").

WITNESSETH:

WHEREAS, Consignor manufactures and distributes, among other medical devices, a proprietary line of transcatheter heart valve therapy systems (hereinafter, the "Products"); and

WHEREAS, Consignee is an existing customer for Products and requires the ready availability of Products for implantation in patients as the need arises, and wishes to maintain an inventory of Products at its premises at [Hospital Address] (hereinafter, the "Premises") on a consignment basis; and

WHEREAS, Consignor is willing to supply Products to Consignee on a consignment basis subject to the terms and conditions set forth below ("Consigned Products"); and

WHEREAS, Consignor has heretofore shipped to Consignee, and Consignee maintains in storage at the Premises on the date of this Agreement, the Products more particularly described in Exhibit A attached hereto (hereinafter, the "Existing Consigned Products" and, together with Products hereafter shipped by Consignor to Consignee pursuant to Section I below, the "Consignment Inventory").

NOW, THEREFORE: in consideration of the mutual promises and accommodations contained herein, the parties agree as follows:

I. SHIPMENT, STORAGE, AND PURCHASE/SALE OF PRODUCTS

1. Inventory of Consigned Products. From time to time during the term of this Agreement the level and product mix of the Consignment Inventory maintained at the Premises pursuant to this Agreement may be changed by mutual written agreement of the parties to meet the changing needs of Consignee's operations by executing an amendment to Exhibit A; however, Consignor may provide additional Inventory as needed by a Consignee for a specific case beyond Consignment Inventory levels set forth in its respective Exhibit A ("Short Term Consignment") upon receipt of a no charge purchase order. Due to the temporary nature of such Short Term Consignment, a written amendment increasing par levels shall not be required for the short term basis, but such Short Term Consignment Inventory shall nevertheless be subject to the terms and conditions of this Consignment Agreement.

Notwithstanding the foregoing, if in the course of its inspections performed pursuant to Section 7 below Consignor determines that models in Consignment Inventory have not been used by Consignee in the preceding three (3) month period, Consignor shall have the right, but not the obligation, to remove such models from Consignment Inventory and adjust Consignee's par levels and product mix as deemed necessary in Consignor's reasonable discretion. Consignee shall use the Consignment Inventory only for its own internal use. All Products ordered by Consignee to maintain as the Consignment Inventory, as well as all of the Existing Consigned Products, shall be considered to have been consigned pursuant to the terms of this Agreement.

2. Delivery and Sales Terms. The parties acknowledge that Consigned Products shall be deemed to be consigned to Consignee FOB destination, freight prepaid, via carriers selected by Consignor with the exception of special delivery and/or air shipments requested by Consignee. Such special delivery and/or air shipment charges shall be prepaid by Consignor and invoiced to Consignee for payment. Consignee shall at that place and time promptly take possession of the Consigned Products and pay all costs incident to the eventual arrival and storage of the Consigned Products at the Premises. All anticipated purchases of Consigned Products by Consignee shall be governed by the terms and

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One Edwards Way · Irvine, CA USA 92614
Phone: 949.250.2500 · Fax: 949.250.2525 · www.edwards.com

conditions of this Agreement and those additional terms and conditions set forth in the current pricing or purchasing agreement in effect between Consignee and Consignor for Consigned Products, if applicable. This Agreement will take precedence in the event of any conflict with the provisions set forth in any other agreement with respect to the consignment of Consigned Products.

3. Ownership. Anything in this Agreement to the contrary notwithstanding, the Consigned Products will remain the sole and exclusive property of Consignor until purchased as provided below, at which point title to each of the Consigned Products shall pass from Consignor to Consignee. Consignee shall not represent itself to any third party as being the owner of any such Consigned Products, claim any rights of ownership therein, nor encumber, lease, transfer or otherwise dispose of (other than in accordance with the terms of Section 6 below) any such Consigned Products.

4. Storage of Consigned Products. Consignee shall hold the Consigned Products at the Premises as agent and bailee of Consignor, and will store the Consigned Products at the Premises at no cost to Consignor. Consignee shall have full responsibility for the care and condition and the safe and satisfactory storage and maintenance of the Consigned Products and exercise due care when shipping or returning any Consigned Products to Consignor. Consignee assumes full liability for any Consigned Products that are missing, damaged, destroyed, or otherwise no longer in saleable condition (i.e., properly stored and maintained and in unopened and undamaged packages) resulting from any cause whatsoever, including but not limited to breakage, theft, damage by water, fire, or other occurrences. Consignor shall remove and may replace expired Consigned Products at no cost to Consignee and upon expiration of Consigned Product, Consignor shall review product usage and determine if Consigned Product(s) will be replaced to the Consignee or an adjustment to Consignee's consigned inventory levels is necessary. Consignee shall be solely responsible for all taxes and charges imposed with respect to the Consigned Products while they are stored at the Premises. Consignee further agrees to segregate the Consigned Products physically from any Products owned by Consignee and to post one or more signs conspicuously identifying the Consigned Valves as the property of Consignor.

5. Insurance. Consignee shall procure and maintain in force at all times during the term of this Agreement, at Consignee's expense, all-risk property insurance acceptable to Consignor covering the Consigned Products, in an amount at least equal to the aggregate prices as set forth in Consignor's published price list for Consigned Products in effect for the period of the insurance by Consignor for all Consigned Products stored in the Premises, Upon request from Consignor, Consignee shall furnish a certificate of the existence of such insurance executed by Consignee's insurance carrier.

6. Purchase of Consigned Products. Consignee shall have the right to withdraw Consigned Products from storage, from time to time, but only for immediate use in providing care to Consignee's patients. Consignee agrees to withdraw for use those Consigned Products, from the Consignment Inventory, which have the shortest remaining shelf life, based on the expiration date on the package. Upon such withdrawal, or upon report by Consignor to Consignee of any "Discrepancy" as described in Section 7 below, Consignee shall be considered to have purchased the pertinent Consigned Products. Following such purchase of each Consigned Product, Consignee shall promptly issue to Consignor an order, but in no event later than seven (7) days after such purchase, for a replacement Consigned Product, thereby fully replenishing the Consignment Inventory (unless the parties have implemented an automated process, such as RFID, that detects withdrawal of Product and automatically places an order for replenishment). Consignee shall be responsible for maintaining traceability of the Products used. All orders for Consigned Products shall include: (i) the Product name and catalog/item number; (ii) serial number of Consigned Product purchased; (iii) the number of units to be delivered; (iv) the delivery address; (v) any special shipping instructions; and (vi) reference to this Agreement. Upon receipt of any such order, Consignor will issue an invoice for the Consigned Product or Products that was or were purchased. Consigned Products purchased by Consignee will be billed to Consignee at the price set forth in the current pricing or purchasing agreement in effect between Consignee and Consignor for Consigned Products at the time of shipment of the replacement Consigned Product.

7. Inspection. Upon request, Consignor shall have the right to conduct a physical inspection of the Consigned Products at the Premises to verify the quantity and condition of the Consigned Products, to ensure that the Consignment Inventory is being maintained. Consignor will identify and report to Consignee any discrepancy between



(a) the Consigned Products located at Premises that are undamaged and in saleable condition, and
(b) the Consignment Inventory

(hereinafter, a "Discrepancy"). If, within seven (7) days of Consignor's report of a Discrepancy, Consignee fails to issue to Consignor an order for Consigned Products sufficient to replenish the Consignment Inventory, Consignor is entitled to deliver Consigned Products sufficient to replenish the Consignment Inventory and/or issue an invoice for Consigned Products subject to the Discrepancy. Consignee shall provide Consignor's representatives reasonable access to the Premises to conduct such inspections.

8. Payment for Consigned Products. Within thirty (30) days of the date of invoice for the Consigned Product that was purchased, payment shall be due from Consignee to Consignor for such Consigned Product.

9. Obligations Upon Termination. Notwithstanding any past, present, or future commitment by Consignor to ship Products to Consignee, Consignee shall, no later than ten (10) days following the expiration or termination of this Agreement: (i) return to Consignor, through an authorized Consignor sales representative, any or all Consigned Products then in Consignee's possession, FOB the Premises, that are unexpired, undamaged, and in saleable condition, together with a certificate (Exhibit B) stating that Consignee has at all times stored and maintained the returned Consigned Product as required in the Product Directions for Use; (ii) issue a final order for all Consigned Products that are not returned or that are not in saleable condition, including any Consigned Products that are lost, opened, or damaged; and (iii) pay any outstanding invoices by the payment due date, including for the final order. At that time, Consignee shall prepare, pack, and crate the applicable Consigned Products for shipment, and arrange for shipment to such new location and via such carrier as Consignor directs.

10. Evidence of Ownership of Consigned Products. Consignee agrees to execute and deliver to Consignor, at any time and from time to time upon Consignor's request, such documentation as Consignor may deem necessary or advisable to evidence Consignor's ownership of the Consigned Products. Consignee will pay all costs and expenses of recording same, in order to establish, preserve, protect, and maintain Consignor's right and title to and ownership of the Consigned Products.

II. GENERAL PROVISIONS

11. Term and Termination. This Agreement shall commence on the Effective Date and remain in full force and effect for an initial term of 2 years from the date hereof, unless sooner terminated in accordance with the terms and provisions of this Agreement. Upon expiration of the Term, this Agreement shall be renewed automatically for successive renewal terms equivalent in duration of one (1) year terms (each, a "Renewal Term"). This Agreement may be terminated by either party upon the giving of at least thirty (30) days advance written notice to the other party of its intention to terminate.

12. Waiver. No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by an authorized representative of both parties hereto. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

13. Intent. The parties do not intend that any payments made under this Agreement be in return for the purchasing or ordering of any goods or services other than the specific Products described in this Agreement.

14. Entire Agreement. This Agreement, including the exhibits attached hereto, constitutes the entire agreement, superseding all prior or contemporaneous agreements, understandings, representations, and negotiations, between the parties on the subject hereof; and there are no conditions to this Agreement that are not set forth herein. No modification to this Agreement or the exhibits attached hereto shall be effected by the acknowledgement or acceptance of any order or shipping instructions forms or similar documents containing terms or conditions at variance with or in

addition to those set forth herein. In the event of a conflict between this Agreement and the exhibits hereto, the terms of this Agreement shall control.

15. Severability. In the event any provision of this Agreement shall be held invalid or unenforceable by any court of competent jurisdiction, such holding shall not invalidate or render unenforceable any other provision hereof.

16. Assignment. This Agreement shall be binding upon and shall inure to the benefit of the successors and permitted assigns of the parties. Consignee may not assign or otherwise transfer (through merger, consolidation, sale of assets, or otherwise) this Agreement or any interest herein without the prior written consent of Consignor. Any purported assignment without such required consent shall be void. No assignment shall relieve any party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

17. Counterparts; Facsimile Signature Pages. This Agreement may be executed by the parties by facsimile and in one or more counterparts, each of which shall be deemed an original and all of which, taken together, shall constitute one and the same instrument.

18. Governing Law. This Agreement shall be governed by and construed in accordance with the laws, without reference to principles of conflicts of laws, of the State of California.

IN WITNESS WHEREOF, the parties to those present have caused the same to be executed as of the day and year first hereinabove written.

[HOSPITAL NAME]		**EDWARDS LIFESCIENCES LLC**	
By:	_____	By:	_____
Name:	_____	Name:	Kristen Skelton
Title:	_____	Title:	SVP Sales, THV US
Date:	_____	Date:	_____

Edwards Lifesciences
One Edwards Way · Irvine, CA USA 92614
Phone: 949.250.2500 · Fax: 949.250.2525 · www.edwards.com

EXHIBIT 2



Pricing Agreement

This Pricing Agreement (this "Agreement") is effective as of the date this Agreement is executed by the last party to sign below ("Effective Date"), between Edwards Lifesciences LLC, a Delaware limited liability company, with an address of One Edwards Way, Irvine, California 92614 ("Edwards") and [Hospital Name], with an address of [Hospital Address] ("Purchaser"). Purchaser desires to buy the products listed in the attached Schedule A ("Products") from Edwards at the prices set forth therein ("Prices"). Edwards is willing to supply the Products to Purchaser upon the terms and conditions set forth herein.

1. **Products**. Edwards agrees to supply Purchaser with the Products, and Purchaser agrees to buy the Products solely for its own use from Edwards. Edwards does not accept bulk buy purchasing of Products. Any purchases that may be considered a bulk buy or outside of expected procedure use must be reviewed and approved by Edwards prior to acceptance of the order. Edwards reserves the right to reject orders in such cases and such orders will not be invoiced. Edwards does not provide credit or replacement for expired transcatheter heart valve Products or accessories.

2. **Term**. This Agreement will be in effect for 2 years from the Effective Date ("Term"). Based on mutual written consent of both parties, this Agreement may be renegotiated at any time with 60 days notice for an effective change in pricing terms ("New Term"). Upon expiration of the Term, this Agreement shall be renewed automatically for successive renewal terms equivalent in duration of one (1) year terms (each, a "Renewal Term"). This Agreement may be terminated by either party upon the giving of at least thirty (30) days advance written notice to the other party of its intention to terminate. Upon termination of this Agreement, Edwards will not issue credits or re-bills for Products ordered or received after the date of termination.

3. **Pricing; Payment**. Payment terms are net 30 days from invoice date. Purchases shall be shipped FOB destination, freight prepaid, via carriers selected by Edwards, with the exception of special delivery and/or air shipments requested by Purchaser, and made in accordance with such further terms (including returned goods policies) as set forth in Edwards' policies and product price list in effect on the date of shipment. Such special delivery and/or air shipment charges shall be prepaid by Edwards and invoiced to Purchaser for payment. Purchase order placement, confirmation, and invoices for Products shall be sent by use of electronic data interchange (EDI), except where Purchaser does not have such capability. Edwards may suspend sales of the Products to Purchaser or terminate this Agreement with respect to Purchaser in the event that Purchaser delays payment or fails to pay any sum owed by Purchaser to Edwards hereunder.

4. **Limited Warranty**. EDWARDS WARRANTS THAT EACH OF THE PRODUCTS IT MANUFACTURES, WHEN USED IN ACCORDANCE WITH THE DIRECTIONS ON THE LABELING, IS FIT FOR THE PURPOSES AND INDICATIONS DESCRIBED IN THE LABELING. A PRODUCT DISTRIBUTED BY BUT NOT MANUFACTURED BY EDWARDS IS WARRANTED BY ITS MANUFACTURER. UNLESS A PRODUCT IS USED IN ACCORDANCE WITH ITS INSTRUCTIONS, THESE WARRANTIES ARE VOID AND OF NO EFFECT. THERE ARE NO OTHER EXPRESSED OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. EDWARDS' SOLE OBLIGATION AND PURCHASER'S EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY SHALL BE, AT EDWARDS' OPTION, TO REPAIR OR REPLACE THE PRODUCT. EDWARDS SHALL NOT BE LIABLE FOR PROXIMATE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES.

5. **Force Majeure**. Edwards will use commercially reasonable efforts to fill orders, but Edwards shall not be liable for nonperformance or delays caused by shortage of raw materials, manufacturing problems, labor problems, acts of regulatory agencies, discontinuation of a product line, acts of God, or other causes beyond Edwards' control. Purchaser agrees that in such events Edwards may allocate products among all purchasers without liability. In the event that Edwards ceases to manufacture or distribute any of the Products for any reason, Edwards shall have no obligation to supply such Product.

6. **Direct Order Purchases**. Edwards will provide the Products to Purchaser through direct order only at the Prices set forth herein.



7. **Intent**. The parties do not intend that any payments made under this Agreement be in return for the purchasing or ordering of any goods or services other than the specific Products described in this Agreement.

8. **Schedules Attached to This Agreement**. The following Schedules are hereby incorporated into and made a part of this Agreement: Schedule A – Products and Pricing – Transcatheter Heart Valves, Schedule B – Accessory Components: Transcatheter Heart Valves.

9. **General**. This Agreement, including without limitation Schedules attached hereto, shall supersede all other agreements between Edwards and Purchaser with respect to the Products. No changes to this Agreement, including any conflicting or additional terms contained in any purchase order or other document submitted by Purchaser, shall be valid unless approved in writing by Edwards at its home office. This Agreement shall not be assigned by Purchaser without the prior written consent of Edwards. This Agreement shall be governed by and construed in accordance with the laws of the State of California. Any invoice claims or disputes by Purchaser must be made in writing within ninety (90) days of invoice date. Edwards will not make payments for or investigate any invoice claims or disputes that are made more than ninety (90) days after invoice date. Purchaser and Edwards agree not to disclose the financial terms and conditions of this Agreement without the prior written consent of the other party, except as required by applicable law or regulatory authority. Each party agrees that all information provided to it by the other party pursuant to this Agreement, including information concerning pricing, products, and customers, is confidential and proprietary information of the disclosing party. Each party agrees not to disclose such confidential information directly or indirectly to any third party or to use such confidential information for any purpose other than for fulfilling its obligations under this Agreement. Upon either party's request, the other party shall return all confidential information to the requesting party or destroy all such information and certify in writing as to its destruction. This provision shall survive the termination or expiration of this Agreement.

This Agreement is not binding until approved by Edwards at its corporate headquarters located at One Edwards Way, Irvine, California 92614.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date:

[HOSPITAL NAME]	**EDWARDS LIFESCIENCES LLC**
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

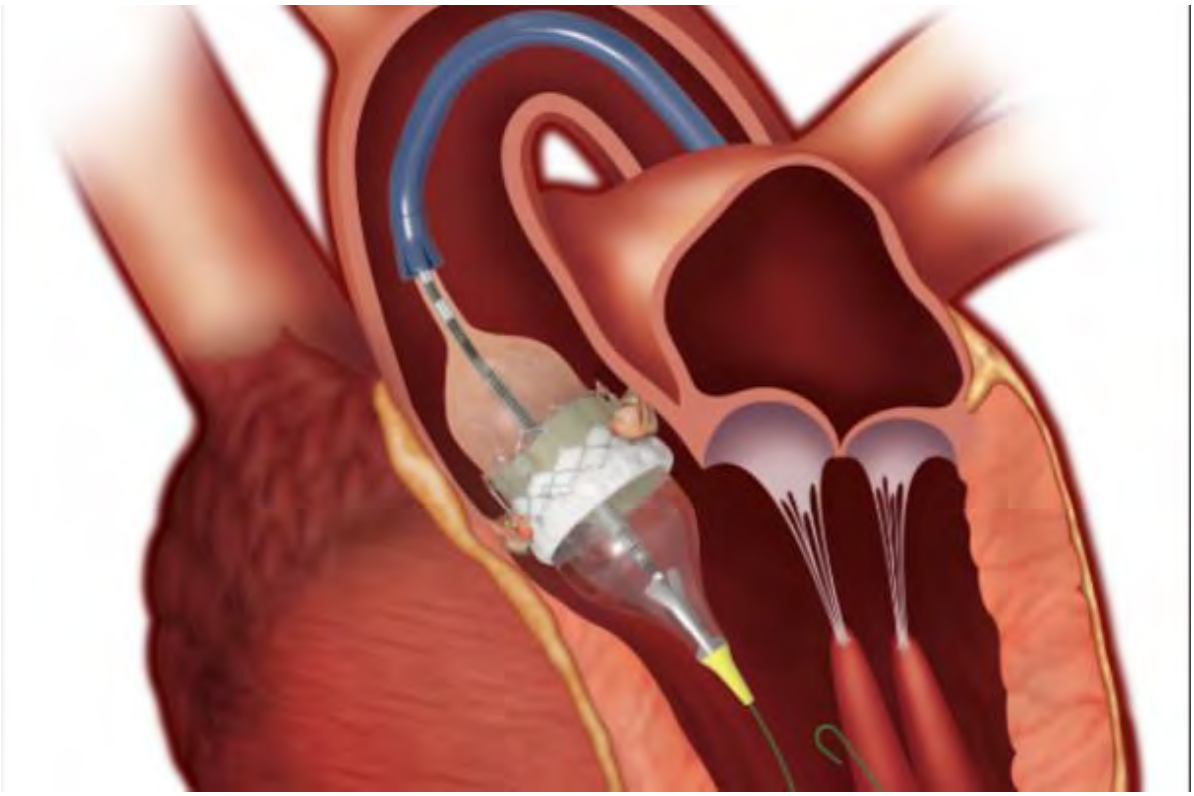
EXHIBIT 5

Diagnostic and Interventional Cardiology
(/)

FEATURE | HEART VALVE TECHNOLOGY (/CHANNEL/HEART-VALVE-TECHNOLOGY) | NOVEMBER 17, 2020

TAVR Is Now Dominant Form of Aortic Valve Replacement in the United States

Data from the STS/ACC TVT Registry provides insights on state of TAVR, outcomes steadily improving



The Edwards Lifesciences Sapien 3 TAVR valve. The annual volume of TAVR has increased each year and in 2019 TAVR volume (72,991) exceeded all forms of SAVR (57,626), coinciding with the U.S. Food and Drug Administration (FDA) approval of TAVR for low-risk patients.

November 17, 2020 — Since the approval of the first transcatheter aortic valve replacement (TAVR) device in 2011, more than 276,000 patients have undergone a TAVR procedure in the United States. According to a report from The **Society of Thoracic Surgeons (STS) (http://www.sts.org)/American College of Cardiology (ACC) TVT Registry (https://www.sts.org/registries-research-center/stsacc-tvt-registry#:~:text=The%20STS%2FACC%20TVT%20Registry,treatments%20for%20valve%20disease%20patients.)**, volumes have increased every year. In 2019 TAVR exceeded all forms of surgical aortic valve replacement (SAVR) for the first time.

In addition, over time the 30-day mortality and stroke rates have decreased, while pacemaker need remains largely unchanged. The full report was published Monday in the ***Journal of the American College of Cardiology*** **(https://www.jacc.org/doi/10.1016/j.jacc.2020.09.595)** and *The Annals of Thoracic Surgery* simultaneously.[1]

"The STS/ACC TVT Registry allows us to see major trends occurring in the real-world TAVR patient population, including a rapid growth in both the number of hospital sites performing TAVR and case volume as we treat a broader spectrum of patients. We have also seen TAVR become the leading choice for aortic valve replacement compared to the open surgical approach," said **John D. Carroll, M.D. (http://cudoctors.com/Find_A_Doctor/Profile/6459)**, chair of the STS/ACC TVT Registry Steering Committee and the lead author on the report. "Furthermore, the data on outcomes after TAVR document a substantial improvement in quality of care in the last nine years."

Since the first TAVR device approval, access has been extended from patients considered inoperable or at extreme risk (2011), at high-risk (2012), intermediate-risk (2016) and low-risk (2019) for SAVR. Researchers examined data in the STS/ACC TVT Registry for all TAVR procedures performed at sites active through 2019. An early TAVR experience was defined as patients treated from late 2011 through 2013 and was compared to current TAVR experience, which was defined as patients treated in 2019.

Data in 2019 are from hospitals located in 49 U.S. states, as well as two sites in the District of Columbia and two sites in Puerto Rico. In August 2020 there were 715 U.S. TAVR sites. As of the opening of a site in Wyoming in 2020 TAVR programs exist in all 50 states. The only U.S. TAVR sites not included in the STS/ACC TVT Registry are those in military hospitals and the Veterans Authority (VA) medical system: as of mid-2019 there were eight VA TAVR programs.

Watch the related **VIDEO: Tracking Transcatheter Valve Outcomes in the STS-ACC TVT Registry (https://www.dicardiology.com/videos/video-tracking-transcatheter-valve-outcomes-sts-acc-tvt-registry)**— Interview with John Carroll, M.D.

TAVR Procedure Volumes In the Unites States

The annual volume of TAVR has increased each year and in 2019 TAVR volume (72,991) exceeded all forms of SAVR (57,626), coinciding with the U.S. Food and Drug Administration (FDA) approval of TAVR for low-risk patients. The number of TAVR procedures performed per site varies, but as the number of sites performing TAVR has increased, the total annual volume has increased. In 2019 sites performed 84

TAVR procedures on average with 161 sites performing less than 50 cases. An expert consensus document published by stakeholders — including the ACC and STS — ncluded a recommendation of a 50-case annual threshold minimum for sites performing TAVR.

TAVR Patient Demographic Statistics

Data showed the median age of patients undergoing TAVR has slightly gone down from early TAVR experiences. In 2019 mostly males (56%) underwent TAVR, a shift away from the early TAVR period when there was a nearly equal male/female distribution of patients undergoing the procedure. For all years, patients undergoing TAVR were predominantly white with the persistence of under-representation of blacks, based on overall U.S. demographics, at 4% despite the substantial growth of sites offering TAVR. This finding will stimulate further research into its possible causes ranging from barriers to health care access to differences in the prevalence of disease. From 2011 thru 2018 extreme and high-risk patients remain the largest cohort undergoing TAVR, but in 2019 intermediate-risk was the largest cohort. In 2019, the first year TAVR was FDA-approved for low-risk patients, this population made up 11.5% of all TAVR patients and had a median age of 75.

Smaller TAVR Sheaths Allowed Large Increase in Femoral Access Procedures

In the early TAVR period with very large vascular sheaths required for the first-generation TAVR delivery catheters, only 57.1% of TAVR procedures used femoral artery access. By the current TAVR period in 2019, femoral access accounted for 95.3% of vascular access sites for the procedure. In 2019 the axillary-subclavian was the most commonly used alternative access approach, a shift from the use of transapical and direct aortic approaches that were the common alternative access point in the early TAVR period.

TAVR Length of Stay

The median length of stay for patients has declined from seven days to two days for all patients over the course of the report. For patients assessed as low-risk, the median length of stay in 2019 was only one-day —an overnight hospital stay—with some patients discharged the same day. In the early TAVR period, most patients were discharged to another care facility. In 2019 90.3% of patients were discharged home, while 6.6% were discharged to a rehabilitation or extended care facility and 2.45% to a nursing home.

U.S. TAVR Mortality, Stroke and Pacemaker Rates

Researchers also found a steady and dramatic shift in mortality from the early TAVR period to 2019. In-hospital mortality fell from 5.4 to 1.3% and 30-day mortality decreased from 7.2 to 2.5%. In-hospital and 30-day stroke rates also fell from the early TAVR period to the current TAVR period. However, the 30-day

pacemaker implantation rate has remained largely the same. The in-hospital rate has fallen in the context of the shorter length of stay at the hospital.

TAVR Quality of Life Assessments

The STS/ACC TVT Registry has been innovative in gathering data from patients on their assessment of their individual health status, using the Kansas City Cardiomyopathy Questionnaire (KCCQ) before treatment. The registry also gathers data on whether there are changes post-TAVR in component metrics on quality of life (QOL), functional state and other patient reported outcomes. In 2018 — the most recent year with one-year outcomes data for patients treated on or before Sept. 30 — 80.7% of all patients who were alive at one-year post-TAVR and had complete KCCQ data reported a good QOL. In addition, a subgroup analysis revealed that this benchmark was achieved in 77.7% of high-extreme risk, 83.6% of intermediate-risk and 85.8% of low-risk patients.

According to the researchers, this report also provides a preliminary real-world assessment of patients having TAVR who were classified as being low-risk after the FDA approved these patients for TAVR in August 2019.

Related TAVR Content:

VIDEO: Tracking Transcatheter Valve Outcomes in the STS-ACC TVT Registry (https://www.dicardiology.com/videos/video-tracking-transcatheter-valve-outcomes-sts-acc-tvt-registry)— Interview with John Carroll, M.D.

U.S. TAVR Outcomes Need Improvement Based on TVT Registry Analysis (https://www.dicardiology.com/content/us-tavr-outcomes-need-improvement-based-tvt-registry-analysis)

Boston Scientific Pulls Lotus Edge TAVR Valve Off The Market (https://www.dicardiology.com/article/boston-scientific-pulls-lotus-edge-tavr-valve-market)

FDA Approves TAVR for Low-risk Patients Creates A Paradigm Shift in Cardiology (https://www.dicardiology.com/article/fda-approves-tavr-low-risk-patients-creates-paradigm-shift-cardiology)

TAVR Expected to See Rapid Growth in Next 5 years (https://www.dicardiology.com/article/tavr-expected-see-rapid-growth-next-5-years)

Boston Scientific Launches Acurate neo2 Transcatheter Aortic Valve System in Europe (https://www.dicardiology.com/content/boston-scientific-launches-acurate-neo2-transcatheter-aortic-valve-system-europe)

Acurate neo TAVR Valve Fails to Meet Noninferiority With Medtronic CoreValve Evolut (https://www.dicardiology.com/article/acurate-neo-tavr-valve-fails-meet-noninferiority-medtronic-corevalve-evolut)

VIDEO: Interventional Structural Heart Advances Are Rapidly Expanding (https://www.dicardiology.com/videos/video-interventional-structural-heart-advances-are-rapidly-expanding) — Interview with Juan F. Granada, M.D.

Boston Scientific Launches Acurate neo2 Transcatheter Aortic Valve System in Europe (https://www.dicardiology.com/content/boston-scientific-launches-acurate-neo2-transcatheter-aortic-valve-system-europe)

TAVR Non-Inferior to Surgery in U.K. Review of Surgery vs. TAVR (https://www.dicardiology.com/content/tavr-non-inferior-surgery-uk-review-surgery-vs-tavr)

Find more TAVR news (https://www.dicardiology.com/channel/heart-valve-technology)

Reference:

1. John D. Carroll, Michael J. Mack, Sreekanth Vemulapalli, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. 2020 Nov, 76 (21) 2492–2516. (https://www.jacc.org/doi/10.1016/j.jacc.2020.09.595)

EXHIBIT 6

Doc Code: **TR.PROV**
Document Description: Provisional Cover Sheet (SB16)

PTO/SB/16 (11-08)
Approved for use through 05/31/2015. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Inventor(s)

Inventor 1 Remove

Given Name	Middle Name	Family Name	City	State	Country
Ali		Shahriari	Indianapolis	IN	US

All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Title of Invention	TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR
Attorney Docket Number (if applicable)	58330-221639

Correspondence Address

Direct all correspondence to (select one):

(•) The address corresponding to Customer Number	( ) Firm or Individual Name
Customer Number	23634

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

(•) No.

( ) Yes, the name of the U.S. Government agency and the Government contract number are:

Doc Code: **TR.PROV**
Document Description: Provisional Cover Sheet (SB16)

PTO/SB/16 (11-08)
Approved for use through 05/31/2015. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

Entity Status

Applicant claims small entity status under 37 CFR 1.27

- (●) Yes, applicant qualifies for small entity status under 37 CFR 1.27
- ( ) No

Warning

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Signature

Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Jeffrey T.G. Kelsey/			Date (YYYY-MM-DD)	2012-11-07
First Name	Jeffrey	Last Name	Kelsey	Registration Number (If appropriate)	63696

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.**

Privacy Act Statement

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

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

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

TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Cross-reference is made to co-pending U.S. Provisional Patent Application Serial No. 61/567,458 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair," which was filed by Ali Shahriari on December 6, 2011 and is expressly incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure relates to a device and method of using same for repair of aortic valve disease, aortic stenosis, ascending aortic aneurysms, aortic insufficiency, aortic regurgitation, ascending aneurysm, bicuspid valve disease, and/or Type A dissections.

BACKGROUND

[0003] The normal aortic root and the ascending aorta are composed of 1) the aortic annulus, 2) sinuses of Valsalva, 3) sinutubular junction, and 4) 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 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. 1A-1C, which have been reproduced from the referenced article.

[0004] Type A aneurysms are most commonly found in younger patients and patients with connective tissue disorders such as Marfan syndrome. The anatomical characteristics of Type A aneurysms are dilatation of the sinuses of Valsalva with or without dilatation of the aortic annulus. The sinutubular junction is most often dilated. The valve could be normal, stenotic or insufficient. An example of a Type A aneurysm is shown in FIG. 1A.

[0005] The anatomical characteristics of Type B aneurysms are dilatation of the tubular portion. Initially the sinutubular junction may be normal or mildly dilated, however as the aneurysm grows, it stretches the sinutubular junction and may eventually lead to aortic insufficiency. The valve could be normal, stenotic or insufficient. The bulk of the aneurysm is at the level of the tubular aorta. An example of a Type B aneurysm is shown in FIG. lB.

[0006] The anatomical characteristics of Type C aneurysms are dilatation of the sinuses of Valsalva, sinutubular junction and the tubular portion of the aorta. The valve could be normal, stenotic or insufficient. Type B and C aneurysms are most commonly found in an older group of patients. An example of a Type C aneurysm is shown in FIG. 1C.

[0007] Currently there are devices clinically used for endovascular repair of ascending aortic aneurysms. Although transcatheter valves are a clinical reality today, 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.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

[0009] FIG. 1A is an example of a Type A aneurysm;

[0010] FIG. 1B is an example of a Type B aneurysm;

[0011] FIG. 1C is an example of a Type C aneurysm;

[0012] FIG. 2 is a side elevation view of an exemplary transcatheter valve including a dual-frame component and a valve component;

[0013] FIG 3 is a side elevation view of a self-expanding outer frame of the dual-frame component of FIG. 2;

[0014] FIG. 4 is a side elevation view of a balloon-expandable inner frame of the dual-frame component and the valve component of FIG. 2;

[0015] FIG. 5 is a perspective view of the transcatheter valve of FIG. 2;

[0016] FIG. 6 is a cross-sectional elevation view of the balloon-expandable inner frame of the dual-frame component and the valve component of FIG. 2;

[0017] FIG. 7 is a plan view of the transcatheter valve device of FIG. 2 showing the inner frame unexpanded;

[0018] FIG. 8 is a view similar to FIG. 7 showing the inner frame expanded;

[0019] FIG. 9 is a view of the transcatheter valve device of FIG. 2 positioned in the aorta with the balloon-expandable inner frame unexpanded; and

[0020] FIG. 10 is a view of the transcatheter valve device of FIG. 2 positioned in the aorta with the balloon-expandable inner frame expanded.

DETAILED DESCRIPTION OF THE DRAWINGS

[0021] Referring now to FIGS. 2-10, a transcatheter valve device (hereinafter device 10) is shown. The device 10 includes a dual-frame component 14 and a valve component 12 secured to the dual-frame component 14. The dual-frame component 14 includes a self-expanding outer frame 16 and a balloon-expandable inner frame 18 that is secured to the self-expanding outer frame 16. The device 10 may be deployed via a transfemoral or trans-axillary route, as will be described in greater detail below.

[0022] As shown in FIG. 3, the self-expanding outer frame 16 is configured in an open-cell arrangement. The frame 16 is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. The self-expanding outer frame 16 is formed as a single, integral structure. However, the frame 16 may also be formed as separate pieces that are later assembled. The self-expanding frame 16 may be completely or partially covered by polyester, ePTFE or other nonporous covering material.

[0023] In the illustrative embodiment, the outer frame 16 includes an uncovered tubular stent 20 that has a height of approximately 15 mm and a diameter of approximately 32 mm. The height and diameter of the frame 16 may also vary according to the anatomy of the patient. It should be appreciated that in other embodiments the stent 20 may be covered and may have different dimensions to accommodate configuration of a particular patient's aorta. The stent 20 defines a passageway 22 in the outer frame 16.

[0024] In the illustrative embodiment, collagen fibers 24 are attached to the stent 20 to aid in preventing paravalvular leaks and migration of the transcatheter valve device 10 within the aortic walls. The fibers 24 extend outwardly from the stent 20 and inwardly into the passageway 22. It should be appreciated that in other embodiments the outer frame 16 may be covered with hydrogel or other sealing materials. In other embodiments, a plurality of barbs or hooks may be attached to the stent 20. The hooks may be configured to further engage the tissue of the aorta and inhibit or prevent migration of the device 10.

[0025] In the illustrative embodiment, the outer frame 16 has a generally hourglass shape. The outer frame 16 includes a lower inwardly tapered section 26, an upper outwardly tapered section 28 and an elongated section 30. In one particular, non-limiting example, the inwardly tapered section 26 is constructed to be approximately 10 mm in length, and the diameter tapers from a proximal end of section 26 from approximately 32 mm to approximately 22 mm at a distal end of section 26. The inwardly tapered section 26 may be covered or uncovered depending on the indication for which the device 10 will be used. In the illustrative embodiment, the inwardly tapered section 26 of the outer frame 16 is uncovered.

[0026] The upper outwardly tapered section 28 of the outer frame 16 is constructed to be approximately 10 mm in length, and tapers outwardly from proximal end of section 26 to a distal end. More specifically, in one particular

non-limiting example, outwardly tapered section 28 expands from a diameter of approximately 22 mm to a diameter of approximately 34 mm. As shown in the illustrative embodiment, the outwardly tapered section 28 is covered.

[0027] The outwardly tapered section 28 mates with the elongated section 30. The elongated section 30 is configured with a length that is greater than the length of the tapered sections 26, 28. In one particular non-limiting example, the length of the elongated section 30 is approximately 30 mm and has a diameter of approximately 34 mm. As shown in the illustrative embodiment, the elongated section 30 is covered.

[0028] A portion of the outer frame 16, including portions of the sections 26, 28, 30, may be uncovered or covered with polyester, ePTFE or other appropriate material. In the illustrative embodiment, approximately 30 mm to approximately 40 mm of the distal portion of the outer frame 16 is covered.

[0029] As described above, the device 10 also includes a balloon-expandable inner frame 18 that is secured to the outer frame 16. Referring now to FIG. 4, the inner frame 18 includes a tubular stent 32 that has with a length of approximately 15mm and an expanded diameter of 26 mm. In the illustrative embodiment, the tubular stent 32 is constructed of a metallic material in an open-cell fashion. It should be appreciated that in other embodiments the tubular stent 32 may be formed from a polymeric material. In the illustrative embodiment, the tubular stent 32 is covered with low-profile polyester.

However, it should be appreciated that the tubular stent 32 may be covered with standard polyester, ePTFE or other nonporous materials.

[0030] As described above, the device 10 also includes a valve component 12 that is secured to the inner frame 18. In the illustrative embodiment, the valve component 12 is bicuspid, but may be tricuspid, and may be configured from treated bovine pericardium or other suitable proven biological or synthetic material.

[0031] Referring now to FIG. 5, the inner frame 18 of the dual-frame component 14 is secured to the outer frame 16 via a plurality of stitches 34. It should be appreciated that in other embodiments soldering, welding or other fasteners may be used to secure the inner frame 18 to the outer frame 16. As shown in FIGS. 5-8, the inner frame 18 and the valve component 12 are positioned in a passageway 22 defined in the self-expanding frame 16. When the inner frame 18 is unexpanded, the outer surface 36 of the tubular stent 32 is spaced apart from the fibers 24 attached to the outer frame 16. In the illustrative embodiment, a gap 40 is defined therebetween, and the gap 40 has a magnitude of about 2 mm to about 3 mm.

[0032] As shown in FIG. 8, the balloon-expandable inner frame 18 may be expanded in the direction indicated by arrows 44. In that way, the outer surface 36 of the stent 32 engages the fibers 24 (and hence the stent 20 of the outer frame 16) and the gap 40 is closed. The fibers 24 create a seal between the inner frame 18 and the outer frame 16.

[0033] The delivery of the transcatheter valve device 10 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 device 10 into the aorta. After the guidewire has been placed into the left ventricle via the iliofemoral, subclavian, or carotid vessels, the device 10 is delivered through the common femoral artery and passed across the native aortic valve. After performing an angiogram to delineate the location of the coronary arteries, the self-expanding outer frame 16 is deployed, thereby stabilizing the device 10 in place (see FIGS. 9 and 10). The inwardly tapered portion 26 of the self-expanding frame 16 may then be positioned across the origins of the coronary arteries to ensure uninhibited coronary circulation. When the self-expanding frame 16 is fully deployed, the device 10 is stabilized in place.

[0034] As shown in FIGS. 9 and 10, the inner frame 18 is initially unexpanded within the passageway 22 of the self-expanding frame 16. The inner frame 18 is deployed by expanding the balloon assembly. Expansion of the balloon-expandable inner frame 18 compresses the collagen fiber/hydrogel coated stent 20 of the outer frame 16 against the aortic annulus 60, thereby sealing the annulus 60 and the paravalvular areas 62, and thus, prevents paravalvular leakage (see FIG. 10).

[0035] 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.

[0036] 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.

[0037] 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.

CLAIMS

1. A transcatheter valve, comprising:

a dual-frame component including (i) a self-expanding outer frame having a passageway defined therein, and (ii) a balloon-expandable inner frame positioned in the passageway and secured to the self-expanding outer frame,

a valve element secured to the balloon-expandable inner frame, and

a plurality of fibers attached to the self-expanding outer frame and extending into the passageway,

wherein the balloon-expandable inner frame is expandable between (i) an unexpanded position in which an outer surface of the balloon-expandable inner frame is spaced apart from the plurality of fibers and an expanded position in which the balloon-expandable inner frame is engaged with the plurality of fibers.

2. The transcatheter valve of claim 1, wherein the valve element is a bicuspid or tricuspid valve.

3. The transcatheter valve of claim 1, wherein the self-expanding outer frame includes an uncovered portion and a covered portion.

4. The transcatheter valve of claim 3, wherein the uncovered portion has a first diameter that is smaller than a portion of the covered portion.

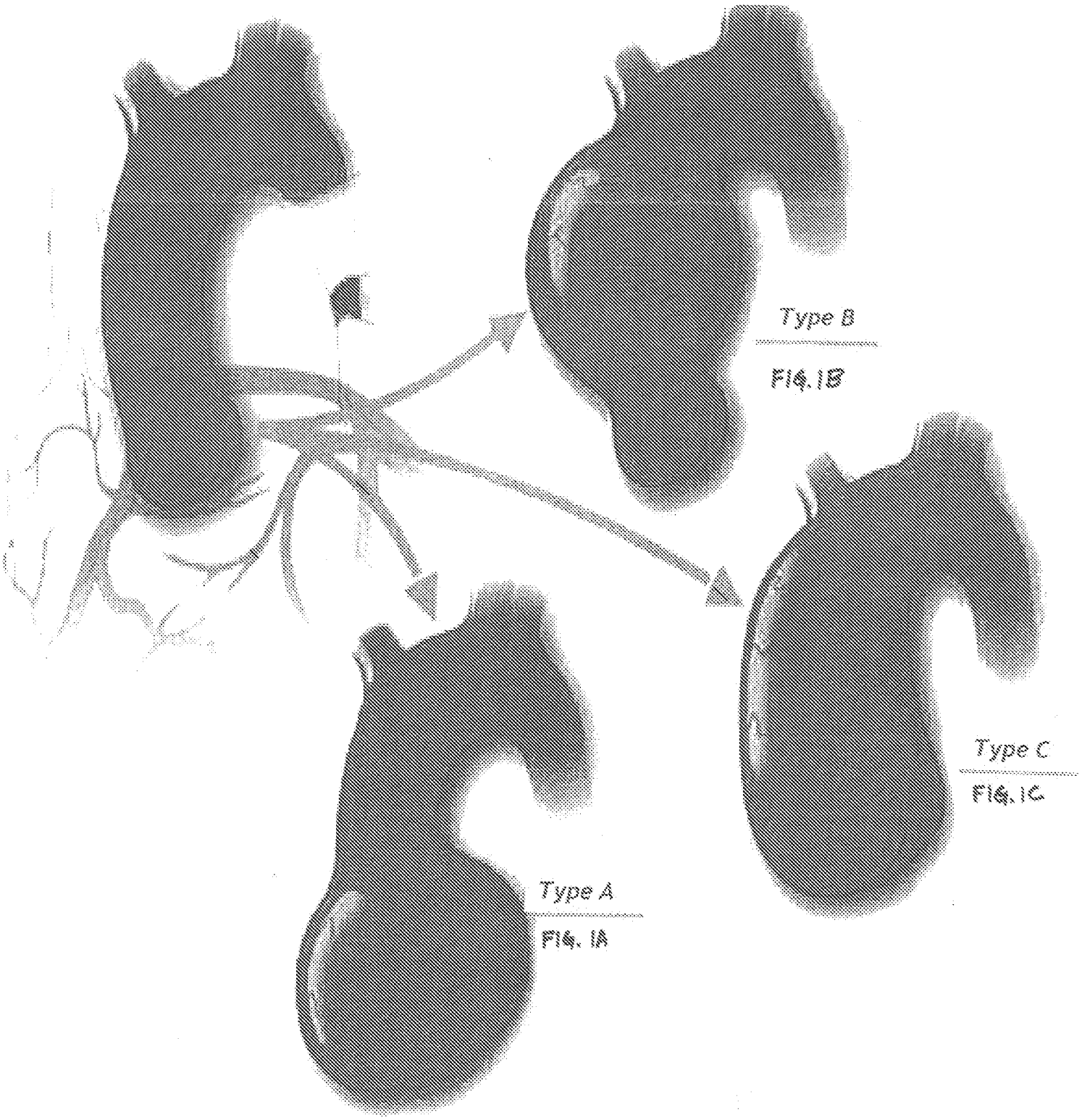
5. The transcatheter valve of claim 1, wherein the self-expanding outer frame is covered with collagen or hydrogel.

6. The transcatheter valve of claim 1, wherein the self-expanding outer frame has an hourglass shape.

7. The transcatheter valve of claim 1, wherein the self-expanding outer frame has a tapered section and an elongated section.

ABSTRACT OF THE DISCLOSURE

A transcathetar valve is disclosed for treating aortic aneurysms and valvular disease.



Type B

FIG. 1B

Type C

FIG. 1C

Type A

FIG. 1A

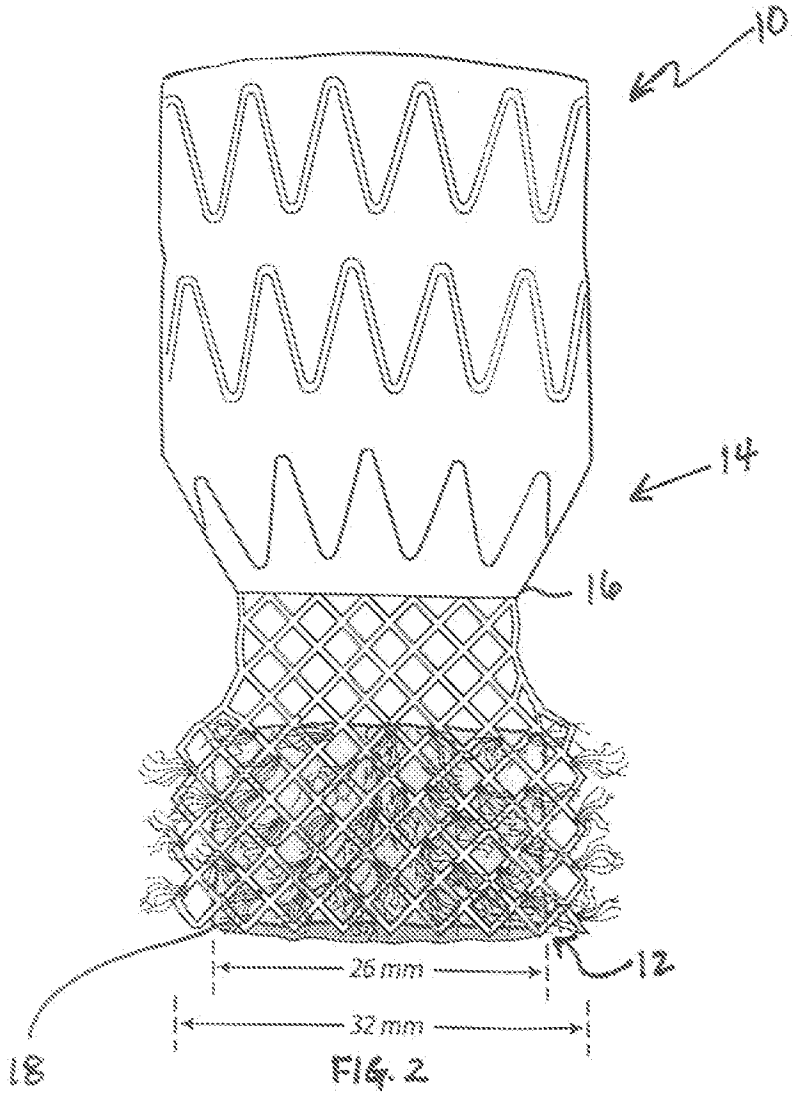


FIG. 2

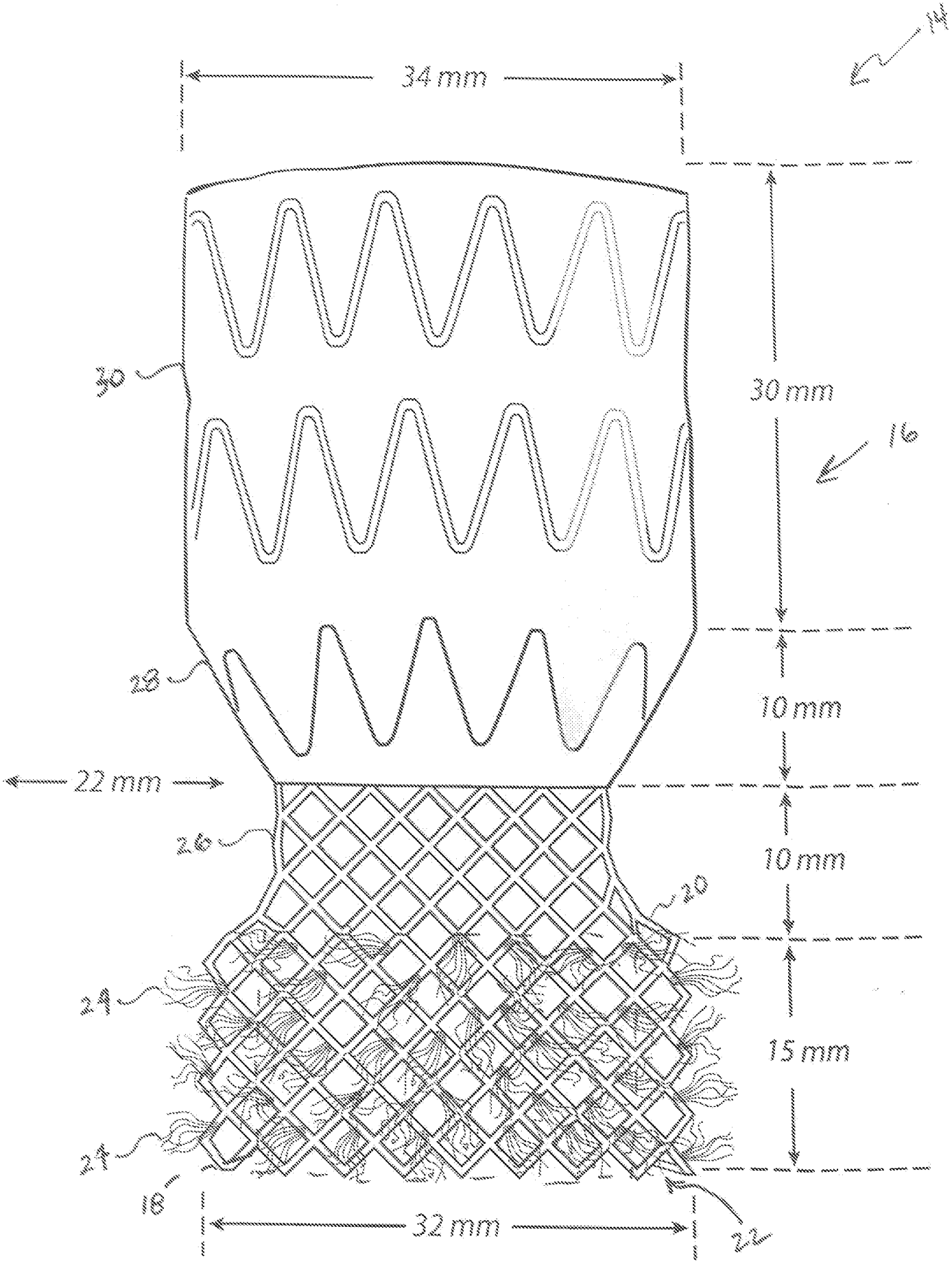


FIG. 3

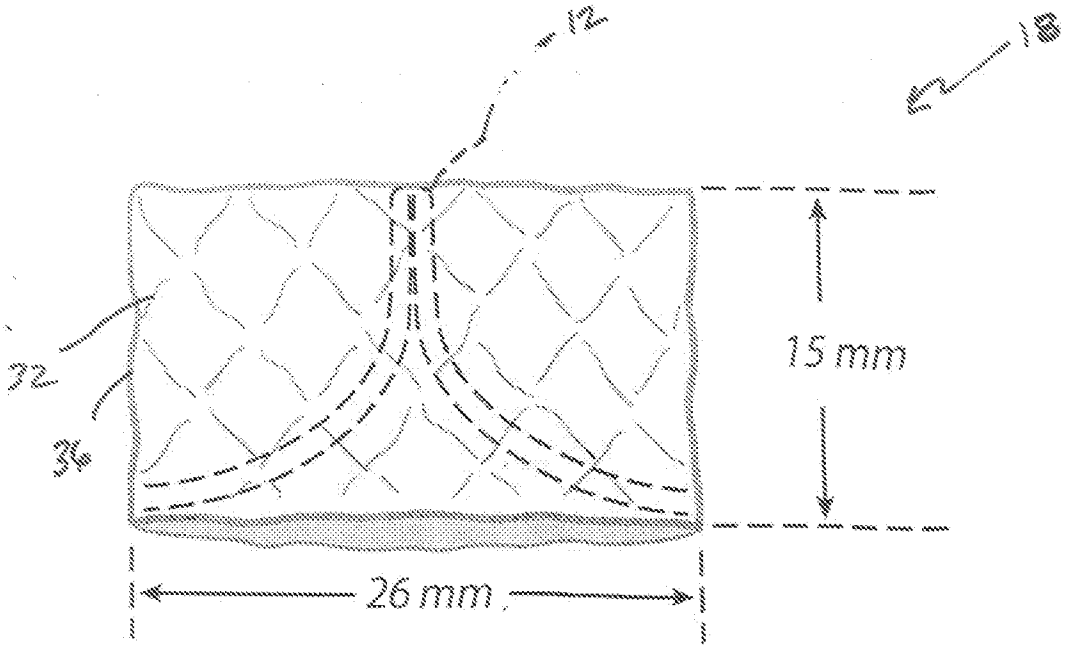


FIG. 4

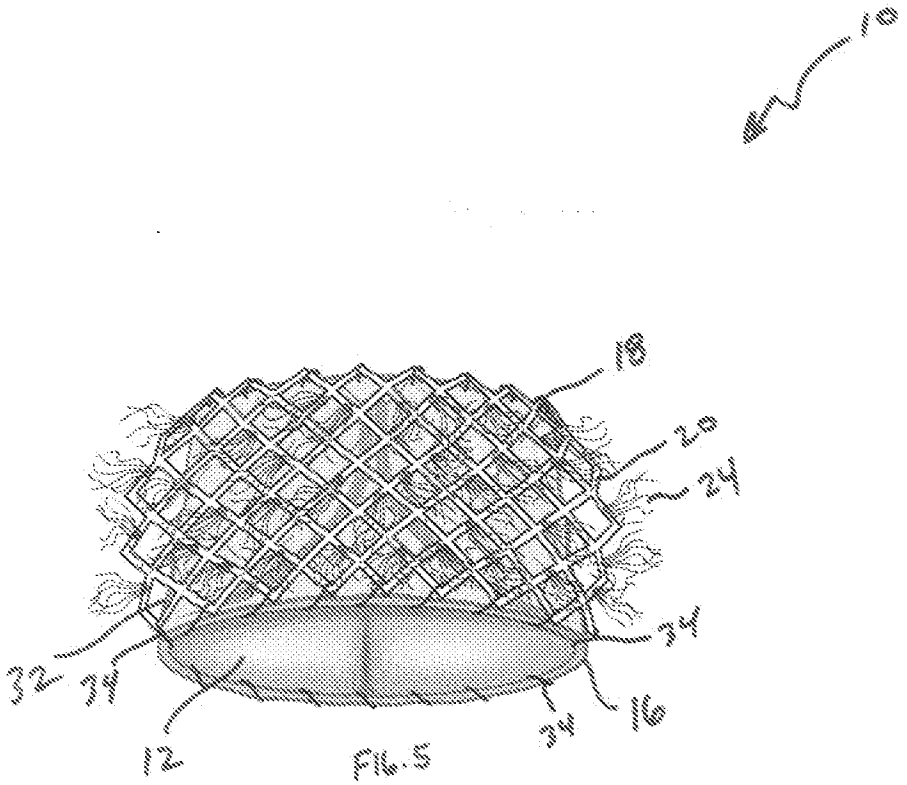


FIG. 5

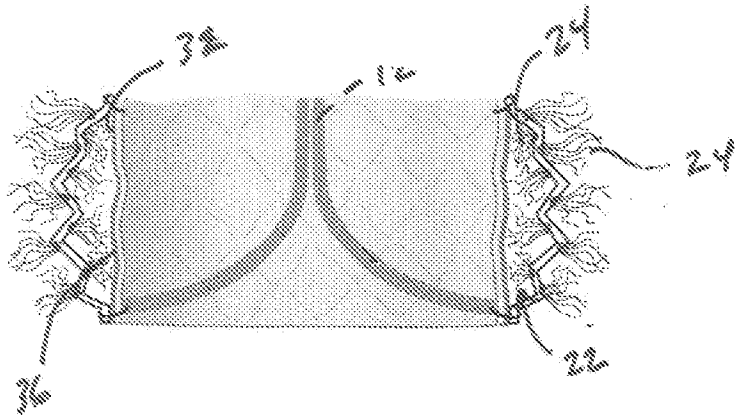
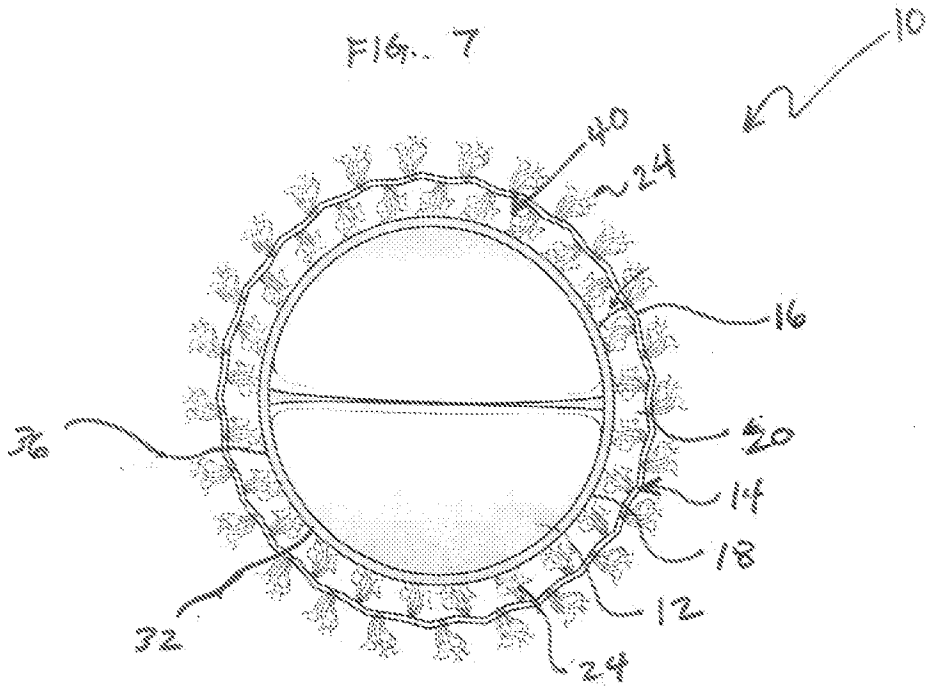


FIG. 6

FIG. 7



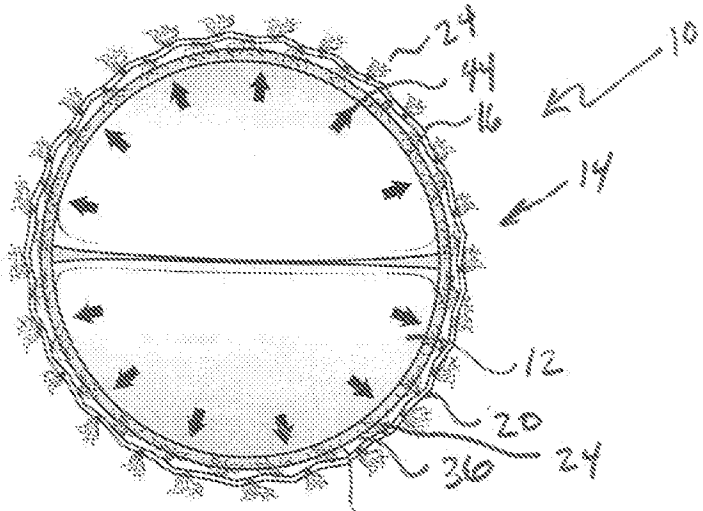


FIG. 8

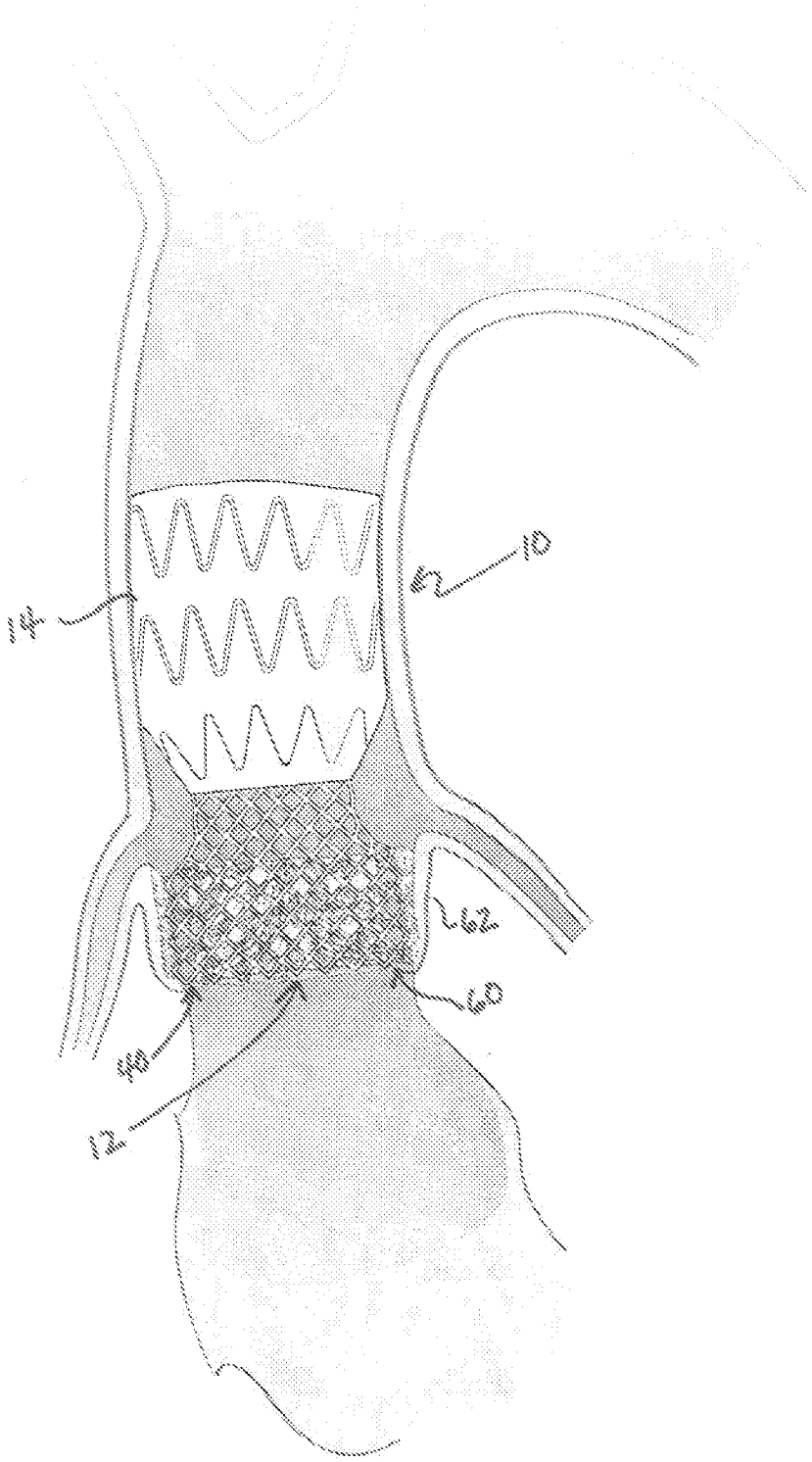


FIG. 9

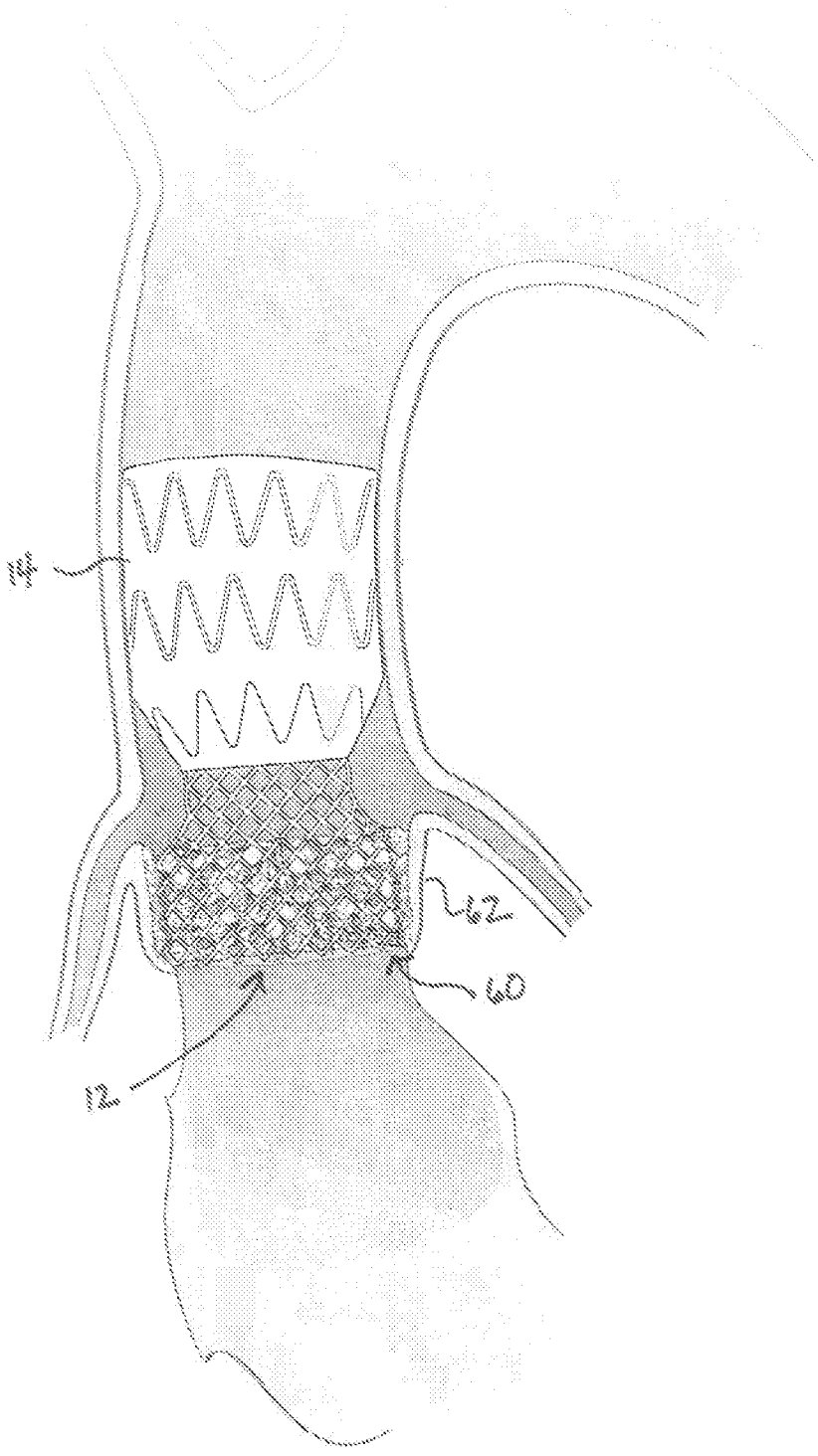


FIG. 10

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR
First Named Inventor/Applicant Name:	Ali Shahriari
Filer:	Jeffrey T.G. Kelsey
Attorney Docket Number:	58330-221639

Filed as Small Entity

Provisional Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Provisional Application filing fee	2005	1	125	125
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**125**

Electronic Acknowledgement Receipt

EFS ID:	14170714
Application Number:	61723446
International Application Number:	
Confirmation Number:	5732
Title of Invention:	TRANSCATHETAR AORTIC VALVE FOR ENDOVASCULAR AORTIC REPAIR
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	23643
Filer:	Jeffrey T.G. Kelsey
Filer Authorized By:	
Attorney Docket Number:	58330-221639
Receipt Date:	07-NOV-2012
Filing Date:	
Time Stamp:	14:32:46
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$125
RAM confirmation Number	799
Deposit Account	100435
Authorized User	

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

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Provisional Cover Sheet (SB16)	ProvisionalCoverSheet.pdf	2071141 b491926c34fb4c4c46f91826ab6039353c0db4c8	no	3
Warnings:					
Information:					
2	Specification	PPAppln.pdf	93279 1c52898abd1fda2efc61c777a9ea683afe7c2221	no	14
Warnings:					
Information:					
3	Drawings-only black and white line drawings	Drawings.pdf	1164182 e9f0fdf68c6c8ff2fe060b4532f543c6ae3444e5	no	8
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	29686 4ccff26083fdaf5571c3a5ad9bc97a0e93d36a7f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3358288		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

DocCode - SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 61723446 Document Date: 11/07/2012

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

- Drawings – Other than Black and White Line Drawings

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

To access the documents in the SCORE database, refer to instructions developed by SIRA.

At the time of document entry (noted above):

- Examiners may access SCORE content via the eDAN interface.
- Other USPTO employees can bookmark the current SCORE URL (http://es/ScoreAccessWeb/).
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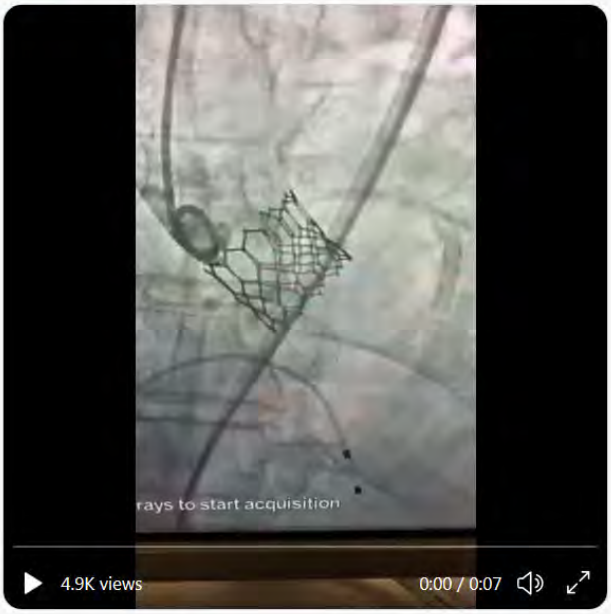
Form Revision Date: February 8, 2006

EXHIBIT 7

Thread

William Suh, MD @willsuh76 · Jul 7, 2020

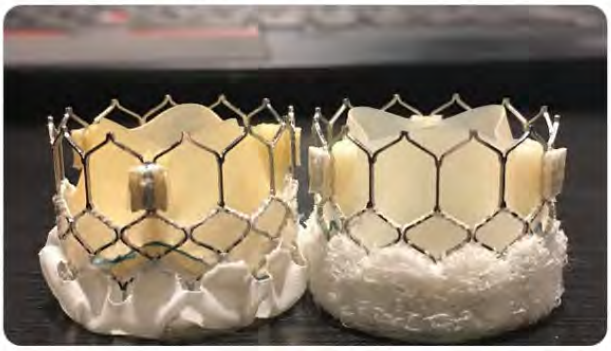
SAPIEN3 Ultra @TemeculaValHosp. First in Inland Empire.
90/10 implant. No pacemaker. PVL be gone!
But can you see the abnormality???
#TAVR



11 17 78

William Suh, MD @willsuh76 · Jul 7, 2020

Ultra is short for ultra low PVL. How? It's all about the skirt. Taller and tufted to maximize seal around the annulus. See the difference between SAPIEN3 (left) vs SAPIEN3 Ultra (right) #TAVR



7 21

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William Suh, MD Follow
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Interventional Cardiologist. Tweets my own, not medical advice & not opinion of any institution.

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EXHIBIT 8

Contact

www.linkedin.com/in/rich-steigerwalt-077bbb52 (LinkedIn)

Top Skills

Medical Devices
Operating Room
Product Launch

Rich Steigerwalt

Sr. Field Clinical Specialist at Edwards Lifesciences
Chester Springs

Experience

Edwards Lifesciences
Sr. Field Clinical Specialist Transcatheter Heart Valve/ Field Trainer
April 2011 - Present (10 years 6 months)

University of Pennsylvania Health System
Surgical Technologist
June 2005 - April 2011 (5 years 11 months)

Education

Western Maryland College
· (1997 - 2001)

Episcopal academy
· (1993 - 1997)

EXHIBIT 9

NewHeartValve.com
by Edwards Lifesciences

Find a Transcatheter Aortic Valve Replacement (TAVR) Hospital

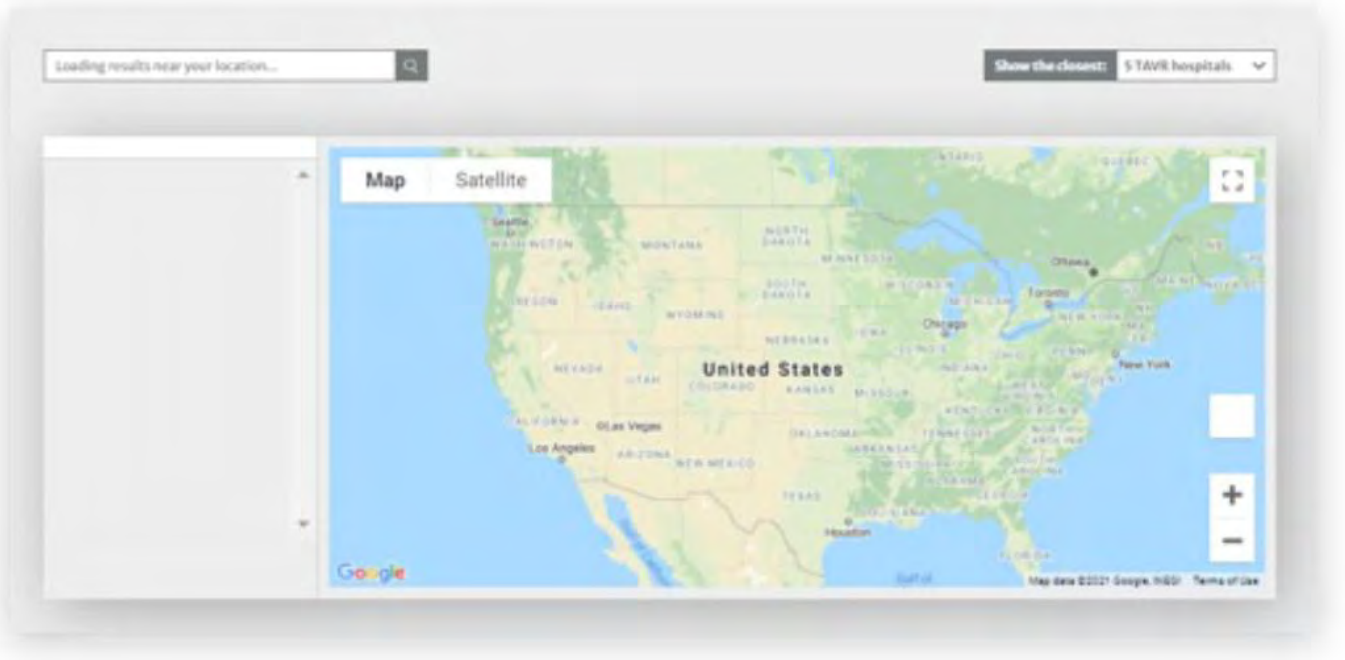
Today is the day to take charge of your severe aortic stenosis and your health. Treatment can't wait.

TAVR should be considered for all severe aortic stenosis patients who are experiencing symptoms. Use our search tool to find a TAVR Hospital near you where you will be evaluated for all your treatment options for severe aortic stenosis, including less invasive TAVR. On average, TAVR is a 1-hour procedure that can treat your severe aortic stenosis with next day discharge for most patients. This allows you to get back to your life quicker.

Once you find a TAVR Hospital near you, click on the provider to view listing details. Contact the Valve Clinic Coordinator (VCC) at the phone number provided to schedule an evaluation. The VCC is usually the first point of contact at a TAVR Hospital and can help navigate you through the process.

Enter zip code, city/state, or hospital name

Important Risk Information



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:

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.
- 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

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.

Stay Informed

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

Join now

Contact Us

Call:

1 (949) 250-2012

Important Risk Information

Edwards Lifesciences Corporation
Attn: Patient Education Center
One Edwards Way
Irvine, CA 92614

Email

NewHeartValve – US

Important Risk Information

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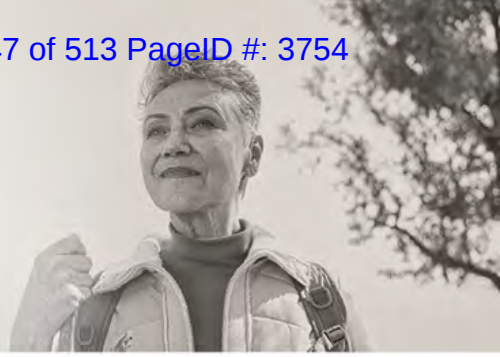
COOKIE PREFERENCES

Edwards

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EXHIBIT 10

TAVR Hospital Listings



Visit a Transcatheter Aortic Valve Replacement (TAVR) Hospital Near You

As requested, below is a list of TAVR hospitals closest to you.

Bayhealth Medical Center
640 S. State Street
Dover, DE 19901

Phone: 302-674-7400

Christiana Care Health System
Center for Heart and Vascular Health
4755 Ogletown-Stanton Road
Newark, DE 19718

Primary Contact
Mary Kate Carroll
Phone: 302-733-1507

TidalHealth Peninsula Regional
100 E Carroll Street
Salisbury, MD 21801

Primary Contact
Steve Wilson
Phone: 410-546-1353

Chester County Hospital
600 East Marshall Street
Suite 303
West Chester, PA 19380

Phone: 610-738-2690

AtlantiCare Regional Medical Center
Structural Heart Clinic
65 West Jimmie Leeds Rd.
Pomona, NJ 08240

Phone: 609-404-7616

The Hospital of University of Pennsylvania
Penn Medicine Heart Valve Center
3400 Spruce Street
5000 Ravdin Courtyard - Cardiac Surgery/TAVR
Philadelphia, PA 19104

Phone: 215-662-4387

The Cardiovascular Institute at Our Lady of Lourdes Medical Center
1600 Haddon Ave.
Camden, NJ 08103

Phone: 856-757-3958

The Johns Hopkins Hospital
1800 Orleans St.
Baltimore, MD 21287

Penn Presbyterian Medical Center
51 N 39th St
Heart and Vascular Center
Suite 2A
Philadelphia, PA 19104

Phone: 215-662-9595

Please visit TAVRLocator.com for a complete listing of all hospitals that perform TAVR in your area.

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

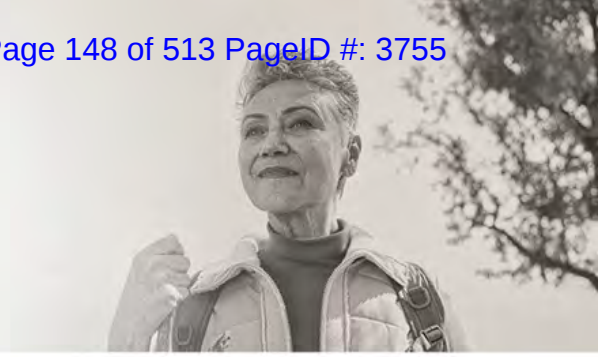
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EXHIBIT 11

US008940040B2

(12) **United States Patent**
Shahriari

(10) **Patent No.: US 8,940,040 B2**
(45) **Date of Patent: Jan. 27, 2015**

(54) **DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME**

(71) Applicant: **Aortic Innovations LLC**, Indianapolis, IN (US)

(72) Inventor: **Ali Shahriari**, Indianapolis, IN (US)

(73) Assignee: **Aortic Innovations, LLC**, Boca Raton, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 150 days.

(21) Appl. No.: **13/706,896**

(22) Filed: **Dec. 6, 2012**

(65) **Prior Publication Data**

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Related U.S. Application Data

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

(51) **Int. Cl.**

A61F 2/06	(2013.01)
A61F 2/07	(2013.01)
A61F 2/962	(2013.01)
A61F 2/24	(2006.01)

(Continued)

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

CPC . ***A61F 2/07*** (2013.01); ***A61F 2/962*** (2013.01); ***A61F 2/2418*** (2013.01); *A61F 2002/067* (2013.01); *A61F 2220/0008* (2013.01); *A61F 2220/0016* (2013.01); *A61F 2230/001* (2013.01); *A61F 2250/0048* (2013.01); *A61F 2/89* (2013.01); *A61F 2/90* (2013.01); *A61F 2220/0058* (2013.01); *A61F 2220/0075* (2013.01); *A61F 2230/0034* (2013.01); *A61F 2220/0025* (2013.01); *A61F 2230/0067* (2013.01)

USPC **623/1.35**; 623/1.36; 623/1.12; 623/1.13

(58) **Field of Classification Search**

USPC 623/2.14, 1.12

See application file for complete search history.

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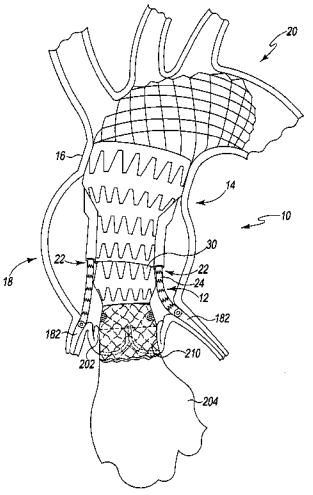
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Primary Examiner — Thomas J Sweet
Assistant Examiner — Tiffany Shipmon
(74) *Attorney, Agent, or Firm* — NKK Patent Law, PLLC

(57) **ABSTRACT**

A device and method for endovascular repair of a patient's aorta is disclosed. The device includes a frame component that has a balloon-expandable frame and a self-expanding frame secured to the balloon-expandable frame. The device also includes a valve element positioned at the proximal end of the frame component. The device may include another prosthetic component that may be secured to the frame component. The prosthetic component may include at least one conduit configured to receive a covered stent.

24 Claims, 19 Drawing Sheets



(51) **Int. Cl.**

A61F 2/89	(2013.01)
A61F 2/90	(2013.01)

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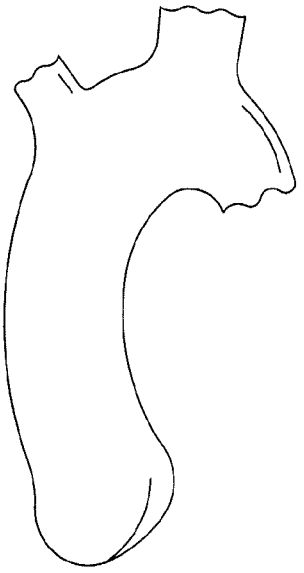


Fig. 1

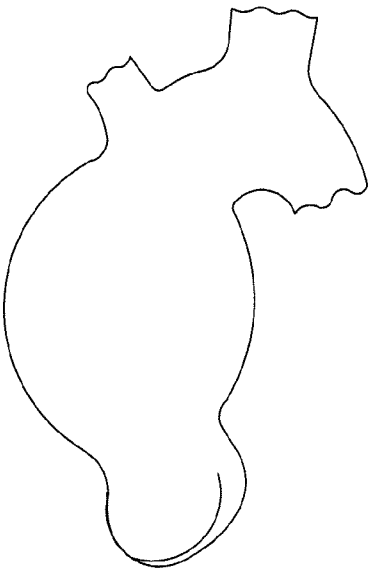


Fig. 1B

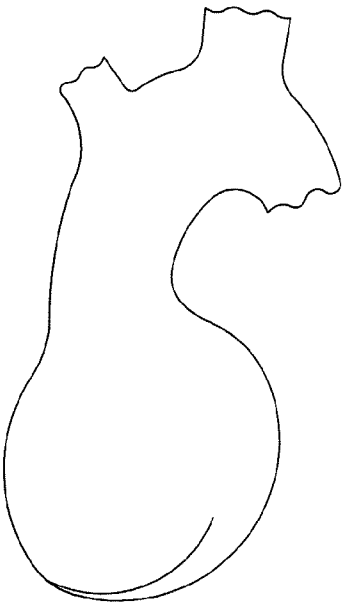


Fig. 1A

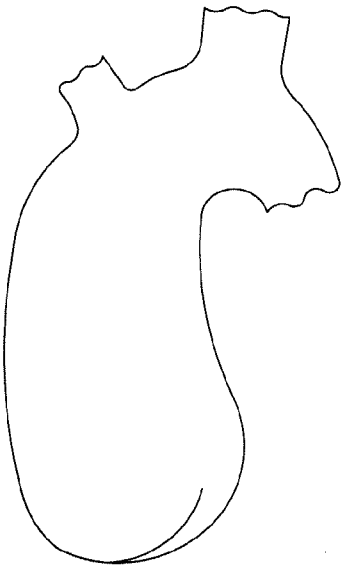


Fig. 1C

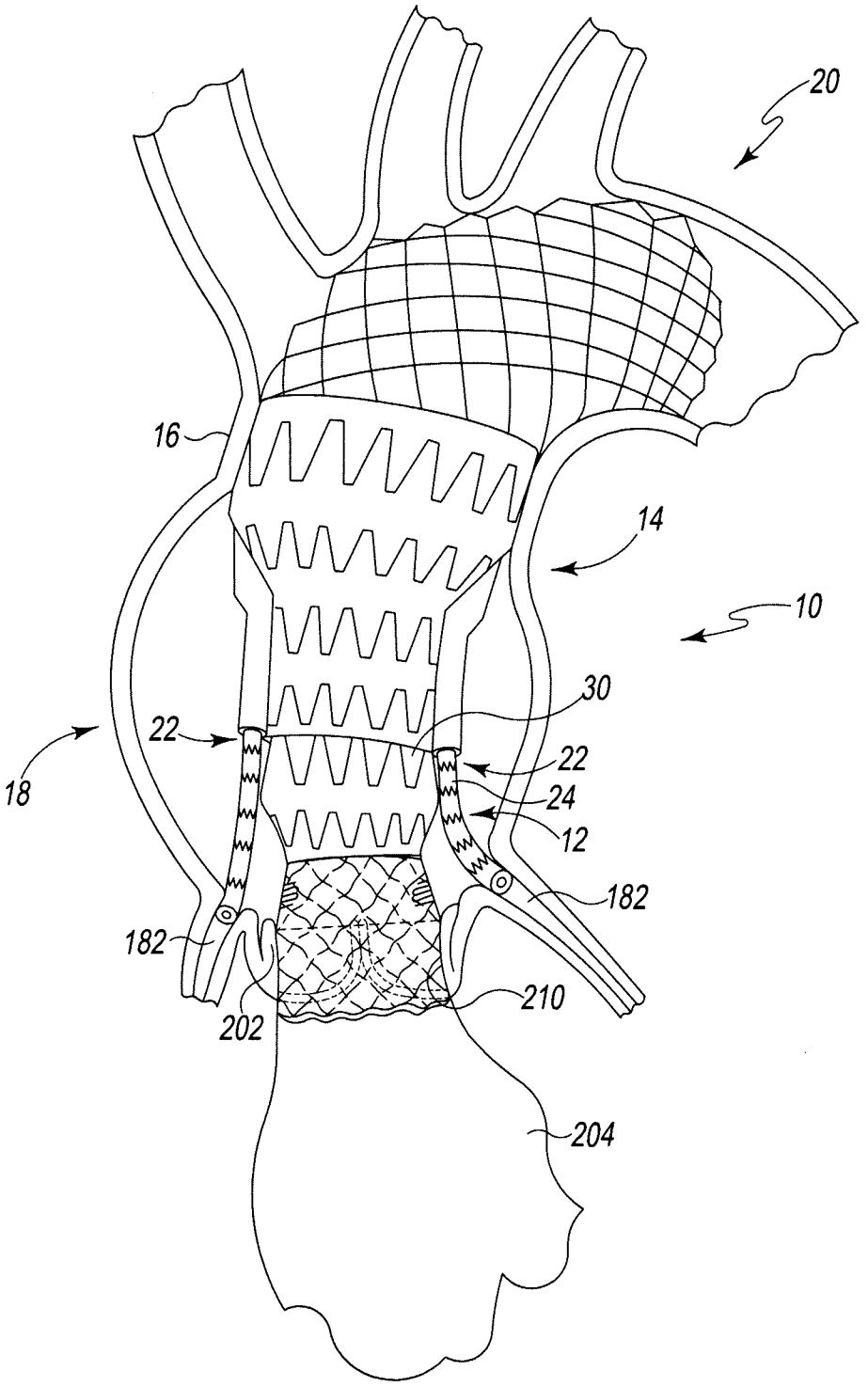


Fig. 2

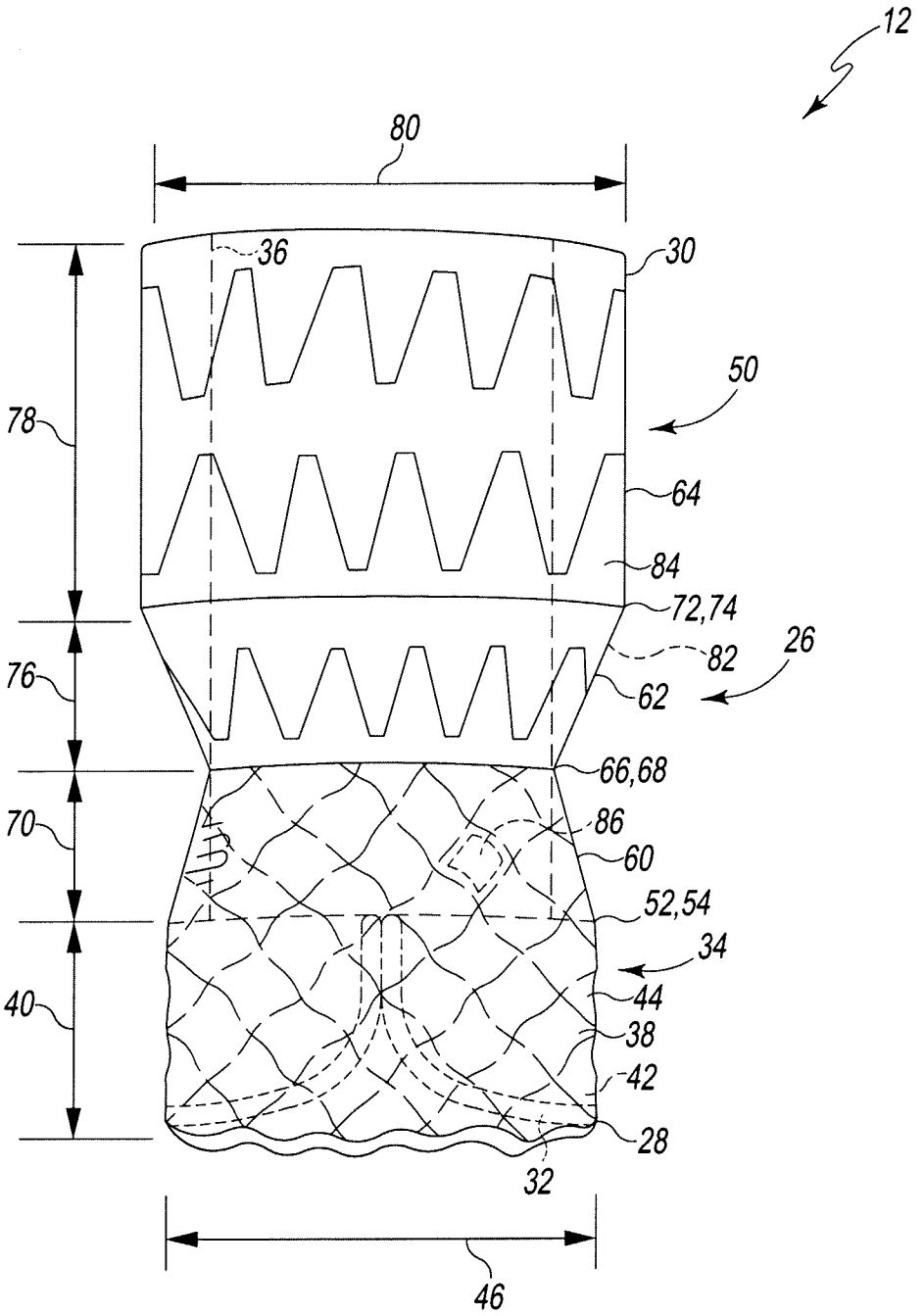

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Fig. 3

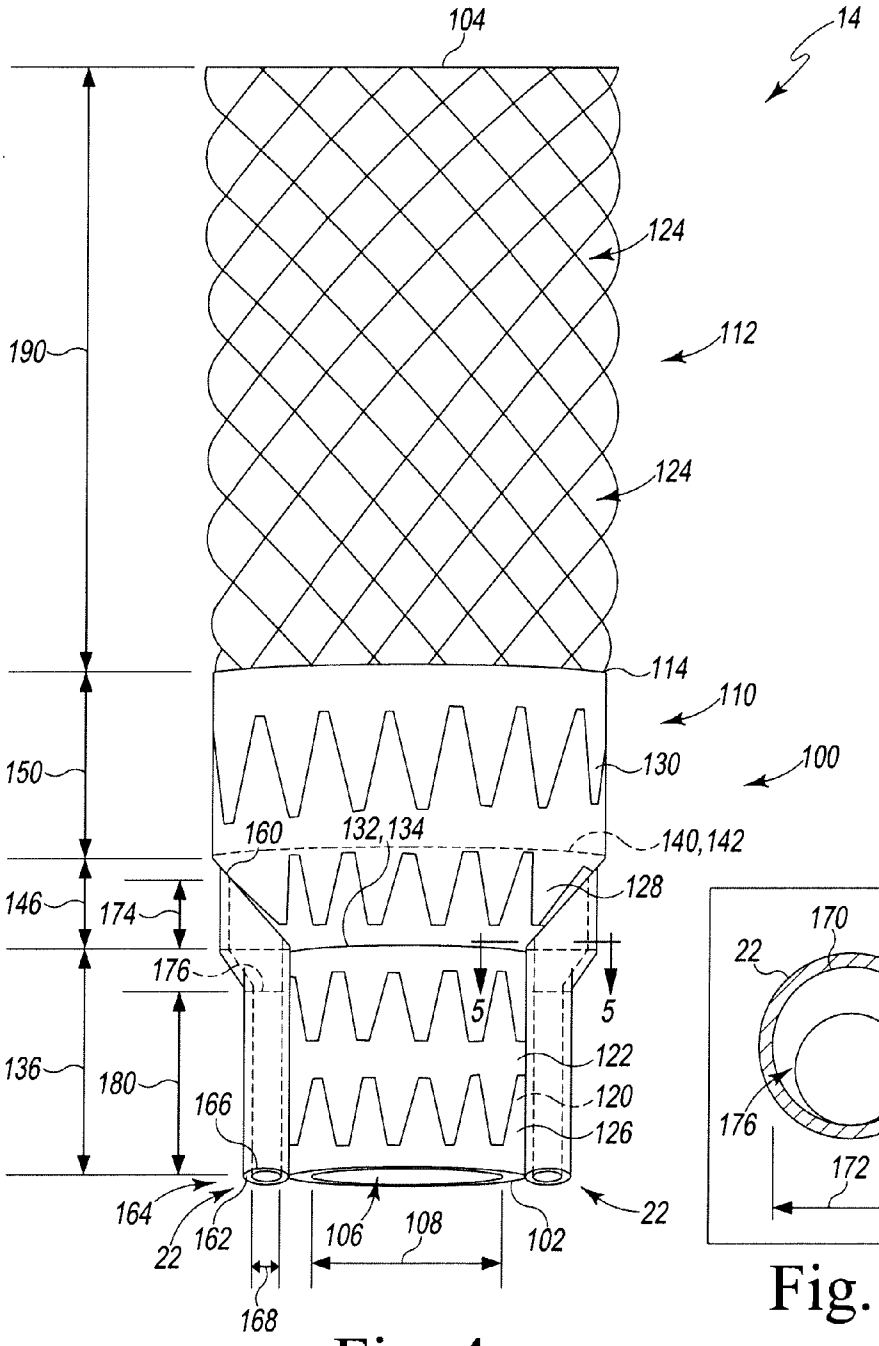

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Fig. 4

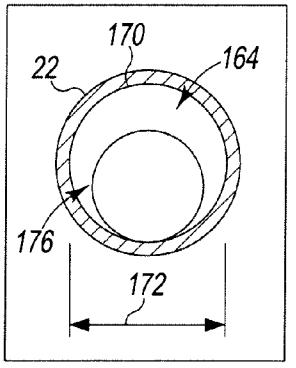

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Fig. 5

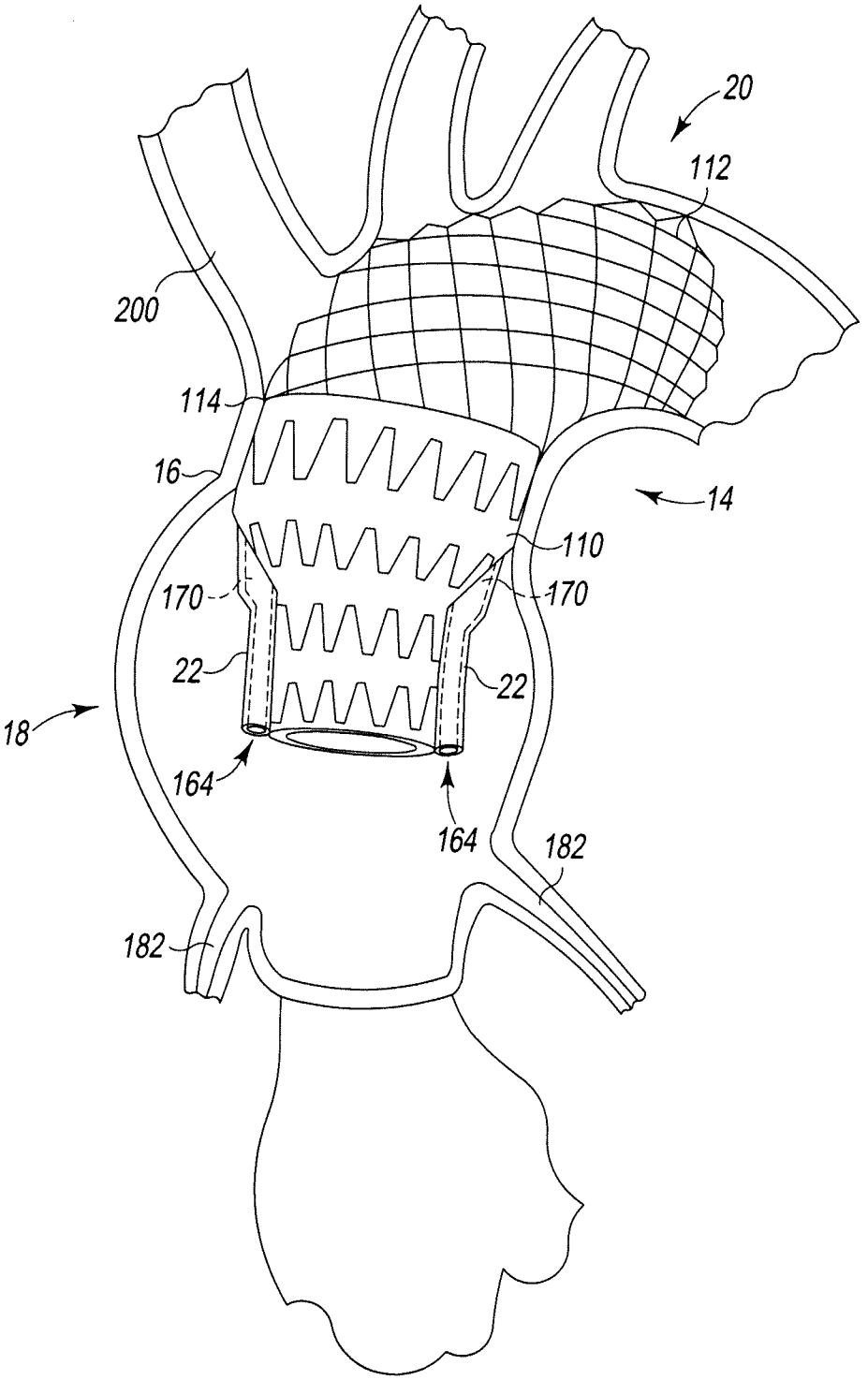


Fig. 6

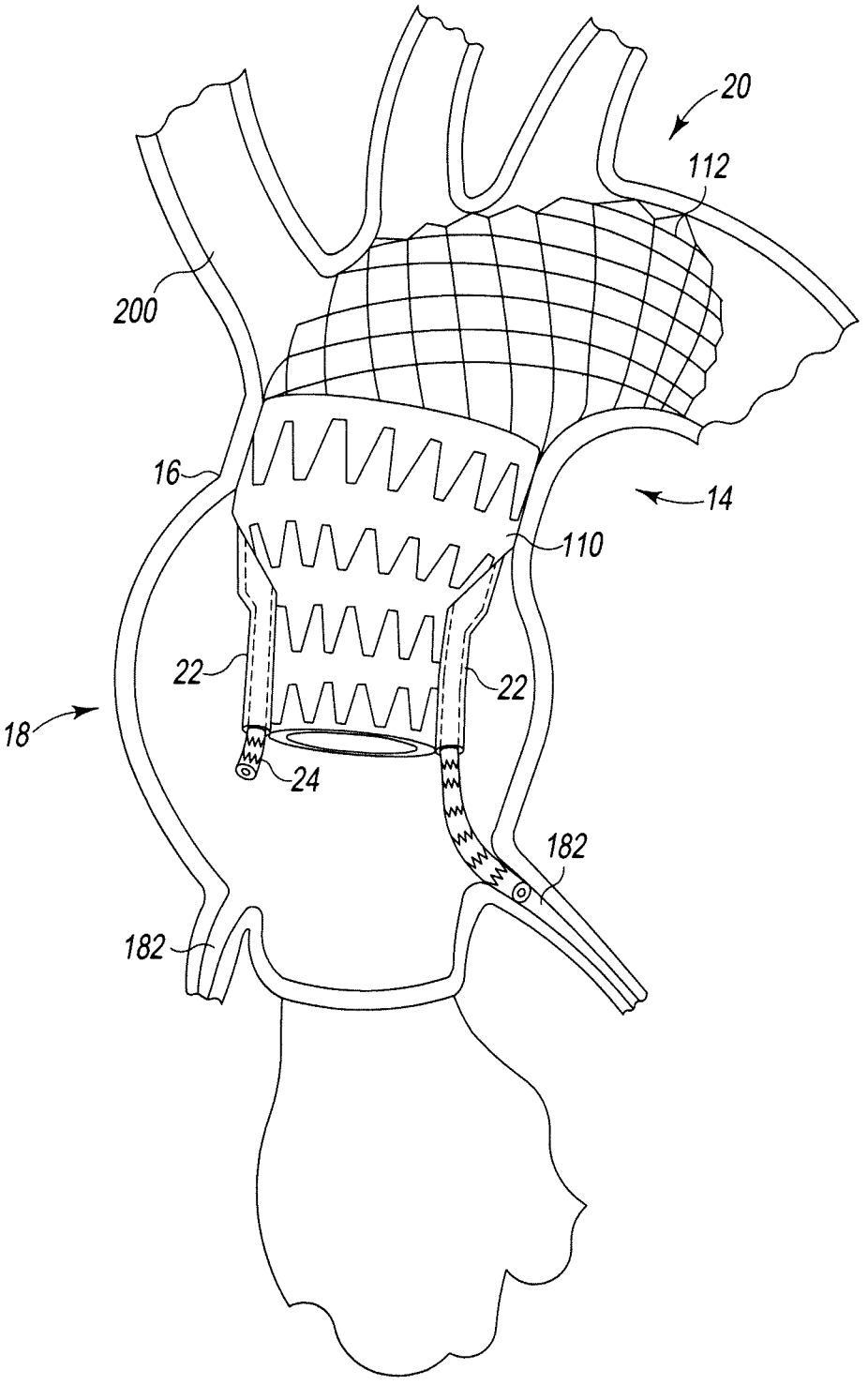


Fig. 7

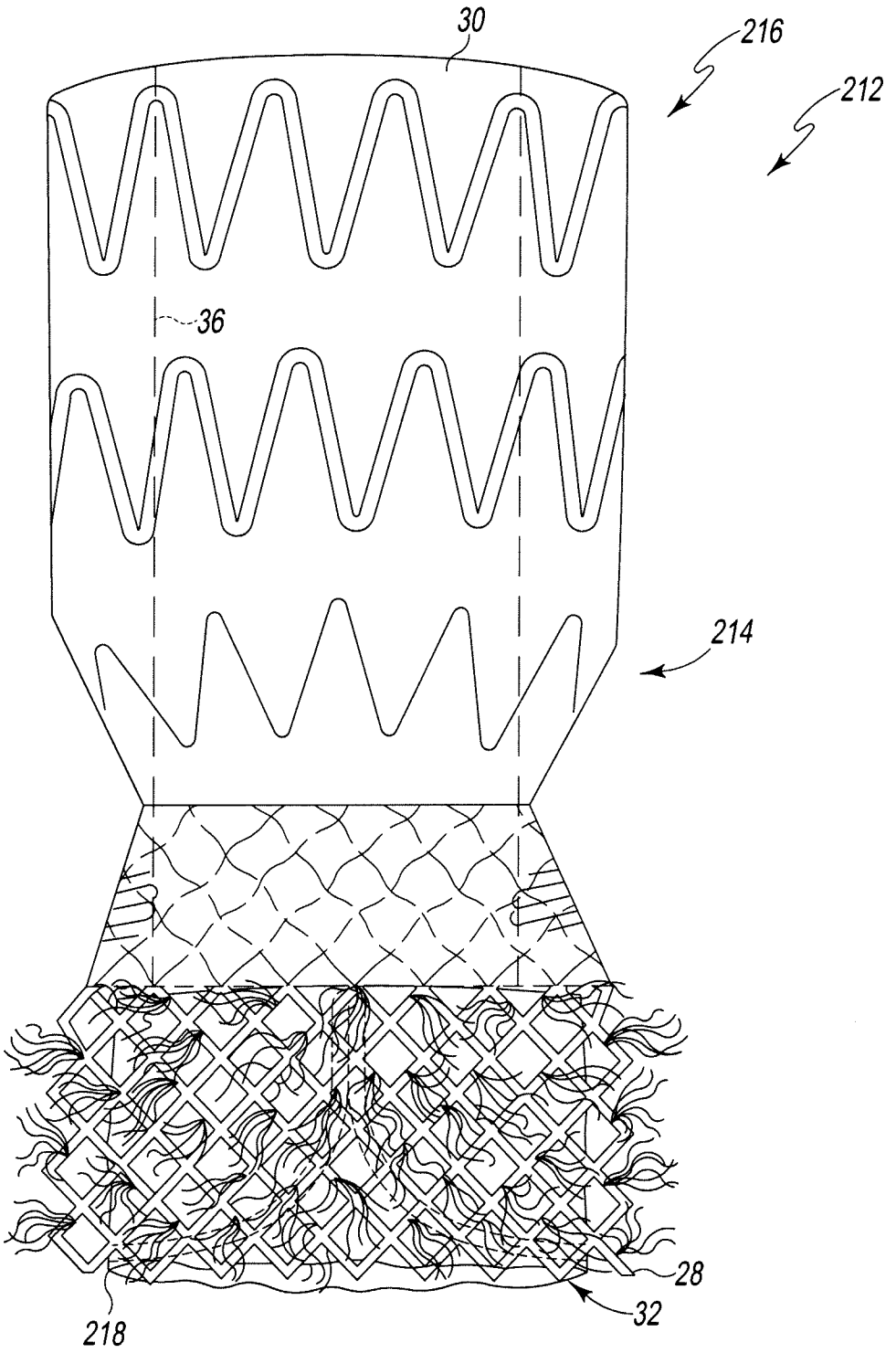


Fig. 8

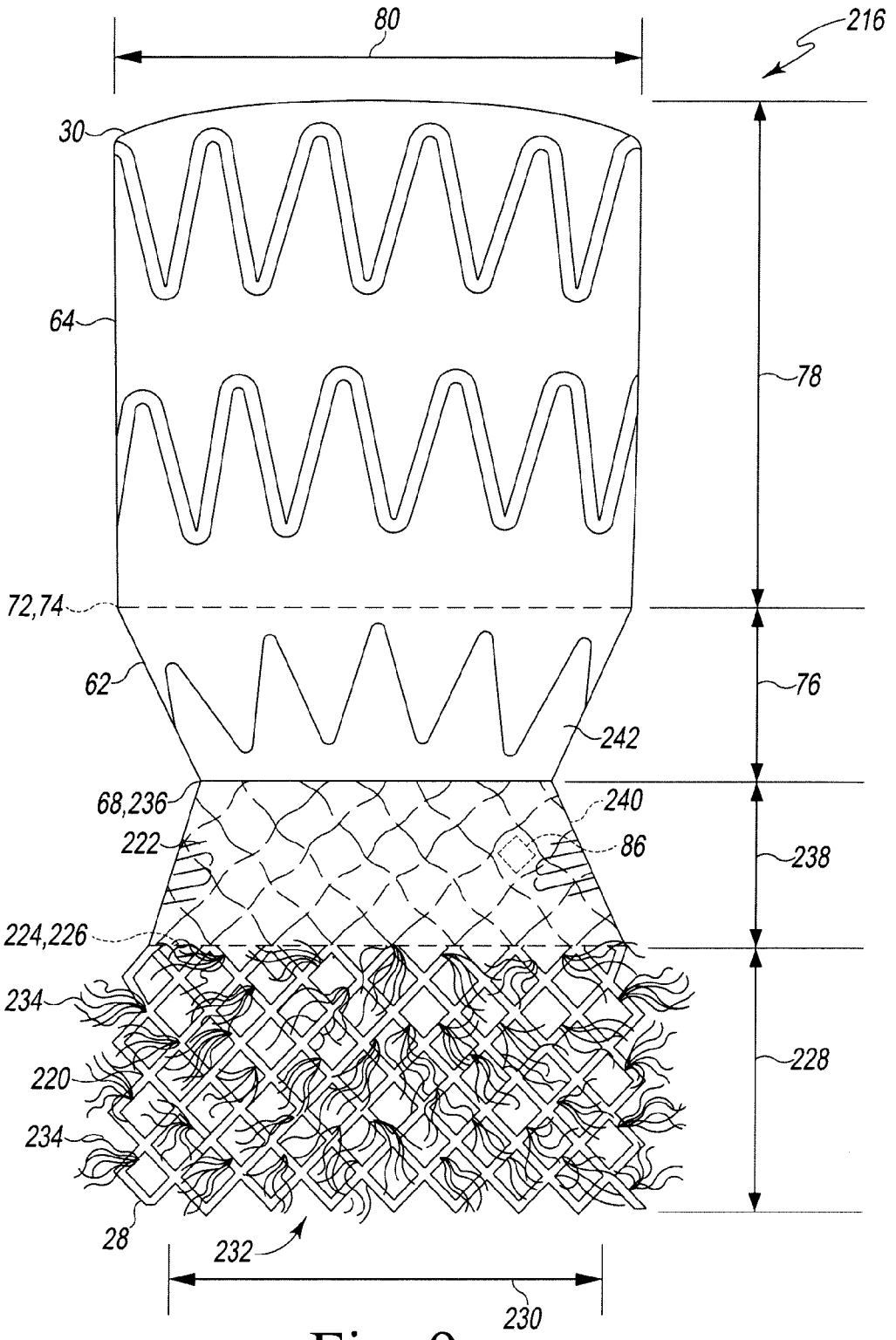

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Fig. 9

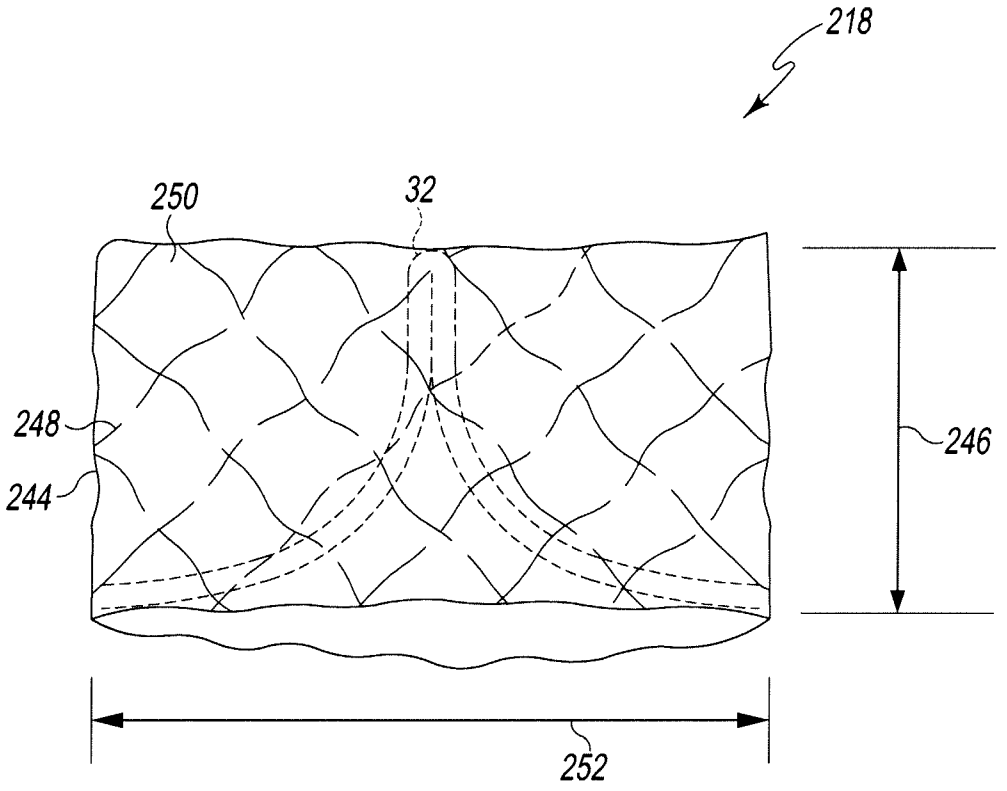


Fig. 10

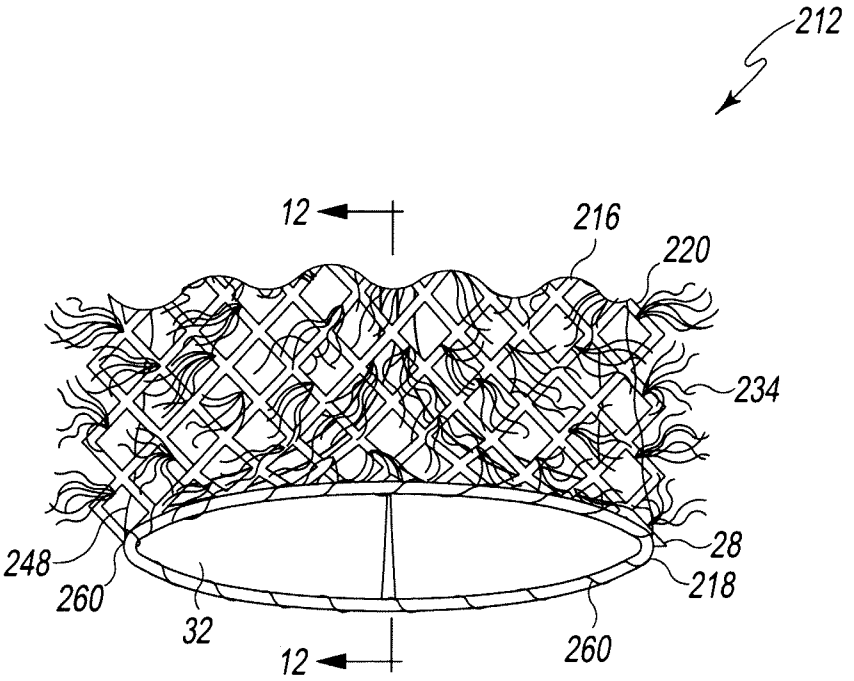


Fig. 11

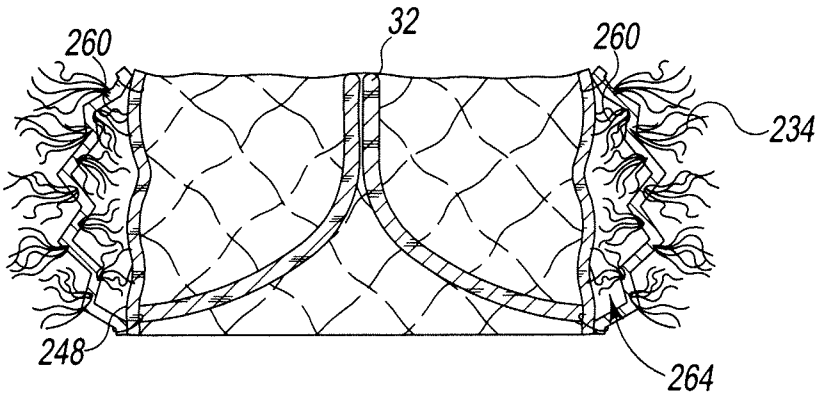


Fig. 12

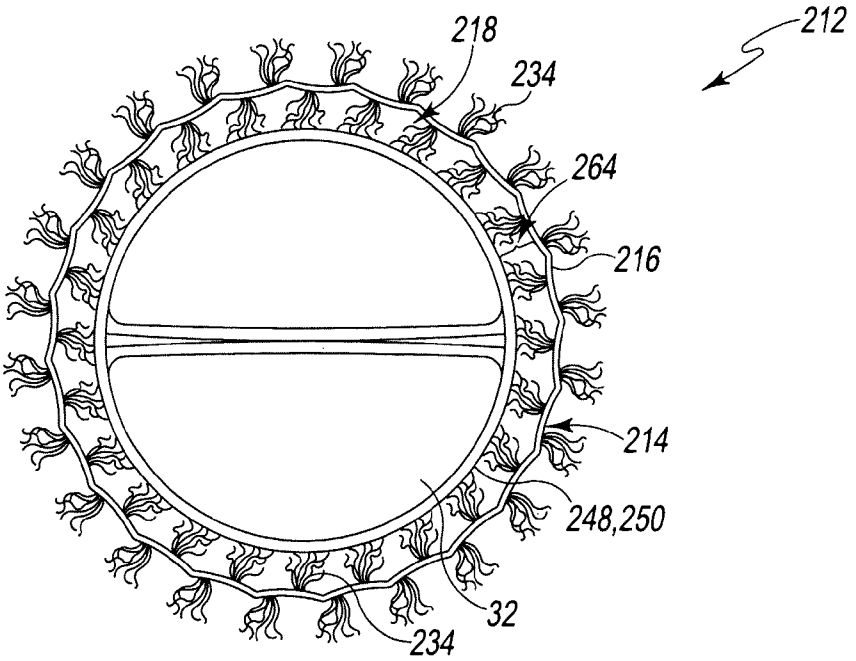

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Fig. 13

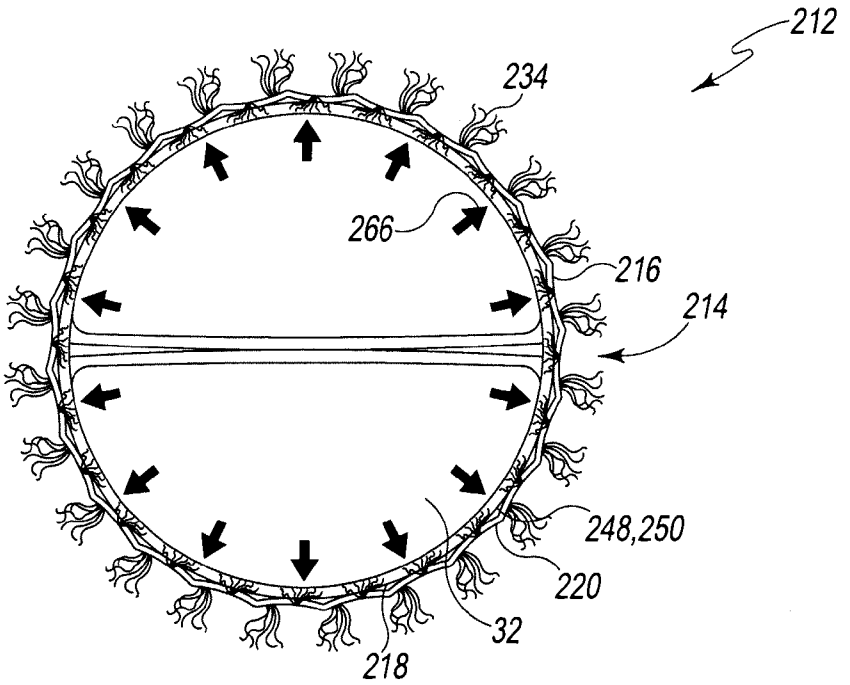

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Fig. 14

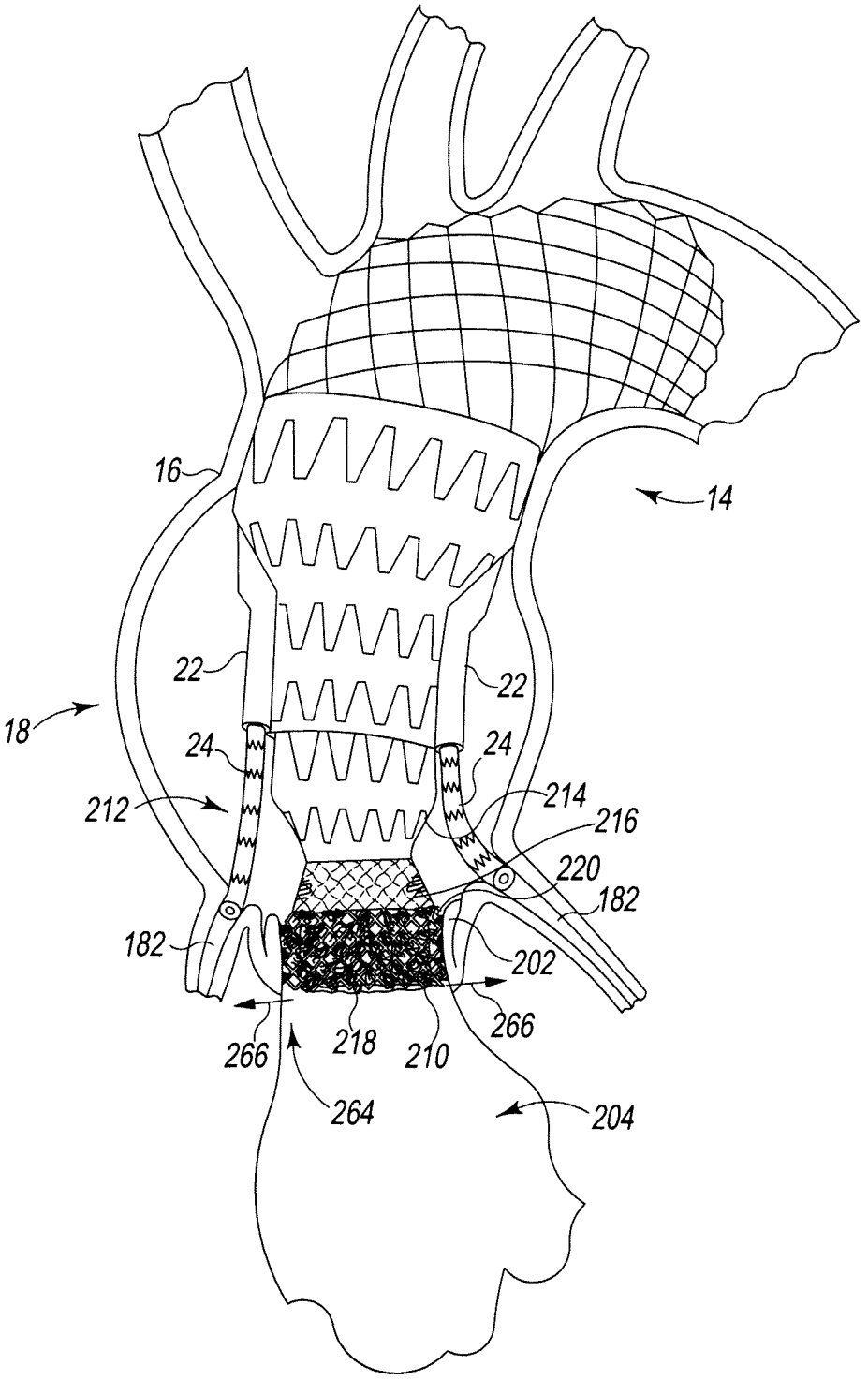

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Fig. 15

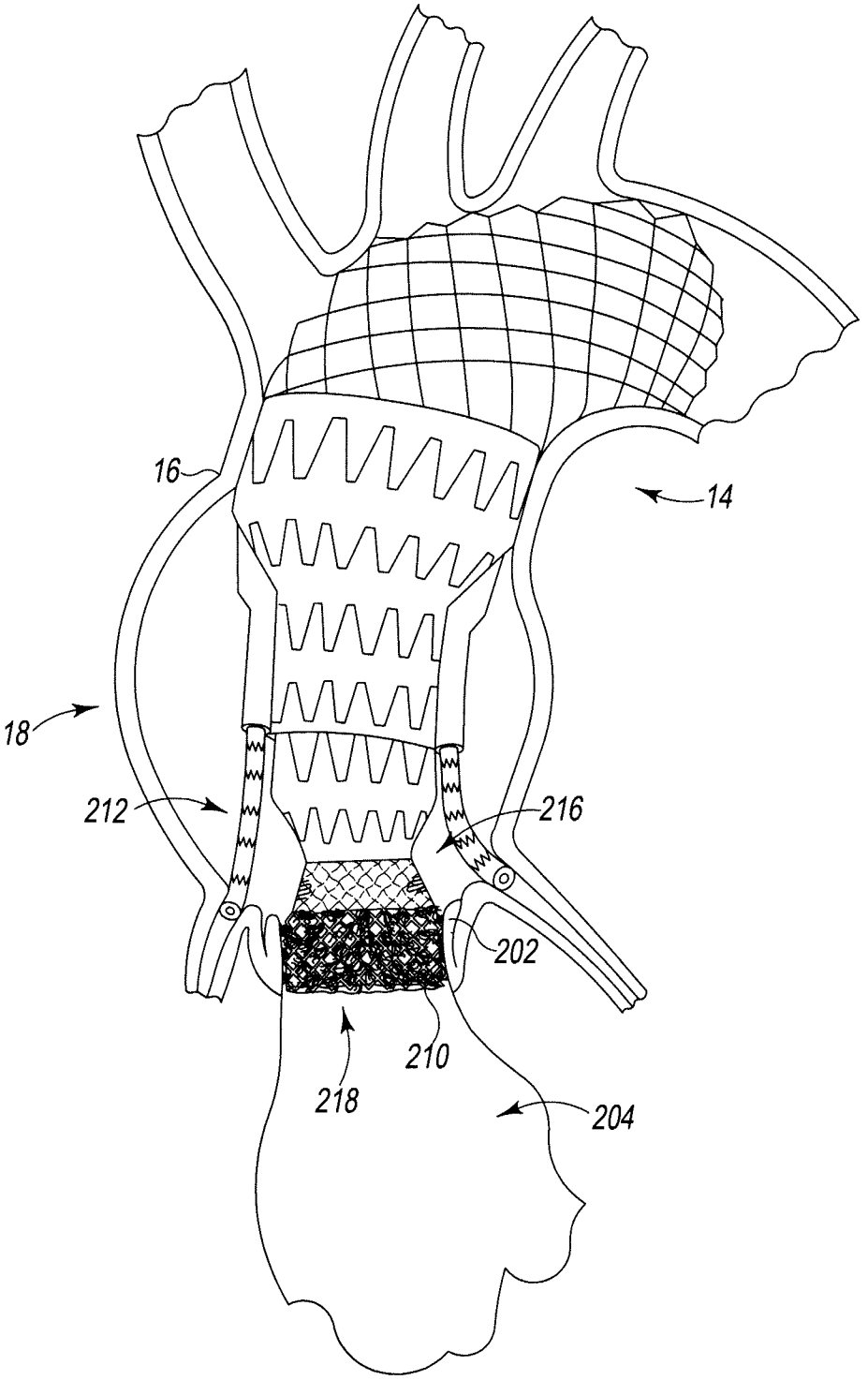


Fig. 16

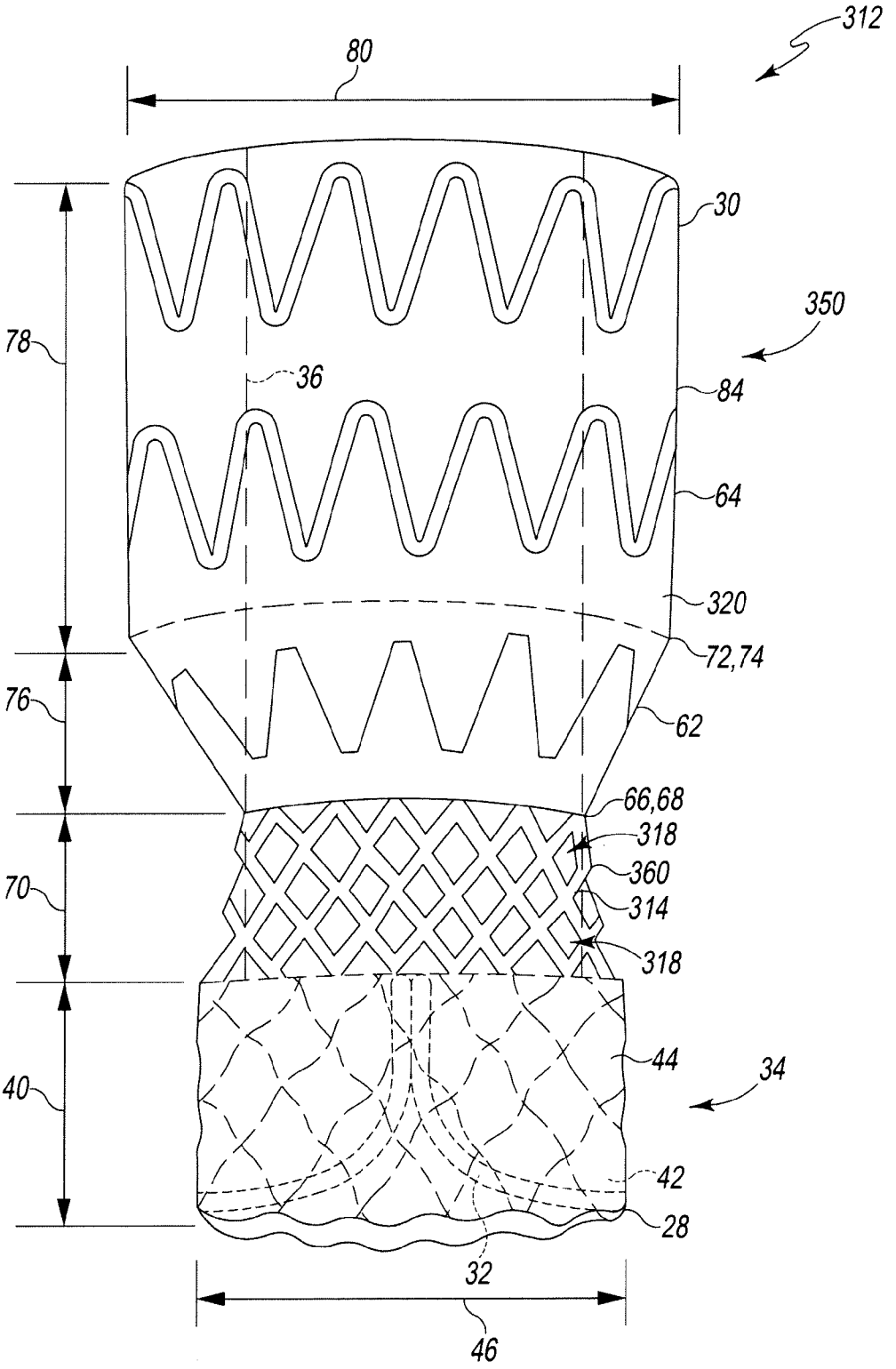

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Fig. 17

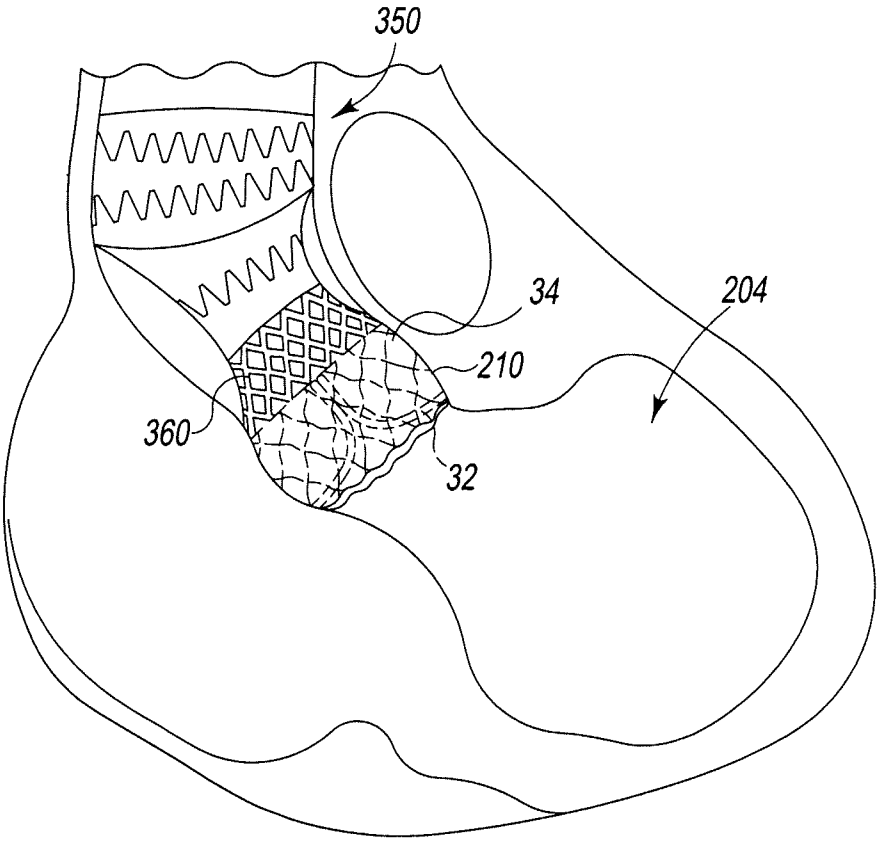


Fig. 18

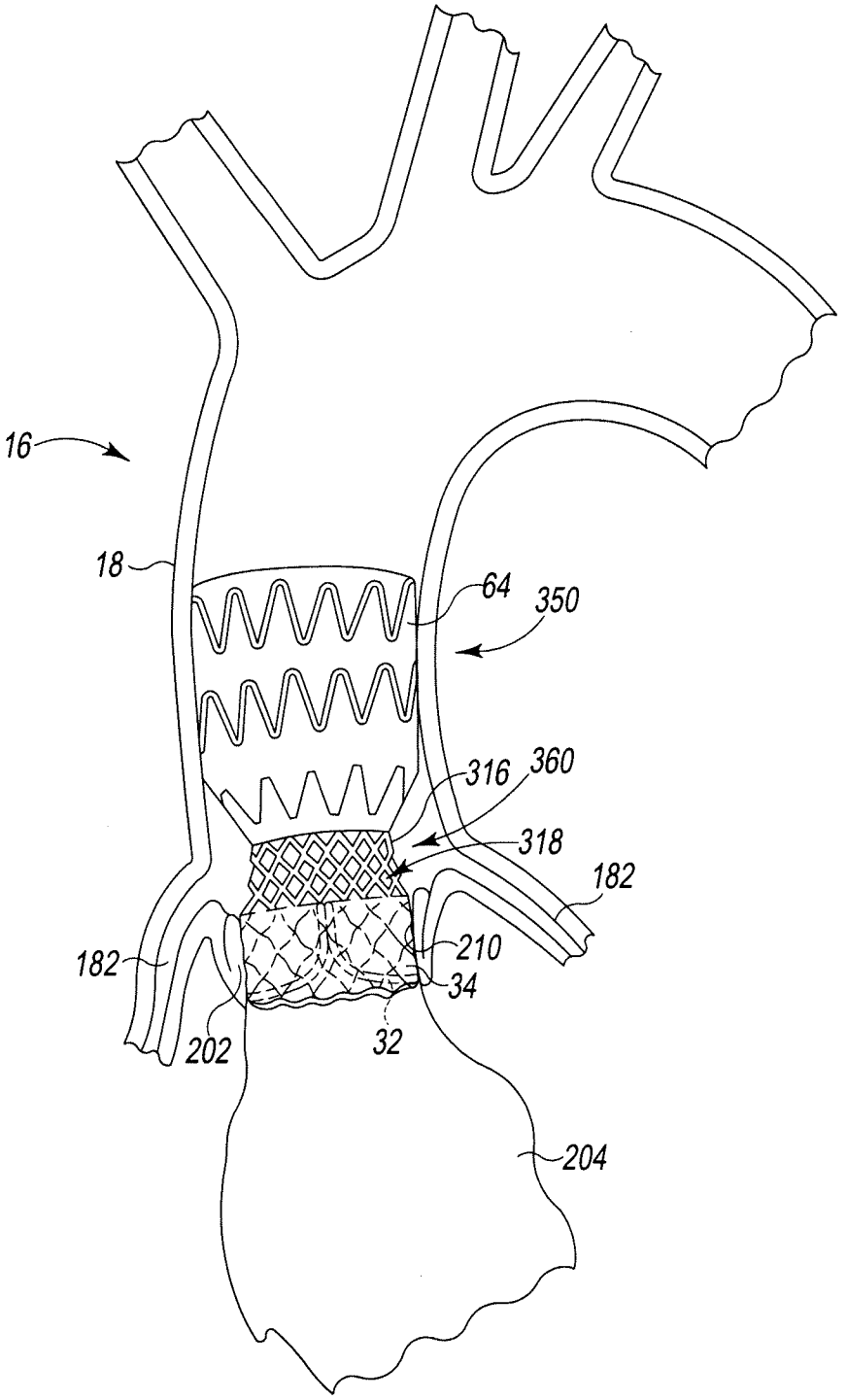


Fig. 19

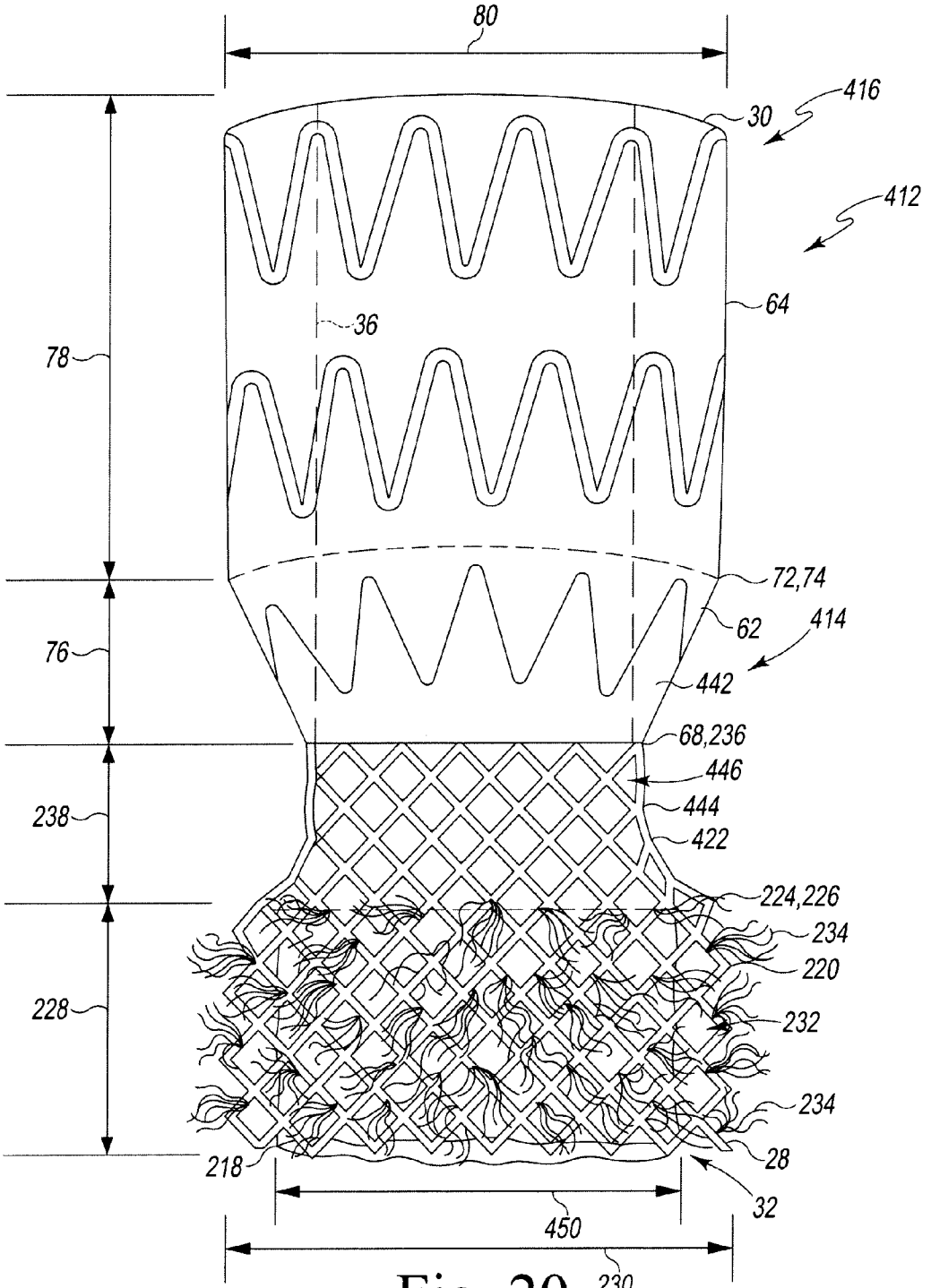

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Fig. 20

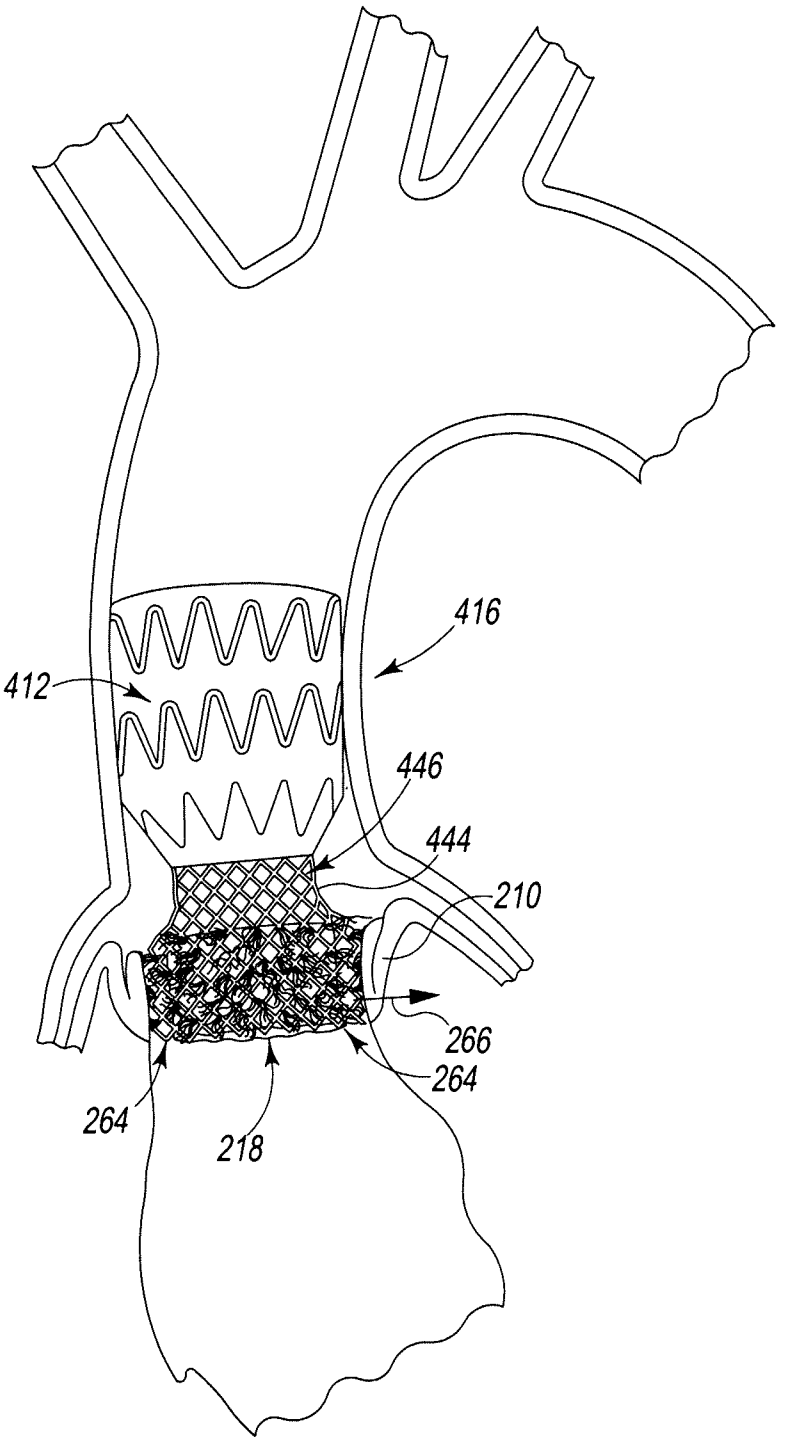


Fig. 21

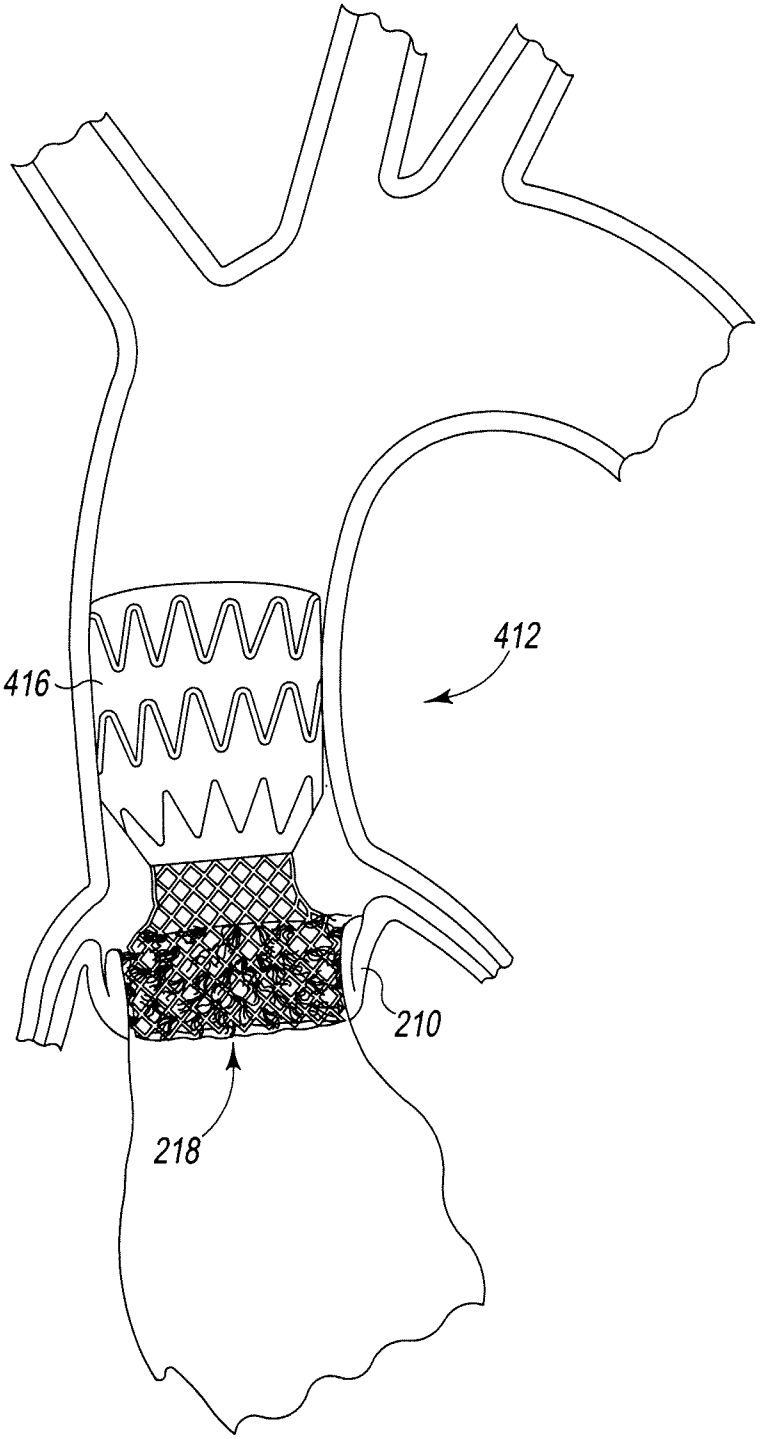


Fig. 22

DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME

This application claims priority 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 by Ali Shahriari on Dec. 6, 2011 and is expressly incorporated herein by reference. This application 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 by Ali Shahriari on Nov. 7, 2012 and is expressly incorporated herein by reference.

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 embodi-

ments 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 hourglass 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 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 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 la endoleak. The trapdoors **86** in components **12**,

312 would allow for coil embolization of the area of the leak. Two trapdoors at 180 degree location would allow access to the entire area above the aortic annulus. Since the coronary arteries **182** are protected by the conduits **22** in the distal component **14**, coil embolization of this area would not compromise the coronary blood flow. Coil embolization of paravalvular leaks are already being performed clinically after heart valve surgery if there are additional leaks around the valve.

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 endograft device for endovascular repair of ascending aortic aneurysms, comprising:

a first prosthetic component comprising (i) a proximal frame, and (ii) a distal frame secured to the proximal frame and extending to a distal end of the first prosthetic component,

at least one conduit secured to the first prosthetic component and positioned adjacent to the proximal frame,

a second prosthetic component secured to a proximal end of the first prosthetic component, the second prosthetic component comprising (i) a balloon-expandable frame extending distally from a proximal end of the second prosthetic component, and (ii) a self-expanding frame connected to the balloon-expandable frame and extending to a distal end of the second prosthetic component, and

a valve element secured to the balloon-expandable frame at the proximal end of the second prosthetic component.

2. The endograft device of claim **1**, wherein the self-expanding frame has an hourglass shape.

3. The endograft device of claim **2**, wherein the self-expanding frame includes:

a first section that tapers inwardly between a proximal end and a distal end, and

a second section having a proximal end that is connected to the distal end of the first section, the second section tapering outwardly between the proximal end of the second section and a distal end of the second section.

4. The endograft device of claim **3**, wherein the proximal end of the first section is secured to a distal end of the balloon-expandable frame.

5. The endograft device of claim **3**, wherein:

the self-expanding frame includes a third section extending proximally from the proximal end of the first section, the third section having a passageway defined therein, and

the balloon-expandable frame is positioned in the passageway of the third section of the self-expanding frame.

6. The endograft device of claim **5**, wherein the balloon-expandable frame is expandable between (i) an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and (ii) an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

7. The endograft device of claim 6, wherein a plurality of fibers are attached to the third section of the self-expanding frame, and when the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame is engaged with the plurality of fibers.

8. The endograft device of claim 1, wherein the proximal frame of the first prosthetic component has a passageway defined therein, and the distal end of the second prosthetic component is positioned in the passageway of the first prosthetic component.

9. The endograft device of claim 1, wherein the at least one conduit includes a pair of conduits positioned on opposite sides of the first prosthetic component.

10. The endograft device of claim 1, wherein the at least one conduit has a proximal opening that is positioned adjacent to a proximal end of the first prosthetic component.

11. The endograft device of claim 10, wherein the proximal frame includes (i) a first section secured to the distal end of the second prosthetic component, and (ii) a second section connected to the first section, the second section tapering outward between a proximal end connected to the first section and a distal end, and the at least one conduit has a distal opening defined in the second section of the proximal frame.

12. The endograft device of claim 11, further comprising 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.

13. The endograft device of claim 1, wherein:

an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component are covered such that fluid is prevented from passing therethrough, and

an outer surface of the distal frame of the first prosthetic component is uncovered such that fluid is permitted to pass therethrough.

14. A transcatheter valve, comprising:

a frame component comprising:

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 including (i) a first section that tapers inwardly between a proximal end and a distal end, and (ii) a second section that tapers outwardly between a proximal end secured to the distal end of the first section and a distal end, and

a valve element positioned in the balloon-expandable frame at the proximal end of the frame component.

15. The transcatheter valve of claim 14, wherein:

the frame component is a dual-frame component,

the self-expanding frame is an outer frame of the dual-frame component and has a passageway defined therein,

the balloon-expandable frame is an inner frame of the dual-frame component and is positioned in the passageway defined in the self-expanding frame, and

the balloon-expandable frame is expandable between (i) an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and (ii) an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

16. The transcatheter valve of claim 15, wherein a plurality of fibers are attached to the self-expanding frame, and when the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame is engaged with the plurality of fibers.

17. The transcatheter valve of claim 14, wherein an outer surface of the first section of the self-expanding frame is uncovered such that fluid is permitted to pass therethrough and an outer surface of the second section of the self-expanding frame is covered such that fluid is prevented from passing therethrough.

18. The transcatheter valve of claim 14, wherein the self-expanding frame includes an elongated section extending distally from the second section, the elongated section having a length that is greater than a combined length of the first section and the second section.

19. The transcatheter valve of claim 14, wherein the self-expanding frame is covered with at least one of a collagen or hydrogel.

20. The transcatheter valve of claim 14, wherein the valve element is one of a bicuspid valve and a tricuspid valve.

21. An endograft device for endovascular repair of ascending aortic aneurysms, comprising:

a first prosthetic component comprising (i) a proximal frame for being installed within a portion of an aorta of a patient, and (ii) a distal frame secured to the proximal frame and extending to a distal end of the first prosthetic component, the distal frame being engaged with the ascending aorta when installed within a patient,

at least one conduit secured to the first prosthetic component and positioned adjacent to the proximal frame and engaging with stent extending from a coronary artery of the patient when installed,

a second prosthetic component separate from the first component and being selectively secured to a proximal end of the first prosthetic component, the second prosthetic component comprising (i) a balloon-expandable frame extending distally from a proximal end of the second prosthetic component, and (ii) a self-expanding frame connected to the balloon-expandable frame and extending to a distal end of the second prosthetic component, and

a valve element secured to the balloon-expandable frame at the proximal end of the second prosthetic component.

22. The endograft device of claim 21, wherein the self-expanding frame has an hourglass shape, wherein the conduit engages the first prosthetic component at a position distally placed from the self-expanding frame.

23. The endograft device of claim 21, wherein the proximal frame of the first prosthetic component has a passageway defined therein, and the distal end of the second prosthetic component is slideably positioned in the passageway of the first prosthetic component.

24. The endograft device of claim 21, wherein the at least one conduit includes a pair of conduits positioned on opposite sides of the first prosthetic component, each of the pair of conduits receivably engaging a stent member for engaging the coronaries when installed within the patient.

* * * * *

EXHIBIT 12

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14033075
Filing Date	2013-09-20
First Named Inventor	Gregory A. Wright
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	HVTVC-6596

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14033075
	Filing Date	2013-09-20
	First Named Inventor	Gregory A. Wright
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	HVTVC-6596

	1	International Search Report from Corresponding PCT Application No. PCT/US2013/061467 mailed January 2, 2014.	☐

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14033075
Filing Date	2013-09-20
First Named Inventor	Gregory A. Wright
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	HVTVC-6596

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Pui Tong Ho, Reg. No. 44,155/	Date (YYYY-MM-DD)	2014-11-13
Name/Print	Pui Tong Ho	Registration Number	44155

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

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gregory	A.	Wright	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Orange	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	Edwards Lifesciences
Address 2	One Edwards Way; Legal Department

City	Irvine	State/Province	CA
Postal Code	92614	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	30452		
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Application Information:

Title of the Invention	SYSTEMS AND METHODS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT		
Attorney Docket Number	HVTVC-6596	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

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	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

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Customer Number	30452		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	61705495	2012-09-25

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Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [i] (if applicable)

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

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

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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☐ Authorization to Permit Access to the Instant Application by the Participating Offices

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. [X]

Organization Name	Edwards Lifesciences Corporation		
Mailing Address Information:			
Address 1	One Edwards Way		
Address 2			
City	Irvine	**State/Province**	CA
Country [i]	US	Postal Code	92614
Phone Number		Fax Number	
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Assignee 1

Complete this section only if non-applicant assignee information is desired to be included on the patent application publication in accordance with 37 CFR 1.215(b). Do not include in this section an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest), as the patent application publication will include the name of the applicant(s).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information:

Address 1	
Address 2	

City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

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Remove

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature	/AnneMarie Kaiser/			Date (YYYY-MM-DD)	2013-09-20
First Name	AnneMarie	Last Name	Kaiser	Registration Number	37649

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This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

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

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

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

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

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

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

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

SYSTEMS AND METHODS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT

FIELD

This application relates to methods, systems, and apparatuses for safely replacing native heart valves and aorta with prosthetic heart valves and conduits.

BACKGROUND

Prosthetic heart valves have been used for many years to treat cardiac valvular disorders. The native heart valves (such as the aortic, pulmonary, tricuspid and mitral valves) serve critical functions in assuring the forward flow of an adequate supply of blood through the cardiovascular system. These heart valves can be rendered less effective by congenital, inflammatory, or infectious conditions. Such conditions can eventually lead to serious cardiovascular compromise or death. For many years, the definitive treatment for such disorders was the surgical repair or replacement of the valve during open heart surgery.

More recently, a transvascular technique has been developed for introducing and implanting a prosthetic heart valve using a flexible catheter in a manner that is less invasive than open heart surgery. In this technique, a prosthetic valve is mounted in a crimped state on the end portion of a flexible catheter and advanced through a blood vessel of the patient until the valve reaches the implantation site. The valve at the catheter tip is then expanded to its functional size at the site of the defective native valve, such as by inflating a balloon on which the valve is mounted.

Alternatively, the valve can have a resilient, self-expanding stent or frame that expands the valve to its functional size when it is advanced from a delivery sheath at the distal end of the catheter.

Balloon-expandable valves are commonly used for treating heart valve stenosis, a condition in which the leaflets of a valve (e.g., an aortic valve) become hardened with calcium. The hardened leaflets provide a good support structure on which the valve can be anchored within the valve annulus. Further, the catheter balloon can apply sufficient expanding force to anchor the frame of the prosthetic valve to the surrounding calcified tissue.

Often, heart valve problems, such as calcification, are associated with other heart problems such as aortic aneurysms. Although the delivery techniques described above address heart valve deficiencies to some extent, less invasive approaches to other heart problems are also desired. It would be particularly advantageous to be able to address both valve and aorta problems with a minimally invasive approach.

SUMMARY

A medical device for use in a heart having a native heart valve and a vessel extending therefrom is disclosed. The medical device includes a balloon-expandable conduit and a prosthetic valve. The delivery system includes a catheter having a balloon that is disposed inside the balloon-expandable conduit. The prosthetic valve is coupled to an end of the balloon expandable conduit. The prosthetic valve includes a self-expandable material configured to expand in a radially outward direction to frictionally engage at least a portion of the native heart valve. The frictional engagement prevents axial movement of the prosthetic heart valve and the balloon-expandable conduit relative to the native heart valve.

The balloon-expandable conduit may include a balloon-expandable tubular frame and a sleeve extending along and against the balloon-expandable frame. The self-expandable material may include a self-expandable tubular frame. The prosthetic valve may include valve leaflets supported within the self-expandable tubular frame. The balloon-expandable tubular frame and

self-expandable tubular frame may be contiguously formed of a nitinol alloy. The self-expandable tubular frame may have an expanded memory shape.

The prosthetic valve may include an annular ring of woven material coupling the valve leaflets to the self-expandable tubular frame.

The sleeve may be formed of a bioprosthetic tissue. For example, the bioprosthetic tissue may include a bovine pericardium, a porcine pericardium or an allogenic or autogenic collagen matrix tissue. The bioprosthetic tissue sleeve may be glycerolized to facilitate dry storage.

The sleeve may also include a coating, such as a polymer or gel coating.

The medical device may also include a retractable sheath that defines an interior portion. The retractable sheath holds the prosthetic valve in a radially compressed configuration. The retractable sheath may include one or more radiopaque markers on its outer surface.

The balloon expandable material may be a plastically deformable metal material such as a stainless steel or nitinol.

Also included in the medical device may be one or more anchors. The anchors are coupled to and extend radially from an outer surface of the medical device. For example, the anchors may be supported by the balloon-expandable conduit or the self-expandable prosthetic valve. The anchors may include structure that facilitates tissue ingrowth, such as beads, dimples or fenestrations. The anchors may circumferentially spaced about the outer surface of the medical device.

A method includes delivering a balloon-expandable conduit coupled to a self-expandable prosthetic heart valve into a vessel extending from a native heart valve. Also, the self-expandable prosthetic heart valve is delivered into the native heart valve. The method also includes inflating a balloon disposed within the balloon-expandable conduit such that an outer

surface of the balloon expandable conduit is urged toward the vessel. The self-expandable prosthetic heart valve is expanded within or near the native heart valve by axially moving a retractable sheath.

The delivering method may also include engaging the vessel or native heart valve with anchors coupled to the conduit or prosthetic heart valve.

A method of assembling a medical device includes coupling a self-expandable prosthetic heart valve adjacent a balloon-expandable conduit. Also, the method includes disposing a balloon and balloon catheter within an interior portion of the balloon-expandable conduit. The method further includes compressing the balloon-expandable conduit and the self-expandable prosthetic valve radially inwardly. The method also includes disposing at least the self-expandable prosthetic valve into an interior portion of a retractable sheath.

Coupling the self-expandable prosthetic heart valve adjacent the balloon-expandable conduit may include forming a contiguous frame, coupling a bioprosthetic sleeve to at least one end of the frame and valve leaflets to the other end of the frame. The other end of the frame is then formed to have an expanded memory shape.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a medical device including transapical delivery of a coupled conduit and valve with the conduit being balloon expanded into an aorta;

FIG. 2 is a partial sectional view showing a bioprosthetic sleeve extending over a stent frame holding an expandable tissue valve;

FIG. 3 is a sectional view of a delivery catheter holding a coupled balloon-expandable conduit and self-expanding valve;

FIG. 4 is a perspective view of the medical device of FIG. 1 with the valve self-expanding into frictional engagement with a native heart valve to anchor the coupled conduit; and

FIGS. 5-8 are enlarged schematics of various anchors that can be coupled to outer surfaces of the medical device for improved anchoring into native tissues.

DETAILED DESCRIPTION

Implementations of the present disclosure now will be described more fully hereinafter. Indeed, these implementations can be embodied in many different forms and should not be construed as limited to the implementations set forth herein; rather, these implementations are provided so that this disclosure will satisfy applicable legal requirements. As used in the specification, and in the appended claims, the singular forms "a", "an", "the", include plural referents unless the context clearly dictates otherwise. The term "comprising" and variations thereof as used herein is used synonymously with the term "including" and variations thereof and are open, non-limiting terms.

The inventor has observed a need for improved methods, systems, and apparatuses for delivering expandable prosthetic heart valves and conduits in a minimally invasive manner with a delivery device having a smaller diameter. The inventor has further recognized that trans-valvular technologies provide opportunities to repair aortic pathologies, such as in the thoracic aorta or aortic arch. Conduits to supplement or replace the aorta may be delivered through minimally invasive routes, such as transapical or transvalvular routes.

The methods and devices described below may be used to replace native heart valves that have calcified leaflets associated with aortic stenosis and, at the same time, to repair defects in

the aortic arch or thoracic aorta. Furthermore, the methods and devices desirably enable precise and controlled simultaneous delivery of the prosthetic valve and the conduit.

Disclosed below are representative embodiments of a medical device that can be secured within a native heart valve. For illustrative purposes, embodiments of the medical device are described as being delivered to the aortic valve and associated aorta. It should be understood that the disclosed medical device may be configured for use with other heart valves that have associated conduits.

Also, a range of aortic pathologies may be addressed, such as aortic or thoracic aneurysms, aorta stenosis, or aorta/thoracic dilatation.

As shown in FIG. 1, a medical device 10 includes an expandable conduit 12, a prosthetic heart valve 14 and a delivery device 16, including a balloon catheter 40. The expandable conduit 12 may include one or more inner or outer sleeves 18 supported by a frame or stent 20. The sleeve(s) 18 may be a bioprosthetic tissue wrapped, molded or sewn about the frame or stent 20. Coupled to an end of the expandable conduit is the prosthetic heart valve 14. For example, the prosthetic heart valve may include a portion of the frame 20 with soft tissue valve leaflets 22 sewn therein. As shown in FIG. 3, the conduit 12 and heart valve 14 may be crimped on the balloon catheter 40 for percutaneous deployment, or some other minimally invasive deployment approach, such as a transaortic or transapical approach.

Advantageously, the frame or stent 20 may be constructed of a balloon-expandable material for the conduit 12 portion and a self-expandable material for the prosthetic heart valve 14 portion. As shown in FIG. 2, this allows the prosthetic heart valve 14 to first be anchored precisely at the native heart valve 24 and then, as shown in FIG. 1, the conduit 12 expanded into place to protect the ascending aorta 26.

Also advantageously, the self-expanding nature of the prosthetic heart valve 14 allows it to be mounted over a portion of the balloon catheter 40 that does not have a balloon 28. This provides for a lower diameter and easier delivery.

The device 10, including the conduit 12, prosthetic heart valve 14 and delivery device 16 can have multiple sizes accommodating biological variation in patient valve and aorta anatomy.

The frame or stent 20, as shown in FIGS. 1-4, may be comprised of a plurality of struts 30 that are interconnected to provide a lattice configuration with closed cells. The frame 20 may be comprised of a range of materials, including metals and plastics. For example, the frame may be comprised of a shape memory metal, such as a stainless steel or nitinol (nickel-titanium) alloy. Nitinol has the advantage of being able to withstand large strains and other deformations. Forming the struts 30 for metal frames 20 may include, for example, laser-cutting a nitinol or stainless steel stock tube to form the holes between the struts.

The frame 20 may be constructed in parts of the same or different materials and later welded, sewn or otherwise bonded together. For example, the balloon expandable portion of the stent 20 that makes up the conduit 12 may be constructed of a biocompatible stainless steel material cut from a stainless steel tube as described above. The lattice frame 20 formed from the stainless steel may then be mounted (with or without some initial expansion) over the balloon 28 for later plastic deformation by the balloon into the expanded shape.

The prosthetic heart valve 14 portion of the stent 20 may be constructed of nitinol, expanded into a deployed shape by a balloon and then heat treated to have an expanded memory configuration. This expanded memory configuration is assumed upon deployment from the delivery device 16, i.e., when a retractable outer sleeve or sheath 32 of the delivery device (as shown in FIG. 3) is withdrawn. After formation, both portions of the stent frame 20 may then be

attached to each other by bonding, welding or having adjacent ends sewn to each other using the holes defined by the struts 30.

A particularly elegant solution (as shown in the figures herein) is to cut the entire frame or stent 20 out of a single tube of nitinol and then subject the nitinol to different treatments to selectively train axial portions for mixed expansion. For example, the cut nitinol tube may be partially expanded and heat treated at the prosthetic valve end to have an expanded memory shape. The remainder of the frame or stent 20 could be maintained in a cooled condition to avoid imprinting a memory shape or the memory shape may be the compressed condition. This compressed condition is then overcome by large plastic deformations from later expansion of the balloon 28. Advantageously, forming the stent 20 using differential techniques but the same monolithic materials avoids the need for later attachment, provides for a continuity of struts, improved structural integrity, etc.

As another alternative, the stent 20 may be entirely balloon expanded or entirely self-expanding. If entirely balloon expanded, a longer or larger balloon 28 may be used for simultaneous expansion of the entire conduit and valve combination. However, the combination of balloon and self expanding has particular advantages as described elsewhere herein.

The sleeve 18, as shown in FIGS 1 and 4, may extend within an inner surface of the frame 20 so as to protect the struts 30 of the frame from adhesions, clotting and other issues occurring from interaction with the blood flowing through the device 10. Alternatively, or in addition, the sleeve 18 may extend over the outside of the frame 20 or struts 30 so as to provide a surface on which to adhere to or fill the space between the frame and the surrounding native tissues of the aorta or valve of the heart. The sleeve 18 may also extend over both the inner and outer surfaces of the stent or frame 20.

Regardless of which surfaces it covers, the sleeve 18 is configured to provide a structure that helps to deflect and guide high pressure blood flow through the insufficient or compressed heart valve and the aneurismal aorta. Advantageously, the sleeve 18 and/or underlying frame 20 may have strategically placed openings, such as at the various branch vessels of the aorta (carotid or coronary arteries) to ensure perfusion of the heart and branch vessels.

The sleeve 18 may be constructed of a range of biological and/or synthetic materials and be applied or attached to the frame 20 in different ways. The sleeve may include, for example, bioprosthetic tissues such as bovine pericardium, porcine pericardium, or an allogenic and/or autogenic collagen matrix tissue. Bioprosthetic materials could be treated to withstand age and the environment, such as by being glycerolized to enable dry storage and improve lubrication. The bioprosthetic tissue could also be stored in glutaraldehyde.

As another option, polymers and gels (biological or synthetic) may be used for the sleeve 18. Non-biological polymers may be used for a solid polymer sleeve 18 or covering, such as silicone or polyurethane. The non-biological polymers may also include PET, PTFE or polyester films. Plant or animal derived collagen gels are an example of biological polymers or gels. Gels would generally be applied to some type of a substrate, such as an absorbable polymer substrate, a woven polyester, or bovine collagen matrix.

The sleeve 18 may also (optionally) be composed of a known graft material for treating aortic aneurysms, such as Dacron or PTFE cloth.

The sleeve 18 could also include combinations of some of the aforementioned materials. For example, the Dacron or PTFE cloth could be coated with the polymer or gel.

The different material types may be attached in different ways. For example, the sleeve 18, if comprised of a gel or polymer, may be applied as coating or as a molding or extrusion onto

the surfaces of the frame 20. This facilitates a bonding attachment along a large portion of the surfaces of the frame 20, with some material extending into the holes defined between the struts 30.

The sleeve 18 may also be partially or wholly applied mechanically, such as by wrapping or sewing onto the frame 20. For example, a cloth of the sleeve 18 could be formed into a tube around the frame 20 by use of a longitudinal stitch to attach long edges of a rectangular, flat material. The same longitudinal stitch could extend between the struts 30 to anchor the sleeve 18 to the stent 20.

As another option, the cloth (Dacron or PTFE) sleeve 18 may have additional layers applied to it such as an outer or inner coating or layer of gel or polymer. The gel or polymer could be applied as a coating, molding or extrusion onto the cloth (before or after the cloth's attachment) to form the multiple layered sleeve 18.

The sleeve 18 may also optionally extend over the (and be considered part of) the prosthetic heart valve 14, as shown in FIGS. 2 and 3. Or, the sleeve 18 may terminate prior to reaching the axial end of the heart valve 14, a shown in FIGS. 1 and 4, even leaving a gap therein to facilitate blood flow to the coronary arteries extending from the aorta near the aortic valve root.

As shown in the cross-section of FIG. 3 and in FIG 2, the prosthetic heart valve 14 includes an axial portion of the stent 20, soft tissue valve leaflets 22, a ring 34 and a plurality of stitches 36.

As described above, the portion of the stent 20 (or its own frame or stent if separately formed and attached) used to support the valve is a self-expanding material such as nitinol alloy with an expanded memory shape. A free end 38 of the stent 20 may terminate in a flared,

crenellated memory configuration when deployed at the native heart valve 24, as shown in FIGS. 1 and 4. It takes this shape, for example, because there is no surrounding native tissue to constrain it from assuming the fully open memory shape. The flared shape may advantageously avoid interfering with blood flow from the heart.

Also advantageously, the expanded portion of the stent 20 exerts a radially outward force. Thus, the expanded stent 20 frictionally engages at least a portion of the native aortic valve 24. This substantially prevents axial movement of the prosthetic valve 14 and the balloon-expandable conduit 12 relative to the aortic valve 24.

The ring 34 extends around an outside (as shown in FIG. 2) or inside (as shown in FIG. 1) (or both) of the stent 20 and provides a structure for attachment and support of the valve leaflets 22. The ring 34 may be constructed of a polymer, tightly woven cloth material, such as a PET fabric or a PTFE fabric. Sutures or stitches 36 may be used to attach the cloth material ring 34 to the stent frame 20 by extending through the cloth material, over the stent frame on inside and outside surfaces and through the stent openings, as shown in FIG. 3. Additionally, the stitches 36 may attach the stent frame 20 and cloth ring 34 to the sleeve 18, whether the sleeve extends over the inside and/or outside surfaces of the stent frame.

The valve leaflets 22 are preferably constructed of a soft, pliable material such as thin bioprosthetic material, such as bovine pericardium. The valve leaflets are sewn, bonded or otherwise attached to the cloth ring 34 around its inside surface to form a one-way tricuspid valve structure. In this manner, with the attachments described above, the valve leaflets 22 are firmly anchored to the cloth ring 34 which is attached via stitches 36 or other means to the frame 20 and the sleeve 18. This prosthetic heart valve 14 construction then, as described herein, serves as the anchor for the remaining medical device 10 and for the conduit 12.

The stitches 36 may be constructed of a heavy suture material for a firm interconnection of the above-listed components. Various stitches are shown herein including long axially-directed loops (FIG. 2) that extend over ends of the ring 34. Or, as shown in FIG. 4, alternating zig-zag stitches may pierce and extend through the ring 34. Generally, the stitching pattern may be adapted to suit the thickness of the material layers, geometry of the stent and other variations described herein.

The delivery device 16, as shown in FIG. 3, shows the assembled medical device 10 ready for delivery of the conduit 12 and valve 14. The delivery device 16 includes the retractable outer sheath 32 and the balloon catheter 40 mounted within a central lumen of the outer sheath. The balloon catheter 40 includes a guide wire 42, an inflation catheter 44 and the balloon 28.

The guide wire 42 is a semi-flexible wire that is placed through the skin and up through the aortic valve 24 and into the ascending aorta in a transapical approach, as shown in FIG 4. Conversely, the guide wire 42 may use a transfemoral approach by extending up the femoral artery and down the aortic arch through the aortic valve 24. Alternative approaches may also be used, including a more direct transaortic approach. Various approaches may or may not use a guide wire 42. Placement of the guide wire 42 may also use various devices such as an obturator to define gradually increasing diameter access holes, such as a transapical access hole.

The inflation catheter 44 defines a central lumen 46 by which it can be sleeved over the guide wire 42 once the guide wire is in place. The inflation catheter also includes an inflation lumen 48 which terminates within the walls of the balloon 28 mounted on the inflation catheter 44. At the proximal operator end, it may be attached to a gas or fluid supply for inflation of the

balloon 28 during the deployment procedure. Construction and use of a balloon inflation catheter are well known to those of ordinary skill in the art.

The balloon 28, as shown in FIGS. 1 and 3, includes a balloon wall 50 that is configured to form a toroid cylinder shape extending along an axial portion of the inflation catheter 44. The balloon wall in FIG. 3 is crimped against the inflation catheter 44 and extends under the conduit 12 but stops short of the prosthetic heart valve 14. The balloon 28 may be directly beneath the frame 20 in some embodiments or may be under the sleeve 18 when the sleeve extends inside the frame in other embodiments, or in some combination of both.

The outer sheath 32 is another elongate, flexible tube that is configured to hold the expandable conduit 12 and the heart valve 14 in the crimped condition, as shown in FIG. 3. The prosthetic heart valve 14 extends around and is crimped onto the inflation catheter 44 not supporting the balloon 28. The expandable conduit 12 is crimped over the portion supporting the balloon 28. The lack of the intervening balloon 28 allows the leaflets 22 of the prosthetic heart valve to be compressed directly on the inflation catheter. This allows for a more uniform, smaller diameter of the medical device 10 in its crimped configuration. Smaller diameter delivery allows for use of the device 10 with a wider range of patients and less invasive procedures.

In the crimped condition, the soft tissue of the bioprosthetic sleeve 18 is notably bunched or crimped along the length of the delivery device 16. The soft tissue is then smoothed out during inflation and plastic deformation of the supporting frame or stent 20. Similarly, the valve leaflets 22 unfold or uncrimp, although under self-expansion by the shape memory effect of the supporting portion of the stent 20.

Also notable, is that the approach used for delivery may dictate whether the prosthetic heart valve is near the distal end of the outer sheath 32, such as for a transfemoral approach, or may be on a more proximal end (relative to the expandable conduit 12) of the outer sleeve (as shown in FIGS. 1 and 4) for the transapical approach.

Also, the delivery device 16 may include the use of radiopaque markers for targeting an aneurysm or the dilated portion of the diseased aorta or other vessel for easier implantation. Flush valves may also be included in the delivery device 16.

In addition, the retractable outer sheath 32 may include one or more radiopaque markers 64 supported on an outer surface of the sheath, as shown in FIG. 1. These markers 64 are designed to help position the delivery system and can be used to specifically position the system to target an aneurysm or dilated portion of a diseased vessel.

The medical device 10 may have additional features to facilitate its anchoring and later incorporation (by healing) into the surrounding tissue. For example, additional cloth PET portions could be used at the opposing ends extending around the outer frame 20 or sleeve 18.

The medical device 10 may also be stabilized by a plurality of metal anchors 52, as shown in FIGS. 1 and 4. The anchors 52 may extend radially about 2 mm to about 4 mm from the outer surface of the conduit 12 and/or the prosthetic heart valve 14. In addition, the anchors 52 may be circumferentially spaced apart along the length of the expandable conduit 12 or heart valve 14. In other embodiments, one or more anchors 52 may be defined on the frame or stent 20. Or the anchors may extend from the bioprosthetic sleeve 18.

The anchors may be constructed of a range of biocompatible materials, such as stainless steel, Nitinol or polymeric materials.

FIGS. 5-8 illustrate various embodiments of the anchors 52. As shown in FIG. 5, the anchor 52 includes a base 54 topped by an irritation bead 56 defining a dimple 58. The base 54 is attached to the stent frame 20 (as shown) or directly to the sleeve 18. The irritation bead 56 is a spherical structure formed on or bonded to the base 54. It functions to irritate the surrounding tissue and induce a growth response to help anchor the conduit 12. The dimple 58 is a small golf-ball-like recess that further enhances irritation and tissue ingrowth.

As shown in FIG. 6, the anchors 52 may include a base 54 that supports a discrete field of fenestrations 60 that extend radially outward. The fenestrations 60 are configured to frictionally engage tissue of the native vessel. These fenestrations, for example, may be formed as a knurled crisscross patterns of pyramidal structures by cold rolling the metal from which the anchors 52 are cut.

As shown in FIGS. 7 and 8, the anchors 52 may include a base 54 that supports a disc-shaped protrusion 62. The disc shape has a top surface that extends in the axial direction of the underlying frame 20. The diameter of the disc protrusion 62 is larger than the supporting base 54. This shape facilitates its anchoring on the tissue walls. The tissue becomes lodged under the disc 62, between it and the base 54 or underlying conduit 12.

In another embodiment, each of the anchors 52 may include a plurality of arms that extend outwards and are configured to frictionally engage the surrounding tissue.

A method of construction of the expandable conduit 12 and the prosthetic heart valve 14 may include coating or covering the interior surface, exterior surface, or both of the frame or stent 20 with (1) a bioprosthetic tissue, which may be selected from the group comprising a bovine pericardium, porcine pericardium, and allogenic/autogenic collagen matrix tissue, (2) a polymer, (3) a gel applied to a substrate or (4) a cloth, such as PTFE or Dacron, to form the

sleeve 18. The sleeve 18, if it has a biological component, may then be glycerolized to facilitate dry storage. The method may also include applying a covering, such as a cloth, and coating the covering with a gel or polymer to form multiple layers.

During assembly of the medical device 10, the expandable conduit 12 is sleeved over the inflation catheter 44 until over the balloon 28. The prosthetic heart valve 14 is also sleeved (as the expandable conduit 12 is sleeved) over the adjacent portion of the inflation catheter 44 without the balloon. The prosthetic heart valve 14 is in the expanded condition due to its shape memory properties while the expandable conduit 12 is still relatively compact. A crimper is then used to crimp the conduit and valve, and underlying balloon 28, which are inserted into the outer, retractable sleeve 32 of the delivery device 16.

During delivery, the guide wire 42 is placed through the transapical or transfemoral approaches, as described above, until part of the wire extends through the aortic arch 26 and part of the wire through the native heart valve 24. Some preliminary balloon expansion may be performed to open the calcified native heart valve.

The balloon catheter 40 is then sleeved over the guide wire and into the native heart valve 24 and aortic arch 26. The outer sheath 32 is withdrawn to allow the prosthetic heart valve 14 to expand into and compress the native heart valve 24, as shown in FIG. 4. The inflation lumen 48 of the inflation catheter 44 is used to pump saline or other fluid into the balloon 28, expanding the balloon wall 50 and surrounding conduit 12, as shown in FIG. 1. The anchors 52 impinge upon or engage the surrounding vessel and anchor thereto.

Advantageously, the medical device 10 described above can achieve a smaller compressed diameter to facilitate minimally invasive delivery of a prosthetic heart valve together with an attached conduit.

CLAIMS

1. A medical device for use in a heart having a native heart valve and a vessel extending from the native heart valve, the medical device comprising:

a balloon-expandable conduit; and

a prosthetic valve coupled to an end of the balloon-expandable conduit,

wherein the prosthetic valve comprises a self-expandable material configured to expand in a radially outward direction to frictionally engage at least a portion of the native heart valve and inhibit axial movement of the prosthetic valve and the balloon-expandable conduit relative to the native heart valve.

2. The medical device of Claim 1, wherein the balloon-expandable conduit includes a balloon-expandable tubular frame and a sleeve extending axially along and against the balloon-expandable frame.

3. The medical device of Claim 2, wherein the self-expandable material of the prosthetic valve includes a self-expandable tubular frame and the prosthetic valve includes valve leaflets supported within the self-expandable tubular frame.

4. The medical device of Claim 3, wherein the balloon-expandable tubular frame and self-expandable tubular frame are contiguously formed of a nitinol alloy.

5. The medical device of Claim 4, wherein the self-expandable tubular frame has an expanded memory shape.

6. The medical device of Claim 5, wherein the prosthetic valve further comprises an annular ring of a woven material coupling the valve leaflets to the self-expandable tubular frame.

7. The medical device of Claim 2, wherein the sleeve includes a bioprosthetic tissue.

8. The medical device of Claim 7, wherein the sleeve extends along an inner diameter surface of the balloon-expandable tubular frame.

9. The medical device of Claim 7, wherein the bioprosthetic tissue is selected from a group consisting of a bovine pericardium, a porcine pericardium, and an allogenic/autogenic collagen matrix tissue.

10. The medical device of Claim 9, wherein the bioprosthetic tissue is glycerolized to facilitate dry storage.

11. The medical device of Claim 2, wherein the sleeve includes at least one of a polymer or gel coatings.

12. The medical device of Claim 1, further comprising a retractable sheath, the retractable sheath defining an interior portion into which at least the prosthetic valve is compressed radially inwardly.

13. The medical device of Claim 12, wherein the retractable sheath comprises at least one radiopaque marker on an outer surface of the retractable sheath.

14. The medical device of Claim 2, wherein the balloon-expandable tubular frame comprises a plastically deformable metal material.

15. The medical device of Claim 1, further comprising one or more anchors that extend outwardly from at least one of the balloon-expandable conduit or the prosthetic valve.

16. The medical device of Claim 15, wherein the one or more anchors comprise a tissue irritation structure to induce tissue ingrowth.

17. The medical device of Claim 16, wherein the tissue irritation structure includes at least one of a fenestration or a dimple.

18. The medical device of Claim 15, wherein the one or more anchors are circumferentially spaced apart about an outer surface of the medical device and extend radially outwardly.

19. A method, comprising:

delivering a balloon-expandable conduit coupled to a self-expandable prosthetic heart valve into a vessel extending from a native heart valve and the self-expandable prosthetic heart valve into the native heart valve;

inflating a balloon disposed within the balloon-expandable conduit such that an outer surface of the balloon-expandable conduit is urged substantially toward the vessel; and

expanding the self-expandable prosthetic heart valve within or near the native heart valve by axially moving a retractable sheath away from an outer surface of the self-expandable prosthetic heart valve.

20. The method of Claim 19, further comprising engaging at least one of the vessel or native heart valve with one or more anchors coupled to at least one of the conduit or prosthetic heart valve.

21. A method comprising:

coupling a self-expandable prosthetic heart valve adjacent a balloon-expandable conduit;

disposing a balloon and balloon catheter within an interior portion of the balloon-expandable conduit;

compressing the balloon-expandable conduit and the prosthetic valve radially inwardly; and

disposing at least the self-expandable prosthetic valve into an interior portion of a retractable sheath.

22. The method of Claim 21, wherein coupling the self-expandable prosthetic heart valve adjacent the balloon-expandable conduit includes forming a contiguous frame, coupling a bioprosthetic sleeve to at least one end of the frame and valve leaflets to the other end of the frame.

23. The method of Claim 22, further comprising forming the other end of the frame to have an expanded memory shape.

24. The medical device of Claim 1, further comprising a catheter with a balloon disposed inside the balloon expandable conduit.

ABSTRACT

A medical device includes an expandable conduit, a prosthetic heart valve and a delivery device, including a balloon catheter. The expandable conduit may include one or more inner or outer sleeves supported by a frame or stent. The sleeve(s) may be a bioprosthetic tissue wrapped, molded or sewn about the frame or stent. Coupled to an end of the expandable conduit is the prosthetic heart valve. The conduit and heart valve may be crimped on the balloon catheter for percutaneous deployment. The frame may be constructed of a balloon-expandable material for the conduit portion and a self-expandable material for the prosthetic heart valve portion. The prosthetic heart valve is anchored at the native heart valve and then the conduit to be expanded into place to protect the aorta. The self-expanding prosthetic heart valve avoids the need for balloon mounting. This provides for a smaller diameter and easier delivery.

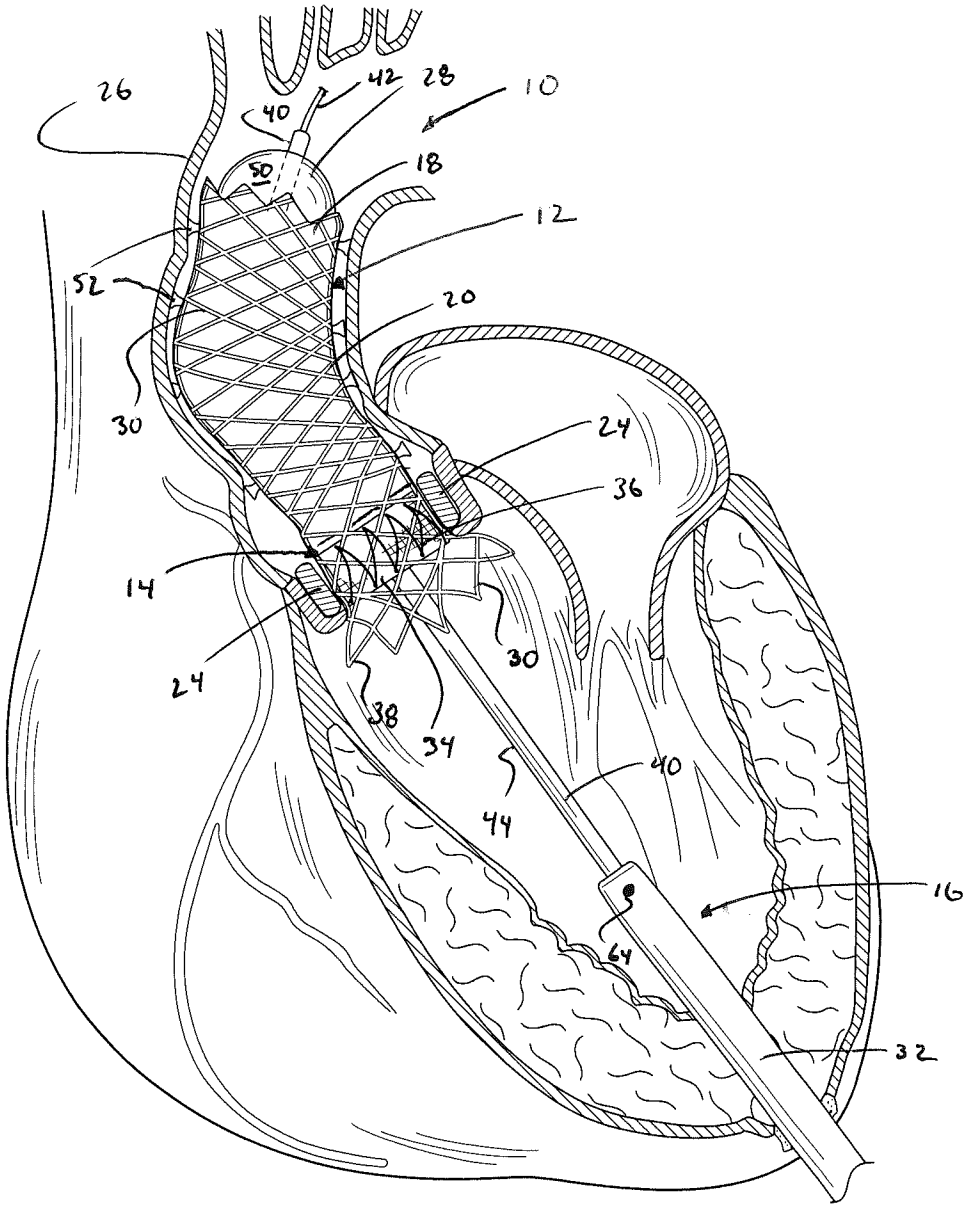


FIG. 1

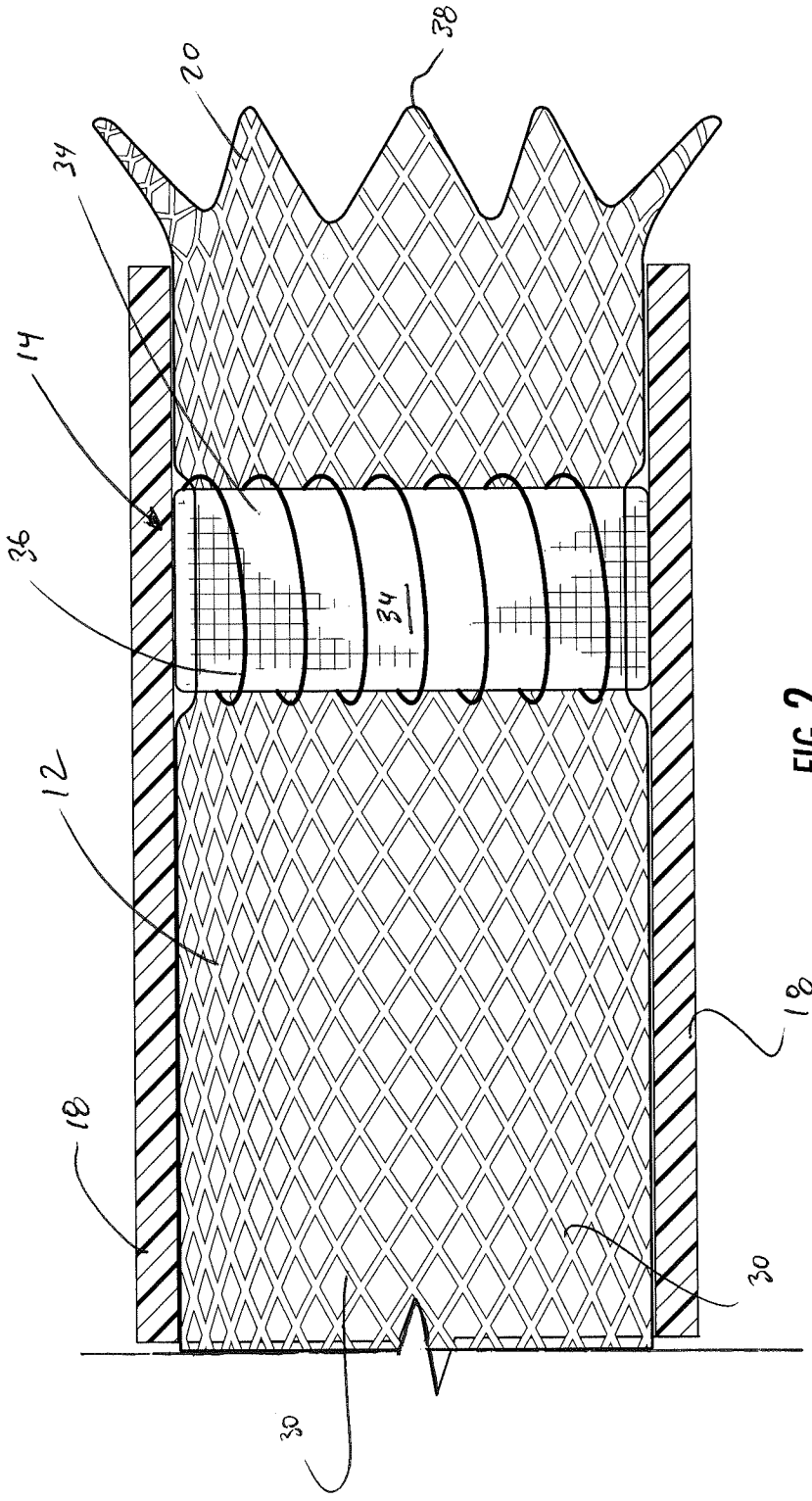


FIG. 2

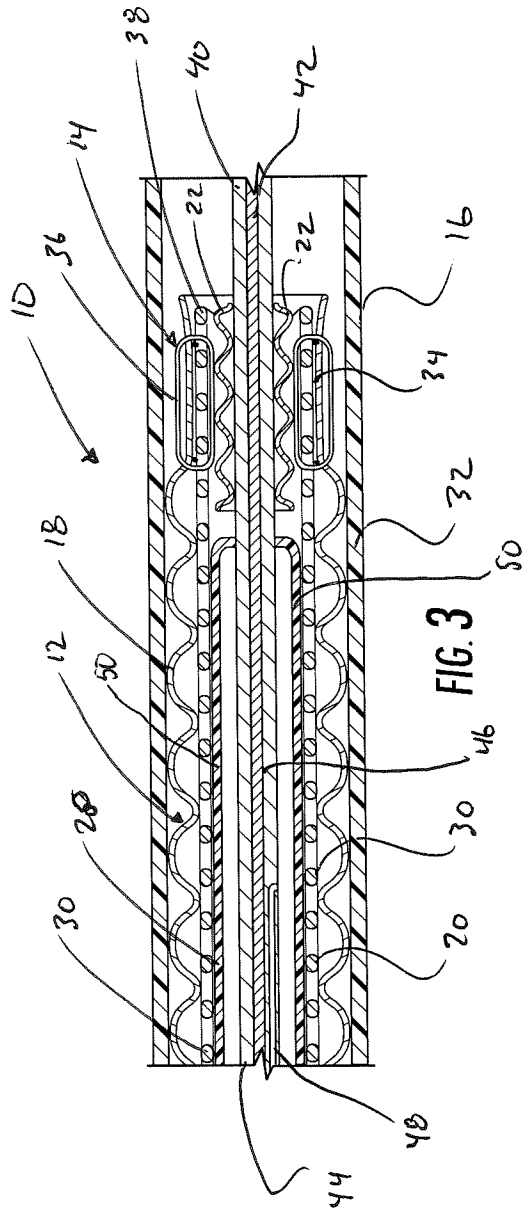


FIG. 3

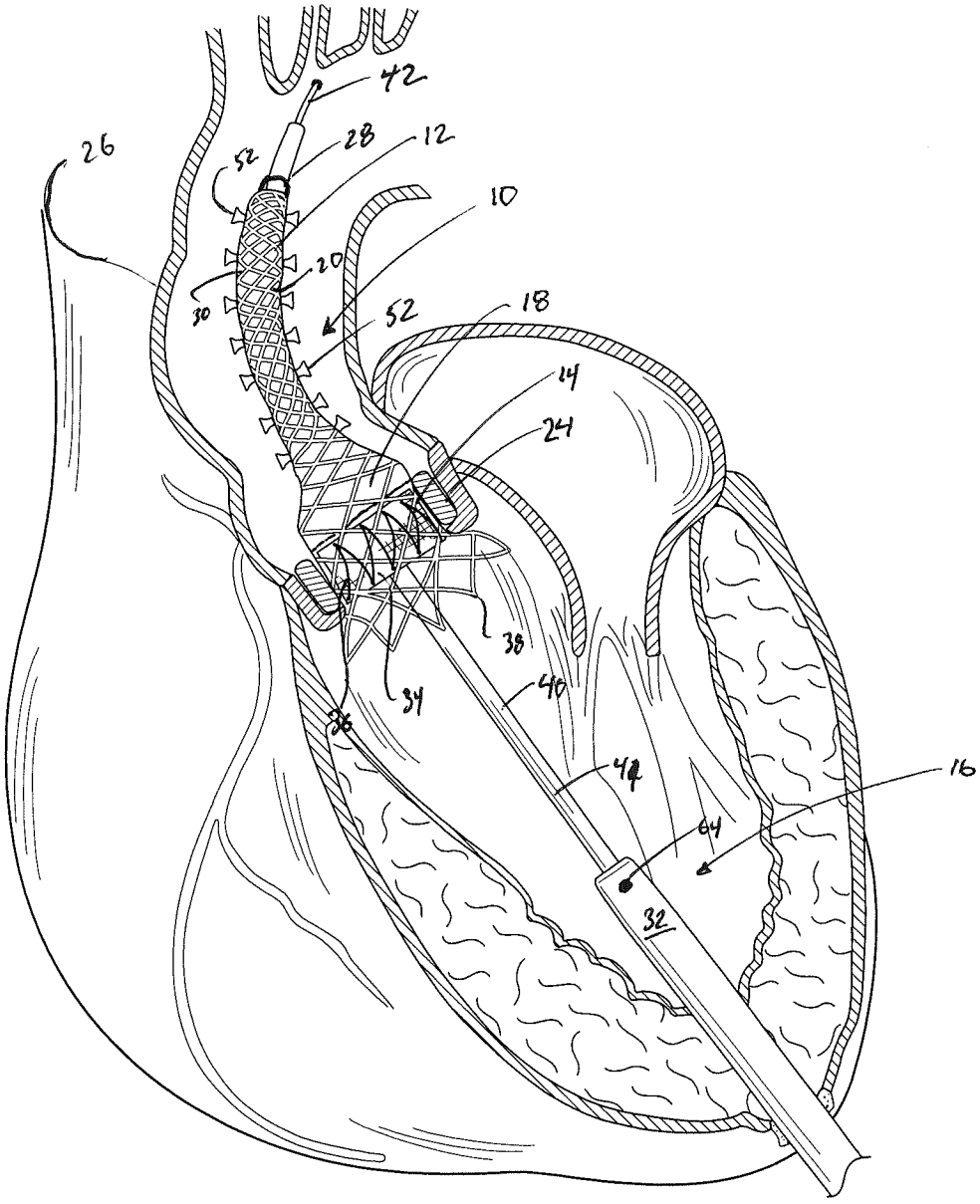


FIG. 4

Title: Systems and Methods for Replacing a Native Heart Valve and Aorta With a Prosthetic Heart Valve and Conduit
1st Named Inventor: Gregory A. Wright
Docket No.: HVT-6596

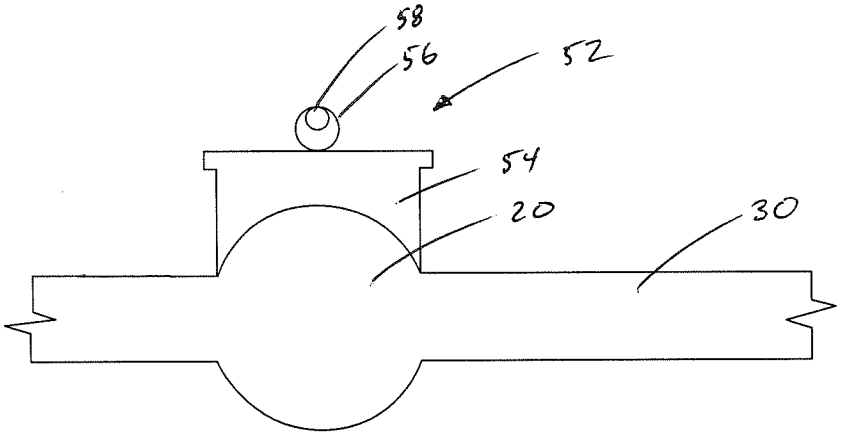


FIG. 5

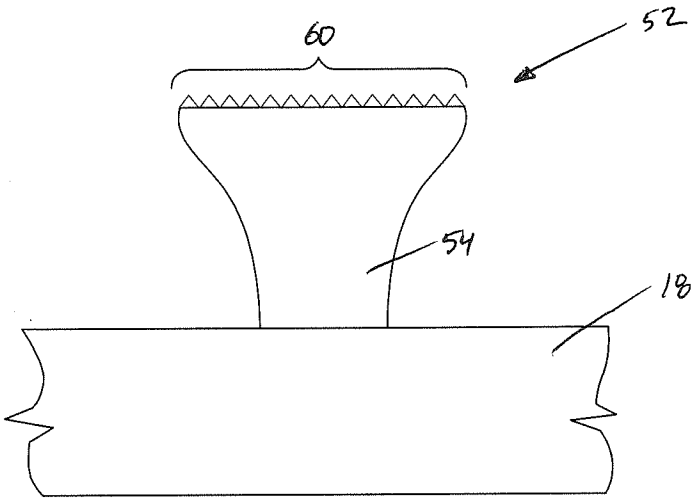


FIG. 6

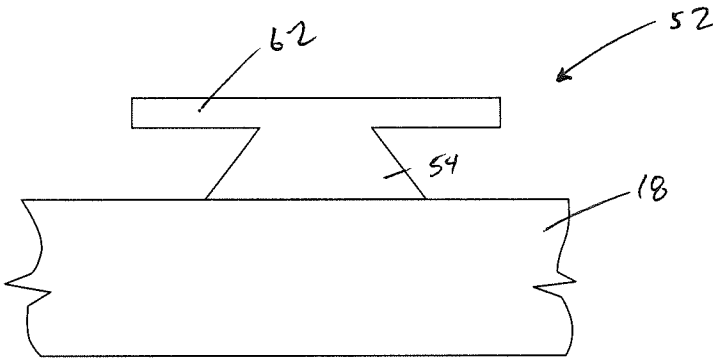


FIG. 7

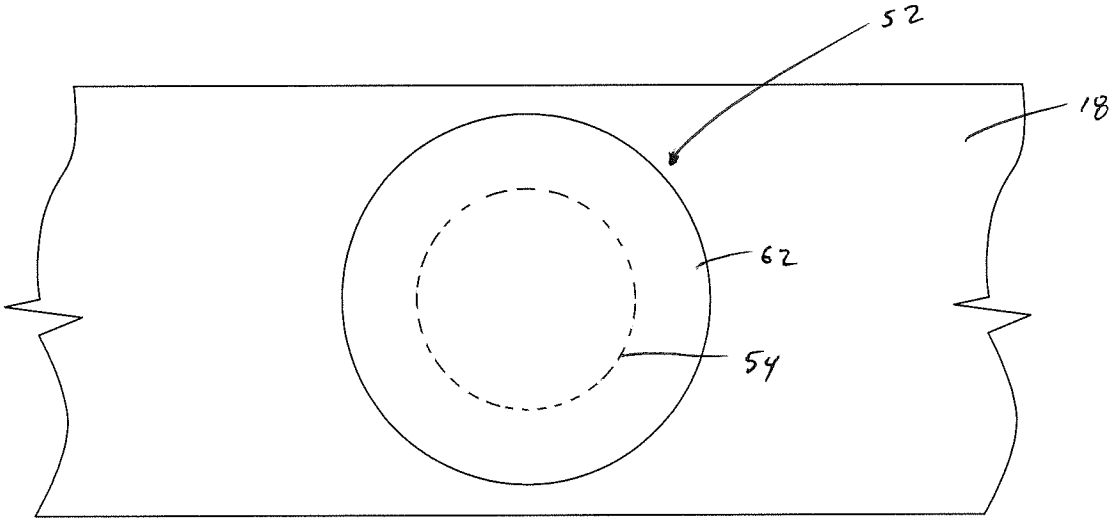


FIG. 8

EXHIBIT 13

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[Continued on nextpage]

(54) Title: DEVICE FOR ENDOVASCULAR AORTIC REPAIR AND METHOD OF USING THE SAME

(57) Abstract: A device and method for endovascular repair of a patient's aorta is disclosed. The device includes a frame component that has a balloon-expandable frame and a self-expanding frame secured to the balloon-expandable frame. The device also includes a valve element positioned at the proximal end of the frame component. The device may include another prosthetic component that may be secured to the frame component. The prosthetic component may include at least one conduit configured to receive a covered stent.

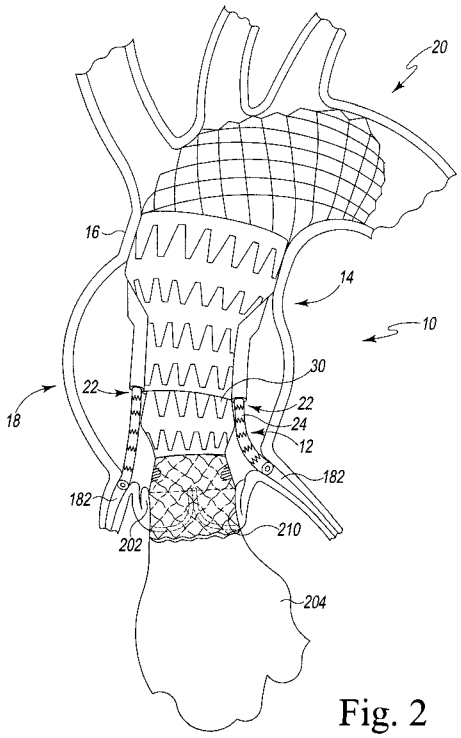


Fig. 2

WO 2013/086132 A1

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(H))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(Hi))*

— *of inventorship (Rule 4.17(iv))*

Published:

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DEVICE FOR ENDOVASCULARAORTIC REPAIR AND METHOD OF USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority under 35 U.S.C. § 119 to U.S. Provisional Application Serial No. 61/567,458 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair," which was filed by Ali Shahriari on December 6, 201 1 and is expressly incorporated herein by reference. This application also claims priority under § 119 to U.S. Provisional Application Serial No. 61/723,446 entitled "Transcathetar Aortic Valve for Endovascular Aortic Repair," which was filed by Ali Shahriari on November 7, 2012 and is expressly incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure relates to a device and method of using same for endovascular aortic repair, including repair of aortic valve disease, aortic stenosis, ascending aortic aneurysms, aortic insufficiency, aortic regurgitation, ascending aneurysm, bicuspid valve disease, and/ or Type A dissections.

BACKGROUND

[0003] The normal aortic root and the ascending aorta are composed of the aortic annulus, the sinuses of Valsalva, the sinutubular junction, and the tubular portion. The challenge facing practitioners of endovascular repair of ascending aortic aneurysms is that there is a very short proximal landing zone at the level of the sinutubular junction, there is variable coronary anatomy from patient to patient, and, in many cases, there is involvement of the aortic valve with either stenosis or insufficiency. Generally speaking, and as discussed in the article SURGERY INSIGHT: THE DILATED ASCENDING AORTA— INDICATIONS FOR SURGICAL INTERVENTION, by James E. Davies and Thralf M. Sundt published in Nature Clinical Practice Cardiovascular Medicine (2007), the contents of which are incorporated herein by reference in

its entirety, there are three basic types of involvement of the ascending aorta, designated as Type A, B, or C. These will be discussed in further detail below and are shown in FIGS. 1A-1C, which have been reproduced from the referenced article.

[0004] Type A aneurysms are most commonly found in younger patients and patients with connective tissue disorders such as Marfan syndrome. The anatomical characteristics of Type A aneurysms are dilatation of the sinuses of Valsalva with or without dilatation of the aortic annulus. The sinu tubular junction is most often dilated. The valve could be normal, stenotic or insufficient. An example of a Type A aneurysm is shown in FIG. 1A.

[0005] The anatomical characteristics of Type B aneurysms are dilatation of the tubular portion. Initially the sinu tubular 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. IB.

[0006] The anatomical characteristics of Type C aneurysms are dilatation of the sinuses of Valsalva, sinutubular junction and the tubular portion of the aorta. The valve could be normal, stenotic or insufficient. Type B and C aneurysms are most commonly found in an older group of patients. An example of a Type C aneurysm is shown in FIG. 1C.

[0007] There are devices clinically used for endovascular repair of ascending aortic aneurysms. Although transcatheter valves are a clinical reality, none in clinical use have been designed with the purpose of endovascular repair of multiple types of ascending aortic aneurysms. Indeed, a device is needed that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions. A device is also needed that would allow for treatment of different coronary anatomical variations among the patient population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

SUMMARY

[0008] According to one aspect of the disclosure, an endograft device for endovascular repair of ascending aortic aneurysms is disclosed. The endograft device includes a first prosthetic component that has a proximal frame and a distal frame that is secured to the proximal frame and extends to a distal end of the first prosthetic component. The endograft device also includes at least one conduit that is secured to the first prosthetic component and that is positioned adjacent to the proximal frame, and a second prosthetic component that is secured to a proximal end of the first prosthetic component. The second prosthetic component includes a balloon-expandable frame extending distally from a proximal end of the second prosthetic component and a self-expanding frame that is connected to the balloon-expandable frame and extends to a distal end of the second prosthetic component. The endograft device also includes a valve element that is secured to the balloon-expandable frame at the proximal end of the second prosthetic component.

[0009] In some embodiments, the self-expanding frame may have an hourglass shape. In some embodiments, the self-expanding frame may include a first section that tapers inwardly between a proximal end and a distal end. The endograft device may also include a second section having a proximal end that is secured to the distal end of the first section. The second section may taper outwardly between the proximal end of the second section and a distal end of the second section. Additionally, in some embodiments, the proximal end of the first section may be connected to a distal end of the balloon-expandable frame.

[0010] In some embodiments, the self-expanding frame may include a third section that extends proximally from the proximal end of the first section. The third section may have a 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.

[001 1] In some embodiments, a plurality of fibers may be attached to the third section of the self-expanding frame. When the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame may be engaged with the plurality of fibers.

[0012] In some embodiments, the proximal frame of the first prosthetic component may have a passageway defined therein, and the distal end of the second prosthetic component may be positioned in the passageway of the first prosthetic component.

[0013] In some embodiments, the conduit may include a pair of conduits positioned on opposite sides of the first prosthetic component. Additionally, in some embodiments, the conduit may have a proximal opening that is positioned adjacent to a proximal end of the first prosthetic component.

[0014] In some embodiments, the proximal frame may include a first section secured to the distal end of the second prosthetic component, and a second section connected to the first section. The second section may taper outward between a proximal end connected to the first section and a distal end. The conduit may have a distal opening defined in the second section of the proximal frame.

[0015] Additionally, in some embodiments, the endograft device may include a stent having a distal end positioned in the proximal opening of the at least one conduit and a proximal end configured to be positioned in a coronary artery.

[0016] In some embodiments, an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component may be covered such that fluid is prevented from passing therethrough. Additionally, an outer surface of the distal frame of the first prosthetic component may be uncovered such that is fluid permitted to pass therethrough.

[0017] According to another aspect, a transcatheter valve is disclosed. The transcatheter valve includes a frame component having a balloon-expandable frame extending distally from a proximal end of the frame component and a self-expanding frame secured to the balloon-expandable frame. The self-expanding frame includes a first section that tapers inwardly between a proximal end and a distal end, and a second section that tapers outwardly between a proximal end secured to the distal end of the first section and a distal end. A valve element is positioned in the balloon-expandable frame at the proximal end of the frame component.

[0018] In some embodiments, the frame component may be a dual-frame component. The self-expanding frame may be an outer frame of the dual-frame component and may have a passageway defined therein. The balloon-expandable frame may be an inner frame of the dual-frame component that is positioned in the passageway defined in the self-expanding frame. Additionally, the balloon-expandable frame may be expandable between an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

[0019] In some embodiments, a plurality of fibers may be attached to the self-expanding frame. When the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame may be engaged with the plurality of fibers. Additionally, in some embodiments, an outer surface of the first section of the self-expanding frame may be uncovered such that fluid is permitted to pass therethrough and an outer surface of the second section of the self-expanding frame may be covered such that fluid is prevented from passing therethrough.

[0020] In some embodiments, the self-expanding frame may include an elongated section extending distally from the second section. The elongated section may have a length that is greater than a combined length of the first section and the second section. Additionally, in some embodiments, the self-expanding frame may be covered with at least one of a collagen and hydrogel.

In some embodiments, the valve element may be one of a bicuspid valve and a tricuspid valve.

[0021] According to another aspect, a method of repairing a patient's aorta is disclosed. The method includes introducing a first prosthetic component into the patient's aorta such that a proximal frame of the first prosthetic component is positioned in the ascending aorta and a distal frame of the first prosthetic component is positioned in the aortic arch of the patient's aorta, advancing a covered stent through a conduit defined in the first prosthetic component into a coronary artery of the patient's aorta, securing a second prosthetic component to a proximal end of the first prosthetic component in the patient's aorta, and expanding a proximal section of the second prosthetic component into engagement with the aortic annulus of the patient's aorta such that a valve secured to the proximal section is positioned in the aortic annulus proximal to the coronary arteries.

[0022] In some embodiments, expanding the proximal section of the second prosthetic component may include operating a balloon-expandable frame. Additionally, in some embodiments, expanding the proximal section of the second prosthetic component may include permitting a self-expanding frame to expand into engagement with the aortic annulus, and operating the balloon-expandable frame may include advancing an outer surface of the balloon-expandable frame into engagement with an inner surface of the self-expanding frame after the self-expanding frame is engaged with the aortic annulus.

[0023] In some embodiments, operating the balloon-expandable frame may include advancing an outer surface of the balloon-expandable frame into engagement with the aortic annulus.

[0024] In some embodiments, an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component may be covered such that fluid is prevented from passing therethrough. Additionally, an outer surface of the distal frame of the first prosthetic component may be uncovered such that is permitted to pass therethrough.

[0025] In some embodiments, introducing the first prosthetic component into the patient's aorta and advancing the covered stent through the conduit defined in the first prosthetic component into the coronary artery of the patient's aorta may be performed during a first surgical procedure. In some embodiments, securing the second prosthetic component to the proximal end of the first prosthetic component and expanding the proximal section of the second prosthetic component into engagement with the aortic annulus of the patient's aorta may be performed during a second surgical procedure different from the first surgical procedure.

[0026] In some embodiments, the method may also include introducing the second prosthetic component into the ascending aorta prior to introducing the first prosthetic component.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Embodiments of the present disclosure will now be described by way of example in greater detail with reference to the attached figures, in which:

[0028] FIG. 1 is an illustrative aorta;

[0029] FIG. 1A is an example of a Type A aneurysm;

[0030] FIG. IB is an example of a Type B aneurysm;

[0031] FIG. 1C is an example of a Type C aneurysm;

[0032] FIG. 2 is partial cutaway view of an aorta with an embodiment of an endovascular prosthetic device implanted therein;

[0033] FIG. 3 is an elevation view of a proximal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0034] FIG. 4 is an elevation view of a distal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0035] FIG. 5 is a cross sectional view of the distal prosthetic component of FIG. 4 taken along the line 5-5 in FIG. 4;

[0036] FIG. 6 is a partial cutaway view of the aorta with the distal prosthetic component of FIG. 3 implanted therein;

[0037] FIG. 7 is a view similar to FIG. 6 showing stents extending from the distal prosthetic component;

[0038] FIG. 8 is an elevation view of another embodiment of a proximal prosthetic component of the endovascular prosthetic device of FIG. 2;

[0039] FIG. 9 is an elevation view of a self-expanding outer frame of the proximal prosthetic component of FIG. 8;

[0040] FIG. 10 is an elevation view of a balloon-expandable inner frame of the proximal prosthetic component of FIG. 8;

[0041] FIG. 11 is a perspective view a proximal end of the proximal prosthetic component of FIG. 8;

[0042] FIG. 12 is a cross-sectional elevation view of the proximal prosthetic component of FIG. 8 taken along the line 12-12 in FIG. 11;

[0043] FIG. 13 is a plan view of the proximal prosthetic component of FIG. 8 showing the inner frame in an unexpanded position;

[0044] FIG. 14 is a plan view similar to FIG. 13 showing the inner frame in an expanded position;

[0045] FIG. 15 is a partial cutaway view of the aorta with the distal prosthetic component of FIG. 4 secured to the proximal prosthetic component of FIG. 8;

[0046] FIG. 16 is a view similar to FIG. 15 showing the inner frame in an expanded position;

[0047] FIG. 17 is an embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. 3;

[0048] FIGS. 18-19 are partial cutaway views of the aorta with the transcatheter valve of FIG. 17 implanted therein;

[0049] FIG. 20 is another embodiment of a transcatheter valve device similar to the proximal prosthetic component of FIG. 8; and

[0050] FIGS. 21-22 are partial cutaway views of the aorta with the transcatheter valve of FIG. 20 implanted therein.

DETAILED DESCRIPTION OF THE DRAWINGS

[0051] While the concepts of the present disclosure are susceptible to various modifications and alternative forms, specific exemplary embodiments thereof have been illustrated by way of example in the drawings and will herein be described in detail. It should be understood, however, that there is no intent to limit the concepts of the present disclosure to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

[0052] Terms representing anatomical references, such as anterior, posterior, medial, lateral, superior, inferior, distal, proximal, etcetera, may be used throughout the specification in reference to the orthopaedic implants and surgical instruments described herein as well as in reference to the patient's natural anatomy. Such terms have well-understood meanings in both the study of anatomy and the field of orthopaedics. Use of such anatomical reference terms in the written description and claims is intended to be consistent with their well-understood meanings unless noted otherwise. For example, the term "proximal" refers to the direction that is generally closest to the heart, and the term "distal" refers to the direction that is generally furthest from the heart.

[0053] Referring to FIGS. 2-16, exemplary designs of an endovascular prosthetic device or endograft device 10 (hereinafter device 10) are shown. The device 10 is intended for the treatment of most ascending aortic aneurysms and is configured to treat any type of ascending aneurysm regardless of involvement of the aortic valve and the sinuses of Valsalva. As described in greater detail below, the device 10 permits future coronary and aortic valve interventions as well as extension of a fenestrated/ branch graft into the aortic arch. Part of the device 10 may also be modified and used as a transcatheter valve, as described in greater detail below in regard to FIGS. 17-22. Such a valve may be introduced transfemorally or through the subclavian artery or the apex of the heart.

[0054] Referring now to FIGS. 2-7, the device 10 includes a proximal component 12 that is attached to a distal component 14. As shown in FIG. 2, the distal component 14 may be secured to the proximal component 12 when implanted into a patient's aorta 16. When implanted, the proximal component 12 is positioned in the patient's ascending aorta 18, while the distal component 14 extends distally into the arch 20 of the patient's aorta 16. The distal component 14 includes a pair of "Endo-cabrol conduits" or conduits 22, and each conduit 22 is sized to receive a catheter or stent 24 for coronary blood flow, as described in greater detail below. The device 10 is configured to treat all ascending aneurysms with or without dilated sinutubular junctions and aortic valve disease.

[0055] As shown in FIG. 3, the proximal component 12 includes a frame 26 that extends from a proximal end 28 to a distal end 30. The frame 26 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 12. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. It should be appreciated that in other embodiments the valve 32 may be tricuspid or quadracuspid. The valve 32 may be constructed from treated bovine pericardium or other suitable proven biological or synthetic material. When the proximal component 12 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the proximal component 12.

[0056] The valve 32 is housed in a balloon-expandable frame 34 of the frame 26. As shown in FIG. 3, the balloon-expandable frame 34 is embodied as a balloon-expandable stent 38 that extends distally from the proximal end 28 of the component 12 and has a length 40 of approximately 15 mm. In other embodiments, the stent 38 may be longer or shorter depending on, for example, the patient's anatomy. The stent 38 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 38 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative

embodiment, the outer surface 42 of the stent 38 is covered with low-profile polyester, ePTFE, or other nonporous covering material 44 that prevents fluid from passing through the outer surface 42. However, it should be appreciated that the stent 38 may be covered with standard polyester or other nonporous materials.

[0057] As shown in FIG. 3, the stent 38 of the balloon-expandable frame 34 has a diameter 46. As described in greater detail below, the balloon-expandable frame 34 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 46. In the illustrative embodiment, the expanded diameter 46 is equal to approximately 26 mm when the frame 34 is expanded. In other embodiments, the expanded diameter may be greater than or less than 26 mm depending on, for example, the patient's anatomy. Examples of balloon-expandable stents are described in U.S. Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft" by Julio C. Palmaz and U.S. Patent No. 6,582,462 entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis" by Henning Rud Andersen et al., which are expressly incorporated herein by reference. In the illustrative embodiment, the diameter 46 is oversized relative to the diameter of the aortic annulus 210 (see FIG. 1) such that an interference fit is created between the stent 38 and the annulus 210 when the component 12 is implanted and the stent 38 is expanded, as described in greater detail below.

[0058] The balloon-expandable frame 34 is attached to a self-expanding frame 50. In the illustrative embodiment, the distal end 52 of the balloon-expandable frame 34 is secured to the proximal end 54 of the frame 50 by stitching or sewing the frames 34, 50 together, thereby forming the frame 26 of the component 12. It should be appreciated that in other embodiments the frames 34, 50 may be secured together via welding or other fasteners. The frames 34, 50 may also be formed as a single, monolithic frame.

[0059] As shown in FIG. 3, the self-expanding frame 50 has a generally hourglass shape and is formed from a metallic material, such as, nitinol,

stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the frame 50 may be formed from a polymeric material. The frame 50 includes an inwardly tapered proximal section 60, an outwardly tapered middle section 62, and an elongated distal section 64. The section 60 includes the proximal end 54 of the frame 50 and has a distal end 66 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 60 tapers inwardly between the ends 54, 66 from approximately 26 mm at the end 54 to approximately 22 mm at the end 66. In the illustrative embodiment, the proximal section 60 has a length 70 of approximately 10 mm. It should be appreciated that in other embodiments the dimensions of the section 60 may vary depending on, for example, the patient's anatomy.

[0060] The outwardly tapered middle section 62 of the self-expanding frame 50 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy. Among other things, the tapered sections 60, 62 of the proximal component 12 permit the placement of the stents 24 that extend from the distal component 14 to the coronary arteries, as described in greater detail below.

[0061] The elongated distal section 64 of the self-expanding frame 50 extends distally from the proximal end 74 to the distal end 30 of the component 12. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 25 mm and has a diameter 80 of approximately 28 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the

distal section 64 may taper between the proximal end 74 and the distal end 30.

[0062] As shown in FIG. 3, the proximal section 60 of the self-expanding frame 50 is formed in an open-cell stent configuration, and the sections 62, 64 are formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 60, 62, 64 may be formed in a single configuration, including an open-cell stent configuration or Z-stent configuration. The sections 60, 62, 64 may also be formed as a single monolithic component. The outer surface 82 of the self-expanding frame 50 is covered with low profile polyester, ePTFE, or other nonporous covering material 84 such that fluid is prevented from passing through the surface 82. In that way, the entire outer surface of the component 12 is covered to prevent fluid from passing therethrough. The covering material 84 immediately distal to the balloon-expandable frame 34 is equipped with a "trap door" 86, which may be opened to permit the passage of one or more surgical instruments for embolization of possible paravalvular leaks. The entire outer surface of component 12 may be also covered with low-profile Dacron or other synthetic material. It should also be appreciated that all or part of the component 12 may be covered with hydrogel or other sealing material.

[0063] As described above, the device 10 also includes a distal component 14, which is secured to the distal end 30 of the proximal component 12 when the device 10 is implanted in the patient's aorta 16. Referring now to FIG. 4, the distal component 14 includes a frame 100 that extends from a proximal end 102 configured to be secured to the proximal component 12 to a distal end 104. The frame 100 has a passageway 106 defined therein, which extends through the ends 102, 104 of the component 14. The passageway 106 has a diameter 108 and is sized to receive the distal end 30 of the proximal component 12 when the device 10 is assembled.

[0064] In the illustrative embodiment, the components 12, 14 are secured together via an interference fit between the frame 100 and the distal end 30 of the proximal component 12. Specifically, the diameter 108 of the passageway 106 is less than the diameter 80 of the proximal component 12.

In the illustrative embodiment, the diameter 108 is equal to approximately 26 mm. It should be appreciated that in other embodiments the components 12, 14 may be secured together via stitching or other fastening means.

[0065] As shown in FIG. 4, the component 14 includes a proximal frame 110 that is connected to an elongated distal frame 112. The proximal frame 110 and the distal frame 112 are formed from metallic materials, such as, nitinol, stainless steel, or other implant grade metallic materials. It should be appreciated that in other embodiments the frames 110, 112 may be formed from a polymeric material. The proximal frame 110 is formed in a Z-stent configuration, and the distal frame 112 is formed in an open-cell configuration. Each of the frames 110, 112 is self-expanding. In the illustrative embodiment, the distal frame 112 is secured to the distal end 114 of the proximal frame 110 by stitching or sewing the frames 110, 112 together. It should be appreciated that in other embodiments the frames 110, 112 may be secured together via welding or other fasteners. The frames 110, 112 may also be formed as a single, monolithic frame.

[0066] The proximal frame 110 has an outer surface 120 that is covered with low profile polyester, ePTFE, or other nonporous covering material 122. As a result, fluid is prevented from passing through the surface 120. The distal frame 112 is uncovered such that fluid is permitted to pass through the openings 124 formed therein.

[0067] As shown in FIG. 4, the proximal frame 110 includes a proximal section 126, an outwardly tapered section 128 extending distally from the proximal section 126, and an elongated distal section 130. The proximal section 126 includes the proximal end 102 of the component 14 and has a distal end 132 connected to the proximal end 134 of the outwardly tapered section 128. In the illustrative embodiment, the proximal section 126 has a length 136 of approximately 25 mm. It should be appreciated that in other embodiments the dimensions of the section 126 may vary depending on, for example, the patient's anatomy.

[0068] The tapered section 128 of the frame 110 has the proximal end 134 and a distal end 140 connected to the proximal end 142 of the elongated

distal section 130. The section 128 tapers outwardly from a diameter of approximately 26 mm at the end 132 to a diameter between approximately 44 mm and 48 mm at the end 140. In the illustrative embodiment, the tapered section 128 has a length 146 of approximately 10 mm. It should be appreciated that in other embodiments the dimensions of the section 128 may vary depending on, for example, the patient's anatomy.

[0069] The elongated distal section 130 of the frame 110 extends distally from the proximal end 142 to the distal end 114 of the frame 110. In the illustrative embodiment, the section 130 has a length 150. In one particular non-limiting example, the length 150 of the elongated distal section 130 is approximately 20 mm. The section 130 also has a diameter 152 of between approximately 44 mm and 48 mm. In other embodiments, the dimensions of the section 130 may vary depending on, for example, the patient's anatomy.

[0070] As described above, the distal component 14 also includes a pair of conduits 22, which are connected to the proximal frame 110. Each conduit 22 has a distal end 160 secured to the tapered section 128 of the frame 110 and a proximal end 162 positioned adjacent to the proximal end 102 of the component 12. As shown in FIG. 4, the conduit 22 does not extend beyond the proximal end 102 of the component 12. Each conduit 22 has a passageway 164 that extends through the ends 160, 162 and is sized to receive a stent 24.

[0071] The passageway 164 has a proximal opening 166 defined in the end 162. The opening 166 has a diameter 168 that in the exemplary embodiment is equal to approximately 5 mm. As shown in FIG. 5, the passageway 164 has a distal opening 170 that is defined in the end 160 and the tapered section 128 of the frame 110. The distal opening 170 has a diameter 172 that is greater than the diameter 168. In the illustrative embodiment, the diameter 172 is equal to approximately 8 mm. The passageway 164 measures approximately 8 mm in diameter over a distance 174 of approximately 5 mm and tapers smoothly into the approximately 5 mm diameter 168 at a junction 176. The passageway 164 maintains the diameter 168 between the junction 176 and the proximal opening 166. In the

illustrative embodiment, the passageway 164 has a length 180 of approximately 2 cm between the junction 176 and the proximal opening 166.

[0072] Each conduit 22 is wire reinforced and allows for passage of catheters or stents 24 and easier cannulation of the coronary ostia, regardless of deployment orientation. This configuration allows stenting of the coronary arteries 182 (see FIG. 1) prior to the deployment of component 12, as described in greater detail below. In the illustrative embodiment, the tapered 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 sinu tubular junction and the device 10 itself.

[0073] As shown in FIG. 4, the elongated distal frame 112 of the component 14 extends distally from the distal end 114 of the frame 110 to the distal end 104 of the component 14. In the illustrative embodiment, the frame 112 has a length 190. In one particular non-limiting example, the length 190 of the elongated frame 112 is approximately 10 cm, which is sufficient to cover the arch 20 of the aorta 18 when implanted therein. In other embodiments, the dimensions of the frame 112 may vary depending on, for example, the patient's anatomy. The distal frame 112 permits the accurate deployment of component 14 without compromising the circulation to supra-aortic branches. It also allows for cannulation of the supra-aortic branches, if placement of a fenestrated/ branch arch device is necessary.

[0074] To implant the device 10 in the patient's aorta 16, a surgeon may obtain open exposure or percutaneous access to the common femoral artery. The iliac arteries or an iliac conduit may also be used. After obtaining access and placing a stiff wire in the ascending aorta 18, the device 10 and the delivery system are prepared. In the illustrative embodiment, the delivery system is composed of a 100-105 cm hydrophilic sheath. As shown in FIG. 6, the distal component 14 is delivered first. After performing a lateral oblique thoracic aortogram, the component 14 is deployed such that the distal end 114 of the proximal frame 110 is positioned proximal to the innominate artery 200, thereby ensuring that the distal openings 170 of the conduits 22 are at 12 and 6 o'clock positions in relationship to the innominate artery 200.

[0075] Using the contralateral common femoral artery wires, standard coronary guide catheters are introduced through the distal frame 112 of the component 14 into each conduit 22. The conduits 22 may then be cannulated with the catheters prior to insertion of the stents 24. Alternatively, the conduits 22 may be pre-cannulated. Using the catheters, access is obtained to the right and left coronary arteries 182. The stents 24 are advanced into the passageways 164 through the distal openings 170 and out of the conduits 22 to bridge the arteries 182 and the conduits 22, as shown in FIG. 7. In that way, each artery 182 is connected to its respective conduit 22. Each stent 24 is covered and may be embodied as a balloon-expandable stent or a self-expanding stent. It should be appreciated that coronary artery bypasses may be performed to the right and left coronary systems prior to the placement of the component 14.

[0076] The proximal component 12 may be deployed after the implantation of the distal component 14. The components 12, 14 may be deployed in a single surgical procedure taking place on a single day or the component 14 may be deployed in one procedure, and the component 12 may be deployed in another, separate procedure at a later date. As shown in FIG. 1, the proximal component 12 is deployed into the position across the native aortic valve 202.

[0077] To do so, a stiff wire is passed through the aortic valve 202 into the left ventricle 204. The delivery system for the proximal component 12 is passed through the valve 202. An example of a delivery system is described in U.S. Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft" by Julio C. Palmaz, which is incorporated herein by reference. When the delivery system is in position, the proximal component 12 is released by unsheathing the system, thereby permitting expansion of the self-expanding frame 50. As described above, the self-expanding frame 50 engages the proximal end 102 of the distal component 14 to secure the components 12, 14 together and seal the distal end 30 of the component 12 within the distal component 14. As shown in FIG. 2, the proximal end 28 of the proximal component 12 is

positioned in the aortic annulus, and the hour-glass shape of the component 12 provides a space for the native aortic valve leaflets such that the leaflets are not pressed against or over the openings of coronary arteries 182.

[0078] The balloon-expandable frame 34 may be now deployed by inflating the balloon within the delivery system. This deploys the frame 34 to the predetermined expanded diameter 46 and advances the frame 34 into engagement with the aortic annulus 210, thereby sealing the aortic annulus 210 such that fluid is permitted to pass from the left ventricle 204 only through the valve 32. As shown FIG. 1, the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182. It should be appreciated that the deployment of the component 12 may be performed during rapid ventricular pacing (RVP). In cases with aortic stenosis, the valve 32 may be dilated with balloon angioplasty prior to the introduction of the proximal component 12.

[0079] Referring now to FIGS. 8-16, another embodiment of a proximal component 212 of the device 10 is shown. Some features of the embodiment illustrated in FIGS. 8-16 are substantially similar to those described above in reference to the embodiment of FIGS. 1-7. Such features are designated in FIGS. 8-16 with the same reference numbers as those used in FIGS. 1-7. Similar to the proximal component 12 of FIGS. 1-7, the proximal component 212 may be secured to the distal component 14 when implanted into a patient's aorta 16. When implanted, the proximal component 212 is positioned in the patient's ascending aorta 18, while the distal component 14 extends distally into the arch 20 of the patient's aorta 16.

[0080] As shown in FIG. 8, the proximal component 212 includes a dual-frame 214 that extends from a proximal end 28 to a distal end 30. The frame 214 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 212. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. It should be appreciated that in other embodiments the valve 32 may be tricuspid or quadracuspid. The valve 32 may be constructed from treated bovine pericardium or other suitable proven biological or synthetic material. When the proximal component 212 is

implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the proximal component 212.

[0081] The dual-frame 214 of the proximal component 212 includes a self-expanding outer frame 216 and a balloon-expandable inner frame 218 that is secured to the self-expanding outer frame 216 and houses the valve 32. Referring now to FIG. 9, the self-expanding outer frame 216 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the outer frame 216 may be formed from a polymeric material. The outer frame 216 includes an elongated proximal section 220, an inwardly tapered section 222, an outwardly tapered middle section 62, and an elongated distal section 64.

[0082] The elongated proximal section 220 of the outer frame 216 includes the proximal end 28 of the component 212 and has a distal end 224 connected to a proximal end 226 of the inwardly tapered section 222. The proximal section 220 is embodied as a tubular stent. It should be appreciated that in other embodiments the section 220 may be shaped as a prism, cone, or other geometric shape depending on the patient's anatomy.

[0083] In the illustrative embodiment, the proximal section 220 has a length 228 that is equal to approximately 15 mm. The proximal section 220 also has a diameter 230 of approximately 32 mm. It should be appreciated that in other embodiments the dimensions of the frame 216 may vary according to the anatomy of the patient. In the illustrative embodiment, the diameter 230 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the proximal section 220 and the annulus 210 when the component 212 is implanted, as described in greater detail below. As shown in FIG. 9, the proximal section 220 defines a passageway 232 in the outer frame 216.

[0084] In the illustrative embodiment, collagen fibers 234 are attached to the proximal section 220 to aid in preventing paravalvular leaks and migration of the proximal component 212 within the aortic walls. The fibers 234 extend

outwardly from the proximal section 220 and inwardly into the passageway 232. It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials. In other embodiments, a plurality of barbs or hooks may be attached to the proximal section 220. The hooks may be configured to further engage the tissue of the aorta and inhibit or prevent migration of the device 10.

[0085] The inwardly tapered section 222 of the outer frame 216 includes the proximal end 226 and has a distal end 236 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 222 tapers inwardly between the ends 226, 236 from approximately 32 mm at the end 226 to approximately 22 mm at the end 236. In the illustrative embodiment, the inwardly tapered section 222 has a length 238 of approximately 10 mm.

[0086] The outwardly tapered middle section 62 of the self-expanding frame 216 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy.

[0087] The elongated distal section 64 of the self-expanding frame 216 extends distally from the proximal end 74 to the distal end 30 of the component 212. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 30 mm and has a diameter 80 of approximately 34 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[0088] As shown in FIG. 9, the proximal section 220 and the inwardly tapered section 222 of the self-expanding frame 216 are formed in an open-

cell stent configuration, and the sections 62, 64 are formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 62, 64, 220, 222 may be formed in a single configuration, including an open-cell stent configuration or Z-stent configuration. The sections 62, 64, 220, 222 may also be formed as a single monolithic component. The outer surface 240 of the sections 62, 64, 222 are covered with low profile polyester, ePTFE, or other nonporous covering material 242 such that fluid is prevented from passing through the surface 240. The covering material 242 immediately distal to the proximal section 220 is equipped with a "trap door" 86, which may be opened to permit the passage of one or more surgical instruments for embolization of possible paravalvular leaks. The outer surface 240 of the sections 62, 64, 222 may be also covered with low-profile Dacron or other synthetic material. It should also be appreciated that all or part of the frame 216 may be covered with hydrogel or other sealing material.

[0089] As described above, the outer frame 216 of the dual-frame 214 is secured to a balloon-expandable inner frame 218, which is positioned in the passageway 232. As shown in FIG. 10, the frame 218 houses the valve 32. The balloon-expandable frame 218 is embodied as a balloon-expandable tubular stent 244 that has a length 246 of approximately 15 mm. In other embodiments, the stent 244 may be longer or shorter depending on, for example, the patient's anatomy. The stent 244 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 244 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface 248 of the stent 244 is covered with low-profile polyester, ePTFE, or other nonporous covering material 250 that prevents fluid from passing through the outer surface 248. However, it should be appreciated that the stent 244 may be covered with standard polyester, ePTFE or other nonporous materials.

[0090] As shown in FIG. 10, the stent 244 of the inner frame 218 has a diameter 252. As described in greater detail below, the balloon-expandable

frame 218 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 252. In the illustrative embodiment, the expanded diameter 252 is equal to approximately 26 mm when the inner frame 218 is expanded. In other embodiments, the expanded diameter may be equal to, or greater than, the diameter 230 of the proximal section 220 of the outer frame 216. In the illustrative embodiment, the expanded diameter 252 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the proximal section 220 and the annulus 210 when the component 212 is implanted, and the inner frame 218 is expanded, as described in greater detail below.

[0091] Referring now to FIG. 11, the inner frame 218 of the dual-frame component 214 is secured to the outer frame 216 via a plurality of stitches 260. It should be appreciated that in other embodiments soldering, welding or other fasteners may be used to secure the inner frame 218 to the outer frame 216. As shown in FIGS. 11-14, the inner frame 218 and the valve component 32 are positioned in the passageway 232 defined in the self-expanding frame 216. When the inner frame 218 is unexpanded, the outer surface 248 of the stent 244 is spaced apart from the fibers 234 attached to the outer frame 216. In the illustrative embodiment, a gap 264 is defined therebetween, and the gap 264 has a magnitude of about 2 mm to about 3 mm.

[0092] As shown in FIG. 14, the balloon-expandable inner frame 218 may be expanded in the direction indicated by arrows 266. As described above, the diameter 230 of the proximal section 220 of the outer frame 216 is oversized relative to the diameter of the aortic annulus 210. As such, when the component 212 is implanted, the proximal section 220 is reduced to the diameter of the annulus 210. Because the expanded diameter 252 of the stent 244 is greater than the diameter of the annulus, the outer surface 248 of the stent 244 engages the fibers 234 (and hence the inner surface of the proximal section 220 of the outer frame 216) through the covering material 250. In that way, the gap 264 is closed, and the fibers 234 and the covering material 250 create a seal between the inner frame 218 and the outer frame 216.

[0093] To implant an endograft device 10 that includes proximal component 212 in the patient's aorta 16, a surgeon may obtain open exposure or percutaneous access to the common femoral artery. The surgeon may then implant the distal component 14 in the manner described above in regard to FIGS. 1-7 and advance the stents 24 into position in the arteries 182. The proximal component 212 may be deployed after the implantation of the distal component 14. To do so, a stiff wire is passed through the aortic valve 202 into the left ventricle 204. The delivery system for the proximal component 212 is then passed through the valve 202.

[0094] When the delivery system is in position, the proximal component 212 is released by unsheathing the system, thereby permitting expansion of the self-expanding frame 216. The self-expanding frame 216 engages the proximal end 102 of the distal component 14 to secure the components 212, 14 together and seal the distal end 30 of the component 212 within the distal component 14.

[0095] When the frame 216 is unsheathed, the proximal section 220 expands into engagement with the aortic annulus 210, thereby creating an interference fit between the frame 216 and the annulus 210 and stabilizing the device 10 in place. As shown in FIG. 15, the inner frame 218 is initially unexpanded within the outer frame 216. The inner frame 218 may be deployed by expanding the balloon assembly. Expansion of the balloon-expandable inner frame 218 engages the inner frame 218 with the outer frame 216 and compresses the collagen fiber/ hydrogel coated proximal section 220 of the outer frame 216 against the aortic annulus 210. As shown in FIG. 16, the combined engagement of the frames 216, 218 seals the annulus 210 and the paravalvular areas, and thus, prevents paravalvular leakage. As such, fluid is permitted to pass from the left ventricle 204 only through the valve 32 of the component 212. As shown FIGS. 15-16, the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182. It should be appreciated that the deployment of the component 212 may be performed during rapid ventricular pacing (RVP). In cases with aortic stenosis, the valve

32 may be dilated with balloon angioplasty prior to the introduction of the proximal component 212.

[0096] In each of the embodiments described above, the self-expanding frame portion of proximal components 12, 212 significantly improves the accuracy and control of the deployment of the device 10. The bicuspid configuration of the valve 32 serves three distinct purposes, including (1) by reducing the number of valve commissures to two, the profile will be reduced, (2) the valve 32 may conform better to the aortic annulus, and (3) when the annulus is asymmetrical, the incidence of aortic insufficiency may be reduced.

[0097] Referring now to FIGS. 17-22, the proximal component 12 or the proximal component 212 may be used as a transcatheter valve with slight modification. Such a valve may be deployed via a transfemoral or trans-axillary route, as will be described in further detail below.

[0098] Referring now to FIGS. 17-19, one embodiment of a transcatheter valve component 312 is shown. Some features of the embodiment illustrated in FIGS. 17-19 are substantially similar to those described above in reference to the proximal component 12 of FIGS. 1-7. Such features are designated in FIGS. 17-19 with the same reference numbers as those used in FIGS. 1-7. Similar to the proximal component 12 of FIGS. 1-7, the transcatheter valve component 312 includes a frame 26 that extends from a proximal end 28 to a distal end 30. The frame 326 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the valve component 312. When the valve component 312 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the valve component 312.

[0099] The valve 32 is housed in a balloon-expandable frame 34 of the frame 26. As shown in FIG. 17, the balloon-expandable frame 34 is embodied as a balloon-expandable stent 38 that extends distally from the proximal end 28 of the transcatheter valve component 312 and has a length 40 of approximately 15 mm. In other embodiments, the stent 38 may be longer or shorter depending on, for example, the patient's anatomy. The stent 38 is

tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent 38 may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface 42 of the stent 38 is covered with low-profile polyester, ePTFE, or other nonporous covering material 44 that prevents fluid from passing through the outer surface 42. However, it should be appreciated that the stent 38 may be covered with standard polyester, ePTFE or other nonporous materials.

[00100] As shown in FIG. 17, the stent 38 of the balloon-expandable frame 34 has a diameter 46. As described in greater detail below, the balloon-expandable frame 34 is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter 46. In the illustrative embodiment, the expanded diameter 46 is equal to approximately 26 mm when the frame 34 is expanded. In other embodiments, the expanded diameter may be greater than or less than 26 mm depending on, for example, the patient's anatomy. In the illustrative embodiment, the diameter 46 is oversized relative to the diameter of the aortic annulus 210 such that an interference fit is created between the stent 38 and the annulus 210 when the transcatheter valve component 312 is implanted.

[00101] The balloon-expandable frame 34 is attached to a self-expanding frame 350. In the illustrative embodiment, the distal end 52 of the balloon-expandable frame 34 is secured to the proximal end 54 of the frame 350 by stitching or sewing the frames 34, 350 together, thereby forming the frame 26 of the transcatheter valve component 312. It should be appreciated that in other embodiments the frames 34, 350 may be secured together via welding or other fasteners. The frames 34, 350 may also be formed as a single, monolithic frame.

[00102] As shown in FIG. 17, the self-expanding frame 350 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the frame 350 may be formed from a

polymeric material. The frame 350 includes an inwardly tapered proximal section 360, an outwardly tapered middle section 62, and an elongated distal section 64. The section 360 includes the proximal end 54 of the frame 350 and has a distal end 66 connected to the proximal end 68 of the outwardly tapered middle section 62. The section 360 tapers inwardly between the ends 54, 66 from approximately 26 mm at the end 54 to approximately 22 mm at the end 66. In the illustrative embodiment, the proximal section 360 has a length 70 of approximately 15 mm.

[00103] The outwardly tapered middle section 62 of the self-expanding frame 350 has the proximal end 68 and a distal end 72 connected to the proximal end 74 of the elongated distal section 64. The section 62 tapers outwardly from a diameter of approximately 22 mm at the end 68 to a diameter of approximately 28 mm at the end 72. In the illustrative embodiment, the middle section 62 has a length 76 of approximately 10 mm. In other embodiments, the dimensions of the section 62 may vary depending on, for example, the patient's anatomy.

[00104] The elongated distal section 64 of the self-expanding frame 350 extends distally from the proximal end 74 to the distal end 30 of the valve component 312. In the illustrative embodiment, the section 64 has a length 78 that is greater than the combined length of the tapered sections 60, 62. In one particular non-limiting example, the length 78 of the elongated distal section 64 is approximately 30 mm and has a diameter 80 of approximately 34 mm. In other embodiments, the dimensions of the section 64 may vary depending on, for example, the patient's anatomy. In one exemplary embodiment, the distal section 64 may taper between the proximal end 74 and the distal end 30.

[00105] As shown in FIG. 3, the proximal section 360 of the self-expanding frame 350 is formed in an open-cell stent configuration, and each of the sections 62, 64 is formed in a Z-stent configuration. It should be appreciated that in other embodiments the sections 360, 62, 64 may be formed in a single configuration, including the open-cell stent configuration,

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

[00106] As shown in FIG. 17, the outer surface 314 of the proximal section 360 of the frame 350 is uncovered such that fluid is permitted to pass through the openings 318. The outer surface 316 of the sections 62, 64 are covered with low profile polyester, ePTFE, or other nonporous covering material 84 such that fluid is prevented from passing through the surface 320. The outer surface 320 of the valve component 312 may also be covered with low-profile Dacron or other synthetic material. The uncovered, open cell stent section 360 is configured to allow for coronary artery perfusion. The covered sections 62, 64 serve to stabilize the valve component 312 against the aorta 18 and provide a docking station to ascending aortic extensions or fenestrated/ branch arch grafts. The covered sections 62, 64 would also permit endograft extension of the valve component 312 for suitable type B aneurysms without dilation of the sinu tubular junction.

[00107] The delivery of the transcatheter valve component 312 may begin by gaining access to the left ventricle across the native aortic valve. An ascending aortogram may be performed to locate the right and left coronary arteries. An over the wire introducer system, including a guidewire, is used to introduce the valve component 312 into the aorta 18. After the guidewire has been placed into the left ventricle 204 via the iliofemoral, subclavian, or carotid vessels, the valve component 312 may be delivered through the common femoral artery and passed across the native aortic valve 202. After performing an angiogram to delineate the location of the coronary arteries 182, the valve component 312 is released by unsheathing the delivery system, thereby permitting expansion of the self-expanding frame 350, as shown in FIGS. 18-19.

[00108] The balloon-expandable frame 34 may be now deployed by inflating the balloon within the delivery system. This deploys the frame 34 to the predetermined expanded diameter 46 and advances the frame 34 into engagement with the aortic annulus 210, thereby sealing the aortic annulus 210 such that fluid is permitted to pass from the left ventricle 204 only

through the valve 32 and the valve 32 is positioned in the aortic annulus 210 proximal to the coronary arteries 182, as shown in FIGS. 18-19. The openings 318 of the uncovered section 360 of the valve component 312 permit blood flow to the coronary arteries 182 for promote circulation. It should be appreciated that the deployment of the valve component 312 may be performed during rapid ventricular pacing (RVP).

[00109] Referring now to FIGS. 20-22, another embodiment of a transcatheter valve component (hereinafter valve component 412) is shown. Some features of the embodiment illustrated in FIGS. 20-22 are substantially similar to those described above in reference to the proximal component 212 of FIGS. 8-16. Such features are designated in FIGS. 20-22 with the same reference numbers as those used in FIGS. 8-16. Similar to the proximal component 212 of FIGS. 8-16, the valve component 412 includes a dual-frame 414 that extends from a proximal end 28 to a distal end 30. The frame 414 is attached to a valve 32 (shown in phantom), which is positioned at the proximal end 28 of the component 412. In the illustrative embodiment, the valve 32 is configured as a bicuspid valve. When the valve component 412 is implanted into the patient's aorta 16, the valve 32 replaces the aortic valve and permits fluid (i.e., blood) to selectively pass from the heart and into a passageway 36 extending through the valve component 412.

[00110] The dual-frame 414 includes a self-expanding outer frame 416 and a balloon-expandable inner frame 218 that is secured to the self-expanding outer frame 416 and houses the valve 32. Referring now to FIG. 9, the self-expanding outer frame 416 has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the outer frame 416 may be formed from a polymeric material. The outer frame 416 includes an elongated proximal section 220, an inwardly tapered section 422, an outwardly tapered middle section 62, and an elongated distal section 64.

[00111] The elongated proximal section 220 of the outer frame 416 includes the proximal end 28 of the component 412 and has a distal end 224

connected to a proximal end 226 of the inwardly tapered section 222. The proximal section 220 is embodied as a tubular stent. It should be appreciated that in other embodiments the section 220 may be shaped as a prism, cone, or other geometric shape depending on the patient's anatomy.

[001 12] 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.

[001 13] 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.

[001 14] 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.

[001 15] 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.

[001 16] 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.

[001 17] 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.

[001 18] As described above, the outer frame 416 of the dual-frame 414 is secured to a balloon-expandable inner frame 2 18, which is positioned in the passageway 232 and houses the valve 32. As described above, the balloon-expandable frame 2 18 is expandable during implantation from an unexpanded diameter 450 to the expanded diameter (not shown).

[001 19] 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 2 10, thereby creating an interference fit between the frame 416 and the annulus 2 10 and stabilizing the valve component 412 in place. As shown in FIG. 2 1, the inner frame 2 18 is initially unexpanded within the outer frame 416. The inner frame 2 18 may be deployed by expanding the balloon assembly. Expansion of the balloon-expandable inner frame 2 18 engages the inner frame 2 18 with the outer frame 416 and compresses the collagen fiber/ hydrogel coated proximal section 220 of the outer frame 416 against the aortic annulus 2 10.

[00120] As shown in FIG. 22, the combined engagement of the frames 2 18, 416 seals the annulus 2 10 and the paravalvular areas, and thus, prevents paravalvular leakage. As such, fluid is permitted to pass from the left ventricle 204 only through the valve 32 of the component 412. The openings 446 of the uncovered section 422 of the valve component 412 permit blood flow to the coronary arteries 182 for promote circulation.

[00121] It should be appreciated that the design of components 12, 14, 2 12 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, 2 12, paravalvular leaks may be corrected. More specifically, with respect to a paravalvular leak (type la endoleak), leakage around the valve 32 would act as a type la endoleak. The trapdoors 86 in components 12, 312 would allow for

coil embolization of the area of the leak. Two trapdoors at 180 degree location would allow access to the entire area above the aortic annulus. Since the coronary arteries 182 are protected by the conduits 22 in the distal component 14, coil embolization of this area would not compromise the coronary blood flow. Coil embolization of paravalvular leaks are already being performed clinically after heart valve surgery if there are additional leaks around the valve.

[00122] Aortic insufficiency (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.

[00123] Structural valve degeneration may also be corrected. More specifically, the bicuspid valve design allows for placement of another transcatheter valve across the first device without compromising valvular flow area.

[00124] Coronary insufficiency may also be corrected. The Cabrol endo-conduits 22 in conjunction with the tapered section 128 of component 14 ensure uninterrupted coronary blood flow. By first deploying the component 14, the surgeon will be able to work through the Cabrol conduits 22 and using standard catheters and guidewires to cannulate the right and left coronary arteries. Stents 24 are deployed from the coronary arteries into the Cabrol conduits 22. Deployment the component 12 or component 212 may be delayed until coronary blood flow is secured. The tapered design will mitigate the risk of compression of the coronary stents between the device 10 and the aortic wall.

[00125] For the transcatheter valves 312, 412, paravalvular leaks may also be corrected in that the open cell midsections 360, 422 of the valve allow the cannulation and stenting of the coronary arteries with potential coil

embolization of the leak after the protection of the coronary artery if necessary.

[00126] Structural valve degeneration in the transcatheter valves 312, 412 may be corrected in that the bicuspid valve design permit for placement of another transcatheter valve across the first device without compromising valvular flow area.

[00127] The dual frame component may also take the form of other transcatheter valvular replacement devices such as, for example, prosthetic mitral and tricuspid valves. The dual frame component may also be used to enhance sealing zones of endovascular devices to treat abdominal and thoracic aneurysms, and in applications to treat peripheral vascular disease.

[00128] It will be appreciated that the devices and methods described herein have broad applications. The foregoing embodiments were chosen and described in order to illustrate principles of the methods and apparatuses as well as some practical applications. The preceding description enables others skilled in the art to utilize methods and apparatuses in various embodiments and with various modifications as are suited to the particular use contemplated. In accordance with the provisions of the patent statutes, the principles and modes of operation of this disclosure have been explained and illustrated in exemplary embodiments.

[00129] It is intended that the scope of the present methods and apparatuses be defined by the following claims. However, it must be understood that this disclosure may be practiced otherwise than is specifically explained and illustrated without departing from its spirit or scope. It should be understood by those skilled in the art that various alternatives to the embodiments described herein may be employed in practicing the claims without departing from the spirit and scope as defined in the following claims.

[00130] The scope of the disclosure should be determined, not with reference to the above description, but should instead be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. It is anticipated and intended that future developments will occur in the arts discussed herein, and that the disclosed

systems and methods will be incorporated into such future examples. Furthermore, all terms used in the claims are intended to be given their broadest reasonable constructions and their ordinary meanings as understood by those skilled in the art unless an explicit indication to the contrary is made herein. In particular, use of the singular articles such as "a," "the," "said," etc. should be read to recite one 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.

WHAT IS CLAIMED IS:

1. An endograft device for endovascular repair of ascending aortic aneurysms, comprising:

a first prosthetic component comprising (i) a proximal frame, and (ii) a distal frame secured to the proximal frame and extending to a distal end of the first prosthetic component,

at least one conduit secured to the first prosthetic component and positioned adjacent to the proximal frame,

a second prosthetic component secured to a proximal end of the first prosthetic component, the second prosthetic component comprising (i) a balloon-expandable frame extending distally from a proximal end of the second prosthetic component, and (ii) a self-expanding frame connected to the balloon-expandable frame and extending to a distal end of the second prosthetic component, and

a valve element secured to the balloon-expandable frame at the proximal end of the second prosthetic component.

2. The endograft device of claim 1, wherein the self-expanding frame has an hourglass shape.

3. The endograft device of claim 2, wherein the self-expanding frame includes:

a first section that tapers inwardly between a proximal end and a distal end, and

a second section having a proximal end that is connected to the distal end of the first section, the second section tapering outwardly between the proximal end of the second section and a distal end of the second section.

4. The endograft device of claim 3, wherein the proximal end of the first section is secured to a distal end of the balloon-expandable frame.

5. The endograft device of claim 3, wherein:

the self-expanding frame includes a third section extending proximally from the proximal end of the first section, the third section having a passageway defined therein, and

the balloon-expandable frame is positioned in the passageway of the third section of the self-expanding frame.

6. The endograft device of claim 5, wherein the balloon-expandable frame is expandable between (i) an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and (ii) an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

7. The endograft device of claim 6, wherein a plurality of fibers are attached to the third section of the self-expanding frame, and when the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame is engaged with the plurality of fibers.

8. The endograft device of claim 1, wherein the proximal frame of the first prosthetic component has a passageway defined therein, and the distal end of the second prosthetic component is positioned in the passageway of the first prosthetic component.

9. The endograft device of claim 1, wherein the at least one conduit includes a pair of conduits positioned on opposite sides of the first prosthetic component.

10. The endograft device of claim 1, wherein the at least one conduit has a proximal opening that is positioned adjacent to a proximal end of the first prosthetic component.

11. The endograft device of claim 10, wherein the proximal frame includes (i) a first section secured to the distal end of the second prosthetic component, and (ii) a second section connected to the first section, the second section tapering outward between a proximal end connected to the first section and a distal end, and the at least one conduit has a distal opening defined in the second section of the proximal frame.

12. The endograft device of claim 11, further comprising 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.

13. The endograft device of claim 1, wherein:

an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component are covered such that fluid is prevented from passing therethrough, and

an outer surface of the distal frame of the first prosthetic component is uncovered such that fluid is permitted to pass therethrough.

14. A transcatheter valve, comprising:

a frame component comprising:

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 including (i) a first section that tapers inwardly between a proximal end and a distal end, and (ii) a second section that tapers outwardly between a proximal end secured to the distal end of the first section and a distal end, and

a valve element positioned in the balloon-expandable frame at the proximal end of the frame component.

15. The transcatheter valve of claim 14, wherein:

the frame component is a dual-frame component,

the self-expanding frame is an outer frame of the dual-frame component and has a passageway defined therein,

the balloon-expandable frame is an inner frame of the dual-frame component and is positioned in the passageway defined in the self-expanding frame, and

the balloon-expandable frame is expandable between (i) an unexpanded position in which an outer surface of the balloon-expandable frame is spaced apart from an inner surface of the self-expanding frame and (ii) an expanded position in which the outer surface of the balloon-expandable frame is engaged with the inner surface of the self-expanding frame.

16. The transcatheter valve of claim 15, wherein a plurality of fibers are attached to the self-expanding frame, and when the balloon-expandable frame is in the expanded position, the outer surface of the balloon-expandable frame is engaged with the plurality of fibers.

17. The transcatheter valve of claim 14, wherein an outer surface of the first section of the self-expanding frame is uncovered such that fluid is permitted to pass therethrough and an outer surface of the second section of the self-expanding frame is covered such that fluid is prevented from passing therethrough.

18. The transcatheter valve of claim 14, wherein the self-expanding frame includes an elongated section extending distally from the second section, the elongated section having a length that is greater than a combined length of the first section and the second section.

19. The transcatheter valve of claim 14, wherein the self-expanding frame is covered with at least one of a collagen or hydrogel.

20. The transcatheter valve of claim 14, wherein the valve element is one of a bicuspid valve and a tricuspid valve.

21. A method of repairing a patient's aorta, comprising:

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 element secured to the proximal section is positioned in the aortic annulus proximal to the coronary arteries.

22. The method of claim 21, wherein expanding the proximal section of the second prosthetic component includes operating a balloon-expandable frame.

23. The method of claim 22, wherein expanding the proximal section of the second prosthetic component includes:

permitting a self-expanding frame to expand into engagement with the aortic annulus, and

operating the balloon-expandable frame includes 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.

24. The method of claim 22, wherein operating the balloon-expandable frame includes advancing an outer surface of the balloon-expandable frame into engagement with the aortic annulus.

25. The method of claim 21, wherein:

an outer surface of the second prosthetic component and an outer surface of the proximal frame of the first prosthetic component are covered such that fluid is prevented from passing therethrough, and

an outer surface of the distal frame of the first prosthetic component is uncovered such that is permitted to pass therethrough.

26. The method of claim 21, wherein:

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 are performed during a first surgical procedure, and

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 are performed during a second surgical procedure different from the first surgical procedure.

27. The method of claim 21, further comprising introducing the second prosthetic component into the ascending aorta prior to introducing the first prosthetic component.

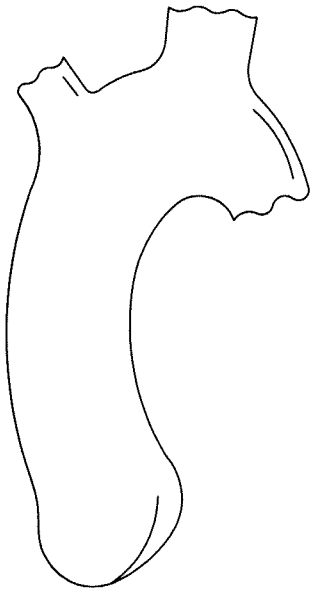


Fig. 1

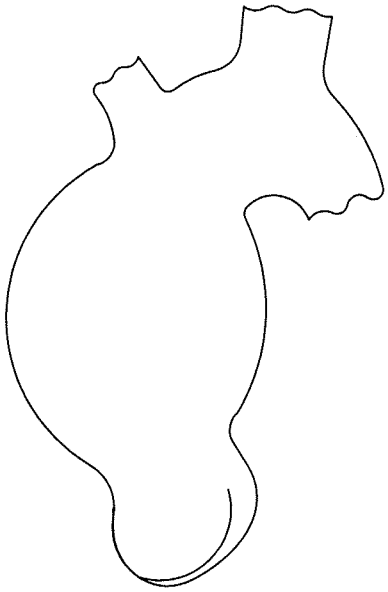


Fig. 1B

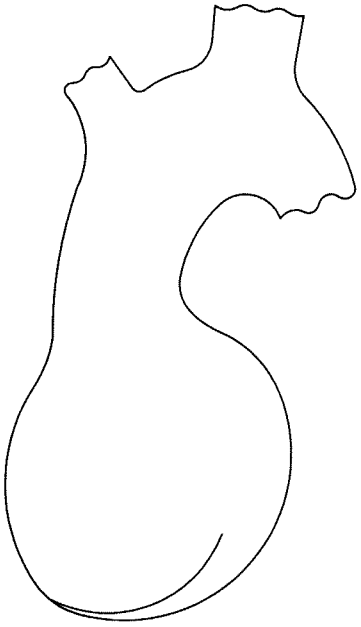


Fig. 1A

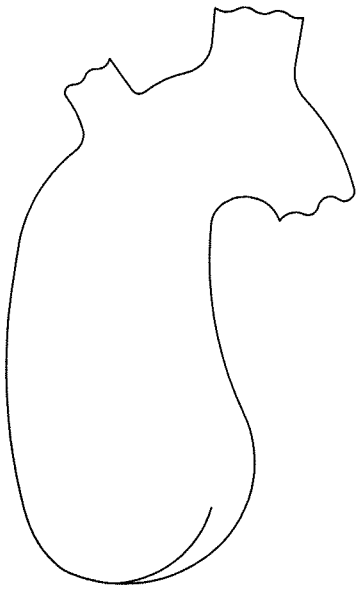


Fig. 1C

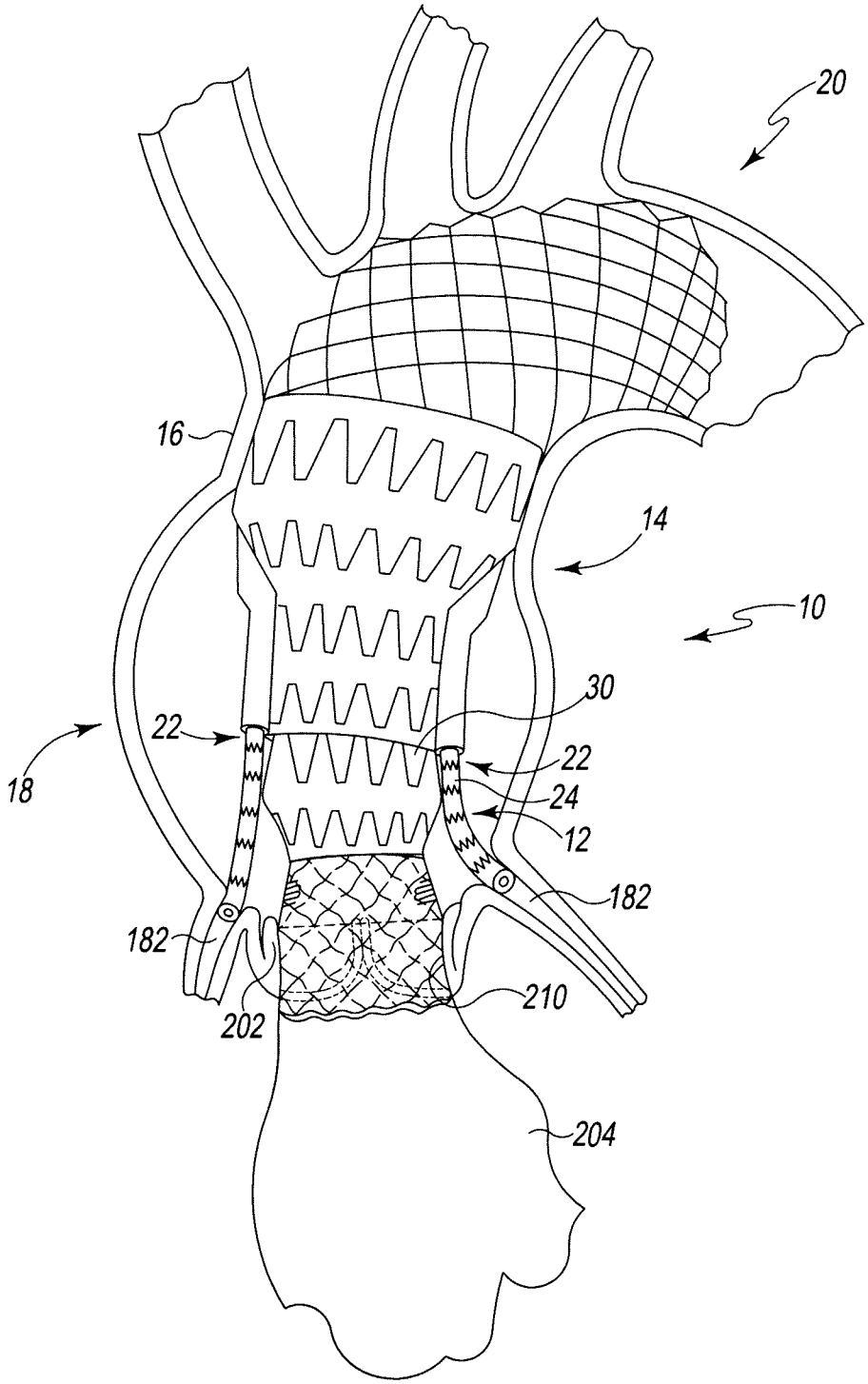


Fig. 2

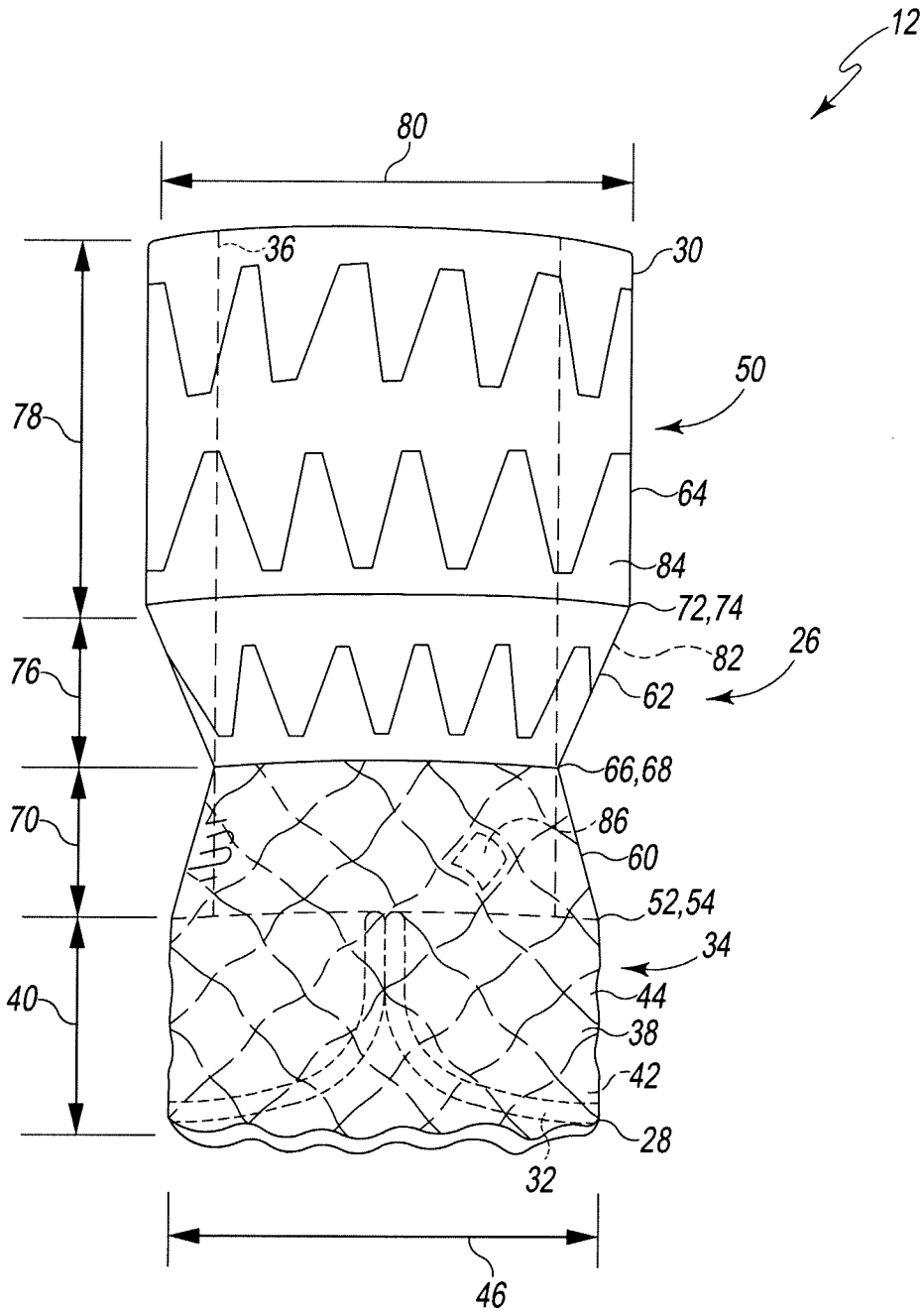

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Fig. 3

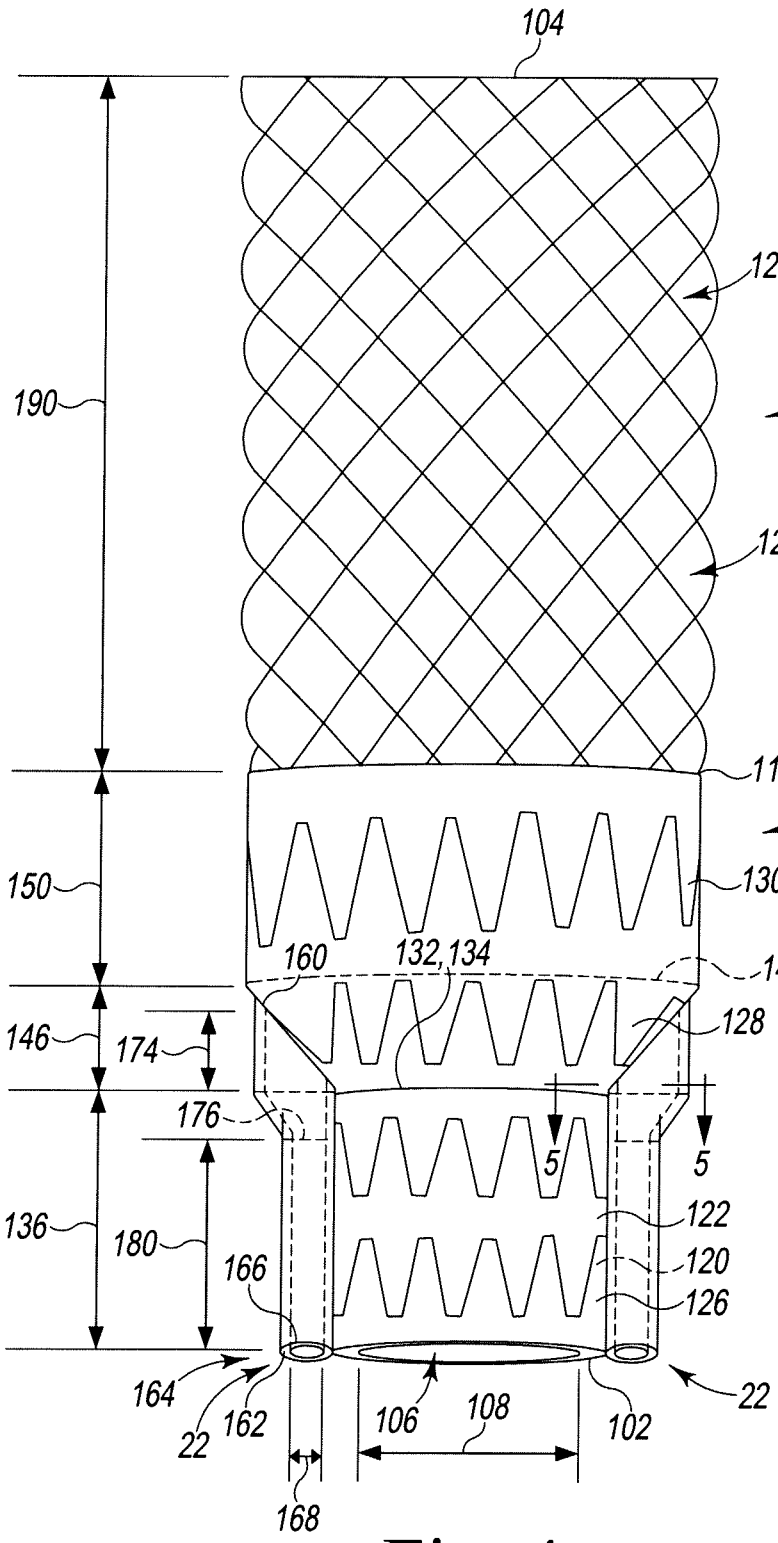

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Fig. 4

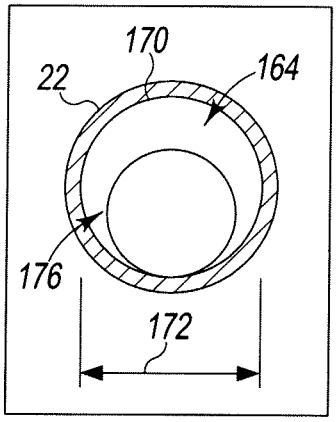

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Fig. 5

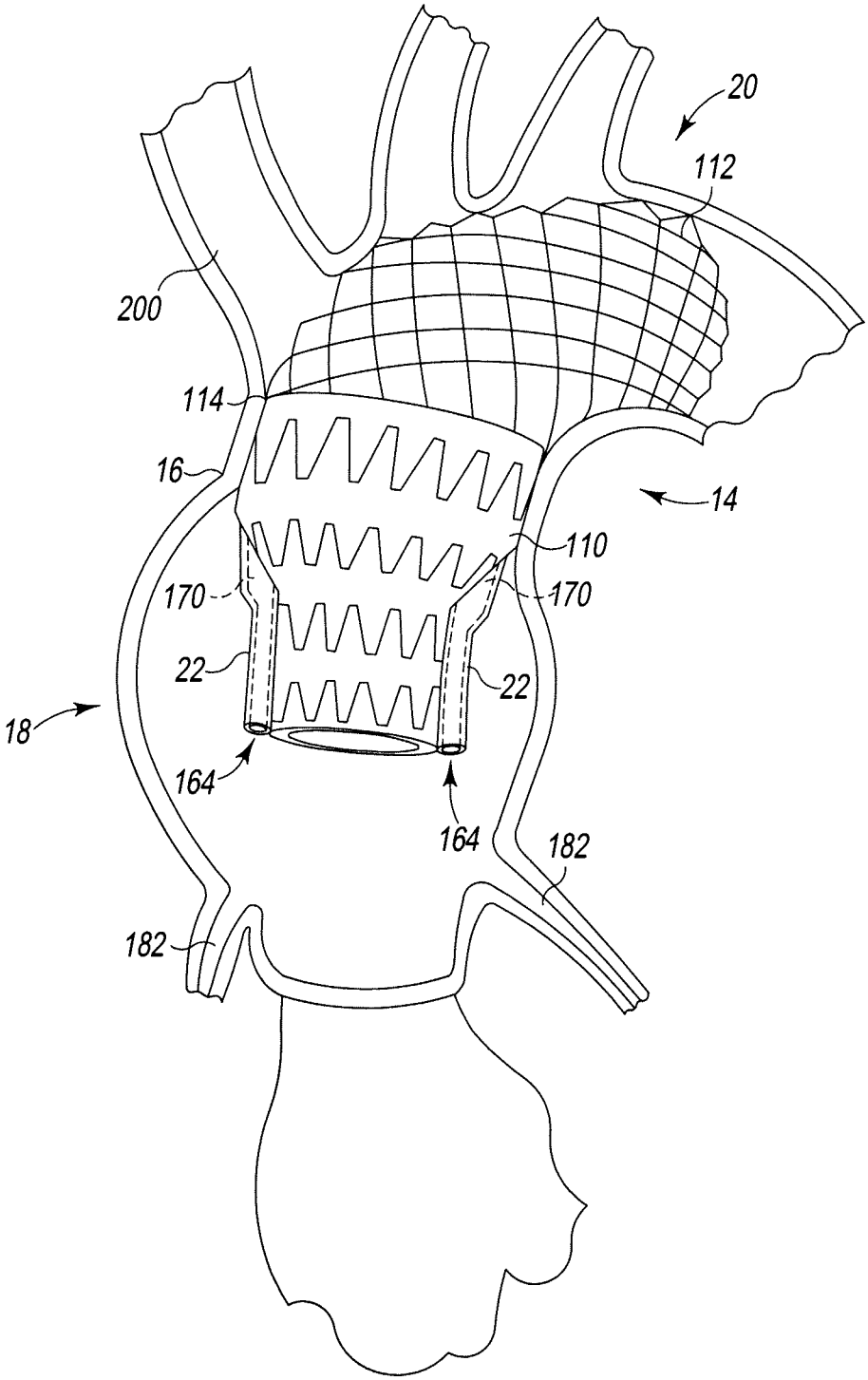


Fig. 6

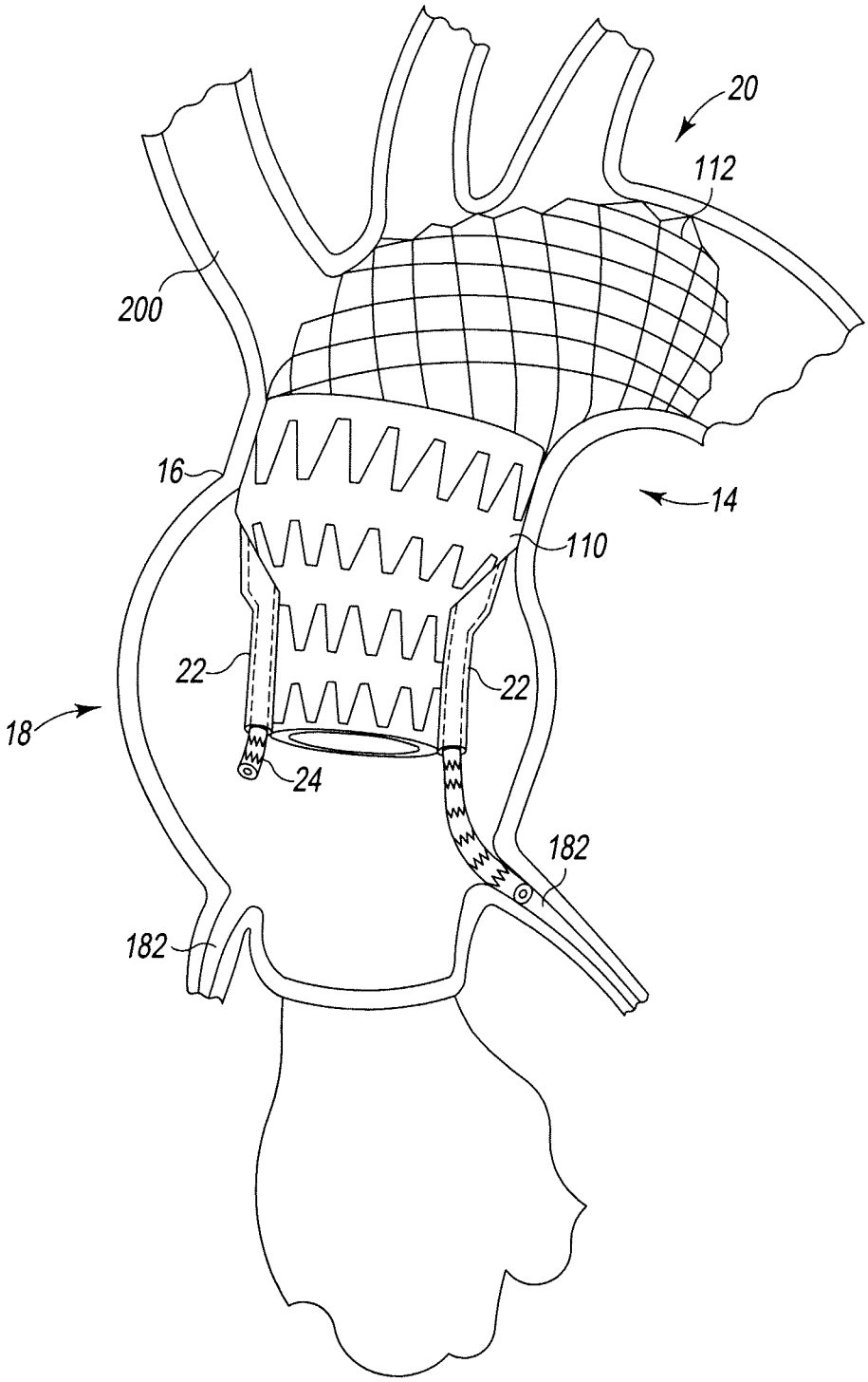


Fig. 7

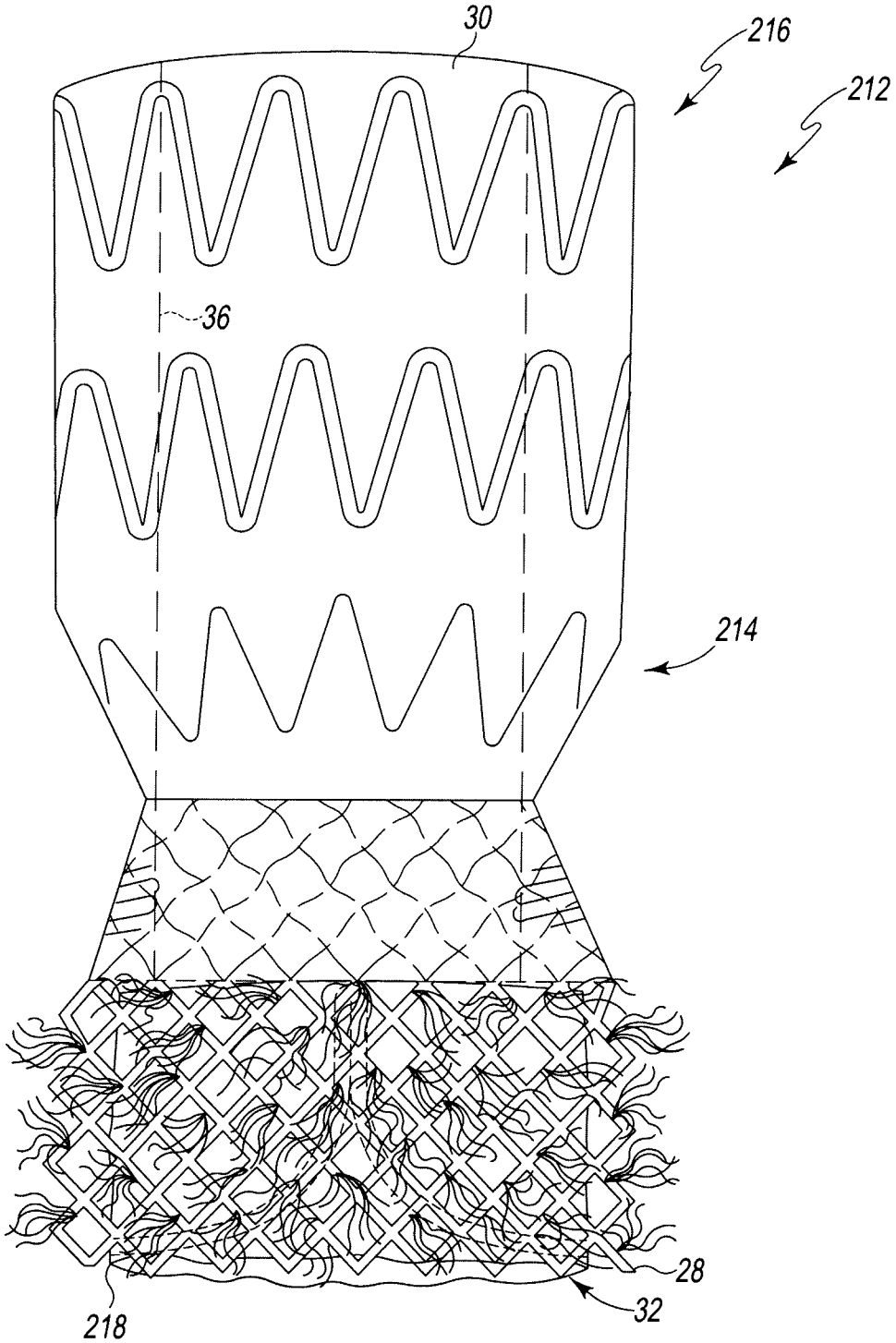


Fig. 8

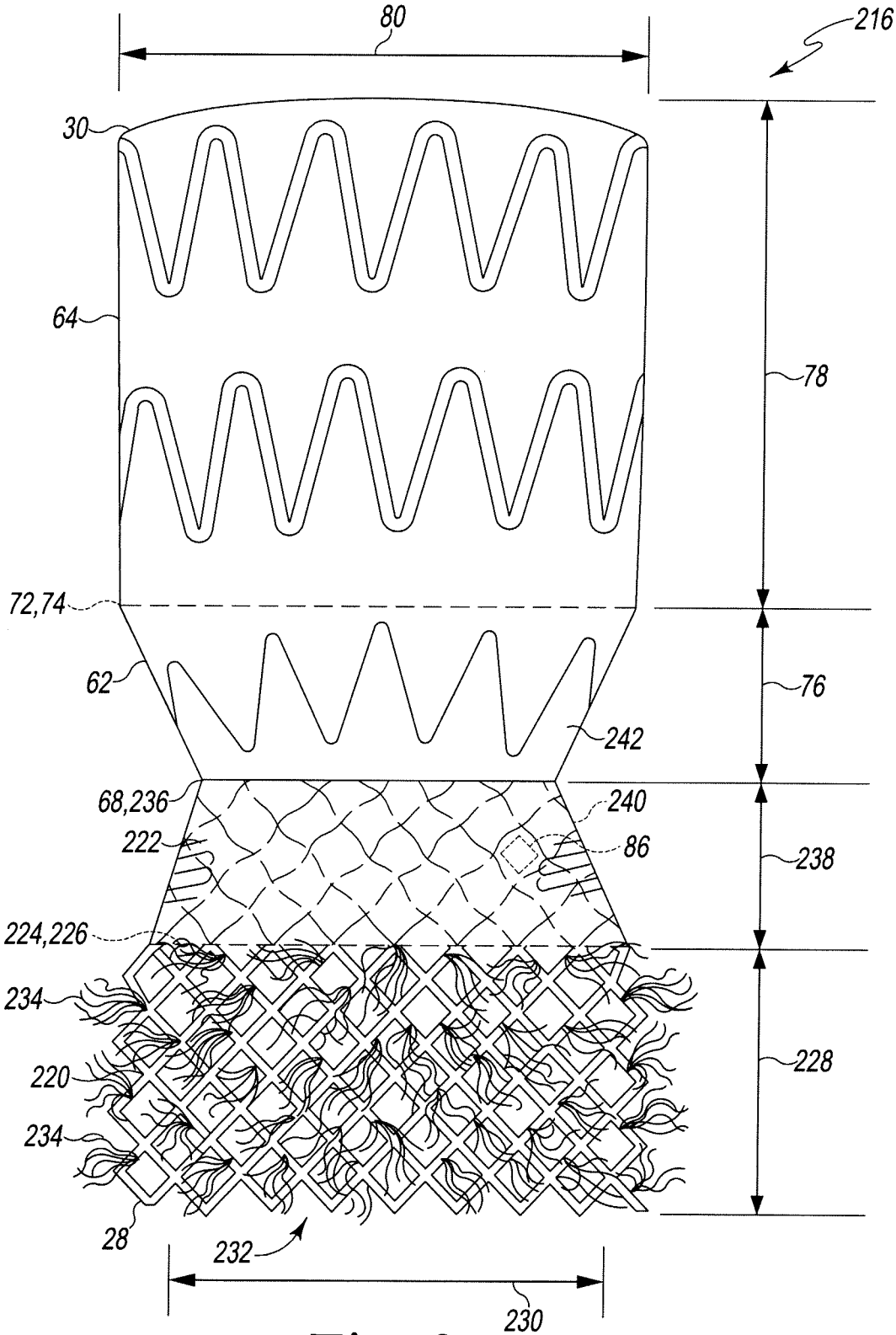

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Fig. 9

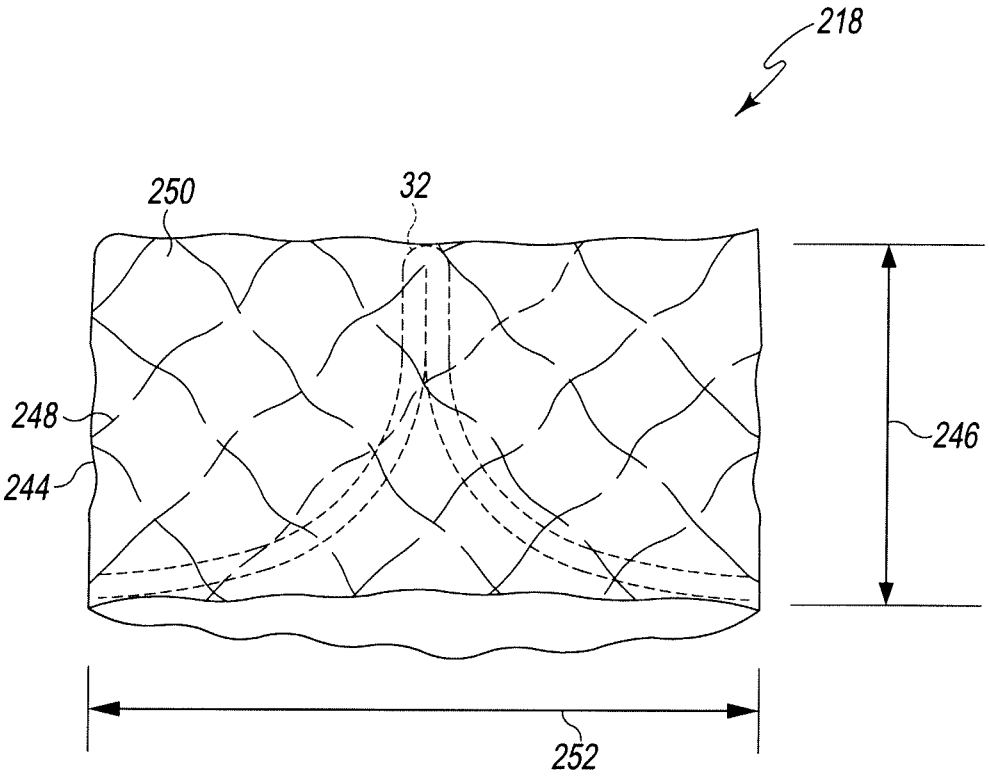


Fig. 10

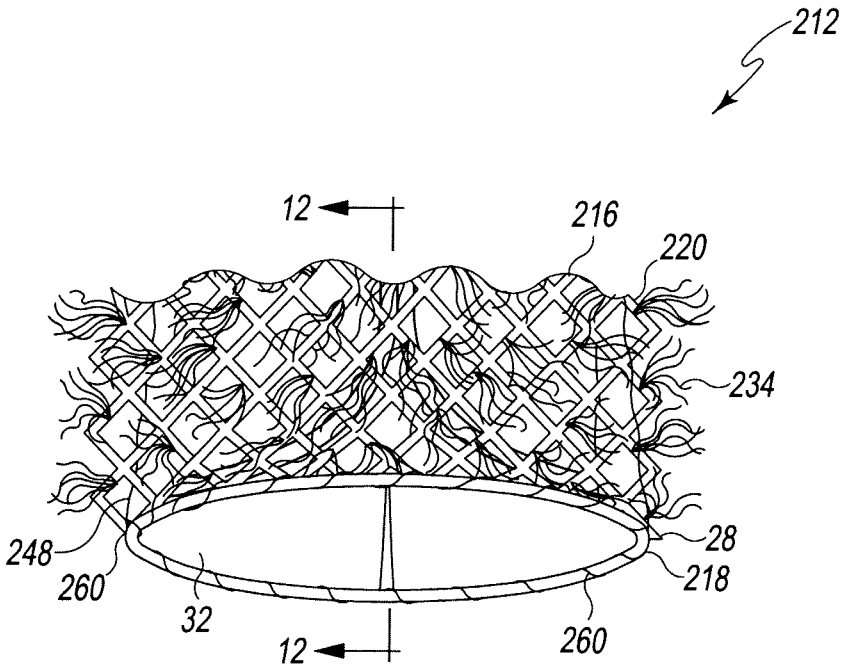


Fig. 11

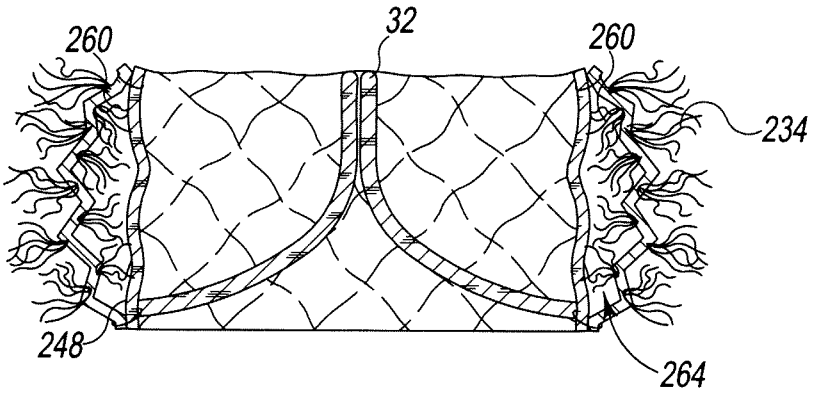


Fig. 12

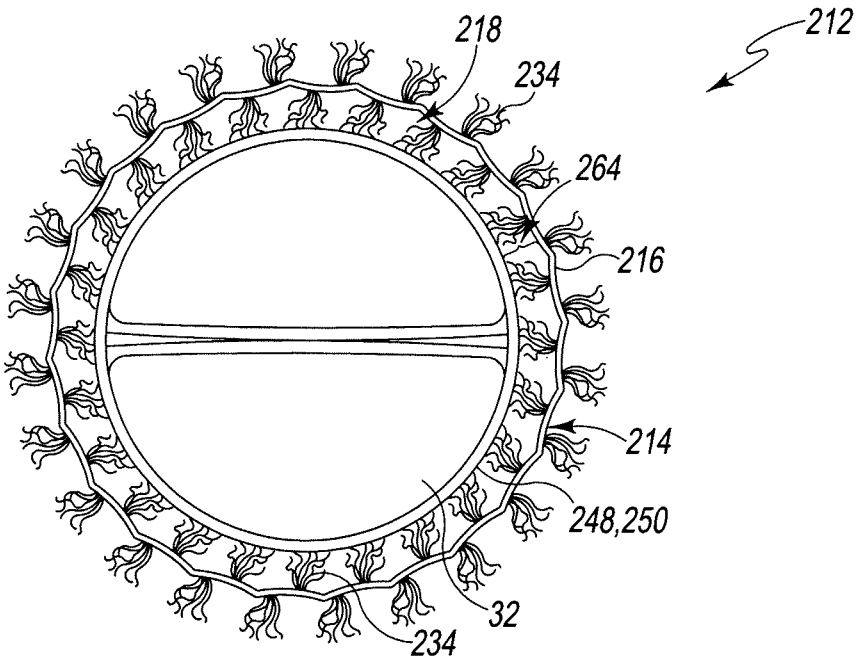

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Fig. 13

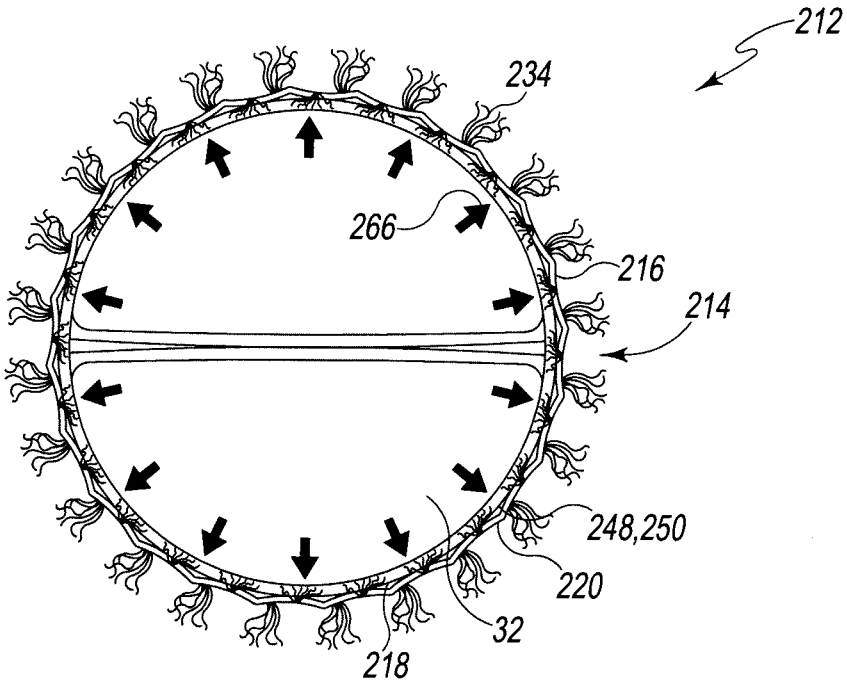

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Fig. 14

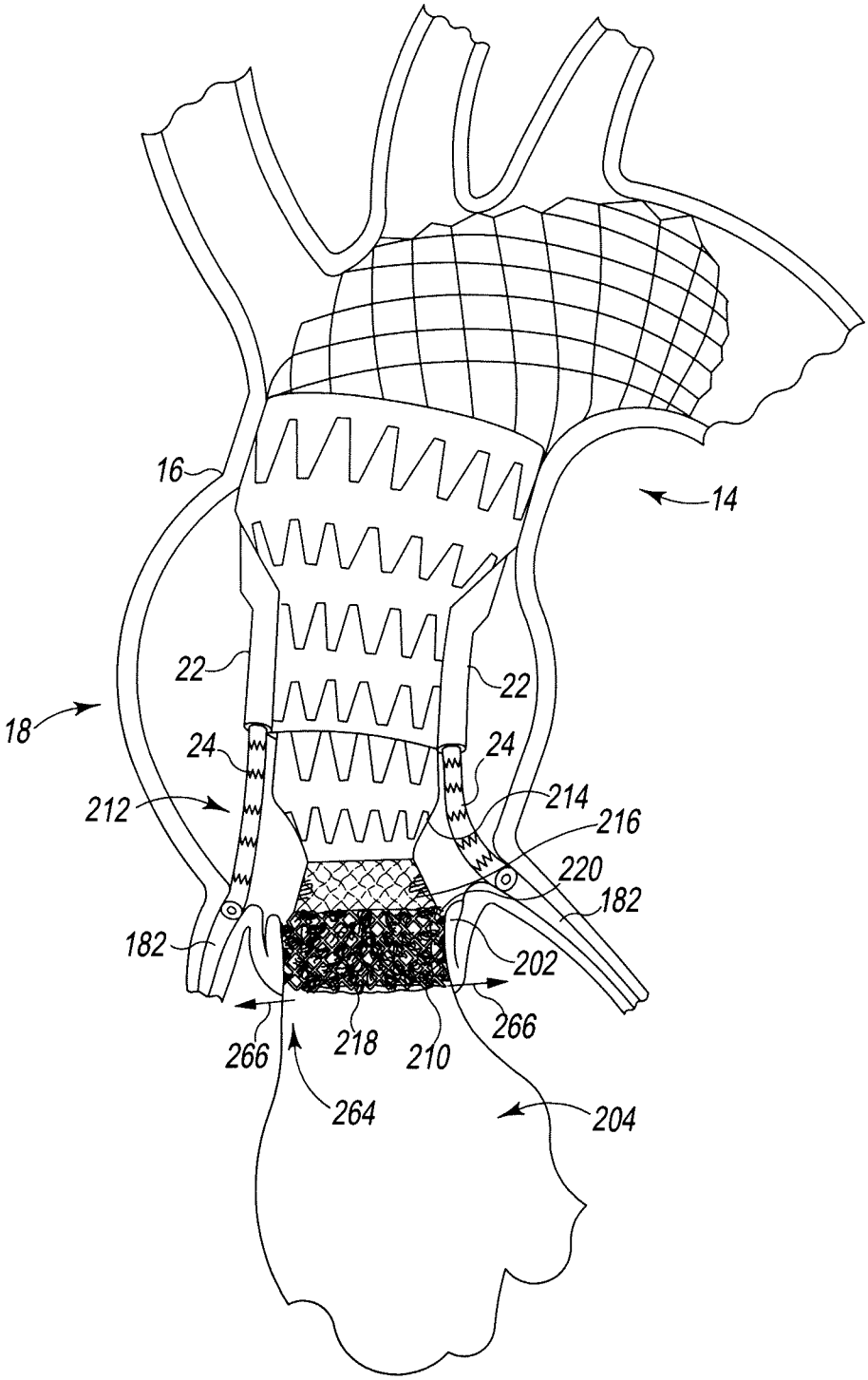

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Fig. 15

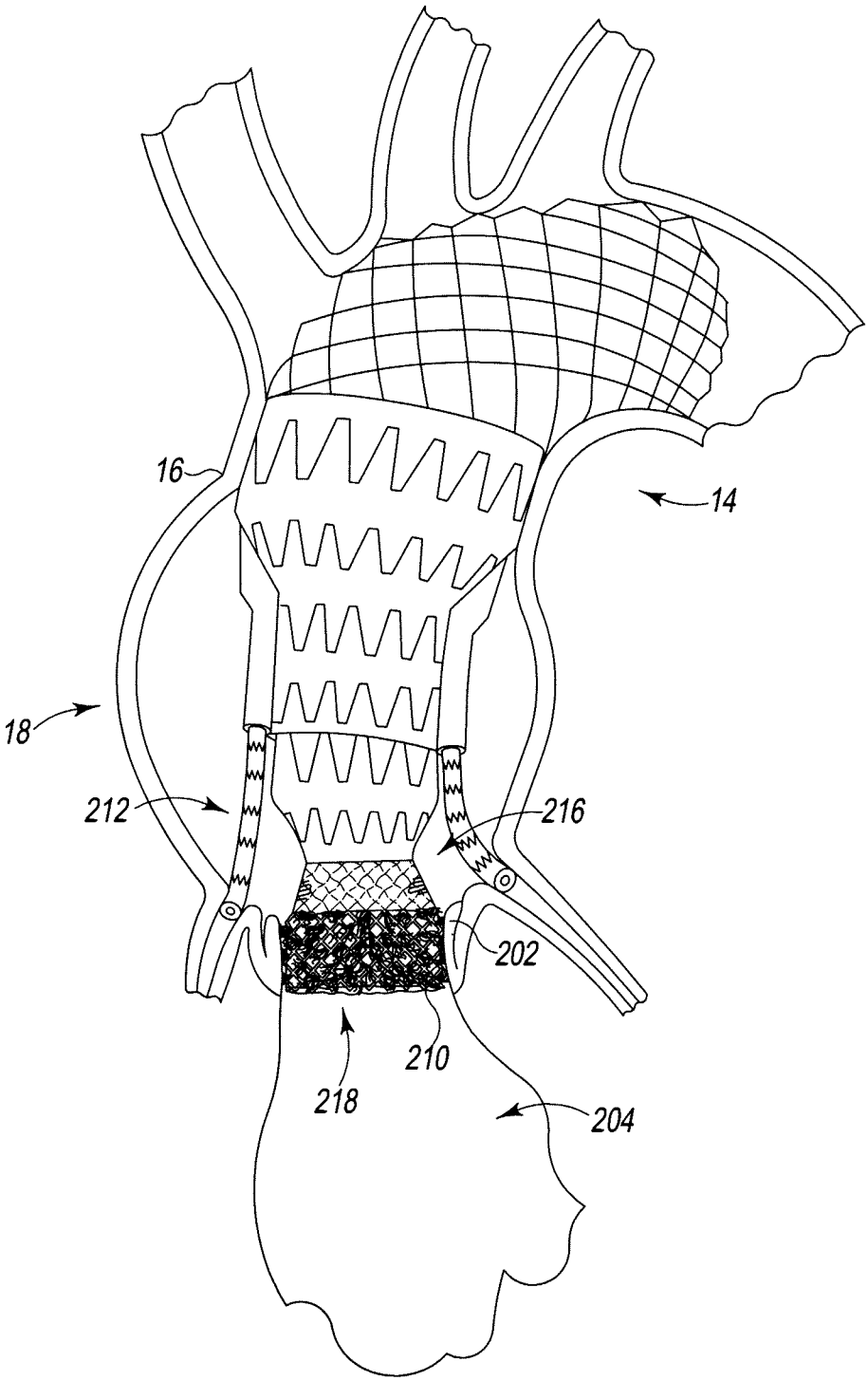


Fig. 16

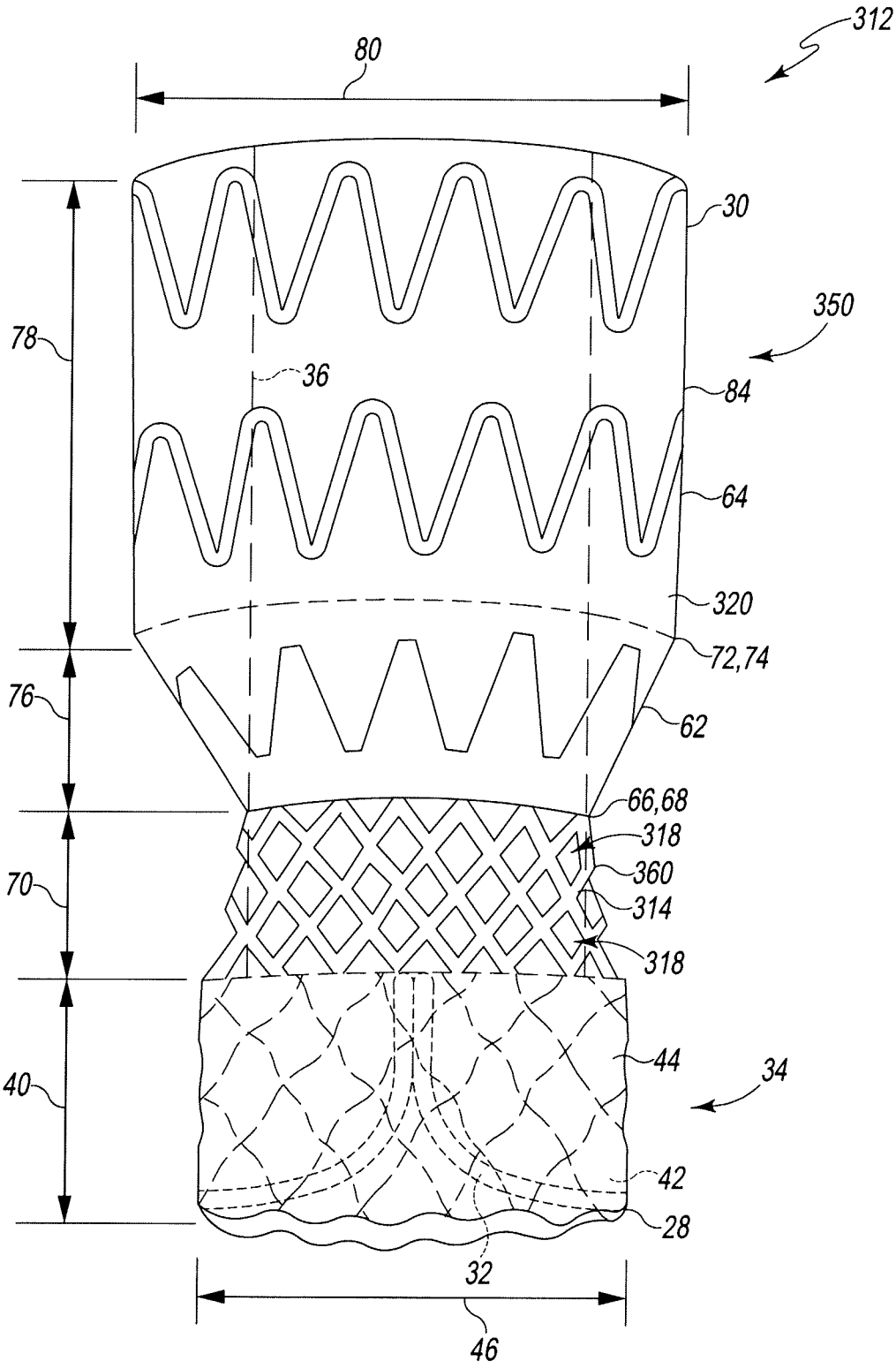

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Fig. 17

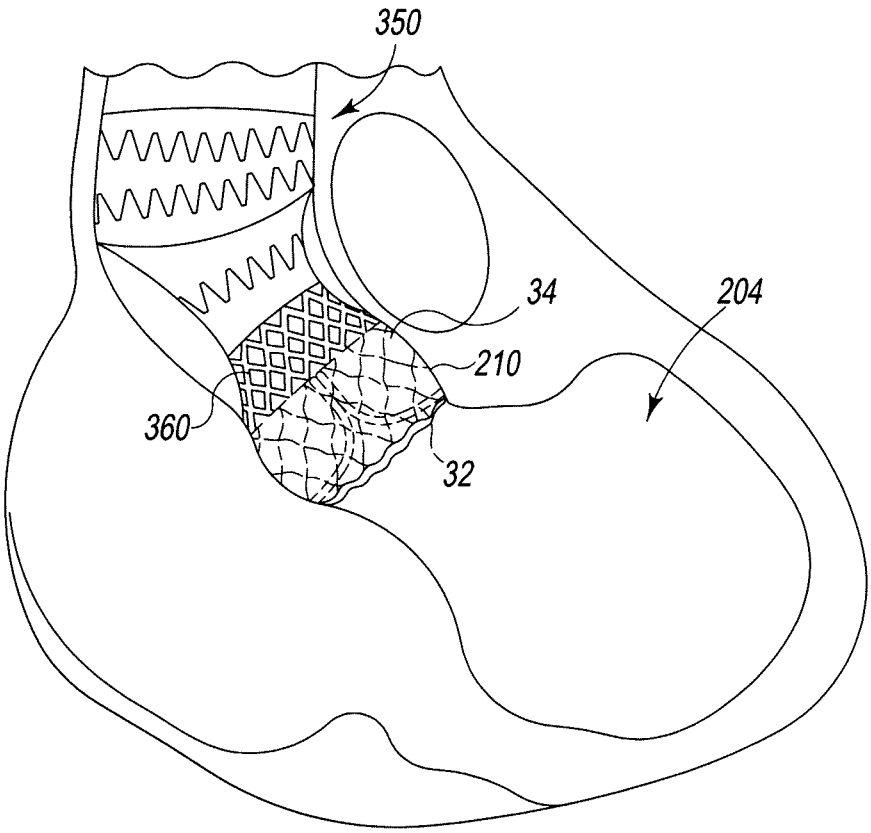


Fig. 18

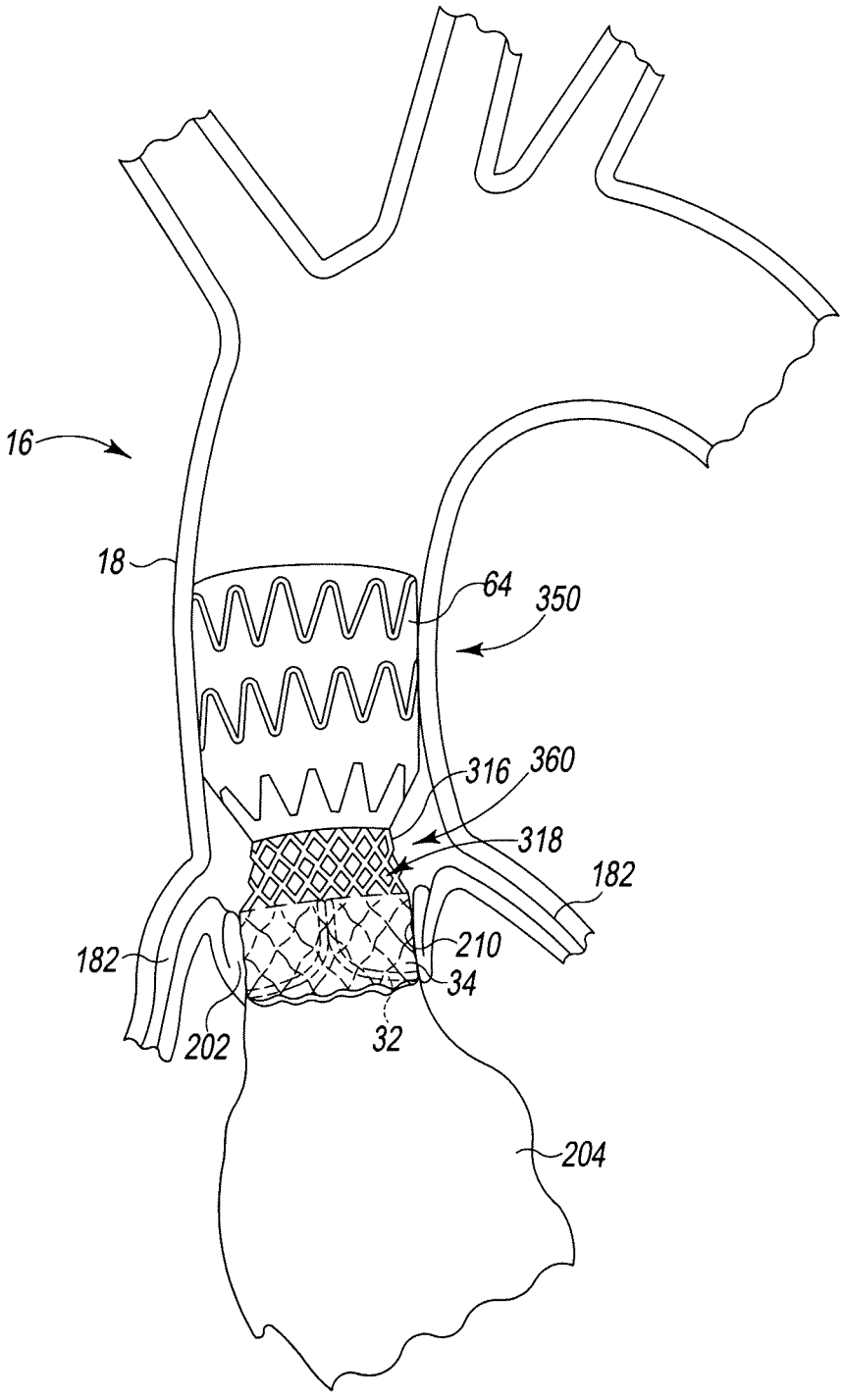


Fig. 19

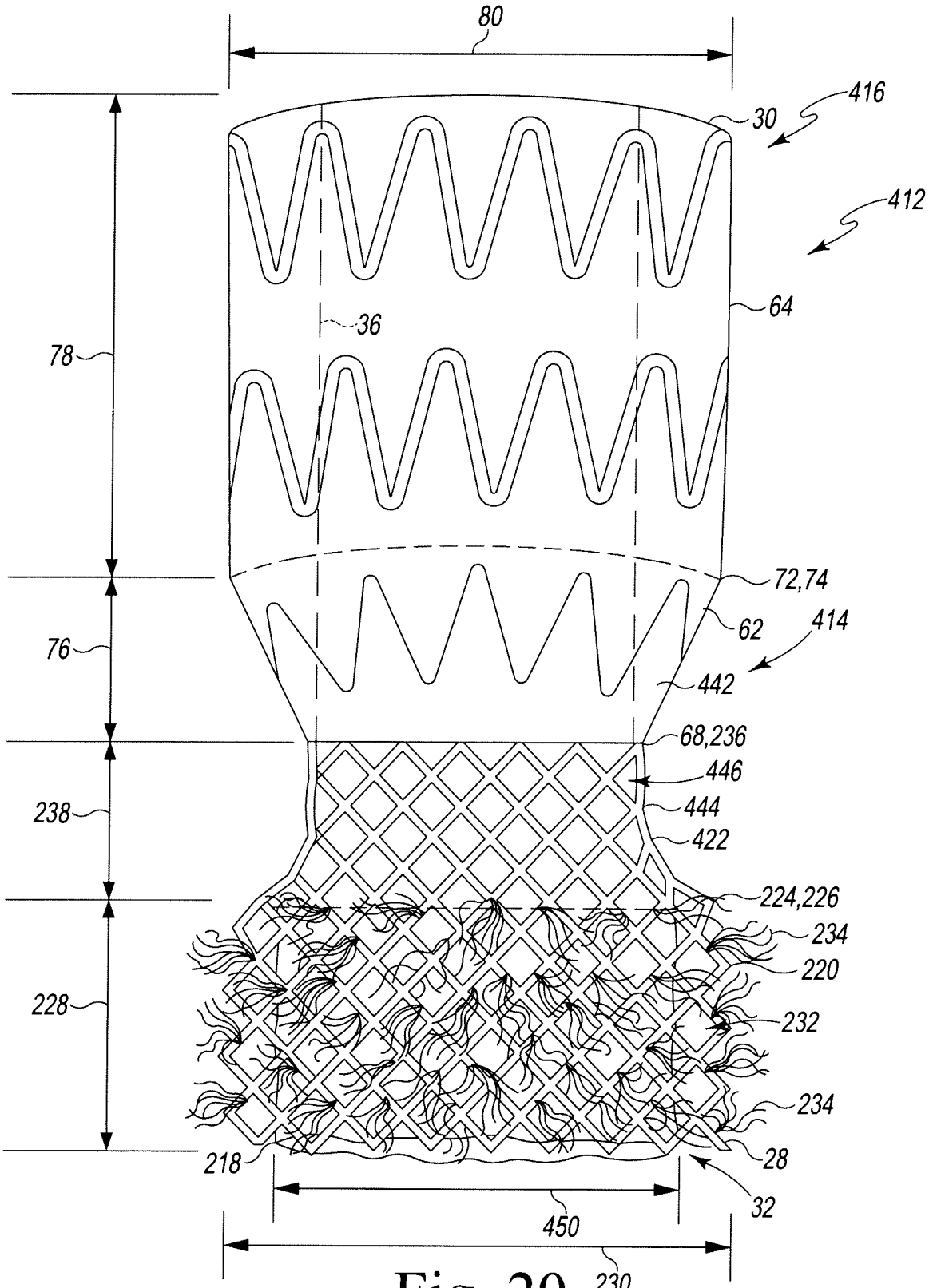

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Fig. 20

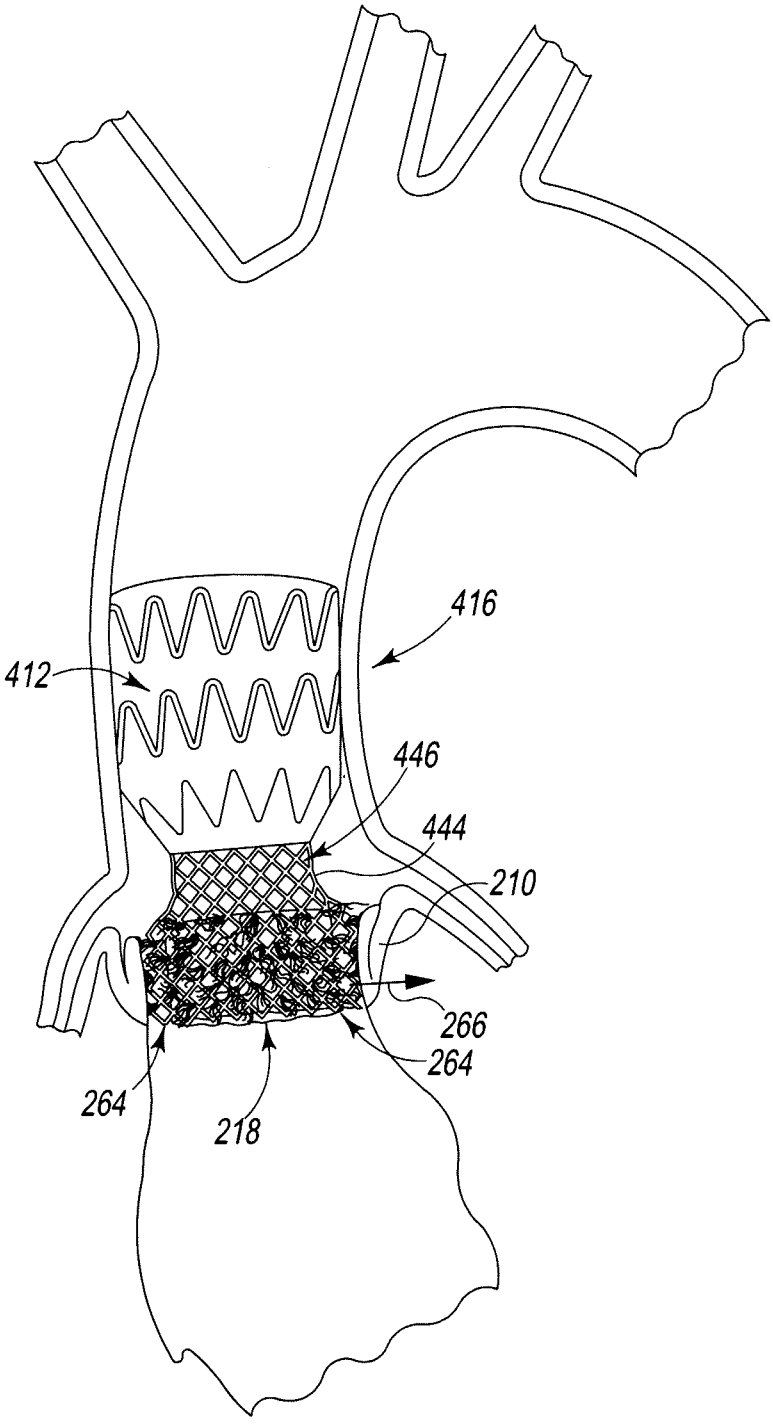


Fig. 21

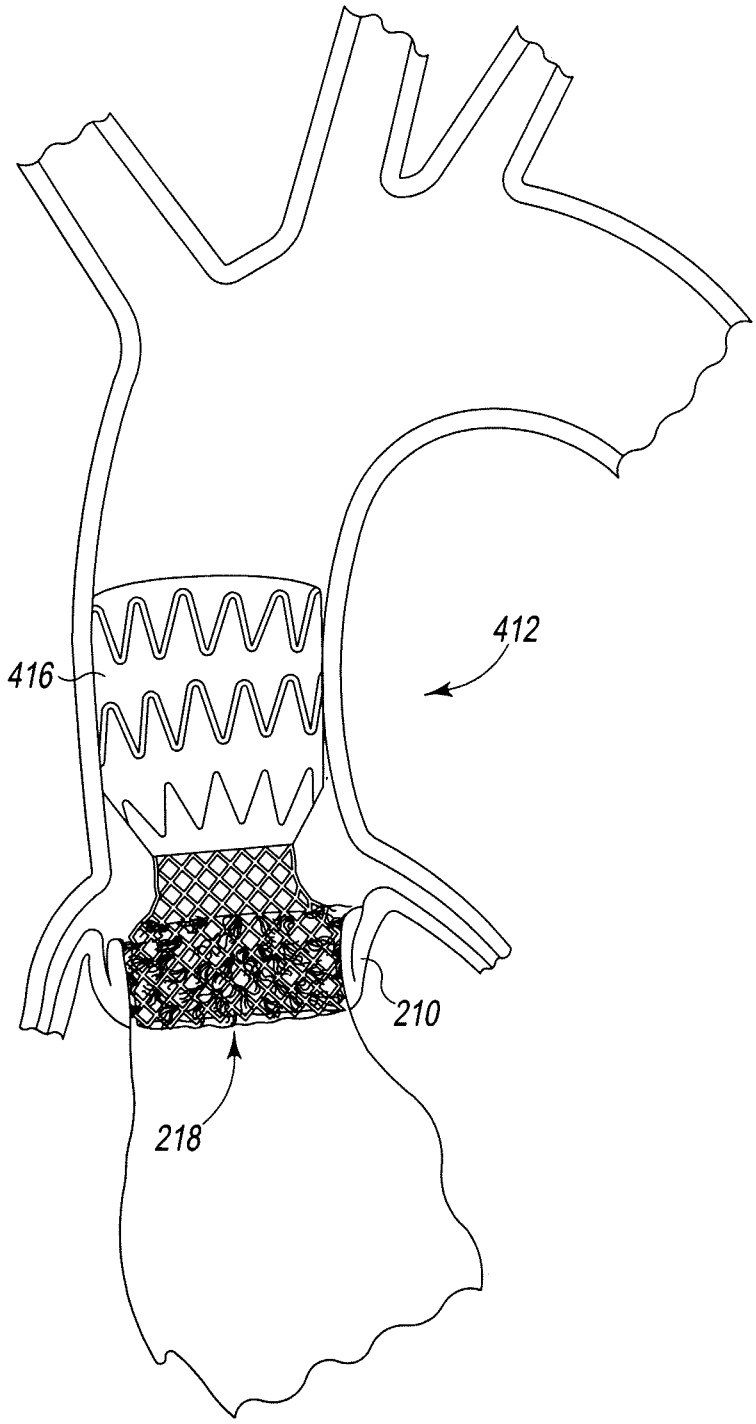


Fig. 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US12/68165

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/24 (2013.01)
USPC - 623/2.14, 2.18, 2.1 . 900, 904, 902, 2.17, 2.12, 1.1, 1.15, 1.16, 1.24, 1.13, 1.24
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61F 2/24 (2013.01)
USPC: 623/2.14, 2.18, 2.1 , 900, 904, 902, 2.17, 2.12, 1.1, 1.15, 1.16, 1.24, 1.13, 1.24

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent (US-Granted, US-Applications, EP-A, EP-B, WO, JP, DE-G, DE-A, DE-T, DE-U, GB-A, FR-A); Google/GoogleScholar; IP.com; PubMed/MEDLINE: ascending, aorta, aneurysm, balloon, stent, frame, valve, collagen, hydrogel

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7799072 B2 (GREENBERG, RK) September 21, 2010, entire document	1-4, 8-15, 17, 18, 20-27
Y		5-7, 16, 19
Y	US 8002826 B2 (SEGUIN, J) August 23, 2011; figure 1; column 5, lines 29-34	5-7, 16
Y	US 7947074 B2 (MERETEI, A) May 24, 2011, column 12, lines 23-29	19

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 February 2013 (05.02.2013)	15 FEB 2013
Name and mailing address of the ISA/US	**Authorized officer:**
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

EXHIBIT 14

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15445651
Filing Date	2017-02-28
First Named Inventor	Gregory A. Wright
Art Unit	3731
Examiner Name	Not Yet Assigned
Attorney Docket Number	HVTVC-6596US03

	2	2478871	EP	A2	2012-07-25	Aesculap Ag		☒
	3	03007795	WO	A2	2003-01-30	Edwards Lifesciences Corp		☒
	4	2006/013234	WO	A1	2006-02-09	Roux, Daniel		☒
	5	2013/086132	WO	A1	2013-06-13	Aortic Innovations Llc		☒
	6	2006004679	WO	A1	2006-01-12	Cleveland Clinic Foundation		☒
	7	2013116785	WO	A1	2013-08-08	Hlt, Inc		☒

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	International Search Report from Corresponding PCT Application No. PCT/US2013/061467 mailed January 2, 2014.	

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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

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Examiner Name	Not Yet Assigned
Attorney Docket Number	HVTVC-6596US03

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Thomas C. Richardson/	Date (YYYY-MM-DD)	2017-03-29
Name/Print	Thomas C. Richardson	Registration Number	58,521

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

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596US03
	Application Number	
Title of Invention	SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
Mr.	Gregory	A.	Wright	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Orange	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	Edwards Lifesciences		
Address 2	One Edwards Way; Legal Department		
City	Irvine	State/Province	CA
Postal Code	92614	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	30452		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT		
Attorney Docket Number	HVTVC-6596US03	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	6	Suggested Figure for Publication (if any)	

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	Application Number	
Title of Invention	SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	30452		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Patented	Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
	Division of	14/033075	2013-09-20	9585748	2017-03-07

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596US03
	Application Number	
Title of Invention	SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
14/033075	Claims benefit of provisional	61/705495	2012-09-25
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.			

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.			

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

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596US03
	Application Number	
Title of Invention	SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596US03
	Application Number	
Title of Invention	SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:	

If the Applicant is an Organization check here. ☒

Organization Name	Edwards Lifesciences Corporation

Mailing Address Information For Applicant:

Address 1	One Edwards Way		
Address 2			
City	Irvine	**State/Province**	CA
Country	US	Postal Code	92614
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596US03
	Application Number	
Title of Invention	SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Thomas Richardson/			Date (YYYY-MM-DD)	2017-02-28
First Name	Thomas	Last Name	Richardson	Registration Number	58,521

Additional Signature may be generated within this form by selecting the Add button.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	HVTVC-6596US03
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3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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

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

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SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT

ABSTRACT

A medical device includes an expandable conduit, a prosthetic heart valve and a delivery device, including a balloon catheter. The expandable conduit may include one or more inner or outer sleeves supported by a frame or stent. The sleeve(s) may be a bioprosthetic tissue wrapped, molded or sewn about the frame or stent. Coupled to an end of the expandable conduit is the prosthetic heart valve. The conduit and heart valve may be crimped on the balloon catheter for percutaneous deployment. The frame may be constructed of a balloon-expandable material for the conduit portion and a self-expandable material for the prosthetic heart valve portion. The prosthetic heart valve is anchored at the native heart valve and then the conduit to be expanded into place to protect the aorta. The self-expanding prosthetic heart valve avoids the need for balloon mounting. This provides for a smaller diameter and easier delivery.

CLAIMS

What is claimed is:

1. A system for use in replacing a native aortic heart valve and repairing a defect in a section of the aorta contiguous with the native aortic heart valve, the system comprising:

a catheter having a balloon thereon;

a retractable sheath defining an interior portion into which at least the prosthetic valve is compressed radially inwardly

a medical device sleeved over the catheter having a length sufficient to extend from a first end secured at the native aortic heart valve to a second end attached within and extending along the aorta at least as far as the aortic arch, the medical device comprising:

a self-expandable prosthetic valve located at the first end compressed radially inwardly and held in a delivery state by the retractable sheath and configured to expand in a radially outward direction to frictionally engage at least a portion of the native heart valve;

an aortic conduit comprising a balloon-expandable tubular frame and a tubular sleeve extending axially along and against the balloon-expandable frame, the aortic conduit being coupled to an end of the prosthetic valve and crimped around the balloon, the balloon extending along the conduit but not within the prosthetic valve.

2. The system of claim 1, wherein the balloon-expandable tubular frame comprises a plastically deformable metal material.

3. The system of claim 1, wherein prosthetic valve includes a self-expandable stent and flexible valve leaflets supported within the self-expandable stent.

4. The system of claim 3, wherein the balloon-expandable tubular stent and self-expandable stent are a single stent contiguously formed of a Nitinol alloy.

5. The system of Claim 3, wherein the prosthetic valve further comprises an annular ring of a woven material coupling the valve leaflets to the self-expandable tubular frame.

6. The system of claim 1, wherein the tubular sleeve is an inner tubular sleeve that extends axially along and within the balloon-expandable tubular frame to provide a tubular barrier between the balloon-expandable conduit and blood flowing through the aortic conduit.

7. The system of claim 5, further including an outer tubular sleeve extending axially along and outside of the balloon-expandable tubular frame to provide a tubular surface between the aortic conduit and surrounding native tissue.

8. The system of claim 1, wherein the tubular sleeve comprises a collagen gel absorbed into a woven polyester substrate.

9. The system of claim 1, wherein the tubular sleeve comprises bioprosthetic tissue selected from a group consisting of a bovine pericardium, a porcine pericardium, and an allogenic/autogenic collagen matrix tissue.

10. The system of claim 9, wherein the bioprosthetic tissue is glycerolized to facilitate dry storage.

11. The system of claim 1, further comprising one or more anchors that are circumferentially spaced apart about an outer surface of the medical device and extend radially outwardly to facilitate attachment to surrounding tissue.

12. A system for use in replacing a native aortic heart valve and repairing a defect in a section of the aorta contiguous with the native aortic heart valve, the system comprising:

a catheter having a balloon thereon;

a retractable sheath defining an interior portion into which at least the prosthetic valve is compressed radially inwardly

a medical device sleeved over the catheter having a length sufficient to extend from a first end secured at the native aortic heart valve to a second end attached within and extending along the aorta at least as far as the aortic arch, the medical device comprising:

a prosthetic valve comprising a self-expandable stent and located at the first end, the prosthetic valve compressed radially inwardly and held in a delivery state by the retractable sheath and configured to expand in a radially outward direction to frictionally engage at least a portion of the native heart valve

an aortic conduit comprising a balloon-expandable tubular frame and a tubular sleeve extending axially along and against the balloon-expandable frame, wherein the tubular frame and the self-expandable stent are a single stent contiguously formed of a Nitinol alloy, the aortic conduit being coupled to an end of the prosthetic valve and crimped around the balloon.

13. The system of claim 12, wherein prosthetic valve includes flexible valve leaflets supported within the self-expandable stent.

14. The system of Claim 13, wherein the prosthetic valve further comprises an annular ring of a woven material coupling the valve leaflets to the self-expandable tubular frame.

15. The system of claim 12, wherein the tubular sleeve is an inner tubular sleeve that extends axially along and within the balloon-expandable tubular frame to provide a tubular barrier between the balloon-expandable conduit and blood flowing through the aortic conduit.

16. The system of claim 15, further including an outer tubular sleeve extending axially along and outside of the balloon-expandable tubular frame to provide a tubular surface between the aortic conduit and surrounding native tissue.

17. The system of claim 12, wherein the tubular sleeve comprises a collagen gel absorbed into a woven polyester substrate.

18. The system of claim 12, wherein the tubular sleeve comprises bioprosthetic tissue selected from a group consisting of a bovine pericardium, a porcine pericardium, and an allogenic/autogenic collagen matrix tissue.

19. The system of claim 18, wherein the bioprosthetic tissue is glycerolized to facilitate dry storage.

20. The system of claim 12, further comprising one or more anchors that are circumferentially spaced apart about an outer surface of the medical device and extend radially outwardly to facilitate attachment to surrounding tissue.

SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT

RELATED APPLICATIONS

[0001] The present application is a divisional of U.S. Patent Application Serial No. 14/033,075, filed September 20, 2013, which claims priority under 35 U.S.C. §119 to U.S. Provisional Application Serial No. 61/705,495, filed September 25, 2012. Both U.S. Patent Application Serial No. 14/033,075 and U.S. Provisional Application Serial No. 61/705,495 are incorporated by reference in their entirety.

FIELD OF THE INVENTION

[0002] This application relates to methods, systems, and apparatuses for safely replacing native heart valves and aorta with prosthetic heart valves and conduits.

BACKGROUND OF THE INVENTION

[0003] Prosthetic heart valves have been used for many years to treat cardiac valvular disorders. The native heart valves (such as the aortic, pulmonary, tricuspid and mitral valves) serve critical functions in assuring the forward flow of an adequate supply of blood through the cardiovascular system. These heart valves can be rendered less effective by congenital, inflammatory, or infectious conditions. Such conditions can eventually lead to serious cardiovascular compromise or death. For many years, the definitive treatment for such disorders was the surgical repair or replacement of the valve during open heart surgery.

[0004] More recently, a transvascular technique has been developed for introducing and implanting a prosthetic heart valve using a flexible catheter in a manner that is less invasive than open heart surgery. In this technique, a prosthetic valve is mounted in a crimped state on the end portion of a flexible catheter and advanced through a blood vessel of the patient until the valve reaches the implantation site. The valve at the catheter tip is then expanded to its functional size at the site of the defective native valve, such as by inflating a balloon on which the valve is mounted.

[0005] Alternatively, the valve can have a resilient, self-expanding stent or frame that expands the valve to its functional size when it is advanced from a delivery sheath at the distal end of the catheter.

[0006] Balloon-expandable valves are commonly used for treating heart valve stenosis, a condition in which the leaflets of a valve (e.g., an aortic valve) become hardened with calcium. The hardened leaflets provide a good support structure on which the valve can be anchored within the valve annulus. Further, the catheter balloon can apply sufficient expanding force to anchor the frame of the prosthetic valve to the surrounding calcified tissue.

[0007] Often, heart valve problems, such as calcification, are associated with other heart problems such as aortic aneurysms. Although the delivery techniques described above address heart valve deficiencies to some extent, less invasive approaches to other heart problems are also desired. It would be particularly advantageous to be able to address both valve and aorta problems with a minimally invasive approach.

SUMMARY

[0008] A medical device for use in a heart having a native heart valve and a vessel extending therefrom is disclosed. The medical device includes a balloon-expandable conduit and a prosthetic valve. The delivery system includes a catheter having a balloon that is disposed inside the balloon-expandable conduit. The prosthetic valve is coupled to an end of the balloon expandable conduit. The prosthetic valve includes a self-expandable material configured to expand in a radially outward direction to frictionally engage at least a portion of the native heart valve. The frictional engagement prevents axial movement of the prosthetic heart valve and the balloon-expandable conduit relative to the native heart valve.

[0009] The balloon-expandable conduit may include a balloon-expandable tubular frame and a sleeve extending along and against the balloon-expandable frame. The self-expandable material may include a self-expandable tubular frame. The prosthetic valve may include valve leaflets supported within the self-expandable tubular frame. The balloon-expandable tubular frame and self-expandable tubular frame may be contiguously formed of a nitinol alloy. The self-expandable tubular frame may have an expanded memory shape.

[0010] The prosthetic valve may include an annular ring of woven material coupling the valve leaflets to the self-expandable tubular frame.

[0011] The sleeve may be formed of a bioprosthetic tissue. For example, the bioprosthetic tissue may include a bovine pericardium, a porcine pericardium or an allogenic or autogenic collagen matrix tissue. The bioprosthetic tissue sleeve may be glycerolized to facilitate dry storage.

[0012] The sleeve may also include a coating, such as a polymer or gel coating.

[0013] The medical device may also include a retractable sheath that defines an interior portion. The retractable sheath holds the prosthetic valve in a radially compressed configuration. The retractable sheath may include one or more radiopaque markers on its outer surface.

[0014] The balloon expandable material may be a plastically deformable metal material such as a stainless steel or nitinol.

[0015] Also included in the medical device may be one or more anchors. The anchors are coupled to and extend radially from an outer surface of the medical device. For example, the anchors may be supported by the balloon-expandable conduit or the self-expandable prosthetic valve. The anchors may include structure that facilitates tissue ingrowth, such as beads, dimples or fenestrations. The anchors may circumferentially spaced about the outer surface of the medical device.

[0016] A method includes delivering a balloon-expandable conduit coupled to a self-expandable prosthetic heart valve into a vessel extending from a native heart valve. Also, the self-expandable prosthetic heart valve is delivered into the native heart valve. The method also includes inflating a balloon disposed within the balloon-expandable conduit such that an outer surface of the balloon expandable conduit is urged toward the vessel. The self-expandable prosthetic heart valve is expanded within or near the native heart valve by axially moving a retractable sheath.

[0017] The delivering method may also include engaging the vessel or native heart valve with anchors coupled to the conduit or prosthetic heart valve.

[0018] A method of assembling a medical device includes coupling a self-expandable prosthetic heart valve adjacent a balloon-expandable conduit. Also, the method includes disposing a balloon and balloon catheter within an interior portion of the balloon-expandable conduit. The

method further includes compressing the balloon-expandable conduit and the self-expandable prosthetic valve radially inwardly. The method also includes disposing at least the self-expandable prosthetic valve into an interior portion of a retractable sheath.

[0019] Coupling the self-expandable prosthetic heart valve adjacent the balloon-expandable conduit may include forming a contiguous frame, coupling a bioprosthetic sleeve to at least one end of the frame and valve leaflets to the other end of the frame. The other end of the frame is then formed to have an expanded memory shape.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 is a perspective view of a medical device including transapical delivery of a coupled conduit and valve with the conduit being balloon expanded into an aorta;

[0021] FIG. 2 is a partial sectional view showing a bioprosthetic sleeve extending over a stent frame holding an expandable tissue valve;

[0022] FIG. 3 is a sectional view of a delivery catheter holding a coupled balloon-expandable conduit and self-expanding valve;

[0023] FIG. 4 is a perspective view of the medical device of FIG. 1 with the valve self-expanding into frictional engagement with a native heart valve to anchor the coupled conduit; and

[0024] FIGS. 5-8 are enlarged schematics of various anchors that can be coupled to outer surfaces of the medical device for improved anchoring into native tissues.

DETAILED DESCRIPTION

[0025] Implementations of the present disclosure now will be described more fully hereinafter. Indeed, these implementations can be embodied in many different forms and should not be

construed as limited to the implementations set forth herein; rather, these implementations are provided so that this disclosure will satisfy applicable legal requirements. As used in the specification, and in the appended claims, the singular forms "a", "an", "the", include plural referents unless the context clearly dictates otherwise. The term "comprising" and variations thereof as used herein is used synonymously with the term "including" and variations thereof and are open, non-limiting terms.

[0026] The inventor has observed a need for improved methods, systems, and apparatuses for delivering expandable prosthetic heart valves and conduits in a minimally invasive manner with a delivery device having a smaller diameter. The inventor has further recognized that transvalvular technologies provide opportunities to repair aortic pathologies, such as in the thoracic aorta or aortic arch. Conduits to supplement or replace the aorta may be delivered through minimally invasive routes, such as transapical or transvalvular routes.

[0027] The methods and devices described below may be used to replace native heart valves that have calcified leaflets associated with aortic stenosis and, at the same time, to repair defects in the aortic arch or thoracic aorta. Furthermore, the methods and devices desirably enable precise and controlled simultaneous delivery of the prosthetic valve and the conduit.

[0028] Disclosed below are representative embodiments of a medical device that can be secured within a native heart valve. For illustrative purposes, embodiments of the medical device are described as being delivered to the aortic valve and associated aorta. It should be understood that the disclosed medical device may be configured for use with other heart valves that have associated conduits.

[0029] Also, a range of aortic pathologies may be addressed, such as aortic or thoracic aneurysms, aorta stenosis, or aorta/thoracic dilatation.

[0030] As shown in FIG. 1, a medical device 10 includes an expandable conduit 12, a prosthetic heart valve 14 and a delivery device 16, including a balloon catheter 40. The expandable conduit 12 may include one or more inner or outer sleeves 18 supported by a frame or stent 20. The sleeve(s) 18 may be a bioprosthetic tissue wrapped, molded or sewn about the frame or stent 20. Coupled to an end of the expandable conduit is the prosthetic heart valve 14. For example, the prosthetic heart valve may include a portion of the frame 20 with soft tissue valve leaflets 22 sewn therein. As shown in FIG. 3, the conduit 12 and heart valve 14 may be crimped on the balloon catheter 40 for percutaneous deployment, or some other minimally invasive deployment approach, such as a transaortic or transapical approach.

[0031] Advantageously, the frame or stent 20 may be constructed of a balloon-expandable material for the conduit 12 portion and a self-expandable material for the prosthetic heart valve 14 portion. As shown in FIG. 2, this allows the prosthetic heart valve 14 to first be anchored precisely at the native heart valve 24 and then, as shown in FIG. 1, the conduit 12 expanded into place to protect the ascending aorta 26.

[0032] Also advantageously, the self-expanding nature of the prosthetic heart valve 14 allows it to be mounted over a portion of the balloon catheter 40 that does not have a balloon 28. This provides for a lower diameter and easier delivery.

[0033] The device 10, including the conduit 12, prosthetic heart valve 14 and delivery device 16 can have multiple sizes accommodating biological variation in patient valve and aorta anatomy.

[0034] The frame or stent 20, as shown in FIGS. 1-4, may be comprised of a plurality of struts 30 that are interconnected to provide a lattice configuration with closed cells. The frame 20 may be comprised of a range of materials, including metals and plastics. For example, the frame may be comprised of a shape memory metal, such as a stainless steel or nitinol (nickel-titanium)

alloy. Nitinol has the advantage of being able to withstand large strains and other deformations. Forming the struts 30 for metal frames 20 may include, for example, laser-cutting a nitinol or stainless steel stock tube to form the holes between the struts.

[0035] The frame 20 may be constructed in parts of the same or different materials and later welded, sewn or otherwise bonded together. For example, the balloon expandable portion of the stent 20 that makes up the conduit 12 may be constructed of a biocompatible stainless steel material cut from a stainless steel tube as described above. The lattice frame 20 formed from the stainless steel may then be mounted (with or without some initial expansion) over the balloon 28 for later plastic deformation by the balloon into the expanded shape.

[0036] The prosthetic heart valve 14 portion of the stent 20 may be constructed of nitinol, expanded into a deployed shape by a balloon and then heat treated to have an expanded memory configuration. This expanded memory configuration is assumed upon deployment from the delivery device 16, i.e., when a retractable outer sleeve or sheath 32 of the delivery device (as shown in FIG. 3) is withdrawn. After formation, both portions of the stent frame 20 may then be attached to each other by bonding, welding or having adjacent ends sewn to each other using the holes defined by the struts 30.

[0037] A particularly elegant solution (as shown in the figures herein) is to cut the entire frame or stent 20 out of a single tube of nitinol and then subject the nitinol to different treatments to selectively train axial portions for mixed expansion. For example, the cut nitinol tube may be partially expanded and heat treated at the prosthetic valve end to have an expanded memory shape. The remainder of the frame or stent 20 could be maintained in a cooled condition to avoid imprinting a memory shape or the memory shape may be the compressed condition. This compressed condition is then overcome by large plastic deformations from later expansion of the

balloon 28. Advantageously, forming the stent 20 using differential techniques but the same monolithic materials avoids the need for later attachment, provides for a continuity of struts, improved structural integrity, etc.

[0038] As another alternative, the stent 20 may be entirely balloon expanded or entirely self-expanding. If entirely balloon expanded, a longer or larger balloon 28 may be used for simultaneous expansion of the entire conduit and valve combination. However, the combination of balloon and self expanding has particular advantages as described elsewhere herein.

[0039] The sleeve 18, as shown in FIGS 1 and 4, may extend within an inner surface of the frame 20 so as to protect the struts 30 of the frame from adhesions, clotting and other issues occurring from interaction with the blood flowing through the device 10. Alternatively, or in addition, the sleeve 18 may extend over the outside of the frame 20 or struts 30 so as to provide a surface on which to adhere to or fill the space between the frame and the surrounding native tissues of the aorta or valve of the heart. The sleeve 18 may also extend over both the inner and outer surfaces of the stent or frame 20.

[0040] Regardless of which surfaces it covers, the sleeve 18 is configured to provide a structure that helps to deflect and guide high pressure blood flow through the insufficient or compressed heart valve and the aneurismal aorta. Advantageously, the sleeve 18 and/or underlying frame 20 may have strategically placed openings, such as at the various branch vessels of the aorta (carotid or coronary arteries) to ensure perfusion of the heart and branch vessels.

[0041] The sleeve 18 may be constructed of a range of biological and/or synthetic materials and be applied or attached to the frame 20 in different ways. The sleeve may include, for example, bioprosthetic tissues such as bovine pericardium, porcine pericardium, or an allogenic and/or autogenic collagen matrix tissue. Bioprosthetic materials could be treated to withstand age and

the environment, such as by being glycerolized to enable dry storage and improve lubrication. The bioprosthetic tissue could also be stored in glutaraldehyde.

[0042] As another option, polymers and gels (biological or synthetic) may be used for the sleeve 18. Non-biological polymers may be used for a solid polymer sleeve 18 or covering, such as silicone or polyurethane. The non-biological polymers may also include PET, PTFE or polyester films. Plant or animal derived collagen gels are an example of biological polymers or gels. Gels would generally be applied to some type of a substrate, such as an absorbable polymer substrate, a woven polyester, or bovine collagen matrix.

[0043] The sleeve 18 may also (optionally) be composed of a known graft material for treating aortic aneurysms, such as Dacron or PTFE cloth.

[0044] The sleeve 18 could also include combinations of some of the aforementioned materials. For example, the Dacron or PTFE cloth could be coated with the polymer or gel.

[0045] The different material types may be attached in different ways. For example, the sleeve 18, if comprised of a gel or polymer, may be applied as coating or as a molding or extrusion onto the surfaces of the frame 20. This facilitates a bonding attachment along a large portion of the surfaces of the frame 20, with some material extending into the holes defined between the struts 30.

[0046] The sleeve 18 may also be partially or wholly applied mechanically, such as by wrapping or sewing onto the frame 20. For example, a cloth of the sleeve 18 could be formed into a tube around the frame 20 by use of a longitudinal stitch to attach long edges of a rectangular, flat material. The same longitudinal stitch could extend between the struts 30 to anchor the sleeve 18 to the stent 20.

[0047] As another option, the cloth (Dacron or PTFE) sleeve 18 may have additional layers applied to it such as an outer or inner coating or layer of gel or polymer. The gel or polymer could be applied as a coating, molding or extrusion onto the cloth (before or after the cloth's attachment) to form the multiple layered sleeve 18.

[0048] The sleeve 18 may also optionally extend over the (and be considered part of) the prosthetic heart valve 14, as shown in FIGS. 2 and 3. Or, the sleeve 18 may terminate prior to reaching the axial end of the heart valve 14, as shown in FIGS. 1 and 4, even leaving a gap therein to facilitate blood flow to the coronary arteries extending from the aorta near the aortic valve root.

[0049] As shown in the cross-section of FIG. 3 and in FIG 2, the prosthetic heart valve 14 includes an axial portion of the stent 20, soft tissue valve leaflets 22, a ring 34 and a plurality of stitches 36.

[0050] As described above, the portion of the stent 20 (or its own frame or stent if separately formed and attached) used to support the valve is a self-expanding material such as nitinol alloy with an expanded memory shape. A free end 38 of the stent 20 may terminate in a flared, crenellated memory configuration when deployed at the native heart valve 24, as shown in FIGS. 1 and 4. It takes this shape, for example, because there is no surrounding native tissue to constrain it from assuming the fully open memory shape. The flared shape may advantageously avoid interfering with blood flow from the heart.

[0051] Also advantageously, the expanded portion of the stent 20 exerts a radially outward force. Thus, the expanded stent 20 frictionally engages at least a portion of the native aortic valve 24. This substantially prevents axial movement of the prosthetic valve 14 and the balloon-expandable conduit 12 relative to the aortic valve 24.

[0052] The ring 34 extends around an outside (as shown in FIG. 2) or inside (as shown in FIG. 1) (or both) of the stent 20 and provides a structure for attachment and support of the valve leaflets 22. The ring 34 may be constructed of a polymer, tightly woven cloth material, such as a PET fabric or a PTFE fabric. Sutures or stitches 36 may be used to attach the cloth material ring 34 to the stent frame 20 by extending through the cloth material, over the stent frame on inside and outside surfaces and through the stent openings, as shown in FIG. 3. Additionally, the stitches 36 may attach the stent frame 20 and cloth ring 34 to the sleeve 18, whether the sleeve extends over the inside and/or outside surfaces of the stent frame.

[0053] The valve leaflets 22 are preferably constructed of a soft, pliable material such as thin bioprosthetic material, such as bovine pericardium. The valve leaflets are sewn, bonded or otherwise attached to the cloth ring 34 around its inside surface to form a one-way tricuspid valve structure. In this manner, with the attachments described above, the valve leaflets 22 are firmly anchored to the cloth ring 34 which is attached via stitches 36 or other means to the frame 20 and the sleeve 18. This prosthetic heart valve 14 construction then, as described herein, serves as the anchor for the remaining medical device 10 and for the conduit 12.

[0054] The stitches 36 may be constructed of a heavy suture material for a firm interconnection of the above-listed components. Various stitches are shown herein including long axially-directed loops (FIG. 2) that extend over ends of the ring 34. Or, as shown in FIG. 4, alternating zig-zag stitches may pierce and extend through the ring 34. Generally, the stitching pattern may be adapted to suit the thickness of the material layers, geometry of the stent and other variations described herein.

[0055] The delivery device 16, as shown in FIG. 3, shows the assembled medical device 10 ready for delivery of the conduit 12 and valve 14. The delivery device 16 includes the

retractable outer sheath 32 and the balloon catheter 40 mounted within a central lumen of the outer sheath. The balloon catheter 40 includes a guide wire 42, an inflation catheter 44 and the balloon 28.

[0056] The guide wire 42 is a semi-flexible wire that is placed through the skin and up through the aortic valve 24 and into the ascending aorta in a transapical approach, as shown in FIG 4. Conversely, the guide wire 42 may use a transfemoral approach by extending up the femoral artery and down the aortic arch through the aortic valve 24. Alternative approaches may also be used, including a more direct transaortic approach. Various approaches may or may not use a guide wire 42. Placement of the guide wire 42 may also use various devices such as an obturator to define gradually increasing diameter access holes, such as a transapical access hole.

[0057] The inflation catheter 44 defines a central lumen 46 by which it can be sleeved over the guide wire 42 once the guide wire is in place. The inflation catheter also includes an inflation lumen 48 which terminates within the walls of the balloon 28 mounted on the inflation catheter 44. At the proximal operator end, it may be attached to a gas or fluid supply for inflation of the balloon 28 during the deployment procedure. Construction and use of a balloon inflation catheter are well known to those of ordinary skill in the art.

[0058] The balloon 28, as shown in FIGS. 1 and 3, includes a balloon wall 50 that is configured to form a toroid cylinder shape extending along an axial portion of the inflation catheter 44. The balloon wall in FIG. 3 is crimped against the inflation catheter 44 and extends under the conduit 12 but stops short of the prosthetic heart valve 14. The balloon 28 may be directly beneath the frame 20 in some embodiments or may be under the sleeve 18 when the sleeve extends inside the frame in other embodiments, or in some combination of both.

[0059] The outer sheath 32 is another elongate, flexible tube that is configured to hold the expandable conduit 12 and the heart valve 14 in the crimped condition, as shown in FIG. 3. The prosthetic heart valve 14 extends around and is crimped onto the inflation catheter 44 not supporting the balloon 28. The expandable conduit 12 is crimped over the portion supporting the balloon 28. The lack of the intervening balloon 28 allows the leaflets 22 of the prosthetic heart valve to be compressed directly on the inflation catheter. This allows for a more uniform, smaller diameter of the medical device 10 in its crimped configuration. Smaller diameter delivery allows for use of the device 10 with a wider range of patients and less invasive procedures.

[0060] In the crimped condition, the soft tissue of the bioprosthetic sleeve 18 is notably bunched or crimped along the length of the delivery device 16. The soft tissue is then smoothed out during inflation and plastic deformation of the supporting frame or stent 20. Similarly, the valve leaflets 22 unfold or uncrimp, although under self-expansion by the shape memory effect of the supporting portion of the stent 20.

[0061] Also notable, is that the approach used for delivery may dictate whether the prosthetic heart valve is near the distal end of the outer sheath 32, such as for a transfemoral approach, or may be on a more proximal end (relative to the expandable conduit 12) of the outer sleeve (as shown in FIGS. 1 and 4) for the transapical approach.

[0062] Also, the delivery device 16 may include the use of radiopaque markers for targeting an aneurysm or the dilated portion of the diseased aorta or other vessel for easier implantation. Flush valves may also be included in the delivery device 16.

[0063] In addition, the retractable outer sheath 32 may include one or more radiopaque markers 64 supported on an outer surface of the sheath, as shown in FIG. 1. These markers 64 are

designed to help position the delivery system and can be used to specifically position the system to target an aneurysm or dilated portion of a diseased vessel.

[0064] The medical device 10 may have additional features to facilitate its anchoring and later incorporation (by healing) into the surrounding tissue. For example, additional cloth PET portions could be used at the opposing ends extending around the outer frame 20 or sleeve 18.

[0065] The medical device 10 may also be stabilized by a plurality of metal anchors 52, as shown in FIGS. 1 and 4. The anchors 52 may extend radially about 2 mm to about 4 mm from the outer surface of the conduit 12 and/or the prosthetic heart valve 14. In addition, the anchors 52 may be circumferentially spaced apart along the length of the expandable conduit 12 or heart valve 14. In other embodiments, one or more anchors 52 may be defined on the frame or stent 20. Or the anchors may extend from the bioprosthetic sleeve 18.

[0066] The anchors may be constructed of a range of biocompatible materials, such as stainless steel, Nitinol or polymeric materials.

[0067] FIGS. 5-8 illustrate various embodiments of the anchors 52. As shown in FIG. 5, the anchor 52 includes a base 54 topped by an irritation bead 56 defining a dimple 58. The base 54 is attached to the stent frame 20 (as shown) or directly to the sleeve 18. The irritation bead 56 is a spherical structure formed on or bonded to the base 54. It functions to irritate the surrounding tissue and induce a growth response to help anchor the conduit 12. The dimple 58 is a small golf-ball-like recess that further enhances irritation and tissue ingrowth.

[0068] As shown in FIG. 6, the anchors 52 may include a base 54 that supports a discrete field of fenestrations 60 that extend radially outward. The fenestrations 60 are configured to frictionally engage tissue of the native vessel. These fenestrations, for example, may be formed as a knurled

crisscross patterns of pyramidal structures by cold rolling the metal from which the anchors 52 are cut.

[0069] As shown in FIGS. 7 and 8, the anchors 52 may include a base 54 that supports a disc-shaped protrusion 62. The disc shape has a top surface that extends in the axial direction of the underlying frame 20. The diameter of the disc protrusion 62 is larger than the supporting base 54. This shape facilitates its anchoring on the tissue walls. The tissue becomes lodged under the disc 62, between it and the base 54 or underlying conduit 12.

[0070] In another embodiment, each of the anchors 52 may include a plurality of arms that extend outwards and are configured to frictionally engage the surrounding tissue.

[0071] A method of construction of the expandable conduit 12 and the prosthetic heart valve 14 may include coating or covering the interior surface, exterior surface, or both of the frame or stent 20 with (1) a bioprosthetic tissue, which may be selected from the group comprising a bovine pericardium, porcine pericardium, and allogenic/autogenic collagen matrix tissue, (2) a polymer, (3) a gel applied to a substrate or (4) a cloth, such as PTFE or Dacron, to form the sleeve 18. The sleeve 18, if it has a biological component, may then be glycerolized to facilitate dry storage. The method may also include applying a covering, such as a cloth, and coating the covering with a gel or polymer to form multiple layers.

[0072] During assembly of the medical device 10, the expandable conduit 12 is sleeved over the inflation catheter 44 until over the balloon 28. The prosthetic heart valve 14 is also sleeved (as the expandable conduit 12 is sleeved) over the adjacent portion of the inflation catheter 44 without the balloon. The prosthetic heart valve 14 is in the expanded condition due to its shape memory properties while the expandable conduit 12 is still relatively compact. A crimper is then

used to crimp the conduit and valve, and underlying balloon 28, which are inserted into the outer, retractable sleeve 32 of the delivery device 16.

[0073] During delivery, the guide wire 42 is placed through the transapical or transfemoral approaches, as described above, until part of the wire extends through the aortic arch 26 and part of the wire through the native heart valve 24. Some preliminary balloon expansion may be performed to open the calcified native heart valve.

[0074] The balloon catheter 40 is then sleeved over the guide wire and into the native heart valve 24 and aortic arch 26. The outer sheath 32 is withdrawn to allow the prosthetic heart valve 14 to expand into and compress the native heart valve 24, as shown in FIG. 4. The inflation lumen 48 of the inflation catheter 44 is used to pump saline or other fluid into the balloon 28, expanding the balloon wall 50 and surrounding conduit 12, as shown in FIG. 1. The anchors 52 impinge upon or engage the surrounding vessel and anchor thereto.

[0075] Advantageously, the medical device 10 described above can achieve a smaller compressed diameter to facilitate minimally invasive delivery of a prosthetic heart valve together with an attached conduit.

Title: SYSTEMS FOR REPLACING A NATIVE HEART VALVE AND AORTA WITH A PROSTHETIC HEART VALVE AND CONDUIT
Inventor: Gregory A. Wright
Docket No.: HVTVC-6596US03

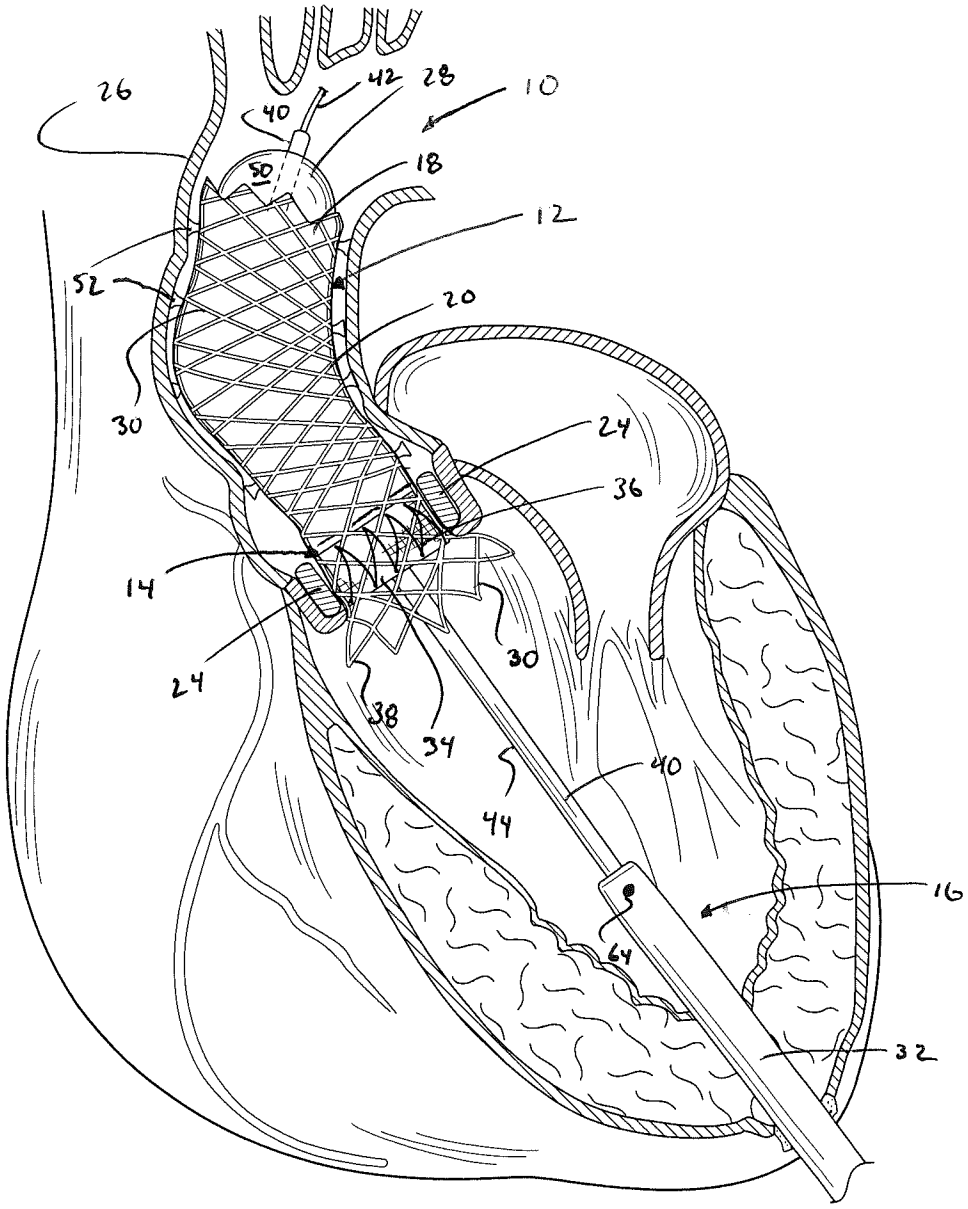


FIG. 1

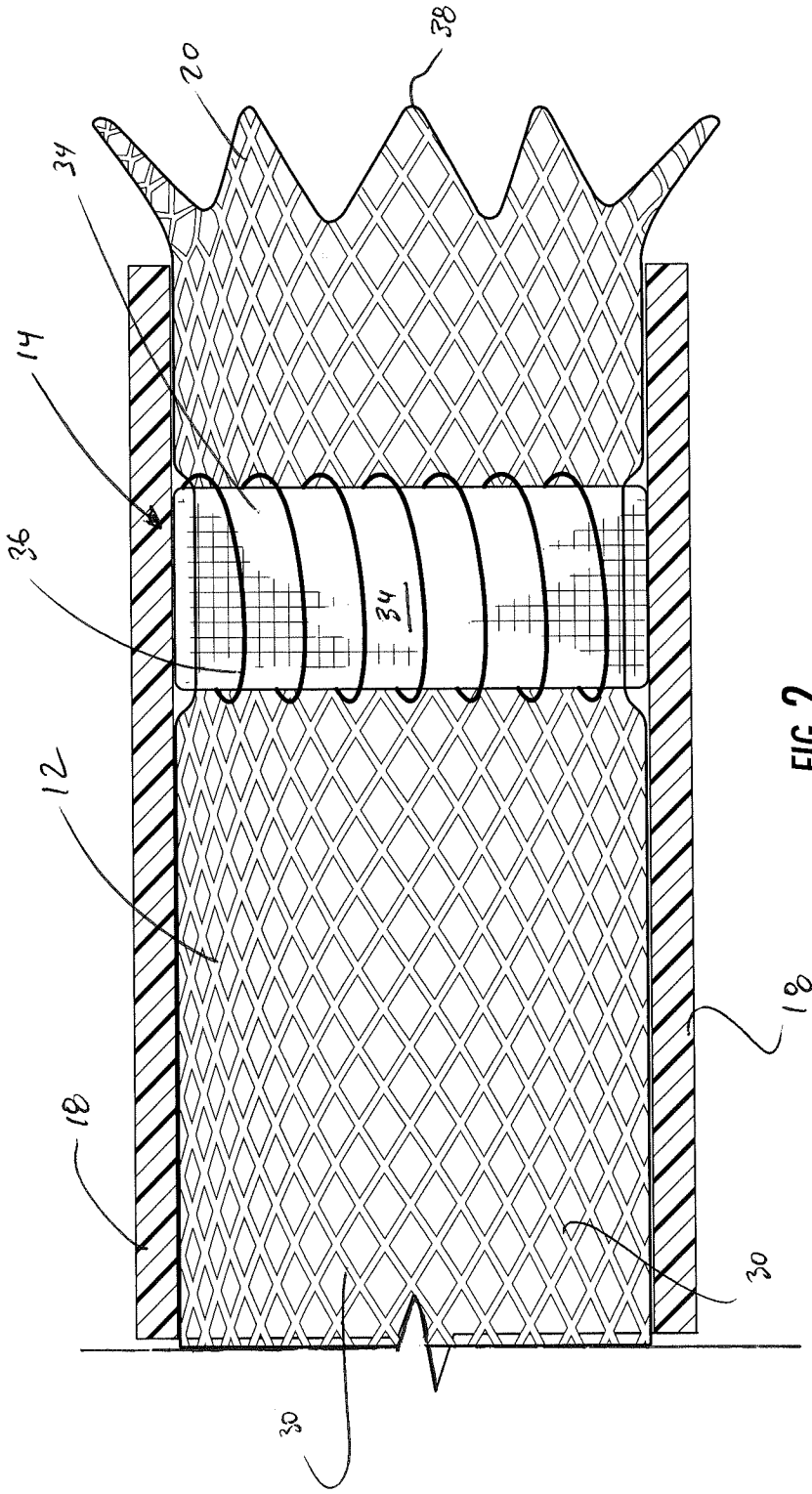


FIG. 2

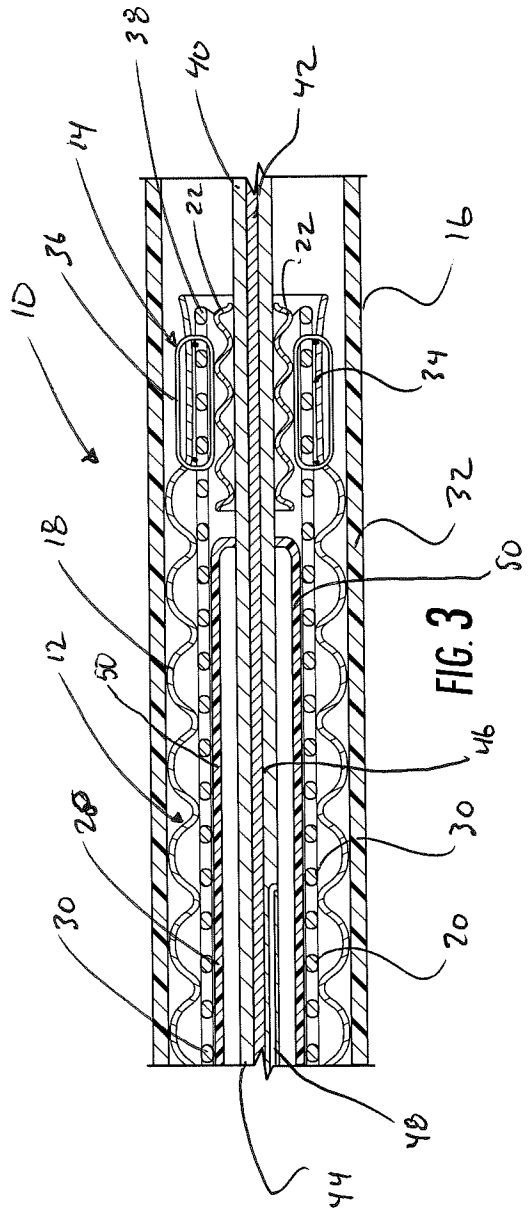


FIG. 3

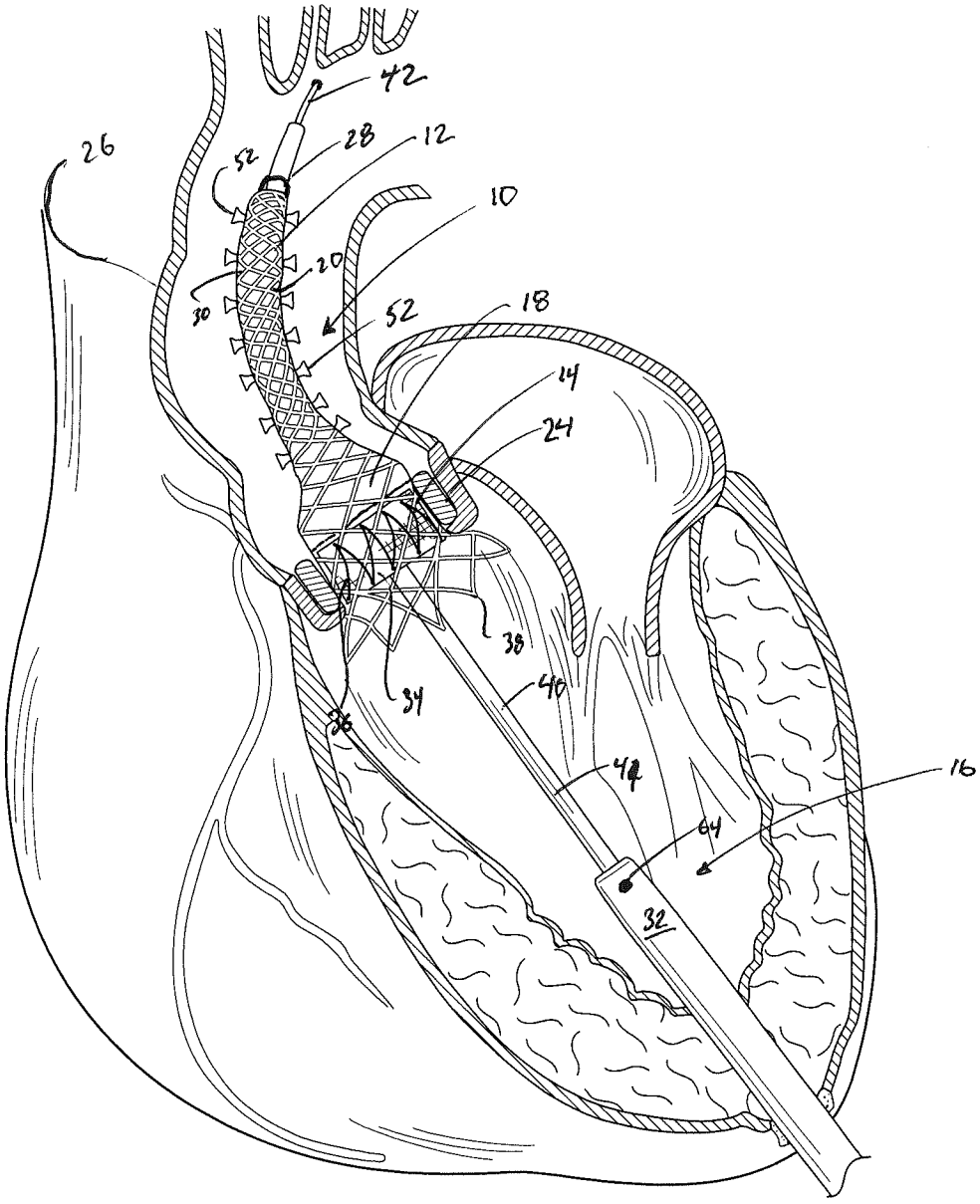


FIG. 4

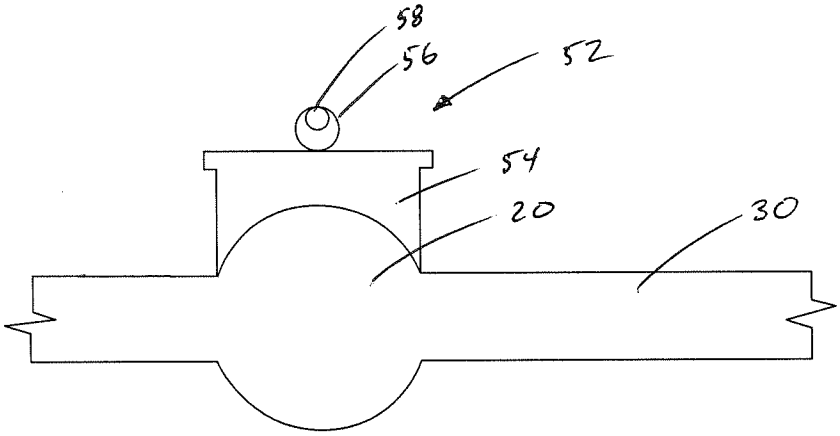


FIG. 5

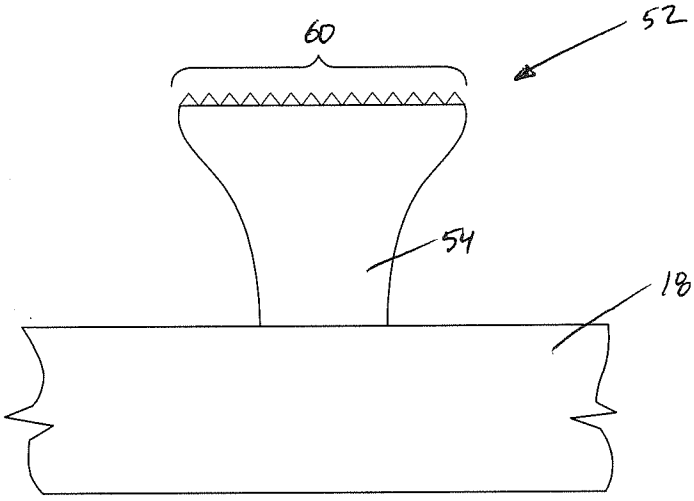


FIG. 6

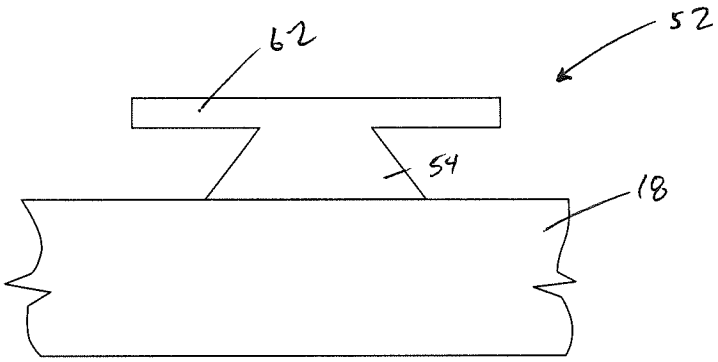


FIG. 7

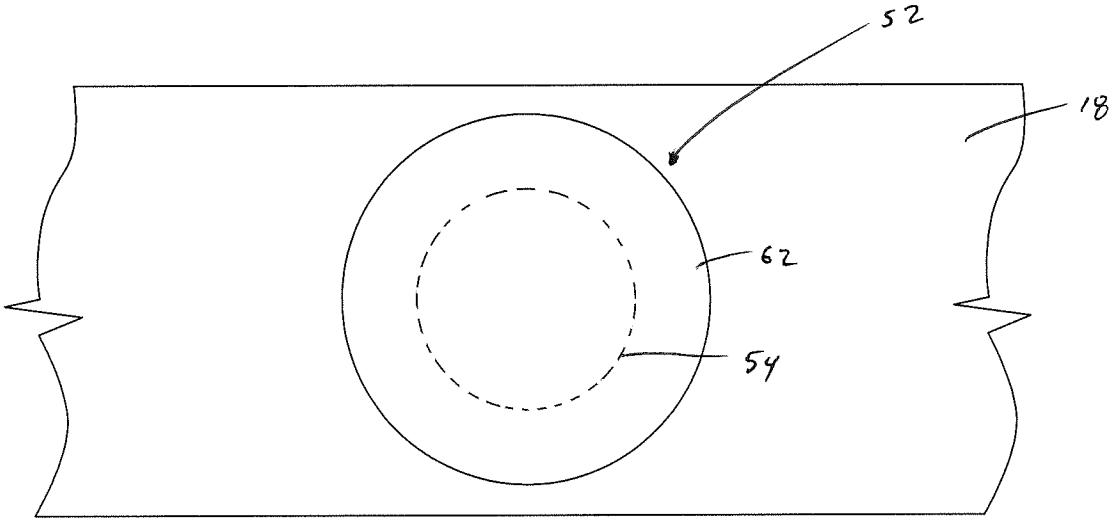


FIG. 8

EXHIBIT 15

From: **Ali Shahriari** <consult@myaorta.com>
Date: Wed, Apr 19, 2017 at 8:49 AM
Subject: Ascyrus Medical LLC.
To: Don_bobo@edwards.com, Larry_wood@edwards.com

Dear Mr. Bobo and Mr. Wood,

My name is Ali Shahriari. I am the CEO of Ascyrus Medical. I am a cardiac surgeon in my original trade and received your names from an Edwards employee. We are a clinical stage device company with the aim to improve the care of patients with acute type A dissection. As you know there has been no new progress for this disease in the last few decades and the patients frequently require additional invasive operations or die within 10 years of the acute event. Ascyrus has developed a novel hybrid graft that works in combination with the current surgical standard of care (replacing the ascending aorta with a polyester graft). In 20% of these cases an aortic valve replacement is conducted concomitantly. The device is very easy to use and does not require guide wire/ catheter skills. We have completed our FIM implant. The device performed very well and shows radiographic evidence of aortic healing. We are starting to explore our next steps as we will be approaching OUS commercialization stage within the next 18 months. As this product has great synergy with the surgical and transcatheter valve market, our team wanted to connect with the Edwards team and discuss our company in more detail. I am attaching an introductory slide deck to this email. You can also find additional information on our website www.ascyrus.com. Our next generation device for the same indication is transcatheter in nature and intended to work in tandem with a transcatheter valve designed for use by the current Heart Team approach. The IP for modular use of a transcatheter valve with an aortic graft has been granted to us.

I would like to set up a call to discuss Ascyrus in more detail. Please let me know if there is availability over the next several weeks. I am looking forward to your feedback.

Best regards,

--
Ali Shahriari MD
President/ CEO



EXHIBIT 16

Subject:	Ascyrus Medical | Dr. Ali Shahriari, Don, Bernard, Larry, Jack, Amir
Location:	US 877-437-9924; Int'l 720-356-4312; Code 250-0193
Start:	Tue 5/2/2017 5:00 PM
End:	Tue 5/2/2017 5:45 PM
Show Time As:	Tentative
Recurrence:	(none)
Meeting Status:	Not yet responded
Organizer:	Don Bobo

Israel: Midnight
East Coast: 5:00p
West Coast: 2:00p

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EXHIBIT 17

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
62/513,348	05/31/2017		260	THVVA-9034US01		

CONFIRMATION NO. 2170

FILING RECEIPT

30452
EDWARDS LIFESCIENCES CORPORATION
LEGAL DEPARTMENT
ONE EDWARDS WAY
IRVINE, CA 92614

OC000000091888690

Date Mailed: 06/06/2017

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Lien Huong Thi Hoang, San Juan Capistrano, CA;
Son V. Nguyen, Irvine, CA;
Hien Tran Ngo, Irvine, CA;
Vivian Tran, Santa Ana, CA;
Russell T. Joseph, Las Flores, CA;
Dinesh L. Sirimanne, Irvine, CA;
Kevin D. Rupp, Irvine, CA;

Applicant(s)

Edwards Lifesciences Corporation, Irvine, CA

Power of Attorney:
Anne Marie Kaiser--37649

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 06/06/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 62/513,348**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No
Title

SEALING MEMBER FOR PROSTHETIC HEART VALVE

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where

the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-9034US01
	Application Number	
Title of Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Lien	Huong Thi	Hoang	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Juan Capistrano	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	Edwards Lifesciences		
Address 2	One Edwards Way; Legal Department		
City	Irvine	State/Province	CA
Postal Code	92614	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Son	V.	Nguyen	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Irvine	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	Edwards Lifesciences		
Address 2	One Edwards Way; Legal Department		
City	Irvine	State/Province	CA
Postal Code	92614	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Hien	Tran	Ngo	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-9034US01
	Application Number	
Title of Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE	

City	Irvine	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	Edwards Lifesciences		
Address 2	One Edwards Way; Legal Department		
City	Irvine	State/Province	CA
Postal Code	92614	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Vivian		Tran	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Santa Ana	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	Edwards Lifesciences		
Address 2	One Edwards Way; Legal Department		
City	Irvine	State/Province	CA
Postal Code	92614	Country	US

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Russell	T.	Joseph	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Las Flores	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	Edwards Lifesciences		
Address 2	One Edwards Way; Legal Department		
City	Irvine	State/Province	CA
Postal Code	92614	Country	US

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Dinesh	L.	Sirimanne	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Irvine	State/Province	CA	Country of Residence	US

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-9034US01
	Application Number	
Title of Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE	

Mailing Address of Inventor:

Address 1	Edwards Lifesciences		
Address 2	One Edwards Way; Legal Department		
City	Irvine	**State/Province**	CA
Postal Code	92614	**Country**	US

Inventor 7 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Kevin	D.	Rupp	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Irvine	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	Edwards Lifesciences		
Address 2	One Edwards Way; Legal Department		
City	Irvine	**State/Province**	CA
Postal Code	92614	**Country**	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	30452		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE		
Attorney Docket Number	THVVA-9034US01	**Small Entity Status Claimed**	☐
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	11	**Suggested Figure for Publication (if any)**	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-9034US01
	Application Number	
Title of Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	30452		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-9034US01
	Application Number	
Title of Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE	

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

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

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-9034US01
	Application Number	
Title of Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-9034US01
	Application Number	
Title of Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

○ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
◉ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	THVVA-9034US01
	Application Number	
Title of Invention	SEALING MEMBER FOR PROSTHETIC HEART VALVE	

Assignee 1

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Signature	/AnneMarie Kaiser/			Date (YYYY-MM-DD)	2017-05-31
First Name	AnneMarie	Last Name	Kaiser	Registration Number	37,649

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SEALING MEMBER FOR PROSTHETIC HEART VALVE

FIELD

[001] The present disclosure relates to implantable, expandable prosthetic devices and to methods and apparatuses for such prosthetic devices.

BACKGROUND

[002] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require replacement of the native valve with an artificial valve. There are a number of known artificial valves and a number of known methods of implanting these artificial valves in humans. Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For example, collapsible transcatheter prosthetic heart valves can be crimped to a compressed state and percutaneously introduced in the compressed state on a catheter and expanded to a functional size at the desired position by balloon inflation or by utilization of a self-expanding frame or stent.

[003] A prosthetic valve for use in such a procedure can include a radially collapsible and expandable frame to which leaflets of the prosthetic valve can be coupled. For example, U.S. Patent Nos. 6,730,118, 7,393,360, 7,510,575, and 7,993,394, which are incorporated herein by reference, describe exemplary collapsible transcatheter heart valves (THVs).

[004] A challenge in catheter-implanted prosthetic valves is the process of crimping such a prosthetic valve to a profile suitable for percutaneous delivery to a subject. Another challenge is the control of paravalvular leakage around the valve, which can occur for a period of time following initial implantation.

[005] Paravalvular leakage has been a known problem since the first replacement valves were introduced. The earliest prosthetic heart valves, those that were implanted surgically, included a circumferential sewing ring that was adapted to extend into spaces in the tissue surrounding the

implanted prosthesis to prevent paravalvular leaking. For example, U.S. Patent No. 3,365,728 describes a prosthetic heart valve for surgical implantation that includes a rubber "cushion ring" that conforms to irregularities of the tissue to form an effective seal between the valve and the surrounding tissue. From there, vascular stents or stent grafts were developed that could be implanted by non-surgical catheterization techniques. These stents included a fabric covering that allowed the stent to be used to isolate and reinforce the wall of a blood vessel from the lumen of the vessel. These fabric coverings served essentially the same purpose on stents as did the sealing rings on surgical heart valves—they reduced the risk of blood leaking between the prosthesis and the surrounding tissue. Multiple graft designs were developed that further enhanced the external seal to prevent blood from flowing between the graft and surrounding cardiovascular tissue. For example, U.S. Patent No. 6,015,431 to Thornton discloses a seal secured to the outer surface of a stent that is adapted to occlude leakage flow externally around the stent wall between the outer surface and the endolumenal wall when the stent is deployed, by conforming to the irregular surface of the surrounding tissue. U.S. Patent Publication 2003/0236567 to Elliot similarly discloses a tubular prosthesis having a stent and one or more fabric "skirts" to seal against endoleaks. U.S. Patent Publication 2004/0082989 to Cook et al. also recognized the potential for endoleaks, and describes a stent graft having a cuff portion that has an external sealing zone that extends around the body of the stent to prevent leakage. The cuff portion could be folded over to create a pocket that collects any blood passing around the leading edge of the graft to prevent an endoleak.

[006] Building on this technology, in the late 1980's, the first permanent bioprosthetic heart valve was implanted using transcatheter techniques. U.S. Patent No. 5,411,552 to Andersen describes a THV comprising a valve mounted within a collapsible and expandable stent structure. Certain embodiments have additional graft material used along the external and internal surface of the THV. As with stent grafts, the covers proposed to be used with THVs were designed to conform to the surface of the surrounding tissue to prevent paravalvular leaks.

[007] Like with stents, "cuffs" or other outer seals were used on THVs. U.S. Patent No. 5,855,601 to Bessler describes a self-expanding THV having a cuff portion extending along the

outside of the stent. Upon collapse of the stent for delivery, the outer seal collapses to form pleats, then expands with the stent to provide a seal between the THV and the surrounding tissue.

[008] Thereafter, a different THV design was described by Pavcnik in U.S. Patent Application Publication 2001/0039450. The enhanced sealing structure of Pavcnik is in the form of corner "flaps" or "pockets" secured to the stent at the edges of each "flap" or "pocket" and positioned at discrete locations around the prosthesis. The corner flap was designed to catch retrograde blood flow to provide a better seal between the THV and the vessel wall, as well as to provide an improved substrate for ingrowth of native tissue.

[009] Thus, fabric and other materials used to cover and seal both internal and external surfaces of THVs and other endovascular prostheses such as stents and stent grafts are well known. These covers can be made with low-porosity woven fabric materials, as described, for example, by U.S. Patent No. 5,957,949 to Leonhardt et al., which describes a valve stent having an outer cover that can conform to the living tissue surrounding it upon implantation to help prevent blood leakage.

[010] Several more recent THV designs include a THV with an outer covering. U.S. Patent No. 7,510,575 to Spenser discloses a THV having a cuff portion wrapped around the outer surface of the support stent at the inlet. The cuff portion is rolled up over the edge of the frame so as to provide a "sleeve-like" portion at the inlet to form a cuff over the inlet that helps prevent blood leakage. U.S. Patent No. 8,002,825 to Letac and Cribier describes an internal cover that extends from the base of the valve to the lower end of the stent and then up the external wall of the stent so as to form an external cover. The single-piece cover could be made with any of the materials disclosed for making the valve structure, which include fabric (e.g., Dacron), biological material (e.g., pericardium), or other synthetic materials (e.g., polyethylene).

[011] While covers used on the external surface of an endovascular prosthesis to prevent paravalvular leaking are well known, there remains a need for improved coverings that provide enhanced sealing while still providing a small profile suitable for percutaneous delivery to a patient.

SUMMARY

[012] Embodiments of a radially collapsible and expandable prosthetic valve are disclosed herein that include an improved outer skirt for reducing perivalvular leakage, as well as related methods and apparatuses including such prosthetic valves. In several embodiments, the disclosed prosthetic valves are configured as replacement heart valves for implantation into a subject.

[013] In one representative embodiment, a prosthetic heart valve comprises an annular frame that comprises an inflow end and an outflow end and is radially compressible and expandable between a radially compressed configuration and a radially expanded configuration. The prosthetic heart valve further includes a leaflet structure positioned within the frame and secured thereto, and an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient. The sealing member can comprise a mesh layer and pile layer comprising a plurality of pile yarns extending outwardly from the mesh layer.

[014] In some embodiments, the mesh layer comprises a knit or woven fabric.

[015] In some embodiments, the pile yarns are arranged to form a looped pile.

[016] In some embodiments, the pile yarns are cut to form a cut pile.

[017] In some embodiments, the height of the pile yarns varies along a height and/or a circumference of the outer skirt.

[018] In some embodiments, the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is less than a height of the yarns of the second group.

[019] In some embodiments, the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is greater than a height of the yarns of the second group.

[020] In some embodiments, the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt, a second group of yarns along a downstream portion of the outer skirt, and a third group of yarns between the first and second group of yarns, wherein the yarns of the first and second groups have a height that is greater than a height of the yarns of the third group.

[021] In some embodiments, the prosthetic heart valve further comprises an inner skirt mounted on an inner surface of the frame, the inner skirt having an inflow end portion that is secured to an inflow end portion of the outer sealing member.

[022] In some embodiments, the inflow end portion of the inner skirt is wrapped around an inflow end of the frame and overlaps the inflow end portion of the outer sealing member on the outside of the frame.

[023] In some embodiments, the mesh layer comprises a first mesh layer and the outer sealing member further comprises a second mesh layer disposed radially outside of the pile layer.

[024] In some embodiments, the outer sealing member is configured to stretch axially when the frame is radially compressed to the radially compressed state.

[025] In another representative embodiment, a prosthetic heart valve comprises an annular frame that comprises an inflow end and an outflow end and is radially compressible and expandable between a radially compressed configuration and a radially expanded configuration. The prosthetic heart valve further comprises a leaflet structure positioned within the frame and secured thereto, an outer sealing member mounted outside of the frame and adapted to seal against surrounding tissue when the prosthetic heart valve is implanted within a native heart valve annulus of a patient. The sealing member can comprise a fabric having a variable thickness.

[026] In some embodiments, the thickness of the fabric layer varies along a height and/or a circumference of the outer sealing member.

[027] In some embodiments, the fabric comprises a plush fabric.

[028] In some embodiments, the fabric comprises a plurality of pile yarns and the height of the pile yarns varies along a height and/or a circumference of the outer skirt.

[029] In some embodiments, the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is less than a height of the yarns of the second group.

[030] In some embodiments, the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt and a second group of yarns along a downstream portion of the outer skirt, wherein the yarns of the first group have a height that is greater than a height of the yarns of the second group.

[031] In some embodiments, the pile yarns comprise a first group of yarns along an upstream portion of the outer skirt, a second group of yarns along a downstream portion of the outer skirt, and a third group of yarns between the first and second group of yarns, wherein the yarns of the first and second groups have a height that is greater than a height of the yarns of the third group.

BRIEF DESCRIPTION OF THE DRAWINGS

[032] FIG. 1 is a perspective view of a prosthetic heart valve, according to one embodiment.

[033] FIG. 2 is an enlarged, perspective view of the inflow end portion of the prosthetic heart valve of FIG. 1.

[034] FIG. 3 is a cross-sectional view of the prosthetic heart valve of FIG. 1, showing the attachment of the outer skirt to the inner skirt and the frame.

[035] FIGS. 4-10 show an exemplary frame of the prosthetic heart valve of FIG. 1.

[036] FIGS. 11-12 show an exemplary inner skirt of the prosthetic heart valve of FIG. 1.

[037] FIGS. 13-15 show the assembly of the inner skirt of FIG. 11 with the frame of FIG. 4.

[038] FIGS. 16-17 show the assembly of an exemplary leaflet structure.

[039] FIG. 18 shows the assembly of commissure portions of the leaflet structure with window frame portions of the frame.

[040] FIGS. 19-20 show the assembly of the leaflet structure with the inner skirt along a lower edge of the leaflets.

[041] FIGS. 21-23 are different views of an exemplary outer skirt of the prosthetic heart valve of FIG. 1.

[042] FIG. 24-26 are cross-sectional views similar to FIG. 3 but showing different embodiments of the outer skirt.

[043] FIGS. 27-28 show an alternative way of securing an outer skirt to an inner skirt and/or the frame of a prosthetic heart valve.

[044] FIGS. 29-32 show another way of securing an outer skirt to an inner skirt and/or the frame of a prosthetic heart valve.

[045] FIGS. 33-35 show another embodiment of an outer sealing member for a prosthetic heart valve.

DETAILED DESCRIPTION

[046] FIG. 1 shows a prosthetic heart valve 10, according to one embodiment. The illustrated prosthetic valve is adapted to be implanted in the native aortic annulus, although in other embodiments it can be adapted to be implanted in the other native annuluses of the heart (e.g., the pulmonary, mitral, and tricuspid valves). The prosthetic valve can also be adapted to be implanted in other tubular organs or passageways in the body. The prosthetic valve 10 can have four main components: a stent or frame 12, a valvular structure 14, an inner skirt 16, and a perivalvular outer sealing member or outer skirt 18. The prosthetic valve 10 can have an inflow end portion 15, an intermediate portion 17, and an outflow end portion 19.

[047] The valvular structure 14 can comprise three leaflets 40 (FIG. 17), collectively forming a leaflet structure, which can be arranged to collapse in a tricuspid arrangement. The lower edge of leaflet structure 14 desirably has an undulating, curved scalloped shape (suture line 154 shown in FIG. 20 tracks the scalloped shape of the leaflet structure). By forming the leaflets with this scalloped geometry, stresses on the leaflets are reduced, which in turn improves durability of the prosthetic valve. Moreover, by virtue of the scalloped shape, folds and ripples at the belly of

each leaflet (the central region of each leaflet), which can cause early calcification in those areas, can be eliminated or at least minimized. The scalloped geometry also reduces the amount of tissue material used to form leaflet structure, thereby allowing a smaller, more even crimped profile at the inflow end of the prosthetic valve. The leaflets 40 can be formed of pericardial tissue (e.g., bovine pericardial tissue), biocompatible synthetic materials, or various other suitable natural or synthetic materials as known in the art and described in U.S. Patent No. 6,730,118, which is incorporated by reference herein.

[048] The bare frame 12 is shown in FIG. 4. The frame 12 can be formed with a plurality of circumferentially spaced slots, or commissure windows, 20 (three in the illustrated embodiment) that are adapted to mount the commissures of the valvular structure 14 to the frame, as described in greater detail below. The frame 12 can be made of any of various suitable plastically-expandable materials (e.g., stainless steel, etc.) or self-expanding materials (e.g., nickel titanium alloy (NiTi), such as nitinol) as known in the art. When constructed of a plastically-expandable material, the frame 12 (and thus the prosthetic valve 10) can be crimped to a radially collapsed configuration on a delivery catheter and then expanded inside a patient by an inflatable balloon or equivalent expansion mechanism. When constructed of a self-expandable material, the frame 12 (and thus the prosthetic valve 10) can be crimped to a radially collapsed configuration and restrained in the collapsed configuration by insertion into a sheath or equivalent mechanism of a delivery catheter. Once inside the body, the prosthetic valve can be advanced from the delivery sheath, which allows the prosthetic valve to expand to its functional size.

[049] Suitable plastically-expandable materials that can be used to form the frame 12 include, without limitation, stainless steel, a biocompatible, high-strength alloys (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloys), polymers, or combinations thereof. In particular embodiments, frame 12 is made of a nickel-cobalt-chromium-molybdenum alloy, such as MP35N® alloy (SPS Technologies, Jenkintown, Pennsylvania), which is equivalent to UNS R30035 alloy (covered by ASTM F562-02). MP35N® alloy/UNS R30035 alloy comprises 35% nickel, 35% cobalt, 20% chromium, and 10% molybdenum, by weight. It has been found that the use of MP35N® alloy to form frame 12 provides superior structural results over stainless steel. In particular, when MP35N® alloy is used as the frame material, less material is needed to

achieve the same or better performance in radial and crush force resistance, fatigue resistances, and corrosion resistance. Moreover, since less material is required, the crimped profile of the frame can be reduced, thereby providing a lower profile prosthetic valve assembly for percutaneous delivery to the treatment location in the body.

[050] Referring to FIGS. 4 and 5, the frame 12 in the illustrated embodiment comprises a first, lower row I of angled struts 22 arranged end-to-end and extending circumferentially at the inflow end of the frame; a second row II of circumferentially extending, angled struts 24; a third row III of circumferentially extending, angled struts 26; a fourth row IV of circumferentially extending, angled struts 28; and a fifth row V of circumferentially extending, angled struts 32 at the outflow end of the frame. A plurality of substantially straight axially extending struts 34 can be used to interconnect the struts 22 of the first row I with the struts 24 of the second row II. The fifth row V of angled struts 32 are connected to the fourth row IV of angled struts 28 by a plurality of axially extending window frame portions 30 (which define the commissure windows 20) and a plurality of axially extending struts 31. Each axial strut 31 and each frame portion 30 extends from a location defined by the convergence of the lower ends of two angled struts 32 to another location defined by the convergence of the upper ends of two angled struts 28. FIGS. 6, 7, 8, 9, and 10 are enlarged views of the portions of the frame 12 identified by letters A, B, C, D, and E, respectively, in FIG. 5.

[051] Each commissure window frame portion 30 mounts a respective commissure of the leaflet structure 14. As can be seen each frame portion 30 is secured at its upper and lower ends to the adjacent rows of struts to provide a robust configuration that enhances fatigue resistance under cyclic loading of the prosthetic valve compared to known, cantilevered struts for supporting the commissures of the leaflet structure. This configuration enables a reduction in the frame wall thickness to achieve a smaller crimped diameter of the prosthetic valve. In particular embodiments, the thickness T of the frame 12 (FIG. 4) measured between the inner diameter and outer diameter is about 0.48 mm or less.

[052] The struts and frame portions of the frame collectively define a plurality of open cells of the frame. At the inflow end of the frame 12, struts 22, struts 24, and struts 34 define a lower

row of cells defining openings 36. The second, third, and fourth rows of struts 24, 26, and 28 define two intermediate rows of cells defining openings 38. The fourth and fifth rows of struts 28 and 32, along with frame portions 30 and struts 31, define an upper row of cells defining openings 40. The openings 40 are relatively large and are sized to allow portions of the leaflet structure 14 to protrude, or bulge, into and/or through the openings 40 when the frame 12 is crimped in order to minimize the crimping profile.

[053] As best shown in FIG. 7, the lower end of the strut 31 is connected to two struts 28 at a node or junction 44, and the upper end of the strut 31 is connected to two struts 32 at a node or junction 46. The strut 31 can have a thickness S1 that is less than the thicknesses S2 of the junctions 44, 46. The junctions 44, 46, along with junctions 64, prevent full closure of openings 40. The geometry of the struts 31, and junctions 44, 46, and 64 assists in creating enough space in openings 40 in the collapsed configuration to allow portions of the prosthetic leaflets to protrude or bulge outwardly through openings. This allows the prosthetic valve to be crimped to a relatively smaller diameter than if all of the leaflet material were constrained within the crimped frame.

[054] The frame 12 is configured to reduce, to prevent, or to minimize possible over-expansion of the prosthetic valve at a predetermined balloon pressure, especially at the outflow end portion of the frame, which supports the leaflet structure 14. In one aspect, the frame is configured to have relatively larger angles 42a, 42b, 42c, 42d, 42e between struts, as shown in FIG. 5. The larger the angle, the greater the force required to open (expand) the frame. As such, the angles between the struts of the frame can be selected to limit radial expansion of the frame at a given opening pressure (e.g., inflation pressure of the balloon). In particular embodiments, these angles are at least 110 degrees or greater when the frame is expanded to its functional size, and even more particularly these angles are up to about 120 degrees when the frame is expanded to its functional size.

[055] In addition, the inflow and outflow ends of a frame generally tend to over-expand more so than the middle portion of the frame due to the “dog-boning” effect of the balloon used to expand the prosthetic valve. To protect against over-expansion of the leaflet structure 14, the

leaflet structure desirably is secured to the frame 12 below the upper row of struts 32, as best shown in FIG. 1. Thus, in the event that the outflow end of the frame is over-expanded, the leaflet structure is positioned at a level below where over-expansion is likely to occur, thereby protecting the leaflet structure from over-expansion.

[056] In a known prosthetic valve construction, portions of the leaflets can protrude longitudinally beyond the outflow end of the frame when the prosthetic valve is crimped if the leaflets are mounted too close to the distal end of the frame. If the delivery catheter on which the crimped prosthetic valve is mounted includes a pushing mechanism or stop member that pushes against or abuts the outflow end of the prosthetic valve (for example, to maintain the position of the crimped prosthetic valve on the delivery catheter), the pushing member or stop member can damage the portions of the exposed leaflets that extend beyond the outflow end of the frame. Another benefit of mounting the leaflets at a location spaced away from the outflow end of the frame is that when the prosthetic valve is crimped on a delivery catheter, the outflow end of the frame 12 rather than the leaflets 40 is the proximal-most component of the prosthetic valve 10. As such, if the delivery catheter includes a pushing mechanism or stop member that pushes against or abuts the outflow end of the prosthetic valve, the pushing mechanism or stop member contacts the outflow end of the frame, and not leaflets 40, so as to avoid damage to the leaflets.

[057] Also, as can be seen in FIG. 5, the openings 36 of the lowermost row of openings in the frame are relatively larger than the openings 38 of the two intermediate rows of openings. This allows the frame, when crimped, to assume an overall tapered shape that tapers from a maximum diameter at the outflow end of the prosthetic valve to a minimum diameter at the inflow end of the prosthetic valve. When crimped, the frame 12 has a reduced diameter region extending along a portion of the frame adjacent the inflow end of the frame that generally corresponds to the region of the frame covered by the outer skirt 18. In some embodiments, the reduced diameter region is reduced compared to the diameter of the upper portion of the frame (which is not covered by the outer skirt) such that the outer skirt 18 does not increase the overall crimp profile of the prosthetic valve. When the prosthetic valve is deployed, the frame can expand to the generally cylindrical shape shown in FIG. 4. In one example, the frame of a 26-mm prosthetic

valve, when crimped, had a first diameter of 14 French at the outflow end of the prosthetic valve and a second diameter of 12 French at the inflow end of the prosthetic valve.

[058] The main functions of the inner skirt 16 are to assist in securing the valvular structure 14 to the frame 12 and to assist in forming a good seal between the prosthetic valve and the native annulus by blocking the flow of blood through the open cells of the frame 12 below the lower edge of the leaflets. The inner skirt 16 desirably comprises a tough, tear resistant material such as polyethylene terephthalate (PET), although various other synthetic materials or natural materials (e.g., pericardial tissue) can be used. The thickness of the skirt desirably is less than about 0.15 mm (about 6 mil), and desirably less than about 0.1 mm (about 4 mil), and even more desirably about 0.05 mm (about 2 mil). In particular embodiments, the skirt 16 can have a variable thickness, for example, the skirt can be thicker at at least one of its edges than at its center. In one implementation, the skirt 16 can comprise a PET skirt having a thickness of about 0.07 mm at its edges and about 0.06 mm at its center. The thinner skirt can provide for better crimping performances while still providing good perivalvular sealing.

[059] The skirt 16 can be secured to the inside of frame 12 via sutures 70, as shown in FIG. 20. Valvular structure 14 can be attached to the skirt via one or more reinforcing strips 72 (which collectively can form a sleeve), for example thin, PET reinforcing strips, discussed below, which enables a secure suturing and protects the pericardial tissue of the leaflet structure from tears. Valvular structure 14 can be sandwiched between skirt 16 and the thin PET strips 72 as shown in FIG. 19. Sutures 154, which secure the PET strip and the leaflet structure 14 to skirt 16, can be any suitable suture, such as Ethibond Excel® PET suture (Johnson & Johnson, New Brunswick, New Jersey). Sutures 154 desirably track the curvature of the bottom edge of leaflet structure 14, as described in more detail below.

[060] Known fabric skirts may comprise a weave of warp and weft fibers that extend perpendicularly to each other and with one set of the fibers extending longitudinally between the upper and lower edges of the skirt. When the metal frame to which the fabric skirt is secured is radially compressed, the overall axial length of the frame increases. Unfortunately, a fabric skirt

with limited elasticity cannot elongate along with the frame and therefore tends to deform the struts of the frame and to prevent uniform crimping.

[061] Referring to FIG. 12, in contrast to known fabric skirts, the skirt 16 desirably is woven from a first set of fibers, or yarns or strands, 78 and a second set of fibers, or yarns or strands, 80, both of which are non-perpendicular to the upper edge 82 and the lower edge 84 of the skirt. In particular embodiments, the first set of fibers 78 and the second set of fibers 80 extend at angles of about 45 degrees (e.g., 15-75 degrees or 30-60 degrees) relative to the upper and lower edges 82, 84. For example, the skirt 16 can be formed by weaving the fibers at 45 degree angles relative to the upper and lower edges of the fabric. Alternatively, the skirt 16 can be diagonally cut (cut on a bias) from a vertically woven fabric (where the fibers extend perpendicularly to the edges of the material) such that the fibers extend at 45 degree angles relative to the cut upper and lower edges of the skirt. As further shown in FIG. 12, the opposing short edges 86, 88 of the skirt desirably are non-perpendicular to the upper and lower edges 82, 84. For example, the short edges 86, 88 desirably extend at angles of about 45 degrees relative to the upper and lower edges and therefore are aligned with the first set of fibers 78. Therefore the overall general shape of the skirt is that of a rhomboid or parallelogram.

[062] FIGS. 13 and 14 show the inner skirt 16 after opposing short edge portions 90, 92 have been sewn together to form the annular shape of the skirt. As shown, the edge portion 90 can be placed in an overlapping relationship relative to the opposite edge portion 92, and the two edge portions can be sewn together with a diagonally extending suture line 94 that is parallel to short edges 86, 88. The upper edge portion of the inner skirt 16 can be formed with a plurality of projections 96 that define an undulating shape that generally follows the shape or contour of the fourth row of struts 28 immediately adjacent the lower ends of axial struts 31. In this manner, as best shown in FIG. 15, the upper edge of the inner skirt 16 can be tightly secured to struts 28 with sutures 70. The inner skirt 16 can also be formed with slits 98 to facilitate attachment of the skirt to the frame. Slits 98 are dimensioned so as to allow an upper edge portion of the inner skirt 16 to be partially wrapped around struts 28 and to reduce stresses in the skirt during the attachment procedure. For example, in the illustrated embodiment, the inner skirt 16 is placed on the inside of frame 12 and an upper edge portion of the skirt is wrapped around the upper

surfaces of struts 28 and secured in place with sutures 70. Wrapping the upper edge portion of the inner skirt 16 around struts 28 in this manner provides for a stronger and more durable attachment of the skirt to the frame. The inner skirt 16 can also be secured to the first, second, and/or third rows of struts 22, 24, and 26, respectively, with sutures 70.

[063] Due to the angled orientation of the fibers relative to the upper and lower edges, the skirt can undergo greater elongation in the axial direction (*i.e.*, in a direction from the upper edge 82 to the lower edge 84). Thus, when the metal frame 12 is crimped, the inner skirt 16 can elongate in the axial direction along with the frame and therefore provide a more uniform and predictable crimping profile. Each cell of the metal frame in the illustrated embodiment includes at least four angled struts that rotate towards the axial direction on crimping (e.g., the angled struts become more aligned with the length of the frame). The angled struts of each cell function as a mechanism for rotating the fibers of the skirt in the same direction of the struts, allowing the skirt to elongate along the length of the struts. This allows for greater elongation of the skirt and avoids undesirable deformation of the struts when the prosthetic valve is crimped.

[064] In addition, the spacing between the woven fibers or yarns can be increased to facilitate elongation of the skirt in the axial direction. For example, for a PET inner skirt 16 formed from 20-denier yarn, the yarn density can be about 15% to about 30% lower than in a typical PET skirt. In some examples, the yarn spacing of the inner skirt 16 can be from about 60 yarns per cm (about 155 yarns per inch) to about 70 yarns per cm (about 180 yarns per inch), such as about 63 yarns per cm (about 160 yarns per inch), whereas in a typical PET skirt the yarn spacing can be from about 85 yarns per cm (about 217 yarns per inch) to about 97 yarns per cm (about 247 yarns per inch). The oblique edges 86, 88 promote a uniform and even distribution of the fabric material along inner circumference of the frame during crimping so as to reduce or minimize bunching of the fabric to facilitate uniform crimping to the smallest possible diameter. Additionally, cutting diagonal sutures in a vertical manner may leave loose fringes along the cut edges. The oblique edges 86, 88 help minimize this from occurring. Compared to the construction of a typical skirt (fibers running perpendicularly to the upper and lower edges of the skirt), the construction of the inner skirt 16 avoids undesirable deformation of the frame struts and provides more uniform crimping of the frame.