IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AORTIC INNOVATIONS LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**C.A. NO. _____**
	)	
EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES (U.S.) INC.,	)	**DEMAND FOR JURY TRIAL**
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Aortic Innovations LLC ("Aortic" or "Plaintiff") files this 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"); and 11,389,310 ("the '310 Patent") (collectively, "Patents-in-Suit") (Exs. 1-2).

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

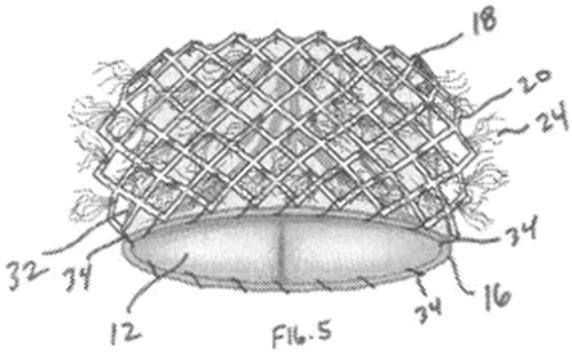
the first time in 2019. Ex. 5, *TAVR Is Now Dominant Form of Aortic Valve Replacement in the United States* (November 17, 2020), https://www.dicardiology.com/article/tavr-now-dominant-form-aortic-valve-replacement-united-states.

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 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]

[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.

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.

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

[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.

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 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	Sept 28, 2021	Defendant

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

Corporation, et al., 1-21-cv-01377 (DDE)		
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.

BACKGROUND

A. DR. SHAHRIARI'S TAVR INVENTIONS

23. 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.

24. 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

25. 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.

26. 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.

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

28. 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.

29. 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.

30. 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.

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

32. 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.

33. 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.

34. 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.

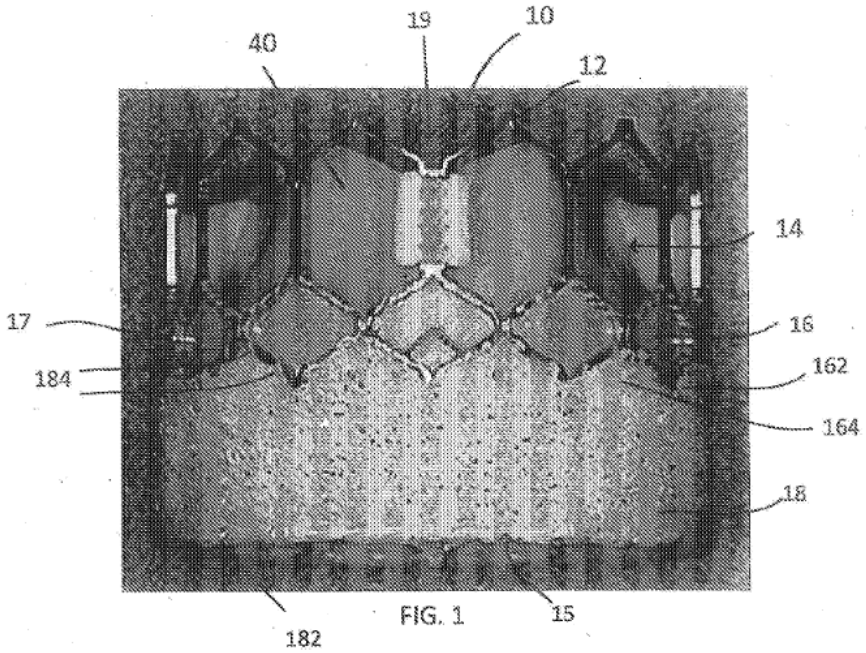
35. Not only was Edwards aware of Aortic's patent and technology as a result of its patent prosecution activities, but Edwards also learned of Dr. Shahriari's inventions directly from discussions with Dr. Shahriari. Specifically, on or around early 2017, Dr. Shahriari contacted Edwards to discuss his 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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*.

44. 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.

45. 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:

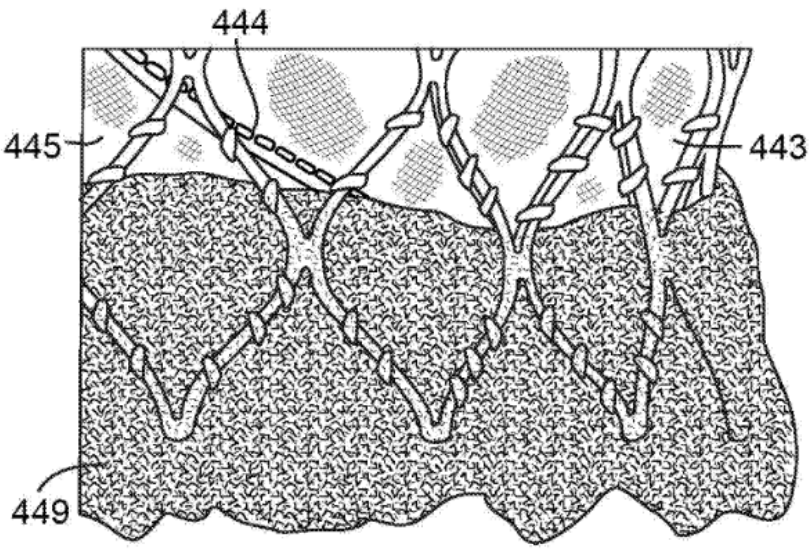


FIG. 38

Ex. 21, 071, Figure 38.

46. 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.

47. 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.

48. 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.

49. Edwards has admitted to knowledge of the '310 and '834 Patents and Aortic's accusations of infringement. For example, Edwards attached the '310 and '834 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. On information and belief, despite receiving notice, Edwards has not ceased practicing any of the Aortic Patents-in-

Suit. Instead, Edwards has continued the manufacture, offer for sale and sell the Sapien 3 Ultra, has launched the Sapien 3 Ultra with Resilia leaflets and is continuing to develop and test the Sapien X4 TAVR device for marketing. Ex. 63.

C. TAVR IMPROVEMENTS AND MARKET GROWTH

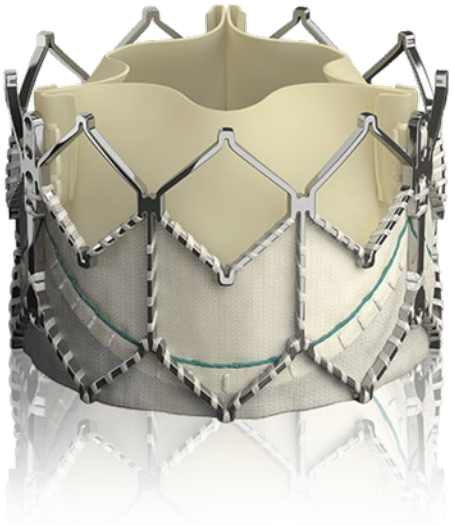
50. TAVR was not widely accepted technology in the field in 2011. The first FDA approved TAVR device was not approved until November, 2011, slightly more than a decade ago for extreme risk patients. TAVR was then approved for intermediate risk patients in 2016. Following further advancements in TAVR 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.

51. 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.*

52. 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.

53. 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:

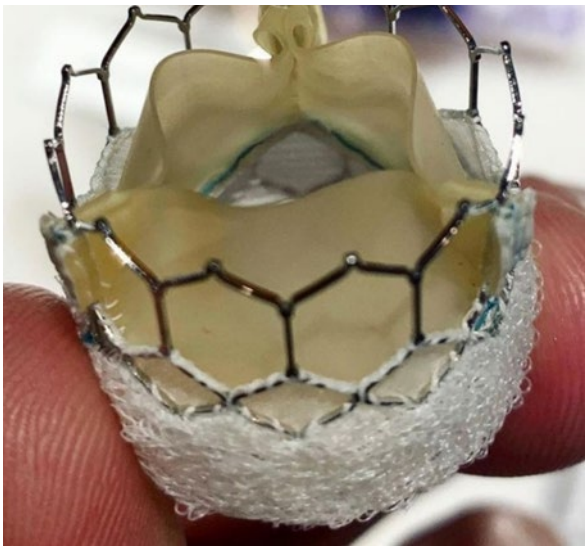


Ex. 26, https://www.edwards.com/gb/devices/heart-valves/sapien-xt-valve.

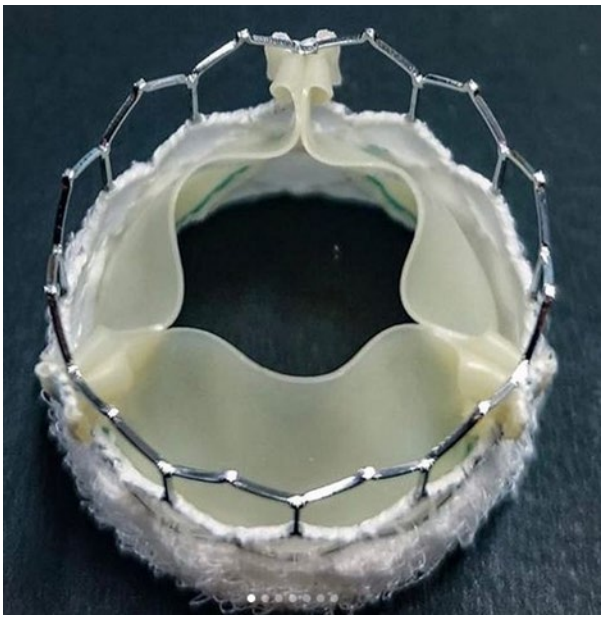
54. Edwards also introduced the Sapien 3 TAVR, which included a loosely fit outer skirt with openings that would provide minimal sealing to attempt to address PVL. On information and belief, the sealing was accomplished by the billowing of the skirt, and retrograde blood flow into the skirt. On information 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.

55. 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.

56. 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

[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 specify that Edwards Lifesciences LLC is a subsidiary of Edwards which is included in these filings.

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).

57. 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.

58. 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, 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.

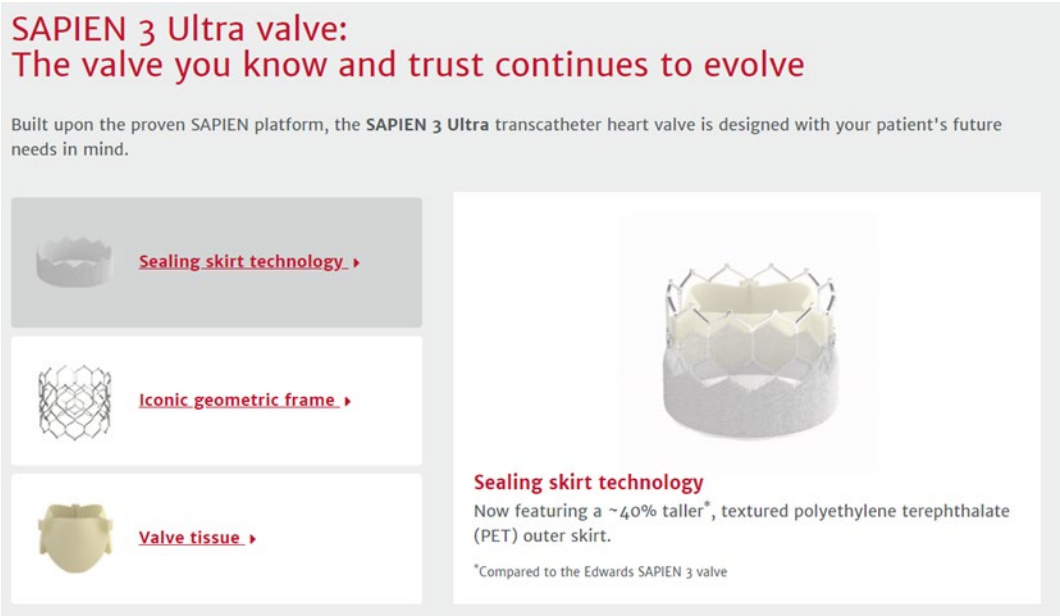
EDWARDS'S ACCUSED PRODUCTS

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

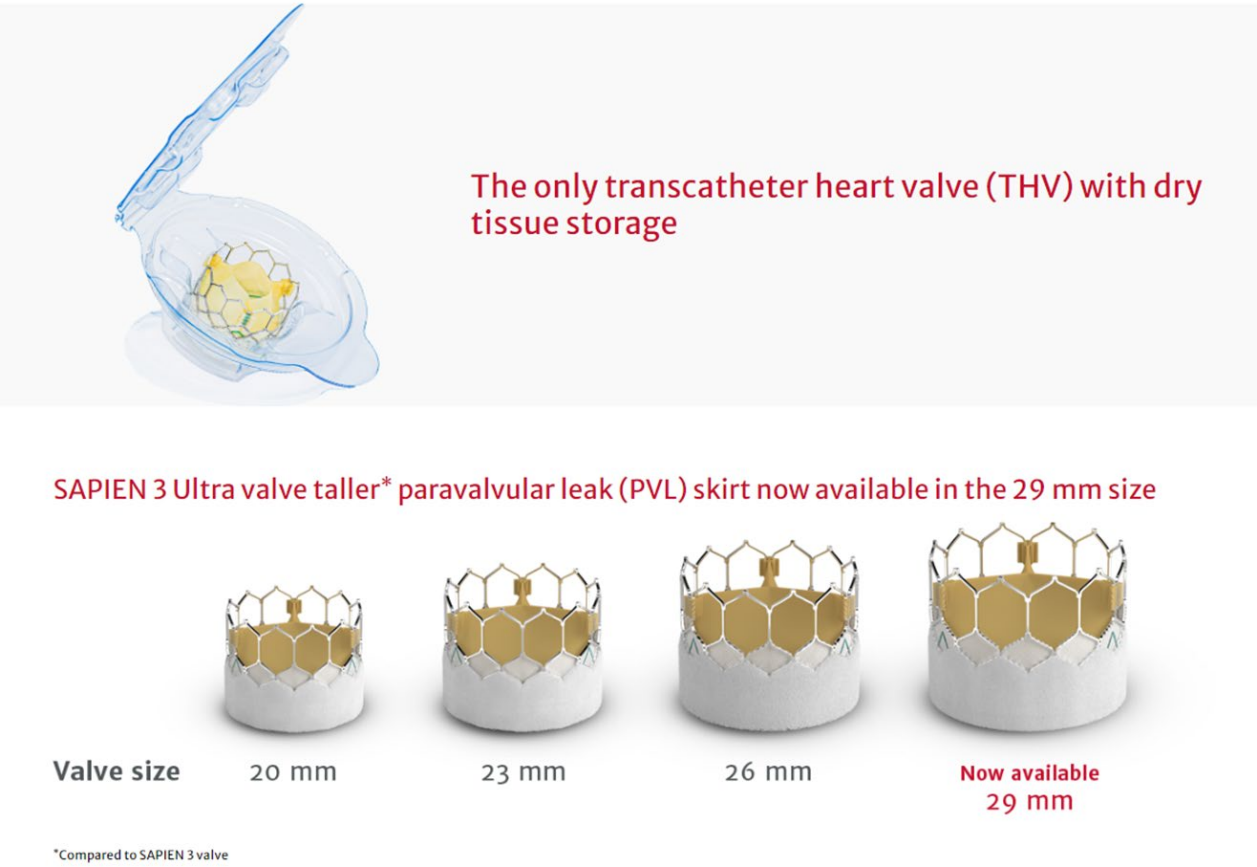
59. Edwards makes, imports, exports, uses, sells, and/or offers for sale TAVR devices that infringe at least one claim of each of the Patents-in-Suit ("Accused Products").

60. 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.

61. 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.

62. 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.

63. 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).

64. 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.

65. 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.

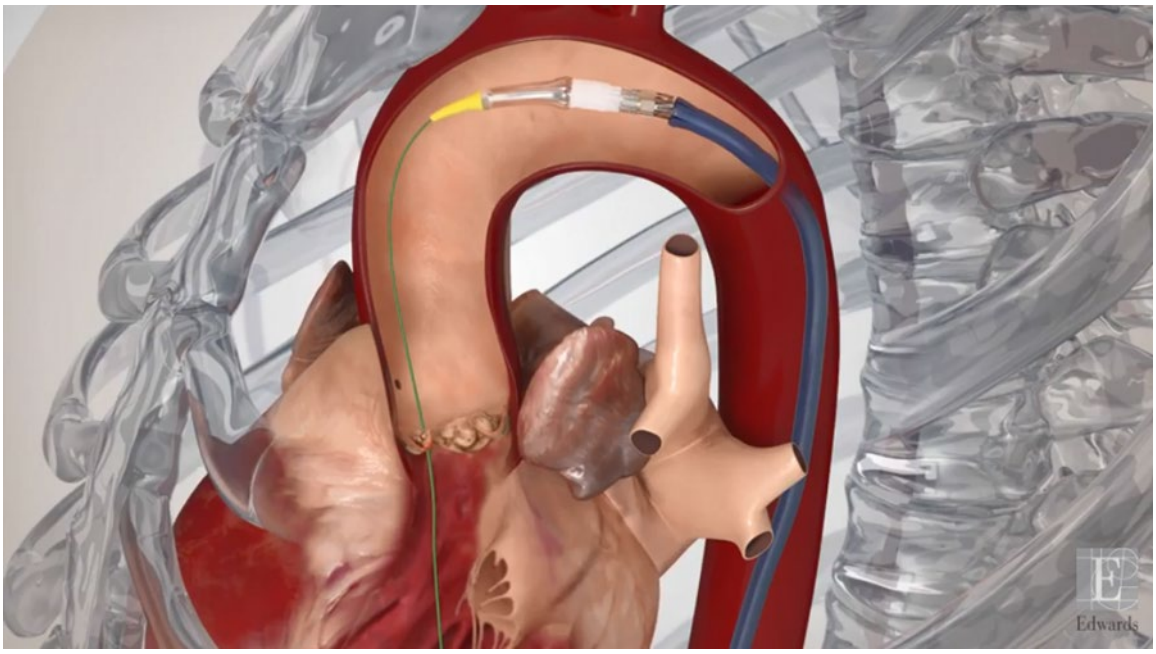
66. Edwards also regularly includes information concerning the production and sale of Sapien 3 Ultra in Edwards Lifesciences Corporation's SEC filings and presentations to Edwards' investors. *See, e.g.*, Edwards Lifesciences Corporation, Annual Report (Form 10-K)

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

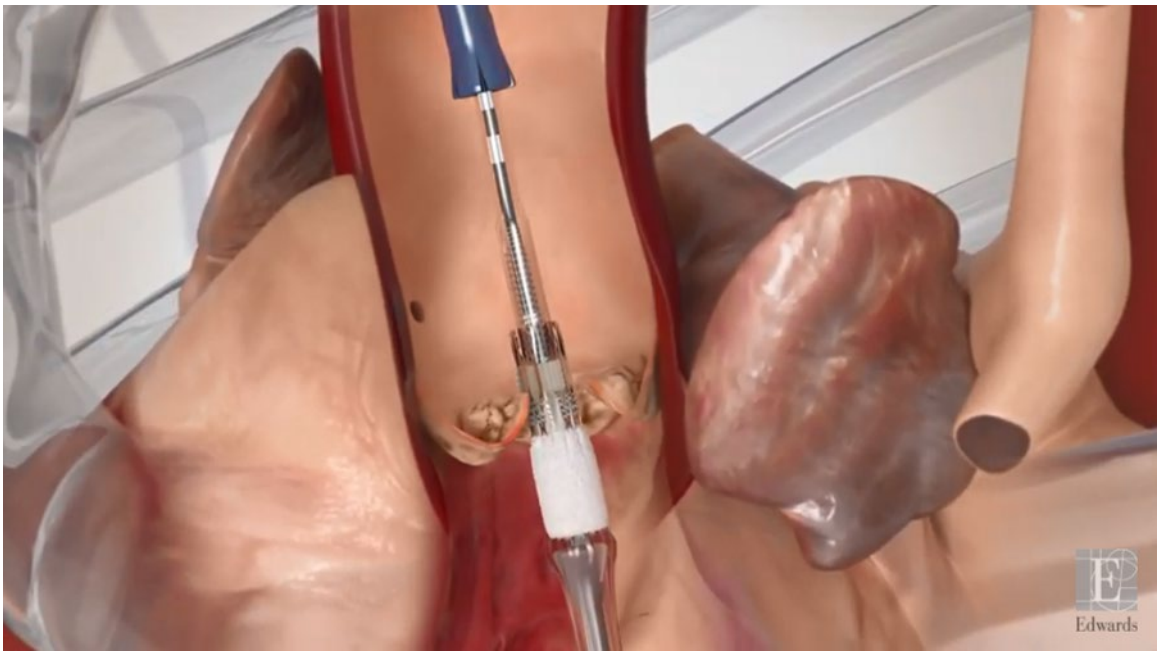
(December 31, 2022), available at Ex. 55, https://d18rn0p25nwr6d.cloudfront.net/CIK-0001099800/8e36830a-715c-4dcc-be2e-70dff0f309a3.pdf; Ex. 53, Edwards Lifesciences Corporation, Form 10-K (Dec. 31, 2021); Edwards Lifesciences Corporation Form 10-K (2020) at 2, 24, available at Ex. 36; Edwards Lifesciences 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]

67. 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. 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 configured, designed, manufactured, and tested by Edwards to be an endovascular prosthetic heart valve endovascularly deliverable though a femoral artery of a patient.

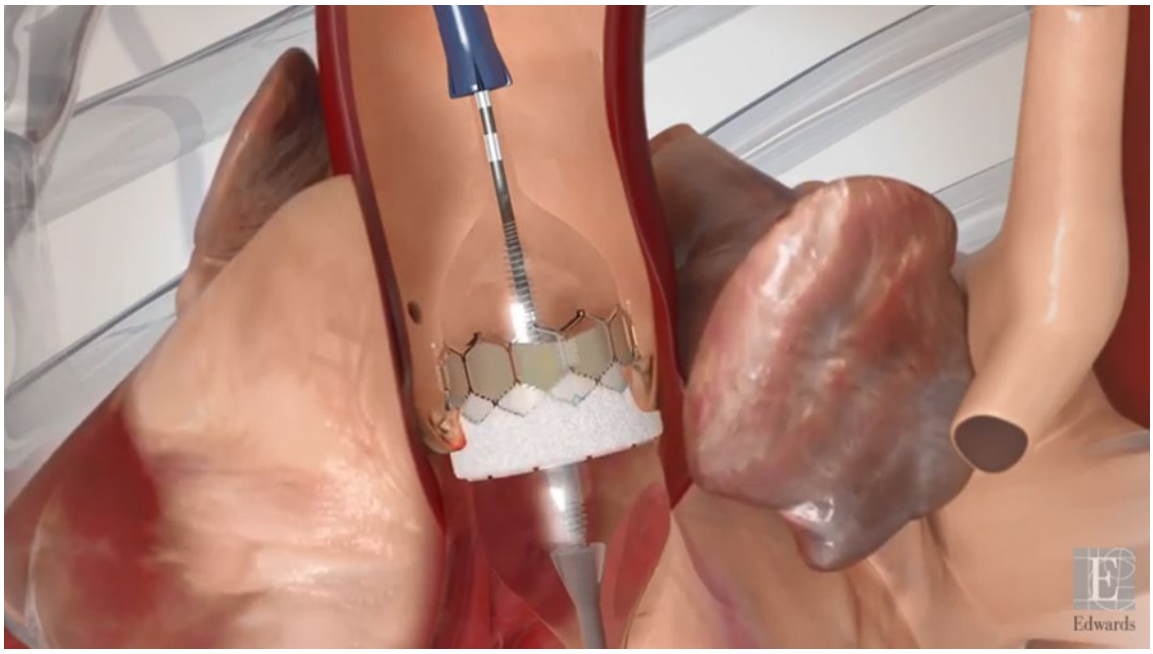
[10] *See* Footnote 7, *supra*, noting that such information includes information from Edwards Lifesciences LLC.



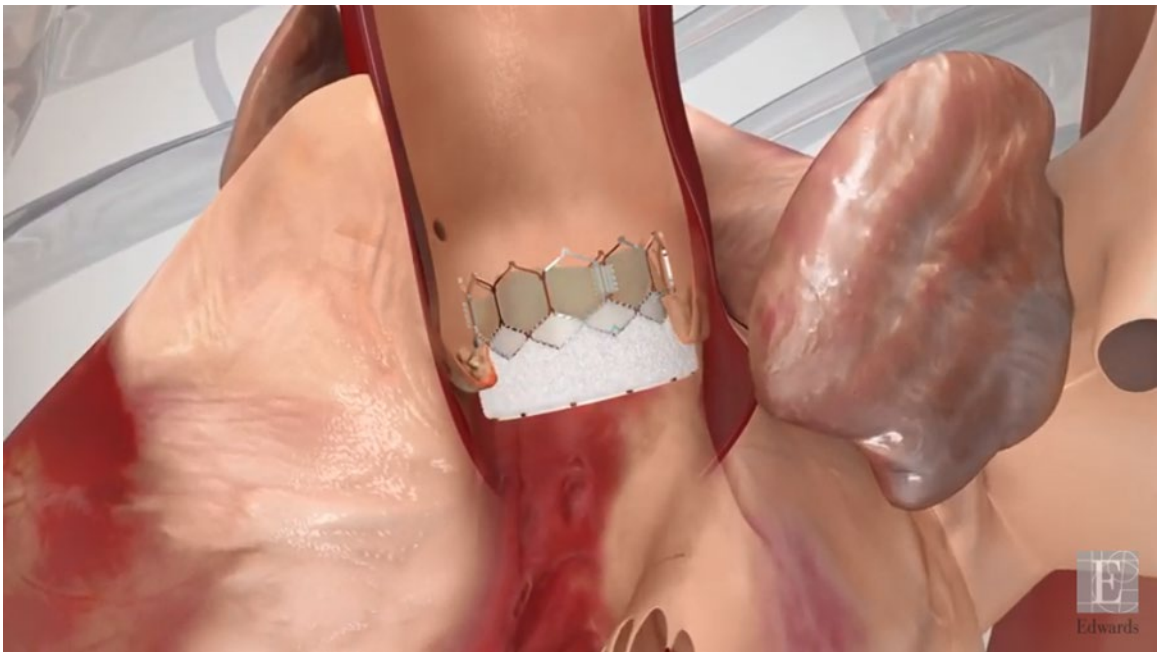
Id. at 1:08.



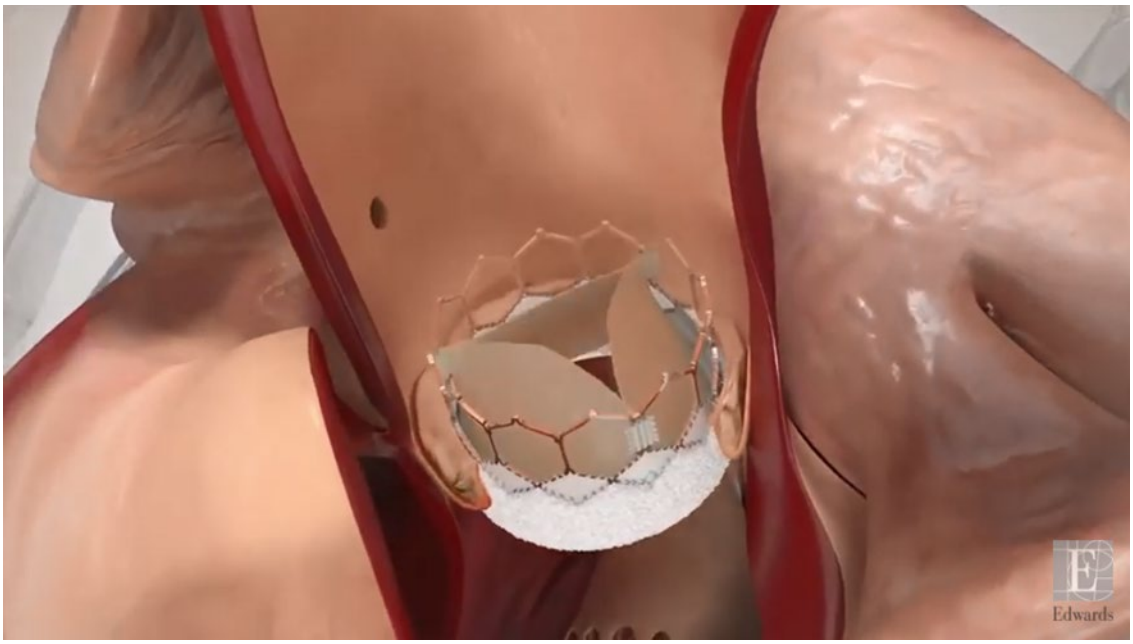
Id. at 1:13.



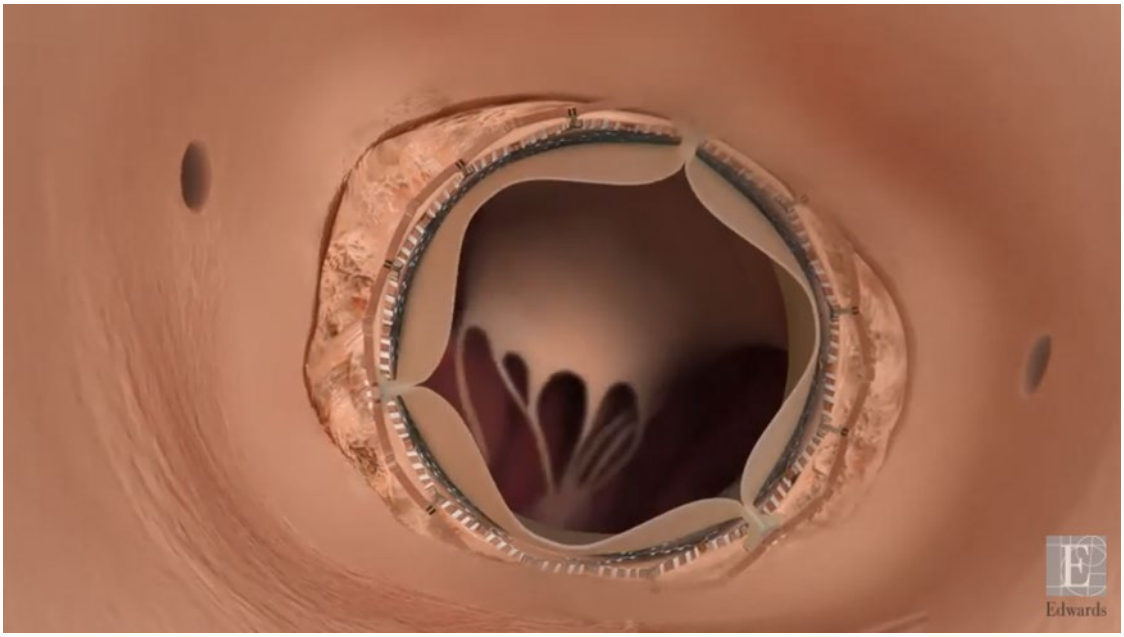
Id. at 1:25.



Id. at 1:48.

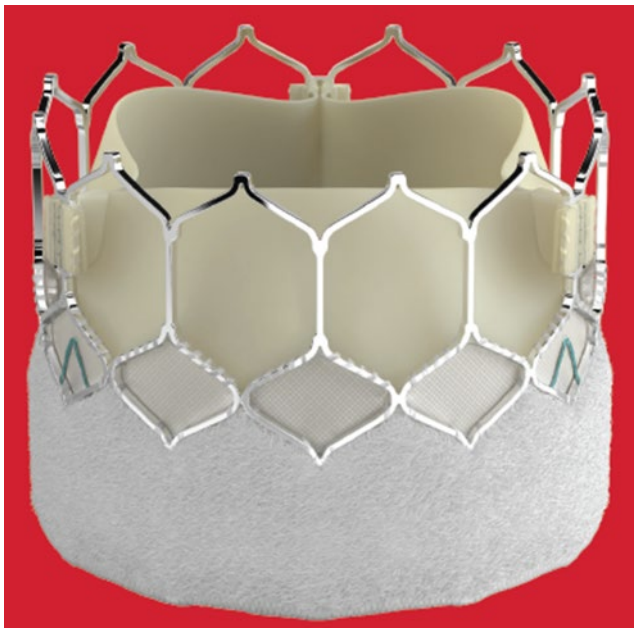


Id. at 1:54.

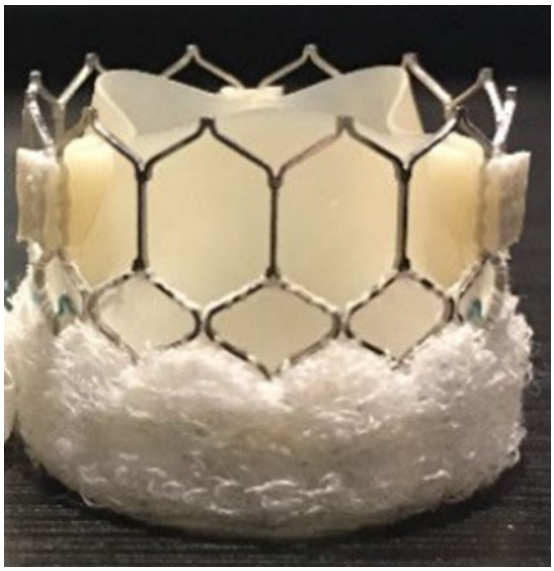


Id. at 1:59.

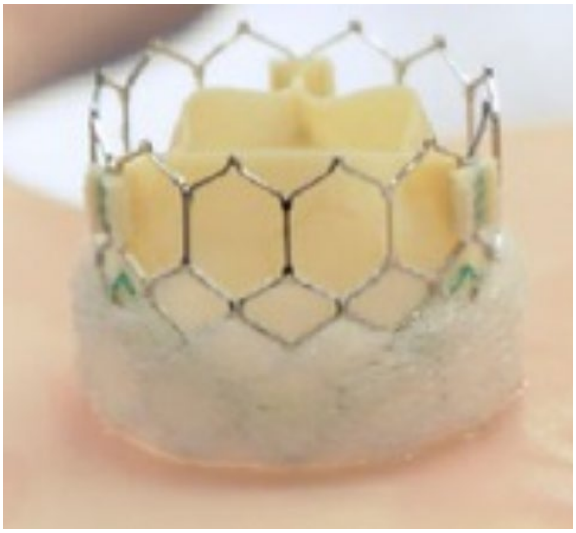
68. On information and belief, the Sapien 3 Ultra includes a frame made from a metallic material in an open cell configuration with an inflow end and an outflow end.



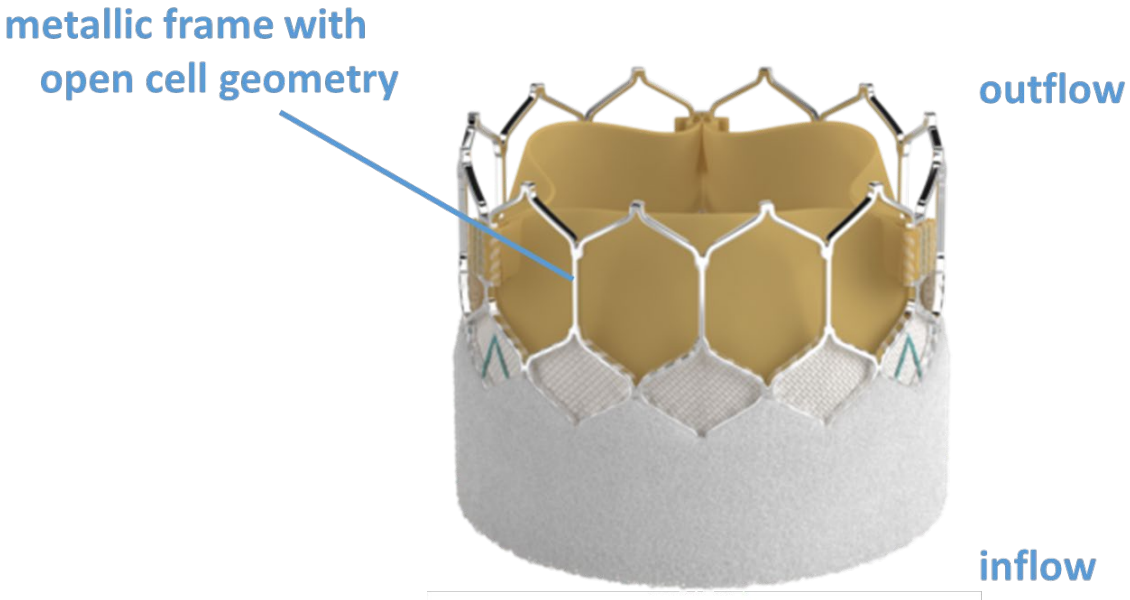
Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 1-2, Ex. 43, https://edwardseducation.com/eacts2020/documents/PP--EU-0118%20v1.0%20S3%20Ultra%20on%20Commander%20Implanter%20Brochure.pdf.



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/

69. 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

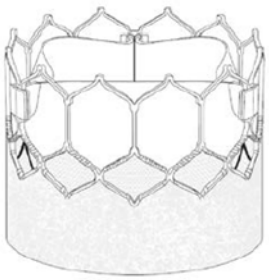
1.0 Device Description

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

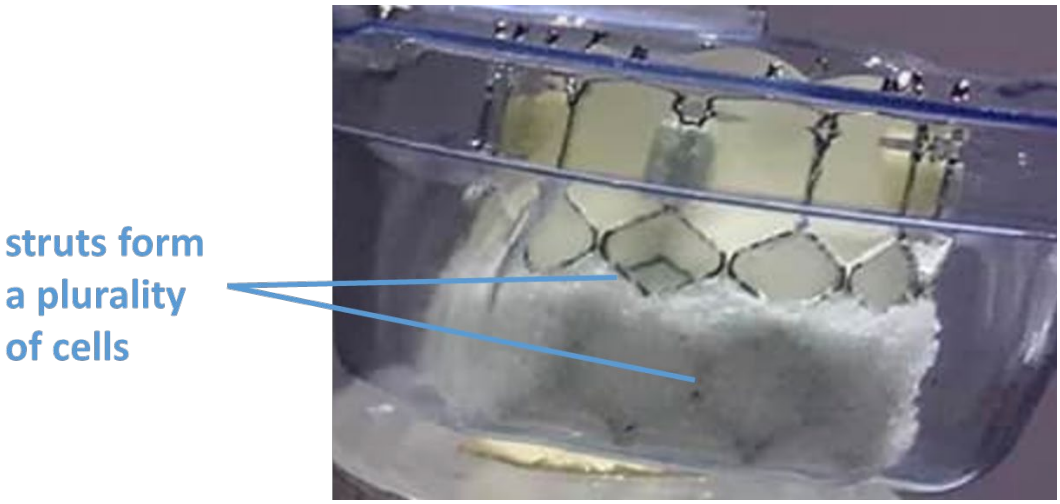
Valve Size	Valve Height
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm

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.

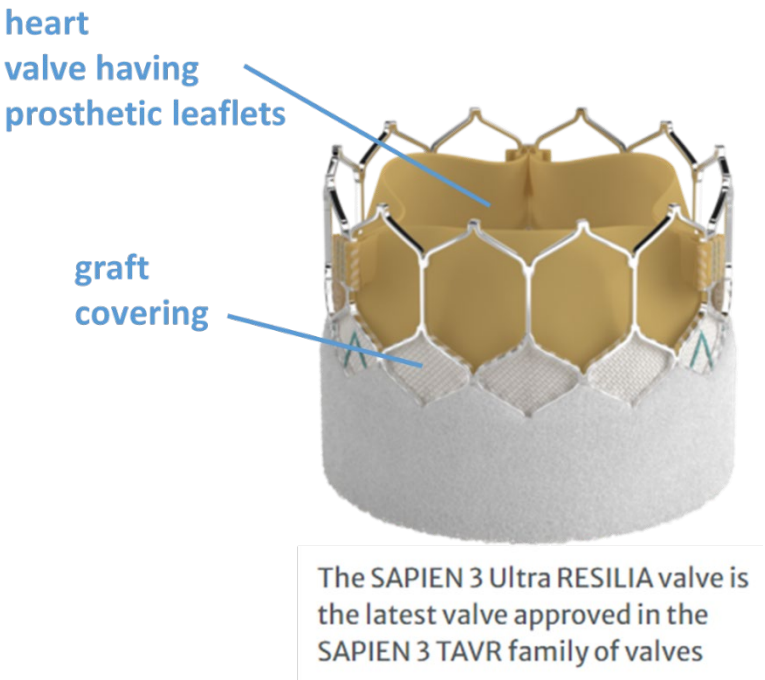
70. On information and belief, the Edwards Sapien 3 Ultra frame is formed by a plurality of struts that together form a plurality of cells with at least two rows of cells at an inflow end of the frame.

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



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

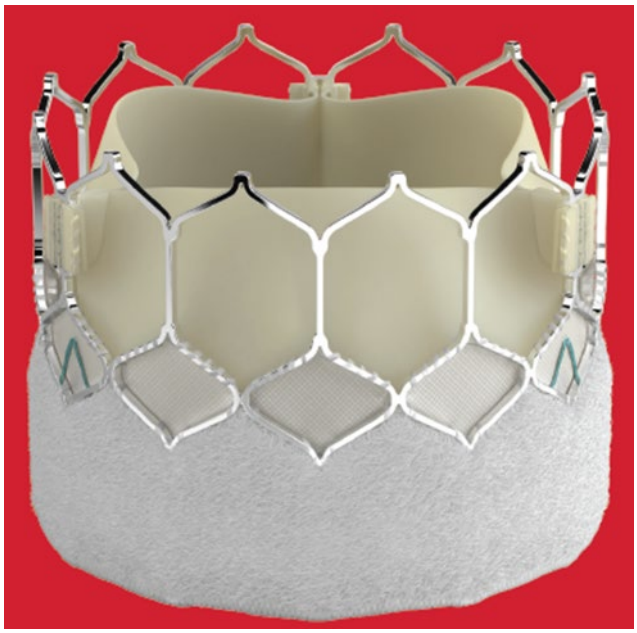
71. On information and belief, the Edwards Sapien 3 Ultra includes a polymer graft covering that houses the prosthetic heart valve leaflets. Sapien 3 Ultra Instructions for Use at 2, Ex. 44, https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf; *see also* Sapien 3 Ultra (PMA P140031/S085)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



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

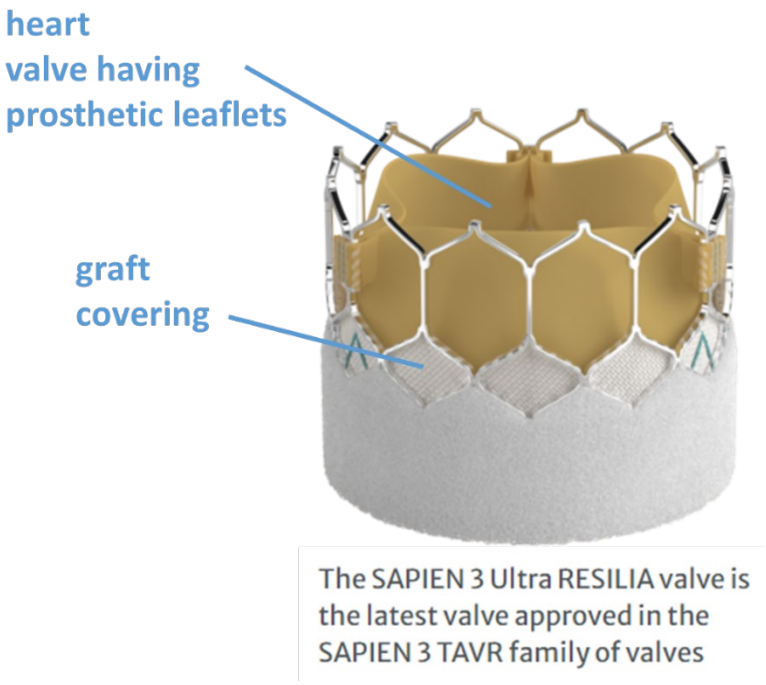
Ex. 61, https://tavrbyedwards.edwards.com/why-edwards-tavr/.

72. 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/.

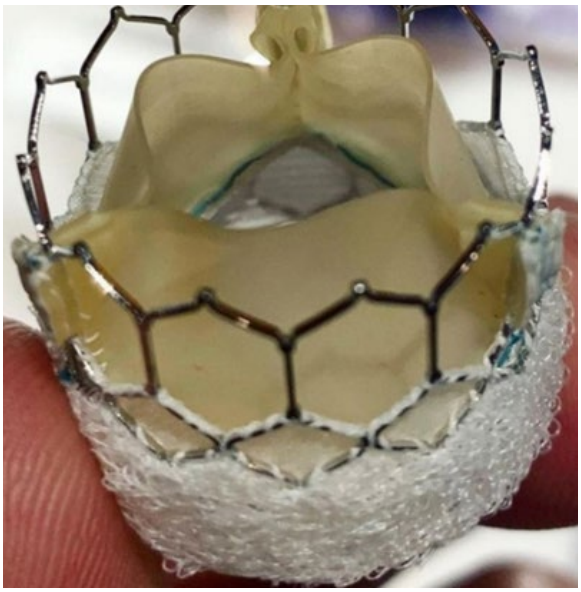
73. On information and belief, the frame is secured to the polymer graft covering by a plurality of stitches.

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).

74. 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.

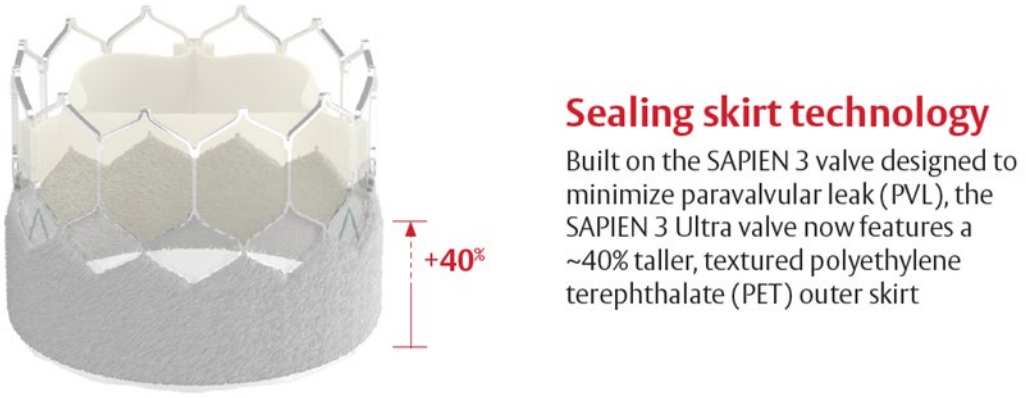
Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 2 (showing stitching attaching leaflet assembly to the polymer graft covering).



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

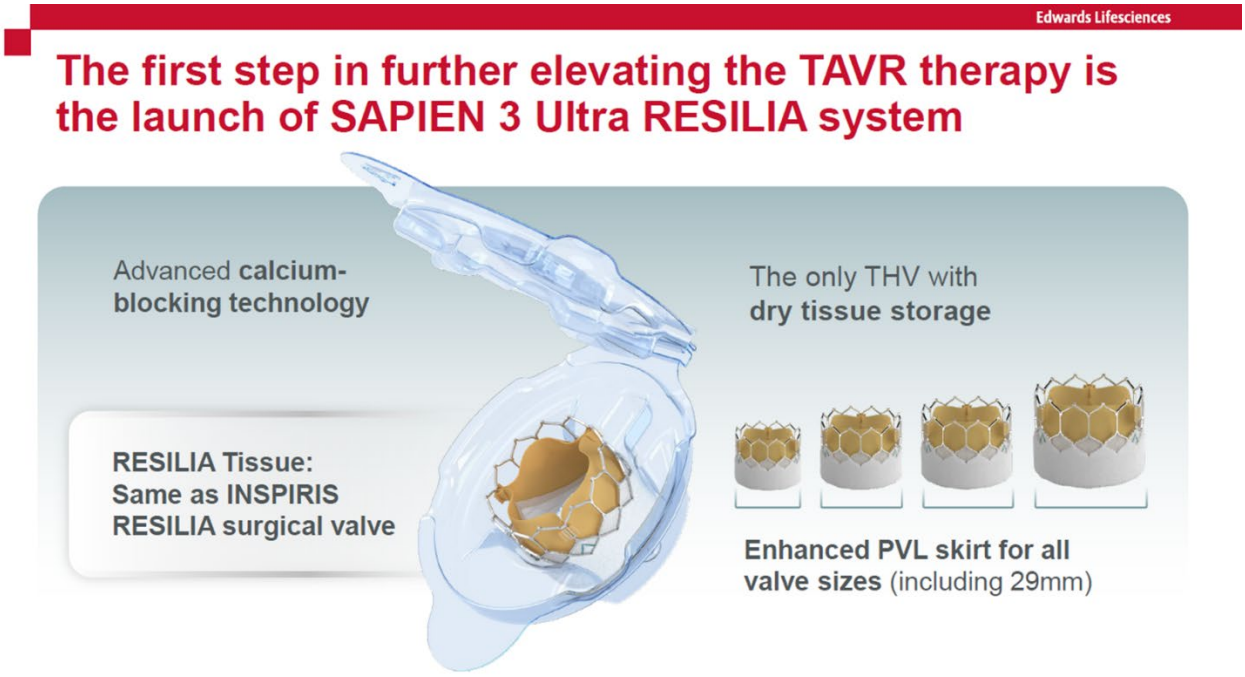
Ex. 33, https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added) (showing polymer graft covering positioned inward of the metallic frame and outward of the valve leaflets).

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

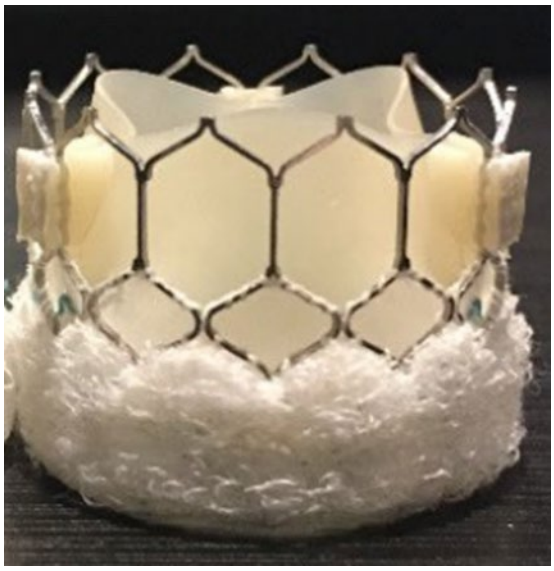


Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3 Ultra valve" at 2.

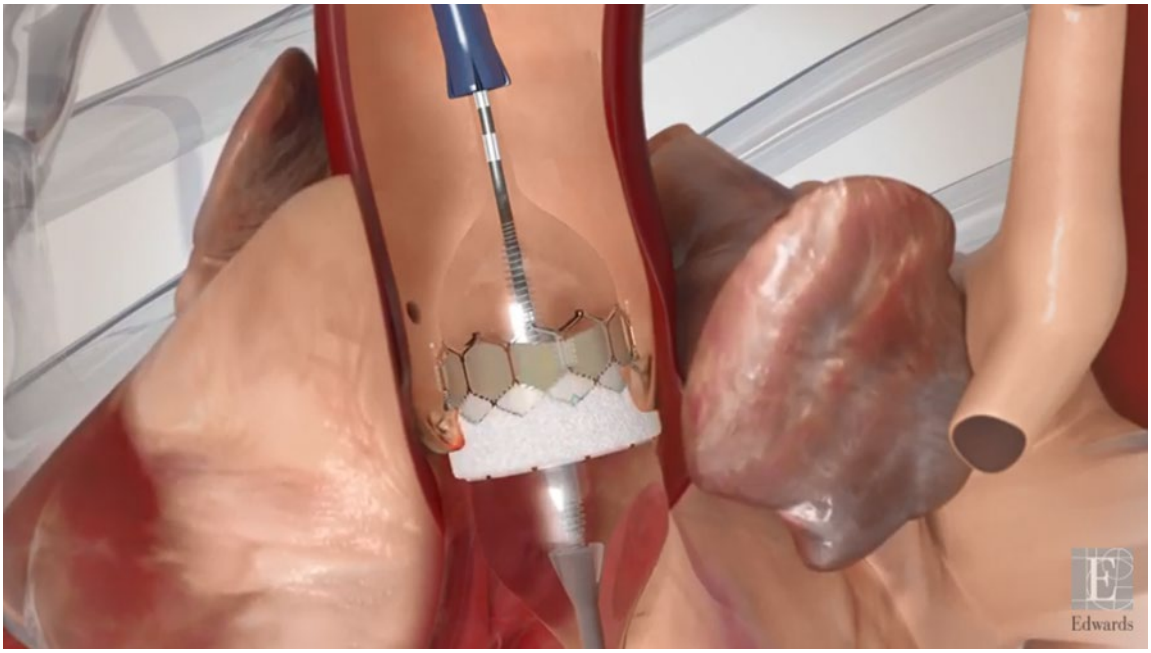
Ex. 62, https://twitter.com/RajTayalMD/status/1587518463127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg.



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

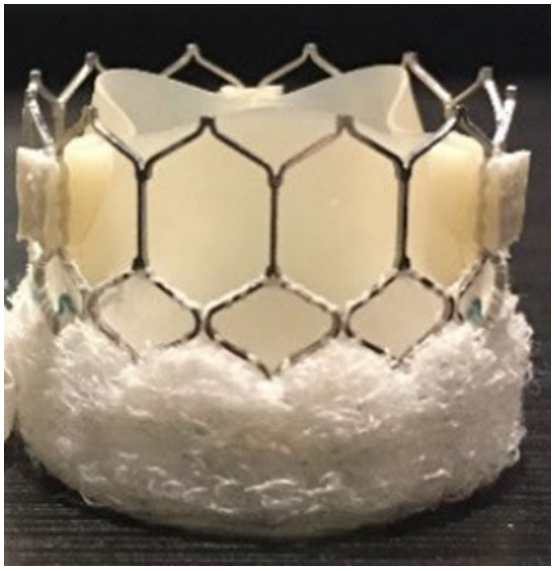


Sapien 3 Ultra image by William Suh, MD at Ex. 7, https://twitter.com/willsuh76/status/1280708440734617600/photo/1.

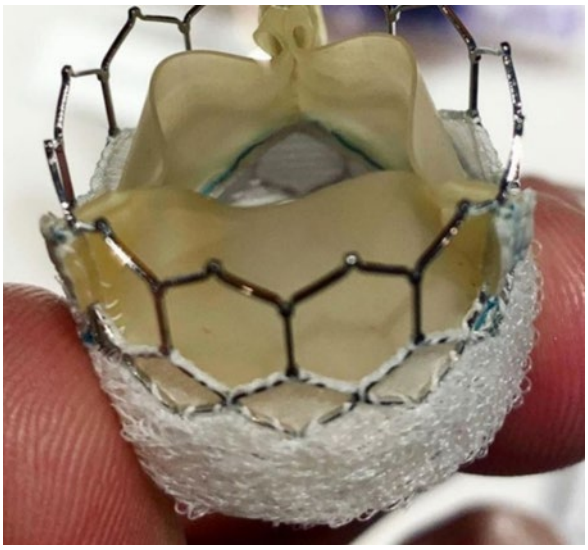


Ex.37, "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I at 1:25.

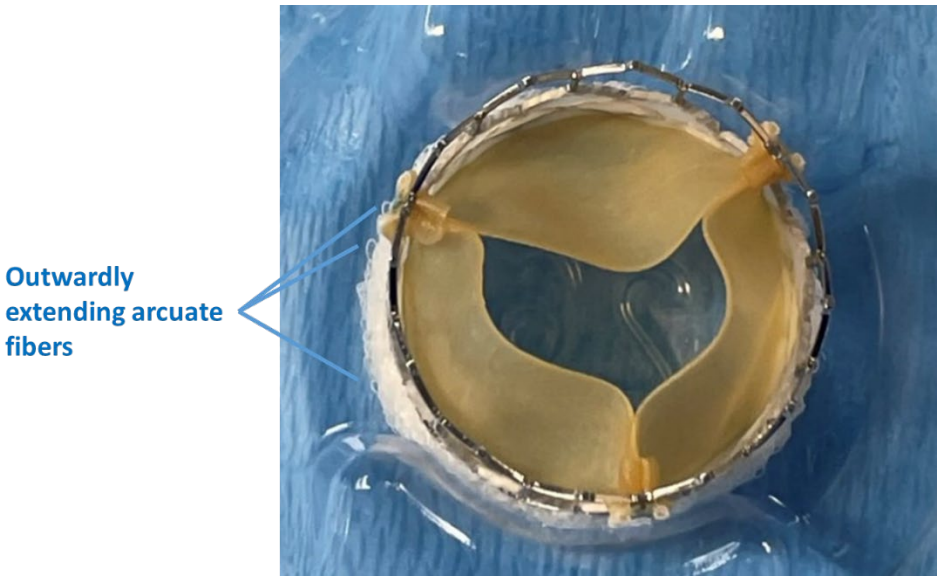
76. On information and belief, the Sapien 3 Ultra sealing material includes a plurality of outwardly extending arcuate fibers that extend outwardly, away from the frame for providing sealing against paravalvular leakage. On information and belief, the sealing material is attached to and includes fibers extending over each of at least two rows of cells in the frame at the inflow end.



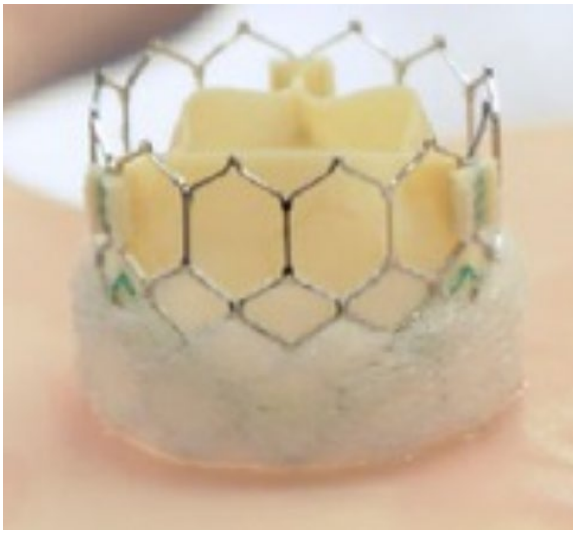
Sapien 3 Ultra image by William Suh, MD at Ex. 7, https://twitter.com/willsuh76/status/1280708440734617600/photo/1.



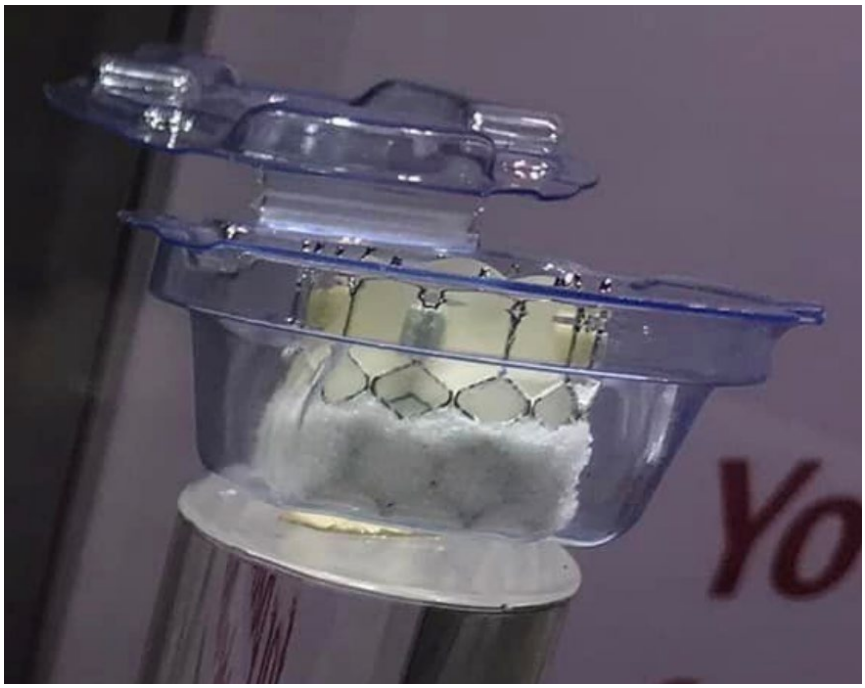
Ex. 29, https://www.instagram.com/p/BysjboFBLiG/ (showing outwardly extending fibers).



Ex. 64, https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw.

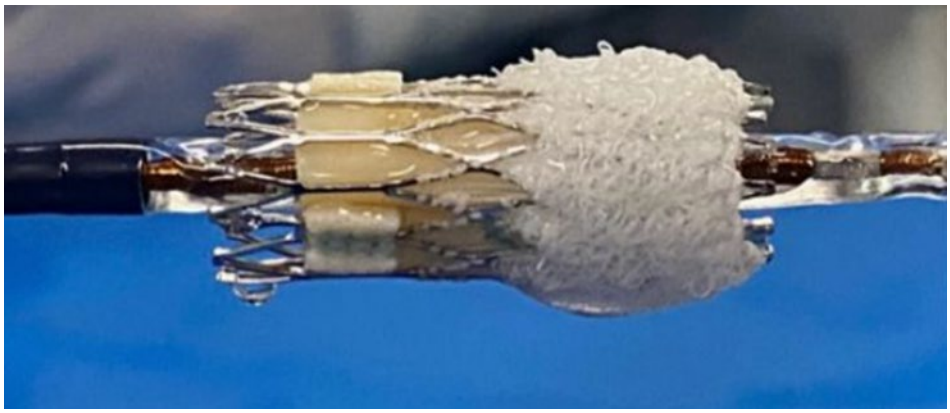


Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve.

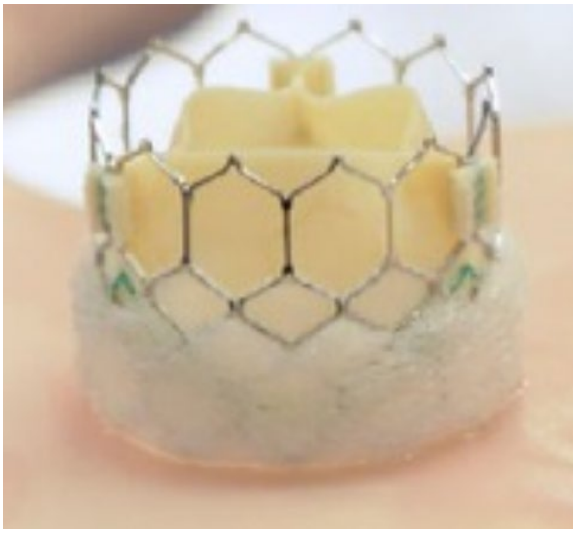


Ex. 3, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing fibers extending over at least two rows of cells).

77. 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.

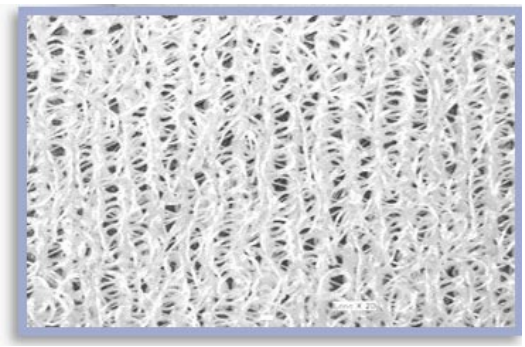


Ex. 48, https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU.

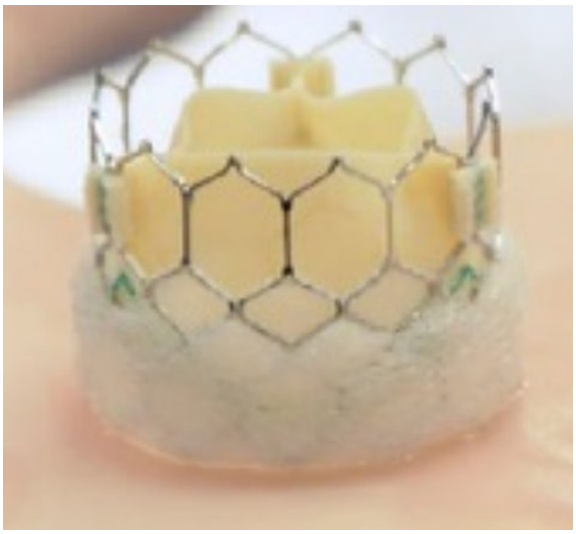


Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve.

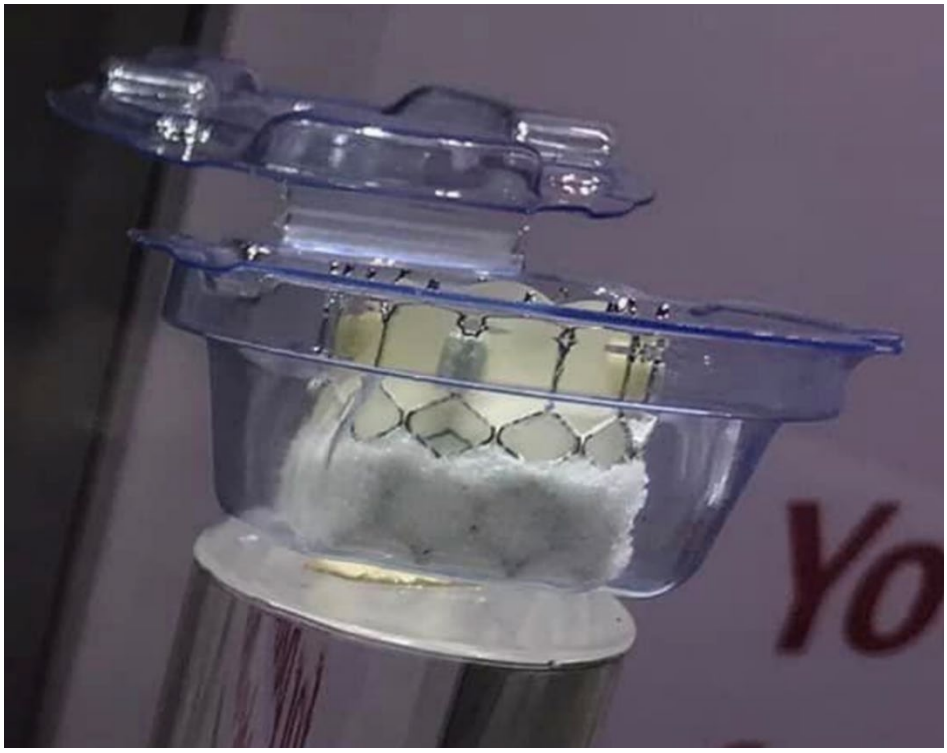
78. On information and belief, the Sapien 3 Ultra defines spacings extending radially through a thickness of the plurality of fibers that begins at an outermost portion of the fibers and through the cells of the frame.



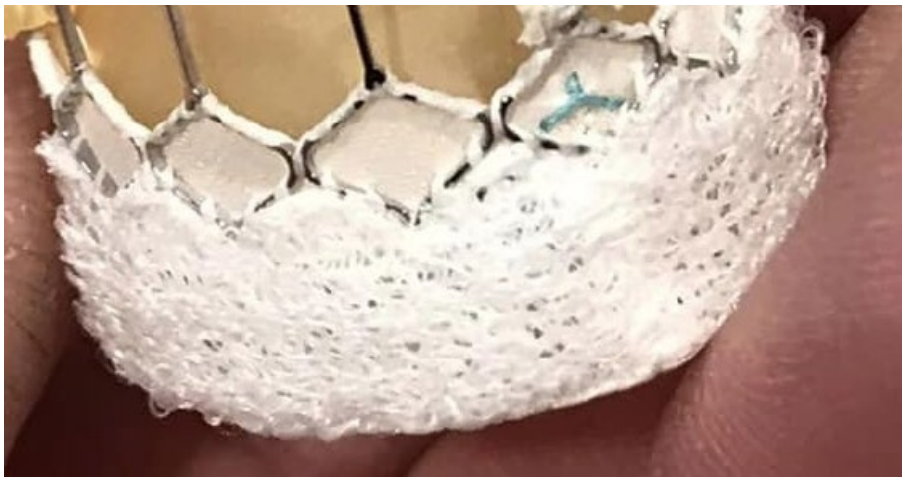
Ex. 66, https://www.heartvalves.com/gb/edwards-sapien-3-tavi/edwards-sapien-3-ultra-valve.



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

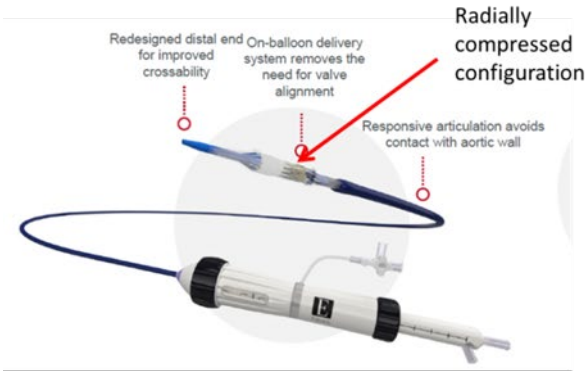


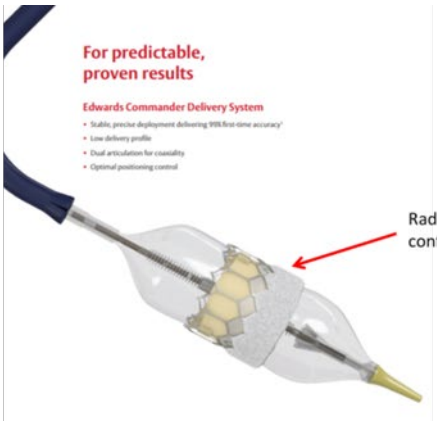
Ex. 3, Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing spacings).



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

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

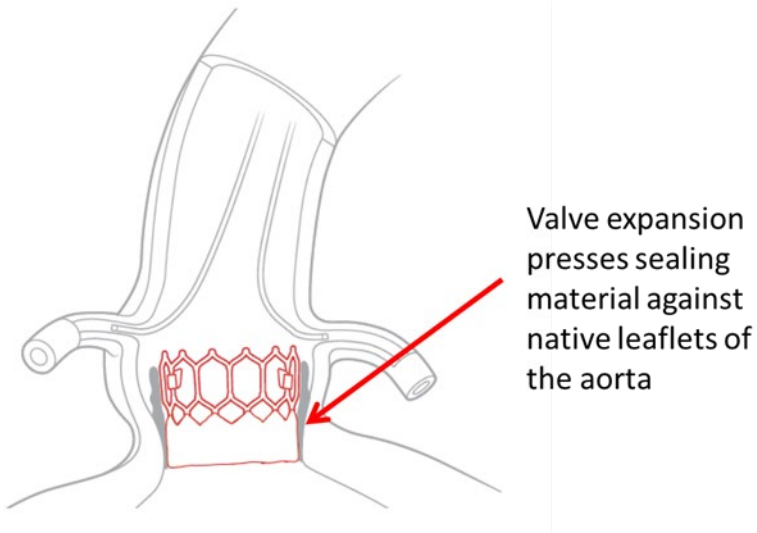




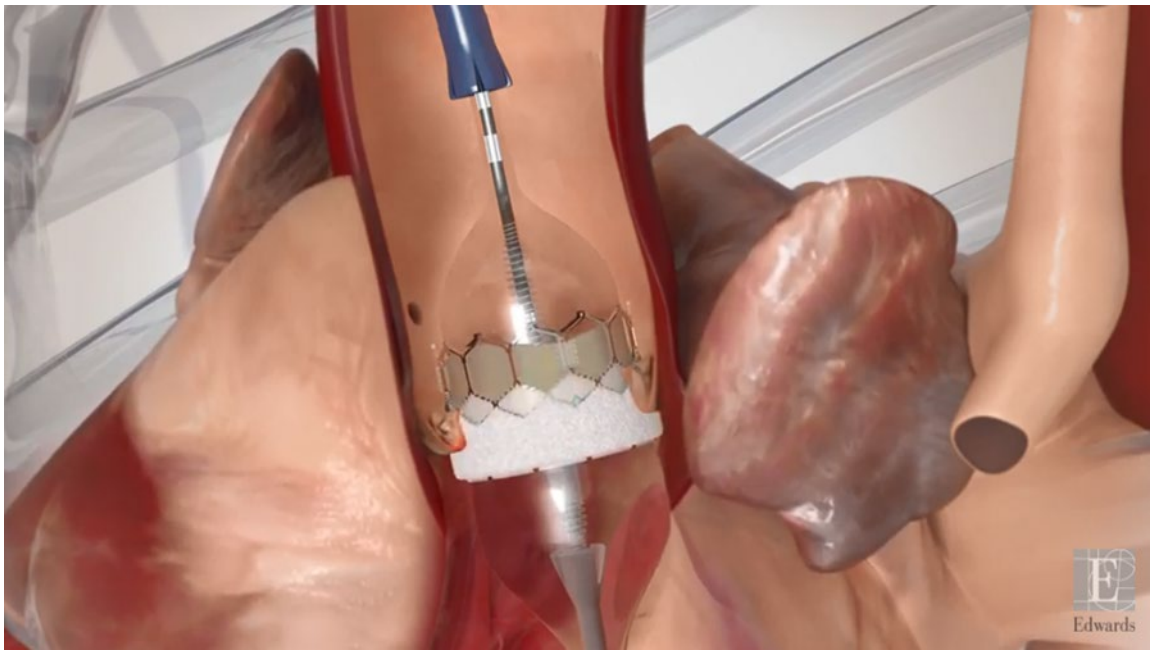
Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), Ex. 47, http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf; Ex. 46, Edwards Brochure entitled "Introducing the Sapien 3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

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

orientation to a radially expanded orientation to press 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 the spacings to create a seal.



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.

81. 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, tested, and intended for endovascular deployment and delivery through a femoral artery of a patient by Edwards.

82. 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.

83. 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.

84. 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.

85. In addition, the '735 asserted claims are infringed when Edwards offers for sale and sells the '735 patent Accused Instrumentalities. Edwards offers for sale and promotes the '735 patent Accused Instrumentalities, 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.

86. 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#

87. 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, 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.

88. 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

89. Edwards has infringed and continues to directly 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) and/or (f), including but not limited to one or more of making, using, selling, offering for sale, importing, exporting the Accused Products, in this District and elsewhere in the United States.

90. As a result of Edwards' infringement, Aortic has suffered and will continue to suffer harm in the form of damages. 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.

91. 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 and '834 Patents (to which Edwards has admitted to monitoring and having knowledge of as discussed further supra.).

92. 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.

93. 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

94. 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.

95. 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.

96. 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.

97. 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.

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

99. 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.

100. 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.

101. 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 Sapient 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.

102. 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.").

103. Further, as noted above, Edwards has admitted to knowledge of the '310 and '834 Patents and Aortic's accusations of infringement. For example, Edwards attached the '310 and '834 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. 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.

104. 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 and '310 Patents at least as of the dates of their issuance on May 24, 2022 and July 19, 2022, respectively.

105. As demonstrated by the foregoing, Edwards' infringement of the Patents-in-Suit has been, and continues to be, without permission, consent, authorization, or license.

COUNT I: INFRINGEMENT OF THE '834 PATENT

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

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

108. 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.

109. 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.

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

111. 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.

112. 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.

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

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

115. 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.

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

117. 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.

118. 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.

119. 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.

120. 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.

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

122. 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, 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.

123. 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.

COUNT II: INFRINGEMENT OF THE '310 PATENT

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

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

126. 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.

127. 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.

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

129. 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.

130. 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.

131. 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.

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

133. 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.

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

135. 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.

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

137. 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.

138. 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.

139. 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,

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.

140. 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.

DEMAND FOR JURY TRIAL

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

PRAYER FOR RELIEF

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

1. an award of damages adequate to compensate Aortic for infringement of the Patents-in-Suit by Edwards, in an amount to be proven at trial, including supplemental post-verdict damages until such time as Edwards ceases its infringing conduct;

3. the costs of this action, as well as attorneys' fees as provided by 35 U.S.C. § 285;

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

5. all other relief, in law or equity, to which Aortic is entitled.

Dated: February 13, 2023

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